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**Florence Claire Ruth Brown (née Richardson)**
Hugh Brown
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**Jack Philip Lask**
Judy Trewin
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**Kathleen Joyce McCarthy (née Evers)**
Fiona Subotsky
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**Edmund Rainey**
Joe Tosh
BMJ 2007;334:1119, doi:10.1136/bmj.39210.725961.BE

**Charles James Crawford Renton**
Morag Renton
BMJ 2007;334:1119, doi:10.1136/bmj.39217.725694.BE
Intestinal nematode infection and anaemia in developing countries

Deworming and iron supplementation are cheap and effective

In low and middle income countries, about 1.2 billion people are infected with roundworm (Ascaris lumbricoides), and more than 700 million are infected with hookworm (Necator americanus or Ancylostoma duodenale) or whipworm (Trichuris trichiura). Infection with intestinal nematodes is linked with poverty because of its association with unsafe disposal of faeces, in which the infective stages develop.

Infection can occur in all age groups but is most common in school age children. Though infection can be fatal, the major burden of disease is due to its insidious effects on physical and cognitive development during childhood. Anaemia, for example, is commonly associated with infection and can impair cognitive ability. In areas of high prevalence of infection in East Africa, 15-25% of anaemia in schoolchildren is due to hookworm infection.

In this week’s BMJ, a systematic review of randomised trials by Gulani and colleagues assesses the effect of routine deworming on haemoglobin concentrations. It finds that deworming increases haemoglobin by 1.71 g/l (95% confidence interval 0.70 to 2.73), which could translate into a small (5-10%) reduction in the prevalence of anaemia. However, some elements of the study design suggest that this may be an underestimate of the impact, and that the results may have broader implications for practice.

Most deworming programmes assume that it is unnecessary to diagnose the specific infection as the commonly used benzimidazoles are effective against common worm species. This can make it difficult to assess the results of clinical trials because the species of worm profoundly influences the risk of anaemia.

Hookworms adhere to the gut mucosa, feed on blood, and leave areas of intraluminal microhaemorrhage when they detach. Daily blood loss due to A duodenale is estimated at 0.2 ml per worm, equivalent to 100 ml in heavy infections. This is about 10 times greater than with N americanus infection, and surveys in Africa confirm that anaemia is more common with A duodenale infection. Blood loss during whipworm infection comes mainly from the inflamed gut mucosa, and at 8.6 ml/day is less than with hookworm. Blood loss is not typical of roundworm infection, and it is unclear whether the low serum retinol and serum ferritin concentrations associated with fat malabsorption result in anaemia. Therefore, the review by Gulani and colleagues does not, or perhaps could not, differentiate between the effects of different worm species in contributing to anaemia and the potential impact of deworming.

Not differentiating between species and anthelmintics also makes it difficult to assess the effects of specific drugs. The World Health Organization recommends the use of albendazole, mebendazole, pyrantel, and levamisole. Of the 14 studies included in the review, one used an anthelmintic that is no longer recommended (bephenium hydroxynaphthoate), three used mebendazole, and 10 used albendazole. While both benzimidazoles have similar high efficacy against roundworm and moderate efficacy against whipworm, single dose mebendazole is much less effective against hookworm, with cure rates typically below 60%. In almost a third of the trials, treatment (dose and choice of drug) was less than optimal for the hookworm infection that would probably contribute most to anaemia. Thus, the review probably underestimated the effect of deworming on anaemia.

So what practical lessons does the review offer? Firstly, the number of doses of anthelmintic did not predict effectiveness. This suggests that less frequent and therefore cheaper approaches may be adequate; this should encourage a review of current guidelines on the frequency of anthelmintic treatment in the community. Secondly, analysis of the studies (around half) that gave iron supplements and anthelmintics found that coadministration of iron significantly increased the size of the effect of deworming on anaemia.

Available evidence suggests that removing the source of blood loss alone is unlikely to replenish iron stores in the short term, and the review provides more evidence of the value of combining deworming with iron supplements. The lack of iron supplementation in half the studies would also tend to underestimate the effectiveness of the approach in improving haemoglobin concentrations.

Because the review tended to underestimate the impact of deworming, and given the remarkably low cost of deworming and iron supplementation, combining the two approaches in programmes for young people should be encouraged. Given the high prevalence of both anaemia and worm infection in pregnancy, a similar review is needed in pregnant women.
The role of pharmacists in primary care

Needs reconsideration in light of the evidence of an unfavourable impact on patient outcomes

The National Health Service recently launched Choosing health through pharmacy,1 an initiative aimed at enhancing the contribution of pharmacists to improving the public's health and reducing health inequalities. The initiative assumes that, on the basis of their knowledge, skills, and proximity to the public, pharmacists are an untapped resource for health in the United Kingdom. However, evidence that pharmacists' involvement with the public improves health outcomes is mixed.2-3

This week's BMJ includes two studies about the role of community pharmacists in primary health care.4-5 In the first, Salter and colleagues explore the role of pharmacists in giving advice to older patients during medication review.4 They find that although many opportunities were available for pharmacists to offer advice, information, and instructions to patients, this was often resisted or rejected. This caused “interactional difficulties” during consultations between pharmacists and patients. In the second study, Holland and colleagues report a randomised controlled trial assessing whether medication review and advice by community pharmacists reduced hospital admissions or mortality in patients with heart failure, compared with usual care.5 It found no significant difference in hospital readmissions at six months (134 v 112 in controls; rate ratio 1.15, 95% confidence interval 0.89 to 1.48), quality of life, or mortality. The fact that both studies using different research methods produced unfavourable findings raises important questions about the role of pharmacists in primary health care.

Holland and colleagues’ findings may have been negative because their trial assessed the global impact of the intervention rather than outcomes related to specific aspects of the interaction between the pharmacist and the patient. This would mean that the relative, and potentially positive, contribution of these different aspects could not be ascertained.

Salter and colleagues are clearer about the negative impact of pharmacists giving advice, and emphasise the potential harm of (unsolicited) advice on patients’ sense of competence and self governance. By analysing the discourse between pharmacists and patients they highlight the problems with medication review where advice giving is didactic and controlled by professionals. Their conclusions support the growing body of literature in which the relationship between the “expert” and the lay person is deconstructed.6-8 and where “concordance” around the goals of treatment is prioritised.9 This literature suggests that healthcare professionals have the greatest impact when they give serious consideration to patients’ agendas for health and how they rationalise decisions.

Although the overall findings of the studies are negative, there are positive aspects that the authors do not consider. Salter and colleagues do not elaborate on their assertion that pharmacists found many opportunities to offer advice, information, and instruction (presumably because of problems with elderly patients’ drug regimens). Holland and colleagues look at this aspect in more detail. They report that pharmacists’ home visits to patients with heart failure resulted in 384 recommendations to general practitioners. These recommendations were made despite patients having unusually high levels of adherence to their drug regimes. In other words, the recommendations to doctors were not related to non-adherence.

The recommendations reported by Holland and colleagues resulted in visits to doctors, drug reviews, and sometimes (re)admission to hospital. Holland and colleagues interpret the outcome of increasing hospital admissions as negative (assuming that intervention by a pharmacist should reduce admissions). However, any responses to pharmacists’ advice, including readmission to hospital, may have reduced iatrogenic illness and possibly saved lives. The study did not assess these specific actions.

Pharmacy as a profession has reoriented its practice from a clinical service model to a pharmaceutical care

model—a practice philosophy with parallels to the concept and goals of the patient centred care model adopted by medicine. Both models proclaim a commitment and responsibility to enhance outcomes for patients through developing an alliance between the professional and the patient. Pharmaceutical care is uniquely focused on the pharmacists’ responsibility for the patient’s drug related needs. Those needs are not limited to specific clinical problems and goals but to all of the patient’s medications, medical conditions, and outcome parameters.

Yet public recognition of the potential role of pharmacists in reducing the medical and economic costs of inappropriate drug use is lacking. This might be because any positive impact that pharmacists may have is not captured by the appropriate study designs. It might also be due to patients’ perceptions of the status of the pharmacist in the health professional hierarchy. This is shown by Salter and colleagues with reference to many examples where patients “call on the higher authority of the doctor” as a means to challenge the advice given by the pharmacist.

If the Department of Health is to provide pharmacists with a more expansive role in public health in the UK, a campaign is needed to educate the public and the medical community about the harms of inappropriate use of medication and how pharmacists can be a potential resource for patients who take medicines. A strategy to increase the public’s exposure to pharmacists working in primary care, separate from the dispensing of products—the new pharmaceutical carepractitioner model—may help. Finally, the agenda for research into the impact of pharmacists on health should be refined. A good start would be to explore the nature of the drug related problems in elderly people highlighted by Salter and colleagues, and what specific recommendations were made to the doctors of patients with heart disease in Holland and colleagues’ study.


The future of specialist training in the UK
Doctor’s anger and mobilisation are at last forcing a rethink

The United Kingdom’s doctors are for once united, but not for the moment under the auspices of the BMA, their trade union and professional body. Instead, their growing outrage about new rules for junior doctors’ specialist training has found its voice through two pressure groups, while the chairman of the BMA’s council has been forced to resign for failing to reflect members’ views. RemedyUK’s legal challenge (see p1075)—due to conclude after the BMJ goes to press—is likely (even if they lose their case) to force a rethink of the way in which training posts are filled, while surveys of doctors run by an ad hoc group of senior academicians under the leadership of Morris Brown (see bmj.com/cgi/letters/334/7601/0#165660) have brought consultants and junior doctors together in a rare show of solidarity. Jim Johnson’s unprecedented resignation (see eletters/334/7601/0#165660) have brought consultation to specialist training but for those already in training a big bang implementation, not only for new entrants to specialist training but for those already in training posts. The system was not piloted, its ability to discriminate between good and less good candidates was not validated, and (as revealed in RemedyUK’s judicial review) the software was neither finished nor tested before it was put in place.

Among the hundreds of postings to medical and newspaper websites in the past few weeks are many proposals for rescue from the immediate crisis, some of
them more feasible than others. RemedyUK’s position, initially calling for the whole system to be scrapped, is now to honour job offers but only as temporary appointments that will not count towards specialist training. Morris Brown’s position is that the temporary appointments should be retroactively accredited towards training. While both groups have touched a nerve and given the BMA a master class in how to mobilise members, neither are representative bodies that can be held to account. The BMA is. Last month’s junior doctors’ conference did not support temporary posts, taking the view that most candidates are likely to be accommodated through further iterations of the first round of interviews and extended provision of interviews and posts in round two.

No one doubts that this is an enormous mess. We will know more about where to apportion blame when John Took’s independent review reports at the end of the year. Meanwhile, the profession as a whole has suffered a hard knock from which its leaders are clearly keen to learn. Most people I have spoken to acknowledged that the BMA has let junior doctors down. They also feel that the organisation needs to modernise, that it needs to find better ways to stay in touch with its members, and that it needs to find a better balance between representation and leadership and between working with government while remaining strongly independent of it. Failure could put at risk the BMA’s official monopoly on representing the UK’s doctors. The threat of mass resignations by junior doctors confirms that this is a position the BMA needs continuously to earn.

Now is the time for the profession to put aside it’s differences. We need a comprehensive rethink, a chance perhaps to put this miserable episode to good use. We need solutions for the immediate problem, including a better understanding of how many additional posts are needed and how these can be filled with the best candidates. All parties then need to work together—the BMA, the colleges, government, and RemedyUK—to design and pilot a specialist training scheme fit for the future of health care in the UK.

Rationing in the NHS
The BMA asks the right questions but answering them will be difficult

Over the past two decades or so rationing has been debated more than almost any other area of health policy. However, the debate has been punctuated by periods of relative silence when policy makers have been reluctant to tackle the key problems. The past few years have been one such period as new money appeared to have flushed away old concerns. Now, however, those concerns are back, underlined by the hectic race to balance the National Health Service’s books and the realisation that the days of rapid growth in its budget are almost over.

A new factor is adding to these concerns. If in the past the NHS was a model of economy, it was partly because no one had an incentive to maximise activity. But as the new model NHS emerges, payment by results to hospital providers will provide such an incentive. As the NHS inevitably becomes a demand generating machine, so the challenge of accommodating competing demands within a constrained budget will become more acute.

The BMA has therefore rightly made rationing one of the themes of its report on the future of the NHS, published on 8 May 2007. The main point of the report is the need to separate national politics from the everyday running of the NHS. The report recognises that “priority setting and, hence, rationing is inevitable,” as it is in all healthcare systems. But if hard choices are inevitable, how are they to be made? The BMA’s report suggests a double headed strategy. Parliament “informed by expert professional and public opinion” would determine the “core services” that should be available nationally, and set priorities for the whole NHS. Local health economies, however, would then decide what additional services should be provided from within their budgets.

It appears to be a neat formula. But is it realistic? The report recognises that decisions about who should get what involve social and political choices, as well as professional expertise. However, it also proposes machinery for protecting the NHS from day to day politics, with an independent board accountable to parliament and a much diminished role for the Department of Health. It is not likely that we can have it both ways. If decisions about resources are inevitably political, can the NHS really be protected? Putting parliament centre stage would complicate rather than solve the dilemma. It presumes a constitutional revolution. The House of Commons is a decision reviewing body, not a decision making one. Giving it responsibility for defining core services would imply a new relation between executive and legislature.

But assuming that there are no major institutional changes, and that the Department of Health retains at least a strategic role, the notion of core services—that is, identifying both entitlements and exclusions—remains highly contestable. Many countries have tried to define the menu of entitlements, but in practice excluded services have tended to creep in by the back door. More troubling still, the concept of a core service is flexible as it does not necessarily imply a particular level or depth of service; for example, staffing ratios, drug budgets, or the number of diagnostic tests. No doubt some of these can be specified in national service frameworks, but only at the risk of reducing scope for the local professionally led initiatives that the BMA proposals are designed to encourage.

So we come to the second leg of the BMA’s strategy—giving more freedom to local health economies. This is a
welcome recognition of the central role of primary care trusts. Many trusts have set up the machinery for prioritising competing claims on resources, deciding what drugs are to be prescribed, and scrutinising referrals. Their methods for doing so vary, as do the decisions taken. Furthermore, we know that there are large unexplained variations in what different primary care trusts spend on particular services, such as cancer and mental health. So we come to some crucial questions. When does local discretion become postcode rationing? If central prescription is at odds with local priorities—as in the case of some National Institute for Health and Clinical Excellence recommendations—which should prevail?

The answers to such questions will largely depend, as the BMA recognises, on the perceived legitimacy of local bodies. For it is at the local level, if anywhere, that there is a democratic deficit in the NHS. Hence the BMA's proposal for elected local health councils. The notion may sound appealing, but it risks compounding the confusion of accountabilities in the NHS. Elected governors of foundation trusts are still in search of a role and local authority committees are flexing their muscles, all on top of a raft of patient involvement initiatives. The danger is that the NHS may become caught in a web of mechanisms, none of which is effective but all of which clog up policy and practice processes. Moreover, the question remains of how to make individual clinicians—who take crucial decisions about whom to treat and how—accountable for the decisions they make, without inhibiting professional discretion and introducing an extra layer of regulatory bureaucracy.

Whatever the reservations about the details of the BMA proposals, they have breathed fresh life and new ideas into an old debate in danger of going stale. Although the proposals can be criticised, it should be recognised that they pose an urgent challenge.

Antipsychotic drugs in children with autism

Inadequacies in care should not be masked by the indiscriminate use of symptom controlling drugs

The core problems of autism—those involving social interaction, communication, and restricted and repetitive activities—can be compounded by behavioural problems, including severe tempers, aggression, and irritability. Severe aggression places a special burden on carers; it is more common in people with marked intellectual retardation and is related to poor daily living skills and impaired communication. Currently, no drugs are available to treat the underlying autistic condition. Specialised educational programmes, behaviour therapy, and environmental changes can improve aggressive behaviour, but if they fail drug treatments should be considered.

Behavioural problems related to depression or attention deficit can be addressed by relevant therapy; but if the problem of aggression is unresponsive to these manoeuvres the need for symptom control arises. Major tranquillisers in particular have been used off-label, but their place has been uncertain because of doubts about safety and (until recently) efficacy.

Two well conducted double blind placebo controlled studies have compared placebo and the atypical antipsychotic risperidone in children with autism and behavioural problems. One study included 101 children with diagnosed autism. The other included 79 children with the broader category of "pervasive childhood developmental disorder," the largest subset (n=55) having autism. Both studies showed that risperidone significantly improved a mixture of behavioural symptoms and irritability as measured by the clinical global impression checklist.

Adverse events were also reported such as somnolence (risperidone 67% v placebo 23%), extrapyramidal symptoms (risperidone 29% v placebo 10%), weight gain (risperidone 5% v placebo 0%), and raised prolactin concentrations (risperidone 43% v placebo 2%). Although prolactin concentrations tend to decrease with time, even while continuing risperidone, they are still higher than at baseline in longer term open label studies. The effect of this on growth (including bone mineral density) and sexual maturation is not known.

The licence holder (Jansen-Cilag) for risperidone applied to the UK licensing authority, the Medicines and Healthcare Products Regulatory Agency, for a licence to market risperidone for the treatment of aggression in children with autism in the UK. 3

three further studies (two in animals and one clinical) was a condition of approval.

How should clinicians react? We consider that off-label use is still justified when other approaches fail or are unfeasible, and when underlying causes of aggression such as any physical condition or illness that causes distress to the child, adverse upbringing, or hyperkinetic disorder have been considered. These conditions are not contraindications to antipsychotic drugs, but attention to them may make medication unnecessary.

The assessment report on the use of risperidone in autistic children is available on the MHRA website. It recommends a conservative approach—that this type of drug should be prescribed by experts in the treatment of autism who are prepared to undertake careful diagnosis, appropriate screening, and monitoring.

Diagnosis should distinguish between aggression and other seriously challenging behaviours (which may justify an antipsychotic agent) and lesser levels of “irritability” (which may not). Screening should uncover any physical problems causing behavioural problems, such as seizures, or remediable problems in the care environment, such as a lack of special measures to promote appropriate communication. Ideally, monitoring should include a pretreatment baseline period, and growth (height, weight, sexual maturation, evidence of gynaecomastia), behavioural change (somnolence, paradoxical exacerbation of behavioural problems), extrapyramidal symptoms, bowel habit, and blood pressure should be monitored. Routine invasive monitoring, such as blood testing, is not a condition of prescribing as it is often unacceptable to affected children, but if a child is more than 10 centile points above the expected weight, fasting blood glucose, lipids, and prolactin concentrations should be measured if possible. Urinary glucose testing may be done if blood tests are not practical.

Children with autism are among the most vulnerable in our society, and as such should not be deprived either of effective medication or of precautions to optimise safety. Historically, society has not offered these children the highest standards of care, and it is vitally important that inadequacies in care provision are not masked by the indiscriminate use of symptom controlling drugs.

7 Food and Drug Administration. Risperidone labelling. www.fda.gov/cder/foi/label/2006/22144s008s015;020588s024s028s029;020272s036s041dbl
Planning for triage of scarce resources needed

In the face of a flu pandemic, it is not simply an abstract moral dilemma: it remains unsolved at the highest levels of international planning. Europe remains two to three years away from a state of preparedness for a flu pandemic. Previous modelling has shown that a massive and focused use of antivirals and vaccines in places where flu may originate—probably developing countries—is vital to mitigating a pandemic. This strategy presupposes that available limited resources will be distributed fairly in developing countries. This presumption is currently unrealistic.

A recent analysis of pandemic preparedness plans worldwide noted three goals of pharmaceutical interventions: reduction of morbidity and mortality (21 plans), continued maintenance of essential services (13 plans), and minimisation of social and economic impacts (13 plans). The overarching goal for the early pandemic phases in the World Health Organization’s plan is to coordinate international efforts to delay or possibly avert a pandemic. WHO seeks to identify needs and encourage international assistance to resource-poor countries. Yet, its plan contains no specific guidance on allocating the scarce resources needed to achieve the strategic objective. It just encourages countries to reduce disease burden in the initial outbreak locations.

We face the problem of triaging scarce resources when donating countries retain effective control over limited resources. Recipient countries retain sovereignty over capabilities, and WHO (or another international intermediary) is responsible for setting global allocation priorities.

The global public health community must delineate epidemiological, legal, and ethical principles supporting a multilateral framework through which states, international institutions, and non-governmental organisations can allocate and administer scarce resources during global public health emergencies. A starting point could be a WHO expert consultation that analyses substantive and procedural aspects of this problem and develops the framework for effecting resource triage in global public health emergencies.

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Competing interests: None declared.


2. Watson R. Europe needs two or three years to prepare for pandemic flu. BMJ 2007;334:442. (3 March)


Government proposals conflict

The new draft plan published jointly by the Department of Health and the Cabinet Office does indeed strive to set out a framework for tackling pandemic flu at the local level. The government advises: “Those who believe they are ill will be asked to stay home in voluntary isolation. Voluntary home isolation may be recommended for close contacts at early stages to contain/slow the spread” (section 3.2, p 35). Yet to ensure rapid access to antiviral medicines, it also proposes: “In England, plans should assume that a friend or relative will be available to collect the patient’s antiviral treatment course from the designated distribution point on production of proof of identity and authorisation from the coordination centre” (section 9.9, p 90).

Both proposals are sensible, but they conflict: the friends and relatives who go out to collect the antiviral medicines will be the same people who should remain in voluntary isolation because of their close contact with those with possible flu. There are no easy solutions: voluntary isolation is
with any affective disorder is impractical and unnecessary, and may lead to an inappropriate use of specialist services. Finally, O’Keane and Marsh say that women taking antidepressants should gradually stop breast feeding to reduce withdrawal phenomena in the newborn. This is not recommended as routine practice in the guideline. Difficulties for the infant may arise not just from withdrawal symptoms but also from serotonin toxicity (the symptoms are similar), in which case the strategy they advise is not appropriate.

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Competing interests: SP receives funding from NICE for the development of NICE clinical guidelines in mental health.


DEEPRoGNIA

oes is concerning

As the developers of the recent NICE guideline on antenatal and postnatal mental health1 we found some aspects of the article by O’Keane and Marsh on depression during pregnancy of concern. Firstly, by focusing on depression it perpetuates the myth that depression is the only important mental disorder of pregnancy and the postpartum period, when other disorders are also important, notably, anxiety disorders. Secondly, it is written from a secondary care perspective when the burden of care for women with common mental disorders during the antenatal and postnatal periods falls on primary care. Thirdly, the article and the NICE guideline are inconsistent. The authors do not mention that for mild to moderate depression and anxiety a range of interventions such as various forms of guided self-help, and brief psychological treatments (including listening visits) are effective.1 2 3 The risk:benefit ratio for antidepressants does not normally support their use in mild depression.1

Pregnant women are often reluctant to take drugs and so are unlikely to complete a course of antidepressants, but this is not acknowledged by the authors, who recommend antidepressants for women with moderate depression. In contrast, the guideline recommends that equally effective psychological therapies are to be preferred.1 It also sets out recommendations for prompt access for pregnant women to psychological therapies.

O’Keane and Marsh say that women with an affective disorder who are planning a pregnancy should be referred to specialist psychiatric services, and that those with a history of recurrent depression or bipolar disorder should be referred to perinatal psychiatric services where these exist. Although this should be carefully considered for women with bipolar disorder or recurrent depression, referring women

DEEPRoGNIA

Article is concerning

ends never justify means

The world has long known, and feared, the fallacy of consequentialism—claiming that ends can justify means—because ends simply cannot be predicted. We can never foresee the ultimate consequences of our actions.

In this world of increasing public scrutiny, it is beyond naivety to suggest the medical profession could espouse lying, without evoking a gross loss of trust in our profession, in our integrity or in the validity of any doctor-patient discourse, to name but a few consequences. How is the anaesthetist, busy drawing up her propofol, to weigh up all the chaotic, myriad future consequences of her lie against the benefits of relieving a few seconds’ anxiety?2

Where will this all end? One has only to look across the former Iron Curtain, where I have taught communication skills to doctors, to witness how erosion of the absolute requirement for truthfulness leaves an irrevocable legacy of a deep and pervasive distrust of anything a doctor may say. And if doctors should willingly lie, why not other professions? Our bank manager perhaps? Our lawyer? Our politicians? Sokol’s world is not one where I would choose to live.

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Competing interests: TSH is a patient registered with a general practitioner in the United Kingdom, with an intense interest in not being deceived by the medical profession during future healthcare interventions.

1 Sokol DK. Can deceiving patients be morally acceptable? BMJ 2007;334:984-6. (12 May.)
Study links diabetes drug to heart deaths

Janice Hopkins Tanne NEW YORK

A meta-analysis of 42 trials of the type 2 diabetes drug rosiglitazone (Avandia) has shown a significantly raised risk of myocardial infarction and an increase in cardiovascular deaths that did not quite reach statistical significance (New England Journal of Medicine 2007 May 21 doi: 10.1056/NEJMa072761).

The analysis by Steven Nissen and Kathy Wolski, of the Cleveland Clinic, Cleveland, Ohio, included 15,560 patients randomly assigned to regimens that included rosiglitazone, and 12,283 patients assigned to regimens that did not. The mean age of patients was 56 years, and the mean baseline glycated haemoglobin concentration was about 8.2%.

Patients receiving rosiglitazone had an odds ratio for myocardial infarction of 1.43 (95% confidence interval 1.03 to 1.98, P=0.03). The odds ratio for death from cardiovascular causes was 1.64 (0.98 to 2.74, P=0.06).

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UK may use hybrid embryos for research

Michael Day LONDON

In an apparent U turn the UK government has signalled its support for controversial research involving hybrid human-animal embryos.

Leading medical scientists were furious when in December last year a Department of Health white paper proposed a ban on such experiments (BMJ 2007;334:12).

The researchers said a ban would seriously impede the search for breakthroughs in treatments for illnesses such as Alzheimer’s disease and cystic fibrosis.

Now, after intense lobbying by scientists, MPs, and patients’ groups, the minister for public health, Caroline Flint, last week announced the draft Human Tissue and Embryos Bill, which calls for an all party parliamentary committee to revise the proposed restrictions.

As it stands the draft bill still outlaws the formation of embryos with hybrid human-animal genomes.

However, the appointment of Phil Willis, a vociferous supporter of such research, as the new committee’s chairman is seen as a clear indication that ministers back such experiments.

The special committee, which will include prominent legal and scientific experts, must report back to ministers by 25 July with its proposals.

Ms Flint has also written to Mr Willis, who also chairs the House of Commons Science and Technology Committee, assuring him that key research projects already proposed by scientists at King’s College London and at Newcastle University are permissible under existing legislation.

