Assessing the effectiveness of cold chain management for childhood vaccines

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ABSTRACT

INTRODUCTION: Effective immunisation programmes require a stable cold chain to maintain potency of vaccines from national stores through to delivery sites.

AIM: To assess the effectiveness of the New Zealand cold chain and examine the possible impacts of policy changes over the same time period on cold chain effectiveness.

METHODS: Heat- and freeze-sensitive monitors were attached to 5% of randomly selected childhood vaccines from 2002 to 2008. Six-monthly reports on data collected from monitor cards were collated and analysed to look for changes over time in freeze and heat exposure failures for vaccines.

RESULTS: From December 2002 to June 2008 a total of 21 431 monitor cards were included in vaccines distributed from the national store; 9474 (44.2%) of all cards were returned and 8249 (38.5% of total) were correctly completed. Over this period the percentage of valid returns recorded as heat exposed decreased from 38% to 7% (χ^2 371, p<0.001); heat failures decreased from 3% to 0.3% (χ^2 371, p< 0.0001); freeze failures decreased from 16% to 2% (χ^2 134.228, p< 0.0001), and overall wastage from 17% to 2% (χ^2 163.83, p<0.0001), giving estimated annual savings of nearly NZ$4 million.

DISCUSSION: Significant improvements can be made in cold chain management with resulting savings in vaccine wastage. This study demonstrates that such improvements have been made in New Zealand in recent years. This is likely to be due to a combination of improving equipment, systems, education and training, increased provider attention and quality standards.

KEYWORDS: Vaccination; cold chain; refrigeration; primary health care

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Introduction

The term ‘cold chain’ is defined as the maintenance of vaccines at stable temperatures throughout the process of transportation and storage from site of manufacture through to vaccine administration. Maintaining the vaccine cold chain is an essential part of a successful immunisation programme, because immunological potency of vaccines can be compromised on exposure to extreme temperatures. Retaining stability of vaccine potency from manufacturer through to delivery requires maintenance at every step of a cold chain infrastructure.[1]

The World Health Organization guidelines and manufacturers’ guidelines all recommend national schedule vaccines be kept at +2 to +8°C (except oral polio).[2] Potency cannot be guaranteed when vaccines fall outside the manufacturer’s recommended range.[1] Environmental damage by freezing is generally the most significant threat to vaccine integrity, with the most freeze-sensitive vaccine being the hepatitis B vaccine.[3] Exposure to freeze damage is a significant problem internationally, with reports of as much as 75–100% of freeze-sensitive vaccine being damaged.[4]

Good cold chain management and reduction in vaccine wastage is an important quality and financial aspect in maintaining an effective national immunisation programme.[5] Vaccine wastage and its associated costs is a common problem for all immunisation programmes.[6] For example, a US study conducted in 1998/1999 estimated a national wastage of approximately US$6–31 million worth of vaccine compromised by cold chain failure or lapses in expiration in the public sector.[7]

When the delivery of vaccines occurs in primary care, breaks in the cold chain are common, particularly with exposure to unacceptably cold temperatures. As many as one quarter of all primary care refrigerators may be freezing vaccines.[8]

Assessing the frequency and causes of vaccine wastage can help to target efforts to reduce vaccine potency failures and minimise unnecessary extra service delivery costs.[7] New Zealand (NZ) purchases scheduled vaccines nationally, distributes them to regional stores, and from there on to the primary care practices which are the main site of vaccination delivery. Historical cold chain surveys in NZ have shown that around one-fifth of freeze-sensitive vaccines had been cold exposed at some stage along the distribution chain and nearly 8% of heat-sensitive vaccines had been heat exposed.[9]

In December 2002, routine ongoing monitoring of the NZ cold chain between the National Vaccine Store (NVS) and the point of delivery was introduced. Vaccine vial monitors (VVMs) have been used to monitor and measure the adequacy of the cold chain since that time.[10] Five percent of scheduled childhood immunisation vaccine packs have a heat-sensitive monitor (WarmMark®) or a cold-sensitive monitor (ColdMark®) attached at the NVS, along with a record card.

