EDITORIAL

German Mammography Screening Program: Quality Assurance

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Editorial to accompany the article: „The Incidence of Interval Cancers in the German Mammography Screening Program“ by Heidinger et al. in this issue of *Deutsches Ärzteblatt International*

How come I've got a tumor? I was only just screened." Probably every woman has heard something like this from a friend or a neighbor, and in some cases it may make the difference between going for screening mammography or not.

The aim of the German mammography screening program is to achieve a lasting decrease in breast cancer mortality. The program's success, however, can be accurately evaluated only after at least 10 years have elapsed. Therefore other criteria, the so-called surrogate parameters defined in the European guidelines (1) and adapted for use in the German program, are employed to assess the quality and efficacy of screening at an early point in time. The Mammography Cooperative (*Kooperationsgemeinschaft Mammographie*) evaluates the relevant data according to section 23 paragraph 1 of the cancer screening guideline and publishes the findings in regular reports (2).

Open Questions

We know that screening does not prevent a tumor, just detects it at an early stage. However:

- How can it happen that a tumor is discovered more or less incidentally, for example by self-examination, less than 2 years after normal findings on a mammography?
- And how often does this happen?

Let us start with the second question: How often does it happen that cancers occur within 1 to 2 years after screening? The frequency of these so-called interval cancers is one criterion of the quality of the program, as laid down, for example, in the European Union guidelines (1). Heidinger et al. (3) set out to answer this question by detailed matching of data from two sources. They used the records of the cancer registry of North Rhine–Westphalia to establish how many of the women who had been screened at facilities in North Rhine–Westphalia were diagnosed with breast cancer within 24 months of screening. Although a few aspects of the matching procedure may lead to slight inaccuracies, as discussed in detail by the authors, they have come up with good estimates: Almost a million women (878 764) took part in the mammography screening program in North Rhine–Westphalia between 2005 and 2008. Around 2000 women, 0.23 % of those screened, developed breast cancer in the next 2 years despite "normal" mammography. In other words, about 2 in

every 1000 women who thought they did not have breast cancer were suddenly confronted with a disturbing diagnosis.

The data from North Rhine–Westphalia are comparable with those from German model projects and from international publications. One conspicuous finding, however, requires further investigation: the proportion of interval cancers in stages T2 to T4 is surprisingly high, at 44%. The authors' explanation is that these tumors are highly aggressive and can indeed only be diagnosed in the interval between screenings because of their rapid growth.

Now for the first question that the women ask themselves: How can it happen that a tumor is discovered more or less incidentally less than 2 years after mammography? Theoretically, various reasons can be advanced:

- The tumor was already there but was overlooked.
- The tumor is very aggressive and has grown in a very short time.
- Biopsy was recommended but carried out incorrectly or not at all.

First answers

The cancer registry data evaluated by Heidinger et al. (3) are not sufficient to answer the question.

No legal framework is yet in place for the classification of interval cancers (into true, radiologically occult tumors, false-negative or unclassifiable tumors, and tumors with minimal signs) by inspection of the diagnostic mammograms at the so-called reference centers.

Problems in evaluation of the mammography screening program arise partly from the fact that epidemiological competence, and particularly the experience gained from cancer registries, became involved in the evaluation process at a relatively late stage. Moreover, Germany has no legal structure for the matching of data from the mammography screening program with the information in cancer registries. The processing of implementing relevant laws is cumbersome because of the federal system in this country. While it is essential for confidentiality to be preserved and for data protection regulations to be followed to the letter, the urgently necessary quality assurance measures should not be delayed or even prevented completely by data protection concerns or by controversial interpretations in different federal states.

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Evaluation is vital

A costly program was implemented, but only now, some time later, are measures being taken to evaluate it.

There are many reasons—among them the introduction of screening at different times and the differing incidences of breast cancer—why the data from North Rhine–Westphalia cannot be entirely extrapolated to Germany as a whole; however, the results clearly show the importance of evaluating the program. It should be stressed that only a population-based, complete cancer registry like that in North Rhine–Westphalia and many other federal states of Germany enables assessment of the quality of screening. This is true not only for breast cancer; similar evaluations for skin cancer screening and colonoscopy are equally important.

Positive prospects

Let us look confidently into the future: the German Federal Office for Radiation Protection (Bundesamt für Strahlenforschung, BfS) has announced a study in which the quality of the mammography screening program will be evaluated. Additional exposure of healthy women to radiation can be justified only if the program yields a clear benefit in the form of reduction in mortality from breast cancer. The BfS study will begin soon, and it is to be hoped that all participating institutions and representatives of the professions will lend their full support.

Furthermore, we can be cautiously optimistic and hope that something has been learned from the experience gained and the mistakes made in implementing the mammography screening program. The screening programs for bowel cancer, cervical cancer, and skin cancer should be subjected to early and reliable evaluation.

The German Federal Government has proclaimed its intention to provide a legal framework for screening programs and cancer registries in the context of implementation of the National Cancer Plan. Let us hope that the regulations will permit not only data collection but also the evaluation of all aspects of the fight against cancer—from screening through to diagnosis, treatment, and follow-up.

Conflict of interest statement

The authors declare that no conflict of interest exists.

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REFERENCES

1. European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth Edition. www.euref.org/european-guidelines; last accessed 24.10. 2012
2. www.mammo-programm.de/cms_upload/datenpool/evaluationsbericht_2008–2009_web.pdf; last accessed 24.10. 2012
3. Heidinger O, Batzler WU, Krieg V, Weigel S, Biesheuvel C †, Heindel W, Hense HW: The incidence of interval cancers in the German mammography screening program—results from the population-based cancer registry in North Rhine–Westphalia. *Dtsch Arztebl Int* 2012; 109(46): 781–7.

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