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Implementation of evidence in nephrology using clinical practice guidelines

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



School of Public Health
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Declaration

This thesis is submitted to the University of Sydney in fulfilment of the requirement is for the Doctor of Philosophy. The work presented in this thesis is, to the best of my knowledge and belief, original. I hereby declare that I have not submitted this material, either in full or in part, for a degree at this or any other institution.

Signature:..... Date:.....

Author's Contribution

The work presented in this thesis has been carried out by the author under the supervision of Professor Jonathan Craig, School of Public Health, University of Sydney and Professor Michael Frommer, Sydney Health projects group, School of Public, University of Sydney.

The author planned the research, designed the studies, obtained ethics approval, collected, managed and analysed the data, interpreted results, drafted and revised the manuscripts for submission to peer-reviewed journals, and wrote and compiled this thesis.

Ethical Clearance

The study presented in Chapters 3, 4 and 6 was approved by The Children's Hospital at Westmead Ethics Committee.

All study participants gave written informed consent for participation in the study.

ABSTRACT

Chronic kidney disease (CKD) is becoming increasingly common in today's society. It is estimated that 16% of the Australian population have some form of CKD. In 2007 over 16 000 were undergoing treatment for end stage chronic kidney disease (ESKD) this includes over 2000 new patients. Over 1600 died whilst undergoing treatment for ESKD in 2007.

There has been a proliferation of evidence-based clinical practice guidelines for the treatment of chronic kidney disease patients, both locally and internationally. The Caring for Australasians with Renal Impairment (CARI) guidelines are guidelines produced for Australian and New Zealand practitioners. The CARI Guidelines have been written by doctors, nurses, allied health professionals and consumers on a voluntary basis. They are published on-line and in the journal *Nephrology* as biennial supplements. The use of these guidelines in practice is aimed at reducing mortality and morbidity for chronic kidney disease patients.

Evidence shows that the attainment of evidence-based guideline recommendations is variable between practitioners, renal units, states and countries, often with a gap between guideline recommendations and practice. Research into the use of guidelines in practice is a new and emerging field of research. Current research into the strategies to bridge this gap has been

unable to suggest one effective method to increase the rate of guideline implementation into practice.

The research projects that form the basis of this thesis aimed to explore current implementation strategies used in chronic kidney disease and research best methods of implementation for evidence-based CKD guidelines within a framework of exploring barriers and enablers to this process.

In chapter 2 of this thesis, to understand what is already known about the implementation of evidence-based guidelines in CKD, a systematic review of all published studies on implementation of evidence-based guidelines was undertaken. Twenty two studies including seven randomized controlled trials and 15 before-after studies were included. Four main interventions were evaluated in over 700 dialysis centres/hospitals or general practices: audit and feedback, computerized decision support system (CDSS), opinion leader/multidisciplinary team and passive dissemination of guidelines. Audit and feedback significantly increased 14 of the 25 study outcomes with a median improvement of 2.5% (range: -4.5-48.4%). CDSS significantly increased three of the four study outcomes with a median improvement of 12.8% (range: 1.1-42.1%). Opinion leader/multidisciplinary team significantly increased 24 of the 30 study outcomes with a median improvement of 8.2%(range: -4.0-79.8%). Dissemination of guidelines resulted in a median improvement in study outcomes of 2.7% (range 0.5-25.8). Well planned and executed interventions were able to improve CKD management to varying

degrees. The achievement of quality indicators was associated with improved patient outcomes.

In Chapters 3 and 4, to gain a detailed understanding of the opinions of the end users of the CARI guidelines a survey was undertaken of all nephrologists and renal nurses in Australia and New Zealand.

Chapter 3 outlines the results of the 211 nephrologists (70% of practising nephrologists) who responded. Over 90% agreed that the CARI guidelines were a useful summary of evidence, nearly 60% reported that the guidelines had significantly influenced their practice and 38% reported that the guidelines had improved health outcomes for patients. Only 8% indicated that the guidelines did not match the best available evidence. Older age and being male showed some association with a less favourable response for some domains.

Chapter 4 discusses the results from the 173 renal nurses who responded. They were more positive in their responses, than nephrologists, in the range of 10-20% in many question domains. and improvements in positive responses regarding the guidelines in the range of 10-30% were seen in many domains between 2002 and 2006.

Chapter 5 builds on the information obtained in the survey of nephrologists to further understand the role that guidelines have in clinical practice and clinical decision making. Face to face interviews with Australian nephrologists were undertaken. The results were analysed qualitatively and four major themes emerged. 1) There was a high degree of trust in the CARI process and output;

2) Guidelines had a range of functions in clinical practice, they provided a good summary of evidence, were a foundation to practice, an educational resource, could justify funding requests to policy makers, and promote patient adherence; 3) There was also non-guideline influences on clinical decision making, such as quality of life or patient needs, opinion leaders, previous experience, the clinical setting, the regulation and subsidy framework for drugs and devices, logistics, and other sources of evidence; 4) Nephrologists suggested facilitators of guideline implementation such as audit and feedback and reminders. The process by which nephrologists engaged with and used the guidelines was noted and compared to Rogers' diffusion of innovation theory. Some additional steps were added to this theory to make it applicable to the implementation of guidelines in CKD. Improvements in the evidence which underpins guidelines and improvements in the content and formatting of guidelines are likely to make them more influential on decision making.

In chapter 6, to test strategies for implementation in CKD, we established an implementation project in six renal units in Australia. This centered on the implementation of the CARI iron guideline utilising audit and feedback, the use of an opinion leader and a purpose-designed computerised decision support system. Wide variation of iron indices was observed across the centres in the study. In the active implementation units, we saw improvements in iron indices, especially in units that at baseline had iron scores well below the CARI guideline recommendations. We found that with a senior motivated opinion leader, the targeting of barriers and the use of a decision support

system, implementation of a guideline can indeed be successful. Support from an external body such as CARI may be of assistance.

The overarching purpose of these studies was to gain a better understanding of the place of guidelines in CKD practice and how we can ensure that evidence-based guidelines are used in practice and by doing so improve clinical outcomes for CKD patients. The findings show that guidelines hold a prominent place in clinical nephrology practice with both nephrologists and renal nurses, but there are many other competing influences on clinical decisions. Implementation of guidelines is possible and guideline groups should pursue this actively, utilising evidence-based implementation strategies. Strategies vary in their effectiveness and appropriate strategies should be used in differing situations. Renal nurses are an important resource in the implementation process. They should be involved in the guideline development process and their requirements for dissemination should be taken into account. Guidelines should be written using best methods that encourage implementation, such as the use of action statements, the provision of targets, be based on high levels of evidence, kept up to date and assistance given to encourage implementation into practice. Guideline groups should also foster close links with trials groups to facilitate a generation of evidence in required clinical areas. Finally, implementation requires hard work, by dedicated individuals at all levels, including the guideline producers and writers and those at the clinical level. A high level of detail regarding the implementation process is required, such as a thorough evaluation of barriers and strategies to overcome these. There is a need for guideline producers to

understand their differing target audiences and tailor the guidelines depending on the needs, usage and processes of these target groups.

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Publications arising from this thesis

Irving MJ, Johnson D, McDonald S, Walker R, Frommer F, Craig J.

Results of a national survey of nephrologists: Opinions on the content and effects of chronic kidney disease guidelines in Australia and New Zealand.

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Irving M, Gallagher M, Frommer M, Polkinghorne K, McDonald S, Roger S, Kairaitis L, Walker R, Craig JC. Effectiveness of multifaceted intervention strategy for the Australasians with renal Impairment (CARI) guidelines.

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Irving M, Johnson D, McDonald S, Walker R, Frommer M, Craig JC.

Evaluation of the CARI guidelines - by guideline users. *Nephrology* 2007;

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Presentations

Irving MJ, Tong A, Rychetnik L, Walker RG, Frommer MS, Craig JC.

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Irving MJ, Gallagher M, Frommer M, Polkinghorne K, McDonald S, Roger S, Kairaitis L, Walker R and Craig JC. Externally lead implementation of clinical practice guidelines: Overcoming barriers to implementation of iron management guidelines in chronic kidney disease patients. Guidelines International Network Conference. Toronto Canada, 21-25 August 2007.

Irving MJ, Gallagher M, Frommer M, Polkinghorne K, McDonald S, Roger S, Kairaitis L, Walker R and Craig JC. Evaluation of the effectiveness of an intervention strategy for the implementation of the CARI iron guideline. Australian and New Zealand Society of Nephrology annual symposium. Gold Coast, Australia, 9-12 September, 2007.

Irving MJ, Johnson D, McDonald S, Walker R, Frommer F, Craig J. Evaluation of the CARI guidelines - by Australian/New Zealand Nephrologists: A survey. Australian and New Zealand Society of Nephrology annual symposium. Gold Coast , 9-12 September, Australia 2007.

1.0 Introduction

1.1 Background

Chronic kidney disease (CKD) is an incurable condition that progresses at varying rates to end-stage kidney disease (ESKD). In ESKD the patient has little or no kidney function and requires regular dialysis or, where possible, kidney transplantation. [1] Before ESKD develops, the patient often has few or no symptoms and progression can go unrecognised in 80-90% of cases. [2] The diagnostic criterion for CKD is considered to be a glomerular filtration rate of less than 60ml/min/1.73m² of body surface area for three months or more. Patients with CKD have a 10-20 fold increased risk of cardiovascular disease [2] and it is estimated that 16% of the Australian population has at least one predictor of CKD. [3] In 2007, a total of 16,751 Australians had ESKD, including 2,311 newly-diagnosed patients commencing dialysis or receiving a transplant. A total of 1,603 Australians died in 2007 whilst undergoing treatment for ESKD.[4]

For the purposes of this thesis, CKD refers to the full spectrum of chronic kidney disease including ESKD, CKD, dialysis and transplantation.

Evidence-based guidelines that set out the best treatment options for patients have been or are being formulated in many areas of medicine, including CKD. CKD is a complex condition, with many manifestations matched by complex treatments and treatment options. This complexity creates a need for

guidelines. Clinical practice guidelines for CKD have been published internationally and in Australia and New Zealand. The local guidelines, the Caring for Australasians with Renal Impairment (CARI) guidelines,[5] have been written with input from doctors, nurses, allied health professionals and consumers and they can be found both on-line and in the journal *Nephrology*.

Despite the existence of guidelines, a gap between evidence and practice persists. [6-9] For example, a baseline study of six Australian renal dialysis centres showed considerable variability in attainment of recommended iron and haemoglobin target ranges. Across the six centres, between 30% and 68% of patients had serum ferritin levels within the target range of 300-800 µg/L; 65-73% of patients had serum transferrin saturation levels within the target range of 20-50%; and only 25-32% of patients had haemoglobin levels within the target range of 110-120g/L. [8]

Several explanations have been advanced for the gap between evidence and clinical practice, and a field of research into the best methods for implementing evidence in practice has emerged. Current approaches to implementation include distribution of educational materials, educational meetings, local consensus processes, educational outreach visits, the use of local opinion leaders, patient-mediated interventions, audit and feedback, reminders, the use of marketing methods and the use of mass media.[10] The effectiveness of clinical practice guidelines appears to depend on active implementation using one or a combination of these approaches, not just passive dissemination.

From a systematic review of 235 studies of the effectiveness and efficiency of guideline dissemination and implementation conducted in 2004, the authors concluded that the methods used produced only modest to moderate improvements in patient care.[10] Many factors affect the process of implementation of guidelines into clinical practice, and implementation is notoriously difficult. Currently no single formula or process exists to ensure that guidelines are used in practice.[11]

It is theorised that changes in clinical behaviour, such as the adoption of guidelines, depends on individuals having all the required knowledge and a favourable attitude.[12] Many barriers exist between the formulation of a new clinical practice recommendation and behaviour change. These include a lack of familiarity with the relevant guideline, disagreement with the recommendation, lack of motivation to change, and external factors such as patient preferences. [13, 14] The Australian National Institute of Clinical Studies (NICS) has classified the barriers into several levels: the guideline itself, the patient, the social context, the organisational context, the economic context and the political context. [15] An important step in the implementation process is to understand the barriers that apply across all guidelines, to particular guidelines, and to individual practitioners.

1.2 Aims of this thesis

The primary aims of the research described in this thesis are:

1. To summarise and critically appraise current research data on interventions to implement evidence in the management of CKD patients.
2. To ascertain and analyse the views of nephrologists and renal nurses on the content, structure and effectiveness of evidence-based Australasian CKD guidelines.
3. To determine the extent to which research evidence is used in practice in renal units in Australasia, and to identify the factors that influence the use of guidelines in clinical practice.
4. To determine and explore the barriers to, and enabling factors for, the implementation of evidence-based CKD guidelines in Australasian renal units.
5. To evaluate the effectiveness of selected implementation methods in renal units in Australasia.

1.3 Overview of the thesis

This thesis presents five papers that examine different aspects of the implementation of guidelines for the management of CKD patients. The research explores reasons why gaps between evidence and practice persist even in areas covered by established guidelines, and what can be done to close this gap. The papers summarise and evaluate implementation research in relation to CKD, study attitudes to CKD guidelines with the intent of understanding the role of guidelines in practice, and identify the barriers to their use. The papers also describe a trial of implementation of guidelines in the management of iron status in CKD patients.

The thesis comprises seven chapters including this chapter. Chapter 2 presents a systematic review of all published implementation strategies used in relation to CKD guidelines, and their resulting improvements in patient care. The studies included in the systematic review were also evaluated with respect to indicators of quality for implementation strategies.

Chapter 3 and 4 present reports of surveys of nephrologists and renal nurses. The surveys collected data on the attitudes and views of the nephrology professional community regarding guidelines, especially the CARI guidelines, with question domains on guideline content, effect and structure of the guidelines.

Chapter 5 discusses a qualitative study that involved face-to-face semi-structured interviews of 19 Australian nephrologists. Its aim was to find out how guidelines in general, and the CARI guidelines in particular, influenced clinical practice and clinical decision-making, in the context of other factors that influence clinical decisions. Chapter 5 includes suggestions from the nephrologists as to the factors that could increase or decrease the use of guidelines in practice.

Chapter 6 outlines an implementation strategy that was trialled in three Australian renal dialysis centres. Three other dialysis centres, which were monitored without other interventions, served as controls. All six centres were followed from August 2005 to October 2007. Strategies utilised were those that targeted known barriers to implementation, such as audit and feedback, the use of opinion leaders and the provision of a computerised decision support system.

Chapter 7 concludes the thesis and provides a summary of the main findings and recommendations for the implementation of the CARI guidelines and recommendations for future research.

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2.0 Interventions to improve the quality of care for patients with chronic kidney disease: a systematic review

2.1 Abstract

Background: Audits of the care of patients with chronic kidney disease (CKD) consistently show a gap between research and clinical practice. Our aim was to evaluate the effectiveness of interventions used to implement evidence-based medicine into renal clinical practice.

Methods A comprehensive search of Medline and Embase from January 1966 to June 2007 was conducted for studies that described interventions to implement guidelines and evidence-based medicine into clinical practice, in renal medicine. Researchers independently reviewed titles and abstract and extracted data from the identified studies. All studies which described the effects of an intervention to improve clinical practice, gave results in quantitative terms and described the intervention sufficiently to be replicated, were included.

Results: 22 studies including seven randomized controlled trials and 15 before-after studies were included. Four main interventions were evaluated in over 700 dialysis centres/hospitals or general practices: audit and feedback, computerized decision support system (CDSS), opinion leader/multidisciplinary team and passive dissemination of guidelines. Audit

and feedback significantly increased 14 of the 25 study outcomes with a median improvement of 2.5% (range: -4.5-48.4%). CDSS significantly increased three of the four study outcomes with a median improvement of 12.8% (range: 1.1-42.1%). Opinion leader/multidisciplinary team significantly increased 24 of the 30 study outcomes with a median improvement of 8.2 % (range: -4.0-79.8%). Dissemination of guidelines resulted in a median improvement in study outcomes of 2.7% (range 0.5-25.8).

Limitations: Meta-analysis was not possible due to the heterogeneity of the studies.

Conclusion: Well planned and executed interventions were able to improve CKD management to varying degrees. More active and multifaceted interventions are more effective than passive dissemination and single strategy methods. Interventions need to address all barriers to implementation and provide adequate workforce assistance. Specific quality indicator targets are associated with greater improvements in care.

2.2 Background

A major international investment in the retrieval and distillation of evidence has led to the proliferation of clinical practice guidelines (CPGs) and other practice recommendations over the last decade.[1-7] However, much less has been invested in the development of methods for the implementation of these guidelines and practice recommendations into routine clinical care, and relatively little consideration has been given to evaluating the effect of guidelines and practice recommendations on knowledge, processes of care or patient outcomes.

Nephrology is one field in which the uptake of evidence into clinical practice has been demonstrably slow. A European study from 2003 showed that only two-thirds of chronic kidney disease (CKD) patients achieved guideline-recommended haemoglobin levels[8], and in an Australian dialysis population, only between one-third and two-thirds of patients achieved serum ferritin targets [9]. Another study published in 2006 showed that less than one-third of CKD patients were dialyzed through an arteriovenous fistula, considerably less than target given in evidence-based guidelines.[10]

Effective strategies to bridge the gap between research and practice remain elusive. This systematic review aims to summarize the strategies that have been used to promote the implementation of research in the management of patients with CKD and to evaluate the influence of these strategies on clinical practice.

2.3 Methods

Inclusion criteria

Studies were included in the systematic review if they were confined to patients with renal or related conditions, described strategies for the implementation of CPGs and other practice recommendations in sufficient detail to be replicated, included a comparative analysis (e.g. a control group or a before-after comparison) in the evaluation of each strategy, and included measures that encompassed clinicians' attitudes towards evidence uptake, extent of adherence to guideline recommendations and patient outcomes.

Identification and selection of studies for inclusion

Electronic searches of Medline (January 1966-June 2007) and Embase (January 1988-June 2007) were conducted using a comprehensive search strategy combining implementation terms and terms associated with CKD, as listed in Appendix A1. Titles and abstracts of articles identified in the searches that appeared to fulfill eligibility criteria were selected for full text review. Uncertainties about the inclusion of individual articles were resolved by one of us (JC). A manual search of the reference lists of the final selection of articles was conducted to check that all studies meeting the inclusion criteria had been selected.

Data extraction and critical appraisal

Two independent reviewers assessed each article and extracted data on the study population, the implementation methods used and the results. In the

appraisal of each article, the quality of the research was assessed against established criteria according to the Cochrane Effective Practice and Organisation of Care (EPOC) Review Group checklist.[11]

Analysis

Where possible, the results reported in each article were expressed in proportional terms as a change in practice (from baseline to post intervention). Where there were multiple outcomes reported in each study, all appropriate outcome results were included in the assessment of each intervention. Two measures of change in practice were evaluated. We calculated a median change in effect across all health outcomes for all studies with the same intervention, based upon the method outlined by Grimshaw. [12] We also calculated the proportion of reported outcomes that were statistically significant for each intervention. Where confidence intervals and statistical significance were not reported, they were calculated where possible using the chi-square test statistic for differences in proportions with one degree of freedom. Although comparisons of medians gives equal weights to the degree of change for all outcomes, we considered it to be informative to combine outcomes in this way as it enabled the relative effects across different groups of interventions and expressed the results using a measure that is readily understood. Because the details of almost all interventions evaluated were specific to each study and not common to more than one study we were unable to calculate summary estimate of effects using meta-analytic methods.

2.4 Results

Search strategy

The search and associated checks yielded 4,583 articles. Of these, 225 were potentially relevant after screening titles and abstracts. Articles were then excluded for one or more of the following reasons: did not relate to CKD (23), did not deal with implementation of research (55), reported only audit results(39), reported only on barriers to implementation (21), only discussed a guideline (not its implementation) (56), only suggested an implementation plan (but did not evaluate it) (34), did not contain data on changes attributable to the research-based evidence (four), did not describe implementation method in sufficient detail (five), and did not report on any comparisons (eight). This left 22 articles that fulfilled all the selection criteria (Figure 2.1).

Study characteristics

Most of the selected articles referred to two or more types of intervention methods for promoting the uptake of evidence in practice, which we grouped into four main types of interventions: (i) audit and feedback; (ii) computerized decision-support systems (CDSS), (iii) opinion leader and/or multidisciplinary team approaches, and (iv) dissemination of guidelines. Studies evaluating multidisciplinary team approaches usually highlighted the role of an opinion leader in the team, so these two approaches were combined in our analysis. Table 2.1 summarizes the study design reported in each article, the aim of the intervention, the setting, the target group and year of publication. The selected articles were published during the period 1997-2007. The majority reported

on studies based in haemodialysis centres. Approximately two-thirds of the studies were conducted in the USA.

A definition of these four intervention methods and an example from an included study is given in table 2.2. More details on the included studies are given in appendix A2- A5.

Audit and feedback was the main intervention method in three randomized controlled trials (RCTs) and three before-after studies. Four of these six studies also incorporated another intervention such as education, summaries of evidence, changes to legislation and monitoring. The duration of the interventions ranged from 21 weeks to six years. CDSSs comprised the main intervention in three before-after studies evaluating programs to improve drug administration ranging from 4-14 months in length. Opinion leader and/or multidisciplinary team approaches were the interventions in four RCTs and seven before-after studies. Nine of these 11 studies also incorporated another intervention such as barrier analysis (2), provision of an algorithm or decision tree (2), protocol creation, education and new staff. The duration of the interventions ranged from three to 48 months. Dissemination of evidence or guidelines was the intervention in two before-after studies, both of which evaluated the release of different Kidney Disease Outcome Quality initiative (K-DOQI) guidelines in the USA. Duration of follow-up ranged from one to six years.

Quality of the selected studies (Appendix A.6 and A7)

Section 6.4 of the EPOC checklist[11] sets out criteria to be applied in assessing interventions for systematic reviews. Three responses are possible for each criterion: 'done', 'not done' and 'not clear'. According to the criteria, the majority of the selected studies had methodological limitations, as summarized in Appendices A6-A7. Of the 16 before-after studies, three were categorized as 'not clear' for reliable primary outcome measures, follow-up of professionals and follow-up of patients. [13-15] Of the seven RCTs, three were categorized as 'not clear' for concealment of allocation[16-18], two as 'not clear' or 'not done' for follow-up of patients[16, 19], one as 'not clear' for blinded assessment of primary outcome[20], three as 'not clear' for reliable primary outcome measures[16, 18, 20], and two as 'not clear' for protection against contamination[19, 21]. No studies reported consumer involvement.

The before-after studies were placed in two categories: (i) studies for which the response for any quality criterion was 'not clear' or 'not done', and (ii) studies for which the response for any quality criterion was 'done' or 'not applicable'. The studies that did not fulfill the quality criteria (category (i)) tended to show smaller and non- statistically significant effect sizes when compared to studies that did fulfill the quality criteria ($\chi^2=9.5$, 1df, $p=0.002$). The RCTs could not be evaluated in this way because none of them met all of the quality criteria.

Studies were assessed for unit of analysis error [12, 22], where patients are incorrectly used as the unit of analysis when assessing clinician behavior, four studies addressed this and provided additional data allowing for the clustering effect of clinicians, or unit of randomization. [16, 18, 19, 23]

Effects of interventions

Many diverse outcomes were assessed, and few studies addressed the same outcomes. Most outcomes were process of care outcomes rather than health outcomes. Quality of life was not reported as an outcome in any study.

Survival was reported as an outcome in one study only. Figure 2.2 summarizes the median and range of effects on clinical practice, for each intervention strategy and shows the number of outcomes that reached statistical significance. The median effect of all outcomes was just over 8.2% with a range of -7 to 79.8%. Table 2.3 summarises the outcomes reported in each study, with the studies grouped by main intervention strategy.

