

**Reverse SOP through true story of administering SputnikV™ COVID Vaccine; by
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Why reverse SOP?

SputnikV™ is the 3rd Emergency Use Authorization [EUA] vaccine in India requiring subzero temperature for storage and transportation [$< -18^{\circ}\text{C}$ as per coy] unlike the other two EUA vaccines [Covishield and Covaxin in use since 16th Jan 2021 in India] requiring $+2$ to $+8^{\circ}\text{C}$ with which service providers are very familiar since 1985 Universal Immunization Programme [UIP].

COVID-19 is one of the Vaccine Preventable Diseases, multiple vaccines being available for prevention itself is a bright silver line/the biggest boon.

For easy understanding by the vaccinators, it is comfortable to start from the outreach to the center -- the basic principle of any successfully implementable micro-plan more so for COVID [bottom up approach].

On reaching the outreach session site, we familiarized ourselves with the organizing institution, acclimatized & organized ourselves quickly for delivering vaccination services including display of back-drop, banners, IEC materials, Standee for facilitating "I am Vaccinated" selfies, for sharing in mass media, promoting others to participate, job-aids on responsibilities of vaccinator, immunization safety including waste management, key messages to the beneficiaries and possible adverse events with contact number(s) etc.

1st easy point: Route of administration of Sputnik vaccine is Intra Muscular [IM] like that of Td for a pregnant woman which we are already endowed with the skill, relieved our anxiety towards administration of this newer vaccine. We made sure that every syringe 'graduated' 0.5mL on filling with vaccine and expelling the air, observed the bottom of the ampoule looking for a piece of frozen vaccine if any for drawing it full.



We meticulously administered vaccine IM in the deltoid area, preferably left hand taking care to avoid Intra Vascular entry of this vector vaccine to prevent **Thrombosis with Thrombocytopenia Syndrome (TTS)** & post injection traumatic neuritis causing **wrist drop**.

The vaccinee is given a dry sterile swab to keep at the injection site pressed, not for massaging, sat for ~2 minutes and discarded the swab in the respective color bag before proceeding to observation room, watching him / her **walking out**. Similar to marking on a multi dose vial of Covishield, we wrote number, date and time of starting and ending after administering 5th dose on every carton. At the end of the day, if 20 cartons were spent, we took a group photo of 20 cartons for documentation as per SOP.

2nd easy point: Familiar common measures of **Immunization waste** management [using hub-cutter, black/red/yellow bags/ puncture proof containers], **AEFI KIT** & reporting, between Covid Vaccination and RI Vaccination services made us further free from tension.



Currently Sputnik is meant for administration by the **Private CVC holders** at the facility level but globally vaccination is one of the most important and cost effective clinical public health practices under the realm of essential primary health care services.

Hence vaccinating beneficiaries in the outreach close to their residence enhances community participation: a novel venture by **Dr Anand Lakshman**, a public health specialist, CEO & Founder of **AddressHealth** – a private primary health care service provider in a metropolitan city-Bengaluru of Karnataka State. This promotes Covid Vaccination coverage very much required for curbing evolution of lethal variants generating recurrent waves; lifting or liberalizing lock-downs, booming socioeconomic growth, re-starting & sustaining offline education, infusing sound mental & physical health etc.

3rd Easy Point: Adherence to Covid Appropriate Behavior [CAB] for compliance with pandemic guidelines, **key messages** to the vaccinees, Common, Un-common, rare AEFIs, contraindications / to be cautious are all largely common to all 3 Covid Vaccines + RI vaccines.



