



Update on NEW VVMs in support of SARS-COV2 vaccine delivery

(including Ultra Cold Chain)

Ted Prusik

DCVMN Annual General Meeting (Virtual): Vaccines, a healthy future



3 November 2020 to 5 November 2020

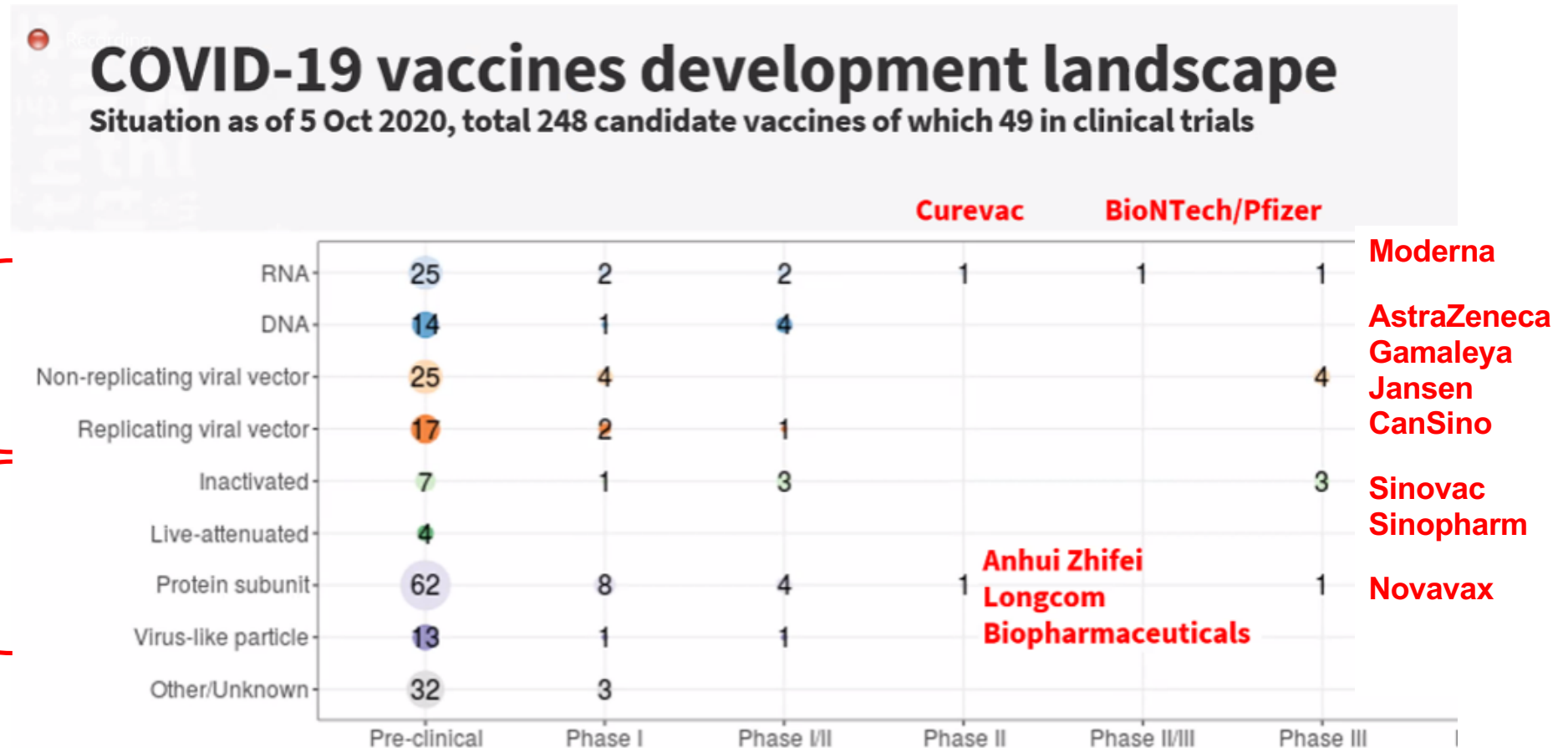
Webex



Agenda

- COVID-19 Target Product Profile
- Vaccine platforms with widely varying stability
- Current VVM types and new types for less stable formulations
- Temptime preparedness to supply VVMs on pandemic scale
- A call to manufacturers to provide stability information

Tremendous response from Private & Public sponsors...



