

## Sigmoidoscopy screening for colorectal cancer

May reduce mortality, but longer term results are awaited



### RESEARCH, p 1363

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Evidence supporting colorectal screening, aside from randomised trials of faecal occult blood testing, comes mainly from observational studies. In the linked paper interim results of the Norwegian Colorectal Cancer Prevention (NORCCAP) trial are presented.<sup>1</sup> NORCCAP is one of three ongoing trials of once only screening sigmoidoscopy.<sup>1-3</sup> The findings suggest that the intervention may be effective in reducing mortality from colorectal cancer.

The NORCCAP trial randomised 55 736 people aged 55-64 years to usual care or to once only flexible sigmoidoscopy with or without a single round of immunochemical faecal occult blood testing. The primary outcome for this first report is 7 year cumulative incidence of colorectal cancer (anywhere in the colon); the secondary outcome is 6 year mortality from colorectal cancer. Colonoscopy, which was done in 21% of patients screened, was recommended for people with a positive screening result, defined as any polyp 10 mm or larger in diameter, any histologically verified adenoma or carcinoma, or a positive faecal occult blood test. Follow-up was obtained from the Cancer Registry of Norway and the Norwegian Cause of Death Registry, both of which are virtually 100% complete.

Of 13 653 people invited for screening sigmoidoscopy, 8846 (65%) underwent sigmoidoscopy; 41 092 individuals served as controls. The overall incidence of colorectal cancer did not differ significantly between screened and control groups (134.5 *v* 131.9 cases per 100 000 person years). The incidence of rectosigmoid cancer among attendees was reduced by 27% (58 *v* 79 per 100 000 person-years; *P*=0.10). The intention-to-screen analysis showed no significant difference in mortality from colorectal cancer (hazard ratio 0.73; 95% confidence interval 0.47 to 1.13), while the per protocol analysis showed a significant reduction in mortality for any colorectal cancer (0.41; 0.21 to 0.82) and for rectosigmoid cancer (0.24; 0.08 to 0.76). Compared with the control and non-attending groups, people with screen detected colorectal cancer tended to have earlier stage disease and had a lower case-fatality rate, though neither outcome was compared statistically.

If the study and findings are accepted as rigorous and valid, what explains the lack of a difference in cumulative incidence of colorectal cancer between screened and control groups, and how important is this finding?

Previous data on sigmoidoscopy screening come largely from high quality case-control studies suggest-

ing a 60-80% reduction in mortality from distal but not from proximal colorectal cancer.<sup>4,5</sup> A case-control study suggested that endoscopic procedures (sigmoidoscopy and colonoscopy) of the large bowel reduced incidence of colorectal cancer by 50% for up to six years.<sup>6</sup> The Telemark clinical trial showed an 80% reduction in cancer incidence with sigmoidoscopy screening alone, but no effect on mortality from colorectal cancer, and an increase in all-cause mortality, due mostly to cardiovascular disease.<sup>7</sup> The reduction in cancer incidence was observed after 13 years of follow-up. Cumulatively, these data suggest that sigmoidoscopy should be expected to reduce incidence and mortality related to colorectal cancer, at least for lesions within reach of the sigmoidoscope.

NORCCAP chose a high but appropriate bar by including the (prevalent) cancers initially detected by sigmoidoscopy in the measure of overall cumulative incidence. Excluding these prevalent cancers would have biased the results in favour of screening because of inability to exclude them in the unscreened control group. Using overall (as opposed to distal) incidence further raises the bar, since sigmoidoscopy would be expected to have a greater effect on incidence of distal cancers. With a smaller benefit on overall incidence expected, more time may be needed to detect it.

Since screening is expected to increase the detection of early stage curable cancer, we might expect a reduction in cancer mortality to occur before the reduction in incidence that results from removal of adenomas. In a trial of annual guaiac-based faecal occult blood test screening, a reduction in mortality from colorectal cancer was reported seven years earlier than a reduction in incidence.<sup>8,9</sup> Although the difference between the groups was not significant, the reduction in overall mortality from colorectal cancer in NORCCAP is encouraging. The per protocol analyses more clearly indicate a reduction in mortality, but these findings may be prone to selection bias. Longer follow up will clarify these effects.