These projects involve the injection of human genomes into empty animal egg cells. As such the resulting embryos are genetically over 99% human.

Life’s lottery: are we slaves to our genetic code?

Annabel Ferriman BMJ

An exhibition of pictures that explore the essence of identity and free will has opened in Ely, Cambridgeshire. The artists, Esther Appleyard and Craig Kerrecoe, use DNA as their subject to investigate these topics.

This picture is entitled Life Lottery and shows not only a collection of chromosomes but also faint outlines of UK lottery tickets.

The exhibition, A Series of Lines, is at Three Cups Gallery, Ely, Cambridgeshire, until 7 July. See www.ovendenart.com.

BMA chairman resigns over MTAS letter to the Times

Lynn Eaton LONDON

In an unexpected move, the BMA’s chairman, Jim Johnson, has resigned after protests at a letter he wrote to the Times newspaper published on 17 May [www.timesonline.co.uk/ol/comment/debate/letters/article1800798.ece]. His letter supported the government’s reforms of medical education and stated that continuing to use the flawed medical training application service (MTAS) system for appointing round 1 candidates was the “best available solution.”

His letter, written with Carol Black, chairwoman of the Academy of Medical Royal Colleges, upset BMA members and led to Mr Johnson’s decision to resign last Sunday.

Jonathan Fielden, chairman of the BMA’s Central Consultants and Specialists Committee, was one of the council members who called for Mr Johnson’s resignation.

“The history of this goes back to the last annual representative meeting,” he said. “There was a considerable amount of concern that Jim was not expressing the views of membership.

“Over the MTAS issue it was clear that his views, particularly around the chief medical officer, don’t reflect the huge amount of anger and distress that the profession, in particular junior doctors, are feeling,” said Dr Fielden.

Mr Johnson fiercely denied Dr Fielden’s allegations, however, describing them as “absolute nonsense.” “I have reflected entirely what members think throughout the year,” he said. “And I have never welcomed the government’s reforms.”

Dr Fielden’s allegations were “not borne out by the comments I have been making,” said Mr Johnson.

Many junior doctors were furious that the BMA representatives on the MTAS review group had gone along with the proposal to continue with existing interviews despite them being based on the flawed MTAS computer system.

Mr Johnson claims his letter to the Times was merely reiterating existing BMA policy.

Mr Johnson told the BMJ that he had not thought it necessary to consult the BMA before writing to the Times. “The BMA policy is that we support Modernising Medical Careers,” he said. “We can’t have a policy we are ashamed of. I don’t have to consult every time I write a letter.”

Mr Johnson said it was “completely untrue” that he wasn’t angry about what had happened over MTAS.

Mr Johnson was going to stand down from the BMA next month in any case, after being at the helm for four years. “I was feeling for a long time that four years was enough,” he said. “But I wouldn’t have chosen to end it in this way.” (see p Ø1067)
Judicial review will decide trainees’ future in MTAS fiasco

Owen Dyer LONDON

The professional futures of thousands of junior doctors throughout England could hinge on the result of a judicial review of the government’s web based medical training application service, known as MTAS.

The MTAS website has been closed since April, and was last week abandoned by health secretary Patricia Hewitt. Its flawed software failed to select the best applicants for jobs and permitted serious security breaches. In some cases doctors were able to read each other’s personal data.

Although the decision to abandon MTAS was widely welcomed, no agreement has been reached on what to do with the thousands of applications that have already led to interviews.

An MTAS review group appointed by the government, in which the BMA participated, hammered out a compromise solution in April, in which every junior doctor is guaranteed one interview for their preferred post, and an overhaul of the system is planned for next year.

But junior doctors’ group Remedy UK disagreed with the review group’s recommendation that job offers made after the first round of MTAS applications should stand. Remedy UK applied for judicial review of the review group’s decisions, arguing that this year’s application process was “so conspicuously unfair as to amount to an abuse of power.”

Since winning leave for judicial review, Remedy UK has dropped its call to reopen applications for posts for which interviews had already been held.

“We are arguing that the posts awarded should be made temporary, just for this year, until a fairer applications system is in place,” said Remedy UK spokesman Matthew Jameson Evans, a junior surgeon.

Thomas de la Mare, counsel for Remedy UK, last week told the High Court that Ms Hewitt’s announcement of the abandonment of MTAS made the case for judicial review “yet more imperative.”

He told Mr Justice Goldsmith that there would be “no advantage whatsoever for affected doctors in reverting to a system of deanery appointments.” Changes made by the review group, which prevented applicants from reordering their preferences, had removed the “only remaining feature of MTAS with any merit,” he added.

A decision was expected on Wednesday 23 May, and any job offers stemming from the first round of interviews will probably be withheld until then.

Incidence of euthanasia in the Netherlands falls

Tony Sheldon UTRECHT

Five years after it was legalised, euthanasia in the Netherlands seems to be declining in favour of palliative sedation, whereby terminally ill patients are kept in a coma while decisions that may shorten their lives are made, such as withdrawal of fluids.

Now the euthanasia lobby and MPs are warning that palliative sedation, which does not involve the same reporting obligations as euthanasia does, must never become a convenient “short cut” to ending the life of someone who is dying.

New government sponsored research that evaluated the effect of the 2002 euthanasia law shows that the number of cases of euthanasia fell from 3500 (2.6% of deaths) in 2001 to 2325 (1.7%) in 2005. By contrast the number of cases of palliative sedation rose from 8500 (5.6%) to 9700 (7.1%). The number of requests for euthanasia and assisted suicide fell from 9700 to 8400.

Dutch law requires doctors to report euthanasia to committees that assess whether the legal requirements have been met. Patients have to be experiencing hopeless and unbearable suffering and to have made a voluntary request for euthanasia, and a second opinion has to have been found.

The researchers, who questioned doctors about more than 5000 deaths, conclude that the 2002 law has more or less achieved its aims of creating legal certainty and greater transparency and control and improving the quality of care.

Reporting of cases has risen sharply, from 54% to 80%. Most of the unreported cases involved the use of morphine, and doctors did not perceive their actions to be necessarily “life ending.” The researchers used responses to confidential questionnaires to estimate the number of unreported cases.

The health minister, Jet Bussemaker, said that the increase in the number of cases being reported demonstrated the care with which decisions about euthanasia were now being made. “There can be no question of a slippery slope in the Netherlands.”

Evaluation: the Termination of Life on Request and Assisted Suicide Act is available at www.zonmw.nl
Cost of prescribed drugs can vary fourfold, audit shows

Adrian O’Dowd LONDON

Up to £300m (£440m; $590m) could be saved every year in England through smarter prescribing by GPs, the government’s spending watchdog said last week.

The National Audit Office (NAO) has published a report saying that smarter prescribing—particularly the prescribing of generic drugs—could save primary care trusts more than £200m a year, and cutting back on unused drugs could save a further £100m.

For the report the NAO surveyed 1000 GPs, polled advisers on prescribing in primary care trusts, analysed prescriptions written between August 2005 and July 2006, and interviewed GPs, NHS trusts, academics, pharmacists, and the drug industry.

The report identifies wide variation among trusts in the extent to which local GPs prescribe cheaper drugs for the same conditions.

The authors analysed the way in which four common types of drug were prescribed. They looked at:

- The percentage of statins prescribed as generic simvastatin
- The percentage of drugs affecting the renin-angiotensin system prescribed as angiotensin converting enzyme (ACE) inhibitors
- The percentage of proton pump inhibitors

“Globalisation of research requires better implementation of international ethical guidelines. This is particularly true in areas like health research. But new areas, such as nanomedicine and bio-piracy, also call for new or adapted standards.”

The conference learnt that of the 100000 clinical trials carried out around the world each year, some 10% occur in developing countries, where patients are readily available, regulatory requirements are less strict, and costs are lower. By 2010 European and US drug companies are expected to spend £1.5bn (£0.8bn; €1.1bn) on trials in India alone.

However, many developing countries, especially in Africa, do not have the logistical support, financial resources, or trained personnel to establish effective ethical committees or to supervise the research being carried out among their citizens.

Dr Potočnik said that as the number of clinical trials in developing countries grows it is increasingly important to ensure that participants enjoy the best possible protection.

“This requires analysis in many areas, including access to health care, cultural and local traditions, and the role of multinational companies, particularly in the pharmaceutical sector,” he said.

The commission is hoping that its own ethics reviews may serve as an example that can be adapted to local conditions.

These reviews ensure that EU funded research undertaken anywhere in the world complies with fundamental ethical principles. Those trials that do not—and 10% of research proposals for EU funding raise serious ethical and social issues—are rejected.

Developing countries need stronger research guidelines

Rory Watson BRUSSELS

The European Commission has begun to work more closely with developing countries to establish high ethical standards for research worldwide. It is examining ways to involve such countries more in drawing up, disseminating, and implementing ethical guidelines that are adapted to their specific circumstances.

Impetus for the initiative came at a two day conference in Brussels last week on ethics, research, and globalisation that brought together 150 delegates from international organisations, governments, research bodies, and academia.

Janez Potočnik, the European Union’s commissioner for science and research, told participants:

“Smarter prescribing could save PCTs more than £200m a year and cut back on unused drugs”
Screening for abdominal aortic aneurysms could save lives

Susan Mayor LONDON

Ultrasound screening of men aged 65 to 79 for abdominal aortic aneurysms significantly reduces the number of men who die from the condition, a systematic review has concluded.

The review of trials that evaluated screening says that between 5% and 10% of men in this age group have abdominal aortic aneurysms of which they are unaware (Cochrane Database of Systematic Reviews 2007;(2):CD002945).

Rupture of these aneurysms carries a very high risk of death. Screening by abdominal ultrasonography can detect these aneurysms, many of which can be treated with surgery.

In its review the Cochrane peripheral vascular diseases group searched its trials register for randomised controlled trials of population screening for abdominal aortic aneurysms. They found four studies, conducted in the United Kingdom, Denmark, and Australia and involving 127,891 men and 9342 women. (Only one of the studies included women.)

All four studies offered one-off abdominal ultrasonography screening for abdominal aortic aneurysm to people aged over 65 years. Participants with a strongly positive result were investigated further and offered surgery.

The results of the review showed a significant 40% decrease in mortality from abdominal aortic aneurysm among men three to five years after screening (odds ratio 0.6 (95% confidence interval 0.5 to 0.8) but not among women (odds ratio 2 (0.4 to 10.9)). Mortality included death from rupture and from emergency or elective surgery for aneurysm repair.

Screening was also associated with a lower incidence of ruptured aneurysm in men (odds ratio 0.5 (0.2 to 1)) but not in women (odds ratio 1.5 (0.3 to 8.9)). Men who were screened were more likely than men who weren’t screened to undergo surgery for abdominal aortic aneurysm (odds ratio 2 (1.6 to 2.6). This was not reported in women.

Mortality from all causes did not differ significantly between screened and unscreened participants, in either men or women.

Croatian academic is found guilty of plagiarism

Geoff Watts LONDON

A Croatian government committee that is investigating a senior academic and obstetrician has ruled unanimously that allegations of plagiarism in his published work are well founded.

In an opinion issued on 15 May the Committee for Ethics in Science and Higher Education declared that Asim Kurjak of Zagreb University Medical School was guilty of “violations of the [committee’s] ethics code . . . and of common norms in biomedical publishing.”

The allegations were originally made in the BMJ by Iain Chalmers of the James Lind Library in Oxford (BMJ 2006;333:594-7 doi: 10.1136/bmj.38968.611296.F7).

The saga began in the late 1980s when Dr Chalmers was preparing a systematic review of epidural anaesthesia. He noticed that much of the text and data in a 1974 paper co-authored by Professor Kurjak were identical to those in a paper from a different group of authors published three years previously.

He reported his observations to the editor concerned and to Professor Kurjak’s university. Both requested that the matter be handled discreetly.

In 2006 Dr Chalmers discovered that Professor Kurjak continued plagiarising.

“When I found out after 14 years that he (Professor Kurjak) was still at it, I felt stupid for having acquiesced in the [original] request to be discreet,” said Dr Chalmers.

As at the beginning of this week the dean of the medical school, Nada Cikes, said that she had still not received a copy of the committee’s opinion.

However, she confirmed that she was aware of its content, she said. All she could say was that it would be considered by the university’s “court of honour.”

She added: “This has to analyse all relevant facts, including [holding] a hearing with Professor Kurjak, and then it will reach a final decision.”

When asked to comment on the committee’s decision, Professor Kurjak said (on 21 May) that he had not received a copy of the decision and had been informed by the medical school that no decision had been made. He added that the medical school’s internal investigation into the allegations against him of plagiarism was “not finished.”
IN BRIEF

US drug maker fined for misleading public: The Connecticut based Purdue Frederick Company has pleaded guilty to misbranding the opiate analgesic OxyContin (oxycodone hydrochloride) with intent to defraud and mislead the public over its addictive qualities. The drug maker was fined $634.5m (£320m; €470m).

Watchdog calls for vitamin enriched bread: Bread should be fortified with folic acid to reduce birth defects such as spina bifida, the UK Food Standards Agency recommended last week. Government ministers will consider the move. There are concerns that adding the vitamin could mask a deficiency in vitamin B-12 in some patients.

Stabbing related admissions rise by almost a third: The number of stabblings resulting in hospital admissions in England has increased by almost a third in eight years. Between 1997 and 2005, admissions after an assault involving a sharp object rose from 3770 to 4891 (Journal of Public Health 2007 May 11 doi: 10.1093/pubmed/fdm018).

West African countries get $58m for yellow fever vaccines: The Gavi Alliance is to give a $58m (£29m; €43m) grant to support special immunisation campaigns in 12 west African countries at high risk of yellow fever epidemics. The aim is to vaccinate more than 48 million people in the next four years.

Extra support for families with disabled children: The UK Treasury has announced that families caring for children with disabilities are to receive £340m (£500; €670) in the next three years to improve childcare and support. Sir Al Aynsley-Green, the children’s commissioner for England, said the extra cash was a good “down payment,” but he called for better funding “to deliver a comprehensive and well funded service” for disabled children.

Global Fund says AIDS treatment reached a million people: The Global Fund to Fight AIDS, Tuberculosis, and Malaria announced this week that more than one million people with HIV have received antiretroviral treatment through the AIDS programmes that it supports, approximately doubling the results reported last year. The fund’s programmes to fight malaria have also distributed around 30 million insecticide treated nets to families at risk. See www. theglobalfund.org.

US comes last in international comparison of health systems

Janice Hopkins Tanne NEW YORK

Three times in a row the US health system has come last in the US Commonwealth Fund’s survey of health systems in six industrialised nations.

The United Kingdom was ranked first overall, scoring highest on quality, efficiency, and equity. In terms of “healthy lives”—measured by numbers of preventable deaths and life expectancy—Australia ranked highest.

The US and the UK had poor scores on indicators of healthy lives, the report said. Both countries had high mortality (in 1998) from treatable conditions. Mortality was 25% to 50% higher in the US and the UK than in Canada and Australia.

The US ranked last on the five dimensions of a high performance health system: quality, access, patients’ safety, efficiency, equity, and healthy lives. The analysis drew results from three international surveys of patients and primary care doctors.

The US performed best of all the countries in preventive care, “an area that has been monitored closely for over a decade by managed care plans,” the fund said.

The non-profit Commonwealth Fund, which works for improvements in health care, found that the US system did not achieve better health for its citizens than systems in Australia, Canada, Germany, New Zealand, and the UK—even though $6102 (£3100; €4540) is spent on health care for each citizen in the US, more than twice the median spend of $2571 in other countries in the Organization for Economic Cooperation and Development. The fund’s comparisons in 2004 and 2006 showed similar results.

Unlike the other five industrialised countries in the comparison, the US does not have universal health insurance coverage. About 47 million US citizens, or about 16% of the population, do not have health insurance. While other countries provide citizens with a “medical home,” a long term tie to a general practitioner or family doctor, US citizens with insurance must often move from one doctor to another if they change jobs or if their company changes health insurance provider.

Karen Davis, president of the Commonwealth Fund, said that the US’s “failure to insure health insurance for all and encourage stable, long term ties between physicians and patients shows in our poor performance on measures of quality, access, efficiency, equity, and health outcomes.”

“In light of the significant resources we devote to health care in this country,” Dr Davis added, “we should expect the best, highest performing health system.”

Without access to a family doctor many Americans did not seek care that could have been provided by a family doctor, or they went directly to an emergency department.

Americans with below average incomes were much less likely than similar people in other countries to visit a doctor when they were ill, the survey said.

The US is also behind other countries in adopting information technology. The survey says that the US spent only $0.43 per person on health information technology in 2005, whereas in the UK the figure was $192 per person.


“AVERAGE ANNUAL SPENDING ON HEALTH CARE PER PERSON

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Source: Commonwealth Fund

COMMONWEALTH FUND’S RANKINGS OF HEALTHCARE SYSTEMS IN FIVE INDUSTRIALISED COUNTRIES (2007)

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Source: Commonwealth Fund
Keeping the scientists in step with society

In the week that the UK government unveiled its bill merging the Human Fertilisation and Embryology Authority and the Human Tissue Authority, Lisa Hitchen talks to the woman who is currently in charge, Shirley Harrison

Lisa Hitchen LONDON
Hardly a week goes by in the United Kingdom when the Human Fertilisation and Embryology Authority (HFEA) is out of the news. With one in seven couples having problems conceiving and greater pressure on assisted reproduction clinics to improve their success rates, together with rapid progress in research using embryonic stem cells, this is not surprising.

So the job of heading a n organisation that is responsible for monitoring treatment and research in the area of assisted reproduction is a formidable one. That task has been given to Shirley Harrison, who from January this year has been chairing the HFEA as well as the Human Tissue Authority, the body responsible for monitoring the use and storage of tissue samples.

Ms Harrison will oversee the work of both authorities until, through new legislation, they merge to become the Regulatory Authority for Tissue and Embryos (RATE), expected to be in place in 2009 (see News p1075). A review of the 1990 HFEA Act is also due to take place, because many of today's ethical dilemmas were not anticipated when it was passed.

After taking a philosophy degree at Lancaster University, Ms Harrison worked in marketing and public relations, later taking a variety of roles in public sector organisations, while in a non-professional role she has been involved in criminal justice, education, and health. She was chief publicity officer at Sheffield City Council from 1986, where she managed the city’s communications concerning the Hillsborough stadium disaster. Later she lectured on public relations at Leeds Metropolitan University, and she has written or edited two books, Public Relations: An Introduction (a standard public relations textbook) and Disasters and the Media: Managing Crisis Communications.

She was also a member of the Human Tissue Authority and its interim chairwoman before the latest appointment.

A patient herself—having had breast cancer, which is now in remission—she has been involved in several bodies that represent patients, and it is through this work that she has found her way to her present position. Among the groups she has been involved in are the National Cancer Research Network’s consumer liaison group, the North Trent Cancer Research Network’s consumer research panel, and the Sheffield cancer services advisory group.

But Ms Harrison is not someone who overplays her personal story. Instead she uses it to inform her work.

“You use the experience you have had to inform how you explore other parts of the forest, if you like, rather than taking a personal agenda,” she said. She thought that people who pursued a personal agenda too closely discredited patients’ groups in the eyes of clinicians and scientists.

Just five months into the job and Ms Harrison is already overseeing some big debates. The authority is holding two consultations at present: one on multiple births after in vitro fertilisation (IVF) and one on the ethical implications of using human-animal embryos (hybrids and chimeras) in research.

The HFEA is often expected to comment on issues that are connected with its work but are not within its control. However, it is the authority’s ability to anticipate what researchers, the public, clinic staff, or the media might throw at it that enables it to respond promptly when called on.

One such example arose in the past few weeks, when the HFEA received applications from two couples with a history of breast cancer asking for pre-implantation genetic diagnosis. The HFEA had anticipated that it would eventually be confronted with such requests and had already taken the step of approving the extension of embryo gene screening—from genetic mutations with 100% penetrance (those in which an individual who inherits the mutation will definitely develop the illness, such as Huntington’s disease) to those with lower penetrance, such as BRCA1 and BRCA2 mutations for breast cancer, in which people with the mutation have a 50% to 80% chance of developing the disease.

Again, Ms Harrison’s own experience and interest in research gave her insight into the complexity of the issues involved.

“I had genetic testing because of my family history. It was in its infancy [then]. Everything in this field moves so fast, and because it makes such a great story it is always the latest breakthrough in the newspapers.

“It is difficult to get across to people that these are individual cases and that you have to look at each on a case by case basis, because each will differ depending on the effect [that the genetic mutation] is likely to have through the generations.”

Using pre-implantation genetic diagnosis for a wider range of diseases has brought the HFEA into conflict with disability groups, who see it as a tool that is increasingly being used to select out people with disabilities or illnesses altogether. Does she fear that embryo screening could go too fast and too far?

“Because we look at each disease on a case by case basis, I don’t think we are in danger of going too fast. Always there will be opportunities to find things out in science. Just because you can do it does not mean that you should.

“That is why we have an ethics and law committee in the authority, which will look at any sort of potential for a slippery slope, for [the dreaded word] ‘eugenics’ or ‘designer babies,’ [and] to ensure that we are not going any faster than society is keen for us to go.”

The full version of this article is at bmj.com.
Trialists should register their results

Many clinical trials are never published and effectively disappear without trace, leaving doctors, patients, and policy makers with incomplete evidence on which to base their decisions. Registering trials on publicly available databases is one solution, and in 2005 the International Committee of Medical Journal Editors decided to make public registration a condition of publication in peer reviewed journals. Since then, entries on ClinicalTrials.gov, the world’s largest register, have soared from an average of 30 new trials a week to more than 200. The records have also improved in quality and completeness, writes a team from the US National Library of Medicine, which is responsible for ClinicalTrials.gov. Drug companies are no longer coy about naming the compound under study, for example. Until recently, about one in 10 industry sponsored trials on the register referred only to “an investigational drug.”

Public registers contain lots of useful information, but as yet there is no imperative for researchers to record their results. Unpublished findings still disappear or languish without external scrutiny on drug company databases, says the article. Finding a way to register results that are accurate, trustworthy, and megadose antioxidants mean that plenty of viewers will disagree. JAMA 2007;297:2131-3

US health care no longer “best in the world”

A fundamental change has occurred in the way US citizens view their health service, writes one bioethicist. The public has finally accepted that health care in the US is no longer “the best in the world,” and politicians, journalists, or anyone else who repeats that now historical phrase is more likely to be laughed at than applauded for their patriotism. The deficiencies are so widespread that even the rich can no longer buy protection from medical errors, iatrogenic infections, or system failures.

Other previously cherished notions have also been abandoned, he writes. Firstly, few people still believe that health care is so special that it is exempt from all consideration of cost. Spending on health care means less money for other essentials such as food, heating, and education. Health care, just like other social goods, must represent good value.

Secondly, Americans are ending their longstanding love affair with new drugs and technologies. It may still be possible to say “new is better” on television without risking ridicule, but high profile failures such as rofecoxib, hormone replacement therapy, and megadose antioxidants mean that plenty of viewers will disagree. JAMA 2007;297:2081-91

Aspirin slightly reduces risk of pre-eclampsia

A meta-analysis of 31 randomised trials reports that taking low dose aspirin during pregnancy reduces the risk of pre-eclampsia by 10% compared with taking placebo (relative risk 0.90, 95% CI 0.84 to 0.97). The authors found a similar reduction in the risk of preterm birth (0.90, 0.83 to 0.98) but not in risk of perinatal death or the infant being small for gestational age. Aspirin reduced the risk of any serious adverse outcome by 10% overall (0.90, 0.85 to 0.96). The authors estimate that 51 women would need treatment to prevent one serious adverse outcome. Aspirin seemed safe in the short term for both mother and baby.

The trials included more than 32 000 women, most of whom had a low or moderate risk of pre-eclampsia. Despite these numbers, the authors could not pinpoint any subgroup most likely to benefit. Even those with risk factors such as diabetes or hypertension were no more likely to benefit than other women.

So who should doctors treat? A linked
Better primary care may prolong survival in elderly people with depression

Depression care managers in primary care practices help doctors take better care of depressed patients and may even save lives, according to a reanalysis of data from a published randomised trial. In 20 US practices, having a depression manager was associated with a significant survival advantage for elderly people with major depression; risk of death was reduced by 45% (hazard ratio 0.55, 95% CI 0.36 to 0.84) over five years. Gains were mostly due to a reduced risk of death from cancer (8.9 v 20.6 deaths per 1000 person-years). Among elderly people with minor depression, however, depression care managers had no impact on mortality (from cancer or anything else). The study included 1226 people with a mean age of 71.

The authors aren’t sure why improving care for depression at a practice level might prevent deaths from cancer. It’s possible that having an extra person around improves care in a non-specific way for everyone, although the authors found no evidence for a non-specific effect in this study: elderly people with a mean age of 71.

In a comparative study from Finland, young adults born at an average gestational age of 29 weeks and weighing less than 1500 g had worse insulin resistance, higher serum concentrations of glucose two hours after a glucose load, and higher blood pressure than similar young adults who had been born at term. The differences were significant, potentially important clinically, and not explained by differences in body mass index or body composition. The cohort with very low birth weight had a mean systolic blood pressure nearly 5 mm Hg higher than controls (95% CI 2.1 to 7.4). They were also significantly shorter (by 5.3 cm in women and 5.9 cm in men).

These adults were born 20 years ago. Improvements in neonatal care mean that an increasing proportion of very low birthweight babies will survive to adulthood. They may well benefit from early lifestyle advice to help them avoid the consequences of glucose dysregulation and insulin resistance, say the authors.

Blood transfusions don’t transmit cancer

A large database study from Scandinavia has laid to rest fears that cancer might be transmitted in blood transfusions. The authors studied 354 094 people who had received blood products between 1968 and 2002. The 12 012 (3%) who received products from donors who later developed cancer were no more likely to develop cancer themselves than other recipients (adjusted relative risk 1.00, 95% CI 0.94 to 1.07), over a median follow-up of seven years. These reassuring findings survived several sensitivity analyses, held firm for all types of cancer, and were derived from reliable national data on all transfusions and donations in both Sweden and Denmark. The authors are fairly sure that the risks of cancer remain negligible even 20 years after transfusion of products from an affected donor. Donors were said to have preclinical cancer if they developed disease less than five years after donating blood.

This study was not designed to assess the overall risks of cancer associated with transfusion, say the authors. It’s still possible that blood products alter immune surveillance in a way that could increase a recipient’s risk of cancer. But it does suggest that blood from donors who go on to develop cancer is no more risky than blood from donors who don’t.

