Electronic Health Records for Research

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INTRODUCTION

- EHR (Electronic Health Record) includes a whole range of data in comprehensive and summary form. It's a digital version of a patient's paper chart.
- Our EHR system Centricity is replaced by EPIC in 2012.
- A new core facility is developed to retrieve data from EPIC and Centricity (retrospective research).
- Data is migrated from Centricity to EPIC in phases. Retrospective data can still be obtained from Centricity (1989).
- UNMC and 60% academic health centers implemented EPIC

About EHR system

- EHR reduces transcription, re-filling and storage cost.
- It saves time and cost through eliminating redundant diagnostic testing, paper charting and decreasing storage and retrieval cost.
- This digital format enables healthcare professionals to communicate and track data for specific patients.
- Combined as a single large database, a tool to conduct comparative effectiveness research

- Database available for public health (e.g., immunization rates) or health outcomes (e.g., diabetes care outcomes)
- Quality indicators (e.g., readmissions, provider or unit comparisons) or cost of care
- Assess or compare adherence to best practices (e.g., smoking cessation referrals, immunization rates, monitor markers of disease outcomes)
- Appropriate medication administration

- Meaningful use ($) driving some outcomes
  - Adoption of electronic health records (EHR)
  - Adoption of electronic medication orders
  - Use of Family history, depression screening, patient portals, addressing Body Mass Index
  - Reporting on patient outcomes

Limitations with centricity

- Some data elements are not routinely captured
- Not a relational database
- Ethnicity is merged with race
- Medications prescribed <> medications taken (not filled, compliant, or absorbed; prescribed by another provider, taking other family's meds)
- Immunizations are part of medications
- Nutritional products/ OTC taken (e.g., aspirin and non-steroidal medications, birth control)
- Text files: diagnoses requiring word search where diagnoses variably described
- Smoking and alcohol use may not be updated

How is EPIC different??

EPIC will improve some of these things as everyone will be using the same EHR in all clinics and units (customized to clinics)

Examples

- Current EPIC database (Clarity) is a relational database
- Smoking and aspirin will be more reliably recorded
- Medications and problem lists will be reliably maintained
- Primary care physician will be more reliable to track by unit
- Some search functions of your own patients will be available (like social history, medical history, family history)
- Immunizations are recorded separately
- Diagnosis is linked to medication and procedures
- More discrete data available compared to centricity

Modules

Ambulatory

- Encounters
- Diagnosis
- Orders
  - Medications
  - Procedures
  - Immunizations

In-Patient

- Encounters
- Admit/discharge dx
- Orders
  - Medications
  - Procedures
- Registries
- Notes

- Op time
  - Surgical procedures
  - Surgical cases and resources
- Stork – Ob/Gyn
  - Mother Baby linkage
  - Delivery records
- ASAP – Emergency data
  - ER episodes
  - Transfers
- Anesthesia
  - Anesthesia events
  - Administration types and staff involved
- Beacon – Oncology
  - Cancer staging
  - Treatment plans and cycles

EPIC DataMarts (Chronic Disease Registries)

DataMarts (Registries) can be created and populated upon request.

- Asthma
- Coronary artery disease
- Congestive heart failure
- Chronic kidney disease
- Chronic obstructive, pulmonary disease (COPD)
- Diabetes (Populated)
- HIV
- Hypertension
- Osteoporosis
- Obesity

NEW DATAMARTS

EPIC 2014(Registries)

- Cystic Fibrosis
- Chronic Liver Disease

EPIC 2015 release

- Pre-Diabetes
- ALS
- Chronic Lung Disease
- ICU Stay
- Tobacco

Wellness Registries

- These wellness registries (healthy patients but still need some preventive maintenance) are broken down by age, and after age 13, they are also broken down by gender.