The aims of this study were to examine the results from the VVMs to assess the effectiveness (in terms of levels of heat/cold exposures and failures) of the NZ cold chain over the time period 2002–2008, and to examine the effect of policy changes during this time on cold chain effectiveness. Throughout this period there were significant changes to policy and education for cold chain management. These were:

- The development in 2002 of the Ministry of Health *National Guidelines for Vaccines Storage and Distribution.*[11] These were distributed to all primary care deliverers of the national schedule vaccines in 2003.

WHAT GAPS THIS FILLS

What we already know: Cold chain integrity is important to the maintenance of a quality immunisation programme.

What this study adds: Implementing a range of changes such as improving equipment, systems, education and training, increased provider attention and quality standards in an immunisation programme can significantly improve the cold chain, reduce wastage and make efficiencies in a health budget.

- Training for all Vaccinators and Immunisation Coordinators on the National Cold Chain Audit was provided. This started in 2003 and has been included in training for all new vaccinators since this date and in refresher courses which are required for vaccinators every two years.
- A Ministry of Health initiative in 2004 to 2005 funded the full purchase cost of new pharmaceutical fridges for all general practices delivering childhood immunisations.
- The introduction of the 'Cold Chain Accreditation' process for all providers of the national schedule vaccines was introduced from 2004 to 2005. This is a Ministry of Health initiative for all primary care practices to demonstrate effective management of vaccine stocks in the cold chain, involving a three-yearly practice self-audit followed by a review by an immunisation coordinator.

Methods

Heat- and freeze-sensitive monitors were routinely attached to 5% of randomly selected childhood vaccines packed at the NVS in the ESR (Institute of Environmental Science and Research).

A ColdMark® shows exposure to temperatures below 0°C when a clear bulb turns to violet, indicating that vaccine potency has been reduced due to freeze exposure. WarmMark® tracks cumulative heat exposure over 10°C and displays this by slowly turning windows on the monitor red. A WarmMark™ status of Index 2 means that two windows are completely red, indicating that the vaccine potency has been reduced, and effectiveness is in doubt. Each monitor had a record card attached at the NVS at the ESR. These record cards are required to be filled out at each transport and storage stage up until the administration of the vaccine. The monitor card with completed records is returned to the ESR after vaccines have been delivered or exposed to temperatures significant enough to reduce their potency.

Six-monthly reports on the data collected from the monitor cards were collated and analysed from December 2002 to June 2008. Data was entered into Microsoft Excel and the frequencies of heat/cold exposures and failures were compared over time. These were tested using the chi square for linear trend (χ^2).

Figure 1. Percentage of monitors classified as heat exposed

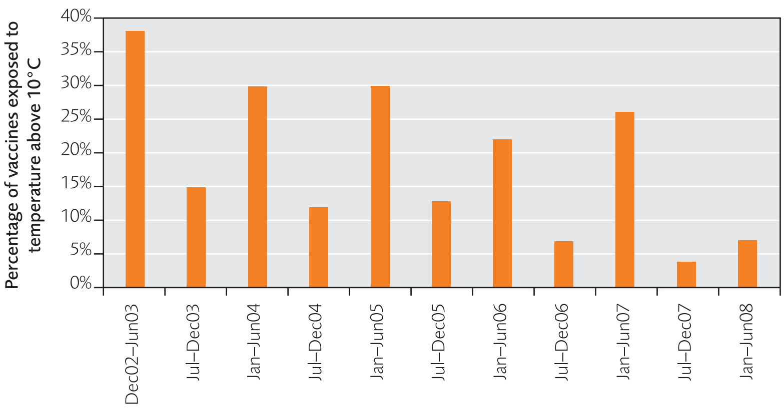
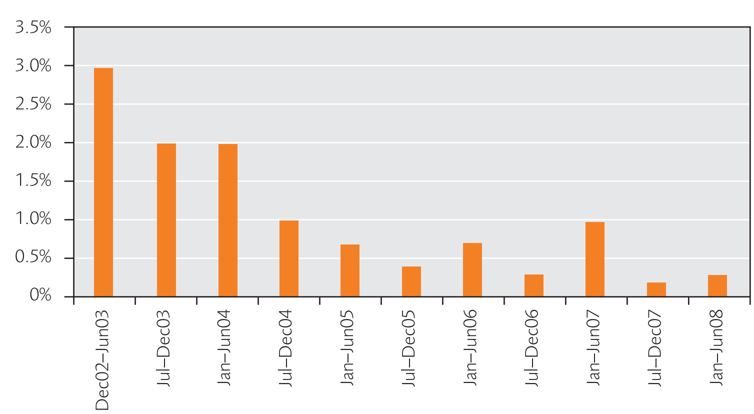


Figure 2. Percentage of monitors classified as heat failure



Ethical approval was not required because this was an audit on national level, anonymous collated data and did not involve patients.

