Conducting high-quality, culturally-appropriate primary healthcare research with Aboriginal and Torres Strait Islander peoples

Sara Farnbach  
RN, MPHTM

A thesis submitted in fulfilment of the requirements for the degree of Doctor of Philosophy in the School of Public Health

The University of Sydney

2018
STATEMENT OF ORIGINALITY

I, Sara Farnbach, certify that the intellectual content of this thesis is the product of my own work and that all the assistance received in preparing this thesis and sources have been acknowledged. It does not contain any material previously published or written by another person. This thesis has not been submitted for any degree or other purposes.

I, Sara Farnbach, understand that if I am awarded a higher degree for my thesis entitled ‘Conducting high-quality, culturally-appropriate primary healthcare research with Aboriginal and Torres Strait Islander peoples’ being lodged herewith for examination, the thesis will be lodged in The University of Sydney library and be available immediately for use. I agree that the University Librarian (or in the case of a department, the Head of the Department) may supply photocopy or microform of the thesis to an individual for research or study or to a library.

....................

Sara Farnbach

12 July 2018
ABSTRACT

Health research should inform culturally-appropriate, evidence-based primary healthcare (PHC), potentially enhancing social and emotional wellbeing (SEWB) among Aboriginal and Torres Strait Islander (hereafter referred to as Indigenous) peoples. When conducting health research with Indigenous peoples, scientific and ethical quality should be forefront.

Aim

To identify approaches and enablers to conducting high-quality, culturally-appropriate Indigenous-focused SEWB PHC research.

Methods

This thesis comprises three sections: firstly, two systematic reviews of the Indigenous-focused SEWB PHC research literature; secondly, an in-depth critical and reflective case study of an Indigenous-focused SEWB PHC research project entitled Getting it Right: the validation study (hereafter referred to as Getting it Right); finally, a process evaluation of Getting it Right using a grounded theory approach.

Results

Twenty-five research projects were included in the systematic reviews. Two were judged as high quality using scientific and ethical criteria. Research projects that were judged as ethical used approaches that were culturally sensitive, had a focus on developing relationships and involved community members. These approaches also appeared to enable this research. Getting it Right had an adaptive protocol (where localised approaches were developed within certain requirements) and PHC services were reimbursed (on a per participant basis). The research was evaluated as meeting scientific and ethical quality criteria. The process evaluation showed that the research was acceptable to most participating staff (n=36), community members (n=4) and participants (n=500). Many were willing to participate in research and speak about SEWB. Staff reported that the reimbursement provided to the service sufficiently resourced the research.
Conclusion

High-quality, culturally-appropriate Indigenous-focused SEWB PHC research can be facilitated by culturally-sensitive, flexible, collaborative and sufficiently-funded approaches. There is a pressing need for more research to inform culturally-appropriate PHC to reduce health inequality in Australia.
DEDICATION

For my family. Especially, Mum the kindest, Dad the smartest, Simon the one to whom we all turn, Kate my closest ally in life. And Dave, for making me better, together, always.
ACKNOWLEDGEMENTS

Firstly, to A/Professor Maree Hackett who took me on as a student of research and life, mentee, project manager, and friend. Maree has guided me through this thesis with wisdom, patience and humour. She has style in spades. I am grateful for the skills, opportunities and tact Maree has shown and taught me, and I hope to take these with me in life. I am grateful to all my supervisors, who have each supported different aspects of my learning. Professor John Evans has provided cultural advice, academic advice and encouraged me to take a common sense approach. Professor Nick Glozier has provided clinical insight, academic advice, and occasional triathlon training advice! Professor Josephine Gwynn has provided academic advice, shared her experiences and shown great kindness.

Although not formally part of my supervisory team, Dr Anne-Marie Eades and Dr Graham Gee have been mentors and cultural guides to me throughout this research. Thank you, I have learnt magnitudes from you both. Anne-Marie and Graham completed second coding of the process evaluation interviews, and are co-authors of journal articles. Anne-Marie also completed the second review of the systematic reviews and critical evaluation. I am especially grateful to the people who agreed to act as members of the Indigenous Advisory Group. Without you, this research would not have been possible: Dr Graham Gee, Dr Anne-Marie Eades, Professor John Evans, Dr Jamie Fernando, Ms Belinda Hammond, Mr Matty Simms and Ms Karrina DeMasi.

Thank you also to the Getting it Right researchers, for having me on your project and supporting my part of it. I have learnt from each of you: A/Professor Maree Hackett, Professor Nick Glozier, Professor Timothy Skinner, Associate Professor Armando Teixeira-Pinto, A/Professor Deborah Askew, Dr Graham Gee, Professor Alan Cass and Professor Alex Brown. Special thanks to Alex, the co-authors and the Aboriginal communities, for completing the background work to Getting it Right. I would also like to acknowledge the National Health and Medical Research Council for the funding towards Getting it Right and The University of Sydney for the Cross Cultural Public Health Research Award.
Like so many others, I am indebted to Professor John Chalmers for his tireless support of future researchers. Thank you to John and The George Institute for providing funding towards my PhD scholarship.

Special thank you to the organisations, communities and individuals who agreed to take part in Getting it Right. I have been welcomed throughout this project and have learnt so much about the rich and strong Indigenous people, communities and cultures around these nations. Specifically, I have learnt of true community bonds and connections, which I have seen repeatedly. We have so much to learn from you.

Thank you to Ms Lei Cameron who provided copyediting and proofreading services, according to the guidelines in the ‘Thesis and examination of higher degrees by research procedures 2015.’ Thank you to Dr Sabine Allida for completing the second review of the critical evaluation.

Thanks also to my friends, for asking and also not asking about my thesis at the right times, so I know your friendship is enduring.

Finally, thank you to those who have read and discussed my ideas along the way. Especially to Mum, Dad, Dave, Kate, Simon, Anne and Maree. Of course, to Sacha for the inspirational sticker work.
TABLE OF CONTENTS

STATEMENT OF ORIGINALITY I
ABSTRACT II
DEDICATION IV
ACKNOWLEDGEMENTS V
TABLE OF CONTENTS VII
LIST OF FIGURES XIII
LIST OF TABLES XIV
LIST OF APPENDICES XVIII
A NOTE ON TERMINOLOGY XX
LIST OF ABBREVIATIONS AND ACRONYMS XXI
PUBLICATIONS AND PRESENTATIONS XXIII
  Peer-reviewed publications XXIV
  Peer-reviewed publications (related to but not contained within this thesis) XXV
  Authorship attribution statements XXVI
  Presentations arising from this thesis [oral] XXIX
  Research grants supporting this thesis XXIX
ACKNOWLEDGEMENT OF COUNTRY XXIX
CHAPTER 1 INTRODUCTION 1
  1.1 Developing evidence for culturally-appropriate social and emotional wellbeing 2
  1.2 Incorporating perspectives within the research team 4
  1.3 Summary of thesis aims 5
  1.4 Thesis structure 6
  1.5 Significance of this thesis 10
CHAPTER 2 METHODS: SYSTEMATIC REVIEWS OF
  INDIGENOUS-FOCUSED SOCIAL AND EMOTIONAL
  WELLBEING PRIMARY HEALTHCARE RESEARCH 11
  2.1 Introduction 11
  2.2 Methods (publication) Australian Aboriginal and Torres Strait Islander-focused primary healthcare social and emotional wellbeing research: a systematic review protocol 11
| 2.2.1 | Additional methods used in systematic reviews | 18 |
| 2.3 Conclusion | 20 |
| **CHAPTER 3** RESULTS: SYSTEMATIC REVIEWS OF INDIGENOUS-FOCUSED SOCIAL AND EMOTIONAL WELLBEING PRIMARY HEALTHCARE RESEARCH | 21 |
| 3.1 Introduction | 21 |
| 3.2 Results 1 (publication) The quality of Australian Indigenous primary healthcare research focusing on social and emotional wellbeing: a systematic review | 22 |
| 3.3 Results 2 (publication) The conduct of Indigenous primary healthcare research focused on social and emotional wellbeing involving collaborations: a systematic review | 31 |
| 3.3.1 Additional (unpublished) results from the systematic review | 42 |
| 3.4 Translation of research arising from systematic reviews | 46 |
| 3.5 Conclusion | 46 |
| 3.6 Addendum | 47 |
| **CHAPTER 4** PROTOCOL, PROCESSES AND RESULTS OF GETTING IT RIGHT | 54 |
| 4.1 Introduction | 54 |
| 4.2 Background to Getting it Right | 54 |
| 4.2.1 Previous work informing Getting it Right | 54 |
| 4.2.2 Developing the research team and obtaining research funding | 56 |
| 4.3 Summary of the Getting it Right study protocol | 56 |
| 4.3.1 Process evaluation of Getting it Right | 59 |
| 4.3.2 Developing an Indigenous Advisory Group for the process evaluation | 60 |
| 4.4 Conducting Getting it Right and the process evaluation | 60 |
| 4.4.1 The major milestones during Getting it Right | 61 |
| 4.4.2 Adapting the study protocol at each participating service | 68 |
| 4.4.3 Resources provided through flexible financial reimbursement | 68 |
| 4.4.4 Research start-up and training visits | 69 |
| 4.4.5 Delivering training in Getting it Right procedures to staff | 69 |
| 4.4.6 Processes established to minimise risk to staff and participants | 72 |
4.4.7 Additional activities involved with conducting *Getting it Right* 74

4.5 Community feedback of research results 75

4.6 Summary of the *Getting it Right* results 76

4.7 Review of *Getting it Right* according to the main components in the study protocol 77

4.8 Conclusion 84

**CHAPTER 5 CRITICAL EVALUATION OF *GETTING IT RIGHT*** 85

5.1 Introduction 85

5.2 Methods 85

5.2.1 Methods used to determine scientific quality 85

5.2.2 Methods used to determine ethical quality 86

5.2.3 Standard quality assessment tools used during this critical evaluation 86

5.3 Results 88

5.3.1 Quality assessment of *Getting it Right* using the modified quality assessment criteria 88

5.3.2 Community acceptance assessment of *Getting it Right* 94

5.3.3 Values and Ethics Guideline\(^7\) assessment of *Getting it Right* 95

5.4 Discussion 98

5.4.1 Risk of bias and strategies to mitigate risk 98

5.4.2 Assessment using community acceptance criteria and Values and Ethics Guideline\(^7\) 103

5.4.3 Community involvement at different stages of research 105

5.5 Conclusion 106

**CHAPTER 6 REFLECTIVE CASE STUDY OF *GETTING IT RIGHT*** 108

6.1 Introduction 108

6.2 Background to case study research and reflection during research 108

6.3 Aims 109

6.4 Methods 110

6.5 Results: my cultural competence as a researcher 110

6.6 Results: enablers and barriers to *Getting it Right* 112

6.6.1 Enablers to *Getting it Right* 113

6.6.2 Barriers to *Getting it Right* 119
6.7 How my reflections impacted on the research process for *Getting it Right*  

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.7.1 Continued development of processes to minimise impact on staff and participant times</td>
<td>123</td>
</tr>
<tr>
<td>6.7.2 Sharing information and SEWB resources with staff</td>
<td>125</td>
</tr>
<tr>
<td>6.7.3 Ongoing focus on relationship building</td>
<td>126</td>
</tr>
<tr>
<td>6.7.4 My considerations about research design during the Getting it Right process evaluation (written in February 2017)</td>
<td>126</td>
</tr>
</tbody>
</table>

6.8 Enhancing workforce and research capacity through *Getting it Right* 127

6.9 Lessons relevant for future research 127

6.10 Conclusion 128

**CHAPTER 7 METHODS AND KEY RESULTS: PROCESS EVALUATION OF GETTING IT RIGHT** 130

7.1 Introduction 130

7.2 Aims 131

7.3 Methods (publication) Process evaluation of a primary healthcare validation study of a culturally-adapted depression screening tool for use by Aboriginal and Torres Strait Islander people: study protocol 131

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.3.1 Data collection and analysis</td>
<td>140</td>
</tr>
<tr>
<td>7.3.2 Approach to the process evaluation</td>
<td>142</td>
</tr>
</tbody>
</table>

7.4 Results (publication) Process evaluation of Getting it Right: the acceptability and feasibility of a culturally-adapted depression screening tool for use by Aboriginal and Torres Strait Islander people 145

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.4.1 Abstract</td>
<td>146</td>
</tr>
<tr>
<td>7.4.2 Introduction</td>
<td>148</td>
</tr>
<tr>
<td>7.4.3 Methods</td>
<td>149</td>
</tr>
<tr>
<td>7.4.4 Results</td>
<td>150</td>
</tr>
<tr>
<td>7.4.5 Discussion</td>
<td>152</td>
</tr>
<tr>
<td>7.4.6 Acknowledgements</td>
<td>154</td>
</tr>
</tbody>
</table>

7.5 Additional (unpublished) results from the process evaluation 154

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.5.1 Staff perceptions about the conduct of <em>Getting it Right</em> according to the study protocol</td>
<td>155</td>
</tr>
<tr>
<td>7.5.2 Contextual factors surrounding <em>Getting it Right</em></td>
<td>156</td>
</tr>
<tr>
<td>7.5.3 Impact and consequences of conducting <em>Getting it Right</em></td>
<td>159</td>
</tr>
<tr>
<td>7.5.4 Enablers to conducting <em>Getting it Right</em></td>
<td>161</td>
</tr>
<tr>
<td>7.5.5 Barriers to conducting <em>Getting it Right</em></td>
<td>163</td>
</tr>
</tbody>
</table>
CHAPTER 8 PROCESS EVALUATION RESULTS: PERSPECTIVES OF STAFF AND PATIENTS ABOUT PARTICIPATING IN SEWB RESEARCH

8.1 Introduction

8.2 Aims

8.3 Results (publication) ‘We’re here to listen and help them as well:’ A qualitative study of staff and patient perceptions about participating in social and emotional wellbeing research at primary healthcare services

8.4 Conclusion

8.5 Addendum

CHAPTER 9 PROCESS EVALUATION RESULTS: RESOURCING AND RESOURCE USE DURING RESEARCH

9.1 Introduction

9.2 Aims

9.3 Results (publication) What are the resourcing requirements for an Aboriginal and Torres Strait Islander primary healthcare research project?

9.4 Conclusion
LIST OF FIGURES

CHAPTER 2

Figure 2.1 Potential levels of Indigenous communities .............................................18

CHAPTER 4

Figure 4.1 Major steps involved with establishing and conducting Getting it Right at each participating service ..................................................61

Figure 4.2 Getting it Right artwork.................................................................75

APPENDICES

Figure A1 Flow of participants through the Getting it Right study.........................301

Figure A2 Proportion of the 500 participants diagnosed with major depressive event, generalised anxiety disorder and post-traumatic stress disorder, with the MINI.................................................................302

Figure A3 Receiver operating characteristic (ROC) curve for the aPHQ-9 score. .....303

Figure A4 Receiver operating characteristic (ROC) curve for the aPHQ-2 score. .....304
LIST OF TABLES

CHAPTER 3

Table 3.1 Summary of key enablers and barriers to research reported by authors ......44

Table 3.2 Indigenous-focused PHC SEWB research published between January 2015 and May 2018..................................................................................................................49

Table 3.3 Assessment of risk of bias of qualitative study identified in the systematic review update ..................................................................................................................52

Table 3.4 Assessment of risk of bias of cross-sectional studies identified in the systematic review update ..................................................................................................................52

CHAPTER 4

Table 4.1 Summary of major milestones of Getting it Right and its process evaluation ........................................................................................................................................62

Table 4.2 Summary of processes during Getting it Right in order to receive local and state ethics approval ..................................................................................................................................67

Table 4.3 Summary of research processes and characteristics of participating services during Getting it Right.............................................................................................................71

Table 4.4 Processes established to minimise risks to staff and participants during Getting it Right ..................................................................................................................................73

Table 4.5 Review of Getting it Right according to the study protocol113 ..................80

CHAPTER 5

Table 5.1 QUADAS-2118 assessment of the design and conduct of Getting it Right...90

Table 5.2 STARD checklist117 identifying important aspects reported in Getting it Right .............................................................................................................................................92

Table 5.3 Assessment using community acceptance criteria of Getting it Right ............94
Table 5.4  Demonstration of how the principles of Reciprocity, Respect, Equality, Responsibility, Survival and Protection, and Spirit and Integrity were considered in *Getting it Right*. 96

CHAPTER 6

Table 6.1  Project manager’s reflections of the enablers to *Getting it Right* and how they relate to the Values and Ethics Guideline. 113

Table 6.2  Project manager’s reflections of barriers to *Getting it Right*. 119

CHAPTER 7

Table 7.1  Collection and analysis of qualitative interview data from staff interviews during the *Getting it Right* process evaluation. 141

Table 7.2  Summary of similarities, strengths, weaknesses of methods considered for the conduct of the *Getting it Right* process evaluation. 143

Table 7.3  Demographic information for staff and community members who completed qualitative interviews. 151

Table 7.5  Staff perceptions about conducting the research according to the study protocol. 155

Table 7.6  Environmental, social, historical and cultural contextual factors that affected the conduct of *Getting it Right*. 156

Table 7.7  Impact and consequences of conducting *Getting it Right* at participation services. 159

Table 7.8  Enablers to conducting *Getting it Right*. 161

Table 7.9  Barriers to *Getting it Right* and steps taken or suggested to overcome barriers (as reported by staff). 163

CHAPTER 8

Table 8.2  Theme one – staff considering the needs, risks, preferences for and impact of SEWB research participation for staff, patients and community. 174
Table 8.3  Theme one – patients considering the needs, risks, preferences and impact of research participation for community and themselves.................................177

Table 8.4  Theme one – contrasting perspectives of staff and patients about having a connection ...........................................................................................................179

Table 8.5  Theme two – building staff confidence speaking to patients about research and SEWB problems .................................................................................181

Table 8.6  Theme three – Patients speaking openly about SEWB .................................183

CHAPTER 9

Table 9.1  Theme one – the influence of reimbursement on participating services and the research project......................................................................................200

Table 9.2  Theme two – the influence of human resources on the research project at participating services......................................................................................202

Table 9.3  Theme three – the consequences of offering vouchers to participants on the research project .........................................................................................204

APPENDICES

Table A1  Definitions and potential actions/processes that relate to the Values and Ethics Guideline7 .................................................................................................230

Table A2  Actions/processes identified during this thesis addressing the Values and Ethics Guideline relating to Indigenous-focused SEWB PHC research conducted by research teams.................................................................233

Table A3  Summary of studies included in systematic review grouped according to methods (Supplementary Table 1) .................................................................236

Table A4  Summary of key learnings identified during risk of bias and community acceptance assessment (Supplementary Table 2).................................................239

Table A5  Risk of bias for qualitative studies (40) (Supplementary Table 3)..............243

Table A6  Risk of bias for quantitative studies (41) (Supplementary Table 4).............244
Table A7  Risk of Bias for randomised control trial (41) (Supplementary Table 5).....248
Table A8  Community Acceptance (Supplementary Table 6)...............................249
Table A9 Demographic characteristics of participants (n=500) in the Getting it Right study ..........................................................................................................................295
Table A10 Clinical history of participants (n=500) in the Getting it Right study .......296
Table A11 Operational characteristics of the aPHQ-9 and aPHQ-2 for screening or diagnosis of a major depressive episode .................................................................298
Table A12 Participant feedback on the acceptability of the aPHQ-9 plus additional 7 questions (n=500)..........................................................299
Table A13 Quality assessment of Getting it Right using Observational Cohort and Cross-Sectional Studies(106) to assess the design and conduct .................312
Table A14 Getting it Right process evaluation framework........................................336
Table A15 Examples of how resourcing in the research project related to the principles of Reciprocity, Respect, Equality, Responsibility, Survival and Protection, and Spirit and Integrity7 .................................................................339
**LIST OF APPENDICES**

**APPENDIX 1:** definitions and actions/processes identified relating to the values and ethics guideline\(^7\) ................................................................. 230

**APPENDIX 2:** supplementary tables from the systematic review - results ..... 236

**APPENDIX 3:** letters of approval from aboriginal health and medical research council of NSW of systematic review publications ...... 256

**APPENDIX 4:** example of research translation arising from this thesis ........ 258

**APPENDIX 5:** Getting it Right study protocol ......................................................... 264

**APPENDIX 6:** researcher safety and response protocol ........................................... 272

**APPENDIX 7:** Getting it Right results publication ................................................... 285

**APPENDIX 8:** terms of reference for the indigenous advisory group .......... 305

**APPENDIX 9:** screen shot of a MINI role play .......................................................... 307

**APPENDIX 10:** materials provided to staff about vicarious trauma during training ........................................................................................................ 308

**APPENDIX 11:** training certificate provided to staff outlining skills developed during training for Getting it Right......................................................... 310

**APPENDIX 12:** Getting it Right community report summarising background to research and results ......................................................................................... 311

**APPENDIX 13:** quality assessment of Getting it Right using observational cohort and cross-sectional studies\(^{109}\) to assess the design and conduct ............................................................................................ 312

**APPENDIX 14:** example of communication methods used to communicate with the community about Getting it Right .............................................. 314

**APPENDIX 15:** interview guides for process evaluation ........................................... 315
APPENDIX 16: ETHICAL APPROVAL FOR THE PROCESS EVALUATION ..........................321

APPENDIX 17: GETTING IT RIGHT PROCESS EVALUATION FRAMEWORK ....................336

APPENDIX 18: DATA REVIEWED TO IDENTIFY ENVIRONMENTAL, SOCIAL, HISTORICAL AND CULTURAL FACTORS THAT AFFECTED RESEARCH CONDUCT ..............................337

APPENDIX 19: SUPPLEMENTARY TABLE FROM CHAPTER 9 ........................................339
A NOTE ON TERMINOLOGY

The term ‘Indigenous peoples’ is respectfully used in this thesis and refers to all Aboriginal and/or Torres Strait Islander peoples of Australia. I acknowledge the cultural diversity of Australia’s Indigenous First peoples, and that they do not represent a homogenous group. When referring to a person who identifies as Aboriginal, Torres Strait Islander or both, these terms are used in place of Indigenous.

The ‘A’ in Aboriginal, ‘I’ in Indigenous and ‘C’ in Country are capitalised to demonstrate reference to the Indigenous peoples of Australia and that Indigenous peoples have enduring ownership of traditional lands.
### List of Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCHS</td>
<td>Aboriginal Community Controlled Health Service</td>
</tr>
<tr>
<td>ADL</td>
<td>activities of daily living</td>
</tr>
<tr>
<td>AHMRC</td>
<td>Aboriginal Health and Medical Research Council of NSW</td>
</tr>
<tr>
<td>AHW</td>
<td>Aboriginal Health Worker(s)</td>
</tr>
<tr>
<td>AIMhi</td>
<td>Australian Integrated Mental Health Initiative</td>
</tr>
<tr>
<td>AIMhi PDP</td>
<td>Australian Integrated Mental Health Initiative Priority Driven Partnership</td>
</tr>
<tr>
<td>AMS</td>
<td>Aboriginal Medical Service</td>
</tr>
<tr>
<td>ANZCTR</td>
<td>Australian New Zealand Clinical Trials Registry</td>
</tr>
<tr>
<td>aPHQ-9</td>
<td>adapted-Patient Health Questionnaire-9</td>
</tr>
<tr>
<td>AUC</td>
<td>area under the curve</td>
</tr>
<tr>
<td>CI</td>
<td>chief investigator</td>
</tr>
<tr>
<td>CRF</td>
<td>case report forms</td>
</tr>
<tr>
<td>DSM</td>
<td>Diagnostic and Statistical Manual&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>DOR</td>
<td>diagnostic odds ratio</td>
</tr>
<tr>
<td>GAD</td>
<td>generalized anxiety disorder</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice guidelines</td>
</tr>
<tr>
<td>Getting it Right</td>
<td>Getting it Right: the validation study</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner(s)</td>
</tr>
<tr>
<td>HREC</td>
<td>Human Research Ethics Committee</td>
</tr>
<tr>
<td>Indigenous PHC services</td>
<td>Aboriginal Community Controlled Health Services and Aboriginal Medical Services</td>
</tr>
<tr>
<td>IQR</td>
<td>interquartile range</td>
</tr>
<tr>
<td>KICA-Dep</td>
<td>The Kimberley Assessment of Depression of Older Indigenous Australians&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>LR</td>
<td>likelihood ratio</td>
</tr>
<tr>
<td>MDE</td>
<td>major depressive episode</td>
</tr>
<tr>
<td>MINI 6.0.0</td>
<td>Mini International Neuropsychiatric Interview 6.0.0&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>MRC guidance</td>
<td>Medical Research Council’s guidance on process evaluations of complex interventions</td>
</tr>
<tr>
<td>NPV</td>
<td>negative predictive value</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>PDP</td>
<td>Priority Driven research Partnership</td>
</tr>
<tr>
<td>PHC</td>
<td>primary health care</td>
</tr>
<tr>
<td>PHQ-9</td>
<td>Patient Health Questionnaire-9</td>
</tr>
<tr>
<td>PM</td>
<td>project manager</td>
</tr>
<tr>
<td>PPV</td>
<td>positive predictive value</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>PTSD</td>
<td>post-traumatic stress disorder</td>
</tr>
<tr>
<td>RN</td>
<td>Registered Nurse(s)</td>
</tr>
<tr>
<td>ROC</td>
<td>receiver operating characteristic</td>
</tr>
<tr>
<td>SC</td>
<td>steering committee for the research project (<em>Getting it Right: the validation study</em>)</td>
</tr>
<tr>
<td>SD</td>
<td>standard deviation</td>
</tr>
<tr>
<td>SEARCH</td>
<td>Study of Environment on Aboriginal Resilience and Child Health&lt;sup&gt;4-6&lt;/sup&gt;</td>
</tr>
<tr>
<td>SEWB</td>
<td>social and emotional wellbeing</td>
</tr>
<tr>
<td>TGI</td>
<td>The George Institute for Global Health</td>
</tr>
<tr>
<td>Values and Ethics Guideline</td>
<td>Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research&lt;sup&gt;7&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
## Publications and Presentations

### Peer-reviewed publications

<table>
<thead>
<tr>
<th>Publication</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Farnbach S</strong>, Eades AM, Fernando JK, Gwynn JD, Glozier N, Hackett ML. The quality of Australian Indigenous primary healthcare research focusing on social and emotional wellbeing: a systematic review. Public Health Res Pract. Online early publication. <a href="https://doi.org/10.17061/phrp27341700">https://doi.org/10.17061/phrp27341700</a></td>
<td>Published</td>
</tr>
<tr>
<td><strong>Farnbach S</strong>, Eades AM, Gwynn JD, Glozier N, Hackett ML. Conduct of Indigenous primary healthcare research focused on social and emotional wellbeing involving collaborations: a systematic review. Public Health Res Pract. <a href="https://doi.org/10.17061/phrp27451704">https://doi.org/10.17061/phrp27451704</a></td>
<td>Published</td>
</tr>
<tr>
<td><strong>Farnbach S</strong>, Gee G, Eades AM, Evans J, Fernando J, Hammond B, Simms M, DeMasi K, Glozier, N and Hackett ML. Process evaluation of <em>Getting it Right</em>: the acceptability and feasibility of a culturally-adapted depression screening tool for use by Aboriginal and Torres Strait Islander people</td>
<td>Awaiting journal submission</td>
</tr>
<tr>
<td><strong>Farnbach S</strong>, Gee G, Eades AM, Evans J, Fernando J, Hammond B, Simms M, DeMasi K, Glozier, N and Hackett ML. <em>We’re here to listen and help them as well:</em> A qualitative study of staff and patient perceptions about participating in social and emotional wellbeing research at primary healthcare services</td>
<td>Under review by journal</td>
</tr>
<tr>
<td><strong>Farnbach S</strong>, Gee G, Eades AM, Evans J, Fernando J, Hammond B, Simms M, DeMasi K, Glozier, N and Hackett ML. What are the resourcing requirements for an Aboriginal and Torres Strait Islander primary health care research project?</td>
<td>Under review by journal</td>
</tr>
</tbody>
</table>
### Peer-reviewed publications (related to but not contained within this thesis)

<table>
<thead>
<tr>
<th>Publication</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hackett ML, <strong>Farnbach S</strong>, Glozier N, et al <em>Getting it Right</em>: study protocol to determine the diagnostic accuracy of a culturally-specific measure to screen for depression in Aboriginal and/or Torres Strait Islander people BMJ Open 2016;6:e015009. <a href="http://dx.doi.org/10.1136/bmjopen-2016-015009">http://dx.doi.org/10.1136/bmjopen-2016-015009</a></td>
<td>Published</td>
</tr>
<tr>
<td>Hackett ML, Teixeira-Pinto T, <strong>Farnbach S</strong>, Glozier N, Skinner T, Askew D, Gee G, Cass A, Brown A and the <em>Getting it Right</em> collaborative group. Validation of a culturally-specific measure to screen for depression (aPHQ-9) in Aboriginal and/or Torres Strait Islander people: the <em>Getting it Right</em> study.</td>
<td>Under review by journal</td>
</tr>
</tbody>
</table>
Authorship attribution statements

Chapter 2 of this thesis contains:

Farnbach S, Eades AM, Hackett ML. Australian Aboriginal and Torres Strait Islander-focused primary healthcare social and emotional wellbeing research: a systematic review protocol. Systematic Reviews. 2015;4(189)
https://doi.org/10.1186/s13643-015-0180-6

I developed the study protocol and data extraction tools; identified standard quality assessment tools (and modified them to determine scientific quality); established a research team (co-authors); developed and ran the database search strategies; and collated, and incorporated the editorial suggestions of co-authors. I contacted authors to request relevant articles and program reports for data analysis. I drafted the manuscript and submitted it for publication. I published a summary of the review on PROSPERO 2015: CRD42015024994
http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015024994

Chapter 3 of this thesis contains two publications:


I reviewed the articles identified in the database searches (first reviewer) with the second reviewer, extracted and analysed data, conducted the quality assessment, liaised with the authorship team to interpret findings and summarise results, collated and incorporated their editorial suggestions (where appropriate) and drafted and submitted the manuscript. I submitted the manuscripts to the Aboriginal Health and Medical Research Council of NSW (AHMRC) for review and approval (Appendix 3).
Chapter 7 of this thesis contains two publications:


I led the planning and conduct of this process evaluation, convened an Indigenous Advisory Group to oversee the research and developed the process evaluation protocol. I developed and pilot tested the interview guides (in consultation with the Indigenous Advisory Group and CI Hackett) (Appendix 15); gained ethics approval for the protocol from eight Human Research Ethics Committees (Appendix 16); collected and analysed the data; and arranged independent double-coding of 10 interview transcripts (AME and CI Gee). I incorporated editorial suggestions from the Indigenous Advisory Group and CI Hackett (where appropriate), and drafted and submitted the manuscripts for publication.

Chapter 8 of this thesis contains:

**Farnbach S**, Gee G, Eades AM, Evans J, Fernando J, Hammond B, Simms M, DeMasi K, Glozier, N and Hackett ML. We’re here to listen and help them as well:’ A qualitative study of staff and patient perceptions about participating in social and emotional wellbeing research at primary healthcare services.

I led the conduct of this research, collected and analysed the data, wrote the final manuscript based on feedback from the Indigenous Advisory Group and CI Hackett and submitted it for publication.
Chapter 9 of this thesis contains:

Farnbach S, Gee G, Eades AM, Evans J, Fernando J, Hammond B, Simms M, DeMasi K, Glozier, N and Hackett ML. What are the resourcing requirements for an Aboriginal and Torres Strait Islander primary health care research project?

I led the conduct of this research, collected and analysed the data, wrote the final manuscript based on feedback from the Indigenous Advisory Group and CI Hackett and submitted it for publication.

………………

Date 10 July 2018

SUPERVISOR’S CONFIRMATION OF AUTHORSHIP ATTRIBUTION

As supervisor for the candidature upon which this thesis is based, I can confirm that the Authorship Attribution Statement is correct.

A/Prof Maree Hackett ………………… 10 July 2018

Supervisor Name Signature Date
Presentations arising from this thesis [oral]

July 2017  School of Public Health’s 2017 Research Showcase – presented the results of a systematic review on Indigenous health research processes

June 2017  Invited speaker at the Sydney Medical Program Research Methods seminar series on Research with Vulnerable Populations

June 2017  NSW Aboriginal Mental Health and Wellbeing Workforce Forum – presented the results of a systematic review on Indigenous health research processes

July 2016  Aboriginal and Torres Strait Islander Health Research Forum – presented Getting it Right: the validation study and my PhD research

December 2016  Society for Mental Health Research Conference – presented the results of a systematic review on Indigenous health research processes

Research grants supporting this thesis

2017  Postgraduate Research Support Scheme by The University of Sydney

2016  John Chalmers Program Grant Scholarship by The George Institute for Global Health

2016  Cross Cultural Public Health Research Award The University of Sydney
ACKNOWLEDGEMENT OF COUNTRY

I would like to acknowledge and pay respect to the traditional owners of the land where this research was conducted. Through this research I have met and worked with Ngunnawal, Yuggerah, Worimi, Barkindgi, Wilykali, Darawal, Larrikia, Aranda, Kaura, Noongar and Darkinjung people. The Gadigal people are the traditional owners of the Eora nation, where I work, live and where the University of Sydney is located. It is with deep respect that I recognise Aboriginal ways of being, knowing and enduring Custodianship of Country.
CHAPTER 1
INTRODUCTION

Aboriginal and Torres Strait Islander (hereafter referred to as Indigenous\(^1\)) people are the original custodians of Australia. Indigenous people have occupied traditional lands for at least 50,000 years,\(^8,9\) making them the oldest continuing civilisation on earth. Indigenous cultures are rich and diverse, and include approximately 250 distinct language groups.\(^10,11\)

Before colonisation, traditional Indigenous life was governed by strong social structures, based around kinship that promoted collective and individual wellbeing.\(^10,12\) Life was closely connected with the land, and sophisticated farming, fishing and cultivation practices produced a nutritious diet\(^13,14\) and a healthy physical and social existence.\(^15\)

Colonisation dislocated communities from traditional lands, disconnected families and communities and disrupted cultural and social structures.\(^16,17\) The harms of colonisation are ongoing, and it is now well established that colonisation is a major cause of the current gap in the health status between Indigenous and non-indigenous communities.\(^17,18\) Despite this disruption, Indigenous cultures are resilient and remain strong today.\(^19\)

Traditional Indigenous perspectives of health are often holistic, involving spiritual connections to community, culture and Country.\(^12,20\) These contrast with Western perspectives that are predominantly focused on the absence of disease or symptoms.\(^21\) Today, definitions of Indigenous health commonly comprise social and emotional wellbeing (SEWB), which includes mental health within a holistic framework that recognises that wellbeing is interconnected with land, culture, family and community, as well as being influenced by historical, political and cultural determinants.\(^12\)

SEWB-related healthcare is often delivered at primary healthcare (PHC) services\(^22\) and it is now broadly agreed that delivering culturally-appropriate PHC is important to

\(^1\) The term ‘Indigenous peoples’ is respectfully used in this paper and refers to all Aboriginal and/or Torres Strait Islander peoples of Australia. I acknowledge the cultural diversity of Australia’s Indigenous First peoples, and they do not represent a homogenous group.
maximise health of Indigenous people.\textsuperscript{23-26} Around Australia, a network of Indigenous-focused PHC services (including Aboriginal Community Controlled Health Services (ACCHS), Aboriginal Medical Services (AMS)\textsuperscript{27} and other services that deliver PHC in Indigenous communities) operate and aim to deliver culturally-appropriate care. These services often focus on strengthening SEWB by building resilience,\textsuperscript{17, 28} and focusing on other protective factors (such as connection to land, culture, spirituality and ancestry, kinship and self-determination\textsuperscript{16}) as well as assessing and treating physical and mental health problems.\textsuperscript{29}

To contribute to health gains and reduce the high rates of psychological distress among Indigenous Australians compared to non-indigenous Australians,\textsuperscript{30} these services need access to high-quality evidence to inform culturally-appropriate PHC delivery.

\subsection*{1.1 Developing evidence for culturally-appropriate social and emotional wellbeing}

There is limited research evidence available to Indigenous PHC services to inform culturally-appropriate screening, assessment and treatment of people with SEWB problems (defined in this thesis as depression, anxiety and post-traumatic stress disorder (PTSD), and thoughts of self-harm, suicidal ideation or intent). For example, there are few empirical data about the burden and consequences of depressive illness,\textsuperscript{31} few assessment resources that are culturally-appropriate and valid,\textsuperscript{32-34} and limited information on effective strategies to build resilience\textsuperscript{35} or suicide prevention programs.\textsuperscript{36} Research can provide the framework where such evidence is developed.

All research comes with potential risks\textsuperscript{37} that should be considered to ensure a net benefit is achieved.\textsuperscript{38} There are particular concerns related to research involving Indigenous people\textsuperscript{39, 40} arising from some research that is now considered culturally inappropriate and had caused harm or oppressed Indigenous communities.\textsuperscript{41} For example, early research after colonisation focused on ‘observing, analysing, studying, classifying and labelling’ individuals and communities\textsuperscript{42} and drew offensive conclusions about the inferior nature of Indigenous people.\textsuperscript{12, 38}

More recently, some studies have been said to provide little or no community benefit\textsuperscript{43, 44}, or have focused on describing the size and nature of the problem without offering
solutions. Some commentators have suggested that despite large numbers of Indigenous-focused health issues being studied, only modest improvements in health have occurred, therefore, they have called for research that is focused on delivering tangible outcomes at the community level where the research is conducted. There is also discussion in the literature about the use of Western research methods which do not consider the ways in which Indigenous people view the world. Despite these concerns, there are continued calls for high-quality culturally-appropriate research:

The need to tackle health inequality for Indigenous people brings a sense of urgency and responsibility to health research. To facilitate culturally-appropriate research, a national guideline for Indigenous-focused research was developed, namely, Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (hereafter referred to as the Values and Ethics Guideline). This document states that ‘to ignore the reality of inter-cultural difference is to live with outdated notions’, highlighting the challenges experienced when conducting traditional academic research in Australia (which has developed within a Western perspective) that is appropriate within Indigenous communities. The influence of this document on facilitating culturally-appropriate research is unclear, because only few researchers have reported how their study addressed the Values and Ethics Guideline.

As is highlighted in the Values and Ethics Guideline, ethical relationships between Indigenous and research communities can occur, and some such relationships are in the form of research teams involving community members, PHC staff (hereafter referred to as staff) and researchers external to the community who collaborate to conduct research in Indigenous-focused PHC services. As well as developing the evidence base around culturally-appropriate approaches to PHC (and other) health service delivery, research teams like these may contribute to research translation by ensuring research is culturally appropriate and encouraging the uptake of evidence into PHC service delivery.

Some research teams have described the processes they used when planning and conducting research, providing information about approaches that may be useful to other teams. However, routine reporting of the processes used by research teams is not widespread, which limits the sharing of learning about effective processes, ways to
address common challenges and the resources needed to conduct high-quality, culturally-appropriate research that produces community-level outcomes.

1.2 Incorporating perspectives within the research team

One challenge for research teams is to incorporate the perspectives of everyone involved in the research projects, that is, community members, research participants, staff and researchers. For instance, some researchers may perceive that designing a line of investigation that is of a ‘high quality’ and results in rigorous scientific outcomes is the priority, because it is likely to contribute to improvements in health. However, some research designs that produce such evidence may be considered culturally-inappropriate in some Indigenous communities, and therefore require modification or are ultimately unsuitable for Indigenous communities to use.

Although randomised controlled trials and systematic reviews of randomised controlled trials are purported to provide the highest quality evidence using standard academic criteria (Level 1)63, 64, some Indigenous communities may perceive them to be culturally-inappropriate and therefore, this research design may require modification63 or not to be appropriate for use at all.65 Similarly, frameworks used to evaluate health services may be inappropriate and require modification.66

Balancing these various requirements and conducting research that is high quality and culturally appropriate may be a challenge for some research teams.48, 60, 65 This research may be further challenged by commonly reported barriers, such as staffing shortages,67 difficulties recruiting participants67, 68 and limited resources to address logistical barriers, such as phone and travel costs for participants to travel to research sites.69

In this thesis research will be considered as planned and conducted over four broad stages. Initially, in the pre-research stage, literature and available knowledge is collated to identify whether a perceived gap in evidence is genuine. In the developmental stage, a research project is designed which will address the gap in evidence or answered the associated question about lack of evidence. Next, data are collected and analysed (research conduct stage), followed by the reporting of results and a translation of research findings into practice (research translation stage). Having Indigenous people in research leadership roles throughout these four stages70-72 or involving Indigenous
community members is considered\textsuperscript{7,52,73-75} essential to facilitating research that is acceptable and culturally appropriate.

The stage where communities become involved research may vary. Some research is driven by The Lowitja Institute (Australia’s national institute for Aboriginal and Torres Strait Islander health research) which aims to involve community members at all stages of research,\textsuperscript{71,72} while some research is developed and driven by Indigenous-focused PHC services.\textsuperscript{76} Sometimes research projects may be developed outside a community, which results in Indigenous-focused PHC services becoming involved in the research conduct or translation stages.\textsuperscript{44} To manage such research, some communities have established community governance structures to review research projects\textsuperscript{55,77} or Local Protocols which they use to communicate community preferences for standards of behaviour to external researchers.\textsuperscript{78}

Research teams who formally share their experiences and processes of conducting high-quality, culturally-appropriate SEWB PHC research provide examples for other research teams, communities and policy-makers that may assist with planning future research.\textsuperscript{75} This sharing may also reduce the risks of repeating past mistakes. Routine reporting of research processes by research teams is not yet widespread.

1.3 Summary of thesis aims

Overall, a strong argument can be made that high-quality, culturally-appropriate Indigenous-focused SEWB PHC research is critical to ‘close the gap’ between Indigenous and non-indigenous health outcomes. This research needs to provide tangible benefits that are relevant, effective, culturally-respectful and feasible.\textsuperscript{75} Such research is often conducted by research teams which involve community members, PHC staff and researchers external to the community. In this thesis, I aim to identify approaches and enablers to the conduct of high-quality, culturally-appropriate Indigenous-focused SEWB PHC research by research teams, by exploring multiple perspectives of research, including scientific and ethical perspectives of quality, and the perspectives of staff, PHC patients, researchers and myself.

I will use the example of an Indigenous-focused SEWB PHC research project that I managed, entitled \textit{Getting it Right: the validation study} (hereafter referred to as \textit{Getting}}
it Right) to: (i) explore the use of scientific and ethical criteria; (ii) report my reflections as the project manager (PM); and (iii) use qualitative interviews to document the perspectives of staff involved with the research.

1.4 Thesis structure

CHAPTER 2

METHODS: SYSTEMATIC REVIEWS OF INDIGENOUS-FOCUSED SOCIAL AND EMOTIONAL WELLBEING PRIMARY HEALTHCARE RESEARCH

Objectives

To outline the systematic methods used to determine the quality of Indigenous-focused SEWB PHC research:

1. To present the scientific and ethical criteria used to determine the quality of the research.

2. To present the methods used to identify the enablers and barriers to the research, and the implications of the research within participating communities.

In Chapter 2 I will outline how I will collate researchers’ perspectives. I will describe the methods I will use to identify and synthesise Indigenous-focused SEWB PHC research in the upcoming systematic reviews. It includes a publication of the systematic review protocol and describes the methods I will use when reviewing the literature in Chapter 3 to determine the scientific quality and community acceptance of research projects, and if and how the authors reported addressing the Values and Ethics Guideline during the research.

CHAPTER 3

RESULTS: SYSTEMATIC REVIEWS OF INDIGENOUS-FOCUSED SOCIAL AND EMOTIONAL WELLBEING PRIMARY HEALTHCARE RESEARCH

Objectives

To examine how authors report Indigenous-focused SEWB PHC research:
1. To determine research quality with the use of scientific and ethical criteria (including criteria to determine community acceptance and assessment to identify if and how research addresses the Values and Ethics Guideline).

2. To identify common barriers and enablers that are reported by authors when conducting research.

3. To identify research outcomes.

In Chapter 3 I will present two systematic reviews and an additional results section. I will identify what is known about high-quality, culturally-appropriate research, the enablers and barriers to research and research outcomes.

CHAPTER 4
PROTOCOL, PROCESSES AND RESULTS OF GETTING IT RIGHT

Objectives

1. To describe the protocol and processes of setting up and managing Getting it Right.

2. To outline the main results from Getting it Right.

In Chapter 4 I will briefly describe the Getting it Right protocol and results and outline the processes of identifying and setting up an Indigenous-focused PHC research project. Considerations that may be particular to Indigenous-focused PHC SEWB research will be identified and highlighted. The origins of the process evaluation will also be described (Chapters 7 to 9).

CHAPTER 5
CRITICAL EVALUATION OF GETTING IT RIGHT

Objective

1. To determine the scientific and ethical quality of Getting it Right using the community acceptance criteria and to identify if and how the Values and Ethics Guideline was adhered to during the research.

In Chapter 5 I will explore how scientific criteria compliment and sometimes conflict with ethical criteria during Indigenous-focused PHC SEWB research. I will compare
Getting it Right with similar research projects and illustrate how 10 Indigenous-focused PHC services were involved with the pre-research, developmental, research conduct and research translation stages.

CHAPTER 6

REFLECTIVE CASE STUDY OF GETTING IT RIGHT

Objectives

1. To document my reflections on the enablers and barriers to Getting it Right, and my lessons learnt as the PM.

2. To link my reflections to the Values and Ethics Guideline\(^7\) to explore if and how my experiences relate to this document.

3. To demonstrate how my reflections informed how I conducted the research and their impact on my cultural competence, before I began the process evaluation (Chapters 7 to 9).

In Chapter 6 I will present my perspective as PM of Getting it Right. I will reflect on my cultural competence working with Indigenous communities and identify how my reflections during the research influenced my approach to the research.

CHAPTER 7

METHODS AND KEY RESULTS: PROCESS EVALUATION OF GETTING IT RIGHT

Objectives

1. To explore the experiences of PHC staff and participants with the depression screening tool under investigation during Getting it Right, including their perceptions about the acceptability and feasibility of using the tool.

2. To determine if the research project was conducted in accordance with the study protocol.

3. To explore the context, impact and consequences of Getting it Right.

4. To explore the experiences of PHC staff and participants during Getting it Right, including about the approaches, enablers and barriers to conducting the research.
In Chapter 7 I will examine the perspectives of staff and PHC participants about *Getting it Right*. These results add to the information presented in the critical evaluation in Chapter 5 by identifying if, when and why the research deviated from the study protocol, identifying if the research results can be relied upon. In Chapters 8 and 9 I will present additional results from the process evaluation.

**CHAPTER 8**

**PROCESS EVALUATION RESULTS: PERSPECTIVES OF STAFF AND PATIENTS ABOUT PARTICIPATING IN SEWB RESEARCH**

**Objective**

1. To explore the perspectives and experiences of staff and patients about their willingness to participate in the Indigenous-focused SEWB PHC research.

In Chapter 8 I will explore novel themes that arose from the process evaluation and identify staff and patients’ experiences about their willingness to participate in *Getting it Right* and speak about SEWB.

**CHAPTER 9**

**PROCESS EVALUATION RESULTS: THE ROLE OF RESOURCES IN RESEARCH**

**Objective**

1. To explore the role of resourcing and resources during Indigenous-focused SEWB PHC research.

In Chapter 9 I will explore more novel themes that arose during the process evaluation, such as: (i) the influence of financial reimbursement to Indigenous-focused PHC services during research; (ii) the influence of human resources on research; and (iii) the consequences of offering participants vouchers to reimburse them for the time involved with research.

**CHAPTER 10: SUMMARY AND RECOMMENDATIONS**

In Chapter 10 I will summarise the main findings and provide key recommendations from this thesis on approaches and enablers to the conduct of high-quality, culturally-
appropriate Indigenous-focused SEWB PHC research. Strengths and limitations will also be discussed.

1.5 Significance of this thesis

Considerable attention is currently being focused on achieving sustainable Indigenous health gains. There is a need for evidence-based outcomes from high-quality, culturally-appropriate research that translates to changes at the community-level. This thesis may benefit Indigenous-focused PHC services interested in research by:

1. Providing information about the quality of research with the use of scientific quality criteria, community acceptance criteria and the Values and Ethics Guideline. This will highlight the strengths and opportunities for future culturally-appropriate, evidence-based PHC research studies.

2. Documenting and sharing an example of a national Indigenous-focused SEWB PHC research project from the perspectives of staff, patients and community members. This will identify opportunities to build on enablers and mitigate common barriers during future research.

3. Documenting the perceptions and preferences of community members about research. This will allow for future research that is in-line with community preferences.

4. Highlighting novel ideas occurring during Getting it Right to inform communities, researchers and policy makers about the strengths, weaknesses and feasibility of conducting research.

This research was conducted within an established network of PHC services associated with Getting it Right and includes extensive community engagement, which supports the transferability of its findings to PHC services and the community.
CHAPTER 2

METHODS: SYSTEMATIC REVIEWS OF INDIGENOUS-FOCUSED SOCIAL AND EMOTIONAL WELLBEING PRIMARY HEALTHCARE RESEARCH

2.1 Introduction

In this chapter, I present the methods I used to conduct two systematic reviews of Indigenous-focused SEWB PHC research (presented in Chapter 3). I outline how I determined the scientific quality, community acceptance and if and how research addressed the Values and Ethics Guideline, as well as how I identified the enablers and barriers to research and the research outcomes within the communities involved. Furthermore, I outline how I collated the perspective of researchers by reviewing how they reported on the research.

This chapter includes the following publication of the systematic review protocol and additional methods that I developed after the protocol was published:

Farnbach S, Eades AM, Hackett M. Australian Aboriginal and Torres Strait Islander-focused primary healthcare social and emotional wellbeing research: a systematic review protocol. Systematic Reviews. 2015;4(189).

https://doi.org/10.1186/s13643-015-0180-6

2.2 Methods (publication)

**Australian Aboriginal and Torres Strait Islander-focused primary healthcare social and emotional wellbeing research: a systematic review protocol**

**Overview of publication**

This publication summarises the protocol I followed in the two systematic reviews of Indigenous-focused SEWB PHC research. The aims, search methods, outcome measures, data extraction and data analysis methods are described. The definitions of the values described by the Value and Ethics Guidelines used in the systematic review are presented in Appendix 1.
Australian Aboriginal and Torres Strait Islander-focused primary healthcare social and emotional wellbeing research: a systematic review protocol

Sara Farnbach1,2*, Anne-Marie Eades1,2 and Maree Lisa Hackett1,2

Abstract

Background: Research with a focus on Aboriginal and Torres Strait Islander Australians (hereafter referred to as Indigenous) needs is crucial to ensure culturally appropriate evidence-based strategies are developed to improve health. However, concerns surrounding this research exist, arising from some previous research lacking community consultation, resulting in little community benefit or infringing on important cultural values. Values and Ethics: Guidelines for Ethical conduct in Aboriginal and Torres Strait Islander Health Research (hereafter referred to as Values and Ethics), developed by The National Health and Medical Research Council of Australia in 2003, is the ethical standard for Indigenous-focused health research. Researchers must address its Values in research design and conduct. However, its impact on research processes is unclear. Local Protocols should also be considered. This review aims to systematically examine practices related to Values and Ethics, Local Protocols and the processes of conducting Indigenous-focused primary healthcare research in collaboration with external researchers.

Methods: The following electronic databases and grey literature will be searched (2003 to current): MEDLINE, EMBASE, CINAHL, Informit and HealthInfoNet—an Indigenous-specific research and program website. Indigenous-focused research will be included. Research must be conducted in one or more primary healthcare services, in collaboration with external researchers and with a focus on social and emotional well being. One reviewer will review titles and abstracts to remove obviously irrelevant research articles. Full-text research articles will be retrieved and independently examined by two reviewers. Data and quality assessment will be completed by one reviewer and verified by a second reviewer. Quality will be assessed using modified versions of established quality assessment tools.

Discussion: This review will provide information on research processes and the impact of Values and Ethics on Indigenous-focused primary healthcare research, informing communities and primary healthcare staff around research practices, and researchers and policy makers of strengths and weaknesses of practice.

Systematic review registration: PROSPERO CRD42015024994

Keywords: Aboriginal and Torres Strait Islander, Indigenous, Australia, Primary healthcare, Research, Social and emotional wellbeing, Mental health

* Correspondence: sfarnbach@georgeinstitute.org.au
1The George Institute for Global Health, PO Box M201Missenden Road, Camperdown, New South Wales, Australia
2The University of Sydney, Sydney, New South Wales, Australia

© 2015 Farnbach et al. Open Access This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.
Background

Health research intended to benefit Aboriginal and Torres Strait Islander (hereafter referred to as Indigenous) people has frequently been conducted poorly, with little collaboration between the researchers and Indigenous communities, often without providing any short- or long-term benefit to the communities or individuals involved. Non-Indigenous researchers have commonly held control of Indigenous-focused research [1], and health research has been criticised for its repetitive portrayal of poor Indigenous health status, lack of community collaboration [2], and little or no clear positive benefit to the communities or individuals involved [3, 4]. These factors, on the historical backdrop of colonisation, have led to a distrust of Western researchers by some Indigenous people [5, 6].

There has been a concerted effort to change the approach to Indigenous-focused health research, placing a greater emphasis on community benefit, collaboration, knowledge transfer and relationships between communities and researchers. This has resulted in the development of several strategies to improve research processes. The Interim Guideline on Ethical Matters in Aboriginal and Torres Strait Islander Health Research was developed in 1991 [7]; however, it was quickly revised, as it was found to lack focus on sound research principles [8], failed to establish processes for the ongoing review of projects, and was considered to be ‘watered-down’ from its original principles [5].

In 2003 the revised Value and Ethics: Guideline for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research [9] (hereafter referred to as Value and Ethics) was published. Value and Ethics [9] was developed as an authoritative statement and has the same status as the National Statement for Health Research [10]. It outlines the following Values that researchers, academic institutions and funders must consider when conducting Indigenous-focused health research: reciprocity, respect, equality, responsibility, survival and protection, and spirit and integrity [9]. The impact of Value and Ethics [9] on research processes, and on community benefit, is unclear [11, 12].

Value and Ethics [9] emphasises several key principles, including the conduct of research that addresses community-determined priority areas, developing community capacity through skills or knowledge development and including communities as equal partners in the research process. To complete research according to these principles, researchers need to be adaptable, and additional time and resources may be necessary in comparison with non-Indigenous focused research. However, there has been a perception that funding agencies, institutional and academic structures rarely allocate sufficient resources or make allowances for researchers to complete this work. This presents a unique and challenging environment for Indigenous-focused research to occur [11–13]. An evaluation of Value and Ethics [9] is being jointly conducted by The Lowitja Institute and National Health and Medical Research Council of Australia and revisions of the document are under consideration [14, 15].

Increasingly, researchers and communities are documenting components of setting up and managing research projects. Examples of community-controlled research [16], community participation in research [17], documentation of Local Protocols [18, 19], a description of important principles for research [20] and recommendations for completing specific research methods with Indigenous communities, for example conducting survey-based research [8], have been published. However, there are few examples specific actions taken by researchers to address Values and Ethics [9] when conducting health research [21, 22].

One setting where consideration of Values and Ethics [9] is required is research conducted in Primary Health Care (PHC) services. PHC is an important component of the healthcare system. Effective PHC in Indigenous communities has been effective in improving patient outcomes and reducing costs in the hospital system [23]. Health research set in, and relevant to Indigenous communities is needed to ensure that services are of high quality, use the best available evidence, and are culturally appropriate. PHC research is a challenging and resource-intensive process [24], and additional challenges exist when conducting research in Indigenous-focused PHC services [25]. PHC research may be initiated externally, by researchers who identify a problem and approach PHC services to participate, or initiated within a PHC service, where staff identify a problem and conduct their own research—they may also invite external researchers to be involved.

Maintaining and improving the social and emotional wellbeing (SEWB) of Indigenous people is often the goal of PHC services and staff. The term SEWB describes a strength-based holistic perspective of mental health that acknowledges the socio-historical and personal influences on mental health [26]. This term is preferred by some communities, including by many Indigenous Australians. The SEWB of Australia’s Indigenous people is poor compared to Australia’s non-Indigenous population. Suicide rates are twice as high, and Indigenous people are nearly three times as likely to experience high or very high levels of psychological distress than the non-Indigenous population [27]. This disparity exists within a complex historical and social environment. Evidence-based strategies to improve the SEWB of Indigenous communities must be developed.

Conducting Indigenous-focused health research in the PHC setting is challenging; however, it is crucial, as
culturally appropriate SEWB services are needed to address the disparity in health between Indigenous and non-Indigenous Australians [13]. An understanding of externally and internally initiated PHC-based research to improve SEWB, including the barriers and enablers to conducting research in this setting, is needed.

We will undertake a systematic review of research conducted with collaboration between Australian PHC services and external researchers, and a focus on improving Indigenous SEWB.

**Methods**

This protocol has been registered with PROSPERO CRD42015024994 and reported adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-P (PRISMA) statement [28]. Research will be assessed according to Rationale and Standard for the systematic review of qualitative literature in health services research [29] and MOOSE Guidelines for Meta-Analyses and Systematic Reviews of Observational Studies guidelines [30].

**Objective**

We will systematically review the conduct of published Indigenous-focused SEWB PHC research in relation to Values and Ethics [9]. Our primary aim is to identify actions, (as reported by the author and identified by the reviewers), that relate to Values and Ethics [9] and Local Protocols (any processes or procedures developed by a community that researchers are expected to adhere to when conducting research or interacting with the community). Our secondary aims are to identify the enablers and barriers to research (as reported by authors) and to comment on ways the research may be translated into practice.

This review will support improved community-researcher relationships by providing Indigenous communities and PHC staff with information to understand current practices, and policy makers and researchers working in the field with information on how research is planned and implemented in line with Values and Ethics [9].

**Types of research**

Research using qualitative, quantitative or mixed methods in the PHC setting, designed to improve Indigenous SEWB will be included. For the purpose of this review, this includes research addressing workforce issues, training, service coordination, resource development, evaluation of interventions, PHC planning, service-level policy, services, processes or the evidence base related to PHC. Only research where the researchers generated original data will be included.

**Research setting**

Research must be mostly conducted (where at least half of the research or recruitment occurs) in one or more PHC services and include collaboration between PHC service staff and external researchers.

**Types of participants**

Eligible research must have an explicit focus on Australian Indigenous patients or staff of an Indigenous-focused PHC service.

**Types of interventions**

Interventions aiming to improve the SEWB of Indigenous people attending PHC services, including those focusing on social, emotional, spiritual and cultural wellbeing will be included. Eligible research will have an explicit focus on one of the following areas:

- The broad concept of SEWB or mental health
- Depression disorders
- Anxiety disorders
- Smoking or alcohol use, including dual diagnosis

**Excluded research**

We will exclude research with no collaboration between external researchers and PHC service staff or patients, e.g., opinion pieces, internal evaluations, resource reviews or literature reviews. Research with a focus on a specific component of SEWB (e.g., violence, suicide, parenting or perinatal care) rather than the broad concept of SEWB will be excluded, with the exception of research related to depression, anxiety, alcohol consumption, smoking and dual diagnosis. Study protocols with no available findings will be excluded.

**Types of outcome measures**

Research meeting the above criteria will be analysed for actions taken that relate to the Values outlined in Values and Ethics [9] and Local Protocols. A list of potential actions, based on Values and Ethics [9], will be used to describe where values were met (or otherwise) according to the definitions in Additional file 1. We will document the Values that have been explicitly followed. Where processes are described that are in line with Values and Ethics [9] but no explicit reference to Values and Ethics [9] is provided, we will describe these actions.

We will outline where researchers have followed Local Protocols. Drawing on the data described above, we will comment on ways the research may be
translated into practice and impact on community-researcher relationships.

**Search methods for identification of research**

The following databases will be searched (from 2003) to identify research published in English: MEDLINE, EMBASE, CINAHL and Informit. HealthInfoNet, a website containing a regularly updated list of Indigenous-focused health research, programs and other knowledge, will also be searched. This timeframe was selected to correspond with the development of Values and Ethics [9]. A comprehensive search strategy using the following key words will be developed: primary healthcare, Aboriginal and Torres Strait Islander social and emotional wellbeing. An example of the search strategy is illustrated in Table 1. Programs and projects listed on the HealthInfoNet website, categorised under the social and emotional wellbeing topic area will be reviewed. The full search strategy for other databases will be available upon request.

**Data collection and analysis**

**Selection of research**

All research articles (titles and abstracts) identified during the search will be imported into an EndNote library [31]. Duplicates will be removed. One reviewer (SF) will review titles and abstracts according to the criteria, to remove obviously irrelevant articles. Full text articles will be retrieved, and the remaining articles will be independently examined by two reviewers against the criteria. Disagreement surrounding the inclusion of an article will be resolved by discussion, or reviewed by a third reviewer (MH) if a consensus cannot be reached.

Programs and projects listed on the HealthInfoNet website social and emotional wellbeing page will be reviewed by SF, and obviously irrelevant programs will be excluded. The remaining programs and projects will be reviewed following the process mentioned above. Where there is a lack of clarity surrounding the project or program, up to three attempts will be made to contact the authors, via phone or email, to determine if further documents are publicly available. Only programs with a publication, report or evaluation will be included in the review.

**Data management and extraction**

Data extraction and quality assessment will be completed simultaneously. Data will be extracted by one reviewer (SF) and verified by a second reviewer (AME). Research articles will be examined and data related to the outcome measures and review questions will be identified and extracted using data extraction forms specificity designed for this review.

To address the primary outcome, actions related to the use of Values and Ethics’ Values (reciprocity, respect,

**Table 1 Medline via Ovid search strategy**

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Search Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>(Primary care or General pract* or Primary health care)tw. or Community mental health services/or Family practice/or Home care services/or Family physicians/or Community health services/or Community health nursing/or Community pharmacy services/or Community health workers/or Preventive health services/</td>
</tr>
<tr>
<td>2.</td>
<td>(Community mental health* or Family practice or Family medicine or Family physician* or Home care or Home based or Home health* or Community health* or Community nurse* or health visit* or Community pharmac* or Preventive care or Prevention program* or Preventive service* or Preventive health or Health promotion or aboriginal medical service or aboriginal community medical service).tw.</td>
</tr>
<tr>
<td>3.</td>
<td>1 or 2</td>
</tr>
<tr>
<td>4.</td>
<td>oceanic ancestry group/or aborig<em>tw. or indigenous.tw. or Torres strait</em>islander.tw.</td>
</tr>
<tr>
<td>5.</td>
<td>exp australia/ or australia<em>tw. or au.in. or australia</em>.in. or northern territory.tw. or northern territory.in. or tasmania.tw. or tasmania.in. or new south wales.tw. or new south wales.in. or victoria.tw. or victoria.in. or queensland.tw. or queensland.in.</td>
</tr>
<tr>
<td>6.</td>
<td>4 and 5</td>
</tr>
<tr>
<td>7.</td>
<td>3 and 6</td>
</tr>
<tr>
<td>8.</td>
<td>mental health/</td>
</tr>
<tr>
<td>9.</td>
<td>mental health.mp.</td>
</tr>
<tr>
<td>10.</td>
<td>mental disorder.mp.</td>
</tr>
<tr>
<td>11.</td>
<td>mental disorder/</td>
</tr>
<tr>
<td>12.</td>
<td>(social adj2 wellbeing).mp.</td>
</tr>
<tr>
<td>13.</td>
<td>(well adj2 being).mp.</td>
</tr>
<tr>
<td>14.</td>
<td>(social and emotional wellbeing).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]</td>
</tr>
<tr>
<td>15.</td>
<td>grief/</td>
</tr>
<tr>
<td>17.</td>
<td>Stress, Psychological/</td>
</tr>
<tr>
<td>18.</td>
<td>stress.mp.</td>
</tr>
<tr>
<td>19.</td>
<td>(trauma adj2 abuse).mp.</td>
</tr>
<tr>
<td>20.</td>
<td>domestic violence/or child abuse/or elder abuse/or spouse abuse/</td>
</tr>
<tr>
<td>21.</td>
<td>(removal adj2 famil*).mp.</td>
</tr>
<tr>
<td>22.</td>
<td>substance-related disorders/or alcohol-related disorders/or amphetamine-related disorders/or inhalant abuse/or marijuana abuse/or psychoses, substance-induced/</td>
</tr>
<tr>
<td>23.</td>
<td>(substance adj2 (abuse or misuse)).mp.</td>
</tr>
<tr>
<td>24.</td>
<td>(family adj2 (breakdown or breakup)).mp.</td>
</tr>
<tr>
<td>26.</td>
<td>Prejudice/or racism.mp.</td>
</tr>
<tr>
<td>27.</td>
<td>(racial adj2 discrimination).mp.</td>
</tr>
<tr>
<td>28.</td>
<td>Socioeconomic Factors/</td>
</tr>
<tr>
<td>29.</td>
<td>(social adj2 disadvantage*).mp.</td>
</tr>
<tr>
<td>30.</td>
<td>Depression/or depression.mp.</td>
</tr>
<tr>
<td>31.</td>
<td>anxiety/or anxiety*.mp.</td>
</tr>
<tr>
<td>32.</td>
<td>distress.mp.</td>
</tr>
<tr>
<td>33.</td>
<td>8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32</td>
</tr>
</tbody>
</table>

Footnote:* includes all available forms of that word e.g Australia* includes Australia, Australians and Australia’s
equality, responsibility, survival and protection and spirit and integrity) [9] and Local Protocols as reported by the author or identified by the reviewer will be extracted.

To address the secondary outcomes, the enablers and barriers as reported by the author and the implications for research practice will be extracted.

Data synthesis
The main findings will include a narrative synthesis of Value and Ethics’ use, enablers and barriers to research, impact on practice and impact on community-researcher relationships.

Quality assessment of research findings
Research meeting the above criteria will be categorised according to the research method and assessed for quality using the Qualitative Research Checklist from Critical Appraisal Skills Programme [32] (qualitative), Quality Assessment Tool For Quantitative Studies [33] (quantitative), or the Cochrane Collaboration’s tool for assessing risk of bias [34] (clinical trials).

Quality will be assessed by one reviewer (SF) and verified by a second reviewer (AME). Both reviewers will discuss research if a lack of consensus occurs. Assistance from a third interviewer (MH) will be sought if consensus cannot be reached. For research using multiple methods, research will be assessed according to the method that relates most closely to the primary aim of the research. Where mixed methods including a randomised control trial are used, a risk of bias assessment will also be completed. No research will be excluded based on quality.

Discussion
This systematic review will provide an overview of the research processes, enablers and barriers and impact on practice and on community-researcher relationships, to conducting Indigenous-focused SEWB PHC research in relation to Values and Ethics [9]. The findings from this review will provide Indigenous communities and PHC staff with information regarding current practices, high- light the use of Values and Ethics [9] and enable policy makers and researchers to identify better processes in order to plan and implement future research in line with Values and Ethics [9].

The identification of successful processes will assist future research design. By systematically identifying and collating enablers and barriers encountered when conducting research, this review will fill an important gap in the healthcare literature, relating to the successful and ethical conduct of Indigenous-focused PHC research conducted in collaboration with the external researchers. This review will provide insight into the impact and implementation of Values and Ethics [9].

Endnotes
1 The term “Indigenous peoples” is used throughout the paper refers to all Aboriginal and/or Torres Strait Islander peoples of Australia. It is used to reflect the fact that Australia’s Indigenous people do not represent a homogenous group.

Additional file

Additional file 1: Definitions and potential actions for the Values. (32.6 kb)

Abbreviations
Indigenous: Aboriginal and Torres Strait Islander; Local Protocols: any processes or procedures developed by a community that researchers are expected to adhere to when conducting research or interacting with the community; PHC: primary healthcare; PRISMA: Preferred Items for Systematic Review and Meta-Analysis protocols; PROSPERO: International prospective register of systematic reviews; SEWB: social and emotional wellbeing; Values and Ethics: Value and Ethics: Guideline for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.

Competing interests
The authors declare that they have no completing interests. No funding has been received to complete this review. Anne-Marie Eades was in receipt of a National Health Research Scholarship APP1056434. Maree L Hackett was in receipt of a National Heart Foundation Future Leader Fellowship 100034. These funding bodies had no role in the conduct or reporting of this review.

Authors’ contributions
SF and MH conceived and designed the protocol. SF will lead this review as part of her Doctor in Philosophy. SF will develop the search strategy and retrieve the electronic results. AME will be the second reviewer. MH supervises SF and AME will provide advice related to the review and act as the third reviewer where required. All authors read and approved the final manuscript.

Acknowledgements
The authors would like to acknowledge staff at The University of Sydney Medical Library, for their help developing the search strategy for this review.

Received: 28 September 2015 Accepted: 21 December 2015 Published online: 30 December 2015

References


2.2.1 Additional methods used in systematic reviews

After submitting the protocol for publication, I identified additional methods required for systematic reviews. These methods were necessary to assess Indigenous community acceptance during the research, as presented below.

2.2.1.1 Defining an Indigenous ‘community’

The definition of a ‘community’ was needed to determine community acceptance of the research. Defining what constitutes, and who represents, an Indigenous community can be challenging because there are various levels of involvement within communities that may be important in different situations. Each have different meanings for individuals (Figure 2.1). For the purpose of this thesis, the Indigenous community is defined by the community, and commonly includes staff, patients, families, carers, community members and community representatives.

![Figure 2.1 Potential levels of Indigenous communities](image-url)
2.2.1.2 Indigenous community acceptance criteria

To assess Indigenous community acceptance, I reviewed key Indigenous health research guidance documents\(^7,\ 52,\ 71,\ 73-75\) and identified components that are commonly described as important in Indigenous research. A central theme across these documents is the involvement of Indigenous communities throughout the research stage (i.e. development and conduct to research translation stages) to plan and conduct research that is acceptable to the community. Therefore, I developed four criteria to determine community acceptance of research.

**CRITERIA 1. INDIGENOUS COMMUNITY GOVERNANCE OF RESEARCH**

Authors explicitly mentioned:

1. Evidence of community governance for example, approval for research from an Indigenous-focused PHC service\(^2\)/Health Board\(^3\) (or similar); or

2. Community oversight of research via a Reference/Advisory Group (or similar) that includes Indigenous membership; or

3. Research led by an Indigenous-focused PHC service.

**CRITERIA 2. INDIGENOUS COMMUNITY INVOLVEMENT IN RESEARCH DEVELOPMENT**

1. Authors explicitly mentioned how a community became involved during research development (research question generation) and design; or

2. Research was led by an Indigenous-focused PHC service. If the first author was a staff member that service, this was judged to indicate community involvement in research development.

**CRITERIA 3. INDIGENOUS COMMUNITY INVOLVEMENT IN STUDY CONDUCT**

Authors explicitly mentioned how the community was involved during the conduct stage, e.g. data collection, recruitment, study coordination or data analysis.

---

\(^2\) Indigenous-focused PHC services include ACCHS, AMS or organisations that represent a local Indigenous community.

\(^3\) Health Boards involve any group of community representatives established to review and approve research conducted in their Indigenous community. This includes community research boards, community research committees and community juries. In this thesis, when a Health Board uses a specific name this is used.
CRITERIA 4. INDIGENOUS COMMUNITY INVOLVEMENT IN RESEARCH REPORTING

1. Authors explicitly mentioned how the community was involved during the reporting of research findings, e.g. reviewed manuscript, provided intellectual input; or

2. Representative(s) from Indigenous-focused PHC services were authors. If research was led by a service, or if the first author was from the service, this was judged to indicate involvement in reporting. However, if the author was a subsequent author, this was deemed to be unclear (i.e. deemed unclear Indigenous involvement in reporting because the role of the author in reporting research is unclear, e.g. authorship may be due to conduct or inception of the research, rather than involvement with its writing.)

If a study is linked with other studies or larger projects, this was noted and scored as unclear because these methods may be reported elsewhere and not captured in this study report. Where possible we identified and reviewed reports of larger studies.

Overall assessment was completed in the following manner:

1. High community acceptance: 3 or 4 criteria met, with no more than one unclear rating.

2. Low community acceptance: 0 or 1 criterion met.

3. Unclear community acceptance: 2 or more unclear ratings and no criteria clearly met.

2.2.1.3 Defining SEWB for the systematic review

For the purposes of these reviews, the definition of SEWB presented on page 2 (Chapter 1) is used. Research focused on smoking and alcohol misuse were also included in the review when authors mentioned an aim to address SEWB as part of the research.

2.3 Conclusion

In this chapter, I present the methods that I use in the systematic reviews (Chapter 3) to determine the scientific quality, community acceptance, and if and how the Values and Ethics Guideline was addressed during the research. In Chapter 3, I will present the results from two systematic reviews that identify the conduct of high-quality and culturally-appropriate Indigenous-focused SEWB PHC research.
CHAPTER 3

RESULTS: SYSTEMATIC REVIEWS OF INDIGENOUS-FOCUSED SOCIAL AND EMOTIONAL WELLBEING PRIMARY HEALTHCARE RESEARCH

3.1 Introduction

In this chapter, I systematically review the literature to provide information from the perspectives of researchers by determining how they reported Indigenous-focused SEWB PHC research. The methods used in this chapter are presented in Chapter 2. The results of these systematic reviews comprise two publications. The first review identifies the designs, processes, results and quality of the included research, and the second review identifies actions that authors reported that address the Values and Ethics Guideline\(^7\) or Local Protocols. An additional unpublished results section is presented and describes the enablers and barriers to conducting research (as reported by authors) and the implications of research within the communities involved (reviewers’ assessment).

This chapter examines quality from scientific and ethical perspectives to identify what is known about the conduct of high-quality and culturally-appropriate Indigenous-focused SEWB PHC research. This chapter includes two publications:


**Farnbach S**, Eades AM, Gwynn JD, Glozier N, Hackett ML. The conduct of Indigenous primary healthcare research focused on social and emotional wellbeing involving collaborations: A systematic review Public Health Res Pract. Online early publication [https://doi.org/10.17061/phrp27451704](https://doi.org/10.17061/phrp27451704)
3.2 Results 1 (publication)
The quality of Australian Indigenous primary healthcare research focusing on social and emotional wellbeing: a systematic review

OVERVIEW OF PUBLICATION

This systematic review of Indigenous-focused SEWB PHC research identifies designs, processes and main results, as well as determining the quality of research by using scientific quality and community acceptance criteria. Supplementary tables included in the publication are presented in Appendix 2. This systematic review was reviewed by the Aboriginal Health and Medical Research Council of NSW (AHMRC) before submission to a journal (Appendix 3).
The quality of Australian Indigenous primary health care research focusing on social and emotional wellbeing: a systematic review

Sara Farnbacha,b,i, Anne-Marie Eadesa,b, Jamie K Fernando, Josephine D Gwynnd,e, Nick Glozierefg and Maree L Hacketta,b,h

a The George Institute for Global Health, UNSW, Sydney, Australia
b School of Medicine, University of Sydney, NSW, Australia
c School of Medicine and Public Health, University of Newcastle, NSW, Australia
d Poche Centre for Indigenous Health, University of Sydney, NSW, Australia
e Faculty of Health Sciences, University of Sydney, NSW, Australia
f Brain and Mind Centre, University of Sydney, NSW, Australia
g Central Clinical School, University of Sydney, NSW, Australia
h Faculty of Health and Wellbeing, University of Central Lancashire, Preston, UK
i Corresponding author: sfarnbach@georgeinstitute.org.au

Abstract

Objectives and importance of the study: Primary health care research focused on Aboriginal and Torres Strait Islander (Indigenous) people is needed to ensure that key frontline services provide evidence based and culturally appropriate care. We systematically reviewed the published primary health care literature to identify research designs, processes and outcomes, and assess the scientific quality of research focused on social and emotional wellbeing. This will inform future research to improve evidence based, culturally appropriate primary health care.

