Implementing Lab LOINC in Germany – the Medical Informatics Initiative (MII)

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TMF. A common platform for medical research

- non-profit umbrella organization for academic medical research consortia and institutions
- established by Federal Ministry of Education and Research (BMBF) in 1999
- funded by three federal ministries: BMBF (Education & Research), BMG (Health), BMWT (Economy & Technology)
- supported by funding bodies (e.g. DFG)
- involved in EU-funded projects (FP7, ESFRI, Innovative Medicine Initiative)
LOINC work in Germany started in 2001 …

2001 first LOINC implementation in EPR system (OS) & first hospital IT projects …

2002 Go-Live in LVA Westphalia (public rehab. company group)

2003 Go-Live in University Hospital Kiel

2002 first publications & project reports
Subsequent efforts 2004-2015 ... (with no final breakthrough)

LOINC User Group Deutschland

Die LOINC User Group Deutschland hat sich am 10. 03. 2004 in Berlin gegründet als freier Zusammenschluss von Anwendern und Interessierten für den internationalen Standardizer LOINC. Die Benutzergruppe arbeitet an der Weiterentwicklung der Software, an der Verbreitung der Standards in Deutschland und in Europa, der Ausbildung von Nutzern und an der Kommunikation mit den Herstellern.

DGKL, 2008/09 ...
GMDS, 2008 ...

DIMDI: - Tutorial, 2007
- Translation Handbook, 2010
- (part.) Translation Codes, 2013
Challenge 1:
Fragmentation of German health care system

A) Different (and widely independent regulated) "sectors" in German Health Care System:

<table>
<thead>
<tr>
<th>Out-Patient Sector</th>
<th>Acute Care Hospital Sector</th>
<th>Rehabilitation Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians` Associations</td>
<td>State Hospital Association</td>
<td>Various Interest Groups</td>
</tr>
<tr>
<td>Financed by social or private health insurance funds or employers` liability insurance associations</td>
<td>Financed by social or private health insurance funds or employers` liability insurance associations</td>
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</table>

Data not accessible for research

B) Different responsibilities for & separated development in medical research and patient care

Different
- Governance
- Funding Schemes
- Coding & Documentation (IT-Systems)
- Data Repositories & Responsibility

No
- Overall Interoperability
- Overall Data Access & Integration
- Joint Regulated Framework
Challenge 2: Fragmented political and legal framework

- 1 Federal Government
- 16 States
- 16 Financial Responsibilities
- 16 Infrastructure Budgets
- European Law vs. Federal Law vs. State Law
- 16 different Laws on State Level
  - State Data Protection Acts
  - State Hospital Acts
- 16 Regulatory Authorities
- 16 Data Protection Offices
- ...
Fragmented legal framework for medical research

- Different data protection laws on state level
- Different hospital laws on state level
  (relevant for use of patient care data for medical research)

Source: TMF Legal Expertise on secondary use of patient care data, U.Schneider 2015
Lack of sector-crossing governance! 
→ relevant for setting standards

Further reading on the German „self-governance“ health care system
(Lancet, 2017)
DOI: https://doi.org/10.1016/S0140-6736(17)31280-1

2013/15: TMF Strategy Papers for the German Ministry of Health
(German only)
Medical Informatics Initiative (MII) Germany – Aims and Overview

- Improve **research opportunities and patient care** through innovative IT solutions (initial focus on university hospitals, but including further partners)
- Intensify the **exchange and sharing of data** between the biomedical research community and the health care delivery system (data sharing across institutions and sites)
- Position medical informatics as a progressive field in research, teaching and continuing education
- Funded by the **Federal Ministry for Education and Research (BMBF)** – in close cooperation with the Federal Ministry for Health (BMG) – over the next decade (2016-2025):
  - **150 Millions €** for the years **2018-2021**
    (funds for 2022-2025 to be defined)
- Coordination office: TMF, Berlin (with partners VUD+MFT)
Timeline

Support activities

Supplementary funding modules

Conceptual phase
2016 – 2017

Development and networking phase
2018 – 2021

Consolidation and further development phase
2022 – 2025

Audit
Audit
Consortia and participants within MII

DIFUTURE
CONSORTIUM PARTNERS:
- Aachen
- RWTH Aachen University
- Unitklinik RWTH Aachen
- Berlin
- ID Information und Dokumentation im Gesundheitswesen GmbH & Co. KG