Preterm babies face metabolic challenges later in life

For babies born at term, low birth weight is associated with metabolic disadvantages that can lead to obesity, type 2 diabetes, and cardiovascular disease later in life. Researchers now confirm that premature babies with very low birth weight face the same kind of metabolic challenges.

Abdominal aortic aneurysm screening is cost effective in elderly men

Screening elderly men for abdominal aortic aneurysms saves lives and is cost effective over at least seven years, according to long term data from a large randomised trial in the UK. Men aged 65-74 who were offered screening with ultrasonography were significantly less likely to have an aneurysm related death than controls (hazard ratio 0.53, 95% CI 0.42 to 0.68). Screening also reduced mortality from all causes (0.96, 0.93 to 1.00). Screened men had surgery on all aneurysms measuring at least 5.5 cm in diameter. Men with smaller aneurysms were rescanned at regular intervals. Each extra quality adjusted life year gained by screening cost between $7600 (£3830; €5598) and $19 500, well below the traditional threshold for cost effectiveness.

US guidelines already recommend screening and treatment for men in this age group, but only those with a history of smoking, says an editorial (pp 749-50). These findings support their position. But the picture is different for women. With few decent trials and little prospect of more, doctors must fall back on the pragmatic decision making of old and screen only women with strong risk factors, such as family history and hypertension.
Use of anabolic steroids alters myocardial function

Body builders who are long term users of anabolic androgenic steroids have sub-clinical impairment of myocardial function, with a strong dose dependent effect. Italian researchers investigated 45 top level competitive athletes who had trained intensively for 15-20 hours a week for more than five years. Twenty had used anabolic androgenic steroids for at least five years; the rest (plus 25 healthy, age matched sedentary controls) were non-users.

Standard Doppler echocardiography, colour Doppler imaging, and strain rate imaging disclosed that the users of anabolic androgenic steroids had lower early diastolic peak velocities and impaired systolic deformation indices of the left ventricular lateral wall muscle and the intraventricular septum, despite the subjects being asymptomatic. The number of weeks’ use of steroids annually and the weekly dose were determinants of the impaired strain rate.

The implications for cardiac events are unknown, but other studies have suggested a fourfold rise in 12 year mortality in power lifters who use anabolic androgenic steroids, compared with controls.

Br J Sports Med 2007;41:149-155

Meningitis in infancy affects exam results at age 16

Children who survived bacterial meningitis in the first year of life performed less well in academic examinations at age 16, even when they had been in mainstream schooling. A national cohort in England and Wales of 739 such children and 480 matched controls were recruited in 1985-7 and reviewed at age 5 years and 13 years. At age 16-17 years, 461 of the meningitis group and 289 of the controls responded to a questionnaire about education. Thirty six (8%) of the meningitis pupils attended special schools (but 1.7% of the national population), and a further 20 meningitis pupils and 10 controls had been identified at their mainstream (comprehensive) schools as having special educational needs.

Participants were asked about their grades in the GCSE examinations (the system used in England and Wales to assess pupils at the end of compulsory secondary education). Of those attending comprehensive schools, 184/385 (48%) of the meningitis group and 59/232 (25%) of the controls failed to achieve the national yardstick of passes at grade C or above in five subjects. Over a quarter of cases but only 7% of the controls (and 3.7% nationally) failed to gain any passes at this level. Cases who had seemed unscathed at age 5 scored just as badly.

The authors recommend continuing follow-up throughout their school years and educational support for all children who have meningitis in infancy.

Arch Dis Child March 2007, doi: 10.1136/adc.2006.105916

Burning sugar cane for harvesting may provoke asthma

Air quality in Brazilian cities has improved with the substitution of ethanol (refined from sugar cane) for petrol (gasoline) but at the expense of those living in rural areas. Daily measurements were made of total suspended particles for 16 months in an area from sugar cane for petrol (gasoline) but at the expense of those living in rural areas. Daily measurements were made of total suspended particles for 16 months in an area harvested have paid a high price in terms of public health, so that cities with heavy use of road vehicles can have less polluted air.

J Epidemiol Community Health 2007;61:395-400

Honey, I glued the kid

A child’s father glued his son’s facial laceration with domestic “superglue” after being told previously at an accident and emergency department that his own forearm laceration was being repaired with superglue. His son’s wound extended to periosteum and was inflamed, with glue present throughout, necessitating removal and irrigation under general anaesthesia. Staff in emergency departments need to know that tissue adhesive is not synonymous with superglue and should not be referred to as such.

Emerg Med J 2007;24:228-9

One week of triple therapy usually eradicates H pylori

One week of treatment with omeprazole, clarithromycin, and amoxicillin is as effective as two weeks of this treatment in eradicating Helicobacter pylori in patients with duodenal ulcer. This is clear from a double blind, placebo controlled study in more than 900 consecutive patients, based both on intention to treat and per protocol analyses. This triple therapy eradicated the organism in about 80% of patients (compared with just over 40% of those who took only omeprazole and amoxicillin). The one week and two week treatments were similar for safety and compliance.

Gut 2007;56:475-9
"They came at dawn. Two police cars, full of officers, brake in front of Hope Cottage in Wilmslow. Sally is in the kitchen in her dressing gown. There is a knock at the front door …"

This is how John Batt, a solicitor who was part of Sally Clark’s legal team, recorded the moment almost 10 years ago when her already shattered world collided with what was then the harsh reality of the investigation of sudden unexpected death in infancy (SUDI) in England and Wales. Much has happened since Mrs Clark’s arrest in 1998 for the murder of her two infant sons, Christopher and Harry: her imprisonment in November 1999, the failure of her first appeal in October 2000, her successful appeal in January 2003, and, on 16 March this year, her own death.

The consequences of Mrs Clark’s case, devastating for her family, have also been far reaching for the medical and other professionals involved and for the child protection system as a whole in England and Wales.

A positive legacy is, however, emerging from the tragedy. From April next year all sudden unexpected infant deaths in England and Wales will be investigated in accordance with a new multiagency protocol, introduced as part of the reforms of the 2004 Children Act and the Kennedy report. The template chosen for the protocol in the Kennedy report was one that had been developed by Peter Fleming and colleagues for their investigations in Avon. As the Kennedy report was being finalised, the 2004 Children Act was going through parliament. One of its measures obliged local authorities to set up local safeguarding children boards responsible for establishing panels to investigate each unexpected death of a child in their area. This function, which has been optional since April 2006, becomes compulsory from next April, and the statutory guidance for the panels was produced by a working group of professionals, many of whom also worked on the Kennedy report, including Fleming.

The statutory process by which the Kennedy protocol will have become obligatory by April next year has been astoundingly fast. This, says Fleming, "reflects a huge concern within the professions that professionals and families were being ranged reforms to the way unexplained infant deaths are handled. Jonathan Gornall describes how they should make a difficult situation less traumatic for both parents and professionals"
let down by the system because nobody knew quite what was required of them. We were getting it wrong in both directions. Families were suffering and so were professionals.

“From the point of view of protecting families, always having a team of professionals involved means that an over-zealous police officer or an over-suspicious paediatrician is less likely to have a disastrous effect.”

New procedures
The protocol, which establishes a standard routine for a collaborative multiagency response to every sudden unexpected infant death, details what is expected from ambulance crews, accident and emergency staff, child protection coordinators, coroners, coroners’ officers, general practitioners, health visitors, midwives, paediatricians, pathologists, police, and social workers. It emerged out of the Avon cot death studies, which began in the early ‘80s. Fleming and colleagues had introduced their first structured arrangements for home visits and multiagency review of sudden unexpected infant deaths in 1984, and the benefits quickly became apparent:

“Every one of the major risk factors for cot death was first identified here in the ‘80s, and it was through that approach,” says Professor Fleming, who believes that not only will the protocol ensure more robust and reliable investigations of sudden unexpected infant deaths but that it could also lead to a halving in the number of deaths from sudden infant death syndrome. One of the responsibilities of the new boards will be to collate data on deaths in their regions and report important factors to the Confidential Enquiry into Maternal and Child Health. The inquiry will in turn aggregate the regional data and draw nationally applicable conclusions.

The protocol fundamentally changes the way sudden unexpected infant deaths are investigated. A key shift is that the investigating police officer should visit the home with a paediatrician. “If your child was ill, you wouldn’t ask a policeman to tell you what was wrong with it,” says Professor Fleming.

It also calls for a change of attitude among the police, who traditionally have treated sudden infant deaths like any other unexplained deaths—with suspicion. This contrasts with the Kennedy report, which stressed that “An important starting point is the acknowledgement that in the vast majority of cases where babies suddenly die, nothing unlawful has taken place.”

Professor Fleming, having worked on the protocol for the past four years with every police force in the Southwest, is convinced that forces nationwide will embrace the concept of investigating sudden infant deaths in partnership with a paediatrician.

“Initially, many of them were suspicious and concerned but once they’d become engaged they recognised that in a sense it takes a lot of the pressure off them as well. They are no longer having to look for medical clues and there’s no question that two sets of eyes and ears pick up a lot more information.”

Instead of treating the scene of death as a crime scene and arriving in the small hours of the morning to seize potential evidence, trained, plain clothed officers attend the house at a civilised hour and in partnership with a paediatrician. The parents benefit from post-traumatic debriefing in the setting in which the trauma occurred and the investigators benefit because “when you talk to people about what’s happened in the place where it has happened, they remember much more of the detail and, indeed, they want to give us the information.”

Geared to the importance of the first “golden hour” of any investigation, police were concerned initially that vital evidence would be lost, but the Avon researchers found that the information gathered in this way often pointed them in the direction of particular tests that needed to be done on the baby and which might not have given valid results if the pathologist did not examine the body for two or three days.

Recruitment problems
There are, however, major practical obstacles to be overcome if the protocol is to function smoothly. For one thing, Professor Fleming is under no illusion that it will be easy to recruit paediatricians to be home visitors. A report by the Royal College of Paediatrics and Child Health earlier this year found that child protection had become something of a poisoned chalice for paediatricians, who are increasingly the targets of unfounded complaints. These had had “a profound impact on the professional and private lives of some paediatricians and had influenced their willingness to undertake future child protection work.”

In the Southwest region, where the protocol has been used for four years for all deaths in children under 2 years, Professor Fleming and colleagues have trained at least one paediatrician in every centre, but even here “it has become very clear that most paediatricians feel very uncomfortable in that role.” As a result, he and his colleagues are now exploring the possibility that the lead role...
An important starting point is the acknowledgement that in the vast majority of cases where babies suddenly die, nothing unlawful has taken place. Deaths. An objective review of 450 sudden unexpected infant deaths carried out by the Confidential Enquiry into Stillbirths and Deaths in Infancy had “demonstrated serious deficiencies when the post-mortem examination was carried out by a non-paediatric pathologist.” Essential tests had been omitted in up to 70% of children and the diagnosis was incorrect in an estimated 20% of cases. This had led to a “failure to recognise inherited conditions and on occasions led to inappropriate suspicion of harm.”

The protocol emphasises the importance of the role of the pathologist in great detail. For instance, traditionally permission has had to be sought from the coroner before samples can be taken from a body. Under the new protocol, however, coroners will be expected to approve a routine set of up to 11 samples that can be taken in emergency or paediatric departments.

“Certain investigations need to be done very quickly in order to allow us to be clear about the answers,” says Fleming. “If the baby dies on a Friday and the post-mortem isn’t done until Monday or Tuesday, many of the tests will be totally useless.”

It’s a lesson direct from the Clark experience. Flawed pathology lay at the heart of the case and, Professor Fleming believes, the trial would have never have taken place had the multiagency protocol been in operation in 1998. Sally Clark’s second appeal, in January 2003, succeeded after it emerged that the results of microbiological tests carried out on Harry had not been put before the jury at her trial. That, ruled the court, made her conviction unsafe.

“Sally Clark was sent to prison for life for murder on the basis of a trial that didn’t hear important information, which was that a spinal fluid sample had grown a pure growth of a known pathogen,” says Professor Fleming. “The problem was that the sample was taken 24 hours after that child died and the pathologist had assumed it was contaminant. The question of whether it was or wasn’t can’t be proved one way or the other, but it raises reasonable doubt and therefore the case should never have come to trial. Had a spinal fluid sample been taken immediately after death, we’d know the answer.”

Fleming is confident that the protocol will protect professionals, as well as parents and children: “Many paediatricians have reservations about getting into this area because they might end up having to give evidence if a case does turn out to be a non-natural death. It’s not something that any of us enjoys, but we have to do it because part of our job is protecting children. Now, at least, we will be doing it within a recognised and accepted framework, so in theory we can be criticised only if we have failed to do what we should have done, rather than merely for being there.”

Jonathan Gornall is a freelance journalist.

Competing interests: None declared.

In part two next week, the author looks at expert witnesses and child protection.
Is presumed consent the answer to organ shortages?

Veronica English deputy head of medical ethics, British Medical Association, London WC1H 9JP venglish@bma.org.uk

YES In the UK in the year to 31 March 2007, 440 people died waiting for a donated organ (UK Transplant, personal communication). At the same time bodies were buried or cremated intact—it seems likely that this was not because those people objected to donating their organs but simply because they never got around to making their wishes known. Surveys show that 90% of the UK population support organ donation, yet our current law assumes, when people die, that they are in the minority who do not wish to donate. By changing the default position to presumed consent—assuming people want to donate unless there is evidence to the contrary—we can help save and transform more lives while respecting the wishes of those who want to donate and protecting the rights of those who do not.

Although 90% of the population support donation, only 23% have registered their wish to donate, and so the decision falls to the family when they have just been told that their relative has died or is dying. Not surprisingly, when they do not know their relative’s wishes a large number (40%) opt for the default position, which is not to donate. Despite major efforts to improve transplantation rates over the past decade—through publicity and education, simplifying the registration process, and changes in legislation—the gap between the number of organs available and the number of people needing a transplant shows no sign of narrowing and the waiting list for organs stands at an all time high.

How would presumed consent work? Presumed consent is often portrayed in its extreme form where, if an individual has not opted out, the organs will automatically be used if it would cause severe distress to the relatives. In this way, relatives are still involved but the approach is easier for all concerned.

Of course, the key question is does it work? It is notoriously difficult to prove a causal relation between particular determinants and donation rates and to extrapolate from the experiences of one country to another. Nevertheless, careful analyses seem to indicate that presumed consent improves donation rates. Analysis of 28 countries found that those countries that consistently implemented a policy of presumed consent had higher donation rates than those that did not. Abadie and Gay did a detailed regression analysis comparing 22 countries over 10 years taking account of determinants that might affect donation rates: gross domestic product per capita, health expenditure, religious beliefs, legislative system, and number of deaths from traffic crashes and cerebrovascular diseases. They concluded that “When other determinants of donation rates are accounted for, presumed consent countries have roughly 25-30% higher donation rates than informed consent countries.” One explanation is that, even if the family has the final say, countries with presumed consent legislation have fewer refusals.

Spain has the highest recorded donor rate in the world, at 35.1 donors per million population (compared with 12.8 in the UK). So what can we learn from there? Spain has a presumed consent system (although in practice relatives are consulted) and has invested heavily in transplantation: over a decade the number of transplant coordinator teams increased from 23 to 139. This combination of a system of presumed consent, which portrays a positive attitude towards donation, major financial investment, and good organisation, seems to be the way forward.

Public attitudes Any such change must have public and professional support. This seems to be increasing in the UK, although we have yet to see the sustained education and debate that is required. It is not acceptable for the government to continue arguing that there is a lack of support for presumed consent without any serious attempt to test this assertion.

We all have the same aim: to improve donation rates. Current efforts to achieve this should be supported, but how long should we continue to doggedly pursue the same strategy that has failed, so dramatically, to improve donation rates over the past decade? We cannot afford to wait another five years before beginning to consider alternatives because the longer we procrastinate the more lives are lost unnecessarily. Now is the time for a public debate about presumed consent so we are ready to implement it when, as seems likely, we are having the same debate in five years’ time.

A move to presumed consent is the way forward. It would be:

- Good for those who support donation—because they have to make no effort to ensure their wishes are followed
- Good for those who oppose donation—because their wishes will be formally recorded and must be followed
- Good for families—because they are relieved of the burden of decision making when they have just been told their relative has died or is dying
- Good for those who need a transplant—because with more organs available more lives can be saved.

Competing interests: None declared.

References are in the full version on bmj.com
The supply of donor organs cannot keep up with demand. **Veronica English** argues that assuming people want to donate unless there is contrary evidence will increase availability, but **Linda Wright** believes the problem is more complex.

**Presumed consent**

Presumed consent will not answer the organ shortage. It has not eliminated waiting lists despite evidence that it increased organ donation in some countries. Systems of opting out do not ensure higher rates of donation than opting-in systems. Strategies to encourage people to donate and public education seem to help and are independent of whether people have to opt in or out. The shortage of organs has multiple causes; no single strategy is likely to solve it.

**Influences on donation rates**

The effect of presumed consent is hard to evaluate as it is implemented in different ways in different contexts, with different results. More organs may be available for transplantation because of the number of intensive care beds, transplant surgeons, coordinators, and specialised units or because of which organs are needed and the predominant cause of deaths. The rate of donation in France in 2005 was 22.2 donors per million population while in Spain it was 35.1 per million. Both countries operate presumed consent and routinely ask families for their consent to donation, yet their organ donation rates vary greatly. In Austria, where such permission is not routinely sought, the rate of donation was 24.8 in 2005.

Spain expands its donor pool by using declarations of death based on not only neurological but also cardiocirculatory criteria—that is, declaring death when the cardiorespiratory system is believed to have stopped functioning. This system has been credited with increasing donation rates in some parts of the US, which has an opting-in system. Singapore’s law on presumed consent makes exemptions for Muslims on religious grounds. The need for public acceptance of organ donation means that a strategy may work in one society, but not another.

Other factors that might explain Spain’s enviable rates of organ donation include an environment that treats organ donation as a priority. Transplantation has a strong support system, a dedicated budget, and accountability for performance. Staff are trained how to approach grieving families about organ donation. Donation will not increase without the necessary equipment, trained staff, and intensive care beds to enable a potential donor to donate viable organs. These institutional factors contribute to the donation rate and seem to account for some of the variation in rates of organ availability.

**More people might donate if they were offered financial incentives**

**Strategies to encourage donation**

Currently organ donation is conceptualised as an altruistic act, and legislation exists in most countries to outlaw any material benefit for donation. However, more people might donate if they were offered financial incentives. Another possible incentive would be to give increased priority for a donor organ to people who have recorded their willingness to donate. Tactics to identify those who want to donate and encouraging them to inform their families about their wishes would inform the procurement system about a donor’s wishes and facilitate decision making on organ donation.

Donor cards would surely help families decide whether to donate a relative’s organs. We must not forget that many countries today are multicultural societies, where diverse groups view organ donation differently. Trust in the healthcare system is not universal. Presumed consent could alienate even further those groups that lack this trust, and feed negative attitudes towards organ donation. Engagement of the leaders of communities and attention to religious and cultural beliefs and practices around organ donation may help the public to build the necessary trust to favour organ donation.

**Meeting demand**

Given the challenge of comparing behaviours in societies with different belief systems and laws, it is imperative that we increase our knowledge of the variables influencing donation rates. Organ donation has increased in Spain, where presumed consent and additional strategies are used. Are some of these variables more effective than others? Are any or all of them adaptable and acceptable to other countries?

Finally, meeting the demand for organs may require not only increasing organ supply but also optimising prevention of disease and selection of recipients. Given the multifactorial nature of the problem, presumed consent alone will not solve the organ shortage.

**Competing interests:** None declared.

References are in the full version on bmj.com

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Requests for cosmetic genitoplasty: how should healthcare providers respond?

Demand for cosmetic genitoplasty is increasing. Lih Mei Liao and Sarah M Creighton argue that surgery carries risks and that alternative solutions to women’s concerns about the appearance of their genitals should be developed.

Women’s concerns about their appearance, fuelled by commercial pressure for surgical fixes, now include the genitalia. A share of this consumer demand is being absorbed by National Health Service specialists. This article was prompted by the increased numbers of women asking for labial reduction and the concerns of clinicians about the rising number of referrals for cosmetic genital surgery.

A new complaint

More and more women are said to be troubled by the shape, size, or proportions of their vulvas, so that elective genitoplasty is apparently a “booming business.” Advertisements for cosmetic genitoplasty are common, often including before and after images and life changing narratives. Google produced around 490,000 results when we entered “labial reduction.” Forty seven of the first 50 results were advertisements from clinics in the United Kingdom and United States offering cosmetic genital surgery. Television programmes and articles in women’s magazines on “designer vaginas” may also fuel desire for surgery, especially with the rising popularity of cosmetic surgery in general. The latest survey by the British Association of Aesthetic Plastic Surgeons reported a staggering 31% increase in uptake of cosmetic surgery in the UK; women accounted for 92% of this uptake.

Decisions about surgically altering the genitalia may be based on misguided assumptions about normal dimensions. Recently, we reported dimensions of female genitals based on 50 premenopausal women. Labial and clitoral size and shape, vaginal length, urethral position, colour, rugosity, and symmetry varied greatly. These findings bring into question assumptions about “normal” genital appearances.

NHS stakeholders are unlikely to encourage demand for cosmetic genitoplasty, but availability in the private sector could put pressure on services and distort the allocation of resources. The doubling of the number of labial reductions in the past five years (figure) in the NHS suggests that this may already be happening.

A non-evidence based practice

Most reports look only at technical aspects of surgery, and outcome data are sparse. Women are unlikely to admit to having had genital surgery, so that problems may go unreported. Psychological effects should also be thoroughly investigated because, even if an “abnormality” is clearly identified, the decision to have surgery always has a strong psychological basis. But few psychometrically robust measures exist to evaluate the long term impact of plastic surgery in general, let alone genital surgery. The few reports that exist on patients’ satisfaction with labial reductions are generally positive, but assessments are short term and lack methodological rigour.

In the absence of reliable evidence, guidelines have been produced for plastic surgery in the NHS. Lih Mei Liao

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The Department of Health publication *Plastic Surgery: Information for Patients* offers specific guidance on surgery for labial reduction. However, there is no indication that practitioners adhere to guidelines. The apparent lack of interest in developing guidelines and collecting evidence about cosmetic genitoplasty has led some doctors to align the practice with “female genital mutilation.” The sentiment is not without justification when girls in their preteens are being operated on. Cosmetic genitoplasty is certainly challenging to arguments against medicalising even mild symbolic forms of female circumcision as a harm reduction strategy in some African countries. The lack of nuanced understanding of help seeking processes in our society precludes meaningful discussion about the benefits and harms of surgical solutions. It also hinders development of a wider range of solutions.

Most requests are for labial reduction, carried out by gynaecological or plastic surgeons in the NHS and private sector. Surgical incision to the labia carries risks. The labia minora contain many nerve fibres that are highly sensitive; during sexual arousal, they become engorged and everted and contribute to erotic sensation and pleasure. Some women request reduction of the clitoral prepuce or corpus. Research involving women with atypical genitalia (for whom genital surgery is common) has shown that clitoral surgery is associated with inability to reach orgasm. Furthermore, impaired sensitivity is specific to the site of surgery. Recent research has emphasised the role of the vulvar epithelium in sensuality and arousability. Incision to any part of the genitalia could compromise sensitivity—an important aspect of sexual experience. So what makes women take such risks when their genital characteristics fall within typical ranges?

The current medical literature provides little help—reports focus mostly on anatomical outcomes of labial reduction using various surgical techniques. We therefore interviewed healthy adults who had undergone surgical reduction of normal labia, so that they could talk about their experience without undue concern about access to treatment. Our aim is to develop an informed research protocol with robust evaluation tools that can be used for women seeking cosmetic genital surgery in the NHS and the private sector. We were struck by our interviewees’ ambivalence and struggle for clarity about their decision (see box).

### A gendered desire

As in previous reports, our patients sometimes cited restrictions on lifestyle as reasons for their decision. These restrictions included inability to wear tight clothing, go to the beach, take communal showers, or ride a bicycle comfortably, or avoidance of some sexual practices. Men, however, do not usually want the size of their genitals reduced for such reasons. Furthermore, they find alternative solutions for any discomfort arising from rubbing or chaffing of the genitals.

Our patients uniformly wanted their vulvas to be flat with no protrusion beyond the labia majora, similar to the prepubescent aesthetic featured in advertisements. Not unlike presenting for a haircut at a salon, women often brought along images to illustrate the desired appearance. The illustrations, usually from advertisements or pornography, are always selective and possibly digitally altered.

There is nothing unusual about protrusion of the labia minora or clitoris beyond the labia majora. It is the negative meaning that makes it into a problem—meanings that can give rise to physical, emotional, and behavioural reactions, such as discomfort, self disgust, perhaps avoidance of some activities, and a desire for a surgical fix.

### A vicious cycle

The increased demand for cosmetic genitoplasty may reflect a narrow social definition of normal, or a confusion of what is normal and what is idealised. The provision of genitoplasty could narrow acceptable ranges further and increase the demand for surgery even more. More research is needed to learn about the social and psychological processes that have enabled many women to develop their own solutions to similarly negative preoccupations.

Resource issues aside, availability of surgical interventions could undermine the development of other ways to help women and girls to deal with concerns about their appearance in general. Surgery does not connect women with their ability to solve problems, with the result that some women just become preoccupied with the next “defect” to be fixed.

### A questions for the NHS

Interventions that produce enduring psychological and functional benefits should not be dismissed. However, surgery is an extreme and unproved intervention in this instance, and it may not obviate the need for more specialist interventions. In the absence of local or national guidelines for surgeons, practice is likely to remain idiosyncratic.

Alleviation of suffering is fundamental to all healthcare professions, so who should tackle this emerging problem? When we reviewed general practitioners’ letters of referral, we observed that they might have been unsure how to respond to their patients’ intimate concerns without trivialising them. Some referrals may have been made in the hope that experts would persuade the woman that she was normal and deter her...
from surgery. But the lack of immediate reassurance and referral to a specialist might be interpreted as proof of the need for surgery. An increased desire for the longed for fix could subsequently compromise the patient’s capacity to process information on risks and limitations about their desired intervention. Even with psychological expertise, the surgical context is unlikely to encourage women and girls to acknowledge and explore their struggles to develop a range of solutions.

