White Paper :

Use of new intelligent automated IT systems

to

prevent administration of ineffective vaccines

and

reduce vaccine wastage.

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1 Executive summary

Vaccines must be stored between 2°C - 8°C and continuous monitoring of storage temperature is critical to ensure vaccine potency. Despite the advancement in automated temperature monitoring technology, the majority of vaccination providers are still monitoring vaccine storage temperatures manually using a basic min/max thermometer. Many cold chain failures still remain undetected or are only detected after the event, leading to the potential ***administration of ineffective vaccines*** and ***significant vaccine wastage***. The annual wastage cost is between 2% to 5% of the National Immunisation budget; this translates to a loss of $5.6-$14M in 2005.

Annual vaccine wastage of up to $14M can be minimised or prevented by one of the following actions;

- Introduction of new standards that mandate the use of electronic data loggers to provide critical data for decision making such as alarm duration, min/max temperature and temperature profile of vaccines following alarm conditions.
- Introduction of a rebate scheme for GP's to use intelligent monitoring systems or a dedicated vaccine fridge that prevents freezing of vaccines.
- Deployment of intelligent monitoring systems nation wide that will immediately prevent freezing of vaccines. Broadband availability provides the opportunity for a totally networked monitoring system across Australia.

The solution for minimising vaccine wastage is now available. The business case indicates that the cost for deploying intelligent monitoring systems to prevent freezing can be recovered within 10 – 24 months, saving millions of dollars annually. Cost savings can then be used to fund additional vaccines on ATAGI's list of recommended vaccines.

2 Vaccine wastage - A growing problem

Vaccines and Immunisation programs are becoming increasingly more expensive with new vaccines being added to the National Immunisation Program. The National Immunisation Program budget for 2001-2002 was $84.6M[1] and is estimated to exceed $280M[2] for 2005-2006. Assuming a 2%-5% vaccine wastage rate, the potential cost of vaccine wastage has risen from $1.7M – $4.2M to $5.6M - $14M. 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].

Given the increasing cost of vaccine wastage, the need exists for automated systems that can monitor the extent and causes of vaccine wastage with the aim of reducing wastage to a minimum level.

3 What has been done to address vaccine wastage?

The immunisation cold chain can be 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.

4 Shortcomings of current vaccine temperature monitoring practices

The majority of vaccination providers use domestic fridges for vaccine storage together with a min/max thermometer to monitor storage temperature in accordance with the current guidelines for vaccine storage. 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 providers site. Freezing accounts for over 70% of vaccine wastage[3].

The Immunisation cold chain is recognised as a key problem area by medical professionals resulting in the National Immunisation Workshop in June 2004 to identify and share useful information relating to vaccine storage. Recommendations from this workshop have been included in the new National Vaccine Storage Guidelines. Key findings from this workshop indicate that domestic fridges are not designed for vaccine storage. They require modifications to ensure suitability for vaccine storage and require that vaccination providers have an indepth knowledge of their fridge performance[9-13].

4.1 Lack of understanding of domestic fridge performance

Modifying a domestic fridge for appropriate vaccine storage is unique to each fridge. Understanding fridge characteristics and performance is critical to effective storage conditions.

Domestic fridges exhibit the following characteristics[9];

- Temperature variations of up to 5°C within the same compartment.

- Areas around air vents and evaporative cooling plates are subject to temperatures below 0^oC.
- Temperature fluctuations during compressor on-off cycles.
- Changes in ambient temperature can affect the internal cooling temperature.
- Fridges that provide a strong cooling effort are likely to freeze vaccines when the compressor is on.

The vaccine storage guidelines recommend mapping the fridge to identify "hot and cold spots" for appropriate placement of heat and freeze sensitive vaccines. Without appropriate tools to record temperature it is almost impossible for vaccination providers to successfully determine fridge performance and to modify it's performance for effective vaccine storage.

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.

4.2 Limitations of min/max thermometers

Vaccination providers are required to record and chart both the minimum and maximum temperature daily and manually reset the min/max readings. Min/max thermometers detect temperature excursions outside the 2^oC-8^oC range but do not provide any indication of the duration or the temperature profile of an "out of range" condition. This means that vaccine providers and health authorities are unable to determine with accuracy whether vaccines remain effective following alarm conditions. A best guess is made based on the scant data available with the tendency to err on the side of caution. This generally leads to vaccines being discarded representing a significant cost to either the vaccine provider or the government. Min/max thermometers can only indicate "out of range" conditions and the lack of detailed "out of range" information contributes to vaccine wastage! [13]

4.3 Irregular use of electronic temperature monitoring

Electronic data loggers are already used by DGP's to provide a refrigerator logging service to GP's and to perform annual audit 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 together with a min/max thermometer will provide information for decision making. An investment of $100 - $150 is all it takes to potentially prevent thousands of dollars worth of vaccines from being discarded!

