Implementing iron management clinical practice guidelines in patients with chronic kidney disease having dialysis

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ABSTRACT

Objective: To evaluate the outcomes of and barriers to implementing standard guidelines (Caring for Australasians with renal impairment [CARI]), using iron management in patients having dialysis as an example.

Design and setting: On-site review of iron management processes at six Australian dialysis units varying in size and locality. Patients' iron indices and haemoglobin levels were obtained from the Australian and New Zealand Dialysis and Transplant Registry.

Participants: Patients with chronic kidney disease who were dependent on dialysis.

Main outcome measures: Processes for assessing indices of iron stores and iron supplementation; comparison with target indices in the CARI guidelines.

Results: There was considerable variability among the units in achievement of haemoglobin and iron targets, with 25%–32% of patients achieving haemoglobin targets of 110–120 g/L, 30%–68% achieving ferritin targets of 300–800 μg/L, and 65%–73% achieving transferrin saturation targets of 20%–50%. Implementation barriers included lack of knowledge, lack of awareness of or trust in the CARI guideline, inability to implement the guideline, and inability to agree on a uniform unit protocol. Factors associated with achieving the CARI guideline targets included nurse-driven iron management protocols, use of an iron management decision aid, fewer nephrologists per dialysis unit, and a "proactive" (actively keeping iron levels within target range) rather than "reactive" (only reacting if iron levels are out of the range) protocol.

Conclusions: Variability in achievement of iron targets, despite the availability of a clinical practice guideline, may be explained by variability in processes of care for achieving and maintaining adequate iron parameters.

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Studies examining the link between research evidence and clinical practice have consistently shown gaps between the evidence and current practice. Some studies in the United States suggest that 30%–40% of patients do not receive evidence-based care, while in 20% of patients care may be not needed or potentially harmful.[1] However, relatively little information exists about how to apply evidence in clinical practice, and data on the effect of evidence-based guidelines on knowledge uptake, process of care or patient outcomes is limited.

In Australia and New Zealand, national guidelines for treating patients with chronic kidney disease — the Caring for Australasians with renal impairment (CARI) guidelines[2] — were published and disseminated to nephrologists in March 2000, with details and updates on the CARI website (http://www.cari.org.au). They provide nephrologists, renal nurses and other health carers with an evidence base for patient management and improving outcomes.

The focus of one of the CARI guidelines[2] is anaemia, a common complication of chronic kidney disease. Management of iron levels in patients with chronic kidney disease involves both excluding iron deficiency in uraemic–anaemic patients, and providing adequate iron stores to allow patients to efficiently maintain target haemoglobin concentrations, especially with the concomitant use of supplementary erythropoietin proteins (epoetin). Failure to achieve adequate iron stores and availability is the major cause of epoetin resistance, which may result in increased costs to correct the anaemia.[3] In observational studies of haemodialysis patients, it has been shown that the relative risk of death and hospitalisation increases significantly with haemoglobin levels below the target.[4]

In an effort to understand the impact of guidelines, our study was designed to evaluate the outcomes of a standard implementation strategy (passive dissemination of guidelines in hardcopy form and on the Internet) of the CARI guidelines using an example — iron management of dialysis patients in Australia. In assessing this strategy, we sought to identify barriers to guideline implementation[5-7] using a "process of care" approach, with a view to developing strategies to increase uptake of evidence into practice. We hope that lessons learned from this process can be applied in other clinical environments.

METHODS

Guidelines for iron

From the CARI guidelines biochemical and haematological targets,[2] the guideline for iron was chosen for this study because:

- it has high levels of supporting evidence;
- it is of clinical relevance to all renal units;
- there are potentially high costs associated with not applying this guideline (related to greater epoetin product use); and
- it involves easily measured parameters, and the necessary data are collected by the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA; <http://www.anzdata.org.au>).[8]

The evolution of the evidence base has led to changes in target levels. Initially, the CARI guidelines (March 2000) set a target minimum haemoglobin level of 120 g/L for patients having dialysis for chronic kidney disease. The current revised minimum haemoglobin target level is 110 g/L, but, as previously, the level should not exceed 120 g/L for patients with diabetes or established additional cardiovascular risk.[2] For patients having dialysis, the target ranges of iron values are: serum ferritin level, 300–800 μg/L; and transferrin saturation (TSAT), 20%–50%, and/or percentage of hypochromic red blood cells < 2.5%.

