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Maintenance treatment for adults with chronic asthma

Treatment rankings from network meta-analysis can be unreliable when dominated by indirect evidence

Christopher Cates senior clinical research fellow,
Population Health Research Institute, St George's
University of London, UK
ccates@sgul.ac.uk

Which treatment for asthma is most likely to reduce the risk of exacerbations in adults? In a linked paper, Loymans and colleagues seek to address this question using network meta-analysis.¹ The authors compared 16 different treatment approaches, using evidence from randomised trials of at least 24 weeks' duration. The primary outcome was severe exacerbations (leading to admission to hospital, a visit to the emergency department, or a course of oral steroids).

The following is an example of how the network approach works. Loymans and colleagues' objective was to determine whether combination treatment with a long acting β agonist and a low dose inhaled corticosteroid ranked better or worse than combination treatment with a long acting β agonist and a high dose of inhaled corticosteroid. In figure 2 of their paper showing the network diagram, the authors labelled these approaches COMBI FIX and COMBI FIX H. An inhaler containing a long acting β agonist and a low dose corticosteroid as maintenance and reliever therapy was labelled separately as COMBI MAR.

Surprisingly, results from the network indicated that lower dose COMBI FIX was more likely to be best at preventing exacerbations than the higher dose combination. However, only one trial randomised participants to the two combinations. So the network of trials contained just one direct (head to head) comparison between these two treatments. Not much information to go on. Five indirect comparisons were, however, achievable because COMBI FIX and COMBI FIX H were both compared, five times each, with a common comparator—that of high dose inhaled steroids.

The aim of a network meta-analysis such as this is to combine the indirect comparisons with the single direct comparison to rank which treatment is likely to work best. The extra indirect information comes at a price though!

Indirect comparisons lose the protection of randomisation, so it is important that consist-



Don't hold your breath

ency is present between the results of the direct and indirect evidence. It is also important to compare the characteristics of the participants who were enrolled into all the randomised trials in the network, to see whether important differences existed between them in the different trials that might confound the indirect comparisons.²

The authors checked for consistency and found no significant differences between most of the direct and indirect comparisons. The test for consistency is, however, weak when direct evidence is sparse, so important differences between direct and indirect evidence cannot be ruled out. A potentially bigger problem is the wide range in asthma severity across the different trials in the network. This is all transparently laid out by the authors in supplementary table S1 (on bmj.com) and is mentioned by them as a limitation.

This variation in asthma severity can confound comparisons dominated by indirect evidence. From table S1, for example, it appears that the participants in trials of COMBI FIX H had more severe asthma

and more frequent exacerbations than participants in trials of COMBI FIX. This could explain the rather surprising conclusion from the overall network that the low dose combination has a higher ranking than the higher dose one for preventing severe exacerbations of asthma. Participants given the higher dose treatment were sicker and the rankings may be unreliable because of confounding by asthma severity.

Controlling inflammation in the airways of people with asthma remains an important goal of treatment, and the most effective way to achieve this is with an inhaled corticosteroid. Loymans and colleagues' network meta-analysis does not separate trials on patients at different treatment steps for their asthma, and therefore the rankings are difficult to apply to treatment choices in clinical practice. Higher doses may be required to control inflammation in the airways of patients with severe asthma³ but would not be used for mild asthma (in trials or in practice). Although the addition of a long acting β agonist can be helpful in improving day to day asthma symptoms, the agonist on its own is definitely not a substitute for good inflammatory control with an inhaled corticosteroid. Long acting β agonists have been shown to be dangerous when used alone.⁴

Better together

Direct evidence from systematic reviews⁵⁻⁸ supports the superiority of combined long acting β agonists and inhaled corticosteroids over other treatment options for adults with asthma who remain symptomatic despite regular use of inhaled corticosteroids. Data from Cochrane reviews suggest that for every 100 adults treated for 24 weeks, a combination of a long acting β agonist and inhaled corticosteroid helps prevent between one and four exacerbations when compared head to head with options such as current best practice, a higher dose corticosteroid alone, or a leukotriene receptor antagonist combined with an inhaled corticosteroid.

Above all, patients with chronic asthma need treatment that is carefully tailored to their clinical needs. Health professionals still need to work with individual adults to titrate their dose of inhaled corticosteroid up or down according to the severity of symptoms. It would be unwise to rely too heavily on rankings from a network meta-analysis dominated by indirect evidence when making decisions about treatment.

