2020 WHO Product Development for Vaccines Advisory Committee (PDVAC)
Virtual Consultation 5: The Vaccine Innovation Prioritisation Strategy (VIPS)
8 July 2020

Participants:

PDVAC: Isabelle Bekeredjian-Ding (for Klaus Cichutek), Sinead Delany-Moretlwe, Bernard Fritzell, Gagandeep (Cherry) Kang, Ruth Karron, David Kaslow (PDVAC Chair), Jerome Kim, Claudio Lanata, Shabir Mahdi, Yiming Shao, Beno Nyam Yakubu; Mark Papania, Alejandro Cravioto (SAGE chair, ex-officio member)

Apologies: Barney Graham, Peter Smith, Marian Wentworth

WHO: Birgitte Giersing, Mateusz Hasso-Agopsowicz, Erin Sparrow, Siobhan Botwright, Richard Isbrucker, Martin Friede

Observers and non-member participants:

Executive Summary

*Rationale for topic: Innovative approaches are needed to address immunisation barriers and achieve global immunisation coverage and equity goals. The **Vaccine Innovation Prioritisation Strategy (VIPS)** represents an unprecedented three-year collaboration between the Gavi Secretariat, World Health Organization (WHO), Bill & Melinda Gates Foundation (BMGF), United Nations Children's Fund (UNICEF) and PATH – known as the VIPS Alliance - to develop a single integrated framework to evaluate and prioritise innovations in vaccine product delivery, and to drive these innovations forward. The VIPS process concluded in May 2020 with a decision to prioritise 3 innovations / approaches that the Alliance will continue to engage to advance development, policy, and access. The intent of this PDVAC session is to communicate to the vaccine R&D community the VIPS decision-making outcome and the rationale for the selection of the prioritised innovations / approaches, and to raise awareness of desirable product presentation attributes, from a low- and middle-income country perspective, and their impact on programmatic delivery considerations for pipeline vaccines.*

PDVAC Conclusions and Recommendations:

- *The VIPS process and outcomes are fully endorsed by PDVAC. PDVAC undertakes to support and promote communication of these priorities in its activities, including in development of preferred product characteristics (PPCs) and target product profiles (TPPs) for new and next generation vaccines.*
    - *The development of PPCs and TPPs for outbreak pathogens is under the remit of the WHO R&D Blueprint; however, PDVAC should provide comments during the consultation stage.*
- *PDVAC was encouraged by the progress made in manufacturing development of micro-array patches (MAPs) (higher throughput, potential for scalability, and interest from at least one multi-national company). However, ongoing consultation with manufacturing stakeholders, to understand the current barriers and identify concretely what incentives are needed to engage over the long term, remains critical to continue advancing this innovation towards transforming vaccine delivery in LMICs.*

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- *Development of a Full Value of Vaccines Assessment (FVVA) for novel delivery technologies will be needed to facilitate manufacturers' investment decisions, shape the market, and advance the application of these technologies, particularly to vaccines targeted to LMICs.*
    - *Fundamental to the FVVA and market shaping is the need to define the value of the innovation at the country level, and establish willingness to pay*
    - *With respect to MAPs, the value assessment may be improved by considering the application of this technology to small molecules/therapeutics*
- *The next phase of VIPS (5-year horizon) presents an opportunity to leverage investments in innovations that will be advanced for COVID-19 vaccine development, policy recommendation, and deployment. Close collaboration with initiatives driving COVID-19 vaccine development is encouraged.*
- *VIPS should prioritise vaccines that have a potential dual market to enable early engagement with national regulatory authorities (NRAs), such as the US FDA and EMA, particularly for novel technologies that lack regulatory precedence. Early engagement with high-income country, mature NRAs will accelerate articulation of regulatory expectations and harmonisation across less mature NRAs.*
- *In addition to early engagement and scientific advice meetings with the US FDA and EMA, VIPS should prioritise workshops with NRAs within LMICs to raise awareness of new innovations and accelerate the harmonisation of regulatory oversight.*
    - *The purpose and outcomes of VIPS should be presented as a workshop to the African Vaccine Regulatory Framework (AVAREF), the Southeast Asian Regulatory Network (SEARN) and other regional and international regulatory fora.*

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1. Context of the meeting

Vaccine product innovations offer important means to simplify logistics, increase the acceptability and safety of immunisation, minimise missed opportunities, and facilitate outreach. There is increasing recognition of the need to employ targeted solutions to extend vaccine access to reach the unreached.

