

LETTERS

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STATINS AND THE BMJ

The debate on statins must stay in the public domain

As a medical journalist, I’m concerned about the recommendation of the panel considering the retraction of two *BMJ* papers that the ongoing statin debate “be conducted primarily in medical journals rather than in the lay media.”¹

How could this be enforced? Could I be fined or imprisoned for reporting dissenting data? And what about *The BMJ*’s support for transparency? Debate behind closed doors ensures that drug consumers hear only the official line, which for decades has been that statins are safe, save lives, and should be widely prescribed.

A few brave dissenting medical voices have spoken out, but opposing the might of the National Institute for Health and Care Excellence (NICE), the Medicines and Healthcare Products Regulatory Agency, and a range of prestigious heart charities is not professionally rewarding. Rory Collins’s response to criticism—to accuse his critics in the press of killing people—is a vivid illustration of this.²

The panel might prefer to avoid such unseemly public spats, but in whose interest is it for such eminence based medicine to be wielded in private? “Don’t fund that chap Abramson: very unsound, no grasp of statistics at all.” Having it in the press allows the sunshine in.

Without the open letter to NICE setting out expert objections to the proposed expansion of statin prescribing, few of the healthy people now eligible for treatment would be able to have any informed discussion on the risks and benefits.

The panel’s findings highlighted two important issues that bring into question the reliability of the Cholesterol Treatment Trialists’ conclusions—that no independent researchers have been able to view the raw data and that the organisation relies solely on drug company trials for estimates of the frequency of side effects.

These two issues need more public discussion, not less, especially with a new generation of more powerful and expensive cholesterol lowering drugs in the pipeline.

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1 Godlee F. Statins and The BMJ. *BMJ* 2014;349:g5038. (7 August.)

2 Boseley S. Doctors’ fears over statins may cost lives, says top medical researcher. *Guardian* 2014. (21 March.)

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NICE ON STATINS

NICE must do better at summarising evidence on statins

Rabar and colleagues’ summary of the National Institute for Health and Care Excellence (NICE) guideline on statins omits the key information clinicians need: the number needed to treat (NNT) with statins in different risk groups, at different levels of treatment intensity.¹ This is not *The BMJ*’s shortcoming. NICE advises doctors to discuss this information with their patients, but it is missing from the NICE guideline itself.

The most attentive reader might find—in row 10 of 32, in table 43, on page 143—that for every 1000 people without cardiovascular disease taking a statin, overall there would be seven fewer non-fatal myocardial infarctions. To establish the time period over which this figure applies, or whether it relates to the important new 10% 10 year risk population, requires downloading and reading Appendix C, a separate document. Table 60 summarises data from a 2013 Cochrane review, which (arguably) relates to a 15% 10 year risk population, and reports an NNT of 88 for “total CHD events” over five years. Attentive readers could deduce that these events must be non-fatal, or perhaps mixed fatal and non-fatal, because the NNT for all cause mortality in the same table is higher.

NICE advises doctors to give clear information on the benefits of statins. This implies that, after scrutinising a 302 page NICE report to find the numbers above, GPs should then do a literature search, read and appraise the trial data, synthesise it (at different risk strata and treatment intensities), then use the appropriate formulas to create NNT for easy interpretation by patients. Clinicians might expect NICE—a well resourced national body with extensive technical expertise—to have done this for them.

Clear summaries of information on benefit and risk are the bedrock of informed patient choice. They should be our highest priority,² not a poor second cousin. A simple table in NICE’s own summaries—giving NNTs we know, and highlighting those we don’t—might be a good place to start.

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Competing interests: I receive income from writing and speaking to lay and professional audiences on problems in science, including poor communication of risk and badly designed trials.

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2 Goldacre B, Smeeth L. Mass treatment with statins. *BMJ* 2014;349:g4745. (23 July.)

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NON-ALCOHOLIC FATTY LIVER DISEASE

Unselective liver screening may not be cost effective

Sattar and colleagues review the epidemiology, manifestations, and management of non-alcoholic fatty liver disease.¹ They recommend considering screening for other liver conditions such as chronic viral hepatitis, autoimmune liver disease, haemochromatosis, and drug induced liver injury. The value and cost implications of such screening in people with abnormal results in liver function tests are unclear.

A prospective study in 11 primary care practices of 1290 people with abnormal liver function results established a diagnosis in less than 5% of cases.² Only 17 (1.3%) people were diagnosed with a condition that needed specific treatment, with most (13) having viral hepatitis.

In a study of 1118 patients in primary care, non-alcoholic fatty liver disease and alcohol related liver disease were the most common causes of abnormal liver function tests (26.4% and 25.3%, respectively).³ Autoimmune and inherited metabolic conditions accounted for only 1% each.

