

VIPS Phase I executive summary: Combined Vaccine Vial Monitor (VVM) and Threshold Indicators (TI)

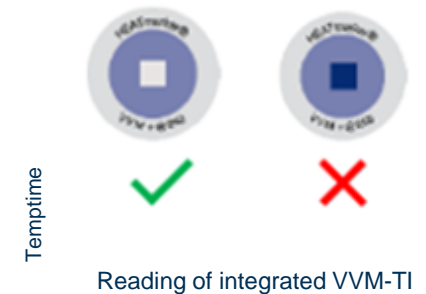
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Combined Vaccine Vial Monitor (VVM) and Threshold Indicators (TI)



About Combined VVM and TIs

- Currently, VVMs and TIs are not integrated. VVMs are placed on primary containers and standalone TIs are used in addition to VVMs when vaccines are kept in a controlled temperature chain (CTC). These TIs must be purchased and distributed separately from the vaccine and kept at temperatures below their threshold. They are placed in vaccine carriers and cold boxes (without icepacks) during CTC storage and transport.
- Although a VVM alone changes colour in response to cumulative heat exposure, its response is not rapid enough at higher temperatures (e.g. above 37°C or 40°C), whereas the TI reacts rapidly if exposed at or above a defined threshold temperature.
- A combined VVM-TI on primary containers undergoes gradual colour change up to a specified peak threshold temperature and rapidly reacts if exposed at or above the threshold temperature.
- There are two types of combined VVM-TIs:
 - **VVM and TI together:** both indicators are placed on the same label and require a review of VVM and TI separately.
 - **TI is integrated into the VVM:** combined features of both VVM and TI in one indicator, which looks and is interpreted identically to the existing VVMs.



Stage of development

- **WHO prequalification (PQ) specification and verification protocols** have been **developed and published**.
- One **integrated VVM-TI (VVM250-TI40)** has received **WHO prequalification**, however this is a product that does not have the appropriate specifications for currently qualified CTC vaccines.
- Other integrated VVM-TIs have been developed, but will need to pass regulatory and WHO PQ approvals.

Combined Vaccine Vial Monitor (VVM) and Threshold Indicators (TI) scorecard

Comparator: VVM on primary containers used with stand-alone TI



Quality of evidence: Low to Moderate

VIPS Criteria		Indicators	
Primary criteria	Health impact	Ability of the vaccine presentation to withstand heat exposure	Neutral
		Ability of the vaccine presentation to withstand freeze exposure	Neutral
	Coverage & Equity impact	Ease of use ^a	Better
		Potential to reduce stock outs ^b	Better
		Acceptability of the vaccine presentation to patients/caregivers	Neutral
	Safety impact	Likelihood of contamination	Neutral
		Likelihood of needle stick injury	Neutral
		Total economic cost of storage and transportation of commodities per dose	Neutral
	Economic costs	Total economic cost of the time spent by staff per dose	Better
		Total introduction and recurrent costs ^c	Neutral
Potential breadth of innovation use		Applicability of innovation to one or several types of vaccines	All vaccines are candidates.
	Ability of the technology to facilitate novel vaccine combination	No	
Secondary criteria			

Priority indicators - Country consultation		
RI* Facility	RI* Community	Campaigns
+	++	++
+	+	++
	+	+
		+
+		
++	++	+

* RI : Routine immunisation

++	Given significantly more importance
+	Given more importance
	Kept neutral

^a Ease of use can prevent missed opportunities and impact ability for lesser trained personnel to administer the vaccine, including self-administration

^b Based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities

^c Total economic cost of one-time / upfront purchases or investments required to introduce the innovation and of recurrent costs associated with the innovation (not otherwise accounted for)

Combined Vaccine Vial Monitor (VVM) and Threshold Indicators (TI): Antigen applicability



- Combined VVM and TIs could be **applied to all vaccines**, but is likely to be most **useful for vaccines prequalified for use in a CTC**.
- WHO CTC priorities on the VIPS priority antigen list include **hepatitis B and HPV vaccines**.

Combined Vaccine Vial Monitor (VVM) and Threshold Indicators (TI): Assessment outcomes



KEY BENEFITS

- **Potential to positively impact coverage and equity:**
 - ++ May be **easier to use:**
 - The combined VVM-TI is reviewed in a single step, whereas a VVM and separate TI require review of two indicators.
 - It provides a more accurate assessment of the heat exposure status of a vaccine, particularly when used in the CTC.
 - Potential to **reduce TI stock-outs: VVM and TI are integrated** into a single indicator placed on vaccine primary container, so there is only one component to be procured, distributed, and tracked, therefore helping to eliminate the need to store and transport separate Tis.
- ++ May **save health care worker time:** with the combined VVM-TI, only one indicator needs to be reviewed to determine if excessive heat exposure has occurred.
- **Broad applicability** to all vaccines, even if likely to be **most useful for vaccines prequalified for use in a CTC.**

KEY CHALLENGES

- No key challenges related to Phase I assessment have been identified.
- ++ Important attribute for at least 2 settings or for the 3 settings based on the country consultation (see slide 3)
- + Important attribute for campaigns or routine facility-based immunisation based on country consultation (see slide 3)

Combined Vaccine Vial Monitor (VVM) and Threshold Indicators (TI): Rationale for prioritisation



- The combined VVM-TIs are **recommended to be prioritised** for further analysis under Phase II given their **potential to facilitate use of vaccines in a CTC and in support of the suggested prioritisation of heat stable CTC qualified liquid vaccines.**
- The technology **improves upon the current use of VVMs with separate TI indicators** offering **increased ease of use, fewer components, and saving staff time.**

Additional important information to be analysed in phase II (if prioritised for Phase II):

- How best to align with and provide complementary value to WHO's evolving requirements regarding use of VVM-TIs on specific vaccines.