The Triage of Adult Patients Requiring Intensive Care during Pandemics

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Word Count

Total Words: 39818 (Chapter 1 – Introduction to Chapter 7 - Reflection)

Contents

Abstract

The Triage of Adult Patients Requiring Intensive Care during Pandemics

A future pandemic could overwhelm intensive care resources. Triage systems can be used to prioritise the order in which patients are treated in a pandemic, when the demand for intensive care services exceeds the availability of intensive care resources.

In 2009, the New South Wales Health Department introduced a triage system as part of pandemic planning. However, there were many ethical issues involving triage systems and little evidence to guide their use. Consequently, this thesis was started. The objective was learn more about the public's views on intensive care triage, in order to optimise the allocation of intensive care resources in a future pandemic.

This thesis consisted of three studies. The second and third studies were conducted during the COVID-19 pandemic.

A cross-sectional survey in Australia and New Zealand, using the Australian Electoral Commission (AEC) and New Zealand Electoral Commission electoral rolls, was used to determine public opinion on how ICU beds should be allocated in an influenza pandemic, and the public perception of fairness of the different methods. The study demonstrated that respondents considered both the use of a senior doctor or pre-determined health department criteria to be the fairest way to triage ICU patients.

The results led to a multicentre survey in Australia, of surrogate decision-makers of patients in the ICU, to determine the fairness of triage criteria to allocate intensive care resources in an influenza pandemic. The completion of this study has been delayed by the COVID-19 pandemic. The interim results demonstrated that respondents had four contradictory viewpoints on the fairness of triage criteria, with no clear majority view.

A further survey in Australia using the AEC electoral roll was used to determine which of four theoretical methods to triage intensive care patients in a pandemic using chronic comorbidity was perceived to be the fairest by the general public. The majority of respondents perceived all four of the methods to be fair. However, there was a sizable minority who perceived each of the four methods to be unfair.

We conclude that triage systems should be used to allocate intensive care resources in a pandemic where the demand for intensive care services exceeds the availability of intensive care resources. Triage systems should use predetermined triage criteria contained in a triage protocol first, with a final triage decision being made by a group of senior doctors. Several other conclusions are made which may help with future pandemic planning, however achieving public consensus on triage planning is likely to be difficult.

Foreword

An innocuous email.
To herald the start.
The inbox cluttered. Every morn.
Left-click the mouse. The clutter was gone.

But the clicking stopped here.
This one the attention caught.

A new protocol the health department had.
Stakeholder consultation was required.
The delete icon beckoned. But curiosity prevailed.

2009 was busy. Too busy.
The ICU strained. The pandemic petered.
The bullet dodged. The brave staff soldiered on.

To John the protocol I mentioned.
Flu was seasonal. It would return.
Luck could desert us next time.

This protocol could help. Scepticism yielded to enquiry.
Unanswered questions awaited. But at the forefront was concern.
Protocols didn't always work.

A simulation to provide the answer.
John and Manoj were keen.
Bolstered by Ian and Priya.
Mike and Kalpesh supported.
Nikki from Queensland.
The question answered.

But more posed. Expansion the program needed.
The journey rationale. To supervise others.
That's what David said.
The other David agreed. I was doing this anyway.

The reigns Vasi and John took.
Enthusiasm.
Meticulous attention to detail.
The straight and narrow.

The flu now faded from memory.
The protocol remained. Society's reaction unknown.
Shay and Rachael heard the presentation.
To Aotearoa the study went.
Another question answered. But more remained.

Then came Corona.

The invisible enemy.

A toll it took.
An ICU nurse quietly sobbed.
Consoled by a colleague.
Numbers dwindled. Redeployment. Furlough.
Managing the sick while supervising the inexperienced.
The impossible tasks.
A brave face.
For months this would last.

But together we banded.
Clinicians, academics, researchers.
Statisticians, ethicists, lawyers.
Economists, analysts, consumers.

Dedicated strangers.
The common goal.
Humanity would triumph.

Herewith the journey paused.
Knowledge now enhanced.

Time to reflect.
Time to regroup.

If not for that email. And not to delete.

Declarations

Statement of Originality

The Triage of Adult Patients Requiring Intensive Care during Pandemics

This is to certify that to the best of my knowledge, the content of this thesis is my own work. This thesis has not been submitted for any other degree.

I 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.

Winston Cheung
22 February 2023

Supervisor Statement

The content of this thesis represents the work of Winston Cheung. He has led every aspect of the studies described in this thesis.

I certify that the intellectual content of this thesis is the product of Winston Cheung's own work and that all the assistance received in preparing this thesis and sources have been acknowledged.

Vasi Naganathan
22 February 2023

Author Attribution Statement

The work contained in the body of this thesis are the results of my own investigations.

The iPIT 1 and iPIT 2 studies were conducted before this PhD program started. The iPIT 3, iPIT 4, IPT 5 studies were conducted as part of this PhD thesis.

The iPIT 1 Study (A Multicentre Evaluation of Two Intensive Care Triage Protocols for Use in an Influenza Pandemic) was published in the Medical Journal of Australia. I conceived the study. John Myburgh and I designed the study. I wrote the study protocol; oversaw the ethics application and site specific applications for the study sites; conducted the study; entered and analysed the data; and wrote the study publication manuscript. The site investigators evaluated patients and collected data at the study sites. All the coinvestigators reviewed and provided intellectual input for the study protocol and manuscript.

The iPIT 2 Study (Development and Evaluation of an Influenza Pandemic Intensive Care Unit Triage Protocol) was published in Critical Care and Resuscitation. I conceived the study. John Myburgh and I designed the study. I analysed the data and wrote the study publication manuscript. The writing of the study protocol; the ethics application and site specific applications for the study sites; and data collection and entry were performed during the iPIT 1 study. All the coinvestigators reviewed and provided intellectual input for the study protocol and manuscript.

The iPIT 3 study (A Cross-Sectional Survey of Australian and New Zealand Public Opinion on Methods to Triage Intensive Care Patients in an Influenza Pandemic) was published in Critical Care and Resuscitation. I conceived the study. John Myburgh and I designed the study. I chaired the study management committee and coordinated the study in Australia. I wrote the study protocol and created the study questionnaires. I oversaw the ethics and Australian Electoral Commission (AEC) applications; arranged the printing, logistics and distribution for the questionnaires; and collated the data in Australia. Shay McGuinness coordinated the study and oversaw the ethics and funding applications in New Zealand. Rachael Parke collated the data in New Zealand. I analysed and interpreted the data. John Myburgh, Vasi Naganathan and I drafted the manuscript. All the coinvestigators reviewed and provided intellectual input for the study protocol and manuscript. A graphics designer helped with the design of the questionnaire.

The completion of the iPIT 4 study (A Survey of Surrogate Decision-Makers for Intensive Care Patients on the Use of Triage Criteria in an Influenza Pandemic) has been delayed for the reasons described in Section 4.2. I designed the study, chaired the management committee and coordinated the study. I wrote the study protocol; created the study questionnaires; oversaw the ethics application; arranged the printing, logistics and distribution for the questionnaires; and collated, analysed and interpreted the interim data. All the coinvestigators reviewed and provided intellectual input for the study protocol. A graphics designer helped with the design of the questionnaire.

The IPT 5 study (A Survey of Australian Public Opinion on Using Comorbidity to Triage Intensive Care Patients in a Pandemic) has been completed, and a manuscript is being prepared for publication. I designed the study, chaired the management committee and coordinated the study. I wrote the study protocol; created the study questionnaires; oversaw the ethics application and Australian Electoral Commission applications; arranged the printing, logistics and distribution for the questionnaires; and collated, analysed and interpreted the data. I am currently writing the manuscript draft. All the coinvestigators reviewed and provided intellectual input for the study protocol. A graphics designer helped with the design of the questionnaire.

The IPS program (ICU Pandemic Surveillance Program) has only completed the pilot phase, and awaits funding to continue. I designed the program; chaired the management committee; wrote the protocol; developed the data collection tool; and oversaw the ethics application. Coinvestigators provided intellectual input for the study protocol, including statistical, data management, modelling, and economics advice. A graphics designer helped with the design of the data collection tool.

Conflicts of Interest Declaration

I declare that I have no conflicts of interest in relation to this PhD thesis.

I have previously convened educational events that have received financial assistance from 3M, AB Applied Biosystems, AB Sciex, Abbott Medical Optics, Actelion, Advanz Pharma, Alcon, Amgen, Aquatic Solutions, Aspen, Avant Mutual, Bayer Healthcare, BD, Bioline, Boehringer-Ingelheim, B Braun, Celgene, Charcot-Marie-Tooth Association of Australia, CSL Biotherapies, Fresenius Kabi, Glaxo Smith Kline, Genzyme, Immune System Therapeutics, Infusion 360, Invitrogen, Ipsen, Janssen-Cilag, Johnson and Johnson, Leica Microsystems, Life Technologies, Lilly, Macrogen, Medtronic, MACS Miltenyi Biotec, Merck Sharpe and Dohme, National Home Doctor Service, Novartis, Pfizer, PPS Mutual, Roche, Sanofi-Aventis, Schering Plough, Servier, and Wyeth.

Shay McGuinness and Rachael Parke, co-authors in the three studies in this PhD program, received competitive research grants from The A+ Charitable Trust.

None of the other co-authors of the published studies in this PhD program have declared any relevant competing interests.

Thesis Overview

The theme of this thesis is pandemic disaster planning. In 2009, the New South Wales Health Department (NSW Health) published a triage protocol to manage patients requiring admission to an intensive care unit during a pandemic. Consequent to this, I started a program of research on pandemic planning. The overall objective of this research program was to optimise the allocation of intensive care resources in a future pandemic. This PhD thesis arose from this pandemic research program.

Chapter 1

Chapter 1 describes the background to this thesis. It includes details on the two studies that were important in the rationale for the studies conducted during this thesis. These two studies were the influenza Pandemic ICU Triage (iPIT 1) Study - A Multicentre Evaluation of Two Intensive Care Triage Protocols for Use in an Influenza Pandemic; and the influenza Pandemic ICU Triage 2 (iPIT 2) Study - Development and Evaluation of an Influenza Pandemic Intensive Care Unit Triage Protocol.

These studies highlighted significant ethical issues with pandemic disaster planning that were then explored during the thesis. These two studies were conducted before this PhD thesis commenced.

Chapter 2

Chapter 2 explores the ethics of disaster planning. It examines the problems with triage, the ethical concepts involved in resource allocation and public health, and the significant ethical issues with pandemic disaster planning that this thesis attempted to address.

Chapter 3

Chapter 3 describes the rationale, objectives and hypotheses for the thesis.

Chapter 4

Chapter 4 describes the first two studies conducted in this thesis. These were the influenza Pandemic ICU Triage 3 (iPIT 3) Study - A Cross-Sectional Survey of Australian and New Zealand Public Opinion on Methods to Triage Intensive Care Patients in an Influenza Pandemic; and the influenza Pandemic ICU Triage 4 (iPIT 4) Study - A Survey of Surrogate Decision-Makers for Intensive Care Patients on the Use of Triage Criteria in an Influenza Pandemic.

These studies examined public attitudes to intensive care triage in a pandemic. The iPIT 3 study was conducted before the COVID-19 pandemic. The iPIT 4 study was conducted during the COVID-19 pandemic.

The objective of the iPIT 3 study was to determine public opinion on how ICU beds should be allocated in an influenza pandemic. The study demonstrated that two methods of triage for intensive care resources appeared to be acceptable, but questions remained on whether triage decisions would be accepted by those directly affected by the decisions.

The objective of the iPIT 4 study was to determine whether surrogate decision-makers for patients in the ICU perceived triage criteria to be fair. The completion of this study has been delayed by the COVID-19 pandemic. Only interim results for this study are available at the time of writing of this thesis.

Chapter 5

Chapter 5 explores the ethical problems with disaster triage that were identified during planning for the COVID-19 pandemic, and describes the final study in this thesis, the ICU Pandemic Triage Study (IPT 5) - A Survey of Australian Public Opinion on Using Comorbidity to Triage Intensive Care Patients in a Pandemic. The IPT 5 study was conducted during the COVID-19 pandemic.

The objective of the IPT 5 study was to determine if chronic comorbidity and other selection criteria could be used to triage patients who required intensive care treatment in a pandemic. The study results suggested that the use of chronic comorbidity to triage patients would likely meet significant societal opposition.

Chapter 6

Chapter 6 summarises the findings from this thesis, provides an interpretation of the findings, and suggests future direction for pandemic research.

Chapter 7

Chapter 7 is my reflection on the lessons that I learnt during the course of this PhD thesis.

Appendix 7

Appendix 7 summarises the other research work related to pandemic planning for COVID-19 (the ICU Pandemic Surveillance (IPS) Program) that was undertaken during the course of this thesis. This work was not included in the body of the thesis as it did not receive funding to proceed, and only the pilot phase was completed.

Chapter 1 – Introduction and Background

1.1 Pandemic Triage in New South Wales

1.1.1 Triage

The concept of triage, derived from the French verb *trier* (to sort), can be used to allocate medical resources in mass casualty events where the volume of patients presenting for medical attention exceeds the capacity to provide effective healthcare, such as a natural disaster.[1,2] Triage involves making decisions about the order in which patients will be treated based on the urgency of patient needs.[3] Triage systems have been used to prioritize patient management on the battlefield, but the ethical issues surrounding the concept of triage are challenging.[1-4] Triage systems to allocate intensive care resources have not been used before in a pandemic in New South Wales (NSW), Australia or elsewhere.

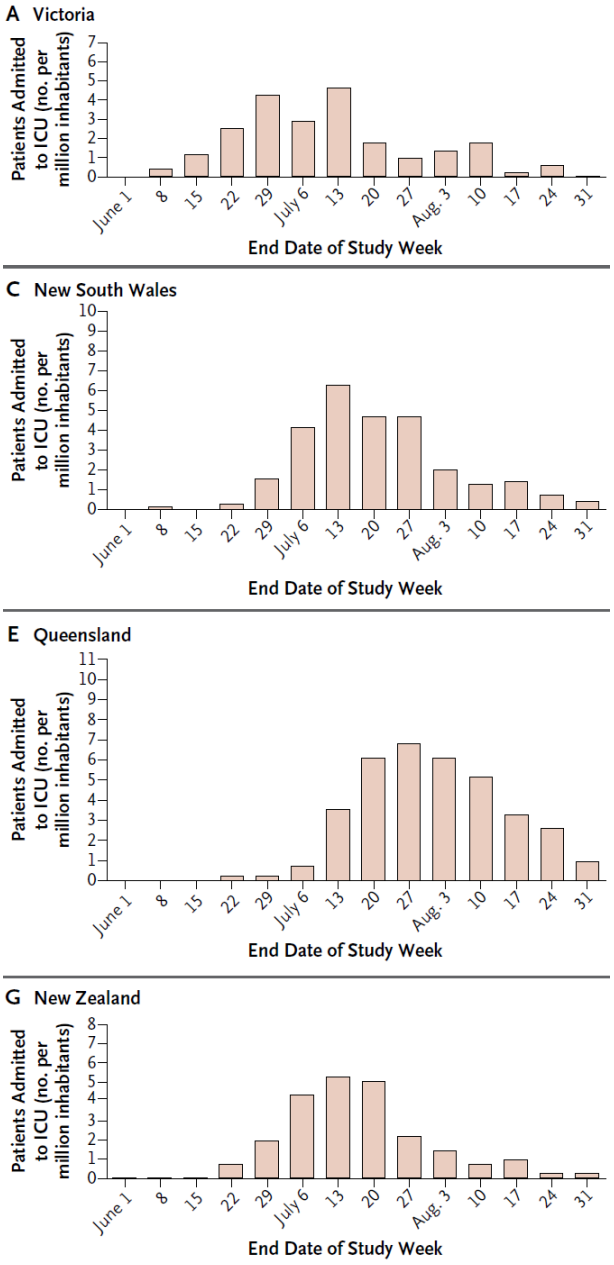
1.1.2 The 2009 Influenza Pandemic

The 2009 H1N1 influenza pandemic in Australia and New Zealand required the provision of critical care services to large numbers of patients.[5] The number of patients admitted to Australian and New Zealand intensive care units (ICU) with influenza pneumonia was 15 times the number that would normally be admitted with viral pneumonia.[5] At the time, NSW had 519 ICU beds available, to service a population of 7.2 million people.[6,7] This equated to 72 ICU beds per million people.

Most patients that required ICU level care during the 2009 pandemic needed invasive respiratory support using ventilators. Under normal circumstances if an ICU exceeds its operational capacity, such as in a geographically discreet disaster, patients are transferred to alternative ICUs that have redundant capacity. However, the 2009 influenza pandemic affected all areas in Australia and New Zealand in quick succession, and the ICU occupancy peaks in the major regions all occurred at similar times (Figure 1A).[5] The ramification for this observation was in a future pandemic it would be unlikely that ICU capacity constraints could be alleviated by transferring patients to other facilities, because all ICUs would be affected simultaneously.

Figure 1A is shown on the next page

Figure 1A – The Number of Patients Admitted to ICUs in Victoria, New South Wales, Queensland and New Zealand in June, July and August 2009.



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From an operational standpoint there were two potential methods to manage ICU capacity in a future pandemic, if the surge of patients exceeded the normal operational capability of the ICUs. The first method would be for ICUs to increase capacity to manage the excess patients. In 2009, NSW equipment stockpiles could increase the state's ventilator capacity in a pandemic, but only by an additional 70%.[6] The second method would be to limit the number of patients admitted to the ICU.

1.1.3 The NSW Health Department Response to the 2009 Influenza Pandemic

The Australian Government's review of the health sector response to the 2009 H1N1 influenza pandemic made the recommendation to

> *"…develop a health sector surge capacity strategy to address the anticipated increase in demand for health services during a pandemic and the need to sustain provision for long periods of time"*. [8]

As a result, towards the end of the H1N1 influenza pandemic, in July 2009, the NSW Health Department (NSW Health) instituted a triage protocol to manage patients requiring ICU level care during an influenza crisis where the surge in demand exceeded capacity by 50%.[6]

The NSW triage protocol predominantly used criteria from an existing protocol used in Minnesota, USA, and added on an element from a Canadian protocol, the Ontario Health Plan for an Influenza Pandemic (OHPIP - henceforth known as the Ontario pandemic protocol).[9,10] Prior to 2009, no influenza or viral pandemic triage protocol had been subjected to prospective evaluation or directly implemented during an actual pandemic anywhere in the world.

The Minnesota triage protocol for mechanical ventilation (also known as, and henceforth referred to as the Minnesota triage tool) was developed in 2006 in response to the outbreak of severe acute respiratory syndrome (SARS) that began in 2002, and the growing possibility of biological terrorist attacks using agents that caused lung injury, such as anthrax.[9] The triage protocol would decide which patients would be eligible for an ICU admission, if it were activated during a viral pandemic. The Minnesota triage tool is summarised in Appendix 1.

The Ontario pandemic protocol was developed in 2005 in response to the avian influenza (H5N1) outbreak in Canada.[10] The protocol was developed to ensure equitable and efficient use of critical care resources if scarcities occurred during another influenza pandemic. The Ontario pandemic protocol is summarised in Appendix 2.

The NSW Pandemic Guidelines Triage Protocol adopted the majority of its parts from the Minnesota triage tool, with a small part derived from the Ontario pandemic protocol.[6,9,10] The rationale behind the development of the NSW protocol was to enable limited and finite resources to be distributed in an ethical, equitable, and practical manner.[6] The NSW protocol stated that, in a pandemic, critical care be prioritized to a patient who was at more immediate risk of death without such care; more likely to benefit from the treatment; likely to suffer greater harm without treatment; likely to suffer less burden or ill-effects from the treatment; or likely to gain the same therapeutic benefit from the treatment more rapidly. This NSW triage protocol is summarised in Appendix 3.

Following the promulgation of the NSW Pandemic Guidelines Triage Protocol in July 2009, there was uncertainty whether the protocol would actually work in practice. No prospective validation of the NSW protocol had been performed. There had been no other prospective validation studies of any other triage protocols, in an Australian setting. The number of potential ICU beds that could be made available for use with the implementation of the NSW Pandemic Guidelines Triage Protocol was unknown, and the outcomes of patients fitting exclusion and inclusion criteria for this or any of the other protocols was also uncertain. I therefore started a program of research to evaluate the use of ICU triage protocols in viral pandemics.

The first two studies in the program were led by myself, and conducted prior to undertaking the studies presented in this thesis. The results of these first two studies provided the impetus to generate the hypotheses and objectives for the subsequent three studies described in this thesis.

The first study implemented in this research program, prior to starting this PhD thesis, was the influenza Pandemic ICU Triage (iPIT 1) Study.[12] This study was designed to prospectively evaluate the use of the NSW Pandemic Guidelines Triage Protocol and the Ontario pandemic protocol. The Minnesota triage tool was not evaluated because the NSW triage protocol had already copied most of the elements of the Minnesota triage tool. The following section briefly summarises this study and is similar in content to the published article.[12]

1.2 The Evaluation of Intensive Care Triage Tools

1.2.1 The influenza Pandemic ICU Triage (iPIT 1) Study - A Multicentre Evaluation of Two Intensive Care Triage Protocols for Use in an Influenza Pandemic

The influenza Pandemic ICU Triage (iPIT 1) Study (A Multicentre Evaluation of Two Intensive Care Triage Protocols for Use in an Influenza Pandemic) was a prospective, evaluation study of the NSW Pandemic Guidelines Triage Protocol and the Ontario pandemic protocol, conducted in eight Australian, adult, general ICUs between September 2009 and May 2010.[12] The primary objective of this study was to determine the increase in ICU bed availability that would result from the use of the two triage protocols. The second objective was to compare the increase in ICU bed availability of the NSW triage protocol to the Ontario pandemic protocol.

All patients who were admitted to the participating ICUs during a six week study period, excluding those who had elective surgery, were prospectively evaluated using the NSW and the Ontario pandemic protocols, simulating a pandemic situation, to determine whether they qualified for admission to the ICU. However, the decision to admit the patient to the ICU and the patient's medical management was not actually altered by the study.

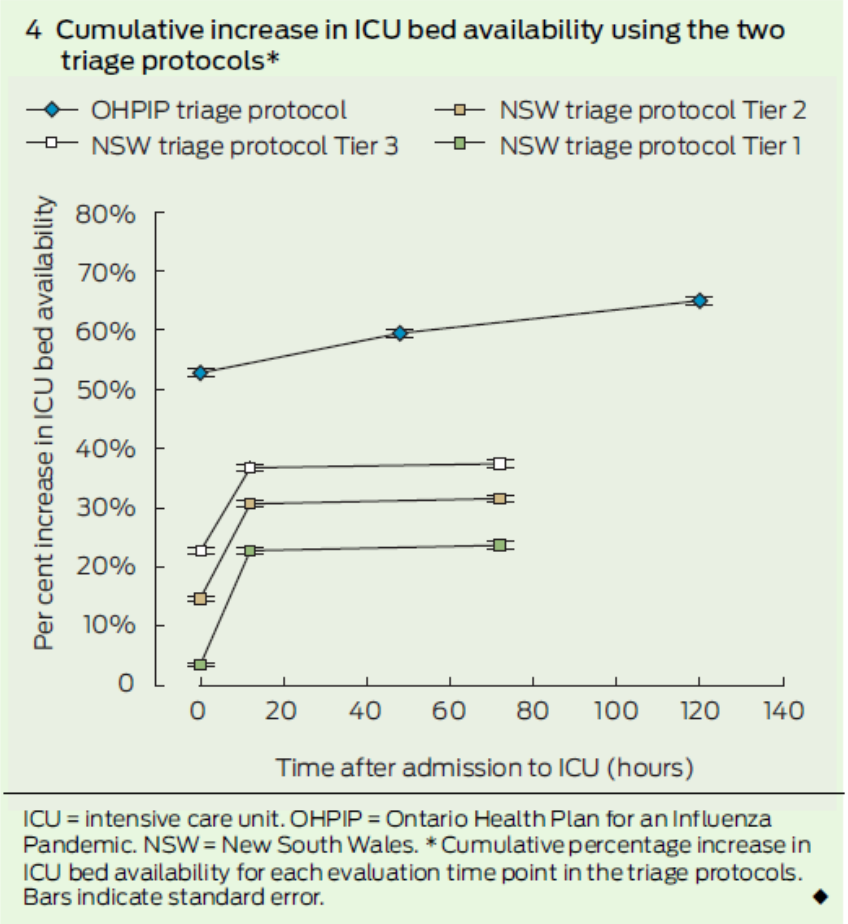
After the simulated admission triage assessment the patients were evaluated again, using the NSW protocol at 12 and 72 hours (as specified in the NSW protocol) and using the Ontario pandemic protocol at 48 and 120 hours (as specified in the Ontario pandemic protocol), to determine whether they should be discharged from the ICU.

The primary outcome measure was increase in ICU bed availability, defined as the percentage of the total bed days spent by patients in the ICU after the triage protocols had excluded them from admission or discharged them from the ICU. Increase in ICU bed availability was calculated at admission to ICU, and at the various time points in each protocol.

The study evaluated 805 patients using the NSW and Ontario triage protocols. The increase in ICU bed availability using tiers 1, 2 and 3 of the NSW triage protocol and the Ontario pandemic protocol are shown in Figure 1B.

Figure 1B is shown on the next page

Figure 1B – Cumulative Increase in ICU Bed Availability Using the NSW and Ontario pandemic protocols



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Using the NSW triage protocol at admission, the increase in ICU bed availability using tiers 1, 2 and 3 was 3.5%, 14.7% and 22.7%, respectively. The maximal cumulative increase in ICU bed availability was 23.7%, 31.6% and 37.5%, respectively, seen at 72 hours.

Using the Ontario pandemic protocol at admission, the increase in ICU bed availability was 52.8%. The maximal cumulative increase of 65.0% was seen at 120 hours.

Applying the study results, a 17 bed general ICU would expect to make available approximately 0.5 to 4 beds using the NSW protocol at admission, depending on which tier was used, and approximately 9 beds using the Ontario pandemic protocol at admission. The NSW protocol would make an additional 3 beds available at 12 hours, but few beds thereafter. The Ontario pandemic protocol would make 1 additional bed available at 2 days and 5 days, respectively.

The iPIT 1 study, conducted in the months after an influenza pandemic, found that the application of both protocols increased ICU bed availability, with two distinct patterns of increased bed availability. Using the NSW triage protocol, all three tiers provided increases in ICU bed availability when patients were re-evaluated at 12 hours, but the largest increases in ICU bed availability occurred

with Tier 3. The Ontario pandemic protocol provided the greatest increase in ICU bed availability overall, with the cumulative increase in ICU bed availability being greater than any tier in the NSW triage protocol.

The explanation for the differences in ICU bed availability between the two protocols appeared to reside in the medical acuity of the patients being excluded or discharged. The NSW protocol focused on excluding patients with significant organ failures or comorbidities at admission. Smaller numbers of patients fulfilled the NSW criteria, hence excluding these patients resulted in smaller bed availability savings. The Ontario pandemic protocol, however, made more beds available early in the triage process by excluding the large proportion of patients who had a low risk of death. This resulted in more patients being excluded or discharged from the ICU at all the time points.

The conclusion for the iPIT 1 study was that, when tested in a non-influenza pandemic setting, both the NSW and Ontario pandemic protocols provided increases in ICU bed availability, but the Ontario pandemic protocol provided the greatest increase overall. This increase occurred because the Ontario pandemic protocol excluded patients from ICU admission with the lowest risk of death.

The results of the iPIT 1 study posed several questions. Both triage protocols appeared to work in a post-pandemic setting, but the protocols had still not been tested in actual pandemic conditions. A major ethical question has whether the NSW and Ontario pandemic protocols treated patients fairly. Another major ethical question was whether the community would find the use of ICU triage protocols acceptable in a pandemic.

The justification for excluding patients with high predicted mortality rates in an ICU triage protocol was that these patients were less likely to survive, and therefore less likely to have outcomes improved by ICU care. The justification for excluding patients with low predicted mortality rates in an ICU triage protocol was that these patients were likely to survive anyway, even if they did not receive ICU level care. However, from an ethical perspective, the selective application of triage criteria may be considered ethically unjust if patients with similar ICU mortality rates are treated differently.[1] The preliminary assessment of the mortality data from the iPIT 1 study appeared to suggest that some patients excluded from the ICU by the triage protocols could have mortality rates similar to those of patients not excluded from the ICU.

We therefore thought it was important that the mortality rates for patients excluded by triage protocols were accurately determined. Based on these mortality rates we wanted to examine whether a “fairer” triage protocol could be developed. This led to the development of the influenza Pandemic ICU Triage 2 (iPIT 2) Study. The following section briefly summarises this study and is similar in content to the published article.[13]

1.2.2 The influenza Pandemic ICU Triage 2 (iPIT 2) Study - Development and Evaluation of an Influenza Pandemic Intensive Care Unit Triage Protocol

The influenza Pandemic ICU Triage 2 (iPIT 2) Study (Development and Evaluation of an Influenza Pandemic Intensive Care Unit Triage Protocol) was a post hoc analysis of the influenza Pandemic ICU Triage (iPIT 1) Study.[13] The study had three main objectives. The first objective was to determine the ICU mortality rates of the patient groups excluded from ICU admission by the individual exclusion criteria contained in the NSW and Ontario pandemic protocols. The second objective was to develop a new influenza pandemic ICU triage protocol that only excluded patients with the highest and lowest predicted mortality rates. The third objective was to determine the increase in ICU bed availability that resulted from using the new protocol.

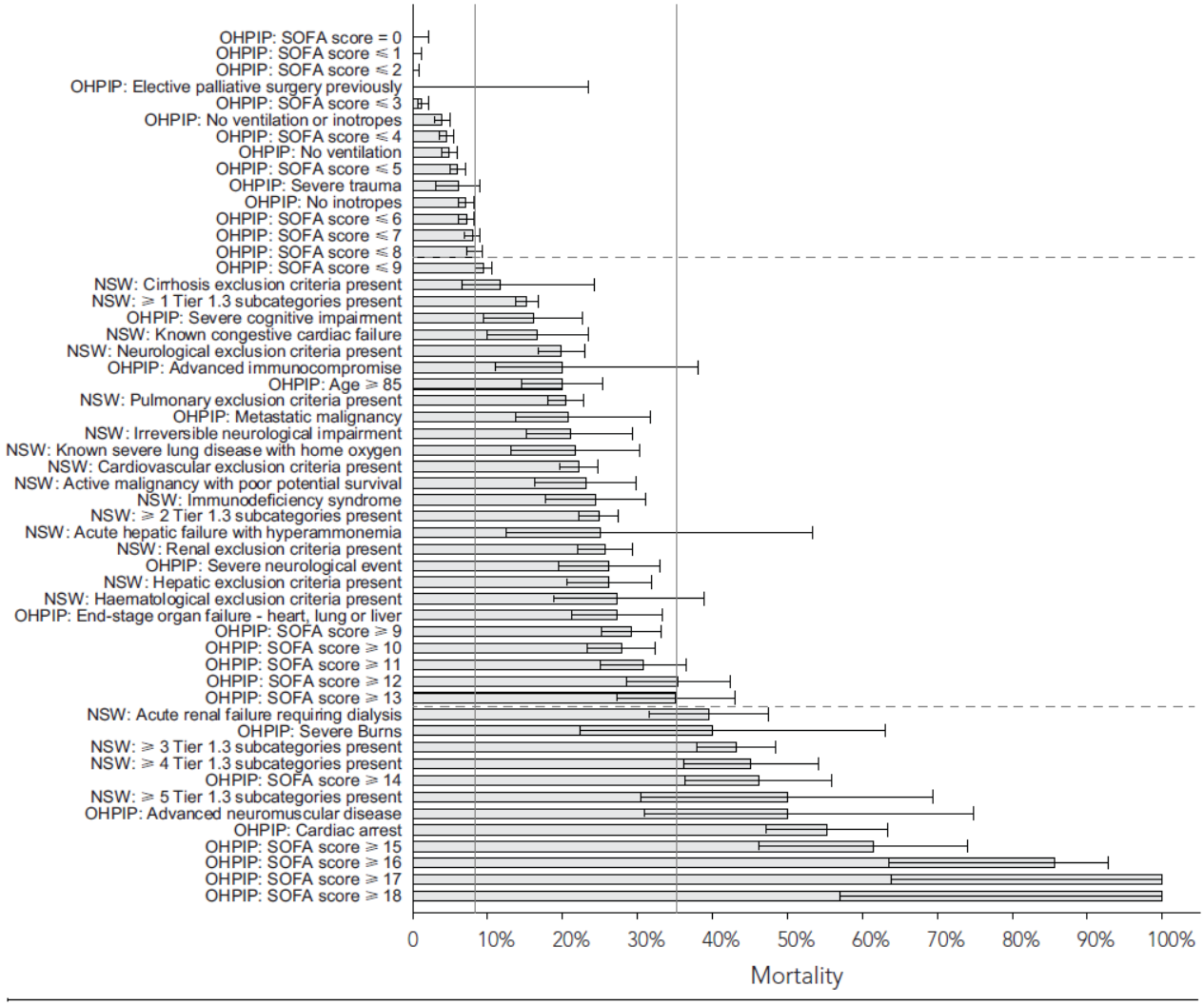
ICU mortality rates were calculated for all patient groups theoretically excluded from admission to or who would have been discharged from the ICU using the individual exclusion criteria in the NSW and Ontario triage protocols. ICU mortality rates were also calculated for the patients based on Sequential Organ-Failure Assessment (SOFA - also known as Sepsis-related Organ Failure Assessment) score.[11]

From a hierarchical analysis, the 25th and 75th percentiles for ICU mortality were used as exclusion limits for the new influenza pandemic ICU triage protocol. The individual triage criteria from the NSW and Ontario pandemic protocols that resulted in ICU mortality rates outside of these exclusion limits were then used as exclusion criteria for ICU admission in the new ICU triage protocol, called the iPIT-1 triage protocol. An analysis of the original patient dataset was subsequently performed using the iPIT-1 triage protocol, and the results compared to the NSW and Ontario pandemic protocols.

The primary outcome measure was the increase in ICU bed availability. This was defined as the percentage of the total bed days available spent by patients in the ICU after the triage protocol had excluded them from admission or discharged them from the ICU.

The study evaluated the same 805 patients who were included in the iPIT 1 study.[12] The ICU mortality rates for the patient groups excluded from the ICU by the individual triage criteria in the NSW and Ontario pandemic protocols are shown in Figure 1C.

Figure 1C – ICU Mortality Rates of Patient Groups Excluded from the ICU using the individual exclusion criteria and Sequential Organ Failure Assessment (SOFA) Score from the NSW and Ontario pandemic protocols.



Vertical grey lines and horizontal dotted lines indicate the 25th and 75th percentile (lower and upper quartiles). I-bars indicate standard error.

OHPIP = Ontario Health Plan for an Influenza Pandemic (Ontario pandemic protocol)
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The lowest mortality rates were seen in patients who did not require mechanical ventilation, did not require inotropes or vasopressors, had sustained severe trauma (defined as an Injury Severity Score (ISS) of greater than 15), had received palliative surgery earlier in their hospital admission, or had a SOFA score at admission less than or equal to 8.[14,15] Excluding these patients increased ICU bed availability by 27.7%, 53.2%, 10.4%, 0.6%, and 61.8% respectively. There were 675 (83.9%) patients with SOFA scores less than or equal to 8.

The highest mortality rates were seen in patients with acute renal failure requiring dialysis, severe burns, cardiac arrest, a SOFA score greater or equal to 14, or who had 3 or more NSW tier 1.3 exclusion criteria present. Excluding these patients increased ICU bed availability by 3.2%, 1.3%, 3.9%, 3.7%, and 9.6% respectively. There were 26 (3.2%) patients with SOFA scores greater than or equal to 14.

The new Influenza Pandemic ICU Triage protocol derived from this data is detailed in Figure 1D. The individual triage criteria from Figure 1C that resulted in ICU mortality rates below the 25th percentile (conditions with a mortality rate less than 8.3%) and above the 75th percentile (conditions with a mortality rate greater than 35.2%) were used as exclusion criteria for ICU admission in this new protocol.

Figure 1D is shown on the next page

Figure 1D – The influenza Pandemic ICU Triage (iPIT) Protocol

Step 1: inclusion criterion

Only admit patients requiring invasive ventilation or inotropes/vasopressors

Step 2: exclusion criteria 1

Exclude the patient if they have any of the following conditions:

A. Elective palliative surgery

B. Severe trauma

Step 3: exclusion criteria 2

Exclude the patient if they have any of the following conditions:

A. Acute renal failure requiring dialysis

B. Severe burns with any two of the following: age > 60 years; > 40% of total body surface area affected; inhalational injury

C. Cardiac arrest with any of the following: unwitnessed cardiac arrest; witnessed arrest not responding to defibrillation or pacing; recurrent cardiac arrest

D. Advanced untreatable neuromuscular disease

Step 4: calculate Sequential Organ Failure Assessment (SOFA) score*

	Score				
Variable	0	1	2	3	4
Respiratory: PaO_2/FiO_2	> 400	⩽ 400	⩽ 300	⩽ 200	⩽ 100
Haematological: platelet count, × 10^6/L	> 150	⩽ 150	⩽ 100	⩽ 50	⩽ 20
Hepatic: bilirubin level, mg/dL (μmol/L)	< 1.2 (< 20)	1.2–1.9 (20–32)	2.0–5.9 (33–100)	6.0-11.9 (101–203)	> 12 (> 203)
Cardiovascular: hypotension†	None	Mean arterial blood pressure < 70 mmHg	Dopamine ⩽ 5	Dopamine > 5; epinephrine ⩽ 0.1; norepinephrine ⩽ 0.1	Dopamine > 15; epinephrine > 0.1; norepinephrine > 0.1
Neurological: Glasgow Coma Scale	15	13–14	10-12	6–9	< 6
Renal: creatinine level, mg/dL (μmol/L)	< 1.2 (< 106)	1.2–1.9 (106–168)	2.0–3.4 (169–300)	3.5–4.9 (301–433)	> 5 (> 434)

* Adapted with kind permission from Springer Science and Business Media: Vincent et al.[5] † Doses of dopamine, epinephrine and norepinephrine in μg/kg/min.

Step 5: exclusion criteria 3

Exclude the patient if they have the following result from Step 4:

A. SOFA score ⩽ 8

B. SOFA score ⩾ 14

Step 6: calculate number of organ systems failing‡

Determine the number of following laboratory or clinical criteria for organ failure that the patient has present:

A. Pulmonary: acute respiratory distress syndrome; ventilatory failure; refractive hypoxia

B. Cardiovascular: left ventricular failure; hypotension; new ischaemia

C. Renal: hyperkalaemia; oliguria despite fluid resuscitation; increasing creatinine

D. Hepatic: transaminase levels more than twice the normal upper limit; increased bilirubin or ammonia levels

E. Neurological: altered mental status not related to fluid volume status; metabolic or hypoxic source; stroke

F. Haematological: clinical or laboratory evidence of disseminated intravascular coagulation

G. Cirrhosis with ascites, history of variceal bleeding, fixed coagulopathy, or encephalopathy

H. Irreversible neurological impairment that makes the patient dependent for personal care (eg, severe stroke, congenital syndrome, persistent vegetative state)

Step 7: exclusion criterion 4

Exclude the patient if they have three or more criteria from Step 6 present

Additional discharge criteria

Step 8: discharge criterion 1

Between Day 2 (48 hours) and Day 6 (144 hours) after admission, discharge the patient if they are no longer receiving invasive mechanical ventilation

Step 9: discharge criterion 2

On Day 7 (168 hours) after admission, discharge the patient from the ICU

For patients excluded or discharged, continue non-ICU level care and provide palliative care if indicated

‡ Adapted with kind permission from NSW Health — Policy Directive PD2010_028,[2] and John Wiley and Sons: Hick and O'Laughlin.[4]

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Using new Influenza Pandemic ICU Triage protocol to theoretically triage patients from the original dataset resulted in an increase in ICU bed availability of 71.7% at admission.

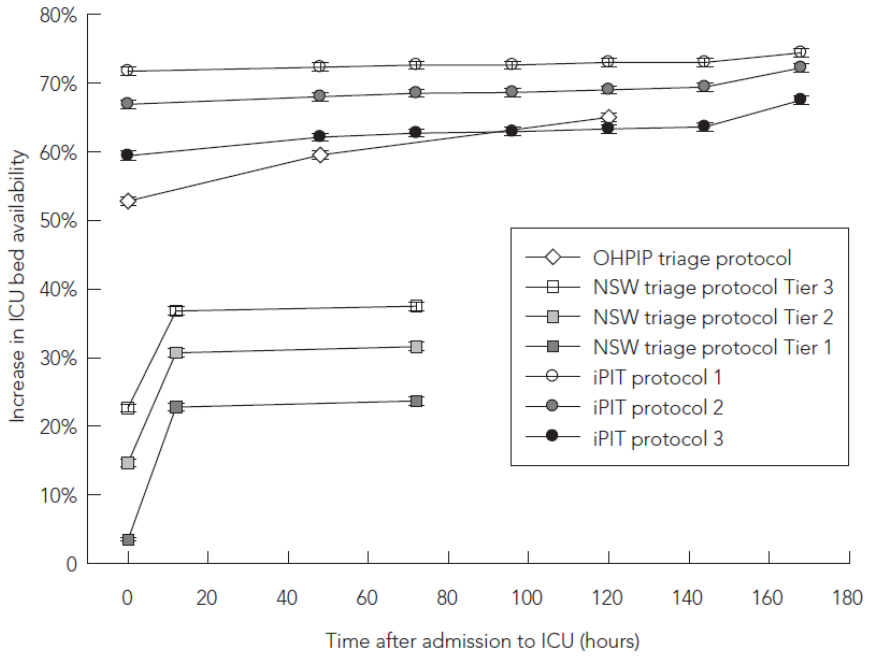
As a SOFA score at admission less than or equal to 8 resulted in the single largest increase in ICU bed availability of any individual criteria, the iPIT protocol was altered to determine the effect that lowering the SOFA score exclusion criteria would have on this. These two new triage protocols were named the iPIT-2 and iPIT-3 protocols. The altered protocols were the same as the iPIT protocol, except the iPIT-2 protocol excluded patients at admission who had SOFA scores less than or equal to 6, and the iPIT-3 protocol excluded patients with SOFA scores less than or equal to 4.

At admission, the new iPIT-2 and iPIT-3 protocols resulted in an increase in ICU bed availability of 66.9% and 59.4%, respectively.

The view of the authors was that a triage tool should also place limits upon the duration of patient stay in the ICU. These limits had previously not been placed on the NSW or Ontario pandemic protocols. Therefore, two additional discharge criteria were added to the iPIT protocols. These are detailed in Steps 8 and 9 of the iPIT Protocol (Figure 1D previously).

The increase in bed availability using the iPIT protocols, with the NSW and Ontario pandemic protocols shown for comparison, is depicted in Figure 1E.

Figure 1E – Cumulative Increase in ICU Bed Availability Using the Influenza Pandemic ICU Triage (iPIT) Protocols 1, 2 and 3, the NSW Triage Protocol (Tiers 1, 2 and 3) and the Ontario Pandemic Protocol



There were significant differences in the increase in ICU bed availability between all triage protocols at admission (Yates' continuity-corrected χ^2 test; $P < 0.001$) and within all three iPIT protocols when comparing admission to compulsory discharge at 7 days (iPIT-1 protocol, $P = 0.002$; iPIT-2 and iPIT-3 protocols, $P < 0.001$). I-bars indicate standard error.

OHPIP = Ontario Health Plan for an Influenza Pandemic (Ontario pandemic protocol)
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The iPIT 2 study demonstrated that increases in ICU bed availability could be achieved using an alternative influenza pandemic ICU triage protocol that excluded patients with the lowest and highest predicted ICU mortality rates. The iPIT protocol made more ICU beds available than the NSW and Ontario protocols. Decreasing the lower SOFA score exclusion limit resulted in less patients being excluded, providing a potential method for altering ICU bed availability as demand for critical care services changes in a pandemic.

The iPIT 2 study showed that the largest increases in ICU bed availability resulted from the exclusion of the large number of patients with low predicted mortality rates. Using ventilation or cardiovascular support as exclusion criteria accounted for a third of the increase in bed availability. Excluding patients on the basis of a low SOFA score accounted for another third. Excluding patients with high predicted mortality rates resulted in much smaller increases in bed availability due to the smaller numbers of patients.

The conclusion from the influenza Pandemic ICU Triage 2 (iPIT 2) Study was that our alternative influenza pandemic ICU triage protocols, when tested in a non-influenza pandemic setting, provided increases in ICU bed availability, while excluding patients with the lowest and highest ICU mortalities. Because the patients excluded from ICU admission had similar mortality rates it could be argued that the new protocols were fairer from an ethical perspective.

The results provided healthcare policy makers with more information to develop influenza pandemic policies. However, the important question of whether the restrictive measures used in the triage protocols were actually acceptable to the community remained unanswered.

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Chapter 2 - Ethics of Disaster Planning

2.1 Disasters and the Problems with Triage

2.1.1 Disasters

The definition of what constitutes a disaster varies. The World Health Organisation (WHO) defines a disaster as "an occurrence disrupting the normal conditions of existence and causing a level of suffering that exceeds the capacity of adjustment of the affected community".[1] International Federation of Red Cross defines a disaster as "a serious disruption to the functioning of a community that exceeds its capacity to cope using its own resources".[2]

The WHO declared COVID-19 a worldwide pandemic in March 2020, and subsequent to this COVID-19 was declared a disaster in many countries.[3,4] As of December 2022 there had been more than 640 million confirmed cases of COVID-19 worldwide, resulting in more than 6.6 million deaths.[5] However, over 100 other disasters occurred during the first six months of the COVID-19 pandemic, with over 50 million people affected worldwide.[6] More than 10 disasters during this time affected over 250,000 people each.[6] These disasters included weather related events, such as floods, fires and drought; earthquakes; volcanic activity and disease outbreak.

A disaster may result in a relative scarcity of available resources.[7] Many disasters do not result in an actual scarcity of resources, but data on resourcing may not be accurate due to the limitations of disaster research.[8] Relative scarcity of resources may result from the lack of time, because potentially large numbers of patients can present over a short period of time.[7]

2.1.2 Problems with Triage

Triage is considered an established process to sort and prioritise patients in both ordinary and disaster situations.[9] However, no triage is actually required if there are no resource limitations, as all patients can be treated optimally. Triage is often planned for in a disaster response, because the volume of patients may far exceed the availability of resources.[9] Triage may also be required because the least serious casualties tend to present early in a disaster, potentially obstructing resources for more seriously ill patients who present later.[7]

There are several theoretical problems with using triage systems in a disaster. Triage creates the potential for conflict, because decisions may be made for some patients not to receive treatment.[9] Undertriage may occur, where there is an inability of triage processes to identify all patients in need of immediate life-saving interventions, and therefore some patients are undertreated.[8] Overtriage may occur, where patients with lower priority problems may be inaccurately prioritised higher for treatment, potentially overburdening the health system with noncritically ill patients whose care could otherwise have been safely delayed.[7]

Triage also requires medical personnel to make potential life-or-death decisions. The skill and experience of the person or persons making the triage decision is therefore important, but the degree of skill or experience required to accurately triage remains unknown.

There is currently no evidence that demonstrates that triage systems actually improve outcomes for individuals or for society as a whole, in a major disaster. No studies have demonstrated that using triage systems to sacrifice potentially salvageable patients results in more lives being saved overall.[7]

2.2 Ethical Concepts in Resource Allocation and in Public Health

2.2.1 Ethics

Ethics reflects the moral values of society. If society views that there is no moral right or value to health care then there is theoretically no ethical problem with the concept of triage.[7] However, in western societies there is a perceived moral right to health care because of the principle of the right to life. The problem with putting this principle into practice is that though a right to life may exist, this right in itself does not necessarily imply a right to a specified length of life, nor does it imply a right to a particular resource in order to sustain that life, especially if that resource is scarce.[10]

This problem is further illustrated in Queensland, where the perceived moral right to health care has some legal basis. The Human Rights Act 2019 (QLD) is the only act in Australia to contain an explicit right to healthcare, but it provides only the right to access health services free from discrimination.[11,12] It does not guarantee access to specific health services, such as intensive care.

The ethics of public health differ from usual clinical ethics as the common good is promoted over protecting individual autonomy.[13] Disasters potentially require health care providers to prioritise the likelihood of survival instead of giving everyone a fair and equal opportunity to receive medical treatment.[9]

As a result, the principles that guide resource allocation in a disaster setting have traditionally been predominantly utilitarian in nature, where the objective is to do the greatest good for the greatest number of people. Due to the potential for conflict, the ethics of triage need to account for both the individual and the community.[14]

2.2.2 Principles and Values

A principle may be defined as “a basic truth or a general law or doctrine that is used as a basis of reasoning or a guide to action or behaviour”.[15] Principles are considered action guides that summarise and encapsulate a whole moral theory, and therefore assist a person in making a moral decision.[15]

Principles often concern human behaviour and govern interactions between people. They are part of traditions and philosophies over the ages, and have been woven into the fabric of societies throughout human history.[16] Principles are therefore permanent, unchanging and universal in nature.

Values are beliefs and opinions that people hold regarding specific ideas.[16] Values are internal, subjective and malleable. They are beliefs and opinions that can be altered if the conditions are right. Values can therefore differ to principles, because values may change over time.

2.2.3 Solidarity

A key concept in addressing resource allocation in public health is that of solidarity. Solidarity is the notion that a group of people are committed to abiding by the outcome of a process or collective decision-making.[9]

At the core of the concept of solidarity is the perception of mutual obligations between members of a community. Solidarity is a moral value and a social attitude regarding those in need of support. Solidarity emphasizes a sense of togetherness and implies a commitment to prioritise those who are disadvantaged. Without solidarity, society's efforts to allocate resources in a manner that benefits society as a whole in a major disaster, such as a pandemic, are likely to fail.

2.2.4 Principlism

Principlism has been the dominant approach to western bioethics over the last few decades.[17] However, principlism has its critics and its concepts are not all universally accepted.[19]

The main principles of western biomedical ethics were summarised in the Belmont Report prior to the creation of the USA National Research Act, in 1974.[15,18] The report identified three basic principles.[18] These principles were intended to guide research involving human subjects, but have since been used in clinical bioethics as well. The three principles were: respect for persons; beneficence and justice.

In the years following the Belmont Report, the Belmont principle of beneficence was divided into two separate principles – the principle of beneficence and the principle of nonmaleficence.[15,17] This modification to the Belmont principles led to the four principle approach to biomedical ethics that is now commonly known as principlism. The four principles of principlism are: respect for autonomy; nonmaleficence; beneficience; and justice.[15]

The principle of autonomy refers to an individual being able to self-govern, free from controlling interference by others and from limitations that prevent meaningful choice.[15] Some patients, however, do not have decision-making capacity or competence, therefore other principles besides autonomy may need to be invoked to guide action.[15]

The principle of nonmaleficence refers to the duty to refrain from causing harm. It underlies the medical maxim "Primum non nocere – above all (or first) do no harm".[15] The principle of nonmaleficence supports several specific moral rules, the relevant ones to the concept of triage being "do not kill" and "do not deprive others of the goods of life".[15] Harmful acts are generally considered wrong, but may not be considered wrong if the harm is justifiable. The harm is justifiable if there is a just, lawful excuse or reason for the act or omission.[15]

The principle of beneficence asserts the duty to help others further their important and legitimate interests. Beneficence compels those to whom it applies to act affirmatively. This is different to nonmaleficence, where those to whom it applies are compelled to refrain from acting.

The principle of justice refers to how social benefits and burdens should be distributed. Justice requires that equals are treated equally and unequals can be treated unequally, but in proportion to their inequalities.[7]

In recent times the concept of common morality has been suggested as a fifth principle for principlism.[31] Common morality is a basic set of moral standards, defined as groups of rules and moral principles which constitute a rational and socially stable set of rights and wrongs that are so widely accepted and spread that they form a true "social institution".[31] Examples of common morality is the understanding that it is forbidden to kill, steal or lie.[31]

Although principlism is generally accepted as the dominant framework for modern western bioethics there are many criticisms.[19] It is argued that the principles are not actually guides to action, but instead are names for a collection of superficially related matters for consideration when dealing with a moral problem.[19] The principles lack any systemic relationship with each other. The principles often conflict with each other, and these conflicts are unresolvable. This is because there is no unified moral theory from which they are all derived.

Bioethical and biolaw principles in Europe do not necessarily align with principlism, because they can differ according to country, and because principlism is considered an American concept.[30] This divergence of principles is seen by the different approach individual European countries take to bioethical issues such as euthanasia. For example, bioethics and biolaw in Austria is dominated by legal tradition that is limited by Catholic theology and a German inspired legal tradition for the protection of human dignity and integrity. Italian bioethics is marked by differences between Catholic and secular bioethics. However, bioethics and biolaw in France uses a strong principlist approach.

