Gavi Alliance Programme and Policy Committee Meeting

26-27 May 2020
Virtual Meeting

Tuesday 26 May: 14.00-18.00 (Geneva time)
Wednesday 27 May: 14.00-18.00 (Geneva time)
Quorum: 9

Document list

No.	Document
00a	Document list
00b	Agenda
01a	Declarations of interest
01b	Minutes from 23-24 October 2019
01c	Workplan
02	CEO Update – No paper
03	Strategy: Progress, Challenges and Risks and implications of COVID-19 on Gavi 5.0 operationalisation
04	Review of the Gavi Gender Policy
05	COVID-19 Pandemic Response: An Alliance update
06	COVID-19 Pandemic: Vaccine Development, Access and Delivery
07	Gavi 5.0: Measurement Framework/Strategy indicators
08	*Review of decisions – No paper*
09	*Any other business – No paper*

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Agenda

DAY ONE – Tuesday 26 May

Item	Subject	Action	Schedule
1	**Chair's report** • Declarations of interest • Minutes • Workplan Helen Rees, Chair	**INFORMATION**	14.00-14.05
2	**CEO Update** Seth Berkley, CEO	**DISCUSSION**	14.05-15.00
3	**Strategy: Progress, Challenges and Risks and implications of COVID-19 on Gavi 5.0 operationalisation** Anuradha Gupta, Deputy CEO - *Gavi's approach to engagement with former and never-eligible Middle-Income Countries* - *Funding Policy Review*	**DECISION**	15.00-17.15
4	**Review of the Gavi Gender Policy** Wilson Mok, Head, Policy	**DECISION**	17.15-18.00

DAY TWO – Wednesday 27 May

Item	Subject	Action	Schedule
5	**COVID-19 Pandemic Response: An Alliance update** Santiago Cornejo, Director, Immunisation Financing & Sustainability Alex de Jonquieres, Director, Health Systems & Immunisation Strengthening Zeenat Patel, Head, Vaccine Implementation	GUIDANCE	14.00-15.30
6	**COVID-19 Pandemic: Vaccine Development, Access and Delivery** Wilson Mok, Head, Policy	GUIDANCE	15.30-16.45
7	**Gavi 5.0: Measurement Framework/Strategy indicators** Daniel Hogan, Head, Corporate Performance Monitoring & Measurement, Monitoring & Evaluation	GUIDANCE	16.45-17.55
8	**Review of decisions** Joanne Goetz, Head, Governance	INFORMATION	17.55-18.00
9	**Any other business**		18.00

Next Programme and Policy Committee Meeting: 28-29 October 2020, Geneva

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Meegan Murray-Lopez, Senior Manager, Governance, +41 22 909 2937, mmurraylopez@gavi.org

Please note that the meeting will be recorded. This recording will be used as an aid to minute the meeting. A transcription of the full proceedings will not normally be made. Should a transcription be made it will be used only as an aid to minute the meeting.

Gavi Alliance Programme and Policy Committee Meeting

26-27 May 2020, Virtual Meeting

Tuesday 6 May: 14.00-18.00 (Geneva time)
Wednesday 27 May: 14.00-18.00 (Geneva time)
Quorum: 9

Declarations of Interest

Declarations

Section 5.5 of the Conflicts of Interest Policy for Governance Bodies states “Members involved in decision-making processes on behalf of Gavi must take appropriate action to ensure disclosure of Interests and Conflicts of Interest and take the necessary action in respect thereof.”

Section 6.2 of the Conflicts of Interest Policy for Governance Bodies further states, “The duty to disclose [in 6.1 above] is a continuing obligation. This means that Members are obliged to disclose any Interests and/or Conflict of Interest, whenever the Member comes to know the relevant matter.”

The following declarations were made by members of the Programme and Policy Committee on their most recent annual statements:

Member	Organisational Interests	Financial/Personal/Advisor Int
Helen Rees, Chair	Chair, South African Health Products Regulatory Authority (SAHPRA) Board; Co-Chair, National Health Data Advisory and Coordinating Committee (HDACC); Member, South African National Advisory Group on Immunisation (NAGI) and focal point for HPV vaccines; Member, National Institute of Communicable Diseases Scientific Advisory Committee; Chair WHO AFRO Regional Immunization Technical Advisory Group (RITAG); Member, IHR Emergency Committee on COVID 19Chair, WHO International Health Regulations (IHR) Committee on Polio; Co-Chair WHO SAGE Working Group on Ebola Vaccines; Member SAGE Working Group on the Decade of Vaccines and Global Vaccine Action Plan; Member, WHO HSV Vaccine	None

Member	Organisational Interests	Financial/Personal/Advisor Int
Helen Rees, Chair	Advisory Group; Chair, WHO STI Vaccine Roadmap Expert Advisory Committee and advisor to WHO on STI vaccine research; Member, WHO's Cervical Cancer Elimination Expert Committee; Chair, Coalition for Epidemic Preparedness Innovations (CEPI) Scientific Advisory Board; Non-Voting Board member, Coalition for Epidemic Preparedness Innovations (CEPI); Member, Facilitation Committee COVID19 Clinical Research Coalition; Member USAID PEPFAR Scientific Advisory Board PrEP Expert Working Group; Chair, 'A Dose Reduction Immunobridging Study of two HPV vaccines in Tanzanian girls.' (DoRIS) London School of Hygiene and Tropical Medicine Trial; Member, Scientific Advisory Committee (SOC) Regional Scientific Hub in the WHO-AFRO region and Africa (VACFA-AFRO Hub Scoping Project SOC); Member, Wellcome Trust Expert Working Group, PREVENT (Pregnancy Research Ethics for Vaccines Epidemics and New Technologies) Project; Member, UNICEF and Bill and Melinda Gates Foundation Equity Reference Group for Immunisation; Chair, Bill and Melinda Gates Foundation HPV Vaccine One Dose Advisory Group; Member, The Sabin-Aspen Vaccine Science and Policy Group.	None
Violaine Mitchell	Bill and Melinda Gates Foundation (Deputy Director for Vaccine Delivery)	None
Michael Kent Ranson	The World Bank (Senior Economist, Health)	None

Member	Organisational Interests	Financial/Personal/Advisor Int
Robin Nandy	UNICEF (Principal Adviser and Chief of Immunization, Health Section, Programme Division)	None
Kate O'Brien	WHO (Professor-Department of International Health & Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, United States of America)	None
Ahmed Abdallah	Government of Comoros (AFRO Francophone)	National project coordinator COMPASS project financed by the WB Gavi-appointed special adviser
Vandana Gurnani	Government of India (SEARO/WPRU)	Gavi-appointed special adviser
Edna Yolani Bátres	Government of Honduras (AMRO/EURO)	Gavi-appointed special adviser
Kelechi Ohiri	Health Strategy and Delivery Foundation, Nigeria (AFRO Anglophone)	Gavi-appointed special adviser
Joan Valadou	Government of France (DE/FR/LU/EC/IE)	None
Lene Lothe	Government of Norway (NO/ NL/SE)	None
Susan Elden	Government of the UK (UK/QA)	Member of the GVAP Technical Working Group for WHO/SAGE
Naomi Dumbrell	Government of Australia (US/AU/JP/KR)	None
Joan Benson	IFPMA Merck (Executive Director, Public Health Partnerships, Global Vaccines Public Policy)	None
Mahima Datla	Developing Countries Vaccine Manufacturers Network (Biological E Ltd, Managing Director)	Biological E; ME; Vaccine Sales
Lubna Hashmat	CSOs	Civil Society Human and Institutional Development Programme - CHIP Chief Executive Officer 2007
William Schluter	Research & Technical Health Institutes Constituency (RTHI) Centers for Disease Control and Prevention (CDC), Director of the Global Immunization Division in the Center for Global Health	None

Member	Organisational Interests	Financial/Personal/Advisor Int
Seth Berkley (non-voting)	None	Professor, University of Geneva; Policy Advisory Board, Gilead Sciences; Board Member, ID2020; Member, Polio Oversight Board; Agency Head, Global Action Plan for Healthy Lives and Wellbeing for All (GAP)
Alejandro Cravioto	Independent expert	Strategic Advisory Group of Experts on Immunization of the World Health Organization (SAGE)

Participation

Section 6.2 of the Policy states, “During the course of a Board or Board Committee meeting, a Gavi Person with an actual, perceived or potential Conflict of Interest shall disclose the interest to the Chair of the meeting as soon as possible upon learning of a possible Conflict of Interest and in no event later than at the beginning of discussion of the pertinent agenda item.”

Section 6.3 states, “It shall be the prerogative of the Chair of the meeting, in consultation with the Managing Director, Law and Governance, as appropriate, to determine the scope and level of a conflicted person’s participation in the discussion and the necessity of recusal from voting given the type of interest disclosed. The minutes of the meeting shall reflect the conflicted member’s disclosure and whether the conflicted member participated in the discussion and/or abstained from voting.”

Minutes

Gavi Alliance Programme and Policy Committee Meeting
23-24 October 2019
Gavi Alliance Offices, Geneva, Switzerland

1. Chair's report

1.1 Finding a quorum of members present, the meeting commenced at 09.07 Geneva time on 23 October 2019. Helen Rees, Programme and Policy Committee (PPC) Chair, chaired the meeting.

1.2 The Chair gave a particular welcome to two PPC members who were attending their first PPC meeting: Naomi Dumbrell (US/Australia/Japan/South Korea constituency) and Joan Valadou (Germany/France/Luxembourg/European Commission/Ireland constituency).

1.3 She also informed the PPC that two members would join the meeting remotely: Violaine Mitchell (Bill and Melinda Gates Foundation) and Vandana Gurnani (India).

1.4 The Chair had approved two observers at this meeting. The first was an exceptional approval of Naoki Akahane from the Japanese mission in Geneva, following the launch of Gavi's replenishment case in Japan in August. The second was Nina Schwalbe, Chair of the Evaluation Advisory Committee. The Chair also indicated that two guests would attend portions of the meeting: Julian Schweitzer, Funding Policy Review Steering Committee Chair, for agenda item 4, and Clifford Kamara, Independent Review Committee (IRC) Chair, for agenda item 9.

1.5 Standing declarations of interest were tabled to the Committee (Doc 01a in the Committee pack).

1.6 The minutes of the PPC meeting of 8-9 May 2019 were tabled to the Committee for information (Docs 01b in the Committee pack). The minutes had been circulated and approved by no-objection on 16 July 2019.

1.7 The Chair referred to the PPC workplan (Doc 01c) and the Action Sheet (Doc 01d). She reminded Committee members that they may contribute to the workplan by raising issues with either herself or the Secretariat.

1.8 The Chair referred to a tabled document relating to the financial implications of the recommendations being proposed at this meeting, as had been reviewed by the Audit and Finance Committee (AFC) at its meeting on 10 October 2019.

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2. CEO Update

2a CEO Update

2a.1 Seth Berkley, CEO, provided an update to the Committee, focusing on both progress on Gavi 4.0 and preparations for Gavi 5.0, highlighting key items in the broader landscape of relevance for the Alliance, and reporting back on key country updates as well as previous discussion areas and decisions.

2a.2 Dr Berkley took a moment to recognise one former PPC member, Susan McKinney, who is retiring from USAID after 15 years and many years of engagement with Gavi.

2a.3 He informed the PPC about several new members of the Secretariat leadership team: Thabani Maphosa (Managing Director, Country Programmes), who was in attendance at the PPC meeting; and two new Directors who will join in November, Jelena Madir (Director, Legal) and Laura Boehner (Chief Technology and Knowledge Officer).

2a.4 Dr Berkley informed the PPC that in September Gavi had received the prestigious 2019 Lasker Bloomberg Public Service Award for 'providing sustained access to childhood vaccines in the world's poorest countries, saving millions of lives and highlighting the power of immunisation to prevent diseases.'

2a.5 He provided an update on the latest WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) that were made available in July and the effect of the update on Gavi indicators. From a results perspective, the estimates indicate that we are on track to achieve our 2020 mission indicator targets.

2a.6 He reported that there has been positive progress since the start of the strategic period on the number of under-immunised children, zero-dose children, and MCV1 coverage. He also stated that breadth of protection has increased significantly since 2015, with coverage of PCV and rota in Gavi countries now higher than the global average. DTP3 coverage has decreased slightly after two years of improvement and it remains a challenge to get ahead of the continued population growth. Equity indicators by wealth and maternal education have not changed since 2017, largely due to a lack of new survey data.

2a.7 In terms of preparing for Gavi 5.0, he provided an update on the six key operationalisation workstreams and highlighted those for which the PPC would receive the first set of detailed updates at this meeting: Funding Policy Review and Measurement and Accountability Framework. Other areas, such as portfolio management processes, partnership engagement, innovation, and programmatic areas such as the Middle Income Countries (MICs) approach and gender, are also underway and the PPC will receive regular updates through regular reporting, including bringing specific areas to the PPC and Board for guidance and decision, as required.

2a.8 Dr Berkley referenced the two key vaccine programme decisions that would be discussed by the PPC at this meeting: Ebola and malaria.

2a.9 He also provided an update on progress on developments leading up to Gavi's Replenishment pledging event, which will take place in London on 4 June 2020.

2a.10 Dr Berkley highlighted several developments in the broader landscape, including the launch of the Global Action Plan for Healthy Lives and Wellbeing for All (GAP).

2a.11 He also provided several programmatic updates and reported back on previous Board and PPC decisions, including polio, Nigeria, DRC, Syria and India.

2a.12 Finally, Dr Berkley provided two Alliance and Secretariat updates. First, the third Alliance Health Survey was completed in October 2019, with participation across the Gavi Secretariat, WHO, UNICEF, World Bank and Centers for Disease Control and Prevention (CDC). Overall partner engagement scores remained stable and Alliance partners remain proud to be part of the Gavi Alliance partnership. Second, the Secretariat successfully implemented a new enterprise resource planning (ERP) system on 1 October 2019 using SAP.

Discussion

Several PPC members asked for clarification regarding replenishment, and what PPC members can do to help during preparations. It was clarified that PPC members can engage and discuss Gavi's investment case when they see an opportunity, and highlight that Gavi's equity approach and focus on reaching zero-dose children is a pro-poverty and pro-gender approach. In response to a query, Dr. Berkley clarified that Gavi's Investment Opportunity for 2021-2025 highlights the Alliance's ambition to build on its proven success by providing the most comprehensive package of protection yet. In order to deliver on its ambitious plans for 2021-2025, Gavi will need at least US$ 7.4 billion in additional resources.

- PPC members noted the recent success of the TICAD Gavi replenishment launch event in Yokohama in August, and more broadly the successful replenishment for the Global Fund to Fight AIDS, Tuberculosis and Malaria, which was hosted in France in October.

- There was broad support for further strengthening the linkages between the PPC and other Board Committees, such as the Evaluation Advisory Committee (EAC) and the Audit and Finance Committee (AFC), and appreciation that the PPC Chair had undertaken initial discussions with counterparts in this regard.

- Several PPC members raised ongoing concerns about the status of polio eradication and the growing number of vaccine-derived polio cases, and the situation for the inactivated polio vaccine (IPV), including requesting clarity on whether there are supply challenges. It was clarified that there does not currently seem to be a shortage based on existing programme requirements, but that Gavi needs to keep on engaging with manufacturers to increase capacity and to build diversity of suppliers as programme requirements evolve.

- PPC members expressed support for Gavi's involvement with the launch of the Global Action Plan (GAP). It was noted that there are several global strategies under development that are interrelated (e.g. Immunisation Agenda 2030) but will be finalised at different times. PPC members tended to agree that Gavi should not slow down to wait for the others to be completed, but alignment with other initiatives should be sought, where relevant.

- With the increased focus on zero-dose children in Gavi 5.0, PPC members indicated that the Alliance needs to have a discussion on terminology to be sure there is clarity for countries and that one set of measures are in place.

- PPC members commended the work undertaken so far on operationalisation of Gavi 5.0 and the openness to redesign and simplify, and noted that this has been reflected in the agenda for this meeting.

- PPC members heard about recent experiences in Pakistan and Afghanistan with challenges around primary health care (PHC) packages and mechanisms for delivery.

- One PPC member asked for clarification on when the Middle Income Countries (MICs) approach will be considered by the Gavi Alliance Board. The Secretariat noted that an update will be provided at the December 2019 Board meeting, and a decision will be requested in June 2020, after discussion at the PPC in May 2020.

- On Nigeria, one PPC member asked for more information about the timing of the high-level visit to Nigeria and it was explained that Gavi is proactively following-up with the Government to confirm the timing of the visit and receive the formal invitation. One PPC member asked about whether Gavi had already engaged at the state level. It was clarified that while Gavi is engaging at the federal level, the process to engage at state level has started given the importance of ensuring state-level accountability.

2b Sudan's Eligibility for Gavi support in 2020

2b.1 As part of the CEO Update, Dr Berkley presented a decision point related to Sudan's eligibility for Gavi support in 2020 (Doc 02b).

2b.2 Sudan's 3-year Gross National Income (GNI) per capita average is above Gavi's eligibility threshold of US$ 1,630, and, based on current policy, the country is set to enter the accelerated transition phase in 2020. However, the country has experienced significant political, social and economic turmoil over the last two years, culminating in a 34% drop in GNI per capita in 2018 to US$ 1,560, below Gavi's eligibility threshold. Available economic projections from the IMF indicate that the country's GNI is not expected to recover in the near future, and the country has been classified as fragile in both 2018 and 2019.

Discussion

- PPC members queried whether Sudan would be required to co-finance if the Board decides to approve this recommendation. It was clarified that Sudan has not entered the last phase of transition and if this decision is approved, it will remain in preparatory transition phase. Therefore, the co-financing requirements will be in accordance with the Co-Financing Policy and the country will not face rapid ramp up of co-financing.

- It was noted by the PPC that Sudan is one of the countries that regularly struggles to finance non-Gavi supported routine vaccines.

Decision One

The Gavi Alliance Programme and Policy Committee **recommended** to the Gavi Alliance Board that it:

Approve, exceptionally, that the determination of Sudan's eligibility for 2020 will be based on the latest GNI data point instead of the average GNI per capita over the past three years.

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3. 2016-2020 Strategy: Progress, Challenges and Risks

3.1 Anuradha Gupta, Deputy CEO, presented a report to the PPC on progress in implementing the 2016-2020 Strategy (Doc 03).

3.2 The report included a summary of the progress, challenges and associated risks of achieving the Alliance's 2016-2020 Strategy, including a holistic view across the Alliance's portfolio of support to countries including vaccine programmes, Health System and Immunisation Strengthening (HSIS) support, and technical support provided by partners under the Partners' Engagement Framework (PEF).

3.3 The report also included an update on the ongoing operationalisation of Gavi's 2021-2025 Strategy.

Discussion

- In response to a question of whether current challenges will be addressed under Gavi 5.0, it was noted that experiences from the current implementation period have informed problem statements for each of the Gavi 5.0 operationalisation workstreams. Specifically, the problem statements relating to the Alliance's funding policies will be presented in the Funding Policy Review item at this meeting. Moving forward, through the strategic operationalisation of Gavi 5.0, the intention is to develop the necessary tools and approaches to address the current challenges.

- PPC members raised the data analysis constraints resulting from a dependency on surveys. Further discussion on this was requested as surveys do not

necessarily take place in the intervals and the pace desired. The Secretariat clarified this will be discussed as part of the work on the Measurement & Accountability Framework for Gavi 5.0.

- PPC members requested that the Secretariat carefully consider monitoring metrics for Gavi 5.0 as the current indicators do not always make it possible to measure progress on a timely basis.

- The flat dropout rate since 2015 was identified as a priority to be addressed. The Secretariat noted that this is an ongoing challenge, and Ms Gupta provided a brief overview of the work being done by the Alliance to more systematically identify and address demand-side challenges.

- The PPC welcomed the focus on re-balancing the channeling of funds to countries and the transparency on sustainability challenges. The Secretariat was urged to use the information available to inform Gavi 5.0 and think carefully about how to streamline funding to countries in the next strategy period.

- The PPC also discussed risk appetite versus long term sustainability and country capacity, noting the considerable amounts of funding that pass through fiduciary mechanisms of partners, Gavi should reconsider the balance between the short-term results and long-term sustainability. Gavi's current low risk tolerance should be reconsidered in Gavi 5.0.

- The Secretariat responded to questions on the sources of domestic finances which countries use to pay for co-financing and confirmed that loans from the World Bank are seldom used. Ms Gupta highlighted that when Gavi first started, 75% of countries were not paying for their traditional vaccines, and now 80% of countries are covering the costs of non-Gavi vaccines themselves.

- The PPC discussed gender at length, highlighting the need to ensure there is the required capacity and expertise across the Alliance to take to effectively prioritise and mainstream gender. The PPC also noted the capacity challenges of measurement and reporting at country level. The Secretariat noted that a common understanding on gender among the Alliance is required, underlining that challenges remain in policy implementation and highlighting the need to further mainstream a gender lens in Gavi's programmatic approaches. It was noted that gender is central to Gavi's 5.0 Strategy and that the updated Gender Policy and implementation plan will be discussed at the PPC in May 2020. It was highlighted that Gavi is considered a leader in gender equity, as per the recent Global Health 50/50 Report.

- On post-transition countries, it was noted that the majority are performing well and sustaining vaccines introduced with Gavi support. The Secretariat noted that impacts and learnings from post-transition support will be included in future presentations and discussions. It was further discussed that a number of countries that are due to transition will be transitioning with inequities still to be addressed.

- One PPC member underlined the importance of carefully considering vaccine supply security in Gavi 5.0, noting the serious challenges countries face when stock shortages occur preventing vaccine introduction.

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4. Gavi 5.0: Funding Policy Review

4.1. Julian Schweitzer, Chair of the Funding Policy Review (FPR) Steering Committee (SC), provided a brief introduction to the process, scope and strategic context for the Steering Committee, as well as some reflections on Gavi's future. His view was that while Gavi's model has served it well within an overall development context and at a time when its core function was as a financing mechanism, that this model will not necessarily continue to serve its purpose in the context of some of the current key drivers of change across global health and development, such as increased fragility, economic volatility, the need for speedy responses (e.g. to pandemics), and the need to harmonise global agendas. To do so will require that Gavi adopt some new approaches, allowing for manoeuvrability within an ever-shifting global environment, and this will require greater policy flexibility, including a nimble, innovative and forward-looking Secretariat working with Alliance partners to implement the new 5.0 Strategy.

4.2. Wilson Mok, Head, Policy briefly presented the overall Funding Policy Review process (Doc 04), including overall timeline, key activities, topics under discussion at this meeting, and the path forward.

PART A – Eligibility and Transition Policy

4.3. Santiago Cornejo, Director, Immunisation Financing & Sustainability (IF&S), presented Part A of the Funding Policy Review on the Eligibility and Transition Policy.

4.4. He recalled that the Eligibility and Transition Policy sets forth the principles and criteria that determine which countries can access Gavi support and how this support is phased out over time. It enshrines the key principles that inform Gavi's developmental approach, including that Gavi support is focused on the poorest countries in the world, that it is time-limited, catalytic, and directly linked to a country's ability to pay, as proxied by their GNI per capita.

4.5. He noted that despite broadly positive performance to date, evidence and experiences from a subset of transitioning countries that faced programmatic challenges, stakeholder consultations and preliminary conclusions from the external evaluation of the Eligibility & Transition and Co-financing policies identified three areas that should be addressed to further strengthen Gavi's policies:

- To adapt Gavi's approach to further mitigate risks of unsuccessful transition;
- To clarify the mechanics of (re-)gaining eligibility; and
- To reconsider the inclusion of the generic programme filter.

Discussion

- PPC members appreciated that the proposed approach was country centric and tailored. They further noted that Gavi's eligibility should remain at country-level, with the possibility of sub-national level considerations to be potentially discussed in the future.

- The PPC agreed that the approach seemed to strike the right balance of being enabling and not overly prescriptive, and encouraged further simplification.

- One PPC member highlighted that country ownership will be key and suggested to consider introducing a social contracting framework that would allow civil society organisations (CSOs) to be involved and to better reach the unreached.

- The definition of financial sustainability was discussed in the context of balancing domestic and external sources of funding. It was noted that the current definition of financial sustainability is fit-for-purpose as it acknowledges both sources of funding while focusing on the importance of the predictability of the funding.

- The PPC endorsed an approach whereby early and continuous dialogue and engagement with countries would help identify and tackle programmatic challenges to support successful transition. The Secretariat and Alliance partners would track country performance against a specified set of programmatic criteria which would provide 'early warning signals' and support early engagement for successful transitions. The PPC and Board would be regularly updated on this progress on country performance and would provide guidance on potential risks.

- In specific rare cases, a country might still enter the accelerated transition phase at high risk of unsuccessful transition out of Gavi support. Working closely with Alliance partners, the Secretariat would be entrusted with identifying these countries at risk and proposing flexibilities. The countries at risk would be identified based on immunisation outcome-level criteria, and specific proposed flexibilities would be based on a robust health system component-level analysis (the specific criteria and flexibilities to be defined in the final Policy). Gavi's CEO would then be responsible for approving the necessary time-limited extension of the accelerated transition phase, and specific flexibilities. In addition to already being aware of countries at risk through regular country performance review, the PPC and Board would be informed of the application of these flexibilities. The PPC emphasised the importance of putting in place strong accountability frameworks for countries to avoid inadvertently incentivising low performance. In the next phase of the review, the specific criteria (aligned with the Gavi strategic indicators) and flexibilities will be brought to the PPC and Board.

- PPC members debated the proposed shift in decision-making for identification of countries at risk and flexibilities from the Board to the CEO. The PPC held differing views, but was broadly supportive of the direction to empower the CEO to make these decisions as it acknowledged the importance of being proactive and nimble. However, the PPC highlighted that the identification of countries at risk should be based on a defined criteria in policy and an inclusive and robust process with

strong consultation and inputs from Alliance partners. The PPC also requested that the PPC and the Board should be regularly and proactively updated on potential countries at risk and be informed of the decisions made by the CEO. The PPC requested more clarification of the process for the Board in Annex B. In addition, the PPC emphasised the importance of putting in place strong accountability frameworks for countries to avoid inadvertently incentivising low performance. One PPC member also noted that the paper had presented countries identified at risk in terms of coverage but queried whether there had been any early thinking on those at risk in terms of equity. Another member queried whether there would be a time limitation or financial limitation for the flexibilities available to what is expected to be a handful of countries with an adjustment of the accelerated transition phase. The Secretariat clarified that the specific criteria to identify countries at risk will be aligned to the Gavi strategic indicators and along with the potential flexibilities will be included in the final policy document to be brought for decision to the next PPC and Board.

- It was noted that, while the introduction, in 2015, of the three-year GNI pc average to determine eligibility has been useful to give countries improved visibility and predictability about transition timelines as their economies increased, it did not account for the exceptional cases of countries facing severe, rapid drops in GNI pc. According to current policy, countries with falling GNI pc only (re)gain eligibility once the 3-year rolling average is below the eligibility threshold. This creates an inequity whereby an ineligible country may have a GNI pc level below that of countries receiving support but remains ineligible because its 3-year GNI pc average is still above Gavi's eligibility threshold. The PPC recommended addressing this inequity in access to support by additionally including the most recent estimate of GNI pc to determine countries' eligibility when their economies decrease, noting these circumstances have historically been rare.

- The PPC agreed to recommend the removal the programme filter, but also that it would be important to carefully consider introducing alternative mechanisms at vaccine programme-level to ensure country readiness. PPC members also requested that Gavi consider mechanisms to safeguard against degraded coverage resulting from the removal of the filter. It was proposed that Alliance partners work on that problem together.

- Several PPC members asked for alignment with other global plans and sought further information about how the Global Action Plan (GAP) had been considered in the work of the Steering Committee, indicating that this presented an opportunity for alignment to be built in.

Decision Two

The Gavi Alliance Programme and Policy Committee **recommended** to the Gavi Alliance Board that it:

Approve the following, which will be incorporated into Gavi's policies in June 2020:

i. using the latest point estimate of GNI per capita alongside the average GNI per capita over the past three years to determine countries' eligibility for support; and for countries (re)gaining eligibility, adoption of a tailored approach based on the country context;

ii. adoption of an approach to tailor the accelerated transition phase as described in Annex B to Doc 04 as amended by discussions at the PPC;

iii. removing the programme filter requiring 70% or higher coverage of the 3rd dose of DTP-containing vaccine for a country to access new support for select vaccines (as set out in the Eligibility & Transition Policy).

PART B – Co-financing Policy

4.6. Santiago Cornejo, Director, Immunisation Financing & Sustainability (IF&S), presented Part B of the Funding Policy Review on the Co-financing Policy.

4.7. He noted that Gavi's Co-financing Policy has helped catalyse over US$ 1 billion in domestic public financing for Gavi-supported routine vaccines since its introduction in 2008.

4.8. He reported that country consultations and preliminary conclusions from the external evaluation of the Co-financing and Eligibility & Transition Policies have confirmed that the Co-financing Policy has been successful in achieving its intended goal of promoting greater financial sustainability of vaccines introduced with Gavi support. However, since the policy's last revision in 2015, important lessons learnt from implementation have also emerged, and – in line with Board guidance to simplify and differentiate Gavi's support in the context of Gavi 5.0 and the findings of the independent external evaluation – two specific areas for improvement were identified to enhance the achievement of the policy's objectives, plus one cross-cutting issue:

- Simplification and greater consistency of co-financing rules;
- Institutionalisation of flexibilities to co-financing in exceptional circumstances;
- A cross-cutting issue was also identified regarding the strategic deployment of co-financing requirements which will be discussed along with incentives at the next PPC meeting.

4.9. The PPC was asked to review and recommend for Board approval a simplified approach for the calculation of co-financing requirements, as well as an approach for the identification and approval of flexibilities to co-financing requirements for

countries undergoing exceptional circumstances (humanitarian crisis / severe fiscal distress).

Discussion

- PPC members were very supportive of the proposed approach to co-financing rules and enthusiastic about the direction taken and its contribution to simplification, noting this change would enhance country ownership.

- There were questions about how exactly countries will transition to the new calculation and how to manage changes to current levels; and exactly which antigens and types of support (routine immunisation, campaign) were included. The Secretariat indicated that minimising disruption from the changes had been discussed by the Steering Committee and it would revert with further detail for the next meeting. The Secretariat also noted that the proposed co-financing simplification focuses on routine vaccines and would align co-financing requirements for measles routine vaccines with the rest of the portfolio. It was noted that IPV is expected to continue to be exempt from co-financing requirements as per the previous Board decision.

- PPC members also asked for clarification about whether this would be cost neutral. It was clarified that this is the aim, although minor changes at country-level are possible.

- The PPC agreed that the policy should allow for more flexibility and responsiveness in order to support the few instances in which countries might face these circumstances. Given the unpredictable and unique nature of such events, it would not be possible to define a priori indicators and thresholds that would be universally valid to identify countries which might need co-financing flexibilities. However, as with flexibilities envisaged to mitigate the risk of unsuccessful transitions, the PPC emphasised the importance of ensuring strong consultation with and input of expert partners and clear reporting to and engagement with the PPC and the Board for oversight.

Decision Three

The Gavi Alliance Programme and Policy Committee **recommended** to the Gavi Alliance Board that it **approve** the following, which will be incorporated into Gavi's policies in June 2020:

a) calculating **vaccine co-financing** for all countries based on the share of doses needed by a country; and
b) adopting an approach to apply co-financing flexibilities as described in Annex B to Doc 04 as amended by discussions at the PPC, in countries facing **severe fiscal distress** and countries facing a **humanitarian crisis**.

PART C - Health System and Immunisation Strengthening (HSIS) Support Framework

4.10. Alex de Jonquières, Director, Health System and Immunisation Strengthening, introduced Part C of the topic on the Health System and Immunisation Strengthening (HSIS) Support Framework, and presented on health systems strengthening (HSS) grants, Cold Chain Equipment Optimisation Platform (CCEOP), and performance-based funding (PBF).

4.11. He explained that while the overall framework remains largely fit for purpose and relevant as the Alliance prepares for Gavi 5.0, some targeted policy changes may be required to align with the 5.0 strategy and to address specific challenges that have been encountered in operationalising the current framework. Four problem statements were identified and endorsed by the FPR Steering Committee as well as partner and country consultations:

- Problem statement 1: Equity as an organising principle for 5.0 is insufficiently reflected in the formula used to allocate Gavi's HSS resources across countries;
- Problem statement 2: Inadequate differentiation of grant design;
- Problem statement 3: Lack of integration of Gavi support, ensuring greater alignment between HSIS grants and considering whether CCEOP should be integrated into the HSIS Framework; and
- Problem statement 4: Immunisation-related results are ineffectively incentivised.

Discussion

- On problem statement 1, the PPC agreed to recommend an option whereby HSS resources would be allocated according to four criteria: equity (number of zero-dose children based on DTP1), coverage (number of underimmunised children based on DTP3), ability to pay (Gross National Income (GNI) per capita (pc)), and population in need (birth cohort), with all four criteria equally weighted.

- The PPC agreed to recommend the removal of the cap of US$ 100 million over five years currently applied to total country HSS ceilings, but to retain the floor of US$ 3 million. One PPC member asked the Secretariat to monitor the impact that this might have on small countries.

- On problem statement 2, PPC members broadly agreed with the identified principles to differentiate HSS support and indicated that the principles of country ownership and integration could to be strengthened.

- On problem statement 3, the PPC agreed to recommend the integration of support for CCEOP into HSS support. However, some PPC members did query whether in doing so, Gavi could inadvertently compromise its ability to market shape, and if this proves to be the case, it would be worth considering ring fencing this support within the HSS envelope, which the Secretariat will explore. One PPC member also suggested a grace period for those countries that just recently applied.

- On problem statement 4, the PPC agreed to recommend the discontinuation of the generic Performance Based Funding (PBF) mechanism for the reasons set out in the paper. It was noted that Gavi should consider alternative country centric mechanisms to incentivise strong performance.

- More generally on the HSIS Framework, one PPC member questioned whether the framework is right to achieve Gavi 5.0 goals and whether CSO partners and others have been sufficiently included in the approach.

- Several PPC members raised the importance of integration around the primary health care (PHC) agenda and universal health care (UHC) agenda including through the *Global Action Plan for Health and Wellbeing for All*. One PPC member suggested that Gavi as an Alliance look at what its contribution could be to these agendas. It was also suggested that Gavi seek to incentivise countries to design more integrated approaches, including for different age ranges and new programmes.

Decision Four

The Gavi Alliance Programme and Policy Committee **recommended** to the Gavi Alliance Board that it **approve** the following, which will be incorporated into Gavi's policies in June 2020:

a) allocating HSS resources according to four criteria: **equity** (number of zero-dose children), **coverage** (number of underimmunised children), **ability to pay** (GNI pc), and **population in need** (birth cohort), with all four criteria equally weighted;

b) removing the cap of US$ 10 million over five years currently applied to total country HSS ceilings, but retaining the floor of US$ 3 million;

c) integrating support for CCEOP into HSS support; and

d) discontinuing the mechanism of awarding Performance Payments (as set out in the HSIS Support Framework)

4.12. As a final component of the Funding Policy Review agenda item, Zeenat Patel, Head, Vaccine Implementation, presented on Gavi's cash support for campaigns and other supplemental delivery strategies (Ops).

4.13. She noted that Gavi's Ops window is currently limited to the funding of campaigns and is calculated on a per target person basis, without consideration for the epidemiological or country context. This structure provides incentives for large campaigns, while restricting support to deploy other delivery strategies to close immunity gaps.

4.14. She also described the current misalignment between outbreak response funding and planned campaigns, in which funding levels for outbreak response are not tiered by transition phase as is done for planned campaigns. Initial analyses

supporting realignment of Gavi's Ops support and outbreak response funding were presented to the PPC.

4.15. The PPC was asked to provide guidance on the redesign of Gavi support for supplemental delivery strategies to close immunity gaps to incorporate a broader range of options in the next strategic period and on realignment of outbreak response funding with funding for planned campaigns.

Discussion

- PPC members welcomed the clear presentation on a complex topic and the opportunity to provide comments on this area of Gavi support.

- It was noted that the strategies presented while not yet implemented with Gavi support, do exist as part of the essential immunisation programme. Shifts in Gavi policy to be more substantially supportive of these strategies would be welcome.

- It was discussed that the reason why these approaches are not being implemented consistently and at scale is that they are not one-size-fits all. It was suggested that it would be important to do a barrier study to better understand the factors limiting uptake.

- Some PPC members expressed concern about ongoing outbreaks and associated cost and the substantial funding needs and gaps for outbreaks. It would be important also to do further analysis of those contexts, e.g. of Rohingya populations.

- It was noted that it will be important to look more carefully at some of the programmatic campaign elements. At the Bill & Melinda Gates Foundation, a grant was just financed to look at campaign effectiveness (bed nets, etc.) and it was suggested that it would be good to connect Gavi to that work.

