

Are eligibility criteria for over the counter statins appropriate?

EDITOR—Low dose statins are now available for purchase over the counter by people at moderate risk of coronary heart disease (10 year risk of coronary heart disease 10-15%). Eligible people are identified using an assessment of age, sex, and number of risk factors for coronary heart disease as described in guidelines from the Royal Pharmaceutical Society of Great Britain.¹ The guidelines also recommend that blood pressure and cholesterol should be checked to identify people at high risk who should see their general practitioner, but these tests are not always available in pharmacies.¹ People at high risk (10 year risk of coronary heart disease $\geq 15\%$, identified using Framingham equations) are eligible for a prescribed statin, usually at higher dose than over the counter statins.²

We investigated how the Royal Pharmaceutical Society's criteria for over the counter statins compare with Framingham estimates of risk of coronary heart disease, using data from the Scottish Health Survey 1998, based on a subset of people with all data available to assess risk of coronary heart disease.³ While this risk was used in this analysis to allow comparison with the criteria from the Royal Pharmaceutical Society, more recent prescribing guidelines recommend estimating cardiovascular risk (coronary heart disease risk $\geq 15\%$ equivalent to cardiovascular risk $\geq 20\%$).²

Over 40% of people aged 40-74 in the Scottish survey 1998 would have been eligible for a statin (prescribed or over the counter), when the above criteria are applied. When criteria from the Royal Pharmaceutical Society are used, up to 28% of participants in the Scottish survey aged 40-74 were eligible for statins over the coun-

Distribution of 10 year risk of coronary heart disease among participants in the Scottish Health Survey 1998 and proportions eligible for over the counter statins by criteria from the Royal Pharmaceutical Society¹ including or excluding blood pressure and cholesterol data

10 year risk derived from Framingham equation (%)	No eligible for over the counter statins ¹ (% in Framingham risk category)	
	With blood pressure/cholesterol	Omitting blood pressure/cholesterol
<10 (n=1587)	177 (11)	278 (18)
10-15 (n=528)	100 (19)	238 (45)
≥ 15 (n=645)	35 (5)	250 (39)
Total (n=2760)	312 (11)	766 (28)

ter. There was poor agreement of risk assessment with Framingham equations, and up to 18% of people at low risk and 39% of those at high risk would have been misclassified as being at moderate risk using the criteria from the Royal Pharmaceutical Society. The results are summarised in the table and show the effect of including blood pressure and cholesterol in the assessment.

Use of Royal Pharmaceutical Society criteria could therefore lead to undertreatment of high risk individuals and unnecessary treatment of people at low risk. These findings are one potential explanation for the apparent fall in statin prescribing observed after over the counter statins were introduced.⁴ If Framingham derived cardiovascular risk, including blood pressure and cholesterol, cannot be checked in the pharmacy, we recommend that people are referred to their general practitioner for an accurate risk assessment.

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- 3 Scottish Health Survey 1998. Volume 1. www.show.scot.nhs.uk/seh/d/scottishhealthsurvey/sh8-00.html (accessed Aug 2005).
- 4 Dobson R. Statin prescribing fell after drug became available over the counter. *BMJ* 2006;333:569. (16 September.)

Implications of ejection fraction value for trastuzumab

EDITOR—We are concerned about the final appraisal determination document from the National Institute for Health and Clinical Evidence (NICE) for trastuzumab (Herceptin), which gives an absolute left ventricular ejection fraction of 55% as an eligibility criterion for adjuvant or neoadjuvant use in early stage breast cancer.^{1,2} The reliance on an absolute ejection fraction is clinically problematic.

Firstly, the value depends on the measurement technique. In the United Kingdom three non-invasive methods are used—nuclear techniques, echocardiography, and cardiovascular magnetic resonance imaging—depending on local availability. The techniques vary considerably in method, reproducibility, and accuracy.³

Secondly, no consensus exists about the definition of a normal left ventricular ejection fraction. In echocardiography normal values range from 50% to 80%.⁴ The normal value measured by nuclear techniques varies by department, the important issue being its reproducibility. Echocardiography tends to give the highest values, followed by cardiovascular magnetic resonance imaging, with nuclear techniques giving the lowest results. The ejection fraction can vary by up to 15% depending on the methods used.³

These data have important implications in deciding who is eligible for adjuvant trastuzumab. A patient could be eligible for trastuzumab in one institution and refused it in another, depending on the method used to assess ejection fraction, resulting in a postcode lottery.

A national consensus, agreed by cardiologists and oncologists, is needed on the definition of an acceptable left ventricular ejection fraction in the eligibility criteria for trastuzumab. It needs to embrace the considerable variability between centres and the methods of measurement to maintain consistent, effective, and safe implementation of the NICE guidance on the use of adjuvant trastuzumab throughout the United Kingdom.

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2 White C. Final guidance issued on Herceptin after appeal rejected. *BMJ* 2006;333:409. (26 August.)

