UNICEF SUPPLY DIVISION & GAVI:

CCE Programme and Market updates on COVID-19 and Gavi 5.0

CCE Industry Consultation

5 November 2020

Agenda

- Update on the COVAX facility
- COVID-19 cold chain equipment response
  - Scope of Gavi support for COVID-19 CCE
  - Country needs and demand estimates and related mitigation planning
  - Application and procurement planning
  - Q&A

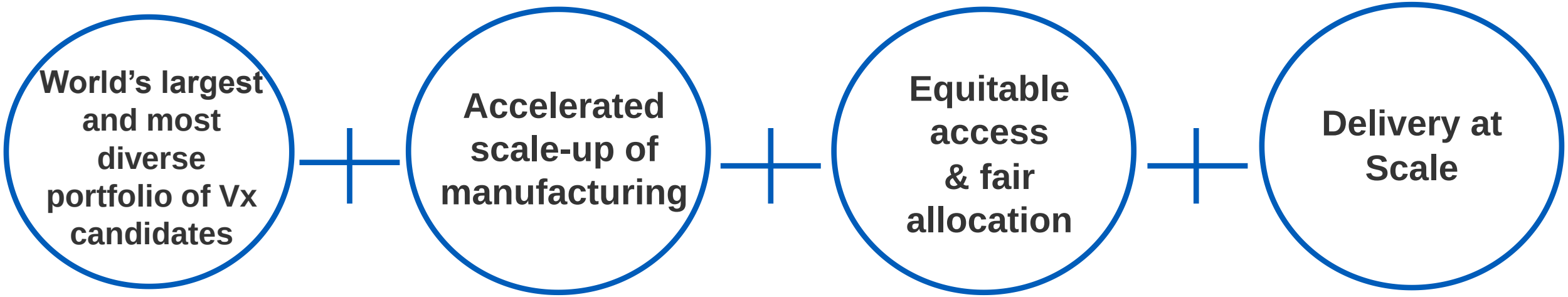
- Update on UCC tender

BREAK (5 minutes)

- Gavi 5.0 planning update
- Update on timelines for SDD/ILR tender in 2021

COVAX Facility overview

COVAX Facility: An end-to-end solution focused on transparency, global access and impact



- To secure 2 billion doses to all Facility participants by end of 2021
- Rapid progress in few months – pivot from design to operationalisation

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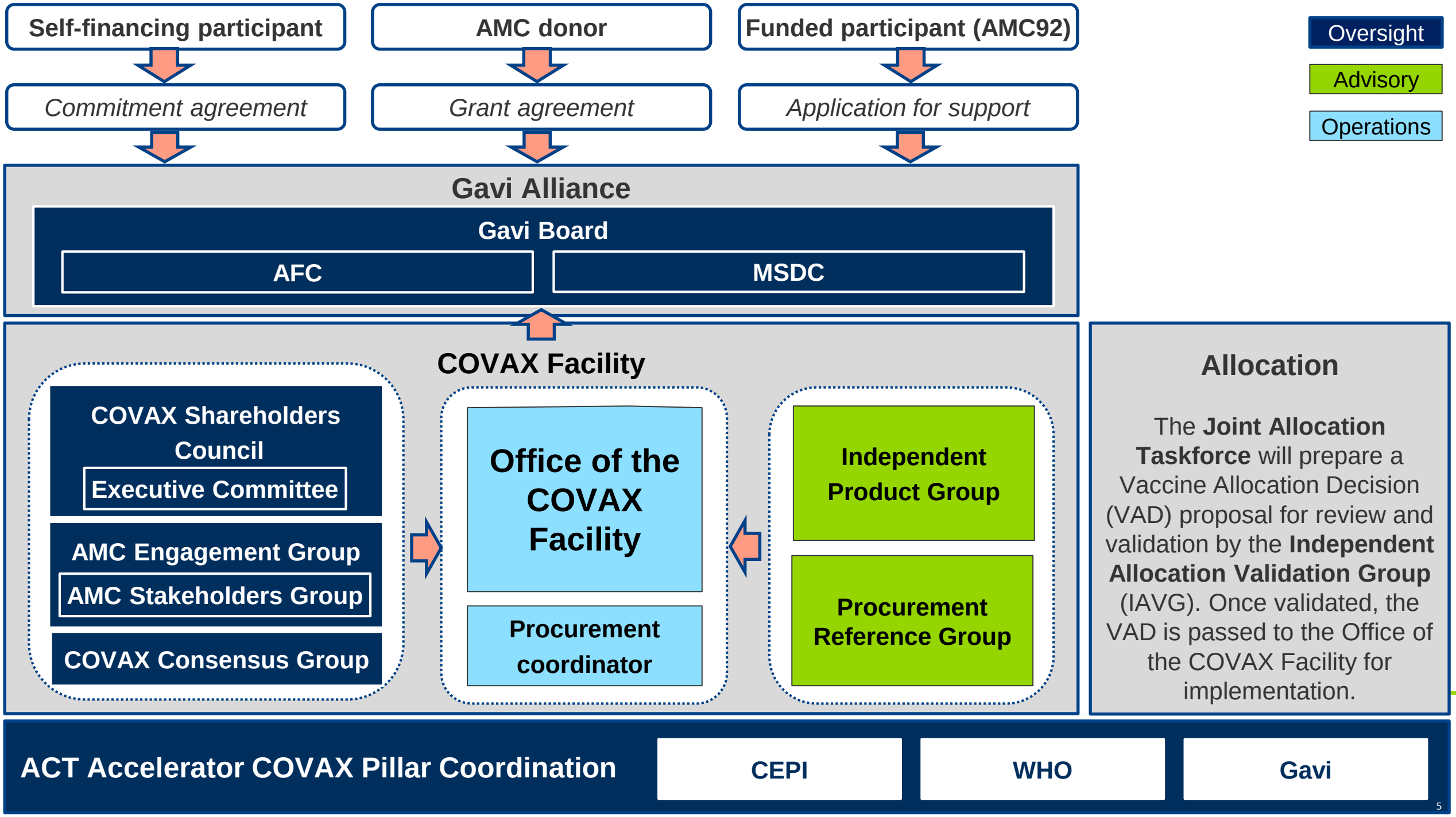
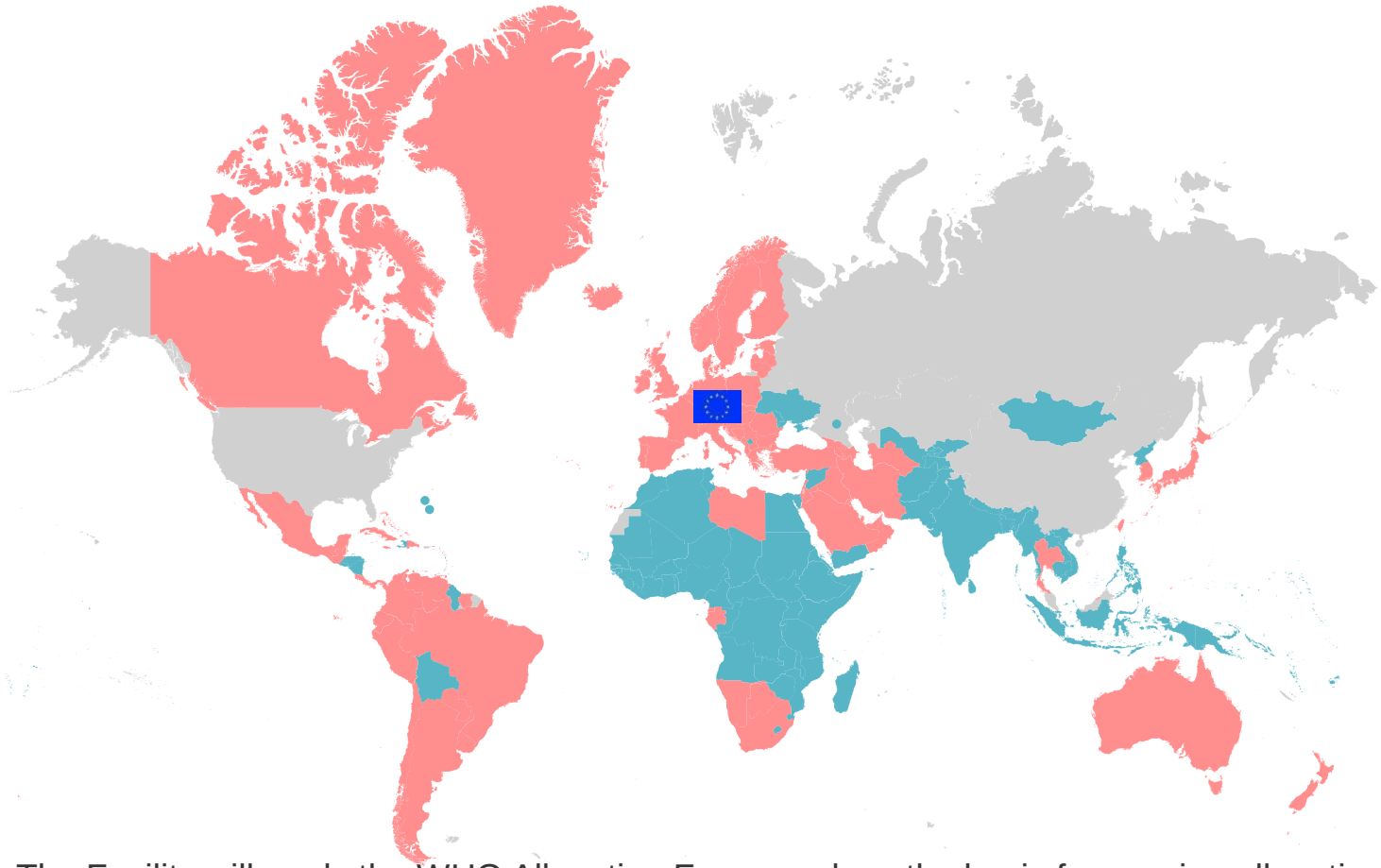