WHO COVID-19 Vaccine Target Product Profile (March 2020)

Summarized TPP table <https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines>

#	Vaccine characteristic	Preferred	Critical or Minimal
1	Safety	Highly favourable benefit/risk profile with only mild, transient adverse events	Safety and reactogenicity whereby vaccine benefits outweigh risks
2	Efficacy	70%	50%
3	Duration of protection	1 year min.	6 months min.
4	Number of Doses	Single-dose	Two dose
5	Route of Administration	Oral / Nasal	Any route
6	Presentation (doses / vial)	Multi-dose for campaigns	
		Multi- or mono- dose acceptable	
		Multi-dose formulated, managed and discarded in compliance with WHO's multi-dose vial policy	
7	Stability and Storage	Higher storage temperatures and high thermostability	Shelf life: at least 6-12 months. Storage: as low as -60 -70°C (Long term: -20°C or higher) at least 2-weeks stability at 2-8°C
		VVM, proof of feasibility and intent to apply to the primary container	

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COVID vaccines present extreme distribution challenges

Challenging cold chain to point of administration**

Distribution



On-site Storage (2 - 8°C)

5 days*

ON-SITE VACCINE STORAGE

Frozen (-70 °C ± 10 °C)

- Must be used/recharged within 10 days
- Storage in shipping container OK (replenish dry ice within 24 hours of receiving shipment and again 5 days later)

Thawed but NOT reconstituted (2-8 °C)

- Must use within 5 days (discard unused doses after 5 days)

Reconstituted (room temperature)

- Must use within 6 hours (discard any unused, reconstituted vaccine after 6 hours)

14 days*

ON-SITE VACCINE STORAGE

Frozen (-20 °C)

- Storage in shipping container OK

Refrigerated (2-8 °C)

- Must use within 14 days

Room temperature

- Must use within 6 hours (discard any unused vaccine after 6 hours)

90 days**

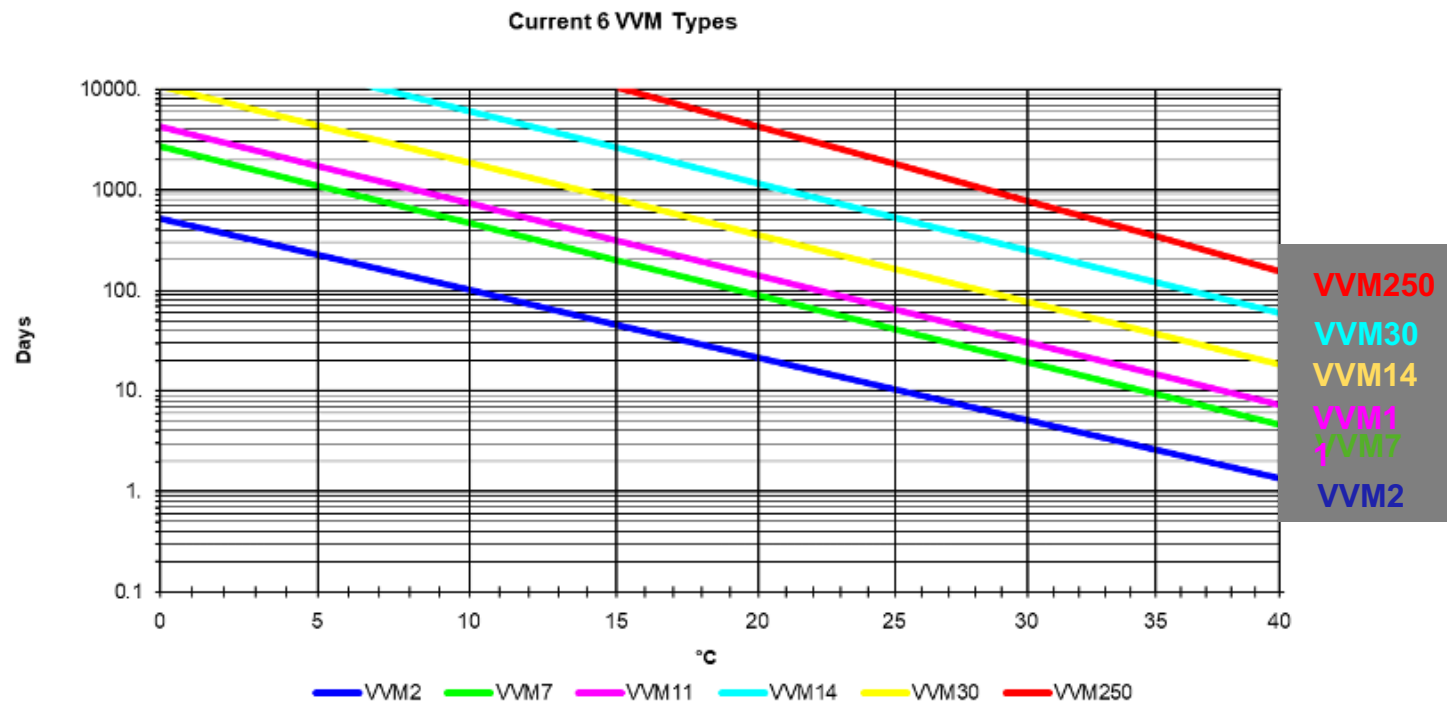
The J&J vaccine will be shipped frozen, but can be stored in liquid form at refrigerator temperatures for three months, whereas two of the front-runner candidates must be frozen or kept at ultracold temperatures until shortly before use.

