The Ethics of Childhood Influenza Immunisation:
Should Australian children be immunised against influenza?

By

Judy Wilyman

PhD Candidate

Abstract:

Objective: The Western Australian Government began a campaign in 2008 to promote the influenza vaccine free to children 6 months to 5 years of age. A decision to include another vaccine on the childhood immunization schedule should be based upon accurate scientific knowledge not a fear campaign. This paper investigates the evidence being used to promote this vaccine. It also examines the ethics of adding another vaccine to the already full childhood schedule and the information this decision is based upon. **Methods:** Methodology involved a literature review of Health Department policies and medical journals. In particular, this research examines the Cochrane Systematic Review of influenza vaccines and whether the evidence from this study is being used to develop immunization policies. **Results:** The study finds that influenza is not a serious risk for most children. It also finds evidence that inactivated flu vaccine is ineffective in children under 2 years of age – the age of most complications. **Conclusion:** It concludes that it is inappropriate and unethical to add another vaccine to the childhood schedule if the majority of children are not at serious risk from this disease and if the vaccine is not proven to be effective. The promotion of this vaccine to the public in WA has been based on a fear campaign and not scientific evidence. **Implications:** There is much debate about the use of multiple vaccines in children. Mandatory and coercive policies are unethical if the evidence is inconclusive and promotional campaigns are based upon fear and not facts. Authorities should select carefully the vaccines that are recommended to children and adults.

Keywords: children's influenza vaccine, risk assessment, ethics

Introduction:

Western Australia is the first Australian State to participate in a campaign offering free influenza vaccine to children. This campaign is being conducted through the Telethon Institute for Children's Health Research and funded by the vaccine companies – CSL Laboratories and Sanofi - Pasteur at a cost of $1.2 million (1a). The stated purpose of the trial is a pre-emptive attempt to protect young children from influenza and to assess the efficacy of the vaccine in preventing influenza in the community (1a).

There are a number of ethical questions that should be examined before we continue to add more vaccines to the already full childhood schedule. In Australia in 2010, parents are being coerced into using 13 vaccines in their infants under two years of age (2a). In order to opt out of this procedure parents must sign a conscientious objectors form that must also be signed by a doctor (2a). Although vaccination in Australia is not compulsory our right to choose this procedure has been compromised. Parents are made to feel it is their responsibility to vaccinate. This is a very ethical issue as there are risks in taking a vaccine as well as risks in getting a disease. This paper investigates the risk assessment of vaccines to determine what evidence is being used to support immunization policies.

An important question that needs to be supported by evidence-based science is: *should we be using multiple vaccines in children whose body systems are still developing and if so how many?* In order to answer this question we need to look at the hard evidence we have available to claim it is safe to use multiple vaccines in children's bodies. The most conclusive evidence for determining the health effects of combining multiple vaccines in infant bodies comes from long-term prospective studies on animals and humans (3). This type of study provides the most conclusive evidence for the multiple health effects of the combined immunization schedule because it illustrates the cumulative, synergistic and latent effects of the chemicals in vaccines (4). A search of government and medical documents shows neither of these studies has been done (2b). This means that advisory committees on immunization policy are making value judgments about the safety of using multiple vaccines in infants without this hard evidence. The evidence being used by advisory committees to claim it is safe to use multiple vaccines in infants comes from short-term epidemiological (statistical) studies observing one or two vaccines at a

time (2b). This does not give us the complete picture of how the combination of vaccines will affect children's health.

In the absence of conclusive evidence on the safety of childhood immunization, data on the ecological health of Australian children should be examined to determine if it is suggestive of a link between the use of multiple vaccines and the significant increase in chronic illness that has been observed in children over the last couple of decades. This research examines this evidence.

We must also establish whether influenza is a serious risk to the majority of children before recommending the vaccine and if it isn't a serious risk, what other reason could there be for vaccinating. In order to recommend the vaccine to children the government must support the recommendation with evidence of the effectiveness of the vaccine. Other ethical issues that need to be considered in our assessment of this childhood vaccine relate to the way in which the vaccine is promoted to parents: *is the vaccine promoted on accurate and balanced information about the risks of the disease and the risks and efficacy of the vaccine?* This paper discusses and evaluates this evidence with respect to the underlying ethical principles of public health policies.

