SUBJECT
New technology can provide an optimal vaccine storage solution to prevent the administration of ineffective vaccines and reduce vaccine wastage.

PURPOSE
To seek opinion on new options to reduce vaccine wastage and prevent the administration of ineffective vaccines.

BACKGROUND

1. The cost of vaccine wastage in Australia may be in excess of $26M for 2005-2006. The latest estimated vaccine wastage rate is 10% of total annual budget (General Practice Divisions of Victoria). Approximately, $105,000 worth of vaccines has been discarded in Victoria in January 2006 due to cold-chain failures ***(Appendix 1)***.

2. All cold chain failures are not detected or only detected after the event, so wastage figures could be higher. Freezing continues to be a major cause of vaccine wastage.

3. The majority of vaccination providers use domestic fridges for vaccine storage and monitor temperatures manually using a basic min/max thermometer. Cold chain failures continue yet new temperature monitoring technology is now available to prevent this.

4. The immunisation cold chain is difficult to 'get right' despite efforts to minimise wastage with significant training and guidelines **(*Appendix 2)***.

5. Key findings from the National Immunisation Workshop (June 2004) indicate that domestic fridges require modifications to ensure suitability for vaccine storage and require that vaccination providers have an in depth knowledge of their fridge performance[9-13].

6. New wireless temperature monitoring technology now provides vaccination providers with live temperature readings and immediate graphical display of fridge performance. Intelligent systems can even prevent freezing of vaccines ***(Appendix 3)***.

7. A review of options to minimize cold chain failures and reduce wastage cost has occurred. Potentially, a return on investment can be realized immediately and recovered within 8 months. A summary of comparisons is attached (***Appendix 4***).

ISSUES

8. Lack of consequence for vaccine wastage – most vaccination providers are not willing to invest in new technology that can prevent wastage as they do not have to pay for vaccines; no ownership for vaccine wastage.

9. Full extent of vaccine wastage and administration of ineffective vaccines is unknown as the current system relies on manual reporting of events. Current technology does not detect all cold chain events (case study results) and some events are not reported [4] ***(Appendix 5)***.

10. Limitations of min/max thermometers – no comprehensive data on each cold chain event, i.e., duration, temperature profile during the event, min/max temperatures if more than one event occurs before the min/max thermometer is reset. This contributes to vaccine wastage.

11. Insufficient use of electronic temperature monitoring - Studies have shown that electronic temperature loggers aid the understanding of refrigerator performance significantly [14], however, only very few vaccination providers use data loggers for continuous temperature monitoring (***Appendix 6***).

12. Lack of forum to evaluate and recommend new technologies for vaccine monitoring and storage, eg. new intelligent electronic temperature monitoring systems can provide a domestic fridge with the same safety mechanism to prevent freezing of vaccines that is provided by a dedicated vaccine fridge at a fraction of the cost. This example of new technology should be presented to such a forum.

OPTIONS

13. Update the national vaccine storage standards to mandate the use of electronic data loggers.
    a. provides critical data such as alarm duration, min/max temperature and temperature profile of vaccines following alarm conditions for informed decision making;
    b. the cost of a basic electronic logger ranges from $100-$150 and is a cheap solution to help prevent potential vaccine wastage;
    c. will not prevent freezing of vaccines and does not address the issues raised in the case study presented in appendix 5;
    d. there is insufficient data available today to estimate the true savings of this option.

14. A nation wide deployment of intelligent electronic monitoring systems.
    a. prevents vaccines freezing (except during power outage) and ensures that cold chain events are always detected;
    b. cost of deploying is approximately $12.1 MAud;
    c. ease of implementation - deployed by mail, easy to self install;
    d. fast implementation - within 6 to 12 months;
    e. the return on investment can be realised immediately and recovered within 8 months;

15. The options for a nationwide deployment of purpose built vaccine refrigerators, and a rebate scheme for dedicated vaccine fridges or intelligent monitoring systems were assessed, but were less attractive options for having an immediate impact on reducing vaccine wastage.

RECOMMENDATION

The most viable option is the deployment of intelligent monitoring systems to prevent freezing.

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APPENDIX 1: Vaccine wastage cost

- The National Immunisation Program budget for 2001-2002 was $84.6M[1] and is estimated to exceed $260M[2] for 2005-2006. Assuming a 10% vaccine wastage rate, the potential cost of vaccine wastage has risen from $8.4M to $26M.