Study type: Systematic review in accordance with PRISMA and MOOSE guidelines.

Methods: Four databases and one Indigenous-specific project website were searched for qualitative, quantitative and mixed-method published research. Studies that were conducted in primary health care services and focused on the social and emotional wellbeing of Indigenous people were included. Scientific quality was assessed using risk-of-bias assessment tools that were modified to meet our aims. We assessed community acceptance by identifying the involvement of community governance structures and representation during research development, conduct and reporting. Data were extracted using standard forms developed for this review.

Results: We included 32 articles, which reported on 25 studies. Qualitative and mixed methods were used in 18 studies. Twelve articles were judged as high or unclear risk of bias, four as moderate and five as low risk of bias. Another four studies were not able to be assessed as they did not align with the risk-of-bias tools. Of the five articles judged as low risk of bias, two also had high community acceptance and both of these were qualitative. One used a phenomenological approach and the other combined participatory action research with a social–ecological perspective and incorporated ‘two-
Values and ethics

For ethical conduct in Indigenous health research, a set of guidelines and improvements in health outcomes are limited. To amount of research completed, community-level benefit research arise from the perception that, despite the large culturally appropriate. Concerns about this type of healthcare provided is evidence based and culturally appropriate, community-acceptable research. Researchers and ethics committees on the conduct of culturally appropriate, community-acceptable research.

Conducting research that is culturally appropriate and acceptable to the Indigenous community where it is being completed may require modification of traditional research designs and processes. For example, use of participatory action research designs or research processes that involve extensive community consultation may mean that traditional approaches need to be adapted. Increasingly, Indigenous research methods and designs are being used. When conducting research that is culturally appropriate, researchers must balance using culturally appropriate methods with the need for research that is of high scientific quality.

The term ‘social and emotional wellbeing’ (SEWB) is preferred by many Indigenous people to ‘mental health’, as it implies a holistic, strengths-based perspective of mental health. SEWB is an important aspect of health, and the SEWB of Australia’s Indigenous people is reported to be poor compared with the non-Indigenous population. Culturally appropriate, evidence based research strategies are needed to effectively improve the SEWB of Indigenous people.

As the health system’s ‘front line’, primary health care services often provide SEWB-related care, including screening, early intervention and management. The stigma associated with seeking help for SEWB-related issues and the perception by some people that hospitals are unwelcoming may hinder access to mainstream mental health and state-run services. Primary health care services offer a discreet and independent alternative, and these services are often where Indigenous-focused SEWB research is conducted. This research is commonly conducted by teams that include primary health care staff, community members and researchers external to the community. Primary health care research is a challenging and resource-intensive process, and Indigenous-focused primary health care research must also comply with Values and ethics and be acceptable to the community.

In this review, we aim to identify the study designs, processes, outcomes and quality indicators of Indigenous-focused SEWB primary health care research conducted by teams that include researchers who are located outside the community. A subsequent review will describe actions relating to Values and ethics and local protocols.

Methods

A protocol for this review has been published previously, and is in accordance with PRISMA and MOOSE guidelines. This study is registered with PROSPERO (CRD42015024994). Database searches were conducted in Medline, Embase, CINAHL, Informit databases and HealthInfoNet, an Indigenous-specific research and project website, using the following terms: ‘Indigenous’, ‘social and emotional wellbeing’, ‘mental health’ and ‘primary health care’. To capture studies conducted since the development of Values and ethics, a date limit was applied from January 2003 to February 2015.

Published studies were included if they used qualitative, quantitative or mixed methods, focused on Indigenous SEWB, and were conducted in one or more primary health care services. Journal articles, reports and evaluations were included. We included studies involving research teams, including primary health care staff, community members and researchers located outside the community. SEWB describes a strengths-based holistic perspective of mental health that acknowledges the sociohistorical and personal influences on mental health. We included SEWB/mental health, depression disorders, anxiety disorders, dual diagnosis (SEWB and drug or alcohol use), and smoking and alcohol use.

We excluded studies that did not generate original data or where at least half the research occurred outside a primary health care service. Primary health care services included Aboriginal Medical Services (AMSs).
Aboriginal community controlled health services, and health services that provide primary health care or had general practitioners as staff members. In this review, the term AMS includes Aboriginal community controlled health services and Indigenous health services. ‘Community’ refers to primary health care or AMS staff, patients, families or community members. For the purpose of this review, Indigenous refers to Australian Aboriginal and/or Torres Strait Islander people.

One reviewer screened titles and abstracts, and excluded obviously irrelevant studies and duplicates. Two reviewers examined full-text versions of the articles remaining after screening. Data were extracted using data extraction forms developed for this review. In accordance with our protocol, we assessed risk of bias using adapted versions of existing risk-of-bias assessment tools. Studies using mixed methods were assessed according to the dominant method used. To assess community acceptance, we considered common aspects described in key Indigenous research documents, and identified if the following criteria were reported: 1) community governance; 2) community representation in study development; 3) community representation in study conduct (data collection, data analysis); and 4) community representation in reporting. Refer to the supplementary tables (available from: www.researchgate.net/publication/317099307_FINAL_2017_05_25_Farnbach_Systematic_Review_Supp_Tables) for details of the community acceptance assessment. We considered studies meeting three or four of the criteria as acceptable.

Results

A total of 2288 articles and program reports were identified (Figure 1). We removed 402 duplicates and excluded 1491 studies based on their title or abstract. There were 395 studies that required full-text assessment. To ensure all relevant articles and program reports were identified, we attempted to contact 50 authors to request additional data. Of these, 36 replied and 24 provided new data. A total of 37 articles relating to 25 studies were included in the review.

Multiple articles that reported findings relating to the same study (such as one evaluation, one project, one survey, one interview/focus group session, or one questionnaire) were considered as a single study, and all references were included. The included studies focused on:

- SEWB (nine studies)
- Alcohol misuse (five studies)
- Smoking cessation (four studies)
- Dual diagnosis – SEWB and drug or alcohol misuse (three studies)
- Depression, or a mental health worker program (four studies)
- Nineteen studies were conducted in AMSs, four in services aimed at providing primary health care

Study design

Qualitative methods were used in 18 studies, six of which used mixed methods, and one of which was a quasi-experimental design. Quantitative methods on their own were used in five studies. One case study was included. Participatory action research principles were used in combination with yarning techniques, a social–ecological perspective or as part of a mixed-
methods study.19,20 Two-way learning approaches were described by three studies.15,16,19,20,23,24 Sociological action research principles were used once.42 One study involved a review of existing case management models, followed by a staff survey and training.36

Three studies were part of the Australian Integrated Mental Health Initiative (AIMhi).19,30,35,36 AIMhi aimed to improve outcomes for Indigenous clients of remote mental health services. AIMhi 1 developed a mental health ‘brief intervention’ and conducted a randomised controlled trial to evaluate the intervention.19,20 AIMhi 2 used mixed methods to examine service-level challenges30, and AIMhi 3 developed and assessed an electronic mental health resource.31 AIMhi was followed by the AIMhi Priority Driven Research Partnership, which involved the community, AMS and external researchers.32

Voices United for Harmony constituted three substudies27,28,33,35 to develop and assess the effectiveness of a participatory singing program to improve SEWB and physical health. AMS staff coordinated the studies’ activities and participants were AMS patients. Three related studies used qualitative, mixed-methods and quantitative designs to examine staff practices35 and experiences37, and quantify the effect of staff training on alcohol screening and brief interventions in AMSs.36

Primary health care staff and patients were the most common participants. In four studies, families29,43 and carers39,43 of primary health care patients were participants. Community elders, families and residents were involved in the establishment of the AIMhi Priority Driven Research Partnership.32 Voices United for Harmony involved community leaders during study design and implementation.27,28,33,34

Study initiation process

Seven studies appeared to be initiated by researchers external to the primary health care service23,24,27,28,33,37, seven arose from research partnerships15,16,19,20,30,32,38,46 and three appeared to be jointly initiated.25,26,40,42 A community also invited a researcher from outside the community to evaluate a SEWB service.29 It was unclear how the remaining seven studies were initiated.17,18,21,29,33,41,43-45

Study outcomes

Primary outcomes were identified and met in 16 studies.19-29,31,33-37,39,42,43,45. Outcomes related to identifying participant perceptions and experiences13,24,26,34,35,39,42,43; evaluating an intervention19,20,27,28,33,34,36, a service24 or training37; and developing and assessing the acceptability of a resource.25,31

Two primary outcomes were identified and met in three studies.21-26 For example, one study assessed the acceptability of an alcohol-related intervention21 and identified cut-off scores of an alcohol dependence screening tool for Indigenous clients.22 Two of these articles reported on data that appear to have been collected at one time point.26,28

We were unable to identify primary outcomes in eight studies. These included a case study46; AIMhi 236, the AIMhi Priority Driven Research Partnership35; a study to develop and assess a psychological assessment tool44; and projects focused on depression46, a case management model38 and capacity development relating to dual diagnosis.17,18 The primary outcome was somewhat met in one study, where a workplace policy was developed as planned, but acceptability testing was pending.41 The AIMhi 1 and Voices United for Harmony evaluations demonstrated improved outcomes for participants who received the intervention.19,20,27,28,33,34

Risk of bias and community acceptance

We included peer-reviewed journal articles and articles from other publications describing processes, including an evaluation, description of a partnership and development of a model. Consultation, training and project reports were also included. Four studies did not align with the standard risk-of-bias assessment tools and therefore could not be assessed.15-18,32,38

In 12 studies, the risk of bias was judged to be high19,20,27,28,30,33,35,37,39,46 or unclear21,22,27,36,40,45. four were at moderate risk of bias19,20,25,26,41,42,44 and five were at a low risk of bias.23,24,29,31,39,43 AIMhi 1 was assessed using the qualitative19 and randomised controlled trial20 risk-of-bias tools, because these methods were reported separately.

Using the qualitative risk-of-bias tool, most studies were deemed to have a moderate25,26,41,42,44 or high20,25,30,35,37,40,46 risk of bias. These ratings were because of missing or unclear reporting of many of the criteria used to assess bias. For example, actions related to ethical issues were not reported in more than half the studies. Processes related to informed consent, confidentiality or consideration of the impact of the authors’ relationship with the participants were described by authors of six studies.23,24,29,31,39,42,43

Assessment of quantitative studies presented specific challenges. Quantitative studies included a survey21,22, quality improvement cohort study36, case study40, validation study45 and cohort analytic quasi-experimental design.27,28,33,34 Many assessment criteria were not applicable for these designs. For example, assessing intervention integrity was not applicable when assessing the validation study25 or the quality improvement cohort study.36

The Voices United for Harmony quasi-experimental designs27,28,33,34 were found to have high risk of bias because of participant self-selection (selection bias), confounding, lack of blinding and the high number of dropouts in two of the studies.33,34 In these studies and the case study, participant selection methods were developed in response to community feedback and were based on participants’ ability or willingness to take part in the program or intervention, rather than using sampling.
randomised or consecutive methods. Two of the Voices United for Harmony initiatives used valid and reliable data collection tools, leading to a low risk of bias for this criteria.

The AIMhi randomised controlled trial was judged to have a moderate risk of bias. Documentation of allocation concealment and blinding of participants and personnel during outcome assessment was unclear.

Communities’ perspectives were rarely reported. However, nine studies were assessed as having high community acceptance (three to four criteria met), leading to a low risk of bias for this criteria.

Two of the included studies were part of large, ongoing research partnerships, which may have involved extensive community engagement, but this was not described. We were unable to determine community acceptance in four studies. This was because of the lack of reporting between linked articles or because primary health care service staff were co-authors and the extent of their involvement during research development, conduct and reporting was not described. Two studies were judged as having high community acceptance and low risk of bias.

Discussion

We identified only two studies that were judged to be scientifically robust and acceptable to the community. Other studies with high community acceptance were deemed to have a moderate risk of bias, unclear or high risk of bias, or were unable to be assessed using standard assessment tools. This results in uncertainty about the strength and generalisability of their findings. Where community perspectives were unclear, it was difficult to determine if this was because of underreporting (possibly related to publication word limits) or if it reflected community dissatisfaction. Although not explicitly reported, involving community members in key positions or extensive community consultation may suggest acceptance and have led to culturally appropriate designs.

A variety of designs and processes were used in the included studies. These depended on the study aim, the collaboration and the community involved. This variation, together with the diversity among Indigenous communities, makes drawing general conclusions about designs challenging.

Qualitative studies appeared to have greater community acceptance and lower risk of bias than quantitative and mixed-methods studies. However, qualitative research is considered Level IV evidence in the scientific community, meaning there is a lack of certainty when drawing conclusions from its findings. In addition, the primary outcomes identified in most of the qualitative studies involved identifying perceptions or experiences, suggesting limited impact on primary health care delivery.

Concerns about randomised controlled trials that involve Indigenous communities include the perception that randomisation is unethical. However, randomised controlled trials are considered Level I evidence in the scientific community. Two studies in this review involved randomised controlled trials, and both used flexible randomisation processes. In one study, participants were randomised into ‘early’ and ‘late’ intervention groups, meaning that all participants received the intervention at different time points. Although the authors did not provide justification for this approach, the study was part of a large, ongoing initiative, suggesting collaboration with the community. In the other study, the design was modified to a nonrandomised, quasi-experimental design in response to community feedback. Both studies were assessed as having a high risk of bias, demonstrating the challenges of implementing study designs in Indigenous communities that are considered high quality in the academic community.

These challenges surrounding randomised controlled trials have been reported previously, including by the authors of one study who described modifying the design to address challenges and encourage recruitment. The researchers ceased this study, citing clinic, patient, staff and study design–related factors that made the project untenable. Evidence based research methods have developed within a Western cultural perspective, which does not incorporate Indigenous social, cultural or historical perspectives. These examples demonstrate how evidence based research methods may not be appropriate for Indigenous communities, because of these differing perspectives.

Culturally sensitive approaches, including two-way learning, participatory, social–ecological and phenomenological approaches were used in five studies. In one, participatory action research was used to localise an intervention and study design. These approaches appeared to improve community acceptance by incorporating local perspectives. We propose that research projects incorporate these culturally sensitive approaches, as identified in this review.

There is increasing focus on methods that incorporate Indigenous perspectives and Indigenous ways of knowing, being and doing. Regardless of the topic under investigation, research incorporating Indigenous perspectives will lead to primary health care that is better aligned with the needs of Indigenous people. However, there appear to be few examples of their implementation in practice.

In this review, we identified outcomes related to evaluating interventions, services or training in seven studies or assessing resources in two. These outcomes indicate potential impact at the community level. Research should improve health
and result in community-level benefit.\textsuperscript{2} We propose that research is reported according to the following outcomes:

1. Process outcomes that describe steps taken during planning and implementation
2. Academic outcomes that describe dissemination and academic achievements
3. Clinical outcomes that describe efficacy, impact, cost-effectiveness and research translation
4. Community outcomes that describe ongoing implementation and efficacy, cost savings, access changes, community engagement and other outcomes that the community determines to be relevant.

Reporting these outcomes will provide a balanced description of how to achieve high-quality, community-endorsed research that is likely to affect clinical practice and health outcomes. We suggest considering these outcomes, together with the community-acceptance principles highlighted in this review, when assessing the quality of Indigenous-focused research.

There are several limitations to this review. The breadth of formats included (evaluations, reports and journal articles) did not fit easily with standard risk-of-bias assessment tools, and we modified these tools to make assessment feasible. We were restricted to the information reported in articles, which may exclude some information. Although we have identified criteria to indicate community involvement and acceptance, we recognise this may not comprehensively capture all aspects of culturally appropriate research. In addition, we recognise that the diversity of Indigenous communities throughout Australia means that a process that is suitable in one community may not be suitable in another.

Conclusion

There are few examples of Indigenous-focused SEWB primary health care research that are of high scientific quality and acceptable to the community. This provides many opportunities for improvements for research in all domains. Use of participatory action research, social-ecological approaches and incorporation of two-way learning principles appears to facilitate research that incorporates Indigenous perspectives. We recommend that consideration of community-level outcomes and the community-acceptance principles highlighted in this review are kept at the forefront throughout research. This will improve culturally appropriate research that positively impacts the SEWB of Indigenous people.

Acknowledgements

We acknowledge staff at the University of Sydney Medical Library for their help developing the search strategy. AE was in receipt of a National Health and Medical Research Scholarship (APP1056434). JF was in receipt of the Rowan Nicks Russell Drysdale Fellowship and MH was in receipt of a National Heart Foundation Future Leader Fellowship (100034). These funding bodies had no role in the conduct or reporting of this review.

Competing interests

None declared

Author contributions

SF led this review. AE was the second reviewer for the data extraction and analysis. MH supervises SF and AE and provided oversight to this review. NG helped to develop the study protocol and reporting. JF and JG provided input on the discussion and conclusions. All authors reviewed and contributed to writing the manuscript.

References


3.3 Results 2 (publication)
The conduct of Indigenous primary healthcare research focused on social and emotional wellbeing involving collaborations: a systematic review

OVERVIEW OF PUBLICATION

This systematic review of Indigenous-focused SEWB PHC research examines actions reported by authors that addressed the Values and Ethics Guideline and community preferences for standards of behaviour (Local Protocols) during the research. This manuscript was reviewed by the AHMRC before submission to a journal (Appendix 3). The supplementary tables included in this publication are presented in Appendix 2.

I developed a list of potential actions identified during this thesis (Appendix 1) to explore if and how research addresses the Values and Ethics Guideline. This list includes actions identified during the systematic reviews and the case study of Getting it Right (Chapters 4 to 6).

PUBLICATION DETAILS

Abstract

Objectives and importance of study: Values and ethics: guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research (Values and ethics) describes key values that should underpin Aboriginal and Torres Strait Islander (Indigenous)-focused health research. It is unclear how research teams address this document in primary health care research. We systematically review the primary health care literature focusing on Indigenous social and emotional wellbeing (SEWB) to identify how Values and ethics and community preferences for standards of behaviour (local protocols) are addressed during research.

Study type: Systematic review in accordance with PRISMA Guidelines and MOOSE Guidelines for Meta-Analyses and Systematic Reviews of Observational Studies.

Methods: We searched four databases and one Indigenous-specific website for qualitative, quantitative and mixed-method studies published since Values and ethics was implemented (2003). Included studies were conducted in primary health care services, focused on Indigenous SEWB and were conducted by research teams. Using standard data extraction forms, we identified actions taken (reported by authors or identified by us) relating to Values and ethics and local protocols.

Key points

• Authors of Australian Indigenous primary health care research rarely report how their research addresses the national ethical guidelines, Values and ethics: guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research (Values and ethics)
• Culturally sensitive approaches, developing relationships and involving community members appear to enable research, and uphold the principles in Values and ethics
• The academic community should focus on developing the Indigenous research workforce
• Authors should be encouraged to report actions and processes taken during research, to inform research planning and learning between research teams.
Results: A total of 25 studies were included. Authors of two studies explicitly mentioned the *Values and ethics* document, but neither reported how their actions related to the document’s values. In more than half the studies, we identified at least three actions relating to the values. Some actions related to multiple values, including the use of culturally sensitive research processes and involving Indigenous representatives in the research team. Local protocols were rarely reported.

Conclusion: Addressing *Values and ethics* appears to improve research projects. The academic community should focus on culturally sensitive research processes, relationship building and developing the Indigenous research workforce, to facilitate acceptable research that affects health outcomes. For *Values and ethics* to achieve its full impact and to improve learning between research teams, authors should be encouraged to report how the principles are addressed during research, including barriers and enablers that are encountered.

Introduction

Primary health care research focusing on Aboriginal and Torres Strait Islander (Indigenous) peoples’ needs is crucial to ensure evidence-based and acceptable care is available. Perceptions that some past Indigenous-focused health research has provided minimal benefit, or excluded Indigenous people, have led to concerns surrounding Indigenous-focused research practices. To guide researchers, ethics committees and communities, *Values and ethics: guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research* (Values and ethics) and its companion document were developed. For research involving Indigenous people, *Values and ethics* has the same status and authority as the National statement on ethical conduct in human research. Although some authors have described addressing the *Values and ethics* document during research, its impact on research conduct is unclear. An evaluation of *Values and ethics* by the Lowitja Institute and the National Health and Medical Research Council (NHMRC) is under way.

Primary health care services are considered the ‘frontline’ of the health system and are well positioned to identify and manage problems relating to social and emotional wellbeing (SEWB). The high rates of suicide and psychological distress among Indigenous people call for a particular focus on ensuring that SEWB care is effective, evidence-based and acceptable. Research provides the framework to explore and assess SEWB care. Many Indigenous-focused primary health care services have programs or teams focusing on providing SEWB care. These services are often part of research teams involving primary health care staff, community members and externally located researchers, who collaborate to conduct SEWB research. Particular consideration of this research is needed because of the sensitive nature of research focused on SEWB and the challenges of implementing research in primary health care services.

*Values and ethics* identifies the following six values as key in underpinning research: reciprocity, respect, equality, responsibility, survival and protection, and spirit and integrity (see review protocol for definitions). *Values and ethics* is an authoritative statement on Indigenous-focused health research. Other guidance documents include a practical guide for researchers, a guideline for the ethical conduct of research and a document identifying important principles for Indigenous-focused health research. In previous work, authors have drawn on the principles to examine the processes and procedures required to address its recommendations.

There is overlap across these documents, with a common feature being to involve Indigenous representatives. However, there may be a lack of involvement, or reporting of involvement, of Indigenous people in research. This is demonstrated in a review of Indigenous child health research that identified involvement in only 28.6% of the 217 studies included.

Alongside *Values and ethics*, communities’ preferences and priorities should be considered during research planning and conduct. Community preferences can be formally documented local protocols, or undocumented standards of behaviour that research projects must adhere to within a community.

Using examples of Indigenous-focused SEWB primary health care research, we review and identify actions taken during research related to the application of *Values and ethics* and local protocols. Our previous review described the study designs, processes and main findings, and assessed the quality of the identified studies.
Methods

The methods used in this review are previously published\textsuperscript{13,19}, and are in accordance with PRISMA and MOOSE guidelines. This study is registered with PROSPERO (CRD42015024994). In brief, we searched Medline, Embase, CINAHL, Informit and HealthInfoNet. A date limit of January 2003 to February 2015 was applied to capture qualitative, quantitative or mixed-method studies conducted since the publication of *Values and ethics*. We included studies that were conducted in primary health care services, focused on Indigenous SEWB and that were conducted by research teams. We defined research teams as collaborations developed to conduct research that include primary health care staff or community members and researchers located outside the community. We included journal articles, reports and evaluations.

SEWB describes a strengths-based, holistic perspective of mental health that acknowledges social, historical and protective factors.\textsuperscript{20} In this review, we included SEWB, mental health, smoking or alcohol use, and depression and anxiety disorders. Primary health care services include Aboriginal medical services (AMSs), Aboriginal community controlled health services, and health services that provide primary health care or have general practitioners as staff members. Community refers to primary health care or AMS staff, patients, families or community members.

Data were extracted onto standard forms developed for this review. We identified when authors reported, or we identified actions taken relating to, the values detailed in *Values and ethics* using a previously developed list of potential actions\textsuperscript{13} and local protocols.

Results

Our search identified 2288 articles and projects. Following screening, 402 were found to be duplicates and 1491 articles were removed as they did not meet our inclusion criteria (described previously\textsuperscript{19}). A total of 395 articles were reviewed by two reviewers, and 32 articles relating to 25 studies were included in the review (Supplementary Table 1 provides a full reference list; available from: www.researchgate.net/publication/317099307_FINAL_2017_05_25_Farnbach_Systematic_Review_Supp_Tables). When two articles reported on one evaluation\textsuperscript{21,22} or project\textsuperscript{23,24} and 26,29, or articles appeared to report data collected from one set of surveys\textsuperscript{27,28}, interview/focus group sessions\textsuperscript{29,30} and 31,32 or questionnaires\textsuperscript{33,34}, we included both articles and considered it as a single study.

The included studies focused on SEWB (nine)\textsuperscript{25,26,31-40}, alcohol misuse (five)\textsuperscript{27,28,41-44}, smoking cessation (four)\textsuperscript{29,30,45,47} or dual diagnosis (SEWB and drug/alcohol misuse; three)\textsuperscript{23,24,48,49}. Two studies focused on depression.\textsuperscript{50,51} One focused on depression or anxiety\textsuperscript{62} and another on a mental health worker program.\textsuperscript{21,22}

Three studies were part of the Australian Integrated Mental Health Initiative (AIMhi)\textsuperscript{25,26,37}, a large research initiative aiming to improve outcomes for Indigenous clients of remote mental health services. The AIMhi 1\textsuperscript{25,26}, AIMhi 2\textsuperscript{26} and AIMhi 3\textsuperscript{37} studies have involved a research team known as the AIMhi Priority Driven Partnership, which involved community-based and university-based researchers.\textsuperscript{38} Three studies were part of the Voices United for Harmony program, which developed and assessed a participatory singing program aimed at improving SEWB and physical health.\textsuperscript{33,34,39,40} Another three focused on alcohol screening and brief interventions in AMSs.\textsuperscript{41-43} One study that modified a psychological screening instrument\textsuperscript{52} was followed by another assessing its validity.\textsuperscript{51}

Use of *Values and ethics* and local protocols

Authors explicitly mentioned *Values and ethics* in only two studies.\textsuperscript{44,45} In one\textsuperscript{44}, authors identified their use of participatory action research methods as being in line with the document, and in the other study\textsuperscript{45}, authors reported following *Values and ethics* during the research process. However, neither described specific actions relating to the values detailed in *Values and ethics*.

From the 25 studies, we identified 88 actions that related to (endorsed) the values in *Values and ethics*. Because each action could relate to more than one value, we identified a total of 146 endorsements of the values across all studies (Table 1). Several actions were identified in multiple studies (Table 2). Most common was acknowledging the contribution of primary health care staff\textsuperscript{27,34,36,37,39,40,43,49}, services\textsuperscript{21,22,31-34,39,40,43,50}, patients\textsuperscript{33,34,39,40,42,49}, communities\textsuperscript{27,28}, Indigenous organisations\textsuperscript{30} or community members\textsuperscript{52} in publications, or including staff as authors on publications.\textsuperscript{29,30,38,44,47,49-52} This endorsed five values. Authors of two studies\textsuperscript{35,42} reporting visiting the community during research planning, with visits helping authors to understand the local context.\textsuperscript{43} Carey reports\textsuperscript{35}:

*The researcher spent approximately 12 months travelling to the community to develop and build relationships … these visits provided the principal researcher with an enhanced awareness of the functioning of the community, helped inform the design of the research, and promoted a greater understanding of the purpose of the research by members of the community.*

The largest number of actions we identified from a single study was seven (\(n = 3\) studies)\textsuperscript{25,26,30,52} Some actions endorsed several values. For example, three studies used participatory action research methods\textsuperscript{25,26,30,47} demonstrating respect, equality, responsibility, and spirit and integrity. In one study\textsuperscript{33,34},
authors modified the study to a nonrandomised design following community feedback, demonstrating reciprocity. This recognised the community’s aspirations and demonstrated commitment to work within the spirit and integrity of the community.

Table 1. Percentage of studies with actions that endorsed values and the number of endorsements for each value

<table>
<thead>
<tr>
<th>Value</th>
<th>Studies with actions identified by reviewers that endorsed each value (N = 25 studies), % (n)</th>
<th>Number of endorsements for each value (n = 88 actions; n = 146 endorsements)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect</td>
<td>96 (24)</td>
<td>62</td>
</tr>
<tr>
<td>Reciprocity</td>
<td>60 (15)</td>
<td>20</td>
</tr>
<tr>
<td>Survival and protection</td>
<td>32 (8)</td>
<td>18</td>
</tr>
<tr>
<td>Responsibility</td>
<td>48 (12)</td>
<td>17</td>
</tr>
<tr>
<td>Equality</td>
<td>44 (11)</td>
<td>16</td>
</tr>
<tr>
<td>Spirit and integrity</td>
<td>52 (13)</td>
<td>13</td>
</tr>
</tbody>
</table>

*a “Endorsements” are the number of times an action related to a value. Some actions endorsed (or related to) multiple values."
Table 2. Summary of reported (by author) and identified (by reviewers) use of Values and ethics

<table>
<thead>
<tr>
<th>Action or process identified as addressing the values in Values and ethics (number of studies)</th>
<th>Reciprocity</th>
<th>Respect</th>
<th>Equality</th>
<th>Responsibility</th>
<th>Survival and protection</th>
<th>Spirit and integrity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgement in the publication of primary health care staff (n = 11)27,34,36,37,39,40,42,49,52, services (n = 8)21,22,31,34,39,40,43,55, patients (n = 5)33,34,39,41,42,45, communities (n = 1)27,28, Indigenous organisations (n = 1)29,30, or community members (n = 1)52</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publication authorship includes primary health care staff (n = 7)38,44,45,46,47,49,51, or Indigenous organisation staff (n = 2)29,30,52</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research team involves Indigenous representatives: Community Elders (n = 3)33,34,39,40, primary health care staff6 (n = 3)33,34,39,40, steering committee membership (n = 1)55, reference group membership (n = 1)64, as investigators (n = 1)25,26, or families, carers and communities were involved (n = 1)38</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research interventions were informed by previous locally conducted studies (n = 2)41,43, or feedback from primary health care staff/patients/community (n = 3)25,26,47,50</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention developed within a collaborative framework (n = 1)46</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants reimbursed for participation (n = 5) (voucher amount: $25, $40, $50)27,28,40,45,51</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexible interview location (n = 2)29,52, time (n = 1)46, or methods (n = 1)31,32</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community identified need for research (n = 3) (drug and alcohol services48, formal service evaluation15, or alcohol screening and brief intervention65)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resources adapted for use by Indigenous people (n = 3) (screening cut-off points27,28, depression screening tool25, or mental health strategy25,28)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participatory action research methods used (n = 1)25,26,66 Used in combination with social–ecological perspective (n = 1)29,30 or yarning techniques (n = 1)47</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research approved by community research governance committee (n = 4)25,26,31,32,44,45</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultation informed resources and training materials (n = 1)23,24, or study instruments (n = 1)27,28,60</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study planning and implementation driven by primary health care staff (n = 2)38,46,66</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular visits during planning to understand local processes/context (n = 1)45 or to develop research methods (n = 1)56</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informed consent involved two-step process (n = 1)36 or written, pictorial and translation options (n = 1)35,26</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘Two-way learning’ processes used (n = 2)21,22,29,30</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Continued next page
<table>
<thead>
<tr>
<th>Action or process identified as addressing the values in <em>Values and ethics</em> (number of studies)</th>
<th>Reciprocity</th>
<th>Respect</th>
<th>Equality</th>
<th>Responsibility</th>
<th>Survival and protection</th>
<th>Spirit and integrity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action plan developed to implement research findings <em>(n = 1)</em>&lt;sup&gt;a&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resources will remain with the community <em>(n = 1)</em>&lt;sup&gt;b&lt;/sup&gt;&lt;sup&gt;c&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phenomenological research methods used <em>(n = 1)</em>&lt;sup&gt;d&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interviews conducted by Indigenous community member <em>(n = 1)</em>&lt;sup&gt;e&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chief Executive Officer at primary health care service approved publications or results before release <em>(n = 1)</em>&lt;sup&gt;f&lt;/sup&gt;&lt;sup&gt;g&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intention to provide information to other communities by identifying processes instead of programs in evaluation <em>(n = 1)</em>&lt;sup&gt;i&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study design developed in conjunction with the research governance committee (health board) <em>(n = 1)</em>&lt;sup&gt;j&lt;/sup&gt;&lt;sup&gt;k&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Project underpinned by six Iga Warta principles for Aboriginal health projects (prevention, coordination, sustainability, social determinants of health, sensitivity to Indigenous notions of time and space, and community and family) <em>(n = 1)</em>&lt;sup&gt;l&lt;/sup&gt;&lt;sup&gt;m&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focus on knowledge translation, and findings provided to stakeholders <em>(n = 1)</em>&lt;sup&gt;n&lt;/sup&gt;&lt;sup,o&lt;/sup&gt;&lt;sup&gt;p&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cultural mentorship of researchers by respected Elder <em>(n = 1)</em>&lt;sup&gt;q&lt;/sup&gt;&lt;sup,r&lt;/sup&gt;&lt;sup&gt;s&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Visits by researcher during research according to Aboriginal medical service needs and preferences <em>(n = 1)</em>&lt;sup&gt;t&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study proposed by the Indigenous organisation <em>(n = 1)</em>&lt;sup&gt;u&lt;/sup&gt;&lt;sup&gt;v&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Regular feedback provided to stakeholders. Steering committee (including community representatives) provided feedback on findings <em>(n = 1)</em>&lt;sup&gt;g&lt;/sup&gt;&lt;sup&gt;x&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authors did not publish some findings to protect participant confidentiality <em>(n = 1)</em>&lt;sup&gt;y&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Focus on providing training to primary health care staff <em>(n = 1)</em>&lt;sup&gt;z&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research underpinned by empowerment principles <em>(n = 1)</em>&lt;sup&gt;aa&lt;/sup&gt;&lt;sup&gt;ab&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study modified to nonrandomised design following community feedback <em>(n = 1)</em>&lt;sup&gt;ac&lt;/sup&gt;&lt;sup&gt;ad&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* a Study appeared to be led by primary health care staff  
 b Community participatory approach used  
 c ‘Two-way learning’ processes used  
 d Pilot tested before use  
 e Support provided by external researchers
Involving Indigenous community representatives in key positions incorporated Indigenous knowledge and experience into research (respect). It was common to involve Community Elders, primary health care staff, families, carers and communities, or any of these as members of a steering committee, reference group or as investigators. Consultations to inform resources or study instruments development were reported twice. Acknowledging the contribution of participants (respect) by providing shopping or food vouchers was reported in five studies. Willingness to modify research according to a community’s values and aspirations through flexible research processes (reciprocity) was also common. This included flexible interview times, locations or methods, multiple visits during planning, or modifying study design following community feedback.

Authors of three studies reported using ‘two-way learning’ principles, which demonstrated equality, survival and protection (efforts to reduce the threat to cultural distinctiveness); and respect (incorporating Indigenous knowledge). This included the Aboriginal Mental Health Worker Program evaluation and a smoking cessation study with Aboriginal health workers. The smoking cessation study also used participatory action research methods, had a cultural mentor to advise researchers and was underpinned by Iga Warta principles, a set of guiding principles for community participation and service delivery in Indigenous communities. These actions also demonstrated survival and protection, spirit and integrity, and respect.

Some of the other actions relating to survival and protection included involving families, carers or community representatives in the research team. In addition to using participatory action research methods, Indigenous researchers in AIMhi 1 were investigators, demonstrating efforts to sustain equality and reduce the threat to cultural distinctiveness (survival and protection). Authors of one study decided not to publish some findings to protect the confidentiality of participants.

No authors reported compliance with documented local protocols; however, a respected Elder provided cultural mentorship to the research team in one study. This suggests consideration of locally acceptable standards of behaviour.

Discussion

Our results show that reporting of how research addresses Values and ethics is lacking. This suggests that authors may find it difficult to put value statements into practice, a lack of focus on or knowledge of the document, perceptions that reporting observance is unimportant, or that it is not perceived as useful. Reporting incorporation of local protocols is also lacking. Some actions may be underreported because academic journals often impose word limits, restricting reporting of nonmandatory elements of research.

Many of the actions identified that related to Values and ethics were reported as enablers to conducting the research. This suggests that awareness and consideration of the document may improve research implementation. For example, relationships are a key component of Values and ethics, and authors of three studies reported strong relationships as an enabler. These relationships were fostered through:

- Involving community organisations and/or key community representatives; this endorses reciprocity, respect, equality, responsibility, spirit and integrity, and survival and protection
- Visiting communities before starting the research; this endorses reciprocity, and spirit and integrity
- A focus on empowerment principles, which endorses reciprocity.

Actions that related to (or endorsed) multiple values used culturally sensitive research processes, rather than one-off actions incorporated into traditional evidence-based research methods. These included two-way learning, yarning, participatory action research methods, and Iga Warta principles. In one study, the design was changed to a nonrandomised design following community feedback, demonstrating the challenges associated with aligning community preferences with what is usually considered scientifically rigorous research.

Involving Indigenous community members in research roles was common, although recruiting Indigenous staff was cited as a barrier to research implementation in one study. A focus on developing the Indigenous research workforce may address challenges with staffing and participation by facilitating research with greater community endorsement.

There are a few examples of others who have documented research according to Values and ethics. Interestingly, these examples identify relationships and partnerships as important facilitators to their research, echoing the processes identified in this review.

We suggest that research teams consider the actions identified that relate to Values and ethics. These include culturally sensitive approaches, a focus on relationship building and involving community members. Where appropriate, we recommend that reporting of research includes documentation of actions, experiences and community perspectives, and how these relate to Values and ethics. This will support shared learning between research teams and help clarify the effectiveness, cost and time required to implement research.

This review suggests that it is difficult to understand how Values and ethics is put into practice. Identifying and using culturally appropriate research methods requires commitment from research teams and the academic community. Academic publications may need to increase word limits so research teams can report...
Conduct of Indigenous research

research processes from all perspectives. This will provide information on the role and potential for Values and ethics to support high-quality, community-accepted research when primary health care services and external researchers collaborate.

We have considered the values outlined in Values and ethics throughout this review. The second reviewer and author is an Aboriginal researcher and has been involved since this review’s inception, including during protocol development, data extraction and analysis. This manuscript has been reviewed by the Aboriginal Health & Medical Research Council of New South Wales. This review responds to ongoing calls for improved research practices of Indigenous-focused research. We hope it provides useful information to Indigenous communities, primary health care services and research teams.

This review is limited to the information reported by authors. Additional actions may have been completed but not documented. Determining cultural appropriateness and community perspectives from the literature is challenging. We have identified where this is reported, but this may not fully identify the extent to which this has occurred. Indigenous communities are diverse, and an appropriate action in one community may not be suitable for another community.

Conclusion

Despite a lack of reporting, it appears that incorporation of the principles in Values and ethics improves research implementation. A focus on relationships and involving community members facilitates research in accordance with the Values and ethics document. Research teams should incorporate flexible, culturally sensitive designs to inform localised interventions, and focus on developing Indigenous researchers. Comprehensive reporting of how research is conducted should be encouraged to ensure community-level benefit and learning between research teams. The evaluation by the Lowitja Institute and the NHMRC will provide further information on the future of Values and ethics.

Acknowledgements

We acknowledge staff at the University of Sydney Medical Library for their help developing the search strategy for this review. AE received a National Health Research Scholarship (APP1056434). MH received a National Heart Foundation Future Leader Fellowship (100034). These funding bodies had no role in the conduct or reporting of this review.

Peer review and provenance

Externally peer reviewed, not commissioned

Competing interests

None declared

Author contributions

SF led this review. AE was second author and second reviewer. NG and JG contributed to the methods and discussion. MH supervises SF and AE. All authors contributed to the final manuscript.

References


3.3.1 Additional (unpublished) results from the systematic review

Additional data analysis identifying enablers, barriers to and implications of the included studies was completed. Limited data were identified in these areas, resulting in insufficient information to warrant inclusion in either publication. However, the results provide information that is relevant to the aims of this thesis and are therefore included below.

3.3.1.1 Enablers and barriers to research (reported by authors)

Fourteen enablers and 20 barriers to conducting Indigenous-focused SEWB PHC research were reported by authors of 16 studies (Table 3.1). No formal process evaluation was reported. Of the 25 studies, authors of three\textsuperscript{59, 79-81} mentioned that the existence of strong collaborative relationships within the research team enabled the research. In one study\textsuperscript{79, 80} where attempts to recruit Indigenous interviewers were unsuccessful, authors reported that relationships were enhanced by engaging a cultural mentor, whose cultural input ensured Local Protocols were respected by non-Indigenous researchers when interviewing Indigenous participants. In this study\textsuperscript{79, 80} mutual trust and respect within the research team facilitated two-way learning and shared ownership. In the AIMhi PDP,\textsuperscript{59} authors reported that long-term relationships were enablers to research, because they enhanced the research team’s understanding of the ’right ways of working’ together.

The use of consultation or other qualitative processes to develop localised interventions was reported as enablers by authors of three studies.\textsuperscript{82-86} Authors of one study reported that a flexible smoking cessation intervention, where it was adapted to meet the needs of participants, facilitated the success of the study.\textsuperscript{83} Culturally-appropriate research methods, incorporating participatory research and yarning techniques were reported as enablers because this enhanced staff participation in the development of a no smoking workplace policy.\textsuperscript{87}

In one study, authors described how having an Indigenous community member conduct qualitative interviews with PHC patients enabled the prompt identification of participants and provided a sense of connection between the research team and the community.\textsuperscript{88} However, they also described this connection as a potential barrier,
because it may have caused participants to feel obliged to participate or to avoid in-depth reflections during interviews.

In five studies where barriers were reported, circumstances external to the study were raised, such as the perception by some AMS staff about the roles and duties of Aboriginal Health Workers (AHW), causing research uptake to be limited:

General perceptions among health-care providers that community-based AHW’s roles in alcohol screening brief intervention was limited may have contributed to this lower level of participation [in the study].

In another study, a lack of clarity concerning the ongoing roles of staff at the participating PHC services led to an uncertain environment that negatively impacted the research.

Another external barrier involved the turnover of staff and organisational changes, which reduced PHC service attendance and opportunities to identify participants.

During the Aboriginal Mental Health Workers Program evaluation, authors reported that staff turnover resulted in long delays where temporary staff were appointed or the service was understaffed, and the program had unclear aims which limited the researcher’s ability to use traditional evaluation processes. Incomplete medical records at the participating service(s) also limited the data available for analysis.

Difficulties in recruiting Indigenous staff to work on a study, patients to participate in a study, and timing/funding constraints were also reported. For some people, smoking cessation may have been a sensitive topic, and this was reported as a barrier when engaging with staff in a study to develop a smoke-free workplace policy in a PHC service. However, the authors reported that using culturally-appropriate research techniques encouraged engagement and the study was able to be completed.

Several other barriers were reported in a study aiming to design and implement a case management model to address problematic alcohol consumption. Three barriers included; (i) varied beliefs among staff concerning appropriate approaches to reducing alcohol use (individual versus population-based interventions); (ii) project’s evolution from its original aims; and (iii) low staff attendance at training sessions. Despite an
initial interest, staff did not continue to support or endorse the study and busy training calendars, competing priorities and changes in funding were reported.

While ethics processes can take substantial time, difficulties acquiring ethical approval (ethics application was unsuccessful) was reported in only one of the 25 studies.

**Table 3.1 Summary of key enablers and barriers to research reported by authors**

<table>
<thead>
<tr>
<th>Key enabler described by authors</th>
<th>Key barrier described by authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Existence of strong collaborative relationships within research team fostered commitment to the studies (n=3)</td>
<td>Factors external to the study:</td>
</tr>
<tr>
<td></td>
<td>Staff turnover (n=2), or clinical and organisational changes (n=2) reduced participant attendance at clinics, staff attendance at training or impacted continuity</td>
</tr>
<tr>
<td>Locally developed interventions increased acceptability of the studies (n=3)</td>
<td>A lack of role clarity negatively impacted on the research environment or limited research uptake (n=2)</td>
</tr>
<tr>
<td>Flexible intervention encouraged uptake of the intervention by participants (n=1)</td>
<td>Incomplete medical records limited data available for analysis (n=1)</td>
</tr>
<tr>
<td>Visits by external researchers to the research setting helped to understand local context (n=1)</td>
<td>Unclear program aims limited the ability to use traditional evaluation processes (n=1)</td>
</tr>
<tr>
<td>Use of culturally-appropriate research methods encouraged participant engagement with the study (participatory action research and yarning) (n=1)</td>
<td>Challenges in recruiting Indigenous staff to conduct interviews (n=1)</td>
</tr>
<tr>
<td>Mutual trust and respect within the research team facilitated a productive research environment (n=1)</td>
<td>Challenges in identifying potential participants into the study (n=1)</td>
</tr>
<tr>
<td>Cultural mentorship by respected Elders ensured non-Indigenous researchers were aware of Local Protocols (n=1)</td>
<td>Low literacy and numeracy levels among some participants required modification of the study questions (n=1)</td>
</tr>
<tr>
<td>Group discussions during visits by external researchers improved AMS staff understanding and acceptance of the intervention (n=1)</td>
<td>A collection of self-reported behaviour data through group interviews may have biased findings (n=1)</td>
</tr>
<tr>
<td>Use of an empowerment model led to an enhanced sense of community pride and leadership which enhanced the study (n=1)</td>
<td>Timing and funding constraints resulted in a small sample size (n=1)</td>
</tr>
<tr>
<td></td>
<td>The sensitive issue of smoking cessation impacted on participant engagement (n=1)</td>
</tr>
<tr>
<td></td>
<td>Interviews conducted by a community member may have caused participants to feel obliged to participate or impact on responses (n=1)</td>
</tr>
<tr>
<td></td>
<td>Few staff attended study training sessions resulting in limited staff available to complete study activities (n=1)</td>
</tr>
</tbody>
</table>
### Key enabler described by authors

Interviews were conducted by a community member, which ensured local knowledge was considered during the study and enabled prompt identification of participants (n=1)

### Key barrier described by authors

A lack of support for the study by AMS staff (n=1)

Service level factors (training calendars, service priority and changes in funding) limited staff availability for the study (n=1)

Tensions around a population-based approach versus an individual approach to case management affected staff interest with the study (n=1)

The study evolved from its original aims, causing impact on its implementation (n=1)

A lack of culturally-appropriate measures led to uncertainty around the validity of findings (n=1)

---

**Total enablers = 14 (11 studies)**

**Total barriers = 20 (12 studies)**

**Abbreviations:** AMS – Aboriginal Medical Service

### 3.3.1.2 Reviewers’ assessment of the implications of research within participating communities

We determined that the findings of most studies were mostly relevant within the participating communities. This may indicate that the findings may not necessarily be generalisable to other communities. Six studies were evaluations of PHC programs or interventions providing potentially useful information about the effectiveness of these programs or interventions in clinical practice. Evaluations were planned in a further three studies.

Resources were developed as part of five studies which may be useful for clinical practice within the communities involved and at other PHC services. For example, AIMhi and the validation studies made resources publicly available, and in another study, cut-points for risky or unhealthy alcohol consumption for use by Indigenous people were identified (AUDIT-C and AUDIT-3 assessment tools).

The SEWB Service evaluation identified processes that were important to the success of the SEWB Service, rather than specific activities, providing potentially useful information for other PHC services and research teams. In other studies, consultation
processes were used that may be beneficial when planning future research projects.\textsuperscript{82, 84, 87}

Most exploratory studies were linked to, or followed by, interventional studies, which demonstrated that exploratory work may be more challenging interventional research. In one study\textsuperscript{82, 84} funding applications were underway to train staff to undertake dual diagnosis, indicating the potential impact on practice.

### 3.4 Translation of research arising from systematic reviews

After completing the systematic reviews, I was invited to contribute as a second author of one systematic review aimed at identifying literature on dietary intakes among Indigenous communities (Appendix 4). Based on the criteria I use in this chapter, I worked with the lead author to develop quality criteria that included an assessment of reporting Indigenous community involvement during research that was included in this systematic review. My contribution to this work demonstrates how the methods I developed have already been translated, via their use in other research projects and by establishing methods to determine the quality of Indigenous-focused health research.

### 3.5 Conclusion

In this chapter I present what is known about the quality (scientific and ethical) of Indigenous-focused SEWB PHC research, the common enablers and barriers to this research, and the implications of this research within the communities involved. A few examples of research were assessed to be of a high scientific quality, acceptable to the community, and as addressing the Values and Ethics Guideline.\textsuperscript{7} Examples that addressed the Values and Ethics Guideline\textsuperscript{7} and enabled the research included culturally-sensitive approaches, developing strong relationships within the research team and involving community members. Opportunities for achieving community-level outcomes appeared to include developing localised and flexible resources and evaluating PHC programs or interventions.

In Chapters 4 to 9, I will apply this knowledge to conduct an Indigenous-focused SEWB PHC research project \textit{(Getting it Right)}. In Chapter 4, I will describe \textit{Getting it Right}'s processes and protocol, and present the research results. Following on, I will complete
an evaluative case study to determine its quality, present a reflective case study to
describe my experiences as the PM (Chapters 5 and 6), and conduct a process
evaluation of Getting it Right to report the experiences of staff and patients who were
involved (Chapters 7 to 9).

Together, these chapters will provide multiple perspectives of Getting it Right. In
Chapter 10, I will compare and contrast these perspectives with the findings from the
systematic reviews to identify effective approaches and enablers to conducting high-
quality, culturally-appropriate Indigenous-focused SEWB PHC research.

3.6 Addendum

The addendum summarises the Indigenous-focused PHC SEWB research published
since the systematic review search was completed. I re-ran simple searches in Ebsco,
Embase, Informit from 2015 to 2018, which led to the identification of three additional
studies, two of which\textsuperscript{4, 5} were linked to studies included in the systematic review. These
studies reported cross-sectional survey data collected by the Study of Environment on
Aboriginal Resilience and Child Health (SEARCH) partnership, a long-term
collaboration established to address community determined research priorities. They
referenced a protocol that was published outside of the search timeframe\textsuperscript{6} (2015-2018),
which is included in this update for completeness. The third study\textsuperscript{106} was of mixed-
method design aimed to examine the impact of a new approach to SEWB care that
involved employing an Indigenous psychologist and social worker to deliver SEWB
services at the Indigenous-focused PHC service.

All studies are examples of research conduct that involves communities throughout the
research process, have multiple actions related to the Values and Ethics Guideline\textsuperscript{7} and
appear to have formed strong relationships within the research team. The SEARCH
studies appeared to be based on community-determined priorities.\textsuperscript{4-6} The SEWB service
delivery study may have implications within the community by evaluating program
delivery (to determine efficacy) and demonstrating the impact of the new approach,
providing evidence that may support ongoing funding.\textsuperscript{106}

The SEWB service delivery study\textsuperscript{106} identified initial concerns among some staff and
patients about involving an Indigenous social worker and psychologist, due to the
potential for personal information being shared within the community, possibly causing shame for individuals. However, once the staff member began working at the service, their cultural backgrounds were thought to improve access to the service because patients felt comfortable due to their shared cultural identity.

Descriptive research, such as SEARCH studies, have been said to result in limited tangible implications for the communities involved. However, they are part of a larger longitudinal research project based on community-determined priorities that may have other implications for the communities involved, however, not identified in these publications. For example, other studies arising from SEARCH partnerships that were included in the systematic review provided evidence on culturally-adapted SEWB resources.

The authors of the SEARCH studies took a strengths-based approach to identify factors that may inform health-promoting policies and programmes, and to reduce the stigmatisation from deficit-based research. They described challenges in identifying and retaining appropriate staff and suitable premises to conduct the research, echoing findings from the systematic review. A summary of the SEARCH studies is explained in Table 3.2, and quality assessments are presented in Tables 3.3 and 3.4.
Table 3.2  Indigenous-focused PHC SEWB research published between January 2015 and May 2018

<table>
<thead>
<tr>
<th>Summary of study or quality criteria</th>
<th>SEARCH studies(^4,6)</th>
<th>Hepworth et al(^{106})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Longitudinal cross-sectional survey</td>
<td>Mixed-method research design</td>
</tr>
<tr>
<td>Study initiation processes</td>
<td>Part of the SEARCH partnership (includes researchers, ACCHSs and AHMRC)</td>
<td>Study initiated within the Indigenous-focused PHC service</td>
</tr>
<tr>
<td></td>
<td>SEARCH is built on strong community partnerships under Aboriginal leadership, and addresses community priorities</td>
<td></td>
</tr>
<tr>
<td>Study outcomes (identified and met)</td>
<td>Identified and met Based on the SEARCH cohort: 1. Determine the proportion of carers of children who meet the Kessler Psychological Distress Scale (K10) criteria for high levels of psychological distress 2. Examine associations between demographic, health and community (neighbourhood and social) factors and psychological distress 3. To identify factors associated with ‘good’ mental health among Aboriginal children</td>
<td>Identified and met To determine the impact of employing a psychologist and social worker at an Indigenous-focused PHC service</td>
</tr>
<tr>
<td>Risk of bias</td>
<td>Unable to determine</td>
<td>Low risk of bias</td>
</tr>
<tr>
<td>Community acceptance</td>
<td>4 out of 4 criteria met</td>
<td>4 out of 4 criteria met</td>
</tr>
<tr>
<td>Governance of research</td>
<td>Steering group is composed of study investigators, representatives of participating ACCHOs and AHMRC</td>
<td>Research was approved by the Community Jury</td>
</tr>
<tr>
<td></td>
<td>Research was approved by four Indigenous community organisations (ACCHOs) and AHMRC</td>
<td></td>
</tr>
</tbody>
</table>

\(^4\) Search et al., 2015; \(^5\) Pizzey et al., 2016; \(^6\) Dela Cruz et al., 2016; \(^106\) Hepworth et al., 2017.
<table>
<thead>
<tr>
<th><strong>Summary of study or quality criteria</strong></th>
<th><strong>SEARCH studies</strong>&lt;sup&gt;4-6&lt;/sup&gt;</th>
<th><strong>Hepworth et al</strong>&lt;sup&gt;106&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research development</strong></td>
<td>Indigenous representatives involved with determining priorities (question generation) and authorship included Aboriginal researchers and PHC staff</td>
<td>Research is led by an Indigenous-focused PHC service</td>
</tr>
<tr>
<td><strong>Research conduct</strong></td>
<td>Interviews were conducted by Aboriginal Research Officers; Aboriginal researchers were involved with study coordination and data analysis</td>
<td>Interviews were conducted by Aboriginal researchers</td>
</tr>
<tr>
<td><strong>Research reporting</strong></td>
<td>Representatives from community organisations were authors</td>
<td>Results were disseminated to the Community Jury and staff. Representative from community organisations were the authors</td>
</tr>
<tr>
<td><strong>Actions related to the Values and Ethics Guideline</strong></td>
<td>Acknowledgment of PHC staff and communities in the publication; Publication authorship included staff; Research was approved by the community research governance committee; Interviews were conducted by Indigenous community member; Community identified the need for research</td>
<td>Acknowledgment of PHC staff and communities in the publication; Publication authorship included staff; Results were disseminated to the Community Jury and staff at a staff forum; Participants were reimbursed for participation; Flexible interview location was determined; Research was approved by community research governance committee; Study planning and implementation were driven by PHC staff; Recommendations from the Community Jury were incorporated into the research conduct; Two-step consent process where participants were first contacted, informed about the study and provided consent for the researchers to contact them was followed; Interviews were conducted by Indigenous community member (where possible); Study was proposed and driven by the Indigenous organisation; SEWB approach was based on community feedback (employment of Aboriginal or Torres Strait Islander SEWB staff)</td>
</tr>
<tr>
<td>Summary of study or quality criteria</td>
<td>SEARCH studies[^4][^6]</td>
<td>Hepworth et al[^106]</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Actions related to local Protocols</td>
<td>Steering group and long-term partnerships within the research team may provide advice on Local Protocols</td>
<td>Recommendations from the Community Jury were incorporated into research conduct (indicating Local Protocols were observed)</td>
</tr>
<tr>
<td>Colour key</td>
<td>Low</td>
<td>Unable to determine</td>
</tr>
</tbody>
</table>

Abbreviations: ACCHO – Aboriginal Community Controlled Health Organisation; AHMRC – Aboriginal Health and Medical Research Council of NSW; SEARCH: Study of Environment on Aboriginal Resilience and Child Health; PHC – primary healthcare; SEWB – social and emotional wellbeing
Table 3.3  Assessment of risk of bias of qualitative study identified in the systematic review update

<table>
<thead>
<tr>
<th>Assessment Criteria</th>
<th>Hepworth et al</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear statement of aims</td>
<td>Y</td>
</tr>
<tr>
<td>Appropriate methods</td>
<td>Y</td>
</tr>
<tr>
<td>Appropriate recruitment strategy</td>
<td>Y</td>
</tr>
<tr>
<td>Ethical considerations</td>
<td>Y</td>
</tr>
<tr>
<td>Data address research aim</td>
<td>Y</td>
</tr>
<tr>
<td>Rigorous data analysis</td>
<td>Y</td>
</tr>
<tr>
<td>Consideration of researcher-participant relationship</td>
<td>Y</td>
</tr>
<tr>
<td>Clear statement of findings</td>
<td>Y</td>
</tr>
<tr>
<td>Research value</td>
<td>Y</td>
</tr>
</tbody>
</table>

Colour key: Low

Overall assessment: Low

Table 3.4  Assessment of risk of bias of cross-sectional studies identified in the systematic review update

<table>
<thead>
<tr>
<th>Criteria to identify risk of bias</th>
<th>SEARCH studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the research question or objective in this paper clearly stated?</td>
<td>✓</td>
</tr>
<tr>
<td>Was the study population clearly specified and defined?</td>
<td>✓</td>
</tr>
<tr>
<td>Was the participation rate of eligible persons at least 50%?</td>
<td>✓</td>
</tr>
<tr>
<td>Were all subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?</td>
<td>✓</td>
</tr>
<tr>
<td>Was a sample size justification, power description, or variance and effect estimates provided?</td>
<td>✓</td>
</tr>
<tr>
<td>For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?</td>
<td>NA#</td>
</tr>
<tr>
<td>Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?</td>
<td>NA#</td>
</tr>
<tr>
<td>For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?</td>
<td>NA#</td>
</tr>
<tr>
<td>Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?</td>
<td>NA#</td>
</tr>
<tr>
<td>Was the exposure assessed more than once over time?</td>
<td>×</td>
</tr>
<tr>
<td>Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?</td>
<td>✓</td>
</tr>
<tr>
<td>Criteria to identify risk of bias(^{109})</td>
<td>SEARCH studies(^4-6)</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Were the outcome assessors blinded to the exposure status of participants?</td>
<td>NA(^g)</td>
</tr>
<tr>
<td>Was loss to follow-up after baseline 20% or less?</td>
<td>✓</td>
</tr>
<tr>
<td>Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?</td>
<td>NA(^g)</td>
</tr>
</tbody>
</table>

**Quality rating – risk of bias**

<table>
<thead>
<tr>
<th>Colour key</th>
<th>Low</th>
<th>High</th>
<th>Unable to determine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbreviations: NA – not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(\square\): yes

\(\times\): no

Note: To provide consistency with the other tools used in this thesis, I have modified the wording for the ratings used in the guidance\(^{109}\) from ‘good’, ‘fair’ or ‘poor’, to ‘low’, ‘medium’ or ‘high’ risk of bias. Other assessment criteria are consistent with the original guidance.
CHAPTER 4
PROTOCOL, PROCESSES AND RESULTS
OF GETTING IT RIGHT

4.1 Introduction

In Chapters 4 to 6, I present a detailed example of a national Indigenous-focused PHC SEWB research project that was informed by the Values and Ethics Guideline. In Chapter 4, I describe the main processes and steps involved in conducting the study, Getting it Right, in 10 Indigenous-focused PHC services (participating services). Furthermore, I describe the background to Getting it Right, summarise the study protocol and results, describe the origins of the process evaluation that was conducted alongside the research, and examine if the research was conducted in accordance with the study protocol.

In this Chapter, I describe my role during the research and highlight considerations I identified that may be specific to Indigenous-focused PHC SEWB research. It provides the background for the evaluative and reflective case studies (Chapters 5 and 6) and the process evaluation (Chapters 7 to 9).

4.2 Background to Getting it Right

4.2.1 Previous work informing Getting it Right

The Getting it Right project follows on from work completed during the Men, Hearts and Minds project led by Professor Alex Brown et al. During this multi-stage, mixed-methods project, researchers worked with Aboriginal communities in Central Australia to explore their experiences and manifestations and consequences of emotional distress and depression, as well as to examine the interplay of psychosocial factors and cardiovascular risk in Aboriginal men. The project confirmed that depressive symptoms are common in these communities, and that depression is expressed and understood differently by the Aboriginal community from other populations, but the term ‘depression’ was well understood.
The project\textsuperscript{31,110,111} highlighted the need for SEWB resources that are concordant with Indigenous ways of expressing and understanding depression, and to inform strategies that facilitate health gains among Indigenous people. However, at that time of the project, few resources had been culturally adapted for use by Indigenous people and none were freely available and validated broadly for use across all Indigenous populations.

This knowledge underpinned the next stage of the *Men, Hearts and Minds* project,\textsuperscript{31} which aimed to culturally adapt a screening tool to identify depression. The extensive adaptation process involved five language groups of Central Australian Aboriginal men. Initially, each group selected their preferred screening tool from a selection of tools provided by the researchers. Each group independently selected the 9-item Patient Health Questionnaire (PHQ-9). Next, the groups reviewed and adapted the PHQ-9 wording to ensure it was culturally relevant and able to be translated into language and back again without losing meaning.

This process took 12 months, continuing until consensus was reached, resulting in the 11-item adapted-Patient Health Questionnaire (aPHQ-9) to be pilot tested against a semi-structured diagnostic interview based on DSM criteria.\textsuperscript{1} During this process, the groups identified an additional seven concepts that were not covered by the aPHQ-9 but were considered important when determining depression. These concepts were developed into an ‘additional seven questions’ to the aPHQ-9 and related to: anger, weakened spirit, homesickness, irritability, excessive worry, rumination, and drug/alcohol use.

Research involving 78 Indigenous people in Central Australia showed a similar internal consistency in Aboriginal men (\(\alpha=0.776\)) and Aboriginal women (\(\alpha=0.767\)).\textsuperscript{112} Due to the diversity across Indigenous populations, broader validation to include other Indigenous Australian populations and people from rural and urban settings was required before the aPHQ-9 could be widely recommended for use by Indigenous people outside the community where the adaptation was completed.
4.2.2 Developing the research team and obtaining research funding

The following investigators formed a steering committee (SC) to plan and conduct Getting it Right:

1. A/Professor Maree Hackett (CI Hackett), The George Institute for Global Health (TGI), Sydney (CIA and Chair)
2. Professor Alan Cass, Menzies School of Health Research, Darwin
3. Professor Nick Glozier (CI Glozier), Brain and Mind Research Institute, Sydney
4. Professor Timothy Skinner, Charles Darwin University, Darwin
5. Associate Professor Armando Teixeira-Pinto, The University of Sydney, Sydney
6. A/Professor Deborah Askew, Queensland Health, Queensland
7. Mr Graham Gee (CI Gee), Victorian Aboriginal Health Service, Victoria
8. Professor Alex Brown (CI Brown), South Australian Health and Medical Research Institute, Adelaide

CI Hackett drafted and the SC edited the study protocol. The project was awarded with a National Health and Medical Research Council (NHMRC) project grant in 2013 to commence in 2014. I was employed as the PM at TGI (administering institution) in February 2014, and Version 1 of the study protocol was finalised in April 2014.

4.3 Summary of the Getting it Right study protocol

The study protocol was submitted and accepted for publication in 2016 (Appendix 5). The main elements of the study protocol are summarised briefly in this section.

Primary aim: to determine the validity of the aPHQ-9, against the MINI International Neuropsychiatric Interview 6.0.0 (MINI) as a screening instrument for depression.

Secondary aim: to determine the contribution of the seven additional questions identified have to detecting depression using theaPHQ-9.
Eligibility criteria for Getting it Right

Inclusion criteria

To be included in Getting it Right, PHC attendees at any of the participating services must meet the following criteria at the time of informed consent:

1. \(\geq 18\) years of age,
2. Self-identifies as Aboriginal and/or Torres Strait Islander,
3. Able to communicate sufficiently to answer study questions,
4. Able to give informed consent.

Exclusion criteria

People with known psychosis or bipolar disorder are ineligible to participate.

Participant recruitment and data collection and management processes

Participants were prospectively recruited via ten participating services (processes to identify participating services presented in Section 4.4.1.1). The study protocol was adaptive, meaning that localised approaches were developed within certain requirements. Within the adaptive protocol, participants could be identified and recruited with the following requirements: (i) consecutive identification; (ii) informed consent; (iii) Interview 1 (aPHQ-9); and (iv) Interview 2 (MINI\(^3\)) must be completed by a second interviewer within seven days of the first interview (Interview 1).

Interview 2 included relevant modules of the MINI\(^3\) for diagnosing depression including: depressive episode/disorder (current, recurrent), PTSD (past month) and generalised anxiety disorder (past 6 months). This interview included questions on smoking and alcohol consumption and could be completed face-to-face or telephone if required. The second interviewer as blinded to the results from Interview 1 (aPHQ-9).

Trained staff from participating services collected data via hard copy case report forms (CRF) or entered data directly into the computer database (developed specifically for Getting it Right); CRFs could be completed by participants with the support of a staff
member, if needed. Only staff who had completed training in *Getting it Right* were provided with passwords and usernames (individually allocated) to access the database.

**Participant safety**

A Safety and Response Protocol (Appendix 6) was developed which included the following main components:

- Discussion and agreement about depression, deliberate self-harm and suicidal ideation and intent protocols to ensure follow-up and care of participants.
- Identification of a ‘nominated reviewer’ to check all responses to the aPHQ-9 questions.
- Sending an automatically generated safety email for each participant to the nominated reviewer daily.

**Statistical analysis**

An *a priori* statistical plan was developed (led by Associate Professor Armando Teixeira-Pinto). The aPHQ-9 responses were compared with the MINI responses for each participant, using two common criteria for detecting major depression:

1. MDE I: Score of two or above on one of the first two items of the aPHQ-9, plus four or more items with a score of two or above.
2. MDE II: Total score of 10 points or above.

The scoring from the original PHQ-9 was used to score ‘split questions’ (questions 5 and 8 on the original PHQ-9) on the aPHQ-9 and these questions were scored once only. The properties of other cut-off points were explored by constructing a receiver operating characteristic (ROC) curve. The sensitivity and specificity were computed for subgroups (e.g. individuals with chronic disease) using logistic regressions to allow adjustment for potential demographic differences between the subgroups.

The additional seven questions were also compared with the MINI. Each question’s contribution was analysed separately to identify questions for further analysis (if they contributed to a better discrimination property of the aPHQ-9 while maintaining the internal validity of the instrument).
**Missing data**

The following plan was established to manage incomplete aPHQ-9 questionnaires (if any were collected). For incomplete questionnaires with five or more questions answered, we would compute a partial score summing the answered questions. The global score would be derived with a proportional transformation of the partial scores, based on the number of unanswered questions. Questionnaires with four or fewer answered questions would be excluded from the analysis.

**Ethics**

Approval from each participating services was obtained before the research began at each service (Section 4.4.1.1). Participation was voluntary and participants provided written or verbal informed consent before interviews began. Precautions were taken to respect the privacy of participants during the research (e.g. only de-identified information was viewable by researchers outside the relevant participating service).

*Getting it Right* received approval from the following (Human Research Ethics Committee [HRECs]): The University of Sydney Human Research Ethics Committee (HREC) [2014/361], Aboriginal Health and Medical Research Council in NSW [1044/14], ACT Health HREC [ETH.8.14.207], Queensland Health Metro South HREC [HREC/14/QPAH/503], Central Australian HREC [HREC-15-287], Menzies School of Health Research [2014-2289], Aboriginal Health Council of South Australia [04-15-622] and Western Australian Aboriginal Human Research Ethics Committee [607].

**4.3.1 Process evaluation of *Getting it Right***

During discussions with staff at participating services during the research start-up process, some reported positive experiences with research, while others reported times when research was onerous, challenging or, where significant, barriers made it infeasible. These stories led CI Hackett and me to design a process evaluation of *Getting it Right* and present it to the SC, who provided approval. We wanted to determine whether *Getting it Right* would be a positive experience for staff, and if it would allow us to identify barriers that would hinder its conduct.
The process evaluation was designed to explore: (i) the context surrounding, impact and consequences of Getting it Right; (ii) the experiences of staff, patients and participants with the research; and (iii) determine if the study was conducted in accordance with the protocol and acceptability; and (iv) the applicability of the aPHQ-9. Process evaluation methods and results will be presented in Chapters 7 to 9.

4.3.2 Developing an Indigenous Advisory Group for the process evaluation

I led the process evaluation by establishing an Indigenous Advisory Group to provide cultural oversight and input from a multitude of perspectives about the research project to enhance design, data analysis and interpretation, which was completed alongside Getting it Right. This group was separate to the SC for Getting it Right. Terms of reference for the Indigenous Advisory Group are available in Appendix 8.

To establish membership of the Indigenous Advisory Group, I contacted the coordinating staff member for Getting it Right at each participating service to discuss the process evaluation and invite them to join, or suggest another staff member interested to join the group. Two staff who were invited to join declined and did not provide a reason. I also invited other Indigenous researchers with experience in collecting qualitative data. (A detailed description of the steps taken during the process evaluation are presented in Chapter 7.)

4.4 Conducting Getting it Right and the process evaluation

Getting it Right was conducted with 10 Indigenous-focused PHC services nationally and was guided by the Values and Ethics Guideline. In this next section, I describe the major steps involved with Getting it Right that may be specific to Indigenous-focused PHC research, as well as highlight areas that relate to the Values and Ethics Guideline. (A detailed discussion of how Getting it Right relates to the Values and Ethics Guideline is presented in Chapter 5.)

The major processes to establish and manage recruitment with each participating service is presented in Figure 4.1. The blue section indicates pre-research and developmental stages (before recruitment began); orange indicates the research conduct stage (recruitment of research participants and data collection); and green indicates the
process evaluation and feedback of results to participating communities (research translation stage).

Initial contact with participating service → Receive local approval from communities → Receive jurisdictional approval

Additional training provided as required → Participant recruitment commences (n=1) → Complete research start-up and training

Weekly contact during recruitment → Bi-monthly reimbursement to participating services → Review recruitment target if required

Identify interest in completing process evaluation interviews → Feedback of clinical information to each PHC service → Participant recruitment finishes (n=500)

Complete process evaluation interviews → Feedback results to services and participants to contribute to interpretation of results

Figure 4.1 Major steps involved with establishing and conducting Getting it Right at each participating service

4.4.1 The major milestones during Getting it Right

NHMRC funding for Getting it Right was received by TGI in 2014 when I was employed as the PM. Ethics and community approval was obtained. Rolling set-up of each participating service was completed to allow us to support each service’s needs. After the recruitment target (N=500) was achieved, staff at each participating service were invited to complete process evaluation interviews; results were reported to their
corresponding participating service via face-to-face visits or Skype. (Major milestones of *Getting it Right* are summarised in Table 4.1.)

Table 4.1  Summary of major milestones of *Getting it Right* and its process evaluation

<table>
<thead>
<tr>
<th>Date</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td><em>Men, Hearts and Minds</em> project completed; aPHQ-9 developed&lt;sup&gt;(23, 97, 98)&lt;/sup&gt;</td>
</tr>
<tr>
<td>2013</td>
<td>SC formed, NHMRC grant application written, and NHMRC project grant awarded</td>
</tr>
<tr>
<td>Feb 2014</td>
<td>PM employed at TGI</td>
</tr>
<tr>
<td>Apr 2014</td>
<td>Study protocol V1.0 finalised</td>
</tr>
<tr>
<td>May 2014</td>
<td>Received ethical approval from the lead HREC (Table 4.2)</td>
</tr>
<tr>
<td>May to Nov 2014</td>
<td>Database build completed</td>
</tr>
<tr>
<td>May 2014</td>
<td>Initial discussions with Participating Service A about <em>Getting it Right</em></td>
</tr>
<tr>
<td>Jun 2014</td>
<td>Visit to Participating Service B to present <em>Getting it Right</em> to the Health Board to receive community consent (CI Hackett and PM) Further information requested about <em>Getting it Right</em></td>
</tr>
<tr>
<td>Aug 2014</td>
<td>Revisited Participating Service B to present requested information to the Health Board (PM) – approval received (Chapter 4, Section 4.4.1.1)</td>
</tr>
<tr>
<td>Jul 2014</td>
<td>Visited Participating Service C to present <em>Getting it Right</em> to the Health Board – approval received (CI Hackett and PM)</td>
</tr>
<tr>
<td>Aug 2014</td>
<td>Visited Participating Service 4 to present <em>Getting it Right</em> to the Health Board – approval received (CI Hackett and PM)</td>
</tr>
<tr>
<td>Oct 2014</td>
<td>First contract between TGI and Participating Service A signed</td>
</tr>
<tr>
<td>Jan 2015</td>
<td>Visit to Participating Service 1 for research start-up and training (CI Hackett and PM; CI Glozier via Skype)</td>
</tr>
<tr>
<td>Feb 2015 to Mar 2016</td>
<td>Visited Participating Services 2-10 for research start-up and training (CI Hackett and PM; CI Glozier via Skype or in person where possible)</td>
</tr>
<tr>
<td>Mar 2015</td>
<td>First participant recruited into <em>Getting it Right</em></td>
</tr>
<tr>
<td>May 2016</td>
<td>Reached 50% (n=250) of recruitment target</td>
</tr>
<tr>
<td>Mar 2016</td>
<td>Indigenous Advisory Group for process evaluation formed (PM)</td>
</tr>
<tr>
<td>Aug 2016</td>
<td>Process evaluation received ethical approval from lead HREC (Table 4.2)</td>
</tr>
<tr>
<td>Nov 2016</td>
<td>Final participant recruited into <em>Getting it Right</em> (n=500)</td>
</tr>
<tr>
<td>Nov 2016 to Jun 2017</td>
<td>Visited (or Skype) participating services to complete process evaluation interviews completed (PM)</td>
</tr>
<tr>
<td>Jul 2017</td>
<td>Initial data analysis for research project completed</td>
</tr>
<tr>
<td>Jul 2017</td>
<td>SC meeting for results release and to discuss research findings. PM unblinded to results</td>
</tr>
<tr>
<td>Aug 2017 to Jul 2018</td>
<td>Revisited (or Skype) participating services to present and receive feedback on results (5 visits, 3 videoconferences and 1 planned for August 2018; 1 chose to receive feedback via printed reports)</td>
</tr>
</tbody>
</table>
4.4.1.1 Time needed to identify and consult with PHC services

The process of identifying and consulting with staff and the community at the 10 participating services to establish their role in *Getting it Right* varied across services and began before research funding was received and continued until all 10 services were established. Four Indigenous-focused PHC services who participated in *Getting it Right* were involved in some aspect of the research design and planning through:

1. Kanyini Vascular Collaboration (three participating services): *Getting it Right* was presented as a pre-research concept by CI Hackett and discussed at the annual meeting three times during the development phase. Staff representatives from three participating services were present during these discussions. They indicated their interest in *Getting it Right* and were followed up after funding was granted. The Kanyini Vascular Collaboration brought together researchers, health services, communities and policy makers to develop, implement and evaluate strategies that improved the health of Indigenous people presenting with chronic disease ([http://www.kvc.org.au/](http://www.kvc.org.au/)).