Audit and feedback

Of the six audit and feedback studies, three reported a single outcome, one reported two outcomes, one reported four outcomes and one reported ten outcomes. Of the three single-outcome studies, one was based on two different interventions – a nurse intervention and a pharmacist intervention. Audit and feedback were significantly associated with 9 of the 20 outcomes: (increased) number of patients with dialysis prescription review; (increased) proportion of patients undergoing dialysis with prescribed blood flow, change in Kt/V (a measure of dialysis adequacy) [19]; review of adequacy of dialysis documented in chart; mean urea reduction ratio (URR), and (increased) mean treatment time [20]; (increased) correct drug prescriptions [24]; (increased) haemoglobin levels, (decreased) blood pressure and (increased) dialysis dose [25]. Seven of the 20 outcome estimates were reported without

confidence intervals or significance levels and we were unable to calculate them from information given in the articles. Three of these outcomes, from two studies, were clearly of clinical significance[15, 20], while the remaining four remain were difficult to interpret without significance testing.[20] The median effect size for all outcomes associated with audit and feedback was 2.5 percent, and the range was -4.5% to 48.4%.

Computerized decision support systems

Of the three studies evaluating CDSSs, one reported two outcomes and two reported one outcome. CDSS was significantly associated with (enhanced) appropriate drug prescriptions [14, 26, 27]. The median effect size for the outcomes associated with CDSS was 12.8% with a range of 1.1% to 42%.

Opinion leaders and/or multidisciplinary teams

In the 11 studies, an opinion leader or group of opinion leaders was chosen, either from within an existing team or as an addition to a team, to implement a change in health care delivery. The outcomes were (improved) patient monitoring [18], the (increased) use of fistulas in haemodialysis[10, 28-31], (increased) referral rates for children with urinary tract infections [16]; (decreased) hospitalization rates [28]; (improved) pre-dialysis co-ordination [32] (reduced) recurrent bacteraemia, (reduced) septic death, antibiotic selection, dose and duration [17] bone disease and calcium metabolism[33], (reduced) vascular access complications[30] and (improved) and (greater) mean URR[23]. The interventions were significantly associated with 27 of the 42 outcomes. The median effect size for all the outcomes associated with opinion leader/multidisciplinary team was 8.2% with a range of -4% to 79.8%.

Dissemination of guidelines

Dissemination of guidelines as an intervention strategy was evaluated in two studies. Both studies indirectly evaluated the dissemination of K-DOQI guidelines by assessing health outcomes that could be expected to follow from treatment according to guideline recommendations. The outcomes were quality indicators relating to hematocrit, URR and fistula rates[13] and (decreased) mean calcium, serum phosphate, calcium and phosphate product and parathyroid hormone levels[34]. Two of the seven results were clearly of clinical significance. The median effect size for the outcomes associated with dissemination was 2.7% with a range of 0.5% to 25.8%.

2.5 Discussion

Carefully planned and implemented strategies can be effective in promoting the uptake of evidence-based guidelines or treatment recommendations in nephrology practice. Interventions that were active rather than simple dissemination and are multifaceted are more likely to be effective. Change in nephrology practice appears to be more likely if those wanting to bring change comprehensively evaluate and address all the possible barriers to the implementation process locally. Specific goal targets such as haemodialysis adequacy Kt/v targets rather than general goals are also more likely to be effective.

Audit and feedback as an implementation strategy was used in majority of cases when targeting practice change for individuals, for example adequacy of dialysis or biochemical targets. In contrast, the use of opinion leaders and/or multidisciplinary teams, as a strategy was most likely to be used where change was targeted at processes, protocols or service arrangements level of a clinical unit. According to some studies, either strategy was successful, although most studies evaluated the simultaneous effect of other strategies as well. These included education, barrier analysis, the introduction of protocols creation of new staff roles and personal visits from interventions staff. No one additional strategy could be identified as critical for a successful intervention. CDSSs were effective in improving the appropriate prescription of medications in renal patients. All three studies showed a significant association of CDSSs with adherence to the prescription of recommended medication regimens. In

both included studies of dissemination, improvements occurred in outcomes, but many confounding factors were likely to have influenced the results (e.g. local intervention strategies). Dissemination alone is an important first step in promoting the uptake of evidence in practice, but it relies on the ability and motivation of individuals to carry out local adaptation and introduce guideline recommendations, and is therefore variably effective at best and alone would often be ineffective.

Many factors could influence the magnitude of the effect that each implementation study achieved. In our review a lower quality score on the EPOC review group-data collection checklist for systematic reviews of interventions in health-care practice for before and after studies [11] tended to show smaller effects. This may have been due to the relatively large effects achieved with CDSSs, two of which were categorized as high quality. The factors contributing to smaller effect sizes in some studies may have included lack of an educational component within the intervention[33], lack of or insufficient staff to promote and assist with the intervention [20, 29, 33], use of didactic education methods only (which have been shown to be ineffective) [29], small numbers of subjects with lack of statistical power [21], lack of agreement on which the evidence that the intervention was based [21] , and longer follow-up period than other studies- giving more time for relapse back to baseline clinical practice to occur.[20] There is a potential for bias in the majority of the studies, with only four studies including an analysis of the clustering effect of clinicians or units on the measured patient outcomes. Implementation studies in renal medicine should include this analysis in the future. [22]

Our findings were consistent with the evaluation of guideline implementation in general medicine, although the overall median effect of outcomes was less for renal medicine (8.2%) compared to all implementation studies (10%). [35] Opinion leader and multi-professional collaboration demonstrated an effect for chronic conditions, CDSS is effective when implementing a change in drug prescriptions, audit and feedback has mixed results but is effective when targeting test ordering and prevention, reminders. Total quality management showed improvements when assessed for single sites, but no effect when included in an RCT.[36] A Cochrane review of audit and feedback in all areas of health reported a median of 16% increase in compliance for continuous data and a median of 5% increase for dichotomous outcomes which is higher than our overall result of 2.5%, which is possibly due to our inclusions of before and after studies. They conclude that the relative effectiveness of audit and feedback is greater when baseline adherence to recommended practice is low. We agree that audit and feedback can improve practice, but the results are variable.[37] Similarly a Cochrane review of the use of tailored interventions, including opinion leaders as an implementation strategy found a median increase in compliance of 10% which is slightly higher than our 8.2%. They concluded opinion leaders chosen by consensus are more likely to be successful.[38]

Further well-designed research studies on implementation in renal medicine are needed to determine what factors within an implementation strategy are responsible for having strong effects, and to determine how an understanding of the effectiveness of one type of intervention can be translated to others.

Our study shows that improvements in the quality of care delivered to patients with CKD and in line with evidence-based practice recommendations is a realistic aim. In this review the median effect size of all included studies was just over eight percent. Different interventions vary in their effectiveness and the types of situations in which they are effective. CDSS seems to be highly effective for changes in drug prescriptions. The use of opinion leaders and multidisciplinary teams and audit and feedback seem to be effective when the interventions are well planned and executed with adequate numbers of support staff for the intervention. Dissemination of guidelines is effective to some degree, as it increases knowledge and awareness, and is an important first step.

Guideline groups should actively implement their guidelines to continue to bridge the gap between evidence and practice. In preparation for an intervention guideline groups should use studies such as this to determine which intervention strategy would best suit their guideline and target group. An active approach using various strategies to overcome all known barriers is advantageous ensuring there is adequate workforce support for staff to facilitate the necessary changes to their practice and that published criteria for quality in implementation are considered and utilised.

Figure 2.1: Process of identification and selection of studies on implementation research for inclusion in systematic review.

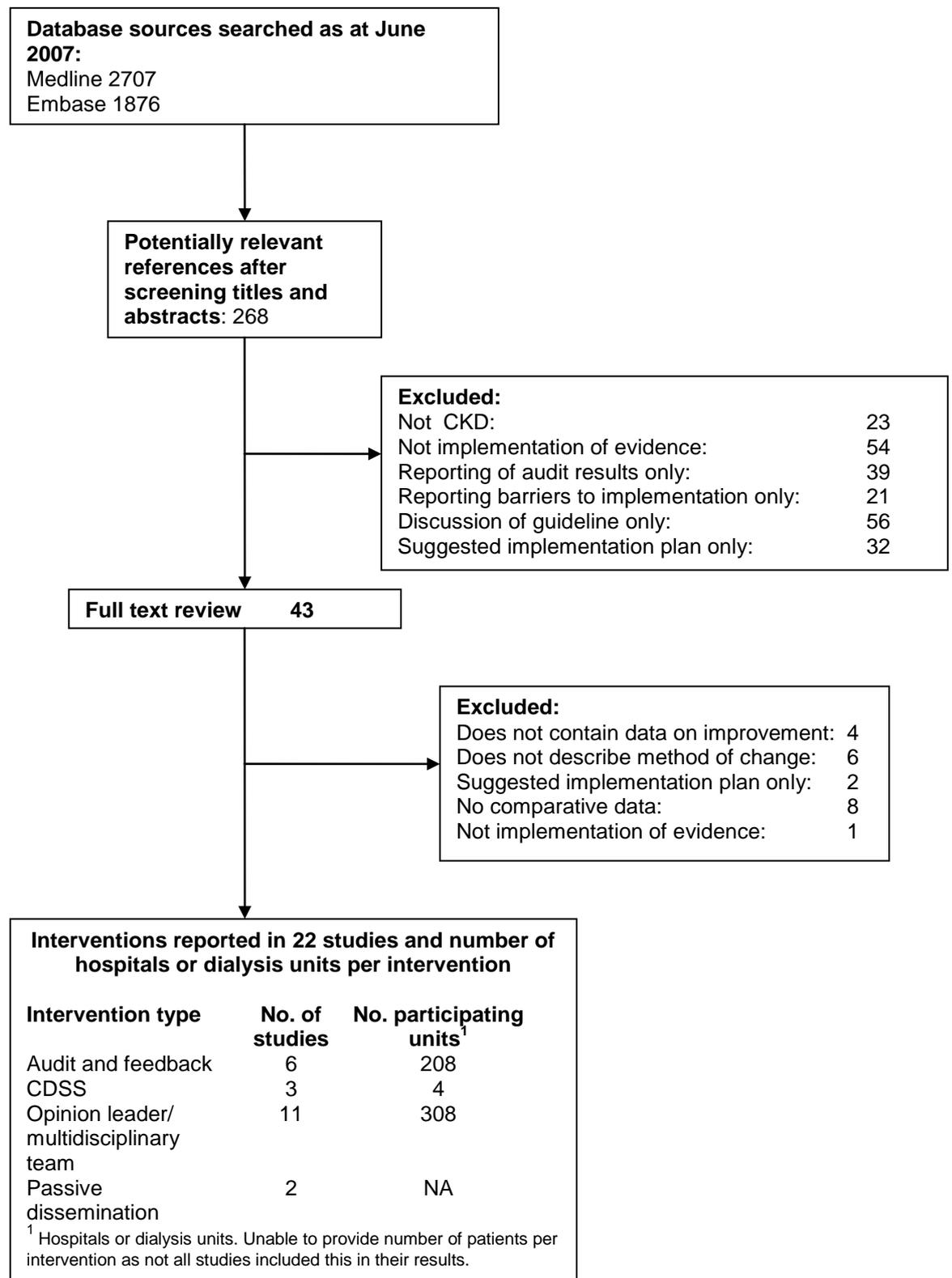


Table 2.1: Characteristics of included studies

Main strategy	Ref	Study design	Aim	Place/ Country	Setting	Target group		Year	
						n	n		
Audit and feedback	[21]	RCT	Increase proportion of patients on CAPD over haemodialysis	Missouri, USA	Dialysis centres	5	Nephrologists Patients	10 107	1998
	[19]	RCT	Increase haemodialysis dose	Northeast Ohio, USA	Dialysis centres	29	Nephrologists Patients	44 169	2002
	[15]	Before/ After	Improve hematocrit level, urea reduction ratio, serum albumin and blood pressure.	USA	Renal networks	18	Renal networks	18	2003
	[20]	RCT	Improve quality of care indicators: Dialyzed with prescribed blood flow, mean urea reduction ratio, documented review of prescription, time on dialysis	Atlanta, Georgia, USA	Dialysis centres	42	Nephrologists/ renal nurses Patients	NA 4280	2004
	[25]	Before/ after	Improve care in following areas: Dialysis dose, anemia hypertension, calcium/phosphate levels	Germany	Dialysis centres	111	Patients	7,000	2004
	[24]	Before/ after	Reduce excessive medication administration	New York, USA	Hospital	3	Clinicians	NA	2005
Computerised Decision Support System	[14]	Before/ After	Improve management of iron	Cleveland, USA	Dialysis centre	2	Nephrologists Patients	69 NA	1997
	[26]	Before/ After	Guided medication guide to reduce inappropriate drug orders	USA	Tertiary Care Hospital	1	Physicians Patients	NA 7490	1998
	[27]	Before/ After	Reduce contra-indicated medications	University of Illinois USA	Hospital and medical centre	1	Nephrologists Patients	NA NA	2005
Opinion Leader / Multi-disciplinary team	[18]	RCT	Improve monitoring, management and outcome of: anemia, bone disease and CMV management	Europe	Dialysis centres	6	Nephrologists Patients	NA NA	2000
	[28]	Before/ After	Increase arteriovenous fistula rates	Hackensack USA	University Medical centre	1	All staff Patients	NA 222	1999- 2001
	[32]	Before/ After	Quality indicators for new patients: eGFR at registration <10ml/min, pts not known to services prior to dialysis, patients attending education	Royal Melbourne Australia	Dialysis unit	1	All staff New HD pts	NA 595	2005
	[33]	Before /after	Increase the number of patients within K-DOQI targets for bone disease	Spain	Haemodialysis units	3	Patients	342	2006
	[17]	RCT	Reduce bacteremia episodes of tunnel cuff catheter	USA	Dialysis centres	7	Nephrologists	NA	2000
	[16]	RCT	Improve GP's diagnosis of UTI in infants.	UK	General Practice	1	GPs Patients	346 107 000	2003
	[30]	Before/after	Reduce vascular-access related complications	Netherlands	Dialysis centres	27	Patients	2300	2007
Passive dissemination	[31]	Before/ after	Increase use of arteriovenous fistulas	Denver, Colorado	Dialysis centres	8	New HD pts HD pts	81 1904	2002
	[23]	Before/ after	Improve dialysis adequacy	Georgia, USA	Dialysis units	196	patients	5753	2002
	[10]	Before/ after	Increase use of arteriovenous fistulas	5 USA states	Dialysis units	46	HD patients	2940	2007)
	[29]	Before/ after	Increase use of arteriovenous fistulas	Netherlands	Dialysis units	12	patients	1034	2007
	[13]	Before/ after	Quality indicators: hematocrits, erythropoietin dosing, haemodialysis adequacy, fistula and catheter utilization	USA	Dialysis units	All	All renal staff Patients	-	2000
	[34]	Before/ after	Increase the number of patients within K-DOQI targets for bone disease	25 states of the USA	Dialysis units	178	All renal staff	-	2007

NA: Not available, GP: General Practitioners, RCT: Randomized controlled trial, pt: patient

Table 2.2: Intervention types, definitions and examples from included studies

Intervention	Definition	Example from studies
Audit and feedback	A synthesis of data related to current practice is made available to clinicians. The synthesis is usually aimed at highlighting gaps between practice and evidence.	Clinical information reports: Results of audits against clinical performance measures. Networks required to translate audit findings into facility specific activities to improve patient care. Reports were sent by mail yearly for 6 years. Data was compared to pre-implementation data. Length of study: 60 months. [15]
Computerized decision support systems	A computerized system or program, usually within a computerized patient record or prescribing system that prompts decisions according to evidence.	Computer assisted erythropoietin algorithm Method: Blood test results automatically downloaded into database. The program recommends changes to epoetin doses per patient according to dosing rules. Primary nurse reviews recommendations and 'signs' off or changes recommendations. Physicians can opt in or out of the use of the algorithm for their patients and retain routine responsibility. Data was compared to pre-implementation data. Length of study: 4 months. [14]
Opinion leader/multidisciplinary team	The use of peer support to make changes in a clinical environment in which health-care professionals from different disciplines function as a coordinated team.	Implementation of program to improve the number of patients prepared for haemodialysis adequately, including timing of referral from Nephrologist to dialysis unit, timing of referral for vascular access, adequate pre-dialysis education Method: Creation of multidisciplinary teams lead by a trained team leader for each barrier above. Teams consisted of all levels of management and discipline, would met regularly to collect and analyze data, evaluation and formulate recommendations. Data compared to pre-implementation data Length of study: 39 months.[29]
Dissemination	The distribution of statements (e.g. guidelines or treatment recommendations) to users (e.g. clinicians), with or without additional activities to promote awareness and implementation of the statements.	The release of the K-DOQI guidelines on dialysis adequacy, anemia treatment and vascular access Study length: 1994-2000. [13]

Table 2.3: Results of interventions

Main strategy	Ref	Outcomes/Measure	Baseline		Post intervention		Difference#	p		
			Control	Intervention	Control	Intervention				
Audit and feedback	[21]	No. patients on CAPD	n(%)	1(2.4)	17(15.3)	2(4.9)	20(18)	0.2% RR 3.4 (0.7-15.5)	0.09	
	[19]	Change in Kt/V (baseline- mean Kt/V, SD)		1.18 (0.12)	1.16(0.15)	+0.10	+0.20	0.10	<0.001	
	[15]	Proportion of pts with a 3 month mean URR \geq 65%	(%)	43		82		39%	‡	
		Proportion of pts with mean delivered Kt/V \geq 1.2	(%)	74		86		12%		
	[20]	URR \geq 65	(%)	70.7	75.0	80.4	85.4	0.7	0.8	
		Dialyzed prescribed time	(%)	60.1	61.4	70.3	69.3	-1.1	‡	
		Dialyzed with prescribed dialyzer	(%)	99.5	97.0	98.6	99.3	3.2	‡	
		Dialyzed at prescribed blood flow	(%)	58.2	47.6	54.2	60.4	17	‡	
		Dialyzed at prescribed dialysate flow rate	(%)	94.3	87.6	92.7	89.7	3.9	‡	
		Review of adequacy documented in chart	(%)	44.4	36.0	25.4	66.9	48.4	0.01	
		Prescription change based on adequacy	(%)	31.8	29	22.2	20.4	0.2	‡	
		Mean URR		68.2	68.1	69.1	70.9	1.89	0.0002	
		Mean blood flow (cc/min)		384.4	398.7	401.8	413.7	-4.5	0.5	
		Mean treatment time (min)		215.1	211.4	213.3	218.8	9.4	0.03	
		[24]	No. of incorrect drug prescriptions							
			- Nurse intervention	n(95%CI)	23.2(21.1-25.3)		17.3 (16.1-18.6)		5.8(3.4-8.3)†	<0.001*
			- Pharmacist intervention	n(95%CI)	23.2(21.1-25.3)		16.8 (14.4-19.4)		6.4(3.9-8.8)†	<0.001*
		[25]	Dialysis dose (hour)		4.22		4.37		0.15hrs	<0.05
			Haemoglobin levels (g/dl)		10.6		11.5		0.9 g/dl	<0.05
			Blood pressure (systolic/diastolic mmHg)		142/77		138/74		4/3	<0.05
		PTH (pg/ml)		270		274		4	>0.05	
Computerised decision support system	[14]	Mean Hct (%)		30.4		31.5		1.1	<0.001	
		Epoetin use (U/kg/dose)		66		63		3	0.45	
	[26]	No. of inappropriate drug prescriptions (%)	n	6298(70)		2714(49)		21% RR 0.58 (0.55-0.60)	<0.001	
	[27]	% of pts receiving contra-indicated drug prescription	(%)	89		47		42	<0.001	
Opinion Leader/ multi-disciplinary team	[18]	Appropriate monitoring of patient care	(%)	50	68	45	79	6 (1-11%)	0.05	
		Appropriate management of patient care	(%)	86	57	92	87	-4 (-9-1)	>0.05	
		Improve outcome of patient care	(%)	42	55	47	55	-7(-14-1)	>0.05	
	[28]	Fistulae used at first HD	n(%)	3(4.7)		9(12.9)		8.2(95%CI:-1.2-17) †	0.09*	
		Fistulae used after 1 st HD but within 3 mnths	n(%)	9(4.7)		21(30)		16(95%CI:2.3-30) †	0.027*	
		Fistulae used 3mnths-1year	n(%)	1(1.6)		10(11.4)		9.8(95%CI:1.7-17.8) †	0.007*	
		No. of fistulae	n(%)	12(20.4)		42 (60)		39.6(95%CI:24.5-	<0.001	
	No. of PTFE grafts	n(%)	17(26.6)		5(7.1)		54.7)†	<0.001		
	Hospitalization rates	(%)	98		79		18.9(95%CI:6.5-31.3) †			
							19 OR 0.88(0.83-0.94)			

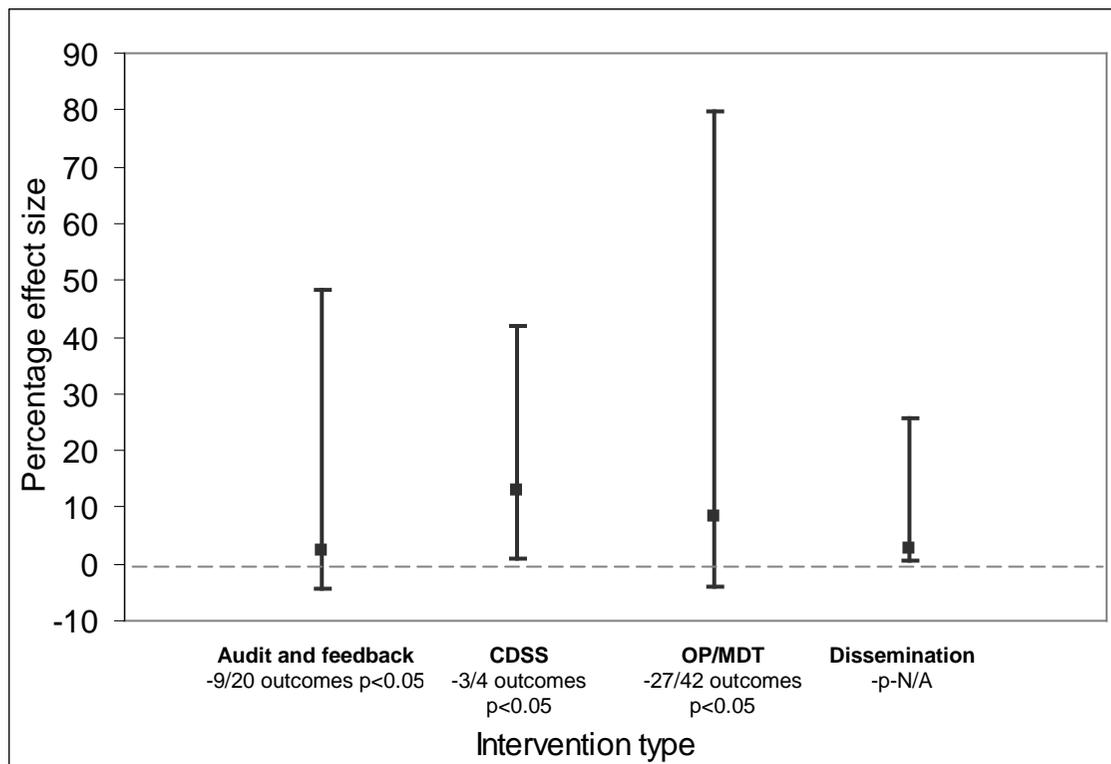
	[32]	Proportion of pts eGFR<10ml/min at notification	n(%)	32(29)		11(6)		23 OR 0.2 (0.1-0.4)	<0.0001
		No. of pts attending predialysis education	n(%)	56(50)		135(74)		24 OR 1.4 (1.0-2.2)	0.042
		No. of pts commencing dialysis with permanent access	n(%)	27(24)		151(83)		59 OR 3.5(2.2-5.6)	<0.0001
		Median time from registration to dialysis (months)		1		14		13	
	[17]	Episodes of recurrent bacteremia with same organism	n(%)	8 (15)		10(18)	7(6)	12(95%CI:1.3-22.8) †	0.015
		No. of septic death	n(%)	3(5)		3(6)	0(0)	6(95%CI:-0.3-12.3) †	<0.02
		Infectious complications	n(%)	10(18)		2(4)	5(4)	0(0)	NS
		Appropriate antibiotic selection	n(%)	51(89)			107(96)	7(95%CI:-1.9-15.9) †	<0.03
		No. of pts receiving correct antibiotic dose and duration	n(%)	36(63)			97(87)	34(95%CI:20-48) †	<0.001
	[16]	Refer00ral rates for UTI – all children (/1000/children/year)		3.45		6.42		3.08 OR 1.86(1.42-2.44)	<0.001
		Referral rates for UTI- < 1 year (/1000/children/year)		0.24		0.92		0.68 OR 3.84(1.94-9.32)	<0.001
		Referral rate for UTI in children with non-specific symptoms (/1000/children/year)		0.24		1.49		1.25 OR6.1(3.47-11.76)	<0.001
	[33]	Proportion of patients within K-DOQI guidelines							
		- Serum PTH –pg/ml	n(%)	71(25.6)		55(18.7)		6.9(0.1-13.7)	0.048*
		- Serum Calcium	n(%)	107(38.7)		136(16.6)		7.9(0.7-15)	<0.01
		- Serum phosphate	n(%)	157(56.9)		164(56.2)		0.7(-7.5-8.9)	NS
	[30]	No. of new Arteriovenous fistulas	(%)	69		77		8‡	<0.01
		No. of prevalent Arteriovenous fistulas	(%)	61		64		3‡	<0.01
		No. temporary subclavian vein catheters	(%)	34		11		23‡	<0.01
		Interventional treatment for vascular access (/pt/year)		0.39		0.50		0.11‡	<0.001
		No. of surgical revisions for malfunctioning access (/pt/year)		0.06		0.12		0.06‡	<0.001
		Continuing education for staff on vascular access no. units(%)		8(33)		21(88)		13(54)	‡
	[23]	Mean Urea Reduction Ratio		64.7± 1		69.8± 1		5.8%	0.001
	[31]	No. of new HD pts starting with AV fistula n(%) (95%CI)		5(11.6) (4.4-25.9)		9(23.7)(12.0-40.6)		12.1(95%CI:-4.6-28.6) †	0.45
		No. of pts with 1 st perm access an AV fistula n(%) (95%CI)		23(53.5) (37.8-68.5)		20(52.6)(36.1-86.7)		0.9(95%CI:-20.8-22.6) †	0.94
		No. of prevalent pts with AV fistula n(%) (95%CI)		176(29.1)(25.5-32.9)		733(38.5) (36.3-40.1)		9.4(95%CI:5.2-13.6) †	<0.001
		No. units with protocol for Vascular access (units)		3		4		1	‡
		Increase no. of units with vascular access co-ordinator (units)		1		6		5	‡
	[10]	No. of prevalent pts with AV fistula	n(%)	912(31.3)		1637(56.2)		79.8(77.8-81.7)	<0.001
	[29]	Use of arteriovenous fistula for Haemodialysis	n(%)	1026(65.5)	639(58.5)	1174(67.3)	721(62.7)	2.3% (-6.6-10.9)	>0.05
								Regression lines of AVF use at baseline on Change AVF use/year for intervention VS control significantly different	<0.05
Dissemination	[13]	Proportion of pts with 3 mnth average hematocrit ³ 36%	(%)	4.1		29.9		25.8%	‡
		Average URR	(%)	63.8		69.9		6.1%	‡
		Simple fistula rates (/1000pt years at risk)		Not given		71.1		13.4%	‡
	[34]	Mean calcium levels (mg/dl) mean±SD		9.38±0.65		9.33±0.65		0.05	‡
		Mean serum phosphate (mg/dl) mean±SD		5.49±1.3		5.36±1.29		0.13	‡
		Mean CA´ P product mean±SD		51.37±12.34		49.96±12.19		1.41	‡
		Mean PTH values mean±SD		263.28±244.84		260.02±219.42		3.26	‡

