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COVID-19 Vaccine Introduction – Key Issues

As the COVID-19 pandemic continues its upward trajectory, there has been unprecedented international collaboration to accelerate access to essential medical, diagnostic, preventive and therapeutic supplies and equipment globally for preparedness and response.

With the recent efficacy results from three different vaccines, there is real urgency for countries to assess their readiness and develop a National Deployment and Vaccine Plan (NDVP), if not already done.

This paper discusses some of the key issues for consideration and immediate actions to be taken by the health sectors and other government agencies in Pacific Island countries and areas to meet the requirements for COVID-19 vaccine introduction accessed through the COVAX Facility.

Heads of Health are invited to identify areas of technical and operational collaboration with the newly formed Vaccine Pillar of the Pacific COVID-19 Joint Incident Management Team for health sector support, and mechanisms for timely information sharing moving forwards.

1. BACKGROUND

The COVID-19 pandemic is the greatest public health challenge of our lifetime, the scale and severity of which was last experienced during the 1918-19 H1N1 influenza pandemic. Since 30 January 2020 when the WHO Director General declared that COVID-19 constitutes a Public Health Emergency of International Concern (PHEIC) based on the recommendations of the International Health Regulations (IHR) Emergency Committee, to 24 November, a cumulative total of close to 60 million cases, including ~1.4 million deaths, have been reported to WHO. More cases of COVID-19 have been reported in the past four weeks than in the first six months of the pandemic. Across Europe and North America, hospitals and intensive care units are rapidly filling or full.

As of 24 November, the Western Pacific Region (WPR) has reported 840,703 cases, or 1.4% of the global cumulative cases since the beginning of the outbreak despite being home to 1.9 billion people. Countries in the region have responded rapidly and effectively to their first cases and clusters or have suppressed outbreaks by planning for the worst-case scenario, adhering to protective measures of hand, respiratory and environmental hygiene, and consistently applying non-pharmaceutical interventions including physical distancing and mask use when needed, and through

strong leadership and coordination. However, despite these efforts second waves of transmission have occurred in some WPR countries, with clusters of cases arising from transmission in bars, other entertainment venues, hotels, workplaces, military bases, quarantine facilities, or from religious gatherings.

Pacific island countries and areas (PICs) have reported a cumulative total of 20,396 cases, including 180 deaths, with a case fatality proportion (CFR) of 0.9% which is lower than the global CFR of 2.4%. Most PICs remain COVID-19 free or have reported only imported cases and/or small clusters. French Polynesia, Guam and Papua New Guinea are experiencing large scale community transmission, contributing 99% of the cases and 97% of deaths reported in the Pacific region.

In this global context, through the Access to COVID-19 Tools Accelerator (ACT-Accelerator) launched in April 2020, there has been unprecedented international collaboration to accelerate production and equitable access to essential medical equipment and supplies, treatments, diagnostics and vaccines. The COVAX facility is the Vaccine Pillar of the ACT-Accelerator, co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO, while UNICEF is the global procurement agency for COVAX. Its goal is to help end the acute phase of the pandemic by end 2021 by providing access to at least 2 billion doses of safe and effective COVID-19 vaccines to the most vulnerable in all participating countries/economies regardless of income levels. COVAX includes both self-financing economies and economies funded through the Gavi COVAX Advance Market Commitment (AMC).

The purpose of this paper is to update the Pacific Heads of Health (HoH) on progress to date and key issues arising, and to ensure effective coordination at the leadership, policy and operational levels moving forwards.

2. PROGRESS, ISSUES ARISING AND CHALLENGES

Safe and effective COVID-19 vaccines are anticipated to end the acute phase of the pandemic. There are several steps to ensure country readiness for COVID-19 vaccine introduction.

2.1 COVID-19 Vaccine Introduction Readiness Assessments

There are three main vaccine introduction readiness assessment and planning tools for use by countries.

