Using Epic Data for Research and QI

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TEMPLE HEALTH

Lots and Lots of Data

- Since Mid-October 2010
  - 1.4M **patients** in the “patient” table, but only 1M with some encounter activity (office visits, telephone call, “orders only,” etc)
  - 588K **patients with at least one office visit**
  - 4.8M **office visits** total (TUP and TPI)
  - 639K patients with **161M Lab results** (but remember a single CBC is about 10 results)
  - 594K patients with **15M Medication orders**
- Between July 2012 and November 2017
  - 166K admissions of 100K patients

What kinds of data are available?

- Captures unstructured text from clinical notes as well as discrete data on
  - Ambulatory scheduling activity
  - Admission activity
  - Vitals
  - Labs
  - Allergies
  - Special studies
  - Medication orders/dispensing
  - Diagnoses/DRGs
  - Procedure orders
  - Social history (esp smoking)
  - Past Medical Hx/Fam Hx

Investigations 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.

Investigations with Epic

Quality Measurement

- 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…

Investigations with Epic

Quality Improvement

- Smoking Cessation
  - I need to know everyone whose smoking status went from “current smoker” to “quit” between 2-5 years ago whose status has not been validated in the past year. I’m going to contact them to ensure that they have not started smoking again.
- Anaphylaxis
  - I need to know everyone with severe allergies to environmental exposures and contact them about difficulties getting an EpiPen
- Visit Adherence
  - I need to know who has missed more than 2 visits in the past year to contact patients their barriers to attending scheduled visits.

Investigations with Epic

Prospective Interventions

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

The Good News

- Epic has a great deal of data on thousands of patients spanning 6 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 2012-2016 and detailed inpatient data since Aug 2016

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 patient 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

Research vs Quality Improvement

	Human Subjects Research	Quality Improvement
Purpose	**designed to develop or contribute to generalizable knowledge**	**designed to implement knowledge**, assess a process or program as judged by established/accepted standards
Starting Point	knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis	knowledge-seeking is integral to ongoing management system for delivering health care
Design	follows a rigid protocol that remains unchanged throughout the research	adaptive, iterative design
Benefits	might or might not benefit current subjects; intended to benefit future patients	directly benefits a process, system or program; might or might not benefit patients
Risks	may put subjects at risk	does not increase risk to patients, with exception of possible patients' privacy or confidentialty of data
Participant Obligation	no obligation of individuals to participate	responsibility to participate as component of care
Endpoint	answer a research question	improve a program, process or system
Analysis	statistically prove or disprove hypothesis	compare program, process or system to established standards
Adoption of Results	little urgency to disseminate results quickly	results rapidly adopted into local care delivery
Publication/Presentation	investigator obliged to share results	QI practitioners encouraged to share systematic reporting of insights

https://irb.research.chop.edu/quality-improvement-vs-research

QI Versus Research

What difference does it make?

