

Ebola Outbreak: Use of Experimental Therapies

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Project goals:

- Investigating regulations for the use of Ebola experimental therapies
- Assessing their risks and benefits
- Evaluating the best design for clinical trial

Background

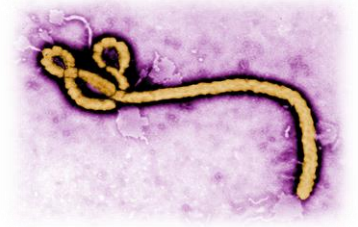
- Ebola is a lethal viral disease with 50% mortality rate
- Countries affected in 2014 Outbreak: Guinea, Sierra Leone and Liberia
- Case counts: 24,957 total cases, 10,144 deaths (As of March 14, 2015, Source: CDC)
- No registered Ebola therapies
- Several Ebola experimental therapies under development, need testing for efficacy and safety



Fig 1. Map of Ebola-stricken countries in 2014 outbreak

Regulations

- World Health Organization provides general guidelines for the use of Ebola experimental therapies
- e.g. Respect for human rights, national and local laws
- Ebola-stricken countries need to make science-based decision before use
- Legal to use experimental therapies in the USA under FDA's compassionate use



Risks and Benefits

Therapies	Expected Benefits	Potential Risks
TKM-Ebola (drug)	Reduce viral load	Drug resistance Kidney failure
Zmapp™ (monoclonal antibodies)	Confer passive immunity	Hypersensitivity reaction type 3
VSV-EBOV (Vaccine)	Confer active immunity	Opportunistic infections

Stepped-wedge Trial Design

- It is administration of intervention to all participants at different times of the study
- I propose the stepped-wedge trial as the best way to test Ebola therapies:
 - potential benefit to all participants
 - continual study gives more data

Conclusion

- It is ethical to use experimental therapies to treat Ebola provided their use is closely monitored
- Efficacy/safety trials are currently underway in West Africa



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