THE COLD CHAIN AND THE EXPANDED PROGRAM ON IMMUNIZATION IN CHILE: AN EVALUATION EXERCISE[1]

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A major 1980 measles epidemic in Chile encouraged investigation of the "cold chain"—the method of storage, handling, transport, and distribution facilities responsible for ensuring vaccine potency. This article reports the results of that investigation.

Introduction

The progress of medicine has provided us with immunizing agents that are highly effective in controlling certain communicable diseases. In many countries these agents have made it possible to control, and in some cases to eradicate, diseases vulnerable to them. Nevertheless, in most developing countries communicable diseases preventable by immunization continue to pose important health problems.

This state of affairs has led PAHO/WHO to devise a strategy for extending the benefits of immunization to the whole population of the Americas *(1)*. This strategy, developed under the auspices of the WHO Expanded Program on Immunization (EPI), is directed at six diseases of epidemiologic importance—tuberculosis, poliomyelitis, diphtheria, tetanus, whooping cough, and measles. To meet the program's basic requirements, this strategy calls for standardizing the procurement, handling, and control of the immunizing agents involved *(2)*.

Chile, which is participating in this program, has largely met the EPI requirements for the immunizing agents currently being used *(3)* with regard to vaccine efficacy, ease of administration, absence of intense general or local reactions to immunization, and the need to keep costs compatible with available health service funds. The only need not fully satisfied is that of maintaining the agent's biological stability—that is, conserving the vaccine's antigenic strength so that useful antibody levels will be achieved.

Biologically, EPI vaccines are labile products that demand a delicate and complicated system of protection. The virus vaccines (against poliomyelitis and measles) are particularly sensitive to sunlight and increases in temperature; their average life is limited even under optimum storage conditions; and they can be denatured by the presence of halogenated residues in the inoculum.

Chile has subscribed to the EPI and is applying it through the nation's preexisting health structure. In so doing, it is continuing to treat immunization activities as part of the health promotion and protection activities for which the Government is entirely responsible and which are provided free of charge to the population. These immunization activities are currently carried out through a network of 27 health services that reaches numerous hospitals, clinics, and rural health posts and that covers the entire national territory. In the Metropolitan Region, which includes the capital city of Santiago, seven of these health

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services provide immunizations to 40 per cent of the national population (over four million people).

The central authority in charge has decentralized the administration, execution, and daily responsibility for the immunization programs to these 27 services; but it has retained the functions of standardization, control, and evaluation. For these purposes it utilizes such subordinate agencies as the supply center (for the purchase of equipment and materials) and the Institute of Public Health (which serves as a national laboratory and reference center for diverse programmed activities).

The fact that this system covers the entire national territory has made it possible to achieve fairly high coverage rates with measles and DPT vaccines (for example, these rates were 83.7 and 83.0 per cent, respectively, in 1980) *(4)*. Although short of ideal, such rates of coverage should have produced a substantial decline in the incidence of measles, diphtheria, whooping cough, and tetanus, and a cessation of epidemic outbreaks. But this has not occurred; instead, a 1980 measles outbreak caused over 50,000 reported cases, bringing overall measles morbidity that year to 316 cases per 100,000 inhabitants *(5)*.

There was strong evidence that this situation was intimately connected with the cold chain, the closely interrelated "chain" of storage, handling, transport, and distribution facilities at the central, regional, and local levels upon which the preservation of vaccine potency depends *(6, 7)*. Accordingly, it was decided that a study of the cold chain should be conducted in an effort to identify situations that could be corrected and to improve the technical and administrative development of the program.

Specifically, the objectives of the study were as follows:

1. To determine the degree to which the EPI standards for procurement, receipt, transfer, control, maintenance, and distribution of vaccines were being met.
2. To assess the turnover, knowledge, and training of auxiliary vaccination personnel against the relevant standards established for vaccine and cold chain management.
3. To determine the antigenic potency of measles vaccine samples available at the time visits were made to local clinics, regional health storage sites, and the central supply facility.
4. To test a written instrument designed for the express purpose of assessing achievement of the first two objectives cited.

Materials and Methods

The study sought to provide a descriptive assessment of work being performed at the central, regional, and local levels in the Metropolitan Region. The operating units involved included the airport and main supply center at the central level; the seven storage facilities of the Metropolitan Region's seven health services; and 40 of the Metropolitan Region's 78 local clinics providing maternal and child health care. These 40 clinics, selected by lot, represented 51 per cent of the region's 78 clinics and provided coverage for 49 per cent of the population assigned to the region's health services.