2. A CI on the grant and SC member was a staff member at the fourth Indigenous PHC service spoke to staff and community members about *Getting it Right* to identify the initial interest in the research.

The remaining six participating services were contacted after the research and development were completed, as follows:

1. CI Hackett and I were introduced to staff at potential services by staff at participating services (two services participated).

2. I contacted two participating services after identifying them through an Internet search. I contacted 23 services via phone or email to discuss *Getting it Right*.

3. A SC member introduced the CEO of one participating service to CI Hackett and me.

4. A colleague at TGI introduced CI Hackett and me to staff at one participating service.

SC members introduced me to staff at an additional three PHC services, whom I contacted to discuss *Getting it Right*, however, they chose not to become involved because of limited staff availability for research at that time or they were pursuing other research interests.
Currently, evidence of community consultation and approval of research is required by most HRECs when reviewing Indigenous-focused research projects to demonstrate that the community has considered the risks and benefits involved. Therefore, to discuss and gain approval for *Getting it Right*, CI Hackett and I visited participating services at least once to distribute documentation about *Getting it Right* to staff or Health Boards (in accordance with local processes and instructions by staff) (Table 4.2).

At one participating service, two visits were necessary, because some members of the Health Board had concerns about the need for *Getting it Right* in their community. These concerns related to justification for the research because the aPHQ-9 was already being used for health assessments at this service, leading to queries about the need to validate the aPHQ-9 if it was already in use. The members asked two questions:

1. Are you doing the study because the aPHQ-9 doesn’t work?
2. Why is our clinic using it if they don’t know if it works?

Following this discussion, these concerns were addressed by a clinical staff member at a participating service that supported *Getting it Right*. He explained that it was important to ensure that the best possible tool was used and that he believed *Getting it Right* would provide this information. Approval from the Health Board was obtained at the second meeting. These processes to consult with, and gain consent from, the communities demonstrate respect, deemed necessary by the SC to conduct *Getting it Right* in accordance with the Values and Ethics Guideline. Associated travel was budgeted for in the grant.

### 4.4.1.2 Ethical approval and modification of the study protocol during *Getting it Right*

The process and timeframe involved with obtaining ethical approval for *Getting it Right* varied across states with each HREC requiring unique submission documents (Table 4.2). The study protocol was amended three times after its initial approval. Decisions were made by the SC twice about changes to data collection requirements or research processes, and subsequent changes were made based on feedback from staff at participating services about their preferences around research procedures. The researcher’s safety and response protocol was amended twice to respond to staff
feedback about their preference for safety processes. Modifications of the research processes, according to feedback and at the request of staff, were deemed necessary by the SC to conduct the research in line with the Values and Ethics Guideline (reciprocity).

**Study protocol amendments**

1. **August 2014** (initiated by the SC during the developmental phase while still finalising data collection needs and research processes):
   - Reimbursement offered to participants was in the form of food and fuel vouchers (not cash).
   - Participants could elect for interview results (aPHQ-9 and MINI) to remain confidential, that is, not to be communicated to their clinician unless the level of risk was such that a breach of privacy was needed for their safety. The SC identified the potential for some participants to be concerned if information about their SEWB was made available to staff whom they knew within their community.
   - Questions in the CRFs included details on smoking and alcohol usage.

2. **September 2014** (initiated by the SC during the developmental phase while still finalising data collection and research processes): Removed MINI modules that were not contributing directly to depression diagnosis (suicidality and panic).

3. **February 2016** (initiated by the SC as a response to a request from a community): Modified the definition of PHC in the study protocol to include drug and alcohol services as potential recruitment sites. This followed a request from a Residential Drug and Alcohol Service that accepted male patients who were interested in completing recruitment. The SC discussed and agreed on this approach. The amendment included the option for members of the Health Board (of the service) and other community members to participate as research participants (although they were not patients of the services). Additional safety protocol steps were established to include these participants.

**Researcher safety and response protocol amendments**

1. **December 2015** (initiated by the SC in response to feedback from staff):
   - Removed the requirement for research interview data to be signed and stored in patients’ clinical records (to interview data stored at the discretion of staff). Online data were considered source data.
- Removed automatically generated general practitioner (GP) letters sent to treating clinician for interviews conducted at the participating service (only planned to be sent for centrally conducted phone interviews, none of which occurred) (Appendix 6: Safety and Response Protocol, Attachment 3). The GP letter was in addition to an automatically generated safety email (Table 4.4).


2. **February 2016** (initiated by the SC in response to feedback from staff). Modified wording of the automatically generated safety email sent to the nominated reviewer.
Table 4.2  Summary of processes during *Getting it Right* in order to receive local and state ethics approval

<table>
<thead>
<tr>
<th>Process or characteristic of <em>Getting it Right</em></th>
<th>Participating services</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td>Process to receive ethics approval</td>
<td></td>
</tr>
<tr>
<td>Approximate timeframe to receive state HREC approval for <em>Getting it Right</em> (months)</td>
<td>1.5</td>
</tr>
<tr>
<td>Approximate timeframe to receive HREC approval for process evaluation (months)</td>
<td>2</td>
</tr>
<tr>
<td>Process to receive local approval from each participating service</td>
<td></td>
</tr>
<tr>
<td>CEO approval</td>
<td>✓</td>
</tr>
<tr>
<td>Health Board* approval: PM and CI Hackett visited to present to the Health Board</td>
<td>✓</td>
</tr>
<tr>
<td>Health Board* approval: Documents submitted by PM</td>
<td>✓</td>
</tr>
<tr>
<td>Service-specific documents completed for Health Board review</td>
<td>✓</td>
</tr>
</tbody>
</table>

Abbreviations: CEO – chief executive officer; CI Hackett – Chief Investigator Maree Hackett; PE – process evaluation; PM – project manager (Sara Farnbach)

*Health Boards involved any group of community representatives established to review and approve research conducted in their community. This included community research boards, community research committees and community juries.
4.4.2 Adapting the study protocol at each participating service

The study protocol was adaptive to enable localised approaches when identifying potential participants and managing participant safety during and after research interviews, within certain requirements. After community and ethics approval was received, research start-up commenced, which involved delivering training in research processes and adapting the protocol to fit each participating service’s requirements. The adaptive approach was taken by the SC to ensure the research considered local preferences in accordance with the Values and Ethics Guideline (reciprocity and respect).

Management at each participating service nominated staff to work on Getting it Right. Staff included Indigenous and non-Indigenous workers, as well Aboriginal Health Workers (AHW), research staff, nurses, GPs, clinical staff and administrative staff.

Consecutive recruitment allowed staff to establish processes for approaching participants that fit in with their existing workflow, while considering every person for the research following a specific process. For example, at some services staff considered each person who arrived at the clinic for two hours on a Wednesday morning or considered each person who attends established groups (art groups or other groups facilitated by the service).

Recruitment was completed through a variety of processes, including existing clinic workflows (appointment systems, drop-in appointments), discussions at community events (community barbeques hosted by the service, community events or community groups) and recalling patients who were due for their annual health check. After the study protocol was amended (Section 4.4.1.2), a Residential Drug and Alcohol Service participated in the study, which provided services to male patients only, and recruited patients, members of the Health Board and community members.

4.4.3 Resources provided through flexible financial reimbursement

Reimbursement was provided to participating services on a per completed participant basis. It was flexible for services to allocate as they deemed appropriate. The reimbursement was for a 0.5 full-time equivalent Personal Support Package level two
for one year, provided by NHMRC via TGI and paid bi-monthly. A computer/tablet and 4G WiFi dongle (when required) were also provided to each participating service to facilitate direct online data entry. Services had the option to choose between offering food vouchers or fuel vouchers as reimbursement for participants completing both interviews.

4.4.4 Research start-up and training visits

Research start-up and training was completed during visits to each participating service by CI Hackett, CI Glozier (where possible) and me. Visits took 1-3 days (excluding travel time) where we aimed to:

1. Learn about the local community and participating service.
2. Meet staff and introduce them to *Getting it Right*.
3. Support participating services to identify staff who were willing and available to complete research activities (by hiring new staff or selecting existing staff).
4. Work with the identified staff to establish site-specific processes.
5. Deliver training in research skills according to Good Clinical Practice (GCP) requirements (i.e. gaining informed consent, confidentiality, entering data into the research database, using the CRFs, research interviews, understanding all the safety protocols and maintaining research documentation).
6. Establish safety processes to provide appropriate care for participants who indicated thoughts of self-harm, suicidal ideation or intent during an interview. Staff had the opportunity to discuss any concerns with CI Glozier (psychiatrist) who reviewed and approved the safety processes at each service before recruitment commenced.
7. Identify a senior clinician at each service to be the nominated reviewer who was responsible for ensuring follow-up was provided to participants during *Getting it Right*.

4.4.5 Delivering training in *Getting it Right* procedures to staff

All staff involved with *Getting it Right* completed training in its procedures to ensure the study protocol was systematically implemented across participating services. We encouraged open discussions which enabled us to learn about the local context and staff
when considering and raising concerns. CI Hackett and I deemed it necessary to learn about each community so that the research could be conducted with spirit and integrity.

The staff conducting the MINI interview completed further training which included information about the MINI scoring algorithm and required practice when eliciting a ‘yes’ or ‘no’ answer to the interview questions from participants. Before each visit, CI Glozier and I video recorded four role plays with ‘mock’ patients completing MINI interviews conducted by CI Glozier, made available via a weblink for staff to watch during or after our visit, either within a group or individually (Appendix 9). Role plays took between 10 to 25 minutes to watch; each interview recorded different responses and diagnoses, and some included incorrect ‘skips’ to determine staff confidence in their knowledge.

After the training session delivered by CI Glozier, lasting approximately one hour, staff accessed one or more role plays to practise the MINI algorithm on the CRF. Once completed, I collected staff responses and compared them with CI Glozier’s responses to determine concordance. CI Glozier and I discussed the results and determined if further practice or training was required. If staff were required to complete further role play(s), I provided them with feedback and arranged further role play(s). GI Glozier phoned two staff to provide further clarification about some aspects of the MINI

A summary of research processes and characteristics at each participating service is presented in Table 4.3.
### Table 4.3  Summary of research processes and characteristics of participating services during Getting it Right

<table>
<thead>
<tr>
<th>Process or characteristic of Getting it Right</th>
<th>Participating services</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research project activities at participating services</strong></td>
<td>A  B  C  D  E  F  G  G  I  J</td>
</tr>
<tr>
<td>Type of Indigenous-focused PHC service</td>
<td>A* B A A A A A A C*</td>
</tr>
<tr>
<td>Number of participants completing two interviews (initial target = 50 for all)</td>
<td>50 60 50 50 18 50 50 30 43 99</td>
</tr>
<tr>
<td>Time between first and last participant recruited (months)</td>
<td>19 8.5 3 10 9^ 10.5 6 7 6 6</td>
</tr>
<tr>
<td>Food or fuel vouchers offered to participants</td>
<td>✓✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Number of staff trained during research start-up and training visit</td>
<td>2 4 6 12 3 6 3 5 4 4</td>
</tr>
<tr>
<td>Number of additional staff requiring training during research</td>
<td>5 0 0 26^ 1 8 1 1 2 0</td>
</tr>
<tr>
<td>Total number of visits by the PM (project presentation and approval, training, retraining, PE interviews and feedback of results)</td>
<td>3 6 4 2 4 2 1 2 1 3</td>
</tr>
</tbody>
</table>

Abbreviations: CEO – chief executive officer;
A= Aboriginal Medical Service or Aboriginal Community Controlled Health Service
B= Indigenous Primary Healthcare Service
C= Residential Drug and Alcohol Service
* Participants recruited through client designed for high risk participants or through chronic disease team
^ Service accepts male patients only
^ Recruitment ceased at request of staff members due to multiple competing responsibilities
✓ Vouchers offered to participants for part of research timeframe, after staff decided to use vouchers
^ Additional training requested by staff at participating service. Travel expenses funded by participating service
I developed training slides, research guides and a training pack (available upon request) to structure the training and for staff to refer to after our visit because it was necessary to cater for the broad range of skills and experience when conducting research and speaking to patients about SEWB among staff. The training slides covered essential research requirements (Section 4.4.5, point 5) whereas the research guides included detailed explanations of the research procedures and screen-by-screen guidance on using the research database. The training packs included:

1. Informed consent form, participant information sheet and CRF.
2. MINI interview role play information.
3. Login information for staff to access and practice the ‘test’ database, entering new participant details and becoming familiar with its functionality. (The test database mirrored the operations of the research database.) I entered a series of mock participants into the test database so that staff could view participant information at various stages.
4. Resources and referral information on depression, post-traumatic stress disorder (PTSD) and generalised anxiety disorder.
5. Information on vicarious trauma to minimise the risk to staff when conducting interviews (Appendix 10).

I developed a personalised training certificate outlining the skills and information covered during the training session which was provided to each staff member who completed their training (Appendix 11).

4.4.6 Processes established to minimise risk to staff and participants

Generally, research comes with risks to researchers and participants. To demonstrate a transparent process in accordance with responsibility (as defined in the Values and Ethics Guideline) during the development phase, the SC and I identified the risks and established several processes to reduce each risk (Table 4.4). Two specific concerns were identified:

1. Risk to participant or staff wellbeing from completing research interviews that asked directly about illicit, sensitive and traumatic information.
2. Risks (or perceived risk) to participant confidentiality or relationships between staff and patients if interviewing staff knew participants outside the work environment (such as staff interviewing family members or friends who were patients of the service).

Table 4.4 Processes established to minimise risks to staff and participants during Getting it Right

<table>
<thead>
<tr>
<th>Person at risk</th>
<th>Risk identified</th>
<th>Process established to minimise risk</th>
</tr>
</thead>
</table>
| Staff          | Experiencing vicarious trauma through hearing traumatic stories during research interviews | Staff training in signs and symptoms of vicarious trauma  
Staff provided with a self-care checklist during the research start-up process (Appendix 10) |
| Participants   | Becoming upset/distressed during research interview | Staff training in researcher safety and response protocol  
Psychiatrist reviewed service processes for assessing and treating SEWB problems and provided advice (if necessary)  
Opportunity for staff to discuss concerns with the psychiatrist during the research via a dedicated phone line |
| Participants   | Thoughts of self-harm, suicidal ideation/intent or previously untreated SEWB-related conditions identified during research interviews | Psychiatrist reviewed service processes for assessing and treating SEWB problems and provided advice (if necessary)  
Psychiatrist provided training to staff in talking about thoughts of self-harm and suicidal ideation/intent  
Nominated reviewer (senior clinician) identified to follow-up participants  
Safety email automatically generated for each participant and sent to the nominated reviewer |
| Participants   | Patients and staff may have concerns about confidentiality or the sharing of confidential information if interviewing staff knew participants outside the service (such as family members). This may cause patients concerns about participation, result in sharing of confidential information or impact on relationships between staff and participants | SC deemed the participating services would follow their usual processes to ensure patient confidentiality during the research  
To prepare staff, if it was raised as a concern during research start up and training visits, they were encouraged to consider and plan steps they would take if this situation arose |

Abbreviation: SC – steering committee SEWB – social and emotional wellbeing
In addition, *Getting it Right* addressed other risks not described above by complying with the research standards, such as the National Statement on Ethical Conduct in Human Research\(^ {37}\) and the principles GCP and the Declaration of Helsinki.\(^ {114}\) For example, informed consent is gained to ensure that participants provide open, willing and informed participation in research, confidentiality and data security.

### 4.4.7 Additional activities involved with conducting *Getting it Right*

Some examples of other activities involved with conducting *Getting it Right* included:

1. Identifying and commissioning an Aboriginal artist (Kylie Cassidy) to design artwork to represent *Getting it Right*: This was completed to recognise Indigenous cultural aspirations and to recognise the cultural acceptability of *Getting it Right* (respect) (Figure 4.2).\(^ 7\)

2. Modifying recruitment approaches at some participating services: For example, staff at two participating services suggested that a poster describing *Getting it Right* displayed in the waiting room may encourage recruitment. Posters were jointly developed by staff and the PM, and approved by the relevant HREC.

3. Monitoring progress towards recruitment targets at each participating service and towards overall research targets: Developed and sent a ‘halfway congratulations’ certificate to staff when they reached the midway point of their recruitment target.

4. Maintaining communications and providing reports to HRECs and participating services: HRECs required the submission of an annual report, and some participating services required quarterly reporting about the progress of the research.

5. Collecting a list of all the staff involved with *Getting it Right* and their signatures to acknowledge all contributors in the main research publication.
4.5 Community feedback of research results

As outlined *a priori* in our publication plan, after data lock and following initial data analysis, we discussed the initial research results with staff at participating services during ‘feedback sessions’ before they were finalised and shared broadly. During these feedback discussions, CI Hackett and I (CI Brown attended, where possible) presented the research background and initial results; staff had the opportunity to comment and discuss if the initial results matched their expectations. This process provided an opportunity for staff feedback to inform their interpretation of the final results and demonstrate equality between communities and researchers.⁷
Feedback sessions were completed via visits (six) or Skype (three). Feedback to one service was planned for July 2018, however, a delay was requested by staff as a result of staff turnover and organisational changes. Staff at the 10th service opted not to participate in feedback sessions because they had developed new processes around SEWB care since participating in Getting it Right which did not involve the aPHQ-9. Therefore, they reported that they did not wish to participate in the feedback sessions, so we provided a written report instead.

After completing feedback with staff, the SC and I developed a one-page summary report (A4 and A3 poster size) and sent copies to each participating service to pass onto participants and community members who were interested in receiving information about the results of the research (Appendix 12). During data collection, staff asked participants about their preference for receiving feedback and a list (re-identifiable data only by staff) of interested participants was provided to staff so they could make contact. Participants who indicated interest in the results were contacted by staff and provided with the report.

Services were also provided with data specific to their service, including the number of people shown to have depression, PTSD and generalised anxiety disorder during the MINI interview. The SC deemed it necessary to develop mechanisms to gain input into the interpretation of the research results (equality), provide feedback to individuals and communities about their research results (responsibility), and to conduct research according to the Values and Ethics Guideline.7

4.6 Summary of the Getting it Right results

The manuscript containing the main results from Getting it Right was submitted for publication in July 2018 (draft publication available in Appendix 7). In brief, 913 people were screened for eligibility, 540 consented to participate and 500 people completed the two research interviews and were included in the final analysis (reasons for exclusion provided in flow of participants in Appendix 7). Recruitment was completed via 10 participating services, including the Residential Drug and Alcohol Service where male patients,
members of the Health Board and community members were recruited (all results in this thesis include data collected from all 10 services).

There were no differences in baseline characteristics between the final sample and the 40 participants who were excluded. According to the MINI³ (criterion standard):

- The prevalence of current MDE was 22% (95% CI 18 to 25%), generalised anxiety disorder was 21% (95% CI 18 to 25%) and PTSD was 11% (95% CI 8% to 14%).
- 70% (n=347) of participants with no diagnosis from the MINI³.
- 5% (n=27) of participants diagnosed with all three conditions.

**Primary outcome analysis**

Using our *a priori* criteria for internal consistency of the aPHQ-9 and adequate sensitivity and specification (refer to Section 4.3):

- The 9 questions from the aPHQ-9 showed very good internal consistency (α = 0.88).
- MDE I: sensitivity of 54% (95% CI 40 to 68%), a specificity of 91% (95% CI 88 to 94%) and a positive predictive value (PPV) of 64% was shown.
- MDE II: the area under the ROC curve for a score of ≥10 was 0.88 (95% CI 0.85 to 0.92). The cut-point at 10 points has a sensitivity of 84% (95% CI 74 to 91%) and a specificity of 77% (95% CI 71 to 83%).

Results from the secondary outcome (pertaining to the additional seven questions) will be published separately.

**4.7 Review of Getting it Right according to the main components in the study protocol**¹¹³

In this section I examine whether *Getting it Right* was conducted as described in the published study protocol.¹¹³ Of the 20 main components described in the study protocol,¹¹³ I identified sufficient evidence to indicate compliance with 17 components and partial compliance with three. As the completed components are
largely self-evident, the following section describes three components judged as partially met (details of all components and remedial actions are reflected in Table 4.9).

**Partial participant screening log completion at one participating service**

Screening logs were routinely collected from the coordinating staff member at each service every two months during recruitment. On one occasion, one staff member reported to me that the screening log was only partially completed for two months. This occurred after additional staff (who had not completed training in the research processes and were not involved in research interviews) began screening patients to increase participation rates but did not accurately complete the screening log. After I provided additional training, we estimated screening numbers for these two months.

**Safety emails temporally disabled after webpage ‘hack’**

The *Getting it Right* safety protocol involved sending automatically generated safety emails from the research database to a senior clinician at each participating service summarising the aPHQ-9 and MINI³ responses for their participants 24 hours after the second interview (Interview 2). The webpage used to access the research database was disabled temporarily when ‘hackers’ put a block on the webpage interface; the database and its contents remained secure. When the database was reconfigured, the automatically generated safety emails were disabled by error, resulting in no emails being sent for 11 weeks at a time when five participating services were actively recruiting. During this period, a list of all participants recruited with potentially relevant clinical responses was provided to the coordinating staff member at the five participating services and all were followed-up by staff to ensure the safety of participants. No adverse events were reported.

**Protocol deviations recorded during Getting it Right**

Two minor protocol deviations were recorded at two participating services during *Getting it Right*, both relating to consent processes:
1. Verbal informed consent: The process to obtain verbal consent was outlined in the study protocol\textsuperscript{113} for staff who deemed that a participant had low English literacy or was unable to read the consent documents. This process involved staff reading the information to them aloud in the presence of an independent witness. On one occasion, a staff member acted as the witness, however, this was not considered ‘independent’ of the participating service.

2. Unsigned consent document: One participant left the participating service without signing the consent document but completed both interviews, as well as other elements of informed consent.

In both instances, remedial action involved revising the consent process with the relevant staff. New processes were developed to identify an independent witness for future verbal consent at the first participating service. At the second service, multiple phone calls were made and letters were sent to contact the participant to obtain a signature retrospectively, but to no avail.
## Table 4.5 Review of *Getting it Right* according to the study protocol\(^{113}\)

<table>
<thead>
<tr>
<th>Component described in the <em>Getting it Right</em> protocol(^{113})</th>
<th>Data source/s reviewed</th>
<th>Findings</th>
<th>Component met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethics and consent</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Written approval from each participating service</td>
<td>B</td>
<td>Consent letters received from each participating service</td>
<td>✓</td>
</tr>
<tr>
<td>2. Ethics approval</td>
<td>A</td>
<td>Approval received from the relevant ethics committee</td>
<td>✓</td>
</tr>
<tr>
<td>3. Participant informed consent (written or verbal)</td>
<td>E</td>
<td>Screening CRF verified informed consent obtained before unlocking interview CRFs</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>F</td>
<td>Database logic required staff to verify consent was provided before unlocking interview CRFs</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>Protocol deviations reported at two participating sites: 1. Verbal consent completed without ‘independent’ witness (occurred once) 2. Signature missing from consent documents (occurred once)</td>
<td>?*(\approx)2 services</td>
</tr>
<tr>
<td></td>
<td>A</td>
<td>Deviations reported to the relevant ethics committee. Remedial actions: (i) retraining in consent processes; (ii) developing new processes (to identify independent witness); and (iii) re-contacting participant to obtain signature</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Participant selection</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Recruitment per eligibility criteria</td>
<td>E</td>
<td>CRF outlines inclusion and exclusion criteria</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>F</td>
<td>Database logic verified criteria before unlocking interview CRFs</td>
<td>✓</td>
</tr>
<tr>
<td>5. Participant screening and enrolment documents</td>
<td>C</td>
<td>Partial participant screening log completed at one participating service on one occasion due to inaccurate records kept by new staff. Screening numbers estimated for two months at this service</td>
<td>?*(\approx)1 service</td>
</tr>
<tr>
<td>6. Prospective data collection</td>
<td>J</td>
<td>Prospective recruitment completed</td>
<td>✓</td>
</tr>
<tr>
<td>Component described in the <em>Getting it Right</em> protocol(^{1,13})</td>
<td>Data source/s reviewed</td>
<td>Findings</td>
<td>Component met</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>------------------------</td>
<td>----------</td>
<td>--------------</td>
</tr>
<tr>
<td><strong>Reference standard</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Reference standard likely correctly classifies depression</td>
<td>J</td>
<td>MINI(^3) has acceptably high validation and reliability scores (used in over 100 countries)</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Flow and timing of interviews</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. aPHQ-9 completed before MINI(^3) interview</td>
<td>F</td>
<td>Database logic required the aPHQ-9 to be completed before unlocking the MINI(^3) CRF</td>
<td>✓</td>
</tr>
<tr>
<td>9. Interval between index and reference case</td>
<td>J</td>
<td>Intervals were between 0 and seven days for participants included in analysis (N=500). One interview was completed at eight days, and excluded from analysis. Average time between interviews was &lt;1 day (IQR=0)</td>
<td>✓</td>
</tr>
<tr>
<td>10. MINI(^3) (reference standard) interpreted without knowledge of aPHQ-9 (index test)</td>
<td>J</td>
<td>Reference standard completed by blinded second interviewer</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Training</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Training delivered to interview staff</td>
<td>G</td>
<td>Initial training in-person; subsequent training via Skype/phone. Training materials included elements outlined in protocol</td>
<td>✓</td>
</tr>
<tr>
<td>12. MINI(^3) training included inter-rater assessment</td>
<td>G</td>
<td>All staff completing MINI(^3) interview completed inter-rater assessment</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Participant safety</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Identified site-specific protocols to manage depression, deliberate self-harm and suicidal ideation/intent</td>
<td>I</td>
<td>Site-specific protocols documented and reviewed by study psychiatrist</td>
<td>✓</td>
</tr>
<tr>
<td>14. Senior clinician checked interviews and provided follow-up care (if needed)</td>
<td>H</td>
<td>Senior clinician identified at each participating service</td>
<td>✓</td>
</tr>
<tr>
<td>15. Automatically generated safety emails sent to senior clinician for each participant</td>
<td>F</td>
<td>Database automatically generated emails summarising participants’ responses (aPHQ-9 and MINI(^3)) and sent to senior clinician</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>Emails blocked by firewalls (one service) and sent manually until resolved</td>
<td>✓</td>
</tr>
<tr>
<td>Component described in the <em>Getting it Right</em> protocol\textsuperscript{13}</td>
<td>Data source/s reviewed</td>
<td>Findings</td>
<td>Component met</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-----------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>F</td>
<td></td>
<td>Webpage blocked by ‘hackers,’ disabling safety emails for 11 weeks – sent to five participating services (five services were actively recruiting at the time). No breach to data or confidentiality occurred. No adverse events or safety concerns occurred as a result.</td>
<td>(?=5 \text{ services})</td>
</tr>
<tr>
<td>B</td>
<td></td>
<td>Remedial actions: \begin{enumerate} \item Automatically generated emails re-enabled \item List of participants with potentially relevant clinical responses provided to coordinating staff member. Each participant followed-up \end{enumerate}</td>
<td>✔</td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>All ethics committees notified</td>
<td>✔</td>
</tr>
</tbody>
</table>

**Statistics and outcome assessment**

<table>
<thead>
<tr>
<th>16. Sample size of 500</th>
<th>D</th>
<th>N=500</th>
<th>✔</th>
</tr>
</thead>
<tbody>
<tr>
<td>17. Baseline characteristics presented as discrete variables</td>
<td>J</td>
<td>Even spread of age, gender and other characteristics indicated sample is representative</td>
<td>✔</td>
</tr>
<tr>
<td>18. Assessed validity of aPHQ-9; determined contribution of an additional seven questions</td>
<td>J</td>
<td>Validity analysis completed (using score of 10 or more). Contribution of an additional seven questions completed</td>
<td>✔</td>
</tr>
</tbody>
</table>

**Data management, confidentiality and privacy**

<table>
<thead>
<tr>
<th>19. Internet-based data management system with password-protection</th>
<th>F</th>
<th>Research database was password protected. Only trained staff assigned passwords</th>
<th>✔</th>
</tr>
</thead>
<tbody>
<tr>
<td>20. Uphold privacy and confidentiality of participants</td>
<td>F</td>
<td>Unique identifier generated for each participant (data de-identified) and used during communications</td>
<td>✔</td>
</tr>
<tr>
<td>Component described in the <em>Getting it Right</em> protocol</td>
<td>Data source/s reviewed</td>
<td>Findings</td>
<td>Component met</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>------------------------</td>
<td>----------</td>
<td>---------------</td>
</tr>
</tbody>
</table>

Abbreviations: aPHQ-9 – adapted Patient Health Questionnaire-9; CRF – case report forms; IQR - interquartile range; MINI – MINI International Neuropsychiatric Interview 6.0.0; SF – Sara Farnbach

✓ = indicates component was met

?*= indicates component was partially met at these participating services due to protocol deviations for two participants

?^ = indicates component was partially met at this participating service due to partial screening log kept on one occasion

A: Ethics applications and correspondence
B: Communication logs kept by SF of discussions relating to *Getting it Right*
C: Participant screening logs (de-identified logs provided to SF)
D: Participant recruitment tracker
E: Case report forms used by staff to collect research data during *Getting it Right*
F: Database documentation (backend logic; correspondence with database developers and database user statistics)
G: Training logs and materials developed for *Getting it Right*
H: Site activation forms completed by SF during study start-up
I: Deviation log
J: Main results publication: Hackett ML, Teixeira-Pinto ATP, Farnbach S et al. *Validation of a culturally-specific measure to screen for depression (aPHQ-9) in Aboriginal and Torres Strait Islander people: The Getting it Right study*
4.8 Conclusion

In this chapter, I describe my specific role in setting up and conducting Getting it Right, as well as highlight specific areas where the research addressed the Values and Ethics Guideline.\textsuperscript{7} This includes receiving community approval, working with staff to implement the study protocol, and identifying and mitigating potential risks involved with conducting Indigenous-focused SEWB PHC research.

Furthermore, I identify considerations that may be specific to Indigenous-focused SEWB PHC research when conducted by research teams. These considerations include: (i) steps taken to establish relationships between Indigenous communities and researchers; (ii) processes of working with communities to gain approval for the research; and (iii) how the study protocol was modified in response to requests or feedback from staff about the research process.

I also present the main results from Getting it Right, which showed that the aPHQ-9 has good performance characteristics as a screening tool for depression to be used by Indigenous people attending the PHC. Overall, Getting it Right was conducted as described in the protocol,\textsuperscript{113} with some minor deviations that were unlikely to have compromised the overall reliability or generalisability of the results.

In chapters 5 and 6, I will present an evaluative and reflective case study of Getting it Right to identify the quality of the research from scientific and ethical perspectives, including my perspectives of the research. Then I will explore the perspective of staff and patients about Indigenous-focused SEWB PHC research through a process evaluation (Chapters 7 to 9). The process evaluation will add to the information presented in this chapter about the conduct of Getting it Right, by exploring whether staff and patients perceived that it was conducted in accordance with the protocol.
CHAPTER 5
CRITICAL EVALUATION OF GETTING IT RIGHT

5.1 Introduction

In this chapter I explore the scientific and ethical quality of Getting it Right, following the methods used in the systematic reviews of Indigenous-focused SEWB PHC research in Chapter 2. I also focus on: (i) considering if the modified quality assessment tools used in Chapter 2 are appropriate for determining the quality of Getting it Right; (ii) identifying other standard tools specific to observational, cross-sectional diagnostic accuracy designs (hereafter validation design); and (iii) identifying any specific considerations when using a validation design in Indigenous-focused SEWB PHC research.

By using the community acceptance criteria, I also identify the point where each participating service became involved with Getting it Right (pre-research, research development, research conduct and/or research translation). The perspectives of the participating service staff about their involvement in the various stages of the research will be presented in the process evaluation (Chapters 7 to 9).

5.2 Methods

5.2.1 Methods used to determine scientific quality

Critical evaluations to determine the scientific quality of research can identify if research is designed, conducted and reported with sufficient information to generate reliable results that influence decisions to be made by community members, clinicians and policy makers about care, clinical practice, policy or funding.\(^{115}\) Such evaluations can be completed using standard quality assessment tools during systematic reviews (which can provide useful summaries of evidence to inform recommendations about healthcare)\(^{116}\) and by reviewers (when grants are submitted for funding, and manuscripts are submitted for publication).

Standard quality assessment tools are based on criteria that assess important aspects of research design, such as qualitative,\(^{108}\) randomised,\(^{116}\) or diagnostic accuracy studies\(^{117}\).
(e.g. *Getting it Right*). When determining quality, two main components of research are generally considered:

(i) Design and conduct; and
(ii) Reporting.

I have identified standard quality assessment tools that are relevant to a validation design as an observational, cross-sectional diagnostic accuracy study:

1. QUADAS-2: A revised tool for the quality assessment of diagnostic accuracy studies in systematic reviews (QUADAS-2)\(^\text{118}\)
2. STARD 2015 for reporting of diagnostic accuracy studies (STARD)\(^\text{117}\)
3. Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies\(^\text{109}\)

### 5.2.2 Methods used to determine ethical quality

These standard quality assessment tools do not consider (nor do they aim to), components that are described as important when conducting ethical research in Indigenous-focused research guidance documents,\(^\text{7, 71, 74, 75}\) such as including Indigenous communities during the pre-research, development, conduct or translation stages of research; or if the communities involved considered the research was of high quality. The following criteria were used to determine the quality of *Getting it Right* from an ethical perspective:

1. Community acceptance criteria based on components identified in key guidance documents relating to Indigenous-focused health research (Section 2.2.1.2)\(^\text{7, 71, 74, 75}\)

2. The values described in the Values and Ethics Guideline.\(^\text{7}\) I identify where actions related to the Values and Ethics Guideline\(^\text{7}\) are explicitly reported by authors in publications or in Chapter 4, Section 2.2. I add these actions to the list of potential actions that we identified in the systematic review (Appendix 1).

### 5.2.3 Standard quality assessment tools used during this critical evaluation

In this section, I describe the standard quality assessment tools used in this critical evaluation and if, how and why they were modified.
5.2.3.1 Assessment of design and conduct of diagnostic accuracy studies using QUADAS-2\textsuperscript{118}

QUADAS-2\textsuperscript{118} was designed to be used in systematic reviews to determine the quality of the design and conduct of validation designs by identifying the risk of bias based on important aspects (domains) of research design. These include: (i) participant selection; (ii) conduct and interpretation of the index case (diagnostic test being examined for accuracy); (iii) conduct and interpretation of the reference standard (diagnostic test to compare with the index test); and (iv) flow and timing of participants completing the tests and through the research.

The guidance document\textsuperscript{118} for using the QUADAS-2 recommends steps to be taken when the tool is used during systematic reviews. In this chapter, the QUADAS-2 is used to measure the risk of bias in a standardised way (rather than as part of a systematic review), meaning that modifications from the processes described in the guidance document\textsuperscript{118} were needed. These modifications included:

1. Removal of the ‘applicability’ questions to determine if the methods were applicable to the aims of the systematic review.

2. Developing a review aim rather than a review question. (The aim was to identify any important risks to bias in \textit{Getting it Right}).

3. Specific guidance was developed in agreement with the second reviewer, but not independently piloted before use as it would be in a systematic review.

5.2.3.2 Assessment of the reporting of diagnostic accuracy studies using STARD\textsuperscript{117}

In order to assess research design and conduct, reproduce results (to establish if results are true) or build on previous research (e.g. to update a systematic review or test results in other settings),\textsuperscript{116} important aspects of research must be reported.\textsuperscript{119} Thorough reporting may be particularly pertinent in SEWB research and other psychology and psychiatry research where the reproducibility of research findings has been shown to be low.\textsuperscript{120} The STARD checklist\textsuperscript{117} was designed to demonstrate the completeness of reporting validation designs by identifying important components that should be reported when using this design. Therefore, the STARD checklist\textsuperscript{117} can be used to determine the quality of reporting of \textit{Getting it Right} without modification.
5.2.3.3 Justification for not using the Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies\textsuperscript{109}

I used the Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies tool\textsuperscript{109} in the systematic review (Chapter 2) and found that many of the criteria were unable to be answered when assessing the validation design that was included in the review.\textsuperscript{91} Although validation designs are a type of cross-sectional design, their function differs significantly from the purpose of many cross-sectional designs, which often measure disease prevalence (by measuring exposures and outcomes in a population) or compare prevalence in different populations or among people with different characteristics at one point in time.\textsuperscript{121}

As a result, many of the standard criteria used to determine the quality of cross-sectional designs involved assessing how ‘exposures’ were managed (e.g. assessing the timeframe between the exposure and outcome, and if outcome assessors were blinded to the participants’ exposure status). These criteria were not relevant for \textit{Getting it Right}, because this research was designed primarily to determine the validity of the aPHQ-9 as a depression screening tool. Although validation designs are also a type of cross-sections design (in that data from a population at a specific time point are analysed, and disease prevalence is estimated), determining disease prevalence was not the primary purpose of this research.

Due to this tool\textsuperscript{109} being designed to determine the quality of a cross sectional rather than a validation study, I did not include this tool in this critical evaluation. For completeness, an assessment of \textit{Getting it Right} using this tool\textsuperscript{109} is included in Appendix 13.

5.3 Results

5.3.1 Quality assessment of \textit{Getting it Right} using the modified quality assessment criteria

I completed an initial assessment of \textit{Getting it Right} using these tools and discussed and agreed on these results with independent second reviewers (SA was second reviewer for Sections 5.3.1. AME was second reviewer for Sections 5.3.2 and 5.3.3).
5.3.1.1 Assessment of design and conduct using QUADAS-2\textsuperscript{118}

Using QUADAS-2,\textsuperscript{118} Getting it Right was deemed to have a low risk of bias in the four domains (Table 5.1). There was some doubt about the reference standard used during Getting it Right, because the ultimate gold standard measure was an experienced, culturally competent psychiatrist or highly trained mental health clinician using a semi-structured clinical interview based on Diagnostic and Statistical Manual\textsuperscript{1} (DSM) criteria. While culturally competent and trained staff administered the MINI,\textsuperscript{3} this tool had not been validated specifically for use with Australia’s Indigenous people, leading to uncertainty that it correctly classifies major depressive episodes in this group.

The potential for the introduction of selection bias was identified through the recruitment of research participants who may have had a higher risk of experiencing depression symptoms and misused substances (Residential Drug and Alcohol Rehabilitation Service, high risk and chronic disease patients). The inclusion of a recruitment site that had only male patients may also have resulted in an overrepresentation of males (community and board members were also recruited at this site). Due to the consecutive recruitment approach, broad selection criteria and large sample size, these factors were not deemed to have caused bias, rather they enhanced the generalisability of the results by including those people often excluded from research.
Table 5.1 QUADAS-2 assessment of the design and conduct of *Getting it Right*

<table>
<thead>
<tr>
<th>Domain and questions to identify risk of bias</th>
<th>Assessment of risk in <em>Getting it Right</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain 1: Participant selection</strong></td>
<td></td>
</tr>
<tr>
<td><em>Description</em></td>
<td></td>
</tr>
<tr>
<td>Describe methods of participant selection</td>
<td>Consecutively identified by staff at 10 PHC services</td>
</tr>
<tr>
<td></td>
<td>Consecutive recruitment of patients via Aboriginal Medical Service, or Aboriginal Community Controlled Health Service (n=6), Indigenous Primary Healthcare Service (n=1) and Residential Drug and Alcohol Services (male patient, community members and board members; n=1).</td>
</tr>
<tr>
<td>Consecutive identification via high risk clinics (n=1) or a chronic disease clinic list (n=1) (refer to Section Chapter 4, 4.4.12 &amp; 4.4.7)</td>
<td></td>
</tr>
<tr>
<td>Describe included patients (previous testing, presentation, intended use of index test [aPHQ-9], and setting)</td>
<td>Included: &gt;18 years, Indigenous, provided consent, able to communicate sufficiently to answer questions and presented at PHC</td>
</tr>
<tr>
<td></td>
<td>Excluded: diagnosis of psychosis or bipolar (due to symptom overlap)</td>
</tr>
<tr>
<td></td>
<td>PHC is where the aPHQ-9 would be used (if valid)</td>
</tr>
<tr>
<td><em>Signalling questions</em></td>
<td></td>
</tr>
<tr>
<td>Was a consecutive or random sample of participants enrolled?</td>
<td>✓</td>
</tr>
<tr>
<td>Was a case-control design avoided?</td>
<td>✓</td>
</tr>
<tr>
<td>Did the study avoid inappropriate exclusions?</td>
<td>✓</td>
</tr>
<tr>
<td><em>Risk of bias</em></td>
<td></td>
</tr>
<tr>
<td>Could the selection of participants have introduced bias?</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Domain 2: Index case – aPHQ-9</strong></td>
<td></td>
</tr>
<tr>
<td><em>Description</em></td>
<td></td>
</tr>
<tr>
<td>Describe the index test (aPHQ-9) and how it was conducted and interpreted</td>
<td>a-PHQ-9 is an extensively culturally adapted depression screening tool with good face validity</td>
</tr>
<tr>
<td></td>
<td>Interviews were conducted in a confidential setting by PHC staff</td>
</tr>
<tr>
<td></td>
<td>Results were interpreted following standard published criteria during data analysis</td>
</tr>
<tr>
<td><em>Signalling questions</em></td>
<td></td>
</tr>
<tr>
<td>Were the index test (aPHQ-9) results interpreted without knowledge of the results of the reference standard?</td>
<td>✓</td>
</tr>
<tr>
<td>If a threshold was used, was it pre-specified?</td>
<td>Total score of 10 points or above (similar to the cut-off for the original PHQ-9)</td>
</tr>
</tbody>
</table>
### Domain and questions to identify risk of bias | Assessment of risk in *Getting it Right*

<table>
<thead>
<tr>
<th><strong>Risk of bias</strong></th>
<th><strong>Domain 3: Reference standard – MINI³</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Could the conduct or interpretation of the index test have introduced bias?</td>
<td>Low</td>
</tr>
</tbody>
</table>

**Description**

Describe the reference standard (MINI³) and how it was conducted and interpreted.

- MINI³ interview (MDE, generalised anxiety disorder and PTSD modules)
- Interviews conducted by trained culturally competent staff, as nominated by PHC services
- Investigators delivered training in MINI³ administration and scoring; inter-rater assessments completed
- Results were interpreted according to MINI³ algorithm for the MDE module

**Signalling questions**

- Was the reference standard (MINI³) likely to correctly classify the target condition?  ✓
- Were reference standard (MINI³) results interpreted without knowledge of the index test results?  ✓

<table>
<thead>
<tr>
<th><strong>Risk of bias</strong></th>
<th><strong>Domain 4: Flow and timing</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Could the reference standard (MINI³), its conduct, or its interpretation have introduced bias?</td>
<td>Low: MINI³ is the most widely used psychiatric structured diagnostic interview instrument and has been used in more than 100 countries, including non-Western cultures. There is no diagnostic test validated to use in this population</td>
</tr>
</tbody>
</table>

**Description**

Describe participants who did not receive the index test(s) and/or reference standard, or who were excluded from the 2 x 2 table (refer to flow diagram).

- Participants recruited = 533; completed index test (aPHQ-9) = 530; completed index test and reference standard = 500
- Reasons for exclusion reported in the flow diagram

Describe the time interval and any interventions between index test(s) and reference standard.

- Index and reference interview completed within seven days (inter-quartile range = 0 days between interviews)
- 434 interviews were completed on the same day

**Signalling questions**

- Was there an appropriate interval between index tests and the reference standard?  ✓
- Did all participants receive a reference standard?  ✓ All participants included in the analysis completed the reference test
- Did participants receive the same reference standard?  ✓ Reasons for exclusion reported in flow diagram
5.3.1.2 Assessment of reporting using the STARD criteria

All except one STARD\textsuperscript{117} assessment criterion were reported in the Getting it Right protocol or the results publication, or both (Table 5.2). Systematic recording of adverse events was not completed during Getting it Right because this research was not an intervention trial, and the SC and ethics committees deemed monitoring of adverse events unnecessary. However, they were informally monitored by the PM and C.I. Hackett; no serious adverse events were detected.

Table 5.2 STARD checklist\textsuperscript{117} identifying important aspects reported in Getting it Right

<table>
<thead>
<tr>
<th>Manuscript section and topic</th>
<th>Component of diagnostic research design</th>
<th>Location of component reporting (page)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title or abstract</td>
<td>Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)</td>
<td>P1, R Abstract</td>
</tr>
<tr>
<td>Abstract</td>
<td>Structured summary of study design, methods, results and conclusions</td>
<td>P1, Abstract</td>
</tr>
<tr>
<td>Introduction</td>
<td>Scientific and clinical background, including the intended use and clinical role of the index test</td>
<td>P1-2, Introduction</td>
</tr>
<tr>
<td></td>
<td>Study objectives and hypotheses</td>
<td>P2, Introduction</td>
</tr>
<tr>
<td>Methods Study design</td>
<td>Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)</td>
<td>P2, Methods</td>
</tr>
<tr>
<td>Participants</td>
<td>Eligibility criteria</td>
<td>P2-3, Methods</td>
</tr>
<tr>
<td></td>
<td>On what basis were potentially eligible participants identified (such as symptoms, results from previous tests, inclusion in registry)?</td>
<td>P3, Methods</td>
</tr>
<tr>
<td>Manuscript section and topic</td>
<td>Component of diagnostic research design</td>
<td>Location of component reporting (page)</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Where and when potentially eligible participants were identified (setting, location and dates)?</td>
<td>R3, Methods P3</td>
<td></td>
</tr>
<tr>
<td>Did participants form a consecutive, random or convenience series?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test methods</td>
<td>Index test in sufficient detail to allow replication</td>
<td>P3, R Study design and participants P3, R Study design and participants</td>
</tr>
<tr>
<td></td>
<td>Reference standard in sufficient detail to allow replication</td>
<td>P3, R Study outcomes</td>
</tr>
<tr>
<td></td>
<td>Rationale for choosing the reference standard (if alternatives exist)</td>
<td>P5, R Procedures</td>
</tr>
<tr>
<td></td>
<td>Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory</td>
<td>P5, R Procedures</td>
</tr>
<tr>
<td></td>
<td>Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory</td>
<td>P4, R Procedures</td>
</tr>
<tr>
<td></td>
<td>Whether clinical information and reference standard results were available to the performers/readers of the index test</td>
<td>P4, R Procedures</td>
</tr>
<tr>
<td></td>
<td>Whether clinical information and index test results were available to the assessors of the reference standard</td>
<td>P5, R Procedures</td>
</tr>
<tr>
<td>Analysis</td>
<td>Methods for estimating or comparing measures of diagnostic accuracy</td>
<td>P5, R Statistical methods</td>
</tr>
<tr>
<td></td>
<td>How indeterminate index test or reference standard results were handled</td>
<td>P5, R Statistical methods</td>
</tr>
<tr>
<td></td>
<td>How missing data on the index test and reference standard were handled</td>
<td>P5, R Statistical methods</td>
</tr>
<tr>
<td></td>
<td>Analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory</td>
<td>P5</td>
</tr>
<tr>
<td></td>
<td>Intended sample size and how it was determined</td>
<td>P5, R Statistical methods</td>
</tr>
<tr>
<td>Results Participants</td>
<td>Flow of participants, using a diagram</td>
<td>R Figure A1</td>
</tr>
<tr>
<td></td>
<td>Baseline demographic and clinical characteristics of participants</td>
<td>R Table A9</td>
</tr>
<tr>
<td></td>
<td>Distribution of severity of disease in those with the target condition</td>
<td>R Table A11</td>
</tr>
<tr>
<td></td>
<td>Distribution of alternative diagnoses in those without the target condition</td>
<td>R Figure A2</td>
</tr>
</tbody>
</table>
5.3.2 Community acceptance assessment of *Getting it Right*

*Getting it Right* had high community acceptance with all four criteria met (Table 5.3).

**Table 5.3  Assessment using community acceptance criteria of *Getting it Right***

<table>
<thead>
<tr>
<th>Evidence of conduct addressing criterion</th>
<th>Criteria met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criterion one: Indigenous community governance of research</strong></td>
<td>✓</td>
</tr>
<tr>
<td>– Approved by Health Boards/CEO or other relevant decision makers at participating services (Section 4.4.1.1)</td>
<td></td>
</tr>
<tr>
<td>– Two CIs are Aboriginal and involved in planning the approaches used during the research</td>
<td></td>
</tr>
<tr>
<td><strong>Criterion two: Community involvement in research development</strong></td>
<td>✓</td>
</tr>
<tr>
<td>– Research was discussed at Kanyini Vascular Collaboration meetings for three years, which involved three of the participating communities during the developmental stage (Section 4.4.1.1). The remaining participating services were invited to participate after the design was completed</td>
<td></td>
</tr>
<tr>
<td>– Two CIs are Aboriginal and involved with developing the study protocol and grant application</td>
<td></td>
</tr>
<tr>
<td><strong>Criterion three: Community involvement research conduct (data collection, analysis)</strong></td>
<td>✓</td>
</tr>
</tbody>
</table>
– All data collection and patient contacts were completed by staff nominated by management at participating services
– Initial research results were presented and discussed among the SC members, which included the Aboriginal investigators
– Initial research results were presented to participating services during feedback sessions, providing opportunity for staff to contribute to the interpretation of final results (Section 4.5)

<table>
<thead>
<tr>
<th>Criterion four: Community involvement in reporting of research results</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Opportunity for staff and community to contribute to the reporting of results through participating in discussions at feedback sessions</td>
</tr>
<tr>
<td>– A publication policy agreed by SC at the beginning of the research involved a review of the manuscript by staff at participating services before publication</td>
</tr>
<tr>
<td>– Aboriginal CIs named co-authors (one is the senior author) on the manuscript with the main results</td>
</tr>
<tr>
<td>– Contribution of all staff is acknowledged on the manuscript of the results publication (as named co-authors pending journal approval)</td>
</tr>
</tbody>
</table>

Abbreviations: CEO – Chief Executive Officer; CI – chief investigator; SC – steering committee

5.3.3 Values and Ethics Guideline assessment of Getting it Right

Twelve actions were identified from Getting it Right that related to the Values and Ethics Guideline (Table 5.4). Respect, responsibility and ‘spirit and integrity’ were the most commonly endorsed values, and several actions related to multiple values.

Two actions related to the study protocol: (i) use of an adaptive protocol to enable an individualised approach to recruitment based on local preferences (reciprocity and respect); and (ii) protocol was modified in response to a request from a community (respect). We provided flexible financial arrangements to compensate participating services for the time involved with completing research activities. This endorsed multiple values in the following ways:

1. **Reciprocity:** The allocation of funds was paid to services and allocated at the discretion of each participating service. This enabled them to use the funding towards operations, resources or staff development, or in any way they deemed to be appropriate. This demonstrated reciprocity by providing the opportunity to enhance the capacity of communities beyond the research through funding community-determined priorities.

2. **Respect:** Providing financial reimbursement to participating services recognised the time, commitment and role of their involvement in the study, as well as demonstrated respect for the contribution made by individuals and communities.
3. **Spirit and Integrity**: Providing financial reimbursement acknowledged the complexity surrounding cultural, social and spiritual cohesion. Acknowledgment of these factors involves additional resources and time and demonstrates integrity by the researchers. Taking part in the research required additional resources and time. This demonstrated integrity by understanding cultural, social and spiritual cohesion, including workable timeframes.

Table 5.4 Demonstration of how the principles of Reciprocity, Respect, Equality, Responsibility, Survival and Protection, and Spirit and Integrity were considered in *Getting It Right*

<table>
<thead>
<tr>
<th>Reciprocity</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Study was initiated following the <em>Men, Hearts and Mind</em> project,(^{31,110,111}) which responded to community-identified needs for strategies to address SEWB</td>
</tr>
<tr>
<td>– Flexible financial arrangements enhanced communities’ capacity beyond the research through funding community-determined priorities</td>
</tr>
<tr>
<td>– An adaptive study protocol enabled staff at each service to develop individualised steps and processes based on service needs in line with community values and aspirations</td>
</tr>
<tr>
<td>– Incorporating requests from services to adapt the study protocol to facilitate recruitment and meet staff and community needs demonstrated a willingness to modify the research according to community values and aspirations*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Respect</th>
</tr>
</thead>
<tbody>
<tr>
<td>– The PHQ-9 was adapted by representatives from five Aboriginal communities over 12 months (completed during the <em>Men, Hearts and Mind</em> project)(^{31}) to produce the aPHQ-9 which incorporated Indigenous knowledge and experience</td>
</tr>
<tr>
<td>– Presentation of <em>Getting it Right</em> to community Health Boards provided consent/approval for the research to be conducted at a service, therefore, demonstrating engagement with local processes</td>
</tr>
<tr>
<td>– Approval from the AHMRC demonstrated engagement with local processes</td>
</tr>
<tr>
<td>– Providing financial reimbursement recognised the time, commitment and role of the participating services, and acknowledged the contribution made by individuals and communities</td>
</tr>
<tr>
<td>– Offering vouchers to reimburse participants for their participation and costs associated with the research acknowledged the their contribution (not all services took up this offer; this was also respected)</td>
</tr>
<tr>
<td>– Recognising the contribution of staff by providing them with training certificates listing skills and providing participating services with ‘Halfway Congratulations’ certificates*</td>
</tr>
<tr>
<td>– A publication protocol that included a series of feedback meetings with participating communities where specific results will be presented. Joint sign-off of the manuscript before publication*</td>
</tr>
<tr>
<td>– An adaptive study protocol demonstrated efforts to minimise the effects of difference blindness^</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Equality</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Acknowledging all staff involved with the research on the main publication, (according to staff preferences) demonstrated equality</td>
</tr>
<tr>
<td>– Gaining input from staff at participating services ensured correct interpretation of research findings (visits, phone or Skype conversations as determined by each participating service)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Responsibility</th>
</tr>
</thead>
</table>

---

96
The purpose, methods, conduct and planned dissemination of results and potential outcomes/benefits of research demonstrated transparency.

A thorough researcher safety and response protocol outlining the duty of care of patients and processes was followed if safety issues were identified during the research demonstrated transparency of research conduct.

Feedback of research-related clinical information in a timely manner and format to facilitate the ongoing management of patients’ health after participation in the research demonstrates efforts to do no harm during research.

Service staff were able to contact the project manager and psychiatrist directly via telephone or email to discuss concerns and to minimise the likelihood of any unintended consequences arising from or after Getting it Right demonstrated efforts to do no harm during the research.

A publication protocol described joint sign off of publication and the protection of individual and community identities.

Mechanisms to provide feedback to communities and individuals about research results before the publication demonstrated responsibility and researcher accountability.

**Survival and Protection**

- Provision of training and support to staff by the researchers included gaining consent to participate in the research (i.e. being voluntary, the ability to withdraw consent at any time, the information provided is confidential), interview skills, record keeping and documentation demonstrated the contribution to social or cultural bonds among Indigenous communities.
- Participant interviews completed ‘in language’ demonstrated strategies to reduce threats to cultural distinctiveness.
- The use of service-identified staff to ensure cultural integrity and appropriateness during the interviews demonstrated strategies to reduce threats to cultural distinctiveness.
- An Aboriginal artist commissioned to design and complete artwork to represent Getting it Right on research-related materials provided opportunities for communities to better advocate for cultural distinctiveness.

**Spirit and Integrity**

- Providing service resources so that staff could easily complete research activities (tablet computer for data entry, provision of research-specific internet connection) demonstrated an understanding of cultural, social and spiritual cohesion.
- Flexible financial arrangements provided to services (by NHMRC via TGI) to compensate for staff time to conduct research activities demonstrated an understanding of cultural, social and spiritual cohesion.
- Interviews and interactions with patients were completed by nominated members of staff (not by external researchers) demonstrated a commitment to working within the spirit and integrity of the communities.
- Efforts by the project manager and chief investigator to learn about each community by ensuring adequate time was available when visiting participating services, attending service and community events prior to and throughout the research and seeking out and sharing stories demonstrated personnel integrity.

Abbreviations: AHMRC – Aboriginal Health and Medical Research Council of NSW; aPHQ-9 – adapted Patient Health Questionnaire-9; NHMRC – National Health and Medical Research Council; SEWB – Social and Emotional Wellbeing; TGI – The George Institute.

^ Difference blindness: to misrecognise or fail to recognise cultural differences

* Indicates where information was from supporting information in Chapter 4, and not presented publications arising from Getting it Right.
5.4 Discussion

Overall, this critical evaluation shows that *Getting it Right* was reported, designed and conducted well, and was of sufficient quality to provide reproducible, reliable and generalisable results, according to standard quality assessment criteria for validation designs. In addition, Indigenous communities and representatives were involved at various stages of the research and many actions were identified that related to the Values and Ethics Guideline. It was apparent that validation designs can meet scientific and ethical criteria that are important when conducting Indigenous-focused SEWB PHC research.

5.4.1 Risk of bias and strategies to mitigate risk

The QUADAS-2 highlighted areas where the research may have been vulnerable to bias, including the use of a reference standard that was not the ultimate gold standard and the selection of a sample with a potentially higher prevalence of depression than the general practice populations. To explore if and how these potential biases were managed in other similar research projects, I discuss these results with regard to two other Indigenous-focused SEWB research projects of similar design (validation design). Because the aim of Chapter 5 is not to systematically review Indigenous-focused validation studies, I have not completed a comprehensive quality assessment of these research projects, but instead reviewed two journal articles of similar design and aims to *Getting it Right*:

1. Esler D, Johnston F, Thomas D, et al. The validity of a depression screening tool modified for use with Aboriginal and Torres Strait Islander people. Australian and New Zealand Journal of Public Health. (2008) (hereafter the modified PHQ-9 study). The aim of this research was to assess the reliability of a modified version of the PHQ-9 (modified via focus groups), completed separately to the Men, Hearts and Mind study. This research was included in the systematic review.

2. Almeida OP, Flicker L, Fenner S, et al. The Kimberley Assessment of Depression of Older Indigenous Australians: Prevalence of Depressive Disorders, Risk Factors and Validation of the KICA-dep Scale (2014) (hereafter KICA-dep study). The aim of this research was to develop and validate a culturally acceptable scale to assess depressive symptoms in older Indigenous people,
determine prevalence of depressive disorders and investigate a range of factors associated with depression. This research was not included in the systematic review because it did not appear to meet the review’s inclusion criteria (more than half the research conducted in PHC service).

5.4.1.1 Identifying an appropriate reference standard

There are no diagnostic tests for depression that have been validated for use among Indigenous communities. The SC identified and discussed the lack of a valid ‘reference standard’ during the research development stage and selected the MINI during Getting it Right because it was the most widely used structured psychiatric diagnostic interview instrument, and had been used in more than 100 countries, including non-Western cultures, indicating it is likely to be appropriate for classifying depression in Indigenous communities. Many clinical conditions, particularly mental health conditions do not have a validated diagnostic tool, therefore, most validation designs use the best available and practical ‘reference standard’) to classify the condition during validation research.

The ultimate gold reference standard for diagnosing major depression is a semi-structured clinical interview by an experienced culturally-competent consultant psychiatrist or highly trained mental health clinician. Due to resource constraints, large number of recruiting sites, distribution of PHC services across Australia and the limited number of clinicians available with these skills, the SC deemed that the ultimate gold standard was impractical and selected the MINI as the best available and practical alternative. Furthermore, no data were available to show that a standard psychiatric assessment, based on diagnostic criteria, misclassifies Indigenous people presenting with depression.

Despite the widespread use of the MINI, some concerns have been raised about its use in classifying depression (and other tools based on DSM criteria) in non-Western cultures. In brief, these concerns relate to the potential for definitions of depression to differ cross-culturally (meaning they may not be detected by the MINI) and the DSM diagnostic criteria could rate severity differently among various cultural or language groups, known as a ‘category fallacy’.
To explore a definition of depression in Australia’s Indigenous cultures, the concept of ‘depression’ was examined in the Men, Hearts and Mind project\textsuperscript{111} where it was found that depressive symptoms are common and largely consistent with symptoms seen in non-Indigenous groups.\textsuperscript{110} Furthermore, the concept of depression was understood and other terms were not required for depression in Central Australia. This suggests that category fallacy is unlikely during Getting it Right.

In two similar research projects, the reference standards used were also not the ultimate gold standard, indicating that similar challenges were experienced. During the KICA-Dep study,\textsuperscript{2} interviews were completed by a consultant psychiatrist and checked by an independent physician using DSM-IV-TR and ICD-10 criteria. In the modified PHQ-9 study,\textsuperscript{91} interviews were completed by a GP who was registered to provide psychiatric services and apply DSM IV\textsuperscript{1} criteria.

With regard to the cultural competence of the interviewer (the second component of the ultimate gold standard), Getting it Right assessments were completed by those nominated by the participating services. The SC selected this approach to enable the identification of interviewers who were culturally-competent and understood local idioms. In the other two studies,\textsuperscript{2,91} it was not mentioned whether the interviewers were culturally competent. However, community members and assistants completed the recruitment process in the KICA-Dep study,\textsuperscript{2} and the GP was a staff member at the local PHC service in the modified PHQ-9 study,\textsuperscript{91} indicating this may be likely.

This indicated that there are a limited number of experienced and culturally-competent consultant psychiatrists or highly trained mental health clinicians able to take part in multi-site validation studies. This may result in similar challenges in future research projects until ongoing research to fill this gap is completed and published (such as the project to evaluate the Structured Clinical Interview for DSM-5 in the diagnosis of mental disorders in Indigenous Australians (NHMRC Project Grant 2014–2018).\textsuperscript{131}

5.4.1.2 Generalisability of research findings to the target population

Due to some recruitment occurring at clinics where attendees may have a high risk of depression (Residential Drug and Alcohol Rehabilitation Service, or through high risk clinics or chronic disease client lists) selection bias may have occurred in Getting it
Right, potentially resulting in an overrepresentation of people with a higher risk of experiencing depression than the general population (Indigenous PHC attendees). There was also potential for an overrepresentation of males because the Residential Drug and Alcohol Rehabilitation Service recruited predominantly males (Chapter 4, Sections 4.4.12 & 4.4.7). However, the literature shows that 30% of Indigenous people reported having a high or very high psychological distress level during the National Survey of Indigenous Australians, which is comparable to the prevalence of MDE (22%) identified during Getting it Right. However, as no significant difference between males and females recruited into the research were found, this selection bias did not occur.

The adaptive approach to recruitment (allowing for this to be determined by staff) was agreed upon by the SC to recognise the diversity across Indigenous-focused PHC services and to enable the research to fit within the requirements and workflows of each participating service. The consecutive recruitment approach, broad inclusion criteria and large sample (N=500) allowed the aPHQ-9 to be tested in different geographical locations and cultural groups, which contributed to the generalisability of results.

Similar selection and response biases may have occurred in the KICA-dep study arising from the recruitment process that was facilitated by community leaders and assistants. The role of community leaders potentially identified a certain type of participant (those who had a pre-existing relationships with the interviewer, potentially causing selection bias) and for participants to answer questions differently due to social pressures (potentially causing response bias). These pre-existing relationships can lead to the confirmation bias, which occurs when interviewers seek out information that supports a preconceived belief about the interviewee.

The KICA-dep study included people 45 years or older from one geographical location, and a small number of people with depression, thus limiting the generalisability of the results and preventing analyses of important subgroups of participants (e.g. males, females, those with a history of depression). Validation only occurred in the community where the questionnaire was adapted (limiting generalisability) and the study design only required participants who had a KICA-Dep score of greater or equal to nine to complete second interviews. This may mean that sensitivity and specificity and/or their confidence intervals might not be as precise as if all participants (including those
without depression) completed second interviews. However, a pseudo-random sample (i.e. every third potentially eligible person being approached, including people living in residential care facilities) was used to recruit participants from one of the seven participating communities, demonstrating attempts to minimise the impact of selection bias. The authors reported that nearly all eligible participants were included. Although it was not stated by the researchers, having community members and assistants complete the recruitment process may have been considered a culturally-appropriate approach.

The modified PHQ-9 study\textsuperscript{91} recruited a small sample (n=34) due to time and funding constraints; only people with ischemic heart disease were included (which was acceptable given the aims of the research was to validate the modified PHQ-9 in people with ischemic heart disease, however, limits the generalisability of findings). Validation only occurred in the community where the tool was adapted. This, together with the small sample and even smaller number of participants with depression, limits the precision of conclusions drawn from the research and also demonstrate the challenges with conducting such research in Indigenous-focused PHC services.

Although recruitment methods can introduce some bias, they may indicate consideration of cultural and contextual factors that are important when addressing the Values and Ethics Guideline.\textsuperscript{7} Furthermore, common challenges reported in the Indigenous-focused research literature, such as limited resources (including financial and human resources)\textsuperscript{67, 69} and challenges identifying research participants\textsuperscript{67, 68} may indicate that these approaches are necessary to ensure feasibility, however, they must be scientifically rigorous to be of clinical value.

**5.4.1.3 Use of standard quality tools for Indigenous-focused SEWB PHC research**

The QUADAS-2\textsuperscript{118} has provided a useful guide when considering validation designs, and as intended, during systematic reviews, to identify if appropriate and valid reference standards are used, and if a representative population is recruited. It is important when research is conducted with ethnic-specific groups to establish if authors report whether reference standards are culturally validated.

The STARD\textsuperscript{117} guideline was easy to use for identifying the completeness of reporting validation designs. As a purpose-built tool, it is relevant for to validation designs.
However, neither the QUADADS-2\textsuperscript{118} or STARD\textsuperscript{117} have criteria to evaluate if cultural, community and other contextual factors are incorporated into research, and if this impacts on the quality, reporting (nor did they aim to consider such criteria) or generalisability of the study results. Therefore, when critically evaluating Indigenous-focused SEWB PHC research, consideration of environmental, social, historical and cultural factors surrounding the research need to be balanced with what is traditionally considered as high scientific quality.

5.4.2 Assessment using community acceptance criteria and Values and Ethics Guideline\textsuperscript{7}

When determining community acceptance of \textit{Getting it Right}, I identified areas where the criteria could be improved (Section 2.2.1.2). Criterion four (Indigenous involvement in reporting) states that the second or subsequent authors should be scored as ‘unclear’, and when evaluating \textit{Getting it Right}, I (and AME) determined that ‘unclear’ did not sufficiently recognise the contribution that the Aboriginal authors (CI Brown and CI Gee) made to the \textit{Getting it Right} study. According to the International Committee of Medical Journal Editors Recommendations for Authorship Definitions,\textsuperscript{132} authorship (regardless of order) should be based on the following criteria:

- Contributing to the concept or design of the work; or the acquisition, analysis or interpretation of data for the work
- Drafting the work or revising it critically for important intellectual content
- Approving the final version for publication
- Agreeing to be accountable for all aspects of the work to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.\textsuperscript{132}

Those designated as authors who fulfilled the four criteria for authorship should be identified as authors. However, those who did not meet the criteria should be acknowledged. Consequently, if using these or similar criteria, in order to meet the standard for authorship, a significant contribution must be made to the manuscript. I recommend that regardless of the order of the authorship, if representatives from
Indigenous-focused PHC services are named as authors, this criterion has been achieved.

Calculating an overall assessment score according to the number of criteria met (e.g. all four criteria) may not fairly represent that each criterion holds more or less weight. Some criteria may introduce more bias than others, and this should be demonstrated when reporting assessment scores. Therefore, I suggest using a scoring system where each domain is assessed independently (similar to the QUADAS-2 approach), rather than generating an overall quality score, or a traffic light system, similar to the Cochrane model which provides no score, but clearly demonstrates how research was performed according to each criterion.

There are other actions that may be important to consider when determining community involvement in research that are not included in the community assessment criteria used in this thesis (Section 2.2.1.2). For example, determining if research enhanced capacity or if culturally-appropriate community engagement was achieved may provide greater insight into community involvement and acceptance of research. Additionally, caution may be needed when determining if the involvement of any Indigenous representative indicates genuine involvement and acceptance by the community where research is being conducted (refer to definition of community in Section 2.2.1.1).

These criteria are still useful to demonstrate if research was reviewed by community governance structures and when community representation was included (pre-research, development, conduct and reporting phases). This provides minimum criteria to determine if research is likely to be acceptable and meet community needs.

The Values and Ethics Guideline are currently being reviewed by NHMRC and The Lowitja Institute. This review includes an evaluation report and public consultation. An expert working committee is considering recommendations from this review. An updated version of the guideline will be soon be released and may provide further guidance on conducting culturally-appropriate research. However, until such time, the Values and Ethics Guideline remains as the national guideline.
5.4.2.1 Challenges assessing community acceptance based on the published literature

Many of the actions identified during *Getting it Right* as addressing community acceptance criteria and the Values and Ethics Guideline\(^7\) are documented as supporting information presented in Chapter 4. I know this occurred from my involvement in the project, rather than the information being documented in the publications arising from the research. It is likely that journal word limits lead to underreporting of community consultation and the actions taken during research planning and conduct, which may limit the development of evidence in this area.

5.4.2.2 Potential measures to determine community acceptance

During discussions with authors of research included in our systematic review (Chapter 3), I attempted to contact authors whose research was included and became aware of work to develop a rating tool to assess the scientific quality and cultural appropriateness of indicators used to measure health and social outcomes in Indigenous communities.\(^{136, 137}\) Although this work relates to health indicators (rather than to research), similar tools could be designed to assess whether research is of high quality and culturally appropriate.

5.4.3 Community involvement at different stages of research

In the *Getting it Right* research project, six participating services were invited to be involved after the study had been designed, funded and planning for the research project was complete (development stage complete). This may be similar to studies identified in the systematic review, where seven of the included studies involved communities after the research was initiated by researchers external to the participating PHC service, and another seven arose from research partnerships involving externally located researchers. It is unclear if these communities would have wanted to participate in their earlier stages or if their involvement would have changed the study design or conduct.

Six *Getting it Right* services reviewed and approved the research, were involved in research conduct (conduct stage), and were invited to participate in the feedback of results to service staff and community and the process evaluation (translation stage). However, the extent to which they chose to be involved with the subsequent stages...
varied, with one service choosing not to take part in the process evaluation and another choosing not to receive face to face or video feedback of results; instead electing to receive a written report.

Information about why PHC service staff chose to participate in the *Getting it Right* study, and if they wanted to continue their involvement in the various stages of the research, are explored in the process evaluation (Chapters 7 to 9).

### 5.5 Conclusion

In Chapter 5, I demonstrate that research can be of high scientific and ethical quality, and that important aspects of validation designs were planned in the *Getting it Right* study protocol and detailed in the results, suggesting that the research was designed and reported in accordance with accepted standards. Chapter 5 follows on from information presented in Chapter 4 (which showed that overall, *Getting it Right* was conducted as planned in the study protocol), and is added to during the process evaluation (Chapters 7 to 9) where staff perspectives are explored and specific aspects about the conduct of the research are presented.

Similar to the findings from the systematic review (Chapter 2) and other comparable research projects, this chapter showed that the reporting guidelines and risk of bias tools had some potential limitations for the generalisability of results, resulting from a lack of access to a culturally valid reference standard and potential participant selection bias. However, these biases appeared to arise from adaptations that were made to address the Values and Ethics Guideline and may be necessary for research to be ethical and feasible when conducted with Indigenous communities, demonstrating some tensions with conducting research that meets scientific and ethical criteria.

Journal word limits are also identified as potentially restricting reporting of how research addresses the Values and Ethics Guideline and of processes that involve community representatives. In this chapter, I identify many actions during *Getting it Right* that relate to the Values and Ethics Guideline. These include the adaptive protocol and flexible financial reimbursement arrangements that appeared to endorse multiple values and demonstrate tangible processes that can be followed to develop and plan research.
In Chapter 6 I will present my perspectives as the PM of *Getting it Right* about the barriers, enablers and lessons learnt during the research, as well as my development as a culturally-competent researcher.
CHAPTER 6
REFLECTIVE CASE STUDY OF GETTING IT RIGHT

6.1 Introduction

In Chapter 6, I present my reflections, my perceptions about the enablers and barriers to Getting it Right, and the lessons that I learnt as the PM through a reflective case study. My reflections are linked to the Values and Ethics Guideline\(^7\) so that I can explore if and how they relate to this document. Furthermore, I describe how my reflections informed new processes that I established during the research and how my cultural competence as a non-Indigenous researcher and PM developed during the research. This chapter may provide useful information for others working in Indigenous-focused SEWB PHC research about the lessons I learnt during Getting it Right.

To ensure my reflections were not influenced by staff and patient perspectives or the results of the critical evaluation, I completed this reflection in 2016 before I began the process evaluation interviews and the critical evaluation (both completed between November 2016 to July 2017).

6.2 Background to case study research and reflection during research

Case study research can be used to explore a specific event or phenomena. Through exploring individuals, organisations, interventions, relationships and communities, case studies can provide information to develop or test a theory, evaluate programs or describe a situation.\(^{138}\) They can also be used to explain, explore or describe events within a specific real life context.\(^{139}\) Various approaches can be used to guide case study research, depending on its aims.

In brief, a case study can be approached as an empirical inquiry\(^{139}\) guided by a structured research design following a research protocol.\(^{140}\) Alternatively, a broader approach can be used which provides flexibility to follow avenues of inquiry that arise during the research, potentially resulting in a rich description of the case.\(^{141}\) Using this broader approach, the case under investigation may need ‘fencing-in’ to provide clarity
and set parameters. In this approach to case study, the investigation was informed by a literature review to develop a theoretical framework to guide the research process.

Another case study approach classifies cases as ‘intrinsic’, placing the needs of the case as dominant during the case study, or ‘instrumental’ where it is the issue under investigation that takes priority and drives the research. In contrast to a protocol-driven case study approach in an intrinsic case study, the process is flexible and may be adapted according to the direction of the case study.

I identified a need to incorporate critical reflective elements into the case study to explore my own role and learning during the research. Critical reflection processes can provide a framework to reflect an individual’s research (or clinical) practice, and can uncover a researcher’s social, cultural and professional positions. The power dynamics resulting from these positions can reveal the role of the researcher in the research. Reflective frameworks often involve considering a series of questions with regard to a specific situation (e.g. What were the power dynamics in a situation? How did I influence the situation?).