Chapter 2: Interventions to improve the quality of care for patients with chronic kidney disease:

A systematic review

Ref: Reference, NS: Not significant; #If study has a control and intervention arm differences are based on the difference between the change in the intervention arm minus the change in the control arm. *p value not given in study, determined by authors using a chi squared test statistic for differences in proportions with 1df. †-95% confidence intervals not given in study but determined by authors using estimation of confidence intervals for a chi square test statistic for differences in proportions. ‡ p value and/or confidence limits unable to be determined from information given in studies.

Figure 2.2
Median and range of intervention effects on practice by intervention type



*CDSS: Computerized decision support system, OP/MDT: Opinion leader/multidisciplinary team, N/A- results not available

2.6 References:

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3.0 Opinions on the content and effects of clinical practice guidelines for CKD: A survey of nephrologists in Australia and New Zealand

3.1 Abstract

Introduction: Evidence-based clinical practice guidelines have been a major development in nephrology internationally, but it is uncertain how the nephrology community regards these guidelines. This study aimed to determine the views of nephrologists on the content and effects of their local guidelines (Caring for Australasians with Renal Impairment: CARI).

Methods: In 2006, a self-administered survey was distributed to all Australian and New Zealand nephrologists. Seven questions were repeated from a similar survey in 2002.

Results: 211 nephrologists (70% of practising nephrologists) responded. Over 90% agreed that the CARI guidelines were a useful summary of evidence, nearly 60% reported that the guidelines had significantly influenced their practice. The proportion of nephrologists reporting that the guidelines had improved patient outcomes rose from 14% in 2002 to 38% in 2006. The proportion of nephrologists indicating that the guidelines did not match the

best available evidence decreased from 30% in 2002 to 8% in 2006. Older age and being male showed some associations with a less favourable response for some domains.

Conclusion: The CARI approach of rigorous evidence-based guidelines has been shown to be a successful model of guideline production. Almost all nephrologists regarded the CARI guidelines as useful evidence summaries, although only one-third believed that guidelines affected health outcomes. Attitudes to the guidelines have become more favourable over time; this may reflect changes in the CARI process or attitudinal changes to evidence among nephrologists. Evaluation, by the end user, is fundamental to ensuring applicability of guidelines in clinical practice in the future.

3.2 Background

In nephrology globally, the formulation of clinical practice guidelines aimed at improving outcomes for patients with chronic kidney disease has been a major initiative over the past 10 years, since the inception of the Dialysis Outcome Quality Initiative (DOQI) guidelines in 1997.[1] Other national and international guidelines groups have been formed subsequently, including the European Best Practice Guidelines,[2] the Canadian Society of Nephrology Guidelines[3], the United Kingdom CKD guidelines[4] and the "Caring for Australasians with Renal Impairment" (CARI) guidelines in Australia and New Zealand[5]. More recently, a global initiative, Kidney Disease: Improving Global Outcomes (KDIGO)[6] has evolved as a focus on a worldwide approach to developing and implementing evidence-based guidelines.

Although the investment in these guidelines has been substantial, their effect on practice is still unclear. Many studies have evaluated the consistency of clinical practice in nephrology with guideline recommendations, either as cross sectional studies or before-after studies,[7-12] with a wide variation in results. Fewer studies assess outcomes associated with adherence to guidelines, but none to our knowledge has evaluated the users' opinions on outcomes of guidelines. In this paper, we report on a detailed survey of nephrologists undertaken in 2006, aimed at determining the opinions of Australian and New Zealand nephrologists on the content and effects of the CARI guidelines. We sought to ascertain opinions of nephrologists on each major step in the knowledge transfer chain – change in knowledge, practice,

and health outcomes. – and to compare results with a previous study of the same target group in 2002. [13] We also aimed to determine whether attitudes varied with differences in demographic or practice characteristics of nephrologists.

3.3 Methods

CARI background

The CARI guidelines are the national guidelines for Australian and New Zealand nephrologists. They commenced in 1999 through a joint effort of the Australian and New Zealand Society of Nephrology (ANZSN) and Kidney Health Australia (KHA). Guidelines cover many areas of chronic kidney disease, dialysis and transplantation. The CARI Guidelines have always been strictly evidence-based. All guidelines are based on Level I or II evidence according to the National Health and Medical Research Council (NHMRC)[14] evidence classification system (systematic reviews or randomised controlled trials). Guidelines are reviewed every 3 years. Guidelines are written on a voluntary basis through an invited convenor and selected writers who are supported by the CARI editorial office and steering committee which consists of clinicians, nurses, allied health workers and consumers.[5] Guidelines are peer and public reviewed before publication in the Asia-Pacific Journal of Nephrology (Nephrology) twice yearly as supplements [15] and on the CARI website.[5]

Survey details

Members of the CARI Steering Committee developed a self-administered questionnaire in 2006. This was based on a survey undertaken in 2002 with the same target group, together with published standards for the formulation of surveys[16-19]. The questionnaire contained a total of 23 items (Appendix

B1) which were designed to elicit opinions of nephrologists on the following four domains.

1. The effect of the guidelines on knowledge, practice, patient outcomes and medico-legal issues, and their value in arguing for clinical resources.
2. The structure of the guidelines, primarily concerning the use of evidence and the formulation of the recommendations.
3. The content of the guidelines, primarily concerning existing and future coverage.
4. The preferred distribution methods and frequency of use of the guidelines.

The questionnaire also included items of internal relevance to CARI only (e.g. the organisation's name and logo which are not discussed here).

Closed response sets were provided for all questionnaire items. Seven questions were identical to a survey completed by 155 Australian and New Zealand nephrologists (response rate of 90%) in 2002, the results of which have been published previously. [13].

A pilot study was conducted with five trainee nephrologists who did not contribute data to the parent survey. Feedback from respondents was used to improve the readability and accuracy of the questionnaire. Survey responses were anonymous. The responses from 2002 and 2006 were compared as unpaired data, as the anonymity of respondents in both surveys did not enable us to compare individuals' responses over time.

Recruitment of respondents

Almost all nephrologists in Australia and New Zealand are members of the Australian and New Zealand Society of Nephrology (ANZSN), of which membership is voluntary. The membership includes retired nephrologists, nephrology trainees, some industry personnel and allied health personnel. The ANZSN supplied a full list of its 491 members as of the 15th June 2006. The questionnaire was e-mailed to all 491 members, but only practising nephrologists were invited to respond. The e-mail notification contained a survey in Microsoft Word® format and details of access to the survey on the CARI website (www.cari.org.au/survey). Respondents could answer the questions on paper or electronically. They were asked to indicate their professional role (either nephrologist in training, nephrologist, renal nurse, renal technician, renal nurse educator) to ensure that only practising nephrologists' were analysed. A pre-survey introductory e-mail, an initial survey e-mail and three e-mail reminders were sent.

Statistical methods and software

Nephrologists' demographic and practice characteristics were analysed using descriptive statistics. The chi-square test was used to examine the differences among responses from different demographic groups and changes between the 2002 and 2006 surveys. SPSS software, version 13 (SPSS Inc, Chicago III, USA) was used for this statistical analysis. Ordinal logistic regression was done to determine characteristics of respondents that were independent predictors of favourable attitudes to CARI for each question. Age was grouped into categories <40, 41-50, 51-60 and >60 years and place of practice was

classified as urban or rural. Responses were grouped as agree, neutral, and disagree, where 'strongly agree' and 'agree' were combined as 'agree' and 'strongly disagree' and 'disagree' were combined as 'disagree'. This analysis was completed using SAS statistical software version 9.1 (SAS Institute Inc., Cary, NC, USA)

Ethics approval

This study had ethics approval from the Human Research Ethics Committee of The Children's Hospital at Westmead, Australia.

3.4 Results

Recruitment of respondents

Of the 491 ANZSN members, 303 were identified as practising nephrologists, 149 were excluded because they were not practising clinically, were trainees, had retired or were industry employed, and the status of 39 could not be determined. Of the 303 practicing nephrologists identified, 211 (70%) responded to the survey (figure 1).

Characteristics of respondents

Demographic characteristics of respondents are outlined in Table 3.1. Three-quarters were male, aged less than 50 years, and worked in a University-affiliated Hospital. About one-half had less than 10 years of clinical practice.

Effect of the guidelines

More than 90% of respondents agreed that the CARI guidelines were a useful summary for practice (Figure 2). Sixty percent reported that the guidelines had influenced their practice, and just fewer than 40% reported that the guidelines had improved health outcomes for their patients.

Structure of the guidelines

Over 70% disagreed with the statement that the treatment recommendations in the CARI guidelines do not adequately match the evidence. More than 70% agreed that the guidelines should be based on best available evidence in areas where randomised controlled trials (RCTs) do not exist. As well as level

of evidence (study design), 60% of respondents considered that guideline recommendations should also consider the quality of other relevant studies, the consistency of the published evidence and the relevance of the outcomes reported in studies to patients.

Content of the guidelines

Nearly 90% of respondents considered that content of the guidelines were appropriate. Many expressed a desire for more guidelines on general nephrology (CKD stages 1-5), transplantation (CKD stages 1-4T) and dialysis (CKD stage 5D). Over half wanted more detailed evidence on harms and benefits for sub-groups as well as the general population.

Guideline usage

Over 36% of respondents referred to the web-based guidelines at least monthly, 46% less than monthly and 17% never; and 38% referred to the hard-copy version of the guidelines at least monthly, 42% less than monthly and 19% never.

Comparison of responses from the 2002 and 2006 surveys

The responses to the common questions in the 2002 and 2006 surveys are provided in table 3.2. Characteristics of respondents were similar in the two surveys. While the proportion of males was slightly higher in 2006 than 2002 (76% vs 74%), the proportion of guideline writers was lower (29% vs 39%) and the proportion aged <40 years increased (40% vs 30%), none of these differences was statistically significant. Similar proportions of respondents in

both surveys agreed that the CARI guidelines were a useful summary of the evidence for practice. Those who believed that the CARI guidelines had influenced their practice increased from just under 40% to 60% ($p < 0.001$). The proportion of respondents who considered that the guidelines had improved health outcomes for their patients increased from 14% to 40% ($p < 0.001$). The proportion who considered that the CARI guidelines did not match best available evidence dropped from 29% to 8% ($p < 0.001$).

Variability of responses in the 2006 survey

Overall there was little evidence of variability in responses based upon respondent demographics or practice characteristics. Questions which elicited significant differences in responses among respondents are shown in table 3.3. On univariate analysis, in general younger, female nephrologists, practising in an urban setting were more favourably disposed to the CARI guidelines, but although statistically significant the magnitude of differences in attitudes was small. Respondents who were not current or previous guideline writers were more likely to indicate that they would like to see more general nephrology ($p = 0.02$), transplantation ($p = 0.001$) and dialysis ($p = 0.002$) guidelines when compared to current or previous guideline writers, but their responses were not significantly different to non-writers for all other questions.

Only question 8 showed statistically significant responses for more than one variable. Using multivariate ordinal logistic regression modelling, after adjusting for other sources of variability, older ($\chi^2 = 4.98$, 1 *df*, $p = 0.03$, OR 1.4, (1.0-1.9) and male ($\chi^2 = 6.48$, 1 *df*, $p = 0.01$, OR 4.2, (95% confidence

interval 1.3-8.7) respondents were more likely to agree with the statement that “The treatment recommendations in the CARI guidelines do not adequately match the available evidence”.

3.5 Discussion

Our study has shown that the vast majority of Australian and New Zealand nephrologists find the CARI guidelines a useful source and summary of evidence; many indicated the guidelines had significantly influenced their practice and increasingly thought the guidelines had improved outcomes for patients. Compared to a survey in 2002, the 2006 survey showed a substantially more favourable attitude towards the CARI guidelines.

The path from dissemination to implementation (knowledge to outcomes) is complex, for any guidelines group. In this survey of the CARI guidelines we found an attenuation of positive responses, from knowledge (90%) to practice (60%) to outcomes (40%). This is not an uncommon phenomenon. Roger's diffusion of innovation[20] is one of many health behaviour theories that outline the steps from knowledge to practice. At each step, barriers impede individuals from moving to the next step. There are many barriers to the implementation of guidelines in any setting [21-24] including nephrology. Approaches, such as the National Institute of Clinical Studies (NICS) processes for identifying barriers to evidence uptake [25] can be useful in pinpointing barriers within each clinical setting and devising solutions within each health system. NICS suggest that barriers can exist at different levels, such as the health team, patient, organisation and the guideline (or innovation) itself, that require targeted strategies to overcome. Barriers that could apply in renal medicine could include: concordance of the guideline content with clinicians' existing beliefs, trust in the method of development of

the guideline, the nature of the clinical setting, local opinion leaders' views, lack of resource availability- both staff and physical, disincentives to change as well the source from which the guideline is disseminated, and the formatting and layout of the guideline. [22, 23, 26]

Seventy per cent of respondents believed that the CARI guidelines recommendations matched the best available evidence, suggesting a high level of trust in the guidelines and the writing process. Only a minority of respondents considered that the stringent evidence base for the CARI guidelines, which are based entirely on systematic reviews or RCTs (level I or II evidence only), was too restrictive, yet 70% would like recommendations to incorporate other evidence in addition to RCTs . The inclusion of evidence of other types in the formulation of the guidelines could improve their applicability in clinical settings. RCTs and cohort studies have complimentary roles. Trials demonstrate the effectiveness of an intervention in a well defined group. Cohort studies provide the data to identify which groups of patients are likely to receive more harm than good by the administration of the intervention and so provide essential applicability data. [27] Recognising that not all effective interventions have been trialled, the format of the CARI guidelines was changed to include “suggestions for clinical care” which are based on level III and IV evidence. These are, though, separated from the guidelines based on level I and II evidence to make them easily distinguishable for the reader.

The observation that nephrologists appeared to be more positive about the guidelines in 2006 than 2002 could have several explanations. Many changes occurred in the CARI guideline writing process between 2002 and 2006. These changes were broad and encompassed all areas of the writing process, such as changes in the governance structure, increased administration support for writers, and improved policy and conflict of interest disclaimers. Since 2002 more guidelines have been published on aspects of chronic kidney disease and transplantation. Some dialysis guidelines were reviewed and re-published before the 2006 survey was administered. The nephrologists' positive perceptions could also reflect a growing acceptance and appreciation of the value of guidelines across all clinical fields, as well as the increased evidence base available in renal medicine on which to base the guidelines. Because the demographic characteristics of the respondents were similar in 2002 and 2006, potential confounders such as age and sex are not likely to be contributory. Further research is required to determine what aspects of the guidelines and guideline process influence nephrologists to utilise the guidelines and what factors evoke trust in the guidelines.

Although attitudes to the guidelines varied among respondents, mostly this was unexplained on the basis of demographic or practice characteristics. For some questions, respondents who were older and male were less favourable towards the guidelines, but although statistically significant, the magnitude of the differences was small. Older age and being male showed some associations with a less favourable response for some domains. Older age of the respondents might imply longer years of practice, and broader nephrology

knowledge and experience leading to more reliance on judgement than external evidence. Current or previous guideline writers were less likely to want more guidelines than non-guideline writers, most likely because they were aware of the work required in guideline production. These results are consistent with other studies. A study by Arroll et al[26] of 378 General Practitioners (GPs) on their views and use of guidelines found older GPs and male GPs were less likely to be high users of guidelines. A study of intensive care nurses found that senior nurses were the most likely to disagree with guidelines. [28] Differences, between sexes, have been highlighted in many areas, such as career choice[29], interests and knowledge acquisition[30], and there is some limited evidence that female gender is associated with an increase in favourable responses in closed set survey responses[31]. Further research is needed on possible reasons for the effects of age and sex on attitude to guidelines and the barriers these may create.

As far as we are aware, this is the first study to assess nephrologists' views on their guidelines, but we found these results to be consistent with the findings of other studies that have examined clinicians' attitudes to guidelines, in general medicine. In a systematic review of 30 studies undertaken between 1990 and 2000 on clinicians' attitudes to clinical practice guidelines, Farquar et al [32] reported that clinicians saw guidelines as a helpful source of evidence, as having educational value, and as having the potential to improve quality. However, some clinicians also considered guidelines to be too rigid and likely to reduce physician autonomy, oversimplify medicine, increase litigation and facilitate cost-cutting by healthcare funders.

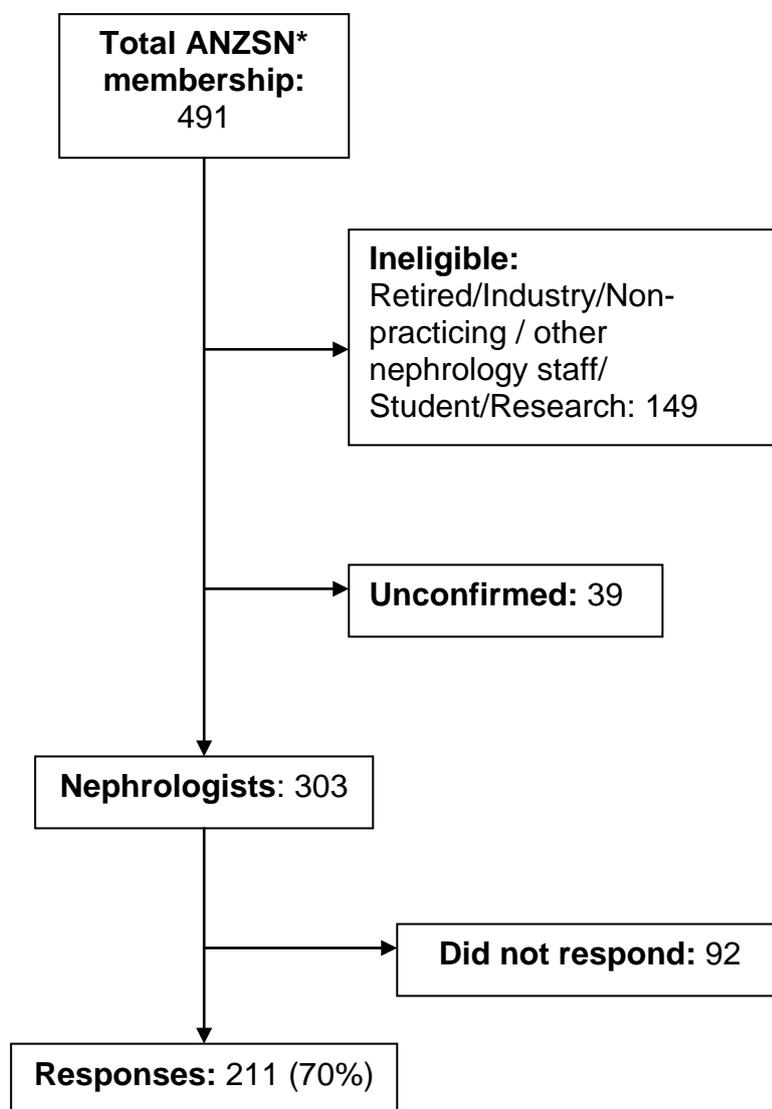
A comparison of some guideline process among the major guidelines in Kidney Disease is provided in table 3.4 [33]. This shows that the major renal guideline groups have evolved to similar processes regarding evidence assessment. Evaluation of adherence and implementation of guidelines has been measured by all guideline groups, although this is done mostly through observational studies and the measurement of process evaluation (guideline compliance) rather than measurement of outcomes (patient outcomes related to the guideline compliance). [8, 12, 24, 34, 35] Research on the attribution of changes in patient outcomes to guidelines is difficult, but the true value of guidelines can only be assessed in relation to improvements in patient's outcomes and/or the efficiency of health care. For some areas change in practice can easily be tracked using national registries: evaluation of change in other practice areas may require further studies. More detailed studies on the use of guidelines and the variations of practice are still required to assess the effect of clinical guidelines on practice. Future studies should include comparisons of opinions regarding the CARI guidelines compared with other renal guidelines.

A potential limitation of this study was a selection bias, with 30% of practising Australian and New Zealand nephrologists who did not respond to the survey. Although respondents typically differ from non-responders[36], no information was available on the demographic and other characteristics of non-responders to our survey. A 70% response rate is considered to be adequate for a survey of this nature, and rates are often poorer. A review of published

surveys of physicians found a mean response rate of only 54%. [6] A further limitation of the study was its reliance on nephrologists' self-reports of the effect of clinical guidelines on outcomes, rather than actual behaviour. It also evaluated nephrologists' general impressions of the guidelines rather than assessing attitudes to specific guidelines.

The CARI approach of rigorous evidence-based guidelines has been shown to be a successful model of guideline production, with respondents generally indicating that the guidelines and process have intellectual integrity. The CARI approach was generally more valued in 2006 than in 2002. The formulation of guidelines that have credibility with their target audience is a first step to the guidelines being used in practice; differences in responses by age, sex and other demographic variables should be monitored. There are several further steps to the ultimate goal of improving health outcomes for patients; however the next challenge for CARI lies in assessing implementation and outcomes of these guidelines in actual clinical practice. Evaluation, by the end user, is fundamental to ensuring applicability of guidelines in clinical practice in the future.