The scope of VIPS includes completely new product presentations and packaging, or adaptations to existing products that could provide measurable financial or programmatic benefits to LMICs, such as increased coverage and equity, or vaccine effectiveness.

The VIPS process involved in-depth research, stakeholder consultations, and development and application of a methodology capable of evaluating a variety of technologies at different stages along the product development pipeline continuum. The approach required understanding countries' needs to consider the expected impacts of innovations; developing common principles across the Alliance to assess the long-term benefits of those innovations; and convening a platform of stakeholders to articulate a clear and aligned perspective on priorities. By prioritising innovations in vaccine products, the goal of VIPS is to provide greater clarity to manufacturers and partners to inform and influence investment decisions. VIPS outcomes also represent a catalyst to mobilise key decision-makers and funders and to chart a strategic pathway forward for the prioritised innovations.

The VIPS process was designed and implemented by a working group composed of members from each of the VIPS partners, with oversight from an expert steering committee. The process concluded in May 2020 with a decision to prioritise 3 innovations / approaches for which the Alliance will engage to advance development, policy, and access:

- **Microarray patches** – an upstream novel delivery device;
- **Heat stable and Controlled Temperature Chain qualified vaccines** - a combined formulation, regulatory, and novel programmatic approach to vaccine management;
- **Barcodes on primary packaging**- an implementation/system innovation

The next steps for the VIPS Alliance are to define end-to-end strategies for the 3 prioritised innovations, including developing clear action plans to accelerate their advancement to uptake and impact.

Objectives of the meeting:

- To inform vaccine development stakeholders about the VIPS process and prioritisation outcomes;
- To discuss if and how these outcomes could be incorporated into product development strategies for pipeline vaccines;
- To identify ways to promote awareness of desirable product presentation attributes and their impact on programmatic delivery considerations for pipeline vaccines

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3. Meeting summary

3.1 *The rationale for VIPS (Birgitte Giersing, WHO)*

Immunisation programmes will fail to reach more than 19 million children in 2020, mainly in sub-Saharan Africa and Asia. Immunisation coverage has plateaued over the last decade and we are struggling to reach coverage goals; eradication targets for diseases such as polio and measles remain out of reach. Immunisation challenges affect both Gavi-supported low-income and non-supported middle-income countries – 60% of the children at risk reside in the lowest socio-economic groups of 10 countries that are highly populated, most with the weakest health system infrastructures. New vaccine delivery strategies and technologies are urgently needed to reach these hard-to-reach, and sometimes inaccessible populations, and likely to become more of an urgent need in the era of the COVID-19 pandemic. The next decade will need to see a shift to differentiated products being used in the same country to improve the levels of equitable coverage.

Several vaccine delivery innovations have been developed, licensed, and prequalified (PQ'd) in the past two decades. The disposable syringe jet injector and the Uniject have been PD'd for some years, but uptake and impact in immunisation programmes has been low. Numerous vaccines may be suitable for delivery within the controlled temperature chain (CTC), but to date only a handful have been CTC-qualified and delivered using this strategy. The microarray patch has been promoted as a potential 'gamechanger' for vaccine delivery in resource-constrained settings, yet, until recently, development with vaccines for which they could have the most impact had barely progressed in the past 10 years.

When it comes to product selection at the country level, this low level of uptake could be because novel vaccine products do not appropriately reflect country preferences, priorities or programmatic fit, or because there is insufficient data to demonstrate a clear use case and incremental impact, particularly if the vaccine is more costly than for existing vaccines. In addition, there is currently no commitment or mechanism to procure these novel vaccines products. From the perspective of vaccine manufacturers and innovation developers, this can translate into a lack of incentive to invest in development of novel vaccine products, particularly when effective, low cost vaccines already exist. The demand and development pathway for new vaccines and innovative products is often not clear, presenting risk and opportunity cost, reinforced by a lack of commitment or mechanism for procurement.

