

8th PNHRS Week Celebration Pre-Conference Seminar:

Ethical Issues in Public Health Research in Disaster Areas

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Presentation Outline

- Disaster situation in the Philippines
- Fields of PH research in emergencies and disasters
- Ethical issues in PH research in emergencies and disasters

Disaster situationer in PHL

“The Philippines is one of the most hazard prone countries in the world.”

World Bank. Disaster Risk Management: Philippines. c 2013. Accessed 06 Aug 2014 from <<http://go.worldbank.org/E4A8PZMH30>>



1

PHL's global rank in terms of reported events

2.1 per 100,000

disaster mortality in PHL

12.6%

Filipinos who are disaster victims

USD 1.3-B

economic damage of disasters in PHL

PHL as one of most hazard prone countries worldwide

The Philippines is one of the most hazard prone countries in the world. Its location in the tropics and in the Pacific Ring of Fire exposes it to multiple natural hazards including typhoons, floods, drought, as well as earthquakes and volcanic eruptions. This inherently high disaster risk is exacerbated by the effects of unplanned urbanization, environmental degradation, and global climate change. The resulting human and economic costs of disasters are significant. Over the last ten years, the Philippines have witnessed over 6,000 people killed, over 23 million people affected, and about 1.3 billions of dollars in economic damage (EM-DAT).

World Bank. Disaster Risk Management: Philippines. c 2013. Accessed 06 Aug 2014 from <<http://go.worldbank.org/E4A8PZMH30>>

Annual Disaster Statistical Review 2011 The numbers and trends. Centre for Research on the Epidemiology of Disasters (CRED) Institute of Health and Society (IRSS) . Université catholique de Louvain – Brussels, Belgium

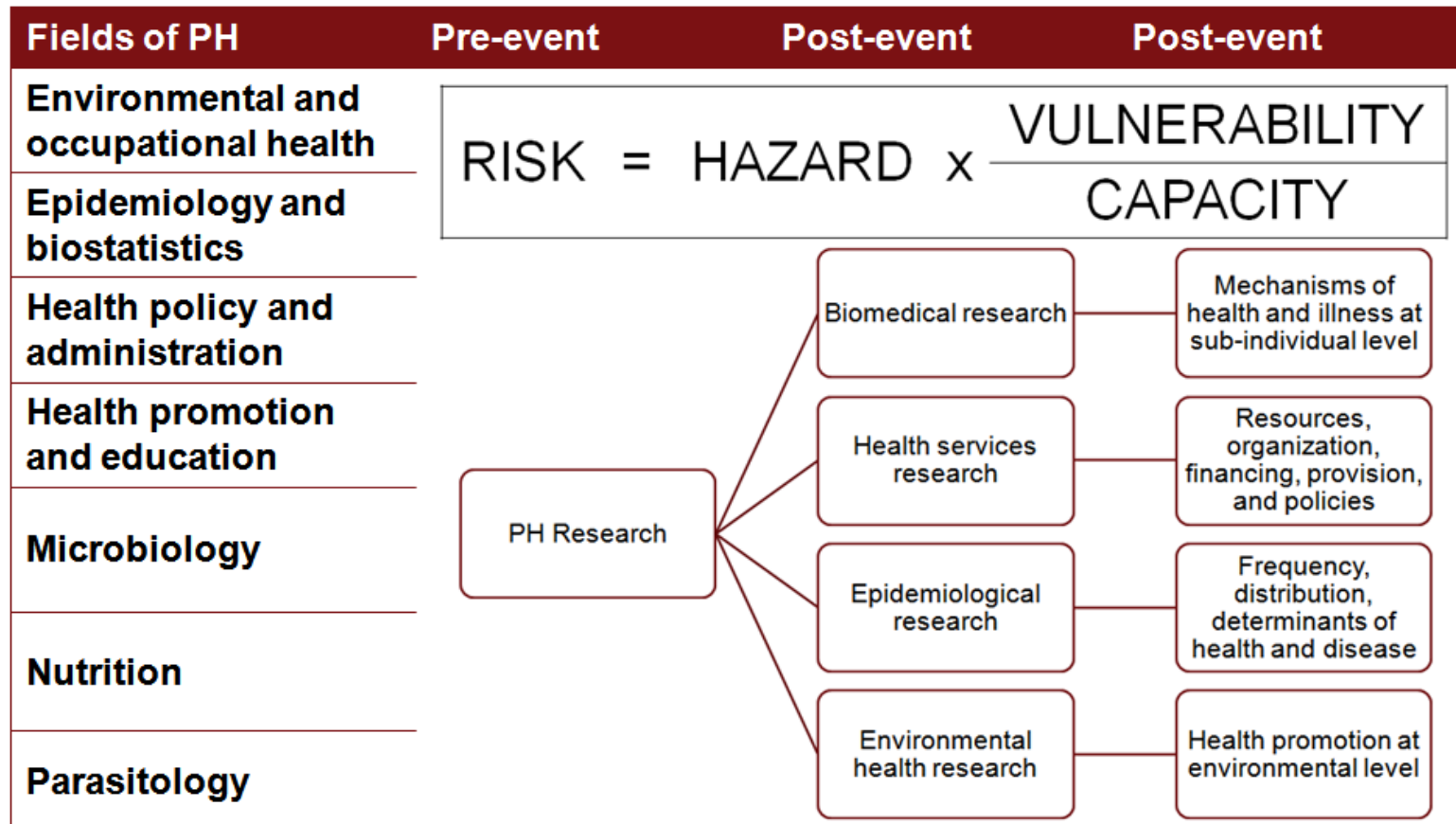
Fields of PH research in emergencies and disasters

