



Ancillary Care Obligations

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Main Learning Objective

- Understand the obligations investigators and sponsors have to research participants during the conduct of a trial (e.g. ancillary care)

Ancillary Care

Belsky and Richardson 2004: 1494-6

- Care that is needed by research subjects in low-resource settings, but that is not required...
 - To ensure scientific validity, or
 - To ensure safety, or
 - To redress research injuries

The Question of Ancillary Care

- For what reasons and under what conditions might investigators and sponsors have a moral obligation to provide or facilitate ancillary care to research participants?

Example

Merritt and Taylor 2012

- Nutrition study in impoverished community
- Researchers enter households to collect data on measures of child health
- Likely to encounter children with treatable severe malnutrition

Parameters for Ethical Guidance

Georgetown Workshop Paper 2008

- The Four P's
 - Positive obligation
 - Planning
 - Partnership
 - Practical Steps
- Plus three questions for Research Ethics Committees to consider
 - Needs?
 - Alternatives?
 - Strength of obligation?

Positive Obligation

Georgetown Workshop Paper 2008

- Investigators & sponsors have **some positive moral obligation** to provide or facilitate ancillary care in low-resource settings
- Multi-part rationale
 - Do not treat any person as a mere means
 - Duty of rescue
 - Duty of justice
 - Researcher-participant relationship

Example

Belsky and Richardson (2004), p. 1494

- Study monitoring toxicity and effectiveness of an experimental drug for a rare disease
- Participants have discomfort caused by the disease (not by the research)
- Palliative care for discomfort is not needed for safety or scientific validity
- Palliative care is unavailable to participants through local health system

Do Not Treat Any Person as a Mere Means

- Foundational moral commitment in ethics of research with human participants
- On this basis, in at least some cases:
 - Investigators are morally obligated to provide ancillary care; and
 - Sponsors have a corresponding obligation to support the provision of ancillary care.
- Basic moral standard for all protocols for research in low-resource settings (Merritt 2011)

Example

Merritt, Taylor, and Mullany 2010; Tielsch et al. 2007

- Community-based efficacy trial of one-time chlorhexidine skin cleansing for promoting newborn survival
- Impoverished district of Nepal
- 17,306 mother-infant pairs enrolled
- Study team high prevalence of hookworm among pregnant women

Duty of Rescue

- Nepal study team provided deworming drugs to pregnant women
- Duty “to help persons in serious need whom nobody else can help, or whom one can predict that nobody else will help, when one is able to help them without serious sacrifice or risk”
 - (Merritt 2011, p. 5, citing Richardson and Belsky 2004, p. 26)

Duty of Justice

Georgetown Workshop Paper 2008, pp. 0710-0711

- Treat people fairly
- Researchers have some obligation “to do their part” in alleviating global injustice
- What is it for researchers *to do their part*?
 - Depends on one’s theory of global justice; see for example Pratt et al., 2013.

Researcher-Participant Relationship

- Potential basis for role-specific duties (beyond baseline duties of rescue, justice, and not treating people as mere means)
 - Entrustment: “...by entering a study or clinical trial, research participants automatically entrust certain aspects of their health into the researchers’ care.”
 - Georgetown Workshop Paper 2008, p. 0711)
 - Whole-person: moral significance of researcher’s relationship with participant as a whole person
 - Dickert and Wendler 2009

Sponsors' Institutional Duties

- Rescue: Do sponsors bear an institutional duty to rescue, as distinct from whatever individual duty to rescue researchers bear,?
 - Millum and Rulli 2016; MacKay and Rulli 2017
- Justice: likewise, do sponsors bear an institutional duty of justice?
 - Pratt et al. 2013
- Support for investigators' role-specific duties

The Four P's (Refresher)

Georgetown Workshop Paper 2008, Box 2

- Positive obligation

Just discussed

Coming up now, more briefly

- Planning
- Partnership
- Practical Steps

Planning

Georgetown Workshop Paper 2008, p. 0712

- Different parts of multi-part rationale for positive obligation vary in how controversial they are.
- The non-controversial parts are enough to indicate that researchers and sponsors ought to plan for ancillary care.

CIOMS Guideline 6 (2016)

Caring for Participants' Health Needs

- “...researchers and sponsors must make adequate provisions for addressing participants' health needs during research”, including
- “how care will be provided when researchers discover conditions other than those under study (‘ancillary care’)”

Partnership

Georgetown Workshop Paper 2008, p. 0712

- Plan “in dialogue and partnership with the host community”
 - Interact respectfully
 - Do not unduly perturb local health system
 - Include representation for “potential study participants, community advisory boards, and the local medical community”
- See also CIOMS (2016) Guideline 6, paragraph on “Consultation with relevant stakeholders”

Practical Provisions

Georgetown Workshop Paper 2008, p. 0712

- Act on the above responsibilities concretely
 - Add local personnel with relevant healthcare competence to study team
 - Budget specifically for ancillary care
 - Leverage relationships with other institutional actors who have needed capabilities, like NGOs or development agencies

Role of Research Ethics Committees

Georgetown Workshop Paper 2008, pp. 0711-0712

- Finally, with regard to any particular research protocol, RECs play a critical role in applying The Four P's to help investigators identify their ancillary care obligations.
- Three Questions
 - Needs?
 - Alternatives?
 - Strength of obligation?

Likely Ancillary Care Needs?

Georgetown Workshop Paper 2008, Box 1

- Local disease burdens and contextual factors affecting participants' health?
- In local context, what needs are researchers likely to encounter through carrying out study procedures?

Available Alternatives?

Georgetown Workshop Paper 2008, Box 1

- What care for likely needs is available and accessible to participants through the local health system?
- Are there points of vulnerability in local health system capacity (like human resources) that ought to be buffered from study-generated ancillary-care referrals?

Strength of Obligations?

Georgetown Workshop Paper 2008, Box 1

- What would happen to study participants if their ancillary care needs remain unmet?
- What is the expected intensity (duration, extensiveness, closeness) of study team's interaction with participants?
- Costs of meeting ancillary care needs and resources available from sponsors and third parties?

Summary

- Investigators and sponsors conducting research with human participants in low-resource settings have a responsibility to plan and prepare for ancillary care needs.
- This is a team effort with many other players, including local study partners, representatives of participants and communities, local health systems, & RECs.

Works Cited

Works with full bibliographic citations in Merritt 2011 (optional reading assigned for this session)

- Belsky and Richardson 2004
- Dickert and Wendler 2009
- Merritt, Taylor, and Mullany 2010
- Merritt and Taylor 2012
- Tielsch et al. 2007

See also:

- MacKay and Rulli 2017. The duty to rescue and investigators' obligations. *Kennedy Institute of Ethics Journal* Vol. 27(1):71-105
- Pratt et al. 2013. Ancillary care: from theory to practice in international clinical research. *Public Health Ethics* 6(2): 154-169.
- Rulli and Millum 2016. Rescuing the duty to rescue. *Journal of Medical Ethics* 42: 260-264

Online Training Resources

- Global Health Network Ancillary Care Topics Page,
<https://bioethicsresearchreview.tghn.org/topics/ancillary-care/>
- Global Health Network Short Course on Ethics of Ancillary Care in Research,
<https://globalhealthtrainingcentre.tghn.org/elearning/short-courses/ancillary-care/>