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ASSESSMENT OF COLD CHAIN FUNCTIONING IN POST EVIN ERA IN NAINITAL DISTRICT

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ABSTRACT: Background: A vaccine supply chain is the complex system of steps, processes, equipment, vehicles and locations involved in getting vaccines from their origin to their destination. Failure to understand and properly address this system can greatly reduce the impact of any vaccine. It is also necessary that the condition of cold chain equipment i.e., deep freezer and ice-lined refrigerator (ILR) is maintained appropriately and emergency plan in case of cold chain failure is followed adequately. **Material and Methods:** An observational cross-sectional study was carried out to assess the functioning of cold chain points after implementation of eVIN (electronic vaccine intelligence network) from January 2022 to August 2022. 34 out of 40 cold chain points in district Nainital who responded were visited and assessed. Collected data were compiled in MS Excel and analyzed using percentages. **Result:** The findings of this assessment suggest positive changes in the areas of vaccine utilization, stock management and distribution and documentation. The findings revealed that the exposure to sub-zero temperature and $>8^{\circ}\text{C}$ occurred at all levels, from state vaccine store to healthcare facility. The manual temperature records did not match with data logger readings. Further, noncalibrated temperature monitoring devices, long hours of power cut and shortage of trained cold chain handlers affected the maintenance of cold chain. **Conclusion:** States are benefitting with the implementation of eVIN and have been able to improve planning, management of stocks and distribution of vaccines to the last mile knowledge of vaccine handlers on cold chain and vaccine management. Supportive supervision and regular training would improve their work efficiency.

INTRODUCTION: The cold chain supply is essential for vaccine storage and logistics services. In a country like India, the last-mile logistics of vaccines is a challenging task. The recommended temperature range for most of the vaccine is from 2°C to 8°C however the range varies for the storage and transport.

Any refrigerator or freezer used for vaccine storage must maintain the required temperature range year-round. Thermometers should be placed in a central location in the storage unit adjacent to the vaccine. Temperatures should be read and documented twice each day, once when the office or clinic opens and once at the end of the day.

A proper temperature charting has to be maintained by the vaccine provider and the recipient should make a habit of checking those register before purchasing the vaccines or getting the vaccine administered from the doctor¹. To enhance the immunization coverage and ensure equality, sustained availability and accessibility to quality

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vaccines is a prerequisite. It is essential to empower the vaccine store managers and cold chain handlers with a management information system which equips them with the ability to view and assess data on vaccine stocks and storage temperatures. The electronic Vaccine Intelligence Network (eVIN) introduced by the Ministry of Health and Family Welfare and implemented by the United Nations Development programmers provides an integrated solution to address constraints of infrastructure, monitoring and human resource, often inadequate vaccine stocks and related challenges². eVIN is a technology system that digitizes vaccine stocks through a smart phone application and builds the capacity of program managers and cold chain handlers to integrate technology in their regular work. Over 29 thousand vaccine storage centres or cold chain points are live on eVIN and regularly use the platform to perform daily transactions with respect to vaccine and logistics management.

To evaluate the usefulness of eVIN implementation and to visualize its benefits and challenges, a programmatic assessment was undertaken. Although several immunization supply chain studies including the “National Effective Vaccine Management (EVM) Assessment” by the National Cold Chain Vaccine Management Resource Centre has been conducted on vaccine and cold chain management, no assessment has been conducted on the implementation of eVIN and its programmatic outcomes. This study was planned and conducted as similar ones are very limited till date.

Aims and Objectives: The study aims to assess the functioning of cold chain in post- eVIN (electronic vaccine intelligence net work) era in Nainital

district and to find out challenges of cold chain handlers, if any.

MATERIAL AND METHODS: Across-sectional study was conducted in 34 Cold Chain points of Nainital District from January 2022 to August 2022. All 8 blocks in District was included. Study was conducted in all cold chain points in the selected blocks as well as DIS of district.

