WEEKLY EPIDEMIOLOGICAL REPORT

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Vaccine Vial Monitor– Taking a Closer Look (Part I)

This is the first in a series of two articles on Vaccine Vial monitors

Vaccine Vial Monitor (VVM) is a Time-Temperature Indicators (TTI) included in the label of vaccine vials to register cumulative heat exposure over time.

Figure 1. Illustration and instructions for VVM use.

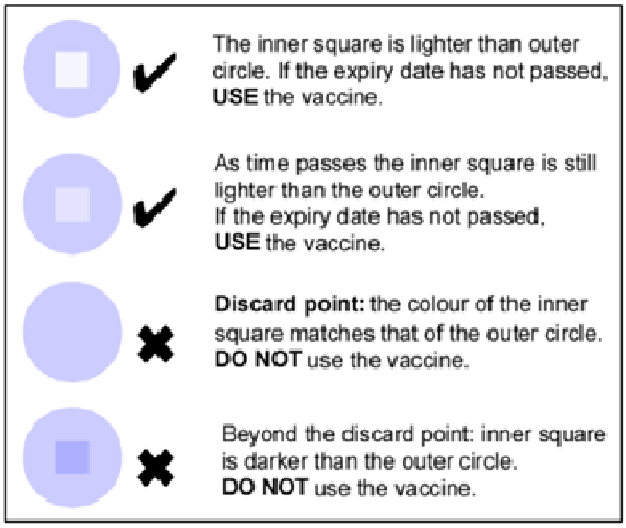

Table 1-VVM variants with common vaccine types using each

VACCINE VIAL MONITOR TYPE	VACCINE TYPES ASSIGNED, *inter alia*
VVM2 ("D. Least Stable")	OPV
VVM7 ("C. Moderate Stability")	BCG, DTP, MEA, MMR, PNU_{cn}
VVM14 ("B. Medium Stability")	DTP_{w}, HIB, ROT
VVM30 ("A. High Stability")	HBV

History

Time-Temperature Indicators (TTI) devices have been in use in foods and pharmaceutical industries to monitor the cumulative exposure of both time and temperature in order to measure or predict the degradation of temperature-sensitive products. In 1979, as a consequence of good experience with other TTIs at higher levels of the cold chain, WHO conceived the concept for VVMs in order to extend such monitoring to the periphery. Over the 1980s and until the mid-to-late 1990s, several different VVM technologies were pursued by several companies.

The first VVM was developed for the freeze-tolerant but highly heat-sensitive oral polio vaccine (OPV) and first applied in 1996 to vaccine vials used in the Expanded Programme on Immunization (EPI). Over the past decade, Temptime Corporation has remained the sole world manufacturer of VVMs for use on vaccines in the EPI.

WHO and the United Nations Childrens Fund (UNICEF) now mandate the use of VVMs on all vaccines procured through UNICEF to help ensure that administered product has not been damaged by heat and to reduce wastage when still-potent vaccines are discarded unnecessarily, such as when breaks of unknown severity occur in the cold chain.

Beginning in the early 2000s, an expanding number of vaccine types beyond the original OPV were required to have VVMs.

Principles of Application

VVMs are intended to show whether and when a pre-set limit of cumulative temperature exposure over time has been reached. This is indicated by a gradual change in color dark-

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ness of a special indicator ink imprinted on the label (Figure A). This indicator is surrounded by a circle printed with reference ink that does not change colour. When the darkness of the inner indicator is equal to or greater than the darkness of the outer reference ring, then the VVM is considered to have reached, so to speak, its "endpoint conversion" or to have "converted" (Refer figure 1 please).

Currently there are four distinct versions of VVMs, each designed to reflect a different degradation rate in order to match better the actual thermostability of specific vaccines (Table 1). These different "models" are currently referred to as VVM2, VVM7, VVM14 and VVM30 with the number indicating the approximate number of days by which the VVM would convert if held at +37℃.

Mechanism of Action

This change in darkness of colour in the VVM – more precisely measured mechanically as optical density (OD) – is the result of an irreversible chemical reaction based on the polymerization of substituted diacetylene monomers in the VVM . The OD change is irreversible, even if the VVM returns to cold temperatures. This change in OD is reported to occur within certain parameters in accordance with the Arrhenius formula, which predicts the usual rate of a chemical reaction as influenced by temperature. The change in OD is intended to integrate the effect of each unit of time spent at each temperature. The "Arrhenius" relationship defines the rate constant, k, of a variation with temperature:

$k = A_o \exp(-E_a/RT)$

"In this equation, A_o and E_a are experimentally determined constants specific to the reaction and R is the universal gas constant. The activation energy, E_a , determines how the rate changes with temperature, T, which is expressed in degrees Kelvin.

For a VVM30, the colour changes essentially linearly with time and reaches its endpoint by 30 days at 37℃, so the rate constant equals 1/30 per day at this temperature.

Although the time until a VVM indicator reaches endpoint and the time until a vaccine loses its potency may both be observed over various temperatures to follow an "Arrhenius" equation, it is important to realize that these equations are not necessarily the same between the VVM and the vaccine. Their experimentally-determined activation energy constants (the E_a in the formula that sets its slope) may be entirely different.