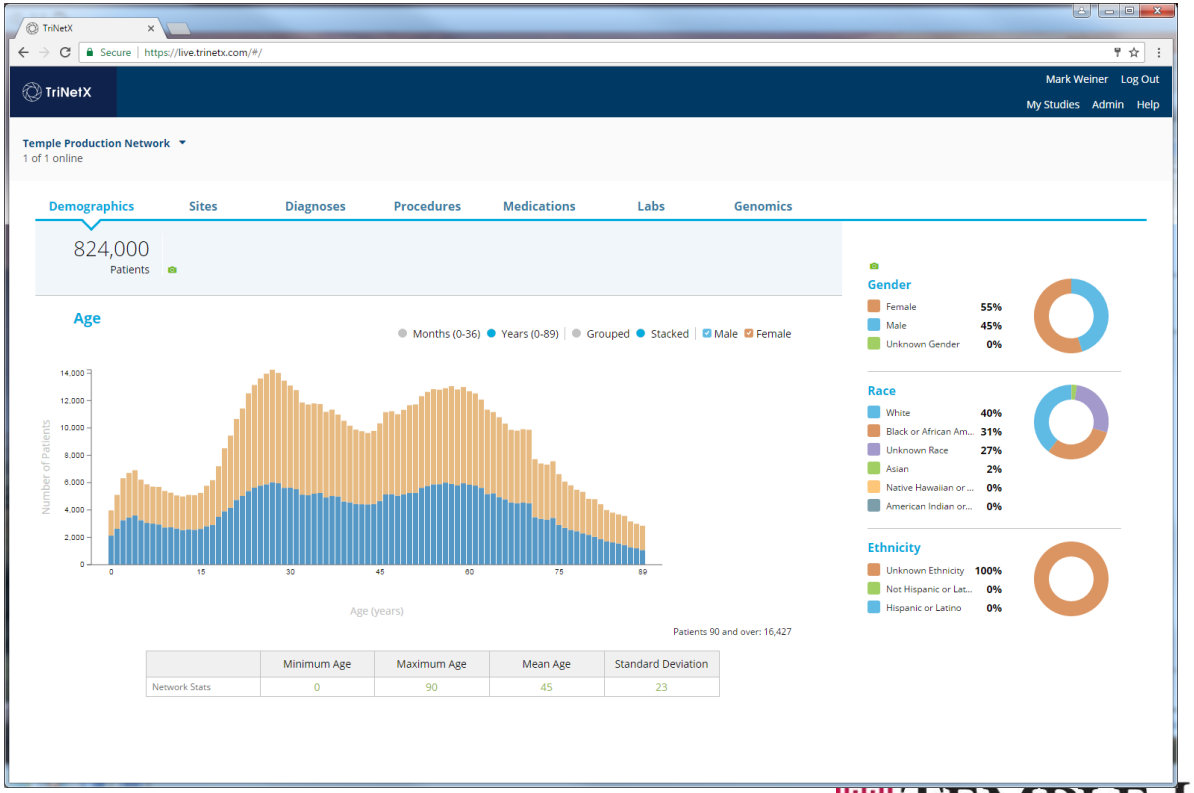
- Research
  - Need to develop a formal protocol outlining exactly what you intend to do that gets approved by the IRB before you can begin work
  - Need to have a “HIPAA Authorization” for prospective studies when patients are actively enrolled or a an IRB-approved waiver of HIPAA Authorization to use retrospective data that includes identifiers
- Quality Improvement
  - Does not require IRB approval, and use of identifiers is permitted under HIPAA based on its more “operational” imperative.
  - For resident QI – need to track the conduct of the project and justify its status as QI as opposed to research

QI Versus Research

What difference does it make?

- BOTH QI and Research--- **DATA SECURITY**
  - Need to be mindful of “minimal necessary use” – justify what you need
  - Need to keep identifiable data on TUHS-connected machines
    - NO portable computers unless they are TUHS-supplied with whole disk encryption
    - Make use of the ”U” Drive – This is your TUHS “My Documents” folder that is accessible from anywhere you log in to a TUHS machine as yourself, or via Citrix
  - Be Mindful about mechanisms of transferring data
    - DO NOT USE external hard disks or thumb drives unless they are encrypted in a manner approved by the CISO

Accessing the Data



Accessing the Data

- Many personnel have access to Epic, but…
  - Must use Epic consistent with scope of practice
  - Clinicians and medical students looking through current and past patient charts related to clinical care is OK
  - Clinicians and medical students looking through patient charts with a research notion in mind is different – *You cannot just look around*

Accessing Data with Epic

- If the medical students are abstracting charts to pull out labs, medications, vital signs, smoking status, visit activity, *they are wasting their time and your money*!
- All of these data, and other information that is recorded discretely in Epic are available as a batch data dump if you have a list of MRNs of patients for whom you need these data
- If you need abstraction of content buried within notes, or scanned items or EKGs, that still requires Epic access for manual review

Medical Students involved in Research

- 1st and 2nd year medical students do not have automatic access to Epic, but access can be requested for research projects
  - Needs supervision from faculty and specific justification for access
  - No Citrix access*. Goal is to promote supervision by having them work in or around clinical department offices rather than from home
  - Needs to be listed as study personnel on research protocol
    - If exploratory work being done preparatory to research, work need special justification
  - Needs to complete eLearnings for Epic
  - Needs HIPAA and CITI training
  - Needs "EARF" form and special online form completed to capture essential information

*exception for students at St Lukes

Medical Students involved in Research

- 3rd and 4th year medical students already have automatic access to Epic, so the path to engage them in research seems more straightforward… BUT
  - Needs supervision from faculty and specific justification for access
  - Goal is to promote supervision by having them work in or around clinical department offices rather than from home – even if they have citrix access
  - Needs to be listed as study personnel on research protocol
    - If exploratory work being done preparatory to research, work need special justification
  - Needs HIPAA and CITI training
  - **More difficult to track centrally, but above requirements are just as important as for 1st and 2nd year students!**

Research Staff Access to Epic

- Recognize that job roles of many, but not all, research staff require access to Epic, and that research staff are likely to be on multiple protocols over time
  - Needs supervision from faculty and specific justification for access
  - Most work should be done on site (Citrix access not settled)
  - Needs to be listed as study personnel on research protocol
    - If exploratory work being done preparatory to research, work needs special justification
  - Needs to complete eLearnings for Epic
  - Needs HIPAA and CITI training
    - HIPAA training different for LKSOM vs TUH employees
  - Needs “EARF” form and special online form completed to capture essential information