We maintained inter-personal communication with CVC site manager / verifier; frequently matched the number registered / vaccinated and the doses spent as per check list. We confirmed that every vaccinee got SMS and digital certificate before they left the premises on completion of observation period. This largely prevents pointing CoWIN for loss

/ mismatch of data & non-accessibility of authentic digital certificate. We entered vaccine brand, batch number, next due date, vaccinator's signature & key messages in the vaccination card, requested vaccinees to bring the same while coming for the 2nd dose for doubly ensuring **100% specificity & authenticity**. We entered time of vaccination on the consent form, retained with us for enabling office staff for line listing, developing duelist for timely reminding 2nd dose, track the AEFIs / drop-outs & the most important – the **Operational Research [OR]**; this substitutes session site Tally Sheet recommended in the micro-plan guideline but not operationalized.

Sputnik special: Thawing of the vaccine: Sputnik vaccine is in frozen condition at $\leq -18^{\circ}\text{C}$. Depending on the number of candidates whose authenticity is verified and ready to receive vaccine, generally in multiples of 5 in the forenoon session, say if 25 to 30 eligible candidates are ready, we were given 25 ampoules of single dose ampoules, kept in the vaccine carrier; required ampoules liquefied and administered IM using 0.5mL AD syringe.

Administering too cold vaccine can injure locally, often yielding a firm nodule in due course. It is wise to procure a few ampoules less than actually required as once thawed, it has to be used within 120 minutes and cannot re-freeze for eventual use. Currently no Covid vaccine is decorated with VVM. Loss of a single dose amounts to loss of ~Rs 1000+/- . Towards the end of the session, say after 4pm, we were given actual number of ampoule needed for achieving zero wastage.

Breaking the ampoule: Each ampoule has body, neck, terminal portion with a blue dot close to the neck. The body of the ampoule was held between thumb and against index & middle fingers of left hand; terminal portion was tapped gently so that any liquid vaccine in this portion would gravitate to the body. The terminal portion was held between thumb and ring finger of right hand and successfully broke the ampoule at the neck. When it was too difficult to break this way for some of the ampoules, we 'filed' the neck and then broke to prevent breakage of the body which wastes vaccine and injures finger(s).

Recommended interval between Component 1- the first dose [AD26: Dhoom1] and Component 2 [AD5: Dhoom2] is 3 weeks [21 days] shortest amongst the 3 available vaccines was emphasized; it is 4 to 6 weeks & 12 to 16 weeks for Covaxin and Covishield respectively. The beneficiaries were asked to confirm receipt of post vaccination message and the certificate in their mobile phone for authenticity of vaccination & proud gratification.

Procuring Sputnik Vaccine ampoules from the Ice Lined Deep Freezer on wheel [ILDF]: For outreach purpose, one dedicated ILDF is fitted in a vehicle, in which required amount of vaccine is loaded in minimum 2 different trays in 2 tiers. 1 to 2 cold gel packs were also placed in the vaccine trays. At the facility while loading, the temperature of ILDF was at -25°C . This ILDF has 6 to 8 hrs of cold-hold-over time to reach -18°C depending on external

ambient temperature. However, on reaching the outreach in an hour, vehicle was parked close to the vaccination room, through voltage stabilizer connected to the power plug using extension cord. At the outreach, a designated person maintains ILDF temperature close to -25 °C. The **VERTICALLY OPENING HORIZONTAL LID of the ILDF** which minimally disturbs cool air of the cabinet on opening was partially opened for a very short period of **~10 seconds** by the designated staff owning the key pulled out required number of secondary carton(s) from the upper tray, transferred to 2.9L vaccine carrier with 4 large gel icepacks for maintaining minus temperature and handed over to us for vaccination, adhering to **DRL guidelines**.