**https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

**<https://www.washingtonpost.com/health/2020/09/23/coronavirus-vaccine-jj-single-shot/>

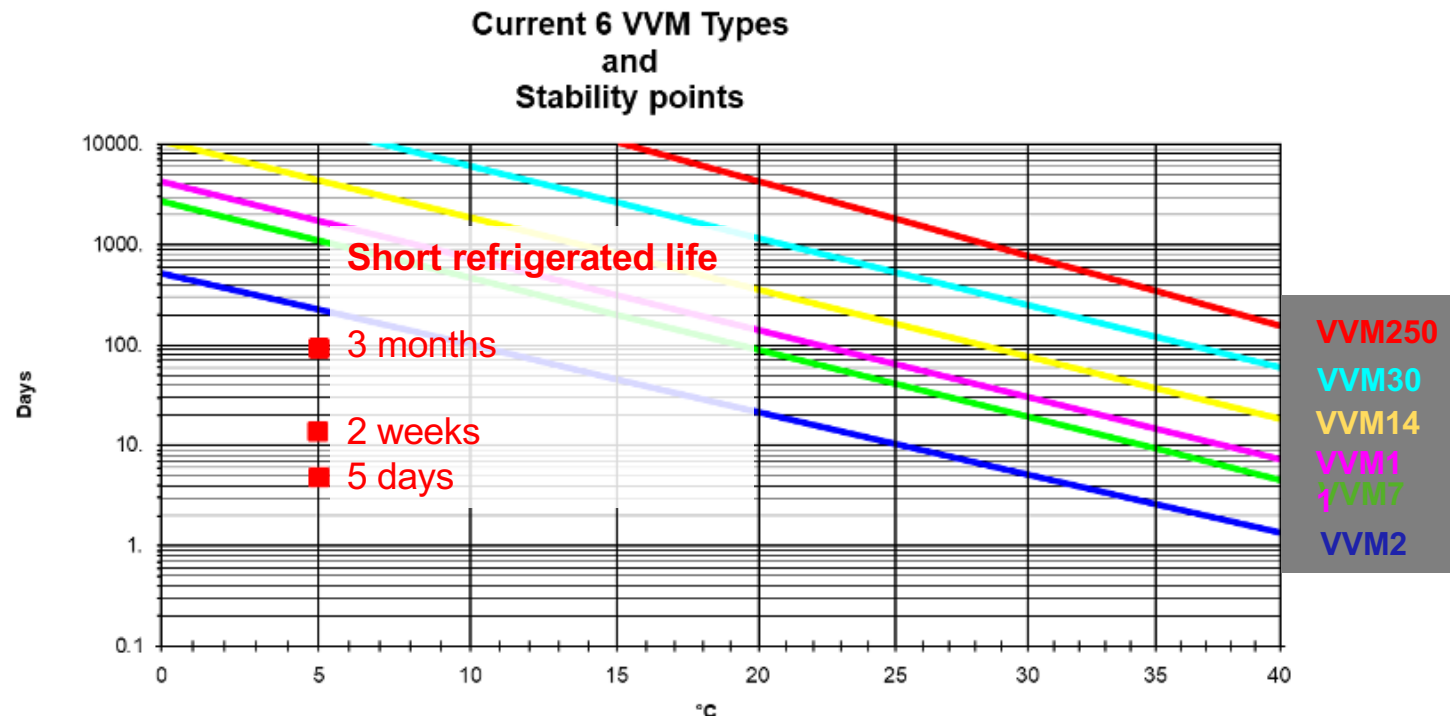
Current six VVM types

7 months at refrigerated temperature to years at room temperature