4.4 Case Study 1: Use of domestic fridge with a min/max thermometer

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 is 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°C-8°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°C-8°C range in the upper shelf (Figure 1). The lower shelf readings (Figure 2) were consistent with readings from the min/max thermometer.

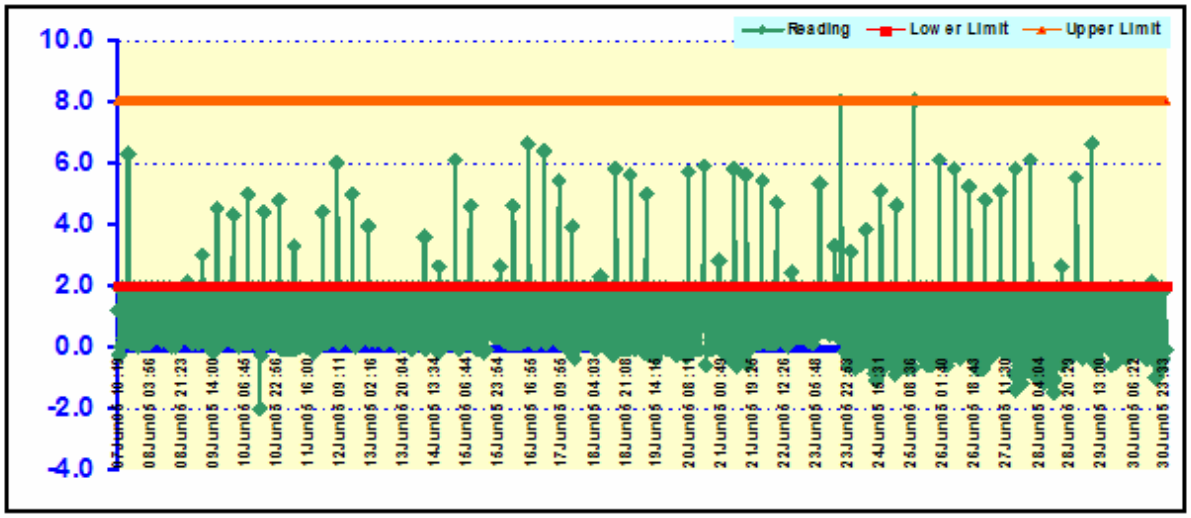

Figure 1 : Probe 1, Upper shelf: Vaccine storage temperature in a Victorian medical practice for June 2005.

