Examining ethical considerations with patient and public involvement in the design, conduct, analysis, and reporting of clinical trials

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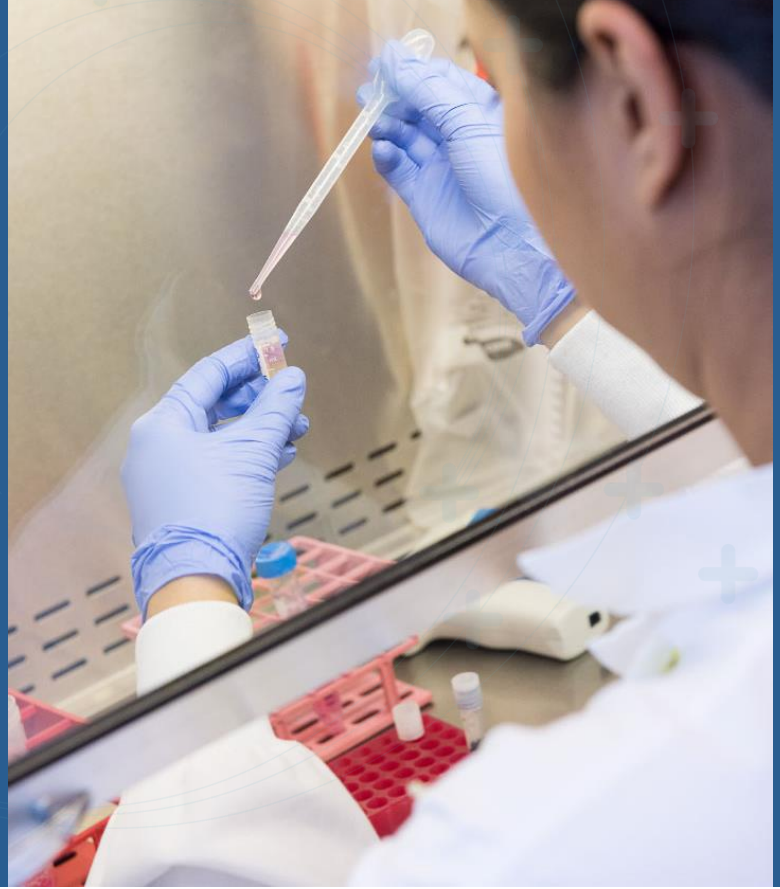

Disclosure

- No financial conflicts
- Purveyor of really bad puns

Patient and Public Involvement (PPI) in clinical trials

Medicines & Healthcare products Regulatory Agency

Government response

Consultation on legislative proposals for clinical trials

Published 21 March 2023

Ensuring patient safety was an overarching theme of the responses, and there was strong support for the legislation to **embed public involvement**. Trial participants and their safety have always been our prime consideration and our proposals reflected that this must remain the foundation for all clinical trials. We will ensure greater patient involvement in trials by introducing detailed guidance to support embedding the patient voice into the design and conduct of trials. We will work to ensure participants come from diverse backgrounds, reflecting the clinical needs across the whole population through the development of explicit guidance. We will also ensure increased public transparency about trials that are being carried out and their results.

- Lastly, we will be producing guidance on patient and public involvement, which will highlight best practice rather than legislating for this. This will give trials more flexibility, which is important because appropriate patient and public involvement is different at different stages or types of trials. Responses highlighted that legislation could be too prescriptive and add to potential delays to trial set ups, as well as cause an additional administrative burden, which ultimately may be a disincentive for trials to be carried out in the UK. However, we may consider legislating for this in the future.

TransCelerate BIOPHARMA INC.

FEATURED SOLUTION:
PATIENT PROTOCOL ENGAGEMENT TOOLKIT (P-PET)
DELIVERED BY THE PATIENT EXPERIENCE INITIATIVE

Patient input leads to study design change reducing patient burden

74 NOVARTIS

CLINICAL DEVELOPMENT PROGRAMS[2]

comprising 85 clinical trials, had a patient engagement component to obtain the patient perspective on the design and/or conduct of clinical trials.

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Evidence of involvement & impact

Ethical challenges remain

- Ethical challenges remain e.g.
  - What are the roles and responsibilities of patients and members of the public in research?
  - What boundaries, if any, should be placed around their involvement in research?
  - How can research teams involving patients and members of the public engage in research in ways that promote mutual respect and trust?
  - How can research teams ensure that engaging with patients and members of the public is not tokenistic?
- In this session, we identify and critically discuss ethical issues raised by the inclusion of patients and members of the public as partners in clinical trials and trial-related research.

Program

Dawn Richards, PhD
Director, Patient and Public Engagement, Clinical Trials Ontario

Introduction to patient engagement and patient partners' perspectives

Cory E. Goldstein, PhD
Postdoctoral Fellow, Ottawa Hospital Research Institute

Engaging patient partners in the development of ethics guidelines

Jenny Leese, PhD
Postdoctoral Fellow, Ottawa Hospital Research Institute

Engaging with patients during the conduct of pragmatic clinical trials: a relational ethics perspective

Beatriz Goulão, PhD
Advanced Research Fellow,
University of Aberdeen

Involving patients and the public in numerical aspects of trials – the PoINT programme

Kate Gillies, PhD
Professor & MRC Senior Fellow
University of Aberdeen

Reporting and sharing trials results: considerations for the involvement of patients and the public

Patient partners' perspectives on the ethics of patient engagement in clinical trials

Dawn Richards, PhD
Director, Patient and Public Engagement
Clinical Trials Ontario

May 22, 2023

Clinical Trials Ontario

10th Anniversary

Vision

Make Ontario a preferred location for global clinical trials, while maintaining the highest ethical standards.

Mission

Strengthen, promote and capitalize on Ontario's competitive advantages to conduct high-quality clinical trials.

Strategic Priorities

Streamline

Streamline processes to help make high-quality clinical trials more timely, efficient and cost-effective.

Engage

Engage with patients and the public to increase awareness, foster collaboration and improve how clinical trials are conducted.

Promote

Promote Ontario's competitive advantages and clinical trial capacities to attract more trials and industry investment to the province.

Patient Engagement (PE)

Patient is *"overarching and is inclusive of individuals with personal experience of a health issue and informal caregivers, including family and friends."*

Patient Engagement is *"about meaningful collaboration. Patients become patient partners in the project and can be actively engaged in governance, priority setting, developing the research questions, and even performing certain parts of the research."*

Patient Engagement will be used interchangeably with **Patient and Public Involvement (PPI)**

https://cihr-irsc.gc.ca/e/45851.html

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Patient Engagement (PE) in clinical trials has:

Potential benefits

- ✓ Identify core outcomes and domains (e.g. fatigue in arthritis)
- ✓ Improved tailoring and delivery of interventions (minimal burdens to participants)
- ✓ Improved enrollment and retention
- ✓ Help in dissemination (e.g. meaningful and understandable)
- ✓ Everyone learns and grows together

Potential risks

- ⚠ Frustration – research takes a long time
- ⚠ Suggestions not always feasible
- ⚠ Resources required
- ⚠ Tokenism is possible
- ⚠ Re-living painful and traumatic experiences
- ⚠ No single 'protocol'

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- Forsythe LP, Carman KL, Szydlowski V, Fayish L, Davidson L, Hickam DH, et al. Patient Engagement In Research: Early Findings From The Patient-Centered Outcomes Research Institute. Health Aff (Millwood). 2019;38(3):359-67.

