

# International Observer

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Dr. Samant and colleagues help remind us that even the best vaccine programs are limited by our ability to distribute the vaccine and maintain its potency. Vaccines are sensitive biological substances that lose their potency, particularly when exposed to higher temperatures. Of course, the places where the vaccination programs are operating are rural areas in developing countries with limited resources and limited staff. Things as simple as coolers or refrigerators may not be available. The article describes the vulnerable areas where potency loss is most likely to occur: out in the rural districts. One can see that the vulnerability increases as the vaccine moves from the larger medical centers to the smaller centers.

The number of facilities studied is small, but the data illustrate a real world concern: distance and potency (maintaining the cold chain) were inversely related. The authors do recommend appropriate practices for improving the potency; however, several require capital that may not be available, such as investing in a reliable electrical source for the clinics. This article reminds us that public health requires tools beyond instruments and pharmaceutical agents, and some of these tools are fairly simple. Effective vaccination programs in the developing world can be severely limited by things that are normally taken for granted in the more developed countries.

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## EVALUATION OF THE COLD-CHAIN FOR ORAL POLIO VACCINE IN A RURAL DISTRICT OF INDIA

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Vaccine preventable diseases like polio, measles, and hepatitis are a major cause of morbidity and mortality among children in developing countries.<sup>1</sup> Vaccination is one of the most effective disease prevention strategies when implemented properly across all sections of the at-risk population. Immunization against a disease is achieved only if a potent vaccine is administered. The system used for keeping and distributing vaccines in good condition is called the “cold chain.” This consists of a series of storage and transport links, all of which are designed to keep the vaccine at the correct temperature until it reaches the recipient. A typical cold chain system for vaccine is shown in Figure 1.<sup>2,3</sup>

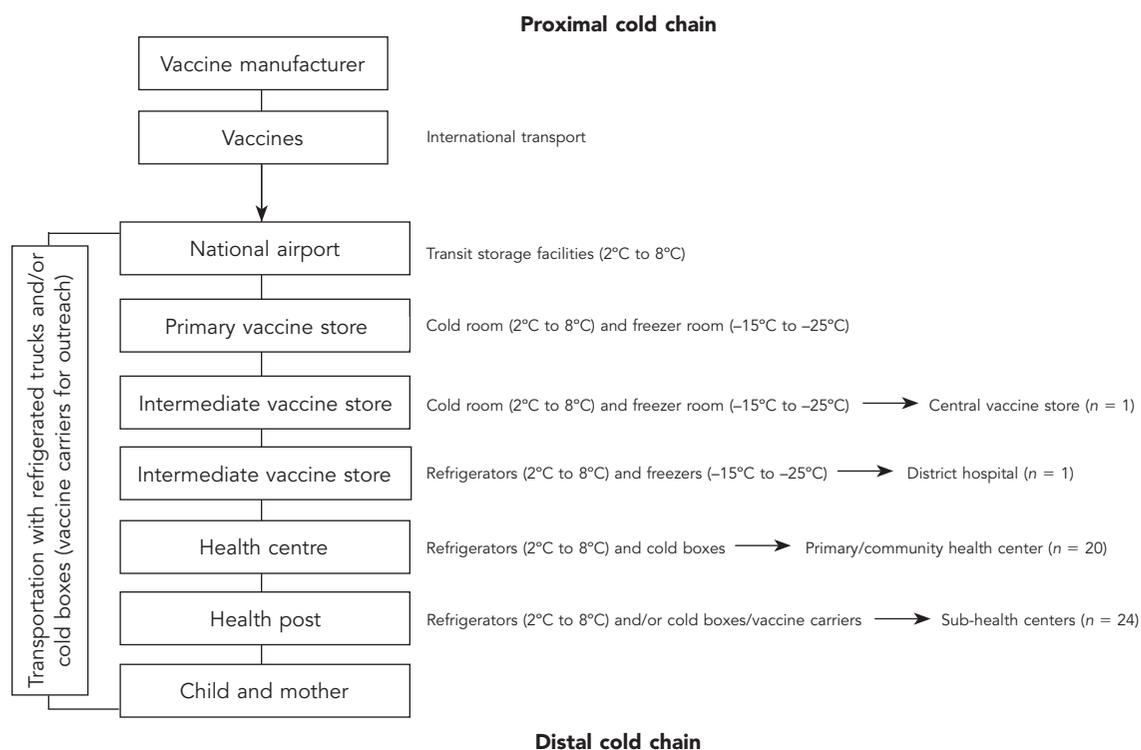
Literature concerning vaccination rates in India indicates a considerable disparity between children in urban compared with rural areas.<sup>4,5,6</sup> In addition, 75% of the health infrastructure, medical personnel, and other health resources are concentrated in urban areas of India, whereas only 27% of the population lives in the urban parts of the country.<sup>7</sup> The weak health