Self-financing participant
AMC donor
Funded participant (AMC92)
Commitment agreement
Grant agreement
Application for support
Oversight
Advisory
Operations
Gavi Alliance
Gavi Board
AFC
MSDC
COVAX Facility
COVAX Shareholders Council
Executive Committee
AMC Engagement Group
AMC Stakeholders Group
COVAX Consensus Group
Office of the COVAX Facility
Procurement coordinator
Independent Product Group
Procurement Reference Group
Allocation
The Joint Allocation Taskforce will prepare a Vaccine Allocation Decision (VAD) proposal for review and validation by the Independent Allocation Validation Group (IAVG). Once validated, the VAD is passed to the Office of the COVAX Facility for implementation.
ACT Accelerator COVAX Pillar Coordination
CEPI
WHO
Gavi

To date*, countries with approximately 90% of world population covered

65 Commitment Agreements received & 29 Team Europe; 92 AMC economies

186 participants are in scope of the Facility, of which 92 are AMC eligible



AMC 92

92 economies

3.9+ bn people

The Facility will apply the WHO Allocation Framework as the basis for vaccine allocation decisions

* End October 2020

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CCE needs for COVID-19 vaccines are being defined and supported by the Supply & Logistics sub-group within the COVAX/ACT-A Country Readiness and Delivery workstream, and is co-lead by WHO and UNICEF

Country Readiness and Delivery Working Groups:

Communication, Advocacy & Training
Global advocacy, communication and training materials

Data & monitoring
Data and system requirements and monitoring

Coordination
Project management coordination with partners and regions and planning delivery costing

Implementation & Guidance
Operational "how to" guidance and tools, split into 3 teams:

- **Vaccine introduction**
  Readiness checklist, delivery approach, vaccine use
- **Demand**
  Demand & acceptance, community engagement, risk communication, social listening
- **Supply & logistics**
  Supply distribution, logistics and cold chain

CCE

Stakeholders involved:

World Health Organization
unicef
Gavi The Vaccine Alliance
CEPI
IFRC
THE WORLD BANK IBRD • IDA | WORLD BANK GROUP
BILL & MELINDA GATES foundation

Note: While vaccine allocation (product type, volumes) is informed by supply chain considerations, it is an independent (non-Gavi) body within the COVAX facility. Its principles are being established by WHO in consultation with others (e.g. Gavi, UNICEF, SAGE, etc)

Note: Safety, Regulatory and Legal work is being conducted by different workstreams, but in close alignment and communication with the Country Readiness and Delivery group

COVID-19 CCE Response

CCE for COVID-19 Vaccines: Funding available and eligibility for Gavi-funded Cold Chain Support

- Gavi Board decision (end-Sept 2020) approved $150M of Gavi funding for catalytic support CCE and Technical Assistance; **Of this funding envelope, ~$50M is for CCE**

- Per Gavi Board decision, **priority will be for the 56 Gavi-eligible participants**
  - Support to India to be determined through a separate dedicated mechanism with Board decision on funding envelope in Dec 2020

- Remaining **35 AMC participants will also be eligible for CCE support,** based on need and availability of funding

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CCE for COVID-19 Vaccines: Scope of equipment supported

- **Focus will be on** equipping participants to meet vaccine storage needs at **upper levels of the supply chain (national, regional)**
  - **Limited support for lower levels (e.g. district)** will likely be available, where justified;

- **Primary focus on 2-8C (and -20C);** approach to investments in UCC under discussion (freezers + passives)

- **This support includes:**
  - Deployment and installation “service bundle” per CCEOP
  - Remote temperature monitoring (RTMDs)
  - Exploring additional services (e.g. short-term cold storage rentals to bridge capacity gaps)

