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

Risks and Benefits

<table>
<thead>
<tr>
<th>Therapies</th>
<th>Expected Benefits</th>
<th>Potential Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>TKM-Ebola (drug)</td>
<td>Reduce viral load</td>
<td>Drug resistance, Kidney failure</td>
</tr>
<tr>
<td>Zmapp™ (monoclonal antibodies)</td>
<td>Confer passive immunity</td>
<td>Hypersensitivity reaction type 3</td>
</tr>
<tr>
<td>VSV-EBOV (Vaccine)</td>
<td>Confer active immunity</td>
<td>Opportunistic infections</td>
</tr>
</tbody>
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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

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

The Honors Program at
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