These cold chain points cover the total population of 954,605(2011 census)¹. Closest CCP is 0 km from GMC college while distant one is 97kms. As sample size is not much, hence complete enumeration was chosen. A total of 34 cold chain points were included in the study. (**Fig. 1**) The administrators were contacted before hand and explained about the procedure and appointments were obtained for data collection. If any CCP declined to participate or unavailable after contact made for 3 times was removed from the study. Ethical clearance was obtained from ethical committee, GMC, Haldwani, Uttarakhand vide letter no. 624/GMC/IEC/2021/Reg. No. 584.

Informed and written consent was taken before data collection from all study participants and district central authority. Complete confidentiality of the informant was maintained.

All cold chain equipments along with their monitoring and backup equipments were observed and looked out for standards criteria fulfilment. Their compliance with eVIN app usage was also seen. CCH were asked for the challenges they are facing in using eVIN in any aspect in semi-open Questionnaire. Also, their recommendations sought for further improvements.

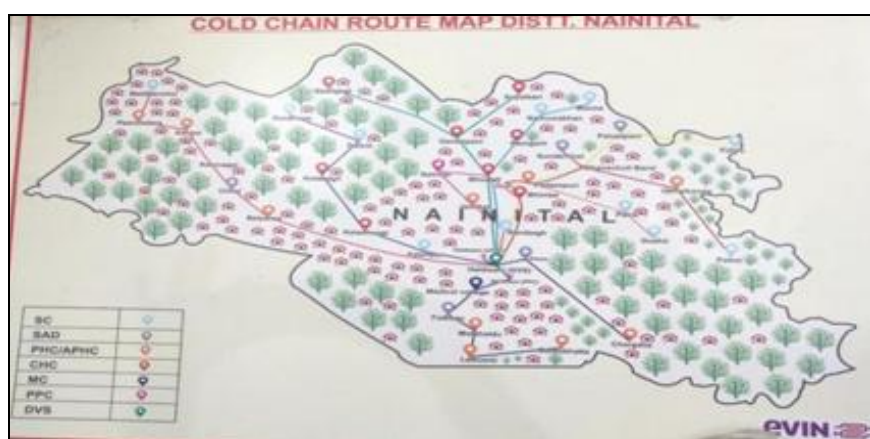


FIG. 1: COLD CHAIN POINT MAP (SOURCE: DISTRICT IMMUNIZATION OFFICE)

The data was compiled in MS Excel and SPSS version. For presentation of variables, frequency and percentage were used.

Inclusion Criteria: Cold chain handlers who will be available at centre, if not available they will be followed up during the next 3 visits. All cold chain handlers with minimum experience of 1 month were included.

Exclusion Criteria: While those CCHs who refused to participate and who have not provided any type of data, not found even after three visits or through any type of contact method and less than 1 month of experience as cold chain handlers were excluded from the study.

Operational Definitions:

Cold Chain Handler: Any staff (regular/contractual), as assigned by the facility in charge, with the responsibility of vaccine and cold chain management at any level of vaccine stores is known as Cold Chain Handler.

Cold Chain Equipment: It is a set of equipment which helps in providing recommended

temperature for the vaccines to preserve their quality during storage and transportation from the site of manufacture till their administration to the target beneficiary.

Recommended Temperatures: All vaccines under the National Immunization Programme are Stored at a temperature range of +2°C to +8°C. Diluents of vaccines should also be stored at a temperature range between +2°C to +8°C at least 24 hours before use.

Regular Defrosting: It is recommended that the Cold Chain Equipment be defrosted when frost thickness on the inner wall is more than 5 mm or once in a month (whichever is earlier).

Conditioning of the Ice-Packs: Before placing ice packs inside a cold box or vaccine carrier, they need to be kept at room temperature to prevent damage to the freeze-sensitive vaccines. This process is called conditioning. An ice pack is correctly conditioned when the water covers its surface and the sound of water is heard on shaking it.

