Scientific Research Project Proposal

Supervisor name (same as in SRP checklist): Tim Postema
Supervisor email address (same as in SRP checklist): tim.postema@nictiz.nl
Position: Manager Strategy and Advice, Nictiz
Telephone: +31 6 5476 1029

Title of SRP project: Impact analysis of information requirements for quality indicators and registries

Location of SRP project: Nictiz, The Hague, the Netherlands, with hybrid working and stakeholder interviews

Introduction

Healthcare professionals record data primarily to support patient care. Information standards, clinical information models, terminologies, value sets and implementation guides help healthcare organisations record and exchange these data consistently. Dutch examples include information standards and clinical information models such as zibs, SNOMED CT and FHIR implementation specifications.(1,2,3,4)

The same data are reused for quality indicators, outcome measurement, transparency, research and other secondary purposes. This reuse is becoming more important in the European Health Data Space, which establishes a legal framework for both primary and secondary use of electronic health data. Indicator guides and quality registries therefore specify which data healthcare organisations must submit.(5)

These secondary-use requirements do not always match the products used for primary care. They may also differ from one submission or registry to another, even when they appear to ask for the same concept. Such differences can reduce data quality and comparability and can create duplicate maintenance and additional registration work.(6)

A phased impact analysis is needed to make these differences visible. The analysis will start with indicator guides and will then be tested on a limited selection of quality-registry requirements. It will show what primary-use information products already cover, where secondary requirements differ from each other, and what changes are needed to bridge the gaps.

Description of the Problem and SRP Project

Problem

Responsibility for secondary-use information products is spread across several organisations. Coordination between the management of primary-use and secondary-use products is still limited. As a result, the same concept may be defined, coded or released differently in separate submissions. This creates a risk of semantic divergence, double maintenance, extra implementation work and data that cannot be compared reliably.

1HL7 International. (2023). FHIR Release 5, version 5.0.0. https://hl7.org/fhir/

2SNOMED International. (n.d.). What is SNOMED CT? https://www.snomed.org/what-is-snomed-ct

3Nictiz. (n.d.). Zibs and information standards. https://www.nictiz.nl/wat-we-doen/activiteiten/zibs/zibs-en-informatiestandaarden/

4Nictiz. (n.d.). Standards for health data and exchange. https://www.nictiz.nl/standaarden/

5European Parliament and Council of the European Union. (2025). Regulation (EU) 2025/327 on the European Health Data Space. https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng

6Kahn, M. G., et al. (2016). A harmonized data quality assessment terminology and framework for the secondary use of electronic health record data. eGEMs, 4(1), 1244. https://doi.org/10.13063/2327-9214.1244

Scope and phased approach

The unit of analysis is one required data item in an indicator guide or quality registry. Phase 1 will analyse two or three indicator guides. Phase 2 will apply the method to a manageable set of requirements from one or more quality registries. Patient-level data are outside scope; the study analyses definitions, specifications and stakeholder knowledge.

Examples of differences to be studied

Concept	Possible difference between submissions	Question for primary-use coverage
Date of diagnosis	First clinical diagnosis versus confirmation date or registry-entry date.	Is the intended event and date already represented, or is an extra rule required?
Smoking status	Different categories, reference dates or rules for unknown values.	Can one value set be reused, or are mappings and submission-specific rules needed?
Blood pressure	Latest value versus average value; different measurement windows or patient positions.	Are the measurement context and calculation rules available in the primary data?

Method

1. Select two or three indicator guides and a limited quality-registry case with comparable concepts.
2. Record each required item: meaning, population, inclusion rules, timing, unit, permitted values, terminology and calculation rules.
3. Group items that concern the same or a closely related concept and compare their requirements across submissions and registries.
4. Compare each requirement with relevant primary-use information products, including the new clinical information building blocks. Classify coverage as direct match, match after a rule or mapping, partial match, or no match.
5. Record each difference in an impact matrix, including missing data, additional mapping or specification, ownership, maintenance, release agreements and implementation effects.
6. Validate the findings with product owners, indicator experts, quality registries, healthcare providers and software suppliers.

