Gavi and UNICEF – CCEOP, IMPT and procurement updates

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Agenda

• Overview of the CCEOP programme
• CCEOP progress to date
• Covid-19 impact and mitigation measures
• CCEOP impact analysis & lessons learned
• CCE Programme in Gavi 5.0
• Intelligent Maintenance and Planning Tool (IMPT)
OVERVIEW OF THE CCEOP PROGRAMME
The Cold Chain Equipment Optimisation Platform (CCEOP) was established with 3 primary objectives:

**Coverage & equity**

Ensure functioning cold chain equipment is available wherever it is needed to support coverage and equity and protect vaccines.

- Currently Equipped: 90
- Country Plans: 105
- Potential Impact: 135
- Facility extension: 90
- Facility upgrade: 90

**Accelerate uptake**

Help countries introduce new, climate-friendly technologies, better suited to their needs.

**Market shaping**

Shape the market to help accelerate innovation, improve supply and reduce price.

**Total cost of ownership**

2,3, USD

- Absorption: 4,990
- SDD: 2,850

-40% reduction

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1: Estimations for 55 countries eligible for platform funding based on Board presentation (excluding India)
2: Based on Board presentation assuming a Dometic RCW 90EG (24L) as absorption and a BFRV15 (15L) as SDD
3: Operating expenses estimated from PATH TCO calculation model assuming 10 year lifetime of equipment

Through the platform, countries have access to “optimal” equipment which will improve vaccine potency in-country

With the 5-year $250M funding envelope, the CCEOP effectively represents a $50M per year “insurance policy” to safeguard Gavi’s ~$1.3B per year vaccine investments

Optimal products, to better protect vaccine potency

- “Grade A” freeze protection
- Extended ambient temperature range of equipment (i.e., 10 to 43°C)
- Bundled voltage stabilizers
- Bundled temperature monitors

“Service bundle”, to deploy CCE more quickly and reliably

- Suppliers are accountable for in-country distribution, installation, and training of end-users at facilities
- MOH / UNICEF or supplier is responsible for customs clearance, depending on the country situation

In 2020 Gavi added ‘country ownership of data’ to the CCEOP requirements for equipment performance data generated by any Gavi-funded CCE
Various tools are now available to countries and technical partners to support CCEOP applications & equipment selection: How do stakeholders use these and what else is needed?

- **PATH Total Cost of Ownership (TCO) tool**
- **CCEOP Application guidelines**
- **CCEOP Technical & target requirements, and other application tools and templates**
- **UNICEF SD CCE Catalogue**
- **WHO PQS Catalogue**
CCEOP PROGRESS TO DATE
The CCEOP is addressing critical gaps in the cold chain, with 51 countries approved, representing ~60-65k units of optimal CCE in-country by 2020. Expected CCEOP total end 2021: ~80-85k units.

65% of CCE to replace low performing or outdate equipment significantly increasing vaccine safety; 25% is targeted to extend access to newly-equipped facilities; 10% to expand capacity to meet RI and NVI storage needs.

The 51 approved countries (end Q3 2020) are positioned to radically transform the cold chain - both in performance and coverage impact.

* Internal Gavi approvals and Decision letters pending

48,658 units on PO
39,816 units Delivered to country
33,306 units installed
Quality of Service Bundling has been good with 84% PII visits classified as ‘acceptable’.
Initial country applications led to a less healthy market development, but with corrective action by the Alliance and responsiveness by the Industry, the situation is gradually improving.
>100 unique products have been pre-qualified (75 ILRs /SDDs now CCEOP platform-eligible), but less than half are in demand
COVID-19 IMPACT AND MITIGATION MEASURES
COVID-19 impact on CCEOP: Important delays, but the situation is improving

