Health Services Research

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Agenda

• Why is some research better than others?
• Case example about behavioral health
• Role of patients in research
• When is science good enough to inform policy?
Clinical trials are the gold standard for comparing therapies

Essential characteristics of a robust clinical trial:

• A pre-established protocol
• A meaningful control group
• Random assignment of subjects to treatment or control
• Blinded assessment of outcomes
Why write a protocol?

- If the data are not working out the way you hoped, it is tempting to change the plan to find some way to make it look better.
  - Change the outcome variable
  - Change the study subjects
  - Change the analytic methods

When this happens, the results are much less likely to be reproducible and generalizable to other populations.
Why have a control group?

- People get better on their own without therapy.

*We need to know “what if we hadn’t used the new treatment?”*
Why randomize which subjects get which treatment?

- If the only difference between the active and control groups at baseline is which treatment they get, we can conclude that any differences in outcomes are due to treatment.
- Doctors are smart - they select treatments for (sometimes) very good reasons.
- Randomization takes treatment assignment out of the hands of the doctors.

Randomization means the active and control groups are probably similar before treatment.
Why blinding?

The people who measure the outcomes and do the analysis can’t see which group the subjects are in.

• We scientists like to think of ourselves as impartial and unbiased.

• However, deep down, we usually favor one group or the other.

• Subconscious preferences can come out during measurement and analysis.

  Blinding reduces the chances of bias.
Case example: Behavioral Health

• Common Mental Health issues
  • Anxiety, Depression, etc.

• Common Substance Abuse issues
  • Alcohol, Tobacco, Drugs

• Common Lifestyle issues
  • Diet, Exercise, Medications, Sleep, etc.

• Stress

• Huge prevalence, impact & costs
3 Models of Behavioral Health in Primary Care

Most Behavioral Health (BH) issues present to Primary Care (PC).

How can we get services to needy patients?

1. Refer to outside BH clinician (MD, MS, PhD, etc.)
2. Co-location (BH at the same address)
3. Integrated BH and PC
Integrated Behavioral Health

- Shared space
- Shared records
- Evidence-based BH services
  - Automatic systems for managing BH patients:
    - Screening
    - Scheduling
    - Monitoring
    - Follow-up
  - Frequent communication among providers
  - Stable reimbursement for BH services
Current research at UVM

*Integrating Behavioral Health and Primary Care for Comorbid Behavioral and Medical Problems (IBH-PC)*

- Funded by The Patient-Centered Outcomes Research Institute (PCORI)
- $18.5M over 5½ years
- Executive Committee
  - Rodger Kessler, PhD
  - Connie van Eeghen, DrPH
  - Jennifer Lavoie
- Many, many others at UVM and across the country
The IBH-PC Intervention

- Online **Skills** training for BH providers, PCPs and staff
- A **Toolkit** of suggested tactics for integration
- **Protocolized Process** for facilitated redesign of Primary Care practices
  - 12 hour intensive team exercise to plan changes
  - Toyota Production System LEAN method
Aims

Aim 1: Determine if increased integration results in better patient-centered outcomes.

Aim 2: Determine if protocolized process techniques are effective in increasing BH integration.

Aim 3: Explore how contextual factors affect the implementation and patient-centeredness of integrated BH care.
Design: Randomized Trial

- 40 PC practices with co-located BH
- Randomized to stay in co-location or become integrated
- Recruit a random sample of 75 patients per practice
- Assess patients (and practices) at baseline and every 12 months
- Unit of randomization is the practice (n=40)
- Unit of analysis is the patient (n=3,000)
Study Design

40 Practices

Randomize

Baseline Measures

Practice Redesign Process

Follow-up Measures

Integration

Baseline Measures

Usual Care

Follow-up Measures

Co-location

18 Months
40 Primary Care Practices

• Family Practice or General Internal Medicine
• Commitment to having BH clinician onsite
• Willing to engage in integration efforts
• Electronic medical records
• Private practices, Federally Qualified Health Centers, Academic clinics, etc.
3,000 patients

- At least one chronic medical problem:
  - Arthritis
  - Asthma/COPD
  - Diabetes
  - Heart Failure/Hypertension
- At least one Behavioral Health problem:
  - Anxiety/Depression
  - Chronic pain/Headache/Fibromyalgia
  - Insomnia
  - Irritable Bowel Syndrome
  - Alcohol or Substance use disorder
Outcomes

• Primary: Symptoms & Functional Status
• Secondary:
  • Communication
  • Empathy
  • Self-management
  • Adherence
  • Time lost to disability
  • Emergency Room and hospital visits
  • Disease specific outcomes (blood sugar control, blood pressure)
• Did the practices change?
“Patient Centered” means collaboration

- The study team includes patients (and caregivers) at every step:
  - Framing the question
  - Which conditions?
  - Outcome measures
  - Recruitment strategies
  - Consent process
  - Analysis
  - Dissemination of results

- Patient partners serve on:
  - Co-investigator teams (% effort salary)
  - Strategic Advisory Group (honoraria and expenses)
  - Practice redesign teams (honoraria and expenses)
Why is IBH-PC “robust”? 

• It has a published protocol. 
  • No changing the rules after the game has started 
• It randomizes assignment to treatment vs. control. 
  • No hand-picking “most likely to succeed” 
• The control is a viable alternative. 
  • No “straw-man” comparisons that are easily bested 
• It has pre-specified outcomes. 
  • No cherry picking 
• Measures are blinded. 
  • The outcomes are not measured by someone with an interest in the study results 
• The research sites are real-world clinics from all over. 
  • Not just special research clinics with unusual characteristics
Why do robust designs matter?

• They are much less likely to be biased
• The results are much more likely to apply in other settings

• Most published “science” is either
  • Preliminary
  • Over-interpreted
  • Biased
  • Not generalizable, or
  • Fraudulent
Making policy?

- Ignore press releases and brochures
- Discount “science” that is produced by commercial interests
- Insist on, at the least, peer review
- Look for Randomized Trials

Ask for help – you have a whole University eager to help you!
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• The views, statements, and opinions presented in this meeting are solely the responsibility of the author(s) and do not necessarily represent the views of PCORI, its Board of Governors or Methodology Committee.

• PCORI is an independent, nonprofit organization authorized by Congress in 2010. Its mission is to fund research that will provide patients, their caregivers, and clinicians with the evidence-based information needed to make better-informed healthcare decisions. PCORI is committed to continually seeking input from a broad range of stakeholders to guide its work.
Thanks!

- Benjamin Littenberg, MD
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www.IBHPC.blogspot.com