Using Epic for Clinical Research

Mark Weiner, MD

Assistant Dean for Informatics, Temple University School of Medicine
Chief Medical Information Officer, Temple University Health System
mark.weiner@tuhs.temple.edu

Aaron Sorensen

Director for Informatics, Temple University School of Medicine

Temple University
Health System

My mantra

In attempting to arrive at the truth, I have applied everywhere for information, but in scarcely an instance have I been able to obtain hospital records fit for any purpose of comparison. If they could be obtained, they would enable us to decide many other questions besides the one alluded to. They would show the subscribers how their money was being spent, what good was really being done with it, or whether the money was not doing mischief rather than good.

Temple University **Health** System

What is Epic

- The Electronic Medical Record of all ambulatory practices (TUP and TPI) at Temple University Health System since 2011. Inpatient go-live August 5, 2016

- Captures unstructured text from clinical notes as well as discrete data on
  - Vitals
  - Labs
  - Medication orders
  - Diagnoses
  - Social history (esp smoking)
  - Past Medical Hx/Fam Hx

Temple University Health System

Research with Epic

Retrospective Research

- Descriptive epidemiology and patterns of care
    - What are the demographic characteristic of our population with <you name it disease>, and how are they initially managed?
- Comparative Effectiveness
    - How do people treated for <you name it disease> with <therapy A> differ from people receiving <therapy B> and how do their outcomes differ?
- Predictive analytics
    - What characteristics of people with <you name it disease> are associated with higher rates of admission.

Temple University
Health System

Research with Epic

Quality of Care Research

- Process measures
  - How many patients with Diabetes received appropriate preventative screening or meds (ophtho/ foot exams, ACE-I)

- Intermediate measures
  - How many patients with Diabetes have A1c < 7.0, BP< 130/90 and LDL < 100

- Outcome measures
  - How many patients with Diabetes developed end stage renal disease, AMI, foot amputation

- Stratify the above by provider…

Temple University Health System

Research with Epic

Prospective Research

I'd like to survey/intervene upon people with the following characteristics

- smokers with COPD who have had an ED visit in the past year
- Patients on 4 BP meds who have BPs > 160/90
- Patients who missed a colonoscopy appointment
- Providers with > 50% panel with BP > 150/90
- Patients hospitalized with CHF who are readmitted within 30 days
- Patients with Lupus with stage 3 renal disease
- Patients with Diabetes whose GFR dropped by 50% in the past 2 years
- Patients on NSAIDs with GI bleed
- Patients started on coumadin yesterday

Temple University Health System

The Good News

- Epic has a great deal of data on thousands of patients spanning 4 years

- Lots of discrete data on demographics, meds, labs, diagnoses, and changes in these variables over time

- Possible to look up unstructured data (notes, path reports, radiology impressions) on a focused set of patients who meet other clinical criteria

- We can span ambulatory data with coarse information on admissions

Temple University
Health System

The challenges

- Defining the "computable phenotype"
  - Who has your disease of interest?
  - Who really has an incident case of your disease of interest?
  - What should count as a drug exposure?
- Regulatory issues in working with data
  - Who is authorized to receive and work with data, and how do identifiers matter
  - How can these data be transmitted?
  - Where can these data be stored and used for analysis
- There is a difference between "raw" data and an analytical data set

Temple University
Health System

Caveats in using Epic Data

Is the data Accurate?

Accuracy = truth?

- – If the information system says a patient has asthma, then the patient has asthma

Accuracy = true representation of the source data?

- – If the information system says a patient has asthma, then the source data for the patient includes a code for asthma or other diagnostic testing results consistent with asthma

Temple University
Health System

Caveats in using Epic Data

Is the data Accurate?

Clinical data is used in real clinical practice so it must be accurate except…

– Physician patient communication/misunderstandings

– Busy doctors don't code/document everything

– Idiosyncrasies of the clinical setting in which data is collected

– Ambiguity inherent in the practice of medicine

– Code creep-

- Early codes before diagnosis of gallstones is confirmed may suggest simple abdominal pain

- Changing billing rules can alter the recording of diagnoses

Temple University
Health System

Adapted and expanded from O'Malley KJ, Cook KF, Price MD, 10 KR, Hurdle JF, Ashton CA Measuring Diagnoses: ICD Code Accuracy Health Services Research 2005. 40:1620-39.

