

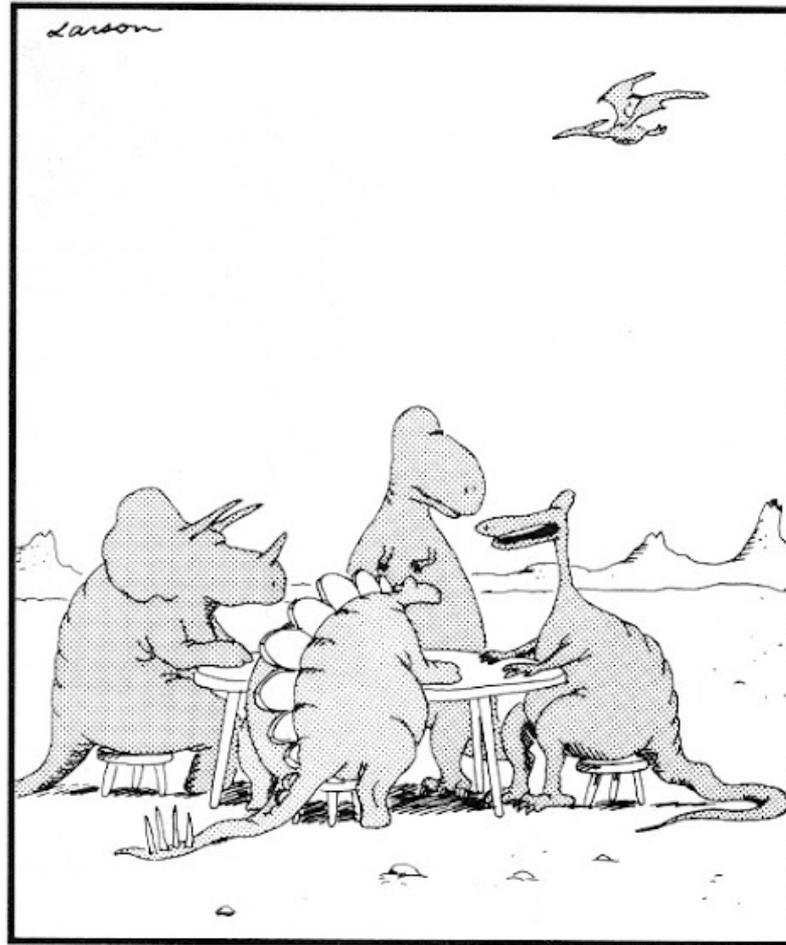


Semantic Interoperability of Laboratory Results for Public Health

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“Well, time for our weekly brain-stem-storming session.”

The Issue is Obvious

(Coals to Newcastle)

- Why is this a problem:
 - Much of the EHR is laboratory data
 - Individual decision support mandates semantic interoperability
 - ***Public Health epidemiology and decision support mandate semantic interoperability***

A Common, Trivial Scenario.....

- 64 year old man is clinically diagnosed with Influenza A in Fresno, California.
- Next:
 - Physician orders laboratory test
 - Lab reports result: Influenza A1/H3
- But.....
 - Hospital A is unaware of a similar case in Hospital B one mile away....
- And.....
 - Hospital B performs a similar test but from a different manufacturer than Hospital A..

Same Scenario, Slight Change

- 64 year old man is clinically diagnosed with Influenza A in Fresno, California.
- Next:
 - Physician orders laboratory test
 - Lab reports result: *Chlamydophila*
- Now
 - Is this correct?
 - Hospital A is unaware of a similar case in Hospital B one mile away....
- How can we use Bayes theorem and treat appropriately
 - Semantic interoperability is essential...

The Solution, Humbly Offered Should Be Trivial 😊

- Quoting Dr. Jim Cimino:
 - *Look for ways to solve problems through terminology.*
- Tools are already available:
 - **LOINC**
 - **SNOMED**
 - **HL7/SPL**
 - **UDI (Unique Device Identifier)**
 - **GMDN** (less necessary but useful)

Model

- **LOINC** – What is the question...
- **SNOMED** – What is the answer...
- **HL7** – How do we get the information where we need it...
 - Version 2
 - Confidential data
 - For requestor
 - EHR
 - Clinical decision support (local)
 - Deidentified data
 - Clinical decision support (community/geographical)
 - CDC – notifiable/epidemiological

Model (II)

- **UDI (Unique Device Identifier)** – Which specific device are we talking about...
 - Glue that can make model work
 - Still details to be resolved re: in vitro diagnostics
 - Unique key to additional device information
- **GMDN** – What does the test do....
 - Less necessary but potentially useful
- **SPL** – Wrapper for UDI/LOINC/SNOMED/GMDN information
 - Accessible file identified by UDI number
 - Machine/human readable
 - NLM hosting (?)

Proposed Pilot Project

- Standardized SNOMED coding for selected assays
 - ELISA
 - Qualitative PCR-based assays
 - Lead: Dr. Michael Waters
- SPL/HL7-wrapper for *in vitro diagnostic* devices
 - Device UDI identifier
 - Device LOINC codes
 - SNOMED result coding
 - ? GMDN codes

NB:

- This reflects nothing fundamentally unique
 - Not dissimilar from PHIN or other efforts
- What makes this a propitious time
 - UDI (Unique Device Identifiers)
 - ONC efforts/meaningful use
- Not a regulatory initiative!

Stakeholders

- Industry
 - IICC (IVD Industry Connectivity Consortium)?
 - Manufacturer (particularly pilot)
- CDC (Domain experts, pilot?)
- National Library of Medicine (Hosting SPL)?
- FDA
 - Consistency
 - Pre-market consultation
 - Guidelines
- HL7
- Academia

Issues

- Guidelines
 - Non-FDA devices/assays
 - Hosting
 - UDI
 - Extensibility (NB: not a regulatory initiative)
 - Updates
- HL7 version 3
- Hosting mechanism/access
- GMDN
- Resources, etc., etc.

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