Transcript extracts: a real dilemma

The decision about whether to undergo cosmetic surgery is said to be a dilemma for women as it is “problem and solution, oppression and liberation, all in one.” And so, despite their satisfaction with the treatment, most of our interviewees were hesitant about recommending it to other women. For example, “There’s a there’s a there’s a balance [[I] would be interested actually to know how many women truly do need the operation out of all of us [research participants], because it would be interesting.”

“... if it’s, purely [:] for cosmetic reasons and to me it looked, fine, I will have my doubts [I] think it just varies, it’s just, opinion.”

The need for the complaint to be real was thought to be an important basis for surgery, and what made it real was, firstly, the consistency with which it had troubled them and, secondly, by that trouble having been physical,

“So I think you know sometimes you just have to be very careful. [:] You know when it’s how someone sees themselves, or how they think, because then, you know that that can change with the wind, but if it’s how they feel, based on a you know a physical feeling ...” or psychological,

“There need to be strong reasons, like in my case, when my partner comes near me, I want to avoid it [partner looking at her genitals] ...”

In the absence of either physical or psychological unease, however, it was the psychologically arduous process—the “work” involved—in seeking help from “proper” NHS doctors that authenticated the preoperative complaint,

“... I thought, I’ve had to think about this, you know and I’ve had to [!] it’s not, so it can just be oh I’m going I’m ... Every other woman can say well I might as well have that done, I’ve had this done I’ve had that done I might as well have that done you know ... it’s the available thing isn’t it ... but once you’ve had to work to get it ... You know to me, psychologically if you, if you go through the right channels [general practitioner and specialist] ... rather than feeling that you can just, get it done just like that [!]. There’s no understanding behind that is there?”

“True” needs and “ untrue” needs cannot easily be separated in this context. The hesitancy of these otherwise articulate women may mirror that of surgeons who operate on women yet cannot reconcile their practice in principle or to recommend it as policy. These transcripts also suggest that genital surgery may be just one of a series of cosmetic operations in a woman’s lifetime. One of the women had had breast augmentation to relieve her from “self-consciousness.” Another one was saving for a “face lift.” One young woman had had her labia reduced at the age of 17 to stop her feeling anxious. However, she was still sexually anxious and avoided sex, so she was now seeking excision of her remaining labia. Like women born with atypical genitals, the surgical fix is so compelling that it can be difficult to explore the psychological basis for surgery beforehand, or even afterwards.21

Key to transcript notation: []=noticeable pause; . =text omitted; [text]=text inserted by authors for clarification; text=said with emphasis; [:]=interviewee’s minimal encouragers

It should be thought of as the last resort, not the first port of call.

Multiagency initiatives involving health agencies, educational bodies, the voluntary sector, and the media are needed to help girls and women deal with feelings of insecurity about their genitals and about their bodies in general. We also need more commitment and investment in research as well as innovative interventions in the community to help women and girls to approach concerns about their appearance skilfully and imaginatively.

We are grateful to our patients and interviewees and to Naomi Crouch, Iain Morland, and Mary Boyle for their help and suggestions.

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Contributors and sources: LML is a consultant clinical psychologist with broad academic interests in women’s health and she works clinically with adolescent and adult women with disorders of sex development. SMC is a consultant gynaecologist and a specialist in disorders of sex development and more broadly adolescent gynaecology.

Competing interests: None declared.

Ethical approval: Obtained from UCL and UCLH.

Provenance and peer review: Non-commissioned; externally peer reviewed.

References


Primary care research networks in the United Kingdom

Frank Sullivan and colleagues describe the new bodies emerging to coordinate and boost primary care research in the four UK countries.

In British primary care, where 80% of National Health Service consultations take place, policy decisions often depend more on optimistic theory than on evidence. Conducting research has generally been a low priority for primary care clinicians in the United Kingdom. The ethos of independent small business in general practice tends more towards innovation than research, and scarce academic training opportunities are associated with a culture where research is not much expected, valued, or rewarded. Yet with leadership, resource, and good relationships between researchers and service providers, primary care research can underpin effective and efficient practice in ways that specialist perspectives alone cannot.

Moreover, the UK has developed primary care research infrastructures that have been enabling and influential internationally. Most recently, the new national health research strategy aims to “re-engineer the environment in which clinical research is conducted” through the UK Clinical Research Network (UKCRN), which involves primary care centrally (figure). This network is intended to offer a managed approach to hosting high quality research in the health service and to assuring recruitment and retention of study participants. In primary care this contrasts with the previously established diverse, capacity building, practitioner centred networks. The four countries of the UK are using different approaches in primary care to realise this new network. We describe them briefly here, to demonstrate the direction and scale of the changes.

England

In England (population >50 million) one primary care research network has been established across the whole country. This is part of a wider initiative, which will include six topic specific networks and a comprehensive clinical research infrastructure through which service support, research governance, and academic staff will also be funded. The England wide primary care research network comprises central coordination of eight distinct local networks. These networks link interested practice teams and local academic units of general practice to participate in a wide range of national projects led from the service, universities, and industry. The leadership is currently negotiating a sometimes painful transition away from prioritising capacity building for research at the local level and towards national priorities.

A National School for Primary Care Research was established in 2006. Focused initially on the five English academic departments of general practice and primary care scoring 5 or 5* in the last research assessment exercise, it has two aims. These are to improve primary care through evidence from research at each stage along the patient pathway (from prevention to management of long term conditions) and to work with UKCRN and other interested organisations to develop a world class UK primary care research portfolio.

Scotland

Scotland (population 5 million) was the first part of the UK to establish, in 1999, a school of primary care. The Scottish Executive and NHS Education Scotland fund the Scottish School of Primary Care to build research capacity and capability through a network called Scottish Practices and Professionals Involved in Research. The Scottish Funding Council has also recently provided extra funds to a consortium of all Scottish higher education institutions engaged in primary care research. This virtual organisation includes all Scottish academics with an interest in primary care research and the many clinicians who undertake, participate in, and facilitate research while carrying out their normal clinical work (currently 1700 people).

Wales

Wales (population 3 million) will have a single unified research infrastructure—Clinical Research Collaboration Cymru—covering primary, secondary, and tertiary health care and social care. The Welsh Assembly has commissioned a research professionals’ network to support research and recruit patients into high quality, peer reviewed studies. The network will eventually include up to 22 accredited “nodal” research general practices, each with a half time research nurse or equivalent resource. These practices will recruit patients into studies, develop research in neighbouring general practices and other primary health and social care facilities, and link with research professionals in hospital settings. Plans for a Welsh School of Primary Care Research are being developed.

Northern Ireland

Northern Ireland (population 1.7 million) has no ring fenced investment for research in primary care. The Northern Ireland Research and Development Office supports several “recognised research groups” which focus on specialised areas of care and are encouraged to include primary care in their work.

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Ireland Clinical Research Network is developing currently, with planned provision of a comprehensive infrastructure and central administrative resource for research in primary, secondary, tertiary, and social care. This network will collaborate with UKCRN to avoid duplication of policy and procedure development and to achieve mutual benefit in enhancing local capacity for high quality research projects. Whether a specific network similar to that for primary care in England will be established remains undecided; the progress of networks in other areas of the UK will undoubtedly inform this decision.

These models reflect a range of cultures and priorities in both the service and research arms of the health services serving the four nations. The vision of effective UK wide networking in research is not yet, however, reflected by current realities. The challenges and transaction costs of collaborations between local organisations, let alone between nations, are high. Setting of timescales and management of human and other resources will have to be realistic if the best that is promised is not to become the enemy of the evolving good.

Competing interests: FS is director of the Scottish School of Primary Care, CB is the associate director (primary care) CRC Cymru, and A-LK was associate director UKCRN (primary care) from 2005 to 2007. The opinions expressed here are not necessarily those of these organisations.

Provenance and peer review: Non-commissioned; peer reviewed.

The surgeon stands accused

After my father had undergone emergency surgery for small bowel obstruction, I visited him in a local hospital. He was pleased with the quality of care he had received but had some reservations about the consultant surgeon who had operated on him late the previous night. He recalled the consultant smelling strongly of alcohol, and my father felt that he had been drinking before attending the hospital to carry out the emergency surgery.

This concerned me greatly until I, too, was accused of smelling of alcohol. An impromptu clinical trial of using the hand sanitiser at the foot of the bed confirmed my hypothesis. The alcohol based hand rub was the guilty party and not the consultant surgeon.

Nowadays, hand washing is a cornerstone of hospital good practice. The National Patient Safety Agency’s Clean Your Hands campaign was deemed a success partially because of its initiative to provide hand sanitiser on each patient’s bed. Perhaps the next step in the campaign should be to find a product with a more satisfactory odour.

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Effect of administration of intestinal anthelmintic drugs on haemoglobin: systematic review of randomised controlled trials

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ABSTRACT
Objective To evaluate the effect of routine administration of intestinal anthelmintic drugs on haemoglobin.

Design Systematic review of randomised controlled trials.

Data sources Electronic databases and hand search of reviews, bibliographies of books, and abstracts and proceedings of international conferences.

Study selection Included studies were randomised or quasi-randomised controlled trials using an intestinal anthelmintic agent in the intervention group, in which haemoglobin was evaluated as an outcome measure. Trials in which treatment for schistosoma (praziquantel) was given exclusively to the intervention group were excluded.

Results The search identified 14 eligible randomised controlled trials. Data were available for 7829 subjects, of whom 4107 received an anthelmintic drug and 3722 received placebo. The pooled weighted mean difference (random effect model) of the change in haemoglobin was 1.71 (95% confidence interval 0.70 to 2.73) g/l (P<0.001; test for heterogeneity: Cochran Q=51.17, P=0.001; I²=61% (37% to 76%)). With the World Health Organization’s recommended haemoglobin cut-offs of 120 g/l in adults and 110 g/l in children, the average estimated reduction in prevalence of anaemia ranged from 1.1% to 12.4% in adults and from 4.4% to 21.0% in children. The estimated reductions in the prevalence of anaemia increased with lower haemoglobin cut-offs used to define anaemia.

Conclusions Routine administration of intestinal anthelmintic agents results in a marginal increase in haemoglobin (1.71 g/l), which could translate on a public health scale into a small (5% to 10%) reduction in the prevalence of anaemia in populations with a relatively high prevalence of intestinal helminthiasis.

INTRODUCTION
Anaemia is a widespread public health problem with major consequences for human health as well as social and economic development. The adverse health consequences associated with this malady include increased mortality in mothers and children with severe anaemia, impaired cognitive and physical development of children, and reduced work productivity of adults.1 Anaemia is estimated to affect nearly a third of the global population.2 It is more widespread in South Asia (53%) than in other regions of the world.3 From a public health perspective, iron deficiency is believed to be the most important causal factor for anaemia. The fact that most anaemia control programmes, particularly in the developing world, rely on iron supplementation as the core strategy is therefore not surprising. Whether iron intervention alone can control anaemia on a public health scale is now, however, increasingly being questioned. A recent systematic review of randomised controlled trials of iron supplementation in children estimated that an average of between 38% and 62% of baseline anaemia (haemoglobin<110 g/l) is responsive to iron supplementation among children aged under 6; the corresponding range for malarial hyperendemic regions is 6% to 32%.4 Administration of intestinal anthelmintic agents has been proposed as an additional intervention to reduce anaemia. Around two billion people globally are estimated to be infested with helminths, and 300 million of them have severe and permanent impairments.5 Observational data suggest an inverse relation between intestinal helminthiasis and haemoglobin concentrations.6 However, intervention trials using anthelmintic drugs have provided conflicting evidence; some authors have documented improvements in haemoglobin concentration,7-8 whereas other investigators have found no such benefit.9-10 To aid public health decisions, we did a systematic review of randomised controlled trials to evaluate the effect of routine administration of intestinal anthelmintic agents on haemoglobin and identify any predictors of effect.

METHODS
Searches
We did Medline and extended Medline searches (1966 to 31 July 2006) by using the search words [haemoglobin OR hemoglobin OR anaemia OR anemia] AND (deworming OR anti-helminthic OR anthelmintic OR anthelminth OR mebendazole OR praziquantel OR pyrantel OR piperazine OR nirazoxanide OR levamisole OR albendazole OR buphenium OR niclosamide) with limits pertaining to “human” subjects for clinical trial, review, meta-analysis, and randomised
We assessed the quality of trials by using recommended criteria.\textsuperscript{7,8} We classed concealment of allocation as adequate, unclear, or inadequate. To assess attrition, we classified studies by percentage of participants lost to follow-up (<4.9%, 5-9.9%, 10-19.9%, and ≥20%). For the purpose of this calculation, we considered the number of patients available at the last follow-up (at which data were retrievable). We classified blinding as double blinding, single blinding, no blinding, or unclear.

### Data abstraction

AG and JN used pre-formed questionnaires to abstract the data in duplicate. The data included in this review were derived from the published papers or provided by the authors. If needed, and wherever possible, we contacted the authors for clarifications.

### Quantitative data synthesis

For calculating pooled estimates, we needed the sample size, the mean change in haemoglobin or serum ferritin from the beginning to the end of the intervention, and the standard deviation of this change in the intervention and control groups. We used the following principles for derivations if actual variables were not stated: in a group, we assumed the lower of the two stated sample sizes at the beginning or end of a trial to be the sample size for the change; wherever feasible, we back calculated the standard deviation from the stated standard errors, t, or P values; wherever it was not stated, we calculated the mean change in the outcome variable as the difference between mean post-intervention and pre-intervention values; and wherever it was not stated, we assumed the mean age of patients to be approximately equal to the median age, or the same as that of the entire study group.

The standard deviation for the change in haemoglobin was available or could be back calculated in several but not all trials. For the rest, we calculated this standard deviation by assuming correlations of 0.5 and 0 (independent) between the pre-intervention and post-intervention variances. Considering the number of assumptions and calculations involved, to be confident about the interpretation we calculated four types of pooled estimates. In the first, we used the available values for the change. In the second and third, we calculated the standard deviation for the change for values that were missing or could not be back calculated, with the assumptions of a correlation (p) = 0.5 or of independence (p) = 0. For the fourth, we used the post-intervention scores and their respective standard deviations.

We evaluated the presence of publication bias in the extracted data by using funnel plots.\textsuperscript{9} We used the “metabias” command in Stata software to test funnel plots for asymmetry. We calculated the pooled estimates of the weighted mean difference of the evaluated change in outcome variable between the control and intervention group by both fixed effects and random effects model assumptions by using the “metan” command in Stata software. We mainly report random effects estimates here, because most of the pooled results obtained were statistically heterogeneous.

We carried out prespecified stratified analyses for age group, developing or developed country, malaria endemicity, schistosoma endemicity, pre-intervention worm load, methodological quality, compliance monitoring, number of anthelmintic courses, co-administration of iron, baseline haemoglobin concentrations, and change variances not stated (n=2)
and baseline anthropometry (in children). We also explored the contribution of these variables to heterogeneity by meta-regression with the “metareg” command in Stata software with the restricted maximum likelihood option. In the study in which one control group was used for two intervention groups, the estimates of treatment effect were thus correlated. We explicitly modelled this correlation in obtaining the maximum likelihood estimate of the treatment effect pooled across all studies.

**RESULTS**

We identified 36 potentially eligible randomised controlled trials. Twenty two studies were ineligible,* and nine in Africa) on pre-schoolchildren and school-aged children (11/14). One study was done in non-pregnant adults, one in pregnant women, and one in all age groups. Ten of the studies used albendazole as the anthelmintic drug, three used mebendazole, and one used benphenum. Iron was used as co-intervention in more than half of the studies (7/12). Twelve studies were done in areas classified as endemic for malaria, and six were done in areas endemic for schistosoma.

**Quantitative data synthesis**

We found no evidence of asymmetry of the funnel plot (fig 2), suggesting an absence of publication bias. We confirmed this by using the Egger’s (weighted regression) method [P for bias=0.11] and the Begg’s (rank correlation) method (continuity corrected P=0.11).

Data were available for 7829 patients, of whom 4107 received deworming treatment and 3722 received placebo. The pooled weighted mean difference (random effects model) of the change in haemoglobin (pre-intervention to post-intervention difference) after deworming was 1.71 (95% confidence interval 0.70 to 2.73) g/l [P<0.001; test for heterogeneity: Cochran Q=51.17, P<0.001; I²=61%, (37% to 76%)](fig 3, table B on bmj.com). The results were similar when we calculated the missing standard deviations by assuming independence and with post-intervention scores (independence: weighted mean difference 1.77 (0.75 to 2.80) g/l, P=0.001; post-intervention scores: weighted mean difference 2.01 (0.58 to 3.44) g/l, P=0.006). The effect size was marginally higher when we restricted the analysis to those studies with available standard deviation scores for the change in haemoglobin (weighted mean difference 2.55 (1.52 to 3.57) g/l, P<0.001; test for heterogeneity: Cochran Q=19.89, P=0.225; I²=20% (0% to 55%)).

Other markers of iron status were estimated in only three of the studies, which precluded a formal meta-analysis. Also, one study did not make it clear whether serum ferritin concentration was depicted as the arithmetic or geometric mean. Deworming increased the serum ferritin and erythrocyte iron status.

**Table 1**  
Meta-regression analyses for haemoglobin (g/l) weighted mean difference* (WMD) (restricted maximum likelihood method)

<table>
<thead>
<tr>
<th>Study characteristic</th>
<th>Univariate analysis</th>
<th>Controlling for all variables†</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>WMD (95% CI)</td>
<td>P</td>
</tr>
<tr>
<td>Study quality:</td>
<td></td>
<td></td>
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<tr>
<td>Allocation concealment (not adequate v adequate)</td>
<td>0.98 (−0.96 to 2.92)</td>
<td>0.321</td>
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<tr>
<td>Attrition (10% v &gt;10%)</td>
<td>0.81 (−1.14 to 2.76)</td>
<td>0.414</td>
</tr>
<tr>
<td>Blinding (not double blind v double blind)</td>
<td>−0.72 (−2.92 to 1.50)</td>
<td>0.527</td>
</tr>
<tr>
<td>Adults included v children only</td>
<td>2.85 (1.00 to 4.70)</td>
<td>0.002</td>
</tr>
<tr>
<td>Malaria hyperendemic v not</td>
<td>0.35 (−2.00 to 2.70)</td>
<td>0.770</td>
</tr>
<tr>
<td>Schistosoma hyperendemic v not (n=19)</td>
<td>−0.72 (−2.62 to 1.18)</td>
<td>0.460</td>
</tr>
<tr>
<td>Worm load high v low (n=20)</td>
<td>0.76 (1.06 to 2.58)</td>
<td>0.414</td>
</tr>
<tr>
<td>Unit increase in No of anthelmintic courses (n=20)</td>
<td>−0.49 (−1.13 to 0.15)</td>
<td>0.132</td>
</tr>
<tr>
<td>Iron co-intervention v none</td>
<td>1.92 (0.22 to 3.62)</td>
<td>0.027</td>
</tr>
<tr>
<td>Unit increase in mean baseline haemoglobin status (g/l)</td>
<td>0.04 (−0.06 to 0.14)</td>
<td>0.387</td>
</tr>
<tr>
<td>Unit increase in weight for age z score (n=15)</td>
<td>1.45 (−0.40 to 3.29)</td>
<td>0.124</td>
</tr>
</tbody>
</table>

Ni=not included in multivariate analyses as numbers of variables that can be included is limited and information missing in some variables.

*Calculations done by standard deviation calculated with assumption (p)=0.5.
†Sample size for multivariate analysis is 20 analytic units.
protoporphyrin concentration in pre-schoolchildren and schoolchildren in Zanzibar after 12 months of anthelmintic treatment.\textsuperscript{w5,w30} The third study included pregnant women and documented a decrease in mean serum ferritin concentration from the baseline to the third trimester in all patients.\textsuperscript{w31} However, use of albendazole did not result in any significant increase in serum ferritin concentrations.

Sensitivity analyses (table B on bmj.com) suggested a greater rise in haemoglobin (non-overlapping confidence intervals) in trials that included adults. Meta-regression (table 1) by univariate analysis suggested that inclusion of adults and use of iron as a co-intervention were significant predictors of a positive effect of the deworming agent. However, on multivariate analysis, neither of these variables was identified as a significant predictor.

We also estimated the average expected reduction in the prevalence of anaemia with deworming on the basis of the calculated weighted mean difference by using varying haemoglobin cut-offs to define anaemia (table 2). With the World Health Organization’s recommended haemoglobin cut-offs of 120 g/l in adults and 110 g/l in children, the average estimated reduction in the prevalence of anaemia ranged from 1.1% to 12.4% in adults and from 4.4% to 21.0% in children. The estimated reductions in the prevalence of anaemia increased with lower haemoglobin cut-offs used to define anaemia.

**DISCUSSION**

The results from these largely heterogeneous data derived from randomised controlled trials show that deworming without previous screening marginally improves haemoglobin concentration (weighted mean difference 1.71 (95% confidence interval 0.70 to 2.73) g/l, \(P<0.001\)). Inclusion of adults and co-administration of iron emerged as significant predictors of greater haemoglobin response and heterogeneity requiring further exploration. The projections of expected average reductions in baseline anaemia through routine deworming ranged from 5% to 10%. The estimated reduction in the prevalence of anaemia was higher with lower haemoglobin cut-offs.

**Strengths and limitations**

The main conclusion about the rise in haemoglobin after routine administration of intestinal anthelmintic agents remained stable over a large spectrum of sensitivity analyses. Influence analysis—namely, the effect of omitting one study at a time (data not shown)—did not reveal an overwhelming effect of any single trial.

Several limitations merit consideration. Firstly, most of the trials did not specifically evaluate the iron status of the patients. Secondly, in trials with missing data on the variability of the change in haemoglobin, we made several imputations on the basis of the prespecified assumptions. The sensitivity analysis suggested that these imputations were robust. Finally, we did multiple subgroup and meta-regression analyses for important prespecified variables, which increased the possibility of false positive results. The identified significant predictors of greater haemoglobin response and heterogeneity should therefore be considered as only exploratory in nature, rather than definitive.

**Implications**

A few interesting observations emerged that have programmatic implications and can provide direction for future research. Information on iron status was provided in only three studies. In the two studies done in children, deworming increased the serum ferritin and protoporphyrin concentrations\textsuperscript{w5,w30} whereas the study in pregnant women found no change in the iron status.\textsuperscript{w31} The physiological changes induced by pregnancy, including excessive demand for iron, may have
WHAT IS ALREADY KNOWN ON THIS TOPIC

Anaemia is a widespread public health problem with major consequences for human health, as well as for social and economic development.

Iron deficiency is believed to be the most important causal factor for anaemia, but whether iron intervention alone can control anaemia on a public health scale is questionable.

Administration of intestinal anthelmintic drugs has been proposed as an additional intervention to reduce anaemia.

WHAT THIS STUDY ADDS

Routine administration of intestinal anthelmintic drugs results in a marginal increase in haemoglobin concentration.

On a public health scale, this could translate into a small (5% to 10%) reduction in the prevalence of anaemia in populations with a relatively high prevalence of intestinal helminthiasis.

Prevented a relative increase in indicators of iron status in the dewormed group in this study. The studies in children suggest that routine deworming may be increasing haemoglobin by enhancing iron status, possibly by preventing helminth induced blood loss. However, further data are needed in this context, and future studies could usefully incorporate indicators of iron status in serum and of iron and blood losses in stool.

Surprisingly, the baseline helminthic prevalence did not emerge as a significant predictor of haemoglobin response. This may have been because the egg density would be a better quantification of the helminthic load than single prevalence data. However, these data were not available in all the studies to allow a pertinent analysis. Alternatively, the host could have dynamically regulated the iron absorption in relation to the presence or absence of intestinal helminths.

An increase in the number of doses of anthelmintic agent was not a significant predictor of haemoglobin response. Further trials could include information on the time sequence of helminthic reinfection and haemoglobin concentrations to gain better insight into this observation. Furthermore, we need to remember that this observation does not stem from a head to head comparison of single versus multiple doses of anthelmintic drug. Another systematic review also could not document a greater effect on mean weight change in children with multiple doses of anthelmintics.

The programmatic implications of these findings should be examined. Projections suggested that this marginal increase in haemoglobin could translate into a small (5% to 10%) reduction in the prevalence of anaemia on a public health scale. Better returns may occur in adults and in populations receiving iron supplementation and with a high prevalence of intestinal helminthiasis. However, in this context, no leads emerge regarding the optimal frequency and period of anthelmintic treatment, particularly in combination with iron prophylaxis, are also important. In the absence of specific data, commenting on this aspect would be difficult; however, with the projected reductions in the prevalence of anaemia, the cost effectiveness would be unlikely to be substantial.

Conclusion

Routine administration of intestinal anthelmintic drugs results in a marginal increase in haemoglobin (1.71 g/l), which could translate on a public health scale into a small (5% to 10%) reduction in the prevalence of anaemia in populations with a relatively high prevalence of intestinal helminthiasis.

We acknowledge the efforts of Nidhi Gupta in helping with the search and retrieval of the full text of the articles.

Contributors: AG and JN prepared the protocol, applied the search strategy, retrieved the articles, and extracted data. CO contributed to the statistical analysis. HPSS developed the idea for review, finalised the protocol and search strategy, and did the statistical analysis. All authors contributed to the drafting of the final version of the paper. HPSS is the guarantor.

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Effectiveness of visits from community pharmacists for patients with heart failure: HeartMed randomised controlled trial

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ABSTRACT
Objective To test whether a drug review and symptom self management and lifestyle advice intervention by community pharmacists could reduce hospital admissions or mortality in heart failure patients.
Design Randomised controlled trial.
Setting Home based intervention in heart failure patients.
Participants 293 patients diagnosed with heart failure were included (149 intervention, 144 control) after an emergency admission.
Intervention Two home visits by one of 17 community pharmacists within two and eight weeks of discharge. Pharmacists reviewed drugs and gave symptom self management and lifestyle advice. Controls received usual care.
Main outcome measures The primary outcome was total hospital readmissions at six months. Secondary outcomes included mortality and quality of life (Minnesota living with heart failure questionnaire and EQ-5D).
Results Primary outcome data were available for 291 participants (99%). 136 (91%) intervention patients received one or two visits. 134 admissions occurred in the intervention group compared with 112 in the control group (rate ratio=1.15, 95% confidence interval 0.89 to 1.48; P=0.28, Poisson model). 30 intervention patients died compared with 24 controls (hazard ratio=1.18, 0.69 to 2.03; P=0.54). Although EQ-5D scores favoured the intervention group, Minnesota living with heart failure questionnaire scores favoured controls; neither difference was statistically significant.
Conclusion This community pharmacist intervention did not lead to reductions in hospital admissions in contrast to those found in trials of specialist nurse led interventions in heart failure. Given that heart failure accounts for 5% of hospital admissions, these results present a problem for policy makers who are faced with a shortage of specialist provision and have hoped that skilled community pharmacists could produce the same benefits.
Trial registration number ISRCTN59427925.

