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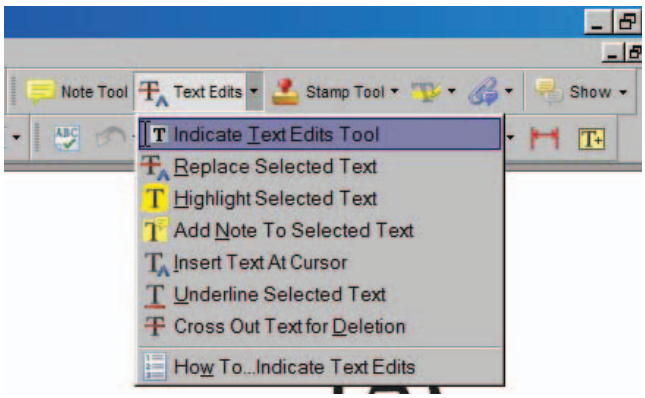

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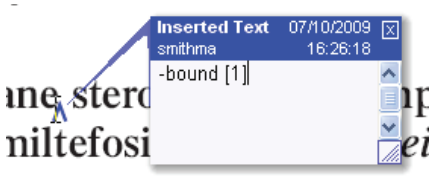

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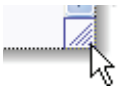

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UNCERTAINTIES INVOLVED IN THE ESTIMATION OF MEAN GLANDULAR DOSE FOR WOMEN IN THE NORWEGIAN BREAST CANCER SCREENING PROGRAM (NBCSP)

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The aim of this study was to reflect on the estimation of the mean glandular dose for women in Norway aged 50–69 y. Estimation of mean glandular dose (MGD) has been conducted by applying the method of Dance *et al.* (1990, 2000, 2009). Uncertainties in the thickness of approximately ±10 mm adds uncertainties in the MGD of approximately ±10 %, and uncertainty in the glandularity of ±0 % will lead to an uncertainty in the MGD of ±4 %. However, the inherent uncertainty in the air kerma, given by the European protocol on dosimetry, will add an uncertainty of 12 %. The total uncertainty in the MGD is estimated to be ∼20 %, taking into consideration uncertainties in compressed breast thickness (±10 %), the air kerma (12 %), change in HVL by −0.05 mm (−9.0 %), uncertainty in the s-factor of ±2.1 % and changing the glandularity to an age-dependent glandularity distribution (+8.4 %).

The aim of this study was to reflect on the estimation of the mean glandular dose (MGD) for women in Norway aged 50–69 y. Estimation of MGD has been conducted by applying the method of Dance *et al.* (1990, 2000, 2009). Uncertainties in thickness of approximately ±10 mm adds uncertainties in the MGD of approximately ±10 %, and uncertainty in the glandularity of ±10 % will lead to an uncertainty in the MGD of ±4 %. However, the inherent uncertainty in the air kerma, given by the European protocol on dosimetry, will add an uncertainty of 12 %. The total uncertainty in the MGD is estimated to be ∼20 %, taking into consideration uncertainties in compressed breast thickness (±10 %), the air kerma (12 %), change in HVL by −0.05 mm (−9.0 %), uncertainty in the s-factor of ±2.1 % and changing the glandularity to an age-dependent glandularity distribution (+8.4 %). Due to the potentially carcinogenic effect of the ionising radiation to the glandular tissue in the breast, it is important to monitor the MGD. In 2007, the International Commission on Radiological Protection[(1)] issued new weight factors reflecting the increased concern about glandular tissue dose, which reflects that the assessment of MGD is important and should be estimated as accurately as possible. Medical use of X ray, including screening programmes, is regulated in Norway by the 'Act and regulations on radiation protection and use of radiation'[(2)]. The annual technical quality controls in the Norwegian Breast Cancer Screening Program (NBCSP) are conducted by the Norwegian Radiation Protection Authority (NRPA), and these controls follow the European guidelines to a large extent[(3)].

The MGD for women screened in the NBCSP[(4)] has been estimated[(5)] using the method of Dance *et al.*[(6–8)] applying the following equation:

$$\mathrm{MGD} = K \times g \times c \times s \quad (1)$$

where K is the measured entrance surface air kerma without backscatter and g is the incident air kerma to mean glandular dose conversion factor (g-factor). The g-factor was based on a model where it was assumed that the breast contains 50 % glandular tissue[(6)]. A revised model[(7)] was therefore developed in order to correct for the fact that not all breasts consist of 50 % glandular tissue. The c-factor corrects for glandular content differing from 50 % and the s-factor corrects for target and filter combinations differing from molybdenum target and molybdenum filter originally posted by Dance[(6)].