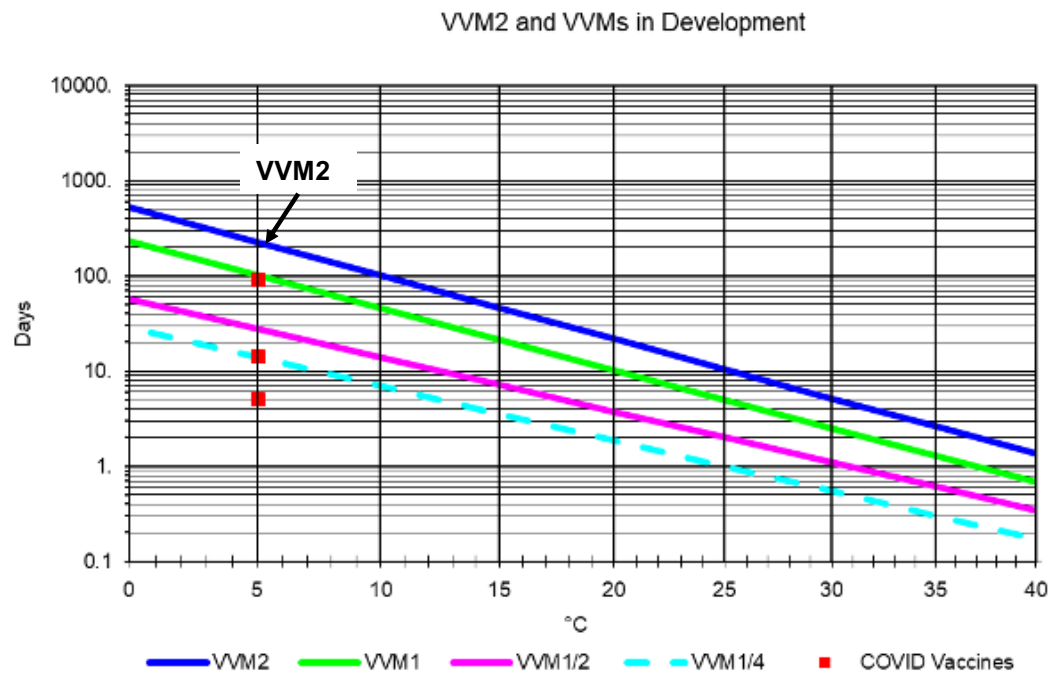
Less stable novel platforms

Requiring Ultra cold chain, frozen distribution with short shelf life



New VVM types for short shelf life vaccines at 2 - 8°C

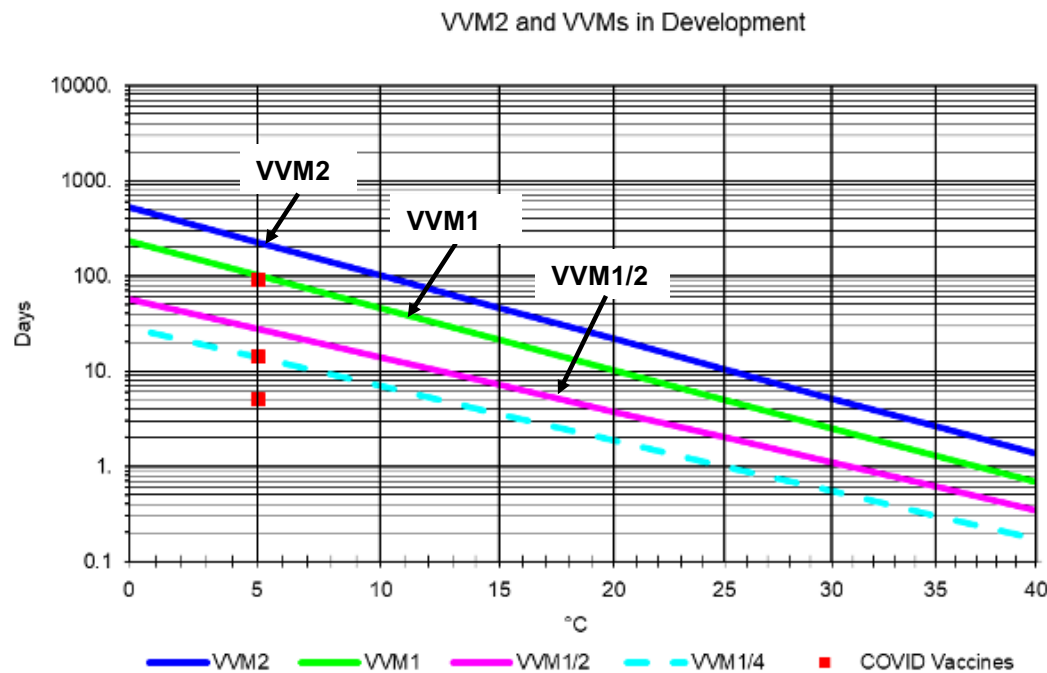
VVM PQS Specification revised to include VVM1 and VVM1/2



