Secondary use of EHR data

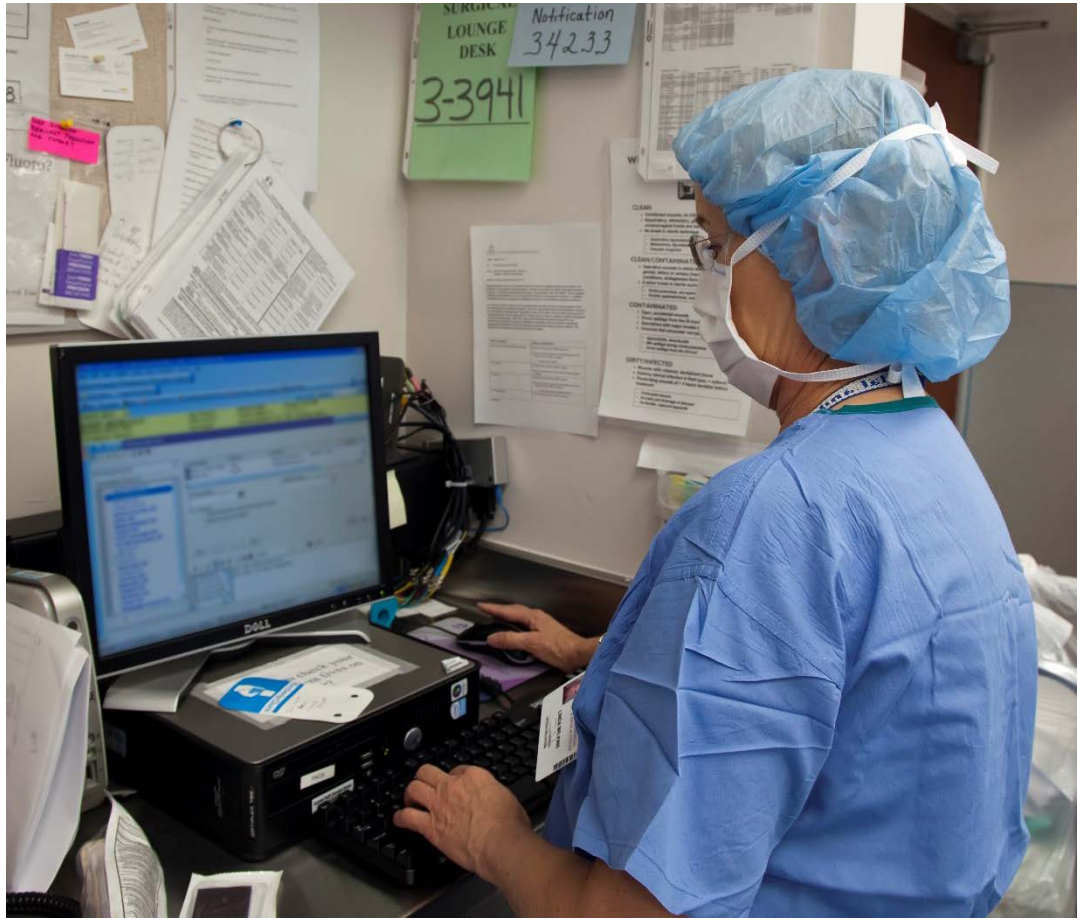
Mark Hoffman, Ph.D.
Chief Research Information Officer
@markhoffmankc

Disclosures

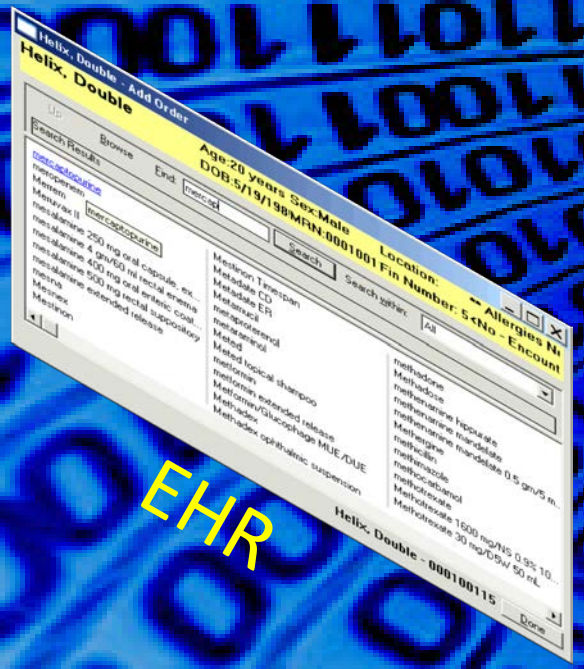
- Employed by Children's Mercy
- Former employee of Cerner Corporation (1997-2013)
  - *Inventor on 19 issued patents and multiple pending patents, no ownership stake*
  - *Divested stock options and liquid stocks*
  - *Retain limited 401k holdings*
- Board member Lee's Summit Healthcare Foundation
- Some work funded by Centers for Disease Control and Prevention
  - Grant NU47OE000105-01-01

Primary uses of EHR data

- Support point of care decisions
- Enable immediate access to documentation
- Promote compliance
- Protect patient privacy
- Automate and streamline clinical operations
- Billing



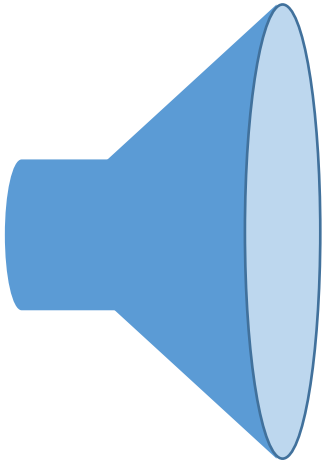
Clinical Data



EHR

The “Meaningful” in Meaningful Use

Clinical Data



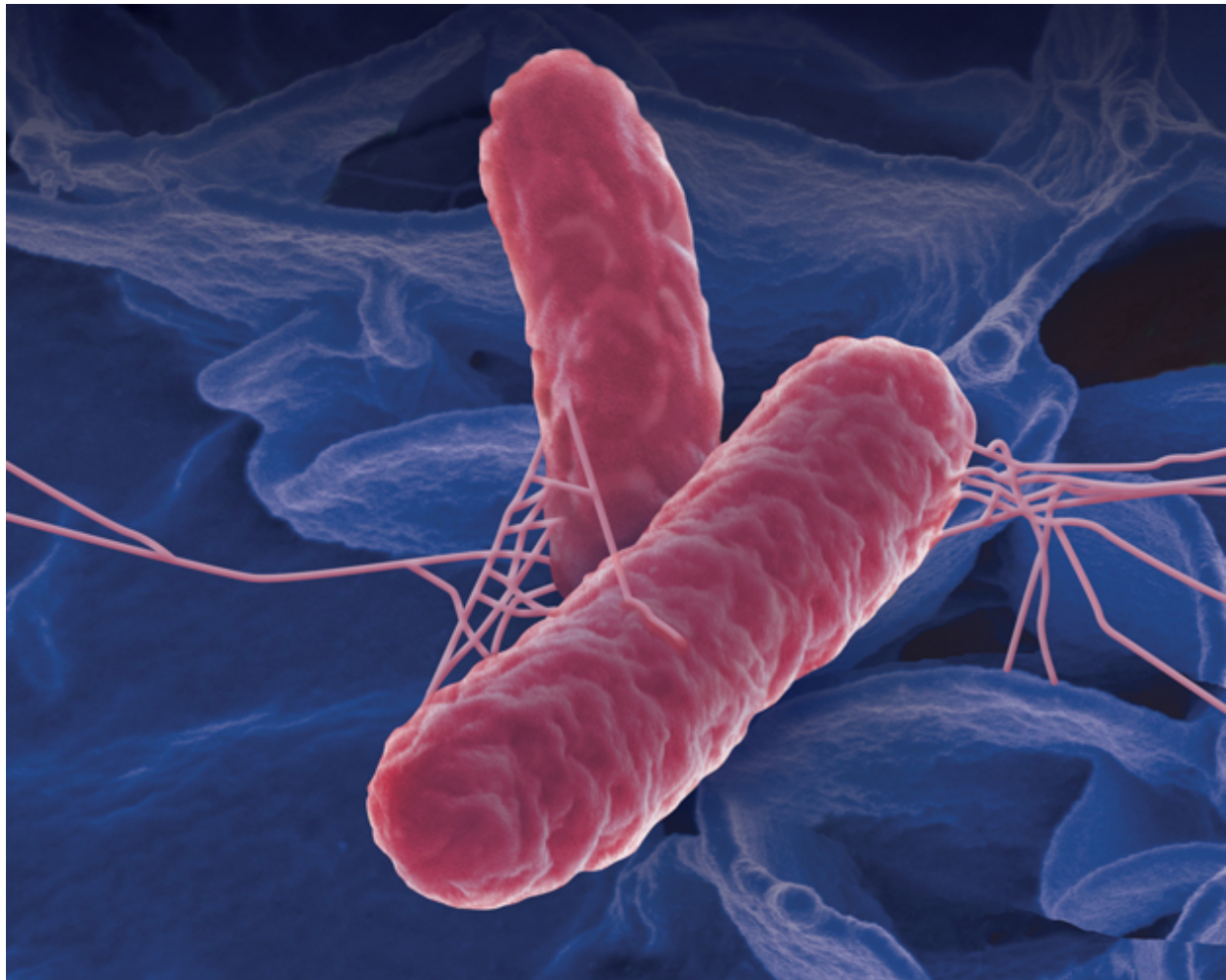
Value!

