

Advancing Justice and Equity in Pragmatic Clinical Trials

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Justice and equity in pragmatic clinical trials: Considerations for pain research within integrated health systems

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Achieving Health Equity in Embedded Pragmatic Trials for People Living with Dementia and Their Family Caregivers

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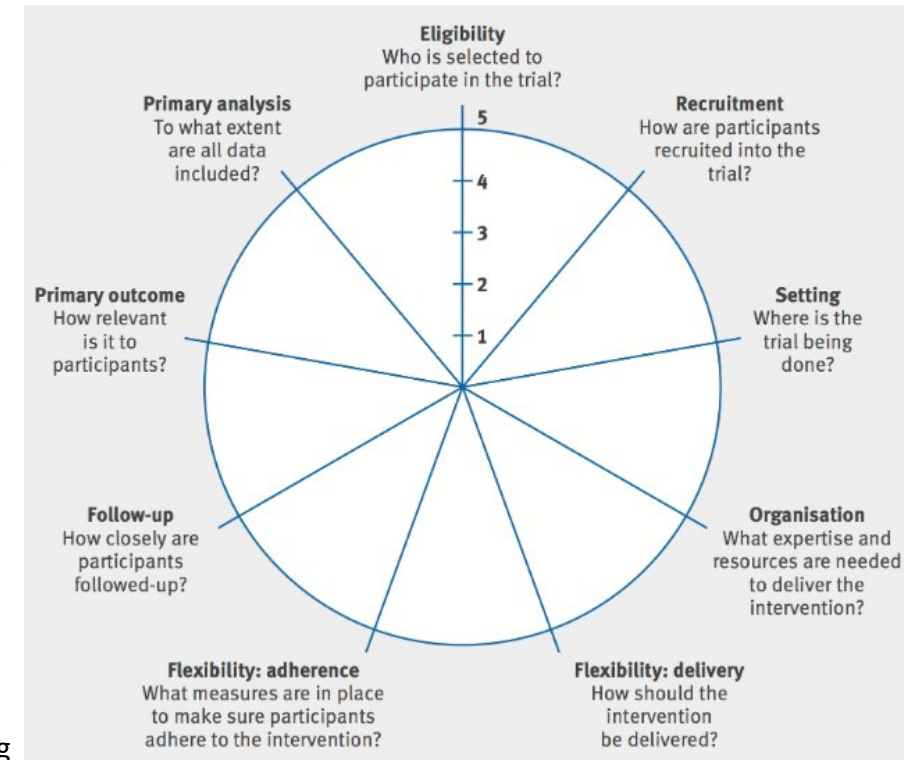
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Pragmatic clinical trials: an inclusive ethos?

- “Pragmatic trials generally include patients who are representative of the diversity of patients who would receive the intervention in clinical care and across broader healthcare delivery systems than the traditional explanatory trial designs.”¹
- “Modern pragmatic trials, on the other hand, contain intentionally inclusive eligibility criteria and overtly eliminate barriers to enrollment, and thus generate results with broad applicability.”²

1. Davies-Teye BB, Medeiros M, Chauhan C, Baquet CR, Mullins CD. Pragmatic patient engagement in designing pragmatic oncology clinical trials. *Future Oncology*. 2021 Jul;17(28):3691-704.

2. Grant MJ, Goldberg SB. Precise, pragmatic and inclusive: the modern era of oncology clinical trials. *Nature Medicine*. 2023 Jul 31:1-2.



Belmont Report (1978/9)

- **Principle of Justice**

- Fair distribution of the benefits and burdens of research
 - Fair procedures and outcomes in the selection of research participants
- “An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.”
- Focus was on *distributive justice* and *avoiding exploitation* in research

NOTE: Belmont also sought to conceptually distinguish “research” from “practice,” in effect reinforcing the separation of normative governance across these two spheres

Meeting justice obligations through integrative research approaches?

“Duties to contribute to a just health care system provide a basic moral justification for integrating learning into practice. At the same time, we need to facilitate research-practice integration in less than just contexts in order to provide the knowledge base necessary for the system to become more just.”

Might we have a moral obligation to blur the research-practice distinction, and to do so in “less than just contexts”?

Faden RR, Beauchamp TL, Kass NE. Learning Health Care Systems and Justice. Hastings Center Report. The Hastings Center. July-August 2011 41(4).

Further considerations: structural injustice

- Where aspects of clinical research are flexibly embedded in practice settings (e.g., PCTs) to advance integrated learning health systems...

