CHAPTER 3 GLOBAL HEALTH POLICY AND AUSTRALIA'S NATIONAL IMMUNISATION PROGRAM (NIP)

PART 1 GLOBAL PUBLIC HEALTH POLICY

3.1 Introduction

This chapter provides an overview of global health politics during the 1990's when the Australian government was developing its National Immunisation Program (NIP). Australia's vaccination policies were part of a global vaccination campaign that was directed by the WHO/UNICEF and aimed to increase the vaccination rates of children in all countries. Global health politics in the 1990's provide an explanation for the Australian government expanding its NIP at a time when infectious diseases were a very low risk to Australian children. See chapter 2. The development of global vaccination policies and the Australian NIP from 1990 are described in this chapter.

This chapter also provides a discussion of the strategies that have been adopted in Australia to emphasise the responsibility of individuals to participate in vaccination programs. These strategies pressure the public to use a medical procedure 'for the good of the community'. The theory of 'vaccine-created' herd immunity has been used by the government to suggest that high participation rates in vaccination programs are necessary to *prevent* infectious diseases. A discussion of the Australian government's reason for emphasising participation rates in vaccination programs is provided here as well as the reason for increasing the number of vaccines recommended in the NIP. I have also provided a discussion of the ingredients of vaccines because the increased use of vaccines increases the risk of adverse events due to the excipients and non-human protein combined in the vaccine carrier.

Recently the government has implemented recommendations for vaccines to be mandatory in a number of Australian workplaces. A discussion of the implementation of vaccination policies in occupational settings at a time when infectious diseases are not a serious threat is provided in this chapter. Policies that use financial incentives to pressure individuals to vaccinate for employment and schooling contradict the Australian government's claim that vaccination in Australia is not compulsory. In many cases people cannot afford to lose their jobs by choosing not to vaccinate and some

parents are also dependent upon childcare facilities and welfare benefits for their livelihood. A discussion of the impact of the government's vaccination policies on the freedom to choose a medical procedure for healthy people has been presented in this chapter. Chapter 4 provides a description of the way in which the NIP is implemented into Australian communities and the surveillance methods that are used to assess the risk of communicable diseases to the community. An overview of the governance of Australia's vaccination policies is provided in Appendix 3. There are many ethical implications in a public health policy that recommends a medical procedure to healthy people and a discussion of these issues with the guidelines for good medical practice is provided in chapter 5.

3.2 Global Health Policy

The WHO Expanded Program on Immunisation (EPI)

This section describes the influence of public-private partnerships with WHO/UNICEF that are influential in the development of global and national public health policies. It also describes the influence that global health policy has had on the development of Australian vaccination policies. I have relied largely on Roalkvam, McNeill and Blume (eds) 2013 *Protecting the World's Children: Immunisation Policies and Practice* because this is the most current and comprehensive text on global health policies. The directive to increase the participation rates in Australian vaccination programs from the 1980's onwards was part of a global health initiative and a description of how this developed is provided below.

The WHO is a United Nations multilateral agency and is composed of United Nations member countries who accept the WHO constitution (WHO Countries). Since the 1940's and up to 1990, the WHO and the United Nations Children's Fund (UNICEF) have been the dominant influence in designing international health policy (IOM 1993). In 1974, the WHO established the Universal or Expanded Program on Immunisation (EPI) through a World Health Assembly (WHA) resolution (WHO ISD). At this time the WHO provided policy guidance for people of all ages and UNICEF was involved in implementing childhood vaccines into global programs. After the launch of this program UNICEF/WHO set vaccination policies and standards for vaccination coverage that were to be achieved by each member country (WHO ISD). As of 2014 there were

194 member countries (WHO Countries). The goal of this program was to increase the vaccination rate of children worldwide to ensure that all children benefit from 'life-saving vaccines' (WGO ISD). It was founded on the belief that vaccination programs had been successful in eradicating smallpox globally (WHO ISD). This was despite the warning by the WHO director-General, Halfdan Mahler, in 1980, stating that smallpox eradication had provided important lessons but claiming that other diseases could be singled out for worldwide eradication was not one of them (Blume et al 2013a p7). However, the WHO proceeded to recommend that member states develop immunization and surveillance programs for some or all of the following diseases according to their epidemiological circumstances: diphtheria, pertussis, tetanus, measles, poliomyelitis, tuberculosis and smallpox. The program was formalized by the UNICEF-WHO joint committee in 1975 with an emphasis on member countries taking ownership of their own programs and advice and assistance in obtaining vaccines being provided by the WHO/UNICEF (Blume et al 2013a p8).

In 1976 the WHA assessed progress of the expansion of vaccination programs and observed that they were not reaching the majority of children in developing countries. At this time another health report by the UNICEF-WHO committee was produced that emphasised poverty and ignorance as well as the integration of vaccination in health programs in developing countries. This led to the WHO director-general, Mahler, establishing the goal of 'health for all by 2000' at the WHA in 1976 (Blume et al 2013a). A conference in Alma-Ata, Kazakhastan in 1978 resulted in the Declaration of Alma-Ata that focused on the significance of socioeconomic development and primary healthcare, including community participation and lay health advocates as the cornerstone of public health, rather than a reliance on biomedical technologies such as vaccination (Blume et al 2013a p9). Vaccination programs were seen in this directive as part of a larger program of primary health care, not the main focus. Not everyone agreed with this strategy. Walsh and Warren, from the Rockefeller Foundation, believed it to be unrealistic. They claimed it was impossible to fund the clean water, nutritional requirements and basic primary health care for the world's population (Blume et al 2013a p9). They suggested that selective primary health care with a major emphasis on vaccination was the way to proceed, even though the cost of providing multiple vaccines to developing countries in a sustainable manner most likely outweighed the cost of providing basic healthcare services. The selective primary healthcare would give

priority to ‘high risk’ diseases and focus on measles and DPT vaccination, tetanus toxoid for pregnant women, encourage breast feeding, provide chloroquine for malaria-infested regions and oral rehydration therapy (ORT). This did not provide a direct focus on the main cause of deaths in developing countries – diarrhea, and was seen by some as a betrayal of the holistic approach agreed to at Alma-Ata in 1975 (Blume et al 2013a pp10-11).