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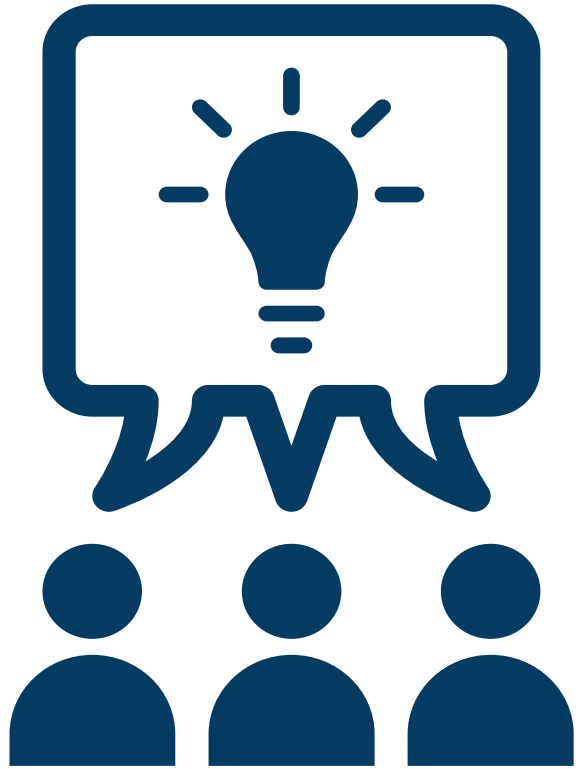
The ethics of PE in clinical trials

These thoughts come from members of CTO's College of Lived Experience:

- Individuals who reflect the diversity of patients and public who are interested in clinical trials in Ontario
- Provide input and thoughts to CTO projects and is available to our community
- Not disease or condition specific and is large enough that members can decide which projects to participate in



Donna Lillie | Maureen Smith | Mike Lapenna

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Patient partner roles on clinical trial teams

Clarity and training

- Training is important
- “Is governance ‘our job’ in clinical trials – especially when it comes to data? “

- Clear about role and expectations – provide options of potential roles and tasks associated with them
- Right patient partner for the role

Schoemaker CG, Richards DP, de Wit M. Matching researchers’ needs and patients’ contributions: practical tips for meaningful patient engagement from the field of rheumatology. Annals of the Rheumatic Diseases. Online 5 January 2023. doi: 10.1136/ard-2022-223561

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Fostering mutual respect and trust is important

…and some ways to do this:

- Clear communications
- Transparency about what is feasible, what is not, what can change and what is set
- Meeting the team members before making a final commitment
- Avoid tokenism

Tokenism is "*when researchers include a patient voice in their project, but mostly ignore it.*"

Here are some strategies to avoid it:

- Provide a "what we heard"
- Show how input is used, ensure it happens
- Structure meetings so everyone can participate (e.g. at start or end and having dedicated 'go round')

Ethics Guidance for Developing Partnerships with Patients and Researchers - https://cihr-irsc.gc.ca/e/51910.html

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Re-living health experiences for the sake of research

Patient partners can't always predict or know if/when they may be 'triggered'

- Teams should:
  - Understand patient partners' motivations and areas that are very personal to them (...and that they may or may not be able/willing to contribute in these areas)
  - Avoid (as much as possible) potentially triggering situations: give people lots of time to prepare, provide all meeting materials in advance, provide choice about participation (how and if)
  - Learn about how to be trauma informed

Other thoughts

- Is it ethical to engage patient partners and not use their input?
- There is a moral obligation to engaging patient partners
- Training that is built for researchers should be adapted for patient partners

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Some tools to help - co-created with patient partners

Decision aids for engaging patients as partners on clinical trial teams

- Self-guided decision aid
- Interactive
- Lots of basic info on clinical trials, research, PE
- English only (French translation underway)

A How-to Guide to engaging patients as partners on research teams

- 4 interactive, self-paced learning modules
- Lots of basic info on research, the research process, PE
- English and French (narration on/off)
- Completion certificates

CIHR IRSC
Institute of Musculoskeletal Health and Arthritis
Institut de l'appareil locomoteur et de l'arthrite

https://www.ctontario.ca/patients-public/resources-for-engaging-patients/decision-aids-for-patient-partner-engagement-with-clinical-trials/
https://cihr-irsc.gc.ca/e/27297.html#a2

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Thank you!

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Thank you to Michael Lapenna, Donna Lillie and Maureen Smith

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Engaging patient partners in the development of ethics guidelines

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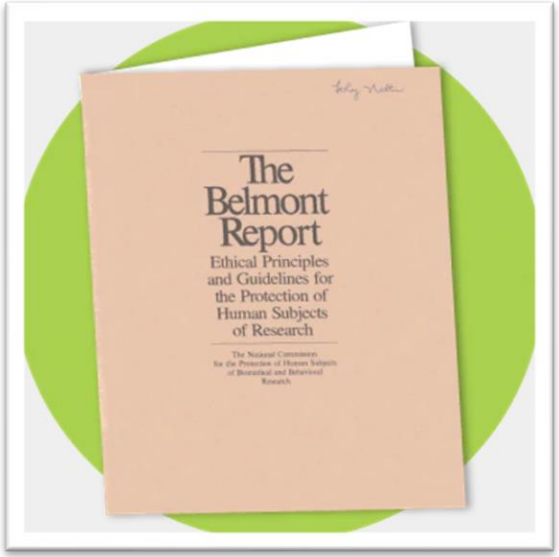
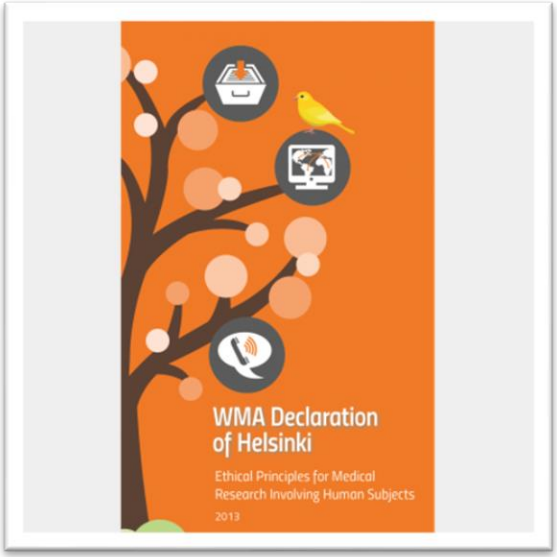
Disclosure

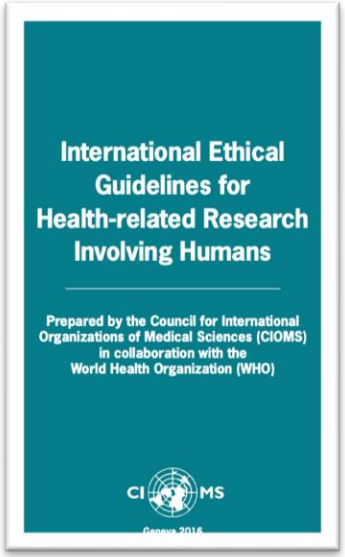
No conflicts of interest to disclose.

Ethics guidelines: documents that provide recommendations for how to conduct research in a way that protects the **rights and welfare of participants**

International ethics guidelines outlining ethics principles and recommendations







CIOMS International Ethics Guidelines

Working group

- 7 profs of bioethics, medical ethics, philosophy
- 2 MDs with experience/degree in bioethics
- 1 government health advisor
- 1 researcher with experience in bioethics
- 1 health writer/reporter and health provider educator

Advisors

- 1 prof of medical ethics
- 3 MDs with experience in bioethics and epidemiology
- 1 researcher with experience/degree in bioethics

Observer

- 1 bioethicist PHD/LLM

"All members of the Working Group were internationally recognized for their expertise in research."

"The composition of the Working Group ensured that different cultural perspectives were present, members varied in experience and expertise, and gender balance was achieved."

