GEISINGER

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

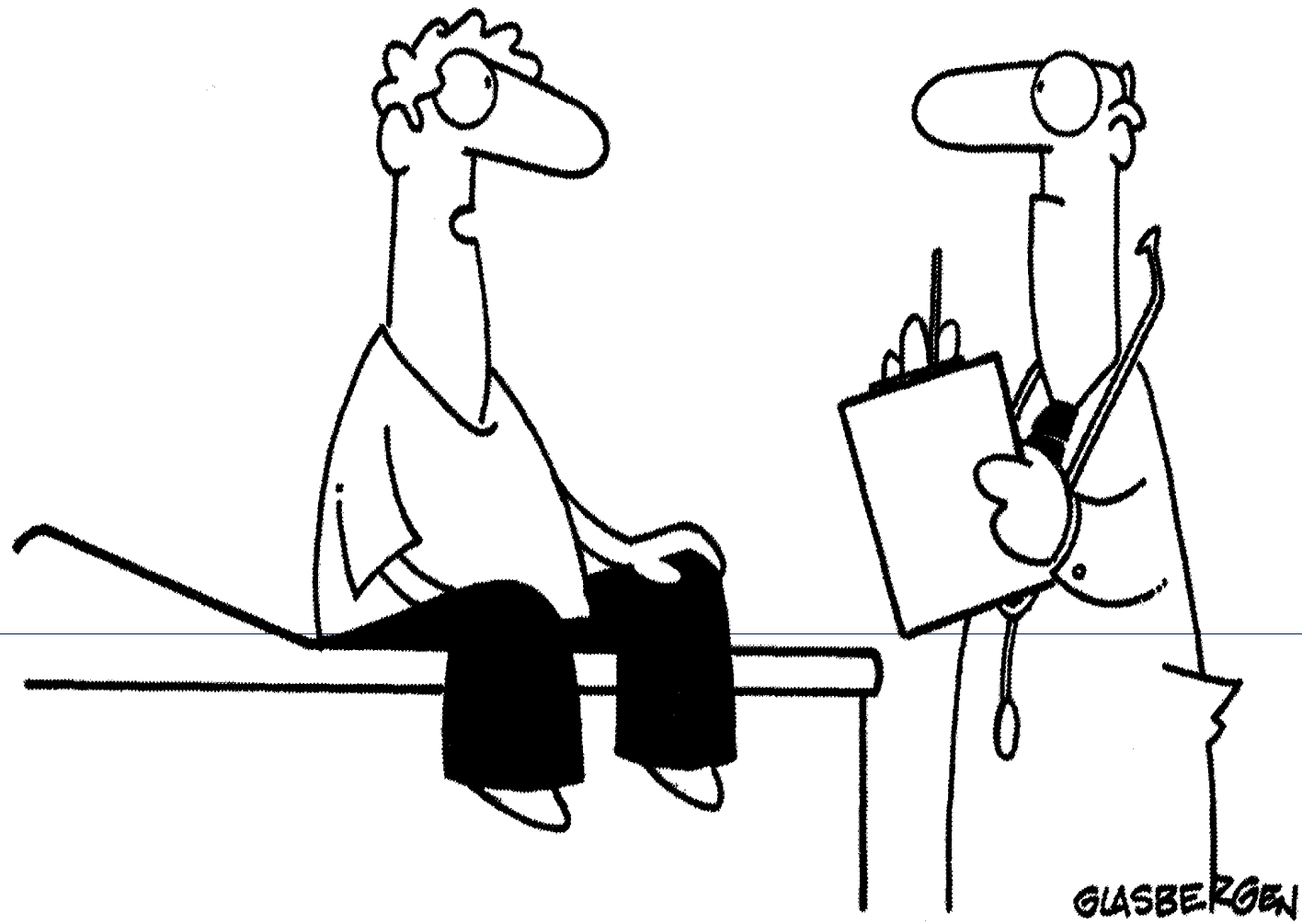
LIMITS TO WHAT WE KNOW

- 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

RETROSPECTIVE DATA ANALYSIS

- 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?