Competing interests: I am coordinating editor of the Cochrane Airways Group, which is funded by the National Institute for Health Research and has carried out many Cochrane systematic reviews on the included treatments for asthma.

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References are in the version on bmj.com.

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- ▶ Editorial: Doctors need to take the lead on poverty's effects on health (*BMJ* 2013;347:f7540)
- ▶ Editorial: Adolescents and young adults who are not in employment, education, or training (*BMJ* 2013;347:f5270)
- ▶ Editorial: Austerity policies in Europe—bad for health (*BMJ* 2013;346:f3716)
- ▶ News: Half a million people using food banks in UK as food poverty grows (*BMJ* 2013;346:f3578)

Poverty in the United Kingdom: from bad to worse

By design and drift the UK has become more unequal, less inclusive, and less caring

Graham Watt Norie Miller professor of general practice, University of Glasgow, Glasgow G12 9LX, UK
 graham.watt@glasgow.ac.uk

In 1973 the National Children's Bureau published *Born to Fail*, which described how large numbers of children in the United Kingdom were being born and brought up to fail—first in the educational system and then in employment and the wider economy.¹ In 1980 the Black report on inequalities in health recommended that “above all, the abolition of child poverty should be adopted as a national goal for the 1980s.”²

In 1979, 10% of children were being brought up in households with less than half of average income—the definition of child poverty at that time. A decade later, it was 30%. A Unicef report on child neglect in rich countries laid the blame firmly at the door of the laissez faire market based policies introduced by most Anglo-American countries as they sought to extricate themselves from recession.³ An editorial in *The BMJ* put it succinctly: “Markets fail children.”⁴

UK governments have been struggling ever since to reduce child poverty. Using comparable statistics, the National Children's Bureau estimates that the number of children in poverty increased from two million in 1969 to 3.5 million in 2013.⁵ The trend is simply incompatible with current understanding of the importance of investment in the early years to improve health and narrow health inequalities.⁶

Since 2008, UK governments have had to deal with the national implications of an international financial crisis, and history is repeating itself, with vulnerable groups hit hardest by austerity measures. Although spending on health and pensions has increased since 2010, spending on welfare has been pegged. As a result of cuts in housing benefit and changes to council tax support, around 1.75 million of the poorest families have seen an absolute cut in their income.⁷ The UK government admits that a further 200 000 children will move into poverty because of its decision to increase certain family benefits by 1% each year for the next three years, rather than in line with the cost of living.⁸

Since 2007, UK food prices have risen by 12%.⁹ Not only for those on benefits, but also for those on low incomes, food security has disappeared. Food banks are proliferating. The Trussell Trust



PHILIP WOLMUTH/PANOS

Please sir, I want some more

reports that nearly one million people in the UK were helped in 2012-13 by its programme alone.¹⁰ The nutritional consequences of current austerity measures, and their effects on public health, are unknown. Earlier this month, 170 experts in public health proposed a working group to monitor UK nutrition and hunger status.¹¹ Such work is necessary, but insufficient, because it deals with the consequences and not the causes of a public scandal.

Rudolf Virchow defined social medicine as diagnosing and treating the ills of society. “Medicine is a social science and politics nothing but medicine on a large scale.”¹² Although a pathologist, he did not confine himself to the medical model. For the prevention of typhus, he prescribed “education, together with its daughters, freedom and welfare.”¹² Who is practising social medicine today?

When Prime Minister Cameron talks of “our country” it is a very different country from 30 years ago. Many of the 30% of UK children who were born and raised in relative poverty in the 1990s are now the parents of children being brought up under the austerity policies of the 2010s. As street begging and selling of the *Big Issue* were normalised in the 1990s, food banks are being normalised now. None of these phenomena is inevitable, necessary, or desirable in the sixth richest country in the world.