Prior to VIPS, although all the constituent VIPS Alliance partners were engaging in developing or advocating for new vaccine delivery technologies and approaches, there was no robust, aligned process for evaluating and communicating a set of priority innovations, or cohesive strategy to advance them. In this context, the aim of VIPS is therefore to *pursue a common agenda of driving vaccine product innovation to better meet country needs*, and specifically to prioritise innovations in vaccine delivery attributes. The goal is to *provide greater clarity to manufacturers and immunisation partners to make investment decisions* and drive these priority innovations forward towards uptake and impact. On forming the VIPS collaboration, one of the key underlying principles was to ensure that innovations would be evaluated through the lens of the country immunisation barriers, to ensure that the prioritisation process is driven to address the most prevalent programmatic delivery challenges and country needs.

Key questions for PDVAC discussion:

- Does PDVAC support the VIPS prioritisation process and outcomes?
- How can we promote the need to optimise product presentation, i.e. thermostability, for pipeline vaccines?
- What opportunities are there to include novel delivery technologies in the development of pipeline products, and what are the implications of this?

3.2 *An overview of the VIPS prioritisation process and next steps (Marion Menozzi-Arnaud, Gavi)*

The VIPS prioritisation process is summarised in Figure 1 and consisted of two phases:

- phase I consisted of a landscaping and scoping exercise, informed by partner and expert consultations, that enabled the identification of 24 innovations for consideration. These included existing and potential future vaccine product innovations that could provide measurable financial or programmatic benefits to low-and-middle-income countries (LMICs). This initial list of 24 innovations were evaluated based on their characteristics or design features and potential public health value, as well as their potential 'breadth of use' (applicability to several antigens). The public health value aspect was informed by an extensive country consultation to better understand barriers to immunisation. This phase culminated with the identification of 9 innovations for further analysis in combination with representative priority vaccines in phase II.

- phase II during which 9 shortlisted innovations from phase I were analysed in the context of a set of representative priority vaccines to identify the final list of three vaccine product innovations that were determined to have the highest potential to address immunisation issues.

Phase I was presented to PDVAC previously; this presentation focused on phase II and the rationale for the final prioritisation outcomes.

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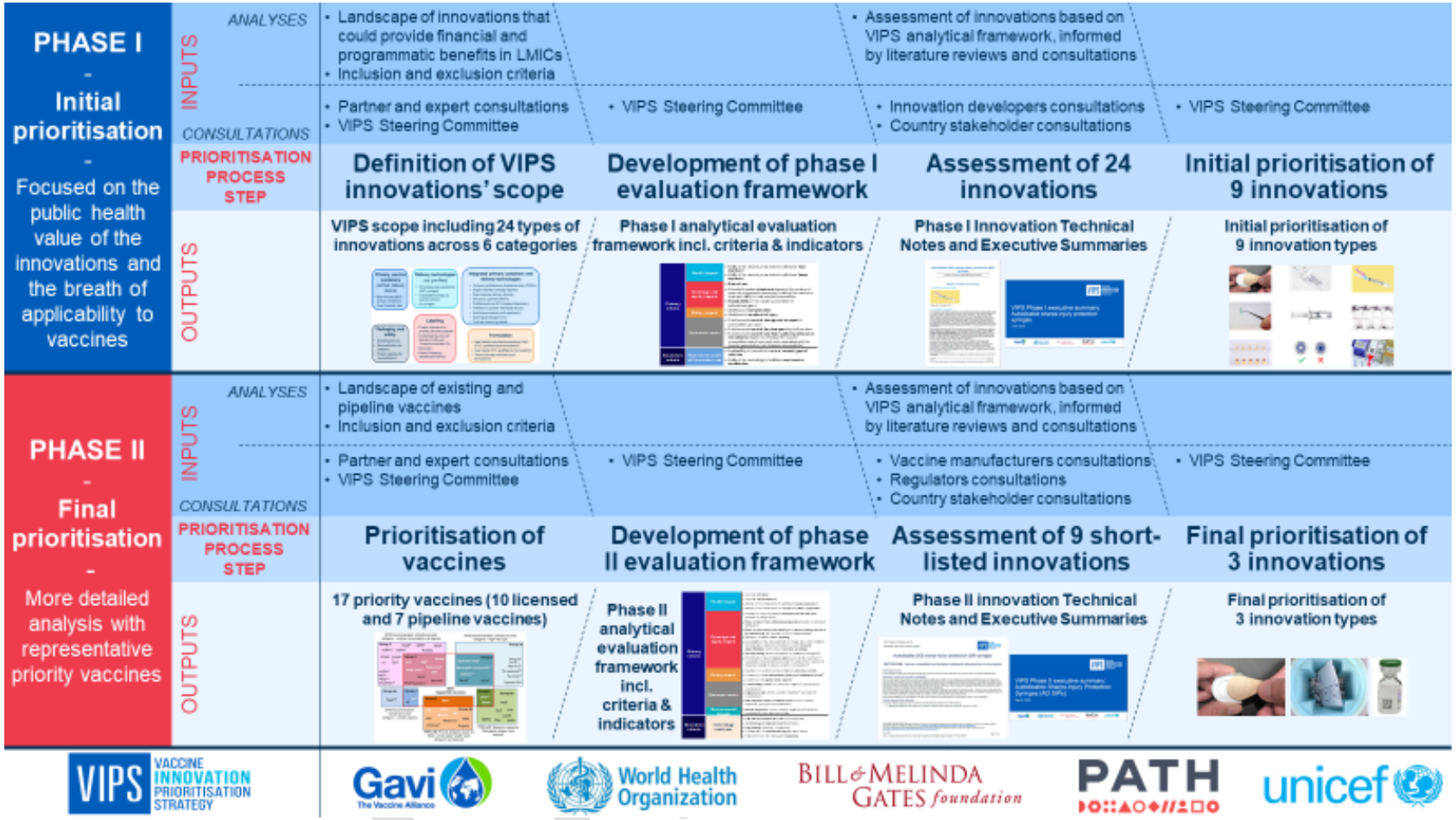