HIGMed
CONSORTIUM PARTNERS:
- Berlin
- Robert Koch Institute
- Ada Health GmbH
- Universitätsmedizin Berlin – Campus Charité Mitte
- Brunswick
- Brunswick University of Technology (TU Braunschweig)
- Helmholtz Centre for Infection Research GmbH (HZI)
- Darmstadt
- Darmstadt University of Technology (TU Darmstadt)
- Erlangen
- Siemens Healthineers GmbH
- University Medical Center Göttingen
- HAWK University of Applied Sciences and Arts Göttingen
- Hannover
- Hannover Medical School
- Hannover University of Applied Sciences and Arts
- Heidelberg
- Heidelberg University Hospital
- the Medical Faculty of Heidelberg
- German Cancer Research Center
- NCE Laboratories Europe
- Heilbronn
- Heilbronn University

currently 33/35 university hospital sites in Germany

> 90 % of University Hospital Sites
> 10 % of all Inpatient Cases
Project structure & Governance

NATIONAL STEERING COMMITTEE (NSC)

CONSORTIA

Consent working group
Data sharing working group
Interoperability working group
Communications working group

BMBF
Dialogue forum
Annual general meeting
Coordination office

MEDICAL INFORMATICS INITIATIVE GERMANY
Central data access to patient care data for medical research

- Formal Check
- Distribute Proposal
- Contracts Use & Access
- Project registration

Researchers

U&A Handling (request broker)

- Select & Package Data
- Archive Data Package
- Provide Data
- UAC

DIC 1
DIC 2
DIC n

Application Data request
MII Demonstrator Study: Preliminary Results (02/2019)

Charlson-Index vs. Type of discharge

- 20 Sites
- 10 Permissions
- 1,380 Million Patients
- 2.5 Million Cases
## Roadmap – Milestones

### 1. Standards for patient consent
- M 1.1: Versions of the sample text are consented
- M 1.2: Conference of Information Commissioners has agreed
- M 1.3: Standardized electronic consent is available

### 2. Trusted Third Parties (TTP)
- M 2.1: Specification for consortial TTPs
- M 2.2: Requirement paper for the federation of TTPs
- M 2.3: Overarching identity management & record linkage for selected applications is available

### 3. Rules for Use & Access
- M 3.1: Joint Key Issues Paper “Common Terms of Use”
- M 3.2: Technical support for use & access operations is available

### 4. Data privacy and data protection
- M 4.1: First data protection concepts are available
- M 4.2: Authentication and authorization of users according to defined roles are available
- M 4.3: More advanced data protection concepts are available

### 5. Semantic Interoperability
- M 5.1: Content and terminologies are agreed (definition of core data set, core data set is available, extensions are agreed)
- M 5.2: Structures, information model, syntax (available for core data set, available for extensions)
- M 5.3: Metadata concept is available (for the dimensions quality, availability, provenance)
- M 5.4: Overarching framework for services (regarding terminologies and metadata)

### 6. Methods of data sharing
- M 6.1: Overarching queries and data sharing are possible (core data set and extensions)
- M 6.2: Interoperable run time environments

### 7. Common use cases to show the benefits
- M 7.1: Common use cases are specified
- M 7.2: “Projectathons” take place

### 8. Patient empowerment
- M 8: Workshop “Harmonize approaches for patient involvement”

### 9. Strengthening research, teaching and education
- M 9: Activities to strengthen research and teaching (workshop, status symposium)

### 10. Consolidation and further development phase
- M 10: Audits from Q2 2021
Towards a core data set of clinical patient care documentation

Core Data Set

Basic Module
- Diagnosis
- Procedures
- Demography
- Person
- Case Data

Advanced Modules
- Oncology
- Pathology
- Payment Data
- Biomaterial
- Imaging
- Costs Data
- Genetic Data
- Intensive Care
- Structure Data

Payment Data
Results, Current State of Work, Results

- Nationwide broad consent template
  - accepted by all of the 17 data privacy authorities in Germany
  - Consenting process with 52 ethics committees ongoing

- Nationwide Use & Access rules & contract

  **Establishing nationwide LOINC standardisation of lab data**
  - in every participating university hospital until the end of 2020!
  - Standardisation already in the patient care IT system, not in the research database!
  - Starting point: LOINC Lab parameter subset – 300 analyses (80%)

- Concept development for standardisation of medication data
  - Lack of electronic documentation in the inpatient sector
  - Problematic situation concerning drug data bases

- Introduction of SNOMED CT in Germany (in 2019)

- Building central services (e.g. central data access point, harmonized meta data services)

- Establishing Patient Involvement and Communication
Interoperability with lab data

Access → ETL & Data Integration → Semantic Annotation → standardized Data structure → Cross-site Research use

LIS

PDMS

Terminology → Data Structure → HL7 FHIR → Comparability of Data?

