EVALUATION OF THE AVAILABILITY OF COLD CHAIN TOOLS AND AN ASSESSMENT OF HEALTH WORKERS PRACTICE IN DAMMAM

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Aim: To evaluate the availability of cold chain tools and assess the practice of health workers in immunization rooms in health clinics in the Dammam area.

Methodology: A cross-sectional approach was used for the study. A stratified random sampling technique was used to obtain a sample of 10 governmental primary health care centers from the total of 20 centers that serve the Dammam area, and five out of 17 private health clinics. The Maternity and Child Health Hospital was included. A field survey was done at all sample sites. Data collection, analysis, and interpretation were done from July to September 2007, using a check list designed for this study according to cold chain criteria set by the Ministry of Health (MOH) and World Health Organization (WHO).

Result: According to the MOH and WHO criteria, around 91% of governmental health facilities (GHF) and 80% of private health care (Private HC) rooms were suitable. Less than 20% of the private HC maintained proper vaccine temperatures during storage, compared with all (100%) of GHF clinics (p < 0.05). The difference in the appropriate handling and usage of vaccines during immunization sessions was also highly significant between GHF (90-100%) and private HC (20%) (p < 0.05). The knowledge of refrigeration maintenance by GHF and private HC health workers was also highly significant between GHF (90-100%) and private HC (20%) (p < 0.05).

Conclusion: Evaluation of the availability of cold chain tools and assessment of health workers practice were important to measure the performance of governmental and private health care. The private health clinics maintained proper vaccine temperatures during storage. The knowledge of refrigeration maintenance by health workers was also high in both GHF and private HC.

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workers including keeping the refrigerator from dust, emergency retrieval and storage procedures in case of equipment failure or power outages, keeping the range of recommended temperature between 2°C- 8°C was 100% for GHF and for the Private HC’s ranged from 20%-40% (p<0.05). Vaccine vials on the refrigerator shelves was appropriate in all (100%) of the GHF and in only 40% for the Private HC (P<0.05).

**Conclusion:** This study showed that private health clinics did not comply with standards defined by the MOH or WHO for cold chain tools and needed constant supervision and training as health care professionals. All personnel handling vaccines should understand the purpose and function of various cold chain tools in their setting for immunizations.

**Key Words:** Primary health care, cold chain.

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**INTRODUCTION**

‘Cold chain’ is the system of transporting and storing vaccines within the safe temperature range of 2°C to 8°C. The chain begins with the refrigerator or freezer at the vaccine manufacturing plant, vaccine distributor and then to the provider’s office (immunization clinic) and ends with the administration of the vaccine to the recipients.1,2

Cold chain components include equipment transport and storage, trained personnel, and efficient management procedures. All three elements must be maintained at every link in the chain to ensure that the administration of the vaccine is safe. Any alteration in temperature such as exposure to excessive heat or cold damages the vaccines, resulting in loss of potency. Vaccines are powerful public health tools that require a conscious effort to evaluate the cold chain at different levels. Managers of immunization services have to organize staff training and plan for the physical and budgetary implications of any problems of storage or handling.3,4

A vaccine vial monitor (VVM) enables the health worker to know whether the vaccine has been damaged by heat. The combined effects of time and temperature give information about exposure to heat and potency. VVM which is now applied directly to each vaccine vial by the manufacturer enables the health worker to verify at the time of use, whether the vaccine is in a usable condition and has not lost its potency and efficacy a result of temperature variation. It is also important to note that different types of VVMs are designed for different types of vaccines depending on their heat stability.5,8

Various articles have shown that critical management and equipment failure continue to plague primary and intermediate vaccine stores. Such failures, which may result in the destruction of large quantities of vaccine, can place the immunization services of an entire country at risk.5,10 The researcher has not found local studies similar to ours except one done to assess the utilization of cold chain and the knowledge and practices of health care workers at primary health care facilities in Riyadh and the Eastern Province of Saudi Arabia.11.