COVID-19 IMPACT ON CCEOP IMPLEMENTATION

- Applications – Initial delays for submission; Gavi organised a special IRC session to allow for submissions that were delayed
- ODPs and country approvals – Country lock downs contributed to delays in some countries extending implementation timelines
- Shipments – Some shipments faced delays given lockdowns, and suppliers requested to store CCE until shipments could be facilitated; additional costs incurred for storage in many cases
- Deployments – Delays were observed in many countries attributed to lockdowns, lack of site readiness and rainy seasons, though deployments were able to proceed / resume in some countries (including some that are now completed)
- PIIIs – PIIIs largely paused, though looking to resume in many countries in Q4 2020

The Alliance implemented mitigation measures, including working with governments to secure special arrangements for continued deployment wherever feasible & with manufacturers to manage storage needs & costs
CCEOP IMPACT ANALYSIS & LESSONS LEARNED
Evaluating the impact of the following CCEOP objectives

- Strong and efficient supply chains to deliver potent and safe vaccines
- Increased storage capacity especially at peripheral levels
- Contributing to improving immunization coverage
- Reducing inequities and reaching the last child

Trend Analysis of 10 countries (2019, UNICEF analysis):
Haiti, DRC, Djibouti, South Sudan, Niger, Sierra Leone, Liberia, Uganda, Malawi & Togo
Impact analysis: Key findings (1 of 2)

**IMMUNIZATION COVERAGE**

- The trend shows an increase in immunization coverage and a decrease of penta3 drop-out rate and children missed (as observed during field visits at most rural and hard-to-reach HCs)

<table>
<thead>
<tr>
<th></th>
<th>Wakiso District - Uganda</th>
<th>Sierra Leone</th>
<th>Bombali District</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q1-Q2 2016</td>
<td>Q1-Q2 2019</td>
<td>2017</td>
</tr>
<tr>
<td>Penta3</td>
<td>75%</td>
<td>90%</td>
<td>76%</td>
</tr>
<tr>
<td>MCV</td>
<td>72%</td>
<td>90%</td>
<td>89%</td>
</tr>
</tbody>
</table>

source: Wakiso District Biostatistician data

- Parents are motivated to bring their child to HCs for immunization as they know it will take them less time from work and family because:
  - the distances to walk to the HCs are shorter
  - the waiting times have decreased
  - enough vaccines will be available

  ➢ Which results in increased number of children immunized each year

<table>
<thead>
<tr>
<th></th>
<th>Sierra Leone SLIMS HC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># of children immunized</td>
</tr>
<tr>
<td>Penta3</td>
<td>1,377</td>
</tr>
<tr>
<td>MCV</td>
<td>1,566</td>
</tr>
</tbody>
</table>

source: internal data from HC

- Number of immunization sessions increased with new CCE:
  ➢ from 1-2 times a week up to 5 times a week for static, on average
  ➢ from 1-2 per month up to 3-4 per month, on average

**EQUITY**

- **Outreach sessions** have increased in the rural and underserved communities because the accessibility of vaccines, cool packs and storage capacity have increased due to extension of system reach from solar powered CCE; it results in:
  ➢ immunizing more children that don’t normally come to health facilities
  ➢ allowing HWs to get to know the families and know who has not received immunization or who is pregnant

- A significant increased in storage capacity and accessibility of vaccines in underserved communities is seen as multiple new HCs that had no CCE before are now becoming sub-hub for their neighbouring HCs. This results in:
  ➢ Increasing number of outreach sessions
  ➢ Increasing in number of children seen during a session
  ➢ Increasing the quality of immunization services to last mile children
Impact analysis: Key findings (2 of 2)

QUALITY OF CARE

- Increased trust from health workers because:
  - they are no longer afraid of losing vaccines due to electricity outages or gas shortage
  - they will not have to turn away children during a session due to a vaccine shortage
  - the risk of AEFI happening is decreased with reliable refrigerators

- This is a direct impact of:
  - increased storage capacity
  - potent vaccines available at all times as the new CCE reliable
  - reducing the risk of adverse events following immunization as told by the HWs