1. The *COVID-19 Vaccination Program Interim Operational Guidance for Jurisdictions Playbook* is being used by the US Affiliated Pacific Islands (USAPI) to plan and operationalise their vaccination response to the pandemic.
2. The *COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT)*, a self-assessment tool intended to be used by Ministries of Health with support from WHO and UNICEF Country Offices as needed, was developed to provide a roadmap for COVID-19 introduction and a structure framework for countries to self-monitor their readiness progress against key milestones.

3. The World Bank's *Vaccine Readiness Assessment Framework (VRAF)*. On 13 October 2020, the World Bank's Board of Executive Directors approved an envelope of USD 12 billion for developing countries to procure and deploy COVID-19 vaccines once the vaccines have been approved by several highly respected, stringent regulatory agencies. World Bank (WB) financing teams will work with countries to confirm eligibility for financial resources, that includes completing VRAF which is compulsory in nature being linked to the WB funding allocation.

Other multilateral development banks (e.g., ADB) are also providing COVID-19 vaccine and delivery financing and may have additional assessment tools.

UNICEF, WB and WHO are coordinating closely to combine and streamline VIRAT and VRAF readiness assessments under a common *Vaccine Introduction Readiness Assessment Framework (VIRAF).* COVAX eligble countries have recently received letters from the WB Managing Director of Operations on behalf of the COVAX facility requesting that countries indentify a single senior national focal point to coordinate the assessment and development of a single National Deployment and Vaccine Plan to guide the deployment of COVID-19 vaccine and other tools. WHO has developed interim *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines* to assist in this process, using the VIRAT and VRAF assessment tools as roadmaps for implementation.

Assessments using VIRAT and VRAF are occurring across the Pacific but with varying degrees of progress in completing these vaccine readiness assessments which may affect delivery times of vaccine once available, including through COVAX.

To prevent duplication of effort, the HoH are requested to share readiness assessments and National Deployment and Vaccine Plans (NDVP) with the relevant lead partners UNICEF, WB and WHO, and to approve the routine sharing of these resources across the development partners of the JIMT for coordinated country support.

Situational update

WHO and UNICEF country teams are working jointly to support Pacific Ministries of Health and immunisation managers to populate the Vaccine Introduction Readiness Assessment Tool (VIRAT) with micro-steps for a 3-year workplan. COVAX coordination mechanisms are in place at the national level in each PIC.

Development of cost estimates for implementation of the 3-year VIRAT plan for all 14 PICs, that both UNICEF and WHO support, is under way and will continue as the situation evolves. The Gavi application has been released and all Gavi AMC-35 and AMC-57 countries are in the process of preparing the application and associated deliverables, including development of the Technical Assistance Plan, the NDVP, the Vaccine Request and the cold chain equipment assessment. All 14 countries have provided information on existing cold chain status of equipment which will feed into the Gavi Cold Chain Equipment support application due March 2021.

The timeline for vaccine release of the first emergency use listing / emergency use authorisation vaccines is estimated for mid January-mid April 2021. All 14 PIC health ministries have access to the vaccine characteristics such as availability, price, and complexity of vaccine delivery for the vaccines expected to be part of the first release. In Nadi, Fiji, UNICEF's regional cold chain storage

capacity recently increased from 40 to 80 cubic meters and is ready to absorb COVAX vaccines if 2-8°C refrigeration capacity is needed.

Ministries of Health have on-going organisational support from UNICEF and WHO in strengthening national immunisation systems as part of broader health system strengthening. Both agencies support immunisation service delivery, training and supervision and monitoring and evaluation.

In support of COVID-19 vaccine introduction, UNICEF will provide targeted support for logistics planning, supply chain management support, cold chain capacity improvements and monitoring, training and microplanning, C4D communication and social mobilisation, demand generation, and development of supplementary immunisation activities (SIAs) with support to campaigns to build public consensus and reduce any fear and concerns associated with the new vaccine introduction.