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5. Malaria Vaccine Pilots and Long-term Supply

5.1 Wilson Mok, Head of Policy, informed the PPC that the paper (Doc 05) had two objectives: First, it provided an update to the PPC on progress of the Gavi-supported Malaria Vaccine Implementation Programme (MVIP), a pilot programme designed to generate evidence to inform WHO policy recommendations on the broader use of the RTS,S/AS01 vaccine. The paper presented a funding recommendation for the MVIP for 2021-2023, which would enable completion of the pilots and provide key evidence to inform a future Gavi investment decision on broader roll-out.

5.2 Second, the paper described a manufacturer decision that needs to be taken with regard to whether to continue production of a vaccine, in 2020, beyond the doses required for the pilots. Not continuing to produce in the near-term would delay availability of doses for broader roll-out in the future, if there is a policy

recommendation and investment decision. However, continuing production has financial implications. Two options for Gavi engagement were presented: (1) no funding for continued production; (2) risk-share with the manufacturer via a funding commitment to enable continued production.

5.3 For this item, the IFPMA Constituency representative, who is an employee of GSK (the manufacturer of this vaccine), recused herself from the discussion and the decision. Prior to her recusal, she was invited to comment. She reiterated GSK's full commitment to the RTS,S/AS01 vaccine. She noted GSK had invested US$ 350 million in the vaccine over the past 30 years, with an additional total budget of over US$ 300 million secured for activities related to the pilots and Phase IV studies. Gavi's decision was highlighted as critical in signaling to other potential funders who are considering whether to invest or not in RTS,S, such as to support tech transfer to a lower cost manufacturer.

5.4 The GSK representative responded to a question from a PPC member on the future of the production facility if production is discontinued. She clarified that the facility would be put on hold and the trained personnel would either leave or be assigned to other activities. She then left the room.

Discussion

- On the MVIP recommendation, there was general agreement by the PPC to support the recommendation to the Board.

- On the long-term supply question, the PPC was divided over whether it should recommend one of two presented options to the Board. Some PPC members were very supportive of proceeding with production and expressed concern that stopping production would send the wrong message to manufacturers and other stakeholders and that an eventual delay would decrease the impact of a future programme. Other PPC members, despite wishing for this programme to go ahead, did not feel that it is the role of Gavi to de-risk a manufacturer.

- The PPC agreed that this is a critical strategic question that the full Gavi Alliance Board should have the opportunity to discuss. The PPC agreed to present three options for the consideration of the Board, with the new option being to identify a third-party to cost-share with Gavi an investment for continued production, whereby Gavi's financial risk exposure would be minimised.

- One PPC member inquired if Gavi would consider an Advanced Purchase Commitment (APC) for the RTS,S/AS01 vaccine. The Secretariat explained that an APC is not an ideal vehicle in this case because it would commit Gavi to purchase vaccines even if certain conditions do not materialise, such as WHO prequalification or the results of the pilot supporting the cost-effectiveness and programme feasibility of the vaccine in an investment case. It was also noted that an APC would not provide the flexibility to deal with the sliding risk scale.

- It was noted that since the Phase 3 trial concluded and recommendation to conduct implementation pilots was made, important new information has emerged,

such as 1) the persistence of the beneficial effects of the vaccine up to seven years 2) the absence of the observed safety signals from the Phase 3 trial in other studies using RTS,S, and 3) evidence that the 4th vaccine dose in the schedule may be less important than previously perceived. Since the time of the decision to go ahead with implementation of pilot evaluations, a framework for WHO policy-making has also been approved.

- PPC members cautioned that this vaccine has no high-income market and there could be serious impact from a decision not to proceed on the global health environment, and on thousands of children in the three pilot countries who would no longer be able to receive vaccines if production is stopped. It could also jeopardise the likelihood of a successful tech transfer to occur, as no other manufacturer may be willing take on the production of RTS,S.

- On existing tools for malaria control, it was noted that scaling up Insecticide-Treated Nets (ITNs) has been challenging and does not constitute a viable solution to combat malaria in isolation. It was noted that no new interventions are on the horizon in the short or intermediate term and the RTS,S vaccine was described as the first new intervention for malaria that the community has had in a long time. Finally, the importance of applying an equity lens was underlined.

- A PPC member underlined the importance of the Gavi Board having a full picture of the debate and taking an informed decision, with the new data and potential third-party funding partners being woven in the discussion. The PPC and the Secretariat underlined the critical need to have the latest information since the recommendation for implementation pilots available by the Board meeting in December 2019. It was suggested that the presentation to the Board on this topic would be split into two: first, a section on the evidence by WHO, and second, a section on the PPC recommendation by the Secretariat. Although it was suggested that the decision regarding future supply be deferred until more information is available, the need to take a decision now was confirmed.

- Concerns on long-term implications were expressed by donors, particularly on setting a precedent. Some donors asked how Gavi is coordinating with Unitaid and the Global Fund. The Secretariat commented that Gavi was leading the discussions regarding a risk-share mechanism given previous experience with innovative mechanisms and the relationship with GSK but noted that discussions have taken place with both organisations on how to potentially construct the investments of the three organisations if there is a positive policy recommendation and ensure coherence in fund raising as well as vaccine deployment.

Decision Five

The Gavi Alliance Programme and Policy Committee **recommended** to the Gavi Alliance Board that it:

Malaria Vaccine Implementation Programme

a) **Approve** an amount up to US$ 11.6 million to continue the malaria vaccine implementation programme from 2021-2023;

Long-term Malaria Vaccine Supply

EITHER:

Option 1

b) **Defer** providing an investment for continued production of RTS,S bulk antigen pending a WHO policy decision and Gavi investment case for broader roll-out;

OR

Option 2

c) **Approve** providing an investment for continued production of RTS,S bulk antigen pending a WHO policy decision and Gavi investment case for broader roll-out; and

d) **Note** that the Market Sensitive Decisions Committee will make a final determination of the structure of the investment

OR:

Option 3

e) **Request** the Secretariat to work with stakeholders to identify third-parties to cost share whereby Gavi's financial risk should be minimised or reduced to zero to provide for an investment for continued production of RTS,S bulk antigen pending a WHO policy decision and Gavi investment case for broader roll-out; and

f) **Approve** an investment for continued production of RTS,S bulk antigen between Gavi and third-parties whereby Gavi's financial risk exposure should be minimised as much as possible, with reassessment of support on an annual basis, subject to the final terms being reviewed and endorsed by the Market Sensitive Decisions Committee.

Kate O'Brien (WHO) recused herself and did not vote on part a) of Decision Five above.

An Vermeersch (IFPMA) recused herself and did not take part in discussion or vote on Decision Five above.

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6. 2021-2025 Measurement Framework

6.1 Seth Berkley, CEO, provided introductory comments and indicated that the purpose of this agenda item was to seek an early steer from the PPC as Gavi embarks on the process to develop the monitoring and evaluation (M&E) system for Gavi 5.0. This includes the overall approach and principles as well as starting to flag any key considerations to inform development of the evaluation workplan and development of strategy level performance measurement.

6.2 Nina Schwalbe, Chair of the Gavi Evaluation Advisory Committee (EAC) then provided an update on the work of the EAC and its role vis-à-vis evaluation.

6.3 Daniel Hogan, Head, Corporate Performance Monitoring & Measurement, Monitoring & Evaluation, presented on the development of the 2021-2025 Measurement Framework (Doc 06).

6.4 He recalled that key shifts in the Gavi 5.0 strategy objectives and goals necessitate new ways of approaching monitoring and evaluation building on lessons learned from Gavi 4.0.

6.5 He noted that proposed improvements in the Gavi 5.0 M&E system include developing a theory of change underpinning the Gavi 5.0 strategy goals and objectives with well-articulated causal pathways and key assumptions. This would then be used to: 1) outline the measurement and learning objectives from the outset of the strategy period, and 2) establish indicators interlinked across the results chain and risks that are routinely monitored and used for timely performance management and shared accountability for delivering results.

Discussion

- PPC members were very supportive of the theory of change approach. One PPC member noted that in addition to using the theory of change at the organisation level, that it would be beneficial to also have this country-by-country.

- Several PPC members asked if the mission level indicators had the balance right between coverage and equity, given the change in focus towards equity in 5.0. It was suggested to add an indicator on the number of introductions built into routine immunisation.

- One PPC member suggested that Gavi be careful that the indicators are easy to understand for a broader audience.

- Several PPC members indicated that they were interested in engaging in the measurement framework development, underscoring the importance of consultation. It was also flagged that country level representation was not evident on the Technical Working Group (TWG) for the development of the measurement framework.

- Several PPC members noted that it will be important to align the strategic and M&E frameworks across initiatives (e.g. IA 2030, Global Action Plan, PHC operational framework, UHC 2030), and across countries using the sector wide approach, so it is as straightforward as possible for countries. Gavi should try to be as inclusive as possible. Some PPC members also noted the importance of considering the burden on countries of any additional reporting requirements.

- Several PPC members suggested that we carefully consider the direction on gender, using sex disaggregated data, and how to capture a gender transformational approach in the theory of change.

- When identifying indicators, Gavi should aim to use validated indicators and select ones that are known to actually be measuring what they are supposed to be measuring.

- Several PPC members suggested that Gavi needs to monitor process indicators, e.g. timely disbursement of funds. It will be important to understand the frequency of reporting on all indicators.

- Additional areas to further develop include HSS, market shaping, accountability, country ownership, and sustainability.

- With respect to evaluation in 5.0, several points were mentioned:
  - Important to set the learning agenda for 5.0 up front;
  - Important to do joint evaluations with others, where possible;
  - Potential topics include: impact of Gavi HSS support for 5.0, including effects on sustainability/integration; wider systems effect of Gavi at country level; effectiveness, role and impact of stockpiles and stockpiling.

- Several PPC members also wished to acknowledge the excellent contribution of Abdallah Bchir, Head, Evaluation, who will soon be retiring from Gavi.

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7. Alliance Update: Alliance Partners on routine immunisation, campaigns and outbreak response

7.1 Kate O'Brien, Director Immunization, Vaccines and Biological Department, WHO, presented this item providing background on the different vaccination strategies including routine immunisation (RI) supplementary immunisation activities (SIAs), and outbreak responses, which all aim to achieve high equitable coverage (Doc 07).

7.2 She explained the different vaccination strategies and their impacts and benefits, particularly in relation to measles. She also highlighted concerns relating to the use of SIAs including potential inefficiency and ineffectiveness of SIAs at reaching under-immunised and zero dose children, adverse effect on RI, and financial issues including cost effectiveness, perverse incentives and fiduciary risks. She highlighted key focus areas going forward, including the importance of prioritising

and incentivising RI improvement, ensuring SIAs are focused on closing immunity gaps and reaching zero-dose sub-populations, exploring approaches other than nation-wide non-selective campaigns, and improving the quality and efficiency of campaigns.

Discussion

- Several PPC members commended the presenter for an excellent presentation and requested permission to use the slides for other purposes. It was suggested that the slides could also be shared with Expanded Programme on Immunization (EPI) workers.

- Several members commented on polio campaigns. One PPC member mentioned that the numerous campaigns on polio were adversely affecting RI and expressed concern over the lack of information sharing from campaigns to the RI programme. The Secretariat noted this was the case in measles SIAs and campaigns as well, thereby, preventing children from being integrated in the RI system.

- On the issue of 95% coverage threshold, it was mentioned that this metric is not sufficiently nuanced. The presenter clarified that the Strategic Advisory Group of Experts (SAGE) working group will be considering if there was another policy and programmatic oriented metric that could be used.

- Several members commented on the ten-dose vial size and that it would be worth tailoring use of five- or ten-dose vials depending on whether the context is routine immunisation or campaign.

- Another PPC member stressed that continuous and multiple SIAs have a negative effect on RI and in this background emphasised the need for a new approach in the countries as a part of HSIS support. It was noted that the impact of campaigns is not only on RI but also on other services, e.g. on antenatal services.

- It was noted that Gavi financing is an opportunity to drive change, and incentivise a variety of supplemental delivery strategies and targeted SIAs focused on reaching zero-dose children and bringing them into the RI programme. It was further noted that technical guidance on a variety of supplemental delivery strategies exist to reach missed children but the incentives don't exist to encourage the use of these strategies, where appropriate.

- The PPC agreed with the proposed focus areas presented, and urged Alliance partners to pursue these actions with specific focus on prioritising and incentivising RI improvement, ensuring SIAs are focused on closing immunity gaps and reaching zero-dose sub-populations, exploring approaches other than nation-wide non-selective campaigns, and improving the quality and efficiency of campaigns.

- Various PPC members emphasised the need for Alliance partners to improve guidance in relation to SIAs, including identifying and reaching zero dose children, ensuring zero dose children are brought into the RI programme, planning and

undertaking targeted SIAs, and developing demand generation strategies for unserved communities.

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8. Gavi's engagement in Ebola vaccine

8.1 Seth Berkley, CEO, provided an introduction to this agenda item, highlighting the rationale for taking this decision now and explaining that an Ebola programme would provide opportunities to address and advance several programmatic and strategic questions that are relevant for Ebola and emerging infectious diseases.

8.2 Aurélia Nguyen, Managing Director, Vaccines & Sustainability, presented on Gavi's engagement in Ebola vaccine (Doc 08). She explained that the current Ebola vaccine funding envelope approved in 2014 is coming to an end in 2020, and a licensed and WHO prequalified vaccine is anticipated in 2020.

8.3 The proposed approach enables the earliest possible procurement of Ebola vaccines whilst allowing flexibility based on public health need, availability of one or more WHO pre-qualified products with different use cases, and future SAGE recommendations. This would comprise support for reactive vaccination for outbreak response through an emergency stockpile – including vaccination in neighbouring countries – and preventive vaccination of high-risk groups outside of an outbreak (such as certain healthcare workers in countries classified as being at high risk).

8.4 The PPC was asked to recommend to the Board the opening of a funding window for an Ebola programme, contingent on WHO prequalification and SAGE recommendation. Once the conditions are met, this funding window would replace the time-limited Ebola envelope approved in 2014. In the interim period before a licensed vaccine is available, this HSS/operational cost support window from the 2014 Ebola envelope would be available to provide any required operational support for the use of investigational vaccine.

Discussion

- PPC members noted that this is an area that continues to develop rapidly and welcomed acknowledgement of the uncertainties and emphasis on flexibility. Several PPC members provided updates on recent events that have occurred since the PPC papers were distributed. It was noted that the US CDC's Advisory Committee on Immunization Practices just considered the use of the Ebola vaccine as a preventive measure, targeting approximately 5,000 healthcare workers, laboratory personnel and first responders, and that this would be revisited in February 2020 assuming vaccine licensure. The US Government will maintain its own vaccine stockpile.

- It was reported that the SAGE Working Group on Ebola vaccine had recognised the need to revisit the preventive vaccination approach outside of outbreaks and provide clear definitions, and that this work would be carried out as quickly as

possible. It may be necessary to hold country consultations already at this stage to learn more about what countries are considering for preventive vaccination, including target populations and strategies.

- PPC members requested additional detail about the proposed International Coordinating Group (ICG)-like mechanism for stockpiles mentioned in the paper. It was clarified that it was described as ICG-like because the Alliance will need to bring in additional Ebola expertise and experience related to use of highly-targeted vaccination strategies. One PPC member expressed concern that having multiple stockpiles could prove burdensome for manufacturers. It was proposed to have regular engagement and close coordination between stakeholders and periodic reviews to ensure efficiency in global allocation of vaccine.

- PPC members also queried the proposed approach on co-financing, in particular for preventive vaccination in non-outbreak settings, and how to incentivise countries to co-finance. It was suggested that co-financing would not apply initially during the learning phase (e.g. for 2 years after the start of program) and that Gavi would then reconsider whether to maintain that approach in alignment with the co-financing policy.

- It was noted that WHO is working with partners, including Gavi, on a global plan for Ebola supply security.

- PPC members noted that if the financial implications were to change materially as more is known, the PPC would want the chance to review. It was also confirmed that the Secretariat would provide regular updates on implementation of the Ebola programme.

- PPC members asked for clarification on how decision making would take place for preventive vaccination in non-outbreak settings. If there is huge demand for preventive strategies, this could become difficult to manage and will need careful consideration. It was suggested that the Global Task Force on Cholera Control be considered as a potential model for engaging multiple partners in reviewing country requests for preventive vaccination.

- It was proposed to take a structured look at the operational costs associated with Ebola vaccination, and for Gavi to be proactive and clear on its scope of support.

- PPC members noted the cold chain requirements are problematic for the first vaccine that is likely to be available. The Secretariat noted that it had engaged with the manufacturer regarding the urgency to try to develop a new vaccine that would have better requirements, but that this was not possible with the first iteration.

Decision Six

The Gavi Alliance Programme and Policy Committee recommended to the Gavi Alliance Board that it:

a) **Approve** the opening of a funding window for the establishment of an Ebola programme for licensed vaccines used for i) reactive and preventive vaccination in an outbreak setting through an emergency stockpile and ii) preventive vaccination in a non-outbreak setting, both contingent on WHO prequalification of vaccine and SAGE recommendation, in line with Board-approved policies and decisions with adjustments laid out under b), c) and d);

b) **Approve** Gavi support for vaccines for preventive use without a co-financing obligation for Gavi eligible countries with the co-financing policy for Ebola vaccine subject to review after two years from start of programme;

c) **Approve** Gavi operational cost support for both reactive and preventive vaccination that is tailored to each country based on context;

d) **Approve** the principle of providing non-Gavi eligible countries access to vaccines for preventive vaccination, where possible. These countries would bear the cost of the vaccine;

e) **Note** the financial implications associated with the above approvals for vaccine procurement, operational cost support and Secretariat and partner resources for 2020 is expected to be approximately US$ 9 million and for 2021-2025 is expected to be approximately US$ 169 million. Gavi will seek to absorb the Secretariat and PEF-related components in the 2020 estimated costs within the 2020 budget submission;

f) **Note** that the Secretariat will work with partners to further develop processes to enable allocation of vaccines and operational cost support for both reactive and preventive use;

g) **Approve** retaining the operational cost and health system support component of the 2014 Ebola envelope for the interim period before a licensed vaccine is available in order to provide operational support for use of investigational vaccines and closing the remainder of the 2014 Ebola envelope; and

h) **Note** the remaining balance of the operational cost and health systems support component of the 2014 Ebola envelope of US$ 52.4 million.

Kate O'Brien (WHO), Robin Nandy (UNICEF), Adar Poonawalla (DCVMN), and An Vermeersch (IFPMA) recused themselves and did not vote on Decision Six above.

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9. Update on Key Recommendations of the Independent Review Committee and High Level Review Panel

9.1 Clifford Kamara, Chair of the Independent Review Committee (IRC), provided the PPC with an overview of the IRC process over the past year (Doc 09), including a summary of the key recommendations stemming from these reviews and the subsequent actions taken by the Alliance.

9.2 Anuradha Gupta, Deputy CEO, then provided an update on the High Level Review Panel process. She noted that the IRC Chair is a member of the HLRP, and acknowledged the contribution of WHO and UNICEF, together with the Managing Director of Country Programmes, Thabani Maphosa, and the Managing Director of Vaccines & Sustainability, Aurelia Nguyen.

Discussion

- PPC members raised the ongoing issue of the role of Technical Assistance (TA) in preparing applications for Gavi support and the importance of striking the right balance between improving the quality of applications, while ensuring country ownership and capacity building.

- PPC members discussed the role of the National Immunisation Technical Advisory Groups (NITAGs), highlighting a number of related issues such as the need to revise the ToR of NITAGs and ICCs in order to address the disconnect between them.

- The role of Civil Society Organisations (CSOs) in application development was discussed and was highlighted as an important area to focus on.

- One PPC member raised the extent of the challenges in country's preparing high quality applications, including incomplete budgets in the funding applications as indicated in the report, adding that based on country experience, lump sum budgets that are presented are sometimes difficult to break down. The IRC Chair noted that incomplete budgets pose certain challenges and can also delay resolution of IRC recommendations, causing subsequent late disbursements.

- It was recommended that the Alliance continue to pursue simplification of guidelines and processes, as some countries face implementation challenges due to lack of understanding of the application process, including IRC comments.

- Surveillance was also identified as an important focus area. It was noted that often countries do not have visibility on disease-specific or integrated-disease surveillance and this issue was raised during the discussions on Gavi 5.0.

- The PPC also noted the developments made in the Alliance's renewal and HLRP process. The PPC acknowledged the more robust vaccine dose renewal process, and emphasised the importance of ensuring HSS and TCA investments are holistically reviewed for greater complementarity and alignment.

10. Review of decisions

10.1 Joanne Goetz, Head, Governance, reviewed the decision language with the Committee which was approved by them.

10.2 Committee members noted that the Funding Policy Review, Malaria, and Ebola items would be standalone for the December 2019 Board meeting and that the Sudan Eligibility recommendation would be presented to the Board on its consent agenda.

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11. Any other business

11.1 PPC members noted 2020 meeting and dates to be held on Tuesday 26 May 2020 and Wednesday 27 May 2020.

11.2 PPC members noted that SAGE is looking for new members from some regions with a 31 Oct deadline for applications.

11.3 Finally, the PPC recognised the three PPC members who will rotate off the Committee before the next meeting: Dure Samin Akram, Adar Poonawalla, and An Vermeersch.

11.5 After determining there was no further business, the meeting was brought to a close.

Mrs Joanne Goetz
Secretary to the Meeting

Attachment A

Participants

Committee Members

- Helen Rees, Chair
- Dure Samin Akram
- Edna Yolani Batres
- Naomi Dumbrell
- Susan Elden
- Abdul Wali Ghayur
- Vandana Gurnani* (Agenda items 1, 2, 4)
- Lene Lothe
- Violaine Mitchell*
- Robin Nandy
- Kate O'Brien
- Adar Poonawalla (except Agenda Item 05)
- Michael Kent Ranson
- William Schluter
- Joan Valadou
- An Vermeersch
- Seth Berkley, Chief Executive Officer
- Alejandro Cravioto

Regrets

- Ahmed Abdallah

Other guests

- Julian Schweitzer,* Chair, Steering Committee, Funding Policy Review (Agenda Item 04)
- Clifford Kamara,* Independent Review Committee (IRC) Chair (Agenda Item 9)

Observers

- Naoki Akahane, Japan
- Nina Schwalbe,* Chair, Gavi Evaluation Advisory Committee
- Ruzan Gyurjyan, Special Adviser to the EURO constituency
- Gloria Kebirungi, Special Adviser to the Board Chair (Day 2)
- Pratap Kumar Special Adviser to the EMRO constituency
- Rolando Pinel, Special Adviser to the PAHO constituency
- Bruno Rivalan, Special Adviser to the CSO constituency
- Khant Soe, Special Adviser to the SEARO/WPRO constituency

* denotes participation by Webex

Gavi Secretariat

- Anuradha Gupta
- Nadine Abu-Sway (Agenda Items 3, 5, 9)
- Johannes Ahrendts (Agenda Items 2, 3)
- Pascal Bijleveld
- Anthony Brown (Agenda Items 4, 5, 8)
- Adrien de Chaisemartin
- Santiago Cornejo
- Anne Cronin (Agenda Items 3, 7)
- Sally Dalgaard
- Assietou Diouf
- Marthe Sylvie Essengue Elouma
- Joanne Goetz
- Daniel Hogan (Agenda Items 3, 6)
- Hope Johnson
- Alex de Jonquières
- Thabani Maphosa
- Wilson Mok (Agenda Items 3, 4, 5, 8)
- Meegan Murray-Lopez
- Aurélia Nguyen
- Zeenat Patel (Agenda Items 2, 3, 4, 7, 8, 9)
- Marie-Ange Saraka-Yao (Agenda Item 8)
- Colette Selman
- Prachi Shah (Agenda Item 7)
- Jacob van der Blij
- Charlie Whetham

PROGRAMME AND POLICY COMMITTEE WORKPLAN

Graphical Format

PPC Agendas	Jul-Sept 2020	28-29 Oct 2020	16-17 Dec 2020 Bd	Jan-Apr 2021	May 2021	June 2021 Bd
STANDING ITEMS AT EACH REGULAR MEETING						
Chair's report (Decl. of Int., Minutes, Workplan, Update)		Information			Information	
CEO Update		Discussion			Discussion	
2016-202 Strategy: Progress, Challenges and Risks		Discussion			Discussion	
Alliance Update		Discussion			Discussion	
Review of decisions		Information			Information	
Any other business		N/A			N/A	
STANDING ITEMS ONCE PER YEAR						
IRC & HLRP Report		Information				
Market shaping update					Information	
Monitoring & Evaluation update		Information				
Risk and assurance report		Guidance	Decision			
ITEMS AS REQUIRED						
Strategy						
Gavi 5.0 - Measurement Framework		Decision	Decision		Decision	Decision
Gavi 5.0 - Partner's Engagement Framework		Decision	Decision			
Gavi 5.0 - Update on operationalisation of workstreams		Information			Information	
Gavi policies, procedures and processes						
Funding Policy Review (to be resumed in late 2020 or 2021 - timeline TBD)					Decision	Decision
Supply & Procurement Strategy		Guidance			Decision	Decision
Country support updates and processes						
Gavi's approach to engagement with former and never-eligible Middle Income Countries (MICs)					Decision	Decision

Traditional Format

Programme and Policy Committee
28-29 October 2020
Geneva
Ref: PPC-2020-Mtg-2

Day 1

Chair's report (Decl. of Int., Mins, Actions, Wkplan, Update)	**INFORMATION**
CEO Update	**DISCUSSION**
2016-2020 Strategy: Progress, Challenges and Risks	**DISCUSSION**
Gavi 5.0 – Measurement Framework	**DECISION**
Partners' Engagement Framework	**DECISION**
Supply & Procurement Strategy	**GUIDANCE**

Day 2

Alliance Update	**DISCUSSION**
Gavi 5.0 – Update on operationalisation of workstreams	**INFORMATION**
IRC & HLRP Report	**INFORMATION**
Monitoring & Evaluation update	**INFORMATION**
Risk and assurance report	**GUIDANCE**
Review of decisions	**INFORMATION**
Any other business	

Programme and Policy Committee
May 2021 (TBD)
Geneva
Ref: PPC-2021-Mtg-1

Day 1

Chair's report (Decl. of Int., Mins, Actions, Wkplan, Update)	**INFORMATION**
CEO Update	**DISCUSSION**
2016-2020 Strategy: Progress, Challenges and Risks	**DISCUSSION**
Market Shaping update	**INFORMATION**
Gavi's approach to engagement with former and never-eligible Middle Income Countries (MICs)	**DECISION**
Gavi 5.0 – Measurement Framework	**DECISION**

Day 2

Alliance Update	**DISCUSSION**
Gavi 5.0 – Update on operationalisation of workstreams	**INFORMATION**
Funding Policy Review	**DECISION**
Supply and Procurement Strategy	**DECISION**
Review of decisions	**INFORMATION**
Any other business	

As of 5 May 2020

* This workplan is indicative and subject to change. In light of the current global context, the workplan and agendas for upcoming PPC meetings are likely to be modified to adapt to changing circumstances.

Report to the Programme and Policy Committee
26-27 May 2020

SUBJECT:	**CEO UPDATE**
Agenda item:	02
	No paper

Report to the Programme and Policy Committee

26-27 May 2020

SUBJECT:	**STRATEGY: PROGRESS, CHALLENGES AND RISKS AND IMPLICATIONS OF COVID-19 ON GAVI 5.0 OPERATIONALISATION**
Agenda item:	03
Category:	For Decision

Section A: Introduction

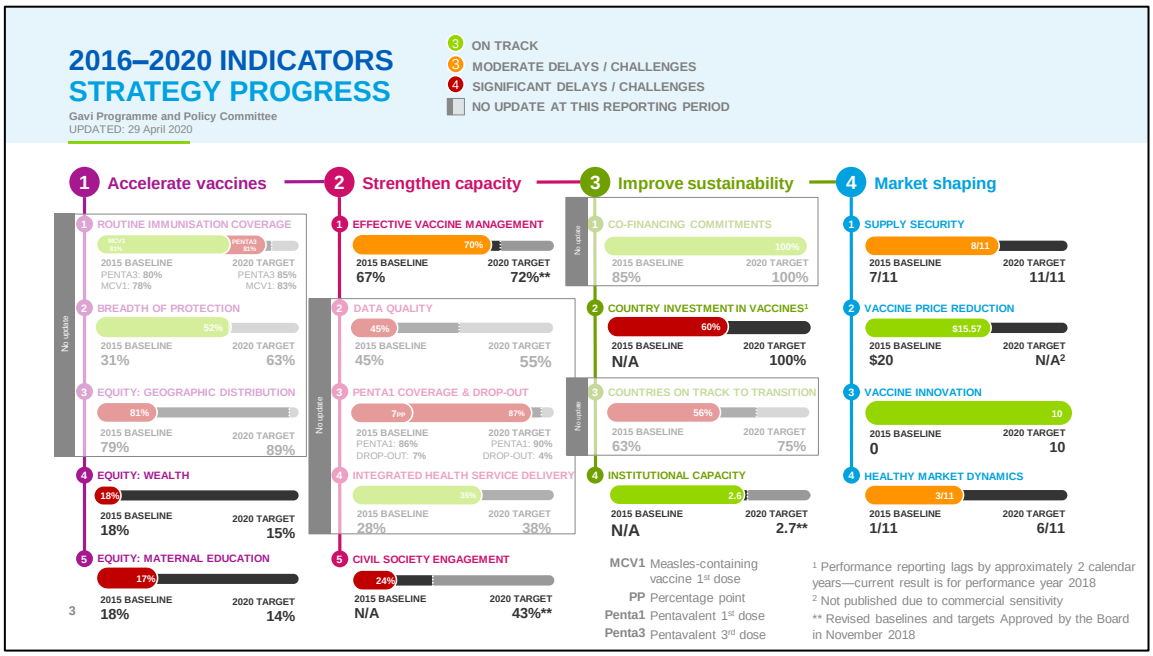
- **2020 is the last year of Gavi's 2016-2020 Strategy ('Gavi 4.0') and this is the ninth report to the Programme and Policy Committee (PPC) on progress in implementing the strategy and on the associated risks**[1]. This report traditionally gives an overview of how the Alliance is delivering against its Strategic Goals, including a holistic view across the Alliance's portfolio of support to countries including vaccine programmes, Health System and Immunisation Strengthening (HSIS) support and technical support provided under the Partners' Engagement Framework (PEF).

- **As the COVID-19 pandemic unfolds, this report also provides an overview on the immediate impact on achieving the targets of Gavi 4.0, the Alliance's proactive response to the crisis and the potential implications on Gavi 5.0 priorities and its operationalisation over the next 18 months**. A more exhaustive view on the impact on immunisation programmes in countries and Gavi's response is provided in Docs 05 and 06. One specific Gavi 5.0 element impacted by COVID-19 is the Funding Policy Review, which has been paused as recommended by the Steering Committee (see Annex D). However, the PPC is requested to recommend to the Board that it approve the immediate roll-out of select policy shifts which were already approved and, in addition, remove the joint investment requirement for Gavi support for Cold Chain Equipment (CCE).

[1] Associated risks refer to the top risks described in the 2019 Risk & Assurance Report (see https://www.gavi.org/news/document-library/gavi-risk-and-assurance-report-2019). The COVID-19 pandemic has led to an extraordinarily uncertain environment with a significant impact on Gavi's risk profile, as described on a high-level in the AFC update on risk management (Annex C) and for programmatic risks in more detail in Docs 05 and 06.

Section B: Gavi 4.0 strategy: Progress, Challenges and Risks and immediate impact of COVID-19

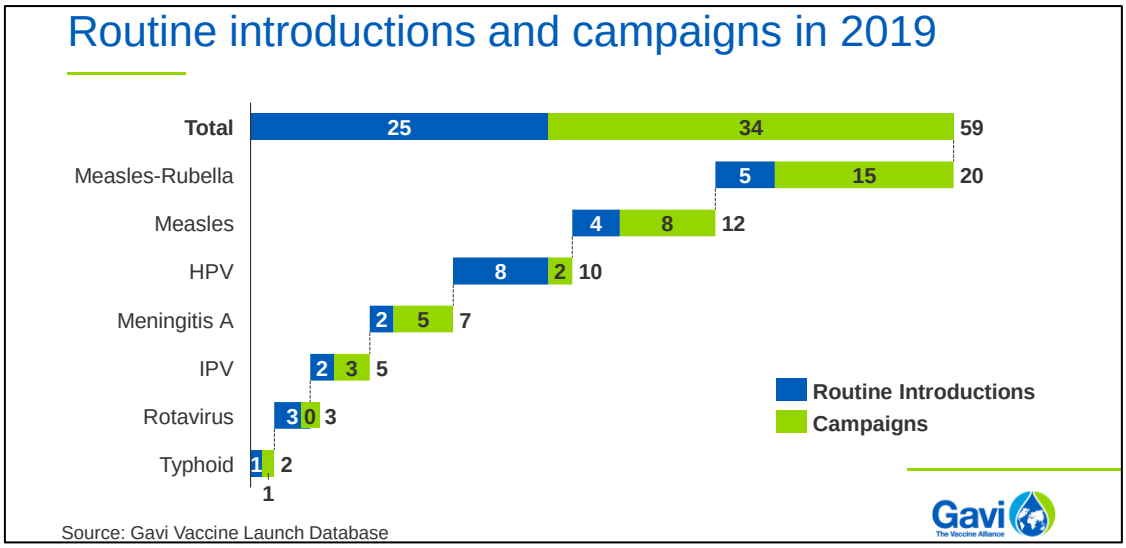
1.1 **Despite the COVID-19 pandemic the Alliance is very close to reaching its mission target of averting five to six million deaths**, and should **reach its goal of immunising 300 million additional children** in the current five-year strategic period unless routine immunisation coverage falls by more than ~50% in 2020[2]. However, **COVID-19 is expected to impact progress and poses risks to the health, economic, social and political landscape in Gavi-eligible countries**. While the full implications will only become clearer over time, the pandemic has already had a significant and visible impact on vaccine introductions, routine immunisation, planned campaigns and fiscal space in Gavi-supported countries, placing a disproportionate burden on the most marginalised populations. The Alliance is taking a proactive approach in responding to the pandemic (see Doc 5).



Strategic Goal 1: Accelerate Vaccines

1.2 **2019 saw a record number of vaccine introductions, 20% more than 2018.** With 25 routine introductions and 34 campaigns, the target of 56 launches was exceeded by three.

[2] Mission indicators will be updated after the release of WHO-UNICEF vaccination coverage estimates (WUENIC) in July 2020. The latest mission indicators dashboard can be found in Doc 03 of the October 2019 PPC meeting.



1.3 **Pakistan has become the first country worldwide to introduce typhoid conjugate vaccine (TCV) into its routine immunisation programme.** The introduction is phased over three years and includes integration into routine immunisation programmes and one-time catch-up immunisation. In late 2019, the first phase of the introduction was conducted in Sindh province, which is the centre of an ongoing extensively drug-resistant (XDR) typhoid outbreak. Gavi is funding an evaluation of TCV's impact on typhoid incidence and antimicrobial resistance to optimise Gavi's TCV support and enable TCV introduction decision making in Gavi-eligible countries.

1.4 **To date, 27 Gavi eligible countries have been approved for human papillomavirus (HPV) routine programmes and 21 for multi-age cohort catch-up vaccination.** Of these, 19 routine and four multi-age cohort introductions have been completed to date. In spite of COVID-19, three further routine introductions are expected to occur in 2020. The ongoing supply constraints have delayed 15 multi-age cohort introductions to the next strategic period or later. As a result, 14 million vaccinations of girls with a corresponding ~300,000 deaths averted will be achieved in Gavi 4.0, compared to the previously targeted 40 million vaccinations and ~900,000 deaths averted. To continue progress despite COVID-19, many countries have adapted their delivery strategy from school to health facility and community based. With that, for instance, Lao PDR is achieving a coverage of ~70% (dose 1) during the pandemic. Many countries plan to apply the WHO guidance for having a dose interval of ~12-15 months to catch up the missed girls after the pandemic.

1.5 In 2018, the Board approved support for inactivated polio vaccine (IPV) beyond 2020, including the introduction of a second dose of IPV (IPV2). **The introduction of IPV2 will begin following the completion of catch-up activities to vaccinate missed birth cohorts** due to global supply constraints. 66 countries are now expected to introduce IPV2 in the next strategic period. The risk of COVID-19 exacerbating the circulation of wild and vaccine-derived poliovirus will need to be carefully watched.

