Government of Western Australia
Department of Health

Ministerial Review into the Public Health Response into the Adverse Events to the Seasonal Influenza Vaccine

Final Report to the Minister for Health
July 2010

Professor Bryant Stokes

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1.0 EXECUTIVE SUMMARY

The seasonal influenza vaccination program for 2010 was ceased approximately four weeks after it began because of an alarming rise in adverse events following immunisation (AEFI). This Review, ordered by the Western Australian (WA) Minister for Health, has revealed what appears to be a serious deficiency in the current reporting mechanisms for these events.

However, it is clear that the WA Health Executive responded quickly and appropriately once the rate of adverse reactions were known to them and the Minister was informed immediately. It is clear from the information gathered that the decision to suspend the program was correct.

It is disturbing that neither this State nor the Commonwealth put in place the measures recommended by the World Health Organisation (WHO) in August 2009 regarding the surveillance and reporting of adverse events following the introduction of pandemic vaccination programs. This Review did not assess the processes in other States.

In August 2009 the World Health Organisation (WHO) made recommendations about surveillance and reporting mechanisms following the introduction of pandemic vaccination programs. These recommendations were put in place when Australia conducted the H1N1 vaccination program in 2009. It is unfortunate in the Reviewer's mind that these recommendations have not been continued in the routine vaccination programs in this country and especially in Western Australia when in the 2010 vaccination program against seasonal influenza, a vaccine significantly different from previous years was being used, and when the program involved young children from six months to five years.

In the limited trials which could be performed with this vaccine before distribution there was a higher reported incidence of vomiting and diarrhoea than had been noticed in previous influenza vaccines.

The current dual mechanism of reporting adverse events to either the Therapeutic Good Administration Branch (TGA) of the Commonwealth Department of Health and Ageing (DoHA) or to the Public Health Division of the State Department of Health (DoH) is confusing and does not allow for a timely and comprehensive collection of data on these events. This combined with the lack of knowledge at any given time of the number of vaccinations already given so that the rate of adverse events could be quickly calculated added further to reporting difficulties.

This Review has revealed an adverse event reporting system that is not robust or timely and which does not conform to WHO recommendations concerning mass immunisation programs. In addition, there is evidence that the Communicable Disease Control Directorate (CDCD) of the WA DoH was informed of a significant rise in AEFIs by e-mail in early April 2010, but did not take any further action whilst they gathered data to carefully analyse the situation.

The Reviewer believes it would have been appropriate for the CDCD to have informed the Executive Director of Public Health of a possible emerging situation. The Executive Director of Public Health was only aware of the issues a day before the program was suspended. The CDCD did notify Public Health Units to be alert for an emerging trend but failed to notify hospital Emergency Departments (ED) or general medical practitioners or immunisation clinics. Thus, no State-wide alert was given in a timely manner. The role of the Epidemiology and Surveillance Branch of the CDCD in this matter is unclear.

The CDCD and its relationship to the Public Health Division of the WA DoH appears to be a fractured hierarchy and needs repair. The CDCD must develop a reporting system to the Executive Director of Public Health which is timely and informative. It also needs to become more responsive and supportive to immunisation providers in the field. E-mails and conversations appearing to show a trend in AEFIs early in the immunisation program have been noted in this Review.

The CDCD also had inquiries from South Australia on April 15, 2010 and Victoria on April 16, 2010 concerning increased incidence of AEFIs to the seasonal influenza vaccine.

There is evidence as previously stated, that the CDCD did report a trend of AEFIs, without specific detail, by e-mail to the TGA, but responses from that organisation appeared to be slow. This is most likely due to the fact that information concerning the number of vaccinations administered was not available and hence an AEFI incident rate could not be measured. The CDCD was asked by the TGA on April 15, 2010 to expedite AEFI reports. The log of reports from the TGA reveals that by April 15, 2010, only one report of a febrile convulsion had been received by the TGA.

It was also reported by the TGA on July 2, 2010 that they had only received 16 reports of febrile convulsions (FC) from WA at the time that the WA program was suspended on April 22, 2010, despite the CDCD and Princess Margaret Hospital (PMH) having sent further reports of 23 cases of FC. These cases were received by the TGA on April 20, 2010. Following suspension of the program many more AEFI reports were received by the TGA. All these events occurred prior to the suspension. These issues made assessment of the situation difficult both for the TGA and the CDCD. This would indicate that the reporting system is not timely and is cumbersome and does not reflect issues in real time.

In the course of the Review questions emerged as to the advisability of the TGA having both a regulatory and licensing authority function, as well as having a reporting and surveillance role for adverse reactions or events to medicines. From a governance perspective, these two functions should be separated. This has occurred in the United States with the Food and Drug Authority (FDA) licensing and regulatory role being separated from the surveillance role of the Centres for Disease Control and Prevention (CDCDP).

The recent announcement by the TGA to separate these functions within the TGA does go someway to achieve this goal, but in the Reviewer's opinion may not go far enough in this regard.

Because of the short time frame to decide on, manufacture and test the influenza vaccine for each year, the ability to test large numbers of subjects to assess adverse events is significantly limited.

The bio-security of Australia depends on adequate and timely surveillance of infectious diseases as well as having a system in place which is open, transparent and accountable to both State and National Governments. In the course of this Review it became apparent that communication between WA and the TGA was not efficient and this has led to frustration on both sides and has not served the public well.

The body of this report details what appeared to be the deficiencies in the system that occurred after the introduction of the vaccination program. All are discussed under the various headings with recommendations to correct these issues.

In summary, it is clear to the Reviewer that there was a slow response both by this State and the Commonwealth to apparent emerging adverse events arising from the 2010 vaccination program. While no one cause for the slow response can be elucidated, it is clear that governance and the current reporting system needs correction and a timely process put in place.

It is also clear that the function and composition of the State CDCD needs review to ensure it functions less as a silo and disconnected hierarchy in the DoH and instead shares its information in a more timely fashion with the Department, health providers and the public.

It is also appreciated that information to be given to the public has to be handled carefully so as not to cause panic.

Sadly, public perception of vaccination programs has been damaged by these events and it will take time to reverse this view.

Apart from the detailed general recommendations in the report, the recommendations below encapsulate the general findings of the Review.

GENERAL RECOMMENDATIONS:

Governance

It is recommended that:

1 The general governance and policy for vaccination programs remain the responsibility of the Commonwealth with input from the States.

2 The actual administration of the programs be carried out by each State which will control the mechanism by which they are performed.

3 The development of an open trusting and transparent partnership between the States and Commonwealth concerning the issues of vaccination and possible adverse events must be achieved without delay. The minutes and discussions of significant meetings concerning vaccinations should be sent without delay to the Director Generals of jurisdictional Health Departments. The only exception to this would be issues of national security which would be communicated to States in a different way. This would be a rare event.

4 The separation of functions between licensing and regulation and monitoring and surveillance must be achieved so the process is open and transparent especially to those whom they serve, namely the public.

5 The WA CDCD governance structure needs to develop a stronger reporting system to the Director General of Health in a timely manner. Alerts, even if later shown to have no foundation, must be reported in a formal manner with documentation. Word of mouth comments as notification are unacceptable and may lead to misinterpretation and risk. Restructure of the CDCD may be necessary to incorporate its function more fully into the governance of the Public Health Division and that of the Western Australian Department of Health.

Monitoring and Reporting Mechanisms

The Review has revealed that the current paper based reporting method of AEFI, while it may contain great detail for analysis, does not deliver information in a timely way. This is compounded by two factors: firstly, the paper information is processed in batches and forwarded to either the TGA or CDCD and secondly, the ability to choose either a Commonwealth or State reporting mechanism is confusing and does not allow a real time collection of emerging events.

Whilst there is the current capacity for on-line reporting it is not well used and as demonstrated by the Review it is difficult to use and not operator friendly. It is noted that States and Territories, together with the Commonwealth, have been discussing issues concerning reporting AEFI for a number of years, but no definitive progress has been made. There appears to be urgency in completing this work.

It is **recommended** that a robust web-based user friendly system, such as the Victorian AEFI reporting system (SAEFVIC), could be enhanced easily to simultaneously transmit AEFI information to both the CDCD and TGA. It should incorporate a "flag system" so that when an AEFI occurs in a pattern outside the accepted norm an alert is issued. This would allow both the State and the Commonwealth to be aware of issues at the same time.

This system could also be used in Western Australia for the notification of infectious diseases.

The success of this system, however, depends on the recipients of the information acting upon the alerts in a timely and appropriate fashion.

As most of the AEFIs in this instance appeared six to eight hours after immunisation, the ability to report by hospital emergency departments and indeed consumers themselves needs to be incorporated in this system.

It is also **recommended** that an accurate and timely mechanism, similarly web-based, be developed to record the number of vaccinations including product name and batch number given on any day, so that the denominator can be used efficiently to measure AEFIs and assess their incidence in real time.

It is also **recommended** that *healthdirect* be assisted to develop a mechanism by which spikes in calls related to vaccinations (either as queries or seeking advice concerning AEFIs) or communicable diseases can be quickly assessed and that information is included in the State and Commonwealth reporting mechanism for early detection of incidents. *healthdirect* should also be assisted to develop a mechanism to alert the DoH concerning calls in relation to communicable diseases or other public health matters.

Relationships to consumers

The consumer information that accompanies the vaccine product says little about product testing. In this instance, the Reviewer found no information concerning the side effects of vomiting and diarrhoea, which had been recorded in field testing CSL's Fluvax. These side effects had not apparently been observed in previous years' vaccines. This information was in the professional information material, but was not conveyed to parents.

Vaccination providers, as well as parents and adult patients are also consumers of the vaccination product. It was unacceptable that when it appeared there were an increasing number of AEFIs that vaccination providers, especially family practitioners, were not informed to particularly report issues and indeed inform parents of possible complications in an appropriate manner. The only information distributed was sent about a week before the program was ceased to Public Health Units and some of these reported that they did not consider this to be an alert.

Two doctors reported adverse events in their own children after vaccination but even this professional input did not spark a response in a timely fashion.

It is therefore **recommended** that more information is provided about the content, testing and safety of vaccines being supplied to the public, especially when a new vaccine is introduced. This can be done sensitively to give consumers and vaccine providers' support and advice.

It is further **recommended** that where there appears to be an emerging issue of AEFI, an early warning is sent to vaccination providers together with well constructed information to the public to keep them informed. This can be done without causing panic in the community. As many consumers have indicated to the Review, this would show leadership by the Department of Health.

The terms of reference for this Review did not include investigating how decisions are made concerning acceptable levels and severity of AEFI. It has become increasingly apparent from parents that the community expects more integrated information to be made available to them.

Implementation of these recommendations should go a long way in restoring public confidence in vaccination programs as well as the public health system.

2.0 Introduction

The 2010 seasonal influenza vaccination campaign commenced in Western Australia (WA) on March 19, 2010, with the official media launch attended by the Director of CDCD, the Chair of the Osborne General Practice Network and consumer representatives. However, there is evidence that the vaccine began to be administered in WA on March 8, 2010. This vaccine was a trivalent vaccine different from previous years as it contained H1N1 (swine flu) and inactivated virus (see Appendix B).

The campaign was supported by media, which commenced on March 19, 2010. On March 18, the CDCD provided notification to immunisation providers including general practitioners, regarding the campaign.

The rate of adverse reaction to vaccinations is generally considered to be 1 in 1000 to 1 in 10,000. "The frequency of adverse events can be classified as follows: very common (>10%), common (1-10%), uncommon (0.1 – 1%), rare (0.01 – 0.1%) and very rare (0.01%)" [1].The rate of febrile convulsion is considered to be 1 in 1000. The rate of febrile convulsions reported for the 2010 seasonal influenza vaccination program was 9 in 1000 [2].

Conversations amongst immunisation providers and the community began to reflect an increased number of adverse reactions being experienced. On April 8, 2010 the senior nurse from the Central Immunisation Clinic (CIC) contacted CDCD by e-mail stating that she was, "getting phone calls from parents regarding flu vaccine adverse reactions. High fever and vomiting approximately five hours post vaccination". This was different to previous years when they had had very few calls regarding AEFI. There was also further confirmation that there was a higher rate than expected of children presenting to Princess Margaret Hospital (PMH) with febrile reactions and FCs on April 12, 2010 (Appendix F).

There was some delay with formal adverse events report forms arriving at CDCD. This appeared to be due to inadequate information on vaccination batch numbers and the number of vaccinations given. During this reporting process, copies of the AEFI were sent to the TGA. These reports came in batches from immunisation providers, the CIC and PMH. The Reviewer is of the view that batch reporting is not timely.

CDCD staff worked through the weekend of April 17 and 18 to follow up with parents and complete essential report details for the TGA, and the first large batch of reports was sent to the TGA on April 19, 2010.

The CDCD was working closely with specialist staff at PMH and a WA expert group was called together to examine the adverse events information on April 21, 2010. At that time, PMH figures showed that about 22 children had presented following a FC that was possibly linked to the vaccine in the past month. The expert group reconvened on April 22, 2010 and reached the

decision to recommend the suspension of the WA campaign, for all children aged six months to under five years of age.

On April 22, 2010 the Minister for Health Dr Kim Hames was alerted to the increased incidence of adverse reactions to the 2010 seasonal influenza vaccination and suspended the campaign.

Following the suspension, further data was collated by the CDCD showing that there had been 556 reports of AEFI from the seasonal influenza vaccine in WA. According to the TGA there were 58 FCs in WA and 100 cases reported nationally (See Table 1).

Table 1: Estimated seasonal influenza vaccine related AEFIs in WA in Children <5 years of age in 2010

	TOTAL
Febrile convulsion	58
Febrile reactions (no convulsions)	5
Other reactions	481
Local reaction/swelling	14
TOTAL	556

Thus, it is clear to the Reviewer that the correlation of information was incomplete in a timely fashion, which made an accurate assessment of the situation impossible. This reflects poorly on the mechanisms put in place to undertake the surveillance of an influenza vaccination program (Appendix C) [3].

In the previous year, during the pandemic swine influenza program accurate data was kept in a timely fashion [4].

2.1 Establishing the Review

The Minister for Health, Dr Kim Hames put a submission to the State Cabinet on May 16, 2010, requesting a Review into the public health response into the adverse reactions to the seasonal influenza vaccine, experienced by children in WA. The Terms of Reference (TOR) for the Review are attached in Appendix A.

On May 24, 2010 Professor Bryant Stokes was appointed to undertake the Review. Two experienced research advisors, Ms Jaynie Kirkpatrick and Ms Fiona Hope were seconded to the Review.

As part of the Review process Professor Bryant Stokes interviewed 27 key personnel and 12 parents of children who experienced FCs following seasonal influenza vaccinations.

The interim report for the Minister, as outlined in the TOR was submitted on June 18, 2010.

3.0 Background

The WHO states that influenza vaccines have been used for more than 60 years and have an established record of safety in all age groups [5].

In August 2009, the WHO advised all countries administering pandemic vaccines to conduct intensive monitoring for safety and efficacy. Neither Australia nor WA appears to have undertaken this recommendation. The WHO also stated that mass vaccination campaigns can generate significant safety data within a few weeks [3].

Australia has a Commonwealth funded, targeted influenza vaccination program for people at risk of complications from influenza infection. The target group includes:

- All individuals 65 years of age and older.
- All Aboriginal and Torres Strait Islander people aged 15 years and over.
- Individuals aged six months and older with health conditions which would predispose them to severe influenza - such as cardiac disease, chronic respiratory conditions, and other chronic illness requiring regular medical follow up or hospitalisation [1].

Some countries have established universal vaccination for seasonal influenza in young children and these are outlined in Table 2 below.

Table 2: Countries with universal vaccination for seasonal influenza

Country	Age Group	Date Initiated
United States	6-23 months	2002
Canada	6-23 months	2004
United States	6-59 months	2006

There are no similar age specific, universal programs for young children in Australia.

The Australian Technical Advisory Group on Immunisation (ATAGI) reconvened the Influenza Working Party in 2008, to consider recommendations for influenza vaccination in children. “Deciding on whether to recommend universal annual influenza vaccination in young children is complicated by the relative paucity of data on the effectiveness on trivalent inactivated vaccines (TIV) in reducing the burden of disease” [6].

Because of three deaths from influenza in WA of young children under the age of five in 2007, it was decided in WA that the seasonal influenza campaign should include children from six months to under five years of age.

3.1 Western Australian Immunisation and Vaccine Effectiveness Study (WAIVE)

The Western Australian hospital morbidity data shows that hospital separations for children aged six months to five years of age due to seasonal influenza is twice the rate of any other age group.

The Western Australian Influenza Vaccine Effectiveness Study (WAIVE) is a longitudinal study to run over five years to determine the effectiveness of the paediatric seasonal influenza vaccine. The study has been designed to monitor for influenza and influenza like illnesses in acute care settings such as PMH and nominated general practices. This research is evaluating the effectiveness of vaccination of all children aged six months to under five years of age against seasonal influenza, using trivalent inactivated influenza vaccine (TIV). One of the key measures is the impact of the campaign on the burden of disease experienced by young children and their families. [6]

The Reviewer has noted that while the WAIVE study has estimated influenza vaccine effectiveness at 83%, the number of patients recruited to the study was too low to be statistically significant [7]. The researchers have altered the study methodology to improve patient recruitment for the duration of the study.

The Reviewer understands the unique opportunity this study provides, “to obtain Australian data on the effectiveness of influenza vaccine in young children who bear a high burden of infection and will help inform national policy on influenza vaccine use” [6]. The study needs to be promoted and supported to increase patient recruitment and enable the longitudinal study findings to be robust.

4.0 Seasonal Influenza Vaccine

Influenza vaccines traditionally contain three strains, two current influenza A subtypes and one influenza B subtype [1]. In 2010, the Australian Influenza Vaccine Committee (AIVC) (see Section 12.5) agreed to adopt the WHO [8] recommendations for the components of the 2010 seasonal vaccine (see Appendix B). This vaccine also contained the H1N1 (swine flu) strain.

There were three manufacturers of the vaccine used in the campaign; Commonwealth Serum Laboratories (CSL) products Fluvax and Fluvax Junior, the Sanofi Pasteur product Vaxigrip and Solvay's (Abbott) product Influvac. The later was not officially included in the WA campaign, but may have been issued to some vaccination providers. By and large, the majority of the adverse events appeared to be related to the CSL Fluvax and Fluvax Junior. These products were predominantly used in the WA campaign.

4.1 The 2010 Seasonal Influenza Vaccine

4.1.1 Clinical Trials

Following the annual recommendations made by the WHO in September, 2009 [8], Australia had only a short time frame, of approximately three to five months, to develop and test the vaccine. During this time the composition of the seasonal influenza vaccine needed to be approved and manufactured.

As a result, clinical trials of the flu vaccine are limited. For 2010, CSL tested Fluvax with children six months to nine years of age. According to CSL, "There were no reports of serious adverse events related to the Fluvax vaccine during the vaccination period" [9]. A total of 298 children were vaccinated; 22.5% aged six months to three years experienced a temperature of greater than 37.5°C within seven days of vaccination, while 15.6% of children aged between three and nine years experienced a fever after their first dose. Other adverse events reported in the trial group included high irritability, rhinitis and more than a fifth reported vomiting and / or diarrhoea [9].

It would appear that there was a higher incidence of adverse events in the clinical trial than in previous years. In particular, vomiting and diarrhoea had not been a reaction to previous influenza vaccinations.

It is also important to note that clinical trial information for all influenza vaccinations provided in Australia is not included on the vaccine brand customer (public) medicine information sheets [10-12].

4.1.2 Composition of Vaccine

There has been wide speculation following the suspension of the WA and national seasonal influenza vaccination program about the composition of the

vaccine. Some researchers suggest there is too much ribonucleic acid (RNA) in the vaccine, while others suggest the reaction may relate to a pyrogen in the vaccine [13-14]. Currently, the Review is unaware of any evidence to support either of these issues. The TGA is currently assessing the Fluvax and Fluvax Junior for what may have been responsible for the AEFIs.

Thus the Review is unable to comment on the composition of the vaccine and if it had an affect on the AEFI in WA. The Reviewer is not suitably qualified to do so.

4.2 Cold Chain Issues

The seasonal influenza vaccine can to be stored for a maximum of one year at 2-8°C. This vaccine cannot be frozen and should be discarded if exposed to temperature of 0°C or less [1]. According to CDCD, the higher the temperature the vaccine is stored at, the shorter the shelf life [15]. This is shown in Table 3 below. If a vaccine exceeds a temperature of 25°C, the vaccine is only safe to use for approximately five days.

Table 3: Influenza Vaccine Storage Temperatures and Cold Chain Breaches

Vaccine	0°C & Below	8°C - 14°C	15°C - 21°C	22°C - 25°C	>25°C
Influenza	Discard	Continue to use	Continue to use but shorten expiry to 1 month	Continue to use but shorten expiry to 2 weeks	Continue to use for 2 days ≥5 days: Do not use

[15]

The Prevention and Control Branch (PCB) has undertaken a review of WA's cold chain standards and made recommendations for regional immunisation co-ordinators to assess cold chain breaches. The draft document was developed in June, 2008. In November, 2008, the Branch sought advice from ATAGI regarding any national guidelines for vaccine use when they have been stored outside the recommended temperature. ATAGI advised that the National Immunisation Committee (NIC) was considering this matter and a formal request was anticipated from the NIC to ATAGI. The Branch submitted the draft WA guidelines for potential cold chain breaches in February, 2009 to ATAGI. In April, 2010 following the Perth storm CDCD revisited the progress of the development of national guidelines.

To date the matter has not been resolved at a national level through the NIC. The draft guidelines were updated in WA in January, 2009 [15] and are utilised by vaccine providers across WA.

4.2.1 Seasonal Influenza Campaign 2010

All vaccines for the WA DoH immunisation program are stored at the CSL warehouse in Northbridge. After the launch of the paediatric seasonal influenza campaign on Friday March 19, on the following Monday (March 22, 2010), Perth experienced a severe storm which caused power outage at the

CSL warehouse in Northbridge. Power outages also occurred in some doctors' surgeries.

Due to the power outage at the CSL warehouse, the vaccines were transported to another storage facility. During this time (approximately 30 minutes) the temperature of the vaccine was not constantly monitored. CDCD contacted all manufacturers of vaccines stored at the facility, including Solvay (Abbott) and CSL requesting them to indicate if their vaccines could have been compromised. It was noted that there was no Sanofi Pasteur vaccine (Vaxigrip) stored at the warehouse at this time.