WHO will continue its normative and standards setting functions in support of regulatory pathways, support to risk assessment, prioritisation, targeting and COVID-19 surveillance, vaccine safety and pharmacovigilance, AEFI surveillance, infection prevention and control and clinical waste management, health information systems, risk communication and communty engagement, and support to governance and coordination. WHO delivered a virtual Regional Training on Vaccine And Immunisation Safety In the Western Pacific: Preparation for Safety Events During Covid-19 Vaccine Deployment on 16-19 November 2020.

2.1.1 Governance

The COVID-19 pandemic requires a whole-of-government and whole-of-society response. Countries participating in the COVAX AMC are requested to establish a national multidisciplinary coordination mechanism for COVID-19 vaccine introduction for policy and operations. Key activities include to develop a NDVP for COVID-19 vaccines, work with partners to secure additional financing, prepare for vaccine delivery including indemnification and liability considerations, prime regulatory processes, and prepare any needed infrastructure.

Pacific COVID-19 Joint Incident Management Team Vaccine Pillar

Since January 2020, the Pacific COVID-19 Joint Incident Management Team (JIMT) comprising 20 development partners has been supporting the health sector response to COVID-19 in PICs. The recently convened JIMT Vaccine Pillar aims to support country readiness for the introduction of COVID-19 vaccines in line with the interim *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines*. The Vaccine Pillar includes UNICEF and WHO country office staff across the Pacific and other key development partners (currently ADB, DFAT, MFAT, NZ MedSafe, PIHOA, SPC, UNICEF, US CDC, WB and WHO). Additional specialised technical support is also provided by WPRO and WHO HQ. All members of the JIMT will be kept updated and discuss opportunities for collaboration through regular JIMT meetings.

To ensure that the JIMT's technical and operational support to the health sector response is fit for purpose and validated by the Pacific health leadership, regular communication and information sharing with the Heads of Health is recommended. Options include regular virtual meetings on progress in readiness for vaccine introduction, HoH representation at JIMT Vaccine Pillar meetings, regular reporting of JIMT activities at national vaccine introduction coordination meetings, or a combination of the above.

2.1.2 Planning and Coordination

National operational planning for COVID-19 introduction and deployment should consider the following: regulatory readiness; planning and coordination; risk communication and community engagement; target populations; vaccination delivery strategies; supply chain and management of health care waste; human resources management and planning; vaccine acceptance and uptake (demand); pharmacovigilance (vaccine safety monitoring, surveillance and management of adverse events following immunisation (AEFI) and injection safety; information systems; COVID-19 surveillance; and the evaluation of COVID-19 vaccine introduction, including vaccine effectiveness.

To develop a health sector support plan for COVID-19 vaccine introduction based on the areas of readiness above, the JIMT Vaccine Pillar seeks inputs from the HoH on priority areas for policy, technical and operational support.

2.1.3 Regulatory, indemnity and pharmacovigilance

The COVID-19 vaccine development landscape is complex and rapidly changing. There are currently 47 candidate vaccines in human clinical trials, with 10 candidate vaccines in Phase IIb/III and III. Eight of the 9 candidate vaccines from the COVAX research and development portfolio are undergoing human clinical trials. Candidate vaccines vary in terms of technology platform (viral vectors, mRNA, DNA, protein-based and inactivated), dosage schedule (one or two dose), dosing interval, age-specific effectiveness and cold chain requirements, with at least two vaccines (mRNA vaccines) requiring ultracold chain (–70°C), storage at –20°C and/or dry ice for transportation.

Despite the rapid pace of vaccine development, internationally agreed criteria for safety, efficacy and quality are being observed for COVID-19 vaccines. However, not all vaccines available for procurement or via donation may be best suited to the policy, programmatic and operational environment in individual countries.

Steps in regulatory readiness at the country level include registration pathways for early entry such as emergency use approval or conditional approval; regulations for vaccine donations; regulations on importation, regular market supervision, and prevention and control of substandard and/or falsified vaccines. There is an urgency for regulatory engagement in country because WB resources for vaccine purchase will require in-country authorisation, leveraging either WHO prequalification and approval by 1 Stringent Regulatory Authority (SRA) or approval by 3 SRAs in three regions.