Stability information and programme need required to set the future VVM plan

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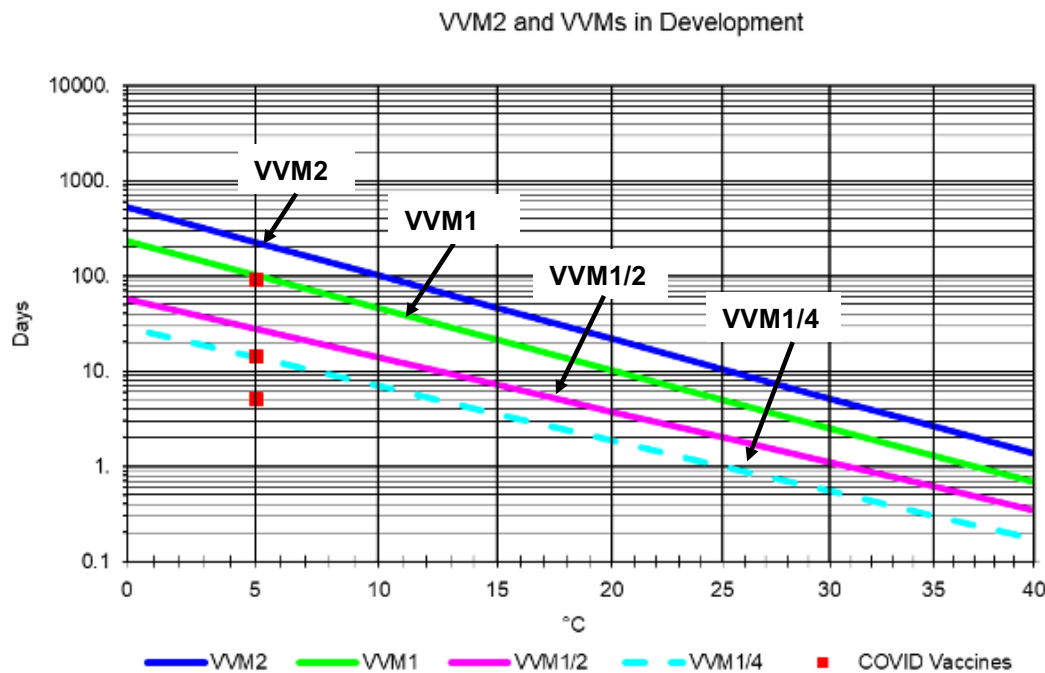


- **VVM1** and **VVM1½** included in latest revision of WHO PQS specification
- **VVM1** to be conditionally prequalified in December 2020

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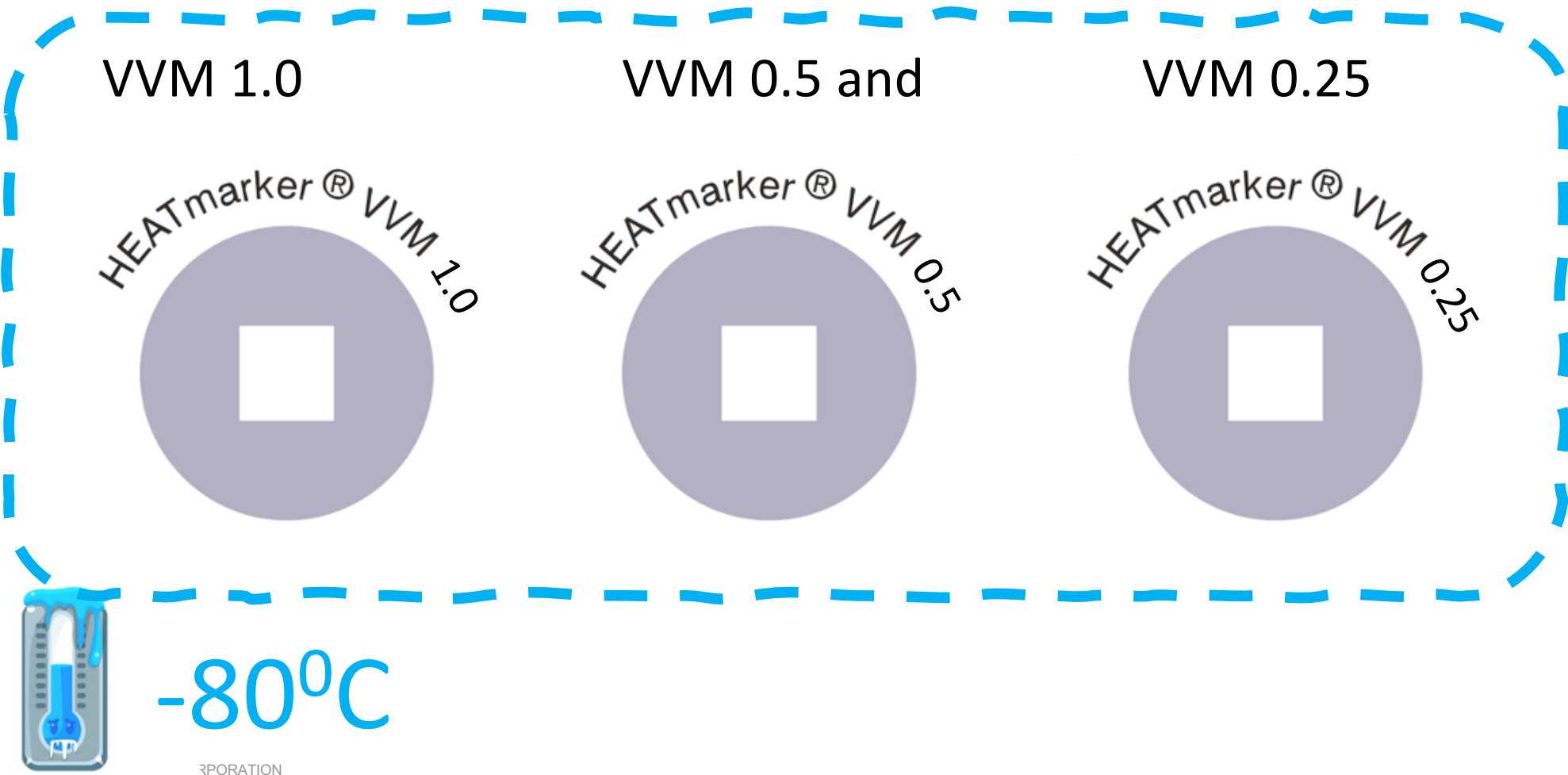
VVM PQS Specification revised to include VVM1 and VVM1/2



