

# EMR Systems and the Conduct of Clinical Research

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# Clinical Research Environment

- Research protocols are becoming more complex
- In response to “precision medicine” paradigm, research teams support a greater number of protocols
- Multicenter protocols are increasing in comparison to single center protocols

# Current Environment

- Greater focus on safety for clinical care
- Adverse events in clinical research frequently result from care that deviates from the approved protocol
- EMRs are becoming a favored method for providing decision support to enhance quality and safety of care

# Clinical Research Environment

- Clinical research protocols do not scale well
  - Complex protocols that apply to a small number of research participants
  - IT cost per patient in clinical research protocol generally higher than average clinical patient
  - Estimated around 40 hours of programming time to create all the IT support per protocol

# EHRs and Research in Academic Medical Centers

- Academic Medical Centers are making substantial investments in integrated EHRs
- Decisions about functionality of EHRs are driven by clinical, not research, needs
- Integrated EHRs provide unprecedented opportunities for supporting medical discovery

# CRF IT Roundtable

- Need for research leaders in AMCs to provide road map for how to best leverage the EHR
- Progress will require cooperation of AMC IT leadership, clinical and research faculty, vendor community and regulatory offices (new focus on adding patients as well)
- With help from IT Roundtable Advisory Committee we organized 2 day conference to address these issues held October 2013

# Conference Organization

- Goal was to provide a set of recommendations from the AHC Researcher Perspective for how to best leverage the EHR for research
- Attendees included:
  - 75 clinical researchers and IT professionals from 38 AHCs
  - 11 representatives from EHR and CTMS vendors
  - 5 representatives from PHARMA

# Conference Organization

- 3 use cases
  - Randomized clinical trial
  - Clinical research registries
  - Secondary data analyses
- Small groups worked through the most important EHR functions needed to support each type of study (2 facilitators per group)
- Scrambled small groups to address overlying issues such as governance
- Complete group convened at end to make sense of recommendations and discuss next steps



# Conference Output

- Extensive reports generated at time of conference and posted online for use by members
- White paper written by Co-leaders of conference
  - Peter Embi (Ohio State)
  - Daniel Ford (Johns Hopkins)
  - Peter Winkelstein (SUNY Buffalo)
- [http://www.clinicalresearchforum.org/vertical/sites/%7B97FFC4B0-AA89-45B2-8F74-9693F47D3CB0%7D/uploads/4-23-14\\_IT\\_RT\\_paper\\_Draft.pdf](http://www.clinicalresearchforum.org/vertical/sites/%7B97FFC4B0-AA89-45B2-8F74-9693F47D3CB0%7D/uploads/4-23-14_IT_RT_paper_Draft.pdf)

# Recommendations

- Identification of Eligible Research Participants
- Enable Data Collection for Research Case Report Forms and Registries
- Engage Patients in Research
- Enhance Reuse of Clinical Data for Research
- Manage Data Access for Research

# Recommendations

- Integrate Data from Multiple Sources (ex, EHR, Echocardiography, MRI, Research data)
- Create Governance Model
- Make the Case for the Value of EHRs and Research
- Facilitate Registration of Research Participant Consent and Preferences
- Create Metadata Surrounding Research Data

# Deeper Dive on Recommendations

- *Recommendation A1*: Develop a standardized process for requesting patients' authorization to be contacted about participating in clinical research.
- 
- *Recommendation A2*: Ensure that all patients understand that their entry into a given health care system constitutes consent to allow their de-identified data to be used for observational studies in a way that protects their confidentiality while advancing new medical discovery

# Deeper Dive on Recommendations

- *Recommendation A3*: Make EHRs useful for screening patients for clinical studies by enabling researchers to integrate information from several resources, such as:
  - Biorepositories
  - Laboratory tests
  - Clinical Trial Management Systems
  - Patient Self-reported Outcomes

# Deeper Dive on Recommendations

- *Recommendation A4*: Include the following minimal dataset in EHRs to help researchers identify and screen potential study participants:
- Basic patient characteristics, such as age, sex, and race
  - Metadata (such as who determined a patient's ethnicity) to assess the data's validity
  - Diagnoses with date of onset (ideal)
  - Accurate smoking status
  - Patient authorizations to be contacted about participating in research and ability to track changes in this authorization
  - As use of a standard dataset for eligibility increases, study sponsors would be encouraged to match eligibility criteria to this common dataset

# Deeper Dive on Recommendations

- *Recommendation A7:* Create efficient EHR alerts at time of visit reminding clinicians to ask patients meeting preliminary eligibility criteria about willingness to be contacted by research staff about participating in a study.
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- *Recommendation A8:* Create a governance structure within the AHC that manages the use of EHR research reminders that is respectful of clinician's time and ability to attend to multiple messages, the patient's primary focus on addressing clinical issues, and the public needs to complete research studies and advance medical knowledge.

