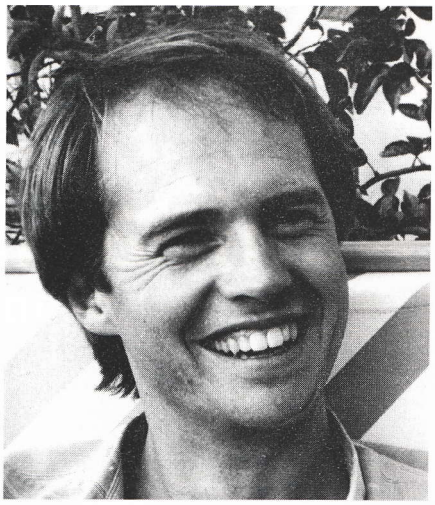
Vaccine Storage in Cape Town: State of the Cold-chain in General Practice

– Nicol Coetzee



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Summary:

During a recent outbreak of measles in Cape Town, the vaccine efficacy of measles-mumps-rubella (MMR) vaccine was found to be lower than expected. As a result of this finding and because of previous reports of shortcomings in the MMR cold-chain, a study was undertaken to investigate vaccine storage procedures in general practice.

The study population consisted of general practitioners listed in the 1992/1993 Cape Peninsula telephone directory (N=669). A pre-tested and standardised questionnaire was used to conduct telephonic interviews with a systematic sample of 103 practitioners. 80% (95% CI 70,2 - 87,7%) reported that they do administer vaccines. MMR is the vaccine given by the highest proportion of doctors (65%). 97% of practitioners who vaccinate also store their own vaccines. 81% of doctors did not monitor their refrigerator temperature and more than 50% had no appropriate temperature monitoring device. 33% showed a total lack of knowledge of the correct vaccine storage temperature. 54% used their vaccine refrigerator to store additional items (food and drinks), and 60% kept vaccines in the door of the refrigerator.

General Practitioners need to be made aware of the correct vaccine storage procedures and requirements. Vaccine failure due to incorrect storage can and must be prevented. In most cases corrective measures that need to be implemented are readily available and cheap.

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KEYWORDS:
Physicians, Family; Vaccines; Temperature

Introduction:

Immunisation remains one of the most cost effective but under-utilised means of preventing disease.[1] To address the problem of excess morbidity and mortality due to vaccine preventable diseases, the World Health Organisation (WHO) established the Expanded Programme on Immunisation (EPI) in 1974.[1,2]

Since then major advances have been made in vaccine efficacy and improved population access and coverage. Ensuring correct vaccine temperatures during shipment and storage remains difficult to implement and is often overlooked.[3] Despite recent advances in improved vaccine heat stability and the fact that vaccines differ in their sensitivity to adverse storage conditions, the maintenance of a "cold-chain" remains central in ensuring efficacy.[4] The effect of exposure to adverse temperatures is cumulative and therefore it is crucial to maintain vaccine temperatures within a constant range at all stages of distribution. Only if the recommended temperature range has been sustained since manufacture will primary care workers have the

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assurance of vaccine potency up to the specified date of expiry.[4,5]

Guidelines for the correct storage and transportation of vaccines have been developed by the EPI.[6] These emphasise the importance of keeping vaccines at 0-8°C at all times; using a single-purpose refrigerator; nominating one person at each level of the cold-chain to take responsibility for maintaining correct temperatures; and packing vaccines at the centre of the refrigerator to facilitate free air circulation.