- The February Immunisation Program newsletter (Issue 21) quoted that about $105,000 worth of vaccines have been discarded in Victoria since Jan 2006 due to cold-chain failures

- Despite extensive cold chain training and awareness programs, research by the SAICU on vaccine wastage indicates that over 90% of reported wastage is due to cold chain failures at the vaccination provider's site. Freezing accounts for over 70% of vaccine wastage[3].

- Further research indicates that vaccine wastage rates could be considerably higher. Many cold chain events are undetected potentially resulting in the administration of ineffective vaccines. The true cost of vaccine wastage in Australia remains unknown due to inconsistent monitoring and reporting of data [3-6].

- Our limited trials presented in case study 1 (Appendix 5) also indicate that many cold chain events go undetected or only detected after the event potentially resulting in administration of ineffective vaccines. If the results of case study 1 are truly representative of cold chain failure in general practices throughout Australia, vaccine wastage could exceed 20% of the Immunisation budget.

- Vaccines and Immunisation programs are becoming increasingly more expensive with new vaccines being added to the National Immunisation Program.

APPENDIX 2: The vaccine cold chain is difficult to 'get right'

Efforts to minimise vaccine wastage have resulted in two major initiatives;

1) establishment of processes for the transportation and distribution of vaccines.

   - Each state government in Australia has a well established process to ensure safe transportation and distribution of vaccines, including an ordering process to prevent overstocking of vaccines.
   - These processes may vary between the different states but are now well entrenched and vaccine wastage has been reduced.

2) establishment of The Australian Immunisation Handbook (8th Edition) [7] and National Vaccines Storage Guidelines : Strive for 5 [8]

   - To increase the proportion of effective vaccines that are administered and to reduce vaccine wastage by equipping those involved with the appropriate knowledge to maintain the vaccine cold chain.
   - It includes a comprehensive listing of modifications required to domestic fridges for vaccine storage and the minimum monitoring requirements to ensure integrity of the immunisation cold chain.

The different performance characteristics, sizes and types of domestic fridges available adds to the complexity of modifying a domestic fridge for effective vaccine storage, however technology is now available to simplify this task.

APPENDIX 3: New temperature monitoring technology

Wireless temperature monitoring systems

- Until now, the drawback of electronic data loggers is that it has not been possible to detect a cold chain breach until the data is manually downloaded and practice staff cannot act on any cold chain event as they occur.

- With automated electronic temperature monitoring systems, multiple probes allow different levels in a fridge to be monitored simultaneously, simplifying the task of temperature mapping a fridge. Graphical display of logged data shows temperature fluctuations due to compressor on-off cycles, enabling the addition and placement of sufficient thermal mass. The graphical display also enables the average temperature to be established easily allowing accurate setting of the thermostat to the optimal 5°C. Alarm alerting functions provide notification of alarm conditions to enable immediate actions to be taken.

- The extracted sample data (Figures 1 and 2) shows that with awareness of factors affecting refrigerator performance and with appropriate tools for monitoring refrigerator performance, domestic fridges can maintain a constant storage range between 2°C-8°C.

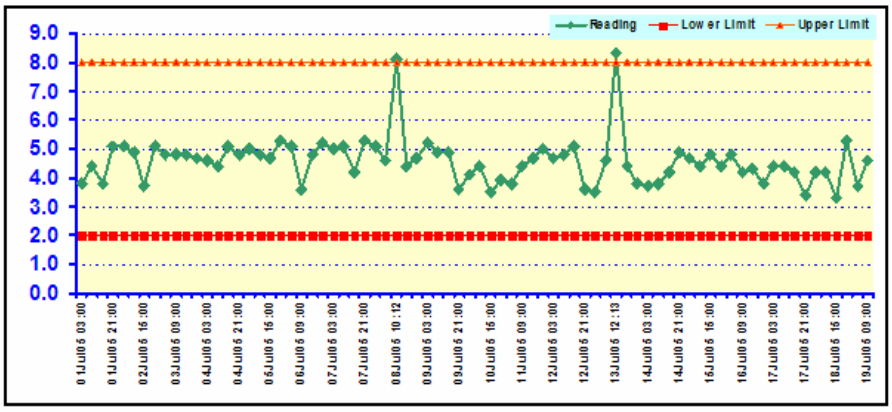

Figure 1: Probe 1, Upper shelf. Storage temperature for month of August.

