Registries for Quality and Research
A Tale of 1+1 Registries

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Disclosures/COI

• Disclosures
  – St. Jude Medical (travel/honoraria)
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• I have permission to show the patient photos in this presentation
# The Quality of Health Care Delivered to Adults in the United States

## Table 3. Adherence to Quality Indicators, Overall and According to Type of Care and Function.

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of Indicators</th>
<th>No. of Participants Eligible</th>
<th>Total No. of Times Indicator Eligibility Was Met</th>
<th>Percentage of Recommended Care Received (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall care</td>
<td>439</td>
<td>6712</td>
<td>98,649</td>
<td>54.9 (54.3–55.5)</td>
</tr>
<tr>
<td>Type of care</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preventive</td>
<td>38</td>
<td>6711</td>
<td>55,268</td>
<td>54.9 (54.2–55.6)</td>
</tr>
<tr>
<td>Acute</td>
<td>153</td>
<td>2318</td>
<td>19,815</td>
<td>53.5 (52.0–55.0)</td>
</tr>
<tr>
<td>Chronic</td>
<td>248</td>
<td>3387</td>
<td>23,566</td>
<td>56.1 (55.0–57.3)</td>
</tr>
<tr>
<td>Function</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screening</td>
<td>41</td>
<td>6711</td>
<td>39,486</td>
<td>52.2 (51.3–53.2)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>178</td>
<td>6217</td>
<td>29,679</td>
<td>55.7 (54.5–56.8)</td>
</tr>
<tr>
<td>Treatment</td>
<td>173</td>
<td>6707</td>
<td>23,019</td>
<td>57.5 (56.5–58.4)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>47</td>
<td>2413</td>
<td>6,465</td>
<td>58.5 (56.6–60.4)</td>
</tr>
</tbody>
</table>

“(clinicians) generally know what constitutes best practices and show up every day to do the best for their patients, but reliably and consistently offering those services at the point of care delivery requires a systems approach...with specific actions to ensure delivery of optimal care.”
Quality Improvement—An Overview

- Traditional clinical research evaluates interventions delivered in well-controlled environments, increasing the likelihood that patients receive the intervention.
- In contrast, QI interventions are often designed to
  - Enhance the implementation of proven therapies
  - Use data routinely collected in clinical practice

Fan E et al., JAMA 2010;304:2279-2287.
Registries for Robust Evidence

• While RCTs are essential for establishing efficacy of interventions, they cannot address all needs
  – Timely determination of safety and effectiveness of different interventions used in diverse “real-world” patients and settings
  – Increasing interest in the role of observational studies, including registries and electronic data sets

Beyond Mortality
Future Clinical Research in Acute Lung Injury

Roger G. Spragg¹, Gordon R. Bernard², William Checkley³, J. Randall Curtis⁴, Ognjen Gajic⁵, Gordon Guyatt⁶, Jesse Hall⁷, Elliott Israel⁸, Manu Jain⁹, Dale M. Needham³, Adrienne G. Randolph¹⁰, Gordon D. Rubenfeld¹¹, David Schoenfeld¹², B. Taylor Thompson¹³, Lorraine B. Ware², Duncan Young¹⁴, and Andrea L. Harabin¹⁵

NHLBI Workshop

Comparative Effectiveness Research in Lung Diseases and Sleep Disorders
Recommendations from the National Heart, Lung, and Blood Institute Workshop

Tracy A. Lieu¹,², David Au³, Jerry A. Krishnan⁴, Marc Moss⁵, Harry Selker⁶, Andrea Harabin⁷, Virginia Taggart⁷, Alfred Connors⁸, and the Comparative Effectiveness Research in Lung Diseases Workshop Panel*
The Toronto Intensive Care Observational Registry (iCORE) Project

Eddy Fan, MD, PhD
Project Lead

Interdepartmental Division of Critical Care Medicine Steering Committee Meeting
Thursday, September 11, 2015
Objective

• To create a high quality registry of mechanically ventilated patients through city-wide collaboration of academic health centres performing uniform data collection
  – Minimum data set – all patients
  – Modular data sets
  – Centrally-trained/quality-assured study assistants
  – Central data management/security
Inputs

• Minimum data sets collected daily in ICU for all eligible patients
  – Demographics, ICU admission diagnosis, severity of illness

• Modular data sets
  – Investigator-initiated
  – Hypothesis-driven
  – Time-limited
Outputs

• Epidemiology
  – MV, ARDS, specific therapies/interventions, outcomes

• Prevention
  – Risk factors for progression/development of ARDS
  – Linkage to population-level administrative data