The problem of vaccine cold-chain maintenance is by no means unique to tropical countries[3] and temperate regions have also reported considerable cold-chain shortcomings.[7-9] It is important to note that too cold storage temperatures may damage certain vaccines (diphtheria, tetanus and pertussis) with resultant adverse reactions upon administration.[6,10] Very few investigations into the status of the vaccine cold-chain have been published in South Africa,[11-13]

Vaccine failure can easily and cheaply be prevented

and only one of these has focussed on vaccine delivery in private practice.[12]

During a measles outbreak investigation at a Cape Town school in September 1992, the efficacy of trivalent measles-mumps-rubella (MMR) vaccine (used almost exclusively in private practice) was found to be significantly less than that of the monovalent measles vaccine (used in the public health services).[14] The low MMR vaccine efficacy is thought to have resulted from a break in the cold-chain at local level. This hypothesis is supported by a 1989 study of the private sector cold-chain in Cape Town where the weakest link was at the wholesale distribution level and to a lesser extent between the retail pharmacist and the general practitioner.[12]

Too cold temperatures may damage certain vaccines

Since 1989 corrective steps have been taken to improve the integrity of the vaccine distribution cold-chain in the private sector. However, no attention has been given to the conditions under which vaccines are stored in general practice. Investigations from other countries indicate serious defects at this level.[8,9] This investigation was therefore prompted by the need to gain additional evidence in explanation of the recently reported decrease in MMR vaccine efficacy. The aim of this study was to assess reported vaccine storage and temperature monitoring procedures in general practice in Cape Town.

Methods

The study population consisted of all general practitioners in private practice as listed in the 1992/1993 Cape Peninsula telephone directory (N=699). A systematic sampling method with random starting point was used to select 103 subjects for inclusion into a descriptive study. Practitioners who were no longer practicing or had moved, were excluded and replaced by the following subject on the sampling frame. During February and March 1993 five trained interviewers administered a pretested and standardised questionnaire to respondents by means of telephonic interviews. All study subjects were assured of anonymity and confidentiality of information. Data analysis consisted of the calculation of proportions and percentages with exact 95% confidence intervals (CI) given in brackets.

Results

Ninety (90) practitioners responded – giving a response rate of 87% (90/103). Non-responders consisted of those who could not be reached after three attempts to telephone them, or who declined participation in the study.

Eighty percent (80%) (CI 70,2 - 87,7%) of doctors reported that they do administer vaccines in their practices. 76% (CI 50,2 - 71,2%) of these vaccinating doctors administer vaccines to children. A wide variety of vaccines are administered and

At least 815 doses of MMR administered per month in Cape Town

MMR is given by 65% (CI 53,1 - 76,1%) of vaccinating doctors. The distribution of doctors giving other vaccines is as follows: influenza 54%; tetanus 36%; hepatitis B 31%; DPT 17%; and polio 4%. The frequency with which MMR vaccine is given by individual doctors each month, ranges from <3 doses (44%), 3-10 doses (34%), 11-20 doses (4%), and unknown (18%). 93% (CI 84,5 - 97,7%) of vaccinating practitioners store their own vaccines. The vaccine storage practices of these general practitioners is summarised in Table 1.

Seventy five percent (75% (CI 63,4 - 84,5%)) of vaccinating general practitioners receive their supplies directly from the wholesaler. The remaining practitioners receive their vaccines via retail pharmacists. 63% (CI 50,3 - 73,6%) of general practitioners indicated that they do not receive their vaccine supplies on ice.

Discussion

The use of telephonic interviews accounted for the high response rate. A major limitation of the study is that reported vaccine storage practices could not be validated. Some paediatricians and other specialists in private practice do administer vaccines and their exclusion from the sampling frame must be considered when generalising results.

A high proportion of doctors vaccinate (80%) and most of these also store their own vaccines (93%). These figures are higher than a previous Cape Town study where

Table 1: Reported vaccine storage practices by general practitioners in Cape Town

	n	%*
1. Refrigerator use:		
Single-purpose vaccine storage	31	46
Shared-purpose (food, drink, other)	36	54
2. Vaccine kept in refrigerator door:		
Yes	27	40
No	40	60
3. Ideal storage temperature (°C):		
0-8	45	67
>8	13	19
Not Known	9	14
4. Designated person responsible for fridge:		
Doctor	7	10
Nurse/receptionist	6	9
None	54	81
5. Frequency of temperature monitoring:		
Daily	7	10
Once/week	4	6
Once/month to once/year	2	3
Not monitored	54	81
6. Temperature monitoring device:		
None	33	50
Mercury thermometer	7	10
Liquid crystal thermometer	2	3
Other or not sure	25	37

* n=67 (67 of the 90 respondents store vaccines).