1.6 **The share of campaigns among overall vaccine launches has continued to increase, largely driven by the strategy to control measles and introduce rubella-containing vaccine (RCV).** In 2019, Gavi funded 18 preventive Measles and Measles-Rubella (MR) campaigns, and another five MR catch-up campaigns for the routine introduction of RCV. Thanks to Gavi support for RCV introduction and scale-up in 32 countries, RCV1 coverage increased from 3% in 2012 to 54% in 2018. Gavi's investments have also led to a steady increase in people protected with two doses of Measles-containing vaccine (MCV2), with coverage increasing from 7% in 2007 to 54% in 2018 across Gavi 68 countries. To further encourage countries to strengthen routine immunisation for MCV, and target missed children, the Board approved additional flexibilities in 2018 for the use of operational costs[3]. However, efforts to implement more tailored and targeted campaigns have not fully materialised. Nationwide non-selective campaigns have continued to be preferred for a range of reasons, including the accumulation of children with insufficient measles immunity since the last nationwide campaign, recent nationwide decreases in coverage, inadequate MCV2 coverage, unreliable data quality at sub-national level, and the risk of importing cases from neighbouring countries. Nevertheless, engagement with countries has led to the design and testing of new approaches, such as selective vaccination and electronic immunisation registries (in Zambia) and the follow-up of measles zero-dose children in the post-campaign period (in Zambia and Burundi).

1.7 Although four countries[4] have published new surveys in 2019, **there is no significant change in the wealth and gender equity indicators.** Two of these, Zambia and Cameroon, report a narrowing gap in equity by wealth, while in the other two, the Gambia and Lesotho, the gap has widened. For equity by maternal education, Zambia and Lesotho report a narrowing gap, while the gap has widened in the Gambia and Cameroon.

1.8 **COVID-19 already has a measurable impact on introductions and campaigns. Of the up to 65 introductions initially forecasted for 2020, ten** Gavi-supported vaccine introductions have already been delayed, with a further five at risk and 25 campaigns covering at least 140 million people have been suspended or delayed and another 9 are at risk in 2020. While long-term impact of COVID-19 is uncertain, it is already clear that **millions of people in Gavi-supported countries will miss out on immunisation**. A significant growth in the number of susceptible persons increases the **risk of vaccine-preventable disease outbreaks** (e.g. measles, polio, diphteria) exacerbating existing inequities and putting the most marginalised and poorest communities at greatest risk. A more detailed update on the immediate impact of COVID-19 and Gavi's response to maintain and restore immunisation programmes is provided in Doc 5.

[3] Countries are able to apply for operational costs support for M/MR follow-up supplementary immunisation activities (SIAs) up to the national 9-59 month population, to be used for national SIAs, subnational SIAs and enhanced routine immunisation activities targeted at reaching missed children

[4] Zambia, Cameroon, Gambia, Lesotho.

Strategic Goal 2: Health System Strengthening

1.9 **In order to increase immunisation coverage and equity, a further eight countries have received approval for Health System Strengthening (HSS) flexibilities[5] since October 2019, bringing the total number to 30.** Of these, nine are countries classified as fragile[6] and can access up to 50% of their HSS ceiling under the Fragility, Emergencies and Refugees (FER) policy. A total of US$ 238 million has been approved under these flexibilities, US$ 151 million for non-fragile, and US$ 86.8 million for fragile countries. Most of the countries have used the flexibilities to address sub-national coverage and equity challenges, including strengthening of the cold chain, improving community demand for immunisation and capacity building of health workers. As the COVID-19 pandemic impacts routine immunisation services (see below), some countries may require additional time to implement the activities under these flexibilities in 2021.

1.10 **There is further progress in accelerating the time to disburse cash grants.** Across all 57 new HSS, vaccine introduction (VIG) and operational support (Ops) grants [7] disbursed in 2019, it took 10.9 months from Independent Review Committee (IRC) recommendation for approval to disbursement. This is higher than the target of nine months, but significantly lower than the 17.5 months reported in 2018. On excluding those grants that were impacted by vaccine supply constraints, the average further drops to 10.1 months. As part of Gavi 5.0 operationalisation, a new portfolio management process is being designed and planned to be rolled out starting in Q4 2020. This is expected to further reduce timelines and to align better with country needs. The Secretariat has also increased the absolute level of HSS disbursements from US$ 284 million in 2018 to US$ 331 million in 2019, driven primarily by the aforementioned HSS flexibilities.

1.11 **Effective vaccine management (EVM) continues to improve. All six countries with EVM assessments in 2019[8] have improved their score, with an average increase of 6.5 percentage points**. The average composite score across all 67 Gavi-supported countries with an EVM assessment was 70% at the end of 2019, unchanged from 2018 due to the limited number of assessments conducted in 2019. Due to the COVID-19 pandemic, EVM assessments are halted for 2020.

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[5] In order to advance Gavi's strategic goal of increasing immunisation coverage and equity, for the remainder of the strategic period through 2020, the Board granted Gavi the flexibility to increase an individual country's allocation ceiling for HSS support by up to 25% beyond the total amount of the ceiling

[6] The list of countries classified as fragile is reviewed and updated annually every July based on the OECD States of Fragility report, the Fund for Peace Fragile States Index and the World Bank Harmonised List of Fragile States. The list of countries facing fragility for July 2019- July 2020 are: Afghanistan, Burundi, Central African Republic, Chad, DR Congo, Eritrea, Haiti, Mali, Papua New Guinea, Solomon Islands, Somalia, South Sudan, Sudan, Syria, Yemen.

[7] Excludes aforementioned HSS flexibilities.

[8] Burkina Faso, Comoros, Democratic People's Republic of Korea (DPRK), Democratic Republic of Congo (DRC), Ethiopia and Guinea-Bissau; all six assessments were conducted based on the EVM 1.0 assessment tool.

1.12 As of Q1 2020, **49 out of the 57 countries eligible to the Cold Chain Equipment Optimisation Platform (CCEOP) have applied to the platform.** Three countries, Democratic People's Republic of Korea (DPRK), Cambodia and Syria are expected to submit applications in 2020. The Alliance has procured over 42,000 units of Ice-lined (ILR) and Solar Direct Drive (SDD) Refrigerators and was, before the COVID-19 pandemic, on track to reach its targets of procuring 65,000 units by 2020. **The CCEOP has led to better quality equipment supplied by a larger set of suppliers at lower prices in 2019.** Eight CCE suppliers now supply equipment fulfilling specified quality requirements, up from six before the CCEOP was launched. The concentration of market share has decreased, with the market share by volume of the two largest manufacturers shrinking from ~80% in 2018 to ~65% as of end 2019. At the same time, significant price reductions (>10%) were achieved for both ILRs and SDDs through shifting country preferences to more cost-effective options and through pooling procurement to unlock volume discounts and achieve service bundling. However, the risk of unhealthy market shares and potential for higher prices and reduced incentives for innovation remains. An independent CCEOP midline evaluation confirmed that the platform responds to country needs and has been coordinated well among partners, while identifying specific areas of improvement such as communication around technical service bundle details. Acknowledging the overall success of the model, several donors and partners have also approached Gavi to **explore whether the CCEOP could be used to help support the broader response to COVID-19** (see Doc 05).

1.13 **Gavi has continued to step up its work on demand generation, communities and gender through the demand hub,** led by UNICEF and the Secretariat with WHO, United States Centers for Disease Control (CDC), Bill and Melinda Gates Foundation (BMGF), John Snow, Inc. (JSI), International Federation of Red Cross and Red Crescent Societies (IFRC) and the Civil Society Organisation (CSO) constituency. For instance, support from the Alliance has made it possible for UNICEF to conduct human centred design workshops framed around the demand hub's 'caregiver journey' in Zimbabwe, Indonesia, South Sudan, Myanmar and Pakistan. As an example, this innovative approach was used in Zimbabwe to better frame immunisation within the belief system of religious leaders, which made it possible for the community to accept the services. At the Secretariat, an integrated hub for demand generation, communities and gender as well as an updated Gender Policy (pending final Board approval) ensure a holistic vision and approach (see Doc 04). In the context of COVID-19, the Alliance's work on demand, communities and gender is pivoting towards sustaining demand and rebuild trust during and after the pandemic (see Doc 05).

1.14 **Improving the performance of technical assistance provided to countries by partners under the Partners' Engagement Framework (PEF) and its alignment with HSS support remains a strong focus.** Building on six independent Targeted Country Assistance (TCA) assessments conducted throughout 2019 and reported on at the last PPC

in October 2019, a meta-review with key cross-country findings and recommendations was concluded in early 2020. The meta-review recommended to further leverage the comparative advantage of a large set of partners and ensure that the Alliance creates a level-playing field for these partners to engage with countries and become TCA implementers. The report emphasised that such a new approach would help ensuring that partners are selected based on their merit, comparative advantage and relevance to meet needs for technical assistance. The report also recommended to move from single year to multiyear TCA planning and funding; and to focus the monitoring process on a limited set of intermediate outcomes. The PEF Management Team has discussed these findings extensively and has recommended them to be integrated into the new partnership model for Gavi 5.0 (see section D).

1.15 **Whilst the longer-term trajectory of COVID-19 in Gavi-supported countries remains uncertain, there are significant risks and visible disruptions to immunisation and other essential health services in Gavi-supported countries**. Although most health facilities are reportedly open and continuing to offer fixed site immunisation, nearly half of countries in Africa have partially or entirely suspended outreach, which is likely to disproportionately impact the most marginalised communities. Health workers in the most affected countries are increasingly being diverted to the COVID-19 response. Suspended international shipments and restrictions on movement have hindered vaccine distribution in some countries. Demand for immunisation is also impacted with reports from many countries suggesting significant drops in attendance at immunisation sessions due to challenges in accessing health facilities (e.g. due to restrictions on movement or concerns about COVID-19 exposure). Demand is also at risk due to misinformation about vaccines with a surge in rumours and conspiracy theories surrounding COVID-19 circulating on social media. **Doc 05 includes a more detailed update on the immediate impact of COVID-19 on countries and their immunisation programmes and Gavi's programmatic response to maintain and restore services.**

Strategic Goal 3: Improve Sustainability

1.16 **Gavi's co-financing policy continued to show unprecedented success in 2019, with co-financing performance reaching an all-time high:** 49 out of 50 countries met their 2019 co-financing commitments on time[9], with Liberia being the only defaulting country. This represents the highest share of countries fulfilling their obligations on time and the lowest number of defaulters since the co-financing policy was implemented in 2008. Furthermore, all three countries which defaulted on their 2018 co-financing obligations (Cameroon, Ghana and Sierra Leone) complied with their default payment plans in 2019. These achievements confirm a positive trend since 2014, when the number of defaults peaked at 17, and testify to

[9] Ethiopia, Kenya and Pakistan co-financing obligations are due by 30 June 2020 due to alignment with their fiscal years. South Sudan was approved for a waiver until 2020 for co-financing requirements and therefore was not included in the total number of countries with co-financing requirements due.

the increasing country ownership of vaccines introduced with Gavi support. The total amount invested by countries in co-financing vaccines has now exceeded US$ 1 billion, with an additional US$ 700 million estimated to have been invested by India and self-financing countries to fund vaccines introduced with Gavi support.

1.17 **Transitioned countries have also consistently sustained programme performance.** Of the 15 countries that transitioned more than a year ago[10], nine transitioned from Gavi support with DTP3 coverage above 90% and have maintained this level. Of the remaining six countries, all but one have either maintained or improved their coverage levels since transitioning (the exception being Bolivia, where Penta3 coverage fell by 1 percentage point from 84% before transition to 83% in 2018).

1.18 **However, COVID-19 and the severe economic downturn the pandemic is expected to cause are likely to negatively affect these positive trends.** Many countries will struggle with revenue underperformance, emergency budget reallocations, and tighter liquidity management. These constraints are likely to limit the available fiscal space to fund immunisation and other essential health services, resulting in a higher **risk of co-financing defaults**. Similarly, **sustainable transition is at risk** with expected transition trajectories being affected as GNI per capita growth rates decelerate or turn negative. Many current Gavi-eligible countries will see their progression through the phases of support delayed, with several moving backwards. COVID-19 may also increase the **risk of backsliding** in transitioned countries. As per the Board's decision at its 11 May 2020 meeting Gavi will implement a number of measures to address these challenges, balancing this acute need with the objective to **continue to incentivise countries on their path to a successful transition** (see Doc 05).

Strategic Goal 4: Shape Markets

1.19 **Market shaping indicators were largely on track in 2019.** The indicators on healthy market dynamics and vaccine price reduction were fully on track to meet 2020 targets, while the other two (supply security and vaccine innovation) experienced moderate challenges.

1.20 **Healthy market dynamics: In 2019, three out of eleven markets were identified as exhibiting moderate or high levels of healthy market dynamics (from a 2019 target of four and a 2020 target of six).** All three (pentavalent, pneumococcal and yellow fever) were categorised as having moderate health. Of the eight other markets assessed to be low health, measles, meningitis A and Japanese encephalitis were exposed to low supplier diversity, but all considered within acceptable risk levels due to sufficient capacity and strong track record of the dominant supplier.

[10] Excludes Vietnam, which has transitioned at the end of 2019 and for which it is too early to assess progress.

1.21 **Vaccine price reduction: The cost of fully vaccinating a child with pentavalent, rotavirus and pneumococcal conjugate vaccine (PCV) has continued to decrease.** From 2018 to 2019, the weighted average prices for a full course of the three vaccines decreased by 2%, from US$ 15.90 to US$15.57, driven by price reductions in pentavalent (from US$ 2.69 to US$ 2.58 per course) and rotavirus (from US$ 4.25 to US$ 4.03 per course). The overall price reduction since the 2015 baseline now stands at 22%. In the Pentavalent market the priority shifts to ensuring market stability and maintaining low supply security risks, with further price reductions neither expected nor desired. Pricing trends for rotavirus and PCV markets may have further room for decrease as market mix evolves.

1.22 **Supply security: Eight vaccine markets out of eleven had sufficient and uninterrupted supply in 2019** (Pentavalent, Rotavirus, PCV, Measles-Rubella, Measles, Japanese Encephalitis, Yellow Fever, Meningitis A), while there were supply constraints for HPV, IPV and Oral Cholera Vaccine (OCV). It is expected that HPV supply to Gavi-eligible countries will improve significantly in Gavi 5.0. IPV supply is also expected to improve during the upcoming tender period, based on the advent of new manufacturers, allowing for catch-up immunisation and the introduction of a second routine dose, as recommended by the Strategic Advisory Group of Experts (SAGE) on Immunization. For OCV, there is a high risk that supply will not meet Gavi's base-case demand scenario in the short-term through ~2023 due to uncertainties surrounding pipeline candidates, while supply will increasingly meet demand in the medium-term and exceed demand in the longer-term.

1.23 **Vaccine innovations: Three additional innovations were added to the Gavi vaccine portfolio in 2019:** A PCV product with extended 4-year shelf-life, enabling more flexible stock management in country and in the supply chain; a rotavirus product with improved primary container (blow-fill-seal) that reduces the cold chain footprint and ease of use; and a new measles-rubella (MR) product available in a 5-dose vial presentation, improving wastage rate while retaining low volume in the cold chain.

1.24 **The Vaccine Innovation Prioritisation Strategy (VIPS) has shortlisted nine vaccine delivery innovations and further assessed these innovations with licensed and pipeline antigens to facilitate final prioritisation**. The VIPS Steering Committee will make its final recommendations at the end of May. In order to maintain momentum, some work on post-prioritisation steps such as developing an outline for an action plan for each prioritised innovation are being fast-tracked. Planning is underway for further consultations with developers and manufacturers to understand critical activities to accelerate relevant innovations in their portfolio.

Section C: Gavi's immediate response to COVID-19 over the next 18 months

2.1 As COVID-19 pandemic unfolds, **Gavi has taken swift and proactive action to support countries as they prepare to respond to the**

pandemic. In early March, Gavi made available up to US$ 200 million in support of countries' COVID-19 preparedness and response plans. This includes allowing countries to reallocate up to 10% of their health system strengthening (HSS) grants, their PEF TCA, and post-transition support. The primary purpose was to **help prepare countries' health systems to deal with the impact of COVID-19, and help protect immunisation programmes and maintain services** to the extent possible. All Gavi support is aligned to countries' Strategic Preparedness and Response Plans and coordinated with other donors. **Gavi has approved HSS reprogramming of over US$ 51 million for 32 countries** [11] . Another four applications are under review. Under the Partners' Engagement Framework (PEF), the Alliance is also realigning and reprioritising its work to monitor and respond to COVID-19. **Doc 05 provides further details** on the Alliance's support to countries' immediate response.

2.2 Beyond the immediate support provided to countries, Gavi's response in the next 18 months is articulated around a **comprehensive approach to support countries to maintain and restore immunisation** and **to accelerate equitable access to COVID-19 vaccines** for developing countries. This response is described further in Docs 05 and 06. The implications of COVID-19 and Gavi's response for Gavi 5.0 priorities and operationalisation are outlined in the next section.

Section D: Impact of COVID-19 on Gavi 5.0 priorities and operationalisation

3.1 **The Alliance remains grounded in the Gavi 5.0 strategy.** Gavi 5.0's vision of leaving no one behind with immunisation and equity as the organising principle is more relevant than ever in the light of the pandemic. The poorest and most vulnerable are likely to be the most affected by the COVID-19 pandemic and at highest risk of vaccine-preventable diseases (VPDs) outbreaks and related mortality and morbidity. However, the challenges brought by the pandemic and Gavi's response necessitate a review and reprioritisation of some **elements of Gavi 5.0**:

a) **Strategic Goal 1 – Introduce and Scale up Vaccines:** With the impact of COVID-19 on countries' priorities, the introduction of new vaccines might be considered less urgent as countries focus on restoring immunisation coverage (see section B). The rollout of the various vaccines approved through the vaccine investment strategy (VIS) in 2018 might have to be deferred and reassessed after the acute phase of the pandemic. Once available and approved by the Board, the rollout of COVID-19 vaccines will become an additional priority for the Alliance. The pandemic also highlights the critical importance of early detection of pathogens with epidemic potential and strong preparedness for

[11] The risk of misuse by countries may be heightened with a fast-tracked application and review process, audits on hold and in-country fiduciary agents being impaired. However, a risk lens was applied with lower risk personal protective equipment being the largest area of funding, which are procured by UNICEF Supply Division.

response. As VPD outbreaks could intensify, access to stockpiles may become even more important. The Alliance may want to look into how it could take a more deliberate approach in this area, particularly in infectious disease surveillance.

b) **Strategic Goal 2 – Strengthen Health Systems to Increase Equity in Immunisation:** As described in section B, COVID-19 is likely to result in millions of children being missed for immunisation, and particularly impact the most marginalised communities. While countries are likely to face delays in planning and implementing Gavi's health system support, equity – with a focus on zero-dose children and marginalised communities – will be at the heart of Gavi's efforts to maintain and restore immunisation services. **This provides an opportunity to test new ways of working and accelerate progress on equity** through highly differentiated, targeted and tailored approaches involving local partners and communities and a subnational focus. Coordination with other donors and partners will be more important than ever, maximising opportunities for integrated and equitable primary health care (PHC) service delivery. Finally, several donors and partners have also approached Gavi to explore whether the **Cold Chain Equipment Optimisation Platform (CCEOP) could be used to help support the broader response to COVID-19.** Doc 05 describes this in more detail.

c) **Strategic Goal 3 – Improve sustainability of immunisation programmes:** The long-term goal to promote domestic public resource allocation for immunisation and PHC remains as important as ever. However, as outlined in section B, COVID-19 puts at risk some countries' ability to prioritise domestic public resources for immunisation and to transition successfully out of Gavi support. Hence, Gavi's ambition for levels of co-financing and number of successful, sustainable transitions will need to be adjusted in line with the ultimate impact of COVID-19. Flexibilities to mitigate the acute impact of the pandemic, such as freezing eligibility and co-financing levels as well as waiving co-financing waivers, approved by the Board at its 11 May 2020 meeting, need to balance this acute need with the objective to continue to incentivise countries on their path to a successful transition and more efficient domestic resource allocation.

d) **Strategic Goal 4 – Ensure healthy markets for vaccines and related products:** Healthy markets and innovation for vaccines and vaccine-related products will continue to be a priority for Gavi. In addition to the existing vaccine portfolio, Gavi has started to design an approach to shape the market for COVID-19 vaccines to ensure equitable access to sufficient, timely and affordable supply of vaccines. Doc 06 provides more details on Gavi's engagement. The Alliance is also prioritising ensuring uninterrupted supply of its existing vaccine portfolio during the pandemic.

3.2 **COVID-19 also poses challenges to operationalising the Gavi 5.0 strategy.** The operationalisation is a consultative process articulated

across six workstreams and aims to review and transform Gavi's policies, strategic approaches, processes and tools to ensure alignment with the new strategy. Given the uncertain impact of COVID-19 in countries and bandwidth constraints in the Secretariat, the Alliance and countries, **some of the operationalisation work is being slowed down and adjusted to respond to the new realities in countries. More specifically, Gavi anticipates the following implications across the six workstreams:**

a) **Measurement & accountability**: The design of Gavi 5.0 measurement framework indicators will continue with the support of a technical working group of Alliance partners. Many strategy indicators developed over the past six months so far are anticipated to remain relevant for Gavi 5.0, however indicators related to the COVID-19 response will be needed and target-setting must consider the impact of COVID-19 on programmes and performance data. A detailed update is provided to this PPC (Doc 07) and a decision on the framework is still expected for the December 2020 Board meeting with some potential aspects delayed in particular on targets due to uncertainty on the impact of COVID-19 on baselines.

b) **Funding Policy Review (FPR):** The Steering Committee guiding the FPR recommended that the review be paused in light of the COVID-19 pandemic given limited country capacity to enact new policies. However, it is proposed that some FPR shifts (approved by the Board in December 2019) still move forward following the June 2020 Board meeting, alongside the broader COVID-19 response (see Doc 05). These specific provisions facilitate countries' full and timely access to funding, align with new funding cycles and remove unnecessary requirements. These include: the HSS allocation formula so amounts can be communicated to countries entering planning processes; removing the cap of US$ 100 million on HSS allocation ceilings; removing the poorly performing performance-based funding (PBF) approach; integrating CCE into the HSS envelope and removing the generic programme filter. In addition, the FPR Steering Committee in principle agreed with removal of the joint investment requirement for CCE as a follow-on to integrating CCE into HSS. Currently, a majority of the countries fund their portions from their HSS allocation, while the requirement for joint investment has created considerable operational complexity. The rationale for joint investment is now less strong, as many countries have used their HSS to fund their portion of CCE costs, and integration of HSS and CCE funding will mean both portions would be funded through HSS. Removal of the joint investment is consistent with rest of HSS (no other capital investment requires joint funding); will considerably lower transaction costs for countries, Gavi and UNICEF; and allow for greater speed in CCE procurement and deployment advancing healthy market goals. There are no financial implications of removing the condition that countries make a joint investment in CCE using Gavi HSS. Further details on these provisions can be found in annex D. **The PPC is requested to recommend to the Board that it authorise the immediate implementation of these shifts.**

c) Aligning Gavi's **programmatic approaches** to Gavi 5.0 priorities will continue at a slower pace and prioritise the design of an approach to reaching zero-dose children and missed communities. The comprehensive approach **to support former and never Gavi-eligible middle-income countries (the MICs Approach)** that was designed prior to the outbreak of COVID-19 will be temporarily put on hold for the duration of the pandemic, reflecting that many countries targeted by the approach will be focussing on responding to COVD-19. **Elements of the approach could be adapted to support former Gavi-eligible countries to respond to the crisis** and **other elements may be relevant to the work on COVID-19 vaccines**, as described in more details in Doc 5 and annex E. Once the crisis subsides the MICs approach will be reviewed and brought back to the PPC and Board for consideration.

d) The design of a new model for Gavi's **portfolio management processes** continues as simplification and differentiation of Gavi's processes are as relevant as ever. As part of this work the Secretariat is also refining its processes to nimbly implement the additional flexibilities to maintain and restore immunisation services. These pieces of work will be fast-tracked (see Doc 05). To adapt to Secretariat and partners' bandwidth the rollout of the full new model to countries will have to be delayed.

e) **Partnership model**: As the new model designed for Foundational Support and Special Investments in Strategic Focus Areas will be delayed to 2022, bridge funding for 2021 will ensure similar Foundational Support as for 2020 to Alliance partners, pivoted to the COVID-19 response. In parallel, the rollout of the new model for Targeted Country Assistance (TCA) will also be delayed, following the adjusted pace of the redesign of Gavi's portfolio management process.

f) **Innovation:** The Gavi 5.0 innovation approach is under development and expected to be validated by the Board in December 2020. Innovation will be critical for countries to maintain and restore immunisation services in light of COVID-19. Hence, specific elements of the approach related to the COVID-19 response such as an initial menu of innovations for countries potentially associated with catalytic funding to scale them will be accelerated. The overall conceptual work on the Gavi 5.0 innovation approach will continue at a slower pace, acknowledging the reduced bandwidth within the Secretariat and key partners.

Section E: Actions Requested of the PPC

The Gavi Alliance Programme and Policy Committee is requested to **recommend** to the Gavi Alliance Board that it:

1. **Grant** the Secretariat the authority to implement the following policy shifts from 1 July 2020 within the existing policy framework, noting that these shifts were

approved by the Board in December 2019 for incorporation into Gavi's new funding policies:

a) Removing the programme filter requiring 70% or higher coverage of the 3rd dose of DTP-containing vaccine for a country to access new support for select vaccines (as set out in the Eligibility & Transition Policy);

b) Allocating HSS resources according to four criteria: equity (number of zero-dose children), coverage (number of underimmunised children), ability to pay (GNI pc), and population in need (birth cohort), with all four criteria equally weighted;

c) Removing the cap of US$ 100 million over five years currently applied to total country HSS ceilings, but retaining the floor of US$ 3 million;

d) Integrating support for CCEOP into HSS support; and

e) Discontinuing the mechanism of awarding Performance Payments (as set out in the HSIS Support Framework).

2. **Approve** a modification to the Cold Chain Equipment Optimisation Platform (CCEOP) tiered funding model for new applications as of 1 July 2020, whereby country joint investment will no longer be a condition of Gavi support for CCE, as part of the integration of CCE support into Health System Strengthening support.

Annexes

Annex A: Updated Alliance KPIs dashboard

Annex B: Strategy Indicators reported as originally defined

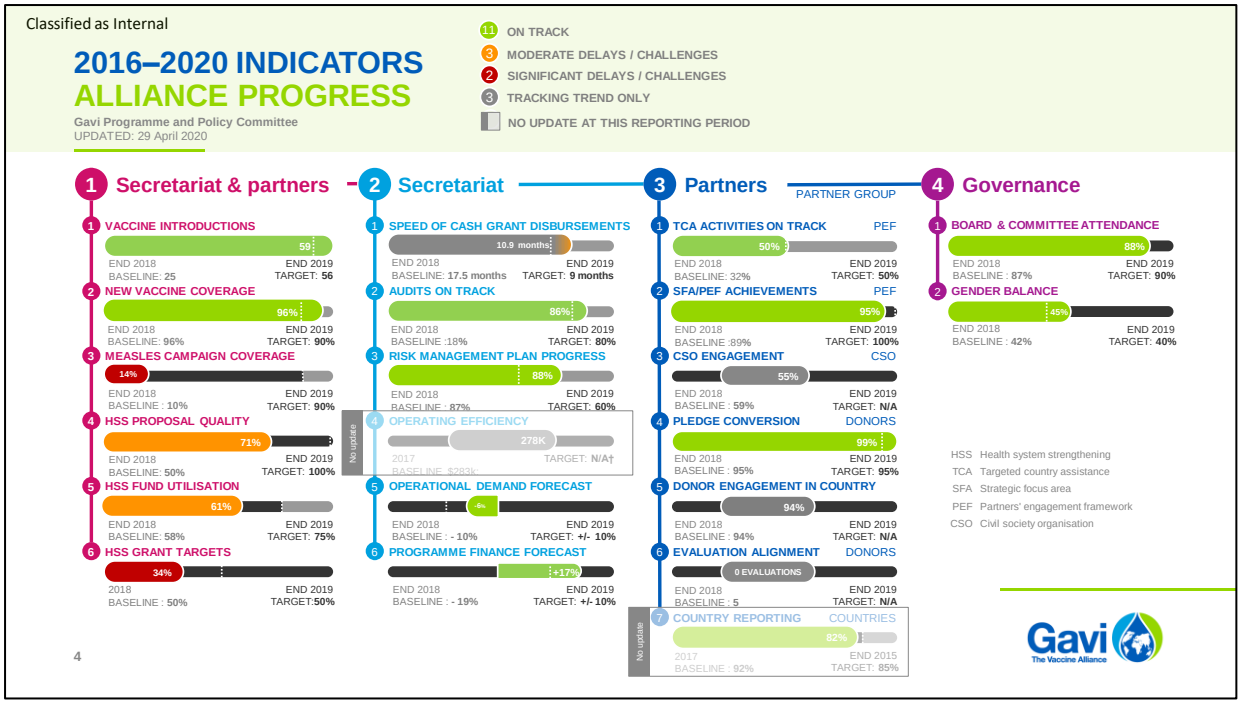
Annex C: AFC update on risk management

Annex D: Update on Funding Policy Review

Annex E: Gavi 5.0 MICs Approach and COVID-19

Report to the Programme and Policy Committee

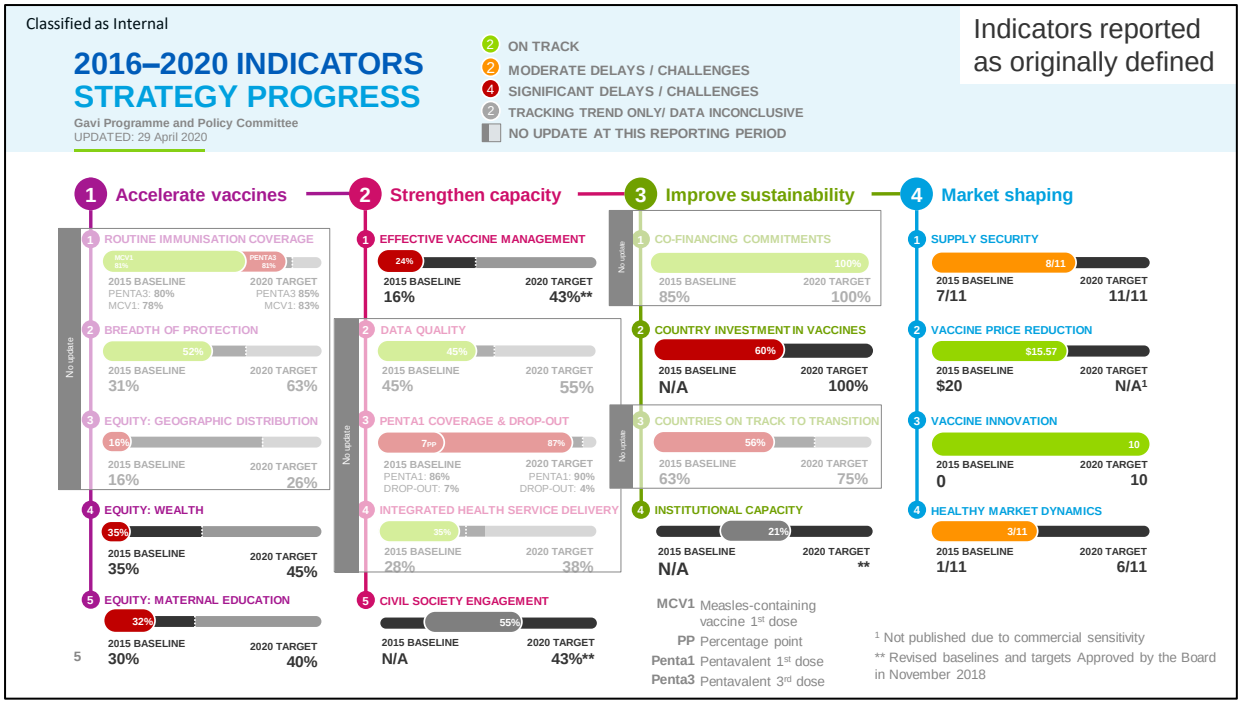
Annex A: Updated Alliance KPI dashboard



Gavi The Vaccine Alliance

Report to the Programme and Policy Committee

Annex B: 2016-2020 Strategy progress dashboard with original indicator definitions



Report to the Audit and Finance Committee

6 May 2020

SUBJECT:	**RISK MANAGEMENT UPDATE**
Agenda item:	06
Category:	For Information

Section A: Summary

- This paper provides a high-level update on major changes in Gavi's risk profile since the Risk & Assurance Report was discussed by the Board at its December 2019 meeting, as well as an update on progress in strengthening risk management across the Alliance.

Section B: Risk Management update

1. Changes in Gavi's risk profile since December

1.1 The COVID-19 pandemic has led to an extraordinarily uncertain environment with a significant impact on Gavi's risk profile. Depending on how the pandemic evolves, it has the potential to significantly affect Gavi's mission and strategic goals, as well as the operations of the Secretariat and Alliance Partners, both during the acute crisis and the eventual recovery phase.

1.2 Many of Gavi's existing corporate and programmatic top risk[1] are impacted, but risks may look different across different scenarios depending on how the pandemic unfolds. Significant uncertainties exist regarding the severity and spread of the pandemic, the breadth and duration of control efforts such as social distancing measures, the economic and financial impact of those measures, and the effectiveness of the policy response to mitigate the economic impact.

1.3 **It is possible that the current lock-down measures in many developed countries (staying at home, travel restrictions) will last or return regularly based on a surge in cases until a vaccine is available**, e.g. due to an inability to find suitable exit strategies, the possibility of second waves and resurgence of the disease, potential reinfection or reactivation in recovered patients, or a virus mutation. This situation would significantly affect corporate risks related to **Secretariat disruption**, **Secretariat capacity** and **Partner capacity**. Although the current work-from-home situation is manageable for now, an extended period will increase already mounting risks related to staff wellbeing, mental health and productivity (due to childcare and home-schooling duties). It could also impair efficient

[1] See https://www.gavi.org/news/document-library/gavi-risk-and-assurance-report-2019. Bolded risks in this paper refer to top risks described in more detail in the Risk & Assurance Report.

collaboration (including among Alliance partners) and decision-making (including in virtual Board meetings) and could affect staff capacity and institutional knowledge due to sick leave or even deaths, combined with hiring and onboarding difficulties given travel restrictions. This could also include disruption to Board or Secretariat leadership. The risk of **IT disruption** is also heightened with the increased demand on IT systems for working virtually. With a global increase in cyber-attacks aiming to take advantage of the current situation, Gavi may be targeted specifically due to increased visibility during replenishment and as part of the global COVID-19 response. The Secretariat's crisis management team continues to monitor the evolution of the pandemic on a daily basis and ensures that appropriate actions are taken to minimise risks to Secretariat operations and business continuity. Staff is kept informed and staff morale is supported through frequent newsletters, a dedicated intranet site, all-staff meetings, a staff survey to better understand challenges and virtual wellness classes.

1.4 Prolonged travel restrictions would furthermore continue to impair adequate grant oversight, technical assistance and progress monitoring in Gavi-supported countries. It also increases the risk of **misuse by countries** with audits on hold and in-country fiduciary agents being impaired in their assurance activities. Emergency reprogramming of HSS funding (to help countries respond to the COVID-19 pandemic and keep immunisation programmes going) used a fast-tracked application and review process, but a risk lens was applied with lower risk personal protective equipment being the largest area of funding, procured by UNICEF Supply Division. Lock-downs also pose a heightened risk of **global supply shortages** with closed borders potentially delaying shipments and manufacturers potentially needing to close businesses for social distancing purposes. This is being monitored closely and UNICEF is in constant contact with existing suppliers. A diverse supply base is an existing mitigation across all markets.

1.5 **It is also possible that a relatively quick de-escalation of the pandemic will take place**, e.g. due to the virus dying out, roll-out of large-scale testing and targeted isolation of cases, effective treatment or a vaccine becoming available, or a change in acceptance of the health impact in favour of the economy. When restrictions will be (gradually) lifted, there is a risk that the facilities and staff are not yet ready or do not yet feel safe for a return to the office. The Secretariat is preparing for appropriate measures including desk and meeting room spacing (if social distancing will still be required) and a continued work-from-home policy to drive new ways of working. Flexibility will be required as cases could increase again, and restrictions may be re-escalated.

1.6 If a COVID-19 vaccine would become available, there is a risk that access will not be equitable, and the Alliance is not able to effectively roll this out in Gavi-supported countries as soon as possible. The Secretariat's COVID-19 project team is working through different workstreams on influencing the global community and R&D processes to prioritise vaccine candidates which reflect the needs and preferences of Gavi-supported countries, incentivising the manufacturing, allocation and procurement of suitable

vaccines for Gavi-supported countries, and ensuring that vaccination programmes and guidance are available for countries to rapidly deliver COVID-19 vaccines where they are most needed. Being part of a COVID-19 vaccine roll-out will likely attract global attention and therefore capitalising on this poses a clear opportunity to advance Gavi's mission. It can however equally come with reputational and security risks in case of failures, adverse events following immunisation (AEFIs), or due to geopolitical tensions, social unrest and anti-vaccine sentiment and conspiracy theories surrounding COVID-19. The Secretariat is looking into monitoring and mitigating these risks as well.