infrastructure and unsanitary conditions contribute to the increased incidence of diseases like polio, cholera, and hepatitis in rural compared with the urban areas.<sup>8</sup> The rural manifestation of polio in India is confirmed by the number of polio cases reported in prevalence studies and independent reports on polio.<sup>9,10,11</sup>

The oral polio vaccine (OPV) has proven to be effective in preventing the transmission and spread of polio. Along with acute flaccid paralysis case surveillance, OPV immunization has tempered the spread of polio in India; the number of polio cases dropped from 1,600 in 2002 to 45 in 2005.<sup>12</sup> The majority of these cases were found in north and north-central regions of the country.<sup>12</sup>

OPV may lose 4% to 13% of its potency per day at 25°C, 11% to 21% per day at 31°C, and 26% to 34% per day at 37°C.<sup>13</sup> Such high temperatures are typical in parts of north and north-central regions of India from April until June. Polio incidence spikes during these months and wanes toward end of the year.<sup>12</sup> Thus, the cold chain plays a central role in the polio eradication initiative in the rural areas, given the frequent power failures and high summer temperatures.<sup>14,15</sup>

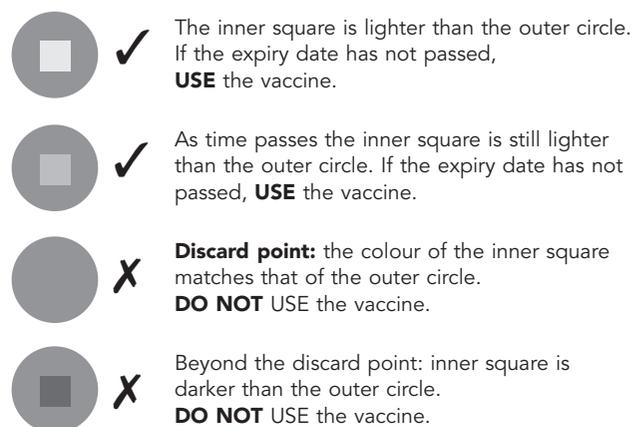
In order to maintain potency of the OPV over extended periods, the World Health Organization (WHO) has recommended a protocol for temperature maintenance and equipment requirements at each level in the cold chain system. The cold chain system extends from the manufacturing site to the point of vaccine administration (Figure 1). The WHO uses a vaccine vial monitor to assess the maintenance of the cold chain at each level in the storage and distribution

**Figure 1. Pictorial representation of WHO protocol for cold chain maintenance**

SOURCE: World Health Organization. Vaccines, immunization and biologicals. The cold chain [cited 2006 Oct 18]. November 26, 2002. Available from: URL: [http://www.icn.ch/matters\\_colds.htm](http://www.icn.ch/matters_colds.htm)

of the OPV<sup>16</sup> (WHO, 2002). The vaccine vial monitor is designed to progressively and permanently change its color if exposed to high temperatures over an extended period of time (Figure 2).

Prior cold chain evaluation studies have been reported as rapid assessments of the cold chain system in small sectors of urban India such as Bangalore, Chandigarh, and Delhi.<sup>17,18,3</sup> Researchers reported defects in the cold chain and the need to strengthen this mechanism to achieve successful polio eradication.<sup>17,18,3</sup> Aggarwal et al., in their assessment of the cold chain in New Delhi, reported 15% of vaccination clinics had a shortage of vaccine carriers.<sup>18</sup> Goel et al. reported unsatisfactory maintenance of the cold chain equipment in their evaluation of cold chain system in Chandigarh.<sup>3</sup> However, these studies have not evaluated the cold chain in a rural area as a series of storage and transport links in a hierarchical fashion (from Intermediate-1 Level to Health Post Level as shown in Table 1) using the WHO-India protocol, and, thus, the findings are unable to pinpoint gaps in the cold chain as a whole entity.