Results

For the period of December 2002 to June 2008 a total of 21 431 monitor cards were sent, of which 9474 (44.2%) were returned. Of the returned cards, 8249 (38.5% of the total) were correctly completed and 1229 (5.7% of the total) were incorrectly filled out and therefore not included in the analysis. The most common cause of incorrect completion was the failure to record at every step of the way along the process until the delivery of the vaccine to the patient. The percentage of incorrectly completed returned monitors significantly decreased over the time period. The initial six-monthly audit of the period December 2002 to June 2003 showed 20% of monitors were incorrectly completed, and this reduced over time to 6% in the January to June 2008 six-monthly report (p<0.0001).

The percentage of correct returns recorded as heat exposed showed clear seasonal fluctuations, but overall rates decreased from 38% in the December to June 2003 quarter to 7% in the January to June 2008 quarter (p<0.001) (refer Figure 1). Not all cases of heat exposure result in heat failure. The frequency of heat failures (classified as Index 2) reduced from 3% in the quarter December 2002 to June 2003 to 0.3% in the January to June 2008 period (p< 0.0001) (refer to Figure 2).

The percentage of correct returns recorded as freeze failures decreased from 16% in the December 2002 to June 2003 quarter to 2% in the January to June 2008 quarter (χ^2< 0.0001) (refer to Figure 3).

The overall percentage of vaccines requiring to be discarded ('wasted') due to cold chain failure decreased from 17% in the quarter December 2002 to June 2003 to 2% in the January to June 2008 (p<0.0001) (refer to Figure 4).

The recorded location of cold chain failures is recorded in Figure 5. The most common location was at the site of delivery (the general practice) in overall 49% of cases, followed by in transport for

46% of cases, and at the regional vaccine store in 5% of cases.

From January to June 2008 a total of 428 213 dosages of childhood vaccine valued at NZ$13 155 300 were distributed. With the reduction in vaccine wastage achieved from December 2002 to June 2008 (a reduction from 17% to 2%) this represents an estimated annual saving of $NZ3 946 590.

Discussion

This study shows there has been a significant improvement in cold chain management for the national schedule vaccines in NZ from December 2002 to June 2008. This improvement has meant less wastage which equates to an estimated saving of nearly $NZ4 million a year.

The changes in policy and practice that were put in place during this period were a combination of improved equipment, development and implementation of national standards, provider education and systems for more attention and accountability at the provider level. It is not possible to identify the effects of any individual intervention with certainty. As can be seen in Figures 1–3, the most improvement occurred from July 2004 to December 2006. This was the period when pharmaceutical fridges were purchased for all practices in NZ. However this was also the period when the national *Annual Cold Chain Management Guide*[11] was produced and circulated. As there were improvements not just at the provider level, but also with transportation, the overall improvements in the cold chain function are unlikely to have been due solely to the new fridges.

Improvements in cold chain performance over time have been seen in both heat-sensitive and cold-sensitive vaccines. However, it is noteworthy that there continues to be significant seasonal fluctuations seen in the amount of heat exposure occurring every year. On average, heat exposure figures more than double during the summer months (January to June).

The greatest improvements have been seen with freeze-sensitive vaccines. This may have been due

Figure 3. Percentage of monitors classified as freeze failure

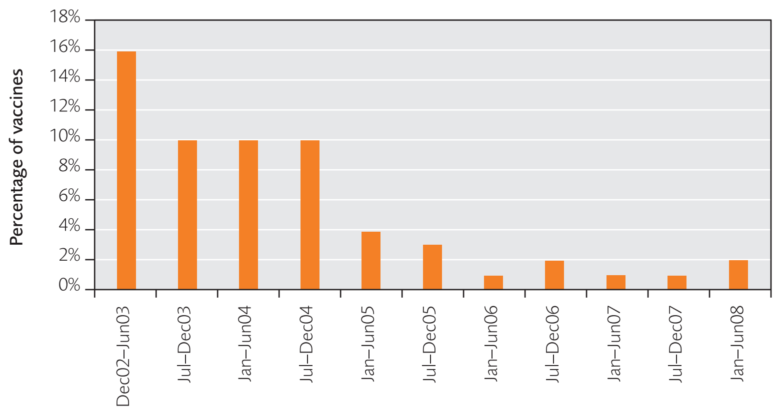


Figure 4. Percentage of monitors recorded as requiring vaccines to be wasted due to cold chain failure