When working cross-culturally, critical reflection can explore and make explicit the power dynamics that the ‘dominant’ culture has, which can in turn improve the researcher’s cultural competence.

By researchers partaking in critical reflection during Indigenous-focused SEWB PHC research and sharing their reflections, successes can be built upon and past mistakes may be avoided. Examples of authors reflecting on Indigenous-focused health research include reflection on a research relationship and reflection to improve cross-cultural practice in mainstream health organisations.

6.3 Aims

In this Chapter, I document my reflections about how I developed my practice as a culturally-appropriate researcher, the enablers, barriers and lessons I learnt as the PM of Getting it Right and demonstrate how my reflections informed the processes that I established during the research. I also reflect on how the enablers I identified relate to the Values and Ethics Guideline.
6.4 Methods

In this chapter I adopt elements of case study research and critical reflection methods to complete this case study. *Getting it Right* is dominant in this case study\(^{142}\) and therefore, it is central to the research. I report examples of my critical reflections on my practice as a researcher during the research.\(^{143}\) Because this case study is a personal reflection of my experiences as the PM, a narrative account is provided, and this section is unreferenced. I link my reflections of the enablers to the Values and Ethics Guideline\(^7\) to explore my perspectives relate to this document. If links to the Values and Ethics Guideline\(^7\) have been discussed in previous chapters, I only briefly mentioned them in this chapter.

I base my reflections on my own notes taken during the research (using a reflective framework process\(^{143}\)), and where relevant, review study administrative documents (including communication logs, training logs, site activation reports), however, a detailed analysis of the documentation will be completed during the process evaluation (Chapters 7 to 9).

6.5 Results: my cultural competence as a researcher

As I reflected during this research, I gained a deeper appreciation of how my background (non-Indigenous, female, nurse and external researcher) influenced my perspectives, priorities and approaches, and how I was perceived by others. Before and throughout my PhD research and work as a PM, I aimed to explore and understand the influence of race and culture in my work and personal life. Being ‘white’, I exist in a social environment that privileges and promotes people from my race (including myself), and I recognise that my race holds social and institutional power (in settings such as universities\(^{146}\) and the health system) over some people from Indigenous and other minority cultural backgrounds.\(^{147, 148}\) Similar to other researchers,\(^{149, 150}\) I aim to develop my understanding of these factors, to shape and improve my awareness and skills, so I can be a culturally safe researcher, and human.

Aware of the potential power imbalances arising from being from the ‘dominant’ culture, I was mindful to always emphasise my view that staff are the experts in their community, and therefore they have the skills and knowledge to plan and conduct the
research, and that this was a set of skills that I lacked. I actively sought out perspectives from staff about how they perceived the research, its potential challenges and how they thought community members would respond.

Initially, I felt awkward when Acknowledging Country, possibly because I was aware of the harms of colonisation and felt self-conscious about its impact on Indigenous communities. But I quickly learnt that this was a good way to start conversations about local histories and cultures, which helped my learning and gave me valuable insight into local priorities, histories and community life.

As well as gaining a deeper appreciation of the ongoing impact that colonisation and government policies have on individuals, families and communities, I saw many positive examples of strong cultural and community lives, often focused around the participating services. For instance, I was invited to attend a NAIDOC event run by a participating service and was overwhelmed by the vibrant atmosphere, the high attendance, and the community members’ obvious enjoyment of the event (although there was torrential rain, it did not hamper the celebrations at all!)

This experience showed me how close and connected the community was; and it gave me an appreciation for what it was like to be an ‘outsider’. In particular, I was touched by the respect shown to the Elders, who were provided with a dedicated marquee, bathrooms and lunch, and were cared for by staff and other community members throughout the day. I reflected on how it may be difficult for elderly people to attend community events in my own neighbourhood (such as finding a nearby car park, walking long distances and using portable bathrooms), and I felt embarrassed about how little respect is shown to my Elders at such events.

I saw firsthand the resilience within communities. Once, I arrived in a community on a day when a tragedy was unfolding. I quickly offered to leave and return at another time to complete the research. However, staff invited me inside to join them for morning tea before I left. Over morning tea I saw how the community worked together and supported each other, by quickly making a plan to arrange lunch to bring the community together in this challenging time, including transport, so that family members who were far away could join them, and by offering emotional support. I was touched by the
response within the community and later reflected: *Today I have really learnt the meaning of the word 'community'.*

I also saw many examples of community successes, such as community-led programs, including a before school surfing group, (where young adults picked up school-aged children before school and take them surfing), breakfast clubs and art therapy groups. These examples appeared to have positive outcomes within communities and were often run by volunteers and with very limited budgets.

I learned about the power of terminology during this thesis. I use the term Indigenous in this thesis and recognise that some people may prefer use of Aboriginal and Torres Strait Islander, to recognise the cultural diversity of Aboriginal and Torres Strait peoples, and that they do not represent a homogenous group. Furthermore, I use Indigenous-focused PHC services to include AMS, ACCHS and other services that provide PHC within Indigenous communities. AMS and ACCHS are community-led services and this may not be fully reflected in this phrase.

My experience working with Indigenous staff and communities involved with *Getting it Right* has given me a deeper appreciation for the harms done by colonisation and about the resilience, strength and connections within Indigenous communities. For me, this highlights a missed opportunity for the ‘dominant’ non-indigenous Australian culture to learn from the wealth of knowledge across Australia’s Indigenous cultures. I believe my experience has improved my cultural competence as a researcher, and a human, and I will take the lessons I learnt from the people whom I worked with in my personal and professional life.

### 6.6 Results: enablers and barriers to *Getting it Right*

Conducting the research involved many complex activities. However, most of the major enablers and barriers that I identified related to participant recruitment because it was the area with the most variability and presented the most significant barriers and/or challenges. The main enablers I identified to *Getting it Right* and how they may relate to the Values and Ethics Guideline³ are summarised in Table 6.1.
6.6.1 Enablers to *Getting it Right*

<table>
<thead>
<tr>
<th>Enablers to <em>Getting it Right</em></th>
<th>Relevance to Values and Ethics Guideline²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptive study protocol</td>
<td>– Reciprocity and respect (Section 5.3.3)</td>
</tr>
<tr>
<td></td>
<td>– Ensuring workable timeframes demonstrated an understanding of cultural, social and spiritual cohesion (spirit and integrity)</td>
</tr>
<tr>
<td>Staggered research start-up to provide sufficient time to support sites at they start the research</td>
<td>– Demonstrating the use of research methods that recognise different values, norms and aspirations (respect)</td>
</tr>
<tr>
<td></td>
<td>– Recognising the diversity of cultures by enabling service-specific needs to be incorporated into research planning (spirit and integrity)</td>
</tr>
<tr>
<td></td>
<td>– Demonstrating researcher integrity through personal reflections informing the greater skills as a culturally-competent researcher (spirit and integrity)</td>
</tr>
<tr>
<td>Research ‘champions’ at participating services through nomination of staff by participating services</td>
<td>– Having local champions drive the research so that Indigenous knowledge and experience are incorporated into the research (respect)</td>
</tr>
<tr>
<td>PHC staff time allocated to research</td>
<td>– Ensuring workable timeframes demonstrate an understanding of cultural, social and spiritual cohesion (spirit and integrity)</td>
</tr>
<tr>
<td>Multiple staff interested in <em>Getting it Right</em></td>
<td>– Receiving approval from Health Boards and other relevant staff to demonstrates that the research responds to a community-identified need (reciprocity)</td>
</tr>
<tr>
<td>Establishing open, trusting relationships between myself and staff</td>
<td>– Spirit and integrity (Section 5.3.3)</td>
</tr>
</tbody>
</table>

6.6.1.1 Adaptive study protocol

The SC recognised the diversity among Indigenous communities, the complexity of PHC research and the potential challenges when conducting SEWB research (because it may be considered to be a sensitive topic). As a result, the SC developed an adaptive approach to the research that enabled staff to tailor research processes according to their preferences, values and aspirations by:

1. Developing individualised strategies when identifying consecutive potential participants.
2. Conducting research interviews in a way that fits with their existing workflows and preferences, and at a location chosen by them or the participants (over the phone, in-person, at a PHC service or in the community).

3. Collecting interview data using their preferred method (i.e. hard copy or entered directly into the research database).

Approaches to identifying potential participants varied across participating services and occurred during clinic appointments, drop-in appointments, community barbeques, community events, community groups and recalling patients who were due for their annual health check (Chapter 4, Section 4.4.7). After the research start-up visit, staff at most participating services requested time (ranging from a few weeks to months) to discuss how they would identify participants and allocate staff roles and responsibilities among themselves. Sufficient time was factored into planning the research project to allow these discussions to occur. This demonstrated an understanding of the need for researchers to recognise the social and cultural cohesion among staff and communities (spirit and integrity).\footnote{7}

The study protocol was amended after the research project was underway in accordance with local preferences and with respect to community requests. Initially, the protocol was amended to include the male only Residential Drug and Alcohol Rehabilitation Service (Chapter 4, Sections 4.4.12 & 4.4.7). The study protocol was also amended after \textit{Getting it Right} was presented to the Health Board to seek approval for the research at this service where its members asked if they could participate (although they were not patients of the services), and if community members who were not patients could also participate.

During discussions, the SC agreed to amend the study protocol, which included the consideration that a male only service and participants who are Health Board and community members (who were not PHC attendees at the time of research participation) had the potential to impact on the representation of the sample and generalisability of results, responding to the community feedback was the priority. The SC deemed that it was potentially unethical not to respond to the community request; that it was crucial to facilitate a positive experience with the research by community members; and that a decision not to respond to this request had the potential to harm relationships with the
community and the reputation of researchers. As a result, a decision was made to amend the study protocol.

At the discretion of staff, some CRFs were filled in by the participants, which reduced the amount of data entry work required by staff, increased transparency for participants and involved them in data collection. To enable potential biases to be managed during data analysis (e.g. social desirability bias or interviewer bias), the method of completion (self or interviewer completion) was captured in the CRFs.

6.6.1.2 Staggered research start-up to provide sufficient time to support sites

A staggered start-up of Getting it Right where one service started over a 15 month period was planned in advance in an attempt to recognise that services may have activities that needed to be considered and incorporated into planning. The number of visits to each participating service is described in Chapter 4, Table 4.3. This approach allowed us to: (i) focus on each service’s unique situation; (ii) provide focused support to staff when beginning recruitment and completing research interviews; and share experiences between participating services. It also enabled me to draw on my reflections during the research to improve its processes and my own practice as a culturally-appropriate researcher (Section 6.7). The time provided by this approach led me to embark on a PhD and the process evaluation, which was in addition to the work funded as part of the NHMRC grant.

6.6.1.3 Research ‘champions’ through nominations of staff by participating services

At some participating services, one or more staff had a particular interest in Getting it Right that appeared to provide on-the-ground support for the research. These staff appeared to act as ‘champions’ for the research. Champions were staff nominated by the participating service to work on the research; therefore, I considered that they were likely to have relevant knowledge of the local community. They were Indigenous and non-indigenous and included GPs, nurses, managers and research coordinators (defined as staff with part/all of their duties dedicated to research activities at their service). Formal identification of champions was not part of the study protocol, nor was it specified during start-up.
At one service, the champion facilitated research by writing an article about *Getting it Right* to be included in the service’s regular newsletter to inform the community about the study (Appendix 14). I discussed this with the relevant ethics committee members who agreed that if staff requested this approach and approved the text, then it was appropriate. This was a process I could not deliver (through my role as the PM), but I believed that it may have helped to increase awareness about the research project among patients and staff.

At the time, I wondered if champions facilitating the research by communicating with staff and myself and incorporating their local knowledge and experience into research (demonstrating respect) would help to adapt the study protocol and promote the research and recruitment within the service.

The reasons why these champions were interested in *Getting it Right* are uncovered in the process evaluation. I perceived that champions were motivated by their:

1. Belief that the research was useful and valuable
2. Desire and enjoyment of contributing to a large research project,
3. Support for them to facilitate research from within the participating service (e.g. staff employed as research coordinators)
4. A sense of commitment to reaching the recruitment targets following agreement
5. Belief that SEWB was a priority in their community.

### 6.6.1.4 PHC staff time allocated to research

The diversity across participating services meant that each service managed staff workloads, workflows and contacts with patients differently, therefore, affecting the amount of staff time available to work on the research. To allocate sufficient time to work on the research was an important enabler for *Getting it Right* to reach its recruitment target. Staff time was made available through:

1. Reallocation of staff from their existing clinical duties to work on the research
2. Existing or new staff who had dedicated time to work on research were hired (reimbursement provided to participating services to contribute to staff time is presented in Section 4.4.3).

Staff were reallocated from their clinical duties to focus entirely on the research project for a specified time at five participating services, resulting in their recruitment targets being met in the shortest timeframe. At one service, staff were allocated three hours on Wednesday mornings to speak to patients about Getting it Right and to complete interviews. At another two, recruitments were completed on designated recruitment days.

At four participating services, there was at least one staff member employed as a Research Coordinator before Getting it Right, who facilitated communications between staff and me, had ring-fenced times to focus on the research and acted as a research champion. At one service, the financial reimbursement provided by the research was used to hire new staff to coordinate Getting it Right and other research projects, which resulted in them having dedicated time to identify potential participants and complete research interviews. The provision of the financial reimbursement allowed for workable timeframes, which demonstrated an understanding of cultural, social and spiritual cohesion (spirit and integrity).³

However, research coordinators were not necessary for services to meet the recruitment target. At two participating services, neither of which had completed research before or had a research coordinator, the recruitment target was quickly achieved; one service increased its target from 50 to 99 participants. At each of these services, staff time was allocated to work on the research.

6.6.1.5 Multiple staff interested in Getting it Right

When multiple staff (clinical, management and executive staff) within participating services showed interest in Getting it Right, recruitment targets were achieved in shorter timeframes and required fewer communication between myself and staff. Approval from Health Boards (when these were established) appeared to be important to demonstrate that the research responded to a community-identified need (reciprocity).³
which helped to gain support from staff, and time and equipment was made available to complete research activities.

When managers were interested in *Getting it Right*, they facilitated the research by allocating staff time to work on it and by supporting them to approach participant recruitment differently if recruitment was progressing slower than planned. At one participating service, despite ongoing efforts, staff experienced challenges when identifying participants through their ‘drop-in clinic’ and appointment systems (using the recruitment plan they originally made during start-up). To increase recruitment, clinical and management staff hosted weekly barbeques to encourage potential participants to attend the service. During the barbeques, being a relaxed environment (because patients were not visiting in relation to a health problem), staff spoke to patients, giving them ample time to consider their decision of whether to participate and complete research interviews. This approach proved to be effective and the target was quickly achieved. However, it may not have been viable without commitment from management (to allocate resources and funding) and staff (to host the barbeque and complete interviews).

### 6.6.1.6 Establishing open, trusting relationships between staff and me

Strong relationships between staff and me appeared to facilitate the research for those who felt comfortable speaking to me about their concerns; we could discuss and resolve challenges quickly. These relationships were established during visits by CI Hackett and me to participating services during the research start-up and training when we allocated time to become familiar with staff and the community, sharing stories about our families and interests outside of work (Sections 4.4.4 & 4.4.5). At the beginning of each visit, we acknowledged that we were on Aboriginal land and asked about the local history, community and traditional owners. This created a relaxed atmosphere to begin visits and a collegial approach to training. During each visit, staff often learnt new information about each other, such as work experiences and people they knew in common.

These discussions were also important for us to learn about the perspectives, priorities and contexts where staff worked and lived, which helped us to appreciate each community’s uniqueness and possible challenges. Staff introduced us to community
members three times during these visits. We made substantial efforts to continue to foster these relationships by communicating regularly, providing ongoing support and responding quickly to concerns.

6.6.2 Barriers to Getting it Right

The main enablers I identified to Getting it Right are summarised in Table 6.2.

<table>
<thead>
<tr>
<th>Barriers to Getting it Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff turnover at participating services</td>
</tr>
<tr>
<td>Multiple competing priorities at participating services</td>
</tr>
<tr>
<td>Technology-related barriers to Getting it Right</td>
</tr>
<tr>
<td>Delays with gaining ethics approval and amendments to the study protocol</td>
</tr>
</tbody>
</table>

6.6.2.1 Staff turnover at participating services

After research start-up and training visits and before recruitment was completed, six staff who had completed training left their employment and another five were reallocated elsewhere within the service, resulting in ceasing their involvement with Getting it Right. Turnover occurred at various levels within the organisation, including staff identified to complete research activities, management staff and executive staff. Staff turnover appeared to delay progress towards research targets while new staff were identified/hired and completed training in the research. I felt that it took time for us to develop our relationships to a point where we could work together effectively (compared to those whom I had already met in person).

I was aware of the importance of building ethical relationship during the Indigenous-focused research, therefore, aimed to achieve this with the newly identified staff. It was challenging to establish these relationships because we were usually completing training remotely (via phone, Skype and email, often over many sessions) rather than in person (Section 4.4.5).

After a manager left one participating service, the new manager identified 13 additional staff to be trained in the research to allow staffing combinations to become available to
complete research activities effectively. I was unable to visit the service at that time and so I had to deliver the training remotely via Skype, including phone calls and emails by CI Glozier and me. I found it challenging to deliver training and develop rapport with the 13 staff using remote methods. There were fewer opportunities to discuss the research in a relaxed environment, to learn their stories, and to identify and address potential issues. Management at another service allocated funding to cover my travel costs for visiting and completing additional training with newly identified staff.

At one service a major restructure was underway which resulted in changes at the executive level; this appeared to disrupt research activities and engagement with the research by other staff. After I made contact with the new acting executive, I found out that the new executive was not aware of *Getting it Right*, so I informed him about the research to determine if he were interested in becoming involved and to work with his staff to develop a plan for the research. During this restructure, a supervising staff member was reallocated to another clinic within the service (where the research was not being conducted), resulting in additional staff being identified to work on the research. I wondered if such a high turnover was the norm in all research projects, or if the turnover I was experiencing was higher than what would occur in other settings.

### 6.6.2.2 Multiple competing priorities at participating services

During discussions with staff, many told me that their heavy workloads and multiple priorities hindered the research project by limiting time available to complete research activities. Although heavy workloads may not be unique to staff involved with *Getting it Right*, I wondered if the range of services that are provided by Indigenous-focused PHC services which may not be matched with sufficient funding, caused additional pressure on staff duties. Staff told me about their duties including providing support with childcare, navigating the justice system and income support services; drug and alcohol-related care; and running community groups, as well as delivering PHC. Available staff time may have been limited due to the additional complexity arising from providing this range and level of services.

Many staff had commitments to other programs, clinical responsibilities or were regularly required to respond to urgent patient issues. On several occasions, staff told me about how their plans to work on the research did not eventuate because a situation
would arise that required immediate support, leading to a backlog of work. At one participating service, over 30 research projects were running concurrently, resulting in substantial pressure on staff to allocate time to the research. This service had established processes to review, plan and manage research projects to ensure each project was feasible and fit with other projects and clinic operations. I am unsure how other research projects progressed.

This multitude of priorities sometimes resulted in challenges in contacting staff; many attempts to make contact were not returned or acknowledged. In most instances, when I made contact with them, they told me that they were committed to the research and that they were frustrated about being unable to allocate time to its activities. What I found challenging was that there was little I could do to alleviate the pressures they were experiencing. I varied the times of day I contacted them through various methods, such as phone, email, text message, mail, video-conference and visits, where feasible. Limited or no contact sometimes continued for weeks, during which time limited or no recruitment occurred. The number of visits I completed to each participating service is presented in Table 4.3. To address this challenge, the research timeframes were sometime extended (after discussions with relevant staff and CI Hackett).

6.6.2.3 Technology-related barriers to Getting it Right

Maintaining a stable internet connection via the loaned 4G dongle (provided using study funds) or using existing connections was often problematic when services were located outside major metropolitan centres (resources provided as part of the research are described in Section 4.4.3). Staff reported that access to the research database during interviews was not reliable. To rectify this challenge, they sometimes used alternative connections (such as their personal phones and tablets), or paper CRFs (which required additional time to enter data into the research database at a later time). Staff using paper CRFs also had to manually calculate ‘skip’ and ‘count’ algorithms during the interviews, which added complexity to the research interviews.

Some staff used existing computers to access the research database, which was configured for use with common internet browsers. However, at some services the browsers were incompatible with the research database, resulting in a reduced functionality and challenges for staff when entering data.
At one service, firewalls and security settings hindered communications about participant safety when they blocked the automatically generated safety emails, resulting in us having to establish a separate system where I manually sent the safety email to the nominated staff for each participant. Despite substantial efforts by database developers and IT staff at the participating service, this situation was unable to be rectified.

Sometimes the functionality of the provided tablet slowed data entry or resulted in data entry errors. Some staff reported challenges when entering free-text data into the research database and using the keyboard function on the tablet (which displays the keyboard on its screen, rather than separately as on a laptop). In addition, some tablets had the autofill function activated which included the option of selecting a response from a list of responses that had been previously entered (and automatically saved by the tablet). Some staff told me that deleting the previous responses and disabling this function was problematic.

### 6.6.2.4 Delays with gaining ethics approval and amendments to the study protocol

For the research to be conducted at 10 participating services, approval was required from eight registered NHMRC ethics committees, each with its own submission documents. As well as requiring proof of the community approval of research (usually in the form of a letter from participating services), some ethics committees reviewed research according their own ethical guidelines (in addition to the Values and Ethics Guideline). The research was significantly delayed when one review and protocol amendment took five months, which meant that the protocol being changed to include the Health Board and community members could not be implemented during that time.

### 6.6.2.5 Other barriers identified during the research

I identified other barriers during my time as the PM, including:

1. Negative experiences of some staff with other research projects and external researchers, leading to scepticism that affected initial discussions about *Getting it Right*. 

2. The research database was disabled temporarily due to a ‘hack’ to the webpage interface which resulted in additional time required from staff and me (identified by CI Hackett before the developers were aware) (Chapter 7).

A potential barrier discussed among the SC during planning and by some staff during start-up visits was the potential for some patients to be unwilling to participate due to concerns about confidentiality (e.g. if staff knew them outside of work) or if patients were uncomfortable speaking about their SEWB because it was a difficult topic to discuss. Although this was sometimes discussed by staff during start-up visits, once the research was underway, no staff mentioned to me that this was a barrier to recruitment.

6.7 How my reflections impacted on the research process for Getting it Right

In this section, I describe how my reflections informed the changes I made to some of the research processes during the research.

6.7.1 Continued development of processes to minimise impact on staff and participant times

Initially, I developed processes to minimise the time required from staff and participants. These included:

1. Establishing straightforward and clear training materials for outlining research processes and materials.
2. Printing informed consent forms and other research documentation for services.
3. Purchasing vouchers and tablets on behalf of services.
4. Developing a straightforward and user-friendly database. For example, I set up the usernames (to access the database) using the first name of each staff member, and they would select their own passwords rather than randomly allocating passwords. I also aimed to minimise number of ‘clicks’ required when navigating through each step of the database and CRF.

As my relationships with staff developed, I gained a greater appreciation of the competing priorities at Indigenous-focused PHC services and multiple demands on staff time. All day-to-day research activities at services were completed by staff nominated by the service because my ability to support them at this level was limited.
6.7.1.1 Immediate monitoring of data entry

Many staff informed me when they were planning to recruit participants into *Getting it Right*, which allowed me to be available to clarify information about participant inclusion/exclusion criteria, and to provide support with operating the database and accessing CRFs. I also monitored data entry in real time, allowing for quick identification of incomplete or missing data.

My availability during the recruitment process proved beneficial, for example, on several occasions, I identified missing data (questions or entire sections) and was able to immediately alert staff who then entered the data. During subsequent discussions, in most instances, staff told me that they had already entered the data but it was not saved in the research database. This may have been due to technical challenges described previously. By monitoring data entry in this way, the number of outstanding data queries for staff to follow up was reduced (minimising the demand on their time) and data entry was completed to a high standard. This was demonstrated by the high completion rate of aPHQ-9 interviews (three participants out of 500 had missed aPHQ-9 data – each missing only one question, therefore, total scores were still able to be calculated).

6.7.1.2 Adapting data management processes to reduce investment of staff time

During the research, I modified the ‘data query’ system that was established to document communication about missing or incomplete data between staff and me via the research database. This type of data query system is commonly used during research, but I found it was not practical during *Getting it Right* because staff found it burdensome and did not regularly check and respond to data queries via the system, resulting in data queries remaining unresolved. Being aware that a study is only as good as its data, I contacted staff via phone, emails or text message and documented data queries separately. This resulted in thorough data checking and minimised the impact on PHC staff time.
6.7.1.3 Purchasing tablets and laptops to complete set-up before providing them to participating services

Initially, I arranged to have the tablet or laptop delivered directly to each participating service. As a result of challenges with the autofill function reported by some sites, I arranged to purchase and set up tablets and deliver them to services after I had configured the functionality, which included disabling the autofill function and bookmarking the study database page.

6.7.1.4 Additional processes identified to minimise impact on staff time

I identified additional opportunities to streamline future research processes to reduce the impact on staff time that I was unable to change during Getting it Right but would implement in future research:

i) Research database: Developing ‘one click access’ to CRFs rather than two (one to access CRF information, another to open the CRF).

ii) Research documentation: Formatting the screening log and enrolment logs with obviously different formats so they can be easily identified as different (such as landscape and portrait format). The Getting it Right logs had similar formatting which caused confusion when providing screening logs to me during routine collection. During Getting it Right I printed the screening and enrolment logs on different coloured paper (orange for the screening log and green for the enrolment log). However, when additional copies were needed, staff printed them on-site onto white paper, so the distinction was lost.

6.7.2 Sharing information and SEWB resources with staff

I was surprised by how many staff told me that they appreciated the resources (such as SEWB resources and contact calling cards) I brought during start-up and other visits (Section 6.8). As a result, I sought other opportunities to provide resources and share potentially useful information with staff, such as SEWB resources, clinical guidelines and conference/training information that were not directly related to Getting it Right but potentially of use to PHC service staff.
6.7.3 Ongoing focus on relationship building

During the research, I experienced multiple situations where the strong relationships between staff and me facilitated the research because staff appeared comfortable when speaking to me about their concerns, which allowed us to discuss and resolve challenges quickly. This contributed to my belief that an ongoing investment in building relationships was important for the research to achieve its aims. Therefore, I always ensured that substantial time was invested for building relationships early in the research, where possible. (Sections 4.4.4, 4.4.5 and 6.5.1.6 discuss how we approached establishing these relationships.)

6.7.4 My considerations about research design during the Getting it Right process evaluation (written in February 2017)

I developed the protocol for the process evaluation based on my understanding, at that time, about potentially relevant theories and on the process evaluation literature (a detailed description of the methods is presented in Chapter 7). I was unable to find in the literature any process evaluation conducted with Indigenous communities to provide examples of the process an evaluation that incorporates Indigenous research methods or culturally-appropriate approaches.

When I began analysing interview data during the process evaluation, I found it particularly challenging to use a top-down approach where ‘existing theory’ is used to analyse staff perspectives (as is common when using the approaches selected for the process evaluation).\(^{151,152}\) I had the impression of forcing data into existing frameworks, rather than allowing it to drive the analysis and genuinely explore staff perspectives as they were presented (as was my aim).

I had also specified in the process evaluation protocol that I would use a grounded theory approach,\(^{153}\) which enables new themes to develop and inform data analysis, rather than using existing theories. I found this approach was better suited to my intention to identify and report the perspectives of staff. This also ensured that I, a non-Indigenous researcher, did not force Indigenous peoples’ perspectives collected during interviews into non-Indigenous frameworks, which is unlikely to be appropriate during Indigenous-focused research.\(^{49,50,154}\)
Therefore, I modified my approach to data analysis, and used grounded theory as the dominant approach, which enabled me to develop process evaluation results based on how staff reported their perspectives. This would not have been possible using a top-down approach that forces data into existing theories.

6.8 Enhancing workforce and research capacity through *Getting it Right*

I was aware of the importance of identifying opportunities to enhance research capacity during research, as described in the Values and Ethics Guideline. During the research, I identified opportunities to share information with staff or develop networks that may have enhanced the capacity of staff or participating services. When visiting services to complete research start-up and other visits, I took potentially useful resources that I was aware of, such as culturally-adapted SEWB resources and contact calling cards for mental health hotlines, and gave them to staff to provide to their patients. Some staff told me that they appreciated these resources because they had previously tried to access them, and were unsuccessful.

Through my networks at TGI, I learned of a scholarship that provided research training for Aboriginal and Torres Strait Islander health workers, which formally acknowledged any research experience they had. I shared this information with staff, some of whom applied and received the scholarship. I put one service in contact with another team at TGI, which resulted in them becoming involved with another research project.

I provided a reference letter for one staff member to give to a potential employer and hoped that this reference and/or the certificates I developed and gave to all staff (Appendix 11) were useful to demonstrate their skills and contribution to *Getting it Right*. These examples may illustrate ways to enhance capacity during the Indigenous-focused SEWB PHC research.

6.9 Lessons relevant for future research

This chapter highlights examples from my perspective about conducting Indigenous-focused SEWB PHC research that may be useful to other research teams. These include:
1. An adaptive protocol enabled staff to develop recruitment processes based on service needs, and in line with values and contexts.

2. Research champions facilitated communication about the research and may have incorporated Indigenous knowledge and experience into research. Although we did not formally identify champions, this experience suggests that future research may benefit from formally identifying such champions, though in turn, part of their success may have been because they were self-selected. This may require additional funding to hire or reallocate staff to these duties.

3. Staggered start-up ensured adequate time is available for external researchers to learn about local communities so they can facilitate their research through communicating effectively, developing strong relationships and recognising diversity during research planning.

4. Sufficient time and resources to cover ongoing training and travel expenses should be identified. Delivering training remotely may compromise its quality and limit the ability to form open and trusting relationships and ownership of the research. Sufficient time and resources may also assist with addressing challenges associated with high staff turnover by developing relationships with recently hired staff.

5. Completing critical reflection during Indigenous-focused SEWB PHC research has the potential to improve the cultural-competence and practice of researchers and clinicians.

6. Streamlined research database via ‘one click access’ to CRFs (Section 6.6.1.4).

7. Clear formatting of the screening log and enrolment logs (Section 6.6.1.4).

6.10 Conclusion

In this chapter, I document my reflections of Getting it Right and show how, through a staggered approach to start-up at participating services, I used my reflections to improve research processes during the research, which in turn facilitated progress towards research targets. My reflections identify several enablers to the research that are also in line with the Values and Ethics Guideline, including a staggered approach to research start-up and establishing strong relationships within research teams.

Through documenting my reflections, I demonstrate how I developed my skills as a culturally-appropriate researcher, which may have helped me to conduct the process
evaluation of *Getting it Right* (Chapters 7 to 9). The process evaluation will provide information from the perspectives of staff and participants who were involved with the research project.
CHAPTER 7

METHODS AND KEY RESULTS: PROCESS EVALUATION OF

GETTING IT RIGHT

7.1 Introduction

In Chapters 3 to 6, I described how Getting it Right was conducted, outlined the main research results and presented an evaluative and reflective case study of the research. In Chapters 7 to 9 I describe and present the results of a process evaluation of Getting it Right. The aim of this process evaluation is to explore how the research was conducted from the perspectives of PHC staff who participated in the research, to identify if staff and patients considered that the aPHQ-9 was acceptable and feasible to use, and if they perceived Getting it Right was conducted as per protocol. Chapter 7 contributes to the overall recommendations from Getting it Right to be considered alongside the good performance of the aPHQ-9 as a depression screening tool, as identified in Chapter 4. This chapter complements Chapter 5 by highlighting areas that may have impacted on the research’s quality from the perspectives of staff.

The process evaluation is presented in four publications over three chapters. In this chapter, I present the first two publications. The first outlines the methods used during the process evaluation. I elaborate on the methods used to provide detail that was not possible within the word limit of the publication.


The second publication (under review by co-authors) explores the acceptability and feasibility of the aPHQ-9.

I also briefly present the results of the analysis conducted to identify PHC staff perceptions about the context, impact and consequences of the research and barriers and enablers they experienced. For the purpose of the process evaluation ‘patient’ includes PHC patients in general or before consenting to the research project and ‘participants’ are patients who have consented. These results may provide information useful to those planning Indigenous-focused PHC-based research. In Chapters 8 and 9, I explore the novel concepts identified during the process evaluation.

7.2 Aims

The aims of this chapter are to:

1. Determine the acceptability and feasibility of the aPHQ-9 for PHC staff and patients, including their perceptions of its usefulness.

2. Explore if PHC staff perceived that the research project was conducted as outlined in the protocol.

3. Explore the context, impact and consequences of Getting it Right.

4. Explore the experiences of PHC staff and participants who took part in Getting it Right, including approaches, enablers and barriers to conduct of the research.

7.3 Methods (publication)

Process evaluation of a primary healthcare validation study of a culturally-adapted depression screening tool for use by Aboriginal and Torres Strait Islander people: study protocol

Overview of publication

This publication summarises the protocol of the process evaluation, including the aims, methods used to collect and analyse data, and steps taken to receive input from the Indigenous Advisory Group.

Publication details

ABSTRACT

Introduction Process evaluations are conducted alongside research projects to identify the context, impact and consequences of research, determine whether it was conducted per protocol and to understand how, why and for whom an intervention is effective. We present a process evaluation protocol for the Getting it Right project, which aims to determine validity of a culturally adapted depression screening tool for use by Aboriginal and Torres Strait Islander people. In this process evaluation, we aim to: (1) explore the context, impact and consequences of conducting Getting It Right, (2) explore primary healthcare staff and community representatives’ experiences with the research project, (3) determine if it was conducted per protocol and (4) explore experiences with the depression screening tool, including perceptions about how it could be implemented into practice (if found to be valid). We also describe the partnerships established to conduct this process evaluation and how the national Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research is met.

Methods and analysis Realist and grounded theory approaches are used. Qualitative data include semistructured interviews with primary healthcare staff and community representatives involved with Getting It Right. Iterative data collection and analysis will inform a coding framework. Interviews will continue until saturation of themes is reached, or all participants are considered. Data will be triangulated against administrative data and patient feedback. An Aboriginal and Torres Strait Islander Advisory Group guides this research. Researchers will be blinded from validation data outcomes for as long as is feasible.

Ethics and dissemination The University of Sydney Human Research Ethics Committee, Aboriginal Health and Medical Research Council of New South Wales and six state ethics committees have approved this research. Findings will be submitted to academic journals and presented at conferences.

Trial registration number ACTRN12614000705684.

STRENGTHS AND LIMITATIONS OF THIS STUDY

Iterative data collection, supported by an Aboriginal and Torres Strait Islander Advisory Group will enable novel theory to be developed concerning the context, impact and consequences of conducting research in primary healthcare services.

Important information will be identified about the feasibility of conducting primary healthcare research that may enhance future research planning.

Results will contribute to the interpretation of a culturally adapted depression screening tool's validity and acceptability for use by Aboriginal and Torres Strait Islander people, and inform its translation into practice (if optimal validity is established).

Potential limitations are the overlapping roles of researchers which may limit the sharing of negative experiences during data collection, but conversely may facilitate information sharing, analysis and interpretation. As per qualitative research guidelines this is acknowledged a priori.

INTRODUCTION

Process evaluations aim to assess how a strategy or programme is implemented; its impact, and how, why and for whom it is effective. This understanding is essential to determine whether a strategy is feasible, acceptable and applicable and can inform its roll-out, if it is shown to be effective. Typically, process evaluations are combined with complex health strategies or interventions. However, they can also highlight the unintended consequences of research, such as additional burden on staff or insufficient resourcing to conduct research according to the study’s protocol. For these reasons, process evaluations are increasingly being combined with research projects, and publication of process evaluation protocols is necessary for planning.
becoming more commonplace. This paper describes a process evaluation protocol of an Australian research project—Getting it Right: The validation study (hereafter referred to as the research project).

This national research project is focused on the social and emotional well-being (SEWB) of Aboriginal and Torres Strait Islander peoples (hereafter referred to as Indigenous). It aims to determine the validity of the adapted-Patient Health Questionnaire-9 (aPHQ-9), a culturally adapted depression screening tool developed to identify depression. If validity is established, the aPHQ-9 would be the first culturally adapted, free-to-use, nationally validated, depression screening tool for use by Indigenous people and could be recommended for use in primary healthcare (PHC) and other healthcare settings. An understanding of experiences of PHC staff involved with the research project, including their perceptions about how the aPHQ-9 could be implemented, may inform the aPHQ-9’s implementation and future research in this area.

The research project study protocol is published elsewhere. In brief, recruitment of 500 Indigenous people attending PHC was completed in 2014 to 2016 at 10 PHC services (hereafter referred to as participating sites) nationally. Conducting the research project required coordination of many processes in the complex PHC setting, including the need to create a good fit alongside existing clinical requirements. This required commitment on multiple levels at each of the participating sites. Study processes were tailored by PHC staff, with support from researchers from The George Institute. SEWB includes mental health within a broad well-being framework and recognises well-being as interconnected with land, culture, family and community and recognises the role of historical, political and cultural determinants.

In Australia, research involving Indigenous Aboriginal and Torres Strait Islander people should address the ethical standards outlined in Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (hereafter Values and Ethics guideline). Partnerships and community involvement is a central principle of this guideline. Increasingly, research teams are describing how research partnerships are formed and operate. However, descriptions of how the Values and Ethics guideline is used are scarce.

In this paper, we present our process evaluation protocol, including a description of the partnerships we have established to conduct this evaluation and documentation of how the Values and Ethics guideline is met. Data collection for this process evaluation began in December 2016 and is ongoing.

**Process evaluation aims**

In this process evaluation of the research project, we aim to:

1. Explore the context, impact and consequences (intended and unintended) of conducting the research project at participating sites.
2. Explore the experiences of PHC staff and community representatives with conducting the research project, including approaches to the research.
3. Determine if the research project was conducted as outlined in the protocol.
4. Explore the experiences of PHC staff with the aPHQ-9, including perceptions about potential for use of the aPHQ-9 (if found to be valid) and its acceptability and applicability.

Qualitative data will be considered alongside administrative data for the research project and feedback from PHC patients collected during the research project. This process evaluation may explain any variation in the research project’s results and will provide information on how, why and for whom the aPHQ-9 does or does not work. This will inform implementation of the aPHQ-9 in clinical practice (if validity is established) and will also be useful when planning future research involving PHC staff and external researchers.

**METHODS AND ANALYSIS**

**Approach to this process evaluation**

This process evaluation incorporates components of the *Medical Research Council’s guidance on process evaluations of complex interventions (MRC guidance)*, grounded theory and a realist theoretical approach. We use qualitative methods (semistructured interviews and thematic analysis). These data will be supplemented with administrative data and feedback from PHC patients (quantitative and free-text) about the research project and the aPHQ-9, collected during the research project. Data are collected, analysed and reported according to *consolidated criteria for reporting qualitative research*.

The complex intervention under investigation in this process evaluation is the research project’s conduct at participating sites. Our aims differ from those of many process evaluations of complex interventions, where a causal assumption is under investigation, making elements of the *MRC guidance* unsuitable. For example, rather than applying existing theories (as is common when investigating causal assumptions), we are exploring the context and experiences of staff members as they are presented to us. Therefore, an existing theoretical framework is not necessary or appropriate.

We draw on elements of grounded theory, as this is consistent with our aim to explore participants’ experiences as they are presented, to generate new theories. In addition, grounded theory is useful when there is little...
existing evidence in a research area, as is the case here. Grounded theory does not predefine codes for use during analysis, rather codes are identified from data as they are collected. In line with the MRC guidance and grounded theory, we are iteratively analysing qualitative data so emerging ideas can be explored in subsequent interviews. A realist approach to evaluations is becoming increasingly common, as it explores how, why and for whom an intervention is effective, therefore facilitating translation from research to practice. This approach recognises that the intervention itself may not wholly cause an outcome. Instead, it recognises that participants interact with an intervention and that the activities surrounding it (mechanism) within the social and cultural circumstances (context) alongside participant’s circumstances and beliefs, can influence outcomes. We use a realist approach to explore the context, mechanisms and outcomes (intended and unintended) related to conducting the research project.

Research partnership and reflexivity

The research team comprises a partnership established to complete this evaluation. This partnership involves an Aboriginal and Torres Strait Islander Advisory Group (the Group; established March 2016) and the research project’s project manager (SF) and chief investigator (MLH). The Group is made up of Aboriginal and Torres Strait Islander researchers and staff members from the research project’s participating sites. The Group provides cultural oversight and local input from sites to enhance and inform data collection, analysis and reporting. The Group’s aims are to:

- Provide feedback and oversight of the appropriateness and quality of the semistructured interviews (interviews, setting, questions asked and prompts used)
- Identify emerging themes from the data
- Guide interview questioning according to the emerging themes (iterative process)
- Develop a manuscript of results.

We have jointly developed this protocol in line with the Values and Ethics guideline. SF is the lead author of this research and data collected during this project will contribute towards her PhD research.

Qualitative data collection and analysis

We are collecting and analysing qualitative data through semistructured interviews using inductive grounded theory methods and coding data using constant comparison. Open coding is used to identify and label emerging ideas. We are concurrently collecting and analysing data, and are adapting our interview guide during the research. This process informs the coding framework, develops theory and is in line with a realist evaluation perspective.

An interview guide including prompts is used during interviews. Interviews are face-to-face at the participating sites if possible, or via the phone. SF conducts interviews and another member of the Group joins interviews, when feasible. We plan to continue interviews until thematic saturation is achieved. We estimate approximately 8 of the 10 participating sites will take part, with 3 to 6 participants at each participating site. Therefore, an estimated 40 interviews will be conducted. However, the final numbers will depend on saturation of themes and availability of participants.

SF will code all interview transcripts. Two to three full interview transcripts are independently double-coded by SF and another member of the Group, at three times during data collection (six to eight interviews in total). During double-coding, interview transcripts are independently coded, then codes are compared and discussed until agreement around meaning is reached. SF completes coding for the remaining transcripts based on the agreed coding. Memos are used to document comments and discussion among the Group. Once the coding framework is finalised, we will attempt to relate the results to the values in the Values and Ethics guideline.

We will consider if and how the codes can be attributed to the values described in the guideline using a set of previously developed definitions.

To address our fourth aim related to the aPHQ-9, process evaluation interviews are conducted after recruitment into the research project is complete and before results are available. This ensures PHC staff and community representatives have recent experience with the research project and using the aPHQ-9, and reduces potential bias that may be introduced by unblinding the interviewer or interviewee during interviews and analysis. The primary interviewer (SF) and members of the Group will be blinded to outcomes for as long as feasible. Should results be made available before the process evaluation is completed, this will be acknowledged during thematic analysis.

Data sources and triangulation

We are collecting qualitative data through semistructured interviews with PHC staff and community representatives at recruitment sites. Administrative and feedback data (quantitative and free-text) will be considered alongside qualitative data to determine the acceptability and applicability and potential for use of the aPHQ-9.

Administrative data include screening logs, communication logs and study tracking documents for the research project. Feedback data include structured (quantitative) and free-text (thematic analysis) feedback from PHC patients about the research project and the aPHQ-9. Feedback was collected immediately after completing the aPHQ-9. Structure quantitative feedback section, PHC patients were asked to rate their satisfaction with the number, type and wording of the aPHQ-9 questions, level of comfort with the questions, time available to respond to questions and response category options. They were then asked to provide any additional comments in the free-text section.

Data are triangulated in the following way:

1. Two (or more) members of the team code data and agree on appropriate codes (six to eight transcripts).
2. The Group reviews and provides feedback on an ongoing basis. Where necessary, further verification is sought from participants. This provides the opportunity for additional member checking.

3. The coding framework is compared with administrative data from the research project and quantitative and free-text feedback on the research project and aPHQ-9 collected from PHC patients during data collection. This provides further context for the data, opportunity to verify with study records and with PHC patients’ experiences who have experience using the aPHQ-9.

**Sampling technique and data management**

Participants may include any PHC staff or community representatives involved with some aspect of the research project’s design, approval or conduct. This includes members of community research boards (or alike) involved with community-level review and approval of research. Participants are purposively identified, through their existing involvement with the research project.

Participating sites nominate a staff member to facilitate engagement with this process evaluation. This staff member distributes the study information sheet and consent forms to potential participants (refer to online supplementary files 1 and 2). Potential participants will be invited to meet with the interviewer to show interest in participating sites and local references) will be removed from transcripts. To ensure access to SEWB support is available if required, referral information on local services is provided to participants. We identified the potential risk of interview staff working on the research project experiencing vicarious trauma. We provide resources on vicarious trauma to participants. Reimbursement (store voucher) for the time and costs associated with participation is available to participants, as determined by each participating site. Approval for this process evaluation is obtained from each participating site.

**Ethical considerations**

Each participating site’s nominated staff member makes initial contact with potential participants. This ensure participants can consider risks and benefits of participation and do not feel obliged to take part. Identifying information (including names of individuals, participating sites and local references) will be removed from transcripts. To ensure access to SEWB support is available if required, referral information on local services is provided to participants. We identified the potential risk of interview staff working on the research project experiencing vicarious trauma. We provide resources on vicarious trauma to participants. Reimbursement (store voucher) for the time and costs associated with participation is available to participants, as determined by each participating site. Approval for this process evaluation is obtained from each participating site.

Ethical approval for this process evaluation has been provided by the following committees: The University of Sydney Human Research Ethics Committee (2014/361), Aboriginal Health and Medical Research Council of NSW (1044/14), ACT Health HREC (ETH.8.14.207), Queensland Health Metro South HREC (HREC/14/QPAH/503), Central Australian HREC (HREC-15–287), Menzies School of Health Research (2014–2289), Aboriginal Health Council of South Australia (04-17-705) and Western Australian Aboriginal Health Ethics Committee (607).

**Dissemination of results**

A manuscript will be submitted for publication in an academic journal. The final manuscript will be approved by the Group prior to submission. Findings relevant to the aPHQ-9 will be presented to the research project’s Steering Committee for consideration during the interpretation of research results.

**DISCUSSION**

Understanding the contexts that surround and shape the way mechanisms can facilitate successful research is important to ensure research is acceptable to communities and results in health gains. Understanding how, why and for whom strategies work (or do not work) is key when translating research into practice, especially in complex and diverse settings with multiple competing priorities. In this evaluation, we aim to address these issues by exploring and documenting the experiences of PHC staff and community representatives involved with a complex national SEWB research project focused on Indigenous people.

The importance of involving community representatives with research is well established, however, systematic reporting of how this is completed not yet commonplace. This is demonstrated by a recent review project relates to the *Values and Ethics guideline* has been previously published.

**How this process evaluation addresses the Values and Ethics guideline**

**Box** demonstrates how the methods and approach used in this process evaluation address the *Values and Ethics guideline*. Further information on how the research
Box  Demonstration of how the principles of reciprocity, respect, equality, responsibility, ‘survival and protection’, and ‘spirit and integrity’ are considered in the Getting it Right process evaluation

**Reciprocity**
- Getting it Right was initiated following the Men, Hearts and Mind study. This responds to community-identified need for social and emotional well-being strategies.
- Process evaluation follows discussions with primary healthcare staff about their preferences surrounding research conduct. This provides the opportunity for formal feedback to researchers and may enhance capacity by informing improved planning of future research.
- Process evaluation aims to evaluate research processes. This may contribute to the advancement of the health and well-being of communities by providing useful information on effective and appropriate research processes.
- It is anticipated that members of the Group may develop new connections and skills through involvement with this evaluation. This may enhance capacity beyond this research.
- The Group’s processes facilitate reciprocal learning between non-Indigenous and Aboriginal and Torres Strait Islander researchers.
- Option to provide participants with reimbursement (store voucher) for their input. This acknowledges participants’ contributions.
- Flexibility around interview timing and location. Option for individual or small group interviews. This demonstrates willingness to modify research processes according to communities’ values and aspirations.

**Respect**
- The Group was established to guide the evaluation’s planning, conduct, analysis and reporting. This incorporates local knowledge and experience.
- Each participating site has the option to nominate a representative to be on the Group. This acknowledges the diversity of communities.
- Members of the Group are authors on research publications. This acknowledges the contribution of individuals and the expertise they provide.
- Publication plan includes input from participating site via the Group. Results will be presented to the Group, and proposed publications discussed including risks and benefits. This process incorporates Aboriginal and Torres Strait Islander knowledge and experience.
- Processes established around data management and publication. This will protect participants and communities’ identities.
- Approval for evaluation gained from community research boards (or alike) and ongoing information is provided, as required. This demonstrates community satisfaction with research.

**Equality**
- Each participating site has the opportunity to nominate a representative to be on Group. This demonstrates equality between individuals, communities and researchers.
- A commitment to list all members of the Group on the main publication, if they wish to have their contribution acknowledged in this format. This demonstrates equality between researchers.
- Opportunity for all members of the Group to contribute to all aspects of the study, as determined by each member. This demonstrates equality between researchers.
- Research documents use clear concise language. Local processes or documents used (where developed). Researchers attend community research board meetings (when requested). This demonstrates intention to ensure understanding of research by individuals and communities.
- Participant information sheet and consent forms with clear usable language. This demonstrates the intention to ensure understanding of research by individuals and communities.

**Responsibility**
- Ethics approval obtained from eight Human Research Ethics Committees, including three Aboriginal and Torres Strait Islander committees. This demonstrates transparency by researchers and a commitment to ensure research is conducted ethically, the methodologies are appropriate and the research has benefit for people and communities.
- This manuscript has been reviewed and approved by an Aboriginal and Torres Strait Islander committee. This demonstrates transparency by researchers and a commitment to ensure research is conducted ethically, the methodologies are appropriate and the research has benefit for people and communities.
- The purpose, methods, conduct, and planned dissemination of results and potential outcomes/benefits of research outlined in an approved study protocol. Publication of the study protocol demonstrates agreements and transparency by researchers.
- Participants are provided with resources on social and emotional well-being and referral information. This demonstrates responsibility by researchers to ensure participants have access to confidential support, if required.
- Option to reimburse participants (store voucher) for the time and costs associated with participation. This demonstrates responsibility by reducing potential for harm to participants.
- A publication plan that involves joint sign off for publication and the protection of individual and community identity.
- The Group provides mechanism for representatives to guide feedback of findings to communities.
- The Group provides mechanism for ongoing community review of this evaluation.

**Survival and protection**
- Opportunity/intention for members of the Group to participate in data collection through joint completion of interviews. This may protect against discrimination of individuals and cultures.
- Guidance to non-Indigenous researcher provided by researchers in the Group. This reduces threats to cultural distinctiveness.
- Input from community representatives on Group reduces threats to cultural distinctiveness.

Continued
of child health research, which found reporting of if or how involvement was achieved in only 28.6% of the 217 studies included. By describing our research partnership which involves community representatives and external researchers, this paper contributes to the literature in this area.

The need for high-quality research to influence gains in health outcomes among Indigenous peoples is well recognised. Authors of a recent review focused on adolescent health research called for particular attention for SEWB research focused on Indigenous adolescents, due to the lack of evidence in this area. However, there appears to be challenges associated with conducting this research, including identifying Indigenous research staff, recruiting participants and resourcing. This research project will provide much needed SEWB evidence. This process evaluation will describe how the research project was conducted and the experiences of the PHC representatives involved. In this protocol, we describe our partnership established to conduct this evaluation and identify some actions relevant to the Values and Ethics guideline.

The overlapping roles of some members of the research team are a strength and weakness of this evaluation. These dual roles provide an in-depth understanding of the research project, which may enhance data collection, analysis and provide substantial opportunity for verification. However, these roles have the potential to bias data collection and interpretation. The position of the project manager as the main interviewer and the existing relationships may influence the responses provided by participants. We have attempted to identify some key areas where this evaluation addresses the Values and Ethics guideline. We acknowledge this is not a comprehensive list and that overlap between values occurs. We recognise that the diversity among Aboriginal and Torres Strait Islander communities means that our findings may not be relevant to other communities.

CONCLUSION

We are conducting a process evaluation of a large, complex research project focused on the SEWB Indigenous people and conducted at 10 PHC services around Australia. We are exploring the experiences of the PHC staff and community representatives involved with the research project at the participating sites, including their perceptions about how the aPHQ could be implemented into practice. We have established an Aboriginal and Torres Strait Islander Advisory Group to guide this work. We publish this protocol to contribute to the literature and to inform planning of research with Indigenous people, with regard to the Values and Ethics guideline.

Acknowledgements

We gratefully acknowledge the contributions of participants and the PHC representatives in their partnering communities. We also thank our Advisory Group and the PHC representatives involved in the conduct of this research. We acknowledge the international and local expertise involved in the conduct of this research. This research was supported by the Australian Government Department of Health and the Australian Government Department of Education, Skills and Employment.

Financial support

The study was funded by the Australian Government Department of Health and the Australian Government Department of Education, Skills and Employment. The funding body had no role in the design, conduct, analysis or reporting of this study.

Competing interests

None declared.

Ethics approval

The University of Sydney Human Research Ethics Committee (2014/361), Aboriginal Health and Medical Research Council of NSW (1044/14), ACT Health HREC (ETH.8.14.207), Queensland Health Metro South HREC (HREC/14/QPAH/503), Central Australian HREC (HREC-15-287), Menzies School of Health Research (2014-2289), Aboriginal Health Council of South Australia (104-17-705) and Western Australian Aboriginal Health Ethics Committee (607).

Provenance and peer review

Not commissioned; externally peer reviewed.

Open Access

This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially.
and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.
© Article author(s) (or their employer(s) unless otherwise stated in the text of the article) 2017. All rights reserved. No commercial use is permitted unless otherwise expressly granted.

REFERENCES
Process evaluation of a primary healthcare validation study of a culturally adapted depression screening tool for use by Aboriginal and Torres Strait Islander people: study protocol

Sara Farnbach, John Evans, Anne-Marie Eades, Graham Gee, Jamie Fernando, Belinda Hammond, Matty Simms, Karrina DeMasi and Maree Hackett

BMJ Open 2017 7:
doi: 10.1136/bmjopen-2017-017612

Updated information and services can be found at:
http://bmjopen.bmj.com/content/7/11/e017612

These include:

References
This article cites 22 articles, 4 of which you can access for free at:
http://bmjopen.bmj.com/content/7/11/e017612#BIBL

Open Access
This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/

Email alerting service
Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Topic Collections
Articles on similar topics can be found in the following collections

Qualitative research (720)

Notes

To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/
7.3.1 Data collection and analysis

The following data were used in the process evaluation:

1. Qualitative data from PHC staff interviews (including community members).

2. Participant feedback about the aPHQ-9 and their experiences with the research project entered onto CRFs by patients or the interviewing staff immediately after completing the first research interview.

3. Study administrative data (participant screening logs, communication logs, training logs, site activation reports, communication logs, training manuals, ethics documentation, protocol deviation logs, ethics amendments and budget tracking documents).

4. Getting it Right results presented in Chapter 4 (demographic data and sensitivity and specificity analysis to determine the performance of the aPHQ-9 as a depression screening tool).

The timeframes for staff interview data collection and analysis are presented in Table 7.1. Data from points 2 to 4 above were collected during the planning and conduct of the research project between February 2014 and November 2016.
### Table 7.1  Collection and analysis of qualitative interview data from staff interviews during the Getting it Right process evaluation

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Purpose</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Qualitative interview planning</strong></td>
<td>Develop interview guide. Reviewed by Advisory Group (V1)*</td>
<td>Guide without predetermined ideas, gain insight and cultural input</td>
<td>Jan to Mar 2016</td>
</tr>
<tr>
<td><strong>Qualitative interviews – iterative data collection and analysis</strong></td>
<td>Interview stage 1: 13 interviews</td>
<td>Open questioning allows new ideas to develop</td>
<td>Nov to Dec 2016</td>
</tr>
<tr>
<td></td>
<td>Transcripts coded (open and focused) and developed into coding framework (SF)</td>
<td>Open codes identify new ideas. Prevalent and important ideas are developed into focused codes</td>
<td>Dec 2016 to Jan 2017</td>
</tr>
<tr>
<td></td>
<td>4 transcripts double-coded</td>
<td>Compare codes, gain insights and cultural input</td>
<td>Dec 2016 to Jan 2017</td>
</tr>
<tr>
<td></td>
<td>AG reviews summary of interviews/codes</td>
<td>Gain insight and cultural input from multiple perspectives</td>
<td>Feb 2017</td>
</tr>
<tr>
<td></td>
<td>Revise interview guide (V2)* based on analysis and feedback</td>
<td>Interviews are guided by developing themes and feedback</td>
<td>Feb 2017</td>
</tr>
<tr>
<td></td>
<td>Interview stage 2: 12 interviews</td>
<td>Interviews are guided by developing themes and feedback from independent coders and AG</td>
<td>Mar to Apr 2017</td>
</tr>
<tr>
<td></td>
<td>Steps 2-6 repeated using revised guide (V2)*</td>
<td>Interviews are guided by developing themes and feedback from independent coders and AG</td>
<td>Apr to Jul 2017</td>
</tr>
<tr>
<td></td>
<td>3 transcripts double-coded</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Interview stage 3: 11 interviews and 1 community member interview (4 participants)</td>
<td>Interviews are guided by developing themes and feedback from independent coders and AG</td>
<td>Aug to Oct 2017</td>
</tr>
<tr>
<td></td>
<td>Steps 2-6 repeated using revised guide (V3)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 transcripts double-coded</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Developing the PE framework</strong></td>
<td>Re-analyse data using focused codes. Identify themes and subthemes</td>
<td>Sort, synthesise and integrate data</td>
<td>Aug to Oct 2017</td>
</tr>
<tr>
<td></td>
<td>Synthesise data into draft PE framework</td>
<td>Interpret findings to respond to PE questions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Discuss PE framework with second coders</td>
<td>Gain insights and cultural input</td>
<td>Aug to Oct 2017</td>
</tr>
<tr>
<td></td>
<td>AG reviews summary of interviews/codes</td>
<td>Gain insight and cultural input from multiple perspectives</td>
<td>Aug 2017</td>
</tr>
</tbody>
</table>

Abbreviations: AG – Indigenous Advisory Group; PE – process evaluation; SF – Sara Farnbach; V – version * Interview guides available in Appendix 15
7.3.2 Approach to the process evaluation

The protocol described three approaches (grounded theory, MRC Guideline approach and realist evaluation) that have similarities, strengths and weaknesses when considering their use during the process evaluation (Table 7.2). In brief, all can use iterative processes where data is collected (staff qualitative interview data), analysed (coded) and used to update subsequent interview guides based on the themes as they develop. This process allowed relevant themes to be explored as they are developed. Triangulating PHC staff perspectives (qualitative interview data) with a range of administrative data (screening logs, communication logs, ethics documentation) and feedback from participants about the aPHQ-9 will provide a greater understanding of the context, impact and consequences of Getting it Right compared to analysing qualitative data alone.

The MRC guidance and realist approaches were not directly applicable to the Getting it Right process evaluation because they were processes designed to understand behaviour change resulting from the implementation of complex interventions, often in a randomised controlled trial setting (usually a health program where a resource is provided that requires a response, such as a pamphlet/education). The Getting it Right study determined the validity of a depression screening tool, and was not a ‘complex intervention’. There was no intent to change behaviour beyond short-term changes required to implement the study protocol.

The theoretical underpinnings of these approaches were also different. Grounded theory was aimed to generate new theory and hypotheses; while other approaches drew on existing theories to test and understand the functionality and mechanisms of behaviour change related to a complex intervention.

To guide the process evaluation, I developed a framework that drew on relevant elements of these approaches (Appendix 17).
Table 7.2  Summary of similarities, strengths, weaknesses of methods considered for the conduct of the *Getting it Right* process evaluation

<table>
<thead>
<tr>
<th></th>
<th>Grounded theory&lt;sup&gt;153&lt;/sup&gt;</th>
<th>MRC Guideline&lt;sup&gt;151&lt;/sup&gt;</th>
<th>Realist evaluation&lt;sup&gt;152&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td>To inductively generate theories regarding social phenomena</td>
<td>To understand the functioning of a complex intervention,* by examining implementation, mechanisms of impact, and contextual factors</td>
<td>To understand what works, for whom, in what respects, to what extent, in what contexts, and why? Explores mechanisms for behavioural change involved with complex interventions&lt;sup&gt;^&lt;/sup&gt;</td>
</tr>
<tr>
<td>Iterative data</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>collection and</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>analysis processes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uses qualitative and</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>quantitative data</td>
<td></td>
<td></td>
<td>Method neutral</td>
</tr>
<tr>
<td>Method explores</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>context and</td>
<td>Uses the paradigm model which aims to identify conditions under which a phenomena occurs; the relevant contextual factors; and actions arising from; interactions to and the consequences of the phenomena</td>
<td>Uses the process evaluation framework to evaluate implementation, mechanisms of impact, and context surrounding a complex intervention&lt;sup&gt;*&lt;/sup&gt;</td>
<td>Uses context-mechanism-outcome configurations to provide theoretical explanations about what works, for whom and why, with regard to a complex intervention&lt;sup&gt;^&lt;/sup&gt;</td>
</tr>
<tr>
<td>mechanisms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approach to</td>
<td>Does not use existing theories</td>
<td>Uses theory to understand causal assumptions underpinning complex interventions and how actions will produce change</td>
<td>Theory-driven approach to identify and tests theories (mechanisms) that explain responses to the complex interventions.&lt;sup&gt;^&lt;/sup&gt; Begins and ends with theory</td>
</tr>
<tr>
<td>existing theory</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strength for process evaluation</td>
<td>Grounded theory</td>
<td>MRC Guideline</td>
<td>Realist evaluation</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>----------------</td>
<td>---------------</td>
<td>-------------------</td>
</tr>
<tr>
<td></td>
<td>Identifies new ideas/theories</td>
<td>Provides a framework to evaluate the research conduct</td>
<td>Explores context and mechanisms that underlie a complex intervention^&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Useful to explore processes</td>
<td>Aims to understand pathways/mechanisms of change</td>
<td>Can be used to construct middle-range theories (that integrate theory with empirical research)&lt;sup&gt;155&lt;/sup&gt; which can be used to demonstrate lessons learnt from complex intervention. This may be a useful approach to share lessons with other research teams</td>
</tr>
<tr>
<td></td>
<td>Useful when there is little existing evidence in a research area</td>
<td>Uses iterative data collection and analysis processes</td>
<td>Can be used with MRC guidance</td>
</tr>
<tr>
<td></td>
<td>Uses iterative data collection and analysis processes</td>
<td></td>
<td>Uses iterative data collection and analysis processes</td>
</tr>
</tbody>
</table>

| Weakness for process evaluation | Limited application as an evaluative method | Evaluates complex interventions that produce change. The process evaluation aims to evaluate the conduct of the research project (short-term), and does not aim to produce change. | Explores mechanisms of behavioural change from complex interventions<sup>6</sup>. The process evaluation aims to evaluate the conduct of the research project (short-term), and does not aim to produce change. |
|                                |                                                    | Uses existing theory to understand causal assumptions underpinning interventions, conflicting with the aim to report staff perspectives as they are presented | Theory-driven approach conflicts with our aim to present staff perspectives as they are reported |

| Use in process evaluation      | Uses grounded theory approaches for data collection and analysis | Process evaluation framework draws on the MRC framework to evaluate what worked or did not work? | Process evaluation framework draws on realist approaches by recognising that under different contexts, the research project may work (or not) differently for different people |

Abbreviations: MRC – Medical Research Council

Key: ✓ indicates method includes specified aim or process

* Defined as an intervention with multiple complex components (such as changing difficult behaviours or facilitating change across multiple levels within an organisation) which interact to produce change.

^Defined as program that provides a resource and requires a reasoned response of the participants to that resource.

Note: This table is not an exhaustive analysis of all components of these methods.
7.4 Results (publication)
Process evaluation of Getting it Right: the acceptability and feasibility of a culturally-adapted depression screening tool for use by Aboriginal and Torres Strait Islander people

OVERVIEW OF PUBLICATION

This publication summarises the results from Aim 1 of the process evaluation. It explores the experiences of PHC staff and patients with the aPHQ-9 to identify its acceptability and feasibility as a depression screening tool for use by Indigenous people. Submission of this publication has been withheld until the Getting it Right main results paper has been finalised, submitted and accepted for publication.
Process evaluation of *Getting it Right*: the acceptability and feasibility of a culturally-adapted depression screening tool for use by Aboriginal and Torres Strait Islander people

Sara Farnbach\textsuperscript{a}, Graham Gee\textsuperscript{b}, Anne-Marie Eades\textsuperscript{a}, John Evans\textsuperscript{c}, Jamie Fernando\textsuperscript{d}, Belinda Hammond\textsuperscript{e}, Matty Simms\textsuperscript{f}, Karrina DeMasi\textsuperscript{g}, Nick Glozier\textsuperscript{h}, Alex Brown\textsuperscript{i}, Maree Hackett\textsuperscript{j} on behalf of the *Getting it Right* Investigators

\textsuperscript{a} The George Institute for Global Health, PO Box M201, Missenden Road, Camperdown, New South Wales, 2050, Australia, University of New South Wales, Sydney 2052, Australia and The University of Sydney, New South Wales, 2006, Australia
\textsuperscript{b} Victorian Aboriginal Health Service, Victoria, 3065, Australia and University of Melbourne, Victoria 3000, Australia
\textsuperscript{c} The University of Technology and The University of Sydney, New South Wales, 2006, Australia
\textsuperscript{d} The University of Newcastle, New South Wales, 2308, Australia
\textsuperscript{e} Nunkuwarrin Yunti of South Australia, South Australia, 5000, Australia
\textsuperscript{f} The Glen Centre (Ngampie), New South Wales, 2261, Australia
\textsuperscript{g} Aboriginal Medical Services Alliance Northern Territory, 0801, Australia
\textsuperscript{h} Brain and Mind Centre and Central Clinical School University of Sydney, New South Wales 2052, Australia
\textsuperscript{i} South Australian Health and Medical Research Institute, Adelaide, Australia
\textsuperscript{j} The University of Central Lancashire, PR1 2HE, United Kingdom

*Corresponding author email: sfarnbach@georgeinstitute.org.au

7.4.1 Abstract

**Objective and importance of the study**

*Getting it Right* (N=500) was a study to determine the validity of the culturally-adapted Patient Health Questionnaire-9 (aPHQ-9) for use by Aboriginal and Torres Strait Islander people. The aim of this process evaluation was to determine whether the aPHQ-9 was considered acceptable and feasible to use in primary healthcare, by staff and participants.

**Study type**

Process evaluation using grounded theory approaches.
Method
We triangulated thematically analysed data from qualitative semi-structured interviews with staff from primary healthcare services involved with Getting it Right with participant feedback (responses to questions about the aPHQ-9 and free-text feedback collected during the study) and interviewer field notes.

Results
Primary healthcare staff (n=36) and community members (n=4) from nine of the 10 participating primary healthcare services completed interviews. All Getting it Right research participants answered at least six of the seven feedback questions and 20% provided qualitative feedback. Most staff said they would use the aPHQ-9 during conversations with patients, and most participants said that the questions were easy to understand (87%), response categories made sense (89%) and they felt comfortable answering the questions (91%).

Discussion
Staff and participants indicated that they would consider using the aPHQ-9 beyond the research project.

Conclusion
The aPHQ-9, being the first culturally-adapted, nationally-validated, freely-available depression screening tool for use by Indigenous people, was considered by staff and primary healthcare patients to be acceptable and feasible to use.

Key words
Aboriginal and Torres Strait Islander; primary healthcare; depression screening; social and emotional wellbeing; process evaluation

Key points
1. The aPHQ-9 was considered acceptable and practical for use by primary healthcare staff and research participants.
2. The feedback provided by Indigenous research participants demonstrated that they valued their contribution to the research and had a genuine desire to improve the aPHQ-9.

7.4.2 Introduction

Depression is a leading cause of the global burden of disease, resulting in calls for an increased focus on prioritising public health efforts to reduce this burden.\textsuperscript{156} In Australia, an estimated 6.2\% of the population have experienced depression or another affective disorder during the previous 12 months,\textsuperscript{157} and Aboriginal and Torres Strait Islander people (Indigenous peoples) are nearly three times as likely to experience high or very high levels of psychological distress, compared to non-indigenous Australians.\textsuperscript{30} The true prevalence rates and burden of depression among Indigenous communities remain unclear, in part because the measure used to capture these data\textsuperscript{30} measure of ‘psychological distress’\textsuperscript{158} was developed around Western concepts of mental health that did not incorporate Indigenous definitions of social and emotional wellbeing.\textsuperscript{12} Previous works have identified low rates of screening for depression and other social and emotional wellbeing problems (mean screening rate of 26.6\%) in Indigenous-focused primary healthcare (PHC) services, limiting opportunities to identify and treat depression.\textsuperscript{29} There is a small body of research\textsuperscript{2, 31, 91, 105} that has aimed to adapt and validate culturally-appropriate tools for detecting depression among Indigenous peoples, however, to the best of our knowledge, these tools have not been validated outside the Indigenous communities where they were developed.

We designed the Getting it Right: the validation study\textsuperscript{113} (hereafter Getting it Right) to determine the validity of the culturally-adapted Patient Health Questionnaire-9 (aPHQ-9)\textsuperscript{31, 111} as a depression screening tool to be used by Indigenous people. Getting it Right was conducted in 10 Indigenous-focused PHC services (participating services) nationally between 2014 and 2016. Results from Getting it Right indicated that when used with a cut point of 10 (as per the original PHQ-9 algorithm) the aPHQ-9 has a sensitivity of 84\% (95\% CI 74 to 91\%) and specificity of 77\% (95\% CI 71 to 83\%). In order for the aPHQ-9 to be recommended for use, we conducted a process evaluation to explore PHC staff and research participant perspectives about using the tool during Getting it Right research interviews.
7.4.2.1 Aim

To explore PHC staff and research participant perspectives of the perceived acceptability and feasibility of the aPHQ-9.

7.4.3 Methods

The methods of Getting it Right and its process evaluation have been described previously. In brief, participating services nominated staff to recruit participants to the research and complete an interview using the aPHQ-9 and a second interview with another staff member using the semi-structured MINI International Neuropsychiatric Interview 6.0.0 (MINI). After the aPHQ-9 interview, all participants were asked to provide feedback through explicit questions about their perceptions of the aPHQ-9 and additional seven questions; experiences answering the aPHQ-9 questions (number of questions, questions easy to answer, easy to understand, the response categories made sense, had time to answer the questions, felt comfortable answering the questions) and to provide free-text feedback about their viewpoints of Getting it Right in general. They provided feedback on the aPHQ-9, as well as an additional seven questions that were identified as potentially relevant for detecting depression during in-depth qualitative research. The additional questions did not contribute significantly to the aPHQ-9, and in-depth exploration of the value of the additional seven questions will be covered in a separate publication. The additional of one or more questions were not recommended for use during depression screening (Section 4.6.2).

After the Getting it Right recruitment process was completed (before results were available) and once approvals from participating services and ethics committees were received, the process evaluation was conducted. The staff member coordinating the research at each participating service approached staff and community members (purposive identification), inviting them to complete qualitative semi-structured grounded theory interviews. Process evaluation interviews were conducted by SF between November 2016 and June 2017 in a confidential setting, in-person at participating services or via the phone. SF is a female registered nurse and PhD candidate who has completed training in qualitative data collection, analysis and reporting. As the PM of Getting it Right, she had formed existing relationships with staff and community members for a period of one to three years.
Process evaluation interviews with staff were conducted using an interview guide in three phases. SF and AME piloted the first interview guide. Interviews involved questions about staff experiences with *Getting it Right* and using the aPHQ-9 during research interviews. Staff interviews were recorded and transcribed verbatim. NVivo 10 for Windows software was used to manage data. Independent double coding of 10 (25%) interviews was completed by two co-authors (GG and AME) and all authors were provided with reports of the interviews. A record of codes, their properties, interpretations, and feedback from authors were kept in memos, which were analysed and grouped into themes and integrated into subsequent interview guides (three interview guides were developed). Process evaluation interviews continued until all willing potential staff or community members took part.

The qualitative data from staff interviews were triangulated with participant feedback and field notes taken by SF. To address our aim, we examined the process evaluation data to identify the perspectives of staff and participants about the acceptability and feasibility of the aPHQ-9.

For the purpose of this paper, we define ‘patient’ as an individual using PHC services in general or before an individual consented to participate in *Getting it Right*, and ‘participant’ is described as any patient who provided informed consent to participate in *Getting it Right*. This process evaluation was conceived, designed and conducted according to the Values and Ethics Guideline. Ethical approval details are available in the published study protocol.

### 7.4.4 Results

Process evaluation interviews were completed with four community members (a group interview) and 36 staff (34 individually and two as a group interview) including managers (n=10), Aboriginal Health Workers (AHW) (n=9), Allied Health Staff (n=8), research coordinators (n=5) and general practitioners (GPs) (n=4) from nine of the 10 participating services. Substantial staff turnover and organisational changes occurred at the tenth participating service after *Getting it Right*, therefore, it chose not to take part in the process evaluation. Open coding did not identify any new codes in the final two
interviews, indicating data saturation. Participant demographic information is presented in Table 7.3.

### Table 7.3 Demographic information for staff and community members who completed qualitative interviews

<table>
<thead>
<tr>
<th>Staff characteristics</th>
<th>N=36</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>24</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Indigenous</td>
<td>17</td>
</tr>
<tr>
<td><strong>Years working at participating health service</strong></td>
<td></td>
</tr>
<tr>
<td>Less than one year</td>
<td>0</td>
</tr>
<tr>
<td>1-2 years</td>
<td>11</td>
</tr>
<tr>
<td>2-3 years</td>
<td>2</td>
</tr>
<tr>
<td>3-4 years</td>
<td>6</td>
</tr>
<tr>
<td>5+ years</td>
<td>13</td>
</tr>
<tr>
<td>Data unavailable</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Community members’ characteristics</th>
<th>N=4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>2</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Indigenous</td>
<td>4</td>
</tr>
</tbody>
</table>

Five hundred people participated in *Getting it Right* and completed two research interviews. All participants answered at least six of the seven feedback questions. Seven feedback questions were missing answers. Approximately 20% of participants provided free-text feedback, which mostly related to the additional seven questions to the aPHQ-9 (in-depth analyses of these seven questions are outside the confines of this thesis) or to the ‘difficulties question’ (to determine symptom-related difficulty) which includes unmodified wording from the original PHQ-9.

### 7.4.4.1 PHC staff and participant views about the acceptability and feasibility of the aPHQ-9

Over half the staff who completed process evaluation interviews reported that they would use the aPHQ-9 when speaking to patients about their social and emotional wellbeing. Many reported that participants responded well to the aPHQ-9 because it used ‘simple’ or clear language:
They [participants] thought that the aPHQ-9 was better – the ones that mentioned it – and I didn’t ask them mostly; they would offer that information. They did say it is a lot easier to understand. (Aboriginal Health Worker, male, Indigenous, site D, #17)

In response to acceptability and feasibility questions in the case report forms, participants reported: (i) being comfortable with the number of questions asked (90%); (ii) questions were easy to understand (87%); (iii) questions were easy to answer (82%); (iv) response categories made sense (89%); (v) feeling comfortable answering the questions (91%); (vi) there was sufficient time to answer the questions (98%); and (vii) they were comfortable with what was asked (86%). These results are available in Table 4.8 (Chapter 4).