Instructions and written data collection instruments were prepared for collecting information at each level. These were designed to obtain appropriate data about refrigeration, transport, temperature control systems, vaccine stocks, and vaccine handling. In addition, information was sought at the local clinics regarding the measles vaccine administration procedures and the training and turnover of vaccination post personnel.

The study dealt with measles vaccine because it was the most sensitive to handling deficiencies and because it was considered the most accurate indicator of variations in immunologic potency. At each local clinic a sample of the measles vaccine in use, already diluted, was collected and transferred under appropriate conditions to the Institute of Public Health for titration. A slightly different procedure was followed at each health service storage facility, where a freeze-dried specimen of measles vaccine was collected and a vial of diluent was added.

The titration of the vaccine samples was performed at the Virology Department of the Institute of Public Health in accordance with WHO international standards *(8)*. The tests were conducted with Vero cell cultures (monkey kidney cell line). The vaccines to be tested were serially diluted with M.199 medium (especially for Vero cells) from 10^1 to 10^5 times, and four test tubes containing Vero cells were inoculated with 0.1 ml of each dilution. The test tubes were examined under the microscope for 10 days in order to detect any cytopathic effects.

Statistical estimates of the median tissue culture infective dose ($TCID_{50}$) were derived using the Karber method, which accepts as a minimum titer the preestablished figure of 3.0 log 10 (one thousand) $TCID_{50}$ based on the reference standard. In our study, vaccines yielding titers less than 0.5 log 10 of the preestablished titer were considered negative.

The study data and measles vaccine specimens were collected on 25-27 November 1980 by three teams of professionals that made unannounced visits to the designated operating units.

Results: Accreditation

As Table 1 shows, the units studied failed to satisfy half the investigated EPI standards. That is, the average achievement rating of the three levels combined (49.3 per cent) fell short of half the desired 100 per cent. Special attention should be directed at the relatively low scores of the central and regional levels, and also at the relatively better local level showing with regard to program implementation and procedures.

Implementation

The central level. The airport unit met very few of the EPI implementation standards, scoring only 20 per cent in this area. Deficiencies were found in systems for shipping vaccine in cold boxes, for making cold rooms permanently available, and for providing adequate vaccine transportation.

The central supply facility, responsible for the purchase, storage, distribution, and maintenance of an adequate vaccine stock, had an achievement score of only 41 per cent. This facility did not have any self-contained energy source, cold rooms, or freezers exclusively for vaccines, or any permanent recording system for monitoring the temperature of the existing refrigeration equipment.

The regional level. Some of the major implementation deficiencies found at the regional level are indicated by the data in Table 2. The observed deficiencies in vaccine receipt were due primarily to the fact that refrigerated vehicles, insulated boxes, and other equipment helping to ensure proper refrigeration were not employed.

Regarding refrigeration, the scores fell far short of the desired standard. This was primarily due to lack of freezers separated from refrigerators, lack of sufficient space for storing vaccines (in six of the seven facilities), and lack of freezer space for storing virus vaccine (in four of the seven facilities). Also, nearly half the refrigerators lacked the temperatur

Table 1. EPI accreditation ratings at different levels of the cold chain in Chile's Metropolitan Region, 1980.

	% satisfaction of EPI standards for:			% of standards met
	Implementation	Procedures	Control	
Central level	30.5	63.5	45.0	46.3
Regional level	58.8	52.0	25.0	45.0
Local level	67.0	65.0	38.0	56.7
Average	51.8	60.2	36.0	49.3

Table 2. Percentage scores of the seven regional storage facilities indicating the degree to which they satisfied specific standards for EPI implementation activities.

Activity rated	% meeting EPI standards for the indicated activity
Receipt of vaccines	27
Refrigeration	48
Use of temperature control cards	57
Vaccine stock surveillance	64
Condition of physical plant	67

control card needed for direct evaluation and for monitoring the temperature of the apparatus; and the physical plants accommodating the refrigerators did not satisfy the required conditions in 33 per cent of the cases, the rooms involved tending to be narrow, hot, and inadequate.

The local level. Some types of implementing actions at the local level were found to be relatively satisfactory. As Table 3 shows, the most common deficiencies involved the cold boxes, which were found suited to the use made of them in only 13 per cent of the clinics studied.