What are the implications of the current findings? Since site specific cancer mortality is generally considered the most appropriate end point for evaluating screening interventions,<sup>10</sup> we should be encouraged by NORCCAP's interim findings. Evidence to date strongly suggests that one time screening sigmoidoscopy can reduce incidence and mortality from distal colorectal cancer and may be a legitimate strategy. We await the further results of this landmark trial and of the other ongoing trials of sigmoidoscopy screening.

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## Treatment of enteric fever

Fluoroquinolones remain the best option in areas where resistance is uncommon



GMB AKASH/PANOS

Enteric fever (typhoid and paratyphoid), caused by *Salmonella enterica* serovar Typhi or serovar Paratyphi A, represents a major burden of disease in communities that lack clean water and adequate sanitation. More than 27 million cases of enteric fever occur worldwide each year, with 216 000 deaths.<sup>1</sup> Community based studies in Asia have shown a yearly incidence greater than 400/100 000 population in infants and children.<sup>2</sup> In developed countries, returning travellers or those visiting friends and relatives in their family's country of origin are at risk.<sup>3</sup> In endemic areas, most patients are treated with oral antibiotics as outpatients, and only those with severe disease need hospital admission. Relapse may complicate the illness, and faecal carriage can become chronic and lead to onward transmission. In the linked systematic review, Thaver and colleagues compare the effectiveness of fluoroquinolones as firstline agents with that of other antibiotics for treating enteric fever.<sup>4</sup>

Until the late 1980s, two to three weeks of chloramphenicol was the treatment of choice for enteric fever. Plasmid mediated multidrug resistant (MDR) strains then emerged that were resistant to chloramphenicol, amoxicillin, and co-trimoxazole. Fluoroquinolones (ciprofloxacin and ofloxacin), extended spectrum cephalosporins (ceftriaxone and cefixime), and azithromycin were suitable alternatives for resistant organisms and five to 10 days of an oral fluoro-quinolone became a widely used regimen.<sup>5</sup>

In areas where fluoroquinolones, such as ciprofloxacin, were widely used, isolates with decreased susceptibility to ciprofloxacin (DCS) appeared, and these strains have reached high levels in Central, South, and South East Asia.<sup>6</sup> Infections caused by strains with DCS respond poorly to ciprofloxacin and ofloxacin, with prolonged recovery times and increased rates of clinical failure.<sup>7</sup> The laboratory detection of DCS strains is problematic because they are still classified as susceptible.<sup>8</sup> Isolates with DCS are usually resistant to the first generation quinolone, nalidixic acid, and this is a useful, but not 100% reliable, surrogate laboratory

marker for resistance. In some areas of Asia, isolates that are fully resistant to ciprofloxacin have emerged at the same time as the proportion of MDR infections has declined.<sup>5</sup> So, should fluoroquinolones continue to be used as a firstline treatment for enteric fever?

The systematic review and meta-analysis by Thaver and colleagues compares the effectiveness of fluoroquinolones, chloramphenicol, ceftriaxone, cefixime, and azithromycin for treating enteric fever.<sup>4</sup> Only 21 of 70 trials were of sufficient quality to be included; many included small numbers of patients, and few trials were in children. In adults, fluoroquinolones significantly reduced clinical relapse compared with chloramphenicol (odds ratio 0.14, 95% confidence interval 0.04 to 0.50), clinical failure and relapse when compared with cefixime (0.05, 0.01 to 0.24), and clinical failure compared with ceftriaxone (0.08, 0.01 to 0.45). The fluoroquinolones significantly shortened fever clearance times compared with all three antibiotics. No trials compared fluoroquinolones with chloramphenicol or ceftriaxone in children, although in one trial fever clearance time was significantly shorter with ofloxacin than with cefixime. Oral azithromycin and the newer generation fluoroquinolone gatifloxacin were both effective against infections with DCS isolates.<sup>9-12</sup>

Ciprofloxacin or ofloxacin remain the best choice for patients with enteric fever in areas where isolates with DCS are uncommon, such as in Africa, South America, and Central America. Concern that widespread use of ciprofloxacin in these areas will lead to the emergence of isolates with DCS highlights the need to understand the factors that determine this. Is it because the ciprofloxacin dose is too low, the duration of treatment is too short, or because the lack of a satisfactory diagnostic test means that ciprofloxacin is used indiscriminately in all patients with fever?