The official launching of the EPI program with an overriding focus on achieving maximum vaccination coverage for the world’s children occurred in 1983 (Obamsawin 1998). This program was implemented despite the critical voices describing the destructive effects that EPI was causing at the community level in many countries (Newell 1988 p905; Obomsawin 1998). Vaccination coverage therefore became the key measure that WHO/UNICEF would use to assess the success of the EPI in achieving ‘health for all by 2000’. The EPI or Universal Childhood Immunisation (UCI) was promoted in 1982/3 on the initiative called the ‘Child Survival Revolution’ established by James Grant, the Executive Director of UNICEF, qualified in economics and law, not public health (Blume et al 2013a pp11-12). Other institutions and individuals involved with this initiative included the Rockefeller Foundation and Robert McNamara, former President of the World Bank. In the 1980’s neoliberalism was the political and economic model adopted by many countries. This model is based on the assumption that economic growth can be stimulated by freeing markets from government influence (WHO CSDH 2005). Neoliberalism became the dominant influence on global health in the 1990’s and policies were controlled by the ‘Washington consensus.’ This term is derived from the fact that global health policies are dominated by the US government, the World Bank, and the International Monetary Fund – all based in Washington (WHO CSDH 2005).

When neoliberalism was becoming the dominant model in global politics the WHO/UNICEF began to present mixed messages in addressing global health. Whilst the WHO ‘Health for All’ vision from the 1970’s strongly recognised social and environmental determinants of health (SEDH) as the primary influence on health outcomes, this approach was abandoned when neoliberalism became dominant. This ideology focuses on privatisation, deregulation, free markets and technology-based health programs (WHO CSDH 2005). The World Bank had an increased influence in global health policy from the early 1990’s onwards. Neoliberal policies were imposed

on developing countries by donor organizations and governments through bilateral arrangements mostly set up through the World Bank and the International Monetary Fund (WHO CSDH 2005). When sponsors provide money for health programs it diminishes the control governments have over their health programs. A nation's autonomy over its own health program depends upon the financial status and medical expertise of the country (McNeill et al 2013 pp66-67). Donors have a major influence on health policies in poor countries.

In 1983 all political leaders of the WHO member countries, 158 at this time, were directed to make a commitment to raising the vaccination coverage in their countries to 80% by 1990 (Obomsawin 1998). In the discussion of the necessity for this program there was no mention of the different risk profiles that infectious diseases had in different countries, only that the strategy was building on the success of the global smallpox eradication program (WHO ISD). A conference was held at the Rockefeller Foundation's Bellagio Conference Centre in 1984 entitled 'Protecting the World's Children'; it focused on childhood diseases that could be prevented by vaccination. UNICEF became a dominant voice on global health policies at this time and the EPI became focused on increasing the vaccination coverage of the world's children even though this strategy conflicted with the emphasis on primary healthcare services advocated by the Director-General of the WHO at Alma-Ata (Blume et al 2013a p11). As a result of UNICEF's influence global health policies for infectious disease became narrowly defined as selective primary healthcare (PHC) programs which removed the focus from the social and environmental determinants of health and targeted only **G**rowth monitoring, **O**ral rehydration therapy, **B**reastfeeding and **I**mmunisation – known by the acronym GOBI (WHO CSDH 2005). In reality these programs were even narrower with most countries only addressing oral rehydration and vaccination (WHO CSDH 2005). By 1990 the program had achieved its goal of increasing the global vaccination rate of children to 80% for all the basic childhood vaccines – polio, diphtheria, pertussis, tetanus, measles and tuberculosis (WHO ISD; IOM 1993). The Institute of Medicine (IOM) states that the EPI raised the global vaccination levels from 5% to 80% during the period 1974-1990 (IOM 1993).

The Child Survival Revolution was celebrated at the UNICEF World Summit for Children in New York in 1990. This program was funded by the US Congress even though it was rare for foreign aid to be given priority by its members or constituents

(Blume et al 2013a pp11-12). The vaccination goal was re-set by the WHO to achieve 90% vaccination coverage by the year 2000 and the child survival campaign was used to continue public support for the program in the political arena. However, vaccination coverage doesn't inform authorities about the burden of disease and disability in a population, namely about the *health* of populations (see section 2.8). This indicator is used on the *assumption* that vaccines prevent disease and that they do this without causing serious or frequent adverse health effects in the population. These assumptions are hidden to the public because there is little or no surveillance of adverse events caused by vaccines in most countries (Obomsawin 1998). See chapters 6, 7 and 9. There is no systematic, active surveillance of long-term health outcomes in any country (CDC VAERS). In the early 1990's there was a digression in public health policies from local initiatives and community action to a focus on medical technologies using sophisticated media campaigns to sell the message. This caused a rupture in political opinion at the international and national level. GOBI was criticised as being poorly conceived and a simplistic approach to complex health problems (Basch 1994 pp45-6).