Mappings will be described transparently, including their purpose, direction and limitations, in line with recognised mapping principles. Management and release recommendations will distinguish ownership, maintenance decisions and change control, consistent with the principles of NEN 7522.[7]

Analysis and ethics. The comparison and impact matrix will support a thematic analysis of recurring difference types and their effects. The study does not require patient-level health data. Interview participants will receive study information and give informed consent. Identifiable interview data will be minimised, stored securely and reported in aggregated or anonymised form in accordance with UvA requirements.

Research objective and research questions

Research objective

The objective is to develop and test a practical method that shows where selected secondary-use information requirements agree with each other, where they differ, how well they are covered by primary-

7NEN. (2021). NEN 7522:2021 Health informatics - Development and maintenance of standards and systems of standards. https://www.nen.nl/en/nen-7522-2021-en-324054

8International Organization for Standardization. (2014). ISO/TR 12300:2014 Health informatics - Principles of mapping between terminological systems. https://www.iso.org/standard/51344.html

use information products, and what governance, release and implementation changes are needed to close the gaps.

Main research question

To what extent do selected Dutch indicator guides and quality registries use the same meaning and requirements for comparable data concepts, how well are these requirements covered by primary-use information products, and what changes are needed where they differ?

Subquestions

1. Which data concepts, definitions, values, time rules and inclusion rules are required by the selected indicator guides and quality registries?
2. When different submissions request the same or a similar concept, where do their meanings and requirements match and where do they differ?
3. Which requirements are covered directly, after a rule or mapping, partly or not at all by existing primary-use information products, including the new clinical information building blocks?
4. Which data, mappings or additional specifications are needed to close the identified differences?
5. What changes in ownership, maintenance and release agreements are needed to keep information products and submissions aligned?
6. What is the likely impact of these changes on software, testing, data capture and data submission?

The questions were checked for clarity, focus, complexity and answerability using the University of Minnesota guidance on research questions. The selected cases will be defined before data collection so that the scope remains feasible within the SRP period.9

Expected results

1. A simple and reusable comparison method and impact-analysis template.
2. An inventory of concepts and rules in the selected indicator guides and quality-registry cases.
3. A comparison showing where submissions request the same concept but use different meanings, values, reference dates, populations or inclusion rules.
4. A coverage matrix showing which requirements match primary-use information products directly, after a rule or mapping, partly or not at all.
5. A gap list describing missing data, mappings and specifications, with examples such as diagnosis date, smoking status and blood pressure.
6. An assessment of the effects on ownership, maintenance, release planning, software, testing, data capture and submission.
7. A prioritised action list and a proposal for extending the analysis to additional quality registries.

The final academic outputs will be an SRP thesis and presentation. The practical outputs will help Nictiz and partner organisations decide which differences can be solved through a shared definition, which require a mapping or submission-specific rule, and which require changes to primary or secondary information products.

9University of Minnesota Libraries. (n.d.). Characteristics of a good research question. https://libguides.umn.edu/c.php?g=1337354&p=9854773

References

1. Nictiz. (n.d.). Standards for health data and exchange. https://www.nictiz.nl/standaarden/
2. Nictiz. (n.d.). Zibs and information standards. https://www.nictiz.nl/wat-we-doen/activiteiten/zibs/zibs-en-informatiestandaarden/
3. SNOMED International. (n.d.). What is SNOMED CT? https://www.snomed.org/what-is-snomed-ct
4. HL7 International. (2023). FHIR Release 5, version 5.0.0. https://hl7.org/fhir/
5. European Parliament and Council of the European Union. (2025). Regulation (EU) 2025/327 on the European Health Data Space. https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng
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7. International Organization for Standardization. (2014). ISO/TR 12300:2014 Health informatics - Principles of mapping between terminological systems. https://www.iso.org/standard/51344.html
8. NEN. (2021). NEN 7522:2021 Health informatics - Development and maintenance of standards and systems of standards. https://www.nen.nl/en/nen-7522-2021-en-324054
9. University of Minnesota Libraries. (n.d.). Characteristics of a good research question. https://libguides.umn.edu/c.php?g=1337354&p=9854773

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