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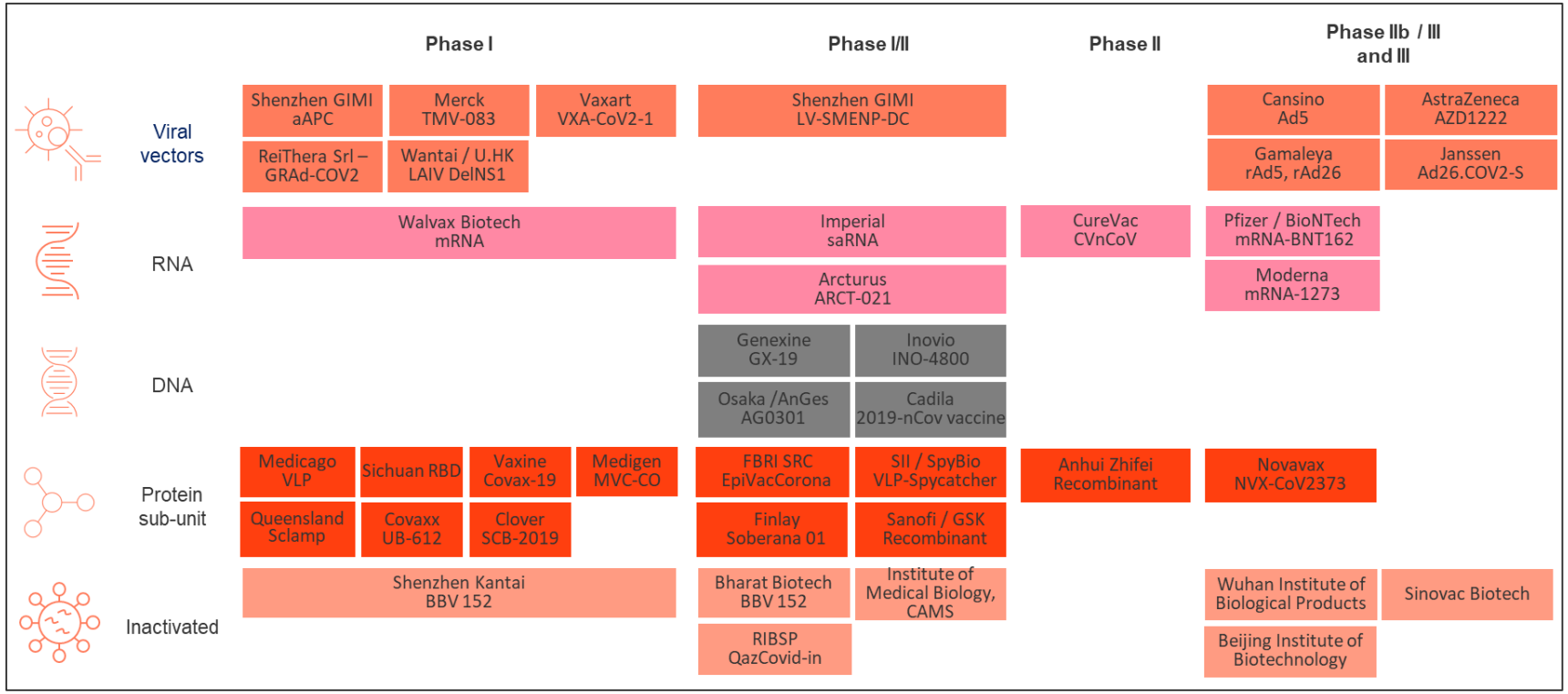
Timing, dose volumes and cold storage needs of first vaccine(s) to COVAX facility still uncertain

44 vaccine candidates are in clinical development, with 10 currently in Phase IIb / III and III; majority expected to require 2-8C or -20C cold storage

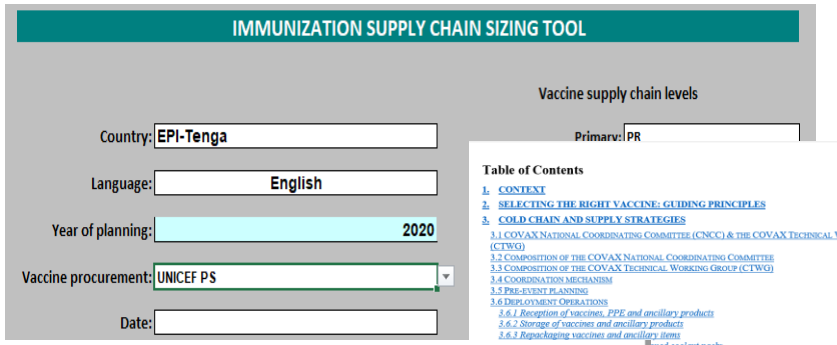


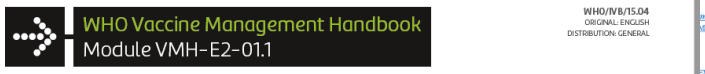
Factors impacting CCE needs:

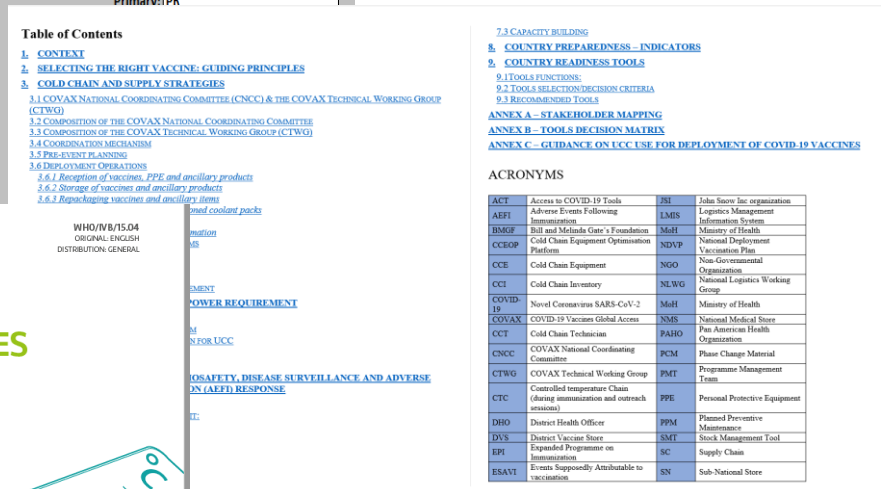
- Target population for COVAX doses (eg, 3-20%)
- Vaccine cold storage profile / shelf-life stability
- Timing of dose availability
- Number of different vaccines a country could be allocated (e.g., will switches happen?)
- Size and frequency of deliveries to national level
- Supply chain distribution strategy to lower levels
- Target populations and delivery strategies selected
- Funding allocations per country
- If -80C required, what storage and delivery strategies selected?

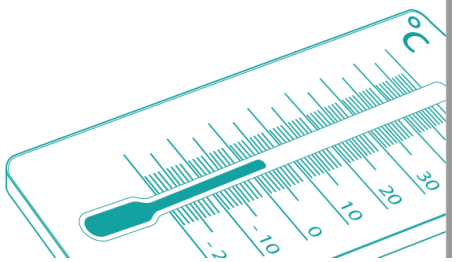
Country Readiness & Delivery in COVID context: Supply & Logistics

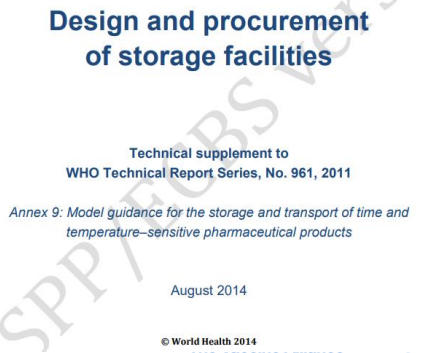
- Guidance to countries leverages existing practices and SOPs
- Built on the premise that the NLWG is the country coordination mechanism
- General guidance includes:
  - Mapping of all cold chain storage points and transportation options (public and private)
  - Gap analysis to determine needs utilizing existing tools