Justice can be understood as:

- Ensuring fair distribution of the benefits and burdens of research (Belmont)

and

- ***Paying attention to structural inequities and injustices*** in health/healthcare that readily transfer to (embedded) health research

Framing concepts in a PCT context

- In pragmatic research, ***inequity*** results from unfair distribution or realization of benefits and burdens of the research that stem from social conditions and/or structural characteristics of the healthcare systems where PCTs are conducted.
- Inequities can be described as a form of ***injustice***, especially if they arise from the inadvertent neglect of a basic moral, legal, or human right—or from overt or systemic discrimination.

Ali J, Davis AF, Burgess DJ, Rhon DI, Vining R, Young-McCaughan S, Green S, Kerns RD. Justice and equity in pragmatic clinical trials: Considerations for pain research within integrated health systems. *Learning Health Systems*. 2022 Apr;6(2):e10291.

NPTs for pain management: an opportunity and challenge

- Dynamic interaction of factors within and across the biological, psychological and social domains of pain
- Experiences under any one domain (e.g., history of racial or sexual harassment and discrimination) can have broad biological, psychological, and social effects
- Non-pharmacological treatments (NPTs) for pain often seek to address pain in an integrated way, acknowledging its multiple influences
- Negative experiences with health systems can interfere with some groups' participation in pain PCTs, the delivery of NPTs, and pain recovery

Key messages (so far)

- We need refreshed engagement with the principle of *justice* in health research
- Structural and sociocultural challenges that exist within health systems can be barriers to inclusive pragmatic research
- Some individuals with chronic pain are vulnerable to injustice
- PCTs involving NPTs provide one lens through which injustices may be identified and addressed with the input of a broad range of stakeholders

Challenges & Recommendations

SELECTED EXAMPLES

Study Context & Design

- Example Challenge:
 - Potential for biases, prejudices, and inequities to transfer from health systems to PCTs
- Example Mitigation Strategies:
 - Understand, prospectively, community attitudes and beliefs regarding a health system and how these might transfer to aspects of trial implementation
 - Develop, share, and enforce standards for equity and inclusion across the study team and for supporting personnel
 - Develop and employ innovative tools to prioritize equity on a routine basis across a health system (e.g., electronic reminders about common health inequities that affect medical treatment)

Participant Recruitment and Retention

- Example Challenge:
 - Limited participation of some individuals and groups due to diversity-insensitive recruitment approaches and materials
- Example Mitigation Strategies:
 - Identify potential barriers to trial participation prospectively, including through patient questionnaires designed for this purpose
 - Create and include patient engagement groups as part of the research team who can review and offer feedback on recruitment methods and materials
 - Include within recruitment materials culturally sensitive and specific images and language that include populations experiencing lower access to care or other known disparities within the study's health system

Study Interventions



- Example Challenge:
 - Interventions that do not align well with contextual needs or strong preferences of certain patient populations
- Example Mitigation Strategies:
 - Identify multiple strategies (e.g., individual and group-delivered interventions; condensed treatment schedules; multi-lingual therapy) to facilitate intervention delivery for different types of patient populations.

Stakeholder Engagement

- Example Challenge:
 - Limited racial, ethnic, and ability diversity among providers, investigators, and study staff
- Example Mitigation Strategies:
 - Use known strategies to attract and engage investigators from underrepresented groups
 - Engage with diverse patient groups who can review and offer feedback on study design and implementation choices
 - Invite patients who represent a study population formally to be members of the research team
 - Offer structural competency and cultural sensitivity training for research and healthcare staff involved in PCTs



A historical review of pain disparities research: Advancing toward health equity and empowerment

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Racism Exposure and Trauma Accumulation Perpetuate Pain Inequities— Advocating for Change (RESTORATIVE): A Conceptual Model

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Confronting Racism in Pain Research: A Call to Action

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p878-892

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Confronting Racism in All Forms of Pain Research: Reframing Study Designs

Janelle E. Letzen, Vani A. Mathur, Mary R. Janevic, ... Burel R. Goodin, Lisa C. Campbell, Ericka N. Merriwether
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Confronting Racism in All Forms of Pain Research: A Shared Commitment for Engagement, Diversity, and Dissemination

Anna M. Hood, Staja Q. Booker, Calia A. Morais, ... Claudia M. Campbell, Vani A. Mathur, Mary R. Janevic
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More Work Needed!

- To develop measures and evidence related to understanding the impact of various inequities and injustices on PCTs
- To better demarcate *responsibilities* across different stakeholder groups (e.g., trialists, research institutions, health system leadership, sponsors, etc)
- To develop and test interventional strategies that address some of the psychological and social factors bridging both the experience of pain and the experience of inequity/injustice

Thanks