The Children's Vaccine Initiative (CVI) and GAVI (1990-2015)

Globalisation changed the processes of vaccine development and production from 1990 onwards. In the 1980's there was a realisation that many of the countries that needed vaccines would not be able to afford them. There is little incentive for vaccine manufacturers to invest in the development of vaccines if there is limited commercial value (Basch 1994 p8). This problem was solved with the establishment of public-private partnerships in the 1990's. Prior to globalisation, the vaccine market was unstable and virus strains and production processes were not protected by patents, therefore fewer companies were competing to develop vaccines (Blume et al 2013b p31). A new Children's Vaccine Initiative (CVI) was launched in the 1990's to harness nascent technologies in the development of new combination pediatric vaccines and to continue to reach the 20% of children in developing countries who were not receiving vaccines (IOM 1993). This initiative had a wider range of stakeholders supporting its implementation than the EPI. Whilst the stakeholders still included the WHO and UNICEF they were now joined by the Rockefeller Foundation, the World Bank and the United Nations Development Program (UNDP) (IOM 1993). These organisations worked together with private industry providing directives for global public health policy through the WHO. The CVI consultative group included commercial vaccine

manufacturers, public-sector vaccine manufacturers, donors and national development assistance agencies, research institutes, representatives of national immunisation programs, the US Food and Drug Administration (FDA), US Agency for International Development (USAID) and the US Centers for Disease Control and Prevention (CDC). Rising costs and the complexity of vaccine development were hindering the research and production of new combination vaccines however the new financial partnerships with industry in the CVI, supported by the Vaccine Fund, overcame many of these problems (Muraskin 2004 p1922).

An example of private-public partnerships is the Program for Appropriate Technology in Health (PATH). This group was set up as a non-government organization (NGO) in 1977 and it received 4 of the 20 largest individual grants from the Bill and Melinda Gates Foundation (BMGF) from 1999-2007 (McNeill et al 2013 p68). The new partnerships resulted in global policy being designed in a manner that was contrary to the WHO charter (Muraskin 1998 pp43-5). The WHO has a mandate to promote global health according to the charter for health promotion adopted in Ottawa in 1986. This charter emphasises autonomy and promotes community input and ownership of public health policies. It is required to promote a bottom-up model not a top-down model. Consequently, the goals of private and public organizations are very different and the CVI was constantly in disagreement about global health policy and the WHO controlling the CVI. Private organizations whose goal is profit provided the funding to support the development and research of new vaccines in the CVI that were promoted to governments through global health policies. This initiative resulted in new vaccines being implemented into countries without input from the community and local health authorities. When the health needs of countries are determined by outside experts they do not always fulfill the needs of the community (Basch 1994 p9). Although the CVI consultative group met annually at an international forum many of the organisations were from the USA. The influence of the new stakeholders in the WHO advisory board for global health policy resulted in agendas for national immunisation policies reflecting US interests (IOM 1993 p22).

The US provided assurance for the funding of the CVI through UNICEF in 1991/2 even though the Europeans, particularly the Nordics, did not approve of this sponsorship. They believed that the development, testing and introduction of new vaccines into government programs should be secondary to the support for the EPI. This is because

there was uncertainty about the sustainability of the fundamental vaccines provided to developing countries in the EPI (Muraskin 1998 pp49-50). Hence, UNICEF became the funder for all activities that did not involve research and development. It funded the infrastructure that facilitated the implementation of the vaccines yet at the outset of the design of the initiative UNICEF was seen as the vehicle for funding to be channeled into vaccine product development. This initiative was seen by Europeans as a creation of the US to support multinational corporations in the biotechnological revolution. The WHO also had concerns about working with industry to create the resources needed for vaccine development. For example, the low prices of vaccines offered to countries through the EPI could only be provided because of the profits generated from the commercial market. Companies could pay off the initial capital investment through private sales to make a reasonable profit and this enabled the pharmaceutical companies to sell the vaccines to the public sector at a lower cost than production: a two-tiered pricing system. The mass ordering of vaccines for the public sector resulted in economies of scale that lowered the prices for the private and public sectors. However, the WHO was compromised in this arrangement that allowed companies to gain significant private profit (Muraskin 1998 p62). There was also concern over WHO receiving royalties from private organisations that used WHO research. This included patents, licenses, technical knowledge, trademarks and copyright. It was felt that this conflict of interest in working with private industry would compromise its goals therefore it chose to participate only in joint research projects and not cooperative market agreements.

In the late 1990's the shortage in funding for the CVI resulted in the development of the Global Alliance for Vaccines and Immunisation (GAVI). This alliance was initiated by the Head of the World Bank in 1998 at a summit for the WHO, UNICEF, the pharmaceutical companies, international agencies, health ministers and academics (GAVI HoG). The agenda was driven by the fact that there was no incentive for pharmaceutical companies to supply vaccines to the developing countries because they were unable to afford the 6 new vaccines that had already been introduced into developed countries. The Bill and Melinda Gates Foundation (BMGF) donated US $750 million to the cause and this was matched by the governments of developing countries resulting in US $1.67 billion (McNeill et al 2013 p69). The BMGF joined the GAVI alliance advisory board and the collaborative venture was launched at the World

Economic Forum in 2000 (GAVI HoG). As stakeholders in the alliance, the BMGF, the Rockefeller Foundation and pharmaceutical companies were influential in shaping global public health policies (McNeill et al 2013 p73).

3.3 The Influence of GAVI in Global Policy

After the GAVI alliance was established a working party that included the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) designed policies with a global focus on new vaccine production and implementation. This direction in public health policy conflicted with the priorities that some countries wanted to choose for their health agendas. Many donor and recipient countries were critical of the singular focus GAVI had on vaccines (Muraskin 2004 p1922). It operates on a top down model that undermines community action and its focus on vaccines is not formed by a consensus in the international public health community. There was discussion that GAVI should be an independent organisation however it became an alliance with the WHO working party issuing global directives from 1998-2008. GAVI increased its governance powers and took over many of the WHO functions in member countries (McNeill et al 2013 p75). Global public health policies are now focused on technocratic governance and technologies and not traditional primary health care. The increased emphasis on vaccination programs has been to the detriment of programs targeting nutrition, sanitation, health education, clean water, child and maternal health, prevention and control of endemic disease and medicines (Obomsawin 1998; Blume et al 2013 p27). This focus on vaccination policies could not have occurred without private partnerships with the Gates Foundation, the input from the IFPMA and the Vaccine Fund supported by the developed nations (Muraskin 2004 p1922). Global public health policies promoted by the WHO are being designed by a governing board that includes the World Bank and members of many commercial vaccine manufacturers whose products are promoted by GAVI (GAVI HoG). Further, GAVI provides representatives to ‘educate and financially entice’ countries to accept GAVI’s vaccination goals (McNeill et al 2013 p82). GAVI has also established vaccine advisory committees to advise governments about the recommendations for policy. These are known as the National Technical Advisory Groups for Immunisation (NTAGI) and their stated purpose is to provide ‘informed’ and ‘transparent’ policy advice (WHO ITAG 2008). They are composed mainly of scientific and medical experts, usually with one

consumer representative. The advice provided by GAVI/WHO is influenced by the IFPMA and pharmaceutical companies whose representatives can attend meetings and present information (Gessner et al 2010 A2).