# Deeper Dive on Recommendations

- *Recommendation A5*: Create systems to store computable consent forms that can be queried to determine whether patients have agreed to be contacted about clinical research participation, might be willing to participate in such research, and have agreed to allow their biospecimens and/or data to be used in research
- *Recommendation A6*: Create systems and redesign workflow to efficiently manage communications with patients who have agreed to be contacted about participation in a study



# Deeper Dive on Recommendations

- *Recommendation F1:* Provide substantial flexibility in EHR data entry but standardize mechanisms for integrating EHR data with data from other sources.
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- *Recommendation F2:* Create standards for integrating data from several sources.
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- *Recommendation F3:* Develop site-based, project-based, and source-specific security mechanisms, including audit trails, encryption, and de-identification, and enable non-employees (such as representatives of sponsors and regulatory agencies) to monitor these systems.

# Deeper Dive on Recommendations

- *Recommendation G1:* Operationalize research IT governance structures that enable an evidence-generated medicine paradigm alongside one that values evidence-based medicine
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- *Recommendation G2:* Create best practices for governance structures that bring together relevant stakeholders to enable appropriate and efficient policies for data access, stewardship and security, in order to facilitate rather than hinder data-driven research activities.
- 
- *Recommendation G3:* Assign a senior staff member (e.g., research IT director, chief research information officer, etc.) as a counterpart to the chief information officer or chief medical information officer to be responsible for all research IT strategy at the institution.
- Embi P, Payne PRO. Evidence Generating Medicine: Redefining the research-practice relationship to complete the evidence cycle. *Medical Care* 2013; August; 51:S87-S91.

# Conclusions

- IT technical capacity in EHRs is rapidly progressing
- Next phase is discipline to focus on standards and managing interfaces to link data
- New focus on using EHRs to engage patients in research
- Academic centers will be challenged to manage resources and culture to leverage EHR for research

**Simple, Easy,  
Nearly FREE!**



# Utilizing EHR for Research at Johns Hopkins

# What are the main IT tasks?

- Prompt indicator that patient is in a research study
- Recruitment and registration
- Ordering clinical and research tests
- Open scheduling to create convenient visits with multiple components
- Ordering research medications
- Documentation of research visits

# Decision Support

- Information about research study for the clinical team
- Investigational drug – assess for drug interactions and duplicate drugs
- Best practice advisories
  - “Do not start an antibiotic without checking with the research team.”
- Research team pushed data if research participant admitted or seen in ER

# Promise of EMRs

- Improve recruitment through smart point of service identification and referral
- Improve coordination of care between research and clinical team
- Improve adherence to protocol
- Improve safety



# What is needed to realize the promise of EMRs?

- Research team (PIs, research coordinators, schedulers, investigational pharmacy) that meet regularly to develop agenda for research
- Someone with research perspective on all of the clinical teams working on EMR implementation
- A universal Clinical Trial Management System (CTMS) adds considerable value

# What is needed to realize the promise of EMRs?

- Address perception that clinical care needs require fast turn around and research is on a slower timeline
  - Cohort discovery needs to be fast
  - Research teams cannot wait months to get their investigational drugs entered into pharmacy and order sets
- Research teams need to be willing to standardize work flows

# Research and Epic @ Johns Hopkins

## Johns Hopkins Health System includes:

- 5 hospitals in Baltimore-Washington Region
- 150 employed physicians in largest primary care network in Maryland
- 350,000 patients enrolled in the Johns Hopkins Health Plan
- An Accountable Care Organization

## Epic deployment in progress, in use today at:

- 3 community hospitals (enterprise)
- 2 academic medical center outpatient areas
- State-wide primary care network

## Research activity at John Hopkins:

- \$650M sponsored research
- 5000 active protocols, 1300 protocols using investigational medications
- 1500 unique Principal Investigators

# Guiding Principles

For the safety of our study participants, clinical research data relevant to patient care should be in Epic and viewable by the care team, just like other clinical data

Research data which are not needed for patient care are not required to be in Epic

There are a few special cases of sensitive research data that are needed for patient care – decide on approach with guidance from governance bodies

