Clinical Systems: What Works... And What We Wish Worked

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Factors Driving Change

- Patient Data should be available where the patient is (Interoperability)
  - With suitable privacy precautions patient data should be available across sites and settings
- Systems should include knowledge that improves quality and safety of care
  - Systems should incorporate decision support functions to improve quality and prevent errors
- Systems should capture data in a way that is analyzable

Relevant Design Principles

- Use of componentry (service oriented architecture)
  - Modularity, scalability, maintainability
- Utilize common information model
  - Apples to Apples
- Utilize common terminology
  - Concept portability
- Utilize standard format for data interchange and messaging

Challenges

- In 2004
  - You can easily get a credit report showing every major purchase and use of credit for the last 20 years
  - But....
    - No two hospitals can reliably share a medication list for a patient
    - There is no broadly adopted standard for the transmission of labs between laboratories
    - In most states you cannot transmit a prescription electronically
    - Most systems could not support a query like “show the number of diabetics that did not get an eye exam this year”
Example 1: Interoperability of Drug Information

The Tower of Babel, Pieter Bruegel the Elder (about 1525 - 1569)

Safety Focus: Medication Errors
- Bates et al. Estimate error rate at 10.7, and 7.6 per 1000 pt-days
  - 5.1%, and 3.4% incidence rates/admission (approx 1 in 20, or 1 in 25 admissions)
- Lessar et al. Estimates serious medication error at 5.3% of admissions in NY teaching hospital
- Gandhi estimates in ambulatory care: 3% visits with ADE, 770,000 people injured due to ADE/yr. In US, 7000 of these die
  - One ADE every 41 secs
  - One death due to fatal ADE every 1.25 hrs

Problem Statement
- **Goal**: develop a single reference standard medication terminology
  - To allow for movement of drug data between systems
  - To support ubiquitous decision support
- **Reality**: historical evolution and wide deployment of different medication terminologies preclude sharing of data or standard decision support

Where is Drug Information Used?
- EHR
- Consumer
- CPOE
- Ambulatory EMR
- Retail Pharmacy
- Hospital Pharmacy System
- PBM Administering Nurse

Medication Terminology Sources
- National drug codes (NDC)
  - Insufficient for applications
- Vendors
  - De facto “standards”
- VA NDF
- UMLS

NDC
- Information on packaged drugs
- Maintained by FDA, HCFA, vendors
  - There is no definitive source
  - Lists are not the same (FDA, 90,000/FDB 200,000)
  - Codes have been deleted, re-used
- FDA oversight is improving and current efforts may impact NDCs in the near future
- HIPAA role is unclear
- Resources:
  - http://www.hiwaycode.com/ndc/ndc.htm
What is a drug?

Core Concept: (Active) Ingredients
- Active ingredients (chemicals)
  - What is “in” the drug
  - Example: Rofecoxib
- Systems usually identify allergies at the level of ingredients
- Many systems represent the ingredients in a multi-ingredient drug as a specific entity in their data model

Core Concept: Routed Generic
- Active Ingredients
- Route
- Examples: Rofecoxib PO
- Many inpatient orders utilize concept of routed generic
- Key concept for some decision support functions (Like Drug - Drug Interactions)

Core Concept: Clinical Drug (Generic)
- Active ingredients
- Route
- Strength (amount, units, volume, volume units)
- Dosage form
- Examples:
  - Rofecoxib 25 mg tablet
  - Rofecoxib 25 mg/5ml oral suspension
- Key concept for systems used by physicians
- Prescriptions are usually specified at level of clinical drug

Orders versus Prescriptions
- Orders
  - Amount-centric
  - Partially specified (Pharmacist assisted)
  - Routed Generic is core KB element
  - Example: Amoxicillin PO, 250mg TID
- Prescriptions
  - Strength/Form-centric
  - Fully specified
  - Clinical drug core KB element
  - Example: Amoxicillin suspension 250mg/5ml, 1 tsp PO TID