Caveats in using Epic Data

Research using billing and even EHR data must account for all of the realities inherent in the underlying data

- **Absence of evidence is not evidence of absence**
  - Just because you don't see evidence of a disease doesn't mean the patient doesn't have the disease
- **Vigilance in exploring for a condition, even if it turns out NOT to be present, has clinical relevance**
  - Providers may look harder for the presence of a condition or a physical finding in some patients more than others
- **Clusters of visits are significant, but not necessarily directly related to the condition being studied**
  - Someone with a lot of visits related to asthma may get a cholesterol drawn sooner than a patient without asthma whose cholesterol management is being done more routinely.

Temple University
Health System

Caveats in using Epic Data

To find patients with a certain disease, you need to consider all the ways the disease may be represented in diagnosis codes and ancillary test results

- – URI/bronchitis/tracheitis/pharyngitis/sinusitis are harder to reliably distinguish that most people would like to think.

- – Green sputum is not always bacterial and Yellow sputum is not always viral

- – If you alter your notion of a billing code from "the patient definitely has this disease" to "the patient has something like this disease" or "the doctor is worried about this disease," and incorporate that ambiguity into your analysis, you will be much happier

Temple University
Health System

Caveats in using Epic Data

Data from uncaptured clinical settings
- – Received Angioplasty at Temple. Hospitalized Einstein for GI bleed.

Logical inconsistencies across information systems
- – Allergy to Drug Z listed, but prescriptions for Drug Z exist

Temporal issues
- – Presence of murmur AFTER echo report (or cardiology visit)
- – Heart failure reported AFTER starting ACE-I

Temple University Health System

Caveats in using Epic Data

Unmeasured confounders

Treatment bias
- – Medications are prescribed because the provider believes the patient needs them
- – Sicker patients may systematically receive certain types of medicine more than others

Testing bias
- – Patients who test positive for certain tests are more likely to receive additional testing (related or unrelated)

Temple University
Health System

Caveats in using Epic Data

Unmeasured confounders

Formulary issues
- Insurer rules limiting the use of some meds to patients with certain underlying conditions or who have already failed other meds?

Practice variation
- Some meds are favored because of non-clinical issues

OTC Meds
- Aspirin, other NSAIDs, PPIs

Temple University **Health** System

Requirements for the appropriate application of Epic data in clinical research

- **Know what the right questions are**
  - Instead of asking, "How many patients have high cholesterol?" the better question is "How many patients have a pattern of cholesterol values that may be interesting for my research?"
- **Let preliminary analyses inform decisions about cohort selection criteria and predictor and outcome variable selection**
  - "Show me everyone with this diagnosis code." is not the best way to begin
 - Instead, think about what you are trying to find through your research

Temple University
Health System

User Interaction

- **How many patients have a diagnosis code 253.6**
  - Easy Answer: 300
  - Response : "Thanks!"

User Interaction

- **How many patients have a diagnosis code 253.6**
  - Better answer : Hmm. 253.6 is a code for SIADH which is a euvolemic condition associated with hyponatremia. Perhaps we can look for patients with low serum sodium who are not on diuretics and do not have diagnoses or medications for Congestive Heart Failure
  - Response – "You can do that??"

Temple University Health System

# Temple University Health System
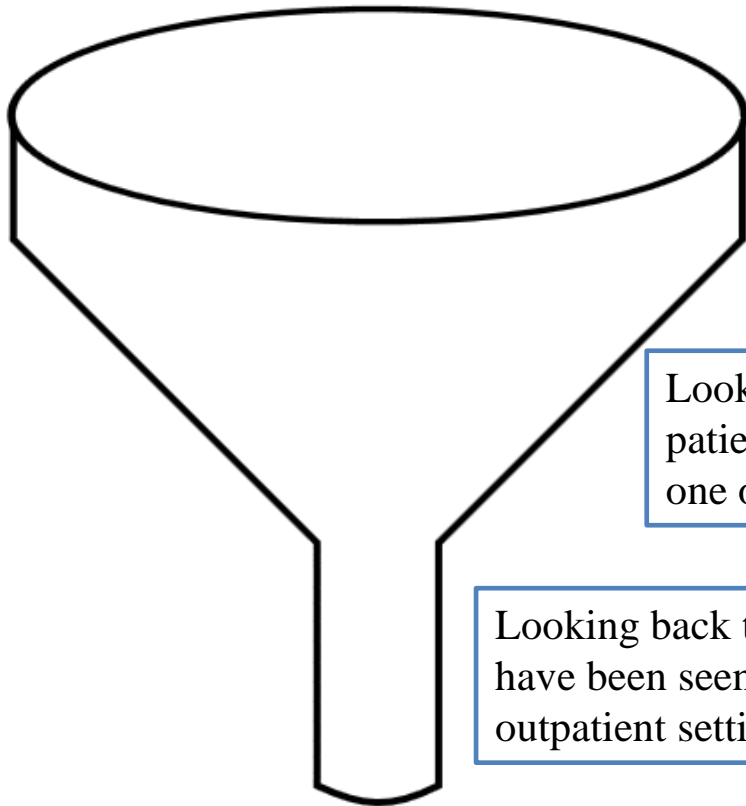
From October, 2010 to the present, about 430,000 patients have had one or more outpatient visits at one or more of 200 active departments.

