Practice nurses best protect the vaccine cold chain in general practice

AUTHORS

Christine Carr
PhD, MMedSc, GradDipHSSc, RN, RM
Area Immunisation Coordinator, Hunter New England Health Service, Wallsend, New South Wales, Australia.
chris.carr@hunterlink.net.au

Julie Byles
Professor, Director of Research Centre for Gender, Health and Ageing, Faculty of Health, University of Newcastle, Newcastle, New South Wales, Australia.
julie.byles@newcastle.edu.au

David Durrheim
Professor, MBChB, DrPH,
Service Director for Health Protection at Population Health, Hunter New England Health Service, and Conjoint Professor of Public Health, University of Newcastle, Wallsend, New South Wales, Australia.
david.durrheim@hnehealth.nsw.gov.au

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KEY WORDS

general practice nurse, vaccine cold chain, vaccine storage, general practice, Hunter, immunisation

ABSTRACT

Objective
Maintenance of the vaccine cold chain is integral to administering potent vaccines thereby protecting individuals and communities against vaccine preventable diseases. Previous studies have highlighted threats to vaccine cold chain integrity. The aim of this study was to assess vaccine cold chain integrity and to identify local factors affecting vaccine cold chain integrity in Hunter general practices, where approximately 85% of vaccines are administered.

Design
A quasi experimental research design was used to conduct a site audit of general practice vaccine storage facilities in both urban and rural areas of the Hunter region of New South Wales. Practice staff who handled vaccines completed a practices and knowledge questionnaire during the audit visit.

Setting
General Practice.

Subjects
This study was an area-wide survey of all Hunter general practice immunisation service provider sites (n=256) where an audit was conducted of all vaccine refrigerators in use at the time of the audit, and one questionnaire per site was completed with respect to the cold chain management of all vaccine consignments delivered within the previous three months (n=924).

Main Outcome Measures
Main outcome measures were adherence to acceptable vaccine cold chain management practices as identified by National Health and Medical Research Council guidelines and maintenance of vaccine refrigerator temperatures within the World Health Organization's (WHO) recommended range of 2°C and 8°C.

Results
A key finding from this study was the positive influence of general practice nurses on general practices achieving vaccine cold chain integrity as defined by WHO. Ninety-eight percent (98%) of general practices where a general practice nurse was employed maintained vaccine cold chain integrity whereas only 42% of general practices where no general practice nurse was employed (95% CI: 10, 58) achieved the same result.
Two types of vaccine refrigerators were identified in Hunter general practices; these were non-bar type and bar-type. Of 150 non-bar type refrigerators in Hunter general practices 97% operated within the safe temperature range for the storage of vaccines, while only 58% of the bar-type fridges maintained acceptable temperatures for vaccine storage (95% CI: 8 - 69).

Conclusions
Study findings highlighted the value of employing general practice nurses in general practice in relation to maintaining vaccine cold chain integrity, and encouraging such nurses to become authorised immunisers so they can participate in ongoing immunisation education. The study findings supported the argument to outlaw bar-type refrigerators for storing vaccines as these posed an unacceptable threat to vaccine cold chain integrity.

INTRODUCTION

In New South Wales (NSW), approximately 85% of childhood vaccination and almost all adult vaccination are undertaken in general practice. Immunisation coverage data suggests that vaccination uptake for children improved dramatically during the late 1990s (National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases 2002) following the implementation of a variety of national, state and local strategies. National strategies (Australian Government 1997) included the establishment of the Australian Childhood Immunisation Register, provision of financial incentives to encourage parents to vaccinate their children on time, provision of service provider financial incentives to encourage reporting of vaccine administration to the Australian Childhood Immunisation Register and increase the proportion of children fully vaccinated by individual service providers, and provision of immunisation coverage rate data by state, division of general practice and by area health service (Health Insurance Commission 1999).

Local strategies in the Hunter region of NSW since 1992 included improved access by service providers (registered nurses), particularly general practice nurses, to specific immunisation education, and qualifications. Since 2001 authorisation under NSW Poisons and Therapeutic Goods Act 1966 Amendment 2001) (NSW Government 2001) allows registered nurses to assess clients' suitability for vaccination and administer such vaccines as recommended by the National Health and Medical Research Council without a doctor's written orders. This qualification was supported by the local Area Health Service by providing annual immunisation education to all Hunter authorised nurse immunisers, ensuring that they were kept informed of current immunisation recommendations and acceptable practice, including vaccine cold chain management. If improved vaccination rates are to be translated into optimal protection against vaccine-preventable diseases for individuals and the community then vaccines need to be transported and stored at temperatures that ensure their potency (between 2°C and 8°C). Inappropriate transportation, improperly maintained or outdated refrigeration equipment, deficient temperature monitoring, and inadequate immunisation service provider education, may all compromise the vaccine cold chain and, thus, the effectiveness of immunisation.

