

LETTERS TO THE EDITOR

Quantitative estimates of sensitivity and specificity in mammographic screening

SIR—Warmerdam *et al* rightly point out that breast screening in the German decentralised health care system may not be worth implementing.¹ They conclude that if up to 20% of the total cost of a screening programme can be spent on quality improvement, screening may be cost effective. However, the modelling exercise used by the authors, though academically interesting, is of questionable validity in the German situation. The microsimulation model (MISCAN) was originally developed for populations into which screening is being introduced for the first time.² This does not hold for Germany, where approximately 2 million women are already screened every year.³ In consequence, the critical stage distribution probably differs from the Dutch distribution which was used in the MISCAN model. This may explain the cancer detection rate of about 3% in the prevalence round of the German mammography study (DMS).

Warmerdam *et al* concede that they did not consider the effect of spontaneous screening "since it is difficult to measure." However, this effect is important because if the level of spontaneous screening is high, introduction of population based screening as a competing service is probably not cost effective when the marginal costs and benefits are balanced against each other. In addition, a modelling approach for population based screening using the DMS data may not be valid, since this study did not adhere to the European Union guidelines.^{4,5}

Thus, the authors derive sensitivity values from a screening interval of 1.1 year, although a screening interval of 2 years is recommended for women in the age group 50-69 years. As sensitivity values depend on the screening interval chosen, obtaining sensitivity values comparable to the Dutch ones using a shorter screening interval is not a valid approach. It makes the high quality scenario referred to an unlikely possibility.

It is difficult to obtain reliable epidemiological data in Germany. However, where available, data should be used. It is difficult to understand why the authors did not include some of the original data made available in 1993-94,^{4,5} rather than hypothetical assumptions and under-referenced "expert opinion".

The authors do not discuss their current findings in the light of their previous analysis.⁶ A modelling approach is required which takes into account the context of German health care and the level of opportunistic screening. As Muir Gray formulated, "Never think about screening tests, only about screening programmes."⁷ In Germany, the options for early detection of breast cancer are being reviewed. German decision makers now require sound epidemiological advice based on robust evidence which is applicable to the reality of the German decentralised health care system. Result based on partly invalid

and sometimes merely hypothetical assumptions do not help this process.

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- 1 Warmerdam PC, de Koning HJ, Boer R, *et al*. Quantitative estimates of the impact of sensitivity and specificity in mammographic screening in Germany. *J Epidemiol Community Health* 1997;51:180-6.
- 2 Van Oortmarssen GJ, Habbema JDF, van der Maaspij DE *et al*. A model for breast cancer screening. *Cancer* 1990;66:1601-12.
- 3 Schwing C. Miserable Trefferquote, weil zu teure Biopsien. *Medical Tribune* 16 January 1996.
- 4 Frischbier HJ, Hoeffken W, Robra BP. *Mammographie in der Früherkennung: Qualitätssicherung und Akzeptanz*. Stuttgart: Ferdinand Enke Verlag, 1994.
- 5 Bundesverband der BKK und IKK. *Qualitätssicherung in der Mammographie*. Dokumentation der 1 Expertentagung in Frankfurt am 2 November 1993.
- 6 Beemsterboer PMM, de Koning HJ, Warmerdam PG *et al*. Prediction of the effects and costs of breast cancer screening in Germany. *Int J Cancer* 1994;58:623-8.
- 7 Muir Gray JA. Evidence-based healthcare. *How to make policy and management decisions*. Edinburgh: Churchill Livingstone, 1997.