Renal unit data

A review of iron management processes in six renal units in New South Wales, Victoria and the Australian Capital Territory was performed in September 2004. All units approached gave consent for staff to be interviewed on the process of iron management in both peritoneal dialysis and haemodialysis (in-centre, satellite and home dialysis patients).

1 Demographic characteristics, iron scores and dialysis details of patients at six renal units

Variable	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	*P**	All Units†	Australian dialysis population	*P*‡
Demographic characteristics										
No. (%) patients	115 (6%)	296 (17%)	322 (18%)	428 (24%)	413 (23%)	189 (11%)		1763 (100%)	7699	
Sex							0.3			0.001
No. (%) males	66 (57%)	190 (64%)	183 (57%)	273 (64%)	257 (62%)	117 (62%)		1086 (61%)	4465 (58%)	
No. (%) females	49 (43%)	106 (36%)	139 (43%)	155 (36%)	156 (38%)	72 (38%)		677 (39%)	3234 (42%)	
Age in years, median (IQR)	70 (19)	60.5 (25)	59 (22)	63 (21)	61 (26)	61 (22)	< 0.001	62 (23)	63 (23)	< 0.001
No. (%) Indigenous§								54 (3%)	760 (10%)	< 0.001
No. (%) non-Indigenous								1709 (97%)	6939 (90%)	
Iron scores, median (IQR)										
Haemoglobin (g/L)	120 (22)	119 (23)	112 (22)	116 (20)	121 (21)	118 (22)	< 0.001	118 (21)	118 (21)	0.36
Ferritin (μg/L)	309 (200)	165 (290)	163 (225)	348 (316)	393 (279)	501 (401)	< 0.001	319 (353)	386 (432)	< 0.001
TSAT (%)	—¶	25% (16%)	25% (14%)	25% (13%)	29% (16%)	23% (13%)	< 0.001	26% (15%)	26% (15%)	0.88
Dialysis										
Type of dialysis, no. (%) patients							< 0.001			< 0.001
Hospital haemodialysis	44 (38%)	61 (21%)	16 (5%)	30 (7%)	38 (9%)	30 (16%)		219 (12%)	2080 (27%)	
Satellite haemodialysis	32 (28%)	79 (27%)	80 (25%)	223 (52%)	224 (54%)	77 (41%)		715 (41%)	3063 (40%)	
Home haemodialysis	20 (17%)	86 (29%)	78 (24%)	73 (17%)	35 (9%)	23 (12%)		315 (18%)	776 (10%)	
Peritoneal dialysis**	19 (16%)	70 (24%)	148 (46%)	102 (24%)	116 (29%)	59 (31%)		514 (29%)	1780 (23%)	
Taking epoetin, no. (%) patients							< 0.001			< 0.001
Yes	109 (95%)	261 (88%)	271 (84%)	386 (90%)	356 (86%)	147 (78%)		1530 (87%)	6930 (90%)	
No	6 (5%)	35 (12%)	51 (16%)	42 (10%)	57 (14%)	42 (22%)		233 (13%)	769 (10%)	
Duration of dialysis in years, median (IQR)	4 (4.4)	3.5 (5.0)	4 (4.6)	3.5 (4.3)	3.8 (4.5)	4 (5.0)	0.6	3.5 (5.2)	2.8 (4.3)	< 0.001

IQR = interquartile range; TSAT = transferrin saturation.

* χ^2 test or Kruskal–Wallis test used for univariate analysis among units.

† Units represented: The Canberra Hospital, ACT; Central Coast Area Health Service, NSW (Gosford Hospital); Central Sydney Area Health Service, NSW (Royal Prince Alfred Hospital, Concord Hospital and the Dame Edith Walker Centre); Monash Medical Centre, Vic; Royal Melbourne Hospital, Vic; and Sydney West Area Health Service, NSW (Westmead Hospital and Blacktown Hospital).