New Reports

2014 release

- Cather associated UTIs
- Hospital transfer and discharge
- Readmission (30 day)
- Ventilator-Associated Pneumonia
- Central line associated bloodstream infections
- Umbilical catheter associated bloodstream infections

2015 release

- ICU stay
- In-Patient Psychiatry services core measurement sets

Limitations of EPIC

- Not all data is discrete
  - Pulmonary function tests
  - Ejection Fraction
- Pathology and radiology results as text files
  - Results in comments or text versions
- Usage of smart data elements
  - Not being widely used
- Encounter and procedural data (in-patient) available only after 2012

EHR Data Access Core: getting started

- Step 1. Get and begin to complete a request form
- Step 2. Think about what data you need. Examples:
  - "Diabetes" From the problem list, discharge diagnoses or both? Which ICD-9 code (type 1, type 2 with or without complications)? Or based on A1C threshold?
  - "Polycystic ovarian syndrome": might want to also look for "amenorrhea", "hirsutism", or "hyperandrogenism"
- Step 3. Meet with the EHR Data Access Core staff
- Step 4. IRB Application. Required if you want "Protected Health Information (PHI)" and don't have ethical access

Protected Health Information (PHI)

- Name
- Date of Birth
- SSN
- Address
- Phone numbers
- Medical record numbers
- Full face photographs
- Fax numbers
- Email address
- Health plan numbers
- IP address
- Any other unique identifiers
- Biometric identifiers (finger prints/voice prints)
- Account numbers
- URLs
- Certificate/license numbers
- Vehicle IDs/serial #
- Device identifiers

Ethical Access

- Who has ethical access?
  - You for your own patient data (or your unit/clinic for health outcomes/ performance improvement projects or professional certification)
  - Non-PHI data: anyone as “not human subject research”
  - Requests for retrospective data for health outcomes is generally exempt
  - Feasibility requests (to determine sample size available for clinical trial) also considered exempt.
  - Trainees require faculty signature
  - All other requests will require formal IRB approval with evidence of informed consent
- Questions regarding ethical access data can be forwarded to Deb Meyer, RN (Associate research subject advocate)

Many requests require the following:

- Inclusion criteria: need to be specific and need to consider what data is likely to be available and reliable
  - Age: at what date—today or at the time of the encounter?
  - Disease: what ICD-9 codes?
  - Gender
- Exclusion criteria: be specific
  - Do not exclude more than you need to
- Specific data elements you need---think through everything you might need as time consuming and expensive to go back and do it again
- What is the name of the laboratory test in the database when there is more than one
    - Medication brand names including generic and combination medications
    - LDL: calculated and measured?
    - 3. Which PSA measurement, screening, total, diagnostic?
- Datasets can be generated on regular intervals if needed

Types of projects EHR Access can help

- Retrospective data analysis
- Cross sectional studies
- Health outcomes
- Clinical trials (Grade, Pre-Diabetes)
- Feasibility analysis to compete for NIH multicenter trials or decide if it is worth contract negotiation for a pharma trial
- Case finding for subject recruitment of IRB approved trials
- Quality improvement
- Transfer data to a registry (RAIN Database)
- Specific data fields to correlate with or add to other data collected elsewhere

Use cases for Research

- Type 2 Diabetes patients on metformin only and never on Insulin
- Pregnant women who had prenatal care and delivered babies at UNMC
- Infants in NICU with gestational age < 32
- Renal transplant patients diagnosed with Cardiovascular problems after transplant
- Sepsis or CAP (Pneumonia) in-patients in ICU or step down with positive blood cultures.
- Thirty day readmission patients.
- Patients who had joint replacement surgery and had spinal anesthesia
- Clinical Trials: Identifying patients for research recruitment

Who can request for data ??

- Any UNMC faculty, TNMC physician, student or trainee with an approved/credentialed mentor
- UNMC/TNMC staff with ethical access
- Investigators outside UNMC must have collaborator within UNMC
- Corporations outside UNMC cannot request data other than that established through MOUs such as UHC, AHA, or other collaborative groups

Request Form for Electronic Health Data

https://unmcredcap.unmc.edu/redcap/surveys/?s=9TsTE2UGsM

REQUEST FOR ELECTRONIC HEALTH DATA

Date of Request:_____ Organization/Dept:_____
Requestor(s):_____ Collaborator:_____
Requestor phone:_____ Collaborator phone:_____
Requestor zip:_____

Billing Dept Acct #:_____ Cost Center #:_____ Billing Exempt: ____ Health operations ____Feasibility ____Other

I am requesting:

	De-identified information only (skip to 1b)		Individually identifiable health information (specify in 1a)

1. Requested information

a. I request the following Protected Health Information (individually identifiable health information or PHI):