Value of secondary use

- Surveillance – early warning
- Investigate patterns in patient outcomes
- Inform quality improvement
- Improve operational efficiencies
- New discoveries
- Prediction

Disease Surveillance – Public Health

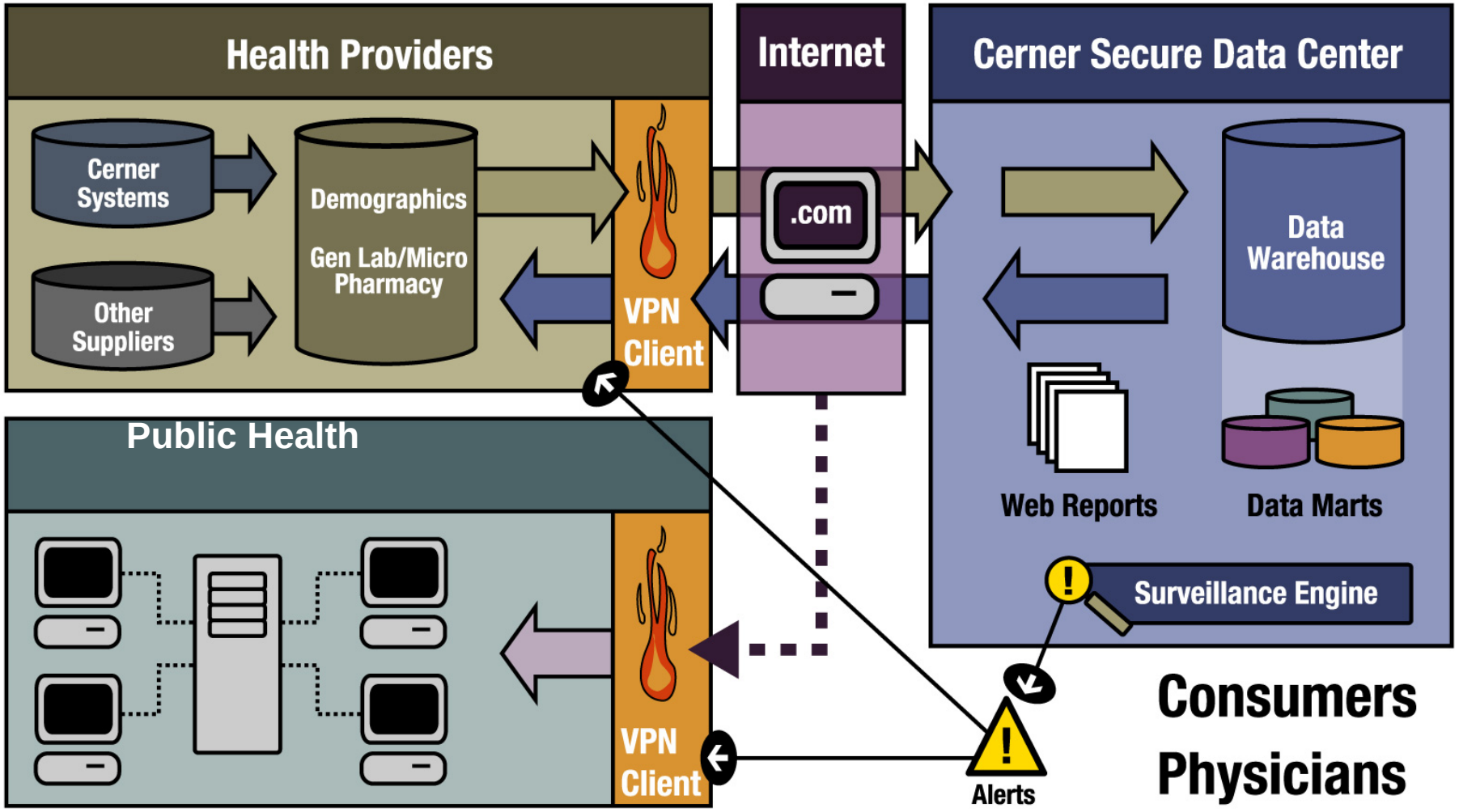
- Some pathogens require notification of public health
  - Highly contagious
  - Food poisoning
  - Bioterrorism
- Requirements vary by jurisdiction
- Historically notification was by FAX, mail or phone call
- Electronic reporting directly from EHR offers multiple benefits



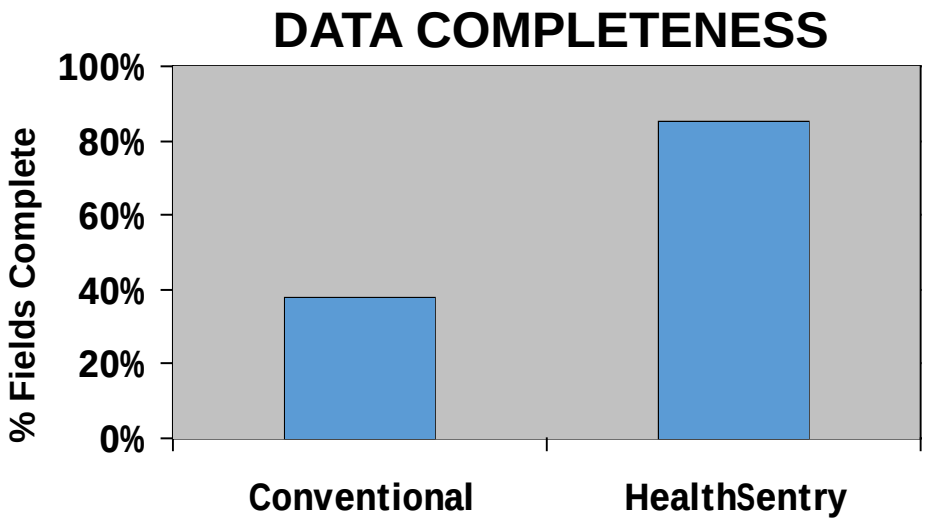
2001 - Anthrax

- Anthrax contaminated letters sent to news media and U.S. Senators
- 5 fatalities, 17 infections
- Kansas City Health Department and Cerner agreed to collaborate