These conflicts of interest in the design of public health policies for the 'good of the community' are hidden from the global population. During the 1990's the WHO distrusted the profit motives of the private sector and there was conflict over the direction of these policies (McNeill et al 2013 pp70-75). This was solved by the establishment of private-public partnerships through NGO's. When Gates became a partner in the GAVI alliance with many transnational corporations he moved the centre for policy development from Geneva to Seattle. In addition to these conflicts of interest, the majority of members of the WHO, UNICEF and EPI advisory boards that are involved in developing vaccination programs come from professional backgrounds with financial links to industry; many are scientists and administrators from developed nations (McNeill et al 2013 p69). Conflicts of interest and the composition of stakeholders on vaccine advisory boards play a significant role in the direction of global and national health policies in the New Public Health era. These are discussed further in chapter 6.

Global health policies have targeted children in both the developing and developed countries with vaccines, even though deaths and illness to infectious diseases had been significantly reduced in developed countries by 1950. Hence the narrow focus on vaccination programs did not address the different risk profiles that infectious diseases had in different countries. They have also been promoted with moral authority to policy-decision makers and the global community. They are framed as 'saving children's lives' in campaigns that are akin to a crusade (McNeill et al 2013 pp67-68). This is because the GAVI alliance has been founded on the claim that 'if a vaccine is available on the international market, to not make it available to all children, particularly those whose poverty makes them most vulnerable, is a form of moral neglect on the part of the international community' (Sandberg and Justice 2013 p87). This policy claim is given further credibility as a 'social justice' program by the Johns Hopkins School of Public Health and the London School of Health and Tropical Medicine (McNeill et al 2013 p68).

GAVI skewed the direction of WHO funding to universal recommendations on vaccination coverage in all WHO member countries despite the knowledge that public health officials had of the etiological factors involved in disease outcomes from infectious agents. It has also funded new vaccine producers in India, Brazil and Indonesia to compete with the large pharmaceutical companies. This presents a further conflict of interest between vaccine producers and WHO global policy directives; GAVI recommends vaccines to the global community that some of its members profit from. GAVI claimed that funding new vaccine manufacturers would result in significant price reductions for vaccines but according to McNeill et al (2013 p69) this never eventuated. In addition, vaccines cannot be used without harming a percentage of the population but this harm is not being systematically monitored or factored into the economic modeling for key measures of health. Vaccine producers and patent holders that profit from vaccines are represented on both global and national vaccine advisory boards (McNeill et al 2013 p69) and this conflict of interest is not made transparent to the public in the recommendations of global health policies by the WHO. Vaccines are described in the 1986 US National Childhood Vaccine Injury Act as 'unavoidably unsafe' (Holland 2011 p12) and the increased risk from the use of an increasing number of vaccines and achieving higher vaccination rates is not quantified in a risk/benefit analysis for each country in the implementation of this global policy (WHO ISD; Obomsawin 1998).

Since the CVI initiative was first launched the policy has expanded to target many more diseases. The vaccines have been introduced in developed countries for diseases that were a low risk to the majority of the population at the time they were introduced. They have also been introduced without discussion of the context in which people get these diseases (AG IAP 2004; Mercae 2003 p197). GAVI is using economic modeling influenced by industry to show health problems that governments are not aware of, and using financial incentives to create the 'political will' for governments to implement new vaccines as the solution. This is despite the health problems not being a priority and it results in unnecessary vaccines with increased risk of adverse health outcomes for some individuals. The cost-effectiveness data for new vaccines is produced by industry - not the WHO - and it is being presented to enhance the possible benefits of vaccines whilst ignoring the risks (McNeill et al 2013 p78-9). In other words, advocacy from GAVI representatives using manipulated statistics and hidden assumptions is being used to ensure countries commit to new vaccines. Chee et al state that GAVI does not always

have strong scientific evidence or universal support for its strategic policies, for example, the introduction of Hib vaccine, and therefore it is perceived to push new vaccines inappropriately (Chee et al 2008 p19).

3.4 National Immunisation and Technical Advisory Groups (NITAG)

The WHO/GAVI alliance places high priority on establishing vaccine advisory boards in member countries for the development of national immunisation programs (Duclos 2010 A18). These groups are referred to as national immunisation and technical advisory groups (NITAG). In Australia this group is called the Australian National Technical Advisory Group on Immunisation (ATAGI). WHO/GAVI assist in their establishment and influence the advice they provide in the following ways (Duclos 2010 A23-24):

- Providing technical guidance in the formulation of immunisation policies
- Providing global and regional policy recommendations and providing the evidence for these recommendations
- Providing the latest developments on vaccines to the chair of ATAGI
- Guidance in providing sources of financial support
- Developing training and educational materials
- Facilitating exchange between global NITAG's and participation of the chair in regional immunisation meetings

These activities are influenced by the US Centers for Disease Control and Prevention (CDC), the ProVac Initiative launched in 2006 and the Supporting Independent Immunisation and Vaccine Advisory Committees (SIVAC) through WHO/GAVI. (Duclos 2010 A24). The influence of pharmaceutical companies in the advice provided by the Australian vaccine advisory board (ATAGI) and in the production of scientific evidence in clinical trials is described further in chapter 6.