# Good Governance is Critical

Epic Executive Council – C-band leadership. The buck stops here

Epic Coordinating Council – Addresses **cross-application, cross-institutional issues**, reports to Executive Council

Epic Research Task Force – Provide **high level vision for research use** of Epic. Reports to Coordinating Council

Epic Research Request Review (R-cubed) Committee – **reviews & prioritizes** enhancement requests. Reports to Research Task Force

Institutional Review Boards (IRBs)

Johns Hopkins Data Trust – access to clinical data for research and other purposes

Research Data  
Which We've Decided  
**SHOULD** be in the Epic EMR

# Patient on a Study

The screenshot displays the Epic Hyperspace interface for a patient named James Tstrsh Bond. The patient's information includes DOB: 07/11/1980, SSN: xxx-xx-7564, and MRN: JH77500071. The patient is currently on a research study, indicated by the 'Research: Active' status. The 'Allergies' section shows 'Unknown: Not on File'. The 'Research Studies' window is open, showing a list of studies. The first study is 'EXERCISE FACILITATES LEARNING' by RICHARDSON, ROBERT o... with Study Code CRMS-56015. The study description is '/ NA\_00077352 / CRMS-56015 /'. The associated encounter is dated 04/01/2013, with the status 'Appointment - Completed' at JHOC INTERNAL MEDICINE, performed by Lyman Dwight Wooster, MD. The second study is 'PH1 SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF MEDI4736 IN SUBJECTS WITH ADVANCED SOLID TUMORS' with a report link for CLINRESEARCH, CRBQA-... The interface also shows a sidebar with navigation options like Snapshot, Chart Review, and Research Studies, and a bottom status bar with the time 10:30 AM.

- For patient safety, clinicians need to know about research studies
- The study title can be modified by the investigator (in the CTMS)
- We do not display study association for retrospective data studies

# Scanned Research Consent

Chart Review (Last refresh: 11:42:24 AM)

Thumbnail View | Filters | Preview | Refresh | Select All | Deselect All | Review Selected | Side-by-Side | Route | View/Play | Historical Scanned Documents

Encounters | Surgeries | Labs | Pathology | Imaging | Cardiology | Procedures | Other Orders | Meds | Episodes | Letters | Notes | Referrals | Media | Misc Reports

36 records loaded, all records loaded

No filters applied

	Date/Time	Document Type	Description	Enc Date	File Attached to
	12/31/2013 12:00 AM	Bone Marrow Transplant Documentation	CELL THERAPY REQ 12/...	12/31/2013	Scanned Document on 12/31/2013 with Unknown, Provider
	12/31/2013 12:00 AM	Bone Marrow Transplant Documentation	CELL THERAPY REQUI...	12/31/2013	Scanned Document on 12/31/2013 with Unknown, Provider
	12/31/2013 12:00 AM	Bone Marrow Transplant Documentation	CELL THERAPY - LAB 1...	12/31/2013	Scanned Document on 12/31/2013 with Jones, Richard John
	12/09/2013 12:00 AM	Bone Marrow Transplant Documentation	INTERPRETATION 12/9/13	12/09/2013	Procedure visit on 12/9/2013 with Sidorski, Amy C, CRNP
	09/16/2013 12:00 AM	Bone Marrow Transplant Documentation	INTERPRETATION 09/16/...	09/16/2013	Scanned Document on 9/16/2013 with Jones, Richard John,
	08/06/2013 12:00 AM	Bone Marrow Transplant Documentation	PROCUREMENT AND IN...	08/06/2013	Scanned Document on 8/6/2013 with Pratz, Keith William, M
	07/22/2013 12:00 AM	Bone Marrow Transplant Documentation	INTERPRETATION	07/22/2013	Scanned Document on 7/22/2013 with Unknown, Provider
	09/24/2013 12:00 AM	Clinical Trial-Research Documentation	CTD-ASFC	09/24/2013	Scanned Document on 9/24/2013 with Gore, Steven David, M
	07/23/2013 12:00 AM	Clinical Trial-Research Documentation	E2906\NA_00069866	07/23/2013	Scanned Document on 7/23/2013 with Unknown, Provider
	07/22/2013 12:00 AM	Clinical Trial-Research Documentation	J121118\NA_00077575	07/22/2013	Scanned Document on 7/22/2013 with Unknown, Provider
	07/22/2013 12:00 AM	Clinical Trial-Research Documentation	J121118\NA_00077575	07/22/2013	Scanned Document on 7/22/2013 with Unknown, Provider
	07/22/2013 12:00 AM	Clinical Trial-Research Documentation	E3903\NA_00037574	07/22/2013	Scanned Document on 7/22/2013 with Unknown, Provider
	12/20/2013	Consent Forms	INFORMED CONSENT O...	12/20/2013	Visit Encounter on 12/20/2013 with Nurse, Jhh Ipop
	12/20/2013	Consent Forms	NON-MELOABLAIVE ALL...	12/20/2013	Visit Encounter on 12/20/2013 with Nurse, Jhh Ipop
	11/22/2013 12:00 AM	Consent Forms	BLOOD PRODUCT CON...	11/22/2013	Documentation on 11/22/2013 with Gladstone, Douglas Edw
	11/22/2013 12:00 AM	Consent Forms	BLD ADM/REFUSAL CO...	11/22/2013	Visit Encounter on 11/22/2013 with Nurse, Jhh Ipop
	09/10/2013 8:23 AM	Insurance Card-Primary			Stonehocker, George A [JH45359461]
	09/10/2013 8:23 AM	Insurance Card-Secondary			Stonehocker, George A [JH45359461]