Figure 3.1: Flow chart of respondents



* Australian and New Zealand Society of Nephrology

Table 3.1: Demographic and practice characteristics of respondents (n=211)

Characteristic		%
Gender	Male	74
	Female	26
Age (years)	20-40	40
	41-50	33
	51-60	15
	>60	12
Duration of practice (years)	1-5	23
	6-10	23
	11-15	17
	16-20	13
	>20	24
Type of practice	Metropolitan	84
	Regional	16
Work description*	University affiliated	77
	hospital	18
	Local hospital	6
	Satellite unit	18
	Private practice	
Guideline writer	Previous/current	29

*Respondents could choose more than one.

Figure 3.2: Nephrologists opinions on the content, structure and effects of CARI guidelines

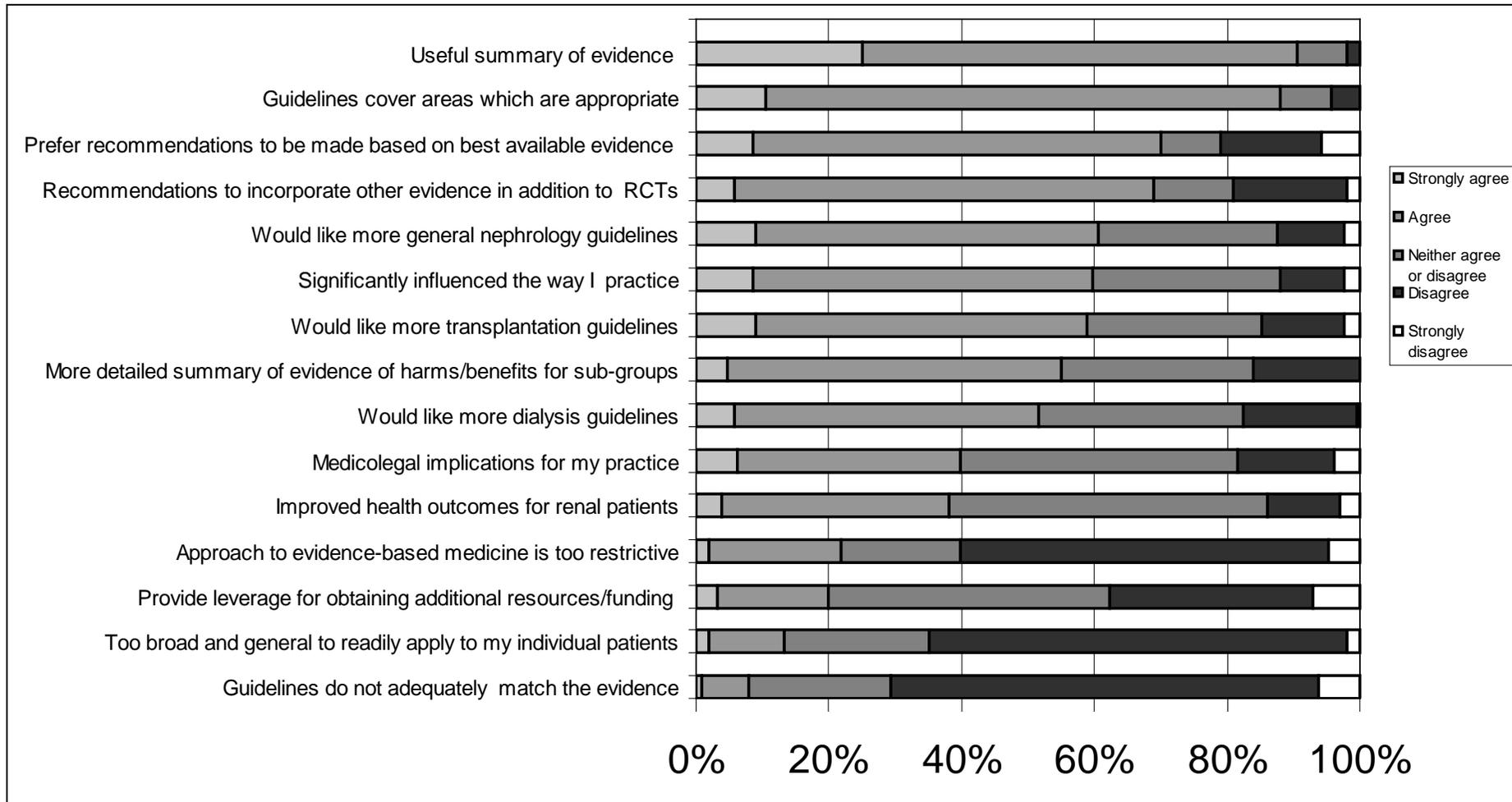


Table 3.2: Comparison of responses from nephrologists in 2002 (n=140) and 2006 (n=211) surveys

Statement	Year	Strongly agree (%)	Agree (%)	Neither agree nor disagree (%)	Disagree (%)	Strongly disagree (%)	P*
The CARI guidelines have significantly influenced the way I practice.	2002	1.4	37.9	30	28.6	2.1	<0.001
	2006	8.6	51.2	28.2	9.6	2.4	
The CARI guidelines provide a useful summary of evidence from which to draw information to help me in my clinical practice.	2002	23.6	65	8.6	2.1	0.7	0.5
	2006	25.1	65.4	7.6	1.9	0	
The CARI guidelines have significant medico-legal implications for my practice.	2002	10.7	33.6	35	23	4.3	0.5
	2006	6.2	33.6	41.7	14.7	3.8	
The CARI guidelines have provided useful leverage for obtaining additional resources/funding for my patients.	2002	0.7	12.9	31.4	37.1	17.9	<0.001
	2006	3.3	16.7	42.4	30.5	7.1	
The CARI guidelines have improved health outcomes for renal patients	2002	0	13.6	48.6	33.6	4.3	<0.001
	2006	3.8	34.6	48.1	11	2.9	
The CARI guidelines are too broad and general to readily apply to my individual patients.	2002	0.7	15	20	57.9	6.4	0.8
	2006	1.9	11.4	21.8	63	1.9	
The treatment recommendations in the CARI guidelines do not adequately match the available evidence.	2002	2.1	25.7	21.4	47.1	3.6	<0.001
	2006	0.9	7.1	21.3	64.5	6.2	

*Chi Square test for linear association between responses given in 2002 and 2006.

NB: Question 7 of the 2006 survey was not included in the 2002 survey

Table 3.3: Responses to survey questions stratified by respondent characteristics for responses which showed variability in responses by characteristics (either actual or close to statistical significance)

Question	Demographic	Strongly agree (%)	Agree (%)	Neither agree nor disagree (%)	Disagree (%)	Strongly Disagree (%)	p*
I think the CARI approach to evidence-based medicine is too restrictive	Age (years):						
	<40	0.0	13.0	16.7	65.6	4.7	
	40-49	0.0	27.5	18.8	50.7	3.0	
	50-60	3.2	19.5	19.4	51.6	6.4	
	>60	12.0	24.0	12.0	44.0	8.0	0.007
The treatment recommendations in the CARI guidelines and suggestions for clinical care do not match the evidence	Gender:						
	Male	1.3	8.3	25.5	58.6	6.4	
	Female	0.0	1.9	9.6	82.7	5.8	0.007
	Age:						
	<40	0.0	0.0	17.9	75.0	7.1	
	40-49	1.4	13.0	20.3	62.3	3.0	
	50-60	0.0	9.7	25.8	51.6	12.9	
	>60	4.0	12.0	32	48.0	4.0	0.002
	Work Location:						
	Metro	0.6	6.3	21.3	64.4	7.5	
	Regional	2.9	11.8	25.3	61.8	0.0	0.05
I would like to see more general nephrology guidelines	CARI guideline writer:						
	Current/Previous	6.6	37.7	41.0	9.4	2.0	.02
	Never been a writer	10.1	57.0	21.5	9.4	2.0	
I would like to see more transplantation guidelines	CARI guideline writer:						
	Current/Previous	3.3	44.3	24.6	23.0	4.9	0.001
	Never been a writer	11.4	51.7	27.5	8.1	1.3	
I would like to see more dialysis guidelines	CARI guideline writer:						
	Current/Previous	3.3	31.1	39.3	26.2	0.0	0.002
	Never been a writer	6.7	52.3	27.5	12.8	0.7	

*Chi square test for linear association

Table 3.4: Comparison of process steps performed by various guideline groups

ACTION*	NHMRC/ APRAC	CARI	KDOQI	EBPG	KDIGO
1. Define topic/issue	2	1	2	1	2
2. Assess the need for guidelines	1		1		1
3. Convene multidisciplinary committee to develop guidelines	3	2	3	2	3
4. Develop health care questions appropriate for intended guidelines	4	3		3	4
5. Identify (or commission) systematic reviews of the scientific literature relating to health questions	5	4	4	4	5
6. Review evidence of the impact of socioeconomic position in relation to condition of interest					
7. Assess evidence for: strength; quality; size of effect; relevance	6	5	5	5	6
8. Apply evidence to clinical/ health care situation to determine benefits/ harms	8				7
9. Compare costs and benefits of health care interventions	7				
10. Apply evidence to clinical/ health care situation to determine cost-effectiveness and feasibility					
11. Develop evidence-based guidelines or update existing guidelines	9	6	6	6	8
12. Advertise for public consultation	10	7	7	7	9
13. Disseminate and implement guidelines	11	8	8	8	10
14. Develop publication(s) to target other stakeholders	12		10		
15. Maintain, evaluate and update the guidelines	13	9	9	9	

*Various actions are based on "NHMRC standards and procedures for externally developed guidelines," Feb 2005, Canberra: Australia. Numbers indicate order in which steps are performed by groups.

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4.0 Opinions on the content and effects of the CARI guidelines: a national survey of renal nurses and comparison with the opinions of nephrologists

4.1 Abstract

Aim: Renal nurses in Australia and New Zealand are critical to the care of patients with chronic kidney disease (CKD), especially those on dialysis. We aimed to obtain the opinions of renal nurses in Australia and New Zealand on the Caring for Australasians with Renal Impairment (CARI) Guidelines.

Methods: A self-administered survey was distributed to all members of the Professional organisation for renal nurses (Renal Society of Australasia) in 2006. The results were compared with those from a similar survey in 2002 and an identical 2006 survey of Australian and New Zealand nephrologists.

Results: Of the 173 respondents, more than 95% considered the Guidelines to be a good synthesis of the available evidence; 80% indicated that the Guidelines had significantly influenced their practice; and 86% considered that the Guidelines had improved patient outcomes. Older respondents were less likely to perceive that the Guidelines had improved patient outcomes, and renal nurse educators were more likely to consider that the Guidelines were based on the best available evidence than other respondents. Respondents

were generally more positive about the Guidelines in 2006 than in 2002.

Although nephrologists were generally positive about the CARI guidelines, renal nurses were more positive, especially regarding the effect of the Guidelines on practice and the improvement in health outcomes.

Conclusion: Australian and New Zealand renal nurses valued the CARI Guidelines highly, used them in practice, and considered that they led to improved patient outcomes. Positive responses towards the Guidelines increased between 2002 and 2006.

4.2 Background

The Caring for Australasians with Renal Impairment (CARI) Guidelines[1] comprise a set of regionally relevant evidence-based Guidelines, the development of which began in 1999 as a joint initiative of the Australian and New Zealand Society of Nephrology (ANZSN) and Kidney Health Australia (KHA). Like many other renal guideline organisations internationally[2-6], the CARI Guidelines aim to improve the health care and outcomes of patients with chronic kidney disease (CKD) by promoting evidence-based practice to doctors and other clinicians. The CARI Guidelines have been written by doctors, nurses, allied health professionals and consumers on a voluntary basis. They are published online and in the Journal *Nephrology* as supplements.

Although substantial investments have been made in developing the CARI Guidelines and other guidelines for the management of patients with CKD, little is known about how such guidelines are actually used in practice. To date, many studies evaluating the application of renal guidelines have used 'before-after' designs, large administrative datasets, and have focused on uptake by nephrologists[7-10]. As renal nurses play a critical role in the delivery of health care to patients with CKD, especially those on dialysis, it is important to evaluate the usefulness of guidelines from a nursing perspective. In this paper, we report on a survey of Australian and New Zealand renal nurses conducted in 2006 which aimed to determine nurses' opinions on the content of the CARI Guidelines and their effects on practice, whether attitudes

to the Guidelines varied with nurses' demographic or practice characteristics, whether responses differed between nurses and nephrologists who completed the same survey[11], and whether responses had changed since a similar survey was conducted in 2002.

4.3 Methods

Survey details

A self-administered survey questionnaire was developed with advice from nephrologists, renal nurses and a consumer, all of whom were members of the CARI Steering Committee. The questionnaire was based on questions used in a 2002 survey of the same target group, and it was developed using published standards for surveys.[12-16] The questionnaire (see Appendix B1) contained a total of 23 items designed to elicit opinions of renal nurses in four domains: (i) the effect of the Guidelines on knowledge, practice, patient outcomes and medico-legal issues, and the Guidelines' value as a basis for requesting clinical resources; (ii) the structure of the Guidelines, with particular reference to the ways in which evidence is used and recommendations are formulated; (iii) the content of the Guidelines, primarily concerning existing and future coverage; and (iv) the preferred method(s) of distributing the Guidelines as well as the frequency with which users obtain access to the Guidelines. The questionnaire also included items of internal relevance to the CARI organisation only, such as logo and name, which are not analysed here.

Closed response sets were provided for all questionnaire items. Seven questions (numbers 1-6 and 8) were identical to the survey completed by the same target audience in 2002 (n=162). The response sets used a Likert scale with responses ranging from 'strongly agree' to 'strongly disagree'.

Nephrologists completed the same survey concurrently with the renal nurses. The results of the responses from nephrologists have been published elsewhere. [11]

Recruitment of respondents

A paper copy of the anonymous survey, with an introductory letter and return postage, was attached to the August 2006 newsletter of the Renal Society of Australasia (RSA), and sent to all members of the RSA in Australia and New Zealand. There were 960 RSA members at this time; the majority of this membership was renal nurses with a small portion of these being scientists or technicians. The RSA is the major professional body for renal nurses and affiliated professionals in Australia and New Zealand. The survey was also distributed at the August 2006 RSA Conference (held in Melbourne, Australia). In both situations, completed survey forms could be returned either by fax or mail, or respondents could complete the survey online through the CARI website (<http://www.cari.org.au/survey>). Respondents were asked to complete the survey once only. Any member of the RSA who self-identified as a renal nurse was eligible to respond. Because responses were anonymous, it was not possible to send individual reminders to encourage people to complete the survey.

Statistical methods

Demographic and practice characteristics were analysed using descriptive statistical methods. A Mantel-Haenszel chi-square test for linear association was used to examine the differences in responses from different demographic

groups, changes between the 2002 and 2006 surveys and the difference in responses from renal nurses and nephrologists. SPSS software version 13 (SPSS Inc, Chicago Ill, USA) was used for this analysis.

Ethics approval

The Human Research Ethics Committee for The Children's Hospital at Westmead, Westmead, Australia, approved the study.

4.4 Results

In all, 173 renal nurses responded to the survey (Table 1). The total number of renal nurses in Australia and New Zealand is unknown, but is estimated at approximately 800, of which many do not work full-time. Ninety-two percent of respondents were female. Half of the respondents were aged 40-50 years, and just under half had worked in renal nursing for >15 years. More than 70% worked in a metropolitan location.

Responses to survey questions

Effects of the Guidelines

Ninety-six percent of respondents indicated that the CARI Guidelines were a good summary of evidence, and more than 80% indicated the Guidelines had significantly influenced their practice (see figure 1). While 86% considered that the Guidelines had improved outcomes for renal patients, 65% thought that they had potential medico-legal implications for practice.

Content and format of the Guidelines

Sixty percent of respondents felt that the Guidelines reflected the best available evidence, but 34% were unsure. Over 80% indicated that they valued recommendations based on the best available evidence when randomised controlled trials (RCTs) did not exist. More than 75% indicated a need for evidence other than that drawn from RCTs. Nearly 90% of respondents considered the content of the CARI Guidelines to cover

appropriate areas in the management of renal patients. Many indicated a need for further guidelines covering general nephrology, transplantation and dialysis topics. A majority wanted more detailed summaries of benefits and harms for subgroups of patients. Less than a quarter reported that they referred to the Guidelines at least monthly, either in print or online, and more than three-quarters replied that a CD-ROM format would be useful.

Variability of responses in the 2006 survey

Perceptions of the effects of the CARI Guidelines on renal patient health outcomes varied with age of the respondent (grouped in 10-year age brackets); older respondents were less likely to perceive that the Guidelines had improved patient health outcomes (chi-square test for linear trend, $p=0.02$). Renal nurse educators were more likely to agree that the Guidelines were based on best available evidence than other respondents ($p=0.002$). State or Territory of residence, gender and number of years worked in nephrology were not significant predictors of responses.

Comparison of 2002 and 2006 survey results

Figure 4.2 shows that respondents in the 2006 survey were more likely than 2002 respondents to report that the Guidelines had influenced their practice ($p=0.004$). Compared with those in 2002, the 2006 respondents were less likely to agree that the Guidelines did not match the best available evidence ($p<0.001$). The 2006 respondents were more likely to agree that the Guidelines had improved health outcomes for patients ($p<0.001$), had

provided leverage for gaining additional funding ($p < 0.001$) and had significant medico-legal implications for practice ($p = 0.017$).

Comparison of 2006 responses between nurses and nephrologists

The responses of both renal nurses and nephrologists were very similar overall, but in general, nurses were more positive about the Guidelines, in the range of 20-40%, compared to nephrologists. Nurses were more likely to indicate that the Guidelines had significantly influenced practice, had provided leverage for obtaining resources, and had improved health outcomes for patients. More nurses also requested more dialysis guidelines than nephrologists. Nurses were also more likely to prefer the use of the best available evidence when RCTs did not exist and they favoured inclusion of non-RCT as well as RCT-based evidence in guidelines. Nurses also responded that the Guidelines had increased medico-legal implications for their practice when compared with responses from nephrologists.

4.5 Discussion

The overall response to the CARI Guidelines from renal nurses was positive. Survey respondents reported that the Guidelines were a useful synthesis of evidence. They regularly used the Guidelines in their practice and perceived that the Guidelines led to benefits for their patients.

Although the attitudes towards CARI were generally very favourable, there was some variability, and this was largely unexplained on the basis of nurse demographic or practice characteristics. Renal nurse educators were more likely to consider that the Guidelines were based on the best available evidence than other respondents, who remained neutral. This may reflect that renal nurse educators are more likely to have postgraduate training which may encompass evidence-based practice methods. Older renal nurses were less likely than their younger counterparts to perceive benefits for health outcomes as being attributable to the CARI Guidelines. This may have been due to a broad generational shift, with younger health professionals generally having greater familiarity with evidence-based medicine and a greater tendency to recognise the value of and rely on, evidence-based guidelines and practice recommendations rather than their clinical experience only.

The 2006 survey respondents were more positive about the value of the CARI Guidelines than the 2002 respondents, even though the 2002 respondents were also generally favourable. This could be due to the continuing evolution of the Guidelines, improvements in format, and the publication of new and

revised Guidelines on aspects of CKD and transplantation over this time. It could also reflect a national and international trend towards the acceptance and use of guidelines generally.[17, 18]

Both nephrologists and renal nurses were similar in their responses to the survey. Both agreed that the CARI Guidelines were a good synthesis of the available evidence, but nurses responded more positively than nephrologists for some questions, such as the influence of guidelines on practice and health outcomes. This may reflect a professional ethos in nursing which places greater emphasis on using treatment protocols. The finding that nurses were more likely than nephrologists to be concerned about the medico-legal implications of guidelines for their practice was unexpected. In general in Australia, medical practitioners would be perceived to have a greater risk of being subject to litigation than nurses. The New Zealand, no-fault accident compensation scheme means neither nurses nor doctors are at greater risk of litigation.

Research into nurses' attitudes towards guidelines is limited. A study of intensive care nurses in Ireland found that guidelines were adapted according to professional judgement and experience. Senior nurses thought junior nurses would find the guidelines useful, and senior nurses were more likely to deviate from guideline recommendations.[19] A survey of Hong Kong nurses regarding their use of research found that nurses understood the value of research but required assistance in the implementation of research findings, because they lacked the confidence to change patient care.[20] Assessment

of the effect of guidelines on patient outcomes is complicated by the difficulty of attributing observed improvements in patient outcomes to guideline recommendations. No study of the reported opinions on the content and effects of other CKD guidelines such as Kidney disease outcome quality initiative (KDOQI) and Kidney disease: Improving global outcomes (KDIGO) exist.

One potential limitation of our study is the low response rate, which means our study may not be representative. Our findings are based on 173 responses from a workforce of unknown size. Despite the large number of responses received, it is unclear whether they were representative of all renal nurses. However, a recent study indicated that the average age of Australian dialysis nurses is 43 years [21] which was very close to the estimated average age of the 2006 survey respondents which was 43.5 years (based on the distribution of age ranges). Although responders typically differ from non-responders[22], no information was available on other characteristics of non-responders to our survey. This study aimed to elicit opinions on the CARI guidelines and self-reported effects on their use and patient outcomes. Further studies are required to determine actual use and effects on patient outcomes. The survey results inform on attitudes to the guidelines, which is an important first step in the implementation process. The 2006 survey was carried out by the CARI guidelines office as a quality improvement process. The majority of authors are involved with writing, editing or dissemination of the guidelines.

Renal nurses in Australia and New Zealand value and use the CARI Guidelines in their nursing practice. Our repeated surveys showed that nurses have become more positive in their attitudes towards the Guidelines between 2002 and 2006. Indeed, their responses to the 2006 survey indicated that they were more positive than nephrologists in some domains.

Our findings suggest that the formulation of renal guidelines should involve input from renal nurses with regard to content, and that the dissemination of the guidelines should take account of nurses' preferences with regard to information access. Nurses in specialised roles, such as dialysis, might also represent a relatively underused resource for developing implementation strategies for clinical practice guidelines.