‡ χ^2 test or two-sample Wilcoxon rank-sum (Mann–Whitney) test used for analysis between all units and Australian dialysis population data.

§ Numbers for all units combined given, as individual unit numbers for Indigenous patients were too small.

¶ Unit 1 does not routinely test for TSAT, but for percentage of hypochromic red blood cells, and these data are not available through the Australian and New Zealand Dialysis and Transplant Registry.

** Peritoneal dialysis includes continuous ambulatory peritoneal dialysis, automated peritoneal dialysis and intermittent cycler peritoneal dialysis. ◆

Each dialysis unit received an on-site visit. Fifteen staff from the six units were interviewed, with the number interviewed at each unit being determined by the size and configuration of the unit. Nursing and medical staff were given a standardised interviewer-completed questionnaire about the details of their unit's iron protocols, and the processes for managing anaemia.

From each unit, we retrieved copies of anaemia and iron-related documentation (iron management policies and procedures, blank or de-identified patient medication charts, nursing care plans, intravenous iron standing orders, and administration protocols). The local process for iron management was mapped and reported for each unit. On completion, reports were returned to unit staff for ratification before analysis. Data tabulated for each unit included the different protocols (compared with the CARI guideline), whether a protocol was followed, and a comparison of unit protocols and practices for target iron parameters and thresholds for prescribing or withholding intravenous iron.

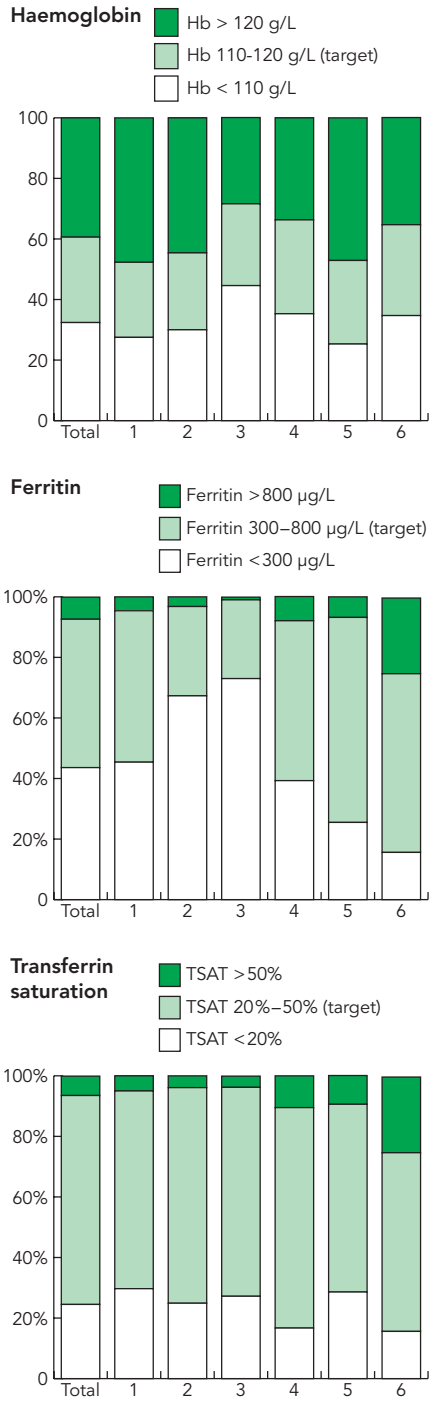
Demographic characteristics and iron-related data

ANZDATA records incidence, prevalence and outcome data for all patients treated for end-stage kidney disease. Relevant to the current study, ANZDATA also routinely collects demographic, haematological and biochemical data, type of dialysis, dialysis prescription, and complications and death rates.[8] For our review, with specific permission from the Units concerned, de-identified data on patients' haemoglobin levels and the results of iron studies (serum ferritin and TSAT), as well as demographic characteristics, were released by ANZDATA. These data were from the March 2004 ANZDATA survey, and the iron studies were the most recent for each patient before that date.

