genic or mutagenic. Furthermore, these processes may reduce the efficacy of blood. For example, losses owing to tests and safety measures now reduce the red cell content of a blood pack by 10%, and some patients will therefore require more units, adding to the risk.

We think that these large and recurring expenditures on blood safety should be balanced against the costs of the clinical trials still needed to provide an adequate evidence base for the use of transfusion, alternatives, and avoidance strategies. The decisions should involve a well informed public and be understood, and accepted, by them.

Brian McClelland *strategy director*

Scottish National Blood Transfusion Service, Blood Transfusion Service, Royal Infirmary, Edinburgh EH3 9HB (brian.mcclelland@snbts.csa.scot.nhs.uk)

Marcela Contreras *national director of diagnostics, development and research*

National Blood Service, London NW9 5BG

Competing interests: None declared.

1 Donaldson L. Department of Health. *On the state of the public health: annual report of the chief medical officer 2003*. 28 July 2004.
2 Wells AW, Mounter PJ, Chapman CE, Stainsby D, Wallis JP. Where does blood go? Prospective observational study of red cell transfusion in north England. *BMJ* 2002;325:803.
3 Hebert PC, Wells G, Blajchman MA, Marshall J, Martin C, Pagliarello G, et al. A multicenter, randomized, controlled clinical trial of transfusion requirements in critical care. Transfusion requirements in critical care investigators, Canadian Critical Care Trials Group. *N Engl J Med* 1999;40:409-17.
4 Walsh TS, McArdle, F, McLellan SA, Maciver C, Maginnis M, Prescott RJ, et al. Does the storage time of red blood cells influence regional or global indices of tissue oxygenation in anemic critically ill patients? *Crit Care Med* 2004;32:364-71.
5 Kirpalani H, Whyte R, Andersen C, Asztalos E, Blajchman M, Heddle N, et al for PINT Investigators. Conservative transfusion regimens are not associated with higher mortality or morbidity in ELBW infants—the premature in need of transfusion (PINT) randomized controlled trial. www.pas-meeting.org/2004SanFran/Abstracts/LateBreakers/Abstracts.htm#LB15 (accessed 2 Dec 2004).
6 Stanworth SJ, Brunskill SJ, Hyde C, McClelland DBL, Murphy MF. Is fresh frozen plasma clinically effective? A systematic review of randomized controlled trials. *Br J Haematol* 2004;126:139-52.
7 Finfer S, Bellomo R, Boyce N, French J, Myburgh J, Norton R. SAFE Study Investigators. A comparison of albumin and saline for fluid resuscitation in the intensive care unit. *N Engl J Med* 2004;350:2247-56.
8 Stainsby D, Jones H, Milkins C, Gibson B, Norfolk DR, Revill J, et al for the Serious Hazards of Transfusion Steering group. *Serious hazards of transfusion annual report 2003*. Manchester: SHOT Office, 2004.
9 Simmonds P, Kurtz J, Tedder RS. The United Kingdom blood transfusion service: over a (patent) barrel? *Lancet* 2002;359:9319.
10 Peden AH, Head MW, Ritchie DL, Bell JE, Ironside JW. Preclinical vCJD after blood transfusion in a PRNP codon 129 heterozygous patient. *Lancet* 2004;364:527-9.
11 Gregori L, McCombie N, Palmer D, Birch P, Sowemimo-Coker SO, Giulivi A, et al. Effectiveness of leucoreduction for removal of infectivity of transmissible spongiform encephalopathies from blood. *Lancet* 2004;364:529-31.
12 AuBuchon J. Pathogen reduction technologies: what are the concerns? *Vox Sanguinis* 2004;s84-9.

Test and treat for dyspepsia—but which test?

Urea breath test and stool antigen test are better than serological tests

Managing dyspepsia costs the NHS over £500m annually.[1] European dyspepsia guidelines and those from the National Institute for Clinical Excellence (NICE) say that patients with persistent or recurrent uncomplicated dyspepsia should have a non-invasive *Helicobacter pylori* test and, if the test is positive, receive triple therapy.[2–4] With a policy requiring non-invasive testing and treatment we need to use an accurate test so that the patients receive the correct treatment. The urea breath test and serology were the first non-invasive tests available; the urea breath test is the more accurate. This test detects products of the enzyme urease produced by live *H pylori* in the stomach and is 95% sensitive and specific.[5] The breath test has not been used much in primary care in the United Kingdom, probably because it is time consuming as it requires two breath samples, taken 20 minutes apart.