Uncertainties in the kerma, g-, c- or s-factors will affect the MGD. The g-factor varies with the compressed breast thickness and the half-value layer (HVL), while the c-factor varies with the compressed breast thickness, the HVL and the glandularity. The s-factor varies with the selected target/filter/kV combination. The automatic exposure control will, for many mammography units, choose the target/

filter/kV combination based on the compressed breast thickness. An uncertainty in compressed breast thickness will thus also affect the selected radiation quality and therefore the selected s-factor. In order to simplify the calculations of the s-factor, Dance *et al.*[7] have assigned a single s-factor to each target/filter combination independent of HVL and breast thickness. The simplification will incur a maximum relative uncertainty of 2.1 %. For the different mammography units there is a difference between the measured and the readout compressed breast thickness[9–14], and this will affect the choice of g- and c-factors, as well as the choice of target, filter and kV. The European protocol on dosimetry in mammography has estimated the accuracy of determination of the incident air kerma[15].

The aim of this study was to try to estimate the uncertainties in the MGD, when applying uncertainties in the compressed breast thickness, HVL, glandularity, s-factor and air kerma. Data from 1220 women exposed to screening mammography were used to estimate the MGD with and without the inherent uncertainties, and then the difference in MGD with and without the uncertainties was estimated per exposure.

MATERIALS AND METHODS

Data included

This study is based on exposure factors collected from 1220 women examined at one full-field digital mammography screening unit, Siemens Mammomat Inspiration, in the period between 25 January and 26 February 2010.

For each exposure, the applied compression force, compressed breast thickness, laterality (CC or MLO), view position (left or right), the tube voltage (kV_p), target material, filter material and exposure tube current and tube loading (mA s). In addition, the year of birth of the woman was recorded. The exposure factors were all recorded on paper by the radiographers, and the data later manually transferred to Excel files.

Because only the year of birth of the women was recorded, an uncertainty of ± 1 year will be inherent in the data set. The age of the women invited to screening in the NBCSP ranges from 50 to 69 y. Because of the uncertainty in age, all women aged 49–70 y old are included in the study.

The total number of collected data were 1281, but 61 women were excluded from the data set; 14 due to lack of birth year, 36 due to a compressed breast thickness <20 mm for one or more projections, 3 women due to being outside the age range of 49–70 y, three for missing HVL, 2 for missing radiation output for 2 radiation qualities (W/Rh/24 kV and W/Rh/25 kV), 2 due to missing data for 1 projection, 2 for missing compressed breast thickness for 1 or more projections and 1 for missing mA s value. The reason for excluding 36 women who had a compressed breast thickness <20 mm is that Dance *et al.* [6, 7] have only published conversion factors in order to estimate the MGD for breast thicknesses between 20 and 110 mm. Even if an extrapolation could have been performed for the g- and c-factors, it was decided instead to exclude these women from the data material.

Estimating the MGD

The MGD per exposure was estimated using the model published by Dance *et al.*:

$$\mathrm{MGD} = K \times g \times c \times s \qquad (2)$$

An s-factor of 1.042 is applied for the target/filter combination W/Rh[7]. In order to tabulate c-factors Dance *et al.*[7] used prior studies by Young *et al.* [16] and by Beckett and Kotre[17] on breast composition of women attending screening. c-factors were tabulated depending on glandular content, compressed breast thickness and HVL. To simplify the estimation of the mean glandular dose, c-factors for average glandular content for the age group of 40–49 (Table 7 in Dance *et al.*[7]) and for the age group of 50–64 (Table 8 in Dance *et al.* [7]) for a range of thicknesses (2–11 cm) and a range of HVLs (range: 0.30–0.60 mm Al) were tabulated by Dance *et al.*[7]. In Norway, women between the age of 50 and 69 y are screened, and therefore it would be natural to estimate the c-factor for typical glandularities for this age range.

A software program for dose calculations has been developed[18], and this program is widely used when estimating the MGD in accordance with the model developed by Dance *et al.*[19]. In Norway, the NRPA uses its own Excel spreadsheet, so instead of using Table 8, the c-factor may be found from Table 6 in Dance *et al.*[7] where the c-factor is given for breast thicknesses of 2–11 cm (in 1 cm intervals), HVLs 0.30–0.60 mm Al (in 0.05 mm intervals) and 0.1, 25, 75 and 100 % breast glandularity.