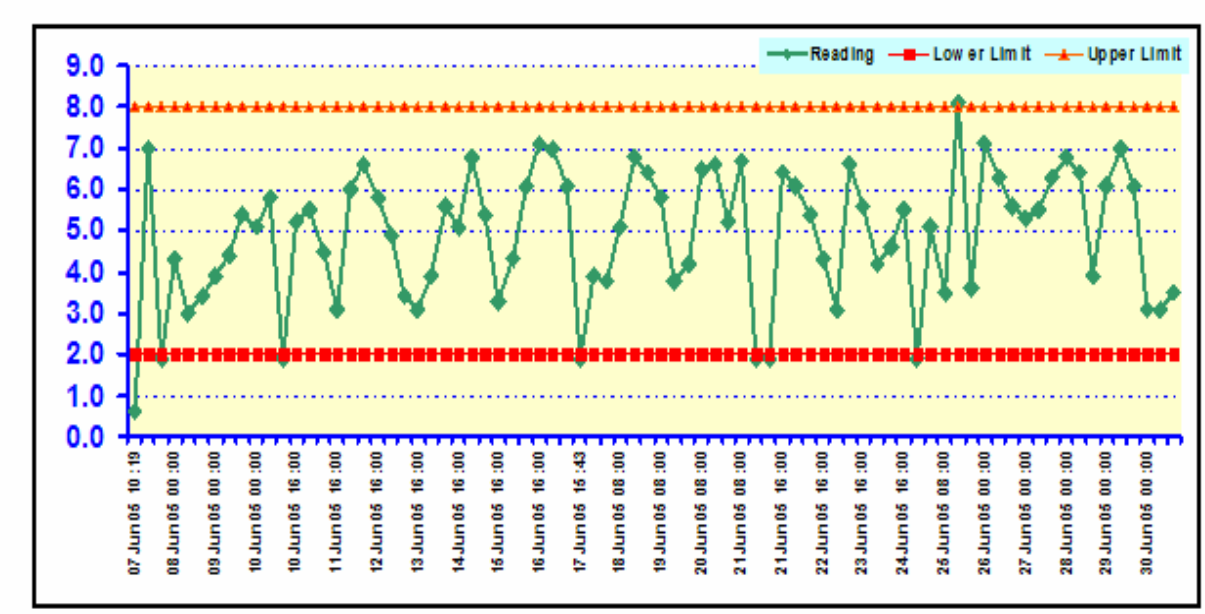

Figure 2 : Probe 2, Lower shelf: Vaccine storage temperature in a Victorian medical practice for June 2005.

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.

A final question arises regarding the effectiveness of the vaccines exposed to freezing temperatures that were administered to patients at these GP's - *Vaccinated but not immunised?*

5 Solutions to immunisation cold chain problems

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. This has changed with the newer generation of automated temperature monitoring systems. Data is automatically downloaded to a PC (wired or wireless transmission) for storage and enables immediate visual display of current and historical data.

Multiple probes allow different compartments of 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 in all the required places. 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. Finally, intelligent monitoring systems can detect abnormal events and takes over temperature management to prevent freezing of vaccines.

5.1 Automated electronic temperature monitoring systems

Whilst recommendations from the National Immunisation workshop indicate that domestic fridges are unsuitable for vaccine storage, results from vaccination providers using ***TEMP°Track®*** indicate that they have successfully modified domestic fridges for vaccine storage. Feedback from these users indicate that refrigerator performance is automatically tracked and visible from graphs which are viewed regularly, enabling relevant corrective measures to be taken as necessary.

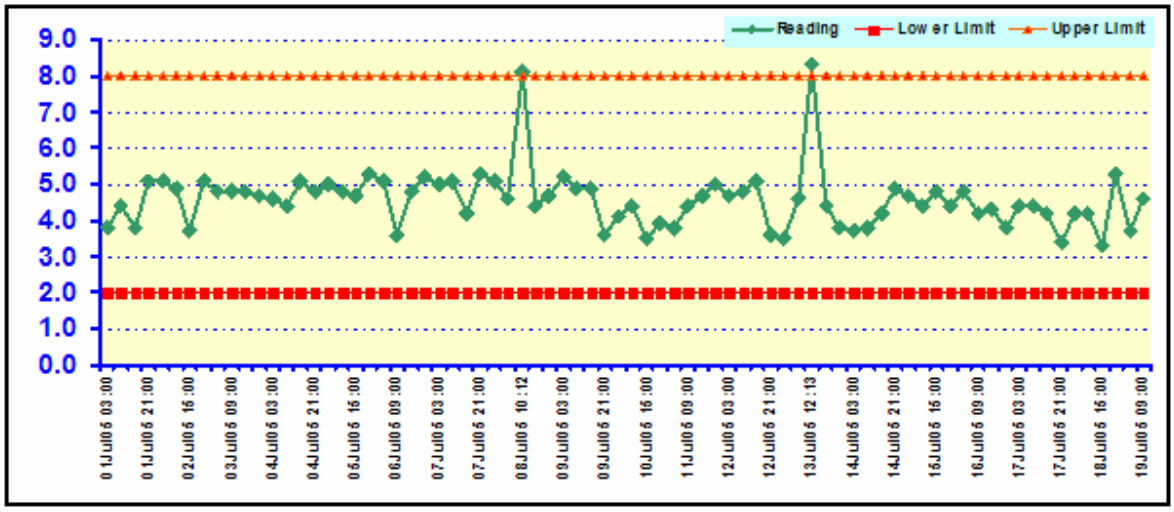

Figure 3: Probe 1, Upper shelf. Storage temperature for month of August.

