

Researcher Access to Clinical Data

Introduction to Clinical Research July 25, 2013

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Where do researchers get data?



TODAY

- Electronic Patient Record (EPR) 4M patients
- Allscripts / Sunrise Clinical Manager (JHH inpatient)
- Meditech (Bayview)
- Many Departmental Systems (ED, OR, Anesthesia)
- Multiple result reporting systems (Lab, Rad, etc)
- IDX (professional fees)
- Casemix Datamart (diagnoses, procedures)

This is NOT an exhaustive list!

FUTURE - an "Epic" opportunity

.

Methods for Data Access



Historically: Researcher Negotiates Access With Clinical System Technical Staff

-Logistically & technically challenging

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Approaches for Data Access



Back end or informal access underestimates the complexity of the data and likely violates HIPAA and JHM PHI protection policies

Approved access points:

- 1. Clinical Research Management System (CRMS)
- **2. EPR2020** researcher self-serve for patients on your studies
- 3. Center for Clinical Data Analysis (CCDA) Service
- 4. I2b2 cohort discovery tool
- 5. caTissue Biospecimen data

1. Clinical Research Management System (CRMS)



CRMS Contains:

- Administrative data about your study & participants
- Can create research "Forms"

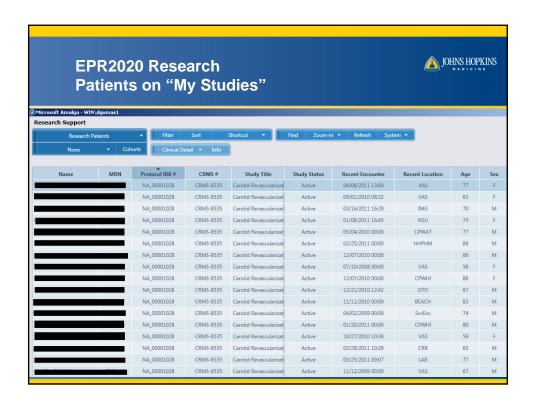
You can extract data from CRMS via

- Canned Reports (e.g. enrollment report, demographics)
- Ad-hoc querying using SQL database language

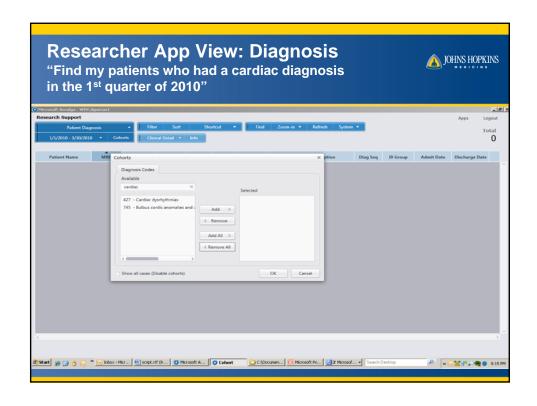
For more info: CRMSHelp@jhmi.edu

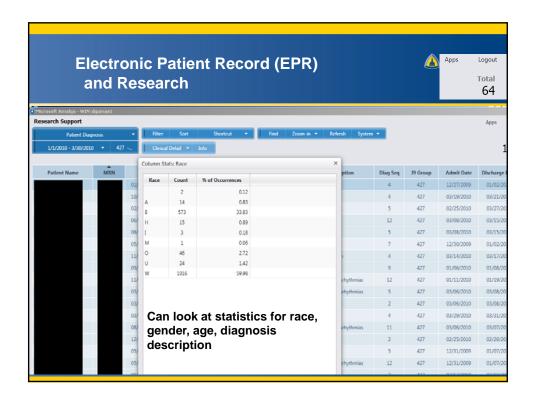
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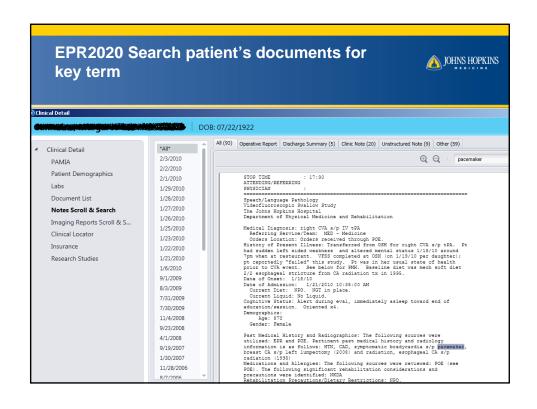
JOHNS HOPKINS 2. EPR2020 Clinical Data Repository **EPR-JHH & JHBMC EPR2020** 4.4M Patients, Read-Only 36.2M Visits **Data Discovery** 16.2M Documents 8.6M Rad Results For: 402M Lab Results **Clinical Care** 5.8M Inpatient Diagnoses 1.7M Problems Research **Quality Improvement** Patients on Study **Clinical Research Management System** Diagnoses/Procedures HDM/Casemix **JHCP FUTURE** Other JHH/JHBMC **Clinical Systems External Labs Additional Hospitals**