Beckett and Kotre[17] found the following relationship between compressed breast thickness (t), different ages (a) and glandularity ($G_{a,t}$) for women in the UK:

$$G_{a,t} = at^3 + bt^2 + ct + d$$

where the factors a, b, c and d are tabulated for women aged 50–64 y in Table 4 in Dance *et al.*[7]. This relationship was used to find the glandularity for the women in this study. The tabulated c-factors for the women in the age group 50–69 y could then

be found more accurately, although Beckett and Kotre[17] found that the mean glandularity does not change significantly from age 64 to 69. Overall, for women aged between 50 and 70 y, the mean glandularity seems to decrease from ~30 % at age 50 y to ~20 % at age 70 y[17]. This was also found by Yaffe *et al.*[20], although they applied a volumetric breast density (VBD) analysis, and estimated the VBD as a function of age:

$$\mathrm{VBD_{sk}} = -0.4813\,\mathrm{age} + 52.71 \quad (3)$$

where $\mathrm{VBD_{sk}}$ is the volume breast density including the skin, and age is measured in years.

The air kerma for the units in the NBCSP is always measured with the compression paddle in contact with the chamber. The original tabulation of g-factors by Dance *et al.*[6] simulated a chamber in contact with the compression paddle, but did not model the scatter from the paddle. In Dance *et al.*[8] published in 2009, the air kerma was measured for different geometries. The configuration with the compression paddle in contact with the ionisation chamber has been normalised to 1.000[8]. In other words, no correction is needed when the air kerma is measured with the chamber in contact with the compression plate.

The tube output (mGy mA s^{-1}) and the HVL were measured for this screening unit and all applied beam qualities (target/filter/kV_p) as part of the annual quality control (April 2009). When measuring the radiation output the compression plate was in contact with the ionisation chamber. When measuring the HVL, the compression plate was at least 180 mm above the table. No extra collimation was applied. These measurements were performed with an ionisation chamber assembly (Radcal Corporation, Monrovia, CA, USA) and with the compression plate in the radiation field. High-purity (99.9 %) aluminium foils were used when measuring the HVL. The centre of the ion chamber was placed 60 mm in from the chest wall side of the breast support edge and 45 mm above the table, and centred laterally. The aluminium foils were placed in the compression plate ~180 mm from the breast support table.

Uncertainties applied in the estimation of the MGD

The MGD per exposure was first estimated for the reported exposure parameters [compressed breast thickness, the tube voltage (kV_p), target material, filter material, exposure tube current and tube loading (mA s)], then in turn uncertainty in compressed breast thickness, HVL and glandularity were added, and the percentage difference per exposure between the dose estimated for the added uncertainty [MGD (with uncertainty)] and the originally estimated dose (MGD) were estimated. The difference (%) per exposure is given as

$$\text{Uncertainty}\,(\%) = \frac{\text{MGD}\,(\text{with uncertainty}) - \text{MGD}}{\text{MGD}} \times 100\%$$

Radiographically, the breast has been considered to consist of two components, fibroglandular tissue and fat[21, 22]. Breast density is the area of the mammogram that appears to be 'glandular' divided by the total area[23]. Breast density is not a static factor[21], but changes with the pre- and postmenopausal phases, height, parity, age at first birth, age and body weight[24–28]. Determination of the breast density can be done by applying qualitative methods, which are highly subjective, or quantitative methods, which are objective[21]. Quantitative methods, such as two-dimensional methods or volumetric density are the two broad classes to determine breast composition[21, 29], but the only accurate way to determine breast density is histopathologic analysis of mastectomy specimens[22]. Large differences can be found between quantitative and qualitative methods[21]. Earlier studies have shown that the main source of uncertainty in estimating glandularity is the uncertainty in the measured compressed breast thickness[9, 10, 30, 31]. Due to the uncertainty in the breast thickness, the volumetric method has not proved more accurate than the area-based method[21]. The glandularities that Dance *et al.*[7] based their measurements on were achieved using two-dimensional information, and is defined as the percentage of glandular tissue within the glandular disk[29], while glandularity is in fact a three-dimensional tissue, and may be defined in different ways than just as an area-based glandularity[29]. Yaffe *et al.*[20] found a mean VBD of 14.3 % with a standard deviation of 10.3 % with the skin excluded. In other words, quite a large uncertainty in the glandularity was found. The MGD in this study was estimated using an uncertainty of 10 % for the glandularity.