Serology is the main non-invasive test used in the United Kingdom and is notably less accurate than the urea breath test.[5 6] A positive serology result can mean one of three things: that the patient is infected at the time of the test; that the patient was once infected, but by the time of the test, infection has resolved, either by specific therapy or naturally; or that the test is detecting non-specific cross reacting antibodies.

Another accurate non-invasive test is now available. The stool antigen test detects *H pylori* antigens passed in the faeces. The first commercially available test, which used polyclonal antibody raised in rabbits, has been used in thousands of patients across Europe and is almost as specific (91.9%) and sensitive (92.4%) as the urea breath test.[7] Some centres have, however, found appreciable variation between batches, and a monoclonal antibody kit is now available commercially, which avoids this.[8] The monoclonal test is reported to be as accurate as the urea breath test (specificity 97.5%, sensitivity 94.7%)[8] It uses similar laboratory methods to the serology test and can be introduced with ease into routine laboratory practice.[9 w1]

Antibody concentrations to *H pylori* fall slowly after eradication of the infection.[10] In contrast to serology, stool antigen testing is useful for confirming eradication of the infection following treatment.[7 8 w1] Although equivalent to the urea breath test in performance (see table on bmj.com), the stool test is considerably less expensive and less time consuming, and investigators have found it acceptable to patients.[11] A disadvantage of breath and stool antigen tests is that patients must stop taking proton pump inhibitors for at least two weeks before the test and H_2 receptor antagonists for one day.[7 w2 w3] Any antibiotics must be stopped four weeks before.

The accuracy of *H pylori* tests has been determined mainly in patients at endoscopy in whom the prevalence of *H pylori* is high and the positive predictive value of all tests therefore high. However, as the prevalence of *H pylori* falls, the positive predictive value of all tests falls.[12] The lower the specificity of a test, the greater the fall in positive predictive value with falling prevalence. When using the urea breath test or monoclonal stool antigen test in developed countries, where typically 25% of dyspeptic patients are *H pylori* positive, only 3% (62 for

P+ *Additional references w1-w5 and table are on bmj.com*

BMJ 2005;330:105–6

stool, 65 for urea breath test of 2000) of patients will receive unnecessary antibiotics.[3 5] In contrast, using a serology based test 255 of the 2000 patients tested are likely to receive an incorrect diagnosis of active *H pylori* infection and receive inappropriate treatment.[2 3 5]

Serology leads to at least four times as many false positive results as the urea breath test or second generation monoclonal stool antigen test, with associated unnecessary treatment and increasing risks of antibiotic resistance in other bacterial flora. If the dyspepsia "test and treat" guidance is implemented widely across Europe the number of patients receiving treatment to eradicate *H pylori* could easily double. We need to have an easy, accurate diagnostic test and the stool antigen test is just that. The European Helicobacter Study Group[4] and NICE dyspepsia guidance[3] now endorse the use of urea breath tests or stool antigen tests over serology. Any small additional cost to the healthcare provider will be far offset by improved diagnostic accuracy and reduced use of antibiotics. Furthermore, as these tests replace serology and market forces come into play, the price of the breath and stool tests is likely to come down. Clinicians are therefore best advised to inform patients that the minor inconvenience of providing a stool or breath sample is far outweighed by the increased accuracy of the tests. Clinicians should request healthcare providers to fund office based tests or local laboratories to include these tests in their repertoire.

Cliodna McNulty *consultant medical microbiologist*

Health Protection Agency Primary Care Unit, Microbiology Department Gloucestershire Royal Hospital, Great Western Road, Gloucester GL1 3NN (jill.whiting@hpa.org.uk)

Louise Teare *consultant medical microbiologist*

Mid-Essex, Department of Microbiology, Chelmsford CM2 OYX

Robert Owen *head*

Campylobacter and Helicobacter Reference Unit, Health Protection Agency, Specialist and Reference Microbiology Division, London NW9 5HT

David Tompkins *laboratory director*

Health Protection Agency, Yorkshire and the Humber, Leeds Laboratory, Leeds LS15 7TR

Peter Hawtin *clinical scientist*

Health Protection Agency, Southampton Laboratory, Southampton General Hospital, Southampton SO16 6YD