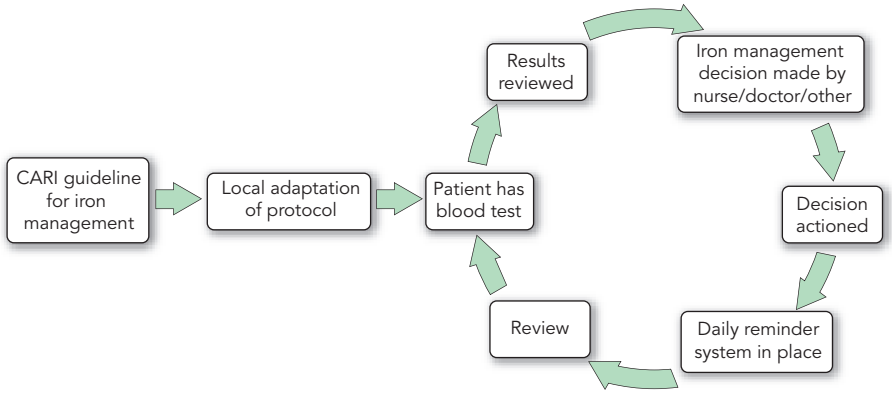
Statistical analysis

Renal units were compared descriptively using percentages for qualitative parameters (eg, patients' sex) and using medians and interquartile range for quantitative

2 Haemoglobin and iron indices ranges (all units) by dialysis unit (1 to 6) for patients taking epoetin



3 Clinical pathway for iron management in patients with renal impairment



CARI = Caring for Australasians with renal impairment. ◆

parameters (eg, iron parameters, age, duration of dialysis). We used χ^2 tests for proportions, and Kruskal–Wallis or Mann–Whitney tests for quantitative parameters. A non-parametric approach was necessary for quantitative parameters because of the 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 11.5.1 (SPSS Inc, Chicago, Ill, USA).

RESULTS

There were 1763 patients in the dataset from the six units (Box 1). Statistically significant differences were found between median values for haemoglobin ($P < 0.001$), ferritin ($P < 0.001$) and TSAT levels ($P < 0.001$). Among the units, patients' median haemoglobin levels ranged from 112 g/L to 121 g/L, median ferritin levels from 163 µg/L to 501 µg/L, and median TSAT percentages varied from 23% to 29%.

Box 2 shows the proportion of patients who were within or outside CARI target iron parameters for each unit. The proportions were significantly different across the units. The greatest difference was in ferritin levels in Unit 3 compared with Unit 5, with 26% versus 68% of patients in the target range, respectively.

Box 3 shows the process pathway for iron management across the units. Each unit varied each of the steps depending on local protocols. Practices differed widely from the CARI guideline and between the units. Most units agreed with the CARI guideline on the lower margin of the range for iron stores, but there was a tendency for all units in their local adaptation of the guideline to adopt a lower level for the upper limit for iron stores. Units also varied widely in the frequency with which iron studies were undertaken, as well as whether oral or intravenous iron therapy was administered and what dosages were used.

The process for iron management was different for each unit. All units had a written iron protocol, but not all units complied with their protocol. Units 1, 5 and 6 had a written, agreed and implemented protocol. Units 1 and 5 had a standing order for iron that allowed nursing staff to administer iron within this specified protocol. Units 1, 5 and 6 had a decision aid for administering iron. Many variables affected the iron management process. A summary of each unit's iron management process is given in Box 4.

The possible barriers to more successful implementation of the guideline, which were identified from the results of the review of the six units, are listed in Box 5.

Each staff member interviewed was aware of the CARI guidelines and the iron guideline disseminated in March 2000. Not all were aware that the website carries updates.

