DCVMN
Roadmap to future vaccines

End-to-end vaccines and vaccination from science to implementation from, for and in low- and middle-income countries and for the world
Looking back and currently

Manufacturing capacity moving from the ‘global north’ to the ‘global south’, particularly during the pandemic for all platforms other than mRNA
Stakeholders in the development to uptake continuum

• Developing vaccine candidates-academics, start-ups, vaccine companies

• Supporting the development of vaccine candidates- Funding agencies, government research agencies, funding philanthropies, CEPI

• Burden of disease estimates-academia, public health agencies

• Prioritization, policy- PDVAC, NTAGI, ITAG

• Recommendation-WHO, ITAG, NITAG

• Implementation, including impact/safety-Government and partners
Outline of a process for new vaccine product development-to-uptake of a vaccine intended for global use

**Discovery & preclinical**
- Academic Institutions, Biotech: e.g. Antigen/platform/assays/models for preclinical proof of concept and translation to the clinic

**Early clinical**
- Regulators: oversee the design of clinical study design and vaccine approval for use

**Clinical Proof-of-Concept**
- Vaccine impact modellers and epidemiologists: Model health and economic impact to guide development and investment

**Pivotal Efficacy study**
- WHO’s SAGE: review the data and evidence to support a global policy recommendation for use, considering e.g. cost effectiveness

**Registration**
- WHO PQ: e.g. considers quality (including GMP aspects), safety and efficacy programmatic fit

**WHO policy & PreQual.**
- WHO PQ: e.g. considers quality (including GMP aspects), safety and efficacy programmatic fit

**Effectiveness/Pharmacovigilance /Implementation**
- EPI managers and healthcare workers, can help to assess the acceptability and feasibility of vaccine delivery, in pre-implementation research

**Financing**
- Financing orgs** could be global, i.e. Gavi, or regional, i.e. PAHO Revolving Fund

**Procurement**
- Global organisations, e.g. Global Fund, USAID may support pilot or implementation/post-licensure effectiveness or pharmacovigilance studies

**Introduction**
- EPI managers and healthcare workers, develop a national immunization strategy and deliver the vaccine through the immunization programme

**Sustainable Supply**
- Implementation partners, e.g. Medicines sans Frontiers, International Red Cross, deliver the vaccines particularly in hard-to-reach areas and campaigns

**Academic Institutions, Biotech**
- e.g. Antigen/platform/assays/models for preclinical proof of concept and translation to the clinic

**Vaccine developers and manufacturers**
- e.g. as for academics/biotech; may in-license from academics/biotech or develop in house; includes process development, manufacturing scale up, sponsorship of regulatory submissions, clinical studies and licensure strategy

**Communities and civil society organisations**
- e.g. advocate / articulate demand for vaccines, participate in acceptability studies, inform vaccine parameters and aspects of clinical trial design and implementation / operational research

**Country (NITAG) and/or regional (RITAG) policy makers**
- * advise government, e.g. considering the public health need for the vaccine, cost effectiveness within the context of other interventions

**Vaccine R&D funders and product development partners**, e.g., BMGF, NIAID, Wellcome Trust, IAVI, PATH

**Global procurement agencies**, e.g. UNICEF, develops tenders and pricing strategies

**Ministry of health and Ministry of Finance within countries**
- determine whether or not to procure a vaccine, vaccine either through UNICEF or bilaterally

**SAGE: Strategic Advisory Group of Experts; PQ: Prequalification BMGF: Bill & Melinda Gates Foundation; NIAID: National Institute of Allergy and Infectious Diseases, PHAHO: Pan-African health organisation**

*National immunization technical advisory committee (NITAG); Regional immunization technical advisory committee (RITAG); ** Financing by Gavi and PAHO Revolving Fund is contingent on WHO Prequalification and policy recommendation
Which new vaccines need to be developed and deployed?

• At country level-disease burden estimates
• At global level-what is the threat? WHO’s R & D Blueprint, CEPI, BARDA, etc

• But implementation in routine immunization and implementation in a pandemic are very different
Comparing development to uptake for two important diseases

**COVID-19**
- Global disease burden
- Urgent need for vaccines recognized globally
- Multiple manufacturers, multiple platforms
- Regulatory facilitation
- Rapid clinical trials and EUA/EUL
- Rapid implementation

**Tuberculosis**
- Unevenly distributed disease burden
- No new product for nearly a century
- Difficulty in identifying manufacturers for potential new candidates
- Standard regulatory pathway but challenges in target populations, outcome definitions in endemic areas
- Clinical trials long
- Implementation?? Given existing vaccine and likely moderate efficacy?
Context for the need for Evidence Considerations for Vaccine Policy (ECVP)

Preferred Product Characteristics: (PPC): defines product attributes for LMIC use

Scientific advice meetings: Data on safety, quality and efficacy for licensure

Vaccine Product (priority popln)
Vaccine Delivery
Vaccination (other target population)
Regulatory Strategy Considerations to facilitate policy review
Implementation Considerations (introduction/program implementation, data used in Gavi VIS)

EVIDENCE CONSIDERATIONS FOR VACCINE POLICY: evidence anticipated to facilitate global policy recommendations developed before phase III clinical studies

SAGE Evidence to Recommendation framework

WHO Position paper

Summary

• Science has accelerated at a previously unimagined pace
• We have the opportunity to make new vaccines, and manufacturers have demonstrated their ability to scale
• Between science and manufacturing, and manufacturing and implementation are areas where we need to ensure that gaps are identified and have begun to be bridged before the need

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