

Development and Implementation of Standardized, Structured Clinical Reporting for Oncology

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Abstract. Reuse of clinical data within the healthcare process and for secondary purposes is particularly valuable. This study emphasizes the crucial role of Standardized, Structured Reports (SSRs) in supporting continuity of care while also advancing reusability of data, decision support functionalities, and accommodating future developments. Integrating SSRs with existing information systems poses a serious challenge. The integration of SSRs with information standards enhances their utility in diverse applications. The significance of SSRs is further highlighted by their seamless integration into healthcare processes, and development and implementation is supported by various available applications. This research contributes to the evolution of medical informatics by emphasizing the importance of collaborative efforts in standardized, structured reporting, all aimed at enhancing patient care.

Keywords. Concepts, interoperability, exchange, registration at the source, reuse

1. Introduction

Reuse of health information from Electronic Health Records (EHRs) is essential for continuity of care and for improving the quality of care through secondary use of data [1]. However, despite many efforts to improve the quality of source data, interoperability in healthcare still lags behind other sectors, and reuse of health data comes at a huge investment to complete and clean up datasets. To address this problem, in this paper we explore the important role of standardized, structured clinical reporting (SSR) in healthcare and present a reusable methodology for developing and implementing SSR's for both continuity of care and reuse for secondary purposes [2]. As a representative example we present a national SSR template for a multidisciplinary tumor board on

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breast cancer, developed in close collaboration with National Breast Cancer Platform of the Netherlands (NABON), that was successfully implemented in several hospitals nationwide. We further discuss several challenges that need to be addressed for successful scaling and maintenance.

This article is the second of a three-part series, delving sequentially into the applied methodology governing an information standard, clinical reporting, and algorithmic decision support. Together, these elucidated methods serve as a robust foundation for effective clinical information management, essential for a learning health system [3].

2. Methods

In the process of digitizing guidelines and standardizing clinical reporting, the National Breast Cancer Platform of the Netherlands (NABON) and the Netherlands Comprehensive Cancer Organization (IKNL) have jointly initiated a project focused on breast cancer. This collaborative effort involves the comprehensive conversion of the entire breast cancer guideline into clinical decision trees, and the development of templates for standardized, structured reporting in radiology and multidisciplinary team meetings. This study specifically focused on the 'primary treatment' process step, aiming to enhance the reporting of the preoperative multidisciplinary team meeting using the methods outlined in this manuscript.

2.1. Care process analyses

At a macro-level, the development of a standardized, structured report (SSR) starts with a comprehensive analysis of the care process and the relevant clinical knowledge. Care process implementations can differ widely across hospitals. To come to a national SSR, we derived an accepted care process from the Dutch Clinical Practice Guideline for breast cancer [4], supplemented by experts through working groups sessions. Concepts within SSRs are composed from the information standard element dataset, following the methodology outlined in the initial paper of this series. Information needs differ at successive moments during the care process. Insights and knowledge about a patient and their condition accumulate as the care process advances. Additionally, various diagnostic and therapeutic interventions provide insight into the patient and their disease based on clinical needs. For example, a choice can be made to determine the size with a sufficient degree of certainty. For instance, in the case of a clinical suspicion of early-stage breast cancer, a mammography can be opted for, or in the case of a suspicion of a higher stage or uncertainty, an MRI of the breast. Underlying this choice is a different patient profile, which should be taken into account when setting up optimal reporting in the templates to be developed.

Various types of examinations are documented during the care path, all building on the image of the patient and their disease that approaches the current situation optimally at a specific moment. Consider, at minimum, intake forms, radiology and pathology reports, clinical notes, treatment plans, and reports of multidisciplinary discussions. The first four types of reports concern initial primary sources, where data is generated based on diagnostic examinations. By harmonizing data via semantic information standards across the entire care pathway, secondary sources like treatment plans and multidisciplinary discussion reports can reuse data from primary sources, such as pathology and radiology reports.

2.2. *Template structuring*

An extensive analysis is done for optimal configuration of clinical reporting at the meso level. Again based on clinical processes, a structure of the template is first established in the form of grouping various concepts. For example, personal details first, then History and Physical Examination (H&P), performance status, and additional research. Next, within the framework of solid cancers, data about the primary tumor, regional lymph nodes, and distant metastases are subsequently recorded. This is followed by a conclusion, of which within oncology often staging is part, and finally (if relevant) advice for further action. Groups can be created at (theoretical) an infinite number of levels. For example, within the group 'diagnostics', the subgroups 'imaging' and 'pathology' can exist, and the subgroup 'imaging' can be subdivided into 'radiology' and 'nuclear medicine', and so on.