**Figure 2. Vaccine vial monitor**

**Table 1. Definition and sampling of the WHO-India cold chain protocol**

<i>Indian terminology (WHO terminology)</i>	<i>Number of facilities</i>	<i>Number sampled (percent sampled)</i>	<i>Definition</i>	<i>Cold-chain protocol</i>
Central vaccine store (Intermediate-Level 1)	1	1 (100%)	This is a central vaccine storage facility with cold-and freezer-rooms. The rural district under study receives all vaccines from this facility. It is located 50 kilometers away from the district hospital.	<ul style="list-style-type: none"> <li>• Presence of walk-in freezer or cold rooms</li> <li>• Temperature maintenance charts</li> <li>• Temperature 2–8° C</li> <li>• Power generator</li> <li>• Formed ice packs</li> <li>• Adequately maintained vaccine carriers (not cracked)</li> </ul>
District hospital or facility (Intermediate- Level 2)	1	1 (100%)	The district hospital is a health facility that is a state-funded institution, which serves as the highest level health care facility in the rural area under study. This facility receives all vaccines including OPV from central vaccine store. From here vaccines are sent to health center levels and health post levels for vaccine storage and distribution.	<ul style="list-style-type: none"> <li>• Walk-in freezer rooms, cold rooms, ice-lined refrigerators, or deep freezers</li> <li>• Supported on wooden blocks</li> <li>• 10 centimeters away from the wall</li> <li>• Temperature maintenance charts</li> <li>• Adequately maintained vaccine carriers (not cracked)</li> <li>• Formed ice packs</li> <li>• Temperature: 2–8° C</li> </ul>
Primary health center/community health center (Health center)	56	20 (36%)	Health centers act as an intermediary between the Intermediate Level-2 facility and the health posts located in remote areas of this district.	<ul style="list-style-type: none"> <li>• Ice-lined refrigerators, deep freezers, or refrigerators</li> <li>• Supported on wooden blocks</li> <li>• 10 centimeters away from the wall</li> <li>• Temperature maintenance charts</li> <li>• Adequately maintained vaccine carriers (not cracked)</li> <li>• Formed ice packs</li> <li>• Temperature: 2–8° C</li> </ul>
Sub-health center (Health post)	196	24 (12%)	Health posts act as the distal point in the cold chain where vaccine is administered. The vaccines are stored at this level for only a short period.	<ul style="list-style-type: none"> <li>• Adequately maintained vaccine carriers (not cracked)</li> <li>• Formed ice packs</li> <li>• Temperature: 2–8° C</li> </ul>
Total	254	46 (18%)		

A recent study evaluating the cold chain at different levels of storage in northern India attributed weaknesses in the cold chain to the loss of vaccine potency.<sup>19</sup> However, this study used the vaccine vial monitor to evaluate the cold chain and did not include the evaluations of the cold chain equipment or temperature maintenance requirements. A review of the literature yielded two studies conducted more than a decade ago evaluating the cold-chain equipment in rural India. Aggarwal et al. reported a number of shortcomings concerning the cold chain such as power

failures and improper and inadequate maintenance of the equipment.<sup>14</sup> Bachani et al. reported a shortage of temperature maintenance equipment. In this study, only 58% of the sub-health centers reported having vaccine carriers to transport the vaccines.<sup>20</sup>

Our study was designed to evaluate the cold-chain equipment in a rural district of central India. In this article, we present data concerning the compliance of equipment and temperature maintenance at each level (i.e., type of health center) of the cold chain in the rural district under study.

## MATERIAL AND METHODS

### Confidentiality

This research did not involve human subjects and was exempt from individual informed consent requirements. Permission to include health centers for cold chain maintenance was obtained from the District Health Officer, who is responsible for overseeing health centers in the study district. At the request of District Health Officers, none of the health centers included in this study is identified by name.