Methods:

The methodology for this research involved a literature review of government health department documents and medical journals to determine why influenza has been included in the childhood schedule of vaccines. The analysis included information on the risk of influenza to the majority of children as well as the effectiveness and safety of the vaccine. In order, to determine whether influenza is a serious risk to children mortality and morbidity data was collected for children in Western Australia and nationally. The influence of social conditions was considered in this assessment and also the opinion of doctors that was obtained from a published survey. In order to determine if the combination of childhood vaccines is a risk to children's health the ecological evidence of Australian children has been investigated to see if the rise in chronic illness is correlated with the increase in the use of childhood vaccines.

This research analyses the government's stated reasons for including this vaccine on the childhood schedule and makes a comparison with the recommendations from the CDC's Advisory Committee on Immunisation in America. The methodology also included information

from the Cochrane Systematic Review of Vaccines relating to the efficacy of influenza vaccine in different age groups. An attempt was also made to obtain documents which have evaluated influenza hospitalization and mortality data for previous influenza campaigns such as those for the elderly. This was to ensure that these campaigns are being promoted because they are achieving the desired outcomes.

The discussion of the ethical issues of childhood influenza immunization has been based upon two fundamental ethical principles of public health policies:

1. The requirement of health practitioners "To practice and prescribe to the best of my ability for the good of my patients and try to avoid harming them" and " To keep the good of the patient as the highest priority" as stated in the AMA ethical code (5)
2. The Precautionary Principle. This public health principle states that the burden of proof of harmlessness of any new procedure / chemical is on the proponent and *not* the general public (1f).

This research assesses the data to see if these principles have been utilized in the implementation of this policy. It examines the way in which the vaccine has been promoted to parents and uses all the data collected to make conclusions about the implementation of this policy in Western Australia.

Results:

An investigation of the mortality data for influenza indicates that the number of deaths for children under 5 years of age in Western Australia is between 0 – 3 deaths per year (6). This has been the number of deaths for the last 4 decades and is similar to all other Australian states (6). National deaths from influenza in children under 5 have been between 0-3 since 1977 (6). These statistics do not justify the general vaccination of children for influenza (7).

It is stated in the Cochrane review of influenza vaccines that the consequences of influenza in children and adults is mainly absenteeism from school and work (8). The hospitalization and mortality data shows that the risk of complications and deaths from influenza is greatest in people over 65 years old and that there is an increased risk of complications from influenza in children under 2 (6).

The assessment of the risk of this disease should also include the morbidity from complications of influenza and an assessment of the social circumstances surrounding hospitalized cases.

Social conditions should be assessed with cases of this disease because the incidence of infectious diseases increases with poor living standards and other social factors such as nutrition (9). Currently this data is not reported (1e). It should also be noted that a decision to vaccinate all children for influenza should not be based upon data from other countries as local factors such as living conditions, nutrition, available healthcare and patterns of childcare will affect the benefits of using the vaccine (7). The excess rates of influenza-related hospitalization vary substantially by age, season and country (7). Yet the Western Australian Health Department has based its childhood influenza campaign on data from other countries (1b).

It is observed that the attack rates for influenza are consistently high in children during annual outbreaks (7). However, even when the attack rates are 20-30% it is known that the majority of these children make a full recovery and discomfort is the main symptom of illness (7). It is known that epidemics of influenza are "generally very mild" (7, p.225)

A recent survey of US pediatricians illustrated that 43% actively opposed the universal vaccination of children and 27% were unsure (7). This would not be the case if health professionals considered influenza to be a serious risk to children. These are front line health professionals who observe the risk of this disease on a daily basis. In addition, 50% of pediatricians were concerned about the safety of the inactivated vaccine (7).

Bacterial illnesses such as acute otitis media, croup, bronchitis, pneumonia and other respiratory diseases such as asthma are considered complications of influenza. These are described as influenza-associated hospitalizations and are highest in children younger than 3 years of age (7). Most children with influenza-associated conditions are not hospitalized and it is observed that infants and young children with underlying medical problems are at highest risk of being hospitalized (7). The highest risk of influenza-associated hospitalization is in infants under 6 months of age yet the inactivated influenza vaccine is only licensed for use in children 6 months and over (7).