To prove the applicability of a VVM for a vaccine, they both must be tested at a minimum of three fixed temperatures over the range of temperatures in which they are expected to work. The closer and straighter their corresponding shelf life plots (used in the calculation of expiry date of a vaccine), the more accurately does the VVM predict when the vaccine loses potency.

To explain how a VVM works when subjected to varying temperatures for varying times, consider a VVM30 with an intended limit, at a steady +37℃, of 30 days. For the sake of this discussion, this number of days may be considered 100% of its useful life. If the VVM30 is kept at +37℃, the color of the inner square will match the color of the reference circle at or around 30 days. If the VVM is kept at a cooler temperature, say +25° C, then the VVM will reach its endpoint after a much longer period (~193 days according to specifications), which is considered equivalent to the same heat damage or potency loss that would have occurred upon 30 days at +37℃.

One may also think of the thermostability of a VVM (as well as that of a vaccine itself) as a kind of bank account with an initial balance of funds when the vaccine is first filled and labeled. Different amounts of money will be debited from the account for each unit of time (minutes, hours, etc.) according to the temperature to which it is exposed. When the account balance reaches zero, the vaccine is no longer potent and should be discarded

Compiled by Dr. Madhava Gunasekera of the Epidemiology Unit

Source-Preliminary Review of Vaccine Vial Monitors available from *www.who.int/entity/immunization_delivery/TLAC-Report_**2009**-03.pdf*

Table 3 : Water Quality Surveillance
Number of microbiological water samples - July / 2012

District	MOH areas	No: Expected *	No: Received
Colombo	12	72	NR
Gampaha	15	90	3
Kalutara	12	72	NR
NHIS	2	12	NR
Kandy	23	138	NR
Matale	12	72	3
Nuwara Eliya	13	78	15
Galle	19	114	NR
Matara	17	102	0
Hambantota	12	72	15
Jaffna	11	66	7
Kilinochchi	4	24	0
Manner	5	30	14
Vavuniya	4	24	0
Mullatvu	4	24	NR
Batticaloa	14	84	NR
Ampara	7	42	NR
Trincomalee	11	66	NR
Kurunegala	23	138	68
Puttalam	9	84	NR
Anuradhapura	19	114	9
Polonnaruwa	7	42	NR
Badulla	15	90	NR
Moneragala	11	66	85
Rathnapura	18	108	NR
Kegalle	11	66	7
Kalmunai	13	78	0

* No of samples expected (6 / MOH area / Month)
NR = Return not received

to be continued

Table 1: Vaccine-preventable Diseases & AFP

11th – 17th August 2012 (33thWeek)

Disease	No. of Cases by Province									Number of cases during current week in 2012	Number of cases during same week in 2011	Total number of cases to date in 2012	Total number of cases to date in 2011	Difference between the number of cases to date in 2012 & 2011
	W	C	S	N	E	NW	NC	U	Sab					
Acute Flaccid Paralysis	01	00	00	00	00	00	00	00	00	01	03	51	60	- 15.0 %
Diphtheria	00	00	00	00	00	00	00	00	00	-	-	-	-	-
Measles	00	00	01	00	00	02	00	00	00	01	02	35	98	- 64.3 %
Tetanus	00	00	00	00	00	00	00	00	00	00	01	08	15	- 46.7 %
Whooping Cough	00	00	00	00	00	00	00	00	01	01	00	60	25	+ 140.0 %
Tuberculosis	68	00	00	03	00	00	00	04	15	90	127	5763	5775	- 0.2 %

Table 2: Newly Introduced Notifiable Disease

11th – 17th August 2012 (33thWeek)

Disease	No. of Cases by Province									Number of cases during current week in 2012	Number of cases during same week in 2011	Total number of cases to date in 2012	Total number of cases to date in 2011	Difference between the number of cases to date in 2012 & 2011
	W	C	S	N	E	NW	NC	U	Sab					
Chickenpox	10	00	12	00	04	11	03	04	09	53	55	2960	2906	+ 01.8 %
Meningitis	01 GM=1	01 KD=1	01 GL=1	02 JF=1 VU=1	00	02 KR=2	01 AP=1	01 BD=1	01 RP=1	10	04	474	563	- 15.8 %
Mumps	15	03	09	02	14	09	08	02	15	77	82	3107	2053	+ 51.3 %
Leishmaniasis	00	01 ML=1	02 MT=1 HB=1	00	01 TR=1	01 KN=1	16 AP=16	00	00	21	11	624	475	- 31.4 %

Key to Table 1 & 2

Provinces: **W**: Western, **C**: Central, **S**: Southern, **N**: North, **E**: East, **NC**: North Central, **NW**: North Western, **U**: Uva, **Sab**: Sabaragamuwa.

