Semantic Interoperability for Integration of Clinical Information and Quality Indicators - Research Plan -

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Abstract. Quality indicators are tools to measure the quality of healthcare. To ensure the validity and comparability of obtained results and to save time, clinical quality indicators should ideally be derived automatically based on previously collected clinical data. Main problems on the path towards automated derivation are the lack of semantic interoperability between quality indicators and clinical data, as well as between heterogeneous clinical data sources, and insufficient data quality. To reach semantic interoperability, I will formalise quality indicators and represent them as well as clinical data in a suitable format in order to apply quality indicators in practice. The novelty of the expected results lies mainly in a method for standardisation and formalisation of quality indicators and a generic approach to automatically calculate quality indicators. Regarding the problem of insufficient data quality, I will contribute data-driven feedback methods to increase the quality of data and awareness on the current performance regarding quality indicators during data entry. The designed methods will be tested in a clinical environment to evaluate their feasibility in practice.

1 Introduction

If you can not measure it, you can not improve it.
Lord Kelvin

A quality indicator[1] is "a measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality, and hence change in the quality, of care provided" [10]. According to Donabedian [4], quality indicators can be related to structure, process or outcome. Process and outcome indicators generally average over specific populations, and are

* I am currently approaching the end of my first year, and this document contains a plan for the next three years.

[1] The term quality indicator is used interchangeably with clinical / medical indicator / measure in this proposal. However, as most measures are only indicators of quality, the term indicator is preferable [12].

often expressed by a fraction or percentage, such as "the percentage of diabetes patients who received regular foot care". More and more clinical quality indicators are released by governments, patient associations, scientific associations and insurance companies in order to monitor or improve the quality of delivered care and to support patients in making informed choices. The increasing amount of indicators together with the fact that they evolve from year to year makes the manual calculation of indicators difficult and time-consuming. In my PhD project, I will integrate quality indicators and clinical data sources to automatically calculate indicators. Users who are capturing clinical data will be supported with timely, personalised feedback on the quality of the entered data and on the current performance with respect to relevant quality indicators.

2 Background: GIOCA

In this project, the GIOCA (Gastro-Intestinal Oncology Centre Amsterdam) will be the clinical domain to carry out research. The GIOCA is a specialised outpatient clinic within the AMC (Academic Medical Centre) where rapid diagnosis is performed for patients with (suspected) cancer in the intestinal tract. Its goal is to put the patient in a central position and to gather all required specialists around him. As the concept of the GIOCA is innovative, its founders are interested in measuring its performance. The GIOCA will be the environment both for the analysis of the current situation regarding the derivation of quality indicators and for the implementation and evaluation of the proposed approach. However, the approach itself will be generalizable.

3 Research Questions and Goals

The main research questions which will be addressed in this project are:

RQ1. What are the requirements to derive quality indicators unobtrusively by using data already collected during the clinical care process?
RQ2. To what extent must and can current processes and systems be adjusted to facilitate data capture at the required quality levels?

The goal of my research is to investigate the requirements regarding the representation of clinical data and the definition of quality indicators to allow for their automated derivation. A second goal is to investigate how current processes and systems must / can be adjusted to facilitate data capture at the required quality levels. All designed methods will be implemented at the GIOCA to prove the concept and to evaluate their feasibility in practice.

4 Addressed Problems

The first addressed problem (Section 4.1, related to RQ1) is that quality indicators are currently not derived automatically from clinical data. The second problem (Section 4.2, related to RQ2) is the lack of adequate data quality to allow for secondary uses of clinical data. Figure 1 depicts these problems.