"**One of the members represented the perspective of research participants**."

Patient engagement in research

Clinical trials

- Assist in the design and conduct of trials.
- Improve participant enrollment and retention, delivery and adherence to interventions, and selection of outcomes.
- Frameworks and toolkits exist to guide best-practices for engagement.

Clinical guidelines

- Lived experience with a particular disease/illness.
- Empowers and informs consumers' decisions.
- More patient-centered trustworthy guidelines
- Numerous organizations recommend or require patient engagement.

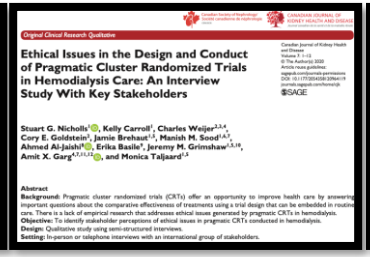
Ethics guidelines

Co-developing ethics guidance

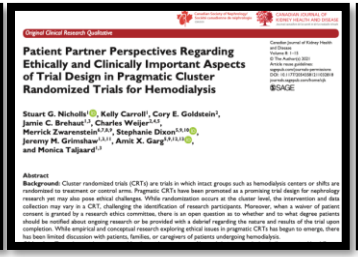

Trials

REVIEW Open Access

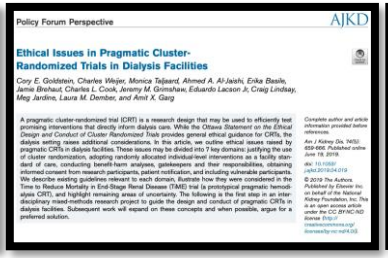
Reporting of key methodological and ethical aspects of cluster trials in hemodialysis require improvement: a systematic review


Original Clinical Research Qualitative

Ethical Issues in the Design and Conduct of Pragmatic Cluster Randomized Trials in Hemodialysis Care: An Interview Study With Key Stakeholders


Original Clinical Research Qualitative

Patient Partner Perspectives Regarding Ethically and Clinically Important Aspects of Trial Design in Pragmatic Cluster Randomized Trials for Hemodialysis


Policy Forum Perspective

AJKD

Ethical Issues in Pragmatic Cluster-Randomized Trials in Dialysis Facilities


Western Graduate&PostdoctoralStudies

Western University Scholarship@Western

Electronic Thesis and Dissertation Repository

3-30-2022 9:00 AM

A Critical Examination of Informed Consent Approaches in Pragmatic Cluster-Randomized Trials

Cory E. Goldstein, *The University of Western Ontario*

Supervisor: Weijer, Charles, *The University of Western Ontario*

A thesis submitted in partial fulfillment of the requirements for the Doctor of Philosophy degree in Philosophy

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Systematic review | Stakeholder interview | Patient partner interview & focus group | Identification of issues | Analysis of issues

Patient advisory group

Background information

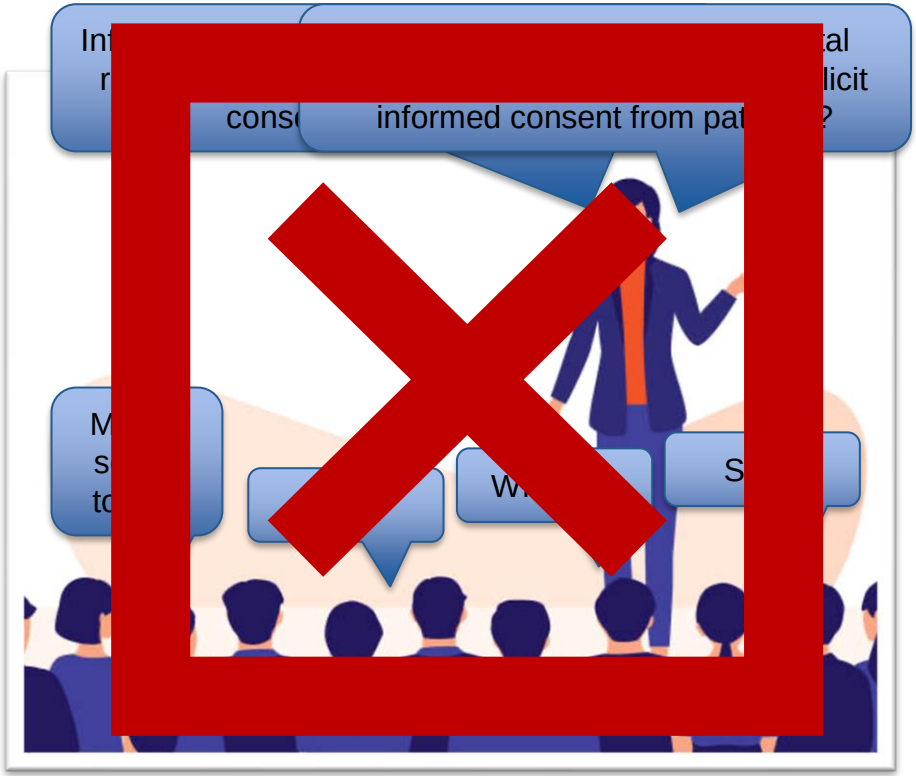
Brief presentation (~10 min)

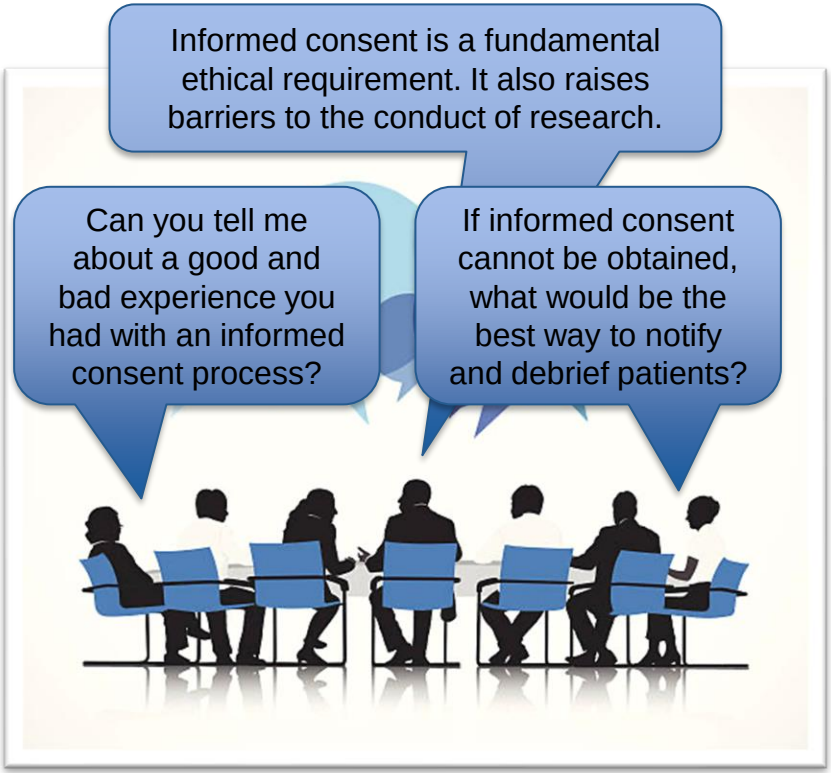
Discussion (~75 min)

Wrap up and next steps (~5 min)

Working group

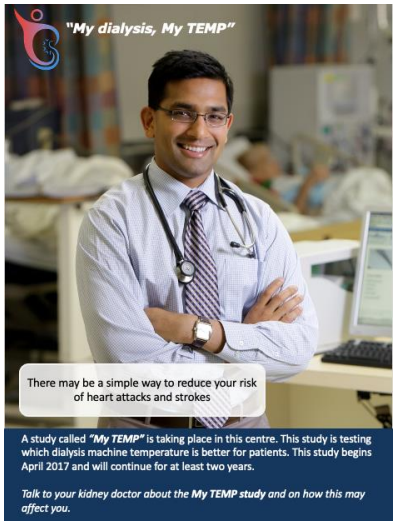
Patient advisory group discussions





How stories influence guidance

Recommendation: patients should be notified of ongoing research when informed consent is not being solicited.