Write Access to Epic for Research

- Authorization has been inconsistently provided in the past
  - There have not been standards for what information, or how the information, should be recorded.
  - Need to be mindful of visibility of documentation to clinicians and potential for billing issues
  - Can non-clinical research staff queue up research orders in Epic per a research protocol?
  - Need to be mindful of sponsor agreements
  - Can provide write access to research staff with appropriate justification

Accessing Data with Epic

- In the past, IT Staff from Frank Erdlen's shop were exclusive providers of these custom extracts of data
- Now, for operational queries, IT staff can still provide data, though there is a second group, led by Dinakar Rajkumar, that handles inpatient reporting.
- Most research requests for data from Epic are now handled by the Data Broker Office in the TCRI
- "Temple Population Access Utility (T'PAU)" is an IRB approved protocol providing the regulatory oversight for our group to work with PHI to help investigators in a manner consistent with the stage and nature of their research
- Lots of coordination with the TUHS Data Governance Committee

TUHS Data Governance Committee

- Part of the overall TUHS IT Governance process
- Makes recommendations regarding policy related to clinical and research use of data
- Takes a special interest in intended use and storage of the data for research, complementary to that of the IRB
  - If you receive data on patients for a protocol that *overlaps importantly* with another clinical domain, or if the patients come from outside your own domain, we will require notification of a physician lead for that area.
    - If a GI doc is looking at the impact of PPI on AMI, it makes sense to involve, or at least make a cardiologist aware
  - Not all protocols are reviewed by Temple IRB – WIRB-reviewed studies do not always focus on details of data storage or approach to recruitment.

Show me the data!

- If you have IRB approval, we can provide you with data you specifically are authorized to have, as designated by the protocol
  - This is why it helps to work with us in ADVANCE of your IRB submission
- We need to see the protocol, not just the approval, to know what data is OK for you to have
- Is the work preparatory to research – you are doing some initial explorations to get a sense for study feasibility?
  - Aggregate counts of data do not require IRB approval
  - Can provide PHI on a limited number of patients so you can look at charts to assess accuracy of billing codes, or look for other evidence of appropriateness for inclusion
  - Any identifiable data must stay WITHIN TUHS and NO PATIENT CONTACT!

Show me the data!

- Are you “just” doing retrospective reviews?
  - No IRB approval required for aggregate data pulls – basically counts of patients meeting criteria that you specify
    - easy to obtain, but not useful for work beyond preliminary explorations
    - Not likely to be enough for a quick abstract submission
  - No IRB approval required for use of truly de-identified individual-level patient data – meaning no names, MRNS, zip codes, dates.
  - However, in many cases, you will still need IRB approval since inevitably, research team will need to look at a representative sample of charts to understand the context of the data a little better
  - Even if your analytic data set does NOT contain identifiers, you still need IRB approval if you began with source data that has identifiers. You will likely be keeping a crosswalk between “fake” and real identifiers so you can explore idiosyncrasies that are unmasked through the analysis

Show me the data!

- Do you plan to recruit patients for a research protocol?
  - Still working out the details of a set of SOPs
  - ALWAYS requires IRB approval
  - Most straightforward when patients opt-in in response to posted fliers or if the investigator reaches out to his own patients when they are being seen for a clinical appointment with that physician
  - Increasing regulatory challenges as recruitment extends to other practices, or if research staff need to recruit via mail, or phone
  - Targeted recruitment will involve developing “computable phenotype” in which a database query is constricted incorporating the various clinical criteria. Patients are stratified by providers they have seen, and the providers, in turn, review these patient lists to authorize recruitment.

Show me the data!