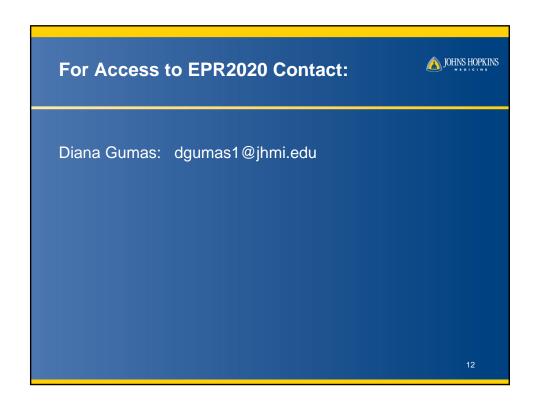














3. Center for Clinical Data Analysis (CCDA)

Provides periodic (monthly/quarterly) bulk data extracts

- Preliminary, anonymous data for feasibility, grant applications and statistical sample-size estimates
- IRB-approved case-finding--for study enrollment (mailings, phone solicitation), chart review, and cohort/case-control studies
- Research data extracts monthly/quarterly integrated extracts from EPR, POE, ORMIS, lab/PDS, billing systems, vaccination/transfusion/culture data, etc.

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How CCDA works



For IRB-approved research:

- Provide full protocol + IRB approval
- Meet to discuss query methods, format
- Iterate, then schedule production (email extracts, Jshare)
- Hourly cost

For non-IRB projects (exploratory analyses, QI)

- Same process, cost subsidized by ICTR/JHM (?)
- Do NOT implicitly morph QI into IRB

For more information, contact: David Thiemann - dthiema1@jhmi.edu

Structuring a data request Who? List of MRNs or cohort defined by characteristics? What? Procedures? PCP encounter? Diagnosis? Free Text Search? Lab results? When? Age of individual? Date/range of event? Where? Where? Zip code? Unit? Floor? Hospital? PCP location? Why or How? Why or How? Mage of individual? Company the procedures of the procedure of the procedures of the procedure of the procedures of the procedure of the procedur

Data Sources



- EMR Data
- Financial Data
- Registry Data
- State / National / Public data sets
- Research study data sets

JHM has a great deal of data:

- It is structured for source production systems
- Challenging to data mine
- Very difficult to join across systems.
- Inappropriate access can lead to significant legal implications

Johns Hopkins Medicine Clinical Systems **Environment** EPIC MyChart EPIC MyChart **Patient Portal** EPIC MyChart MyChart MyChart Meditech / Epic, GE (IDX) Registration / Meditech GE (IDX) Scheduling ADT Keane Meditech Meditech McKesson Inpatient EMR Allscripts Meditech Meditech McKesson Information Exchange **Ambulatory EMR EPIC** (CRISP) Varied Varied Varied Specialties EPR2020 **Enterprise Clinical Data and Document repository Hospital Billing** Keane Meditech Professional Billing GE (IDX) GE (IDX) GE (IDX) GE (IDX) GE (IDX) 17