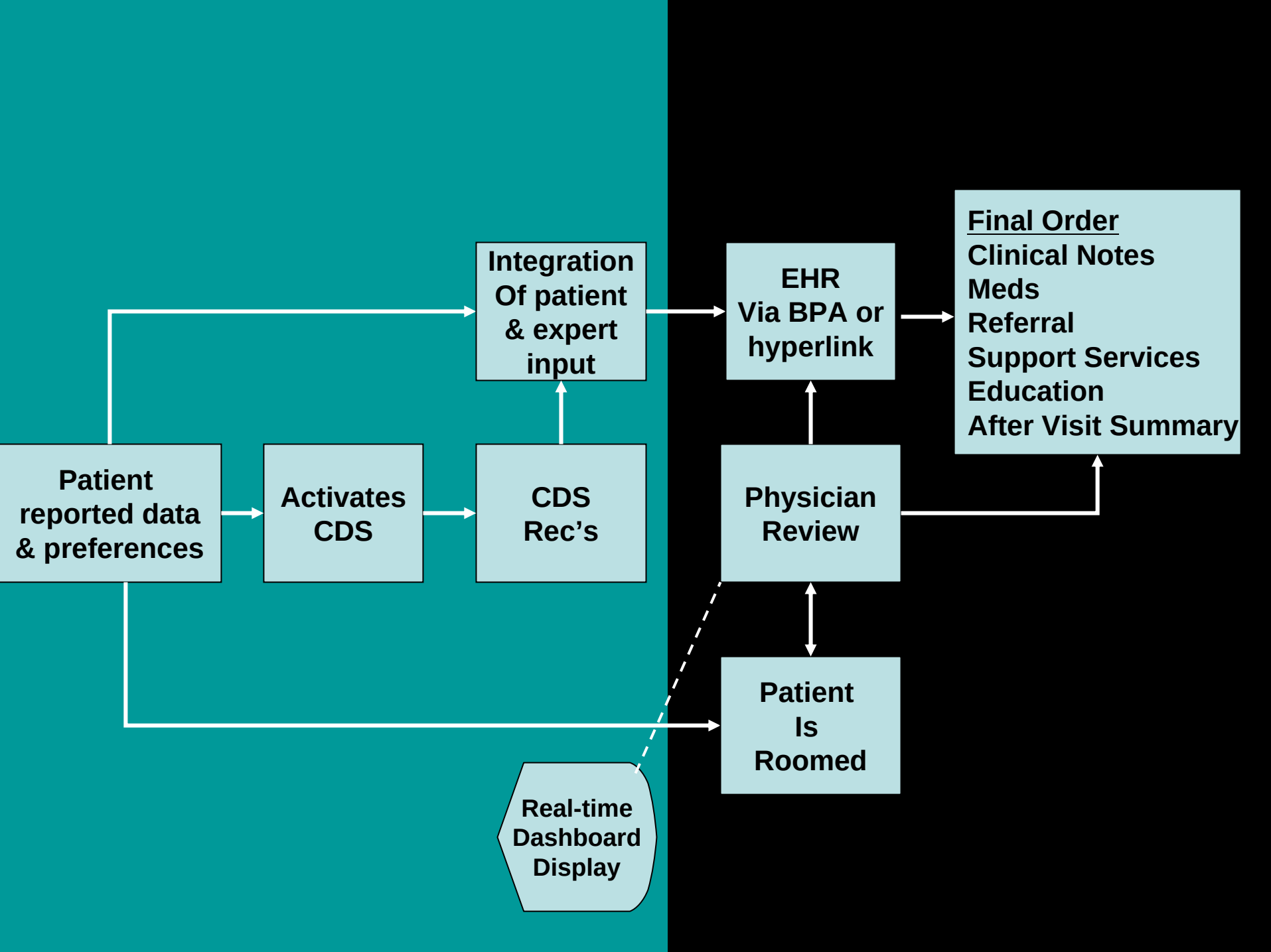
USING KNOWLEDGE IN PRACTICE

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
EHR Via BPA or hyperlink
Final Order
Clinical Notes
Meds
Referral
Support Services
Education
After Visit Summary
Physician Review
Patient Is Roomed
Real-time Dashboard Display

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