

Memorandum “Open Metadata”*

Open Access to Documentation Forms and Item Catalogs in Healthcare

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Keywords

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Summary

At present, most documentation forms and item catalogs in healthcare are not accessible to the public. This applies to assessment forms of routine patient care as well as case report forms (CRFs) of clinical and epidemiological studies. On behalf of the German chairs for Medical Informatics, Biometry and

Epidemiology six recommendations to developers and users of documentation forms in healthcare were developed. Open access to medical documentation forms could substantially improve information systems in healthcare and medical research networks. Therefore these forms should be made available to the scientific community, their use should not be unduly restricted, they should be published in a sustainable way using international standards and sources of documentation forms should be referenced in scientific publications.

Problem Statement

Medical documentation is the basis of most information systems in healthcare, public health, and medical research. Documentation forms, such as assessment forms or case report forms (CRFs), are in general designed specifically for each information system, clinical trial, epidemiological study or registry database. Furthermore, data elements, code lists, and layout (i.e. metadata) are usually configured from scratch. At present, re-using existing data structures is complicated. Therefore the workload to generate documentation forms is high. More importantly, data integration from different sources and analysis is complex because of incompatible data structures. Overall, re-use of documentation forms and item catalogs would contribute to more efficient and effective information systems as well as data sharing. Open metadata provides a first step towards open data [1], but is not associated with any re-identification risk for confidential patient data.

At present, most documentation forms and item catalogs in healthcare are not available to the scientific community. This holds true for routine patient care as well as clinical and epidemiological research.

- Routine patient care: Software vendors of clinical information systems provide medical documentation forms to their

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customers. In addition, a large set of site-specific forms are customized, often with considerable support from the clients. However, publication of these forms is usually not permitted due to standard contractual arrangements. This refers to almost all types of forms, for instance regarding medical history, assessments, findings, order entry, quality assurance, and billing.

- Clinical research: At present, the vast majority of CRFs from clinical trials is not available to the scientific community, neither for completed studies nor for ongoing trials. This holds true both for investigator initiated trials (IITs) and for commercial trials. In particular, industry is reluctant to release CRFs. Only eligibility criteria – corresponding to approximately 1% of CRFs only – are available to the public [2]. And even these inclusion and exclusion criteria are not provided completely [3]. Even though more and more study protocols are being published, at present CRFs are mostly not made available.
- Epidemiological research: In epidemiological studies and long-term registry projects, CRFs are usually not available to the public and access is limited to project partners.

All over there exists a great variety of medical forms: ClinicalTrials.gov [2] lists more than 190,000 clinical studies (as of June 2015). The international market of clinical information systems is fragmented, with hundreds of available systems [4]. These systems are customized individually for each clinical site (for example in Germany approximately 2,000 hospitals). For each study or information system, a magnitude of 100+ forms has to be considered [5], in large-scale clinical information systems sometimes more than 1,000 forms per site. In an international setting, forms in different languages might be used.

Scope

This memorandum is addressing metadata of structured medical documentation and is not referring to confidential patient data. Those metadata include data elements, code lists, and layout information.

Goals

Open access to medical documentation forms and item catalogs could considerably advance information systems in healthcare, public health and medical research networks:

- In general: Sharing "best practice", i.e. learning from previous documentation projects, is facilitated. When documentation forms are available to the scientific community, type and quantity of data elements can be discussed. This discussion fosters consensus on compatible data structures and thereby data integration.
- Routine patient care and public health: Development of interfaces between information systems is facilitated, in particular documentation context and semantic aspects of data can be adequately taken into account (for example: is data element "size" referring to body size or something else?). In addition, already existing syntactic standards for data transfer can be applied more consistently. Furthermore, design of application-specific forms can benefit from related work in other organisations.
- Medical research: Open access to medical forms can speed up development of CRFs for new studies. Quality of documentation instruments can be improved by comparison with instruments from similar projects. Potentially more efficient CRFs can be designed. This is important, because increased regulatory requirements for clinical trials are associated with a high burden of documentation. Open access forms enable to compare different data sources: It can be determined what kind of data integration is feasible for pooling of data, meta-analysis, or evidence synthesis.
- Legal and ethical aspects: Open access to medical forms can support transparency according to data protection laws and informational self-determination. In principle, each citizen has a right to know what kind of data is collected about him or her [6, 7].
- Benefits for authors: Design of medical documentation usually requires quite a lot of resources. Therefore, authors of documentation forms and item catalogs

in healthcare should receive academic credit.

- Reproducible research: More transparency regarding data collection will help to make research more reproducible. It is important that CRFs and assessment forms are appropriately published (e.g. [8]). Publication may be limited by business secrets (for instance regarding item catalogs of medicinal products) or copyright (e.g. commercial drug catalogs or licensed questionnaires).

Recommendations

The authors of this Memorandum provide the following recommendations to developers and users of documentation forms in healthcare, in particular in a scientific setting:

1. In general, documentation forms and item catalogs for patient care and research should be made available to the scientific community, and their use should not be unduly restricted.
2. Software vendors of clinical information systems should allow open access to documentation forms and item catalogs integrated into their products, as far as possible from a legal perspective. They should grant their customers the right to publish and share locally customized documentation forms.
3. CRFs from all types of studies should be published as early as possible. Preferably, CRFs should be published jointly with the study protocol at the beginning of each study. At the latest, CRFs should be published together with study results. This recommendation is in line with an increasing demand for transparency in the field of clinical trials as addressed in the European clinical trials regulation (536/2014) [9].
4. Sources of documentation forms (e.g. similar forms with an overlapping subset of data elements) and item catalogs should be referenced in scientific publications to honor intellectual achievement by the authors.
5. Documentation forms and item catalogs should be published in a sustainable way (e.g. as supplement to a scientific publication or in a dedicated re-

pository) and in a reusable technical format (i.e. computable format, preferably as semantically annotated catalog of data elements).

6. International standards – such as CDISC ODM [10], ISO/IEC 11179 [11], CEN/ISO EN13606 [12], HL7 CDA [13] – should be applied to describe documentation forms and item catalogs in a computable format. Mappings from local terminologies and classifications to international standards should be provided where applicable. Information regarding comparability of forms in different languages should be provided as appropriate.

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