ANCILLARY CARE – WHO SHOULD HOLD THE BAG?

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INTRODUCTION

Ancillary care

- Ancillary care is that which is not required to make a study scientifically valid, to ensure a trials safety, or to redress research injuries.
- So treating ailments that are unrelated to study's aims would be ancillary care.

Ancillary care in developing countries.

- Medical resources are scarce.
- Access to medical care is limited.
- Increasing prevalence of chronic diseases.

Declaration of Helsinki

⑥ In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests

⑰ Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

World Medical Association (2000) Declaration of Helsinki: Ethical principles for medical research involving human subjects. Revision adopted by the 59th World Medical Assembly.

Reasons for positive ancillary care obligations.

- Concern for welfare:

  Due concern for the welfare of those with whom one interacts arguably requires addressing one's research participants' serious medical needs when one has the capacity to do so and they lack other recourse .

Rescue especially when needs are urgent

- Researchers in Benin studying vaginal microbicides discovered in one of the trial participants an ectopic pregnancy that did not result from the microbicides and that urgently called for surgery not available at the trial location.
  They agonized about what to do about it, ultimately deciding to pay for the woman's surgery at another clinic.

Justice

- While it is not up to medical researchers or their sponsors to remedy global injustice in the provision of health care, they do encounter many who suffer from injustices and have some obligation to do their part in alleviating this suffering, where they are competent to do so.

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Entrustment

- While these first three considerations potentially apply to those who are not research participants as well as to those who are, there is considerable consensus that ancillary-care obligations are specially owed to research participants. One way of thinking about this special obligation is to take it that, by entering a study or clinical trial, research participants automatically entrust certain aspects of their health into the researchers' care.

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Ancillary care is not an obligation

- Strain the budgets.
- Monopolize the scarce time of trained persons.
- Distort the incentives of participants in an inappropriate way.
- Often take the health care responsibilities of host government or local organizations.

Guidelines of ancillary care

- Ethical guidelines that more specifically address ancillary care issues are rare.
- Most explicit statement is the statement in the commentary at the council for International organization of medical sciences guideline 21 that

"Although sponsors are, in general, not obliged to provide health care services beyond what is necessary for the conduct of research, it is morally praiseworthy to do so."

www.kme-nmec.si/Docu/CIOMS.pdf

UNAIDS "host/community/sponsor/dialogue."

Guidance Point 14: Care and Treatment Participants who acquire HIV infection during the conduct of a biomedical HIV prevention trial should be provided access to treatment regimens from among those internationally recognized as optimal.
Prior to initiation of a trial, all research stakeholders should come to agreement through participatory processes on mechanisms to provide and sustain such HIV-related care and treatment.

http://data.unaids.org/publications/IRC-pub01/jc072-ethicalcons_en.pdf

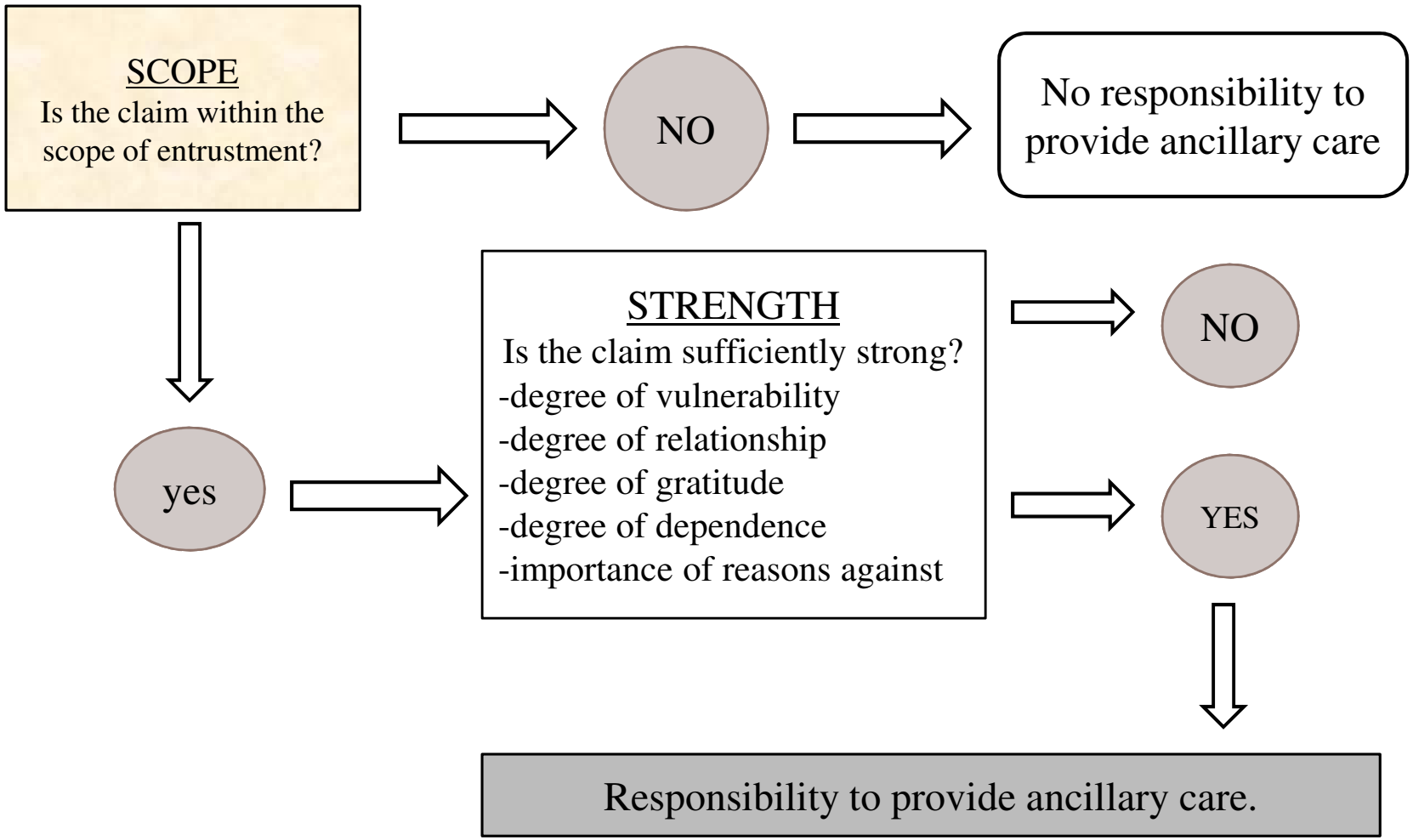
Principal investigator

- Leaving burden of assessing ancillary care claims and logistical burden of planning for them in hands of individual principal investigators is unfair, unduly exposing them to controversy and to charges of unethical behaviour.

HUMANITY FIRST

DISCUSSION

How to assess researcher responsibility for ancillary care?



Research protocol

- It should outline how they will address participants ancillary care needs.
- For the needs which could not be anticipated, review protocol should be made.

REC

- Assess investigators plans for meeting ancillary care needs.
- Protocol-to-protocol review is essential.
- Are there any alternatives?

SPONSOR

- Support investigator by supplementing study budgets or by reinterpreting or easing restrictions on providing ancillary care that is not related
- Pay due attention to defining and costing appropriate ancillary care implications.

Guidelines and policies

- Should be addressed to research sponsors and should be international, so as to minimize the danger that a country's stringent ancillary care research studies to locate elsewhere.
- Duty
- How to plan
- Partnership with host community
- Practical provisions.

Conclusion

Thus, if we provide ancillary care in a right minded way, we can give an equitable justice.

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