Four staff and one participant reported that the term ‘spirit’ was not used in their community or that it was not relevant when used in the following aPHQ-9 question: ‘Have you been feeling unhappy, depressed, really no good, that your spirit was sad?’ and the additional question: ‘Have you felt that your spirit was weak?’ Conversely, one participant reported:

Love[d] the way is asked with the word SPIRIT. (Indigenous participant, male, 55 years)

Eight participants recommended adding questions to the aPHQ-9 and five recommended including a comment box for participants to provide additional information if required. With regard to response category options ('none, a little bit, most of the time, all of the time'), two participants recommended including more options, while another two recommended limiting options to ‘yes/no’ answers. Some staff reported that the response categories used appropriate phrasing; others reported that there were too many options and suggested limiting response options to ‘yes/no’ only:

Because [the multiple options] gives them the option of saying, ‘well, look, sometimes …’ (Manager, Indigenous, site F, #24)

7.4.5 Discussion

Overall, the process evaluation showed that the aPHQ-9 was well accepted by PHC staff and participants, and was considered feasible to use. Although some participants
reported that they did not want to answer the aPHQ-9 and additional questions because they were too personal (5%), most were ‘comfortable’ or ‘ok’ (98%) answering all or most of the questions. This indicates that the aPHQ-9 was acceptable to most participants. We suggested that clinicians be encouraged to screen for depression when appropriately skilled, and for them to have access to assessment and treatment options to refer their patients to if depression risk is identified.

Feedback from staff and participants about the term ‘spirit’ was mixed. In the aPHQ-9 development work completed in central Australia\textsuperscript{31,111} and subsequent work,\textsuperscript{110} ‘spirit’ was identified as a central concept to physical, emotional and spiritual wellbeing and was considered the most appropriate term to use to replace ‘hopelessness’, which provided significant conceptual, linguistic and translational difficulties.\textsuperscript{111} Our results suggested that ‘spirit’ may be understood differently across contemporary Indigenous cultures. Reduced connections with spiritual practices may be a consequence of the dislocation from traditional systems, rituals and ceremonies that is caused by colonisation.\textsuperscript{12} Previous authors have suggested that in modern day Indigenous cultures, people may experience spiritually in different ways.\textsuperscript{161} Further qualitative research is needed to explore how the concept of spirit relates to depression across cultural groups. We suggested that the aPHQ-9 question where ‘spirit’ appears also includes the concepts of ‘feeling unhappy, depressed or really no good’ as options that relate to depression.

To the best of our knowledge, this is the first process evaluation of a large PHC-based Indigenous depression research project. The completeness of participant feedback provides valuable insight into participants’ perspectives of the aPHQ-9 and Getting it Right. Our findings indicate that participants understood the aims of the research, valued their contribution to the research, and were motivated to provide information that would help to further enhance the aPHQ-9.

A strength of the process evaluation was the in-depth knowledge of the study and its process of the authors who were staff (JF, BH, MS and KD), investigators (MH and GG) and the project manager (SF) on Getting it Right. However, we also acknowledge that our varying roles could produce different biases, such as potentially influencing staff responses about their experiences using the aPHQ-9 and how data were
interpreted. With this in mind, a particular focus has been given to themes that indicate potential problems using the aPHQ-9. An alternative to this approach could have been to use a person completely independent of *Getting it Right* to conduct the process evaluation. This would introduce different challenges relating to the lack of knowledge of *Getting it Right*, and long lead times in developing relationships with staff sufficient for them to agree to participant in in-depth interviews about their research practices.

Further information about patient perspectives may be gained from speaking directly with patients, such as during process evaluation interviews. However, these would need to be conducted immediately after participants completed the aPHQ-9 and before the MINI, and would have added significant burden for participants. In addition, the large number of patients involved with this research meant it was beyond the scope of the process evaluation, therefore, we sought written feedback instead.

In-depth prospectively planned evaluations of research projects provide insight from the perspectives of PHC staff and patients on tools that were under investigation during the research, providing important information when planning PHC service delivery that is acceptable and feasible. This contribution to the evidence base on ethical and acceptable PHC service delivery facilitated an environment where research could contribute to culturally-appropriate PHC and importantly, aligned with the Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.7

7.4.6 Acknowledgements

We would like to acknowledge all participating services and participants of *Getting it Right: the validation study* and this process evaluation for their contribution to this work. We also acknowledge the investigators of the research project: Maree Hackett, Armando Teixeira-Pinto, Nick Glozier, Timothy Skinner, Deborah Askew, Graham Gee, Alan Cass and Alex Brown.

7.5 Additional (unpublished) results from the process evaluation

Additional analyses were completed during the process evaluation that are relevant to Aims 2, 3 and 4 but were not included in the publication. Some themes identified during
data analysis confirm what is already known and mentioned, but are not elaborated on (indicated by red text), while other themes identify novel ideas or provide new insights, as presented in Chapters 8 and 9 (indicated by blue text). The remaining themes are in green text and are briefly described below for completeness.

7.5.1 Staff perceptions about the conduct of Getting it Right according to the study protocol

Most staff reported that they conducted the research according to the study protocol (Table 7.5). A few staff told stories that may have indicated some areas where the research was not conducted in accordance with the study protocol, namely, participant recruitment.

| Theme related to the conduct of Getting it Right | Conducting the research according to the protocol | Non-consecutive recruitment approaches used |

Conducting the research according to the protocol

Most staff reported their perception that the research was conducted according to the study protocol at their service, that is, recruitment processes, data entry and safety follow-up processes were aligned with the study protocol.

Non-consecutive recruitment approaches

Staff from seven participating services who completed process evaluation interviews described using consecutive recruitment processes, as outlined in the study protocol, while staff from two reported sometimes using non-consecutive approaches.

At one service, the manager reported that some staff chose not to speak to some patients for reasons unknown. At another service, staff reported speaking to patients whom they knew from previous interactions, believing their existing relationship meant these patients were more likely to participate:
I just talked to people I already had a relationship with … I found it was easier to recruit people who knew me and trusted me already rather than when I tried to recruit people in the clinic who I hadn’t met before, not many of them were agreeable. (Nurse, non-indigenous, site F)

According to the manager at this service, recruiting people whom they already knew led to honest conversations, which resulted in accurate research data. This manager reported that this approach was necessary to overcome the ‘hurdles’ they experienced in reaching their recruitment target of 50 participants:

Everyone’s [staff] on holidays and you’ve got four clients that need INRs [blood test] and you’re trying to validate [recruit participants] … sometimes research doesn’t take the priority … We just have to be able to be opportunistic. (Manager, Indigenous, site F)

A review of the Getting it Right participant data showed a spread in demographics and illness burden across participants and services (data not presented).

### 7.5.2 Contextual factors surrounding Getting it Right

Contextual themes were developed from staff interviews about external factors to Getting it Right that affected the conduct of the research by influencing staff and participant responses and the likelihood of them participating initially and while the research was underway. These were grouped into environmental, social, historical and cultural factors (Table 7.6) and data reviewed to identify these themes are available in Appendix 18.

<table>
<thead>
<tr>
<th>Type of factor</th>
<th>Contextual factors that affected Getting it Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment</td>
<td>Staff available to do research at participating services</td>
</tr>
<tr>
<td></td>
<td>High clinical demands</td>
</tr>
<tr>
<td></td>
<td>Physical environment</td>
</tr>
<tr>
<td>Social</td>
<td>Existing staff-patient relationships</td>
</tr>
<tr>
<td></td>
<td>Patient interest in research and topic</td>
</tr>
<tr>
<td></td>
<td>Staff interest in research topic</td>
</tr>
<tr>
<td></td>
<td>Staff enhancing skills and capacity through research</td>
</tr>
<tr>
<td>History</td>
<td>Negative experiences with research in the community</td>
</tr>
</tbody>
</table>
### Type of factor | Contextual factors that affected *Getting it Right*
---|---
Patients’ complex personal and medical history
Culture | Culture among staff (organisational culture)
Culture among patients (generated by usual activities completed by patients at the participating service)

#### Staff interest in research topic

Staff reported that their interest and the interest of other staff in the research topic affected their decision to becoming involved with the research initially and continuing to work on *Getting it Right* once it was underway. This was perceived as affecting *Getting it Right* by influencing staff motivation:

> I think that the health workers felt like they were contributing to something that was going to make a difference, and so the ones [staff] that really did step up had a red hot go. (Non-indigenous, female, manager, #18)

#### Patient personal and medical histories

Staff reported that patient personal and medical histories affected the research by influencing how patients responded when introduced to the research, which impacted on achieving recruitment targets. Some patients who were unwell were unwilling to participate and patients with complex medical histories were occasionally approached about the research multiple times. Analysis of the screening logs showed a participation rate of 55% with the majority of reasons for non-participation including: (i) no reason documented (68%); or (ii) ineligible (33%). Staff perceived that patient personal histories influenced their likelihood to participate because:

> People who were reluctant were suspicious that answering [the interview questions] was going to affect their lives, that the government would come and check them out because of their answers. (Indigenous, female, AHW, #28)

#### Culture among staff (organisational culture)

Many staff described their services as having a ‘research culture’ that contributed to the interest of staff becoming involved. Experience with other similar research studies also
made integrating the research interviews into existing workflows straightforward because it was a common practice.

Conversely, some staff reported that a culture of resistance to research among staff or a lack of a ‘buy in’ for the research from management existed. This limited internal support resulted in insufficient time allocated to staff to complete their research activities. One staff member cautioned that research should not be ‘pushed’ onto staff who are not interested in participating:

I think there were varying levels of engagement with research in a service like this. Some people in the health service, some of the clinicians, doctors and nurses, will be more open to research than others. (non-indigenous, male, GP, #9)

*Culture among patients (generated by usual activities completed by patients)*

Similarly, staff reported that the usual activities completed by patients when visiting a participating service generated a culture amongst its patients, which affected recruitment by influencing their willingness to participate. At one service where patients regularly held open group discussions about SEWB as part of its usual service activities, staff suggested that patients were willing to participate and answer questions openly because they were accustomed to speaking about SEWB.

They do a lot of group counselling sessions, so these men in particular are quite open and used to talking about their health and other issues, including emotional issues and their past. (Indigenous, male, GP, #35)
### 7.5.3 Impact and consequences of conducting *Getting it Right*

Table 7.7 Impact and consequences of conducting *Getting it Right* at participation services

<table>
<thead>
<tr>
<th>Major theme – staff</th>
<th>Sub-theme – staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensions between staff</td>
<td>From challenges in conducting research</td>
</tr>
<tr>
<td></td>
<td>From clashes between research projects</td>
</tr>
<tr>
<td>Considering involvement in future research</td>
<td>Positive experiences have changed our approach to research</td>
</tr>
<tr>
<td></td>
<td>Would not do research again</td>
</tr>
<tr>
<td>Identifying staff members with SEWB problems</td>
<td>During research interviews</td>
</tr>
<tr>
<td>Staff advocating for research participants</td>
<td>After research interviews</td>
</tr>
<tr>
<td>Staff considering the needs, risks, preferences for and impact of SEWB research participation for staff, patients and community</td>
<td>Perceiving a need for research</td>
</tr>
<tr>
<td></td>
<td>Feeling pressure to provide positive patient experiences, respond appropriately and because of their dual role as a researcher and community member</td>
</tr>
<tr>
<td></td>
<td>Assessing suitability of patients and staff for research</td>
</tr>
<tr>
<td></td>
<td>Being prepared to ask hard questions and respond to patients</td>
</tr>
<tr>
<td>Building staff confidence speaking to patients about research and SEWB problems</td>
<td>Enhancing skills speaking about research and depression</td>
</tr>
<tr>
<td></td>
<td>Enhancing staff-patient relationships</td>
</tr>
<tr>
<td></td>
<td>Perceiving positive outcomes</td>
</tr>
<tr>
<td>The influence of reimbursement on participating services and the research project</td>
<td>Managers considering research involvement</td>
</tr>
<tr>
<td></td>
<td>Allocating reimbursement within the organisation</td>
</tr>
<tr>
<td></td>
<td>Reimbursement impacting on research conduct</td>
</tr>
<tr>
<td>The influence of human resources on the research project at participating services</td>
<td>Human resource requirements for research</td>
</tr>
<tr>
<td></td>
<td>Research champion</td>
</tr>
<tr>
<td></td>
<td>Human resource challenges</td>
</tr>
<tr>
<td>The consequences of offering vouchers to participants on the research project</td>
<td>Achieving research targets</td>
</tr>
<tr>
<td></td>
<td>Patients benefiting from participation</td>
</tr>
<tr>
<td></td>
<td>Considering unintended negative consequences</td>
</tr>
<tr>
<td></td>
<td>Ambivalence towards providing vouchers</td>
</tr>
<tr>
<td>Building staff confidence speaking to patients about research and SEWB problems</td>
<td>Enhancing skills speaking about research and depression</td>
</tr>
<tr>
<td></td>
<td>Enhancing staff-patient relationships</td>
</tr>
<tr>
<td></td>
<td>Perceiving positive outcomes</td>
</tr>
<tr>
<td>Major theme – participants</td>
<td>Subtheme – participants</td>
</tr>
<tr>
<td>Patients considering the needs, risks, preferences and impact of research participation for community and themselves</td>
<td>Feeling comfortable</td>
</tr>
<tr>
<td></td>
<td>Perceiving a need</td>
</tr>
<tr>
<td></td>
<td>Having a connection</td>
</tr>
<tr>
<td></td>
<td>Declining to participate</td>
</tr>
</tbody>
</table>
**Tensions between staff**

Tensions were reported between some staff at three services when achieving recruitment targets was harder than anticipated. These staff reported speaking to other staff about making plans to recruit participants:

> Sometimes they [staff] got fed up with me, but you had to be visible for this study to continue and then get it done. (Non-Indigenous, female, research coordinator, #6)

At one participating service where two SEWB-related research projects were being conducted concurrently, a manager reported that the projects ‘clashed’ because some staff perceived that the projects were competing for participants and some were unwilling to recruit participants into *Getting it Right* (non-Indigenous, female, manager, interview 8).

**Considering involvement in future research**

Eight staff reported that they would consider becoming involved with research again. Of these, three reported that they would initially consider more carefully: (i) staff availability; (ii) feasibility of integrating research into their work; and (iii) the steps involved with the research, because these were the major challenges they faced during this research project. Staff preferences about the level of involvement with research varied, with some staff aiming to identify and develop their own research projects while others were willing to recruit patients and collect data for established research projects.

One manager stated that his positive experience with *Getting it Right* ‘changed our attitudes towards research’, and described having a ‘two-way’ relationship with the researchers, where he received benefit, such as reimbursement and skills development. Furthermore, the researchers recognised that research was not their core business through providing adequate time and reimbursement to conduct the project (Group interview: Indigenous and non-Indigenous, males, managers, #34). In future, they would seek similar opportunities.

Another manager perceived that the challenge to reach the recruitment target of 50 participants during *Getting it Right* may have caused some staff to be reluctant when considering future research. The challenges reported at this participating service
included: (i) identifying patients to participate; (ii) maintaining ongoing time commitments to the research; and (iii) following up participants within seven days.

**Identifying staff members with SEWB problems**

Managers at two participating services reported that some staff (who were also patients but not involved with *Getting it Right*) participated in *Getting it Right* and had SEWB problems identified during their research interviews. These managers had to consider how to respond appropriately while maintaining confidentiality of their staff.

**Staff advocating for research participants**

Some staff told stories about advocating for participants after hearing information that a participant shared during interviews and linking them with additional services or support. This AHW recalled accompanying a patient to an appointment with a GP after they had completed the second research interview:

> She was scared that the doctor was going to growl at her … So I went back to the doctor with her, sat through the consult … I said, okay, so let’s get things rolling. So I got her into counselling. I hooked her up with ‘Elders Group’, because she’s been here for a few years but don’t know anyone in the community. So I hooked her up with the Elders Group so she could meet people her age and a bit older and go into the socialising groups. Then from there, she got offered a part time job with them, which she was really happy about. (Indigenous, AHW, female, #5)

### 7.5.4 Enablers to conducting *Getting it Right*

Some staff identified specific approaches that enabled the research conduct. These are summarised in Table 7.8.

**Table 7.8 Enablers to conducting *Getting it Right***

<table>
<thead>
<tr>
<th>Theme</th>
<th>Sub-theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enablers to <em>Getting it Right</em></td>
<td>Staff being flexible and adaptable when identifying research participants</td>
</tr>
<tr>
<td></td>
<td>Team work among clinical, administrative and management staff</td>
</tr>
<tr>
<td></td>
<td>Research was well supported and respectful</td>
</tr>
<tr>
<td></td>
<td>Reimbursement enabled staff to try flexible approaches during recruitment and provided resources for research</td>
</tr>
<tr>
<td></td>
<td>Having a connection (between staff and patients)</td>
</tr>
<tr>
<td>Theme</td>
<td>Sub-theme</td>
</tr>
<tr>
<td>-------</td>
<td>-----------</td>
</tr>
<tr>
<td></td>
<td>Champion advocated for the research within participating service and with patients</td>
</tr>
<tr>
<td></td>
<td>Participant vouchers helped achieve research targets</td>
</tr>
<tr>
<td></td>
<td>Staff were available to do research at participating services</td>
</tr>
<tr>
<td></td>
<td>Patients felt comfortable in the physical environment</td>
</tr>
<tr>
<td></td>
<td>Patients perceived a need for research addressing community priorities</td>
</tr>
</tbody>
</table>

**Staff being flexible and adaptable**

Many staff told stories about how they were flexible, trying new approaches to overcome barriers that arose. For instance, they would take the opportunity to discuss the research with patients when they felt the timing was appropriate and participants were relaxed, such as in the car when driving to appointments or establishing new processes, such as speaking to participants in the waiting room when research participants had not arrived for their interviews and staff had time available. (Refer to Sections 5.4.3 and 7.4.4.1 for discussion about non-consecutive recruitment.)

**Team work among clinical, administrative and management staff**

According to many staff, team work among clinical, administrative and management staff helped to integrate the research into existing service activities.

> So us workers, us researchers work with the admin team, so the admin team are aware of the research that’s going on, we try to let the whole service know what’s going on with any research project that we’re doing … And in terms of the admin ladies, utilising their knowledge about who to approach and who not to approach. (Indigenous, Research Coordinator, female, #7)

**Research was well supported and respectful**

Most staff stated that support from the research team was provided when necessary, thus, enabling them to conduct the research by troubleshooting challenges immediately. For instance, when staff needed support when they experienced challenges in screening participants, collecting data or entering data into the study database, the research team responded quickly to their query via phone or email. The importance of a respectful approach to this research study and others was reported by many staff, with many stating their perception that *Getting it Right* was conducted in a respectful way:
But the way that the study was run was really good. It was really respectful. Everyone was easy to get along with and easy to access. If we needed something, we could just call and someone would be there to help us. (Indigenous, Research Coordinator, female, #27)

### 7.5.5 Barriers to conducting Getting it Right

Most staff described experiencing barriers when conducting *Getting it Right* (Table 7.9), many of which related to identifying participants. Staff offered suggestions of steps to be taken the next time research is undertaken to ensure the impact of these barriers are minimised.

#### Table 7.9 Barriers to *Getting it Right* and steps taken or suggested to overcome barriers (as reported by staff)

<table>
<thead>
<tr>
<th>Barrier reported by staff</th>
<th>Steps taken or suggested to overcome barrier by staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Limited human resources available to plan, prepare and conduct research (due to high turnover, staff shortages and heavy workloads)</td>
<td>Non-clinical staff identify potential participants, complete screening and some research documentation. Reallocate clinical staff from duties to free up time to work on research. Hire staff with dedicated research duties.</td>
</tr>
<tr>
<td>2. Multiple research projects underway simultaneously</td>
<td>Research governance process to manage research commitments. Management and clinical staff involved with planning to minimise overlap of projects.</td>
</tr>
<tr>
<td>3. Slower than expected recruitment because many patients:</td>
<td>Testing and adapting various approaches to recruitment (hosting lunch at the service, displaying pamphlets/posters in the waiting room, administrative staff providing information on arrival or staff sitting in the waiting room and speaking with patients about research).</td>
</tr>
<tr>
<td>– Were sick, not interested or sceptical of research</td>
<td></td>
</tr>
<tr>
<td>– Declined participation</td>
<td></td>
</tr>
<tr>
<td>4. Achieving research targets took longer to complete than originally planned because:</td>
<td>Address staffing challenges (refer to barrier 1).</td>
</tr>
<tr>
<td>– Insufficient human resources were available to complete the research</td>
<td>Staff politely informing participants about their limited time to complete research interviews.</td>
</tr>
<tr>
<td>– Patients shared personal stories during interviews</td>
<td>Allocate sufficient time to provide follow-up care after interviews.</td>
</tr>
<tr>
<td>– Providing follow up care took longer than expected</td>
<td></td>
</tr>
<tr>
<td>Barrier reported by staff</td>
<td>Steps taken or suggested to overcome barrier by staff</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>5. Culture (staff) at service does not include research. Staff concerns patients may:</td>
<td></td>
</tr>
<tr>
<td>– Respond negatively to depression as a topic</td>
<td>Involve staff who have an interest in research (refer to ‘culture among staff’ Section 7.4.1)</td>
</tr>
<tr>
<td>– Become upset from speaking about SEWB problems</td>
<td>Ongoing advocacy by one or more staff for research with other staff</td>
</tr>
<tr>
<td>– Be offended by being asked about research/SEWB problems</td>
<td>Establish thorough safety follow-up processes and communication about safety plans to alleviated concerns about patient wellbeing</td>
</tr>
<tr>
<td>6. Complex research processes including:</td>
<td></td>
</tr>
<tr>
<td>– Academic wording used in consent documentation</td>
<td>Allocate sufficient time to discuss the risks and benefits of research</td>
</tr>
<tr>
<td>– Two-step interview process (required for validation design)</td>
<td>Simplify language on consent documentation</td>
</tr>
<tr>
<td>7. Logistical barriers arising from insufficient resources available for research (when reimbursement allocated to non-research expenses), intermittent internet, challenges accessing the study database or limited computer functionality</td>
<td>First interviewer introduces the participant to second interviewer</td>
</tr>
<tr>
<td>8. Difficulty identifying participants (for second interview)</td>
<td>Identify alternative resources to complete data entry (use of personal phone/computer)</td>
</tr>
<tr>
<td>Establish processes to complete second interview immediately after first interview</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: SEWB – Social and emotional wellbeing

**Two-step interview process (required for validation design)**

Some staff reported that the research design contributed to challenges in conducting the research. The two-step interview process in conjunction with the validation research design meant that participants were required to complete the second interview with a different interviewer to the one who completed the first interview. Some staff reported that the idea of speaking with a second interviewer was a challenge for some participants because they had already developed a rapport with the first interviewer. To overcome this challenge, these staff reported reassuring participants and introducing them to the second interviewer face-to-face, which helped to put participants at ease before completing the second interview.

**7.6 Conclusion**

Using the process evaluation, I demonstrate that the aPHQ-9 was well accepted by PHC staff and participants involved with the research and show that apart from some non-
consecutive recruitment at two participating services (which did not appear to be widespread), staff perceived that the research was conducted according to the protocol. Although some non-consecutive recruitment occurred, the demographic characteristics appear to be reflective of the Indigenous population attending each service, (data not presented), suggesting that the adaptive approach enabled research that was rigorous, and allowed sufficient flexibility to address challenges when identifying research participants, a challenge that commonly impacts on timely research conduct. This verifies the findings from Chapter 5, which showed that Getting it Right was conducted to a high standard and in accordance with academic research principles. The results presented in this thesis include data arising from the Residential Drug and Alcohol Services, which was a participating service. Including this type of service had potential to affect the representation of the sample and generalisability of results because it may have different time pressures (residential stay where participants live on site during rehabilitation) and a different patient group (mostly males, who may have had a higher risk of experiencing depression symptoms) from other Indigenous-focused PHC services. However, responding to the request to include this service was deemed to be crucial to the ethical conduct of the research by the SC and it did not appear to have caused bias (discussed in Chapter 5).

Difficulties associated with the informed consent process suggest that consideration of alternative research processes and simplified consent forms when gaining informed consent, may be beneficial during Indigenous-focused SEWB PHC research. In addition, training on gaining informed consent may need to be provided on more than one occasion during study conduct, especially when new staff begin working on the research. The importance of planning and conducting research carefully, using a respectful approach, may also facilitate ongoing relationships with research teams increasing participation in future research projects, and reducing the time spent training research naïve staff. It is acknowledged that research can cause tension among staff, therefore, careful consideration must be given when taking on similar research projects. Staff who also used the PHC service as patients, required very careful consideration by the PHC services and the external research team. This situation required additional consideration by management, but may have provided some benefits by identifying and
referring people with SEWB problems who may have otherwise had conditions undetected.

In Chapters 8 and 9, I will explore novel ideas that arose during the process evaluation that related to staff and patients’ willingness to participate in the research, and speak about their SEWB, and the role that resources and resourcing played during the Indigenous-focused PHC based research.
CHAPTER 8
PROCESS EVALUATION RESULTS: PERSPECTIVES OF STAFF AND PATIENTS ABOUT PARTICIPATING IN SEWB RESEARCH

8.1 Introduction

In the last chapter I presented the main results from the process evaluation of Getting it Right, which demonstrated that the research was conducted as described in the protocol, that the aPHQ-9 was well accepted by the PHC staff and participants, and it was considered feasible to use.

In Chapters 8 and 9 I present novel findings from the process evaluation to inform future Indigenous-focused SEWB PHC research. In this chapter, I explore PHC staff and patients’ willingness to participate in SEWB research and speak about their SEWB. In Chapter 9 I will explore the complex and sometimes overlooked role of ‘sufficient’ resourcing for the successful conduct of Indigenous-focused PHC based research. This chapter is presented as a publication:

Farnbach S, Gee G, Eades AM, Evans J, Fernando J, Hammond B, Simms M, DeMasi K, Hackett M. ‘We’re here to listen and help them as well:’ A qualitative study of staff and patient perceptions about participating in social and emotional wellbeing research at primary healthcare services (submitted)

8.2 Aims

The aim of this chapter is to explore PHC staff and patients’ experiences and perspectives of their willingness to participate in research and speak about SEWB during PHC-based research. The methods for this chapter are presented in detail in Chapter 7. I use grounded theory approaches and triangulate semi-structured interview data, participant feedback data and study administrative data. This is presented as a publication.
8.3 Results (publication)
‘We’re here to listen and help them as well:’ A qualitative study of staff and patient perceptions about participating in social and emotional wellbeing research at primary healthcare services

OVERVIEW OF PUBLICATION

In this publication I explore PHC staff and patients’ experiences of and perspectives around their willingness to participate in research and speak about SEWB during PHC-based research.
‘We’re here to listen and help them as well’: A qualitative study of staff and patient perceptions about participating in social and emotional wellbeing research at primary healthcare services

* Sara Farnbach\textsuperscript{a}, Graham Gee\textsuperscript{b}, Anne-Marie Eades\textsuperscript{a}, John Evans\textsuperscript{c}, Jamie Fernando\textsuperscript{d}, Belinda Hammond\textsuperscript{e}, Matty Simms\textsuperscript{f}, Karrina DeMasi\textsuperscript{g}, Maree Hackett\textsuperscript{h} on behalf of the *Getting it Right* Investigators

\textsuperscript{a} The George Institute for Global Health, PO Box M201, Missenden Road, Camperdown, New South Wales, 2050, Australia, University of New South Wales, Sydney 2052, Australia and The University of Sydney, New South Wales, 2006, Australia
\textsuperscript{b} Victorian Aboriginal Health Service, Victoria, 3072, Australia and University of Melbourne, Victoria, 3000 Australia
\textsuperscript{c} The University of Technology and The University of Sydney, New South Wales, 2006, Australia
\textsuperscript{d} The University of Newcastle, New South Wales, 2308, Australia
\textsuperscript{e} Nunkuwarrin Yunti of South Australia, South Australia, 5000, Australia
\textsuperscript{f} The Glen Centre (Ngampie), New South Wales, 2261, Australia
\textsuperscript{g} Aboriginal Medical Services Alliance Northern Territory, Northern Territory, 0801, Australia
\textsuperscript{h} The University of Central Lancashire, PR1 2HE, United Kingdom

* Corresponding author email: sfarnbach@georgeinstitute.org.au

8.3.1 Abstract

\textit{Background}

Research can inform culturally-appropriate care to strengthen social and emotional wellbeing (SEWB) among Aboriginal and Torres Strait Islander (hereafter Indigenous) peoples. We explore the perspectives of primary healthcare staff and Indigenous patients about their willingness to and experiences participating in SEWB research.

\textit{Method}

Process evaluation using grounded theory approaches of *Getting it Right: the validation study*, a national validation designed Indigenous SEWB research project (N=500). Primary healthcare staff (n=35) and community members (n=4) from nine of ten primary healthcare services involved with the research project completed qualitative semi-structured interviews. Interview data were triangulated with participant feedback
(responses to structured questions and free-text feedback collected during *Getting it Right*), study administrative data (participant screening logs, communication logs, study protocol, deviation logs and ethics correspondence) and interviewer field notes.

**Results**

Three themes about staff, patient and community perspectives concerning research participation were developed: (1) considering the needs, risk, preferences and impact of participation in research for staff, patients and community; (2) building staff confidence speaking to patients about research and SEWB problems and (3) patients speaking openly about their SEWB. Some staff described pressure to ensure patients had a positive experience with the research, to respond appropriately if patients became upset or SEWB problems were identified during interviews, or due to their dual role as community member and researcher. Patients and staff reported that patients were more likely to participate if they knew the staff outside of the service, especially staff with a shared cultural background, and they perceived SEWB as a community priority. Staff reported their skills speaking to patients about the research and SEWB improved during the research, which built their confidence. Contrary to staff preconceptions, staff and patients reported that many patients appreciated the opportunity to speak about their SEWB and contributing to research that may eventually enhance SEWB in their community.

**Conclusion**

Our research project was considered acceptable by most staff and patients. The positive outcomes reported by staff and feedback from patients highlights the importance of providing opportunities for people to speak about their SEWB and for research-informed SEWB PHC care.

**Trial registration**

*Getting it Right* is registered on ANZCTR 12614000705684

**Keywords**

Depression screening; primary healthcare; Aboriginal and Torres Strait Islander; qualitative research
8.3.2 Background

Research focused on Aboriginal and Torres Strait Islander (hereafter referred to as Indigenous) people may inform evidence-based and culturally-appropriate strategies that strengthen social and emotional wellbeing (SEWB)\(^52\). When planning and conducting this research, consideration of its impact on participants, research staff and the community is important to ensure it leads to joint ownership, tangible benefits in participating communities and is feasible.

While strengthening SEWB by building resilience is one focus of many Indigenous-focused PHC services,\(^15, 28\) delivering care\(^29\) and conducting research\(^32\) focused on the assessment and treatment of mental health problems may also be needed to reduce the high rates of psychological distress experienced by Indigenous Australians compared to non-Indigenous Australians.\(^30\)

When considering whether to become involved with SEWB research, PHC staff likely consider their experiences with earlier research projects, general preconceptions about research and the topic (whether grounded in experience or not). Negative experiences such involvement with research perceived as resulting in little or no tangible benefit to the community,\(^44\) or limited to describing the size and nature of the problem, without offering solutions,\(^20\) or concerns that asking about suicidal ideation, may increase suicidal tendencies may deter staff from becoming involved.\(^162\) PHC staff and patients perspectives should be central during research planning to ensure it provides tangible benefit, is relevant, effective, culturally respectful and feasible.\(^7, 75\)

We present the results from a process evaluation designed to explore the perspectives of PHC staff and patients about their willingness to and experiences of participating in research and speaking about SEWB. The work was part of a NHMRC-funded, national, Indigenous-focused SEWB PHC-based research project *Getting it Right: the validation study*\(^113\) (hereafter the research project), conducted in ten PHC services (hereafter participating services).
8.3.3 Methods

The methods of the research project and process evaluation have been previously described. In brief, coordinating staff at participating services invited staff and community members (purposive identification) to complete qualitative semi-structured grounded theory interviews. Staff interviews were conducted by SF between November 2016 and June 2017 (after recruitment was completed for the research project) in a confidential setting, in-person at the participating service or over the phone. SF is a female registered nurse and PhD candidate, and has completed training in qualitative data collection, analysis and reporting. She was project manager of the research project and had relationships with staff and community members for between one and three years. All interviews and most of the thematic analysis were completed before the results of the research project were released to SF, the Indigenous Advisory Group (GG, JE, AME, JF, MS, BH and KD) or participating communities.

The research project was designed to determine the validity of a culturally-adapted depression screening tool (the adapted-Patient Health Questionnaire-9) for use by Indigenous people and recruited 500 participants (2014 to 2016). It was managed centrally from The George Institute for Global Health in Sydney, Australia. The study protocol was adaptive, meaning participating services nominated existing or hired new staff to conduct the research (based on their assessment of staff skills, backgrounds and availability) and developed individualised recruitment and safety follow-up plans (with support from researchers) while the core elements of the protocol were unchanged. One staff member interviewed consenting participants (PHC patients) using the depression screening tool and another using the semi-structured MINI International Neuropsychiatric Interview (MINI) 6.0.0 (depression, anxiety and Post-Traumatic Stress Disorder (PTSD) modules). Patient interviews involved questions about SEWB problems (defined as depression, anxiety and PTSD, and thoughts of self-harm, suicidal ideation or intent) and feedback on the research.

We defined ‘patient’ as PHC patients in general or before they consent to participate in the research project and ‘participant’ as a patient who has provided informed consent. SEWB includes mental health within a holistic framework that recognises wellbeing as interconnected with land, culture, family and community and recognises the role of
historical, political and cultural determinants. Indigenous-focused PHC services include Aboriginal Medical Services and Aboriginal Community Controlled Health Services.

Process evaluation staff interviews were conducted using interview guides, digitally recorded and transcribed verbatim. NVivo 10 for Windows was used to manage the data. Qualitative interview data were triangulated with participant feedback about the depression screening tool and their experiences with the interview (responses to questions and free-text feedback entered onto case report forms by patients or interview staff immediately after the first research interview), administrative data from the research project (participant screening logs, communication logs, study protocol and ethics correspondence) and field notes (SF). We also report our observations of the research project as project manager (SF) and investigators (GG and MH).

Process evaluation staff interviews continued until all potential staff or community members were considered by the coordinating staff. Data were coded inductively. No new open codes were identified in the final two interviews, indicating data saturation. Interviews and coding were conducted in three stages and codes constantly compared during analysis. Authors were provided with regular reports of interviews and themes as they developed. A record of codes, their properties, our interpretations, and feedback from authors were kept in memos. Codes and memos were grouped into themes, which were integrated into subsequent interview guides (total=3). SF and AME piloted interview guide one. Ten (25%) transcripts were independently double-coded by Aboriginal authors (GG and AME).

This process evaluation was conceived, designed and conducted while following the Values and Ethics Guideline and received state-based ethics approval (refer to protocol). Consent from each participating service was also provided.

8.3.4 Results

Interviews were completed with 36 staff (34 individually and as a group interview) and four community members (group interview) from nine of the ten participating services, resulting in 1324 minutes of transcribed interviews. Due to staff turnover and organisational change at the tenth service, these staff did not complete interviews.
Managers (n=9), Aboriginal Health Workers (AHW) (n=9), Allied Health Staff (n=8), Research Coordinators (n=5), and General Practitioners (GPs) (n=4) were interviewed (Table 7.3).

Three themes related to staff, patients and community perspectives about their willingness to participate in SEWB research were developed: (1) considering the needs, risk, preferences and impact of participation in research for staff, patients and community; (2) building staff confidence speaking to patients about research and SEWB problems and (3) patients speaking openly about their SEWB.

8.3.4.1 Theme one: staff considering the needs, risks, preferences for and impact of participation in SEWB research for staff, patients and community

Staff said the research project was needed because it addressed SEWB, which was a community priority (Table 8.2). Staff described feeling pressure surrounding how patients would perceive or respond to the research project, which they managed by assessing if patients were suitable to participate, including considering patients’ personal circumstances and connection with staff, before inviting them to participate. Some staff (mostly managers) assessed which staff were suitable to conduct the research interviews, speak to patients about SEWB problems and provide follow-up referral (if required). Some staff described preparing themselves to hear about traumatic events during the research interviews.

<table>
<thead>
<tr>
<th>Subtheme</th>
<th>Description of subtheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceiving a need</td>
<td>For research addressing community priorities</td>
</tr>
<tr>
<td>Feeling pressure</td>
<td>To ensure patients had a positive experience with the research, which could be harmed if:</td>
</tr>
<tr>
<td></td>
<td>– Patients respond negatively to depression as a topic</td>
</tr>
<tr>
<td></td>
<td>– Patients become upset from speaking about SEWB problems</td>
</tr>
<tr>
<td></td>
<td>– Patients are offended by being asked about research/SEWB problems</td>
</tr>
<tr>
<td></td>
<td>To respond appropriately to patients became upset or if SEWB problems were identified during research interviews</td>
</tr>
<tr>
<td></td>
<td>Because their dual role as researcher and community member contributed to pressure to ensure that research benefited patients and community after completion</td>
</tr>
</tbody>
</table>
Assessing suitability  Of patients’ circumstances before inviting them to participate  Of skills of interviewing staff to assess and treat SEWB  
Being prepared  To support patients appropriately (if needed)  To ask about suicidal ideation/intent or hear about traumatic events

**Abbreviations:** SEWB – social and emotional wellbeing

---

**Perceiving a need**

Many staff reported that there was a need for SEWB research because it addressed a priority in their community or there was a lack of research to inform SEWB care:

> We do need an appropriate screening tool to help pick up people with depression and suicidal ideas so we can manage those things specifically, effectively in primary care. (Non-Indigenous, GP, male, #9)

**Feeling pressure**

Many staff described pressure to ensure patients had a positive experience with the research project, and viewed participation as a potential risk because patients may have a negative response to the topic of depression, become upset during interviews or be offended by being asked to participate.

Some staff described depression as a ‘sensitive’ topic or suggested that patients may be concerned about stigma if diagnosed with depression. These staff perceived that patients’ perceptions could be a barrier for patients when considering research participation:

> So me and the other research officer thought, hmmm, might be a bit of a tight one, people opening up about their inner feelings. A lot of blacks don’t like doing that. (Indigenous, AHW, female, #4)

Some staff reported initial concerns about speaking to patients about SEWB problems because it could cause problems for patients, by bringing up upsetting or traumatic issues. By asking patients to repeat traumatic stories during the research interviews, staff were concerned they may unnecessarily burden patients by ‘flaring things up,’ especially if an existing condition was known to clinicians and they were already receiving treatment (Non-Indigenous, GP, male, #9).
Some staff reported feeling concerned they could offend patients by inviting them to participate in research about depression. These staff described carefully framing the conversation to avoid ‘Pigeonhole or tag[ing] people that have mental health conditions’ (Non-Indigenous, GP, male, #1).

Several staff reported feeling pressure to respond appropriately to patients if they became upset, were identified with a disorder (depression, anxiety or PTSD) and/or indicated thoughts of suicidal ideation or intent during a research interview. Some staff reported concerns that they may not be equipped to deal with these situations, while for other staff, this was not a concern because it was ‘part of the job’.

Several staff who were also involved with their local community reported that their dual role (researcher and community member) contributed to pressure to ensure that research had benefit to patients and community. One AHW described being ‘the face of the research’:

There comes a responsibility that sits on my shoulders then as the face of that, being the Aboriginal worker and being from this community … to ensure that it’s successful and that things work well, and that people are happy with the way things go. (Indigenous, AHW, female, #7)

**Assessing suitability**

Several staff described assessing patients’ suitability by considering the patient’s circumstances and their connections with the patient in the community before inviting them to participate. Patients deemed unsuitable by staff were those with multiple complex health priorities, an acute illness or who were experiencing stressful events which staff felt should be the focus during their visit to the participating service.

Staff, particularly managers, considered which staff were suitable to complete research interviews, by reviewing staff skills assessing and treating SEWB problems. One manager reported that having staff with existing SEWB assessment and treatment skills ensured they were prepared to respond appropriately if a SEWB problem was identified.

Some staff reported having to ‘think on their feet’ to immediately assess and manage unexpected issues that arose during research interviews. For example, one staff member
heard a story about ‘violence from their [participant's] partner, who was in the next room’ (Indigenous, manager female, interview 24).

**Being prepared**

Most staff reported prioritising planning the safety protocol(142) because it was important to support patients appropriately and minimise patients’ risks (by having a plan for follow-up care if required) and staff risks, by outlining a process if patients reported thoughts of self-harm or suicidal ideation or intent during a research interview.

Some staff also described preparing themselves emotionally to ask ‘tricky’ questions during the research interviews which sometimes involved ‘listening to traumatic stories’ (non-Indigenous, nurse, female, #22). Another described that hearing traumatic stories was difficult:

> Family abuse, sexual abuse, domestic violence, children being taken away, and then the difficulty of getting a child back. I found that really, really difficult. And I remember one patient who just bawled their eyes out … And I ended up crying with her because the situation was so difficult. (Non-Indigenous, research coordinator, female, #6)

Some staff reported completing regular debriefing sessions and receiving support from managers around maintaining a work-life balance. While this was not reported by all staff, we did not specifically ask about it during the process evaluation.

**8.3.4.2 Theme one: patients considering needs, risks, preferences and impact of research participation for community and themselves**

Patients appeared to prefer to participate in research and speak about SEWB problems if they were comfortable in the environment, perceived that the research addressed a community priority and/or had a connection with a staff member. According to staff, some patients choose not to participate because they had concerns about research, about speaking about depression or were too sick or busy (Table 8.3).

| Table 8.3  Theme one – patients considering the needs, risks, preferences and impact of research participation for community and themselves |
|---------------------------------|---------------------------------------------------------------|
| Subtheme                        | Explanation of subtheme                                      |
| Feeling comfortable             | In the physical environment/setting where research is occurring |
Perceiving a need

For research addressing community priorities

Having a connection

Between staff and patients, including shared cultural background (contrasting perspectives explored in table 4)

Sometimes connections can:

- Be inappropriate to interview family members
- Require additional time to complete research interviews

Declining to participate

Because of concerns about research or speaking about SEWB problems

Too busy, too sick or had other priorities

Abbreviations: PHCS – primary healthcare service (participating service); SEWB – social and emotional wellbeing

**Feeling comfortable in the environment**

Some staff reported that patients were more likely to complete research interviews and speak about their SEWB outside the clinical environment where they were more relaxed, for example in a local park, car or in their own homes. At one participating service, all patients regularly participated in group counselling sessions and this was cited as a reason for the high recruitment rate of 100% because ‘it may have been easier for these guys to talk about their emotional state’ (Indigenous, GP, male, #35).

**Perceiving a need**

Some patients reported that SEWB was priority in their community and this research topic motivated them to participate:

[The research is] beneficial for Aboriginal people getting into depression. (Indigenous participant, female, 61 years)

Verifying this view many staff reported that patients were interested in participating because of the research topic. According to one GP, patients were: ‘impressed the service was doing something about it [depression]’ (Indigenous, GP, male, #35).

**Having a connection**

In participant feedback 90% reported feeling comfortable participating and this may be due to their existing connection with the staff conducting the research interviews. In the free-text feedback one participant reported:
I felt comfortable answering the questions because I was talking with someone I trusted, if it was a stranger I would feel different. (Indigenous participant, male, 71 years)

Having a cultural connection also contributed to patients’ comfort. One AHW reported clarifying information during informed consent by ‘speaking the lingo’ (Indigenous, AHW, female, #4), rather than using the formal academic language on the consent form, which resulted in patients participating in the research. Participant feedback verified that a shared cultural background made them comfortable answering the questions:

Because a Murri woman from this community was asking them. (Indigenous participant, female, 56 years)

The perspectives of some staff and patients about the impact of their connections differed, with some staff reporting concerns that connections would dissuade patients from participating, and patients reporting this connection made them comfortable to participate (Table 8.4).

### Table 8.4 Theme one – contrasting perspectives of staff and patients about having a connection

<table>
<thead>
<tr>
<th>Explanation of having a connection</th>
<th>Staff perspective</th>
<th>Patients’ perspective</th>
</tr>
</thead>
</table>
| Between staff and patients, including shared cultural background | - Some staff perceived that patients may be concerned about confidentiality due to connections, and therefore may not participate or be willing to have SEWB discussions  
- Some staff were surprised that their connections encouraged patients to participate  
- Some staff perceived their connections with patients established trust, which facilitated participation | Patients reported connections made them comfortable to participate and have SEWB discussions (through established trust and/or shared cultural background) |

**Abbreviations:** SEWB – social and emotional wellbeing

Staff perspectives about how their community connections would impact on patients’ willingness to participate were mixed. During start-up training and process evaluation interviews, some staff reported that some patients may be unwilling speak to staff who they knew from the community, because of concerns that their personal information may be shared:
I didn’t know how people were going to open up to me… they were either going to be more comfortable with me and happy to share or they were going to be no, I’m not going to say nothing because you know my family. (Indigenous, AHW, male, #5)

Despite initial concerns, once research interviews begun, these staff were surprised to realise that their role within the community encouraged patients to participate because it fostered patients’ trust with staff and therefore the research:

I thought they might not do it … But no, they were fine with me doing it actually. I think some of them did it because it was me. (Indigenous, AHW, female, #4)

In contrast, other staff reported their connections were important to establish trust which may increase the accuracy of data because ‘you don’t get the story unless you know the person’ (Indigenous, manager, female, interview 24). One RN described a couple who were:

First asked by someone else [to participate] and they said no, but said yes to me because they knew me and had a relationship with me. (Non-indigenous, RN, female, #21)

Some staff described how these connections prolonged the research interviews. One AHW recalled feeling pressure to complete interviews in shorter timeframes because of other service priorities. This was difficult because when a patient is:

Opening up to you … you can’t just get what you want, okay, get out the door. It doesn’t work like that in our mob. We’re here not just for the research. We’re here to listen to them and help them as well. (Indigenous, AHW, female, #4)

**Declining to participate**

Staff reported that some patients did not participate because of concerns about research generally, speaking about their SEWB or they were too busy, sick or had other priorities. The screening logs showed a participation rate of 55% (number screened/number participated). Most of the patients who were screened and did not participate declined with no reason documented (64%) or were ineligible (32%) because they did not meet the inclusion/exclusion criteria.
Two AHWs reported that the community had concerns about research generally and one described ‘defend[ing] research’ when talking about the research with some patients (Indigenous, male, AHW, #10). These AHWs reported that these concerns arose from negative experiences with research or suspicion about the motives behind the research because the ‘government would check them out’ (Indigenous, AHW, female, interview 28) if they participated.

In contrast to some patients who appeared to perceive that SEWB research was needed, some staff reported that some patients may be concerned about the stigma associated with depression and may have chosen not to participate. This stigma may have caused:

A reluctance of clients, they didn’t really want to talk about stuff when they realised it was about depression and anxiety. (Non-Indigenous, male, RN, #25)

8.3.4.2 Theme two: staff building confidence speaking about research and SEWB problems

Staff became more confident speaking to patients about research and SEWB problems as they gained experience and skills conducting research interviews (Table 8.5).

<table>
<thead>
<tr>
<th>Subtheme</th>
<th>Explanation of subtheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhancing skills speaking about research and depression</td>
<td>From experience conducting research interviews</td>
</tr>
<tr>
<td></td>
<td>From experience speaking to patients about SEWB problems</td>
</tr>
<tr>
<td>Enhancing staff-patient relationships</td>
<td>Through discussions arising from research</td>
</tr>
<tr>
<td>Perceiving positive outcomes</td>
<td>Through identifying problems and providing care</td>
</tr>
<tr>
<td></td>
<td>Therapeutic benefit for patients from research interviews</td>
</tr>
</tbody>
</table>

**Abbreviations:** SEWB – social and emotional wellbeing

**Staff enhancing skills speaking to patients about research**

When reflecting on the research, some staff reported being nervous before the first research interview because they had minimal experience speaking to patients about SEWB or completing research. For some staff, their involvement sparked an ongoing
interest in research. One GP went on to complete further study and reported that the skills of other staff were enhanced during the research (Indigenous, GP, male #35).

Some staff reported that their experience with the research resulted in greater integration of conversations about SEWB into routine practice:

> I was always a little bit reluctant to ask that stuff [SEWB assessment], whereas just now, for all workers, it’s become just sort of a normal part of the work process. (Aboriginal, AHW, male, #17)

Some staff described that the research empowered them in their work and personal lives, attributing this to their experiences speaking with patients about depression and responding appropriately:

> I think that she left the interview feeling like a weight had been lifted off her shoulders … So you know, that was pretty empowering for me and it made me feel like well I’ve got a job to do here, you know. (Indigenous, AHW, male, #5)

**Enhancing staff-patient relationships through research**

Many staff reported that their relationships with patients were enhanced through conducting research interviews, because the interviews provided an opportunity for in-depth conversations about patients’ lives. These conversations built therapeutic relationships and developed connections ‘in a different way, on a different level’ (Indigenous, manager female, #24) to those had before the research project. Because of time constraints, opportunities for in-depth conversations were often limited during their usual roles. Staff reported that their enhanced relationships was a positive outcome of the research.

**Perceiving positive outcomes**

Most staff considered the many patients identified with depression, anxiety or PTSD during the research and provided with follow-up care was a positive outcome of the research:

> Nine times out of 10 people were coming out with psychology appointments or psychiatrist appointments, or medication or both. (Non-Indigenous, RN, male, #3)
Staff reported that some patients become upset when talking about their problems and this concerned staff who gave patients time to speak, offered support, provided referral (if necessary) and offered to stop the interview. Staff reported that sometimes more time was needed to provide follow-up care than what was originally allocated to the research, but that providing follow-up care was part of the job. These staff reported that upset patients wanted to continue interviews and the interviews may have had therapeutic benefit:

And I remember one patient who just bawled their eyes out and I tried to stop the interview, but she didn’t want to because she said she needed to get it out of her system. (Non-Indigenous, research coordinator, female, #6)

**Counter-opinion of negative outcomes for participants**

One staff member recalled a negative patient outcome from the interview:

The patient already had other mental health issues that their GP knew about anyway. And that patient talked about all that but also came up with some other things … At the end of it, I didn’t realise that that patient got a bit upset or distressed. (Non-Indigenous, research coordinator, female, #6)

### 8.3.4.3 Theme three: patients speaking openly about SEWB

Many patients appeared to speak openly, share personal stories and appreciate the opportunity to participate, because it provided an opportunity to speak about their SEWB and to contribute to community outcomes. Many staff reported being surprised that patients spoke openly because staff expected they would be uncomfortable speaking about SEWB problems: ‘especially given the sensitivity of the topic’ (Non-Indigenous, GP, male, #9) or if they knew the interviewing staff member (Table 8.6).

**Table 8.6 Theme three – Patients speaking openly about SEWB**

<table>
<thead>
<tr>
<th>Subtheme</th>
<th>Explanation of subtheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharing personal stories</td>
<td>Patients speaking openly about family histories and cultural exchange</td>
</tr>
<tr>
<td>Appreciating the opportunity</td>
<td>To speak about their SEWB and SEWB problems</td>
</tr>
<tr>
<td></td>
<td>To contribute to community outcomes</td>
</tr>
</tbody>
</table>

**Abbreviations:** PHCS – primary healthcare service (participating service); SEWB – social and emotional wellbeing
Sharing personal stories

Many staff reported feeling privileged hearing patients’ stories during interviews. However, sharing stories prolonged interview timeframes:

I felt very privileged to be sitting down with people and starting difficult conversations … and there was one client … I was there for three and a half hours… he was telling me about his family and his connections and the disconnected side of things, talked a lot about repossession … Showed me his family history book, and where he was from and all about his Country and all the things that he’d put in place for his family. (Indigenous, manager, female, #24)

For some Indigenous staff, sometime cultural information was exchanged. One AHW recalled interviewing Elders in his community who wanted to have lengthy discussions with him. This AHW reported feeling obliged to continue discussions and give the Elders time to talk due to cultural protocols, but was also aware that other participants were waiting to complete interviews, so had to find a way to politely shorten conversations.

Appreciating the opportunity

Some patients appeared to appreciate the opportunity to speak about their SEWB during the research and provided positive feedback about the interview questions or about having an opportunity to reflect on their SEWB:

Questions are good at making you think about things you would not normally think about yourself – that it was good to make [you] aware of your emotions and identify if you have any problems. (Indigenous participant, male, 32 years)

Many staff verified this perspective and reported that many patients appreciated speaking about their SEWB and that staff were interested in their lives:

But I think clients quite enjoyed being asked a particular question [relating to suicidal ideation]. It gave them an opportunity to talk. (Indigenous, research coordinator, female, #30)

One manager reported being thanked by the family of a participant after a lengthy interview:
And two days later … he’d become very unwell and subsequently passed away. And so really the last person that had had this big conversation with him was me… it is very powerful, because the family members came to me, saying, you really, you were one of the last, and how wonderful [PARTICIPATING SERVICE] was for providing this extra service. And I thought, in actual fact, it’s part of the study. (Indigenous, manager female, #24)

Some staff reported that patients appreciated contributing to community outcomes through their involvement with the research and ‘enjoyed being part of something’ (Indigenous, AHW, male, #33). One GP reported how:

Impressed some of the clients were, in regard to mental health issues in men being addressed or being researched into … they were quite proud to be involved with that. (Indigenous, GP, male, #35)

Quantitative feedback demonstrated overwhelmingly that participants were comfortable answering the questions (91%) and perceived that the screening tool was easy to understand (87%). 86% reported that they were comfortable with how much personal information was asked. Approximately 20% of participants provided free-text feedback, which mostly related to the depression screening tool (pertaining to specific questions and response category options) or to their positive experience with the research project: happy to take part in [the] study, through [sic thought] it was good that the research was being done (Indigenous participant, female, 40 years).

8.3.5 Discussion

Overall, our results show that despite some initial uncertainty among staff, many patients were willing and appreciated participating in SEWB research, especially when they had existing connections with staff and perceived that the research addresses a community priority. Some staff reported that their confidence speaking to patients about SEWB improved and that some patients benefited therapeutically from participation, demonstrating potential ongoing positive implications of research. Some staff reported pressure of their dual roles within the community, highlighting a need to consider the wider implications of research for staff and patients and for flexible research protocols. These results illustrate some of the principles described by Jamieson et al\textsuperscript{75} about conducting beneficial, relevant, effective and culturally respectful research, and ensuring research addresses community priorities and incorporates capacity building.
Many staff and patients reported that building SEWB was a community priority. The positive participant feedback demonstrated engagement with the research topic. This was a surprise to some staff who were initially concerned that patients may respond negatively when asked to participate in research about depression. Previous research shows that asking about suicidal ideation can reduce rather than increase suicidal ideation. Some participants of trauma-related research viewed participation as a positive experience, regardless of their trauma history and even those who became upset did not regret participation because they believed it had personal and community level benefit. It is not surprising that staff reported that some patients seemed to benefit just from participation in the research project, regardless of whether SEWB problems were identified that would otherwise have been missed. This demonstrates that it is important to provide patients with opportunities to speak about SEWB and that trained staff can ask directly about SEWB problems.

Developing existing capacity is particularly relevant during Indigenous-focused research because local staff may have existing relationships within communities that may put some Indigenous people at ease, and this may also facilitate interest in the research. Previous research has indicated that some Indigenous people prefer speaking to staff who they have close and ongoing relationships with during research and when accessing health care. In our research, staff-patient relationships appeared to facilitate participation and SEWB conversations, and some staff suggested it may also have improved the accuracy of the research data. Involving Indigenous researchers may also enhance research through the local expertise they bring which may help to promptly identify participants, facilitate research that is in-line with cultural protocols, is respectful and addresses community priorities.

However, our research highlights some considerations for researchers working within their own community. Our protocol focused on the safety of patients and we assumed that staff care was provided by participating services as part of their usual processes. Pressure on staff, and staff preparing to hear traumatic stories, were raised as sub-themes in our research and we feel it prudent to remind researchers that the safety of all participants (community, patients and staff) is paramount. The role of AHWs as emotional brokers may contribute to emotional exhaustion leading to burnout, and the
emotional labour resulting from cultural and family obligations, the complex needs of many clients or backlash if poor outcomes occur has been identified among Indigenous maternal health workers.\textsuperscript{169} Similarly, an Indigenous researcher has highlighted the potential impact of their research on their relationships with other community members, the way they are viewed in their community or the way they viewed themselves.\textsuperscript{170} Our research highlights the need to focus on the wellbeing of research staff during research.

To the best of our knowledge, this is the first Australian PHC-based, Indigenous-focused research exploring staff and patients’ perspectives around participating in research and speaking about SEWB. Our results suggest that when appropriately planned and supported, these services are a viable setting for SEWB research.

Our research confirms some of the principles described by Jamieson et al\textsuperscript{75} pertaining to the importance of research that addresses a community determined priority and is focused on enhancing capacity. Additionally, with use of an adaptive protocol, research can be flexible so staff can determine localised research processes while maintaining scientific rigour.\textsuperscript{75}

Delivering training to PHC staff about culturally-appropriate SEWB screening, assessment and treatment may enhance the likelihood of staff speaking to patients about SEWB outside of research. To ensure appropriate SEWB care is available at PHC services, referral pathways and evidence-based management guidelines are needed.

PHC services are well positioned to engage in SEWB research. When developing SEWB research, we recommend:

1. Identifying adequately trained, culturally-competent staff, or ensuring adequate training and support of staff is provided by the researchers,

2. Allocating adequate time for conversations around research and ensuring PHC services have capacity to follow up (if required) people who are identified with SEWB concerns,

3. Developing evidence-based SEWB management guidelines and referral options.
Finally, we suggest that the potential risks and pressures on Indigenous staff who participate in SEWB research may be minimised by ensuring staff have autonomy to manage cultural pressures, complete self-care and opportunities to access therapy or support.

8.3.6 Strengths and limitations of this research

SF was the project manager of the research project and led the process evaluation allowing for in-depth understanding of the project and surrounding events which enhanced data collection, analysis and interpretation. The relationships and rapport developed during the research project facilitated discussions during staff interviews. However, these relationships may have influenced the process evaluation interviews because staff may have avoided reporting negative experiences related to the research project. By blinding the authors to the results of the research project, we reduced the risk of main study findings influencing the interview discussions.

Our ability to draw conclusions based on patients’ perspectives is limited to feedback collected during the research project after the first research interview and staff opinions of patients’ perspectives. The opinions of staff and patients unwilling or unable to engage with the research were not collected, potentially limiting us capturing the perspectives of the most unwell patients or specific reasons for non-participation among staff or patients. We are aware of at least two staff who were trained in the research and chose not to conduct research interviews.

Although staff from nine diverse PHC services contributed data, findings may not be generalisable to other Indigenous-focused PHC services. However, these data provide useful insights for future Indigenous-focused PHC SEWB research.

8.3.7 Ethics, consent and permissions

This research was reviewed and approved by: The University of Sydney Human Research Ethics Committee [2014/361], Aboriginal Health and Medical Research Council of NSW [1044/14], ACT Health HREC [ETH.8.14.207], Queensland Health Metro South HREC [HREC/14/QPAH/503], Central Australian HREC [HREC-15-287], Menzies School of Health Research [2014-2289], Aboriginal Health Council of South
Australia [04-17-705], Western Australian Aboriginal Health Ethics Committee [607]. All participants provided written informed consent to participate in this research project and in *Getting it Right*. All authors reviewed this manuscript. The datasets analysed during this research are not publicly available due to the research methods used (qualitative) but may be available from the corresponding author on reasonable request. The authors(s) declare that they have no competing interests.

During the completion of this work, Sara Farnbach was in receipt of a University of Sydney Faculty of Medicine Cross Cultural Public Health Research Award and a George Institute for Global Health John Chalmers Program Grant Scholarship; Maree L. Hackett was in receipt of a National Heart Foundation Future Leader Fellowship #100034 and an NHMRC Career Development Fellowship Level 2 APP1141328; Anne-Marie Eades was funded by NHMRC APP1117198 Centre of Research Excellence: Indigenous Health and Alcohol and 2018 Scientia Fellow UNSW. *Getting it Right: the validation study* was supported by National Health and Medical Research Council (NHMRC) Australia grant number APP101767.

SF leads this research including protocol development, conducting interviews and coordinating feedback from the group. JE and MH are SF's PhD supervisors and have supported protocol development and research conduct. A-ME, JF and GG have supported protocol development. A-ME and GG completed data coding of transcripts. BH, MS, KDM, GG, A-ME, JF and JE comprise the Advisory Group. All authors contributed to the manuscript.

We would like to acknowledge all the participating services and participants of *Getting it Right: the validation study* and this process evaluation for their contribution to this work. We also acknowledge the Investigators of the research project: Maree Hackett, Armando Teixeira-Pinto, Nick Glozier, Timothy Skinner, Deborah Askew, Graham Gee, Alan Cass and Alex Brown.

### 8.4 Conclusion

In this chapter I show that Indigenous-focused SEWB PHC research can be acceptable to staff and patients. The confidence of many staff involved with *Getting it Right* improved during the research when speaking to patients about research and SEWB, and
many patients were willing to and appreciated the opportunity to participate. This indicates that when adequately planned and supported, research can have benefit beyond the research project. Many patients found it acceptable to speak to adequately trained and culturally competent staff about their SEWB, contrary to the concerns of staff before the research started. In the next chapter, (9) I will explore novel themes and examine the role of resourcing in Indigenous-focused SEWB PHC research.

8.5 Addendum

This addendum discusses additional information that arose from this research around historical trauma and community preferences about data collection methods that was not included in this manuscript. I did not directly ask PHC staff about the impact of historical trauma during research and no staff mentioned it during interviews. However, while writing the manuscript and through discussions with co-authors I became aware of the potential impact of historical trauma on Indigenous researchers and therefore provide the following discussion.

8.5.1 Potential risk of historical trauma impacting on Indigenous research staff

In the manuscript I highlighted the need to discuss stress and burnout of research staff and this was also discussed during site training. For Indigenous PHC staff, it may also be appropriate to consider their risks within the context of historical trauma, which is increasingly being recognised as contributing to some of the poorer outcomes among Indigenous communities in colonised countries around the world.\(^{171,172}\) The risk of hearing traumatic stories that lead to secondary harm may be greater for staff with histories of trauma\(^ {173}\) demonstrating the importance of recognising and respecting past experiences during research.\(^ {75}\)

Historical trauma is defined as long-term population-level trauma from colonisation, war or genocide that manifests in those with a higher prevalence of social, psychological or physiological problems, even several generations after the original trauma occurred.\(^ {171}\) Early qualitative research exploring Indigenous Australians’ experiences of historical trauma\(^ {174,175}\) has indicated that trauma stemming from colonisation can be transmitted between and across multiple generations. Associational
research shows that families of parents who were removed from their families experience higher rates of emotional and behavioural difficulties\textsuperscript{176} and higher trauma symptom severity\textsuperscript{177} than families where no removal occurred.

Research involving Native Americans\textsuperscript{178} found that over half the American Indian adult participants reported being reminded of and thinking about their historical loss from colonisation at least occasionally, and this was correlated with higher levels of distress. There may be similar potential for distress in Australia’s Indigenous peoples. These risks should be considered during research to ensure that research does not harm staff, that staff have access to adequate support and to identify staff who are well prepared to hear traumatic stories (though this does not guarantee that the stories will not result in further trauma, called vicarious trauma).

There is minimal specific guidance for managing vicarious trauma of staff working in Indigenous-focused PHC services. However, related literature provides some guidance about potential strategies to minimise risk, such as providing counselling to staff to manage their own trauma history.\textsuperscript{179} During research, completing thorough ethical assessment, explicitly having a vicarious trauma safety protocol, training and supervision for research staff may be beneficial to minimise risk of harm.\textsuperscript{180}

8.5.2 Community members preferences of data collection methods

Feedback from community members indicated their preference for flexible data collection methods (such as yarning circles) during research. However, these methods may not always be feasible because discussing some issues (such as SEWB) in a group environment may be inappropriate. This demonstrates that the complexity of conducting Indigenous-focused research in PHC services still needs to be considered in relation the research topic, so realistic expectations, timelines and budgets are developed.
CHAPTER 9

PROCESS EVALUATION RESULTS: RESOURCING AND RESOURCE USE DURING RESEARCH

9.1 Introduction

In the last chapter (8) I showed that many PHC patients were willing to participate in SEWB research and that the confidence of some PHC staff when speaking to patients about research and SEWB improved during Getting it Right. In this chapter, I present more novel themes that arose during the process evaluation related to the role of ‘sufficient’ resourcing for the successful conduct of Indigenous-focused SEWB PHC research. This chapter includes the following publication:

Farnbach S, Gee G, Eades AM, Evans J, Fernando J, Hammond B, Simms M, DeMasi K, Glozier N, Hackett M. The role of resources in Aboriginal and Torres Strait Islander primary healthcare research: Process evaluation results (submitted)

9.2 Aims

In this chapter I aim to explore the process evaluation data relating to the role resources played during Getting it Right. I use grounded theory approaches (described in detail in Chapter 7) and triangulate semi-structured interview data, participant feedback data, study administrative data and field notes. This chapter is presented as a publication.

9.3 Results (publication)

What are the resourcing requirements for an Aboriginal and Torres Strait Islander primary healthcare research project?

OVERVIEW OF PUBLICATION

In this publication I explore and present results from the process evaluation related to resources in Indigenous-focused, SEWB PHC-based research.
What are the resourcing requirements for an Aboriginal and Torres Strait Islander primary healthcare research project?

* Sara Farnbach\textsuperscript{a}, Graham Gee\textsuperscript{b}, Anne-Marie Eades\textsuperscript{a}, John Evans\textsuperscript{c}, Jamie Fernando\textsuperscript{d}, Belinda Hammond\textsuperscript{e}, Matty Simms\textsuperscript{f}, Karrina DeMasi\textsuperscript{g}, Nick Glozier\textsuperscript{h}, Maree Hackett\textsuperscript{a,i} on behalf of the \textit{Getting it Right} Investigators

\textsuperscript{a} The George Institute for Global Health, PO Box M201, Missenden Road, Camperdown, New South Wales, 2050, Australia, University of New South Wales, Sydney 2052, Australia and The University of Sydney, New South Wales, 2006, Australia
\textsuperscript{b} Victorian Aboriginal Health Service, Victoria, 3072, Australia and University of Melbourne, Victoria, 3000 Australia
\textsuperscript{c} The University of Technology and The University of Sydney, New South Wales, 2006, Australia
\textsuperscript{d} The University of Newcastle, New South Wales, 2308, Australia
\textsuperscript{e} Nunkuwarrin Yunti of South Australia, South Australia, 5000, Australia
\textsuperscript{f} The Glen Centre (Ngampie), New South Wales, 2261, Australia
\textsuperscript{g} Aboriginal Medical Services Alliance Northern Territory, Northern Territory, 0801, Australia
\textsuperscript{h} Brain and Mind Centre and Central Clinical School University of Sydney, New South Wales 2052
\textsuperscript{i} The University of Central Lancashire, PR1 2HE, United Kingdom

* Corresponding author email: sfarnbach@georgeinstitute.org.au

9.3.1 Abstract

\textit{Objective and importance of the study}

To explore the role of resourcing and resources use during an Aboriginal and Torres Strait Islander primary healthcare research project.

\textit{Study type}

Process evaluation using grounded theory approaches to guide qualitative semi-structured interviews with primary healthcare staff and community members from primary healthcare services (participating services) involved in a national Aboriginal and Torres Strait Islander research project (N=500) named \textit{Getting it Right: the validation study}. 
**Methods**

Semi-structured interviews with thirty-five primary healthcare staff and four community members from nine of ten participating services. Interviews included questions about the resources needed to conduct the research project, including flexible reimbursement to participating services (allocated within services), human resources and reimbursement to research participants (vouchers). Qualitative data were triangulated with participant feedback (questions about the aPHQ-9 and free-text feedback collected during the research project), study administrative data (budgets, contracts, communication logs and ethics correspondence) and field notes kept by the interviewer.

**Results**

Most managers considered whether the reimbursement was sufficient to resource the research project within the participating service and the communities’ health needs, before becoming involved with the research. Reimbursement was allocated to research expenses (human resources and logistics) or non-research expenses (service operations, equipment and conference attendance costs). Most services opted to offer vouchers to compensate participants for their time, which staff considered was appropriate recognition of participants’ contributions and facilitated recruitment. Some staff described some potential unintended negative consequences from vouchers, including creating a welfare mentality or the wrong precedent. ‘Research champions’ emerged who advocated within participating services and with patients which facilitated the research project.

**Conclusion**

Primary care research requires adequate resourcing, which may vary for each participating service and community.

**Key words**

Primary healthcare; research; workforce planning

**Key points**

1. Indigenous-focused primary healthcare research must be sufficiently funded and resourced to be ethical and feasible.
2. Local decision-making processes about the allocation of research funding may maximise available funding and enhance capacity according to local priorities.

3. The use of participant vouchers in research requires careful consideration on a site-by-site basis. While some consider reimbursement recognises individual and community contributions, others have concerns about unintended negative consequences.

9.3.2 Introduction

Primary healthcare (PHC) research can inform culturally-appropriate care that contributes to Aboriginal and Torres Strait Islander (hereafter Indigenous) health. Research should be sufficiently resourced to be feasible and ethical. When insufficiently resourced, securing staff time to work on the research can be challenging, potentially delaying participant recruitment and achieving research targets.

Diversity across Indigenous communities and Indigenous-focused PHC services, (including size, funding, infrastructure and workforce) means each may have unique resource requirements. Flexible and sufficient resources are needed for research to be relevant, effective and culturally respectful. Sufficient resourcing may also facilitate compliance with the Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (hereafter Values and Ethics Guideline) by funding travel that may foster ethical relationships between external researchers and communities.

There is limited information available on what constitutes sufficient research resourcing, what specific resources are required and who, when and how decisions about resourcing should be made. The various approaches towards compensating research participants for their time and expenses indicates uncertainty about if and how participants should be compensated.

9.3.2.1 Aim

We present process evaluation results on the resourcing of a National Health and Medical Research Council (NHMRC)-funded Indigenous-focused PHC-based research project Getting it Right: the validation study (hereafter the research project)
conducted at ten Indigenous-focused PHC services (hereafter participating services) to determine the validity of a culturally-specific depression screening tool.

### 9.3.3 Methods

The research project and process evaluation methods have been described previously.\textsuperscript{113, 159} In brief, the coordinating staff member of the research project at each participating service approached staff and community members (purposive identification\textsuperscript{151}) to invite them to complete qualitative semi-structured grounded theory interviews with SF between November 2016 and June 2017 (after the research project was complete and before results were available), in a confidential setting, in-person at participating services or via the phone. SF is a female Registered Nurse (RN) and PhD candidate who has completed training in qualitative data collection, analysis and reporting. She was project manager of the research project and had existing relationships with staff and community members for between one and three years.

Process evaluation interviews were conducted using an interview guide, in three phases. SF and AME piloted the first interview guide. Interviews were transcribed verbatim. Data were managed using NVivo 10 for Windows software.\textsuperscript{160} Independent double coding of 10 (25\%) interviews was completed by co-authors (GG and AME) and interview reports were provided to all authors. Interview data were coded inductively to identify codes related to resourcing. A record of codes, their properties, interpretations, and feedback from authors were kept in memos, which were analysed and grouped into themes and integrated into the subsequent two interview guides. Codes were triangulated against the research project’s administrative data (budgets, contracts, communication logs and ethics correspondence), participant feedback (responses to questions about the aPHQ-9 and free-text feedback collected during the research), and SF’s field notes. Process evaluation interviews continued until all potential staff or community members who wished to, took part. Open coding of the final two interviews identified no new open codes, indicating data saturation.

The research project\textsuperscript{113} aimed to determine the validity of a previously developed,\textsuperscript{111} culturally-adapted depression screening tool for use by Indigenous people. The 10 participating services recruited 500 participants between 2014 and 2016. Each
participant completed two research interviews with staff members at the participating services. The study protocol\textsuperscript{113} was adaptive and participating services developed local recruitment processes, while core elements of the protocol were unchanged.

Resourcing included flexible reimbursement (hereafter reimbursement) provided to each participating service to compensate for staff time to recruit participants, conduct research interviews and complete study documentation. Reimbursement was provided on a per-completed-participant-basis, to allocate as they deemed appropriate, via the coordinating organisation (The George Institute). Reimbursement was for a 0.5 full-time equivalent Personal Support Package level two, for one year. Resourcing included one computer/tablet and WiFi dongle (when required) per participating service (to facilitate online data entry) and reimbursement for food/fuel vouchers to local supermarkets or food stores (hereafter vouchers) to offer to participants completing both interviews, as compensation for their time. Vouchers were provided at the discretion of participating service staff. Staff sometimes requested vouchers to be restricted from purchasing alcohol or cigarettes. Vouchers and the resourcing arrangements were approved by the NHMRC project grant process and ethics committees.

‘Patient’ includes PHC patients in general or before consenting to the research project and ‘participants’ are patients who have consented. Research expenses include research-related human resources (staff time) and logistics (transport and catering). Indigenous-focused PHC services include Aboriginal Community Controlled Health Services and Aboriginal Medical Services.\textsuperscript{183} This process evaluation was conceived, designed and conducted according to the Values and Ethics Guideline,\textsuperscript{7} received ethical approvals (presented in the protocol)\textsuperscript{113} was approved by participating services.

\subsection*{9.3.4 Results}

Interviews were completed with four community members (group interview) and 36 staff (34 individually and two as a group interview) including: managers (n=10), Aboriginal Health Workers (AHW) (n=9), Allied Health Staff (n=8), Research Coordinators (n=5), and General Practitioners, (GPs) (n=4) from nine of the 10 participating services. Staff at the tenth participating service chose not to participate in the process evaluation due to staff turnover and organisational change. Participant
demographics are presented in Table 7.3. Three themes and ten sub-themes related to resourcing and resources were developed from the data.

**9.3.4.1 Theme one: the influence of reimbursement on participating services and the research project**

Several managers reported that they considered the reimbursement when deciding whether to become involved with the research project (Table 9.2). Managers reported that the reimbursement was sufficient to resourcing for research expenses, and contributed to the participating services’ financial capacity. One manager at a service that had not conducted research previously reported:

We’ve knocked back a few research projects since ‘cause there’d be nothing in it for us … No staff involvement so there’s no potential for up skilling staff … We wouldn’t have been able to do it if there wasn’t money involved, it would’ve been a big drain on us. (Indigenous and non-Indigenous, males, managers, #34)

Alongside resourcing, many managers considered community priorities when deciding whether to take part and their view that research focused on depression was relevant to the needs in their community.