**AIM OF THE STUDY**

Cold chain needs continuous supervision and assessment at different levels to prevent the loss of vaccine potency during storage and handling. This is important as new and expensive vaccines that require different approaches to storage are introduced. This study was done to evaluate the availability of cold chain tools in governmental primary health care and private health clinics and assess the practice of health workers in the Dammam area.

**METHODOLOGY**

Letters were sent out to local health authorities to ask permission to conduct the study and solicit their cooperation in the resolution of any ethical issues. The population of the Dammam area in the year 2007 comprised approximately 533414 Saudi and 284671 non Saudi nationals that were covered by 20 governmental primary health care centers. Vaccines are distributed to the primary health care centers by the main medical (vaccine) supply storage of the Eastern Province, and Dammam primary health care preventive service office. The sampling of the health centers was done by a cross-sectional, stratified random technique from 20 governmental primary health care centers and 17 private health care centers. Ten PHC centers were selected to represent the geographic area of...
Dammam and five centers from the private sector as well as the Maternity and Children's Hospital (MCH) as the first contact with immunizations. The overall total was 16 health facilities, 11(68.75%) of which were governmental and 5(31.25%) private.

DATA COLLECTION AND ANALYSIS
Field study at all sample sites, data tabulation, analysis, and interpretation were done from July to September 2007. A designed structured check list was filled by the investigator by observation. WHO guidelines were followed in interpreting the vaccine vial monitor (VVM), cold chain monitor card (CCM), temperature recording, the clinical procedures for proper immunization from the cold chain MOH manual and the policy and procedure manual.\textsuperscript{5,12,13}

A pilot study was conducted in the Dammam area, in two health centers not involved in the study to test the check list and make any required modifications as well as test the suitability of the study tools, availability of the needed data and the feasibility of the research methods. Based on the results of this pilot study, some useful modifications were made to the study format and a more feasible timetable for implementation was constructed.

Data were entered into a personal computer using Statistical Package for Social Sciences (SPSS) version 14.0. Quantitative data were summarized as mean, standard deviation (SD); and qualitative data as percentages. Comparisons were made, Chi-square and Fisher's exact test were used in cases of qualitative data to test significance, with a p-value ≤0.05 indicating statistical significance; 95% confidence intervals.

RESULT
The governmental health facilities (GHF) included the MCH and PHC clinics since MCH is the only governmental children hospital serving Dammam to have introduced the administration of the first dose of vaccine immediately after birth. A total of 11(68.75%) governmental health facilities will, therefore, be discussed. We found that all personnel in the vaccination clinics were female nurses, nine of whom were Saudis (56.25%). They all had substitute nurses to cover their duties when there were absent. Only 45.5% of the governmental nurses had had some training in the previous year, but none of the private sector nurses had had any training in the preceding year.

It was found that 72.7% of GHF took delivery of their vaccine vials monthly, 90.9% of them in a cold box, but only 25% of them used a foam pad. When off duty, except national holidays, the staff left the vaccine in the care of attendants. All (100%) of the private health clinics took delivery of their vaccine vials every three months from facilities of the provider. When off duty, the vaccines were left in the care of substitute attendants since the clinics functioned at weekends and on national holidays.

Cold chain tools in vaccination rooms
The following include collected data for the availability of cold chain tools starting from the vaccination room where vaccines are locally stored, vaccine handling, and waste disposal procedures. Figure 1 shows a comparison of the presence of cold chain component tools between GHF and private HC clinics. Around 91% of GHF and 80% of Private HC rooms met the MOH and WHO criteria,\textsuperscript{2,12,13} having good ventilation and air-conditioning facilities (81.8% and 100% respectively). Fire extinguishers with valid expiry dates were also available in all facilities.

