Building Public Participation in Research

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Who Am I

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Validation is Internal

"I'm already drowning in regulatory burden put in place by your predecessors. If you want me to do one more useless thing just so people like you can have jobs and publish touchy feely crap, then take away an existing regulatory burden.”

Reputation is External
Belonging Builds Solidarity

Wasn't that the definition of home? Not where you are from, but where you are wanted.
Abraham Verghese
Public involvement in primary health research

- Active involvement of end users is a key feature of quality research culture
- Many research funders require researchers to demonstrate how patients and public have been involved in design of study
- Research with public as collaborators: doing research with or by the public not ‘for’ the public
Why is public engagement important?

The Epistemological argument

Patients and members of public can bring knowledge and experimental insight to research. Hence interpretation of research results are more accurate and less distorted.

Patients are more than passive suppliers of data
Why is public engagement important?

The Ethical argument

- Tax-payers are part owners of the health care system and contribute to publicly funded research
- Public involvement empowers marginalized and disadvantaged groups
Why is public engagement important?

Effectiveness and Safety

- Public involvement has the potential to improve the quality safety and relevance of health research.
- One of the most important stages of the research process is for members of the public to be involved in research design in order to maximize research influence and impact.

[Diagram showing effectiveness and efficiency with the messages: Doing the right things and Doing things right.]
Overall goal

- Encourage integration of citizen research involvement and to enjoy working as an effective team with funders, researchers, regulators, patients and members of the public.

- To build better research and advance knowledge together as equal partners with different skills and contributions answering research question as a team.

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The **application** of what we **know already** will have a bigger impact on health and disease than any drug or technology likely to be introduced in the next decade.

*Sir Muir Gray.*
Hole in The Wall

Participatory Action Research
Research Assumptions

This counting really making us crazy!

They are 4  No.. 3
By helping the public and patients initiate and participate in health research we contribute to generating knowledge, start to redress the imbalance in the research agenda and help participants gain the confidence and competence to make informed decisions. (AJ Burls, 2015)
The Way We See Guides Movement

Good or Evil
"The Radium Water Worked Fine Until His Jaw Came Off"

Wall Street Journal 1926
The Public Helping Themselves

Problems or Possibilities?

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Innovation = Time + Money + Relationships

But when will he publish?
Failed It: Patients Not Included

- Expensive Phase 4 FDA trial
- 5157 registered
- 456 consented
- 237 after extra screening
- 18 randomized to treatment
- Statistically significant
- Clinical Value?

Web-based trial to evaluate the efficacy and safety of tolterodine ER 4 mg in participants with overactive bladder: REMOTE trial

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Keywords:
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Abstract:
Introduction: Participatory patient-centered, web-based methods could streamline and improve the convenience of clinical trial participation. We used an entirely web-based approach to conduct a randomized, placebo-controlled, Phase 4 (REMOTE) trial under an investigational New Drug (IND) application to evaluate tolterodine extended release (ER) 4 mg for overactive bladder. Method: The trial was designed to replicate previous clinic-based trials of tolterodine ER but was conducted via the web from one clinical site overseen by physicians. Participants were recruited via the web, screened for eligibility using web-based questionnaires, had laboratory testing in their community, and entered a run-in phase requiring bladder e-diaries. Informed consent was obtained using an interactive web-based method with physician countersignature. Study medication was shipped directly to participants.

Results: With a goal of 283 randomized participants, 5157 registered on the trial website. Of 456 who passed initial screening, identification verification, and signed consent, 237 passed additional medical screening and were countersigned by the investigator. After laboratory testing, 118 entered the placebo run-in; only 18 passed e-diary assessments and were randomized to treatment. At week 12, the mean change from the baseline in micturitions/24 hours (primary endpoint) was −2.4 for tolterodine ER versus −0.8 for placebo [treatment difference (95% CI): −1.6 (−3.9, 0.6)].

Conclusion: The REMOTE trial is the first entirely web-based trial conducted under an IND application. The efficacy observed was consistent with results from conventional trials. With simplification of multi-step screening and testing, web-based trials or their component parts should provide a participant-friendly approach to many clinical trials.
NAILED IT *** Patients Included

- Did Systematic Review
- Platform tested for trial
- Pilot trial feedback included
- Qualitative Prior & Post
- 250 randomized & enrolled
- 12% lost to follow up
- Statistically & Clinical significance

Internet-based treatment of stress urinary incontinence: a randomised controlled study with focus on pelvic floor muscle training

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Trial registration number http://www.clinicaltrials.gov (ID: NCT01031236)

What's known on the subject? and What does the study add?
- Stress urinary incontinence (SUI) affects 10-35% of women and is sometimes very distressing. Pelvic floor exercises are the first line of treatment, but access barriers or embarrassment may prevent women from seeking help. There is a need for new, simple, and effective ways to deliver treatment.
- Management of SUI without face-to-face contact is possible, and Internet-based treatment is a new, promising treatment alternative.

Objective
- To compare two treatment programmes for stress urinary incontinence (SUI) without face-to-face contact: one Internet-based and one sent by post.

Patients and Methods
- The study included 250 community-dwelling women aged 18-70 years, with SUI = 1 time/week. Consecutive online recruitment.
- The women had 3 months of either: (i) An Internet-based treatment programme (124 women), including e-mail support and cognitive behavioral therapy assignments or (ii) A treatment programme sent by post (126). Both programmes focused mainly on pelvic floor muscle training.
- Primary outcomes: symptom-score (International Consultation on Incontinence Questionnaire Short Form, ICQ-UI SF) and condition-specific quality of life (ICQ-Lower Urinary Tract Symptoms Quality of Life, ICQ-UUTS(QoL)). Secondary outcomes: (i) Patient Global Impression of Improvement, (ii) Incontinence aids, (iii) Patient satisfaction, (iv) Health-specific Qol. (EQ5D-Visual Analogue Scale), and (v) Incontinence episode frequency. Follow-up after 4 months via self-assessed postal questionnaires.