INTRODUCTION
Research on the treatment of heart failure focuses on drug treatment, yet evidence from trials of multidisciplinary interventions suggests that education and drug review interventions are effective at reducing hospital readmission and mortality.1 Trials to date have generally used heart failure specialist nurses to deliver these interventions, almost all involved fewer than 200 patients, and most were done outside the United Kingdom, although one of the most positive trials was carried out by specialist nurses in Glasgow.2 Unfortunately, few heart failure nurses exist throughout the UK, so developing local packages of specialist care equivalent to that in the Glasgow study may be difficult. Equally, using hospital based staff in rural areas is likely to be inefficient because of time lost in travel.

Community pharmacists, of whom there are more than 12,000 in the UK, provide a possible alternative. They are well placed geographically to provide a local service. They are highly trained in therapeutics, used to dealing with patients on a one to one basis, and skilled in drug problems and adherence. Furthermore, the UK government has been encouraging an extension to the role of community pharmacists, including independent prescribing, medicine use review, and a health promotion role to provide advice about, among other things, smoking cessation and diet.3-5 Although pharmacists seem to be an excellent resource with which to provide a Glasgow-style intervention, the only UK evidence to support their use is from two small studies that were limited by their size.6,7 We have therefore assessed a community pharmacist led intervention in a large randomised controlled trial.
METHODS

Recruitment and assignment
Researchers recruited patients from three large district general hospitals. Eligible patients were adults (aged over 18 years), admitted as an emergency in which heart failure was an important ongoing clinical condition, and prescribed two or more drugs (from any drug class) on discharge. We excluded patients if they were living in a residential or nursing home, awaiting surgery for ischaemic or valvular heart disease or heart transplantation, or had terminal malignancy. We randomised patients to receive the pharmacist intervention or usual care. We used third party telephone randomisation based on a computer generated random allocation sequence. We stratified randomisation by New York Heart Association class (class I/II—no or mild limitation, III—moderate limitation, or IV—severe limitation) and recruitment site. We obtained written informed consent from all participants.

Outcome data and analysis
The primary outcome was total emergency admissions to hospital over six months. Secondary outcomes included deaths and self assessed quality of life measured with the EQ-5D (a generic instrument) and the Minnesota living with heart failure questionnaire (a disease specific instrument). The EQ-5D gives scores varying from 1 (perfect health) to −0.59 (worst imaginable health state) and includes a visual analogue scale from 100 (perfect health) to 0 (worst imaginable health state).

Community pharmacists could participate if they held a postgraduate qualification in pharmacy practice or had recent continuing professional development in therapeutics. These pharmacists were not independent prescribers and so could not directly modify patients’ drug regimens. All participated in a one day training course, including lectures on heart failure, heart failure drugs, exercise, diet, and smoking cessation advice (contact time=7 hours). More than half of the pharmacists attended two evening training events on communication skills (contact time=4 hours). Additionally, 14 of the 17 study pharmacists had received training in drug review as part of a previous trial (contact time=14 hours). The other three study pharmacists received an additional one day’s training on drug review.

Table 1 | Baseline comparison of intervention and control group patients. Values are numbers (percentages) unless stated otherwise

<table>
<thead>
<tr>
<th>Demographic/clinical variables</th>
<th>Intervention group (n=149)</th>
<th>Control group (n=144)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female sex</td>
<td>54 (36.2)</td>
<td>53 (36.8)</td>
</tr>
<tr>
<td>Mean (SD) age (years)</td>
<td>77.6 (9.0)</td>
<td>76.4 (9.5)</td>
</tr>
<tr>
<td>Living alone</td>
<td>58 (38.9)</td>
<td>52 (36.1)</td>
</tr>
<tr>
<td>Mean (SD) length of stay at baseline (days) (from HES data)</td>
<td>7.3 (15.5)</td>
<td>7.8 (11.6)</td>
</tr>
<tr>
<td>Mean (SD) abbreviated mental test score*</td>
<td>9.2 (1.0)</td>
<td>9.3 (1.0)</td>
</tr>
<tr>
<td>NYHA class (self classification):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>6 (4.0)</td>
<td>11 (7.6)</td>
</tr>
<tr>
<td>II</td>
<td>43 (28.9)</td>
<td>37 (25.7)</td>
</tr>
<tr>
<td>III</td>
<td>52 (34.9)</td>
<td>47 (32.6)</td>
</tr>
<tr>
<td>IV</td>
<td>48 (32.2)</td>
<td>49 (34.0)</td>
</tr>
<tr>
<td>Social class (I, II, IIIN)†</td>
<td>63 (44.1)</td>
<td>76 (54.7)</td>
</tr>
<tr>
<td>Mean (SD) No of prescribed items taken daily</td>
<td>7.9 (2.6)</td>
<td>7.7 (2.3)</td>
</tr>
<tr>
<td>Drugs at discharge included:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE inhibitor/A2RA</td>
<td>118 (79.2)</td>
<td>109 (75.7)</td>
</tr>
<tr>
<td>Loop diuretic</td>
<td>144 (96.6)</td>
<td>140 (97.2)</td>
</tr>
<tr>
<td>Spironolactone</td>
<td>60 (40.3)</td>
<td>56 (37.5)</td>
</tr>
<tr>
<td>ß blocker</td>
<td>53 (35.6)</td>
<td>61 (42.4)</td>
</tr>
<tr>
<td>Antiarrhythmic</td>
<td>16 (10.7)</td>
<td>19 (13.2)</td>
</tr>
<tr>
<td>Warfarin</td>
<td>51 (34.2)</td>
<td>49 (34.0)</td>
</tr>
<tr>
<td>Antiplatelet drug</td>
<td>78 (52.3)</td>
<td>76 (52.8)</td>
</tr>
<tr>
<td>Digoxin</td>
<td>52 (34.9)</td>
<td>44 (30.6)</td>
</tr>
<tr>
<td>Mean (SD) Frusenide dose, where applicable (mg)</td>
<td>88.0 (49.0)</td>
<td>87.9 (61.6)</td>
</tr>
<tr>
<td>Help with drugs‡</td>
<td>88 (60.3)</td>
<td>76 (54.3)</td>
</tr>
<tr>
<td>Drug adherence aid§</td>
<td>39 (26.5)</td>
<td>22 (15.5)</td>
</tr>
<tr>
<td>Mean (SD) length of stay at baseline (days) (from HES data)</td>
<td>12.5 (16.0)</td>
<td>12.8 (12.8)</td>
</tr>
<tr>
<td>Mean (SD) time from recruitment to discharge (days) (from HES data)</td>
<td>7.3 (15.5)</td>
<td>7.8 (11.6)</td>
</tr>
<tr>
<td>CCI/ICU/HDU admission during baseline admission¶</td>
<td>11 (7.4)</td>
<td>13 (9.1)</td>
</tr>
</tbody>
</table>

A2RA=angiotensin-2 receptor antagonist; ACE=angiotensin converting enzyme; CCI=coronary care unit; HES=Hospital Episode Statistics; HDU=high dependency unit; ICU=intensive care unit; NYHA=New York Heart Association.

*Not recorded for one patient in intervention group.
†Not recorded for four patients in each group and not classifiable for two intervention patients and one control patient.
‡Not applicable for three intervention and four control patients who were not taking drugs before their baseline admission.
¶Current use of adherence aid not recorded for one patient in each group and not known by one patient in each group.
§No data for one patient in control group.
Fig 1 | Flow of patients through the study

The Minnesota living with heart failure questionnaire consists of 21 questions each scored from 0 to 5. Total scores thus vary from 0 to 105, with higher scores implying a worse condition, and the questionnaire’s authors consider a change of 5 points to be clinically significant. In addition, participants completed a questionnaire that measures drug adherence (medication adherence report scale or MARS; R Horne, personal communication, 2002) and the European heart failure self care behaviour scale. We introduced the last questionnaire as an additional measure eight months into recruitment. We also collected data on primary care activity, including numbers of home visits by general practitioners or nurses, practice attendances by patients, numbers of drugs prescribed, and telephone calls to or from patients.

Emergency admission data came from Hospital Episode Statistics. The Office for National Statistics provided mortality data. We mailed questionnaires up to three times to participants at three and six months, and the project coordinator contacted all patients before sending the questionnaires each time to maximise response. Because of resource constraints, we collected primary care data on a subgroup of trial patients (those within practices containing more than three trial patients).

We used Poisson regression to compare the number of readmissions between groups. We analysed mortality by using survival analysis comparing the two groups with the Cox proportional hazard ratio. In both analyses, we made adjustments for the two stratification variables (New York Heart Association class and recruitment site). We analysed questionnaire data at six months by using analysis of covariance, adjusting for baseline scores, New York Heart Association class, and recruitment site. We used Poisson regression to compare home visits by general practitioners and attendance at general practitioner practices, entering practices into the model as a random effect and adjusting for the two stratification variables.

We analysed patient data according to randomisation group, irrespective of whether or not they received the intervention as planned (the intention to treat principle). We used Stata version 8.0 and set statistical significance at the 5% level.

Sample size calculation
Local admission data suggested a rate of 0.6 admissions per heart failure patient within six months of discharge. Previous randomised controlled trials suggested that this could be reduced by 40% over six months—that is, from 0.6 to 0.36 admissions. Sample size calculations based on a normal approximation to the Poisson distribution indicated that we needed 306 patients to confer 80% power to show this reduction at the 5% significance level (two sided).

RESULTS
Participant flow and follow-up
Figure 1 shows the flow of patients through the trial. We approached a total of 555 patients to participate after screening them for eligibility between December 2003 and March 2005. We randomised the 339 (61%) patients who agreed. We excluded 46 patients after randomisation because of death before discharge (n=18), heart failure diagnosis not confirmed (n=17), discharge to nursing/residential home (n=7), planned cardiac surgery or terminal malignancy (n=2), and previously recruited (n=2). Table 1 shows that the two groups were similar at baseline, except that fewer intervention participants were from non-manual social classes (44% v 55%) and intervention participants more often used some form of drug adherence aid (27% v 16%). Two patients moved out of the study area, so primary outcome data were available for 291 (99%) patients.

<table>
<thead>
<tr>
<th>Group</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Total admissions</th>
<th>Person years of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>70</td>
<td>49</td>
<td>13</td>
<td>9</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>112</td>
<td>64.58</td>
</tr>
<tr>
<td>Intervention</td>
<td>72</td>
<td>42</td>
<td>18</td>
<td>12</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>134</td>
<td>67.18</td>
</tr>
</tbody>
</table>

Table 2 | Number of emergency hospital readmissions by group during six months’ trial follow-up
study pharmacists and intervention visits
We recruited 17 study pharmacists. Of 149 patients in the intervention group, 136 (91%) received first visits. Seven (5%) patients were unavailable for various reasons, including death or early readmission, and six (4%) patients or their carers refused to be visited. Study pharmacists made a median of nine first visits each. Second visits were carried out for 119 (80%) patients; most of the losses were the result of death or readmission. Pharmacists spent an average of 5 hours 53 minutes delivering each patient’s intervention. This time was split reasonably evenly between visits (first visits mean length 72 minutes, second visits 50 minutes), administration (mean 114 minutes), and travel (mean 131 minutes). Pharmacists reported that they provided lifestyle advice (exercise, diet, and salt restriction advice) to more than 95% of visited patients and advice on symptom self management to all but one patient. Alcohol and smoking cessation advice were delivered to a lower proportion of patients, as few smoked (n=6) or drank alcohol (median reported weekly alcohol intake=0 units). Visits generated a total of 384 recommendations to general practitioners (2.8/visited patient), 257 after first visits and 127 after second visits. Approximately one third of recommendations related to heart failure drugs or monitoring; the remainder generally referred to other drug advice or monitoring. Pharmacists reported that 131 (51%) first visit recommendations were fully or partly enacted and 54 (21%) were not enacted; no data were available on the remaining recommendations.

Secondary outcomes
Mortality—Mortality data were available for all patients. Fewer deaths occurred in the control group than in the intervention group (24 v 30). Figure 2 shows the Kaplan-Meier survival graph. The hazard ratio comparing intervention and control groups was 1.18 (95% confidence interval 0.69 to 2.03; P=0.54).

Quality of life—EQ-5D scores at six months could be compared for 108 intervention patients and 104 controls (91% of surviving intervention patients and 87% of surviving controls) (table 3). Whereas intervention patients’ scores were unchanged, controls’ scores decreased by 10% (worsened), although the difference between groups was not significant (adjusted mean difference=0.07, 95% confidence interval −0.01 to 0.14; P=0.08). Scores on the visual analogue health scale improved slightly for both groups, but again did not differ significantly between groups. Minnesota living with heart failure questionnaires were completed by 78 intervention patients and 80 control patients at six months (66% of surviving intervention patients and 67% of surviving controls). Whereas intervention patients’ scores increased (worsened) slightly, those for control patients decreased (improved) slightly.

Table 3 | Mean EQ-5D scores, health visual analogue scale (VAS) scores, and Minnesota living with health failure questionnaire (MLHFQ) scores for groups at baseline and at three months and six months follow-up

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Score (SD)</td>
<td>No of respondents</td>
</tr>
<tr>
<td>EQ-5D at baseline†</td>
<td>0.58 (0.32)</td>
<td>147</td>
</tr>
<tr>
<td>EQ-5D at 3 months†</td>
<td>0.54 (0.33)</td>
<td>113</td>
</tr>
<tr>
<td>EQ-5D at 6 months†</td>
<td>0.58 (0.29)</td>
<td>108</td>
</tr>
<tr>
<td>VAS at baseline†</td>
<td>56.6 (19.0)</td>
<td>143</td>
</tr>
<tr>
<td>VAS at 3 months†</td>
<td>58.4 (20.8)</td>
<td>107</td>
</tr>
<tr>
<td>VAS at 6 months†</td>
<td>58.2 (19.6)</td>
<td>105</td>
</tr>
<tr>
<td>MLHFQ at baseline‡</td>
<td>45.9 (24.4)</td>
<td>139</td>
</tr>
<tr>
<td>MLHFQ at 3 months‡</td>
<td>49.6 (28.4)</td>
<td>85</td>
</tr>
<tr>
<td>MLHFQ at 6 months‡</td>
<td>47.7 (26.3)</td>
<td>78</td>
</tr>
</tbody>
</table>

*Based on analysis of covariance comparing results at six months adjusted for baseline score, site, and New York Heart Association class.
†High scores imply better health.
‡Low scores imply better health.
This difference was not significant (adjusted mean difference $= 3.73, -3.67$ to $11.13; P=0.32$).

**Drug adherence and behaviour change**—Patients in both groups reported very high levels of adherence at all times of follow-up; no between group differences were evident. Final adherence scores were marginally higher (better) in the intervention group (adjusted mean difference $= 0.12$ units, $-0.48$ to $0.73$ units; $P=0.68$) (table 4). Heart failure behaviour scores improved in both groups, although the final scores were non-significantly lower (better) in the intervention group (adjusted mean difference $= 1.7$ units, $-4.9$ to $1.5$ units; $P=0.29$) (table 5).

**Appropriateness of visit and patient satisfaction**—Pharmacists considered that the first visit was definitely useful for 68 (50%) patients and probably useful for 51 (38%) patients; they considered second visits to be definitely useful for 37 (31%) patients and probably useful for 58 (49%). One hundred and two (82% of those surviving) intervention patients responded to the satisfaction questionnaire at three months, of whom 75 (74%) considered the visits to have been extremely or very useful.

**Primary care data**—We included 135 patients from 25 practices in this analysis (70 intervention patients, 65 controls). The intervention seemed to increase primary care activity both in the home and in the general practice surgery, and increased numbers of prescription items. However, with the exception of general practitioners’ telephone calls and prescription items, differences between the groups were not statistically significant (table 6). Given these findings, we did one unplanned (post hoc) analysis, which summed all primary care activity (that is, all home visits, attendances at general practices, and phone calls). This analysis suggested that the intervention led to a 17% increase in primary care activity (rate ratio $= 1.17$, 95% confidence interval 1.06 to 1.29; $P=0.002$).

**DISCUSSION**

**Principal findings of the study**

The results suggest that this community pharmacist intervention does not lead to reductions in hospital admissions, in contrast to those found in trials of specialist nurse led interventions in heart failure. Instead, the intervention may increase emergency hospital admissions, although this result was not statistically significant. Equally, the intervention seemed to lead to a concomitant increase in primary care activity.

In terms of secondary outcomes, the intervention had no clear effect on mortality, although deaths were greater in number in the intervention group. The intervention led to no clear improvement in quality of life or drug adherence; we saw some indication of improved self care, but changes were not statistically significant.

**Strengths and weaknesses in relation to other studies**

Most non-pharmacological trials in heart failure have tended to be small (median 180 patients). By comparison, this study was larger (n=293). Early meta-analyses in this area suggested that reductions of 25-40% in admissions might be possible. However, more recent meta-analyses, published after this trial started, have suggested that such interventions yield more modest reductions in admissions of approximately 10-20%. This trial did not have a sample size based on this smaller effect. Our confidence limit around the main outcome, however, suggests that at best our intervention could lead to either a small decrease (10%) or a potentially substantial increase (50%) in admissions.

Despite these problems related to sample size, the finding that the intervention at best had no clear positive effect did seem to be consistent. Instead, it would seem to have increased health service activity in both secondary and primary care with no comparable health improvement (as measured by quality of life and mortality). The intervention, although appreciated by patients, affected their heart failure “self care” only modestly, if at all. Little gain seemed to be made in adherence, as patients reported very good adherence even at baseline, although such self report data should be considered with some caution. Finally, the two quality of life measures seemed to move in different directions.

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**Table 4** | Medication adherence report scale (MARS) scores

<table>
<thead>
<tr>
<th>Time</th>
<th>Intervention group (n=149)</th>
<th>Control group (n=144)</th>
<th>Adjusted mean difference (95% CI); $P$ value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (median)</td>
<td>No of respondents</td>
<td>Mean (median)</td>
</tr>
<tr>
<td>Baseline</td>
<td>23.82 (25)</td>
<td>133</td>
<td>23.64 (25)</td>
</tr>
<tr>
<td>3 months</td>
<td>24.11 (25)</td>
<td>112</td>
<td>24.09 (25)</td>
</tr>
<tr>
<td>6 months</td>
<td>23.74 (25)</td>
<td>101</td>
<td>23.55 (25)</td>
</tr>
</tbody>
</table>

Scores can range from 5 (very poor adherence) to 25 (perfect adherence).

*Analysis of covariance comparing results at six months adjusted for baseline score, site of recruitment, and New York Heart Association class.

---

**Table 5** | European heart failure self care behaviour scale scores

<table>
<thead>
<tr>
<th>Time</th>
<th>Intervention group (n=149)</th>
<th>Control group (n=144)</th>
<th>Adjusted mean difference (95% CI); $P$ value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Score (SD)</td>
<td>No of respondents</td>
<td>Score (SD)</td>
</tr>
<tr>
<td>Baseline</td>
<td>31.1 (8.69)</td>
<td>90</td>
<td>30.6 (9.07)</td>
</tr>
<tr>
<td>3 months</td>
<td>26.08 (10.04)</td>
<td>60</td>
<td>26.58 (10.47)</td>
</tr>
<tr>
<td>6 months</td>
<td>26.58 (9.45)</td>
<td>60</td>
<td>28.27 (8.66)</td>
</tr>
</tbody>
</table>

This questionnaire was included from the mid point of the study, so data are available on only a subset of participants; scores can range from 12 to 60; low scores imply better self care behaviour.

*Analysis of covariance comparing results at six months adjusted for baseline score, site of recruitment, and New York Heart Association class.
Meaning of the study

One may conjecture about possible explanations for our failure to detect a positive effect size as large as 40% seen in some studies. One possible explanation is that the intervention was not delivered as intended. This seems unlikely, as pharmacists reported delivering all components of the intervention and this was corroborated by the substudy, which recorded a sample of interventions and identified that each component was indeed delivered. The substudy also suggested that the pharmacists seemed to use good consultation styles, as measured by the Henbest and Stewart rating scale. Furthermore, the visits seemed to be well received by patients, almost all of whom considered them to have been useful and of the right length and that the pharmacists had an appropriate level of knowledge. Nevertheless, a good communication style alone is unlikely to be sufficient. Indeed, the intervention was reasonably brief, and further research is needed to examine whether more focused interviewing skills of motivating behavioural change or promoting shared decision making would improve outcomes for patients.

Our intervention may have also been too late in the disease course to evoke behaviour change. This study included a broad mix of heart failure patients, and many patients may have already made changes to their behaviour (such as stopping smoking). Equally, others may have already adapted their lifestyle to their diagnosis (for example, by reducing their exercise), which potentially would have made them more resistant to accepting advice. A recent study of a specialist nurse led intervention also found no overall effect, but suggested possible effectiveness in newly diagnosed patients.

Unanswered questions and future research

The non-significant findings in this study mean that definitive conclusions are not possible. The confidence interval around our primary outcome can not exclude our intervention causing a modest decrease in admissions. However, the consistency of the results across the variety of study outcomes suggest that community pharmacists have no clear effect and may potentially increase use of health services. This last possibility was previously suggested by the HOMER trial, also done by our group. In contrast to this trial, HOMER recruited older patients with any disease. However, although our HeartMed intervention was focused on heart failure, pharmacists also gave advice and recommendations on patients’ complete drug regimen, and indeed over half of their recommendations to general practitioners related to other conditions. Thus, this trial adds further evidence to suggest that drug review type interventions may not necessarily yield positive health service gains, even when they are focused on one disease area. Whether a more intense version of our intervention could have yielded more positive effects is unknown. Equally, other examples exist of interventions that seem to have the potential to decrease health service activity but in reality may not affect it (such as the experience of NHS Direct) or may even increase use. Such interventions, although often appreciated by patients, may simply lower the threshold for seeking medical advice, increasing the cost of health care without concomitant improvements in health.

Given that heart failure accounts for 5% of hospital admissions, these results present a problem for policy makers who are faced with a shortage of specialist provision yet desire services that are widely available and can reduce admissions. The next research steps should be to rigorously evaluate whether initiatives to deliver specialist care across larger geographical areas have been successful, but also to determine how intense such services need to be.

We thank Anne Blyth, Vivienne Maskrey, Bett Barrett, Julia Hill, Jane Trippett-Jones, Jeannette Blacklock, and Lisa Regan for their hard work recruiting patients collecting data. We thank Catherine Heywood, clinical pharmacist, Norfolk and Norwich University Hospital (NNUH); Janis Riches, Norwich PCT smoking cessation adviser; Esmarie Van Tonder, senior community dietitian, NNUH; Janice Nash, physiotherapist, NNH; Phillip Ralphs (patient representative); and Toni Hardman, cardiologist specialist nurse, NNUH, for delivering the heart failure questionnaire.

Table 6 | Primary care activity data for subgroup of patients for whom these were collected

<table>
<thead>
<tr>
<th>Intervention group (n=70)</th>
<th>Control group (n=65)</th>
<th>Rate ratio*</th>
<th>Adjusted rate ratio†</th>
</tr>
</thead>
<tbody>
<tr>
<td>GP home visits</td>
<td>134</td>
<td>99</td>
<td>1.28 (0.97 to 1.68); P=0.08</td>
</tr>
<tr>
<td>Nurse/other visit</td>
<td>84</td>
<td>67</td>
<td>1.13 (0.82 to 1.57); P=0.46</td>
</tr>
<tr>
<td>Practice attendance—GP</td>
<td>289</td>
<td>263</td>
<td>1.05 (0.88 to 1.26); P=0.56</td>
</tr>
<tr>
<td>Practice attendance—nurse/other</td>
<td>373</td>
<td>316</td>
<td>1.13 (0.96 to 1.33); P=0.13</td>
</tr>
<tr>
<td>GP phone calls to/from patient</td>
<td>109</td>
<td>69</td>
<td>1.62 (1.17 to 2.23); P=0.003</td>
</tr>
<tr>
<td>Nurse/other phone call to/from patient</td>
<td>74</td>
<td>35</td>
<td>1.80 (1.17 to 2.75); P=0.007</td>
</tr>
<tr>
<td>Mean (median) drugs prescribed over 6 months</td>
<td>47.0 (41)</td>
<td>41.0 (38)</td>
<td>1.12 (1.06 to 1.18); P=0.001</td>
</tr>
</tbody>
</table>

GP=general practitioner.
*Participants’ general practice entered as random effect.
†Additionally adjusted for number of drugs prescribed at baseline.
training for the participating community pharmacists and Richard Youngs, Chris Abell, and Alexia Papageorgiou, UEA, for providing communication skills training for the community pharmacists. We also thank all the participating pharmacists, Norfolk Local Pharmaceutical Committee, and the study participants.

Contributors: RH, EL, IH, LS, and RS designed the study. RH, LH, EL, and KA analysed the results. All authors interpreted the results and contributed to writing revisions and approved the final manuscript. RH is the guarantor.

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Competing interests: None declared.

Ethical approval: Norwich District, King’s Lynn, and Great Yarmouth and Waveney local research ethics committees.

9 British Heart Foundation. Living with heart failure. London: British Heart Foundation, 2004. (Heart Information Series No 8.)
29 British Heart Foundation. Heart failure nurses. www.bhf.org.uk/living_with_heart_conditions/patient_support__resources/heart_nurses/heart_failure_nurses.aspx.

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“I haven’t even phoned my doctor yet.” The advice giving role of the pharmacist during consultations for medication review with patients aged 80 or more: qualitative discourse analysis

Charlotte Salter, lecturer in consultation skills, Richard Holland, senior lecturer in public health medicine, Ian Harvey, professor of epidemiology and public health, Karen Henwood senior lecturer

Objective To explore the advice giving role of pharmacists during consultation for medication review with patients aged 80 or more.

Design Discourse analysis.

Setting Participants’ homes.

Participants Subsample of consultations within a large randomised trial of home medication review among patients aged 80 or more who had been admitted to hospital.

Main outcome measures Extent to which advice given by pharmacists was accepted and acknowledged by patients.

Results Pharmacists found many opportunities to offer advice, information, and instruction. These advice giving modes were rarely initiated by the patients and were given despite a no problem response and deliberate displays of competence and knowledge by patients. Advice was often resisted or rejected and created interactional difficulties and awkward moments during the consultations.