Letters received by CDCD from the manufacturers advised that all vaccines were safe for continued use (See Appendix D and E). CSL noted that Fluvax is stable to use for seven days at 25°C. Distribution of the vaccines re-commenced on March 31, 2010, from the CSL warehouse to immunisation providers (for a detailed timeline see Appendix F).

After extensive research, the Review has reached the conclusion that the issue of cold chain and storage following the Perth storm appears to be an unlikely factor in the AEFI reported in Western Australia.

4.1.3 Recommendations

- Detailed product information must include information about the content, testing and safety of vaccines being supplied to the public to enable informed decisions about the vaccine before administration.
- Product information must be written in a way that is clear to all sections and groups in the community.
- The State draft guidelines are endorsed in the absence of any national guidelines on cold chain breaches.

5.0 Recording of Vaccine Information

5.1 Australian Childhood Immunisation Register (ACIR)

The Australian Childhood Immunisation Register (ACIR) run by Medicare Australia, records vaccinations given to children under seven years of age. The register includes all vaccines on the National Immunisation Program (NIP). ACIR was established in 1996 and this register provides a permanent record which can be accessed by all doctors in Australia [16].

Most doctors and immunisation providers document all vaccinations administered to patients, in the individual's medical record, through their practice management software. The practice management software is responsible for the automatic transfer of information to the ACIR database.

One important aspect of ACIR is the link it has with Medicare Australia's General Practice Immunisation Incentive (GPII). The GPII provides financial incentives quarterly to doctors to provide immunisations on the National Immunisation Program to children seven years of age and younger [17], but not for the WA seasonal influenza campaign.

5.2 CDCD Line Reporting

Following the commencement of the WAIVE Study in 2008 (Section 3.1) CDCD implemented a line reporting system, requiring immunisation providers to complete a survey detailing the patient's name, the number of doses, the brand of vaccine and the batch numbers provided for that year. At this stage, ACIR's collection of information for the influenza vaccine was in its infancy, compared to the other vaccines on the NIP.

After the first year of the WAIVE study in WA, CDCD learnt from doctors and immunisation providers, that the additional reporting to CDCD was resource dependent and it was an additional form of reporting outside their usual practice management reporting system to ACIR. At the end of 2009, following the second year of the WAIVE program, the data from CDCD line reporting and ACIR were compared. It was found that the ACIR data was more complete.

The reporting to ACIR through the general practice software had shown some errors in the later part of 2009 and both Medicare and the TGA were informed of this by CDCD. Also, the seasonal influenza campaign in WA was not a part of the NIP and therefore was not part of the incentive program for GPs to report through ACIR and to receive remuneration.

As a result, in 2010 CDCD did not employ a line reporting system, rather relying on ACIR to provide the data on the number of vaccines given during the paediatric seasonal influenza campaign. It is unclear why this decision was made. No alternative process was put in place.

5.3 Seasonal Influenza Campaign 2010

5.3.1 General Practice Immunisation Incentive

As stated before one of the main issues in relying on ACIR to provide data for the seasonal influenza campaign offered to all children aged six months to under five years (only funded in WA), is that doctors do not receive incentive for entering information into ACIR, as this vaccine is not part of the NIP. From talking with general practitioners and immunisation providers as part of the Review, most have noted that they do enter seasonal influenza vaccination into their practice management system and migrate it to ACIR. However, due to busy appointment schedules and limited resources, entering data into ACIR is often a last priority.

The Review notes the possible underestimation of ACIR's data for the WA child seasonal influenza program.

5.3.2 Practice Management Software problems

In late 2009, CDCD contacted Medicare Australia and reported concern after learning from local doctors that they were having difficulty capturing influenza vaccination (including Fluvax and Panvax) in ACIR, via their practice management software. The problems with certain practice management software continued in 2010, with some practice software not migrating immunisation records to ACIR.

To date, the Review is concerned that ACIR data still remains inaccurate and there is no definitive denominator of the number of influenza vaccination doses given in WA in 2010, to children aged six months to under five years.

5.3.3 State reporting system

Over the weeks leading up to the suspension of the seasonal influenza vaccination campaign targeting children aged six months to under five years, CDCD were in contact with the TGA (see Section 7.3) trying to ascertain the rate of AEFI in 2010 compared with previous years. However, due to problems with ACIR and the practice management software, the denominator (the number of vaccinations given) was difficult to determine. And as indicated above the final number of doses of vaccine of all types is still unknown.

After a meeting on Wednesday April 28, 2010 between CDCD, the TGA National Manager and the Chair of ATAGI, it was determined that ACIR was not going to be able to provide an accurate denominator for the 2010 seasonal influenza program.

CDCD reverted back to directly contacting all general practitioners and immunisation providers on Thursday May 6, 2010. GPs were requested to

notify CDCD of the number of doses of vaccine and batches that were administered to children aged six months to under five years during this campaign. The turn around time of this request was the close of business on May 10, 2010. This was essential to estimate the denominator. CDCD received approximately 75% of the surveys back and have adjusted the estimated denominator, based on the surveys returned to provide a figure reflective of 100% (See Table 4 below). But this is only an estimate and no true figure is available.

Table 4: Number of doses of seasonal influenza administered in WA in 2010

	Confirmed number of doses	**Estimated number of doses**
Seasonal Influenza aged 6 months to 5 years.	13,540*	18,937**

Note: * based on GP survey repsonses reflective of 75% doses administered.
** Estimated doses, reflects projected 100% of doses administered in WA.

5.3.4 Surveillance system

Although the problems outlined above are important to this Review, it must be noted that the function of both ACIR and CDCD line reporting system were to provide the number of doses and children vaccinated by the end of the winter season. Neither system was created with the intent of being a surveillance system or having the capacity to provide real time data. For example, neither system has the capacity to provide the denominator – the number of injections given at any given point in time over any campaign, nor can the existing systems capture adverse events in a timely way.

The Review notes, that in the absence of a surveillance data system to provide real time data, the timeliness of determining the rate of AEFI in WA was difficult. The WHO [3] recommends that all countries administering pandemic vaccines need to have an intensive monitoring system to ensure safety and efficacy of the vaccine program. The reviewer believes that the same process should apply in all vaccination programs. It is important to note that consumers believed that this was always occurring.

5.4 Recommendations

- A web-based mechanism to record the number of vaccinations, including batch number and product name, to provide real time data, including the denominator over the program duration.
- A surveillance system to provide ongoing monitoring of vaccination programs.
- ACIR and practice management software developers need to have effective communication and develop processes to enable these systems to work seamlessly.

6.0 Summary Events Timeline

The Review has composed this summary timeline of events leading up to the suspension of the WA and National seasonal influenza vaccine campaign. This summary timeline and the detailed timeline (Appendix F) are based on information gathered during interviews and from information provided by key personnel.

2007

Influenza related deaths in young children in WA

2008

WAIVE program commences to immunise all children six months to five years of age with seasonal influenza vaccine.

2009

WAIVE program continues to immunise all children six months to five years of age with seasonal influenza vaccine.

2010

Monday March 8, 2010

Trivalent Seasonal Influenza Vaccine distribution began.

Friday March 19, 2010

Official launch of vaccination program.

Monday March 22, 2010

Perth storm.

Wednesday March31, 2010

Wickepin Health Service called and e-mailed Public Health Nurse, Wheatbelt: Reported reactions six out of nine children vaccinated yesterday with Fluvax seemed to be feverish, including one child who went to Narrogin Hospital.

Thursday April 1, 2010

Public Health Nurse, Wheatbelt e-mailed CDCD: Informing of reactions to vaccine and child who went to hospital.

CDCD e-mailed Public Health Nurse, Wheatbelt: Reassured nurse reactions are common, asks for nurse to report to TGA.

Tuesday April 6, 2010

PMH Immunologist called Paediatric Immunologist PMH, Director of the Vaccine Trials Group Telethon Institute for Child Health Research (TICHR), Director, and Associate/Professor School of Paediatrics and Child Health, (SPACH) UWA: concerned as their own child had a high temperature after being vaccinated with Fluvax.

Thursday April 8, 2010

Senior Nurse, CIC e-mailed CDCD: Number of calls from parents advising of vomiting, fever after child received the seasonal influenza vaccine.

Friday April 9, 2010

PMH: Anecdotal reports from nursing staff of children in ED presenting "unwell" after seasonal influenza vaccination.

Bunbury Hospital called CDCD: Adult presentation at ED suspected reaction to seasonal influenza vaccine.

CDCD e-mailed CIC: In reply, confirmed have heard some children this year experiencing high fever, pain and vomiting with some taken to hospital following immunisation.

Queensland: Suspected death of two year old following flu vaccine (post mortem could not determine cause of death).

Monday April 12, 2010

PMH: Six reports of suspected reaction to seasonal influenza from nurses in ED at PMH.

Geraldton parent called CDCD: Noticed several children with febrile reactions following seasonal influenza vaccine at Geraldton Hospital.

CDCD called Doctor at Geraldton Public Health Unit: CDCD requested any AEFI be reported to CDCD and TGA.

Parent called CIC: Daughter had adverse reaction, rang PMH and was told they were experiencing an increase in presentations at ED.

CIC e-mailed to CDCD: Rang concerned, informing three phone calls from parents all reporting adverse reactions to seasonal influenza vaccine.

PMH to CDCD: Three children had presented at ED at PMH with seizure within 24 - 48 hours of receiving seasonal influenza vaccine.

CDCD e-mailed PMH: Requested AEFI reports to be sent to TGA and provide CDCD with copies.

CDCD called TGA: Informing of AEFIs and if other states were reporting similar.

Nurse, PMH to Director of ED, PMH: Six children in ED with suspected reactions to flu vaccine, within 24- 48 hours after receiving the vaccine.

Tuesday April 13, 2010

PMH: Ten patients presented to the ED identified as having reaction after seasonal influenza vaccination. Requested look back in EDIS.

CDCD e-mailed TGA: Following up from phone call. Notifying of seizures, FCs and asking whether other states had reported similar symptoms.

TGA to CDCD: Indicating a medical officer who handles enquires will be in contact.

Wednesday April 14, 2010

PMH: PMH conducted an EDIS extraction.

CDCD e-mailed TGA: Follow up on e-mail, no phone call from Medical Officer as promised.

TGA e-mailed CDCD: Provided number identified from WA involving Panvax and Panvax Junior (swine flu vaccine).

TGA to CDCD: Advised four AEFI reports for seasonal influenza so far nationwide.

South Australia Nursing Director Immunisation Section - Communicable Disease Control Branch called CDCD: Asking if any AEFI in WA, as SA are seeing AEFI related to seasonal influenza.

CDCD e-mailed TGA: Provides summary of situation in WA so far, request information from other states.

CDCD e-mailed Regional Public Health Units: Informing of possible AEFI, requesting forms to be sent through.

Public Health nurse, Wheatbelt e-mailed CDCD: Verbal reports of clusters of cases (three or four kids) with high temperatures for 12 hours.

Thursday April 15, 2010

PMH: Informed more presentations overnight, reviewed case notes and established database. These reports were received by the TGA on April 20, 2010.

Microbiology Registrar called Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA: Own child had FC after seasonal influenza vaccine.

CDCD e-mailed PMH: Requesting list of children who presented with AEFI from seasonal influenza vaccine.

PMH e-mailed CDCD: 27 patients so far, five with confirmed FCs.

CIC faxed CDCD: Noting an increase in notification of reactions, attached eight reports of suspected adverse reaction to seasonal influenza vaccine.

South Australia Nursing Director Immunisation Section - Communicable Disease Control Branch e-mailed TGA, DoHA and all State Health Departments including CDCD: South Australia is receiving increased numbers of vomiting and high fever in children following the influenza vaccine.

CDCD e-mailed Public Health Units: All AEFI reports to be provided immediately "not in a month's time".

Friday April 16, 2010

PMH e-mailed CDCD: 90 presentations possibly related, 22 are notifiable AEFIs (seizures, temperatures over 40 degrees).

CDCD called Parents of children who experienced febrile reactions following the flu vaccine: To gather more information regarding the brand of vaccine and place of administration.

Update of Prevention and Control Branch (PCB) for Director of CDCD: Initiated assessment of AEFI following seasonal vaccinations, as yet, unverified reports.

TGA e-mailed South Australia Nursing Director Immunisation Section - Communicable Disease Control Branch, TGA, DoHA and all State Health Departments including CDCD: TGA report 62 AEFI reports in 2010, with 22 of these reports for people 18 and younger. Request all unsubmitted reports from all states.

Victoria Health Department e-mailed TGA, DoHA and all State Health Departments including CDCD: Informing Victoria had been receiving reports regarding seasonal influenza vaccine including high fevers and vomiting.

Monday April 19, 2010

Director of National Centre for Immunisation Research & Surveillance e-mailed TGA, SA, ASCOM, AEFI Clinic, NSW: Difficult syndrome to identity as it appears to be non-specific.

PMH: Sent 23 AEFI reports to the TGA. These were received by the TGA on April 20, 2010.

PMH e-mailed CDCD: Over past three days, further 22 ED presentations to PMH. A total of 111 presentations to PMH.

CDCD e-mailed PMH: On the agenda for the National Immunisation Committee meeting in Canberra on Wednesday April 21, hope to get more information about other states at this meeting.

PMH: In the evening, child with severe reaction presented at ED. This child later went to ICU.

Tuesday April 20, 2010

Paediatric Nurse, Rockingham General Hospital (RGH) e-mailed Microbiology Registrar called Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA: Noticing AEFI at ED. Asks if this is happening elsewhere?

Microbiology Registrar called Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA e-mailed Paediatric Nurse, RGH: Acknowledging PMH has seen similar, requested numbers of patients presenting at their ED.

CIC: Stopped using CSL Fluvax and Fluvax Junior.

Microbiology Registrar called Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA called CDCD: Very sick child following the seasonal influenza, now in ICU.

St John of God Hospital Murdoch e-mailed CDCD: Notifying ten AEFI presented at ED.

Wednesday April 21, 2010

Director of Emergency, RGH e-mailed PMH: Triage nurses will commence collection of data and the medical staff to finish it.

Microbiology Registrar called Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA called Executive Director of Child and Adolescent Health Service: Concerned about a cluster of AEFI at PMH.

Director of ED at PMH called CDCD: Concerned of AEFI at PMH, one child in ICU.

Expert Teleconference: CDCD, Director of NCIRS, Microbiology Registrar called Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA and Staff Inoculation & Immunisation, Clinical Nurse Consultant in PMH Infection Control: Issues remain with ACIR. PMH – 130 presentations to ED, 19 seizures with fever. Most are not admitted and go home. South Australia has reported AEFI and anecdotal reports from Victoria and Sydney. No need to go to media yet.

Executive Director of Child and Adolescent Health Service called the Director General of Health: Informing of AEFI presenting at PMH and other hospitals.

Thursday April 22, 2010

CDCD e-mailed TGA: Follow up from earlier contact.

CDCD e-mailed Commonwealth Chief Medical Officer, Australian Government Department of Health and Ageing: Provided WA AEFI information, for his meeting with TGA.

CDCD e-mailed ATAGI Chair: Informing ATAGI of CDCD trying to engage TGA.

PMH: Sent eight reports of AEFIs to TGA.

09:35
Microbiology Registrar called Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA e-mailed CDCD, PMH, Executive Director of Child and Adolescent Health Service, Director NCIRS: Providing data collected from PMH ED Presentations.

Executive Director of Public Health: Is informed by CDCD learns of the child in ICU and other AEFI in children.

12:00
Executive Director of Child and Adolescent Health Service contacted Director General of Health: Informing of more adverse event cases. The Director General requested for the Minister for Health to be informed, regarding suspension of the program.

15:00 – 16:00
Teleconference CDCD, PMH, TGA, DoHA, NCIRS: Febrile reactions to influenza vaccine, two very serious, with an increase in presentations to ED at PMH compared to previous years. Full investigation required. Risk of damaging the program.

16:00 to 17:00
Teleconference with CDCD, WA Department of Heath Executive Director of Public Health and Community and Adolescent Health: Suspend the program, while we gather further information, may be able to introduce an alternative vaccine.

16:45
Minister for Health called Executive Director of Child and Adolescent Health Service.

17:30 Minister for Health suspends WA seasonal influenza program for children

18:10
CDCD called *healthdirect*: Alerting to the suspension of the program in WA.

20:00
CDCD faxed/e-mailed doctors and Immunisation providers: Informing of the suspension to the program.

CDCD e-mailed *healthdirect:* Information sheet provided with questions and answers for when parents call.

Friday April 23, 2010

PMH: Five reports of AEFI sent to the TGA.

09:00
CDCD e-mail/faxed doctors and immunisation providers: Suspension includes children aged five years and younger.

Commonwealth Chief Medical Officer, Australian Government Department of Health and Ageing Media Statement: suspension of National program.

13:00
CDCD e-mailed/faxed doctors and Immunisation providers: Suspension of the National program.

CSL Biotherapies Press Release: Withholding further distribution of paediatric influenza vaccine nationally.

Queensland Health e-mailed CDCD: Qld data for FCs looks to be higher in March and April, 2010.

Monday April 26, 2010

New Zealand Health: Ceased using CSL Fluvax and Fluvax Junior vaccines, however continued with flu program with other brands of flu vaccine.

7.0 Reporting of Adverse Events Following Immunisation

An AEFI is a significant, usually disabling side effect following a vaccination. It may include anaphylaxis, seizure and death (Appendix G). The AEFI reporting system in Western Australia is a dual system, with immunisation providers and general practitioners able to report either to the TGA or directly to CDCD [1]. In theory, all reports received by either entity are sent to the other agency on a regular basis.

7.1 Communicable Disease Control Directorate

Medical practitioners and immunisation providers can report to CDCD using the adverse event report form (Appendix H). This form can be downloaded and printed from the WA Public Health website www.public.health.wa.gov.au, and after completion can be faxed or sent to CDCD. This process alone of locating an AEFI form from CDCD is an onerous one, taking too long. If a member of the public wants to report an AEFI, they are advised to contact their doctor or provider.

The Review has explored the processes employed by other states across Australia to gain information on AEFI. A particularly good resource is the Victorian website: www.health.vic.au/immunisation/general/saefvic. The Surveillance of Adverse Events Following Immunisation in the Community (SAEFVIC) is a user friendly site primarily for health professionals. The Review would support a similar approach being implemented in WA, with increased scope to enable parent or carer reporting.

It is a statutory requirement, under *Health (Notification of Adverse Event After Immunisation) Regulations 1995* [18] (Appendix I) that the Executive Director of Public Health is notified of all adverse events after immunisation in WA "within 14 days of becoming aware of the adverse event" [19]. This does not often occur, and the Reviewer considers that this time frame is far too long. After CDCD receives an AEFI report, the form is copied and sent to the TGA. The AEFI forms are then filed for future reference.

The Review is informed that these forms are assessed, but cannot confirm the timeliness in which they are reviewed and actioned.

On April 19, 2010 a specific database was established for the seasonal influenza campaign to enter the details of the large number of AEFI reports received by CDCD.

7.1.1 Issues with the CDCD Reporting System

The Reviewer notes several issues with the CDCD reporting system:

- Difficulty in locating or accessing an AEFI reporting form.
- People who observe and report AEFI are often not immunisation providers including medical practitioners, as typically AEFI occur several hours after the vaccine is administered, often outside of business hours and at home.

The Review learned that if concerned parents or other members of the public contact CDCD, they are referred to their GP or provider to complete the form on their behalf.

- Under the *Health Regulations Act 1995* AEFI are to be reported within 14 days. This is considered by most stakeholders to be too long.
- The *Health Regulations Act 1995* also states that the Executive Director of Public Health should be informed of all AEFI, however, in this situation the Executive Director was not informed until April 21, 2010 (Appendix F) despite CDCD receiving notifications on April 8, 2010 and formal reports the following week.

7.2 Therapeutic Goods Administration

The TGA is a business unit of the Commonwealth Department of Health and Ageing. For more information on the TGA see Section 11.0.

Reports of adverse reactions to medicines or vaccines can be made by contacting the TGA by phone on the consumer Adverse Medicine Events Line: 1300 134 237. This phone-in service is provided by the Mater Hospital, Brisbane and is available for members of the general public who suspect they have experienced an adverse reaction to a medication. This service forwards reports of suspected adverse reactions to the TGA Office of Medicines Safety Monitoring (OMSM) (for more information on OMSM see Section 11.1).

Health professionals can forward reports of suspected adverse reactions to the TGA by completing a 'blue card' (see Appendix J) and faxing the information to the TGA, or by completing it online at www.ebs.tga.gov.au. The reporting processes for lodging an adverse event are clearly outlined on the TGA website.

The Review experienced some difficulties in getting the date fields correct when lodging an electronic form for a suspected adverse event to a medication. The date fields in the electronic form would be an area for improvement, so that these areas are not so format sensitive and time consuming to complete.

7.3 CDCD relationship with the TGA

The Reviewer has interviewed key personnel regarding the role and function of the TGA, specifically in relation to the TOR for the Review.

The CDCD advised that they alerted the TGA to concerns about AEFI by e-mail with the seasonal influenza vaccine on April 12, 2010. CDCD sought to understand if these issues were also emerging in other states. By the end of that week, April 16, 2010, CDCD was aware that other states had concerns, primarily South Australia (see detailed timeline Appendix F).

The perception from CDCD is that the TGA did not respond to e-mails and phone calls in a timely manner and did not provide the states with much advice. However, the TGA did not receive AEFI reports until April 20, 2010.

Up to and including April 22, 2010 (at 1:30pm WST) CDCD had sent 48 AEFI reports to the TGA, with a large batch of reports sent from PMH to the TGA on April 19, 2010.

CDCD convened the first meeting of an expert committee on April 21, 2010. Through the meeting process it was noted that the clinicians from PMH were seriously concerned. The expert group reconvened on April 22, 2010.

7.3.1 Issues with TGA reporting system

During the Review it has become evident that the "dual process" is confusing. CDCD sends all copies of reports to the TGA however, CDCD rarely receives copies of reports or detailed information from the TGA. The timeliness of the reports being sent and received remains under question.

7.3.2 AEFI forms

In a recent publication by a group of international experts, an improved AEFI form was developed. This form has been endorsed by the WHO [20]. The Review team compared this form with the TGA 'blue card' (Appendix J) and CDCD AEFI form (Appendix H). Both the TGA and CDCD forms did not have key mandatory information fields such as family history and patient vaccination history. In addition, both the CDCD form and 'blue card' layout have limited space for providing adequate information.