Looking only at the last year, about 220,000 patients have had one or more outpatient visit at one or more of 200 active departments.

Looking back to 2010, about 86,000 patients have been seen ten or more times in an outpatient setting.

Temple University
Health System
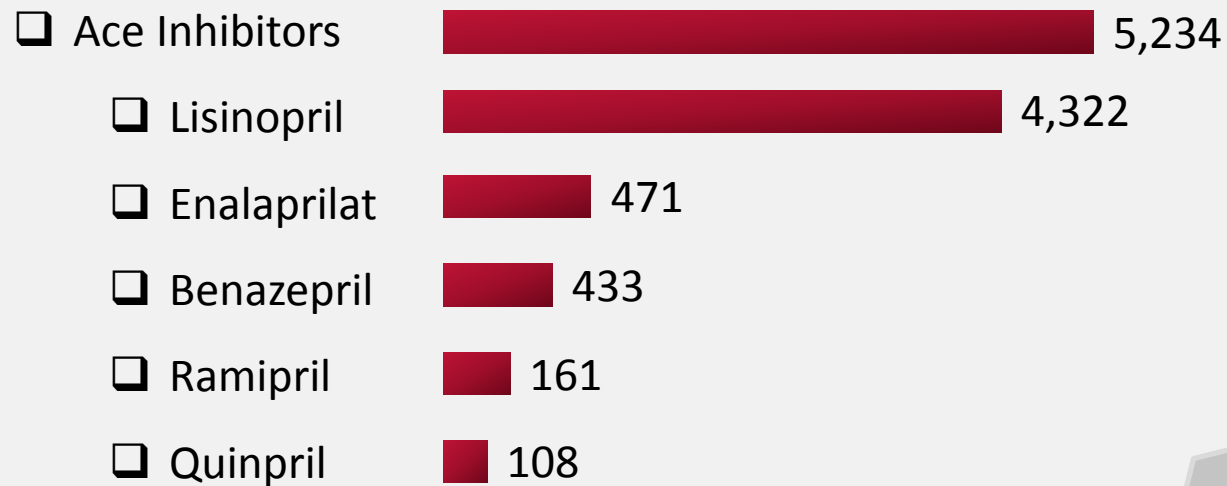
Temple University Health System
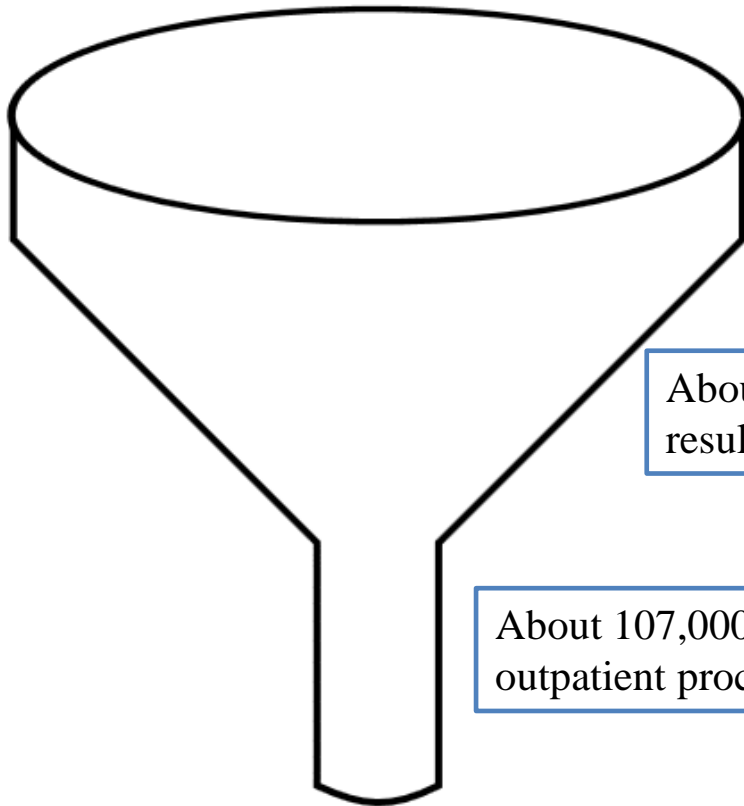
From October, 2010 to the present, about 370,000 patients have had one or more outpatient medications prescribed.

