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.

URSULA WERNEKE
Maudsley Hospital, London SE5 8AZ

- 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 unsymptomatic 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.

H J DE KONING
P G WARMERDAM
B-P ROBRA

Department of Public Health, Erasmus University,
Rotterdam, The Netherlands

- 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

to the question, "are restrictions on availability justified?" posed in its title. The relationship between the supply of the drug and its use in overdose is relevant to the discussion, but such factual information is insufficient in itself to justify the proposed changes. We also need to consider the values which underpin our provision of health services. The title encourages us to believe that clarification of facts alone can justify our actions. Such shorthand is dangerous since it may lead some to miss out other vital considerations altogether.

The authors conclude from an association between availability of paracetamol and the levels of its use in overdose that sales of this drug should be restricted. At least three relevant debates which question this have been identified in the past.

The restriction of sales is intended to reduce the harm caused by overdose. When considering the benefits of the suggested intervention, we need to also look at the associated costs. Such restrictions on sales will create inconvenience and extra costs which will be born by the vast majority of users who do not abuse the product. Are such measures affecting many warranted with regard to the few who will benefit? I would tend to believe they are, particularly when we consider those affected include not only the people who have overdosed and their friends and families, but also the wider public who help fund services such as liver units which support survivors. Others have argued differently. Fagan and Wangan recently expressed the opinion that "The extra investment costs, if passed to the consumer, would seem an unfair penalty for the millions who heed recommended doses."

Secondly, we need to consider the nature of such restrictive interventions. Gunnell notes that most people who take paracetamol in overdose realise its potential to cause serious harm. If we take this fact on face value, the proposals are unashamedly paternalistic, and could be attacked on this basis. It has been argued that all drug prescription laws are paternalistic as people are aware in general of the potential dangers and their relative ignorance in this area.¹ In fact, research has found that people do hold inaccurate beliefs regarding paracetamol. For example, it is commonly thought that one side effect of the drug is drowsiness, and most over estimate the fatal dose.⁵ This does not, however negate the need to discuss the potential for over-enthusiastic paternalism.

Thirdly, there is a possible hidden cost of reducing the availability of paracetamol. We value self reliance of the general public regarding their own health care. This is an issue of special importance to general practitioners who often see development of these skills as an integral part of their work. This view has been previously expressed, for example by Dr O'Connell who wrote earlier this year regarding the Medicine and Control Agency's proposals on paracetamol.² "If implemented, the proposals will have a massive impact on general practice. They will further destroy public confidence in paracetamol as a safe drug for pain and fevers. Patients are consulting their general practitioner before taking medicines for self limiting complaints, and this practice will increase when paracetamol is harder and more expensive to obtain."⁶

Gunnell's research is extremely useful in highlighting the public health effect of policies regarding drug availability. We need to remain aware of the link between accessibility and choice of method of attempted

suicide—and possible links with overall suicide rates. However, as Gunnell has pointed out elsewhere, we also need to remember that "The prevention paradox, whereby there is disadvantage to the many from interventions that can only benefit the few, is important . . . where the outcome to be prevented is as rare as suicide."⁷

The debate regarding the availability of paracetamol needs to be widened beyond the factual issues to include discussion of the values underlying the various options. The authors of the recent article are obviously aware of this necessity. However, their choice of title is potentially misleading. This is a minor point, but in view of the complex issues which are skimmed over as a result, I feel it is important.