The Australian mortality data for influenza and a survey of doctors indicates that this disease is a very low risk for children. In addition, Heikkinen et al (2006) state "influenza-associated

mortality in children is extremely low" (7, p.224). A decision to use an influenza vaccine for all children should be based upon accurate information of the risk of the disease and its associated complications versus the effectiveness and safety of the vaccine.

Today's children receive multiple vaccines and inclusion of the influenza vaccine results in some children receiving up to 14 vaccines before five years of age (1c). The combination of multiple vaccines must be considered when weighing up the risks of diseases as vaccines contain antibiotics, preservatives and aluminium adjuvants that are known allergens and neurotoxins (10). The cumulative and synergistic effects of the increased number of vaccines must be considered. It is also necessary to determine how effective the vaccine is in preventing influenza in the community.

Safety and Efficacy of Influenza Vaccine

Influenza is a disease that is caused by many strains of virus, however the vaccine only protects against one to three strains depending on the type of vaccine used (1d). The government uses two definitions to describe the effectiveness of the vaccine. The term *efficacy* is used to describe how well the vaccine protects against the 3 strains of influenza covered by the vaccine. For example the current vaccine protects against Type A (H1N1), Type A (H3N2) and Type B (1d). The term *effectiveness* of the vaccine is used to describe the ability of the vaccine to protect against 'influenza-like illness' (ILI), that is, the influenza cases that are not laboratory confirmed and the strain of virus is unknown (1d).

Therefore, some ILI will be caused by strains of virus that are present in the vaccine and these cases will not be recorded in the surveillance of influenza. So the only real indicator of whether vaccine programs are reducing the incidence of influenza in the community is to monitor the hospitalizations and death due to all influenza-like illness (ILI) each year – not just a percentage of cases that are sub-typed for strains covered by the vaccine. At present the WA government is reporting only on some hospitalizations that are sub-typed for the strains of influenza covered in the vaccine to support its policy (1e).

Influenza viruses spread easily and new strains develop regularly (11).The World Health Organization (WHO) recommends the strains that should be included in the vaccine for each new season (11). This prediction occurs a year in advance in order to have the flu vaccine ready for

the new season. Scientists must predict which strains of the virus will be most severe and the vaccine will only be effective if a good match has been made (11). But the government must still provide evidence to the public that a well matched vaccine will reduce the incidence of influenza-associated illness in the community. It is possible that because there are many viruses causing influenza illness in the community reducing the circulation of 2 or 3 will not reduce ILI in the community as other strains of influenza will infect.

This is another reason why it is important to analyze hospitalization and mortality data to ensure this program is achieving its outcomes. An assessment of this data will confirm whether predicting the most severe strain of influenza virus a year in advance is a successful strategy.

In Australia the flu vaccine has been offered free to people 65 years and older since 1999. This program has had an uptake rate of 79% (2b). The strongest evidence for the effectiveness of this campaign would be an analysis of the hospitalization data and deaths in this age group since the program started ten years ago. This analysis has not been published or presented as evidence in the formulation of current influenza policy (12).

A recent Cochrane Review of all the studies conducted on the effectiveness of influenza vaccines in children stated that the efficacy of inactivated vaccines for children under two (against strains contained in the vaccine) was similar to placebo, that is, not effective at all (8). It should also be noted that the Cochrane Review states that neither type of influenza vaccine – inactivated or weakened influenza viruses (nasal sprays) were good at preventing ILI in children over 2 (8). This is significant because ILI cases are those caused by other influenza strains and respiratory viruses plus a percentage caused by strains covered by the vaccine. Whilst Heikkinen et al (2006) claim the average *efficacy* of inactivated vaccines in children is 70-80% they admit that *effectiveness* in the community is substantially reduced against influenza-like illness (7).

It was also concluded in the Cochrane Review that due to the variability in study design an analysis of safety data for influenza vaccines in children was not feasible (8). Inactivated vaccines are the most commonly used vaccines in young children and only one safety study has been done of these vaccines in children under two years of age (8). Heikkinen et al, 2006, claim the vaccine to be “safe and effective” but do not support this statement with evidence (7, p.224). In addition, there are no long-term health studies that have examined the safety of influenza

vaccines when combined with multiple other vaccines in children (12). In other words, our scientific knowledge on this issue is incomplete.