In order to harmonize the European principles, it has been suggested that the European bioethical principles should be: autonomy, dignity, integrity and vulnerability.[30]

Under European principles, there are five meanings for autonomy. Autonomy can be the capacity of creation of ideas and goals for life; the capacity to have moral insight, "self-legislation" and privacy; the capacity of decision and action with lack of outer constraint; the capacity of political involvement and personal responsibility; and capacity of informed consent.[30]

The principle of dignity expresses the outstanding position of human beings in the universe. It refers to the inviolability of human life and the moral responsibility to the human person.[30]

The principle of integrity refers to the totality of life. It has four meanings. Integrity is considered a narrative totality, wholeness and completeness; a personal sphere of self-determination; a virtue of uncorrupted character; and a moral coherence of the legal or medical system.[30]

The principle of vulnerability is closely linked to integrity, and is the characteristic of the human condition that requires protection. It is a balance between the struggle for immortality and the presence of suffering, and addresses problems such as disability.[30]

For this thesis, I focus on addressing the western bioethical principles of principlism, but acknowledge that other bioethical principles exist, and that these can vary between countries.

2.2.5 The Principle of Justice in Resource Allocation

The potential methods for distributing resources in a manner that upholds the principle of justice are controversial. These methods include: distribution according to equal share; according to need; according to effort; according to contribution; according to merit; and according to free-market

exchanges.[15] As a result, four ethical theories are commonly used to address problems with justice. These theories are known as the utilitarian, egalitarian, libertarian and communitarian theories of justice.[7]

Utilitarian theories of justice espouses the greatest happiness principle, where the concept is that "actions are right in proportion as they tend to promote happiness".[7] The goal is the greatest total happiness, not necessarily the greatest happiness for the greatest number. Using this theory, the most just decisions increase the net usefulness to society, both by maximising benefits and minimising harms.

Egalitarian theories of justice proposes that scarce resources should be distributed equally.[7] Strong egalitarianism proposes that all individuals receive an identical share. Maximin or qualified egalitarianism accepts inequalities provided that it benefits those who are the worst off or it is no longer possible to improve those who are the worst off.[15]

Libertarian theories of justice espouse freedom from external or arbitrary control. The individual is determined to be the best judge of their own health needs, so priorities are self-driven, and usually reflect the capacity to pay.[7]

Communitarian theory of justice is focused on creating a "good" or "virtuous" society.[7] This involves selecting the right individuals to further this goal.

In disaster triage, the ethics of public health in promoting the common good over protecting individual autonomy are utilitarian in nature.[13] However, the utilitarian system significantly interferes with equality and may undermine those who are in the greatest need of health care services. By concentrating on societal good, the burden of sacrifice may be unfairly placed on individuals and subpopulations.[7] Therefore the egalitarian qualities of equality and fairness are also important components of justice when determining resource allocation in disaster triage.

2.2.6 First Come, First Served Approach to Resource Allocation

If no systems are in place to decide the treatment priority of patients when resources are limited, then patient care is likely to be provided on a first-come, first-served basis.[20,7] The reason for this is medical personnel may find it too difficult to prioritise patients without adequate guidance or protections in place, so may defensively treat all patients regardless of illness severity or prognosis until resources are exhausted. In a disaster setting, the first-come, first-served approach is considered neither utilitarian nor egalitarian, but is considered to be morally justifiable and fair, when no other systems to allocate resources exists.[20]

There are several ethical issues with using a first come, first served approach to allocate patients for ICU management in a disaster.[7] First, patients who live in close proximity to an ICU are more likely to be allocated than those who do not. Second, patients who are affected early in a pandemic are more likely to receive ICU management than those who present later. Third, patients who are highly dependent on medical care, and have regular contact with the hospital system (for example, patients undergoing in-hospital dialysis, in-hospital chemotherapy, or recurrent admissions for a chronic medical condition) have a greater chance of accessing ICU resources. Fourth, patients who do not have access to transportation or who do not have access to media may be discriminated against.[7] In a first-come, first-served approach to patient care, treatment is started in the first patient to arrive, regardless of the need of subsequent patients.

2.2.7 Age, Intergenerational Equity and Triage Criteria

A utilitarian approach to disaster triage may discriminate on the basis of age. Older patients admitted to the intensive care unit have worse outcomes than younger patients, but this may be due to frailty and comorbidities rather than age per se.[21,22] Experience from disasters demonstrates worse mortality outcomes in older patients.[7] Older patients are more likely to have comorbidities, therefore triage systems that use comorbidities as triage criteria may discriminate against older people, even though this may not be its primary intent.

There are several arguments used to justify the use of age to ration resources or guide triage decisions in a disaster situation.[7] The first is based on the concept of a "tolerable death". This concept argues that life-sustaining treatment can be ethically withheld once an individual reaches the end of a natural lifespan, because life's possibilities have been achieved and death is therefore seen as a relatively acceptable event.

Intergenerational equity, also called the "life-cycle" concept and the "fair innings" concept, argues that the old have lived longer than the young, therefore it is only fair to allow the young the opportunity to live to a comparable age and through the various phases of life, from childhood to old age.[13] There is some survey evidence that society believes that younger patients should be prioritised over older patients when resources are scarce.[23] However, intergenerational equity is only logical at the extremes of the ages. The smaller the age difference between the young and the old, the less any ethical distinction.

Another justification of using age to triage in a disaster setting is that of the prudential lifespan model.[7] In this model the fair distribution of resources occurs over the course of an individual's lifespan. This implies that younger patients should receive more health care resources because older patients have already received those resources.

There are significant problems with triaging on the basis of age. The underlying moral problem is that older patients may not be seen to be as worthy of saving as younger patients. A potential legal problem is the law does not generally discriminate on the basis of age. For example, criminal offenses generally have the same penalties regardless of age of the victim. There are also problems with accurately determining biological age, as opposed to chronological age. Not all patients age similarly and therefore prognoses may vary.

2.2.8 Chance and Resource Allocation

Some people end up worse off than others because of bad luck or chance.[24] The term "social lottery" is sometimes used to describe this concept.[7] Resources may distributed unequally because of bad luck or chance. There are many arguments for and against luck or chance induced inequalities being unjust.[24] Luck may nullify responsibility, but luck may also nullify merit. Therefore, for justice to occur, luck or chance should theoretically be accounted for. The underlying assumption is that differential standing in society that results from luck is morally undesirable and unjust.[24]

From a disaster triage perspective, bad luck because of social circumstance can be mitigated by discriminating in favour of those affected adversely. During the 2009 H1N1 influenza pandemic, Aboriginal and Torres Strait Islanders, Maori and Aboriginal Canadians were overrepresented in ICU admissions compared to the overall population.[25,26] This overrepresentation may have been due to the socio-economic hardship of disadvantage, such as crowded or inadequate housing, lower

educational achievement, higher unemployment, lower income, increased comorbidities, or reduced access to health care.[25] Because of the problems resulting from bad luck or chance, it is argued that disadvantaged populations should receive a greater degree of resource allocation in a pandemic disaster.

2.2.9 Social Value, Reciprocity and the Multiplier Effect in Resource Allocation

Social value refers to ones worth in society.[25] Allocating resources in a disaster based on social value is a reflection of a judgment on an individual's past and future contributions to society. This is different to instrumental value, which refers to an individual's ability to carry out a specific function that is essential to prevent social disintegration or to mitigate harm.[13]

From a disaster triage perspective, there has been no agreement on criteria that differentiates one person as being intrinsically more worthy of saving than another.[25] However, there is an ethical argument that the one specific aspect of social value that may have a role in disasters is the ability to provide medical care.[7]

In a good and just society there is an ethical responsibility to look after those who risk their lives for the benefit of the society. There is therefore an ethical argument that individuals with training in medical care provision should receive preferential triage, especially if those individuals place themselves or their families at risk of harm for the benefit of society, such as "frontline" staff in a pandemic. This concept is known as reciprocity.

Rapidly treating "frontline" individuals so that they can return to their duties may enhance the ability to treat other patients. This is known as the "multiplier effect".[13] The utilitarian argument is that prioritising these individuals in disaster triage serves a greater societal good in the long term and is ethically just. However, an argument against this is that in many disasters medical resources are not limited and medically skilled personnel are not a scarce resource. Patients requiring ICU level care will likely require long recovery times negating their ability to reenter the workforce in time to fulfil their instrumental roles.[13] It is also unknown which roles, in reality, are truly indispensable in a pandemic disaster.

2.2.10 Life-Years Concept and Triage

The life-years concept broadens the utilitarian aim to accomplish the greatest good by considering the number of years of life saved in addition to the number of lives saved.[13] If the chances of short term survival are the same, an individual who is healthy is likely to have more life-years saved than an individual of the same age who has significant comorbidities, and therefore a limited life expectancy. The ethical justification for incorporating this utilitarian concept in a disaster triage system is that it is better to save more years of life than fewer.

2.3 Ethical Approach to Disaster Planning

Given the many different and conflicting principles, concepts and theories which can be applied to resource allocation and public health, there are challenges in deciding which ones should be used in

disaster planning. When resources are scarce in a disaster, not all the principles espoused in principlism can be applied. This is because there may not be enough resources to allow individual autonomy in decision-making or to prevent harm from occurring to all individuals.

The biomedical ethical principles of autonomy, nonmaleficence and beneficence cannot be actioned for all individuals when there is a scarcity of resources, therefore the ethical approach to disaster planning focuses on the principle of justice, determining how the scarce benefits and significant burdens can be distributed. Triage planning for disasters has traditionally been based on utilitarian theories of justice, where the intent is to maximise survival, benefiting society as a whole, at the expense of individual needs.[7] However, some egalitarian and communitarian values are also used.

Given that all the traditional biomedical ethical principles cannot be applied simultaneously, there are many ethical values encompassing all the ethical concepts and theories that have been proposed to address concerns about disaster planning instead.[9,27,28] One proposed value is that of maximising benefits and preventing harms.[27,28] This implies that prioritisation of intensive care services in a pandemic should maximise benefits to society and the harm generated should be less than if intensive care services were not prioritised.

Another proposed value is that of equal moral concern.[27] This concept proposes that people should be treated as moral equals, and that discrimination should not occur on the basis of morally irrelevant characteristics, such as race, ethnicity or religion. In a pandemic, this concept implies that communities with higher or lower burdens of disease can be treated differently given each communities unique needs.

Mitigating disadvantage is another proposed value.[27] This implies that priority for scarce resources in a disaster, such as intensive care, should be given to people who are disadvantaged or who face discrimination. The disadvantage could be on the basis of race, ethnicity, religion or other factors, such as geographical distance from health care support. As a minimum, already disadvantaged groups should not be further disadvantaged by resource allocation decisions in a disaster.

The concept of reciprocity is also proposed to address concerns about disaster planning.[27] Preferential allocation of resources should be given to people who in the past have mitigated harms for others, while facing a disproportionate burden.

The concept of instrumental value proposes that benefits should be provided for people who can, in the future, mitigate harm and disadvantage for others.[27] Instrumental value is not considered an independent value, but is used to facilitate other values, such as maximising benefits or minimising harm. This implies that intensive care resources in a pandemic should be prioritised to people who provide a vital role for the stable functioning of society, or who can improve the health of the population.

Other values that need to be considered in disaster planning are those of transparency, engagement, consistency, proportionality, accountability and responsiveness to evidence.[27,28] These values are considered procedural rather than ethical.

All of the proposed values for disaster planning are not independent. They coexist with other values. Because of this, these values should not receive absolute priority on their own. The priority of the values should be balanced against and shaped by the other values. However, which values should be prioritised in particular circumstances currently remains unclear, and how these values should actually be operationalised in a disaster remains unknown.

2.4 Unanswered Ethical Questions in Disaster Triage

The ethics of disaster triage poses many unanswered questions. No rationing is required in a disaster setting if there are no limitations to resources. Therefore, triage systems are also not required.[9] However, if resources are limited in a disaster setting, and no systems are in place to decide the treatment priority of patients, then patient care is likely to be provided on a first-come, first-served basis.[20,7]

From an intensive care perspective, the justification for the use of triage systems in a disaster setting, where the demand for intensive care resources exceeds the availability of those resources, is an assumption that society finds the first-come, first-served approach to resource allocation unacceptable. It is assumed that society believes it is better to have some sort of process to allocate resources rather than no process at all. However, there is no actual evidence to support this assumption.

Using triage is one alternative to a first-come, first-served approach to resource allocation in a disaster setting that addresses many of the issues related to upholding the principles of justice. However, there are other potential methods to allocate scarce resources in a disaster. These include using a senior clinician with the appropriate medical expertise to decide; using random selection; using a person's ability to pay to decide or the free market principle; or using some measure of the importance of the patient to society to decide.

In determining how the health system in Australia allocates scarce intensive care resources in a future pandemic disaster, the first unanswered ethical questions that need to be addressed are whether society rejects the concept of the first-come, first-served approach to intensive care resource allocation, and whether society has true solidarity in supporting the use of triage systems. These questions have never been addressed in Australia. It is important to answer these questions because if the process of using triage to prioritise and ration resources in a pandemic is perceived as being unfair the legitimacy of a public health response may be challenged, and restrictive measures may not be adhered to.[13]

If society prefers the first-come, first-served approach to allocating health care resources in a disaster then no further work needs to be done in regards to resource allocation. The treatment of patients in this context can be based on the absolute supply of resources, and not on how those resources are allocated. The focus for disaster management then moves to ensuring enough resources are available to facilitate the first-come, first-served approach.

If society rejects the first-come, first-served approach to allocating resources in a disaster then the next step is to determine if society accepts the use of triage systems, given that triage systems are considered the most appropriate method to allocate resources. If society rejects the use of triage systems to allocate scarce health care resources in a disaster then the next step is to determine what type of alternative resource allocation system is the most acceptable. If society accepts the use of triage systems then work needs to be done to determine the optimal method to triage, that best upholds society's ethical values.

It was with these unanswered questions in mind that the first study in this PhD thesis, the influenza Pandemic ICU Triage 3 (iPIT 3) Study, was developed.[29] The following chapter describes the rationale, hypotheses and objectives of this and the other studies in this PhD thesis.

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Chapter 3 – Rationale, Objectives and Hypotheses

3.1 Rationale, Objectives and Hypotheses for Thesis

The theme of this PhD thesis is pandemic disaster planning. The rationale for undertaking this thesis in pandemic disaster planning was threefold.

The first reason for undertaking this thesis was a major pandemic had the potential to overwhelm current intensive care resources, therefore pandemic planning had significant public health importance. Both the Australian Federal Government and NSW Government had emphasized the need to develop legitimate public health strategies to manage health care resources in a pandemic. NSW Health stated in its 2009 influenza pandemic policy that:

> *"…the process for prioritization of critical care resources during a pandemic should be understood and accepted by the community. Prioritisation strategies should therefore be based on carefully formulated and considered criteria, which are open for discussion and public scrutiny well in advance of a pandemic".*[1]

The second reason for undertaking this thesis was, while triage protocols to allocate resources were one of the NSW Government's prioritisation strategies, there was genuine uncertainty at the time regarding whether the public would find the use of triage protocols to be acceptable, in a public health crisis such as a pandemic. Compliance with restrictive public health measures was dependent on such measures being acceptable to the public. Public involvement in setting priorities was considered essential because deciding which principles guided the allocation of life-saving resources during a public health emergency was a value judgment, rather than scientific judgment.[2]

The third reason for undertaking this thesis was there was little literature documenting the views of stakeholders in guiding decision-making during pandemics. Apart from our work with the iPIT 1 and iPIT 2 studies, there had been no studies in Australia or New Zealand examining pandemic triage.

The overall objective was learn more about the public's views on intensive care triage, in order to optimise the allocation of intensive care resources in a future pandemic. Objectives were devised and hypotheses were generated for the three studies described in this PhD thesis, the influenza Pandemic ICU Triage 3 (iPIT 3) Study (Section 4.1), the influenza Pandemic ICU Triage 4 (iPIT 4) Study (Section 4.2), and the ICU Pandemic Triage (IPT 5) Study (Section 5.2).

The influenza Pandemic ICU Triage 3 (iPIT 3) Study - A Cross-Sectional Survey of Australian and New Zealand Public Opinion on Methods to Triage Intensive Care Patients in an Influenza Pandemic (Chapter 4)

A first-come, first-served approach was likely to be used to allocate resources if no systems were in place to decide the treatment priority of patients if resources were limited in a disaster. The ethical arguments to why this approach should not be used in a pandemic disaster were presented in Chapter 2. An alternative approach to allocating intensive care resources in a pandemic disaster is to

use triage systems. Triage systems are ethically acceptable, but other alternative methods are also available to allocate scarce resources in a pandemic.

The primary objective of the iPIT 3 study was to determine public opinion on how ICU beds should be allocated in an influenza pandemic.

The secondary objective of the iPIT 3 study was to determine public perception of fairness for the different methods that could be used to allocate ICU beds.

The first hypothesis for the iPIT 3 study was that society would reject the first-come, first-served approach to allocating intensive care resources in a pandemic disaster.

The second hypothesis for the iPIT 3 study was that society would accept the use of triage systems to allocate intensive care resources in a pandemic disaster.

The study was designed to answer these hypotheses, and also determine what alternative method of intensive care resource allocation was likely to be the most acceptable to society, if triage systems were found to be not acceptable.

The iPIT 3 study demonstrated that respondents considered both the use of a senior doctor or pre-determined health department criteria to be the fairest way to triage ICU patients in an influenza pandemic. However, questions remained on whether triage decisions would be accepted by those directly affected by the decisions. To address the ethical question of whether families of patients directly affected by these triage decisions would find intensive care triage acceptable, we conducted the influenza Pandemic ICU Triage 4 (iPIT 4) Study.

The influenza Pandemic ICU Triage 4 (iPIT 4) Study - A Survey of Surrogate Decision-Makers for Intensive Care Patients on the Use of Triage Criteria in an Influenza Pandemic (Chapter 4)

Serendipitously, soon after starting the iPIT 4 study, the COVID-19 pandemic began. This provided us with the opportunity to conduct the iPIT 4 and IPT 5 studies in actual pandemic conditions. The additional rationale for continuing this PhD research program was ICU admission for invasive ventilation and other ICU treatments (ICU therapy) was at the time the main therapy that improved survival in patients with severe COVID-19. The number of ICU beds in Australia were limited and finite, and therefore needed to be managed in a manner during the pandemic that maximised the best outcomes for the community.

The primary objective of the iPIT 4 study was to determine how surrogate decision-makers for patients in the ICU perceived the fairness of the use of triage criteria to allocate intensive care resources during an influenza pandemic, using a rating scale.

The first hypothesis for the iPIT 4 study was that surrogate decision-makers for patients in the ICU would find triage criteria to be unfair and unacceptable, if the patient who they were responsible for was excluded from ICU resources in a pandemic.

The second hypothesis for the iPIT 4 study was that surrogate decision-makers for patients in the ICU would find triage criteria to be fair and acceptable, if the patient who they were responsible for was allowed access to ICU resources in a pandemic.

The iPIT 4 study would specifically survey surrogate decision-makers of patients in the ICU on how they perceived the fairness of the use of triage criteria.

The ICU Pandemic Triage (IPT 5) Study - A Survey of Australian Public Opinion on Using Comorbidity to Triage Intensive Care Patients in a Pandemic (Chapter 5)

At the start of the COVID-19 pandemic there was urgency to plan for the possibility that intensive care resources in Australia could be overwhelmed. Triage was considered a possible solution, but there were several reasons why further research into public views on intensive care triage needed to be conducted. These reasons were why we continued this PhD research program during the COVID-19 pandemic. The ethical issues are described in Section 5.1.

There was genuine uncertainty regarding what method to triage patients on the basis of chronic comorbidity would be acceptable to the general public. There was uncertainty regarding the degree of supportive measures provided to vulnerable and disadvantaged people in a pandemic that the public would find acceptable. There was also uncertainty regarding the degree of supportive measures provided to frontline healthcare workers in a pandemic that the public would find acceptable. It was on this basis that the ICU Pandemic Triage (IPT 5) study was developed.

The primary objective of the study was to determine which method to triage intensive care patients using chronic comorbidity was perceived to be the fairest by the general public in a pandemic. The secondary objectives were to determine if the general public perceived providing preferential ICU treatment to vulnerable or disadvantaged people to be fair, and to determine if the general public perceived providing preferential ICU treatment to frontline healthcare workers to be fair, in a pandemic.

The first hypothesis was that the general public would perceive the four main methods to triage on the basis of comorbidity to be similar in fairness, in a pandemic disaster where the demand for intensive care services significantly exceeded the availability of intensive care resources.

The second hypothesis was that the general public would not perceive giving preferential ICU treatment to vulnerable or disadvantaged people to be fair, in a pandemic disaster where the demand for intensive care services significantly exceeded the availability of intensive care resources.

The third hypothesis was that the general public would perceive giving preferential ICU treatment to frontline workers to be fair, in a pandemic disaster where the demand for intensive care services significantly exceeded the availability of intensive care resources.

The IPT 5 study was therefore designed to address these three hypotheses by surveying the general Australian population.

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Chapter 4 – Public Attitude to Intensive Care Triage in a Pandemic

4.1 The influenza Pandemic ICU Triage 3 (iPIT 3) Study - A Cross-Sectional Survey of Australian and New Zealand Public Opinion on Methods to Triage Intensive Care Patients in an Influenza Pandemic

4.1.1 Objectives

The primary objective of the influenza Pandemic ICU Triage 3 (iPIT 3) Study (A Cross-Sectional Survey of Australian and New Zealand Public Opinion on Methods to Triage Intensive Care Patients in an Influenza Pandemic) was to determine public opinion on how ICU beds should be allocated in an influenza pandemic. The secondary objective was to determine public perception of fairness for the different methods that could be used to allocate ICU beds.

4.1.2 Methods

The study was a binational postal survey using a self-completed, paper questionnaire, posted to a random sample of 2000 registered voters extracted from the Australian Electoral Commission (AEC) electoral roll and a random sample of 2000 registered voters extracted on the New Zealand Electoral Commission (NZEC) electoral roll.[1] The iPIT 3 study was the first study conducted in this thesis.

Ethical approval to conduct the study was obtained from the Sydney Local Health District - Concord Repatriation General Hospital - Human Research Ethics Committee (Approval Number HREC/13/CRGH/290 – CH62/6/2013-205 - 5th February 2014). Approval to access electoral roll data was obtained from the Australian Electoral Commission (Ref: 2014/331 – 218610 - 16th July 2014). After the study had been approved in Australia, collaborators in New Zealand obtained separate ethical approval to conduct the study in New Zealand, separate approval to access the New Zealand Electoral Commission electoral roll, and separate funding.

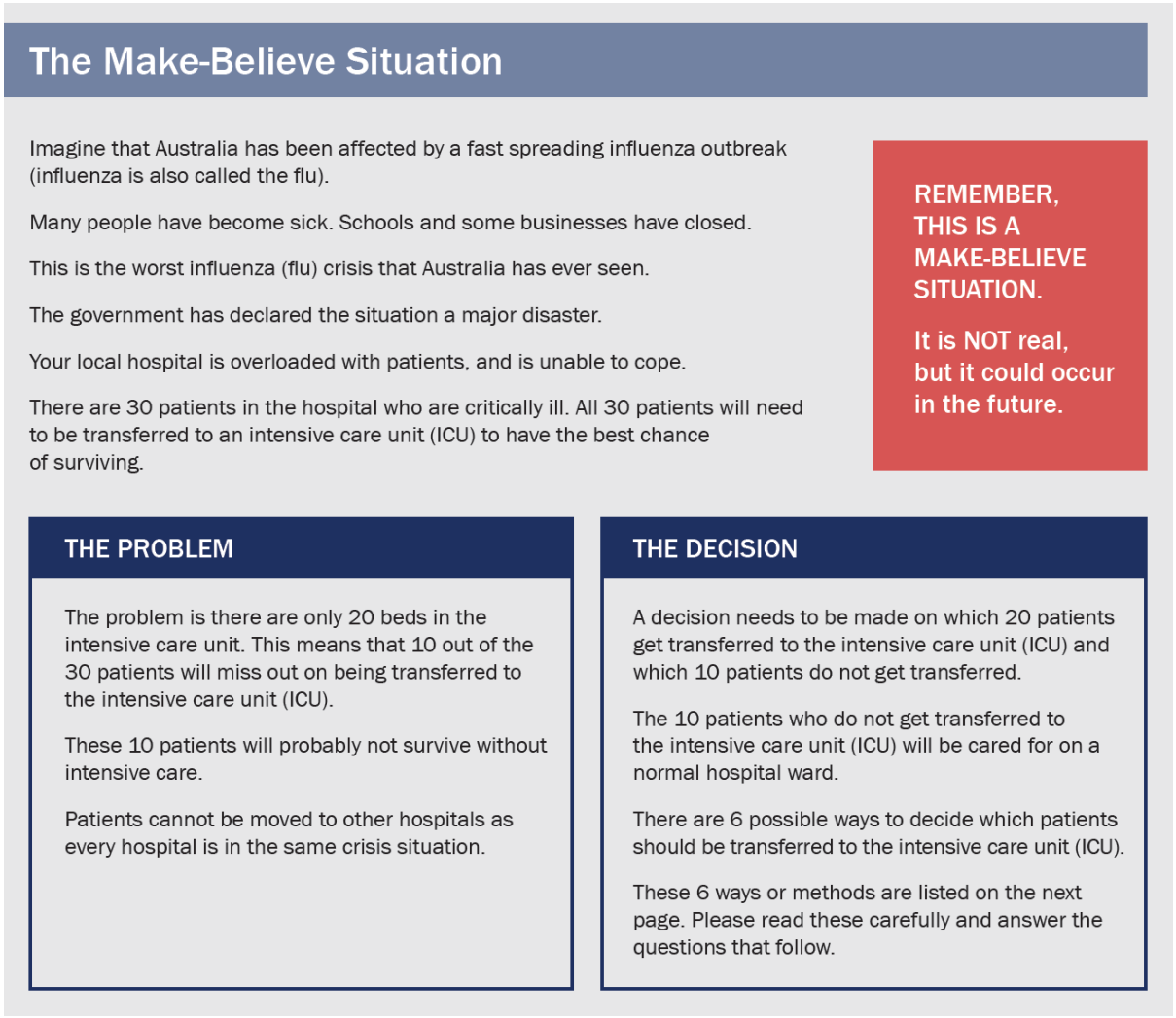
The study was endorsed by the Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group (26th June 2014). The study was coordinated from Concord Repatriation General Hospital in Australia and Auckland City Hospital in New Zealand.

4.1.3 Questionnaire

A specific questionnaire was developed for the study (Appendix 4). A graphic designer helped with the colour scheme and layout of the questionnaire. Participants were sent a pre-notification letter 4 weeks before the questionnaire was posted. No incentives or remuneration were offered to participants. Questionnaires were returned using a reply-paid envelope.

The six-page questionnaire contained a scenario that was adapted for an Australian or New Zealand participant (Box 4A).

Box 4A – Influenza Pandemic Scenario used in the iPIT 3 Questionnaire (Australian Version)



The Make-Believe Situation

Imagine that Australia has been affected by a fast spreading influenza outbreak (influenza is also called the flu).

Many people have become sick. Schools and some businesses have closed.

This is the worst influenza (flu) crisis that Australia has ever seen.

The government has declared the situation a major disaster.

Your local hospital is overloaded with patients, and is unable to cope.

There are 30 patients in the hospital who are critically ill. All 30 patients will need to be transferred to an intensive care unit (ICU) to have the best chance of surviving.

REMEMBER, THIS IS A MAKE-BELIEVE SITUATION.

It is NOT real, but it could occur in the future.

THE PROBLEM

The problem is there are only 20 beds in the intensive care unit. This means that 10 out of the 30 patients will miss out on being transferred to the intensive care unit (ICU).

These 10 patients will probably not survive without intensive care.

Patients cannot be moved to other hospitals as every hospital is in the same crisis situation.

THE DECISION

A decision needs to be made on which 20 patients get transferred to the intensive care unit (ICU) and which 10 patients do not get transferred.

The 10 patients who do not get transferred to the intensive care unit (ICU) will be cared for on a normal hospital ward.

There are 6 possible ways to decide which patients should be transferred to the intensive care unit (ICU).

These 6 ways or methods are listed on the next page. Please read these carefully and answer the questions that follow.

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The primary question asked respondents which of six triage methods they preferred (Box 4B and 4C) and required a single multiple choice answer.

Box 4B - Methods used in iPIT 3 Questionnaire to Triage ICU Patients (Australian Version)

THE CHOICES

A

Use a first come, first served approach to decide

What does this mean? The first patients to arrive at the hospital get to be transferred to the intensive care unit. Once the intensive care unit (ICU) is full, those arriving later miss out.

B

Let a senior doctor decide

What does this mean? A senior doctor will decide which patients get transferred to the intensive care unit (ICU), and which patients don't. The senior doctor would take into account a patient's health and chances of surviving when deciding.

C

Use a set of criteria or rules that have been determined by the Health Department to decide

What does this mean? A set of criteria or rules is used to decide which patients can be transferred to the intensive care unit (ICU). Patients who do not meet the criteria set out in the rules will not be transferred to the intensive care unit (ICU).

D

Use random selection to decide

What does this mean? Patients are picked at random to be transferred to the intensive care unit (ICU), such as drawing a person's name from a hat.

E

Use a patient's ability to pay to decide

What does this mean? Patients who can afford to pay for their treatment, or who have private insurance will be transferred to the intensive care unit (ICU). Those who cannot afford to pay, or who do not have insurance will miss out.

F

Use the importance of the patient to decide

What does this mean? Patients who are thought to be more important to the functioning of society will be transferred to the intensive care unit (ICU). Those who are thought to be not as important will miss out. For example, an engineer who maintains the city's water supply may be more likely to be transferred to the intensive care unit than a person who does not work.

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Box 4C – Question 1 of the iPIT 3 Questionnaire (Australian Version)

Question 1: Which of the 6 methods do you think is the best way to decide which patients get to be transferred to the intensive care unit (ICU) in a major influenza pandemic disaster, when there are not enough resources to treat everyone? (Choose only 1 option)

- ☐ A Use a first come, first served approach to decide
- ☐ B Let a senior doctor decide
- ☐ C Use a set of criteria or rules that have been determined by the Health Department to decide
- ☐ D Use random selection to decide
- ☐ E Use the patient's ability to pay to decide
- ☐ F Use the importance of the patient to decide
- ☐ G I'm not sure which answer I think is the best

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The six secondary questions asked respondents to rate each of the six triage methods for fairness using a horizontal, seven-point, category rating scale with qualifiers. An example of a secondary question (Question 2) is detailed in Box 4D.

Box 4D – Example of a secondary question from the iPIT 3 Questionnaire (Australian Version)

For Questions 2 to 10 draw a circle around the number that matches the answer you think is the best, like so

Extremely unfair			Neither unfair or fair			Extremely fair
1	2	3	(4)	5	6	7

Examples:
If you think the best answer is "extremely unfair" then circle 1.
If you think the best answer is "extremely fair" then circle 7.
If you think the best answer is "unfair", but not "extremely unfair", then circle 2 or 3.
If you think the best answer is "fair", but not "extremely fair", then circle 5 or 6.

Question 2: How fair do you think it is to use a first come, first served approach to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair			Neither unfair or fair			Extremely fair
1	2	3	4	5	6	7

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Three additional questions using the same rating scale asked respondents to rate for fairness the use of age, predicted mortality and chronic comorbidity as selection criteria. Respondents could also provide their own comment using optional free-text.

The questionnaire was refined after pilot testing with consenting volunteers. To mitigate order-effect bias, participants were randomly allocated one of 12 versions of the questionnaire with the order of the six triage methods and secondary questions randomised so that they appeared first and last in the same frequency. To mitigate possible participant distress associated with receiving the questionnaire, an initial batch of 200 questionnaires was sent in both countries to determine safety. The returns over this 4 week safety phase were reviewed and approved by an independent safety monitor before the remaining 1800 questionnaires in each country were posted, in the main study phase. All returned questionnaires were included in the final analysis.

In Australia, the Australian Electoral Commission did not allow personal information to be retained, for privacy reasons, so participants were not contacted to follow up for non-completion. Only questionnaires returned within 10 weeks after being sent were included in the study.

In New Zealand, the New Zealand Electoral Commission allowed participant-identifying information to be kept, and reminder questionnaires were sent to non-completing participants after 8 weeks. An additional 6 weeks was allowed for these returning questionnaires to be included in the study. To avoid potential contamination, the 4-week safety phase and main 10-week study period ran concurrently in both countries, between October 2015 and February 2016.

4.1.4 Questionnaire Design

The questionnaire designed for the study (Appendix 4) contained sections requiring multiple choice answers, ratings scales, bivariate answers, and free text. In 2013, we conducted an extensive literature search to inform the questionnaire design and considered many factors. The following is a summary of how the literature at the time influenced the design of the questionnaire.

The traditional techniques used for rating scales were visual analogue scales and category ratings scales. Each of these could be used fully labelled at all points along the scale; partially labelled or with qualifiers at intermittent points along the scale; or could be used with end labels only.

The numbers of points could vary with 2, 3, 4, 5, 6, 7, 9, 10 and 11 point scales used in the literature.[2-5] The optimal number of response points that should be used on a scale was controversial.[2,5] Rating scales with large numbers of response categories or complicated question formats were less likely to function well than simpler scales.[6] One reason for this observation was, as the number of response categories increased, the complexity of the choice also increased, leading to a deterioration in response accuracy.

The literature suggested that visual analogue scales were probably more difficult to use compared to category scales.[7-9] Numerical rating scales appeared to have better compliance, responsiveness and ease of use compared to visual analogue scales.[4] The orientation of the scales probably had an effect on scores, with vertical scales producing higher scores compared to horizontal scales.[10] Scales anchored with terms or labels were likely to produce floor or ceiling effects.[13] Scales which used zero in the rating (eg. 0 to 9) may produce different ratings to scales that did not use zero (eg. 1 to 7).[10]

Two-point, three-point and four-point scales had poor reliability, validity and discriminating power.[2] Five-point scales produced lower means and lower floor and ceiling effects compared to 10-point

scales.[3] A study of four-point, five-point, six-point and 11-point rating scales seemed to indicate that more scale points reduced skewness.[11] Only the higher point scales followed normal distributions on statistical applications.

Reliability and validity appeared to increase as the number of response alternatives increased, the optimum number being between four and seven.[12] Scales with more response options produced lower scores, relative to the upper limit of the scale.[13] Respondents seem to prefer seven-point and nine-point scales and 10-point scales.[2]

Overall, the differences between different rating scale techniques were potentially small, but not necessary negligible. Interpretation of the literature in 2013 appeared to point to a horizontal, seven point (1 to 7), category rating scale, with qualifiers, as probably the best rating scale to use. This was therefore the type of rating scale that we decided to use in the iPIT 3 questionnaire. A review of the literature published since then (Sections 4.2.4 and 5.2.4) has not revealed new insights to suggest that if the questionnaire was designed now a different rating scale should be used.

The questionnaire schedule or order in which questions were asked could affect the answers.[14] Questions could potentially exert a positive or negative bias on the answers to subsequent questions. Early questions could have anchoring effects or create an expectation that influenced responses to later questions.

In order to mitigate this order-effect bias we decided to randomise the order in which the main study questions were presented to the respondent. The questionnaire had six main questions based on six triage options presented to respondents. To cover every randomisation permutation of these six questions would require 720 different versions of the questionnaire. This was impractical, therefore we decided to develop only 12 questionnaires, where the six main questions had the same frequency in appearing as the first and the last question in the series, with the remaining questions in between being randomly allocated. Potential participants were randomly allocated one of the 12 questionnaires.

In order to maximize the completion of the questionnaire, demographic questions, and potentially difficult or objectionable questions were be placed at the end of the questionnaire.[14] The theory behind this was that by the time a respondent had reached the end of the questionnaire they were more likely to have developed a positive response set. Also, non-completion of these questions were deemed less important that non-completion of the main study questions.

In 2014, few studies had examined the use of paper-based versus web-based or internet-based surveys for healthcare studies.[15] Preference for completing internet-based health surveys appeared to be dependent on computer ownership.[15] Computer-based surveys conducted in healthcare settings had similar reliability and validity compared to paper-based surveys.[16-20] One study showed a slightly higher response rate using a paper-based survey when compared to three types of solely or partially internet-based surveys, including the use of incentives.[21] However, the costs of running the paper-based survey were double that of the internet-based surveys. On the basis of this limited evidence, we decided to use a traditional paper-based questionnaire, instead of an electronic questionnaire, for the iPIT 3 study.

4.1.5 Sampling Frame

Before expanding the study to include participants from New Zealand, the original intent of the iPIT 3 study was to draw its sample from the entire Australian population, so that its results could be generalizable to the entire Australian community. The New Zealand arm of the study was added after the study protocol that had been approved by the study HREC was presented at an Australia and New Zealand intensive care research conference.

Surveying an entire population is inherently expensive and extremely difficult to do logistically. Therefore the partial investigation of a finite population has become the acceptable norm when gathering statistical variables on groups of individuals.[22]

Probability sampling is the preferred method of sampling to avoid bias.[22] Probability sampling is an approach to sample selection where every person in the sampling frame has a known probability of selection, and that probability is also not zero.[22] This eliminates selection biases and the randomly selected samples are objective and acceptable to the public. However, at the time of the iPIT 3 study, Australia had no database that contained contact information on every person in the country. Probability sampling could not be performed in Australia if the intention was to draw a sample from the entire Australian population. Therefore, the iPIT 3 study had to use a non-probability sampling technique.

Random samples for the iPIT 3 study were be taken from a population within the target population, in this case, voters registered on the Australian Electoral Commission (AEC) electoral roll.[23] It was compulsory for all Australian citizens who had turned 18 years old and who had lived at their residential address for a period of one month to enrol with the Australian Electoral Commission and maintain their enrolment. It was estimated that 95% of Australians eligible to vote were enrolled in the Australian Electoral Commission electoral roll in 2016.[24] It was acknowledged that one of the limitations of this study was external validity as the results could only be generalizable to the population that they were drawn from, not the entire Australian community.

Other potential survey methods to sample the Australian population were considered for the iPIT 3 study. Surveys could either use a self-completion method or an interviewer-based method. A self-completion survey was where a questionnaire was given to a participant in paper form or in electronic form. An interviewer-based method involved direct questioning of a participant by trained data collectors. These interviews could be in-person, or telephone-based.

At the time of the iPIT 3 study in 2015, video-based interviews and video-conferencing capability were not routinely available to most of the Australian population. A common in-person interview technique at the time was the door-to-door census approach. Telephone interviewing was also performed and commonly used a computer-assisted technique utilising telephone databases. The major sampling frames from which random lists of participants could be generated were internet databases, telephone listings or electoral rolls.

In 2015, the door-to-door census approach generated the highest participation and response rates in Australia, but was labour-intensive, expensive, confined to distinct geographical areas, and were dependent on visits coinciding with times that householders were at home.[25,26] The electoral roll provided the next widest sampling rate. In a study that interviewed people living in a defined NSW post code area using door-to-door interviews, the electoral roll was found to list 84.3% of the participants and the telephone directory listed 82.2%.[25] The study found that younger people, people who did not own their own home, and people born outside of Australia were less likely to be included in the electoral role and telephone directory sampling methods. The telephone directory

was more likely to exclude people with higher occupational prestige, while the electoral role was more likely to exclude unmarried persons and males. The study was conducted in 1997, and the Australian Bureau of Statistics had shown that the use of fixed or landline phones had been declining.[27]

Telephone sampling has other sources of bias. Access panels may not be truly random, as many respondents in surveys respond for reward (such as shopping discounts), or the surveys were established for particular sampling purposes. Also, truly random telephone dialling in Australia in 2015 was confined to landline dialling, and did not access mobile phones at the time. Less than half of the Australian population aged over the age of 14 years in 2013 owned a Smartphone.[28]

In 2015, internet databases were problematic due to limited coverage, and the reliance on people with access to computers.[26,27] At the time, the largest global internet databases, such as "Survey Monkey", had established access panels for countries such as the USA, but not for Australia.

The last Australian Census of Population and Housing (the Census) to use solely an in-person data collection technique was in 2011, but this Census required the employment of 43000 data collection staff.[29] The first digital-based, online Census was not held until 2016.[30] The 2016 and 2021 Census' used a newly developed National Address Register. However, the register only recorded property addresses, and did not record the names of individuals residing at those addresses.

The use of electoral commission rolls from individual states, such as the NSW Electoral Commission, only captured participants within the state. This may not have provided results that were generalizable to the wider Australian community. The Australian Electoral Commission electoral roll had been used successfully to recruit participants in case-control studies, cross-sectional studies, and in targeting populations with specific demographics.[26] Australian Electoral Commission records had good coverage and accuracy. Because of these reasons we decided to use the Australian Electoral Commission electoral role as the sampling frame for our study.

4.1.6 Australian Electoral Commission

The Commonwealth laws which governed the Australian Electoral Commission recognised the importance of conducting medical research, however the primary purpose of the Commonwealth electoral roll was to register Australian citizens to vote in federal elections.[23] Medical research was only considered an ancillary use of the personal information. The laws were designed to ensure that the privacy of individuals was protected, and ensure that the public interest in the medical research was properly considered against the privacy breach that necessarily resulted when the personal information was provided by the Australian Electoral Commission to third parties.

The Australian Electoral Commission was considered a Commonwealth agency and was therefore subject to the provisions contained in the Privacy Act 1988.[31] This Act regulated the collection, storage, use and disclosure of personal information. The Australian Electoral Commission was also subject to the specific provisions contained in the Commonwealth Electoral Act 1918 (The Electoral Act) dealing with the use and disclosure of information from the Commonwealth electoral roll.[32]

The information contained on the electoral roll included the name and address of electors together with some other identifiers and therefore came within the scope of the definition of "personal information" in the Privacy Act 1988. It was this information which made it an ideal sampling frame for the iPIT 3 study.

The Electoral Act contained provisions that regulated the people and organisations that the Australian Electoral Commission was lawfully able to use information from the Commonwealth electoral roll, the information that was able to be disclosed, and the permitted lawful uses of that information. To be an eligible to appear on the electoral roll, a person had to be 18 years of age and an Australian citizen, with the exception of some British subjects who enrolled prior to 26 January 1984.

Under the Electoral Act, a public version of the Commonwealth electoral roll was required to be made available by the Australian Electoral Commission for public inspection at premises occupied by the Australian Electoral Commission during office business hours. Any person, including medical researchers, had a legal right to attend an Australian Electoral Commission office and to inspect the public version of the Commonwealth electoral roll. However, there were some limitations on this right. No copies or images of the electoral roll were allowed to be taken. The public version of the electoral roll was accessible only on a computer at the Australian Electoral Commission premises. Finally, the public version of the electoral roll that could be inspected did not include the address details of all eligible electors. Some "silent electors" and certain other categories of electors were excluded.[23] This meant that researchers had to obtain more detailed information directly from the Australian Electoral Commission if they wanted to use the electoral roll for medical research.

One "permitted purpose" for the use of the Commonwealth electoral roll was to supply information for use in conducting medical research. This use had to be in accordance with the “Guidelines Under Section 95 of the Privacy Act 1988”, issued by the National Health and Medical Research Council (NHMRC).[33] The Guidelines required that any proposals by a medical researcher to a Human Research Ethics Committee (HREC) had to specify the reasons why identifiable personal information was needed, the source of the data, the amount of data needed, and a list of the information privacy principles (IPP) that may be breached.

The proposal had to set out the reasons why the public interest in carrying out the proposed research outweighed, to a substantial degree, the public interest in adhering to the information privacy principles. Also, if the Australian Electoral Commission subsequently agreed to release the personal information from the Commonwealth electoral roll, a researcher was required to advise the elector of the complaints mechanism to the Human Research Ethics Committee and the Office of the Australian Information Commissioner about the proposed use of the personal information. This information had to be included in the proposal to the Human Research Ethics Committee and the protocols that were developed to support the medical research.

The Human Research Ethics Committee was required to determine whether the public interest in the medical research outweighed the public interest in the protection of the elector's privacy. The Australian Electoral Commission viewed that the larger the data-set that was requested the larger the privacy breach that would be committed if the Australian Electoral Commission agreed to comply with the request.

The final decision to disclose personal information rested with the Australian Electoral Commission, who could decline disclosure of the personal information even though a Human Research Ethics Committee had approved medical research in accordance with the guidelines and laws. A pragmatic issue that also had to be factored into any application to access the Australian Electoral Commission electoral roll, was the limited staff capacity that the Australian Electoral Commission had during times of state and federal elections to attend to medical research requests.

Following the Human Research Ethics Committee approval of the iPIT 3 protocol, the Australian Electoral Commission approved our application to use the Australian Electoral Commission electoral

roll as the sampling frame for the study. Our application fulfilled all the necessary legal requirements and our request was made during a time when there were no upcoming state and federal elections.

4.1.7 Safety Phases

Initial testing of the questionnaire was conducted on consenting volunteers and no safety issues were identified. However, there were concerns that the sensitive material contained in the questionnaires could still be potentially psychologically confronting for some participants and could cause distress. Due to this concern the study was conducted in two phases.

The first phase was a 4-week safety phase where 200 questionnaires were sent initially to a random sample of registered voters extracted from the Australian Electoral Commission electoral roll and 200 questionnaires were sent to a random sample of registered voters extracted from the New Zealand Electoral Commission electoral roll. These were used to determine if there were any unknown safety concerns that were not apparent during the initial consumer testing. The responses to these first 200 questionnaires were reviewed by an independent safety monitor after 4 weeks. No additional safety concerns were identified by the independent safety monitor, therefore the study was allowed to proceed to the second phase.

The second phase was the main 10-week study phase where the remaining 1800 questionnaires in Australia and the remaining 1800 questionnaires in New Zealand were distributed.

4.1.8 Statistical Analysis

The response rate was defined as the number of questionnaires returned divided by the number of questionnaires sent.[34] Our literature review of studies using the Australian Electoral Commission electoral roll for mail-out surveys found that the best response rate in any study at the time was 21%.[43] Assuming that the least popular answer was chosen by 5% of the respondents, it was estimated that 1800 questionnaires would need to be sent to obtain a 95% confidence interval (CI) of 10% for the least popular answer. Rounding up, we set the mail-out size at 2000.

Expected population figures were derived from Australian Bureau of Statistics data from June 2015 and New Zealand Census data from 2013.[35-38] In a planned analysis, proportions with 95% CIs were calculated for the primary question. We used histograms, means, standard deviations, medians and interquartile ranges to describe the secondary answers. Analysis was performed by an independent statistician using Excel 2010 (Microsoft).

4.1.9 Results

The response rate in the main 10-week study period was 15.1% (301 replies) in Australia and 18.0% (359 replies) in New Zealand. In New Zealand, a further 181 replies were received in the 6 weeks after the reminder questionnaire mail-out for non-completing participants, giving a final response rate in New Zealand of 27.0%.

The residing state, territory or province of respondents is shown in Figure 4A, with expected population figures. The age of respondents is shown in Figure 4B, with expected population figures.

Figure 4A - Proportions and numbers of questionnaire responses, by state, territory or province of respondent and actual population proportions

Figure 4A-A – Proportion and number of Australian questionnaire respondents according to state or territory

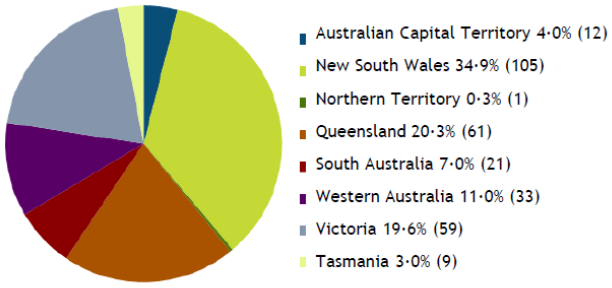


Figure 4A-B – Proportion and number of New Zealand questionnaire respondents according to province

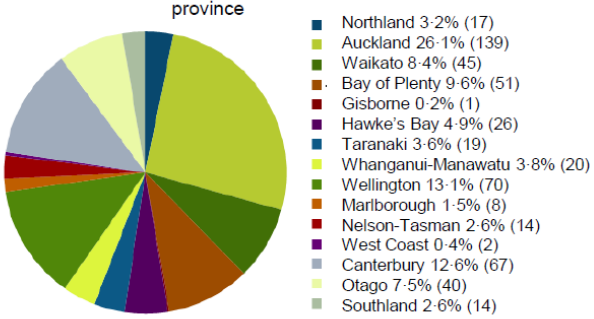


Figure 4A-C – Actual proportion of Australian population residing in state or territory *

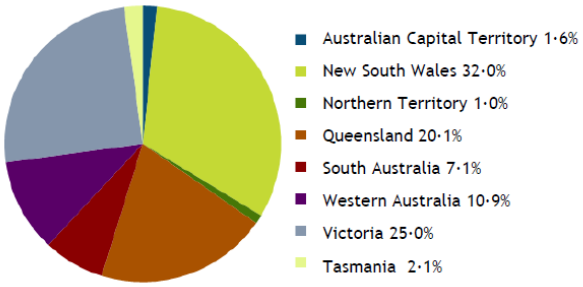
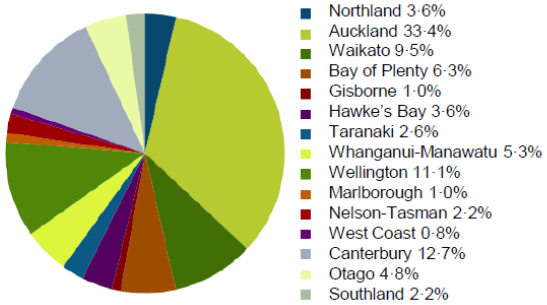


Figure 4A-D – Actual proportion of New Zealand Population residing in province **



* According to Australian Bureau of Statistics data from June 2015.[35]

** According to New Zealand Census data from 2013.[36]

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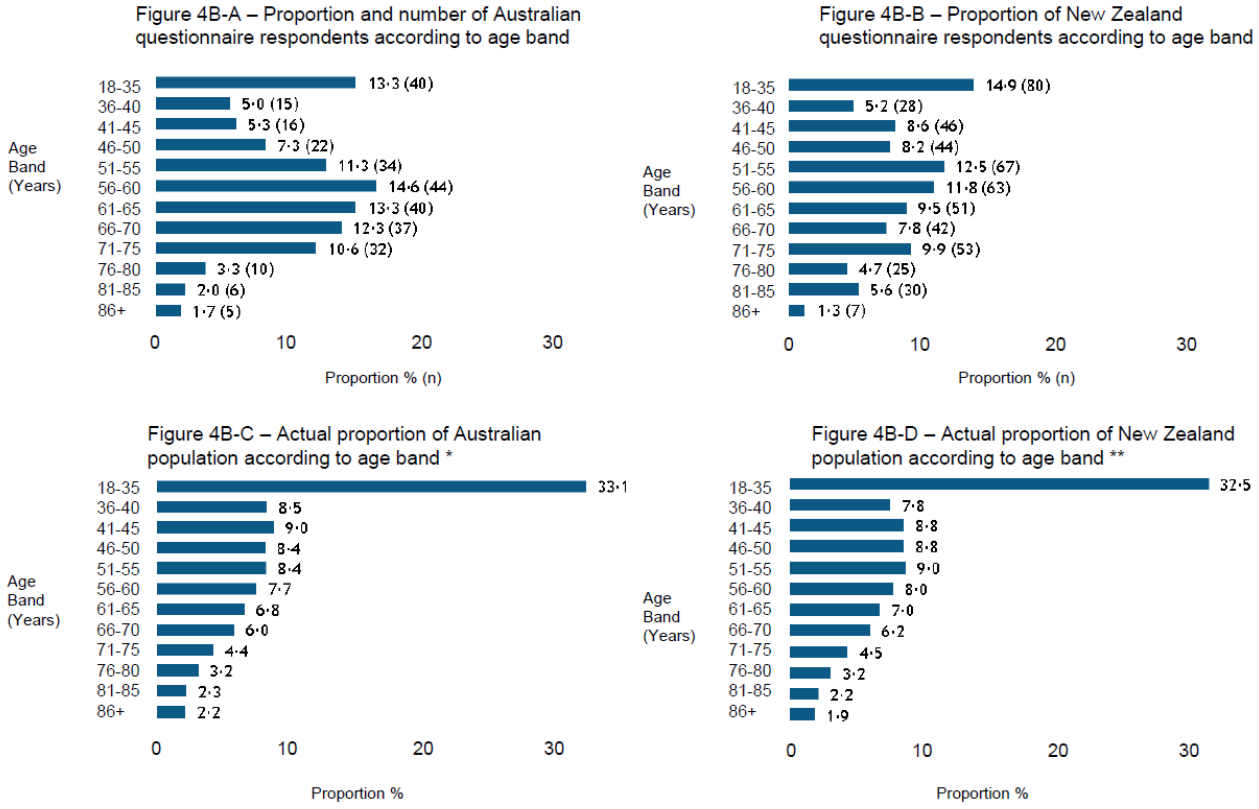
Figure 4B - Age of questionnaire respondents, and actual age distribution of the population



* According to Australian Bureau of Statistics data from June 2015.[37]

** According to New Zealand Census data from 2013.[38]

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The proportion of male respondents was 44.4% (132 respondents) in Australia and 42.7% (228 respondents) in New Zealand. The population proportion of men in Australia was 49.3% and 48.5% in New Zealand.[37,38]

The preferred method chosen by respondents to triage patients to the ICU in a major influenza pandemic is shown in Figure 4C.

