OVERVIEW OF RESEARCH IN EPIDEMICS, CRITICAL AREAS FOR RESEARCH AND THE NECESSARY PREPARATIONS

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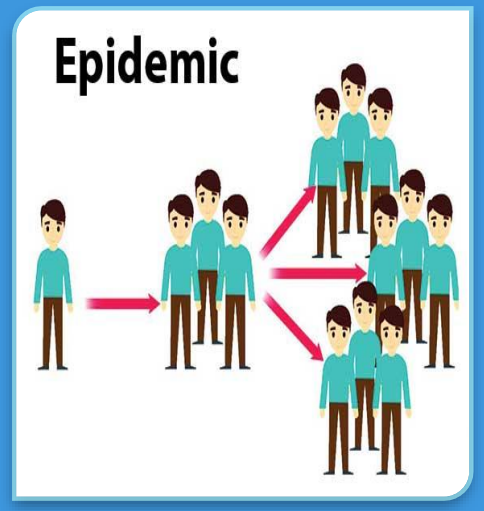
WHAT IS AN EPIDEMIC?



- An epidemic is a rapid spread of disease to a large number of people in a given population within a short period of time.
  - change in the ecology of the host population (e.g., increase in the density of a vector species),
  - a genetic change in the pathogen – virulence/resistance
  - the introduction of an emerging pathogen to a host population
- Increased occurrence or episodes of a disease in a population
- Epidemic VS Pandemic

CONDITIONS IN AN EPIDEMIC

- Refers to a disease situation that's out of control,
  - Sick people, and there may be multiple death
  - Poor/Broken down/overwhelmed health systems
  - Lack/shortage of treatment
  - Confused/disoriented/ apprehensive or even aggressive population
  - There may be breakdown in governance structures leading to disorder
  - Community mistrust

- Are these ideal situations for research?
- Is research in outbreaks necessary?
- Is research in outbreaks acceptable?

WHAT IS THE IDEAL SITUATIONS FOR RESEARCH IN AN EPIDEMIC

- No ideal or none ideal situation for research
  - Research may be conducted in all situations
- Though, outbreak situations are challenging situations to conduct research
  - Research may cause direct harm or inadvertently add to existing injustice and exploitation of the researched population
  - But there are also risks in not conducting research – for example the risks of providing inadequate, ineffective, or even harmful care.
  - It may be the only natural opportunity

IS RESEARCH NECESSARY IN OUTBREAK SITUATIONS?

1

Research during outbreaks is an opportunity to collect important information that can contribute to improving outbreak control measures, such as conducting clinical or vaccine trials.

2

Better evidence about what helps or does not help during an outbreak is needed in order to improve the response to the health emergency or the outbreak.

3

Research conducted during the outbreak may play a crucial role in obtaining this evidence, and helps support the immediate response, as well as learning for response to future outbreaks

"Research is important because it is key to an evidence-based approach"

Lisa Guppy June 2015, Research in crises: examples from the Ebola outbreak

IS RESEARCH DURING OUTBREAKS ACCEPTABLE?

- According to the "International ethical guidelines for biomedical research involving human subjects. http://www.cioms.ch/ethical-guidelines-2016:

"to be ethically acceptable, research must have a realistic prospect of generating information that constitutes an adequate basis for learning. In the case of an emerging infectious disease outbreak, ethically acceptable research must provide the information needed to put stakeholders in a better position to understand and make decisions regarding the use of new interventions and to address similar outbreaks in the future "

CRITICAL AREAS FOR RESEARCH DURING OUTBREAKS

- Highest priority is research that can quickly answer specific, critical questions in a way that impact response very quickly.
- Another high priority area is research that answers critical questions that come up repeatedly in different responses, so that response is made more effective in the future.
- Researchers in emergencies need to pose clear questions and design a methodology that answers those questions with the minimum of resources, and can produced evidence and advice to influence action in real time.

PREPARING FOR RESEARCH DURING OUTBREAKS

- When should we prepare for research during outbreaks?
  - Preparedness and response to outbreaks is an ongoing activity so too should preparations for research during outbreaks
  - In preparedness plans for outbreaks, we identify threats, risks and gaps; and should identify research questions that can be addressed as a component activity of preparedness efforts.
  - Identifying recognizable gaps during an outbreak is an urgently needed process. This process should generate research questions for high-priority study

PREPARING FOR RESEARCH DURING OUTBREAKS

- a systematic analysis of gaps encountered after an outbreak will probably identify research questions that can be addressed in another ooutbreak
- The knowledge that is generated through well-designed, effectively executed research in anticipation of, in the midst of, and after an outbreak is critical to achieving the overarching goals of preparedness and response:
  - preventing injury, illness, disability, and death and supporting recovery.