Table 3. Percentage scores of the 40 local clinics indicating the degree to which they satisfied specific standards for EPI implementation activities.

Item rated	% achievement
Cold boxes	13
Control cards	37
Vaccines	77
Refrigerators	77
Inoculation materials	97

This point merits special attention, since the EPI requirements stipulate that such boxes should be used to preserve the vaccines needed for one day in order to avoid frequent opening of the refrigerator and a consequent rise in the temperature of the interior.

The state of the clinic refrigerators was examined in detail, since they are the basic cold chain instruments and because deficiencies in their operation or handling can be easily and cheaply overcome. As Table 4 indicates, only 10 per cent of the 40 clinics studied fully met the EPI standards for refrigerators, and only 35 per cent satisfied 89 per cent of the requirements. Some 32 per cent of the refrigerators (listed in the first three columns of the Table) appeared very inadequate. All of them had far outlived their usefulness at the time of the study, and all needed to be replaced by new appliances.

The rest of the refrigerators with deficiencies could be improved by repairing such items as the rubber strip around the door and other features that cost little but greatly affect proper operation. There was thus a clear need to create an administrative mechanism for efficient and expeditious repair of clinic refrigerators, especially since the repair of our health service system's machinery and equipment often involves considerable delay.

Only 37 per cent of the clinics used a temperature control card, despite its insignificant cost. Lack of such a card creates control problems, because the refrigerator's temperature variations are unknown, and so it is more difficult to monitor the apparatus and to take appropriate corrective measures in the event of problems. The lack of cards in so many cases

Table 4. EPI standards met by refrigerators at 40 local clinics in the Metropolitan Region, 1980.

	Degree to which refrigerator standards were met					
	33%	56%	67%	78%	89%	100%
No. of clinics	3	3	7	9	14	4
% of clinics	7.3	7.5	17.5	22.5	35.0	10.1

also reveals the low degree of supervision and control achieved.

Procedures

Relatively higher levels of achievement were attained in satisfying EPI standards of procedure. Nevertheless, the overall percentage satisfaction of these standards at all three levels (see Table 1) was only 60 per cent, indicating an unsatisfactory performance.

The central level. Only two of the five procedural steps studied at the airport were satisfactorily performed. That is, the date and time of each vaccine shipment's scheduled arrival were known. However, the vaccine did not always arrive on the date specified; there was intermediate unrefrigerated storage of unknown duration; and pertinent customs clearance procedures were not carried out before the vaccine arrived.

A higher proportion (87 per cent) of the specified procedures were satisfactorily performed at the central supply facility. The only deficiencies observed involved lack of appropriate placement and arrangement of vaccines in the cold rooms, and these problems could easily be resolved.

The regional level. The seven regional level facilities performed only 52 per cent of the specified procedures in a satisfactory manner. As at the airport, the date and time of arrival of vaccines was known, and the vaccines were immediately transferred to refrigerators under adequate light and temperature conditions. However, deficiencies were found in important procedures involving such matters as proper use of thermometers, ice packs, and refrigerator bottles.

The local level. As Table 1 shows, the 40 local clinics studied were found to satisfy 65 per cent of the EPI procedural standards. Nevertheless, attention should be drawn to certain deficiencies in refrigeration and vaccine management (see Table 5), especially because many of those found are easy to correct.

Regarding correct use of the refrigerator, the most marked problems related to handling of the freezer and ice packs. Most freezers were poorly managed and were not defrosted as often as necessary; and although most clinics had ice packs, there was generally an insufficient number, and their spacing within the freezers was generally not correct. Deficiencies relating to refrigerator bottles included having too few bottles, positioning them incorrectly, and failing to keep water in them.

Table 5. Percentage scores of the 40 local clinics indicating the degree to which they met specific EPI procedural standards.

Procedure	% of clinics meeting EPI standards
Refrigerator use:	
Correct location	63.8
Correct positioning	71.2
Correct handling of freezer	20.0
Correct handling of ice packs	17.5
Correct handling of refrigerator bottles	54.2
Handling of vaccines:	
Correct location of vaccines	57.5
Condition of unpacked vaccines	22.5
Condition of labeled vaccines	20.0
Condition of dry vaccines	95.5
Condition of vaccines in perforated containers	10.0
Condition of activated vaccines	92.3

Control Activities

Although effective control is implied by achievement of appropriate implementation and procedural standards, control activities were considered separately in this study—partly because of their important bearing on full realization of programmed activities and partly because of frequent failure to expeditiously program and implement control measures.