When Margaret Thatcher reinterpreted the parable of the Good Samaritan for the benefit of the General Assembly of the Church of Scotland, she emphasised the importance of the Good Samaritan having enough personal wealth to make charitable donations possible.¹³ The only increases in personal wealth since 2008, however, have been in people who were already wealthy. The anti-

patented US-style philanthropy has not occurred. Giving in the UK stands at around 1% of gross domestic product, roughly half the US level.¹⁴

Mrs Thatcher argued that there is no such thing as society, only individual men and women, and their families, looking after themselves first of all, and then looking after others. The emergence of high profile fundraising events, such as Children in Need, Sport Relief, and Comic Relief, encourages giving by individuals, but it is no substitute for fully subscribed and properly funded public programmes.

Return of the undeserving poor

Support for welfare spending is at a historical low and “appears to be moving in line with political policy and rhetoric, rather than economic circumstances.”¹⁵ A collection of “comfortable myths about poverty” surrounds and protects this indifference: “they” are lazy and don't want to work; “they” are addicted to drink and drugs; “they” are not really poor; “they” are on the fiddle; and “they” have an easy life.¹⁶ By design and by drift the UK has become more unequal, less inclusive, and less caring.

Mrs Thatcher was a divisive politician, and the consequences of her policies continue to unfold. In Scotland and Wales, the democratic deficit, whereby electorates were subjected to policies they had not voted for, made devolution necessary. In Scotland, it has made independence possible. The Scottish referendum campaign has little to do with kilts, bagpipes and ancient history, and a great deal to do with the nature of society, now and in the future, and whether change is more likely inside or outside the UK.

Whatever the outcomes of the Scottish referendum in September 2014 and the UK general election in May 2015, there are challenges and choices ahead. The current situation has relatively recent political origins. What has been done can be undone. Politicians who would like to tackle the increase in poverty in the UK will have to win public support, match their words with deeds, and, in terms of scale, measure up to the task.

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- ▶ Views & reviews: Medicine still needs feminism (*BMJ* 2014;348:g2623)
- ▶ Editorial: Tackling female genital mutilation in the UK (*BMJ* 2013;347:f7150)
- ▶ Editorial: Female genital mutilation/cutting (*BMJ* 2013;347:f5603)
- ▶ Feature: UK's shameful record on female genital mutilation (*BMJ* 2012;345:e8121) <http://www.bmj.com/content/345/bmj.e8121>
- ▶ Clinical Review: Female genital mutilation: the role of health professionals in prevention, assessment, and management (*BMJ* 2012;344:e1361)

Collecting data on female genital mutilation

UK government's actions still characterised by a failure to think things through

Katrina Erskine consultant obstetrician and gynaecologist, Homerton Hospital, London E9 6SR, UK
katrina.erskine@nhs.net

Female genital mutilation is defined by the World Health Organization as “all procedures that involve partial or total removal of the external female genitalia or other injury to the female genitalia for non-medical reasons.” A horrendous form of child abuse, in its most extreme form (type 3) it involves removing the clitoris and labia and narrowing the vaginal introitus. More than 100 million women worldwide are affected.

The procedure has many complications including dyspareunia, sepsis, and death—procedure related mortality was estimated at 2.3% in one country.¹ It is done for many reasons—there is no single religious basis. In some cultures a woman who has not undergone the procedure may be thought unmarriageable. In women with type 3 mutilation, the introitus may be too narrow for childbirth, and the tissues that have sealed together need to be separated; this is termed deinfibulation. Female genital mutilation was made an offence in 1985 in the United Kingdom, with a penalty of up to 14 years in prison.

A government declaration to end the practice in the UK and around the world was announced in February this year.² To demonstrate this commitment several measures were announced; these included £100 000 (€122 380; \$169 100) to fund community engagement within the UK, and £35m to support work in Africa—the biggest ever international contribution. Simultaneously, it was announced that all acute NHS hospitals will be required to record female genital mutilation and report the data centrally. No funding accompanied this requirement.

The Department of Health followed this by issuing an e-bulletin in March regarding mandatory collection of data on the practice.³ Data should include whether a woman has undergone female genital mutilation or a related procedure and whether there is a family history of the practice.⁴ A personal communication to me from Vanessa Lodge of NHS England (2014), after I had requested clarification, stated that women attending maternity, family planning, gynaecology, and urology clinics (among others) should be asked routinely about the practice.