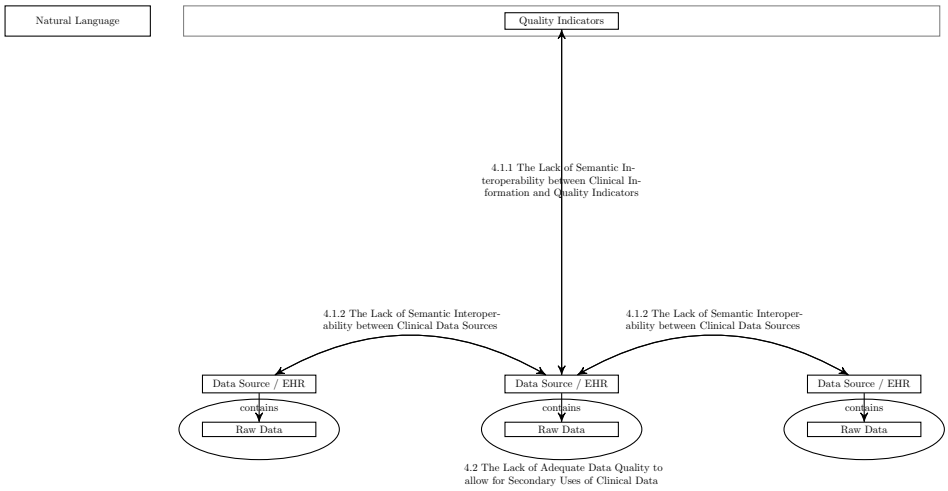

Fig. 1: Addressed Problems (numbers correspond to section numbers)

4.1 The Lack of Support for Automated Derivation of Quality Indictors

Quality indicators are often calculated manually. This problem is mainly caused by two subproblems: The lack of semantic interoperability between clinical information and quality indicators (Section 4.1.1) and the lack of semantic interoperability between several clinical data sources (Section 4.1.2).

The Semantic Health Report [19] identifies four levels of interoperability, two of them relating to semantic interoperability: (0) no interoperability at all, (1) technical and syntactical interoperability, (2) partial semantic interoperability and (3) full semantic interoperability. One of the major goals of this project is to investigate which steps are needed to reach full semantic interoperability between quality indicators and several clinical information sources within the same care-providing organisation in order to facilitate the aggregation of clinical data according to its meaning.

According to [19], the standardisation of the capture, representation and communication of clinical data relies upon three layers of artefact to represent meaning:

1. Generic reference models for representing clinical data
2. Agreed clinical data structure definitions (i.e. information models)
3. Clinical terminology systems

To allow for full semantic interoperability, both the representation of indicators and clinical data must be based on all three layers of representation. True semantic interoperability implies the ability to deal with semantically equivalent constructs and concepts, even if they are heterogeneously represented, i.e. if they use different information models, and / or terminological systems [19].

4.1.1 The Lack of Semantic Interoperability between Clinical Information and Quality Indicators Due to the fact that most indicators are released in *natural language*, the current state of interoperability between quality indicators and clinical data is level 0 (paper), or at most level 1 (pdf). To operationalise quality indicators, they are typically formalised in an ad-hoc manner, which leads to reduced indicator reliability[2] and thus to different formalizations in different institutions. This again causes reduced validity and comparability of their results.

4.1.2 The Lack of Semantic Interoperability between Clinical Data Sources Another aspect of semantic interoperability concerns the aggregation of data that is required to calculate quality indicators. Currently, clinical information is often scattered among several information silos that use different coding schemes, so that it can not be seamlessly aggregated and integrated.

4.2 The Lack of Adequate Data Quality to allow for Secondary Uses of Clinical Data

The calculation of indicators is only one of the many possibilities to (re-)use clinical data. Others are for example the recruitment of eligible patients for clinical trials, decision support, monitoring of public health, reimbursement, the early detection of epidemics and the generation or testing of medical hypotheses. To allow for secondary uses of clinical data, the data needs to be of adequate quality.

5 Approach

The following sections contain an outline of what is already known about each of the addressed problems, the planned approach and methods for solving them, as well as the expected results. Section 5.1 presents the approach to solve the problem that indicators are currently not derived automatically from clinical data (problem 4.1), and Section 5.2 the approach to solve the problem of lacking adequate data quality to allow for secondary uses of clinical data (problem 4.2). Figure 2 gives an overview of the approach.

