BEYOND RCTs

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OVERVIEW

• What do we know and what are the limits to what we know?
• What else do we need to know?
• How can EHRs help us?
  – Use what we know
  – Discover what we need to know
• How important are patient reported data?
WHAT DO WE KNOW?

• Largely based on industry funded RCTs
  – Not primarily intended as a source of evidence

• Limits to generalizability
  – Restricted inclusion/exclusion criteria, Follow-up time, Outcomes

• Usually confined to a single intervention for a single clinical domain
  – Statins for LDL, not relative impact of statins in reducing Acute MI in diabetics using other interventions
LIMITS TO WHAT WE KNOW

• General claims for broadly defined intervention classes is strong
  – Statins reduce LDL

• Evidence on comparative effectiveness is weak
  – Largely based on Meta-analysis

• Evidence about more nuanced decision of what works best for whom is weak
  – Risks and benefits of using anti-hypertensives in patients 75+
  – Benefits of combination therapies in control of LDL, BP, serum glucose, etc
  – How much do the nuances matter?
LIMITS TO WHAT WE KNOW

• Evidence is largely in clinical silos
  – Limited knowledge on comparative value of interventions across multiple conditions

• A Dominant Gap
  – Patients with multiple co-morbidities
  – More of them everyday
  – Relative gain in outcome for each condition specific intervention
  – Relative cost per unit gain in the outcome
THE PROMISE OF EHRs, ASSOCIATED TOOLS, AND CARE PROCESSES…
“I already diagnosed myself on the Internet. I’m just here for a second opinion.”
FOUR USE SCENARIOS

• Retrospective analysis of data
• Performance improvement initiatives
• Effective use of knowledge in practice
• Real time practice based clinical trials
• Many uses
  – Comparative effectiveness
  – What works best for whom
  – New treatment indications
  – Relative gain in outcomes per treatment intervention

• Fundamental Limitations: Usual Suspects
  – Data quality, completeness, and specificity
  – Confounding and error
STRONG USE CASES

• Primary outcome: Laboratory measure and selected clinical measures
  – Control of LDL, serum glucose control, kidney function
  – Blood pressure (i.e., even given the many sources of error)

• Safety and side effects are serious (i.e., likely to be detected) or are not a significant concern
WEAK USE CASES

• Where the primary endpoint relies on patient reported outcomes
  – Common chronic episodic conditions: Pain disorders, psychiatric disorders, GERD, allergic rhinitis, etc
  – Surgical outcomes: back, prostate, knee or hip replacement, bladder surgery

• Where adverse effects influence adherence or the overall evaluation of outcomes
  – Depression, migraine, surgery intervention options, etc
PERFORMANCE IMPROVEMENT

• System level opportunities for ROI
  – Business case for new and sustainable care processes
  – Substantial investment of resources
  – Concerted effort to innovate and standardize care

• Recent examples at Geisinger
  – Diabetes Bundle initiative
  – Medical Home
PI vs HEALTH SERVICES RESEARCH (HSR)

• HSR weaknesses
  – Modify variables (a few), not processes
  – Business case?
  – Sustainability and scalability
  – Translation questions after study is completed

• PI Weaknesses
  – Evaluation design and measurements are secondary
  – Why did it work?
USING KNOWLEDGE IN PRACTICE
USING EVIDENCE: 1ST STEP

• Variation in clinical decisions and outcomes
  – What one knows
  – Data obtained
  – Data evaluated
  – Knowledge retrieved
  – Interpretation (i.e., ordering)
  – Patient preferences and options
  – Patient motivation
  – Patient instruction/education
EHR EXTENDERS

- Tools that are independent of but that interact with EHRs
- Patient data capture
- Clinical and patient decision support
  - Data extraction processes
  - Data analytic processes
- Intuitive visual display
- Patient intentions and choice
Patient reported data & preferences
Activates CDS
CDS Rec’s
Integration Of patient & expert input

Real-time Dashboard Display

Physician Review
Patient Is Roomed

EHR Via BPA or hyperlink

Final Order
Clinical Notes
Meds
Referral
Support Services
Education
After Visit Summary
RELEVANCE TO EVIDENCE

- Integrating patient reported data with care process
- Standardize care processes
  - Reduces variation
  - Possibly reducing confounding
- More explicit data on patient choice
- Tools are relevant to real time identification of clinical equipoise
RANDOMIZING UNCERTAINTY

• Gap between what we know and have to do is an everyday occurrence
  – Constant state of change
  – Need for an everyday solution
  – Evidence creation takes a long time
  – Challenges with confounding and bias

• Identify conditions where there is meaningful uncertainty
  – Understanding what is most valuable for a patient with multiple co-morbidities
  – What is the patient’s ROI for each intervention they buy?
RANDOMIZING UNCERTAINTY

- Physician
  - Requires a more explicit understanding of what we do not know
  - Can a convincing case be made to randomize clinical care?
- Patient
  - Being explicit about what we do not know
- IRB
  - Is the current art of clinical decision where evidence is uncertain better or worse than randomization?
- Outcomes
  - More deliberate efforts to measure the right outcomes at the right time
DATA CHALLENGES

• Completeness
  – What is missing most often: patient reported data
  – Unscheduled data collection is similar to a missing data problem

• Are data in a useable form?
  – Fixed data fields, standardized text, unstructured text, PDFs
PATIENT REPORTED DATA

• Is there a business case for collecting data from patients?
  – Saves time
  – Increases RVUs/time
  – Better data

• Many Operational Challenges
  – Authentication of patient
  – How should data be collected for use in real time?
  – Where should data be collected?
  – How does a practice decide what is collected and when it should be collected?
HOW TO COLLECT DATA

- Home monitoring
- Digital pen
- Scan form
- Pentab
- Touch Screen

- Too much data
- Low adherence
- Unstable technology
- Staff time required
- Scanner breaks down
- Risk of breaking after dropping
- Industrial strength is too heavy
- User friendly
HOW TO COLLECT DATA

- By mail
- By computer at home
- In waiting area
- In exam room

- Uncertain and incomplete
- Low percentage of effective users
- Front desk time required
- Authentication logistics
- Disrupts workflow
- Eliminates authentication
- Fits workflow when there is time between nurse and physician
DATA ON TREATMENT ADHERENCE

- Patient questionnaire
- Medication reconciliation and documentation
  - Exam room protocol
- Accessing pharmacy claims data
  - EHRs only indicate what is prescribed, not what is being used
  - Are serial Rxs equivalent to Rx claims data