The immunisation cold chain

Why is it so hard to get right?

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BACKGROUND Although the standards for vaccine storage required for accreditation of general practices, and the Guidelines for Australian Immunisation are widely available, all research to date suggests that in Australia compliance with these standards has not been readily achieved.
OBJECTIVE The New South Wales Central West Division of General Practice (NSWCWDGP) and the Public Health Unit of the New South Wales Mid Western Area Health Service (NSW MWAHS) worked together from 1999 to 2001 to produce an intervention that would gather information about current vaccine storage, and provide practical help to storage sites which were not complying with accepted standards.
DISCUSSION Cooperation between a general practice division and the public health unit can deliver coverage of 100% of vaccinators in a large geographic region. We have demonstrated that the lack of a designated person to take on ultimate responsibility for vaccines at a site is associated with less chance of achieving safe storage. Persistent difficulty in 'getting it right' has been documented. One new measure we have suggested and trialled is the installation of affordable commercial thermostats in the domestic refrigerators that are now widely used. Another is the piloting of a general practice division administered mailout program of temperature dataloggers to document the ongoing compliance of vaccine storage sites with accepted standards.

Why does the cold chain matter?

Keeping vaccines potent

Vaccines are temperature sensitive biological agents. Prolonged warming, but especially any subzero storage, reduces or destroys potency of many vaccines.[1] Unfortunately, inactivated vaccines undergo no change in appearance after poor storage, and can easily be inadvertently administered to patients. The patient then risks being misled into thinking they are immunised when they may have missed out on any protective effect. The only way for general practitioners storing vaccines to be sure they are not short changing their patients is documented compliance with cold chain measures.

How well do we do now?

Worldwide, a considerable body of research evidence has been compiled which establishes the need to improve on existing organisation and vigilance in the care of vaccines.[2-16] The major focus of studies has been the measures taken to avoid storage of vaccines outside the recommended temperature range of 2-8ºC. Work reported in 1994 and 1996 from the Northern Territory[12,13] demonstrated that the greatest threat to vaccine potency at the time was storage of vaccines below zero degrees Celsius. It is perhaps understandable that health workers in tropical

and desert regions would perceive heat as a threat to their vaccine safety and potency. It is also a likely unintended consequence of the title 'cold chain' itself, and suggests that a renaming to 'cool chain' may be warranted.

Popular misconceptions

During research in country NSW there was a lack of understanding among vaccinators that storage at less than zero degrees cannot be reliably identified by physical freezing of a vaccine, and that it is not necessary for a 'freeze sensitive' vaccine to achieve an icy state to compromise its potency.[17]

Research published in the USA[15] indicates that even in a different health system the problems we identified and addressed in NSW are replicated. We believe there are elements of under performance that relate to human nature and incomplete understanding of important issues, and vaccine storers need targeted help to overcome these identified barriers.

Persistent problems

Domestic refrigerators

Refrigerators designed for household kitchens are the commonest choice for general practices.[17] The thermostats in these units were not designed for constant maintenance of the 2-8ºC range, and in Australian research some are incapable of such performance. They require trial and error in the temperature dial setting to achieve appropriate refrigeration, after which there is no failsafe means to prevent the setting being changed.

Commonly used maximum/minimum thermometers give no indication of the duration of 'out of range' temperature recordings, and therefore are of little practical help in assessing the likelihood of inactivation of vaccines present in the refrigerator. This can lead to expensive waste of subsequently discarded vaccines.

In recent NSW general practice research,[17] refrigerators containing a freezer section without a door within the main cabinet, persistently failed in temperature monitoring.

Role confusion

One person, with backup for their absences, needs to be tasked with the responsibility for both caring for vaccines, and documenting compliance. Although this is a clear recommendation in immunisation guidelines, it often breaks down in general practice when staff turnover, illness or holidays supervene.

Loss of focus

General practices that achieve the vaccine storage standards are known to have a significant rate of failure if monitored again in the next 1-2 years.[14,17] Reasons for this are likely to include the refrigerator limitations listed above, and the relaxation of focus which may occur after accreditation assessments are successfully concluded.

Practical solutions

Commercial thermostats

Local refrigerator technicians are able to install alternate thermostats into domestic refrigerators that can be permanently set to a desired temperature range (Figure 1a, b, c).

This was trialled in central western NSW at a cost of approximately $150 per installed refrigerator. Subsequent performance of even previously inappropriate refrigerators was documented to be optimal. The alternative of purpose built vaccine refrigerators currently cost approximately $2000.

Refrigerator choice

Large versus bar sized refrigerators were as likely to pass or fail cold chain monitoring in recent research. In the experience of triallists in NSW, the only refrigerator which appears to be incapable of adjustment or modification was that with an open freezer compartment within the refrigerator cabinet.