Refrigerator maintenance and temperature monitoring
GHF workers appeared to be better than the private HC workers at storing and handling vaccines. None of the private HC had suitable vaccine monitoring or storage facilities in comparison with GHF clinics (P ≤0.05). All GHF clinics (100%) stored vaccines in a single refrigerator/freezer unit, while Private HC used small personal units contrary to MOH or WHO criteria.\textsuperscript{12,13} There were thermometers in all facilities, but 9% of GHFs and all (100%) of the private (p <0.05) did not keep up-to-date temperature cards.

The refrigerator for vaccines should be placed in a cool room, away from direct heat or sunlight, at least 20cm from the wall with at least 40 cm of clear space above it.\textsuperscript{12,13} Indices concerning refrigerator maintenance was highly significant (p<0.05) between the knowledge of GHF health workers and the private HC health workers. This includes keeping the refrigerator for vaccine free from dust, and what to do in the event of a break down. The study revealed that 72.7% of GHF nurses and 80% of private HC nurses did not dust the refrigerator or keep it in the proper place (63.6%,20% respectively) (p<0.05).

In 40% of the private HCs and 90.9% of the
GHFs the refrigerator temperature settings were found to be within the normal range (2-8°C). It was observed that in the HGFs, thermometers, temperature charts, freezing indicators were kept, and there was proper maintenance of the correct temperature in cold boxes and vaccine carriers. All GHF nurses recorded the temperature twice a day. Only 20% of the private HC nurses did this (p≤0.05). This difference was also observed with regard to nurse's signature on the daily chart, as 81.8% of GHF nurses and 20% private HC nurses signed their documents (p≤0.05). Most of GHF nurses (90.9%) and more than half (60%) of the Private HC nurses could state the correct temperature range (2°C-8°C) for the storage of vaccines. None of the GHFs and the private clinics recorded room temperature or humidity.

The cold box, vaccine carrier, ice bag, and water bottles, essential for vaccine cold chain handling (Table 1) were all in the range of 90.9%-100% for GHF, but varied from 100%-20% only (p≤0.05) in the private HCs. VVM and other indicators, essential for the monitoring of vaccines (temperature monitor card, freezing indicator) were present in all of GHFs (81.8%-100%), but only present in ≤20% of private HC (p≤ 0.05).

**Table 1: Cold chain tools in government and private clinics**

| Tools                        | GHF % | Private HC % |
|------------------------------|-------|--------------|
| Cold box                     | 90.9  | 40.0         |
| Vaccine carrier              | 100.0 | 20.0         |
| Ice bag                      | 100.0 | 100.0        |
| Water bottles                | 100.0 | 100.0        |
| VVM                          | 100.0 | 20.0         |
| Temperature monitor card     | 90.9  | 0.0          |
| Freezing indicator           | 81.8  | 20.0         |

GHF=Government health facilities/clinics  
HC=health care clinics

**Vaccine monitoring, handling and observed storage conditions**

There was a highly significant difference between GHF and private HC (p≤0.05) in the appropriate handling and usage of the vaccine during the vaccine sessions. Adherence to the guidelines on quality is important and guarantees the potency of the vaccines. These guidelines include all required arrangement of vaccines on the different shelves of the refrigerator and the allowance of sufficient
space between them to ensure circulation of air, vaccines are to be arranged by expiry dates with dilutes close to the proper vaccine vials. In general, there were highly significant differences between the GHF and private HC health workers (90%-100% and 20% respectively) in the variables. Among the GHF sample, 54.5% adhered to the MOH official guidelines for cold chain maintenance, but none of the private did ($p < 0.05$).

Storage of the vaccines on the proper shelves of the refrigerator was appropriate in all (100%) of the GHF and only 40% of the private HC ($p \leq 0.05$). However, a close inspection of the arrangement of vaccine packages according to expiry dates so that those close to expiry would be easily accessible for use, showed that 81.8% of the GHFs adhered to this arrangement, but the private HCs did not ($p < 0.05$). In 60% of the private HC, vaccines were stored in the door compartments of the refrigerator and 100% at the bottom of the refrigerator but this was not observed in the GHF ($p < 0.05$). There should be spaces between products stored in the refrigerator to allow circulation of air. This was observed in 100% of GHFs, but not in the private HCs (0%) as boxes were packed closely together in the refrigerators ($p \leq 0.05$).