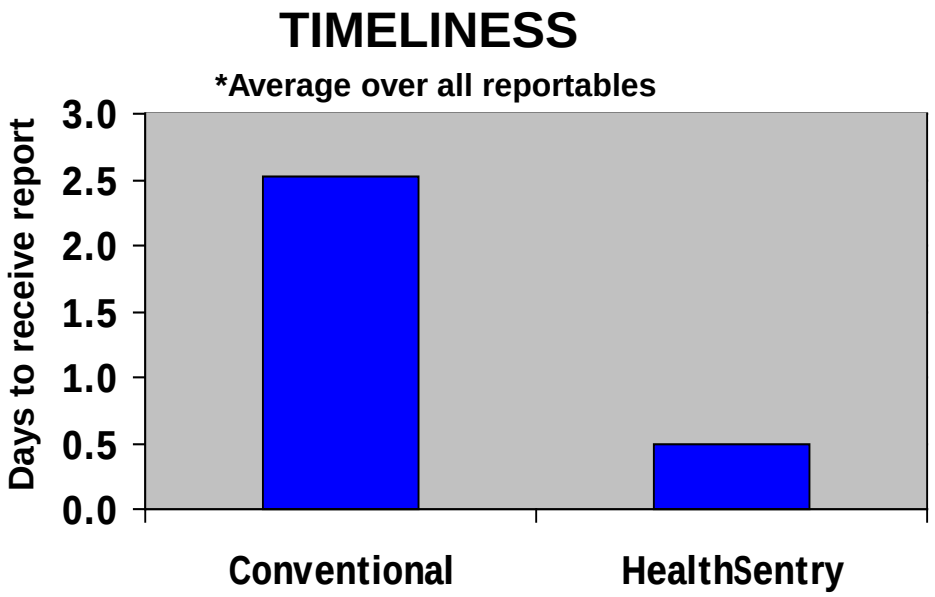
Surveillance Architecture

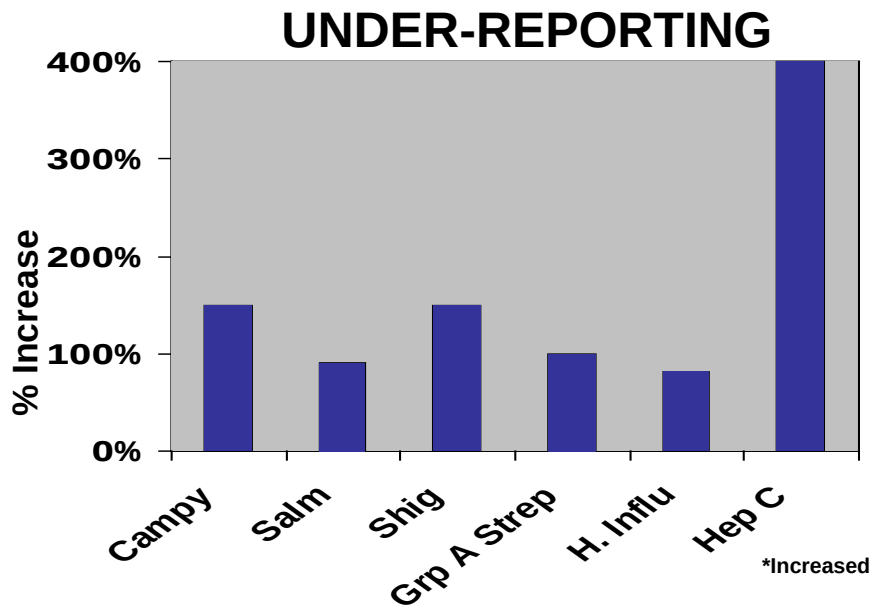


Improved public health reporting



Reportable cases (non-STD): March-Sept 2002
*Average over 6 key data fields

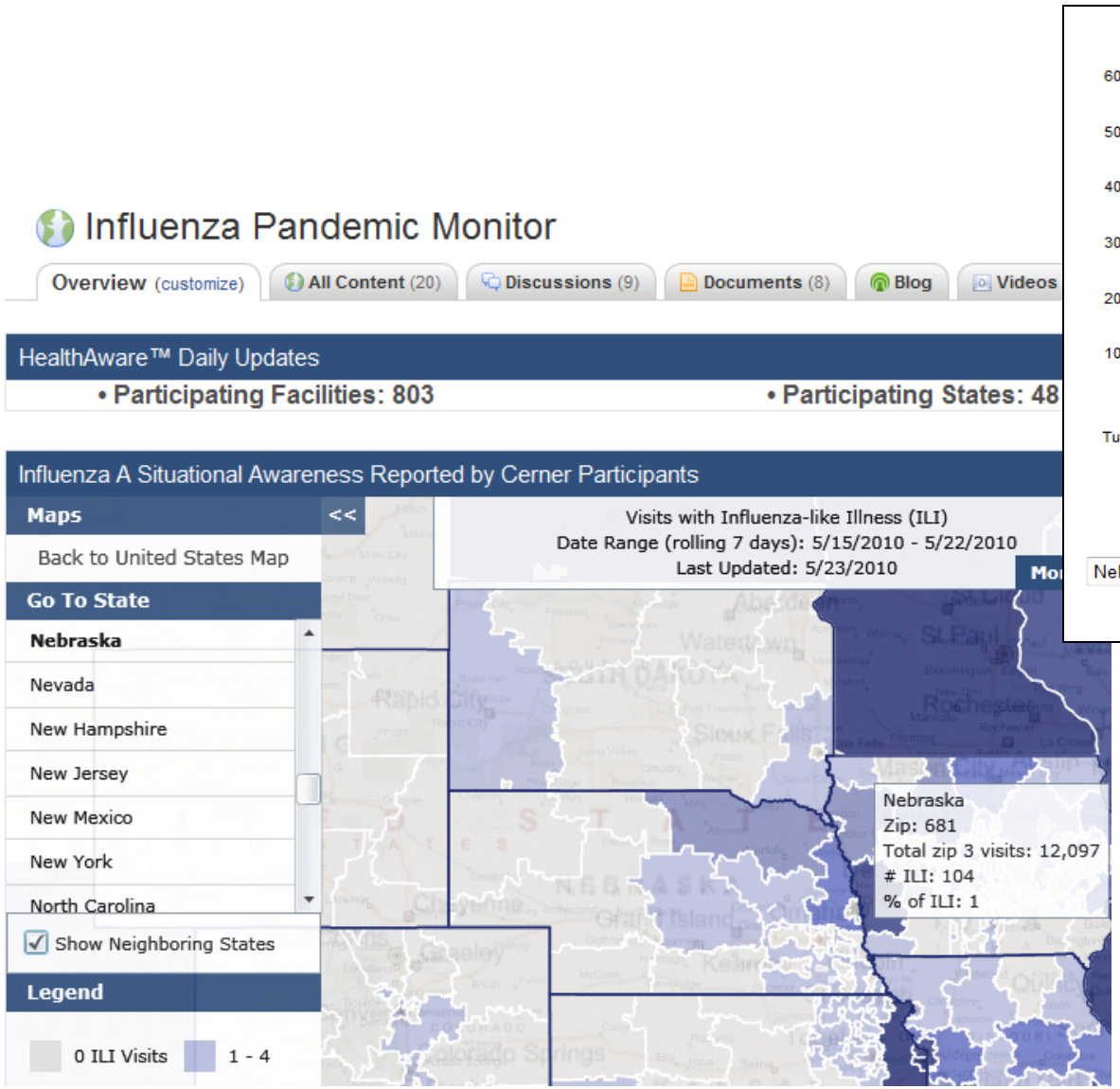


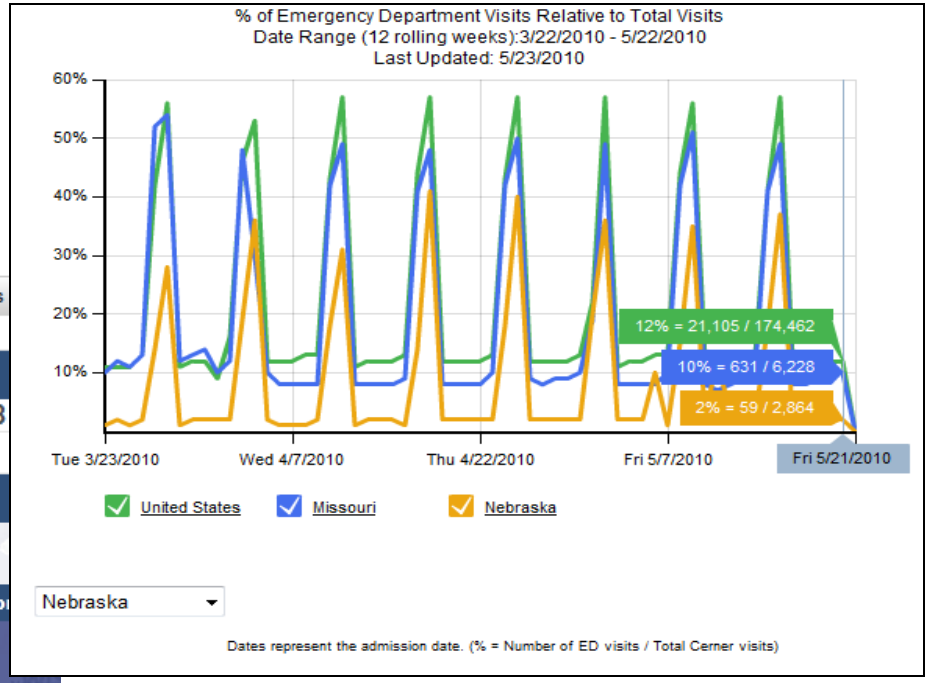


*Increased overall reporting by 96%

Hoffman, MA., Wilkinson, T, Bush, A, Myers, W, Griffin R, Hoff, G, Archer, R. “Multijurisdictional approach to Biosurveillance, Kansas City” Emerg. Inf. Dis. 2003 9(10):1281-1286 PMID: 14609464

Public Health Network: 2009 Influenza initiative





- Opt-in at project level
- 850+ facilities, 48 States
- 57 million cases processed
- Positive influenza A results, ILI, ED utilization
- Worked with CDC, state and local public health


DETOUR

Public Health – The Garden

- Data capture instruments are designed by experts
- Weeds are pruned out
- Data is “validated”
- Labor intensive
- With few exceptions, small size

NHANES – A very lovely garden

- National Health and Nutrition Examination Survey (NHANES)
- CDC managed
- Approximately 5000 people surveyed every year
- Socioeconomic
- Demographic
- Health
- Some lab tests

NHANES Survey Topics

Component or lab test conducted on original sample description | Change from original sample descript

Component	Sample description	1999–2000	2001–2002	2003–2004	2005–2006	2007–2008	2009–20
Survey participant (SP) questionnaire							
Acculturation (ACQ)	12 years and over	■	■	■	■	■	■
Allergy (AGQ)	1 year and over				■		
Air quality (AQQ)	16 years and over					■	■
Balance (BAQ)	40 years and over	■	■	■			