The role of NITAG's 'is to facilitate a systematic, transparent process for developing policies by making evidence-based technical recommendations to the national government' (WHO ITAG 2008 pp2-3). Over the last 15 years evidence-based policy making (EBPM) has been formalised as the foundation for developing public health policy (Belague et al 2009). This is a system of knowledge that aims to use clinical evidence obtained from systematic research to support policy decisions. It gained

prominence in the 1970's due to Archie Cochrane's emphasis on the need for a systematic evaluation of the safety and efficacy of innovative interventions/products in medicine. The Cochrane Collaboration was established in 1993 and the evidence-based methodology is now being applied to many non-clinical areas of policy development such as education, public policy and public health. EBPM implies that the methodology is based on scientific evidence. However, this needs to be examined in the broader political context where the interpretation of research findings can be shaped by the research donor (Belague et al 2009 p1539). EBPM is a move away from the use of common-sense and local knowledge in the formation of policy. This is significant in public health policy design where environmental context plays a significant role in health outcomes and where the scientific knowledge is often not complete. See chapter 4 for the significance of non-technical information in the risk assessment for health hazards.

EPBM is being used by governments to justify new policies that are replacing established policies of proven benefit. This results in a narrower approach to health that does not offer comprehensive solutions to context-specific health issues (Behague et al 2009). Whilst contextualisation of globally recommended policies is acknowledged as being an important factor in promoting health (WHO ITAG 2008) it cannot be achieved in practice because research activities are being dominated by a focus on achieving internationally set agendas. In the New Public Health Era of public-private partnerships local researchers who are familiar with a country's specific health issues do not have access to the government health department. Governments are framing policy on the advice of global sponsors and economic modeling influenced by industry, and not local needs. This is observed in the adoption of the Millennium Developmental Goals (MDG). Many countries are achieving the MDG's at the expense of primary health care and community input into health policies. The interventions being recommended in many countries are reflecting the sponsor's needs and not the local context (Behague et al 2009 p1542). The use of the EB methodology without non-technical input is resulting in limited healthcare practices that have been detrimental to health and environmental outcomes in many countries (Behague et al 1009 p1540; Baum 2008 p101; Basch 1994; Obomsawin 1998).

In Australia the childhood schedule has expanded to include vaccines to protect against 16 diseases with 11 vaccines recommended before an infant is one year of age (AG IAP

2013). This schedule has expanded in line with GAVI's directives in the first phase of its program (2000-2005) to 'save children's lives' and 'protect people's health through widespread use of vaccines' (McNeill et al 2013 p75-6). GAVI uses many strategies to implement its directives. One of them is to provide financial support to each country's vaccination services through a performance-based reward system (Chee et al 2008 p41). Other strategies include supporting the financial sustainability of programs at country level and influencing vaccine supply and demand.

Global health strategies have resulted in a decline in the authority of governments over the control of population health even though governments formally have the right to decide health policies for their own regions and populations (Sandberg and Justice 2013 p88). This is a fundamental principle of the international community and transgressing this principle results in a loss of authority over human rights for individuals. Vaccination is a technological procedure and its adoption in government public health policy, using coercive and mandatory strategies, infringes on the fundamental human right to bodily integrity and informed consent. This right is protected in the Geneva Declaration which includes the physicians oath declaring that they will not use their medical knowledge to 'violate human rights and civil liberties, even under threat' (WMA 1948). Ethics and vaccination programs are discussed further in chapter 5. The EPI has been proven to be ineffective in the long-term in preventing outbreaks of infectious diseases in global communities because the program does not target the social and environmental determinants of health (WHO CSDH 2005 p19; Mercae 2003 p210). In addition, there is no obligation for governments to provide financial and technical resources to support capacity-building (Fidler and Gostin 2006 p88). This situation could undermine the new International Health Regulations (IHR).

Well documented outbreaks of infectious diseases continue to occur in highly vaccinated populations. (Nkowane et al 1987; Boulianne et al 1991; De Serres et al 2012; Lee et al 2004; Lopez et al 2006; Dayan et al 2008; Witt et al 2012; Mercae 2003 p198). This evidence clashes with the claim that vaccine-created herd immunity can prevent infectious diseases. The fact that unexpected outbreaks continue to occur in vaccinated populations has led some health professionals to question the theory of vaccine-created herd immunity that vaccination policies are founded on (Obomsawan 1998). In addition, it is the *severity* of the disease and not just the occurrence of disease that is significant to the health of populations.

The WHO states that an estimated 83% of children less than 1 year of age globally have received 3 doses of Diphtheria-Tetanus-Pertussis (DTP) vaccine (WHO IC 2013). Yet there have been many epidemics of pertussis (whooping cough) reported in highly vaccinated populations over the last two decades (Beherman 1998; Wendelboe 2005; Klein et al 2012; Mihalovic 2012). This includes outbreaks in Australia, the United Kingdom, and the USA where vaccination rates for pertussis have been above 90% since 1995 (Wendleboe et al 2005; Burgess et al 1998). This evidence suggests that vaccine-created herd immunity to whooping cough is not sufficient to prevent whooping cough outbreaks in many populations. Infectious disease epidemics have been reported with surprising frequency in developed countries where vaccination coverage is high due to the EPI (Obomsawin 1998). Muraskin (2004) describes GAVI's focus on vaccination as a major flaw in public health policy. He states that the only reason countries are using so many vaccines is because of the major financial enticements. The core constituencies, including field workers and governments of developing countries, do not prioritise this goal and European bilateral donors have strong doubts about vaccines being the best strategy for achieving healthy outcomes in the developing world (Muraskin 2004 p1925).

