Development of an improved vaccine with focus on LMIC

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Development Pathway

Goal: Define development pathway for improved vaccine that is feasible for delivery in LMIC

Definition of improved vaccine:
  broader and longer protection
  early goal: drift-proof
  later goals: shift-proof

Some issues raised during the presentations and discussion, particularly with respect to the draft PPC, which is intended to guide the development pathway by defining goal
Epidemiology of Influenza in LMIC

• Better defining unmet public health need in LMIC will support uptake and resources available

  • Case definitions needed
  • Incidence by age and severity
  • Transmission patterns (schools, children to elders)
  • Potential efficacy studies of current vaccines (probe)
Clinical Trial Plan including LMIC Trials

• Possibility of different outcomes in different regions
  • more or less immunogenic
  • consequences of influenza may differ

• Trial design may face more constraints
  • Medical care and surveillance (including post-licensure)
  • Laboratory infrastructure
  • More incentive to develop a minimal dose and regimen (extra trials?)

• Correlate of protection should be sought (search can be expensive)
Potential for Innovative Trial Designs

• Clinical Trials
  • Iterative small Ph1 trials to refine regimen
  • Ph2B trials (efficacy endpoints but not large enough to be pivotal)
  • large simple trials
  • cluster randomized trials (indirect effects)
  • transmission reduction as feature of trial design
  • multi-year trials for duration of protection after one yr immunization

• Animal models and passive transfer of antibody
• Human challenge
Design Vaccine for LMIC Feasibility

- Cost
- Stability
- Presentation
- Minimal regimen and dose
- Duration—may be able to assess exact duration post licensure
- Production capacity
- Platform for delivery
- Funding
More Complex Regulatory Path

• “Local” or regional data requirements?
• Extended follow up mechanism after trial is analyzed and reported to establish longer-term effectiveness
• Many individual countries—possibility of joint review, common application?
• Early WHO prequalification