Belief that posters are an excellent mechanism for notifying patients; in front of weight scales.

Patients are more concerned about their weight than the information on posters.

Patients often ignore posters on notice boards.

Prefer written communication.

Lessons learned

Patient advisors are integral to ethics guideline development.

Providing materials in advance of the meeting was useful for keeping discussions on topic.

Providing a brief overview and having three questions helped structure discussions.

A dedicated expert ensures ample and equal chances to share stories and ideas.

Difficult to solicit feedback on complex or unfamiliar issues.

Engaging patient advisors outside of meetings was difficult.

Who should be engaged in the development of ethics guidelines?

There is much room for improvement for patient partner engagement in the development of ethics guidelines.

Engaging patient partners in the development of ethics guidelines

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Engaging with patients during the conduct of pragmatic clinical trials: A relational ethics perspective

Jenny Leese, PhD
Postdoctoral Fellow
School of Epidemiology & Public Health
University of Ottawa
Ottawa Hospital Research Institute

May 22nd, 2023

Disclosures

- No Relevant Disclosures

What is relational ethics?

- Builds on traditional principles of bioethics
  - Autonomy (respect for a person's ability to make their own choices)
  - Beneficence (the principle of doing good to others and avoiding doing them harm)
  - Justice (the principle of fairness)
- Expands ethical considerations beyond arena of REB scrutiny
- Refers to day-to-day ethical issues that may not appear to be of great consequence from a traditional standpoint of bioethics
- Supports careful consideration of the ethical significance of our relationships
  - Is that how I *should* treat someone else? Is that how someone else *should* treat me?

Beauchamp and Childress, 2004; Bergum, 2005; Austin, 2001; Ellis, 2007

Why draw on a relational ethics lens?

- Fostering good relationships is considered a key component of practicing meaningful PPI
- Raises issues that are relational and ethical in nature
  - Spending time to nurture **reciprocity, mutual respect and trust**
  - **Power imbalances and tokenistic engagement**
- A small number of studies specifically address ethical issues associated with patient partnership in healthcare research

Staniszewska, 2018; Shippee, 2013; Richards, 2023; Kirwan, 2017; Sibbald, 2014; Leese 2021; Hahn, 2017; Curry, 2022; Martineau, 2020

Our Focus

- **Draw on a relational ethics lens to better understand experiences of relationships between PPI partners* and researchers engaging in pragmatic clinical trials**

*a member of the public, patient, user of health and social care services and/or caregiver (including family and friends) involved in all or any part(s) of the research process, including the choice of research topic, design, planning, conduct, and/or dissemination.

Qualitative Approach

- One online, semi-structured interview (approx. 60 mins) – *ongoing*
  - Purposively sampling researchers who self-reported PPI in a pragmatic trial
  - Requesting researchers to invite 1-2 PPI partners
- Simultaneous reflexive thematic analysis drawing on a relational ethics lens
- Engaging with PPI partners

Braun & Clark, 2022, 2019

Participant characteristics

- 13 researchers (7 women; 6 men); 77% white; residing in Europe (54%), North America (38%), and Africa (8%)
- 25% reported engaging with PPI partners in LMICs
- Between 2-250 PPI partners involved from pre-protocol stage, protocol development stage, or trial conduct stage
- 3 PPI partners (2 men; 1 trans-woman); 100% white; residing in North America (67%) and Europe (33%)

3 Main Themes

1. Respecting relational autonomy
2. Attending to relational solidarity
3. Gaining trust

1. Respecting relational autonomy

- *"**[a PPI partner] was intimidated by others** on the steering committee […] she would reach out to me separately after the committee and express what she wasn't so comfortable in saying… she was as equal a voting member and we weren't gonna let her get steamrolled". [P10]*

2. Attending to relational solidarity

- *"[PPI partners] are giving their time and* ***there's a responsibility on researchers to make sure that they get some reward****… [PPI partners] are not necessarily in employment… you want to make sure they get expenses back quickly". [P8]*

3. Gaining trust

- *"there are groups who have very little trust in the health system… **building trust takes time.** You can't do that overnight. […] [PPI partners] trusted each other and trusted it was worth being involved because it might make a difference [P8]*

- *the orthodox medical practice people felt like you can't delegate responsibilities to a [PPI partner]. And we are coming up with an argument that **we can trust them** [P1]*

Implications

- Tentative findings suggest emerging issues of relational autonomy, relational solidarity and trust, based on experiences of researchers.
- Better understanding of these issues may help to better support researchers and PPI partners to foster good relationships.
- Valuable step in supporting ethically-aware practices of PPI in pragmatic clinical trials.

Acknowledgments

- Study Participants
- Monica Taljaard, Senior Scientist, Clinical Epidemiology Program, Ottawa Hospital Research Institute
- Stuart Nicholls, Senior Clinical Research Associate, Ottawa Hospital Research Institute
- Ian Graham, Professor, School of Epidemiology & Public Health, University of Ottawa
- Kelly Carroll, Research Coordinator, Ottawa Hospital Research Institute
- Linda Rowan, PPI partner

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THANK YOU !

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HSRU
Promoting Excellence in Health Services Research

Involving patients and the public in numerical aspects of trials – the PoINT research programme

Beatriz Goulao, PhD

Advanced Research Fellow

Chief Investigator of the PoINT programme

HSRU is core funded by the Chief Scientist Office of the Scottish Government Health and Social Care Directorates. The author accepts full responsibility for this talk.

CHIEF SCIENTIST OFFICE

1495 UNIVERSITY OF ABERDEEN

Disclosure

HSRU

- No relevant disclosures

Background

- Patient and Public Involvement (PPI) in trials increased over the years, but quality varies a lot and tokenism remains an issue
- Statistics and numerical aspects (e.g. what is an important treatment difference, interpretation of trial results, handling of missing data) underpin how trials are conducted and, more importantly, what trial results actually mean
- However, public partners are rarely involved in numerical aspects of trials

Is that good enough?

HSRU

"I have heart disease and there is a cardiology trial running at the moment that I could be a participant on and I've chosen not to because the primary outcome is an extra 30 seconds on a treadmill and that difference is…

completely meaningless to me.

So why should I take a medication and put myself at all the risks of side effects …for an extra 30 seconds on a treadmill?"

- Public partner at the PoINT consensus meeting

Experiences & expectations of PPI in numerical aspects from public partners' perspective

Goulao *et al. Trials* (2021) 22:499
https://doi.org/10.1186/s13063-021-05451-x

Trials

RESEARCH Open Access

Patient and public involvement in numerical aspects of trials (PoINT): exploring patient and public partners experiences and identifying stakeholder priorities

Beatriz Goulao*, Hanne Bruhn, Marion Campbell, Craig Ramsay and Katie Gillies

Abstract

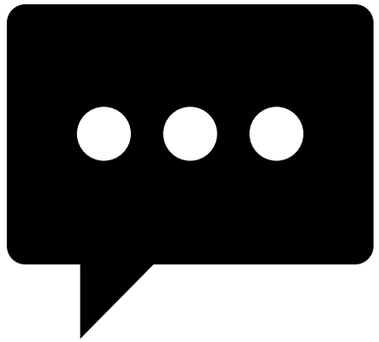
Background and aims: Patient and public involvement is increasingly common in trials, but its quality remains variable in a lot of settings. Many key decisions in trials involve numbers, but patients are rarely involved in those discussions. We aimed to understand patient and public partners' experiences and opinions regarding their involvement in numerical aspects of research and discuss and identify priorities, according to multiple stakeholders, around the most important numerical aspects in trials to involve patients and the public in.

