RESEARCH DURING PUBLIC HEALTH EMERGENCIES- ETHICAL ISSUES

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Public health Emergency

❖ Hallmark of a Public Health Emergency

❖ is the urgency to control
❖ to conduct research
❖ in the face of uncertainty,
❖ suboptimal conditions and pressure.
Research in Public health emergency

Only way to learn how to improve care for current and future patients and to potentially prevent an epidemic from occurring again
mAb 102.4

- Efficacy and safety of investigational products – **outbreaks are the only setting**
- Animal studies can not be extrapolated to humans
- Research must be designed to generate evidence - efficacy & safety

“the need to learn as much as possible, as quickly as possible” WHO 2016
Research during public health emergency

- Mitigating morbidity and mortality
- Accelerating the end of the outbreak
- Developing regulatory level data to license products that can be used to prevent and mitigate future outbreaks.
Ethics - basic principles

1. Respect for person - Autonomy
   - Special protection of persons with ↓d autonomy

2. Beneficence
   - Maximize benefits and minimize harms or risks

3. Justice
   - Equitable distribution of burden and benefits
   - Selection of subjects
Respect for person - Autonomy

- To respect the dignity of each person

- Special protection to people with diminished autonomy - children, prisoners etc

- Requires that informed consent must be obtained from all subjects involved in research
Ethical challenges - Autonomy

- Limitations of obtaining informed consent
  - The potential participants are likely to be extremely sick, isolated

- Communication between researcher and patient with limited time

- Compromise capacity to take decision – vulnerable and so need special protection
Informed consent - How can it be eased

- Simplifying language and reducing information - only very essential

- Time of interaction - while diagnosis is being confirmed and before isolation

- If potential participants’ ability to provide consent is compromised
  - Family/community
Informed consent - How can it be eased

• Involvement of the **community** - getting the confidence - Research is not to advance knowledge, but should align with outbreak priorities

• Involvement of **local scientists**
  • familiar with culture, attitudes, language and socio-economic context even more important
Beneficence

The obligation to maximize possible benefits and to minimize possible harms and wrongs ('do good')

non-maleficence:

Safeguarding against possible harms and abuses ('do no harm')

A trial should be initiated and continued only if the anticipated benefits justify the risks.
Beneficence- benefit- risk assessment

• Look for benefits
  • improve the chances of survival or reduce the probability of infection

• Look for increase risk
  • result in serious temporary or irreversible adverse reactions, including death
  • risks to health care workers and response teams are minimized
Beneficence - benefit - risk assessment

- Measures to minimize risk for study participants - detailed follow up plan

- Standardized assessment of AE & SAE

- Risk associated with handling of samples
- Interim analysis - DSMB/ independent monitoring - Stopping rules
Justice

Fairness in distribution
To give each person what is due to him

Inclusion of pregnant females and children

Selection of patients
Justice – Fairness, equity and maximization of benefit

- Exclusion of pregnant women and children
  - Medicines are used without sufficient evidence, including the appropriate dose
  - Social injustice and reduced social values
  - Less availability of the interventions
  - Impact of studies on routine patient care
  - Sharing of results with participants and their communities
Design of the study

- Is it ethical to use unregistered interventions
  - WHO 2016 - ethical to use unregistered interventions that have shown promising results in the laboratory and in animal models but have unknown adverse effects in humans
- Most appropriate research study designs
  - The extent of uncertainty about the safety and efficacy should be clearly acknowledged and communicated
Design - RCT

- Therapeutic intervention / comparator - placebo?
- Control group should receive the best available supportive care
  - what constitutes best available care
  - best possible supportive care,
    - most sophisticated interventions, expensive
  - community engagement to address community level concerns
Adaptive trial designs

- An adaptive trial design can be utilized to evaluate patient outcomes beginning early in the clinical trial and the trial can be modified in accordance with those findings
  - dosage, sample size, treatment arms and patient selection criteria
  - Add or drop patient groups or treatment arms as more information becomes available
  - Interim analysis, stopping rules
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THANK YOU