The COVAX Vaccine Allocation Model includes product choice to the degree possible by to integrate product preference into vaccine allocations and establish 'best-matches' between products and country preferences; however, receipt of vaccines with the preferred characteristics cannot be guaranteed given likely supply exceeding demand and other constraints. Given this complex landscape and the number and diversity of candidate vaccines in development, WHO and UNICEF recommend that PICs work with the COVAX facility, donors and partners to select the most suitable vaccine candidate for their local context to minimise immunisation program implementation risks and the operational challenges of using more than one vaccine in the same population.

Close collaboration between Ministries of Health and the Ministries involved in bilateral relations, and with the authority to approve vaccine donations, will be critical in this regard to ensure that decisions about accepting or declining vaccine donations have taken into consideration the

preferred characteristics submitted to COVAX, and whether the donated vaccine has been WHO prequalified (PQ), for Emergency Use Listing (EUL) or has received regulatory approval from stingent national regulatory authorities.

To facilitate access to medicines and vaccines of assured quality, safety and efficacy for people in the Western Pacific Region, WPRO has established a regional regulatory authority network to support countries without, or with nascent, national regulatory authorities to strengthening pharmaceutical regulations through cooperation. The JIMT Vaccine Pillar is leveraging this network to provide regulatory support to PICs on request.

Indemnification

All vaccines supplied through COVAX will undergo a rigorous regulatory process and will be approved for general use; however, given the speed and scale of deployment, manufacturers are unwilling to self-insure for product liability claims and are requiring all participants receiving vaccine to indemnify them against such claims. Lack of such an indemnification by a participating country will limit access to vaccines. A model indemnification provision is being developed to facilitate this process. COVAX is working to obtain the cooperation of the International Development Law Organization (IDLO) to assist interested AMC-eligible participants in respect of the above if required.

COVAX AMC countries are requested to indemnify vaccine manufacturers for potential vaccine injury or report whether new or revised legislation or regulations are needed to enter into an indemnity agreement, and the lead time to passing such legislation. COVAX is developing a global no-fault compensation mechanism for severe AEFI associated with the vaccines supplied by COVAX.

PICs that choose to procure vaccines or accept donations of vaccines that fall outside the COVAX provisions are encouraged to ensure that they meet international quality and safety standards and take into consideration regulatory implications and indemnification requirements.

Pharmacovigilance

Countries also need to ensure strong national pharmacovigilance systems with robust immunisation safety surveillance capacity to detect, investigate and report rare and serious AEFIs to ensure the safety of vaccine recipients, and maintain public trust and demand for vaccines and immunisation programs. WHO and the regional network of national regulatory authorities can provide technical support to strengthen national pharmacovigilance systems, AEFI surveillance and in the investigation of AEFI events.

Given the potential for very rare, severe AEFIs, post-marketing surveillance is crucial. Reporting AEFIs via existing national and international mechanisms, including timely reporting under the International Health Regulations, will enable the linkage of similar safety signals for further investigation. The WHO Global Vaccine Safety Initiative has developed a number of tools for the investigation of AEFIs including a reporting form, *Aide-Memoire on AEFI investigation*, *Aide-Memoir on causality assessment*, an e-learning course and AEFI causality assessment software.

2.1.4 Prioritisation and targeting

Given the urgency and wide-ranging effects of the COVID-19 pandemic, WHO's Strategic Adivosory Group of Experts (SAGE) on Immunisation has developed a *Roadmap for Prioritizing Uses of COVID-19 Vaccines* that considers priority populations for vaccination under different epidemiologic and

vaccine supply conditions. This Roadmap builds on the *WHO SAGE values framework for the allocation and prioritisation of COVID-19 vaccination*.

Donor-funded vaccine doses through COVAX will be distributed across AMC-eligible countries. The current target is for donor-funded doses to reach 20% of the population, depending on vaccine development success, dose price, vaccine characteristics, and available resources.

