GVIRF 2016: Gavi's Vaccine Investment Strategy (VIS)	
Rapporteurs: Justin Ortiz	
Session Outline	**Chair:** Helen Rees (U. of Witwatersrand) **Opening remarks:** Judith Kallenberg (Gavi): How does Gavi make vaccine investment decisions? **Presentations:** • Bernadette Abela Ridder (WHO): **Rabies vaccines:** How has the VIS process influenced the vaccine research agenda? • Saad Omer (Emory U.): **Maternal influenza vaccines**: How has the VIS process influenced the vaccine research agenda? **Discussants:** • Seth Berkley (Gavi) • Kate O'Brien (Johns Hopkins U.) **Closing Remarks**: Helen Rees (U. of Witwatersrand)
Objectives of the session	• To discuss the methodology used in the VIS to prioritise vaccines for Gavi support and data and information needs for a comparative assessment and decision-making. • To discuss reasons why some vaccines have not been shortlisted for Gavi support in the past, drawing on examples from rabies and influenza vaccines, and to review how the VIS process has influenced the vaccine research and development agenda. • To discuss potential research priorities to support future Gavi decisions and ways to engage the research community in the next VIS process that starts in 2017.
Main outcome	• The VIS process is widely supported and transparency and inclusiveness appreciated. • VIS decisions have helped to focus the research agendas for vaccines that were not prioritised due to lack of evidence. Going forward, Gavi should signal data gaps even earlier. • Lack of evidence on 'real life' implementation feasibility and impact of new vaccines, without proof of concept in high-income countries, hampers their assessment in Gavi's VIS and could slow down access. • There is a need for new global health partnerships to support post-licensure research on vaccines in low-income settings.
Summary (400-500 words)	The Gavi Vaccine Investment Strategy (VIS) is an evidence-based approach to identifying potential new vaccine priorities for Gavi support. The process involves a review of relevant vaccine and disease evidence, stakeholder consultations, and independent expert advice. It occurs once every five years, and is aligned with the fundraising cycle. The VIS process relies on researchers and public health professionals to generate the quantitative and qualitative data necessary to assess the relative value of different vaccines for potential Gavi support, in absolute terms and in comparison to alternative vaccine investments across a number of criteria. Through its investment reviews, Gavi has learned a number of critical lessons. The varied data availability and data quality for vaccines under review has proven a challenge for comparisons. There are uncertainties regarding projections for pipeline vaccines, such as typhoid conjugate vaccines. And

	there remain critical evidence gaps for "neglected vaccines," such as rabies vaccines VIS process receives high praise for its transparency and inclusiveness. Vaccines expected to be reviewed in the next VIS will be different from previous rounds: more regionally focused, lower (mortality) impact than others in Gavi's current portfolio, and several opportunities for the maternal vaccine platform. Gavi's increased emphasis on coverage and equity issues is an important strategic shift, as is the increasing global focus on emerging infectious diseases, outbreak preparedness and response. Gavi's research investment in rabies vaccines will help inform the next VIS with more robust data on burden and unmet need. Vaccine delivery for post-exposure prophylaxis remains challenging for the most underserved communities. While exciting data on reduction of maternal and newborn influenza disease was reviewed in the last VIS, there was insufficient evidence for Gavi to make a decision. Much work is now ongoing to better understand health impact of maternal influenza vaccination, supply and delivery logistics, and regulatory and policy needs. At present Gavi supports vaccine purchase, some health system strengthening, and limited research, but there are no funds to robustly evaluate program impact. The transition from trials to implementation in Gavi-eligible countries is a somewhat immature step in the process of bringing vaccines to scale. The time of 'slam dunk' vaccines that have been used successfully in high-income settings and can be rolled out rapidly in low-income countries may be over (e.g. RTS,S, dengue). There is a need for new partnerships and funding for post-licensure impact/implementation studies in developing countries to enable and limit delays in vaccine use. While the VIS is a useful framework for highlighting the evidence needed to inform vaccine prioritization for Gavi, earlier and more intentional communicating of key gaps will help the research and development community to prioritize these gaps for evidence generation. Finally, it is important to consider that while Gavi will continue to review new vaccines, enhanced coverage of existing vaccines could generate more impact than another new vaccine.
Key references or quotes (up to 5)	We do not yet have a mature approach to the post-policy phase where assessments of routine use impact should be done. Unlike high income countries where national governments are typically articulating the body of evidence needed to assess a new vaccine introduction, Gavi countries have neither domestic financial/technical capacity (usually), nor is there an entity whose mandate it is to assure a sensible portfolio of post-introduction assessments including disease impact are designed, implemented and funded. This limits the available evidence to inform country policy decision making and SAGE's ability to make tailored policy recommendations'