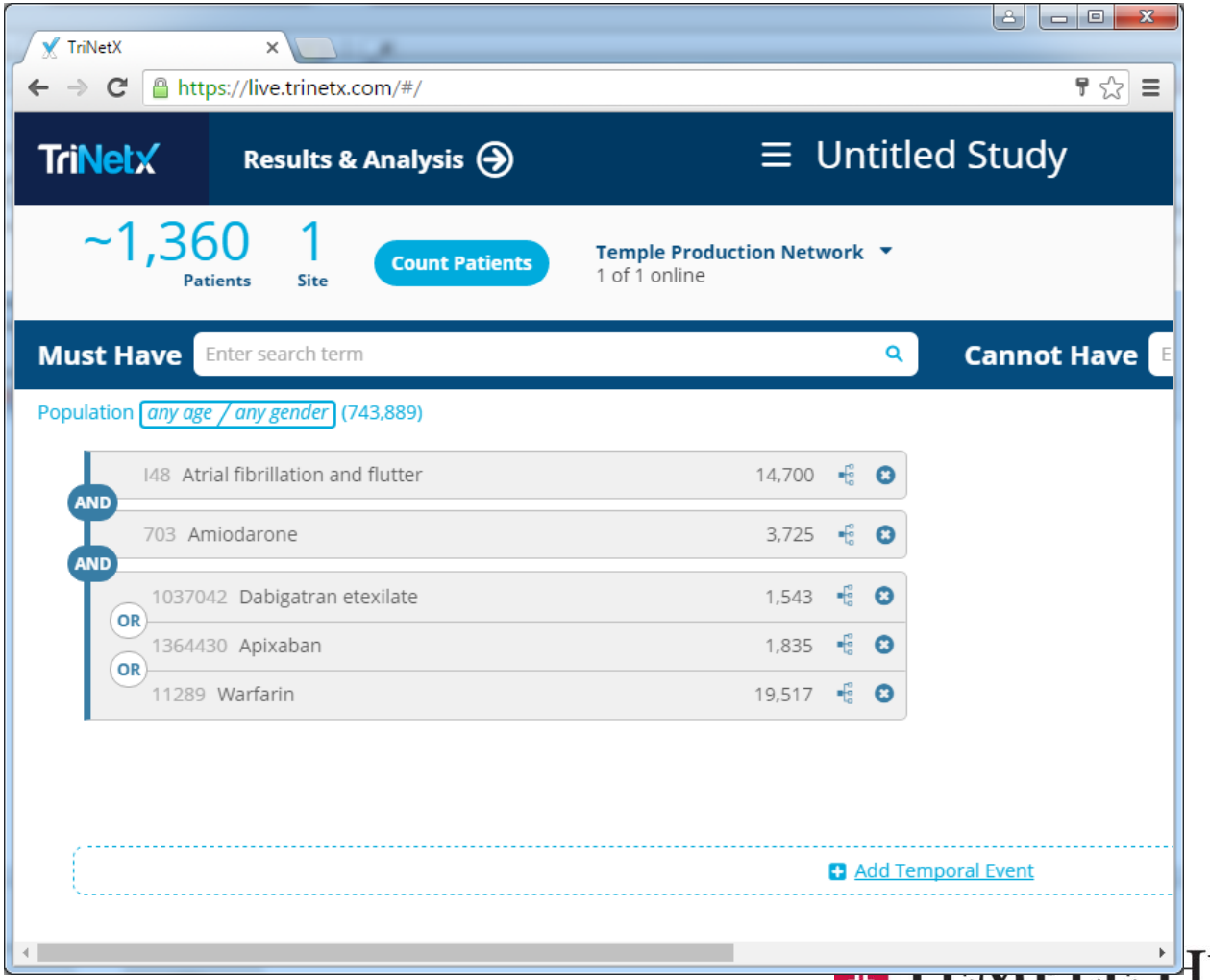
- Sometimes you will have a list of patients that you know you need data
- Sometimes you have a sense of clinical criteria of patients that you are interested in exploring in more depth
  - Your first sense is often helpful, but usually requires a lot of refinement – I have another whole talk on this
- In either case, we can provide structured output of all encounters, diagnoses, labs, medications, etc on the cohort of patients you provide, or that we define through a “computable phenotype”
- **Having the data ≠ being able to work with the data**

Data Broker Services

- The Data Broker Office is able to work with you to understand your research need and provide **raw** data most appropriate to your goals
- **We are not geared toward creating a cleaned and analysis-ready data set**
  - Creating such a data set requires **several iterations with investigators** to fully understand the idiosyncrasies of the data, refine the criteria, and hone in on specific variables of interest
- I have organized a **formal 3-credit class to train faculty and staff with skills to work with raw data to develop analytic data sets**
  - **New course starts Jan 19 running for 7 Saturdays, 6 hours each Jan–March 2019**

Data Self Service

- Epic has a “reporting workbench” capability that allows you to query for patients with certain characteristics.
- We have been working with a vendor, TriNetX to create an easy-to-use interface that would allow investigators and research staff like you to explore Temple’s data in an intuitive, interactive fashion
- Goal is to enable you to become a better consumer of data, NOT to enable you to generate an abstract-ready data set
- Expectation is that investigators can explore the data to do some early refinement of their own research ideas BEFORE sitting down with Data Broker office.