### The World Health Organization-India guide for cold chain maintenance

The WHO has a global protocol for cold chain maintenance, as shown in Table 1. Further, the Ministry of Health and Family Welfare, Government of India, developed a country-specific guideline for cold chain maintenance.<sup>21</sup> We used these protocols for our evaluation of the cold chain (it is referred to as the WHO-India protocol from here onward in this article).

The health facilities that constitute the cold chain in rural India are defined in Table 1 along with the terminology used by the Government of India. Briefly, the central vaccine store (WHO Intermediate Level-1) is the storage facility with cold rooms and walk-in freezer rooms. The district hospital (WHO Intermediate Level-2) serves as the highest level health care provider in a rural area. Primary/community health centers (WHO health centers) act as an intermediary between the district hospital and the sub-health centers located in remote areas. Sub-health centers (WHO Health Posts) act as the farthest point in the cold chain at which the vaccine is administered.

As seen in Table 1, the protocol recommends walk-in freezers or cold rooms at the central vaccine storage facility; ice-lined refrigerators, deep freezers, refrigerators, walk-in freezers and vaccine carriers at district hospitals; ice-lined refrigerators, refrigerators, deep freezers, or cold boxes and vaccine carriers at primary/community health centers; and vaccine carriers at sub-health centers.<sup>21</sup>

WHO-India recommends that each vaccine storage and distribution facility with electrically operated refrigeration equipment have a power generator to secure a reliable source of electricity. A temperature maintenance chart is recommended at all facilities in a cold chain that have electrically powered refrigeration or freezers.<sup>21</sup>

WHO-India also recommends that ice-lined refrigerators and deep freezers be supported on wooden blocks, be kept shaded from sources of heat or sunlight, and be located at least 10 centimeters away from walls. It is also recommended that ice-lined refrigerators, deep

freezers, and refrigerators maintain a temperature of  $\geq 2^{\circ}$  to  $\leq 8^{\circ}$  centigrade for OPV.<sup>21</sup>

Vaccine carriers and cold boxes are non-electrical equipment used for vaccine storage and transportation. The vaccine carriers use properly frozen icepacks to maintain an adequate temperature.<sup>21</sup>

### Study area

The cold chain evaluation was conducted in a rural district of central India. This district has an area of 5,000 square kilometers and a population of about 1.2 million. The district is served by one district hospital, 46 primary health centers/community health centers, and 196 sub-health centers. Five compatible polio cases and 64 acute flaccid paralysis cases were reported in this district in 2004. [Note: A polio-compatible case is one in which one adequate stool specimen was not collected from a probable case within two weeks of the onset of paralysis, and there is either an acute paralytic illness with polio-compatible residual paralysis at 60 days, or death takes place within 60 days, or the case is lost to follow-up. In acute flaccid paralysis, the polio virus affects the anterior horn cells in the spinal column which control movement of the trunk and limb muscles including the intercostals muscles. An affected limb becomes floppy and poorly controlled.]

The classification of health centers in the study area was tailored to the WHO classification (Table 1) after consultation with local WHO and India government personnel. Assessment of the cold chain was initiated at a central vaccine storage facility located 50 kilometers from the district hospital and terminated at remote sub-health centers in this study area (Figure 1).

### Cold chain evaluation instrument

The cold chain evaluation instrument was designed using the WHO-India cold chain maintenance protocol.<sup>21</sup> Public health researchers from the Division of Health Services Research, University of Minnesota, assisted with this process. Further consultation was sought for completeness and accuracy of the evaluation instrument from the WHO representative and the District Immunization Officer posted in the study area.

The evaluation instrument included information on demographics, electrically powered vaccine storage equipment (e.g., ice-lined refrigerators, deep freezers); non-electrical vaccine storage equipment (e.g., cold box, vaccine carriers); icepacks, power generators, and temperature monitoring charts; assessment of the set-up and maintenance of electrical equipment; problems relating to frequency and seasonal trends of power failure; availability of a repair technician; and a vehicle for transporting the vaccines (Figure 3).