1.7 **It is possible that the health impact in (some) Gavi-supported countries will become significant** when the pandemic fully spreads to and within these countries (if this is not already the case given likely under-reporting of cases due to poor **data quality** and disease surveillance). COVID-19 may equally overwhelm very weak health systems in Gavi-supported countries, while control measures currently used in developed countries to avoid this (e.g., staying at home and closing businesses) will not be implementable in many developing country settings. This situation would risk significant disruption of Gavi-supported routine immunisation programmes, as **country management capacity** in EPI (Expanded Program on Immunization) units and frontline health workers may be diverted to respond to COVID-19 or may suffer from absenteeism and fatalities, and **Partner capacity** to deliver technical assistance may also be impaired. Furthermore, there may be **insufficient demand** for routine immunisation due to social distancing measures or fear of visiting a health clinic, or due to disinformation about vaccines (there is already an alarming surge in rumours and conspiracy theories surrounding COVID-19 circulating on social media). Unused vaccine stock may expire and result in **closed-vial vaccine wastage**. With routine services interrupted it will be a struggle to reach existing communities, let alone to **reach the under-immunised** in missed communities. Vaccine introductions and planned preventive campaigns have already been suspended and this will affect coverage and equity targets. It will also lead to a significant growth in the number of susceptible persons, increasing the risk of **vaccine-preventable disease outbreaks** (e.g. measles, polio, diphtheria), although social distancing measures may help limit transmission in some contexts for a while.

1.8 A significant surge in the need to help countries respond to the COVID-19 pandemic and the need for reprogramming may overwhelm **Secretariat capacity** and may have opportunity costs. It could also lead to budget overruns, but as there may equally be underspend on core activities and routine immunisation, the overall impact on **forecasting variability** may be limited financially (although demand forecasts will likely be affected).

1.9 After the immediate crisis ends (or impact in some Gavi-supported countries turns out to be lower than expected, e.g. due to age distribution or climate-related factors), there is a risk that the Alliance is not ready to restore affected health systems and routine immunisation, launch mass vaccination campaigns to catch up on missed cohorts, and reach a potentially enlarged

number of zero-dose communities. **Country management capacity** and resources may fall short to plan and coordinate a large amount of catch-up campaigns, and short timelines may result in **sub-optimally planned campaigns** that do not achieve intended results. There is also a risk that Gavi may spend more time battling **vaccine-preventable disease outbreaks** at the expense of routine immunisation activities.

1.10 The Secretariat's COVID-19 project team is working through different workstreams on maintaining high and equitable immunisation coverage in Gavi-supported countries during and after the pandemic by providing flexible support to countries to protect, sustain and restore immunisation and frontline health services.

1.11 **It is also possible that the pandemic will trigger significant economic impact** globally (e.g. a deep global recession) and/or in Gavi-supported countries, e.g. due to the economic impact of prolonged lock-downs with closed businesses, travel restrictions and reduced demand given social distancing, an insufficient or ineffective monetary and fiscal policy response, increased protectionism and trade barriers, a redirection of global supply chains, or severe debt crises (e.g. with a rising USD and a slump in commodity prices). This situation would significantly affect risks related to prioritisation of domestic immunisation financing by Gavi countries and may result in more co-financing defaults (if co-financing waivers won't be applied) and health workers not receiving salaries. It will also pose risks to a **Sustainable transition** out of Gavi support as countries reprioritise work on transition, or already transitioned countries may see backsliding or regain eligibility. Severe economic crises in Gavi countries can furthermore lead to political instability, social unrest and conflicts.

1.12 Economic distress may also result in critical suppliers defaulting, which could lead to disruption in the supply and production of vaccines, syringes and cold chain equipment, or an inability to recover already committed expenses (e.g. on flight tickets with airlines and travel agencies at particular risk). There is also a risk of considerable foreign exchange fluctuations, lower investment asset prices and liquidity, and a reduction in IFFIm's frontloading capacity (due to a lower gearing ratio), or a potential downgrade of IFFIm, lower pledges or even defaulting by IFFIm donors. While globally attention for infectious diseases and global health security has increased and this may pose an opportunity for replenishment and **donor support**, a deep recession may shift donor country priorities towards domestic challenges and constrain their budgets. Major foreign exchange fluctuations may also pose difficulties for the valuing of donor pledges.

2. Risk Management update

2.1 The Risk function has been engaging actively with the business, and continues to do so, to ensure that COVID-19 related risks are timely identified, managed and monitored. As part of the initial Secretariat's preparedness group (established before the outbreak developed into a pandemic and a crisis management team was set up) risks to business

continuity and staff health and safety were identified and measures put in place based on a defined set of escalation triggers. The Secretariat Risk Committee has discussed the high-level changes in Gavi's risk profile as described above and is aligned on potential programmatic effects on health systems, health financing and Gavi processes to inform planning assumptions for Gavi's broader programmatic response.

2.2 The Risk function is also in the process of undertaking its review of the application of the Three Lines of Defence[2] model in Gavi, rethinking its scope, structure and roles, and capacity and capabilities. An initial Risk Committee discussion examined the potential need to differentiate between defining three lines based on risks related to the Secretariat's role in grant management versus defining three lines based on risks related to in-country immunisation programmes. There was also recognition that the model may need to be expanded to include all types of risks (including corporate risks), with risk themes as the basis for structuring rather than assigning existing teams to different lines of defence.

Section C: Actions requested of the AFC

This report is for information only.

[2] The best practice Three Lines of Defence model separates roles and responsibilities across first line functions to understand, monitor and actively manage risks, second line functions to provide objective specialist advice and appropriate checks and balances, and a third line audit function to provide independent assurance on the effectiveness of risk management by the first and second lines.

Annex D: Update on Funding Policy Review

Section A: Executive Summary

As part of operationalising Gavi 5.0, the Secretariat conducted a two-phase review of Gavi's existing funding policies: **Eligibility & Transition Policy, Co-Financing Policy and the Health System & Immunisation Strengthening (HSIS) Support Framework**[1]. The purpose of this paper is to inform the Programme and Policy Committee (PPC) of the status of this Funding Policy Review (FPR) in light of the COVID-19 pandemic.

Implementation experience, evaluations, consultations and analyses demonstrated that for the most part these policies functioned well in Gavi 4.0. However, new directions for Gavi 5.0 and lessons learned from Gavi 4.0 drove a proposed evolution of Gavi's funding policy approach. A Steering Committee (SC) was established to guide this review, and their feedback shaped the recommendations to the PPC and Board. The aim of the FPR was to develop a set of updated funding policies for Gavi 5.0.

The first phase of the FPR occurred from June to December 2019, at the end of which a first set of proposed policy shifts were approved by the PPC and Board in October and December 2019. The second phase of the FPR, from January to June 2020, includes additional proposed policy shifts and would have resulted in final revised funding policies for Board approval in June 2020 and implementation from July 2020 onward. At the April 2020 SC meeting, however, members acknowledged the COVID-19 pandemic makes long-term policy changes difficult, given the uncertainty around the duration and impact of the pandemic as well as post-recovery needs. They also highlighted the importance of maintaining short-term flexibility to support countries to address COVID-19. The SC recommended to pause the FPR given these challenges, focus on a flexible broader response in the interim (see Doc 05) and revisit the FPR at a later stage once the situation has stabilised to best meet the needs of countries post-COVID-19.

Section B: Content

1. Scope and Context of the FPR

1.1 The FPR is an integrated review to update the core policies which define Gavi funding to countries[2]**: the Eligibility & Transition Policy; the Co-financing Policy; and the Health System and Immunisation**

[1] The HSIS support framework operates in a similar manner as a Gavi policy, but with a greater level of detail. The FPR seeks to resolve this inconsistency with other Board-approved policies.
[2] While the Funding Policy Review recommends alignment of funding to countries with funding for technical assistance through the Partners' Engagement Framework (PEF), PEF itself is included in a separate 5.0 operationalisation workstream on 'Partnerships'.

Strengthening (HSIS) Support Framework[3]. Until now, these policies have been developed and updated individually and separately. This concurrent review enabled an aligned update to the funding policies, simplifying burdensome processes and realigning objectives and incentives.

1.2 **These three policies describe Gavi's principles and approach to the funding it provides.** Implementation experience indicates that **these policies have functioned largely well under the stable 'standard' conditions for which they were developed,** alongside the Fragility, Emergencies, Refugees Policy[4] and Gender Policy[5]. The Secretariat will need to revisit the funding policies once the COVID-19 acute phase is over to assess whether their principles and overall approach continue to be fit-for-purpose for the next strategic period.

1.3 The **Eligibility & Transition Policy** articulates which countries can access Gavi support and how this support phases out over time. It enshrines the key principles of time-limited and catalytic support focused on the poorest countries in the world, linked to a country's ability to pay as proxied by their gross national income per capita (GNI p.c.). It also provides a clear, institutionalised pathway for a country's eventual exit from Gavi support in conjunction with the Co-financing Policy. The **Co-financing Policy** helps build long-term financial sustainability of vaccines introduced with Gavi support by requiring countries to invest resources to procure a certain share of these vaccines.

1.4 The **Health System and Immunisation Strengthening (HSIS) Support Framework** sets out the objectives, funding levels and essential requirements for HSIS support (including how health system strengthening (HSS) support is allocated across countries), to contribute to sustainable improvements in equitable coverage of immunisation. Through the framework, countries have access to HSS support and other allocations which include support for vaccine introductions, operational support for campaigns and performance payments (performance-based funding).

1.5 Overall, these three policies have facilitated Gavi's mission of saving lives by sustainably extending the breadth and reach of immunisation while focusing Gavi's support on the poorest countries in the world. However, in response to the new Gavi 5.0 strategy and lessons learned from Gavi 4.0,

[3] This includes health system strengthening (HSS) grants, vaccine introduction grants (VIGs) and operational support for campaigns (Ops). The review also covered the Cold Chain Equipment Optimisation Platform (CCEOP), which is not currently part of the HSIS framework.

[4] The Fragility, Emergencies and Refugees Policy provides flexibilities to a country facing significant challenges due to exceptional circumstances as identified by humanitarian and emergency response partners. This policy went into effect in July 2017 and is not in scope for the Funding Policy Review.

[5] A revised Gender Policy will come into effect pending Board approval in June 2020. It is a programmatic policy designed to ensure that a gender lens is taken in Gavi's approach to supporting countries and country programming of Gavi's support to ensure access to immunisation for all.

select refinement of Gavi's policies could further drive success towards its mission.

2. Approach to the Review

2.1 Examination of **strategic shifts for Gavi 5.0** and **lessons learned from Gavi 4.0** resulted in a set of **problem statements** where Gavi's policies would benefit from a shift in approach. The problem statements and proposed solutions were identified and validated through **consultations with partners and countries, external evaluations** and **extensive analyses** and drew from **Board deliberations on Gavi 5.0** (e.g., March 2019 Retreat). A Steering Committee (SC) was established to provide strategic guidance and includes representatives from the **PPC/Board, Alliance constituencies, peer organisations and technical experts** with relevant subject matter expertise. The SC met four times, in June and September 2019 and in March and April 2020.

2.2 The timeline for this two-phase review was from June 2019 to June 2020. In the **first phase**, from June to December 2019, the problem statements were identified and validated. Select problem statements were analysed to develop proposed policy shifts, which were approved by the PPC and Board in October and December 2019. In the **second phase**, from January to June 2020, final detailed approaches for the initial approved shifts and options for the remaining problem statements were developed. The final step would have been to bring all policy elements together in **an updated set of funding policies,** to be reviewed by the SC prior to submission for PPC and Board approval in May and June 2020.

3. COVID-19 Impact

3.1 While originally the revised policies would have been brought to the PPC and Board this cycle, shortly prior to the April SC meeting the COVID-19 crisis became a more critical concern with increasingly dire public health and economic consequences. The **SC requested the Secretariat to consider and articulate any implications COVID-19 would have on the provisions in the revised funding policies**. The April SC agenda, intended to cover the remaining problem statements for the second phase, was adjusted to include discussion of COVID-19 and the suitability of Gavi's policy model to respond to the acute and medium-term needs of countries.

3.2 During the meeting, the SC reflected on the objectives and underlying assumptions of the funding policies. While the members felt the direction of the **policy shifts were indeed the right ones in a non-pandemic setting**, they ultimately believed this would **not be the right time to enact policy changes**. The SC considered four main circumstances that have changed since the start of the FPR:

a) **Gavi's policy model was designed for stable contexts, but in the rapidly changing environment of a pandemic it does not allow for timely decision-making**. For example, GNI p.c. informs country eligibility and phases of support, which determine levels of co-financing and funding for operational support for vaccine implementation (e.g., operational support for campaigns). However as GNI p.c. data are updated once a year from the previous year's data, the economic impact of COVID-19 in 2020 would only start to emerge in the data at its next release in June 2021, and would only influence eligibility and phase of support from 2022 onwards.[6]

b) Countries are confronting a number of challenges in the face of COVID-19 as they attempt to implement control measures and plan for diversion of health resources towards the pandemic. This has already resulted in some primary health care interventions being deprioritised; e.g. mass preventive immunisation campaigns have been suspended in a number of Gavi countries. **Changes in policy at this stage would not be a priority for countries whose capacity is fully utilised to respond to COVID-19 and would instead add an undue burden**.

c) In addition, it is **difficult to predict the conditions of the post-COVID-19 world and which elements of the revised funding policies would still be relevant**. The policies would need review to identify any additional adjustments for changed circumstances prior to implementation.

d) Gavi has already **extended initial flexibilities to countries** to urgently address COVID-19. A **broader programmatic response** to support countries with COVID-19 is under development (see Doc 05).

3.3 In light of these circumstances, the **SC recommended to pause the FPR** at this time, monitor the progression of the pandemic to determine the right moment to revisit the timeline and in the interim identify key flexibilities which would be part of the broader response. They also noted that some FPR provisions which had already been approved should move forward as part of this broader response. These are further detailed in paragraph 6 (Next Steps).

3.4 The following two sections provide information on the work conducted and decisions taken thus far. While the final approval of the updated funding policies will be paused until an appropriate time following containment of COVID-19, the intention would be to **re-start the FPR using the current status as the starting point and taking into account lessons learnt that might emerge from COVID-19**.

[6] For example, 2021 eligibility status is decided in mid 2020, based on 2019 actuals of GNI pc. This effectively creates a 2-year time lag. This approach is appropriate for a "steady state" of country development, but is less suitable for a context in which major and rapid shifts of GNI pc could take place in many countries.

4 Summary of Outcomes from the First Phase

4.1 The SC met for the first time in June 2019, following the Gavi Board meeting. At this SC meeting, the members reviewed and validated the problem statements, agreeing that these were the appropriate scope of required shifts across the funding policies. Subsequently, the Secretariat conducted benchmarking, quantitative and qualitative analyses and consultations with country stakeholders, core Alliance partners and technical experts to identify proposed options to address these problem statements. An external evaluation of the Eligibility and Transition, and Co-financing Policies was also conducted, the recommendations of which were incorporated into the FPR. At the SC meeting in September 2019, the outcomes of this work and the resulting options were reviewed, and recommendations developed to bring to the PPC in October and Board in December.

4.2 The following table describes the outcomes of Board decisions and PPC guidance from the first phase of the review.

Problem Statement	Board decision or PPC guidance
Eligibility and Transition Policy	
The policy does not allow to tailor and adjust support to transitioning countries to **mitigate the risk of unsuccessful transition**.	Board approved the proposed approach to allow an adjustment of the duration of the accelerated transition phase in exceptional cases of countries at risk of unsuccessful transition out of Gavi support. These countries at risk would be identified based on coverage and equity criteria.
Gavi's current policy allows **countries to (re)gain eligibility** only once their 3-year rolling average of GNI p.c. is below the eligibility threshold, creating inequity with countries with higher GNI p.c. but benefiting from Gavi support, and is not explicit about Gavi support applying in those cases.	Board approved using the latest point estimate of GNI p.c. alongside the average GNI p.c. over the past three years to determine countries' eligibility for support; and for countries (re)gaining eligibility, adoption of a tailored engagement based on the country context.
'**One size fits all' requirement** to have ≥70% coverage of DTP3 for new vaccine introduction does not account for differences across vaccine programmes and their varying prerequisites for success.	Board approved removing the programme filter requiring 70% or higher coverage of the 3rd dose of DTP-containing vaccine for a country to access new support for select vaccines (as set out in the Eligibility & Transition Policy). At the antigen-specific level, existing country readiness measures will be retained, and the Secretariat will work

	closely with Alliance partners to identify other programmatic readiness criteria.
Co-financing Policy	
Implementation of the policy has become **overly complex given variation in the calculation of co-financing** across vaccines and phases.	Board approved calculating vaccine co-financing for all countries based on a share of doses needed by a country.
The exceptional situation where countries continue to be required to increase their co-financing payments while **experiencing a severe economic downturn** creates an inconsistency with the principle that co-financing should increase as countries become wealthier. Co-financing flexibility can only be granted reactively (e.g. once default happens) to **countries with widespread conflict or affected by major disasters**.	Board approved an approach to apply co-financing flexibilities in countries facing: • severe fiscal distress, whereby the co-financing increases of the previous phase may be applied. • a humanitarian crisis, as a subset of countries qualifying to access flexibilities as per the Fragility, Emergencies and Refugees Policy, whereby co-financing may be waived on an annual basis.
HSIS Support Framework	
Equity as an organising principle for 5.0 insufficiently reflected in the formula used to allocate Gavi's HSS resources across countries.	Board approved adding equity (the number of zero-dose children) as a fourth criteria to the formula for allocating HSS resources in addition to the existing three (coverage (number of underimmunised children), ability to pay (GNI p.c.), and population in need (birth cohort)). All four criteria will be equally weighted. Board also approved removing the cap of US$ 100 million for country HSS allocations but retaining the floor of US$ 3 million.
Countries are not **sufficiently incentivised to achieve immunisation-related results** or to increase domestic investments in immunisation coverage and equity.	Board approved discontinuing the mechanism of awarding Performance Payments (as set out in the HSIS Support Framework) and endorsed an approach focused on setting the right incentives on a country-by-country basis.
Limited differentiation of grant design to focus on equity and how to build long term sustainability, to account for different needs according to country contexts.	PPC broadly agreed with the principles to differentiate HSS support and indicated an increased focus on equity.
Lack of integration between Gavi HSIS with the Cold Chain Equipment Optimisation Platform (CCEOP) results in fragmented support.	Board approved integrating Cold Chain Equipment (CCE) support into broader HSS support.
Gavi's funding model does not adequately incentivise selection of the **most**	PPC welcomed broadening definition of operational support for campaigns to

appropriate delivery strategy to achieve the intended goal/outcome with lens to long-term sustainability.	include tailored delivery strategies, coupled with strengthened programmatic guidance.
The funding structure for **outbreak response** and preventive vaccination efforts is misaligned (e.g. funding is not tiered by transition phase).	PPC agreed with tiering the funding for Ops for outbreak response by transition phase in alignment with preventive campaigns.

5 Summary of Outcomes from the Second Phase

5.1 Following the approval of the policy shifts from the first phase, where necessary, the Secretariat completed further analyses on remaining questions across those problem statements in the second phase. In addition, the Secretariat also developed **options against the problem statements which were not brought for approval in the first phase**. As part of a broader consultation on Gavi 5.0, a comprehensive consultation was conducted at the end of February 2020 as part of a **'Country & Partner Retreat' with 100+ country stakeholders and country, regional and global partners**.

5.2 *Remaining Options for the Second Phase*

5.3 The following problem statements and their proposed solutions were shared with the SC prior to its April meeting. Given the shift in focus towards COVID-19 in the April SC meeting, these finalised options were not fully reviewed and formally agreed, but they did receive broad support from the SC.

a) **Mitigating risk of unsuccessful transition**: following the Board approval of the high-level approach, the Secretariat conducted additional analyses to identify the appropriate indicators and thresholds to identify countries at risk, and the types and levels of support these countries might receive. To ensure alignment with Gavi 5.0 strategic indicators, it was recommended to measure equity via coverage of the first dose of diphtheria, tetanus, pertussis vaccine (DTP) (DTP1; as an indicator of zero-dose children) and coverage through coverage of the third dose of DTP (DTP3). The countries considered at risk of unsuccessful transition would be those with DTP1 coverage ≤90% or DTP3 coverage ≤85%. With regard to the types and levels of support available to countries at risk, the accelerated transition phase may be extended by 1-5 years, during which the country would remain eligible for HSS, Targeted Country Assistance (TCA) and vaccine introduction support, with annual levels following standard Gavi guidelines. An extension of financing support for already introduced vaccines would require Board approval.

b) **Simplification of co-financing calculation**: following the Board approval of the shift to calculate co-financing as a share of doses for all Gavi countries, the Secretariat conducted further analyses to articulate the details of the proposed approach. It was recommended that all low-income countries would co-finance a uniform share (10%) of doses for all vaccines[7]. Upon entering the preparatory transition phase, the share would increase initially by 3 percentage points (pp) per year, and then by 5pp from the 5th year in the preparatory transition phase onward. Co-financing share increases in accelerated transition phase would remain the same as in the current policy. It was further noted that all low-income countries should shift to the new co-financing calculation (10% of doses) at the same time.

c) **Equity in HSS**: While the Board approved the formula to allocate HSS, they also noted that how HSS is programmed will be critical to deliver on Gavi's 5.0 goals, particularly reaching zero-dose children and missed communities. The Secretariat proposed that countries should be required to allot a portion of their HSS to equity investments including overcoming gender related barriers. Gavi would indicate to countries this minimum allotment – based on the allocation formula – when communicating their ceiling.

d) **Closing measles immunity gaps**: The PPC and SC supported extending the funding window for operational support for campaigns to include tailored supplemental delivery strategies, in particular to close measles immunity gaps. The Secretariat convened a technical consultation chaired by WHO which included a number of Alliance partners to validate an approach that would differentiate between higher-performing countries and lower-performing countries. [8] Higher-performing countries would be directed towards using Ops for tailored delivery strategies [9] to move away from nationwide non-selective measles follow-up campaigns, while lower-performing countries would be incentivised to strengthen campaign quality and reach.

e) **Aligning funding for outbreak response**: The PPC and SC agreed in principle that realigning operational cost support for outbreak response with support for preventive campaigns should be further examined, as preliminary analysis suggested both types of campaigns incur similar costs. Further analysis supported this: the cost of conducting an outbreak response campaign is similar to that of a preventive campaign, with similar coverage levels. In addition, analysis suggested that a 2-dose campaign did not incur the same amount of costs across both doses, though a subset of activities did need to be repeated. It was

[7] IPV would maintain its current separate approach to co-financing levels.
[8] The proposed indicators to differentiate performance included the coverage levels of the first and second dose of measles-containing vaccines.
[9] Such strategies could include periodic intensification of routine immunisation, bolstered mobile and outreach, catch-up at school entry, and other strategies that specifically target unimmunised children.

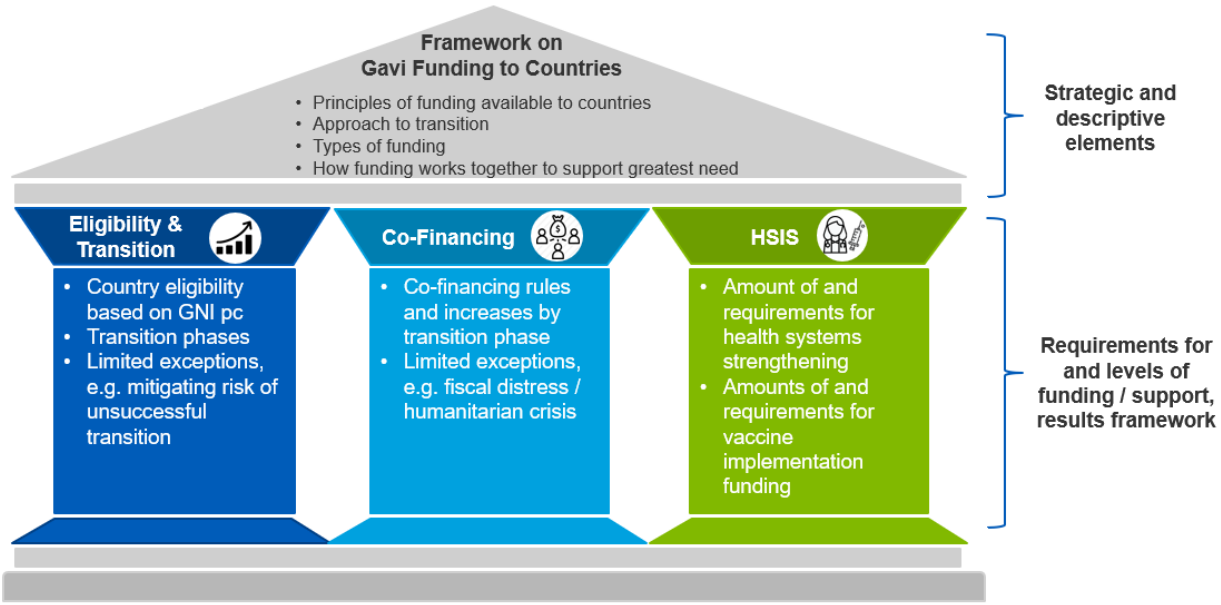
recommended to tier funding by phase of support for both preventive campaigns and outbreak response and provide an incremental amount of funding of 50% of the first dose for additional required doses.

5.4 *Updated Funding Policies*

5.5 The final step was to bring together the policy elements into a set of updated policies. Given the pause on the FPR, the revised funding policies were not reviewed by the SC, and they will need to be revisited in light of changed circumstances post-COVID-19. The initial hypothesis on structuring the revised funding policies is presented below.

5.6 The SC noted at the start of the FPR that Gavi policies often contain a mix of strategy, policy and guideline content, as well as some inconsistency in level of detail across different policies. The **SC recommended that revised policies should sit at a higher level, focused on key parameters rather than operational details to enable greater policy flexibility and longevity**. The revised funding policies would have reflected this guidance in two ways: inclusion of an overarching framework to describe Gavi's intentions around its funding, and a consistent structure and level of detail across the individual policy documents. Each revised funding policy would have been accompanied by a Results and Measurement Framework, outlining how the policy contributes to desired outcomes and impact.

5.7 To ensure the policies provide clarity on the core questions of which countries receive Gavi funding and what and how much funding, the strategic and descriptive elements of the policies were consolidated into an **overarching framework**. This framework is intended to provide an 'umbrella' across the three policies which in turn serve as 'pillars' to the framework. Each policy is streamlined to contain the specific requirements and procedures it governs.



a) The **Framework on Gavi Funding to Countries** describes the principles of Gavi's funding to countries and the different types of funding and how they fit together to support immunisation programmes where the need is greatest. It also articulates Gavi's approach to transition and how funding shifts to meet countries' needs as they progress along the transition pathway.

b) The **Eligibility and Transition Policy** covers the requirements and procedures to determine country eligibility based on GNI p.c. and to identify the phases of support (e.g. transition phases); and the limited exceptions to these procedures such as tailoring the duration of the accelerated transition phase in specific rare circumstances.

c) The **Co-financing Policy** covers the requirements and procedures for country co-procurement of vaccines for routine immunisation and limited exceptions such as adjusting co-financing for countries experiencing severe fiscal distress or humanitarian emergencies.

d) The **Health System and Immunisation Strengthening (HSIS) Policy** covers the procedures and funding levels for health system strengthening and vaccine implementation support, including the requirement to focus HSS on equity investments such as for reaching zero-dose children and addressing gender-related barriers to accessing immunisation, and the filter for differentiating countries for delivery strategies to close measles immunity gaps.

6 Next Steps

6.1 While the SC recommended that the FPR be paused, members also recognised that some FPR provisions that the Board had approved in December 2019 should move forward alongside the broader COVID-19 response (see Doc 05) to facilitate countries' access to the full amount of Gavi's funding. This includes the following:

a) **Formula to allocate HSS and removal of the US$ 100 million cap for HSS allocation ceilings:** Several countries are expected to enter the full portfolio planning phase for HSS this year and Gavi will need to identify and communicate their funding allocations. These will be based on the new allocation formula without a cap. The Secretariat would indicate to each country the portion of the HSS allocation that is provided based on the number of zero-dose and underimmunised children and would therefore be expected to be programmed for equity, given the continued paramount importance of reaching these children and their communities.

b) **Removing the performance-based funding (PBF) approach:** As noted in December, PBF inadvertently creates an inequity in access to funding as only higher-performing countries tend to meet performance requirements. In the context of COVID-19, this would mean that countries who are least negatively affected by the pandemic would be more likely to receive PBF funding.

c) **Integration of cold chain equipment (CCE) into the HSS envelope and removal of the joint investment requirement:** New CCE funding will be integrated into the HSS envelope on a case-by-case basis and dependent on potential future expansion of the CCEOP in the broader COVID response (see Doc 05). This has implications for the tiered 'joint investment' model, in which Gavi provides 50% of the funding for accelerated transition countries or 80% of the funding for low-income and preparatory transition countries, with countries funding the remainder. This model was put in place to help incentivise domestic investments in CCE. In practice, majority of the countries fund their portions from their HSS allocation, while the requirement for a joint investment has created considerable operational complexity. The rationale for maintaining a joint investment requirement within a single HSS envelope is less strong with both portions now funded from HSS. Removal of the joint investment is consistent with rest of HSS (no other capital investment requires joint funding); will considerably lower transaction costs for countries, Gavi and UNICEF; and allow for greater speed in CCE procurement and deployment advancing healthy market goals. There are no financial implications to Gavi of removing the condition that countries make a joint investment in CCE. However, this may reduce the total amount of CCE some countries procure if those who have used domestic resources or other donor funding for their joint investment were to reprioritise that funding for other purposes. In the longer-term, increasing and mandating domestic investments in maintenance in a phased manner post-COVID-19 will be explored as a component of CCE funding, as will potential restrictions on using Gavi funds to replace existing equipment in countries approaching transition, to promote sustainability.

d) **Removing the generic programme filter**: While introducing new vaccines might not be a priority for most countries in the immediate term, removing the filter reduces barriers in equitable access for those countries that might prioritise introductions in the recovery period.

6.2 Finally, **the Secretariat will continue to** monitor the impact and progress of the COVID-19 pandemic to identify the best timing to revisit the FPR. Once the FPR is restarted, all policy shifts would be reviewed to determine if they are still fit-for-purpose for the post-COVID-19 world.

Annex E: Gavi 5.0 – Middle Income Countries (MICs) approach and COVID-19

1. Introduction

1.1 In June 2019, **the Board agreed that the Alliance's approach to former Gavi-eligible countries be institutionalised** in Gavi 5.0. They requested that the Secretariat develop an approach with the objectives of **introducing key missing vaccines** and **preventing backsliding in immunisation coverage levels** post-transition. At that time, the envisaged package of support for former Gavi-eligible countries included political advocacy, technical assistance, innovation, market shaping, and catalytic financial support to jumpstart vaccine introductions.

1.2 Building on this foundation, the Board also requested **the Secretariat to explore how some elements of this approach could be extended to some[1] never Gavi-eligible middle-income countries** (MICs). The engagement with never Gavi-eligible MICs would have a particular focus on **new vaccine introductions**, thereby addressing the inter-country equity challenge that is impossible to disregard in light of Gavi's ambitious goal of 'leaving no-one behind with immunisation'. The Board agreed that engagement with former and never-eligible Gavi countries should account for no more than **3% of Gavi 5.0 planned expenditure** (approximately US$ 300 million) for the delivery of the MICs approach.

1.3 Following this decision last year, the Secretariat has been developing the detailed MICs approach in close collaboration with countries, donors, partners, expanded partners, and other key stakeholders. The Secretariat had prepared to bring this approach to the PPC and Board for decision in May and June 2020. Section 2 of this paper outlines the approach that had been developed prior to COVID-19 and Section 3 indicates the implications of COVID-19 on this approach and how the Secretariat will act in response.

2. The MICs approach that had been developed prior to COVID-19

2.1 The MICs approach, as had been prepared for presentation to the PPC and Board, had two primary objectives: to **prevent backsliding in vaccine coverage in former Gavi-eligible countries**, and to **drive the sustainable introduction of key missing vaccines in both former and select never Gavi-eligible countries**. Alongside these primary objectives, the approach had a number of important secondary objectives: to improve inter- and intra-country **equity**; to maintain and improve access to **sustainable vaccine pricing**; to open up access to **new technologies and innovations**; and to **mobilise and maximise domestic resourcing**.

[1] Never Gavi-eligible countries in scope of the MICs approach included countries with a Gross National Income per capita (GNI p.c.) up to US$ 6,000 and that were missing at least one of three key vaccines (pneumococcal conjugate vaccine (PCV), rotavirus and human papillomavirus (HPV)). The Secretariat was also proposed the inclusion of some select small island states, in line with the World Bank definition of international development assistance (IDA).

2.2 The approach was designed to **leverage the existing expertise and activities of Alliance partners and expanded partners**, as well as to build on the **considerable wealth of knowledge and capacities of MICs**. Significant emphasis was placed on working through **new partners**, on **deepening Gavi's collaboration with the Global Fund**, engaging with **Civil Society Organisations (CSOs)**, and supporting **regional and country-led platforms**.

2.3 The approach was also based on a **learning agenda**: recognising the scale of the challenge of engaging with never-Gavi eligible MICs, whilst having confidence in the Alliance partners' deep expertise. Successful implementation of the MICs approach required **new ways of working**, and the Secretariat was ready to operate in an iterative manner, reflecting and improving at each step, as well as remaining flexible to adapt both the way we worked and the tools that we had at our disposal.

2.4 A significant amount of learning was taken from the experience of **post-transition engagement** in the design of the approach, for example: ensuring that investments would be mid-to-long term, results-orientated, and with clear accountability frameworks; and that country support be targeted and catalytic, with a clear exit strategy.

2.5 Taking as a foundation the package of support that had already been approved by the Board for former Gavi-eligible countries, the Secretariat designed the MICs approach around **three mutually-reinforcing levers**, designed to both tackle the causes of backsliding and to address the bottlenecks that prevent sustainable new vaccine introductions. The three levers were:

a) **Advocacy and political will building**: Strengthening countries' political commitment to immunisation and new vaccine introductions by using the convening power of the Alliance to bring together leaders and decision makers, demonstrating the value of immunisation by sharing and promoting evidence on the value of immunisation, and working globally, regionally and at country level in a multi-dimensional approach to advocacy.

b) **Enhancing the immunisation ecosystem**: Engaging with countries in a deeply targeted way, along a clear theory of change, to address specific identified bottlenecks that lead to a risk of backsliding or that prevent new vaccine introductions. Leveraging the extensive expertise of partners to deploy relevant interventions to strengthen institutions, build the vaccine investment case, mobilise domestic resources, improve efficiencies, build capacity, support evidence-based decision making, and to find and share innovative approaches (for example to reach zero-dose children) and information about new technologies.

c) **An innovative financing facility for procurement**: An innovative financing facility to augment UNICEF SD's existing procurement model, leveraging Gavi's financing capacities to provide long-term demand guarantees and short-term liquidity to assure timely payments. Together, these features would have reduced the risk of unpredictable demand and addressed a key bottleneck for countries unable to pre-pay, providing manufacturers with the opportunity to offer more sustainable vaccine prices, in line with tiered pricing principles. Procurement support to countries would have also included some limited vaccine catalytic financing to jump-start new vaccine introductions, building on the successful experience of this tool in other Gavi-supported countries.

2.6 Across the three levers there would have been a **differentiated approach** to working with the different 'tiers' of countries[2]. These tiers reflected the Board's previous approval to support former Gavi-eligible countries with an agreed package and a desire to see the energy of the Secretariat mainly focused on former Gavi-eligible countries. The differentiation also reflected the Board's guidance to differentiate between never Gavi-eligible MICs with a GNI p.c. up to US$ 4,000 and those with a GNI p.c. between US$ 4,000 - US$ 6,000[3]. For example: whilst all countries would have benefitted from regional and global efforts to strengthen political commitment to immunisation, former and never Gavi-eligible LMICs would additionally have received country-focused advocacy support; and vaccine catalytic financing would not have been available for never Gavi-eligible MICs with a GNI between US$ 4,000 - US$ 6,000. This differentiated approach was also reflected in the planned Secretariat resourcing.

2.7 The approach was designed to fully align with the Alliance's comparative advantages and to leverage available resources in a way that delivered the greatest impact. As such, it was not envisaged that health systems strengthening support or financing multi-year procurement of vaccines would be part of the engagement with countries.