UK intercollegiate recommendations on tackling female genital mutilation, published in 2013, pointed to the importance of data collection.⁵ However, how these requirements for data collection will contribute is unclear. Staff will be asked to record the grade of mutilation, which cannot be done without a genital assessment. It seems intrusive to insist on genital examination for all women from communities that practise cutting, regardless of their symptoms, and healthcare staff are unlikely to feel confident in making such an assessment.⁶

Many more questions than answers

Although initial data returns will be anonymous, there is uncertainty about what should be done if female genital mutilation is identified. The document states that all women presenting with genital mutilation within the NHS should be referred to the police “with the woman's consent.” Without a clear strategy, there is little point in asking every woman (or possibly men if they have a positive “family history”). What do we do with the information? Are women going to volunteer the evidence if they fear they will be automatically referred to the police? And what would the police do with the information?

The Royal College of Obstetricians and Gynaecologists' guideline on female genital mutilation recommends that every pregnant woman should be asked if she has been cut.⁷ At my hospital, which serves an ethnically diverse population, such data have been recorded since 2008. Last year, 76 of 6780 women who

booked for delivery were identified as having been cut—about half of them from Somalia. We have no midwife specialising in female genital mutilation; midwives are taught about the practice in their annual mandatory training week, and all consultant obstetricians have experience with deinfibulation. Any woman identified as having been cut, who has not yet had a vaginal birth, is offered an appointment with a consultant to discuss antenatal deinfibulation. Women who have been cut are not routinely referred to a social worker, but the information is shared with health visitors.

Although there have been no successful prosecutions for female genital mutilation in the UK, a doctor in London was recently accused. It was alleged that after delivering a patient he had repaired the genital mutilation that had previously been performed on her.⁸ This highlights the confusion about basic clinical management⁹; furthermore, conflating female genital mutilation with whatever a professional may do at the time of delivery potentially diverts us from the real problems.

Antenatally, women who have been cut should be assessed and, if necessary, offered deinfibulation before the birth. And women (and men) need to be supported to ensure that they realise that the practice is a crime, and that their daughters should not suffer; we need guidance on which agencies should be informed and what strategies should be recommended. The introduction of mandatory reporting of information, without funding and without appropriate training for staff, will probably result in inaccurate data collection. At best, this will be a waste of clinical time in an already hard pressed NHS service; at worst, it is a distraction from the crucial campaign to identify and protect children at risk. Finally, we need to support organisations that are actively campaigning to support women in countries where the practice is endemic and ensure that no precious resources are wasted on strategies of no benefit.

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References are in the version on [bmj.com](http://www.bmj.com).

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Unkindest cut of all

SIMON MANIA/AP/GETTY IMAGES

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- ▶ Research news: Bad experiences in early childhood can lead to “health harming life course,” study shows (*BMJ* 2014;348:g3097)
- ▶ Views & reviews: Bring in universal mental health checks in schools (*BMJ* 2013;347:f5478)
- ▶ Research: Classroom based cognitive behavioural therapy in reducing symptoms of depression in high risk adolescents: (*BMJ* 2012;345:e6058)

Why schools should promote students' health and wellbeing

Education policy shouldn't focus solely on academic attainment

Chris Bonell professor of sociology and social policy, Institute of Education, University of London, London WC1H 0AL, UK c.bonell@ioe.ac.uk

Neil Humphrey research co-ordinator, Manchester Institute of Education, University of Manchester, Manchester, UK

Adam Fletcher senior lecturer in social science and health, DECIPHER, Cardiff University School of Social Sciences, Cardiff, UK

Laurence Moore director, Medical Research Council/Chief Scientist Office Social and Public Health Sciences Unit, University of Glasgow, Glasgow, UK

Rob Anderson associate professor of health economics and evaluation, University of Exeter Medical School, Exeter, UK

Rona Campbell professor of public health research, School for Social and Community Medicine, University of Bristol, Bristol, UK

Education policy in England increasingly encourages schools to maximise students' academic attainment and ignore their broader wellbeing, personal development, and health.¹ Schools are now monitored on attainment in a narrow range of academic subjects. Participation in the National Healthy Schools Programme no longer benefits from governmental targets or funding.