Blood pressure and cholesterol (BPQ)	16 years and over	■	■	■	■	■	■
Cardiovascular disease (CDQ)	40 years and over	■	■	■	■	■	■
Cognitive functioning (CFQ)	60 years and over	■	■				
Demographic background (DMQ)	Birth and over	■	■	■	■	■	■
Dermatology (DEQ)	6 years and over[1]	■	■	■	■	■	■
Diabetes (DIQ)	1 year and over	■	■	■	■	■	■
Diet behavior and nutrition (DBQ)	Birth and over	■	■	■	■	■	■
Dietary screener module (DTQ)	2–11 years						■
Dietary supplements (DSQ) and medications (RXQ)	Birth and over	■	■	■	■	■	■
Disability status (DLQ)	1 year and over						
Early childhood (ECQ)	Birth–15 years	■	■	■	■	■	■
Health insurance (HIQ)	Birth and over	Note C			■	■	■
Hearing/audiometry (AUQ)	1 year and over	■	■	■	■	■	■

Survey example

- Tightly structured
- Every surveyor asks same questions
- Coding consistent

SCQ.220 Are {you/any of the persons in this household} now on full-time active duty with the Armed Forces of the United States?

YES	1	(SCQ.230)
NO	2	(SCQ.245)
DK	9	(SCQ.245)
RF	7	(SCQ.245)

CAPI INSTRUCTIONS: IF CODED “1” AND THIS IS A SINGLE PERSON HOUSEHOLD, OR IF ALL HOUSEHOLD MEMBERS ARE "1", THE HOUSEHOLD IS “INELIGIBLE” AND THE SCREENER IS TERMINATED AFTER THE COLLECTION OF THE TELEPHONE NUMBER (SCQ.430); ELSE

IF THE HOUSEHOLD IS MORE THAN A SINGLE PERSON HOUSEHOLD, THE SKIPS SHOULD BE FOLLOWED AS SPECIFIED ABOVE.

Limitations of public health model

- Small sample size
- Difficult and expensive to scale
- Discord with practice

Healthcare – The Jungle

- Limited standardization
- Limited “data validation”
- Wide variation locally and regionally
- Far more coverage
- Many hazards