	Names		Address elements (other than State)		Fax numbers
	Telephone numbers		Date elements (other than year)		Electronic mail address
	Medical record numbers		Device identifiers/serial numbers		Account numbers
	Certificate/license numbers		Vehicle identifiers/serial numbers		Health plan numbers
	URL's		Biometric identifiers (finger/voice prints)		IP addresses
	Social Security Numbers * provide justification for use in section 2a		Full face photographic images/comparable images		Any other unique indentifying number/characteristic/code - specify in section 2a

b. Describe other information needed :(inclusion/exclusion criteria, ICD codes). Please attach.

c. Date range for the data requested: _____

d. Requested report completion date: _____

2. Purpose for which requested information will be used

Brief description of purpose, including any planned uses & disclosures: Attach abstract or description. Include such things as the name of the study if research related and how this information is to be used.

a. Health Care Operations – Dept Mgr/Medical Director approval required.

- ☐ Performance Improvement/Quality Assurance (i.e. patient safety, add other examples)
- ☐ Pay-for-Performance/Physician Quality Reporting Initiative (PQRI)
- ☐ Health Professional Board Certification
- ☐ Regulatory Oversight (i.e. Center for Medicare/Medicaid Services, FDA, Joint Commission)
- ☐ Business Operation Support
- ☐ Other:

Describe your job-related need for this information:

Signature of Dept Mgr/Medical Director

OR

b. Research or Research Preparation *<Research is defined as link to IRB definition of research>*

	No IRB # required		Feasibility Study – De-identified (requesting none of the elements of PHI in section 1a)

IRB #_____		Feasibility Study-Identifiers (requesting elements of PHI) Need IRB #
		IRB approved PHI Data Sets – requires Ethical Access statement
		Review preparatory to research (includes PHI) – requires Ethical Access statement
		Retrospective Study - requires Ethical Access statement

Describe your ethical access to information requested: *<<link to or attach IRB policy definition of ethical access>>*

1. I agree to comply with UNMC Policy 6045, "Privacy, Confidentiality and Information Security" and UNMC Policy 6051, "Computer Use and Electronic Information Security".
2. I certify that use of the PHI/de-identified data described above will be used only for the purpose stated above.
3. I certify that the requested data is the minimum amount of PHI/de-identified data necessary to accomplish the purposes stated above.
4. I agree to destroy the PHI/de-identified data after use.
5. I agree to store the PHI/de-identified data on secure network servers or encrypted AND password protected local computer drives or mobile devices.

If I am requesting PHI for a review preparatory to research, I certify that:

1. Review of the protected health information will be conducted solely to prepare a research protocol or for similar purposes preparatory to research;
2. I will not copy nor remove any protected health information from the University of Nebraska Medical Center campus in the course of review; and
3. The protected health information for which use or access is sought is necessary for research purposes.

_____ _____
Requestor Signature/Title Date

4. Mail completed form: Deborah K Meyer, Zip 5210 or Fax Attn: Deborah K Meyer to 402-559-4565

For Questions, contact Deborah K Meyer at 402-559-6941

For Office Staff - to be completed by ?Info Custodian? Individual providing requested data:

The above request meets HIPAA Minimum Necessary standards.

_____ _____
Signature Date

_____ _____
File Name Completion Date

(Maintain a hardcopy in department files for six years after date of last disclosure)

Send data via e-mail with the following reminder:

Your requested data extract has been completed. As a reminder, this data can only be used for the purpose stated on your request form. The data must remain on a UNMC server in the data center and should not be saved to your local computer drive. All portable devices containing data must be both password protected and encrypted. The data must be destroyed after the applicable retention period has expired.

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On-line request form for EHR data

https://unmcredcap.unmc.edu/redcap/surveys/?s=9TsTE2UGsM

You can request purnima.guda@unmc.edu or dmeyerk@unmc.edu for this link and other questions or concerns

BIOBANK

- Nebraska Biobank is made up of residual blood samples from patients who want to take part (consented).
- Serum, DNA and Plasma are recovered from the consented samples and stored for future research studies.
- Deidentified data from Electronic Health Record (EHR) is linked to the stored samples.
- Any faculty member from the University of Nebraska system may request samples from the biobank for their research projects after review of requests.

Online form:

http://www.unmc.edu/cctr/ne-biobank.htm

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