The Duke / Pew Charitable Trusts Common Healthcare Data Interoperability Project

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The Transformation of Healthcare ...

What’s the Common Denominator?

Clinical documentation
Administrative reporting
Quality and performance
Registry submission
Analytics
Big Data
Machine learning
Etc.
Exchange, Use, and Reuse of Data Requires Shared Data Definitions (including semantics)
THE Foundational Issue

Tower of Babel

Pieter Bruegel the Elder and Pieter Bruegel the Younger, 1563
Common Healthcare Data Interoperability Project

Improving the Interoperability of Healthcare Data

- **Aim 1**: To compare the CRFs of >20 registries & identify data elements that are common (>50% prevalence) across those registries
- **Aim 2**: To characterize the data elements in the context of healthcare data standards and other predicate work
- **Aim 3**: To produce an implementation guide that catalyzes the governance, structural, operational, and technical transformations needed to implement a common clinical data element set across registries, followed by EHI and national data models

Supported by funding from The Pew Charitable Trusts
Table 1: Draft USCDI Version 1 Data Classes

<table>
<thead>
<tr>
<th>Draft USCDI Version 1 Data Classes</th>
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</thead>
<tbody>
<tr>
<td>1. Patient name</td>
</tr>
<tr>
<td>2. Sex (birth sex)</td>
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<tr>
<td>3. Date of Birth</td>
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<tr>
<td>4. Preferred Language</td>
</tr>
<tr>
<td>5. Race</td>
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<tr>
<td>6. Ethnicity</td>
</tr>
<tr>
<td>7. Smoking Status</td>
</tr>
<tr>
<td>8. Laboratory tests</td>
</tr>
<tr>
<td>9. Laboratory values/results</td>
</tr>
<tr>
<td>10. Vital signs</td>
</tr>
<tr>
<td>11. Problems</td>
</tr>
<tr>
<td>12. Medications</td>
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<tr>
<td>13. Medication Allergies</td>
</tr>
<tr>
<td>14. Health concerns</td>
</tr>
<tr>
<td>15. Care Team members</td>
</tr>
<tr>
<td>16. Assessment and plan of treatment</td>
</tr>
<tr>
<td>17. Immunizations</td>
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<tr>
<td>18. Procedures</td>
</tr>
<tr>
<td>19. Unique device identifier(s) for a patient’s implantable device(s)</td>
</tr>
<tr>
<td>20. Goals</td>
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<tr>
<td>21. Provenance</td>
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<tr>
<td>22. Clinical Notes</td>
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</tbody>
</table>
Common Clinical **Data** Elements

*Clinical concepts shared across clinical, research, and regulatory contexts NOT unique to a discipline, are captured as data, and already have bindings to standardized terminologies:*

- Demographics, administrative data (ONC)
- Vital signs, tobacco use history (ONC)
- Procedure codes (CPT)
- Laboratory data (LOINC)
- Medications (RxNorm)
- UDI and reference device data (GUDID)
## Native, Interoperable Data Standardization

<table>
<thead>
<tr>
<th>OSI Model</th>
<th>Layer</th>
<th>Data Management</th>
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</thead>
<tbody>
<tr>
<td>Host Layers</td>
<td>Data</td>
<td>Physical Data Management</td>
</tr>
<tr>
<td></td>
<td>Application</td>
<td>UI (humans)</td>
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<tr>
<td></td>
<td>Network</td>
<td>API-ETL-FHIR (computers)</td>
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<tr>
<td></td>
<td>Processes</td>
<td>Translation</td>
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<td></td>
<td>Encryption</td>
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<td></td>
<td>Communication</td>
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<tr>
<td>Media Layers</td>
<td>Segments</td>
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<td></td>
<td>End-to-End Connections</td>
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<td></td>
<td>IP Addressing</td>
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<td></td>
<td>Logical Addressing</td>
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<td></td>
<td>Physical Addressing</td>
<td></td>
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<tr>
<td></td>
<td>Physical Transmission</td>
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</tbody>
</table>

- Data field name
- Data format
- Clinical definition
- Business rules (e.g., range limits, allowed values)
- Terminology binding
Key CDE Metadata

1. Clinical concept label (e.g., human prompt for CRF, data entry screen)
2. Db field label (all caps, no spaces, underscores only, limited chars ...)
3. Clinical definition of the concept, synonyms thereof
4. Data type / format (e.g., free text, constrained list, integer, ...)
5. Allowed values (aka permissible values = value set; VSAC?)
6. Allowed values definitions
7. Business rules (e.g., range / edit checks, consistency, validation)
8. SDO binding(s)
9. Published reference(s)
ONC
- Common Clinical Dataset - USCDI
- Interoperability Standards Advisory

FDA
- MDEpiNet, CRNs, Women’s Health
- Regulatory use cases
- Global coordination
- Demonstration via projects

NEST / NESTcc
- Coordination of medical devices

DCRI / Academia
- Need for CDEs
- Academic publishing

The Playbook - Content
- General (core) CDEs
- Domain-specific CDEs
- UDI: GUDID, AUDI
- Outcomes: AHRQ
- Data models
- Patient ID, matching
- Data aggregation
- Distributed analysis

Professional Societies
- Registries
- Domain-specific CDEs
- Structured data capture

NIH / NLM ...
- VSAC repository
- CDE repository

EHI Vendors
- EHR, other HIT systems
- Structured reporting

HL7-CIC, CIIC, CIMI ...
- The Playbook: Process for CDE modeling
- Tooling, repository of logical CDE models
- Registry domain analysis modeling

NQRN Registries on FHIR
- Environmental scan
- ID / spec of general (core) CDEs
- Demonstration / implementation
Data standards are like toothbrushes:

*Everybody agrees we need them, but nobody wants to use anyone else’s.*

Various attributions
Common Healthcare Data Interoperability Project

- **Request 1**: provide CRFs and corresponding data dictionaries to the DCRI team (Rebecca Wilgus, James Tcheng) *(anonymized & confidential)*
- **Request 2**: attend follow-up meeting at Pew in Washington, DC (August 21) to review findings
- **Request 3**: work with your IT team to plan for implementation of the work product *(implementation guide)*

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