DPDHS Divisions: **CB**: Colombo, **GM**: Gampaha, **KL**: Kalutara, **KD**: Kandy, **ML**: Matale, **NE**: Nuwara Eliya, **GL**: Galle, **HB**: Hambantota, **MT**: Matara, **JF**: Jaffna, **KN**: Killinochchi, **MN**: Mannar, **VA**: Vavuniya, **MU**: Mullaitivu, **BT**: Batticaloa, **AM**: Ampara, **TR**: Trincomalee, **KM**: Kalmunai, **KR**: Kurunegala, **PU**: Puttalam, **AP**: Anuradhapura, **PO**: Polonnaruwa, **BD**: Badulla, **MO**: Moneragala, **RP**: Ratnapura, **KG**: Kegalle.

Data Sources:

Weekly Return of Communicable Diseases: Diphtheria, Measles, Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps.

Special Surveillance: Acute Flaccid Paralysis.

Leishmaniasis is notifiable only after the General Circular No: 02/102/2008 issued on 23 September 2008.

Dengue Prevention and Control Health Messages

Check the roof gutters regularly for water collection where dengue mosquitoes could breed.

Table 4: Selected notifiable diseases reported by Medical Officers of Health

11th – 17th August 2012 (33thWeek)

DPDHS Division	Dengue Fever / DHF*		Dysentery		Encephalitis		Enteric Fever		Food Poisoning		Leptospirosis		Typhus Fever		Viral Hepatitis		Human Rabies		Returns Received
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	%
Colombo	297	6426	3	94	0	7	5	132	0	31	5	119	0	3	2	78	0	3	**69**
Gampaha	106	4894	0	58	0	9	0	41	0	22	3	144	0	14	1	220	0	0	**53**
Kalutara	45	1705	1	58	0	2	1	26	0	26	1	160	0	2	0	20	0	2	**69**
Kandy	31	1659	2	75	0	1	0	15	1	54	1	50	0	85	2	50	0	0	**70**
Matale	6	339	3	64	0	5	0	8	0	7	1	31	0	3	0	31	0	0	**75**
Nuwara	6	234	2	127	0	3	0	21	1	2	5	28	1	51	0	15	0	1	**69**
Galle	32	963	4	87	1	6	0	8	6	17	1	79	4	39	0	2	0	0	**58**
Hambantota	9	398	0	26	1	2	0	5	0	25	1	61	1	34	0	14	0	0	**92**
Matara	34	1088	2	46	0	8	0	15	0	19	1	99	4	54	3	84	0	0	**88**
Jaffna	6	304	6	122	1	13	8	279	1	67	0	2	0	247	1	11	0	0	**92**
Kilinochchi	0	56	0	7	0	2	0	25	0	40	0	4	0	29	0	4	0	1	**25**
Mannar	2	102	0	49	0	3	1	20	0	14	0	16	0	40	0	2	0	0	**40**
Vavuniya	0	41	0	20	0	21	0	6	0	15	0	17	0	1	0	1	0	0	**50**
Mullaitivu	0	17	1	12	0	1	0	6	0	2	0	3	0	5	0	0	0	0	**50**
Batticaloa	5	592	9	135	0	2	0	14	3	208	0	8	0	0	0	6	0	4	**71**
Ampara	0	86	0	53	0	0	1	4	0	8	0	19	0	0	0	2	0	0	**57**
Trincomalee	5	117	6	114	0	1	0	16	4	8	0	35	0	14	0	4	0	0	**67**
Kurunegala	47	1564	9	121	1	14	1	75	0	32	4	112	1	21	2	105	0	3	**81**
Puttalam	8	664	1	30	0	6	0	10	0	1	0	21	0	13	0	3	0	1	**42**
Anuradhapu	2	234	2	43	0	6	0	11	4	16	0	71	0	21	1	48	0	1	**68**
Polonnaruw	0	164	0	28	0	0	0	1	0	1	0	38	0	2	0	33	0	1	**14**
Badulla	6	240	5	85	0	3	4	45	0	3	1	31	7	76	0	34	0	0	**76**
Monaragala	3	181	1	46	0	4	0	16	0	7	0	54	4	63	0	139	0	2	**73**
Ratnapura	128	2492	3	153	0	25	2	40	0	11	10	206	1	32	9	80	0	1	**78**
Kegalle	61	2007	0	45	0	9	0	19	0	10	3	132	4	45	12	399	0	0	**82**
Kalmune	1	165	0	187	0	1	0	5	0	76	0	2	0	0	0	7	0	3	**38**
SRI LANKA	**840**	**26732**	**60**	**1885**	**04**	**154**	**23**	**863**	**20**	**722**	**37**	**1542**	**27**	**894**	**33**	**1392**	**00**	**23**	**68**

Source: Weekly Returns of Communicable Diseases WRCD).
***Dengue Fever / DHF** refers to Dengue Fever / Dengue Haemorrhagic Fever.
****Timely** refers to returns received on or before 17thAugust, 2012 Total number of reporting units 329. Number of reporting units data provided for the current week: 226
A = Cases reported during the current week. **B** = Cumulative cases for the year.

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Comments and contributions for publication in the WER Sri Lanka are welcome. However, the editor reserves the right to accept or reject items for publication. All correspondence should be mailed to The Editor, WER Sri Lanka, Epidemiological Unit, P.O. Box 1567, Colombo or sent by E-mail to **chepid@sltnet.lk.**

ON STATE SERVICE

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