“Public health refers to all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole.”

WHO. Glossary of globalization, trade and health terms [Internet]. c 2013 [cited 13 Nov 2013]. [Link](#).



PH addresses a wide range of research questions in disasters and emergencies



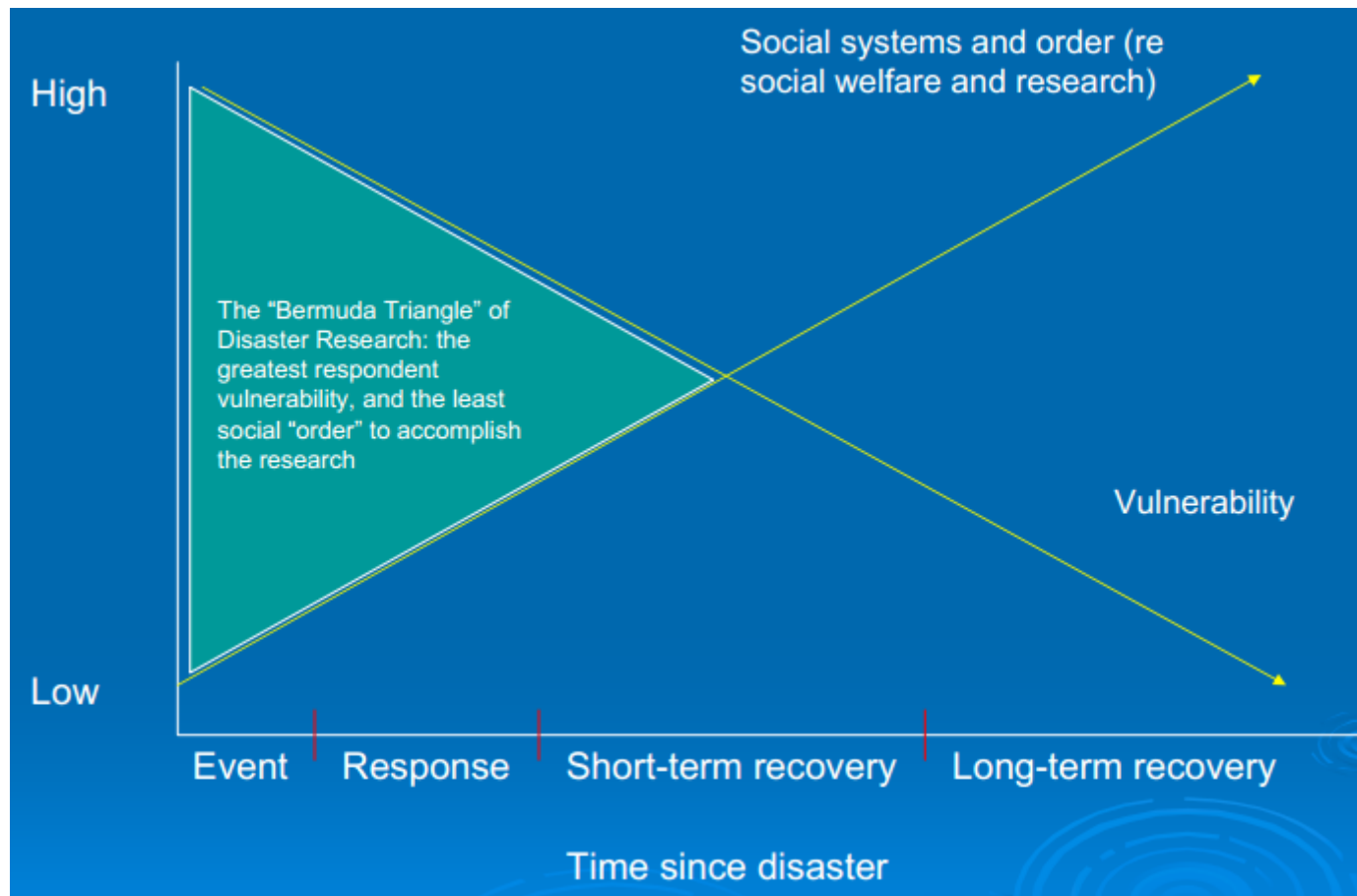
Ethical issues in public health research in E&D