7.4 Recommendations

- An open, trusting and transparent partnership is required between the State and Commonwealth.
- Policy and governance for vaccination programs is undertaken by the Commonwealth, with input from the states.
- Administration of vaccination programs to be carried out by the states.
- A web-based user friendly reporting system is established which simultaneously transmits AEFI information to both the State and Commonwealth.
- A flag system must be incorporated into the web-based reporting system, to indicate immediately when AEFI are occurring outside the expected norm.
- Where a web-based system is not possible, a National AEFI report form is required.
- A timely mechanism of measuring the number of vaccinations given must be developed so that the rate of AEFIs can be calculated in real time.

8.0 Communicable Disease Control Directorate

The Communicable Disease Control Directorate (CDCD) is a division of Public Health within the WA DoH. The Prevention and Control Branch (PCB) of CDCD is responsible for the development and implementation of policy for the WA immunisation programs. The PCB liaises with immunisation service providers such as CIC, public health units, GP Divisions, and regional health services. They also provide training and education in immunisation.

8.1 Seasonal Influenza Campaign 2010

Through the Review process, key members indicated that there were vacant positions within the PCB, which meant the existing team was relied upon to assume additional tasks, beyond their normal duties (see Appendix K for CDCD Organisational Structure). Because of the increased demand on CDCD over the years, the Nursing Coordinator of that Branch also had to assist in the Epidemiology and Surveillance Branch (ESB) of the directorate, which made for a significant increase in workload. From a clinical nursing perspective the directorate would appear to be under resourced.

8.1.1 Key management roles within CDCD

Over the past decade, the Director of CDCD and the PCB Medical Coordinator position have experienced regular personnel changes. The corporate memory and knowledge of the unit is held within the middle management tier of the directorate. It is apparent to the Reviewer, that there is inadequate support and communication within the directorate, and between the Director of CDCD and the Executive Director of Public Health.

Current mechanisms that appear to foster this include the geographic location of CDCD in Shenton Park, a variable communication process across the directorate and the delivery of information in a timely fashion to the Executive Director of Public Health. The Reviewer has formed the view that these key positions do not work well collaboratively and that the CDCD has become a disconnected hierarchy.

In addition, the Director of CDCD and the Medical Coordinator position of PCB involve regular travel interstate and within WA. They are WA Health representatives on various national committees including the Communicable Diseases Network Australia (CDNA) and the National Immunisation Committee (NIC) (see Governance Section 12.0). From the time when AEFI began to be reported to CDCD on April 8, 2010, key staff at CDCD had interstate and regional WA travel commitments.

8.1.2 Communication

CDCD contacted public health units on April 14 and 15, 2010 to raise awareness about adverse events occurring and encouraging immunisation providers to report adverse events promptly (See Section 6).

According to GPs, no communication in mid-April was made alerting them to be aware of a rise in adverse events.

Several alerts were sent via e-mail or fax to immunisation providers advising of the suspension on April 22, 2010. Further updates were sent in the following weeks regarding the program updates and the investigation into what happened (see Appendix F).

The Reviewer has formed the view that communication regarding alerts or raising the level of surveillance should be targeted to EDs, *healthdirect* and GPs, all of whom would see or hear of patients with adverse reactions to the vaccine. The Reviewer noted that vaccination providers were rarely the first point of contact when severe symptoms became apparent.

8.13 Recommendations

- The structure and composition of CDCD needs to be reviewed to make it function less as a silo within the DoH by strengthening risk management and communication processes.
- CDCD need to develop a stronger reporting system to alert the Executive Director of Public Health and the Director General of Health of emerging issues.
- Implement an effective communication strategy with fax stream to immunisation providers, general practitioners and hospitals to ensure alerts and information about AEFI reporting is regularly communicated.

9.0 Consumer Engagement

The Reviewer was very interested to understand the consumer perspective. Ms Michele Kosky, Executive Director for the Health Consumers Council of WA, was invited to assist with the process of engaging with parents to hear their stories.

A random sample of nine children was selected from the list of children who experienced FCs. Letters were sent inviting the parents of these children to participate in semi-structured interviews with Ms Kosky and Professor Stokes. Seven parents and grandparents responded to the letter, and participated in interviews. An additional four parents were approached and interviewed; these were the parents of the two children who were admitted to ICU following the seasonal influenza vaccine in 2010. One parent made direct contact with the Review office.

The Review interviewed a total of 12 parents and grandparents. The parents were asked about their experience and how, in their view, the system could be improved.

The sample of parents included those whose children had received vaccinations across the seasonal influenza program's duration, with the first child from this sample being vaccinated on March 17, 2010 and the last child in the afternoon of April 22, 2010, the day that the program was suspended.

9.1 Key Themes from a Consumers Perspective

9.1.1 Vaccine Safety

Before participating in the Review interview, several parents had researched the vaccine, following the adverse event experienced by their child. Parents were concerned that there was very little data available on the vaccine trials. This lead to concern that the vaccine was not adequately trialled, and the safety and quality of the product was not well established before the product was registered for use by the TGA, and especially for use in young children.

The Reviewer outlined that the seasonal vaccine was produced each year and the timeframes precluded extensive clinical trials, given that the vaccine needed to be ready to be administered prior to the winter influenza season.

Parents indicated that product information given to them needed to include more detail, outlining the product trial findings, the risk of adverse events and the more common side effects of the vaccination. Parents also noted that vomiting and diarrhoea were not indicated as an expected side effect, although both these issues occurred as adverse events following the vaccination and this concerned them.

The Review heard that children were not always experiencing a high fever of over 40 degrees when they began to have a seizure. Two children were in

fact cold and clammy to touch, with no clinical evidence of a fever at the time of the FC. Not all children with adverse events had their temperature measured.

It was apparent that the AEFIs that occurred including seizures appeared between six and eight hours after the injection.

9.1.2 Consumer Information

Parents understood that the seasonal vaccine was produced each year and administered to precede the winter influenza season. A recommendation from parents was that there should be scripted follow up phone interviews of one in ten seasonal influenza vaccine recipients on a random basis, to ensure that adverse events and side effects were identified and acted upon in a timely fashion.

This is in keeping with the WHO recommendations in August 2009 [3].

This consumer perspective is consistent with specialist views shared in the Review following the suspension of the program.

Parents requested a standard process for following up children who had experienced adverse events. While parents understood the adverse event had been recorded, they were concerned about any longer term effects this event could have on their child, and how this would be monitored.

9.1.3 Adverse Event Reporting

The Reviewer outlined the dual reporting processes currently in place in WA to the parents that were interviewed.

The DoH, through the Public Health Division had established an information line for the community to access information about the seasonal vaccine or to report an adverse reaction to the vaccine. The phone number for the WA Vaccine Information Line: 1800 186 815 was promoted at the time of the vaccine suspension through the WA media and appears on the Public Health website [21].

A number of parents shared that they had tried to report their children's adverse reaction using this number or the Swine Flu Hot Line number, provided by *healthdirect* (180 2007) and had experienced difficulties. The Review tested both these numbers on June 29, 2010 and experienced similar difficulties. The 1800 186 815 phone number was answered by *healthdirect*, who then referred the caller on to the Swine Flu Hot Line. The Swine Flu Hot Line confirmed that it did not record adverse events from vaccination and referred the caller to the WA DoH main switchboard. The DoH had no record of a WA Vaccine Information Line and referred the caller to the CDCD.

Parents indicated strong support for a "one stop" reporting process; this was perceived to be essential to re-establish public confidence.

The Review proposes that adverse event reporting would go to the state CDCD and TGA simultaneously. The correct contact number for reporting adverse events needs to updated and promoted in the community. Through discussions with parents, the Reviewer gained a clear view from the consumer that the 14 day statutory reporting obligation was too long and needed to be considerably shorter.

The Reviewer has considered the research titled 'Guidelines for collection, analysis and presentation of vaccine safety data in surveillance systems' [20]. These guidelines have been developed by the Brighton Collaboration and specifically address vaccine safety data in surveillance systems. The guidelines have also been endorsed by the WHO.

9.1.4 Making the best use of Health Intelligence

Through the interview process, the Reviewer shared the time line of the incidence of FCs with parents, leading up to the campaign's suspension. As outlined earlier, the parents who agreed to participate in the Review had experienced adverse events from March 17, 2010 to April 22, 2010.

Parents felt that the intelligence from *healthdirect* should be overlaid with ED presentations and GP presentations to capture the adverse events in close to real time.

Several parents who attended PMH with their child stated that they had overhead staff saying that the vaccine would be withdrawn soon. Parents gained the impression that nursing staff had seen a lot of febrile reactions and FCs to the influenza vaccination. This gave little comfort to parents when their child went on to be admitted for observation, only to find other parents who had had the same experience on the ward.

The Reviewer has considered recent research by Dr Michael Gold et al [22]. This research outlines how data linkage between immunisation, hospital admission and ED presentation records are valuable in surveillance for AEFI. Further, the researchers indicated, "it is increasingly being recognized that a global data linkage network needs to be established in order to develop the capacity to evaluate very rare safety signals" (p.4308).

9.1.5 Public Perception

Parents indicated that this incident is perceived to have damaged the immunisation program more broadly than just the seasonal influenza campaign and that this event will have damaged public confidence.

This quote from the mother of a severely damaged child following vaccination encapsulates the public perception of a vaccination campaign that was not appropriately monitored and in which adverse events did not appear to be acted upon in a timely fashion:

"*I feel so disappointed, distressed and angry, I trusted the Department of Health to provide advice that is safe for my children. I got the letter promoting the seasonal influenza vaccine from the Department, if the monitoring systems had been working, I should have got another letter shortly afterwards saying the vaccine was suspended due to an increase in adverse events – that would have been quite acceptable. As a parent I would not have lost faith in the system".*

9.2 Recommendations

- Detailed product information must provide information about the content, testing and safety of vaccines being supplied to the public; to enable informed decisions about the vaccine before administration.
- Product information must be written in a way that is clear to all sections and groups in the community.
- The process for reporting an adverse event by parents or consumers is established in WA and outlined on parent advice brochures.
- A web-based mechanism to record the number of vaccinations, including batch number and product name, to provide real time data such as the denominator.
- A surveillance system to provide ongoing monitoring of vaccination programs.
- Intensive surveillance is required to follow up with one in ten recipients (randomised) of the seasonal influenza vaccine to ensure adverse events are identified, recorded appropriately and case managed
- A web-based user friendly reporting system which can be used by all, including consumers, is established which simultaneously transmits AEFI information to both the State and Commonwealth.
- This reporting system will provide immediate feedback and efficient follow up to AEFI reports.
- WA DoH implements active data linkage processes to make the best use of health intelligence across the system.

10.0 Other WA Stakeholders

10.1 *healthdirect* Australia

10.1.1 Background

healthdirect Australia is the collective name for the National Health Call Centre Network (NHCCN) which was operated by McKesson Asia Pacific Ltd for the Departments of Health for the Australian Capital Territory (ACT), New South Wales (NSW), Northern Territory (NT), Tasmania, South Australia (SA), and WA. *healthdirect* is a toll free 24 hour, seven day a week health advice line for people calling from those states. Call centres are located in Sydney, Melbourne, Adelaide and Perth [23]. From July 1, 2010 Medibank Private acquired Asia Pacific Ltd.

The service was established in WA in 1999 as *healthdirect* (now *healthdirect* Australia). All *healthdirect* calls are answered by qualified and experienced nurses with additional training in telephone triage [24]. *healthdirect* has a medical advisory committee. The States involved have a trans-jurisdictional management which is headquartered in WA.

Triage nurses use computerised decision support protocols to help them reach the correct disposition for a given call. Telephone triage is not a diagnostic service; rather, it is designed to provide recommendations and help callers make informed decisions. The service also provides information on where health services are located [24].

10.1.2 Seasonal Influenza Campaign 2010

healthdirect is a service on which many WA families rely. The Reviewer interviewed *healthdirect* to understand their experience during the 2010 seasonal influenza campaign. *healthdirect* was formally notified of the 2010 seasonal influenza campaign on March 24, 2010. The organisation would normally experience an increase in callers regarding symptoms following vaccination during the campaign. This has been *healthdirect*'s experience over the past two years.

State Trends

The protocols of *healthdirect* do not include a specific one for seasonal influenza vaccination. There are two protocols for triage staff to use in assessment and advice for consumers. One protocol is for childhood immunisation, which includes the seasonal influenza vaccination. A second protocol requested by the National Bio-security Centre is available, for H1N1 or swine flu vaccine. The trend data had shown that triage calls for paediatric immunisations including seasonal influenza in WA, were logged against both protocols.

The number of triage calls in relation to both immunisation protocols did increase in WA, from the commencement of the campaign on March 19, 2010.

The number of calls reduced over Easter and the first week of the school holidays before rising steeply in the second week of the school holidays, until the program was suspended on April 22, 2010 (see Graph of Western Australian *healthdirect* triage calls regarding Immunisation triage at Appendix L). This is shown in Table 5 below.

Table 5: Number of calls concerning childhood immunisation and swine flu to *healthdirect* from March 15 to April 25 2010

Date	**15/03 - 21/03**	**22/03 - 28/03**	**29/03 - 04/04**	**05/04 - 11/04**	**12/04 - 18/04**	**19/04 - 25/04**
	Campaign began 19/03	Perth Storm 22/03	Easter Good Friday 02/04	1st week of school holidays	2nd week of school holidays	Program suspended 22/04
WA Calls	90	146	100	100	313	446
National Calls (incl. WA)	221	307	215	235	462	637

National Trends

The National trend lines also show that there were increased calls to *healthdirect* across Australia regarding symptoms following vaccination (Table 5). Despite other states only offering the vaccine to at risk children aged six months to five years of age (see Graph of *healthdirect* national triage calls regarding immunisation at Appendix M).

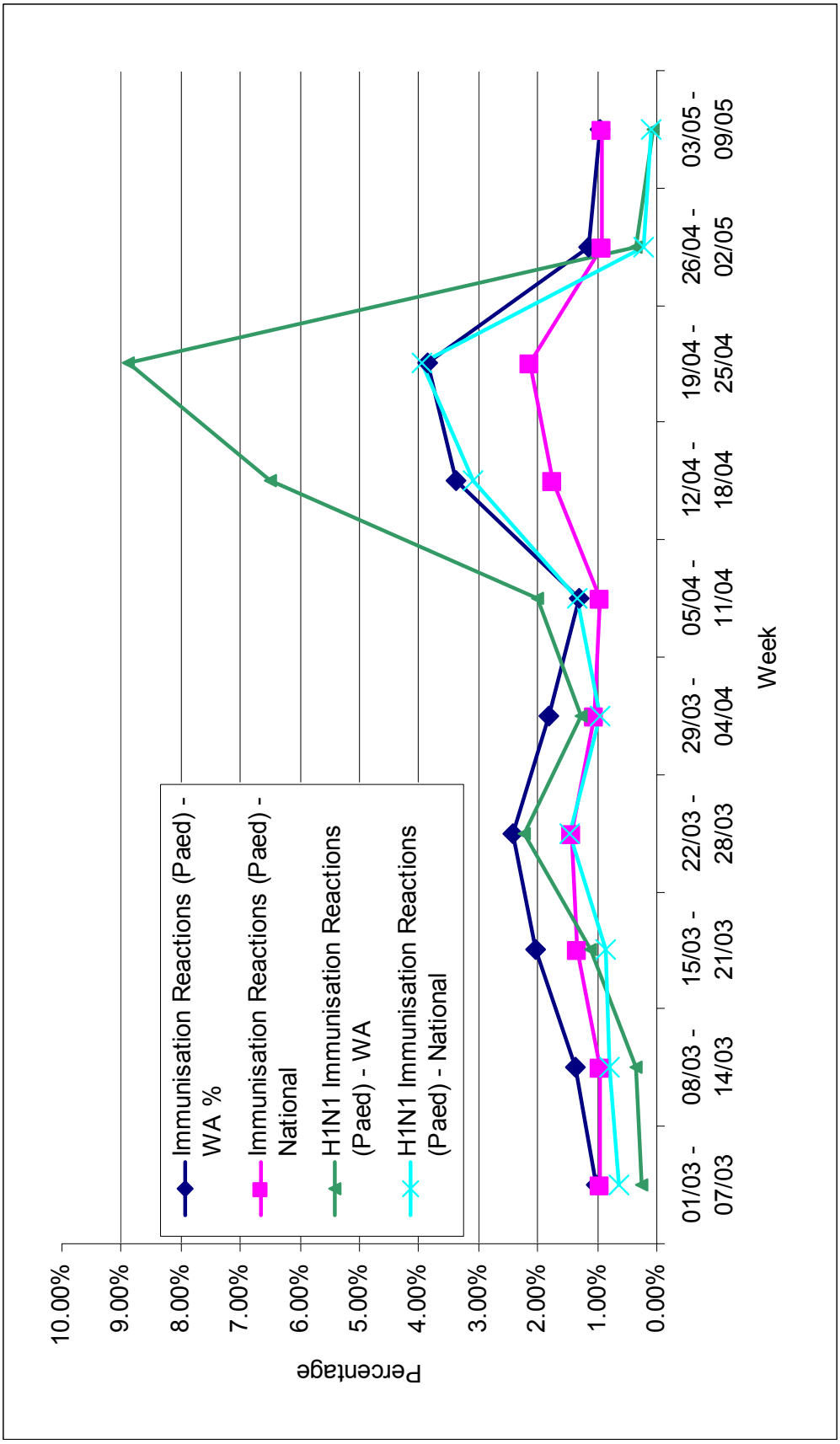
The Graph 1 below of National and WA *healthdirect* triage calls in relation to immunisation shows the state and national triage calls in percentages received by *healthdirect*. The triage calls decreased significantly when the WA campaign was suspended on April 22, 2010 and the national campaign was suspended shortly after on, April 23, 2010.

With hindsight, it is clear that this increase in activity was of significance. The percentage of immunisation triage calls managed by *healthdirect* was less than 10% of the total number of calls in any day or week during this period. This did not raise an alert within *healthdirect*, despite the calls increasing from a rate of 0.27% of all calls in the week March 1, 2010 prior to the campaign, and peaking at 8.9% the week the campaign was suspended.

The systems in *healthdirect* were not set up to specifically monitor AEFI and as stated previously, this increase in calls while significant for this particular issue did not appear to be of major concern in the overall rate of calls.

healthdirect forwards the triage call information to the National Biosecurity Centre every second day, for analysis as part of the system of surveillance for national security.

Graph 1: National and WA healthdirect Triage Calls in Relation to Immunisation



10.1.3 Consumer Feedback

The Reviewer noted some perceived issues with some of the information provided to parents when they contacted *healthdirect,* and shared by parents through the interview process. The Review has listened to the audiotapes of the parent calls and has determined that the appropriate advice was given by *healthdirect* at the time of the calls.

10.1.4 Notification to *healthdirect* of the Season Influenza Program Suspension

One parent had made contact with *healthdirect* just prior to 7pm on the evening of April 22, 2010 after hearing that the program had been suspended, as her two children had been vaccinated that same afternoon. At this point *healthdirect* was not aware of the suspension.

The Review has confirmed that *healthdirect* was contacted by a senior officer at CDCD regarding the suspension of the seasonal influenza campaign at 6.08pm on April 22, 2010. This informal advice was conveyed to McKesson at 6.47pm and followed up by the media statement from the Minister for Health at 8.08pm. McKesson circulated this information across all divisions of *healthdirect* immediately. It is noted that the parent called *healthdirect* prior to any staff having advice that the program had been suspended. This timeline is essentially acceptable.

10.1.5 Recommendations

- A mechanism is developed by which spikes in *healthdirect* calls related to vaccination either as queries or seeking advice concerning AEFIs can be quickly assessed, and that information is included in the State and Commonwealth reporting mechanism for early detection of incidents.
- The adverse event reporting phone number for the childhood immunisation protocol for *healthdirect* is established.

10.2 Central Immunisation Clinic (CIC)

10.2.1 Background

The Central Immunisation Clinic (CIC) is situated in Rheola Street in West Perth. The CIC has been the subject of a number of reviews in the past five years. The clinic was formerly managed through CDCD, however, in July 2008 the CIC was realigned with Child and Adolescent Community Health Service (CACHS) [25].

The first of the reviews occurred while CIC was aligned with CDCD. This draft report outlined a statewide role for CIC in monitoring and surveillance of AEFI through CDCD. It proposed a specialist clinic at CIC for children who had experienced AEFI or who were complex cases. No action appeared to be taken on this report [26].

Another review was undertaken in 2008, 'Delivery of Immunisation Services across the Perth Metropolitan Area' and was published by CACHS in November 2008, when CIC was realigned from CDCD to CACHS. This review was endorsed. There were 28 recommendations in the report and subsequently the role and functions of the CIC changed significantly [27].

The Review sought an update on the progress of the changes being implemented at CIC as part of CACHS. According to the draft progress report "Of the 28 recommendations identified through the review eight have been completed, 17 are currently being progressed and two are to be commenced. Recommendation six is not able to be met due to human resource constraints" [28]. Key achievements include:

- the appointment of permanent nursing staff;
- installation of data loggers in all vaccine refrigerators;
- commencement of a client appointment system;
- a telephone clinical advice service continues to take in excess of 23 calls per day.

It was noted by the Review that a database to record the content and outcome of these calls is not yet operational. The progress with an AEFI clinic lead by a medical specialist has not been finalised.

A key change is that CIC no longer provides a statewide service. The Reviewer is unclear as to how this has been communicated to immunisation providers and public health units across WA. Despite the change of function outlined for the CIC in 2008, the clinic is still listed as the contact number for WA in the *Australian Immunisation Handbook* (9th Ed.) [1], and for all other WA immunisation promotional material. Thus, the clinic continues to address 5.5 hours of statewide calls daily, providing support to GPs with immunisation queries and consumer concerns.

The operational capacity of CIC is invested in the North Metropolitan Area Health Service (NMAHS). The CIC has focused on training and education in

immunisation and targets operational effort towards at risk groups for immunisation within the NMAHS. This was a significant change in function for the CIC within the WA health system.

10.2.3 Seasonal influenza campaign 2010

The CIC received supplies of the vaccine Influvac for the seasonal influenza campaign on March 8, 2010. The second delivery of vaccine included Fluvax and Fluvax Junior. The CIC noticed an increase in parent concerns being conveyed to the clinic by phone when they started using the CSL products.

The CIC sent 33 AEFI reports to CDCD between April 9 and April 30, 2010. The first batch of eight AEFI were sent on April 15, 2010. The CIC did not receive any phone call or fax from CDCD acknowledging receipt of the reports. The CIC staff independently notified their line manager on April 20, 2010, that the CIC would no longer be administering Fluvax or Fluvax Junior until the AEFI had been resolved and they started using the alternative product, Influvac.

