## Vaccine Vial Monitors: Lessons learned and how to be better prepared for the next pandemic

October 21, 2022



Photo courtesy of Umit Kartoglu

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## Compliments to UNICEF's Dashboard



#### Lessons Learned:

#### 1) Can VVM manufacturing capacity support pandemic and routine demand?

 Early on, we assumed demand would be 1-2 billion vaccine doses through COVAX potentially needed, with a mix of 10, 5 and 1 dose vials

#### Actions taken:

- o Made strategic purchases of raw materials to assure an uninterrupted supply of VVM
- Increased inventory levels on key VVM categories
- o Expanded frozen storage capacity to manage higher finished goods inventory
- Added headcount in manufacturing and QC departments

#### Temptime made and shipped over 1 billion indicators for routine and COVID vaccines in 2021 alone.



#### Lessons Learned:

#### 2) VVM does not delay access to novel or pandemic-quantity vaccines

- One out of 11 suppliers has put VVM on COVID vaccine
- Urgency for supply, a worry over delaying the process, and not having sufficient stability data were rationales for not applying
- Sinopharm ordered 200 million VVMs for single dose vials
- Our production for Sinopharm was about 12 million VVMs/day
- VVM was included on 20% of 2021 vaccine deliveries, and 10% across 2021-22. It did not delay access
- Supply to Sinopharm also met their timing requirements



#### Lessons Learned:

#### 3) For VVM, only accelerated stability data needed

- As the world grapples with generating real-time stability data on shelf life for novel and variant vaccines, VVM selection only requires accelerated stability data.
- Selecting a VVM type is not an interdependency, but a complement, ensuring what is produced remains effective as it moves through the cold/supply chains.
- During the pandemic, VVM was moved to the preferred category. Had it been critical (and accelerated testing was complete), it would not delay introduction.

"Use of Stability Modeling to Support Accelerated Vaccine Development and Supply" Use of Stability Modeling to Support Accelerated Vaccine Development and Supply - PubMed (nih.gov)

#### Recap:

- Temptime has excess capacity to support pandemic and routine demand
- Adding VVM does not slow down production or access to novel vaccines
- Selecting a VVM type only requires accelerated stability data, and ensures every vial of pandemic vaccine with a VVM can be confidently delivered
- As WHO, UNICEF, SAGE, and industry are discussing the future of COVID vaccines, we hope the programmatic value of VVM is considered moving forward





#### Strong Endorsement at the Front Line

HCW and supply chain staff very positive attitude for VVM use on COVID



#### **Surveys** e.g., PATH's Living Labs survey in East Africa

- "VVM's trustworthiness cannot be replaced by another validation test"
- "It makes me uncomfortable when I am giving the vaccine (without VVM) as with this COVID-19 vaccine"
- 98% of those HCWs surveyed said they were concerned or worse by the lack of VVM

### Improving Effectiveness

Knowledge, Attitudes, and Practices surveys in Kenya, Pakistan, and Ghana

Surveys in Kenya, Pakistan, Ghana show how well VVM is being interpreted:



- Surveys found that VVM is still easy and intuitive to use
- However, the surveys also showed weaker vaccinator interpretation of VVM at discard point; 83-85%
- Potentially remedied with mHealth tool, WHO globally rolling out their Effective Vaccine Management (EVM) App

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## Digital Innovation: VVM App Built into WHO EVM App



## WHO App (Today) and Temptime Innovations (Tomorrow)

What this App does versus future options

- Currently, the VVM tool is embedded within EVM App, which uses a human eye to judge actual VVM on vial and match with the image
- Confirms "use" or "discard"
- Provides a time estimate in days/months remaining on the VVM
- This app does not scan the VVM
- Zebra is developing a scannable barcode that will allow a mobile device to complement the human eye



## **Digitized Temperature Sensor – VVM or "eVVM"**

#### 2D barcodes on vials scannable with an Android device:

- Reduce time in recording BN, EXP date, vaccine
- Date, time and location of immunization and vaccinator
- Product authentication
- Serialized supply chain tracking
- Opportunity to link child data when combined with immu. card

#### Adding digitized temperature sensors will provide:

- Automated capture of VVM status
- Warning to HCWs
- View of heat exposure across whole cold chain
- Additional product authentication



ZEBRA TECHNOLOGIES

# Thank You

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