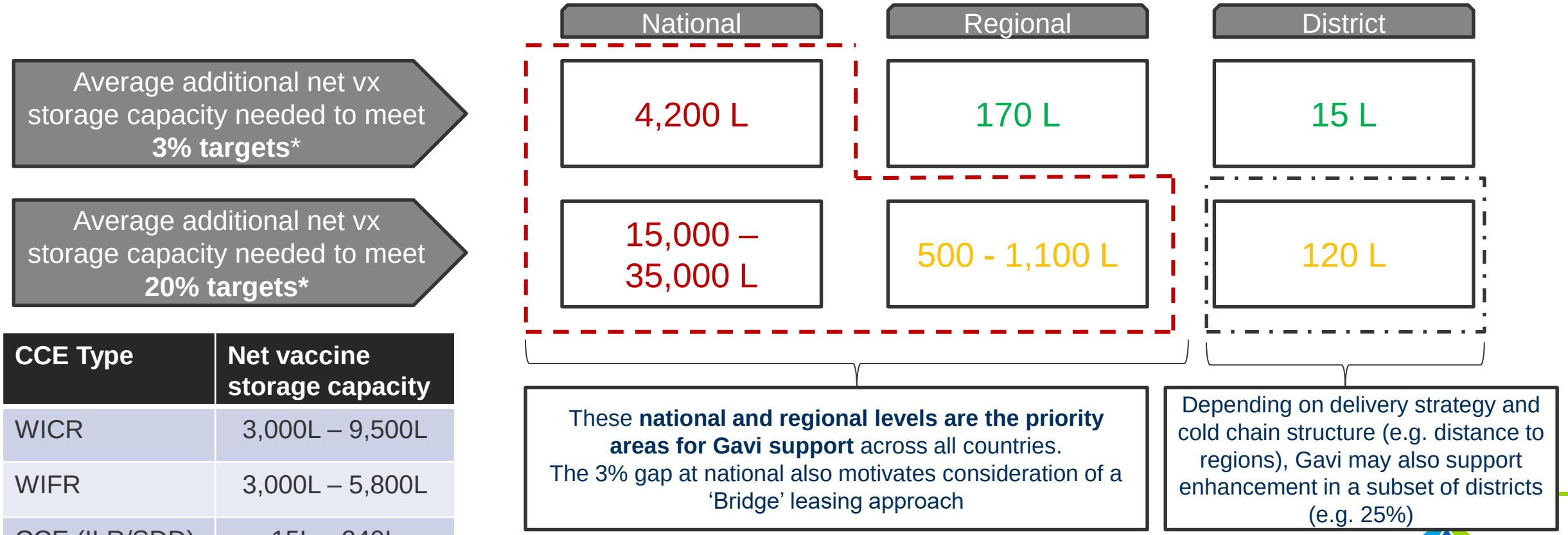


Guidance and Options include:

- Staggered vaccination campaigns
- Split shipments & increased distribution frequency
- Procurement of capacity (ICL and storage)
- Leasing

When we look at the impact of a COVID vaccine, needs are likely to be most acute at the upper levels of the cold chain and stage over time

Based on cold chain inventory (CCI) and modelling data, we find that 2-8C/-20C storage gaps are most acute at the higher levels of the cold chain, with lower levels expected to better absorb COVID-19 vaccine volumes



CCE Type	Net vaccine storage capacity
WICR	3,000L – 9,500L
WIFR	3,000L – 5,800L
CCE (ILR/SDD)	15L – 240L

*Across all volume scenarios, we assume multiple deliveries of vaccine -- National (2 - 4), Regional (4 - 8), District (4).
NB: National level volumes will be heavily influenced by vaccine availability and international freight conditions.

CCE for COVID-19 vaccines: Modelled NEEDS estimate for additional CCE capacity at 2-8C and/or -20C (number of units); Gavi funding will not meet full needs

Target population	National level – WICR	Regional level - WICR	Regional level – ILRs	Regional level – mains + SDD freezers (primarily for ice packs)	District level - ILRs	District level - SDDs	District level – mains + SDD freezers (primarily for ice packs)
20% of AMC56	45 - 215	20 - 55	1,050 - 2,700	600 - 1,550	1,500 - 4,250	500 - 1,450	5,250 - 14,000
20% of AMC92	100 - 500	125 - 300	1,600 - 4,000	1,000 - 2,600	4,500 - 12,000	1,500 - 4,000	9,700 - 25,900
20% of AMC91 (excluding India)	75 - 300	50 - 140	1,600 - 4,000	900 - 2,350	3,350 - 9,000	1,075 - 2,900	9,150 - 24,500

Key assumptions:

- Assumes 100% vaccines countries receive to vaccine 20% of their population require 2-8C or -20C, with majority of vaccines requiring 2-8C
  - Upper range of 2-8C CCE needs estimates assumes 100% of COVID-19 vaccines countries receive need 2-8C
  - 2-6 deliveries per campaign to national level; 4 deliveries per campaign to lower levels
- 10R dose vaccine vials with a 3% wastage rate
- Where country CCI capacity data was unavailable, we assumed no excess capacity for COVID-19 vaccines; this is likely an over-estimate of needs
- Freezer capacity needed for ice packs may be reduced if countries opt to rent this cold space or depending on how they organize vaccine distribution to lower levels of the health system; additional freezer capacity needed for ice packs and national level not estimated
- Excludes any recent procurement through UNICEF or by countries directly with suppliers to address anticipated COVID CCE gaps

Note: Actual country needs will be verified through country CCE support applications expected to be submitted from end November onwards

While AMC immunization programs are better positioned to manage traditional profile vaccines (2-8C, -20C), some may require (or opt for) private sector solutions to upper-level storage needs in the near term rather than only procure CCE to meet needs

Many central and some regional/provincial level stores operate with tight storage margins, which may be constrained by COVAX doses in some settings.

Challenges that have been identified by Alliance partners include:

- Potential **long lead-times** to deploy large-format cold storage (e.g. WICRs)
- **Difficulty preparing sites** to install large-format cold storage (e.g. power access, sufficient floor space / enclosure availability)
- **Lack of long-term utility** for large-format cold storage (i.e. repurposing post-COVID);

In light of this, the Alliance would like to explore the ability of logistic service providers (national, regional and global) to provide solutions to countries to the following scenarios.

Scenario B1 (Bridge Lease)

AMC Participant secures access to supplemental national-level and/or regional storage for 3-9 months as 'bridge' until installation is completed

Scenario B2 (Long-Term)

AMC Participant secures access to supplemental national and/or regional storage for 12 -24 months (full COVID immunization period)

High-potential solutions will be ones that:

- Can be readily implemented with short lead-times (3-4 months);
- Are cost-competitive (in $/L/mo) with next-best alternatives (e.g. procuring WICR equipment for immunization programs)
- Demonstrate strong responsiveness to government accountability and service delivery needs.
- Are able to demonstrate how PQS (or equivalent) requirements will be met and monitored throughout the implementation period.
  - *Important where non-standard solutions such as reefer containers are being proposed.*

While considerable uncertainty exists and countries have not yet applied/indicated their actual demand, against available Gavi funding we estimate the following demand may materialize in 2020-2021

Equipment	Health system level(s)	Number of units
WICR (Nat/Reg levels)	Nat / Reg	200 - 300
ILRs	Nat / Reg / District	3,700 - 5,000
SDDs	District	200 - 500
Ice pack freezers	Reg / District	TBD
RTMDs – WICR systems	Nat / Reg	150 - 300
RTMDs – Fridge systems	Nat / Reg / District	3,500 - 5,000
Passives	Distribution	TBD

Notes:

- Some of the national level demand may not materialize as procured equipment; countries instead my choose more leasing options
- Break between ILR and SDD at district level highly undertain
- Freezer units and WIFRs not included as of yet; greater information on country delivery strategies needed to estimate volume of ice packs required (including any leasing of freezer space), as well as information on doses requiring -20C that will be supplied to AMC countries
- All demand subject to change given supply distribution strategies countries adopt, which includes dependencies upon vaccine shipment frequencies to national levels
- Excludes demand which may materialize outside of Gavi funding
- Excludes expected demand for India

To note: *Alternate funding sources (other donors, domestic financing) and demand outside of AMC92 and/or Gavi funding are not included in these estimates*

Ultra-cold chain (UCC, -80C) vaccines pose a challenge for AMC participants given their stringent storage requirements and the lack of existing capacity

At present, there is no UCC vaccine in the COVAX portfolio. However, some promising COVID candidates have indicated UCC requirements, and as such may end up being a key part of the dose pipeline for COVAX.