2.2 Operations

2.2.1 Risk communication and community engagement

In preparing for COVID-19 vaccine introduction, all countries will be required to manage an extremely challenging communications landscape of supply and demand for vaccines. RCCE planning is a core component of the NDVPs for COVID-19 vaccines introduction readiness that all countries are encouraged to develop. WHO and UNICEF strongly recommend that countries develop a RCCE plan as soon as possible in anticipation of vaccine introduction.

From a communications and community engagement perspective anticipated challenges include: managing stakeholder expectations and uncertainty; communicating effectively about target populations and their prioritisation, and on the safety and efficacy, modes of action and administration schedules of candidate vaccines; and managing different scenarios of demand and supply. As co-financing vaccine procurement through the COVAX Facility targets 20% of the national population of eligible countries, health care workers, other first responders, the elderly and vulnerable individuals are the recommended priority groups for the first tranche of vaccines. Self-financing countries may also receive vaccine in tranches depending on global supply. There may be insufficient vaccine available after the initial allocation to vaccinate other sectors of the population.

With a likely staged roll out of vaccines, population immunity will not be achieved immediately. It will be critical that governments maintain capacities at international points of entry for case detection, testing, tracing and quarantine, while communities and individual continue to adhere to protective behaviours and non-pharmaceutical interventions (NPIs), including physical distancing and mask use when necessary, to prevent transmission and maintain successful containment of COVID-19. Governments may be required to address public concern or dissatisfaction about the need for some of these measures even after vaccines become available.

Vaccine hesitancy is already a recognized challenge to COVID-19 vaccine introduction in some countries, in part because of the speed at which COVID-19 vaccine development is occurring. Studies have shown a significant relationship between disinformation campaigns about vaccine safety on social media and declining vaccination coverage, with implications for successful COVID-19 vaccine introduction. Conversely, if demand exceeds supply, effective RCCE will help to manage public expectations, perceptions of risk and reduce the likelihood of outrage in individuals who are not in the priority groups for vaccination.

2.2.2 Health Information for COVID-19 vaccine introduction

Information management for COVID-19 introduction is another core component of country readiness but is likely to pose challenges for some PICs. All but one of the current vaccine candidates

requires two doses, the target population will intially be adults and vaccinated individuals will require documentation of immunisation.

Proof of vaccination is already being flagged as a future requirement for international travel, and digital or paper-based COVID-19 vaccination records will necessitate mutual recognition between countries. Stringent controls will need to be in place to guarantee the accuracy of COVID-19 vaccination data, including a form of validation that an individual's vaccination record has been issued by a authorised agency or provider. WHO is leading discusions on options for an international certificate of vaccination, whether digital or paper-based. There is no definite position yet, but issues being considered include legal and ethical aspects, vaccination requirements, the status of SARS-CoV-2 immunity science, data security and data privacy.

Most South Pacific island countries currently rely on paper or paper-electronic hybrid systems for measuring vaccination coverage which can result in delayed information gathering, while extracting and transferring data from paper-based records to electronic records is time consuming and can introduce transcription errors.

Effective and efficient national implementation of COVID-19 vaccination will depend on the ability to access, receive and share information rapidly between health managers and staff at all levels. To enable timely decision-making, information from different data sources on COVID-19 such as the local epidemiology, vaccine deployment, performance and coverage monitoring, vaccine and supply management, AEFI surveillance, and immunisation waste management should be collected, collated analysed and disseminated. The real-time monitoring of uptake, safety and effectiveness of COVID-19 vaccines would benefit from use of electronic information platforms while recognsing that in some Pacific islands contexts, appropriate paper-based or partially digitizted systems may be preferable.

Given the urgency, standalone information management solutions to capture the data needed to support COVID-19 vaccine introduction may be necessary in some PICs, while the longer-term objective is to strengthen national immunisation programs by building and strengthening electronic immunisation information systems leveraging the resources made available in response to COVID-19.

WHO highly recommends that countries being to pre-register the individuals identified to receive the first traches of vaccine in line with national prioritisation policy.

2.2.3 Vaccine procurement

UNICEF will lead the procurement and coordination of the COVID-19 vaccine under the COVAX Facility. The COVAX Facility is global, i.e. open to all countries regardless of their wealth and ability to pay for vaccines. However, countries will be treated differently based on their income classification.

