

# Practical issues with antibody supply for generation of International Antibody Standards

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# Resources needed

- Antibody
  - Human plasma/serum
    - Post-vaccination, convalescent
  - Monoclonal antibodies
    - Human (preferred)
    - Animal (mouse)
    - Recombinant (e.g. from phage display libraries; scFv or Fab fragments)
    - Pools of monoclonal antibodies
  - Animal plasma/serum
    - Hyper-immune
    - Post-infection



# Resources needed (2)



- Freeze-drying capacity
- Network of laboratories to evaluate new antibody standard
  - At short notice in case of pandemic emergency
  - Statistical support
- Funding
- Alignment with WHO Expert Committee for Biological Standardisation (ECBS)
  - Meeting once a year (October)



# Antibody supply issues



- Speed of supply
  - Human serum/plasma
    - early in pandemic, no post-vaccination sera will be available; need access to convalescent sera
    - Coordination with Epidemiology Working Group may be helpful
  - Animal serum/plasma
    - May be fairly quick
      - Post-infection within weeks of availability of virus – can sufficient volume of serum be produced from small animals (ferrets)?
      - Hyper-immune: depending on immunogenicity of new virus, 8 – 12+ weeks; if larger animals can be used, volume less of an issue
  - Monoclonal antibodies
    - Minimum of 2 months?
    - How much time for production of sufficient quantities?



# Antibody supply issues (2)



- Speed continued:
  - Collaborative study to evaluate candidate standard and assign unitage
    - Shipping issues (especially with animal sera)
- Volume
  - Demand for IS will be high in a pandemic
  - Target  $\geq 1000$  ampoules of freeze-dried antibody



# Preparation for production of IS



- Evaluate alternative candidate antibody standards (animal sera, monoclonals) prior to a pandemic
  - Follow-up MN/HI comparative CONSIZE study as a good opportunity
    - Offer of human monoclonals from University of Oxford (Alain Townsend)
    - Other sources to be explored
- Mapping the pathway for production of an antibody IS
  - See John Wood's presentation!
- Establish network of laboratories willing to participate in collaborative study
- Decide whether an IS is needed or whether a working reagent may be sufficient (potentially extra time required for IS due to ECBS timetable)