Jungle – life saving, dangerous

- Digitalis - digoxin
- Cinchona calisaya - Quinine

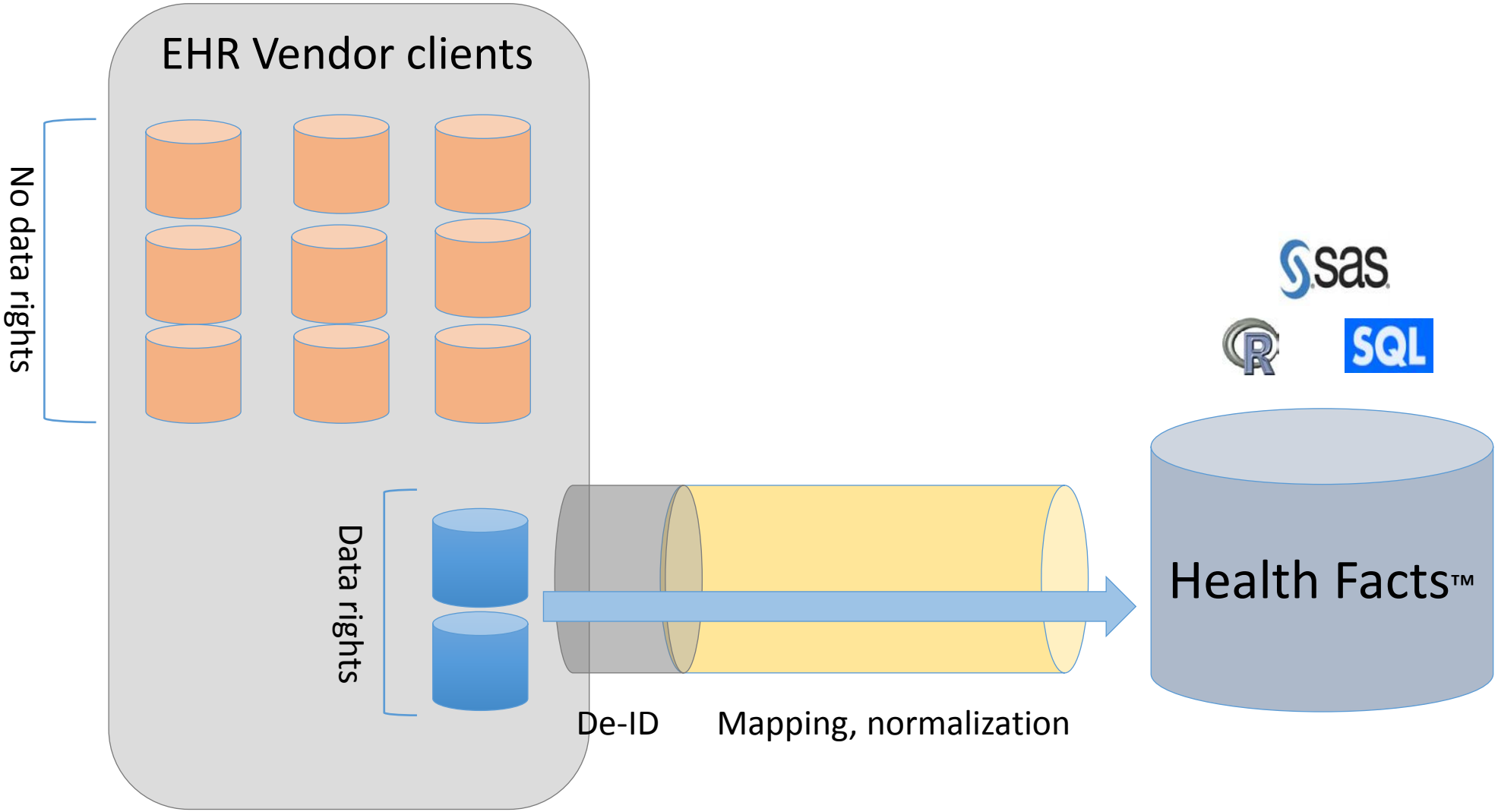
- Dangers

Health Facts – one corner of the jungle

- Voluntary data rights agreement between Cerner and **subset** of U.S. clients
- Began in 2000
- More than 860 healthcare facilities represented
- More than 100 organizations

- Epic Cosmos sounds similar

Health Facts



Cerner Health Facts - Summary

Data type	Current release
Unique patients	63 million
Total laboratory results	4.3 billion
Total facilities	863
Total medication orders	734 million
Total diagnoses	489 million

- Actual, not potential data

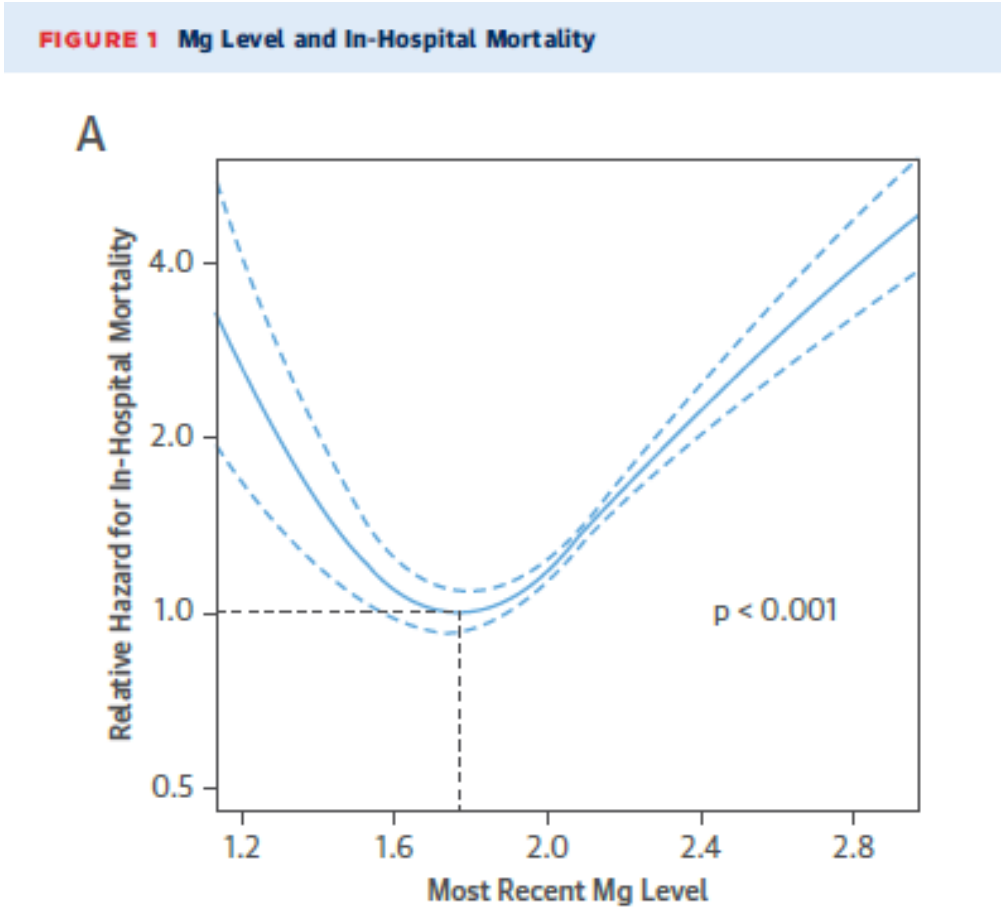
Other data in Health Facts

- Vitals
  - BP, temp, respiratory rate, pulse
- Pain scale
- Falls
- BMI
- Provider specialty
- Apgar
- Smoking
- Surgery
- ASA
- Charges

Health Facts Examples

Mg and AMI - Mortality

- Mg supplementation recommended after AMI but little evidence
- After inclusion/exclusion – **11,683** HF patients with AMI and Mg results
- Both **Low** and **High** Mg levels correlate with higher risk of in-hospital mortality

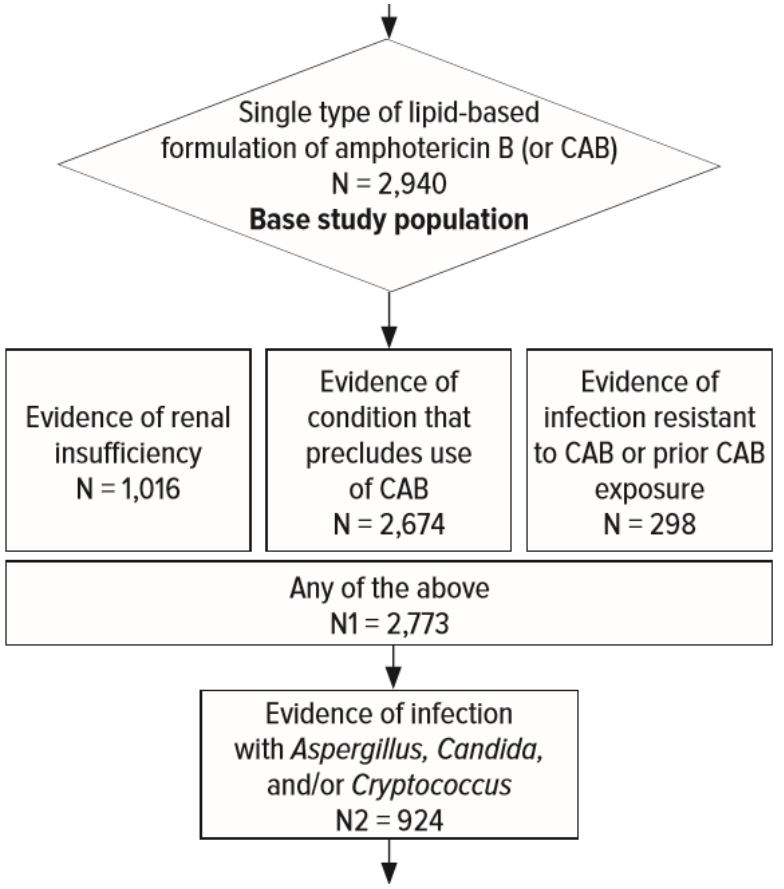


Shafiq et.al. – J. Amer. Coll. Card. June 2017

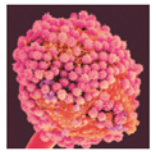
HF: Drug safety

Table 4 Nephrotoxicity and Comparison of Outcomes: Conventional and Lipid-Based Amphotericin Versus Lipid-Based Amphotericin (Unadjusted)