PREPARING FOR RESEARCH DURING OUTBREAKS

- Some or most outbreaks can be predicted, and what needs to be in place for appropriate response and research can be thought of well in advance, leading to better research and better health outcomes altogether.
- Those planning to undertake research in an outbreak need to engage seriously and respectfully with those whose interests are fundamentally affected by the outbreak:
  - national governments and research institutions;
  - local health services, voluntary organisations in the affected area;
  - members of affected communities.

PREPARING FOR RESEARCH DURING OUTBREAKS

- Study protocols should be developed with the input of local communities, in order to ensure that proposed procedures are acceptable:
  - Is this the right study for this location and this population / subpopulation?
  - Who has been involved in identifying the problem that the research seeks to answer?
  - Will local populations benefit from any positive findings?
  - Is this the right design for this location and this population?
  - How have local needs, concerns, or preferences been considered?

PREPARING FOR RESEARCH DURING OUTBREAKS

- Any exclusion criteria from studies should be clearly justified with reference to the risks and benefits for the group in question. There should not be an automatic exclusion of ‘vulnerable groups’ such as children, pregnant women, or older people. In practice, exclusion may make those groups more vulnerable.
  - Case of Zika virus immunization studies
  - Use of placebos

PREPARING FOR RESEARCH DURING OUTBREAKS

- SOME WORDS OF CAUTION:

- Research must be undertaken and supervised by qualified researchers.
- Research with human subjects should be carried out only by, or strictly supervised by, suitably qualified and experienced investigators.
- People should not be asked to take part in health research when their basic health needs are not being met, OR when it will not help reduce suffering.

KEY COMPONENTS OF RESEARCH RESPONSE IN THE CONTEXT OF PUBLIC HEALTH EMERGENCIES.

Table 1. Key Components of Research Response in the Context of Public Health Emergencies.

Component	Actions before the Event	Actions during the Event
Identify questions that will need to be addressed for common scenarios and develop generic study protocols	Identify experts in research design and in key topic areas Develop and gain approval from institutional review boards for key study protocols	Convene experts, and review and amend protocols as needed
Ensure that appropriate cadres of scientists are available to respond to events	Roster experts in research design and in topical areas of concern Develop an on-call research "ready reserve" of clinicians, scientists, and other experts in government, academia, and industry	Convene experts (and potentially others with concerns) to identify areas for priority research
Develop a process for activating research response	Incorporate the concept of an "incident commander for research" into response plans Determine criteria for activation of research response	Identify an "incident commander for research" and representatives from relevant science agencies that will be charged with supporting and conducting research Notify prerostered experts
Identify and prioritize research needs	Identify potential knowledge gaps and research questions	Convene experts and others, such as those in affected communities, to review previously identified gaps, identify unforeseen and emerging knowledge gaps, prioritize research and baseline data-collection needs, and recommend to researchers and funders which to pursue in the short term
Ensure conditions for rapid data collection	Develop and preapprove generic protocols and survey instruments so that only changes to them require review when the event occurs Develop protocols for collecting and storing biospecimens	Modify preexisting survey and other data-collection tools for event-specific conditions
Ensure rapid and appropriate human-subjects review	Establish a Public Health Emergency Research Review Board Promote a commitment to expedite review by grantee institutions and prepositioned research networks	Facilitate rapid review of protocols by national or local institutional review boards
Ensure mechanisms for rapid funding	Use prefunded research networks and preawarded but just-in-time funded research contracts Incorporate research response to public health emergency in specific aims on grant awards to better facilitate administrative supplements Identify nongovernmental funders, both regionally and by sector, with an interest in addressing knowledge gaps	Convene potential governmental and nongovernmental funders Share prioritized research agenda
Ensure that response workers and other exposed persons are identified and rostered	Develop and use a Rapid Response Registry Identify potential monitoring and tracking devices to facilitate exposure monitoring (e.g., among emergency responders)	Activate registry enrollment and designated data-collection networks, including for biospecimens, when appropriate Deploy monitoring and tracking devices, when appropriate
Understand concerns of affected communities	Identify generic list of concerns to address, drawing on community-based participatory research and experience with previous events	Engage community representatives in discussion of concerns and potential studies Ensure mechanism to share findings with community

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- There are also several training courses on research in emergencies…. LSHTM /Prof. Jimmy Whitworth

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