**Figure 3. Sample evaluation instrument**

Evaluator number: \_\_\_\_\_

Facility name: \_\_\_\_\_

Facility type: \_\_\_\_\_

Distance from intermediate level-2: \_\_\_\_\_

	Present	Temp monitoring				Adequately maintained	Notes
		1st	2nd	3rd	Average		
Ice-lined refrigerators							
Deep freezers							
Refrigerator							
Vaccine carrier							
Cold box		NA	NA	NA	NA		
Ice packs		Formed		Not Formed		NA	
Temp maintenance chart		Maintained				Not maintained	
Generator		Yes				No	
Vehicle		NA				No	
Repair technician		NA				NA	

Only items relevant items to this manuscript have been displayed in this instrument.

NA = not applicable

**Sampling**

A stratified multi-stage sampling strategy was used in this study. Stage I involved sampling of vaccine storage and distribution facilities at each level in the cold chain (Table 1). Stage II involved sampling equipment used to store and transport the OPV within each vaccine storage facility that was sampled in Stage I.

**Stage I**

In order to evaluate the first point of breach, we moved up the cold chain until we reached a facility that was in full compliance with the WHO-India recommended protocol. The central vaccine storage facility located outside the study area had 100% compliance, so this was the starting point for the evaluation of cold chain failures (Figure 1).

The next facility sampled in the chain was a single district hospital that served the four zones of the rural district. Using a random number table, five primary/community health centers and six sub-health centers were sampled from each of the four zones in this district. Twenty primary/community health centers (36%) and 24 sub-health centers (12%) were

evaluated. Including the central vaccine storage facility located in a major city 50 kilometers from the district hospital, the sample included 46 vaccine storage and distribution facilities.

**Stage II**

Cold chain equipment (ice-lined refrigerators, deep freezers, vaccine carriers, etc.) used to store and distribute OPV was randomly sampled at each of the health centers included in Stage I sampling.

**Central vaccine storage facility.** The central vaccine storage ( $n=1$ ) facility had a single walk-in freezer for vaccine storage. This facility was included because it was the only vaccine storage and distribution center for the rural district under study. The walk-in freezer was assessed for compliance to temperature maintenance protocols. On the day of evaluation, no vaccine carriers were being used for transportation of the vaccines from this facility to the district hospital; thus, no vaccine carriers were included in the sample at this level.

**District hospital.** The district hospital ( $n=1$ ) receives all vaccines including OPV from the central vaccine

store and sends them to primary/community health centers and sub-health centers for vaccine storage and administration. Of the eight pieces of vaccine storage equipment (ice-lined refrigerators, deep freezers, refrigerators) present at this level, four were evaluated. In addition, the four vaccine carriers used for transporting the vaccines to the health centers were evaluated. This represented all of the vaccine carriers that were used by the facility.

**Primary/community health centers.** These facilities act as an intermediary between the district hospital and the sub-health centers located in remote areas. Twenty out of 56 facilities at this level were evaluated. At each facility, the number of ice-lined refrigerators, deep freezers, or refrigerators ranged from zero to six. Although each of these facilities had 10 to 100 vaccine carriers, not all of the carriers were in use on any given day. When cold chain equipment was present, a 25% random sample of equipment was evaluated. Based on this protocol, the sample included no more than two pieces of equipment at this level.

At least one of the vaccine carriers used for transportation of OPV on the day of the evaluation (5%) were evaluated. For example, if a health center had 20 vaccine carriers that were used for OPV transportation, then one vaccine carrier was evaluated. The number of vaccine carriers included in the sample at this level ranged from zero (i.e., no carriers were present) to three.

In addition, at least one cold box was included in the sample at this level. WHO-India recommends the presence of at least one cold box at primary/community health centers. A cold box is non-electrical vaccine storage equipment and is similar to vaccine carriers, but can store large amounts of vaccine for longer periods. It is used to store vaccines and transport large amounts of vaccine and in case of power failures.

**Sub-health center.** Twenty-four of 196 sub-health centers at the distal end of the cold chain were sampled. The vaccines are stored at this level for only a short period. These facilities are not required by the WHO-recommended protocol to have any electrical vaccine storage equipment; the vaccine carriers serve the purpose of storing the vaccines. When present, 25% of vaccine carriers were included in the sample for evaluation. The number of vaccine carriers included in the sample at this level ranged from zero to two.