Conclusions
- Concerning primary outcomes, treatment effects were similar between groups whereas for secondary
Finding People

- Social media
- Advocacy/patient groups
- Universities
- Community
- Clinic
- Schools
- Word of Mouth

You don’t need a village to raise your research, a few good citizens will do

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The Reimbursement Maze
Keys For Collaboration

- Clarify roles & match tasks
- Frequent constructive feedback
- Help just enough!
- Clarify roles & match tasks
- Have fun!
- Extra Time
- Train well include fully & inform
- Listen
- Have fun!

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We Can Do This Together

Identify Prioritize Protocol Apply to Fund
Build Pilot Run Evaluate Implement
External Motivation

Choose one from Each Column


Design  Implementation  Evaluation

- Defining research questions, issues or topics
- Proposals/bids
- Assessing research outcomes
- Defining research methods/tools/approaches
- Peer recruitment
- Assessing research processes
- Choosing or developing research methods/tools/approaches
- Data collection
- Assessing the impact of service user involvement
- Deciding the purpose/objectives of user involvement in the research
- Data analysis/interpretation
- Assessing the quality of service user involvement processes
- Planning approaches/processes of service user involvement in the research
- Developing outputs
- Providing support
- Education/training
- Dissemination

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Solve a Group Problem

Part Two

10 minutes
Assumption is based on prior experience.

We assume the elephant has four legs, so we don’t see the 5th leg until we concentrate.

Could assumption blunt accuracy or bias communication in research?
"Just remember, it's a small business and a long life. You're going to see all these people again."

Richard Parsons, former chairman, Citigroup AP via Steve Ross, the former CEO of Time Warner From the 2008 HACR Roundtable
The Need

“The first thing we need is a list of those things that make people feel powerless and a set of achievable objects to start removing the barriers to people taking control of the health science process” (Dr Andy Biddulph, 2015).
Involving the Public?

Why Bother?

What if nobody wants this? Why am I really doing all this? Isn’t there something easier to do? And other questions...
“The stem cells they do not want you to have.”
Research Involvement

Tell me and I FORGET.

Teach me and I may REMEMBER.

Involve Me and I will LEARN.
Help & Training From Cochrane
Free Citizen Systematic Review
ayyan App
Tools For Research Participation
How to implement Patient Review and Navigate the BMJ Patient Involvement Statement

Authors: Amy Price, Sara Schroter, Tessa Richards, Elizabeth Loder, Sam Parker
BMJ Patient Review is NOT like this

“We want to include you in this decision without letting you affect it.”

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Objectives

Since 2014, *The BMJ has been* inviting patients to review research papers alongside traditional peer reviews. In addition, The BMJ introduced a mandatory statement for reporting patient involvement in research. We will describe potential barriers and helpful solutions for reporting patient and public involvement and we will outline the differences between what is expected for patient versus peer reviews.
Patients and members of public can bring knowledge and experimental insight to research.

- Health literacy increases with exposure.
- Interpretation of research results may be less distorted with real world end user input.

The Epistemological Argument
Patient Reviewers

• Are the study's aims and the issue and questions that the paper addresses relevant and important to you as a patient? Do you think it would be relevant to other patients like you? What about carers?

• Are there any areas that you find relevant as a patient or carer that are missing or should be highlighted?

• From your perspective as a patient, would the treatment, intervention studied, or guidance given actually work in practice? Is it feasible? What challenges might patients face that should be considered?

• Are the outcomes that are being measured in the study or described in the paper the same as the outcomes that are important to you as a patient? Are there others that should have been considered?
“The one thing I am looking for is empowerment of the patient.”

“How do we adapt the language of ‘medicine’ from formal and technical to one that can be appreciated by all?”

“It was hard to review because I was a little scared but I learned a lot and would do this again.”

“As patients we are at the bottom of the pyramid in every possible way, even though we are the heart of medicine.”

“Although I have agreed to attempt this review, I feel very strange and yet, if this conversation really heralds a change between medicine and the patient, then I shouldn’t falter. But does it?
Questions to Authors

- How was the development of the research question and outcome measures informed by patients’ priorities, experience, and preferences?
- How did you involve patients in the design of this study?
- Were patients involved in the recruitment to and conduct of the study?
- How will the results be disseminated to study participants?
- For randomised controlled trials, was the burden of the intervention assessed by patients themselves?

Have you thanked patient advisors by name in the acknowledgements as a contributor?
What your author is thinking

The BMJ WikiRecs Story

WE'RE STILL WORKING ON IT

Every beginning starts with a seed
Growing Research

1. Do you have any suggestions that might help the author(s) strengthen their paper to make it more useful for doctors to share and discuss with patients?

2. Consider the level of patient involvement in the research described, and if and how it could have been improved.

3. If there was no patient involvement we would welcome your ideas on how this could have been done.
“Medicine has been practiced formally for centuries and patients are still vulnerable, helpless and easily intimidated.”

“It is wonderful to have open access to The BMJ for a year as a thank you for doing a review.”

“I learned more about research and why methods matter, learning to review helped me to be able to tell good science from marketing in the magazine headlines and on the internet.”
Does BMJ Patient Review Work

Results:

Early feedback shows patients, authors, and editors find patient review a beneficial but challenging endeavor.

Some researchers may report initial discomfort with including and reporting patient involvement in research, however they are finding both practices can add valuable insights for putting research into practice.
Thank You

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