Hauge *et al.*[14] found that for the compressed breast thickness, the largest underestimation was 13 mm, while the largest overestimation was 8 mm. The average difference between the measured and the readout compressed breast thickness was ±2 mm for the 18 cm×24 cm format, and ±4 mm for the 24 cm×30 cm format[14].

Dance *et al.*[7] showed that the maximum uncertainty in the s-factor is 2.1 %, which is equivalent to 0.0219 (1.042×0.021, range: 1.020–1.064). An uncertainty in the s-factor of 2.1 % will lead to an uncertainty in the MGD of 2.1 %.

In the European protocol on dosimetry[15], the accuracy and precision of the dosemeter, accuracy and

precision of tube loading meter and accuracy of the backscatter factor has been estimated to ±10, ±5, ±5 and ±1 % (known HVL), respectively. The overall uncertainty in the entrance surface air kerma (ESAK) will then be

$$U_{\mathrm{ESAK}} = \pm\sqrt{10\,\%^2 + 5\,\%^2 + 5\,\%^2 + 1\,\%^2} = \pm 12\,\%$$

RESULTS

Age distribution and uncertainty

All women aged 49–70 y were included in this study. The average age is 57.8 y (95 % confidence interval: 57.5–58.1 y). The age distribution for the women in this study is shown in. Naturally, there are fewer women in the age intervals 45–49 and 65–74 y, because primarily women aged 50–69 y are invited, and therefore there are fewer women in the age intervals 45–49 and 65–74 y. Removing these two age intervals changes the age distribution (Figure 1). In this study, there seems to be more women aged 50–54 and 60–64 y, and less women aged 55–59 and 65–69 y. Since glandularity depends on age, the MGD estimates will be affected, and will not reflect the true age distribution in the population.

An uncertainty of ±1 y has been introduced due to the method of recording. The glandularity is age dependent, and changing the age by ±1 y will change the VBD by ±0.5 %, respectively, according to the relationship between age and VBD developed by Yaffe *et al.*[20]. Assuming the same change in glandularity, a change of ±0.5 % in glandularity results in a change in MGD of 0.2 and −0.2 %, respectively.

Figure 2 together with the age distribution for all women in Norway[32]. In this study, there are more women aged 50–64 y, and fewer women aged 45–49 and 65–74 y compared with the overall age distribution for women in Norway. Naturally, there are fewer women in the age intervals 45–49 and 65–74 y, because primarily women aged 50–69 y are invited, and therefore there are fewer women in the age intervals 45–49 and 65–74 y. Removing these two age intervals changes the age distribution (Figure 1). In this study, there seems to be more women aged 50–54 and 60–64 y, and less women aged 55–59 and 65–69 y. Since glandularity depends on age, the MGD estimates will be affected, and will not reflect the true age distribution in the population.

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Compressed breast thickness distribution

The average compressed breast thickness is 49.5 mm [95 % confidence interval: 49.2–49.8 mm (CC: 47.8–48.5 mm, MLO: 50.4–51.4 mm)]. The distribution of compressed breast thicknesses is shown in Figure 3.

Compression force distribution

The average compression force is 120.3 N [95 % confidence interval: 119.5–121.1 N (CC: 111.8–113.8 N, MLO: 126.6–129.0 N)], and ranges from 27 to 203 N. The average compression force for different thickness intervals is shown in Figure 4. The average compression force for the CC projection seems not

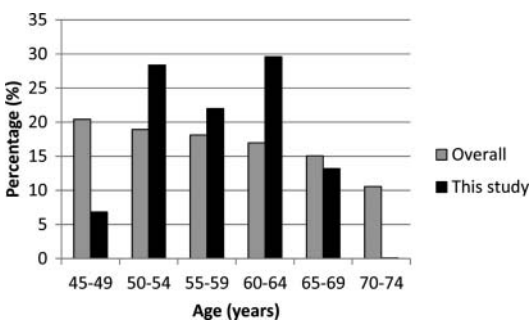

Figure 1. Age distribution for the women in this study compared with the overall age distribution in Norway for women aged 50–69 y.