About 302,811 patients have at least one lab result in Epic.

About 107,000 patients have had at least one outpatient procedure performed.

Temple University
Health System

Example of potential medication output from "Patients with Diabetes that have A1c < 7.0 and LDL < 100" Query

Medications

- ❑ Ace Inhibitors — 5,234
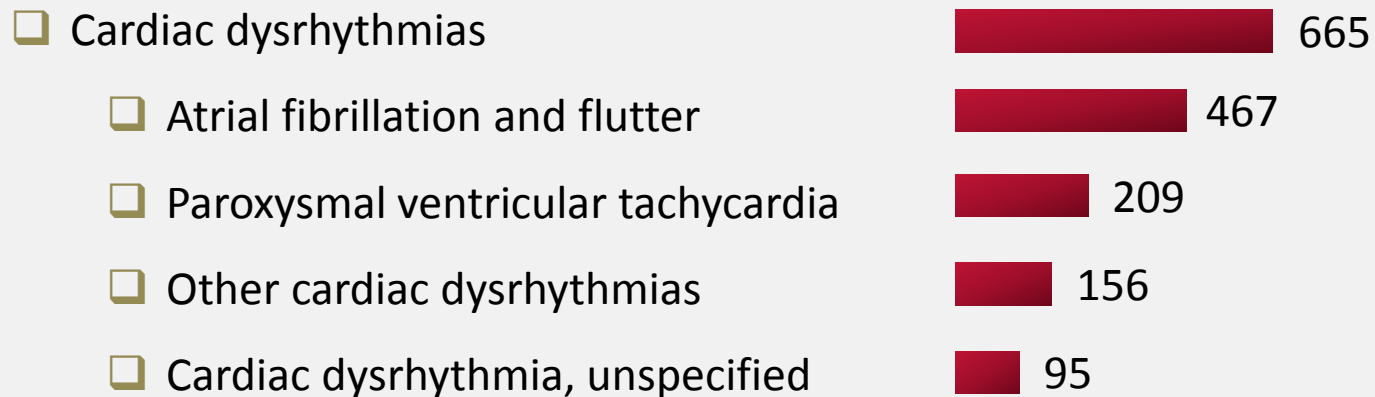 - ❑ Lisinopril — 4,322
  - ❑ Enalaprilat — 471
  - ❑ Benazepril — 433
  - ❑ Ramipril — 161
  - ❑ Quinpril — 108

Temple University **Health** System

Example of potential lab-result output from "Patients on NSAIDs with GI bleed" Query

Labs

	Mean ± SD	Min	Min
Aspartate aminotransferase [enzymatic activity/volume] in serum or plasma	26.80 ± 8.95	17	41
Carbon dioxide, total [moles/volume] in serum or plasma	23.85 ± 5.82	15	32
Glucose [mass/volume] in serum or plasma	103.33 ± 21.93	74	133
Calcium [mass/volume] in serum or plasma	9.00 ± 0.55	8	10
Albumin [mass/volume] in synovial fluid	3.53 ± 0.76	2	4
Chloride [moles/volume] in serum or plasma	102.50 ± 3.44	98	109

Example of potential comorbidity output from "Heart failure reported AFTER starting ACE-I" Query

Diagnoses

- ❑ Cardiac dysrhythmias — 665
    - ❑ Atrial fibrillation and flutter — 467
    - ❑ Paroxysmal ventricular tachycardia — 209
    - ❑ Other cardiac dysrhythmias — 156
    - ❑ Cardiac dysrhythmia, unspecified — 95

Temple University
Health System

Example of potential procedure output from "patients with low serum sodium who are not on diuretics or other CHF meds and do not have a CHF Dx" Query

Procedures

❑ Reduction of fracture and dislocation   164

   ❑ Open reduction of fracture with internal fixation   111

      ❑ Open reduction of fracture with internal fixation, tibia and fibula   53

      ❑ Open reduction of fracture with internal fixation, femur   21

ersity
Health System

Conclusions

- We have the technical capability to address research information needs with data, particularly discrete data, from Epic

- We are working on the policies that will enable us to provide these data to investigators in a consistent fashion that meets regulatory requirements.

- Be mindful of the challenges of dealing with raw data, and the work required to perform analyses. Success requires statistical knowledge and content expertise.

Temple University
Health System