3 Bellenger NG, Burgess MI, Ray SG, Lahiri A, Coats AJ, Cleland JG, et al. Comparison of left ventricular ejection fraction and volumes in heart failure by echocardiography, radionuclide ventriculography and cardiovascular magnetic resonance; are they interchangeable? *Eur Heart J* 2000;21:1387-96.

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Extensively drug resistant tuberculosis

Beware patients lost to follow-up

EDITOR—Lawn and Wilkinson report on the global emergence of extensively drug resistant tuberculosis.¹ An outbreak of extensively drug resistant tuberculosis has been ongoing for a decade in Norway.² In 1994 treatment was started in a patient with pulmonary tuberculosis who was lost to follow-up. One year later, the same patient was admitted to hospital with smear positive, pulmonary, extensively drug resistant tuberculosis.² In the following 10 years, 23 other patients were diagnosed with a strain of *Mycobacterium tuberculosis* that carried the same IS6110 RFLP and spoligotyping DNA patterns. Of these, 15 had extensively drug resistant tuberculosis (table). Among 3131 patients diagnosed with tuberculosis in Norway during these 12 years *M tuberculosis* was isolated from 2284. Multidrug resistant tuberculosis was identified in 37 of them. The 15 cases of extensively drug resistant tuberculosis in the current outbreak are 0.66% of all culture positive cases and 40% of the multidrug resistant cases diagnosed in the country during 1994-2005.

Numbers of cases diagnosed with isolates of *Mycobacterium tuberculosis* carrying indistinguishable IS6110 RFLP and spoligopattern in Norway

Year	Drug resistant tuberculosis	Extensively drug resistant tuberculosis	Total
1994	2	0	2
1995	0	1	1
1996	2	3	5
1997	5	1	6
1998	0	1	1
1999	1	2	3
2000	0	3	3
2001	0	0	0
2002	0	1	1
2003	0	1	1
2004	0	0	0
2005	0	2	2

This outbreak in a country with a low incidence and a well functioning tuberculosis control programme shows the long-lasting effect that one case lost to follow-up may have on the public health of a country. Such effects may lead to disasters in countries with a high incidence, where patients are commonly lost to follow-up.

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Problem will get worse in South Africa unless poverty is alleviated

EDITOR—The rising incidence and death rate from tuberculosis, as well as the emergence of multidrug resistant organisms in South Africa and elsewhere,¹ result more from social than medical failure. With living conditions for millions of people remaining at the level of pre-industrial revolution Britain and with inadequate healthcare services that cannot even remotely provide treatment for all who need it in good time and for the full duration required, the problem of multidrug resistance can only get worse.^{2,3} Longstanding recognition of the reasons for failure of tuberculosis control has had little effect on governments or the corporate world of economic power.^{4,5}

The substantial economic growth in South Africa since 1994 has been achieved by largely abandoning pre-transition plans for a reconstruction and development programme in favour of neo-liberal economic policies that benefit a limited segment of the population. Many jobs have been lost, new job creation has been limited, and movement towards a social democratic and labour intensive productive industrial state has been inadequate.²

As a result, almost half of all South Africans live in desperate and worsening poverty under conditions that promote the spread of infectious diseases and emergence of multidrug resistance—not only in relation to tuberculosis but also potentially for HIV/AIDS if that treatment programme is not implemented in association with improved primary healthcare facilities.

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Clinical examination for non-cephalic presentation

Royal College of Midwives' response to research

EDITOR—Nassar et al conclude that a third of breech pregnancies are missed using abdominal palpation.¹ The Royal College of Midwives recommends caution before using this research to advocate more reliance on technological solutions rather than clinical examination.

This study was carried out in Australia, where antenatal care practices are different from those in the United Kingdom. In the United Kingdom midwives provide most maternity care and are highly trained in

abdominal palpation, defining the position of the fetus.

Good clinical skills are important in assessing the fetal position during pregnancy. Some babies in breech position may be missed, which reinforces the need to use this research to inform current education and training of midwives and obstetricians. As the authors say, to rely further on increasing technology such as ultrasound scans may reduce practitioners' clinical skills. Some clinicians in the study may not have been as vigilant as they could have been because they knew that their findings were going to be checked with an ultrasound scan.

The Royal College of Midwives agrees that ultrasound scans would identify fetal position effectively, but the issues of cost, resources, and the long term effect on mother and baby have not been fully evaluated. Scans are already used to provide a second opinion when there is difficulty in palpation—perhaps for overweight women. However, women must be given unbiased information and the choice of whether to have an additional scan.

Instead of following the technology path the royal college advocates audit and feedback to develop practitioners' accuracy and diligence in carrying out clinical examination.

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- 1 Nassar N, Roberts CL, Cameron CA, Olive EC. Diagnostic accuracy of clinical examination for detection of non-cephalic presentation in late pregnancy: cross sectional analytic study. *BMJ* 2006 333:578-80. (16 September).

