

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

Kristin Pedersen and Gunnar Saxebøl
Norwegian Radiation Protection Authority

Breast cancer

- **Breast cancer the most frequent cancer in women both worldwide and in Europe.**
- **Estimated for the year 2000 [1]:**
 - 350 000 new breast cancer cases in Europe.
 - Number of deaths 130 000.

Screening for breast cancer

- **Screening: 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.**
- **Mammography the only proven effective method of breast cancer screening [2]:**
 - sufficient evidence for the efficacy of screening women aged 50-69
 - limited evidence for the efficacy in women aged 40-49 years

Mammography screening: risk and benefit

- **Ionizing radiation has the potential to induce biological damage, specifically cancer.**
- **Population-based screening programmes based on the use of x-rays: 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 typically lies in the range 5 to 10 cancers detected per 1000 women screened.
 - In other words, for each cancer found, more than 990 healthy women are examined.
- **Organised mammography screening is already offered in many European countries.**
- **The total population in Europe is approaching half a billion people.**
- **Were population based mammography screening to be implemented on a grand scale in Europe today, this would translate into tens of millions of healthy women receiving regular mammographic examinations.**

Mammography screening: risk and benefit

- **In a recent assessment [3] 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 concludes 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.**

Mammography screening: quality assurance, quality control

- **Steps to ensure the delivery of high quality mammography has been taken in several places in the world**
 - in the USA, the delivery of mammography is regulated by the Mammography Quality Standards Act [4].
 - Legislation 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 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].
 - The fourth in a series of guidelines.
 - Development and implementation depended on the co-operation of scientists, clinicians and paramedical staff, advocates, health care planners and administrators across Europe.
 - The stated objective is to provide the same high level services for breast screening across the continent.

Mammography screening in Norway

- **Introduced as a trial project in 1995.**
- **Gradually developed into a national programme.**
- **As of early 2004, the programme covers the whole country.**
- **Both centralised and local functions.**
 - Locally: Performance of the screening examination, and any further medical procedures if necessary.
 - Centrally: Quality assurance.
- **Development of a system for quality assurance given high priority during the early phase of the project.**
 - Working groups established for all relevant personnel groups.
 - Procedures for QA/QC documented in a QA manual that has subsequently been revised regularly.

QC of the physical and technical aspects of mammography screening in Norway

- **Responsibility given to the Norwegian Radiation Protection Authority.**
 - Two chapters in the QA manual
 - Constancy (frequent) controls, performed by local personnel.
 - Status (infrequent) controls: performed annually by NRPA staff.
 - 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.
- **A limit is set for the maximum dose allowed for the exposure of a “standard breast” under “clinical conditions”.**

Digital mammography and doses

- **Digital systems: dose range within which the system produces images with acceptable quality is dramatically wider than for analogue systems.**
- **The dose level employed becomes dependent on the manufacturer's optimisation strategy.**
- **We and others have decided to keep the dose limits at its current ("analogue") levels or lower.**
- **This has possibly made manufacturers 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).**
- **Current European recommendations are to monitor dose levels over the full range of relevant breast thicknesses.**

"Patient" doses

- **The NRPA annually collects exposure data from a representative selection of screening examinations and calculates the doses to the screened women.**
- **This 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.**

Training and education of radiographers

- **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 for radiographers 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

- **Status before the mammography screening trial project [6] :**
 - only about one third of the sites conducted some form of regular quality control
 - film optical densities varied considerably between the sites.
 - An increase in the implementation of quality assurance and quality control was recommended.
 - The need for national standards and recommendations in certain specific areas was pointed out [6].
- **In the NBCSP, the NRPA not only assumed the role of issuing standards and collecting survey data, but also 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.**
- **This has allowed us to follow up closely with regard to how the individual sites adhere to the standards.**
- **In a regional survey of mammography equipment in southern Sweden in 1997, Hemdal and Bengtsson found large variation between measured results for several parameters and also 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, 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.**

References

- [1] Tyczynski, J.E., Bray, F., and Parkin, D. M., 'Breast Cancer in Europe', ENCR Cancer Fact Sheets, Vol. 2, December 2002
- [2] Vainio H, Bianchini F. (eds.) (2002). 'Breast cancer screening'. IARC Handbooks of Cancer Prevention. IARC Press, Lyon
- [3] Faulkner, K., 'Mammographic screening: is the benefit worth the risk?', Radiation Protection Dosimetry, Vol.117, No. 1-3, 2005, pp. 318-320.
- [4] <http://www.fda.gov/CDRH/MAMMOGRAPHY/frmamcom2.html>
- [5] 'European guidelines for quality assurance in mammography screening and diagnosis'. 4th edition. Luxembourg: Office for Official Publications of the European Communities, 2006.
- [6] Olsen, J.B. and Widmark, A. StrålevernRapport 1995:5 'Mammografivirksomhet i Norge, Tekniske resultater'. Østerås: Statens strålevern, 1995.
- [7] Hemdal, B. and Bengtsson, G., 'Kontroller av mammografiutrustningar i södra sjukvårdsregionen'. 1997, Stockholm, Socialstyrelsen.