RESULT AND DISCUSSION:

TABLE 1: STATUS OF COLD CHAIN EQUIPMENT AT CCPs

Characteristics	Deep Freezer (n = 33*)		Ice Lined Refrigerator (n=31**)	
	Yes	No	Yes	No
Placed on wooden block	33	0	31	0
Placed at least 10cm away from wall	33	0	31	0
Exposure to direct sunlight	1	32	0	31
Working thermometer available	33	0	31	0
Record of temperature twice day	33	0	31	0
Signature of person recording temperature	33	0	31	0
Defrosting recorded on temperature chart	33	0	31	0
Thickness of ice on side walls <5mm	32	1#	28	3#
Anything other than ice packs kept	0	33	1	30
Plugged to socket permanently	33	0	31	0
Store room fully ventilated	27	6	27	4
Temperature chart– Separate	33	0	31	0
Temperature chart-Up to date	33	0	31	0
Temperature chart– Signed by Supervisor/MO	33	0	31	0
Lids secured tightly	33	0	31	0

* DF Not available at one point/** ILR not available at 3 points. #in defrosting condition at time of inspection so could not be assessed for ice thickness.

Table 1 shows that all Deepfreezer (DF) and ILR were properly placed in 100% of the CCPs. In one of the CCPs we observed direct sunlight exposure of the DF. Both were connected to permanent socket. 27 CCPs have been found to have adequate

space and ventilation for the storeroom. A functional thermometer was placed inside every DF and ILR attached along with twice daily recording of temperature chart. No frozen vaccine and vaccine vial beyond expiry date were found in any

of the CCPs. None found to have ice thickness of more than 5mm while one DF and 3 ILR had been kept for defrosting at the time of inspection. Temperature chart was separate for each CCE and attached with them, all are up to date and countersigned by the supervisor/MO. In test of lid secure all of them had adequate secured tight lid. Vaccines were found to be stocked neatly and expired vaccines were labelled accordingly. Haldar *et al.*, (2022) ³ showed Ice lined refrigerator (ILR) were properly placed in 75% of the CCP. A functional thermometer was placed inside every ILR, and twice daily recording of temperature was found in all the CCPs. No frozen vaccine and vaccine vial beyond expiry date were found in any of the CCPs.

Gautam *et al.*, (2019) ⁴ reported that in 19/23 facilities, the ILRs were kept as per the guidelines. Daily twice recording of temperature was reported in 18 facilities. In 6/23 facilities the diluents were placed in cold chain 24 hours before the immunization sessions. Mend he *et al.* (2018) ⁵ showed that in 92% CCPs, the temperature of cold chain equipment (CCE) was recorded twice a day,

in 93% CCPs, vaccines were correctly stored in ILR, in 75% CCPs, icepacks were correctly stored in DF, 90% vaccine cold chain handler (VCCH) could correctly demonstrate temperature reading from thermometer. In study conducted by Sinha *et al.* (2017) ⁶, functional thermometer was available in 75% CCPs, out of which 65% had temperature in the recommended range. Twice daily recording of temperature was found only in 95 % CCPs. Record of power failures and defrosting was noted in temperature log books in 70% CCPs. The correct placement of ice packs in side Deepfreezer was observed in only one CCPs.

Jadhav *et al.* (2016) ⁷ observed that centre didn't have Ice line refrigerator or Deepfreezer, 13 centres didn't have deep freezer. In 22 centres, Cold Chain equipment were attached to stabilizer, 7 centres placed equipment as per standard norms, 3 centres had not maintained temperature charts, 3 centres didn't have thermometers. 10 centres showed discrepancy in recorded temperature. Vaccines at the session site were in zipper pouch in vaccine carrier at 23 centres.