JHM Data Source Systems



System	Contact	Notes
EPR2020 / EPR	CCDA Diana Gumas David Thiemann	Some search functionality. Integration with CRMS. Data mining is SQL based hand work. Tables are very complex and require domain expertise. Usually requires an IRB request and funding source.
Allscripts (SCM)	CCDA Marty Hamburg	Data mining is SQL based hand work. Tables are very complex and require domain expertise. Usually requires an IRB request and funding source.
Meditech	Andy Frake	Reporting capability
Epic	Jim Ham	TBD process, outpatient and Community Division data
Casemix	David Plaut	Billing data, requires access permissions, some standard reports
Speciality	System Owner	ORMS, Metavision, TheraDoc, EBB, etc
12b2	Sam Meiselman	Counts, deidentified data, pre-IRB

Types of data



- Clinical Data Labs, Radiology, Clinical Documentation
- Casemix
- Billing what items were charged to the patient, quantity, charge \$(not cost), date and location at time of charge
- Payment data \$ paid against a bill by a paper, not the \$ paid per item on the bill
- Costs (limited) what did an item cost vs what we charged
- Pharmacy dispensing and adminstration detail (JHH only)
- Census & transfers (where are patients)
- Readmissions
- Outpatient Scheduling

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Coding schemes



Code Type	Inpatient or Outpatient
ICD-9 Diagnosis	In & Out
ICD-9 Procedures	In
CPT	Out
MS DRG	In
APR DRG	In
CPC DRG (Charge/Case, MD only)	In
APG	Out
CPV APG (Charge/Visit, MD Only)	Out
RPC (charge item catalog)	In & Out
ICD- 10 coming soon	

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Financial vs. Clinical data

- All coding schemes are financially driven
- There may be a diagnosis code for a disease that the patient does not actually have, however, <u>resources</u> were expended to rule that diagnosis out.
- Coding is driven by physician documentation

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Challenges



- Silos of Data implemented over time
- Enterprise systems
 - EPIC
 - EPR / EPR 2020
 - Allscripts (Sunrise Clinical Documentation)
 - HMED (Emergency Room)
 - ORMIS (GE Centricity Periop Manager)
 - MetaVision (Anesthesia Documentation)
 - Casemix / Datamart / HDM
 - Theradoc
 - Electronic Bed Board (EBB)
 - OB Documentation (GE Centricity Perinatal)
 - Labs, Radiology and Pharmacy source system
- Patient case identification and matching between systems

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Some Lessons Learned



Data Mining

- Must have strong clinical leadership and pervasive buy-in for research project
- 2. Must understand clinical workflow and source documentation to translate to the research study
- 3. Must stay within scope of readily known data
- 4. Must audit for completeness and accuracy
- 5. Retrospective Data Important Caveats

Data Dictionary / Version Control

Documentation Consistency over time and source systems

Documentation Purpose (Billing vs Clinical Documentation)

Discovery of new diagnosis – recoding historical data

Clinical Relevance and Intrepretation (time series data, lab and medication data)



Other Internal Sources for Research Data



National Registries

Maryland Trauma Registry Tumor Registry UNOS Registry (Transplants) NSQIP VQI – Vascular Quality Initiative

Specialty Research Databases

School of Medicine School of Public Health Kennedy Kreiger Institute

National CV Registries

STS Adult Cardiac Surgery STS Congenital Cardiac Surgery Registry STS Thoracic Registry STS Cardiac Anesthesia Registry STS/ACC TVT Registry

INTERMACS VAD Registry
PEDIMACS VAD Registry
ELSO Registry (ECLS Registry)
PC4 Registry (Pediatric Cardiac Critical Care)

ACC NCDR Action Registry -GWTG
ACC NCDR IMPACT (Ped & Adult Congenital)
ACC ICD (Generator & Leads)
ACC Cath PCI Registry



Data Registries and Internal Database Initiatives



What will Epic do for researchers?