The CIC has gone through a protracted period of transition. The CIC no longer has a medical officer as part of the staffing profile, the clinic operates as a nurse led clinic, adhering to the immunisation schedule. The realignment of the CIC with CACHS has not strengthened the clinical governance for the CIC as an integral part of the statewide immunisation program.

10.2.4 CIC staff concerns

The CIC staff has been on a steep learning curve to provide the level of immunisation service and expert support expected by the State. During the interviews and data collection, staff raised a number of issues with the Review that included:

- Immunisation providers need to be confident that the products being marketed are safe, and contain accurate product information.
- Parent information provided at the time of vaccination needed to include monitoring the child's temperature and administering Parecetamol if the child's temperature goes above a certain point, for example 38 degrees.
- Immunisation providers needed to be kept informed of emerging issues to re-establish confidence with parents and consumers.
- The reporting system needed to be fully integrated so information emerging from GPs, CIC, EDs, *healthdirect* and CDCD could be collated and considered in a timely manner.

10.2.5 Recommendation

The Reviewer recommends that CIC be realigned and managed through CDCD to strengthen clinical governance.

10.3 Princess Margaret Hospital

Princess Margaret Hospital (PMH) is the specialist paediatric hospital in WA. The main role of PMH in immunisation is treating children which present at the ED experiencing AEFI, as most occur several hours after the vaccine, often after business hours.

10.3.1 Seasonal Influenza Campaign 2010

Outpatient Clinic

In 2010, PMH set up an opportunistic vaccination booth within the outpatient department offering children attending the outpatient clinic a free seasonal influenza vaccination. The clinic began on March 22, 2010 and ran until the suspension on April 22, 2010. This clinic provided 855 doses of influenza vaccine over the five week period.

Emergency Department

There are approximately 60,000 ED presentations at PMH every year, on average 80 per year are seasonal influenza related presentations. From the beginning of the program in March, 2010 until the suspension of the program in April, 2010, there were more than double the number of ED presentations compared with previous years (see Appendix N and O). Of these ED presentations associated with the influenza vaccine, 38 presented with FCs, 149 with febrile reactions (no convulsions), five other reactions and three local reactions.

10.3.2 Seasonal Influenza Campaign Issues

Adverse Events Following Immunisation (AEFI)

PMH played an important role in identifying and reporting a large proportion of the AEFI in WA. As outlined in detail in the timeline (Appendix F), clinical staff at PMH began to hear of AEFI as early as April 6, 2010. On April 12, three children had presented at PMH with febrile seizures. It was at this stage the Staff Inoculation & Immunisation; Clinical Nurse Consultant at PMH alerted CDCD and the Director of Emergency at PMH.

On the April 14, 2010 an Emergency Department Information System (EDIS) extraction was conducted which confirmed PMH suspicions that they were seeing more children present at ED with AEFI following the 2010 influenza vaccine. On April 15, PMH established a specific database to collate AEFI patient information and introduced a new reporting form for ED Staff to complete (see Appendix P). The database was updated daily and sent to CDCD for their information.

PMH sent their first batch of 23 reports to the TGA, with copies sent to CDCD on April 19, 2010. Further AEFI reports were sent to TGA on April 22, 23 and 27, 2010.

Delay in Reporting

PMH was very quick to identify clusters of AEFI and contact CDCD with their concerns. However, there was great difficulty due to limited staff resources in retrieving patient records to complete the AEFI forms. For this reason, there was a substantial delay between notification and formal reporting, with the first formal AEFI report to both CDCD and TGA on April 19, more than a week after staff suspected an issue.

To expedite completion of the AEFI forms PMH and CDCD developed a new form (Appendix P) for the staff in ED to complete. The form required more information than the previous form (Appendix H) including; time of vaccination, if the patient had swine flu vaccine in past, if they had a fever, if they had a seizure and whether the child was discharged to home or a hospital ward (including ward number). This updated form allowed for an immediate record of information which could then be sent off to TGA and CDCD. In addition, CDCD sent three staff to PMH to assist in the retrieval of patient records between April 19 and 21, 2010.

PMH Communication

Upon speaking to staff at PMH as part of the Review, it became evident that the communication between departments within the hospital could be improved. Although clinical staff were discussing possible AEFI as early as April 8, 2010, limited communication was escalated to the Executive level.

The Reviewer notes improved communication among departments at PMH is needed to ensure that in times of emergency, such as this, the response can be coordinated and as timely as possible.

10.3.3 Recommendations

- A simple method to report AEFI in ED to ensure that AEFI are reported in a timely manner.
- PMH establish clear communication processes and protocols to handle AEFIs at the hospital between departments to ensure all AEFI data is captured.

10.4 Metropolitan Non-Teaching Hospitals

10.4.1 Background

The Review contacted the EDs of metropolitan non-teaching hospitals (MNTH) (public and private) to gain an understanding of their awareness about the adverse reactions following seasonal influenza vaccination.

The data for ED activity at most of these hospitals is linked into the Emergency Department Information System (EDIS), and had been reviewed by CDCD at the time of contact.

10.4.2 Emergency Department Information System (EDIS)

In the month leading up to the campaign being suspended EDIS did not have any alert facility in place to identify the AEFI in relation to influenza vaccination.

Some directors indicated that the cases of AEFI or FC could have been coded to a number of diagnostic codes in EDIS, which could potentially present problems in determining the exact number of AEFI following seasonal influenza vaccination. CDCD also experienced problems with the EDIS data as key information was omitted in fields such as the patient contact details and the patient's general practitioner. This caused considerable delay in completing the adverse events reports.

10.4.3 Seasonal Influenza campaign 2010

In discussion with the ED Directors at the MNTH, it was apparent that adverse event reporting was a rare operational requirement. Two hospitals had made contact with CDCD to report adverse events leading up to the suspension of the program.

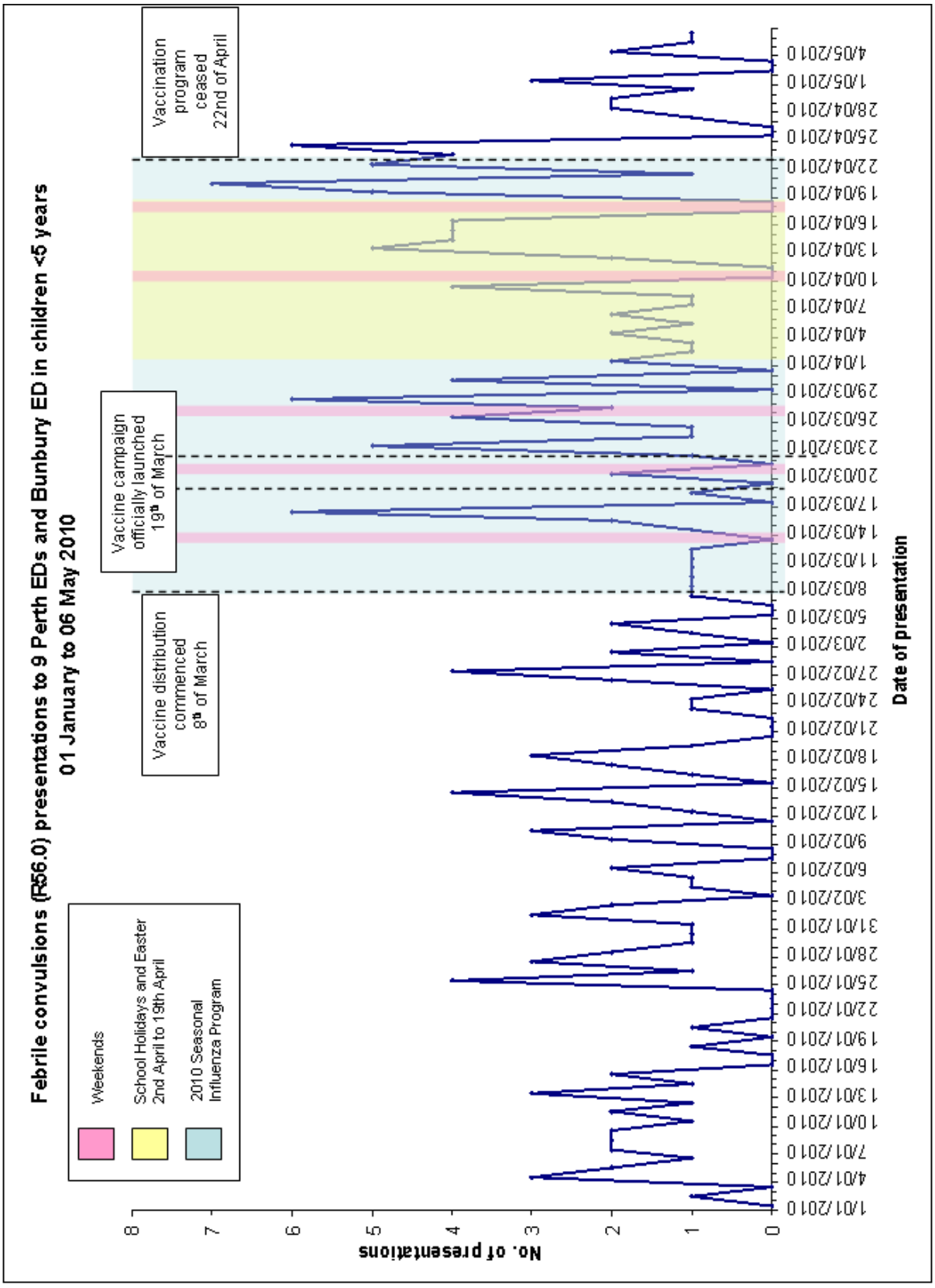
Rockingham General Hospital (RGH) contacted the vaccine specialist at PMH on April 20, 2010 indicated that they had seen a number of young children.

St John of God Murdoch contacted CDCD on around April 20, 2010 to alert them to ten cases of adverse reactions which had presented to the ED.

Generally, ED Directors did not have a sense that they were seeing more febrile illnesses or reactions until after the suspension was called and the EDIS data was reviewed. Graph 2 below outlines the children with FCs who presented to metropolitan EDs, including Bunbury, from January to May, 2010.

Some EDs were fortunate to have medical staff who also worked at PMH and thus they became aware of the concerns through informal information sharing.

Graph 2: Febrile Convulsions (R56.0) presentations to 9 Perth EDs and Bunbury ED in children < 5 years 01 January to 06 May 2010



The Review established that PMH sees approximately 50% of the paediatric emergency presentations for the metropolitan area. The remaining 50% are seen at the MNTH, however these sites were not formally advised of the emerging situation with adverse events.

10.4.4 Recommendations

- Implement an effective communication strategy with fax stream to immunisation providers, general practitioners and hospitals to ensure alerts and information about AEFI reporting is regularly communicated.
- Mandatory fields in EDIS concerning patient demographics and GP contact number are established.
- An EDIS flag needs to be developed for AEFI.

10.5 General Practice Network WA (GPNWA)

The GPNWA provides support to general practice through immunisation co-ordinators in each division or network. From the GPNWA perspective, the reporting process for AEFI is straight forward. General Practitioners (GPs) report to the TGA using the 'blue card' (form) either on line or by fax or phone.

GPNWA indicated that communication needed to be improved with early advice if there is an emerging issue. Fax stream was considered to be the most helpful method of communication to raise awareness in the busy operations of general practice.

10.6 General Practitioners

The Reviewer interviewed GPs to understand their experiences with adverse events. The Reviewer learned that the distribution and logistic processes for the vaccine could be improved. A number of practices had to cancel or reschedule vaccination clinics due to inadequate supplies of vaccine, only to find that the vaccines arrived the next day. This has staffing and patient ramifications for general practice.

The Reviewer learned that GPs had used one type of vaccine without any adverse events for one or two weeks of the campaign. The practices received another type of vaccine the following week and immediately heard of concerns with febrile reactions and vomiting. GPs did not report the adverse events formally, as they had not seen the patient and the process of reporting was perceived to be onerous.

The GPs stated they had not received information from DoH concerning a perceived rise in AEFIs and felt that it would have been timely to have been told in early April, 2010 that there were issues that needed monitoring. A robust alert process to keep immunisation providers informed of any emerging events is obviously essential.

10.7 WA Rural Sector

The Reviewer met with the Acting Area Director of Population Health of WA Country Health Service (WACHS), to understand the rural perspective. The WACHS has seven public health units that provide a range of public health services to the regions, including support and advice to immunisation providers, primarily GPs, Aboriginal Health Services and appropriately credentialed community nurses in their region.

WACHS reported 130 AEFI following vaccination for seasonal influenza. Table 6 indicates the distribution of the AEFI across the regions.

Table 6: AEFI by region

Region	AEFI reports	ED Presentations	Admissions
Midwest	14	6	0
Kimberley	6	0	0
Great Southern	9	1	0
Goldfields	0	0	0
Pilbara	2	1	0
South West	44	14	4
Wheatbelt	53	8	2
Total WACHS	130	30	6

Note: There was 1 febrile convulsion reported in Wheatbelt.

The Reviewer was advised that the majority of WACHS hospitals do not have the same database as metropolitan facilities (which use EDIS), and therefore the information was not as easy to collate centrally. The coding of ED presentations for AEFI in rural areas is captured in Health Care And Related Information Systems (HCARe).

The Reviewer was advised that public health units (PHU) were not aware of the concerns being considered by CDCD or the extent of the problem with adverse reactions. On 1 April, 2010 CDCD was contacted by a PHU nurse from the Wheatbelt notifying of a few reactions in children following the seasonal influenza including one child who presented at Narrogin Hospital.

Almost two weeks later, CDCD e-mailed the PHUs on April 14 and 15, 2010, however, most PHUs did not consider these messages to be 'alerts'. The significance of the problem became apparent after the campaign was suspended as information about adverse events was collated (See Appendix F).

WACHS has also clarified that GPs in the rural sector could report to the TGA directly or to CDCD. The community nurses would report AEFI to CDCD. WACHS considered the reporting obligation of 14 days for AEFI to be too long. Feedback from WACHS stressed the importance of robust alert processes between PHUs, CDCD and immunisation providers regarding any emerging issues.

It was also clear to the Reviewer that the dual reporting process for AEFI was confusing and complicated.

11.0 Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is a branch or division of the DoHA and is essentially funded by the pharmaceutical companies and manufacturers of medical devices, seeking registration of their products in Australia. The TGA is fully cost-recovered and collects revenue primarily through annual charges, evaluation and assessment fees and license fees [29]. The information above has been obtained from their website: www.tga.gov.au.

On June 28, 2010 a new structure for the TGA was announced and listed on the TGA website. The information outlines the TGA Executive and the three key functional areas of: Market Authorisation Group, Monitoring and Compliance Group and the Regulatory Support Group. The Review has noted that the regulatory functions have been separated from the adverse events' reporting, with the later being a responsibility of the Office of Product Review within the Monitoring and Compliance Group. As of July 1, 2010, this functional area will be managed by the Chief Regulatory Officer, a member of the TGA executive [30].

The Reviewer acknowledges the recently announced restructure of the TGA and that this may foster increased transparency in the role and functions of the TGA but probably may not go far enough. This has also been an issue raised by consumers.

11.1 Advisory Committee on the Safety of Medicines

The new Advisory Committee on the Safety of Medicines (ACSOM) is a key advisory committee to the TGA [31]. According to the media release on February 2, 2010, "the ACSOM replaces and expands on the role of the Adverse Drug Reactions Advisory Committee (ADRAC) and focuses on the safety aspects of medicine regulation and the detection, assessment, understanding and prevention of adverse effects" [32]. The announcement articulates the development of risk management plans for medications and the implementation of more open and transparent arrangements at the TGA.

The Office of Medicines Safety Monitoring (OMSM) receives reports of suspected adverse reactions to prescription medicines, vaccines, over-the-counter medicines and complementary medicines. The OMSM provides the secretariat for the ACSOM. All adverse event notifications come either from reports direct to the OMSM or via state and territory health departments. The OMSM investigate all AEFIs in accordance with internationally consistent protocols. All AEFIs are reviewed at the ACSOM meetings every six weeks [33].

All AEFI reports for the period are provided to the immunisation expert representative of ASCOM at the meeting for consideration. The number of AEFI reports range from 200-300, making it very difficult to provide an informed view or advice on the AEFI during the committee proceedings.

Summary data from the ACSOM is provided to the WHO annually and as required.

The Reviewer is of the view that whilst this seemingly lengthy time between reporting and correlation of adverse events depends upon obtaining a realistic understanding of the true incidence of events across the nation, there must be flags put in place to detect early, an adverse trend.

11.2 Seasonal Influenza Campaign 2010

From a systems perspective, the TGA is one agency in a range of stakeholders on the National Immunisation Committee, and performs the role of national regulator and national surveillance and reporting of AEFI.

The Review learned that representatives from the TGA and ATAGI had visited WA in the week following the suspension of the program. Key personnel in WA indicated that the TGA did not appear to believe that the number of adverse events reported in WA were significant. This position was substantiated to the Reviewer when several senior officers independently conveyed their concerns about the perceived inadequacy of triggers within the TGA's processes. However, to be fair the TGA did not receive the AEFI reports in a timely fashion. This again brings up the question of a timely reporting system.

A senior WA DoH official quoted a senior TGA official allegedly sharing that, "the total number of FCs nationally in 2009 was six, and there had been 18 FCs reported for WA in 2010". The senior official noted that this had occurred in just seven weeks. This is a three fold increase in FCs in a short time frame. The 2010 seasonal influenza campaign experience was quite different to that experienced in WA in 2008 and 2009.

A number of issues remain unclear to the Reviewer following meetings with key personnel and independent specialists:

- What are the TGA performance indicators for timeliness of responding to AEFIs?
- What are the TGA escalation protocols for a signal?
- What are TGA communication protocols when an event is emerging or a signal has been detected in one jurisdiction?

It would appear to the Reviewer that the TGA would need to have formal mechanisms to convey this information to the National Immunisation Committee (NIC) in a timely manner for the matters to be considered and actions or decisions reached on the next steps.

The stakeholders in WA were left with the view that the TGA did not respond to the concerns raised in a timely manner. State health officials were frustrated by the perceived lack of engagement and leadership shown by the TGA in providing advice to WA on the decision to suspend the campaign. However, as previously stated, the TGA had not received the AEFI reports in a timely way.

This decision to suspend the campaign was made by the Minister for Health, Dr Kim Hames, following a briefing session of the second WA expert committee meeting on April 22, 2010.

The Reviewer has formed the view that the relationships between the divisions of the TGA and the State (CDCD) are not functional. The Review has become aware of a number of issues raised with the TGA senior officers and divisions since August, 2009, by CDCD. To date, these issues have not elucidated a formal response from the TGA, or their committees and divisions. Examples of this include:

- The recommendation by the WHO to implement intensive surveillance and reporting during the national pandemic vaccination program has not been applied to the seasonal influenza vaccination program [3].
- The requests to address perceived ACIR reporting issues in readiness for the 2010 seasonal influenza campaign (see Section 5.0).

11.3 Reported adverse events following seasonal influenza vaccination in WA

The Review sought clarification from the TGA as to the exact number of FCs reported by WA to the TGA as a consequence of vaccination for seasonal influenza. Advice received on June 28, 2010 indicated that there had been 58 FCs in WA and 100 cases of FCs reported Australia wide. Further detail of the WA cases was not provided.

During the progress of the Review it has been difficult to undertake an assessment of the systems and processes in place at the TGA to enable effective and timely communication between the TGA divisions and the CDCD in the DoH.

11.4 Current Status of the Investigation into the AEFI for 2010 Seasonal Influenza Vaccine

On July 2, 2010 the DoHA published a status report on the "Investigation into Febrile Reactions in Young Children Following 2010 Seasonal Trivalent Influenza Vaccine" [34]. The TGA states, "that at the time the WA program was suspended the TGA had received 25 spontaneous reports of FCs following vaccination in children under ten years across Australia, with 16 cases from WA, 14 of which were notified to the TGA on 20 April, 2010" (p.1). It would appear that AEFI reports sent earlier than April 20, 2010 by CDCD and PMH were not received by the TGA [35].

In previous years the TGA received five reports of FC in the first six months of 2008 and one report in 2009 for the same period. The report goes on to say that, "as at June 4 2010 the TGA has received 1729 reports concerning the 2010 TIV" (p.2). Following a detailed case review, "the TGA has concluded that there have been 100 confirmed cases of febrile convulsion in children under the age of five years across Australia, 58 of which were reported in WA" (p.2) [35].

The TGA status report states, “at this stage based on the findings from the two TGA audits and the information from the US FDA audit, it has not been possible to identify a manufacturing deficiency that is causally linked to the occurrence of a higher than expected rate of febrile convulsions” (p.6). In conclusion the report states, “despite extensive analyses the biological basis for the excess cases of fever and febrile convulsions remains unclear” (p.7) [35].

11.5 Recommendations

- A specific national form for the reporting of AEFI is developed in accordance with WHO endorsed guidelines to improve monitoring and surveillance of AEFI.
- A national system for AEFI reporting and surveillance, with standardized procedures for states and territories is developed in accordance with WHO endorsed guidelines.
- The NIC develops a clearly articulated and transparent set of key performance indicators for the:
  - Time frames for reviewing and responding to AEFI reports in consultation with the state and other jurisdictions.
  - Outline the escalation protocols for an emerging signal and establish benchmarks for alerts.

12.0 Governance arrangements for the National Immunisation Program in Australia

The Review has investigated the governance arrangements in place for the National Immunisation Program (NIP) in Australia.

12.1 Communicable Diseases Network Australia

The Communicable Diseases Network Australia (CDNA) was established in 1989 as the Communicable Diseases Control Network, as a joint initiative of the National Health and Medical Research Council and Australian Health Ministers' Advisory Council. Its website says, “The CDNA will provide national public health co-ordination on communicable disease surveillance, prevention and control, and will offer strategic advice to governments and other key bodies on public health actions to minimise the impact of communicable diseases in Australia and the region” [36].

12.2 National Immunisation Committee

The National Immunisation Committee (NIC) is a subcommittee of the CDNA and is the peak body for the NIP.

The Review focused on the systems and processes in place for the monitoring and surveillance of AEFI, by the peak body. The publication, *National Vaccine Safety Workshop: summary and draft recommendations* (2006) stated, “the aims of the workshop were to review current post-licensure vaccine safety practices in Australia and work towards developing a national vaccine safety strategy” (p.378)[37].