Conclusions The advice giving role of pharmacists during consultations with patients aged 80 or more has the potential to undermine and threaten the patients’ assumed competence, integrity, and self governance. Caution is needed in assuming that commonsense competence and knowledge by patients. Advice was often resisted or rejected and created interactional difficulties and awkward moments during the consultations.

INTRODUCTION

The UK government white paper “Choosing health” proposes an approach to healthier lifestyles that involves people making healthy choices through the provision of increased access to information and low intensity interventions and support services. Community pharmacists have been seen as ideally placed to deliver many of these preventive healthcare initiatives.

The new community pharmacy contract offers a raft of wide ranging activities. Medication review is one such enhanced service. Medication review is described as a cornerstone for the management of modern medicines and is recommended by the national service framework for older people and by the National Health Service plan.

In practice the changing role of the community pharmacist in the United Kingdom is uncertain and under-researched. Despite the pharmacy being the most often visited healthcare outlet and viewed as ideally placed between lay and professional networks pharmacists are still ultimately viewed as shopkeepers and dispensers of medicines. Furthermore, the role of the community pharmacist as advice giver or drug counselor is ill defined and diverse. Little training exists for these new roles and even less in-depth research has been done into the implications of this new philosophical approach to the work of community pharmacists and its effect on relationships between healthcare professionals and patients.

The literature on doctor-patient communication has a strong evidence base to suggest that good communication skills in the consultation have a significant positive effect on patient satisfaction and healthcare outcomes such as adherence. A growing body of knowledge also shows that these skills can be taught. Research shows that patients’ reception of advice is influenced by the conversational environment in which the advice is delivered. Premature advice that is given without any previous questioning of the client about the topic or without any attempt to elicit the patient’s perspective is often not picked up or acknowledged by the patient and is often rejected.

We previously evaluated whether domiciliary medication review affects hospital admission rates and quality of life among people aged 80 or more. The trial produced the counterintuitive finding that the intervention was associated with increased hospital admission and home visits by general practitioners and did not significantly improve quality of life or reduce the numbers of deaths. We report on a
### Table 1 | Baseline characteristics of pharmacists in primary trial and qualitative study. Values are numbers (percentages) unless stated otherwise

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Primary trial (n=22)</th>
<th>Qualitative study (n=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>13 (59)</td>
<td>6 (86)</td>
</tr>
<tr>
<td>Mean (SD) age (years)</td>
<td>41.8 (7.4)</td>
<td>43.4 (5.2)</td>
</tr>
<tr>
<td>Mean (SD) years since first registration</td>
<td>17.4 (8.2)</td>
<td>22.5 (5.8)</td>
</tr>
<tr>
<td>Higher qualification after registration:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diploma, masters degree, or PhD</td>
<td>7 (32)</td>
<td>4 (57)</td>
</tr>
<tr>
<td>Postgraduate certificate only</td>
<td>10 (46)</td>
<td>2 (29)</td>
</tr>
<tr>
<td>Main employment:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community pharmacist</td>
<td>12 (32)</td>
<td>5 (71)</td>
</tr>
<tr>
<td>Locum community work</td>
<td>3 (14)</td>
<td>2 (29)</td>
</tr>
<tr>
<td>Hospital pharmacist</td>
<td>5 (23)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>2 (9)</td>
<td>1 (14)</td>
</tr>
<tr>
<td>Previous experience:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication review</td>
<td>13 (77)*</td>
<td>4 (57)</td>
</tr>
<tr>
<td>Home visits†</td>
<td>5 (29)</td>
<td>2 (29)</td>
</tr>
</tbody>
</table>

*Data on 17 pharmacists.
†Not including delivery of drugs or supply of oxygen.

Qualitative element of the trial that focuses on the medication review consultation. This element was built into the original trial proposal from its inception. Using in-depth interviews and discourse analysis techniques we explored the ways in which pharmacists and older patients engage in the medication review consultation.

### Participants and Methods

We invited patients recruited to the HOMER (home based medication review by pharmacists) trial between October and December 2002 to take part in the additional study. Twenty nine of 758 eligible participants with an abbreviated mental test score of eight or more (88.7% of the trial sample) were recruited.

Eleven of the 22 review pharmacists recruited to the parent trial expressed an interest in taking part in the substudy. Seven took part in the 29 observed and taped consultations and four were excluded for reasons of distance, availability, or matters concerning their patients. Six of the pharmacists were women. The pharmacists did not know the patients before visiting them as they were not necessarily from the same locality. They were all working as community pharmacists and were paid on an ad hoc basis to provide the medication review service. They had a minimum of 15 years’ experience (range 15-40) and at least one postgraduate qualification each (table 1). All pharmacists participated in a two day training course, including lectures on adverse drug reactions, prescribing in elderly people (aged 80 or more), improving concordance, and communication skills.

Sample selection was essentially pragmatic and dependent on the availability of review pharmacists, the researcher (CS), and the agreement of patients, during the fieldwork period (97% of those approached agreed to participate in this substudy). Participants were representative of the parent trial (table 2). Sample saturation was judged to have been reached when no new styles of consultation were witnessed and when each of the seven review pharmacists had each done a minimum of three consultations. Patients gave informed written consent.

One researcher (CS), a social scientist, observed, taped, and transcribed the 29 medication review consultations. She noted down any non-verbal cues, facial expressions, and body language. Participants were revisited by CS within a month of the original consultation to collect data on their perceptions of the encounter. In-depth interviews were carried out with the pharmacists before and after the medication review consultation. In addition, formal feedback meetings with the pharmacists followed by focus group discussion, enhanced validation of the analysis and findings. Meetings once every two months with an advisory panel ensured constant discussion of the credibility of the research process and its findings. One to one monthly supervision between CS and KH ensured the analysis stage involved iterative and rigorous procedures. This three pronged approach to data collection increased the trustworthiness of the data and subsequent analysis.

### Analysis

CS transcribed and examined the transcriptions and field notes by hand. The transcription conventions adopted were those of Jefferson (box 1).

Discourse analysis is a methodological approach that can be used in the study of communication in healthcare consultations. Activity type analysis permits the identification of characteristic forms of talk such as advice giving. Fine grained analysis of the conversational properties of the consultation enabled recognisable patterns of awkward or critical moments to be identified. We highlighted instances where the

### Table 2 | Baseline characteristics of participants in primary trial and qualitative study. Values are numbers (percentages) unless stated otherwise

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Primary trial (n=855)</th>
<th>Qualitative study (n=29)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>534 (62.4)</td>
<td>18 (65)</td>
</tr>
<tr>
<td>Mean (SD) age (years)</td>
<td>85.5 (4.0)</td>
<td>83.3 (3.1)</td>
</tr>
<tr>
<td>Living alone</td>
<td>531 (61.1)</td>
<td>21 (65.5)</td>
</tr>
<tr>
<td>Mean (SD) abbreviated mental test</td>
<td>8.9 (1.5)</td>
<td>9.2 (0.7)</td>
</tr>
<tr>
<td>Mean (SD) total No of drugs</td>
<td>6.3 (2.6)</td>
<td>6.7 (2.6)</td>
</tr>
<tr>
<td>Monitored dose system</td>
<td>152* (18.6)</td>
<td>9 (31)</td>
</tr>
<tr>
<td>Social class†</td>
<td>333‡ (42)</td>
<td>11 (37.9)</td>
</tr>
<tr>
<td>Baseline diagnosis:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>278 (32.5)</td>
<td>10 (34.5)</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>126 (14.7)</td>
<td>8 (27.6)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>101 (11.8)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>97 (11.3)</td>
<td>4 (13.7)</td>
</tr>
<tr>
<td>Neurological</td>
<td>65 (7.6)</td>
<td>2 (6.8)</td>
</tr>
<tr>
<td>Other</td>
<td>188 (22.0)</td>
<td>5 (17.4)</td>
</tr>
</tbody>
</table>

*Data on 817 patients.
†Il, II, or Illm.
‡Employment details available for 793 patients.
Box 2 | Conversational attempts to resist advice
1. Ph 05. Have you had any changes since you’ve been into hospital
2. Pt 04. What medication
3. Ph 05. Hhm
4. Pt 04. No still the same things as I said to you the only thing they give
5. Pt 04. me is hhm=
6. Ph 05. =Paracetamol
7. Pt 04. Because I do take co-codamol=
8. Ph 05. =You do
9. Pt 04. Yes from the doctors
10. Ph 05. Do you know that you can’t take the two together
11. Pt 04. Oh I don’t take the co-codamol at the moment
12. Ph 05. You don’t=
13. Pt 04. =No= 14. Ph. =Do you take these (paracetamol)=
14. Pt 04. =Yes not while I’ve got those=
15. Ph 05. =So you know that it’s either one thing or the other=
16. Pt 04 =Yes they did tell me at the hospital
17. Pt 04. How many would be a maximum of those
18. Ph 05. How many would be a maximum of those
19. Pt 04. Well I was having four a day when I first went in with the pain
20. Pt 04. in fact I kept on having an injection as well but as its eased off I
21. Pt 04. take two in the morning and then two at night before I go to bed
22. Ph 05. Well the maximum is eight in twenty four hours
23. Pt. 04 Yes I know I do know yes I wouldn’t do any more than that=
24. Ph 05. =You have to be careful with paracetamol as you already realise
25. Ph 05. because co-codamol contains paracetamol and=
26. Pt 04. =Yes I have read all the leaflets because you know=

Communicative competences of the participants were put under pressure. The transcripts have been selected for their representative nature and simplified for presentation and ease of reading. (Further transcripts are available from the corresponding author).

RESULTS
The medication review consultations lasted an average of 45 minutes each. The results showed a uniform shape to the consultations. A strong mode of talking or discourse of advice giving was identified. It was during many of these identified episodes of advice giving that disruptions or critical moments occurred.

The style of advice giving was essentially didactic. The pharmacists provided advice, information, or instruction on a constant basis throughout the consultation. During the 29 taped consultations almost no patient initiated requests for advice or information. On only one occasion did a patient specifically announce that he wanted to ask a question. Advice given was often unsolicited and invariably in the absence of a patient initiated problem or request for advice. It was often resisted or rejected by the patients. The patients adopted a variety of conversational strategies, including direct or indirect challenges to the pharmacists’ authority and knowledge boundaries.

Patients’ knowledge and experience as a challenge to the pharmacists’ advice giving role
Conversational attempts by the patients to resist advice included assertions of knowledge and experience. The extract in box 2 illustrates an interrogative sequence of the type that was common during the consultations. A key concern of the pharmacists was over use of analgesics. The sequence begins with the pharmacist asking if the patient has had any changes to her medication. On discovering that the patient has been prescribed both paracetamol and co-codamol the pharmacist asks whether the patient knows she cannot take both together (line 10). The patient says “oh I don’t take the co-codamol at the moment” (line 11), thereby effectively brushing the pharmacist’s question aside. The pharmacist, however, continues cross examining as well as inserting advisory caveats, thus creating a familiar blend of question and instruction (lines 14, 16, and 18). Despite at least four attempts by the patient to reassure the pharmacist that she was not taking both drugs and to assert her competence (lines 11, 15, 17, and 19-21), the pharmacist still advises the patient “well the maximum is eight in twenty four hours” (line 22). At line 24 the pharmacist manages to impart her advice yet again saying “you have to be careful with paracetamol as you already realise because co-codamol contains paracetamol.” The patient interrupts the pharmacist’s repeated advice giving string by saying that, yes, she knows because she has “read all the leaflets” (line 26). This kind of repetitive advice giving was a familiar feature of the consultations.

Patients could also be categorical in their rejection of offers of advice. In the second example (box 3) the pharmacist asks if the patient would like to know what his medicines are for (line 7). The patient’s response is negative and categorical. It represents a rebuttal that embarrasses the pharmacist and causes interactional uncertainty (line 10).
Advice was often given after an interruption by the pharmacist. This meant that the patient’s perspective was unheard and has implications for the reception and take-up of advice. In the sequence in box 4 the pharmacist offers the patient a new medicine tray. The pharmacist interrupts in several instances. The patient, despite the interruption, explains how he manages (lines 2-4). When the pharmacist makes an offer of a new tray (line 18) she receives a rebuttal, with the patient giving an emphatic “no I ain’t that far gone yet.”

Calling on the higher authority of the doctor

One of the strongest rebuttals to the pharmacists’ attempts to counsel and give advice was patients’ use of the higher authority of the doctor. Many examples existed. In one consultation the pharmacist asked the patient if he was still taking his cod liver oil. The patient announced that he would restart but only as “soon as the doctor says I can.” In the sequence in box 5 the patient consistently resists the pharmacist’s intervention and line of questioning with a dismissive “I don’t know” (lines 7, 11, and 15). The patient is a retired nurse and of a nervous disposition because of her physical frailty. Her son manages her medicines for her. Later in the consultation she reveals a wealth of knowledge and experience of medicine taking. However, in common with other patients in the study she did not want information or advice from the pharmacist. Her resistance in this extract culminates in her saying “I haven’t even phoned my doctor yet.”

Patients’ relationships with their doctors are foremost in the management of medicines. The pharmacist was often thwarted in her advice giving role by mention of the doctor. In the sequence in box 6 the pharmacist attempts to counsel the patient with advice about her swollen ankles but is met with resistance and a defensive tone. The patient blocks the pharmacist’s warning by saying that her “own doctor” will “sort out these little problems when he comes” (lines 2-4).

In box 7 the extract takes up after a sequence of advice giving about eye drops. The pharmacist had told the patient that she really ought to be using her eye drops everyday. The patient said she had not done so for a long time and saw no reason as her eyes seemed absolutely fine and that as they did not use eye drops in hospital she had concluded that they could not have been important. The pharmacist is reading through some scripts when the patient begins with praise for her doctors (line 7), particularly her general practitioner. She and her husband both state vehemently that they do not want to be seen as “rocking the boat” or seem to be complaining (lines 15-18). This provides a further illustration of how pharmacists’ intervention can have a potentially unsettling effect on patients and their assumptions about their existing healthcare network and medicines regimen.

**Box 4** Advice given after interruption by pharmacist (italics indicate overlapping speech)

1. Ph 05. Yeah okay and you’re happy with the box that you are using
2. Pt 09. Yeah I can manage them (0.2) they ain’t all the same some of them have
3. Pt 09. got a slide but you have to watch you don’t un uncover more than one
4. Pt 09. hole=
5. Ph 05. =Yes yeah I’ve actually brought some with me here
6. Pt 09. You see
7. Ph 05. I think the one you mean is (0.2) is it like that (0.3) is it like that so you
8. Ph 05. have to be careful when you pull the slides out
9. Pt 09. That’s right yeah they’re the ones
10. Ph 05. Yeah
11. Pt 09. Yeah (0.3) so that just pull one pull pull down to them morning
12. Ph 05. Pull down to the one you want
13. Pt 09. And then the next dinner time
14. Ph 05. Yeah and make sure you only go so far with them=
15. Pt 09. =That’s right
16. Ph 05. Yeah
17. Pt 09. Otherwise you’ll mix your pills up
18. Ph 05. But if you wanted to have one in particular that you felt was easier for
19. Ph 05. you
20. Pt 09. No (0.2) I ain’t that far gone yet I mean I can=

**Box 5** Invoking the higher authority of the doctor: 1

1. Pt 03. My son sorts it all out for me
2. Ph 05. So does he will he fill that up every week
3. Pt 03. He will do=
4. Ph 05. =He will do okay so that’s your yeast tablets they’re fine
5. Ph 05. they’re a course of treatment and how often do you take
6. Ph 05. those
7. Pt 03. I don’t know
8. Ph 05. Do you just do you go by what’s on here
9. Pt 03. What’s put in the box yes
10. Ph 05. So you don’t (0.2) do you look at the labels at all
11. Pt 03. No I don’t dear (0.2) he does
12. Ph 05. And how often do you take this for
13. Pt 03. I don’t know it is all (written) down there
14. Ph 05. How long will you be taking warfarin
15. Pt 03. I don’t know dear
16. Ph 05. ’Til you’re told
17. Pt 03. Yes (0.2) I haven’t even phoned my doctor yet
assumed competence, integrity, and self-governance. These findings complement what is already known about the difficult nature of advice giving in healthcare communication generally,15 17 specifically for pharmacists.11 12 23

Limitations and strengths of the study

The effect of the researcher as an observer is unknown. It could have an effect on the consultation and may inhibit either party. A further limitation of this study is that we only included patients aged 80 or more and it is possible that other patients may accept advice from a pharmacist. This study, however, supports the findings of the only other reported sociolinguistic study of consultations between pharmacists and patients.11 This was a hospital outpatient based study concerned with young patients with cancer and their carers, where pharmacists often give advice and information unilaterally and patients and carers rarely ask any questions or initiate any topic changes.

The strength of this study is that observation and follow-up interviews increase the credibility and trustworthiness of the findings: pharmacists confirm the awkward nature of their advice giving task and patients regularly confirm that they have learnt little from the consultation. In addition, the same speech patterns reported in the results were manifest in interactions involving the sole male pharmacist.

This study raises several key issues for policy and practice: it shows that interventions for medication review need to develop further to ensure their relevance and usefulness; it questions assumptions about the appropriate advice giving role of the pharmacist; it shows the pharmacy professions’ need and desire for further training in communication skills; and it establishes that context and competence are important for advice giving.23

Perhaps even more important are the policy conclusions that can be drawn when the findings of this study are considered in the light of the counterintuitive findings from the parent trial: that medication review consultations raise hospital admission rates, increase the number of home visits by general practitioners, and do not significantly increase quality of life. A possible conclusion that supports other research concerned with advice giving17 24 is that misaligned advice can sow doubt in patients’ minds. This may lead to uncertainty and ultimately to a loss of confidence in a patient’s individual healthcare regimen. This study suggests that caution should be exercised in assuming that common sense interventions necessarily lead to health gain.

We thank the pharmacists and participants.

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Competing interests: None declared

Ethical approval: The protocol for this study was approved by Norwich District, King’s Lynn, and Great Yarmouth & Waveney local district ethics committees.
3 Hibbert D, Bissell P, Ward PR. Consumerism and professional work in the community pharmacy. Sociol Health Illness 2002;24:46-65.

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Psychological approach to managing irritable bowel syndrome

Bu’Hussain Hayee, Ian Forgacs

“It is more important to know what sort of person has a disease than to know what sort of disease a person has.” Hippocrates

The medical management of patients with irritable bowel syndrome is often unsatisfactory. Doctors are still taught that irritable bowel syndrome is a diagnosis of exclusion, and patients readily sense that they are being told that nothing is really wrong with them. Many people soon come to appreciate that the range of medical treatments available is limited in both scope and efficacy. The mood of negativity, once established, is difficult to dispel.

Current medical treatment includes drugs that alter intestinal motility—such as antispasmodics, 5-hydroxytryptamine antagonists, antidiarrhoeals, and laxatives—and dietary changes, including fibre supplementation and identification of food intolerances.1 Response may vary, but the failure rate of these “physical” treatments is high, which may lead to the conclusion that irritable bowel syndrome has a strong psychological component. A diagnosis of exclusion has been made—again with negative, rather than positive therapeutic, connotations.

Although many doctors are aware that antidepressants have been used in irritable bowel syndrome, they seem reluctant to prescribe such agents, not least because suggesting this as a valid option to patients who are clearly not depressed can be difficult. Moreover, other treatments exist that might be classified as “psychological” to varying degrees. Patients with irritable bowel syndrome should be made aware of the existence of these treatments so that they can make informed choices. Specifically, they should be made aware that using a psychological treatment does not mean that the disease is “all in the mind.” This review focuses on psychological treatments for irritable bowel syndrome.

What actually causes irritable bowel syndrome?

Irritable bowel syndrome is best regarded as a complex of symptoms without a single cause. Disordered gut motility, visceral hypersensitivity, intestinal inflammation, and genetic and environmental factors have all been suggested as being causative.1-3 In some cases, a very well defined point of onset of syndrome symptoms seems to exist, such as after gastrointestinal infection.2 Although heterogeneity is likely, the most plausible view is that the symptoms of irritable bowel syndrome are an integrated response to a variety of complex interactions combining biological and psychosocial factors.45 This implies that in many cases psychological and social factors contribute to a patient’s symptoms. The concept of irritable bowel syndrome as a disorder of brain-gut interaction with physical and psychological components,7 which places the emphasis on the perception of symptoms and their impact rather than on the symptoms themselves, is a useful one when selecting treatment strategies.

What is the impact of psychology on irritable bowel syndrome?

The psychological profiles of patients presenting to a doctor with irritable bowel syndrome are well characterised, and up to half have been found to have a demonstrable psychiatric disorder if assessed by research criteria.5 Whether these abnormalities are cause or effect is debated,7 but whatever their relevance, it may well be inappropriate for the clinician to conclude that perceived psychological factors in individual patients are the cause of their symptoms. When interpreting results of the myriad studies, we also need to appreciate that the quoted frequencies of psychological abnormalities are limited to those patients with irritable bowel syndrome who have actually presented to a doctor. Many patients with irritable bowel syndrome have never consulted a doctor. This indicates that the psychopathology associated with irritable bowel syndrome may be of two types: that which is a characteristic of the illness itself and that which causes the patient to seek medical advice.56

Whatever the clinical implications of these observations, patients with irritable bowel syndrome are clearly more likely to have depression and “abnormal”
behaviour patterns, including anxiety, sensitivity, and somatisation. More specifically, some patients develop maladaptive behaviour regarding eating and defecation, which reinforces the magnitude of symptoms and their impact on quality of life. Moreover, concurrent psychiatric disorders are associated with poor outcome in irritable bowel syndrome. An appreciation of this should lead the clinician to identify patients for “psychological” treatment as, if started at an early stage in presentation, the outcome of such treatment is favourable.

**How and why should I make a positive diagnosis?**

To avoid the initial pitfall of engendering a negative attitude by reaching a diagnosis by exclusion, diagnostic criteria have been devised to enable a confident clinical diagnosis of irritable bowel syndrome to be made from the history alone. Although these criteria were introduced to allow standardisation of diagnosis for research studies, they can be readily used in a clinical setting by any practitioner (see example in box 1). These are used only as a basis for diagnosis, taking into account the absence of “alarm” symptoms and the general characteristics of the presenting patient. That a positive, reassuring diagnosis can be therapeutic right from the time of the first consultation has certainly been suggested.

**What are the options for psychological management?**

**Antidepressants**

A growing body of evidence supports the use of antidepressants for irritable bowel syndrome, but the mechanism of action of these drugs in the disorder remains unclear. Their beneficial effect is independent of mood or anticholinergic effects on the gut, which can be important in encouraging patients to accept their use. Clearly, although their antidepressant action is likely to be important in patients with a coexisting depressive disorder, a separate and key action may be to influence psychological pathways leading to reduced somatisation and a reduced tendency to regard gut sensations as indicating illness.

**Tricyclic antidepressants**

In general, studies of tricyclic antidepressants in irritable bowel syndrome are poorly designed by current standards, not least because they were completed two or three decades ago. With this caveat, a meta-analysis of tricyclic antidepressants found an odds ratio for improvement of 4.2 (95% confidence interval 2.3 to 7.9) with a number needed to treat of 3.2 (2.1 to 6.5). Figures 1 and 2 summarise the results of this meta-analysis.

Tricyclic antidepressants seem to be of more benefit when the main symptoms are pain and diarrhoea. As might be expected from anticholinergic side effects, constipation does not improve. With

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**Selected trials of cognitive behaviour therapy (CBT) in irritable bowel syndrome (IBS)**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Design and numbers</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bennett and Wilkinson</td>
<td>RCT; 12 CBT, 12 usual care</td>
<td>Eight week package: stress management training, cognitive therapy, and contingency management v medical treatment (aperients and antispasmodics)</td>
<td>Anxiety reduced in treatment group but not in control group; both achieved improvement in IBS symptoms, restriction of activities, and fatigue</td>
</tr>
<tr>
<td>Lynch and Zamble</td>
<td>RCT; 12 CBT, 12 waiting list</td>
<td>Coping skills, assertiveness training, education, and progressive relaxation v waiting list controls</td>
<td>Significantly greater improvement of IBS symptoms and anxiety in treatment group</td>
</tr>
<tr>
<td>Greene and Blanchard</td>
<td>RCT; 10 CBT, 10 symptom monitoring</td>
<td>Individualised CBT for 10 sessions v daily gastrointestinal symptom monitoring over eight weeks</td>
<td>80% of treatment group showed clinical improvement compared with 10% of controls. Sustained results at three month follow-up</td>
</tr>
<tr>
<td>Guthrie et al</td>
<td>RCT; n=102</td>
<td>Psychotherapy vs “supportive listening,” 12 week study. After study, 33 patients from control group accepted psychotherapy</td>
<td>Psychotherapy significantly superior in terms of physical and psychological symptoms (for women; trend in men). Results sustained at 12 month follow-up</td>
</tr>
<tr>
<td>Boyce et al</td>
<td>RCT; n=105</td>
<td>Three arm trial: all groups received standard care, plus either CBT or relaxation training. Patients with “resistant IBS” not included</td>
<td>Significant improvements for all groups in IBS symptoms, physical/social functioning and general wellbeing, but no significant differences between groups. No difference at 12 month follow-up</td>
</tr>
</tbody>
</table>

RCT=randomised controlled trial.
Selective serotonin reuptake inhibitors

Selective serotonin reuptake inhibitors have fewer side effects than tricyclic antidepressants, which makes their use particularly attractive in patients with irritable bowel syndrome. Moreover, selective serotonin reuptake inhibitors are particularly thought to help with constipation and pain or bloating symptoms (as they accelerate oro-caecal transit and influence colonic sensorimotor responses). Several randomised controlled trials have provided encouraging, if not robust, results on this (although relatively fewer trials have been done than with tricyclic antidepressants). In a study that assessed the symptomatic response to rectal distension, fluoxetine did not significantly affect the threshold for discomfort in patients with irritable bowel syndrome compared with placebo. In those patients with hypersensitivity to rectal distension, abdominal pain improved but bowel habit, global symptom relief, and psychological symptoms were unaffected. Paroxetine improved overall wellbeing in patients with irritable bowel syndrome compared with placebo, as well as improving related anxiety. These benefits were found even in non-depressed patients. However, abdominal pain, bloating, and social functioning were not improved. A study of paroxetine and psychotherapy in combination found that patients with a reported history of sexual abuse responded particularly well, perhaps owing to the tendency to somatisation in this subgroup (as well as patients with coexisting depression).