#### Evaluation protocol

A physician from India and a public health student from the University of Minnesota evaluated the cold

chain equipment. The WHO representative and the District Immunization Officer in the study area provided training on evaluation of the equipment using the evaluation instrument. Data were collected over a period of four weeks using the cold chain evaluation instrument. Typically, only one evaluator assessed equipment at each facility. A WHO representative accompanied the evaluators to nine (20%) health centers in order to monitor data quality and adherence to the study protocols.

The following process was followed for the evaluation of cold chain equipment. First, the evaluators checked for the presence and maintenance of the equipment at each level in the cold chain. Second, the evaluators assessed the equipment for adequate temperature maintenance. Third, if the facility had electrical refrigeration equipment, it was assessed for presence and maintenance of a temperature monitoring chart and presence of a working power generator.

Temperature maintenance of cold chain equipment was assessed with a digital thermometer that had a range of  $-50^{\circ}$  centigrade (C) to  $150^{\circ}$  C (margin of error of  $+1^{\circ}$  C from  $-20^{\circ}$  C to  $120^{\circ}$  C). Temperature was recorded by keeping the thermometer in the sampled piece of equipment for one minute. They measured the temperature three times at five-minute intervals and used the average of the three temperatures to report the temperature for a particular piece of equipment. A piece of equipment that did not conform to the temperature requirements was considered inadequate.

Next, temperature charts were evaluated for the presence and maintenance of proper temperature monitoring for each piece of electrical equipment. Temperature monitoring was deemed inadequate if a monitoring chart was present but not maintained (i.e., if it did not have any temperature recordings in the preceding 24 hours).

Only nonelectrical equipment (such as vaccine carriers) in use on the day of evaluation were included in the sample. Vaccine carriers were assessed for adequate maintenance (not cracked, properly fitting lids), temperature maintenance ( $<8^{\circ}$  C) and the presence of properly formed icepacks (frozen). Cold boxes were evaluated only for being present and not for temperature maintenance, as the authorized health personnel in the health centers of the study district reported them being used only in case of a power failure.<sup>21</sup>

Two primary/community health centers were using generators because of power failure and we were able to obtain information on their working condition. In most instances, information on the power generator was obtained from the authorized personnel at the

facility (for example, the medical officer at a health center facility) because it was not possible to disengage power in order to evaluate the generator.

### Data management and analysis

Data were entered into a Microsoft Excel database.<sup>22</sup> A cold chain compliance score was computed for each level facility. Each item (e.g., temperature chart) included in the cold chain compliance was equally weighted because each component of the cold chain is critical for adequate vaccine storage. Each piece of equipment was given a score of 0–100%, based on it being present and adequately maintained. An average cold chain compliance score based on cold chain equipment was computed for each facility.

For example, at a vaccine storage facility, if four pieces (A, B, C, and D) of equipment were sampled for the purpose of evaluation, then each piece could obtain a score of *up to* 100% depending on it being present and adequately maintained based on the evaluation protocol ( $\{A+B+C+D\}/4 = 100\%$ ). If only three of these four pieces of sampled equipment complied with the protocol, then this facility obtained an average compliance score of 75%.

Data analysis was performed using SPSS.<sup>23</sup> Descriptive analyses were used to obtain demographic information such as number of health facilities at each level in the cold chain and their distance from the district hospital. Chi-squared tests were used to examine the relationship between cold chain compliance scores, type of health facility, and distance between health centers. Regression analysis was used to examine the distance of health centers and cold chain compliance scores.

## RESULTS

As seen in Table 2, a total of 46 facilities were evaluated. This included one central vaccine store, one district hospital, 20 primary/community health centers, and

24 sub-health centers. The mean cold chain compliance score obtained across the health centers in this district was 60%. The range of compliance scores was 0–100%.

### Central vaccine store

The central vaccine storage facility was in full compliance for equipment maintenance, temperature maintenance, temperature monitoring, and electrical power generator. This facility attained a cold chain compliance score of 100%.

### District hospital

All sampled refrigeration equipment was adequately maintained at the district hospital. Two of the four vaccine carriers sampled at this level did not have a properly formed icepack; however, the vaccine carriers were able to maintain the required temperature. This facility had a working electrical power generator. Because icepacks in two of the four sampled vaccine carriers were not frozen, this district hospital was not in full compliance and procured a cold chain compliance score of 87.5%.

