CORRESPONDENCE

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The STARD initiative

Sir—In studies of diagnostic accuracy, the outcomes from one or more tests under assessment are compared with outcomes from the reference standard, both obtained in individuals who are suspected of having the disorder of interest. Diagnostic accuracy can be expressed in many ways, including sensitivity and specificity, likelihood ratios, and the diagnostic odds ratio.

There are several potential threats to the validity and generalisability of studies of diagnostic accuracy. Diagnostic studies with specific design features have been shown to be associated with biased, optimistic estimates of diagnostic accuracy compared with studies without such deficiencies.[1] Complete and accurate reporting should allow the reader to detect the potential for bias in the study and to assess the generalisability and applicability of the results.

At the 1999 Cochrane Colloquium meeting in Rome, Italy, the Cochrane Diagnostic and Screening Test Methods Working Group discussed the low methodological quality and substandard reporting of diagnostic test assessments. The objective of the Standards for Reporting of Diagnostic Accuracy (STARD) initiative formed at the meeting became the improvement of the quality of reporting of diagnostic accuracy studies. After the successful CONSORT initiative,[2] the STARD initiative aimed to develop a checklist of items that should be included in the report of a study of diagnostic accuracy.

A STARD steering committee (for membership and details see http://image.thelancet.com/extras/02cor11089web.pdf) did an extensive literature search and extracted a list of 75 potential items. Subsequently, the STARD steering committee convened a 2-day consensus meeting on Sept 16 and 17, 2000, in Amsterdam, Netherlands, for invited experts including researchers, editors, methodologists, and professional organisations. During the consensus meeting, participants eliminated and consolidated items to form a 25-item checklist.

In addition, the STARD group put substantial effort into the development of a flow diagram for diagnostic studies. A flow diagram has the potential to communicate vital information about the design of a study—including method recruitment and the order of test execution—and the flow of participants in a transparent manner.

Potential users field-tested the first version of the checklist and flow diagram. The checklist was placed on the CONSORT website with a call for comments.

The STARD group received valuable comments and remarks during the various stages of evaluation, and assembled the final, single-page checklist that is published in the first issues of 2003 in several journals, including *Radiology*, *Annals of Internal Medicine*,[3] *BMJ*, *Clinical Chemistry*,[4] and on this journal's website (http://image.thelancet.com/extras/02cor11089web.pdf). A separate document explaining the meaning and rationale of each item and briefly summarising the available evidence is also published in *Annals of Internal Medicine* and *Clinical Chemistry*.[5]

The STARD group plans to release updates of STARD when new evidence on sources of bias or variability becomes available. We welcome all comments to improve the current version.

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1 Lijmer JG, Mol BW, Heisterkamp S, et al. Empirical evidence of design-related bias in studies of diagnostic tests. *JAMA* 1999; **282:** 1061–66.

2 Moher D, Schulz KF, Altman D. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001; **285:** 1987–91.

3 Bossuyt PM, Reitsma JB, Bruns DE, et al. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. *Ann Intern Med* 2003; **138:** 40–45.

4 Bossuyt PM, Reitsma JB, Bruns DE, et al. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. *Clin Chem* 2003; **49:** 1–6.

5 Bossuyt PM, Reitsma JB, Bruns DE, et al. The STARD statement for reporting studies of diagnostic accuracy: explanation and elaboration. *Clin Chem* 2003; **49:** 7–18.

Trade concerns must not be allowed to set the public health agenda

Sir—In November, 2001, trade ministers from around the world agreed to develop mechanisms to increase access to essential drugs in the developing world. Through the Doha Declaration on TRIPS and Public Health, a firm commitment was made by all members of the World Trade Organization (WTO) to put health above trade concerns, stating that: "the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[1]

A year later, those same ministers met to agree in detail how to put their statement into practice. Their earlier promises are not being matched by action, and the negotiations represent a tragic U-turn in the health–trade debate.

Leading industrialised countries are once again putting immense pressure on developing countries to accept dangerous proposals that would limit their ability to access affordable medical tools, effectively reversing the achievement of the Doha Declaration. The USA, European Union (EU), and Japan argued that measures "to protect public health" should be limited to infectious diseases, specifically AIDS, tuberculosis, and malaria. In other words, these industrialised countries are only concerned by diseases in the developing world insofar as they pose a potential threat to their nationals and their economic interests, with the burden on developing countries being almost incidental. Moreover, since negotiators insisted that the tools to respond to them should be limited to drugs, excluding all other medical technologies, such as vaccines and diagnostics.

Most alarmingly, they propose to exclude the growing burden of non-infectious disease in the developing world, where at present millions of people are dying because they are

unable to get basic medicines such as insulin.[2] The individual suffering caused by this growing disease burden[3] contributes enormously to the social and economic difficulties faced by most of the world's population.