The phase I analytical framework was further expanded for the phase II assessment, given that the phase II assessment was conducted for each vaccine-innovation combination which allowed for greater specificity and deeper analysis. An additional primary criterion was added on environmental impact, aimed at assessing the potential impact of vaccine product innovations on waste management. Two new secondary criteria were also added: technology readiness; and commercial feasibility. The technology readiness criterion assessed the innovation's development status (i.e., clinical development status and regulatory, technological and manufacturing complexity), while the commercial feasibility criterion assessed the commercial opportunity for the innovation (i.e., potential market, country stakeholder interest, existence of partnerships, Intellectual Property barriers).

Two country consultations in the form of an online survey and in-depth interviews were conducted to support the assessment of the 9 shortlisted innovations. In the online survey, immunisation experts were provided with a standard list of challenges developed for the 10 licensed priority vaccines and were asked to select the top three challenges for all vaccines they had knowledge about. The survey was targeted to experts in vaccination strategies and existing vaccine products in both Gavi-supported and non-Gavi supported-countries as well as global experts. The top five challenges for each vaccine based on frequency of selection (the number of times a challenge was selected as a top three challenge by respondents from a list of 11 challenges) were reported in the assessments as 'vaccine problem statements' and the ability of the innovation to address them was assessed. In addition, 84 immunisation staff and decision makers were interviewed across 6 countries: Ethiopia, Mozambique, Nepal, Nigeria, Senegal and Uganda to collect feedback on the 9 shortlisted VIPS innovations. Interviewees were first briefed about each innovation (with no information provided on benefits and challenges), and then, per innovation, were asked open-ended questions about foreseen benefits and challenges and specific vaccines for which each innovation could be particularly useful. Lastly, they were asked to select the top three innovations that have the greatest potential to address their immunisation programme challenges.

Vaccine manufacturers were consulted though the WHO- and PATH-led Delivery Technologies Working Group (DTWG), consisting of a broader set of immunisation stakeholders including industry experts, with the objective to collect feedback on the specific innovations. Following a presentation on each of the innovations, DTWG members were asked to complete an on-line survey focused on the technology readiness and commercial feasibility. This feedback was used to inform the assessment of these VIPS phase II secondary criteria.

