Optimizing breast reconstructive surgery in the Netherlands using clinical audit data

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CHAPTER 9

General discussion and future perspectives

GENERAL DISCUSSION AND FUTURE PERSPECTIVES

This thesis describes the constitution and results of the first four years of the Dutch Breast Cancer Audit (NBCA), together with factors that may optimize the use of breast reconstructive surgery.

In the years preceding the NBCA, the National Health Care Inspectorate had started to query individual hospitals regarding the possible relationship between volume and outcomes of provided care for patients with various oncologic conditions.[1,2] The results were published in national media and presented as "rankings" that assumedly reflected the quality of care.

In 2011, the endeavors of many clinicians resulted in the constitution of a nationwide breast cancer audit.[3] The joined effort of these clinicians originating from all involved specialties and stakeholders (patients, insurance companies, government) led to a set of 32 quality indicators to gain insight in all aspects of the multidisciplinary care for patients diagnosed with breast cancer (**Chapter 2**). Full participation of the 92 Dutch hospitals was accomplished within two years, resulting in NBCA data of the breast cancer work-up and treatment of 56,927 patients who had been treated between 2011 and 2014. Many indicators showed improvements within the first four years of auditing: the proportion of individual patient cases being discussed in pre-and postoperative multidisciplinary team meetings (from 83% to 98%), the guideline-directed use of BI-RADS (Breast Imaging-Reporting and Data System) classification in the radiological assessment of breast imaging (from 97% to 99%), the proportion of pathology reports containing all clinically relevant items (from 83% to 97%) as well as the rate of tumor-positive margins after first primary breast conserving surgery for invasive breast cancer (from 5.9% to 4.6%).

The percentage of patients treated by breast conserving surgery remained stable during these four years. Hypothesizing that the mere breast conserving surgery rate does not adequately represent the esthetic outcome of local treatment, the rate of undergoing a breast-contour-preserving procedure (BCPP) was coined as an alternative local outcome parameter (**Chapter 3**). The definition of BCPP

encompasses multiple treatment strategies that preserve or restore the contour of the breast, i.e. upfront breast conserving surgery, breast conserving surgery following neo-adjuvant chemotherapy and mastectomy followed by immediate breast reconstruction (IBR). While the rate of breast conserving surgery as primary treatment for breast cancer remained stable over time, the proportion of patients undergoing BCPP increased from 63% in 2011 to 71% in 2015: both the rates of breast conserving surgery following neo-adjuvant chemotherapy and mastectomy combined with IBR increased. The BCPP rate was similar for most age groups, but the means by which the breast contour was maintained varied largely between these groups. An increased use of primary breast conserving surgery in the elderly, and a concomitant decrease in older patients treated with neo-adjuvant chemotherapy or postmastectomy IBR was found.

On average, IBR was performed in 17% of all patients who underwent a mastectomy and this proportion ranged between 0% and 64% in the 92 hospitals. This observed hospital variation in the use of IBR was the basis for the research in **Chapters 4, 5 and 6** into possible patient, tumor, hospital and physicians' factors explaining this variation. Following case-mix correction (for patient and tumor factors that were associated with a higher rate of IBR such as young age, multifocality, small tumor size, low malignancy grade, absence of lymph node involvement), large variation remained between the hospitals (0% to 43%; **Chapter 4**). Hence, hospital organizational factors were collected and compared for all hospitals in the Netherlands (**Chapter 5**). Factors favoring the uptake of IBR related to the observed variation in the institutional IBR rate were: hospital type (district hospitals more frequently performed IBR compared to university hospitals), more plastic surgeons involved in reconstructive breast surgery, attendance of a plastic surgeon at the preoperative multidisciplinary team meeting and a higher institutional rate of performing mastectomies. Next, the potential effect of the involved medical specialties was studied. Since the final decision to undergo/perform IBR is made by patients and their surgical oncologists and plastic surgeons, personal opinions and attitudes of surgical oncologists and reconstructive plastic surgeons towards the decision to undergo IBR were studied. These professional opinions may vary or even differ and therefore questionnaires were sent to the clinicians in a nationwide survey (**Chapter 6**). Plastic surgeons more frequently

reported patient-related risk factors for wound healing problems as an important contra-indication towards advising IBR, while surgical oncologists more frequently underscored oncological contra-indications as reasons to advise against it. The strive for consensus between physicians regarding indications and contra-indications for IBR may optimize patient counseling and shared decision-making. Moreover, being informed about IBR resulted in a 14 times higher chance to undergo IBR and this stresses the importance for clinicians to inform patients about this treatment option to optimize the decision-making process for surgical breast cancer treatment and IBR (**Chapter 7**). In addition to the medical and technical considerations, knowledge about the self-perceived quality of life of patients who underwent IBR is important to take into account for both patients and surgeons in their respective decision and advice for or against reconstructive surgery. From a patient perspective, the self-perceived quality of life in relation to IBR was investigated using patient-reported outcome measures (PROMs). A nationwide quality of life survey was conducted in patients who had undergone mastectomy with or without IBR (**Chapter 8**). Patients who had undergone IBR following mastectomy reported a better quality of life on important psychosocial, sexual and physical well-being domains than patients who had received a conventional mastectomy.