	LF-AMB (n = 327)	CAB/LF-AMB (n = 81)	*P* Value[a]
Nephrotoxicity, SCr, and Related Outcomes			
Nephrotoxicity, primary outcome[b]			
Post-amphotericin B SCr > 100% increase from the pre-amphotericin B level and an absolute level of > 1.2 mg/dL[c] (n [%])	47 [18.6]	28 [49.1]	< 0.001
SCr, post-amphotericin B peak (absolute value)[b]			
Peak > 1.5 mg/dL (n [%])	120 [47.4]	36 [63.2]	0.032
Peak > 2.0 mg/dL (n [%])	90 [35.6]	23 [40.4]	0.498
Peak > 2.5 mg/dL (n [%])	63 [24.9]	18 [31.6]	0.300
Peak > 3.0 mg/dL (n [%])	46 [18.2]	13 [22.8]	0.422
SCr, post-amphotericin B peak (relative change)[b]			
Peak 1.5 x pre-amphotericin B (n [%])	91 [36.0]	38 [66.7]	<0.001
Peak 1.5 x pre-amphotericin B and ≥ 1.5 ULN (n [%])	51 [20.2]	21 [36.8]	0.007
Peak 2 x pre-amphotericin B (n [%])	53 [21.0]	26 [45.6]	< 0.001
Peak 3 x pre-amphotericin B (n [%])	21 [8.3]	11 [19.3]	0.014
SCr, post-amphotericin B peak[b]			
Peak (absolute value) (mean [SD])	2.1 [1.7]	2.3 [1.5]	0.400
% change (relative change) (mean [SD])	62.2% [107.5]	122.9 [131.7]	<0.001
Other Adverse Events			
Hypokalemia during amphotericin B therapy[d] (n [%])	144 [59.3]	55 [71.4]	0.055
Hypomagnesemia during amphotericin B therapy[e] (n [%])	82 [39.8]	42 [58.3]	0.007
New-onset AST elevation following amphotericin B therapy[f] (n [%])	25 [16.2]	12 [24.5]	0.192
Infusion reaction requiring treatment[g] (n [%])	63 [19.3]	24 [29.6]	0.041
Mortality[h]	104 [32.1]	26 [32.5]	0.945
Hospital LOS			
Overall hospital LOS (days) (mean [SD])	29.0 [27.3]	34.8 [26.9]	0.088
Post-amphotericin B hospital LOS (mean [SD])	15.7 [18.9]	24.1 [21.9]	<0.001



Comparison of Adverse Events and Hospital Length of Stay Associated With Various Amphotericin B Formulations

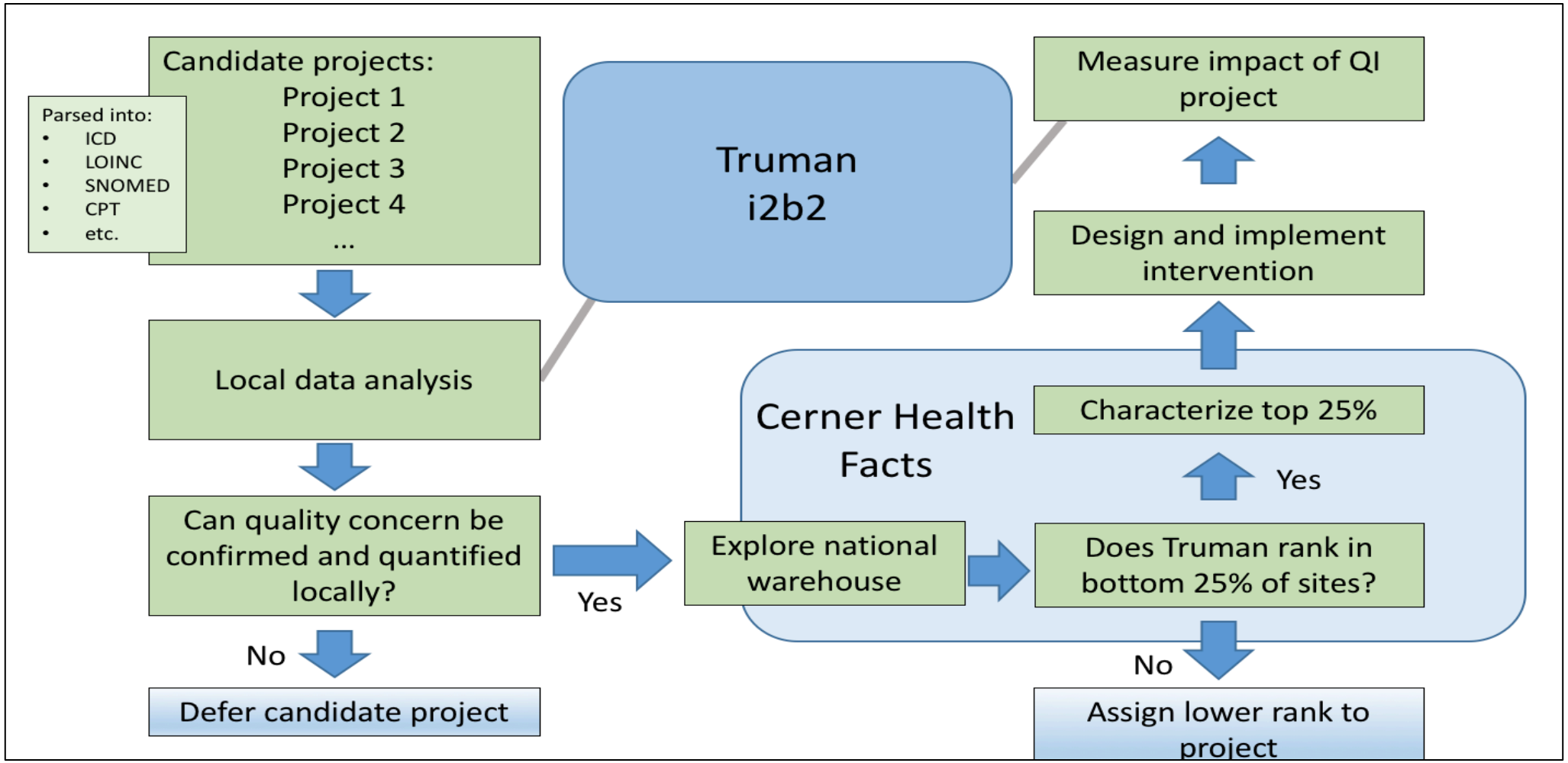


Sequential Conventional Amphotericin B/Lipid Versus Lipid-Only Therapy For the Treatment of Invasive Fungal Infections in Hospitalized Patients