- Joint Commission requires consent forms for all treatment be in medical record
- A centralized service scans the research consent form into Epic
- If Certificate of Confidentiality, then flag is set which causes a review prior to release of medical record



# Research-Linked Encounter

The screenshot shows the Epic Hyperspace interface for a patient named James Bond. The patient's information includes PCP: Grauma..., Allergies: No Known Allergies, Research: Active, Primary Ins.: None, and CSN: None. The chart review displays a table of encounters with the following data:

Date	Type	Department	Specialty	Provider	Research	Acct#
11/07/2012	Office Visit	JHOC IM	Internal Med	Wooster, L. Dwight, MD		550034359
11/07/2012	Office Visit	JHOC IM	Internal Med	Clark, Jeanne Marie, MD		
11/07/2012	Office Visit	WM JHCP PEDS	Pediatrics	Chang, Sylvia Soyun...		
11/02/2012	Office Visit	JHOC IM	Internal Med	Wooster, L. Dwight, MD		550031967
10/31/2012	Clinical Support	JHOC IM	Internal Med	Training, Sarah		550032007
10/30/2012	Transcribe Orders	JHH CRU	Clinical Res	Bedine, Marshall S, MD		
10/24/2012	Admission (Canceled)					
10/23/2012	Transcribe Orders	JHH CRU	Clinical Res	Bedine, Marshall S, MD		
10/22/2012	Orders Only	JHOC IM	Internal Med	Family Medicine, Phy...		
10/18/2012	Office Visit	JHOC NEURO	Neurology	Belzberg, Allan Joel, MD		550028039
10/17/2012	Office Visit	JHOC IM	Internal Med	Wooster, L. Dwight, MD		550023576
10/12/2012	Office Visit	WM JHCP PEDS	Pediatrics	Chang, Sylvia Soyun...		

- All research visits must be scheduled using Epic
- Link encounters to a study to assist with billing

# Clinical Research Documentation

The screenshot displays a clinical documentation interface. On the left is a sidebar with navigation options: Health Mainten..., Synopsis, Doc Flowsheets, History, Allergies, Problem List, Medications, Immunizations, Demographics, Enter/Edit Res..., Patient Station, and More Activities. The main area shows a table of notes:

Enc Type	Note Type	Status	Author	Author Type	Routed
Documenta...	Research Note	Cosign Needed	COORDINATOR-BASIC...	Research Staff	Clark, J
Office Visit	Progress Notes	Signed	CLARK, JEANNE MARI...	Physician	
Office Visit	Research Note	Signed	COORDINATOR-BASIC	Research Staff	

Below the table is a toolbar with icons for Back, Refresh, Print, and Copy. The main content area displays a **Research Note** with the following text:

Mr. Bond was seen today for his first study visit for the Exercise research study. I acquired his signed research study consent, and will be sending to the Clinical Research Billing office shortly. Mr. Bond completed all of the initial baseline questionnaires prior to being seen by the study PI for his physical. During the study visit, he inquired about MyChart, and we discussed how patients at Hopkins can sign up to see information about their health and medical history (both for study related visits and standard of care visits) through the online patient portal. I also told him that if he chose to sign up for MyChart, he would then be able to complete follow up questionnaires online in advance of his next study visit. I will be working with the front desk staff to schedule his 30 day study visit within the next few days, and I told him that we can work with the registration staff if he has any questions regarding his MyChart study activation codes or the MyChart questionnaires that I will be making available to him prior to his next research study visit.