• Biomarker/Genetic Analyses
  – Link phenotypic data to biological specimens (BAL, blood) obtained in subset of patients

• Pilot Data
  – Proof of concept/hypothesis for future grants/clinical trials

• Quality Improvement
  – Adherence/compliance with “best practices” to identify potential targets for local or system-wide QI
Quality Improvement—An Overview

• QI interventions are frequently
  – Context-dependent
  – Complex
  – Iterative
  – Seeking to address barriers to and facilitators of QI
Official Executive Summary of an American Thoracic Society/American College of Chest Physicians Clinical Practice Guideline: Liberation from Mechanical Ventilation in Critically Ill Adults

Dr. Gregory A. Schmidt; Dr. Timothy D. Girard, MD, MSCI; Dr. John P. Kress; Dr. Peter E. Morris; Dr. Daniel R. Ouellette; Dr. Waleed Alhazzani, MD, MSc (epid), FRCPC; Dr. Suzanne M. Burns; Dr. Scott K. Epstein; Dr. Andres Esteban; Dr. Eddy Fan; Dr. Miquel Ferrer; Dr. Gilles L. Fraser; Dr. Michelle Ng Gong; Dr. Catherine L. Hough; Dr. Sangeeta Mehta; Dr. Rahul Nanchal, MD; Ms. Sheena Patel; Ms. Amy J. Pawlik; Dr. Curtis N. Sessler; Dr. Thomas Strøm, MD; Dr. William Schweickert; Dr. Kevin C. Wilson, MD; Dr. Jonathon D. Truwit;

DOI: http://dx.doi.org/10.1164/rccm.201610-2076ST

Published Online: October 20, 2016
Future Considerations

• Cumulative reporting of utilization statistics with trend analysis over time
• First-pass “reality checking” of novel research findings
• Ongoing estimates of disease epidemiology and outcomes through linkage to other prospective clinical research
• Research into outcome methodology and statistical processes
• Expand to include community partners
Comprehensive Programs

1. Hypothesis generation
   - identification of questions from registry (e.g., increased mortality associated with after-hours ICU discharge)

2. Small-scale pilot study of key issues

3. Large-scale multicentre exploration of issues in greater depth, to test generalizability of ideas developed

4. Interventions targeting systematic issues as a result of those findings and determination of effectiveness of the intervention

5. Post-implementation and post-publication surveillance
   - Assessment of uptake, effectiveness, and observation for unexpected outcomes of widespread use of the intervention
Problem

• For studies of extracorporeal support
  – Time, resources, coordination
  – Potentially limited study population

• Need to
  – Efficient trial design
  – Ensure patient-important outcomes are evaluated
  – High quality data – comparability across studies
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International Research Database for Extracorporeal Support

Project Leads:
Eddy Fan (Toronto)
Carol Hodgson (Melbourne)
Randomization within quality registries: a cost-effective complement to classical randomized trials

• Registry RCT (R-RCT) = uses registry for one or several major functions for trial conduct and outcomes reporting

• More than just cost-effective!
  – Identify patients/randomize
  – Maximize use of existing data - efficiency
  – Greater generalizability – less selective populations studied
  – Data quality is of major importance

Incremental Cost per Patient Randomized = $50
Fusing Randomized Trials With Big Data
The Key to Self-learning Health Care Systems?

A novel blend of ‘POC’ + platform designs

• REMAP
  • Randomized
  • Embedded
  • Multifactorial
  • Adaptive
  • Platform trial

• Ex: REMAP Severe Pneumonia
  • EU FP7 PREPARE WP 5 program
  • (Australian NHMRC ‘OPTIMISE’ program)
  • >6,000 patients admitted to ICU with severe CAP
  • Simultaneously test
    • Different anti-microbial strategies
    • Different host immunomodulation strategies
    • Different ventilation strategies
  • Separate RAR and stopping rules for multiple potential subgroups
Innovative Clinical Trials: Important Partners are Onboard!

www.nihcollaboratory.org
www.cihr-irsc.gc.ca
ESPRIT
Extracorporeal Support Platforms and Registries for Innovative Clinical Trials
“Research is only a beginning, and not an end in itself”

Carolyn Clancy, Director, AHRQ
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  – Manal Ahmad
  – Farzad Fattah
  – Stella Triboi
  – Shikha Sharma
  – Roizar Rosales
  – Barwaka Abdallah
  – Richa Menghani
  – Snezhana Bessonova
Questions?

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