### Primary/community health centers

Seventy-three percent of the deep freezers, ice-lined refrigerators, and refrigerators were present and maintained the required temperature. Sixty-five percent of the facilities adequately maintained the temperature-monitoring chart. Ninety-five percent of the vaccine carriers had adequately maintained temperatures. Seventy-five percent of these facilities at this level complied with the cold box requirements. Eighty percent of the icepacks sampled at this level were in proper condition. Only 45% of the health centers had an electrical power generator, and 90% ( $n=18$ ) of these health centers reported frequent power failures. These primary/community health centers ( $n=20$ ) procured an average cold chain compliance score of 74%.

**Table 2. Relationship between facility type and cold chain compliance scores**

Health system nomenclature (India)	WHO cold chain nomenclature	n	Compliance score	Significance
Central vaccine store	Intermediate Level-1	1	100%	NA
District hospital	Intermediate Level-2	1	88%	NA
Primary health center/ community health center	Health center level	20	79% <sup>a</sup>	$p<0.05$
Sub-health center	Health post level	24	48% <sup>a</sup>	

<sup>a</sup>Statistically significant

### Sub-health centers

Only 58% of vaccine carriers maintained the required temperature. Thirty-eight percent of the icepacks lining the sampled vaccine carriers were in the proper condition. These sub-health centers ( $n=24$ ) procured an average cold chain compliance score of 48%.

### The relationship between health centers and compliance scores

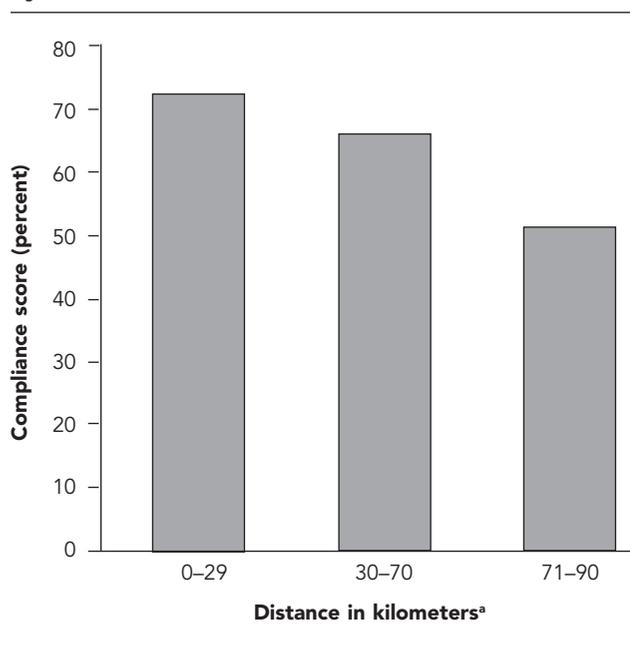
As seen in Table 2, primary/community health centers were more compliant with cold chain requirements than were sub-health centers. Eighty percent ( $n=16$ ) of primary /community health center facilities obtained a cold chain compliance score of more than 50% compared with 33% ( $n=8$ ) of sub-health center facilities ( $p<0.05$ ).

In general, as the distance of the primary/community health centers or sub-health centers from the district hospital increased, the cold chain compliance scores decreased (Figure 4). For every one-kilometer increase in distance, the cold chain compliance score decreased by 0.16 units; however, this relationship was not statistically significant ( $p>0.05$ ).

## DISCUSSION

There is little evidence in the literature on the evaluation of a cold chain for OPV in rural areas of India.

**Figure 4. Cold chain compliance score by distance in kilometers**



<sup>a</sup>Each distance category included approximately 14 health centers.

Given the endemic nature of polio in India, it is critical that measures are taken to better secure the delivery of a potent OPV. Our data indicate that 24% of vaccine carriers across all the levels of the cold chain were noncompliant. This finding is comparable to the data reported by Aggarwal et al. (1995),<sup>14</sup> where 28% of vaccine carriers were found to be noncompliant in a cold chain evaluation in another rural district of India.

Our study found that, overall, the cold chain compliance across all levels in this rural district was 60.4%. Goel et al. (2004)<sup>3</sup> evaluated the cold chain equipment in the city of Chandigarh, India, and reported 91% cold chain compliance. Although there may be methodological differences between the two studies in the evaluation of the cold chain, a significant discrepancy between urban and rural cold chain compliance is evident.