Ofsted reports no longer focus specifically on how well schools promote students' health or personal development.² Personal, social, and health education (PSHE) remains a non-statutory subject, and schools spend less and less time teaching it because of pressure to focus on academic subjects.³ The government recently proposed making the early years foundation stage profile—which offers a holistic view of the child including his or her personal, social, and emotional development—non-statutory. At the same time, it wants to introduce mandatory academic tests in the first year of primary school.⁴

Two ideas apparently underpin these developments. Firstly, that promoting attainment, on the one hand, and health and personal development, on the other, is a “zero-sum game”—with more time spent on health and wellbeing resulting in less time for academic learning and therefore lower attainment. Secondly, that improving attainment is singularly crucial to increasing economic competitiveness.⁵ Both these ideas are deeply flawed.

Sound minds, healthy bodies

Counter to the first idea, research suggests that education and health are synergistic. Those who are well educated have better health and wellbe-



Hint: it's not a zero sum game

ing.⁶ Students in better health have higher academic attainment.⁷ Research on “developmental cascades” suggests that students' progress in accomplishing distinct, seemingly disparate, educational and developmental milestones influence one another over time.⁸ Multi-level studies suggest that schools where students do better academically than might be expected from their social profile also do better in terms of health.⁹

Students' broader development and wellbeing receive more attention in several countries with better academic attainment than in England. Schools in Finland, Sweden, Australia, and Singapore vary in whether provision occurs in specific lessons or is integrated into subject learning, but they all place greater emphasis than schools in England do on students' overall development, and social and emotional learning.¹⁰ This suggests that academic and broader development is not a zero-sum game.

The clinching evidence comes from experimental studies, which suggest that programmes to promote students' broader wellbeing and development also benefit their academic learning. A systematic review of coordinated school health programmes, which aim to promote health through both explicit teaching in the curriculum and broader work to produce a healthier school environment, suggests that these programmes have positive effects on attainment.¹¹ Alongside evidence that they save money in the long run,¹² meta-analyses of experimental studies suggest that social and emotional skills and mental health programmes both boost attainment.^{13 14}

And counter to the second idea, that promoting cognitive development and academic attainment is all that matters economically, there is evidence

that an effective labour force does not merely require cognitive skills gained from academic learning. Non-cognitive skills, such as resilience and team working skills, are also needed,¹⁵ and productivity increases as workers' health status improves.¹⁶

Some schools not only neglect students' health but may actively harm it. A systematic review of qualitative research suggests that in school systems that focus on narrow academic metrics, such as those in England and the United States, some schools respond by focusing on the more able students, and not engaging other students or recognising their efforts. This is associated with many students, especially those from disadvantaged backgrounds, disengaging from school and instead investing in “anti-school” peer groups and risk behaviours, such as smoking, and taking drugs. Furthermore, research suggests that “teaching to the test,” which commonly occurs in school systems with a narrow focus on attainment, can harm students' mental health.¹⁷

This all suggests that schools need to teach students not only academic knowledge and cognitive skills, but also the knowledge and skills they will need to promote their own mental and physical health, and successfully navigate the world of work. But how? There is now a strong evidence base not only for curriculum interventions suitable for PSHE, but also for health promoting interventions in school that combine health curriculums with whole school activities to make schools healthy settings.¹⁸ Health education can be integrated into academic subjects and not taught only in PSHE lessons. Emerging findings from an ongoing synthesis of evidence by one of us (RA) suggest that this can make health education more feasible in busy schools.¹⁹

Education policy could support health interventions by making PSHE a statutory subject, by mandating school inspectors to report specifically on health and personal development, and requiring schools to deploy evidence based PSHE and health promoting interventions to achieve “outstanding” status overall.

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As editor, I have a vested interest in not retracting the articles unless the case for doing so is completely clear. So I have passed this decision to an independent panel

Adverse effects of statins

The BMJ and authors withdraw statements that adverse events occur in 18-20% of patients

Fiona Godlee editor in chief, *The BMJ*, London WC1H 9JR, UK fgodlee@bmj.com

In October last year we published an article by John Abramson and colleagues that questioned the evidence behind new proposals to extend the routine use of statins to people at low risk of cardiovascular disease.¹ Abramson and colleagues set out to re-analyse data from the Cholesterol Treatment Trialists' (CTT) Collaboration. Their contention was that the benefits of statins in low risk people were less than has been claimed and the risks greater.

