REQUIREMENTS REGARDING QUALITY CERTIFICATION OF ELECTRONIC HEALTH RECORDS

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Agenda
Overview

• Introduction and Motivation
• Study design
  – Aims, methods, characteristics
• Selected Results
  – General requirements and important areas for certification
  – Existing certifications and relevant sources for certification
  – Specific requirements regarding EHRs
• Summary and Discussion
Introduction and Motivation

Initial Situation

• Projects are more and more moving from a scientific environment to real life implementations.
• We are on the edge of the realization of nation-wide EHR projects in different countries such as Denmark.
• More and more private organizations join the EHR market e.g. Microsoft, Siemens or Google.
• Heterogeneous stakeholder groups → no consolidated view on requirements, different strength, different interests, …
• So far external quality controls are missing or are insufficient respectively not institutionalized
• Quality Management/Assurance on different levels is needed to guarantee a basic level of quality.
Study design
Aims and methods

• **Aim:**
  – Study is part of the development process of a comprehensive certification framework including a large requirements repository, a quality meta-model, its formal representation, a structural meta-model for requirements, a thesaurus/concept map for requirements and a process model.
  – Determine basic requirements for the development of a quality certification framework

• **Methods:**
  – Qualitative problem-centric interviews (Face to face or CATI)
  – Number of experts was determined using a combination of selective and theoretical sampling
  – Qualitative content analysis
Study design

Characteristics

• **Content:**
  – General requirements with regard to the quality certification of EHRs
  – Most important areas for the certification of EHRs
  – Existing certifications for EHRs and judgment of these
  – Other sources relevant for the development of a quality certification
  – Specific requirements to an EHR that should be included in quality certification

• **Number of experts:** 29 (55 contacted)

• **Domains:** legislation, standards, norms, data security, industry and science.

• **Countries:** Austria, Germany, Belgium, UK, Italy, Slovenia, France
Results
General Requirements regarding Certification 1/2

• In total more than 60 requirements were named by the experts.

• Most important organizational and process related requirements:
  • Certification bodies should be trustworthy; preferably a public body (31%; n=9).
  • Certification should be open and traceable e.g. criteria or processes (24%; n=7).
  • Certification should be repeated in intervals (21%; n=6).
  • The certification should be understandable by citizens (17%; n=5).
  • Certification should be valid for Europe or world-wide (17%; n=5).
  • The certification body itself should be subject to supervision (10%; n=3).
Results
General Requirements regarding Certification 2/2

• *Most important structural requirements and requirements regarding the content:*
  
  • Certification should be adaptable to suit different content e.g., patient-related information versus general medical information (24%; n=7).
  
  • Certification criteria should be taken from existing standards, norms and best practice examples (21%; n=6).
  
  • Certification should be organized as a seal of approval/quality (21%; n=6).
  
  • There should be specialized partial-certifications such as security or usability (17%; n=5)
Results

Most important areas for certification 1/2

- 83% (n=24 experts) named data protection, data security or both of them as an important area for certification. These two areas account for 38% (n=28 answers) of all answers given for this question.
- Followed by usability and accessibility which were mentioned nine times (12% of answers) each.

<table>
<thead>
<tr>
<th>Area of certification</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data protection</td>
<td>15</td>
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<tr>
<td>Data security</td>
<td>13</td>
</tr>
<tr>
<td>Usability</td>
<td>9</td>
</tr>
<tr>
<td>Accessibility</td>
<td>9</td>
</tr>
<tr>
<td>Content</td>
<td>7</td>
</tr>
<tr>
<td>Interoperability</td>
<td>6</td>
</tr>
<tr>
<td>Availability</td>
<td>6</td>
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</table>

<table>
<thead>
<tr>
<th>Area of certification</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functions</td>
<td>3</td>
</tr>
<tr>
<td>Fault tolerance</td>
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</tr>
<tr>
<td>Workflow/Processes</td>
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</tr>
<tr>
<td>Scalability</td>
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<tr>
<td>Stability</td>
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<tr>
<td>Maintainability</td>
<td>1</td>
</tr>
<tr>
<td>Changeability</td>
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</tr>
</tbody>
</table>

Total no. of answers 74
Results

Most important areas for certification 2/2

- In comparison to the ISO 9126 categories the majority of the answers can be assigned to the functionality category (59%, n=44) of the standard.
- This reflects existing certifications such as the ones developed by CCHIT or EuroRec.