TriNetX
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TriNetX
Results & Analysis
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Patients
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Site
Count Patients
Temple Production Network
1 of 1 online
Must Have
Enter search term
Cannot Have
Population
any age / any gender
(743,889)
I48 Atrial fibrillation and flutter
14,700
AND
703 Amiodarone
3,725
AND
1037042 Dabigatran etexilate
1,543
OR
1364430 Apixaban
1,835
OR
11289 Warfarin
19,517
Add Temporal Event

TriNetX

live.trinetx.com/#

TriNetX | Back To Query Builder | Untitled Study | Mark Weiner | Log Out | Network View | Help

~1,360 Patients | 1 Site

Temple Production Network

Unnamed **Must Have:** Atrial fibrillation and flutter AND Amiodarone AND [Dabigatran etexilate OR Apixaban OR Warfarin]

Cohort

Sep 16, 2016 01:12 ~1,360 / 1

Run Again

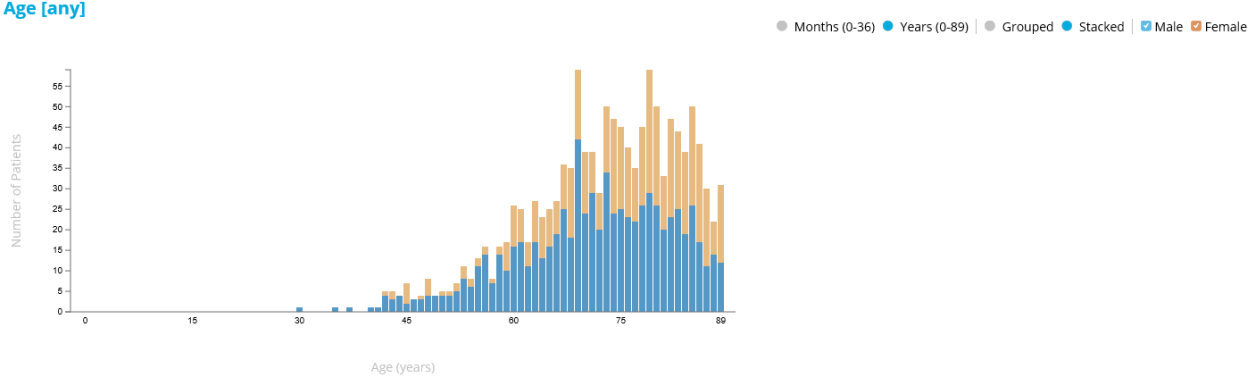
Criteria Analysis | **Arrival Rate**

Demographics | Sites | Diagnoses | Procedures | Medications | Labs | Genomics

~1,360 Unique patients

Demographic Data for Patients in Cohort

Age [any]



