SAVAC Technical Advisory Working Group on Immunoassays

Meeting Summary & Agreed Outputs

Date: 1st June 2025
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Secretary: Alex Keeley, London School of Hygiene & Tropical Medicine

Technical Advisory Work Group Members:

Grace Androga, Malawi Liverpool Wellcome Programme
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Purpose of the Working Group

The overarching aim of the SAVAC Immunoassay Technical Advisory Working Group is to support stakeholders in improving the reproducibility, cross-study comparability, and regulatory relevance of immunological research underpinning the development of safe and effective Strep A vaccines.

Key Discussion Points and actions

Reference Material & Reference Strains

The groupwide consensus was that several fundamental reagents were required urgently in order to standardise immunological research towards a safe and effective vaccine.

Essential:

- Polyclonal reference serum: should show binding activity to known vaccine antigens and demonstrate functional activity against agreed reference strains. Polyclonal reference production must be the single top priority for funding and production. Without polyclonal reference serum to enable standardisation of immunoassays, it would be very difficult for any Strep A vaccine candidate to receive regulatory approval.

- Reference strains: limited to max 4–5. M1, M12, M53, M75 proposed to harmonise with recent ASAVI work characterising reference strains. The group agreed that these strains should be deposited in repositories (e.g., National Collection of Type Cultures) in two separate locations allowing universal access

Reference serum and strain resources should be internationally available and not vaccine manufacturer dependent.

Helpful:

Additional reagents were considered to be of high value but not essential to field.

- Monoclonal antibodies against key antigens for research and bridging assays
- High quality, standardized and universally available antigens

As further research emerges it may become more clear which reagents and antigens would require a higher degree of standardisation, and laboratory networks with standardised reagents and protocols may be value.

Agreed actions:

1. MHRA will outline reference serum development plan, including antigen sourcing options, funding procurement and requirements. This work will contribute to a technical roadmap document,

2. Members of SAVAC TAWG will make the ASAVI reference strains universally available, aligning with a pending publication on reference strain selection.

Stakeholder Engagement & Regulatory Alignment

Purpose: To rapidly map the current landscape of immunoassay usage, reference materials, and perceived barriers across developers, regulators, and academic labs.

- Stakeholders:
    - Vaccine developers
    - National and international regulators
    - Academic researchers
    - Relevant adjacent fields (e.g. Group B strep experience)
- Proposal to conduct **targeted stakeholder interviews** (rather than surveys) using structured questions, with results forming a basis for consensus outputs.
- Regulatory involvement considered essential from early stages.
- SAVAC advocates for sustained multi-stakeholder dialogue to foster harmonisation, consensus, and transparent information sharing. The group acknowledged ongoing Wellcome Trust–funded work on correlates of protection (PI Osowicki, MCRI; Ed Clarke, LSHTM) with input from an Industry and Innovation Advisory Group, as well as parallel efforts through ASAVI. It was agreed that SAVAC representation could

serve to align and integrate these initiatives around their shared strategic objectives.

Agreed actions:

1. Prepare initial stakeholder interview framework and circulate for input.
   Identify industry, academic, and regulatory stakeholders.
   Contact stakeholders for scheduling of interviews.

2. SAVAC will continue to support regular academic-industry dialogue (complimented by Wellcome COP grant Industry and Innovation advisory group).

Technical Roadmap & Publications

Purpose: To consolidate field-wide priorities into a single document outlining the priorities for research and investment and highlighting the technical, logistical, and regulatory considerations towards enhancing immunoassay standardisation and regulatory relevance.

Agreed actions:

Develop a technical roadmap for immunoassay standardisation to guide research, funding, and regulatory priorities, using reports from x2 SAVAC immunoassay meetings and structured interviews with stakeholders.

(Responsible person – tbc with all members of TAWG contributing within their field of expertise, experience and influence)

Funding Considerations

- MHRA identified as suitable lead for developing reference serum but requires external funding.
- Estimated costs range from £1-2million depending on scope, overheads, and inclusion of antigen acquisition.
- SAVAC will act to stress the importance of reference material for the field in order to support funding applications.
- SAVAC could act as applicant or endorsing body to leverage funding opportunities.

Summary Statement

The TWAG reaffirmed that its core, achievable contributions to the Strep A vaccine field are:

- Advocating for the delivering a universally available **polyclonal reference serum**.
- Establishing a **limited, well-characterised set of reference strains**.
- Publishing a consensus **technical roadmap** informed by structured stakeholder input.