DISCUSSION

Passive dissemination of the CARI guidelines in March 2000 resulted in awareness of the iron guideline, but we found significant variation in implementation of the guideline across the six dialysis units examined. All units had an iron management process in place; however, the variability of the levels achieved for the iron indices is a measure of the effectiveness of the process. An effective process seems to depend on the strength of a unit's local protocol and the staff available to drive the protocol processes.

Every step in the iron management clinical process pathway (Box 3) contains factors influencing iron management. Identifying strengths and weaknesses in this process for

individual units will aid implementation. As our study is primarily a qualitative study, drawing statistical inferences is difficult. However, there appears to be a link between achieving higher ferritin concentrations and autonomy given to nursing staff to manage patients' iron levels under an agreed protocol. Other factors that appear to influence guideline adherence and patient outcomes are:

- agreement between nursing staff and nephrologists on a protocol for the unit;
- using an effective decision aid (Box 6);
- the number of nephrologists practising in a particular unit (negative effect with increasing numbers);
- the degree of physician reliance on a protocol being actively implemented; and
- the iron management protocol being "proactive" rather than "reactive". Evidence suggests that a proactive or maintenance-dosing iron therapy regimen is superior to a reactive regimen (ie, only prescribing iron therapy when iron indices are outside the defined ranges).[3,9,10]

Some dialysis facilities had lower target haemoglobin concentrations and lower achieved levels, possibly due to concerns about increased thrombotic risk and mortality rates. These concerns were raised by the publication of a randomised controlled trial linking an increase in mortality to high haemoglobin concentrations in haemodialysis patients with symptomatic heart failure.[11] Another barrier to aggressive iron administration is a reluctance on the part of nephrologists to allow ferritin levels to become "too high". Although all agreed that the lower limit for ferritin should be > 300 μg/L, some believed that the CARI guideline upper limit of 800 μg/L was too high and exposed patients to the risk of iron toxicity (ie, increased risk of infection, oxidative stress,[12] and impaired neutrophil function).[13] Some dialysis units subsequently adopted a revised local protocol, lowering target ferritin concentrations to differing extents. This change in practice is reflected in the new evidence-based CARI guideline published in April 2006 in which the upper limit for ferritin has been reduced to 500 μg/L.[14]

A potential limitation of our study is the small number of dialysis units surveyed. However, the patients in the six units involved were a 23% sample of the Australian dialysis population (March 2004), and care was taken to ensure they were generally representative of the population of patients with chronic kidney disease having dialysis. We included a range of units with different practices and iron indices, and our data show substantial variability, which we sought to explain.

The sample had a lower proportion of Aboriginal and Torres Strait Islander patients compared with the overall Australian dialysis population. Indigenous patients have been reported to have lower ferritin and TSAT values than non-Indigenous patients, and may require different iron management processes.[15] Further research into the needs of Indigenous patients having dialysis is required to determine their particular requirements and the applicability of the CARI guideline to Indigenous patients.

There is a growing body of research on how evidence is taken up into clinical practice. The most common strategies in use — continuing medical education and passive dissemination of guidelines — have consistently been shown to have very little impact on practice patterns or improving patient outcomes.[7,16-19] For successful implementation of guidelines, it is necessary to devise a strategy or plan for the project.[6-8] The first task is to understand the local setting for implementation and the target group,[20] as well as the current process or clinical pathway that needs to be altered (Box 3). Understanding each step in the clinical pathway and how individual units move through these stages will reveal the barriers to change for those units,[5-7,20] and a multifaceted implementation plan can be devised to overcome these barriers.[16,19-21]

In our study, identification of barriers was made at seven different levels of the organisation, using the National Institute for Clinical Studies barrier tool.[22] Box 5 shows the many possible barriers at all units, involving nephrologists, renal nurses, patients, and issues at a unit level, management level or infrastructure level, as well as the guideline

4 Summary of each dialysis unit's iron management processes

Unit	Summary of process
1	Small unit, single nephrologist, nurse-driven standing order, proactive iron regimen
2	Large unit, no agreed protocol, reactive iron regimen
3	Protocol available but not used, reactive iron regimen
4	Physician-reliant protocol, effective decision aid, reactive iron regimen
5	Agreed protocol, decision aid, nurse-driven standing order, proactive iron regimen
6	Agreed protocol, computerised decision aid, proactive iron regimen ◆