- **VVM1** and **VVM1½** included in latest revision of WHO PQS specification
- **VVM1** to be conditionally prequalified in December 2020
- **VVM1¼** formulation ready for qualification
 - possible conditional prequalification in 3 months

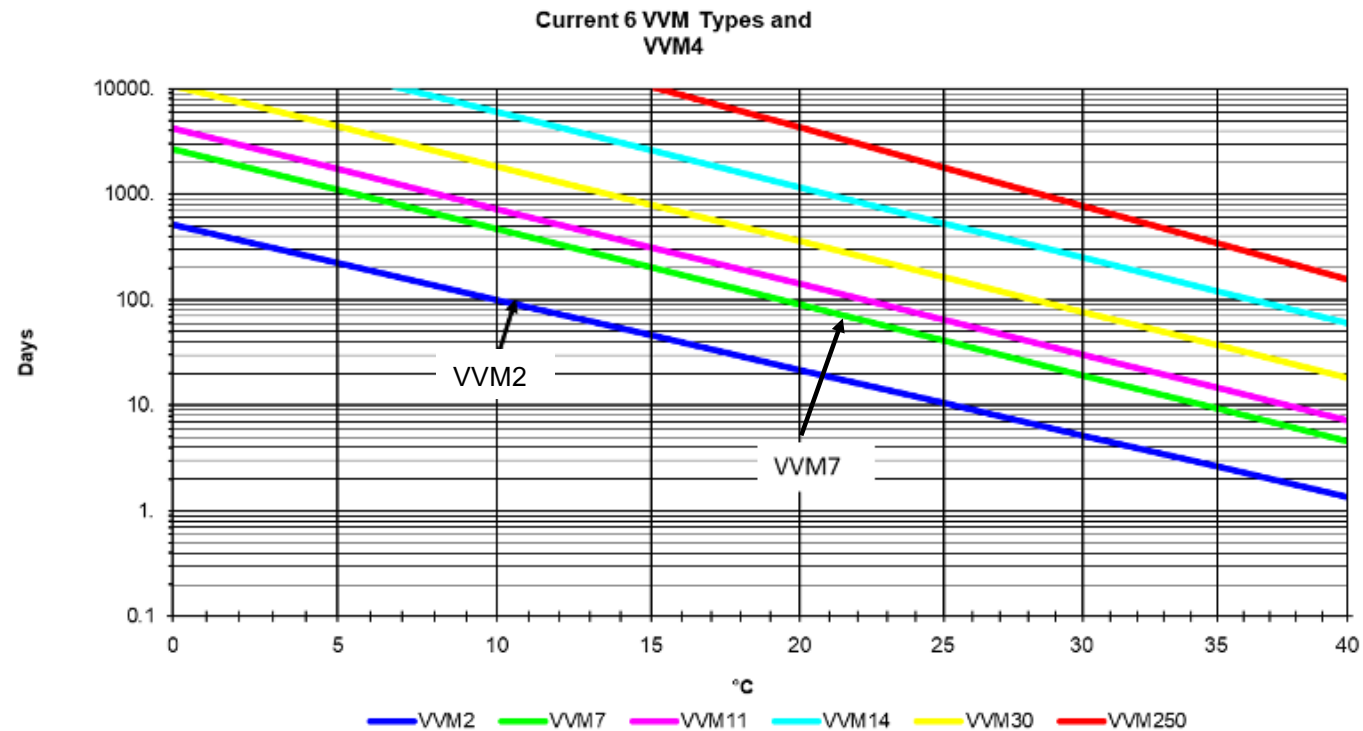
Stability information and programme need required to set the future VVM plan