Core Concept: Manufactured Drug
- Active (and inactive) ingredients
- Strength
- Dosage form
- Trademark
- Inactive ingredients
- Manufacturer
- Also called a “dispensable” drug
- Example:
  - Merck Vioxx 25 mg/5ml suspension
  - Inactives: citric acid, strawberry flavor...
  - Key concept in nurse’s medication administration record
Core Concept: Packaged Product
- All the previous, plus
- Size
- Units
- “Free of”
- Package-specific devices (applicator, syringe, etc.)
- One or more packaged components
- Ex: Vioxx 50mg tab, bottles of 100 (NDC 0006-0074-68)
- Packaged drugs are what the NDC code identifies
- Pharmacy systems are built around the concept of packaged drugs

So...
- Clinical systems utilize drug data at varying levels of detail and granularity
- There are clear requirements
- A single well developed terminology and information model could meet needs for interoperability and machine readability

But...
- There is no standard terminology or information model for drugs
- Vendor supplied “standards” don’t map 1 to 1
- Systems can’t talk....

Case Study 2: Clinical Documentation

Dr. Charles Mayo - 1918
- Documentation Format designed around 1907 by Dr. Henry Plummer

How We Document Today
Why Does It Matter?

- Paper based documentation…
  - Prone to error
  - Lots of information in handwritten notes but no data gathered!
  - Does not integrate with eHealthcare
- Transcription and document imaging have similar shortcomings

The Challenge is to build a tool that both fulfills data capture needs and is as fast and easy to use as dictation

Transcription Not the Answer…

- "The lab test indicated abnormal liver function."
- "Exam of genitalia reveals that he is circus sized."
- "The skin was moist and dry."
- "She stated that she had been constipated for most of her life until 1989 when she got a divorce."
- The patient was to have a bowel resection. However, he took a job as a stockbroker instead.

Examples (things we can’t do)

- Safety/quality monitoring and alerting
  - Reminder to perform eye exam in Diabetic whose last exam was >12 months ago
- Better research data collection
  - Incidence of side effects in chemotherapy trial
- Outcomes measurement and data-mining
  - Exercise tolerance in CHF...
- Automated coding and billing
  - Automated E&M, DRG, or APC assignment

Informatics to the Rescue?

- Good News...
  - Known techniques for improving the quality of documentation
- Bad News...
  - Hard to do without changing clinician behaviors or increasing the time spent on documentation
  - And again...the challenge is to build a tool that both fulfills data capture needs and is usable in today’s pressured work environment

Informatics Holy Grail: Structured, Coded, Documentation

Information Capture With Structure and Codification

- Information Model
- Template
- Controlled Medical Terminology (Codification)
- Data and Reports

- Capture
  - Direct Input
  - Device Capture
- Structured Data
  - Low Level/Check
  - High Level/Check
- Data and Reports
In a Structured, Coded Document...

- Codes underlie all words, including both structural labels and content - enabling machine based sharing and analysis
- Information model defines relationships between concepts and enables improved handling of concepts in groups

Structured Data

- Structured data is organized according to an information model
- Defines the “buckets” into which a data element fits
- Data can be structured without being coded
- Examples
  - The sections of a standard H&P
  - A fall risk assessment form

Standards for Structuring Data

- ASTM E31.28
- HL7 CDA (Clinical Document Architecture)
- Several proprietary (vendor) schemes

Coded Data

- Coded data is data to which codes, representing concepts have been attached
- The codes allow us to identify important concepts, regardless of the words used to describe them
- The codes, and their descriptions are drawn from a standard coded medical terminology

Coded Data

- Examples...

<table>
<thead>
<tr>
<th>Term</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial Infarction</td>
<td>123</td>
</tr>
<tr>
<td>MI</td>
<td>123</td>
</tr>
<tr>
<td>Heart Attack</td>
<td>123</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Term</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold</td>
<td>456</td>
</tr>
<tr>
<td>Cold</td>
<td>789</td>
</tr>
</tbody>
</table>

The Challenge

“Capture the clinical encounter in coded form”

- What will we capture in coded form?
  - Which data should be coded?
- How will we capture it?
  - Input methods, GUI choices
- Where will we put the data captured?
Blumenfeld

What Data Should Be Captured in Structured Coded Form?

- Often coded, easier to achieve
  - Diagnosis, procedure, medications
  - Quantifiable results: e.g. Lab, physiologic parameters
- Rarely coded, difficult to capture
  - Most clinical observations
  - Procedure notes
  - Clinical reasoning

Usefulness of Data

<table>
<thead>
<tr>
<th>100% Free Text</th>
<th>100% Structured &amp; Coded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact on Usability</td>
<td></td>
</tr>
</tbody>
</table>


How will we capture data?