For enteric fever acquired in many parts of Asia, more than 90% of isolates have DCS so ciprofloxacin and ofloxacin should be avoided. Azithromycin, gatifloxacin, or ceftriaxone can be used when MDR or DCS isolates are common. Resistance to ceftriaxone

### RESEARCH, p 1371

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and azithromycin is rarely reported, but isolates that are fully resistant to ciprofloxacin are now being detected in India, and gatifloxacin may not work for these infections. Combinations of these drugs are being used, but evidence for the effectiveness of this strategy is lacking.<sup>12</sup>

High quality adequately powered multicentre clinical trials are needed to compare these treatment options for enteric fever. Trials should include children and ambulatory patients and be completed quickly enough to influence clinical practice in the face of rapidly changing resistance patterns. Finally, prevention should not be forgotten, nor should the potential use of vaccination in areas where the disease burden is high and drug resistance is common.

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## Changing the face of whistleblowing

Statutory protection, regulatory support and culture change are needed



DOMINIC LIPINSKI/PA

A decade after the scandal at Bristol Royal Infirmary<sup>1</sup> whistleblowing is still hazardous to whistleblowers. A whistleblower is a person who informs on another or makes public disclosure of corruption or wrongdoing. Margaret Haywood was struck off by the Nursing and Midwifery Council (NMC) after exposing poor standards of care at Brighton and Sussex University Hospitals NHS Trust.<sup>2</sup> At the same time, prominent individuals have complained that whistleblowing was inadequate at Mid-Staffordshire NHS Foundation Trust,<sup>3</sup> which has been widely reported in terms of hundreds of unnecessary deaths.<sup>4</sup> What is the problem?

Most patients would surely expect doctors generally to protect them from potential harm; doing so has been a key part of medical ethics for centuries. The General Medical Council (GMC) stipulates a professional ethical duty to raise concerns.<sup>5</sup> Doctors and other healthcare staff owe their patients a duty of care. Failure to protect patients from harm may breach this duty, and resulting injury may give rise to civil and criminal legal liability. An NHS doctor is likely to have a contractual duty to participate in clinical governance procedures, which should include systems for raising concerns, and guidance on how to proceed when appropriate action is not taken. How often such systems exist in practice is unknown. Appropriate documented warnings to employers about threats to patient safety should protect individuals from liability.<sup>6</sup> The warnings should

comply with local policy (where it exists), go through the proper channels (not through the media at an early stage), and be documented in writing.

Where governance procedures work smoothly, the term whistleblowing may be misleading. It suggests an escalated disclosure because appropriate action has not yet been taken. Careful consideration is necessary before whistleblowing, which too often harms the whistleblowers themselves. The concerns of Dr Stephen Bolsin, the Bristol whistleblower, about unsafe children's heart surgery, were "cavalierly dismissed," his career stalled, and he now works on the other side of the world.<sup>7</sup>

Whistleblowers may be made to feel that they are the problem. More seriously, they may find themselves the subject of retaliatory complaints and disciplinary action. Wilmshurst reports that in one case of research fraud, whistleblowers were "advised to keep quiet or their careers would suffer."<sup>8</sup> He found that when he made one complaint to the GMC, it gave priority to investigating him for disparagement. He also discovered that his defence body was instrumental in pressurising him to drop his concerns about another case of research fraud. The chairman of the BMA recently described "a culture of threats and bullying that stops whistle-blowing."<sup>9</sup> It is no surprise that whistleblowers can be reluctant.