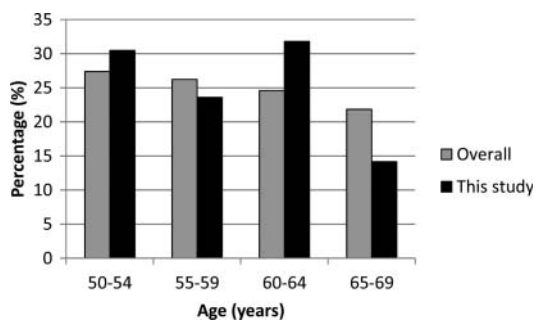

Figure 2. Age distribution for the women in this study compared with the overall age distribution in Norway for women aged 45–74 y.

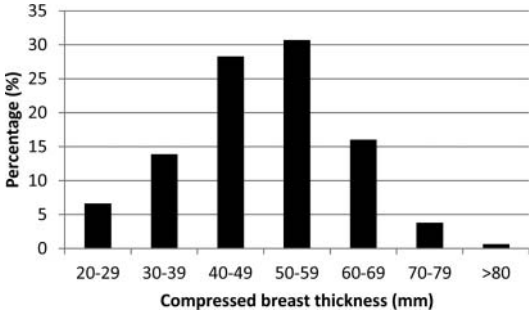

Figure 3. The distribution of compressed breast thicknesses (mm).

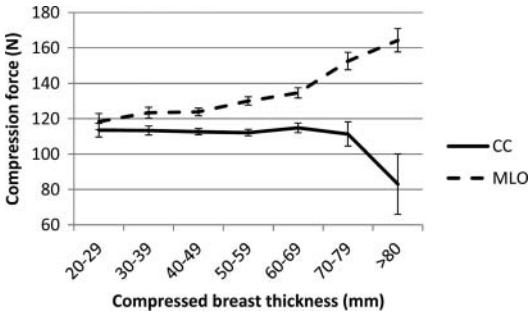

Figure 4. The compression force (N) as a function of compressed breast thickness (mm) for the CC and MLO projections.

to vary significantly with compressed breast thickness, while the average compression force increases with increasing compressed breast thickness for the MLO projection.

Selected target/filter/kV combinations

For the Siemens Mammomat Inspiration, the women were exposed using the 'OPDOSE' program, which selects the kV based on the compressed breast thickness. For compressed breast thicknesses of 20–29 mm, the program selects 26 kV, for 30–39 mm 27 kV is selected, for 40–49 mm 28 kV is selected, for 50–59 mm 29 kV is selected, for 60–69 mm 30 kV is selected, for 70–79 mm 31 kV is selected and for compressed breast thicknesses 80 mm or larger 32 kV is selected. The kV actually chosen for the exposed women are shown in Figure 5.

Glandularity

The relationship between compressed breast thickness and glandularity found by Beckett and Kotre[17] is used to find the glandularity for each projection. Then the average glandularity per woman was found (in general this is the average of four projections). The average glandularity per woman is 31.3 % (95 % confidence interval: 30.3–32.3 %), ranging from 4.8 to 96.9 % per woman. When averaging all projections (4871 projections) the mean glandularity is 37.3 % (95 % confidence interval: 36.8–37.8 %), ranging from 3.4 to 100 %.

Estimated uncertainties for the MGD

The percentage difference per exposure between the dose estimated for the added uncertainty [MGD (with uncertainty)] and the originally estimated dose (MGD) was estimated, and is shown in Figure 6 as percentage uncertainty. This is the total uncertainty in MGD (%). In turn, uncertainty in compressed breast thickness, HVL and glandularity was added. In addition, the uncertainty in kerma and s-factor has been included in Figure 6. The average difference shown in Figure 6 is the average percentage difference for all exposures, minimum is the smallest percentage difference for one exposure and maximum is the largest percentage difference for one exposure.

The total uncertainties in MGD have been ranged in Figure 6 from the smallest to largest uncertainty. The largest contributions to the overall uncertainty in MGD are uncertainties in the air kerma (± 12 %), underestimation of the thickness of $+13$ mm (-10.7 %), change in HVL by -0.05 mm (-9.0 %), overestimation of the thickness of -8 mm ($+8.7$ %) and changing the glandularity to an age-dependent glandularity distribution ($+8.4$ %). A change in the glandularity of ± 10 % will lead to an uncertainty in the MGD of ± 4 %.