Lastly, the VIPS WG also engaged in early consultations with several regulators and regulatory consultants to inform the secondary criteria on technology readiness, and specifically the VIPS WG's assessment of assumptions related to endpoints/surrogate markers for vaccines and the complexity of clinical development used in evaluation of vaccine-innovation products.

The VIPS WG also ensured communication with WHO committees (PDVAC, IPAC, SAGE) throughout the prioritisation process, as well as other organisations such as CEPI, Wellcome, IFPMA and DCVMN.

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The finalisation of the VIPS prioritisation process was during the COVID-19 pandemic. Although the primary goal of VIPS was to prioritise innovations that would ensure access and increase coverage for existing vaccines, the VIPS WG sought to identify 'win-win' scenarios, i.e., to prioritise innovations that would also be valuable for COVID-19 vaccine delivery. The COVID-19 pandemic has created potential funding opportunities for innovations that are relevant for both COVID-19 and other priority vaccines, that could accelerate their product development and/or implementation. This will become even more important in light of the impact of COVID-19 on routine immunization services and the likely future increase of supplemental and outreach immunisation activities that will be needed to catch-up millions of children who will miss out on essential services during this pandemic.

Three innovations were ultimately selected for which VIPS will engage in advancing their development and access:

1. **Microarray patches (MAPs):**
   MAPs are seen as truly 'transformational' innovations that have the potential to address many immunisation barriers identified by countries due to their improved thermostability; better ease of use; avoidance of reconstitution and the associated errors and risks; improved safety (as they are sharps-free); and the fact that they are single-dose presentations, thereby avoiding missed opportunities due to reluctance to open a multi-dose vial. Additionally, MAPs are applicable to a number of use cases including routine, supplemental, house-to-house, and outbreak immunisation. Therefore, development of MAPs should be encouraged for use with several vaccines, including pipeline vaccines and those with elimination and eradication agendas. They are also innovations that may have a positive impact on 'life-course' immunization for broader populations beyond children, including adolescents, adults, and older adults. While MAPs are unlikely to be ready for implementation with first generation COVID-19 vaccines developed in response to the current pandemic, they could be co-developed with vaccines to be positioned for future emergency response, or for use with COVID-19 vaccines in the longer term. However, it was noted that there are still significant technical, biological, and commercial barriers to overcome before MAPs can be implemented, particularly for vaccines intended for use in low resource settings, which will require substantial funding. Additionally, it is not known whether the prices for vaccines on MAPs will be acceptable to end-users, despite the expectation that they may reduce costs at the delivery level and assist with overcoming immunisation barriers.

2. **Heat stable and Controlled Temperature Chain (CTC)[1] -qualified vaccines:**
   Thermostability was identified as the top priority by countries consulted on barriers to immunisation and this innovation directly addresses equity concerns by virtue of improving access to harder to reach communities and offering relief and flexibilities to health care workers burdened by cold chain constraints. As such, the Alliance has prioritised heat stable and CTC-qualified vaccines, including both liquid and dry formulations. Enhanced thermostability is a desirable feature for all vaccines to improve vaccine effectiveness and, where possible and appropriate, to enable higher temperature storage and

[1] CTC-qualified vaccines are approved by regulatory authorities and WHO for use up to a specified threshold temperature for a **minimum** of 3 days prior to administration.

transport in a CTC. Vaccine candidates for CTC use, whether liquid or dry, should have the following attributes: adequate heat stability to achieve regulatory and WHO prequalification for CTC with the longest CTC duration possible (e.g., days, weeks or months), contexts of use that benefit from CTC, and formats that do not increase vaccine wastage or safety risks when used in a CTC. Dry formulations are of interest, only if coupled with technologies that offer additional benefits such as removing the issues associated with manual reconstitution – as would be the case with dual delivery chamber devices, solid dose implants or MAPs. This innovation category is also synergistic with vaccine vial monitors with threshold indicators (VVM-Tis) to facilitate temperature monitoring. VVM-TIs could be further evaluated as part of a future scope. This innovation may be a relatively 'quick win' for existing thermostable vaccines and emerging pipeline vaccines. However, thermostability represents a higher hurdle for existing vaccines that would require reformulation; in such instances greater heat stability and/or CTC could be pursued if vaccines undergo reformulation for another reason.