Table 4.1: Demographics and practice characteristics of respondents (n=173)

Characteristic		%
Gender	Male	8
	Female	92
Age (years)	20-40	28
	41-50	48
	51-60	23
	>61	1
Duration of practice (years)	1-5	18
	6-10	21
	11-15	18
	16-20	19
	>21	24
Type of practice	Metro	73
	Regional	27
Work description*	University affiliated hospital	53
	Local hospital	19
	Satellite unit	31
	Private practice	4
Renal nurse educator		19
Guideline writer	Previous/current	2

* Respondents could chose more than 1 descriptor

Figure 4.1: Responses of Nephrologists (D) and Renal nurses (N) †

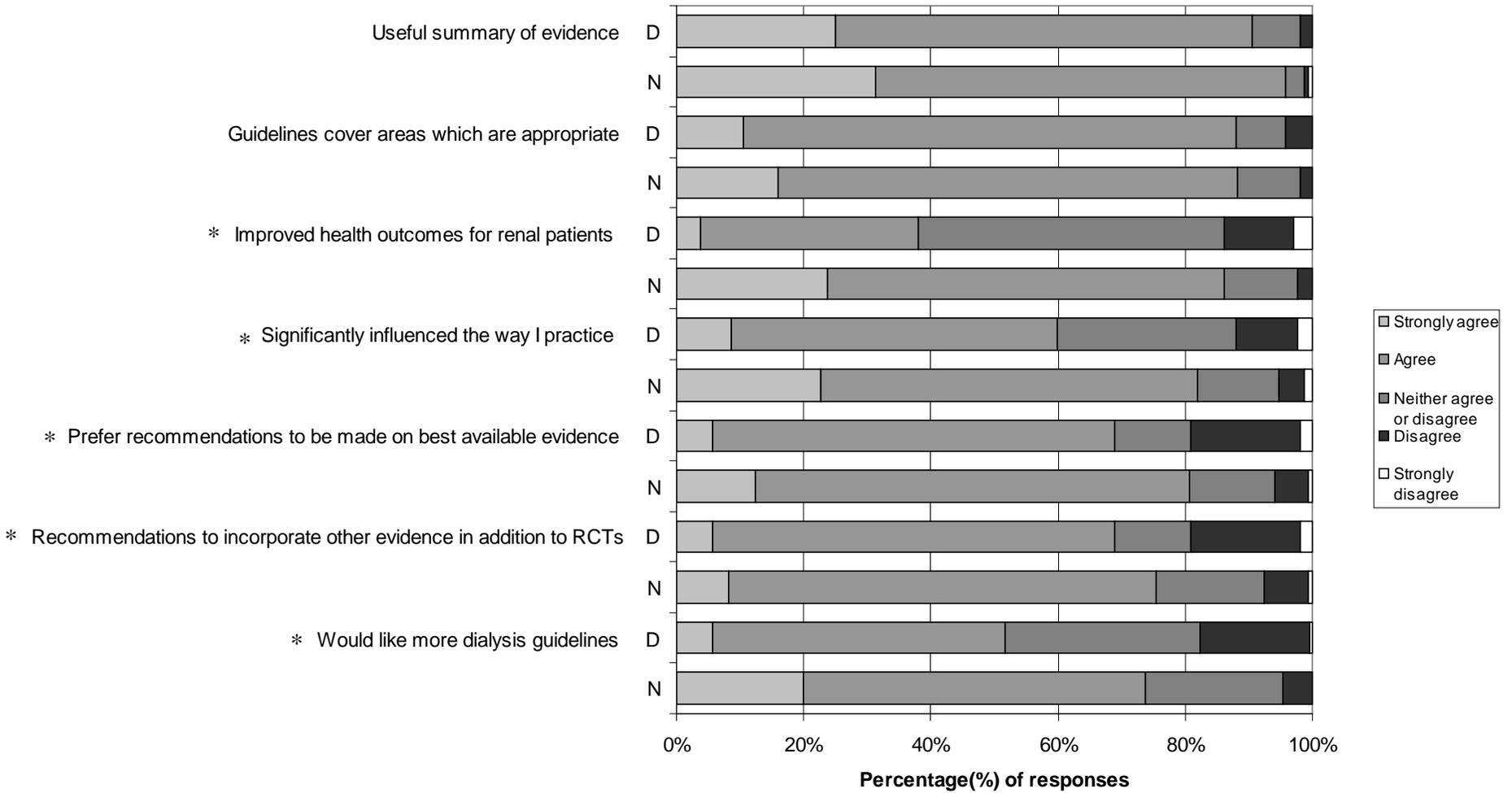
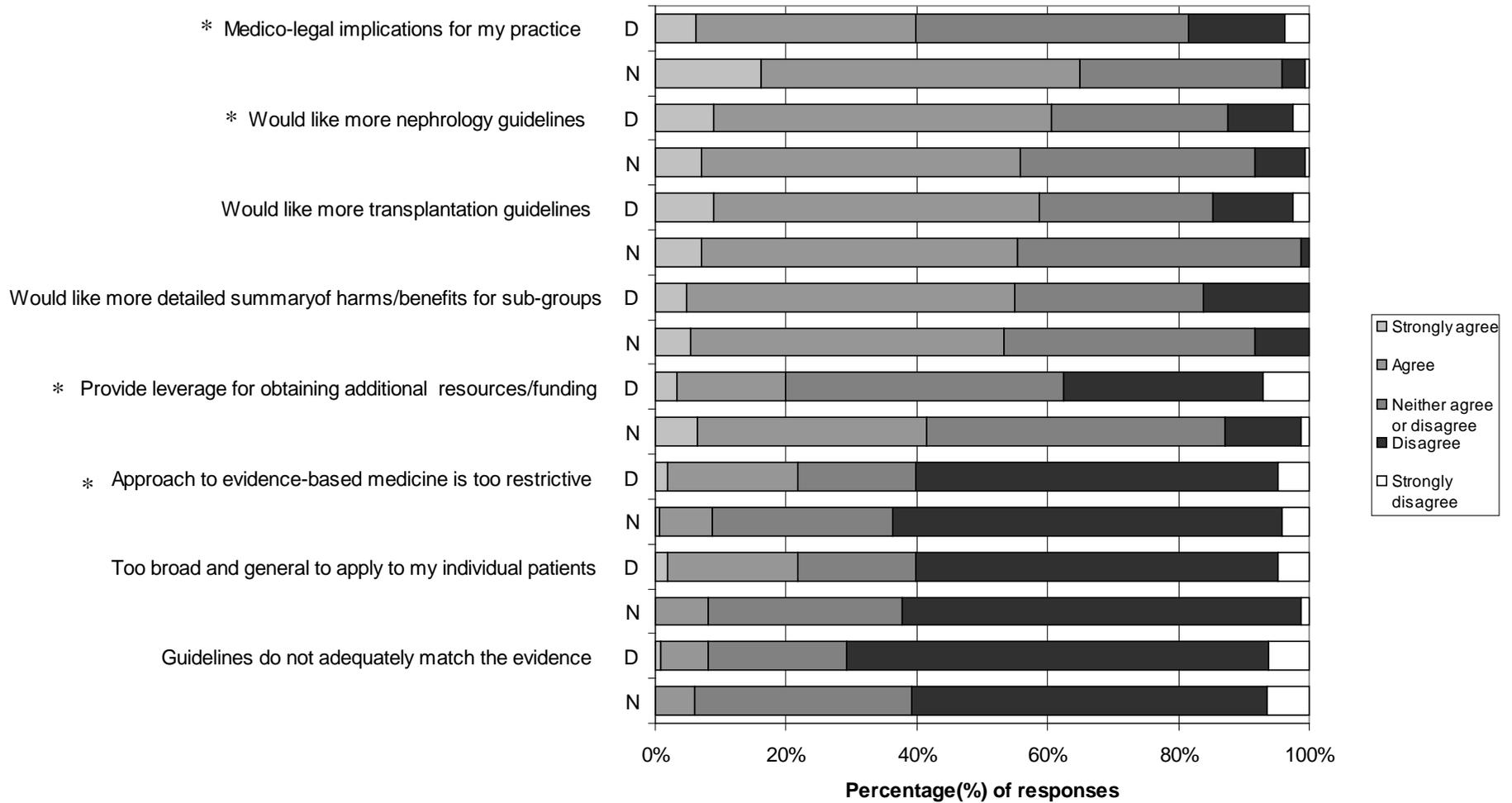


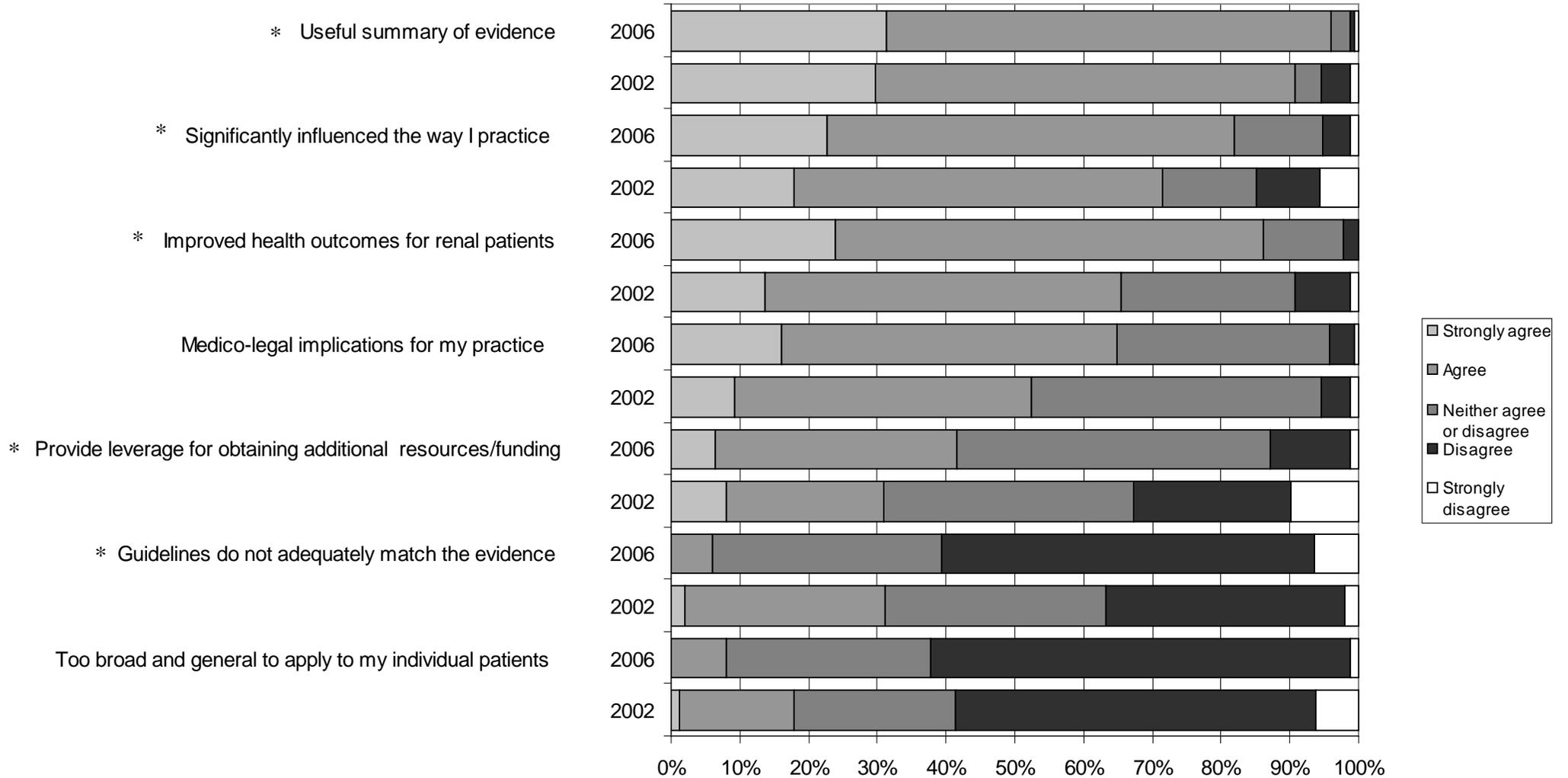
Figure 4.1 continued



* p<0.05

† Responses are ordered from the highest to lowest responses of both strongly agree and agree for renal nurses.

Figure 4.2: Comparison of responses from nurses from the 2002 and 2006 survey[†]



* p<0.05

† Questions in common between 2002 and 2006 surveys, ordered by positive responses in 2006 data

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5.0 Nephrologists' perspectives on the effect of guidelines on clinical decision making: a semi-structured interview study

5.1 Abstract

Background: A consistent gap exists between evidence-based guideline recommendations and clinical practice across all medical disciplines, including nephrology. This study aimed to explore nephrologists' perspectives on guidelines, and to elicit their perspectives on the effects of guidelines on clinical decisions.

Methods: Semi-structured, face to face interviews were undertaken with nineteen nephrologists from a variety of clinical settings across Australia. Participants were asked about their views on clinical practice guidelines in nephrology, both local (Caring for Australasians with Renal Impairment, (CARI)) and international, and their opinions on other factors which shape their decision making. Interviews were recorded, transcribed and analysed qualitatively.

Results: Four major themes were identified. Overall the Nephrologists interviewed trusted the CARI guideline process and output. Second, guidelines served a variety of purposes, they provided a good summary of evidence, were a foundation to practice, an educational resource, could justify

funding requests to policy makers, and promote patient adherence. Third, guidelines were only one input into decision making. Others inputs included individual patient quality of life and circumstances, opinion leaders, peers, nephrologists own experiences, the regulation and subsidy framework for drugs and devices, the policies and work practices of the local unit, and other sources of evidence. Fourth, guideline uptake varied. Factors which favoured use of guidelines included; a strong evidence-base, being current, including specific targets and an explicit treatment algorithm, being sent frequent reminders, local peer support for implementation and the necessary personnel and other resources for effective implementation.

Discussion: Evidence-based guidelines appear to impact strongly on clinical decision making of Australian nephrologists, but are only one input.

Improvements in the evidence which underpins guidelines and improvements in the content and formatting of guidelines are likely to make them more influential on decision making. Trust in the guideline groups' process is a prerequisite for implementation.

5.2 Background

Evidence-based clinical practice guidelines that aim to improve outcomes for patients exist in many areas of healthcare, yet there are clear gaps between these guidelines and what occurs in practice.[1-4] Effective strategies to bridge the gap between research and practice are still relatively unknown.[5] Currently, most implementation strategies which have been evaluated result in variable and small improvements in care.[2, 6] Many factors are known to affect the uptake of guidelines in practice, including the credibility, feasibility, costs of the guideline recommendations, the knowledge, skills and attitudes of practitioners, peer opinion, and organisational factors[7]. Identifying barriers such as these to the implementation of guidelines may be of some benefit to improve health outcomes .[8, 9]

Previous research in the implementation of guidelines in CKD has been predominately quantitative, consisting of before and after studies, and randomised controlled trials of interventions to change practice. [10-15] To gain a more detailed understanding of nephrologists' experiences and perspectives on the use of guidelines in clinical practice we used a qualitative approach to elicit nephrologists' perspectives on guidelines, on both the local, Caring for Australasians with Renal Impairment (CARI) guidelines[16] and international guidelines such as the Kidney Disease –Improving global Outcomes (KDIGO)[17] guidelines. We also aimed to investigate the effect guidelines have on clinical decision making, explore the range of other inputs into this process, and what factors would facilitate implementation of guideline

recommendations. The CARI guidelines consist of published guidelines on chronic kidney disease, dialysis and transplantation. Table 5.1 outlines the current published guideline topics. Further details can be obtained from www.cari.org.au .

5.3 Methods

Qualitative semi-structured face to face interviews were conducted with Australian nephrologists from May to August 2008 and were facilitated by one of the authors (MI).

Participant selection and setting: Participants were eligible if they were a practicing nephrologist in Australia. We used purposive sampling to ensure that we captured the experiences of nephrologists from a range of locations (metropolitan/ regional practices), years of experience, experiences with guidelines and from both men and women.

Ethics approval was given by The Children's Hospital at Westmead Ethics Committee. Participants were recruited by a personal e-mailed letter from the Chair of the CARI steering committee which was followed up by the first author, via e-mail or phone call, if there was no response. Details of the study were discussed with all willing participants and a time was made for the first author to conduct the interview at a time and place convenient for the participants. An information package was e-mailed to participants containing background information regarding the study, an outline of possible questions and a consent form.

Data collection: We developed a preliminary question guide based on previous qualitative studies in implementation of guidelines (Appendix C1) and discussions with the research team. We piloted the questions with three nephrologists. The final schedule (Appendix C2) included the following topics:

prompts for changes in clinical management, factors affecting decision making, awareness of guidelines, influences of guidelines on practice, why guidelines are not used, applicability of guidelines in the clinical environment, guideline relevance to patient outcomes, and specific feedback on the CARI guidelines. As a discussion prompt for the last question, each participant was shown a copy of the CARI Iron guideline[18] and they were asked about their opinion on the guideline to suggest improvements for this guideline and to comment on other guidelines produced by CARI.

Analysis: All interviews were digitally recorded and transcribed in full. The transcripts were reviewed line-by-line by a single author (MI) who developed a preliminary coding structure based on the concepts, themes and ideas within the interviews. Quotes for each theme were stored in Excel®. Themes were read and discussed with other authors (AT & LR) for clarity. Emerging themes were consolidated or merged with others to produce the final set of themes. Notes were taken after each interview on participant characteristics, body language and context in which the interview was conducted.

5.4 Results

Participant characteristics: Thirty eight nephrologists were invited to participate in the study, 16 did not respond and 3 willing participants were unable to participate due to competing commitments. Nineteen nephrologists participated, from; New South Wales (8), Queensland (7) and Victoria (4). Four were female, and six were based in a rural location. Duration of time spent in clinical practice varied widely: 5-10 years (6), 11-20 years (7), 21-30 years (5) and more than 30 years (2). One current and one previous CARI guideline writer were included in the study. Data saturation was achieved at 16 interviews, that is, when little or no new themes were being generated from subsequent interviews compared with what had been elicited previously. Interviews were continued to 19 to ensure data saturation had been achieved.

Major themes: Four major themes from the interviews were identified: trust in the guidelines, the range of functions the guidelines have in clinical practice, non-guideline influences on clinical decision making, and facilitators and barriers of guideline implementation.

The relationship between guidelines and non-guideline influences on clinical decisions and factors that facilitate guideline implementation is summarised in Figure 1.

Theme one: Trust in the guidelines

Overall there was a high level of trust in the CARI guidelines. Nephrologists believed they could trust the CARI guidelines because they trusted the process and the writers who were involved in the process. They believed that locally developed guidelines were more applicable to their setting. They appreciated that the CARI guidelines were developed without industry influence and that the evidence levels of the recommendations were explicit. Responses were mixed for other international guidelines ranging from very positive to very negative.

“...based on what evidence is presented and how the data is presented, yes, I would have faith in the guidelines being a true assessment of the literature in its current state. I wouldn't question it.”
(P11, Male, 5-10yrs nephrology experience)

“I trust my peers that have reviewed the guideline.” (P12, Female, 5-10 years nephrology experience)

“... you know why don't we just adopt KDIGO? The benefit of the local [guidelines] is that they tend to be a bit more sceptical of it, and less prescriptive of things that aren't proven, [to have] a benefit.” (P1, male, 10-20 Years nephrology experience)

Theme two: The varied function of guidelines in clinical practice

Participants noted that the guidelines fulfilled a variety of functions in clinical practice. They provided a summary of available evidence; provided a framework for decision making at an organisational as well as individual, they educated and were able to change practice. They supported funding applications, assisted with patient adherence to treatment and were individualised for their patients.

“They are a fantastic summary; there is no question about that.” (P4, Male, rural, 20-30 years nephrology experience)

Guidelines played a role both at the organisational level when they were integrated into policies and procedures, and in the individual clinician's practice and patient consultations where they provided a general framework within which decisions could be made.

“I think it provides the foundations for what you're benchmarking against and then in turn it informs your department's policies and protocols, which directly then impact on your patient care.” (P9, Female, 5-10 years nephrology experience)

Guidelines were also seen to have an educational role in clinical practice. Many experienced participants (more than ten years nephrology experience) believed the guidelines were a valuable educational resource for the more

junior nephrologists (less than 10 years nephrology experience). However, the more junior participants indicated that the guidelines were often too broad and general for their needs. The participants were receptive to changing their practice in accordance with the guidelines, but the guidelines usually confirmed management practices that had already been implemented.

“...a lot of the time they don't change your practice because in fact, you're already doing it right, so it confirms practice rather than changing it.” (P10, Male, rural, 20-30 years nephrology experience)

They also indicated that guidelines could be used to encourage patient adherence to medical advice and lobby for additional funds, equipment and other resources.

“Sometimes it's helpful to say to the patient; well you know the national body says it should be this...” (P5, Male, rural, 30+ years nephrology experience)

In practice, many participants recognised that treatment decisions were based on the needs, circumstance and preferences of each individual patient. They were not hesitant in individualising treatment they gave to their patients, even when the decision did not accord with the guideline recommendation. The nephrologists felt the guidelines should be viewed as “suggestions” rather than mandatory rules, and expressed concerns about the potential medico-legal implications if guidelines became mandatory allowing no flexibility to individualise treatment.

"I think that the advantage is that they are guidelines, and they are exactly that, otherwise it opens a medico legal minefield that none of us want to go down. Even though the standards are very well researched in these guidelines, they still don't apply to the individual patient and I think it's important that they're written with that in mind." (P13, Male, rural, 10-20 years nephrology experience)

Theme three: Non- guideline influences on clinical decisions

Guidelines were one influence on clinical decisions made by nephrologists in practice, but there was many other factors that also influenced this decision, including individual patient quality of life and circumstances, opinion leaders, peers, nephrologists own experiences, the regulation and subsidy framework for drugs and devices, the policies and work practices of the local unit, and other sources of evidence.

The clinician's perspective of their patient's quality of life, and their values and preferences, was the most important factor when making clinical decisions.

The integration of a guideline recommendation into practice was weighed against the impact that this would have on the patient's quality of life.

Clinicians reported that they chose not to implement the recommendation if they believed it would reduce the patient's quality of life.

“You can’t make their life intolerable, to meet a standard.” (P1, male, 10-20 Years nephrology experience)

“Do I really have to aim to have his cholesterol less than point 5 and do I have to have his blood pressure less than 130 and do I have to have his diabetic control perfect? The answer is to that is, he has to have none of those things, he just has to enjoy the days that he’s got left.”(P10, Male, rural, 20-30 years nephrology experience)

Many nephrologists considered their peers' opinions when making clinical decisions when guidelines or strong evidence did not exist. Sometimes participants sought peer opinion instead of the guidelines. In larger clinical work settings, the nephrologists had regular peer interaction and in turn stayed aware of current practice.

“I mean that’s one the reasons I stay in public practice, we have meetings and I’m in touch with my colleagues all the time to make sure that what I’m doing is the same as the rest of the community.” (P12, Female, 5-10 years nephrology experience)

For rural nephrologists this peer interaction was more difficult. They indicated that guidelines played an important role in staying within current accepted practice as they lacked regular peer interaction. Rural nephrologists also found that resource constraints and location impacted on their clinical decisions.

"It's generally done my way, which can be the wrong way if you don't know about it, I mean it is one of the problems with just working as a single nephrologist that you might not necessarily be doing it the best way." (P4, Male, rural, 20-30 years nephrology experience)

"Logistics, or availability of things, can it be done in this town, whatever it is you're going to do, can I do it, can the GP(General Practitioner) do it?" (P5, Male, rural, 30+ years nephrology experience)

The unit's current practice and their policies and procedures were reported to strongly influence how the participant's practiced. They felt that the unit's policies and procedures were based on the guidelines, but also fitted in with local needs. They would often consult local protocols first. The nephrologists felt their own experience also influenced their clinical decision making. Some felt they could make appropriate decisions without using guidelines or consulting with peers. Others felt that the experience of an adverse event was very influential in how they approached a similar clinical situation in the future.

"I've been doing it for a long time, I kind of feel I know it all, in the back of my head." (P5, Male, rural, 30+ years nephrology experience)

"We're always scarred by what we've seen already, so if you've got a case series of one that went wrong, you tend not to do it again." (P17, Male, 20-30 years nephrology experience)

To keep up to date with the evidence, the participants regularly accessed the literature and other information sources -such as “Up-to-date” [19]. They also referred to other international guidelines if the CARI guidelines did not cover to the clinical problem they encountered. The United States (US) Kidney Disease Outcomes Quality initiative (K-DOQI) guidelines and “Up-to date” were considered to be more ‘prescriptive’ or detailed compared with the CARI guidelines. Some participants thought that the differences between the Australian and American healthcare systems precluded the use of the US K-DOQI guidelines in Australia. Few participants mentioned using the European guidelines but when they did they thought the European guidelines were more transferable to the Australian nephrology environment, compared with American guidelines.

“...they’re [K-DOQI] a point of interest globally, because everyone practices different medicine differently, from a locality of view...we treat our patients differently from Europeans and America etcetera., but its also good to know what other societies do... but I think they really should only pertain to, local societies.” (P16, male, 5-10 years nephrology experience)

Theme four: Facilitating the use of guidelines in clinical practice

The use of guidelines in clinical practice was facilitated by a variety of factors such as the strength of the evidence that underpinned the guidelines, audit and feedback, use of guidelines by nurses, motivated individual to drive

change and specific guideline attributes, although few were aware of, or participated in guideline implementation projects.

Guidelines that were based on strong evidence were more likely to be put into practice. Many participants re-examined the evidence cited in the guideline before changing practice. Participants appreciated that writers explicitly stated which statements were opinion-based and those that were evidence-based. Participants valued statements based on low evidence or opinion when strong evidence was not available. However, others believed that opinion-based statements should be excluded from guidelines.

“I think the expectations are now that the guideline needs to be clear as to what’s opinion, what’s recommendation and what’s strong, level 1, 2 evidence. And I think distinguishing between that has been very helpful.” (P4, Male, rural, 30-40 years nephrology experience)

“There are some guidelines that say no guidelines are possible, but I’m looking [for] a bit more for my day to day practice for instance.” (P2, Male, 10-20 years nephrology experience)

The participants suggested several ideas to increase the uptake of guideline recommendations in clinical care and in particular how the CARL guidelines could improve aspects of the guideline output that would increase uptake. Many suggested that they lacked good quality data on how they measured against the guideline recommendations. Some expressed the desire to

collaborate with 'performing' units to ascertain if there were areas where they could improve.