Limited protection for whistleblowers is afforded by the Public Interest Disclosure Act 1998 (PIDA 1998), which "renders void contractual duties of

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confidentiality between employer and employee to the extent that they preclude the worker from making a ‘protected disclosure’. A protected disclosure is a disclosure which is not itself a criminal offence but which raises legitimate concerns about the employer’s business and is made in good faith through appropriate channels.”

Some believe that the protection the act affords is inadequate, and that it did not help the Bristol whistleblower.<sup>7</sup> PIDA 1998 took effect via amendments to the law of unfair dismissal and there are, arguably, inadequacies in its operation. The act has influenced the development of policies on disclosures in the public interest by NHS trusts, although it is not clear how effective these are in affording protection to whistleblowers or the public interest. Would-be whistleblowers should seek advice from their defence bodies, and possibly the BMA or Public Concern at Work ([www.pcaw.co.uk/individuals/helpline.htm](http://www.pcaw.co.uk/individuals/helpline.htm)).

The document “Blowing the whistle” offers relevant and practical guidance.<sup>10</sup> Of particular importance is the need for whistleblowers to protect their own position. This includes careful documentation and “playing by the rules”—that is, adhering to the employer’s stated policy as far as possible. The Brighton whistleblower was open to NMC disciplinary proceedings because she breached patient confidentiality and did not exhaust internal systems for raising concerns before releasing details to the media. The document also lists techniques used to discredit whistleblowers.

Concerning Mid-Staffordshire NHS Trust, the chairman of the Healthcare Commission indicated that warnings existed about some of its problems for years before the problems became publicly known.<sup>11</sup> Why should staff accept the risks of whistleblowing if warnings are ignored?

The chairman of the Care Quality Commission has criticised staff at Mid-Staffordshire NHS Trust and elsewhere for operating in a “culture of silence.”<sup>9</sup> But

the commission’s plan to assess progress at Stafford does not mention whistleblowers. The secretary of state for health has stated: “I do not understand why clinicians whose primary role is the safety of their patients are somehow concerned about whistleblowing.”<sup>12</sup>

Several measures should be considered, including greater statutory protection, more support from regulatory bodies, and, above all, a culture change to encourage whistleblowing. A start would be for those in official positions to recognise the risks of whistleblowing. Then they might begin to limit the damage wrought by the next Bristol, Brighton, and Stafford, scandals which are probably already happening.

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## The Conservative Party’s policies on health

### Markets not targets will be used to improve performance

With the United Kingdom general election less than a year away and opinion polls showing the Conservative Party well ahead of the Labour Party, there is increasing interest in the opposition’s health policies and their implications for the NHS.

The broad direction of the Conservatives’ thinking has been set out in a series of policy documents published in the period since David Cameron’s election as leader of the party in 2005.<sup>1</sup> At the heart of this thinking is continuing support for a universal, comprehensive, tax funded NHS, alongside plans that are both different from and similar to those pursued by the Labour government.

One of the principal differences concerns the

Conservatives’ commitment to distancing politicians from the day to day running of the NHS. This aim will be achieved through the establishment of an independent board made up of the NHS chief executive, his senior colleagues, and lay people serving in a non-executive capacity. The board will lead the management of the NHS within a framework of objectives set by the government and will report to parliament.

The creation of an NHS board is intended to enable the Department of Health to concentrate on public health issues in support of the stated aim of focusing on health outcomes rather than centrally imposed targets relating to clinical processes. This aim derives from the aspiration to return power to front line staff,

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including doctors, by bringing an end to the micro-management of health care.

In the case of primary care, the Conservatives say they will renegotiate the contract of general medical services in order to facilitate a simplified quality and outcomes framework, the delivery of improved out of hours services, and extended access to services. These proposals echo loudly the policies being pursued by the current government, as do the Conservatives' commitments to increasing the choices available to patients and offering individual budgets to people with long term conditions.

These commitments signal that the Conservatives will use markets rather than targets to improve performance. In so doing, they will take further and faster the policies initiated under Tony Blair that have resulted in the introduction of NHS Foundation Trusts, the use of independent sector providers to treat NHS patients, and the system of payment by results under which money follows patients to the hospitals of their choice. And as Andrew Lansley, the shadow secretary of state for health, set out in a recent speech, the Conservatives will also make renewed efforts to collect and publish information about the performance of providers to support patient choice.<sup>2</sup>

The many similarities between the health policies of the opposition and those of the government should come as no surprise given that the Labour government has pursued market based reforms for almost a decade. The main challenge for the Conservatives will be to show that their policies are ready for implementation if they are elected into office.