- New SDD refrigerators are significantly impacting the reliability on the vaccine potency and accessibility in the last mile Service Points (SP) which results in:
  - Increasing HWs motivation to conduct more immunization sessions
  - HWs no longer need to ensure that they have budget and procure gas and distilled water on time to avoid breakdowns of CCE (gas is $32.50/mth & transport to collect water & vaccines at DVS $6.50/trip)
  - Remote Temperature Monitoring Devices (RTMD) brings an additional layer of security to ensure vaccines potency

COLD CHAIN EQUIPMENT MANAGEMENT

- All countries increased their storage capacity significantly with new equipment. Three strategies were used:
  - equipping service points (SPs) that had no equipment (7 out of 10 countries)
  - replace obsolete, non-PQS compliant or broken equipment (all 10 countries)
  - expand storage capacity (all 10 countries)
- Having new fridges in HCs, allows the HWs to store the oxytocin
  - In Uganda, a plastic box was provided to store the oxytocin separately from the vaccines
  - In Sierra Leone, they use a different a basket
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Key lessons learned from CCEOP evaluation* by JSI: Country-level report (2019 Midline Report)

• **Application and coordination of CCEOP**
  – Proper preparation for CCEOP deployment requires significant investment in time and budget, and needs to be taken into account during planning

• **Programmatic impact**
  – Immunisation service offerings increased across all countries, lending support to how functional CCE can expand EPI programmes reach

• **Deployment / Service Bundle**
  – The SBP has overall achieve its goals of timely installations (though some concerns about costs), with effective monitoring systems for deployment and allowed for minor deviations
  – Training by SBPs was found to be insufficient and required further improvement and clarifications on topics to be covered

• **Maintenance & CCE Monitoring**
  – Lack of clear mechanisms for monitoring CCE performance over time (after installation check) and providing feedback to manufacturers. Warranty processes are unclear in many places, with uncertainty who is responsible for reporting of breakdowns to UNICEF SD / PQS

*JSI is conducting a prospective evaluation of Gavi’s CCEOP in three countries (Guinea, Kenya, Pakistan) and at the global level for both programmatic and market shaping goals. More details available at https://www.gavi.org/our-impact/evaluation-studies/cceop-evaluation*

• **Market Shaping**
  – The CCEOP successfully incentivized new product offerings and led to early widespread uptake of PQS TPPs.
  – Increased product offerings did not organically lead to a healthy market distribution due to initial country preferences and later stage market shaping interventions have been needed to course correct
  – The CCE market continues to have volatility of demand, and efforts to smooth demand are needed in Gavi 5.0
  – Aggregate, annual forecasts have been highly accurate while product specific forecasts and timing of demand materialization have had greater variation

• **COVID-19**
  – While COVID-19 has resulted in delays to CCEOP applications and deployment, the PMTs continued to function / provide oversight
  – Maintenance and repair activities also continued in most countries during the pandemic
  – Demand for immunisation services has decreased, and not fully bounced back once suspended services resumed

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CCE PROGRAMME IN GAVI.50
Potential changes to CCEOP platform in next Gavi 5.0 strategic period (2021-2025) are expected in order to align with the mission of ‘leaving no one behind with immunisation’.
Programme design for ‘CCE in 5.0’: Product options and platform requirements

What changes / additions would you like to see to the following aspects of CCEOP?

**Product categories supported**
- SDDs and ILRs
- Long-term passive devices
- Freeze-free passive devices
- Temperature monitoring devices
- PQS Voltage stabilizers
- Spare parts

**Platform eligibility requirements**
- Grade A freeze protected
- Bundled / integrated voltage stabilizers
- Bundled 30DTRs
- Extended ambient temperatures
- Country ownership of data

**Other product considerations**
- Fridge volume bands: 30L increments

Any other products to consider for 5.0?