Despite significant coverage of the influenza vaccine in the Australian community for many years, both in the elderly and in workplaces, 2007 was described as a severe flu season with notifications being 3.4 times the 5 year mean (13) In Western Australia it was described as being the worst flu outbreak in four years (14). This evidence is not an indication that influenza vaccine is reducing the incidence of this disease in the community.

Although notifications for this disease are highest in the 0-4 year age group this is not a reflection of the severity of the disease in the population. This is because influenza is only considered a serious disease in the elderly and immune compromised and the majority of individuals make a complete recovery after several days (7, 15, 9).

The Health of Australian Children

Our knowledge of the effects of vaccines has now been collected for over 100 years. It is important to look at the ecological health of the population as well as the statistics collected over this time to ensure this procedure is safe. This is because statistics can hide many variables. The ecological evidence is showing that the health of children has not improved as the number of vaccines on the childhood schedule has increased (16). Chronic illness in children has risen dramatically in the last 2 decades and this coincides with the government's push to increase vaccination rates in Australia to 95% with the implementation of the Immunise Australia Program in 1993 (2a).

Children's health and the health of society are dependent upon scientifically proven preventative policies. If it is biologically plausible that the ingredients of vaccines can cause the increase in chronic illness we are observing in children then this possibility must be investigated. The increase in autoimmune diseases in dogs and cats has already been linked to vaccines and we must consider this same possibility in children (17, 18).

In determining the effects of combining vaccines in children it is also important to recognize that there are gaps in our scientific knowledge regarding human immunology. For this reason many of our decisions regarding this practice have become value judgments and this paper discusses

the ethics of how these value judgments are being made in place of scientific debate involving all stakeholders.

The Evaluation and Promotion of Influenza Immunisation in Western Australia

It appears the WA Health Department is using evidence from other countries to claim that influenza is a serious risk to children (1b). Australia is adopting the guidelines set by the Centre for Disease Control's Advisory Committee on Immunization Practices (ACIP, America) which state that annual vaccination of all children aged 6 months to 4 years should continue to be a primary focus of vaccination efforts because these children are at higher risk for influenza complications compared to older children (19). The ACIP also recommends that annual vaccination be administered to all children aged 5-18 years (19).

Western Australia adopted this initiative in autumn 2008. The WA Health Department promoted free childhood influenza vaccines through an advertising campaign in the media. The advertisements used the deaths of three children in 2007 to suggest influenza is a serious risk to all children (14). Further examination of these deaths revealed that the cause of death for these three children was inconclusive and still subject to a coroner's report at the time (1b). The Director of the flu campaign, Dr. Paul Van Buynder stated the information on these deaths was restricted to the public yet the information was used in a state based media campaign (1b). These deaths represent anecdotal evidence of the risk of influenza to children and it was revealed in the media that only one of the children was confirmed with Influenza A as opposed to all three children that the vaccine advertisement had implied (14).

Discussion

Children are considered the main transmitters of influenza in the community (7). Heikkinen et al (2006) therefore suggest it is logical to assume that vaccinating children would lead to substantial reductions in parental work loss due to caring for sick children (7). They also suggest it could lead to decreased morbidity and mortality in the elderly. This is an assumption that ignores the theory of opportunistic infection. It is possible that because there are many strains of

influenza viruses circulating in the community, reducing the incidence of 2 or 3 will still leave individuals susceptible to other circulating strains.

The fact that severe outbreaks of influenza are still being observed despite vaccination campaigns would appear to support this theory. In other words, matching for 2 or 3 strains of influenza virus is not affecting the incidence of influenza-associated illness (ILI) or deaths in the community because there are many other strains that cause influenza like infection.

Heikkinen et al (2006) state that the "average efficacy of inactivated influenza vaccine is approximately 70-80%" (7, p.226). That is, it will reduce 70-80% of influenza caused by the strains of virus covered by the vaccine. These authors then imply that the vaccine will reduce rates of illness, influenza-associated complications and hospitalizations among vaccinees by the same percentage. However, they admit that the overall effectiveness of the vaccine will be reduced substantially in the community because of the other respiratory viruses (including other strains of influenza) in circulation. Therefore, predicting the percentage decline of illness caused by the vaccine in the community is not possible (7). Empirical evidence is essential because of the many variables.