Methods: The study had two stages: (1) online focus groups with patient and public partners recruited via online platforms and analysed using inductive thematic analysis and (2) online priority setting meeting with UK- and Ireland-based stakeholders and following James Lind Alliance methodology. Pre-selected numerical aspects were introduced prior to the meeting and discussed and prioritised based on a voting system.

Results: In stage 1, we held two focus groups with patient and public partners (n = 9). We identified four themes in the analysis: "Determinants of PPI in numerical aspects", "Identity and roles", "Impact of involving patients and the public in numerical aspects". Patient and public partners believed being involved in numerical aspects of research is important and should be facilitated, but communication about these aspects needs to be clearer. An environment

- Stage 1: 2 UK-based focus groups with public partners to discuss experiences and interest in involvement in numerical aspects of research
- Public partners defined as people with previous experience of being involved in research

Themes - Public partner's experiences & expectations



Confidence to ask about numbers

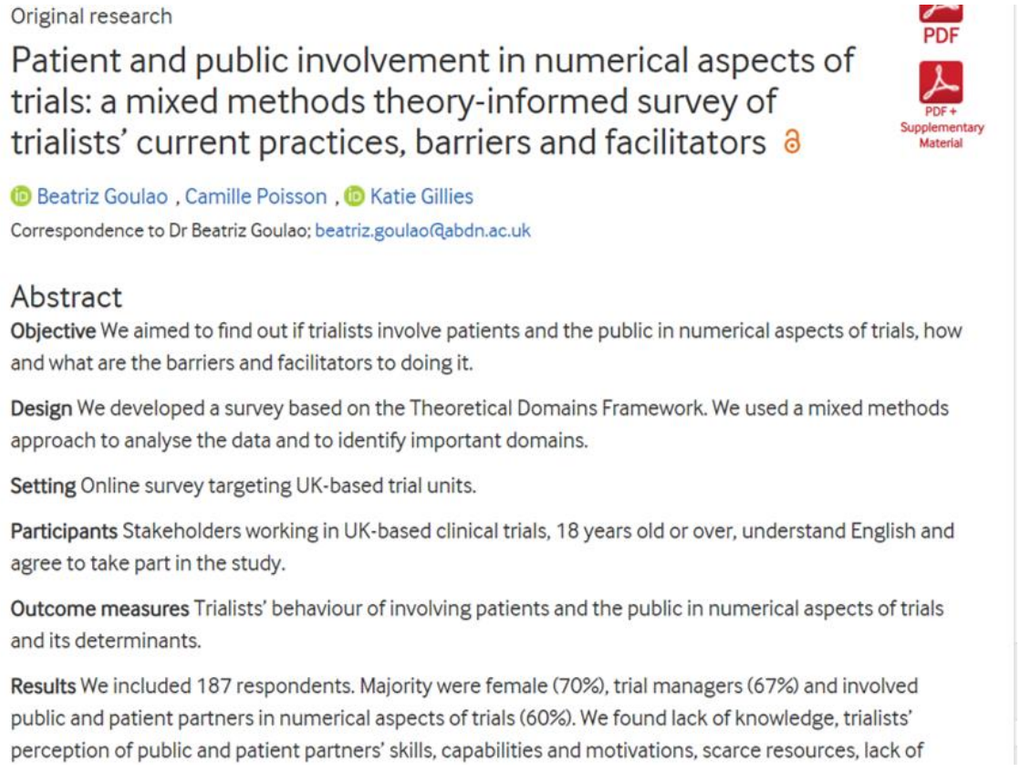
"But I'd like to learn a bit more, so I could ask questions and start to be more effective in this kind of setting…
I sense that the clinicians aren't that confident either and they just get in a statistician as soon as they get to the numbers bit."

Role & impact on public partners

"I think if I'm getting to improve or getting better at writing lay summaries, then I … have to be able to understand the numerical aspects of the initial document … and then produce something which is understandable without taking away from the meaning of the stats. [It is] about understanding that journey … and if you just provide the data without facilitating the understanding, then you just have numbers."

What about trialists' perspectives?

- Survey 187 respondents (trialists in the UK)
- Used a theory-based approach to identify barriers and facilitators to PPI in numerical aspects of trials
- What influenced the decision to involve public partners in numerical aspects?
  - Knowledge
  - Skills and beliefs about capabilities (of partners)
  - Beliefs about consequences
  - Social and professional role



Original research

Patient and public involvement in numerical aspects of trials: a mixed methods theory-informed survey of trialists' current practices, barriers and facilitators

PDF

PDF + Supplementary Material

Beatriz Goulao , Camille Poisson , Katie Gillies

Correspondence to Dr Beatriz Goulao; beatriz.goulao@abdn.ac.uk

Abstract

Objective We aimed to find out if trialists involve patients and the public in numerical aspects of trials, how and what are the barriers and facilitators to doing it.

Design We developed a survey based on the Theoretical Domains Framework. We used a mixed methods approach to analyse the data and to identify important domains.

Setting Online survey targeting UK-based trial units.

Participants Stakeholders working in UK-based clinical trials, 18 years old or over, understand English and agree to take part in the study.

Outcome measures Trialists' behaviour of involving patients and the public in numerical aspects of trials and its determinants.

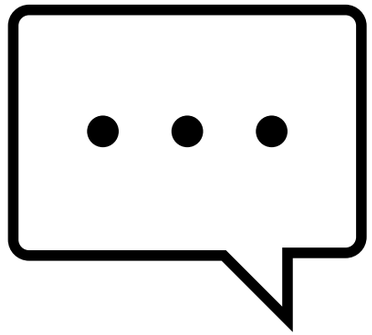
Results We included 187 respondents. Majority were female (70%), trial managers (67%) and involved public and patient partners in numerical aspects of trials (60%). We found lack of knowledge, trialists' perception of public and patient partners' skills, capabilities and motivations, scarce resources, lack of

Themes – trialists' experience

Beliefs about capabilities (of public partners)

"It generally is quite boring for the general public and they do need a basic level of numeracy and appreciation of research methods." (Statistician)

"Often numerical aspects are dictated by statistical programs and I think there is a general feeling that patient or public partners cannot grasp them." (Trial manager)



Social & professional role

[A barrier to involving public and patient partners in numerical aspects of trials is…] "It is not spoken about much and does not always relate directly to job roles." (Statistician)

Beliefs about consequences

"Discussing numerical information with patients helps to distill complex findings into something more simple and acceptable. This helps the researcher to clearly think through what are the results, helps explain information clearly that improves the quality of the trial and will ultimately all benefit the patient." (Trial manager)

Discussion

- **Communication challenges that perpetuate power imbalances**
  - Training who?
- **Roles in PPI in numerical aspects of researcl**
  - Who is responsible to facilitate it?
  - What role do patient or public partners play?
- **What benefits/impact should we look for?**
  - Often focus on impact to numbers or research quality, less on the impact to partners, researchers, partnership and broader societal impact (i.e. increasing patients' and public's data literacy)

