Grand Rounds EHR Workshop Series - Advances at the Intersection of Digital Health, Electronic Health Records and Pragmatic Clinical Trials

Keys to Success in the Evolving EHR Environment

Guest Moderator:
Keith Marsolo, PhD
Duke University

Panel:
Teresa Zayas-Caban, PhD
Office of the National Coordinator for Health Information Technology (ONC)

Christopher A. Longhurst, MD, MS
UC San Diego School of Medicine

Rachel Richesson, PhD
Duke University School of Nursing

George (Holt) Oliver, MD, PhD
ICD Pieces Demonstration Project
National Health Information Technology (IT) Priorities for Research: A Policy and Development Agenda

Teresa Zayas Cabán, PhD, Chief Scientist
Keys to Success in the Evolving EHRs Environment
Advances at the Intersection of Digital Health, Electronic Health Records, and Pragmatic Clinical Trials
June 26, 2020
At the Intersection Between Research and Care Delivery

- Develop and evaluate ONC’s scientific efforts and activities
- Recommend scientific policy to the National Coordinator
- Promote and lead activities that spur innovation, support patient-centered outcomes research, and advance precision medicine

https://www.healthit.gov/topic/scientific-initiatives
• Enormous array of data will require new thinking and pathways for storing, accessing, and analyzing the information.

• Success will require portable electronic health information that is actively exchanged among health care providers, researchers, and individuals.
Advancing Health Data and the IT Infrastructure for Research into the 21st Century

- Increased availability of electronic health data for research
- Challenges to leveraging those data and the health IT infrastructure for research remain
The Vision

Health IT infrastructure that supports alignment between the clinical and research ecosystems so research can happen more quickly and effectively.

https://healthit.gov/research-agenda
Agenda Goals and Associated Priority Areas

**Goal 1: Leverage High-Quality Electronic Health Data for Research**

- Improve Data Quality at the Point of Capture
- Increase Data Harmonization to Enable Research Uses
- Improve Access to Interoperable Electronic Health Data

**Goal 2: Advance a Health IT Infrastructure to Support Research**

- Improve Services for Efficient Data Storage and Discovery
- Integrate Emerging Health and Health-Related Data Sources
- Improve Methods and Tools to Support Data Aggregation
- Develop Tools and Functions to Support Research
- Leverage Health IT Systems to Increase Education and Participation
- Accelerate Integration of Knowledge at the Point of Care
Achieving the Agenda’s vision would support:

the pursuit of more complex research questions,

the development of more rapid and reliable discoveries about health and healthcare to improve outcomes,

and the engagement of a broader, more representative population in research participation.
Advancing the Agenda to Address Research Agency Priorities

• ONC’s Role

• Alignment between priorities and other agencies’ data and infrastructure needs
Thank you!

Contact us!

Teresa.ZayasCaban@hhs.gov
Evidence-based Medicine in the EMR Era

Christopher A. Longhurst, MD, MS
CIO and Associate CMO, UC San Diego Health
Clinical Professor of Medicine and Pediatrics, UCSD School of Medicine

@calonghurst
Research and Applications

Rapid response to COVID-19: health informatics support for outbreak management in an academic health system

J. Jeffery Reeves\textsuperscript{1}, Hannah M. Hollandsworth\textsuperscript{1}, Francesca J. Torriani\textsuperscript{2}, Randy Taplitz\textsuperscript{2}, Shira Abeles\textsuperscript{2}, Ming Tai-Seale\textsuperscript{3}, Marlene Millen\textsuperscript{4}, Brian J. Clay\textsuperscript{4} and Christopher A. Longhurst\textsuperscript{4}

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Received 18 March 2020; Editorial Decision 18 March 2020; Accepted 19 March 2020
Rapid response to COVID-19 for outbreak management

J. Jeffery Reeves, Hannah M. Hollander, Randy Taplitz, Shira Abeles, Ming Tai-Sung, Christopher A. Longhurst

*Corresponding Author: James Jeffery Reeves, MD, University of California, 9300 Campus Point Drive, MC7400, La Jolla, San Diego, CA 92037-7400 USA (jreeves@health.ucsd.edu)

Received 18 March 2020; Editorial Decision 18 March 2020; Accepted 19 March 2020
Electronic Health Record Tools for Managing a Pandemic