The central level. Only 40 per cent of the control activities studied at the airport met the relevant standards. Significant deficiencies included failure to record either the vaccine temperatures reached during transfer or the total

time spent outside the cold chain by vaccines before reaching the central storage facility.

Control activities studied at the central supply facility failed to meet 50 per cent of the relevant standards. The most important deficiencies were failure to supply thermometers for boxes used to transfer vaccines to the central storage area and failure to supervise the transfer of vaccines from the central storage area to regional storage areas.

The regional level. The first observed deficiency occurred with vaccine receipt—because the temperature of the cold boxes used to transport vaccines from the central level could not be read or recorded for lack of thermometers. Also, many regional center refrigerators had serious temperature control card deficiencies—in that refrigerator temperature was not controlled and recorded twice daily in 42.8 per cent of the cases, while freezer temperature was not controlled and recorded daily at any of the centers studied. In addition, only 26.6 per cent of the regional center refrigerators had technical cards giving instructions about operation, maintenance, and repair.

Finally, regarding the control of vaccine stocks, all but one of the regional centers had no vaccine stock cards in their storage areas. Vaccine records were kept in other nonuniform ways, generally by means of papers or books that were used for multiple purposes and were not available for checking.

The local level. Overall, the local clinics met only 38 per cent of the control standards covered on the information collection form (see Table 1). In this vein, it is worth noting the extent to which the clinics met specific standards.

It is recommended that a technical card be attached to each refrigerator so that it will be possible to locate the repair workshop quickly in case of need, and also so that minor repairs can be carried out by unspecialized personnel. However, as Table 6 shows, the use of such cards at the local clinics studied was virtually unknown.

In 8 per cent of the clinics the refrigerator contained food items, a situation that is clearly unacceptable. But even when the refrigerator contained no food, it commonly was not used exclusively for storing vaccines. In fact, since most of the clinics had only one refrigerator, it also had to be used for storing drugs, sera, and even dental material. This arrangement increased the number of users; the refrigerator was opened more frequently than it would otherwise have been; and the vaccination auxiliary on duty tended to share responsibility for the refrigerator with the rest of the users. This situation also caused defrosting to be carried out irregularly, thereby jeopardizing cold chain continuity.

Nevertheless, the most important single refrigerator control deficiency was the lack of temperature control cards. Such a card should be placed in a conspicuous position so as to draw attention to high temperatures. The refrigerator temperature should be recorded twice daily, in the morning and afternoon. The person responsible for recording these temperatures and filling in the card must be the vaccination auxiliary, who should be identified as the responsible party on the card. However, as Table 6 indicates, only 37 per cent of the clinics studied had such cards, and many of those that had them failed to use them in the described manner.

Table 6. Percentage scores of the 40 local clinics indicating the degree to which they met specific EPI standards for control measures.

Subject	% of clinics meeting EPI standards
Refrigerator:	
Technical card used	2.6
Refrigerator did not contain food	92.0
Refrigerator did not contain other unrelated articles	59.0
Temperature control card:	
Card in existence	37.0
% of existing cards that had:	
A conspicuous location	49.0
Properly recorded temperatures	54.0
Person in charge of card named	23.0
Vaccines:	
Record of receipt exists	73.0
Oldest vaccine used first	20.0

Results: Local Personnel

In Chile, each local vaccination post has a nursing auxiliary who is responsible for all vaccination-related duties. She is supervised by the clinic nurse at varying intervals and without any established pattern. The nursing auxiliary responsible for vaccinations also has other clinic duties involving such activities as health checkups, sterilization of clinical material, and so forth, depending on the clinic's size and workload. Eighty per cent of these auxiliaries are permanently assigned to vaccination duties, while the other 20 per cent rotate to other services every three or six months.

A survey of the vaccination auxiliaries' specific knowledge, conducted at the local clinics, produced a number of noteworthy results. To begin with, the local personnel tested showed a relatively good knowledge of vaccine administration (85 per cent correct replies). They had relatively little knowledge of control procedures, however, scoring only 12.5 per cent correct answers. In this regard, they seemed generally unaware of the measles vaccine expiry date at the local level (one month) and appeared incapable of recording above-normal refrigerator temperatures and recognizing them as signs of refrigerator failure.