Next steps

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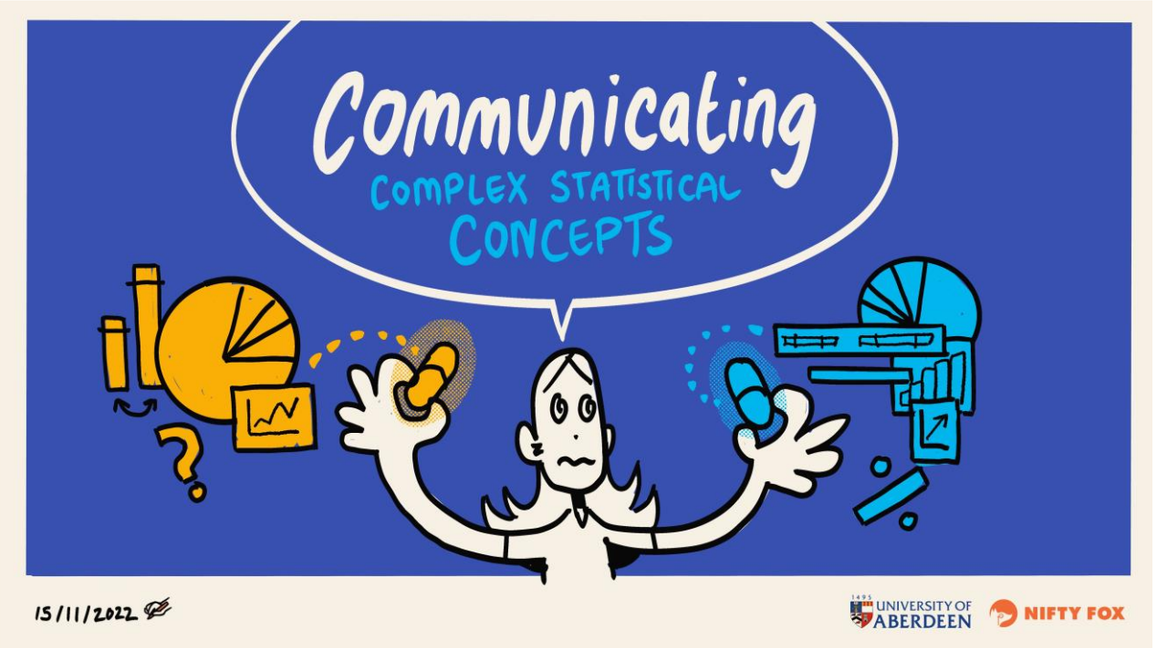
- Improving communication: creative workshops to improve communication of statistics in PPI



- **PINpoINT**: tackling number 1 priority for PPI in numerical aspects - target differences
  - https://www.abdn.ac.uk/hsru/what-we-do/research/projects/pinpoint-348

MRC Medical Research Council

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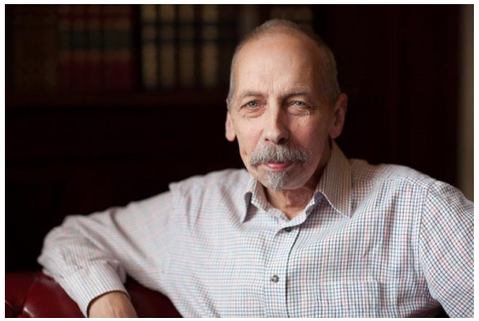

Thank you!

If you would like to discuss further:

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Reporting and sharing trials results: considerations for the involvement of patients and the public

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Disclosures

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The audience

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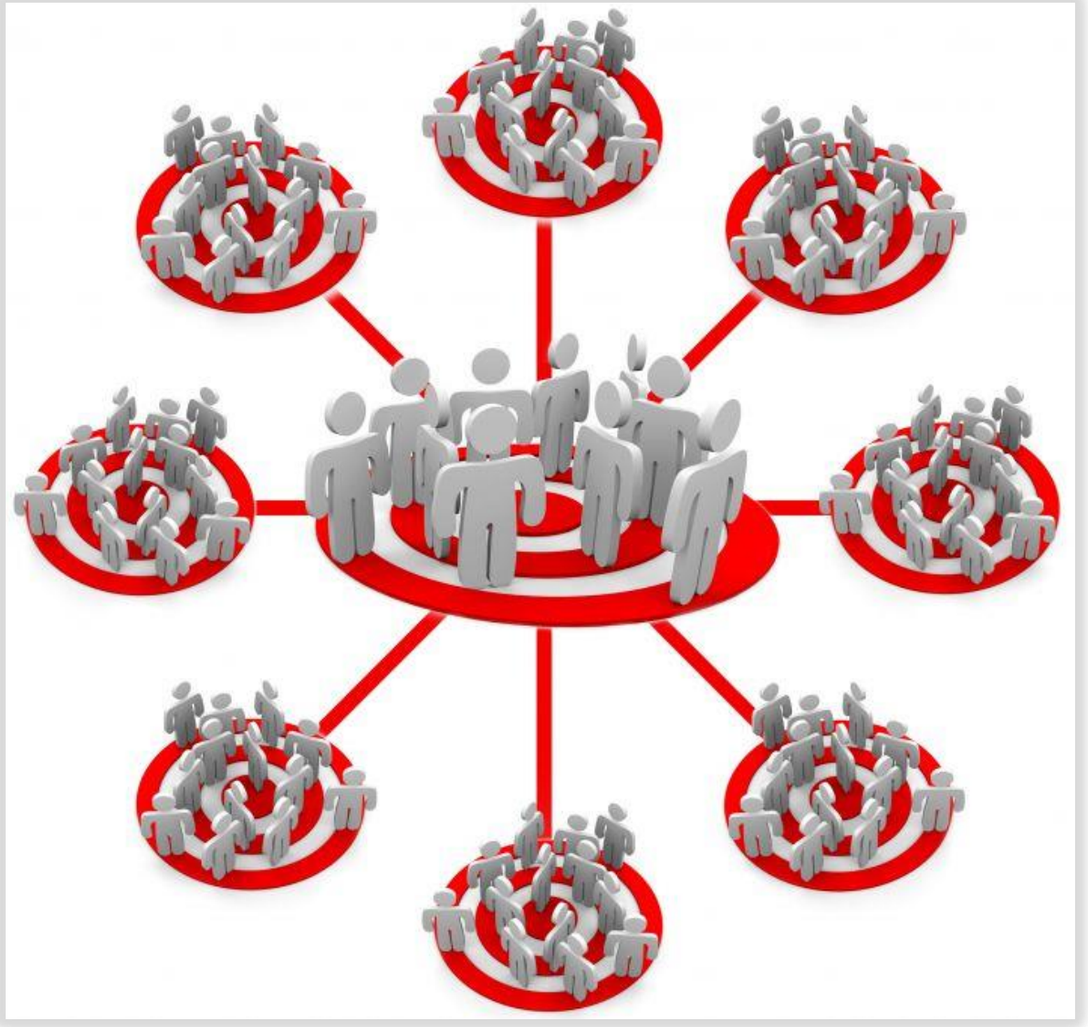
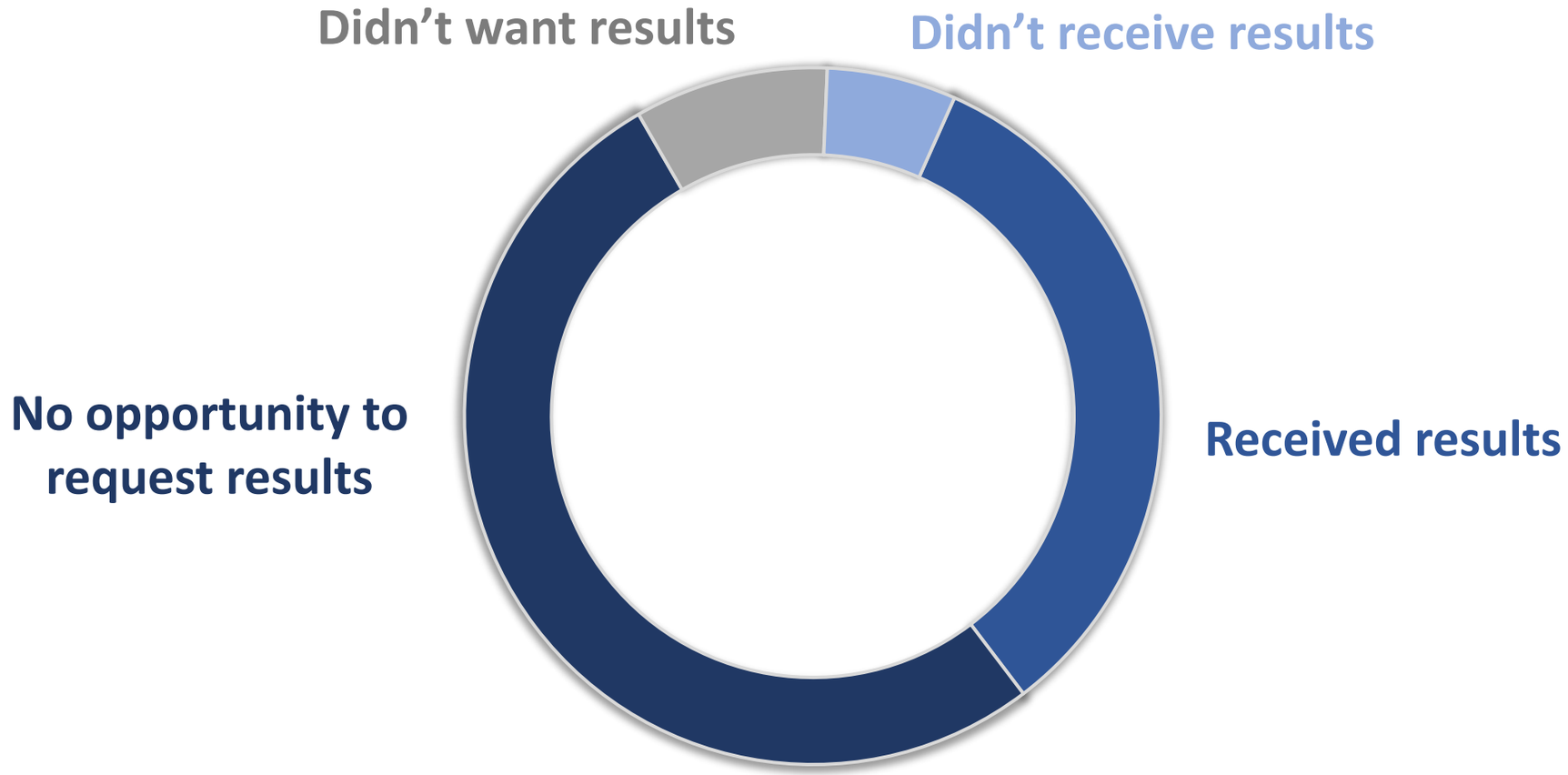