UCC vaccines would pose several challenges for AMC participants, including:

- The **lack of existing UCC install base** within the health/immunization systems;
- The **time-limited nature of need for UCC capacity,** as countries would seek to transition towards more traditional vaccines as available;
- Complicated **handling and distribution requirements**, particularly where UCC products have limited stability at traditional storage temperatures (e.g. < 7 days)

Given these challenges, the Alliance would like to explore the ability of logistic service providers (national, regional and global) to provide solutions to countries to the following scenarios.

Scenario A1 (Wide Access)	Scenario A2 (Cluster)	Scenario A3 (Single)
All 92 AMC participants receive a small volume (e.g. 1%) of UCC vaccine over a single quarter, before transitioning to traditional profile vaccine.	A cluster of AMC participants in the given region receive large volumes (up to 20% of population) of a UCC vaccine over the course of 12 months.	A given AMC participant receives large volumes (20%) of a UCC vaccine over 12 months.

High-potential solutions will be ones that:

- Can be readily implemented with short lead-times (3-4 months);
- Are cost-competitive (in $/L/mo) with next-best alternatives (e.g. procuring UCC equipment for immunization programs)
- Demonstrate strong responsiveness to government accountability and service delivery needs.

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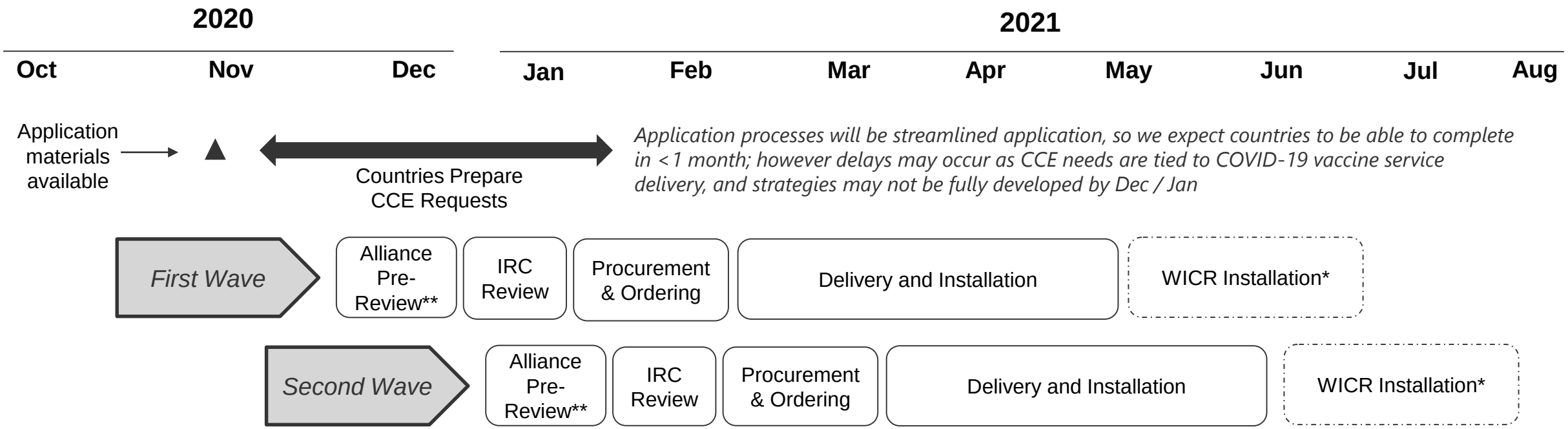
The Alliance is aming to finalize application materials in early November, which would allow the first applications to enter review / pre-review by December. Applications will be simplified versions of CCEOP applications. Procurement expected 1H 2021.

Indicative Timeline for Application Processing



A key bottleneck for this process will be the availability of an **updated cold chain inventory + operational deployment plan**. We are highly encouraging countries that are not already planning for this to do so now.

*Walk-in Cold Rooms (WICRs) often have specialized deployment requirements (levelling, power stabilization, site prep) that can extend timelines, particularly when multiple units need to be deployed at a single site (e.g. national stores)
** Feedback from Alliance members on pre-review mechanisms is still pending

Procurement process for COVID-19 CCE: Expedited & simplified version of CCEOP process

- **In the COVID-19 emergency context, procurement processes will be a hybrid between the CCEOP and standard UNICED SD CCE Procurement Services approaches**
  - **Top priorities will be efficiency, supply availability, VfM and maximizing meeting country needs**
    - Market shaping considerations and country preferences will be secondary to the above priorities
    - In their applications, countries will be asked to include 3 brand preferences, and may be allocated any of these brands; however a portion of demand may be allocated to other suppliers based on above priorities
  - **No country joint investment requirement for COVID-19 CCE needs**
  - **Some of the demand stated in applications may be fulfilled via leasing instead of purchasing equipment**

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Q&A

Update on UCC Tender

unite for children

unicef

ULTRACOLD CHAIN EQUIPMENT

Preparedness for **COVID-19 vaccine** roll out **and** future **Ebola outbreak** response

Tender objectives:

1. To understand the current UCC equipment market situation and
2. To identify potential suppliers capable to respond to sudden surge in demand.

Goal:

- Long term arrangements for 12+12 months

ULTRACOLD CHAIN EQUIPMENT TENDER (1)

Requirements:

- **Technically acceptable** UCC equipment suitable for vaccine storage at ultra-low temperature; **deployable** in LMIC countries;
- Sufficient **production capacity** to quickly supply larger volumes of equipment;
- **Competitive prices**.

ULTRACOLD CHAIN EQUIPMENT TENDER (2)

Products and forecast (2021-2022):

Type	Volume	Low demand	Medium demand	High demand
Small	≥ 80 – <300L	0	0 – **3,000**	up to 9,000
Medium	≥300 – <600L	0	**700** – 1,400	up to 2,100
Large	≥ 600 L	0	**50** – 500	up to 1,000
Transport box				

Demand/needs continue to evolve

ULTRACOLD CHAIN EQUIPMENT TENDER (3)

Response:

- **Invitees:** 12
- **Response:** 8
- **Models offered:** 63
- **Considered for technical evaluation:** 21

Timelines:

- Technical evaluation in progress (mid-Nov 2020)
- Commercial evaluation to follow (end-Nov 2020)

5 Minute Break

Updates: CCEOP in Gavi 5.0

Gavi 5.0: CCE Policy updates

Funding for CCE in Gavi 5.0	• From 2017-2025 the total Gavi investment in CCE through the CCEOP/HSS platform will be up to $400M (inclusive of the current CCEOP funding for $250M) • Additional ~$50M for CCE for COVID-19 response in 2020-2021
CCEOP integration back into HSS grants is currently paused for an anticipated 18-24 months.	• CCEOP will continue to operate as a standalone platform • Prior to operationalizing the CCEOP integration the question of ring-fenced funding for CCE within HSS grants will be decided by Gavi's Board
Continuation of the requirement is country joint investment is up for decision in June 2021	• Gavi's Board will make a decision if country joint investments will remain a requirement of the CCEOP, or if the joint investment will be removed and programme sustainability goals will be achieved through a different approach
Operational process optimizations	• Gavi and UNICEF revisiting application requirements & processes, and procurement processes & approaches to address bottlenecks and create greater efficiencies / reduce delays

Key focus areas for CCEOP updates in Gavi 5.0

- **CCEOP Platform eligibility requirements**
  - Product categories
  - Technical requirements for included products
- **Market Shaping & Procurement Strategy**
  - Adjustment to Roadmap strategies and goals to sustain and build on healthy market gains
  - Align to new Gavi 5.0 Market Shaping Strategy (all vaccine and immunisation-related products)
- **Innovation**
  - Performance monitoring / field data
  - Increased focus on country uptake of innovations

Timelines for various workstreams

Q4 2020

- Consultations and / or surveys with stakeholders (partners, suppliers, countries)

Q1 2021

- Finalize Roadmap update
- Gavi 5.0 demand forecast to be released
- Procurement strategy updates: Long term ILR/SDD equipment and SB LTA tender *(more info later today)*

CCEOP platform-eligibility update for Gavi 5.0: CCE Product Categories

The Alliance is considering if any additional CCE product categories be added that are key for EPI programmes and reaching last mile/ zero-dose populations, and soliciting feedback from country-level stakeholders, global partners and CCE suppliers. Key to consider are what programme challenges any new product categories address, especially at the last mile, and harmonising between HSS and CCEOP platforms.