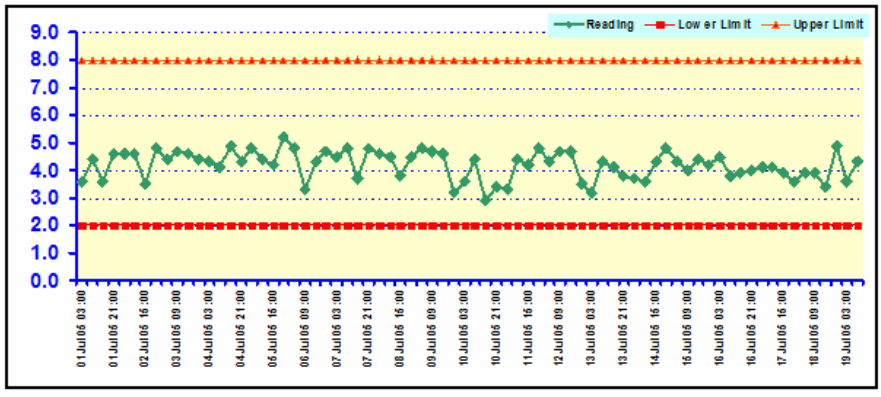

Figure 2: Probe 2, Lower shelf. Storage temperature for month of August.

Intelligent monitoring systems

- Intelligent monitoring systems can detect abnormal events and take over temperature management to prevent freezing of vaccines.
- The latest innovation in electronic temperature monitoring systems enables the supervisory controller (regulator) to “learn and remember” optimum fridge performance.
- In the event of a disturbance such as changes in ambient temperature that can potentially cause freezing, the regulator takes over thermostat control and will attempt to emulate optimum performance previously “learned” as depicted in figure 3 below.
- These new intelligent systems provide a domestic fridge with the same safety mechanism to prevent freezing of vaccines that is provided by a dedicated vaccine fridge.

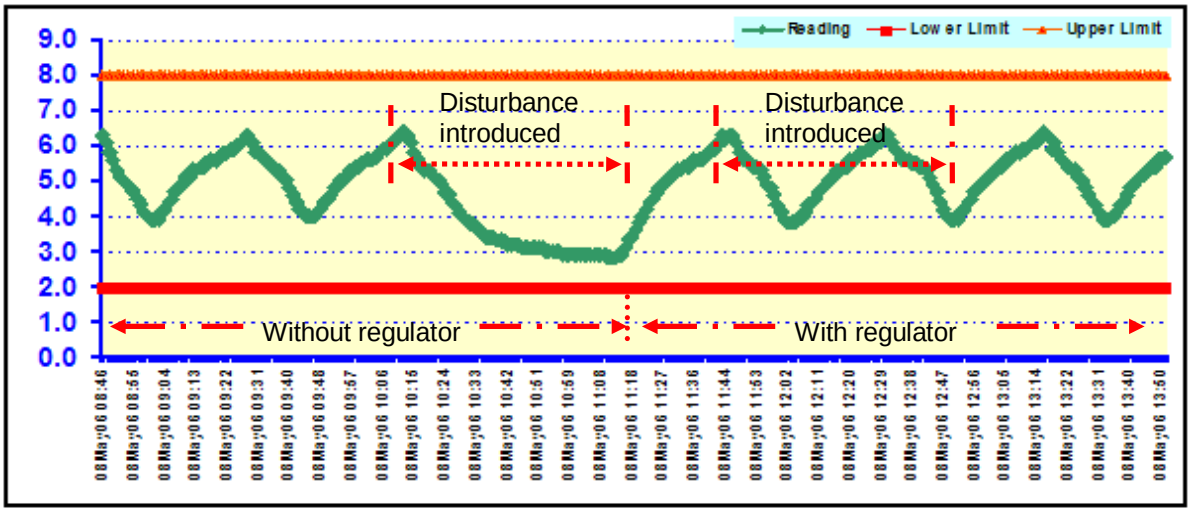

Figure 3. Performance characteristic of intelligent monitoring systems with supervisory control function.