The workshop forum considered the WHO initiatives for AEFI monitoring and reporting to ensure transparency and accountability; a national overview of Australia’s passive AEFI surveillance system, with discussion on strengths and weaknesses of the system; parallels were drawn with regard to national disease surveillance and AEFI processes. Initiatives such as data linkage and specialist clinics for AEFI were discussed. The workshop outlined 16 draft recommendations articulated under key functions of surveillance; clinical management and research and communication [37].

The Review has reached the conclusion that the NIC has made little progress in implementing these recommendations to improve National AEFI surveillance.

12.3 Australian Technical Advisory Group on Immunisation

The Australian Technical Advisory Group on Immunisation (ATAGI) provides advice to the Minister for Health and Ageing on the National Immunisation Program and other related issues [38]. ATAGI is represented on the NIC and has several core functions including consultation with the NIC and to work

collaboratively with the National Health and Medical Research Council to develop the *National Immunisation Handbook*, currently in its 9th edition [1].

12.4 National Centre for Immunisation Research & Surveillance

The Review noted the important role of the National Centre for Immunisation Research and Surveillance (NCIRS). The NCIRS contributes to immunisation and surveillance policy and planning through its representatives on, and reports for, a range of policy and planning groups including the ATAGI, the NIC and the CDNA.

The NCIRS was established by the DoHA in August 1997. NCIRS has a funded partnership arrangement with the DoHA. The Centre's primary function is to perform research aimed at reducing the incidence of vaccine preventable diseases and improving vaccine uptake, in children and adults. The NCIRS provides independent expert advice on all aspects of vaccine preventable diseases and social and other issues related to immunisation. Their research and surveillance activities cover the broad areas of:

- vaccine preventable disease burden
- serosurveillance
- immunisation coverage and ACIR
- adverse events associated with immunisation
- social research and risk communication
- indigenous health
- immunisation program evaluations
- infectious disease modelling, and
- clinical research [39].

The Review considered the AEFI reports prepared by the NCIRS. The Review noted that the report published in 2007 stated, "The data confirm that, despite the low rate of AEFI reporting in Australia, the passive surveillance system is sufficiently robust to detect safety signals which are expected following changes in the immunisation program, allowing these to be investigated further" (p.371) [40]. The 2009 supplementary report on AEFI went on to state, "AEFI highlights the safety of vaccines in Australia and illustrates the value of the national TGA database as a surveillance tool for monitoring AEFIs nationally" (p.365) [41].

The Review does not concur with the position that the passive National surveillance system is robust or adequate. The processes at a National level can be significantly improved with the implementation of the WHO recommendations for vaccine surveillance [3]. Furthermore, data bases need to be linked to strengthen the national surveillance system [22].

While the NCIRS has a clear role in the retrospective annual reporting on AEFI, the internal processes of the TGA in the day to day management of AEFI reports which come into the OMSM, is unclear at the time of writing.

12.5 Issues with Clinical Governance

Stakeholders and independent specialists who have been consulted through the Review process have outlined concerns to the Reviewer regarding perceived conflicts of interest, with expert members of peak bodies in relation to immunisation also being involved in pharmaceutical companies and clinical trials for vaccines.

The TGA has a committee, the Australian Influenza Vaccine Committee which considered the recommendations of the WHO in determining the composition of the seasonal influenza vaccine. It is not clear to the Reviewer how this committee links into the NIC or if there is a link with ATAGI.

Key personnel and independent specialists interviewed through the Review emphasized that the roles of regulation and surveillance needed to be separated. Governance needs to ensure the safety and quality of the NIP. It was suggested that the model in the United States, where the Food and Drug Authority regulates vaccines and the Centre for Disease Control and Prevention undertakes surveillance was robust and transparent.

12.6 Recommendations

- DoHA clearly articulates the governance processes for the NIP to ensure transparency and accountability.
- DoHA appoints a separate body from the TGA to undertake the role of national surveillance and monitoring of AEFI.
- The DoHA formally review and address any perceived or real concerns in peak bodies with regard to Conflict of Interest.
- The NIC implements the recommendations from the National Vaccine Safety Workshop in 2006.

13.0 Notifiable Diseases

13.1 Background

One of the specific TOR for the Review (Appendix A) was to explore the reporting processes for notifiable diseases and make recommendations if required.

The CDNA is the national peak body for notifiable diseases in Australia. It is a joint initiative of the National Health and Medical Research Council and Australian Health Ministers' Advisory Council. The role of the CDNA includes:

- the co-ordination of national communicable disease surveillance; and
- the response to communicable disease outbreaks of National importance[36].

From a national perspective, notifiable diseases are monitored and reported through a range of subcommittees of the CDNA. The present sub-committees reporting to CDNA are:

- Infection Control Guidelines Working Group
- Intergovernmental Committee on AIDS, Hepatitis C and Related Diseases (IGCAHRD)
- Invasive Pneumococcal Disease Surveillance Working Group (joint CDNA/ATAGI sub-committee)
- Meningococcal Disease Committee (MDC)
- National Arbovirus and Malaria Advisory Committee (NAMAC)
- National Enteric Pathogen Surveillance Systems Steering Committee (NEPSSSC)
- National Immunisation Committee (NIC)
- National Surveillance Committee (NSC)
- National Tuberculosis Advisory Committee (NTAC)

CDNA reports to the Australian Health Ministers' Advisory Council (AHMAC) through the National Public Health Partnership (NPHP). From a national perspective, there are fortnightly reporting arrangements established for notifiable diseases, directly to the CDNA [36].

13.2 Epidemiology and Surveillance in Western Australia

The ESB is part of the CDCD.

13.2.1 Reporting of notifiable diseases

In WA, a notifiable disease is required to be reported to the branch, and this can currently be done on a specified form (Appendix Q), by phone, fax or post. The form is accessible through the public health website under ‘publications’.

The form indicates those diseases (with a telephone symbol) for which urgent advice on management are required. The forms are entered into a database in the branch's research area. Any notification form outlining an urgent disease is conveyed to the CDCD Medical Epidemiologist immediately.

Members of the community who perceive they have experienced food poisoning need to report their experience to the relevant local government authority. If the local government authority determines that the matter warrants further investigation, contact is made with the Food Unit at Environmental Health Directorate. Reports of concern are referred to the food-borne disease epidemiologists in ESB, CDCD. Environmental Health, like CDCD, is a directorate of the Public Health division, separate from ESB.

The ESB branch may discover a food borne virus by recognising a cluster reports of an unusual pathogen reported by a GP. At this point the branch would follow up with the GP or laboratory. This method is dependent on the organism identified, as some are less common and are recognized instantly as a possible food borne virus. If the numbers of the cluster are large, a focus group is facilitated to identify a commonality (ie. all affected persons ate at the same restaurant or were all on the same plane flight).

From a national perspective, the DOHA established OzFoodNet in 2000 as a collaborative initiative with Australia's State and Territory health authorities to provide better understanding of the causes and incidence of foodborne disease in the community and to provide an evidence base for policy formulation. OzFoodNet is a member of the CDNA. Foodborne disease surveillance has been recognised as an essential tool to help reduce food poisoning by the WHO and many countries around the world. [42]

The Review understands that in 2008, "the Network covered the whole of the Australian population, which was estimated to be 21,373,998 persons" (p. 401) [43].

13.2.2 ESB reporting processes

The ESB meets weekly to analyse the trends in data, including food borne disease surveillance, sexually transmitted diseases and other notifiable diseases. The Branch has well established reporting processes to the public health units across Western Australia, and to the CDNA.

The Reviewer understands that the standard of reporting for notifiable diseases improved significantly in 2006 when changes where made to the State legislation which stipulated that pathology services were required to notify the branch of any notifiable pathogens identified.

The surveillance of notifiable diseases was further strengthened in 2007 when, "the *National Health Security Act 2007 (National Health Security Act 2007, No. 174, 2007)* received royal assent. This Act provides a legislative basis for, and authorises the exchange of, health information, including personal information between Australian jurisdictions and the

Commonwealth. The Act provides for the establishment of a National Notifiable Diseases List which specifies the diseases about which personal information can be provided. The National Health Security Agreement, signed by Health Ministers in April 2008, establishes operational arrangements to formalise and enhance existing surveillance and reporting systems – an important objective of the Act" (p. 401) [44].

The Reviewer was satisfied that the systems and processes in place for notifiable diseases were robust. The option to develop a web-based reporting system for notifiable diseases was discussed. Key concerns raised when this had previously been considered were: the cost of the development of the application, confidentiality and provider verification.

13.3 Recommendation

A web-based user friendly reporting system for notifiable diseases is established, for members of the public, public health units, local government and the DoH.

Acknowledgements

Professor Bryant Stokes has been assisted in undertaking the Review by Ms Jaynie Kirkpatrick and Ms Fiona Hope. Ms Michele Kosky, Executive Director for the WA Health Consumers Council, has assisted with consumer engagement.

In the course of the Review more than 27 formal interviews were conducted and many e-mails and conversations took place to gather information to gain an understanding of the issues. The Reviewer would like to acknowledge the contribution made by consumers, GPs, GP Networks, independent specialists, salaried officers and employees of the DoH, and DoHA representatives. All have informed the Review, and outlined strategies to improve the systems and processes for AEFI reporting and surveillance, both in WA and nationally.

14.0 Appendices

Appendix A: Terms of Reference

The Review team, led by Professor Bryant Stokes will prepare a report for consideration by the Minister for Health.

The Review will:

- Analyse the systems in place for reporting vaccine side effects in WA and nationally and the protocols in place to determine timing to alert the public and health professionals of heightened risks;

- Assess the timeliness and adequacy of the response with respect to the recent suspension of the seasonal influenza vaccine program for under 5's in WA;

- Interview key stakeholders in WA and those in other jurisdictions including the Commonwealth Department of Health and Ageing (DoHA) and the Therapeutic Goods Administration (TGA) and assess all stakeholders' roles and their ability to develop and act upon the outcomes;

- If necessary, make recommendations as to how the system could be improved to benefit the WA public; including wider reposting of notifiable diseases and food poisoning; and

- Make any further enquiries deemed necessary and advise the Minister of any matters revealed during the investigation which warrant further assessment.

- Provide an interim report to the Minister after 4 weeks and the final report to the Minister after 8 weeks.

The Review will, wherever possible, benchmark the WA Health Public Health Response to the responses in similar services in other jurisdictions within Australia.

Appendix B: Vaccine Information

The influenza vaccines used in Australia are all split virion prepared from purified inactivated influenza virus. The vaccines are cultivated in hens' eggs sometimes leaving egg proteins in the vaccine and different chemicals are used to inactivate the virus. The composition of the influenza vaccine in Australia is decided by the Australian Influenza Vaccine Committee (AIVC).

2010 Seasonal Influenza Season

Table 7: The Recommended Composition of Influenza Vaccine in Southern Hemisphere

Year	*Composition*
2008	• A/Solomon Islands/3/2006 (H1N1)-like virus; • A/Brisbane/10/2007 (H3N2)-like virus; • B/Florida/4/2006-like virus.
2009	• A/Brisbane/59/2007 (H1N1)-like virus • A/Brisbane/10/2007 (H3N2)-like virus; • B/Florida/4/2006-like virus
2010	• A (H1N1): an A/California/7/2009 (H1N1) (Swine Flu) • A (H3N2): an A/Perth/16/2009 (H3N2) - like strain • B: a B/Brisbane/60/2008 - like strain

[8, 45-46]

Recommended doses for 2010

- Six Months – Three years 0.25ml vaccine dose
- Three years + years 0.5ml vaccine dose

Note: For children nine years and under receiving vaccine for the first time, two doses, one month apart are required [1].

Table 8: Seasonal Influenza Vaccine brands [1]

Influenza vaccine	**Company**	**Vaccine information**
Fluvax	CSL Biotherapies	• 0.5ml prefilled syringe contains 15ug of haemagglutinin of 3 strains. • Manufactured in Victoria, Australia.
Fluvax Junior	CSL Biotherapies	• 0.25ml prefilled syringe contains 15ug of haemagglutinin of 3 strains. • Manufactured in Victoria, Australia.
Influvac	Solvay Pharmaceuticals	• 0.5ml prefilled syringe contains 15ug of haemagglutinin of 3 strains. • Manufactured in Netherlands.
Vaxigrip	Sanofi Pasteur Pty Ltd	• 0.5ml prefilled syringe contains 15ug of haemagglutinin of 3 strains. • Manufactured in Lyon, France.

Table 9: Estimated Doses of Seasonal Influenza vaccine administered in 2010, by age, by brand of vaccine.

Brand of Vaccine	≤2 years	3-≤4 years	5-≤7 years	Total
Fluvax (CSL)	4114	3586	2134	9834
Fluvax Junior (CSL)	2084	295	89	2468
Influvac (Solvay)	1519	1856	1290	4665
Vaxigrip (Sanofi)	48	4	3	55
Unknown	20	14	3	37
Total	7785	5755	3519	17059

Note: This data only reflect 75% of the doses administered in WA.

Appendix C: WHO Recommendation

World Health Organization

Safety of pandemic vaccines
Pandemic (H1N1) 2009 briefing note 6

6 AUGUST 2009 | GENEVA -- WHO is aware of some media reports that have expressed concern about the safety of vaccines for pandemic influenza. The public needs to be reassured that regulatory procedures in place for the licensing of pandemic vaccines, including procedures for expediting regulatory approval, are rigorous and do not compromise safety or quality controls.

Vaccines are among the most important medical interventions for reducing illness and deaths during a pandemic. However, to have the greatest impact, pandemic vaccines need to be available quickly and in large quantities.

During the 1957 and 1968 pandemics, vaccines arrived too late to be used as an effective mitigation tool during the more severe phases of the pandemics. Influenza vaccines had not yet been developed when the 1918 pandemic swept around the world, eventually killing an estimated 50 million people.

In 2007, as part of preparedness for an influenza pandemic, WHO worked together with health officials, regulatory authorities, and vaccine manufacturers to explore a broad range of issues surrounding the regulatory approval of pandemic vaccines. [1]

Ways were sought to shorten the time between the emergence of a pandemic virus and the availability of safe and effective vaccines. Different regulatory pathways were assessed, and precautions needed to ensure quality, safety, and effectiveness were set out in detail.

Fast-track procedures for approval

Regulatory authorities have shown great flexibility in developing procedures for fast-tracking the approval and licensing of pandemic vaccines.

In some cases, pandemic vaccines are not regarded by regulatory authorities as entirely “new” vaccines, as they build on the technology used to produce vaccines for seasonal influenza, established procedures for testing and regulatory control, and an extensive body of safety data.

In such cases, approval procedures are similar to those applied to “strain changes” made each year when seasonal vaccines are modified to match circulating viruses in the Northern and Southern Hemispheres.

Specific regulatory procedures have been devised to expedite the approval of pandemic vaccines. In the USA, for example, fewer data are required when the manufacturer already has a licensed influenza vaccine and intends to use the same manufacturing process for its pandemic vaccine.

In the European Union, the European Medicines Agency uses a rolling review procedure whereby manufacturers can submit sets of data for regulatory review as they become available, without having to wait until all data can be submitted together in a single formal application.

Also in Europe, some manufacturers have conducted advance studies using a so-called “mock-up” vaccine. Mock-up vaccines contain an active ingredient for an influenza virus that has not circulated recently in human populations and thus mimics the novelty of a pandemic virus. Such advance studies can greatly expedite regulatory approval.

Special safety concerns

Influenza vaccines have been used for more than 60 years and have an established record of safety in all age groups. While some serious adverse events have been reported, these have been rare.

Nonetheless, special safety issues will inevitably arise during a pandemic when vaccine is administered on a massive scale. For example, adverse events too rare to show up even in a large clinical trial may become apparent when very large numbers of people receive a pandemic vaccine.

Some adverse events will be coincidental – that is, associated in time with vaccine administration, yet not directly caused by the vaccine. Genuine adverse events directly caused by the vaccine may also occur, but cannot be predicted in advance. Given the safety record of seasonal vaccines, such events are expected to be rare.

Time constraints mean that clinical data at the time when pandemic vaccines are first administered will inevitably be limited. Further testing of safety and effectiveness will need to take place after administration of the vaccine has begun.

For these reasons, WHO advises all countries administering pandemic vaccines to conduct intensive monitoring for safety and efficacy, and many countries have plans in place for doing so. On the positive side, mass vaccination campaigns can generate significant safety data within a few weeks.

International sharing of data from such post-marketing surveillance will be vital in guiding risk-benefit assessments and determining whether changes in vaccination policies are needed. WHO has developed standardized protocols for data collection and reporting in real-time, and will communicate findings to the international community via its web site.

Appendix D: CSL Letter to CDCD

CSL Limited
45 Poplar Road Parkville
Victoria 3052 Australia

T +613 9389 1911
F +613 9389 1554
www.csl.com.au

31 March, 2010

Medical Coordinator, Prevention and Control Program
Communicable Disease Control Directorate
Department of Health
Western Australia

Re: Stability of Fluvax due to power outage

Dear Dr

Due to a severe storm on 22nd March 2010 causing loss of power to the CSL distribution facility in WA, all product requiring refrigeration was relocated to an approved off-site storage facility at Perth International Airport. Product was transported using two trucks making multiple trips and was returned to the CSL distribution facility once refrigeration was available on 23rd March 2010.

Data loggers were placed in some of the loads by DHL staff but not all of them and due to incomplete temperature data profile, an assessment has had to be made as to the impact on the quality of each of the products.

According to stability data, Fluvax is stable for up to 7 days at 25°C and the batches affected by the power outage remain fit for use.

Yours sincerely

Vincent Chung
QA Manager
CSL Biotherapies

Appendix E: E-mail from Solvay Pharmaceuticals to CDCD

From: Tony, WILSON-WILLIAMS [tony.wilson-williams@solvay.com]
Sent: Wednesday, 31 March 2010 6:54 AM
To: CDCD

Subject: Re: Solvay Vaccine and Power Outage - Perth - WA Dept of Health Vaccine Storage - VERY URGENT-

Thank you for this additional information.

Bearing in mind all data and information provided to date, the very brief potential worst case - exposure of the outside of the pallets/shipper cartons to an ambient temperature maximum of 21 degrees C, I agree with your opinion.

There is no evidence to suggest the quality of the Influvac 2010 vaccine would have been affected.

Recommendation

It is recommended that the vaccine concerned be released for normal use in accordance with TGA registration.

Regards,

Tony

Appendix F: Detailed Timeline of Events

2007

Influenza related deaths in young children in WA.

2008

WAIVE program commences to immunise all children six months to five years of age.

Monday March 8, 2010

Trivalent Seasonal Influenza Vaccine distribution began.

Friday March 19, 2010

Official launch of vaccination program.

Monday March 22, 2010

Perth storm.

Wednesday March 31, 2010

E-mail and Telephone call:
From: Wickepin Health Service
To: Public Health Nurse, Wheatbelt

- Reporting reactions to flu vaccine.
- Provided detail of child who had severe reaction, including temperature of 40 degrees, respiratory distress, “shaky” and finger tips bluish.
- Child was taken to Narrogin Regional Hospital, received phone call from parent when driving to hospital.
- Reports of six out of nine children vaccinated yesterday with Fluvax were unsettled overnight, seemed to be feverish.
- Not aware of other children requiring health care worker intervention.

Thursday April 1, 2010

Seasonal influenza information mailed out to 30 000 parents in WA.

E-mail
From: Public Health Nurse, Wheatbelt
To: CDCD

- States “could be a coincidence but could be batch number”.
- Child who went to Narrogin Hospital will complete TGA blue card.

E-mail
From: CDCD
To: Public Health Nurse, Wheatbelt

- Assures nurse many children get fever following vaccination, it should subside within 48 hours.
- Please ensure have filled out TGA ADRAC forms to monitor the situation.

Tuesday April 6, 2010

Second batch of seasonal influenza information mailed out to 30 000 parents in WA

Telephone call
From: PMH Immunologist
To: Paediatric Immunologist PMH, Director of the Vaccine Trials Group Telethon Institute for Child Health Research (TICHR), Director, and Associate/Professor School of Paediatrics and Child Health, (SPACH) UWA

- Own children had experienced fevers of 39°C after being vaccinated with Fluvax.

Thursday April 8, 2010

Third batch of seasonal influenza information mailed out to 30 534 parents in WA.

E-mail
From: CIC
To: CDCD

- Had received phone calls from parents of children who had experienced adverse reactions following flu vaccine.
- High fever and vomiting approximately five hours after vaccination.
- Questioning if CDCD had any feedback from other health professionals?

Friday April 9, 2010

PMH:

- Anecdotal reports from ED nursing staff of children presenting at ED "unwell" after seasonal influenza vaccination.
- PMH begin to collect names of patients.

From: Bunbury Hospital
To: CDCD, WA Department of Health

- Vaccine related adult presentation to ED, (CDCD followed up to determine only one turned out to be influenza vaccine AEFI).

E-mail
From: CDCD
To: CIC

- CDCD confirm they have heard children are experiencing high fever, pain and vomiting with some taken to hospital following immunisation.

Queensland
Suspected death of two year old following flu vaccine (post mortem could not determine cause of death).

Monday April 12, 2010

PMH

- Six reports of suspected reaction to seasonal influenza from nurses in ED at PMH.

Telephone call
From: Parent
To: CDCD

- Febrile reactions following flu vaccine at Geraldton Hospital.

Telephone call
From: CDCD
To: Doctor at Geraldton Public Health Unit

- Confirmed there had been AEFI observed.
- CDCD requested any AEFI be reported to CDCD and TGA.

Telephone call
From: Parent/Doctor
To: CIC

- Phoned to inform that her daughter received Fluvax Junior on Friday April 9, 2010
- Daughter had a high temperature, pale, vomited once.
- Told when at PMH that they had been experiencing an increase in presentations post flu vaccine, such as high fevers, FCs and vomiting.
- If PMH is experiencing this, why haven't CIC been informed?

E-mail
From: CIC
To: CDCD

- Informed CDCD of mother/doctor phone call (above).
- CIC had three phone calls that day all reporting children with symptoms five to seven hours after vaccination with fever of 39 or higher, fever, vomiting and pale.
- Asks what is going on?

E-mail
From: Staff Inoculation & Immunisation, Clinical Nurse Consultant at PMH Infection Control
To: CDCD

- Notifying CDCD that three children had presented at ED at PMH with seizure within 24 to 48 hours of receiving seasonal flu vaccine.