Some staff reported that reimbursement was allocated to research logistics or human resources (employing new staff or backfilling existing staff). When staff were hired/backfilled, recruitment targets were achieved in shorter timeframes (average 6 months) compared to when reimbursement was allocated elsewhere (average 9.5 months).

Some staff reported reimbursement being allocated to logistics that facilitated the research. For example, at one participating service, funds were used to host community lunches and on these occasions, staff spoke with attendees about the research project.

At several services reimbursement funded research-related transport expenses which staff reported gave them flexibility to complete research interviews in an environment where patients were comfortable (at the park or their home), at ease and more likely to participate. According to these staff, participants were more honest in a non-clinical environment, which may lead to more accurate research findings. In participant
feedback, 97% reported feeling comfortable answering the questions and none provided free-text feedback about the location of the research.

Some staff reported reimbursement being used for non-research expenses (service operations, purchasing equipment and conference attendance costs for staff). Many reported this benefited the service:

We bought a[n] electric up-down bed, a really expensive one that we didn’t have in our budget, so that was really good ... we halved it [the money], the clinic got half and the research department got half. (Non-Indigenous, female, manager, #27)

Some staff reported that when not allocated to research, there was limited human resources available to the research, creating pressure for staff to complete the research alongside existing duties. One manager reported that some staff were dissatisfied because they believed some funding should be allocated toward equipment used by the team who worked on the research and suggested that funding of specific resources may have enhanced staff satisfaction because:

Some of the other health workers thought it was unfair and voiced that, ‘We’ve done this work and we didn’t get anything out of it.’ (Non-indigenous, female, manager, interview 18)

Sometimes resources were not available to staff during the research. This was most commonly insufficient human resources. At times, access to a computer/tablet was limited or the internet connection was unstable (via the WiFi dongle provided).
Table 9.1 Theme one – the influence of reimbursement on participating services and the research project

<table>
<thead>
<tr>
<th>Subtheme</th>
<th>Description of subtheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managers considering research involvement</td>
<td>Prioritising resources required to conduct research</td>
</tr>
<tr>
<td></td>
<td>Prioritising community health priorities</td>
</tr>
<tr>
<td>Allocating reimbursement within the service</td>
<td>Prioritising research expenses (human resources and logistics)</td>
</tr>
<tr>
<td></td>
<td>Prioritising non-research expenses (service operations, equipment and conference attendance costs)</td>
</tr>
<tr>
<td></td>
<td>Allocation causing tensions between staff</td>
</tr>
<tr>
<td>Reimbursement impacting on research conduct</td>
<td>Reimbursement providing resources for research</td>
</tr>
<tr>
<td></td>
<td>Reimbursement enabling staff to try flexible approaches during recruitment</td>
</tr>
<tr>
<td></td>
<td>When not allocated to research expenses, insufficient resources were available for research</td>
</tr>
</tbody>
</table>

9.3.4.2 Theme two: the influence of human resources on the research project at participating services

Staff spoke of human resources as staff ‘capacity,’ or ‘availability to work on the research project’ (Table 9.3). Two managers reported considering human resource capacity before agreeing to take part and another mentioned they would consider it more carefully in future, because more staff time was required for the research than was originally expected. Most staff reported that it took longer than expected to reach the recruitment target and some stated this was due to insufficient human resources available for the research. Review of the contracts between the participating services and The George Institute showed that recruitment took longer than the originally contracted timeframe (3 months) at eight participating services (average = 8 months).

Many staff described ‘research champions’ who informally emerged and advocated for the research project within the participating service and with patients. Identifying research champions was not specified in the study protocol. Staff reported that research champions introduced the research project to the board/management/other staff, and encouraged them to take part and advocated for the research once it was underway:

I was probably one of the driving forces behind actually keeping everyone on track, by actually organising things on the ground. That constantly [sic constant] reminding, chasing, finding out where we’re up to. (Non-indigenous, female, manager, #16)
Multiple staff reported advocating for the research project with patients. In these instances, the trust established from their relationships with patients appeared to give staff confidence to discuss the research. This AHW described how they described the research:

I encouraged them that it was for a good cause. So this tool could be used, hopefully by GPs in the future, to help our people … I explained what it was about and why we’re part of it. (Indigenous, male, AHW, #33)

Existing research staff (with all/part of their workload allocated to research) were employed at three services during the research project. Staff perspectives varied about whether research staff should be existing or newly hired staff for research. Some reported that new staff could arrange logistics (reducing burden on existing staff); while others reported that existing staff with relationships with patients could facilitate opportunities to discuss research, and make patients feel comfortable:

I’d interviewed a couple, they said they wouldn’t have done it if they didn’t know me ‘cause they were asked by someone else and they said no, but yes because they knew me and had a relationship with me. (Non-indigenous, female, RN, #21)

Participant feedback verified this perspective. Many reported that they preferred to complete the research with someone who they knew:

I felt comfortable answering the questions because I was talking with someone I trusted, if it was a stranger I would feel different. (Indigenous participant, male, 71 years)

Staff reported several external unexpected human resource challenges to the research project, including high staff turnover, staff shortages and heavy workloads. Staff reported frustrations with these challenges and that they contributed to delays achieving recruitment targets.
Table 9.2  Theme two – the influence of human resources on the research project at participating services

<table>
<thead>
<tr>
<th>Subtheme</th>
<th>Description of subtheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human resource requirements for research</td>
<td>Managers assessing human resource capacity when considering research</td>
</tr>
<tr>
<td></td>
<td>Insufficient human resources available for research</td>
</tr>
<tr>
<td>Research champion</td>
<td>Champion advocating for the research within participating service and with patients</td>
</tr>
<tr>
<td></td>
<td>Champions are needed to drive research</td>
</tr>
<tr>
<td>Human resource challenges</td>
<td>High turnover</td>
</tr>
<tr>
<td></td>
<td>Staff shortages</td>
</tr>
<tr>
<td></td>
<td>Heavy workloads</td>
</tr>
</tbody>
</table>

9.3.4.3 Theme three: the consequences of offering vouchers to reimburse research participants

Eight participating services opted to offer participants vouchers. Most staff reported they facilitated recruitment, however, some identified potential unintended negative consequences from vouchers, resulting in their ambivalence about voucher use (Table 9.4). Many staff referred to vouchers as ‘incentives’, ‘thank you gifts’ ‘rewards’ or ‘payments’.

Most staff reported that vouchers facilitated participant recruitment by sufficiently compensating participants for their time and for discussing personal information. Some staff reported that patients are routinely offered vouchers after annual health checks or research participation and this was problematic because it resulted in an expectation to be offered a voucher after research participation. At one participating service, vouchers were not used initially because staff opted to try recruitment without them. However, part way through the research, staff decided to use vouchers and reported they facilitated recruitment. Many staff reported that vouchers were valued and appreciated by participants:

A gift voucher always helps them out … They love it. Just for a $25 gift voucher, they’ll [say], ‘cool, no worries.’ Makes a big difference. (Indigenous, female, AHW, #4)

Some staff considered patients were motivated to participate by the research topic, their existing relationship with the participating service/staff or they did not expect vouchers
because research was viewed as part of the services’ usual program. Some staff chose not to mention the vouchers until after research interviews and some participants were surprised when offered a voucher:

Some people actually turned away the vouchers, they said, ‘No thanks, I didn’t do it for that.’ (Indigenous, male, AHW, #5)

These staff did not specify why these participants chose to participate.

Many staff reported that vouchers formally recognised patients’ contributions, time and their willingness to share sensitive information:

I mean you’ve got [sic] to value people’s time but also … that they’re prepared to talk about something that’s so personal and contribute to that research, so I think it’s needed. (Indigenous and non-Indigenous, males, managers, #34)

A few staff suggested that vouchers were positive because they provided healthy food or financial support and this was important because some patients had financial challenges.

Some potential unintended negative consequences from offering vouchers were reported by staff, including creating a ‘welfare mentality’ or the vouchers setting the wrong precedent (patients will ‘get something’ for research participation), which could be harmful for future research or create the wrong motivation for PHC attendance. One AHW stated:

It’s a slippery slope with those incentives, [vouchers] maybe that’s the reason why some people did the research. It’s linked with that welfare mentality that’s been created for our mob. Stemming back to those old ration days on the mission, it’s really difficult terrain. (Indigenous, male, AHW, #10)

This AHW suggested that PHC and researcher attendance should be encouraged for ‘good health and good health of your family.’ Many staff reported ambivalence for the reasons already described. Two staff described that vouchers could potentially be considered a coercion or bribe. No participant feedback was provided about vouchers.
Table 9.3  Theme three – the consequences of offering vouchers to participants on the research project

<table>
<thead>
<tr>
<th>Subtheme</th>
<th>Description of subtheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieving research targets</td>
<td>Vouchers facilitated recruitment and were valued</td>
</tr>
<tr>
<td></td>
<td>Vouchers did not facilitate recruitment</td>
</tr>
<tr>
<td>Patients benefiting from participation</td>
<td>Vouchers acknowledge patients’ contribution to research</td>
</tr>
<tr>
<td></td>
<td>Vouchers bring resources/food into the community</td>
</tr>
<tr>
<td>Considering unintended negative consequences</td>
<td>Vouchers setting the wrong precedent</td>
</tr>
<tr>
<td></td>
<td>Vouchers creating a welfare mentality</td>
</tr>
<tr>
<td>Ambivalence towards providing vouchers</td>
<td>Considering positive and negative consequences of using vouchers</td>
</tr>
</tbody>
</table>

9.3.5  Discussion

As far as we are aware, this is the first Australian research directly exploring the role of resourcing and resources in Indigenous-focused PHC-based research. These results show that sufficient resources and time\(^75\) were available and addressed challenges that commonly arise during research (staff turnover, staff shortages and heavy workloads\(^{64, 91, 94, 184}\)), without them impacting on overall research targets. The flexible financial arrangements may have enhanced capacity during research (by funding site-specific models to employ/backfill staff\(^75\)) or beyond research (by funding non-research activities: service operations, equipment and conference attendance costs).\(^7\) When allocated to non-research expenses the need to ensure sufficient resources were available and for open discussion with staff about these decisions was apparent.

These results demonstrate how research can build capacity when resource-allocation decisions are made at PHC services. Although capacity building is often a focus during Indigenous-focused research, commonly reported activities include, employing staff; enhancing skills, capabilities or careers of Indigenous staff;\(^{72, 75}\) or developing non-Indigenous researchers’ cultural competence.\(^{38, 72, 75, 185}\) Our findings demonstrate opportunities for research to build capacity through locally-driven decision-making processes.\(^70\)

The emergence of research champions as advocates demonstrates how key staff with an understanding of the ‘lay of the land’ can facilitate research by enhancing community
involvement\textsuperscript{75} and driving research activities. Others suggest that local research champions had local skills and expertise which increased data accuracy,\textsuperscript{61, 167} drove data collection\textsuperscript{186} or facilitated communications with external researchers.\textsuperscript{187} Local research champions, identified early, may facilitate research and they should be formally acknowledged for their unique skills through academic and professional avenues, such as inclusion as authors, recognition in position descriptions/remuneration and provision of dedicated time for research.

According to the National Statement for Health Research, participant vouchers are acceptable:

> It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking … However, payment … or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable.\textsuperscript{37}

While offering participants’ vouchers is often reported during Indigenous-focused research,\textsuperscript{81, 88, 95, 100, 188, 189} to our knowledge this is the first research explicitly exploring staff perceptions of vouchers during research. Research delivering benefit is a well-established key principle during Indigenous-focused research.\textsuperscript{7, 37, 75} These findings suggest that participant vouchers may deliver some benefit to individuals and communities. The concerns raised by staff about vouchers creating problematic expectations,\textsuperscript{190} coercing participation\textsuperscript{191} or causing undue inducement\textsuperscript{192} are not unique to Indigenous research. Although previous research suggests that vouchers do not create problematic expectations,\textsuperscript{190} training of researchers should include how to discuss vouchers, and ways to mitigate potential unintended negative consequences.

Previous research\textsuperscript{193} has shown that Indigenous people consider community-level benefit as the main motivating factor for research participation. We support this finding as some staff reported that some patients were motivated by the research topic, did not accept the vouchers, or were unaware of the vouchers until after the research, indicating they may have prioritised community-level benefit when considering participation and the vouchers did not influence their decision.

We suggest that although identifying sufficient research funding can be challenging,\textsuperscript{64} it is possible within the current systems. Local decision-makers should determine what
resources are needed, and how they are allocated within their service or community, based on a local assessment of resource priorities. Flexible resourcing may maximise resources, provide tangible benefit (in addition to benefits arising from results) and enable PHC services to build opportunities for research champions.

We have identified examples of how sufficient research resourcing facilitates research that addresses the Values and Ethics Guideline\(^7\) (Appendix 19). Flexible reimbursement meant staff could modify approaches according to communities’ values and aspirations (reciprocity); may have enhanced local capacity during (by employing/backfilling staff) and beyond the research (by funding non-research expenses) (reciprocity); and demonstrated respect and equality by compensating services for the costs associated with participating.

The lead researcher’s (SF) roles as researcher and project manager of the research project enabled open discussions during staff interviews and enhanced data collection, analysis and interpretation through an in-depth understanding of the research and surrounding events. These relationships may have influenced staff to provide predominantly positive responses about the research project. With this in mind, negative responses were specifically sought from the data and are highlighted in this paper.

These findings are based on the experiences from nine PHC services from a range of communities. We acknowledge they may not be generalisable to other Indigenous communities and that patients’ perspectives were limited to elicited and spontaneous written feedback during interviews and participants were not specifically asked about resourcing or vouchers.

### 9.3.6 Conclusion

This research confirms the importance of sufficient resourcing during research, which should enhance capacity, recognise diversity and be respectful. How research resources are allocated and participants compensated should be determined by the communities where research is conducted, based on the human capacity needed for research, existing workloads and other capacity needs and priorities of services, and patients.
9.3.7 Acknowledgement

We would like to acknowledge all the participating services and participants of Getting it Right: the validation study and this process evaluation for their contribution to this work. We also acknowledge the Investigators of the research project: Maree Hackett, Armando Teixeira-Pinto, Nick Glozier, Timothy Skinner, Deborah Askew, Graham Gee, Alan Cass and Alex Brown.

9.4 Conclusion

In this chapter I explore the role of resourcing and resources used during Getting it Right and show that sufficient resources were available to address many of the challenges that arose during the research. This research demonstrates how funding can be maximised and capacity can be enhanced beyond the immediate research, when decisions about resource allocation are made locally. Important concerns were reported by some staff about the potential for vouchers to create problematic expectations, indicating that caution should be used when using vouchers in research, but the decisions about their use should remain with community.

In the next chapter (10), I will compare and contrast staff perspectives collected during the process evaluation with the systematic review findings (Chapter 2), the case study (4 to 6) to identify common themes relating to approaches and enablers to conducting high-quality, culturally-appropriate Indigenous-focused SEWB PHC research.
CHAPTER 10
SUMMARY AND RECOMMENDATIONS

My aim in this thesis was to identify approaches and enablers to the conduct of high-quality, culturally-appropriate Indigenous-focused SEWB PHC research completed by research teams, by exploring research from multiple perspectives, including scientific and ethical viewpoints, from researchers, staff and patients, as well as my own. To achieve this, I systematically reviewed the literature; presented Getting it Right as a case study of an Indigenous-focused SEWB PHC research project; analysed the research using scientific and ethical criteria; and spoke to staff about their experiences with the research.

Getting it Right provides an example of a research project that was evaluated as high quality, using standard scientific and ethical criteria; and the conduct and results of Getting it Right appeared to be well accepted by staff and patients at participating services. This demonstrates that scientific rigour can be maintained, community perspectives can be incorporated and research can be conducted in a way that is culturally acceptable. Getting it Right and the process evaluation may also deliver community-level research outcomes by providing evidence about the validity of an original culturally-adapted, freely-available and culturally-acceptable depression screening tool for use by Indigenous people across Australia.

Several key enablers to high-quality, culturally-appropriate PHC SEWB were identified, and some confirm what is already known about conducting such research. Establishing strong relationships within the research team can facilitate the design and development of research to ensure that it is acceptable, feasible and culturally appropriate. When Indigenous people are part of initial discussions about the research, and representatives from multiple levels within communities are involved, the research is more likely to succeed. Involving community members will assist with determining locally relevant priorities and acceptable designs, and this may encourage staff and patients to participate. Similarly, it is pertinent that locally-based staff are involved, those who can advocate and drive the research ‘on the ground’, and managers who can create an environment that is conducive to research.
Getting it Right included Indigenous-focused PHC services where some staff chose to participate after being introduced to the research upon completion of its developmental stage. Their participation was reported as being motivated by three factors: (i) relevance of the research topic within participating communities; (ii) provision of adequate resources to complete research; and (iii) potential benefits to staff and services, including opportunities to increase their skills and other capacity development. It is worth noting that these communities were not directly involved in the development stage, however, other Indigenous researchers and representatives were; which may have contributed to the acceptability of the research. Assessment of the impact of the results of the research (translation and implementation of research findings) is beyond the scope of this thesis.

In-depth prospectively planned examinations of the conduct of research (as conducted in this thesis), including descriptions of the challenges implementing research protocols, provide opportunities for research teams to share and learn from others’ experiences. This contribution to the evidence base on ethical and acceptable research facilitates an environment where research can contribute to culturally-appropriate PHC and is in keeping with the Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.7

Overall, it appeared that interested Indigenous-focused PHC services were well positioned to conduct SEWB research. However, staff must be provided with adequate training, support, resources and time to prepare for research. Flexible approaches and timeframes (such as the adaptive protocol used in Getting it Right) were shown to enable Getting it Right. Other important examples of flexible processes identified in the systematic reviews include using participatory action research and social ecological research (for cultural sensitivity) and having flexible randomisation procedures in randomised controlled trials. Sufficient and flexible resourcing arrangements appear necessary for research to be feasible and have the added benefit of enhancing local capacity when allocated according to local priorities.

Together, these key enablers contributed to a respectful approach to research, which were developed as a common theme across the systematic review, was reported by staff in Getting it Right, and is stated in the Values and Ethics Guideline.7
10.1 Strengths and limitations of this research

A strength of this thesis is the in-depth understanding I have of Getting it Right, gained over four years, which I could draw on during the reflective and evaluative case study and the process evaluation. My long-term involvement also provided me with the time to develop relationships with staff at 10 participating services, which enhanced interview discussions, data collection, analysis and interpretation. However, these relationships may have caused staff to avoid reporting negative experiences during process evaluation interviews. The process evaluation was further enhanced by the involvement of the Indigenous Advisory Group and CI Gee as a second coder (who was also a member of the Getting it Right SC), who together provided multiple perspectives about the research. These contributions contributed to the analysis and interpretation of the data and provided cultural oversight of the research. Throughout this thesis, the perspectives from participants are limited to feedback provided during Getting it Right and to staff opinions of participant and/or patient perspectives; this may limit our understanding of their perspectives. Likewise, researchers’ perspectives were collected from reviewing the literature (where researchers formally report research) and from my own reflections as a researcher, limiting the information presented in this thesis about the experiences of researchers. Further information may be gained from speaking directly with these groups. However, this was beyond the scope of this research.

Findings from the systematic review were restricted to information reported in the literature and my interpretation of some of the actions described; journal word counts may have limited the ability of authors to report processes they followed during the research.

Some challenges were identified when conducting Getting it Right according to traditional academic standards while also being culturally acceptable and feasible. For instance, the varied approaches to recruitment (through high-risk clinics, community barbecues and via the male only Residential Rehabilitation Service) and some non-consecutive recruitment at two services could have contributed to a selection bias, by identifying an over representative sample of people who have a higher risk of experiencing depression than the general population, or more males. However, the spread in demographics and illness burden across participants and services indicates
selection bias was unlikely to have occurred. In addition, inclusion of the Residential Drug and Alcohol Service may have led to an underrepresentation of reporting of the challenges conducting research in Indigenous-focused PHC services because of differences between this type of service and PHC services that may have changed how the research operated. For instance, Residential Rehabilitation Services may have more time available to conduct research, different service delivery priorities and workflows to PHC services (e.g. participant interactions via residential stay compared with health appointments at PHC).

The longer time spent by patients at the Residential Rehabilitation Service during residential stay may have contributed to the relationships between staff and patients, potentially making patients more likely to participate (if they felt more comfortable with the staff). These relationships had potential to introduce a social desirability bias, where participants answered questions in a way that they perceived may be viewed as favourable by the interviewer. The process evaluation highlighted the importance of existing relationships on research participation, indicating this may have occurred.

The SC discussed and agreed that it was important to respond to the request to include this service as a participating service in order to respond to community priorities and preferences. Including these varied approaches and settings could also be considered a strength as it indicates that the aPHQ-9 may be used in different settings (e.g. in PHC, PHC-led community events and in Residential Rehabilitation Services). These deviations from traditional academic standards appear to be necessary to complete research that is culturally acceptable and feasible.

**10.2 Recommendations arising from this thesis**

**10.2.1 Recommendations for research**

In this thesis, I have shown that it is possible to conduct high-quality, culturally-appropriate research that is acceptable to staff and patients of Indigenous-focused PHC services. These results identify approaches and processes that should be considered when conducting such research. Throughout this thesis, the document by Jamieson et al. has provided a useful set of principles to guide Indigenous-focused SEWB PHC
research. In this section, I describe and highlight the implications that findings from this thesis have on research, clinical practice and policy.

Where these approaches confirm recommendations made in the Jamieson et al\textsuperscript{75} document these are \textit{italicized} below:

1. \textit{Flexible processes}\textsuperscript{75} such as adaptive protocols and financial arrangements can deliver research that meets community and academic priorities. These processes can also enable development of localised recruitment approaches that can facilitate progress towards research targets.

2. \textit{Building respectful relationships within a research team}\textsuperscript{75} can enable research that is relevant to local priorities, is appropriate and feasible, as well as foster a productive research environment by enhancing communications within the team so potential challenges can be identified and addressed. Such relationships can be built during visits by external researchers to communities and PHC services, where open discussions are encouraged (to enable them to learn about the local context and for staff to consider and raise concerns), emphasising the unique and valuable skill set that local staff bring to research. Through specific steps such as acknowledging the cultural and historical uniqueness of communities (e.g. commissioning local artwork, engaging with local community events and formally acknowledging Elders and Country) respectful relationship can be achieved.

3. \textit{A focus on building capacity of individuals, organisations and communities during research}\textsuperscript{75} includes:

   a. \textit{Identifying local research champions}\textsuperscript{75} who are interested in research can provide opportunities to develop research skills and drive research towards local priorities, customs and protocols. Existing and unique skills that champions bring concerning the 'lay of the land'\textsuperscript{75} should be built on\textsuperscript{52} and formally recognised through academic and professional avenues (through authorship, in position descriptions and appropriate remuneration).

   b. Approaches that facilitate shared learning within a research team, including two-way\textsuperscript{79, 80, 85, 86, 89, 97} processes to develop the cultural competence of non-Indigenous researchers, and local research skills.
4. All Indigenous-focused research should have Indigenous representation\textsuperscript{75} and research teams should seek to involve communities in all stages of the research (from design and development through to data interpretation and translation). Research teams should also consider and identify opportunities for communities to become involved at all stages of the research.

5. Research teams should document and share the processes they follow during the research through publishing study protocols and their experiences, including modifications to research designs, resources involved, unexpected consequences arising from the research and research processes used (e.g. culturally-appropriate approaches to informed consent). Sharing such information will contribute to the evidence base and may facilitate more high-quality, culturally-appropriate research and minimise the risk of repeated mistakes.

6. Adequately trained, culturally-competent staff should be identified to conduct the research, or researchers should provide adequate training and support to culturally-competent staff considered suitable to be involved with research by the PHC service. The identification of these staff by PHC services\textsuperscript{75} can facilitate research participation and progress towards recruitment targets.

7. The wellbeing of research staff should be considered during the research, such as ensuring access to self-care practices, supervision, therapy and opportunities to debrief. Indigenous staff should have autonomy to manage cultural pressures.

8. Research planning should include the development of clearly defined research safety protocols for staff to follow during research, which cover their safety and that of participants.

9. Sufficient time and resources to compensate for travel and staff costs should be identified, including funding for research teams to meet regularly to enable them to share stories, celebrate successes and address challenges.\textsuperscript{75} Information on realistic expectations about funding requirements should be stated in research funding applications and granted by funding bodies.

10. Realistic assessments of human resource requirements for each research project and the availability of staff should be made before and during the research to ensure necessary resources are available to achieve research targets and minimise stress on staff.\textsuperscript{75}

11. Researchers should be encouraged to critically reflect on their research practices, especially when researching cross-culturally,\textsuperscript{24,145} and continue to develop their cultural competence.
12. Further qualitative research is needed to explore the experiences of Indigenous people presenting with depression. Research should also focus on factors that protect and strengthen SEWB (such as connection to land, culture, spirituality and ancestry, kinship and self-determination).

10.2.2 Implications of the Getting it Right results

As the first culturally-adapted, nationally-validated, freely-available and culturally-acceptable depression screening tool, the aPHQ-9 provides a starting point for measuring the true prevalence of depression across Indigenous communities, and may be useful to PHC services if they are planning and implementing strategies to prevent or manage SEWB problems by providing a culturally-appropriate screening measure. The results go some way to addressing the lack of culturally-appropriate resources for depression in Indigenous populations and should be considered as an assessment tool in the Australian Medicare Benefits Schedule (e.g. Health Assessment for Aboriginal and Torres Strait Islander people) and in SEWB guidelines. Additionally, PHC services appear to be an appropriate setting to screen, assess, prevent and treat depression, and clinicians should be supported to do so as part of their routine clinical practice.

Following on from Getting it Right, further consultation is needed to inform the next steps from the research based on community-identified priorities. This may include an implementation study to prevent and manage depression.

10.2.3 Recommendations for primary healthcare clinical practice and policy

Appropriately-trained, culturally-competent PHC staff should be encouraged to complete screening for SEWB problems through the following means:

1. Ongoing staff training about approaches to culturally-appropriate SEWB screening, assessment and depression treatment options.

2. Access to culturally-appropriate referral and treatment options for people who are identified with SEWB problems. Evidence-based, culturally-appropriate management guidelines are needed.

3. Adequate time allocated for conversations about SEWB to take place, and to provide follow-up care for people who are identified with SEWB problems.
The following recommendations about research policy can be made, and the principles described by Jamieson et al\textsuperscript{75} and in Values and Ethics Guideline\textsuperscript{7} should be addressed during research (including the consideration of recommendations arising from the review\textsuperscript{38,135} of the Guideline\textsuperscript{7} [when they become available]):

1. Funding should be made available to Indigenous-focused PHC services to develop a network of research champions who can drive research within their community. This funding should include a budget for training (face-to-face onsite and offsite, as required) to establish ongoing research positions and to cover travel and logistical costs. This network may facilitate the success of large-scale research projects (that contribute to the national evidence-base) and contribute to the development of research capacity within Indigenous-focused PHC services.

2. Opportunities to improve efficiencies and coordination within PHC and research projects should be identified to maximise available funding. For example, PHC services where multiple projects are underway concurrently (as was the case in several PHC involved with \textit{Getting it Right}) there may be opportunities to share resources, training and travel costs between projects.

3. The items identified in Section 10.1.1 should be considered during the review process and when deciding allocation of funding for Indigenous-focused PHC SEWB research. Incorporating these items may require the allocation of larger budgets or developing research designs that are modified from traditional research methods (e.g. from randomised to non-randomisation designs).

4. Academic processes may need to be modified to enable researchers to adequately adapt and report steps taken to increase the cultural acceptability of research. For example, journals should consider extending word counts, and systematic and other reviews should include criteria to determine the cultural acceptability of the research (such as criteria used in this thesis or suggested by other researchers\textsuperscript{136, 137}). This will also provide information about the time and resources involved with conducting such research, to inform future research projects.

5. Research should be funded through to the translation of research findings, and researchers should be encouraged to pursue policy changes based on their research results (if results indicate a policy change is appropriate).

6. Research can provide evidence to assist Indigenous-focused SEWB PHC services to evaluate programs, respond to community needs and compete for funding. Given this, and the potential benefit to individuals and services, sufficient
funding, resources and training should be provided to Indigenous-focused PHC services to participate in research as a core part of their work. Research activities should be captured during routine reporting by PHC services to funding agencies (to adequately recognise the variety of work completed by these services).

7. Policy should be informed by qualitative research to ensure it is culturally appropriate and addresses community priorities.

10.3 Concluding remark

In this thesis I have demonstrated that high-quality, culturally-appropriate Indigenous-focused SEWB PHC research is possible, acceptable, can result in important evidence to inform clinical practice, and is a priority for PHC staff and patients.

<table>
<thead>
<tr>
<th>Because we all know there are issues, and what can we do to make it better?</th>
</tr>
</thead>
<tbody>
<tr>
<td>We need to have the facts. We need to have the data.</td>
</tr>
<tr>
<td>We need to do research, to make things better.</td>
</tr>
<tr>
<td>(Indigenous, male, AHW, #33)</td>
</tr>
</tbody>
</table>

Research is highly relevant to my work because, if you don’t have the direct evidence that things are beneficial or potentially may even have a negative effect, then it’s hard to be able to recommend things to people … So I think research has an essential part to play, if done correctly.

| (Indigenous, male, GP, #35) |
References


20. Grieves V. Aboriginal Spirituality: Aboriginal philosophy, the basis of Aboriginal social and emotional wellbeing (Discussion Paper No. 9). Darwin: Cooperative Research Centre for Aboriginal Health; 2009.


38. Australian Institute of Aboriginal and Torres Strait Islander Studies and The Lowitja Institute. Researching right way. Aboriginal and Torres Strait Islander Health research ethics: A domestic and International Review. 2013.


72. The Lowitja Institute. Changing the narrative in Aboriginal and Torres Strait Islander health research: Four cooperative research centres and the Lowitja Institute: the story so far. Melbourne: The Lowitja Institute; 2017.
73. National Health and Medical Research Council. The NHMRC Road Map II: A strategic framework for improving the health of Aboriginal and Torres Strait Islander People through research. 2010.
76. Couzos S, Lea T, Murray R, Culbong M. ‘We are not just participants – we are in charge’: The NACCHO ear trial and the process for Aboriginal community-controlled health research. Ethnicity & Health. 2005;10(2):91-111.
135. The Lowitja Institute, Australian Institute of Aboriginal and Torres Strait Islander Studies. NHMRC – Aboriginal and Torres Strait Islander Health Research Ethics Evaluation [Consultation Paper]. 2013.
141. Merriam S, Tisdell E. Qualitative research: A guide to design and implementation: John Wiley and Sons; 2015.


APPENDICES

APPENDIX 1: DEFINITIONS AND ACTIONS/PROCESSES IDENTIFIED RELATING TO THE VALUES AND ETHICS GUIDELINE

Table A1 presents definitions of the values described in the Values and Ethics Guideline and examples of potential actions/processes relating to each value, as used during the systematic review of Indigenous-focused SEWB PHC research (Chapters 2 and 3). (Additional file 1 from publication 1).

Table A1  Definitions and potential actions/processes that relate to the Values and Ethics Guideline

<table>
<thead>
<tr>
<th>Reciprocity: Research that demonstrates inclusion, recognises partners’ contributions or ensures that research outcomes include equitable benefits of value to communities and individuals</th>
<th>Example of potential action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential action</td>
<td>Example of potential action</td>
</tr>
<tr>
<td>Demonstrated intention to contribute to the advancement of the health and wellbeing of participants and community/ies</td>
<td>Implementation of research findings at participating PHCS e.g. incorporation of validated screening tool into medical software</td>
</tr>
<tr>
<td>Research responding to regional, jurisdictional or international priorities, or community-identified need</td>
<td>A PHCS Health Board expressing the need for research to develop tailored SEWB strategies for adolescents in their community</td>
</tr>
<tr>
<td>Nature of the benefit to community/ies, including demonstration of discussions related to benefits prior to approval</td>
<td>Documentation of discussions between researchers and a PHCS Health Board (prior to approval) concerning the obligations and potential benefits of participation in the research</td>
</tr>
<tr>
<td>Demonstrated willingness to modify research according to the community/ies values and aspirations</td>
<td>Altering research design from a RCT to a non-randomised design following community concerns about the fairness of randomisation</td>
</tr>
<tr>
<td>Research processes that enhance capacity of the community/ies beyond the research</td>
<td>Training and involvement of a PHCS staff member with minimal research experience in research design, data collection and analysis to develop the staff member’s skills</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Respect: Research that acknowledges and affirms the rights of people to have different values, norms and aspirations, is not blind to differences, recognises the contributions of others to the research and its consequences</th>
<th>Example of potential action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential action</td>
<td>Example of potential action</td>
</tr>
<tr>
<td>Decision-making processes that acknowledge the diversity of individuals and community/ies</td>
<td>Invitation and involvement of PHCS staff members from several communities as members of the research advisory committee</td>
</tr>
<tr>
<td>Acknowledgement of the contribution of individuals and communities</td>
<td>Inclusion of PHCS staff members involved in the research as authors on publications related to the research</td>
</tr>
<tr>
<td>Efforts to minimise the effect of difference blindness’</td>
<td>Adaptation of an app to improve cultural-appropriateness and relevance</td>
</tr>
<tr>
<td>Incorporation of Indigenous knowledge and experience</td>
<td>Indigenous PHCS staff members guiding the development of a wellbeing program for implementation and evaluation at a PHCS</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Demonstration of negotiation of agreements about ownership and rights to intellectual and cultural property</td>
<td>Community and researchers jointly conducting research into Traditional Bush Medicine, where an agreement is described that protects and maintains Community ownership of intellectual and cultural property arising from the research</td>
</tr>
<tr>
<td>Processes of reaching agreements that demonstrate engaging with local values and/or processes</td>
<td>Following PHCS request, researchers present/discuss research idea with the PHCS Health Board(^a) (local process), and/or modification of the research according to local preference (local values)</td>
</tr>
<tr>
<td>Community/ies expressed satisfaction with research agreements and processes</td>
<td>Approval from the PHCS Health Board(^a) for the conduct of a research study at the PHCS</td>
</tr>
<tr>
<td>Agreements that include data management, publication arrangements and where identity of participants is protected</td>
<td>A contract involving researchers and PHCS that includes: data management, publication arrangement and protection of community and individual identity</td>
</tr>
<tr>
<td>Use of study methods and processes that recognise different values, norms and aspirations</td>
<td>Staggered start up of research sites demonstrates use of research methods that that recognise different values, norms and aspirations</td>
</tr>
</tbody>
</table>

**Equity: Research that recognises the equal value of all people involved in research, distributive fairness and justice**

<table>
<thead>
<tr>
<th>Potential action</th>
<th>Example of potential action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demonstration of equality between individuals, communities and researchers during the research process</td>
<td>Process to gain input from PHCS Health Board(^a) and/or staff members to ensure interpretation of research findings are correct</td>
</tr>
<tr>
<td>Demonstration of community/ies’ understanding (and expressed satisfaction) with the research, its potential benefits and their distribution. This includes prior to research the provision of information to the community in a way that is understood and usable</td>
<td>Researchers attending PHCS Health Board(^a) meeting/s, where all aspects of a potential study are discussed, prior to the provision of consent for the PHCS to participate in the study</td>
</tr>
</tbody>
</table>

**Responsibility: Research that does no harm to individuals and communities and the things that they value, or processes that ensure researcher accountability to individuals, families and communities**

<table>
<thead>
<tr>
<th>Potential action</th>
<th>Example of potential action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demonstration of researcher transparency including negotiations related to research purpose, methodology, conduct and dissemination of findings</td>
<td>Documentation of upfront communications between researchers and PHCS Health Board(^a) members related to expected timeframes for the research</td>
</tr>
<tr>
<td>Establishment of mechanisms to provide ongoing community review of the research</td>
<td>Regular meetings between researchers and PHCS Health Board(^a) members throughout the research to monitor and review its progress</td>
</tr>
<tr>
<td>Demonstrated mechanisms to provide feedback to communities related to expressed concerns, values and expectations (community expressed need is a requirement)</td>
<td>Presentation of research findings identified by the community as relevant, at PHCS Health Board(^a) meetings</td>
</tr>
<tr>
<td>Agreements related to publications arrangements, joint sign-off or the protection of individual and community identity</td>
<td>Agreements where PHCS staff members and researchers jointly review findings and develop publications</td>
</tr>
</tbody>
</table>

**Survival and Protection: Research that demonstrates how it will protect personal and collective bonds, or the cultural distinctiveness of communities**

<table>
<thead>
<tr>
<th>Potential action</th>
<th>Example of potential action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demonstration of the contribution to social or cultural bonds among Indigenous families and communities</td>
<td>A research study into maternal health that involves mothers and grandmothers and is conducted with respect to women’s business</td>
</tr>
<tr>
<td>Existence of safeguards against potential discrimination of individuals or cultures</td>
<td>Decision not to publish certain demographic information (to protect identity) from a study conducted in a small community</td>
</tr>
<tr>
<td>Contribution to the opportunity for communities to better advocate or enjoy cultural distinctiveness</td>
<td>Identifying a local artist to develop artwork to represent the study, promoting local cultural uniqueness and identity</td>
</tr>
<tr>
<td>Existence of strategies to reduce/eliminate threats to cultural distinctiveness</td>
<td>Identifying a local cultural mentor to provide cultural advice to researchers to ensure local context is considered</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Spirit and Integrity: Research that respects the continuity of the past, current and future generations and demonstrates integrity and credibility during the research process. This is an overarching value that binds the other values together</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Potential action</strong></td>
</tr>
<tr>
<td>Demonstration of an understanding of cultural, social and spiritual cohesion, including workable timeframes</td>
</tr>
<tr>
<td>Recognition of the diversity of cultures</td>
</tr>
<tr>
<td>Demonstration of personnel integrity (specifically during study development)</td>
</tr>
<tr>
<td>Commitment to working within the spirit and integrity of the community/ies</td>
</tr>
</tbody>
</table>

Abbreviations: PHCS – primary healthcare service; RCT – randomised control trial

* Difference blindness: to misrecognise of fail to recognise cultural differences.

# Health Boards involve any group of community representatives established to review and approve research conducted in their Indigenous community. This includes community research boards, community research committees and community juries.
Table A2 summarises actions/processes identified during the systematic review of Indigenous-focused SEWB PHC research (Chapters 2 and 3), critical evaluation (Chapter 5) and reflective case study of *Getting it Right* (Chapter 6). This Table provides examples of actions/processes that relate to the Values and Ethics Guideline and is not intended to be used as an exhaustive list or to be used as a checklist for Indigenous-focused health research.

Table A2  **Actions/processes identified during this thesis addressing the Values and Ethics Guideline relating to Indigenous-focused SEWB PHC research conducted by research teams**

<table>
<thead>
<tr>
<th>Action or process identified as addressing the Values and Ethics’ values</th>
<th>Reciprocity</th>
<th>Respect</th>
<th>Equality</th>
<th>Responsibility</th>
<th>Survival and protection</th>
<th>Integrity</th>
<th>Spirit and integrity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgment in research publications of contribution to research by staff, services, patients, communities, organisations or community members (according to individual preferences)</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authorship on research publication includes PHC staff or representatives</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Processes established to provide regular input and feedback into research from PHC staff and/or community representatives during research e.g. via steering committee, reference group, as investigators or feedback to Health Boards during research design and conduct, or jointly developing publications/findings (including joint sign-off of manuscript)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Processes established to provide regular feedback to communities during research e.g via steering committee that includes community representatives</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Research instrument(s), resource(s) or training developed within a collaborative culturally-appropriate framework, incorporating local preferences (e.g. informed by previous research) or developed with PHC staff, representatives or community members</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Provision of vouchers to reimburse/reimbursement to participants to compensate for time spent and costs associated with research participation, as well as contribution to research</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Flexible data collection methods e.g. interview location/time or option to complete research interviews ‘in languages’</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Action or process identified as addressing the Values and Ethics’ values</td>
<td>Reciprocity</td>
<td>Respect</td>
<td>Equality</td>
<td>Responsibility</td>
<td>Survival and protection</td>
<td>Spirit and integrity</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>-------------</td>
<td>----------</td>
<td>----------</td>
<td>----------------</td>
<td>------------------------</td>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>Research responding to community identified need</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research methods used that are consistent with Indigenous notions of health e.g. participatory action research, social ecological approaches, yarning techniques, phenomenological research methods; or grounded theory approaches that privilege Indigenous perspectives</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Engagement with local structures to review and approve research e.g. Health Boards and the AHMRC</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research planning and implementation driven by community representatives</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Externally located researcher(s) visiting communities during pre-research stage to learn about local processes and context and to collaboratively develop appropriate research methods</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Informed consent processes that include multiple approaches to present and discuss research information or opportunities to review consent during research e.g. two-step consent processes, pictorial and translation options, or revisiting consent during follow up research appointments</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Use of ‘two-way learning’ processes which may promote empowerment, shared ownership, demonstrate respect for local knowledge and facilitate collaborative partnerships</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development of a plan to implement research findings (research translation) e.g. processes to discuss and communicate research findings to stakeholders</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resources explored during research remain with the community in an accessible format after research</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identifying and fostering local ‘research champions’ who are nominated by participating services to incorporate Indigenous knowledge and experience into research e.g. identify local priorities, drive and conduct research and data collection</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Research underpinned by empowerment principles or principles important to local communities e.g Iga Warta principles (prevention, coordination, sustainability, social determinants of health, sensitivity to Indigenous notions of time and space and community and family)</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Processes to develop cultural competence of non-Indigenous researchers e.g. mentorship by respected Elder(s) or completing reflection</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Action or process identified as addressing the Values and Ethics’ values</td>
<td>Reciprocity</td>
<td>Respect</td>
<td>Equality</td>
<td>Responsibility</td>
<td>Survival and integrity</td>
<td>Spirit and integrity</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>-------------</td>
<td>---------</td>
<td>----------</td>
<td>----------------</td>
<td>------------------------</td>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>Focus on building capacity of PHC services during research e.g. providing flexible financial reimbursement, delivering training to PHC staff, providing training certificates which list skills obtained</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modifying research design based on community feedback e.g. adapting the research protocol/methods in response to community feedback. Workable research timeframes</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sufficient research budget to compensate PHC services for the time and resources involved with research (e.g. to hire new staff or compensate for existing staff time) and to acknowledged the complexity surrounding cultural, social and spiritual cohesion</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexible financial arrangements involving allocation of research funding as determined by PHC services</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adaptive research protocol that enables steps and processes based on PHC service needs and in line with community values</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processes that recognise and allow for diversity across communities e.g. staggered start-up of research sites during multi-site research to enable localisation of research protocols</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transparent communication of the purpose, methods, conduct, planned dissemination of results and potential outcomes/benefits of research. Publication of research protocol</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identification of potential risks and development of thorough safety processes to follow</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Timely feedback of clinical information collected during research to PHC services to facilitate the ongoing management of patients’ health after participation in research</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incorporation of Indigenous artwork into research to celebrate and advocate for cultural distinctiveness</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Establishing relationships within the research via attending community events prior to and throughout study (NAIDOC Day) and seeking out local stories</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: AHMRC – Aboriginal Health and Medical Research Council of NSW; AMS – Aboriginal Medical Service; PHC – primary healthcare

# Health Boards involve any group of community representatives established to review and approve research conducted in their Indigenous community. This includes community research boards, community research committees and community juries.

## APPENDIX 2: SUPPLEMENTARY TABLES FROM THE SYSTEMATIC REVIEW - RESULTS

### Table A3  Summary of studies included in systematic review grouped according to methods (Supplementary Table 1)

<table>
<thead>
<tr>
<th>Design</th>
<th>Author and Date</th>
<th>Approach to research</th>
<th>Study aim and focus</th>
<th>Data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixed Methods</td>
<td>Clifford et al 2011 3 *</td>
<td>Mixed methods</td>
<td>Service delivery</td>
<td>Pre and post intervention surveys and interview</td>
</tr>
<tr>
<td></td>
<td>AIMhi study 3</td>
<td></td>
<td>No implementation of intervention reported</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dingwell et al 2012 4 *</td>
<td>Mixed methods</td>
<td>Service delivery</td>
<td>Interview and informal consultation</td>
</tr>
<tr>
<td></td>
<td>AIMhi Study 2</td>
<td></td>
<td>No implementation of intervention reported</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nagel 2006 5 *</td>
<td></td>
<td>Observational</td>
<td>Survey and semi-structured interview</td>
</tr>
<tr>
<td></td>
<td>VUH study 3</td>
<td></td>
<td>Service delivery</td>
<td>Qualitative comments, focus group, QoL questionnaire</td>
</tr>
<tr>
<td></td>
<td>Sun et al 2013 6 *</td>
<td>Mixed methods</td>
<td>Implementation of program reported</td>
<td>Focus groups, questionnaire, verbal feedback, evaluation form</td>
</tr>
<tr>
<td>Mixed Methods</td>
<td>Bakos 2008 7,8 *</td>
<td>Mixed methods: project</td>
<td>Service delivery</td>
<td>Survey</td>
</tr>
<tr>
<td></td>
<td>Lovett et al 2014 9 *</td>
<td>Mixed methods: description of development and implementation of a model</td>
<td>Service delivery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>AIMhi study 1</td>
<td></td>
<td>Service delivery</td>
<td>Mixed method: interview, observation, field trip notes, music, photographs, videos, Health of the Nation Outcome Scale, K-10 wellbeing measure, health centre and hospital files and interview</td>
</tr>
<tr>
<td></td>
<td>Nagel et al 10-16 *</td>
<td>Mixed methods: participatory action research followed by RCT</td>
<td>No implementation of intervention reported</td>
<td>SEWB</td>
</tr>
<tr>
<td>Study</td>
<td>Type</td>
<td>Domain</td>
<td>Data collection methods</td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>------</td>
<td>--------</td>
<td>-------------------------</td>
<td></td>
</tr>
<tr>
<td>Clifford et al 2012</td>
<td>Qualitative</td>
<td>Service delivery</td>
<td>No implementation of intervention reported (to inform intervention in (3, 18))</td>
<td></td>
</tr>
<tr>
<td>Esler et al 2007</td>
<td>Qualitative</td>
<td>Service delivery</td>
<td>No implementation of intervention reported (to inform intervention in (20))</td>
<td></td>
</tr>
<tr>
<td>Raphael et al 2010</td>
<td>Qualitative</td>
<td>Observational</td>
<td>SEWB</td>
<td></td>
</tr>
<tr>
<td>Williamson et al 2010</td>
<td>Qualitative</td>
<td>Observational</td>
<td>SEWB</td>
<td></td>
</tr>
<tr>
<td>Allan 2010</td>
<td>Qualitative: sociological action research</td>
<td>Service delivery</td>
<td>No implementation of intervention reported DA and SEWB</td>
<td></td>
</tr>
<tr>
<td>Carey 2013</td>
<td>Qualitative: evaluation, cross-sectional</td>
<td>Evaluation</td>
<td>SEWB</td>
<td></td>
</tr>
<tr>
<td>Harris et al 2007</td>
<td>Qualitative: evaluation</td>
<td>Evaluation</td>
<td>Mental health (AMHW)</td>
<td></td>
</tr>
<tr>
<td>Robinson et al 2004</td>
<td>Qualitative: evaluation</td>
<td>Evaluation</td>
<td>Mental health (AMHW)</td>
<td></td>
</tr>
<tr>
<td>Cargo et al 2012</td>
<td>Qualitative: participatory action research and social ecological perspective</td>
<td>Observational</td>
<td>Smoking cessation</td>
<td></td>
</tr>
<tr>
<td>Dawson et al 2012</td>
<td>Qualitative: participatory action research and social ecological perspective</td>
<td>Observational</td>
<td>Smoking cessation</td>
<td></td>
</tr>
<tr>
<td>Fletcher et al 2011</td>
<td>Qualitative: participatory action research</td>
<td>Workplace policy</td>
<td>Smoking cessation</td>
<td></td>
</tr>
<tr>
<td>Bond et al 2012</td>
<td>Qualitative: phenomenological approach</td>
<td>Observational</td>
<td>Smoking cessation</td>
<td></td>
</tr>
<tr>
<td>Higgins et al 2013</td>
<td>Qualitative: report</td>
<td>Service delivery</td>
<td>Implementation of some intervention/s reported</td>
<td></td>
</tr>
<tr>
<td>Lee et al 2014</td>
<td>Qualitative: descriptive</td>
<td>Observational</td>
<td>Anxiety or depression</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Study Design</td>
<td>Study Goal</td>
<td>Study Methodology</td>
<td>Findings</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
<td>------------</td>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>AIMhi PDP Haswell-Elkins et al 2009</td>
<td>Qualitative: description of a research partnership</td>
<td>Dual diagnosis (DA and SEWB)</td>
<td>Report on partnership SEWB</td>
<td>Meetings, literature review, interviews</td>
</tr>
<tr>
<td>Clifford et al 2013</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>No implementation of intervention reported Alcohol misuse</td>
<td>Patient medical records were extracted</td>
</tr>
<tr>
<td>Esler et al 2008</td>
<td>Quantitative</td>
<td>Evaluation (validation of measure) Depression</td>
<td>Service delivery</td>
<td>Validation study (semi-structured interview)</td>
</tr>
<tr>
<td>VUH study 1</td>
<td>Quantitative</td>
<td>Implementation of program reported SEWB</td>
<td>QoL questionnaire</td>
<td></td>
</tr>
<tr>
<td>Sun et al 2015</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>Implementation of program reported SEWB</td>
<td>QoL questionnaire</td>
</tr>
<tr>
<td>Sun et al 2013</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>Implementation of program reported SEWB</td>
<td></td>
</tr>
<tr>
<td>VUH study 2 Sun et al 2013</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>Implementation of program reported SEWB</td>
<td></td>
</tr>
<tr>
<td>Calabria et al 2013</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>No implementation of intervention reported Alcohol misuse</td>
<td></td>
</tr>
<tr>
<td>Calabria et al 2014</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>QoL questionnaire</td>
<td></td>
</tr>
<tr>
<td>Sun et al 2015</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>QoL questionnaire</td>
<td></td>
</tr>
<tr>
<td>VUH study 1 Sun et al 2013</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>QoL questionnaire</td>
<td></td>
</tr>
<tr>
<td>Calabria et al 2013</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>QoL questionnaire</td>
<td></td>
</tr>
<tr>
<td>Calabria et al 2014</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>QoL questionnaire</td>
<td></td>
</tr>
</tbody>
</table>

Quantitative

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Design</th>
<th>Study Goal</th>
<th>Study Methodology</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sun et al</td>
<td>Quantitative</td>
<td>Implementation of program reported SEWB</td>
<td>QoL questionnaire</td>
<td></td>
</tr>
<tr>
<td>VUH study</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>Implementation of program reported SEWB</td>
<td>QoL questionnaire</td>
</tr>
<tr>
<td>Calabria et al</td>
<td>Quantitative</td>
<td>Service delivery</td>
<td>QoL questionnaire</td>
<td></td>
</tr>
</tbody>
</table>

Case study

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Design</th>
<th>Study Goal</th>
<th>Study Methodology</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>DiGiacomo et al 2007</td>
<td>Case study</td>
<td>Report on intervention Smoking cessation</td>
<td>Patient medical records were reviewed</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:**
AMS – Aboriginal Medical Service; AMHW – Aboriginal Mental Health Worker; AIMhi - Australian Integrated Mental Health Initiative/Aboriginal and Islander Mental Health Initiative; DA – drug and alcohol; PHC – primary healthcare; PHCS – primary healthcare service; QoL – quality of life; RCT – randomised control trial; SEWB – social and emotional wellbeing; VUH - Voices United for Harmony

**Study aim definitions:**
Service delivery: focused on developing or implementing PHC intervention/service. Includes: implemented (where implementation of intervention is reported) or not implemented (where no implementation of intervention are reported). Excludes evaluations. Evaluation: focused on evaluating an existing intervention/service/policy/program. Includes validation of clinical measures. Observational: focused on collecting observational data only, with no intervention description
Report: description of intervention or partnership no research conclusions provided
Workplace policy: focused on developing a new workplace policy

* Journal article format
# Report format
Table A4  Summary of key learnings identified during risk of bias and community acceptance assessment (Supplementary Table 2)

<table>
<thead>
<tr>
<th>Author and Date</th>
<th>Primary outcome identified and met</th>
<th>Risk of bias</th>
<th>Community acceptance score</th>
<th>Key learnings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clifford et al 2011</td>
<td>Identified and met: Yes</td>
<td>H</td>
<td>0/4</td>
<td>Mixed methods When mixed-method studies include an RCT, flexible randomisation processes may increase acceptability. Examples include: VUH study 3 – modified to non-randomised design in response to community feedback. Participants self-selected into intervention group (resulting in selection bias). AIMhi study 1 – intervention was delivered according to ‘early’ and ‘late’ groups (potentially resulting in exposure to different external factors, and reducing the likelihood of concealment/blinding). PAR processes can be used to develop localised interventions: AIMhi study 1 – PAR was completed in initial stages of the study to inform intervention development. Mixed-methods can incorporate two-way learning principles. The various approaches and reporting by authors resulted in challenges assessing the risk of bias and community acceptance of mixed-method studies.</td>
</tr>
<tr>
<td>AIMhi study 3 Dingwell et al 2012</td>
<td>Identified and met: Yes Outcome: Identify perceptions</td>
<td>L</td>
<td>Unclear #</td>
<td></td>
</tr>
<tr>
<td>AIMhi Study 2 Nagel 2006</td>
<td>Identified and met: Unclear Outcome: Unable to determine</td>
<td>H</td>
<td>Unclear #</td>
<td></td>
</tr>
<tr>
<td>VUH study 3 Sun et al 2013</td>
<td>Identified and met: Yes Outcome: Evaluate program</td>
<td>H</td>
<td>2/4</td>
<td></td>
</tr>
<tr>
<td>Bakos 2008</td>
<td>Identified and met: Unclear</td>
<td>N/A*</td>
<td>0/4</td>
<td></td>
</tr>
<tr>
<td>Author and Date</td>
<td>Primary outcome identified and met</td>
<td>Risk of bias</td>
<td>Community acceptance score</td>
<td>Key learnings</td>
</tr>
<tr>
<td>----------------</td>
<td>-----------------------------------</td>
<td>--------------</td>
<td>---------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Lovett et al 2014 9</td>
<td>Identified and met: Unclear</td>
<td>N/A *</td>
<td>Unclear #</td>
<td></td>
</tr>
<tr>
<td>AIMhi study 1 Nagel et al 10-16</td>
<td>Identified and met: Yes</td>
<td>H</td>
<td>2/4</td>
<td>Qualitative designs appear to have lower risk of bias and higher acceptability than mixed-method or quantitative designs. PAR, social ecological perspectives and phenomenological approaches appear to encourage research processes that lead to community acceptance.</td>
</tr>
<tr>
<td>Clifford et al 2012 17</td>
<td>Identified and met: Yes</td>
<td>H</td>
<td>1/4</td>
<td>Qualitative designs appear to have lower risk of bias and higher acceptability than mixed-method or quantitative designs. PAR, social ecological perspectives and phenomenological approaches appear to encourage research processes that lead to community acceptance.</td>
</tr>
<tr>
<td>Esler et al 2007 19</td>
<td>Identified and met: Yes</td>
<td>M</td>
<td>4/4</td>
<td>Most qualitative research outcomes did not result in the implementation of interventions e.g. were limited to identifying perspectives. Two-way learning principles may enhance research deemed to have low risk of bias and high community acceptance (27, 28).</td>
</tr>
<tr>
<td>Raphael et al 2010 21</td>
<td>Identified and met: Yes</td>
<td>M</td>
<td>2/4</td>
<td></td>
</tr>
<tr>
<td>Williamson et al 2010 22</td>
<td>Identified and met: Yes</td>
<td>M</td>
<td>0/4</td>
<td></td>
</tr>
<tr>
<td>Allan 2010 23</td>
<td>Identified and met: Yes</td>
<td>L</td>
<td>0/4</td>
<td></td>
</tr>
<tr>
<td>Carey 2013 24</td>
<td>Identified and met: Yes</td>
<td>L</td>
<td>2/4</td>
<td></td>
</tr>
<tr>
<td>Harris et al 2007 25 Robinson et al 2004 26</td>
<td>Identified and met: Unclear</td>
<td>N/A *</td>
<td>1/4</td>
<td></td>
</tr>
<tr>
<td>Cargo et al 2012 27 Dawson et al 2012 28</td>
<td>Identified and met: Yes</td>
<td>L</td>
<td>4/4</td>
<td></td>
</tr>
<tr>
<td>Author and Date</td>
<td>Primary outcome identified and met</td>
<td>Risk of bias</td>
<td>Community acceptance score</td>
<td>Key learnings</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>--------------</td>
<td>----------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Fletcher et al 2011** 29</td>
<td>Outcome 2: Identify perceptions</td>
<td>M</td>
<td>4/4</td>
<td></td>
</tr>
<tr>
<td>Bond et al 2012** 30</td>
<td>Identified and met: Somewhat met</td>
<td>L</td>
<td>4/4</td>
<td></td>
</tr>
<tr>
<td>Higgins et al 2013** 31</td>
<td>Identified and met: Somewhat met</td>
<td>H</td>
<td>3/4</td>
<td></td>
</tr>
<tr>
<td>Lee et al 2014** 32</td>
<td>Identified and met: Yes</td>
<td>L</td>
<td>1/4</td>
<td></td>
</tr>
<tr>
<td>AIMhi PDP Haswell-Elkins et al 2009** 33</td>
<td>Identified and met: Unclear</td>
<td>N/A*</td>
<td>3/4</td>
<td></td>
</tr>
<tr>
<td>Clifford et al 2013** 18</td>
<td>Identified and met: Yes</td>
<td>?/H’</td>
<td>1/4</td>
<td>Quantitative designs were assessed as high risk of bias, or were unable to be assessed. This indicates there are challenges implementing qualitative research with Indigenous communities.</td>
</tr>
<tr>
<td>Esler et al 2008** 20</td>
<td>Identified and met: Yes</td>
<td>?/H’</td>
<td>4/4</td>
<td>Most quantitative studies involved processes that indicate community acceptance. This may suggest that close collaboration is necessary when conducting qualitative research:</td>
</tr>
<tr>
<td>VUH study 1 Sun et al 2015** 34</td>
<td>Identified and met: Yes</td>
<td>H</td>
<td>3/4</td>
<td>Esler – appears to be driven by AMS. First author was an AMS staff member, study was approved by AMS governance structure and staff were involved in data collection,</td>
</tr>
<tr>
<td>Sun et al 2013** 35</td>
<td>Identified and met: Yes</td>
<td>H</td>
<td>2/4</td>
<td></td>
</tr>
<tr>
<td>VUH study 2 Sun et al 2013** 36</td>
<td>Identified and met: Yes</td>
<td>H</td>
<td>2/4</td>
<td></td>
</tr>
<tr>
<td>Calabria et al 2013** Calabria et al 2014** 37</td>
<td>Identified and met: Yes</td>
<td>?/H’</td>
<td>3/4</td>
<td></td>
</tr>
<tr>
<td>Author and Date</td>
<td>Primary outcome identified and met</td>
<td>Risk of bias</td>
<td>Community acceptance score</td>
<td>Key learnings</td>
</tr>
<tr>
<td>-----------------</td>
<td>----------------------------------</td>
<td>--------------</td>
<td>---------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>DiGiacomo et al 2007</td>
<td>Outcome 2: Identify cut-off points</td>
<td>?/H †</td>
<td>Unclear #</td>
<td>Calabria – study was approved by AMS governance structure, research tools were localised and staff were involved in data collection and reporting, Sun – study was approved by AMS governance structure, Community Leaders were involved in design and implementation and staff coordinated activities. Case study Due to this study’s aim (report on intervention) no conclusions regarding case studies can be drawn.</td>
</tr>
</tbody>
</table>

**Colour key**
- High risk of bias / community acceptance score = <2
- Medium risk of bias
- Low risk of bias / community acceptance score = 3-4

**Abbreviations**: AMS – Aboriginal Medical Service; AMHW – Aboriginal Mental Health Worker; AIMhi - Australian Integrated Mental Health Initiative/Aboriginal and Islander Mental Health Initiative; DA – drug and alcohol; PAR – participatory action research; PHC – primary healthcare; PHCS – primary healthcare service; QoL – quality of life; RCT – randomised control trial; SEWB – social and emotional wellbeing; VUH - Voices United for Harmony
- † NA indicates risk of bias not assessed as these format did not align with risk of bias assessment tools
- † ? Indicates unable to determine risk of bias due to unclear reporting in multiple criteria used to assess risk of bias
- # Unclear indicates unable to assess two or more criteria when assessed using community acceptance criteria
- † Refer to tables 2-6 for full assessment of risk of bias and community acceptance criteria

**Study aim definitions**:
- Service delivery: focused on developing or implementing PHC intervention/service. Includes implemented (where implementation of intervention/service is reported) or not implemented (where no implementation of intervention are reported). Excludes evaluations.
- Evaluation: focused on evaluating an existing intervention/service/policy/program. Includes validation of clinical measures.
- Observational: focused on collecting observational data with no description of intervention
- Report: description of intervention or partnership where no research outcomes are reported
- Workplace policy: focused on developing a new workplace policy
Table A5  Risk of bias for qualitative studies (40) (Supplementary Table 3)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear statement of aims</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Appropriate methods</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Appropriate recruitment strategy</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Ethical considerations</td>
<td>?</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Data address research aim</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>?</td>
<td>Y</td>
<td>?</td>
<td>?</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Consideration of researcher-participant relationship</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Clear statement of findings</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Overall assessment</td>
<td>M</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>H</td>
<td>M</td>
<td>M</td>
<td>H</td>
<td>H</td>
<td>H</td>
<td>L</td>
<td>M</td>
<td>M</td>
<td>L</td>
<td>M</td>
</tr>
</tbody>
</table>

**Colour key**

<table>
<thead>
<tr>
<th>High risk of bias</th>
<th>Medium risk of bias</th>
<th>Low risk of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>L</td>
<td>L</td>
</tr>
</tbody>
</table>

**Abbreviations:** AIMhi: Australian Integrated Mental Health Initiative/Aboriginal and Islander Mental Health Initiative

| H: high; M: moderate; N: no; L: low; Y: yes; ?: Unclear; * Study used mixed methods. Assessed according to qualitative criteria as qualitative is dominant study method |
| # Study uses mixed methods. Both methods assessed as reported separately. Randomised control trial assessed in Table 3 |
| Consultation and training reports (7, 8), an evaluation (25), a description of a partnership (33) and a description of the development and implementation of a model (9) were not assessed as these formats did not align with risk of bias assessment tools |
Table A6  Risk of bias for quantitative studies (41) (Supplementary Table 4)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection bias</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Representative sample</td>
<td>Very likely Clinical records of all patients included</td>
<td>Not likely Convenience sample - community based groups or those seeking treatment</td>
<td>Not likely Participants selected through AMS and community treatment agency</td>
<td>Not likely Self-selected</td>
<td>Somewhat likely Selection through AMS - eligible attendees were asked</td>
<td>Not likely Self-selected participants were in intervention group</td>
<td>Not likely Self-selected participants approached during health checks and agreed to participate</td>
<td>Not likely Self-selected - participants approached during health checks and agreed to participate</td>
<td>Not likely Self-selected - participants approached during health checks and agreed to participate</td>
</tr>
<tr>
<td>Participation rate</td>
<td>80-100%</td>
<td>Less than 10% were ineligible</td>
<td>100%</td>
<td>80-100%</td>
<td>100% – self-selected</td>
<td>100% – self-selected</td>
<td>100% – self-selected</td>
<td>100% – self-selected</td>
<td>100% – self-selected</td>
</tr>
<tr>
<td>Rating Study design</td>
<td>Strong +</td>
<td>Weak</td>
<td>Weak</td>
<td>Weak</td>
<td>Moderate</td>
<td>Weak</td>
<td>Weak</td>
<td>Weak</td>
<td>Weak</td>
</tr>
<tr>
<td>Indicate study design</td>
<td>Cohort. Quality improvement, pre and post intervention. No control group</td>
<td>Descriptive survey. No control group</td>
<td>Cross sectional survey. No control group</td>
<td>Case study of intervention program. No control group</td>
<td>Validation study</td>
<td>Cohort analytic - quasi-experimental design (no randomisation)</td>
<td>Cohort analytic - quasi-experimental design (no randomisation)</td>
<td>Cohort analytic - quasi-experimental design (no randomisation, qualitative methods)</td>
<td></td>
</tr>
<tr>
<td>Rating Confounders</td>
<td>Moderate</td>
<td>Weak</td>
<td>Weak</td>
<td>Weak</td>
<td>Weak</td>
<td>Weak $</td>
<td>Weak $</td>
<td>Weak $</td>
<td>Moderate</td>
</tr>
<tr>
<td>Important differences (prior)</td>
<td>NA $</td>
<td>NA $</td>
<td>NA $</td>
<td>NA $</td>
<td>NA $</td>
<td>No – no significant differences in demographics between groups</td>
<td>Yes - statically significant differences between groups for</td>
<td>? $</td>
<td></td>
</tr>
<tr>
<td>If Yes, what percentage were controlled?</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>?^ - Univariate analysis to control confounders (ANCOVA)</td>
<td>?^</td>
<td></td>
</tr>
<tr>
<td>Rating</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>Weak</td>
<td>?^</td>
<td></td>
</tr>
<tr>
<td><strong>Blinding</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rating</td>
<td>NA*</td>
<td>?^</td>
<td>?^</td>
<td>?^</td>
<td>Moderate</td>
<td>Weak</td>
<td>Weak</td>
<td>Weak</td>
<td></td>
</tr>
</tbody>
</table>

**Data collection methods**

<p>| Data collection tools validity | ?^ | NA – tool (survey) not yet validated. Study to determine acceptability | No | ?^ | Yes – validation interview: semi-structured psychiatric interview with culturally-appropriate communication | Yes | Yes | No |</p>
<table>
<thead>
<tr>
<th>Data collection tools’ reliability</th>
<th>Rating</th>
<th>Yes</th>
<th>Yes</th>
<th>?^</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Withdrawals and dropouts**

<table>
<thead>
<tr>
<th>Withdrawals/dr-op reports</th>
<th>NA</th>
<th>NA – survey: none</th>
<th>NA – survey: none</th>
<th>Yes – case study, all participants were included in findings</th>
<th>NA – case study, automatic completion</th>
<th>NA – number reported, reasons for dropouts not reported 80-100%</th>
<th>No – number reported, reasons for dropouts not reported 80-100%</th>
<th>No – number reported, reasons for dropouts not reported &lt;60%</th>
<th>No – number reported, reasons for dropouts not reported &lt;60%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant completion</td>
<td>NA^</td>
<td>80-100% (94% completed)</td>
<td>80-100% (87% completed)</td>
<td>Yes – case study, all participants were included in findings</td>
<td>NA – case study, automatic completion</td>
<td>NA – number reported, reasons for dropouts not reported 80-100%</td>
<td>No – number reported, reasons for dropouts not reported 80-100%</td>
<td>No – number reported, reasons for dropouts not reported &lt;60%</td>
<td>No – number reported, reasons for dropouts not reported &lt;60%</td>
</tr>
<tr>
<td>Rating</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
</tr>
</tbody>
</table>

**Intervention integrity**

<table>
<thead>
<tr>
<th>Participants received allocated intervention</th>
<th>NA – Cohort study</th>
<th>NA</th>
<th>NA</th>
<th>NA</th>
<th>NA</th>
<th>NA</th>
<th>NA</th>
<th>NA</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention consistency measured</td>
<td>Yes</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
</tr>
<tr>
<td>Unintended intervention (contamination or co-intervention)</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
<td>NA^</td>
</tr>
</tbody>
</table>

**Analysis**

<table>
<thead>
<tr>
<th>Unit of allocation</th>
<th>Organisation</th>
<th>NA^</th>
<th>NA^</th>
<th>NA^</th>
<th>NA^</th>
<th>NA^</th>
<th>NA^</th>
<th>NA^</th>
<th>NA^</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit of analysis</td>
<td>Individual and organisation</td>
<td>Individual</td>
<td>Individual</td>
<td>Individual</td>
<td>Individual</td>
<td>Individual</td>
<td>Individual</td>
<td>Individual</td>
<td>Individual</td>
</tr>
<tr>
<td>Appropriate statistical method use</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>NA – no analysis completed</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Analysis performed by intervention allocation status (i.e., intention to treat) not actual intervention received?</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>NA*</td>
<td>No – per protocol</td>
<td>No – per protocol</td>
<td>No – per protocol</td>
<td></td>
</tr>
<tr>
<td>Global score</td>
<td>Unable to calculate</td>
<td>Unable to calculate</td>
<td>Unable to calculate</td>
<td>Unable to calculate</td>
<td>Unable to calculate</td>
<td>13</td>
<td>15</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Global rating</td>
<td>Unable to calculate</td>
<td>Unable to calculate</td>
<td>Unable to calculate</td>
<td>Unable to calculate</td>
<td>Unable to calculate</td>
<td>Weak</td>
<td>Weak</td>
<td>Weak</td>
<td></td>
</tr>
</tbody>
</table>

**Colour key**
- High risk of bias
- Medium risk of bias
- Low risk of bias

**Abbreviations:**
- NA – Not Applicable; VUH – Voices United for Harmony
- H – high; M – moderate; N – no; L – low; Y - yes;
- * NA Criteria not assessed as this study design/format did not align with risk of bias assessment tools
- ?^* Unclear/unable to assess criteria due to unclear reporting
- ?^/H – unable to assess as >3 criteria are unable to be assessed
- π – Risk of bias assessment completed separately, as data survey designs varied
- * – Study used mixed methods. Assessed according to quantitative criteria as quantitative is dominant study method
- + – Representativeness of sample is given more weight than participation rate
- ¥ – Due to non-randomised design, study judged to be weak
### Table A7  Risk of Bias for randomised control trial (41) (Supplementary Table 5)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Nagel et al 11, 14, 16 #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Low</td>
</tr>
<tr>
<td>Comment: Patients were randomised to ‘early’ and ‘late’ treatment groups using a block randomisation random number sequence technique</td>
<td></td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Unclear</td>
</tr>
<tr>
<td>Comment: Methods to conceal allocation group was not described</td>
<td></td>
</tr>
<tr>
<td>Blinding of participants and personnel</td>
<td>Unclear</td>
</tr>
<tr>
<td>Comment: Blinding of participants and personnel was not described</td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment</td>
<td>Unclear</td>
</tr>
<tr>
<td>Comment: Clinician rated measures were completed by the Principle Investigator. It is unlikely that the Principle Investigator was blinded during outcome assessment. However data collection included patient rated measures and qualitative data</td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed</td>
<td>Low</td>
</tr>
<tr>
<td>Comment: Intention to treat analysis was completed. Mixed model regression analysis was used to handle missing data through estimating maximum likelihood of missing variables</td>
<td></td>
</tr>
<tr>
<td>Free of selective reporting</td>
<td>Low</td>
</tr>
<tr>
<td>Comment: Primary outcome measure: HoNOS and secondary outcome measures: K10, life skills, self-management and substance dependence. Results for all measures were reported</td>
<td></td>
</tr>
<tr>
<td>Free of other bias</td>
<td>Low</td>
</tr>
<tr>
<td>Comment: Authors report that there were no significant differences between the groups at baseline</td>
<td></td>
</tr>
<tr>
<td>Overall risk of bias</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

*Abbreviations: HoNOS – Health of the Nation Outcome Scale; K10 – Anxiety and Depression Checklist

# Study uses mixed methods. Qualitative component assessed in Table 1*
Table A8  Community Acceptance (Supplementary Table 6)

Assessed according to the following criteria drawn from key research documents (42, 43):

1. Community governance of research
2. Community involvement in study development
3. Community involvement in study conduct (collection, data analysis)
4. Community involvement in reporting

<table>
<thead>
<tr>
<th>Study name and references</th>
<th>Risk of bias rating</th>
<th>Community acceptance score</th>
<th>Assessment according to Community Acceptance Criteria 1-4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allan 23</td>
<td>M</td>
<td>1/4</td>
<td>1) Not mentioned. 2) Not mentioned. 3) Not mentioned. 4) Not mentioned.</td>
</tr>
<tr>
<td>Bakos 7, 8</td>
<td>NA*</td>
<td>1/4</td>
<td>1) Indigenous Advisory Group oversaw the project (met 3-4 times to provide cultural advice) 2) Not mentioned. 3) Not mentioned. 4) Not mentioned.</td>
</tr>
<tr>
<td>Bond 30</td>
<td>L</td>
<td>4/4</td>
<td>1) Approved by 2 Indigenous community organisations. 2) Study was led/conducted by urban Indigenous Health Service. 3) Interviews were conducted by Indigenous community members/researchers. First author is from Community Organisation. 4) Results were presented to research team and Indigenous health professionals for discussion and to elucidate potential themes. First author is from Community Organisation. Comment: Study was led by Community organisation and first author is Indigenous, indicating involvement at each stage</td>
</tr>
<tr>
<td>Calabria et al 37, 38</td>
<td>?/H</td>
<td>3/4</td>
<td>1) Approved by ACCHS Board. Steering Committee (including AHW) oversaw the project. 2) Not mentioned. 3) Survey was adapted by non-Indigenous and Indigenous researchers, community members and staff. AHW conducted some interviews. 4) Representatives from ACCHS critically revised the manuscript. CEO approved publications.</td>
</tr>
<tr>
<td>Carey 24</td>
<td>L</td>
<td>2/4</td>
<td>1) Approved by Local Health Board following extensive engagement over 12 months. 2) Local Health Board developed research question and focus. 3) Not mentioned. 4) Not mentioned. Comment: Research aimed to evaluate SEWB program, therefore involvement in criteria 3 may not be appropriate. Researcher was invited by community to conduct research.</td>
</tr>
<tr>
<td>Study</td>
<td>Score</td>
<td>Authors</td>
<td>Approval</td>
</tr>
<tr>
<td>-------</td>
<td>-------</td>
<td>---------</td>
<td>----------</td>
</tr>
</tbody>
</table>
| Cargo 27 Dawson 28 | L H 4/4 | 1) Research was conducted by research team (partnership involving AHCSA and university). This partnership provided governance of research. Indigenous stakeholder groups provided ongoing support.
2) Shared decision making within research team. Representatives from ACHSA involved in design and coordination.
3) Recruitment was guided by Indigenous team members. Representatives from ACHSA involved in design and coordination. Cultural mentorship from Aboriginal Elder.
4) Aboriginal investigators reviewed data and manuscript. Representatives from ACHSA were authors and refined the manuscript (reported in article). |
| Clifford et al 17 | H L 1/4 | 1) Approved by Community Health Boards.
2) Not mentioned. 3) Not mentioned. 4) Not mentioned. |
| Clifford et al 3 | H L 0/4 | 1) Not mentioned. 2) Not mentioned. 3) Not mentioned. 4) Not mentioned. |
| Clifford et al 18 | ?/H L 1/4 | 1) Approved by Chair of ACCHS Boards.
2) Not mentioned. 3) Not mentioned. 4) Not mentioned. |
| DiGiacomo 39 | ?/H L 1/4 | 1) Unclear: refer to comment. 2) Unclear: refer to comment.
3) AHW involved in screening potential participants.
4) Unclear: Representatives from AMS were subsequent authors.
Comment: Representatives from AMS were authors indicating some involvement, however the extent of involvement is unclear. |
| Esler 19 | M H 4/4 | 1) Approved by AMS Management Committee.
2) First author is representative from AMS, indicates involvement in research development.
3) Aboriginal SEWB Director facilitated focus groups.
4) First author is representative from AMS, indicates involvement in reporting. |
| Esler 20 | ?/H L 4/4 | 1) Approved by AMS Management Committee and from community-elected committee.
2) First author is representative from AMS, indicates involvement in research development.
3) Interviews conducted by AHW.
4) First author is representative from Health Organisation, indicates involvement in reporting. |
| Fletcher et al 29 | M H 4/4 | 1) Research part of project led/implemented by VACCHO, indicating approval.
2) As above; study implemented by VACCHO
3) As above; Indigenous project officer conducted interviews
4) Research part of project led by VACCHO; several authors are VACCHO representatives indicates involvement in reporting |
| Harris 25, 26 | NA L 1/4 | 1) Not mentioned. 2) Not mentioned.
3) Cooperative Research Centre for Aboriginal Health provided in-kind support, therefore involved in conduct.
4) Not mentioned. |
<table>
<thead>
<tr>
<th>Author</th>
<th>Study</th>
<th>Score</th>
<th>Engagement Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higgins</td>
<td>1) Project Reference Group included strong Indigenous leadership. Steering Committee also had Community representation. 2) Indigenous organisations involved during research development; Community driven initiative 3) Indigenous staff member conducted interviews; preliminary findings were presented to Reference Group, who provided feedback. 4) Not mentioned.</td>
<td>3/4</td>
<td></td>
</tr>
<tr>
<td>Lee</td>
<td>1) Not mentioned. 2) Not mentioned. 3) Interviews conducted by Indigenous project officer. Data analysis was conducted by Indigenous project officer and the lead ACCHS partner 4) Unclear: Representatives from Community organisation were subsequent authors. Comment: Representatives from Community organisations were subsequent authors indicating some involvement, however the extent of involvement is unclear.</td>
<td>1/4</td>
<td></td>
</tr>
<tr>
<td>Lovett</td>
<td>1) Approved by AMS board; AMS staff on Reference group 2) Previous relationships between AMS and researchers, and reported AMS interest in this area indicates involvement in research development. 3) Unclear: Indigenous researcher (not affiliated with AMS where research is conducted) delivered training and led research 4) Unclear: Indigenous researcher (not affiliated with AMS where research is conducted) is first author, other authors are from PHC indicating some involvement. Comment: First author is Indigenous researcher, not affiliated with AMS where research is conducted. Representatives from Community organisations were authors indicating some involvement in 3-4, however the extent of involvement is unclear.</td>
<td>2/4</td>
<td></td>
</tr>
<tr>
<td>AIMhi study 1 (Nagel)</td>
<td>1) Approved by Health Centres, Local Land Councils and Health Boards. Reference group included Indigenous representatives. 2 Indigenous associate investigators. 2) Not mentioned. 3) AMHW and recovered clients involved in developing intervention. Intervention delivered by Aboriginal research officer an AMHW (where possible). Data reviewed with AMHW. 4) Unclear: Role of 2 Indigenous associate investigators in reporting not mentioned. Not first authors. Comment: Research part of a large ongoing initiative, therefore ongoing collaboration is likely. Community engagement processes may be reported elsewhere.</td>
<td>2/4</td>
<td></td>
</tr>
<tr>
<td>AIMhi study 2 (Nagel)</td>
<td>1) Reference group appeared to provide oversight to study; not explicitly mentioned 2) Not mentioned. 3) Not mentioned. 4) Not mentioned. Comment: Research relates to AIMhi 1, therefore similar processes are likely, however this was not mentioned.</td>
<td>1/4</td>
<td></td>
</tr>
<tr>
<td>AIMhi study 3 (Nagel)</td>
<td>1) Not mentioned. 2) Not mentioned. 3) AMHW were involved in motivational care plan (intervention) development. Not mentioned 4) Not mentioned.</td>
<td>1/4</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Risk of Bias</td>
<td>Community Acceptance</td>
<td>Details</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
<td>----------------------</td>
<td>---------</td>
</tr>
<tr>
<td>AIMhi PDP (Haswell-Elkins)</td>
<td>3/4</td>
<td>H</td>
<td>1) Research Partnership involves Community and university researchers working together; Community empowerment at the core. Indicates approval. 2) Communities led the Research Partnership. 3) Communities led the Research Partnership. 4) Unclear: Some Indigenous community members were authors. Comment: Research relates to AIMhi 1, therefore similar processes are likely, however this was not mentioned.</td>
</tr>
<tr>
<td>Rapheal 21 Williamson et al 2010</td>
<td>2/4</td>
<td>L</td>
<td>1) ACCHS Boards approved of study. 2) Not mentioned. 3) Focus groups facilitated in collaboration with Aboriginal research officers. 4) Unclear: 3 representatives from Community organisation were subsequent authors. Comment: Representatives from Community organisations were authors indicating some involvement, however the extent of involvement is unclear.</td>
</tr>
<tr>
<td>VUH study 1 (Sun et al)</td>
<td>3/4</td>
<td>H</td>
<td>1) Approved by / Community consent from ACCHS Board. 2) Community Leaders played a role in design and implementation of the research. 3) Community Leaders played a role in design and implementation. ACCHS staff members coordinated activities. 4) Not mentioned.</td>
</tr>
<tr>
<td>VUH study 2 (Sun et al)</td>
<td>2/4</td>
<td>L</td>
<td>1) Unclear: Boards appear supportive and provided approval in previous study, not explicitly mentioned 2) Community Leaders played a role in research design and implementation. 3) Community Leaders played a role in research design and implementation. ACCHS coordinated activities. 4) Not mentioned. Comment: Linked with previous study, therefore similar processes are likely, however this was not mentioned.</td>
</tr>
<tr>
<td>VUH study 3 (Sun et al)</td>
<td>2/4</td>
<td>L</td>
<td>1) Unclear: Boards appear supportive and provided approval in previous study, not explicitly mentioned 2) Community Leaders played a role in research design and implementation. 3) Indigenous Advisory Group and consultation. 4) Not mentioned. Comment: Linked with previous study, therefore similar processes are likely, however this was not mentioned.</td>
</tr>
</tbody>
</table>

**Colour key**
- High risk of bias / community acceptance score = <2
- Medium risk of bias
- Low risk of bias / community acceptance score = 3-4
- Low risk of bias and high community acceptance
Reference list for Table A2-7

34. Sun J, Buys N. Effects of Community Singing Program on Mental Health Outcomes of Australian Aboriginal and Torres Strait Islander People: A Meditative Approach. American Journal of Health Promotion. 2015;0(0).
19th December 2016

Ms Sara Farnbach
PhD Candidate
Project Manager, Neurological & Mental Health Division
The George Institute for Global Health
Level 10, King George V Building
83-117 Missenden Road
Camperdown NSW 2050

Dear Ms Farnbach,

RE: Systematic review: Designs, processes and quality of Indigenous social and emotional wellbeing research involving primary healthcare services and externally located researchers.