CCEOP platform currently supports the following CCE product categories for CCE that are prequalified by WHO PQS:

- ILRs / SDDs
- Freeze free passives (long-term storage, cold boxes, carriers)
- 30 DTRs (including bundled with fridges)
- RTMDs for fridges/freezers + data costs
- PQS voltage stabilizers (regular and extended)
- Spare parts

HSS platform supports the following:

All CCEOP categories (including PQS CCE not meeting CCEOP requirements)

AND

- WICR / WIFR
- RTMD for WICR/FR + data costs
- Standard passives
- Non-PQS voltage stabilizers (regular and extended)
- In theory: UCC; energy harvesting kits, others TBC
- Maintenance
- Transport vehicles

CCEOP platform-eligibility update for Gavi 5.0: Technical requirements

The CCEOP currently has 5 platform eligibility requirement:

1. User-independent (“Grade A”) freeze protection
2. Extended ambient temperature operating range (+10C to +43C)
3. ILR/SDDs bundled with 30 DTRs
4. ILRs bundled with voltage stabilizer
5. Country ownership of data (as of Sept 2020)

FEEDBACK REQUESTED:

- If any new PQS TPPs are selected to become CCEOP requirements ahead of schedule, what are the feasible timelines from suppliers for implementation?
- Inclusion of RTM / EMS (either integrated or bundled, optional or mandatory) also under consideration

Key to note:

- Any updates to platform-eligibility requirements should have a clear programmatic rationale – especially in how they are key to improve equity / reaching last-mile & zero dose populations
- Also under consideration: harmonizing technical requirements across Gavi funding streams prior to CCEOP and HSS integration *(note: timeline TBD)*

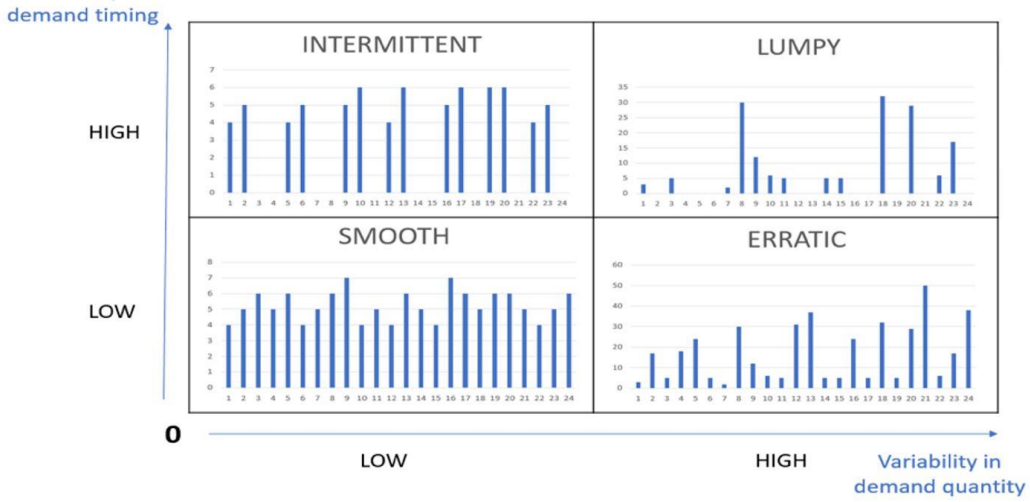
CCEOP **Demand Volatility (DV) Analysis**

Objective: Gavi and UNICEF are working with a management consultant on an external review of the Gavi-funded CCE market to better understand the specific types of volatility within the market and what drives this volatility, and to enable generation of appropriate solutions to address challenges within the Alliance's control

Process:

1. Classification of demand volatility (analysis of data)
2. Analysis of Alliance processes (analysis of data + KIIs)
3. Sources of volatility analysis (analysis of data, KIIs)
4. Consultations / survey of partners and suppliers to inform/verify results & discuss potential solution space

Demand Volatility Classification Patterns:



Timeline:

- Data collection, analysis, KIIs: Aug – Oct 2020
- Consultations: Nov-Dec 2020
- Results finalisation and discussion of potential solutions: Q1 2021

Aggregate Demand Volatility **(DV) Classification**

This is a summary analysis based on CCE partially to fully funded by Gavi (CCEOP + HSS with SB) and procured by UNICEF SD.

Observations

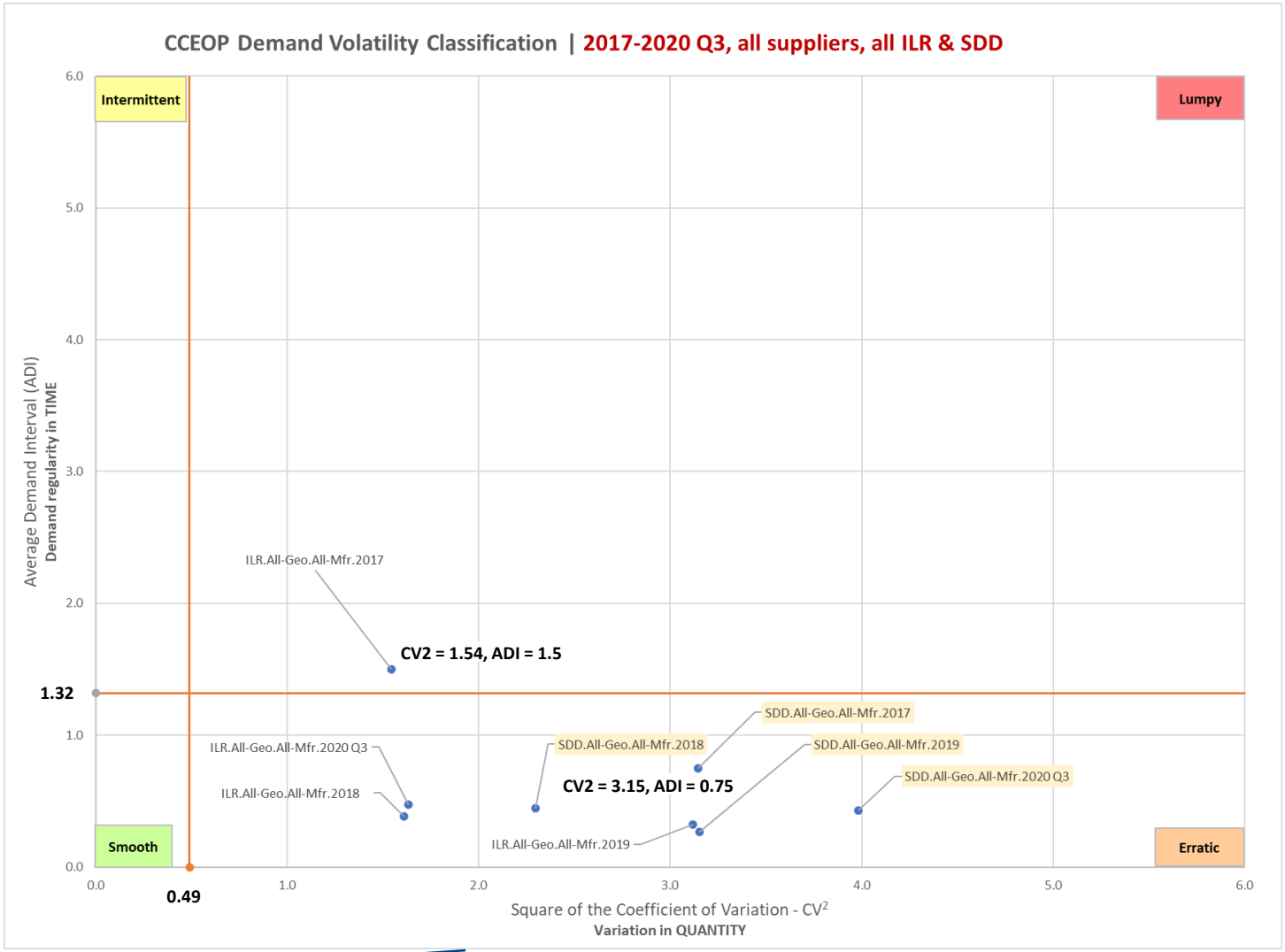
1. At the aggregate level, 'Erratic' demand is most prevalent.
2. Includes aggregate demand patterns of ILR and SDD products deployed through the CCEOP from 2017 through 2020 Q3, shown by year.