3. **Barcodes on primary packaging:**
   Track and trace is considered a priority for vaccines on secondary packaging by Gavi and UNICEF and 2D barcodes on primary packaging would allow for greater accuracy in tracking vaccine products, especially when they are removed from their secondary packaging at lower levels of distribution. It would also support the eventual transition to electronic recordkeeping, in line with the objectives of advancing digital health in Primary Health Care. Barcodes on primary packaging are seen as highly valuable in terms of tracking inventory and immunisation coverage and follow-up of AEFIs, and this is particularly true for deployment of novel vaccines. While this is a mature technology in general, an analysis of the implications of barcodes on primary packaging and a 'push' for implementation based on the analysis of the implications could build upon the existing efforts to place barcodes on vaccine secondary packaging and spur wider implementation of systematic monitoring and surveillance systems. The COVID-19 pandemic may provide an opportunity to leverage investment to catalyse manufacturing of vaccines with barcodes and it was felt that VIPS may be the right avenue to help advocate and support the advancement of this technology. Implementation of barcodes for COVID-19 vaccines is likely not feasible for the current pandemic and the first vaccine deployments, but they may be for later phases of vaccine deployment; and while it will take time to ensure country readiness, a few countries with advanced electronic recordkeeping could benefit from their availability on secondary packaging almost immediately and on primary packaging in the coming years. There is a clear recognition that barcodes themselves are not an innovation but part of a broader innovation ecosystem that will need coordination and integration within the realms of vaccine standards, manufacturing, regulatory, procurement, distribution, and in-country recordkeeping. It was noted that to capture the full benefits from barcodes on primary packaging, electronic inventory and health records transitioning will be required in LMICs which could be a challenging and lengthy process in many countries.

The prioritised innovations are described in more detail on a VIPS page on the Gavi website available now at the following link: https://www.gavi.org/our-alliance/market-shaping/vaccine-innovation-prioritisation-strategy. This page also links to all the assessment documents for each innovation from

phase I and phase II, as well as an overview of the methodology of the whole VIPS process. Three publications are planned by the end of 2020:

- A methodology and outcomes document, summarising the VIPS process, methodology and final outcomes – also available on the VIPS page of the Gavi website
- A summary of the country consultations, including the methodology and results of the three country consultations conducted in phase I and II; submission planned for September 2020
- A perspective assessing strategically what is needed and the unique remit and role of VIPS to position delivery innovations for success; submission planned for the Fall 2020.

Beyond this prioritisation process, the VIPS Alliance WG is looking ahead at what is needed, and how the VIPS Alliance can help, to accelerate development and access of these innovations in LMICs. This focuses on three major workstreams:

1. Development of joint action plan per innovation: bilateral consultations with innovation developers, vaccine manufacturers and existing working group are underway to identify existing bottlenecks and the concrete activities that will help to advance these innovations over the next 5 years.
2. Creation of an enabling environment from the perspective of policy development, procurement mechanisms, and programmatic implications;
3. Creation of a continuous learning environment and evaluation mechanism to maintain horizon scanning of new data or new innovations that may be relevant to VIPS.

3.3 *Perspectives from WHO/IVB committee members, who are also VIPS Steering Committee members*

- *Mark Papania (CDC/PDVAC):*

The most sophisticated, highly immunogenic vaccines are not effective until they are delivered. Bringing trained vaccinators and refrigerated vaccines together with every person that needs vaccination is challenging in many corners of the globe. Logistical challenges to vaccine delivery are one major reason 15-20% of children remain unvaccinated every year.

The VIPS process has been a systematic analytical approach that will help to move the vaccine delivery field forward. It has identified and ranked key barriers to vaccine access, and potential technologies to address these barriers, focusing on both the country and global perspectives. Achieving equitable immunisation will come with a substantial cost; it will cost much more per child to reach the last 15-20% of children than it has to achieve 85% coverage. Novel delivery technologies, like MAPs, that allow minimally trained vaccinators to administer unrefrigerated unit dose vaccines without needles or reconstitution could be a key to reaching the unvaccinated. However, they will require significant investment to develop and may ultimately have a higher per dose cost. The challenge is develop partnerships to share the upfront costs of commercialization and implement pull mechanisms, such as advance purchase commitments, to encourage manufacturing to occur at a scale which results in per dose costs acceptable to end user countries. Current investments in COVID-19 vaccines represent an opportunity to advance equitable vaccine delivery technologies. With respect to PDVAC's role, we need

to keep vaccine delivery considerations in the forefront of our minds as we think about product development for every vaccine that we expect to reach children in LMICs. We should encourage integration of technologies that enable equitable delivery into vaccines in development as well as existing vaccines.

