letters to the editor

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Anaemia investigation in practice

Editor – Mankodi and colleagues (*Clin Med* April 2010 pp 115–8) are to be congratulated for tackling the important issue of optimising investigational strategy in iron-deficiency anaemia (IDA). However, we would urge caution before extrapolating from their results and excluding patients from urgent gastrointestinal investigations if they do not meet strict criteria for IDA.

IDA is a continuum and, as Makondi *et al*'s results nicely illustrate, an increase in specificity is inevitably at the expense of decreased sensitivity resulting in missed cancers (false negatives). In the IDA group 4/14 (29%) patients with cancer had a ferritin >15 ng/ml, while in the non-IDA group at least 2/4 (50%) were in all probability iron deficient. This is alluded to in the discussion where they state that a ferritin threshold of <50 ng/ml increases the sensitivity for cancer detection to 94.4%. However, this is at odds with the central tenet of the paper demonstrating that applying strict thresholds for diagnosing IDA results in a reduction in investigations, and by extension, costs.

We have recently looked at the prevalence of anaemia in a sequential series of 87 patients diagnosed with right-sided colon cancer (caecal and ascending colon) at our institution between 2005 and 2008. At presentation, 72% of patients were anaemic according to the British Society of Gastroenterology criteria used by Mankodi *et al*. However, only 66% of these cases would have been classified as iron deficient using a ferritin level of <15 ng/ml, whereas this rose to 91% using a ferritin cut-off of <50 ng/ml. Therefore, approximately 25% of patients with anaemia secondary to a right-sided colorectal cancer have a ferritin of between 15–50 ng/ml, and would be denied urgent investigation using strict criteria. Furthermore, the mean cell volume is of limited value as, though a microcytosis is useful in suggesting the presence of IDA, 51% of our cohort had a normocytic anaemia. Of these, 58% had IDA using a ferritin threshold of <15 ng/ml, which rose to 83% using a threshold of <50 ng/ml.

Based on these and Mankodi's results we therefore advocate that rather than enforcing strict criteria for the diagnosis of IDA, using a ferritin threshold of <50 ng/ml significantly reduces false-negatives resulting in a higher cancer detection rate that outweighs the burden of increased investigations.

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NHS research governance procedures

Editor – Haynes, Bowman, Rahimi and Armitage (*Clin Med* April 2010 pp 127–9) usefully highlight the need for research governance procedures to be modified in order to improve the conduct of clinical research in the UK. A programme of changes to the research governance process has made further progress since the cases referred to in this article and is beginning to have a demonstrable impact on the practice of clinical research.

Significant progress has been made in streamlining research governance through the introduction of the Integrated Research Application System (IRAS) (January 2008), which provided a single entry point for permissions and approvals for health research in the UK. In addition, the National Institute for Health Research Clinical Research Network (NIHR CRN) has been working with the NHS and regulatory agencies since April 2007 on the Coordinated System for Gaining NHS Permission (CSP), which was introduced in the NHS in November 2008.

CSP is a managed system that uses a standardised, transparent and risk-based approach to NHS permissions for research, and is provided for every NHS trust in England through the NIHR CRN. CSP is streamlining trial set-up. There is evidence now that it is helping to quicken the process and increasing engagement by leading research and development departments is ensuring its continuous improvement. The introduction of the Research Passport scheme to simplify the contractual arrangements for researchers working in the NHS has also addressed one of the key delays in the study set-up process.

The North West Exemplar programme is demonstrating the impact NIHR CRN systems can have on commercial study performance and reliability. Although still in its early stages, the programme is impressing industry partners with set-up times – median time for approval of Exemplar studies is 53 days – and in several instances studies have recruited the first global or EU patient. Full data for phase one of the programme – focusing on effective study set-up – will become available at the end of June (http://nwexemplar.nihr.ac.uk/).[1]

The authors are correct in saying that post-permission study management issues – particularly recruiting to time and to target – need to be addressed, but the twin initiatives of the NIHR Research Support Service (RSS) and ongoing support for delivery of studies from NIHR CRNs will create a much more efficient research support system.

There is still much work to be done, but the NIHR has recognised the issues outlined in the article and is addressing them