Research Encounter Scheduling

Better Research Billing

Electronic research orders/preference lists

Other studies for which your patient is a participant

Report that patient admitted or arrived at ED

Data querying tools accessible by Epic user

Patient Reported Outcomes via MyChart patient portal

Registries from data collected in Epic

Access to codified data across the enterprise

Epic Data



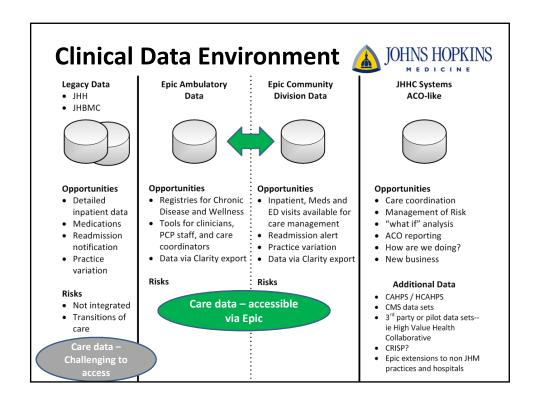
- · Ambulatory, HCGH, Sibley are on-line
- Some historical data migrated to Epic. TBD research utility
- JHBMC and JHH remain with legacy systems for near term future
- · Challenge will be to join inpatient and Epic-data
- Data access for researchers discussions are underway
- Several proposed points of access:
 - Department based TBD readiness
 - I2b2 pilot available now http://i2b2.johnshopkins.edu/
 - Center for Clinical Data Analysis
 - Epic reporting team TBD readiness

How will researchers get access to Epic data for research?



Still under discussion...

Likely to be services provided by CCDA



EMR Data – Chronic Disease – **Planned Business Objects Universes** Chronic Disease Management Diabetes Diabetes Snapshot Date - Diabetes Alcohol & Tobacco Use - Diabetes Diabetes Comorbidities - Diabetes Numeric - Comorbidities - Diabetes Comorbidities - Diabetes Immunizations - Diabetes Diabetes Medications - Diabetes Numeric - Diabetes Most Recent Labs - Diabetes Diabetes Medications - Diabetes Diabetes Pregnancy - Diabetes Visit History - Diabetes Diabetes 628 Objects / 47 tables / 1528 Rows across CHF, Diabetes, Hypertension Registries Epic will be a phenomenal tool, and ... Set up required: We need to check for Clarity, BOE, and future Data Warehouse connections between tables Alignment: We need to align our data access policies with JHM-available tools Deidentified Access: 12b2 can act as a interim bridge to access deidentified Epic data if interface connections are approved Interim Data Warehouse: I2b2 is currently acting as a synthetic data warehouse until the Epic EDW is funded and brought on line.



And finally, some wise words from Dr. David Thiemann



- Real work, not ad hoc/bootstrap
- Need \$\$\$ and FTE(s)
- Smart analyst(s) who know database technology and understand (or can learn) nuances of the sources and content domain
- Hands-on PI management/guidance
- Statistical liaison early, before database schema and ETL methods are set in stone

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The Extract-Transform-Load process: Getting Clinical Data into Research DB



- Raw clinical/administrative data is limited and must be used with caution in research
- Build an intermediate (staging) database
 - <u>Don't</u> do data management in SAS/Stata/Excel
- Data dictionary—derivation for each field
- Templated, tested, <u>documented</u> cleanup scripts/routines.
- Intermediate tables: Log each step/modification
 - For each batch, be able to re-create data transform from scratch
 - Version control, change control and documentation are vital
 - Build data versioning into the database



Transforming Data is Non-Trivial



- Raw data typically string (char/text) fields
- Unanalyzable characters (* < >, comments) still have meaning
 - Put non-numeric data in separate field. Avoid numerical recoding (999)
- ~3% of pts have multiple/non-preferred MRNs
 - Need 1-to-many link table
- Assays/reference ranges/coding changes
 - Avoid using raw codes (CPT/ICD) in research db
 - Map clinical codes to research terms
- Defer analytic assumptions. When recoding data, anticipate problems. Keep options open.

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Understanding Business Logic



Trust but verify: Test coding accuracy

- Providers may habitually use imprecise/inaccurate diagnosis codes (especially in profee data)
- ICD9 procedure indications often a billing fiction
- Trained coders may make systematic errors
- Different content domains may have different standards (inpt vs outpt coders)
- Don't infer/assume dependencies unless enforced by source system.