By introducing conditionality, an effort is made to restrict clinical reporting to the pertinent patient data for each case. This method maximizes overview and minimizes registration burden. The order of the form is determined by a clinically logical structure. An example is first displaying the 'type of referrer' and then the 'reason for referral'. In practice, conditionality also plays an important role in organizing the concepts. This requires first confirming 'distant metastases' before displaying a field for their 'location'. The same applies to groups; the 'pathology' group is only opened if it has been indicated earlier in the form that pathological results are available. The complexity of conditionality can be deepened by dependencies on multiple concepts and/or values.

2.3. *Inputting Concepts*

At the micro level, we recognize two different types of concepts, namely discrete variables and continuous variables. Discrete variables, when recorded in a semantic information standard, have a fixed list of values encompassing all possible manifestations. In specific use cases, only relevant values are necessary, thus shortening the standard value list to those pertinent to the case. While expanding value lists is permissible, it's advisable to include potential additions in the standard for general applicability, with case-specific values being exceptions.

In different use cases, discrete variables may require single-select or multi-select options. For instance, in breast cancer, where multiple tumor nodules may exist, each nodule's characteristics are recorded individually using a multi-select function. The display order of discrete variable values should reflect relevance; for example, in breast cancer, the most common tumor location, such as the lateral upper quadrant, is presented first under 'tumor location', followed by other values ordered by logic and frequency.

For continuous variables the agreed-upon unit, as available from the information standard, is selected. Moreover, it should be considered whether it should be an integer or a decimals number.

Finally, reports contain primary and aggregated variables, such as age (derived from date of birth and current date) or TNM stage (calculated from tumor diameter tumor growth etc). The calculation and decision rules for aggregated data can be included in the form to reduce registration burden and the chance of errors.

2.4. Analysis

Following the development stage, the template is analyzed to assess the quantity of groups and concepts present. These are further subdivided according to specific characteristics, providing insight into the complexity in facilitating the registration of clinical processes.

3. Results

The modeling of the preoperative multidisciplinary team meeting template was successfully executed according to the described method, and published on the NABON website [5]. EHR and radiology information system vendors were able to implement the templates into their application, for use in clinical practice.

The template consists of a total of 58 groups of which 23 are unique groups. The template comprises a total of 11 unique groups at the highest level of which 5 high-level groups (medical history, breast, lymph node, cTNM, conclusion and treatment plan) encompass subgroups. Depending on laterality, number of findings (breast and lymph nodes) and other conditionalities the total number of groups can be expanded to a total of 58 groups. From the 23 unique groups 10 are conditional.

The template records 27 concepts, with the potential for conditional expansion to a maximum of 312 concepts. Among the unique concepts (85), 51 are choice, 2 are dateTime, 8 are decimal, 5 are integer, 17 and 19 are string. Unique concepts have properties such as conditionality (25), mandatory item (14), multiselect (15), and repetitive item (1).

4. Discussion

To support continuity of care and reuse of data, we developed a methodology to define templates for structured standardized reports. we presented a template for pre-treatment multidisciplinary reporting in breast cancer using this approach.

An important success factor was the collaboration with the multidisciplinary standardization committee from NABON. This collaboration led not only to the development and implementation of various structured and standardized clinical reports (SSRs) supporting breast cancer care processes, but also to a clear governance model. Ultimately, this partnership resulted in the incorporation of these templates into the EHR and radiology systems of dozens of hospitals. The versatility of this method extends to other (non-)oncological conditions.

The practical use of SSRs is influenced by various factors, both positively and negatively. The most frequently mentioned barriers are related to the closed nature of the development process and perceived poor usability of the reports when developed by vendors. By collaboratively developing, implementing, and evaluating SSRs with input from clinicians from several hospitals using multiple EHR systems, common barriers could be addressed [6]. By leveraging the potential of international health information standards such as SNOMED CT, attention could be given to prefilling forms from primary source reports following registration-at-the-source principles.

In anticipation of advancements in medical informatics and artificial intelligence (AI), SSRs can serve as a significant catalyst for applying various functionalities to support healthcare providers [7]. Calling upon decision support, such as guideline recommendations, trial inclusion, prediction models, can be more easily implemented with standardized reporting. Additionally, various developments in large language models or federated learning platforms can be rapidly deployed through the use of SSRs, benefiting both healthcare providers and patients significantly.

5. Conclusion

We presented the successful development and implementation of a standardized, structured template for multidisciplinary reporting in breast cancer care. Anticipating future advancements, SSRs are identified as pivotal for data availability, adopting decision support functionalities, and AI applications.

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