Figure 4C - Respondent preference for Question 1 – "Which of the 6 methods do you think is the best way to decide which patients get to be transferred to the intensive care unit (ICU) in a major influenza pandemic disaster, when there are not enough resources to treat everyone? (Choose only 1 option)"

Figure 4C-A – Preferred ICU triage method in Question 1 from Australian respondents

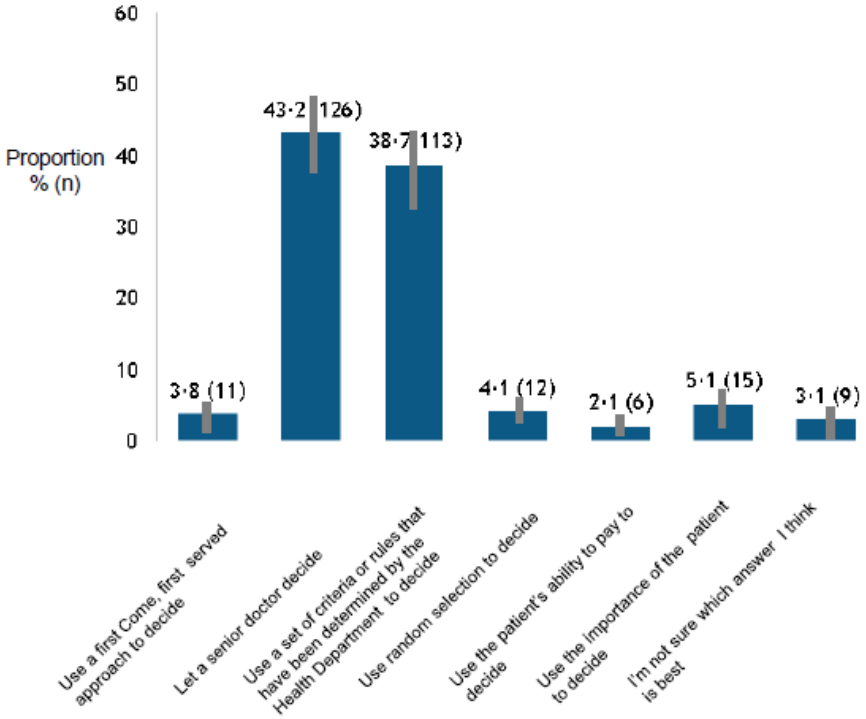
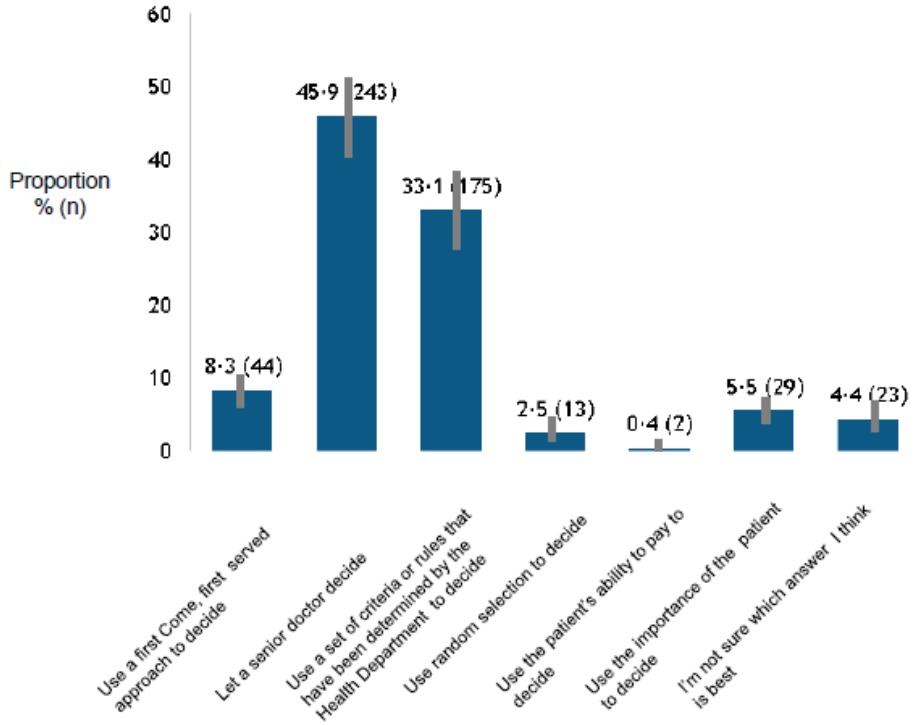


Figure 4C-B – Preferred ICU triage method in Question 1 from New Zealand respondents



I-Bars indicate 95% confidence intervals
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Allowing a senior doctor to decide was the most preferred method (43.2%; 95% CI, 37.5%–48.8%) among Australian respondents, but the next most preferred method of using triage criteria predetermined by the Health Department to decide (38.7%; 95% CI, 33.1%–44.3%) was not significantly different. Among New Zealand respondents, the most preferred method was to allow a senior doctor to decide (45.9%; 95% CI, 41.7%–50.2%). This was significantly higher than the second most preferred method of using triage criteria predetermined by a Health Department to decide (33.1%; 95% CI, 29.1%–37.1%).

Respondents' perceptions of fairness for each of the six methods that could be used to triage ICU patients in a major influenza pandemic are shown in Figure 4D.

Figure 4D is shown on the next 3 pages

Figure 4D - Respondent views on fairness for methods listed in questionnaire to triage ICU patients during an influenza pandemic

Figure 4D-A – Response to Question 2 – "How fair do you think it is to use a first come, first served approach to decide who gets treated in a disaster, when there are not enough resources to treat everyone?"

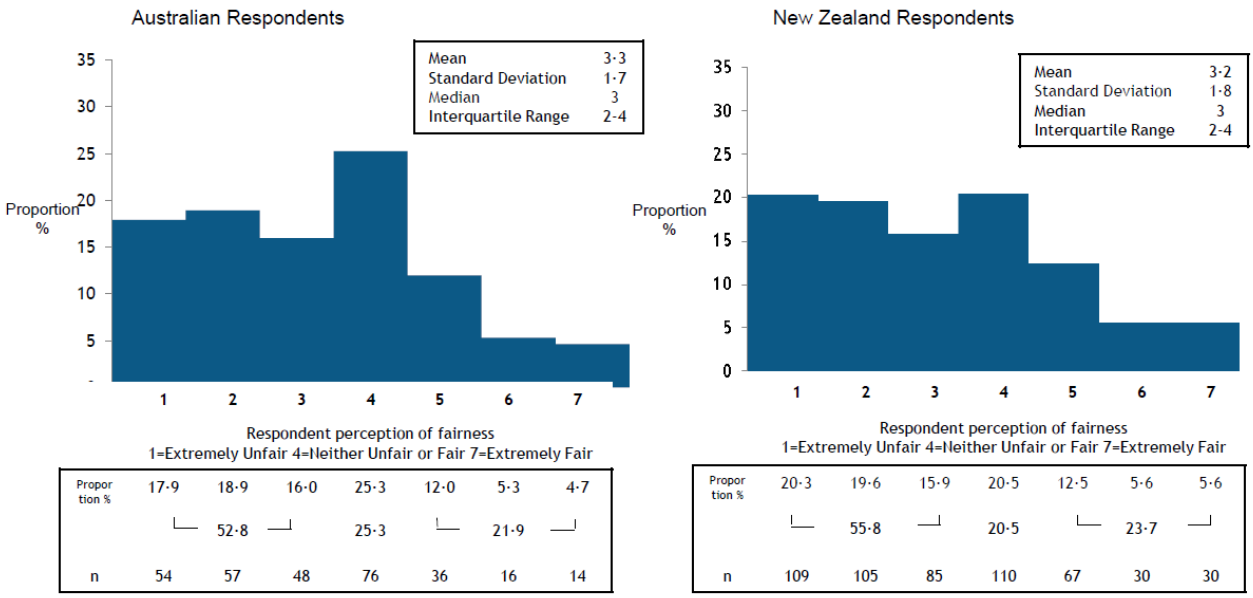


Figure 4D-B – Response to Question 3 – "How fair do you think it is for a senior doctor to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

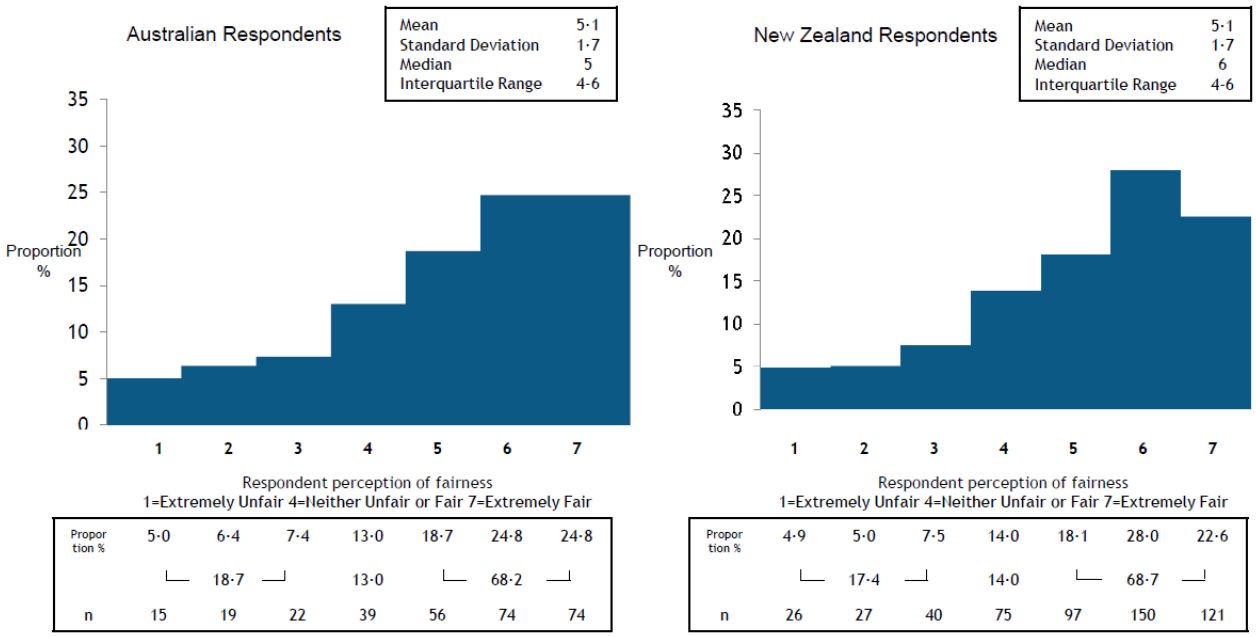


Figure 4D is continued on the next page

Figure 4D-C – Response to Question 4 – "How fair do you think it is to use a set of criteria or rules from the Health Department to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

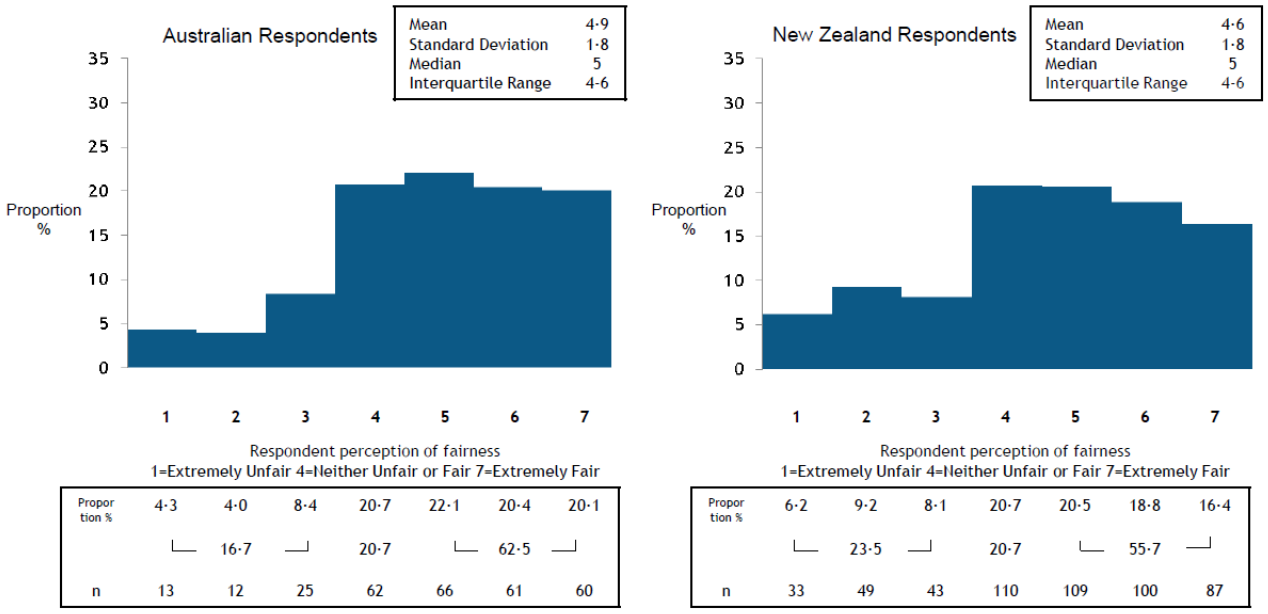


Figure 4D-D – Response to Question 5 – "How fair do you think it is to use random selection to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

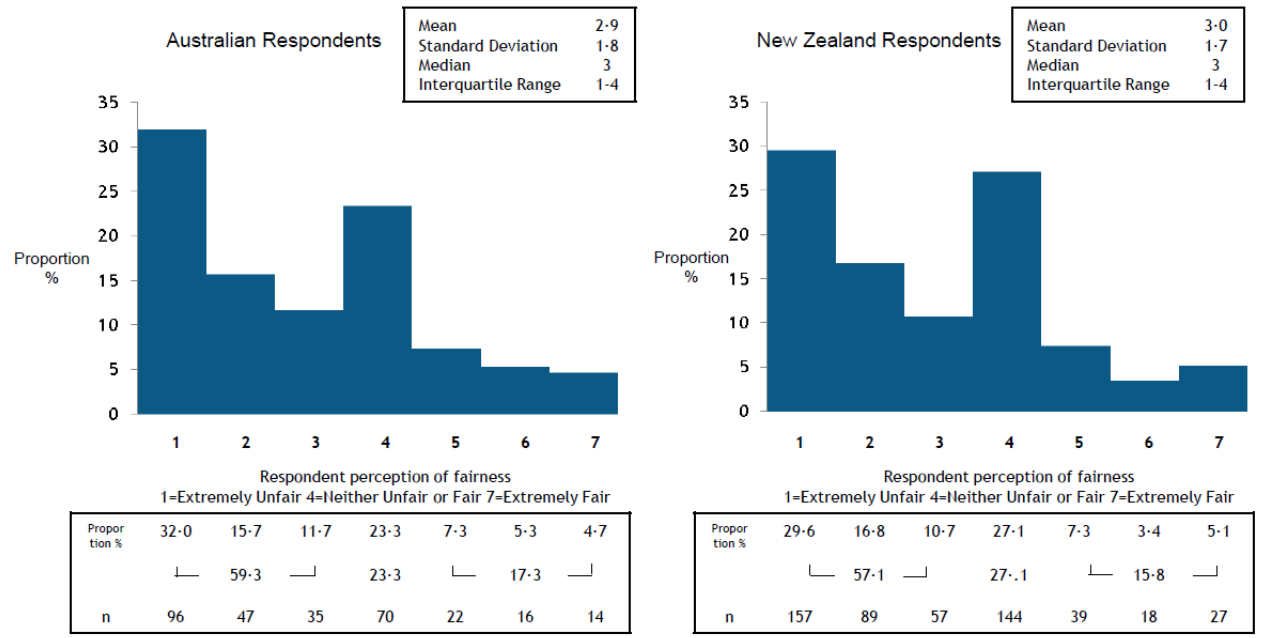


Figure 4D is continued on the next page

Figure 4D-E – Response to Question 6 – "How fair do you think it is to use a person's ability to pay to decide who gets treated in a disaster, when there are not enough resources to treat everyone?"

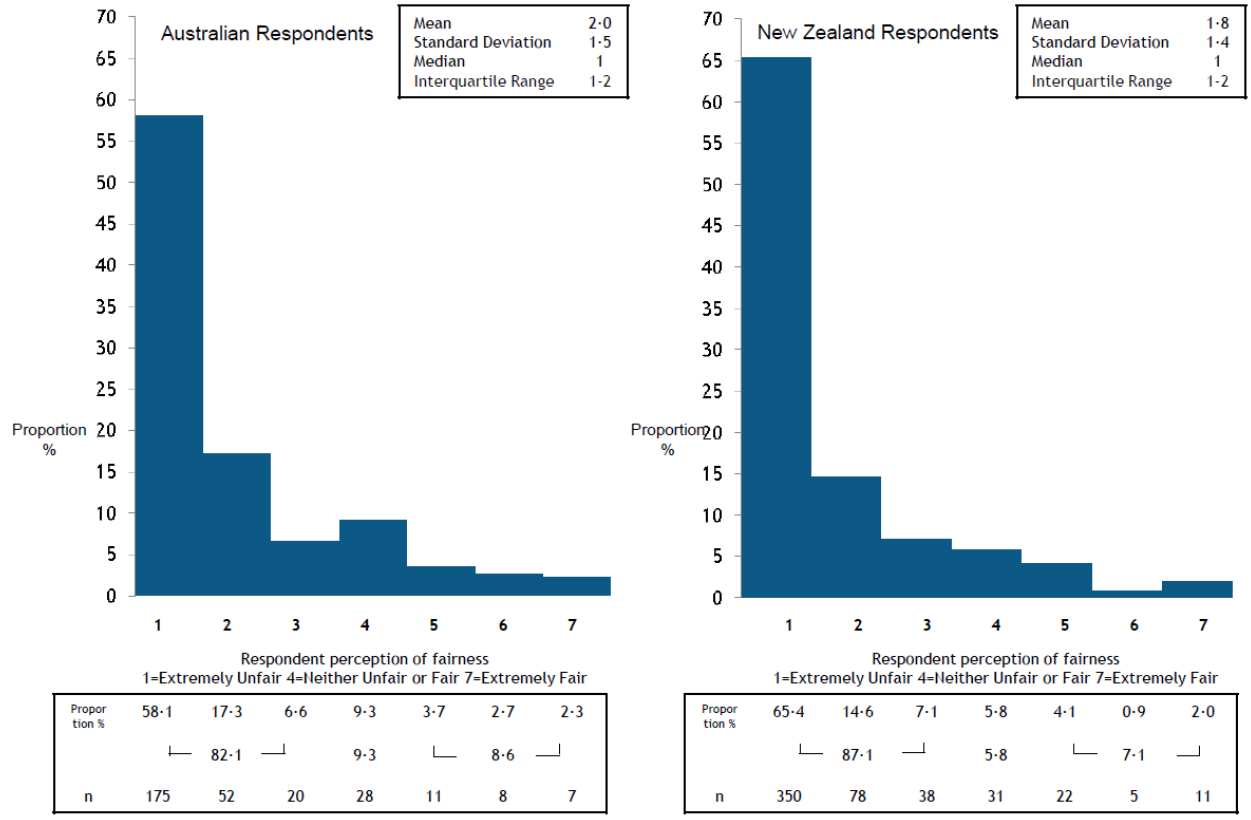
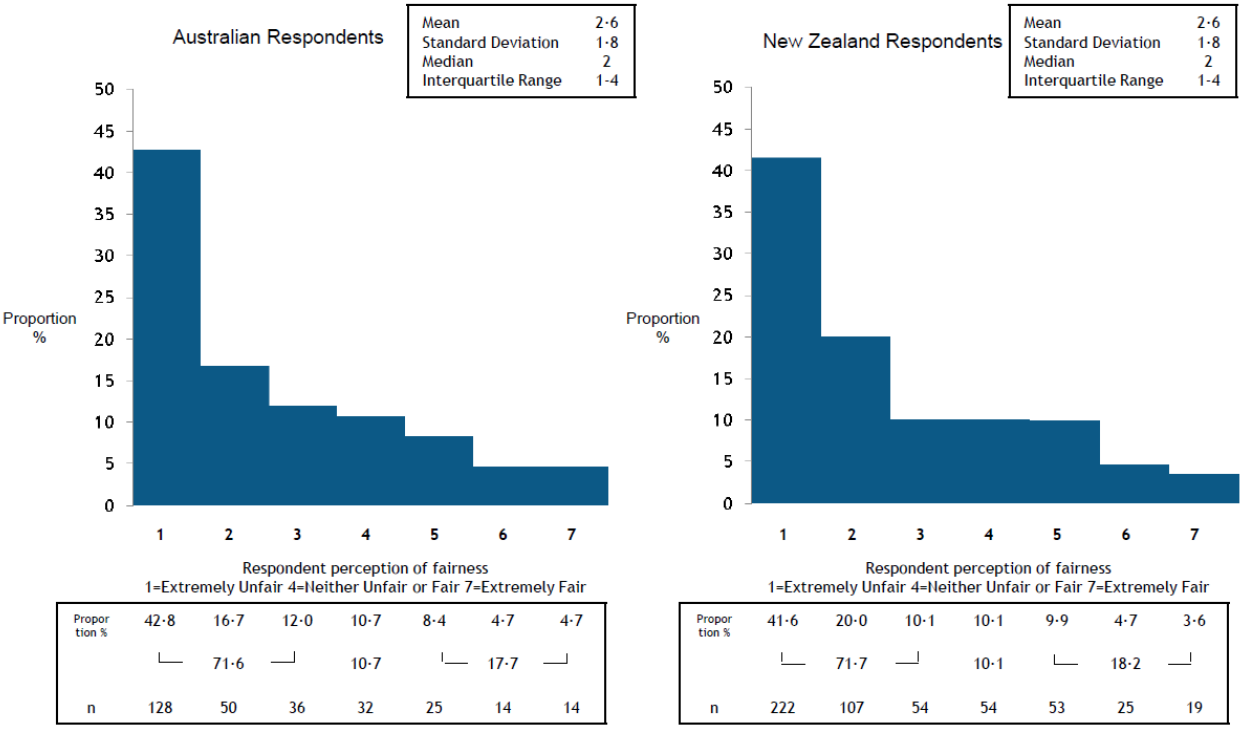


Figure 4D-F – Response to Question 7 – "How fair do you think it is to use a person's importance to decide who gets treated in a disaster, when there are not enough resources to treat everyone?"



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Respondents in both countries considered that both allowing a senior doctor to decide (Figure 4D-B) and using triage criteria predetermined by a Health Department (Figure 4D-C) to decide were fair (rated as greater than four on the rating scale). A large proportion of respondents considered that triage decisions based on a "first come, first served" method (Figure 4D-A), random selection (Figure 4D-D), ability to pay (Figure 4D-E), or a person's importance (Figure 4D-F), were unfair (rated as less than four on the rating scale).

Respondents' perceptions of fairness for three additional selection criteria that could be used to triage patients in a major influenza pandemic are shown in Figure 4E.

Figure 4E – Respondent views on fairness for additional selection criteria listed in questionnaire to triage ICU patient during an influenza pandemic

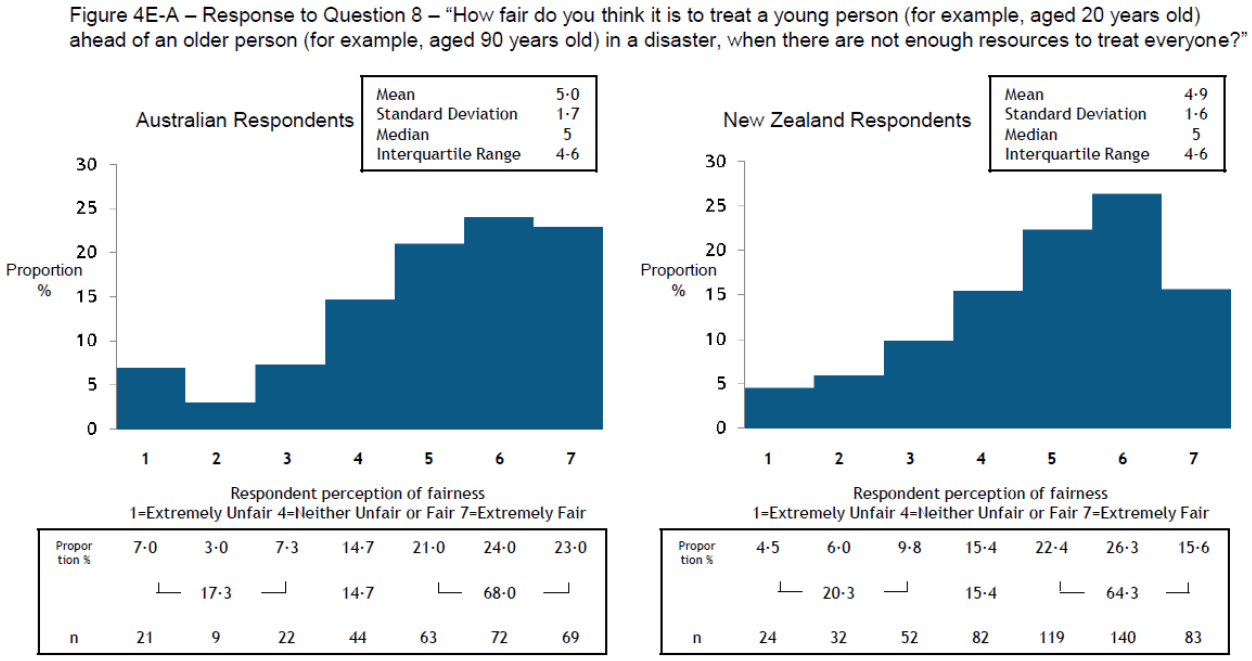


Figure 4E is continued on the next page

Figure 4E-B – Response to Question 9 – "How fair is it to use a person's chance of surviving to decide who gets treated in a disaster, when there are not enough resources to treat everyone?"

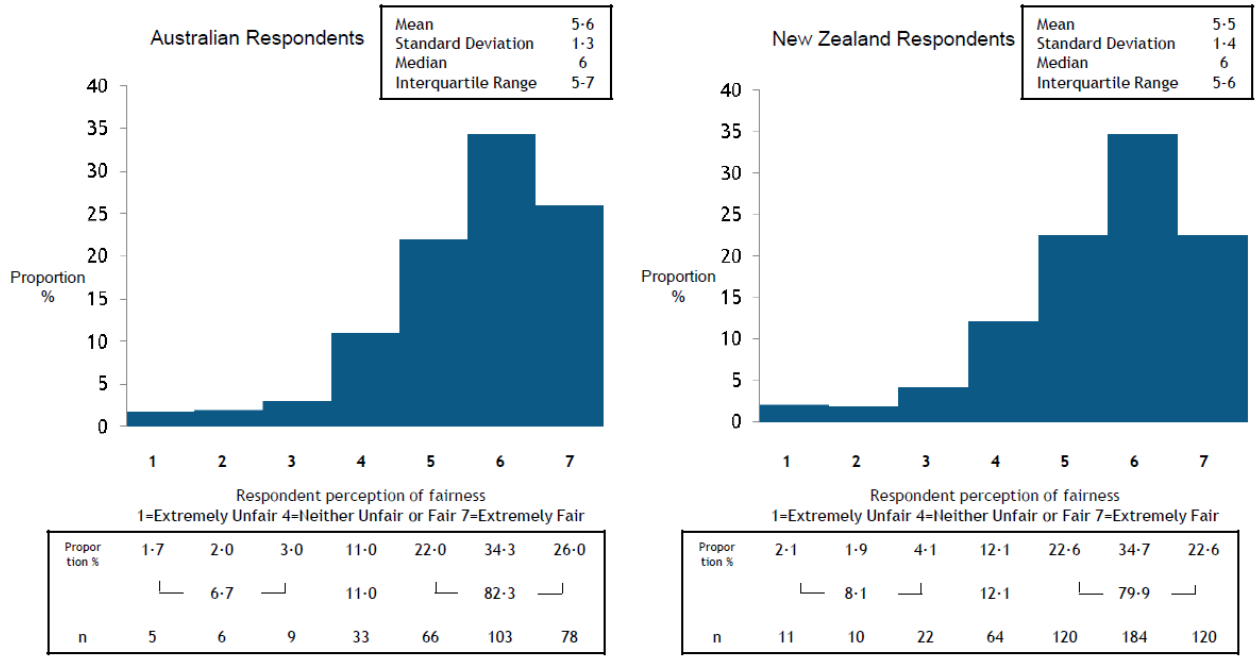
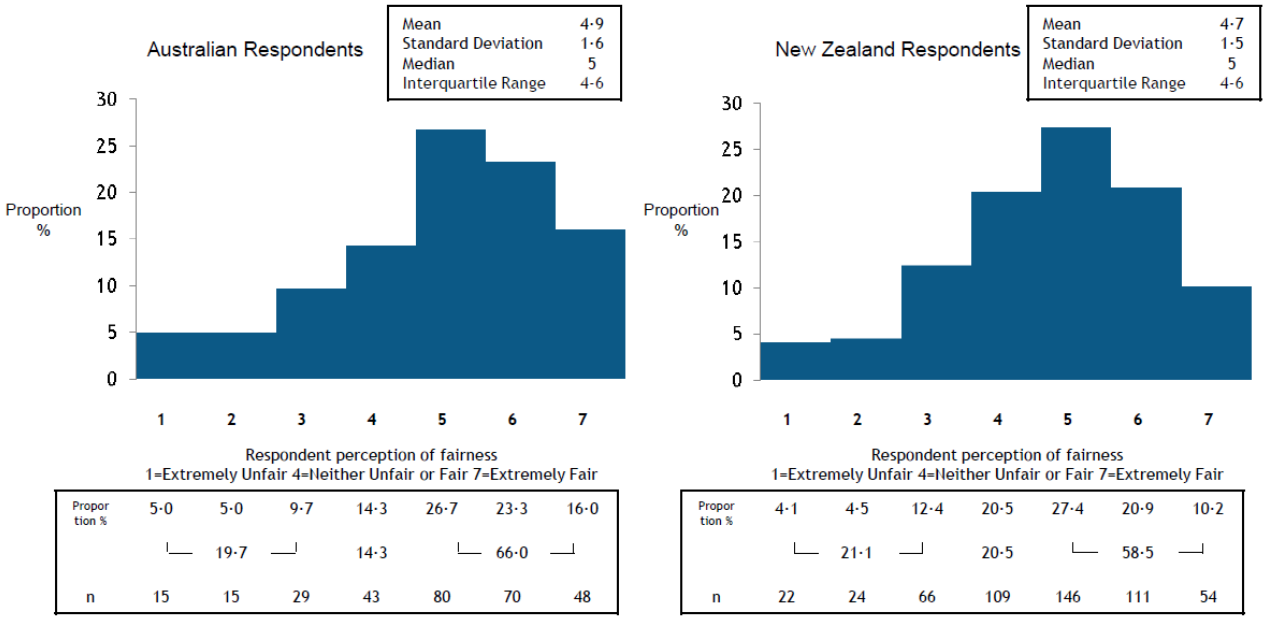


Figure 4E-C – Response to Question 10 – "In a disaster, when there are not enough resources to treat everyone, how fair do you think it is not to treat a person because they have a long term (also called chronic) medical condition which makes them less likely to survive?"



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Most respondents in both countries considered using a person's chance of survival (Figure 4E-B) as a basis for triage decisions to be fair. A smaller majority of respondents in both countries also considered treating younger people ahead of older people (Figure 4E-A) and on the basis of chronic comorbidity (Figure 4E-C) to be fair.

Free-text comments regarding the use of age as a selection criterion reflected that this distinction diminished as the age gap narrowed. Some comments from older respondents were critical of modern medicine prolonging life unnecessarily. Some older respondents indicated that they had lived fulfilling lives, and that they would be happy for a younger person to take their place in the ICU in such a scenario.

Comments suggested that respondents in New Zealand were more trusting of senior doctors and less trusting of government and health departments to look after their best interests in a pandemic scenario. However, respondents who favoured the use of pre-determined criteria ahead of allowing senior doctors to triage cited several reasons. One reason was that placing the burden of decision making in such a difficult circumstance on one or several individuals would be unfair and potentially psychologically traumatic to those individuals. A second reason was that potential bias, prejudice or nepotism could occur if individuals made decisions based on sole discretion. A third reason was that pre-determined selection criteria were more transparent and accountable if they were ever to be legally contested.

4.1.10 Discussion

This binational survey addressed one of the ethical challenges that would present if an influenza pandemic disaster were to occur and the demand for intensive care resources significantly exceeded capacity, in Australia and New Zealand. This study showed that in Australia, most respondents preferred that triage to an ICU in a pandemic scenario be performed by either a senior doctor or by using pre-determined health department criteria. In New Zealand, triage by a senior doctor was the most preferred method. Most respondents in both countries considered both these methods to be fair overall, and perceived the other four triage methods as being unfair.

The reason for the difference between Australia and New Zealand was unknown. Both countries had predominantly universal-access public health care systems, but Australia had a larger coexisting user-pays system. Recent political history in both countries at the time of the study, and comments from the survey, suggested that there may be differences in the trust that the public had in government.

The major benefit of allowing senior doctors to allocate resources using sole discretion, during a resourcing crisis, was the ability to quickly respond to constantly changing supply and demand. However, potential problems with accountability and perception of bias remained using this method. Given that respondents in this study perceived the use of triage criteria also to be fair, we proposed that, during an influenza pandemic, when resources are overwhelmed, ICU triage should be performed using pre-determined criteria to provide a basic framework, with a senior doctor making the final decisions. We proposed that this method would be acceptable to the general public and would provide a degree of transparency and accountability.

The questionnaire contained three questions to specifically gauge the public's view on the use of age, predicted mortality and chronic comorbidity as selection criteria, because these criteria were used in ICU triage protocols at the time.[39-41] As respondents considered all three criteria as being fair, we proposed that it was reasonable to continue the use of these criteria in such protocols.

There were no large cross-sectional studies surveying the views of the general public on methods to triage ICU patients in an influenza pandemic at the time of this study. A small Massachusetts study used focus groups involving 30 members of the public to obtain opinions on scenarios related to pandemic planning.[42] These consumers were strongly opposed to any model of limiting critical care.

4.1.11 Strengths and Limitations

The limitation of the study was non-response bias due to the small sample size and low response rate. A low response rate was expected, based on results of previous studies, the variable willingness of the general public to complete written questionnaires, and the large geographical spread of the populations.[43,44] Many of the randomly selected, invited participants lived in rural areas with limited access to postal services. Privacy concerns by the Australian Electoral Commission prevented follow-up questionnaires being sent in Australia to non-responders. In New Zealand, sending a second questionnaire to non-responders improved the response rate by 50%, but the overall response rate remained low, although consistent with similar studies.

Our study used strategies to mitigate bias and to maximise the generalisability of the results. We performed an extensive literature search and consulted design experts to determine the optimal questionnaire design, specifically using a horizontal, seven-point rating scale with qualifiers, which provided the most accurate results.[8,10] The use of qualifiers, such as "neither unfair or fair" resulted in anchoring effects, especially as seen in Figures 4D-A and 4D-D, but these effects did not significantly influence the final interpretation.

Order effect bias was mitigated by the use of different versions of the study questionnaires with the order of the six triage methods and secondary questions randomised. The questionnaire was extensively tested and potential harm was minimised with the use of an initial safety-phase mail out. Attempts to improve the response rate were made through the use of pre-notification letters, reply-paid envelopes, minimising questionnaire content and the use of a design expert to improve the questionnaire's attractiveness.

The sampling frame was representative of the general adult population in both Australia and New Zealand, because registration on the electoral roll was compulsory. The geographical spread of respondents was consistent with the expected populations, but the higher proportions of women and older respondents in both countries may be a potential source of bias. The reason for this observation is not known, but the age bias was observed in a previous study using the Australian Electoral Commission database.[43] The study did not sample people aged under 18 years of age, nor those not enrolled on the electoral rolls, so our results cannot be generalised to these groups.

During the study's conception, other potential sampling frames were considered, such as internet and telephone databases, but these were discounted due to their lack of generalisability to the overall adult populations of both countries, as well as cost. Internet databases had the potential to generate a large sample size, but were not well established in both countries, and were potentially biased by respondents being financially remunerated, or belonging to specific niche consumer groups.

The study did not invite the public to make an ethical judgment, nor did it offer an ethical analysis of the choices presented in the survey. We merely asked respondents to choose between six different methods of triage, all of which could be said to have a reasonable ethical basis, and to rate these for a single ethical criterion of fairness.

4.1.12 Implications and Unanswered Questions

Our study demonstrated that in Australia, respondents considered both the use of a senior doctor or pre-determined health department criteria to triage ICU patients in an influenza pandemic to be fair. Therefore we proposed that both of these methods would be reasonable and acceptable to the general public for triaging intensive care patients in a future pandemic disaster, where the demand for ICU beds overwhelmed ICU bed availability.

Combining both a senior doctor assessment with pre-determined health department criteria to triage intensive care patients in an influenza pandemic would provide both a degree of transparency and accountability. It could also provide flexibility to adapt quickly to changes ICU demand and ICU bed availability. Using pre-determined health department criteria on its own would be more transparent, but in their current form, pre-determined health department criteria would not have operational flexibility.

Our study also demonstrated that respondents considered it fair to base intensive care triage criteria on age, chance of survival, and chronic comorbidity. We therefore proposed that it would also be reasonable that a senior doctor assessment and pre-determined health department criteria have criteria based on age, chance of survival, and chronic comorbidity. However, our proposals for intensive care triage in a pandemic posed several ethical and legal questions.

First, though the general public appears to indicate that intensive care triage using a senior doctor and predetermined criteria in a theoretical major pandemic is acceptable, it remains unknown whether families and patients directly affected by these triage decisions would find intensive care triage acceptable. We hypothesized that surrogate decision-makers or patients may find the concept of intensive care triage less acceptable than that of the general public because of their first-hand experience with intensive care. Second, basing intensive care triage criteria on age is straight forward as age is easy to determine, but basing triage criteria on chance of survival and chronic comorbidity is problematic because of the potential difficulties in defining these concepts.

Third, under Australian law, basing intensive care triage criteria on age, chance of survival, and chronic comorbidity may not actually be lawful. Fourth, the views and needs of disadvantaged groups, such as indigenous populations, were not examined in this study. It is known that these groups are likely to be disproportionately affected by influenza pandemics.[45,46] It is likely that disadvantaged groups may require more resources in a major pandemics, but how this should be managed and whether the general public find this acceptable has not been determined.

Fifth, our study only examined how to manage intensive care triage in adult patients. It remains unknown how intensive care triage in children should be managed. Sixth, this study was conducted in two developed countries with universal-access public health care systems. Whether the results apply to other countries, particularly those with user-pays or resource-limited health care systems also remains unknown.

In light of some of the unanswered ethical questions we decided to conduct two further studies. To address the ethical question of whether families directly affected by these triage decisions would

find intensive care triage criteria acceptable to exclude patients from the ICU, we conducted the influenza Pandemic ICU Triage 4 (iPIT 4) Study. This study specifically surveyed surrogate decision-makers of patients in the ICU on how they perceived the fairness of the use of triage criteria to allocate intensive care resources in a pandemic. At the time we were not aware of any studies that had ascertained the views of surrogate decision-makers on the use of triage criteria to prioritise intensive care resources in any scenario, let alone during a pandemic disaster.

To address the ethical questions of how to use comorbidity, how to account for disadvantage, and how to incorporate the concept of reciprocity, in triaging intensive care patients in a pandemic, we conducted the ICU Pandemic Triage (IPT 5) Study. Like the iPIT 3 study, this study surveyed the general Australian population. At the time we also were not aware of any studies that had ascertained the views of the general Australian public on these specific ethical issues.

4.2 The influenza Pandemic ICU Triage 4 (iPIT 4) Study - A Survey of Surrogate Decision-Makers for Intensive Care Patients on the Use of Triage Criteria in an Influenza Pandemic

4.2.1 Objective

The primary objective of influenza Pandemic ICU Triage 4 (iPIT 4) Study (A Survey of Surrogate Decision-Makers for Intensive Care Patients on the Use of Triage Criteria in an Influenza Pandemic) was to determine how surrogate decision-makers for patients in the ICU perceived the fairness of the use of triage criteria to allocate intensive care resources during an influenza pandemic, using a rating scale.

4.2.2 Methods

The study was a voluntary survey using a written questionnaire given to surrogate decision-makers of patients in the ICU or patients who had been recently discharged from the ICU. The iPIT 4 study was the second study in this thesis.

As the study was a survey, no single primary outcome measure was used. The overall outcome measures were the ratings that participants provided to the study questions using the rating scale. Further exploratory information in the form of narratives were obtained from participants on their views of the scenarios used in the questionnaire. The planned sample size was 1600 distributed questionnaires.

The study safety phase started in 2019. The study was originally planned to run in non-pandemic conditions, but the start of the COVID-19 pandemic in Australia in 2020 meant that the main study phase was conducted during an actual pandemic. However, the study completion has been delayed because of participant recruitment restrictions during the COVID-19 Pandemic. Visitation by surrogate decision-makers to ICUs in NSW and Queensland, where the IPIT 4 study was being conducted, was significantly limited by State health department policy in 2020 and 2021, and continued to be limited in 2022, at the time of writing this thesis.

Ethical approval to conduct the study was obtained from the Sydney Local Health District - Concord Repatriation General Hospital - Human Research Ethics Committee (Approval Number HREC/18/CRGH/201 – CH62/6/2018-143 – 3rd October 2018). Site Specific Approvals (SSA) to conduct the study were obtained with the assistance of local investigators at the following eight sites in New South Wales and Queensland:

New South Wales

Bankstown Hospital
Blacktown Hospital
Concord Repatriation General Hospital
Nepean Hospital
St Vincent's Hospital
Westmead Hospital

Queensland

Prince Charles Hospital
Rockhampton Hospital

The study was coordinated from Concord Repatriation General Hospital. At the time of writing this thesis the study had been completed at one site (Westmead Hospital); had been partially completed at three sites (Concord Repatriation General Hospital, Prince Charles Hospital and Rockhampton Hospital); and had not commensed at the other four sites. The study originally planned to include two sites in New Zealand, but these sites were unable to participate because if staffing constraints during the COVID-19 pandemic.

4.2.3 Questionnaire

A specific questionnaire was developed for the study (Appendix 5). A graphic designer helped with the colour scheme and layout of the questionnaire. The eight-page questionnaire contained a "make-believe" situation (Box 4E), where Australia had been affected by an influenza outbreak that had been declared a major disaster by the government.

Box 4E is shown on the next page

Box 4E – Influenza Pandemic Scenario used in the iPIT 4 Questionnaire

The Make-Believe Situation

REMEMBER, THIS IS A MAKE-BELIEVE SITUATION.
It is NOT real, but it could occur in the future. Some of the scenarios that follow may be confronting or cause distress for some people. If you feel distressed there is no need to complete this questionnaire.

Imagine that Australia has been affected by a fast spreading influenza outbreak (influenza is also called the flu).

This is the worst influenza (flu) crisis that Australia has ever seen.

Many people have become sick. Schools and some businesses have closed.

The government has declared the situation a major disaster.

Your local hospital is overloaded with patients, and is unable to cope.

THE PROBLEM

There are not enough beds in the Intensive Care Unit (ICU) to treat all the critically unwell patients. This means that some patients will not be treated. These patients are unlikely to survive.

Patients cannot be moved to other hospitals as every hospital is in the same crisis situation.

Imagine that the Health Department has put in place a process to decide which patients will be treated in the ICU because of this disaster situation. This process uses specific criteria or rules (sometimes called triage criteria). These criteria determine the priority in which patients should be treated in a disaster.

The process excludes patients from being treated in the ICU:

- If doctors do not think the patient will survive.
- If the patient has a long-term medical condition (also known as chronic medical condition) that makes them less likely to survive (examples of these conditions include cancer, severe heart or lung conditions, or dementia).
- If the patient is very old (older than 85 years).

The Health Department process is designed to save as many lives as possible, as it is not possible to save everyone in this disaster situation.

YOUR MAKE-BELIEVE SITUATION

Imagine your family member, loved-one or friend is critically unwell and you are responsible for making decisions on their behalf.

On the next 6 pages are 3 different scenarios.
Please read each scenario and answer the questions that follow.

In this theoretical influenza pandemic situation, the Health Department had enacted triage criteria to determine the priority in which patients would be treated in the ICU. Patients would be excluded from the ICU if it was deemed that they would not survive, even with maximal medical therapy; the patient had chronic comorbidities; or the patient was very old. Respondents were given three theoretical scenarios that resulted from this "make-believe" pandemic situation, and were asked to rate how fair and accepting they would be of the decision-making in the scenarios using a horizontal, seven-point, category rating scale with qualifiers and free text answers.

In Scenario 1 (shown in Box 4F), the patient whom the surrogate decision-maker was responsible for was excluded from being admitted to the ICU by the intensive care triage criteria, because other

patients had higher priority. The surrogate decision-maker faced the theoretical prospect that the patient they were responsible for may not survive because they were prioritised lower for access to potential life-saving therapies.

In Scenario 2 (shown in Appendix 5 – Questionnaire Page 4), the patient whom the surrogate decision-maker was responsible for was already admitted to the ICU, but triage criteria had determined that the patient should now be discharged and excluded from the ICU, because other patients had higher priority. The surrogate decision-maker faced the theoretical prospect that the patient they were responsible for may not survive because their access to potential life-saving therapies was to be removed.

In Scenario 3 (shown in Appendix 5 – Questionnaire Page 6), the patient whom the surrogate decision-maker was responsible for was given priority for ICU level treatment, but their admission would require the removal and exclusion of a patient already in the ICU. The family of the other patient did not want them to be removed from the ICU. The surrogate decision-maker faced the theoretical prospect that the patient they were responsible for may not survive because their access to potential life-saving therapies was being blocked by another patient who was considered a lower priority.

Box 4F is shown on the next page

Box 4F - Scenario 1 and Questions 1 and 2 of the iPIT 4 Questionnaire

Scenario 1

Imagine that the person that you are responsible for has recently arrived at the hospital, and is critically unwell.

The hospital is in a disaster situation. There are not enough resources to treat every patient so some patients have to miss out.

The **hospital** has decided that the person that you are responsible for will not be allowed into the ICU for treatment (they are excluded from the ICU). This is because the **hospital** believes it has a better chance of saving someone else instead.

The person that you are responsible for will probably not survive unless they are treated in the ICU.

For Questions 1 and 2 draw a circle around the number that matches the answer you think is the best, like so

Extremely unfair — Neither unfair or fair — Extremely fair

1 2 3 (4) 5 6 7

Examples:
If you think the best answer is "extremely unfair" then circle 1.
If you think the best answer is "extremely fair" then circle 7.
If you think the best answer is "unfair", but not "extremely unfair", then circle 2 or 3.
If you think the best answer is "fair", but not "extremely fair", then circle 5 or 6.

Question 1: How fair do you think it is for the hospital to exclude the person you are responsible for from the ICU, in this disaster situation?

Extremely unfair — Neither unfair or fair — Extremely fair

1 2 3 4 5 6 7

Question 2: How accepting would you be of this decision to exclude the person you are responsible for from the ICU, in this disaster situation?

Not accepting at all — Neither not accepting or accepting — Fully accepting

1 2 3 4 5 6 7

To mitigate order-effect bias, participants were randomly allocated one of 6 versions of the questionnaire with the order of the three scenarios randomised so that they appeared first, second and last in the same frequency. The questionnaire was refined after pilot testing with consenting volunteers.

To mitigate potential participant distress associated with receiving the questionnaire, an initial safety phase was conducted at the coordinating study centre. An initial batch of questionnaires was

distributed at the coordinating study centre until 20 responses had been returned. These responses were reviewed by an independent safety monitor, in August 2019, who deemed there to be no ethical impediment to using the study protocol. Continuation of the study was subsequently approved by the Sydney Local Health District - Concord Repatriation General Hospital - Human Research Ethics Committee (2019/ETH07794 – 8th October 2019).

Site Specific Approval for the study sites was delayed because of the onset of the COVID-19 pandemic. Site Specific Approval was eventually obtained from the study sites on the following dates:

St Vincent's Hospital – April 2020
Westmead Hospital – May 2020
Blacktown Hospital - September 2020
Nepean Hospital – September 2020
Prince Charles Hospital – October 2020
Bankstown Hospital – November 2020
Rockhampton Hospital – April 2021

Due to the COVID-19 restrictions imposed on visitors by the Health Departments and the shortage of research staff later in the pandemic, the study started in Westmead Hospital in June 2020, Prince Charles Hospital in May 2021, and Rockhampton Hospital June 2021, but has not been able to be started at Bankstown Hospital, Blacktown Hospital, Nepean Hospital or St Vincent's Hospital. No changes to the questionnaire design or wording were required as result of the safety phase, therefore all returned questionnaires, including those from the safety phase, were to be included in the final analysis.

4.2.4 Questionnaire Design

The questionnaire designed for the study (Appendix 5) contained sections with ratings scales, free text, and multiple choice answers. Following on from the original literature search in 2013 prior to the iPIT 3 study (Section 4.1.4), a further literature search in 2018 found several new papers relevant to questionnaire design. However, there was no major additional information on rating scales compared to the previous literature search. There was no major additional research on the use of electronic and web-based surveys compared to traditional paper-based surveys.

Visual analogue scales were still found to be more difficult to use than numerical rating scales.[47] One study showed that a seven-point scale was associated with a minor increase in reliability scores when compared to a five-point scale.[48] Since the review of the literature in 2018 did not find a better method of designing the questionnaires rating scales, we decided to use the same rating scale for the iPIT 4 study as that which was used in the iPIT 3 study.

In similar fashion to the iPIT 3 study, in order to mitigate order-effect bias we decided to randomise the order in which the three scenarios portrayed in the questionnaire were presented to the respondent.[14] There were six possible randomisation permutations for the order of the three scenarios, therefore six questionnaires were designed. Potential participants were randomly allocated one of the six questionnaires. In order to maximize the completion of the questionnaire, demographic questions and potentially difficult or objectionable questions were be placed at the end of the questionnaire.[14]

There were several recent studies examining the platforms on which surveys were run. One study showed that patients preferred to use a tablet-based survey rather than a web-based or paper-based survey, in an outpatient setting, but there was no difference in patient understanding of the survey in the different methods.[49] In keeping with the evidence prior to 2018, reliability, correlation and validity appeared to be similar when comparing electronic and paper-based questionnaires.[50]

We decided to continue to use a traditional paper-based questionnaire for the iPIT 4 study for several reasons. Our review of the literature in 2018 did not find that an internet-based questionnaire was superior to a traditional paper-based questionnaire. In addition, we were aware that some surrogate decision-makers had limited access to the internet or limited knowledge on how to access and use the internet-based questionnaires.

4.2.5 Sampling Frame

The sampling frame used in the iPIT 4 study was a convenience sample of surrogate decision-makers for patients in the ICU, or recently discharged from the ICU, in the participating hospitals. The intent of the study was to examine the views of surrogate decision-makers for patients in the ICU. Probability sampling, where every person has a known and non-zero chance of selection, was the preferred method of sampling to avoid bias, as described earlier (Section 4.1.5).[22] However, to apply such a probability sampling method to all surrogate decision-makers in the entire Australian ICU population would be very expensive, and from a practical point of view, logistically impossible given the resources required. This study therefore used a convenience sample, non-probability sampling technique. It was acknowledged that this would limit external validity, as the results could only be generalizable to the population that they were drawn from, not the entire Australian ICU surrogate decision-maker community.

Potential participants were approached directly by study staff from the participating hospitals and asked to participate. The study staff were Intensivists or research nurses. If they agreed, participants were given an information sheet, a study questionnaire and a reply paid envelope. No incentives or remuneration were offered to participants. Questionnaires were returned directly to the study ICU or returned centrally to the coordinating centre using the reply-paid envelope.

4.2.6 Inclusion Criteria

A safety concern for the study was the potential for the questionnaire to cause or worsen distress for a participant. This concern was because participants would be surrogate decision-makers for patients who were already in an ICU or who had been recently discharged from the ICU, and the participant may already be distressed because of the patient's medical condition.

In order to minimise harm, we decided to only recruit participants who were unlikely to be traumatized or suffer emotional distress from completing the questionnaire. We thought that this emotional distress would be less likely to occur if the patient the surrogate decision-maker was responsible for was predicted to survive their ICU admission and predicted to recover well from their illness.

As the questionnaire was written in English, we decided to only recruit participants who could read and answer the questionnaire. We also wanted to recruit only adults, so an age limit of 18 years was set. We wanted to maximise the response rate, so only participants who were predicted to complete the questionnaire were approached.

The inclusion criteria used in the study were:

1. Any surrogate decision-maker for a patient currently in the ICU, or any surrogate decision-maker for a patient who had been recently discharged from the ICU; and

2. The patient was likely to survive their ICU admission, or had been discharged from the ICU alive and was clinically improving.