This challenge takes on added force in the light of independent assessments indicating that Labour's policies on choice and competition have had little impact to date.<sup>3</sup> The improvements in NHS care made in the last decade, such as major reductions in the time patients wait for treatment, have been driven largely by "targets and terror"—the very approach the Conservatives reject—together with increased spending.<sup>4</sup>

The reason that choice and competition have not made much impact derives from the difficulties that exist in applying market principles to health care. The onus is therefore on the Conservatives to explain how their version of competition will be more successful than the current government's approach. Three issues in particular need to be clarified.

The first issue is the opposition's proposal that general practitioners should hold budgets with which to commission services for their patients. This proposal is the Conservatives' alternative to practice based commissioning, a policy that has failed to achieve the enthusiastic engagement of general practitioners on any significant scale.<sup>5</sup> On the basis of the detail provided so far—essentially that budgets will be real and practices will be allowed to invest savings in providing further NHS services—there is no reason to believe that general practitioner budget holding will prove to be any more effective than practice based commissioning. The Conservatives urgently need to explain how they will motivate family doctors to commission services, an

objective that Labour has yet to achieve.

The second issue concerns the role of primary care trusts as commissioners of services alongside general practitioner budget holders. The recent assessment of the performance of primary care trusts on the world class commissioning competences developed by the government showed that all trusts have much work to do in order to negotiate on equal terms with health care providers.<sup>6</sup> With research evidence demonstrating that no system does healthcare commissioning consistently well,<sup>7</sup> the Conservatives have a tough task on their hands to show that they can do better than Labour.

The third issue relates to healthcare providers who fail to compete successfully and how they will be handled. Competition in health care cannot be effective unless there is a real possibility of provider failure and, ultimately, exit from the market. The reluctance to allow providers to fail and, consequently, to accept a reduction in the public's access to services has characterised past attempts by both the Conservatives and Labour to introduce market principles into the NHS. When politics and markets collide, politics usually win out. The Conservatives need to demonstrate that competition will be allowed to run its course, even at the risk of political unpopularity.

These points suggest that a degree of healthy scepticism is needed about the extent to which policies developed in opposition will be carried into practice. The political class in Britain today has little experience outside politics, meaning that its members are often ill equipped to take up the reins of power and lead the reform of major public services like the NHS. This point is well illustrated by the frequent changes of direction in health policy made by the current Labour government.<sup>8</sup> There is no reason to believe that politicians of other parties will fare any better.

Having set out a broad outline of their health policy, the Conservatives now need to add the missing detail if they are to justify their claim to be a credible government in waiting. At a time when trust in politicians is at low ebb, the public has a right to expect full disclosure of policy intentions and detailed plans for implementation as the election draws closer.

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## Science in court

### Does English libel law threaten scientific debate in health care?

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**Simon Singh (above) has been sued by the British Chiropractic Association for libel. He is appealing against a preliminary judgment**

Professor Sir Muir Gray, in his book *Evidence-based Health-care*<sup>1</sup> tells the old joke about the epidemiologist up in court on a serious charge. “How do you plead? Guilty or not guilty?” asks the judge. “I don’t know: I haven’t heard the evidence yet.”

Recent events bring comedy, evidence, and law together as Ricky Gervais, Richard Dawkins, and Sir Iain Chalmers join together in a campaign that weds scientific rigour to free expression. On Wednesday of this week, leading academics, publishers, journalists, performers, clinicians, and scientists issued a public statement<sup>2</sup> backing science writer Simon Singh in his application to appeal against a libel judgment in the High Court. They fear that this judgment—if upheld—would have major implications for the ability of scientists, researchers, and other commentators freely to engage in robust criticism of scientific, and indeed purportedly scientific, work.