"If you can't measure it, you can't manage it." (P8, Male, 10-20 years nephrology experience)

Participants acknowledged that nurses played a key role in guideline implementation. Nurses aimed to achieve the targets recommended by the guidelines; they often notified nephrologists of abnormalities and drafted policies and procedures. Some thought that the approach to guideline dissemination should be targeted at nursing staff as well as nephrologists, due to the increased role that nurses were taking in nephrology.

"Often nurses are involved and point out the abnormalities and so you have frequent review, monitoring and feedback." (P16, male, 5-10 years nephrology experience)

Many nephrologists considered guidelines with clear targets and practical recommendations to be particularly useful and these guidelines were often used more regularly. Many indicated that the executive summary enabled them to access the evidence quickly. The easier a guideline could be translated into a unit's policy and procedures, the more likely it will be used in practice. Nephrologists suggested that guidelines include suggested protocols or clinical pathways that will aid in the creation of policies and procedures.

“Something that’s concrete, worst thing is a waffling guideline...its got to have concrete targets that you can aim for and try and achieve.”

(P11, male 5-10 years nephrology experience)

Other suggestions from nephrologists that would improve the facilitation of the implementation of guidelines into practice included: encouraging clinicians to regularly review the guidelines, update the guidelines more regularly, include a library of resources on the guideline website, improve the website and improve dissemination methods.

There were also clear ideas on barriers to the use of guidelines in clinical practice, such as if the guideline was not up to date, guidelines that were too complex and contained too much information. Some nephrologists, especially those in a rural or remote practice indicated that a lack of resources such as equipment or staff hindered their use of guidelines in some instances

Overall guidelines were accessed based upon clinical need. Few participants reviewed the guidelines regularly. Instead, they only sought guideline recommendations when faced with a clinical problem or concern they were uncertain about. Sometimes nephrologists were challenged by peers on a specific management issue and they would refer to the guidelines to ‘adjudicate’ between them.

5.5 Discussion

We found that there was a high degree of trust by nephrologists in locally produced guidelines. The guidelines had varying functions in clinical practice, such as providing a summary of evidence, informing policies and procedures and encouraging patient adherence, but the perception among nephrologists is that guidelines usually confirmed practice rather than changed it. There were many inputs into the clinical decision making processes of nephrologists, other than guidelines, such as opinion leaders, peers, local policies and procedures, an individual patient's quality of life, values and preferences and other sources of evidence. We also found that the use of guidelines was variable, and can be facilitated by a strong evidence base, audit and feedback, clear guideline targets and practical recommendations, and guidelines which include suggested treatment algorithms.

Previously we had found, in a 2006 survey of more than 200 Australian and New Zealand Nephrologists[20], that over 90% indicated that the guidelines were a good summary of evidence, yet only 60% indicated that the guidelines had significantly influenced their practice. In this study the nephrologists told us that they often change their practices through discussions of new evidence with their peers and through reading published research and uptake new research findings into practice, prior to the publication of the guideline. Thus the guidelines become a reinforcing factor in many cases, rather than a catalyst for changing clinical practice.

It is evident that there are difficulties faced by rural or isolated nephrologists not encountered by their metropolitan counterparts. Rural nephrologists rely on guidelines more heavily as a source of peer support and they face barriers to guideline implementation due to location and logistics. They cited barriers such as access to equipment required for guidelines and inadequate facilities. Guideline developers should be aware of their heterogeneous user base and targeted additional support could be provided to rural nephrologists from guideline groups. This may take the form of development of more specific implementation pathways, based on the guidelines, more regular updates or input into database development for monitoring and managing individual patients.[21]

Qualitative studies on the use of guidelines in medical practice are relatively sparse, and most have focussed on family practitioners.[22-26] There has been one study on the use of nephrology guidelines by family practitioners[27], but none that we are aware of, that has sought to elicit responses from nephrologists. As we have found, other studies of clinicians in other disciplines, have a positive view of guidelines[23, 28] and guidelines were more rapidly implemented if they were based on strong evidence.[29] Patient needs, or patient demands in some cases, were driving forces in clinical decisions.[25, 28, 29] This study provides a clearer understanding of what factors impact on the clinical decision and the process of change for clinicians as they implement guidelines into practice.

Two aspects of CKD guideline development and implementation appear to be different in the Australian context than in the US in particular. CKD care, particularly ESKD care, is almost entirely Government funded, with no HMO equivalent. The framework for guidelines has been primarily in supporting clinicians and policy makers in making evidence-based decisions rather than linking the guidelines to specific key performance indicators and resource allocation. Second, although CARI is indirectly funded from industry, controversy and scepticism regarding specific recommendations which has occurred with KDOQI and KDIGO[30, 31] has not been evident in this study, or in our previously published survey. Reasons for this can only be speculative, but may include no involvement of industry in CARI guideline topic selection, a modest level of funding (a total budget of \$A250,000 per annum for all guideline activities), a higher threshold of evidence for guideline recommendation (randomized trials or systematic review of randomized controlled trials), and a culturally-sceptical renal community.

Our study has several potential limitations. Transferability of these findings beyond this region is uncertain, particularly when there has been no comparable study in other settings. However, our results are consistent with other qualitative studies of guideline users in other medical fields, suggesting our findings would be widely applicable in the nephrological community. We did not conduct multiple interviews with individuals, possibly capturing where perspectives may have changed over time. As with any qualitative study, we did not sample to ensure the representativeness of the responses, but rather we aimed to elicit a broad range of responses from differing demographic and

geographical groups. However, after sixteen interviews, no new themes emerged so we are confident that have captured the broad range of views in amongst nephrologists. Finally, any conclusions about the perspectives of international guidelines, particularly KDIGO, should be viewed with caution. When the study was conducted only one set of KDIGO guidelines had been published. [17]

Sometimes, clinicians found the guidelines were in conflict with their current practice. For those who re-aligned their practice with the guidelines, they went through a process of change. This process of change follows the process follows the process outlined in Rogers' diffusion of innovation theory.[32] However we have included some additional steps that we have found are unique to guideline implementation in this instance. This process is outlined in figure 5.2. We found that nephrologists were less likely to implement a guideline in isolation, but rather they will become aware of a guideline group and trust their writers, process and output and then engage with the guideline group showing interest in the guideline group as a whole. The clinician will then access individual guidelines and increase their knowledge of particular aspects of that guideline, they re-assess the evidence and if strong enough will make a decision to change their practice. External barriers will then need to be overcome before the clinician can change their practice. This change is then evaluated, by the clinician to ensure that the change is producing appropriate outcomes. Guideline groups need to be aware of the clinician's process of change when re-aligning their practice with respect to guidelines.

Each step in this process of change should be assessed, by guideline groups, for potential barriers that may impede movement through this process.

Conclusion

In summary, overall nephrologists were very positive about guidelines and the CARI Guidelines, they appreciated the effort that it took to write the guidelines and they had a high level of trust in their local guidelines that were written and evaluated by their peers. Guidelines provide education and an important framework for clinical practice. Strategies to improve guidelines, their dissemination and implementation given by the nephrologists should be taken into consideration for future and current guidelines such as the production of guidelines with strong evidence that are regularly updated, providing clinical targets and suggested clinical algorithms, providing audit and feedback, regular reminders and easily accessible guidelines as well as the inclusion of clearly labelled opinions that assist in the explanation of high level evidence . To facilitate implementation of guidelines, Guideline groups should assess barriers at each step in the process of change and target strategies to overcome these.

Table 5.1: CARI guidelines: Published guideline topics

Chronic Kidney Disease	Dialysis	Transplantation
<ul style="list-style-type: none"> • Prevention of progression of CKD • Nutrition and growth • Cardiovascular risk • Vitamin D, calcimimetics and phosphate • Urine protein • Kidney stones • Renal vasculitis • Type 2 Diabetes 	<ul style="list-style-type: none"> • Acceptance onto dialysis • Biochemical and haematological targets • Dialysis adequacy • Peritoneal dialysis associated peritonitis • Vascular access 	<ul style="list-style-type: none"> • Deceased donor suitability • Cytomegalovirus and kidney transplantation • Calcineurin inhibitors in kidney transplantation • Living kidney donor suitability

Figure 5.1: Guidelines and the decision making process of nephrologists

Discourages use

Guideline factors

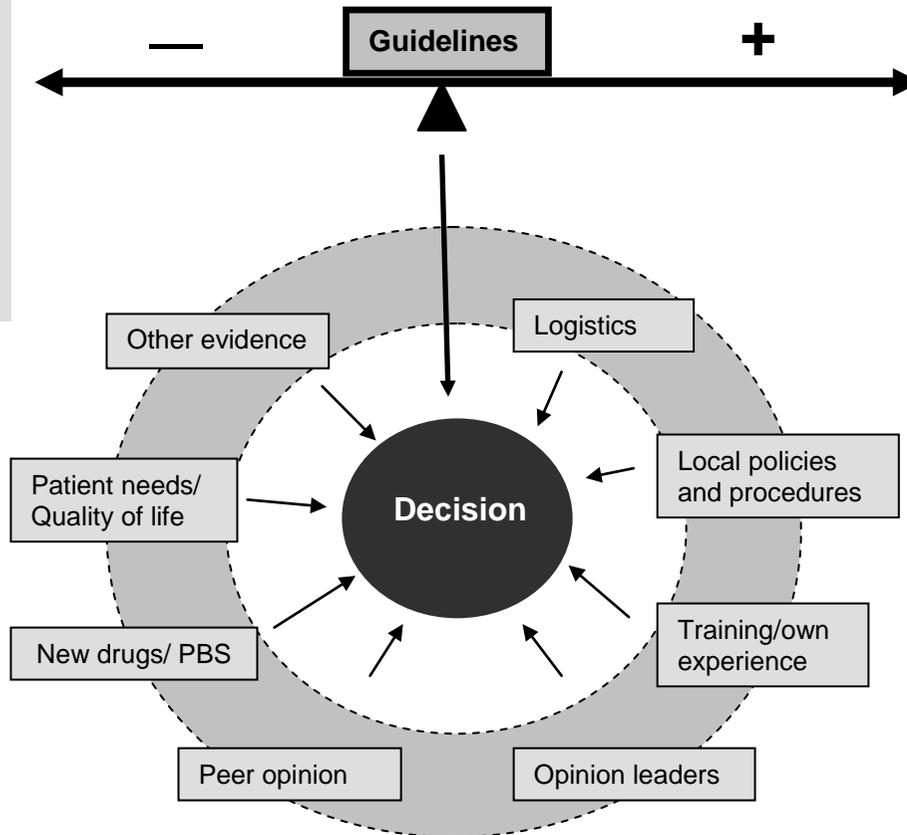
- Weak evidence-base
- Lack of targets
- Too detailed
- Out of date

Setting

- Conflicts current practice
- Insufficient resources for implementation
- Unsupportive peers

Dissemination and implementation

- Lack of audit and feedback
- Difficult to access



Encourages use

Guideline factors

- Strong evidence-base
- Clinical targets
- Suggested protocols
- Up to date

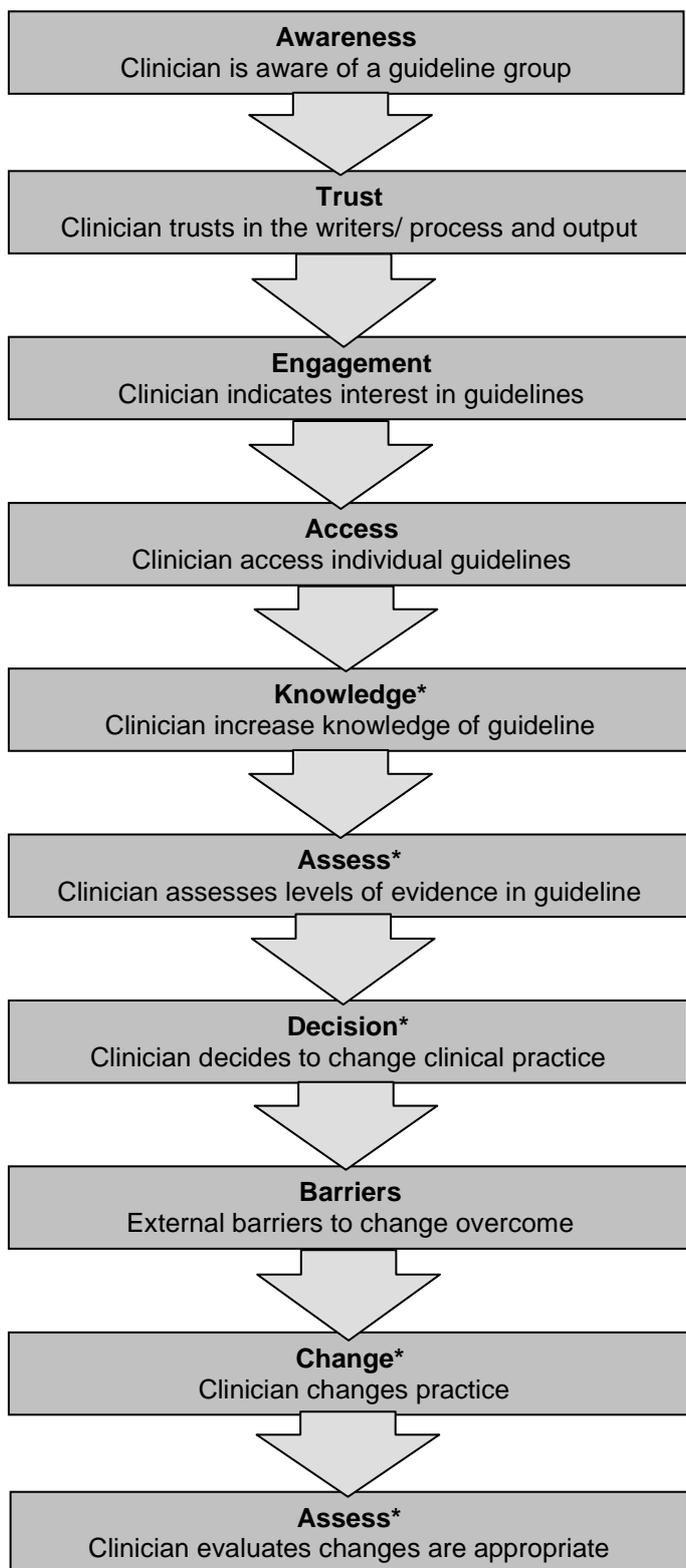
Setting

- Nurses experienced in using guidelines
- Local resources available for implementation
- Supportive peers

Dissemination and implementation

- Audit and feedback
- Easily accessible
- Reminders sent

**Figure 5.2: Clinician's process of change:
Implementation of guidelines into practice**



*- Based upon Rogers' diffusion of innovation

5.6 References

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6.0 Implementation of the clinical practice guideline for iron management in Australian renal centres

6.1 Abstract

Aim: To evaluate the effectiveness of a multifaceted intervention strategy to implement the Caring for Australasians with Renal Impairment (CARI) guideline on iron management in Australian kidney renal centres.

Methods: After a baseline study of six Australian centres, three centres (active implementation centres) agreed to review their iron management practices with the view to implement the CARI iron guideline. In each unit this occurred by developing a locally applicable protocol led by a nephrologist, obtaining multidisciplinary consensus across the unit about an implementation strategy, education, audit and feedback of data on two occasions, and the offer of a computerised decision support system targeting iron and ESA management. The other three centres (current practice centres) continued to be monitored after the baseline study, but did not change practice. Ferritin, transferrin saturation and haemoglobin values were measured at baseline and twice during the 18 month intervention period. The primary outcome was the difference in median ferritin values for all patients and proportions within guideline targets between the active and current practice centres for patients

on ESA. Collectively the six centres care for 1800 dialysis patients or about one-quarter of all dialysis patients in Australia.

Results: Median ferritin values increased from 245 to 306 μ g/L ($p<0.001$) in the active centres and decreased from 396 to 370 μ g/L ($p=0.03$) in the current practice centres. The proportion of patients within the guideline target for ferritin increased in the active centres (from 39.2% to 51.8%, $p<0.001$) but decreased in the current practice centres (from 62.9% to 52.7%, $p=0.004$). Percentage transferrin saturation and haemoglobin concentration did not change appreciably across all 6 centres.

Conclusion: Significant and large scale changes in iron management practices, leading to an increase in the proportion of patients whose ferritin levels are within guideline recommendations, can be achieved with active implementation using a senior motivated clinician-project leader and addressing barriers to change.

INDEX WORDS: Kidney disease; guidelines; implementation; iron; evidence-based medicine; CARI

6.2 Background

Iron deficiency occurs in a large proportion of chronic kidney disease (CKD) patients[1] and is associated with lower overall quality of life.[2] A specific guideline for the management of iron was produced by the Caring for Australasians with Renal Impairment (CARI) guidelines[3] in 2000. The guideline was updated in 2006 and recommended ranges for iron indices were modified. [4] CARI iron guideline recommendations are summarised in Box 6.1.

Despite the increasing availability of evidence-based clinical practice guidelines that aim to improve outcomes for patients with CKD[5-9], gaps between recommended and actual practice persist.[10-13] A baseline study of iron management in six Australian renal dialysis centres in 2004 [12]showed varying levels of concordance with the relevant CARI guideline. Across all centres, 30-68%, 65-73% and 25-32% of patients had ferritin, transferrin saturation (TSAT) and haemoglobin levels, respectively, within the then target ranges.[12]

Research on guideline implementation methods has not revealed any single effective method, [14, 15]reflecting the diversity of barriers that impede changes in practice. [10, 12]This is a follow-up study to evaluate an approach to the implementation of evidence-based guidelines for iron management in the six Australian dialysis centres. The approach addresses barriers to

guideline implementation that were outlined in the baseline study using a combination of methods.

6.3 Methods

This study used the theoretical basis of the Precede-Proceed Model.[16] The Precede-Proceed Model is composed of 5 Precede phases and 4 Proceed phases. Phases 1 to 5 involve the assessment and identification of the barriers and enablers within the participating units at the various levels which were identified in the baseline study. This study builds on these preparation phases and includes phase 6, the implementation phase, and phases 7 to 9 which evaluate the implementation process, the impact and the outcomes of the implementation strategies.

Participating centres: The participating centres comprised six renal dialysis centres in New South Wales, Victoria and the Australian Capital Territory.

More details of centre selection can be found in the baseline study[12], but in brief, centres were chosen from a selection of interested and invited units in Australia, which serve more than 1,800 dialysis patients per year (23% of all dialysis patients in Australia). Data on iron indices collected for the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA) in March 2004 was accessed previously and used as a baseline[12]. Centres involved in the baseline study self allocated to active implementation or continued monitoring only. Three of the six centres initiated a review of their protocols and practices with the aim to implement the CARI guideline targets for iron indices (centres A, B and C). Staff in these three units indicated that they believed they could and should improve their iron management practices. These Centres were designated active implementation centres. The other

three centres agreed to continue monitoring their iron indices only (centres D, E and F). Staff in these centres indicated that they believed their iron management was satisfactory and these centres were designated current practice centres and acted as controls in the study. All six centres were followed over a study period of September 2004 to October 2007, with timing of the intervention varying between the centres, this included time after the final data collection period in December 2006, for qualitative discussions and analysis with the project team from each unit. All current haemodialysis, peritoneal dialysis and home haemodialysis patients at the time of each data collection time point were included in the study.

Outcomes: Outcome and impact variables were measured and reported. The primary outcome measures were changes in median ferritin values for all patients and proportion of patients who were within the appropriate CARI guideline target for patients on erythropoiesis stimulating agent (ESA) eg. Epoetin alfa, Epoetin beta, Darbepoetin alfa. Other outcome variables were percentage transferrin saturation (TSAT) and haemoglobin levels. Impact variables, or behavioural changes, were analysed for active implementation centres. These were whether or not attainment of multidisciplinary agreement on target iron levels was achieved, whether there was adoption of a proactive, nurse driven iron management protocol, and whether a decision aid was used.

Intervention: In each active centre the guideline was implemented by a local nephrologist who led the initiative through the development of a locally applicable, iron management protocol that proactively kept iron indices within

targets. The local nephrologist was chosen on their leadership role they had within their centres availability to complete the project. They were to obtain multidisciplinary consensus across the Centre for the developed protocol and educate relevant staff. A powerpoint presentation was provided to each local nephrologist as audit and feedback to present to their unit on two occasions throughout the study. This contained data on median ferritin, haemoglobin, transferrin saturation as well as percentages within guidelines for these parameters for all units (de-identified for all units except recipients unit) There was also an offer of a computerised decision support system (CDSS) targeting iron management that provided suggestions for iron and erythropoiesis stimulating agent (ESA) dosing for individual patients to assist with the process. The CDSS was based on a protocol that proactively kept iron within guidelines and was nurse driven.

An individual unit approach was utilised to assist implementation, regular contact was made between study staff and the active centres to discuss any unique barriers to their circumstances and ideas were discussed to overcome these. A summary of these strategies are outlined in box 6.2.

The current practice centres D, E and F, received no intervention but their iron related outcomes were monitored. All centres were informed of new iron target ranges introduced in the updated CARI Guideline in April 2006.

Iron indices data were collected by units at 2 time points, March 2006 and December 2006. Centre E did not provide data for the December 2006 data

collection point. Data was assimilated and summaries were sent to each project leader in each active implementation units and Department Heads in both active implementation and current practice centres.

Statistical analysis: Renal centres were compared descriptively using proportions within CARI guideline targets and using medians and interquartile range. Statistical testing was by Pearson's Chi-Square test for proportions, and Kruskal-Wallis test for continuous data. A non-parametric approach was necessary for quantitative parameters due to skewed distribution of some parameters. For consistency this approach was adopted for the analysis of all quantitative parameters. Statistical analysis was completed using SPSS software, version 13 (SPSS Inc, Chicago Ill, USA) and SAS statistical software version 9.1 (SAS Institute Inc., Cary, NC, USA).

6.4 Results

Follow-up data was collected for 1642 eligible patients in March 2006 and 1625 eligible patients in December 2006. The impact and outcomes of the intervention in the active centres is summarised below and compared to the current practice centres.

Impact analysis

Both centres A and B achieved all of the proposed strategies (items c-e in box 2). Agreement on target iron levels was reached amongst the nephrologists and other staff, the intervention protocols that were adopted, proactively kept iron indices within guidelines and were nurse-driven; and a decision aid was used. Centre A implemented the study designed CDSS, and multidisciplinary agreement for this was reached in July 2006. Centre B developed, trialled and implemented a protocol developed in-house, agreement for which was reached in October 2005. Centre C did not achieve these during the study period. They trialled various protocols during this time, but final multidisciplinary agreement on one protocol was not reached at completion of the study.

Management of iron remained unchanged throughout the study in current practice centres, centres D and F. Centre E's protocol remained constant but they ceased to employ a nurse with responsibility for iron-related data collection in early 2005

Iron indices

Iron indices, for all renal centres, are shown in table 6.1 for the study period. Overall there was an increase in the median ferritin concentrations in the active implementation centres (245-306 mg/L, $p < 0.001$) and there was a small decrease in median ferritin levels in current practice centres (396-370mg/L, $p = 0.03$) (figure 6.1). The proportion within guideline targets for ferritin for patients on ESA, increased from 39.2% to 51.8% ($p < 0.001$) in active Centres (Table 6.2) and decreased from 62.9% to 52.7% ($p = 0.004$) in current practice centres. At baseline, active and current practice centres differed in the proportion of patients within the guideline target for ferritin (39.2% and 62.9% respectively, $p < 0.001$), but not at completion of the study (51.8% and 52.7% respectively, $p = 0.8$).

Overall haemoglobin concentrations in active implementation centres values remained stable in active and current practice units. Percentage transferrin saturation, though increased slightly in current practice centres ($p = 0.02$), but remained stable in active implementation centres ($p = 0.2$), (Table 6.1).