TABLE 2: FUNCTIONAL STATUS OF COLD CHAIN EQUIPMENTS IN DISTRICT NAINITAL

Equipments	Total No. of CCE	Functional	Not functional	Decommissioned
Deepfreezer	44	39	4	1
Ice- lined refrigerator	45	33	9	3
Regular Refrigerator	9	9	0	0
Solar Refrigerator	2	1	1	0
Vaccine Carrier	1403	1131	268	10
Cold Box	55	53	6	0
Stabilizer	50	36	13	1
Generator	7	5	2	0
Inverter	12	11	1	0
Solar Backup	1	1	0	0
Icepacks	5242	4834	408	32

Table 2 shows that out of the 34 facilities that were surveyed, all had refrigerators for storing vaccines, had cold boxes, and 2 has solar refrigerators, all have vaccine carriers. Operational water and electricity were available in only 45.7% and 31.4% facilities respectively. In cold chain equipment's functional assessment of CCPs, majority had DFs and ILRs one is found not had DF and 3found to have not ILR. While all collective of 55 DFs 39 are in functional state 4 are non-functional while 1 has reported out of service. Of all 45 ILRs 33 were functional, 9 were non-functional and 3 were out of service declared. In 2

solar refrigerators one is functioning, and one is not. While out of 1403 vaccine carriers 1131 are in useful condition, 53 of cold box, 36 of stabilizer, 5 generator, 11 inverters and 4834 icepacks were in working condition. Solar backup was found at only one CCP but in working condition. (**Table 2**) Aggarwal *et al.* (2019) ⁸ assessed cold chain facilities and revealed that eVIN states have reported sickness rate of 1.9% within the acceptable limit. However, 3.4% sickness rate was reported across on-Evin states that are way beyond the acceptable limit. Bogale *et al.* (2019) ⁹ found that among 60 health institutions, only 46(76.7%)

had functional refrigerators. Twenty-one (35%) had a functional generator for backup service and 28(46.6%) had a car/motorbike for transportation of vaccines in case of refrigerator/power failure. Ojo *et al.* (2019) ¹⁰ found that eleven (31.4%) of the facilities had functional refrigerators for storing vaccines, 16(45.7%) had cold boxes while 13(37.1%) had thermometers for vaccine

temperature monitoring. Sreegiri *et al.* (2017) ¹¹ reported that ILRs and DFs were present and placed properly in all the PHCs with functional thermometer. Frost of > 5 mm was observed in the ILRs in 62.5% of PHCs. At all the session sites (100%), vaccine vials and diluents were placed in a plastic cover (zipper bag). Conditioned ice packs were seen in one session site only.

TABLE 3: SITUATIONAL ANALYSIS OF EVIN PERFORMANCE (N = 34)

eVIN's performance variables	Number of CCP's N(%)
Updating eVIN logs in CCPs	
Utilization log of vaccines in eVIN application	34(100)
eVIN vaccine log receipts	34(100)
eVIN stock count for vaccines, diluents,	34(100)
eVIN vaccine discard	34(100)
eVIN export of inventory	34(100)
Log for RI vaccines	34(100)
Log for open vial entry	34(100)
Log for utilization of vaccines in campaigns	34(100)
Frequency of Updating of stock in eVIN	
Once daily	0(0.0)
Twice daily	8(30.8)
Twice weekly on Wednesday and Friday	0(0.0)
Three to four-times weekly	26(69.2)
After each session	0(0.0)
Not updated for 11 months	0(0.0)
Gotosupport for eVIN related issues	
Technical support using toll-free no	3 (9)
Contact District Cold chain manager	31(91)
Contact District eVIN manager	0 (0)
Discuss the problem with seniors/colleagues	0 (0)
In the case of a network breakdown, Updating is done next day*	0 (0)

*Whenever network is restored till then manual log was maintained.

Table 3 shows that the open vials were labelled during issuing and after return in all 100% of CCPs. The cold chain handlers were enquired for updating stocks in eVIN. The stocks were updated in eVIN on utilization, receipt, and stock count in 100% of blocks.