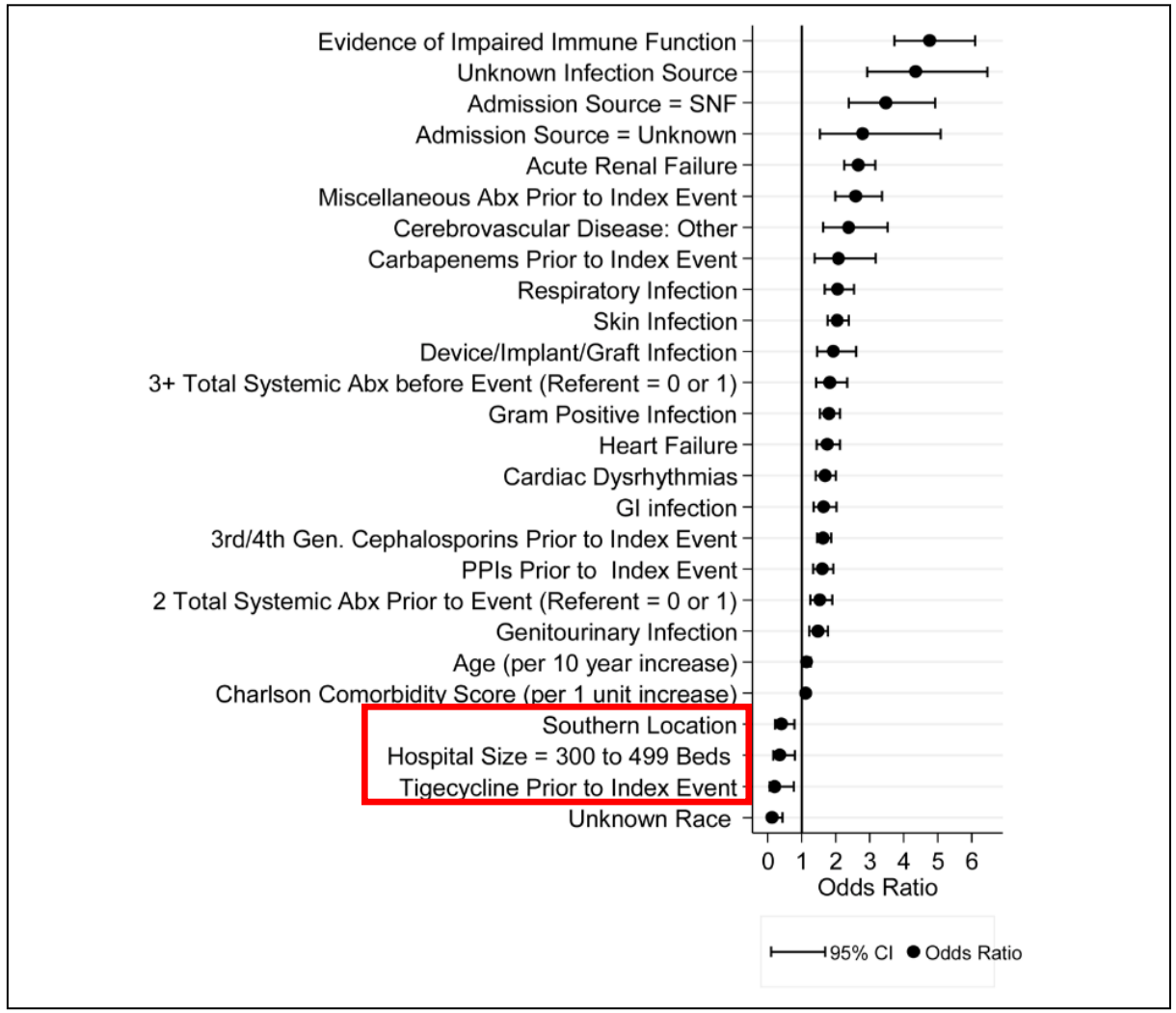
Rolin L. Wade, RPh, MS; Paresh Chaudhari, PharmD, MPH; Jaime L. Natoli, MS, MPH; Robert J. Taylor, AS; Brian H. Nathanson, PhD; and David Horn, MD

P&T 2013 238: vol 5 p. 278-287

Data-informed selection of QI projects



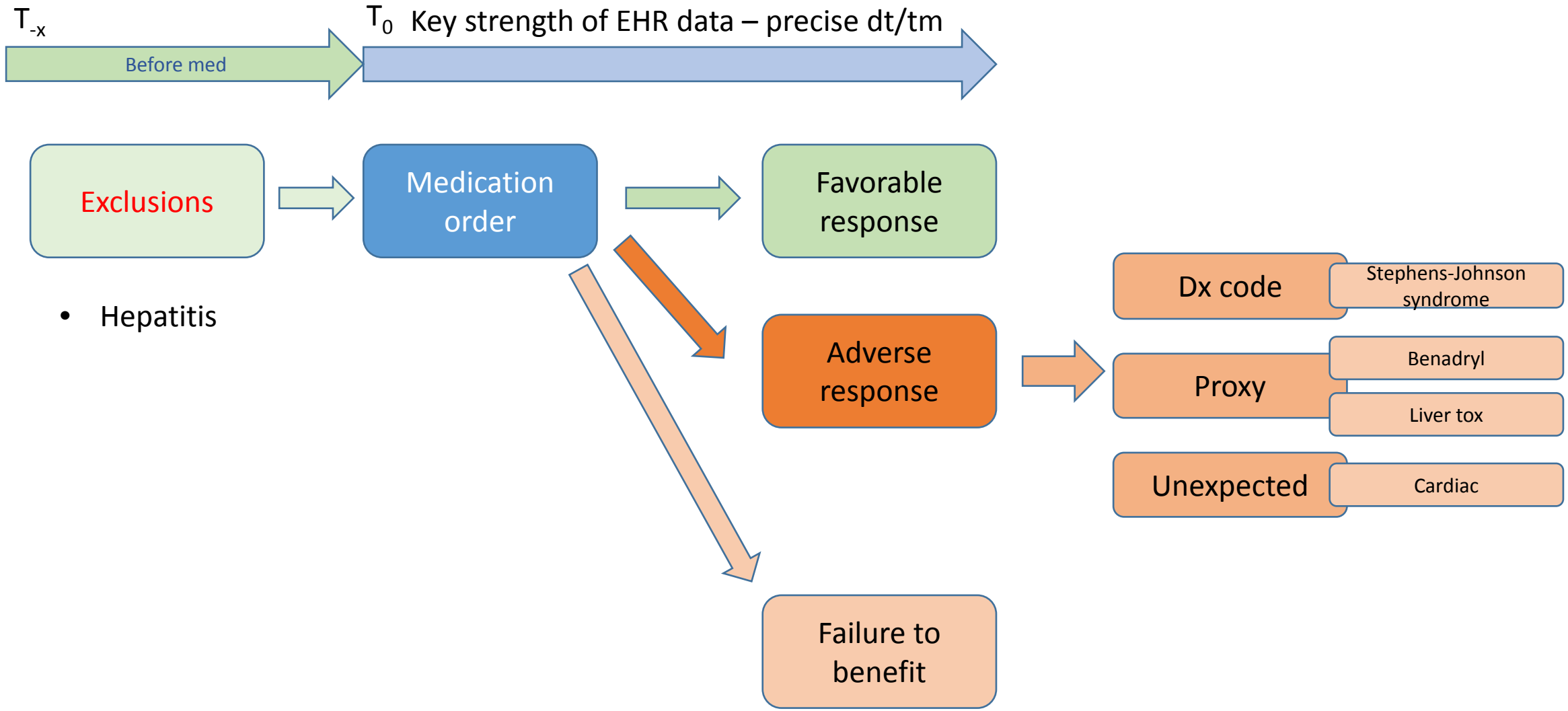
Let the data speak



- Risk factors associated with hospital acquired *C. diff* infections
- Regression analysis
- Does not require a narrow question

Dean B., Campbell R., Nathanson B. et. al. "Risk factors associated with hospital-origin vs community-origin Clostridium difficile-associated diarrhea" ID week 2012

What do we need for safety analysis?



- Hepatitis

What's missing from de-identified EHR data?