Data regarding ESA use was able to be collected for Centres A-D only in the March and December data collections, but not at baseline. Between March and December there was a slight decrease in mean ESA use, per week, in centres A-C, but this was not significant (Unit A: 50.2-49.1 mg/L/week/patient, $p = 0.7$; Unit B: 56.8 – 48.1 mg/L/week/patient, $p = 0.5$ and Unit C: 52.1- 48.8 mg/L/week/patient, $p = 0.2$) (Unit D: 38.4-39.0 mg/L/week/patient $p = 0.9$).

6.5 Discussion

Changes in iron management practices through the use of multiple implementation strategies, including audit and feedback, targeting barriers and led by a senior project leader has led to an increase in median ferritin levels and a significant increase in the proportion of patients who were within the appropriate CARI guideline targets.

We did not evaluate the contribution of the individual components of the multifaceted intervention, but the use of opinion leaders, such as in this project, is considered to be a useful implementation strategy for specialised groups such as chronic kidney disease[17-19]. Gold et al 2007 found that an internal '*champion*' was necessary to move research into practice[20].

Opinion leaders should belong to a professional group, should be senior, and should have professional and academic qualifications [18, 19]. In this study we used a self appointed approach in choosing opinion leaders. Assistance from an external body, such as CARI, may also have been a contributory factor in producing a positive result. CARI provided audit and feedback and administrative duties, such as data assimilation for the units involved in this study, possibly reducing some time constraints and fostering the change in practice.

Despite suggesting that local agreement on what targets within the guideline would be adopted, there was still some disagreement on the guideline in all units. All three Centres' protocols that were, either implemented or trialled

differed and utilised targets from different parts of the guideline. None of the centres aimed to attain the TSAT guideline target as they expressed the belief that there was not enough evidence to support this part of the guideline.

Disagreement with guideline recommendations should be ascertained at the outset of implementation projects, and if present, is a highly probable barrier to implementation. Strategies such as education could be employed to help overcome this.

The role of guidelines in clinical practice is informative and there is little data on the proportion of patients that clinicians should aim to be within guideline recommendations. This will be determined by the predominant case-mix and severity of disease. Clearly there are circumstances where it is difficult to adhere to guidelines such as patients with co-existing conditions, infections, or where quality of life is a major consideration. This should be taken into account when analysing adherence to guideline recommendations.

The aim of achieving target iron management parameters (such as ferritin and TSAT) is to reach haemoglobin concentrations with the minimal use of erythropoiesis stimulating agents for the individual patients. Haemoglobin levels are mainly influenced by the use of an ESA, but adequate iron stores can reduce the amount of costly ESA required to achieve the desired target haemoglobin range. [21] In our study we documented slight to moderate increases in haemoglobin levels in the active implementation centres. As ESA dosages were not ascertained at baseline we cannot be sure whether this haemoglobin increase was due to the increases in iron stores and availability

or an increase in ESA dosage. Although it can be noted that ESA use did not change between March and December data collection points in centres A-D, leading to the conclusion that the increased iron parameters may have had the greatest effect.

The audits of iron indices were de-identified; therefore, we could not match patients to their iron results across the three data sets. The statistical analysis is therefore conservative in that it assumes independence between subjects which we know to be not literally correct. The analysis is however unbiased. Sensitivity analysis of this assumption has been undertaken by assuming modest and moderate degree of correlation between time points. Also, due to the de-identified nature of the data, it could not be analysed to test for a clustering effect by clinicians [22]. The revised CARI guidelines published in 2006 reduced the ferritin target for patients on ESA from 300-800mg/L to 200-500mg/L, which would have accounted for some of the changes in the percentage of patients within CARI targets between baseline and final study results. No attempt was made to compare the case-mix among the centres. This is despite some baseline differences in patient characteristics. Such as; centres B and C had lower baseline Hb levels; centres A and B had lower ferritin levels than the other units.

The greatest degree of change was seen in those units whose baseline results were below the CARI guideline recommendations. These two units also achieved all the proposed strategies for implementation demonstrating an

overall greater relationship with achievement of strategies and attainment of outcomes.

This study shows that with a senior motivated project leader, audit and feedback, targeting barriers and the use of a decision support system, increases in the proportion of patients within appropriate guideline targets is possible. Support from an external body such as CARI may be of assistance but cannot provide the impetus for the implementation within the individual unit. We could highlight the issues and target and facilitate people who could be part of the solution. It is important to gain multidisciplinary agreement on targets and protocols to be implemented.

Box 6. 1: CARI Guidelines – Iron target:

- Achieve and maintain haemoglobin above 110 g/L but not over 130g/L

Recommended Iron stores:

	Prior to starting ESA	During ESA therapy
Serum ferritin	> 100 µg/L	200–500 µg/L
TSAT	> 20%	30–40%
% hypochromic red cells	< 10%.	< 2.5%

*ESA=Erythropoiesis stimulating agent

Box 6.2: Strategies proposed to target barriers to changing iron management in the three active implementation centres.

(a) The offer of a computerised decision support system (CDSS) to assist with implementation of protocols for iron and Erythropoiesis stimulating agent doses; and

(b) Regular contact with study staff to discuss any barriers to improving iron management and possible solutions.

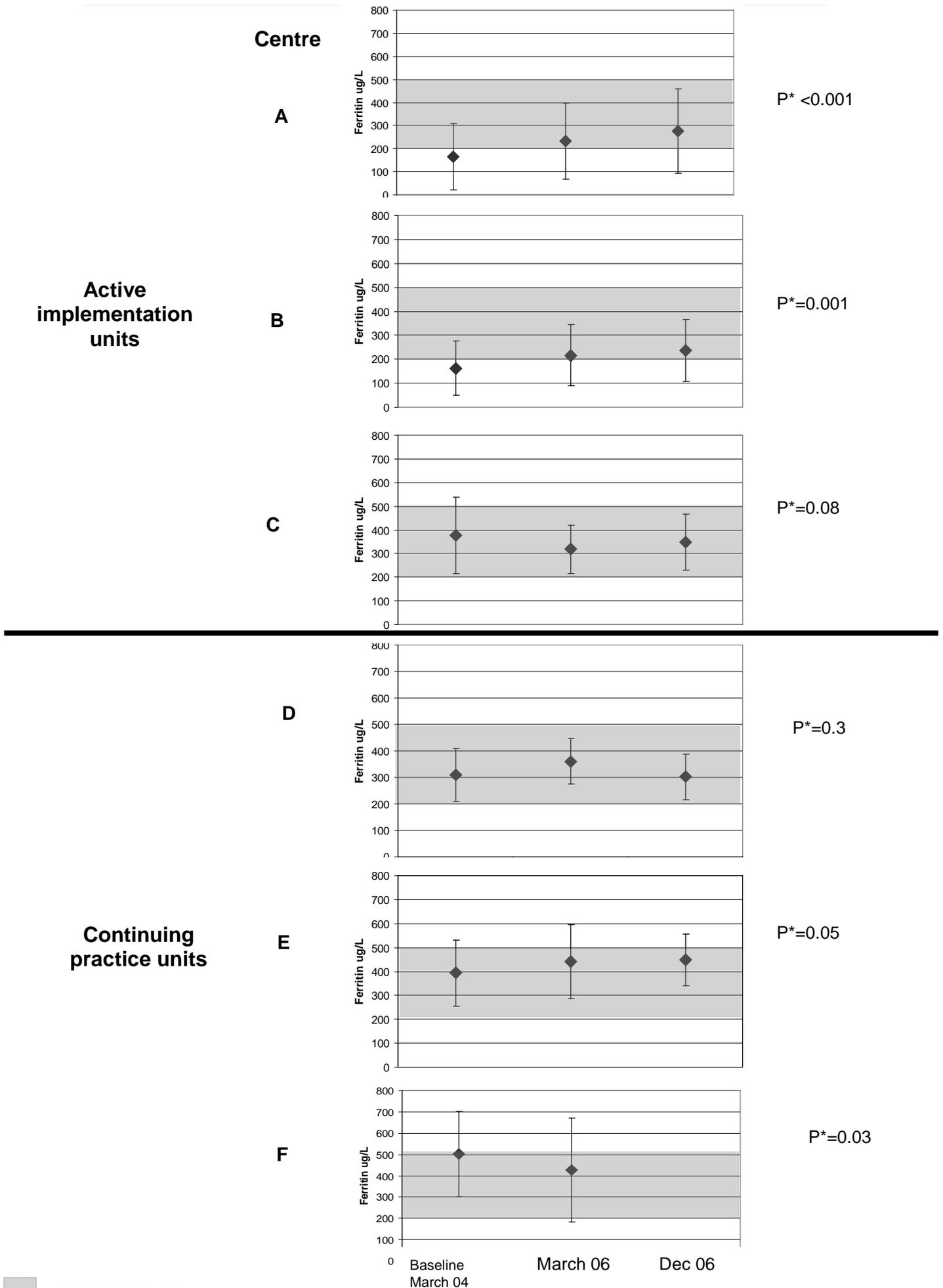
Centres were to:

(c) Prepare a written iron management protocol;

(d) Educate staff on iron management;

(e) Attain multidisciplinary agreement for the introduction of proactive nurse-driven protocols;

Figure 6.1: Median ferritin values (with interquartile ranges) during study period



= 2006 CARI Ferritin target

*Kruskal-Wallis test used for univariate analysis between data collection points in time in each unit.
NA: Data not available

Table 6.1: Comparison of iron indices (median) during study period

		Active Implementation centres				Current Practice centres			
Iron indices		Centre A	Centre B	Centre C	All	Centre D	Centre E	Centre F	All
Ferritin (µg/L)	Mar 2004	165(290)	163(225)	348(316)	245(326)	393(279)	501(401)	309(200)	396(314)
Median (IQR)	Mar 2006	233(327)	216(256)	319(205)	262(263)	441(310)	427(486)	360(172)	409(324)
	Dec 2006	276(369)	236(258)	347(237)	306(270)	449(215)	NA	303(165)	370(250)
	P[†]	<0.001	0.001	0.08	<0.001	0.05	0.03	0.3	0.03
Haemoglobin (g/L)	Mar 2004	119(23)	112(22)	116(20)	115(22)	121(21)	118(22)	120(22)	120(21)
Median (IQR)	Mar 2006	122(23)	113(25)	119(20)	119(22)	122(18)	118(18)	123(23)	121(18)
	Dec 2006	121(20)	115(24)	116(18)	117(20)	122(17)	NA	116(19)	119(19)
	P[†]	.07	0.08	0.02	<0.001	0.51	0.8	.068	0.4
TSAT (%)	Mar 2004	25(16)	25(14)	25(12)	25(13)	29(16)	23(13)	- [‡]	27(16)
Median (IQR)	Mar 2006	23(14)	26(14)	24(14)	24(14)	28(16)	22(11)	- [‡]	26(17)
	Dec 2006	26(13)	26(15)	21(12)	24(13)	28(19)	NA	- [‡]	28(19)
	P[†]	0.63	0.64	<0.001	0.2	0.27	0.02	- [‡]	0.02

IQR=interquartile range; TSAT=transferrin saturation, [†] Kruskal-Wallis test used for univariate analysis among units and within variables between times. [§] Units represented: the Canberra Hospital, ACT; Central Coast Area Health service, NSW(Gosford Hospital); State-wide renal services, NSW(Royal prince Alfred Hospital, Concord Hospital and Dame Eadith walker centre); Monash medical Centre, Vic; Royal Melbourne Hospital, Vic and Sydney west area Health Service, NSW(Westmead Hospital and Blacktown Hospital) [‡] Centre F does not routinely test for TSAT, NA=Not Available, Centre A: 2004 n=296, 2006 n=361, Dec 2006 n=307 Centre B: 2004 n=322, 2006 n=320, Dec 2006 n=323. Centre C: 2004 n=385, 2006 n=339, Dec 2006 n=450 Centre D: 2004 n=352, 2006 n=343, Dec 2006 n=151 Centre E: 2004:n=189, 2006:n= 167. Centre F: 2004 n=115, 2006 n=112, Dec 2006 n=127. Mar= March, Dec=December.

Table 6.2: Proportions of patients, receiving ESA within CARI target range* for ferritin in Active Implementation and Current Practice Centres at baseline and final follow-up

		% in CARI Ferritin target		
		March 2004 (95%CI)*	December 2006(95%CI)*	p‡
Active	Centre A	29.5(23.4-35.6)	38.5(31.3-44.5)	<0.001
	Centre B	26.0(20.5-31.8)	45.9(39.2-52.7)	<0.001
	Centre C	56.0(50.4-61.6)	63.0(57.8-67.7)	0.002
	Total	39.2(35.8-42.7)	51.8(48.3-55.4)	<0.001
Current practice	Centre D	69.1(63.8-74.2)	51.6(41.5-61.6)	0.002
	Centre E	59.2(51.2-67.1)	38.6(30.1-47.0)†	<0.001
	Centre F	50.0(40.5-59.4)	77.0(67.5-86.2)	<0.001
	Total	62.9(58.8-66.8)	52.7(47.0-58.3)	0.004
Difference between active and current centres		23.6(18.2-28.8) p<0.001	0.8 (-5.8-7.5) p=0.8	

*For patients on ESA -March 2004 target was: \geq to 300 mg/L to \leq 800mg/L and December 2007 target was: \geq to 200 mg/L to \leq 500mg/L.

‡ Pearson chi square test used to detect differences in proportions †March 2006 data

6.6 References

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7.0 Discussion and conclusions

7.1 Summary of findings

The papers that make up this thesis illustrate the complexity of implementing evidence-based guidelines in clinical practice relating to patients with CKD.

The research centres on attempting to understand the guidelines' target groups of clinicians and their needs for evidence-based recommendations.

The thesis also summarises the strategies that have been employed to promote guideline implementation in CKD.

The research can be summarised under the following three headings.

(1) Implementation of guidelines in chronic kidney disease. This encompasses a summary of strategies used, and identifies those strategies that are more effective.

(2) Attitudes and opinions of the nephrology professional community regarding guidelines. This asks (a) whether guidelines can influence practice, (b) whether guidelines can improve health outcomes for patients, (c) whether the CARI guidelines are perceived to be based on the best available evidence, (d) how guidelines influence clinical decision-making, (e) what other factors influence clinical decisions, and (f) what would facilitate the use of guidelines in clinical practice.

(3) Implementation research. This comprises of an evaluation of the practical application of implementation strategies in Australian renal dialysis centres.

7.1.1. Implementation of guidelines in CKD

Research on guideline implementation in CKD has grown steadily. The systematic review (Chapter 2) analysed 22 papers on this topic. The quality of the research methods was variable, but where all quality criteria were fulfilled, the effects of the intervention were clearer. The median effect size of all included studies was just over eight percent. Studies were classified as one of four major interventions – dissemination, audit and feedback, computerised decision support systems (CDSSs), and multidisciplinary teams (including an opinion leader). These different interventions varied in their effectiveness and the types of situations in which they are effective. CDSS seems to be highly effective for changes in drug prescriptions. The use of opinion leaders, multidisciplinary teams and audit and feedback seems to be effective when the interventions are well planned and executed with adequate numbers of support staff for the intervention. Dissemination of guidelines is effective to some degree, as it increases knowledge and awareness, and is an important first step. An active approach to implementation using various strategies to overcome all known barriers is advantageous.

7.1.2. Attitudes and opinions of the renal community regarding guidelines

The two surveys (chapter 3 and 4) showed that the vast majority of Australian and New Zealand nephrologists and renal nurses found the CARI guidelines to be a useful source and summary of evidence. Many respondents indicated the guidelines had significantly influenced their practice and increasingly

thought the guidelines had improved outcomes for patients. In comparison to a survey in 2002, the results of the 2006 survey showed a substantially more favourable attitude towards the CARI guidelines. Although nephrologists were very positive in their survey responses overall, the renal nurses were even more positive, in the range of 10-20% for many question domains. (Figure 4.2)

These results indicate that the production of rigorously evidence-based guidelines has been valuable. The formulation of guidelines that are credible to their target audience is an essential requirement for their use in practice. A positive evaluation by the end user is fundamental.

In the survey of nephrologists we found an attenuation of positive responses, from knowledge (90%) to practice (60%) to outcomes (40%). (Figure 3.2) To understand this result and to gain a clearer understanding of the role of guidelines in nephrologist's clinical practice we sought responses from the nephrologists themselves in face-to-face interviews (chapter 5). This affirmed a high level of trust in the locally produced CARI guidelines, which were written and evaluated by their peers. The guidelines had made contributions to clinical practice: they were educational, they provided an important framework for clinical practice by summarising the evidence well, they informed policies and procedures, and they encouraged patients' adherence to recommended treatment. However the guidelines usually confirmed practice rather than changing it, possibly accounting for the attenuation of responses found in the survey.

Overall, nephrologists were very positive about guidelines in general and the CARI guidelines in particular, and they appreciated the effort involved in developing them. However, they identified many other influences on clinical decision-making. These included the views of opinion leaders and peers, local (or institutional) policies and procedures, patients' co-morbidities and quality of life, and information from sources other than the guideline. It appeared that the use of guidelines in practice could be facilitated by the strength of the evidence on which the guidelines were based, audit and feedback, clear guideline targets, and practical recommendations with suggested treatment algorithms. Assessment of barriers at each step in the process of change is important. Resolution of these barriers depended on confidence in the guidelines, and engagement of clinicians in the guidelines and the assessment of the evidence.

From the interviews with nephrologists, it was found that nephrologists based in rural or remote areas faced difficulties not encountered by their metropolitan counterparts. Rural nephrologists rely on guidelines as a source of peer support, but they face extra barriers and a deficiency of resources as a consequence of location and logistics. Guideline developers should be aware of their heterogeneous user base and recognise the possible value of targeted additional support for rural nephrologists.

7.1.3. Implementation research

The study of strategies for the implementation of the CARI iron guideline (chapter 6) shows that increases in the proportions of CKD patients with iron parameters that fell within target ranges set out in the CARI guidelines could be achieved by specific strategies. These interventions included a senior project leader motivated to promote the guidelines, audit and feedback, the identification and resolution of barriers to implementation, and the use of a decision support system.

It seems that support from an external body such as CARI may be of assistance but cannot provide the impetus for the implementation within individual CKD treatment centres.

The use of a self appointed opinion leader was a successful method in this instance. Multidisciplinary agreement on guideline targets and the resulting clinical protocols is essential to their successful implementation into practice. The use of audit and feedback facilitated educational strategies within the centres and the identification and resolution of barriers to implementation were all influential factors in the achievement of increases in the proportion of patients whose iron indices were within CARI guideline targets.

These studies are in agreement with systematic reviews of these interventions. Audit and feedback produce moderate results.[1] The use of

tailored interventions is more likely to be effective when based on knowledge of the problem and setting[2] and the use of opinion leaders is comparable to other strategies.[3] All these reviews suggest that implementation studies include process evaluation to determine useful or not useful aspects of the intervention. In this implementation study, a process evaluation was undertaken and we were able to determine that the opinion leader needed to have seniority and be motivated to implement the changes required in the study. We also found the CARI as an external body could provide support for the project but not the internal impetus for the change.

7.2 Strengths and limitations

The work presented here involves qualitative research, surveys, a systematic review and an implementation trial. The surveys used standard methods for surveys as outlined in chapters 3 and 4. The qualitative research involved semi-structured face-to-face interviews, and the data obtained were analysed thematically. Data saturation was achieved by the time 16 interviews had been completed; a further three interviews were conducted to ensure that no new themes emerged. The systematic review involved both qualitative and quantitative analysis as very few similarities existed among the studies. The implementation trial showed increases in the proportion of patients with iron status indicators within target ranges.

A potential limitation of the surveys was selection bias. Seventy percent of nephrologists responded. A total of 173 nurses responded, but the size of the workforce population from which they were drawn was unknown. No information was available on the demographic and other characteristics of non-responders, so responders and non-responders could not be compared. Despite the large number of responses received from nurses, it is unclear whether they were representative of all renal nurses although a recent study indicated that the average age of Australian dialysis nurses is 43 years. This is very close to the estimated average age of the 2006 survey respondents (43.5 years).

A further limitation of some of the studies included in this thesis was their reliance on respondents' self-reports of the effects of clinical guidelines on outcomes, rather than an assessment of actual behaviour. They also relied on respondents' general impressions of the guidelines, rather than assessing attitudes to specific recommendations.

In the survey of nephrologists, participants were generous with their time and open to discussion of the guidelines and their applications in practice. However, transferability of the findings, especially beyond Australia, is uncertain, particularly in the absence of any comparable study in another setting. However, the findings are consistent with those of other qualitative studies of guideline users in other medical fields. We did not conduct multiple interviews with individuals. These could have captured evidence of changes in perspectives may have changed over time. As with any qualitative study,

we aimed to elicit a broad range of responses from differing demographic and geographical groups and purposive sampling was used. However, after 16 interviews, no new themes emerged, suggesting that the broad range of views amongst nephrologists had been revealed.

In the implementation trial, during the collection of the iron indices data, patient identifying data was not collected, so patients could not be matched across the three data sets. The statistical analysis, therefore, is conservative in that it assumes independence among subjects, while some inter-dependence exists. Further, de-identification of the data also prevented any test for a clustering effect centring on clinicians. The revised CARI guidelines published in 2006 reduced the ferritin target range for patients on ESAs from 300-800mg/L to 200-500mg/L. This would account for some of the changes in the percentage of patients within CARI targets between baseline and final study results.

7.3 Implications for practice

Previous implementation projects have yielded modest results, but they help to construct a theoretical basis for implementation, they provide a framework for understanding the barriers and they point to information that is relevant to guideline implementation in relation to CKD.

It is clear that the quality of the interventions to implement guidelines is a critical factor to the success of the implementation project. Continuing

research has fostered the development of theories that underpin the more successful interventions. The involvement of an opinion leader/in a multidisciplinary team had the greatest effect on improving patient outcomes, but the use of a computerised decision support system produced the most consistent effect in implementing CKD guidelines relating to drug administration. Evaluating barriers to implementation and targeting strategies at those barriers is critical for success.

Continuing evaluation of guideline development and implementation processes is essential. Input from guideline target groups, for example, through surveys of nephrologists and renal nurses, can both improve these processes and help to pinpoint impediments to guideline uptake.

The interviews with nephrologists described in this thesis represented the first substantive examination of clinical decision-making by nephrologists and the contribution of guidelines to it. Overall, nephrologists revealed much confidence in the guidelines, and this promoted their engagement with them.

The thesis also reports on the development of a model for the implementation of guidelines into clinical practice, based on Rogers' Diffusion of Innovation Theory, which includes trust in the guideline development process as a fundamental step. This theory should be used as guide to inform guideline groups as to how guideline users engage and use guidelines in clinical practice. Barriers that impede each step should be identified and resolved for the varying guideline user groups that exist. Differing guideline user groups for

the CARI guidelines may be: nephrologists, nurses, allied health professionals and rural or remote practitioners.

From the results of the surveys and interviews, many suggestions that would facilitate the implementation of the CARI guidelines in Australia and New Zealand were made. These encompassed how the guidelines themselves could be improved and what the CARI guideline group should do to facilitate implementation. These are as follows:

Guidelines should:

- Be based on strong evidence.
- Include suggestions for clinical care where guidelines were not possible (clearly labelled as suggestions to ensure that there was no confusion regarding the evidence base of the statements made).
- Include suggested treatment algorithms where appropriate, to be incorporated into policies and procedures and then into clinical practice.

The CARI guideline group should:

- Provide an audit and feedback mechanism for suggested guideline targets.
- Provide reminders and regular updates of new and current guidelines.
- Update the guidelines on a regular basis.
- Give an indication of the date when the evidence was last reviewed, and set out new relevant evidence, possibly in an attachment.

- Provide a “library of resources”, comprising relevant articles referenced in guidelines.
- Provide summaries of guidelines.
- Improve the CARI website to simplify navigation.
- Publish a guideline reference.
- Make a CARI representative available to present new guidelines to renal dialysis centre staff.
- Support rural nephrologists in implementation of guidelines.

7.4 Implications for research

This thesis could help to understand the influences on the implementation of guidelines for CKD patients, but there is more to be done. The next challenge for CARI lies in further evaluation of the implementation and outcomes of the CARI guidelines in Australian clinical practice.