Patients 90 and over: 90

	Minimum Age	Maximum Age	Mean Age	Standard Deviation
Query Stats	30	90	74	11

Gender

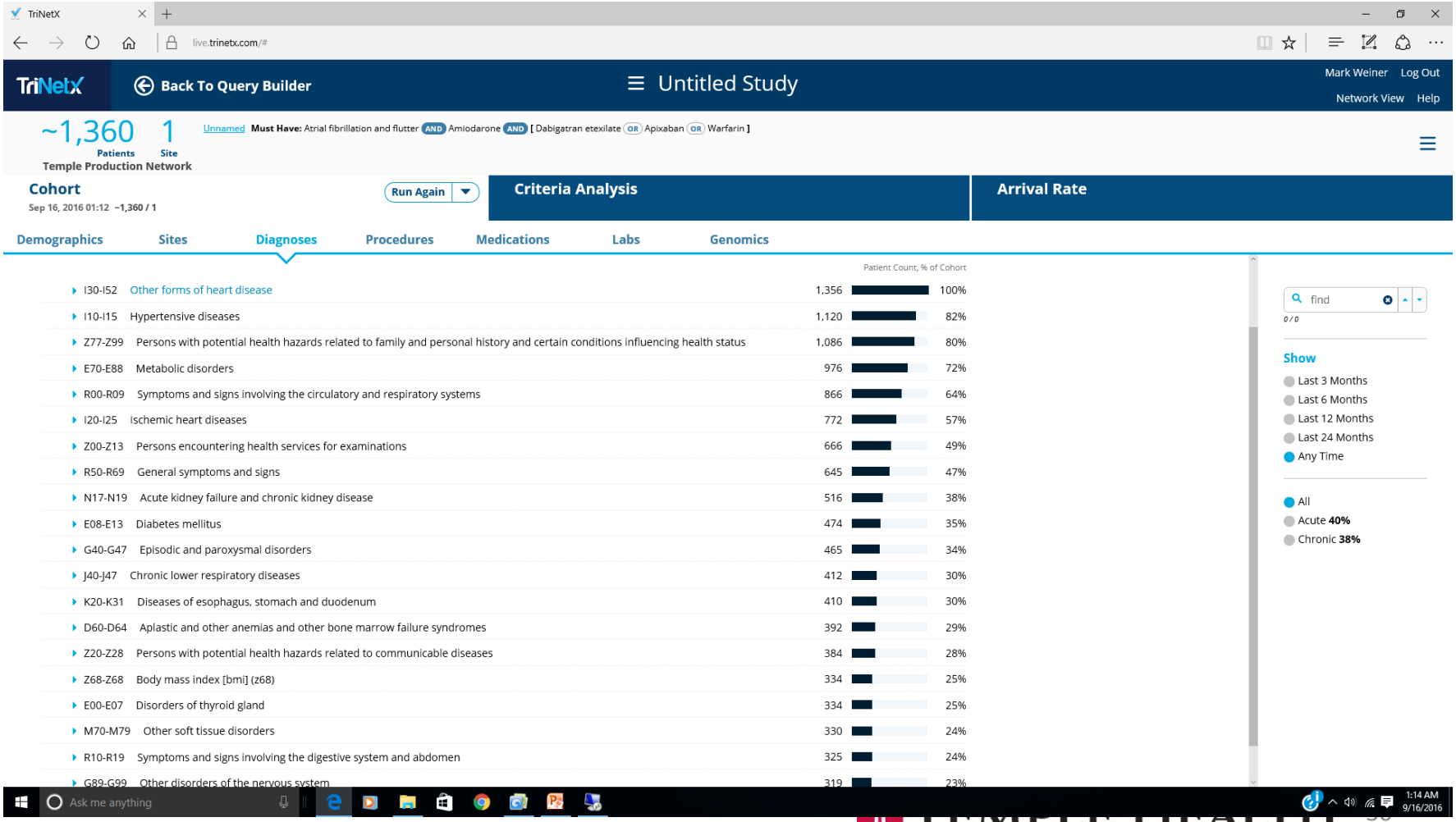
Male	59%
Female	41%
Unknown Gender	0%

Race

White	67%
Black or African A...	23%
Unknown Race	9%
Asian	1%
Native Hawaiian or...	0%
American Indian or...	0%

Ethnicity

Unknown Ethnicity	100%
Not Hispanic or Lat...	0%
Hispanic or Latino	0%


TriNetX
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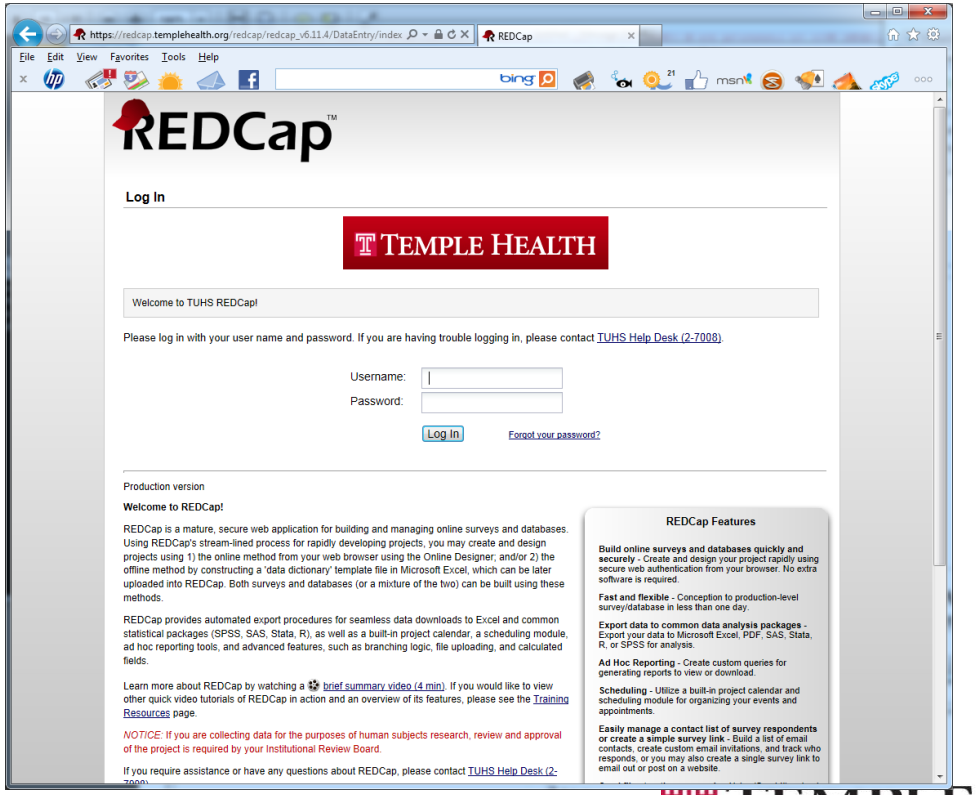
Cohort
Sep 16, 2016 01:12 ~1,360 / 1
Run Again
Criteria Analysis
Arrival Rate
Demographics
Sites
Diagnoses
Procedures
Medications
Labs
Genomics
Patient Count, % of Cohort
I30-I52 Other forms of heart disease 1,356 100%
I10-I15 Hypertensive diseases 1,120 82%
Z77-Z99 Persons with potential health hazards related to family and personal history and certain conditions influencing health status 1,086 80%
E70-E88 Metabolic disorders 976 72%
R00-R09 Symptoms and signs involving the circulatory and respiratory systems 866 64%
I20-I25 Ischemic heart diseases 772 57%
Z00-Z13 Persons encountering health services for examinations 666 49%
R50-R69 General symptoms and signs 645 47%
N17-N19 Acute kidney failure and chronic kidney disease 516 38%
E08-E13 Diabetes mellitus 474 35%
G40-G47 Episodic and paroxysmal disorders 465 34%
J40-J47 Chronic lower respiratory diseases 412 30%
K20-K31 Diseases of esophagus, stomach and duodenum 410 30%
D60-D64 Aplastic and other anemias and other bone marrow failure syndromes 392 29%
Z20-Z28 Persons with potential health hazards related to communicable diseases 384 28%
Z68-Z68 Body mass index [bmi] (z68) 334 25%
E00-E07 Disorders of thyroid gland 334 25%
M70-M79 Other soft tissue disorders 330 24%
R10-R19 Symptoms and signs involving the digestive system and abdomen 325 24%
G89-G99 Other disorders of the nervous system 319 23%
find
0 / 0
Show
Last 3 Months
Last 6 Months
Last 12 Months
Last 24 Months
Any Time
All
Acute 40%
Chronic 38%
Ask me anything
1:14 AM
9/16/2016