E-mail
From: CDCD
To: Staff Inoculation & Immunisation, Clinical Nurse Consultant at PMH Infection Control

- CDCD instructed PMH to provide AEFI reports to TGA and provide CDCD with copies.

Telephone call
From: CDCD
To: TGA

- Informing of increase in AEFIs and asking if other states were reporting similar.

E-mail
From: Staff Inoculation & Immunisation, Clinical Nurse Consultant at PMH Infection Control
To: Director of Emergency, PMH

- Six children in ED with suspected reactions to flu vaccine, either seizure, fever, rash, vomiting etc within 24 to 48 hours after receiving the vaccine.
- Advising reporting needs to go to TGA with a copy of the patient information to be sent to CDCD.
- Offering to assist into looking into specific cases.

Tuesday April 13, 2010

PMH
Staff Inoculation & Immunisation, Clinical Nurse Consultant in PMH Infection Control

- From 5pm on April 12 until 9am April 13, 2010 ten patients presented to the ED identified as having reaction after seasonal influenza vaccination.
- Concerns from medical and nursing staff of advice to parents
- Staff Inoculation & Immunisation, Clinical Nurse Consultant in PMH Infection Control wrote letter for parents to receive on discharge of child from PMH.
- Director of ED, PMH requested look back through extraction from Emergency Department Information System (EDIS).

E-mail
From: CDCD
To: TGA

- Immunisation providers stating children are experiencing high temperatures, really unwell and some with seizures after the vaccine.

- Calls from worried parents.
- Wanting to know if any other states had reported similar symptoms.

E-mail
From: TGA
To: CDCD
- Indicating a Medical officer who handles enquires will be in contact.

Wednesday April 14, 2010

PMH
- PMH conducted an EDIS extraction.

E-mail
From: CDCD
To: TGA
- Follow up on previous e-mail.
- Mentions did not receive phone call from Medical officer as promised.
- Considerable number of parents going to ED with kids temperature and seizures. Ten cases overnight.
- Is this similar to other states?

E-mail
From: TGA
To: CDCD
- Provides case details for reports identified as coming from WA involving Panvax and Panvax Junior (swine flu vaccine).

From: TGA
To: CDCD
- Four AEFI reports for seasonal influenza so far nationwide.

Telephone call
From: South Australia Nursing Director Immunisation Section - Communicable Disease Control Branch
To: CDCD
- Asking if WA had seen AEFI after 2008 and 2009 seasonal influenza?
- Getting reports of AEFI in South Australia.

E-mail
From: CDCD
To: TGA
- There have been a number of AEFI reports, seems to be higher than previous years.
- Mentions WA will compile a line list of reports to sent through.
- Heard reports of AEFI in South Australia.
- Request TGA to look into issue more, check with other states and provide an update at the upcoming NIC meeting in Canberra.

E-mail
From: CDCD
To: Regional Public Health Units

- Notifying there have been children experiencing AEFI including fever and in some cases seizures following seasonal influenza vaccine.
- Are all doctors and EDs sending forms to ADRAC?
- Send through all ADRAC forms.
- Require information on batch number and vaccine brand.

E-mail
From: Public Health nurse, Wheatbelt
To: CDCD

- Verbal reports of clusters of cases (three to four kids from same batch number) with high temperatures for 12 hours.

Thursday April 15, 2010

PMH
Staff Inoculation & Immunisation, Clinical Nurse Consultant in PMH Infection Control

- Informed more presentations overnight.
- Reviewed case notes.
- Commenced special database of patient information received.

Telephone call
From: Microbiology Registrar
To: Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA (on leave)

- Own child had a febrile convulsion following Fluvax vaccination.
- Requested advice if child should have second dose.

E-mail
From: CDCD
To: Staff Inoculation & Immunisation, Clinical Nurse Consultant in PMH Infection Control

- Requesting progress with line listing of children who presented with AEFI from influenza vaccines.

E-mail
From: Staff Inoculation & Immunisation, Clinical Nurse Consultant in PMH Infection Control
To: CDCD

- Reported 27 patients so far, five with confirmed FCs.
- Expecting another list of patients from ED last night.

Fax: “Influenza AEFI”
From: Clinical nurse manager, CIC
To: CDCD

- Noting an increase in notification of reactions post influenza vaccination in children under five years, compared to other years.
- Symptoms: high fever, vomiting.
- AEFI post influenza vaccine.
- Attached eight reports of suspected adverse reaction to vaccines.

E-mail
From: South Australia Nursing Director Immunisation Section - Communicable Disease Control Branch
To: TGA, DoHA, Director NCIRS, Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA and all State Health Departments including CDCD

- South Australia is receiving increased numbers of vomiting and high fever in children following the influenza vaccine.
- Have contacted other states WA and Victoria is also reporting some AEFI.
- Different picture from reports received after children following Panvax.
- Most children are between three and nine years.
- Presentations at EDs and admissions for observation.
- Suggests the rate is more common than found in the clinical trials.

E-mail
From: CDCD
To: Immunisation providers – CIC, Public Health Units.

- Request for additional information following several reactions to the vaccine.
- Additional information included: if Panvax had been given in past, if patient had previous seasonal influenza vaccine, symptoms of reaction, vaccine used e.g. CSL/Solvay/Sanofi Pasteur and batch number.
- Requested that information be provided immediately “not in a month’s time”.

Friday April 16, 2010

E-mail
From: Victoria Health Department
To: TGA, DoHA
Cc: All State Health Departments including CDCD:

- Informing Victoria had been receiving reports regarding seasonal influenza vaccine including high fevers and vomiting.

E-mail
From: Staff Inoculation & Immunisation, Clinical Nurse Consultant in PMH Infection Control
To: CDCD

- Attached a detailed spreadsheet of suspected AEFI ED presentations to PMH, collected daily.

- 90 presentations possibly related, 22 are notifiable AEFIs (seizures, temperatures over 40 degrees).
- Overall symptoms seem to be commencing approximately six to eight hours and peak at 12 hours after vaccination.
- Full recovery period unknown as most children have been discharged not requiring hospitalisation.

Telephone
From: CDCD
To: Parents of children who experienced febrile reactions following the flu vaccine.

- To gather more information regarding the brand of vaccine and place of administration.

Stand up Meeting with Executive Director of Public Health
One page summary of Prevention and Control program update provided to Director of CDCD.

- This week: “Initiated assessment of AEFI following seasonal vaccinations”.
- Hot issues: “As yet, unverified reported of increased febrile reactions after seasonal Fluvax”.

E-mail
From: TGA
To: South Australia Nursing Director Immunisation Section - Communicable Disease Control Branch), TGA, Director NCIRS, Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA and all State Health Departments including CDCD

- Notes the relevant area of TGA has been made aware and is considering the issue.
- A search of their database found that there have been 62 AEFI reports for seasonal influenza vaccine in 2010, with 22 of these reports for people 18 and younger.
- Suggests that issues which need to be examined include: brand of vaccine, batch numbers, the number of doses administered, whether children had previously received Panvax and whether this simply shows an increase in vaccine uptake?
- Requests all states send in all unsubmitted reports so the TGA can look at national data.
- Asks for the number of vaccines given in each state.
- TGA will discuss issue at the NIC next week.

Monday April 19, 2010

E-mail
From: Director of NCIRS
To: TGA, SA, ASCOM, AEFI Clinic, NSW

- Notes the issue was discussed at the PAEDS surveillance group meeting.
- Difficult syndrome to identity as it appears to be non-specific.

- An important issue to consider is how extensively these children were worked up for other causes of fever, especially viral.
- Whether there are currently any viruses circulating at community level, i.e. enteroviruses.

PMH
- Sent 23 reports of AEFIs to TGA.

E-mail
From: Staff Inoculation & Immunisation, Clinical Nurse Consultant at PMH Infection Control
To: CDCD
- Over past three days, further 22 ED presentations to PMH.
- One additional AEFI report.
- Now a total of 111 presentations to PMH, 23 ADRAC notifications post flu vaccination.
- Attached updated PMH spreadsheet, with flu vaccine history and where vaccine given included in spreadsheet.
- Questions if any reported cases elsewhere?

E-mail
From: CDCD
To: Staff Inoculation & Immunisation, Clinical Nurse Consultant in PMH Infection Control
- Mentions the issue is on the agenda for the National Immunisation Committee meeting in Canberra on Wednesday April 21, 2010.
- Hope to get more information about other states at this meeting.

PMH
- In the evening, child with severe reaction presented at ED. This child later went to ICU.

Tuesday April 20, 2010

E-mail
From: Clinical Nurse, Paediatric, RGH
To: Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA
- A number of young children 12 to 18 months old presenting to ED at Rockingham General Hospital 10 to 12 hours after flu vaccine.
- High fevers and some post FC to ED.
- Question if this is happening elsewhere?

E-mail
From: Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA To: Clinical Nurse, Paediatric, RGH
- Acknowledging PMH have seen similar, appears this years vaccine is more reactogenic.

- Requested numbers of patients presenting at Rockingham Hospital.

CIC: Stopped using CSL Fluvax and Fluvax Junior.

Telephone call
From: St John of God Hospital Murdoch
To: CDCD:
- Notifying 10 AEFI presented at ED.

PMH
From: Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA
To: CDCD
- Notifying there was a child very sick following the flu vaccine in ICU.

Wednesday April 21, 2010

National Immunisation Committee Meeting – Canberra.
Attendees: State Health Department representatives including CDCD, DoHA, Director of NCIRS, TGA.

E-mail
From: Director of ED, RGH
To: Staff Inoculation & Immunisation, Clinical Nurse Consultant at PMH Infection Control
- Notes RGH, like PMH has noticed a small cluster of febrile reactions following flu vaccinations.
- Requests some prospective data.
- Will get the triage nurses to commence collection and the medical staff to finish it.

From: Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA
To: Executive Director of Child and Adolescent Health Service
- Concerned of cluster of AEFI at PMH.

From: Director of Emergency at PMH
To: CDCD
- Concerned of AEFI at PMH, one child in ICU.

Teleconference
Attendees: Director of CDCD, CDCD staff, Director NCIRS, Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA and Staff Inoculation & Immunisation, Clinical Nurse Consultant in PMH Infection Control.
- Issues with ACIR.
- PMH – 130 presentations to ED, 19 seizures with fever. Most are not admitted and go home.

- South Australia has reported AEFI and anecdotal reports from Victoria and Sydney.
- No need to go to media yet.
- Reconvene teleconference Thursday (following day) with more information.

From: Executive Director of Child and Adolescent Health Service
To: Director General of Health

Thursday April 22, 2010

National Immunisation Committee Meeting – Canberra.
Attendees: State Health Department representatives including CDCD, DoHA, Director of NCIRS, TGA.

PMH
- Sent eight reports of AEFIs to TGA

Executive Director of Public Health learns from CDCD of the child in ICU and other adverse events following immunisation in children.

09:35
E-mail:
From: Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA
To: CDCD, PMH
Cc: Director of NCIRS, Executive Director of Child and Adolescent Health Service.
- Febrile convulsion data collected from PMH ED Presentations.
- Notes was contacted by registrar from Joondalup Health Campus that morning who reported an increased number of FCs following seasonal influenza vaccine for the first time occurring in children.

12:00
From: Executive Director of Child and Adolescent Health Service
To: Director General of Health
- More AEFI reported at PMH.
- Director General requested the Executive Director to contact the Minister for Health to regarding a suspension of the flu vaccine program.

16:00
E-mail
From: CDCD
To: TGA
(cc: DoHA, Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA, South Australia Nursing Director Immunisation Section - Communicable Disease Control Branch, Executive Director of Public Health, CDCD)

- Mentions the e-mail chain documents that WA e-mailed the TGA on April 13, 2010 expressing concerns.
- Re-contacted TGA the following day as CDCD had still yet to receive a call from the TGA as promised.

16:30
From: CDCD
To: Commonwealth Chief Medical Officer, Australian Government Department of Health and Ageing

- Provide background e-mails to Commonwealth Chief Medical Officer to assist when speaking with TGA.

15:00 – 16:00
Teleconference CDCD, PMH, TGA, DoHA, Director NCIRS

Notes from teleconference

- Febrile reactions to influenza vaccine, two very serious.
- Admissions to PMH with FCs, from EDIS
  - 2008 mid March – mid April 25
  - 2009 mid March – mid April 31
  - 2010 mid March – mid April 44
- 30% increase in percentage of admissions due to FCs, 44 with 22 related to the flu vaccine (five to eight hours later).
- Reports to TGA
  - 2008 whole year 10 two seizures in kids in WA <10 yrs
  - 2009 whole year 5 nil seizures
  - 2010 whole year 48 27 at PMH, more severe, 21 non PMH
- Five other EDs have also reported this issue.
- Question: What to do about the second dose?
- South Australian experts noticed an increase in reports last week related to fluvax. 50% of report kids < nine years. Six hours after vomiting and high fever. No report of FCs.
- WA: Influenza vaccine program.
  - Expected number of complications from CSL
  - 6000 ACIR – no accurate figures of doses in arms.
- TGA batch update
  - 2009 186 report flu vaccine reactions, six FCs
  - 2010 WA 37 cases, 18 FCs
- Five largest GP practises noticed increase in rate of vaccinating kids, like is in the middle of the flu season.
- Very consistent clinical picture, first response to Fluvax
- Phenomenon of trivalent vaccine or product issue
- Full investigation required
- Risk of damaging program.

16:00 to 17:00

Teleconference with CDCD, WA Department of Heath Executive Director of Public Health and Child and Adolescent Health Service

Notes from Teleconference

- Is there a problem? According to clinicians, epidemiological view point.
- How serious is it?
- What do we do? Include risk communication.
- More reactivity to? CSL, CSL junior, Solvay or Sanofi vaccine?
- Almost all kids make a full recovery.
- National message: TGA/Chief Medical Officer.
- Suspend the program, while we gather further information.
- May be able to introduce an alternative vaccine.
- Risk in first 12 hours.

16:45

From: Minister for Health

To: Executive Director of Child and Adolescent Health Service

- Call received during teleconference.
- Minister for Health speaks to Executive Director of Public Health, WA Department of Health.

17:30 Minister for Health suspends seasonal influenza for children

18:10

From: CDCD

To: *healthdirect*

- Alerting of the suspension of the vaccine program in WA.

20:00

Urgent Alert to doctors and Immunisation providers (Distributed via e-mail and fax)

From: CDCD

- Increase in rate of FCs, relative to previous seasons, in young children within 12 hours following receiving the trivalent seasonal influenza vaccination.
- Reactions reported include vomiting, fever.
- More severe fevers have been reported in a small number of cases, with accompanying FCs.
- Decision to suspend the WA program for seasonal influenza vaccination in children six months to four years.
- Vaccination should continue for children who are eligible for vaccination under the national program because of underlying medical conditions.
- Children who have been vaccinated in the last 12 hours should be advised to treat child with paracetamol and to seek medical attention if the child develops a fever which cannot be controlled.
- No other vaccines in the childhood vaccination program have been affected.

20:00
From: CDCD
To: *healthdirect*

- Information sheet provided with questions and answers for when parents they call.

Friday April 23, 2010

PMH

- Five reports of AEFI's were sent to the TGA.

8:00
From: CDCD
To: Chair of ATAGI
Indicating ATAGI should be aware to efforts to engage TGA to pull together a national approach to the issue.

09:00
Urgent Alert to doctors and Immunisation providers (Distributed via e-mail and fax)
From: CDCD

- Change to alert – The temporary suspension includes children five years and younger, including children with medical conditions.
- Nation program including Panvax remains unaffected.

Media Statement: "Seasonal Flu Vaccine and young children"
Commonwealth Chief Medical Officer, DOHA

- Due to increase in WA young children experiencing fever and convulsions following the seasonal flu vaccine, all GPs and immunisation providers to stop giving the seasonal flu vaccine to children five years and under.

13:00
Urgent Alert to doctors and Immunisation providers (Distributed via e-mail and fax)
From: CDCD

- Change to alert – to include suspension of the National program.
- Provision of seasonal influenza vaccine for children aged five years and under is temporarily suspended. Encompassing children eligible for the free WA program (six months to four years) and children up to and including the age of five years with underlying medical conditions.
- The National influenza vaccination program for all other age groups and use of Panvax is unaffected.

Press Release: Seasonal Influenza Vaccine – Paediatric adverse events
From: CSL

- CSL is aware of reports of adverse events following immunisation.
- CSL is investigating the reports with TGA and WA Health Department.
- Withholding further distribution of paediatric influenza vaccine nationally.

TGA Website Statement: Western Australian reports of adverse reactions to 2010 seasonal flu vaccine in children
From: TGA, Commonwealth DoHA.

- TGA is investigating reports of increase in adverse events following immunisation of children with seasonal flu vaccine.
- Rate in WA has not been seen in other states, will test WA batches for any abnormalities.
- Investigating the WA data to distinguish if adverse reactions reported in WA are related to the vaccine or the WA program delivery.
- Until cause can be established the Chief Medical Officer of DoHA is writing to all immunisation providers to advise to suspend administering seasonal flu vaccine for all children five years and under.
- TGA has contacted CSL to confirm batches of vaccines and is obtaining samples to be tested in their laboratories.
- Request states and territories report any adverse events related to the seasonal vaccine to the TGA.
- Parents and caregivers with children who are experiencing adverse reactions should contact their doctor.
- Safe to use Panvax.

E-mail
From: Queensland Health
To: CDCD

- Qld data for FCs looks to be higher in March and April, 2010.

19:00
DoHA Letter to Immunisation providers
From: CDCD

- Advising of suspension of program for children five years and younger.
- Recommendations for children six years and older have not changed.

Friday April 25, 2010

WA DoH global e-mail
From: Director General of Health

- Advising of program suspension.

Monday April 26, 2010

New Zealand Health

- Stops administration of CSL Fluvax and Fluvax Junior vaccines to children under five years of age until more information about whether there is an association with an increased risk of FC in Australian and New Zealand.
- Whether there is an increased risk with Fluvax remains unclear.
- Recommends children at risk of complications from influenza be immunised using other brands available – Influvac, Vaxigrip.

Tuesday April 27, 2010

PMH

- Sent two reports of AEFIs to TGA.

Wednesday April 28, 2010

11:00 Chief Medial Officers (CMO) Teleconference
Attendees: CMO for DoHA, State Health CMO's, Chair of ATAGI, Director of CDCD, TGA, DoHA.

Meeting
Attendees: TGA, ATAGI, CDCD, Paediatric Immunologist PMH, Director of the Vaccine Trials Group (TICHR), Director, and Associate/Professor (SPACH) UWA.

Friday April 30, 2010

Chief Health Officers' Teleconference
Attendees: CMO for DoHA, State Health CMO's, Chair of ATAGI, TGA, DoHA.

Notification to doctors and Immunisation providers (Distributed via e-mail and fax)
From: CDCD

- The investigation into the increase in adverse events following the 2010 seasonal influenza vaccination for children aged five years and under is continuing.
- The TGA and Commonwealth DOHA are coordinating the national investigation, with assistance from WA Department of Health.
- To date, WA has reported to the TGA 57 children with FCs.
- While there has been an increase in FCs associated with the seasonal influenza vaccination for children aged five years in WA, it is unclear if there was an increase in other states or territories.
- Still remains unclear if the adverse events following immunisation are associated to a brand of vaccine or a batch.
- Recommendation no child aged five years or younger should receive the trivalent seasonal influenza vaccine.

Letter to Immunisation Provider: "Continued temporary Suspension of use of seasonal influenza vaccine in children aged 5 years of age and younger"
From: Commonwealth Chief Medical Officer, DoHA

- Update to letter on April 23, 2010.
- Investigation into the apparent increase of children experiencing adverse reactions following immunisation is continuing.
- Children aged five years and younger should not be given the seasonal influenza vaccine.
- If a child has received one dose and is scheduled for their second dose, this should be deferred. An alternative is to vaccinate with the Panvax, swine flu vaccine which is not affected by the suspension.

Thursday May 6, 2010

Notification to doctors and Immunisation providers (Distributed via e-mail and fax)
From: CDCD

- Requesting for information.
- The WA DoH and the TGA are continuing to investigate the apparent increase in febrile reactions associated with the 2010 seasonal influenza vaccination.
- Lack of reliable information on numbers of children vaccinated in WA, including the brand and batch numbers.
- This is associated with the problem with the transfer of influenza vaccination data from practise software systems to the ACIR.
- Due to the uncertainty of the effectiveness of ACIR upload, the WA DoH requested the number of children vaccinated with the seasonal influenza vaccine between dates of March 8 and April 23, 2010, by age, vaccine brand and batch number.
- Request for information by May 10, 2010

Friday May 28, 2010

Letter
From: Minister for Health, Hon. Kim Hames
To: Minister for Health and Ageing, Hon Nicola Roxon

- Enquiring about the status of the national investigation into the reports of an increased number of adverse events to the seasonal influenza vaccine in young children in WA.
- Public and media interest in the suspension of the program are high.
- Advising of announcement of a Ministerial Review of the Public Health Reporting Systems to be carried out by Professor Bryant Stokes.
- Once assured safety would like to reinstate the program ahead of the winter peak in influenza transmission.
- Noted that the WA authorities provided the initial signal to national authorities and made the initial decision to suspend the program.

Tuesday June 1, 2010

Media Statement
Commonwealth Chief Medical Officer, DoHA

- Comprehensive investigation into the safety of seasonal flu vaccine to date.
- Continue the suspension of the seasonal flu vaccine for healthy children under five years.
- Investigations so far have confirmed that a small number of children aged five and under nationally have experienced fever with convulsions within 24 hours after vaccination. These reactions have been mainly associated with the 2010 seasonal Fluvax vaccine manufactured by CSL.

- No apparent clinical, biological or epidemiological factors that would explain the higher than expected rate of fever with convulsions.
- Laboratory testing of the vaccine conducted by the TGA and an audit of CSL manufacturing plant have revealed no abnormalities. However, the investigation is continuing.
- Rate of FCs in children under five years following 2010 seasonal influenza vaccine of 9 per 1000 children, compared to the expected rate of 1 per 1000.
- If a child has medical risk factors where if they got the flu they would suffer serious health effects, parents should discuss with their doctor whether the seasonal flu vaccine would be the best option.
- Higher rate of FCs has been identified using Fluvax, insufficient doses of Influvac and Vaxigrip vaccines in children under five years to accurately determine the rates of these vaccines.
- The cause of the FCs is unknown.
- Panvax, the swine flu vaccine can be used as an alternative for both healthy children and those children with risk factors, as this vaccine has been shown to be safe and effective.
- Influenza often causes fever in young children which can lead to convulsions. However, this year it is clear the rate of FCs is higher.
- TGA will continue to work with overseas Regulators and the US CDC in Atlanta to determine the scientific reason behind this issue.