Other results of this survey were as follows:

- Ten per cent of those surveyed were found to have taken the EPI cold chain course.
- The nursing auxiliaries who had taken the cold chain course and those who had not scored about the same, averaging approximately 60 per cent correct replies. No positive correlation was found between demonstrated knowledge and course attendance.
- Knowledge about the expiry date of vaccines seemed very limited. Only about 10 per cent of the nursing auxiliaries tested answered the question on this subject correctly.
- Personnel permanently assigned to vaccination duties scored slightly better than the rotating personnel, the respective groups answering 65 per cent and 52 per cent of the questions correctly.

Results: Vaccine Potency

It was not possible to determine the titer of measles vaccine stored by the central supply facility—because this facility had no measles vaccine in stock and no new shipment arrived during the study period. However, samples of measles vaccine were collected at six of the seven regional storage facilities studied. As Table 7 shows, potency testing of these samples yielded titers meeting WHO standards.

In addition, measles vaccine samples were obtained from 39 of the 40 local clinics studied; Table 7 also shows the test results obtained with these samples. Overall, 29 (76.3 per cent) of the samples tested yielded adequate titers, 9 (23.7 per cent) yielded inadequate titers, and one sample was contaminated.

Discussion

Three years after preparation and distribution of the 1977 EPI standards, a documented analysis of their use in the field was deemed necessary. In particular, the size of the financial contribution made to supply and administer immunization programs was felt to justify ongoing surveillance to ensure their proper operation and optimal effectiveness.

The cold chain concept was rather new at the time; and personnel, especially in the local operational units, had not achieved the desired degree of familiarity with its main features and components. Within this context, determining the degree to which operating units should be "accredited" for effective performance of program activities and maintenance of the cold chain was a delicate and complex task. The need to simultaneously assess the training of personnel in immunization work and the potency of the vaccines administered added to the difficulty. Nevertheless, the design of the investigation and the written data-collection instruments developed for it simplified matters greatly, and permitted the necessary data to be collected expeditiously (in 45 minutes) at each unit included in the study. No special resources were used in the investigation except those employed to determine vaccine titers.

Table 7. Titers of measles vaccine samples obtained from six of seven regional storage facilities and 39 of 40 local clinics. According to WHO standards, the titer indicating minimal acceptable measles vaccine potency is $10^{-2.50}$. Vaccines with lower titers were rated "inadequate."

Regional storage facility	Vaccine rating		Local clinics	EPI accreditation rating (%)	Vaccine rating	
	Titer	Potency			Titer	Potency
Northern Metropolitan Region	$10^{-3.50}$	Adequate	Valdivieso	79.6	$10^{-2.83}$	Adequate
			Independencia	77.6	$10^{-3.16}$	"
			Quinta Buin	74.5	Contaminated	Unknown
			Til Til	70.8	$10^{-3.50}$	Adequate
			El Cortijo	58.5	$10^{-2.83}$	"
Southeastern Metropolitan Region	$10^{-3.15}$	Adequate	La Bandera	76.1	$10^{-3.50}$	Adequate
			Bellavista	73.2	$10^{-1.83}$	Inadequate
			B. O'Higgins	66.0	0	"
			S. J. de Maipo	59.4	$10^{-3.16}$	Adequate
			A. del Río	59.6	$10^{-3.50}$	Adequate
Southern Metropolitan Region	$10^{-2.83}$	Adequate	La Feria	78.3	$10^{-2.49}$	Inadequate
			Lo Valledor	65.6	$10^{-3.16}$	Adequate
			San Joaquín	64.7	0	Inadequate
			Clara Estrella	62.3	0	"
			S. B. Gerona	62.0	0	"
			Hospital	50.8	$10^{-3.16}$	Adequate
			Joao Goulart	50.3	$10^{-2.49}$	Inadequate
			Dávila Sur	45.6	$10^{-3.16}$	Adequate
			Cisterna Sur	42.2	$10^{-3.16}$	"
Eastern Metropolitan Region	$10^{-2.83}$	Adequate	Peñalolen	66.5	$10^{-2.61}$	Adequate
			Isabel Bravo	64.0	$10^{-2.49}$	Inadequate
			S. A. Las Condes	63.1	$10^{-3.16}$	Adequate
			Sta. Julia	62.3	$10^{-2.82}$	"
			Apoquindo	62.0	$10^{-3.16}$	"
			Salvador Busto	61.6	$10^{-3.50}$	"
			Manuel Montt	55.9	0	Inadequate
			La Faena	52.4	$10^{-3.50}$	Adequate
Central Metropolitan Region	$10^{-2.83}$	Adequate	Maipu	78.3	$10^{-3.50}$	Adequate
			S. J. Chuchunco	41.5	$10^{-3.50}$	"
			Consultorio No. 5	44.5	$10^{-2.83}$	"
			Lo Valledor Norte	33.0	$10^{-3.16}$	"
Western Metropolitan Region	$10^{-2.61}$	Adequate	Andes	61.4	$10^{-3.16}$	Adequate
			Pudahuel	57.8	$10^{-3.16}$	"
			Albertz	53.2	$10^{-3.50}$	"
			Peñaflor	41.0	$10^{-3.50}$	"
			El Monte	36.1	$10^{-3.16}$	"
Northwestern Metropolitan Region	No sample obtained	Unknown	Steeger	62.2	$10^{-3.16}$	Adequate
			Garín	53.3	$10^{-2.83}$	"
			Quilicura	43.9	$10^{-2.83}$	"