External cephalic version should be a maternity service quality indicator

EDITOR—The recent study by Nassar et al highlights the long known clinical failure to diagnose all breech presentations at term, especially in obese women.¹ However, there is little point in improving clinical detection unless it makes a difference to mothers or babies. The point of detecting a breech is to offer external cephalic version and to discuss mode of delivery if persistent. If external cephalic version is successful it avoids the hazards of vaginal breech delivery and caesarean section.^{2,3}

The National Sentinel Caesarean Section Audit showed that only 33% of women in the United Kingdom who were having caesarean sections for breech presentations had been offered an external cephalic version, and less than half of these had had the procedure.⁴ A recent systematic review confirmed the high success rates (>60% in some studies) and the extremely low risks of external cephalic version.⁵ Set against the well documented risks of caesarean section, those obstetricians and gynaecologists who do not offer external cephalic version (or offer it timidly) are failing their patients.

Along with the principles of non-maleficence and informed consent, the NHS

should be providing excellent evidence based care with minimum risks to patients. Maternity units that are not offering and carrying out external cephalic version, as well as training juniors to be proficient, must be considered substandard. Women (and their general practitioners) need to know that urgent referrals at term for external cephalic version can be made and that elective caesarean section should not be the first resort. External quality indicators of maternity services must include not only the proportion of breech presentations diagnosed at term but also the proportions offered external cephalic version and turning success rates.

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slightly different and probably less important question.

Qualitative analysis of the text is also crucial to assess whether any ghosts (writers) are in the background. Although detection of fraud is not their main purpose, reviewers and their reviews are in the best possible position to recognise studies that do not ring true, or are too good or too bad to be true or have been carried out for unscientific reasons (such as status, politics, or marketing).

Editorial peer review lies in the state it was nearly 200 years ago when the first scientific societies were formed and learned journals were founded. While man's sins remain the same as ever, the incentives for unscientific conduct have multiplied. Editorial peer review has been held as a bulwark against this, a role it simply can no longer perform in its current state. The sooner editors, authors, publishers, and governments accept this, the sooner life will become more difficult for the Kurjacks of this world.²⁻⁴

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Detecting plagiarism

See also *Career Focus* article by *Haris*

Current quality control systems don't work

EDITOR—Chalmers highlights serial plagiarism, the inability of current quality control mechanisms to detect it, and the comparatively light way in which it is dealt with once discovered.¹ Systematic reviews could be used to enhance the quality of editorial peer review.

Their lengthy process has several spin-offs. The most experienced and single minded reviewers quickly build in their minds and files a catalogue of what has been written on a topic, who the main authors are, and what their work is like. They become adept at spotting redundant publication, plagiarism, and invented data. In addition, they learn to treat each newly identified study as a new entrant into the family (represented by the studies already in the review).

Often the data "speak": they may ask, for example, why the new entrant is acting as an outlier compared with the family or why its precise estimates are very close to the pooled mean despite poor quality. They may also ask why conduct the study in the first place when there are many similar studies in the family, or why design a study to answer a

Meaning of citations is important

EDITOR—Godlee focuses on plagiarism in her Editor's choice.¹ As editors, reviewers, and readers we also have to attend to the meaning of citations.

Bibliometrics in general and citation analysis in particular have known weaknesses,^{2,3} and we all should be more cautious about the meaning of a lack of citations (such as unsupported assertions) and the meaning of the citations used. I am currently the editor in chief of the *Journal of Social Work Education*. I currently send two standard lines in the decisions to authors after reviewing their manuscript:

- You should clarify the meaning of your citations. If you are citing someone's assertion versus citing someone's empirical findings, then make the distinction clear
- You need to review the entire manuscript carefully for unsupported assertions.

These are the most common problems in typical manuscripts submitted to my journal. Corrosion of the knowledge bases of the professions through plagiarism is a serious problem. We must unearth and correct such degradations. In addition, we need to further improve the quality of scholarly communications by requiring authors to clearly and appropriately cite the sources of their scholarship.

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- 1 Godlee F. On the shoulders of giants [Editor's choice]. *BMJ* 2006;333. (16 September.)
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Google could be the way forward

EDITOR—The widespread availability of medical articles on the internet has made plagiarism a common practice among some students.¹ Most plagiarisers are keen to find short cuts—hence the popularity of cutting and pasting text from the internet rather than laboriously copying from textbooks or articles. This habit, however, makes it easy to identify the cheats.

A favourite trick of mine is to identify plagiarism using the Google search engine. I do this by taking a random piece of text from their work of about six words in length and pasting it into the Google search engine between quotation marks. Although I usually choose a section of text that includes a name or unusual phrase, a search of any sentence plagiarised from the internet will bring up the original work.

Over the past three years I have done this on all pieces of work that have made me suspicious and have a 75% success rate in identifying the original work. So far, the offenders have all been identified at an early stage of their work. I met with them and, after hearing them state that the work was their own, I demonstrated how I found the original work using Google. This embarrassment, along with a warning, has been enough to prevent a repeat. In the light of Chalmers's experience, however, maybe I am being overoptimistic about the effect of this learning experience on them.

A useful addition to universities' websites would be the ability to Google search the subscription only journals. This would allow editors to Google check for plagiarism before publication in a matter of minutes.

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