A multifaceted quality assurance study was conducted in 2003 and 2004 to explore the integrity of the vaccine cold chain during transportation and after delivery to immunisation service providers in general practice. This article concentrates on factors associated with vaccine cold chain performance in general practice surgeries in the Hunter Region of New South Wales. A literature review related to assessment of the vaccine cold chain and possible risk factors associated with vaccine storage practices revealed eight articles. Only one, undertaken on the Central Coast of NSW (Lewis et al 2001), included most of the issues assessed during the Hunter study. No study has assessed the relationship between employment of a nurse and integrity of the vaccine cold chain.

METHODS

Two hundred and fifty-six Hunter general practices participated in this 2003 - 2004 study. Vaccine cold chain knowledge and practices of staff who handled the most recent vaccine consignment at these general practices were assessed by on-site completion of a standardised practices and knowledge questionnaire. A site audit of all vaccine refrigerators was conducted concurrently. A questionnaire was designed which aimed to investigate general practice staff members' mechanisms for ensuring the integrity of the vaccine cold chain. The structure of the questionnaire reflected established World Health Organization (World Health Organization Dept Vaccines and Biologicals 2005) and National Health and Medical Research Council guidelines (National Health and Medical Research Council 2003). Questions addressed : prior immunisation education, ability to read temperature monitors included with consignments, knowledge of correct procedures if vaccines were compromised, and the awareness by

non-clinical staff of vaccine cold chain principles. The questionnaire also assessed the processes used in participants' workplaces, including whether a designated person was responsible for vaccine storage, fridge monitoring and fridge maintenance, whether the site had a process for receiving vaccines to ensure they were refrigerated within 10 minutes of arrival, and whether vaccine condition was noted on arrival. Data was also collected about whether a practice nurse was employed and whether the practice nurse was authorised to immunise without orders from a medical practitioner having undertaken specific NSW immunisation education (NSW Government 2001).

During the site visits, refrigerators used for vaccines were audited using a checklist to reflect established World Health Organization and National Health and Medical Research Council guidelines including whether the type and condition of refrigerator used for vaccine storage met these guidelines, how often temperatures were recorded and the type of thermometer used, whether records reflected that the fridge was functioning within the acceptable temperature range of 2°C and 8°C, placement of vaccine stock within the fridge, evidence of expired vaccines or storage of other items in the vaccine refrigerator, and evidence of correct labelling of the fridge and its power source.

A Tinytag® temperature data logger, a compact battery-powered unit, was used to record internal refrigerator temperatures every fifteen minutes over a period of 72 hours. Tinytag Explorer® data logging software was use to configure and calibrate the logger, and display and graph monitoring results (Tiny Tag 2004).

Data was analysed using Stata 8.0 statistical software (StataCorp 1984-2005). Comparison of proportions was conducted using Chi-square testing with a two-tailed significance level set at p=0.05. Fishers exact test was used where one or more cells had an expected frequency of <5. Differences between urban and rural areas were explored.

Ethical approval was sought from the Hunter Area Health Service Ethics Committee, which categorised the study as a quality assurance exercise.

FINDINGS

Data from the questionnaires and audits found a strong relationship between the employment of a practice nurse and acceptable vaccine cold chain practices (table 1).

Table 1: Service provider and acceptable VCC practices (n=256)

		Acceptable VCC Practices	
		Yes	**No**
PN employed	Yes	155 (95%)	9 (5%)
	No	39 (42%)	53 (58%)
Total		194 (76%)	62 (24%)
x^2 = 87; df = 1, p <0.0001		OR: 23 (95% CI: 10, 58)	
PN and ANI	Yes	121 (98%)	2 (2%)
	No	34 (83%)	7 (17%)
Total		155 (95%)	9 (5%)
x^2 = 14; df = 1, p <0.0005		OR: 12 (95% CI: 2, 126)	

VCC = Vaccine Cold Chain; PN = Practice Nurse; ANI = Authorised Nurse Immuniser

In general practices where the practice nurse was an authorised nurse immuniser with a specific authority under the NSW Poisons and Therapeutic Goods Act 1996, Amendment 2001), acceptable vaccine cold chain management practices were significantly more likely (98%) than in general practices where the practice nurse was not authorised to immunise (83%).