5.1 Automated Derivation of Quality Indicators

The solution to reach semantic interoperability consists of three steps: the formalisation of quality indicators (Section 5.1.1), their representation (Section 5.1.2), and the representation of clinical data (Section 5.1.3). However, adequate representation of both indicators and clinical data is only the pre-condition to automatically derive quality indicators from clinical data. This last, forth step (Section 5.1.4), is the application of quality indicators in practice. Below, these four steps are discussed in detail.

[2] A reliable indicator is defined so precisely that it is measured in the same way on different occasions or by different observers [10].

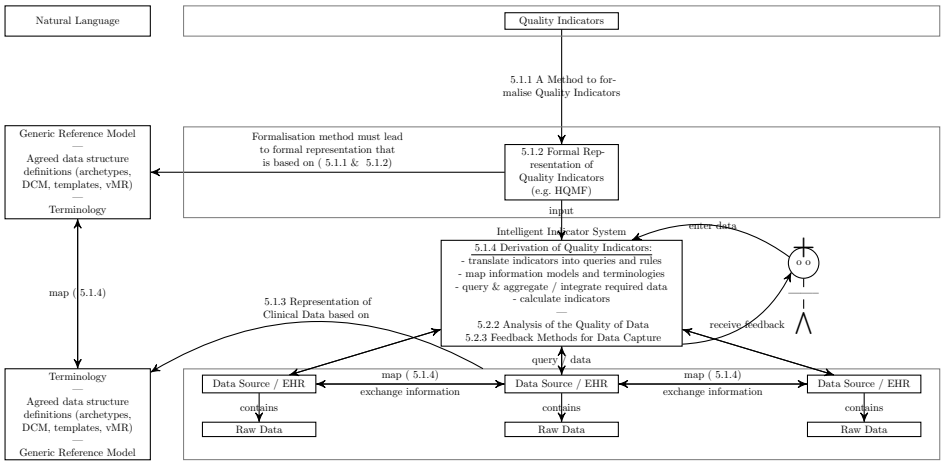

Fig. 2: Planned Approach (numbers correspond to section numbers)

5.1.1 A Method to formalise Quality Indicators

Related Work Some methods to formalise quality indicators from natural language into a representation format have already been proposed (e.g. [21], [18] and [14]), but none of these seems to be ideal. In my opinion, the main problems are that those methods either contain *too little steps* to ensure the equivalence of the natural language representation with all its relevant aspects, or they are not designed to translate indicators into a *computable standardised format*, which is a key requirement to advance semantic interoperability.

Planned Approach and Expected Results The planned approach is to collect requirements that a formalisation method should fulfil. Existing methods will be evaluated with regard to these requirements, and in case that they turn out to be inadequate, a new method will be designed and tested with the help of exemplary quality indicators that are related to gastrointestinal cancer. This method should be as independent of the goal representation format as possible. Data items will be represented using a standard information model, and data values will be represented using a standard terminology (SNOMED CT [3]). The approach could be evaluated by assessing whether the formalisation is reproducible. The expected result is a method for standardisation and formalisation of quality indicators. The method will consist of enough steps to ensure the equivalence of the natural language representation with all its relevant aspects, and translate indicators into a computable standardised format.

5.1.2 Evaluation of Representation Formats for Quality Indicators

Related Work The draft standard Health Quality Measures Format (HQMF)[3], also referred to as eMeasures, is an attempt to introduce a standardised representation of quality indicators. HQMF is aligned with HL7 constructs and allows for consistent and unambiguous representation of indicators. The National Quality Forum (NQF) released a number of quality indicators in the eMeasures format. These eMeasures make use of the Quality Data Model (QDM), an information model that defines concepts used in quality measures. NQF is currently developing a web-based "Measure Authoring Tool" to facilitate the formalisation of quality indicators.

Planned Approach and Expected Results It will be evaluated whether HQMF fulfils all requirements for semantic interoperability. Exemplary quality indicators that are related to gastrointestinal cancer will be expressed in HQMF. The expected result is an evaluation of HQMF, and a set of formalised indicators that are relevant for the GIOCA for further experiments. I will also evaluate whether the developed Measure Authoring Tool by NQF fulfils the requirements for formalisation methods.