Any other eligibility requirements to consider for 5.0? (E.g. energy harvesting, humidity control)

Would a different approach meet programmatic needs?
Programme design for ‘CCE in 5.0’: Temperature Monitoring

Area of exploration: RTM (integrated or standalone) with fridge suppliers contracted for RTMD services

Method of inclusion of RTMDs in fridges

- Physically integrating RTMDs into fridges
- Bundling RTMDs alongside fridges, i.e., no physical integration, but RTMDs to be included in procurements and deployments by fridge suppliers

Data requirements

- Country ownership of data
- Countries should be provided with open APIs to redirect data into existing platforms / databases
- Other interoperability standards?

What are your reactions about these potential methods?

What would EPI supply chains find most helpful?
Other areas for the Alliance is exploring in 5.0

- Maintenance service offerings (or piloting of options)
- Scale up of de-linking (*pending conclusion and evaluation of pilots*)
- Innovation uptake / new ways of incentivizing continued innovation in the CCE market, taking into account forthcoming PQS TPPs
- Procurement and market shaping strategies will also be revisited
- Products and approaches to reach unimmunized populations (*e.g. potential greater focus on passive devices and other last mile innovations*)
Please send any feedback to the questions raised about Gavi 5.0 CCEOP platform design / requirements to:

- Karuna Luthra: kluthra@gavi.org
- Jalia Nanfuka: jnanfuka@gavi.org
INTELLIGENT MAINTENANCE AND PLANNING TOOL (IMPT)
Increased investments in vaccines and CCE in the last few years by countries, Gavi and donors emphasize the need for robust maintenance systems to protect these investments.

Results from the 2015-2019 EVM Assessments (EVMA) in 40 countries compared to prior cycles demonstrate that:

- Maintenance score has improved by 5% in most recent years
- Most Gavi countries do not meet the 80% target for preventive maintenance.
- And yet investments in CCE by Gavi and countries have increased significantly
- As the Alliance continues to explore various maintenance service offerings, the role of countries in establishing functional and efficient maintenance systems is becoming more important
- IMPT emphasizes the use of existing RTM data to inform maintenance decisions at country and global level. This innovation will supplement existing interventions from Alliance partners and countries to address persistent challenges

Source: Gavi analysis of EVM scores (May 2020)
Overview of IMPT

IMPT is a tool that will:

• Provide aggregated CCE performance data (temperature, power, maintenance) at the country and at the global level
• Allow countries to plan proactively for maintenance and hold manufacturers accountable for warranties
• Support evidence-based decision making
• Act as a management and planning tool

IMPT is not: a day-to-day operational tool, an eLMIS or an RTMD dashboard

• Data is anonymized and aggregated before being input into IMPT to maintain data confidentiality
• Countries with smart RTM-enabled CCE or standalone RTM devices installed in the country can access the tool once rolled out
IMPT will help countries answer a broad range of questions with the field performance data generated.

- How are different CCE makes and models performing in the field?
- What are common spare parts?
- Does equipment meet performance and lifetime specifications listed in the PQS and CCEOP?
- How much should we budget for maintenance visits?
- Were my fridges installed correctly?

Note: Many years of consistent equipment performance data are needed for comparing the equipment to its lifetime specification.
Significant progress has been made on the development front despite delays in outreach to countries due to the COVID-19 situation and response.
Thank you
Additional Observations from 2019 Impact Analysis

- Having new technology CCE and adding refrigerators in HCs:
  - reduce transport cost
  - opens possibility to implement new system design for distribution
  - HWs no longer need to go out to procure gas, distilled water for batteries or collect vaccines for immunization sessions as often as before
- Waiting time for caregivers has decreased from 3-4 hours to 1-2 hours coming to vaccinate children
  - It also increased the number of father bringing their child to immunization
- The motivation and dedication of the health workers and vaccinators have increased significantly, as:
  - they trust the reliability of their new CCE
  - they no longer are afraid of running out of doses during a session
  - no longer afraid of having to turn away parents that walked for many hours
  - they have more time to do immunization activities instead of picking up vaccines every week