<table>
<thead>
<tr>
<th>ISO categories</th>
<th>Number</th>
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<tbody>
<tr>
<td>Functionality</td>
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<tr>
<td>Usability</td>
<td>19</td>
</tr>
<tr>
<td>Availability</td>
<td>6</td>
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</table>

<table>
<thead>
<tr>
<th>ISO categories</th>
<th>Number</th>
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</thead>
<tbody>
<tr>
<td>Maintainability</td>
<td>4</td>
</tr>
<tr>
<td>Reliability</td>
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</tr>
</tbody>
</table>
Results
Existing certifications for EHRs and judgment

• 60% (n=15) of all experts asked admitted that they do not know about an EHR specific certification.
• Answers that were given were often very general and ambiguous e.g. an approach of the NHS.
• Skipping non-specific or “wrong” answers only nine experts were able to name one or more EHR-related certifications.

<table>
<thead>
<tr>
<th>EHR-specific certifications</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>10</td>
</tr>
<tr>
<td>Only non specific certifications (e.g., data protection, usability, etc.)</td>
<td>5</td>
</tr>
<tr>
<td>Connectathon/IHE</td>
<td>9</td>
</tr>
<tr>
<td>Q-Rec/ProRec</td>
<td>4</td>
</tr>
<tr>
<td>CCHIT</td>
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<tr>
<td>Cobit</td>
<td>2</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>EHR-specific certifications</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data protection seal</td>
<td>1</td>
</tr>
<tr>
<td>Schleswig Holstein (Germany)</td>
<td>1</td>
</tr>
<tr>
<td>IT basic protection catalogue (IT-Grundschatz, BSI, Germany)</td>
<td>1</td>
</tr>
<tr>
<td>Certifications for Health Websites</td>
<td>2</td>
</tr>
<tr>
<td>Approach of the NHS</td>
<td>1</td>
</tr>
<tr>
<td>Approach in Ireland</td>
<td>1</td>
</tr>
<tr>
<td>Blacklists</td>
<td>1</td>
</tr>
</tbody>
</table>
Results

Other relevant sources

• Very heterogeneous answers could be observed, including one exception, seven experts (24%) mentioned the IHE as an important source for certification.
• Other sources that were mentioned: Health on the Net (HON), CEN 13606, SNOMED, UMLS, ICD 10, openEHR or HL7.
Results
Specific requirements to an EHR – Selected results 1/3

• Usability:
  • Information search must be easy
  • Low complexity of the system
  • Possibility to customize the user interface
  • Only relevant data is displayed
  • Same User interface structure and composition

• Content/Information:
  • A content management system must be offered
  • Only validated information is allowed
  • Information must be correct and complete
  • Author of information must be assigned
Results
Specific requirements to an EHR – Selected results 2/3

- **Security/Data protection:**
  - *In General:*
    - Security relevant parts of the software must be open to the public
    - Sophisticated access-management must be available
    - Single-Sign-On
  - **Confidentiality:**
    - The patient/citizen grants access to his information
    - Secure transmission of data
Results
Specific requirements to an EHR – Selected results 3/3

• Security/Data protection:
  • Availability:
    • Availability is defined by the type of information it concerns.
    • Definition of SLAs.
  • Authenticity:
    • Use of personal signatures
    • Detailed logs about all actions in the system

• General Requirements:
  • Use of Standards within the systems (e.g.: IHE, CEN, openEHR, CDA, DICOM, HL7)
Discussion

Summary

• Summary EHR Certification:
  • Public body in terms of a seal of quality
  • All areas should be covered, particularly functional requirements
  • Open/Understandable to the public including patients
  • Certification criteria and content should be taken from existing standards, norms etc.
• Results show great parallels compared to existing efforts such as EuroRec or CCHIT.
Discussion

Outlook

• Missing importance of non-functional requirements?
• Separation of applications (on user level) and EHR infrastructure necessary?
• EuroRec is currently defining such minimum requirements for EHR-systems and is publishing them under the EuroRec Quality Seal 2010.
Thank you for your attention!

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