2.8 The MICs approach was designed in close collaboration with a wide range of stakeholders including Alliance partners, expanded partners, countries, donors, CSOs, manufacturers, as well as new potential partners such as the Global Fund and global and regional initiatives. Throughout the development process stakeholders were highly engaged and there was open and constructive debate towards the co-creation of the MICs approach.

2.9 Extensive rounds of consultations were undertaken to design and refine the approach. This included numerous country consultations, including dedicated country visits, to explore country barriers and to co-design

[2] Former Gavi-eligible countries, never Gavi-eligible MICs with a GNI up to US$ 4,000 p.c., small island states, never Gavi-eligible MICs with a GNI between US$ 4,000 and US$ 6,000 p.c

[3] In June 2019 the Board provided guidance that engagement with never Gavi-eligible lower middle-income countries (LMICs) - those with a GNI per capita up to US$ 4,000 - would be along the same set of modalities as for former Gavi-eligible countries, but that the modalities of engaging with never Gavi eligible countries with a GNI between US$ 4,000-US$ 6,000 may be different.

solutions. Wide-ranging conversations with representatives from WHO, PAHO, UNICEF SD and PD, World Bank, Global Fund, CSOs, and other initiatives were held (often at global, regional and country level) to identify clear synergies and opportunities for collaboration, and detailed discussions were had with manufacturers to benefit from their perspectives.

2.10 **The draft MICs approach was built to clearly articulate the role and expertise of different partners towards a common objective, showcasing the potential for the Alliance to bring together and amplify the impact of partner's efforts, highlighting the Alliance's unique and comparative advantage to deliver on the approach's objectives.**

3. The implications of COVID-19 on the MICs approach

3.1. Whilst the impact and implications of the COVID-19 pandemic on countries' health systems and economies are still emerging, it is clear that many countries will meet at least some disruption, with the potential for almost all countries to experience significant negative consequences as a result of both the measures taken to respond to the crisis and protect their populations, as well as the wider global economic impact.

3.2. In the face of this new reality, the objectives and spirit of the MICs approach are more relevant than ever:

a) **Preventing backsliding in routine immunisation coverage**: COVID-19 increases both the likelihood and potential extent of backsliding. There is even greater impetus to ensure that immunisation programmes are not decimated by the pandemic.

b) **Supporting the sustainable introduction of new vaccines**: As and when a COVID-19 vaccine becomes available, it will be critical to ensure that access to this vaccine is governed by equitable allocation and sustainable pricing principles.

3.3. The Secretariat recognises, however, that during the pandemic response phase (and possibly also for some time afterwards, depending on the extent of recovery required), new vaccine introductions of PCV, Rota and HPV[4] are unlikely to be the priority in many countries. Furthermore, given the exceptional circumstances in which countries may find themselves over the coming 12-24 months, the original package of support envisaged under the MICs approach may not be sufficient to help countries to meet these challenges.

3.4. In light of this, the Secretariat is requesting guidance from the PPC on Gavi's role and approach to support former Gavi-eligible countries to mitigate the risks of backsliding on gains achieved with Gavi support in the context of COVID-19, including on the extent and modalities of possible Gavi funding. We also raise the question of potential engagement with

[4] These three vaccines were to be the initial focus of the MICs approach in providing support to countries for new vaccine introductions

never-Gavi eligible countries and welcome a steer from the PPC on the benefits and risks of engaging with these countries (see Doc 05). The Secretariat is also exploring measures to enable equitable access to a future COVID-19 vaccine for middle income countries (see Doc 06).

3.5. Once countries have mitigated the worst of the crisis, the Secretariat believes that the original focus of the draft MICs approach will once again be in demand. This includes not only addressing the systematic weaknesses in routine immunisation programmes to prevent backsliding of immunisation coverage, but also tackling the bottlenecks that prevent the sustainable introduction of high impact vaccines such as PCV, Rotavirus and HPV.

3.6. The Secretariat therefore plans, when appropriate, to bring back to the PPC and Board the draft MICs approach. And although the objectives of the approach brought forward at that time may be in line with the original objectives, it may well be necessary to adapt the approach to reflect the realities of countries that are rebuilding after the pandemic.

3.7. Gavi's response to the COVID-19 pandemic in MICs in the coming months and years also presents a real opportunity for significant learning that could and should be incorporated into a refined MICs approach, further justifying the rationale to take time to reflect on the original MICs approach, developed prior to the pandemic, before bringing an approach to the PPC and Board for decision.

Report to the Programme and Policy Committee

26-27 May 2020

SUBJECT:	**REVIEW OF THE GAVI GENDER POLICY**
Agenda item:	04
Category:	For Decision

Section A: Executive Summary

Context

- Gavi has had a Gender Policy to guide its programmatic work since 2008. The original policy focused on eliminating sex discrepancies in immunisation coverage between girls and boys. The current version is a result of a policy review in 2013, which shifted the Alliance's focus to overcoming gender-related barriers to accessing immunisation services. In May 2019 the Programme and Policy Committee (PPC) provided guidance (see Appendix 1) on the process to update Gavi's current Gender Policy, and input into future policy direction.

- The policy has been revised by the Secretariat following a review process including an independent external evaluation and extensive consultation with country representatives, partners, civil society organisations, gender and immunisation experts and donors. The Secretariat is presenting an updated Gender Policy to the PPC and Board for their review and recommendation to the Board for approval.

Questions this paper addresses

- What were the policy review findings and how has the policy been revised to address these?
- What is the relevance of this policy to the COVID-19 pandemic?

Conclusions

- The revisions seek to better align the policy with Gavi's strategy for 2021- 2025 (Gavi 5.0), which focuses on ensuring zero-dose and underimmunised children, individuals and communities are sustainably reached with routine immunisation services. The revised policy is more ambitious and identifies areas for gender-responsive and transformative interventions, underpinned by an updated theory of change which places a new focus on understanding, learning and partnering as approaches to achieve the policy goals. It uses inclusive, non-binary language and considers how other socio-cultural factors can compound gender-related barriers. In addition to caregivers, the policy focuses on two new groups: healthcare workers and adolescents, both of which face specific gender-related barriers to providing or accessing healthcare.

- The Secretariat is working closely with partners to better understand the gendered impacts of the COVID-19 pandemic and proactively suggesting potential approaches to addressing these challenges.

- The PPC is requested to consider the revised Gender Policy (Annex B) and recommend it for final approval by the Board.

Section B: Review of the Gavi Gender Policy

1. Gavi, Gender and Immunisation

1.1 Gender-related barriers are obstacles to access and use of health services that are related to deep rooted social and cultural norms about the roles of women, men, and those with diverse gender identities. Healthcare workers, caregivers and adolescents each face gender-related barriers to providing or accessing health services for themselves or their children. Thus, understanding and addressing gender-related barriers is key to reaching zero-dose and underimmunised children, individuals and communities and ensuring they all receive their full range of vaccines in a timely manner.

1.2 Gavi has long been committed to addressing gender-related barriers to immunisation as a key component of the Alliance's mission to improving immunisation coverage and equity. In Gavi's 2021-2025 strategy (Gavi 5.0), 'gender-focus' has been elevated to a principle, key to achieving the vision of 'leaving no-one behind with immunisation'.

2. Policy review process

2.1 The review process commenced with an external, independent evaluation to assess the policy design, implementation and outcomes, which included an extensive desk review, key informant interviews, a Secretariat staff survey and an analysis of comparator organisations[1]. See Appendix 2 for further information.

2.2 The Secretariat supplemented the evaluation with consultations, which are further detailed in Appendix 3:

- Country-stakeholders: online survey, in-person[2] or phone consultations, and consultations during the Gavi 5.0 Country & Partners' Retreat;

- Partners: WHO, UNICEF and Global Polio Eradication Initiative (GPEI) were closely involved in policy development. Additionally, Board Retreat discussion, consultations with the Alliance Coordination Team (ACT) and engagement with partner[3] gender experts;

[1] Comparator organisations are UNICEF, WHO and The Global Fund to Fight AIDS, Tuberculosis and Malaria
[2] Leveraging regional meetings: East & Southern Africa EPI Managers Meeting & Western Pacific Region Technical Advisory Group on Immunisation
[3] Main partners engaged include: WHO, UNICEF, CDC, World Bank, Bill & Melinda Gates Foundation, GPEI, The Global Fund & UN Women

- Civil Society Organisations (CSOs): Consultations with the Gavi CSO Constituency Steering Committee and country-level experts;
- Donors: Four consultations throughout the review with representatives from 11 donors;
- Gender experts: Expert workshop and additionally leveraging networks such as the Equity Reference Group and Global Action Plan;
- A public consultation on the draft revised policy.

2.3 All opportunities were taken to use the consultation process to sensitise stakeholders to gender-related barriers, and to create joint accountability for policy implementation.

3. Revisions to the Gender Policy

3.1 The Secretariat has revised the Gender Policy to address the review findings. Key updates include:

3.2 *Rationale*

3.2.1 The evaluation found that stronger links could be made between the Gender Policy and Gavi's wider organisational strategy. The revised policy is now strongly aligned with Gavi's 5.0 vision of 'leaving no one behind with immunisation'. With equity as an organising principle, understanding and addressing gender-related barriers is considered key to reaching zero-dose and underimmunised children, individuals and communities.

3.2.2 The evaluation noted that Gavi's current policy does not reflect wider shifts concerning immunisation and gender approaches. In particular, evaluators noted the absence of discussion of intersectionality[4], whereby gender is considered one of many socio-cultural and economic factors which interact at different levels (individual, household, community, health service and institutional) to compound barriers to accessing health services. The revised policy now features the concept of intersectionality in the rationale.

3.2.3 As a result of consultations with gender experts, the revised policy also shifts away from a women-centric and binary definition of gender and uses language that is more inclusive of all gender identities, recognising that each is linked to specific gender norms and societal expectations.

3.3 *Goals*

3.3.1 The goal of the current policy is to *"…increase immunisation coverage by supporting countries to overcome gender-related*

[4] Intersectionality refers to understanding how multiple forms of inequality or discrimination (e.g. age, ethnicity, education, disability) overlap to create obstacles for individuals, for example, access and use of health services.

barriers to accessing immunisation services and to promote equity of access and utilisation for all girls and boys, women and men to immunisation and related health services that respond to their different health needs." Consultations found that country stakeholders were not clear as to the expected impact of the Gender Policy. One way in which this has been addressed is to have one overarching goal that addresses 'what' the policy aims to do, with three sub-goals that address 'how' it will be achieved. The overarching goal of the revised policy is to *"identify and address gender-related barriers to reach zero-dose and underimmunised children, individuals and communities with the full range of vaccines in a timely manner".*

3.3.2 Consultations pointed towards a need to further specify Gavi's level of ambition in addressing gender-related barriers and aiming for gender-transformative approaches where possible. A new sub-goal speaks to Gavi's commitment to encourage and advocate for women's and girls' full and equal participation in decision-making related to health programmes and wellbeing.

3.3.3 Another of the policy sub-goals is to overcome differences in coverage between boys and girls in the pockets where they exist. This position is maintained from the current policy. Whilst we do not see differences in coverage by sex at national level, understanding where and why sex discrepancies in coverage exist sub-nationally is important and should be investigated, for example, through local surveys providing data that can be used to address local barriers to immunisation.

3.4 *Scope and areas of focus*

3.4.1 The Gender Policy remains focused on programmatic gender aspects, with other corporate policies only referenced. Revised Guiding Principles on Gender Balance for Board and Committee Nominations will be submitted to the Board for approval in June, and Secretariat Human Resources Gender Guidelines will be made available on request to the Board once finalised.

3.4.2 The revised policy calls out adolescents as a specific population of interest based on feedback from consultations. It highlights that the development of tailored interventions targeting adolescents provides a unique opportunity to be gender-transformative, as it is during this period that cultural and societal norms are developed. Including adolescents as a specific group acknowledges the need for tailored approaches to reach them with the human papillomavirus (HPV) vaccine.

3.4.3 The current policy only notes caregivers as facing gender-related barriers to immunisation. In order to align with gender policies of other organisations, the revised policy includes a specific focus on health workers. This addition seeks to acknowledge the gender pay

gaps, gender-based safety and security concerns and the prevalence of sexual harassment in the workplace that can negatively impact health workers and the quality of health services.

3.5 *Approaches to achieve Gavi's Gender Policy*

3.5.1 The revised policy includes six priority areas for the Alliance: **Understand** the issues, **Advocate** for change, **Identify** the specific bottlenecks, **Reach** more children with immunisation, **Learn** from experience and **Partner** to leverage expertise. These approaches address the gaps identified in implementation of the current policy by expanding on previous focus areas and highlighting new focus areas:

- Consultations showed a highly variable knowledge and understanding of how gender is relevant to immunisation, particularly at country-level, which resulted in the addition of **understand** as a specific approach.

- Annual monitoring of Gender Policy implementation at country level shows that the quality and availability of evidence and data related to gender-related barriers in countries is still lacking[5]. The revised policy therefore places additional emphasis on the importance of **identifying** gender-related barriers through integrating a gender barriers analysis within a broader analysis of barriers to reaching zero-dose and underimmunised children, individuals and communities.

- Consultations with CSOs, and other stakeholders, called for Gavi to develop a **learning** agenda for gender with the aim of providing contextually relevant information on which gender-related interventions can help reach zero-dose and underimmunised children, individuals and communities and improve coverage, as well as highlight potential unintended consequences.

- The evaluation found that at Alliance-level, there is a need to enhance the commitment of all partners to support, engage and equip country and community stakeholders in implementing the policy. The addition of **partner** as an approach acknowledges that addressing gender-related barriers is a multi-stakeholder and multi-sector effort.

3.6 *Monitoring & Evaluation Framework*

3.6.1 The evaluation found that the current theory of change does not sufficiently articulate a pathway from inputs to outputs and outcomes and thus did not provide an adequate framework to monitor progress

[5]An internal review of 29 HSS proposals which were recommended for approval in 2018-2019 found that 20 countries have identified barriers that are defined as gendered when describing reasons for low immunisation coverage, listed interventions to target the barriers, and allocated budget towards addressing the barriers. However, the quality of gender assessments overall was low.

in implementation. An updated theory of change within the Monitoring & Evaluation (M&E) Framework (see Annex B) was developed as the foundation for the updated policy. It provides a logical flow from the 'issue' – that gender-related barriers contribute to zero-dose and underimmunised children, individuals and communities – through to the 'impact' which is aligned with the Gavi 5.0 goal of reaching these individuals. The deliverables outlined in the theory of change are reflected in the six areas of focus in the policy, described above.

3.6.2 The evaluation found that the Secretariat monitoring plans for gender are under-developed, compounded by poor availability of gender data. The updated M&E Framework includes an approach to track strategy-level, process-level and country-level indicators on an annual basis. Process-level indicators are mapped directly to the theory of change, with proposed indicators to track progress against each approach. The M&E Framework will be aligned with Gavi 5.0 process and indicators, which are still being defined.

4. Initial policy implementation

4.1 Several steps have already been taken to address implementation challenges that were identified as part of the review. Gender continues to be mainstreamed into Gavi's guidelines and processes, including new vaccine and renewals application guidelines, Joint Appraisal reports, zero-dose programmatic guidance, guidelines to conduct equity assessments and Gavi Secretariat's Procurement Policy.

4.2 The Secretariat is in the final stage of hiring two externally funded individuals with gender expertise to join the new Demand, Communities & Gender Hub within the Health System and Immunisation Strengthening (HSIS) team. One of these specialists will be dedicated to gender and will lead the capacity building efforts to enable members of the Country Programmes department to drive the implementation of the Gender Policy.

4.3 WHO is co-developing[6] with the Secretariat a supplementary paper to the Immunisation Agenda 2030 on gender (see Appendix 4). The purpose of the document is to highlight the need for gender-responsive immunisation programming as well as to serve as a compendium on gender-responsive immunisation interventions for countries.

4.4 Finally, the Secretariat continues to seek out partnerships to implement gender-focused interventions. Some recent examples are described in Appendix 5.

[6] Other partners involved include UNICEF, US Centers for Disease Control (CDC), GPEI, The World Bank, Bill & Melinda Gates Foundation (BMGF), UN Women, International Federation of Red Cross and Red Crescent Societies (IFRC), The Core Group and Civil Society Human and Institutional Development Programme-Pakistan

5. Gender & COVID-19

5.1 Gender is an important consideration in programming Gavi's support to countries during the pandemic. As with all major outbreaks the impact of the COVID-19 pandemic is not gender neutral. Men's COVID-19 mortality rates are higher than women's, but there is an emerging consensus on the multiple and disproportionate impacts on women related to the pandemic and response. For example, there is decreased access to reproductive health services, decreased HPV immunisation rates due to school closures, increased gender-based violence and increased security risk to female healthcare workers. The lasting impact of the pandemic will be visible long after the last cases are detected in the number of girls who do not return to school, who have missed critical immunisations and who are less able to find fair and decent employment.

5.2 The Secretariat is working closely with partners to better understand the issues and potential approaches to addressing these challenges. Thus far, country re-programming requests include funding for personal protective equipment, safety measures for health care workers and demand generation. Given the high percentage of women in the frontline health workforce, as well as predominance of women bringing children to health centres, these investments are likely to have positive gendered impact in terms of reducing risks.

5.3 The Secretariat is also participating in several Gender and COVID-19 working groups, along with academics and fellow international agencies (e.g. UN Women, WHO, UNAIDS), to emphasise the importance of gender-disaggregated data during this pandemic, the need for a real-time gender analysis of the COVID-19 outbreak, and how to best mitigate an increase in gender-related risks due to the pandemic.

5.4 The Secretariat is seeking to build on this learning by taking a proactive approach to alerting countries to potential gender-specific risks related to the pandemic. The Secretariat is proposing interventions such as empowering women's organisations to engage caregivers around the importance of immunisation during the pandemic as well engaging UNICEF Supply Division regarding increasing the global availability of female-sized personal protective equipment. Overall, the response to COVID-19 will be an important first test of gender policy implementation.

6. Resourcing for implementation of the Gender Policy

6.1 Implementation of the Gender Policy will involve further mainstreaming of gender into Gavi's processes. All modes of Gavi funding will be leveraged to achieve the goals set out in the policy.

6.2 Countries are encouraged to use their HSS envelope towards programming for equity and reaching zero-dose and underimmunised children, individuals

and communities, which will include prioritising gender[7]. As part of the review of Gavi's funding policies, the Steering Committee agreed that a minimum amount of countries' HSS allocations should be used towards equity investments.[8] (see Annex D to Doc 02). While the funding policy review has been paused in light of the COVID-19 pandemic, this highlights the increasing emphasis on zero-dose and underimmunised individuals in country programming of HSS in the next strategic period. Vaccine Introduction Grants and Operational Support for campaigns will also be leveraged to reach missed communities.

6.3 Technical support through the Partners' Engagement Framework (PEF) Foundational Support, targeted country assistance (TCA) and investments in strategic focus areas (SFAs) will continue to be critical to policy implementation. The mechanisms for providing support on gender through these channels will be further strengthened to encourage prioritisation of funding for gender activities.

6.4 Secretariat and Alliance partners will need to continue to ensure sufficient resourcing of dedicated gender experts to facilitate and coordinate successful policy implementation. Alliance partners will be encouraged to prioritise gender experts within their PEF Foundational Support.

6.5 Finally, country-specific or cross-cutting learning activities of strategic importance should be aligned with Gavi 5.0 and the Gavi Learning Agenda (in development) and will be subject to budget availability.

7. Path forward

7.1 Following approval of the revised policy, the Secretariat will develop a detailed implementation plan to guide the execution of the Gender Policy that aligns with 5.0 operationalisation. The M&E approach will be further refined in parallel with the development of an implementation plan. Progress on implementation of the policy and delivery of the outcomes will be reported to the Gavi Board on an annual basis.

Section C: Actions requested of the PPC

The Gavi Alliance Programme and Policy Committee is requested to **recommend** to the Gavi Alliance Board that it:

Approve the revised Gavi Alliance Gender Policy attached as Annex B to Doc 04.

[7] Addressing gender-related barriers to immunisation is highlighted as an explicit objective within Strategy Goal 2 of Gavi's 2021-2025 strategy, strengthening health systems to increase equity in immunisation

[8] The Funding Policy Review (FPR) has been paused given the uncertainty around the duration and impact of the COVID-19 pandemic and the challenges countries are currently facing in addressing COVID-19. The Secretariat will revisit the FPR at a later date depending on how the pandemic progresses, including reviewing further adjustments to the funding policies to meet the needs of countries post-COVID-19.

Annexes

Annex A: Implications/Anticipated impact

Annex B: Revised Gender Policy and Monitoring and Evaluation Framework

Additional information available on BoardEffect

Appendix 1: May 2019 PPC Paper on the review of the Gavi Gender Policy

Appendix 2: Report of the external evaluation of Gavi's Gender Policy

Appendix 3: Summary of Consultations

Appendix 4: IA2030 Gender Supplementary Paper version 1

Appendix 5: Case Studies on Gender Policy Implementation

Additional reference materials online:

Gavi's Gender Policy: https://www.gavi.org/about/programme-policies/gender/

Annex A: **Implications/Anticipated Impact**

- **Risk implication and mitigation, including information on the risks of inaction.** Gender has been identified as an important determinant of health and immunisation outcomes. Inaction would result in Gavi not being able to reach as many zero-dose and underimmunised children. 'Gender-focus' has been elevated to a principle in Gavi 5.0, key to achieving the vision, so this policy update is necessary to ensure Gavi programming is fit for purpose.

- **Impact on countries.** Gavi-supported countries will require support to identify and address gender-related barriers. The 5.0 vision and this policy raise the priority level of gender within the context of equity and countries will be encouraged to programme their health system strengthening funding to find and reach zero-dose and underimmunised children, an important part of which is addressing gender considerations.

- **Impact on Alliance.** As a cross-cutting policy, the success of implementation will be driven in large part by Alliance partners who will play an integral role in supporting achievement of the policy objectives. A deliverable of the policy is to 'Partner' effectively, which includes mainstreaming gender throughout the Alliance to ensure alignment on goals regarding gender. Implementation of more gender-focused activities will be supported through Gavi's different funding channels and through its engagement with partners.

- **Legal and governance implications.** There are no legal implications with respect to the content of this report. The gender balance of governance structures has been reviewed alongside the policy review and can be found in Appendix 6.

Annex B: Revised Gender Policy

Gavi Alliance Gender Policy
Version 3.0

DOCUMENT ADMINISTRATION

VERSION NUMBER	APPROVAL PROCESS	DATE
3.0	Reviewed by: Programme and Policy Committee	2.0 – 10 October 2013 3.0 – 6 May 2020
	Approved by: Gavi Alliance Board	1.0 – 26 June 2008 Effective from 1 July 2008 2.0 – 21 November 2013 Effective from 1 January 2014 3.0 - *TBD* Effective from: 1 July 2020
	Next review:	At the request of the Board

Definitions

- **Zero-dose** children are those who have not received any routine vaccine. For operational purposes, Gavi measures zero-dose children as those who have not received their first dose of diphtheria-tetanus-pertussis containing vaccine (DTP1).
- **Underimmunised** individuals include children, adolescents and adults that are missing their full course of vaccination.
- **Caregiver** is a person who regularly or intermittently cares for an infant or child. Examples include mothers, fathers, grandparents and siblings.
- **Sex** refers to the biological characteristics that define humans as female, male or intersex and is typically assigned at birth.
- **Gender** is about the roles, norms and behaviours that society considers appropriate for women, men, girls, boys, and those with diverse gender identities, such as transgender. These are socially constructed, fluid, and vary widely within and across time, cultures, religions, class and ethnicity.
- **Gender-related barriers** are related to deep rooted social and cultural norms about the roles of women, men, and those with diverse gender identities, that create obstacles to equitable access and use of health services. For example, when caregivers, primarily women, have not completed secondary education, lack decision-making power, or are unable to move freely outside their homes, there is a greater likelihood that they will not take their children to get vaccinated. In addition, lack of male engagement can contribute to poor child health outcomes.
- **Intersectionality** refers to the overlap between multiple forms of inequality or discrimination which create obstacles for individuals, for example, access and use of health services. Gender identity can intersect with additional factors, including but not limited to age, geographical location, education, ethnicity, religion, class, socioeconomic status, disability, migration/refugee status, sexual orientation.
- **Gender equity** is the process of being fair to women, men and those with diverse gender identities. It recognizes that individuals of different gender identities have different needs, power and access to resources, which should be identified and addressed to rectify the imbalance. Addressing gender equity leads to equality.
- **Gender equality** is the absence of discrimination based on a person's sex or gender identity. It means ensuring that the same opportunity is accessible to each person such as access to and control of social, economic and political resources, including protection under the law (e.g., health services, education and voting rights).
- **Gender-responsive** approaches adopt a gender lens to consider individual needs of different gender identities without necessarily changing the larger contextual issues that lie at the root of the gender inequities and inequalities. For example, employing female health workers will facilitate enhanced immunisation service acceptance and uptake, but would not address the underlying cultural barrier that prevents female caregivers from seeking immunisation services from male health workers.
- **Gender-transformative** approaches are those that attempt to re-define and change existing gender roles, norms, attitudes and practices. These interventions tackle the root causes of gender inequity and inequality and reshape unequal power relations.

1. Rationale

1.1. Leaving no one behind with immunisation is the vision of Gavi, the Vaccine Alliance ("Gavi"). With equity as the organising principle, the focus is to ensure zero-dose and underimmunised children are sustainably reached with routine immunisation services. Zero-dose children are often concentrated in missed communities and key populations[1], with many living in abject poverty. Their families face many compounded vulnerabilities including poverty, socio-economic inequities and stigmatisation that drive and exacerbate barriers to accessing immunisation.

1.2. Gender is an important factor in these barriers to accessing immunisation. Gendered norms in any society typically determine roles for women, men, adolescent girls and boys and people with diverse gender identities. When interacting with additional socio-cultural and economic factors (e.g., age, wealth, education, ethnicity, religion, migrant/refugee status, sexual orientation and disability), gendered norms can impact the ability of caregivers to get their children immunised, or health workers to bring services to communities, creating gender-related barriers to immunisation.

1.3. Gender-related barriers limit immunisation service demand, utilisation, coverage and impact. Therefore, understanding and addressing gender-related barriers through tailored services that are responsive to the needs of different gender identities is key to ensuring zero-dose children, individuals and communities receive the full range of vaccines.

1.4. Gender-related barriers operate at multiple levels. For example, at an ***individual level,*** gender inequalities mean caregivers, often women, may lack education and health literacy to be aware of immunisation services and their value; at ***household level,*** unequal decision-making power and uneven distribution of household resources may limit a caregiver's ability to negotiate for access to services at health facilities; at ***community level,*** gender norms may make women solely responsible for children's health status, limiting men's participation; at ***health service level***, the attitudes or the gender of health workers may discourage caregivers to return for subsequent doses; and at ***institutional level****,* gender-blind government policies and gender imbalance in decision-making may draw less attention to the distinctive needs of women and girls.

1.5. Gender inequity in immunisation can also include differences in immunisation coverage between boys and girls. At aggregate level, there are no significant differences in immunisation coverage between girls and boys. However, differences do exist in some socioeconomically and geographically marginalised populations at sub-national level.

1.6. By promoting gender-responsive and transformative programming, Gavi will not only improve access to immunisation, but also contribute to the broader goal of gender equality and the empowerment of women and girls.

[1] Key populations include the urban poor, remote rural, migrant, refugees, internally displaced populations and those in conflict-affected areas.

2. Goals of Gavi's Gender Policy

2.1. Gavi's Gender Policy aims to support Gavi's bold aspiration of "Leaving no one behind with immunisation" and to strengthen vaccine programmes and health systems to increase equity in immunisation.

2.2. As such, the goal of Gavi's Gender Policy is to identify and overcome gender-related barriers to reach zero-dose and underimmunised children, individuals and communities with the full range of vaccines. This encompasses:

2.2.1. Focusing primarily on identifying and addressing underlying gender-related barriers faced specifically by caregivers, adolescents and health workers.

2.2.2. In the specific pockets where they exist, overcoming differences in immunisation coverage between girls and boys.

2.2.3. Encouraging and advocating for women's and girls' full and equal participation in decision-making related to health programmes and wellbeing.

2.3. In order to reach Gavi's high level of ambition in addressing inequity in immunisation and reaching zero-dose and underimmunised children, individuals and communities, it is vital to consider a spectrum of approaches ranging from gender-responsive to gender-transformative. Gender-responsive programming may be more achievable in the short- to medium-term. However, it will be important to redefine gender norms and tackle the root causes of gender inequity in the long-term through gender-transformative approaches, which Gavi can contribute to through collaborating with relevant institutions and stakeholders.

2.4. Gavi's Gender Policy is embedded in Gavi's wider commitment to ensure equity in all areas of engagement. It is grounded in the existing international human rights and political commitments, including the Sustainable Development Goals, particularly SDG3 on healthy lives and well-being and SDG5 on gender equality and empowering women and girls. These are prerequisites for sustainable and inclusive development. This policy is aligned with the principles of aid effectiveness and international gender commitments as agreed in Busan (2011) and Beijing (1995) and its Platform of Action, respectively. It is in full alignment with the Immunisation Agenda 2030, as well as with Gavi's strategy and policies.

3. Scope and areas of focus

3.1. This policy provides the framework and principles for Gavi's programmatic engagement on gender, including support for vaccines, health systems and technical assistance. It is applicable across the Secretariat, Alliance partners and Gavi's investments to countries' governments and communities.

3.2. This policy is focused on overcoming gender-related barriers faced primarily by caregivers, health workers and adolescents who are central to reaching zero dose and underimmunised children, individuals and communities.

3.2.1. The gendered needs of **caregivers** should be at the heart of immunisation service delivery. Primary caregivers of children, usually women, may not attend immunisation services as they lack the knowledge to do so due to unequal access to information and education, lack time due to unequal responsibilities for household labour, lack agency due to imbalance in household decision making power, or have restricted mobility due to rigid and harmful gender norms. Men's participation in childcare and as influencers in broader societal networks is important in increasing demand for immunisation services. Additionally, service delivery approaches, particularly related to distance to health facility, clinic hours and quality of services, can lower numerous barriers faced by female caregivers.

3.2.2. A special focus on gender-related barriers faced by the **health workforce** is required. Despite almost 70% of frontline health workers being female[2], women only occupy 25% of leadership roles. Gender pay gaps, gender-based occupational segregation and the prevalence of sexual harassment in the workplace negatively impact the quality of health services. In addition, security threats and gender-based violence limit the extent to which female health workers can safely undertake outreach missions and staff clinics.

3.2.3. Including **adolescents** and their needs in the development of tailored interventions provides a unique opportunity to be gender-transformative, as it is during this period that cultural and societal norms are developed. Reaching adolescents with Human Papillomavirus (HPV) vaccine, amongst others, creates positive experiences with the health sector and builds an enabling environment for a lifetime of health-enhancing behaviours for adolescents and their future children.

3.3. Gavi's approach to gender is not limited to immunisation programmes and health care delivery in countries but extends to all aspects, including governance bodies and the Gavi Secretariat's corporate policies and practices. These are **not** in scope for this policy but are reflected in other documents. Examples include:

3.3.1. **Governance**: Gavi seeks to achieve gender balance throughout the Board governance structures and membership as described in the *Guiding Principles on Gender Balance for Board and Committee Nominations*.

3.3.2. **Human Resources**: The Gavi Secretariat is committed to maintaining a workplace that promotes diversity. It aims for gender balance in recruitment, remuneration, recognition and rewards. Key indicators are reported and monitored regularly as outlined in the *Gavi Secretariat HR Gender Guidelines*.

3.3.3. **Procurement**: The Gavi Secretariat requires contractors to consider their impact on gender equality, amongst other economic, social and ethical considerations as described in the Gavi Procurement Policy.

[2] Boniol M, McIsaac M, Xu L, Wuliji T, Diallo K, Campbell J. Gender equity in the health workforce: analysis of 104 countries. Working paper 1. Geneva: World Health Organization; 2019

4. Guiding principles

4.1. The following are the guiding principles for Gavi's programmatic engagement on gender:

4.1.1. **Focus on reaching zero-dose and underimmunised** children, individuals and communities by mainstreaming gender into all Gavi's investments.

4.1.2. **Do no harm**: Gavi and its implementing partner activities should not cause adverse impacts, create new risks or reinforce harmful/damaging gender stereotypes that contribute to marginalisation, social and economic disadvantage, exclusion and gender-based violence.

4.1.3. **Evidence-based, differentiated approaches**: Target and tailor approaches based on country and community context and capacity, recognising that gender issues differ significantly from one country to another and sub-nationally.

4.1.4. **Country ownership**: Promote country ownership and alignment, ensuring that countries are equipped with the resources to identify and address gender- related and additional intersecting socio-cultural barriers to health and health services.

4.1.5. **Community engagement**: Leverage local community knowledge of gender norms and involve communities in the planning, implementation and oversight of interventions to identify and address gender-related barriers to strengthen accountability and sustain impact.

4.1.6. **Integration**: Align and coordinate actions at country level given that interventions to address gender-related barriers require a multi-sectoral approach. Foster delivery of immunisation within a broader package of primary health care services and integrate service delivery with other sectors such as education and economic empowerment.

4.1.7. **Innovation**: Explore new products, services, practices and strategic approaches to address gender-related barriers and promote gender-transformative interventions.

4.1.8. **Accountability**: Ensure effective and representative monitoring and measurement and clear lines of accountability for delivering on Gavi's Gender Policy in line with the theory of change, amongst the entire Alliance at global, national and community level.

5. Approaches to achieve Gavi's Gender Policy

5.1. The following approaches relate to the **Gavi Secretariat, Alliance partners and Gavi's investments in countries' governments and communities**. Gavi will pursue the goals of this policy by integrating a gender lens into its analyses, funding and monitoring through, for example, guidance documents, funding applications, country level dialogue, portfolio management processes, and monitoring and evaluation. Gavi will focus on the following areas:

UNDERSTAND: Building capacity in country on gender and immunisation to understand, recognise and address gender-related barriers.

5.2. Sensitising and building the capacity of stakeholders in the Secretariat, Alliance partners and in-country on the importance of addressing gender-related and additional socio-cultural barriers will enable planning and implementation of immunisation programmes to better target the needs of key populations.

As such, Gavi will:

5.2.1. Integrate learning opportunities into broader Gavi-funded capacity-building activities where possible and ensure effective training on gender and immunisation is available to Secretariat, Alliance Partners and in-country stakeholders.

5.2.2. Develop and optimise use of Alliance tools, guidance and innovations to support understanding of gender-responsive and transformative programming in country within the broader understanding of equity.

5.2.3. Provide advice, resources and expertise to strengthen gender-responsive and transformative approaches and interventions in country programming.

ADVOCATE: Strengthen political commitment for gender equality and women's and girl's empowerment.

5.3. Equitable access to universal health care and gender equality are fundamental human rights. To sustain progress and institutionalise efforts to address gender-related barriers, strong leadership is needed to amplify a unified Alliance voice and advocate for gender equity and equality in global, regional and national policy processes and platforms.

As such, Gavi will:

5.3.1. Shape advocacy and global dialogue to articulate and position gender-responsive and transformative interventions as a critical tool to reach zero-dose and underimmunised children, individuals and communities. Promote coordinated efforts towards the realisation of existing international norms, standards and commitments on gender equality.

5.3.2. Build and strengthen in-country political commitment and community engagement to: (a) integrate a gender lens in implementation of primary health care services and National Immunisation Strategies; (b) allocate resources towards data collection and interventions to overcome identified gender-related barriers; (c) dedicate financing for community health systems to equally remunerate and empower health workers regardless of gender and intersecting socio-cultural factors; and (d) enable active and equal participation of women at all levels in decision-making for health and in leadership positions, including a gender balance in training.

5.3.3. Build commitments to gender equality at an Alliance and country level, including with visible leadership, a unified voice on gender issues and strategic leverage of gender champions at the global, regional, national and sub-national levels.

5.3.4. Advocate for vaccine development and supply to consider gendered considerations and impacts, including the potential disproportionate impact of a disease on any gender (e.g., higher prevalence and/or suffering).

IDENTIFY: Generate and/or consolidate gender-based analyses and data to identify gender-related barriers to reaching zero-dose and underimmunised children, individuals and communities.

5.4. Programmes that are informed by an analysis of gender-related and intersecting barriers take into account the needs of different population groups. It is important to collect, use and monitor such data at sub-national level.

As such, Gavi will:

5.4.1. Ensure that the design and implementation of immunisation programmes is informed by an analysis of gender-related barriers as part of a broader analysis of barriers. A robust analysis of gender-related barriers should include: engagement with community-level stakeholders; a focus on priority populations (including caregivers, adolescents and health workers); collection and use of quantitative and qualitative data from different sectors; and analysis of data disaggregated by sex and additional intersecting socio-cultural factors when available and relevant.

5.4.2. Explore innovative solutions and partnerships to collect and analyse sub-national data on caregivers, children, adolescents, health workers and health services, within and outside the health sector, and consider the contribution of women and girls to the effort.