Taking into consideration the different uncertainties, the total uncertainty in MGD when applying an uncertainty in the air kerma of ± 12 %, underestimation of the thickness of $+13$ mm (-10.7 %), change in HVL by -0.05 mm (-9.0 %), uncertainty in the s-factor of ± 2.1 % and changing the glandularity to an age-dependent glandularity distribution ($+8.4$ %) will be

$$U_{\mathrm{MGD}} = \pm\sqrt{12\,\%^2 + 11\,\%^2 + 9\,\%^2 + 2\,\%^2 + 8\,\%^2} = \pm 20\%$$

DISCUSSION

Uncertainties of the results

Recording data on paper by radiographers and later transferring the data to Excel files could introduce uncertainties. Of the data reported, 2 % (24/1281) of the women were deleted due to missing data. In

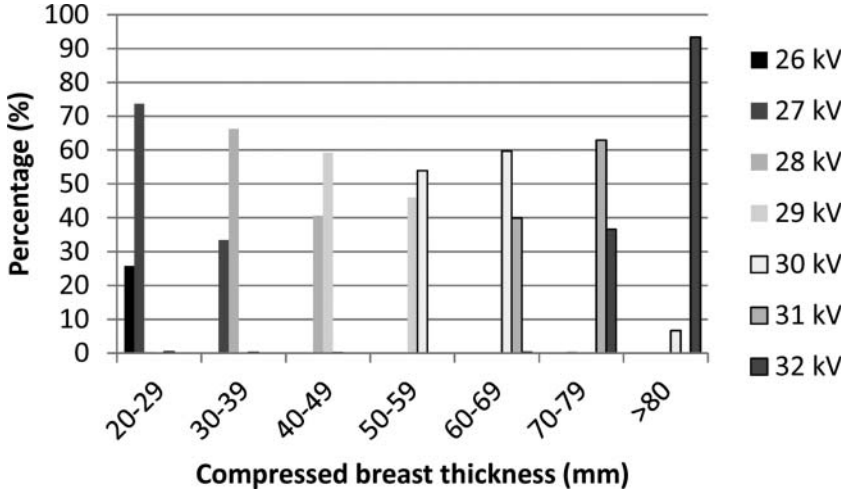

Figure 5. The selected kV for different compressed breast thicknesses.

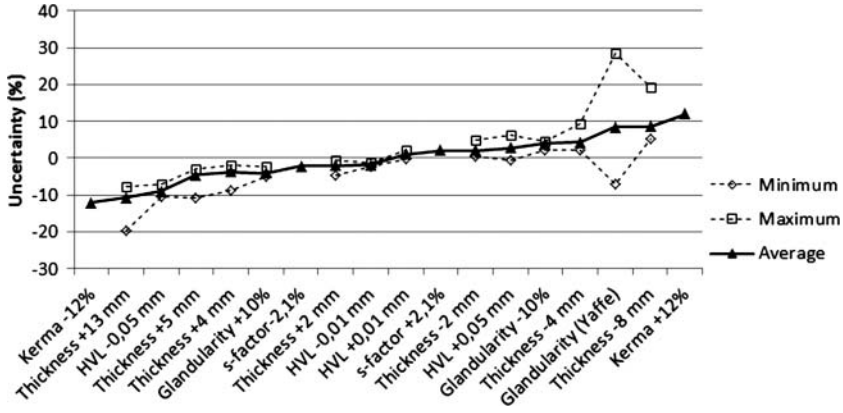

Figure 6. The difference (%) between the MGD estimated for the added uncertainty and the originally estimated MGD for different added uncertainties in kerma, compressed breast thickness, HVL, glandularity and s-factor.

addition, there might be errors in the other exposure values.

The chosen target filter combination depends on the measured thickness, and as a result of the uncertainty the 'wrong' target filter combination is used, which could increase/decrease the dose or affect the image quality.

Tube output and HVL were measured in April 2009, but the exposure factors for the women were collected in January and February 2010. The HVL and radiation output may have changed in this period, adding uncertainty to the data.

CONCLUSION

Uncertainties in thickness and glandularity add to the uncertainty in MGD, but not as much as the inherent uncertainty in the air kerma, given by the European protocol on dosimetry[15]. The total uncertainty in the MGD is estimated to be ~20 %.

ETHICS

Permission to gather data was granted by the Regional Committees for Medical and Health Research Ethics (REC) 22 December 2009. The permission to conduct this study is valid until 31 December 2013. REC is to receive an end report at the latest half a year after the project has ended.

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FUNDING

Q7

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