Run min/max queries, aggregates, outer joins

- Confirm date ranges, data ranges, relative proportions by year
- For ex. Lab results on deceased patients may be legitimate

Don't assume that null rows actually are empty. Maybe the query missed something. 34

4. caTissue for Collecting & Accessing Biospecimen Data



What caTissue can do for you

- · Track collection and storage of specimens
- Clinical annotations
- · Track distribution of specimens
- · Derivation and Aliquotting of specimens
- Reports

Cost

- · No Charge for respositories using basic services
- Hourly charge for legacy data migration, special reports & features

For more information: Diana Gumas dgumas1@jhmi.edu

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i2b2 BackGround



www.i2b2.org

- Informatics for Integrating Biology & the Bedside
- Simple Tool Yielding Accelerated Data Access
- Deidentified Cohort Builder
- Query "Articulator"

12b2



12b2 pilot is a proven path -

- https://www.i2b2.org/
- Cohort Finding Tool
- Some basic data visualization tools
- Flexible and simple Data Mart Schema
- Customizable Ontologies
- Many open source additional modules
- SHRINE as a possible link to non-JHM institution data sets

Shorten cycle time from idea to data for analysis

Self Service + Collaboration

i2b2 at JHMI



Landing Page http://i2b2.johnshopkins.edu/

- Request Access
- Client Launch
- System Information and Announcements
- Help Documentation and Support Links

i2b2 at JHMI



Architecture

- Database
 - Fed from JHMI Source Systems
 - EPR2020
 - SCM
 - Deidentified for i2b2 Users
 - Re-"identifiable" for DBAs
- Web Application
 - JHED authorized security
 - · Web application is only way for Users to access data

i2b2 at JHMI Data Content



Dimensions

- Patients/ Demographics
- Visits/ Encounters
- Providers

"Facts" (clinical findings)

- Numeric Labs
- Inpatient and Outpatient Diagnosis*
- Inpatient Procedures
- Inpatient Medications (in progress)

12B2 inventory			
Data	Status	Q	Notes
Patient Mapping and Dimension	Completed	2.5M	Patients and visits based on EPR2020 identity backbone Including multi-institution and multi-MRN references.
Visit mapping and dimension	Completed	42M	Needs validation of inpatient v. outpatient flags
Provider dim.	Completed	0.35M	Contents of EPR/EPR2020 (CDT provider)
Provider Ontology	In progress		JHH and Bayview providers
Demographics	Completed	2.5M	Includes: Age, zipcode, race, gender
Diagnosis	Completed	40M	Based on ICD9 codes from datamart and IDX via EPR2020. Some gaps identified
Inpatient Procedures	Completed	2M	Based on ICD9 codes from datamart and IDX via EPR2020.
Outpatient Procedures	In Progress		Requires a CPT lookup table and procedure fact records
Lab Data	In Progress	3Years	Ontology and Numeric results complete. Standard Text results, complex test results in progress
Meds	In Progress	TBD	Dispensed meds from SCM (JHH only for now). Current plais to use Multim ontology until rxNorm can be added.

i2b2 at JHMI	•••····
Category	Record Count
Clinical Findings (lab, diagnosis etc)	196156286
Inpatient and Outpatient Visits	45329952
Patients	4781047
Providers	35073
Ontology Concepts	29689

i2b2 and CCDA



Customer Self Service via i2b2

- Feasibility
- Query Articulation

CCDA Extracts/ Data Support Extend Reach

- Ongoing or One Time Extracts
- Variety of Outputs
- Process of Intake, Requirements, Development

Case Studies Richard Moore HIV Studies - Ongoing Database Extracts - Support Large Clinical Review Studies | Natural 1901 forms Anoquement Bush | Declar Color | Declar

S. Melzer ACS Review: Barrett's Esophagus



- 4.4 M patients and 26M visits
- 12.8 M documents / 7.2 M Radiology Reports
- 28M Lab Results

