

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 ≥ 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)