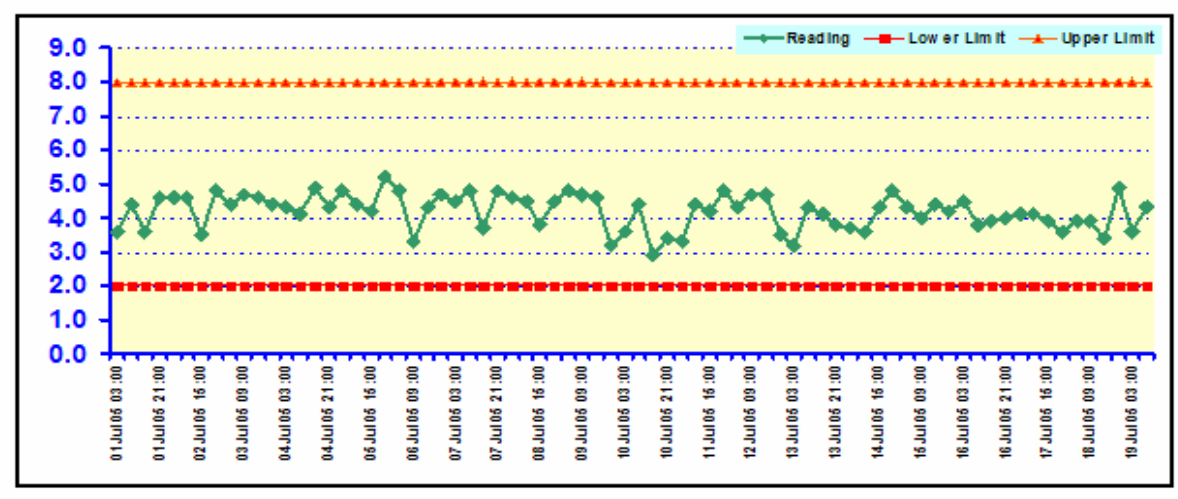

Figure 4: Probe 2, Lower shelf. Storage temperature for month of August.

The extracted sample data (Figures 3 and 4) 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.

5.2 *Intelligent electronic temperature monitoring systems*

The latest innovation in electronic temperature monitoring systems enables the controller to "learn and remember" optimum fridge performance. In the event of a disturbance such as changes in ambient temperature which can potentially cause freezing, the controller takes over thermostat control and will attempt to emulate optimum performance previously "learnt" as depicted in figure 5 below. These new intelligent systems effectively provides a domestic fridge the same safety mechanism to prevent freezing of vaccines that is provided by a dedicated vaccine fridge.

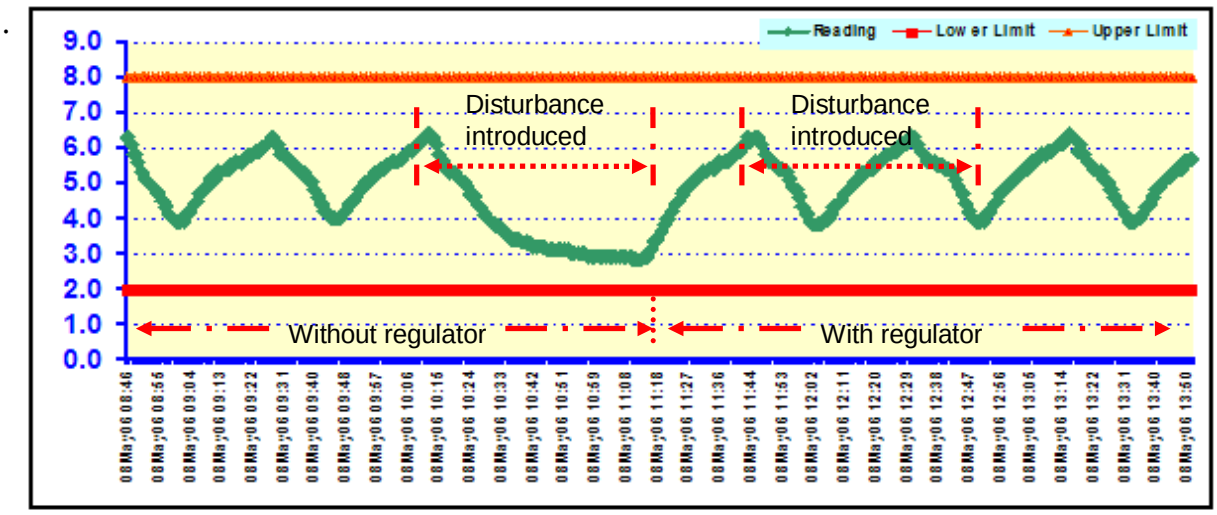

Figure 5. Performance characteristic of intelligent monitoring systems with supervisory control function.

5.3 Purpose built Vaccine refrigerators

Given the complexity in managing fridge performance, it is not surprising that the recommendation from the National Immunisation Workshop is for vaccination providers to purchase purpose built vaccine refrigerators for vaccine storage.