The discarded stocks, on the export of inventory were updated. The entry under open vial was done in all CCPs. The stocks were updated in eVIN mostly three to four- times weekly (69.2%), followed by twice daily in only 8 (30.8%) CCPs. The cold chain handlers were asked an open-ended question about their approach in case they faced any problem. In most of the cases 31(91%), they responded that they contact the district cold chain manager. Only 3 (9%) contact the technical support provided on eVIN. Gurnani *et al.*, (2021) ¹² reported that the programme implementation was found average ranging from 53.6% to 63.8% and

the mechanism of vaccine logistic and cold chain was fair ranging from 71.0 % to 79.4 % across all the states. The mechanism of data recording and reporting was poor in Madhya Pradesh (36.8 %) and Maharashtra (47.0%) and average in the remaining three states. Kumar *et al.* (2019) ¹³ found that the stocks were updated in eVIN on utilization in all 100% of CCPs; in about 80% of blocks on receipt and stock count. The discarded stocks were updated in 21 (72.4%) blocks.

However, the stock update on the export of inventory was done only in 1 of the CCPs. The entry under open vial was done in all 29 blocks; while it was done in 28 (96.5%) PHCs during routine immunizations; and in 26 (89.7%) PHCs during campaigns. The stocks were updated in eVIN mostly daily (69%), followed by twice daily in only 3 (10.3%) PHCs. At three CCPs, it was updated twice weekly on Wednesday and Friday.

The stock was updated on eVIN 3-4 times weekly at one CCP and after each session at another CCP. There was one centre, where the stocks were not updated for the last 11 months. The cold chain handlers were asked an open-ended question about their approach in case they faced any problem. In one third of the cases (34.5%), they responded that they contact the district cold chain manager. One-fifth (20.7%) contact the technical support provided on eVIN, while another three (10.3%) discussed their problems with seniors/ colleagues. At two centres, the stocks were updated the next day in case of network breakdown. One-fourth of the participants gave no response. The cold chain

handlers were then enquired how quickly they received a response. One-fifth of them were responded immediately and another one-fifth within two days. Three cold chain handlers were responded with in 1 day. Half of the participants however didn't answer this question.

Ojo et al., (2019)¹⁰ Consumption record was considered by 69 (69.0%) of healthcare workers when making vaccine requisitions while the required lead time was considered by 24 (24.0%) of them. Only 29 (29.0%) of healthcare workers kept records of vaccines stock on hand.

TABLE 4: SITUATIONAL ANALYSIS OF PERFORMANCE OF eVIN IN DISTRICT NAINITAL (N=34)³¹

Stocks update	Yes	No
Did Manual Stock Management availability improved?	34	0
Does vaccine stock Improved	34	0
Does vaccine availability get better	34	0
Is real time data visibility available now in mobile application	34	0
does it had strengthened health system	34	0
Master chart/Immunization plan available in advance?	34	0
Cold Chain Charts list updated?	16	18
SOP regarding any CCE failure or AEFI provided?	34	0
Has the transportation of vaccines improved?	24	10

As per **Table 4**, Stocks were up to date both in logs and digital platform in all of them. Also, all 100% of them reported vaccine stock, vaccine availability, real time data visibility, health system strengthening, master plan availability and SOP regarding CCE failure or AEFI provision improvement. While 16 of them had provided with Cold chain charts list up to date, and 24 of them responded in transportation improvement following eVIN Implementation.

Asamoah et al. (2021)¹⁴ states regarding cold chain management practices, majority of the facilities had their vaccine vial monitors attached to the vaccines (8/12, 66.7%), had functional fridge tags (8/12, 66.7%), and an appropriate refrigerator to store vaccines (7/12, 58.3%). Also, the study observed that 91.7% (11/12) of the facilities did not have policies and guidelines on cold chain management while all 12 facilities (100%) did not have a contingency plan in place for equipment. Aggarwal et al. (2019)⁸ reported that during pre-eVIN era, only 56.2% facilities utilized Government of India register, whereas, in the post-eVIN period, almost 97% of the facilities utilized the GoI register. They also documented that around 97.2% facilities

spread across eVIN states ensured recording the temperature readings in the log book on the same day, whereas only 81.8% of cold chain facilities have ensured the same in the non-eVIN states. Das and Bora, (2018)¹⁵ stated that in 13 (86.6%) CCPs had dedicated cold chain room and dry storage facility. CCPs maintained records of defrosting. All functional cold boxes were observed to be dirt free and dry from inside and were not kept one above another. In all CCPs, the vaccine vials were correctly arranged inside ILR and all vials were found to be within expiry dates, with readable labels and vaccine vial monitor (VVM) in usable stage. As for open vials are concerned, in all CCPs open vials were stored in separate box/zipper bag. On the contrary, date and time were found written in open vials in 12 (92.3%) CCPs.