Screening Protocols
Triage of Patient Phone Calls
Required Registration/Check-In Screening Questions for All Patients

EHR-Templates
- Specialist and Command Center Information
- Patient and Ambulatory Order Panels
  - Coronavirus testing protocol
  - Required isolation orders
  - Equipment needs for providers
  - Proper specimen collection

Intelligence and Analytics
- National Dashboard Investigation (PUIO) in EHR embedded database
- Social Distancing Channels
  - Secure messaging
  - Data

Data
- Assist in diagnostic imaging
- Managing Technology
  - Virtual Outpatient Clinic Encounters
  - Video w/ video capabilities

JAMIA, March 24, 2020
JAMIA, March 24, 2020
Evidence-Based Medicine in the EMR Era

Jennifer Frankovich, M.D., Christopher A. Longhurst, M.D., and Scott M. Sutherland, M.D.

Many physicians take great pride in the practice of evidence-based medicine. Modern medical education emphasizes the value of the randomized, controlled trial, and we learn early on not to rely on anecdotal evidence. But the application of such superior evidence, however admirable the ambition, can be constrained by trials’ strict inclusion and exclusion criteria — or the complete absence of a relevant trial. For those of us practicing pediatric medicine, this reality is all too familiar. In such situations, we are used to relying on evidence at Levels III through V — expert opinion — or resorting to anecdotal evidence. What should we do, though, when there aren’t even meager data available and we don’t have a single anecdote on which to draw?

We recently found ourselves in such a situation as we admitted to our service a 13-year-old girl with range proteinuria, antiphospholipid antibodies, and pancreatitis. Although anticoagulation is not standard practice for children with SLE even when they’re critically ill, these additional factors put our patient at potential risk for thrombosis, and we considered anticoagulation. However, we were unable to find studies pertaining to anticoagulation in our patient’s situation and were therefore reluctant to pursue that course, given the risk of bleeding. A survey of our pediatric rheumatology colleagues — a review of our collective Level V evidence, so to speak — was equally fruitless and failed to produce a consensus.

approach, using the data captured in our institution’s electronic medical record (EMR) and an innovative research data warehouse. The platform, called the Stanford Translational Research Integrated Database Environment (STRIDE), acquires and stores all patient data contained in the EMR at our hospital and provides immediate advanced text searching capability. Through STRIDE, we could rapidly review data on an SLE cohort that included pediatric patients with SLE cared for by clinicians in our division between October 2004 and July 2009. This “electronic cohort” was originally created for use in studying complications associated with pediatric SLE and exists under a protocol approved by our institutional review board.

Of the 98 patients in our pediatric lupus cohort, 10 patients developed thrombosis, documented
Evidence-Based Medicine in the EMR Era

Jennifer Frankovich, M.D., Christopher A. Longhurst, M.D., and Scott M. Sutherland, M.D.

Results of Electronic Search of Patient Medical Records (for a Cohort of 98 Pediatric Patients with Lupus) Focused on Risk Factors for Thrombosis Relevant to Our 13-Year-Old Patient with Systemic Lupus Erythematosus.*

<table>
<thead>
<tr>
<th>Outcome or Risk Factor</th>
<th>Keywords Used to Conduct Expedited Electronic Search</th>
<th>Prevalence of Thrombosis no./total no (%)</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome — thrombosis</td>
<td>“Thrombus,” “Thrombosis,” “Blood clot”</td>
<td>10/98 (10)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Thrombosis risk factor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heavy proteinuria (&gt;2.5 g per deciliter)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present at any time</td>
<td>“Nephrosis,” “Nephrotic,” “Proteinuria”</td>
<td>8/36 (22)</td>
<td>7.8 (1.7–50)</td>
</tr>
<tr>
<td>Present &gt;60 days</td>
<td>“Urine protein”</td>
<td>7/23 (30)</td>
<td>14.7 (3.3–96)</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>“Pancreatitis,” “Lipase”</td>
<td>5/8 (63)</td>
<td>11.8 (3.8–27)</td>
</tr>
<tr>
<td>Antiphospholipid antibodies</td>
<td>“Aspirin”</td>
<td>6/51 (12)</td>
<td>1.0 (0.3–3.7)</td>
</tr>
</tbody>
</table>

* In all cases, the sentences surrounding the keywords were manually reviewed to determine their relevance to our patient. Pancreatitis was defined as an elevated lipase level (twice the upper limit of normal) coexisting with abdominal pain. We used the word “aspirin” as a proxy for antiphospholipid antibodies, since it is standard practice at our institution to give all patients with these antibodies aspirin; if “aspirin” was found in the chart, then antiphospholipid-antibody status was confirmed by investigating the laboratory results.