As the viral etiology of respiratory infections is rarely determined in outpatient settings vaccinated children will still suffer febrile infections during winter because the vaccine only covers 3 of the many respiratory viruses circulating in the population (7). Many of these will be caused by influenza virus strains not covered in the vaccine.

The evidence being used by policy-makers regarding the efficacy of influenza vaccine is derived from random and quasi-randomised controlled trials and observational studies (20). Jefferson (2006) explains that many of these studies are of poor methodological quality and are known to be affected by bias and confounding factors (21). As a result, these studies provide inconclusive evidence on vaccine effectiveness which leaves the issue open to scientific debate.

In order to provide more conclusive evidence on vaccine effectiveness in the community the government must provide the hospitalization and mortality data of all influenza-like illness monitored over the period of vaccine usage. Until this data is published the effectiveness of influenza vaccine will be debatable.

Conclusion

Influenza has been promoted to the public in WA as a serious risk to children even though the influenza-associated mortality for children is described as very low. The children at highest risk from influenza are children under 6 months of age and the vaccine is not licensed for this age group. In addition, the inactivated flu vaccine has been described as ineffective for children under 2 and this is the group with the highest complications to flu. The other reason for vaccinating children is to see if it lowers the transmission of influenza in the community.

Statistics can hide many variables so it is important that the public is presented with information that best represents the incidence of influenza in the community. As it is not possible for hospitals to sub-type every case of influenza that is hospitalized, the government must monitor and report on all ILI to best show the effectiveness of the vaccine. This is because a percentage of these cases will be caused by strains covered in the flu vaccine. Monitoring ILI will inform us whether the theory of selecting to protect against 2 or 3 strains of influenza is effective in reducing the incidence and mortality of this disease in the community. It is possible that targeting 2 or 3 species only allows a space for one of the many other influenza viruses to cause infections. In this case there will be no reduction in hospitalizations due to influenza-associated illness.

A decision to use another vaccine in children for the benefit of the community must be based on accurate scientific evidence. It must also consider the risks inherent in adding an extra vaccine to the already crowded childhood schedule. Other evidence that should be used in the risk analysis of disease is the ecological evidence in the population. That is, the evidence at the population level not the individual level. It is important to observe overall trends in health when it is known that statistics can hide many variables. In the case of influenza campaigns and children's health, there are two ecological trends that are being observed: 1) communities are still experiencing outbreaks of influenza despite vaccination campaigns in the elderly and in workplaces 2) children's health has declined as the use of vaccines has increased.

Risk analysis is not wholly scientific in nature and value judgments are made when the science is absent. In the case of childhood immunization there are no long-term studies of the health effects of combining 12 vaccines in an infant. This gap in our scientific knowledge of the cumulative

and synergistic effects of vaccines in infants leads to disagreement on the risk involved and therefore different parties will make different value judgments regarding this risk.

A decision to use influenza vaccine must also consider evidence regarding the effectiveness of the vaccine. In 2008, when the WA campaign began, the Cochrane systematic review of vaccines did not suggest this vaccine was effective in children - particularly those under two. In addition, an analysis of hospitalisation data is an important way of ensuring that the outcomes of the influenza vaccination campaigns are being achieved and that the vaccine is effective.

The evidence suggests the Western Australian Government has run a fear campaign in the media, based on misinformation and anecdotal evidence, to encourage parents to vaccinate their children. If the government is misrepresenting the risk of influenza to children and over stating the benefits of the vaccine to the community this policy could have serious consequences for children's health and society. It also undermines the independent nature and credibility of the government. Vaccines are not without risk so it is important that value judgments about the necessity for a vaccine are made from non-biased sources. The government must therefore be seen to be openly informing parents on this issue. It is also essential that governments consider the possibility that multiple vaccines in infants are doing more harm than good particularly as this link has been described in veterinary journals and it is known that individuals can be genetically pre-disposed to chronic illness.

This research has implications for the use of mandatory and coercive immunization policies. The Precautionary Principle should be utilized in policy decision-making until the science on this issue is complete. Governments need to be more selective about the vaccines they recommend on the childhood schedule and immunisation policies should remain fully discretionary until the government can demonstrate that the community is seriously at risk if a vaccine is not used.

Judy Wilyman MSc (Population Health)

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