SARAH JANE HOBSON

School of Epidemiology and Public Health,
University of Manchester

- 1 Gunnell D, Hawton K, Murray V *et al.* Use of paracetamol for suicide and non-fatal poisoning in the UK and France: are restrictions on availability justified? *J Epidemiol Community Health* 1997; 51:175-9.
- 2 Medicines Control Agency. *Analgesic medicines available without prescription: proposed changes to product information and sale or supply of paracetamol*. London: Department of Health, 1996. MLX231
- 3 Fagan E, Wangan G. Reducing paracetamol overdoses. *BMJ* 1996;313:1417-8.
- 4 Rainbolt George W. Prescription drug laws: justified hard paternalism. *Bioethics* 1989;3:45-58.
- 5 Gilbertson RJ. Paracetamol use, availability, and knowledge of toxicity among British and American adolescents. *Arch Dis Child* 1996;75:194-8.
- 6 O'Connell S. Reducing paracetamol overdoses: proposals will have negative effects. Letter. *BMJ* 1997;314:751.
- 7 Gunnell D, Frankel S. Prevention of suicide: aspirations and evidence. *BMJ* 1994;308:1227-33.

NOTICE

VIIth Annual BEES Workshop (British Epidermo-Epidemiology Society) was founded in 1990 with the aim of promoting a high standard of epidemiological research into all forms of skin disease, with emphasis on an interdisciplinary approach. The VIIth BEES Workshop will be held on 16 January 1998 at the University of Nottingham. 100 places only. Further information, contact: Dr Hywel Williams, Department of Dermatology, C Floor, South Block, Queen's Medical Centre, Nottingham, NG7 2UH. Tel: 0115 924 9924 ext 44539. Fax: 0115 970 9003.

BOOK REVIEWS

Health Promotion: An Anthology. Pan American Health Organization. (Pp359; US\$32) Scientific Publication No557, Washington DC, 1996. ISBN 92-75-11557-5.

This book offers a selection of the most important articles and documents on health promotion, its concept, and the different strategies and methodologies. Editors and con-

tributors, grouped around Helena Restrepo and PAHO's Division of Health Promotion and Protection, have achieved a formula acceptable to all involved that has successfully oriented them to the completion of the 26 articles and 4 appendices which comprise this volume. Somehow, this book is a recapitulation of the history of health promotion.

The book is divided into five parts, plus the appendices. The first part consists of five different documents and is an attempt to provide different points of view on both the conceptual framework and health promotion theory. This part clearly establishes the link between health promotion and other views of public health that stress the social constituents of health and disease. The second part of the book is made up of four interesting articles that focus on the concept of public health policies, an essential constituent of health promotion strategies. The third and fourth sections of the work deal with the strengthening of community action and the development of personal skills. Together, both sections offer 14 documents with a wide variety of practical examples. The fifth part of the book focuses on three particular projects aimed at specific issues: young people, AIDS, and physical activity.

There are four appendices at the end of the book which provide interesting documents on the development of health promotion in Latin America and the Caribbean. The book is completed with a glossary of terms.

The PAHO's Scientific Publications series had already published historical compilations of articles in the fields of epidemiology and health services research. The book reviewed here is a step forward in this sense, including versions in both English and Spanish. I think this will be very useful material, especially for teaching and public health research, as all the documents chosen are of great interest. This is, arguably, one of the best books on health promotion available.

LUIS ANDRÉS LÓPEZ-FERNÁNDEZ
Escuela Andaluza de Salud Pública,
Granada, Spain

Women and the Health Care Industry. Peggy Foster. (Pp 218; £40). Buckingham: Open University Press, 1995. ISBN 0-335-09472-4.

This book examines the effectiveness of modern medicine in meeting the health needs of women and the extent to which ineffective or dangerous interventions are perpetuated because of vested interests. To achieve these aims evidence from a wide range of sources is presented. Since providing ineffective or dangerous services for profit in doctor-patient relationships based on trust must be the most unethical form of marketing dangerous products, the book contains important information for researchers and providers as well as users of health care to consider.

The author points out that any bias in citing research findings is in favour of the sceptics. Contradictions in evidence and the validity of research findings are discussed in relation to issues such as the impact on knowledge of not publishing negative findings, biased allocation of research funds, and the influence of organization and funding mechanisms on how vested interests affect services. As critical scrutiny of available evidence is essential for assuring sound knowledge, these are major contributions of the book.