The surrogate decision-maker was defined as any designated decision-maker, and did not need to be a spouse or direct family member. For example, they could be a grandchild, niece, or neighbour. The decision to include surrogate decision-makers of patients who had been recently discharged from the ICU was to increase the number of potential participants. This was because research staff at the participating sites worked mainly on weekdays. This may have resulted in missed recruitment of surrogate decision-makers for patients who had only had short ICU admissions or surrogate decision-makers for patients who had been admitted and discharged on weekends.

4.2.7 Exclusion Criteria

In similar fashion to the inclusion criteria, the exclusion criteria was designed to prevent harm occurring to participants and to maximise the response rate. An additional exclusion criteria was added to mitigate the potential confusion that the questionnaire may be used to decide the current management of the patient, who was critically unwell and unlikely to survive. The questionnaire was not intended or designed to have any influence on the management of a currently admitted ICU patient. We did not want potential participants to perceive that their answers to the questionnaire would affect the ICU care of the patient whom which they were responsible for.

The exclusion criteria used in the study were:

1. Participant is unable to complete a written questionnaire for any reason (including English language difficulties); or

2. The written questionnaire is predicted to cause psychological or emotional distress for the participant; or

3. Participant is predicted to be unlikely to complete a written questionnaire if asked; or

4. The patient of the surrogate decision-maker has a high chance of not surviving the ICU admission, or has been discharged alive from the ICU, but is clinically deteriorating; or

5. The participant is under the age of 18 years.

4.2.8 Participant Safety

The safety of participants was paramount in the iPIT 4 study, and the study used several safety initiatives. Extensive testing and refinement of the questionnaire was performed with volunteers. Several iterations of the questionnaire were tested and revised over several months, looking for missing or missed items, understanding, acceptability, and poorly performing questions.

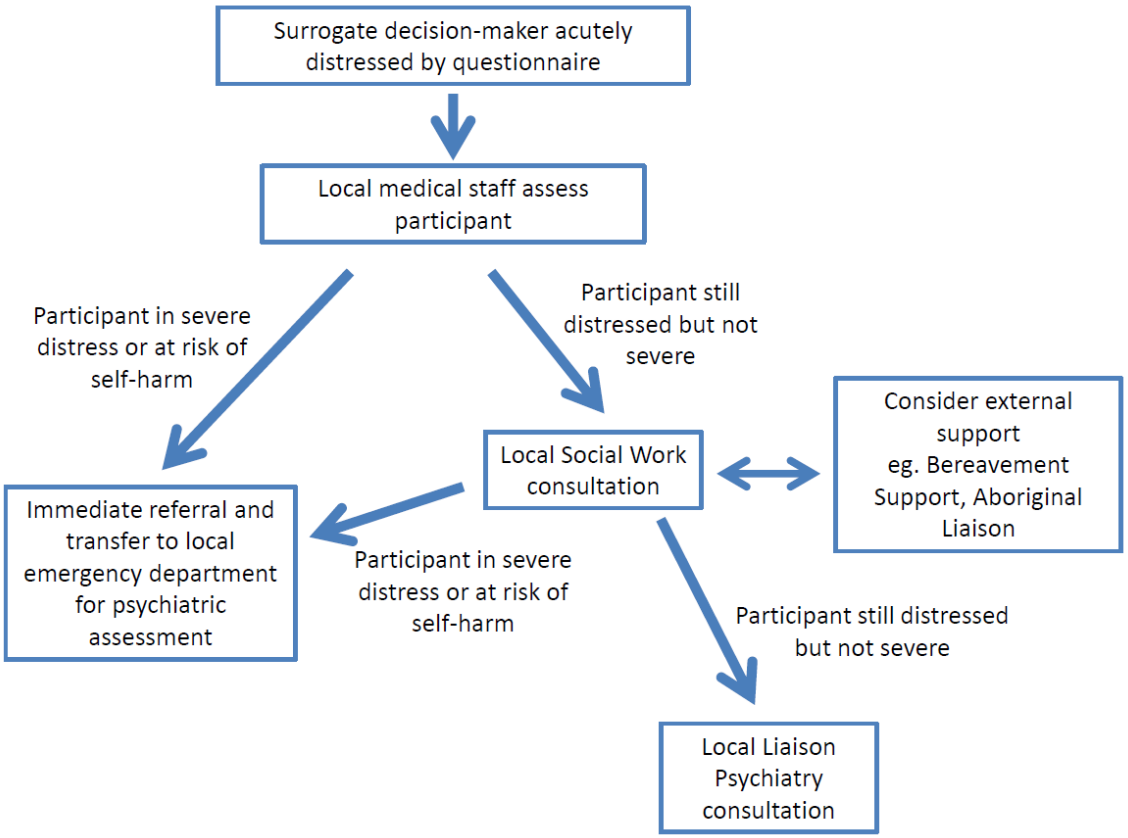
A pilot, safety phase was conducted until 20 questionnaires had been returned, and the questionnaires were reviewed by an independent safety monitor, who was a psychiatrist. The study was initially approved by a Human Research Ethics Committee, who reassessed and reconfirmed the approval following the safety phase.

The study was voluntary, and it was made clear that potential participants were under no compulsion to participate. A replied paid envelope to return questionnaires meant that potential participants could decide whether or not to participate later on. Potential participants were made aware of the fact that the study team and ICU staff would not be aware of who had taken part in the study and that all responses were anonymous. Completion of the questionnaire was considered as consent to participate in the study.

The study had a risk management plan for a participant who became acutely distressed. The risk management plan (Figure 4F) was developed with consultation with the Liaison Psychiatry service and Social Work service at Concord Repatriation General Hospital.

Figure 4F is shown on the next page

Figure 4F – Risk management plan for an acutely distressed participant in the iPIT 4 study



4.2.9 Statistical Analysis

The response rate was defined as the number of questionnaires returned divided by the number of questionnaires distributed.[34] The response rate from the iPIT 3 study in the Australian general population using a random questionnaire sent using the standard postal system was 15% after 10 weeks.[1] A literature search of response rates in recent Australian ICU surveys showed response rates of between 34 and 71%.[51-54] We therefore estimated that the study could potentially achieve a response rate of 50% if the study focused on recruiting only participants who were likely to complete the questionnaire.

The optimal sample size could not be determined, as the participant responses to the questionnaire was unknown. If 200 questionnaires were distributed in 8 ICUs (1600 questionnaires in total), a 50% response rate would provide 800 competed questionnaires. The iPIT 3 study received 841 replies and provided reasonable exploratory information. We believed that 800 replies for this study would provide similar reasonable exploratory information.

Histograms, means, standard deviations, medians and interquartile range were planned to be used to describe the main outcomes. Responses were planned to be analysed according to the following pre-specified subgroups:

ICU site
Male/Female
Age according to 5-year age band
Relationship of person responsible to patient

An interim analysis to assess safety only was performed during the pilot, safety phase. Another interim analysis was performed for this thesis chapter, using data that was available up to 24 January 2023. Due to hospital visitor restrictions during the COVID-19 pandemic there were delays in commencing the study at each site. Participant recruitment has therefore not been completed at all sites.

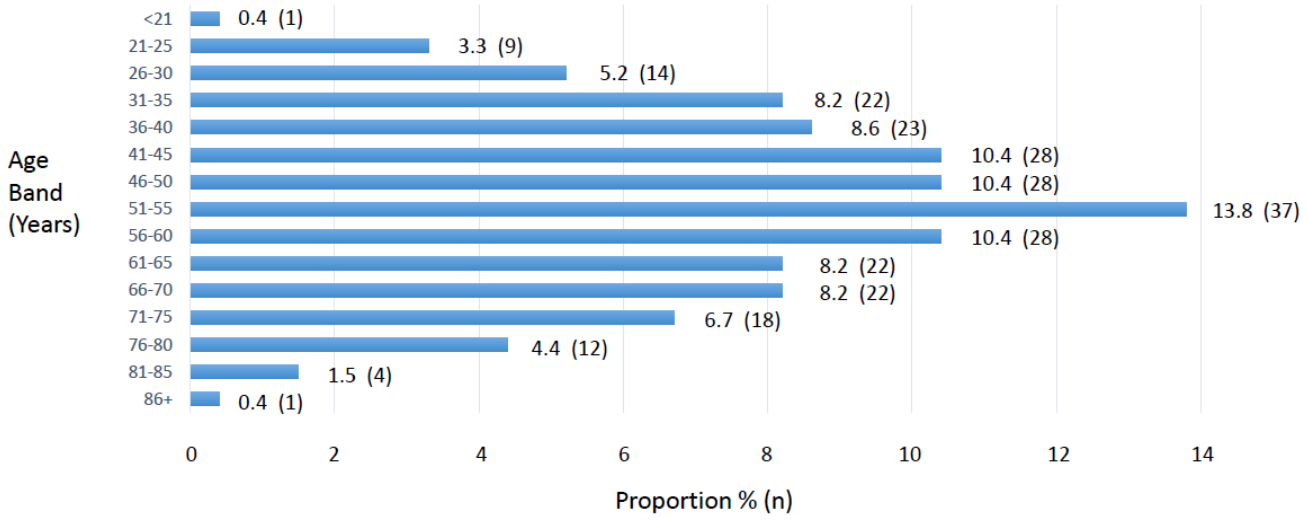
4.2.10 Results

The main study phase of the iPIT 4 study started in June 2020 and the interim analysis presented in this thesis was conducted in January 2023. Recruitment for the study at all sites is scheduled to finish in October 2023.

4.2.10.1 Response Rate and Respondent Population

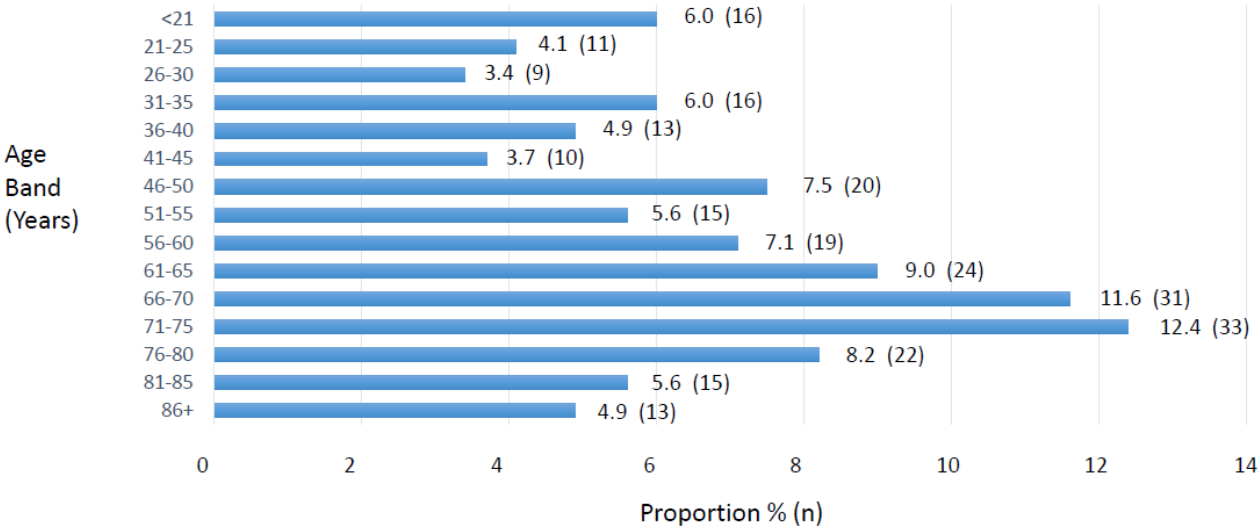
The response rate was 54.2% (263 replies). The age of the respondents is shown in Figure 4G.

Figure 4G – Proportion and number of questionnaire respondents according to age band



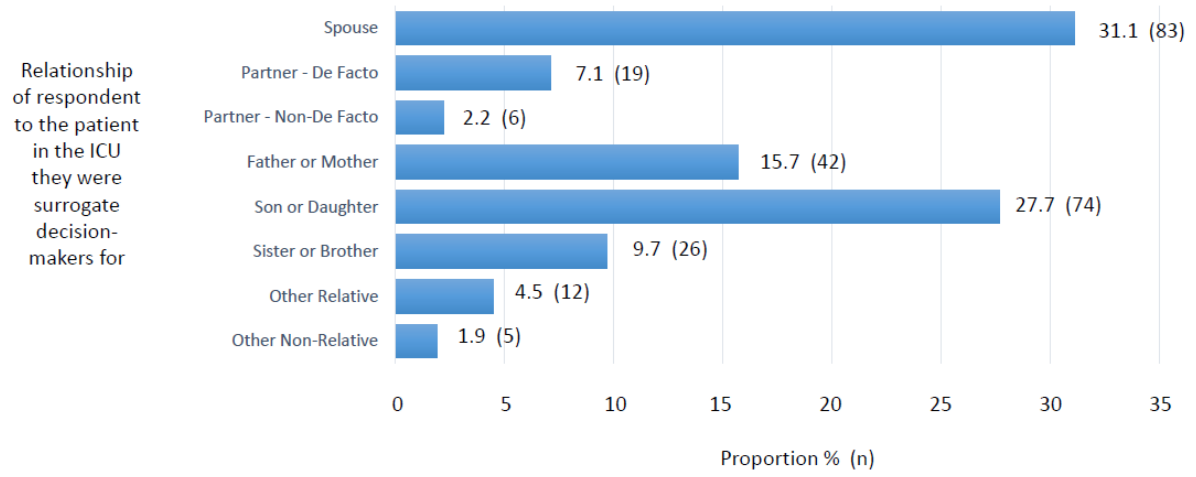
The proportion of female respondents was 65.0%. The age of the patients that the respondents were surrogate decision-makers for in the ICU is shown in Figure 4H.

Figure 4H - Proportion and number of patients according to age band that respondents to the questionnaire were surrogate decision-makers for



The relationship of the respondent to the patient in the ICU they were the surrogate decision-maker for is shown in Figure 4I. The majority of respondents were either the spouse or a child of the patient in the ICU they were the surrogate decision-maker for.

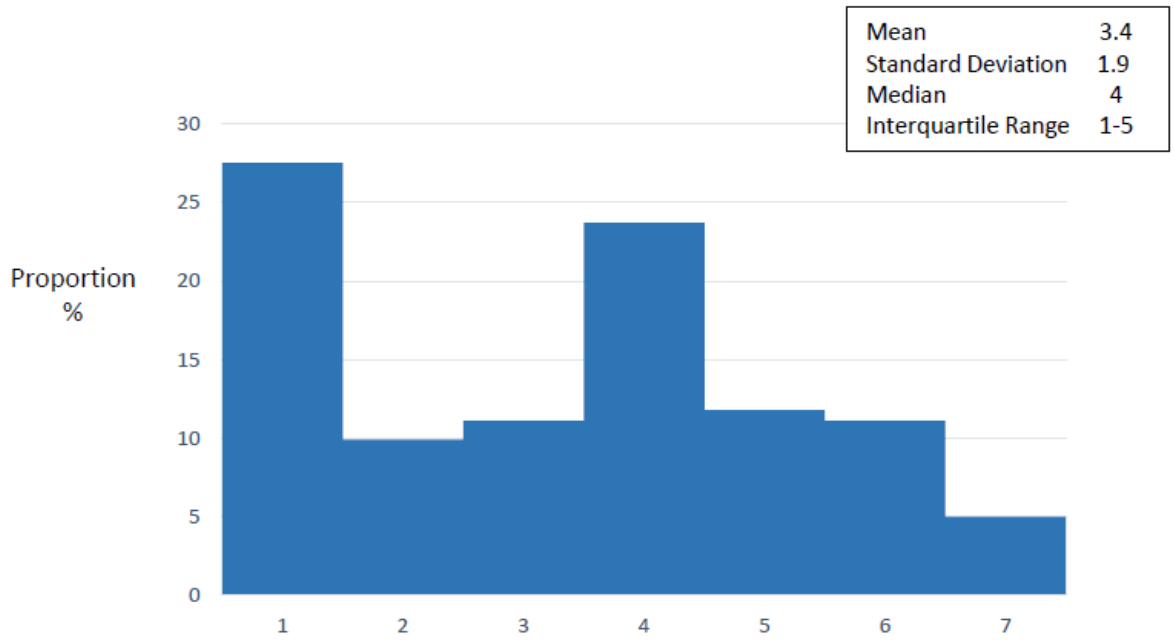
Figure 4I - Relationship of the respondent to the patient in the ICU they were surrogate decision-makers for



4.2.10.2 Respondent Response to Scenario 1

Respondents' perceptions of fairness for the hospital to exclude the patient they were the surrogate decision-maker for, from the ICU in the disaster situation detailed in Scenario 1 (Box 4F), is shown in Figure 4J. A large proportion of respondents (27.5%) perceived this to be extremely unfair (a rating score of "1"), while another large proportion (23.7%) perceived this to be neither unfair or fair (a rating score of "4").

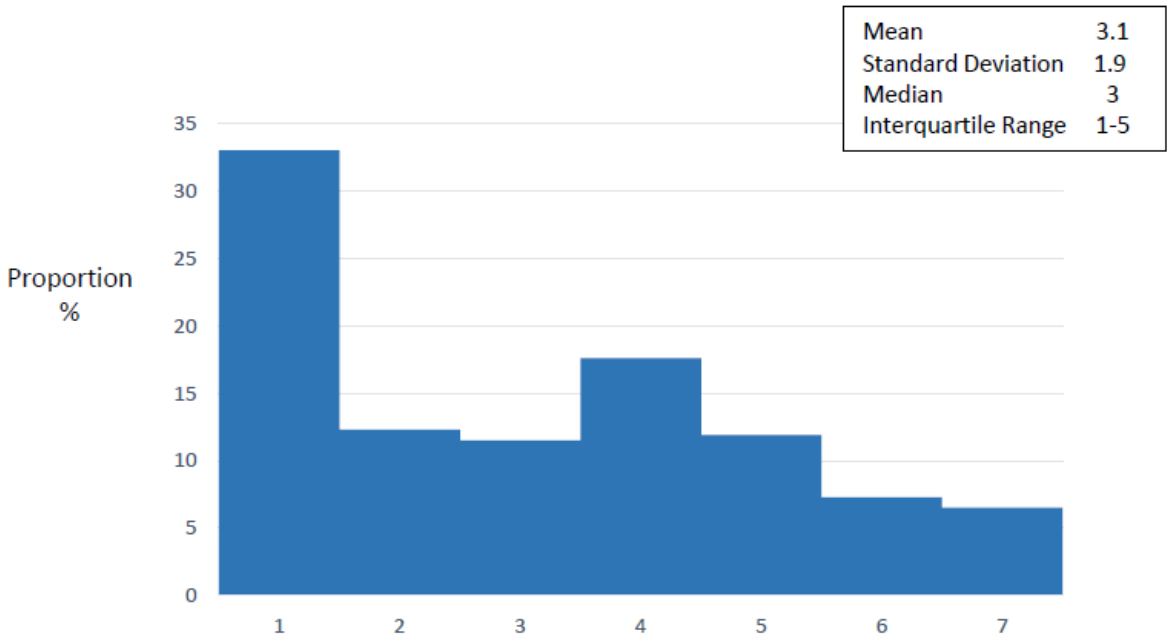
Figure 4J - Responses to Question 1 (from Scenario 1) – "How fair do you think it is for the hospital to exclude the person you are responsible for from the ICU, in this disaster situation?"



Proportion %	27.5	9.9	11.1	23.7	11.8	11.1	5.0
		48.5		23.7		27.9	
n	72	26	29	62	31	29	13

Respondents' acceptance of the decision from the hospital to exclude the patient they were the surrogate decision-maker for from the ICU, in the disaster situation detailed in Scenario 1 (Box 4F), is shown in Figure 4K. The majority of respondents (56.7%) indicated a degree of non-acceptance of this decision from the hospital (a rating score of "1", "2" or "3").

Figure 4K - Responses to Question 2 (from Scenario 1) – "How accepting would you be of this decision to exclude the person you are responsible for from the ICU in this disaster situation?"

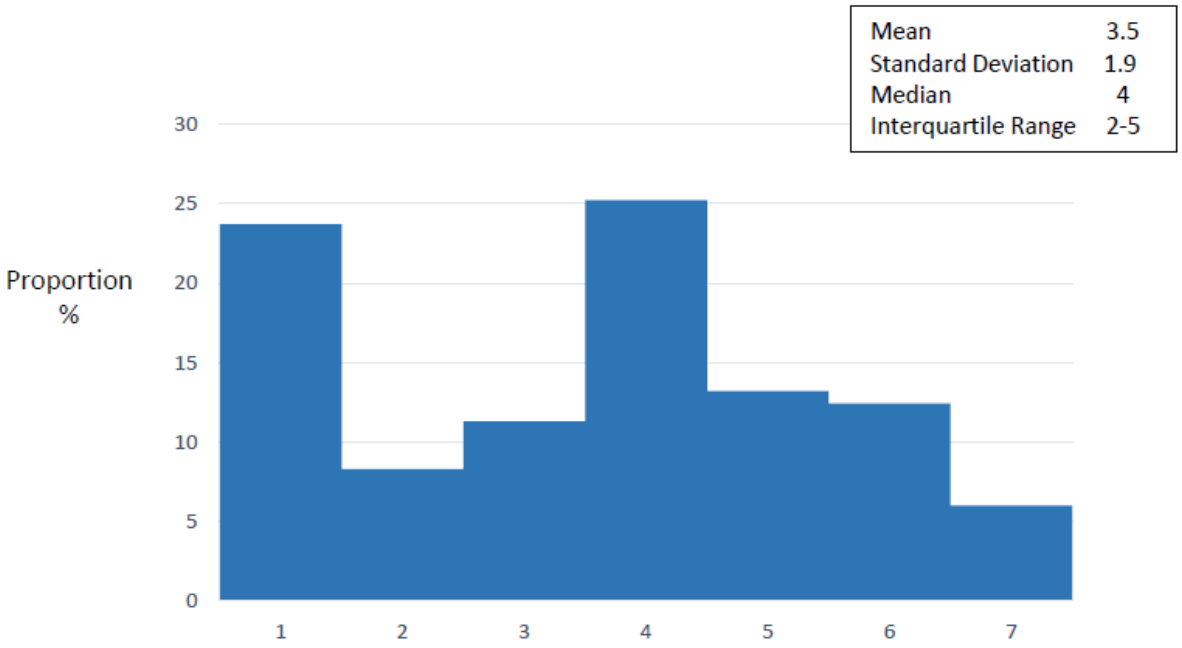


Proportion %	33.0	12.3	11.5	17.6	11.9	7.3	6.5
		56.7		17.6		25.7	
n	86	32	30	46	31	19	17

4.2.10.3 Respondent Response to Scenario 2

Respondents' perception of fairness of the decision from the hospital to move the patient they were the surrogate decision-maker for from the ICU to the general ward, in the disaster situation detailed in Scenario 2 (Appendix 5 – Questionnaire Page 4), is shown in Figure 4L. A large proportion of respondents perceived this to be neither unfair or fair (a rating score of "4"), while another large proportion perceived this to be extremely unfair (a rating score of "1").

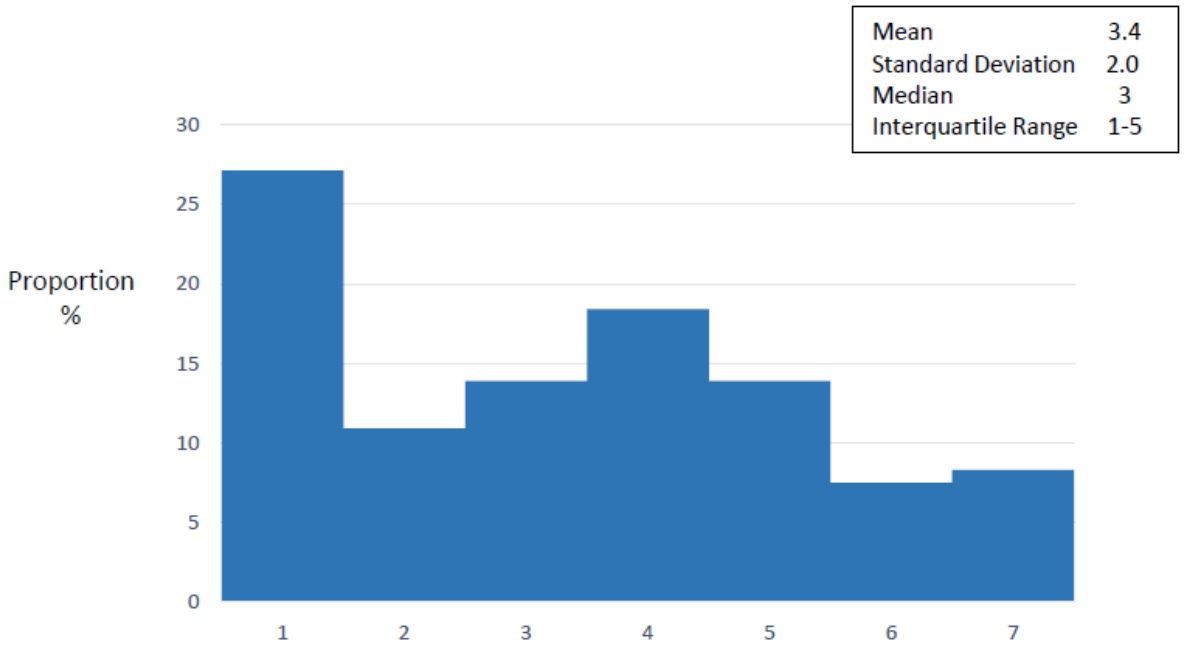
Figure 4L - Responses to Question 4 (from Scenario 2) – "How fair do you think it is for the hospital to move the person you are responsible for from the ICU to a general ward, in this disaster situation?"



Proportion %	23.7	8.3	11.3	25.2	13.2	12.4	6.0
		43.2		25.2		31.6	
n	63	22	30	67	35	33	16

Respondents' acceptance of the decision from the hospital to move the patient they were the surrogate decision-maker for from the ICU to a general ward, in the disaster situation detailed in Scenario 2 (Appendix 5 – Questionnaire Page 4), is shown in Figure 4M. The majority of respondents (51.9%) indicated a degree of non-acceptance of this decision from the hospital (a rating score of "1", "2", or "3").

Figure 4M - Responses to Question 5 (from Scenario 2) – "How accepting would you be of this decision to move the person you are responsible for from the ICU to the general ward, in this disaster situation?"

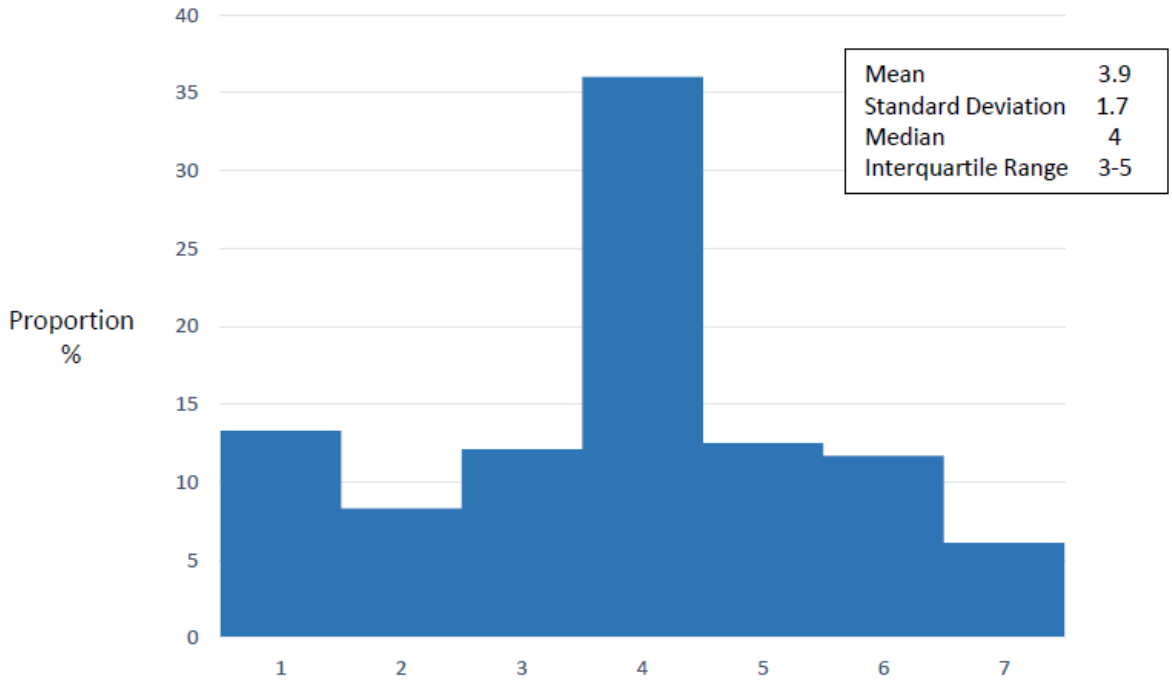


Proportion %	27.1	10.9	13.9	18.4	13.9	7.5	8.3
		51.9		18.4		29.7	
n	72	29	37	49	37	20	22

4.2.10.4 Respondent Response to Scenario 3

Respondents' perception of fairness of the decision from the hospital to move the other patient out of the ICU to a general ward so that the patient they were the surrogate decision-maker for could be admitted to the ICU, in the disaster situation detailed in Scenario 3 (Appendix 5 – Questionnaire Page 6), is shown in Figure 4N. The largest proportion of respondents perceived this to be neither unfair or fair (a rating score of "4"). Less respondents indicated that they thought this to be unfair (a rating score of "1", "2" or "3") compared to their ratings of fairness in Scenario 1 or 2 (Figure 4J and 4L).

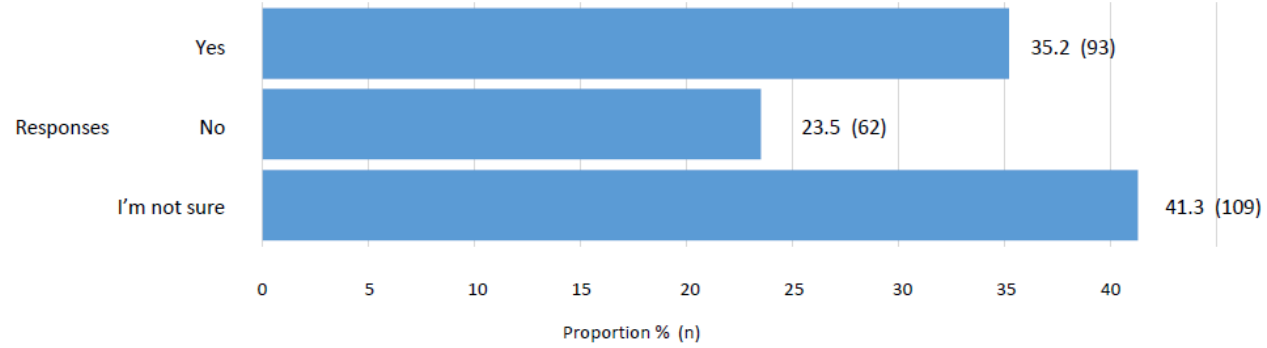
Figure 4N - Responses to Question 7 (from Scenario 3) – "How fair do you think it is for the hospital to move the other patient out of the ICU to a general ward so that the person you are responsible for can be admitted to the ICU?"



Proportion %	13.3	8.3	12.1	36.0	12.5	11.7	6.1
		33.7		36.0		30.3	
n	35	22	32	95	33	31	16

Only 35.2% of respondents thought that the other patient should be moved out of the ICU by the hospital, despite the other family's non-acceptance, in Scenario 3 (Appendix 5 – Questionnaire Page 6), so that the patient they were the surrogate decision-makers for could be admitted in their place (Figure 4O). A large proportion were unsure (41.3%).

Figure 4O - Responses to Question 8 (from Scenario 3) – "If the family or person responsible for the other patient is not accepting of the patient being moved from the ICU to a general ward, should the hospital move them despite of their family's non-acceptance?"



A subgroup analysis was performed on the respondents to Question 1 (Scenario 1 – Box 4F) who perceived the decision to exclude the patient they were the surrogate decision-maker for, from the ICU in the disaster situation, as being extremely unfair (a rating of "1" in Figure 4J). When asked about the fairness of moving the other patient in Scenario 3 out of the ICU, so that the patient they were the surrogate decision-maker for could be admitted in their place, 16% indicated that this was fair (a rating of "5","6" or "7"). When asked whether they thought that the other patient in Scenario 3 should be moved out of the ICU by the hospital, so that the patient they were the surrogate decision-maker for could be admitted in their place, 21% of these respondents answered "Yes", 47% answered "No", and 31% answered "I'm not sure". In other words, these two results indicate that of the respondents who found the hospital moving their loved one out of the ICU to be extremely unfair, only a small proportion thought it was fair to do the same to another family's loved one.

4.2.10.5 Free-Text Comments

Free-text comments generally acknowledged that the situation was difficult for all concerned. They generally indicated that families would have heightened emotional states, and therefore this could affect their judgement. Many respondents stated they would not be accepting of the situation, but acknowledged that the difficult decision-making would be a reality.

Many respondents wanted clear communication from staff, and explanations behind the decision-making. Many wanted decision-making to be transparent and based on predetermined policy that

had been made clear to the public in advance. Some respondents were concerned about bias and nepotism, and wanted multiple people to be involved in decision-making.

Many respondents indicated that they found the scenarios to be unfair and were not accepting of them, but acknowledged that there was little they could realistically do because of the disaster situation and resource constraints. Many respondents who indicated that the decision-making was unfair or unacceptable, indicated that they would advocate for the patient who they were surrogate decision-makers for, and stand their ground. Many would escalate and appeal the decision. Many would ask a politician to intervene, consider legal action, and contact media. Some acknowledged that it may be easier to stop a patient from being discharged from the ICU than to force an ICU admission.

Some respondents stated that they would advocate for the patient who they were surrogate decision-makers for, regardless of the adverse consequences for other patients. However, some stated that even though they would advocate for their patient, they would not want the treatment to be at the expense of another patient.

Many respondents stated that governments and hospitals had to prepare for these scenarios. There were some who expressed a view, that no patient should ever be excluded from the ICU in any circumstance, because all lives were important. There were 18 respondents who indicated in the free-text comments that there should be no scarcity of resources in a disaster. Instead of prioritising the scarce resources in a pandemic, the solution to them was to increase resources (such as building more ICUs) so that no patients missed out on adequate intensive care.

Many respondents indicated that age, comorbidities and chance of survival would change their responses to the questions. Many indicated that priority should be given to the young, those without major comorbidities and those who had the best chance of survival. Others considered quality of life and importance of the patient to the functioning of the family unit (for example, a mother to young children) to be important considerations.

Many respondents indicated they would try to transfer the patient to another ICU or hospital, or pay for a private facility. Some expected the patient to stay in the Emergency Department until an ICU bed became available. Many would help care for the patients themselves.

No respondents indicated that they would use violence or force. However, some indicated that force would need to be considered by authorities (including the military) to enforce disaster policies.

4.2.11 Discussion

This interim analysis of a multicentre study, conducted during an actual pandemic, to determine how surrogate decision-makers for patients in the ICU perceived the fairness of the use of triage criteria to allocate intensive care resources during an influenza pandemic demonstrated that these surrogate decision-makers appeared to have four contradictory viewpoints, with no clear majority view.

The first viewpoint was that decision-making using triage criteria to exclude the person they were the surrogate decision-maker for from the ICU, in a pandemic disaster scenario, was unfair and not acceptable. This was the viewpoint taken by the largest proportion of respondents. However, many respondents who took this viewpoint also acknowledged that in an actual pandemic there would be little that they could realistically do to rectify the situation. This view appeared to be similar,

regardless of whether the hospital excluded a patient from being admitted to the ICU in the first place (Scenario 1 – Box 4F) or removed an already admitted patient from the ICU (Scenario 2 - Appendix 5 – Questionnaire Page 4).

The second, and opposing, viewpoint was that decision-making using triage criteria to exclude the patient they were the surrogate decision-maker for in a pandemic disaster scenario was fair and acceptable. This was the viewpoint taken by the second largest proportion of respondents.

The third viewpoint, taken by a significant proportion of respondents, was that of a neutral stance, where the respondents perceived using triage criteria to exclude the person they were the surrogate decision-maker for from the ICU in a pandemic disaster situation to be neither unfair nor fair, and neither not acceptable nor acceptable. A fourth viewpoint, which was a small minority view, indicated that it was unfair and unacceptable to exclude the patient the respondent was the surrogate decision-maker for, but acceptable to exclude other patients. In other words, it was fair to triage their loved-one ahead of others, but not vice versa.

The iPIT 3 study (described in Section 4.1) demonstrated that in Australia, respondents considered both the use of a senior doctor or pre-determined health department criteria to triage ICU patients in an influenza pandemic to be fair.[1] However, the iPIT 3 study responses were obtained in a non-pandemic setting, and without the emotional stress of the respondent being a surrogate decision-maker for a patient actually in the ICU. Converse to this, the iPIT 4 study was conducted during an actual pandemic, with the respondent being a surrogate decision-maker for a patient actually in the ICU or recently in the ICU. In addition, two of the iPIT 4 "make believe" scenarios explicitly stated that the patients were being excluded from the ICU on the basis of triage criteria. This allowed the respondent to answer the questions with a degree of realism and emotional accentuation, as acknowledged in the free-text comments. This may partially explain the apparent higher degree of opposition to the use of triage protocols seen in these interim result for the iPIT 4 study, compared to the iPIT 3 study.

These interim results indicate that there could be significant societal opposition to any policy of limiting access to intensive care resources in a pandemic. The free-text answers appear to indicate that there is general acknowledgement of the difficulty the disaster scenarios pose. However, some respondents believe that Australian governments and hospitals should not allow such resource limitations to occur in the first instance. The reason for this is twofold. First, the free-text responses indicate that some respondents perceive that there is adequate time for resourcing constraints to be addressed by governments and health care providers before another disaster strikes. Second, the free-text responses indicate that some respondents believe that Australian governments can and are actually willing to increase health care funding to proactively mitigate the intensive care resource constraints.

The apparent opposition, by a large proportion of respondents, to any policy of limiting access to intensive care resources in a pandemic appeared to be similar for both excluding a patient from being admitted to the ICU in the first place (Scenario 1 – Box 4F) and removing an already admitted patient from the ICU (Scenario 2 - Appendix 5 – Questionnaire Page 4). However, the free-text comments indicate that it may be easier for ICU staff, from a confrontational perspective, to refuse to admit a patient to the ICU, rather than prematurely discharge a patient from the ICU when they are already occupying a bed.

Given the likely societal opposition to limiting access to ICU resources, if triage protocols were to be developed and used in a pandemic, the interim results of our study indicates that good communication would be essential to help attenuate opposition or uncertainty. Widespread public

consultation should be undertaken, and the protocols should be promulgated to the public well in advance of any pandemic, as well as during a pandemic. Decision-making during a pandemic disaster should be fair and transparent. These measures may prevent opposition from becoming resistance.

There are currently no published large cross-sectional studies of the views of surrogate decision-makers for patients in the ICU on pandemic triage, under normal circumstances and in other disaster scenarios. As mentioned previously, one small focus group study demonstrated that American consumers were opposed to any model of limiting critical care.[42]

4.2.12 Strengths and Limitations

These results are interim only, but it is likely that similar patterns of responses will be seen when the complete data is analysed.

When completed, this multi-centre Australian study will be the first study to examine of the views of surrogate decision-makers for patients in the ICU on pandemic triage. The views of surrogate decision-makers in these situations are important. This is because the clinical reality is that discussions regarding the admission of patients to or exclusion of patients from the ICU will involve surrogate decision-makers, as patients are often too unwell to have decision-making capacity. This study will also be the second Australian public engagement study on pandemic planning to be conducted during an actual pandemic.

The power of the study is likely to be reduced because of the recruitment constraints caused by the COVID-19 pandemic and constraints on sample size due to cost. However, these interim findings demonstrate that the final results are likely to provide valuable information and insights for intensive care resource planning for future pandemics.

Strategies were used in creating this study to mitigate bias and maximise the generalisability of the results. Adding to the knowledge obtained for the iPIT 3 study, we performed a further literature search and consulted design experts to determine the optimal questionnaire design. The use of qualifiers, such as “neither unfair or fair” appeared to result in anchoring effects, but these did not appear to bias the interim results in a single direction.

Order-effect bias was mitigated again by randomising the order in which the questions were presented. This randomisation was important as the free-text comments appear to indicate that some responses to the early questions may have affected the answers to subsequent questions.

There were several other potential sources of bias. Selection bias was likely to have occurred because potential participants were excluded if they could have been traumatized or could have suffered emotional distress from completing the questionnaire; if they had English language difficulties; or if they were the surrogate decision-maker for a patient unlikely to survive the ICU admission. Respondents with greater emotional accentuation may have answered the questions differently. The largest proportion of respondents were in the 41 to 60 year age groups. This observation is consistent with the majority of respondents to the questionnaire being either a spouse or a child of the patient in the ICU who they were surrogate decision-makers for. The respondents to the questionnaire were from four ICUs, instead of the eight ICUs originally planned for, reducing the generalizability of the results. Non-response bias may also have occurred.

One of the major limitations of the study was that it not possible to determine whether the participant responses reflected their views on the use of triage criteria per se, or reflected their

views on the fact the person they were responsible for could be excluded or discharged from ICU. Regardless, the intent of the study was to see how surrogate decision-makers perceived triage decisions based on triage criteria. This would give an indication of the potential opposition that may be encountered if triage systems were to be actually operationalised in a pandemic.

4.2.13 Implications and Unanswered Questions

These interim results need to be confirmed by completing this study. The results of the iPIT 3 study and the interim results of the iPIT 4 study present conflicting moral views. These can be explained by the settings in which the studies were conducted, the construct of the scenarios, and the way the questions were worded.

It could be argued that the findings from the iPIT 3 study are more objective; more cross-sectional and reflective of a societal view; are less subject to emotional biases. The findings may indicate that the public have some understanding of the resource constraints that may be faced by health systems in a future major pandemic.

The findings from the iPIT 4 study represent the views of a specific group of people who are likely to be less objective, but have greater insights into the question being asked. These people have a “lived experience” of being a decision-maker for a patient in an ICU during a pandemic, and the clinical scenarios explicitly stated that the patient they were responsible for would be excluded or discharged from the ICU.

The results from the iPIT 3 and iPIT 4 studies suggest that views may change according to experience and emotional circumstance. Which viewpoint in our studies should be the dominant view when making public health decisions regarding pandemic planning, and how the different views can be reconciled remains unknown. This requires further exploration.

The views expressed by some in the free-text responses that that there should be no scarcity of resources in a disaster and that more ICU beds should be available could be viewed as “idealistic” but unrealistic by some people. However, it is important to have insight into these opinions and understand this further.

Regardless, these interim results indicate that any policy to exclude patients from accessing intensive care resources using triage criteria in a pandemic is likely to come up against significant opposition from a large proportion of surrogate decision-makers. However, in our opinion, the use of triage is probably the most ethically acceptable method to uphold the principle of justice in a pandemic disaster. Triage systems are both utilitarian and egalitarian.

If triage protocols are to be used in future pandemics then significant and careful development needs to occur. Given the heightened emotional states in an actual pandemic situation where intensive care resources are actually limited, it may be easier from an operational point of view to refuse a patient admission to the ICU in the first place, rather than to try to prematurely discharge a patient from the ICU later on.

Our results suggest that some people expect governments to prepare and plan for disasters. This would support the development of triage protocols as part of disaster planning and the provision of more intensive care resources. However, we acknowledge that we have not specifically asked people about their views on what should be prioritised in disaster planning. We are unaware of any such

studies. It is also acknowledged that people who don't have expertise on disaster planning may not be able to give an informed view on priorities in disaster planning.

The opinion of the people cannot be the sole basis for population-level decision-making. In a liberal democracy these decisions are ultimately made by elected representatives, who take into account the opinion of the public, but also a range of expert advice, including medical, scientific, economic, legal, and others. Elected representatives will also have their own personal and political views. The studies in this thesis provide public opinion on how triage should be performed in a pandemic. How this information is used to provide health care is ultimately up to governments and health departments to decide.

From an ethical perspective, the optimal method for performing triage in a pandemic where resources are scarce is likely to use a combination of senior medical staff and pre-determined triage criteria. The triage criteria that provides maximal acceptability to society remains unknown. This problem and other unanswered ethical questions will be explored in the next chapter.

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Chapter 5 – The COVID-19 Pandemic and Intensive Care Triage

5.1 The COVID-19 Pandemic and Review of Intensive Triage Tools

5.1.1 The COVID-19 Pandemic

In December 2019, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) betacoronavirus emerged as a major pathogen and a major global challenge for public health.[1,2] The new disease that this virus caused was named coronavirus disease (COVID-19) by the World Health Organization (WHO).[3]

In February 2020, the Australian government released a national plan to guide a comprehensive whole of government approach to respond to COVID-19.[4] This emergency response plan recognized that as the pandemic progressed demand for specialist hospital-based healthcare was likely to challenge healthcare capacity.

During the initial COVID-19 outbreak in Wuhan, China, 14% of patients had severe disease with significant respiratory failure.[2] Approximately 5% of patients developed respiratory failure with shock and multi-organ failure.[2] At the time, the only therapy that significantly improved survival in patients with severe COVID-19 was admission to an ICU for invasive ventilation and basic ICU supportive treatments (ICU therapy).[5]

5.1.2 NSW Planning for Intensive Care Triage during the COVID-19 Pandemic

In early 2020, the NSW Health Department convened a working group to develop an ICU triage protocol, to plan for a disaster scenario in NSW during the COVID-19 pandemic, where the demand for intensive care services significantly exceeded the availability of ICU beds. In April 2020, there were 191 ICUs in Australia, with 2378 available intensive care beds.[6] This equated to 94 ICU beds per million people.[6]

The working group consisted of public health experts, clinicians and ethicists. I was invited to be a member of this working group because of my previous pandemic research.

Since the publication of our iPIT 2 study in 2012, no new triage protocols had been published internationally. The NSW working group reviewed the Minnesota, Ontario and iPIT protocols and several unpublished triage protocols from other countries. Despite significant deliberation, no triage protocol or triage technique was deemed to be acceptable by the NSW working group to be adopted in NSW as official public policy.

5.1.3 Unanswered Ethical and Legal Questions

The main ethical issue in developing and then adopting an ICU triage protocol to be used in NSW as official health policy for the COVID-19 pandemic was that it would require a change in the approach to patient care from an ethical point of view. This change would be from the usual clinical approach of protecting and respecting individual autonomy, to a public health approach of promoting the common good.[7] In a public health crisis, the selective application of triage criteria to exclude certain patient groups from access to medical resources may be ethical from a public health perspective, but this may violate other accepted ethical principles, such as the principle of justice. This is because patients, who from an ethical viewpoint are similar because their medical conditions have similar predicted outcomes, are treated differently.[7] For example, a pandemic triage protocol may exclude a patient with severe cardiac disease, but may not exclude a patient with severe vascular disease, who has similar predicted outcomes.

Because of this problem, many different ethical values have been proposed to guide decision-making in planning for a pandemic, as discussed earlier.[8,9] However, Australia is a pluralist society, and it is likely that reasonable disagreement will occur on principles to guide priority setting. Therefore, establishing a fair process for priority setting may actually be easier than agreeing on actual ethical principles.[10,11]

If the process of determining which patients receive and which patients are denied health care resources in a pandemic is perceived as being unfair, the legitimacy of a public health response may be challenged, and restrictive measures may not be adhered to.[7] Resource allocation decisions in healthcare are necessary, and therefore a fair process is justified to establish the legitimacy of such decisions.[9,11]

Under normal, non-pandemic circumstances, the decision to admit or exclude a patient from ICU therapy is made by a clinician or clinicians, usually in consultation with the patient or surrogate decision-maker. However, when ICUs reach capacity in non-pandemic circumstances, a first-come, first-served approach is commonly used. The ethical issues with using a first come, first served approach to select patients for ICU management in a disaster were outlined earlier. The iPIT 3 study showed that the majority of respondents to our survey were against using a first come, first served approach to allocate ICU resources in a pandemic (Figure 4D-A).

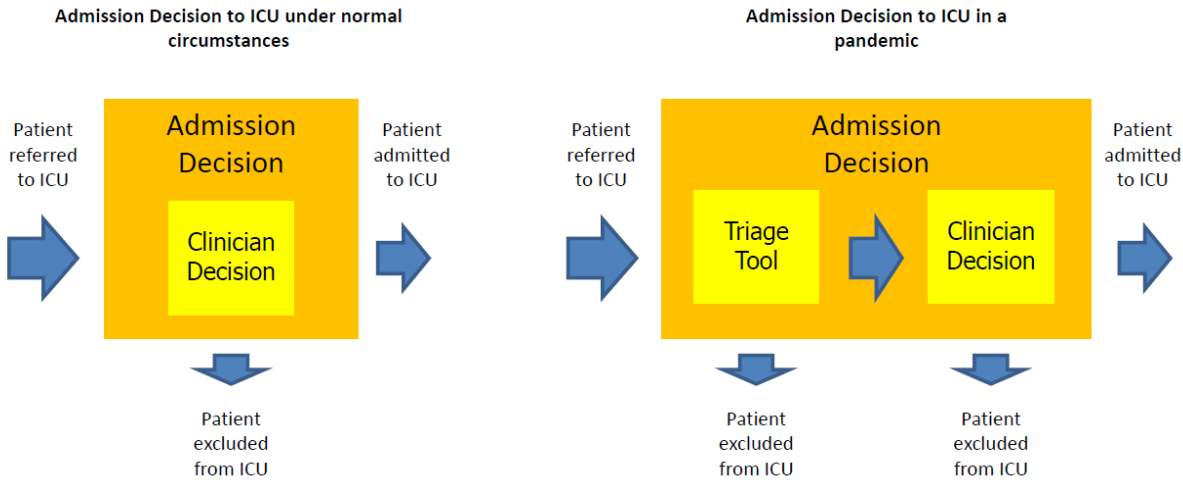
If no strategies to select patients for ICU care are developed for a pandemic, a first-come, first-served approach will most likely be used, because clinicians will find the task of selecting patients in this situation daunting. On the basis of the ethical issues described and the community feedback from the iPIT 3 study, this approach is not acceptable to the Australian public. Therefore, a better method to select or triage patients must be developed.

In our iPIT 3 study, when respondents were asked which of 6 triage methods they preferred health authorities to use to select patients for ICU management in an influenza pandemic, the majority chose two options: “Let a senior doctor decide” and to “Use a set of criteria or rules that have been determined by the health department to decide” (Figure 4C). However, the respondents who did not want clinicians to have sole discretion in allocating ICU resources during a pandemic had three major concerns with this approach. First, the respondents were concerned that bias, prejudice or nepotism could occur if individuals made decisions based on sole discretion. Second, the respondents were concerned that placing the burden of decision-making in such a difficult circumstance on one or several individuals would be unfair and potentially psychologically traumatic to those individuals. Third, pre-determined selection criteria were considered to be more transparent and accountable if they were ever to be legally questioned.

The use of triage protocols negates some of the concerns regarding one or several individuals making sole ICU resource allocation decisions. However, as explained earlier, an ethical problem with triage protocols is that the use of criteria to exclude patients from access to medical resources may violate the principle of justice.

Another disadvantage of using triage protocols is that current protocols do not respond quickly to constantly changing supply and demand. Therefore, in a pandemic, a combination of both triage protocols and clinician decision-making may be a realistic and practical way to allocate ICU beds. Figure 5A shows the comparison of this approach with how decisions are made under normal circumstance.

Figure 5A – ICU admission decision under normal circumstances and in a pandemic



The majority of respondents in the iPIT 3 study thought that selection criteria based upon a person's chance of survival was fair (Figure 4E-B). The majority of respondents also thought that it was fair to not treat patients because of chronic medical conditions, if this reduced their chances of surviving (Figure 4E-C). A smaller majority of respondents in both countries considered treating younger people ahead of older people (Figure 4E-A) to be fair. These results provided guidance to the NSW working group on addressing whether triage should be used in a pandemic, and what triage methods should be used.

From both an ethical perspective and a public engagement perspective, it appeared reasonable to use acute derangements in physiology as triage criteria. This was because the public perceived that it was fair to use a person's chance of survival as triage criteria, and acute derangements in physiology are reasonably accurate at predicting survival.[12] However, the problem with using just a person's chance of survival as sole triage criteria to select patients for ICU admission is that chronic comorbidity is not accounted for.

Patients with significant chronic comorbidity, with poor long-term outcomes, may present with an acute illness that has a good short term outcome. In this situation, if a person's chance of short-term survival was used as sole triage criteria, patients with chronic comorbidity may be selected for ICU

admission ahead of patients with no comorbidity, but who have a more severe acute illness, with a lower chance of survival. For example, if chance of survival to hospital discharge was used as sole triage criteria, an older patient with end-stage cancer but a quickly reversible medical problem would be triaged preferentially over a young patient with a severe infection that has caused multi-organ failure. Therefore, it appeared reasonable, from both an ethical perspective and a public engagement perspective (the findings from the iPIT 3 study), that chronic comorbidity is used as ICU triage criteria.