Friday July 2, 2010

TGA Status Report “Investigation into Febrile Reactions in young children following 2010 seasonal trivalent influenza vaccination” [35].
See Section 11.4 for a summary.

Appendix G: Australian Immunisation Handbook (9th Ed.) definitions of Adverse Events Following Immunisation [1]

Abscess
Occurrence of a fluctuant or draining fluid-filled lesion at the site of injection, with or without fever.

- Bacterial: purulent collection.
- Sterile abscess: no evidence of bacterial infection.

Acute flaccid paralysis [diagnosis must be made by a physician]
Acute onset of flaccid paralysis of one or more limbs following any vaccine.

Allergic reaction (generalised)
A non-anaphylactic, generalised reaction characterised by 1 or more symptoms or signs of skin and/or gastrointestinal tract involvement WITHOUT respiratory or cardiovascular involvement.
(NB. See also 'Anaphylaxis').

Anaphylaxis
A rapidly evolving generalised multi-system allergic reaction characterised by 1 or more symptoms or signs of respiratory and/or cardiovascular involvement AND involvement of other systems such as the skin or gastrointestinal tract.

- Respiratory: difficulty/noisy breathing, swelling of the tongue, swelling/tightness in the throat, difficulty talking/hoarse voice, wheeze or persistent cough.
- Cardiac: loss of consciousness, collapse, pale and floppy (babies), hypotension.

Arthralgia: Joint pain without redness or swelling.

Arthritis: Joint pain with redness and/or swelling.

Brachial neuritis: Pain in arm causing persisting weakness of limb on side of vaccination.

Death: Any death of a vaccine recipient temporally linked to vaccination, where no other clear cause of death can be established.

Disseminated BCG: Disseminated infection occurring after BCG vaccination and confirmed by isolation of *Mycobacterium bovis* BCG strain.

Encephalopathy [diagnosis must be made by a physician]
Encephalopathy is an acute onset of major neurological illness temporally linked with vaccination and characterised by any 2 or more of the following 3 conditions:

- seizures,
- severe alteration in level of consciousness or mental status (behaviour and/or personality) lasting for 1 day or more, and/or
- focal neurological signs which persist for 1 day or more.

Encephalitis [diagnosis must be made by a physician]
Encephalitis is characterised by the above-mentioned symptoms and signs of cerebral inflammation and, in many cases, CSF pleocytosis and/or virus isolation.

Extensive limb swelling
Swelling of the limb, with or without redness, which:

- extends from the joint above to the joint below the injection site, or beyond a joint (above or below the injection site), or
- results in the circumference of the limb being twice the normal size.

Faint : See 'Vasovagal episode'.

Fever: Only very high fever should be reported, eg. >40.5^{o}C.

Guillain-Barré Syndrome (GBS) [diagnosis must be made by a physician]
Acute onset of rapidly progressive, ascending, symmetrical flaccid paralysis, without fever at onset of paralysis and with or without sensory loss. Cases are diagnosed by cerebrospinal fluid (CSF) investigation showing dissociation between cellular count and protein content.

Hypotonic–hyporesponsive episode (shock, collapse)
The sudden onset of pallor or cyanosis, limpness (muscle hypotonia), and reduced responsiveness or unresponsiveness occurring after vaccination, where no other cause is evident such as a vasovagal episode or anaphylaxis. The episode usually occurs 1 to 48 hours after vaccination and resolves spontaneously.

Injection site reaction (severe)
Reaction (redness and/or swelling) at site of injection which:

- persists for more than 3 days AND is associated with ongoing symptoms such as pain or an inability to use the limb (see 'Brachial neuritis' above), and
- does not fulfil the case definition for extensive limb swelling (see 'Extensive limb swelling' above), or
- requires hospitalisation.

Intussusception [diagnosis must be made by a hospital physician]
The invagination of a proximal segment of bowel into the distal bowel lumen.

Lymphadenitis (includes suppurative lymphadenitis)
Occurrence of either:

- at least 1 lymph node, 1.5 cm in diameter or larger, or
- a draining sinus over a lymph node.

Meningitis [diagnosis must be made by a physician]
Acute onset of major illness with fever and often neck stiffness/positive meningeal signs (Kernig, Brudzinski) and with CSF pleocytosis.

Nodule
A discrete or well demarcated soft tissue mass or lump that is firm and is at the injection site in the absence of abscess formation, warmth and erythema.

Orchitis: Swelling with pain and/or tenderness of testes.

Osteitis: Inflammation of the bone due to BCG vaccination.

Osteomyelitis: Proven bacterial infection of bone.

Parotitis: Swelling and/or tenderness of parotid gland or glands.

Rash: Severe or unusual rash.

Screaming (persistent): The presence of crying which is continuous and unaltered for longer than 3 hours.

Seizure
Witnessed sudden loss of consciousness and generalised, tonic, clonic, tonic-clonic, or atonic motor manifestations.

- febrile seizures: with fever ≥38.5oC,
- afebrile seizures: without fever,
- syncopal seizures: syncope/vasovagal episode followed by seizure(s).

Sepsis: Acute onset of severe, generalised illness due to bacterial infection and confirmed by positive blood culture.

Subacute sclerosing panencephalitis [diagnosis must be made by a physician]
Degenerative central nervous system (CNS) condition with laboratory confirmation of abnormal serum and CSF measles antibodies.

Syncope: See 'Vasovagal episode'.

Thrombocytopenia: Platelet count <50 x 10^9/L.

Toxic shock syndrome [diagnosis must be made by a physician]
Abrupt onset of fever, vomiting, watery diarrhoea and shock within a few hours of vaccination as can be associated with other conditions listed here.

Vaccine-associated paralytic poliomyelitis: See 'Acute flaccid paralysis'.

Vasovagal episode (syncope, faint)

- Episode of pallor and unresponsiveness or reduced responsiveness or feeling light headed AND
- occurring while vaccine being administered or shortly after (usually within 5 minutes), AND

- bradycardia, AND
- resolution of symptoms with change in position (supine position or head between knees or limbs elevated).

Other severe or unusual events
Any unusual event that does not fit into any of the categories listed above, but is of medical or epidemiological interest, should be reported with a detailed description of the clinical features.

Report by telephone to State or Territory Health Department or notify by the blue card.

Note: The Brighton Collaboration is an international group considering definitions of adverse events following immunisation. Its website is: http://www.brightoncollaboration.org.

Appendix H: CDCD AEFI report form

Department of Health
Government of Western Australia

REPORT OF SUSPECTED ADVERSE REACTION TO VACCINES

(List of notifiable conditions on reverse)

Patient ID (compulsory): **Date of Birth:** ...../...../.....

Sex: M / F **Weight:** ..... Kg **Date of Onset:** ...../...../.....

Adverse Reaction Description:

Vaccines Given Prior to Adverse Reaction *(please use brand names)*	Date Given *(e.g. 1 Jan 00)*	Dose Number *(e.g. DTP1)*	Batch Number

OUTCOME

Recovered: ☐ Date of Recovery: ...../...../.....
Not yet recovered: ☐
Fatal: ☐ Date of Death: ...../...../.....
Unknown: ☐
Sequelae: Yes ☐ No ☐ Description:
Severity: Life threatening: ☐ Hospitalised: ☐ Required visit to Doctor: ☐
Comments: (e.g. relevant history, allergies, previous exposure to these vaccines):

REPORTING DOCTOR, NURSE, ETC:

Name:
Address: **Postcode:**
Phone:
Signature: **Date:** ...../...../.....

Mail or Fax this page only to:

Communicable Disease Control Directorate
PO Box 8172
Perth Business Centre
WA 6849
Fax No: (08) 9388 4877

LIST OF NOTIFIABLE ADVERSE REACTIONS TO VACCINES

The following conditions should be notified to the Department of Health if they are associated with vaccination.

- No time limit has been set for notifying these conditions since adverse reactions associated with vaccination could occur years after vaccination.
- The inclusion of conditions in the following list does not imply a causal association with vaccination. These conditions may occur coincidentally following vaccination.
- Medical practitioners or other health professionals should use their clinical judgement and common sense to decide which adverse reactions to notify.

Abscess	☐	Lymphadenitis (includes suppurative lymphadenitis)	☐
Acute flaccid paralysis	☐	Meningitis – diagnosis must be made by a physician	☐
Allergic reaction	☐	Orchitis	☐
Anaphylaxis	☐	Osteitis	☐
Arthralgia	☐	Osteomyelitis	☐
Arthritis	☐	Parotitis	☐
Brachial neuritis	☐	Rash (severe or unusual)	☐
Death	☐	Screaming (persistent)	☐
Disseminated BCG	☐	Seizure	☐
Encephalopathy	☐	Sepsis	☐
Encephalitis	☐	Subacute sclerosing panencephalitis	☐
Fever	☐	Thrombocytopenia	☐
Guillain-Barre Syndrome (GBS)	☐	Toxic shock syndrome	☐
Hypotensive-hyporesponsive episode (Shock, Collapse)	☐	Vaccine associated paralytic poliomyelitis	☐
Local reaction (severe)	☐	Other severe or unusual events	☐

Medical practitioners or other health professionals are free to report any adverse reactions that concern them but that are not included in the notifiable conditions above. They should be reported as *'Other reactions'*, including a full description of the adverse reaction. This will enable new and unexpected adverse reactions following immunisation to be identified. In general, minor reactions do not need to be notified.

Communicable Disease Control Directorate, Department of Health, Western Australia, February 2004

Appendix I: Health (Notification of Adverse Event After Immunisation) Regulations 1995

Western Australia

Health Act 1911

Health (Notification of Adverse Event After Immunization) Regulations 1995

As at 05 Mar 2004 Version 01-a0-03
Extract from www.slp.wa.gov.au, see that website for further information

Reprinted under the *Reprints Act 1984* as at 5 March 2004

Western Australia

Health Act 1911

Health (Notification of Adverse Event After Immunization) Regulations 1995

1. Citation

These regulations may be cited as the *Health (Notification of Adverse Event After Immunization) Regulations 1995* [1].

2. Interpretation

In these regulations —

adverse event after immunization means an event that —

(a) is of a kind listed in Appendix 7 of the National Health and Medical Research Council publication "The Australian Immunisation Handbook 7th Edition"; and

(b) occurs following the administration of a vaccine to a person.

[Regulation 2 amended in Gazette 8 Aug 2000 p. 4549.]

3. Adverse event after immunization prescribed as condition of health

An adverse event after immunization is prescribed as a condition of health to which Part IXA of the Act applies.

Reprinted under the *Reprints Act 1984* as at 5 March 2004

Western Australia

Health (Notification of Adverse Event After Immunization) Regulations 1995

CONTENTS

4. Notification by medical practitioner

(1) A medical practitioner must notify the Executive Director, Public Health of an adverse event after immunization within 14 days of becoming aware of that adverse event.

(2) A notification under subregulation (1) must —

(a) be in writing in a form approved by the Executive Director, Public Health; and

(b) include the following information —

(i) a full description of the adverse event after immunization;

(ii) the full name of the person who suffered the adverse event after immunization and that person's address or telephone number;

(iii) where the adverse event after immunization is the death of a person, the full name, and the address or telephone number, of the next of kin or personal representative of the deceased person (if known);

(iv) the name, dose and batch number of the vaccine administered;

(v) the date on which the vaccine was administered;

(vi) the name and address of the place where the vaccine was administered; and

(vii) the full name, address and telephone number of the medical practitioner giving the notification.

(3) A medical practitioner who contravenes subregulation (1) commits an offence and is liable to a penalty which is not more than $1 000 and not less than —

(a) in the case of a first offence, $100;

(b) in the case of a second offence, $200; and

(c) in the case of a third or subsequent offence, $500.

5. Fee for notification

A fee of $5 is payable to a medical practitioner who gives notification under regulation 4 but this regulation does not apply to a medical practitioner who is employed in the Public Service of the State or the Commonwealth, or is employed by an agency or instrumentality of the State or the Commonwealth.

6. Executive Director, Public Health may request provision of information

(1) Where the Executive Director, Public Health —

(a) is notified of an adverse event after immunization; and

(b) has reasonable grounds to believe that a person is able to provide information relating to the adverse event,

the Executive Director, Public Health may request the person to provide such information relating to the adverse event as the Executive Director, Public Health considers necessary for the purpose of achieving the objects of Part IXA of the Act.

(2) A person to whom a request is made under subregulation (1) must comply with the request within 14 days of receiving the request.

(3) A person who, without reasonable excuse, contravenes subregulation (2) commits an offence and is liable to a penalty which is not more than $1 000 and not less than —

(a) in the case of a first offence, $100;

(b) in the case of a second offence, $200; and

(c) in the case of a third or subsequent offence, $500.

Notes

1 This reprint is a compilation as at 5 March 2004 of the *Health (Notification of Adverse Event After Immunization) Regulations 1995* and includes the amendments made by the other written laws referred to in the following table. The table also contains information about any reprint.

Compilation table

Citation	Gazettal	Commencement
Health (Notification of Adverse Event After Immunization) Regulations 1995	14 Nov 1995 p. 5287-9	14 Nov 1995
Health (Notification of Adverse Event After Immunization) Amendment Regulations 2000	8 Aug 2000 p. 4549	8 Aug 2000
Reprint 1: The *Health (Notification of Adverse Event After Immunization) Regulations 1995* as at 5 Mar 2004 (includes amendments listed above)		

Appendix J: TGA AEFI report form 'blue card'

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Office use only

Report of suspected adverse reaction to medicines or vaccines

(See statement about the collection and use of personal information overleaf)
Please attach any additional data to this sheet

Patient initials or medical record number:	Sex: M ☐ F ☐ Weight (kg):	Date of birth or age:

Suspected medicine(s)/vaccine(s)
(please use trade names; include **AUST R or AUST L number** for non-prescription medicines, and batch number (if known)

Medicine/vaccine	Dosage (Dose number for vaccines eg 1st DTP)	Date begun	Date stopped	Reason for use

Other medicine(s)/vaccine(s) taken at the time of the reaction

Medicine/vaccine	Dosage	Date begun	Date stopped	Reason for use

Reaction(s): Date of onset of reaction (or for vaccines time after administration): / /
Describe: (please provide as much detail as possible and include any results of relevant supportive laboratory data and other investigations)

Seriousness:	Life threatening ☐	Hospitalised ☐	Required a visit to doctor ☐

Treatment of reaction:

Outcome:	☐ Recovered, date: / /	☐ Not yet recovered	☐ Fatal, date: / /	☐ Unknown

Sequelae? No ☐ Yes ☐ Describe:

Comments (eg relevant history, allergies, previous exposure to this medicine):

Reporting ☐ doctor, ☐ pharmacist, ☐ other:
Name:
Address:
Postcode:

Contact details (email or phone)

Signature Date: / /

Thank you for taking the time to complete this form

Report of suspected reaction to medicines or vaccines ("Blue card") version 0210

Further information/other comments:

Please note: The personal information in this form is collected and used for the purpose of assessing the safety of medicines under the Therapeutic Goods Act 1989. The personal information is only disclosed: (i) to State and Territory Health Departments (if the information relates to Immunisation Schedule vaccine events); or (ii) where there is a legal requirement to disclose it. The reporter's details are recorded in the database so that reporters can be contacted if further information is required.

Fold here first

www.tga.gov.au/problem Email: adr.reports@tga.gov.au Phone: 1800 044 114 Fax: 02 6232 8392

What to report
You do not need to be certain, just suspicious!
Any information related to the reporter and patient identifiers is kept strictly confidential.
Adverse drug reaction reports should be submitted for prescription medicines, vaccines, over-the-counter medicines (medicines purchased without a prescription), and complementary medicines (herbal medicines, naturopathic and/or homoeopathic medicines, and nutritional supplements such as vitamins and minerals). Please indicate timing of reactions relative to medicine administration where relevant.
The TGA particularly requests reports of:

- All suspected reactions to new medicines and vaccines
- All suspected drug interactions
- Unexpected reactions, ie not consistent with product information or labelling
- Serious reactions which are suspected of significantly affecting a patient's management, including reactions suspected of causing death, danger to life, admission to hospital, prolongation of hospitalisation, absence from productive activity, increased investigational or treatment costs, and birth defects

All reports are assessed by a health professional and entered into the Australian Adverse Drug Reactions System (ADRS).

Fold here second

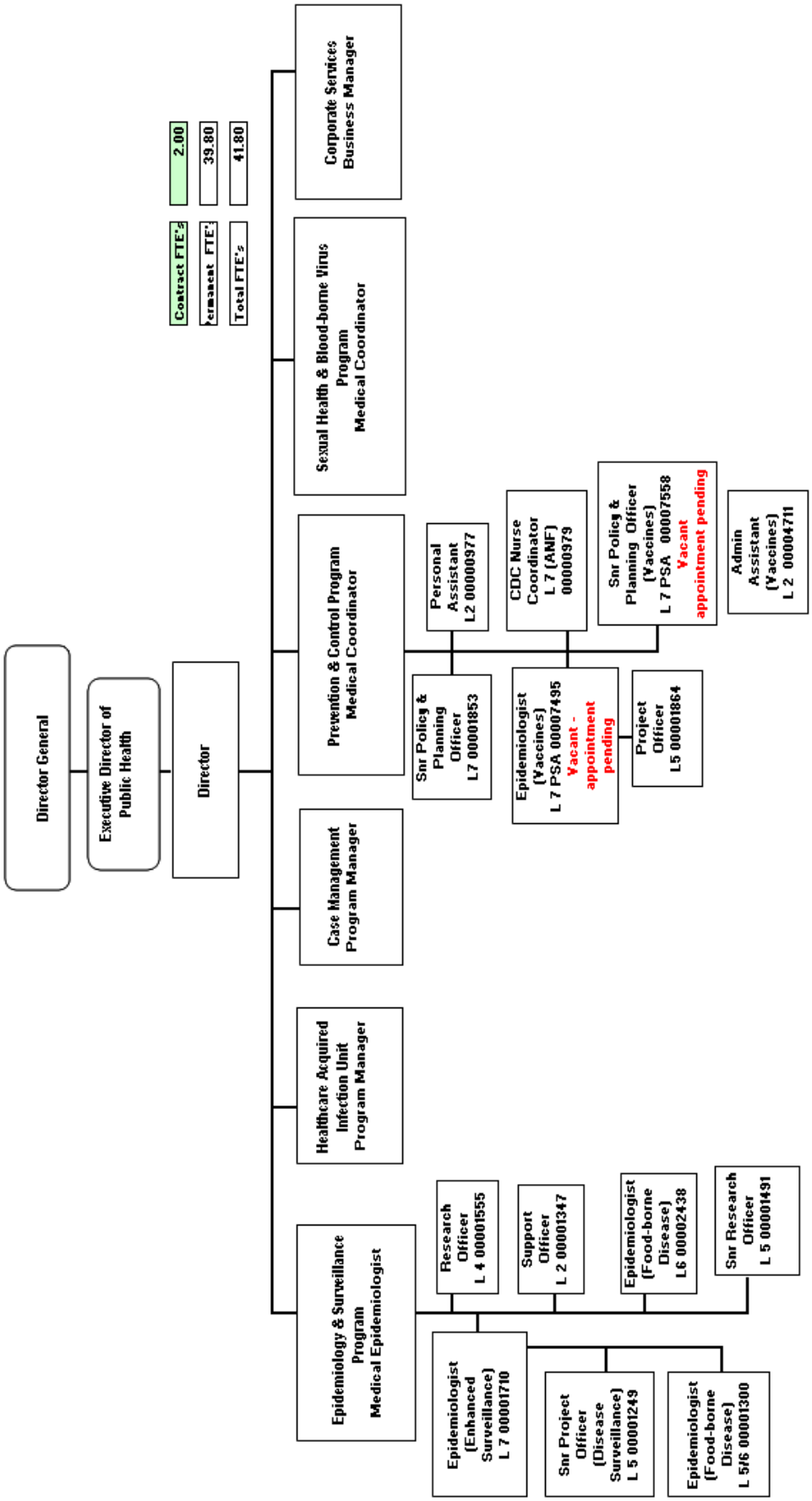
Delivery Address:
PO Box 100
Woden ACT 2606

No stamp required
if posted in Australia

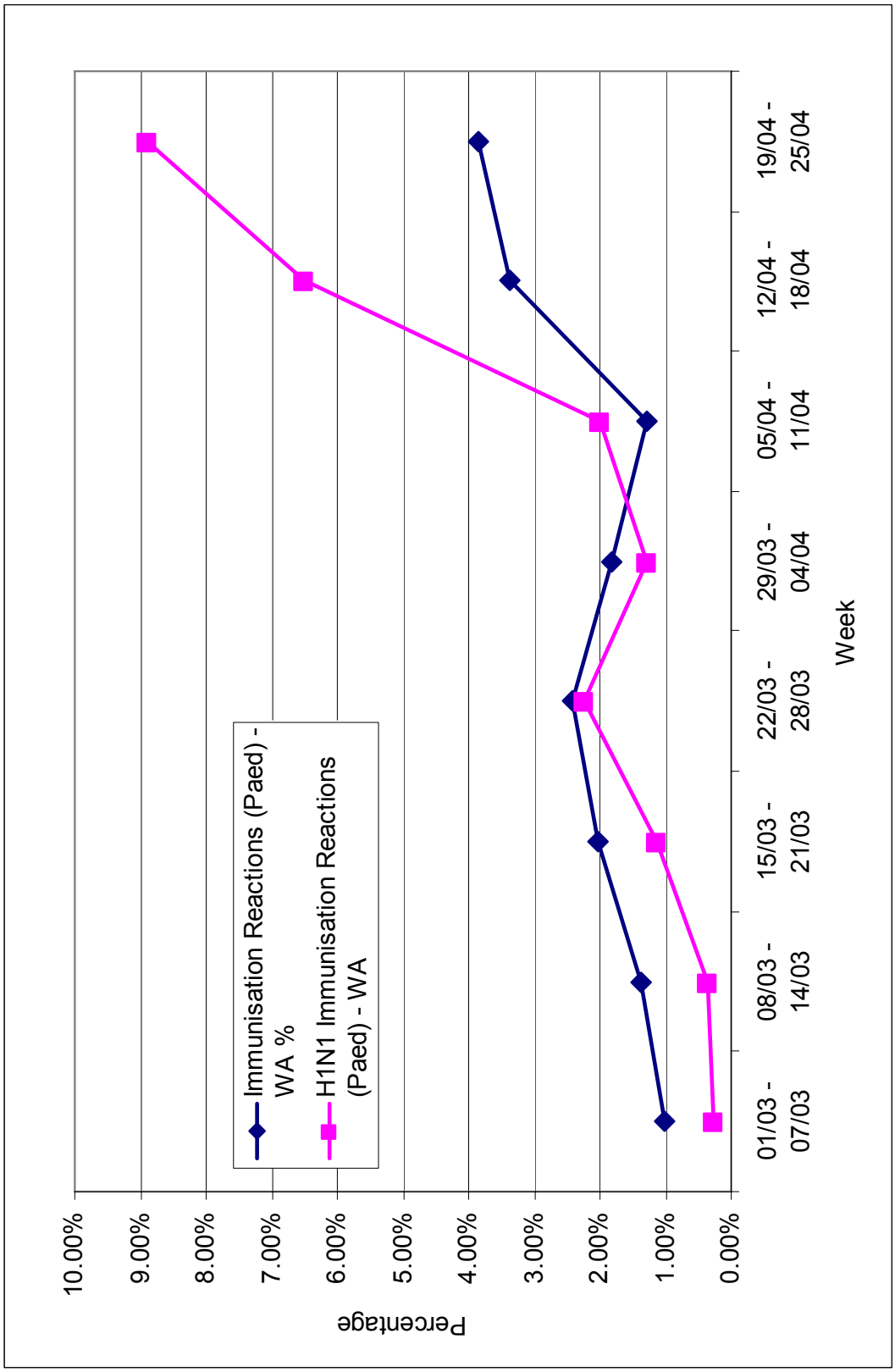
Medicines Safety Monitoring
Reply Paid 100
WODEN ACT 2606