Whilst purpose built vaccine refrigerators will reduce freezing of vaccines, power outages and poor cold chain management practices can still result in vaccine wastage. Purpose built vaccine refrigerators are very expensive, ranging from $1,500 for a bar sized fridge to $4,500+ for a large fridge. 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. For these reasons, the take up rate for purpose built vaccine refrigerator in private practices is very low and vaccine wastage continues to increase.

6 A national approach to minimising vaccine wastage

"As health professionals we need to ensure that people receive an effective health product (i.e a vaccine that has not been adversely affected by heat or cold).

It is important to carefully manage resources. Vaccines are expensive (privately purchased conjugate pneumococcal vaccine can cost up to $180) and can be in short supply.

It is professionally unacceptable as well as uncomfortable to be in a position where you have to inform people that they or their child may have received ineffective vaccine and will require revaccination. "

Extracted from the National Vaccine Storage Guidelines: Strive for 5 (2005).

Despite continued efforts in educating practice staff in cold chain management, freezing continues to be a major cause of vaccine wastage. Our limited trials presented in case study 1 also indicate that many cold chain events go undetected, potentially resulting in administration of ineffective vaccines. We cannot continue to rely on a flawed process thus contributing to the administration of ineffective vaccines and increasing vaccine wastage cost . The solution to cold chain monitoring is now available.

6.1 Change of standards to mandate the use of electronic data loggers

The national vaccine storage standards can be updated to mandate the use of electronic data loggers to provide critical data such as alarm duration, min/max temperature and temperature profile of vaccines following alarm conditions. The data enables the relevant health authorities to make informed decisions prior to discarding vaccines.

The cost of a basic electronic logger ranges from $100-$150 and is a cheap solution to prevent potential vaccine wastage. This solution will not prevent freezing of vaccines and does not

address the issues raised in Case study 1. Whilst this solution can help reduce wastage, there is insufficient data available today to estimate the true savings in choosing this course of action.

6.2 Nation wide deployment of intelligent monitoring systems

The business case for the deployment of intelligent electronic monitoring systems is very attractive. Assuming 12,100[15] vaccination providers of government funded vaccines the estimated cost of deploying this solution is approximately $12.1 M. In this scenario, an intelligent temperature monitoring 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. A nation wide roll-out and training program can be achieved within 6 to 12 months. Assuming vaccine wastage figures of 2%-5%, the return on investment can be realised immediately and recovered within 10-24 months. This solution prevents vaccines from freezing, ensures that cold chain events are always detected, and eliminates administration of ineffective vaccines.

6.3 Nation wide deployment of dedicated vaccine fridges.

A nation wide deployment of purpose built vaccine refrigerators funded by the government will no doubt reduce vaccine wastage in the long run. A mid sized purpose built vaccine fridge (200-300L capacity) costs between $2,500-$3,000. The total funding required will amount to $30.25M-$36.3M. The cost and logistics involved for storing, transporting and installing the vaccine refrigerators nationwide would be significant. The duration for rolling-out such a large project would require considerably more time. Given the significantly larger cost and time to deploy the solution, the return on investment would be at best three times longer if we were to ignore all other costs. When the total running cost of this project is included and taking into account that vaccine wastage will still continue during the roll-out phase of the solution, the total time for return on investment would be much longer.

6.4 Rebate scheme for dedicated vaccine fridges

An alternative approach is to fund the deployment of dedicated vaccine fridges through a partial or full rebate scheme where the vaccination providers are responsible for the purchase of equipment individually. A similar scheme was used 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. The total cost for deploying purpose built vaccine refrigerators is reduced but the return on investment of this approach would be at best 3 times longer than deploying intelligent electronic monitoring systems.

7 Recommendation

The true cost of vaccine wastage in Australia remains unknown due to inconsistent monitoring and reporting of data [3-6]. 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. Regardless of the true cost of vaccine wastage, current practices will continue to see millions of dollars wasted annually unless actions are taken immediately.

At the very minimum, the vaccine storage standards should be updated to mandate the use of basic temperature data loggers to be used with min/max thermometers. This will help reduce the vaccine wastage but cannot prevent accidental freezing of vaccines.

The most viable option is the deployment of intelligent monitoring systems to prevent freezing. The business case indicates that a once off funding will reduce vaccine wastage immediately and the return on investment recovered within 10-24 months. This solution prevents vaccine wastage due to freezing and offers the additional benefit of auditable electronic records. It is the cheapest and quickest solution to deploy that guarantees significant savings.

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