The use of age as triage criteria does not have consensus agreement. From an ethical perspective it appeared reasonable to use age as triage criteria in a pandemic, but it was possible that this use could be unlawful. Respondents in the iPIT 3 study considered it fair to treat younger patients ahead of older patients in a pandemic when resources were scarce.

Age criteria is relatively easy to incorporate into a triage protocol because age is relatively easy to determine compared to other potential triage criteria. There are other ethical rationale, mentioned earlier, why age may be reasonable to use as triage criteria in a pandemic where resources are scarce. However, the ethical differences between younger and older age groups diminishes as the age difference becomes smaller. From a legal perspective, triaging patients on the basis of age may contravene antidiscrimination laws in Australia. Therefore it appeared unlikely that age could be used as triage criteria.

The NSW ICU triage protocol working group, in 2020, still had some significant concerns regarding the ethical and legal ramifications of triage protocols, and there were areas where consensus in the working group could not be achieved. The problem areas still impeding the development of a local NSW ICU triage protocol were:

How to account for chronic comorbidity in the triage protocol

How to avoid discriminating against people who were disabled

How to account for people who may be disadvantaged or vulnerable

To what degree frontline workers in a pandemic should have additional supports, given the high-risk nature of their work

Could triage be performed in older patients without contravening antidiscrimination laws?

5.1.4 Addressing Comorbidity in Intensive Care Triage

To account for comorbidity there are two theoretical methods to allocate ICU resources in a public health emergency, where the demand for intensive care services significantly exceeds the availability of intensive care resources. The first method is to use a disease-based approach. A second method is to use an outcome-based approach.

5.1.4.1 Disease-Based Approach to Triage Using Comorbidity

The traditional theoretical method to triage ICU patients is to use a disease-based selection system. Using a disease-based method, people are prioritized for treatment based on the type and severity of specific medical problems. An example of a disease-based triage system, developed at the start of the COVID-19 pandemic in 2020, from Pittsburgh, USA, is shown in Figure 5B.[13]

Figure 5B - Examples of comorbidities used to triage patients from the University of Pittsburgh triage system

Examples of Major comorbidities (associated with significantly decreased long-term survival)	**Examples of Severely Life Limiting Comorbidities** (commonly associated with survival < 1 year)
• Moderate Alzheimer's disease or related dementia • Malignancy with a < 10 year expected survival • New York Heart Association Class III heart failure • Moderately severe chronic lung disease (e.g., COPD, IPF) • End-stage renal disease in patients < 75 • Severe multi-vessel CAD • Cirrhosis with history of decompensation	• Severe Alzheimer's disease or related dementia • Cancer being treated with only palliative interventions (including palliative chemotherapy or radiation) • New York Heart Association Class IV heart failure plus evidence of frailty • Severe chronic lung disease plus evidence of frailty • Cirrhosis with MELD score ≥20, ineligible for transplant • End-stage renal disease in patients older than 75

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In this Pittsburgh triage protocol, points were assigned to the patient according to the patient's Sequential Organ Failure Assessment (SOFA) score and the presence of comorbidities.[14] Patients with the lowest total scores would be given the highest priority for access to ICU resources. A "Major" comorbidity in Figure 5B would score 2 points and a "Severely Life Limiting" comorbidity would score 4 points. This scoring system for Major" and "Severely Life Limiting" comorbidities was removed in subsequent iterations of the Pittsburgh protocol.[15] The exact reason for this was not explained, but may be related to the issues that we examine later in this chapter.

In Australia, there are two major ethical and legal problems with using a disease-based triage system. The first is that a disease-based triage system potentially violates the principle of justice, because patients who are similar, from an ethical viewpoint, because their medical conditions have similar predicted outcomes, may be treated differently. Selection criteria are arbitrary and patients who fall either side of a cut-off point are treated differently, even though their predicted outcomes are similar. The principle of justice may also be potentially violated because lists of comorbidities may not be exhaustive, and many conditions with similar outcomes (such as peripheral vascular disease) are not traditionally included on these lists. The second problem with using a disease-based triage system is that it potentially contravenes the Disability Discrimination Act.[16]

5.1.4.2 The Disability Discrimination Act 1992

The introduction of the Disability Discrimination Act 1992 had 3 main objectives.[16] The first was to eliminate, as far as possible, discrimination against persons on the ground of disability in many areas, including work, accommodation, education, access to premises, clubs and sport, and provision of goods and services. The second was to ensure that persons with disabilities had the same rights to equality as the rest of the community. The third was to promote recognition and acceptance within the community of the principle that persons with disabilities had the same fundamental rights as the rest of the community.

The definitions of disability, according to the Act, are:

A *Total or partial loss of the person's bodily or mental functions; or*
B *Total or partial loss of a part of the body; or*
C *The presence in the body of organisms causing disease or illness; or*
D *The presence in the body of organisms capable of causing disease or illness; or*
E *The malfunction, malformation or disfigurement of a part of the person's body; or*
F *A disorder or malfunction that results in the person learning differently from a person without the disorder or malfunction; or*
G *A disorder, illness or disease that affects a person's thought processes, perception of reality, emotions or judgment or that results in disturbed behaviour;*

and includes a disability that:

H *Presently exists; or*
I *Previously existed but no longer exists; or*
J *May exist in the future (including because of a genetic predisposition to that disability); or*
K *Is imputed to a person.*

Under the Disability Discrimination Act, a chronic health condition is likely to be considered a total or partial loss of a bodily function. This means that a triage decision to not admit a patient to an ICU because of a chronic comorbidity or medical condition could be interpreted as discrimination on the basis of disability according to the Disability Discrimination Act, and could be considered unlawful. However, a triage decision on the basis of the predicted overall poor physical or social functional outcome of an individual may not be considered discrimination according to the Disability Discrimination Act, if the poor predicted function was not ascribed to specific medical conditions. This implies that a triage approach using predicted outcome, rather than a specific disease or comorbidity, may not necessarily violate the Disability Discrimination Act.

5.1.4.3 Outcome-Based Approach to Triage Using Comorbidity

An alternative theoretical approach to using disease-based triage criteria to allocate ICU resources on the basis of comorbidity in a public health emergency is to use an outcome-based triage system. There are three potential ways to operationalize outcome-based triage criteria. The first is to use a person's predicted long-term survival as selection criteria. The second is to use a person's level of function. The third is to use a person's level of frailty as selection criteria.

Predicting a patient's long-term survival can be based on knowledge of survival outcomes for a patient's medical conditions combined with estimated survival from their overall state of health. Level of function can be assessed using a scoring system for function such as the Glasgow Outcome Scale – Extended (GOS-E).[17] Level of frailty can be assessed using a scoring system for frailty such as the Clinical Frailty Score (CFS).[18]

The advantage of using outcome-based triage criteria is that it avoids the use of arbitrary lists of medical conditions and arbitrary illness severity cut-offs. However, there are many potential problems in using outcome-based triage criteria.

It can be difficult to predict long–term survival. Population level survival estimates do not necessarily provide accurate predictions for an individual patient. It can be difficult to predict future function, especially function at the end of a hospital stay. A patient's current function may be limited by illness and may not be indicative of future function. As illness improves, function may also improve. Scoring systems for function have reasonable sensitivity and reliability, but may not provide discriminatory power for future outcome prediction.[43] Likewise it can be difficult to predict future frailty for similar reasons.

Triage on the basis of function or frailty may still discriminate against people with disability, and may still therefore contravene the Disability Discrimination Act 1992.[16] No scoring system for function or frailty has ever been validated for use in an ICU triage system. There are currently no published triage protocols using function, frailty scoring systems, or long-term survival.

5.1.5 Addressing Vulnerability and Disadvantage in Intensive Care Triage

No published triage protocols account for people who are considered vulnerable or disadvantaged. There is no one agreed way to define or measure disadvantage in Australia.[19] Vulnerable or disadvantaged people may be less likely to have access to ICU care under normal circumstances because of lack of good access to health care. This may because of economic hardship, homelessness, poorer nutrition, and higher levels of chronic disease.

Health inequity in Aboriginal and Torres Strait Islander People has been recognised as a major public health issue.[20] At the time of the 2009 H1N1 influenza pandemic, Aboriginal and Torres Strait Islander People made up 2.5% of the Australian population, but made up 9.7% of the patients with H1N1 influenza admitted to Australian ICUs.[21] Maori represented 13.6% of the New Zealand population, but made up 25.0% of the patients with H1N1 influenza admitted to New Zealand ICUs.[21] Aboriginal Canadians made up 3.8% of the Canadian population, but made up 25.6% of all patients in Canadian ICUs with H1N1 infection.[22] There is currently no agreed approach worldwide on how to triage people who are considered vulnerable or disadvantaged in a pandemic, and there is no scientific evidence or public engagement to help guide decision-making.

There are no federal anti-discrimination laws in Australia that pertain specifically to social disadvantage.[23] The four main Commonwealth anti-discrimination Acts are:

Racial Discrimination Act 1975 [24]
Sex Discrimination Act 1984 [25]
Disability Discrimination Act 1992 [16]
Age Discrimination Act 2004 [26]

All four Acts contain exemptions that allow positive discrimination. The Racial Discrimination Act 1975 considers that special measures to positively discriminate and advance a disadvantaged racial group is not unlawful discrimination. The Disability Discrimination Act 1992 considers that special measures to positively discriminate to ensure equal opportunities exist for people with a disability or to meet the special needs of people with a disability is not unlawful discrimination. The Age Discrimination Act 2004 also contains exemptions to allow positive discrimination on the basis of age.

5.1.6 Addressing Healthcare Workers and Intensive Care Triage

There is currently no scientific evidence or public engagement studies to help guide decision-making when ICU triage involves frontline healthcare and non-healthcare workers who become sick. The concept of reciprocity acknowledges that frontline staff be provided additional supports because of the risks that they take on behalf of society.[22] An example of such supports would be preferential access to ICU beds. However what additional supports are ethically appropriate and acceptable to society has not been established. What societal tasks constitute frontline work also has not been determined.

5.1.7 The Age Discrimination Act 2004

In April 2002, an international commitment to eliminate age discrimination was adopted by the Second World Assembly on Ageing, in Madrid, Spain. Two years after this, the Age Discrimination Act 2004 was enacted by the Australian federal government.[26]

The introduction of the Age Discrimination Act 2004 had five objectives. The first was to eliminate, as far as possible, discrimination against persons on the grounds of age in the areas of work, education, access to premises, the provision of goods, services and facilities, accommodation, the disposal of land, the administration of Commonwealth laws and programs and requests for information. The second was to ensure, as far as practicable, that everyone had the same rights to equality before the law, regardless of age, as the rest of the community.

The third objective of the Age Discrimination Act was to allow appropriate benefits and other assistance to be given to people of a certain age, particularly younger and older persons, in recognition of their particular circumstances. The fourth objective was to promote recognition and acceptance within the community of the principle that people of all ages have the same fundamental rights. The fifth objective was to respond to demographic change by removing barriers to older people participating in society, particularly in the workforce, and changing negative stereotypes about older people.

In simple terms, the Age Discrimination Act 2004 made it unlawful to discriminate against someone on the grounds of age in respect to the following:

A *Employment and related matters*
B *Education*
C *Access to premises*
D *Provision of goods, services and facilities*
E *Provision of accommodation*
F *Disposal of land*
G *Administration of Commonwealth laws and programs*
H *Requests for information on which age discrimination might be based*

For health care provision there were several exemptions built in to the Age Discrimination Act. The relevant exemptions to be considered for the use of age criteria in pandemic disaster triage were:

A *Exemptions for Positive Discrimination*

The Act did not make it unlawful for a person to discriminate against another person, on the ground of the other person's age if the act provided a bona fide benefit to persons of a particular age; the act was intended to meet a need that arose out of the age of persons of a particular age; or the act was intended to reduce a disadvantage experienced by people of a particular age (such as a young person's homeless shelter).

B *Exempted Health Programs*

The Act did not make an exempted health program unlawful (such as, a program for providing free influenza vaccines to older people, based on evidence).

C *Exemption for Individual Decisions - Health or Medical Goods or Services*

The Act did not make it unlawful for a person to discriminate against another person, on the ground of the other person's age, by taking the other person's age into account in making a decision relating to health goods or services or medical goods or services, if taking the other person's age into account in making the decision was reasonably based on "evidence", and "professional knowledge", about the "ability of persons of the other person's age" to "benefit" from the goods or services; and the evidence was reasonably available at the time the decision was made.

The Australian Human Rights Commission also had the power to grant exemptions in specific circumstances, if this was requested.

According to the Age Discrimination Act 2004, using criteria based on age alone in a triage protocol would be discriminatory, and therefore unlawful. However, if a triage decision was made based on comorbidities related to a person's age, and not specifically to the person's age itself, then this decision may not be discriminatory according to the Act and therefore not unlawful, because it would likely be exempt from the Act.

5.1.8 Public Attitude to Intensive Care Triage

Apart from our iPIT 3 study, there was little literature documenting the views of stakeholders in guiding decision-making during a viral pandemic. Our literature search found no other large cross-sectional studies surveying the views of the general public on methods to triage ICU patients in a pandemic. At the beginning of the COVID-19 pandemic, the iPIT 4 study had only just started.

A small Massachusetts study used focus groups involving 30 members of the public to obtain opinions on scenarios related to pandemic planning.[27] These consumers were strongly opposed to any model of limiting critical care. There were no published studies examining the views of the general public on using chronic comorbidity as triage criteria in a pandemic, or on giving preferential treatment to vulnerable or disadvantaged people or frontline workers. If chronic comorbidity was used as criteria in an ICU triage protocol for a major pandemic, or if preferential treatment was given to specific groups, the views of the general public would be paramount, given that there are significant ethical and legal issues with all the possible triage methods.

5.1.9 Justification for Further Research

With the COVID-19 pandemic just beginning, we concluded that there were several reasons why further research into public views on ICU triage should be conducted:

1 A major pandemic had the potential to overwhelm current healthcare resources and cause significant mortality and morbidity in Australia. Therefore pandemic planning had significant public health importance.

2 In patients with severe COVID-19, ICU admission for invasive ventilation and other ICU treatments (ICU therapy) was the main therapy that improved survival, at the time. The number of ICU beds in Australia was limited and finite. Therefore there was an imperative to manage intensive care resources in a manner during a pandemic that maximised the best outcomes for the community.

3 There was genuine uncertainty regarding what method to triage patients that accounted for chronic comorbidity would be acceptable to the general public. Compliance with restrictive public health measures was dependent on such measures being acceptable to the public. Public involvement in setting priorities was also considered essential because deciding which principles guided the allocation of life-saving resources during a public health emergency was a value judgment, rather than scientific judgment.[7]

4 The degree of supportive measures provided to vulnerable and disadvantaged people in a pandemic that the public would find reasonable had not been determined.

5 It was assumed that on the basis of the concept of reciprocity that the public believed it was reasonable for measures that specifically supported frontline workers be implemented in a pandemic. The degree that the public supported these measures had not been determined.

6 There was little literature documenting the views of stakeholders in guiding decision-making during a viral pandemic. Apart from our work, there had been no studies in Australia examining these issues.

It was on this basis that the ICU Pandemic Triage (IPT 5) study was developed. For the IPT 5 Study, we proposed 3 study questions to ask regarding intensive care triage during a pandemic. These were:

1 Which of the four main methods to triage on the basis of comorbidity, one disease-based and the other three outcome-based, were perceived to be the fairest by the general public?

2 Did the general public perceive giving preferential ICU treatment to vulnerable or disadvantaged people to be fair, in a public health emergency where the demand for intensive care services significantly exceeded the availability of intensive care resources?

3 Did the general public perceive giving preferential ICU treatment to frontline workers to be fair, in a public health emergency where the demand for intensive care services significantly exceeded the availability of intensive care resources?

Our study plan was to obtain the views of the general public in Australia using a paper-based survey.

5.2 The ICU Pandemic Triage (IPT 5) Study - A Survey of Australian Public Opinion on Using Comorbidity to Triage Intensive Care Patients in a Pandemic

5.2.1 Objectives

The primary objective of the ICU Pandemic Triage (IPT 5) Study (A Survey of Australian Public Opinion on Using Comorbidity to Triage Intensive Care Patients in a Pandemic) was to determine which method to triage intensive care patients using chronic comorbidity was perceived to be the fairest by the general public in a pandemic. The secondary objectives were to determine if the general public perceived providing preferential ICU treatment to vulnerable or disadvantaged people to be fair, and to determine if the general public perceived providing preferential ICU treatment to frontline healthcare workers to be fair, in a pandemic.

5.2.2 Methods

The study was a voluntary postal survey conducted in Australia using a self-completed, paper questionnaire, posted to a random sample of 2000 registered voters extracted from the Australian Electoral Commission (AEC) electoral roll. The IPT 5 study was the third and final study in this thesis.

Ethical approval to conduct the study was obtained from the Sydney Local Health District - Concord Repatriation General Hospital - Human Research Ethics Committee (Approval Number 2020/ETH02486 – CH62/6/2020-179 – Project ID 2020/PID02777 - 17th February 2021 – Revised 17th November 2021). Approval to access electoral roll data was obtained from the Australian Electoral Commission (8th October 2021).

Despite ethical approval being granted, site specific approval (SSA) to conduct the study was not granted from Concord Repatriation General Hospital because of the perceived risk of reputational damage to the organisation from the study. The study was considered by the hospital adminstration to be too controversial, despite the safety measures undertaken. The study coordination site was subsequently transferred to The George Institute for Global Health – Australia (Amendment 28th January 2022), and the study commenced on 10th March 2022.

Data entry was completed on 7th November 2022 and data analysis on the study started on 10th November 2022. A study report was written for this thesis, but the study had not been published at the time of this thesis submission.

5.2.3 Questionnaire

A specific questionnaire was developed for the study (Appendix 6). A graphic designer helped with the colour scheme and layout of the questionnaire. The first part of the 12-page questionnaire contained a description of the purpose of the questionnaire and background to the questions (Box 5A).

Box 5A – Purpose and Background for IPT 5 Questionnaire

PURPOSE OF THIS QUESTIONNAIRE

The purpose of this questionnaire is to determine Australian public opinion on how patients should be selected for treatment in an intensive care unit (ICU) in a future pandemic, if not enough ICU beds are available.

BACKGROUND

Currently, if a person develops severe COVID-19 the only treatments that improve their chances of survival are those given in an intensive care unit (ICU), such as being put on a ventilator (also known as a life support machine or breathing machine).

ICUs in Australia coped well during the 2020 COVID-19 pandemic, however, future pandemics of COVID-19 or other new viruses may be more severe, and there may not be enough ICU beds for all the patients who need one.

This disaster situation may create an ethical dilemma, because hospitals may need to decide which patients should be treated when it may not be possible to treat everyone.

One of the ways to decide which patients should be treated in the ICU, when there are too many patients and not enough ICU beds, is to use rules or selection criteria (also called triage criteria).

The following questions will ask you about your views on different types of selection criteria that could be used in a future pandemic.

Respondents were given the four theoretical ICU triage methods that could account for comorbidity. The first method was disease-based and used a patient's chronic medical conditions, to triage. The other three methods were outcome-based, and used a patient's predicted long-term survival, predicted level of function at the end of their hospital stay, and predicted level of frailty at the end of their hospital stay, to triage.

Respondents were asked to rate how fair they thought it was to use each of the four triage methods using a horizontal, seven-point, category rating scale with qualifiers. The question on chronic medical conditions is shown in Box 5B.

Box 5B is shown on the next page

Box 5B – Question 1 – Respondents perception of fairness of triage criteria based on chronic medical conditions

Selection Criteria Based on Long-Term (Chronic) Medical Conditions

One way to decide the priority in which people would be admitted to an ICU in a pandemic disaster, when there are not enough resources to treat everyone, is to give a lower priority to people with certain long-term (also called chronic) medical conditions.

Some examples of long-term medical conditions that could be used as selection criteria:

- Moderate Alzheimer's Disease or moderate dementia (person may forget events or personal history such as address, telephone numbers; they may become confused where they are or what day it is; they may have an increased tendency to wander and become lost)
- Cancer with a less than 10 year expected survival
- Heart Failure with marked limitation of physical activity (person is comfortable at rest, but ordinary physical activity results in fatigue or shortness of breath)
- Moderately severe chronic (long term) lung disease (such as emphysema or pulmonary fibrosis – a person's breathing function tests are about 50% of normal)
- End-stage kidney disease (person is on dialysis or will need dialysis in the near future)
- Severe coronary artery disease
- Cirrhosis (of the liver) with previous episodes of liver failure

There are other examples not listed here.

People who do not have any of these long-term medical conditions would be admitted first. People who have any of these long-term medical conditions would have a lower priority.

Question 1: How fair do you think it is to use a person's long-term (or chronic) medical conditions to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair			Neither unfair or fair			Extremely fair
1	2	3	4	5	6	7

Three further questions were posed to the respondents regarding the outcome-based methods to triage on the basis of comorbidity. Respondents were asked what survival target they thought was the fairest, if a long-term survival target was to be used as triage criteria (Question 2B - Appendix 6 – Page 3). Respondents were asked what cut-off point they thought was the fairest if a modified version of the Glasgow Outcome Scale – Extended (GOS-E) was to be used as triage criteria (Question 3B – Appendix 6 – Page 5).[17] Respondents were also asked what cut-off point they thought was the fairest if a modified version of the Clinical Frailty Score (CFS) was to be used as triage criteria (Question 4B – Appendix 6 – Page 7).[18]

Respondents were then asked to rank in order of preference the four ICU triage methods. The final three questions asked respondents to rate the fairness of three scenarios involving vulnerable patients and healthcare workers. The questionnaire also had areas where respondents could provide free-text comments.

To mitigate order effect bias, participants were randomly allocated one of four versions of the questionnaire with the order of the four triage methods randomised so that they appeared first and last in the same frequency, in similar fashion to the iPIT 3 and iPIT 4 studies. The questionnaire was refined after pilot testing with consenting volunteers. The literacy standard was aimed at a Grade 6 level, or 11 to 12 years old.[28]

To mitigate potential participant distress associated with receiving the questionnaire, an initial safety batch of 200 questionnaires was sent. The returns over this 4 week safety phase were reviewed by an independent safety monitor, in June 2022, who deemed there to be no ethical impediment to the continuation of the study. The remaining 1800 questionnaires were subsequently posted, in the main study phase.

Participants were not contacted to follow up for non-completion, because the Australian Electoral Commission did not allow personal information to be retained, for privacy reasons. Only questionnaires returned within 10 weeks after the last questionnaire was sent were included in the study. All questionnaires returned during the 4 week safety phase and 10 week main study phase were included in the final analysis.

5.2.4 Questionnaire Design

The questionnaire designed for the study (Appendix 6) contained sections with ratings scales, free text, and multiple choice answers, in similar fashion to the iPIT 3 and iPIT 4 studies. A further literature search in 2020, following on from the previous literature searches in 2014 and 2018 prior to the iPIT 3 and iPIT 4 studies (Sections 4.1.4 and 4.2.4), found no new major papers relevant to questionnaire design or rating scales. However, there were several new studies on the use of electronic and web-based surveys compared to traditional paper-based surveys.

A systematic review and meta-analysis demonstrated that electronic data capture methods to assess pain were comparable with conventional methods in terms of score equivalence, data completeness, ease, efficiency and acceptability.[29] A small Australian study comparing an email-based survey to a paper survey in patients discharged from hospital showed similar response rates.[30] The email-based survey was slightly cheaper and was less likely to be incomplete. A study comparing a web-based survey to a paper questionnaire in older adults showed that participants who were female, retired, single, who reported a lower level of education, lower self-reported health, and higher levels of depression were less likely to use a web-based survey.[31]

Since the updated literature review showed that a traditional paper-based questionnaire remained comparable to an electronic questionnaire, and demonstrated some advantages, we decided to continue to use a traditional paper-based questionnaire for the IPT 5 study. Since we wanted to use the Australian Electoral Commission electoral roll as our sampling frame we needed to use paper-based questionnaires that could be sent to participants by postal mail, because the Australian Electoral Commission did not have email addresses for all voters in Australia. Also, the Australian Electoral Commission had no rules or regulations at the time covering the use of email addresses to contact voters.

5.2.5 Sampling Frame

The intent of the IPT 5 study was to draw its sample from the entire Australian population, in similar fashion to the iPIT 3 study (Section 4.1.5), so that its results could be generalizable to the entire Australian community. At the time of the IPT 5 study, Australia had no database that contained contact information for every person in the country. There was no data to suggest a better alternative database to the Australian Electoral Commission electoral roll used in the iPIT 3 study (Section 4.1.6). We therefore used a non-probability sampling technique for the IPT 5 study, using the Australian Electoral Commission electoral roll, similarly to the iPIT 3 study.

The study was unable to be conducted in New Zealand because of the lack of available research staff during the COVID-19 pandemic.

5.2.6 Australian Electoral Commission

There had been no changes to the Commonwealth laws governing the Australian Electoral Commission since our application to access the Australian Electoral Commission electoral roll with the iPIT 3 study (Section 4.1.6).[32] Our new application for the IPT 5 study fulfilled all the necessary legal requirements and our request was made during a time when there were no upcoming state and federal elections. Approval to access electoral roll data was obtained from the Australian Electoral Commission (8th October 2021).

5.2.7 Statistical Analysis

The response rate was defined as the number of questionnaires returned divided by the number of questionnaires sent.[33] We estimated the response rate to be 15% based on the response rate in the iPIT 3 study.[34]

The histogram results from the iPIT 3 study showed variability in the fairness rating scores for each of the different methods of ICU triage in that study, but the results from the histograms were still relatively easy to interpret. We therefore chose to use the histogram method as the main method for determining which method for ICU triage using chronic comorbidity was perceived to be the fairest by the general public, in a pandemic.

We assumed that the IPT 5 study would have the same variability in fairness scores as the iPIT 3 study, but that the histograms for the four methods to rate fairness in the IPT 5 study would be more similar to each other than the triage methods used in the iPIT 3 study. This similar ranking could indicate that a respondent's first preference may not be truly reflective of what the respondents perceived overall to be the fairest method for ICU triage using chronic comorbidity in a pandemic. Therefore, we decided to use a respondent's mean preference ranking of the four triage methods as another measure to determine which method for ICU triage using chronic comorbidity in a pandemic was perceived to be the fairest by the general public.

The mean preference ranking was calculated as the mean of the order of preference (from 1st to 4th) of the four methods to triage on the basis of comorbidity. A lower mean preference score therefore would indicate a higher preference ranking, with 1.0 being the highest possible mean preference score, and 4.0 being the lowest. In the iPIT 3 study, respondents were only asked to pick their most preferred ICU triage method, whereas in the IPT 5 study respondents ranked their preference from 1st to 4th.

To indicate uncertainty around the mean we used standard error (SE) and 95% confidence interval (CI).[35] There was no previous data on public perception of fairness for using comorbidity in ICU triage to guide a sample size calculation. Financial considerations limited our mail out size to 2000. If the mail out size was 2000, the response rate was 15%, and the mean preference score was 2.5 then the 95% confidence interval would be 0.1 each side of the mean. On the basis of this we set our mail out size at 2000.

Expected population figures were derived from Australian Bureau of Statistics data from March and November 2022, and Australian Institute of Health and Welfare data from July 2022.[36,37,44,45] The Chi-Squared Goodness of Fit test was used to compare respondent age (in 10 year age bands), state of residence, and the fairness rating of respondents according to age 51 years or greater and age less than 51 years. We used histograms, means, standard deviations, medians and interquartile ranges to describe the secondary answers. Analysis was performed using Microsoft Excel 2013 (Microsoft Corporation). Calculations were confirmed by an independent statistician using Microsoft Excel (Microsoft Corporation) and STATA 17 (StataCorp).

5.2.8 Results

5.2.8.1 Response Rate and Respondent Population

The response rate was 9.7% (194 replies). The residing state and territory of respondents is shown in Figure 5C, with expected population shown in Figure 5D.

Figure 5C – Proportion and number of questionnaire respondents according to state or territory*

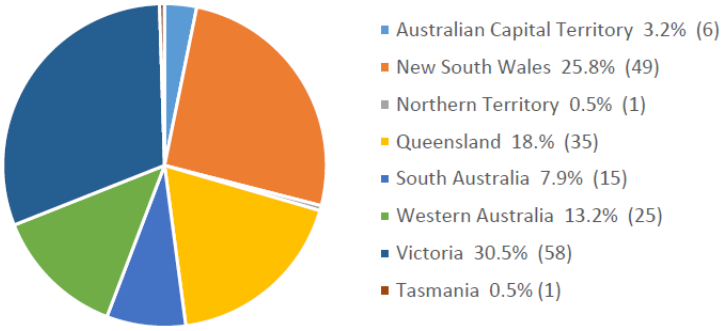
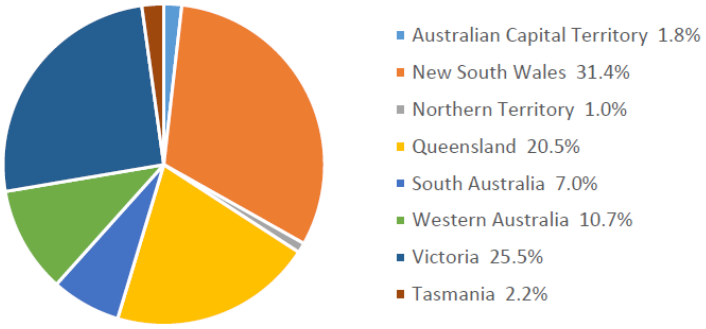


Figure 5D – Actual proportion of Australian population residing in state or territory**



* p 0.24 (Chi-Squared test).
** According to Australian Bureau of Statistics data from March 2022.[36]

There was no statistical difference in the proportions of respondents according to state of residence.

The age of respondents is shown in Figure 5E, with expected population shown in Figure 5F.

Figure 5E - Proportion and number of questionnaire respondents according to age band*

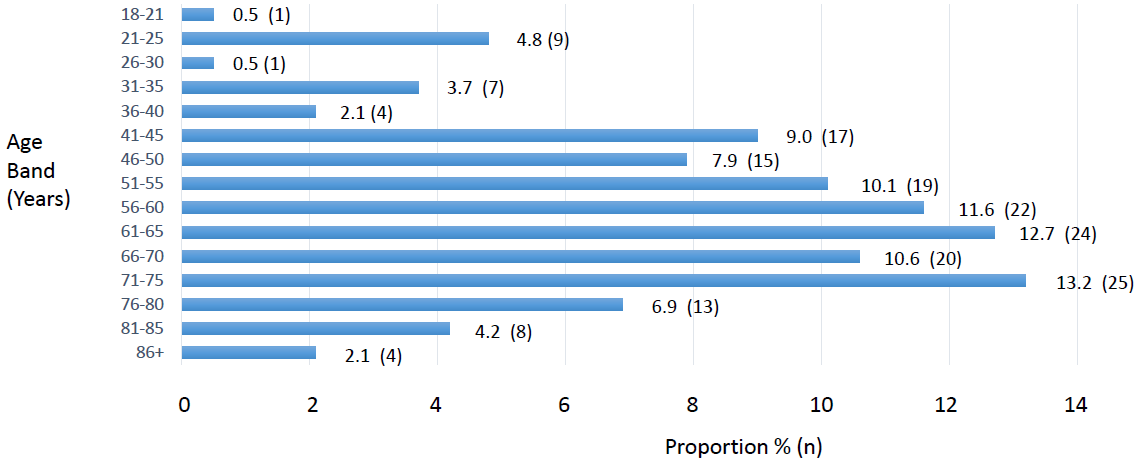
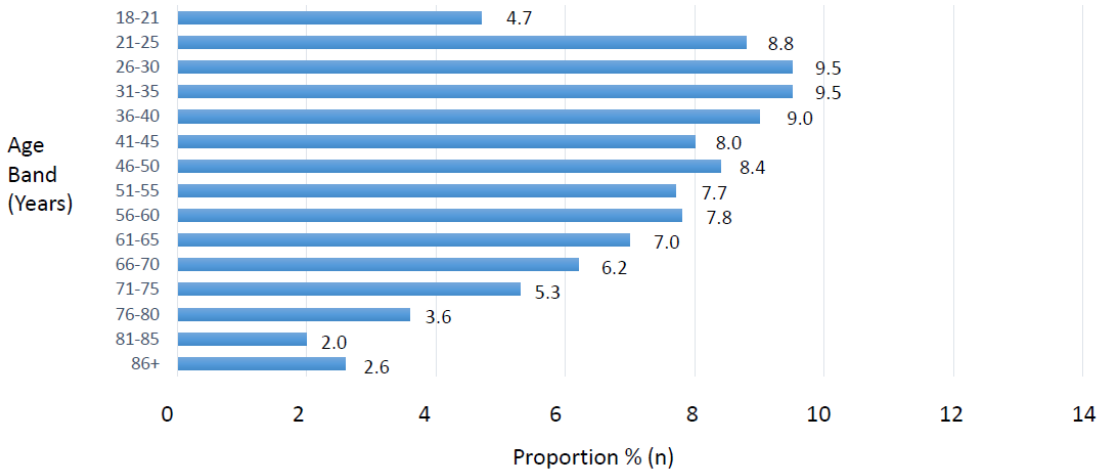


Figure 5F – Actual proportion of Australian population according to age band**



* p<0.001 (Chi-Squared test using 10 year age bands)
** According to Australian Bureau of Statistics data from March 2022.[36]

There was a statistical difference in the number of respondents according to age group, with a lower response rate in younger age groups and higher response rate in the older age groups.

The proportion of female respondents was 56.6% (107 respondents). The population proportion of females in Australia was 50.4%.[36]

The regions where respondents resided in shown in Figure 5G, and the proportion of the Australian population by suburb of residence is shown in Figure 5H.[44]

Figure 5G – Proportion and number of questionnaire respondents according to region (city, town or country area)

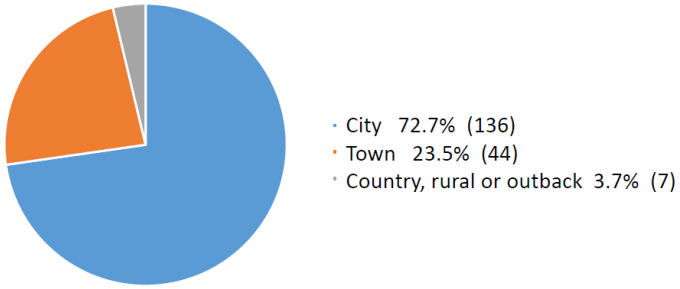
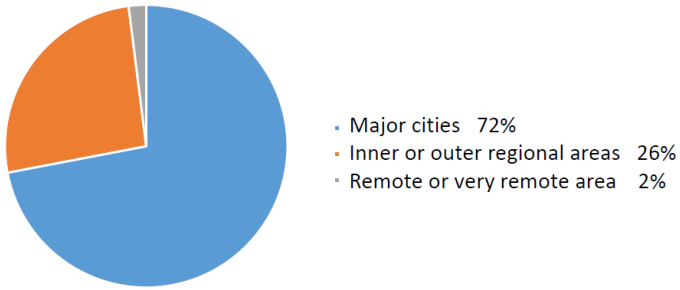


Figure 5H - Proportion of Australian population by suburb of residence*

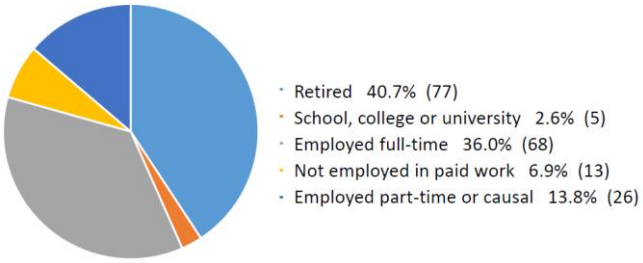


*According to Australian Institute of Health and Welfare data from July 2022.[44]

These proportions were not compared as respondents were only asked whether they resided in a city, town or country area in the questionnaire, and were not asked to state their specific suburb of residence. This meant that respondent region of residence in the questionnaire could not be corroborated with suburb of residence in the Australian Institute of Health and Welfare definitions of city, regional or remote areas.

The employment status of the respondents is shown in Figure 5I.

Figure 5I – Proportion and number of questionnaire respondents according to employment status



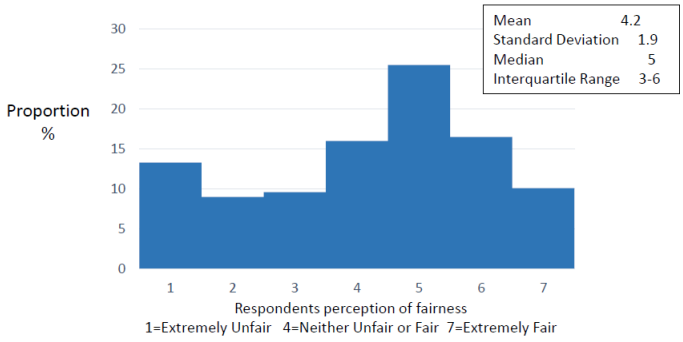
The proportion of the Australian population in full time and part-time employment was 36.9% and 16.0%, respectively.[45]

5.2.8.2 Respondent Perception of Fairness

Respondents' perceptions of fairness for each of four methods that could be used to triage ICU patients on the basis of comorbidity during a pandemic disaster are shown in Figure 5J.

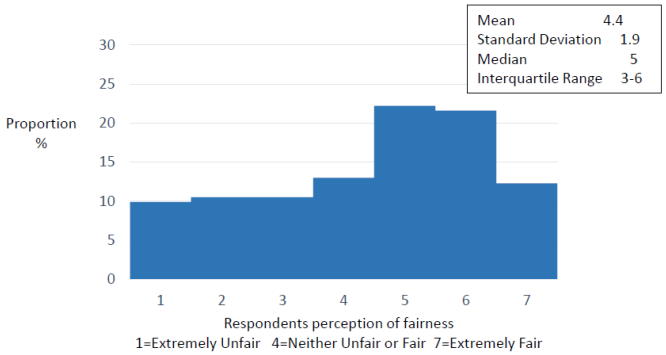
Figure 5J - Respondents' perceptions of fairness for each of four methods that could be used to triage ICU patients on the basis of comorbidity during a pandemic disaster

Responses to Question 1 – "How fair do you think it is to use a person's long-term (or chronic) medical conditions to decide who gets treated in a disaster, when there are not enough resources to treat everyone?"



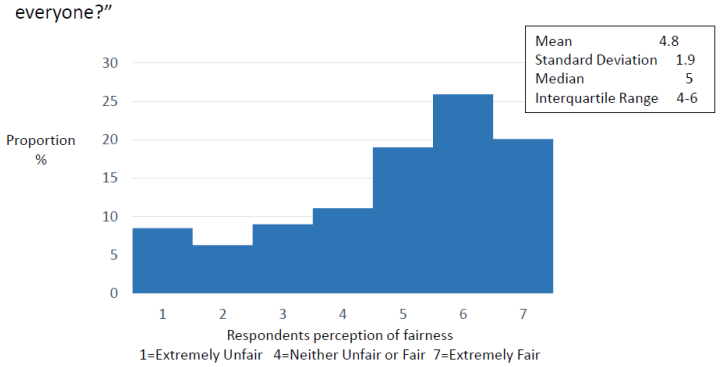
Proportion %	13.3	9.0	9.6	16.0	25.5	16.5	10.1
		31.9		16.0		52.1	
n	25	17	18	30	48	31	19

Responses to Question 2A – "How fair do you think it is to use a person's chance of long-term survival to decide who gets treated in a disaster, when there are not enough resources to treat everyone?"



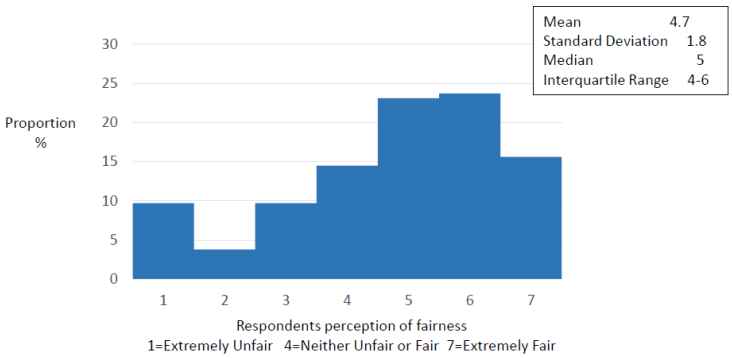
Proportion %	9.9	10.5	10.5	13.0	22.2	21.6	12.3
		30.9		13.0		56.1	
n	16	17	17	21	36	35	20

Responses to Question 3A – "How fair do you think it is to use a person's predicted level of function at the end of their hospital stay to decide who gets treated in a disaster, when there are not enough resources to treat everyone?"



Proportion %	8.5	6.3	9.0	11.1	19.1	25.9	20.1
		23.8		11.1		65.0	
n	16	12	17	21	36	49	38

Responses to Question 4A – "How fair do you think it is to use a person's predicted frailty at the end of their hospital stay to decide who gets treated in a disaster, when there are not enough resources to treat everyone?"



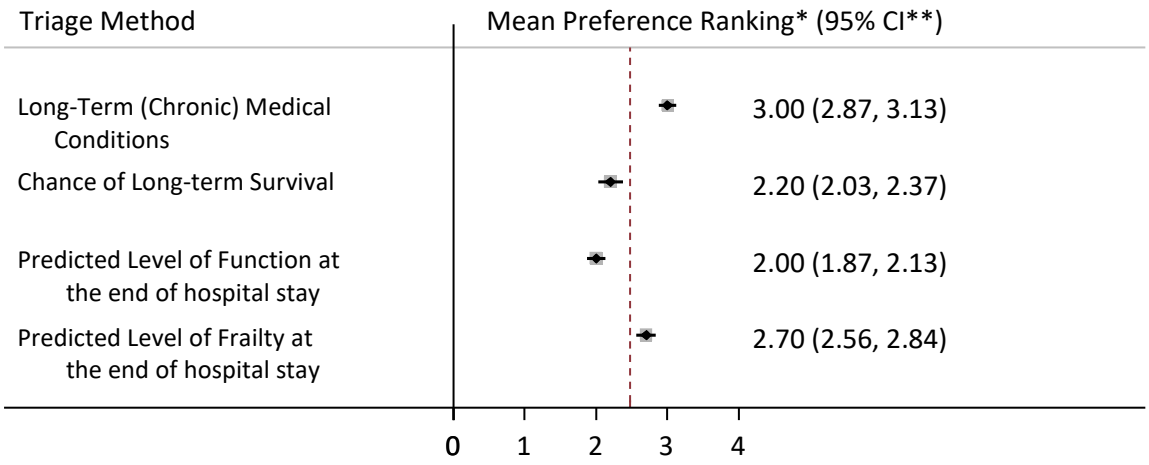
Proportion %	9.7	3.8	9.7	14.5	23.1	23.7	15.6
		23.2		14.5		62.4	
n	18	7	18	27	43	44	29

Respondents considered all four methods to triage on the basis of comorbidity to be fair (rated as greater than four on the rating scale). For each of these four methods, a minority of respondents considered the triage method to be unfair (rated as less than four on the rating scale). The minority was relatively large for the triage methods using a person's long-term (or chronic) medical conditions and a person's chance of long-term survival (31.9% and 30.9%, respectively).

5.2.8.3 Preference Ranking for Triage Methods

The mean preference ranking when respondents were asked to list their order of preference (from 1st to 4th) for the four methods to triage on the basis of comorbidity is shown in Figure 5K. Respondents ranked predicted level of function at end of the patient's hospital stay as the most preferred ICU triage method, with long-term survival target as the next preferred option.

Figure 5K – Respondents' mean preference rankings for the four triage methods



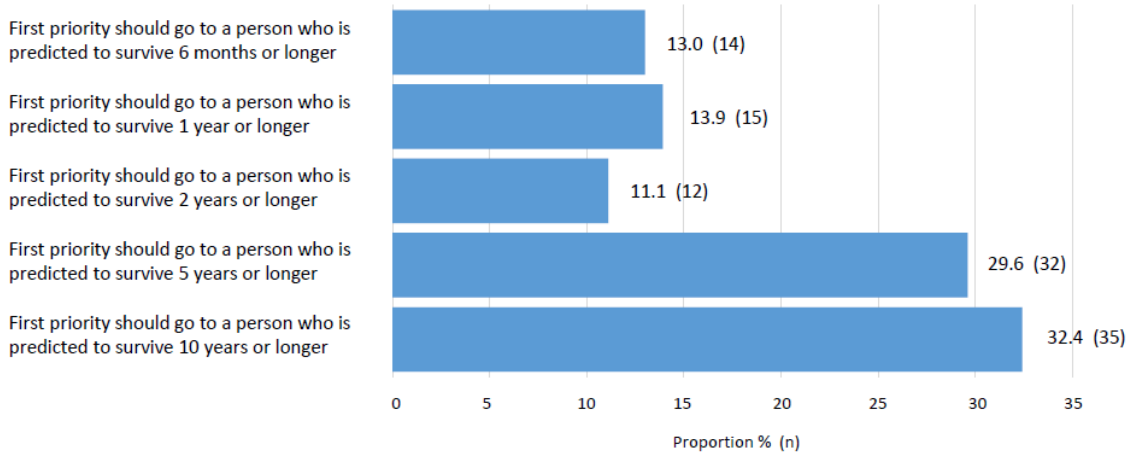
* Mean Preference Ranking (MPR) - a lower score indicates higher preference ranking (1.0 is the highest possible MPR and 4.0 is the lowest possible MPR)

** CI - Confidence Interval

5.2.8.4 Triage Using Predicted Survival

Of the respondents who chose a cut off point if ICU triage was to be performed using predicted survival, the majority indicated that first priority for triage should go to a person who was predicted to survive 10 years or longer, or 5 years or longer (Figure 5L).

Figure 5L – Response to Question 2B – "If a survival target was to be used to decide who gets treated in a disaster, when there are not enough resources to treat everyone, what target do you think is the fairest?"



5.2.8.5 Triage Using Function

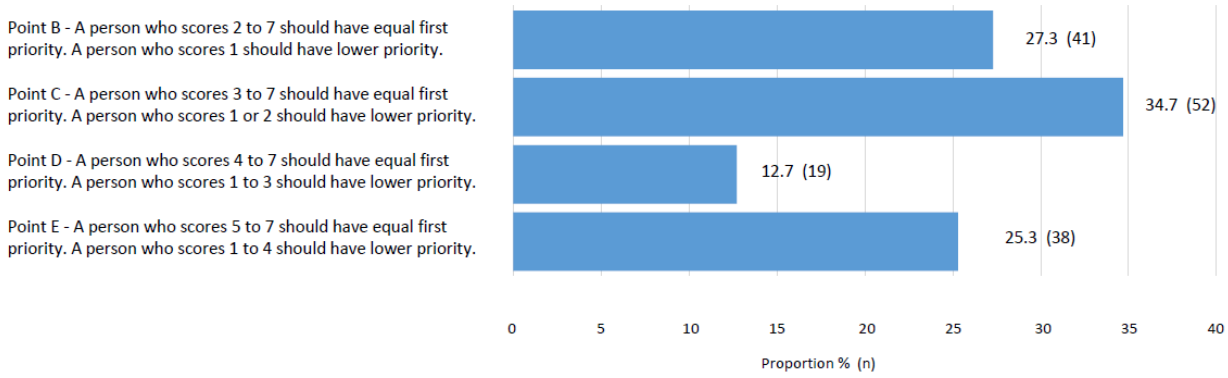
Of the respondents who chose a cut off point if ICU triage was to be performed using the modified version of the Glasgow Outcome Scale – Extended (GOS-E) scoring system for function (Figure 5M), a large proportion (Figure 5N) indicated that ICU triage should be prioritised to people who were predicted to only require partial assistance, at their worst, in activities of daily living at the end of their hospital stay (Point C, Figure 5M and 5N). Using this cut off point, people who were predicted to require full assistance in all activities of daily life or who were in a vegetative state would be prioritised lower.

However, a large proportion of respondents also indicated that this triage threshold should be higher, with ICU triage being prioritised to people who were predicted to be independent and able to resume work or previous activities at the end of their hospital stay, at their worst (Point E, Figure 5M and 5N). Using this cut off point, people who were independent, but could not work, could not go to school or higher education, could not go to previous social activities, or needed any assistance with activities of daily life would be prioritised lower.

Figure 5M – Example scoring system for function used in Question 3B and proposed cut off points*

*The scoring system is based on the Glasgow Outcome Scale – Extended (GOS-E) [17]

Figure 5N – Responses to Question 3B – "If this scoring system was used to decide who gets treated in a disaster, when there are not enough resources to treat everyone, what cut-off point do you think is the fairest?"



5.2.8.6 Triage Using Frailty

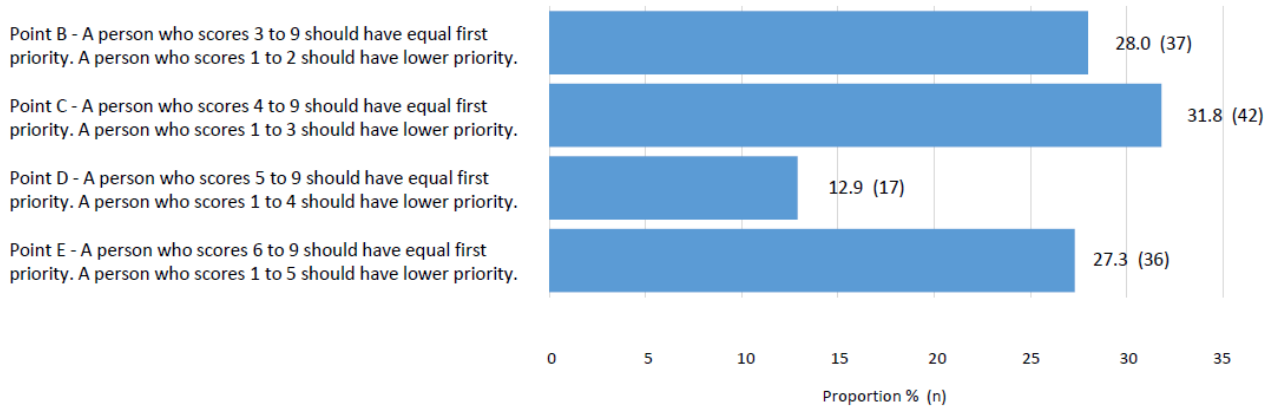
Of the respondents who chose a cut off point if ICU triage was to be performed using the modified version of the Clinical Frailty Score given in the questionnaire (Figure 5O), a large proportion (Figure 5P) indicated that ICU triage should be prioritised to people who, at their worst, were not going to be completely dependent on others for personal care at the end of their hospital stay (Point C, Figure 5O and 5P). However, a large proportion of respondents also indicated that this triage threshold should be higher, with ICU triage being prioritised to people whose symptoms would limit activity at the end of their hospital stay, but whom would not be dependent on others for daily help, at their worst (Point E, Figure 5O and 5P).

Figure 5O – Example scoring system for frailty used in Question 4B and proposed cut off points

	Score	
	1	Approaching end of life, with life expectancy less than 6 months.
	2	Completely dependent on others for personal care and approaching end of life.
Point B →	3	Completely dependent on others for personal care
Point C →	4	Needs help with all outside activities and looking after the house inside. Has problems climbing stairs. May need help with bathing and dressing.
Point D →	5	Slowing down and needs help with finances, transportation, medications, shopping, walking outside alone, meal preparation and housework
Point E →	6	Symptoms limit activity. Not dependent on others for daily help.
	7	Not active beyond routine walking. Medical problems are well controlled.
	8	Can exercise or are very active occasionally. Has no active disease symptoms but less fit than category 9.
	9	Active and energetic

*The scoring system is based on the Clinical Frailty Score [18]

Figure 5P – Response to Question 4B – "If this scoring system was used to decide who gets treated in a disaster, when there are not enough resources to treat everyone, what cut-off point do you think is the fairest?"



5.2.8.7 Additional Questions

Respondents' perceptions of fairness for providing preferential ICU triage in three additional theoretical circumstances are shown in Figure 5Q.