Clinical trials are related to quality indicators because both are based on in- and exclusion criteria, while guidelines are related to indicators because indicators are often derived from guidelines. Both formalisation and application of eligibility criteria and guidelines imply many of the problems that are also encountered when formalising and applying quality indicators. Thus, the suitability of representation languages for eligibility criteria (e.g. BRIDG) and guidelines (e.g. ASBRU or GELLO) will be considered. The Arden syntax has already been assessed to be suitable to represent indicators [9]. Figure 3 shows the relationships between quality indicators and clinical trials and guidelines.

5.1.3 Representation of Clinical Data

The representation of clinical data must be based on generic reference models, information models and terminologies so that data from several sources can be integrated.

Planned Approach and Expected Results Clinical data will be modelled with the help of an information model, such as openEHR archetypes. An archetype represents a clinical concept by constraining instances of the openEHR reference model [7]. I will generate random clinical mock-up data that relies on the OWL representation of archetypes [11] as classes to turn "raw" Electronic Health Record (EHR) data into "archetyped" data. The expected result is clinical data (self-generated mock-up data or data from the GIOCA) that is adequately represented.

5.1.4 Automated Derivation of Quality Indicators

This step consists of the *application* of quality indicators. The basic assumption is that all preconditions for semantic interoperability are given, so that indicators can automatically be derived from eMeasures and (mock-up or GIOCA) data.

[3] http://www.hl7.org/v3ballot/html/domains/uvqm/uvqm.html

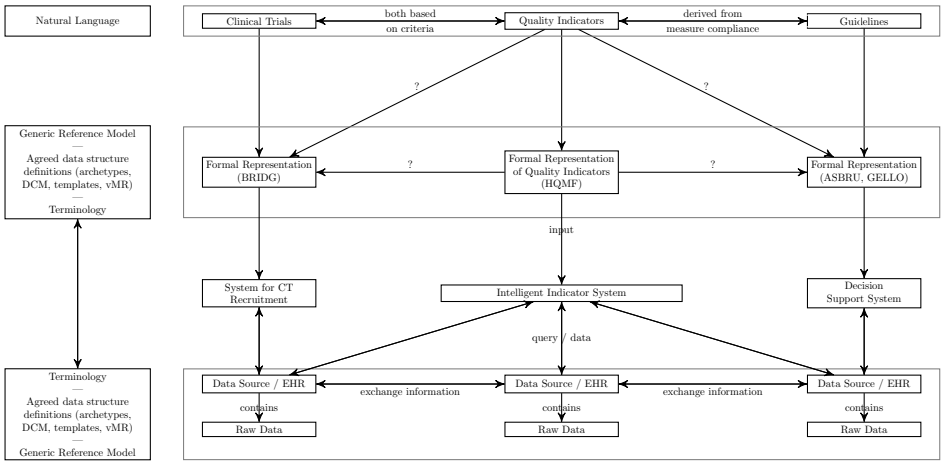

Fig. 3: Relations to Clinical Trials and Guidelines (numbers correspond to section numbers)

Planned Approach and Expected Results To apply quality indicators in practice, the formalised indicators will be *translated* from their formal representation *into executable query and rule languages* to access clinical data and to *calculate indicators* from the retrieved data. Quality indicators usually consist of two queries against an EHR, one for the numerator and one for the denominator. Thus, it seems to be feasible to translate indicators into (semantic) queries. The employed information models (QDM and openEHR archetypes) and terminologies will be *mapped*. I will first derive quality indicators automatically based on mock-up data to prove the concept and to investigate the limitations of current standard query and rule languages and tools such as Semantic Web reasoners and triple stores. Once this proof-of-concept automated derivation of indicators was successful, the approach will be tested on several "real" clinical data sources from the GIOCA. Data from several sources will have to be *aggregated / integrated*. The result will be a generic approach to automatically calculate quality indicators.