Appendix K: CDCD Organisational Structure

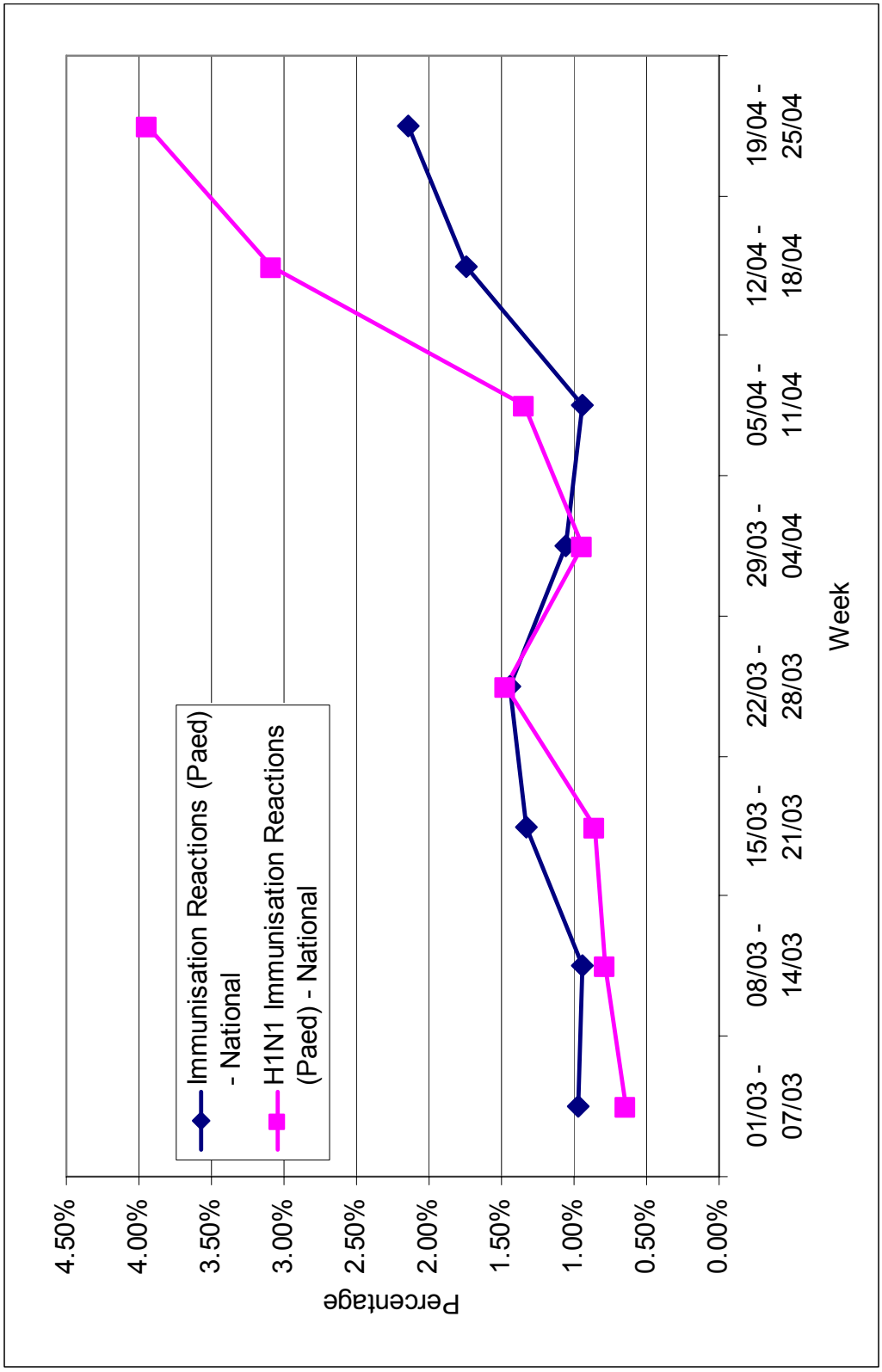
Note: Organisational structure only includes branches and positions in CDCD relevant to the Review.



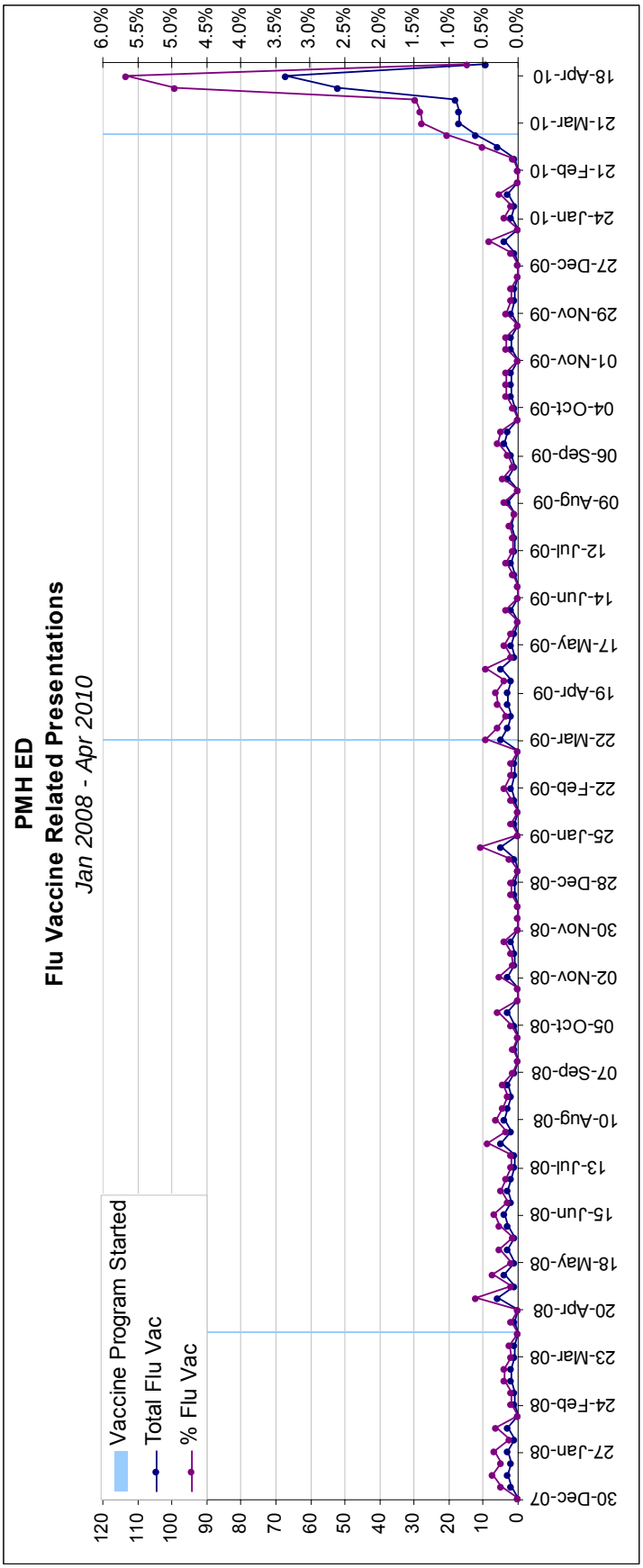
Appendix L: Graph of Western Australian *healthdirect* Triage Calls regarding Immunisation Triage



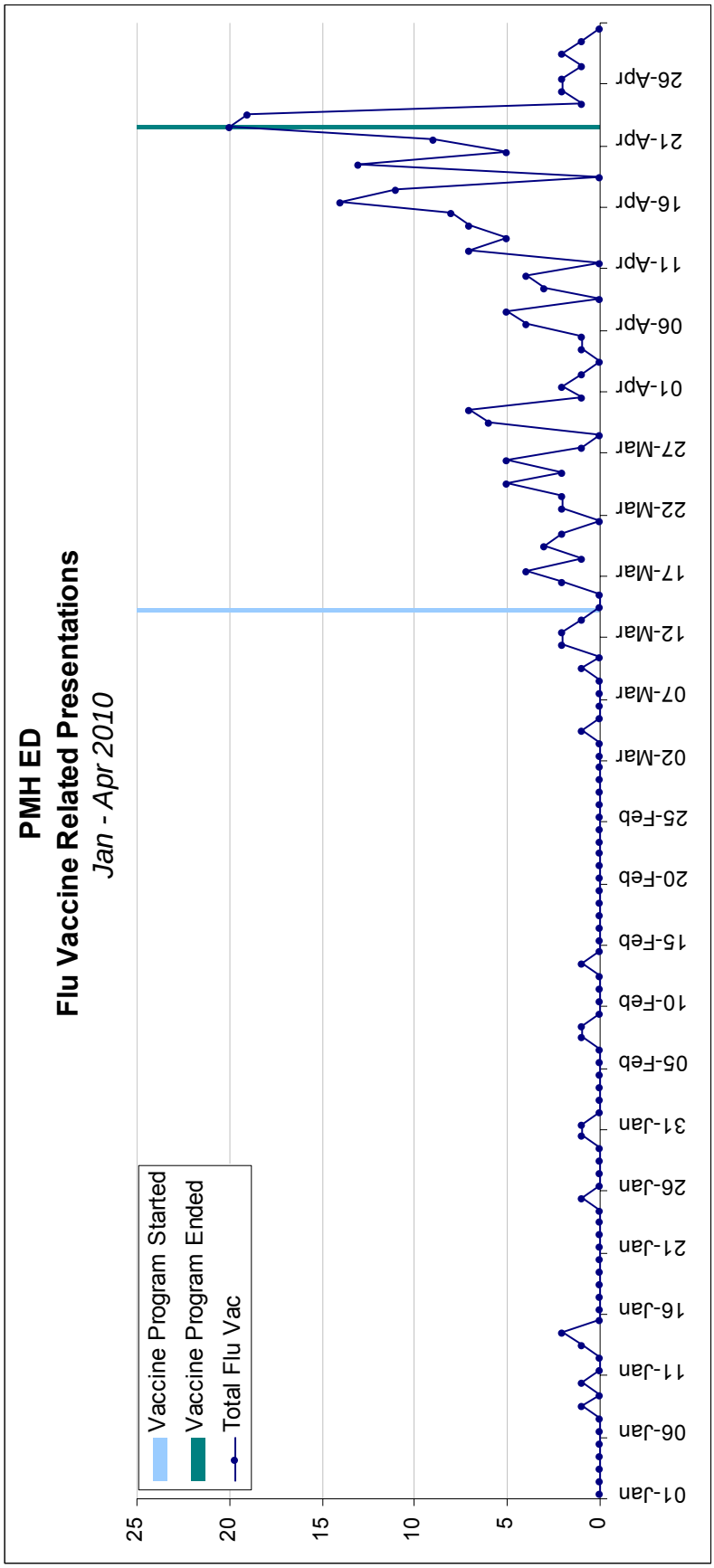
Appendix M: Graph of *healthdirect* National Triage Calls regarding Immunisation



Appendix N: Graph of Emergency Department Presentations at PMH related to Seasonal Influenza



Appendix O: Graph of Emergency Department Presentations at PMH related to Seasonal Influenza, January to April 2010



Appendix P: Princess Margaret Hospital AEFI Form

SUSPECTED ADVERSE REACTION POST INFLUENZA VACCINATION

Affix patient label	Date: ___/____/2010

Date of vaccination	**____/_____/2010**		
Time of vaccination			
Previous H1N1 (swine) flu vaccine given**?**	Yes	No	
First time flu vaccine given?	Yes	No	
Where was flu vaccine obtained? **If at GP, name of GP service**			
Fever	Yes	No	Temp if yes:_____
Seizure **(with or without fever)**	Yes	No	
Other presenting symptoms			
Significant medical history or possible other cause for reaction			
Discharge to	Ward _____		Home

Appendix Q: CDCD Notifiable Diseases Form

Date received by DOH ☐☐ ☐☐ 20☐☐ (dd mm yyyy)

Department of Health
NOTIFICATION FORM

20☐☐ – ☐☐☐☐☐ Notification ID

July 2006

YOU MAY NOTIFY BY POST, TELEPHONE or FACSIMILE
RETURN TO: Communicable Disease Control Directorate
PO Box 8172, Perth Business Centre WA 6849
Telephone: (08) 9388 4852 Fax: (08) 9388 4848
A/H emergency: (08) 9328 0553

1. PATIENT

Family name _____

Given name _____

Street address _____

Suburb/Town _____ ☐☐☐☐ postcode (essential)

Phone ☐☐☐☐☐☐☐☐ Home ☐☐☐☐☐☐☐☐ Work/Mobile

2. PATIENT DETAILS

Sex ☐ Male ☐ Female

Date of birth ☐☐ ☐☐ ☐☐☐☐ (dd mm yyyy)

Occupation, or name of any school/childcare centre attended (please specify)

Recent travel overseas ☐ No ☐ Yes _____ (please specify)

Infection acquired ☐ WA ☐ Interstate ☐ Overseas

Country of birth ☐ Australia ☐ Other _____ (please specify)

Ethnicity ☐ Aboriginal or Torres Strait Islander ☐ Other

3. DETAILS OF CONDITION

How was infection identified? ☐ clinical presentation ☐ contact tracing ☐ screening

Date of onset ☐☐ ☐☐ 20☐☐ (dd mm yyyy) Date of death (if applicable) ☐☐ ☐☐ 20☐☐ (dd mm yyyy)

Was the patient hospitalised? ☐ No ☐ Yes

CONFIRMATION OF DIAGNOSIS

☐ lab ☐ lab pending ☐ linked to lab-confirmed case ☐ clinical only

If lab confirmed, specify method _____

FOLLOW-UP/CONTACT TRACING (☑ tick one or more boxes below)

☐ Client informed that DOH may investigate possible contacts/sources

☐ All contacts have been/will be tested and treated by me

☐ Other _____ (please specify)

4. DOCTOR/HOSPITAL DETAILS (must be complete and legible)

Name ..... ☐☐☐☐☐☐☐☐ telephone (essential)

Address ..... ☐☐☐☐☐☐☐☐ fax (optional)

..... ☐☐☐☐ postcode

Signature Date ☐☐ ☐☐ 20☐☐

Tick this box if you require more forms and pre-paid envelopes (or print from www.notifications.health.wa.gov.au). ☐

5. NOTIFIABLE INFECTIOUS DISEASES

☑ Tick box below

WA Health Act (1911). Please notify ☎ conditions by telephone, plus food-borne illness (2 or more linked cases), and enteric infection in a food handler, health professional or child care worker. Otherwise fax or post the notification form.

- ☐ Adverse event following immunisation – USE SEPARATE FORM
- ☐ Amoebiasis
- ☎ ☐ Amoebic meningitis
- ☎ ☐ Anthrax
- ☎ ☐ Arboviral encephalitis (MVE, Kunjin, JE, other: specify _____)
- ☐ Barmah Forest Virus infection
- ☎ ☐ Botulism (food-borne)
- ☐ Brucellosis
- ☐ *Campylobacter* infection Species:_____
- ☐ *Chlamydia* (genital infection)
- ☎ ☐ Cholera
- ☐ Creutzfeldt-Jakob Disease (CJD: classical or variant)
- ☐ Cryptosporidiosis
- ☐ Dengue fever
- ☐ Giardiasis
- ☐ Gonorrhoea Penicillin sensitivity: ☐ Yes ☐ No ☐ unknown
- ☎ ☐ Haemolytic uraemic syndrome
- ☎ ☐ *Haemophilus influenzae* type b infection (invasive)
- ☎ ☐ Hepatitis A
- ☐ Hepatitis B ☐ newly acquired (<2 yrs) ☐ carrier/unspecified
- ☐ Hepatitis C ☐ newly acquired (<2 yrs) ☐ unspecified
- ☐ Hepatitis (other) ☐ D ☐ E
- ☐ HIV/AIDS – USE SEPARATE NOTIFICATION FORM
- ☐ Hydatid disease
- ☐ Influenza ☐ A ☐ B
- ☎ ☐ *Legionella* infection Species:_____
- ☐ Leprosy
- ☐ Leptospirosis
- ☎ ☐ Listeriosis
- ☎ ☐ *Lyssavirus* infection (ABL, other: specify:_____)
- ☐ Malaria Species:_____
- ☎ ☐ Measles
- ☐ Melioidosis
- ☎ ☐ Meningococcal infection ☐ meningitis ☐ septicaemia
- ☐ Methicillin Resistant *Staphylococcus aureus* (MRSA) infection
- ☐ Mumps
- ☎ ☐ Paratyphoid fever
- ☐ Pertussis
- ☐ Pneumococcal infection (invasive)
- ☎ ☐ Poliomyelitis
- ☐ Psittacosis (ornithosis)
- ☐ Q fever
- ☎ ☐ Rabies
- ☐ Ross River Virus infection
- ☐ Rotavirus
- ☐ Rubella ☐ non-congenital ☐ congenital
- ☐ *Salmonella* infection Serotype:_____
- ☐ Scarlet fever
- ☐ Schistosomiasis (Bilharzia)
- ☎ ☐ Severe Acute Respiratory Syndrome (SARS)
- ☎ ☐ Shiga toxin (Verotoxin) producing *E coli* (STEC/VTEC) infection
- ☐ Shigellosis (Bacillary dysentery) Species:_____
- ☐ Syphilis ☐ 1° ☐ 2° ☐ early latent (<2 yrs) ☐ late latent ☐ 3° ☐ congenital
- ☎ ☐ Tetanus
- ☐ Tuberculosis
- ☎ ☐ Typhoid fever
- ☐ Typhus (Rickettsial infection)
- ☐ Varicella ☐ chickenpox ☐ zoster ☐ unspecified
- ☐ *Vibrio parahaemolyticus* infection
- ☎ ☐ Viral haemorrhagic fevers (Crimean-Congo, Ebola, Lassa, Marburg)
- ☎ ☐ Yellow fever
- ☐ *Yersinia* infection

RARELY NOTIFIED DISEASES

☎ ☐ Diphtheria ☎ ☐ Plague ☎ ☐ Smallpox ☎ ☐ Tularaemia
☐ Chancroid (soft sore) ☐ Donovanosis (*Granuloma inguinale*)

6. CLINICAL COMMENTS

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16.0 Abbreviations

ACIR	Australian Childhood Immunisation Register
ACSOM	Advisory Committee on the Safety of Medicines
ADRAC	Australian Drug Reactions Advisory Committee
AEFI	Adverse event following immunisation
AHMAC	Australian Health Ministers' Advisory Council
AHPC	Australian Health Protection Committee
AIVC	Australian Influenza Vaccine Committee
ATAGI	Australian Technical Advisory Group for Immunisation
CACH	Child and Adolescent Community Health, WA Department of Health
CDCD	Communicable Disease Control Directorate, WA Department of Health
CDNA	Communicable Disease Network Australia
CIC	Central Immunisation Clinic
CMO	Chief Medical Officer
CSL	Commonwealth Serum Laboratories
DOH	WA Department of Health
DoHA	Commonwealth Department of Health and Ageing
ED	Emergency Department
GP	General Practitioner
GPII	General Practice Immunisation Incentive
GPNWA	General Practice Network Western Australia
FC	Febrile convulsions
IGCAHRD	Intergovernmental Committee on AIDS, Hepatitis C and Related Diseases
JHC	Joondalup Health Campus
MDC	Meningococcal Disease Committee
MNTH	Metropolitan Non-teaching Hospital
NAMAC	National Arbovirus and Malaria Advisory Committee
NEPSSSC	National Enteric Pathogen Surveillance Systems Steering Committee
NIC	National Immunisation Committee
NICRS	National Centre for Immunisation Research & Surveillance
NIP	National Immunisation Program
NMAHS	North Metropolitan Area Health Service
NPHP	National Public Health Partnership
NSC	National Surveillance Committee
NTAC	National Tuberculosis Advisory Committee
OMSM	Office of Medicines Safety Monitoring
PHC	Peel Health Campus
PHU	Public Health Unit
PMH	Princess Margaret Hospital
RGH	Rockingham General Hospital
RNA	Ribonucleic acid
SA	South Australia
Tas	Tasmania

TGA	Therapeutic Goods Administration
TIV	Trivalent Inactivated Influenza Vaccine
TOR	Terms of Reference
WA	Western Australia
WACHS	WA Country Health Service
WAIVE	Western Australian Immunisation and Vaccine Effectiveness Study
WHO	World Health Organisation

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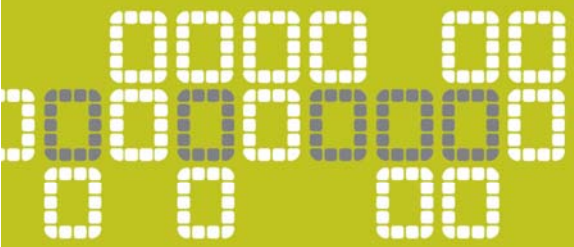

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