Figure 5Q - Respondents' perceptions of fairness for providing preferential ICU triage in three theoretical circumstances

Figure 5Q-A – Fairness of preferential ICU triage for vulnerable or disadvantaged people

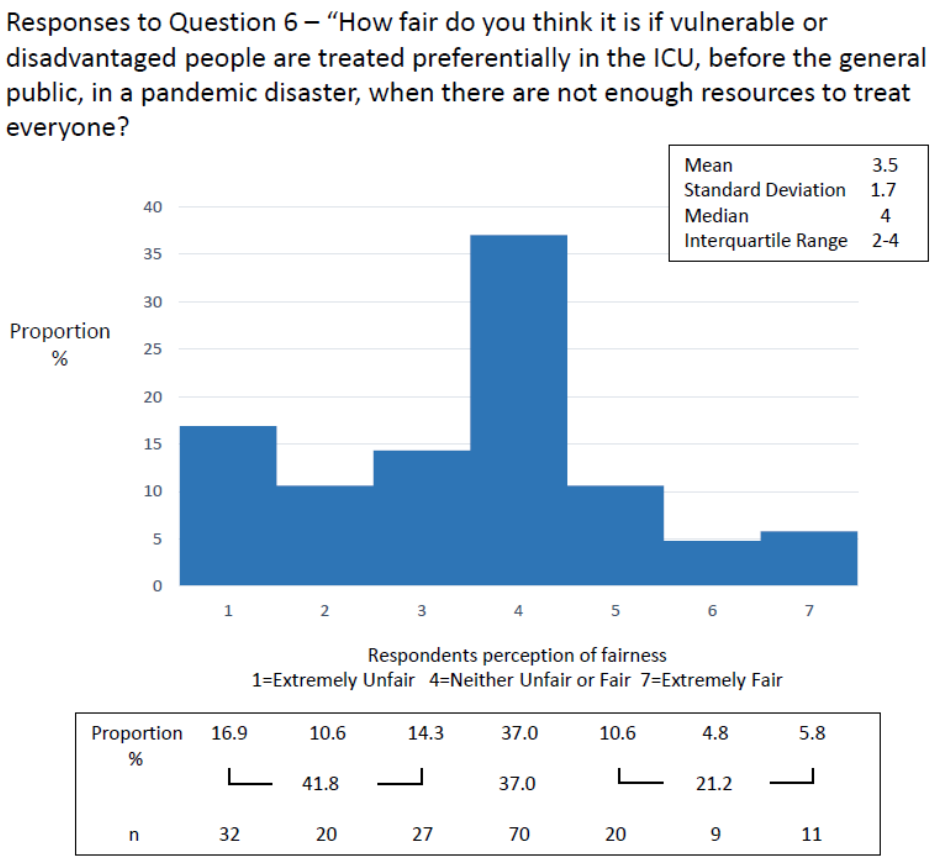
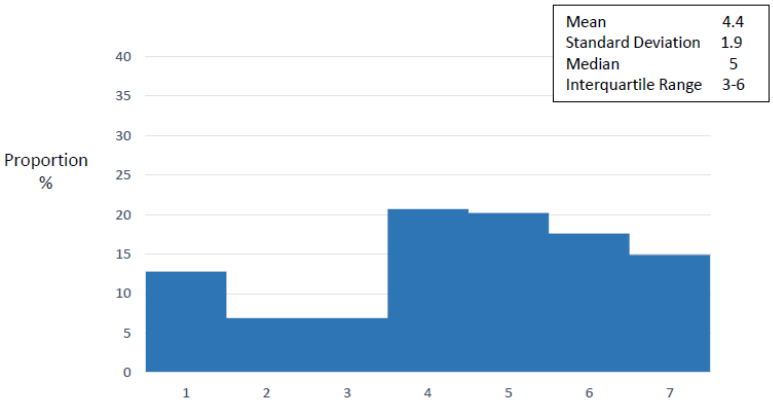


Figure 5Q-B – Fairness of preferential ICU triage for a patient with children

Responses to Question 7 – "Patient A and B are the same age and have the same medical conditions. Patient A is a solo parent and has 2 children, who will be orphaned if Patient A does not survive. Patient B has no children.

How fair do you think it is if Patient A is treated first in the ICU, before Patient B, in a pandemic disaster, when there are not enough resources for everyone?"

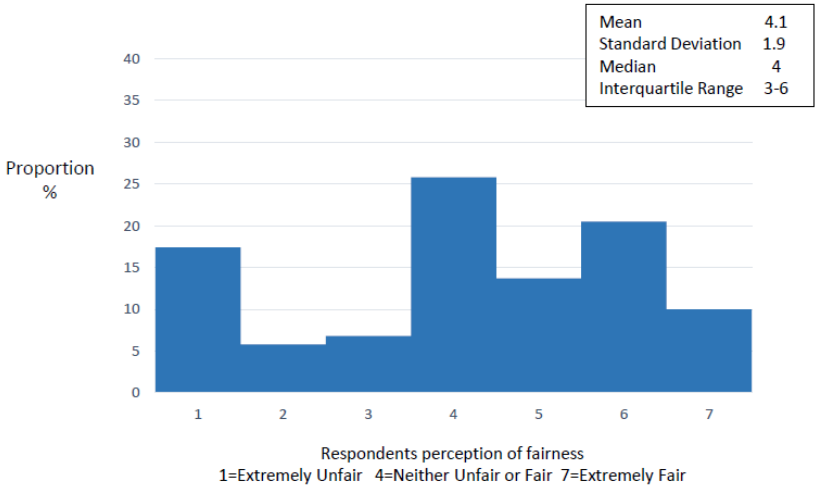


Proportion %	12.8	6.9	6.9	20.7	20.2	17.6	14.9
		26.6		20.7		52.7	
n	24	13	13	39	38	33	28

Figure 5Q-C – Fairness of preferential ICU triage for frontline healthcare workers

Responses to Question 8 – "Patients A and B are the same age and have the same medical conditions. Patient A is a frontline healthcare worker and works in a hospital. Patient B is not a frontline healthcare worker.

How fair do you think it is if Patient A is treated first in the ICU, before Patient B, in a pandemic disaster, when there are not enough resources for everyone?"



Proportion %	17.4	5.8	6.8	25.8	13.7	20.5	10.0
		30.0		25.8		44.2	
n	33	11	13	49	26	39	19

More respondents indicated that it was unfair to provide preferential ICU triage for patients considered vulnerable or disadvantaged, than indicated that it was fair. However, a large proportion of respondents indicated that this was neither unfair nor fair. Respondents considered triaging a solo parent with two children ahead of a person with no children to be fair.

More respondents indicated that it was fair to provide preferential ICU triage for frontline healthcare workers, than indicated that it was unfair. However, the proportion who indicated that this was unfair was large (30.0%). A large proportion of respondents also indicated that this was neither unfair nor fair.

5.2.8.8 Respondent Perception of Fairness According to Age

A post-hoc independent variable analysis was performed, using respondent age 51 years or greater and age less than 51 years, on respondents' perceptions of fairness for each of four methods that could be used to triage ICU patients on the basis of comorbidity during a pandemic disaster. There was no statistical difference in the comparisons using chronic conditions, long-term survival, predicted level of function or predicted level of frailty to triage (p values 0.08, 0.99, 0.14, 0.68, respectively).

Due to the lack of statistical difference in this analysis, no further post-hoc analyses were performed on smaller age bands or on other independent variables (state of residence, sex, and employment status).

5.2.8.9 Free-text Comments

Free-text comments acknowledged the confronting and challenging problem that the questionnaire posed. Many respondents implied that rationing health care resources should not be a consideration in an advanced country such as Australia. Many were of the opinion that governments should ensure that appropriate resources are always available in a disaster, and health care should be better funded. Many respondents stated that no patients should be excluded from treatment in a pandemic, that all lives mattered, and that health care providers should not "play God".

Some had concerns that triage criteria would disadvantage older people, people with disabilities and people with chronic medical conditions. There were concerns that elderly had already been "discounted" during the COVID-19 pandemic by the general community. Some stated that people who were frail or had poor function could still contribute to society, and that other factors affected quality of life, such as family and community support.

Some free-text comments questioned the accuracy of the predictions for future function and long-term survival. Some respondents provided personal accounts where doctors had underestimated the functional outcomes of loved ones, or had underestimated the length of survival.

There was also a view by some that younger people should have priority in pandemic triage, as older people had already "lived their lives". Others commented that there should be greater culpability for lifestyle choices such as smoking and obesity, and there should be greater use of advanced care directives. Some comments implied that it was unfair to prioritise frontline healthcare workers and not prioritise other frontline workers.

5.2.9 Discussion

This national survey, conducted during an actual pandemic, addressed the significant ethical issue of how to account for comorbidity when developing an ICU triage tool to manage a pandemic disaster. The study demonstrated several key findings. First, the majority of respondents to the survey perceived all of the four theoretical methods that could be used to triage ICU patients on the basis of comorbidity in a pandemic disaster to be fair. However, there was a sizable minority who perceived each of the four methods to be unfair. Second, respondents ranked predicted level of function at the end of a patient's hospital stay and a patient's chance of long-term survival as the most preferred of the four methods to perform ICU triage on the basis of comorbidity. However, a concern amongst many respondents was the accuracy of making these predictions. Third, only a small proportion of respondents thought that providing preferential ICU triage to vulnerable or disadvantaged people was fair. Fourth, a large proportion of respondents thought that providing preferential ICU triage to frontline healthcare workers was fair. However, there was a sizable minority who perceived that this was unfair.

How to account for minority views in decision-making is a significant philosophical and ethical problem.[38,39] Democratic societies base decision-making on the views of the majority, but minority groups have significant social roles and can trigger social innovation.[38] Sufficiently large minorities can change societal norms, with the threshold proportion large enough to influence and change the opinion of the majority estimated to be between 10 and 40%.[40]

Though more than 50% of respondents indicated that all four of the triage methods in this study were fair, between 23 and 32% of respondents thought that they were unfair. This sizable minority indicates that there could be significant public opposition if any of these methods were to be used as official health department policy. The free-text comments appeared to support this conclusion.

Respondents ranked predicted level of function at the end of a patient's hospital stay as one of the preferred methods of triage, but there was no consensus for the preferred cut-off point, using the modified Glasgow Outcome Scale – Extended. A large proportion of respondents still prioritised patients predicted to require full assistance in all activities of daily life at the end of their hospital stay as equal priority for ICU admission compared to patients with better function. Only those patients predicted to be in a vegetative state in this circumstance would be prioritised lower. This indicates that it will likely be difficult to obtain consensus on a hard cut-off point for predicted level of function at the end of a patient's hospital stay.

There was greater certainty regarding a preferred cut-off point when using predicted survival as triage criteria, with a 5 year survival target being preferred. However, questions about being able to predict 5 year survival accurately in an individual patient casts doubt on whether this method can be used effectively to triage.[41]

5.2.10 Strengths and Limitations

There were several limitations to this study. The sample-size was relatively small, but this was constrained by cost. The response rate was lower than that of the iPIT 3 study, which used the same sampling frame.[34] The reason for this is unknown, but may be explained by the IPT 5 study having a larger questionnaire (11 pages of text versus 5 pages). The recent COVID pandemic may also have negatively impacted willingness to complete a questionnaire on pandemic planning. The questionnaire was extensive tested and the literacy standard was set at 11 to 12 years of age, but

the content and concepts were complicated.[28] The content may have been more of a hindrance than the literacy standard.

This is the first Australian study to be conducted and completed during an actual pandemic, to engage the public on pandemic health policy in the intensive care. In similar fashion to our previous studies, the IPT 5 study used strategies to mitigate bias and maximise the generalizability of the results. Four different versions of the questionnaire were used to mitigate order-effect bias. Attempts to improve the response rate were made through the use of pre-notification letters, reply-paid envelopes and the use of a design expert to improve the questionnaire's attractiveness. Potential harm from the questionnaire was minimised with the use of an initial safety-phase mail out.

The sampling frame was representative of the general adult population in Australia, because registration on the AEC electoral roll was compulsory, but the higher proportions of women and older respondents may have led to responder bias. The reason for this observation is not known, but the age bias was observed in our iPIT 3 study and another study using the Australian Electoral Commission database.[35,43] The study did not sample people aged under 18 years of age, nor those not enrolled on the electoral rolls, so our results cannot be generalised to these groups.

An electronic, web-based survey would have increased the sample size, but this was limited by the lack of a database containing the email contact details for the entire Australian population. Therefore, conducting the study as a web-based survey would have limited the generalisability of the results.

5.2.11 Implications and Unanswered Questions

The majority of respondents to our survey perceived all of the four theoretical methods that could be used to triage ICU patients on the basis of comorbidity in a pandemic disaster to be fair, but the sizable minority who consider this to be unfair indicates that these triage methods would encounter significant opposition if they were to be enacted in health policy.

It may be possible that the use of chronic comorbidity that is very advanced and end-stage (such as those associated with extremely poor survival or extremely poor function) could be acceptable to the general public for use in as ICU triage criteria, but our study was not designed to examine this in detail.

If our study findings are an accurate reflection of the views of the general public, we conclude that comorbidity currently cannot be used as triage criteria in an ICU triage protocol for a pandemic. This is on the assumption that any triage criteria should take into account the public's view and will need general support from the community. It is likely that using chronic comorbidity for ICU triage contravenes the Disability Discrimination Act. It also appears that a health policy of providing preferential ICU triage to vulnerable or disadvantaged people, or to frontline health care workers is also likely to meet significant opposition, because a sizable minority consider this to be unfair.

Our study provides further information on what triage methods should not be used in an ICU triage protocol, in a pandemic where the demand for intensive care resources is greater than the availability of these resources. The pragmatic question that is now posed is whether it is possible to develop an intensive care triage protocol for a future pandemic in Australia that is ethical, acceptable, lawful and functional?

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Chapter 6 – Conclusion

6.1 Thesis Conclusions for the Triage of Adult Patients Requiring Intensive Care in a Pandemic

The research program for this thesis, which started following the 2009 influenza pandemic, and continued throughout the COVID-19 pandemic, has a number of important findings regarding intensive care triage during a pandemic. Uniquely, this series of studies has increased our understanding of how the public perceive many aspects of intensive care triage. Accordingly, several conclusions can be made regarding the triage of adult patients requiring intensive care during a pandemic. This thesis will help health care systems plan for future pandemics.

Results from the IPT 5 study and the interim results of the iPIT 4 study indicate that a significant proportion of society does not find the limitation of intensive care resources in a pandemic disaster to be acceptable. There is an expectation from some people that all patients who require intensive care should be treated. There appears to be an expectation from the public that there be adequate planning and preparation for disasters in Australia.

Context

The two viral pandemics to affect Australia in the past 13 years showed that there is a theoretical possibility that demand for intensive care services from patients in a future pandemic could overwhelm intensive care resources.

Conclusion 1

Governments and health care providers in Australia must prepare for the increased resourcing of intensive care units that will be required in future pandemics.

Results from the iPIT 3 study support an Australian societal view that the first-come, first-served approach should not be used to allocate intensive care resources in a pandemic.

Context

The first-come, first-served approach to resource allocation is ethically unfair in a pandemic when resources are scarce. Intensive care resources in Australia are finite. Even if increased resourcing is provided by government or health care providers for a pandemic, these resources theoretically could still be overwhelmed.

When there is a scarcity of resources the usual biomedical ethical principles of autonomy, nonmaleficence and beneficence cannot be actioned for every individual. Therefore, the ethical approach to a pandemic where the demand for intensive care services exceeds the availability of those resources, focuses on the principle of justice, determining how the scarce benefits and

significant burdens are distributed. If no plans are in place to allocate scarce intensive care resources in a pandemic, health systems will likely resort to a first-come, first-served approach.

Conclusion 2

Plans must be developed to allocate intensive care resources in a future pandemic where the demand for intensive care services exceeds the availability of the intensive care resources.

The iPIT 3 study showed that there is support in Australian and New Zealand for the use of ICU triage systems in a pandemic where the demand for intensive care resources exceeds the availability of these resources. However, interim results from the iPIT 4 study indicate that a large proportion of surrogate decision-makers for patients in the ICU, when subjected to the emotional stress of being responsible for a critically ill patient during an actual pandemic, find any type of triage or resource prioritisation to be unfair and unacceptable. To reconcile this expectation requires an increase in the amount of intensive care resources, which may not be completely achievable in a pandemic.

Context

Results from the iPIT 1 and iPIT 2 studies, conducted in a simulated pandemic, suggests that triage protocols may work in increasing ICU bed availability in a pandemic. However, there is currently no published experience of the use of intensive care triage protocols in an actual pandemic. Using triage systems to allocate scarce intensive care resources in a pandemic addresses many of the issues related to upholding the ethical principle of justice. Triage systems are both utilitarian and egalitarian, but some triage criteria can violate the principle of justice.

Conclusion 3

Triage systems should be used to allocate intensive care resources in a pandemic where the demand for intensive care services exceeds the availability of intensive care resources.

Results from the iPIT 3 study supported an Australian societal view that the triage of intensive care patients in a pandemic, where the demand for intensive care services exceeds the availability of these resources, should be performed by a both a senior doctor and predetermined triage criteria.

Context

A potential problem with using predetermined triage criteria to triage intensive care patients in a pandemic is that triage protocols do not have significant operational flexibility in their current form. Current triage protocols do not respond quickly to sudden changes in the demand for and the supply of intensive care resources. The use of senior doctors to make resource allocation decisions can potentially overcome this problem.

The potential problems with a senior doctor making resource allocation decisions in a pandemic include the risk of bias, prejudice or nepotism; the placement of the burden of decision-making on one person may be psychologically traumatic and unfair; and there may be problems with accountability and transparency. In my opinion, having a group or committee of senior doctors make the resource allocation decisions, instead of a single individual, potentially overcomes some of these problems. Using predetermined triage criteria to allocate resources potentially provides greater accountability and transparency than using a senior doctor alone. Triage in a pandemic should therefore use both techniques.

Conclusion 4

Triage for intensive care resources in a pandemic where the demand for intensive care services exceeds the availability of intensive care resources should be performed first using predetermined triage criteria contained in a triage protocol, with the final triage decision being made by a group or committee of senior doctors.

Results from the iPIT 3 study supported an Australian societal view that it is reasonable to triage intensive care patients on the basis of their chance of survival.

Context

Triage based on a patient's chance of survival is ethical according to the utilitarian theory of justice. The iPIT 1 and 2 studies and other studies indicate that acute derangements in physiology are reasonably accurate at predicting short-term survival.

Conclusion 5

Acute derangements in physiology should be used in triage criteria for intensive care resources in a pandemic where the demand for intensive care services exceeds the availability of intensive care resources.

The iPIT 3 study supported an Australian societal view that it is reasonable to triage intensive care patients on the basis of their chance of surviving, in a pandemic where the demand for intensive care services exceeds the availability of these resources.

Context

The iPIT 1 and iPIT 2 studies suggested that triage protocols will make more ICU beds available in a pandemic if patients with low predicted mortality and patients who do not require invasive ventilation or cardiovascular support are excluded. These patients are less likely to suffer harm if intensive care resources are prioritised to other patients, because their chances of dying are low. The iPIT 1 and iPIT 2 studies suggested that excluding patients with low predicted mortality theoretically results in greater increases to ICU bed availability than excluding patients with high predicted mortality.

Conclusion 6

Patients with the lowest and highest predicted mortality should be assigned to a lower priority in triage protocols for intensive care resources in a pandemic where the demand for intensive care services exceeds the availability of intensive care resources.

Results from the iPIT 3 study suggests that Australian society believes it is reasonable to triage patients according to age in a pandemic, where the demand for intensive care services exceeds the availability of these resources, if there are extreme differences between the ages of patients.

Context

There are valid ethical arguments supporting why triage based on age is acceptable, in a pandemic.

A legal problem with using age as criteria in a pandemic triage protocol arises from the Age Discrimination Act 2004. Using criteria based on age alone in a triage protocol is discriminatory according to this Act and therefore unlawful. However, triage decisions based on comorbidities related to a person's age, and not specifically to the person's age itself, are potentially exempt from this Act, and therefore potentially not unlawful.

Conclusion 7

Age criteria alone cannot be used in triage criteria for intensive care resources in a pandemic.

Results from the IPT 5 study suggest that the majority of Australians would support triage to intensive care in a pandemic, where the demand for intensive care services exceeds the availability of these resources, using a person's predicted level of function at the end of the person's hospital stay; a person's chance of long-term survival; a person's predicted level of frailty at the end of the person's hospital stay; and a person's chronic medical conditions. However, a sizable minority are not supportive of using any of these four methods. This indicates that there would likely be significant opposition if any of these four triage methods were to be enacted in a triage protocol.

The IPT 5 study did not demonstrate a clear cut-off point for level of function or frailty that would be acceptable to Australian society for use to triage patients to intensive care in a pandemic. The IPT 5 study also did not demonstrate a clearly acceptable cut-off point for long-term survival.

Context

It is likely that triage criteria using chronic medical conditions would contravene the Disability Discrimination Act 1992. Triage criteria based on the predicted overall poor physical or social functional outcome of an individual may not be considered discrimination according to the Act, if the poor predicted function was not ascribed to specific medical conditions. However, triage criteria based on general processes related to ageing could be considered discrimination according to the Age Discrimination Act 2004, unless that decision was based on "evidence", "professional

knowledge", and the "ability of the person" being triaged "to benefit" from treatment. The definition of these terms used in the Age Discrimination Act is open to interpretation.

Using triage criteria based on the chance of long-term survival is not discriminatory according to the Disability Discrimination Act 1992 and the Age Discrimination Act 2004, but there is genuine community and scientific concern regarding the ability of clinicians to accurately predict long-term survival.

Conclusion 8

Chronic medical conditions cannot be used as triage criteria for intensive care resources in a pandemic.

Predicted level of function, chance of long-term survival and predicted level of frailty cannot be used as predetermined triage criteria in triage protocols for intensive care resources in a pandemic, however these methods to determine comorbidity can be taken into account by senior doctors in their triage decision-making, if the decision is based on "evidence", "professional knowledge" and the "ability of the person" being triaged "to benefit" from treatment.

The IPT 5 study suggests that only a minority of Australian society believes it is fair to preferentially prioritise disadvantaged populations in a pandemic.

Context

Societal vulnerability and disadvantage in health care is a significant problem in Australia. There is an ethical basis supporting the preferential prioritisation of disadvantaged populations for access to intensive care resources in a pandemic where the demand for intensive care services exceeds the availability of these resources. However, defining what constitutes disadvantage is difficult.
As a minimum, there is an ethical basis to ensure that disadvantaged populations are not further disadvantaged in a pandemic.

Commonwealth laws in Australia make positive discrimination on the basis of race, sex, age and disability not unlawful in certain circumstances. This indicates that prioritising disadvantaged populations for access intensive care resources in a pandemic may not be unlawful. However, the IPT 5 study indicates that there would likely be significant opposition if preferential triage on the basis of disadvantage were to be enacted in a triage protocol.

Conclusion 9

Using social disadvantage to preferentially triage patients for intensive care resources in a pandemic where the demand for intensive care services exceeds the availability of intensive care resources cannot be recommended. However, there is an ethical basis to ensure that disadvantaged populations are not further disadvantaged in a pandemic.

The IPT 5 study suggests that a sizeable minority of Australian society believes it is unfair to preferentially prioritise frontline healthcare workers in a pandemic.

Context

There is an ethical basis supporting the preferential prioritisation of frontline healthcare workers for access intensive care resources in a pandemic where the demand for intensive care services exceeds the availability of these resources. However, defining what constitutes a frontline healthcare worker is difficult.

The IPT 5 study indicates that there would likely be significant opposition if preferential triage of frontline healthcare workers were to be enacted in a triage protocol.

Conclusion 10

Preferentially assigning frontline healthcare workers as higher priority in triaging for intensive care resources in a pandemic where the demand for intensive care services exceeds the availability of intensive care resources cannot be recommended.

In a liberal democracy, population-level decision-making is ultimately made by elected representatives, who take into account the opinion of the public, as well as a range of expert advice. The opinion of the people is not necessarily the sole basis for population-level decision-making. However, if a public health policy or the process used to enact policy is considered unfair the legitimacy of a public health response may be challenged, and restrictive measures may not be adhered to.

Context

The interim results of the iPIT 4 study indicate that there is likely to be societal opposition to any policy of limiting access to intensive care resources in a pandemic. This opposition is likely to be similar regardless of whether a patient is refused admission to the ICU or is discharged prematurely from the ICU. The iPIT 4 study results indicate that good communication may help attenuate this opposition.

Conclusion 11

Triage planning must undergo widespread public consultation. Pandemic triage policies must be promulgated to the public well in advance of any pandemic.

Staff responsible for instituting pandemic triage policies must ensure adequate communication with patients, families, and surrogate decision-makers.

The studies conducted during this research program pertained to adult patients. None of these studies were designed to address the issues associated with triaging children in a pandemic.

Conclusion 12

No recommendations on intensive care triage for paediatric patients in a pandemic are made in this thesis.

The iPIT 3 study was conducted in Australia and New Zealand. The other studies conducted during this thesis were based entirely in Australia.

Context

This limits the external validity of the results outside of Australia, but it is likely that the results generated by the studies conducted in this thesis are generalizable to countries similar to Australia. There is a paucity of evidence in other countries to guide intensive care resource allocation in a pandemic. Laws pertaining to triage differ in other countries.

Conclusion 13

The recommendations on intensive care triage in a pandemic made in this thesis may be applicable to other countries if they have similar health care systems, similar societal moral values and similar laws to Australia.

6.2 Summary Conclusions for the Triage of Adult Patients Requiring Intensive Care in a Pandemic

Box 6A - Summary Conclusions for the Triage of Adult Patients Requiring Intensive Care in a Pandemic

Governments must prepare and provide for the increased resourcing of intensive care units that will be required in future pandemics.

Triage systems should be used to allocate intensive care resources in a pandemic where the demand for intensive care services exceeds the availability of intensive care resources.

A system to triage adult patients requiring intensive care during a viral pandemic, where the demand for intensive care services exceeds the availability of intensive care resources, should:

- Use predetermined triage criteria contained in a triage protocol first, with a final triage decision being made by a group or committee of senior doctors.

Triage criteria contained in triage protocols should:

- Use acute derangements in physiology;
- Assign patients with the lowest and highest predicted mortality as lower priority;
- Not use age criteria alone;
- Not be based on chronic medical conditions, predicted level of function, chance of long-term survival or predicted level of frailty;
- Not preferentially assign disadvantaged patients as higher priority, but should ensure that disadvantaged populations are not further disadvantaged;
- Not preferentially assign frontline healthcare workers as higher priority.

When making triage decisions, senior doctors:

- Can consider predicted level of function, chance of long-term survival and predicted level of frailty, if the decision is based on “evidence”, “professional knowledge” and the “ability of the person” being triaged to “benefit” from treatment.
- Must ensure adequate communication with patients, families and surrogate decision-makers.

Triage planning must undergo widespread public consultation.

Pandemic triage policies must be promulgated to the public well in advance of any pandemic.

6.3 Future Direction

This PhD thesis and the research program behind this PhD program provide health departments in Australia with guidance on how to triage adult patients requiring intensive care during a pandemic, where the demand for intensive care services exceeds the availability of intensive care resources. The completion of the iPIT 4 study in the next year will clarify the interim findings on the acceptability of triage systems and the problems that may be encountered in operationalising these systems. However, many practical, scientific and ethical issues remain.

Governments should increase spending on and preparation of intensive care resources well in advance of any future pandemic. Our studies suggest that this is the expectation of the general public.

There is support from our work for using intensive care triage systems. Health departments should now work to develop these systems. However, the introduction of these systems will require transparency and significant public engagement.

This thesis does not provide a detailed critique of the legal matters associated with disaster planning. There are legal issues that must be addressed.

The challenge in trying to develop specific triage criteria is that public consensus will be difficult to achieve, as our work has shown. The community should again be surveyed to determine the fairness and acceptability of the new triage protocols. The new triage protocols should be prospectively tested in simulated pandemic conditions to determine theoretical efficacy and identify operational issues, before they are required to be used in an actual pandemic. However, it is acknowledged that whatever the triage method, there will not be overwhelming support for that method.

Our studies did not explore what would be an acceptable, practical and ethical way to account for the views of a senior doctor. In the iPIT 3 study we did not provide any details on what was meant by the phrase “let a senior doctor decide”. It has been suggested that during a pandemic a group of senior doctors could make up a triage committee. It has also been suggested that these committees include other people as well. The number of people required to form a committee of senior doctors and the makeup of this triage committee will need to be determined. The committee concept for triage should be tested for ease of use, accuracy, validity, consistency and acceptability. There are important ethical and governance challenges that will need to be addressed. The psychological effect of pandemic triage decision-making on clinicians should also be examined.

The ICU Pandemic Surveillance (IPS) Program (Appendix 7) has received ethics approval, and awaits funding to become operationalised in a future pandemic. The primary objective of this program was to refine ICU admission and discharge criteria, triage protocols or triage methods in a timely manner, to ensure that ICU therapy was used to maximize the number of lives saved during the COVID-19 pandemic. The program was designed to run in all ICUs in Australia that had the capability to collect daily data during a pandemic.

The optimal method for triaging children in a pandemic remains unknown. Further research is required to address this issue and needs to determine how to perform intensive care triage if children and adults present simultaneously. Finally, it remains unknown whether the findings and recommendations from this thesis apply to other countries, particularly those with user-pays or resource-limited health care systems. Further research should be conducted in these settings.

Chapter 7 - Reflection

When I started my research into pandemic planning in 2009, pandemics were estimated to occur approximately once every 10 years. Because of this observation, the assumption was that the next pandemic would occur around 2019. Other viruses could cause serious illness, however at the time serious illness was most commonly caused by influenza viruses. Therefore the expectation was that an influenza virus would be the major pathogen for the next pandemic. It was deemed less likely that another virus would be the major pathogen. However, on reflection it made sense that a novel virus would cause more severe disease in humans, due to the lack of innate immunity and previous exposure.

Funding for pandemic research prior to the COVID-19 pandemic was difficult to obtain, as pandemic planning was not a government priority. Funding during the COVID-19 pandemic was even harder to obtain, as the research priorities were for treatments for the disease. Triage research was not considered a funding priority. Therefore, this PhD thesis was almost entirely self-funded.

It was serendipitous that the COVID-19 pandemic occurred, as this provided the impetus to answer the important ethical questions regarding intensive care triage. The pandemic also provided the realism to the scenarios portrayed in the questionnaires. The scenarios were hypothetical, but respondents were able to provide responses based on the actual experience of living through a pandemic.

I learnt several important lessons during this PhD thesis.

Gather a Good Team, Seek Advice and Consult Widely

The first lesson I learnt from this thesis was to gather a good team, seek advice and consult widely. I was privileged that the thesis involved collaborating with many experts in their fields. I received invaluable advice from my mentors and from the management committees and coinvestigators for the studies that I developed. My collaborators came from a background of diverse research interests, from ethics to public health, all of which helped greatly in refining the protocols for the studies.

I also received invaluable advice from research managers, research nurses, statisticians, educators and other staff on many of the practical issues related to conducting the studies. Our graphics designer added significant appeal to the questionnaires, a factor that I am sure led to a better response rate. I was told at the start that we would get a better response rate if we could keep the questionnaire size to two pages or less!

An example of the benefits of consulting widely resulted from a presentation that I gave on the iPIT 3 study protocol at a binational intensive care research meeting, to help me with a funding application. Afterwards, I was approached by some New Zealand colleagues who eventually helped me to conduct the study in New Zealand. This doubled the size of the iPIT 3 study and also allowed us to assess the generalisability of the results by comparing two countries. It was this national exposure that also led to the collaboration with our Queensland colleagues.

Perhaps my best example of the benefits of consulting widely was when it was pointed out that we needed to mitigate order-effect bias in the iPIT 3 study. In hindsight, it was an obvious flaw in our

original study design, but we hadn't considered this potential problem until it was recognised. Though it was hard to ascertain whether order-effect bias was a real problem in the iPIT 3 study, this bias became obvious at the end of the iPIT 4 study when reviewing the free-text comments from respondents. Some respondents reported in the free-text that their answers were influenced by the previous questions. Randomising the order in which the questions were presented in all three studies in this thesis therefore undoubtedly improved the validity of the results.

Consult Consumers

The second lesson I learnt from this thesis was to involve consumers. Consumer testing was invaluable in developing the questionnaires. A significant amount of testing and fine tuning was required to get the questionnaires to a standard that would not only be understandable, but would also provide the answers that we needed. Consumer testing was also paramount in ensuring the safety of the participants.

Preparation, Preparation, Preparation

The third lesson I learnt was to anticipate and pre-empt problems if possible through good preparation. An example of this was after the printers had printed 2000 reply paid envelopes for the iPIT 3 study I decided to test the reply paid postal system by sending a batch of test envelopes. To my consternation, I received none of the test envelopes back, despite waiting six weeks. This consternation turned to relief when I discovered that the local Australia Post office had been batching the reply paid envelopes returned, and was planning on forwarding the envelopes to me in batches once a certain amount had been received. Thereafter, for the iPIT 4 and IPT 5 studies I made sure I tested the reply paid system before printing the bulk of the reply paid envelopes.

Australian and New Zealand Electoral Commissions

The Australian Electoral Commission and New Zealand Electoral Commission electoral rolls turned out to be an ideal sampling frames. We found both electoral commissions to be very helpful in providing names and contact details for potential study participants in this thesis.

It was interesting to observe the difference in the approach to privacy and research taken by the Australian and New Zealand Electoral Commissions. Privacy was at the forefront of the Australian Electoral Commission. Stringent processes were in place to ensure that data was kept confidential and destroyed immediately when no longer required. The New Zealand Electoral Commission took a different view. Given that research was being done on the New Zealand public the New Zealand Electoral Commission took the view that they had an obligation to ensure that the research was completed, and used to enhance people's health. Permission was given for data to be retained in New Zealand so that nonresponders to the questionnaires could be contacted again in an attempt to improve the response rate. Ethics committees in New Zealand also mandated that data be collected in New Zealand on ethnicity, so that subgroup analyses could be performed, specifically on the Maori population.

Like all government departments the electoral commissions had periods where they were extremely busy and research became a lower priority. My fourth lesson is to use the electoral roll when they are not busy, outside of state and national election cycles.

Research in Pandemics

My final lesson, is more an observation. The COVID-19 pandemic took a toll on the healthcare staff in the hospitals, but I have never worked with a group of more dedicated and hard-working individuals. I hope that the personal toll suffered by many of these staff is one day properly acknowledged.

Research suffered also during the COVID-19 pandemic. One of the main reasons was research staff were redeployed to clinical areas to support frontline clinical staff. This meant that even basic epidemiological research, information vital to tracking the pandemic, was difficult to do. Of the eight original sites in the iPIT 4 study, four could not start due to lack of research staff. ICUs are still currently struggling to replenish their ranks.

Ethics departments responded quickly to the changing research imperatives by fast-tracking approvals for studies. However, enrolling patients into clinical trials to assess treatments for COVID-19 was extremely difficult due to this lack of research staff. Even simple observational studies examining personal protective equipment or hospital design was difficult due to the deprioritisation of research during the pandemic. This research was only carried out through the dedication and perseverance of researchers. The lack of research staff made combating the pandemic more difficult from a societal perspective.

In future pandemics, research staff, research capacity and research infrastructure must be maintained to allow vital research to continue. Basic sciences research is vitally important in combatting future pandemics. However, it is a folly to expect future pandemics to be rapidly countered if there is no cohesive clinical research network to collect data and conduct clinical trials. Clinical research must remain an important priority in any future pandemic response.

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Australia and New Zealand Intensive Care Society (ANZICS).
Australia and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG).
Australia and New Zealand Intensive Care Society Paediatric Study Group (ANZICS PSG).
Australia and New Zealand Intensive Care Society Centre for Outcome and Resource Evaluation (ANZICS CORE).
Canadian Critical Care Trials Group (CCCTG).
The Sax Institute.

Publications, Presentations and Grants

Publications Related to Thesis

Cheung W, Myburgh J, McGuinness S, Chalmers D, Parke R, Blyth F, Seppelt I, Parr M, Hooker C, Blackwell N, DeMonte S, Gandhi K, Kol M, Kerridge I, Nair P, Saunders NM, Saxena MK, Thanakrishnan G, Naganathan V, on behalf of the The Influenza Pandemic ICU Triage 3 (iPIT 3) Study Investigators and the Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group (CTG). A cross-sectional survey of Australian and New Zealand public opinion on methods to triage intensive care patients in an influenza pandemic. Crit Care Resusc 2017; 19: 254-265. https://ccr.cicm.org.au/Journal-Editions/2017/September/19/Original-Articles/Article-9
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ANZICS 22nd Annual Meeting on Clinical Trials in Intensive Care – "Recommendations for ICU Triage in a Pandemic" – 3 March 2020

ANZICS 18th Annual Meeting on Clinical Trials in Intensive Care – "Influenza Pandemic Study" – 8 March 2016

ANZICS 15th Annual Meeting on Clinical Trials in Intensive Care – "Influenza Pandemic Study" - March 2013

Other Presentations during Thesis

International Society for Rapid Response Systems (iSRRS) and ANZICS Conference – "Minimum ICU Workforce Standards" – 19 July 2022

ANZICS and ACCCN ASM - "Minimum ICU Workforce Standards" – 27 April 2022

AusPEN ASM – "Minimum ICU Workforce Standards" – 20 November 2021

CICM Annual Scientific Meeting 2018 – "Burns Registry and Proposed Studies" - ANZICS Burns Special Interest Group – 25 May 2018

Asia Pacific Society of Respirology Congress 2017 – "Physiology of Non-Invasive Ventilation and High Flow Nasal Cannulae" – 23 Nov 2017

ANZICS 19th Annual Meeting on Clinical Trials in Intensive Care – "Central Venous Catheterisation Insertion Accreditation Study" – 8 March 2017

ANZICS 19th Annual Meeting on Clinical Trials in Intensive Care – "Timing of Cardiopulmonary Resuscitation Accreditation Study" – 8 March 2017

ANZICS Safety and Quality Conference 2017 – "Changing to a 3-tiered rapid response system" – 7 August 2017

Grants Related to Thesis

iPIT 3 Study - The New Zealand arm of this study was supported by The A+ Charitable Trust.

Abbreviations

ACCCN	Australian College of Critical Care Nurses
AEC	Australian Electoral Commission
ANZICS	Australian and New Zealand Intensive Care Society
APACHE	Acute Physiology and Chronic Health Evaluation
APD	Admitted Patient Database
AR-DRG	Australian Related-Diagnosis Related Group
ASM	Annual Scientific Meeting
AusPEN	Australasian Society of Parenteral and Enteral Nutrition
CFS	Clinical Frailty Score
CI	Confidence Interval
CICM	College of Intensive Care Medicine
CORE	Centre for Outcome and Resource Evaluation
CTG	Clinical Trials Group
DSM	Diagnostic and Statistical Manual of Mental Disorders
EQ-5D-5L	EuroQol 5 Dimensions, 5 Levels
FSS	Functional Status Score
GOS – E	Glasgow Outcome Scale – Extended
HREC	Human Research Ethics Committee
ICU	Intensive Care Unit
iPIT	influenza Pandemic ICU Triage
IPP	Information privacy principles
IPT	ICU Pandemic Triage
IQR	Interquartile Range
iSRRS	International Society for Rapid Response Systems
ISS	Injury Severity Score
MBS	Medicare Benefits Scheme
NICU	Neonatal Intensive Care Unit
NSW	New South Wales
NZEC	New Zealand Electoral Commission
OHPIP	Ontario Health Plan for an Influenza Pandemic
PBS	Pharmaceutical Benefits Scheme
PCPC	Pediatric Cerebral Performance Category
PICU	Paediatric Intensive Care Unit
PIM	Paediatric Index of Mortality
PSG	Paediatric Study Group
PTSD	Post-Traumatic Stress Disorder
SD	Standard Deviation
SE	Standard Error
SOFA	Sequential Organ-Failure Assessment
SSA	Site Specific Approval
WHO	World Health Organisation
WHO DAS	WHO Disability Assessment Schedule

Appendices

Appendix 1 - The Minnesota Triage Tool

The Minnesota triage tool had three tiers.[1] The first tier excluded patients from admission to the ICU with high predicted mortality on the basis of severe acute organ dysfunction, or discharged patients from the ICU if they failed to respond to intensive care therapy. The second tier excluded patients from admission to the ICU if they had chronic illnesses that had a high predicted mortality. The third tier would exclude patients using additional criteria that would be decided by a committee when the need arose.

No validation studies had been performed, at the time in 2009, to determine whether the Minnesota triage tool would work in practice. The following table (Table A1-1) shows the three tiers of the Minnesota triage tool.

Table A1-1 – Minnesota Triage Tool [1]

Tier 1: Do not offer AND withdraw ventilatory support for patients with any one of the following:

1. Respiratory failure requiring intubation *with* persistent hypotension (systolic blood pressure <90 mm Hg for adults) unresponsive to adequate fluid resuscitation after 6–12 hours of therapy *and* signs of additional end-organ dysfunction (e.g., oliguria, mental status changes, cardiac ischemia)
2. Failure to respond to mechanical ventilation (no improvement in oxygenation or lung compliance) and antibiotics after 72 hours of treatment for a bacterial pathogen (timeline may be modified based on organism-specific data)
3. Laboratory or clinical evidence of ≥4 organ systems failing
   a. Pulmonary (adult respiratory distress syndrome, ventilatory failure, refractory hypoxemia)
   b. Cardiovascular (left ventricular dysfunction, hypotension, new ischemia)
   c. Renal (hyperkalemia, diminished urine output despite adequate fluid resuscitation, increasing creatinine level)
   d. Hepatic (transaminase greater than two times normal upper limit, increasing bilirubin or ammonia levels)
   e. Neurologic (altered mental status not related to volume status, metabolic, or hypoxic source, stroke)
   f. Hematologic (clinical or laboratory evidence of disseminated intravascular coagulation)

Tier 2: Do not offer AND withdraw ventilatory support from patients with respiratory failure requiring intubation with the following conditions (in addition to those in tier 1):

Patients with pre-existing system compromise or failure including:

1. Known congestive heart failure with ejection fraction <25% (or persistent ischemia unresponsive to therapy and pulmonary edema)
2. Acute renal failure requiring hemodialysis (related to illness)
3. Severe chronic lung disease including pulmonary fibrosis, cystic fibrosis, obstructive or restrictive diseases requiring continuous home oxygen use before onset of acute illness
4. Acquired immunodeficiency syndrome (AIDS), other immunodeficiency syndromes at stage of disease susceptible to opportunistic pathogens (e.g., CD4 <200 for AIDS) with respiratory failure requiring intubation
5. Active malignancy with poor potential for survival (e.g., metastatic malignancy, pancreatic cancer)
6. Cirrhosis with ascites, history of variceal bleeding, fixed coagulopathy, or encephalopathy
7. Acute hepatic failure with hyperammonemia
8. Irreversible neurologic impairment that makes patient dependent for personal cares (e.g., severe stroke, congenital syndrome, persistent vegetative state)

Tier 3: Specific protocols to be agreed upon by guideline development committee. Possibilities include:

1. Restriction of treatment based on disease-specific epidemiology and survival data for patient subgroups (may include age-based criteria)
2. Expansion of preexisting disease classes that will not be offered ventilatory support
3. Applying Sequential Organ Failure Assessment scoring to the triage process and establishing a cutoff score above which mechanical ventilation will not be offered

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References for Appendix 1

1 Hick JL, O'Laughlin DT. Concept of operations for triage of mechanical ventilation in an epidemic. Acad Emerg Med 2006; 13: 223-229. https://onlinelibrary.wiley.com/doi/abs/10.1197/j.aem.2005.07.037 (Accessed 11 July 2023)

Appendix 2 - The Ontario Health Plan for an Influenza Pandemic

The Ontario Health Plan for an Influenza Pandemic (OHPIP, also known as the Ontario pandemic protocol)[1] had four main components to decide whether patients should be admitted to the ICU. These were inclusion criteria, exclusion criteria, minimum qualifications for survival and a prioritization tool.

The following box (Box A2-1) in the Ontario pandemic protocol was used to guide the user through the triage process. Users had to assess whether the patients met inclusion or exclusion criteria, before proceeding to the triage tool.

Box A2-1 – Instructions for the Application of the Ontario pandemic protocol to Determine a Patient's Need for Critical Care during an Influenza Pandemic

1. Assess whether the patient meets the inclusion criteria†
   - If yes, proceed to step 2
   - If no, reassess patient later to determine whether clinical status has deteriorated
2. Assess whether the patient meets the exclusion criteria†
   - If no, proceed to step 3
   - If yes, assign a "blue" triage code; *do not* transfer the patient to critical care; continue current level of care or provide palliative care as needed
3. Proceed to triage tool, initial assessment (see Fig. 1)

*The triage protocol applies to *all* patients undergoing assessment for possible critical care and not only those with influenza-like symptoms.
†See Box 2 for inclusion and exclusion criteria.

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Patients who met inclusion criteria (Box A2-2) in the Ontario pandemic protocol were considered for ICU admission.

Box A2-2 – Inclusion Criteria used in the Ontario Pandemic Protocol

Inclusion criteria

The patient must have 1 of the following:

A. Requirement for invasive ventilatory support
   - Refractory hypoxemia (SpO_2 < 90% on non-rebreather mask or FIO_2 > 0.85)
   - Respiratory acidosis (pH < 7.2)
   - Clinical evidence of impending respiratory failure
   - Inability to protect or maintain airway

B. Hypotension (systolic blood pressure < 90 mm Hg or relative hypotension) with clinical evidence of shock (altered level of consciousness, decreased urine output or other evidence of end-organ failure) refractory to volume resuscitation requiring vasopressor or inotrope support that cannot be managed in ward setting

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Patients who met exclusion criteria (Box A2-3) in the Ontario pandemic protocol were refused ICU admission:

Box A2-3 - Exclusion Criteria used in the Ontario Pandemic Protocol

Exclusion critiera

The patient is excluded from admission or transfer to critical care if *any* of the following is present:

A. Severe trauma
B. Severe burns of patient with any 2 of the following:
   - Age > 60 yr
   - > 40% of total body surface area affected
   - Inhalation injury
C. Cardiac arrest
   - Unwitnessed cardiac arrest
   - Witnessed cardiac arrest, not responsive to electrical therapy (defibrillation or pacing)
   - Recurrent cardiac arrest
D. Severe baseline cognitive impairment
E. Advanced untreatable neuromuscular disease
F. Metastatic malignant disease
G. Advanced and irreversible immunocompromise
H. Severe and irreversible neurologic event or condition
I. End-stage organ failure meeting the following criteria:
   Heart
   - NYHA class III or IV heart failure

   Lungs
   - COPD with FEV_1 < 25% predicted, baseline PaO_2 < 55 mm Hg, or secondary pulmonary hypertension
   - Cystic fibrosis with postbronchodilator FEV_1 < 30% or baseline PaO_2 < 55 mm Hg
   - Pulmonary fibrosis with VC or TLC < 60% predicted, baseline PaO_2 < 55 mm Hg, or secondary pulmonary hypertension
   - Primary pulmonary hypertension with NYHA class III or IV heart failure, right atrial pressure > 10 mm Hg, or mean pulmonary arterial pressure > 50 mm Hg

   Liver
   - Child-Pugh score ≥ 7
J. Age > 85 yr
K. Elective palliative surgery

Note: SpO_2 = oxygen saturation measured by pulse oximetry, FIO_2 = fraction of inspired oxygen, NYHA = New York Heart Association, COPD = chronic obstructive pulmonary disease, FEV_1 = forced expiratory volume in 1 second, PaO_2 = partial pressure of arterial oxygen, VC = vital capacity, TLC = total lung capacity.

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If the patient met the inclusion criteria and did not meet exclusion criteria they proceeded to the triage tool (Figure A2-1). The triage tool used a well-known illness severity scoring system called Sequential Organ-Failure Assessment (SOFA - also known as Sepsis-related Organ Failure Assessment).[2]

Figure A2-1 – Ontario Pandemic Protocol Prioritisation (Triage) Tool – Initial Assessment

Triage code	Criteria	Action or priority
Blue	Exclusion criteria met or SOFA score > 11*	• Manage medically • Provide palliative care as needed • Discharge from critical care
Red	SOFA score ≤ 7 or single-organ failure	Highest priority
Yellow	SOFA score 8–11	Intermediate priority
Green	No significant organ failure	• Defer or discharge • Reassess as needed

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The scoring for the SOFA score used in the triage protocol is shown in Figure A2-2.[2] The SOFA scoring system generated a total score from 0 to 24, with higher scores indicating higher illness severity.

Figure A2-2 - Sequential Organ-Failure Assessment (SOFA) score

	Score				
Variable	0	1	2	3	4
PaO_2/FIO_2, mm Hg	> 400	≤ 400	≤ 300	≤ 200	≤ 100
Platelet count, $\times 10^3$/L	> 150	≤ 150	≤ 100	≤ 50	≤ 20
Bilirubin level, mg/dL (μmol/L)	< 1.2 (< 20)	1.2–1.9 (20–32)	2.0–5.9 (33–100)	6.0–11.9 (101–203)	> 12 (> 203)
Hypotension†	None	MABP < 70	Dop ≤ 5	Dop > 5 Epi ≤ 0.1 Norepi ≤ 0.1	Dop > 15 Epi > 0.1 Norepi > 0.1
Glasgow Coma score	15	13–14	10–12	6–9	< 6
Creatinine level, mg/dL (μmol/L)	< 1.2 (< 106)	1.2–1.9 (106–168)	2.0–3.4 (169–300)	3.5–4.9 (301–433)	> 5 (> 434)

Note: PaO_2 = partial pressure of arterial oxygen; FIO_2 = fraction of inspired oxygen; MABP = mean arterial blood pressure, in mm Hg;
*Adapted, with permission, from Ferreira FL, Bota DP, Bross A, et al. Serial evaluation of the SOFA score to predict outcome in critically ill patients. JAMA 2001;286: 1754-8. Copyright © 2001, American Medical Association. All rights reserved.
†Dop (dopamine), epi (epinephrine) and norepi (norepinephrine) doses in μg/kg per min.

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A patient with a SOFA score of greater than 11 would be refused admission to the ICU, on the basis of a high predicted mortality. Patients with SOFA score less than or equal to 7 had the highest priority for ICU admission, with patients with SOFA score 8 to 11 having the next highest priority.

Patients admitted to the ICU would be reviewed at 48 hours (2 days) and 120 hours (5 days) using the Ontario pandemic protocol prioritization tool to see if they were responding to treatment (Figure A2-3).

Figure A2-3 – Ontario Pandemic Protocol Prioritisation (Triage) Tool – Assessment at 48 and 120 hours

48-hour assessment

Triage code	Criteria	Action or priority
Blue	Exclusion criteria met or SOFA score > 11 or SOFA score stable at 8-11 with no change	• Provide palliative care • Discharge from critical care
Red	SOFA score < 11 and decreasing	Highest priority
Yellow	SOFA score stable at < 8 with no change	Intermediate priority
Green	No longer dependant on ventilator	• Discharge from critical care

120-hour assessment

Triage code	Criteria	Action or priority
Blue	Exclusion criteria met or SOFA score > 11 or SOFA score < 8 with no change†	• Provide palliative care • Discharge from critical care
Red	SOFA < 11 and decreasing progressively	Highest priority
Yellow	SOFA < 8 with minimal decrease (< 3-point decrease in past 72 h)	Intermediate priority
Green	No longer dependant on ventilator	• Discharge from critical care

Note: SOFA = Sequential Organ-Failure Assessment (see Appendix 1, available at www.cmaj.ca/cgi/content/full/175/11/1377/DC1).
*If an exclusion criterion is met or the SOFA score is > 11 anytime from the initial assessment to 48 hours afterward, change the triage code to Blue and proceed as indicated.
†If an exclusion criterion is met or the SOFA score is > 11 anytime from 48 to 120 hours afterward, change the triage code to Blue and proceed as indicated.

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Patients who were not responding to treatment at 48 hours or 120 hours according to the prioritization tool would be discharged from the ICU. Similarly to the Minnesota triage tool, no validation studies had been performed, at the time, to determine whether the Ontario pandemic protocol would work in practice.

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1 Christian MD, Hawryluck L, Wax RS, et al. Development of a triage protocol for critical care during an influenza pandemic. CMAJ 2006; 175: 1377-1381. https://www.cmaj.ca/content/175/11/1377 (Accessed 11 July 2023)

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Appendix 3 - NSW Pandemic Guidelines Triage Protocol

The NSW Pandemic Guidelines Triage Protocol used a three-tiered triage system to determine which patients should have access to ICU resources during an influenza pandemic, with an escalation of exclusion criteria in a step-wise fashion as the level of ICU resources available became exhausted.[1] The Director-General of Health, based on recommendations from the NSW Health Pandemic Operational Coordination Group, would determine the triage tier to be implemented, depending on the level of ICU resource utilization. Tier 1 of the triage tool would be initially implemented, with tier 2 and then tier 3 being implemented as a pandemic worsened, and demand for ICU resources increased.

The three tiers of the NSW Pandemic Guidelines Triage Protocol are detailed in Figure A3-1 and A3-2.

