Challenges in Understanding Research on Medical Practices: Data from a Nationally Representative Sample

Kevin P. Weinfurt, PhD
Jeremy Sugarman, MD, MPH, MA

Background

• There is an array of perhaps surprising ethical, regulatory and practical issues associated with conducting pragmatic clinical research.

• Deliberations about some of these issues, especially those related to acceptability and consent, should be enhanced with empirical data.

• Accordingly, we set out to improve understanding of when and how different stakeholders believe research testing or comparing interventions that are each considered standard of care are acceptable and when traditional or modified approaches to consent for it should be sought.

Methods (Brief)

Sample

U.S. adults from GfK KnowledgePanel
English-speaking
Have seen a health care provider at least once in the past year
Probability-weighted to allow inference to U.S. population

This work is supported by the National Institutes of Health (NIH) Common Fund, through a cooperative agreement (U54 AT007748) from the Office of Strategic Coordination within the Office of the NIH Director.

The views presented here are solely the responsibility of the authors and do not necessarily represent the official views of the National Institutes of Health.
Each person randomized to “experience” and react to 1 of 24 different research scenarios.

CER Designs Tested

Pharmacotherapy

Devices Used at the Institution

(Cluster randomization)

Medical Record Review

Individual Randomization

Multiple approaches to notification and authorization tested for each design

Survey/Materials Development

Plausibility of notification/authorization materials (approx 120 pages)

Reviewed by 2 IRB members (1 chair) from 6 different institutions

Cognitive interviews to evaluate scenario descriptions and survey questions

5 rounds with 31 participants (!)

Approaches to Notification & Authorization

Written consent (with clinical risks included)

Written consent

Oral consent + Info sheet

Oral consent

General notification (with opt-out)

Post-notification after study done

Understanding

Interventions are commonly used

Interventions are randomly assigned

No extra things for research

Interventions are Commonly Used

In this imaginary research study, are both of the medicines commonly used to treat urinary tract infections (UTIs)?

1. Yes
2. No
Interventions are Randomly Assigned

If you were a participant in the research study, how would your medicine be chosen?

1. Doctor chooses
2. Doctor and I choose together
3. Randomly (like flipping a coin)
4. Unsure

No Extra Things for Research

Please answer this question as if you were a participant in this research study. Besides being examined by the doctor, undergoing any tests necessary for your clinical care, and following your prescribed treatment plan, do you recall any extra things you would have to do as part of the study?

1. Yes
2. No
3. Unsure

What types of things do you think you would have to do?

Key Findings

People have significant difficulty understanding aspects of pragmatic trials of commonly used medical practices.

Understanding
Average Correct Across Scenarios

<table>
<thead>
<tr>
<th>Interventions commonly used</th>
<th>Randomization</th>
<th>No Extra Things</th>
</tr>
</thead>
<tbody>
<tr>
<td>80%</td>
<td>45%</td>
<td>59%</td>
</tr>
</tbody>
</table>

"There will be no extra follow-up calls or visits that patients need to do related to the study."
Concluding Comments

- People seem to have significant difficulty understanding aspects of pragmatic trials of commonly used medical practices.
- This may be related to the truncated approaches to disclosure and authorization sometimes used in this setting as well as a lack of familiarity with pragmatic research.
- It will be important to assess whether similar difficulty is encountered in actual research settings.
- As normative and policy matters it will be essential to consider whether and when such misunderstandings are acceptable.