Clinical Research Coordinator-Basic3/14/2014 10:42 AM

Progress Note (part of legal medical record)

- Should contain standard clinical documentation

Research Note (NOT part of legal medical record)

- Created & edited by Research Coordinator. Must be cosigned by clinical user

Both notes are “discoverable”

Both notes are viewable by anyone with permission to see clinical docs

# Research Orders & Results

The screenshot shows the Epic EMR interface for placing orders. The top bar includes navigation icons for Pref List, Interactions, Pharmacy, Providers, Routing, CC Results, Open Orders, Pend Orders, Sign Orders, Financial, and References. Below this is a search bar for new orders and a section for Outpatient Medications. One medication is listed: IRB 00039319 RITONAVIR OR PLACEBO, with instructions to inject 1 mL into the vein continuously. The interface also shows a 'Remove' button and navigation links for previous and next orders.

Place orders (Enc Date: 2/13/2014) - Wt: (Not entered for this visit) Ht: (Not entered for this visit) ? Resize

Pref List Interactions Pharmacy Providers Routing CC Results Open Orders Pend Orders Sign Orders Financial References More

New order:  Search Next Edit Multiple

New order defaults Not using defaults

Outpatient Medications (1 Order)

IRB 00039319 RITONAVIR OR PLACEBO Remove

Inject 1 mL into the vein continuous.  
Normal, Disp-1 mL, R-0

F7- Prev Order F8- Next Order

Can associate a research order with a study

- Research meds – 25 have been built. See naming convention above.
- Research-specific imaging orders built for special research billing rates
- Research blood draws - “nursing communication order” so person doing the draw knows what to draw & who to page once it is available
- Research lab orders in Epic – deferring to future deployment
- Research lab results – come into Epic as unsolicited orders Problematic if seeing result could compromise study blinding. No good solution yet other than to keep it out of Epic.

# Patient Reported Outcomes (PRO)

The screenshot shows a web browser window displaying a MyChart questionnaire. The browser's address bar shows the URL: <https://jhepicmychtpoc.esm.johnshopkins.edu/mychartpoc/inside.asp?mode=questionnaire&m>. The page header includes the Johns Hopkins Medicine logo and a welcome message for Penny Rsh Money, with a "Log Out" button. The user's name, "Penny (Me)", is displayed in the top left. A sidebar on the left contains navigation links: Home, Message Center, Inbox (with sub-links for Send a Message, Sent Messages, Request Rx Refill, Ask Customer Service, and Questionnaires), Appointments, My Medical Record, Billing & Insurance, My Account, and Health Library. The main content area is titled "Mental Health Questionnaire" and features a clipboard icon. Below the title, it asks: "Over the last 2 weeks, how often have you been bothered by any of the following problems?". A note states: "\* Indicates a required field." The questionnaire includes five items, each with four response options: "Not at all", "Several days", "More than half the days", and "Nearly everyday".

JOHNS HOPKINS MEDICINE

Welcome, Penny Rsh Money

Log Out

Penny (Me)

## Mental Health Questionnaire

Over the last 2 weeks, how often have you been bothered by any of the following problems?

\* Indicates a required field.

- \* Have you had little interest or pleasure in doing things?  
Not at all   Several days   More than half the days   Nearly everyday
- \* Have you felt down, depressed, or hopeless?  
Not at all   Several days   More than half the days   Nearly everyday
- \* Have you had trouble falling or staying asleep, or sleeping too much?  
Not at all   Several days   More than half the days   Nearly everyday
- \* Have you felt tired or had little energy?  
Not at all   Several days   More than half the days   Nearly everyday

- To date we have built several research PRO
- There is a high demand for research PROs

# Research Use of Epic Which Remains Challenging

# Challenging Areas

- Quality and consistency of data; sufficient for research use?
- Research note contents & contributors
- Double documenting for sponsored trials with a separate documentation mechanism
- Unsolicited lab results could compromise blinding
- Sensitive studies that shouldn't be in Epic(?)
  - This hasn't happened yet; would complicate billing & safety
- Research coordinator role
- Epic Reports & Registry - Easy access to data, exportability, could lead to misuse

# In Summary

- Study participant safety is paramount
- Any research data needed for patient care should be available in the EHR
- Protect study blinding
- Link encounters & orders to studies for accurate billing in research
- Effective governance is crucial