Vaccine carrier is the trusted **“Brand Ambassador”** of outreach vaccination, decent non electrical cold chain equipment for keeping vaccine away from light & drifts. [2.9L with 4 large gel ice-packs, can hold 12-14 secondary cartons of 5 ampoules each = **60 to 70 ampoules < -18 °C.**]

Transportation of SputnikV Vaccine to the outreach session site from the facility:

AddressHealth [AH] innovated this novel step of mounting an ILDF on wheel to reach the beneficiaries as close to their working / residential place as possible for their homely easy accessibility saving time and extra expenditure to the beneficiaries though it incurs extra expenditure to the service provider. ILDF on wheel was adequately primed to attain and sustain critically set temperature between **-25 °C & -23 °C** by the dedicated Cold Chain Handler [CCH]. Required number of doses loaded to the mobile ILDF at appropriate time depending on the transportation time needed to reach the session site. This ILDF model with **secondary ice-lining** has sufficient cold-hold-over time, sustaining below -20 °C,



more than enough to reach the outreach session site. On reaching the session site, the ILDF through Voltage stabilizer connected to 3 pin power plug using extension cord so that the ILDF regains -25 °C from say -22 °C.

ILDF has dual temperature monitors – digital display and data logger. On a regular basis data from the data logger is transferred to the computer for monitoring / storage / retrieval / validation / Surveillance [specific information for specific action], operational research and sharing with vaccine supplier as and when required. Greatly satisfied with the

quality of cold chain maintenance blended with validation, outreach sessions are being organized. On availability of support from the sponsors / funding agencies / charitable trusts / corporate sector, outreach service can be held in hard to reach distant areas and neighboring districts.

Vaccine storage at the Facility [CVC]:

AddressHealth procured made in India ILDF from **Mssrs Cold Chain Controls, Coimbatore [C4 Model]** for keeping SputnikV™ Vaccine at recommended temperature well below-18 °C. **Temperature range** of this 500L ILDF with 350L cabinet space is critically set between **-25 °C & -23 °C**. It has secondary ice-lining to discourage frost formation especially in **AC room** and augment cold-hold-over time in case of power failure for sufficient hours sparing power inverter / generator. However, **a contingency plan** is also ready with AH.

This ILDF is provided with sliding perforated trays for keeping vaccines ensuring adequate free space for air circulation. There is adequate space for keeping gel ice-packs for freezing both for keeping in the Vaccine Carrier of 2.9L size and prolonging cold-hold-over time. Total of ~4800 doses of component-1 and component-2 [2400 each] can be accommodated. ILDF has vertically opening horizontal lid, on partially opening for short duration of ~10 seconds by the dedicated CCH, the cool air in the cabinet space is least disturbed causing minimum rise of temperature unlike the one with horizontally opening vertical door wherein the cabinet temperature sharply shoots up on opening even for short duration of 10~seconds. This ILDF prevents **matting of the cartons** and facilitates easy removal. It is fitted with two temperature monitors: 1. Continuous Digital display and 2. Temperature logger – can record temperature minute wise. Data is transferrable to the computer for storing, retrieval, surveillance [specific information for specific action], validation, sharing on required basis and operational research.



Frost free, toplid Ice Lined Deep Freezer [ILDF] with sliding trays, provides adequate free air circulation space maintained in Addresshealth, Bengaluru, Karnataka, India.

Receiving SputnikV™ Vaccine on 'D' Day:

AH team was eagerly waiting for the 'D' day of arrival of vaccine. It is the **'D' day for the country** also as mobilizing vaccine at sub-zero temperature to the outreach session is

unprecedented. CEO & his team had enough 'window period' for dressing up as the equipment and the guidelines were received in advance. The liberal guideline gives more time [~10 minutes] for shifting from the insulated celsure box containing 4 Group cartons each with 60 secondary cartons of 5 ampoules each, i.e. 60 ampoules in each Group carton and 1200 in one insulated celsure. CEO of AH preferred strict guideline [~30 seconds]. During the window period, AH team nicely rehearsed with dummy boxes. Author & CCH, our Jackie Chan Mr Deepak successfully transferred all the 4 group cartons from the celsure to the ILDF's cool cabinet at -25 °C within 30 seconds. Later, as and when required, group carton was opened one at a time inside the partially opened ILDF itself and 60 secondary cartons were transferred to the trays kept in tiers, every opening not exceeded 30 seconds; CCH closely watched the digital display for not allowing the temperature to rise beyond -20 °C.