REACH: Utilise Gavi's funding, processes, structures and other levers to promote an integrated approach on gender to reach zero-dose and underimmunised children, individuals and communities.

5.5. Ensuring interventions to address gender-related and additional intersecting socio-cultural barriers are integrated when planning and designing programmes is critical to reaching zero-dose and underimmunised children, individuals and communities.

As such, Gavi will:

5.5.1. Promote the use of Gavi's different funding mechanisms within the countries' grant cycle planning processes to support gender responsive, and where possible, transformative approaches and activities.

5.5.2. Empower voices and perspectives of all genders, key populations and partners in the design of interventions to tackle gender-related barriers. This can be through applying behavioural science and human centred design approaches.

5.5.3. Build capacity and support countries to adequately budget for interventions to overcome gendered barriers, exploring gender-responsive budgeting and have specific and measurable indicators to track progress.

5.5.4. Encourage country plans to integrate immunisation services with adolescent and maternal, newborn and child health services, and other sectors including education, throughout the life-course.

LEARN: Undertake learning activities to assess and identify the most relevant and effective approaches to address gender-related barriers to immunisation.

5.6. Setting and executing a learning agenda can provide contextually relevant information on which gender-related interventions can help reach zero-dose and underimmunised children, individuals and communities and improve coverage, as well as highlight potential unintended consequences.

As such, Gavi will:

5.6.1. Develop and implement a learning agenda that seeks to increase the evidence base on gender and immunisation, as well as additional intersecting socio-cultural factors by supporting in-country learning activities.

5.6.2. Enhance communication and dissemination of evidence generated on gender and immunisation, as well as additional intersecting socio-cultural factors, to increase immunisation service utilisation, coverage and impact.

PARTNER: Establish, strengthen and leverage partnerships within and outside the health sector.

5.7. Overcoming gender-related barriers will require a cross-sectoral approach at global, national and sub-national levels. Partnering with actors within and outside the health sector brings a range of distinctive strengths, experiences and resources to the design and implementation of interventions.

As such, Gavi will:

5.7.1. Develop and leverage existing and new global partnerships[3] across sectors to overcome gender-related barriers through strengthening coordination of response, data collection and fostering learning and knowledge-sharing. Partnerships include the United Nations system, humanitarian organisations, civil society platforms, multilateral and bilateral agencies, academic institutions, private sector organisations and foundations.

5.7.2. Encourage in-country policy coherence and cross-sectoral coordination to advance national priorities on primary health care and/or universal health care. This includes more effective partnerships between the Ministry of Health, Finance and the Ministry responsible for gender, women or child welfare or social development.

5.7.3. Build relationships and regularly engage with national and community-level civil society organisations, women's and youth groups that advocate for gender transformation and social justice. This enables Gavi to leverage their passion, experience and programmes, while building their capacity as advocates, leaders and voices for change.

[3] Including the Global Action Plan for Healthy Lives and Wellbeing for All

6. Timelines for implementation and review

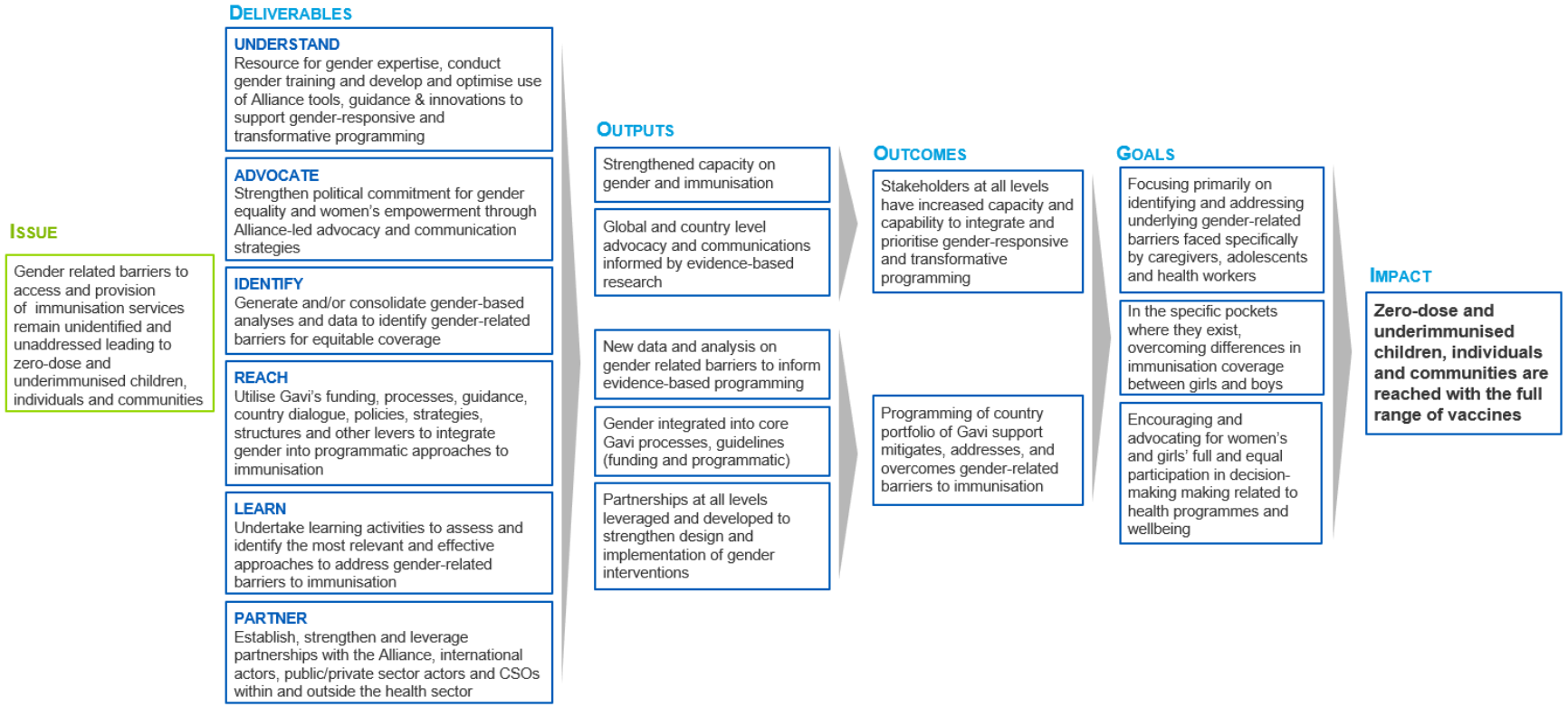
6.1. Gavi's Gender Policy will take effect on 1 July 2020.

6.2. Progress in and impact of implementing Gavi's Gender Policy will be measured through the monitoring and evaluation framework (See Annex A) which outlines the theory of change of this policy and ways in which Gavi will monitor policy implementation and outcomes. The Deputy Chief Executive Officer will be responsible for reporting to the Gavi Board on progress towards delivery of these outcomes on an annual basis.

6.3. This Policy will be reviewed at the request of the Board.

Annex A: Monitoring & Evaluation Framework

Theory of Change



Monitoring Framework

The implementation and adherence to the Gender Policy will be monitored by the Gavi Secretariat on an ongoing basis. This policy also points to the need for better data to be able to assess the need for, and progress of, interventions to tackle gender-related barriers. The implementation of the policy will be monitored at the strategic, process and country-levels. With the implementation of Gavi's new strategy beginning in 2021 these indicators and monitoring processes are subject to evolution and addition.

Strategy-level

Gavi's strategy for 2021-2025 (Gavi 5.0) includes a principle around 'gender-focus'. Monitoring of gender-related performance will sit under Strategic Goal 2: Strengthen health systems to increase equity in immunisation. The specifics will be detailed in strategic implementation monitoring documents.

Process-level

Gavi's progress in implementing the policy will be monitored through process-level indicators on an annual basis, where possible. These process-level indicators map to the six deliverables articulated in the Policy and theory of change and will be monitored at an aggregate level across countries or Alliance partners, and not at individual country or partner level. As gender-related barriers are highly context specific, outcomes will not be monitored at aggregate level but rather country by country, as described in the following section. The process-level indicators will be refined and finalised alongside the new strategy, and include, but not be limited to, tracking the following activities:

Understand

- Number of people trained in gender with Gavi funds (disaggregated by place of work: Gavi Secretariat, Alliance partner, country EPI programme)
- % of teams mainstreaming gender into their processes and deliverables

Advocate

- Number of priority public policy outcomes for which Gavi has driven inclusion of gender language and positioning (at global, regional and country levels)
- % of countries that include gender-related activities in their National Immunisation Strategies

Identify

- % of countries demonstrating that they have assessed gender-related barriers to accessing immunisation services as part of their broader analysis of barriers to reaching zero dose (using for example, equity assessment, gender situational reports)

Reach

- % of countries prioritising at least one intervention to tackle gender-related barriers
- % of countries budgeting for at least one intervention to tackle gender-related barriers
- % of countries tracking their progress in tackling gender-related barriers with at least one context-relevant indicator
- % of HPV support applications that plan for integrated services for adolescents

- % of Gavi grants/ investments through partners supporting implementation of interventions for gender-related barriers

Learn

- % of countries with learning activities implemented to generate evidence on gender and immunisation aimed to increase service utilisation and coverage

Partner

- Number of new partnerships which include a focus on identifying/ solving for gender-related barriers

Data sources might include: annual progress reports from countries, country budgets and implementation plans, trip reports, national immunisation strategies, internal HR documentation.

Country-level

Countries will be strongly encouraged to integrate their own outcome indicators to measure their gender-specific activities and outcomes supported by Gavi. These indicators will vary across countries depending on local priorities and gender-related barriers faced. They will be tracked on an annual basis and used to inform further country programming.

Data sources might include: independent surveys (DHS, MICS, KAP), health sector reviews, EPI reviews, equity assessments.

In line with SAGE recommendations, this policy does not require all countries to report coverage disaggregated by sex (male/female). Whilst some differences have been reported at the subnational level, local surveys provide valid data that is more appropriate than routine collection of coverage data disaggregated by sex. Where sex discrepancies exist, sex disaggregated data should be used to better investigate the problem.

Key assumptions

This policy seeks to mainstream gender throughout the work of the Alliance, with all parties equally committed to the goals stated in the policy. The Secretariat must ensure that the principles of the Gender Policy are integrated into various guidance and funding documents, with the aim that changes brought about through implementing the policy will be catalytic.

As all Gavi-supported countries will have different gender considerations that need to be addressed, context-specific policy implementation and monitoring is key to success.

Evaluation

The Gender Policy will be re-evaluated, to assess its relevance, implementation, effectiveness and contribution to Gavi's overall mission, at the request of the Board.

Report to the Programme and Policy Committee

26-27 May 2020

SUBJECT:	**COVID-19 PANDEMIC RESPONSE: AN ALLIANCE UPDATE**
Agenda item:	05
Category:	For Guidance

Section A: Executive Summary

Context

- The COVID-19 pandemic is the biggest health and economic crisis the world has seen in living memory. As of 12 May, over 4 million cases and 280,000 deaths have been recorded across 187 countries. The global economy is expected to suffer the worst recession since the Great Depression, with global Gross Domestic Product (GDP) likely to contract by at least 3% in 2020. 69 of 73 Gavi-supported countries have confirmed cases of COVID-19. While reported incidence and mortality remain relatively low in most Gavi-supported countries and the future trajectory remains uncertain, rapid increases in the number of cases are being seen along with significant impacts on immunisation programmes as well as broader health systems and economies.

- Gavi has made available up to US$ 200 million in immediate support for countries' COVID-19 preparedness and response plans through flexible reprogramming of existing funding. At its meeting on 11 May 2020, the Board approved three additional flexibilities to help mitigate the fiscal impact on countries including preserving their eligibility status and co-financing at 2020 levels for 2021 and granting the CEO the authority to waive 2020 co-financing obligations on a case-by-case basis. This paper provides a summary of Gavi's response to date and the broader approach which the Secretariat is proposing going forward.

Questions this paper addresses

- How has COVID-19 impacted Gavi-supported countries to date?
- What is Gavi's overall approach to help countries respond to COVID-19?
    - Immediate support for country response
    - Maintaining and restoring immunisation services
    - Ensuring adequate cold chain for the COVID-19 response
    - Responding to the fiscal impact on immunisation programmes

Conclusions

- While the future evolution of the pandemic remains uncertain, it is already clear that COVID-19 will have a major impact on economies, health systems and immunisation programmes in Gavi-supported countries. Building on its support to date, the Alliance will need to make available a range of flexibilities to respond to the different and dynamic needs of countries as they seek to maintain and restore immunisation programmes in response to the pandemic. The Secretariat is seeking the guidance of the Programme and Policy Committee (PPC) on its proposed approach, including whether Gavi should play a broader role in helping countries to strengthen their cold chain, and a recommendation on flexibilities to allow Gavi to support former eligible countries and to delay timing of misuse repayments on a case-by-case basis.

Section B: Content

1. Impact of COVID-19 on Gavi-supported countries and programmes

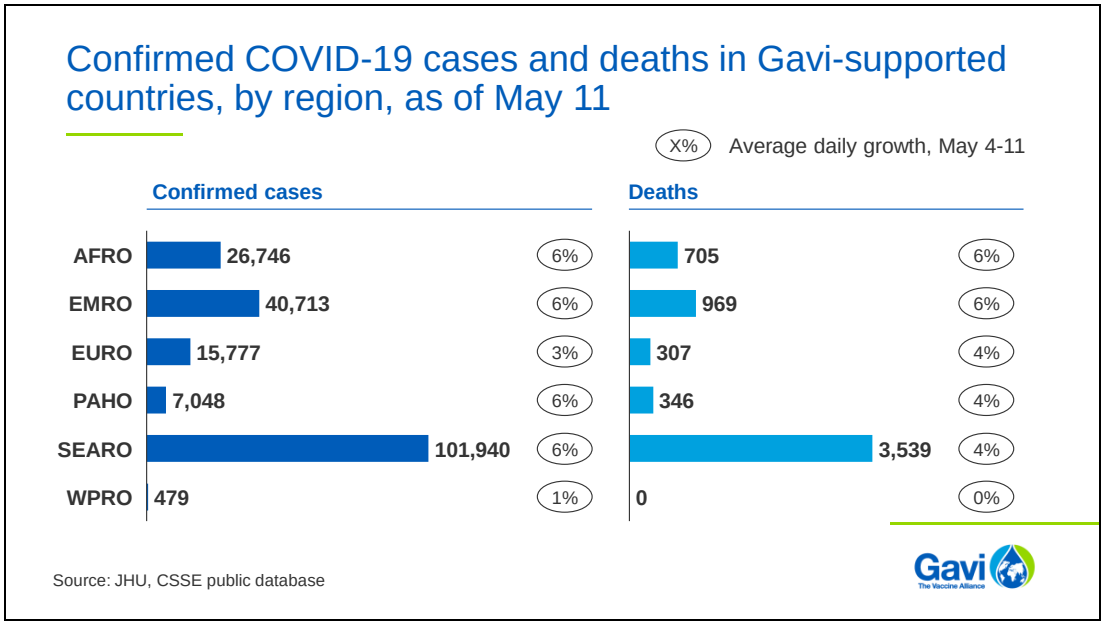
1.1 As of 12 May, over 4 million COVID-19 cases and nearly 280,000 deaths have been recorded across 187 countries. The global economy is expected to suffer the worst recession since the Great Depression, with global GDP likely to contract by at least 3% in 2020. The full health, social, political and economic impact will depend on the trajectory of the pandemic. Ultimately, only safe and effective vaccines will allow the world to stop transmission and prevent the resurgence of COVID-19.

1.2 **69 of 73 Gavi-supported countries[1] have confirmed cases of COVID-19,** accounting for less than 5% of the reported global burden. There is significant regional variability across Gavi-supported countries, with over half of the ~190,000 reported cases and ~6,000 deaths occurring in three large Asian countries (India, Pakistan and Indonesia). While incidence and mortality appear relatively low so far in most Gavi-supported countries, the number of reported cases is doubling every 10-14 days and testing remains limited. Cases are rising particularly rapidly in fragile countries, with an increase of over 50% in the past week (this compounds other major threats including widespread hunger, with the World Food Programme (WFP) projecting that the number of people facing acute food insecurity worldwide will nearly double as a result of the economic impact of COVID-19). Gavi-supported countries are at greatest risk given the relative weakness of their health systems and potential challenges in implementing lockdowns and control measures used elsewhere. Where these have been introduced, they have particularly impacted the poorest and most marginalised who do not have the financial resources or social safety nets to continue to meet their basic needs.

1.3 WHO's Strategic Advisory Group of Experts on Immunization (SAGE) has emphasised that **immunisation remains a core health service** that should

[1] includes Gavi-eligible and post-transition countries

be prioritised during the pandemic[2]. One analysis by the London School of Hygiene and Tropical Medicine looking at the risk of COVID-19 transmission in the context of immunisation visits suggested that for every death due to COVID-19 acquired during routine immunisation clinic visits, over 100 under-five deaths from vaccine-preventable diseases (VPDs) could be averted from sustaining routine immunisation in Africa[3].

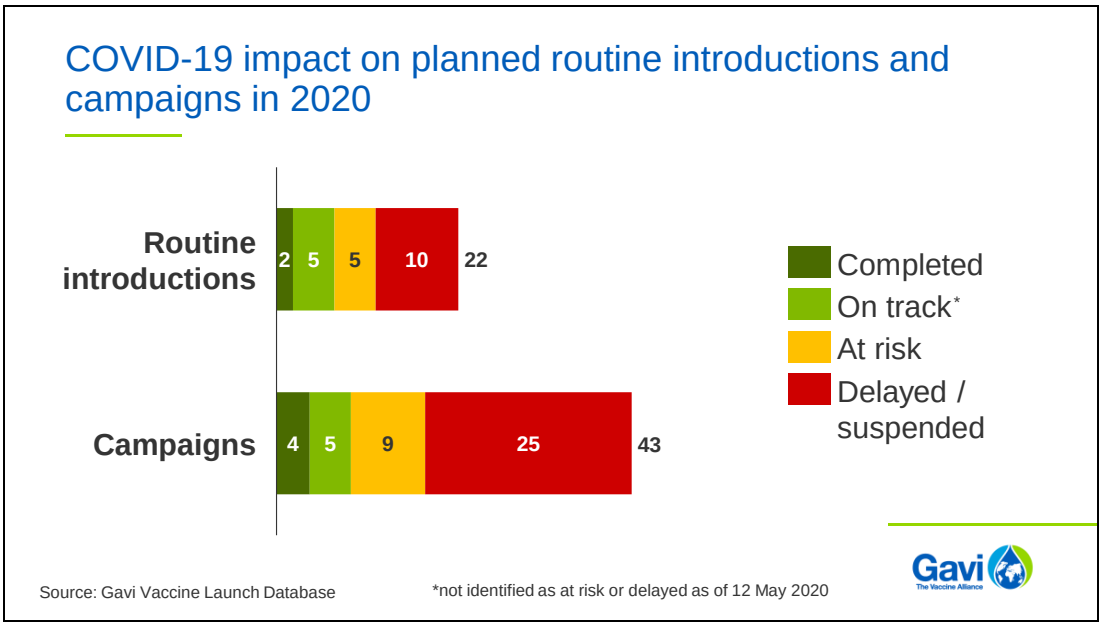


1.4 However, it is already clear that **COVID-19 is impacting immunisation services in a number of ways**:

a) **Vaccine introductions:** WHO has advised countries to carefully re-evaluate decisions on new vaccine introductions and consider postponement. To date, ten Gavi-supported vaccine introductions have been delayed with a further five at risk of delay.

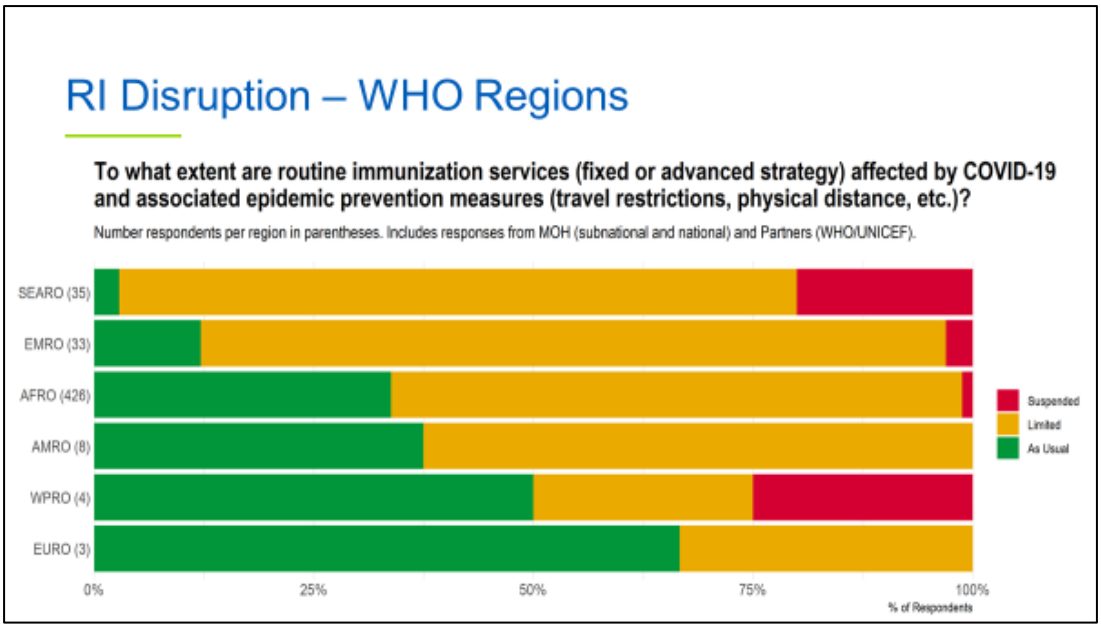
[2] https://apps.who.int/iris/bitstream/handle/10665/331590/WHO-2019-nCoV-immunization_services-2020.1-eng.pdf

[3] https://cmmid.github.io/topics/covid19/EPI-suspension.html



b) **Immunisation campaigns**: SAGE has also recommended that mass preventive campaigns be temporarily suspended in all countries and that a careful risk analysis should inform decisions on conducting outbreak response campaigns. As of 12 May, 25 Gavi-supported campaigns have been suspended or delayed, targeting a total population of at least 140 million people, and another 9 campaigns are at risk in 2020. The Global Polio Eradication Initiative (GPEI) has also halted campaigns. These delays significantly increase the risk of VPD outbreaks.

c) **Routine immunisation services**: In most countries, health facilities are reportedly open and continue to offer fixed site immunisation. However, measures undertaken to contain the spread of the disease - such as physical distancing and lockdowns – are disrupting both supply and demand for immunisation services. In Africa, for example, nearly half of countries have partially or entirely suspended outreach. This is likely to disproportionately impact the most marginalised communities who may not be able to easily access health facilities.



d) **Demand:** ~30% of Gavi-supported countries have reported a decline in attendance at immunisation sessions. This is due both to access challenges and concerns about the risk of COVID-19 exposure (COVID-19 has also been used to fuel anti-vaccine sentiment in some countries). Active community engagement will be needed to reactivate caregiver demand once access to services is fully restored.

e) **Health workforce:** Over half of Gavi-supported countries have frontline immunisation workers involved in the COVID-19 response, and in ~30% of countries this is affecting provision of routine immunisation services. There are increasing reports of absenteeism due to travel restrictions, sickness, self-isolation, and healthworkers' concerns about their own health and a lack of personal protective equipment (PPE). There are also reports in some countries of hostility and harassment of healthworkers given tensions and suspicions related to COVID-19. Since ~70% of healthcare workers in lower middle-income countries are female, women are disproportionately affected.

f) **Supply chains**: The pandemic is having a significant impact on global supply chains. Reduced air cargo capacity has impacted international vaccine shipments causing delays and increasing freight costs by 30-50% on average. Restrictions on movement have hindered distribution of both vaccines and cold chain equipment in some countries. UNICEF has identified 26 countries which have experienced or approached critical stock levels for at least one vaccine, although the shipment situation is now starting to improve. Conversely, countries who have delayed introductions and campaigns may have excessive stock levels and some manufactures are seeing inventories rise due to delays in shipments. This creates a risk of wastage if vaccines reach their expiry date or cannot be adequately stored in the interim. Cold chain equipment installation is facing delays in 11 countries with potential delays in another four, while cold chain equipment optimisation platform (CCEOP)

applications, planning and post-installation inspection have all faced delays. Vaccine and cold chain manufacturing have not been significantly affected to date but the risk will increase if COVID-19 measures persist globally (manufacturers have committed to notify UNICEF if any production disruptions are foreseen).

g) **Gavi engagement:** COVID-19 is impacting the Alliance's ability to engage with countries. With immunisation staff increasingly being diverted to the COVID-19 response, planning for new Gavi support has been delayed. Audits, surveys, assessments and routine planning activities have largely been suspended and some Alliance technical support has been hindered by travel restrictions.

2. Four pillars of Gavi's support for countries to protect, maintain and restore immunisation in response to COVID-19

2.1 At its 19 March meeting, **the Board encouraged the Alliance to be bold** in its response to COVID-19 and use maximum flexibility. Working with partners, the Secretariat has developed an **approach grounded in four pillars**. The first pillar has already been operationalised while the others are designed to support the programmatic response over at least the next 18 months.

a) **Immediate support for country response:** Gavi has made up to US$ 200 million in immediate support available to help countries to protect immunisation services to the extent possible, as well as supporting immediate components of their COVID-19 response, for which other funding was not immediately available.

b) **Maintaining and restoring immunisation services**: Recognising that each country will be impacted by COVID-19 differently, Gavi is proposing a set of flexibilities to support tailored, locally designed plans to maintain essential immunisation services and respond to outbreaks during the pandemic, and restore immunisation programmes as part of broader country recovery plans thereafter.

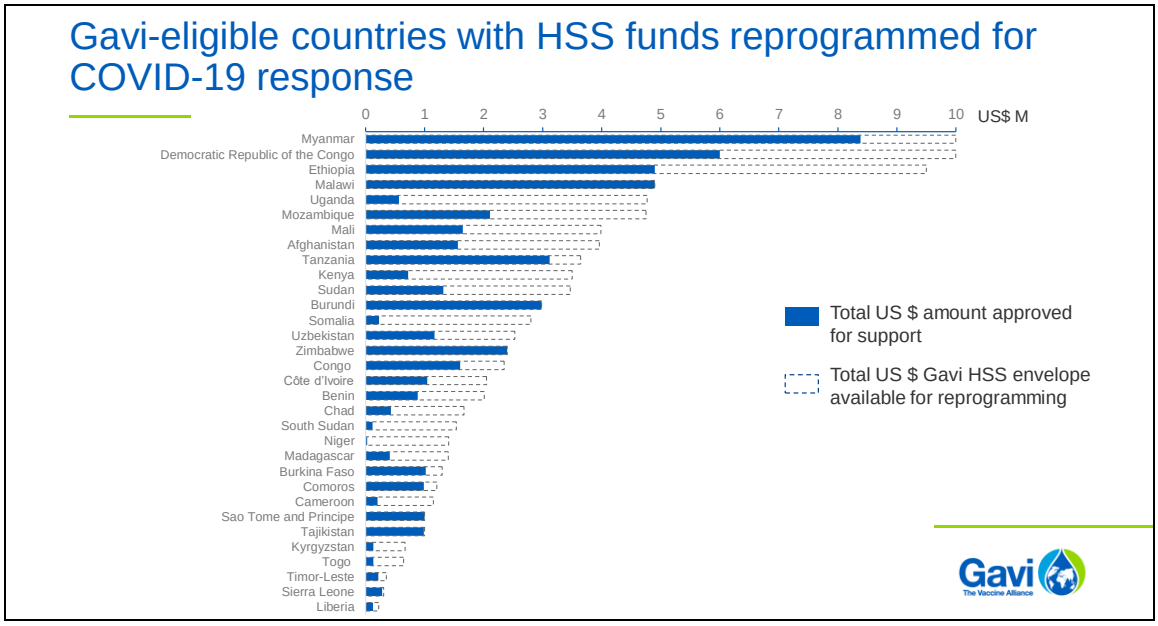
c) **Ensuring adequate cold chain for the COVID-19 response:** Several donors and partners have asked how Gavi can harness the Cold Chain Equipment Optimisation Platform (CCEOP) to support the broader response to COVID-19 recognising that this is an area where the Alliance has a comparative advantage.

d) **Responding to the fiscal impact on immunisation programmes:** The Board has already approved flexibilities in the application of the eligibility, transition and co-financing policies to mitigate the impact of COVID-19 on countries' fiscal space and ensure continued availability of vaccines. The Secretariat is recommending select further measures to support Gavi-eligible countries, and to provide targeted support to former Gavi-eligible countries upon request.

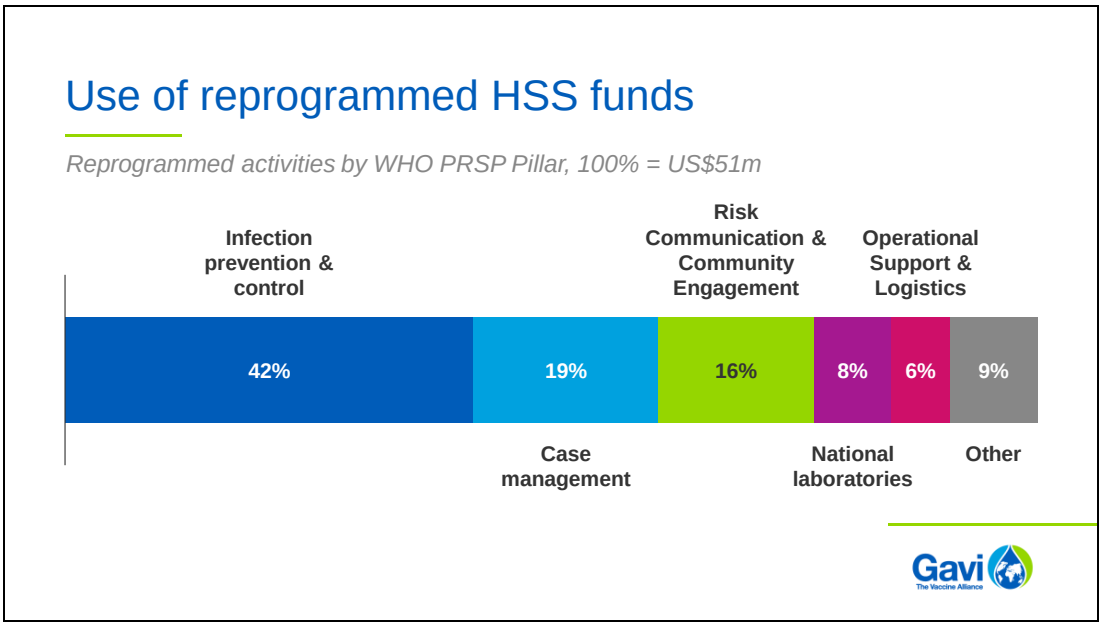
3. Pillar (a): Immediate support for country response

3.1 In early March, Gavi made available up to US$ 200 million to support countries' COVID-19 preparedness and response plans. This included allowing countries to reallocate up to 10% of health system strengthening (HSS) grants, as well as Partners' Engagement Framework Targeted Country Assistance (PEF TCA) and post-transition engagement (PTE). The primary purpose was to help prepare countries' health systems to deal with the impact of COVID-19, protect immunisation programmes and maintain services to the extent possible. All Gavi support is aligned to countries' Strategic Preparedness and Response Plans and coordinated with other donors (e.g. World Bank, Global Fund, Global Financing Facility and bilateral donors). The Secretariat introduced a fast-track application process to review and approve applications within five days of receipt.

3.2 Gavi has approved over US$ 51 million in HSS reprogramming for 32 countries. On average, countries have applied to reprogramme ~55% of the amount available, in order to safeguard funding for essential immunisation activities. PEF TCA and PTE have been reprogrammed in nine countries with no-cost extensions approved in another 25 countries.



3.3 **Over 40% of support approved to date has been for PPE** and other infection prevention and control (IPC) supplies to protect health workers. Another 19% has been allocated for case management and a further 16% for risk communication and community engagement to support behaviour change to prevent COVID-19 spread and maintain demand for essential health services such as immunisation. Other major areas of support include laboratory testing and operational support and logistics. There are reports of countries facing difficulties in procuring critical products to respond to the pandemic due to supply disruptions, increased demand, bidding wars, confiscations, and political tensions. To help address this, the Secretariat has set up a pre-financing mechanism with UNICEF to accelerate countries' access to PPE and diagnostics procured with Gavi support.



3.4 **At global level, the Alliance is reprioritising its work to support the COVID-19 response**. For example, the Demand Hub is using the 2020 demand Strategic Focus Area (SFA) budget to address demand issues caused by the pandemic, reorienting work on service experience to look at caregiver experiences in the context of COVID-19, and convening partners to address digital information challenges. The Supply Chain Steering Committee is reprioritising its activities to address supply chain challenges posed by COVID-19. The Secretariat has recently signed an agreement with UNICEF Supply Division to provide some advance funding to cover increased freight costs for delivery of vaccines in light of the reduced number of commercial flights available and the Alliance is working with governments to secure special dispensation for continued deployment of CCE wherever feasible and working with manufacturers to manage the cost of storing devices where this is not possible. The University of Oslo developed a COVID-19 module for District Health Information Software 2 (DHIS2), the leading health management information system in Gavi-supported countries, building on the integrated surveillance package supported by the Data SFA, and expanded partners can now reprogramme TCA to help countries implement it. The Learning Network for Countries in Transition has shifted its focus to highlight peer-exchanges and best practices on the impact of COVID-19 on immunisation.

3.5 **Many Alliance partners have been supporting COVID-19 response at country level**. The World Bank has committed up to US$ 160 billion to support countries respond to COVID-19 while WHO and UNICEF are playing a critical role in supporting countries to design and implement their response and to maintain immunisation services (including the ~300 staff in WHO and UNICEF country offices funded through TCA). Non-UN partners are also reorienting their support. For example, VillageReach is working with the Ministry of Health in Mozambique to utilise the immunisation supply chain for COVID-19 such as by distributing PPE to rural health facilities with vaccines. In Kenya, KANCO (a CSO consortium) added messaging on

COVID-19 and the importance of routine immunisation to its sensitisation activities with community health workers, religious leaders, communities and journalists. Gavi's private sector partners are also contributing. In Uganda, for example, United Parcel Service (UPS) – Freight in Time (FIT) is supporting the distribution of PPE as part of our last mile delivery partnership, Last Mile Health is scaling its Health Academy to deploy digital training content on COVID-19 for health workers, and Girl Effect is creating COVID-19 related content for young people.

3.6 **Countries are harnessing previous Gavi investments in their health systems for the COVID-19 response.** In Pakistan, for example, the Government of Sindh is using Gavi-supported technology, developed with Innovation for Uptake, Scale and Equity in Immunisation (INFUSE) pacesetter Interactive Research & Development (IRD), to track and monitor COVID-19 patients in Karachi. Similarly, the Government of India is harnessing the National Polio Surveillance Project, which Gavi support has already helped to repurpose for routine immunisation, for COVID-19 surveillance, contact tracing and containment. In Democratic Republic of Congo (DRC), the Expanded Programme on Immunization (EPI) is using the supervision application rolled out with Acasus and Gavi support to track COVID-19 impact on immunisation session attendance and implement a targeted communication plan in partnership with UNICEF. In Angola, the EPI programme is using the electronic Logistics Management Information System (eLMIS) introduced with Gavi and Logistimo support to manage vaccines in real time in 3 regions as well as tracking supplies of PPE. Nine Gavi-supported countries have implemented the DHIS2 surveillance module and are using it for COVID-19 port of entry screening, case-based surveillance, contact tracing and outbreak monitoring (the module is being implemented in another 16 countries).

3.7 **The Alliance is carefully monitoring the impact of COVID-19** on immunisation programmes, including through a cross-agency coordination group, under the leadership of WHO and UNICEF. The PEF management team is meeting regularly to share information and help coordinate the Alliance's response. WHO has disseminated a pulse survey to countries and regional offices are maintaining dashboards on immunisation programme status. Regional working groups are meeting regularly to review developments and exchange information and there are regular touchpoints between partners at the global level. Senior Country Managers remain in frequent contact with their counterparts at Ministries of Health, in-country partners and other major donors. UNICEF is closely monitoring stock levels in countries and WHO, UNICEF and the Secretariat are working together to prioritise vaccine shipments to countries at risk of stockout.