Citalopram was effective in reducing abdominal pain compared with placebo in 23 patients with irritable bowel syndrome over a six week trial period. The benefit was independent of mood; although this trial has been criticised, it remains the only randomised controlled trial to show benefit for a selective serotonin reuptake inhibitor in reducing the actual symptoms of irritable bowel syndrome rather than overall wellbeing or symptoms in a select subset of patients.

Cognitive behaviour therapy

Cognitive behaviour therapy shows patients how events, thoughts, emotions, actions, and physiological responses are interlinked; the perception of sensation and the patients’ thoughts are of particular importance. It is a “short-term intervention oriented towards change, rather than insight for its own sake, and particularly towards the development of new strategies and skills for coping with problems.”

Most strategies involving cognitive behaviour therapy share the features of exploring and attempting to modify the impact of cognition and behavioural patterns on bowel symptoms and psychosocial distress. Comparing data from trials of cognitive behaviour therapy for irritable bowel syndrome is difficult, as methods are heterogeneous. In practice, patients’ reaction to their symptoms may be more important than the symptoms themselves.

The results of several randomised controlled trials support the use of cognitive behaviour therapy for irritable bowel syndrome at an individual level (table), as well as larger studies of a group based approach. A recent meta-analysis of the efficacy of cognitive behaviour therapy (50% reduction of symptoms) gave an odds ratio of 12 (95% confidence interval 5.56 to 25.96) in favour of cognitive behaviour therapy, with a number needed to treat of 2.

Cognitive behaviour therapy is most appropriate for those patients who are considerably distressed by their symptoms, are open to the idea that psychological factors play some role in their difficulties, and are willing to participate in this therapeutic approach. Outcomes may be poorer in women, patients with a diagnosed psychiatric disorder, those with high anxiety, and those with symptoms on a daily basis. In contrast, patients with a reported history of sexual abuse may respond favourably.

Cognitive behaviour therapy is as effective as antidepressant treatment, and its benefits last longer. Combining cognitive behaviour therapy and antidepressants can produce the best response.

**Box 1 | Rome III criteria* for diagnosing irritable bowel syndrome**

- Symptoms of abdominal discomfort or pain, for three days a month in the past three months, associated with two or more of the following three features:
  - Relieved by defecation
  - Onset associated with a change in frequency of stool
  - Onset associated with a change in consistency (form or appearance) of stool

*Criteria fulfilled for the past three months, with onset of symptoms at least six months before diagnosis
Tackling psychosocial factors is increasingly recognised as an important part of the management of irritable bowel syndrome.\textsuperscript{20,21} Although it requires a considerable investment in time and resources, cognitive behaviour therapy has been effective in a primary care setting and deserves to be more widely available.\textsuperscript{22} Recent initiatives to produce more community led and patient led services may provide just such an opportunity for primary care physicians to be able to commission these services.\textsuperscript{23}

Hypnotherapy

The use of non-drug treatments for irritable bowel syndrome is popular with patients who are disappointed by their lack of response to standard drug treatment or concerned about its potential side effects.\textsuperscript{\textsuperscript{23}} Gut directed hypnotherapy has been reported to be an effective intervention for irritable bowel syndrome in small trials.\textsuperscript{\textsuperscript{24}} This approach involves induction of a hypnotic state by using a variety of techniques, including progressive relaxation, to create images related to symptom control and normalisation of gut function (box 2).\textsuperscript{\textsuperscript{24}}

A recent systematic review summarised 18 trials of hypnotherapy for irritable bowel syndrome and concluded that, although 10 showed a beneficial effect, insufficient evidence existed to recommend widespread use of hypnotherapy. The review concluded that this treatment option should be restricted to specialist centres dealing with more severe cases of the syndrome.\textsuperscript{25} Nevertheless, hypnotherapy has the potential to help those patients whose irritable bowel syndrome is severe and has been shown to be particularly effective within a specialist programme of care.\textsuperscript{26}

**Box 2 | Gut directed hypnotherapy\textsuperscript{26}**

This technique has been reported to be effective in irritable bowel syndrome in several small trials

- It is probably best used in specialist centres, within a multidisciplinary programme of care
- The technique is mechanistically well placed within the current model of brain-gut interactions that underpin irritable bowel syndrome, with an emphasis on developing an “internal locus of control”
- Observed benefits are beyond perhypnotic, relaxation induced autonomic changes
- Patients are usually seen for an initial consultation to obtain a full history and to explain the technique, which usually involves 12 weekly sessions of 45-60 minutes each
- Hypnotic induction with progressive relaxation is used as the basis for “suggestion”
- Initially, suggestions based on improving confidence and general wellbeing may be used, as relevant to each individual patient
- Subsequent sessions then focus on imagery and techniques aimed at normalising gut function. For example, patients place their hands on their abdomen, inducing a sense of warmth and comfort; or imagery is used to symbolise the gut, which is then altered accordingly to represent normal function (a commonly used image for patients with diarrhoea predominant symptoms is one of the bowel as a fast flowing river that is then imagined to be flowing slowly and smoothly)
- Audio tapes are also provided from each session for autohypnosis according to patients’ capabilities and understanding

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**Fig 2 | Effect of tricyclic antidepressants on abdominal pain scores (reproduced with kind permission)\textsuperscript{21}**

How should I approach the patient with irritable bowel syndrome?

Doctors need to avoid making the diagnosis of irritable bowel syndrome in a manner that leads patients to believe that nothing is wrong with them or that their symptoms are being ignored, downplayed, or misunderstood.\textsuperscript{\textsuperscript{22}} Making a positive diagnosis of irritable bowel syndrome on the history alone should be possible, guided if necessary by validated diagnostic criteria (table).\textsuperscript{4}

Investigations should be done as appropriate,\textsuperscript{1} but a useful approach may be to let the patient know that you are expecting the results to be normal (with the above in mind). Unless the patient raises the matter, psychological factors need not be explored before a confident diagnosis has been made.

An explanation of the currently favoured theory of the genesis of irritable bowel syndrome involving the complex interaction of biological and psychological factors,\textsuperscript{1} and that the relative contribution of these varies from person to person, is useful. This gives the doctor an entirely legitimate reason for beginning to explore the psychological dimension.

What psychological treatments should I consider?

The selection of treatment should depend on which aspect of the disorder it is to be principally focused on: the physical/physiological or psychological. For example, exploring possible food intolerances or prescribing mebeverine would be pointless if compelling evidence indicates that psychological factors underlie the patient’s symptoms.
The choice of psychological treatment will depend on the individual patient. Some may prefer a non-drug approach. They may express, for example, a preference for hypnotherapy, and certainly the success of cognitive behaviour therapy depends on patients’ motivation. Selecting the most appropriate drug may depend on the pattern of symptoms (for example, tricyclic antidepressant for diarrhea predominant symptoms or selective serotonin reuptake inhibitor for constipation predominant symptoms), but compliance will depend on how such treatment is presented to the patient. Medical practice may divide symptoms into the physical and the psychological, but this may not be helpful to the patient who sees himself or herself as a whole. For this reason, patients with irritable bowel syndrome may be most appropriately managed in primary care, involving a specialist only when diagnostic uncertainty exists. Inevitably, the choice of treatment will be limited by local availability. However, irritable bowel syndrome is undeniably very common, and many patients are probably denied help by lack of access to therapists with the appropriate psychological skills. Increasing provision of primary care services for patients with irritable bowel syndrome will provide an avenue for effective and early psychological treatment for a condition in which real improvement can be achieved.

**SUMMARY POINTS**

Irritable bowel syndrome is believed to result from a variety of biological and psychosocial factors. Irritable bowel syndrome is not a diagnosis of exclusion; a positive diagnosis can usually be made.

The usual medical treatment is often highly unsatisfactory; if psychological factors seem important, these should be dealt with.

Tricyclic antidepressants and some selective serotonin reuptake inhibitors are of value in improving symptoms. Cognitive behaviour therapy has a strong evidence base for its effectiveness.

Gut directed hypnotherapy is an effective treatment and is especially suitable for more severely affected patients who might be prepared to travel to specialist centres.

**ADDITIONAL EDUCATIONAL RESOURCES**


Cochrane Library (www3.interscience.wiley.com/cgi-bin/mrw/home/1065668753/HOME—Search for reviews on irritable bowel syndrome (and psychological treatments))

**Contributors:** Both authors reviewed the literature. BHH wrote the first draft; both authors then critically appraised and improved it and are guarantors.

**Competing interests:** None declared.


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1109
Dysfunctional uterine bleeding is defined as abnormal uterine bleeding in the absence of organic disease. It usually presents as menorrhagia without an underlying cause, and it affects women’s health both medically and socially. Among women aged 30-49 years, one in 20 consults her general practitioner each year with menorrhagia; making dysfunctional uterine bleeding one of the most often encountered gynaecological problems. About 30% of all women report having had menorrhagia, and it accounts for two thirds of all hysterectomies and most endoscopic endometrial destructive surgery.

Excessive menstrual bleeding has several adverse effects, including anaemia and iron deficiency, reduced quality of life, and increased healthcare costs because it is a major indication for referral to gynaecological outpatient clinics. Each year around £7m (€10m; $14m) is spent in the United Kingdom on prescriptions in primary care to treat menorrhagia.

Menorrhagia is a disabling problem for many women and a major clinical challenge for gynaecologists. In half of women with menorrhagia there is no organic cause. Dysfunctional uterine bleeding is therefore a diagnosis of exclusion.

What should I know about this condition?

The pathophysiology of dysfunctional uterine bleeding is largely unknown, but it occurs in both ovulatory and anovulatory menstrual cycles. Ovulatory dysfunctional bleeding occurs secondary to defects in local endometrial haemostasis, while anovulatory bleeding is a systemic disorder, occurring secondary to endocrine, neurochemical, or pharmacological mechanisms. Since diagnosis is by exclusion, you must proceed through a logical, stepwise evaluation to rule out all other causes of the abnormal bleeding.

In most patients dysfunctional uterine bleeding is associated with anovulation, and anovulatory bleeding is common in the pubertal and perimenopausal periods. During these transitional states, the abnormal bleeding has a physiological basis and is secondary to an oestrogen withdrawal. Anovulatory bleeding can also be associated with chronic anovulation. The chronic unopposed oestrogen that characterises this disorder causes a continuous proliferation of the endometrium. This can result in abnormal bleeding and increases the risk of developing endometrial cancer. The goals of treatment for anovulatory bleeding are to stop the acute bleeding, avert future episodes, and prevent long term complications.

What new guidelines have been produced over the past few years?

National Institute for Health and Clinical Excellence (NICE) guidance on diagnosis and management of heavy menstrual bleeding (due 2007).

This guideline is in progress and was due to have been issued in January 2007. The Department of Health has agreed that the guideline should be extended to cover not only hysterectomy but the pathway for diagnosis and management of heavy menstrual bleeding.

Royal College of Obstetricians and Gynaecologists guidelines on managing menorrhagia

The key points from the guidelines are

ADDITIONAL EDUCATIONAL RESOURCES

- YRSHR. Menstrual disorders: www.yrshr.org/informationbase_desc.asp?id=34
- Prodigy guidance. Menorrhagia: www.prodigy.nhs.uk/menorrhagia
- BMJ Learning: www.bmjlearning.com

Pelvic inflammatory disease—diagnosis and treatment
Urinary tract infections in women
Dysmenorrhoea—diagnosis and treatment
### Commonly asked questions—answered by our experts

**What investigations should I do to rule out a cause for abnormal bleeding?**

Women with regular heavy bleeding do not initially need extensive investigation, except for a full blood count. Thyroid function tests are not routinely necessary and should be limited to women with symptoms of hypothyroidism. Investigation of other endocrine disorders is also not usually necessary, but irregular bleeding in a woman with a long history of using combined oral contraceptives may prompt you to check her serum prolactin levels. Serum follicle stimulating hormone levels may be relevant if the woman is increasingly oligomenorrhoeic, especially in her 40s. You should refer older women for a pelvic ultrasound and for endometrial sampling if the endometrium is thickened.

**Which medical treatments for menorrhagia should I use in order of preference?**

Medical treatment should be tailored to each patient, taking into account, among other factors, age, fertility, contraceptive needs, and risk factors. Options include combined oral contraceptives, mefenamic acid, tranexamic acid, and the levonorgestrel releasing intrauterine system. For postpubertal women, try mefenamic acid first and, if this does not work, a low dose (20 µg) combined oral contraceptive. Tranexamic acid is the most effective treatment for curtailing menorrhagia while waiting for a hospital referral.

<table>
<thead>
<tr>
<th>Practical management tips</th>
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<td><strong>Investigation</strong></td>
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| Dysfunctional uterine bleeding is a diagnosis of exclusion. Exclude other conditions such as uterine fibroids, endometrial polyps, and systemic diseases by appropriate investigations, such as a transvaginal ultrasound scan and a full blood count. In adolescent patients, perform investigations for a coagulopathy. In selected cases arrange for an endometrial biopsy with or without hysteroscopic assessment to exclude endometrial cancer.

Only 2% of endometrial carcinomas occur before age 40. They are more common in nulliparous women. Diabetes, obesity, and polycystic ovary syndrome predispose women to developing endometrial carcinoma.

Postmenstrual scans are often useful; after menstrual shedding, the endometrium should be at its thinnest, and polyps and cystic areas are more noticeable.

**Treatment**

Tranexamic acid and mefenamic acid are among the most effective first line drugs for treating menorrhagia. Norethisterone, taken orally in the luteal phase, is probably one of the least effective agents, despite it being used extensively in the past.

Women needing contraception have a choice of combined oral contraceptive, the levonorgestrel releasing intrauterine system, or long acting progestogens.

Danazol, gestrinone, and gonadotrophin releasing hormone analogues are all effective in terms of reducing menstrual blood loss, but side effects and costs limit their long term use. They have a role as second line drugs for a short period in women waiting for surgery.

Endometrial ablation with the Nd:YAG laser, resectoscope, rollerball, and, more recently, other options such as bipolar devices, direct hot saline instillation, microwaves, and thermal balloons, are all available with evidence to support their use.

**When should I refer my patient?**

Refer patients with severe bleeding that is producing anaemia (haemoglobin level <80 g/l), irregular bleeding in women in their late 40s, and bleeding that is unresponsive to medical treatment.

**Common pitfalls**

Irregular heavy bleeding in women in their late 40s is often attributed to starting the menopause. This may be true, but you still need to investigate. Endometrial carcinoma can occur in the late 40s. About 6% of endometrial cancers can occur with heavy regular bleeds. Pathology can be missed on the ultrasound scan in the presence of an intrauterine contraceptive device. Reflections and shadowing can be difficult to assess, even by an experienced ultrasonographer.


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**Confusion?**

As bad luck would have it, both my grandfather and his mother, my great grandmother, ended up in the same hospital at the same time. As is only right in this day and age, they were in separate, single-sex wards.

My father and I went to visit them on our first available weekend. Deciding how best to divide up the allowed visiting time, we decided to see one each and then swap at half time. As we were about to do this, we noticed the shocked expression on the nearby nurses’ faces.

It turned out that they had thought that my grandfather was confused because he kept asking to see his mother. This had kept him in hospital an extra week to run tests. The only test that they hadn’t run was to find out if, indeed, his mother was alive. If they’d checked this they would have found her on the next ward, very much alive, with a broken clavicle.

She was only 92.

The lesson? Sometimes it’s not the patient who’s confused.

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NICE GUIDELINES
Secondary prevention for patients after a myocardial infarction: summary of NICE guidance

J S Skinner,1 A Cooper,2 G S Feder,3 on behalf of the Guideline Development Group

Why read this summary?
Although premature mortality from coronary heart disease in the United Kingdom has fallen since the 1970s, it remains higher than in most other Western countries. After an acute myocardial infarction, many eligible patients are prescribed aspirin, β blockers, angiotensin converting enzyme inhibitors, and statins. Not everyone, however, is offered the most effective secondary prevention—that is, all four of these drugs or other effective drugs—or does everyone receive lifestyle advice and cardiac rehabilitation. This article summarises the most recent recommendations from the National Institute for Health and Clinical Excellence (NICE) on effective secondary prevention in patients after myocardial infarction. The detailed consideration of the evidence is available in the full guideline (www.nice.org.uk/CWG048).

Recommendations
NICE recommendations are based on systematic reviews of best available evidence. For the guidance on secondary prevention for patients after a myocardial infarction, in cases where minimal evidence was available, the guideline development group developed the recommendations on the basis of their own opinions and those of leading specialists; such recommendations are indicated with an asterisk (*).

Every discharge summary after a myocardial infarction should confirm this diagnosis and include results of investigations, future management plans, and advice on secondary prevention.*

Lifestyle
Lifestyle advice should be consistent and take account of patients’ current habits; any changes should be tailored to the individual.

Advise patients:
• To take enough regular physical activity to increase exercise capacity (reduces total mortality), building this up to 20-30 minutes a day to the point of slight breathlessness
• To quit smoking. Offer support, advice, and pharmacotherapy to those wishing to quit4 5
• To eat a Mediterranean-style diet: more bread, fruit, vegetables, and fish; less meat; inclusion of products based on vegetable and plant oils rather than butter and cheese (reduces total mortality and the risk of myocardial infarction)
• To consume at least 7 g of omega 3 fatty acids (from two to four portions of oily fish) a week. If within three months of the patient’s myocardial infarction they are not achieving this, consider offering at least 1 g daily of omega 3 acid ethyl esters treatment licensed for secondary prevention after myocardial infarction for up to four years. It is not recommended that omega 3 acid ethyl esters supplements are routinely prescribed to patients who have had a myocardial infarction more than three months earlier (no evidence of benefit)
• To keep weekly alcohol consumption within safe limits (no more than 21 units a week for men, 14 units for women) and to avoid binge drinking (more than three drinks in 1-2 hours)*
• To achieve and maintain a healthy weight if overweight or obese. Offer appropriate advice and support.6
• Advise patients against taking:
  • Supplements containing β carotene (may increase risk of cardiovascular death)
  • Vitamin E or C supplements (no evidence of benefit)
  • Folic acid supplements (no evidence of benefit).

Cardiac rehabilitation
All healthcare professionals (including senior medical staff) caring for patients after a myocardial infarction should actively promote cardiac rehabilitation.*

• Offer cardiac rehabilitation with an exercise component to all patients (reduces total mortality), and provide access regardless of the patient’s age, sex, ethnicity, socioeconomic status, or comorbidities.
• Include the following components in comprehensive cardiac rehabilitation: exercise (reduces total mortality), health education, and stress management (reduces anxiety, depression and the risk of non-fatal myocardial infarction). However, complex psychological interventions, such as cognitive behavioural therapy, should not be routinely offered.
• Comprehensive cardiac rehabilitation may be offered as a validated home based programme (for example, the Edinburgh Heart Manual7) with follow-up by a trained facilitator.
• Involve partners or carers, if the patient wishes.*
• Include advice on return to work and to activities of daily living, taking into account the patient’s physical and psychological status, the nature of the activity or work proposed, and the work environment.*
• Reassure patients that after recovery from a heart
attack, sexual activity presents no greater risk of triggering a subsequent attack than if the patient had never had one.

- Take into account the patient’s wider health and social needs, which may involve economic needs, welfare rights, or social support issues, especially for those in more deprived situations.*

**Drug treatment after acute myocardial infarction**

- Treat all patients with the following combination:
  1. Angiotensin converting enzyme inhibitor (reduces mortality, the risk of myocardial infarction, and, in selected patients, the risk of developing heart failure)
  2. Aspirin (reduces cardiovascular mortality and morbidity)
  3. β blocker (reduces total mortality and cardiovascular morbidity)
  4. Statin (reduces total mortality and cardiovascular morbidity).

- After a non-ST elevation myocardial infarction, treat patients with both clopidogrel and low dose aspirin for 12 months (reduces cardiovascular mortality and the risk of myocardial infarction and stroke). After an ST elevation myocardial infarction, treat patients for at least four weeks if this combination has been started within the first 24 hours (reduces total mortality and the risk of myocardial infarction and stroke). Thereafter, continue standard treatment, including low dose aspirin without clopidogrel, unless there are other indications to continue both.

- In patients intolerant of both aspirin and clopidogrel, consider treatment with moderate intensity warfarin (aiming for an international normalised ratio of 2-3) instead (reduces the risk of myocardial infarction). In patients intolerant of clopidogrel and who have a low risk of bleeding, consider treatment with aspirin and moderate intensity warfarin combined.

- In patients already taking warfarin for another indication, continue warfarin; in those taking mod intensity warfarin (aiming for an international normalised ratio of 2-3) instead (reduces the risk of myocardial infarction, and, in selected patients, the risk of developing heart failure). In patients intolerant of both aspirin and clopidogrel, consider treatment with moderate intensity warfarin (international normalised ratio of 2-3) and who have a low risk of bleeding, consider adding aspirin.

**Heart failure after myocardial infarction**

- Treat patients with heart failure and left ventricular systolic dysfunction with an aldosterone antagonist licensed for this indication, preferably after treatment with an angiotensin converting enzyme inhibitor, within three to 14 days of the acute myocardial infarction (reduces total mortality and the risk of hospital admission for cardiovascular events, including heart failure).

**Cardiological assessment**

- Offer cardiological assessment, taking account of comorbidity, to all patients so that those who will benefit from coronary revascularisation for secondary prevention (reduces the risk of myocardial infarction and total mortality in appropriately selected patients) or from other cardiological interventions* can be identified.

**Overcoming barriers**

Effective implementation of these recommendations depends on planning between specialist and generalist services. Thus, as secondary prevention measures are generally started before discharge, timely discharge summaries with recommendations for ongoing care are crucial.

Appropriate review and patient education in both primary and secondary care improves concordance with drug treatment. Some drugs will need further monitoring and doses increased for optimal efficacy.

Standard models of care should include advice about lifestyle for all patients. Existing cardiac rehabilitation programmes should evaluate their current provision in relation to the recommendations and ensure continuity of care before and after discharge. The costing tool being developed by NICE can be used to estimate additional costs (www.nice.org.uk/page.aspx?o=tools).

As the NICE guidance includes recommendations for all patients who have had a previous myocardial infarction, general practitioners should review their disease registers and ensure that all eligible patients are being appropriately managed.

**Competing interests:** All authors were members of the Guideline Development Group for the NICE guideline (JSS was the clinical adviser, AC was the lead systematic reviewer, and GSF chaired the development group). During the past five years JSS has received travel grants to attend educational meetings from Novartis, Pfizer, and Sanofi Synthelabo/Bristol Myers Squibb Pharmaceuticals, with none during the past two years.

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Assegais are not enough

PERSONAL VIEW Ian Banks

When it comes to dividing up the national health cake, there are some who would have it and eat it. The BMA has just produced “A Rational Way Forward for the NHS in England,” its response to a motion at its annual representative meeting calling on the BMA Council to address creeping NHS fragmentation and privatisation. It might not be the definitive document stopping Bevan rotating in his grave but it at least addressed the difference between rationing and priority setting. These two words are routinely used interchangeably, despite meaning the opposite of each other. On BBC Radio 4 the two terms are used in the same breath, unfortunately by those who are supposedly protecting the NHS.

It’s more than just words or clever semantics. Getting the distinction right is crucial to the debate over the NHS’s future and for that matter the BMA suffering a low percentage of junior doctors among its membership, despite an overall increase in numbers. Rationing is the equal distribution of a limited resource. Priority setting is the distribution of a limited resource only to those deemed most needy.

During the second world war, King George VI supposedly waved his ration book while in line for his 2 oz scrag end. Rationing was taken seriously, so seriously that as an equal distribution of limited resources it actually reduced children’s mortality, notwithstanding the bombs. People and the police took a dim view of anything that undermined rationing. The black market was so illegal that people went to jail and much worse. But these days, who provides the black market for health care? Us. It’s called private medicine. No queuing for the medical equivalent of scrag end if you can afford fillet.

Rationing is not always effective. During the battle of Isandlwana, South Africa, an overwhelming force of Zulus wiped out an entire British force (along with their support personnel, mainly black men and women). Their quartermaster, conscious of saving the Queen’s Purse, rationed each soldier with the amount of rounds he deemed necessary for the conflict. This he based on the number of Zulus, the speed at which they could run, and the rate of fire from a standard British soldier. He got it all correct except the number of Zulus. The quartermaster was out by a factor of 100.

Soon after, the remaining Zulus turned on Rorke’s Drift. This small outpost had far fewer infantry and even less ammunition than Isandlwana but both were distributed according to the maximum threat of attack. Zulu courage and bravery is without doubt, but, as the Great War demonstrated, sending troops into concentrated and withering fire will always result in horrendous casualties. More so when armed with nothing more than a large dinner knife. An assegai is no match for a rifle, unless you can get close enough to use it.

Today’s UK health professionals face a number of contradictions. They are expected to deliver their services on an equal basis rather than prioritising, which would give a far better impact. Obsession with “targets” further exacerbates the problem. Using out of date equipment and drugs based on economy rather than efficacy, and worse, much worse, they feel that they are infantry pawns for a government more concerned with internal political struggle (not least an illegal war in Iraq) rather than fighting the true common global enemy, public ill health.

Rationing is not always effective, as demonstrated by the Zulu defeat of the British, shown in this painting, The Battle of Isandlwana, 1879, by Charles Edward Fripp

Targeting limited resources to those patients who would benefit most (priority setting) rather than dishing them out irrespective of need (rationing) makes sense even if it is not politically attractive. For any government really wanting to address inequalities there is no other option.

If the BMA enshrines rationing in its policy it will be perceived as the government’s NHS quartermaster. By championing prioritising of care it will however rightfully continue to be the patient’s advocate. Never in the history of the NHS, and the BMA, has there been such a chequered NHS when it comes to delivering care to the most needy. Getting the picture clear is vital. Young doctors entering the NHS are looking to the BMA for leadership. Give them the tools to fight ill health and they will support and defend the NHS. Let them feel a part of the war against poverty related ill health while developing their careers and they will join the BMA. Then they will button up their tunics and resist drinking brandy from the medicine cabinet. It is, after all, a flogging offence.

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See editorial p 1068.
After decades of resistance, doctors must get over their reluctance to have their performance measured, finds Jerome P Kassirer

We Americans were proud to claim that our healthcare system was the best in the world—until we discovered that it wasn’t. Reports in the early 1990s that patient care was riddled with medical errors served as an important wake-up call, and within a few years we were scrambling to figure out what to do about it. The revelations that our life expectancy and child mortality were worse than in dozens of other countries added insult to injury, and the enormous variations in practice patterns across the country disclosed that medicine was more like a lone cowboy mentality (“I do it my way, don’t bother me with rules or requirements”) than scientific practice. For years the only brakes on poor performance were malpractice suits, and they were heavy handed, inadequate governors of practice. But the error mongers spawned evidence based medicine, which in turn begat clinical practice guidelines, a spate of “best practices,” and a focus on team and individual clinical performance as never before.

