GVIRF 2014: Preferred Product Characteristics (PPC) as a way to guide development of products of high public health utility	
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Session Outline	**Chair:** Gerd Zettlmeissl **Opening remarks:** Vasee Moorthy (WHO): *What are WHO Preferred Product Characteristics (and what they are not)* **Presentations:** Claudio Lanata: *Case study 1: Key obstacles to RSV vaccine development for low and middle income countries. Role of WHO preferred product characteristics* Florian Schödel: *Case study 2: Key obstacles to Group A Streptococcus vaccine development for low and middle income countries. Role of WHO preferred product characteristics* David Kaslow: *What do WHO PPCs have to offer: the product developer's perspective, reducing risk, clarifying target groups and intended applications* **Discussants:** Above and Rosanna Lagos **Closing Remarks**: Gerd Zettlmeissl
Objectives of the session	Discuss rationale for development of WHO PPC generically and using two vaccine targets as examples (RSV and Group A streptococcus)
Main outcome	PCCs were presented as a high level roadmap for vaccine R&D based on public health needs. Discussants and audience participants agreed that WHO's PPC concept is a promising approach to stimulate vaccine development for priority diseases.
Summary	The concept of WHO Preferred Product Characteristics (PPCs) was introduced and defined as a WHO document that would provide guidance for early stage Research and Development for products that will meet priority public health needs with a focus on low- and middle-income countries. The PPC would provide information at an early stage of development, e.g. 5-10 years before any products could become available; they would in no way replace a WHO policy recommendation or pre-qualification process. The first goal of a PPC is to identify vaccines that align with public health goals and ensure there is a bona fide need for the vaccine. This goal is achieved through a narrative on the desired public health application of a future vaccine, including geographical distribution of need, target groups, disease control vs. elimination strategies, key considerations for safety and efficacy data, and important endpoints for pivotal trials from a policy perspective. The second goal of PPCs is to translate the vision, strategic goals, and milestones from a vaccine development roadmap into technically relevant details to help guide product development, and will thus be a key strategic development process tool. Note that PPCs will help guide development to the stage of proof-of-concept and are a precursor for the product specific Target Product Profiles (TPPs). PPCs will not cover topics such as programmatic suitability, thermostability, packaging, etc., which is considered by other WHO entities. No WHO PPCs are available yet, although one is in progress for malaria vaccines. A new WHO advisory committee, the Product Development for Vaccines Advisory Committee (PDVAC) will help oversee the process. Two disease case studies, Respiratory Syncytial Virus (RSV) and Group A streptococcus, were presented to highlight some of the challenges and opportunities for new product development. RSV is a major contributor to childhood morbidity and mortality around the world. Of the estimated 65,590 – 253,000 deaths that occur annually, 99% are in developing countries. Six vaccine candidates are currently in Phase I and II trials. Unfortunately, product development has been slow due to an earlier chemically inactivated virus vaccine candidate that caused enhanced disease. Additional challenges include the early age of RSV infection, its capacity to evade the innate immune response, the lack of natural life-long protection following natural infection, and a lack of animal models. Maternal immunization needs further exploration, although the licensing

	pathways may be complicated. Discussions reaffirmed the need for a PPC to identify the ideal path to protect neonates and focus limited resources on the most appropriate vaccine or vaccines. Group A streptococcus causes an estimated 345,000 deaths annually due to conditions such as rheumatic heart disease later in life. Challenges to vaccine development include a low attributable burden of disease, safety concerns following a historical candidate that may have increased rheumatic heart disease, serotype diversity, and questionable commercial interest. However, there are many vaccine candidates in nonclinical trials and one clinical trial likely to begin in 2014. Whether initial efficacy estimates for licensure could be based on strep throat, with future follow up of rheumatic heart disease, remains to be seen. Discussions reaffirmed the need for a PPC to identify and prioritize vaccine clinical efficacy endpoints such as prevention of strep throat, pneumonia, and/or prevention of rheumatic heart disease. Discussants and audience participants agreed that WHO's PPC concept is a promising approach to stimulate vaccine development for priority diseases. PPCs will help to define the right areas and indications for product development and to stimulate interest among developers. WHO guidance early in the vaccine development process is important. As it is a new activity it will be a learning process but should result in good PPCs in the near future.
Key references or quotes	PPCs are WHO documents providing guidance for early stage vaccine R&D for products that meet priority public health needs with a focus on low and middle income countries. Claudio: It is very important that WHO send a signal to the external community that they want a vaccine for where the burden is. Florian: Guidance should not come after the 1st generation product. That is too expensive. Working together prospectively to do guidance early on is the right thing to do. David: PPCs will help identify vaccine products that WHO wants to use if they can be developed.