All countries classified by the World Bank as low- or lower middle-income countries (LIC or LMIC) or (International Development Association) IDA-eligible will have their doses financed by the Facility under the COVAX AMC. UNICEF will procure on behalf of these countries (namely, Fiji, FSM, Kiribati, RMI, Samoa, Solomon Islands, Tonga, Tuvalu and Vanuatu).

All upper middle- or high-income countries (UMIC and HIC) who wish to participate will be expected to fully self-finance their participation (namely, Cook Islands, Nauru, Niue, Palau and Tokelau). UNICEF can procure vaccines (and any other health supplies available in UNICEF's Supply Catalogue) on behalf of these countries through UNICEF's Procurement Services, if a Procurement Services MOU between UNICEF and the country has been established. To date, from the five fully self-financing countries, only Cook Islands has this MOU in place.

For both AMC-eligible or fully self-financed countries, UNICEF Pacific can use the principle of pooled vaccine procurement, where vaccine shipments may be consolidated and shipped to UNICEF Pacific's Regional Cold Storage in Fiji which has recently doubled its capacity to 80 cubic meters, reducing transportation and operational costs through economies of scale and pooling efficiencies. Vaccines can then be repacked according to country specific quantities and dispatched to each country. This option requires further consultation and approval within UNICEF.

UNICEF has also conducted a preliminary, rapid costing of supplies for a phased introduction of a potential COVID-19 vaccine in the Pacific (for 20% of the population, additional 50% and final 30%), based on country population and vaccine and immunisation supplies costs assuming an initial price per dose of USD 2.00 for 20% of the population; USD 11.00 for any additional quantities, and 15% wastage rate, as well as PPE requirements. See Annex 1 for additional information.

2.2.4 Cold chain requirements

UNICEF has done a preliminary, rapid assessment of cold chain capacity for PICs, considering the potential introduction of a COVID-19 vaccine. All PICs have shared their data on cold chain equipment inventory; however, these data may not be up-to-date nor reflect the 2020 inventory. Kiribati, Fiji, FSM, Samoa, Vanuatu, Nauru and Palau have reported their available (I.e. free) cold chain space. The final presentation of the selected vaccine(s) (1, 2, 5 or 10 doses per vial), the required immunisation schedule (one or 2 doses) and the cold chain requirements (e.g., 2-8°C or freezing requirements) will be essential information required to assess the final cold chain country requirements.

As part of COVAX, WHO and UNICEF Regional Offices, together with GAVI, have requested countries to complete a much larger and robust cold chain assessment exercise (WHO's Supply Chain Sizing and Cold chain inventory gap analysis tools). UNICEF's initial rapid assessment can help feed into this exercise. Excluding the Ultra Cold Chain vaccine option, and with the limited information collected from countries, at this stage, no significant investment is expected in terms of cold chain equipment (2-8°C), at least for the estimated low volume of doses that will be required for 20% of the population in the Pacific. It is expected that there will be sufficient storage capacity should COVID-19 vaccine shipments for the Pacific be consolidated and shipped to UNICEF Pacific's regional cold storage facility in Fiji. Additionally, during 2020, UNICEF procured a variety of cold chain equipment for 12 PICs (one Walk-In-Cold Room, 132 refrigerators and freezers, 872 cold boxes and vaccine carriers, and 2,433 temperature monitoring devices) which will support the introduction of the COVID-19 vaccine. Funding has been secured for the procurement of additional cold chain equipment in 2021 (one Walk-In-Cold Room, 152 refrigerators and freezers, 355 cold boxes and vaccine carriers, 814 temperature monitoring devices, among other supplies).

The cold chain equipment procurement from 2020 and planned procurement in 2021 represents a significant investment to expand and strengthen cold chain capacity in all 14 PICs, and it is expected that this will set a firm foundation for the introduction of the COVID-19 vaccine in the Pacific. See Annex 2 for additional information.