We reviewed clinical notes, imaging results, and test results for 338 consecutive patients with abnormal liver function results who presented to a tertiary care hospital over one year. We found that alcoholic liver disease was the most common underlying diagnosis (22%). A thorough history and ultrasonography had the highest diagnostic yield, followed by testing for chronic viral hepatitis, which reached a diagnosis in 14% of patients. The cost per diagnosis varied



Diagnostic yield of investigations for abnormal liver function test results

Investigation	Diagnostic yield (%)	Cost per diagnosis (£)
History	40	N/A
Ultrasonography	30	158
Hepatitis A screening	3	857
Hepatitis B screening	4	1044
Hepatitis C screening	7	265
Autoimmune screen	1	2796
Metabolic tests	0	N/A

£1=€1.26=\$1.66. N/A=not applicable.

substantially between tests (table). The yield of screening for metabolic and autoimmune causes of liver disease was minimal.

Unselective diagnostic testing places a large financial burden on the NHS,⁶ often for limited diagnostic yield. Further prospective studies comparing different diagnostic strategies for patients with abnormal liver function tests are urgently needed to inform clinical practice.

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HEALTH ECONOMIC EVALUATION

Consolidated research agenda for health economics in Europe

The Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Task Force has called on researchers, editors, and reviewers to adhere to reporting standards for health economic evaluations, recognising the importance of clearly communicated economic evidence in health policy decision making.¹ Although such steps are important, it is also pertinent to consider in which technical areas the value of investing in new evidence is greatest, and to what extent the economic evidence resulting from academic endeavour is useful in practice.

The implementation of economic evidence has been most systematically attempted and institutionalised through health technology assessment, largely in the area of drugs, which account for a limited fraction (generally 10-20%) of total health expenditures in Europe.² Beyond drugs, a systematic approach is uncommon and

the uptake of economic evidence across levels of health systems may be hindered by budgetary silos or difficulties in interpreting and applying economic evidence in practice.³ Therefore, it is crucial to examine on one hand what economic evidence is available for decision making, and on the other, how this knowledge and its translation can be improved to increase healthcare efficiency as demographic and epidemiologic pressures on health systems grow.

The World Health Organization in partnership with the European Commission, Organisation for Economic Cooperation and Development, and a range of academic partners is undertaking a research project to outline a Research Agenda for Health Economic Evaluation (<http://www.euro.who.int/en/RAHEEproject>). The project examines what is known about the cost effectiveness of treatments for the 10 highest burden conditions in Europe⁴ as well as contextual factors important for the translation of such knowledge in practice. Integration with ongoing activities is encouraged, and users and producers of evidence are invited to participate in shaping a research agenda for Europe that is responsive to needs and deals with the most important challenges ahead.

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PUBLIC SECTOR WHISTLEBLOWERS

Disappointing progress in public sector whistleblowing

Dyer reports that public sector whistleblowers have received “shocking” treatment from public sector organisations, including NHS ones.¹ The Francis Inquiry concluded that NHS staff have a “duty of candour” to raise patient safety and other concerns,² and the General Medical Council recommends promoting and encouraging a culture that allows all staff to raise concerns openly and safely.³ Yet there is clearly much room for improvement in the area of whistleblower protection.

The charity Public Concern at Work (www.pcaw.org.uk) supports whistleblowers and advises on organisational whistleblowing policies.

Regrettably, one year since the charity introduced the “First 100” initiative (a list of organisations that have signed up to the Whistleblowing Commission’s 2013 code of practice), only 26 organisations have signed up, and just two are NHS organisations. It is unclear whether this poor uptake is due to a lack of awareness of this initiative or a lack of genuine engagement in whistleblowing. If the first option is true, we suggest a renewed advertising and recruitment campaign. If the second one is true, the Department of Health or NHS England needs to take action to change the cultural attitude of NHS organisations to whistleblowers.

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TREATING EBOLA

How the West ignores diseases in undeveloped countries

I was medical superintendent of Kiwoko Hospital during the 2000 Ebola outbreak in Uganda.¹ We had no cases, but I remember the anxiety with each suspected case. There was another outbreak in 2012. I do not know how these were viewed in the Western media because I was in Uganda then. There was talk of a vaccine, not because Ebola affects poor Africans, but because of it being a bioterrorism threat.

We say we want to promote the health, wealth, and overall wellbeing of countries in Africa. But we ignore diseases that paralyse communities because they affect only those who are poor in nations of little international importance, and we consider them only when they become a possible threat to the West. The economic impact of diseases such as sleeping sickness is therefore ignored, yet such diseases affect far more people than Ebola—but again these people are poor and unimportant. If these diseases were in the developed world, we would have found a vaccine or cure long ago, or at least some treatment, as with HIV.

What should we call this? A form of colonialism or ethnocentrism? Or even racism?

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