For vaccines that require Ultra Cold Chain or limited stability in 2-8⁰C



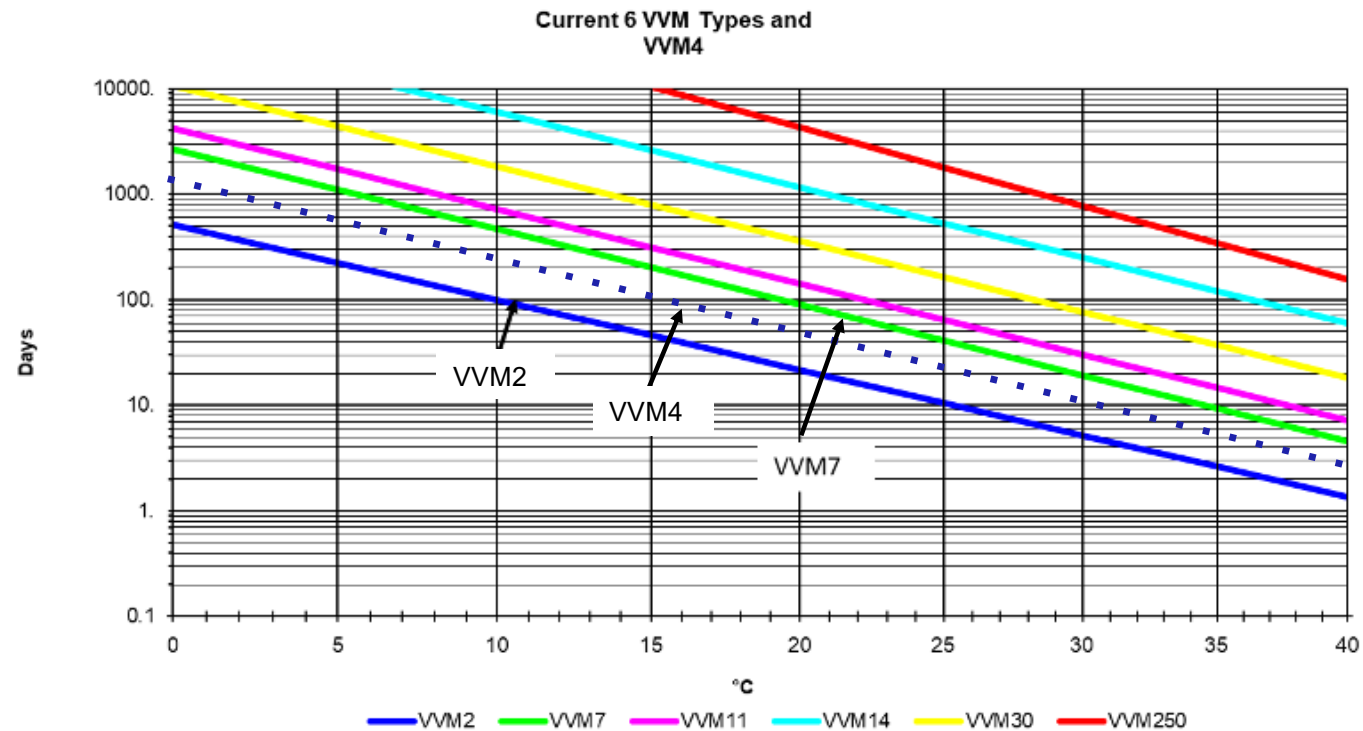
Is VVM4 needed to fill the gap between VVM2 and VVM7?

There is still time to act but guidance is required



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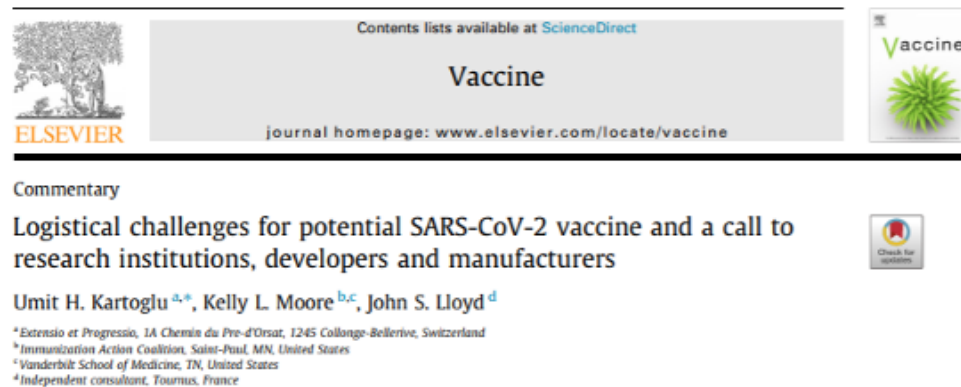