Kenneth McColl *professor of gastroenterology*

University of Glasgow, Western Infirmary, Glasgow G11 6NT

1 Delaney BC, Moayyedi P, Deeks J, Innes MA, Soo S, Barton P, et al. The management of dyspepsia: a systematic review and economic model. *Health Technol Assess* 2000;4(39).
2 Gastroenterologists and Scottish Collegiate Guidelines Network (SIGN). *Dyspepsia guidelines*. www.sign.ac.uk/pdf/sign68.pdf (accessed 8 Jun 2004).
3 National Guideline Research and Development Unit. *Dyspepsia: managing dyspepsia in adults in primary care*. Published 23 August 2004. www.nice.org.uk/pdf/CG017fullguideline.pdf (accessed 26 August 2004
4 Malfertheiner P, Megraud F, O'Morain C, Hungin AP, Jones R, Axon A, et al. European Helicobacter Pylori Study Group (EHPSG). Current concepts in the management of Helicobacter pylori infection. The Maastricht 2-2000 Consensus Report. *Aliment Pharmacol Ther* 2002;16:167-80.
5 Vaira D, Vakil N. Blood, urine, stool, breath, money and Helicobacter pylori. *Gut* 2001;48:287-9.
6 Laheij RJ, Straatman H, Jansen JB, Verbeek AL. Evaluation of commercially available *Helicobacter pylori* serology kits: a review. *J Clin Microbiol* 1998;36:2803-9.
7 Gisbert JP, Pajares JM. Diagnosis of Helicobacter pylori infection by stool antigen determination: A systematic review. *Am J Gastroenterol* 2001;96:2829-38.
8 Makristathis A, Barousch W, Pasching E, Binder C, Kuderna C, Apfalter P, et al. Two immunoassays and PCR for detection of Helicobacter pylori in stool specimens from paediatric patients before and after eradication therapy. *J Clin Microbiol* 2000;38:3710-4.
9 Andrews J, Marsden B, Brown D, Wong VS, Wood E, Kelsey M. Comparison of three stool antigen tests for Helicobacter pylori detection. *J Clin Pathol* 2003;56:769-71
10 Bazzoli F, Zagari RM, Pozzato P, Fossi S, Ricciardiello L, De Luca L, et al. *Helicobacter pylori*: optimum diagnosis and test of cure. *J Chemother* 1999;11:601-5.
11 Chisholm SA, Watson CL, Teare EL, Saverymuttu S, Owen RJ. Non-invasive diagnosis of Helicobacter pylori infection adult dyspeptic patients by stool antigen detection: does the rapid immunochromatography test provide a reliable alternative to conventional ELISA kits? *J Med Microbiol* 2004;53:1-5.
12 McNulty CAM, Wyatt JI. *Helicobacter pylori*. *J Clin Pathol* 1999;52:338-44.

From targets to standards: but not just yet

The challenge will be for ministers not to interfere in a regulated service

The NHS in England marked the fourth anniversary of publication of the NHS Plan[1] in July 2004 with the launch of the planning framework for the next three years and the standards that all organisations will be expected to achieve in delivering NHS care.[2] The planning framework and standards mark a further stage in the reform of England's NHS and are important as an indication of the Labour government's thinking on priorities for the future and the methods that will be used to bring about change.

The planning framework sets out priorities in four areas: access to services, long term conditions, the health of the population, and the experience of patients or users. In each area national targets are identified for 2008 (and beyond in the case of the health of the population). These targets are based on the public service agreement negotiated between the Department of Health and the Treasury—with one exception, the aspiration to reduce infections caused by methicillin resistant *Staphylococcus aureus* (MRSA). The publication of a critical report by the National Audit Office on MRSA[3] after release of the public service agreement explains the late addition of this target.

Three aspects of the planning framework are worth comment. Firstly, more ambitious targets have been set for access to services than before. The government expects a maximum wait of 18 weeks from referral by a general practitioner to hospital treatment by 2008, with most patients being seen more quickly. In effect, this target replaces the objective set out in the NHS Plan that the maximum wait for each stage of treatment (outpatient consultation, diagnosis, and inpatient treatment) should be three months, or nine months in all.

Secondly, the identification of long term conditions as a priority area is new. The national target here is to offer a personalised care plan to vulnerable people most at risk, and to reduce emergency bed days by 5% by 2008. The emphasis on long term conditions reflects international recognition of the changing bur-

BMJ 2005;330:106–7