TABLE 5: RATING OF EVIN APPLICATION BY CCHS (N=34)

What Rating for eVIN application would you give (in performance) on 1 star to 5 star scale	No. of CCHs (n=34)
5	17
4	10
3	6
1	1

Most of the cold chain handlers were satisfied with 5-star rating and lowest been 1 star by one CCH with eVIN with average rating of 4.2. (Table 5) Aggarwal MK et al. (2019)⁸ showed at facility level, performance of eVIN application was rated 5 by 85% cold chain handlers while 15% cold chain handlers have rated 4. Ease of use factor was given rating of 5 by 90% cold chain handlers.

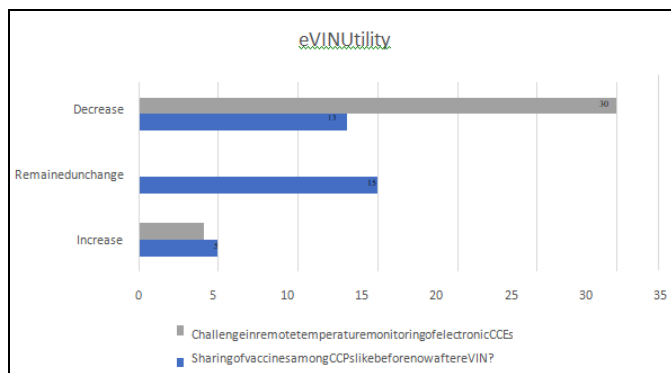


FIG. 2: EVIN UTILITY AND CONSTRAINTS (**1 CCP IS EXCLUDED AS IT IS RUNNING IN PPP)

Traditionally, stem thermometer is used to measure the temperature of cold chain equipment and readings are recorded in the temperature logbook twice a day, i.e. morning and evening. However, installation of eVIN data loggers by UNDP enabled real-time information on temperature of cold chain equipment, to monitor even from a remote distance and thereby made the cold chain management a more robust, effective, and implementable system.

It is evident from Fig. 2 that CCHs share vaccines from CCP to CCP in both pre- and post-eVIN period. Further, 11 CCPs have also shown reduction in the number of dosages shared across CCPs post-eVIN and 15 CCPs have reported condition remain unchanged while 5 of them had reported to increase in sharing, that signifies that states are better enabled in vaccine stock management. Following operationalization of order management tool in the eVIN system, it is expected that CCP to CCP sharing of vaccines will reduce further or completely stop the practice.

Aggarwal et al. (2019)⁸ showed that CCHs of Bihar, Manipur and Nagaland do not share vaccines from CCP to CCP in both pre- and post-eVIN period. Further, states such as Assam, Chhattisgarh, and Madhya Pradesh have also shown reduction in the number of dosages shared across CCPs post-

eVIN that signifies that states are better enabled in vaccine stock management.

Lutukai et al., (2019)¹⁶ cited that ability of cold chain equipment to maintain World Health Organization-recommended temperatures in study sites improved markedly between the baseline and implementation periods, resulting in an improvement in total time spent in the correct range from 83.9% in the baseline period to 90.9% in the intervention period and an improvement in time spent in the too cold range from 6.5% to 1.5%.