Forty-nine refrigerators (19%) did not maintain recommended internal temperatures (table 2). Bar-type refrigerators (44/106, 42%) more commonly failed to maintain acceptable internal refrigerator temperatures compared to non-bar type fridges (5/145, 3%), (p<0001), and bar-type were the only refrigerator type where temperatures fluctuated between too high and too low (table 3).

Table 2: Type of refrigerator in General Practice and maintenance of acceptable internal temperature

		Acceptable temperature maintained	
		Yes	**No**
Type of fridge		145 (97%)	5 (3%)
	Bar-type	62 (58%)	44 (42%)
Total		207 (81%)	49 (19%)
x^2 = 58; df = 1, p <0.0001		OR: 21 (95% CI: 8 - 69)	

Table 3: Refrigerator type and temperature compliance by 72 hour logging

	Type of Refrigerator			
Internal Fridge Temperature	**Purpose-built**	**Domestic**	**Bar-type**	**Total**
Temperature too low, > 2°C	0	3	29	32
Temperature too high > 8°C	1	1	6	8
Temperature > 2°C and > 8°C	0	0	9	9
Temperature maintained between 2°C and 8°C	7	138	62	207

No significant differences were found between urban and rural areas for any of the research outcome measures. There was still scope for improving vaccine cold chain management practices, as 24% of general practices service providers did not meet all vaccine cold chain management practices.

DISCUSSION AND CONCLUSIONS

The result of this study (76% of practices complied with approved vaccine cold chain management practices) compares favourably to that found in previous studies in other areas in Australia (Liddle and Harris 1995; Lewis et al 2001) where vaccine cold chain management practices were assessed in general practice; including maintenance of fridge temperatures between 2°C and 8°C, having a designated person responsible for the vaccine cold chain, recording of temperatures at least daily and inappropriate items stored in the vaccine fridge.

In Australia, the general practice setting is a major provider of primary health care and therefore an appropriate place for preventing rather than merely treating disease (Davidson et al 2007). Immunisation can be safely and effectively administered by appropriately trained general practice nurses. This study found that general practice nurses appeared to play an integral role in ensuring optimal vaccine cold chain practices, particularly where they were authorised to immunise and received annual, immunisation-specific education including that related to vaccine cold chain management . The study's findings highlighted the value of employing general practice nurses, and of investing in their immunisation-specific education.

This study found that 97% of non-bar type refrigerators in Hunter general practices operated within the temperature range that is safe for the storage of vaccines. Most Hunter modified domestic refrigerators maintained temperatures as well as purpose-built refrigerators, providing evidence that smaller domestic refrigerators could be acceptable for vaccine storage for smaller sized surgeries. The Hunter study found bar-type refrigerators were most likely to fail to maintain acceptable temperatures for vaccine storage, fluctuation of temperatures occurred below and above the recommended range. Both the World Health Organization and the National Health and Medical Research Council specifically advise against the use of bar-type refrigerators which may place vaccines at risk of temperature fluctuations, and the findings of this study support that stand.

Limitations of the study included the use of recall and subjective responses to knowledge questions such as whether the staff member could read the heat / freeze monitors and knew the correct procedures following a vaccine cold chain breach.

RECOMMENDATIONS

General practice nursing provides an integral and growing contribution to primary health care in many general practice surgeries throughout Australia, bringing to general practice the recognised nursing strengths of enhanced care and improved care quality (Phillips et al 2009; Annells 2007; Price 2007). Divisions of General Practice and nurse advocates should strongly encourage general practices to employ at least one general practice nurse to oversee immunisation services, including the management of the vaccine cold chain. Further research could identify other immunisation-related issues where the employment of a general practice nurse who is suitably trained to administer vaccines alone, and

who attends on-going immunisation education, could enhance practice improvements, such as timeliness of vaccination, appropriate catch-up regimes for all age groups (children, adolescents and adults), routine assessment of all clients, opportunistic vaccination of clients not age-appropriately immunised, and administration of all due vaccines at a single visit.

World Health Organization's and National Health and Medical Research Council's specific recommendations against the use of bar-type refrigerators should be supported by NSW Health, Divisions of General Practice and health advocates with strong policy statements that bar-type refrigerators should be outlawed for vaccine storage in all health settings.

Further quality assurance studies may be worthwhile to assess any improvements in vaccine cold chain management by vaccine service providers since the introduction of national vaccine storage standards in 2005 (Commonwealth Government Dept of Health and Ageing 2005).

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