The needs of future investigations will dictate changes in the original design of the data collection instruments. However, the data already collected at local clinics and higher levels, some of which are consolidated and presented in this article, provide a realistic basis for assessing actual conditions, finding weak points in the immunization system that are not normally considered in evaluations, and suggesting appropriate ways to overcome the deficiencies detected. In addition, it appears that professionals responsible for overseeing units that store and handle vaccines can use the relevant data collection instruments as a basic guide in field supervision.

The study design was originally intended to

validate an instrument for accrediting the cold chain at the local level by crosschecking accreditation scores against observed vaccine potency. Contrary to what was expected, however, the correlation between the accreditation scores and vaccine potency was very low. This finding prompted a review of the investigation to determine possible reasons, and in this vein the following observations appear to merit attention:

1. All the vaccine specimens tested were collected during a single three-day period. The data collection instrument did not take into account the different ages of the vaccines at the clinics. In some cases these vaccines were less than a week old, while in others they were over a month old when collected. This information should be requested by any subsequent data collection instrument designed to study vaccine potency.
2. No records were available to provide details about the transportation of vaccine shipments from the regional storage facilities to the clinics, and so no such information was obtained. This information is neccesary if one wishes to study all the links in the cold chain.

In general, the length of time a vaccine was exposed to risk, which increased as the vaccine proceeded through the various links of the cold chain, was found to correlate more closely with vaccine potency than did the accreditation scores—presumably because the latter provide a static picture while diminishing vaccine potency is an essentially dynamic time-related phenomenon. This difficulty is believed to be the principal limitation of the study method.

Conclusions

The cold chain accreditation testing of units in the Metropolitan Region—where implementation activities are probably performed better than in other parts of the country—yielded an overall average score indicating that the preestablished EPI standards were being met only about 50 per cent of the time.

The Central Level

At the central level, cold chain implementation and control activities attained achievement scores of only 30.5 and 45.0 per cent, respectively, and thus appeared especially deficient. Since the central level serves as the initial link in the cold chain and is responsible for all the vaccines administered, it is urgent that the indicated deficiencies be corrected in the shortest possible time. With that end in mind, it has been suggested that the following steps be taken at the airport and central supply facility:

At the airport:

- Suppliers should be made to comply with EPI standards governing the mode of vaccine transport and the date of arrival of vaccine shipments.
- Customs clearance should be obtained before the vaccine shipment arrives.
- The shipment should be unloaded directly from the aircraft onto a refrigerated truck; or, alternatively, there should be a sufficient number of appropriate cold rooms ready at the airport well in advance.
- Temperature recording systems should be used at all these stages.

At the central supply facility:

- The supply facility should be provided with an autonomous energy source in case of power failure.
- Rooms should be reserved exclusively for vaccine storage.
- Permanent alarm and temperature monitoring systems should be installed.

The Regional Level

The regional level, represented by the seven storage facilities studied, obtained a lower overall achievement score than the other two levels and appears to be a high-risk link in the cold chain. Implementation and procedural problems, combined with a virtual absence of control systems, have led these facilities into accommodative actions that conflict with actual needs. That is, they have become mere intermediaries that send vaccines to local clinics as soon as the vaccines are received

from the central level. This helps to explain why the observed potency of vaccines held at the local clinics was sometimes higher than that of the emergency stocks held at the respective regional storage facilities.