I refer to correspondence received Wednesday 14th of September 2016 which included the above publication for the AH&MRC Human Research Ethics Committee’s review and response.

The Committee thanks you for providing the opportunity for comment.

The Committee has reviewed this publication and has no objection to it.

On behalf of the AH&MRC Ethics Committee,
Yours sincerely,

Val Keed
Chairperson
AH&MRC Ethics Committee
Dear Ms Farnbach,

RE: Processes that enhance Indigenous primary healthcare research quality for social and emotional wellbeing research conducted by collaborations: A systematic review

I refer to correspondence received 9th of February 2017 which included the above mentioned manuscript.

The Committee has reviewed and approved this manuscript.

On behalf of the AH&MRC Ethics Committee,

Yours sincerely,

[Signature]

Val Keed
Chairperson
AH&MRC Ethics Committee
What do we know about the diets of Aboriginal and Torres Strait Islander peoples in Australia? A systematic literature review

Sarah Whalan,1 Sara Farnbach,2 Lena Volk,2 Josephine Gwynn,3 Mark Lock,4 Kathy Trieu,2 Julie Brimblecombe,1 Jacqui Webster2

Abstract

Objective: To provide an overview of published research on the dietary intake of Aboriginal and Torres Strait Islander peoples.

Methods: Peer-reviewed literature from 1990 to October 2016 was searched to identify studies that measured the dietary intake of Australian Aboriginal and Torres Strait Islander populations. Study quality was assessed using a purposely devised quality appraisal tool. Meta-analysis was not possible due to the heterogeneity in dietary intake assessment methods. A narrative synthesis of study findings, where key themes were compared and contrasted was completed.

Results: Twenty-five articles from twenty studies with outcome measures related to dietary intake were included. Dietary intake was assessed by electronic store sales, store turnover method, 24-hour dietary recall, food frequency questionnaire and short questions. Consistent findings were low reported intakes of fruit and vegetables and high intakes of total sugar and energy-dense, nutrient-poor food and beverages.

Conclusions: While differences between studies and study quality limit the generalisability of the findings, most studies suggest that the diets of Aboriginal and Torres Strait Islander peoples are inadequate.

Implications for public health: A more concerted approach to understanding dietary patterns of Aboriginal and Torres Strait Islander peoples is required to inform policy and practice to improve diet and nutrition.

Key words: Aboriginal health, dietary intake, nutrition assessment

Government policy responses to date, which aim to specifically address the underlying determinants of poor nutrition such as food security, socioeconomic status and household infrastructure, have never been fully implemented and have been widely critiqued in relation to their limitations in addressing nutritional inequalities. Community-led programs to improve the food environment have the potential to benefit health but need to be scaled up to optimise impact.

Accurate, quantitative dietary intake data are required to plan and evaluate both national policies and community-led intervention programs. However, there are limitations in accurately assessing dietary intake and there are additional methodological issues associated with measuring dietary intake in Aboriginal and Torres Strait Islander peoples.

1. Menzies School of Health Research, Northern Territory
2. The George Institute for Global Health, New South Wales
3. Faculty of Health Sciences, University of Sydney, New South Wales
4. School of Medicine and Public Health, University of Newcastle, New South Wales

Correspondence to: Mrs. Sarah Whalan, Menzies School of Health Research, John Mathews Building (Bldg 58), Royal Darwin Hospital Campus, Rocklands Drv, Casuarina, Northern Territory 0810; e-mail: sarah.whalan@menzies.edu.au

Submitted: March 2017; Revision requested: June 2017; Accepted: July 2017

The authors have stated they have no conflict of interest.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2017 The Authors

The most recent National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey (NATSINPAS) 2012-13 is the only nationally representative study reporting on remote and non-remote areas across Australia, but it wasn’t designed to accurately capture dietary patterns of different regions or groups. Without high quality data, it is impossible to understand where best to intervene to achieve dietary improvement and measure the impact of government policy on diet and nutrition.

The objective of this review is to provide an overview of the published research on the dietary intake of Aboriginal and Torres Strait Islander peoples in Australia. This is with a view to identifying what further studies are needed to ensure that policies to improve the diets of Aboriginal and Torres Strait Islander groups are based on robust, culturally appropriate assessments of current dietary patterns.

Methods

Search strategy

The review methodology was registered with PROSPERO (ID number CRD42016032683). A three-step strategy was employed to identify peer-reviewed literature published in English from 1990 to October 2016.

1) Electronic databases were searched: PubMed, HealthInfoNet and PsycInfo. Search terms included: Aboriginal and Torres Strait Islander, Australia and dietary intake. Key words used in combination were: Indigen* OR Aborigin* OR Torres Strait Islander AND Australia* AND diet* OR nutrit* OR food consum* OR eat* NOT virus OR bacteria OR infect* NOT genom* NOT plant* OR tree*. The search results were imported into Endnote (Thomson Reuters) where duplicate records were removed.

2) Titles and abstracts were assessed by two independent reviewers (SW and SF) against the inclusion criteria. To be included, studies needed to focus on Aboriginal or Torres Strait Islander peoples in Australia, of any age and living in any region of Australia, and include a baseline measurement of dietary intake.

3) Where eligibility was unclear, studies were further discussed or a third independent reviewer (JB) was consulted. Electronic searches were supplemented by manual cross checking of the reference lists of publications.

Data extraction

Data were extracted using a standardised table designed and tested for this review including: 1) population characteristics; 2) sample size; 3) study design; 4) measurement method; 5) primary outcome measure; and 6) main findings.

Quality assessment

Study quality was assessed using a purposely devised quality appraisal tool (Supplementary Table 1) developed from two existing tools. Additional domains added related to the involvement of Aboriginal and Torres Strait Islander peoples in the design and implementation of the studies. One reviewer (SW) had primary responsibility for quality assessment. For the first three studies, two reviewers (SW and SF) jointly completed quality assessment and the remaining extraction was completed by the first reviewer and checked by the second reviewer. Disagreements were resolved through discussion or a third independent reviewer (JB) was consulted until consensus was reached.

Results

Search results

The search strategy identified 129 articles (Figure 1). Following elimination of duplicates, initial assessment of titles and abstracts, and evaluation of retrieved articles against the inclusion criteria, twenty-five articles from twenty studies were identified for quality assessment and included in the review. Included studies were conducted between 1991 and 2016, but most studies were conducted in the early 1990s (n=5 studies) or after 2007 (n=14).

Description of studies

Twenty independent studies were included in the analysis but there was a total of twenty-five articles, as several used the same raw data but analysed for different purposes. The most common dietary intake assessment methods used were: electronic store sales data (n=6 studies) and store turnover method (n=3) to measure population-level intake; and 24-hour dietary recalls (n=4), food frequency questionnaire (n=4) and short questions (n=3) to measure individual intake. Fifteen were observational studies and five were intervention studies (Supplementary Table 2).
Location and study population

Most studies were conducted in a remote setting (n=12 studies), with less in rural (n=4) or urban settings (n=4).26 The studies were located in the Northern Territory (NT), n=5 studies; Western Australia (WA), n=4; New South Wales (NSW), n=4; Queensland (QLD), n=2; South Australia (SA) n=2; and Victoria (VIC), n=2. One study included three states and one territory27 (Supplementary Figure 1). For population estimates using electronic store sales and the store turnover method, participant numbers ranged from one to six stores servicing approximately 149 to 5,000 residents. In studies assessing self-reported intake at an individual level, participant numbers ranged from 25 to 2,524 participants.

Dietary intake

All studies reported on several outcomes including: nutrient profile relative to requirement (n=12 articles), major food sources of nutrients (n=7), intake of fruit and vegetables (n=7) and traditional foods (n=2). Estimated per capita energy intakes varied widely depending on study type, sample population and location. Population measures ranged from 9,608kJ/person/day using electronic store sales data collected from stores and purchasing data collected for other food outlets and services in three communities in the NT from 2010 to 201114,25 to 14,720kJ/person/day from electronic store sales data in five community stores in SA in 2012.25 Estimates from dietary recall ranged from 7,570kJ/person/day for children in three urban communities in NSW from 2008 to 200924 to 8,353.5kJ/person/day in girls and 9,689.2kJ/person/day in boys aged 10–12 years residing in three disadvantaged rural communities in NSW in 2012. The recent National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey 2012-13 (NATSINPAS) estimated average energy intake as 7,261kJ/person/day for females and 9,175kJ/person/day for males.15

The recent studies in SA and NT using electronic store sales data showed protein, carbohydrate and fat (including saturated fat) were in or almost within the recommended ranges.13,24,25,27 In contrast, these three studies showed that total sugar provided 22–33.4% of total energy intake.13,24,25,27 which is two to three times that recommended by the World Health Organization (WHO).28 The two NT studies24,25,27 that used electronic store sales data also showed sodium intakes greatly exceeded recommendations,30 while calcium, magnesium, potassium and fibre fell below the population recommended levels.30 Similarly, the children’s dietary survey in rural NSW showed 74% of participants exceeded the upper limit for sodium, while a high proportion of participants did not meet the adequate intake for dietary fibre (77%), potassium (62%) or calcium (65%).30 The NATSINPAS also reported that, on average, the estimated sugar intake provided 21% of total energy intake and sodium intake was 2,379mg,15 which exceeded recommended limits.30 Likewise, the estimated dietary fibre intake of 18 grams and calcium intake of 734mg (males) and 611mg (females)15 was below recommendations.30

Quality assessment

Studies were most likely to be rated as low quality based on validity of dietary assessment measure (n=8 studies), participation rate (n=8) and representativeness of the study sample (n=5). Involvement of Aboriginal and Torres Strait Islander peoples throughout the study process was not reported in nine out of 20 studies. Of the 10 studies that used a food composition table to link foods to nutrient sources of nutrients (n=7), intake of fruit and vegetables (n=7) and traditional foods (n=2).

Table 1: Quality assessment of studies, summarised.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Inclusion and involvement of Aboriginal and Torres Strait Islander people throughout study process</td>
<td>L</td>
<td>U</td>
<td>L</td>
<td>L</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>L</td>
<td>L</td>
<td>U</td>
<td>L</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>L</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
</tr>
<tr>
<td>2. Sample is representative of the underlying population</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
</tr>
<tr>
<td>3. Participation rate is greater than 50% or attempt to quantify characteristics of non-responders</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>U</td>
<td>U</td>
<td>L</td>
<td>H</td>
<td>H</td>
<td>H</td>
<td>H</td>
<td>L</td>
<td>U</td>
<td>L</td>
<td>H</td>
<td>H</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>U</td>
<td>L</td>
<td>H</td>
<td>H</td>
<td>H</td>
<td>H</td>
<td>H</td>
</tr>
<tr>
<td>4. Reliable and valid dietary assessment measures used</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>U</td>
<td>L</td>
<td>H</td>
<td>H</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
</tr>
<tr>
<td>5. Meets criteria for quality of the dietary assessment measure</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
</tr>
<tr>
<td>6. Appropriate food composition tables used and second person has checked linking of foods</td>
<td>L*</td>
<td>L</td>
<td>L*</td>
<td>NA</td>
<td>NA</td>
<td>L</td>
<td>NA</td>
<td>L*</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>H</td>
<td>U</td>
<td>L*</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>H</td>
<td>U</td>
<td>L*</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>H</td>
<td>U</td>
</tr>
<tr>
<td>7. Results appear in enough detail to permit checking for accuracy</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
</tr>
<tr>
<td>8. Study limitations have been commented on and taken into consideration in results</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
</tr>
</tbody>
</table>

Each item was rated as L=low bias, H=high bias, U=unclear, NA= not applicable
*Second person not checking linking of foods
The main contributors to dietary intake were similar both between the studies and over time. Two NT studies in the 1990s that used the store turnover method of dietary assessment identified white sugar, meat and meat products, white flour and bread as the four main foods contributing to available energy.\textsuperscript{6,9,11} More recent studies in SA\textsuperscript{13} and NT\textsuperscript{24,25,27} using electronic store sales data also found that white sugar, meat and meat products, and bread were the primary contributors to energy. A striking finding from these recent studies was the high expenditure on beverages and corresponding high intake of sugar-sweetened beverages.\textsuperscript{13,24,25,27} The intake of energy-dense, nutrient-poor foods and beverages also appears to be high in children and youth, contributing as much as 40–50% of total energy intake.\textsuperscript{9,9,33} The NATSINPAS also reported a high intake of these foods where just over two-fifths (41%) of total daily energy intake was from discretionary foods and beverages, with almost two in five (37%) people reporting daily consumption of soft drinks and flavoured mineral water.\textsuperscript{15}

All four individual-level dietary assessment studies reported that few participants were meeting the recommended two serves of fruit and five serves of vegetables per day.\textsuperscript{21–23,28,13,14} Similarly, the NATSINPAS\textsuperscript{15} showed that over half (54%) of the participants met the recommended serves of fruit and only one in 12 (8%) participants met the recommended number of serves of vegetables per day.\textsuperscript{30} Two studies (one in a remote community in WA and the other in three remote communities in the NT) both reported that fruit and vegetables made up the smallest portions of food and beverage purchasing in community stores, while beverages, particularly soft drink and juice, made up the largest percentage of money spent.\textsuperscript{24,25,15}

Only two studies provided data on the intake of traditional foods. One study in rural Southern Gumbaynggirr Country, NSW, found 96% of the households surveyed regularly consumed food resources from the Nambucca River Estuary, particularly during periods of financial hardship.\textsuperscript{36} An ethnographic survey undertaken in a remote community in WA in 2006 found 22.8% of households had at least one member participating in a hunt each day.\textsuperscript{35} Traditional foods were not a feature of rural children’s diet in the study of 10–12 year olds in NSW.\textsuperscript{9}

### Discussion

This is the first comprehensive overview of the evidence about the diets of Aboriginal and Torres Strait Islander groups in Australia. The relatively low number of studies and varying quality means it is not possible to use the findings to make generalisations about the diets of Aboriginal and Torres Strait Islander peoples in Australia other than those provided from the NATSINPAS. However, a number of important observations can be made to help inform future policy development.

### Study populations

The studies were conducted in a variety of locations across Australia. Most studies have been undertaken in remote environments. Few studies have assessed dietary intake among Aboriginal and Torres Strait Islander peoples in urban areas despite one-third (233,100 people) of the total Aboriginal and Torres Strait Islander population in Australia living in this setting.\textsuperscript{37} As a consequence, the wide variety of dietary practices of the different cultural groups that make up Indigenous Australia may not have been captured.

### Dietary assessment methods

Around half of the studies included used electronic store sales data or store turnover method to assess population intake. Previous research has shown that these methods have less potential for bias compared to the weighed food record, 24-hour dietary recall, food frequency questionnaire and diet history, and are more acceptable to community members.\textsuperscript{27,38} In a rural or remote context the community store is a good setting from which to obtain a ‘community dietary quality profile’ or monitor the impact of dietary interventions,\textsuperscript{6,27} as this is where the majority of food is purchased.\textsuperscript{24,25} However, these approaches yield average per capita consumption estimates rather than taking into account differences relating to gender or age, or other variations of dietary intake patterns.\textsuperscript{19}

While dietary assessment methods such as 24-hour dietary recalls and food frequency questionnaires (FFQ) are much more useful for assessing variation between individuals, they also have their limitations. With self-reported data obtained from either 24-hour dietary recall or a FFQ, participants tend to under- or over-report their food intake.\textsuperscript{29}

While the FFQ can be used to assess dietary intake over periods of more than 24 hours, the development of an appropriate list of food items is crucial to the validity of this method and participants can have difficulty remembering their frequency of consumption of different foods and beverages.\textsuperscript{19} These methods are further limited when used in the Aboriginal and Torres Strait Islander population.\textsuperscript{38} Accurate assessments of diet require 24-hour recalls to be repeated several times. However, the resources required to do this, particularly in remote areas, means it is often not practical. While the recent NATSINPAS used a multiple-pass 24-hour dietary recall, it was decided that repeat surveys would not be performed in remote locations due to the costs involved.\textsuperscript{15} In such cases, a trade-off between accuracy and practicality often has to be made to ensure that adequate data is obtained in the most cost-effective way.

### Quality assessment

The reliability and validity of dietary assessment methods, representativeness of the study population, and lack of comment on the inclusion and involvement of Aboriginal and Torres Strait Islander peoples throughout the study process were the main issues relating to study quality. Several of the studies used assessment methods not specifically validated for Aboriginal and Torres Strait Islander populations. Validation studies are not always feasible as they tend to be large and costly. However, studies should acknowledge the limitations of the dietary assessment used and state in which populations the tool they are using has been validated. There have been only a small number of tools validated for the Aboriginal and Torres Strait Islander populations. Validation studies are not always feasible as they tend to be large and costly. However, studies should acknowledge the limitations of the dietary assessment used and state in which populations the tool they are using has been validated. There have been only a small number of tools validated for the Aboriginal and Torres Strait Islander populations, including the store turnover method\textsuperscript{12} and a food frequency questionnaire.\textsuperscript{40} Ideally, studies should draw from existing validated tools, or questionnaires should be adapted or modified to suit the population being sampled.

None of the identified studies were based on a nationally representative sample of the population, other than the NATSINPAS. That said, Aboriginal and Torres Strait Islander groups are not all the same and there is sometimes a trade-off between aiming for representative population-wide samples and obtaining accurate data on specific groups. More often the studies in
this review aimed to assess dietary intake in a particular community or a specific target population, or to assess the impact of a nutrition intervention on the participants involved in a study. In such cases, it is important not to generalise the results from the sample to the whole Aboriginal and Torres Strait Islander population. With the recent NATSINPAS, some discrete Aboriginal and Torres Strait Islander communities with a small number of Aboriginal and Torres Strait Islander households were excluded in order to manage enumeration costs. The final sample was weighted to population benchmarks to account for these exclusions.15 This national level survey provides us with estimates at the population level, but it is difficult to generalise across different contexts such as very remote vs. remote, therefore it is important to have both nationally representative surveys and targeted studies to get more in-depth information.

The quality of research about Aboriginal and Torres Strait Islander peoples can be improved through the participation of Aboriginal and Torres Strait Islander peoples in the design and implementation of the research programs.41 Only half of the studies included in this review stated if or how Aboriginal and Torres Strait Islander peoples were involved in the study design or throughout the study process. While word limits for peer-review journals limit what can be reported, it would be helpful for community engagement processes to be better described to facilitate quality assessment of future studies.

**Dietary intake**

Overall, these studies suggest a diet of generally poor quality for Aboriginal and Torres Strait Islander peoples. In particular, total sugar intake has been remarkably high since the early 1990s, while fruit and vegetable intake is well below the recommendations. These findings are consistent with the recent National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey, which identified that Aboriginal and Torres Strait Islanders in general consume too little of the five major food groups and too much sugar and other discretionary foods.15

Total sugar intake as a contribution to energy intake in studies included in this review consistently exceeded the WHO recommendation of ≤10% of total energy intake26 by up to three times.8,9,13,24,25,27,32 Total sugar intake was also high at an average of 19.5% of total energy intake in the non-Indigenous population in the Australian National Nutrition and Physical Activity Survey (NNPAS) 2011-12.42 Total sugar intake was found to be higher in the Aboriginal and Torres Strait Islander population living in non-remote areas in the NATSINPAS15 compared to remote areas. Approximately two-thirds (67%) of all free sugars consumed by Aboriginal and Torres Strait Islander peoples came from beverages including sugars added to beverages, i.e. tea and coffee, alcoholic beverages and milk beverages.15 This is consistent with results from studies using the store turnover method and electronic store sales data to estimate diet, which identified high expenditure on beverages and corresponding high intake of sugar-sweetened beverages.13,24,25,27,31 In contrast, few Aboriginal and Torres Strait Islander participants met the recommendations two serves of fruit or five serves of vegetables a day.21-23,28,33 According to the NNPAS, a lower proportion of Aboriginal and Torres Strait Islander adults 19 years and older met the recommendations for vegetable intake compared with non-Indigenous adults (4.4% compared with 6.8%).42 The proportions of participants meeting the recommendations for fruit intake were identical between Aboriginal and Torres Strait Islander adults and non-Indigenous adults (54% for both).42

The intake of fruit and vegetables was consistently low in studies undertaken in all regions: urban, rural and remote. The NATSINPAS found Aboriginal and Torres Strait Islander peoples living in remote areas were less likely than those in non-remote areas to have consumed fruit products and dishes (35% compared with 49%) or vegetable products and dishes (55% compared with 67%).15 In some very remote places, everyday access to affordable and quality fruit and vegetables is variable.41 Remote store products were reported to be 60% more expensive than Darwin supermarket prices and 68% more expensive than Adelaide supermarket prices in a cross-sectional survey.43 Energy-dense, nutrient poor foods tend to be convenient and easily accessed, and provide the cheapest options to satisfy hunger,41 particularly in a remote context, while healthy foods can be in limited supply and at relatively high costs.41 This energy–cost differential helps explain the persistently poor dietary patterns reported in this population.43 Despite this, research suggests that community dietary patterns can be improved through improved food supply and stock management in community stores.45,46 Consequently, the focus of Aboriginal and Torres Strait Islander nutrition-based initiatives has broadened to include improving food quality and access to healthy food in remote communities,45,46 rather than a sole focus on nutrition education.

**Strengths and limitations of study**

A limitation of this review was that it excluded grey literature that did not meet peer-review standards and academic publication quality. However, key policy documents, in particular the most recent NATSINPAS, have been considered throughout. While the search strategy was limited to three main databases, additional cross-checking was performed with the reference lists of studies included in this review; therefore, it is unlikely that studies have been missed from this review. Limited reporting of community engagement methods in the studies also meant it was challenging to assess the quality of the studies in relation to this domain. It would be helpful if future studies could more clearly identify such processes.

**Conclusion**

This is the first systematic review to collate and critique the quality of available data on the dietary intake of the Aboriginal and Torres Strait Islander peoples in Australia, and it has highlighted the varying quality of studies and limited generalisability of sample populations. Although caution is advised in interpreting the outcomes of these studies, consistent findings were low reported intakes of fruit and vegetables and high intakes of total sugar and energy-dense, nutrient-poor food and beverages.

**Implications for public health**

The review demonstrates a clear need for policy and community interventions to improve dietary quality for Aboriginal and Torres Strait Islander peoples. However, the limited number of studies, variable quality and lack of diversity of communities involved could be a barrier to effective policy making and should be addressed.
Acknowledgements

SW had primary responsibility for writing the paper and final content. JB and JW were equal senior authors who contributed to the conceptualisation and development of the review. SW, LV, JB and JW made contributions to the development of the review protocol and search strategy. SW and SF were involved in study selection, data extraction and quality assessment. SW prepared the manuscript with review from SF, LV, ML, KT, JB and JW. JW is supported by a joint National Heart Foundation (NHF) Future Leader Fellowship (ID:100085). JW is supported by a Development Fellowship (App:1082924).

References


Supporting Information

Additional supporting information may be found in the online version of this article: Supplementary Table 1: Quality appraisal tool. Supplementary Table 2: Summary of included studies. Supplementary Figure 1: Map of study locations.
Getting it Right: study protocol to determine the diagnostic accuracy of a culturally-specific measure to screen for depression in Aboriginal and/or Torres Strait Islander people

Maree L Hackett,1,2 Sara Farnbach,1 Nick Glozier,3 Timothy Skinner,4 Armando Teixeira-Pinto,5 Deborah Askew,6,7 Graham Gee,8 Alan Cass,9 Alex Brown10

To cite: Hackett ML, Farnbach S, Glozier N, et al. Getting it Right: study protocol to determine the diagnostic accuracy of a culturally-specific measure to screen for depression in Aboriginal and/or Torres Strait Islander people. BMJ Open 2016;6:e015009. doi:10.1136/bmjopen-2016-015009

ABSTRACT

Introduction: A freely available, culturally valid depression screening tool is required for use by primary care services across Australia to screen for depression in Aboriginal and/or Torres Strait Islander populations. This is the protocol for a study aiming to determine the validity, sensitivity and specificity of the culturally adapted 9-item Patient Health Questionnaire (aPHQ-9).

Methods and analysis: Cross-sectional validation study. A total of 500 people who self-identify as Aboriginal and/or Torres Strait Islander, are ≥18 years of age, attending 1 of 10 primary healthcare services or service events across Australia and able to communicate sufficiently to answer study questions will be recruited. All participants will complete the aPHQ-9 and the criterion standard MINI International Neuropsychiatric Interview (MINI) 6.0.0. The primary outcome is the criterion validity of the aPHQ-9. Process outcomes related to acceptability and feasibility of the aPHQ-9 will be analysed only if the measure is found to be valid.

Ethics and dissemination: Lead ethical approval was obtained jointly from the University of Sydney Human Research Ethics Committee (project 2014/361) and the Aboriginal Health and Medical Research Council of New South Wales (project 1044/14). Results will be disseminated via the usual scientific forums, including peer-reviewed publications and presentations at international conferences following presentation to, discussion with and approval by participating primary healthcare service staff and community.

Trial registration number: ACTRN12614000705684.

BACKGROUND

There is a need to focus our attention on overcoming the health disadvantage experienced by the world’s more than 370 million Indigenous peoples.1 In Australia, chronic disease (cardiovascular disease, cerebrovascular disease, diabetes, chronic kidney disease and chronic obstructive pulmonary disease) accounts for 80% of the life expectancy gap experienced by Aboriginal and/or Torres Strait Islander (hereafter referred to as Indigenous) people2 who are estimated to make up 3% (669 900 people) of the total Australian population.3

It is estimated that up to 20% of the general population with chronic disease will have a diagnosis of comorbid major depression.4 Approximately similar proportions will additionally meet criteria for moderate or minor depression.5 6 Among people with existing chronic disease, comorbid depression is associated with increased disability, longer length of hospital stay, reduced quality of life and higher costs among those who experience an acute vascular event.4 7 Major depression also significantly

Strengths and limitations of this study

- The main strengths of the current study are that it will determine the criterion validity of a culturally adapted depression screening tool (aPHQ-9) for use across multiple States and Territories across Australia.
- A widely used psychiatric structured diagnostic interview, the MINI International Neuropsychiatric Interview (MINI) 6.0.0, is the reference standard.
- There are insufficient resources, nor will it be feasible, to use the ultimate reference standard reference measure, an experienced culturally competent psychiatrist or highly trained mental health clinician using a semistructured clinical interview.

CrossMark

For numbered affiliations see end of article.

Correspondence to Dr Maree L Hackett; mhackett@georgeinstitute.org.au

To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2016-015009).
complicates the long-term management of comorbid conditions by negatively impacting on adherence to medications and other secondary preventive strategies. Mental illness and depression are also considered to be key contributors to the development of chronic disease.\(^8\) The presence of depression approximately doubles the risk of first myocardial infarction or cardiac death, but among patients with established ischaemic heart disease, the risk of a future serious cardiovascular event is increased three to fourfold by comorbid depression.\(^6\,\,13\) However, none of this research has been conducted with, by or in Indigenous populations in Australia.

The identification and proactive management of depression in general primary care in Australia has been shown to improve outcomes (reduced depression and improved treatment intensification sustained over 12 months, with a reduction in 10-year cardiovascular disease risk) in people with diabetes and heart disease.\(^14\) A freely available, culturally valid depression screening tool for use across Australia is required to achieve the same benefit in Indigenous peoples attending primary care.

Two screening tools for depression have been determined valid, in comparison with semi-structured clinical interviews, for use by Indigenous Australians residing in specific Australian communities. The more comprehensive validation study is of the Kimberley Indigenous Cognitive Assessment of Depression (KICA-dep) scale. This study was conducted with 250 Indigenous people (18 with depressive disorder) aged 45 years or more residing in 6 communities in the Kimberley region.\(^15\) In the other study, the 9-item Patient Health Questionnaire (PHQ-9)\(^16\) was adapted for use in a small sample (n=34, 9 with depression) of Aboriginal primary care patients with coronary heart disease attending a single primary healthcare centre in the Northern Territory in Australia.\(^17\) In a subsequent conceptual adaptation study,\(^18\)\(^19\) the original PHQ-9 was assessed by men from five Aboriginal language groups in Central Australia as requiring modification for use in their community and was modified (adapted 9-item Patient Health Questionnaire, aPHQ-9)\(^18\) accordingly to ensure cross-cultural validity, and found valid in a community sample of 78 Indigenous people from Central Australia. No measure has been validated in more than one Australian State or Territory.

Aims
The primary aim is to determine the validity of the aPHQ-9,\(^18\) compared against a reference standard (criterion standard) MINI International Neuropsychiatric Interview (MINI) 6.0.0\(^20\) as a screening instrument for depression. The secondary aim is to determine the contribution that seven additional questions identified during in-depth qualitative research make to the detection of depression via the aPHQ-9 in Indigenous people attending primary healthcare services. A process evaluation will be conducted following the completion of recruitment to formally evaluate the processes, lessons learnt and impact of implementing the study on recruitment sites and staff. Process evaluation methods will be described in a separate protocol.

METHODS
‘Getting it Right’ is a national, multicentre, prospective diagnostic accuracy, observational study to be conducted through a network of Indigenous primary healthcare services across Australia’s States and Territories. The study was conceived, designed and will be conducted in keeping with the principles of Reciprocity, Respect, Equality, Responsibility, Survival and Protection and Spirit and Integrity important to Aboriginal and Torres Strait Islander communities and described in the National Health and Medical Research Council’s Values and ethics: guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research.\(^21\) The investigator team includes Aboriginal and non-Aboriginal researchers, relationships will be developed between the project team and key personnel at each service, local community members will be employed at each service to undertake data collection, the data collected at each site will remain the property of that site, feedback sessions will be conducted at each service for staff and community members and services and individual research participants will receive compensation for participation.

PARTICIPANTS
The study will be conducted in ~10 urban, rural and remote primary healthcare services (sites) in Australia with a predominantly Indigenous client base.

Consent process and participant inclusion and exclusion criteria
Written approval from each participating site’s Board, if a community-controlled organisation, institutional review board, research committee, community jury, letter of support or similar must be obtained, as well as from any local Human Research Ethics Committee or other relevant regional or national body, before recruitment can start.

Inclusion criteria
All patients are eligible for the study if, at the time of presentation at a participating health service or community event, they meet each of the following criteria:
1. ≥18 years of age,
2. self-identifies as Aboriginal and/or Torres Strait Islander,
3. able to communicate sufficiently to answer study questions,
4. able to give informed consent.

Exclusion criteria
Patients will be excluded from the study if at the time of presentation, they are known (diagnosis documented in
medical records or information provided when asked) to have psychosis or bipolar disorder.

**Recruitment**

Consecutive eligible patients will be invited to participate in the study on any given recruitment day. Trained staff members nominated by each service will obtain individual participant written or verbal consent to participate in the study. Recruitment began on 25 March 2015 and will continue until 500 participants have completed both interviews.

**Background care**

All patients within the primary healthcare service or people attending service-led events will be managed by their general practitioner or other allied health professional. Their management should be best practice standard of care according to regional guidelines and the duty of care always remains with the healthcare service.

**Study outcome**

The primary outcome is the criterion validity of the aPHQ-9. The reference standard is a clinical diagnosis of depression ascertained using the MINI 6.0.0 having two categories: ‘current major depressive episode’ and ‘no current major depressive episode’.

In addition, we also aim to determine the contribution that seven additional questions identified during indepth qualitative research make to the detection of depression via the aPHQ-9 criterion validity of the aPHQ-2 (the first two questions of the aPHQ-9) and feasibility of assessment using the aPHQ-9 within primary healthcare services. Should the aPHQ-9 (with or without the addition of one or more of the seven additional questions) have acceptable sensitivity and specificity as a screening tool for depression, we will seek qualitative feedback on feasibility from primary healthcare staff during the ‘feedback of study results’ to sites. Site staff will be asked about the impact of screening on them, their study participants and the practice, the effect on the participant/health-professional relationship, the usefulness of the aPHQ-9 and the extent to which practice routines must be adapted to integrate the aPHQ-9 into their service delivery should it be found to be valid.

**Data collection**

During recruitment, consecutive patients attending the primary healthcare service on a recruitment day or people attending service events, who appear to meet the inclusion criteria, will be approached by a trained clinic staff member. Site study staff will record the date of presentation of all people considered for participation in the study on the study screening log, whether they were eligible, whether they consented to participate and if not, the reason for non-participation. All consecutive consenting participants will be recorded on the study enrolment log.

**TEST METHODS**

The aPHQ-9 and its development have been described previously. In brief, the PHQ-9 was modified to ensure cross-cultural validity. A structured process was followed using the expertise of five focus groups comprising male members of distinct Indigenous language groups in central Australia. Bilingual experts from each language group translated the PHQ-9. Each translation was discussed with the research team, clarity sought on meaning for difficult items and problematic translations were identified, discussed and amended (where necessary). This resulted in some words and phrases being modified to provide linguistic or conceptual equivalence, and single questions with divergent English meanings being split into two. During the modification process, seven key features of depression in Aboriginal men were identified that were not covered by the aPHQ-9. These additional features include anger, weakened spirit, homesickness, irritability, excessive worry, rumination and drug/alcohol use.

**Reference standard: MINI 6.0.0**

The MINI is a short, structured interview for the major Axis I psychiatric disorders. Validation and reliability studies have shown that the MINI has acceptably high validation and reliability scores compared with the Structured Clinical Interview for DSM Disorders and the World Mental Health Composite International Diagnostic Interview, can be administered within 19 min on average and can be modularised and administered by clinicians and lay interviewers after appropriate training. The MINI is the most widely used psychiatric structured diagnostic interview instrument in the world and has been validated for use in over 100 countries. There are insufficient resources (trained personnel) available, nor will it be feasible, to use the ultimate reference standard method of diagnosis of depression by an experienced culturally competent psychiatrist or highly trained mental health clinician using a semistructured clinical interview.

**Assessment 1**

Following consent, a trained member of the primary healthcare service staff will interview each participant using a short paper-based or computer-assisted questionnaire during a face-to-face interview (or telephone if required). Participants can answer questions directly using paper-based or computer-assisted forms or the questionnaire can be interviewer-administered at the discretion of the interviewer and participant. Data will be collected on the method of assessment (interviewer-administered or self-completed, paper-based or computer-assisted, language in which interviews were conducted), response to the 11 questions on the aPHQ-9, the additional seven questions, one question regarding how much any identified problems impact on their daily lives, and questions about the acceptability and ease of use of the aPHQ-9. These questions are
followed by an open-ended question where participants can provide feedback about the aPHQ-9. Study staff will encourage participants to provide feedback about aPHQ-9 acceptability and any issues of concern.

Demographic information to be collected includes gender, age, whether Aboriginal language(s) is spoken at home, marital status, living arrangements (alone/with others), recent activity-restricting illness, recent (in the last 2 months) bereavement, highest educational qualification, lifetime and current occupation, main income earner and medical history (primary history of chronic disease and mental illnesses and whether any associated medications are taken).

If a participant has difficulty reading or requires any assistance for whatever reason, the aPHQ-9 will be read to them by a trained member of staff or an interpreter. This person will also enter the responses onto the paper or computer-assisted form on behalf of the participant. All data will be entered in the secure web-based study database.

**Assessment 2**
On the same day, or within 7 days of completing assessment 1, all participants will be administered the MINI 6.0.0 interview and questions on smoking and alcohol consumption in a face-to-face (or telephone if required) interview by a trained MINI interviewer who did not complete and will be blind to the results of assessment 1. Three MINI 6.0.0 modules will be administered for this study: the full set of major depressive episode/disorder questions (current, recurrent), post-traumatic stress disorder (past month) and generalised anxiety disorder (past 6 months). These will be followed by questions about smoking and alcohol consumption.

**Coenrolment**
There are no methodological contraindications to coenrolment of participants into other research projects.

**Training**
Prior to initiation of the study at any site, all participating primary healthcare service staff involved in the study will receive study-specific training. Training relates to the study protocol, source documentation, screening and enrolment logs, Good Clinical Research Practice, informed consent, questionnaire completion, interviewing participants for research purposes, safety protocols, accessing and completing data entry on the study-specific secure internet-based study database, and study documentation. Training will be provided in person by SF (the project manager) and MLH (the chief investigator) in the first instance. Subsequent retraining, or training of new staff may be provided via telephone and/or video links where available.

Training related to administration and scoring of the MINI will be provided face to face or via video link by NG (the study psychiatrist). This will be followed by inter-rater assessments of up to four prerecorded role plays. Prerecorded role plays will be scored by NG, who will inform SF when the MINI interviewers are competent. Sites will only be activated after MINI results have been checked by and discussed with NG.

**Safety**
The safety and welfare of the participants is of primary importance in the study. Participation is voluntary and non-participation will in no way affect the quality of care provided to the participant by study staff. We will work with each primary healthcare service to ensure depression, deliberate self-harm and suicidal ideation and intent protocols are in place for follow-up and care of study participants.

We require one nominated responsible person at each recruiting primary healthcare service to check all completed aPHQ-9 questionnaires at the end of each day. In addition, we will notify the primary healthcare service of any participant who:
1. scores 10 or more on the aPHQ-9 assessment, and/or
2. is considered to have a major depressive episode during the MINI interview,
3. indicates suicidal ideation or suicidal intent during the aPHQ-9 or the MINI interview.

The primary healthcare service will be notified by way of a standard email. The email will indicate our reason for concern and provide some suggestions on clinical management options based on current guidelines. Completed case report forms can be printed by interviewers and (or electronically) attached to medical records to facilitate ongoing clinical assessment.

We will provide local (to each site) mental health crisis line numbers and access to online psychological interventions (http://www.ecouch.com.au, http://www.mindspot.org.au). Study staff may also offer to email this information to participants.

The suggestions in our email to the primary healthcare service are:
1. Consider non-pharmacological treatments such as advising an increase in social outlets, regular exercise or referral to a clinical psychologist. Clinical psychology can be accessed through the Medicare Better Access initiative and is available free of charge to Australian residents and citizens. There is provision for up to 10 sessions per year as part of a GP mental health treatment plan http://www.health.gov.au/internet/main/publishing.nsf/content/mental-bagasm
2. If you feel that antidepressant medication is necessary, then either yourself or their treating doctor might consider the attached guidelines, https://www.nice.org.uk/guidance/cg90
3. Consider referral to a specialist, for example, psychologist or psychiatrist.

Participants can opt to have any detected condition NOT communicated to their clinician unless it is felt that the level of risk is so great that we need to breach confidentiality: a HIGH on the suicidality risk level on
the MINI. Site study staff will be able to contact the study psychiatrist to discuss any safety concerns via telephone or email.

**STATISTICAL METHODS**

**Sample size**

We computed the sample size based on the target precision for the estimation of sensitivity and specificity of the aPHQ-9 used for the screening of a major depressive episode. Assuming a major depressive episode prevalence (assessed by the MINI) of 10% and a true sensitivity of 0.85, a sample size of 500 participants will give us a precision of 0.1 for the sensitivity’s 95% CI. For the specificity, 500 participants will provide a precision of 0.04 for the specificity’s 95% CI, assuming a true specificity of 0.75 and the same prevalence of 10%. If the prevalence of major depressive episodes is in fact higher, for example, 15%, the precision for the sensitivity will be 0.08. For the analysis of the contribution of additional questions to the aPHQ-9, a sample size of 500 will give us 80% probability (power) of detecting a true improvement of 0.05 in the area under the ROC curve, fixing the type I error at 0.05.

**Data analysis**

For descriptive purposes, baseline characteristics will be presented. Discrete variables will be summarised by frequencies and percentages, continuous variables by use of standard measures of central tendency and dispersion, mean and SD or median and IQR.

**Primary aim analyses**

We will assess the validity of the aPHQ-9 when compared with the MINI, using two common criteria for major depression: I—a score of 2 or above on one of the first two items of the aPHQ-9 plus 4 or more items with a score of 2 or above (the last question is counted if a score of 1 or above is indicated) and II—a total score of 10 points or above, similar to the usual cut-off for the original PHQ-9. The original scoring method will be used with the two ‘split questions’ (questions 5 and 8 on the original PHQ-9) on the aPHQ-9 being scored once only. However, given this is an adaptation of the original questionnaire, we will explore the properties of other cut-off points by constructing an ROC curve. The sensitivity and specificity will also be computed for subgroups (e.g., individuals with chronic disease) using logistic regressions to allow adjustment for potential demographic differences between the subgroups. All the estimates will be presented with 95% CIs.

**Secondary aim analyses**

We will assess the validity of the aPHQ-9 plus the additional seven culturally specific questions when compared with the MINI. The contribution of each question will be initially analysed separately and we will select for further analysis any questions that individually contribute to a better discrimination property of the questionnaire while maintaining the internal validity of the instrument. We will compare the area under the ROC curves of the original score with the one obtained by individually adding each question, in the total sample, and in those with, and in those without chronic disease. We will also compute Cronbach’s α to evaluate if the new question is measuring the same underlying construct as the aPHQ-9.

After this step, we will use a stepwise strategy to evaluate the addition of multiple questions to the aPHQ-9. We will first consider the aPHQ-9 plus the question with highest improvement in the area under the ROC curve, then we will add the second best question and evaluate if this question still contributes to an increase in the area under the ROC curve and so on. If any of the additional questions prove to be useful, we will study the psychometric properties of this new instrument in more detail, as well as recommend major depressive episode screening cut-points.

**Missing outcome data**

The calculation of the global score for the aPHQ-9 is given by the sum of all the answers on the questionnaire. If one question is left unanswered, the score cannot be directly computed. For incomplete questionnaires, as long as there are five or more questions answered, we will compute a partial score summing the answered questions. Then, the global score will be derived with a proportional transformation of the partial scores, based on the number of unanswered questions. For example, if a participant has a partial score of 12 based on 8 questions, the global score will be computed as (12×9)÷8=13.5. The underlying assumption for this procedure is that the unanswered question(s) follows a similar pattern to the answered ones. If a questionnaire has only four or fewer questions answered, it will be excluded from the analysis. For other variables in the study, we will use all the available information for the respective analysis.

**Data management**

The internet-based data management system will be managed centrally by the project manager from The George Institute for Global Health. Registration and data entry will be performed at the participating sites via a password-protected connection. Only trained staff listed in the delegation log will be given unique passwords to access the database. Paper case report forms will be provided to sites preferring to use these for initial data collection.

**Confidentiality and privacy**

Every precaution will be taken to respect the privacy of study participants. Each participant’s MINI result will be provided to and checked by the primary healthcare service. The general practitioner of a participant who is assessed as experiencing a psychiatric disorder will be...
encouraged to arrange reassessment, treatment or formal referral for depressive or other abnormal mood symptoms according to their clinical judgement.

DISSEMINATION
The findings of this study will be disseminated via the usual scientific forums, including peer-reviewed publications and presentations at international conferences following presentation to, discussion with and approval by participating primary healthcare service staff and community. Participants will have the option to receive information (via post, text or email) on the study findings, when available. The study will be administered by the George Institute for Global Health, with the design and conduct overseen by a steering committee (authors). This committee has expertise in Indigenous health, cardiovascular health and mental health research. This study will adhere to the National Health and Medical Research Council Values and Ethics—Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.

CONCLUSIONS
This study responds to the lack of understanding of the natural history, trajectories and outcomes of depression and comorbid chronic disease in the Indigenous people of Australia, and the performance of primary healthcare services in identifying and managing depression and comorbid chronic disease. This work will directly contribute to the evidence base for identifying depression and developing culturally specific primary healthcare depression interventions for Indigenous people by providing the evidence on whether to recommend the use of the aPHQ-9 as a screening tool for depression. If validated, the aPHQ-9 will enable exploration of the burden and correlates of depressive symptoms with comorbid chronic disease and chronic disease risk factors in Indigenous patients routinely attending primary healthcare and assessment of the effectiveness of management strategies for depression in Indigenous patients routinely attending primary healthcare.21

Author affiliations
1Neurological and Mental Health Division, The George Institute for Global Health, The University of Sydney, Sydney, New South Wales, Australia
2University of Central Lancashire, Preston, Lancashire, UK
3Brain and Mind Centre, The University of Sydney, Sydney, New South Wales, Australia
4Charles Darwin University, Darwin, Northern Territory, Australia
5School of Public Health, The University of Sydney, Sydney, New South Wales, Australia
6Southern Queensland Centre of Excellence in Aboriginal and Torres Strait Islander Primary Health Care, Metro South Health, Queensland Health, Brisbane, Queensland, Australia
7Discipline of General Practice, The University of Queensland, Brisbane, Queensland, Australia
8Victorian Aboriginal Health Service, Fitzroy, Victoria, Australia
9Menzies School of Health Research, Darwin, Northern Territory, Australia
10South Australian Health and Medical Research Institute, Adelaide, South Australia, Australia

Contributors MLH, NG, TS, AC and AB conceived the project. All authors (MLH, SF, NG, TS, AT-P, DA, GS, AC and AB) contributed to the design of the study, are involved in the implementation of the project and had the final responsibility for the decision to submit for publication.

Funding This work was supported by the National Health and Medical Research Council (NHMRC), Australia grant number APP101767. During the completion of this work, MLH was in receipt of a University of Sydney Faculty of Medicine Gross Cultural Public Health Research Award and a George Institute for Global Health John Chalmers Program Grant Scholarship. AT-P is partially supported by the NHMRC Program Grant BeatCKD (APP1092957) and AB was in receipt of a Sylvia and Charles Viertel Charitable Foundation Senior Medical Research Fellowship. All authors had full access to the data. All authors had the final responsibility for the decision to submit for publication.

Competing interests None declared.

Ethics approval University of Sydney Human Research Ethics Committee (project 2014/361) and the Aboriginal Health and Medical Research Council of New South Wales (project 1044/14).

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/

REFERENCES


Getting it Right: study protocol to determine the diagnostic accuracy of a culturally-specific measure to screen for depression in Aboriginal and/or Torres Strait Islander people

Maree L Hackett, Sara Farnbach, Nick Glozier, Timothy Skinner, Armando Teixeira-Pinto, Deborah Askew, Graham Gee, Alan Cass and Alex Brown

BMJ Open 2016 6:
doi: 10.1136/bmjopen-2016-015009

Updated information and services can be found at: http://bmjopen.bmj.com/content/6/12/e015009

These include:

References
This article cites 19 articles, 2 of which you can access for free at: http://bmjopen.bmj.com/content/6/12/e015009#BIBL

Open Access
This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/

Email alerting service
Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Topic Collections
Articles on similar topics can be found in the following collections

General practice / Family practice (559)
Mental health (588)
Public health (1884)

Notes

To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/
APPENDIX 6: RESEARCHER SAFETY AND RESPONSE PROTOCOL

As a member of the Validation Study research team, you will be asking participants standardized demographic questions and questions about depression, mood and social and emotional wellbeing. These questions are similar to those asked during a routine appointment with a health care provider. Due to the nature of the questions, there is a risk of participants becoming distressed during an interview or disclosing information to you that they haven’t disclosed to others. The aim of this protocol is to assist you with dealing with these situations. It provides you with a clear protocol so you know what to say if a participant becomes distressed during an interview.

Please refer to this guide during:

- Assessments 1 and 2: Demographic and aPHQ-9 Interviews
- Assessment 3: MINI 6.0.0 Interview

Below are some examples where participants may indicate distress. These include, but are not limited to:

- the person whose mood is deteriorating (without thoughts of harming themselves),
- the person with extremely low mood
- the person with thoughts of ending their life (these thoughts may be fleeting or be regular).
- the person with thoughts of ending their life, and plans in place for suicide.

The highest risk is for those individuals who have thoughts of killing themselves, plans in place as to how they would do so and the available means (e.g. knives, rope, drugs) by which to end their life.

It’s important to remain calm during the conversations, to speak in a compassionate tone and to allow for silences from the participant rather than responding at a whim if it’s distressing to hear (e.g. not saying in an anxious tone, ‘So you’ve got plans? So you’ve got things at home with you? Um, okay, okay … ’). It’s important to validate the person’s experience and to reflect back what they’ve told you (e.g. ‘So you think about killing yourself every day and these kinds of thoughts are happening constantly. And when you have these thoughts, they scare you.’). See Tips for How to Manage Interview Section.
Finally, these conversations can be distressing and unsettling. Please refer to *Tips for How to Manage Interview Section*. If you experience feelings and you want to talk about it, find a trusted colleague to debrief. If you have any questions and would like to speak with a clinician you may call:

Prof Nick Glozier (psychiatrist). Mobile: + 61 2 9993 4589

Assessment 1 and 2: Demographic and aPHQ-9 Interview or Assessment 3 MINI 6.0.0 Interview – conducted at service

Site staff: Each site has nominated a staff member to provide follow-up care, including re-assessment and management, for participants whose aPHQ-9 result indicates depression (a score of 15 or more), or MINI 6.0.0 indicate a case of major depression, post-traumatic stress disorder or generalised anxiety or who become distressed during the interview. This reviewer will receive an automatically generated email outlining the results for every consented participant. It is the responsibility of this staff member to ensure the site’s depression, deliberate self-harm and suicidal ideation and intent protocols are followed. The duty of care for participants remains with the service.

It is your responsibility to ensure that the aPHQ-9 and MINI 6.0.0 forms (unless specifically requested by the participant), regardless of the score, are reviewed by the nominated staff member and follow up actions are documented in the participant’s medical records. Additionally, if you are concerned for a participant’s welfare you must also report this to the nominated staff member. Immediate or subsequent concerns for a participant should be followed using usual duty of care according to usual practice.

The aPHQ-9 screening questionnaire and MINI 6.0.0 have questions asking about suicide and it is possible that a participant may become distressed during this interview. For example, you may be interviewing them when they are already distressed and/or a general discussion about the study (including their mood and mental health history) may trigger painful thoughts, feelings or memories.

Depression (scoring ≥ 10 on aPHQ-9) or MINI 6.0.0 case of major depression, post-traumatic stress disorder or generalised anxiety
Before a participant leaves the clinic you must ensure usual clinic practices are followed and complete the following steps:

1. Acknowledge the person’s low mood.
2. Provide information on resources available (see suggested script below and External Referral and Available Service) e.g. NSW Mental Health Line: 1800 011 551, Lifeline: 13 11 14, Beyondblue: 1300 224 636 MensLine: 1300 789 978. Offer to send them a follow-up email with the resources so that they have it for future reference (if appropriate) (see Email Template for Referral to External Services).
3. Ensure the nominated staff member or Site Principal Investigator is alerted of any immediate or subsequent concerns and actions documented in the patient’s medical records.
4. Document that these steps have been completed, including the date and time, in the participant’s medical records and the online web-based system.

Distress and Suicidality Situations

If a participant becomes distressed, indicates suicidal ideation or intent, or if you feel concerned about their welfare, you must complete the following steps:

1. Acknowledge the person’s distress.
2. Provide information on resources available (see suggested script below and External Referral and Available Service) e.g. NSW Mental Health Line: 1800 011 551, Lifeline: 13 11 14, Beyondblue: 1300 224 636 MensLine: 1300 789 978. Offer to send them a follow-up email with the resources so that they have it for future reference (if appropriate) (see Email Template for Referral to External Services).
3. Before the participant leaves the clinic notify the nominated staff member or the Site Principle Investigator and determine whether the participant needs immediate further follow-up. Ensure these actions are documented in the patient’s medical records.
4. Document that these steps have been completed, including date and time, in the online web-based system and medical record.

Suggested Script for Distress and Suicidality

1. ‘This study is confidential, but if at any time we are really concerned for somebody’s mood or their safety, we have a duty to tell a staff member/GP so that they can be in contact with you. As this is a depression study, part of my role is to keep anybody who participates safe. If you feel you want to talk to someone in the meantime it might be helpful to make an appointment with your GP or contact a telephone service such as Lifeline or …’, see External Referral and Available Services.

Immediate Response / Emergency Situation and Suspending Interviews
If a participant seems to be in an emergency situation or if you feel they are at risk of harming themselves, have just harmed themselves, or plan to harm themselves within an immediate time frame (e.g., within the next few hours or even days), please take the following steps:

1. Acknowledge the person’s distress.
2. If you think the person is in an emergency situation, and are not able or willing to continue with the interview, please suspend the interview and suggest at least three referrals, with one being Lifeline (see suggested script below and External Referral and Available Service).
3. Before the participant leaves the clinic, notify the Principle Investigator or their nominated staff member and determine whether the participant needs immediate further follow-up. Ensure the aPHQ-9 is reviewed by this staff member and actions are documented in the patient’s medical records.
4. Document that these steps have been completed, including date and time, in the online web-based system.

Suggested Script for Immediate Response and Suspending Interviews

‘This study is confidential, but if at any time we are really concerned for somebody’s mood or their safety, we have a duty to tell a staff member / GP so that they can be in contact with you. As this is a depression study, part of my role is to keep anybody who might participate safe. I am worried about you and so we will stop the interview. If you feel you want to talk to someone in the meantime it might be helpful to make an appointment with your GP or contact a telephone service such as Lifeline or …’, see External Referral and Available Service.

Assessment 3: MINI 6.0.0 Interview – if conducted centrally by phone

Distress and Suicidality Situations

The MINI 6.0.0 Assessment questionnaire has questions about suicide and mood and it is possible that participants may become distressed during the interview. For example, you may have called or be speaking with them when they are already distressed and/or a general discussion about the study (e.g. their mood and mental health history) may trigger painful thoughts, feelings or memories.
If a participant becomes distressed, indicates suicidal ideation or intent, or if you feel concerned about their welfare, you must complete the following steps:

1. **Acknowledge the person’s distress.**
2. **Give some information on resources available (see script and External Referral and Available Service) e.g. NSW Mental Health Line: 1800 011 551, Lifeline: 13 11 14, Beyondblue: 1300 224 636 or MensLine: 1300 789 978. Offer to send out an email with the resources so that they have it for future reference (see Email Template for Referral to External Services).**
3. **Arrange for letter to be faxed to the site notifying the outcome immediately and for a standard letter to be mailed as soon as possible. See Attachment**
4. **Document that these steps have been completed including the time and date in the online web-based system.**

**Suggested Script Distress and Suicidality:**

‘This study is confidential, but if at any time we are really concerned for somebody’s mood or their safety, we have a duty to tell a staff member / GP so that they can be in contact with you. As this is a depression study, part of my role is to keep anybody who might participate safe. If you feel you want to talk to someone in the meantime it might be helpful to make an appointment with your GP or contact a telephone service such as Lifeline or …’, see External Referral and Available Service.

**Immediate Response/Emergency Situations and Suspending Interviews – if conducted centrally by phone**

If a participant seems to be in an emergency situation, that is, if you feel that the person is at risk of harming themselves, have just harmed themselves, or plan to harm themselves within an immediate time frame (e.g., within the next few hours or even days), please take the following steps:

1. **Acknowledge the person’s distress.**
2. **If you think the person is in an emergency situation and are not able or willing to continue with the interview, suspend the interview and suggest at least three referrals, with one being Lifeline (see suggested script below and External Referral and Available Services). Offer to send out an email with**
the resources so that they have it for future reference (see Email Template for Referral to External Services).

3. If you think the person is in an emergency situation (see above) you must follow these guidelines:
   a. If you can, before ending the telephone call or interview, inform the participant that you are seeking immediate medical attention on their behalf (i.e. calling emergency)
   b. Before hanging up or before the participant leaves the place of the interview, collect as much information as you can:
      - Their current location and street address, collect as much information as possible
      - Their contact number
      - Details of any significant other who is around them
      - An ALTERNATIVE phone number they can be reached on (e.g. significant others’ contact number, mobile or home phone number)
   c. Call 000 and provide the details to the emergency services.

4. If you feel it is appropriate explain that a letter with their results will be sent to their General Practitioner.

5. Arrange for letter to be faxed to the site notifying the outcome immediately and for a standard letter to be mailed as soon as possible. See Attachment.

6. Document that these steps have been completed including the time and date in the online web-based system.

Suggested Script for Immediate Response/Emergency Situation and Suspending Interview:

‘It sounds like you’re feeling like everything’s so hopeless. As this is a depression study, part of my role is to keep anybody who participates safe. I’m concerned about you, we will now stop the interview. This study is confidential, but any times when we are really concerned for somebody’s mood or their safety, we have a duty to tell your health service so that the clinician can be in contact with you. I am going to call 000 so that someone can come and check on you. If you feel you want to talk to someone in the meantime it might be helpful to make an appointment with your GP or contact a telephone service such as Lifeline or …’, see External Referral and Available Service section.1
Be prepared for a number of responses. Some participants will say nothing, others will express relief, and others will express further hopelessness (e.g. ‘I’ve tried calling x before and it didn’t help’ or ‘Well, if I call ‘Lifeline’ they’ll just tell me to have a rest or something’).

There are always good reasons for their so-called ‘resistance’. They feel despondent. Say to them ‘I know – everything feels helpless now. I’m just really glad you told me about this and I’m happy I can hopefully get you some support.’

Summary of actions for interviewer

<table>
<thead>
<tr>
<th>Interview 1 and 2</th>
<th>Interview 3 - phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Acknowledge distress</td>
<td>1. Acknowledge distress</td>
</tr>
<tr>
<td>2. Provide referral information to telephone help-lines, offer email</td>
<td>2. Provide referral information to telephone help-lines, offer email</td>
</tr>
<tr>
<td>3. In emergency situation: suspend interview</td>
<td>3. In emergency situation: suspend interview</td>
</tr>
<tr>
<td>4. Before participant leaves sites, notify nominated staff member</td>
<td>4. In emergency situation: phone 000</td>
</tr>
<tr>
<td>5. Ensure aPHQ-9 is reviewed by nominated reviewer, and actions documented in medical records</td>
<td>6. Arrange for letter to be sent to health service</td>
</tr>
<tr>
<td>7. Document the steps followed in the online web-based system</td>
<td>6. Document the steps followed in the online web-based system</td>
</tr>
</tbody>
</table>

Tips for How to Manage Interviews

- Address the participant in a calm and respectful manner and let the participant know that you take their concerns seriously and give them high importance.
- Let the person know that you are employed as a researcher etc. and that as such you are not in a position to provide a clinical/therapeutic service. However, explain that it is your role to contact a person who will be able to help. If the participant phoned you, please ask the participant to give you their number in case the call is accidentally disconnected.
- Try to anticipate any likely obstacle to help-seeking (e.g., clinician is engaged) and discuss how the person can manage those (e.g., give at least 3 referrals to mental health services).
Remember that distressed people can feel desperate and may be quite agitated. As a result, they may call a number of potential sources of help and become very mobile. This can mean that their line may be engaged when you call back or that they have left the location. It is therefore helpful to ask for an alternative means of contact such as a mobile phone number to increase the chance of making contact.
Attachment 1 to Researcher protocol: External referral and available services -

Updated with local resources as appropriate

1. For all Medical Emergencies, call 000
2. Mental Health Line: 1800 011 511. The Mental Health Line is a 24-hour telephone service operating seven days a week across NSW. It can also refer callers to their local acute mental health care teams.

4. NSW Mental Health Information Line: 1300 794 991 (Weekdays 9am – 5pm). For services available in your local area - professional as well as self help and support groups.
5. SANE Australia Helpline: 1800 18 3263 Monday to Friday 9:00am-5:00pm EST provides information and a referral only. Free Infopack can be requested 24 hours.
7. Men’s Line: 1300 789 978 (24/7). Professional staff and also has moderated forums including specific spaces for Aboriginal and Torres Strait Islander, Vietnamese, Arabic, rural men, partners / children. Service locator at: http://www.mensline.org.au/
9. beyondblue infoline: 1300 224 636. Provides callers with access to information and referrals for depression and anxiety related matters. Local call cost.
10. POLICE: 131 444 Police Assistance Line (non-emergency).
11. Suicide Call Back Service: 1300 659 467 (24/7). The Suicide Call Back Service is a free nationwide telephone support service staffed by real people with professional qualifications. The Suicide Call Back Service supports callers through a series of six structured 50 minute telephone counselling sessions, scheduled according to the person’s needs. Professional counsellors, with specialist skills in working with suicide-related issues, assist clients to work through difficult emotions.
13. Gay and Lesbian Counselling Service NSW: 02 8594 9596 or 1800 184 527. Gay and Lesbian Counselling Service of NSW (GLCS) is a volunteer based community service providing free, anonymous and confidential telephone counselling, information and referral services and support groups for gay men, lesbians, bisexual and transgender persons (GLBT) and people in related communities throughout New South Wales (NSW) on sexuality and life issues. Available 7 days, from 5.30pm-09.30pm.
Attachment 2: Email template for referral to external services (to be updated with above or relevant services as appropriate)

Hello

This note has a list of services available to you which you can contact for information or support.

<table>
<thead>
<tr>
<th>Service</th>
<th>Phone Number</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beyondblue</td>
<td>1300 224 636</td>
<td><a href="http://www.beyondblue.org.au/">http://www.beyondblue.org.au/</a></td>
</tr>
</tbody>
</table>

From

The *Getting it Right* study team

Validation Study Chief Investigator: A/Prof Maree Hackett, Tel +61 2 9993 4593, email: mhackett@georgeinstitute.org.au
Today’s date

Dear <Insert GP/other clinician Name>

A participant in the Validation study <insert participant name> has identified you as their primary clinician. The Validation study is an NHMRC-funded observational study designed to validate a culturally-specific measure to identify depression for use with Aboriginal and Torres Strait Islander people.

During <insert participant name> ‘s interview they [select and complete all relevant options]

- Reported a clinically significant number of depressive symptoms (<insert aPHQ-9 total score> out of a possible 27) on adapted 9-item Patient Health Questionnaire. Scores of 10-14 indicate moderate depression, scores of 15-19 indicate moderately severe depression, while scores of 20 or more are indicative of severe depression; and/or
- Scored positively for a [select all that apply] current major depressive episode, current/recurrent major depressive disorder; indicated they have had suicidal thoughts.

Below we have provided some clinical management options for you based on current guidelines for depression:

a) Consider non-pharmacological treatments such as advising an increase in social outlets, regular exercise or referral to a clinical psychologist. Clinical psychology can be accessed through the Medicare Better Access initiative and is available free of charge to Australian residents and citizens. There is provision for up to 10 sessions per year as part of a GP mental health treatment plan (http://www.health.gov.au/internet/main/publishing.nsf/content/mental-ba-gsamp).

We have given the participant a number of self-help options including information on crisis lines [insert any site specific info here] and access to online psychological interventions (www.ecouch.com.au, http://www.mindspot.org.au).

b) If the you feel that antidepressant or other medication is necessary, then either yourself or their treating doctor might consider the attached guidelines

[Primary Health Care Service Details]
c) Consider referral to a specialist psychiatrist. We ask you to file this note with your patient records and to follow them up as you see necessary.

Kind regards

<insert Your name>

On behalf of the Validation study team

Validation Study Chief Investigator: A/Prof Maree Hackett

Tel +61 2 9993 4593

e-mail: mhackett@georgeinstitute.org.au

Attachment 4: Standard GP email – sent to Nominated Reviewer for all participants

Hello,

A patient of your service has completed the following assessments as part of the Validation Study. Clinical management options are provided below. You can log on to the database, review results and provide follow-up as required:

Participant Study Number: 14 F_YT

Link to Patient: View Patient Details

✓ Completed aPHQ-9
✗ aPHQ-9 score >= 10 *
✗ aPHQ-9 indicates thoughts of harming themselves or suicide *
✓ aPHQ-9 score < 10
✓ Completed MINI 6.0.0 Interview
✗ MINI 6.0.0 diagnosis: Major Depression *
     MINI 6.0.0 indicates wishes to be dead or ideation/intent to harm themselves or commit suicide. It’s important to distinguish between these clinically as responses could be very different. *

Thank you,

The Validation Study Team

Contact Sara for study issues or Dr Nick Glozier with clinical questions
*Clinical management options based on current guidelines for depression:

1. **aPHQ-9 Scores** of 10-14 indicate moderate symptoms of depression, scores of 15-19 indicate moderately severe symptoms of depression, while scores of 20 or more are indicative of severe symptoms of depression.

2. Consider non-pharmacological treatments such as advising an increase in social outlets, regular exercise or referral to a clinical psychologist. Clinical psychology can be accessed through the Medicare Better Access initiative and is available free of charge to Australian residents & citizens. There is provision for up to 10 sessions per year as part of a GP Mental Health Treatment Plan. Further information available at: [http://www.health.gov.au/internet/main/publishing.nsf/content/mental-ba-gpsamp](http://www.health.gov.au/internet/main/publishing.nsf/content/mental-ba-gpsamp)

   We have given the participant a number of self-help options including information on crisis lines [insert any site specific info here] and access to the below online psychological interventions [www.ecouch.com.au](http://www.ecouch.com.au) [http://www.mindspot.org.au](http://www.mindspot.org.au)

3. If you feel that antidepressant or other medication is necessary, then either yourself or their treating doctor might consider the attached guidelines [https://www.nice.org.uk/guidance/cg90](https://www.nice.org.uk/guidance/cg90)

4. Consider referral to a specialist psychiatrist

This is an automated email from Validation Study.
APPENDIX 7: GETTING IT RIGHT RESULTS PUBLICATION

Validation of a culturally-specific measure to screen for depression (aPHQ-9) in Aboriginal and Torres Strait Islander people: The Getting it Right study

Writing and steering committee members and principal investigators

Maree L. Hackett1,2*, Armando Teixeira-Pinto3*, Sara Farnbach1,3, Nick Glozier4, Timothy Skinner5, Deborah Askew6,7, Graham Gee8, Alan Cass9, Alex Brown10.
*Co-primary first
1Mental Health Program, The George Institute for Global Health, University of New South Wales, Sydney, Australia
2University of Central Lancashire, Preston, Lancashire, United Kingdom
3School of Public Health, the University of Sydney, Sydney, Australia
4The University of Sydney, New South Wales, Australia
5Brain and Mind Centre, the University of Sydney, Sydney, Australia
6Institute of Psychology, University of Copenhagen, Copenhagen, Denmark
7Southern Queensland Centre of Excellence in Aboriginal and Torres Strait Islander Primary Health Care, Metro South Health, Queensland Health, Brisbane, Queensland, Australia
8Discipline of General Practice, The University of Queensland, Brisbane, Queensland, Australia
9Victorian Aboriginal Health Service, Melbourne, Victoria, Australia
10Menzies School of Health Research, Darwin, Australia

Management committee

Maree L. Hackett1,2 and Sara Farnbach1,3

MINI trainer

Nick Glozier4

Statistical analysis

Armando Teixeira-Pinto3

Site staff

Winnunga Nimmityjah Aboriginal Health Service, Australian Capital Territory: Michele Clarke, Saidul Islam Muhammed, Kerin O’Brien, Nadeem Siddiqui; Maari Ma Health Aboriginal Corporation, New South Wales: Jamie Billing, Tiffany Cattermole, Peter Crossing David Doyle, Shannon Edwards, Georgina Tumai Faulkner, Shannon Henderson, Catherine Kennedy, Codi King, Courtney O’Donnell, Holle Pearson, Christine Polanski; Tharawal Aboriginal Medical Services, New South Wales: Danielle Gillette, Nikita Tompkins; Tobwabba Aboriginal Medical Service, New South Wales: Jamie Fernando, Ashlee Hodson, Stephanie Ping, Marcus Rowse, Leann Simon, Tanya Simon; The Glen Centre Central Coast Drug Alcohol Rehabilitation and Ngaimpe Aboriginal Corporation, New South Wales: Jamie Fernando, Matthew Simms; Central Australian Aboriginal Congress, Alice Springs, Northern Territory: Carli Pearson, Wayne Simons, Amanda Swan; Danila Dilba Health Service, Darwin, Northern Territory:
Abstract

**Objectives:** To determine the validity, sensitivity and specificity of the culturally-adapted 9-item Patient Health Questionnaire (aPHQ-9) as a screening tool for depression in Aboriginal and/or Torres Strait Islander populations

**Design:** Prospective, validation study, 25th May 2015 to 2nd November 2016

**Setting:** 10 urban, rural and remote primary health care services (sites) in Australia with a predominantly Aboriginal and Torres Strait Islander client base

**Participants:** 500 adults, ≥ 18 years of age, who identify as Aboriginal and/or Torres Strait Islander, attending one of 10 primary health care services or service events across Australia and able to communicate sufficiently to answer study questions
Main outcome measures: Criterion validity of the aPHQ-9. The criterion standard is the depression module of the MINI International Neuropsychiatric Interview (MINI) 6.0.0.