3 years after demonstrators in Seattle put the needs of the majority of the world firmly at the doorstep of the WTO,[4] very little has changed. Crude compromises on public health are being put forward by trade negotiators with no expertise in the health field. The US and EU postitions seem to protect little beyond the interests of their drug industries. The duty of medical professionals to protect the interests of public health over trade has never been clearer, nor more vital.

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1 World Trade Organization, Doha Ministerial Declaration on the TRIPS Agreement and Public Health. WTO document number WT/MIN(01)/DEC/2 (2001). Qatar: WTO, 2001.
2 Yudkin JS. Insulin for the world's poorest countries. *Lancet* 2000; **355:** 919–21.
3 World Health Organization. Reducing risks, promoting healthy life. Geneva: WHO, 2002.
4 Editorial. Sleep less in Seattle. *Lancet* 1999; **354:** 1917.

Pfizer Diflucan Partnership Program

Sir—In their Medicines, society, and industry paper (Nov 16, p 1590),[1] David Henry and Joel Lexchin represented several facts erroneously.

They comment that Pfizer's Diflucan Partnership Program "has not been so well received because of the limitations imposed by sponsors". However, the Diflucan Partnership Program (DPP) has no limit to dollar and time, and Pfizer is fully committed to it, despite the many hurdles we meet, including very poor infrastructure and poor inventory skills, delayed registration, and drug theft from health facilities.

The DPP not only provides treatment for cryptococcal meningitis, but also for oesophageal candidiasis. The programme was launched in South Africa in December, 2000, and was expanded to all the Southern African Development Community countries, with Swaziland, Botswana, and Lesotho on the programme since February, 2002.

To date 11 African countries are receiving Diflucan, namely South Africa, Botswana, Lesotho, Malawi, Namibia, Mozambique, Ghana, Uganda, Tanzania, Rwanda, and Swaziland. Over three million tablets have been dispersed. The programme was expanded to the world's least developed countries in June, 2001, and several countries will soon be receiving Diflucan, including Zambia, Zimbabwe, Senegal, Côte d'Ivoire, Ethiopia, and Cambodia. Haiti is already on the programme. The programme has also expanded to include non-governmental institutions.

We would have appreciated being contacted before such an article was published in *The Lancet*.

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1 Henry D, Lexchin J. The pharmaceutical industry as a medicines provider. *Lancet* 2002; **360:** 1590–95.

Authors' reply

Sir—We are grateful to Konji Sebati for providing details of the current status of the Diflucan (fluconazole) donations in Africa. We congratulate Pfizer for continuing to support this programme and for extending it to a number of countries. We apologise for this omission from our article.

Our understanding was that Pfizer originally intended to limit donations to patients with cryptococcal infections in South Africa, and extended the programme after protests from governments and advocacy groups.

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The pharmaceutical industry as an informant

Sir—Joe Collier and Ike Iheanacho (Nov 2, p 1405)[1] raise many pertinent points about how the pharmaceutical industry provides information to sectors of society. They are, however, incorrect to suggest that the Men's Health Forum is an example of a patients' advocacy group inappropriately funded by a major pharmaceutical company. They imply that Pfizer exerts an undue influence on the Forum that poses a threat to rational prescribing.

Pfizer is just one of many funders of the Men's Health Forum; the largest single funder is the UK Government's Department of Health and there are seven other pharmaceutical funders. Many of our other industry supporters produce products that compete with those made by Pfizer, including treatments for erectile dysfunction. We also receive funding from various charitable trusts and commercial organisations. The Men's Health Forum has never preferentially advocated any specific treatment for health problems. As a registered charity, the Forum is subject to regulation by the Charity Commission and charity law.

Our pharmaceutical funders have always been clear that their support for the Men's Health Forum is to increase men's awareness of health issues and to improve the delivery of health services to men. They have never asked us to recommend any specific drug or type of treatment and, if they did, we would act to preserve our integrity and autonomy.

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1 Collier J, Iheanacho I. The pharmaceutical industry as an informant. *Lancet* 2002; **360:** 1405–09.

Sir—Joe Collier and Ike Iheanacho[1] are right that the pharmaceutical industry can exert great influence by supplying information to medical practitioners and researchers. Although their comments are generally well balanced, they tend to suggest that bias is a result of all industry-sponsored research. The only proof they offer to lend support to this contention is from anecdotal reports about specific issues—for example, the dispute about third-generation contraceptives.

The influence of industry funding can only be understood with knowledge about the total number of the sponsored research projects, including the ones that are well designed and reported in an unbiased way. Such knowledge might show that any bias is much less prevalent than is suggested by just focusing on the irregularities that have occurred. Of course, these irregularities need to be prevented at all costs. Unfortunately the blame cannot be exclusively laid with "the industry"; badly designed or biased studies are first approved by scientific review boards and ethical committees in hospitals and academic institutions. We as academic researchers and physicians are, therefore, accomplices in the irregularities Collier and Iheanacho refer to. The quality-control system that exists in internal scientific review and ethical approval has, therefore, to be strengthened. The Dutch law on clinical