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72% of practitioners vaccinated and 47% stored vaccines. This finding therefore serves to underscore the importance of evaluating the general practice link of the cold-chain.[12]

Children make up a large proportion of the vaccination target population in general practice. It is therefore not surprising that MMR is the vaccine given most frequently. By extrapolating to the total population of general practitioners in Cape Town, it is estimated that a minimum of 815 doses of MMR are given every month. This high number illustrates the importance of utilising this resource more effectively in the future. If measles control is to be achieved and sustained in South Africa, all participants (both private and public sectors) in the immunisation programme must ensure that the vaccines they administer are potent.

Using the same refrigerator for vaccines and for food and drink will result in changing temperatures and loss of potency

This study shows that general practitioners are unacquainted with safe vaccine storage procedures essential for maintaining maximum potency. Although individual refrigerator temperatures were not validated, reported storage conditions indicate that vaccines are very likely to be exposed to incorrect temperatures.

Correct storage conditions in general practice have to be promoted and could easily be achieved with a minimum of financial expenditure. The following steps are recommended:

(i) Increase practitioners' knowledge and awareness of the need for correct storage conditions and the dangers of loss of potency and potential adverse reactions resulting from temperature deviations;

(ii) National guidelines for vaccine storage at primary care level should be developed and adhered to by all practitioners. Knowledge of individual vaccine sensitivities and how they differ, is of little practical use at primary health care level. Primary health care workers need a uniform safe temperature range they can adhere to in order to be certain that vaccines are potent and will expire at the specified date. Currently the EPI suggested temperature range for vaccine storage is 0-8°C. This differs from the 2-10°c range recommended in the United Kingdom[8,15] and by the department of National Health and Population Development in draft guidelines currently in preparation (personal communication: N Cameron).

(iii) Every practice must identify and train one person who is responsible for monitoring, charting and maintaining correct vaccine storage temperatures on a daily basis. To this effect every refrigerator should have a dedicated thermometer;

(iv) single-purpose vaccine refrigerators should be encouraged as the simultaneous storage of other items (food, drink) results in elevated mean daily temperatures.[6] Vaccines should not be stored in the refrigerator door where temperatures are constantly higher than in the central compartment;[6]

(v) guidelines for the safe transportation and distribution of vaccines between wholesalers, pharmacists and general practitioners need to be developed and implemented. Apart from defects in the storage of vaccines, the fact that 63% of practitioners do not receive their vaccine supplies on ice, indicates the need for strengthening of the local distribution network.

Immunization is the most cost-effective means of preventing disease, yet is badly under-utilised.

A number of important aspects of vaccine storage were not investigated in this study and should form part of future investigations and interventions. These include the regular defrosting of refrigerators, stock rotation, and discarding expired and partially used multidose phials.[6,8]

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Make GPs aware of necessity of correct conditions
Always keep vaccines at 0 - 8°C
Use single-purpose refrigerator
Each refrigerator must have its own dedicated thermometer
Make one person responsible at each level of cold-chain
Put vaccines in the centre of the refrigerator – not in the door
Recieve your vaccine supply only if it is on ice
Check on the transportation and distribution network regularly

During a recent school based measles outbreak where lowered vaccine efficacy was a contributory factor, the attack rate was over 8% and two cases required hospitalisation.[14] This situation serves as a clear illustration and warning of the potential consequences of using vaccine of sub-optimal potency. Vaccination failure is also bound to negatively affect public acceptance and faith in vaccination programmes.

Vaccine failure due to neglect and ignorance of simple cold-chain procedures is costly in terms of childhood morbidity, health care and public credibility. Easily realised measures are available to guarantee the potency of vaccines.

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