6.872/HST.950 Medical Computing

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

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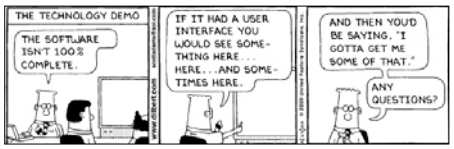


Outline

- Factors driving clinical system design
- Best practices
- Challenges
- Example 1: Systems using drug data
- Example 2: Clinical documentation
- Case Study: Implementing a common allergy repository at Partners Healthcare System
- Summary

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)

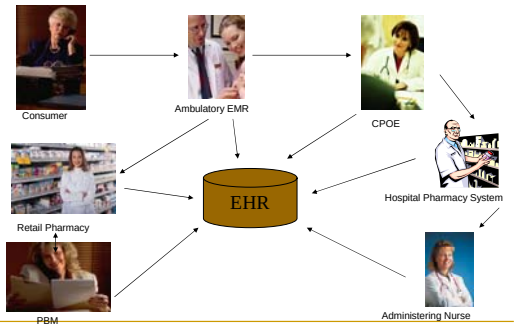
Safety Focus: Medication Errors

- Bates et al. Estimate error rate at 10.7, and 7.6 per 1000pt-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?



Medication Terminology Sources

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

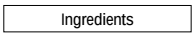
NDC

- 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.fda.gov/cder/ndc/database/default.htm
  - http://www.hipaacode.com/NDC/NDC.htm

What is a drug?

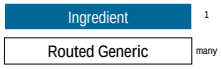
Core Concept: (Active) Ingredients

- 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



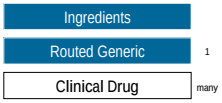
Core Concept: Routed Generic

- 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

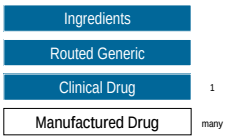


Orders versus Prescriptions

- 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

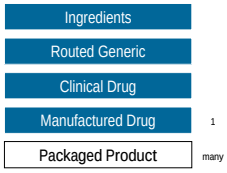
Core Concept: Manufactured Drug

- 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…

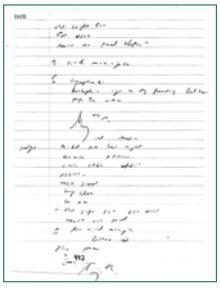
- There is no standard terminology or information model for drugs
- Vendor supplied "standards" don't map 1 to 1
- Systems can't talk….

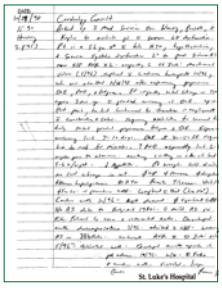
Case Study 2: Clinical Documentation

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 lover 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 stockbroker instead."

"A Problem"

- Documentation is at the core of a clinician's activities and is a principle source of the information in the EMR
- Yet most documentation still occurs in a way that precludes automated sharing or analysis of the data collected...

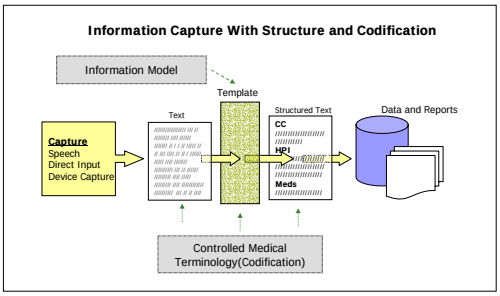
Examples (things we can't do)

- **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



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

Structuring 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...

3 terms, 1 concept

Term	Code
Myocardial Infarction	123
MI	123
Heart Attack	123

1 term, 2 concepts

Term	Code
Cold	456
Cold	789

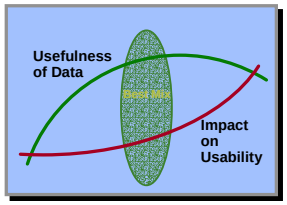
The Challenge

"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?

What Data Should Be Captured in Structured Coded Form?

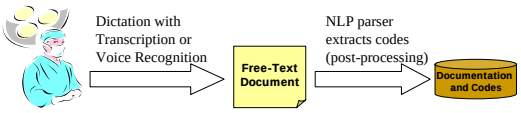
- **Often coded, easier to achieve**
  - Diagnosis, procedure, medications
  - Quantifiable results: e.G. Lab, physiologic parameters
- **Rarely coded, difficult to capture**
  - Most clinical observations
  - Procedure notes
  - Clinical reasoning



Middleton B, Renner K, Leavitt MK. Ambulatory Practice Clinical Information Management: Problems and Prospects
J Hlth Info Mgmt, 11;4:97-112, 1997

How will we capture data?

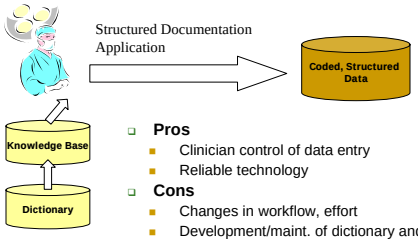
- Approach 1: Post Processing (Extraction of concepts)



- **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



- **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

3,200	Beds
18,500	Births
135,000	Admissions
5.31	Avg. length of stay (days)
21.72	Avg. length of stay, non-acute (days)
.5M	Home health visits
2.4 M	Total Outpatient visits
392,000	Patient visits to community health centers
269,000	Emergency Room visits

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

Functional Requirements

- 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

Merge Data

1459450	BICS	1582249	A	PENICILLINS	TABLE	671	671-672	hives
101003167	BICS	1582249	A	18:50:04 09/15/98	PIC	12	Penicillins	Rash
1459450	BICS	1582270	A	PENICILLINS	TABLE	671	671-672	HIVES, TOLERATED NAF, W/O PROBLEMS
101003167	BICS	1582270	A	08:33:26 09/16/98	PIC	12	Penicillins	HIVES, TOLERATED NAF, W/O PROBLEMS
101003167	LMR	186347	A	PENICILLINS				SWELLING
101003167	LMR	186347	A	00:00:00 12/06/96	PIC	12	Penicillins	SWELLING
101003167	LMR	186348	A	Bee stings				Rash
101003167	LMR	186348	A	12:44:52 11/12/2002	PIC	27	Bee Stings	Rash
101003167	LMR	186349	A	ACETAMINOPHEN		H3EG	900013	Hives
101003167	LMR	186349	A	12:44:52 11/12/2002	HICSN	1605	ACETAMINOPHEN	Hives
101003167	CONV	1582249	A	19:36:38 01/26/2004	PIC	12	Penicillins	Itwas, HIVES, TOLERATED NAF, W/O PROBLEMS, SWELLING
101003167	CONV	186348	A	12:44:52 11/12/2002	PIC	27	Bee Stings	Rash
101003167	CONV	186349	A	12:44:52 11/12/2002	HICSN	1605	ACETAMINOPHEN	Hives

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

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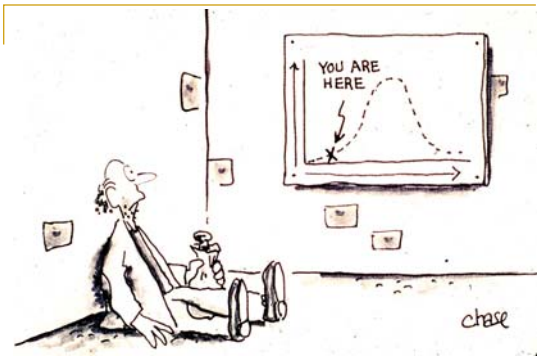

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