- *Kelly Moore* (Vanderbilt University, IPAC)

The VIPS process has been robust, well organised and effectively conveyed an enormous amount of information and data. It's been an unprecedented assessment genuinely driven by evidence and based on integrity – the incorporation of country feedback was crucial to driving the decision-making process.

There has been clear recognition of the rationalisation that is needed to drive the long-term strategy for these innovations, get them to the point of contributing to achieving coverage and equity goals. VIPS is composed of the right organisations who have demonstrated commitment and can influence the market place, by bringing their collective resources and strategic input. The impact of the COVID-19 pandemic upon the process is reflected particularly in the decision to incorporate 2-dimensional barcodes in the final prioritized group of interventions as an example of an innovation that could be incorporated into the investments being made in COVID-19 vaccines without requiring significant ongoing expense to expand to other vaccines. This has been a strong start but there is a lot to do beyond this initial phase.

- *Alejandro Cravioto (University of Mexico, SAGE Chair)*

The COVID-19 pandemic has revealed the fragility of immunisation services, particularly in low resource settings where healthcare workers are exposed to the risk of infection. As a consequence, we will see a leap in the number of unimmunised children in the coming months and years. This is why we need innovation more than ever to increase efficiency of delivery and vaccination. The cost related to these innovations might be high initially but ultimately will have impact in reducing other system related costs. We will need to quantify that to create demand.

The VIPS prioritisation process has already been validated to some extent, in the context of responding to the COVID-19 pandemic – since the three priorities have already been shown to be very relevant to shaping the candidates and delivery considerations. Indeed, this process could be applied to other innovations in the future.

3.4 *Overview of VIPS action plans (Julian Hickling, Working in Tandem)*

The next stage of the VIPS process is to prepare Action Plans (APs) for each of the 3 prioritised innovations. The AP for MAPs was considered as an exemplar, and similar APs are also being developed for heat stable and CTC vaccines and barcodes. This development of the APs involves soliciting views from key stakeholders involved in MAP product development; both MAP developers and vaccine manufacturers to understand their perspectives. In particular we are exploring challenges and barriers that face development of MAP for use in LMICs, and ways in which the VIPS Alliance partners can help address these barriers and help accelerate time to market and uptake. This information will inform specific activities within the AP.

The bilateral consultations focus on 4 key areas.

1. Vision: What is the 5-year goal for the innovation?

		General and company-specific strategy related to the innovation
		What has been, or will be the impact of COVID-19? (potential accelerator?)
2.	Challenges:	Technical, manufacturing, regulatory, commercial challenges
		Potential solutions to challenges/barriers
		Proposed roles for Alliance partners
3.	Vaccines:	Priority targets
		Factors influencing the choice of those targets
		Option on products for global health/LMICs use
4.	Commercial:	Commercial attractiveness of MAPs; key drivers
		Time to first MAP-vaccine product for LMICs
		Approaches to accelerate time to first product

The intent to have these actions plans developed and aligned with VIPS partners by the end of 2020 for implementation in 2021.

4.0 General discussion:

Q: Will there be access to the data and synthesis of information?

Since the meeting, the VIPS WG has finalised a manuscript that details the entire methodology, for submission to a peer reviewed journal in the coming weeks. A version of this, in addition to the technical notes on each of 24 innovations, and the executive summaries of these, have been uploaded onto a dedicated VIPS page on the Gavi website (see link above).

Q: Is infrastructure being put in place at the country level to use innovations such as scanners for reading barcodes?

The major challenge of implementing barcodes into vaccine packaging is integrating their use into, and promoting, electronic medical records systems. So, this will entail a broader systems wide effort that will need consultation and co-ordination to figure out the potential role that VIPS could play and will take time.