Current work includes the implementation of the CARI guideline on vascular access in eight Australian and New Zealand renal dialysis centres. This builds on lessons learnt from the implementation of the guideline on iron management. An extensive analysis of barriers has been undertaken, and a database has been established specifically for the collection of vascular access-related data to provide timely feedback to renal dialysis centres on their attainment of targets. Peer influence is also used in the process of implementation to a greater degree, including regular face-to face meetings of

all participants in the project. Funding has been obtained to continue this implementation research through the implementation of the cytomegalovirus (CMV) guideline.

Further research is also needed into the role that renal nurses play in the implementation of guidelines, especially dialysis guidelines. A qualitative project should be undertaken that uses interviews or focus groups with renal nurses to gain a better understanding of how CARI can utilise this currently untapped resource in the implementation process.

Further surveys of nephrologists and renal nurses are required in the future to gather information on responses to the issues relating to the content, effect and structure of the guidelines and how this may change over time. The survey reported in this thesis could also be expanded to compare Australian and New Zealand practitioners' views on international guidelines and local guidelines.

7.5 Conclusions

In conclusion, this thesis provides a detailed understanding of the function of guidelines in CKD clinical practice, opinions and attitudes to guidelines and the best methods of implementation of guidelines in CKD. Australian nephrologists and renal nurses value guidelines and found that they were a good summary of evidence. They wanted to incorporate the guidelines into practice where possible, but there are many other competing influences on

clinical decisions. They had clear suggestions for facilitating the implementation process and were definite about circumstances where guideline use may not be appropriate.

Implementation of guidelines is possible and guideline groups should pursue this actively, utilising evidence-based implementation strategies.

Implementation of recommendations for the management of iron status was achievable using a senior, motivated project leader, audit and feedback, identifying and resolving targeting barriers, and the use of a decision support system.

Renal nurses are an important resource in the implementation process and more research should be aimed at determining the best methods for engaging this group in the implementation of guidelines process.

Rural or remote practitioners face barriers to guideline implementation that others do not. They should be targeted for continued support for the implementation of guidelines into their clinical practice.

Further research should continue to determine the best use of implementation strategies. Guideline groups should ensure guidelines are written using best methods that encourage implementation, such as the use of action statements and the provision of targets. Guideline groups should also foster close links with trials groups to facilitate a generation of evidence in required

clinical areas. Guidelines should be based on high levels of evidence, be kept up to date and assistance given to encourage implementation into practice.

7.5 References

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Appendix A – Supporting data for chapter 2

A1: Search Terms

1. kidney diseases/
2. kidney failure/
3. kidney failure, chronic/
4. chronic kidney.tw.
5. (kidney adj3 (insuff\$ or diseas\$ or failure)).tw.
6. (renal adj3 (insuff\$ or diseas\$ or failure)).tw.
7. pre-dialysis.tw.
8. predialysis.tw.
9. kidney transplantation/
10. graft survival/
11. graft rejection/
12. exp renal replacement therapy/
13. renal replacement therap\$.tw.
14. (hemodia\$ or haemodia\$).tw.
15. (hemofilt\$ or haemofilt\$).mp.
16. peritoneal dialysis/
17. dialysis.tw.
18. implement\$.tw
19. health plan implementation/
20. practice guidelines/
21. clinical guidelines.tw.
22. guideline adherence/
23. outcome assessment (health care)/.
24. process assessment (health care)/
25. evidence-based medicine/

A2: – Included studies: Audit and feedback: Intervention characteristics

Reference	Intervention	Frequency of exposure to intervention	Delivery of audit and feedback	Comparator	Timing of intervention (Months)
[21]	Reports: Centre specific information, practice patterns, comparisons to other centres, survival rates, age, gender, race distributions, cost saving opportunities, QOL for HD versus PD, complication and hospitalization rates by modality, physician specific information plus summaries of evidence associated with advantages of CAPD	Monthly for 12 months	By mail. Stamped, addressed post card to be sent back upon receipt of report	Reports: reports as for intervention BUT no summaries of evidence	12
[19]	Education/ follow-up: <i>Patient specific:</i> meaning and importance of adequate dialysis, feedback and recommendations. <i>Nephrologist specific:</i> Feedback and recommendations based on barrier analysis	Monthly for 6 months	Personal contact from study co-ordinator	No feedback /education	14
[15]	Clinical information reports: Results of audits against clinical performance measures. Networks required to translate audit findings into facility specific activities to improve patient care.	Yearly for 6 years	By Mail	Pre-implementation data	66
[20]	Report: Quality of care feedback report of audit findings on dialysis adequacy Educational workshops (2): Overview of project, barrier analysis presented to: Centre administration, medical director, director of nursing. Educational materials: For staff and patients- On: Haemodialysis adequacy and other resources to assist staff. Quarterly monitoring: Random survey of patients dialysis adequacy. Technical assistance: From trained staff from dialysis network. Quality Improvement coordinator: Was identified out of each unit who kept in contact with network staff.	4+ as needed	Through dialysis network staff. (US dialysis centres are divided into networks across the states – each network has overseeing staff)	Report: Quality of care feedback report of audit findings on dialysis adequacy	9
[25]	Unit-specific reports: Compilation of data from units on set quality domains. Modules: The development of modules for quality improvement for units to base their quality improvement on. 3 monthly reports on performance regarding main quality indicators.	Quarterly	Not outlined	Pre-implementation data	48
[24]	Quality improvement nurse intervention: First 10weeks: daily personal visits by quality improvement nurse. Pharmacist intervention: Next 10 weeks: daily written feedback sent to units by a pharmacist. Feedback: All feedback outlined any excessive medication dosages prescribed and what the prescription should be.	Daily for 21 weeks	Quality improvement nurse: In-person, Pharmacist: sent to printers in units.	Pre-implementation data	1.2

#- Data not available or occurred at end of intervention

A3 – Included studies: Computerized decision support: Intervention characteristics

Reference	Intervention	Participation	Comparator	Timing of intervention (Months)
[27]	Computerized alert system for medication errors Method: A minimum safe creatinine clearance was established for each inpatient formulary medication. Alerts recommending canceling when medication order was initiated for patients whose estimated creatinine clearance was less than the minimum safe creatinine clearance for the medication.	Physicians can bypass the alert and continue with prescription	Pre-implementation data	11
[14]	Computer assisted erythropoietin algorithm Method: Blood test results automatically downloaded into database. The program recommends changes to epoetin doses per patient according to dosing rules. Primary nurse reviews recommendations and 'signs' off or changes recommendations.	Physicians can opt in or out of the use of the algorithm for their patients and retain routine responsibility.	Pre-implementation data	4
[26]	Computerized decision support system for drug prescription Method: Adjusted dose list, default dose amount and default frequency and notations that adjustments were made based on renal insufficiency, were displayed on the usual computerized prescribing system.	Physicians can bypass the defaults and continue with prescription	Pre-implementation data	14

#- Data not available or occurred at end of intervention

A4: : Included studies: Opinion Leader/ multidisciplinary team: Intervention Characteristics

Reference	Intervention	Comparator	Length of intervention (Months)
[18]	Implementation of guidelines: Method: Nephrologists from 6 Renal units were randomized to develop and implement 2 of 3 guidelines and act as control for a 3 rd . Published guidelines, decision trees, barrier analysis, education on implementation methods was provided for Nephrologists.	Standard care	3
[28]	Implementation of a 'save the vein' project. Method: An endovascular surgeon was recruited to institution. An algorithm was created showing the best course of management for new haemodialysis patients. Education was provided for staff and patients	Pre-implementation	24
[31]	Implementation of program to improve the number of patients prepared for haemodialysis adequately, including timing of referral from Nephrologist to dialysis unit, timing of referral for vascular access, adequate pre-dialysis education Method: Creation of multidisciplinary teams lead by a trained team leader for each barrier above. Teams consisted of all levels of management and discipline, would met regularly to collect and analyze data, evaluation and formulate recommendations.	Pre-implementation data	39
[16]	Implementation of a protocol for the treatment of suspected urinary tract infections Method: Introductory Seminar: Background and aims of study, outline and summary of management guidelines. Support from nurse practitioner, provision of phase contrast microscope.	Standard care	20
[17]	Implementation of collaborative 'team' to reduce bacteremia complications of tunneled cuffed catheters Method: Creation of a team consisting of an infection manager and patient's Nephrologist. Recommendations for antibiotic cover and catheter management given.	Standard care	23
[32]	Implementation of K/DOQI clinical practice guidelines for bone metabolism through new protocol. Assumed use of opinion leader or management stipulation, methods not discussed. Methods: New protocol for management of serum Ca, phosphorous and iPTH	Pre-implementation	12-15
[30]	Implementation of multidisciplinary taskforce designed protocol based on K-DOQI guidelines. Method: 3 vascular access co-ordinators(VAC) visited units and educated teams at the start of the project and throughout, Multidisciplinary team created at unit level, identification of vascular access nurse to co-ordinate at the local level	Standard care	36
[23]	Implementation of a Quality improvement project (QIP)to improve dialysis adequacy Methods: Education on measurements of dialysis adequacy parameters, workshops to assist in methods of conducting a QIP at unit level. (mandatory for units considered to have poor dialysis adequacy, other units could participate but not mandatory)	Pre-implementation	12
[29]	Implementation of guideline for increased use of arteriovenous fistulas (AVF). Methods: Education sessions to all units involved on European guidelines for AVF creation, Translated summaries of the guidelines (English-Dutch), appointment of 0.1FTE vascular access co-ordinator who registered practice patterns, physicians could access their own practice pattern.	Standard care	13.3
[39]	Implementation of a network QI project to improve vascular access rates. Methods: face to face meetings with project staff, K-DOQI summary paper on VA, video and written information for patients and staff, post-op 'fistula care packages' educational meetings, data feedback.	Pre-implementation	12
[10]	Implementation of guideline for increased use of arteriovenous fistulas (AVF). Methods: Units with demonstrated low AVF rates. Nephrologists and surgeons asked to collaborate. root cause analysis(barrier analysis), intervention workshop meetings.	Pre-implementation	48

#- Data not available or analysis occurred at end of intervention

A5:: Included studies: Dissemination

Reference	Comparator	Intervention	Method	Study Time frame
[13]	Pre-dissemination data	The release of the K-DOQI guidelines on dialysis adequacy, anemia treatment and vascular access	Dissemination method not stated, but assumed to be journal publication and website	1994-2000
[33]	Pre-dissemination data	The release of the K-DOQI guidelines on bone metabolism	Dissemination method not stated, but assumed to be journal publication and website	Feb 2003-Sept 2004

A6: Quality* of studies: controlled before-after studies

	[27]	[39]	[10]	[14]	[15]	[13]	[26]	[28]	[31]	[24]	[25]	[30]	[33]	[29]	[23]	[32]
Criteria																
Baseline measurement	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done
Characteristics for studies using second site as control	N/A	N/A	Done	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Blinded assessment of primary outcome(s)	Done	Not clear	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done
Protection against contamination	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Reliable primary outcome measure(s)	Done	Done	Done	Not clear	Not clear	Not clear	Done									
Follow-up of professionals	Done	Done	Done	Not clear	Not clear	Not clear	Done	N/A	N/A	Done	Done	N/A	N/A	Done	N/A	N/A
Follow-up of patients	Done	Done	Done	Not clear	Not clear	Not clear	Done									
Consumer involvement	Not done	Not done	Not done	Not done	Not done	Not done	Not done	Not done	Not done	Not done	Not done	Not done	Not done	Not done	Not done	Not Done

*Source of criteria: Cochrane Effective Practice and Organisation of Care Review Group data collection checklist [11]

A7: Quality* of studies: Randomized controlled trials and controlled clinical trials

Criteria	[21]	[18]	[16]	[20]	[19]	[17]
Concealment of allocation	Done	Not clear	Not clear	Done	Done	Not clear
Follow up of professionals	Done	Done	Done	Done	Done	N/A
Follow up of patients	Done	Done	Not clear	Done	Not done	Done
Blinded assessment of primary outcome(s)	Done	Done	Done	Not clear	Done	Done
Baseline measurement	Done	Not clear	Done	Done	Done	Done
Reliable primary outcome measure(s)	Done	Not clear	Not clear	Not clear	Done	Done
Protection against contamination	Not clear	Done	Done	Done	Not clear	Done
Consumer involvement	Not done	Not done1`				

*Source of criteria: Cochrane Effective Practice and Organisation of Care Review Group data collection checklist[11]

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Appendix B – Supporting data for Chapter 3 and 4

B1 – Survey questions

The CARI Guidelines feedback survey for ANZSN Members: 2006



Dear Colleague,

We are gathering thoughts and opinions on the impact and future direction of the CARI guidelines. Feedback is **an essential part of the guideline process** and will ensure that the guidelines that serve our industry are sound; evidence based and is readily available for ease of use.

It would be most appreciated if you could complete this **short 5 minute survey**, giving your feedback on the CARI guidelines currently and your thoughts for future direction. This survey is voluntary but will be most useful if everyone participates, your time on this is appreciated and your answers will be kept strictly confidential.

If you have any concerns please contact Michelle Irving (details below) or Carolyn Casey (+61 2 9845 1316) Secretary of the Ethic Committee that has approved this project.

Please post or fax your completed form to us (details at end, or use reply paid envelop enclosed). **OR** You can also go to the CARI website (www.cari.org.au) and **complete the survey online**.

Please indicate, **with a mark in the box**, **Ü** the level to which you agree or disagree with each statement and make comments as required.

Kind regards,

A/Prof Rowan Walker
On behalf of the CARI Guidelines Steering Committee

POST TO:

Michelle Irving
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The Children's Hospital at Westmead
Locked Bag 4001
Westmead NSW 2145
AUSTRALIA

FAX TO: + 61 2 9845 1491

EMAIL TO: michelli@chw.edu.au

THE EFFECTS OF THE GUIDELINES:

1. The CARI guidelines have significantly influenced the way I practice.

Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree

Comments: _____

2. The CARI guidelines provide a useful summary of evidence from which to draw information to help me in my clinical practice.

Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree

Comments: _____

3. The CARI guidelines have significant medicolegal implications for my practice.

Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree

Comments: _____

4. The CARI guidelines have provided useful leverage for obtaining additional resources/funding for my patients.

Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree

Comments: _____

5. The CARI guidelines have improved health outcomes for renal patients.

Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree

Comments: _____

STRUCTURE AND CONTENT OF THE GUIDELINES:

6. The CARI guidelines are too broad and general to readily apply to my individual patients.

Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree

Comments: _____

7. I think the CARI approach to evidence-based medicine is too restrictive.

Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree

Comments: _____

8. The treatment recommendations in the CARI guidelines and suggestions for clinical care do not adequately match the evidence.

Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree

Comments: _____

POSSIBLE CHANGES TO THE STRUCTURE AND CONTENT OF THE GUIDELINES:

9. Currently CARI guidelines are written only from evidence from Randomised Controlled Trials (RCTs). In areas without evidence from RCTs, I would prefer recommendations to be made based on best available.

Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree

Comments: _____

IS THERE ANYTHING ELSE YOU WOULD LIKE TO COMMENT ON?

Thank you for taking the time to complete this survey

Appendix C – Supporting data for Chapter 5

Appendix C1: Recently published Qualitative studies on implementation of guidelines

Paper	Target population	Health area	Data gathering method	Aim	Questions asked	Results
[1]	GPs England n=49	Asthma Angina	Interview	To explain rapid implementation of guidelines in both intervention and control groups in an implementation study	Attitudes to guidelines. Changes they had made to practice. Knowledge of guidelines. Formal or informal processes for gathering, sharing and acting upon information.	Most welcomed guidelines Passed some guidelines to nurses then thought little of them. Guidelines that impacted on their everyday treatment were more likely to be adopted. Having to record their decisions meant they had to 'think' more.
[2]	GPs Netherlands n=15	cardiovascular	Semi-structured in-depth interviews	Barriers to GPs following cardiovascular guideline	Awareness of problems they had encountered when implementing guidelines. motivations for deviations from the guidelines	Barriers to implementation: Guidelines itself, environmental factors Deviation from guideline: Lack of knowledge, poor communication (on behalf of GP), work pressure & demanding patients.
[3]	GPs Canada n=13	Cancer	Group interview n=5	Understand which guideline topics GPs considered important in terms of content, format and dissemination	Not given	Screening guidelines were the most requested, followed by treatment. Rural GPs requested follow-up guidelines. Guidelines should be formatted for GPs to quickly identify relevant content. Patient guidelines should only be offered where there is strong evidence, are clearly written and complement GP version. Dissemination was requested to be computer-based.
[4]	GPs Australia n=49	Asthma	Group interview n=6	Priorities for achieving optimal asthma care and barriers they face in delivering this.	"What do you think is needed to achieve best outcomes for asthma care?"	Pt and GP education, pt review, negotiated tmt/mngt plans, medication adherence. Written asthma plans were not a priority.

[5]	GPs England n=13	Asthma angina	Semi- structured interview n=19	Understand factors influencing the adoption of a computerised decision support system (CDSS)	Use of the computer, use of guidelines, experience using the CDSS- both their own and colleagues.	Computers in general were considered a great method, but the 2 CDSS's discussed were both not considered to be useful. They were not easy to navigate, were triggered at inappropriate times during consultation and information was not helpful.
[6]	GPs US n=10	CKD	Semi- structured interviews Exit interview	Adoption of K- DOQI guidelines	Full questions given- Definition of CKD, diagnosis, monitoring, severity, prognosis timeline, complications, follow guidelines, criteria for referral.	Lack of awareness of guidelines – none used regularly, desire for more guided care, persistence of traditional, less accurate diagnostic procedure, variability in the treatment of complications, uncertainty of timing of referral.
[7]	Nurses – Ireland n=17	Intensive care	Focus groups n=6	Explore the relationship between guidelines and actual practice.	Not given - Used a guidelines on endotracheal tube suctioning as example	Guidelines were adapted according to professional judgement and experience. Senior nurses thought junior nurses would find the guidelines useful. Senior nurses were the most likely to deviate from the guideline.
[8](pilot study)	GPs and their practice nurses n=3 Patients n=4	Low back pain	Workshops 1.GPs +nurses 2. Patients	Explore attitudes to back-pain guidelines and the proposal of a nurse-led service	Not given	GPs and nurses rejected the guideline and the proposal of nurse-led service. Patients did not relate nurses with assistance with their back-pain.
[9]	Surgical trainees n=28	Evidence- based medicine	Focus groups n=8 semi- structured interviews n=20	Examine surgical trainees barriers to implementing and adopting evidence- based medicine.	What does the practice of EBM mean to you? What are the things you most need to learn about EMB? What challenges have you had incorporating EBM in your day to day surgical program? Do you see ways to improve or better integrate EBM into your	Barriers: Perceived lack of education in EBM, time constraints, lack of priority, fear of staff disapproval, lack of ready access to surgical EBM resources. Strategies: Staff surgeons with EBM training, coursework in critical appraisal for all staff, improving interdepartmental communication, greater flexibility for EBM training.

					surgical training?	
[10]	GPs Israel n=38	Low back pain (LBP) guidelines	Focus groups n=4	Identify barriers and facilitators for implementation of LBP guidelines from GPs perspective	Not given	GPs had an overall positive attitude to LBP guidelines. The patient-doctor interaction determined the outcome of the encounter. Patient and GPs agendas are often at odds. It is sometimes easier to send a patient for an x-ray rather than follow the guidelines and convince the pt that no action is needed.
[11]	Doctor Canada (GP, internist, surgeon) n=45	Clinical practice guidelines	Semi- structured interview n=45	Understand why doctors did/did not implement innovations such as guidelines	Attitudes, opinions and behaviour regarding guidelines. recount specific experience where they did/did not adopt a guideline in practice	Will implement if in an area of perceived need for change, is based on properly interpreted evidence without increasing risk, opinion leaders adopt, guideline is consistent with current trends, patients/families demand it and is supported by the system ie technology, resources or training,.
[12]	Residents and specialists in pulmonology and internal medicine Netherlands n=18	Pneumonia	Semi- structures interviews n=18	Understanding of factors influencing adherence to community- acquired pneumonia (CAP) guidelines	Doctors were asked to present a recent CAP patient. Perceived barriers to use of guidelines at all levels (patient, doctor, system, guidelines)	Barriers: lack of agreement with guidelines, out of courtesy no one criticises others prescribing, social pressure, organisational issues, delays in lab results, IV drips not started, lack of awareness, distrust in lab results.
[13]	Nursing home staff North Carolina USA n=35	Nursing Homes	Interviews n=35	Identify barriers and facilitators of diffusion of CPGs and protocols in nursing homes	Awareness and attitude to CPGs, barriers and facilitators to adoption. "Can you think of a time when you thought about using a CPG but didn't? Staff were asked to describe the care for a resident in 3 areas where CPGs were available.	CPGs were not used at all in 3 of the 4 studied nursing homes. 3 of 35 interviewed were familiar with CPGs. Resident/family preference can prevent CPGs being used. A checklist of appropriate management was thought to be useful. CPGs may empower nurses to take initiative. Lack of staff meant protocols were often unused. Numerous protocols overwhelm staff.

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Appendix C2 – Suggested questions guide

START INTERVIEW

1. Tell me about your role in [the unit]

2. Can you think of an example when you decided to change your approach or management of an existing CKD patient?
 - a. What change did you make?
 - b. What prompted this change?
 - c. How did you go about it?

3. If they have mentioned guidelines already:

You mentioned guidelines

What role do guidelines play in your day-to-day patient management?

How do guidelines relate to other elements of your decision making?

What other resources do you use to make clinical decisions?

If they haven't mentioned guidelines already:

You have mentioned a number of factors that are important in patient management decisions: [list them here, based on what they have told you in the previous question].

Do you draw on any other resources when you're managing a patient with CKD?

-If guidelines are mentioned: probe – “What role do guidelines play in your day-to-day patient management?”

-If guidelines aren't mentioned: probe “How about guidelines? What role do they play in your day-to-day patient management? What difference do they make to patient outcomes, in your experience?”

4. You make many patient decisions over a day and there are many factors that influence these decisions. What role do guidelines play in these decisions that you make? What are some other major influences on these decisions?

[Probes if needed:

- a. Opinion leaders?
- b. Other staff
- c. Other guidelines?
- d. Other evidence?

5. Imagine that a new guideline is about to be published.

How would you typically become aware of such a guideline?

[Ensure they focus on the process – how might it happen?]

What draws you to a guideline?

What makes you read it?

What makes you seek it out?

6. Can you think of a guideline that has been very influential on practice across your whole practice/unit?

Could you tell me the story of how it came to be adopted?

[Probes if needed:

- § What happened?
- § Who in the clinical team was important to the adoption?
- § How did the process of adoption work?
- § What was it about that particular guideline that led to it being adopted?]

I want to understand the role of guidelines in your unit?

7. Is there a guideline that has influenced you personally, in your practice?

[IF NO – next question]

[IF YES]

Think back to before you knew about the guideline.

Can you tell me the story of how you came to incorporate the guidelines in your practice?

[Probes if needed:

§ how did you find out about it?

§ how did you implement it?

§ what difficulties did you face with implementing this guideline?]

What was it about that particular guideline that led to you taking it up?

I want to understand the role that guidelines play for you personally?

8. What role do you see guidelines having in nephrology today, globally?

9. Do you find some guidelines more useful than others? I.e guidelines with targets

Which ones?

Why?

10. You've told me about guidelines that you have implemented, but what about a guideline that wasn't taken up. What led to it not being taken up? Has there ever been a new guideline published that you have decided not to use in practice? Can you tell me about that? [as above]

PROBE: Guidelines can consolidate ideas or can be different to expectations, have guidelines ever been able to change your views?

11. Can you give me some examples of where you may possibly agree with a guideline, but deviate from it for a particular patient or patient group?

How do you feel about deviating from the guideline?

12. In your experience, how relevant are guidelines to patient outcomes?

13. How do you feel about the CARI guidelines in particular?

14. How do you feel about the CARI guidelines now as compared to 5 years ago?

15. **[Provide copy of your guideline]**

Looking at this particular guideline:

- a. What is your first reaction to this guideline?
- b. If you could give the authors of the guideline some advice, what would you tell them?

16. We did a survey last year **[explain the results]**.

We have been trying to interpret those results.

Based on your clinical experience, how would you interpret those results?

17. My main purpose in the interview today was to try to understand the place of guidelines in managing patients in nephrology. Is there anything important about this that we haven't covered?