3.5 The International Health Regulations (IHR)

Since the mid-19th century governments have maintained international agreements to protect their borders against the spread of infectious diseases. The IHR came into force on 15 June 2007 as an international legal instrument binding on the 194 member countries of the WHO (WHO IHR 2008). The aim of the IHR is to help nations prevent and respond to acute public health risks of global significance. By 1995 the WHO/UNICEF had decided that globalization required a new framework for health and security. Public health, security and democracy were stated to be intertwined in the IHR and the changes were described as 'moving humanity towards larger freedom' (Fidler and Gostin 2006 p85). These changes occurred after private-public partnerships began to dominate WHO policy in 1995 and the new IHR are observed to reflect industry needs and not those of national governments (Sandberg and Justice 2013 p93). Changes to the international regulations in 1998 had allowed data for global health policy to be obtained from non-government sources, including data from industry. WHO was systematically using non-government surveillance information from the Global

Outbreak Alert and Response Network (GOARN) before the new IHR's were completed in 2005 (Fidler and Gostin 2006 p93). The IHR allow the WHO to maintain the confidentiality of NGO sources of data where it is 'duly justified'. However, there are no guidelines to specify when this condition applies (Fidler and Gostin 2006 p88). In 2005, the IHR changed after 10 years of discussion and WHO/UNICEF announced a new global strategy at the same time as the changes to IHR. This policy was to expand current vaccination programs to more populations and new demographics beyond childhood (WHO/UNICEF 2005 p24 in Blume et al 2013a p2).

The WHO supported the IHR's under the belief that timely and open reporting of public health events would make the world a safer place (Flynn 2010). The IHR's gave new powers to the Director-General of the WHO to set up an Emergency Committee (EC) in response to a possible pandemic. Members of the EC are to remain undisclosed to the public. The EC's purpose is to advise the Director-General when to declare the pandemic (WHO IHR 2008). The functioning of the EC in the response to the declaration of a 'Swine Flu' pandemic in 2009 is described in chapter 10. Whilst the old regulations required governments to inform WHO about the transfer of diseases that might be of global concern, the new IHR's require nations to give priority to issues that are of global concern over domestic issues. The new IHR's were stated to be a balance between maintaining the right of governments to protect their people whilst avoiding unnecessary interference with traffic and trade. Essentially the changes implemented were made on the grounds that the IHR's were ineffective against new emerging diseases that presented the threat of pandemics, e.g. AIDS, SARS and Swine Flu. The new IHR's changed the international legal context for the implementation of national public health programs and gave new powers to the WHO (Fidler and Gostin 2006 p86-94).

The new IHR's include the following requirements:

1. An obligation to notify WHO of all events that may lead to a global public health emergency, not just the specific diseases that were previously listed. The list was expanded to include all infectious diseases and biological and chemical warfare. Public health is connected to security concerns because of the potential for terrorism from weapons of mass destruction.

2. Countries must notify WHO of an illness or medical condition irrespective of origin or source that presents or could present significant harm to humans.
3. Increased surveillance of diseases, including the whole territory and not just points of entry and exit.
4. Notifications can be provided to WHO by any source including mass media, the internet and NGO's. This information only needs to be 'verified' by the government concerned.

These changes to the IHR's ensure that global health governance, in partnership with corporations, has authority over national governments, *if they choose to accept them*. The choice to accept these policies is removed for countries that depend upon sponsorship or performance-based reward systems for their health programs. Financial enticements can bind governments to policies. It is noted that the USA has submitted a reservation regarding the acceptance of the IHR's by stating it will implement the regulations in a way that is consistent with American federalism (Fidler and Gostin 2006 p91). The WHO/UNICEF claim that this centralised global strategy is the only way to prevent the threat of emerging pandemic diseases in a way that minimises the disruptions to international trade (Fidler and Gostin 2006 p86). Whilst the WHO claims the strategy is compatible with human rights and state sovereignty, the opposite is true. Global policies are a top-down model that are not driven by community ownership and involvement; a feature that is also contrary to the principles established in the New Public Health statement, declared at the Ottawa Conference in 1986, to address the social determinants of health. See section 2.7.

When the IHR's came into force in 2007 national governments were required to fulfill their obligations by 2012 (Fidler and Gostin 2006 p88). In 2010 Bill Gates declared a 'decade of vaccines' and pledged $10 billion to support this initiative. This led to a Global Vaccines Action Plan that was supported by the WHO, UNICEF and the US National Institute of Allergy and Infectious Diseases (NIAID), a body that is part of the US National Institutes of Health (NIH) (Blume et al 2013a p1). It was claimed in 2011 that the global vaccine market was expected to reach US $34 billion in 2012 with a growth rate of 14% expected for the next 5 years (CVEP 2011 in Blume et al 2013a p2). The growth of the vaccine market has been described as the 'vaccine paradox': a situation where governments control the demand *and* provision of vaccines (Horton and Das 2011 p296 in Sandberg and Justice 2013 p98). Governments are being advised by

GAVI, an alliance with vaccine manufacturers that profit from the vaccines they promote with financial incentives to governments through the WHO. An example of the influence of corporations in the decisions by governments regarding the declaration of a 'Swine Flu' *pandemic* in 2009 is provided in chapter 10.

The introduction of global vaccination programs has not been based on evidence of the epidemiology of infectious diseases in each country, their case-fatalities and limited consequences, but on industry economic modeling and international considerations (Sandberg and Justice 2013 p109). Whilst these programs claim to be 'evidence-based' in high income countries, it is necessary to ask 'who is providing the evidence that is underpinning these policies and how has it been produced?' This question is addressed in chapter 6 and in the case studies provided in chapters 9 and 10.

3.6 Global Preparations for a Pandemic

Under the 2005 International Health Regulations most countries were required to develop Pandemic Preparedness Plans (PPP) (WHO GIP). New and improved tools to prepare and respond to pandemics have become available to the Global Influenza Surveillance Network (GISN) and these have been used by WHO since the emergence of avian influenza A (H5H1) in 1997, to prepare a global pandemic response plan (WHO GIP).

The new tools and technologies that are available include (WHO GIP):

I. Antivirals

II. Nascent technologies to speed the development of pandemic vaccines. These are new patented methods for producing vaccines in a shorter time.