5 Possible barriers to successful implementation of the iron guideline

Nephrologist
- Lack of awareness or knowledge of a guideline
- Lack of knowledge regarding iron requirements
- Lack of "trust" in the guideline
- Lack of ability to implement the guideline in own practice

Renal nurse
- Lack of awareness or knowledge of guideline
- Lack of knowledge regarding iron requirements
- Has to follow/wait for instruction from nephrologist regarding iron management
- Possible increased workload
- Following up home dialysis patients

Patient
- Not accepting iron as important
- Side effects from prescribed treatments
- Comorbid conditions may take precedence
- May be a home dialysis patient

Unit level issues
- Large numbers of nephrologists working within the one dialysis unit
- Lack of agreement on iron targets among nephrologists
- Lack of effective iron protocol available for staff to follow
- Lack of care plan available for staff to follow for iron management

Management issues
- May not realise that iron management is an issue
- Unaware of the reduction in relative cost of anaemia management with epoetin, by provision of adequate iron

Infrastructure issues
- Increased nursing time to check laboratory results of iron studies
- Lack of computerised results
- Laboratories do not automatically send blood test results to dialysis units; nurses are required to access results for their patients
- Iron measurements come from a range of laboratories with different ordering processes and accessibility of results

Guideline
- Lack of evidence for dosage requirements for iron management ◆

6 Iron management decision aid example (used by Unit 5)

Ferritin (μg/L)	TSAT (%)	Dose of iron polymaltose	Frequency
< 300	< 50%	100 mg	Weekly*
300–650	< 20%	100 mg	Fortnightly
300–650	20%–50%	100 mg	Monthly
> 650	< 20%	Nil†	Nil‡
> 650	> 20%	Nil†	Nil

* If patient is taking a weekly dose, withhold iron the week before repeating iron studies every second month.
† Withhold iron infusions for 2 months, then repeat iron studies.
‡ Withhold iron infusions for 2 months, and commence oral vitamin C 250 mg three times a week. TSAT = transferrin saturation. ◆

itself. Individual units wanting to implement the iron guideline can identify which barriers may be applicable to them and devise strategies to overcome these. Once these barriers have been overcome, regular audits are needed to ensure that the performance indicators have improved (ie, the proportion of patients achieving targets has increased). This completes the quality cycle, ensuring ongoing delivery of optimal evidence-based care.

Research into effective methods for implementing clinical practice guidelines lags behind the research methods involved in producing guidelines. Our study highlights the possible barriers to implementing the CARI guideline for iron. To truly gain an understanding of which guideline implementation methods are most successful, controlled-intervention observational studies and completion of the quality cycle, with critical review of the achievement of targets, should be undertaken in renal medicine.

Passive dissemination of the CARI iron guideline (our example) raised awareness of the guideline, but improving iron management and patient outcomes will take commitment to change within the renal care team, an agreed iron protocol with a decision support aid, a working process for iron management, and skills improvement for renal nursing staff. Factors affecting iron management and barriers to change are numerous. For successful guideline implementation, a strategy to overcome these barriers in individual units should be planned and executed.

This example can be adapted to other clinical settings across a range of medical disciplines. Successful implementation of clinical practice guidelines is not achieved by forcing physicians to obey "rules", but rather by creating an environment in which they are given the skills, knowledge, attitudes and support systems to help them provide their patients with the best possible care, based on the best possible evidence.

COMPETING INTERESTS

Simon Roger has made presentations to Sigma Pharmaceuticals (iron polymaltose), and is a past chairman of the now disbanded advisory board of Baxter Healthcare (iron polymaltose). He has received funding from Vifor (iron polymaltose) for an investigator-initiated trial into oral versus intravenous iron polymaltose in patients with chronic kidney disease.

Stephen McDonald has received travel assistance from Amgen Australia, and until March 2005 his salary was partly funded by a grant from Amgen Australia to the ANZDATA Registry.

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