3. FUTURE DIRECTIONS

In the next 100 days, the COVAX Facility is committed to assisting at least 100 countries in preparing for the introduction of COVID-19 vaccines. The resources being made available to countries at this time in response to COVID-19 create an opportunity to strenthen core components of the health systems in the longer term. With the recent efficacy results from three different vaccines, there is real urgency for countries to assess their readiness and develop an operational plan for vaccine introduction and roll-out if not already done.

Immediate readiness measures for countries include:

- Completing readiness assessmemnts and any outstanding documentation for vaccine acceptance, technical assistance and cold chain requirements
- Establishing a national coordination mechanism for COVID-19 vaccine introduction
- Developing a National Deployment and Vaccine Plan
- Confirming to WHO the existence of any expedited regulatory pathway for approval of COVID-19 vaccines
- Completing the WHO SAGE prioritisation and targeting matrix and pre-register the individuals prioritised for the first tranches of vaccines
- Preparing a RCCE plan for demand generation, to address vaccine hesitancy and reduce outrage in sectors of the population outside the vaccination target groups
- Reviewing health information system capacity to support vaccine introduction and provide documentation of immunisation to those vaccinated
- Completing cold chain infrastructure and supply chain assessments and identifying potential logistical constraints to vaccine introduction.

The JIMT Vaccine Pillar stands ready to support Pacific island goverments in their efforts to carry out this work with the guidance of the HoH in identifying their priorities for technical collaboration.

3.1 Recommendations for governments

Heads of Health are invited to:

1. Note the global developments pertaining to COVID-19 vaccine development, regulation, indemnification, procurement and demonstration of readiness for vaccine introduction and roll-out.

2. Share readiness assessments and National Deployment and Vaccine Plans with the relevant lead partners UNICEF, WB and WHO, and to approve the routine sharing of these across the development partners of the JIMT for coordinated country support.

3. Note the immediate readiness activities that countries are requested to progress and report, and consider the governance arrangements that will best facilitate coordination and collaboration between the HoH and partner agencies, including the frequency of information sharing.

4. Work closely with Ministries involved in bilateral relations, and with the authority to accept vaccine donations to ensure that they meet international safety and efficacy standards and are the best fit for the target population, and the local policy, programmatic and operational environment.

5. Work with UNICEF, WHO and the JIMT development partners to identify and prioritise areas requring technical and/or operational collaboration to ensure the JIMT's support to countries is designed and programmed for effectiveness and equity of access to technical and other resources.

6. Establish a Procurement Services MOU, which will enable Ministries of Health to procure life-saving essential supplies for children through UNICEF including vaccines.

7. Complete the supply chain assessment and planning tools developed for the Gavi COVAX application as this will support the rehabilitation of national cold chain and logistics systems and map the required logistics for the introduction of COVID-19 vaccines.

3.2 Recommendations for development partners:

Partners are invited to:

1. Note priority needs and share information on bilateral and multilateral support for COVID-19 vaccine introduction for coordinated and coherent design and programming of technical and operational health sector support.

2. Collaborate on Pacific regional initiatives to ensure that vaccine donations meet international safety and efficacy standards and take into consideration the preferred characteristics submitted by national authorities to COVAX.

3. Support countries to execute the immediate readiness activities, including priority areas for technical assistance and exploring additional financing sources.

Annex 1 - Procurement of COVID-19 Vaccines

UNICEF Procurement Services

UNICEF Procurement Services is a function that is provided to a wide range of development partners, e.g. governments, Non-Governmental Organizations (NGOs), International Governmental Organizations, International Funding Agencies, other United Nations Agencies and Philanthropic Organizations as a complement to UNICEF's core program.

The objective of Procurement Services is to offer UNICEF's knowledge, purchasing capacity and logistics expertise to development partners, so that they can use their own financial resources and donor funds to procure life-saving essential supplies for children, including vaccines and other health supplies.

UNICEF procures vaccines, pharmaceuticals, and essential supplies for primary and first referral care levels. The list of supplies that UNICEF procures is available from the UNICEF Supply Catalogue (https://supply.unicef.org/).