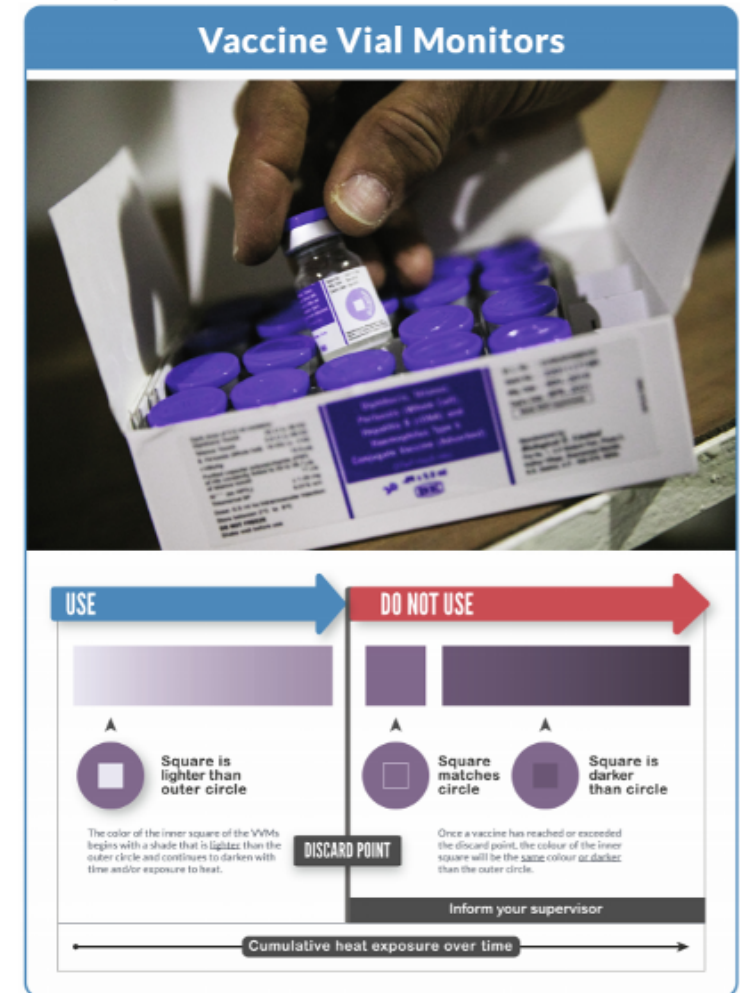
Healthcare workers in LMICs rely on VVMs

Vaccine stability data is needed to define the supply chain

Call to research institutions, developer and manufacturers



- VVMs warn users not to use vaccines that have been damaged any stage of distribution from manufacture until the vaccine is used
- An appropriate VVM attached to the SARS-CoV-2 vaccine permits evaluation of the effect of time and temperature at all levels to ensure quality
- VVM will prevent wastage and facilitate outreach to remote populations



Temptime preparedness for VVM supply in pandemic

Capability, capacity and business continuity plan

Business Continuity Plan

- Contingent inventory of VVM dot types equal to 6 months of historical demand
- 3-year inventory of critical active chemistry
- Inventories stored at two different locations
- Two manufacturing machines and related equipment areas separated by firewalls
- Generator back-up and other risk mitigation measures in place

Capability and Capacity

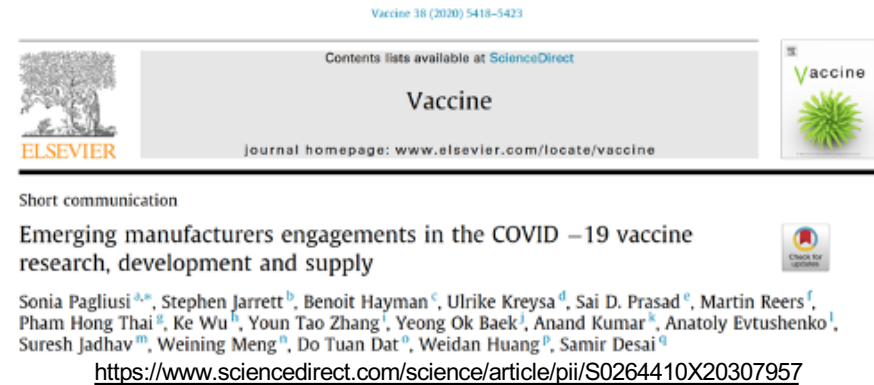
- 5 billion doses in a 10 dose presentation requires 500 million VVMs
- Current demand is approximately 600 million VVMs each year
- Capacity is not a constraint BUT would require appropriate lead time for scheduling



DCVMN members are critical for pandemic response

Congratulations for all your efforts !!!

- Research and Development Efforts and Vaccine Technology Platforms
- Rapid scale up and large-scale manufacturing
- Fill-finish and distribution capabilities
- Many DCVMN members already comply with the Gavi/UNICEF requirements of adhering to GS1 barcoding traceability standards
- Maintaining supply of other essential vaccines



AGM Rio 2019

Thank You !

Questions?

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