4. Pillar (b): Maintaining and restoring immunisation services

4.1 **While the longer-term trajectory of the pandemic remains uncertain, it is already clear that millions of people in Gavi-supported countries will miss out on immunisation**, risking a resurgence of VPDs and outbreaks, exacerbating existing inequities and putting the most marginalised and

poorest communities at greatest risk. There is a real risk of backsliding on decades of progress in strengthening routine immunisation and increasing coverage. In this context, **Gavi's vision to leave no one behind with immunisation – with equity as Gavi 5.0's organising principle – is more important than ever**. It will be imperative to ensure that country response plans prioritise essential health services such as immunisation with a particular focus on missed communities with large numbers of zero dose and underimmunised children, whose number will likely increase as a consequence of the pandemic.

4.2 **WHO has developed practical guidance on delivering immunisation services during the pandemic,** endorsed by SAGE (and is working on guidance for COVID-19 catch-up and recovery efforts). This encourages local adaptation and innovation, given that the spread of the pandemic varies between and within countries. In addition to underscoring that immunisation remains an essential service and recommending a temporary suspension of preventive campaigns, key elements include:

a) **Redesigning immunisation services** to protect health workers, caregivers and the community (e.g. reduced session sizes, physical distancing, strengthened IPC practices).

b) Using a careful risk-benefit analysis to determine whether to conduct **outbreak response mass vaccination campaigns**, and adapting the design of those campaigns (WHO is developing further guidance on conducting outbreak response in the context of COVID-19).

c) Continuously monitoring the effects of COVID-19 on immunisation services, by maintaining VPD surveillance and tracking individuals who have missed immunisation, to inform **strategies to provide missed doses and restore population level immunity** based on local disease epidemiology and transmission dynamics.

4.3 **Countries will need to develop immunisation recovery plans based on this guidance**, embedded into broader primary healthcare (PHC) recovery efforts. These plans will need to account for uncertainty around how the pandemic will evolve, with the possibility that COVID-19 transmission could be sustained until the deployment of a successful vaccine. These plans will require rapid identification of those who have been missed, localised risk assessments to identify populations without access to health services, and a range of tailored delivery strategies that take into account differing disease epidemiology and transmission dynamics. These strategies may have to be redesigned in light of COVID-19 transmission control measures, and may be more expensive than traditional approaches. They will need to be implemented by a health workforce and supply chains which will have already been stretched by the pandemic. Caregiver demand and trust will likely also have to be rebuilt deliberately over time. Ensuring the maintenance and recovery of immunisation programmes will be essential to the successful rollout of a COVID-19 vaccine, which will further stretch EPI programmes given the need to target new populations (e.g. Health Care Workers (HCWs), elderly).

4.4 The Alliance will need to consider how it can best support countries to maintain and restore immunisation services in this context. This will require Gavi to be flexible, creative and adaptive, willing to adjust its support modalities and processes, and to 'reimagine' immunisation in the post-COVID world. The Alliance will utilise all of its funding modalities, including HSIS (health system and immunisation strengthening), PEF TCA and PTE, to maintain and restore immunisation services as quickly as possible, catch-up missed children and support outbreak response where needed. The Secretariat is working with partners to ensure the necessary support is available, grounded in a number of core principles

a) **Vaccine preventable disease control remains Gavi's priority:** Disruption of immunisation puts millions of lives at risk and could rapidly undermine the progress that has been made over the past two decades. Gavi's focus will be on helping countries to mitigate the impact of COVID-19 on immunisation, respond rapidly to VPD oubreaks, and rebuild quickly to ensure high and equitable coverage.

b) **Equity as an organising principle:** Marginalised communities, especially those with large numbers of zero-dose and under-immunised children, will be most impacted by the pandemic and are at greatest risk of VPDs. They must be a priority in the response, (recognising that more children will become 'zero-dose' or under-immunised due to COVID-19). It will also be critical to understand the gender impacts of the pandemic and address gender-related barriers to access these children, such as challenges for women working in the informal economy who may find it even more difficult to access immunisation during clinic opening hours due to increased financial stress (see Doc 04 – Gender Policy Review).

c) **Exceptional situation requiring exceptional and differentiated responses:** COVID-19 will put an enormous strain on immunisation programmes and will require them to adapt their mode of operation, informed by WHO guidance. Given uncertainty in how the pandemic will evolve and the variability that is to be expected across countries, the Alliance will need to remain flexible and agile, further differentiate its portfolio management processes, and provide a range of differentiated support options to meet the needs of different countries. The Alliance will also need a strong learning agenda to track the impact of COVID-19, inform design of recovery strategies and evaluate the effectiveness of the Allaince's response.

d) **Integrated approach to recovery:** Plans to maintain and restore immunisation should be embedded in countries' overall COVID-19 recovery plans and maximise opportunities for integration (including between existing immunisation services, COVID-19 vaccination, and other PHC services). Recovery plans should coordinate restoration of service delivery with strong community engagement to rebuild trust and demand. These efforts can help shape a 'new normal' of integrated and equity-focused PHC delivery, including in communities that have

historically been reached by immunisation but not other routine health services. Gavi will work proactively with other donors and partners at country and global level to ensure its support is coordinated and to enable integration of services.

e) **Seize opportunities to rebuild better:** While COVID-19 is a global crisis, the response is also an opportunity to work differently and rebuild systems that are stronger, smarter, more equitable and more resilient to future health emergencies. The pandemic will force immunisation programmes to review many longstanding practices, including creating an urgent need for more integrated and equitable services, fostering new service delivery strategies (shifting away from large sessions at fixed sites which often do not meet community needs), and underscoring the importance of robust and integrated VPD surveillance, supply chains and community engagement. The COVID-19 crisis has also accelerated momentum to integrate polio and EPI programming at country, regional and global level. The Alliance will be deliberate in helping countries to identify and seize these opportunities and will have a higher risk appetite for testing innovative approaches in the context of the COVID response.

4.5 The Fragility, Emergencies, Refugees (FER) Policy provides an approach to offer flexibilities to countries facing emergencies. Given the global pandemic, the policy now has universal relevance and the Alliance will use these flexibilities to meet the varying needs of countries in maintaining and restoring immunisation services. This will include four types of flexibility:

a) **Additional financing:** Countries will need to adapt immunisation services during and after the pandemic as described above. This will likely result in higher costs (e.g. due to smaller session sizes, the need for enhanced Interpersonal Communication for Immunisation (IPC)). During the recovery phase, countries will also need to implement strategies to provide missed doses and restore population level immunity as determined by local disease epidemiology and transmission dynamics, which are likely to require significantly higher investment. In line with the principles of the FER policy, the Secretariat will make available a range of flexibilities where there is a justified need, including allowing countries to access additional HSS by frontloading their allocation for the 2021-2025 period to support recovery efforts, apply for higher operational costs for modified delivery strategies, and for additional vaccines to replace those that may have been wasted or expired during the pandemic.

b) **Increased flexibility of Gavi support:**. The Secretariat will provide flexibilities for countries to adapt how they programme Gavi support and also to enable more integrated planning of recovery efforts, building on some of the changes already planned through the Gavi 5.0 portfolio management workstream such as providing a single HSIS envelope. It would also include providing more flexibility in the use of Gavi funds to support needed adaptations to service delivery (e.g. funding for PPE

and other IPC measures, funding to support integration of immunisation services with other PHC interventions).

c) **Streamlined Gavi processes**: It is more important than ever to ensure that countries can access support rapidly and reliably, and to minimise the transaction costs of Gavi processes for countries. The Secretariat will develop a streamlined application, approval and disbursement process for recovery support, an expedited process for reprogramming of existing support and will consider flexibility around the duration, extension and rollover of grants where appropriate. The Secretariat has also introduced a simpler vaccine renewal process. Again, these approaches are being planned as part of the redesign of portfolio management processes for Gavi 5.0 and this would be an opportunity to accelerate and test them before broader roll-out.

d) **Accelerated engagement of new partners and innovative approaches:** Responding effectively to COVID-19 will require new ways of working, innovation and the support of a diverse range of actors. Civil society organisations (CSOs), in particular, will have a vital role in engaging communities to rebuild trust and demand, delivering services where there are gaps in government provision and overcoming gender-related barriers. Gavi will advocate for inclusion of CSOs in recovery planning and require countries to explain how CSOs were consulted and will be engaged in implementation as part of the application for Gavi support (and could expand direct contracting of CSOs, where this can help expedite implementation). The Secretariat will also explore framework agreements and direct funding for new global and regional partners who could contribute to recovery efforts, especially in fragile settings. Gavi will seek to accelerate scale-up of innovative approaches by rapidly identifying needs from countries, prioritising potential interventions and potentially providing catalytic funding for roll-out in line with the initial thinking on the Gavi 5.0 innovation approach to be brought to the Board in December.

4.6 The Secretariat is preparing to rapidly operationalise this approach by developing guidance for countries and adjusting its processes as required. The Secretariat will work with Ministries and partners to support the development of robust immunisation and PHC restoration plans as part of national COVID-19 recovery planning, and align Gavi support accordingly.

5. Pillar (c): Ensuring adequate cold chain for the COVID-19 response

5.1 **Several donors and partners have asked Gavi to consider how CCEOP could support the overall COVID-19 response,** focused on two elements:

a) **Addressing countries' overall cold chain needs:** The Alliance is already the largest funder of vaccine cold chain and, through the CCEOP platform, has a well-established mechanism to help countries assess their cold chain needs; finance, procure and deploy equipment at scale; and shape the market for CCE. The Alliance would likely be responsible for helping countries to expand their cold chain to distribute COVID-19

vaccines at scale. Gavi has been asked if it could broaden its role to support countries to plan and meet their overall cold chain needs: most acutely for COVID-19 commodities including diagnostics, therapeutics, and samples, and longer term for the full set of PHC commodities that require cold chain.

b) **Using CCEOP as a platform for health facility solarisation:** WHO, working with a major donor, has identified the CCEOP as the best-available platform to accelerate solarisation of health facilities, which can help build the resilience of health systems in responding to future emergencies. WHO believes that the planning, procurement and implementation modalities of CCEOP provide a robust platform for a more systematic approach to solarisation. The World Bank has also expressed an interest in exploring this. Channelling existing donor funding for solarisation through the CCEOP could accelerate impact, improve coordination and capture synergies between different funding. This aligns with the learning agenda which the Board recently approved to assess how Gavi's investment in solar refrigerators could better contribute to health facility solarisation.

5.2 Both these proposals would harness the comparative advantages of the CCEOP to contribute to broader health system strengthening. They would enable countries to rapidly assess and deploy the cold chain required to scale up the COVID-19 response, including new vaccines, diagnostics and therapeutics. In the longer term, having the Alliance take on this role would help drive a more integrated approach to primary healthcare and supply chains, allowing Ministries of Health to take an end-to-end view of their cold chain needs across programmes, and to align available donor funding through a single mechanism. This would help reduce transaction costs for countries, enable more integrated planning and improve the efficiency of investments by Gavi and other donors. It would also help coordinate product innovation through a more holistic market shaping approach covering the full cold chain (and potentially facility solarisation) market.

5.3 Initial discussions with the Board suggested a willingness for Gavi to explore this role. Gavi was also asked to take the lead work on cold chain as part of the Access to COVID-19 Tools (ACT) Accelerator workstream on health systems. The Secretariat and partners will work together over the coming months to analyse the needs on the demand and supply side, develop potential implementation models, and assess trade-offs including the incremental investment required and potential risks. The Secretariat will make surge capacity available from within its current budget to ensure this can be done on an expedited timeline.

6. Pillar (d): Responding to the fiscal impact of the pandemic on immunisation programmes

6.1 **According to the International Monetary Fund (IMF) and the World Bank, the negative economic impact of COVID-19 is expected to result in the worst peacetime recession since the Great Depression.**

To help shed light on the possible extent of this shock**,** three scenarios were developed based on IMF estimates:

a) **Low Impact**: This scenario, based on the IMF's latest base-case scenario[4] for the global economy, assumes a fall in global output of 3% in 2020 with growth turning positive again in 2021. Larger reductions are expected in developing countries outside of Asia in 2020 as the compounding effects of domestic lockdowns, lower commodity prices, and tighter financial conditions take hold. Despite the magnitude of this economic contraction, the IMF's Managing Director has publicly stated that this scenario may be too optimistic[5].

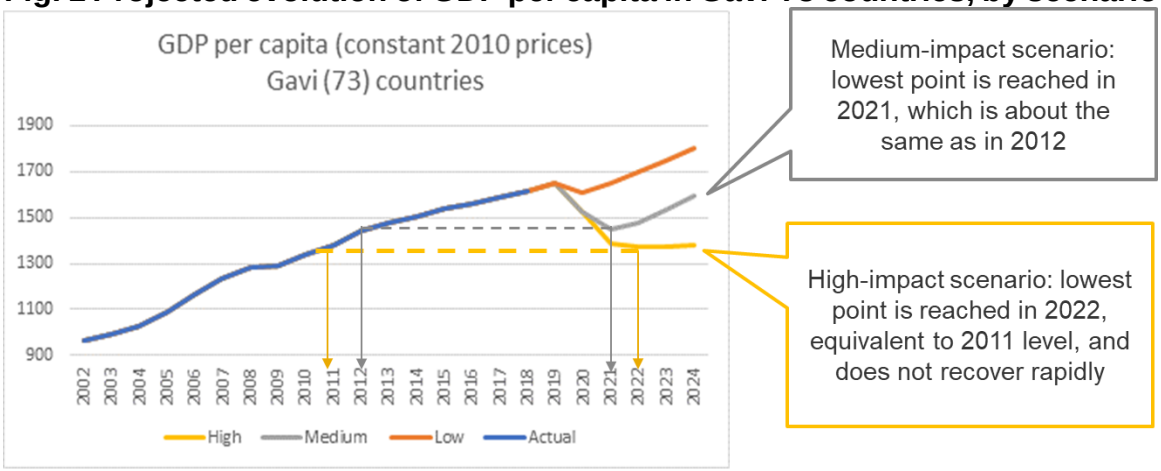
b) **Medium impact**: In this scenario[4], GDP in emerging markets would fall by an additional 2% in 2020 and by a further 5% in 2021.

c) **High impact**: In this scenario the pandemic would lead to even deeper and longer recessions. The expected impact on 2021 GDP levels is assumed to be twice as large as that envisaged in the medium-impact scenario and growth rates between 2022 and 2024 are reduced by 2.5 percentage points. Long-term growth rates are damaged by lower output potential so that the return of global GDP to pre-crisis levels is significantly delayed.

6.2 These scenarios highlight how large the potential economic consequences could be in Gavi countries. The crisis is likely to be particularly acute in countries which are highly indebted (for whom liquidity constraints may become solvency crises) and in those heavily dependent on commodities such as oil, which has seen an unprecedented price collapse in recent weeks. **In the medium- and high-impact scenarios, GDP levels are expected to regress on average to levels last seen a decade ago**.

[4] IMF, World Economic Outlook, April 2020.
[5] "IMF head: Dire economic forecasts may be too optimistic". 17 April 2020. Available online: https://www.bbc.com/news/business-52326853 Accessed 28 April 2020.

Fig. 1 Projected evolution of GDP per capita in Gavi-73 countries, by scenario



Note: average of country GDP levels (unweighted)

6.3 Implications for co-financing and transition and Gavi's response

6.4 **Under all scenarios the economic downturn poses great risks to Gavi-eligible countries' ability to co-finance**. Countries will struggle with severe and potentially prolonged economic distress, including revenue underperformance, emergency budget reallocations, tighter liquidity and a lack of access to hard currency. These constraints are likely to **limit the available fiscal space for immunisation** and other essential health programmes, resulting in a higher risk of co-financing defaults and therefore of stock-outs. **Transition trajectories will also be affected** as growth rates decelerate or turn negative. Many Gavi-supported countries will see their progression through the phases of support delayed, with several regressing compared to what was anticipated in the Gavi 5.0 Investment Case. However, even in the high impact scenario, only one or two countries among those that already transitioned are projected to regain eligibility, given that their Gross National Income (GNI) per capita levels are already considerably above Gavi's eligibility threshold.

6.5 As a result of these concerns, on its meeting on 11 May 2020 **the Gavi Board approved three flexibilities** in the application of Gavi's Eligibility & Transition and Co-financing policies to help countries to mitigate the fiscal impact of COVID-19. The Board agreed to **preserve countries' eligibility status and co-financing at 2020 levels for 2021** and to **grant the CEO the authority to waive 2020 co-financing obligations on a case-by-case basis upon request by a country[6].**

6.6 One additional implication not related to Eligibility & Transition, and Co-financing policies but which is magnified by the economic turmoil is the **repayment of improperly used HSIS funds.** Under the current practice, a country must follow a repayment schedule of HSIS funds that were improperly used by the country, otherwise HSIS support is stopped. This could result in HSIS funding stopping in the midst of the pandemic, further

[6] The flexibilities do not apply to India as it has an earmarked envelope of support. Therefore any flexibilities for India will be managed separately.

exacerbating immunisation financing and delivery challenges. The Secretariat will therefore accordingly extend repayment schedules.

6.6 **Implications for former Gavi-eligible countries[7] and Gavi's potential response**

6.7 In June 2019, **the Board recognised the risk of immunisation coverage backsliding in former Gavi-eligible countries** and, in response, approved the institutionalisation of PTE. They requested that the Secretariat develop and bring back to the Board for approval an approach, and requested a focus on political advocacy, technical assistance, innovation, market shaping and catalytic financial support to jumpstart vaccine introductions. The Board indicated to the Secretariat that when designing this approach for their review and approval, the envelope for engagement with former Gavi-eligible countries, along with that for select never Gavi-eligible countries, should account for no more than 3% of Gavi planned expenditure in the 2021-2025 period.

6.8 As described in paragraph 1.4, **the pandemic could significantly increase both the likelihood and potential extent of backsliding in some countries**. Recent reports from countries however suggest that, for the time being, most countries are managing to maintain the majority of routine immunisation services, including the procurement of vaccines introduced with Gavi support. This is a testament to the strong commitment from countries to immunisation and the sustainability of the Gavi model. Nevertheless, the Secretariat is aware of some specific cases that are extremely worrying. For example, one former Gavi-eligible country has already requested financial support to procure vaccines introduced with Gavi support. In another, more than 80% of health facilities are reporting interruptions in immunisation services, with 30% of outreach activities suspended. And another has suspended immunisation activities entirely - this is of particular concern as the wider region is affected by measles outbreaks and measles/MR campaigns in neighbouring countries have been put on hold during the pandemic. One former-Gavi eligible country is facing a stockout of pentavalent vaccine due to shipment delays caused by COVID-19.

6.9 **These examples indicate that in a few cases, gains made by former Gavi-eligible countries with Gavi support could be jeopardised by COVID-19.** For example, depending on the extent of the pandemic, it is possible that countries faced with severe budgetary constraints may even drop (officially or unofficially) previously introduced vaccines. Furthermore, these countries are likely to seriously struggle to reintroduce any dropped vaccines given that they no longer benefit from Gavi financial support. In countries significantly affected by the pandemic, the previously envisaged package is unlikely to be sufficient to mitigate the heightened risks to backsliding, and the interim measures approved by the Board will not benefit

[7] Former Gavi countries are self-financing countries within the original Gavi 73.

former Gavi-eligible countries. [8] Addressing these exceptional circumstances would require having the capacity to provide a timely and nimble reaction from Gavi.

6.10 **Supporting countries to meet these challenges will require additional resources, and different funding approaches may be explored.** Possible options include 'front-loading' a small share of the funding contemplated for MICs in the 2021-2025 period or exploring possible alternative sources with multilateral development banks in the context of their COVID-19 response efforts to support countries. Leveraging Gavi's own funding is likely to maximise Gavi's ability to respond flexibly and rapidly, however were this option to be deployed it should be applied judiciously on an exceptional basis to avoid creating perverse incentives and long-term negative effects on the sustainability of vaccines introduced with Gavi support. The PPC is requested to provide guidance on Gavi's role and approach to support former Gavi-eligible countries to mitigate the risks of reversing gains achieved with Gavi support following the COVID-19 outbreak, including on the extent and modalities of possible Gavi funding.

6.11 **Implications for never Gavi-eligible countries and Gavi's potential response**

6.12 The Secretariat also reviewed the potential impact of the pandemic on never Gavi-eligible countries, and in particular, whether any of them might gain Gavi eligibility based on scenarios discussed in paragraph 6.1. In spite of projected falls of up to 30% in GDP per capita in the high-impact scenario, no never Gavi-eligible countries are expected to gain eligibility as their GNI p.c. levels are significantly above the Gavi threshold.

6.13 Nevertheless, these countries will likely face significant challenges to their routine immunisation services, particularly those that already experience specific vulnerabilities, such as small island states. Therefore whilst the overall MICs approach will be paused until the acute phase of the pandemic has passed (see Doc 03, Annex E), Gavi may wish to consider specific approaches for these countries, such as technical assistance to support countries to adapt routine immunisation programmes to the new context. The Secretariat welcomes a steer from the PPC on the benefits and risks of engaging with these countries.

Section C: Actions requested of the PPC

The Gavi Alliance Programme and Policy Committee is requested to:

a) **Provide guidance** on whether Gavi's overall approach to maintaining and restoring immunisation programmes in the context of COVID-19 are appropriate;

[8] Note that Gavi's potential response to the impact of COVID-19 in former Gavi-eligible countries was not presented to the Board on the 11 May 2020.

b) **Provide guidance** on how Gavi should consider using the CCEOP to support countries respond to COVID-19 including through ensuring adequate capacity for all commodities and accelerating solarisation of health facilities, recognising that this will require mobilisation of supplementary funding; and

c) **Provide guidance** on Gavi's role and approach to support former Gavi-eligible countries to mitigate a reduction in coverage rates of vaccines introduced with Gavi support following the COVID-19 outbreak, including on the extent and modalities of possible Gavi funding.

Annexes

Annex A: Risk implication and mitigation

Annex A: Risk implication and mitigation

- As discussed in section 1, COVID-19 creates unprecedented risks to the economies, health systems and immunisation programmes of Gavi-supported countries. A failure to respond adequately risks undermining the progress that has been made in strengthening immunisation coverage, equity, financing and programmes in current and former Gavi-eligible countries. If these countries see a sustained backsliding in immunisation coverage, or even drop a vaccine, this will pose serious questions about the sustainability of the Gavi model. The financial cost for countries to address gaps in coverage or to reintroduce vaccines will be significant. The approach described in this paper should help mitigate those risks.

- There is a risk that if many countries are granted flexibilities, this could make the exceptions in the Fragility, Emergencies, Refugees (FER) policy common across the portfolio and thereby limit implementation of Gavi's standard policies. There is also a risk that the Alliance will have to make decisions on adjusting support to countries rapidly and with inadequate information, which could result in suboptimal allocation of resources or fiduciary risk. To mitigate this, the Secretariat will develop a clear approach to determine when and how flexibilities are granted and new HSIS funding applications will be subject to external review to ensure that the requested flexibilities are justified and proportionate. The Secretariat will systematically track all flexibilities and develop a clear approach to transition countries to updated 'standard' policies post-COVID.

- There is a risk that the additional flexibilities will result in accelerated expenditure from Gavi's health system and immunisation strengthening (HSIS) and Partners' Engagement Framework (PEF) envelopes over the next 1-2 years. While this will help countries to respond to the pandemic, it would also mean that additional funding would be required to ensure countries continue to have access to adequate support in the latter years of Gavi 5.0. To mitigate this risk, the Secretariat will continue to monitor the financial impact of the flexibilities granted and report to the Audit and Finance Committee (AFC), Programme and Policy Committee (PPC) and Board.

- There is a risk that Gavi's support is inadequate to mitigate the impact of COVID-19 on countries' immunisation programmes and this could result in a resurgence of Vaccine Preventable Disease (VPD) outbreaks and mortality. To mitigate this risk, the Alliance will engage closely with other development partners to ensure a coordinated approach to help countries maintain and restore immunisation programmes as part of a Primary Health Care (PHC) response. The Alliance will continue to monitor the performance of immunisation programmes and report to the Board if further interventions are needed.

- There is a risk that by taking on a broader role in supporting cold chain beyond immunisation, Alliance staff and resources will be diverted from ensuring adequate cold chain for immunisation programmes. To mitigate this, the Alliance will clearly identify the additional financial and resources that it would require to deliver on a broader cold chain mandate for discussion with the PPC

and Board.

- There is a risk that the Secretariat and Alliance partners may have inadequate capacity to manage the COVID-19 response, while also maintaining existing programmes and preparing for implementation of Gavi 5.0. To mitigate this risk, the Alliance will seek to coordinate support for to COVID-19 recovery with implementation of Gavi 5.0, and will closely monitor whether existing resources are adequate or surge capacity is required.

Report to the Programme and Policy Committee

26-27 May 2020

SUBJECT:	**COVID-19 PANDEMIC: VACCINE DEVELOPMENT, ACCESS AND DELIVERY**
Agenda item:	06
Category:	For Guidance

Section A: Summary

Context

- In the context of the broader COVID-19 response, the Gavi Board has expressed its support for Gavi to partner with others to make affordable vaccines available and accessible to those most in need and planning for deployment of vaccine so they can be delivered as soon as they are available. COVID-19 vaccine development is progressing rapidly and Gavi is engaging with stakeholders to support efforts across vaccine development, access and delivery.

Questions this paper addresses

- How is Gavi working together with other stakeholders on COVID-19 vaccines?
- What is the emerging approach to accelerate the availability of COVID-19 vaccines?

Conclusions

- The Access to COVID-19 Tools (ACT) Accelerator has been established as a global and time-limited collaboration mechanism for COVID-19 diagnostics, therapeutics and vaccines. Gavi is co-leading the ACT Accelerator Vaccine Task Force alongside the Coalition for Epidemic Preparedness Innovations (CEPI). Gavi is leading a workstream on vaccine procurement and delivery at-scale, while CEPI is leading on development and manufacturing and WHO is leading on policy and allocation. All three partners have committed to working together closely to support a seamless effort toward the rapid development and equitable delivery of COVID-19 vaccines.
- Toward this end, the Gavi Secretariat has convened stakeholders to design an Advance Market Commitment (AMC) for COVID-19 vaccines, building on the Alliance's innovative finance experience. The AMC would accelerate the availability of suitable and affordable vaccines through a combination of financial incentives and direct support for manufacturing capacity expansion. Recognising the critical need for global coordination in ensuring the most suitable vaccines are produced at-scale and available to the most vulnerable and high-risk, wherever they are, the AMC would be an access

mechanism available for all countries but could also focus on providing financing for vaccines for lower income countries. The Secretariat is collaborating closely with partners and other stakeholders to advance the work to accelerate the availability of COVID-19 vaccines and will provide a further update to the Programme and Policy Committee (PPC) at its meeting on 26-27 May 2020 for input.

Section B: Content

1. Context

1.1 Countries are currently relying on non-pharmaceutical and behavioural approaches such as hygiene and physical distancing to contain COVID-19. While these can be effective, they are unlikely to be sustainable and come at great cost. Ultimately, **safe and effective vaccines will be critical to protecting the most vulnerable, stopping transmission and preventing resurgence**. Vaccination in countries with weaker health systems or at greater risk of undetected ongoing transmission will be critical to the global effort to end the pandemic.

1.2 **Vaccine development is advancing at an unprecedented pace**. WHO reports that more than 100 candidates are in early stage development, with at least eight having entered clinical evaluation, including Phase II studies[1]. Making vaccines available for broad use in record time will require innovative approaches to compress the standard development timelines as well as immediate planning and 'at risk' investments for downstream steps like manufacturing and delivery.

1.3 New models of coordination will also be necessary and key stakeholders are already coming together. There was the **recent launch of the time-limited Access to COVID-19 Tools (ACT) Accelerator**, hosted by WHO and based on a collaboration of global health actors[2] to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines[3].

1.4 **Gavi is co-leading the Vaccine Task Force within the ACT Accelerator together with the Coalition for Epidemic Preparedness Innovations (CEPI).** CEPI and Gavi's joint leadership on COVID-19 vaccines capitalises on both organisations' strengths and comparative expertise, thereby ensuring effective linkages from upstream development to downstream access and delivery. This builds on the longstanding relationship between the organisations, which has included regular information sharing, strategic discussions and Gavi's participation in CEPI's Joint Coordination Group.

[1] Draft landscape of COVID-19 candidate vaccines – 11 May 2020 https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines
[2] The initial group of global health actors include BMGF, CEPI, FIND, Gavi, Global Fund, UNITAID, Wellcome Trust, WHO and World Bank
[3] ACT Accelerator Call to Action: https://www.who.int/who-documents-detail/access-to-covid-19-tools-(act)-accelerator

1.5 Coordination within the **Vaccine Task Force will be facilitated through a regular COVAX Coordination Meeting**, co-chaired by the board chairs of CEPI and Gavi. Its role is to facilitate coordination across workstreams, alignment among partners and to bridge the work of the Vaccine Task Force with the broader ACT Accelerator initiative. Given the central role of industry, a representative from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and Developing Countries Vaccine Manufacturers Network (DCVMN) companies will also be included. This coordination body is not a legal entity and formal decision-making including decisions on funding stays within all existing bodies, including CEPI and Gavi. Through existing Alliance mechanisms Gavi will also seek broad stakeholder input into its COVID-19 vaccines work. For example, Gavi is leveraging its Civil Society Organisation (CSO) Steering Committee to help develop a mechanism to consult CSO representatives and policy experts on its work on equitable access to COVID-19 vaccines.

1.6 The **Vaccine Task Force will focus on three workstreams** to deliver on the goal of controlling widespread transmission of COVID-19 through the development and deployment of safe and efficacious vaccines, appropriate for global use:

a) **Development and Manufacturing Workstream (led by CEPI)**: selection of and investment in research and development for a set of some of the most promising candidates and support for addressing early manufacturing bottlenecks.

b) **Procurement and Delivery At-Scale Workstream (led by Gavi)**: design and implementation of an Advance Market Commitment (AMC) for COVID-19 vaccines as a mechanism to incentivise/finance manufacturing scale-up in order to secure sufficient, timely and affordable vaccine supply (further described in section 3) and activities to prepare and support lower income countries to deliver vaccines as soon as they are available.

c) **Allocation and Policy Workstream (led by WHO)**: guidance and recommendations on equitable allocation of vaccines based on public health criteria and other key topics (e.g. target product profiles, vaccination strategy, regulatory, ethics, etc.).

1.7 These workstreams are interdependent and CEPI, WHO and Gavi, alongside other stakeholders, will collaborate closely across them. The following sections provide an update on Gavi's engagement in vaccine development (section 2) and vaccine access (section 3). An initial view to costs of vaccine manufacturing, procurement and delivery is provided in section 4.

2. Vaccine development: prioritising candidates with a view to access and delivery

2.1 **Issue**: As COVID-19 vaccine development proceeds along rapidly accelerated timelines, key decisions which would usually be taken

sequentially will need to be taken in parallel and on the basis of more limited information. It will therefore be **vital to establish strong connections between progress in product development and planning for future vaccine deployment**. Within the Vaccine Task Force, an Independent Product Group will be established. This group of independent experts will continuously prioritise the global portfolio of vaccine candidates to inform investment decisions on development and manufacturing capacity. Although Gavi is not a research and development (R&D) actor, it can reflect considerations related to downstream vaccine access and delivery/use for consideration by the Independent Product Group early in development. For COVID-19 vaccines this perspective is likely to be critical in terms of ensuring that vaccines that are developed support access and delivery goals and meet programmatic needs, which is the emphasis of the Procurement and Delivery At-Scale Workstream which Gavi leads.

2.2 **A preliminary assessment of the COVID-19 vaccine pipeline illustrates how vaccine characteristics have implications for downstream access and delivery and the importance of applying this lens to prioritisation.** The pipeline of vaccine candidates is diverse, with both traditional technology platforms (e.g. viral vector, protein based, live attenuated and inactivated virus) and novel platforms (e.g. DNA and RNA) being utilised. Nucleic acid-based technologies (~25% of pipeline) may support rapid progress to Phase 1 trials given the speed at which candidate antigens can be developed and tested. However, this advantage in early stage development may be offset by longer regulatory timelines as there is less experience with these technology platforms. In addition, more support may be required to scale-up production capacity and depending on the product presentation and route of administration there may be implications for delivery (e.g. if electroporation is required). Conversely, more established technologies (such as protein-based, which represent ~33% of the pipeline) may require more time to reach clinical trials but can bring advantages in terms of having a wider pool of existing manufacturing capacity that can be deployed to produce at large scale or programmatic advantages (e.g. reduced need for enhanced pharmacovigilance). These generic examples highlight potential implications, noting there is wide variation in characteristics at the individual vaccine candidate level that would need to be assessed.

2.3 **Approach**: Given the number of candidates in development, **structured processes will be used to prioritise candidates as they move through the development process**. Prioritisation will build on criteria included in the WHO Target Product Profile such as safety and efficacy, standardised assays and animal models, as well as factors related to access and delivery (e.g. manufacturing feasibility and scalability, storage requirements, route of administration, etc.). Gavi can support the development of the prioritisation approach for COVID-19 vaccine candidates driven by the Independent Product Group by **drawing from its experience supporting access to and delivery of vaccines, as well as potentially leveraging established Alliance prioritisation methodologies** for vaccine

investments and technologies. This includes the Vaccine Investment Strategy (VIS) and Vaccine Innovation Prioritisation Strategy (VIPS).

2.4 In addition to supporting candidate prioritisation, Gavi can also leverage the International Finance Facility for Immunisation (IFFIm) to accelerate the availability of donor financing toward development of priority candidates that meet the needs of developing countries. At its 11 May 2020 meeting, the **Gavi Board approved the use of IFFIm to frontload Norway's funding to CEPI** for COVID-19 vaccine development, as well as an **assessment framework to respond to future donor requests** to support vaccine development, manufacturing, procurement and delivery.

3. Vaccine access: COVID-19 AMC

3.1 **Issue**: As vaccines are being developed, it is critical that there is sufficient, timely and suitable COVID-19 vaccine supply and an approach to ensure equitable access based on public health need and that vaccines do not simply go to those countries with the most resources. A number of unique challenges related to COVID-19 vaccines will need to be considered:

a) On the **supply-side**, the global vaccine requirements are likely to be substantial, in the billions of doses. This necessitates working with a number of different vaccine suppliers. Many developers do not have ready access to manufacturing capacity at scale and some vaccine candidates are based on novel technology platforms that will bring new manufacturing requirements. Thus, it will be necessary to draw from all available sources of manufacturing capacity while considering implications for production of other vaccines, which adds complexity. A mapping exercise is underway using the knowledge and expertise of many partners across the Alliance. Common inputs (e.g. raw materials) may also be limiting. As vaccine supply is needed on rapid timelines, ‘at risk’ investments will be required and tolerance that some of these investments may not be successful or could be redundant. Finally, there will also be significant competition for supply, with potential export controls or other efforts to control production.

b) On the **demand-side**, forecasting will be challenging due to evolving understanding of epidemiology and immunology and uncertainties around vaccine characteristics and related vaccination strategy and programme design. Countries will have competing priorities for expenditure, especially for lower income countries that have limited fiscal space. This is in the context of potential reduced perception of risk over time. The COVID-19 pandemic will likely further limit countries' absorptive capacity and weaken health systems, which may constrain their ability to meet vaccination needs (e.g. cold chain capacity; healthcare worker capacity; delivery platforms to reach new target populations; regulatory processes). There may also be potential low vaccine acceptability in some communities.

3.2 In the face of these challenges, a **globally coordinated solution is required**. It is **not possible to predict which vaccine candidates will end**

up having the best characteristics, and those that do emerge should be scaled and used as widely as possible. If individual countries or groups of countries pursue siloed vaccine strategies, whereby each invests to scale-up specific vaccines, resources will not be optimally utilised and many countries will be left without access to supply of the best candidates that emerge from R&D.

3.3 **Approach**: With its focus on equitable access to vaccines, the Gavi Alliance is uniquely positioned to address this global challenge. Drawing from the Alliance's individual and collective experience with market shaping and innovative finance mechanisms, a **COVID-19 Advance Market Commitment (AMC) is proposed** to accelerate the availability of suitable and affordable vaccines. It would **utilise a combination of tools**. This includes **'push' mechanisms** whereby direct financial support is provided to accelerate manufacturing expansion, following the example of the Meningitis Vaccine Project. In addition, **'pull' mechanisms** should also be utilised whereby committed donor funding provides assurance of future demand and financing and serves to incentivise manufacturers to invest in development and manufacturing. Examples of 'pull' mechanisms are the AMC for pneumococcal vaccines and the Advance Purchase Commitment (APC) for Ebola.

3.4 The COVID-19 AMC would **aim for as wide a participation of countries as possible**, building on but not limited to regional blocs like the Pan American Health Organization (PAHO) or the European Commission (EC), to reach a globally coordinated solution on equitable access. The participation of a large number of countries in the Global Coronavirus Response pledging event hosted by the EC is a hopeful sign as most of the leaders highlighted the importance of equitable access and may form a group to work on this. However, ***access* to vaccine supply as facilitated by the AMC mechanism would be separate from Gavi *financing* for vaccine procurement and delivery, which would remain focused on lower income countries**.