Related Work The authors of [15] present a rule-based "Analytics Engine" that is capable of interpreting eMeasure documents and generating reports. The authors of [2] use SWRL for clinical trial recruitment. Patel et al. [16] showed that matching patients to clinical trials can be formulated as a problem of semantic retrieval. None of the above studies (except from [2], that uses a thin information layer composed by observations that connect values taken from the real information model) is based on agreed clinical data structure definitions. Another distinguishing feature of my system is that it will deal with data that stems from several sources.

5.2 Facilitation of High-Quality Data Capture

The current process of data capture and the requirements to optimise the process for capturing high-quality data at the GIOCA will be analysed. To facilitate the capture of high-quality data, I will implement a system that supports staff members at the GIOCA to adequately capture clinical information that is required to calculate indicators. This system will provide its users with feedback on the quality on entered data as well as on the current performance on quality indicators.

Related Work Numerous studies ([6], [5], [22], [9], [17]) have shown that insufficient data quality is a big obstacle to the automated derivation of quality indicators. Easier and faster data capture at the point of care remains a major challenge [8]. Mack et al. [13] developed WebSMR (Surgical Medical Record), a standardised web-based synoptic operative report, to define and improve the quality of cancer surgery. Surgeons record the steps of an operation including elements critical to decision-making in real-time in a standardised, analysable format, and both individual and provincial aggregate outcomes can be reviewed for quality improvement. The improvement of data quality is also relevant in medical registries and clinical audits. Arts et al. [1] developed a framework of procedures for data quality assurance in medical registries. Central and local procedures are "subdivided into (a) the prevention of insufficient data quality, (b) the detection of imperfect data and their causes, and (c) actions to be taken / corrections".

5.2.1 Analysis of the Current Situation and Requirements The current process of data capture and calculation of quality indicators at the GIOCA will be analysed by observations and interviews. Based on this analysis, use case models, interaction models, and class models will be developed. Also, the requirements to optimise the process for capturing high-quality data at the GIOCA will be analysed.

5.2.2 Analysis of the Quality of Data The quality of data captured electronically during the care process at the GIOCA will be analysed. "Archetyped" data could be validated to find integrity constraint violations, such as implausible, incorrect or invalid data values. Also data quality according to Wyatt [23] will be considered. The expected result is an assessment of the quality of the underlying data for a number of relevant quality indicators.

5.2.3 Feedback Methods for Data Capture A system that supports staff members at the GIOCA to adequately capture clinical information that is required to calculate quality indicators will be implemented. It will provide *feedback on the quality of preceding data capture as well as motivation for additional data capture* in the context of specific quality indicators, especially with respect to those data items that need to be entered or further specified. It will make use

of (local) procedures for data quality assurance [1]. The system will additionally provide *data-driven feedback on the current performance on indicators as well as support to increase the performance on process indicators.* The result will be adapted or new software that fulfils the requirements, as well as data-driven feedback methods to increase the quality of entered data. The system will be evaluated based on its performance and previously defined requirements. The quality of data and derived indicator values before and after the introduction of the system will be compared.

6 Open Issues

One of the issues that remains open is how to integrate the three layers of representation. Current data integration efforts typically concern the mapping of only one layer of representation, i.e. terminology. I will additionally work with generic reference models and information models, so that those will also have to be mapped. Difficulties are expected in cases where a construct makes use of a terminology in one of the sources, but is represented in an information model in another source.

Another open issue is the amount and level of detail of the required data, and how / when to collect it. This is also related to the open question of how to deal with missing data elements. Some elements can be collected retrospectively, while others can only be collected during a certain point of time. If a missing element can not be collected retrospectively, it is unclear how to deal with the corresponding patient. Should she be excluded from the population? Or should a probable value be assumed, as in [20]? In some cases, statements that are not known to be true can be interpreted as being false (closed world assumption; e.g. pharmacy data), while in other cases, the absence of a statement does not lead to an interpretation of its truth value (open world assumption; e.g. radiology and laboratory data). Thus, open and closed world reasoning will have to be integrated [16].

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