Storing Data

Need to move away from Excel for primary storage

- Familiar and convenient, but…
  - Exists as loose files on someone's PC
    - Can only be accessed in one place at one time
    - Security and data loss risks
  - Version control is difficult if two people are working on it
  - No access controls for reading or writing data
  - Can be too easy to use in which individual cells are "overstuffed" with data, or data of the wrong type
  - No audit trail of access or updates to data

Better Solution

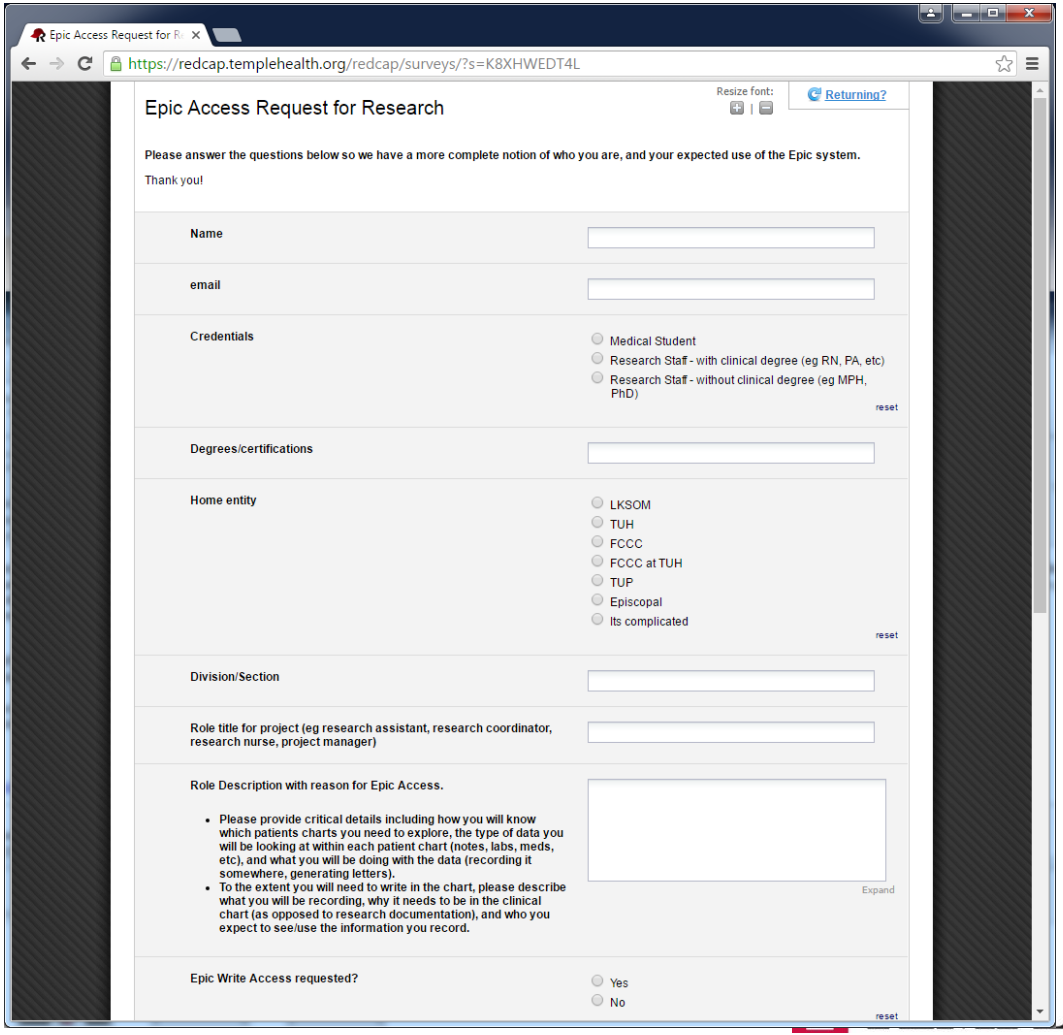


REDCap

- A free, web-based data capture tool developed and continually enhanced by a team at Vanderbilt with a broad, mostly academic user community
- Access from anywhere
- ***You already have access with your TUHS windows credentials***
- Online training videos to get you started
- Data stored in a secure TUHS server that is backed up twice daily
- You create custom data collection forms to capture data as text, radio buttons, checkboxes – including use of “branching logic”
- Has data type enforcement to ensure numbers are numbers, dates are dates, phone numbers have all the expected digits

REDCap

- Access a library of standard data collection instruments to incorporate into your research study
- Renders forms meant for viewing and/or completion by authorized research staff
- Renders forms as surveys meant for study subjects to complete
  - Can send links to surveys in a manner where you can keep track of who has responded
  - Can schedule automated survey reminders
- Audit trails of all access and data updates
- Can export data into SAS/SPSS formats (and Excel)
  - Can flag fields as identifiers that will “hash” values or perform date shifting to avoid unwanted exposure of identifiers with export.


Epic Access Request for R
https://redcap.templehealth.org/redcap/surveys/?s=K8XHWEDT4L
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Returning?
Epic Access Request for Research
Please answer the questions below so we have a more complete notion of who you are, and your expected use of the Epic system.
Thank you!
Name
email
Credentials
Medical Student
Research Staff - with clinical degree (eg RN, PA, etc)
Research Staff - without clinical degree (eg MPH, PhD)
reset
Degrees/certifications
Home entity
LKSOM
TUH
FCCC
FCCC at TUH
TUP
Episcopal
Its complicated
reset
Division/Section
Role title for project (eg research assistant, research coordinator, research nurse, project manager)
Role Description with reason for Epic Access.
Please provide critical details including how you will know which patients charts you need to explore, the type of data you will be looking at within each patient chart (notes, labs, meds, etc), and what you will be doing with the data (recording it somewhere, generating letters).
To the extent you will need to write in the chart, please describe what you will be recording, why it needs to be in the clinical chart (as opposed to research documentation), and who you expect to see/use the information you record.
Expand
Epic Write Access requested?
Yes
No
reset

Conclusions

- The future of research and QI at Temple looks bright with data from our EHR, along with other sources.
- We are able to assist you in addressing the information needs your study requires, but a great deal of the work needs to be done by the investigator's team
- Our team at TCRI is small, but we hope to train people who can work more closely within key departments and divisions
- Need to be mindful of the regulatory issues related to access to Epic, and data generated from Epic.

Useful Links

- REDCap –
  - http://redcap.templehealth.org/redcap
- Epic-for-research access form
  - https://redcap.templehealth.org/redcap/surveys/?s=K8XHWEDT4L
- QI Tracker for residents
  - https://redcap.templehealth.org/redcap/surveys/?s=LNKRY9JKF4
- Data access request
  - https://redcap.templehealth.org/redcap/surveys/?s=L4R9MAPW4M

Fun, but still relevant, links

- Building an airplane that is already flying (like coming up with data access policy in the midst of an active research program)
  - https://youtu.be/L2zqTYgcpfg
- Apollo 13 clip - fixing a design problem for an unanticipated need with spare parts you happen to have available (my world!)
  - https://youtu.be/QETus6zBBvo