Lab Results → Diagnoses → Demography → Procedures → Case Data

Implementing Lab LOINC in Germany  |  Sebastian Claudius Semler | 06/06/2019
A well-known graphic ... – guidance for the approach in Germany

A Few Tests Give Most Results

Vreeman DJ, Finnell JT, Overhage JM. A Rationale for Parsimonious Laboratory Term Mapping by Frequency. AMIA Annu Symp Proc. 2007;771-775.
Modular LOINC-Subset: Starting with a „LOINC 300 Subset“

- 98% coverage by ~2,000 parameters
- 80% coverage by ~300 parameters

- Basic
  - Top 300
  - Top 1000
  - Top 1500

- Use case specific
  - UC Infektiologie
  - UC Onkologie
  - UC Neurologie

acc. to volume of results

Acc. to clinical needs
### LOINC TOP 300 Subset
(based on mappings/rankings of 5 sites)

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</table>
Current challenges on our way to lab LOINC implementation nationwide

- Unify Stakeholder in patient care & research for a common approach
- Data transformations: Different “properties” in Germany require transformations (see graphic)
- Data quality & comparability after data aggregation? (made possible by LOINC standardisation)
- Establishing services for additional identifiers (e.g. UDI/GS1, test codes)
- Mapping assistance in German language? (Relma !?)
- Data aggregation (and statistical power) for research requests? (Groups ??)
- ...

Glucose as example
Germany’s High-Tech Strategy 2025...

- Krebs bekämpfen
- Forschung und Versorgung digital vernetzen
- Gut Leben und Arbeiten im ganzen Land.
- Plastikeinträge in die Umwelt substanziell verringern.
- Nachhaltiges Wirtschaften in Kreisläufen.
- Biologische Vielfalt erhalten.
- Weitgehende Treibhausgasneutralität der Industrie.
- Technik für den Menschen.
- Eine sichere, vernetzte und saubere Mobilität.
- Batteriezellproduktion in Deutschland aufbauen
- Künstliche Intelligenz in die Anwendung bringen
- Neue Quellen für neues Wissen.
Moving ahead: Germany‘s High-Tech-Strategy 2025

05.09.2018: „Hightech-Strategie 2025 der Bundesregierung“:

(with relevance to medical informatics)

German Government will foster:
- „research-compatible“ electronic patient records throughout Germany at all university medicine sites until 2025 (!)
- EHRs from health care sector shall support “research compatibility” (!)
- Usage and products of artificial intelligence
- Open Data
- …
BMBF: Medical Informatics Funding Scheme – Links


5. Project Website: [www.medizininformatik-initiative.de](www.medizininformatik-initiative.de) (GER)  
   [www.medizininformatik-initiative.de/en](www.medizininformatik-initiative.de/en) (EN)

www.gesundheitsforschung-bmbf.de/medi.


www.gesundheitsforschung-bmbf.de/de/medizininformatik.php

www.gesundheitsforschung-bmbf.de/_media/Medizininformatik_englisch_barrierefrei.pdf (EN)


www.bmbf.de/foerderungen/bekanntmachung-1098.html

Project Website: www.medizininformatik-initiative.de (GER)

www.medizininformatik-initiative.de/en (EN)

Shared data, shared benefits
Medical informatics: strengthening research, improving healthcare
At the end - Thanks !
(for open development and international & free disposability)

Thanks to LOINC committee, experts & enthusiasts through the years 1994-2019 ff.

Thanks to Regenstrief Institute

Thanks to the Funders of the LOINC work

A true great contribution to global lab data standardisation (and an important basis for future Digital Global Health)!

Congratulations to the 25th anniversary!
Thank you

More information:  
www.medizininformatik-initiative.de/en

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