Results: 102/500 participants (22%; 95% CI 18 to 25%) had a current episode of major depression (MDE) by the criterion standard. The aPHQ-9 algorithm for the diagnosis of a current MDE had a sensitivity of 54% (95% CI 40-68%), a specificity of 91% (95% CI 88-94%) and a positive predictive value (PPV) of 64%. The aPHQ-9 scoring for screening for a current MDE had an area under the ROC curve for a score of ≥10 of 0.88 (95% CI 0.85-0.92). The cut-point at 10 points held a sensitivity of 84% (95% CI 74-91%) and a specificity of 77% (95% CI 71-83%).

Conclusions: The aPHQ-9 has good performance characteristics when the cut-point ≥ 10 scoring method is used.

Study registration: ANZCTR 12614000705684

Introduction

Depression is a common, chronic, relapsing disorder that contributed the third highest burden of all diseases in Australia in 2011.\(^1\)\(^9\)\(^4\) It is well established that major depression is associated with substantial impairment in functioning, presents a significant social and economic burden, and increases the risk of premature death.\(^1\)\(^9\)\(^5\) Evidence-based management of depression in primary care has been shown to improve outcomes for people with depression.\(^1\)\(^9\)\(^6\) However, clinical presentation with depression leading to diagnosis and effective intervention is rare.\(^1\)\(^9\)\(^7\) Much of the high-quality primary care research has been conducted in the United Kingdom and United States,\(^1\)\(^9\)\(^6\) and almost none with, by or in Aboriginal and/or Torres Strait Islander populations (hereafter referred to as Indigenous) in Australia.

A recent systematic review of diagnostic psychiatric measures found that none of the instruments had been formally validated for use among Indigenous Australians.\(^3\)\(^3\) As a first step in rectifying the paucity of Indigenous Australian-relevant depression research, a freely available culturally-adapted depression screening tool validated in multiple Australian States and Territories is needed. The 9-item Patient Health Questionnaire (PHQ-9)\(^1\)\(^9\)\(^8\) has been used for nearly two decades as a screening tool and measure of symptom severity for depression in wide range of cultural settings. The phrasing of the
PHQ-9 was culturally adapted (aPHQ-9<sup>112</sup>) to ‘Aboriginal English’ and found to be internally consistent in a community sample of 78 Aboriginal men (α=0.776) and Aboriginal women (α=0.767) from Central Australia.<sup>112</sup> During the adaption process, seven key features of depression in Aboriginal men were identified that were not covered by the aPHQ-9: anger, weakened spirit, homesickness, irritability, excessive worry, rumination, and drug/alcohol use.

The objective of the Getting it Right study was to determine the validity of the aPHQ-9<sup>112</sup> as a screening tool for depression for use with Indigenous people attending primary care services in Australia, against a criterion standard, the MINI International Neuropsychiatric Interview (MINI) 6.0.0.<sup>113</sup> The findings from the seven additional questions will be presented separately.

**Methods**

**Study design and participants**

*Getting it Right* was a prospective diagnostic accuracy, observational study conducted across 10 Indigenous primary health care services in Australia. The study was conceived and designed in accordance with the principles of Reciprocity, Respect, Equality, Responsibility, Survival and Protection, and Spirit and Integrity<sup>7</sup>.

People were eligible if at the time of presentation at a participating health service or health service event in the Australian Capital Territory, New South Wales (4 sites), the Northern Territory (2 sites), Queensland, South Australia and Western Australia, they were adults (≥ 18 years of age), who self-identified as Indigenous, were able to communicate sufficiently to answer study questions and give informed consent. People were excluded if they had a diagnosis of psychosis or bipolar disorder. Trained staff members at each service screened all people on recruitment days and obtained written or verbal informed consent. Overall management of the study was coordinated from The George Institute for Global Health (Sydney, Australia). Recruitment began on the 25<sup>th</sup> March 2015.

**Study outcomes**

The reference standard was a diagnosis of depression ascertained using the MINI 6.0.0<sup>3</sup>, a structured interview for the major Axis I psychiatric disorders. The MINI can be modularised and administered by clinicians and lay interviewers after appropriate
training and is the most widely used psychiatric structured diagnostic interview instrument globally having been validated for use in over 100 countries. The interview and algorithm provide dichotomous categories, in this case "current major depressive episode" and "no current major depressive episode."

**Procedures**

Assessment 1: Following consent, a trained, culturally competent staff member from the primary health care service interviewed each participant using a paper-based or computer-assisted questionnaire during a face-to-face interview (or telephone if required). Participants answered the aPHQ-9 questions, 7 additional questions, questions about the acceptability and ease of use of the aPHQ-9 and demographic questions directly themselves, or the questionnaire could be interviewer-administered at the discretion of the interviewer and participant. All data were entered in the secure web-based study database. Participants answered all questions in English or their respective Aboriginal language.

Assessment 2: Within seven days, after Assessment 1, all participants were administered the major depressive episode/disorder (current, recurrent MDE), generalized anxiety disorder (GAD in the past six months) and posttraumatic stress disorder (past month, PTSD) modules of the MINI in a face-to-face interview (or telephone if required). This was conducted by a second, local, trained member of staff who did not participate in, and was blind to the results of, Assessment 1.

**Statistical methods**

Sample size: Assuming a major depressive episode prevalence (assessed by the MINI) of 10% and a true sensitivity of 0.85, a sample size of 500 participants would give a precision of 0.1 for the sensitivity’s 95% confidence interval. For the specificity, 500 participants will provide a precision of 0.04 for the specificity’s 95% confidence interval, assuming a true specificity of 0.75 and the same prevalence of 10%.

Data analysis: Categorical data were summarised as frequencies and percentages, continuous variables by mean and standard deviation (SD) or median and interquartile range (IQR). The chi-square test was used to compare proportions and the t-test was used to compare means. The area under the receiver operating characteristic (ROC) curve was computed to summarise the discrimination ability of the aPHQ-9 scoring
system. The sensitivities and specificities for different thresholds were computed with a generalised estimation equation (GEE), using a logit link and exchangeable working covariance matrix, to account for clustering of participants by centre. A significance level of 0.05, was considered statistically significant for all the hypothesis tests in the analysis. The analysis was performed using R v.3.3.2.

Primary analysis: The validity of the aPHQ-9 when compared to the MINI was assessed using two common criteria for a MDE: I - a score of 2 or above on at least five aPHQ-9 questions (the last question is counted if a score of 1 or above is indicated), one of which corresponds to Question 1 or 2; and II - a total score of 10 points or above, similar to the cut-point for the original PHQ-9. The original scoring method was used with the two ‘split questions’ on the aPHQ-9 (questions 5 and 8 on the original PHQ-9) scored once only and the higher score used. The properties of other cut-points were explored by constructing a ROC curve. The sensitivity and specificity was computed for subgroups (e.g., individuals with chronic disease) using logistic regressions to allow adjustment for potential demographic differences between subgroups. Estimates are presented with 95% confidence intervals. We also evaluated the criterion validity of the aPHQ-2, a shorter version of the aPHQ-9 that only uses the score of the first two questions, when compared to the MINI as a screening tool for depression.

Missing data: There were three participants who missed one aPHQ-9 question but none was the question about suicidal ideation/intent. For these individuals we computed a partial score by summing the answered questions. The global score was then derived multiplying the partial score by the total number of questions divided by the number of answered question, i.e., partial score times 9/8.

Results

We approached 34 primary health care services about participating in Getting it Right. Reasons given for non-participation included not having sufficient staff capacity, having other research interests they were pursuing, or we stopped contacting them after multiple failed attempts. Initial decisions about participation were made by the chief executive office, social and emotional wellbeing team, general practitioners, research staff or clinical managers at each service.

Between 25th March 2015 and the 2nd November 2016, 913 people were screened for eligibility, of whom 540 provided informed consent. The main reasons for non-participation were declining to take part (n=243) or being ineligible (n=124, Figure A1). 9 withdrew consent before completing either interview (1 reporting fatigue, 1 a computing problem, 7 for reasons not specified), 30 did not complete the MINI interview (23 were unable to be contacted, 2 reported their GP was unavailable, 2 too busy, 1 computing problem, 1 on holiday, 1 no reason specified) and 1 completed their second interview more than 7 days after the aPHQ-9 interview) leaving 500 participants who completed the aPHQ-9 and the clinical MINI interview. There were no differences in baseline characteristics between the final sample and the 40 participants who were excluded.

Baseline characteristics are in Table A9. Most participants (98%) identified as Aboriginal, with 2% identifying as Torres Strait Islander and 1% as both. The ages ranged from 18 to 80 years with a mean (±SD) of 43 (±15) years, 53% were female and 60% were the main income earner in their household. A previous diagnosis of depression was reported by 45% and anxiety by 33% (see Table A10). Most (69%) had been diagnosed with at least one pre-specified chronic health condition (excluding depression and/or anxiety) with 15% reporting four or more pre-specified chronic conditions. In the two months immediately before the study 125 (21%) participants reported having a health problem that restricted their activities of daily living.

The prevalence of a current MDE by the criterion standard was 22% (95% CI 18 to 25%), GAD 21% (95% CI 18 to 25%) and PTSD was 11% (95% CI 8% to 14%). 70% (n=347) of participants received no diagnosis while 5% (27) were diagnosed with all three conditions (Figure A2). There were significant subgroup associations with a
current MDE and arthritis, asthma, obstructive sleep apnoea, having a recent (last 2 months) illness that restricted activities of daily living, and having been previously diagnosed with depression or anxiety (Table A10).

The 9 questions of the aPHQ-9 showed very good internal consistency (α = 0.88). Problems with sleeping were the most frequently endorsed on the aPHQ-9 (189, 38% respondents found it hard to sleep most or all the time). Having thoughts of self-harm or being better off dead (a little bit, most of the time and all the time) was reported by 78 (16%) participants, including two who indicated they felt like this all the time. The endorsement of other symptoms, most or all the time, varied between 19% and 31%. (Figure 4.3)

Using the aPHQ-9 algorithm for the diagnosis of a current MDE (MDE I) we found a sensitivity of 54% (95% CI 40 to 68%), a specificity of 91% (95% CI 88 to 94%) and a positive predictive value (PPV) of 64%. When applying the aPHQ-9 scoring for screening for a current MDE (MDE II), the area under the ROC curve for a score of ≥10 was 0.88 (95% CI 0.85 to 0.92). The cut-point at 10 points held a sensitivity of 84% (95% CI 74 to 91%) and a specificity of 77% (95% CI 71 to 83%). A cut-point of 9 increased the sensitivity to 87% and decreased the specificity to 72%, while a cut-point of 11 increased the specificity to 82% but decreased the sensitivity to 81% (results nearly identical when excluding the three incomplete aPHQ-9 questionnaires). Data for selected cut-points are available in Table A12 and Figure A2. If restricting the aPHQ to the first two questions (aPHQ-2) as a screening tool for a MDE, the area under the ROC curve was 0.83 (95% CI 0.78 to 0.87) (Figure 4.3).

Feedback from participants regarding the acceptability of the aPHQ-9 (number of questions, questions easy to answer, easy to understand, the response categories made sense, had time to answer the questions, felt comfortable answering the questions) was predominantly positive. However, 13% of the respondents felt that some or all the questions were too personal (Table A12).

Discussion

Our study has shown, in a heterogenous population of Indigenous Australian adults attending primary care across five States and Territories in Australia, that the aPHQ-9

111
has good performance characteristics when the cut-point $\geq 10$ scoring method is used (similar to PHQ-9 clinical validation studies\textsuperscript{201}. However, the highest positive predictive value (64\%) is obtained when using the diagnostic scoring algorithm for a MDE. Participants and staff considered the aPHQ-9 acceptable and feasible to use. Most (70\%) participants reported good mental health however 74\% had one or more chronic physical health problems, 21\% had a health problem that restricted their activities of daily living in the last two months, 45\% had a previous diagnosis of depression and 33\% of anxiety. A current MDE was identified in 22\%, GAD in 21\% and PTSD in 11\% of participants.

While the point prevalence of a MDE in our study is higher than usually seen in general community populations it is similar to that seen in other Australian general practice populations\textsuperscript{202} and comparable to two other validation studies of depression screening tools for use with Indigenous Australians.\textsuperscript{2, 91} However, the validation studies for these two culturally-adapted screening tools were conducted in the same communities where the original screening tools were modified, potentially limiting the generalisability of results. In a review of assessment tools for social and emotional wellbeing for use with Indigenous Australians, few were validated, cross-culturally adapted or were specific to depression.\textsuperscript{32}

The strengths of our study are the participation of 10 diverse primary health care services, located in multiple States and Territories in Australia, the provision of structured training for site staff, high rates of completion of interviews, sufficient participants with a MDE diagnosis to enable subgroup analyses, and robust methods in line with the NHMRC’s guide for the conduct of Aboriginal and Torres Strait Islander health research. Ideally our criterion standard would have been a semi-structured culturally valid psychiatric interview but the resources and time required for such a large study made this approach infeasible.

Whereas the United States Preventive Services Task Force statement\textsuperscript{203} recommended that screening for depression is feasible and reliable in primary care the Royal Australian and New Zealand College of Psychiatrists’ clinical practice guideline for mood disorders\textsuperscript{204} did not recommend screening for depression in patients routinely attending primary care. Their reasoning, which we support, is that there are insufficient
effective treatment strategies shown to improve outcomes for people with depression, as stand-alone screening programs show little or no benefit.\textsuperscript{205} Concerns were raised after Google™ introduced a link to the original PHQ-9\textsuperscript{198} when people searched for ‘am I depressed?’ (or similar).\textsuperscript{206} Screening alone, without an additional diagnostic interview or an evidence-based treatment strategy with stopping rules, increases the chances of transient distress being incorrectly diagnosed as depression and people receiving unnecessary treatment.

The aPHQ-9 is effective as a screening tool and we recommend practitioners use it following the operational characteristics they value in their practice. We suggest the aPHQ-9 is best used by those who can conduct further structured or semi-structured diagnostic assessments and follow a structured evidence-based treatment strategy e.g. stepped care, complete with stopping rules. As we increase the evidence base for identifying depression for Indigenous Australians using culturally specific methods we must now focus our efforts on culturally-appropriate, cost-effective interventions for the prevention, treatment and ongoing management of depression in Indigenous Australians routinely attending primary health care.

**Contributorship statement**

AB originally suggested the study. MLH, AC, NG, TS, ATP, DA, GG & AB designed the study and obtained funding. ATP conducted the statistical analysis. SF led the process evaluation as part of her PhD. MLH wrote the first draft of the manuscript, and all writing committee members contributed, edited and approved the final version.
Table A9 Demographic characteristics of participants (n=500) in the *Getting it Right* study

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Major Depression Episode*</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>No (n=392, 78%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aboriginal</td>
<td>485 (97)</td>
<td>378 (78)</td>
<td>107 (22)</td>
</tr>
<tr>
<td>Torres Strait Islander</td>
<td>10 (2)</td>
<td>9 (90)</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Aboriginal &amp; Torres Strait Islander</td>
<td>5 (1)</td>
<td>5 (100)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Language used in the interview</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English only</td>
<td>442 (89)</td>
<td>339 (77)</td>
<td>103 (23)</td>
</tr>
<tr>
<td>English and language</td>
<td>19 (4)</td>
<td>17 (89)</td>
<td>2 (11)</td>
</tr>
<tr>
<td>Language only</td>
<td>33 (7)</td>
<td>30 (91)</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
<td>43 (15)</td>
<td>44 (15)</td>
<td>42 (12)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>267 (53)</td>
<td>208 (78)</td>
<td>59 (22)</td>
</tr>
<tr>
<td>Male</td>
<td>233 (47)</td>
<td>184 (79)</td>
<td>49 (21)</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>200 (40)</td>
<td>155 (78)</td>
<td>45 (22)</td>
</tr>
<tr>
<td>Married/de facto relationship</td>
<td>186 (37)</td>
<td>150 (81)</td>
<td>36 (19)</td>
</tr>
<tr>
<td>Widowed</td>
<td>29 (6)</td>
<td>26 (90)</td>
<td>3 (10)</td>
</tr>
<tr>
<td>Separated but not divorced</td>
<td>53 (11)</td>
<td>39 (74)</td>
<td>14 (26)</td>
</tr>
<tr>
<td>Divorced</td>
<td>29 (6)</td>
<td>20 (69)</td>
<td>9 (31)</td>
</tr>
<tr>
<td>Live Alone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>379 (76)</td>
<td>297 (78)</td>
<td>82 (22)</td>
</tr>
<tr>
<td>Yes</td>
<td>118 (24)</td>
<td>92 (78)</td>
<td>26 (22)</td>
</tr>
<tr>
<td>Main Income Earner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>196 (40)</td>
<td>157 (80)</td>
<td>39 (20)</td>
</tr>
<tr>
<td>Yes</td>
<td>300 (60)</td>
<td>234 (78)</td>
<td>66 (22)</td>
</tr>
<tr>
<td>Anyone close died in the last 2 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>328 (66)</td>
<td>263 (80)</td>
<td>65 (20)</td>
</tr>
<tr>
<td>Yes</td>
<td>170 (34)</td>
<td>127 (75)</td>
<td>43 (25)</td>
</tr>
<tr>
<td>Significant illness that restricted daily activities in the past 2 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>391 (79)</td>
<td>319 (82)</td>
<td>72 (18)</td>
</tr>
<tr>
<td>Yes</td>
<td>105 (21)</td>
<td>69 (66)</td>
<td>36 (34)</td>
</tr>
<tr>
<td>Chronic Disease†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>153 (31)</td>
<td>129 (84)</td>
<td>24 (16)</td>
</tr>
<tr>
<td>Yes</td>
<td>347 (69)</td>
<td>263 (76)</td>
<td>84 (24)</td>
</tr>
</tbody>
</table>
Numbers are n (%) unless otherwise indicated

The proportions in the Total column are computed over the valid cases

*Major Depressive Episode using the MINI International Neuropsychiatric Interview (MINI) 6.0.0 major depressive episode module

†One or more of the following: heart disease, stroke, cancer, diabetes, arthritis, asthma, respiratory disease, chronic kidney disease, obstructive sleep apnoea, high blood pressure

Table A10 Clinical history of participants (n=500) in the Getting it Right study

<table>
<thead>
<tr>
<th>Total</th>
<th>Major Depressive Episode*</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>N</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td><strong>Someone close to you passed away (last 2 months)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>328 (66)</td>
<td>127 (75)</td>
</tr>
<tr>
<td>Yes</td>
<td>170 (34)</td>
<td>69 (66)</td>
</tr>
<tr>
<td><strong>Significant illness (last 2 months) restricting ADL</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>391 (79)</td>
<td>319 (82)</td>
</tr>
<tr>
<td>Yes</td>
<td>105 (21)</td>
<td>69 (66)</td>
</tr>
<tr>
<td><strong>Heart disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>412 (84)</td>
<td>323 (78)</td>
</tr>
<tr>
<td>Yes</td>
<td>76 (16)</td>
<td>61 (80)</td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>473 (96)</td>
<td>371 (78)</td>
</tr>
<tr>
<td>Yes</td>
<td>22 (4)</td>
<td>19 (86)</td>
</tr>
<tr>
<td><strong>Cancer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>463 (94)</td>
<td>364 (79)</td>
</tr>
<tr>
<td>Yes</td>
<td>31 (6)</td>
<td>25 (81)</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>368 (74)</td>
<td>290 (79)</td>
</tr>
<tr>
<td>Yes</td>
<td>127 (26)</td>
<td>98 (77)</td>
</tr>
<tr>
<td><strong>Arthritis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>374 (77)</td>
<td>305 (82)</td>
</tr>
<tr>
<td>Yes</td>
<td>113 (23)</td>
<td>80 (71)</td>
</tr>
<tr>
<td><strong>Asthma</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>348 (71)</td>
<td>283 (81)</td>
</tr>
<tr>
<td>Yes</td>
<td>145 (29)</td>
<td>104 (72)</td>
</tr>
<tr>
<td><strong>Respiratory disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>442 (90)</td>
<td>350 (79)</td>
</tr>
<tr>
<td>Yes</td>
<td>47 (10)</td>
<td>33 (70)</td>
</tr>
<tr>
<td><strong>Chronic kidney disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>No (%)</td>
<td>Yes (%)</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------</td>
<td>---------</td>
</tr>
<tr>
<td>Obstructive sleep apnoea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>447 (92)</td>
<td>349 (78)</td>
</tr>
<tr>
<td>Yes</td>
<td>37 (8)</td>
<td>31 (84)</td>
</tr>
<tr>
<td>High blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>419 (87)</td>
<td>339 (81)</td>
</tr>
<tr>
<td>Yes</td>
<td>62 (13)</td>
<td>41 (66)</td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>266 (55)</td>
<td>241 (91)</td>
</tr>
<tr>
<td>Yes</td>
<td>156 (32)</td>
<td>120 (77)</td>
</tr>
<tr>
<td>Anxiety</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>326 (67)</td>
<td>291 (89)</td>
</tr>
<tr>
<td>Yes</td>
<td>160 (33)</td>
<td>93 (58)</td>
</tr>
</tbody>
</table>

The proportions in the Total column are computed over the valid cases.

ADL = activities of daily living

*Major Depressive Episode using the MINI International Neuropsychiatric Interview (MINI) 6.0.0 major depressive episode module.
<table>
<thead>
<tr>
<th>Scoring method</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>Positive LR</th>
<th>Negative LR</th>
<th>PPV</th>
<th>NPV</th>
<th>DOR</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>aPHQ-9</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algorithm (MDE I, diagnostic)</td>
<td>54 (40-68)</td>
<td>91 (88-94)</td>
<td>6.3</td>
<td>0.5</td>
<td>64%</td>
<td>88%</td>
<td>12.6</td>
<td>22%</td>
</tr>
<tr>
<td>Score ≥ 8 (MDE II, screening)</td>
<td>92 (84-97)</td>
<td>66 (61-72)</td>
<td>2.8</td>
<td>0.1</td>
<td>43%</td>
<td>97%</td>
<td>28.1</td>
<td>22%</td>
</tr>
<tr>
<td>Score ≥ 9</td>
<td>87 (78-93)</td>
<td>72 (66-77)</td>
<td>3.1</td>
<td>0.2</td>
<td>46%</td>
<td>96%</td>
<td>20.0</td>
<td>22%</td>
</tr>
<tr>
<td>Score ≥ 10</td>
<td>84 (74-91)</td>
<td>77 (71-83)</td>
<td>3.7</td>
<td>0.2</td>
<td>51%</td>
<td>95%</td>
<td>17.7</td>
<td>22%</td>
</tr>
<tr>
<td>Score ≥ 11</td>
<td>81 (79-89)</td>
<td>82 (77-87)</td>
<td>4.6</td>
<td>0.2</td>
<td>56%</td>
<td>94%</td>
<td>21.6</td>
<td>22%</td>
</tr>
<tr>
<td>Score ≥ 12</td>
<td>70 (56-81)</td>
<td>87 (82-90)</td>
<td>5.3</td>
<td>0.3</td>
<td>59%</td>
<td>91%</td>
<td>15.5</td>
<td>22%</td>
</tr>
<tr>
<td><strong>aPHQ-2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Score ≥ 2</td>
<td>92 (84-97)</td>
<td>49 (42-56)</td>
<td>1.8</td>
<td>0.1</td>
<td>33%</td>
<td>96%</td>
<td>13.6</td>
<td>22%</td>
</tr>
<tr>
<td>Score ≥ 3</td>
<td>74 (63-82)</td>
<td>79 (74-84)</td>
<td>3.6</td>
<td>0.3</td>
<td>50%</td>
<td>92%</td>
<td>10.9</td>
<td>22%</td>
</tr>
<tr>
<td>Score ≥ 4</td>
<td>52 (35-68)</td>
<td>89 (86-91)</td>
<td>4.8</td>
<td>0.5</td>
<td>57%</td>
<td>87%</td>
<td>9.0</td>
<td>22%</td>
</tr>
</tbody>
</table>

aPHQ-2: first two questions of the adapted patient health questionnaire; aPHQ-9: the adapted patient health questionnaire; CI: confidence interval; DOR: diagnostic odds ratio; LR: likelihood ratio; MDE: Major Depressive Episode using the MINI International Neuropsychiatric Interview (MINI) 6.0.0 major depressive episode module; NPV negative predictive value; PPV positive predictive value
Table A12  Participant feedback on the acceptability of the aPHQ-9 plus additional 7 questions (n=500)

<table>
<thead>
<tr>
<th>Question</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Too many questions?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No, the number of questions was fine</td>
<td>449</td>
<td>90</td>
</tr>
<tr>
<td>It would be better if there were fewer questions/Yes, there were too many</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>Don't care/No opinion</td>
<td>19</td>
<td>4</td>
</tr>
<tr>
<td><strong>Questions were easy to understand?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, they were easy to understand</td>
<td>434</td>
<td>87</td>
</tr>
<tr>
<td>I understood most of the questions</td>
<td>52</td>
<td>10</td>
</tr>
<tr>
<td>No, they were too confusing</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Don't care/No opinion</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>Questions were easy to answer?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The questions were easy to answer</td>
<td>412</td>
<td>82</td>
</tr>
<tr>
<td>I was able to answer most questions easily</td>
<td>73</td>
<td>15</td>
</tr>
<tr>
<td>The questions were too difficult to answer</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Don't care/No opinion</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td><strong>The response categories made sense?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, they were fine</td>
<td>446</td>
<td>89</td>
</tr>
<tr>
<td>There is probably a better way to answer how I felt</td>
<td>33</td>
<td>7</td>
</tr>
<tr>
<td>No, they were not a good way of asking</td>
<td>16</td>
<td>3</td>
</tr>
<tr>
<td>Don't care/No opinion</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td><strong>Felt comfortable answering the questions?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, I was comfortable answering all the questions</td>
<td>457</td>
<td>91</td>
</tr>
<tr>
<td>I was ok answering most of the questions</td>
<td>33</td>
<td>7</td>
</tr>
<tr>
<td>No, I was not comfortable answering the questions</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Don't care/No opinion</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td><strong>Had time to answer the questions?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, there was plenty of time to answer the questions</td>
<td>493</td>
<td>98</td>
</tr>
<tr>
<td>No, I needed more time</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Don't care/No opinion</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td><strong>Were the questions too personal?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No, I was comfortable with what was asked</td>
<td>428</td>
<td>86</td>
</tr>
<tr>
<td>Some of the questions were a bit too personal</td>
<td>40</td>
<td>8</td>
</tr>
<tr>
<td>Yes, the questions were all too personal &amp; I didn't really want to answer them</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Don't care/No opinion</td>
<td>7</td>
<td>1</td>
</tr>
</tbody>
</table>
Eligible participants
n=533

Excluded
n=380
Declined participation (n=243)
Ineligible (n=124)

No aPHQ-9
n=3

Withdraw consent before interview (n=2)
IT difficulties (n=1)

No aPHQ-9 negative*
N=429

No aPHQ-9 positive*
N=101

No MINI interview
n=21
Unable to contact (n=6)
>7 days since aPHQ-9 (n=6)
Already participated (N=2)
No time (n=1)
IT failure (n=1)
Too much stress (n=1)

MINI interview
N=408

Final diagnosis†
Major depressive episode present (n=49)

MINI interview
N=92

Final diagnosis†
Major depressive episode present (n=59)
*The adapted 9-item Patient Health Questionnaire (aPHQ) was used to calculate a major depressive episode as a score of 2 or above on at least five aPHQ-9 questions (the last question is counted if a score of 1 or above is indicated), one of which corresponds to Question 1 or 2.

†The MINI International Neuropsychiatric Interview (MINI) was used to determine a final diagnosis using the current major depressive episode module.
Figure A2  Proportion of the 500 participants diagnosed with major depressive event, generalised anxiety disorder and post-traumatic stress disorder, with the MINI⁴

⁴ Prevalence of major depressive event (MDE) 22%, generalised anxiety disorder (GAD) 21% and post-traumatic stress disorder (PTSD) 11%.
Figure A3  Receiver operating characteristic (ROC) curve for the aPHQ-9 score.

The shaded region represents the 95% confidence region for the curve. The cut-offs 8, 9, 10, 11 and 12 for the score are indicated in the figure with the respective cross-type 95% confidence intervals. AUC – area under the curve
The shaded region represents the 95% confidence region for the curve. The cut-offs 2, 3 and 4 for the score are indicated in the figure with the respective cross-type 95% confidence intervals. AUC – area under the curve
APPENDIX 8: TERMS OF REFERENCE FOR THE INDIGENOUS ADVISORY GROUP

Study aims
This study aims to explore the experiences, perceptions and preferences of Indigenous-focused primary healthcare staff and community decision-makers related to Indigenous-focused health research, conducted in collaboration with external researchers. This is an area where little documented evidence currently exists.

This study will be conducted with careful consideration of the Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research and National Statement on Ethical Conduct in Human Research.

Advisory Group purpose
The purpose of the Advisory Group (hereafter referred to as the Group) is to provide guidance and to ensure appropriate conduct of the study.

Membership will consist of a core group of members. In addition, each participating primary healthcare service will be invited to select one or more representative as a Group member. This will provide a local perspective from each community.

Roles and responsibilities
The roles and responsibilities of the Group are to:
- Share insights and knowledge of the Aboriginal and Torres Strait Islander community to support the successful conduct of the study, e.g. study conduct and documents,
- Understand and take an interest in the aims, plans, conduct and outcomes of the study,
- Support open and honest discussions surrounding the study,
- Participate in decision-making processes as required for the study,
- Assist in management of risk or issues arising during the study,
- Provide feedback to the Group or the Chair in a reasonable timeframe (within two weeks),
- Provide perspectives on study findings and assist in the translation of the research findings into policy and practice.

Chair
The roles and responsibilities of the Chair are to:

General Guidelines
- Ensure safe and ethical conduct of the study,
- Plan and coordinate communications amongst the Group, including determining a convenient time and method of contact for each member,
- Provide documents and other materials to Group members in a reasonable timeframe prior to requiring feedback (at least two weeks before feedback is due),
- Provide updates on progress of the study to the Group,
- Support open and honest discussions surrounding the study,
- Be willing and open to the advice and perspectives provided by the Group,
- Keep communications confidential unless specified by the Group,
- Coordinate the conduct of the study according to the decisions made by the Group.

Documentation of communications and decisions

A teleconference or videoconference will be held at most quarterly for the duration of the study. If a time convenient to all members is not able to be identified, discussions may occur using the following methods: teleconference, phone, email and face-to-face meetings where possible.

Additional advice/feedback may be sought from the Group as determined by the needs of the study.

Decisions will be made following adequate timeframes for feedback from the Group (two weeks) according to preferences and advice of the Group.

The Chair will maintain a log of communications and decisions made by the Group. Minutes of meetings will be kept and circulated to Group members within one week of a meeting for review, approval and comment.

Authorship and acknowledgement

Members of the Group will be acknowledged on all publications arising from the study. Authorship of publications related to the study will be determined according to ICMJE guidelines*.

* ICMJE guidelines for publication
APPENDIX 9: SCREEN SHOT OF A MINI ROLE PLAY
What is vicarious trauma?

Vicarious trauma (VT) is an outcome of working with traumatised clients. It is the effects on you of listening to trauma stories of other people.

Vicarious trauma has a life-changing effect on individuals, ultimately affecting their view of the world and their relationships and connections to family, friends and community. Understanding and working with vicarious trauma is both an individual and organisational challenge.

Signs and symptoms of vicarious trauma

The following lists some of the common warning signs and symptoms of vicarious trauma.

- Intrusive thoughts, images or sensations.
- Anxiety before, during, and / or after meeting with an individual with whom you are working.
- Feeling annoyed, angry or frustrated at the people you are working with or at the world in general for no particular reason.
- Changes in sleeping habits or having nightmares.
- Changes in your eating habits, alcohol and / or cigarette use.
- Fear for the safety of your own family, pets or possessions.
- Loss of faith in humanity; personal beliefs and feelings of hopelessness and futility.

Factors that increase the risk of vicarious trauma

- Having a history of your own traumatic experiences
- Overwork
- Ignoring health boundaries
- Taking on too much
- Lack of experience/skills
- Dealing with large numbers of traumatised clients
- Working with large numbers of people who suffer mental health issues
- Having too many negative outcomes
Strategies for preventing vicarious trauma

- Establish a plan of help (preferably before you need it). This may include identifying specific people to approach for help and support, including professional resources you can access.
- Use regular supervision and debriefing at work. If you don’t currently have supervision and debriefing, ask for it to be arranged.
- Allow yourself to feel upset, angry or frustrated. Think about where you can express these feelings safely.
- Arrange counselling if you are struggling with experiences yourself.
- Include regular stress busters in every work day (e.g. taking quick walks, making a cuppa, stretching, and deep breathing).
- When you find work too upsetting:
  - seek ways to reduce the direct contact you have with a client(s)
  - get others involved to help share the load
  - think of other indirect ways you can offer support
  - negotiate with colleagues and your supervisor about certain tasks that you feel may be detrimental to you.
- Look at other causes of stress in your life and try to reduce them.
- Keep your body healthy by exercising and having regular physical examinations.
- Eat a well-balanced diet.
- Get enough sleep and make time to relax.
- Have a personal life outside work with supportive, positive friends.
- Limit your exposure to trauma stories (for example, question whether it is helpful for you to watch or listen to the news regularly, select television shows that don’t involve trauma).
- Find ways to be spiritually satisfied.
- Have some creative interests.
- Discuss work challenges with others who are doing the same sort of work.
- Have very clear boundaries between your work life and your home life. Make sure other people are aware of these boundaries.

Reference: Guidebook on Vicarious Trauma: Recommended Solutions for Anti-Violence Workers Jan I. Richardson of the Centre for Research on Violence Against Women and Children in London, Ontario for the Family Violence Prevention Unit, Health Canada, 2001

Certificate of Training

This is to certify that

has attended the training for the modified version of the M.I.N.I. International Neuropsychiatric Interview (M.I.N.I. 6.0.0) for the Getting it right: the validation study. This modified version includes Major Depression, Post Traumatic Stress Disorder and Generalised Anxiety Disorder.

Date of training: 17/03/2015

Associate Professor Maree Hackett
Why did we do the Getting it Right study?
Many people, including Aboriginal and Torres Strait Islander people are not often asked
about depression. It can be hard for health staff to know if a person has depression.

Currently, there is no culturally-appropriate, free, questionnaire to find out if Aboriginal
and Torres Strait Islander people have depression.

So, Aboriginal people from Central Australia worked with researchers to make a simple
questionnaire (a survey) that would work. They changed an existing survey ‘PHQ-9’ into a
culturally safe set of questions. We call this the adapted PHQ-9, or aPHQ-9 for short.

Now that a new set of questions have been made, we need to test or ‘validate’ them to
make sure they are culturally safe and pick up depression in Aboriginal and Torres Strait
Islander people across Australia. This is what we did in the Getting it Right study.

What did we do?
Ten Aboriginal Health Services and 500 Aboriginal and Torres Strait Islander people
across Australia took part in Getting it Right. They completed the aPHQ-9 and an
interview used to diagnose depression and we compared their answers.

Does the aPHQ-9 work?
Yes. We found that the aPHQ-9 can show if someone has depression. Being able to
know if someone has depression could make it easier to make sure they are getting the
care that they need.

We also found that …
People said the aPHQ-9 was easy to answer, easy to understand, made sense and that
they were comfortable answering the questions.

Health staff said the aPHQ-9 helped people talk about depression.

What are we doing next?
1. We are talking to health staff at the 10 Health Services about the study results.
2. We will talk to Medicare to see if Health Services can be reimbursed when they use the
   aPHQ-9
3. Building on the Getting it Right, what would you like to do now?

This study was funded by the NHMRC, project grant APP101767.
APPENDIX 13: QUALITY ASSESSMENT OF GETTING IT RIGHT USING OBSERVATIONAL COHORT AND CROSS-SECTIONAL STUDIES\textsuperscript{109} TO ASSESS THE DESIGN AND CONDUCT

Many of the criteria (related to ‘exposure’) outlined in the Observational Cohort and Cross-Sectional Studies\textsuperscript{109} were not applicable to Getting it Right as a validation design. A score for Getting it Right using this assessment tool was unable to be determined (Table A8).

Table A13 Quality assessment of Getting it Right using Observational Cohort and Cross-Sectional Studies\textsuperscript{109} to assess the design and conduct

<table>
<thead>
<tr>
<th>Criteria to identify risk of bias</th>
<th>Assessment of risk in Getting it Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the research question or objective in this paper clearly stated?</td>
<td>✓</td>
</tr>
<tr>
<td>Was the study population clearly specified and defined?</td>
<td>✓</td>
</tr>
<tr>
<td>Was the participation rate of eligible persons at least 50%?</td>
<td>✓</td>
</tr>
<tr>
<td>Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?</td>
<td>✓</td>
</tr>
<tr>
<td>Was a sample size justification, power description, or variance and effect estimates provided?</td>
<td>✓</td>
</tr>
<tr>
<td>For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?</td>
<td>NA\textsuperscript{9}</td>
</tr>
<tr>
<td>Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?</td>
<td>NA\textsuperscript{9}</td>
</tr>
<tr>
<td>For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?</td>
<td>NA\textsuperscript{9}</td>
</tr>
<tr>
<td>Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?</td>
<td>NA\textsuperscript{9}</td>
</tr>
<tr>
<td>Was the exposure assessed more than once over time?</td>
<td>NA\textsuperscript{9}</td>
</tr>
<tr>
<td>Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?</td>
<td>✓</td>
</tr>
<tr>
<td>Were the outcome assessors blinded to the exposure status of participants?</td>
<td>NA\textsuperscript{9}</td>
</tr>
<tr>
<td>Was loss to follow-up after baseline 20% or less?</td>
<td>✓</td>
</tr>
<tr>
<td>Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?</td>
<td>NA\textsuperscript{9}</td>
</tr>
</tbody>
</table>
### Criteria to identify risk of bias

<table>
<thead>
<tr>
<th>Criteria to identify risk of bias</th>
<th>Assessment of risk in Getting it Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality rating – risk of bias</td>
<td>Unable to determine</td>
</tr>
</tbody>
</table>

**Abbreviations:** NA – not applicable  
* Recruited from the same population over a 2 year timeframe. Inclusion and exclusion criteria uniformly applied.  
# Assessing 'exposure' (not appropriate for a validation design)  
Note: To provide consistency with the other tools used in this thesis, I have modified the wording for the ratings used in the guidance\(^{(106)}\) from 'good', 'fair' or 'poor', to 'low', 'medium' or 'high' risk of bias. Other assessment criteria are consistent with the original guidance.  
✓: yes  
✗: no
CEO Welcome

Reconciliation Week ran from 27th May to 3rd June. This is a time to promote the importance of respectful relationships between Aboriginal and Torres Strait Islanders and the rest of Australia.

There were many fun things happening this year to celebrate Reconciliation Week and Nunkuwarrin Yunti was fortunate enough to be involved in 7 of them. Here are some photo's of what we got up to.

No words can describe the shear devastation and loss that our community have gone through. We can only hope and pray that we will get through all the heartache and pain in our lives.

Our caring thoughts and prayers are with you all during this difficult time. If we can help provide you with comfort, peace and strength today and the days ahead please contact our Social & Emotional Wellbeing team. They can support you to build the skills and knowledge to regain a healthy spirit, healthy body and healthy mind.

Most sincerely,

CEO.

Sign up to our newsletter by going to our website at www.nunku.org.au and scrolling to the bottom.
APPENDIX 15: INTERVIEW GUIDES FOR PROCESS EVALUATION

Version 1

Introduction and background
- Informed Consent, test & and start recording.
- Introduction: Purpose of the interview, researchers’ role, why recording is necessary, confidentiality, what will happen to data.
- Where are you from? What mob do you belong to? (If applicable)

<table>
<thead>
<tr>
<th>Initial broad question</th>
<th>Probing question</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim 1</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Aim 2</strong></td>
<td></td>
</tr>
<tr>
<td>2. In your experience how was the decision about your service’s involvement in <em>Getting it Right</em> made?</td>
<td>Who? CEO, board, staff, jury or other? What was considered?</td>
</tr>
<tr>
<td>3. What led you to be involved or not to get involved in research?</td>
<td>What was the process?</td>
</tr>
<tr>
<td><strong>Aim 3</strong></td>
<td></td>
</tr>
<tr>
<td>4. What were/are the barriers and enablers to implementing <em>Getting it Right</em>?</td>
<td>What made it work or not? Problems? How did you solve them?</td>
</tr>
<tr>
<td><strong>Aim 4</strong></td>
<td></td>
</tr>
<tr>
<td>5. What are your thoughts on the aPHQ-9? If valid, would you like to use it at your service and how?</td>
<td>How do you find asking the questions? Would you use it? How? Where? With who?</td>
</tr>
<tr>
<td><strong>Aim 5</strong></td>
<td></td>
</tr>
</tbody>
</table>

315
6. Moving away from GIR … What do you think about research generally?

7. What do you think makes research successful for you?

8. What do you expect researchers from outside your service when then come to do research with you?

9. What do you think could be done to improve how research is done?

10. If not already captured: Please describe the steps that Getting it Right followed at your service?

Version 2

Initial question

1. To begin, can you please tell me about your involvement with Getting it Right?

Aim 1

2. What do you think about Getting it Right?

Probing questions

Experience: How was your experience of finding participants? Doing interviews? Did you learn anything new?

Data: How did you collect data (paper or computer?) What did you think about the database? Enough training? Support?

Data: Where did you do interviews? Did you think the setting impacted on peoples answers to the questions? How?

Pos/Neg: Was there anything good to come out of the study for you? Bad? For clients? For the service? Did anything happen that you didn’ t expect because of the study? Did you interview
family members or other important people in the community?
What was this like?
Participants: Was there anything that participants were concerned about?
Safety: Did you have concerns about participant/client wellbeing during the study?

<table>
<thead>
<tr>
<th>Aim 3</th>
<th>3. What were the barriers and enablers to implementing <em>Getting it Right</em>?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>What worked well? What didn’t work well? Did you have problems? How did you solve them? How could it be done better next time? What could we have done to make it better for you? Clients? Service? How long did interviews really take? How did it impact on the service’s planning, programs or financial processes? Did you provide vouchers to participants? What did you think about this? Good/bad? Could we have better prepared you for what was really involved with working on the study? How?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aim 2</th>
<th>4. What led you to be involved or not with the research?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Want to be? Told? Know about the study before it happened? Was there anything that made you interested/not in <em>Getting it Right</em>? Anything you were worried about before/during? Did the topic (depression) impact on your decision to take part? Participant? Ownership/capacity: Did you feel you had control of how the study was done at your service? Was enough time/people available?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aim 4</th>
<th>5. In your experience, how was the decision made for you service to get involved with <em>Getting it Right</em>?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Who? CEO, board, staff, jury or other? What was considered? What was the process? Was the financial reimbursement to the service important?</td>
</tr>
</tbody>
</table>
6. What are your thoughts on the aPHQ-9? If valid, would you like to use it at your service and how?

7. When we have findings – do you have any suggestions for how we could feedback results to the service/community?

Aim 5

8. Moving away from Getting it Right … Do you think research has relevance for your work?

9. How could research be improved?

10. Suppose there is a new research project starting - what do you expect from the researchers when then come to work with you?

11. Have you heard of the Values and Ethics Guideline for Indigenous health research?

Anything else, tell me about that, and then what happened…


Does it impact? How? Why?

If you had the chance, would you like to do more research? What makes research effective/meaningful/worthwhile e.g. evidence, knowledge, topics, improve care, health, new skills? What topic/areas should research focus on? Is there any skills/training you would like to have about research? Or for other people? Should the community have more involvement? What stage? How could this be done? Bring anything? Say anything? Behaviour? Most and least important? What do you want to know about them?
### Version 3

<table>
<thead>
<tr>
<th>Initial broad question</th>
<th>Probing Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim 1</strong></td>
<td></td>
</tr>
</tbody>
</table>
| 1. What do you think about *Getting it Right*? | What is your role?  
Research topic? Advantages? Disadvantages? What worked well? Where did you do interviews?  
Did you interview anyone you knew from outside of work e.g. family or friends?  
Do you usually talk to patients about depression/SEWB? How did you feel talking to people about depression?  
What do you think about giving people who take part vouchers?  
Did you have any concerns about patients’ safety?  
Do you think that the people who took part represent the community? E.g. bias |
| **Aim 2**              |                   |
| 2. In your experience how was the decision about your service’s involvement in *Getting it Right* made? | Who? CEO, board, staff, jury or other? What was considered?  
What was the process? |
| 3. What led you to be involved or not to get involved in research? | Want to be? Told? Know about the study before it happened? |
| **Aim 3**              |                   |
| 4. What were/are the barriers and enablers to implementing *Getting it Right*? | What made it work or not? Problems? How did you solve them? How could it be better next time? How could external researchers help?  
Did you feel that you had enough say/control over what you needed to get the study done? |
| **Aim 4**              |                   |
5. What are your thoughts on the aPHQ-9? If valid, would you like to use it at your service and how?

6. **Aim 5**
   - What do you think about research generally?

7. What do you think makes research successful for you?

8. What do you expect researchers from outside your service when then come to do research with you?

9. What do you think could be done to improve how research is done?

10. If not already captured: Please describe the steps that *Getting it Right* followed at your service?
    Anything else, tell me about that, and then what happened...

    - Would you like to be acknowledged for your work on research? How?
    - How can research be done so it has greater benefit to the community?
    - Bring anything? Say anything? Behaviour? Most and least important?
    - Is there anyone in your service whose job it is to do research? Next time, would you like to have someone from outside the organisation come and work with you?
    - Who did what? How to identify participants? Set or changed during process?
Dear A/Prof Hackett,

RE: 1044/14 - The validation of a culturally-specific measure to identify depression in Aboriginal and Torres Strait Islander people with or without chronic disease.

I refer to recent correspondence received 21st of September 2016 which contained a request to amend the above previously approved study. The amendment requested was to approve the addition of a Process Evaluation for Getting it Right to formally evaluate the processes, lessons learnt and the impact of implementing the study on the study’s recruitment site staff and community members.

The Committee sought further information regarding the amendment request and this information was provided by the 1044/14 research team.

The Committee has reviewed and approved this amendment request.

The conditions outlined in the original letter of approval continue to apply.

On behalf of the AH&MRC Ethics Committee,

Yours sincerely,

Val Keed
Chairperson
AH&MRC Ethics Committee

AH&MRC ETHICS COMMITTEE

14th November 2016

Associate Professor Maree Hackett
The George Institute for Global Health
PO Box M201
Missenden Rd
Camperdown NSW 2050

Dear A/Prof Hackett,

RE: 1044/14 - The validation of a culturally-specific measure to identify depression in Aboriginal and Torres Strait Islander people with or without chronic disease.

I refer to recent correspondence received 21st of September 2016 which contained a request to amend the above previously approved study. The amendment requested was to approve the addition of a Process Evaluation for Getting it Right to formally evaluate the processes, lessons learnt and the impact of implementing the study on the study’s recruitment site staff and community members.

The Committee sought further information regarding the amendment request and this information was provided by the 1044/14 research team.

The Committee has reviewed and approved this amendment request.

The conditions outlined in the original letter of approval continue to apply.

On behalf of the AH&MRC Ethics Committee,

Yours sincerely,

Val Keed
Chairperson
AH&MRC Ethics Committee

Supported by the NSW Ministry of Health

Location
Level 3, 66 Wentworth Avenue
Surry Hills NSW 2010

Postal Address
PO Box 1565
Strawberry Hills NSW 2012

Contact
Phone: +61 (2) 9212 4777
Fax: +61 (2) 9212 7291
E-Mail: ahmrc@ahmrc.org.au
Web: www.ahmrc.org.au

ABN
66 085 654 397
Dear A/Prof Hackett,

RE: 1044/14 - The validation of a culturally-specific measure to identify depression in Aboriginal and Torres Strait Islander people with or without chronic disease.

I refer to recent correspondence received 21st of September 2016 which contained a request to amend the above previously approved study. Additional information received Thursday 27th of October 2016 & Thursday 10th of November.

The amendments requested are:

The amendment requested was to approve the addition of a Process Evaluation for Getting it Right to formally evaluate the processes, lessons learnt and the impact of implementing the study on the study’s recruitment site staff and community members.

Documents reviewed to support these amendments are:

3. C 2016 08 16 Attachment A PIS Draft V 1 Views of PHC.PDF
4. D 2016 08 16 Attachment B Consent V 1 Views of PHC.PDF
5. C_ValidationStudy NEAD V2.0 8 Sep2014Combined.pdf
6. D_Validation_Study_ProtocolSummary_AHMRCv3.0_17Sep2014_clean.pdf
7. 2016 09 21 1044 14 Getting it right Amendment.pdf
8. 2016 10 27 PE Letter of support COMBINED.pdf

The Committee notes this Evaluation’s findings will contribute to Sara Farnbach’s PhD project. If Getting it Right shows the aPHQ-9 to have high validity, the Evaluation’s findings will also support planning for the aPHQ-9’s implementation, as well as for future research conducted with Aboriginal and Torres Strait Islander people.

The Committee has reviewed and approved this amendment request.

The conditions outlined in the original letter of approval continue to apply.
On behalf of the AH&MRC Ethics Committee,

Yours sincerely,

[Signature]

Val Keed
Chairperson
AH&MRC Ethics Committee
Tuesday, 20 September 2016

Assoc Prof Maree Hackett
The George Institute for Global Health; Sydney Medical School
Email: mhackett@georgeinstitute.org.au

Dear Maree

Your request to modify this project, which was submitted on 16 August 2016, has been considered.

The project has been approved to proceed with the proposed amendments.

Details of the approval are as follows:

Project Title: The validation of a culturally specific measure to identify depression in Aboriginal and Torres Strait Islander People

Project No.: 2014/361

Next Annual Report due: 21 May 2017

New Approved Documents:

<table>
<thead>
<tr>
<th>Date Uploaded</th>
<th>Type</th>
<th>Document Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>16/08/2016</td>
<td>Participant Info Statement</td>
<td>A Participant Information Sheet M V6.0, SV2.0 09/06/2016 COMMUNITY</td>
</tr>
<tr>
<td>16/08/2016</td>
<td>Participant Consent Form</td>
<td>B Informed Consent M V6.0, SV2.0 09/06/2016 COMMUNITY</td>
</tr>
<tr>
<td>16/08/2016</td>
<td>Cover Letter/Correspondence</td>
<td>C AH&amp;MRC Approval Letters 05/08/2016 and 16/08/2016</td>
</tr>
<tr>
<td>16/08/2016</td>
<td>Study Protocol</td>
<td>D Getting it right Process Evaluation Protocol V1.0 16/08/2</td>
</tr>
<tr>
<td>16/08/2016</td>
<td>Participant Info Statement</td>
<td>E Participant Information Sheet V1.0 16/08/2016</td>
</tr>
<tr>
<td>16/08/2016</td>
<td>Participant Consent Form</td>
<td>F Informed Consent V1.0 16/08/2016</td>
</tr>
</tbody>
</table>

Special Condition/s of Approval

- Please revise the Evaluation PIS to include a name in place of XX, once the name is known. This should be submitted to the Ethics Office via a Special Condition of Approval form in IRMA.

Please contact the Ethics Office should you require further information or clarification.

Sincerely

Dr Fiona Gill
Chair
Deputy Chair Review Committee
The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council’s (NHMRC) National Statement on Ethical Conduct in Human Research (2007) and the NHMRC’s Australian Code for the Responsible Conduct of Research (2007).
28 November 2016

A/Professor Maree Hackett
The George Institute for Global Health
83-117 Missenden Road
Camperdown NSW 2050

Dear A/Professor Hackett,

HREC Reference Number: 2014-2289

Project Title: The validation of a culturally-specific measure to identify depression in Aboriginal and Torres Strait Islander people with or without chronic disease

The amendment to the above project submitted on 17/11/2016 was approved and will be ratified at the next meeting of the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research (HREC). Please note that this approval applies only to research conducted after the date of this letter.

The following amendments are approved:

1. Completion of a Process Evaluation for Getting it Right to formally evaluate the processes, lessons learnt and impact of implementing the study on the study’s recruitment site staff and community members;
2. Extension to project timeframe from 31/12/2016 to 31/12/2017.

The following documents are approved:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>USyd AHMRC Approval Letters</td>
<td></td>
<td>14/11/2016</td>
</tr>
<tr>
<td>PE Letter of support combined</td>
<td></td>
<td>27/10/2016</td>
</tr>
<tr>
<td>Qualitative Research Process Protocol</td>
<td>1</td>
<td>16/08/2016</td>
</tr>
<tr>
<td>PIS DRAFT v1 Views of PHC</td>
<td>1</td>
<td>16/08/2016</td>
</tr>
<tr>
<td>Consent v1 Views of PHC</td>
<td>1</td>
<td>16/08/2016</td>
</tr>
</tbody>
</table>

Please note that all requirements of the original ethical approval for this project still apply.

Approved timeline: 09/07/2015 – 31/12/2017
Annual progress report due: 31/12/2016

APPROVAL IS SUBJECT TO the following conditions being met:

1. The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
2. The Coordinating Principal Investigator will notify the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research (HREC) of any event that requires a modification or amendment to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found on the Menzies’ website.
3. The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants (e.g. protocol deviations, protocol violations) in accordance with the HREC’s policy and procedures. These guidelines can be found on the Menzies’ website.
4. The Coordinating Principal Investigator will report to the HREC annually and notify the HREC when the project is completed at all sites using the specified forms. Forms and instructions may be found on the Menzies’ website.

5. The Coordinating Principal Investigator will notify the HREC if the project is discontinued at a participating site before the expected completion date, and provide the reason/s for discontinuance.

6. The Coordinating Principal Investigator will notify the HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. The preferred time and method of requesting an extension of ethical approval is during the annual progress report. However, an extension may be requested at any time.

7. The Coordinating Principal Investigator will notify the HREC of his or her inability to continue as Coordinating Principal Investigator, including the name of and contact information for a replacement.

8. The safe and ethical conduct of this project is entirely the responsibility of the investigators and their institution(s).

9. Researchers should immediately report anything which might affect continuing ethical acceptance of the project, including:
   - Adverse effects of the project on participants and the steps taken to deal with these;
   - Other unforeseen events;
   - New information that may invalidate the ethical integrity of the study; and
   - Proposed changes in the project.

10. Approval for a further twelve months, within the original proposed timeframe, will be granted upon receipt of an annual progress report if the HREC is satisfied that the conduct of the project has been consistent with the original protocol.

11. Confidentiality of research participants should be maintained at all times as required by law.

12. The Patient Information Sheet and the Consent Form shall be printed on the relevant site letterhead with full contact details.

13. The Patient Information Sheet must provide a brief outline of the research activity including: risks and benefits, withdrawal options, contact details of the researchers and must also state that the Human Research Ethics Administrators can be contacted (telephone and email) for information concerning policies, rights of participants, concerns or complaints regarding the ethical conduct of the study.

14. You must forward a copy of this letter to all Investigators and to your institution (if applicable).

This letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

Should you wish to discuss the above research project further, please contact the Ethics Administrators via email: ethics@menzies.edu.au or telephone: (08) 8946 8687 or (06) 8946 8692.

The Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research wishes you every continued success in your research.

Yours sincerely,

Dr Lewis Campbell
Chair
Human Research Ethics Committee
of the Northern Territory Department of Health
and Menzies School of Health Research
http://www.menzies.edu.au/ethics
This HREC is registered with the Australian National Health and Medical Research Council (NHMRC) and operates in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research* (2007). NHMRC Reg no. EC00153
A/Prof M Hackett  
Head, Mental Health and Chronic Disease Program  
The George Institute for Global Health  
PO Box M201  
Missenden Road  
Camperdown NSW 2050  

Dear A/Prof Hackett  

**HREC Reference number:** HREC/14/QPAH/503  
**Project Title:** Getting it right: the validation study  

The Office of the Metro South Human Research Ethics Committee noted and approved the following:-

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification of Amendment to update Participant Information Sheet to remove 'XX' to indicate only one interviewer; and to reflect that data will be used towards PhD research.</td>
<td></td>
<td>7 March 2017</td>
</tr>
<tr>
<td>PIS</td>
<td>4</td>
<td>7 March 2017</td>
</tr>
</tbody>
</table>

This will be ratified by the HREC at its 4 April 2017 meeting.

**Please provide a copy of this approval letter to the Research Governance Office.**

It should be noted that all requirements of the original approval still apply. Please continue to provide at least annual progress reports until the study has been completed.

If you have any queries please do not hesitate to contact the Human Research Ethics Committee office on +61 7 3443 8049.

Yours sincerely,

A/Prof Scott Campbell  
A/Chair  
Metro South Hospital and Health Service  
Human Research Ethics Committee (EC00167)  
Centres for Health Research  
Princess Alexandra Hospital, Woolloongabba QLD 4102  

C.c. A/Prof D Askew, Inala Indigenous Health Service
2nd March, 2017

Dear Maree,

RE: HREC Reference number: 607

Project title: Getting it Right – Validation study

Thank you for submitting the above amendment which was considered by the WAAHEC at the out of session meeting held on 24th February, 2017 and approved the request for Amendment providing:

- To formally evaluate the processes, lessons learnt and impact of implementing the study on the study's recruitment site staff and community members. They plan to invite staff involved with the evaluation, in order to provide their perspectives of the study

Should you have any queries about the WAAHEC’s consideration of your amendment please contact ethics@ahcwa.org.

It should be noted that all requirements of the original approval still apply.

The WAAHEC wishes you every success in your research.

Kind regards

Tara Rowe
For, Vicki O’Donnell
Chair, WAAHEC

---

This HREC is constituted and operates in accordance with the National Health and Medical Research Council’s (NHMRC) National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice. The process this HREC uses to review multi-centre research proposals has been certified by the NHMRC.
Good afternoon

The Chair has approved the Progress report and extension request for the project ‘Getting it right: the validation of a culturally-specific measure to identify depression in Aboriginal and Torres Strait Islander people with or without chronic disease’ HREC-15-287. He also approved the notification outlined in your letter of 22nd November and the amendment requested in the letter dated 1st December.

It may take some time for the letter to arrive as I will be on leave until the 27th January.

Amendment 1st December

Chris

Chris Schwarz
Secretariat Support
Central Australian Human Research Ethics Committee
cahrec@flinders.edu.au

PO Box 4066
Alice Springs
NT Australia  0871

Tel       + 61 8 8951 4700
Fax       + 61 8 8951 4777

This email and any attachments may be confidential. If you are not the intended recipient, please inform the sender by reply email and delete all copies of this message.
A/Professor Maree Hackett  
The George Institute for Global Health  
PO Box M201  
Missenden Rd  
Camperdown NSW 2050

Dear A/Professor Hackett,

ETH.8.14.207

Thank you for your letter of 14 November 2016, seeking approval of documents relating to:

The Validation Study: The validation of a culturally-specific measure to identify depression in Aboriginal and Torres Strait Islander people with or without chronic disease

At its meeting of 5 December 2016, the Committee requested further information, and following further correspondence, approved the following:

- Process Evaluation Protocol version 1.0 dated 16 August 2016
- Participant Information Sheet version 3.0 dated 9 January 2017
- Consent Form version 2.0 dated 9 January 2017

The approval has been recorded on the Committee’s files.

Yours sincerely

[Signature]

August Marchesi  
Director  
Research Ethics and Governance  
10 January 2016
13 February 2017

Principal Investigator 1 (as per the AHREC application form): Ms Sara Farnbach
Organisation: The George Institute for Global Health
Via email to the Corresponding Researcher(s): sfarnbach@georgeinstitute.org.au mhackett@georgeinstitute.org.au

RE: The Getting it right process evaluation
AHREC Protocol #: 04-17-705

Dear Sara,

Thank you for your submission requesting ethical review from the Aboriginal Health Research Ethics Committee (AHREC).

I am pleased to inform you that the application was reviewed at AHREC’s meeting held on 9 February 2017 and met with support. The Committee recommended your application for full approval with the standard conditions below.

Whilst approved, the Committee recommended that the appropriate form of reimbursement should be negotiated directly with organisations involved.

We wish you well with the study and look forward to receiving your progress reports. Please be advised that, instead of the anniversary of the approval date, AHREC now requires annual reports to be submitted every November, for this year, by 30 November 2017.

If you require further information, please do not hesitate to contact AHREC.

Sincerely yours,
Dr Gokhan Ayturk on behalf of

Kim Morey
Chairperson, AHREC
Standard Conditions

1) The approvals are granted based on the documentation and scope outlined by the researcher at the time of the review. AHREC must be notified of, and, approve, any changes to the study including minor or major changes to the study parameters, personnel updates and extension requests.

2) Where applicable, the onus of following the appropriate procedure for obtaining informed consent and protecting the well-being of a participant lies solely with researcher(s).

3) AHREC approvals are valid for 3 years from the date of the approval letter unless a maximum of 5 year approval timeframe is specifically requested, for example, in case of longitudinal studies and research projects conducted under Centres of Research Excellence. AHREC does not grant approvals indefinitely.

4) Studies aiming to involve an Aboriginal organisation, e.g., an Aboriginal Community Controlled Health Service, should adapt a partnership approach and go through a meaningful engagement process evidenced by an in-principle support letter or appropriate agreement.
   a. This letter or agreement should clearly articulate the time, expertise and resources required to support the study.
   b. Study timeframes and tools should be implemented with respect to the characteristics of each context engaged without an adverse impact on the quality of care and capacity of service.
   c. The Committee recognises that this process may not always be possible to finalise ahead of the ethical review process and advises that its approval is conditional upon the consultation process occurring to the satisfaction of the Aboriginal organisations and people whose support is sought to achieve study goals.

5) Where studies are granted approvals on the basis of the need to source ongoing advice from an established Aboriginal governance structure (e.g., Aboriginal advisory group, steering committee) or, where researchers indicated that it will be established, studies should be implemented as such. Should the ongoing monitoring of a study find that the original approval parameters were not adhered to by researchers, AHREC may further deliberate on the continued ethical acceptability of the study.

6) All adverse events to participants or local organisations and communities must be reported to AHREC immediately. These may include any serious or unexpected effect, unforeseen events and information that may invalidate the ethical integrity of the study.

7) Where possible, research participants should be supported for their time attending research activities. If the researchers will provide gift cards to incentivise participation, these should be basic cards that cannot be utilised for the purchase of alcohol or tobacco.

8) Research participants should be offered support for transportation to the location where research activities will take place and/or reimbursed for costs incurred e.g., parking, travel costs. This support should ideally be provided to participants up-front.

9) AHREC requires researchers to submit their annual reports every November, by the end of the month, throughout the approval timeframe. Final reports can be submitted at any time. Please find the reporting template at: http://ahcsa.org.au/research-overview/ethical-review-ahrec/

10) As part of AHREC’s monitoring function and in accordance with the NHMRC Guidelines, where the Committee identifies that a study is high risk due to its interest in issues that are highly sensitive to Aboriginal communities or has become high risk due to its overall code of conduct; it requires researchers to submit their manuscripts for review and approval before publication. The researchers are notified of this advice specifically during the approval timeframe.
Dear Associate Professor Hackett

RE: Amendment, Progress Report, Extension and Notification Approval

The Central Australian Human Research Ethics Committee (CAHREC) Chair has considered your application for an amendment to the project ‘Getting it right: the validation of a culturally-specific measure to identify depression in Aboriginal and Torres Strait Islander people with or without chronic disease’. The Chair decided to grant the amendment(s) requested in your letter dated 27th October 2016.

The error in the study database notified in your letter of 22nd November 2016 was reviewed by the Chair and CAHREC does not require any further action on this issue.

The Chair also considered your annual report and application for an extension to the completion date of your research project. The Chair is satisfied the research is being conducted within the guidelines set out by the Ethics Committee. He has granted approval for an extension until the 31st December 2017.

Your Final report is due on the 31st December 2017. Copies of the report form can be downloaded from the CAHREC website.

Yours sincerely

Chris Schwarz
Secretariat Support
Central Australian Human Research Ethics Committee
## APPENDIX 17: GETTING IT RIGHT PROCESS EVALUATION FRAMEWORK

### Table A14  Getting it Right process evaluation framework

<table>
<thead>
<tr>
<th>CONTEXT</th>
<th>IMPLEMENTATION: what was implemented and how? (source data)</th>
<th>RESPONSES AND INTERACTIONS: How did staff and patients react and interact with the research?</th>
<th>PROCESS EVALUATION AIMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assumptions underpinning research</td>
<td>2. Implementation: what was delivered to participating services? Administrative study data (training logs and manuals, site activation reports, communication logs, budgets [to identify resources provided])</td>
<td>5. How did staff respond to the research? Staff interviews</td>
<td>Aim 2: Explore the context, impact and consequences of Getting it Right</td>
</tr>
<tr>
<td>i. Lack of culturally-appropriate resources to identify depression in Indigenous people attending PHC</td>
<td>3. Fidelity: how was research incorporated at the participating services? Staff interviews Administrative study data (screening logs, ethics documentation, protocol deviation logs, ethics amendments)</td>
<td>6. How did patients’ respond to research? Staff interviews (staff perception of patients’ response) Participant feedback (responses to questions about the aPHQ-9 and free-text feedback collected during Getting it Right)</td>
<td>Aim 3: Explore the experiences of PHC staff and patients with conducting the research project</td>
</tr>
<tr>
<td>ii. Research provides evidence about effective resources in non-Indigenous populations</td>
<td>4. Reach: was the target group recruited? Staff interviews; research results (demographic data)</td>
<td></td>
<td>Aim 3. Was Getting it Right conducted as outlined in the protocol?</td>
</tr>
<tr>
<td>iii. Research is feasible in Indigenous-focused PHC</td>
<td></td>
<td></td>
<td>Aim 4. Was the aPHQ-9 perceived as acceptable and applicable by staff and patients (if found to be effective)?</td>
</tr>
</tbody>
</table>

### Description of complex intervention

An adequately-funded PHC-based research project aiming to determine validity of a culturally-adapted depression screening tool (aPHQ-9)

### Abbreviations:

- aPHQ-9 – adapted Patient Health Questionnaire-9; PHC – primary healthcare, research – the research project; SEWB – social and emotional wellbeing

* Context include environmental, social, historical and cultural factors external to the research project
## Appendix 18: Data reviewed to identify environmental, social, historical and cultural factors that affected research conduct

<table>
<thead>
<tr>
<th>Environmental factors</th>
<th>Staff quote</th>
<th>Triangulation source and evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff available to do research at participating services</td>
<td><em>We didn’t have an AOD worker, so juggling both mental health and AOD, and change of staff, so even though we trained the original person with me to do the research, and that person left</em> Indigenous, female, AHW, #19</td>
<td><em>Training logs</em> showed 6 trained staff left the organisation during the research project and 34 staff were trained after research start-up. <em>Recruitment tracker</em> showed delays and revision of original recruitment targets at these participating services.</td>
</tr>
<tr>
<td>Clinical demands</td>
<td><em>You’ve got all other stuff to do, so there’s not really enough time in the clinic but if you’re not opportunistic to do it then, then it doesn’t really seem to ever get done</em> Non-indigenous, female, Registered Nurse, #21</td>
<td><em>Site activation documents</em> showed more than one research projects underway at 6 participating services. <em>Communication logs</em> showed that staff reported busy clinical demands during research.</td>
</tr>
<tr>
<td>Physical environment</td>
<td><em>Very busy corridor, because there are kids playing there, there’s other patients who were waiting to see the GPs … so there’s a lot of hustle and bustle … So I thought, ‘No, this is not the right place to do it.’</em> Non-indigenous, female, Research Coordinator, #6</td>
<td>No triangulation completed</td>
</tr>
<tr>
<td>Social factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Existing staff-patient relationships</td>
<td><em>I just talked to people I already had a relationship with, mainly that I work with throughout the clinic and who I see regularly. So I found it was easier to recruit people who knew me and trusted me already rather than when I tried to recruit people in the clinic who I hadn’t met before, not many of them were agreeable</em> Non-indigenous, female, Registered Nurse, #21</td>
<td><em>Participant feedback</em> showed that patients reported valuing existing relationships with staff.</td>
</tr>
<tr>
<td>Patient interest in research and topic</td>
<td><em>Patients were voluntarily wanting to take part in the study. Some of the patients said they were wanting to do the study just because mental health is such a big issue in the community here. So, they said it would be good if you could do something about it</em> Non-indigenous, female, Research Coordinator, #6</td>
<td><em>Participant feedback</em> showed that approximately 15 participants indicated positive comments about the topic (SEWB).</td>
</tr>
<tr>
<td>Staff interest in research topic</td>
<td><em>I think that the health workers felt like they were contributing to something that was going to make a difference, and so the ones that really did step up had a red hot go</em> Non-indigenous, female, Manager, #18</td>
<td>No triangulation completed</td>
</tr>
<tr>
<td>Staff interest in enhancing skills and capacity through research</td>
<td>We’ve knocked back a few research projects since [this project] ‘cause there’d be nothing in it for us. Nothing. Not one thing. No staff involvement so there’s no potential for up skilling staff. Definitely no money so it’s costing us where with you guys we’re reimbursed. Indigenous, male, Manager, #34</td>
<td>No triangulation completed</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Historical factors</td>
<td>History of research in the community</td>
<td>They [RESEARCHERS] want to come in and use us, then leave … Dealing with you guys, it was a two-way relationship where to be honest, a lot of research isn’t. It’s just, we’ll come in, take what we need and we’ll see you later. Indigenous, male, Manager, #34</td>
</tr>
<tr>
<td>Patients’ personal and medical history</td>
<td>People who were reluctant were suspicious that answering was going to effect their live, that the government would come and check them out be because of their answers. Indigenous, female, AHW, #28 When you actually have someone coming in that’s sick, they don’t want to participate in the study Indigenous, male, AHW, #17</td>
<td>Participation rate = 55% No reason documented (64%) or were ineligible (32%) because they did not meet the inclusion/exclusion criteria.</td>
</tr>
<tr>
<td>Cultural factors</td>
<td>Staff member quote</td>
<td>Triangulation source</td>
</tr>
<tr>
<td>Culture among staff</td>
<td>I think there were varying levels of engagement with research in a service like this. Some people in the health service, some of the clinicians, doctors and nurses, will be more open to research than others. Non-indigenous, male, GP, #9</td>
<td>No triangulation completed</td>
</tr>
<tr>
<td>Culture among patients</td>
<td>They do a lot of group counselling sessions, so these men in particular are quite open and used to talking about their health and other issues, including emotional issues and their past Indigenous, male, GP, #35)</td>
<td>No triangulation completed</td>
</tr>
</tbody>
</table>

Abbreviations: AHW – Aboriginal Health Worker; AOD – alcohol and other drug; GP – General Practitioner; PHCS – primary healthcare services
### APPENDIX 19: SUPPLEMENTARY TABLE FROM CHAPTER 9

Table A15  Examples of how resourcing in the research project related to the principles of Reciprocity, Respect, Equality, Responsibility, Survival and Protection, and Spirit and Integrity

<table>
<thead>
<tr>
<th>Reciprocity</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Flexible reimbursement compensated participating services for the resources involved with the research and provided benefit that was valued by the community</td>
</tr>
<tr>
<td>– Flexible financial arrangements and adaptive protocol enabled staff to modify approaches to participant recruitment</td>
</tr>
<tr>
<td>– Adaptive study protocol demonstrated a willingness to modify research according to the communities’ values and aspirations</td>
</tr>
<tr>
<td>– Reimbursement to employ/backfill staff may have enhanced capacity</td>
</tr>
<tr>
<td>– Flexible financial arrangements funded non-research expenses which enhanced capacity beyond the research (service needs, equipment and conference attendance)</td>
</tr>
<tr>
<td>– Offering vouchers to participants may have enhanced capacities or outcomes by bringing resources/food into the community</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Respect</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Adaptive study protocol demonstrated efforts to minimise the effects of difference blindness*</td>
</tr>
<tr>
<td>– Adaptive study protocol recognised the diversity of Indigenous people and communities by enabling participating services to make decisions about how the research would operate at their service</td>
</tr>
<tr>
<td>– Sufficient reimbursement acknowledged the contribution of participating services to the research by compensating for the true costs associated with the research project</td>
</tr>
<tr>
<td>– Local research champions and staff who drove the research project at the participating service appeared to incorporate local Indigenous knowledge and experience into research</td>
</tr>
<tr>
<td>– Offering vouchers to participants to reimburse for their time recognises the contribution of participants as research partners</td>
</tr>
<tr>
<td>– Flexible financial arrangements enabled participating services to determine whether to offer vouchers to participants, which acknowledged the diversity of Indigenous communities</td>
</tr>
<tr>
<td>– Offering vouchers to participants recognised that research may have consequences for participants</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Equality</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Sufficient reimbursement to compensate for the time involved with the research project recognised the value of staff time and demonstrates equality between individuals, communities and researchers</td>
</tr>
<tr>
<td>– Offering vouchers to participants recognised their time and demonstrated the equal value of individuals, communities and researchers during the research</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Clear demonstration of the demand on staff time and resources involved with conducting the research project (through reimbursement) showed transparency</td>
</tr>
<tr>
<td>– Local research champions may have provided a mechanism for ongoing community review of the research</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Survival and Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Flexible financial arrangements provided to participating services to employ/backfill culturally-appropriate staff to conduct research contributed to social or cultural bonds among Indigenous</td>
</tr>
</tbody>
</table>

---

*difference blindness*
families and communities by facilitating research that was respectful and in-line with cultural protocols

- Adaptive protocol with workable timeframes demonstrated understanding of the relationship between the research and communities’ cultural, spiritual and social cohesion

<table>
<thead>
<tr>
<th><strong>Spirit and Integrity</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Provided resources to staff so equipment was available to complete research activities according to local preferences and protocols (tablet/computer for data entry; research-specific internet connection)</td>
</tr>
<tr>
<td>- Interviews and all interactions with patients completed by staff nominated by the participating service (not by external researchers) contributed to social and cultural bonds among and between Indigenous families and communities</td>
</tr>
</tbody>
</table>