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?