III. Improved molecular and genetic techniques to analyse and track the evolution of influenza viruses

IV. Mathematical methods to model the evolution and spread of a pandemic virus, estimate incidence and prevalence and assess the impact of pharmaceutical and non-pharmaceutical measures on disease transmission and associated morbidity and mortality

The WHO member countries have spent 10 years under the guidance of the IHR's preparing their PPP's for a possible pandemic. Many scientists have expected a pandemic of influenza for a long time and they believe a possible mutation of the swine flu virus poses the biggest danger to the population because it makes existing flu medication and vaccines ineffective (Flynn 2010). Yet there is disagreement on the efficacy of current antiviral medications and influenza vaccines (Cohen and Carter 2010) and their effectiveness in an epidemic is undetermined. The PPP's established by governments globally included strategic stockpiles of antivirals, antibiotics, influenza vaccines and personal protection equipment (WHO GIP). In addition, the IHR's included the surveillance and reporting of all events to the WHO that may represent a public health emergency of international concern. For example, cases of new sub-types of influenza, which were never previously monitored, must be reported (WHO IHR).

A stated milestone for the IHR's was the assessment of member countries' surveillance and response capacities by June 2009 (WHO IHR). Notably the global 'Swine Flu' pandemic was declared on June 11 2009 when the EC changed the definition of a pandemic and removed the requirement for the need to show how severe the impact of the virus would be on the population. Without this change to the definition it would not have been possible to declare a level 6 pandemic. Under the IHR's governments had PPP's that were termed 'sleeping contracts' with pharmaceutical companies, which were to take effect when the WHO declared a pandemic. These contracts required national regulatory authorities to license vaccines developed by various vaccine manufacturers (sometimes following accelerated procedures) to ensure vaccines were available more rapidly than for seasonal flu (Flynn 2010). The events that led to the 2009 'fake' pandemic are described in chapter 8.

3.7 Global Vaccination Policies and Human Rights

The IHR's gave new powers to the WHO. This included:

i) The power to decide if a disease event reported by state parties fits the criteria for declaring an international public emergency and

ii) If an event of international concern is declared, the WHO can recommend non-binding measures for addressing the health risk in each country – temporary or permanent measures.

This gives WHO influence in health measures and in human rights in national policies. The IHR's require that health measures against persons are appropriate to the risk and no more intrusive than available alternatives that would achieve a similar health outcome (Fidler and Gostin 2006 p87). They also require that the measures are applied in a transparent and non-discriminatory way. When implementing compulsory measures for medical examinations governments must apply the least intrusive measure but this is not stipulated in the IHR's for the prevention of disease which includes vaccinations, isolation, quarantine or the use of other prophylactics. When governments apply compulsory health measures the IHR's do not require due process protections. There are binding limits on the strategies that governments can take against public health risks and generally they cannot require invasive medical examinations, vaccination or use of other prophylaxis as a condition for entering a country (Fidler and Gostin 2006 p88). However, the IHR's mechanisms for forcing governments to comply with the recommended health measures are weak which means that in practice the 'binding limits' are not enforceable.

3.8 Contraindications to Vaccines

The EPI has been implemented in many countries with little attention to the known contraindications to vaccines. There are many factors known to put individuals at risk from vaccines. These are termed *contraindications*, for example, a family history of a genetic disease (Obomsawan 1998). An example of this is provided with the whole-cell whooping cough vaccine that was linked to neurological adverse events (Feery 1981 p174; Zeigler et al 1991; NHMRC 1954-86; NHMRC 91). In 1978-1990 a family history of neurological disease was considered a contraindication to vaccines (NHMRC 1978-86; NHMRC 91). In 1980 a British survey (The British Childhood Encephalopathic Study [NCES]) estimated the risk of having a severe neurological reaction with persisting sequelae from whooping cough vaccine to be 1 in 310,000 vaccinations (Feery 1981 p174). This data was re-analysed a decade later using different assumptions and criteria to conclude the 'risk of encephalopathy with permanent brain damage was close to zero' (NHMRC 1991). However, the Australian College of Pediatrics (ACP) stated in 1991 that most neurological events (febrile seizures and non-febrile seizures, encephalopathy and other neurological symptoms) occur in children that do not have known risk factors. They also stated that infants/children who have a

history of convulsions in immediate family members (siblings and parents) have a 3.2-fold increased risk for neurological events compared to those who do not have a family history of the condition (Zeigler et al 1991 p17).

In the 1990's there was disagreement between the contraindications for whooping cough vaccine stated by NHMRC, the American Academy of Pediatrics, the Australian College of Pediatrics and vaccine manufacturers (Zeigler et al 1991; NHMRC 1991). In 1994 the NHMRC adopted the guidelines of the American Academy of Pediatrics which did not include a family history of neurological disease as a contraindication to WC vaccine (NHMRC 2003). Contraindications were stated to be encephalopathy within seven days of vaccination (not including febrile convulsions) and immediate severe allergic reaction, for example, anaphylaxis (NHMRC 2003).

3.9 Vaccine Ingredients

In the US, the Vaccine Injury Compensation Program (VICP) has paid over $2 billion in damages to over 2,500 families since 1988: and these are only the cases that were allowed and were voluntarily reported within 4 hours of the vaccination (Habakus and Holland 2011 p2; Obomsawin R preface). Many other claims were refused based on the criteria for acceptance. Although exemptions to vaccination in the US are allowed doctors can be punished if they grant too many and parents are not made award that exemptions exist (Habakus and Holland 2011 p2). Even though vaccines are described in US law as 'unavoidably unsafe' (Holland 2011 p12) Australians are not informed of the ingredients of vaccines or all the known risks from this procedure. The ingredients of Australian vaccines are presented in Appendix 1. In addition, Australia does not have a compensation scheme for its National Immunisation Program (NIP). This is the case even though coercive practices, such as financial incentives, have been introduced to encourage Australians to use an increasing number of vaccines. Medical practitioners do not describe the ingredients of vaccines to Australian consumers before they vaccinate and the ingredients have not been provided to parents on the Immunise Australia Program (IAP) website (AG IAP 2014). Instead the ingredients are listed as 'components of vaccines' in Appendix 3 of the Australian Government Immunisation Handbook (AG IH 10th Ed 2014). Most vaccines contain preservatives, antibiotics and adjuvant (aluminium compounds) that are described on the IAP website as being in 'trace' amounts.