Receiving results



Current practice - audit

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Open access Original research

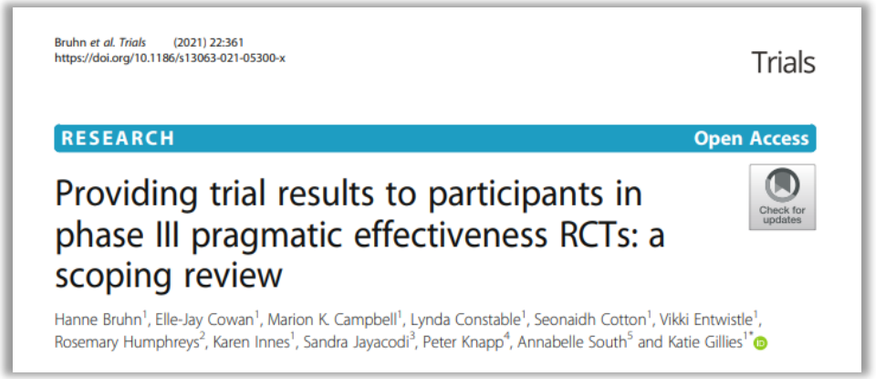
BMJ Open Dissemination of trial results to participants in phase III pragmatic clinical trials: an audit of trial investigators intentions

M Zulfiqar Raza, Hanne Bruhn, Katie Gillies

Trial stage	Intention to disseminate results to participants (n=381)	No intention to disseminate results to participants (n=42)
Design	180 (47%)	16 (38%)
Management	121 (32%)	6 (14%)
Undertaking	123 (32%)	28 (67%)
Analysis	17 (5%)	2 (5%)
Dissemination	227 (60%)	11 (26%)

*Totals for % are greater than 100 as categories are not mutually exclusive and research teams could report PPI across several aspects of the research.

Current practice - review



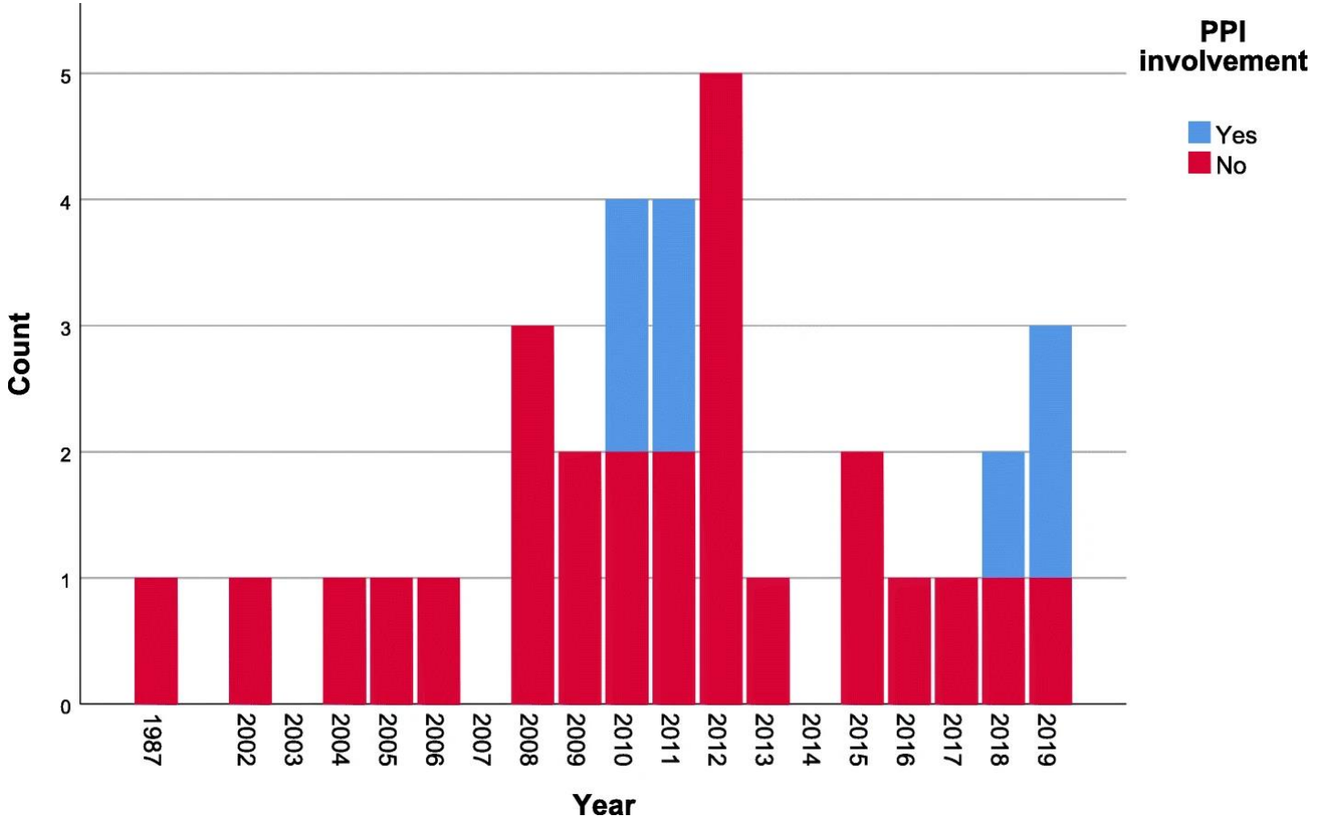
Bruhn *et al. Trials* (2021) 22:361
https://doi.org/10.1186/s13063-021-05300-x