ADI – A measure of demand regularity in TIME.

- The average interval between two demands.
- *"All ILRs in 2017 (12 periods) had 8 demand buckets, ADI = 12/8 or 1.5."*

CV^2 – A measure of variation in QUANTITY.

- *"For all ILRs in 2017, the variation in quantity was 1.54, 50% less variation than SDDs at CV^2 of 3.15."*



Definitions:

SMOOTH –regular in time and quantity, forecastable

ERRATIC – regular occurrences in time, high variations in quantity

INTERMITTENT – high variation in time interval, consistent quantities

LUMPY – high variation in time interval and in quantity

- DV classification informs useful management strategies.
- Only 'smooth' items are forecastable with a low level of error.

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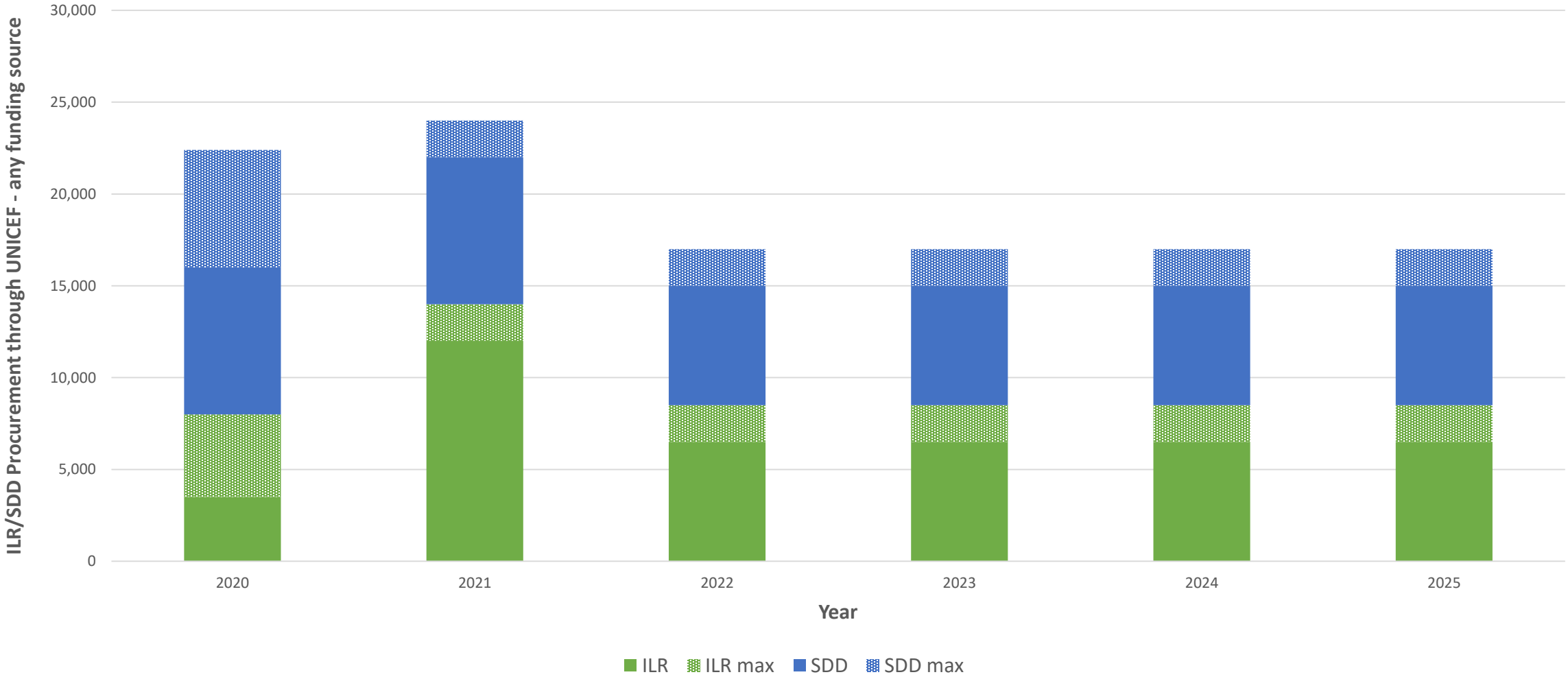
ILR / SDD equipment and SB tender strategy (short and long term)

unite for children

unicef

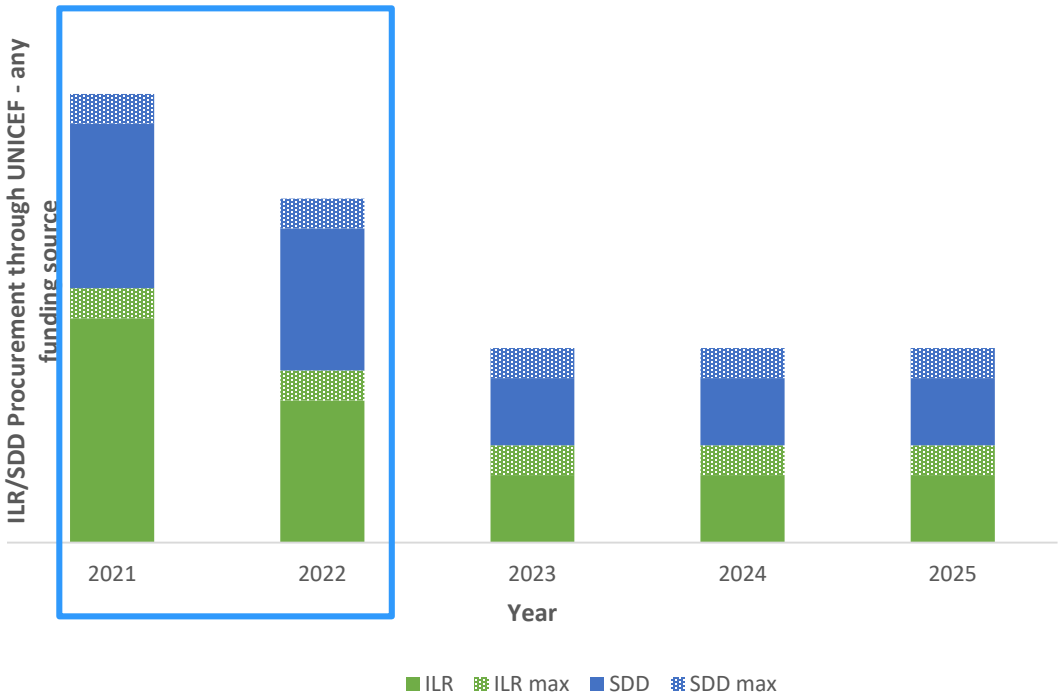
2020-2025 baseline long-term CCE demand forecast procured through UNICEF SD – all funding sources (Gavi + non-Gavi) and deployment options (SB + non-SB)