In their conclusion and in a summary box they said that side effects of statins occur in 18-20% of people. This figure was repeated in another article published in the same week in *The BMJ* by Aseem Malhotra.² *The BMJ* and the authors of both these articles have now been made aware that this figure is incorrect, and corrections have been published withdrawing these statements. The corrections explain that although the 18-20% figure was based on statements in the referenced observational study by Zhang and colleagues—which said that “the rate of reported statin-related events to statins was nearly 18%,”³ *The BMJ* articles did not reflect necessary caveats and did not take sufficient account of the uncontrolled nature of Zhang and colleagues' data.

This editorial aims to alert readers, the media, and the public to the withdrawal of these statements so that patients who could benefit from statins are not wrongly deterred from starting or continuing treatment because of exaggerated concerns over side effects.

But what is the true incidence?

The true incidence of adverse events from use of statins in people at low risk of cardiovascular disease continues to be disputed. Data compiled by the CTT Collaboration show that rates of adverse effects are similar in the active and the placebo arms in trials of statins.

However, generalising from clinical trials to wider populations may be problematic because of patient selection; for example, exclusion of older patients, patients with co-morbid conditions or potential drug-drug interactions, and women. In addition, when compared with the full clinical study reports, published accounts of clinical trials in medical journals report only a minority of adverse events.⁴ Access to the full

data from trials of statins would help determine the rates of serious adverse events in statin and control groups; although in their correction Abramson and colleagues say that this probably won't help to determine the frequency of statin related events that are less than serious.

Readers may like to know how the erroneous statements came to be published, why it has taken us seven months since publication to correct them, and what other action we are considering.

Abramson and colleagues' article was submitted and peer reviewed. The peer reviewers' comments are posted as a web extra, with the reviewers' permission. The initial submission reported that Zhang and colleagues found that “18% of statin treated patients had discontinued therapy because of statin related events.” This was a misreading of Zhang and colleagues' data that was not picked up by the peer reviewers or editors. During the revision process the authors placed more certainty on the 18% figure in their conclusions, and this was rounded up to “nearly 20%” in a summary box. The revised article with these changes was not subject to further external review. This is part of our process that we are now revisiting.

Writing, peer reviewing, and editing are human processes subject to error, which is why we must be, and are, ready to correct things when they are found to be wrong. We were alerted to the error by Rory Collins, professor of medicine and epidemiology at Oxford University and head of the CTT Collaboration whose data were reanalysed by Abramson and colleagues. Collins visited me at *The BMJ* in early December, then took the matter up in the UK media towards the end of March,⁵ and finally put his concerns in a letter to me, marked not for publication, on 31 March. He declined several requests to send a rapid response or letter for publication. Others did send rapid responses questioning the 18-20% figure,^{6,7} and both sets of authors responded.^{8,9} Meanwhile *The BMJ*'s editors sought to unpick the evidence as presented in the paper by Zhang and colleagues and to agree the wording of a correction with the authors, who have cooperated throughout this process. The text of the correction, which includes a further interpretation of Zhang and colleagues' data, has been peer reviewed.

Is a correction enough in this case? Collins thinks not. He has requested retraction of both

articles. Guidelines of the international Committee on Publication Ethics state that journals should consider retracting a publication if there is clear evidence that the findings are unreliable, either as a result of misconduct or honest error.¹⁰ The question in the case of these two articles is whether the error is sufficient for retraction, given that the incorrect statements were in each case secondary to the article's primary focus. In the case of Abramson and colleagues, this was that the CTT data failed to show that statins reduced the overall risk of mortality in people with a <20% 10 year risk of cardiovascular disease; for Malhotra it was that saturated fats are not the main dietary cause of heart disease.

However, as the editor responsible for publishing the articles, I have a vested interest in not retracting them unless the case for doing so is completely clear. So I have decided that the right thing to do is to pass this decision to an independent panel. Iona Heath, former chairwoman of the Royal College of General Practitioners and of *The BMJ*'s ethics committee, has agreed to chair the panel, whose members will include people with no “dog in this fight,” but with expertise in clinical trial and observational study methodology, and in designing and implementing editorial policies on retraction. Full details of the panel and processes will be published shortly. I have asked that all submissions to the panel be placed in the public domain on bmj.com, and I have committed to implementing the panel's recommendations in full.

Meanwhile, *The BMJ* will continue to debate the important questions raised in both these articles: whether the use of statins should be extended to a vastly wider population of people at low risk of cardiovascular disease; and the role of saturated fat in heart disease.

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