Trials

RESEARCH Open Access

Providing trial results to participants in phase III pragmatic effectiveness RCTs: a scoping review

Hanne Bruhn[1], Elle-Jay Cowan[1], Marion K. Campbell[1], Lynda Constable[1], Seonaidh Cotton[1], Vikki Entwistle[1], Rosemary Humphreys[2], Karen Innes[1], Sandra Jayacodi[3], Peter Knapp[4], Annabelle South[5] and Katie Gillies[1*]



What information to include

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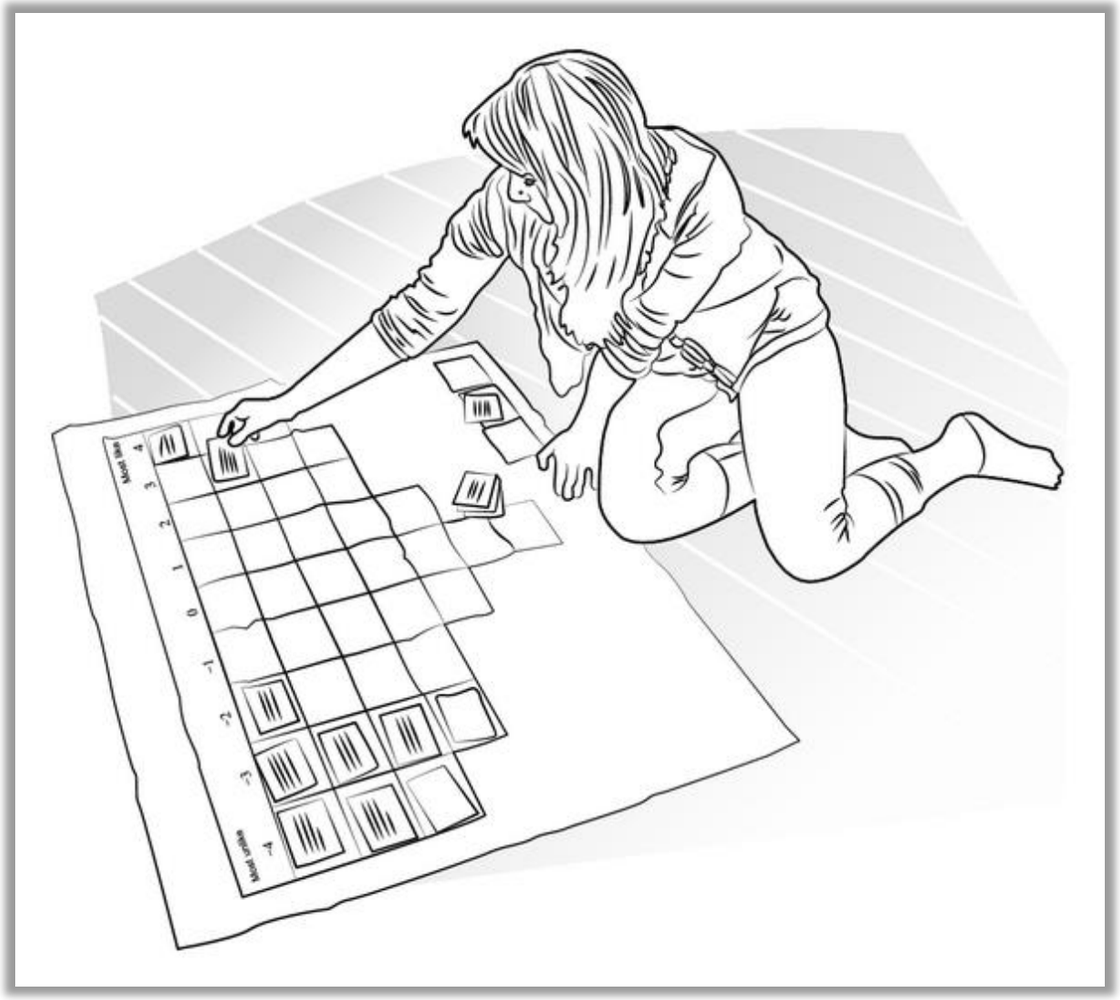

How should results be shared?

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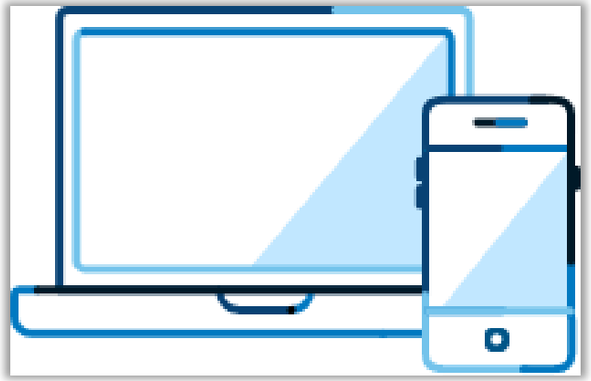
The NEW ENGLAND JOURNAL of MEDICINE



- Social media
- Videos
- Telephone
- Face-to-face

When should results be shared?

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PP1…you can't give a patient a result as soon as they finish, and that should be fully transparent at the beginning that you're going to **get the results when everyone has finished**. Whether that's five years, ten years, whatever it is.

PP2–……you should acknowledge your participation and say, "We anticipate **the final patient completing** in 20 months' time," and then you should write to them again and say, "Everyone has finished, we're now back towards analysis," then **say when the analysis is complete**, so you have constant information'.

you've got to consider that **not everybody manages to complete a trial.** That might not be because of an adverse effect, that might be because something else happens and they **have to withdraw**. They could be really disappointed that they've had to withdraw, but they would **still be really interested in knowing when it's complete, when the analysis is being done, when the findings available**.

*'a friend of mine who took part in a parenting project with an autistic child and she was in a control group, she knew. And **the first she knew of the results was when she read it in the daily paper** in one of the papers, which said, 'super parenting aid for autism'. So, **you can imagine how that made her feel and she hadn't had any results. '***

Who should share results?

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*'A **peer support group**. Yes. I know that comes up with sorts of **problems with confidentiality** and god knows what else, but **people are really keen** on… I never thought about it, but I thought, yes, it might answer some of the questions and also make us all **feel part of it**'*

Key considerations

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✓ Involve patient partners

- ✓ Proactive
- ✓ Consider
- ✓ If results
- ✓ How to d
- ✓ **Mode of**
- ✓ Consider
- ✓ Consider
- ✓ **Training**
- ✓ Funders/

Wider dissemination

- ➢ Consider role in sharing through communities
  - Speaking at advocacy groups/conferences
  - Supported to interface with media
- ➢ Co-authoring papers/policy briefing/funder reports
- ➢ Lay peer review

Final thought……..

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RECAP
reporting clinical trial results appropriately to participants

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