Figure A3-1 – Tier 1 of the NSW Pandemic Guidelines Triage Protocol

Do not offer (AND withdraw) life-sustaining therapy from patients with any of the following:

1. Respiratory failure requiring intubation with persistent hypotension (SBP<90 adults), unresponsive to fluid therapy after 6-12hours AND signs of additional end-organ dysfunction (e.g.. Oliguria, decreased mental status, cardiac ischaemia)
2. Failure to response to mechanical ventilation (no improvement in oxygenation or lung compliance) and antibiotics after 72hrs of treatment for a bacterial pathogen (?organism)
3. Laboratory or clinical evidence of ≥ 4 organ systems failing:
    a. Pulmonary (ARDS, respiratory failure, refractive hypoxia)
    b. Cardiovascular (LVF, hypotension, new ischaemia)
    c. Renal (hyperkalemia, oliguria despite fluid resuscitation, increasing creatinine)
    d. Hepatic (transaminase > x 2 normal upper limit, increased bilirubin or ammonia levels)
    e. Neurological (altered mental status not related to fluid volume status, metabolic, hypoxic or stroke)
    f. Haematological (clinical or laboratory evidence of DIC)
    g. Cirrhosis with ascites, history of variceal bleeding, fixed coagulopathy, or encephalopathy
    h. Irreversible neurological impairment that makes the patient dependent for personal care (e.g. Severe stroke, congenital syndrome, persistent vegetative state)

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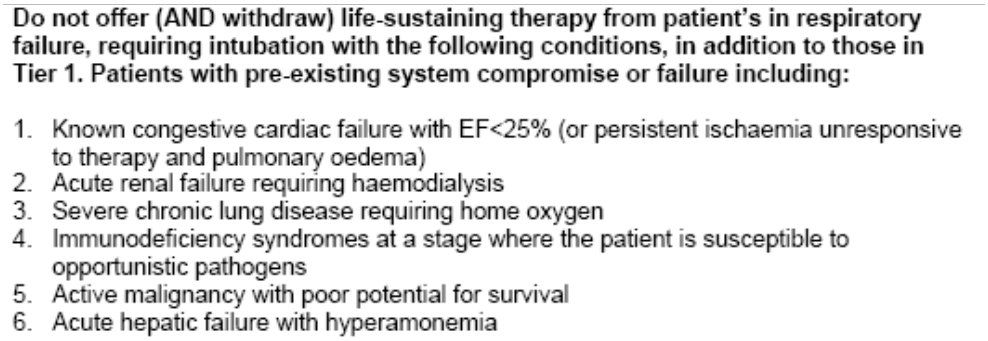
Tier 1 of the NSW triage protocol (Figure A3-1) was based on Tier 1 of the Minnesota triage tool.[2] Part 1 of Tier 1 could only be assessed at 12 hours after a trial of fluid therapy. Part 2 of Tier 1 could only be assessed after 72 hours of treatment. This meant that only Part 3 of Tier 1 could be used at the initial screening to see if a patient qualified for an ICU admission.

As a pandemic worsened and the demand for ICU beds significantly overwhelmed supply, Tier 2 of the triage protocol could be activated (Figure A3-2). Tier 2 of the NSW triage protocol was based on Tier 2 of the Minnesota triage tool.[2]

Figure A3-2 - Tier 2 of the NSW Pandemic Guidelines Triage Protocol



Do not offer (AND withdraw) life-sustaining therapy from patient's in respiratory failure, requiring intubation with the following conditions, in addition to those in Tier 1. Patients with pre-existing system compromise or failure including:

1. Known congestive cardiac failure with EF<25% (or persistent ischaemia unresponsive to therapy and pulmonary oedema)
2. Acute renal failure requiring haemodialysis
3. Severe chronic lung disease requiring home oxygen
4. Immunodeficiency syndromes at a stage where the patient is susceptible to opportunistic pathogens
5. Active malignancy with poor potential for survival
6. Acute hepatic failure with hyperamonemia

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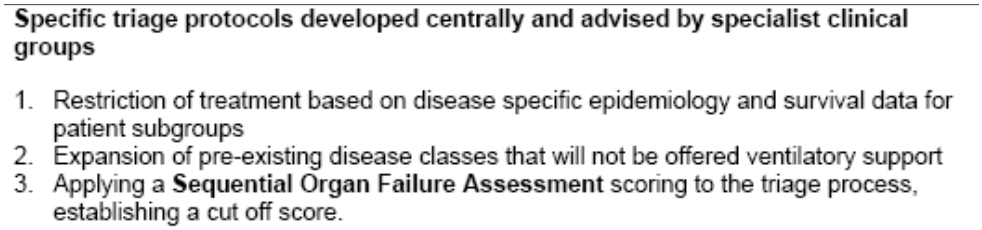
If the pandemic continued to worsen, Tier 3 of the NSW triage protocol could be activated (Figure A3-3). At the time, Part 1 and 2 of Tier 3 had not been defined. Part 3 of Tier 3 of the triage protocol was based on Sequential Organ Failure Assessment (SOFA) scoring criteria of the Ontario pandemic protocol.[3]

Figure A3-3 – Tier 3 of the NSW Pandemic Guidelines Triage Protocol



Specific triage protocols developed centrally and advised by specialist clinical groups

1. Restriction of treatment based on disease specific epidemiology and survival data for patient subgroups
2. Expansion of pre-existing disease classes that will not be offered ventilatory support
3. Applying a **Sequential Organ Failure Assessment** scoring to the triage process, establishing a cut off score.

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The Sequential Organ Failure Assessment score used in Tier 3 is detailed in Figure A3-4 and A3-5.

Figure A3-4 - Sequential Organ Failure Assessment (SOFA) score

	Score				
Variable	0	1	2	3	4
PaO_2/FIO_2, mm Hg	> 400	≤ 400	≤ 300	≤ 200	≤ 100
Platelet count, $\times 10^3$/L	> 150	≤ 150	≤ 100	≤ 50	≤ 20
Bilirubin level, mg/dL (μmol/L)	< 1.2 (< 20)	1.2–1.9 (20–32)	2.0–5.9 (33–100)	6.0–11.9 (101–203)	> 12 (> 203)
Hypotension†	None	MABP < 70	Dop ≤ 5	Dop > 5 Epi ≤ 0.1 Norepi ≤ 0.1	Dop > 15 Epi > 0.1 Norepi > 0.1
Glasgow Coma score	15	13–14	10–12	6–9	< 6
Creatinine level, mg/dL (μmol/L)	< 1.2 (< 106)	1.2–1.9 (106–168)	2.0–3.4 (169–300)	3.5–4.9 (301–433)	> 5 (> 434)

Note: PaO_2 = partial pressure of arterial oxygen; FIO_2 = fraction of inspired oxygen; MABP = mean arterial blood pressure, in mm Hg;
*Adapted, with permission, from Ferreira FL, Bota DP, Bross A, et al. Serial evaluation of the SOFA score to predict outcome in critically ill patients. JAMA 2001;286: 1754-8. Copyright © 2001, American Medical Association. All rights reserved.
†Dop (dopamine), epi (epinephrine) and norepi (norepinephrine) doses in μg/kg per min.

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Figure A3-5 – Part 3 of Tier 3 of the NSW Pandemic Guidelines Triage Protocol

Triage code	Criteria	Action or priority
Blue	Exclusion criteria met or SOFA score > 11*	• Manage medically • Provide palliative care as needed • Discharge from critical care
Red	SOFA score ≤ 7 or single-organ failure	Highest priority
Yellow	SOFA score 8–11	Intermediate priority
Green	No significant organ failure	• Defer or discharge • Reassess as needed

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Tier 3 of the NSW triage protocol excluded patients from the ICU with SOFA scores greater than 11, on the basis of high predicted mortality, the same as in the Ontario pandemic protocol. Patients with a SOFA score less than or equal to 7 or had single organ failure and did not fulfil exclusion criteria in tiers 1 and 2 would be have highest priority for access to ICU resources, with patients with a SOFA score of 8-11 having the next highest priority.

References for Appendix 3

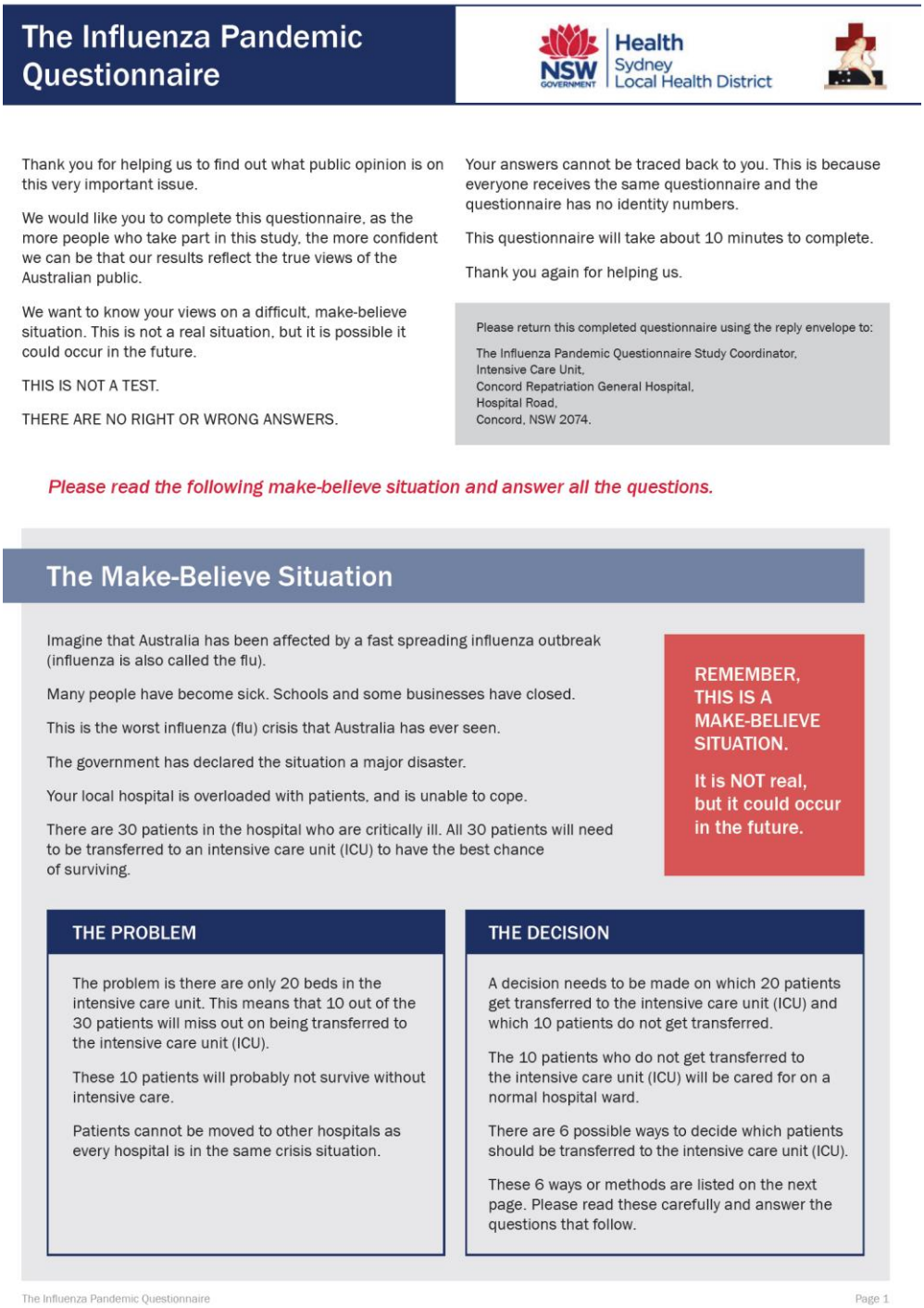
1 Policy Directive - NSW Health – Influenza Pandemic – Providing Critical Care. PD2010_028: 20 May 2010.

2 Hick JL, O'Laughlin DT. Concept of operations for triage of mechanical ventilation in an epidemic. Acad Emerg Med 2006; 13: 223-229. https://onlinelibrary.wiley.com/doi/abs/10.1197/j.aem.2005.07.037 (Accessed 11 July 2023)

3 Vincent JL, Moreno R, Takala J, et al. The SOFA (Sepsis-related Organ Failure Assessment) score to describe organ dysfunction/failure. Intensive Care Med 1996; 22: 707-710. https://link.springer.com/article/10.1007/BF01709751 (Accessed 11 July 2023)

4 Christian MD, Hawryluck L, Wax RS, et al. Development of a triage protocol for critical care during an influenza pandemic. CMAJ 2006; 175: 1377-1381. https://www.cmaj.ca/content/175/11/1377 (Accessed 11 July 2023)

Appendix 4 - The influenza Pandemic ICU Triage 3 (iPIT 3) Study Questionnaire (Australian Version)*



The Influenza Pandemic Questionnaire

NSW GOVERNMENT Health
Sydney Local Health District

Thank you for helping us to find out what public opinion is on this very important issue.

We would like you to complete this questionnaire, as the more people who take part in this study, the more confident we can be that our results reflect the true views of the Australian public.

We want to know your views on a difficult, make-believe situation. This is not a real situation, but it is possible it could occur in the future.

THIS IS NOT A TEST.

THERE ARE NO RIGHT OR WRONG ANSWERS.

Your answers cannot be traced back to you. This is because everyone receives the same questionnaire and the questionnaire has no identity numbers.

This questionnaire will take about 10 minutes to complete.

Thank you again for helping us.

Please return this completed questionnaire using the reply envelope to:

The Influenza Pandemic Questionnaire Study Coordinator,
Intensive Care Unit,
Concord Repatriation General Hospital,
Hospital Road,
Concord, NSW 2074.

Please read the following make-believe situation and answer all the questions.

The Make-Believe Situation

Imagine that Australia has been affected by a fast spreading influenza outbreak (influenza is also called the flu).

Many people have become sick. Schools and some businesses have closed.

This is the worst influenza (flu) crisis that Australia has ever seen.

The government has declared the situation a major disaster.

Your local hospital is overloaded with patients, and is unable to cope.

There are 30 patients in the hospital who are critically ill. All 30 patients will need to be transferred to an intensive care unit (ICU) to have the best chance of surviving.

REMEMBER, THIS IS A MAKE-BELIEVE SITUATION.

It is NOT real, but it could occur in the future.

THE PROBLEM

The problem is there are only 20 beds in the intensive care unit. This means that 10 out of the 30 patients will miss out on being transferred to the intensive care unit (ICU).

These 10 patients will probably not survive without intensive care.

Patients cannot be moved to other hospitals as every hospital is in the same crisis situation.

THE DECISION

A decision needs to be made on which 20 patients get transferred to the intensive care unit (ICU) and which 10 patients do not get transferred.

The 10 patients who do not get transferred to the intensive care unit (ICU) will be cared for on a normal hospital ward.

There are 6 possible ways to decide which patients should be transferred to the intensive care unit (ICU).

These 6 ways or methods are listed on the next page. Please read these carefully and answer the questions that follow.

The Influenza Pandemic Questionnaire Page 1

* There were 12 different versions of the questionnaire created for the study in Australia and 12 different versions of the questionnaire created for New Zealand. Each differed by the randomised order that the choices in Question 1 were presented, and randomised order that Questions 2 to 7 were presented. The version detailed here is the Australian template version.

Reproduced with permission from Cheung W, Myburgh J, McGuinness S, et al. A cross-sectional survey of Australian and New Zealand public opinion on methods to triage intensive care patients in an influenza pandemic. Crit Care Resusc 2017; 19: 254-265.
https://ccr.cicm.org.au/Journal-Editions/2017/September/19/Original-Articles/Article-9
Copyright Critical Care and Resuscitation.

The Make-Believe Situation continues...

THE CHOICES

A **Use a first come, first served approach to decide**

What does this mean? The first patients to arrive at the hospital get to be transferred to the intensive care unit. Once the intensive care unit (ICU) is full, those arriving later miss out.

B **Let a senior doctor decide**

What does this mean? A senior doctor will decide which patients get transferred to the intensive care unit (ICU), and which patients don't. The senior doctor would take into account a patient's health and chances of surviving when deciding.

C **Use a set of criteria or rules that have been determined by the Health Department to decide**

What does this mean? A set of criteria or rules is used to decide which patients can be transferred to the intensive care unit (ICU). Patients who do not meet the criteria set out in the rules will not be transferred to the intensive care unit (ICU).

D **Use random selection to decide**

What does this mean? Patients are picked at random to be transferred to the intensive care unit (ICU), such as drawing a person's name from a hat.

E **Use a patient's ability to pay to decide**

What does this mean? Patients who can afford to pay for their treatment, or who have private insurance will be transferred to the intensive care unit (ICU). Those who cannot afford to pay, or who do not have insurance will miss out.

F **Use the importance of the patient to decide**

What does this mean? Patients who are thought to be more important to the functioning of society will be transferred to the intensive care unit (ICU). Those who are thought to be not as important will miss out. For example, an engineer who maintains the city's water supply may be more likely to be transferred to the intensive care unit than a person who does not work.

Please answer the following questions.

Questions

Now that you have read the make-believe situation and the 6 methods to decide which patients get transferred to the intensive care unit (ICU), please answer the following questions.

Remember, this is a major disaster situation. There are not enough resources to treat everyone.

Questions continue...

For Question 1 place a cross in the box, that matches the answer you think is the best, like so ☒

Question 1: Which of the 6 methods do you think is the best way to decide which patients get to be transferred to the intensive care unit (ICU) in a major influenza pandemic disaster, when there are not enough resources to treat everyone? (Choose only 1 option)

- ☐ A Use a first come, first served approach to decide
- ☐ B Let a senior doctor decide
- ☐ C Use a set of criteria or rules that have been determined by the Health Department to decide
- ☐ D Use random selection to decide
- ☐ E Use the patient's ability to pay to decide
- ☐ F Use the importance of the patient to decide
- ☐ G I'm not sure which answer I think is the best

For Questions 2 to 10 draw a circle around the number that matches the answer you think is the best, like so

Extremely unfair ____ Neither unfair or fair ____ Extremely fair

1 2 3 (4) 5 6 7

Examples:
If you think the best answer is "extremely unfair" then circle 1.
If you think the best answer is "extremely fair" then circle 7.
If you think the best answer is "unfair", but not "extremely unfair", then circle 2 or 3.
If you think the best answer is "fair", but not "extremely fair", then circle 5 or 6.

Question 2: How fair do you think it is to use a first come, first served approach to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair ____ Neither unfair or fair ____ Extremely fair

1 2 3 4 5 6 7

Question 3: How fair do you think it is for a senior doctor to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair ____ Neither unfair or fair ____ Extremely fair

1 2 3 4 5 6 7

Question 4: How fair do you think it is to use a set of criteria or rules from the Health Department to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair ____ Neither unfair or fair ____ Extremely fair

1 2 3 4 5 6 7

Questions continue...

Question 5: How fair do you think it is to use random selection to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair — Neither unfair or fair — Extremely fair

1 2 3 4 5 6 7

Question 6: How fair do you think it is to use a person's ability to pay to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair — Neither unfair or fair — Extremely fair

1 2 3 4 5 6 7

Question 7: How fair do you think it is to use a person's importance to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair — Neither unfair or fair — Extremely fair

1 2 3 4 5 6 7

Question 8: How fair do you think is it to treat a young person (for example, aged 20 years old) ahead of an older person (for example, aged 90 years old) in a disaster, when there are not enough resources to treat everyone?

Extremely unfair — Neither unfair or fair — Extremely fair

1 2 3 4 5 6 7

Question 9: How fair is it to use a person's chance of surviving to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair — Neither unfair or fair — Extremely fair

1 2 3 4 5 6 7

Question 10: In a disaster, when there are not enough resources to treat everyone, how fair do you think it is not to treat a person because they have a long term (also called chronic) medical condition which makes them less likely to survive?

Extremely unfair — Neither unfair or fair — Extremely fair

1 2 3 4 5 6 7

Questions continue...

For Questions 11 to 15 place a cross in the box, like so ☒ that matches your answer.

Question 11: Which state do you live in?

☐ Australian Capital Territory ☐ New South Wales ☐ Northern Territory ☐ Queensland

☐ South Australia ☐ Western Australia ☐ Victoria ☐ Tasmania

Question 12: Which age group do you belong to?

☐ 18 to 35 years old ☐ 51 to 55 years old ☐ 71 to 75 years old

☐ 36 to 40 years old ☐ 56 to 60 years old ☐ 76 to 80 years old

☐ 41 to 45 years old ☐ 61 to 65 years old ☐ 81 to 85 years old

☐ 46 to 50 years old ☐ 66 to 70 years old ☐ 86 years or older

Question 13: Are you male or female?

☐ Male ☐ Female

Question 14: Do you live in a city, a town, or a country area?

☐ City (population more than 10 000 people)

☐ Town (population between 250 to 10 000 people)

☐ Country, rural or outback area (population less than 250 people)

Question 15: What is your current employment status?

☐ Retired ☐ At school, college, or university ☐ Employed full-time

☐ Not employed in paid work ☐ Employed part-time or casual

Question 16 asks about your experiences with hospitals or healthcare.
Please place a cross in either the "Yes" or "No" box, like so ☒

Question 16:

I have been a patient in a hospital or emergency department (ED)	☐ Yes	☐ No
I have had family or close friends admitted to hospital or managed in an emergency department (ED)	☐ Yes	☐ No
I have been a patient in an intensive care unit (ICU)	☐ Yes	☐ No
I have had family or close friends admitted to an intensive care unit (ICU)	☐ Yes	☐ No
I work in a healthcare profession	☐ Yes	☐ No

Health
Sydney
Local Health District

This is the end of the questionnaire.

Please return this completed questionnaire, using the reply envelope, to the address on the front page.
If you have any comments to make about this questionnaire please write them down in the space below.

Thank you again for your help.

Comments:

Appendix 5 - The influenza Pandemic ICU Triage 4 (iPIT 4) Study Questionnaire*

The Influenza Pandemic Questionnaire

Thank you for helping us to find out what public opinion is on this very important issue.

We would like you to complete this questionnaire, as the more people who take part in this study the more confident we can be that our results reflect the true views of the Australian public.

We want to know your views on a difficult, make-believe situation. This is not a real situation, but it is possible it could occur in the future.

THIS IS NOT A TEST.
THERE ARE NO RIGHT OR WRONG ANSWERS.

Please return this completed questionnaire to the ICU, or send it using the reply paid envelope to the address below:

Influenza Pandemic Study Coordinator
Intensive Care Unit
Concord Hospital
Reply Paid 89436
CONCORD WEST
NSW 2138

The Make-Believe Situation

Imagine that Australia has been affected by a fast spreading influenza outbreak (influenza is also called the flu).

This is the worst influenza (flu) crisis that Australia has ever seen.

Many people have become sick. Schools and some businesses have closed.

The government has declared the situation a major disaster.

Your local hospital is overloaded with patients, and is unable to cope.

REMEMBER, THIS IS A MAKE-BELIEVE SITUATION.
It is NOT real, but it could occur in the future. Some of the scenarios that follow may be confronting or cause distress for some people. If you feel distressed there is no need to complete this questionnaire.

THE PROBLEM

There are not enough beds in the Intensive Care Unit (ICU) to treat all the critically unwell patients. This means that some patients will not be treated. These patients are unlikely to survive.

Patients cannot be moved to other hospitals as every hospital is in the same crisis situation.

Imagine that the Health Department has put in place a process to decide which patients will be treated in the ICU because of this disaster situation. This process uses specific criteria or rules (sometimes called triage criteria). These criteria determine the priority in which patients should be treated in a disaster.

The process excludes patients from being treated in the ICU:

- If doctors do not think the patient will survive.
- If the patient has a long-term medical condition (also known as chronic medical condition) that makes them less likely to survive (examples of these conditions include cancer, severe heart or lung conditions, or dementia).
- If the patient is very old (older than 85 years).

The Health Department process is designed to save as many lives as possible, as it is not possible to save everyone in this disaster situation.

YOUR MAKE-BELIEVE SITUATION

Imagine your family member, loved-one or friend is critically unwell and you are responsible for making decisions on their behalf.

On the next 6 pages are 3 different scenarios.
Please read each scenario and answer the questions that follow.

* There were six different versions of the questionnaire created for the study. Each differed by the randomised order that Scenarios 1 to 3 were presented. The version detailed here is the template version.

Scenario 1

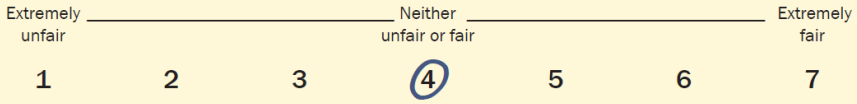
Imagine that the person that you are responsible for has recently arrived at the hospital, and is critically unwell.

The hospital is in a disaster situation. There are not enough resources to treat every patient so some patients have to miss out.

The **hospital** has decided that the person that you are responsible for will not be allowed into the ICU for treatment (they are excluded from the ICU). This is because the **hospital** believes it has a better chance of saving someone else instead.

The person that you are responsible for will probably not survive unless they are treated in the ICU.

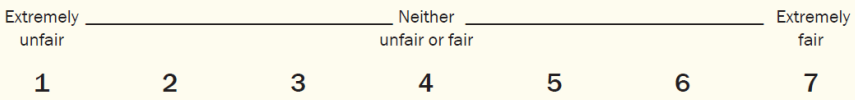
For Questions 1 and 2 draw a circle around the number that matches the answer you think is the best, like so



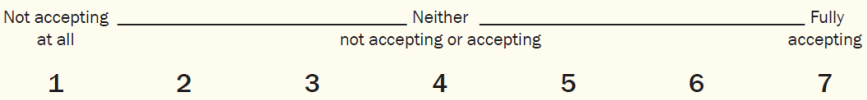
Examples:

If you think the best answer is "extremely unfair" then circle 1.
If you think the best answer is "extremely fair" then circle 7.
If you think the best answer is "unfair", but not "extremely unfair", then circle 2 or 3.
If you think the best answer is "fair", but not "extremely fair", then circle 5 or 6.

Question 1: How fair do you think it is for the hospital to exclude the person you are responsible for from the ICU, in this disaster situation?



Question 2: How accepting would you be of this decision to exclude the person you are responsible for from the ICU, in this disaster situation?



For Question 3 write your answer in the space provided.

Question 3: What measures or steps would you take to get the person you are responsible for to be treated in the ICU?

Question 3 *continues:*

If you have any comments about this scenario write them in the space provided.

Comments:

Scenario 2

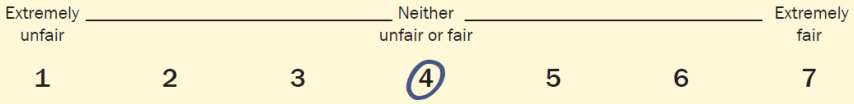
Imagine that the person that you are responsible for has been a patient in the ICU for several days. They remain critically unwell and they have not improved.

The hospital is in a disaster situation. There are not enough resources to treat every patient, so some patients have to miss out.

The **hospital** has decided that the person that you are responsible for will be moved out of the ICU to the general ward (they will not be allowed to stay in the ICU for treatment). This is because the **hospital** believes it has a better chance of saving someone else instead.

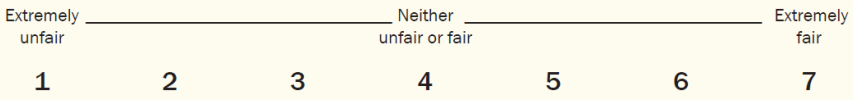
The person that you are responsible for will probably not survive unless they continue treatment in the ICU.

For Questions 4 and 5 draw a circle around the number that matches the answer you think is the best, like so

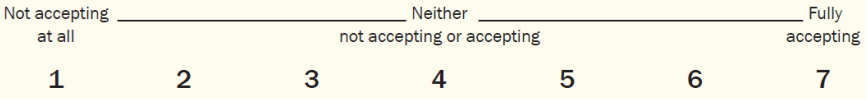


Examples:
If you think the best answer is "extremely unfair" then circle 1.
If you think the best answer is "extremely fair" then circle 7.
If you think the best answer is "unfair", but not "extremely unfair", then circle 2 or 3.
If you think the best answer is "fair", but not "extremely fair", then circle 5 or 6.

Question 4: How fair do you think it is for the hospital to move the person you are responsible for from the ICU to the general ward, in this disaster situation?



Question 5: How accepting would you be of this decision to move the person you are responsible for from the ICU to the general ward, in this disaster situation?



For Question 6 write your answer in the space provided.

Question 6: What measures or steps would you take to get the person you are responsible for to stay in the ICU for treatment?

Question 6 *continues:*

If you have any comments about this scenario write them in the space provided.

Comments:

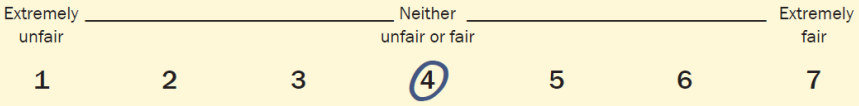
Scenario 3

Imagine that the person that you are responsible for is critically unwell. They need to be admitted to the ICU for treatment, otherwise they probably will not survive.

The hospital is in a disaster situation. There are not enough resources to treat every patient so some patients have to miss out.

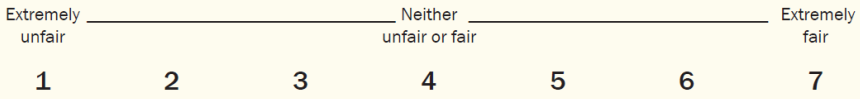
In order to admit the person that you are responsible for to the ICU another patient has to be moved out of the ICU to a general ward. This other patient remains critically unwell. They are unlikely to survive if they are moved out of the ICU, but the **hospital** has decided that the person that you are responsible for should have priority for care in the ICU. The family of the other patient doesn't agree.

For Question 7 draw a circle around the number that matches the answer you think is the best, like so



Examples:
If you think the best answer is "extremely unfair" then circle 1.
If you think the best answer is "extremely fair" then circle 7.
If you think the best answer is "unfair", but not "extremely unfair", then circle 2 or 3.
If you think the best answer is "fair", but not "extremely fair", then circle 5 or 6.

Question 7: How fair do you think it is for the hospital to move the other patient out of the ICU to a general ward so that the person you are responsible for can be admitted to the ICU?



For Question 8 place a cross in the box that matches the answer you think is the best, like so ☒

Question 8: If the family or person responsible for the other patient is not accepting of the patient being moved from the ICU to a general ward, should the hospital move them despite of their family's non-acceptance?

(The person you are responsible for cannot be admitted to the ICU unless the other patient is moved out)

☐ Yes ☐ No ☐ I'm not sure

For Question 9 write your answer in the space provided.

Question 9: What measures or steps would you take to get the person you are responsible for to be admitted to the ICU, if the hospital could not move the other patient?

Question 9 *continues:*

If you have any comments about this scenario write them in the space provided.

Comments:

Demographic Questions

For Questions 10 to 14 place a cross in the box that matches the answer you think is the best, like so ☒

Question 10: Which age group do you belong to?

☐ Under 21 years old	☐ 41 to 45 years old	☐ 66 to 70 years old
☐ 21 to 25 years old	☐ 46 to 50 years old	☐ 71 to 75 years old
☐ 26 to 30 years old	☐ 51 to 55 years old	☐ 76 to 80 years old
☐ 31 to 35 years old	☐ 56 to 60 years old	☐ 81 to 85 years old
☐ 36 to 40 years old	☐ 61 to 65 years old	☐ 86 years or older

Question 11: Are you male or female?

☐ Male ☐ Female

Question 12: What is the age of person you are responsible for?

☐ Under 21 years old	☐ 41 to 45 years old	☐ 66 to 70 years old
☐ 21 to 25 years old	☐ 46 to 50 years old	☐ 71 to 75 years old
☐ 26 to 30 years old	☐ 51 to 55 years old	☐ 76 to 80 years old
☐ 31 to 35 years old	☐ 56 to 60 years old	☐ 81 to 85 years old
☐ 36 to 40 years old	☐ 61 to 65 years old	☐ 86 years or older

Question 13: What is <u>your</u> relationship to the person you are responsible for?

☐ Spouse

☐ Partner - De facto

☐ Partner - Not de facto

☐ Father or mother

☐ Son or daughter

☐ Sister or brother

☐ Other relative (specify (eg. niece, uncle)) _____

☐ Other non-relative (specify (eg. friend, neighbour)) _____

This is the end of the questionnaire.

Please return this completed questionnaire to the ICU, or send it using the reply paid envelope to the address on the front page.

If you have any comments to make about this questionnaire please write them down on a separate piece of paper and attach this to the questionnaire when you return it.

Thank you again for your help.

Appendix 6 - The ICU Pandemic Triage (IPT 5) Study Questionnaire*

The ICU Pandemic Triage Questionnaire

Thank you for taking the time to complete this questionnaire.

The more people who take part in this study the more confident we can be that our results reflect the true views of the Australian public.

Please answer as many questions as you can.

THIS IS NOT A TEST.
THERE ARE NO RIGHT OR WRONG ANSWERS.

Please return this completed questionnaire using the reply paid envelope to the address below:

ICU Pandemic Study Coordinator
Critical Care Division
The George Institute for Global Health
REPLY PAID 89436
PO Box M201
MISSENDEN ROAD, NSW 2050

Some of the questions that follow may be confronting or cause distress for some people. There is no need to complete this questionnaire if it causes you distress.

If you feel distressed, the following website has the contact details for mental health resources and programmes, one-on-one connections to professionals through webchat, and online counselling and phone services. https://www.health.nsw.gov.au/Infectious/factsheets/Factsheets/covid-19-accessing-mental-health.pdf

PURPOSE OF THIS QUESTIONNAIRE

The purpose of this questionnaire is to determine Australian public opinion on how patients should be selected for treatment in an intensive care unit (ICU) in a future pandemic, if not enough ICU beds are available.

BACKGROUND

Currently, if a person develops severe COVID-19 the only treatments that improve their chances of survival are those given in an intensive care unit (ICU), such as being put on a ventilator (also known as a life support machine or breathing machine).

ICUs in Australia coped well during the 2020 COVID-19 pandemic, however, future pandemics of COVID-19 or other new viruses may be more severe, and there may not be enough ICU beds for all the patients who need one.

This disaster situation may create an ethical dilemma, because hospitals may need to decide which patients should be treated when it may not be possible to treat everyone.

One of the ways to decide which patients should be treated in the ICU, when there are too many patients and not enough ICU beds, is to use rules or selection criteria (also called triage criteria).

The following questions will ask you about your views on different types of selection criteria that could be used in a future pandemic.

INSTRUCTIONS

Some of the following questions will look like the one below. To answer these questions draw a circle around the number that matches the answer you think is the best, like so

Extremely unfair — Neither unfair or fair — Extremely fair

1 2 3 (4) 5 6 7

Examples:
If you think the best answer is "extremely unfair" then circle 1.
If you think the best answer is "extremely fair" then circle 7.
If you think the best answer is "unfair", but not "extremely unfair", then circle 2 or 3.
If you think the best answer is "fair", but not "extremely fair", then circle 5 or 6.

Some of the following questions will look like the one below. To answer these questions place a cross in the box that matches the answer you think is the best, like so

☒ Choice A

☐ Choice B

* There were four different versions of the questionnaire created for the study. Each differed by the randomised order that the four methods used to triage based on comorbidities were presented. The version detailed here is the template version.

Selection Criteria Based on Long-Term (Chronic) Medical Conditions

One way to decide the priority in which people would be admitted to an ICU in a pandemic disaster, when there are not enough resources to treat everyone, is to give a lower priority to people with certain long-term (also called chronic) medical conditions.

Some examples of long-term medical conditions that could be used as selection criteria:

- Moderate Alzheimer's Disease or moderate dementia (person may forget events or personal history such as address, telephone numbers; they may become confused where they are or what day it is; they may have an increased tendency to wander and become lost)
- Cancer with a less than 10 year expected survival
- Heart Failure with marked limitation of physical activity (person is comfortable at rest, but ordinary physical activity results in fatigue or shortness of breath)
- Moderately severe chronic (long term) lung disease (such as emphysema or pulmonary fibrosis – a person's breathing function tests are about 50% of normal)
- End-stage kidney disease (person is on dialysis or will need dialysis in the near future)
- Severe coronary artery disease
- Cirrhosis (of the liver) with previous episodes of liver failure

There are other examples not listed here.

People who do not have any of these long-term medical conditions would be admitted first. People who have any of these long-term medical conditions would have a lower priority.

Question 1: How fair do you think it is to use a person's long-term (or chronic) medical conditions to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair			Neither unfair or fair			Extremely fair
1	2	3	4	5	6	7

If you have any comments please write them in the space below:

Selection Criteria Based on Long-Term Survival Target

One way to decide the priority in which people would be admitted to an ICU in a pandemic disaster, when there are not enough resources to treat everyone, is to use a long-term survival target.

The hospital would set a survival target and people who are likely to live longer than the survival target would be admitted to the ICU first. People who are not likely to live to the survival target would have lower priority.

Survival targets could be 1 year, 5 years, or more. The targets could be increased as the shortage of ICU beds worsens.

The higher the survival target, the less likely people with medical conditions that have a reduced life expectancy will reach the target.

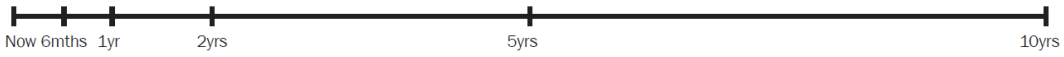
An example:

If the survival target was 5 years, and a person had a condition where it was predicted that they may only survive 2 years, then they would have a lower priority to be treated in the ICU.

Question 2A: How fair do you think it is to use a person's chance of long-term survival to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair			Neither unfair or fair			Extremely fair
1	2	3	4	5	6	7

Question 2B: If a survival target was to be used to decide who gets treated in a disaster, when there are not enough resources to treat everyone, what target do you think is the fairest? (Tick the box below)



- ☐ A: I don't think using a survival target is fair

  or

- ☐ B: First priority should go to a person who is predicted to survive 6 months or longer
- ☐ C: First priority should go to a person who is predicted to survive 1 year or longer
- ☐ D: First priority should go to a person who is predicted to survive 2 years or longer
- ☐ E: First priority should go to a person who is predicted to survive 5 years or longer
- ☐ F: First priority should go to a person who is predicted to survive 10 years or longer
- ☐ G: I'm not sure

If you have any comments please write them in the space below:

Selection Criteria Based on Predicted Level of Function

One way to decide the priority which people would be admitted to an ICU in a pandemic disaster, when there are not enough resources to treat everyone, is to use a scoring system for a person's predicted level of function at the end of their hospital stay.

Example of a scoring system for function

	Score	
Poor Function	1	Vegetative State - Unaware of self and environment
	2	Needs full assistance in all activities of daily life
	3	Needs partial assistance in some activities of daily life
	4	Independent, but cannot work, cannot go to school/higher education, or cannot go to previous social activities
	5	Independent, with some deficits, but can partly resume work or previous activities
	6	Independent, with only minor physical or mental deficits that affects daily life
Good Function	7	Full recovery or minor symptoms that do not affect daily life

A person who is predicted to have a higher score at the end of their hospital stay (for example, 7) would have higher priority for admission to the ICU. A person with a lower score (for example, 1) would have lower priority.

Question 3A: How fair do you think it is to use a person's predicted level of function at the end of their hospital stay to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair			Neither unfair or fair			Extremely fair
1	2	3	4	5	6	7

Question 3B: If this scoring system was used to decide who gets treated in a disaster, when there are not enough resources to treat everyone, what cut-off point do you think is the fairest?

	Score	
Point B →	1	Vegetative State - Unaware of self and environment
	2	Needs full assistance in all activities of daily life
Point C →		
	3	Needs partial assistance in some activities of daily life
Point D →		
	4	Independent, but cannot work, cannot go to school/higher education, or cannot go to previous social activities
Point E →		
	5	Independent, with some deficits, but can partly resume work or previous activities
	6	Independent, with only minor physical or mental deficits that affects daily life
	7	Full recovery or minor symptoms that do not affect daily life

☐ A I don't think using a scoring system for function is fair.

or

☐ B Point B - A person who scores 2 to 7 should have equal first priority.
A person who scores 1 should have lower priority.

☐ C Point C - A person who scores 3 to 7 should have equal first priority.
A person who scores 1 or 2 should have lower priority.

☐ D Point D - A person who scores 4 to 7 should have equal first priority.
A person who scores 1 to 3 should have lower priority.

☐ E Point E - A person who scores 5 to 7 should have equal first priority.
A person who scores 1 to 4 should have lower priority.

☐ F I'm not sure.

If you have any comments please write them in the space below:

Selection Criteria Based on Predicted Level of Frailty

One way to decide the priority which people would be admitted to an ICU in a pandemic disaster, when there are not enough resources to treat everyone, is to use a scoring system for a person's predicted level of frailty at the end of their hospital stay.

Example of a scoring system for frailty

	Score	
Very Frail	1	Approaching end of life, with life expectancy less than 6 months.
	2	Completely dependent on others for personal care and approaching end of life.
	3	Completely dependent on others for personal care
	4	Needs help with all outside activities and looking after the house inside. Has problems climbing stairs. May need help with bathing and dressing.
	5	Slowing down and needs help with finances, transportation, medications, shopping, walking outside alone, meal preparation and housework.
	6	Has some symptoms which limit activity. Not dependent on others for daily help.
	7	Only exercise is routine walking. Medical problems are well controlled.
	8	Can exercise or are very active occasionally. Has no active disease symptoms but less fit than category 9.
Not Frail	9	Active and energetic

A person who is predicted to have a higher score at the end of their hospital stay (for example, 9) would have higher priority for admission to the ICU. A person with a lower score (for example, 1) would have lower priority.

Question 4A: How fair do you think it is to use a person's predicted frailty at the end of their hospital stay, to decide who gets treated in a disaster, when there are not enough resources to treat everyone?

Extremely unfair _____ Neither unfair or fair _____ Extremely fair

1 2 3 4 5 6 7

Question 4B: If this scoring system was used to decide who gets treated in a disaster, when there are not enough resources to treat everyone, what cut-off point do you think is the fairest?

	Score	
	1	Approaching end of life, with life expectancy less than 6 months.
	2	Completely dependent on others for personal care and approaching end of life.
Point B →		
	3	Completely dependent on others for personal care
Point C →		
	4	Needs help with all outside activities and looking after the house inside. Has problems climbing stairs. May need help with bathing and dressing.
Point D →		
	5	Slowing down and needs help with finances, transportation, medications, shopping, walking outside alone, meal preparation and housework
Point E →		
	6	Symptoms limit activity. Not dependent on others for daily help.
	7	Not active beyond routine walking. Medical problems are well controlled.
	8	Can exercise or are very active occasionally. Has no active disease symptoms but less fit than category 9.
	9	Active and energetic

☐ A I don't think using a scoring system for frailty is fair.

or

☐ B Point B - A person who scores 3 to 9 should have equal first priority.
A person who scores 1 to 2 should have lower priority.

☐ C Point C - A person who scores 4 to 9 should have equal first priority.
A person who scores 1 to 3 should have lower priority.

☐ D Point D - A person who scores 5 to 9 should have equal first priority.
A person who scores 1 to 4 should have lower priority.

☐ E Point E - A person who scores 6 to 9 should have equal first priority.
A person who scores 1 to 5 should have lower priority.

☐ F I'm not sure.

If you have any comments please write them in the space below:

Ranking the Selection Criteria

Question 5: Rank in order of preference from "1" to "4" which of the previous four (4) selection criteria you think are the fairest to decide who gets treated in a disaster, when there are not enough resources to treat everyone.

(Write "1" for the choice you think is the fairest, "2" for the second fairest, "3" for the third fairest, and "4" for the choice you think is the least fair. If you don't think any of the selection criteria are fair, or you are not sure, tick one of the bottom 2 boxes instead.)

(Please feel free to go back and check what each criteria means.)

☐ Long-Term (Chronic) Medical Conditions

☐ Long-Term Survival Target

☐ Predicted Level of Function (at the end of their hospital stay)

☐ Predicted Level of Frailty (at the end of their hospital stay)

or tick

☐ I don't think any of the selection criteria are fair

☐ I'm not sure

If you have any comments please write them in the space below:

Additional Questions

Certain people in our society are considered vulnerable or disadvantaged.

These people may be more likely to become ill during pandemics. They may have economic hardship or may be homeless. They may have poorer nutrition, may have higher levels of chronic disease, and may not have good access to health care under normal circumstances.

Question 6: How fair do you think it is if vulnerable or disadvantaged people are treated preferentially in the ICU, before the general public, in a pandemic disaster, when there are not enough resources to treat everyone?

Extremely unfair			Neither unfair or fair			Extremely fair
1	2	3	4	5	6	7

Imagine it is a pandemic disaster and there are not enough resources to treat everyone. The ICU can only take one (1) more patient, but there are two (2) patients (Patient A and Patient B) who are critically unwell. Both patients require admission to the ICU to survive.

A decision needs to be made on which patient will be treated first in the ICU.

Question 7: Patient A and B are the same age and have the same medical conditions. Patient A is a solo parent and has 2 children, who will be orphaned if Patient A does not survive. Patient B has no children.

How fair do you think it is if Patient A is treated first in the ICU, before Patient B, in a pandemic disaster, when there are not enough resources for everyone?

Extremely unfair			Neither unfair or fair			Extremely fair
1	2	3	4	5	6	7

Question 8: Patients A and B are the same age and have the same medical conditions. Patient A is a frontline healthcare worker and works in a hospital. Patient B is not a frontline healthcare worker.

How fair do you think it is if Patient A is treated first in the ICU, before Patient B, in a pandemic disaster, when there are not enough resources for everyone?

Extremely unfair			Neither unfair or fair			Extremely fair
1	2	3	4	5	6	7

If you have any comments please write them in the space below:

Demographics Questions

For Questions 9 to 13 place a cross in the box, like so ☒ that matches your answer.

Question 9: Which state do you live in?

☐ Australian Capital Territory ☐ New South Wales ☐ Northern Territory ☐ Queensland

☐ South Australia ☐ Western Australia ☐ Victoria ☐ Tasmania

Question 10: Which age group do you belong to?

☐ Under 21 years old ☐ 41 to 45 years old ☐ 66 to 70 years old

☐ 21 to 25 years old ☐ 46 to 50 years old ☐ 71 to 75 years old

☐ 26 to 30 years old ☐ 51 to 55 years old ☐ 76 to 80 years old

☐ 31 to 35 years old ☐ 56 to 60 years old ☐ 81 to 85 years old

☐ 36 to 40 years old ☐ 61 to 65 years old ☐ 86 years or older

Question 11: What is your gender?

☐ Male ☐ Female ☐ Other

Question 12: Do you live in a city, a town, or a country area?

☐ City (population more than 10 000 people)

☐ Town (population between 250 to 10 000 people)

☐ Country, rural or outback area (population less than 250 people)

Question 13: What is your current employment status?

☐ Retired ☐ At school, college, or university ☐ Employed full-time

☐ Not employed in paid work ☐ Employed part-time or casual

If you have any final comments about this questionnaire please write them in the space below:

This is the end of the questionnaire.

Please return this completed questionnaire to the address on the front page, using the reply paid envelope.

Thank you again for your help.

Appendix 7 - Other Work Related to PhD Thesis

ICU Pandemic Surveillance (IPS) Program

A7.1 Objectives

The primary objective of the ICU Pandemic Surveillance (IPS) Program was to refine ICU admission and discharge criteria, triage protocols or triage methods in a timely manner, to ensure that ICU therapy was used to maximize the number of lives saved during the COVID-19 pandemic.

There were several secondary objectives. The first was to determine if subgroups of survivors had poor medium-term survival or other outcomes, and therefore should be excluded from ICU therapy in future triage protocols. The second was to determine the cost-effectiveness of triage protocols for specific subgroups. The third was to develop models to help plan ICU therapy for paediatric patients across age-specific (paediatric and adult) ICUs during the COVID-19 pandemic. The fourth was to evaluate whether triage decisions were compliant with relevant legal and regulatory frameworks in each jurisdiction.

A7.2 Background

On 20 March 2020, the borders of Australia were closed to all non-citizens and non-residents because of the worsening COVID-19 pandemic. Two weeks before this, on 3 March 2020, the ANZICS Clinical Trials Group (CTG) convened a special session at the ANZICS 22nd Annual Meeting on Clinical Trials in Intensive Care to discuss the pandemic situation.

At the meeting, three research programs were proposed. Each examined a different aspect of the COVID-19 pandemic. I was tasked with developing a research program to provide data to manage the allocation of ICU beds, because of my previous research work with pandemic triage. The program was named the ICU Pandemic Surveillance (IPS) Program. In Australia and worldwide, no program existed at the time to do this.

I put together a management committee, and over the next 4 weeks a study protocol and funding application to the federal government was developed. The management committee (listed in the acknowledgements section) consisted of over 50 national and international experts, in intensive care medicine, ethics, public health, long-term outcomes research, health economics, systems modelling, law, and medical specialties such as geriatric medicine, emergency medicine and infectious diseases. The program was designed to run in all ICUs in Australia that had the capability to collect daily data during the COVID-19 pandemic.

On 21 April 2020, the IPS program received ethics approval to proceed (Approval number CH62/6/2020-059, 2020/ETH00820, 2020/PID00899 – 21 April 2020 – Sydney Local Health District Human Research Ethics Committee – Concord Repatriation General Hospital).

An application was made to the federal health minister by ANZICS for emergency funding for the IPS program. The funding for the program was not approved, but we were informed that funding would be reconsidered if the pandemic significantly worsened. The IPS program has not proceeded past

the pilot phase because of the lack of funding. This section details the IPS program as described in this funding application.

A7.3 Rationale Behind Instituting an ICU Pandemic Surveillance Program during the COVID-19 Pandemic

There were several compelling reasons why an ICU pandemic surveillance program had to be immediately instituted at the time the COVID-19 pandemic started:

1 The COVID-19 pandemic at the time was highly likely to cause significant mortality and morbidity in Australia.

2 ICU admission for invasive ventilation and other ICU treatments (ICU therapy) was at the time the only therapy that improved survival in patients with severe COVID-19.

3 It was highly possible that health care and intensive care resources would be overwhelmed by demand for these resources during the COVID-19 pandemic.

4 The number of ICU beds in Australia was limited and finite, and therefore had to be managed in a manner during a pandemic that maximised the best outcomes for the community.

5 National, state or local ICU triage protocols, to decide which patients gained access to ICU beds, were likely to be developed and used during the COVID-19 pandemic.

6 No ICU triage protocol had been used or tested in an actual viral pandemic and the performance of these triage protocols was unknown.

7 Australia at the time had no mechanism to monitor the performance of ICU triage tools in managing adult or paediatric ICU beds.

8 Australia at the time had no feedback mechanism to provide timely data to health authorities on ICU demand and resource availability, or how to refine ICU triage tools in a timely manner, in order to maximise the appropriate use of ICU resources to maximise the best outcomes for the community.

9 Australia at the time had no mechanism to monitor and plan for the use of ICU beds in managing critically ill children in adult or paediatric ICUs.

10 Data on ICU bed usage demand and availability was required to correlate to infection rates, to develop models to help plan for the ICU resourcing in the next pandemic.

11 The Australian legal framework for pandemic triage needed clarification across jurisdictions.

12 Medium term patient-centred outcome data was needed to determine if some subgroups of pandemic survivors did more poorly than others from a quality of life and function point of view, and if these groups should be excluded from ICU level care in future ICU triage protocols.

13 Medium term patient-centred outcome data was needed to determine the cost-effectiveness of triage protocols for subgroups.

A7.4 Reasons Why Bed Management Systems Did Not Work in a Pandemic

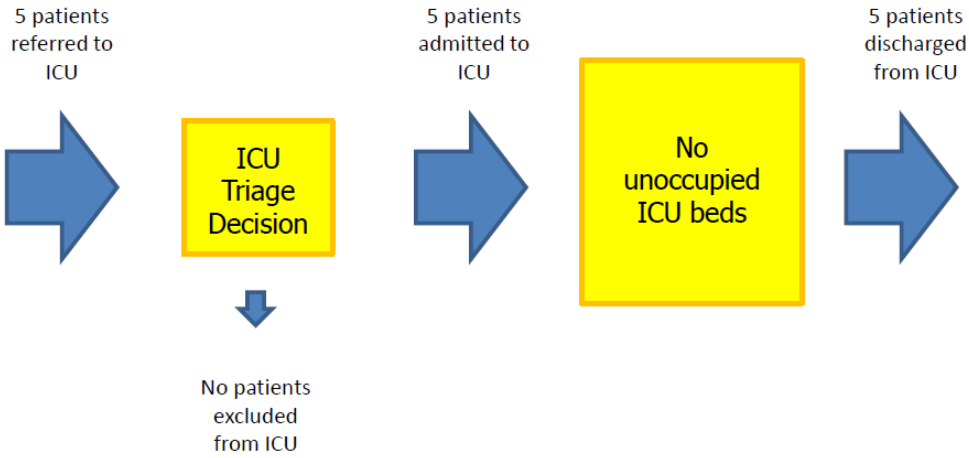
The ICU bed management systems in Australian hospitals at the time collected the following information:

Total number of operational ICU beds
Number of unoccupied ICU beds (available for immediate use)
Number of patients with exit block (unable to be transferred out of the ICU due to lack of destination ward beds)

This basic information was useful to manage basic patient flows, surge capacity and staffing arrangements. However, no information was collected by systems at the time on the numbers of patients excluded from the ICU, and reasons why these patients were excluded.