Figure 1a). Commercial thermostat in fridge

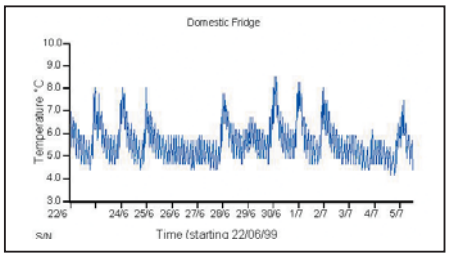

Figure 1b). Domestic fridge complying temperature trace

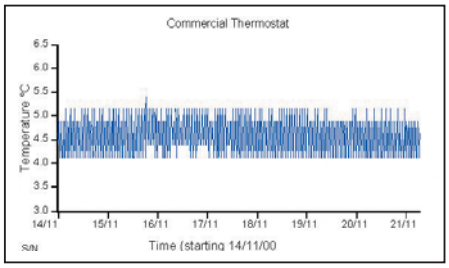

Figure 1c). Commercial thermostat temperature trace

Figure 2. Datalogger with mail pack

Datalogging

The limitations of maximum/minimum thermometers in reporting on refrigerator performance have been discussed above. Electronic temperature recorders (dataloggers) are often used in research of cold

chain compliance (Figure 2) being housed in small plastic containers the size of 35 mm film cannisters, and can be distributed and retrieved by mail.

Simple computer software means that a date and time to begin and end recording can be programmed into the datalogger, so that with planning it is possible to send them through the mail system while they remain inactive. The logger, set to record and log temperature every 15 minutes, can then activate after it has been placed in the target refrigerator and record for two weeks. It can then respond to its programmed instruction to turn itself off before being removed on the appointed day for mail return and download of results.

Ongoing assistance by divisions of general practice

Is a division run datalogging service practical and acceptable to GPs? This has been trialled in central west NSW where partnering with the area public health unit (PHU) resulted in 100% take-up of the service by all general practice, hospital and community health vaccine storage sites.

The benefits of the datalogging approach are that GPs receive a graphic representation of their refrigerator performance. This has proved a potent starting point in situations where changes needed to occur.

In recent research, some sites required three separate return visits to advise and verify effectiveness of remedial measures. Follow up mailout datalogging has also demonstrated a persistence of the problem of complying sites subsequently failing.

It therefore appears that a 'helping' structure is needed to overcome the problems of mechanical and human frailty. Divisions of general practice, in partnership with public health units, are ideally placed to coordinate this ongoing service to vaccine storers.

Background to NSW research

Key areas of interest to our combined division/PHU Steering Committee included documenting the current storage performance of vaccine providers in our region and identifying the factors common to noncomplying refrigerators.

We hoped to identify the factors conducive to being a complying storage site, and create practical and acceptable mechanisms to get under performing sites up to scratch.

The NSWCWDGP and PHU worked together as equal players from the outset because of our belief that the necessary focal point was the patient receiving vaccination, not the providers. It was therefore important that research and application of standards was seen to apply impartially to providers in community health/hospital settings as well as to GPs. In our region all vaccine storage sites were sent a short questionnaire to provide information we thought to be important on the organisational aspects of safe vaccine storage.

The 'best practices' sought were based on the 6th edition Immunisation Handbook. Mail delivered dataloggers proved very practical in our far-flung rural health region, and were the foundation of our achievements. The graphic testimony of a failure temperature trace, achieved objectively without inconvenience to the vaccine storer, was a potent starting point for discussion regarding the measures necessary to deal with the involved vaccines, and future improved storage. Site visits were then carried out, focussing on feeding back the personalised data acquired through the questionnaire and datalogging. The site visit team for all sites comprised a general practice division member, and the PHU immunisation nurse coordinator.

An ongoing program of mailout temperature datalogging is continuing to document continued performance.

Conclusion

Current cold chain measures give little confidence that the potency of vaccines can be assured at all storage sites all of the time. The medical fraternity is convinced of the benefits of immunisation, and should be more concerned about the evidence of ongoing problems in guaranteeing the effectiveness of the vaccines we proffer to our patients. New approaches to overcoming the consistently documented problems are needed. Some ideas discussed here, have been generated in general practice division based research which might be pursued.

SUMMARY OF IMPORTANT POINTS

- Many vaccine storage sites do not understand the issues regarding cold chain vaccine storage.
- Domestic refrigerators require significant effort to make them suitable as vaccine refrigerators.
- A designated person has to be responsible for cold chain issues at every site, every day.
- Using current practices, a significant proportion of refrigerators that comply on one assessment will fail cold chain compliance when reassessed several months later.
- New approaches to these problems need to be identified and implemented.

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