APPENDIX 4: Options to minimise cold chain failures and reduce vaccine wastage

Option	Impact	Cost	Deployment/Lead-time	Return on Investment
Update the national vaccine storage standards to mandate the use of electronic data loggers	• Critical data available for decision making *if* cold chain failure detected. • Cannot prevent vaccine wastage	$200 for 2 loggers (upper and lower shelves)	Immediate	No data for estimating.
A nation wide deployment of intelligent electronic monitoring systems *Note: Broadband availability provides the opportunity for a totally networked monitoring system across Australia.*	• Prevents vaccines freezing (except during power outages) • Ensures cold chain events are always detected • Auditable electronic records • Eliminates administration of ineffective vaccines • Reduction in vaccine wastage immediately	Approx. $12.1MAUD once off cost *(Assuming 12,100[15] vaccination providers of government funded vaccines)*	6-12 months • system would be deployed by mail to each vaccination provider • The system is easy to self install and training for using the system can be provided via training CD's and through the immunisation workshops currently organised by DGP's.	Return on investment realised immediately Cost recovery in 8 months, eg. Preventable wastage = 70% x $26M
A nation wide deployment of purpose built vaccine refrigerators	• Prevents vaccines freezing (except during power outages) • The task of monitoring min/max storage temperature must still be performed to ensure that vaccine storage temperatures do not exceed the 2°C-8°C range. • Reduces vaccine wastage in the long term, however power outages and poor cold chain management practices can still result in vaccine wastage.	Approximately $30.25M-$36.3M; *(based on a mid sized purpose built vaccine fridge (200-300L capacity) costing between $2,500-$3,000).* Purpose built vaccine refrigerators are very expensive, ranging from $1,500 for a bar sized fridge to $4,500+ for a large fridge.	• tedious implementation - the cost and logistics involved for storing, transporting and installing the vaccine refrigerators nationwide is significant	Return on investment would be 24 months (without considering total running cost of this project and also taking into account that vaccine wastage will still continue during the roll-out phase of the solution)
Rebate scheme for dedicated vaccine fridges	• partial or full rebate scheme where vaccination providers are responsible for the purchase of equipment individually; • similar scheme was adopted by the Pharmacy Guild of Australia that mandated the use of purpose built vaccine refrigerators in all pharmacies but the take up rate has been gradual;	As above	• Take up by vaccination providers could be slow	Return on investment of this approach would be at best 3 times longer than deploying intelligent electronic monitoring systems as take-up dependent on GP's

APPENDIX 5: Current technology does not detect all cold chain events

- Several GP's using domestic fridges for vaccine storage participated in the case study. Types of fridges varied from bar fridges, fan forced fridges and fridges with evaporative cooling plates. In most cases the fridges had bottles of water to increase thermal mass.

- Vaccine storage temperature was monitored using a min/max thermometer with the probe placed inside a vaccine box on the middle shelf of the fridge. Daily manual recordings taken from the min/max thermometer indicated that storage temperatures were within $2^{o}C$-$8^{o}C$.

- When a dual probe system was used in a fan forced fridge with probes placed on the upper and lower shelves, vaccines storage temperatures were NOT within the $2^{o}C$-$8^{o}C$ range in the upper shelf (Figure 1). The lower shelf readings (Figure 2) were consistent with readings from the min/max thermometer.

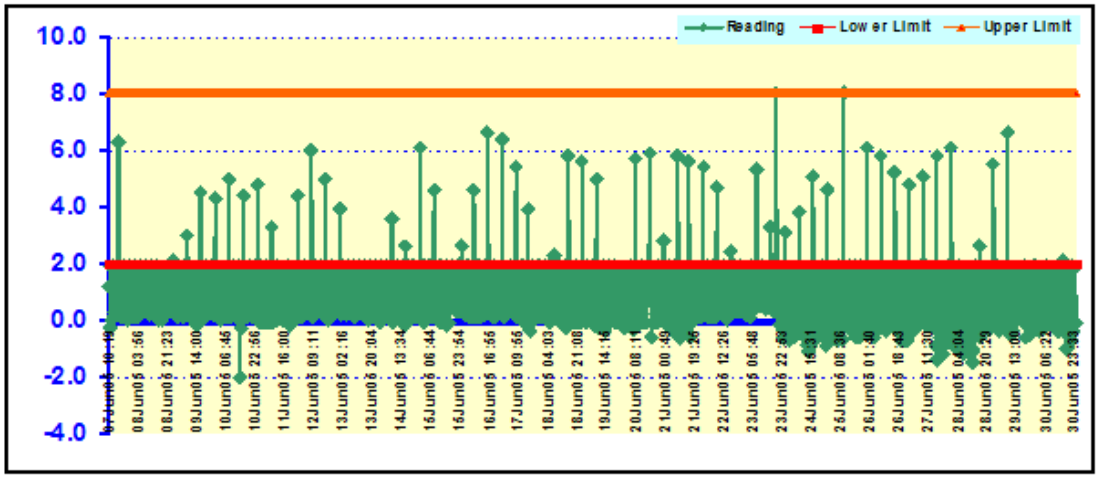

Figure 1 : Probe 1, Upper shelf: Vaccine storage temperature in a Victorian medical practice for June 2005.

