

Ebola, research, and Ethics

Nancy E. Kass, ScD

Berman Institute of Bioethics *and*
Bloomberg School of Public Health

Outline for today

- **Quick overview: framework for public health ethics**
- **Ethics and testing of experimental vaccines**
- **Ethics and testing of experimental treatments**
- **And what else should we be thinking about in research, ethics, and Ebola?**

Public health ethics framework

- What is the **goal** of the proposed program?
- What (and how much) relevant **data** are there?
- What are the **risks/burdens/concerns**?
- How can they be **minimized**/least burdensome option?
- What are **justice/fairness** implications?
- If controversial, what approaches to further **procedural justice**?

Questions about ethics and vaccine trials

- Who is the right target population?
 - Populations at greatest risk (with highest incidence)?
 - Populations to whom we owe most protection?
- Should trials be placebo controlled?
- What else must be provided in vaccine trials?
- Should research target population be same as priority population for vaccine roll out?

Questions about vaccine studies

- Who is right target population?
 - HCWs?
 - Duty of reciprocity to help them
 - They can best understand uncertainties, placebo, etc.
 - But potentially low transmission rate (African HCWs higher incidence rate??)
 - Household members of Ebola patients?
 - At greater risk; little protective equipment
 - Will get answer more quickly

What else must be provided to participants?

- Personal protective equipment?
 - Especially to African HCWs
- To family members?
 - Health education
 - Chlorine?

Should trials be placebo controlled?

- How else can we learn if the vaccines work?
- No point doing research if question cannot be answered
 - Placebo especially important where incidence rates are so low.
- Validity question: should we also be monitoring baseline immunity?
 - Might at-risk populations have mounted natural immune response?

Treatment trials

- What is the right design, ethically?
- Some say to give treatment to all (no placebo)
 - “unethical” to deny potentially lifesaving treatment to people who need it
- NIH trial planned with placebo
 - We need to find out if something works; not unethical if we don’t know whether it works
 - Ethical duty to learn what works

Treatment trials

- Ethical tension:
 - **Efficient** trial --learn as quickly as possible, with rigorous methods allowing valid results
 - **Compassionate** to those who want access
- Ethics is not just figuring out which side poses better arguments
 - Are there other options besides everyone gets drug or 50:50 randomization?

Other options? Adaptive approaches

- Incorporate what we learn as we learn it
- E.g., Adaptive approach #1:
 - E.g., pre-trial: experimental drug to 40 sick patients
 - If dramatic (“magic bullet”) then no placebo needed
 - If unclear, need to use placebo, but less troubling to use placebo when efficacy unclear!
- E.g., Adaptive approach #2:
 - Randomize patients to different experimental treatments and to placebo

What else must be provided to participants?

- Supportive care?
 - May be more important (“compassion”) than access to experimental therapies

What other kinds of research needed, ethically?

- How to prevent Ebola from spreading? What approaches and messages work?
 - Much local engagement, advice, collaboration EARLY
 - Where do people get formal/informal information?
 - Who is trusted (formal and informal)?
 - What can we learn from other efforts (HIV, TB, etc.)
 - Creativity
 - Street theater, radio announcements, YouTube, texts
- Research here also essential to reducing EBV now and in future outbreaks

What else will help now and in future outbreaks?

- Can research and collaborations leave health systems stronger than before?
- Will more local people be trained?
- Will local internet connectivity be improved?