Covid-19 challenge studies: practical and ethical issues

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Disclaimer:

• No relevant conflicts of interest
• Personal views & some unpublished data
• Not necessarily the views of WHO, Working Group, regulators, etc.
Where we are today

- Covid-19 is globally endemic (except a few island nations)
- Massive global disruption
- >100 vaccine candidates
- 5+ in Phase III trials, ~30,000 participants per vaccine tested
Where will we be in the near future?

One possibility:
• At least one of the first vaccines might be shown to be highly effective and safe

Other possibilities:
• First vaccines moderately effective, not effective, or not safe
• Field trials of first vaccines fail to report
• Need to test multiple vaccines
Why not just do vaccine field trials?

**Practical constraints**
- Time
- Multiple vaccines

**Participants**
- Number of participants
- Intensive sampling due to asymptomatic infection

**Public health constraints**
- Timing with an epidemic / public health control measures
Why not just do vaccine field trials?

Heriot et. al. [Pre-print]. Assumptions: (1) 10,000 person field trial, (2) commencing 6 months into epidemic.
How many people get infected per trial?

Heriot & Jamrozik [Unpublished].
Uses for challenge studies in Phase III trials

1. Selection for field trials:
   - Pre-clinical development of vaccine candidates
   - Phase I / II (safety, pharmacology)
   - Challenge study with one or more candidates
   - Field trials
   - Licensure
   - Standard post-market surveillance

2. Compare license & novel vaccine:
   - Challenge comparing new vs. licensed vaccine(s)
   - Safety cohort / field trial
   - Licensure of superior vaccine
   - Standard post-market surveillance
WHO Ethics Key Criteria for Covid-19 challenge

1. Scientific justification
   • Potentially strong
2. Risk-benefit assessment
   • Complex, may need modelling
3. Consultation & engagement
   • Commenced
4. Coordination
   • Commenced
5. Site selection
   • Under consideration
6. Participant selection
   • Must minimise risks
7. Expert review
   • Independent
8. Informed consent
   • Rigorous
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