We recently found ourselves in such a situation as we admitted to our service a 13-year-old girl of our collective Level V evidence, so to speak — was equally fruitless and failed to produce a consensus.

Of the 98 patients in our pediatric lupus cohort, 10 patients developed thrombosis, documented...
A ‘Green Button’ For Using Aggregate Patient Data At The Point Of Care

ABSTRACT Randomized controlled trials have traditionally been the gold standard against which all other sources of clinical evidence are measured. However, the cost of conducting these trials can be prohibitive. In addition, evidence from the trials frequently rests on narrow patient-inclusion criteria and thus may not generalize well to real clinical situations. Given the increasing availability of comprehensive clinical data in electronic health records (EHRs), some health system leaders are now advocating for a shift away from traditional trials and toward large-scale retrospective studies, which can use practice-based evidence that is generated as a by-product of clinical processes. Other thought leaders in clinical research suggest that EHRs should be used to lower the cost of trials by integrating point-of-care randomization and data capture into clinical processes. We believe that a successful learning health care system will require both approaches, and we suggest a model that resolves this dichotomy with a “green button” for the integration of EHRs with clinical care.
Figure 1 – The Green Button in Action

1. **Point of care randomization / large simple trial**
   - Queue / Consider for randomization at point of care

2. **Clinical situation**
   - Guideline available?
     - Yes: Use level A guideline
     - No: Use “Green Button”

3. **Use “Green Button”**
   - Useful byproduct
     - High priority
     - Priority list of clinical situations
     - Increment priority

4. **Large cohort of similar patients present?**
   - Yes: Use practice-based evidence
   - No: Use professional judgment

UC San Diego Health
@calonghurst
Combining healthcare data from across the six University of California medical schools and systems

UC HEALTh

Health Data Warehouse

UC San Diego Health
UCI Health
UCSF Health
UCR Health
UCLA Health
UC Davis Health

UC Health Data Analytics Platform

Atul Butte, MD, PhD
Chief Data Scientist
UC Health
UC Health COVID-19 Patients

UC Health COVID-19 Patients (Data through 6/24/2020 11:59 PM)
Interim report, data subject to correction, UC Health patients only, tests for external partners excluded.

Cumulative Patient Test Status

<table>
<thead>
<tr>
<th>Patients with Pending Tests</th>
<th>633</th>
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</thead>
<tbody>
<tr>
<td>Patients with Results</td>
<td>UCSF 21,901</td>
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</tbody>
</table>

Patients with Pending Tests

<table>
<thead>
<tr>
<th>Patients with Pending Tests</th>
<th>UCD</th>
<th>UCI</th>
<th>UCLA</th>
<th>UCSD</th>
<th>UCSF</th>
<th>UC Health</th>
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<tr>
<td>42</td>
<td>177</td>
<td>0</td>
<td>255</td>
<td>159</td>
<td>633</td>
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</table>

Patients with Results

<table>
<thead>
<tr>
<th>Patients with Results</th>
<th>UCSF 11,688</th>
<th>UCSD 32,681</th>
<th>UCLA 31,770</th>
<th>UCSD 21,901</th>
<th>UC Health 114,084</th>
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<tbody>
<tr>
<td>16,046</td>
<td>11,688</td>
<td>32,681</td>
<td>31,770</td>
<td>21,901</td>
<td>114,084</td>
</tr>
</tbody>
</table>

Total Positives

| Total Positives | 301 | 829 | 1,177 | 514 | 368 | 3,189 |

Cumulative Confirmed Cases by Location

Confirmed Cases by Age

Confirmed Cases by Sex

UC San Diego Health

@calonghurst
All five University of California academic medical centers provide health data to patients through Apple Health

bit.ly/ucappleh
Personal Health Records
More Promising in the Smartphone Era?