TABLE 6: CHALLENGES FACED BY COLD CHAIN HANDLERS IN HANDLING EVIN³¹

Challenge faced	No. (%)
Network issues	19(46%)
Mobile operation	10(24%)
Electricity backup	1(3%)
Maintaining eVIN log at >1CCP sites	1(3%)
No response	10(24%)

On being enquired with open-ended question about the challenges faced by them on working on eVIN, almost half of them had difficulty from network issue 19 (46%) followed by other problems. Kumar et al. (2019)¹³ reported that most of the cold chain handlers were satisfied (86.2%) and comfortable (82.8%) with the new technology of eVIN. On being enquired about the challenges faced by them on working on eVIN, one-fifth of them had difficulty in handling smart phone (20.7%) and another one-fifth had trouble with network connection (20.7%). Three of them (10.3%), reported that they had difficulty in updating data and another two (6.9%) found the previous method of updating the stock better than eVIN.

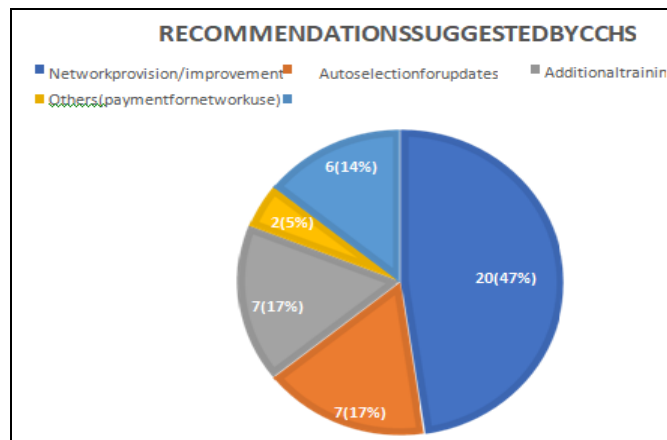


FIG. 3: RESPONSES BY CCHS ON RECOMMENDATIONS FOR IMPROVEMENT

Almost half of the CCHs had suggested for rectification of network issue 20 (47%) followed by 17% who recommended for auto selection of updates in eVIN and additional training for eVIN. (Fig. 5) Kumar et al. (2019)¹³ found that the cold chain handlers who were enquired about their suggestions on tackling their problems. Most basic tips given were the provision of the 3G/4G network in eVIN (6.9%), additional training (6.9%) and auto-selection for updating VVM status (6.9%). Few participants also suggested that there should be the provision of correction of filled data (3.5%) and entry of logistic details in eVIN (3.5%). Gurnani et al. (2021)¹² suggested that programme communication needs considerable improvement. Except Madhya Pradesh (62.4 %), the communication activities were poor in the other four states.

CONCLUSION: Cold chain management for vaccines in public health system is always associated with many challenges. Addressing these challenges require a lot of efforts by CCHs and key stakeholders across the vaccine supply chain.

The findings of this assessment suggest positive changes in the areas of vaccine utilization, stock management and distribution and documentation. States are benefitting with the implementation of eVIN and have been able to improve planning, management of stocks and distribution of vaccines to the last mile knowledge of vaccine handlers on cold chain and vaccine management was poor.

Unreliable power supply at public health centers appears to be the major challenge in maintaining there commended temperature range. Adherence to good storage practices like arrangement of products within the refrigerator, temperature monitoring and recording also needs an attentive eye from cold chain handlers. Budgetary constraints require the attention of higher-level management while most of there stare correctable by low-level administration at public health enters. Supportive supervision and regular training would improve their work efficiency.

Strength and Limitation: This study provides a steppingstone for the goal to achieve. The framework of the study could be used to assess the eVIN on state scale for better depth of gaps. The

sample size is small for generalization of the various findings in the study. Being across-sectional study could not generate the temporal relationship between the various risk factors. Due to time limitation and covering the whole district with restricted supports the data was not collected in extensive manner.

Recommendation: A well-maintained cold chain system is necessary for smooth administration of vaccine to the beneficiaries. There was inadequate emergency power supply at some places, non-availability of contingency plan that need consideration.



FIG. 4: SHOWING PREVIEW IMAGES OF INSPECTION AT SITE

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CONFLICT OF INTEREST: None

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