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.1 This does not hold for Germany, where approximately 2 million women are already screened every year. In contrast, 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 in their model it is difficult to measure.2 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.1

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 make 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 1997, rather than hypothetical assumptions and under-referenced “expert opinion”.

The authors do not discuss their current findings in the light of their previous analysis.3 A modelling approach is required which takes into account the decentralized health care and the level of opportunistic screening. As Muir Gray formulated, “Never think about screening tests, only about screening programmes.”4 The optimistic early detection of breast cancer is 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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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” 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 in the KIFU programme showed that screening had had a substantial effect, but apparently the Medical Tribune did show this in 1996. Even Dr Wernereke can only state that the clinically relevant effect 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, cannot often give 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). 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 Dr Wernereke’s letter, although it is 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 caution, 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 hypothesis, we can only refer to the reality of the Dutch nationwide screening programme and our modelling estimates made beforehand, and these new German data.

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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References

4 Comprehensive Cancer Centres Aachen (Rackl, Mittermayer), Berlin (WARMERDAM), Munich (Engel, Bauer), Würzburg (Schmitz-Heubner, Koller), Stuttgart (Ferdi-
5 Comprehensive Cancer Centres Aachen (Rackl, Mittermayer), Berlin (WARMERDAM), Munich (Engel, Bauer), Würzburg (Schmitz-Heubner, Koller), Stuttgart (Ferdi-

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 for sale of paracetamol.7 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 should arrive by action. Such a 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 restrictive action on sales will create increased 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? It is surely fair to believe they are when we consider those affected include not only the people who have overdosed and their friends and families, but also the 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 need 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 in nature; people are aware in general of the potential dangers and their relative ignorance in this area. In fact, research has found that people do hold inaccurate beliefs regarding their drugs. For example, it is commonly thought that one side effect of the drug is drowsiness, and most over estimate the fatal dose. 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. 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.

Gunnell's research is extremely useful in highlighting the public health effect of policies on 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."

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 skinned over as a result, I feel it is important.

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