Singh, well-known for his books on Fermat’s last theorem and the big bang, wrote an article on 19 April 2008 in the *Guardian* newspaper criticising claims made by chiropractors about the efficacy of spinal manipulation in dealing with childhood conditions such as asthma, colic, and ear infections, among others. He suggested there was “not a jot” of evidence to support such interventions for these ailments, and complained that the British Chiropractic Association “happily promotes bogus treatments”. The British Chiropractic Association has sued for libel.

On 7 May 2009, Mr Justice Eady issued a ruling<sup>3</sup> on two preliminary matters. First, on the question of what meaning to give to the words in Singh’s article, he upheld the assertion of the British Chiropractic Association that the words meant that it knowingly promoted a treatment that they knew to be a sham. An alternative meaning—more helpful to the defence—might be that the association was promoting something that, although ineffective, it sincerely believed to be effective. This would not carry the same implication of dishonesty. Second, and as a consequence of the first, the judge decided that the words represented a statement of verifiable fact, and that Singh therefore could not benefit from a “fair comment” defence. Singh has stated that, under the judge’s interpretation, it would be difficult for him to win the case.

There have been several cases where individuals and commercial interests, including pharmaceutical companies, have sought to prevent the publication in scientific journals of opinions that they believe to be defamatory. By their very nature, examples of such censorship are not readily apparent to readers.

Scientific publishers are subject to the same libel laws as everyone else. They struggle to find the right balance between a “safe” approach that amends or withdraws a proposed publication under threat of legal action and a more “courageous” one that seeks to protect the right of scientists and clinicians to engage in robust criticism of research work, pharmaceutical products, or medical devices.

What Singh’s case reinforces is the increasing recognition that the libel laws in England and Wales give major advantages to the plaintiff, leading to “libel tourism,” with libel cases being brought by foreign business people against authors, themselves often also based abroad, in the courts of London. The jurisdictional reach is then justified on the basis of a handful of copies of the author’s work having been sold in England, or on its being available on the internet. The advantages to the plaintiff under English law include a reversal of the usual burden of proof and a more limited range of defences being available than elsewhere, especially in respect of public interest.

The House of Commons, despite its current travails, has at least found time to attend to this matter, both in debate<sup>4</sup> and in current enquiry by the Culture Media and Sport Select Committee.<sup>5</sup>

However, it is not clear that the government has any intention of changing the law—as can be seen from secretary of state for justice Jack Straw’s evidence to the committee’s inquiry.<sup>6</sup> All the government is carrying out at present is a review of the costs of defending defamation cases,<sup>7</sup> but it has also suggested a review of libel law and the internet.<sup>6</sup> The UK parliament is notoriously slow to protect free speech, given, for example, that it took centuries before the law of blasphemous libel was abolished last year.<sup>8</sup> Indeed only this week I, along with free speech advocates, held a meeting with the same justice secretary to press him to abolish the ancient laws of seditious libel and criminal defamation—neither of which allow truthfulness of the publication to be a full defence to the charge.

It is remarkable that the plaintiffs in this case are representatives of healthcare practitioners, who could, one would expect, make their case in peer reviewed scientific literature as well as through the usual letters columns of whatever newspaper they believe has treated them unfairly. Resorting to litigation against a writer, rather than the writer’s publisher, gives the impression that the British Chiropractic Association is seeking to “chill” criticism of the treatments that it promotes, or of the practitioners who make efficacy claims about such treatments.

It is hard to imagine the British Medical Association, even at its most reactionary, bringing libel proceedings against a commentator for deprecating the good name of doctors in its columns. If it did, neither the British Medical Association nor the *Daily Mail* would ever be out of the courts.

The fundamental point is that it is essential in the scientific sphere, and in particular in the world of medicine, for claims of efficacy to be subject to the most stringent examination and criticism. In the field of health care, the consumer is particularly vulnerable to false promises of cure or symptomatic relief, and all practitioners—especially those in the private sector—need to be able to justify their claims in a transparent and scientific way. If that debate is chilled, then the medical profession, patients’ interests, and scientific discourse are severely undermined.