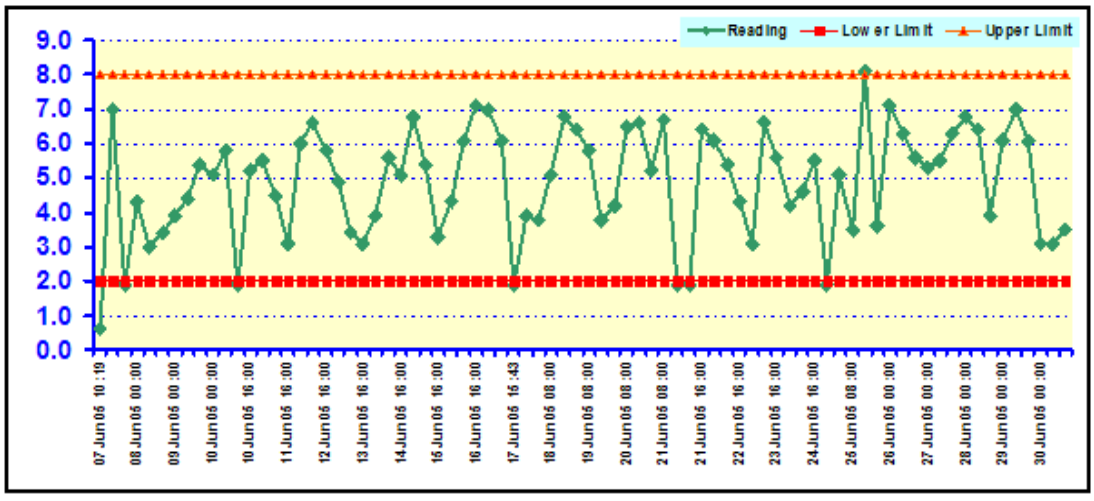

Figure 2 : Probe 2, Lower shelf: Vaccine storage temperature in a Victorian medical practice for June 2005.

- Analysis of the recorded data reveals that the compressor turns on for 20 - 30 minutes each hour, during which the storage temperature at the cold air outlet drops well below 2^{o}C. When the compressor turns off, the temperature returns back within the 2^{o}C-8^{o}C range. Similar data was recorded for 5 out of 10 sites, with the "compressor on" cycle ranging from 15-30 minutes. For fridges with evaporative cooling plates, similar data was obtained with temperature in the lower shelf (instead of upper shelf) freezing during the "compressor on" cycle.

- Whilst the sample size of this trial is insufficient to conclude the extent of undetected cold chain failure, it does highlight the problem that vaccination providers are experiencing – they do not have proper tools to monitor refrigerator performance.

- Use of a second min/max thermometer to monitor the upper shelf may have detected the temperature excursions below 2^{o}C but without frequent recording of temperature, it would be impossible for vaccination providers to understand the effect of compressor on-off cycles on storage temperature.

APPENDIX 6: Current usage of electronic temperature monitoring

- Electronic data loggers are already used by DGP's to provide a short term refrigerator logging service to GP's and to perform annual audits of GP's.

- Data loggers offer continuous temperature recording and a historical record of refrigerator temperatures. They can be set to record temperature at a set frequency ranging from seconds to hours. The recorded data allows temperature variations to be identified and is useful for mapping "hot and cold spots".

- Studies have shown that electronic temperature loggers aid the understanding of refrigerator performance significantly [14], however, only very few GP's use data loggers for continuous temperature monitoring.

- Given that the lack of alarm information contributes to vaccine wastage, the use of basic temperature data loggers ($100-$150) together with a min/max thermometer will provide information for decision making.

- Until now the drawback of electronic data loggers is that it has not been possible to detect a cold chain breach until the data is manually downloaded, which in most cases is too late. Furthermore, it is cumbersome to manage the data into auditable records.

- The introduction of wireless data loggers with a comprehensive database provides a practical tool that simplifies record keeping for audit purposes ***(Appendix 3).***

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