Clinical auditing of breast cancer care in the Netherlands: structuring the outer circle

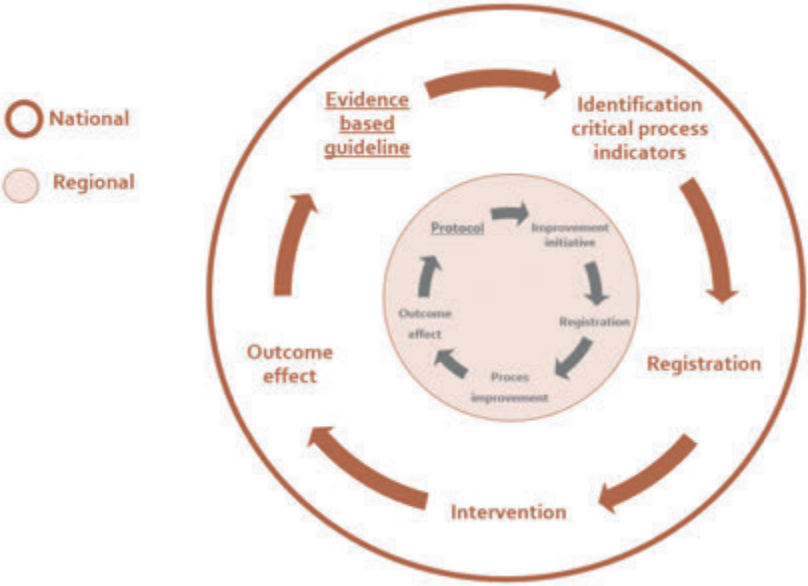
The prelude to the institution of the NBCA was the initiative of the National Health Care Inspectorate to query individual hospitals about the rate of tumor positive margins following breast conserving surgery. The publication of the raw data led to much confusion and it proved to be a poor indicator, because the definition of positive margins turned out to be interpreted very differently by the respective institutions.[4]

After the first year following the initiation of the NBCA and with the introduction of a clear definition of a tumor positive margin, the rate of tumor positive margins following breast conserving surgery proved to be very low and for all participating hospitals well within the confidence interval of the predefined norm. The subsequent publication of the annual results of this indicator and other parameters objectively improved quality of diagnostic work-up and local treatment of breast cancer patients.

From the start of the NBCA in 2011, quality indicators have been adjusted and refined, new ones developed and others abolished, aiming for clearer definitions of process and outcome indicators. Quality parameters should be unambiguous and meaningless indicators should be abandoned. The rate of BCPP, a multidisciplinary indicator of local outcome and an alternative to the mere breast conserving surgery rate well illustrates the continuing adjustment of the Audit's quality parameters. The development of other surgical and non-surgical indicators (e.g. indicators for side-effects related to radiotherapy or chemotherapy) remains "work in progress". Ideally, locoregional recurrence and survival data should become accessible in relation to NBCA data as well. Linking the NBCA data with data in the Netherlands Cancer Registry (NCR) may achieve this without the additional work of collecting more long-term follow-up data.

Measuring quality of care is in itself not a unique concept. Breast cancer audits also exist in other countries like Sweden[5], Australia[6], New Zealand[6] and the United Kingdom[7]. In the United States of America, other databases are used to investigate quality of care to a certain extent.[8] In our country, the NCR has been collecting information regarding treatment and outcomes of breast cancer since 1989 by specially trained data-managers who periodically visit all hospitals in the Netherlands.[9] The NBCA is a result of the collaboration between the Comprehensive Cancer Organization the Netherlands (IKNL), which facilitates the NCR, and the Dutch Institute for Clinical Auditing[10], which facilitates the NBCA. The NBCA has the strength of being initiated by clinicians themselves with drive to improve outcomes of care. It has led to a multidisciplinary, nationwide audit which annually delivers public reports of patient, treatment, and outcome data. Moreover, feedback in the context of benchmark results is provided to individual hospitals and their clinicians treating breast cancer patients, and also an update of the quality parameters. The ongoing process of structuring and restructuring this "outer circle" (**Figure 1**) of the NBCA serves as a quality monitor on a national level and provides a basis to conduct a "Plan Do Check Act" cycle in individual hospitals for the "inner circle".

Figure 1. Outer circle; the Plan Do Check Act cycle on a national level using clinical audit data for improvement of breast cancer care.



