NBCA-R

Start clinical audit: 2020
Number of records included: 1271
Number of hospitals included: 19

1. Initiation & governance

Close cooperation of the NABON, the Comprehensive Cancer Organisation Netherlands (IKNL) and the Dutch Institute for Clinical Auditing (DICA) led to the institution of the NABON Breast Cancer Audit (NBCA) in 2011.

NABON is a Dutch breast cancer working group that aims to improve breast cancer care in the Netherlands by developing national guidelines, defining quality indicators and standards of care, and by organising post-graduate symposia. IKNL is a quality institution for oncological and oncological palliative care, which hosts the Netherlands Cancer Registry (NCR), in which data of all newly diagnosed malignancies in the Netherlands are registered since 1989. Information regarding treatment and outcomes of breast cancer is extracted from the medical records by specially trained data-managers in each hospital in the Netherlands. Moreover, IKNL is the NABON and NBCA secretary [1,2].

The primary goal of the NBCA is the nation-wide monitoring of quality of care and the provision of feedback to the participating individual hospitals on their outcomes in relation to 'real-time' national benchmark information as a first step to improve the quality of breast cancer care in the Netherlands by enabling institutions to evaluate their data and start improvement projects. The aforementioned scientific committee is responsible for the draft and development of a multidisciplinary set of indicators used to express and monitor the various qualitative aspects of care. Other tasks include in-depth outcomes research and preparation of annual reports for public use to improve transparency [1]. Via a multidisciplinary set of quality indicators, the NBCA contains information about diagnostic procedures, surgery, reconstructive surgery, radiotherapy, neo-adjuvant and adjuvant systemic treatment [1].

Until 2020, only basic radiation data from the individual patient have been recorded, i.e. whether someone received radiation (with or without boost) and whether local or locoregional radiotherapy has been given. To gain more insight in the given irradiation quality and the variation between radiotherapy centers, the Dutch Association for Radiotherapy and Oncology (NVRO) have taken initiative to expand the NBCA with radiotherapy parameters. From 2020, radiotherapy treatment and outcome parameters of all breast cancer patients will be systematically recorded in the NBCA-R.

1.1. DICA

Daily management of the registry is facilitated by the DICA. DICA was founded in 2011 with the objective to facilitate the start-up of new nation-wide clinical audits, following the successful initiation of the Dutch Surgical Colorectal Audit (DSCA) in 2009 [2]. DICA manages and supports clinical outcome registries in the Netherlands, aiming at quality improvement, transparency, and saving costs in health care [3]. At this moment, DICA is responsible for facilitating 22 clinical outcome registries with diverse topics [4].

Dataset

The NBCA-R consists of a data set that records information at patient level about the irradiated areas, the dose given to the target areas and the organs at risk.

Several radiotherapy centers participated in the pilot, which resulted in the development of a dataset in which the data can be entered manually per patient within a maximum of 10 minutes. In addition, an automatic upload module was developed in collaboration with MRDM (a certified Trusted Third Party for medical data), which has been tested in six radiotherapy centers and has proven to be effective. Participation in the NBCA-R is mandatory for all NVRO members from January 2020.

Variation in quality
The NBCA-R provides insight into the radiotherapy given and the possible variation. In order to be able to indicate variation in radiotherapy, the data from the NBCA-R and the NBCA will have to be linked. "Real world" outcome indicators will eventually need to be included in the NBCA in order to develop meaningful indicators for radiotherapy.

2. Data collection, preprocessing & validation

2.1. Data collection NBCA-R

Who generated or collected the data?
Each participating hospital appoints a surgeon responsible for (supervising) the data registration. The data in the registry can be filled manually in a survey or automatically by uploading treatment plans to MRDM. Radiotherapy centers use treatment planning systems to carefully plan treatment for patients with cancer. The radiation therapist, radiation oncologist and medical physicus determine the appropriate treatment plan based on the CT-scan. The data of the treatment is stored in several DICOM files. This DICOM standard enables storage of radiation treatment plans in a similar way for diverse radiotherapy centers and facilitates interoperability. Entry and accuracy of data remain the responsibility of the participating hospitals [1]. To remain up to date, the clinical outcome registry undergoes yearly updates, including removal, adjustments or modification of data points [3].

Which type of data is collected? / Which data sources are used for the collection of data?
Radiotherapy centers transfer per patient a treatment plan for further processing. This treatment plan is a DICOM set consisting of a CT-scan, RT Plan, RT Struct and RT Dose as explained below. From these DICOM sets a selection of variables is derived after calculations (see Data processing).

1. *CT-scan:* a scan of the tumor and relevant organs of the patiënt. This scan is used to plan the radiation therapy and in further treatment to correctly position the patient.
2. *RT Plan:* The RT Plan is used to transfer treatment plans generated in a treatment planning system before or during a course of treatment. Such plans may contain fractionation information, and define external beams and/or brachytherapy application setups.
3. *RT Struct:* The RT Struct consists of patient structures and related data defined on CT scanners, virtual simulation workstations, treatment planning systems and similar devices.
4. *RT Dose:* The RT Dose consists of dose distributions calculated by radiotherapy treatment planning systems. These distributions may be represented as 2D or 3D grids, as isodose curves, or as named or unnamed dose points scattered throughout the volume. This may also contain dose-volume histogram data, single or multi-frame overlays and application-defined lookup tables. This IOD does not provide for definition of doses in beam or other coordinate systems.

When applicable, which measurement devices have been used?
The treatment planning systems used for making the treatment plans differ per radiotherapy center. The plans that are processed were created with treatment planning systems such as Raystation, Pinnacle, Eclipse, Monaco (Elekta).

2.2. Preprocessing

What are the steps performed for data (pre)processing?
1. Processing of DICOM files before prefill into the national database
Files are processed by extracting all relevant DICOM-tags. Dose volume histograms are calculated from the information present in the DICOM files. These histograms are curves that show what dose is received within the structures, and how the dose is distributed throughout the volume.

2. Processing of data of the national database before delivering to the researcher
Patient information is anonymised before transfer of the data to the national database. [2]. A certified Trusted Third Party (MRDM) de-identifies data directly after data entry which makes it impossible to trace back to individual patients [3, 5]. This process complies with the General Data Protection Regulation (GDPR, or AVG in Dutch) [3].

2.3. Data validation

What type of data verification takes place?
1. For each variable within the national database limits are set to only enable filling of a specific range: values cannot exceed these limits. For example, the elective fractions in a treatment plan cannot be less than 1 or exceed 40.
2. Logics are put in place to reject values that can't be correct, e.g. a treatment date cannot be placed in time before a birth date.
3. Radiotherapy centers approve the calculated values by the Trusted Third Party (MRDM) in a testing phase. Only after approval, the values will be read in the production version.

What particularities or limitations about the data should other users be aware of?
When a boost is applied in a treatment plan, the boost is always prefilled as a simultaneous integrated boost for radiotherapy centers that upload their plans. In case there are two records for the same patient within 6 weeks, this was a sequential boost. To use the data one should apply logic to change/add the values for these patients or exclude these patients.

3. References

1. Van Bommel ACM, Spronk PER, Vrancken Peeters MTFD, et al.: Clinical Auditing as an Instrument for Quality Improvement in Breast Cancer Care in the Netherlands: The National NABON Breast Cancer Audit. Journal of Surgical Oncology 2017;115:243-249.
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4. DICA. https://dica.nl/dica/over-dica Accessed 4 September 2020
5. Zorgttp. http://www.zorgttp.nl. Accessed 20 May 2015.