3.5 With regards to **Gavi *financing* for vaccine procurement and delivery**, so far Gavi has been defining its scope of supported countries as the 'Gavi 73'.[4] However, this definition is based on historical assessment of eligibility that utilised GNI per capita (p.c.) levels from 10 years ago or more. Hence, the 'Gavi 73' includes upper middle-income countries (UMICs) that are significantly wealthier than some countries that have never been eligible for Gavi support. For COVID-19 vaccines, Gavi could **evolve the scope of countries for financial support to include all low-income countries (LICs) and lower middle-income countries (LMICs)**.[5] This definition would include 78 countries, a small increase from the current list and comprising ~50% of the global population.[6] This would have several benefits: it focuses Gavi support on the poorest countries in the world today,

[4] Gavi 73 includes Gavi-eligible and post-transition countries
[5] Includes all countries with GNI p.c. up to ~US$ 4,000, including West Bank and Gaza.
[6] Six upper middle-income countries currently included in the Gavi 73 would not be included in the 78 countries (Armenia, Azerbaijan, Cuba, Georgia, Guyana and Sri Lanka)

it utilises a recognised definition (World Bank's LIC and LMIC income categories) instead of a Gavi-specific threshold, and it is simple and transparent. Gavi might want to further consider whether small island states should be included in scope for financial support[7]. The specific levels of support for vaccine procurement and delivery would be further defined.

3.6 **For other countries beyond LICs and LMICs, the focus would be on providing *access* through participation in the COVID-19 AMC**. The specific approach for countries to pool their resources toward push and pull funding, as well as procurement mechanisms, would need to be further defined. For some upper-middle income countries, Gavi could consider providing limited support such as for technical assistance to plan for vaccine introduction. The scope of UMICs and parameters of engagement would need to be further considered.

3.7 At the Gavi Board meeting on 11 May 2020, Board members expressed their support for Gavi and partners' approach to the development of a COVID-19 AMC mechanism with the ambition of global participation. The **Secretariat has convened a working group to design a COVID-19 AMC**, which includes the World Bank, CEPI, the Bill and Melinda Gates Foundation (BMGF), UNICEF and WHO and **consultation with industry, donors, civil society, developing countries and other stakeholders and experts**. This work sits within the Vaccine Procurement and Delivery-at-Scale Workstream of the ACT Accelerator. An update on emerging design parameters of the COVID-19 AMC will be shared at the PPC meeting.

4. Indicative vaccination scenario and cost estimates

4.1 WHO and SAGE will define the vaccination strategy for COVID-19 vaccines based on disease epidemiology, vaccine characteristics and other considerations. While these recommendations will only be available over time, the Secretariat has begun discussing with partners potential **interim COVID-19 vaccination scenarios to inform planning assumptions and early forecasts** of dose and funding requirements. An illustrative vaccination scenario could entail **first protecting the most vulnerable: healthcare workers initially along with stopping any uncontrolled outbreaks that are out of control, via a stockpile.** This could be followed by older adults (over 65 years old) and those with known medical risk factors. Vaccination of the productive workforce could be targeted to mitigate societal and economic disruption. Additionally, depending on evolving disease epidemiology and immunity, other groups could also be immunised to contain transmission, such as younger populations.

4.2 Regarding costs, it is extremely difficult to predict given vaccines are still in development and vaccination recommendations are yet to be made. Acknowledging significant uncertainties, Gavi has developed indicative cost estimates with BMGF, CEPI and WHO and with input from other stakeholders. **An initial investment of US$ 2 billion from 2020-2022 is**

[7] The inclusion of small island sates would align with the World Bank's criteria for international development assistance (IDA) lending.

required to support vaccination to protect the most vulnerable and prepare for vaccinating additional high priority groups.[8] Substantial additional funding would be required for vaccination of other much larger target populations. The Secretariat will continue to refine cost estimates together with partners as more information becomes available.

Section C: Actions requested of the PPC

Recognising the fast pace of the work to accelerate availability of COVID-19 vaccines, the Gavi Alliance Programme and Policy Committee is requested to **provide input** on any key updates that will be shared with the PPC during the discussion on this item.

Annexes

Annex A: Implications/Anticipated impact

[8] These estimates are inclusive of costs to support manufacturing, procurement and delivery of vaccine for LICs and LMICs, and manufacturing support costs to enable access to vaccine and technical assistance for some UMICs. It covers vaccination of healthcare workers and a stockpile for emergency response, as well as manufacturing support to secure supply for potential vaccination of additional priority groups. Costs associated with vaccine procurement and delivery for additional priority groups would be incremental. These costs do not include R&D funding requirements.

Annex A: **Risk implication and mitigation**

- **Risks of inaction**

- Gavi brings a wealth of experience in market shaping and utilising innovative finance tools to reach low- and middle-income countries (LICs and MICs). Without Gavi's close engagement within the Access to COVID-19 Tools (ACT) Accelerator and deployment of an instrument such as an Advance Market Commitment (AMC) with the ambition to secure global vaccine access, there is the **risk that when the COVID-19 vaccines becomes available, countries with the most resources will monopolise access**, leaving lower income countries vulnerable to both the direct (health) and indirect (economic, societal) impacts of COVID-19.

- Similarly, if Gavi does not provide input into the vaccine product development process within the ACT Accelerator Vaccine Task Force to establish strong linkages with the future deployment of vaccines in lower income countries, there is a **risk that down-selected COVID-19 vaccine candidates are not optimised for the preferences/needs of lower income countries** and cannot be successfully delivered in sufficient quantities to those in need with an accelerated timeline.

- **Investment risks**

- Given rapid timelines required for vaccine production at-scale, this necessitates "at risk" investments in securing inputs for vaccines and expanding manufacturing capacity, and tolerance that some investments may not ultimately be successful or could be redundant. This risk can be mitigated by setting up arrangements with manufacturers whereby available production capacity can be flexibly reallocated to successful vaccine candidates, where technically feasible. The uncertainties also require an agile approach within the COVID-19 AMC where there can be adaptation of the deployment of various push and pull elements as new information becomes available.

- **Supply risks**

- There is high competition for supply of vaccine inputs (e.g. raw materials) and potential export controls or other efforts to control availability of inputs and finished vaccines. The Secretariat is working with partners, in particular the Coalition for Epidemic Preparedness Innovations (CEPI), to identify supply chain challenges through early engagement with manufacturers and identify potential approaches to address this through the AMC. With regards to export controls, this can be mitigated through broader participation of countries globally in the COVID-19 AMC mechanism and through advocacy at political level for global coordination.

- **Demand risks**

- Current demand forecasting includes uncertainty based on limited availability of data, evolving understanding of epidemiology, immunology and vaccine characteristics and ultimately, the resultant vaccination strategy and programme design. This may result in manufacturers lacking confidence in

making necessary investments to expand production capacity. The AMC's 'pull' funding mechanism aims to address this risk by providing demand assurances to incentivise manufacturer investments.

- **Delivery and administration of the vaccines** to large groups of population **will require infrastructure and systems which may not exist**, as many of the potential target populations are beyond the scope of countries' EPI programmes. This can be mitigated through early Alliance partner engagement with countries to prepare systems and plan for delivery as part of broader COVID-19 recovery efforts.

- Broadly, there is a risk of the anti-vaccination movement capitalising on the COVID-19 vaccine efforts to sow discord and break down public trust in vaccines by spreading misinformation. To mitigate this risk, the Alliance will need to ensure that it engages with countries with compelling science-based information to maintain demand.

- **Alliance risks**

- Working in a complex, fast-paced environment means new ways of coordination across partners are required and there is a **risk of poor stakeholder management leading to suboptimal results.** The ACT Accelerator's Vaccine Task Force is designed to enhance coordination of key stakeholders including WHO, CEPI and Gavi, in order to facilitate an aligned effort regarding COVID-19 vaccine development to deployment.

Report to the Programme and Policy Committee

26-27 May 2020

SUBJECT:	**GAVI 5.0: MEASUREMENT FRAMEWORK/STRATEGY INDICATORS**
Agenda item:	07
Category:	For Guidance

Section A: Executive Summary

- As follow-up to the discussion at the October 2019 meeting of the Programme and Policy Committee (PPC)[1], the purpose of this report is to update the PPC on development of the Gavi 5.0 measurement framework, and to request guidance on proposed mission and strategy indicators. An Alliance Technical Working Group (TWG) is advising on development of the framework and ensuring alignment with Immunization Agenda 2030 (IA2030). An iterative process with broad consultations has been undertaken to vet the identified indicators which included consultations with countries, partners, Civil Society Organisations (CSOs) and other Alliance stakeholders at the Gavi 5.0 Countries and Partners Retreat.

Questions this paper addresses

- How is the 5.0 measurement framework being developed?
- Which mission and strategy indicators are currently suggested for 5.0 strategy monitoring, and which require further development with PPC guidance?
- How does the COVID-19 pandemic affect timelines for finalising the 5.0 measurement framework?

The COVID-19 pandemic will likely delay the finalisation of the 5.0 measurement framework into 2021, largely due to the challenge of setting targets in the context of disruptions to immunisation services in 2020.

Section B: Gavi 5.0: Measurement Framework/Strategy Indicators

1. Facts and Data

1.1 As described in the Gavi 5.0 Measurement Framework paper presented to the PPC in October 2019, the Gavi 5.0 Monitoring and Evaluation (M&E) System will contain three components: Strategy Performance Monitoring, Strategy Implementation Monitoring, and Learning & Evaluation. The purpose of this paper is to provide more details on Strategy Performance Monitoring, which is comprised of the mission and strategy indicators

[1] Doc 06 to the October 2019 PPC meeting

requiring Board approval. These indicators will be used for monitoring Gavi 5.0 strategy performance. They are intended to reflect Gavi's contribution to strategic goals and objectives, with shared accountability across the Alliance.

1.2 The Gavi 5.0 strategy framework "one-pager" (Annex A), approved by the Board in June 2019, includes a list of mission indicators along with four Strategy Goals, each with three objectives.

1.3 The proposed mission and strategy indicators measure key portfolio-level impacts, outcomes or outputs on an annual basis. They represent a subset of the metrics to be used for monitoring progress along Gavi's result chain. Monitoring of specific investments (inputs) and aspects of business performance (processes) will be through indicators within the Strategy Implementation Monitoring component of the Gavi 5.0 M&E system.

1.4 The following principles are used to guide the development of Strategy Performance Monitoring (details provided in Doc 06 to the October 2019 PPC meeting):

a) Measurement focus on the causal pathway to achieving Gavi 5.0 strategic goals.

b) Measurement for shared accountability that facilitates performance management, with an emphasis on informative, timely data.

c) Alliance ownership of strategy goals,objectives, indicators and targets.

1.5 The process of indicator development emphasised the importance of ensuring indicators are connected to the expected strategies, policies, programmes and investments of the Gavi Alliance in 2021-2025. In practice, the Monitoring & Evaluation (M&E) team worked with Secretariat programme teams, in consultation with respective Alliance stakeholders and the Secretariat's Executive Office, to think through theories of change and results chains identifying the key outputs or outcomes that must be measured to understand progress towards the Strategy Goals.

1.6 Consultations during the Gavi 5.0 Countries and Partners retreat in Geneva on 25-27 February 2020 provided useful guidance on potential indicators leading to further refinement.

1.7 A Technical Working Group (TWG) of M&E specialists, including representatives from core Alliance partners, assessed potential indicators and has advised the Secretariat during this process. There is considerable overlap in membership between this TWG and the IA 2030 M&E Taskforce, to help ensure alignment between the Gavi 5.0 and IA2030 M&E frameworks.

1.8 This paper describes current proposals for a subset of Gavi 5.0 mission and strategy indicators for PPC guidance. These are summarised in a dashboard in Annex B and tables in Annex C, with technical details provided in Appendix 1. Strategy Goal 3 (Improve sustainability of immunisation

programmes) indicators are pending decisions on the Funding Policy Review and Gavi's approach to engagement with former and never-eligible Middle-Income Countries (see Doc 03).

2. COVID-19 and the Gavi 5.0 measurement framework

2.1 The onset of the COVID-19 pandemic resulted in less consultation on Gavi 5.0 indicator development than originally planned.

2.2 As progress-to-date largely focused on defining the indicators core to Gavi's mission, most of the indicators developed likely remain relevant for measuring Gavi 5.0 performance.

2.3 However, additional indicators may be required to monitor the effectiveness of Gavi's response to COVID-19 at the request of the Gavi Board.

2.4 Potential delays in setting targets for Gavi 5.0 strategy indicators are anticipated due to COVID-19 disruptions. If disruptions to immunisation services are significant, selection of appropriate baseline values (e.g. for 2020) to use for 2025 targets will be challenging this year, particularly as data for quantifying the full effects on immunisation coverage may be unavailable until July 2021.

2.5 It is possible that finalising certain strategy indicators could be delayed into 2021 where policy development is affected by COVID-19, such as within Strategy Goal 3 and the Funding Policy Review (see Doc 03).

3. Mission Indicators

3.1 As outlined in the Gavi 5.0 strategy framework, Gavi's vision is to "leave no one behind with immunisation" and to "save lives and protect people's health by increasing coverage and equitable use of vaccines". The mission indicators are intended to measure progress on these overall goals, demonstrate Gavi's global impact and enable advocacy. Some are tied to commitments in the Gavi 2021-2025 Investment Opportunity. The draft list of mission indicators is as follows:

a) Child mortality reduction as measured by the under-five mortality rate

b) Lives saved: Number of future deaths averted as a result of Gavi-supported vaccines

c) Future disability adjusted life years (DALYs) averted as a result of Gavi-supported vaccines

d) Equity indicator, as measured by an indicator of zero-dose children

e) Unique children immunised through routine immunisation with Gavi support

f) People (male & female) vaccinated with Gavi support across the lifecourse: Total vaccinations through routine immunisation over the life course with Gavi support

g) People (male & female) vaccinated with Gavi support against outbreak prone diseases: Total vaccinations against outbreak-prone diseases with Gavi support

h) Economic benefits unlocked, as measured by the cost-of-illness averted

3.2 Four of these mission indicators: *under-five mortality rate, future deaths and DALYs averted, and economic benefits unlocked*, are well-established impact indicators explicitly named in the Gavi 5.0 strategy framework and operationalised consistent with previous definitions (i.e. in Gavi 4.0). These are recommended to be maintained as mission level indicators.

3.3 One additional mission indicator is being recommended,*"unique children immunised with Gavi support"*, defined as the number of children immunised with the last recommended dose of at least one Gavi-supported vaccine delivered through routine systems. The rationale for its inclusion is that it is a long-standing Gavi mission indicator frequently used for reporting and accountability, and features prominently in the 2021-2025 Investment Opportunity, with a commitment to reaching another 300 million children.

3.4 Three mission-level indicators in the Gavi 5.0 strategy framework require **more discussion**.

a) *"Equity indicator":* we propose to use an indicator of the *number of zero-dose children* to reflect Gavi's ambitions on equity. There is agreement within the TWG and for IA2030 that "zero-dose" will be defined as children lacking the first dose of diphtheria, tetanus, and pertussis-(DTP-) containing vaccine, as a simple measure of the reach of routine immunisation services. The TWG is still discussing technical issues associated with how this indicator is operationalised, e.g. whether to focus on reductions in zero-dose or increases in the number of zero-dose reached, and whether relative or absolute targets would be set. The aim of these discussions is to ensure reporting which is fit-for-purpose for both Gavi strategy and IA2030.

b) *"People (male & female) vaccinated with Gavi support across the life course"*: As no individual is vaccinated across their life course in one year (with human papillomavirus (HPV), it takes a decade or more), measures of this are complicated to define and interpret. To the extent this indicator was intended to reflect the breadth of routine immunisations and disease protection made possible with Gavi support across the life course, one indicator option is the total number of (completed) vaccinations conducted through routine immunisation across the life course with Gavi support. **The TWG has questioned whether this indicator is needed at mission level**.

c) *"People (male & female) vaccinated with Gavi support against outbreak-prone diseases":* Gavi supports vaccination against outbreak-prone diseases through routine immunisation, preventive campaigns, and outbreak-response. Capturing the extent of this activity is possible through an indicator that measures the total number of Gavi-supported

vaccinations against outbreak-prone diseases (Meningitis A, Yellow fever vaccine (YFV), measles containing vaccine (MCV), oral cholera vaccine (OCV)).[2] However, this indicator is recommended for monitoring without establishing a target, since, while clearly needed in some contexts, increasing the number vaccinated through preventive campaigns and outbreak response (as opposed to routine immunisation) is not necessarily indicative of improved performance. **The TWG has questioned whether this indicator is needed at mission level**.

3.5 Although not listed as a mission indicator on the Gavi 5.0 strategy framework (Annex A), several members of the TWG have signalled the importance of **moving up the four Sustainable Development Goal** (**SDG) 3.b.1 indicators on vaccine coverage to mission-level** (Referring to Section 4.3), to signal alignment to the Sustainable Development Goals. Currently, these indicators are included within Strategic Goal 1 as they are drivers of breath of protection. Without other changes, adding these indicators would expand the number of indicators at mission-level to 12, more than doubling the number of mission-level indicators from Gavi 4.0. Additionally, several stakeholders at the Gavi 5.0 Countries & Partners retreat, as well as TWG members, suggest reducing the total number of mission indicators to facilitate concise messaging about Gavi's mission.

4. Strategy Goal 1 – Introduce and scale up vaccines

4.1 Under Strategy Goal 1 (SG1), the Alliance aims to continue supporting introductions and scale-up of coverage of high-impact vaccines in eligible countries. Specific objectives include (a) supporting countries to identify and prioritise those vaccines that are most appropriate for their local context, capacity and disease burden while also taking into account long-term programmatic and financial sustainability, (b) supporting countries to introduce and scale-up coverage of vaccines for endemic and epidemic diseases, and (c) enhancing outbreak response through availability and strategic allocation of vaccine stockpiles.

4.2 Indicators proposed under SG1 aim to measure progress against these objectives. The draft indicators include three primary outcome indicators:

a) Breadth of protection: Average coverage across all recommended Gavi-supported vaccines in Gavi countries

b) Measles campaign reach: Measure of improved ability of Gavi-supported preventive campaigns to reach children previously unvaccinated for measles

c) Timely responses to outbreak response requests: Measure of the improved efficiency of vaccine stockpile mechanisms to support outbreak response

[2] Ebola vaccine could be included once a stockpile of licensed vaccine is established

4.3 Additional indicators have been identified to complement monitoring of progress towards the first primary outcome (increased breadth of protection). The **key drivers** (determinants of success) **measured** along the pathway towards increased breadth of coverage of Gavi-supported vaccines include the Alliance's performance in supporting Gavi countries to: 1) increase coverage of Gavi-supported vaccines (SDG 3.b.1 indicators); 2) introduce Gavi-supported vaccines into routine immunisation; 3) scale up coverage of newly introduced vaccines; and 4) use robust evidence to inform in-country decisions on vaccine priorities (i.e. **Strategic Objective 1A**).

4.4 *Measles campaign reach*: Preventive campaigns are most effective and efficient if they reach unprotected individuals to close immunity gaps. To reflect this ambition, an indicator of the reach of planned preventive measles campaigns is proposed as a primary indicator within SG1. Measles has been selected due to ongoing measurement efforts to assess campaign reach, and the high coverage threshold required for herd immunity.

4.5 *Timeliness of stockpile response*: This indicator measures the efficiency of the International Coordination Group (ICG) on vaccine provision and Measles & Rubella Initiative (M&RI) mechanisms in responding to vaccine preventable disease (VPD) outbreaks in Gavi supported countries. The indicator can be disaggregated into separate steps, including the timely review, approval and shipment of vaccine doses. Monitoring the efficiency of the stockpile and outbreak response mechanisms will enable the Alliance to systematically identify specific bottlenecks and identify solutions. Concerns with this proposal are that it does not reflect progress of country programmes in terms of learning from outbreak response (e.g. through root cause analyses), or the effectiveness of the outbreak response, both of which warrant further investigation including data available for monitoring.

5. Strategy Goal 2 – Strengthen health system to increase equity in immunisation

5.1 Strategic Goal 2 (SG2) aims to strengthen health systems to increase equity in immunisation. The measurement of progress on SG2 is linked to the mission indicator on reaching *zero-dose children* and bringing them into the routine immunisation system (Strategic Objective 2A) through strengthening subnational efforts to improve equity by supporting countries to improve the supply (Strategic Objective 2B) and demand side of immunisation services including addressing gender-related barriers (Strategic Objective 2C).

5.2 The proposed outcome indicators are as follows, and will be interpreted alongside the mission-level indicator on reaching zero-dose children:

a) Additional children reached beyond the first dose of DTP

b) Geographic equity of zero-dose

Indicators for Strategic Objectives 2B and 2C are pending final development of programmatic approaches, and will be aligned with monitoring of the Gender Policy (see Doc 04).

5.3 The first outcome indicator addresses under-immunised children by measuring progress on ensuring that zero-dose children, once reached, are brought into the immunisation system so they are on the pathway to being fully immunised. The TWG is discussing different **options**:

a) The simplest would be to use lack of DTP3 (the current definition of "under-immunised") to construct the indicator;

b) Or, indicators based on DTP3 and MCV1 could be monitored separately;

c) Or, a composite indicator measuring the co-coverage of DTP3 and MCV, reflecting the proportion of children receiving immunisation touchpoints at 6, 10, 14 weeks and 9 months, could be constructed.

5.4 The second outcome indicator on *geographic equity of zero-dose* is being discussed by the TWG and the IA2030 M&E Taskforce for use in Gavi 5.0 and IA2030. Data quality challenges in monitoring subnational coverage that became apparent from monitoring the GVAP 90-80 target must be taken into account. An indicator to measure progress on subnational equity would be valuable given the key role of subnational targeting to reach zero-dose children and communities.

5.5 As countries are likely to implement activities tailored to address their local supply and demand-side barriers to immunisation, it is difficult to define portfolio-level indicators at outcome level for all elements within Strategic Objectives 2B and 2C . **Process or output measures are anticipated** for development of the these indicators.

6. Strategy goal 4 – Ensure healthy markets for vaccines and related products

6.1 Under Strategy Goal 4 (SG4), Gavi aims to continue to ensure healthy markets for vaccines and immunisation-related products. Specific objectives include (a) ensuring sustainable and healthy market dynamics for vaccines and immunisation-related products, focusing on reliable, consistent and affordable supply; (b) incentivising innovation for the development of suitable vaccines; and (c) scaling-up innovative immunisation-related products.

6.2 Measurement of SG4 will focus on three primary outcomes representing these strategic objectives:

a) Number of markets exhibiting acceptable supply dynamics, as a measure of market dynamics across individual markets of Gavi-supported vaccines and cold chain equipment (CCE)

b) Number of innovative products within the pipeline of commercial-scale manufacturers

c) Number of vaccine and immunisation-related products with improved characteristics procured

6.3 Monitoring healthy market dynamics at portfolio level (Strategic Objective 4A) will reflect the aggregate status for all Gavi-supported vaccine and CCE markets. Each market will be measured individually and along two key dimensions: 1) whether levels of health for specific markets are sufficient or require improvement and 2) whether conditions exist to enable necessary improvements in market health, if required.

6.4 Uptake of innovative products, including those included in VIPS[3], by commercial manufacturers is intended to measure and demonstrate effectiveness of Gavi's interventions in increasing market attractiveness for manufacturers to invest in the commercialisation and production of new innovations (Strategic Objective 4B).

6.5 "Scale up" of improved vaccine products (Strategic Objective 4C) will be measured via a proxy indicator—the number of improved products newly procured by Gavi. This reflects the interpretation that procurement is Gavi's primary tool to influence increased innovation in the marketplace. It is assumed that manufacturers will respond to product specifications for innovations stipulated in Gavi tender documents. Products procured through the tenders will result in increased use of improved products across Gavi-supported countries.

Section C: Actions requested of the PPC

The Gavi Alliance Programme and Policy Committee is requested to provide feedback on the development of the 5.0 measurement framework, and specifically on the following questions:

1. In light of the COVID-19 pandemic, are anticipated potential delays in finalising the 5.0 measurment framework appropriate?

2. Are the proposed eight mission indicators sufficient to meet the needs for monitoring and communicating progress towards Gavi's mission?

   a) In particular, the indicators on people vaccinated over the life course and people vaccinated against outbreak prone diseases?

   b) Where should the four SDG 3.b.1 coverage indicators be located in the measurement framework?

3. For the strategic objectives where indicators have been developed, are there any areas of measurement that are missing or unnecessary, or should be approached differently from a measurement perspective?

[3] Vaccine Innovation Prioritisation Strategy

Annexes

Annex A: Gavi 5.0 strategy framework (i.e. ‘one-pager’)

Annex B: Draft dashboard of Gavi 5.0 strategy performance indicators

Annex C: Summary description of indicator definitions and proposed use case

Additional information available on BoardEffect

Appendix 1: Draft performance indicator reference sheets

Annex A: Gavi 2021-2025 Strategy One-Pager

Gavi, the Vaccine Alliance strategy 2021 - 2025

Vision

Gavi The Vaccine Alliance — **Leaving no-one behind with immunisation** — SUSTAINABLE DEVELOPMENT GOALS

Mission 2025

To **save lives** and **protect people's health** by increasing **equitable and sustainable use of vaccines**

Mission indicators

- **Child mortality reduction** tbd
- **Lives saved** tbd
- **Future DALYs averted** tbd
- **Equity indicator** tbd
- **People (male & female) vaccinated with Gavi support across the life course** tbd
- **People (male & female) vaccinated with Gavi support against outbreak-prone diseases** tbd
- **Economic benefits unlocked** tbd

Principles

- **Missed communities, first priority:** Prioritise children missing out on vaccination including among migrants, displaced and other vulnerable populations
- **Gender focused:** Identify and address gender-related barriers to promote immunisation equity
- **Country-led, sustainable:** Bolster country leadership to sustainably deliver and finance immunisation
- **Community owned:** Ensure community trust and confidence in vaccines by engaging communities in planning, implementation and oversight of immunisation
- **Differentiated:** Target and tailor support to national and subnational needs including fragile contexts
- **Integrated:** Strengthen immunisation as a foundation for integrated primary health care to reach unserved communities in support of universal health coverage
- **Adaptive, resilient:** Help countries leverage immunisation to address the challenges of climate change, Global Health Security, antimicrobial resistance and other major global issues
- **Innovative:** Identify and leverage innovative products, practices and services to reach everyone with immunisation
- **Collaborative, accountable:** Collaborate across stakeholders to achieve the SDGs in a transparent, coordinated and accountable manner

Goals

1. INTRODUCE AND SCALE UP VACCINES
2. STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION
3. IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES
4. ENSURE HEALTHY MARKETS FOR VACCINES AND RELATED PRODUCTS

Objectives

1
- A: Strengthen countries' **prioritisation of vaccines** appropriate to their context
- B: Support countries to **introduce** and **scale up coverage of vaccines** for prevention of endemic and epidemic diseases
- C: Enhance **outbreak response** through availability and strategic allocation of vaccine stockpiles

2
- A: Help countries extend immunisation services to regularly **reach under-immunised and zero-dose children** to build a stronger primary health care platform
- B: Support countries to ensure **immunisation services** are **well-managed, sustainable,** harness **innovation** and meet the needs of all care givers
- C: Work with countries and communities to build resilient **demand,** and to identify and address **gender-related barriers** to immunisation

3
- A: Strengthen national and subnational **political and social commitment** to immunisation
- B: Promote **domestic public resources for immunisation and primary health care** to improve allocative efficiency
- C: Prepare and engage **self-financing countries** to **maintain or increase performance**

4
- A: Ensure sustainable, **healthy market dynamics** for vaccines and immunisation-related products at affordable prices
- B: Incentivise **innovation** for the development of **suitable vaccines**
- C: Scale up **innovative immunisation-related products**

Enablers

- Secure **long-term predictable funding** for Gavi programmes
- Ensure **global political commitment** for immunisation, prevention and primary health care
- Use **evidence, evaluations** and **improved data** for policies, programmes and accountability
- **Leverage the private sector,** including through innovative finance mechanisms and partnerships

Annex B: Draft Gavi 5.0 Indicator dashboard

Gavi 5.0 Mission and Strategy Performance Indicators (WORKING DRAFT)

Mission indicators	• Under-five mortality rate (SDG 3.2.1) • Future deaths averted • Future DALYs averted • Equity indicator: Zero-dose children reached/reduced		• Unique children immunized • Total vaccinations through routine immunization over the life course • Total vaccinations against outbreak-prone diseases • Economic benefits unlocked	
Goals	INTRODUCE AND SCALE UP VACCINES	STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION	IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES	ENSURE HEALTHY MARKETS FOR VACCINES AND RELATED PRODUCTS
Strategy performance indicators	**Breadth of protection** SDG 3.b.1 (DTP3, MCV2, PCV3, HPV coverage) Rate of scale up of new vaccines Number of vaccine introductions Country prioritisation **Preventive campaign reach (measles)** **Timely response to outbreak response requests**	**Additional under-immunized children reached (across key immunization touchpoints in first year of life)** **Geographic equity of zero dose** Indicators for objectives on programmatic areas (e.g., supply, demand, gender barriers) pending further finalization of HSIS programmatic approaches.	Measurement of SG3 pending Alliance discussions on financing and Board decision on the updated eligibility, transition and co-financing policy.	**Number of markets exhibiting acceptable supply dynamics** **Number of innovative products within the pipeline with commercial-scale manufacturers** **Number of vaccine and immunisation-related products with improved characteristics procured**

[1] Zero dose defined as lack of first dose of DTP-containing vaccine

Annex C: Summary of Indicator Definitions[1]

Table 1: Summary Descriptions and Use Cases for Mission Indicators

ID	Indicator	What would be measured	How it would be used
M.1	Under-5 mortality rate	Average probability of a child born in any of the Gavi-supported countries dying before they reach the age of five.	Communicate Gavi's contribution to child mortality reduction
M.2	Future deaths averted[2]	Number of anticipated future deaths prevented as a result of vaccination with Gavi-funded vaccines in the countries we support	Demonstrate Gavi impact on vaccine preventable disease (VPD) mortality.
M.3	Future DALYs averted	Number of disability-adjusted life years (DALYs) averted as a result of vaccination with Gavi-supported vaccines.	Demonstrate Gavi impact on VPD mortality and morbidity.
M.4	Zero-dose children (Equity indicator)	Number of additional zero-dose children reached (or reduced) relative to baseline	Measure of extending routine immunisation services to missed communities. An equity measure.
M.5	Unique children immunised with Gavi support	Number of children immunised with the last recommended dose of a Gavi-supported vaccine delivered through routine systems	Demonstrate reach of Gavi support.
M.6	Total vaccinations through routine immunisation over the life course with Gavi support[3]	Total count of pathogen-level protection from completed courses of Gavi-supported routine immunisations	Demonstrate breadth of Gavi support

[1] Indicators for strategy goal 3 have yet to be defined. Measurement of SG3 pending Alliance discussions on financing and Board decision on the updated eligibility, transition and co-financing policy.
[2] Indicators underlined are included in the 2020-2025 Investment Opportunity and will be used, in part, to report on progress towards meeting commitments made in 2021-2025 Investment opportunity.
[3] This indicator is proposed as the measure of Gavi 5.0 strategic framework's "people (male & female) vaccinated with Gavi support across the life course".

M.7	Total vaccinations against outbreak-prone diseases with Gavi support[4]	Total vaccinations[5] of MenA, YFV, MCV and OCV completed through Gavi-supported routine immunisations, preventive campaigns and outbreak response.[6]	Demonstrate Gavi's contribution to global health security No target would be set.
M.8	Economic benefits unlocked	Calculated as cost-of-illness (COI) averted. COI includes treatment and transport costs, caretaker wages and productivity loss due to disability and premature death.	Demonstrate Gavi impact on economic productivity.

Table 1: Summary Descriptions and Use Cases for Strategy Goal 1 Indicators[7]

	Strategy goal 1: Introduce and Scale up Vaccines		
ID	**Indicator name**	**What would be measured**	**How it would be used**
S1.1	**Breadth of protection**	Average coverage across all recommended Gavi-supported vaccines in Gavi countries.	Summary measure of prioritised vaccine introductions, rate of scale up of newly introduced vaccines, and vaccine coverage.
S1.1.1	Vaccine coverage [SDG 3.b.1 (DTP3, MCV2, PCV3, HPV2)]	Individual coverage of vaccines included in the SDG indicator (DTP3, MCV2, PCV3 and HPV2).	Monitor trends in national coverage of select vaccines. Signal alignment with the SDG agenda.
S1.1.2	Number of vaccine introductions	Number of introductions of Gavi-supported vaccines into routine immunisation.	Monitor incremental changes in number of countries introducing new and under-used vaccines into the routine immunisation schedule.

[4] This indicator is proposed as the measure of the Gavi 5.0 strategic framework's "people (male & female) vaccinated with Gavi support against outbreak-prone diseases".
[5] Ebola vaccine will be added to the definition of this indicator once a stockpile of licensed vaccine is established.
[6] Definition of acronyms: Meningitis A vaccine, Yellow fever vaccine, Measles-containing vaccine and Oral cholera vaccine
[7] Bolded indicators represent primary outcomes of the Strategic Goal. Un-bolded indicators are measures of key outputs or drivers leading to the primary outcomes and warrant reporting to the Board.

S1.1.3	Rate of scale up of newly introduced vaccines	Coverage of routine vaccines (PCV3, Rotavirus, MCV2 and YFV) relative to benchmark vaccine within reference time frame for new introductions.	Evaluate whether new introductions are achieving high coverage within a reasonable timeframe[8]
S1.1.4	Country prioritisation	Percentage of vaccine applications that demonstrate use of evidence to support prioritisation of vaccines appropriate to their context.	Process indicator to monitor the ability of the Alliance to provide support and ensure countries make informed decisions for prioritisation of vaccines as per their programmatic, epidemiological and fiscal context.
S1.2	**Measles campaign reach**	Percentage of under 5 children previously unvaccinated against measles who are reached by planned preventative campaigns.	Monitor quality of Gavi-supported preventative campaigns to ensure that these are addressing measles immunity gaps in the population.
S1.3	**Timely response to vaccine stockpile requests**	Percentage of approved outbreak vaccine requests met in a timely manner for each outbreak prone disease.	Monitor efficiency of Gavi stockpile and outbreak response mechanisms in responding to country requests for support to vaccine outbreaks

[8] Gavi analyses (internal) suggest that it takes, on average, two years post-introduction (for PCV3 and Rotavirus) and three years (for MCV2 and Yellow fever) for a new routine vaccine to achieve at least 90% coverage of the existing routine vaccine following a similar immunisation schedule.

Table 2: Summary Descriptions and Use Cases for Strategy Goal 2 Indicators[9]

Strategy goal 2: Strengthen health systems to increase equity in immunisation			
ID	**Indicator name**	**What would be measured**	**How it would be used**
S2.1	**Additional children reached beyond the first dose of DTP**	Three options under discussion, based on number of children receiving: 1. DTP3 2. DTP3, MCV1 (separately) 3. Both DTP3 and MCV1	Capture reach of routine immunisation beyond the first dose of DTP, e.g., reflecting key immunisation touchpoints at 6, 10, 14 weeks and 9 months.
S2.2	**Zero-dose geographic equity indicator**	TBD	Measures effectiveness of subnational targeting to improve access to routine immunisation services.

Table 3: Summary Descriptions and Use Cases for Strategy Goal 4 Indicators

Strategy goal 4: Ensure healthy markets for vaccines and related products			
ID	**Indicator name**	**What would be measured**	**How it would be used**
S4.1	**Healthy market dynamics**	Number of Gavi vaccine and cold chain equipment markets exhibiting sufficient levels of healthy market dynamics	Monitor trends in market dynamics across individual markets of Gavi-supported vaccines and CCE.
S4.2	**Incentivise innovation for development of suitable vaccines**	Number of innovative products within the pipeline of commercial-scale manufacturers	Monitor effectiveness of Gavi's ability to incentivise uptake of VIPS products by commercial manufacturing partners

[9] Indicators for outputs or outcomes of investments in the supply and demand side of immunisation services including addressing gender-related barriers will be included in the final measurement framework.

S4.3	**Scale up of vaccines and immunisation related products**	Number of vaccine and immunisation-related products with improved characteristics procured.	Demonstrate Gavi's ability to scale up usage of innovative vaccine and immunisation-related products. Procurement is a proxy for scale up.

Report to the Programme and Policy Committee
26-27 May 2020

SUBJECT:	**REVIEW OF DECISIONS**
Agenda item:	08
	No paper

Report to the Programme and Policy Committee
26-27 May 2020

SUBJECT:	**ANY OTHER BUSINESS**
Agenda item:	09
	No paper