What has emerged is the “quality movement,” and its reverberations are experienced by healthcare workers at all levels. Today we wrestle with what to measure, how to measure it, how to report it, and who should be responsible for collecting and analysing the results. Reporting the quality of our performance and attempting to improve it is a form of accountability to which we have been unaccustomed. For many doctors, it represents still another drain on their time, to others an insult to their professionalism, or an intrusion into longstanding modes of practice that have served them and their patients well. Some complain that focusing on specific measures ignores the complexity of a patient’s illness. Almost everybody agrees that it isn’t easy to design measures that accurately reflect performance. Do we measure process or outcomes? Must we use clinical databases or will billing data suffice?

The demand to assess, report, and improve performance is driving some hospital and group practice managers to distraction. Given that the quality movement is still relatively young, opinion varies about which organisations should set the standards. Many, including government agencies, insurers, and not for profit organisations have not only assigned themselves a key role but demand measures so varied that compliance managers find it difficult, burdensome, and expensive to provide them all. One executive of a large hospital network told me that her institution sends reports to seven to 10 different national, state, and local organisations, and she estimated that her organisation is required to report 60 or more unique individual data points. Unfortunately, improving and optimising the quality of care is complicated and difficult. Despite these complexities, aggravations, and added expenses, however, there is little doubt that we have been lax in our attention to the quality of our work.

This backdrop is the setting in which Atul Gawande practises, ruminates about his experiences, and writes. He is an introspective, thoughtful, enthusiastic, and gifted storyteller, one of a tiny cadre of doctors who can explain medicine effectively to the public. This book, a collection of short essays on performance and efforts to better it, covers exceptionally diverse kinds of doctors’ activities: from the mundane task of washing hands to avoid hospital infections, to complicity of physicians in executions of prisoners, to efforts to reduce deaths on the battlefield. In each essay the reader is drawn “up front and personal” into Gawande’s world and given a vision of what he sees and a sense of what he feels. The stories are a reflection of the soul of medicine.

I am a big fan of Gawande and his writing, but I smiled at the advice he gives to medical students—namely, count something and write something. Good advice, but surely incomplete. I’m sure he would add the next logical imperative—namely, improve something: once you see an obvious defect, join the effort to make medicine more effective, safer, and more humane.

Gawande’s stories disclose how hard we try to care for the sick, and how difficult it is to get it right every time. His essays are a brilliant diagnosis of medicine’s ills, and they show that it’s high time for our profession to take responsibility for the cure. After decades of resistance, we must get over our reluctance to have our performance measured. If the analytical measures of quality aren’t perfect, we must stop complaining about them and help to fix them. We must get over our unwillingness to display our results publicly. We must be accountable for what we do well and for what we do wrong; only then can we move towards optimal performance.
Not sick, just low

Every time I open the bathroom cabinet the unopened packet of St John’s wort stares out at me. Why don’t I throw it out? Why did I decide not to take this herbal antidepressant? Was it the feeling of weakness that someone like me, a control freak, could get so low? I am willing to admit to a sustained period of unhappiness that by any biased and highly leading depression questionnaire would have me rated as “clinically” depressed. I am not alone: in the UK last year some 31 million prescriptions for antidepressants were written, a 6% increase on the previous year. Why didn’t I seek such treatment?

With all our wealth, comfort, and “me time” these days, why do so many of us find ourselves in the darkest corner of this gilded cage? It is easy to point the finger of blame at the thoughtless GPs, the naive psychiatrists, the greedy drug companies, and the media, which long ago substituted sensationalism for journalism. But this is all too simple, for there is a broader theme at work—the culture of individualism. We have a society that is strong on rights but short on responsibility. And the result? An atomised society in free fall in the chasm between expectation and reality. Our vast media factories pollute the airways with messages that happiness is an absolute entitlement and comes at no personal cost. We are experiencing a global emotional climate change, with extreme storms of behaviour—and this changed climate is melting the icecaps of stoicism and acceptance.

Medicine needs to move away from intervening in mood issues, for we are destabilising the situation further. Esteem is born from overcoming adversity, so when life’s problems become an illness, and when coping is seen as denial, what hope is there for our sense of self worth?

Depressive pain has a psychological purpose in the same way that physical pain has physiological purpose. Low mood is as normal and as important to our sense of wellbeing as happiness is. This is not to dismiss depression but merely to free it from the totalitarianism of medicine and reflect the heat of these emotions back into broader society. Family and friends—the people who know the context of our lives—are the natural emotional sump. Exercise, walks in the country, and other such “organic” treatment seem a natural solution to many people, but most of all, healing comes with time.

With 31 million prescriptions and a 6% annual growth, medicine should admit that its offer to “cure” depression was naive and wrong. Drug treatment should be reserved for the very few, not the many. Over the years I have taken many a hard look in that bathroom cabinet mirror—the time for the medical profession to look at its own reflection is long overdue.

Des Spence is a general practitioner, Glasgow destwo@yahoo.co.uk

Five go mad in primary care

Raised in rural Ireland, I used to read Enid Blyton just like everybody else, so a locum in the shires a few years ago was just like going home.

On my first morning the vicar waved to me in greeting, like John Major had promised, although I was then a bit surprised to see him slipping off his bike to trade Es with the local hoodies; things sure have changed on Walton’s Mountain, I thought, but hey, that’s the Church being more relevant, out there on the streets with the kids.

And even more quintessentially English, that night I was called to a murder scene. The body was face down in the local cricket club, blood on his scalp, a bloody cricket bat lying beside him, and the assembled committee looking on in fascination.

The policeman introduced himself as Constable Goode, and I felt I’d known him all my life.

“Cause of death,” he pronounced slowly, with the traditional air of intense concentration, writing in a little notebook with the mandatory stubby pencil, “trauma to head by person or persons unknown.”

I knew something was required of me, and I rolled the body over. The shirt had been ripped open, there were fresh bruises and burns on the chest, and the deceased had an annoyed expression on his face.

“Not so fast, sergeant,” I said (I always address coppers thus—a little bit of harmless flattery goes a long way), “there’s not enough blood. I therefore deduce that the head injuries were inflicted after death, as a cunning red herring.”

“A red herring?” mused the constable, “in this place? Then what was the murder weapon?”

I pointed to the corner of the room. “The defibrillator,” I shouted. “J’accuse!”

The club secretary fell to his knees. “OK, I confess,” he wailed.

“We’ve had that machine for five years, paid three grand for it. All those fund-raising garden fetes and sponsored walks and tea dances—if I ever see another cucumber sandwich I’m going to vomit. But in all that time we’ve never had a chance to use it, despite the publicity that people were dying like flies and about how important it was to have one; it’s just been sitting there in the corner, laughing at us. So when Walter took a weak turn at the bar, we saw our chance; he fought bravely but we got him down in the end.”

Then a small curly-haired boy (or girl!) popped her (or his) head round the door.

“Too late George,” said the constable, “this case is closed.”

“P**** it,” said George, “what’ll I do with all this ginger beer?”

Liam Farrell is a general practitioner, Crossmaglen, County Armagh

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I knew a Shropshire lad once and I liked him enormously. I met him not in those blue remembered hills, but in a far off tropical country in which I was working, and to which he also came for work. He had diabetes and he arrived for a check-up. He was a large man, both muscular and fat.

“I suppose,” I said, “that you are careful with your diet.”

“No at all,” he replied.

I soon discovered that he loved rich food, good drink, and company (mine soon to be included).

“There’s not much point in my telling you that your habits are not good for you, is there?” I said. Indeed there wasn’t: he had opted for a short but merry life, and I was glad to get the subject out of the way. What a relief it was to meet someone who had the courage to reject medical advice without pretending otherwise!

It was strange, though, to talk to him about Shropshire—a county I knew quite well because I had once done a locum in a small town there—in that verdant tropic where the temperature rarely varied by more than a degree or two, and where the daylight lasted exactly 12 hours all year round.

I mentioned that, when I was in Shropshire, half my time was occupied by patients who lived in a single road. “Ah, yes,” he said, and then named the road (I still remember its name, though I won’t reveal it now), norstrous at the time throughout the county for domes

My Shropshire lad was not a soldier of the Queen, but he was a soldier against the deadening army of health and safety

moments, I wonder whether a familiarity with death makes for a deeper character.

Does not this verse fit my Shropshire lad? “Oh you had forethought, you could reason, / And saw your road and where it led, / Put the pistol to your head.” Or again: “Come you home a hero, / Or come not home at all, / The lads you leave will mind you, / Till Ludlow tower shall fall.”

Of course, my Shropshire lad was not a soldier of the Queen, but he was a soldier against the deadening army of health and safety, and in my eyes at least a hero. He truly might have said: “Tis late to hearken, late to smile, / But better late than never. / I shall have lived a little while / Before I die for ever.”

So to him I say: “Turn to rest, no dreams, no waking; / And here, man, here’s the wreath I’ve made: / ’Tis not a gift that’s worth the taking, / But wear it and it will not fade.”

Theodore Dalrymple is a writer and retired doctor

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**BETWEEN THE LINES**

Theodore Dalrymple

Stalwart of the county

him: he met his end unafraid and unself-pityingly. He had made his choice and therefore he made no complaint. He was a man who did not measure life with the straight ruler of time.

I cannot read A E Housman’s *A Shropshire Lad* now without thinking of him. A large number of the poems concern, or mention, the early deaths of Shropshire lads (and lasses), although what was considered early with regard to death in those days—1896—was a good deal earlier than in ours. Sometimes, in my more reactionary moments, I wonder whether a familiarity with death makes for a deeper character.

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**MEDICAL CLASSICS**

**The Madness of King George**

Film released 1994

A re-working of Alan Bennett’s original stage play, *The Madness of King George*, is a classic of British cinema. Nigel Hawthorne (of television’s *Yes Minister* fame) stars as the eccentric King George III whose bizarre behaviour, caused by what is now thought to have been an episode of acute porphyria, causes problems of propriety for his family, his subjects, and for the country as a whole.

The story begins in 1788 with the king still finding it difficult to come to terms with the loss of the colonies in North America. The then prime minister, William Pitt the Younger, and the king are far from great friends, but they have a way of getting on. Indeed Pitt feels more secure in his own position with the somewhat malleable George on the throne.

The king busies himself with other activities—outdoor sport and family life. His wife, the Germanic Queen Charlotte (Helen Mirren), has borne him 15 children, and their relationship is a tender and genuine love affair.

Things begin to go awry, however, when George’s mental state deteriorates. Accompanied by symptoms of acute abdominal pain, discoloured urine, and fever, George’s uninhibited behaviour is increasingly outrageous and it soon becomes clear that he is not fit to rule. His son and heir, the opportunistic and idle prince of Wales (Rupert Everett), eyes a chance for power and with the help of Pitt’s rival politician, Charles Fox, a bill is proposed to establish the prince regent, reigning in the king’s stead.

The portrayal of the medical profession is of great interest. Initially three traditional physicians, with establishment backgrounds and hairpieces to match, are consulted. They dare not ask their regal patient a direct question nor look him in the eye, let alone lay their hands upon him. They prescribe a regimen of blistering, purgatives, and hot baths, but there is no improvement. As the king’s condition deteriorates, Dr Willis (Ian Holm), a gritty doctor/pastor from Lincolnshire with experience of treating such symptoms, is summoned. From the outset he is far less mild mannered and makes it clear that he will not tolerate any misbehaviour by the king. The wonderful scene in which doctor and king first meet ends as follows: “I am the king of England.” “No, sir, you are the patient.” By luck or good judgment, George’s convalescence at Kew Gardens is a success. He returns to parliament to reaffirm his position on the throne and to lambast his plotting son.

In reality, the king experienced recurrent episodes of delirium and ultimately the regency was established.

Research has subsequently implicated high arsenic levels in the king’s antimony powders as responsible for the porphyria. What is certain is that *The Madness of King George* is a British historical drama of the highest calibre.

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**“I am the king of England.”**

**“No, sir, you are the patient.”**
Imre Joseph Pál Loeﬂer
Surgeon, controversial writer, and polymath

Imre Loeﬂer was well versed in philosophy, history, ecology, and wildlife conservation, as well as medical education and surgery. In speeches and over 1000 articles and scientiﬁc papers he challenged the status quo in many different disciplines, his inﬂuence extending far from his home in Nairobi.

In 1944 Imre was enrolled in an army cadet school in Budapest and was soon captured by the German army and sent to the Polish war front. After six months he escaped to Germany, where the Americans captured him in May 1945. In the prisoner of war camp he helped in a clinic, performing his ﬁrst operation, the incision of a buttock abscess.

On discharge from prison in Regensburg he worked in a US army hospital preparing histological slides. His parents found him through the Red Cross and took him back to school in Budapest, but he was refused entry to medical school by the communist government because of his “bourgeois” background. Within a month, he escaped from Hungary, on foot across the Austrian border, and returned to Regensburg. There he worked as a coal miner until he could afford to enrol in its medical school. He won the national scholarship, Die Studienstiftung des Deutschen Volkes, with free tuition, a salary, and the chance to study philosophy and history alongside medicine. Here he gained his grounding in philosophy at the feet of, among others, Erwin Schrodinger, Karl Popper, and Pablo Casals.

Reading British and American journals, Imre thought that German surgery had been left behind, mainly because of the way it was organised. He retrained in the United States. Inspired by the reputation of Makerere University in Uganda, he tried to arrange an African assignment but found that neither of his diplomas was recognised by the colonial government. In 1964, however, he gained work at a mission hospital in Uganda, maturing as a surgeon and acquiring his lifelong interest in wildlife.

In 1967 he was invited to join the department of surgery in Mulago, Uganda’s teaching hospital, as a senior lecturer. And in 1970 he was appointed the foundation professor of surgery to Zambia’s new medical school in Lusaka. Here Imre also learnt to ﬂy and became an honorary game warden. His department of surgery was ﬁrmly based on the Mulago principles of service, teaching, and research. However, tensions and jealousies within the medical school resulted in his expulsion from the country in 1975.

Imre was then invited to Nairobi Hospital and spent 31 years there until he retired in 2006. He soon became a very busy surgeon but for many years would spend every Monday ﬂying to remote hospitals to operate and teach. The Nairobi Hospital, a private institution, gave him few teaching opportunities, but he established the library and founded the Proceedings of Nairobi Hospital, which he edited for nine years.

As a council member of the Association of Surgeons of East Africa (ASEA), Imre was responsible for Zambia becoming the ﬁrst additional member country in 1974. Later, as chairman he played a large role in developing and monitoring surgical training throughout the region.

From 1998 to 2005 he was chairman of the East African Wildlife Society; he tried to give a new direction to conservation, believing that people would conserve wildlife only when they received direct beneﬁts from so doing. His advocacy of consumptive utilisation of wildlife threw him into conﬂict with the many non-governmental organisations concerned with animal welfare.

Imre had a weekly column in the East African Standard, which was usually polemical and disturbing, engaging always with topics affecting his fellow Kenyans (he had acquired Kenyan citizenship in the ’80s) such as governmental ineﬁciency and corruption, deforestation, land erosion, the declining water supply. He crossed swords with the Catholic Church for its views on abortion, birth control, and AIDS and weighed frequently into Africa’s root cause for its underdevelopment—namely, its burgeoning birth rates. In his popular Soundings column for the BMJ he consistently stuck to his editor’s brief—to be as splenetic as possible. His essay was the ﬁrst winner of the Wakley prize, established by the Lancet in honour of its founder. He produced many book reviews; those of surgery were always from the viewpoint of a surgeon working in a poor environment and one who believed all surgical practice should be based on the basic principles underlying wound healing, management of infection, and repair of tissues. He decried the advent of the superspecialist and of new procedures that depended on technically complex techniques that were not attainable, or appropriate, outside of the metropolitan hospitals of the West.

He was invited to lecture throughout Africa, Europe, the US, and Australia. In 2005, in recognition of his speaking and writing, the Satima Foundation was established in Kenya to promote essay writing and rhetoric among Kenyans.

Prostate cancer was diagnosed in 2000. He faced his fate with the rational view of the agnostic he was, continuing to work, ﬂy, write, and travel extensively almost to the end. He leaves a wife, Martha, and four children.

John Craven, John Jellis, Francis Omaswa
Imre Loeﬂer, former surgeon in private clinical practice Nairobi (b 1929; q Regensburg, Germany, 1954; FRCS Ed), d 11 March 2007.
Florence Claire Ruth Brown (née Richardson)

Former thoracic surgeon United Kingdom and anaesthetist New Zealand (b 1915; q Royal Free Hospital, London, 1941; FRCSEd), d 22 August 2006. After qualifying, Ruth Richardson was unable to return to her native Jersey, and her request to join the war effort was declined. She therefore pursued her interest in surgery, eventually becoming senior surgical registrar in thoracic surgery at Hill Top Hospital, Bromsgrove. Marriage to a Nottinghamshire general practitioner, Bob Brown, in 1952 prompted her move to Nottingham City Hospital. In 1967 they emigrated to New Zealand, where Ruth took up anaesthetics at the Memorial Hospital in Hastings until 1977, when she and Bob did voluntary medical work for two years in Papua New Guinea. They retired to the South Island of New Zealand, Ruth remaining active in community work. Predeceased by Bob in 1994, she leaves two sons and five grandchildren.

Hugh Brown

Jack Philip Lask

Former general practitioner Ascot and Bracknell, Berkshire (b 1916; q Leeds 1940), died from bronchopneumonia on 31 March 2007. Jack Lask joined the Royal Army Medical Corps in 1940, serving in India, Persia, Iraq, Egypt, Sicily, Italy, and Greece. After the war he joined a singlehanded practice in Ascot, taking over when his partner retired. In 1952 he moved into one of the first housing estates to be constructed in the new town of Bracknell, where he built a house and another surgery. The size of his practice increased with the growth of the town to become a partnership of six doctors. For many years Jack was the doctor at Ascot Races. He also had a large midwifery practice and served on the local medical committee, Jack retired in 1985. He leaves a wife, Clarice; two daughters; and five grandchildren.

Judy Trewin

Kathleen Joyce McCarthy (née Evers)

Former school medical officer London County Council (b 1912; q University College Hospital 1937), died from dementia on 2 January 2007. Head girl at her boarding school and captain of hockey, Joyce was academic, athletic, and passionate. At school and medical school she expressed her feelings on life, love, loss of faith, and even the dissection room, through poetry. In 1945 with four young children she was doctor to LCC (London County Council) school and baby clinics. In the early 1960s she and her husband, John, retired to Butlerstown, County Cork, for 10 years. After John’s death in 1975, Joyce moved near to her daughter. Her loves at this time included her garden and china. She leaves three children and eight grandchildren.

Fiona Subotsky

Edmund Rainey

Former consultant orthopaedic surgeon Pinderfields Hospital, Wakefield (b 1936; q Queen’s University, Belfast, 1960; FRCSI, FRCS Ed), died from oesophageal cancer on 16 February 2007. Edmund Rainey undertook specialist training in orthopaedic surgery at Musgrave Park Hospital, Belfast. In 1971 he was appointed consultant at Pinderfields Hospital, Wakefield, where he worked until his retirement in 1996. He was also a member of the founding committee of Methley Park Hospital, and served on the committee of the Wakefield and District Mobile Physiotherapy Association. He was an active member of Wakefield Round Table, becoming chairman in 1976. He leaves a wife, Rosemary; three children; and seven grandchildren.

Joe Tosh

Charles James Crawford Renton

Former general surgeon Hereford County Hospital (b 1930; q Glasgow 1953; FRCS), d 9 February 2007. Charles Renton trained as a general surgeon in Glasgow, Nottingham, and Sheffield after his early career was interrupted by national service and the Suez crisis. In 1969 he was appointed consultant general surgeon with an interest in vascular and breast surgery in Hereford, where he remained until his retirement in 1995. He was president of the Herefordshire Medical Society and the local branch of the BMA, as well as being involved in local hospital management. On his retirement the Charles Renton Oncology Unit was opened at the hospital. In retirement Charles wrote a book on the history of the Herefordshire Hospitals and another on the history of Hampton Park United Reformed Church. He leaves a wife, Margaret; four daughters; and six grandchildren.

Morag Renton

Ethel Valerie Slater

Former general practitioner Preston (b 1936; q Liverpool 1961; MRCGP), died from malignancy on 1 August 2006. Ethel turned down an interview to read history at Oxford to study medicine at Liverpool. She initially trained as a pathologist at Preston Royal Infirmary before joining her husband in the family general practice in 1966. In the 1970s she began a lifelong involvement in the teaching and training of medical students and general practitioners. She was instrumental in setting up local workshops for the royal college to prepare trainees for the MRCGP oral examinations. During the 1980s she helped provide community cytology clinics. Retiring from general practice in 1996, Ethel worked for the Appeals Service until just a few months before her death. She leaves a husband, Alan; three daughters; and eight grandchildren.

Angela Robb, Sarah Slater, Catherine Steventon

Oliver Smith

Senior house officer in surgery and teaching fellow to Imperial College students Northwick Park Hospital (b 1978, University College London 2001; MRCs), died from colon cancer on 29 March 2007. From 2004 to 2006 Oliver Smith did surgical training at Northwick Park and St Mark’s Hospitals, where he completed his MRCS examinations and published research on restorative proctocolectomy for Crohn’s disease. During his senior house officer rotation Oliver flourished as a teacher. He became an ALS (advanced life support) instructor and then teaching fellow to Imperial College students. His warm and engaging style led to him being nominated by over 30 students for the 2007 NHS teaching award. He also set up a course for A level students to learn about careers in medicine. He leaves a fiancée and his parents.

Daniel Sado, Gillian Park
A direct comparison of continuous antiviral treatment for HIV infected people in India with structured interrupted antiviral treatment reports that the primary end point of maintaining a CD4 count of more than 200x10^4 cells/l at six and 12 months was achieved by both groups. The secondary end points were effective viral suppression, adverse events, and cost. One patient in the continuous therapy group and two in the interrupted group sustained a plasma viral load of more than 400x10^4 copies/l. No serious adverse events or deaths were reported, and a 50% reduction in costs was seen with interrupted therapy (AIDS Care 2007;19:507-13).

Irritable bowel syndrome is sometimes treated in Saudi Arabia with hypnotherapy. A small study involving 26 patients showed that, after 12 sessions of hypnotherapy administered over 12 weeks, patients' quality of life had improved significantly, but more in the men than the women. In particular, dissatisfaction with bowel habits was reduced after treatment, but more in the women than the men (Eastern Mediterranean Health Journal 2007;13, www.emro.who.int/publications/emhj/1302/article10.htm).

Higher levels of spirituality and private religious practices are associated with slower progression of Alzheimer’s disease (Neurology 2007;68:1509-14). There was no correlation between quality of life and speed of decline. The longitudinal study followed 70 patients with probable Alzheimer’s disease, with the mini-mental state examination used to monitor cognitive decline. What’s not known is whether the same variables have their impact if people have enjoyed their spirituality throughout life, or if it’s a recent change.

A 7 year old girl was referred for suspected child abuse leading to multiple fractures of her skull. Clinically, the patient had short stature, with a bone age of 3 years, and features of congenital primary hypothyroidism. The skull anteroposterior x ray shows intrasutural or “wormian” bones along the coronal sutures, erroneously labelled as fracture. The anterior fontanelle is visualised (delayed closure). The skull is brachycephalic, and the paranasal sinuses and facial bones are poorly developed. Wormian bones are typical radiographic findings in congenital hypothyroidism, and they disappear at a bone age of 5 years. Ajit Singh Kashyap (kashyapsajits@gmail.com), department of endocrinology, Command Hospital (Central), Lucknow, India, Kuldip Parkash Anand, Command Hospital (Eastern), Kolkata, India, Dalbara Singh, department of radiology, Command Hospital (Central), Lucknow, Surekha Kashyap, Command Headquarters (Central), Medical Branch, Lucknow

Inoculating rats’ surgical wounds with Staphylococcus aureus and subjecting the infected wounds to seven different types of treatment revealed that a high concentration of locally applied antibiotic inside the wound is effective in killing bacteria in wound cavities, especially where systemic antibiotics have poor penetration. The various local treatments—irrigating the wound with an antibiotic, packing it with antibiotic-loaded flakes of calcium sulphate, and local injection of aqueous antibiotic solution—were compared with systemic approaches (Journal of Bone & Joint Surgery-Am 2007;89:929-33).

Just when complementary health approaches are taking a battering, here’s a systematic review of a Chinese herbal medicine for schizophrenia no less (British Journal of Psychiatry 2007;190:379-84). Seven trials were included, and most evaluated herbal medicine alongside conventional antipsychotic drugs. In most of them, combination therapy was favoured over antipsychotics alone for improving clinical outcome measures.

Another somewhat quirky approach involves weekly, twice monthly, and monthly psychotherapy as “maintenance” treatment for women with recurrent depression. The research question was whether more frequent sessions of psychotherapy have a greater prophylactic effect than a previously validated once monthly session. The answer was a surprising “no”—once a month was sufficient. However, for women who had needed antidepressants as well as psychotherapy before achieving remission, “maintenance” psychotherapy alone was significantly less beneficial (American Journal of Psychiatry 2007;164:761-7).

Transfusions of fresh frozen plasma and of platelets are risk factors for acute lung injury and respiratory distress in critically ill patients and produce more problems than transfusions of red blood cells (Chest 2007;131:1308-14). In this single centre study of 841 critically ill patients, the 298 (35%) who received any blood product transfusion were more likely to develop a serious lung injury (odds ratio 2.14 (95% CI 1.24 to 3.75)).

Transplant patients who develop abdominal graft versus host disease can be treated with oral beclometasone dipropionate to prevent relapse after prednisolone treatment has been tapered off. By day 200 after transplantation, in a randomised placebo controlled trial of oral beclometasone, five patients randomised to the drug had died compared with 16 deaths with placebo (a 67% reduction in the hazard of death). The survival benefit remained one year after randomisation (Blood 2007;109:4557-63).

Results from the “recent immigrant pregnancy and perinatal long term evaluation study” (RIPPLES) indicate that the risk of maternal placental syndromes reduces progressively with the recency of immigration. In other words, women who have recently immigrated to Western nations show that the “healthy immigrant effect” extends to common placental disorders. New immigrants should be discouraged from adopting adverse lifestyle choices. The effect wears off over time (CMAJ 2007;176:1409-26).