Our results demonstrate that as distance from the district hospital increases, there is a concomitant difficulty in maintaining the cold chain. Our data point to the difficulty in reaching rural communities with adequate immunizations. This is consistent with work conducted by Datar et al.<sup>24</sup> These authors reported that as distance from larger health centers increased, immunization coverage decreased.

Another issue of concern is power supply at the primary/community health centers in this rural district. Electrical power or an alternative source of energy is crucial to the maintenance of the cold chain, and our data indicate 90% of all primary/community health centers reporting frequent power failures (5–10 hours) during summer months. This is compounded by the fact that only 45% of these primary/community health centers have a power generator that can help maintain the cold chain. Given these findings, feasibility and potential of solar technology in rural India to improve health infrastructure and, in turn, the cold chain need to be assessed.

Our findings concerning cold chain deficits are also relevant for other heat-labile vaccines such as DPT (diphtheria, pertussis, and tetanus), MMR (measles, mumps, and rubella), and BCG (bacillus Calmette-Guérin) that require storage in controlled temperatures. Previous studies concerning efficacy of heat-labile vaccines (OPV, DPT, MMR, and BCG) have indicated a weak cold chain as a potential threat to potency of these vaccines.<sup>25,2</sup> However, in this study we largely used temperature requirements concerning OPV as a point of reference for evaluation of the cold chain, as OPV is the most heat-sensitive of all the heat-labile vaccines. This certainly restricts us to making only cautious generalizations of our findings to other heat-labile vaccines.

This study has two limitations. First, the small sample size allows a limited generalization of the findings. However, randomization applied at each level helps improve the external validity of this study. Second, this study does not include sampling of vaccine vials for potency testing of the OPV. Thus, the cold chain compliance scores serve strictly as an objective measure based on the WHO-India protocols and are not necessarily a measure of vaccine efficacy.

## CONCLUSIONS

Although our data are from one rural district of central India, cautious generalizations to other rural areas of the country may be made because of similar centralized health infrastructure, socio-political environment, and topography.

These findings are also critical because in spite of incessant efforts by the global community over the past 20 years, polio continues to elude eradication and has been re-emerging in different parts of the developing world. Regardless, it is the most likely among communicable diseases to be globally eradicated. We hope our research effort contributes to these global efforts of polio eradication.

Furthermore, cold chain maintenance is not only important for the polio eradication efforts, but is also critical to other heat-labile vaccines such as DPT, MMR, and BCG. Thus, strengthening the cold chain will benefit the polio eradication initiative as well as efforts to control other vaccine-preventable diseases.

The following recommendations may help to improve the cold chain in rural India and, most likely, other regions of the world:

1. Because primary/community health centers and sub-health centers are located in remote areas, it may be worth investing in a reliable source of electrical supply for these health centers. We recommend conducting feasibility studies using low-cost, globally available resources of alternative energy such as solar energy to maintain sustainable electrical power supply.
2. If a sustainable electrical power supply is available at all the health centers across a rural region, then we recommend decentralization of the vaccine distribution and delivery system. Because vaccines may be stored at all levels in the cold chain, changes should be considered that reduce transit time of vaccines and the long-term exposure of vaccines to higher temperatures for extended periods of time.
3. Vaccine carriers are a critical element in the cold chain. They are the preferred mode of storage for vaccines during transit in rural India. However, our data indicate that vaccine carriers were inadequate for proper vaccine storage at primary/community and sub-health centers. We recommend supplementing the established quality control and maintenance protocols for vaccine carriers with daily written documentation posted on the vaccine carrier. This should include information such as condition of icepacks (frozen or not) at regular intervals over the day and need for repair of the vaccine carrier.
4. Vehicles used for transportation of vaccines become quite hot when they sit in the sun, which may adversely affect the vaccines stored in a vaccine carrier. We recommend the use of a plug-in device such as a portable thermoelectric cooler that may be used to store the vaccines while in transit to remote locations.
5. We recommend that future research include evaluation of the cold chain process in India as well as in other nations. This is particularly important in regions where there is evidence of immunization failure or the reemergence of vaccine-preventable illnesses in warmer climates.

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