A disaster is a “serious disruption of the functioning of a community or a society involving widespread human, material, economic or environmental losses and impacts, which exceeds the ability of the affected community or society to cope using its own resources.”

UNISDR. Terminology. 2007 Aug 30. Accessed 12 Aug 2014. Available from [link](#).



Disaster events are characterized as periods of chaos and social disorder



Chuan VT. Prospective ethics review in infectious disease emergencies. *Asian Bioethics Review*, 2009;1(3):299-303.
Siriwardhana C. Windows of opportunity after a disaster: The case of Sri Lanka. *Asian Bioethics Review*, 2010;2(2):148-151.
Sumathipala A et al. Ethical issues in post-disaster clinical interventions and research. *Asian Bioethics Review*, 2010;2(2):124-142.
Citraningtyas T et al. A second tsunami? The ethics of coming into communities following disaster. *Asian Bioethics Review*, 2010;2(2):108-123

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Ethical challenges and issues

Scientific rigor
and professional
competence

Quality and
adequacy of
ethical review
process

Undue
inducement

Unequal burden

Distributive
justice

Dissemination of
results

The way forward...

How do we balance the need for emergent information (from research) with ethical principles and considerations and the reality of the ethics review process?



Cardinal ethical principles remain relevant in disaster research

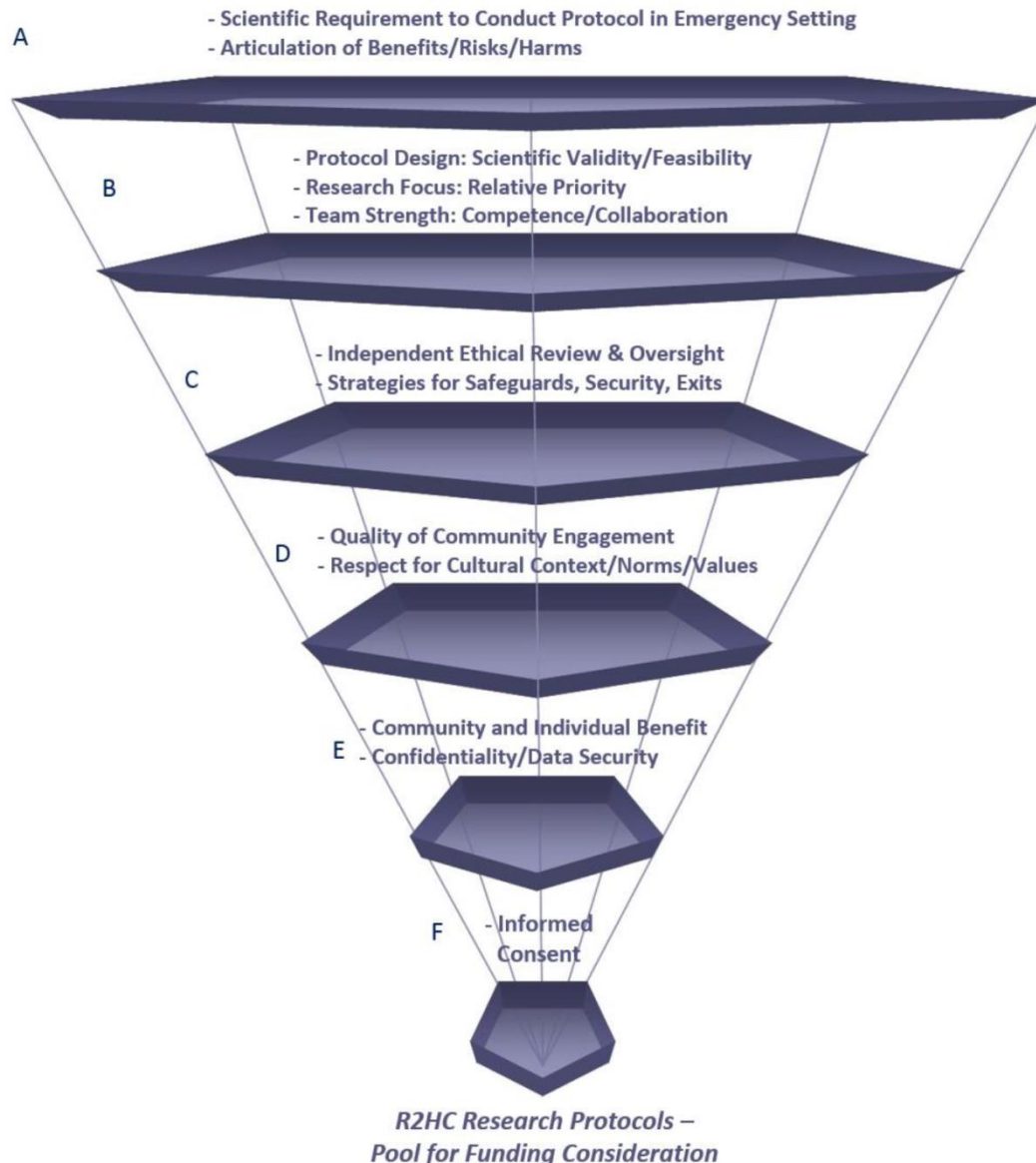
Respect for
persons

Beneficence

Non-
maleficence

Justice

R2HC Ethical Framework – Parameter Clusters



R2HC Framework

Purpose of the Research for Health in Humanitarian Crises (R2HC) framework:

- 1) guide development of research designs and protocols intended for implementation in humanitarian crises and complex emergency contexts to help ensure their ethical viability
- 2) support ethical review of such protocols by independent ethical review bodies (REBs, IRBs), funders, and other organizations of interest
- 3) serve general educational purposes and enhance public understanding of the issues involved in and ethical principles guiding research in such settings

Cluster A: Emergency Context

Requirement/Benefits-Harms-Risks

- Why must this research must be conducted in a humanitarian crisis or emergency context – in short, explain why the expected evidence and benefit cannot be gained from implementation of the protocol in more stable (non-emergency) settings?
- What are the known and potential harms and risks to individuals and the subject population overall by involvement in the proposed research?
- What are the relevant analyses of harm-benefit “ratios”?