As health care delivery organizations shift from implementation of electronic health records to optimization of these systems, the persistent problem of patient data interoperability is becoming increasingly relevant. Interest in accessing medical information from hospital records and databases and providing convenient patient-controlled portable records is increasing. Technology companies are seeking to develop innovative solutions to meet these demands.

Interoperable personal health records are not a novel concept; unsuccessful attempts to collect digital patient records have been pursued by several major technology companies. As 1 of the first 12 health care organizations to integrate one company’s next-generation approach (Apple Health Records) into a patient portal, UC (University of California) San Diego Health is assessing whether this new functionality can overcome prior challenges and catalyze systemic change toward meaningful patient-controlled interoperability.

reported improvement with all 3 of these outcomes. As of fall 2018, UC San Diego Health has hundreds of personal health record users who have downloaded thousands of clinical results and other pieces of medical information though the platform.

As with many other new products and solutions, such enthusiasm is common from early adopters. The platform will need to prove that it is useful, sustainable, scalable, and actually improves health outcomes. The key questions are whether this personal health record will improve patient outcomes and lower costs while also increasing quality. Why might this time be different? Three key developments may contribute to success: the ubiquity of mobile technology, the maturation of health data communications standards, and the widespread use of mobile software distribution platforms.

When Microsoft introduced HealthVault (2007) and Google launched Google Health (2008) personal health records, the first iPhone and Android devices
How do we ensure our healthcare system learns from every patient, at every visit, every time?
Thank you!

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@calonghurst
Advances at the Intersection of Digital Health, Electronic Health Records and Pragmatic Clinical Trials

Use of EHR in Collaboratory Projects

Rachel Richesson, PhD
Co-Chair of the EHR Core
Duke University School of Nursing
## Use of EHR in Collaboratory Projects

<table>
<thead>
<tr>
<th>Trial</th>
<th>Eligibility</th>
<th>Intervention Delivery</th>
<th>Outcome Assessment</th>
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<tbody>
<tr>
<td>Acu-OA</td>
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<td></td>
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<tr>
<td>NOHARM</td>
<td></td>
<td></td>
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<tr>
<td>FM TIPS</td>
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<tr>
<td>OPTIMUM</td>
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<td></td>
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<tr>
<td>ACP PEACE</td>
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<tr>
<td>HiLo</td>
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<tr>
<td>PRIM-ER</td>
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<tr>
<td>EMBED</td>
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<tr>
<td>Nudge</td>
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<td>GGC4H</td>
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<td></td>
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<tr>
<td>ICD-Pieces</td>
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<td>TSOS</td>
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<tr>
<td>SPOT</td>
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<td>PROVEN</td>
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<td>LIRE</td>
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<td>STOP-CRC</td>
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<td>TiME</td>
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<tr>
<td>ABATE</td>
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</table>
EHR integration challenges and lessons from ICD Pieces

June 26, 2020
Combining Data From:
- EHR: EPIC, Allscripts, VA Vista
- Hospital Claims: Commercial Claims, ResDAC
- National Death Index

Use the Data for:
- Unified patient selection algorithm
- Primary and secondary outcome from hospital claims

Begin with the End in Mind
- Final Patient Follow up will be completed Monday!
Should a trials reach exceed its grasp: External Partners

Largest Provider of Renal Replacement services, alternate resources

- In transition EMR: Vista->Cerner
- PHI restrictions

- Most standard
  - Embedded LOINC
  - NDC codes
  - Value Set Authority Center

Lesson Learned:
Embedded analyst >> remote/limited access
Privacy Challenges balanced against expanded trial applicability
Cluster Randomization does not insulate from cluster related challenges

Geographic and Demographic representation with a private practice Northeastern location

- Change in Partner Organizational structure
- Change in Medicare FFS data mid trial QIO->ResDAC
- Change Data warehouse mapping after integration with OptumCare
- Non-Hospital affiliate status gave different data access to claims data
  - Better access in some areas
  - Extra approval steps for Commercial claims
  - Budget implications on ResDAC
Emerging Challenges

- Data Structure:
  - EHR upgrade cycles

- Workflow
  - Personnel turnover

- Integration
  - Minimum necessary
  - Testing, validation, guardrails

- Standards
  - LOINC-wonderful where available
  - Claims, Labs, Vitals are safe spaces
  - Medication metrics robust to visibility