Barcodes will be essential for deployment of electronic immunisation cards, and some countries, such as Peru, are ready for that step.

Part of the rationalisation for barcodes on primary packaging is based on the notion that, if standardized barcodes were a prerequisite, countries' future opportunities to expand electronic medical records and digitizing would not be constrained by the absence of barcodes.

Q: *Have WHO and partners developed a TPP for a future SARS-CoV-2 vaccine. If not, could it be adapted to MAPs? Has PDVAC been or will be involved in such discussions?*

A TPP for COVID-19 vaccines has been developed by the R&D Blueprint:
https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines

PDVAC recently reviewed it and proposed some considerations for the next iteration.

Q: Are there any funding opportunities to support/ partners with manufacturers who might want to develop innovations that are specifically for LMICs?

VIPS is not a funding body, but the Action Plans that emerge may include a remit to support with facilitating potential partnerships between vaccine manufacturers and innovators.

Q: On COVID-19 vaccines, clinical trials registries do not include information on storage conditions and delivery systems of those vaccine candidates. Is there any information available, are some of these candidates already using or introducing some of these innovative characteristics? Has the Group approached developers of these candidates for the introduction of these innovations? Otherwise, these developers would need to develop other extensive post-licensure / authorization trials

Comment: The pace and scope are unprecedented with respect to accelerating novel manufacturing platforms, including novel formulations, presentations, and new product images. To some extent this is being driven by the global glass shortage, driving discussions related to large volume multi-dose formats and the trade-offs with wastage in the context of preservative free formulations. This assessment is especially complex given the number of candidates in development and the uncertainly with respect to the probability of technical and regulatory success. Input from PDVAC and VIPS is being sought on which technologies, presentations and images are appropriate to drive forward now – particularly in light of sub-optimal cold chain requirements for example - and which are more suitable for next generation vaccines that may be 2-3 years down the track.

Q: are there strategies for synergy in MAP development across vaccine antigens?

Formulation of each vaccine needs to be developed and optimised for compatibility to the specific MAP format but as more work is done on this, the learnings can be applied to vaccines of the same type to accelerate development of a broader portfolio.

Please note: for any entity wishing to be involved in consultation to develop Actions Plans for any of the three priority innovations, please contact Birgitte Giersing (giersingb@who.int).

5.0 Closed discussion and PDVAC recommendations:

- *The VIPS process and outcomes are fully endorsed by PDVAC. PDVAC undertakes to support and promote communication of these priorities in its activities, including in development of preferred product characteristics (PPCs) and target product profiles (TPPs) for new and next generation vaccines.*
    - *The development of PPCs and TPPs for outbreak pathogens is under the remit of the WHO R&D Blueprint; however, PDVAC should provide comments during the consultation stage.*
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- *Development of a Full Value of Vaccines Assessment (FVVA) for novel delivery technologies will be needed to facilitate manufacturers' investment decisions, shape the market, and advance the application of these technologies, particularly to vaccines targeted to LMICs.*
    - *Fundamental to the FVVA and market shaping is the need to define the value of the innovation at the country level, and establish willingness to pay*
    - *With respect to MAPs, the value assessment may be improved by considering the application of this technology to small molecules/therapeutics*
- *The next phase of VIPS (5-year horizon) presents an opportunity to leverage investments in innovations that will be advanced for COVID-19 vaccine development, policy recommendation, and deployment. Close collaboration with initiatives driving COVID-19 vaccine development is encouraged.*
- *VIPS should prioritise vaccines that have a potential dual market to enable early engagement with national regulatory authorities (NRAs), such as the US FDA and EMA, particularly for novel technologies that lack regulatory precedence. Early engagement with high-income country, mature NRAs will accelerate articulation of regulatory expectations and harmonisation across less mature NRAs.*
- *In addition to early engagement and scientific advice meetings with the US FDA and EMA, VIPS should prioritise workshops with NRAs within LMICs to raise awareness of new innovations and accelerate the harmonisation of regulatory oversight.*
    - *The purpose and outcomes of VIPS should be presented as a workshop to the African Vaccine Regulatory Framework (AVAREF), the Southeast Asian Regulatory Network (SEARN) and other regional and international regulatory fora.*
-