The interplay between clinicians and the other stakeholders in the management of the NBCA comes with challenges inherent to the differing perspectives of all participants. The common goal of quality assurance through consistent measurement is evidently acknowledged by all. Yet, while most clinicians strive for optimal outcomes in their individual institutions and acknowledge a reduction in undesirable hospital variation is an important goal, patients and insurance companies at the same time may assign value to observed differences between institutions. They seek discriminative information to identify best practices for their treatment or purchasing for contracting institutions. This "constructive friction" has hitherto strengthened the NBCA.

Interpreting NBCA results

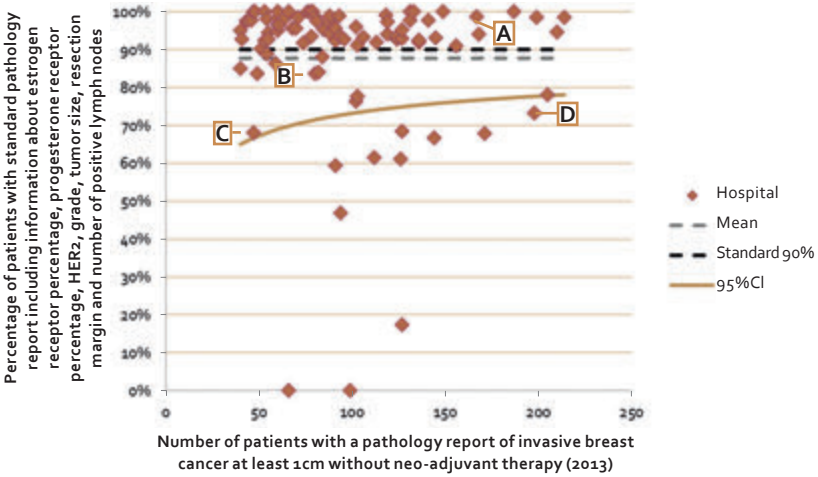
Once quality is unambiguously defined, and a standard of care is translated into a quality indicator with a norm, NBCA results reflect valid and valuable time trends in the delivered breast cancer care in the Netherlands and identify those

institutions that adhere to a predefined quality level. The NBCA has proven its merit by objectifying improvements in the complete tumor excision rates of breast conserving surgery and in radiological and pathological work-up, which underscore the current quality of breast cancer care.[11] Furthermore, a more consistent use of radiotherapy boost was objectivated following publication of national guidelines[12] as well as a decrease in axillary surgery since 2011.[13]

With respect to the identification of true outliers, reality is rather unruly. First, the NBCA usually publishes its annual quality indicator results in funnel plots that depict the indicator for every individual hospital with a certain patient volume within a funnel of 95% confidence intervals corresponding to the number of patients. In a country with approximately 90 hospitals, it is a statistical certainty that two or three hospitals will have divergent results suggesting underperformance, while their results are based on mere coincidence. To overcome this risk of incorrectly identifying underperformers as well as erroneously pointing out best practices, annual benchmark results can be merged by presenting institutional results over a longer time period. This results in tapering of the confidence interval which will enhance interpretation of an institution's audit result. Second, the funnel shaped confident intervals remain at times difficult to explain in particular to the external stakeholders. **Figure 2** shows the quality indicator "percentage of standardized pathology reports for patients with invasive breast cancer". Hospital A (98%) has an unequivocal satisfactory outcome compared to the standard of 90%. Hospital B (83%) is below the standard, but still within the corresponding 95% confidence interval. But for the general public it is less evident that the performance of hospital D (73%) is worse than the performance of hospital C (68%). The provision of quality indicators with funnel plots gives a comprehensive view compared to percentages alone, but also demonstrate that the number of patients should be sufficient.

A standardized pathology report addresses estrogen receptor-, progesterone receptor-, and HER2-status, malignancy grade, tumor size, margin involvement and number of positive lymph nodes (when sentinel node procedure or axillary node dissection was performed)

Figure 2. Funnel plot of variation between hospitals in the percentage of patients diagnosed with invasive breast cancer and with a standardized pathology report. The 95% confidence intervals are displayed around the standard (90%).



In close cooperation with the stakeholders, proper definitions of standards, statistical limitations of data analysis, thorough exploration and interpretation of results are responsibilities of the Clinical Audit Board that accompany its task to publish annual NBCA results.