To be valid, the relationship between UNICEF and a Procurement Services partner must be governed by a Memorandum of Understanding. The MOU is the legal document which sets the terms, conditions and operational rules applying to a contract to be entered under the MOU. The MOU outlines UNICEF Procurement Services processes and sets out the Terms and Conditions for individual transactions.

Having a Procurement Services MOU in place would provide an opportunity for a Ministry of Health to benefit from the purchasing power of UNICEF's global procurement mechanism. It does not mean that the Government is required to procure exclusively from UNICEF – it just provides the legal framework to request cost estimates from UNICEF, should the need arise. The Ministry of Health can then decide to proceed, or not, with procurement via UNICEF.

For more information about UNICEF Procurement Services, please visit:
http://www.unicef.org/supply/index_procurement_services.html.

Vaccines and supplies cost assumptions for a phased introduction of a potential COVID-19 vaccine:

Introduction is phased for three years, for 20% of the population (year 1), additional 50% (year 2) and final 30% (year 3). Quantities are based on country population and vaccines costs assume a two-dose schedule, an initial price per dose of USD 2.00 for 20% of the population and USD 11.00 for any additional quantities. Syringes and safety boxes have also been considered. 15% wastage rate has been used.

For PPE estimated numbers of health workers have been used and the following items have been considered:

- Mask, surgical, typeIIR, ear loop, disp, pack50
- Gown, isolation, nonwoven, disp, pack10
- Faceshield, fog-resistant, full face, disp
- Gloves, w/o powder, nitrile, L, disp, BOX-100
- Hand sanitiser alcohol, 250mL

Annex 2 - Cold Chain Equipment Requirements

A preliminary, rapid assessment on cold chain capacity for PICs has been developed. All PICs have shared their data on cold chain equipment inventory (however, it should be noted that this data may not be up-to-date, not necessarily reflecting the 2020 inventory); Some countries have not managed to fill in the available (i.e. free) cold chain space (except for Kiribati, Fiji, FSM, Samoa, Vanuatu, Nauru, Palau, who did provide this information).

	Functional Cold Chain Equipment													
	Refrigerators 2–8°C						Freezer					Other		
Type	SMALL 30-60 Lite	MEDIUM 90-120 Lite	LARGE >120 Lite	WIC walk-in-cooler roo	Total net refrigeration volume (Liter	Estimated volume (Liters) availal	SMALL 30-60 Liter	LARGE >120 Liter	WIF walk-in-freezer roon	Total net freezing volume (Liter	Estimated volume (Liters) availa	Cold box	Vaccine Carriers	PIPELINE STATUS Deployed, Shipped, Preparir
t Storage		1			105	10						2	3	Deployed
Clinic		1			105	50		1		320			2	Deployed
Maternity Ward		1			90	50							1	Deployed
Dispensary	1				48	25							1	Deployed
Dispensary	1				48	20							1	Deployed
	1				48	20							1	Deployed
Hospital	1				46.6	10				8			1	Deployed
Dispensary													1	Deployed
Dispensary	1				48	30							1	Deployed
Health Center	1				48	32							1	Deployed
Dispensary	1				48	27							1	Deployed
Health Center	1				48	10							1	Deployed
Health Center	1				48	30							1	Deployed
Dispensary	1				48	29							1	Deployed
Dispensary	1				46.6	30				8			1	Deployed
Health Center	1				48	48							1	Deployed
Dispensary	1				48	25							1	Deployed
Dispensary	1				48	25							1	Deployed
Health Center	1		1		150								1	Deployed
Dispensary	1				48								1	Deployed
Health Center	1				48	18							1	Deployed
Health Center	1				48	14							1	Deployed

WHO has developed an Excel-based tool for establishing future cold-chain capacity, transport needs & waste management. Its purpose is to stablish projected capacities for storing & distributing vaccine & safe injection supplies at all levels of a national immunization programme. It can support the rehabilitation of the cold chain & logistics system and mapping logistics for vaccine introduction/SIAs: