PhD Thesis on Vaccination Policy: Scholarly and Socially Relevant

1. Introduction:

In 2015 my PhD thesis investigating the control of infectious diseases in Australia and the design of the government's vaccination policies was accepted by the University of Wollongong (UOW). The thesis was published in open repository on the UOW website in January 2016. It rapidly came under attack from organised lobby groups and within one week of publication these lobby groups were calling for the thesis to be disapproved. However, the University of Wollongong responded saying that it stood by this research.

Three years later and for the first time, there has been an attempt to undertake a scholarly critique of my PhD thesis [1]. The critique alleges flaws in the thesis but in fact there are short comings in the critique. In this response to the critique I will provide a summary of the contents of my thesis and my responses to key claims that the authors made in their critique.

2. Summary of the Content of my PhD Thesis

My PhD makes four main critical points in relation to Australian government vaccination policy [2]:

1. The significant decline in deaths and illnesses from infectious diseases in Australia occurred before the introduction of most vaccines. This indicates that vaccination was not the main factor in controlling infectious diseases.
2. Australian vaccination policies have been designed from the World Health Organisation's recommendations for Global Health Policies. These recommendations do not consider the diversity of genetics in the population or the special ecological conditions that vary between all the WHO member countries. The WHO recommendations for vaccines are a one-size fits all policy in genetically diverse populations.
3. Most of the research on vaccine safety and efficacy that is used by government regulators and advisory boards is carried out or sponsored by pharmaceutical companies. These companies make a profit from selling vaccines. In addition most representatives on vaccine advisory boards have financial conflicts of interests with pharmaceutical companies. Research has shown that conflicts of interest in vaccine

research and on vaccine advisory boards can lead to bias in the design of clinical trials and the conclusions drawn from these studies.

4. There are important areas of research relevant to vaccination policy that have not been performed but are necessary to make claims of safety and efficacy. The undone science includes safety studies using a true inert placebo in the unvaccinated group. A plausible reason for this 'undone science' is that the findings will turn out to be unwelcome to the pharmaceutical companies and government who fund and promote vaccines.

3. The Title of the Paper by Wiley et al in the Journal *Vaccine*

The title of *Wiley et al.'s* paper 'PhD Thesis Opposing Immunisation' does not reflect the investigation that I undertook. My thesis does not oppose immunisation. It provides the evidence to oppose *mandatory* vaccination.

My thesis included an investigation of the historical decline of infectious diseases in Australia – a public health issue not a medical issue - and an assessment of the government's reasons for expanding the vaccination schedule in the 1990's and then *mandating* sixteen vaccines in government policies in 2016, vaccines that most adults had never used.

The authors have misused the term 'immunisation'. My research does not oppose immunisation nor is it discussed in my thesis in this way. My thesis was an investigation of the contribution that *vaccines* have played in reducing the deaths and illnesses to infectious diseases in Australia and whether this has been done without causing significant harm in the community. Vaccination is not immunisation and my conclusions were not about immunisation.

My thesis provides evidence that vaccines are not safe for all children and that children's health in Australia has significantly declined since the vaccination program expanded in 1990. The thesis argues that the chemicals in vaccines are a plausible cause of this rise in illnesses/disability and deaths in children and this needs to be considered in a debate about how many vaccines are necessary to use in children.

4. The Motive for my Research

In several places in this paper the authors have asserted that 'I started from a pre-determined position' about vaccination implying that this was a position opposing immunisation.

Actually I started this research after ***vaccinating my children*** and I do not have any vaccine damaged children.

I have provided an assessment of the historical literature using a systematic methodology that is discussed in Sections 1.2 and 1.3 of the thesis – contrary to the authors' assertions that there was 'no systematic literature review'. The authors have not addressed the specifics of my methodology described in the thesis.

5. The Authors' Conflict of Interest

A key theme in my thesis is the importance of considering conflicts of interest (COI) in the making of vaccination policy. It is therefore appropriate to consider COI of these authors.

Two of the four authors have been involved in the recommendations for Australia's vaccination policies for over 20 years and they have a significant conflict of interest in writing this critique because they are defending their own decisions in these policies. Margaret Burgess and Peter McIntyre were the founding directors of the government National Centre for Immunisation Research and Surveillance *(NCIRS).*

Margaret Burgess was the founding director from 1997 – 2005 and Peter McIntyre was the deputy-director during this time and he became the director from 2005 – 2018. These authors have been involved in designing the Australian government's vaccination policies for the last 21 years – the period over which the national program expanded.

Julie Leask and Kerrie Wiley are also based at the University of Sydney with the NCIRS. Julie Leask surveyed the population to assess the reasons why parents are hesitating to vaccinate and the authors have used her research as the premise for their critique of my PhD thesis.

In other words, they have started from the premise that my academic research is influencing people's decisions on vaccination and they have attempted to reduce its credibility with false and misleading claims. This has been done instead of debating the research in public forums where the government's claims can be challenged.

Their reluctance to debate my research was demonstrated in October 2015 when Peter McIntyre and Julie Leask declined to attend a public forum at the University of Technology Sydney to discuss the evidence for implementing mandatory vaccination policies in Australia [3].

This reluctance to publicly debate the evidence for mandatory vaccination policies was observed again in September 2018. At this time Peter McIntyre was drafted into a Queensland court case, out of proceedings, to respond to my affidavit regarding the vaccination of four children. My affidavit was leaked to the *Sydney Morning Herald* when Peter McIntyre was drafted into the case. This is a federal crime that has been reported to the Australian Federal Police. This criminal offence, presumably by the government's team, prevented the case from being heard and debated in the Federal Circuit court.

Wiley et al have referred to this incident in their critique (p1544) and have referenced this incident with a newspaper article that provides false information about my research.

6. Responses to Specific Claims by *Wiley et al* (Their claims are in Italics):

1. *My PhD thesis was a 'non-systematic descriptive review of the literature with reference to the Australian national vaccine program'*

   The focus of my thesis and the methodology used are described in Sections 1.2 and 1.3 of the thesis.

2. '*The thesis used no primary research and it mostly used the HPV vaccine and the H1N1 2009 influenza vaccine to illustrate its three main claims.'*

   The thesis has used primary sources where it was possible to do so particularly for the historical data on the decline of infectious diseases in Australia. With respect to the government's vaccination program I could only use the government data that was publicly available because any requests for other government documents regarding vaccine safety and efficacy (the material that Wiley et al call 'grey matter') was declined by the government. Responses to these email requests resulted in standard letters stating that 'vaccines are safe and rigorously tested for safety'. Hence my thesis is a critique of the publicly available information on vaccine safety and efficacy.

   The claim that the HPV and Flu vaccines were used as evidence for the three main claims in my thesis is not supported by the summary of the four main points presented above.

3. *Wiley et al have stated that the first of my three main overarching claims is that 'vaccines are unnecessary'.*

   This claim was not made in my thesis. I stated that the government has not provided transparent evidence for the role that vaccines have played in the decline of infectious diseases in Australia. I stated that vaccines may have played a role but the government has not demonstrated this with Australian evidence. I also provided evidence that the majority of this decline occurred before most of the 16 vaccines were developed.

4. *Wiley et al have used Stanley 2001 to claim that vaccines have contributed to the reduction of infant deaths.*

   Stanley et al actually stated: 'Infectious deaths fell before widespread vaccination was implemented' (Stanley, 2001) and she made other comments to this effect [4]. This is an important fact to acknowledge yet the authors have ignored it. Vaccines may have contributed to the decline in infant deaths but if so it was a small contribution that Stanley did not quantify. The risk of death and illness had been reduced for the majority of Australians by 1950/60 as stated by Stanley and all the prominent public health officials of the twentieth century.

   In Australia measles, whooping cough and influenza were removed from the National Notifiable Disease list in 1950 because they were no longer considered diseases of serious concern. The non- serious cases of these diseases still occurred but were not monitored from 1950 – 1988 in Australia because the majority of cases were mild or asymptomatic and resulted in long-term immunity and good community protection. There was no measles vaccine in Australia until 1970 and then it was voluntary. Today the government and mass media report on the non-serious cases of these diseases without informing the public of this or of the vaccination status of the case. This is to encourage the uptake of the recommended vaccines based on the *assumption* that vaccines control these diseases and that all cases of measles infection are 'a public health emergency'. In Perth, WA in January 2019 a single confirmed case of measles resulted in the headline 'WA Health Department Issues a Measles, Alert for Perth Zoo, Ikea and the South West' [5].

Wiley et al have used a reference from 2016 to make a claim about the reduction of deaths due to vaccines. This analysis was not available in 2015 when my thesis was accepted.

5. *Wiley et al claim 'the Australian schedule is set according to best evidence as assessed by ATAGI, not according to WHO directives.'*

In Chapter 3 of my thesis (3.4 p56) I provide the evidence to show that the ATAGI advisory boards are set up in all WHO member countries and they receive advice from the GAVI alliance through the WHO. They are referred to as National Immunisation and Technical Advisory Groups (NTIAG). An important aspect of Australia's vaccination policies is the fact that they are recommended by the WHO under Global Health Policies**.**

6. '*Data used in assessment of risk is Australian where possible, if not, data from other comparable populations is used.'*

The evidence in government policy documents and in the Australian mainstream media of the death rates from infectious diseases is generally the death rates from developing countries – completely *unrepresentati*ve of the Australian situation, a developed country. The comment states 'where possible'. Why is there any situation where the government cannot support its vaccination program with Australian death and disease incidence rates?

7. '*Risk/benefit analysis is done for each vaccine included in the Australian schedule, often using population-specific data'.*

There is no publicly available evidence for this. The government has not provided a transparent risk/benefit analysis for any Australian vaccine to demonstrate that it is using Australian specific data. This data has been requested but never provided to the public. The government uses mathematical models and non-transparent data for the cost-effectiveness assessment of vaccines and the criteria and assumptions of

risk/benefit used in these models are not transparent to researchers or made available to the public.

8. '*There is a wide range of evidence used for various vaccines including RCT's which tested the vaccines for biologically sound and ethically and technically feasible end-points.*'

   I studied the clinical trials for many different vaccines and a standard feature of the RCT's was the lack of an inert placebo in the unvaccinated group and a lack of follow up for long-term health effects. Many trials only use days or weeks of follow up yet the researchers know there can be a latent period of years before many chronic illnesses will develop. This is due to the latency period of the chemical response in the human body. The TGA cannot provide safety studies that use inert placebos over a period of 1- 5 or more years.

9. '*Active safety surveillance is in place in a number of sentinel institutions for an increasing number of vaccines. More recently there is a PAED's*.'

   In 2015 when my thesis was accepted both the TGA and the CDC had admitted that they did not have a surveillance system that could determine causal links to the vaccines. Consequently there are 158 known AE's that have been associated by the pharmaceutical companies with the vaccines for decades yet the government and doctors claim that these are just 'a coincidence' after vaccines are administered.

   For six decades the government has not made any attempt to design RCTs using an inert placebo to study the safety of vaccines. This is the only type of study that can prove or disprove a causal link to the vaccine. Nor are doctors and governments (including the TGA) required to mention the deaths and serious illnesses associated with the vaccines before they implement legislation or give vaccines to patients. The suggestion that active surveillance is now 'in some institutions for an increasing number of vaccines' does not refute my conclusions. It suggests that the government has started to do something about this undone science because the public has become aware that governments do not have the complete scientific evidence to claim that all

vaccines are safe or that the combined schedule of vaccines is safe in the infant or adult body.

10. '*There is a failure to include or address the majority of HPV vaccine safety and efficacy studies and reviews which contradict the arguments of the thesis*.'

The authors have supported this claim with a systematic review of HPV vaccine that was published in 2015. This review was not available when my thesis was completed in 2015. There have also been many controversial reviews of the safety of the HPV vaccine since 2015 and simply citing this review, without any assessment of the studies it included, does not in itself provide contrary evidence to the conclusions about safety that I provided in my thesis.

11. '*The thesis asserts that vaccines are unnecessary*.'

This is not an accurate representation of my conclusions. I have provided definitive evidence that children's health has declined since the introduction of many recent vaccines and hence the current vaccination program cannot be described as a 'protective health program'. I have also provided definitive evidence that the majority of Australian children were not at serious risk of death or illness due to infectious diseases *before* the vaccines were introduced. Hence I have suggested that *some* vaccines are unnecessary and that no vaccine has ever created herd immunity in a community by being used with an uptake rate of 95% to reduce deaths and illnesses to any infectious disease. This means there is no justification to mandate any vaccine in government policies in Australia.

Wiley et al use a study from the Netherlands (2016) to support their claim that vaccines significantly reduced infant mortality from 1950 onwards. However this study is not relevant to my conclusions because most of the vaccines that have been mandated in Australia were not developed in 1950. Further, the Netherlands paper was not published until *2016* – after my thesis was published so it could not have been included in my discussion. The other study that the authors have used to support their claim that 16 vaccines are necessary in Australia is a study from Gambia in 2005 of

the *pneumococcal vaccine.* This paper doesn't provide evidence to support the claim that 16 vaccines are necessary for community health in Australia.

12. '*HPV vaccine significantly reduced high-grade cervical pre-cancer lesions and had an excellent safety profile but these reviews and the literature they discuss are not referred to in the thesis.'*

When my HPV research was published in the *Infectious Agents and Cancer Journal* (2013) [6] [7] the editors ensured that another article written by Hawkes et al (June 2013) was published at exactly the same time [8]. I have provided an analysis of the lack of evidence provided in the Hawkes et al paper in Appendix 5 of my thesis and this includes addressing the claim that HPV vaccines 'reduced high-grade lesions' and that HPV vaccines are 'safe'.

13. '*The thesis fails to present a full account of the technical information used to evaluate vaccines for inclusion on the Australian national schedule.*'

I wrote many letters to the Health Department, the Human Rights Commissioner, the Chief Medical Officer and the Health Ministers requesting the evidence that they have used for a systematic risk assessment of vaccines. On all occasions this resulted in a standard letter of response stating 'vaccines are safe and effective'. Many of these letters are published on my website. Hence the suggestion by Wiley et al that I should have interviewed ATAGI representatives to get this information is of note because it shouldn't have been necessary – the information should have been provided to me on request. I consulted with several public health experts, epidemiologists and HPV researchers before my thesis was submitted for examination.

14. '*Those looking for balanced information about immunisation deserve a balanced critique of this thesis to aid them in their decision-making. We believe our critique serves as an accessible, objective and fair appraisal of the thesis, allowing valid assessment of its author.'*

This claim is written by prominent members of the NCIRS who have an interest in defending their recommendations for Australia's vaccination policy over the last two

decades. It is the NCIRS that should have provided the technical information that they claim is missing from my PhD.

7. Five Essential Questions that were not answered by the Australian Government before Mandating 16 Vaccines in Australian Social Welfare Policies

1) What are the statistics of vaccinated and unvaccinated children in Australia per year i) getting each of the 16 infectious diseases and ii) dying of these 16 infectious diseases?

2) Which global communities have used these 16 vaccines with a 95% uptake rate to control these diseases?

3) What statistics can you provide that show that the overall health of Australian children (chronic illness and other diseases) has improved since 1990 when the vaccination program expanded?

4) i) Are politicians and doctors informed of the ingredients of the 16 vaccines and the serious adverse-events that the pharmaceutical companies have associated with vaccines for six decades? (coincidence is not an ***evidence-based response***).
ii) Do politicians and doctors provide this information to the public and patients in a transparent manner before they recommend vaccines to the community?

5) i) What percentage of Australian children will die or be harmed by this policy because of the known side-effects of the chemicals in the vaccines and the hidden effects that occur in individuals due to their genetic make-up?
ii) What AE's have you included in the risk assessment for each vaccine and how did you arrive at this risk assessment?

Until this evidence is provided by the government in a transparent manner there is no justification to mandate any vaccine in Australian Social Welfare or Public Health Policies.

References:

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