

Quality control and optimisation of patient doses and image quality in the Norwegian Breast Cancer Screening Program

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Breast cancer and screening

Worldwide, breast cancer is the most frequent cancer in women. Breast cancer is also the most common cancer in females in Europe. It is estimated that in the year 2000 there were 350 000 new breast cancer cases in Europe, while the number of deaths from breast cancer was estimated at 130 000 [1].

Screening means the use of tests or examinations on asymptomatic individuals, to identify disease at an early stage (before it becomes clinically apparent) in order to lower the risk of death, or complications of treatment. The only proven effective method of breast cancer screening is mammography. There is sufficient evidence for the efficacy of screening women aged 50-69 years by mammography and limited evidence for the efficacy in women aged 40-49 years [2].

Mammography screening: risk and benefit

It is generally acknowledged that ionizing radiation has the potential to induce biological damage, specifically cancer. One consequence of the introduction of population-based screening programmes where the diagnostic test is based on the use of x-rays is that large numbers of healthy individuals are exposed to a procedure that for them not only has no benefit but might in fact be detrimental. Cancer detection rates in population based mammography screening programmes varies with age, but as a whole typically lies in the range 5 to 10 cancers detected per 1000 women screened. In other words, for each cancer found, more than 99 healthy women are examined. Organised mammography screening is already offered in many European countries. Were population based mammography screening is to be implemented on a grand scale in Europe today, where the total population is approaching half a billion people, this would translate into tens of millions of healthy women receiving regular mammographic examinations.

In a recent assessment of benefit and risk in the British NHS Breast Screening Programme, Faulkner points out that for a screening programme to be justified in radiation protection terms, the benefit of breast screening must be greater than the risk of inducing a cancer by the use of ionising radiation. Justification applies to both the screened population and also at an individual level. He finds, in conclusion, that the NHS Breast screening programme is justified in radiation protection and public health terms. However, quality control and continuous improvement in image quality in the breast screening programme is important, as the detection of small cancers depends upon high image quality mammography [3].

Mammography screening: quality assurance, quality control

Steps to ensure the delivery of high quality mammography has been taken in several places in the world. For instance, in the USA, the delivery of mammography is regulated by the Mammography Quality Standards Act [4]. This piece of legislation was enacted by Congress to

ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. The practical enforcement of the regulations includes a certification and inspection regime. In Europe, the European Commission recently published a revised and extended edition of the European guidelines for quality assurance in breast cancer screening and diagnosis [5]. This was the fourth in a series of guidelines whose development and implementation depended on the co-operation of scientists, clinicians and paramedical staff, advocates, health care planners and administrators across Europe, and for which the stated objective is to provide the same high level services for breast screening across the continent.

Mammography screening in Norway

Mass screening for breast cancer was introduced as a trial project in Norway in 1995. Due to promising results, the project was gradually developed into a national programme. As of early 2004, the programme covers the whole country.

Organisationally, the Norwegian Breast Cancer Screening Programme (NBCSP) has both centralised and local functions. The latter includes performing the screening examination, and any further medical procedures if necessary. Quality assurance is included as one of these central functions.

The development of a system for quality assurance was given high priority during the early phase of the project. Working groups in quality assurance/quality control (QA/QC) were established for all relevant personnel groups (including radiologists, radiographers, pathologists, surgeons). Procedures for QA/QC were documented in a QA manual that has subsequently been revised regularly.

Responsibility for the quality control of physical and technical aspects of mammography screening was given to the Norwegian Radiation Protection Authority, who contributed two chapters to the QC manual: Constancy controls and status controls. The former includes frequent (i.e., daily, weekly,...) system tests and is performed by local personnel (radiographers). The latter consists of annual tests, and is performed by an inspection group from the NRPA.

The two chapters on technical QC set standards for equipment performance and acceptable dose levels. Mandatory reporting of constancy control results coupled with annual status control visits allow the NRPA to monitor the equipment performance status closely.

Some of the recommendations and tests found in the QC manuals are directly or indirectly connected to what dose level the equipment operates at. Most importantly, a limit is set for the maximum dose allowed for the exposure of a “standard breast” under “clinical conditions”. Mammography is currently in the process of “going digital”. With digital systems, the dose range within which the system produces images with acceptable quality is dramatically wider than for analogue systems. The dose level employed thus becomes dependent on the manufacturer’s optimisation strategy. When the first digital mammography systems were introduced on the market, the NRPA, along with groups with similar mandates in mammography and screening programmes, decided to keep the dose limit at its current (“analogue”) level. It is our impression that this made the manufacturers that had previously not primarily focused on the dose levels turn their attention more/earlier to optimising both the dose levels and the image quality. As an example, we found that the dose to the standard breast measured on the same digital equipment, was 30-40% lower after four years compared to at installation. The reason was a change of exposure parameters (chosen automatically by this particular system). We are currently following European recommendations where dose levels

are monitored over the full range of relevant breast thicknesses as opposed to only one thickness with the “standard breast”.

For the last couple of years, and in accordance with national regulations, we have been collecting exposure data from a representative selection of screening examinations. From these data, the doses to the screened women are calculated. Analysis of these data allows us to pick up trends, compare with results from similar programmes in other countries, and identify areas or sites in need of further optimisation. In our first major analysis, including only data from analogue equipment, we found that doses to thick breasts were lower when the equipment’s automatic selection of exposure parameters (anode/filter/tube voltage) was used than when these parameters were selected manually. This has also been found in surveys conducted elsewhere. This finding indicates a need to work closely on further optimisation with sites that have equipment with automatic selection of exposure parameters that are currently not using this option.

As part of its mandate within the NBCSP, the NRPA has been actively involved in education, particularly of radiographers. Technical QC has been one of the main topics of a 7-day course that also covers epidemiology, anatomy, radiology, radiography, etc. It is strongly recommended that all radiographers working in the NBCSP complete this course. As of 2005 a lecture on patient doses in mammography was included in the curriculum.

Mammography screening in Norway: lessons learned

Prior to and in preparation for the mammography screening trial project the Norwegian Radiation Protection Authority conducted a survey of all mammography systems in use in Norway. Among the findings were that only about one third of the sites conducted some form of regular quality control and that the film optical densities varied considerably between the sites. An increase in the implementation of quality assurance and quality control was recommended, as this was believed to have the potential to lower the number of deviations experienced. The need for national standards and recommendations in certain specific areas was also pointed out [6].

Partly due to the previous lack of medical physicists working in diagnostic radiology in Norway, the NRPA not only took a role in which it issued standards and collected survey data in relation to the screening programme. Rather, our institution became closely involved in the practical work of conducting annual physics surveys and following up regularly on the quality control work being conducted by local staff. As mentioned, this happened partly out of necessity, due to the lack of medical physicists in the field. However, this has allowed us to keep a closer watch on the degree to which the individual sites adhere to the standards than would otherwise have been the case. In a regional survey of mammography equipment in southern Sweden in 1997, Hemdal and Bengtsson found large variation between measured results for several parameters. For some parameters they also found a lack of adherence to the performance criteria given in national standards for a significant proportion of systems surveyed. Their results came in spite of the existence of local quality control programmes and follow up. They conclude that comparative regional surveys of this kind, conducted in the same manner and with the same measurement equipment, can provide insights into the status and potential defects of the equipment that might otherwise have gone undetected [7]. They also refer to similar findings in other countries and say that regular, periodic controls are in the planning stage as a consequence of their findings. The existence of a “national physics group” in the NBCSP allows us to closely monitor all mammography systems in the screening programme in a manner as described by Hemdal and Bengtsson on a regular and permanent basis.

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