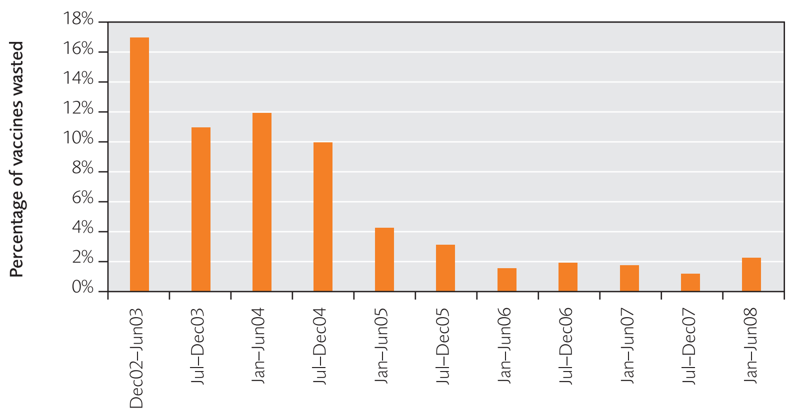
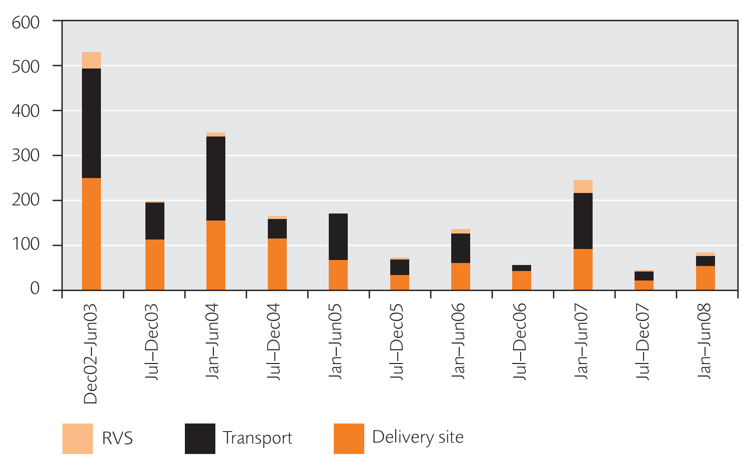


Figure 5. Recorded location of cold chain failure



RVS = Regional Vaccine Store
Transport = transferring between regional vaccine stores to the general practice
Delivery site = primary care site (general practice)

to the fact that pharmaceutical fridges particularly reduce the amount of exposure to temperatures below 0°C. The domestic fridges previously in use were designed to reduce heat exposure in the main and were more effective at this, but less effective at reducing freeze damage.

The major site of cold chain failure continues to be in primary care practices although overall there has been considerable improvement over time. Primary care needs to remain vigilant, as even pharmaceutical fridges can fail and require regular monitoring. The failure rate in transport has decreased even more significantly.

Limitations of the study

The return rate of the monitors sent out with vaccines has been relatively poor throughout the study period, although there have been improvements in the proportion that are correctly completed which is likely due to an emphasis on training and providers becoming more familiar with the use of the monitors. There is also no information on the non-returns, so overall failure rates could be higher or lower than observed in this sample. Because several different interventions took place over the study period, it is not possible to identify which were the most effective in improving cold chain performance.

Conclusions

Significant improvements can be made in cold chain management resulting in considerable savings in vaccine wastage. In NZ this has been demonstrated over a six-year period and is likely to be due to a combination of improving equipment, systems, education and training, increased provider attention and quality standards. Cold chain failures do continue to occur, particularly at the primary care site and in transportation, and this is an area that is worthy of further consideration.

COMPETING INTERESTS
None declared.

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