- New medications take time to be included
- INDs are not represented unless included in RxNorm
- Text notes that could identify adverse events
  - Can't reliably de-identify text notes
- Outpatient scripts
  - Could be addressed in future releases
- Compliance data (fills)

Comparison of HF with HCUP NIS

Category of condition	HCUP	HF	tValue
The Skin, Subcutaneous Tissue & Breast	2.58	2.58	0.20
Blood, Blood Forming Organs & Immunological Disorders	1.36	1.36	0.29
Nervous System	6.03	6.12	0.39
The Kidney & Urinary Tract	4.32	4.30	0.45
Burns	0.11	0.12	0.50
Myeloproliferative Disease & Disorders Poorly Differiantiated Neoplasms	0.91	0.86	0.70
The Hepatobiliary System and Pancreas	2.94	3.03	1.02
The Ear, Nose, Mouth and Throat	1.10	1.17	1.49
The Eye	0.15	0.14	1.53
The Male Reproductive System	0.50	0.55	2.23
Endocrine, Nutritional & Metabolic Disease & Disorders	3.26	3.45	2.44
The Respiratory System	9.79	10.29	2.46
Multiple Significant Trauma	0.27	0.21	3.08
The Digestive System	8.91	9.51	3.10
The Circulatory System	13.64	14.82	3.27
Injuries, Poisonings & Toxic Effects of Drugs	1.56	1.44	3.49
Human Immunodeficiency Virus Infections	0.20	0.13	3.58
The Musculosketal System & Connective Tiisues	9.06	8.15	3.82
Infectious & Parasitic Diseases, Systemic/Unspecified Sites	3.23	2.85	5.12
Newborns & Other Neonates w/ Condition Orginating in Perinatal Period	10.42	8.04	6.94
Mental Diseases & Disorders	3.89	2.22	7.10
Factors Influencing Health Status & Other Contacts with Health Services	1.67	2.28	7.22
Alcohol/Drug Use & Alcohol/Drug Induced Organic Mental Disorders	1.24	0.47	7.68
Pregnenacy, Childbirth & The Puerperium	11.09	4.15	18.67
The Female Reproductive System	1.75	0.55	24.04

Mental/behavioral
Maternity
Women's health

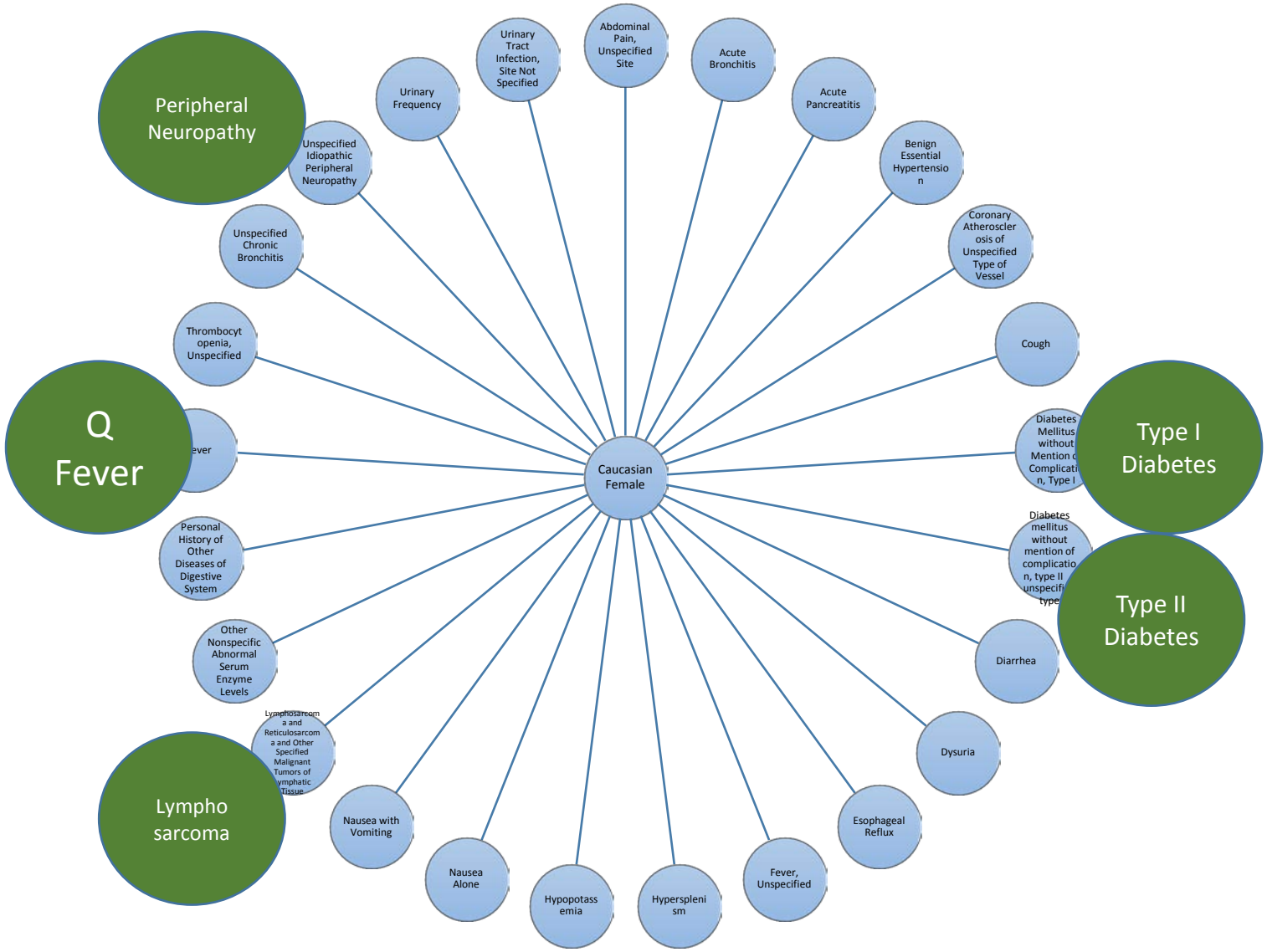
DeShazo, J; **Hoffman, MA** "A comparison of a multistate inpatient EHR database to the HCUP nationwide inpatient sample" BMC Health Services Res. 2015 15(1):384 PMID: 26373538

Pitfalls of EHR data

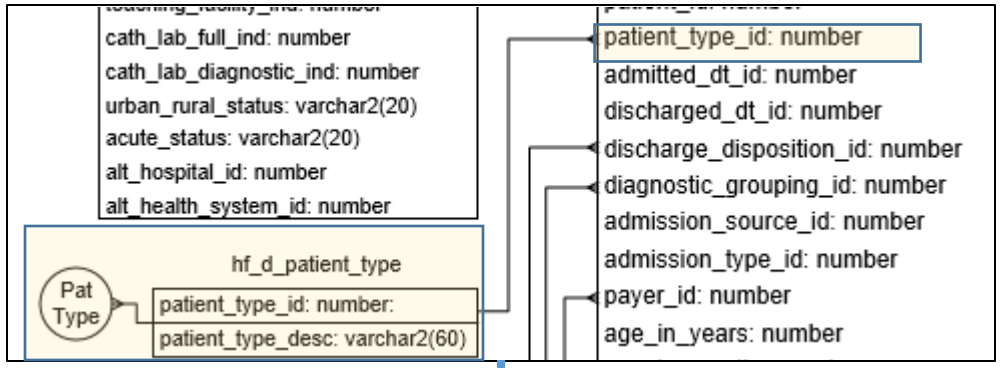
- Variability at every level
  - Individual practitioner
  - Department
  - Organization
  - Region
- Subtle but significant issues

- Configuration changes over time
  - Not always documented, tracked or associated with data distributions

One very ill woman



Patient type categories (subset)



Code	Category
77	Client
78	Clinic
76	Cerner test patient – not valid patients
122	HLA QC
123	Home health
109	Test

Update: Cerner has removed many Non-patient encounters in latest HF data cut

Conclusion

- Aggregate EHR data offers significant opportunity to perform novel safety analysis and surveillance
- Requires deep and practical understanding of EHR content and workflow
  - Theoretical understanding is limited value
  - Implementation science should be represented
- Requires recognition of strengths and limitations of de-identified EHR data
- Statistical methods are still evolving

Thank you!

- Contact:

  Mark Hoffman, Ph.D.
  mhoffman@cmh.edu
  @markhoffmankc
  816-302-1310

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Children's Mercy KANSAS CITY