Approach 1: Post Processing (Extraction of concepts)

- Dictation with Transcription or Voice Recognition
- NLP parser extracts codes (post-processing)

- Pros
  - No change in workflow or habits for clinicians
- Cons
  - Clinicians do not assign codes (or verify concepts)
  - Technology limitations

Approach 2: Pre-processing

- Structured documentation

- Structured documentation Application

- Pros
  - Clinician control of data entry
  - Reliable technology
- Cons
  - Changes in workflow, effort
  - Development/maint. of dictionary and KB

Case Study: Allergies

Partners Healthcare System

Partners Healthcare 2002 Statistics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Beds</td>
<td>3,200</td>
</tr>
<tr>
<td>Births</td>
<td>18,500</td>
</tr>
<tr>
<td>Admissions</td>
<td>135,000</td>
</tr>
<tr>
<td>Avg. length of stay (days)</td>
<td>5.31</td>
</tr>
<tr>
<td>Avg. length of stay, non-acute (days)</td>
<td>21.72</td>
</tr>
<tr>
<td>Home health visits</td>
<td>.5M</td>
</tr>
<tr>
<td>Total Outpatient visits</td>
<td>2.4 M</td>
</tr>
<tr>
<td>Patient visits to community health centers</td>
<td>392,000</td>
</tr>
<tr>
<td>Emergency Room visits</td>
<td>269,000</td>
</tr>
</tbody>
</table>

The Problem

- Business Driver: Patient Safety
- Problem:
  - Allergy information is collected in multiple disconnected systems within a large IDN, resulting in need to enter data redundantly, and potentially, to miss an allergy that is already known "somewhere" in the system.
The Solution

Proposed Solution:
- Make Allergy information available to users of all systems, regardless of where they were originally entered
- Institute Allergy alerting such that clinicians are automatically warned before a patient is exposed to an allergen

Use Cases

- Clinician adds new allergy
  - System should check existing drugs
  - System should create warning and allow clinician to DC drug if allergic
- Clinician adds new drug
  - System should check known allergies and warn if allergy to drug ordered is found
  - System should clinician to DC offending drug

Functional Requirements

- Allergy Checking
  - Allergens: Drugs, Foods, Environmental
  - Levels
    - Possible, probable, definite
  - Overrides
  - Reactions
  - Coding
    - Allergen, reason for override, reactions

- Allergy Repository
  - Record allergen, reactions, overrides
  - History
  - Access
  - Auditing

Another Word About Drugs

- Granularity
  - Ingredients
  - Drugs
  - Groups

Legacy Tyranny

- “We don’t need as much help”
- “We’re busier”
- Different design perspectives
- Different platforms
Into the Sausage Factory

- Merging data from 7 legacy applications
  - NKA vs. NKDA
  - Mandatory overrides
  - Levels
  - Text issues
  - Pending, inactive orders

Merging Magnifies Mistakes

- Text
  - Uncoded allergens
  - None known, no known, unknown, etc.
  - Reaction redundancies
    - Granularity
      - Merging allergies at ingredient, group, drug levels

Deriving the Rules: Which Best Practice is Best?

- Out of the box knowledge vs. local expertise
- Applicability to multiple settings
- "Nuisance alerts"
- Labels

The Dark Side of Customization

- Maintainability
- Impact of services approach
- Interoperability impact

The Evils of Text

- Importance of coded data
  - Machine readability is critical to rules
  - Desire to "learn from past"
- "Special Circumstances"
  - Impact
- Limitations of coding
  - Foods, environmental allergies
Take Homes

- Building a good clinical system is like attaining Nirvana
  - Can’t agree what it is
  - Few will ever get there, but stay on the path
  - Staying on the path is the hardest part
- Succeeding with informatics infrastructure is more about process than technology
  - Educate, Educate, Educate
  - Attain agreement from all stakeholders before coding
  - Knowing where to compromise and where not…
- Achieving national infrastructure with minimal interoperability and machine readability of data will be more expensive and take longer than most realize