Overall, the setting for vaccination was appropriate at the GHFs but documentation of the records was poor. For example, no arrival date was recorded. Vaccination vial name, batch number, expiry date were shown only in 81.8% of GHF, and 20% in the private HC ($p \leq 0.05$).

**Waste disposable**

There should be strict protocol for the management of waste in the vaccination rooms to decrease the possibility of infections. Waste should be separated into infectious and non-infectious receptacles. Mismanagement of healthcare waste puts healthcare workers, patients and the community at risk. Immunization waste includes syringes and needles, empty vaccine vials and ampoules, syringe wrappers, cotton swabs, syringe caps, and packaging. We found that all (100%) of the private HC used safe disposable boxes, while only 72.7% of GHF did, and hand washing after each child was practiced by 18.2% of the nurses in GHF and 100% of the nurses in the private HC.

**DISCUSSION**

Immunization programs are widely recognized as one of the most effective means of health intervention. Cold chain management can enhance the quality, safety and efficacy of an immunization program. Once the potency of a vaccine is lost, it cannot be regained or restored and the vaccine will no longer provide protection against the target disease. Cold chain management includes the storage conditions, refrigerator maintenance and temperature monitoring, and handling of the vaccine during immunization sessions. Our results show a better comparison between the GHF and private HC vaccination clinics than the study done by Al Zamil et al in 2004 which did not identify the study area in the Eastern Province.

In all GHFs, one nurse with a substitute is assigned to the vaccination rooms though only 45.5% of them had been trained in the previous year in continuous medical education programs. De Timóteo Mavimbe et al had similar results in Niassa, Mozambique in a study of cold chain management, where approximately 40% of the health workers had pre-service training in vaccine storage and handling. In a study done in Atlanta, Georgia to estimate the prevalence of offices with suboptimal storage and handling, it was found that most providers (83%) designated a specific person in the office to be responsible for vaccine storage and handling, with a backup in 63% of cases.

All of GHF had refrigerators that matched WHO and MOH criteria and 90.9% of them were kept within the standard range. A study done in central Italy on vaccine storage in the community, found that 23.5% of the study sample did not have refrigerators and that physicians obtained vaccines according to need from neighboring facilities and used them immediately.

In our study 90.9% of GHF and 60% of the Private HC nurses could state the correct temperature range for the refrigeration of vaccines while in Niassa, Mozambique only 52% of the health workers could state the recommended temperature range for vaccine storage. However, in the pediatric offices, Biashi et al found that only 16% of vaccine storage coordinators could state the appropriate storage temperatures for vaccines and 18% were unaware that heat could degrade certain vaccines. It appears to be common practice that the storage temperature was not kept constant. Bell et al also found in his study that several offices had temperature logs that indicated temperatures that had remained outside the recommended ranges for weeks.
Overall, our GHFs show better results than private HC (primary versus pediatric office), while a similar study done by Gazmararian et al\textsuperscript{18} in which a comparison of primary care physician's offices and pediatric offices revealed that the pediatric offices had better compliance to the guidelines for the storage of vaccines.

**CONCLUSION AND RECOMMENDATION**

The importance of cold chain tools should be emphasized to all workers involved in vaccination and at all health care facilities both governmental or private, since there appear to be significant differences between the governmental and private health facilities, on the tools and the assessment of workers. This study highlighted the current situation of the private health facilities run by pediatricians, and the need for a regular schedule of field supervision by the decision makers. All health care facilities should have effective continuous training of staff handling immunization rooms to promote and enhance practice skills for the management of cold chain.

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