Within the NBCA, not only quality indicators with clear standards are monitored, but also data are collected regarding the care of all involved disciplines. Much variation is observed in this data and the observed variation may reflect better or innovative care. In many cases the reasons of this variation and a possible association with quality of care are unclear. In that perspective, variation of IBR was extensively investigated in this thesis while others have studied the use of neo-adjuvant chemotherapy[14], radiotherapy[12] and the use of Magnetic Resonance Imaging (MRI)-scanning in the work-up of breast cancer. Current guidelines advise to use MRI-scanning in case of discrepancy between clinical examination and radiology results in patients with lobular carcinoma or high grade ductal carcinoma in situ (DCIS) with an indication for breast conserving surgery,[15] but there is not a clear standard for its use and this lack of consensus is reflected in the observed use of MRI-scanning. Evaluation of NBCA

data revealed that MRI-scanning increased the number of mastectomies for ductal carcinomas, but decreased the mastectomy rate for lobular cancers.[16] The opposite was found after neo-adjuvant chemotherapy, with decreased mastectomy rates for ductal carcinomas, but not for lobular carcinomas.[17] With evidence-based medicine as cornerstone for initiation of guidelines, this practice-based evidence of observed variation provides feedback on actual performances and strengthens the national guidelines (structuring the outer circle, **Figure 1**).

These results show the delicate balance and weighing of audit results in terms of addressing quality of care, and demonstrate the importance of clear and uniform guidelines. Then again, it is not a goal in itself to eradicate all variation and set norms, because variation may also help us to explore new practice patterns and to learn from each other.

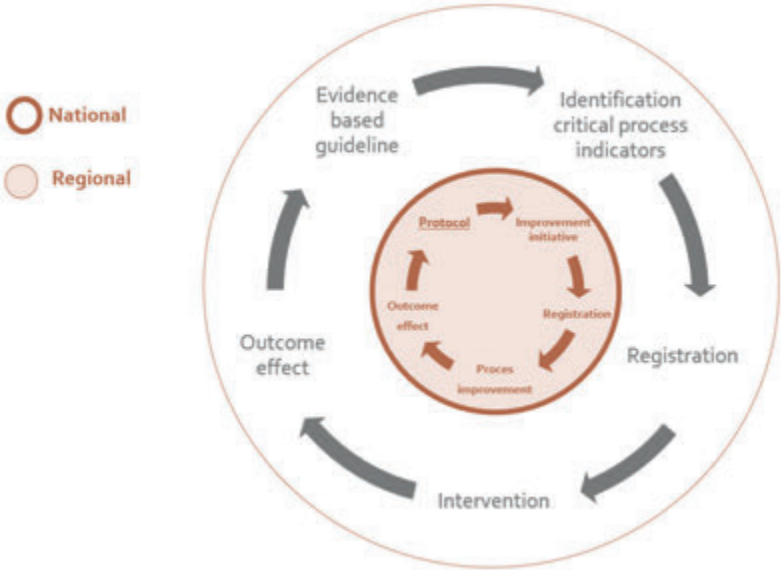
Strengthening the inner circle: the role of Patient-Reported Outcomes Measures (PROMs)

The need for incorporating PROMs in multidisciplinary registries such as the NBCA was called for by patients shortly after the initiation of the NBCA. Adding items that reflect the effects of their disease and its treatment on quality of life enhances the quality overview that the NBCA can deliver for an institution. In addition, the consequences of side-effects of local and systemic treatment, re-interventions, and complications such as breast implant removal or revision due to infection or capsular contracture on patients' psychosocial or sexual well-being, body-image and other quality of life domains may be evaluated.

The additional value of registering PROMs within the context of the NBCA speaks for itself. More important than assessing outcomes using PROMs on a national level is their use in the intimacy of the doctors' office where information regarding other patients' experiences with certain treatments and self-perceived quality of life may better guide shared treatment decisions for the individual patient. Also, PROMs may be used during a patient journey or treatment to compare their quality of life with earlier evaluation moments or with other patients within a similar time frame during an identical treatment. By doing so, this information leads to a greater insight in the effect of the

disease or treatment on perceived quality of life. Some hospitals have started using these PROMs and questionnaires which patients periodically fill out to give them tools when they have to make decisions regarding their treatment. As such, adding results from PROMs have the potency to enhance the inner circle of auditing, i.e. the PDCA cycle in which patients and doctors reflect on the results of and experience with the care that is provided in the institution where the patient is treated (**Figure 3**). By strengthening this inner Audit circle, we will truly live up to the legacy of Ernest A. Codman.

Figure 3. Inner circle; the Plan Do Check Act cycle on a regional and individual hospital level using clinical audit data for improvement of breast cancer care.



With the constitution of a multidisciplinary nationwide audit such as the NBCA, real-world data is disclosed, not only for clinicians, but also for other stakeholders and most importantly for patients. The audit data reveal a good quality of current breast cancer care and areas for improvement with the potential to learn from best practices. With the implementation of PROMs, steps are being made to use these data for personalized medicine, where the data could be used for treatment decisions and self-monitoring of recovery; steps that are essential in achieving an ever-higher level of quality of received care.

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