Model-based Analysis of HL7 CDA R2 Conformance and Requirements Coverage

Abderrazek Boufahja, Eric Poiseau, Guillaume Thomazon and Anne-Gaëlle Bergé (IHE-Europe / gazelle team)
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IHE is an initiative by healthcare professionals and industry to improve interoperability between healthcare IS. A non-for-profit association attached to IHE. Develop Test tools and organize European Connectathon.

Connectathon (CAT)

A meeting between healthcare systems developers in order to test the interoperability between their systems/devices. Next one: Luxembourg.

Gazelle

An open source test-bed platform that provides a wide set of tools to validate information exchange between healthcare systems. Use of CDA validation tools to validate against IHE specifications which are based on CDA standard.
Scope of the paper

- Study the basic requirements in the CDA standard which are not expressed in the XSD schema
- Out of scope:
  - Validation of requirements related to specific implementation guides/profiles
Outline

- State of the art
  - Conformance validation steps
  - CDA conformance validation tools
- HL7 CDA R2 requirements identification
- Gazelle ObjectsChecker methodology
  - Principle and advantages
  - Application 1: National projects Samples Studies
  - Application 2: IHE Schematrons Validation Studies
- Most Frequent Errors in CDA Documents
- Tooling: CDA Basic Requirements Coverage Analysis
Conformance validation steps

- art-decor
- trifolia
- MDHT
- Gazelle ObjectsChecker
- Eclipse Instance Editor
- Nist Validation tool
- schematrons from regional projects
- etc
Extraction of all CDA requirements not expressed in the XSD schema from:

- HL7 Clinical Document Architecture, Release 2.0
- HL7 Reference Information Model, Release 2.07
- Data Types - Abstract Specification, Release 1, 2004
- XML Implementation Technology Specification - Data Types, Release 1, 2004

The output: a document named «HL7 CDA R2 Basic Requirements» (reference 12)

A unique reference that uniquely identifies the CDA basic requirements

Number of requirements found: 160
Gazelle ObjectsChecker methodology
Principle(1)

- Gazelle ObjectsChecker is a tool developed by IHE Europe for the validation of CDA requirements.
- A methodology to describe informal requirements in healthcare IT standards into a formal description.
- Express all the requirements extracted from the CDA standard using a formal constraint language.
Gazelle ObjectsChecker methodology
Principle(2)

- HL7 CDA R2.0
- HL7 RIM R2.07
- DT - Abstract Specification R1
- XML ITS - DT R1

Requirements Entry

- OCL Processor (DresdenOCL)

M2T Processor (Acceleo)

M2T templates

- XML
  - Java XML Binding
  - JAVA Validator
  - Java Unit Testing
  - Validator Documentation
Gazelle ObjectsChecker methodology

Advantages

- Support of complex requirements (complex algorithm, etc)
- Conditional /iterations validation
- Data types requirements checking
- Validation against coded value sets
- Allows linking between rules and requirements

High requirements coverage capability
Application 1: National Projects Samples Studies

153 samples from different European and north American national projects

2200 errors found using Gazelle ObjectsChecker: an average of 14 errors per document!!!
Application 2: IHE Schematrons Validation Studies

- 1700 “valid” IHE CDA samples based on schematrons validation
  - 18000 errors detected by gazelle ObjectsChecker
    - 11 errors per document
  - 60 different kind of errors found

**Conclusion ?**

1- Many CDA basic requirements are not checked by the schematrons
2- The weakness of schematrons could spread to healthcare systems
Most Frequent Errors in CDA Documents found by Gazelle ObjectsChecker

- **DTITS-007**: the use of reference element under an ED data type
- **CDADT008 /CDADT-006**: the use of attributes related to CD data type (nullFlavor, code, displayName, etc)
- **CDADT-011**: the use of UUID structure
- **CDADT-013/CDADT-014**: the specification of URL references
- ...

2 kinds of errors:
- Errors that may create troubleshooting for document consumer systems
- Errors that Corrupt of Healthcare Information
Requirement Coverage Indicator Specification

- Describes the % of requirements tested by a validation tool, regarding the total number of requirements

\[ I_{cov} = \frac{N_{cr}}{N_{tr}} \]
How to identify the conformance of a CDA document regarding the CDA standard and validated against a validation tool?

(Requirements Coverage Indicator, Number of errors found)

\[(I_{cov}, N_{error})\]

Tools of validation SHALL always provide a report of their coverage indicator
Conclusion

- Insufficiency of XSD schema validation for CDA documents
- A big number of CDA validation tools are far from covering 100% of basic CDA requirements
- The national projects in Europe need to improve the validation tools they use to increase the quality of their CDA documents
- Validation tools should provide requirements coverage reporting
- Gazelle ObjectsChecker was efficient to detect errors in national projects samples

Perspective

- Possibility to extends Gazelle ObjectsChecker methodology to other XML based standards like HL7V3, FHIR, etc
- Possibility of coupling Gazelle ObjectsChecker with some editors of CDA requirements
Any question?
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