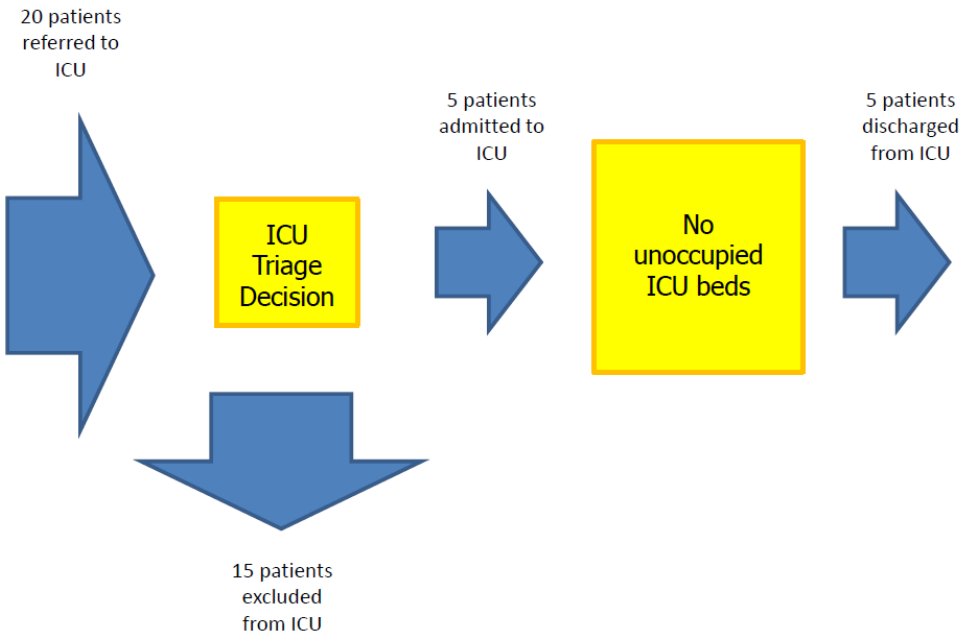
Hypothetically, in a pandemic, an ICU could have had no unoccupied beds and no exit block, but could have had few patients referred on a given day for ICU management (Figure A7-A).

Figure A7-A – Hypothetical ICU patient flow with few patient referrals in a pandemic



Conversely, an ICU could have had no unoccupied beds and no exit block, but could have had many patients referred, and many referred patients may have been excluded from ICU access (Figure A7-B).

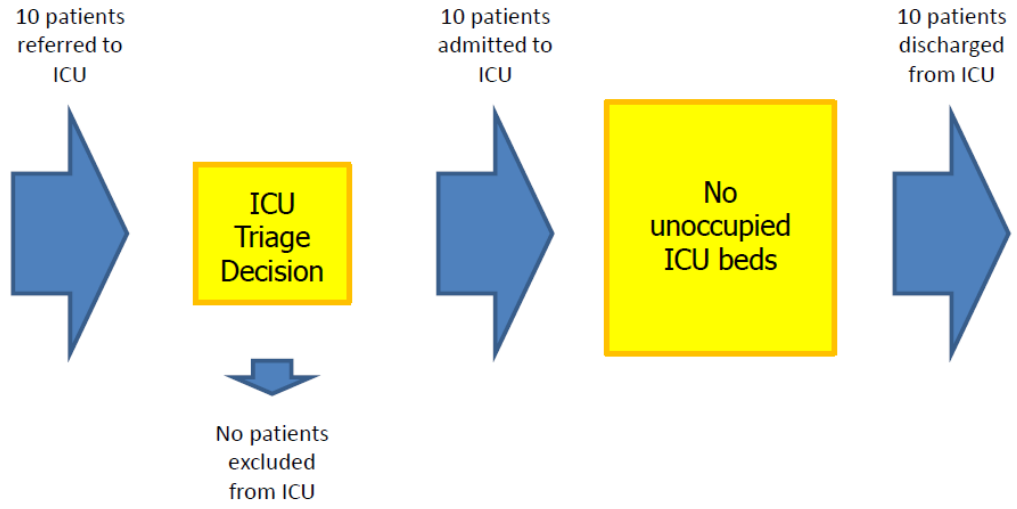
Figure A7-B – Hypothetical ICU patient flow with many patient referrals and exclusions in a pandemic



Some of these hypothetically excluded patients may have been salvaged if other patients had been discharged early from the ICU. However, the ICU bed management monitoring systems at the time were not sensitive enough to detect such problems in a pandemic. In the example in Figure A7-B, the traditional bed management monitoring system would have shown five patients as being admitted to the ICU and five patients being discharged, the same as in Figure A7-A, even though the demand for ICU beds was different.

No information was collected by the bed management systems at the time on the reasons why patients were discharged. For example, hypothetically in a pandemic, an ICU could have had no unoccupied beds and no exit block, but may have had many patients discharged prematurely, before completing an adequate trial of ICU therapy (Figure A7-C).

Figure A7-C – ICU patient flow with many patient referrals and discharges in a pandemic



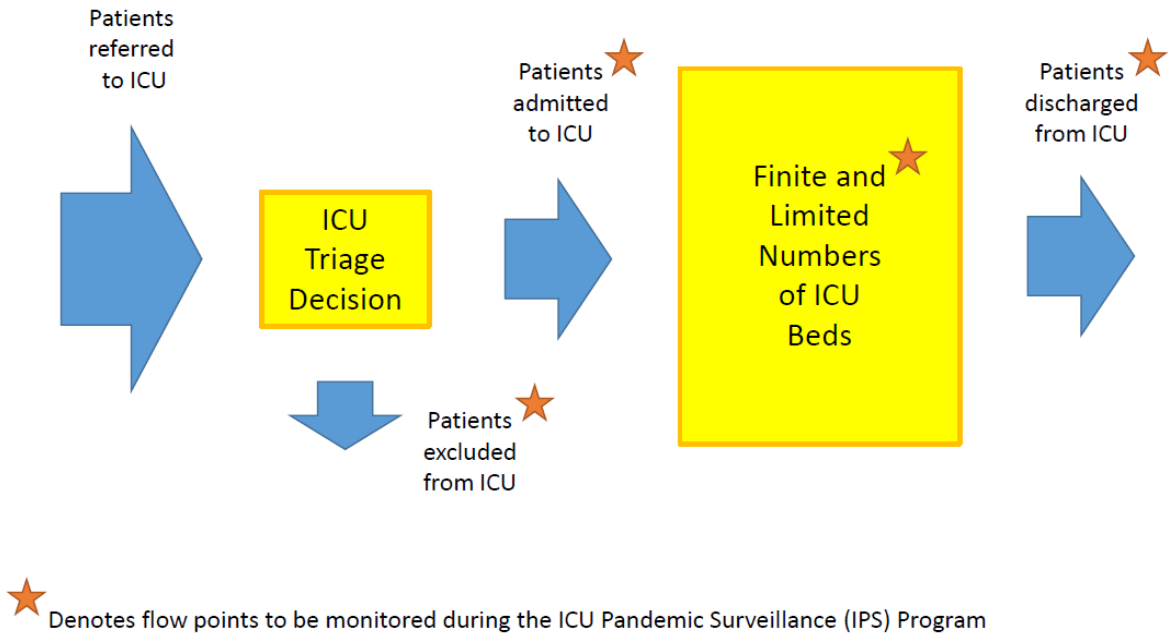
Again, some of these prematurely discharged patients may have been salvaged if other patients had been excluded from the ICU, but the ICU bed management monitoring systems at the time were not sensitive enough to detect such problems.

A7.5 Complexity of an ICU Pandemic Surveillance Program

Data analysis for the ICU Pandemic Surveillance Program was expected to be challenging and complex. This was because patients would be excluded from the ICU for different reasons, and pooled aggregate data would not provide enough discrimination to refine triage protocols or methods accurately. For example, patients may have been excluded from the ICU because they were not sick enough to benefit from an ICU admission, or may be excluded because their illness severity was so great that they were unlikely to survive. Both sets of patients would have significantly different mortality rates and therefore needed to be analysed separately.

Figure A7-D demonstrates the hypothetical patient flows through the ICU during a pandemic where ICU triage methods were used, and the flow points that required more detailed monitoring.

Figure A7-D – Hypothetical patient flows though the ICU during a pandemic



Patients referred to ICU = Patients admitted to ICU + Patients excluded from ICU

The number of patients and mortality outcomes of patients passing through each of the flow points denoted in Figure A7-D were paramount to evaluating the performance of ICU triage protocols. These flow points could be categorized into three important monitoring areas, of which only the first monitoring area was being collected in Australia at the time. The ICU Pandemic Surveillance Program was designed to collect data on these three monitoring areas and a fourth area on triage methods (Box A7-A).

Box A7-A is shown on the next page

Box A7-A – Monitoring areas where data was to be collected during the ICU Pandemic Surveillance Program

1 ICU Resource Availability *

Total number of operational ICU beds
Number of unoccupied ICU beds (available for immediate use)
Number of patients with exit block (unable to be transferred out of the ICU due to lack of destination ward beds)

2 Triage Protocols or Triage Methods being used **

Triage Protocols

Types of triage protocols or triage methods used at the site
Use of "Triage Committees"
Number of people involved in triage decision-making
Training methods
Training oversight

Legal protections or regulatory frameworks in place

Governance and Oversight
Training

3 Patient Demand for ICU beds ***

Number of patients:

Admitted to the ICU

Referred to but excluded from the ICU, who under normal circumstances would not be considered for ICU admission
Subcategories:
*Excluded as unlikely to benefit due to comorbidities**** or high acute illness severity*
Excluded as not unwell enough to benefit

Referred to but excluded from the ICU, who under normal circumstances would be admitted to the ICU
Subcategories:
Excluded due to non-availability of ICU beds
*Excluded by clinician with or without using triage protocol as unlikely to benefit due to comorbidities**** or high acute illness severity*
Excluded by clinician with or without using triage protocol as being not unwell enough to benefit

Discharged from the ICU
Subcategories:
Discharged, no longer requiring ICU level care
Discharged prematurely from the ICU while improving, who in normal circumstances would have remained
Discharged as not improving, or deteriorating
Palliated early
Palliated using usual clinical timeframe
Died

Box A7-A – Monitoring areas where data was to be collected during the ICU Pandemic Surveillance Program (continued)

4 Patient Mortality ***

Mortality of patients:

Admitted to the ICU

Referred to but excluded from the ICU, who under normal circumstances would not be considered for ICU admission

Subcategories:

*Excluded as unlikely to benefit due to comorbidities**** or high acute illness severity*

Excluded as not unwell enough to benefit

Referred to but excluded from the ICU, who under normal circumstances would be admitted to the ICU

Subcategories:

Excluded due to non-availability of ICU beds

*Excluded by clinician with or without using triage protocol as unlikely to benefit due to comorbidities**** or high acute illness severity*

Excluded by clinician with or without using triage protocol as being not unwell enough to benefit

Discharged from the ICU

Subcategories:

Discharged, no longer requiring ICU level care

Discharged prematurely from the ICU while improving, who in normal circumstances would have remained

Discharged as not improving, or deteriorating

Palliated early

Palliated using usual clinical timeframes

* This data was being collected in Australia at the time, and also would be collected by IPS Program
** Central data collectors would contact sites directly at regular intervals during the pandemic to obtain these details.
*** This data was not all collected in Australia at the time, so would be collected by IPS Program.
**** Comorbidities include older age.

Site specific data forms (patient tracking forms – Appendix 8) were developed to collect this information, as well as the names, medical record numbers, and dates of births for patients who underwent early palliation, and those who underwent palliation using usual clinical timeframes. These identifiers would allow reidentification later on for a retrospective review of patients who underwent early palliation. It was possible that clinicians may have palliated patients early when ICU resources were scarce in a pandemic disaster, when other patients competing for ICU resources had a better predicted chance of survival.

A7.6 Previous Research

At the time there had been no studies conducted during any actual pandemic testing the performance of any triage protocol. Our previous work tested two triage protocols, but only in a

simulated pandemic exercise.[1,2] Other studies had attempted to evaluate triage decision-making using desktop simulation exercises.[3] One study demonstrated that excluding patient groups on the basis of anticipated length of stay could be effective due to a more efficient use of critical care bed days.[3] There were no studies correlating infection incidence or prevalence in a pandemic to the number of ICU beds required to manage patients in a pandemic.

A7.7 Methods

The IPS program had two study phases. Phase 1 would monitor and enable refinement of the processes that controlled ICU patient admission and discharge during the COVID-19 pandemic. Phase 2 was a five-year follow-up program of patients who survived their ICU admission during the COVID-19 pandemic.

A7.7.1 Phase 1 – The Start of the COVID-19 Pandemic

Phase 1 of the IPS program was planned to be a prospective audit of all patients being referred to an ICU for consideration for ICU admission, all patients admitted to an ICU, and all patients discharged from an ICU, in Australia, during the initial COVID-19 pandemic and the predicted second COVID-19 pandemic wave. This phase used a paper or electronic data collection form (patient tracking form) and would run for two years.

Phase 1 would monitor the performance of ICU admission and discharge criteria, triage protocols or triage methods during the COVID-19 pandemic; guide necessary refinements or modifications to these criteria, protocols or methods; and provide daily information on ICU bed management. This phase would run in all adult and paediatric ICUs in Australia that had the capability to collect prospective daily data during the COVID-19 pandemic.

At the time, the Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group (CTG) had 81 member ICUs in Australia. The ANZICS Paediatric Study Group (PSG) had 9 member paediatric ICUs in Australia. There were 219 open ICUs in Australia that could be used to manage patients during the COVID-19 pandemic. It was thought that the IPS program could be operationalized at 120 of those sites.

Data was to be collected daily by the participating ICUs, collated centrally and analysed at regular intervals. The data was to be incorporated into a system dynamics model, developed by experts in systems modelling, which mapped relevant patients' flow and hospital management. The model outputs would allow timely feedback to health departments on the performance of ICU admission and discharge criteria; triage protocols or triage methods in managing ICU beds; whether these criteria, protocols or methods need to be modified; future data collection; and broader hospital management that impacted on ICU patient management. Phase 1 of the IPS program would also correlate ICU bed usage data with community COVID-19 rates, in order to develop models to help plan for the number of ICU beds required in future pandemics.

A7.7.2 Phase 2 – Post Pandemic Follow-up

Phase 2 of the IPS program was planned to be a five year (medium term) follow-up of survival, quality of life, function, and health economic outcomes in survivors of the initial COVID-19 pandemic and the predicted second COVID-19 pandemic wave. This phase would determine if subgroups of

survivors had poor medium-term outcomes, and therefore should be excluded from ICU therapy in future triage protocols. Phase 2 was planned to run for five years.

Phase 2 would run in 15 adult ICUs and the paediatric ICUs in Australia that had completed Phase 1 of the program and had elected to participate in Phase 2. Follow-up would occur at six months, one year, 18 months, two years, and then yearly to five years.

A total of 860 adult patients and 100 paediatric patients were planned to be consented to take part in the post pandemic patient follow-up (Section A8.7.8 - Analysis and Statistics). Consent for paediatric patients would be obtained from parents or legal guardians.

Patients would be included if they had been invasively ventilated, for any duration, during the COVID-19 pandemic periods; and had been discharged from hospital alive. Patients were planned to be excluded if they could not provide consent; were unable to complete the program protocol; did not speak the English language; or were discharged for palliative care.

A7.7.3 Paediatric and Neonatal ICUs

A unique feature of the provision of critical care services in Australia was that this was age-specific. ICUs were separated into specialist neonatal, paediatric and adult units, with some mixed units.

Neonatal patients were managed in neonatal intensive care units (NICUs). These are mostly located within the women's hospitals adjacent to delivery suites, with the key focus on preterm babies. Most NICUs did not admit older children in Australia and had restrictions on the admission of neonates who had been discharged home.

In Australia, most paediatric patients (80.5%) were managed in the nine paediatric ICUs (PICUs) located at the major paediatric hospitals.[4] The rest (19.5%) were managed in adult/mixed ICUs. Of admissions to PICUs, 22.4% of patients were admitted via specialist retrieval teams. This approach enabled highly specialized paediatric services to be provided at larger tertiary hospitals, while supporting children with single organ failures or less complicated disease closer to home in mixed units. However, in 2020, there were no mechanisms to jointly operate adult and paediatric ICUs to optimize the use of ICU resources during a pandemic.

At the start of the COVID-19 pandemic in Australia, it was anticipated that the proportion of critically ill children would be low, and the proportion of critically ill adults would be high, based on the international experience at that point.[5] Because of the anticipated lack of capacity in adult/mixed ICUs to continue caring for paediatric patients, preparations started in Australia to increase capacity at the larger tertiary PICUs to care for 100% of the critically ill paediatric patients, instead of the previous practice of 80%.

At the time, PICUs were also discussing, at an individual ICU level, whether adults should be managed in PICUs, if adult ICUs were to be overwhelmed. Converse to this, it was conceivable that a future pandemic could have a disproportionate impact on children instead of adults, leading to an exhaustion of PICU beds, before adult ICU beds.

These challenges highlighted the problem with age-specific ICU resource allocation in Australia. Optimization of triaging and bed usage across adult and paediatric ICUs could help attenuate the surge needs during pandemics, and had potential to result in more cost-efficient service delivery. Because there was no surveillance program at the time to monitor the use of ICU beds across age-

specific ICUs during a pandemic, in Australia or worldwide, the IPS program would incorporate this function.

A7.7.4 Data Collection

A7.7.4.1 Data Collected at Individual ICU Sites

At the start of the IPS program, a paper data collection form (also called patient tracking form – Appendix 8) was planned to be used. This would be completed for each calendar day while the program was running, by data collectors at each participating ICU. An electronic app to perform the data collection was being created at the time, and would be used later. The data collection form would collect the information shown in Box A7-B.

Box A7-B – General information collected on IPS program patient tracking form

ICU name
Date of data collection
ICU bed capacity at Midnight, 08:00Hrs, and 16:00Hrs
- Number of operational beds
- Number of available (empty) beds
- Number of patients exit blocked

Triage method being used on date of data collection in the ICU
- Use of triage committees/number of decision-makers

Names, medical record numbers, dates of birth of all patients excluded from the ICU on date of data collection
- Time of exclusion decision
- Reasons for exclusion

Names, medical record numbers, dates of birth of all patients discharged from the ICU on date of data collection
- Time of discharge decision
- Reasons for discharge

Names, medical record numbers, dates of birth of all patients admitted to the ICU on date of data collection
- Time of admission decision

All patients entered into the data collection form would be followed up at the end of their ICU stay and end of their hospital stay to determine the patient-centred outcome measures detailed in Box A7-C.

Box A7-C – Patient-centred outcomes collected on IPS program patient tracking form

ICU mortality ICU length of stay (LOS) Hospital mortality Hospital length of stay (LOS)

A7.7.4.2 Data Collection from COMET

COMET was the data collection registry used by all ICUs in Australia to collect patient outcome and ICU performance data, and was managed by the ANZICS Centre for Outcome and Resource Evaluation (CORE).[7,9] Acute Physiology and Chronic Health Evaluation (APACHE) II and III scores, or Paediatric Index of Mortality-3 (PIM-3) scores for patients younger than 16 years, would be obtained from the COMET reporting system used at each hospital for each patient admitted to the ICU.[6,7,8]

A7.7.4.3 Epidemiological and Population Data Collection

Incidence data was to be calculated from COVID-19 epidemiological data supplied by daily reports provided by the Australian Government Department of Health National Notifiable Diseases Surveillance System and weekly reports provided by the Australian Government Department of Health Communicable Diseases Intelligence.[10,11] Population data would be based on estimates from the Australian Bureau of Statistics.[12]

Under normal circumstances, the prevalence of the disease being studied should be calculated, as this would report the community burden of disease. However, for the COVID-19 pandemic this calculation would be difficult, as it was impossible to determine when all patients infected with COVID-19 would actually recover. Because of this, modelling for ICU resourcing would be based on incidence calculations, rather than prevalence.

Notification data of COVID-19 would also underestimate the number of cases in the community. Therefore modelling was planned be used to estimate the true incidence.

A7.7.5 Survival Analysis

Patient names would be matched with the new National Births, Deaths and Marriages registry over the next two and five years to determine two and five year survival, and plot survival curves. The new National Births, Deaths and Marriages registry was being developed at the time. If it was not operational in time for this study, the names were planned to be matched with the Registries of Births, Death and Marriages for each state instead.

Baseline demographic data (Box A7-D) would be obtained from the COMET database at the participating site that managed the patient during the pandemic and the IPS program database, to determine if any demographic factors or triage selection factors were associated with poor survival following hospital discharge.[7,9]

Box A7-D - Baseline demographic data collected on IPS program patient tracking form

Age
Sex
Chronic medical conditions
Frailty score
APACHE II and III scores*
Interventions

* Acute Physiology and Chronic Health Evaluation [6]

A7.7.6 Quality of Life and Function

Patients potentially participating in Phase 2 of the IPS program would be contacted by telephone, then sent a participant information sheet and written consent form via post or email using contact information supplied at the time of telephone contact. Remuneration to cover costs for patients was planned to be offered.

Adult Patients

Adult patients who provided written consent would, have the tools detailed in Box A7-E administered to collect information of quality of life and function outcomes.

Box A7-E is shown on the next page

Box A7-E – Tools used in the IPS program to collect quality of life and function outcomes in adult patients

WHO Disability Assessment Schedule (WHO DAS) 2.0 [14]

The WHO DAS was a quality of life instrument that was able to assess health and disability in 6 domains, including cognition (understanding and communicating), mobility (moving and getting around), self-care (hygiene, dressing, eating and staying alone), getting along (interacting with other people), life activities (domestic responsibilities, leisure, work and school, and participation (joining in community activities). This instrument took 5-20min to complete.

The EuroQol 5 Dimensions, 5 Levels (EQ-5D-5L) [15]

The EQ-5D-5L was a standardised measure of health-related quality of life consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), and a visual analogue scale (VAS) of overall self-reported health. This tool was able to provide a utility score which was a calculated health state based on responses. This score was then able to be used for health economic analyses (see Health Economics section). The EQ-5D-5L took 5-10min to complete.

The Post-Traumatic Stress Disorder Checklist (PCL-5) [16]

The PCL-5 was a 20 item self-reported measure to assess the presence and severity of Post-Traumatic Stress Disorder (PTSD) symptoms using the DSM IV criteria. The PCL-5 could be used to quantify and monitor symptoms over time, to screen individuals for PTSD, and to assist in making a provisional or temporary diagnosis of PTSD. The PCL-5 took 5-10 minutes to complete.

Paediatric Patients

Paediatric patients whose parents provided consent would have the tools detailed in Box A7-F administered to collect information of quality of life and function outcomes.

Box A7-F is shown on the next page

Box A7-F – Tools used in IPS program to collect quality of life and function outcomes in paediatric patients

PedsQL™ [17-19]

The PedsQL™ measurement model was a modular approach to measuring health-related quality of life (HRQOL) in healthy infants, children and adolescents, and those with acute and chronic health conditions. It was a 23-item survey is designed for use with ages ranging from 1 month to 18 years. It was multidimensional covering physical, emotional, social, cognitive and school functioning. The PedsQL took 10-15 minutes to complete.

Pediatric Cerebral Performance Category (PCPC).[20]

The PCPC was developed to quantify overall function (general adaptive/physical) and was a 6-point graded scale of increasing disability from normal function (score = 1) to death (score = 6). The PCPC took 2-5 minutes to complete.

Functional Status Score (FSS).[21]

The FSS captured functional status as measured by adaptive behaviour. The FSS contained six domains of function: mental status; sensory functioning; communication; motor functioning; feeding; and respiratory status. Each domain was categorised from normal (1) to severe dysfunction (5). Scores ranged from 6 to 30. The FSS took 5-10 minutes to complete.

A7.7.7 Health Economics

To conduct the health economic analysis, patients included in the program were planned to be linked to the following state and federal-based health administrative databases:

Admitted patient databases (APD)
Emergency department data collection databases
Death registries
Pharmaceutical Benefits Scheme (PBS)
Medicare Benefits Scheme (MBS)

The full linked dataset would be used to determine healthcare resource use over the follow-up period. Healthcare resource use would be costed using the following federal Government cost weights:

MBS item rebates
Australian Related-Diagnosis Related Groups (AR-DRGs)
PBS costs

The linked dataset, including cost estimates, would be used for two analyses:

1 A description of resource use and costs for selected patient subgroups

2 A modelled cost-effectiveness analysis using resource use, cost, mortality and quality of life data to evaluate the cost-effectiveness of the ICU triage protocols for selected patient subgroups.

A7.7.8 Analysis and Statistics

A7.7.8.1 Analysis of Phase 1

In Phase 1 of the IPS program, a system dynamics model of ICU and triage protocols would be created at the start. Surveillance data would be analysed fortnightly for input into the model and the model would inform refinement of the triage protocol. Additional model structure and data related to the broader hospital management related to ICU patient flow would be added at a less urgent basis so as not to burden the frontline health workers, and these would inform other aspects of pandemic response such as staffing management.

During the Phase 1 of the program, ICU activity would also be monitored using the descriptors listed in Section 8.5 - Box A7-A. Further to descriptive analyses, a comparison analysis was planned to be made across ICUs using monitoring tools such as funnel plots to identify potential sites which were outside "control" limits. To assess ICU and hospital mortality taking account potential cluster effects at an ICU level, hierarchical logistic models and time to event (survival) models were planned to be applied. Pre-specified subgroup analyses would also be performed. ICU and hospital length of stays would be assessed by mixed models.

A7.7.8.2 Analysis of Phase 2

In order to assess survival of ICU survivors and identify subgroups that had a poor or extremely good survival in the medium term, we planned to perform multivariable Cox regressions (with a specific frailty or fixed effect variable for the various ICU sites). A piecewise model approach would be fitted if it was considered that the proportional hazard assumption (the constant hazard ratio) of the above Cox model was not appropriate.

Adult Patients

In order to have adequate power we made a sample size calculation based on the assumption that the 2-year survival of the whole cohort of adult ICU survivors was 60%.[22] The number of adult patients needed in this follow-up phase was 860. This is based on two independent sample size calculations and the following assumptions:

1 Potential detection of 50% increase in mortality at 2 years

Assuming a 50% increase in mortality at 2 years, it was assumed that proportions of subjects dying within 2 years was 0.400 for the control group (the ICU population)

and 0.700 for the selected high-risk group. A one-sided test of whether the hazard ratio was one, with an overall sample size of 466 subjects (233 in each arm), achieved 90% power at a 0.025 significance level when the hazard ratio was actually 1.5. Assuming an overall ICU mortality of 11.7%, a sample size of 528 patients was required.[22] These results assumed that the hazard ratio was constant throughout the program and that Cox proportional hazards regression was used to analyse the data.

2 Potential detection of a 50% decrease in mortality at 2 years

Assuming a 50% decrease in mortality at 2 years, a one-sided test of whether the hazard ratio was one, with an overall sample size of 292 subjects (146 in each arm), achieved 90% power at a 0.025 significance level, when the hazard ratio was actually 0.5. We assumed that proportions of subjects dying within 2 years was 0.400 for the control group and 0.200 for the low-risk ICU survivor group. Assuming an overall ICU mortality of 11.7%, a sample size of 332 patients was required.

The conservative overall sample size of 860 ICU survivors (based on the two independent calculations) was also aligned with a minimum sample calculation based on the development of a new prognostic model. This model assumed a desired shrinkage factor of 10% to minimize overfitting, the inclusion of up to 5 predictors, a 2 year follow up and the accrual of 350 deaths (number of events per predictor of 70).

Paediatric Patients

The number of patients this follow-up phase was planned to be 100. For the paediatric component of the program a minimum of 5% of the overall cohort of paediatric patients (sampled from both the Paediatric ICUs and adult/mixed ICUs) was planned to be included. If paediatric numbers exceeded 10% of the entire cohort (which was not expected) then we planned to sample them at random on monthly basis to take account of potential seasonality.

Considering a pre-specified set of covariates (predictors of mortality, and of longer stay in PICU including age, comorbidity, and congenital syndromes), an exploratory survival analysis was planned to be used, with the aim of identifying subgroups of ICU paediatric survivors which were at very high or low risk of medium term mortality as the primary outcome, and ICU length of stay as the secondary outcome.

To facilitate the identification of the covariates set, a cluster analysis (classification and regression tree) and a boosting algorithm to assess the most influential predictors of mortality was planned to be run.

A7.7.8.3 Statistical Software

Sample size calculations were made using PASS2020 and Stata v.16. Project analyses will use SAS, Stata and R.

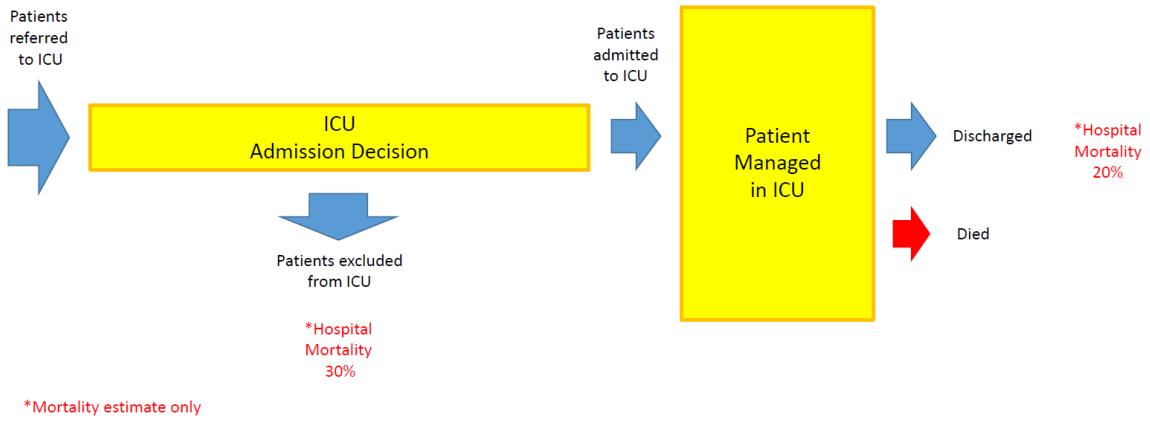
A7.8 Refining Triage Methods and Providing Feedback

As mentioned before, under normal circumstances most ICU bed management systems collect the following information:

Total number of operational ICU beds
Number of unoccupied ICU beds (available for immediate use)
Number of patients with exit block (unable to be transferred out of the ICU due to lack of destination ward beds)

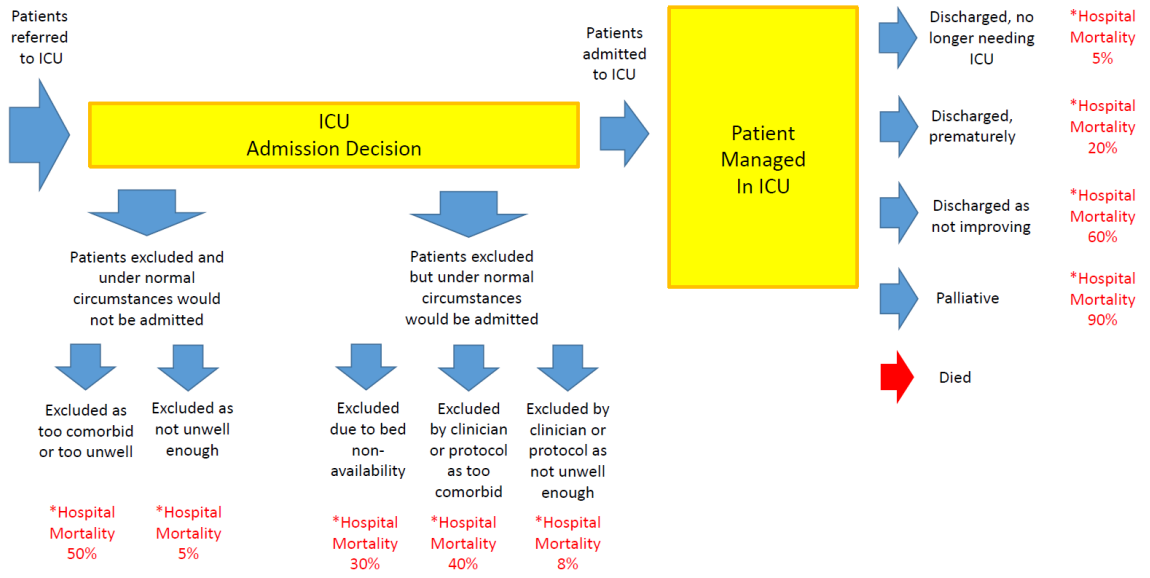
Mortality data is based on the total numbers of patients who die in the ICU and hospital. Mortality data can also be collected on patients excluded from the ICU, but currently this is not collected routinely. A hypothetical example of this is shown in Figure A7-E.

Figure A7-E – Hypothetical estimates of mortality rates in patients excluded and discharged from the ICU in non-pandemic conditions



However, in reality the mortality rates for patients excluded or discharged from the ICU are more complex, especially in a pandemic where resources are limited, and depend on the reasons for exclusion or discharge. A hypothetical example of this is shown in Figure A7-F.

Figure A7-F – Hypothetical estimates of mortality rates in patients excluded and discharged from the ICU in pandemic conditions, according to reasons for exclusion or discharge.



*Mortality estimate only

Using utilitarian public health principles in a pandemic, the aim is “save as many lives as possible”. Therefore, the ideal mortality rate for every group listed in Figure A7-F should be 0%. This is the same aim for patients who are palliative or where a non-escalation treatment decision has been made, because these patients generally still want to recover and survive.

Decisions on which patients to admit, exclude or discharge from the ICU are therefore a balance between competing mortality rates and total mortality. The ultimate aim is to minimize total mortality across the entire group. Also, ideally in a pandemic, those admitted to the ICU should be very unwell, but quick to recover. Admitting patients who take too long to recover may consume unreasonable amounts of limited ICU resources.

Using Figure A7-F as a hypothetical scenario, if it was assumed that 500 patients would be referred for admission to each of 100 ICUs, over a 6 month pandemic period, then 50000 patients in total would be referred. If 5000 patients were excluded due to bed non-availability and 5000 patients were discharged prematurely, then 2500 patients would die, using the hypothetical mortality estimates in Figure A8-F. If ICU triage protocols or methods were modified so that if 50000 patients were referred and zero patients were excluded due to bed non-availability because the number of patients discharged prematurely was increased to 10000, then only 2000 patients would die. This

would save 500 lives. In this hypothetical situation, increasing premature ICU discharge of patients reduced overall mortality. The only way this result could be calculated is to use accurate mortality data.

Collecting accurate mortality data on subgroups of patients excluded and discharged from the ICU is the only way to refine ICU triage protocols or methods in a pandemic disaster, to maximize the number of lives saved. This data was not being collected in Australia at the time.

A7.9 Feasibility

The data collection sheets to be used in the program were piloted at Concord Repatriation General Hospital and Bankstown Hospital, Sydney. The preliminary results showed that the data collection sheets were easy to use and had good compliance with data collection. This indicated that sites should have minimal problems with collecting the daily data.

A7.10 Budget

The proposed budget for the IPS program is detailed in Table A7-A and A7-B.

Table A7-A – Proposed budget for ICU Pandemic Surveillance Program - Phase 1

				Budget for ICU Pandemic Surveillance Program Phase 1		
				Phase 1A - 2020	Phase 1B - 2021	
Staff costs	**Number of staff required**	**Yearly salary**	**Justification**	**Year 1**	**Year 2**	**Total**
Senior Project Manager	1	$ 140,000.00	Operational oversight for Phases 1 and 2. Based on HSM L3 FT with 20% on-cost as per NSLHD	$ 140,000.00	$ 142,800.00	**$ 282,800.00**
Program Assistant	1	$ 80,000.00	To assist with all study documentation and project needs - 0.6 FTE (with 20% on-cost)	$ 48,000.00	$ 48,960.00	**$ 96,960.00**
Program Monitor	1	$ 110,000.00	1.0 FTE for Years 1 and 2 (with 20% on-cost)	$ 110,000.00	$ 112,200.00	**$ 222,200.00**
State Data Coordinators - Adult ICU Sites	6	$ 110,000.00	To collate data from all surveillance sites. One coordinator per major state - 1.0 FTE for Years 1 and 2 (with 20% on-cost)	$ 660,000.00	$ 673,200.00	**$ 1,333,200.00**
State Data Coordinators - Paediatric ICU Sites	0.5	$ 110,000.00	To collate data from all Paediatric ICU surveillance sites. 0.5 FTE for Years 1 and 2 (with 20% on-cost)	$ 55,000.00	$ 56,100.00	**$ 111,100.00**
Statistician	1	$65,000.00	For data analysis in Phase 1 and 2 - 0.5 FTE for Years 1 and 2 (with 20% on-cost)	$ 65,000.00	$ 66,300.00	**$ 131,300.00**
Senior Statistician	1	$40,000.00	For data analysis in Phase 1 and 2 - 0.2 FTE for Years 1 and 2 (with 20% on-cost)	$ 40,000.00	$ 40,800.00	**$ 80,800.00**
Modelling Project Lead	1	$12,500.00	Governance and oversight of modelling project, support for modelling implementation, stakeholder engagement. 10 days FTE year 1. 8 days year 2	$ 12,500.00	$ 10,000.00	**$ 22,500.00**
Modelling Research Coordinator	1	$30,400.00	Stakeholder engagement and consultation, background preparation work, data collation and summary generation. 38 days FTE in year 1. 35 days in year 2.	$ 30,400.00	$ 28,000.00	**$ 58,400.00**
System Dynamics Modelling Coordinator	1	$48,000.00	Model and interface development, interpretation of model findings, after service management as required. 48 days FTE year 1. 44 days year 2	$ 48,000.00	$ 44,000.00	**$ 92,000.00**
Expert Model Review and Technical Support	1	$15,625.00	Quality assurance review of model and to provide technical support. 5 days FTE year 1. 4 days year 2	$ 15,625.00	$ 12,500.00	**$ 28,125.00**
			SUM	**$ 1,118,000.00**	**$ 1,140,360.00**	**$ 2,459,385.00**

Direct Site Costs	**Number**	**Item cost**	**Justification**	**YR1**	**YR2**	**Total**
Site payments for Phase 1 and 2	120 sites	$10000 or $5000	To pay for site costs - Large sites (>25 beds) $10K per year. Smaller sites $5K per year (including peadiatric sites)	$ 600,000.00	$ 600,000.00	**$ 1,200,000.00**
Monitoring and Data Verification and Fidelity Costs	120 sites	$600 per site	To fulfil GCP recommendations for monitoring of data collection for Phase 1 and 2- 120 sites in Year 2. 1 visit per site		$ 72,000.00	**$ 72,000.00**
Ethics and governance fees	120 sites	$500 per site	To cover costs of ethics and governance per site. 120 sites	$ 60,000.00		**$ 60,000.00**
Database build		$ 100,000.00	To build and maintain database	$ 100,000.00		**$ 100,000.00**
Data cleaning and queries		$10,000 per year	To manage database	$ 10,000.00	$ 10,000.00	**$ 20,000.00**
Computer equipment	5	$2000 per item	Portable laptops for site and office use	$ 10,000.00		**$ 10,000.00**
App Developer			To develop audit data collection app to be used at ICU sites	$ 50,000.00		**$ 50,000.00**
Modelling - Stella Architect software and 6 months of online hosting		$ 5,200.00	Software requirement for modelling ($4800.00) and hosting required for stakeholder interaction with model ($400.00)	$ 5,200.00		**$ 5,200.00**
			SUM	**$ 835,200.00**	**$ 682,000.00**	**$ 1,517,200.00**
					Total Budget for Phase 1	**$ 3,976,585.00**

Incorporates 2% CPI

Table A7-B – Proposed budget for ICU Pandemic Surveillance Program - Phase 2

				Budget for ICU Pandemic Surveillance Program Phase 2					
				Phase 2 - 2020	Phase 2 - 2021	Phase 2 - 2022	Phase 2 - 2023	Phase 2 - 2024	
Staff Costs	**Number of staff required**	**Yearly salary**	**Justification**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total**
Senior Project Manager	1	$ 140,000.00	Operational oversight for Phase 3. Based on HSM L3 FT with 20% on-cost as per NSLHD			$ 151,540.50	$ 154,571.31	$ 157,662.74	**$ 463,774.55**
Program Assistant	1	$ 80,000.00	To assist with all study documentation and project needs - 0.6 FTE 20% on-cost			$ 49,939.00	$ 50,937.78	$ 51,956.54	**$ 152,833.32**
State Data Coordinators - Adult ICU Sites	6	$ 110,000.00	To collate data from all Adult ICU surveillance sites. One coordinator per major state - 1.0 FTE for Year 3			$ 686,664.00			**$ 686,664.00**
State Data Coordinators - Paediatric ICU Sites	0.5	$ 110,000.00	To collate data from all Paediatric ICU surveillance sites. 0.5 FTE for Year 3			$ 57,222.00			**$ 57,222.00**
Follow-up Coordinators - Adult ICU Sites	2	$ 110,000.00	To follow-up adult survivors in Phase 3 - 1.0 FTE x2 for adult follow-up Years 1 to 5	$ 220,000.00	$ 224,400.00	$ 228,888.00	$ 233,465.76	$ 238,135.08	**$ 1,144,888.84**
Follow-up Coordinators - Paediatric ICU Sites	0.5	$ 110,000.00	To follow-up paediatric survivors in Phase 3 - 0.5 FTE for Paediatric follow-up Years 1 to 5	$ 55,000.00	$ 56,100.00	$ 57,222.00	$ 58,366.44	$ 59,533.77	**$ 286,222.21**
Statistician	1	$65,000.00	For data analysis in Phase 2 - 0.5 FTE for Years 3-5			$ 67,626.00	$ 68,978.52	$ 70,358.09	**$ 206,962.61**
Senior Statistician	1	$40,000.00	For data analysis in Phase 2 - 0.2 FTE for Years 3-5			$ 41,616.00	$ 42,448.32	$ 43,297.29	**$ 127,361.61**
Health Economics	1	$ 70,000.00	To analyse health economic data - 0.5 FTE for Years 1 to 5	$ 35,000.00	$ 35,700.00	$ 36,414.00	$ 37,142.28	$ 37,885.13	**$ 182,141.41**
Modelling Project Lead	1	$ 3,750.00	Governance and oversight of modelling project, support for modelling implementation, stakeholder engagement. 3 days FTE per year in years 3-5			$ 3,750.00	$ 3,825.00	$ 3,901.50	**$ 11,476.50**
Modelling Research Coordinator	1	$ 8,640.00	Stakeholder engagement and consultation, background preparation work, data collation and summary generation. 11 days FTE per year in years 3-5			$ 8,640.00	$ 8,812.80	$ 8,989.06	**$ 26,441.86**
System Dynamics Modelling Coordinator	1	$ 13,400.00	Model and interface development, interpretation of model findings, after service management as required. 14 days FTE per year in years 3-5			$ 13,400.00	$ 13,668.00	$ 13,941.36	**$ 41,009.36**
Expert Model Review and Technical Support	1	$ 5,040.00	Quality assurance review of model and to provide technical support. 1.5 days FTE per year in years 3-5			$ 5,040.00	$ 5,140.80	$ 5,243.62	**$ 15,424.42**
			SUM	**$ 310,000.00**	**$ 316,200.00**	**$ 1,407,961.50**	**$ 677,357.01**	**$ 690,904.15**	**$ 3,402,422.66**

Direct Site Costs	**Number**	**Item cost**	**Justification**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total**
Site payments for Phase 3	1000 patients	$500 per patient	To pay for site costs - Based on 60 patients per site at 15 sites (900 adult patients), plus 100 paediatric patients	$ 500,000.00					**$ 500,000.00**
Follow-up patient payment	1000 patients	$50 per patient	To reimburse patients for participation in survival follow-up - Based on 60 patients per site at 15 adult sites plus 10 paediatric sites (100 patients)	$ 10,000.00	$ 10,000.00	$ 10,000.00	$ 10,000.00	$ 10,000.00	**$ 50,000.00**
Monitoring and Data Verification and Fidelity Costs	25 sites	$600 per site	To fulfil GCP recommendations for monitoring of data collection for Phase 3. 25 sites in Year 3 to 5. Minimum 3 visits per site			$ 15,000.00	$ 15,000.00	$ 15,000.00	**$ 45,000.00**
Data cleaning and queries		$10,000 per year	To manage database			$ 10,000.00	$ 10,000.00	$ 10,000.00	**$ 30,000.00**
Data linkage			For data linkage costs		$ 40,000.00				**$ 40,000.00**
			SUM	**$ 510,000.00**	**$ 50,000.00**	**$ 35,000.00**	**$ 35,000.00**	**$ 35,000.00**	**$ 665,000.00**
								Total Budget for Part 2	**$ 4,067,422.66**

Incorporates 2% CPI

A7.11 Progress

At the start of the COVID-19 pandemic in Australia, an application was made to the federal health minister for funding for the IPS program, however the funding for the program was not approved. We were informed that funding would be reconsidered if the pandemic significantly worsened. Because of the lack of funding we have not been able to continue the IPS program, after the pilot phase.

Our Canadian ICU colleagues have since used the IPS program and data collection forms to develop a Canadian ICU pandemic surveillance program. To date, their program also remains unfunded and remains also in a pilot phase.

A7.12 References for Appendix 8

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ICU Pandemic Surveillance Program
Patient Tracking Form

ICU Name:	
Date:	/ / 2020

Instructions

IMPORTANT: Please complete ICU Name and Date at top of every page.

For *Section 1: EXCLUSIONS*, do not list RRS or MET calls as exclusions unless asked to review patient for ICU admission. Do not include consultations for general patient management that do not request ICU admission.

ICU Bed Capacity

	At 00:00 Hrs	At 08:00 Hrs	At 16:00 Hrs
Number of operational beds			
Number of non-operational beds			
If non-operational, please state why			
Number of available (empty) beds			
Number of patients exit blocked			

Triage decisions made by:

- ○ Single Clinician decision-maker only
- ○ Two or more Clinician decision-makers
- ○ Hospital appointed "Triage Committee"

Triage method being used today

- ○ No triage protocol used
- ○ Australian Government Department of Health ICU Triage Protocol (if/when written)
- ○ NSW Health ICU Triage Protocol
- ○ Protocol C (if developed)
- ○ Protocol D (if developed)
- ○ Protocol E (if developed)
- ○ Other Protocol - *Specify*

ICU Pandemic Surveillance Program
Patient Tracking Form

ICU Name: _____

Date: ___ / ___ / 2020

Section 1: EXCLUSIONS

List all Patients Excluded from the ICU Today (Between 00:00-23:59 Hrs)

					Under normal non-pandemic circumstances:		Reason for Exclusion:			Patient Excluded by:		Comments	Office Use Only: Died in hospital		
	First Name, Surname	MRN	DOB	Time decision made to exclude patient (24Hr time)	Patient would be admitted to ICU	Patient would not be admitted to ICU	No ICU beds	Too unwell or comorbid to benefit	Too well to benefit	Clinician's decision only	Clinician's decision after using triage protocol	*(Tick to write additional comments at bottom of next page)*	Yes	No	LOS Hosp
1					○	○	○	○	○	○	○	○	○	○	
2					○	○	○	○	○	○	○	○	○	○	
3					○	○	○	○	○	○	○	○	○	○	
4					○	○	○	○	○	○	○	○	○	○	
5					○	○	○	○	○	○	○	○	○	○	
6					○	○	○	○	○	○	○	○	○	○	
7					○	○	○	○	○	○	○	○	○	○	
8					○	○	○	○	○	○	○	○	○	○	
9					○	○	○	○	○	○	○	○	○	○	
10					○	○	○	○	○	○	○	○	○	○	
11					○	○	○	○	○	○	○	○	○	○	
12					○	○	○	○	○	○	○	○	○	○	
13					○	○	○	○	○	○	○	○	○	○	
14					○	○	○	○	○	○	○	○	○	○	
15					○	○	○	○	○	○	○	○	○	○	

ICU Pandemic Surveillance Program
Patient Tracking Form

ICU Name:	
Date:	/ / 2020

Section 1: EXCLUSIONS

List all Patients Excluded from the ICU Today (Between 00:00-23:59 Hrs)

Office Use Only

					Under normal non-pandemic circumstances:		Reason for Exclusion:			Patient Excluded by:		Comments	Died in hospital		
	First Name, Surname	MRN	DOB	Time decision made to exclude patient (24Hr time)	Patient would be admitted to ICU	Patient would not be admitted to ICU	No ICU beds	Too unwell or comorbid to benefit	Too well to benefit	Clinician/s decision only	Clinician/s decision after using triage protocol	*(Tick to write additional comments at bottom of page)*	Yes	No	LOS Hosp
16					○	○	○	○	○	○	○	○	○	○	
17					○	○	○	○	○	○	○	○	○	○	
18					○	○	○	○	○	○	○	○	○	○	
19					○	○	○	○	○	○	○	○	○	○	
20					○	○	○	○	○	○	○	○	○	○	
21					○	○	○	○	○	○	○	○	○	○	
22					○	○	○	○	○	○	○	○	○	○	
23					○	○	○	○	○	○	○	○	○	○	
24					○	○	○	○	○	○	○	○	○	○	
25					○	○	○	○	○	○	○	○	○	○	

Additional Comments	

ICU Pandemic Surveillance Program
Patient Tracking Form

ICU Name:	
Date:	/ / 2020

Section 2: DISCHARGES

List all Patients Discharged from the ICU Today (00:00-23:59 Hrs)

					Reason for Discharge:						(If not deceased) Discharged using:		Comments	Office Use Only: Died in hospital			
	First Name, Surname	MRN	DOB	Time decision made to discharge patient (24Hr time)	Improving and doesn't need ICU	Improving and needs ICU, but discharged early	Not improving or deteriorating and not for escalation	Palliated early	Palliated using usual clinical time-frame	Died	Clinician's decision only	Clinician's decision after using triage protocol	*(Tick to write additional comments at bottom of next page)*	Yes	No	LOS ICU	LOS Hosp
1					○	○	○	○	○	○	○	○	○	○	○		
2					○	○	○	○	○	○	○	○	○	○	○		
3					○	○	○	○	○	○	○	○	○	○	○		
4					○	○	○	○	○	○	○	○	○	○	○		
5					○	○	○	○	○	○	○	○	○	○	○		
6					○	○	○	○	○	○	○	○	○	○	○		
7					○	○	○	○	○	○	○	○	○	○	○		
8					○	○	○	○	○	○	○	○	○	○	○		
9					○	○	○	○	○	○	○	○	○	○	○		
10					○	○	○	○	○	○	○	○	○	○	○		
11					○	○	○	○	○	○	○	○	○	○	○		
12					○	○	○	○	○	○	○	○	○	○	○		
13					○	○	○	○	○	○	○	○	○	○	○		
14					○	○	○	○	○	○	○	○	○	○	○		
15					○	○	○	○	○	○	○	○	○	○	○		

ICU Pandemic Surveillance Program
Patient Tracking Form

ICU Name:	
Date:	/ / 2020

Section 2: DISCHARGES

List all Patients Discharged from the ICU Today (00:00-23:59 Hrs)

					Reason for Discharge:						(If not deceased) Discharged using:		Comments	Office Use Only			
	First Name, Surname	MRN	DOB	Time decision made to discharge patient (24Hr time)	Improving and doesn't need ICU	Improving and needs ICU, but discharged early	Not improving or deteriorating and not for escalation	Palliated early	Palliated using usual clinical time-frame	Died	Clinician/s decision only	Clinician/s decision after using triage protocol	*(Tick to write additional comments at bottom of page)*	Died in hospital: Yes	Died in hospital: No	LOS ICU	LOS Hosp
16					○	○	○	○	○	○	○	○	○	○	○		
17					○	○	○	○	○	○	○	○	○	○	○		
18					○	○	○	○	○	○	○	○	○	○	○		
19					○	○	○	○	○	○	○	○	○	○	○		
20					○	○	○	○	○	○	○	○	○	○	○		
21					○	○	○	○	○	○	○	○	○	○	○		
22					○	○	○	○	○	○	○	○	○	○	○		
23					○	○	○	○	○	○	○	○	○	○	○		
24					○	○	○	○	○	○	○	○	○	○	○		
25					○	○	○	○	○	○	○	○	○	○	○		

Additional Comments	

ICU Pandemic Surveillance Program
Patient Tracking Form

ICU Name:	
Date:	/ / 2020

Section 3: ADMISSIONS

List all Patients Admitted to the ICU Today (00:00-23:59 Hrs)

	First Name, Surname	MRN	DOB	Time decision made to admit patient (24Hr time)	Comments *(write additional comments here or at bottom of next page)*	Office Use Only: Died in ICU Yes	Died in ICU No	Died in hospital Yes	Died in hospital No	LOS ICU	LOS Hosp
1						○	○	○	○		
2						○	○	○	○		
3						○	○	○	○		
4						○	○	○	○		
5						○	○	○	○		
6						○	○	○	○		
7						○	○	○	○		
8						○	○	○	○		
9						○	○	○	○		
10						○	○	○	○		
11						○	○	○	○		
12						○	○	○	○		
13						○	○	○	○		
14						○	○	○	○		
15						○	○	○	○		

ICU Pandemic Surveillance Program
Patient Tracking Form

ICU Name:	
Date:	/ / 2020

Section 3: ADMISSIONS

List all Patients Admitted to the ICU Today (00:00-23:59 Hrs)

	First Name, Surname	MRN	DOB	Time decision made to admit patient (24Hr time)	Comments *(write additional comments here or at bottom of page)*	Office Use Only: Died in ICU Yes	Died in ICU No	Died in hospital Yes	Died in hospital No	LOS ICU	LOS Hosp
16						○	○	○	○		
17						○	○	○	○		
18						○	○	○	○		
19						○	○	○	○		
20						○	○	○	○		
21						○	○	○	○		
22						○	○	○	○		
23						○	○	○	○		
24						○	○	○	○		
25						○	○	○	○		

Additional Comments