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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.

METHODS

Guidelines for iron

From the CARI guidelines biochemical and haematological targets, 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>).

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. 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).
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. 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 parameters.
parameters (eg, iron parameters, age, duration of dialysis). We used $\chi^2$ 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 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 showing that high haemoglobin concentrations and lower TSAT values than non-Indigenous patients have been reported to have lower ferritin (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
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.

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