Potential COVID Impact on Size of CCE, Frontloading of Procurements, and potential for additional CCE required

Factor 1

Potential COVID Impact on Size of CCE and Frontloading of Procurements



Future CCE procurement impact:

- Potential for larger volume CCE procurements (eg, 100-200L+)
- Frontloading of CCE procurements likely in 2021 – 2022
- Additional CCE procured given potential needs above the 5.0 base forecast

Considerations:

- Additional impact on CCE needs of COVID diagnostics and therapeutics currently unknown
- Unknown the cold storage requirements (eg, 2-8C, -20C); additional ice pack freezing capacity for campaigns unknown
- Vaccine doses available to countries and in what years unknown as of now
- Country CC storage and distribution strategies also unknown (eg, private sector leasing, more frequent supply distribution rather than procure more CCE)

Long term ILR/SDD equipment and SB LTA tender schedule

Current ILR/SDD equipment and Service Bundle LTAs (against RFPS-2017-502469 and RFPS-DAN-2017-502485) was extended for a year end October and will expire end Q3 2021.

The process for renewing these LTAs will include the following components and timelines:

Q4 2020: Mobilization of Procurement Reference Group (PRG) for vetting of strategic direction

Q1 2021: Update on the MS Roadmap for ILR/SDDs

Q1 2021: Industry consultation and issuance of LTA tenders

Q2 2021: Bid reviews and award recommendations

Q3 2021: Issuance of LTAs

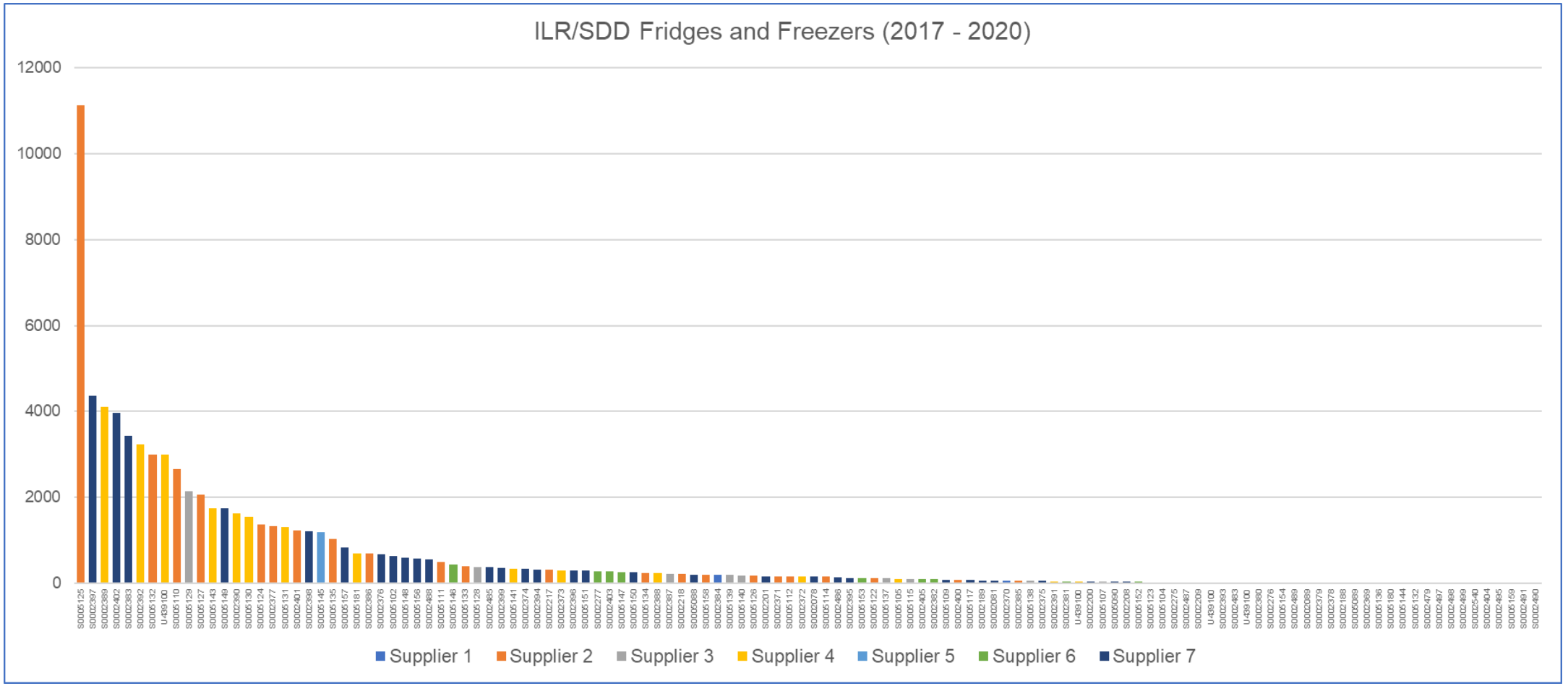
Strategic Reflections regarding new equipment LTAs (1)

To increase transparency and improve planning / budgeting conditions, we may need to:

- Break up product price components so that these clearly reflects the price on the minimum requirements and the add on (service) components.
- Simplify scale pricing structures against agreed up on intervals
- Reconsider / simplify product range intervals including in consultation with Programme (i.e. one volume size per supply level tier).

Strategic Reflections regarding new equipment LTAs (2)

>100 unique products have been pre-qualified (75 ILRs /SDDs now CCEOP platform-eligible), but less than half are in demand



Strategic Reflections regarding Service Bundling (SB) LTA

SB has overall been a success and will continue as a country choice option in the coming period.

The SB demand visibility for 5.0 is becoming less clear. Not all Gavi funded procurement will involve SB (delinking) and some non-Gavi funded procurement will involve SB (institutionalization of concept).

The Alliance and Industry have gained valuable insight in recent years and we – collectively – have a solid base for agile SB response once equipment demand emerges.

As such, current SB LTA set up expected to be reinforced with secondary bidding against LTA and potentially upfront fixed price ranges during the next LTA period.

Country specific SB tender calendar is likely to discontinue. Instead, UNICEF will share running yearly forecast supplemented with aggregated procurement YTD.

Market Shaping & CCE Innovation questions under exploration or being revisited by Alliance in 5.0

The Alliance is considering the following questions as we look to update the CCE Market Shaping Strategy as part of the CCEOP platform update for 5.0, in consultation with partners, countries and suppliers (Q4 2020 – Q1 2021)

Market Health

- What progress has been made against current market shaping Roadmap goals and targets and what changes are needed?
- What market shaping tools / strategies should continue and what additional tools / incentives might be needed?
- What does a healthy demand look like?
- What procurement strategies best enable meeting of programmatic and market shaping goals?

Approach to Innovation

- What innovations will best help reach unimmunized groups in rural /urban settings, and what is the demand for these products?
- What are the key incentives (within Alliance control) to foster continued innovation?
- What are the most critical new TPPs to see widespread uptake of?

Gavi The Vaccine Alliance

Thank you