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Although women no longer need to agonise if they cannot remember up to 34 steps of a systematic breast self examination procedure, or if they forget to do it at “the right time,” the importance of women continuing to be “breast aware” and reporting any unusual changes in their breasts to their general practitioner promptly cannot be overemphasised.<sup>11</sup> This could lead to a reduced delay in the presentation of any symptoms discovered by women themselves.<sup>12</sup>

In the meantime, those of us who have battled against the breast self examination lobby since 1991 can at last say, in the words of the editorial accompanying the publication of the Shanghai trial, that routinely teaching and doing breast self examination is dead.<sup>13</sup>

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## Using clinical databases in practice

### *Individualised prediction of survival for patients with cancer may be possible*

In the past decade clinical databases have become increasingly widely used in all industrialised countries. This has been accompanied by enhancements in their quality as a result of greater understanding of the requirements for scientific rigour and the availability of technology that can automate processes such as validity checking. Meanwhile recognition has been growing of the uses to which high quality clinical databases can be put—evaluative research, clinical audit, and managing services.<sup>1</sup> A further but less widely recognised application is that of helping patients, together with their practitioners, to make informed decisions about their clinical management.

An example of such an application is the use of a breast cancer database in Finland (p 29).<sup>2</sup> The Finprog study uses data on about 2000 women followed up for 10 years to enable an individualised prediction of survival for a new patient by matching her disease profile to that of many previous patients with breast cancer whose outcome is known. The patient and her practitioner can obtain a survival curve for the entire available follow up period, not simply an estimate for a single point in time. Such a system could be applied to any clinical database that includes accurate information on those characteristics of patients that affect clinical outcome.

Such a development could make a major contribution to the promotion of patient centred care and help make meaningful shared decision making a reality.<sup>3</sup> The need for such decision support was recognised by the inquiry into paediatric cardiac surgery in Bristol, which noted the failure of staff to provide parents with accurate prognostic information.<sup>4</sup> This was not because

the information was withheld but because it wasn't available.

The Finprog study illustrates the potential value of such an approach, but it also highlights three challenges that lie ahead. Patients and practitioners are going to require information that is up to date and reflects local clinical services. At present, users of the Finprog study obtain information on the outcomes for a cohort of women diagnosed and treated 10 years ago. But clinical care has moved on. With ongoing recruitment, databases would be able to provide more up to date information (at least for short term outcomes) reflecting current treatment outcomes. The second enhancement needed is the ability to provide data on the outcomes achieved by the healthcare providers a patient is attending, although inevitably the relatively small volume of patients treated in any one setting will limit the statistical confidence of any estimation of prognosis. The third challenge will be to show that this approach not only promotes patients' participation in making decisions but also leads to health benefits.<sup>5 6</sup>

The potential scope for using high quality clinical databases in this way is rapidly expanding with the growth in the availability of such databases. To encourage their use and enhance their quality, a web based directory of clinical databases ([www.docdat.org](http://www.docdat.org)) has recently been developed.<sup>7</sup> This directory is restricted to the United Kingdom, but similar websites could be created in other countries. When complete the directory will provide a description of all multicentre clinical databases that exist in the country and an independent assessment of the extent and quality of the data collected. The growing availability of software such as

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that developed in Finland is an exciting step forward in promoting the use of databases to inform and support clinical decisions that practitioners and patients face every day.

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Competing interests: NB leads the Directory of Clinical Databases (DoCDat) project

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## Reporting diagnostic tests

*Complying with STARD is likely to improve the quality of reporting*

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As a clinician, I need high quality evidence about the usefulness, precision, and accuracy of diagnostic tests, and I need it now. Such evidence is rare even for the clinical examination, the most critical component of the diagnostic process.<sup>1,2</sup> The situation is getting worse with the exponential increase of diagnostic tests, most of which have never been evaluated properly and can mislead the diagnostic process. Although rigorous methodological standards in research about diagnostic tests have been applied more rigorously in the past decade, their reporting and methodological quality remain inadequate.<sup>2-5</sup> Against this background, the proposal in this issue from the authors of Standards for Reporting of Diagnostic Accuracy (STARD) for reporting diagnostic research should be applauded (p 41).<sup>3</sup>

There is a precedent for a favourable effect of such standards in the reporting of randomised trials. Since the development of the Consolidated Standards of Reporting Trials (CONSORT)<sup>6</sup> and their adoption by the International Committee of Medical Journal Editors, the Council of Science Editors, and the World Association of Medical Editors, the reporting of randomised trials has improved. Although some of this may be due to a growing sophistication among trialists in general, the quality of reports in journals that promoted CONSORT (*BMJ*, *JAMA*, and *Lancet*) showed greater improvement than in a journal that did not advocate its use (*New England Journal of Medicine*).<sup>7</sup> Similarly, although Devereaux and colleagues found that six of 11 methodological factors outlined in the CONSORT statement were still reported less than 50% of the time in 105 recently reported randomised trials published in 29 journals,<sup>8</sup> journals that promoted the CONSORT statement did better than those that did not. Although these are encouraging results, referees and editors of journals need to do a better job in ensuring that their authors implement the CONSORT recommendations.

Given that precedent, the STARD criteria, if applied by investigators and required by editors, may lead to more high quality evidence about diagnostic tests. But if this evidence is to be used by busy clinicians,

it must be available quickly and in an easily understandable form. The promise of the "more informative abstract" has to be fulfilled by authors and journals.<sup>9</sup> The STARD methodological criteria provide the basis for more informative abstracts to accompany diagnostic articles.

Will the publication and recognition of the STARD statement have a favourable impact on our clinical practice? Although I agree with the authors of STARD that complete and informative reporting about diagnostic tests can only lead to better health care, I am confident that they would agree that the mere introduction of STARD is unlikely significantly to improve the quality and reporting of diagnostic research. Just as with the CONSORT statement, more intensive efforts to apply the guidelines will have to be made by those who develop diagnostic tests, fund and execute the studies that determine their clinical usefulness, and report and disseminate their results. This will not happen without substantial increases in the support of diagnostic research and in the translation and presentation of its results to the front lines of clinical care. Alliance between high quality diagnostic studies that observe the STARD recommendations and programmes of systematic reviews of diagnostic studies such as the one initiated by Matthias Egger and Daniel Pewsner are welcome. Egger and Pewsner have created the Bayes Library of Diagnostic Studies and Reviews, an international consortium conducting rigorous systematic reviews of studies of diagnostic accuracy. The alliance should provide journal editors and translational services with the raw materials that could give high quality evidence about the usefulness, precision, and accuracy of diagnostic tests to clinicians, and give it to them now.

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Competing interests: SS attended the first STARD consensus conference but did not receive any honorariums.

1 McAlister FA, Straus SE, Sackett DL, on behalf of the CARE-COAD1

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