PTA & DOH (PART A): POST-CLINICAL TRIAL ACCESS IN LOW-RESOURCE SOCIETIES

Session 5:

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Intro.

- Conflict of Interest: None, except a member of LMIC

Importance of Post-Trial Access (PTA)

- Appreciation of the importance of the PTA clause.
- Unethical for a research/Protocol not to have it.
  - REC should reject such protocol -Allen G.R. Ross

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Access to proven/effective interventions beneficial to participants

- Complaints of Pharmaceutical companies after the 2000 DoH review.

  2000, Art, 30: "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic, and therapeutic methods identified by the study."

- Impossible to guarantee post-trial access immediately at the completion of the research because it takes time to make available the proven intervention to the study participants "without regulatory authorization prior to introduction into the public health system in the host country."

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Consequences

- PTA clause has been downgraded from an ethical obligation of the researcher to an item to be described in the research protocol and informed consent process. The revision committees favored "the feasibility arguments over the ethical reasons."
- The requirement of 2013 does not guarantee post-trial access, and it is weaker than the 2000 version which demands.
- Current, 2012: "Prior to a clinical trial, sponsors, investigators, and host country govts should make arrangements for post-study access." This may allow the ethics committee to review the scope of it.

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Access to post-trial proven effective interventions as a right

Is Access to post-trial proven effective interventions a right of participants?

- It is a right; participants are entitled to post-trial access/benefits, Necessity to avoid exploitation of participants (of LMIC population)
- Human dignity makes it unthinkable that a research participant in a precarious health situation could later be left to his own devices because he or she is no longer 'useful.'" (Andanda and Wathuta, Human Dignity, 145.)
- acc. DoH 2013 Art. 34 it "must be disclosed to participants during the informed consent process."

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Dangers of refusal or Withdrawal of PTA from participants …

- In a breast cancer trial, many participants were denied PTA to lapatinib, though it was proven beneficial where other drugs had failed to prove effectiveness. With the provision of PTA in such trials, participants could have enjoyed longer lifespan or symptom-free survival." =Death (Trowbridge RL, Walker S. The FDA's deadly track record. Wall Street J 2007)

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Some Proposals

-a. Researchers & sponsors of a study must provide benefits to the individual participants in the trial, "health-related resources to the host community," and assist with infrastructure development.

-b. the sole requirement for ethical research is that sponsors and researchers must make sure that informed consent is given voluntarily by participants and that they are provided fair benefits for their participation.

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Some Proposals contd

-c. because carrying out clinical trials is expensive in today's economy, sponsors and investigators should not be required to provide health-related resources and infrastructure to the host community in which the trial is being carried out.

Requiring additional or more posttrial services could discourage sponsors. (Vinay Prasad, et al., 2016. Ethics of Clinical Trials in Low-Resource Settings, p2)

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RESPONSE

- How about solidarity with the poor and vulnerable?
- The UN's goal to provide healthcare for all.
- Sustainability of health outcomes by empowering HCPs/Professionals or local researchers in the host community?

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Access to interventions/proven effective/beneficial to the broader community

How about Providing PTA to the broader community/Globe?

- should be available to all who need it globally. (Kurihara et al., 227).
  - i. Because health is a human right. (Constitution of the WHO. 22 Jul 1946.) and derived from "human dignity." (UN The Universal Declaration of Human Rights. 10 Dec 1948.)
  - ii. Acc. to the UN's Sustainable Development Goals (SD 2), the provision of health care is a goal that must be achieved without leaving anyone behind (Kurihara et al., 227).
  - iii. Equitable access to HC must be seen as an ethical responsibility of researchers involving humans. Hence, we should demand it.

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“Ancillary care”

- How far will researchers take responsibility for the care of non-target diseases when conducting a trial in LRSs? E.g.,

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-Being a Scholar/researcher activist.

- Being a Scholar/researcher activist. Being confronted by the metaphor of the margin

making our research an emancipatory study wherein the purpose of going to the marginalized/poor communities will also be to express marginalized voices and present their experiences in authentic ways.

- That is pushing social justice a bit harder

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Who is Responsible for Funding/ Provision of PTA?

Who should pay, fund, or provide the PTA?

- Brazil: bases PTA on the constitutional right to health and contends that researchers/sponsors are to provide them.
  - Pharmaceutical companies vs. the state:
    - "the state should not be compel to take over the sponsors' responsibilities." (Wang Wei, et al., 2012)
- PTA Host country government must support PTA and devise policies along with sponsors and investigators so that providing PTA does not significantly burden any stakeholder.

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Who is Responsible for Funding/ Provision of PTA? Contd.

- Special aid may be provided by governments and funding agencies to provide PTA in developing and resource-poor nations.
- Special research grants may be awarded to sponsors/investigators who have invented new drugs/interventions that were subjected to PTA. This will encourage further research activities, which may otherwise get diluted due to a larger focus on patient care than on hard-core research.

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Framework for Assessing Cost & Benefits in LMISs

- -Human Dignity
- -Fair PTA
- -Patient/people-centered –not profit.
- -Cost effectiveness of people centered research
- -Does the intervention work in a real-life setting, and can the results be generalized to everyday practice, support decision-making by patients, providers, and health system leaders,
- -Sustainable trials, providing capacity, infrastructure health education,
- -Contrast explanatory and pragmatic trials.

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CONCLUSION –THANK YOU

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