Given this state of affairs, the need to deliver vaccines to the local clinics as they require makes scheduling and coordination difficult and prompts excessive vaccine movement at the central level. In this vein, a number of suggestions have been made for the purpose of correcting regional level deficiencies. These are:

- The regional facilities should have physical plants compatible with the functions of cold chain storage areas.
- Each storage facility should have a self-contained energy source that is automatically activated in the event of a failure in the public power network.
- Each facility should possess freezers and refrigerators with the capacity needed to accommodate three months of vaccine stock.
- The recommended system for recording refrigeration temperatures daily and defining recording responsibilities should be used.
- A system for ordering vaccines quarterly and making monthly distributions to conform with program schedules should be organized.
- Each facility should possess enough cold boxes with maximum and minimum recording thermometers to provide for adequate vaccine transport.

The Local Level

The local level, represented by the 40 clinics studied, attained the highest average achievement score of any level (57 per cent). Nevertheless, serious deficiencies also emerged at this level, especially regarding implementation and control activities; and these deficiencies were aggravated by the fact that vaccines undoubtedly encounter a larger number of potentially damaging contingencies at the local level than they do elsewhere. This is borne out by the vaccine potency findings—which indicated that all the test vaccine samples collected at the regional level were usable, despite the deficiencies at that level, but that 23.7 per cent of the vaccine samples collected at the local level yielded unacceptably low titers. These findings could signify increased risk for the population supposedly protected by vaccination, since they may reflect a general situation prevailing at the local level throughout the country.

With a view to overcoming these difficulties, the following suggestions have been made:

- Provide the local units with adequate refrigerators.
- Repair those refrigerators that can be repaired as soon as possible, and provide review from the regional level to ensure that this is done.
- Provide the local units with cold boxes for holding and transferring vaccines as the EPI standards require.
- To reduce procurement costs, the foregoing measures should be made part of a central-level program.
- Control should be promoted through establishment of daily supervision.
- Refrigerators should be used solely for immunizing agents.
- Proper use should be made of temperature control cards and technical cards.
- Turnovers of assigned vaccination personnel should be minimized, and continuing in-service training should be provided.

SUMMARY

Chile, which has been participating in the WHO Expanded Program on Immunization (EPI), has been able to provide fairly high levels of coverage with measles and DPT vaccines. Nevertheless, as of 1980 expected declines in morbidity had not occurred; instead, a major measles outbreak that year caused over 50,000 reported cases. Because of strong evidence that vaccine cold chain problems were involved, a survey of cold chain activities in the Metropolitan Region serving some 40 per cent of the national population was conducted.

This survey examined the extent to which various EPI standards were being met by units at the "central level" (the airport receiving area and

main supply center), the "regional level" (seven regional storage facilities), and the "local level" (40 of 78 maternal and child care clinics). It also tested the knowledge of vaccinators at local units and determined the potency of measles vaccine (the most sensitive of the vaccines handled) available at the regional and local units.

The results indicated that, on the average, less than half of the preestablished EPI cold chain standards were being met. Cold chain implementation and control activities at the airport and main supply center appeared especially deficient—most notably in ensuring regular arrival of vaccine shipments at the scheduled times; securing advance customs clearance for these shipments; recording temperatures; and equipping the main supply center with a self-contained energy source, rooms dedicated exclusively to vaccine storage, and permanent alarm and temperature monitoring systems.

Notable deficiencies found at the regional storage facilities had probably encouraged these facilities to become mere intermediaries that sent vaccines on to local clinics as soon as they were received. To help change this picture, it was suggested that each regional center be given a physical plant compatible with its cold chain functions—including a self-contained power source, enough refrigerator and freezer capacity to store three months of vaccine stock, and enough cold boxes for adequate vaccine transport. Institution of regular ordering, distribution, and temperature recording systems was also recommended.

The local clinics made a better average showing in terms of meeting EPI standards, but they also tended to encounter a larger range of circumstances potentially harmful to vaccines. This presumably helps to explain why 23.7 per cent of the local unit measles vaccine samples tested yielded unacceptably low titers, even though all samples from the regional storage facilities' emergency stocks yielded satisfactory titers. To help overcome common local clinic cold chain problems, it was recommended that all such clinics be supplied with adequate refrigerators and cold boxes, that any refrigerator holding vaccines be reserved exclusively for immunizing agents, that proper use be made of temperature control and technical instruction cards for the refrigerators, that training be provided for assigned vaccination personnel, and that turnover of such personnel be kept to a minimum.

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