Reply

Our article was intended to quantify the impact of the quality of mammographic screening on breast cancer mortality reduction, unfavourable side effects such as biopsies and referrals, and cost.¹ We showed, with the aid of three plausible scenarios, that the breast cancer mortality reduction achieved at population level might well vary between 10-12% (difference of 400 deaths prevented per year) between a "low quality" and "high quality" scenario, and a cost effectiveness ratio between 15 000 and 21 000 DM per life-year gained in a German situation. We did not state or suggest that screening in the decentralised health care system in Germany may not be worth implementing. Given the disease and the possibilities of mammography when screening a large proportion of thus far asymptomatic women, breast screening might still be considered cost effective even in a low quality scenario. It should not, however, be the goal for a national programme, and our analysis simply shows that quality improvement is necessary and cost effective; it is not ethically acceptable not to put much effort into it for the women involved.

Robust evidence is something we are all aiming at. The lack of empirical data in the German setting is clearly stressed throughout our article, and explained for all important aspects and conclusions in the discussion (incidence data, stage distribution, interval cancers). It is the first, and indeed so far the only, cost effectiveness analysis of mammographic screening in Germany. It can only be based on whatever data are presently available. It uses several sources and a well defined model to supplement other data in a consistent way. We have been explicit about this, and the model has been used and cross checked in several contexts. One relatively hard piece of evidence is the incidence and mortality data from Germany, which led us to assume a worse survival rate in Germany compared with The Netherlands. Up to the beginning of the 90s, neither these data nor those from the KFU programme showed that screening had had a substantial effect, but apparently the *Medical Tribune* did show this in 1996. Even Dr Werneke can only state that the clinical stage distribution *probably* differs. The working of the present "wild screening"

in Germany has never been analysed in a rigorous manner. Annual reports on the German screening programme do not give data on these activities. Cancer registries, where they exist, can not often give valid information on the mode of detection. First results from four different regions in Germany, comprising approximately 1350 new breast cancer cases in 1995-96, show that 45% are diagnosed at stage pT1 (≤ 2 cm).³ This corresponds very well with our estimate for the "reference situation" in Germany without a nationwide screening programme.

We are not clear about part of the message in Mrs Werneke's letter. She argues that it may not be worth implementing screening in Germany, claims rather good results from spontaneous screening (having influenced stage distribution and detection rates in an organised screening setting), but ends again with confusion, stating that the high quality scenario exemplified in The Netherlands is unlikely in Germany. Our paper is based on German mammography study results and it is true that the German mammography study may not be identical to a future national mammographic screening programme, should there be such a programme. So far, however, our data are the closest estimate of what would happen and the extent to which quality would influence screening results. As far as the accusations that our approach is partly invalid and sometimes merely hypothetical are concerned, we can but refer to the reality of the Dutch nationwide screening programme and our modelling estimates made beforehand,² and these new German data.³

With estimates from actual German data we concluded that it was likely that up to 20% of the total costs of a screening programme could be spent on quality improvement in order to achieve a substantially higher reduction in mortality while retaining the same cost effectiveness ratio. In that sense, we hope we have helped German decision makers view the reality of the German decentralised health care system, and if not, perhaps other European countries considering implementation of cancer screening programmes.

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- 1 Warmerdam PG, Koning HJ de, Boer R, *et al*. Quantitative estimates of the impact of sensitivity and specificity in mammographic screening in Germany. *J Epidemiol Community Health* 1997;51:180-6.
- 2 Koning HJ de, Fracheboud J, Boer R, *et al*. (National Evaluation Team for Breast Cancer Screening - NETB). Nation-wide breast cancer screening in the Netherlands: support for breast-cancer mortality reduction. *Int J Cancer* 1995;60:777-80.
- 3 Comprehensive Cancer Centres Aachen (Rackl, Mittermayer) Jen (Blümler, Katenkamp), Marburg (Schmidtalbers, Koller), München (Engel, Sauer). Breast cancer—first results from four regions. Abstract 168. In: *Proceedings of the first international meeting on advances in the knowledge of cancer management*. Vienna, Austria June 28 to July 1, 1997.

Paracetamol in suicide and non-accidental overdose—are restrictions justified?

SIR—Gunnell's article is timely in view of recent Government changes to the product information and sale of paracetamol.^{1,2} However, it cannot be seen as the complete answer