- What mitigating strategies and associated costs (planned and potential) have been defined and projected?

Cluster B: - Protocol Design: Scientific Validity/Feasibility; Research Focus: Relative Priority; Team Strength: Competence/Collaborative Structure; Declared Interests

- What is the relative importance/priority that this protocol should enjoy in the larger context of evidence-building for humanitarian response?
- Why are the institutions and individuals involved in the proposed team – including local (in-country) researchers and supporting staff – uniquely qualified to conduct this research? What are the weaknesses or “holes” in the team structure that might be strengthened before the research is implemented?
- How are the declared interests of all investigators and institutions involved in the research relevant to its conduct? Do any these interests represent “conflicts” that might compromise the integrity of the research, the team or the evidence sought?

Cluster C: Independent Ethical Review/Oversight; Safeguards/Security/Exits

- What ethical review processes and review entities (REBs/IRBs: institutional/internal, independent, contracted, local/in-country) will be involved in approving this protocol?
- What are the known and anticipated strengths and weaknesses of these review bodies, including their capacity to provide initial, continuing and summary oversight of the protocol?
- Are there any mitigating strategies around weaknesses and are there costs associated in addressing them?
- What safeguards, security, exit strategies, and associated costs have been developed with regard to research subjects (both those involved in the intervention and those in “control” groups) and the research team itself over the proposed duration of the project?

Cluster D: Community Engagement; Cultural Context/Norms/Values

- What community engagement strategies have been undertaken to date, and what engagement actions are planned?
- How does the protocol address the unique cultural context(s), norms and values of the population(s) involved?

Cluster E: Community/Individual Benefit; Confidentiality/Data Security

- How will the research directly benefit – with reasonable immediacy – the community and individuals involved? If it will not, who will benefit and when? By what process were benefits presented to and affirmed by the research subjects and their community?
- How does the protocol address data confidentiality and security? What are the anticipated risks and mitigation strategies/costs?

Cluster F: Informed Consent

- What informed consent strategies and processes are proposed for subjects of the research as well as the research staff involved?
- Are these strategies credible, and is adequate documentation planned?