From the above we learnt many useful operational points through learning by doing, learning by working together approach: an easy way of capacity building in public health. We got answer for almost all the 15 queries we shared with the techNet-21 viewers last week.

In other CVCs liberal guideline is being followed by the Logistics.

At other Private CVCs – A feedforward for post – “Graduation”:



Deep Freezer with vertical door: cabinet temperature sharply rises even with short opening as heavy cool air from the cabinet space slips down and warm room air fills the cabinet resulting in Temperature Excursion with every opening like domestic refrigerator.



DF without Ice Lining, welcomes early frost formation, grill baskets with large windows, the cartons slip down to the bottom, ***get matted***, CCH may not remove till the stock gets over or while removing vials / ampoules may get broken incurring

preventable monetary loss.

Including SputnikV™ Vaccine in the national COVID Vaccination Programme:

Govt of India is extraordinarily committed both for the nation and the world, even donated vaccine to the needy countries. India approved utilization of Russian made SputnikV™ Vaccine – needs to be stored at a temperature of -18°C to -20°C , currently being administered by private CVCs. Govt is gearing up to include it in the National COVID vaccination programme stating that “ -18°C to -20°C cold chain is not a deterrent because that is also the temperature at which the polio vaccine [OPV] is stored”. However OPV is “amphibious”. As per study, it can undergo a number of freezing-thawing cycles without necessarily losing its initial potency. Vaccine that has been thawed 3 or 4 times can still be **refrozen** as long as the temperature has at no time exceeded 8°C and the aggregate of periods during which the vaccine was thawed is no greater than 24 hours. But SputnikV™ Vaccine once thawed, should not be refrozen for eventual use as per current Sputnik & DRL SOPs.

In our country almost all planning units are provided with ILR [Ice Lined Refrigerator] for keeping UIP vaccines requiring 2 to 8°C and Deep Freezers [DF] mainly for making ice-packs between -15 to -20°C . OPV is stored in minus temperature at regional / state & higher stores in the walk-in freezers below -15°C . In all the planning units it is stored in the ILRs between $+2$ & $+8^{\circ}\text{C}$; whereas the currently available Sputnik needs to be stored at -25°C , **thawing is allowed only once** as per Sputnik SOP.



Above Deep Freezers in the public sector are not having Ice-Lining. Frost formation inside the DF is an unwelcome almost unavoidable phenomenon as long as ambient air has water vapor. **While defrosting, there is a threat of sacrificing vaccine either through breakage or through thawing or both.**

The left model has 2 baskets; each basket [L42xB21xH18cm] can accommodate 150 secondary cartons of 5 ampoules each= 750 doses $\times 2=1500$ doses in 2 baskets. Ideally, minimum indenting is 1200 doses in one celsure / multiples of 1200 doses to be indented - generally.

The right model with 125L cabinet space has 4 baskets; each basket [L34xB11xH30cm] can accommodate one group carton containing 60 secondary cartons of 5 ampoules each= 300 doses $\times 4$ baskets= 1200 single dose ampoules.

CVC / planning unit need to procure one celsure each of Component 1 & Component 2, two DFs of 125L cabinet space are needed. If block can get main stock and distribute small number of doses say 500 per indent, needs to be transported $<20^{\circ}\text{C}$.

I hope all the stake holders / programme managers are convinced that all the currently available DFs in India have to do **“Post Graduation”** to match with **C4** model for maintaining critically set subzero temperatures but it is not at all a deterrent for the Government because of extraordinary commitment and availability of **C4** model in India.

Alternatively, Sputnik Vaccine requiring $+2$ to $+8^{\circ}\text{C}$ can be easily included since the HCWs are very much acquainted with 0++ cold chain for decades till the DFs pass **PG**.

We are sharing this for the holistic purpose of easy capacity building and replication.

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