The Australian Government's vaccination policies are considered coercive because they pressure individuals to use vaccines by providing financial incentives for both parents and doctors. They are also coercive because they require individuals to fill out an exemption form signed by a doctor if they choose not to vaccinate. This is being required of parents who wish to claim the government welfare benefits or childcare places and of employees in some workplaces (AG IAP 2014). These requirements place pressure on parents to be 'responsible' by ensuring their children are 'fully vaccinated.' When parents are not informed of the ingredients of vaccines or the potential health hazards of vaccines it is a breach of their right to fully informed consent. Good medical practice requires that doctors fully inform patients about the risks and benefits of medical procedures and they must recognise and respect a person's right to make their own decisions on healthcare (MBA 2010). See chapter 5.

The community is informed that diseases on the childhood vaccination schedule are not a public health risk because vaccines prevent these diseases (AAS 2012). Medical practitioners state that vaccines are one of medicine's greatest achievements (Offit 2003), even though the historical data shows that the most significant fall in mortality and morbidity due to infectious diseases occurred prior to the use of all vaccines other than diphtheria and smallpox. This was discussed in Chapter 2. Patients place their trust in doctors to be acting with integrity, truthfulness, dependability and compassion (MBA 2010). If a public health policy includes a medical intervention on the basis of claims that are not supported by scientific evidence it is a breach of the public's trust. It also breaches the ethical code of good medical practice that has been adopted by Australian doctors (MBA 2010). Doctors in Australia are required to ensure that any procedures they recommend to patients are necessary and beneficial to their patients (MBA 2010). In 2006 the World Health Organisation (WHO) recognized that many non-infectious diseases pose as serious a threat to world health as infectious diseases (WHO CD 2013). Chronic illness is now the leading cause of death in the world resulting in 63% of all deaths. The scientific community is also aware that a large proportion of the chronic illness is due to autoimmune diseases (WHO CD 2013). Vaccines contain aluminium adjuvants which have been associated with causing autoimmune diseases for many years (Greville 1966; Shoenfeld and Agmon-Levin 2011).

The chemicals in vaccines include mercury (mostly prior to 2000), formaldehyde, aluminum adjuvant, antibiotics, stabilisers and preservatives. However, it wasn't until

1999 that the FDA finally stated that the mercury in vaccines exceeds the Federal Safety Guidelines (FDA Thimerosal). Government officials admitted they had not considered the cumulative effects of the increased number of vaccines (FDA Thimerosal). Herbert Needleman's research on the effects of lead in children has led to claims that there is substantial evidence that environmental toxins (even in trace amounts) are implicated in behavior change resulting from disturbances to the prefrontal lobes in the brain (Needleman 2000). In particular, researchers have linked heavy metals with affects on neurotransmitters – chemical substances needed for the proper functioning of the nervous system (Needleman 2000). Alteration of the prefrontal lobes affects decision-making, choices and resisting impulses (Needleman 2000). Autism is a result of immature development and organization of the brain, in particular of the frontal and temporal lobes (Coulter 1990) and mercury is a heavy metal that has been in many childhood vaccines for decades. See Appendix 2. Mercury and aluminium are described as 'neurotoxins' and they are combined with many other compounds in vaccines. When chemicals are combined they are known to have cumulative and synergistic effects with other chemicals and they are known to be particularly toxic in infants and young children. Toxicity also increases when they are injected into the tissues as opposed to entering the body through natural routes of exposure (Gilbert 2004).

In 2000 the Australian Commonwealth Government issued a directive to remove the mercury-based preservative thimerosal from all childhood vaccines. Since then the government has claimed that there is no mercury (other than a trace amount) in any vaccine on the schedule for children less than five years of age (AG IAP 2012)**.** However, in 2013 thimerosal was still listed as an ingredient in the Energix B vaccine for Hepatitis B given at birth and also for the influenza vaccine Fluad and Fluarix (AG IH 9th Ed 2013). In addition, thimerosal was still present in the infanrix-hexa vaccine, the new 6-in-1 vaccine that will be used most frequently in infants to replace 6 separate vaccines (Austin et al 2010). A 'trace' amount of a toxin is not a quantitative measure and parents have a right to be informed truthfully about the quantities of the ingredients in vaccines. This is particularly the case when parents in Australia are being pressured into using many vaccines under the benevolent claim that it is the responsible thing to do for the community.

PART 2 DEVELOPMENT OF AUSTRALIA'S NATIONAL IMMUNISATION PROGRAM (NIP)

3.10 The Australian National Immunisation Strategy (NIS) (1993)

In 1993, under the WHO's declaration of health for all, the World Health Assembly called on WHO to establish partnerships with the commercial sector to assist in the development of national vaccination strategies (Buse and Waxman 2001 pp1-2). Public-private partnerships were outlined as a core function of WHO's corporate strategy to achieve the goal of health for all and this created industry incentive for the research and development of drugs and vaccines. National vaccination programs were designed by partnerships between industry and intergovernmental organisations from this time onwards and referred to as National Immunisation Programs (NIP) (Buse and Waxman 2001). Partnerships with industry gave the UN access to more resources and industry's involvement in the promotion of public health messages gave the commercial sector an improved corporate image that encouraged new investors and markets.

A milestone in the promotion of global vaccination programs was the 1986 report from the Institute of Medicine (IOM) of the US National Academy of Sciences. This report described the diseases of importance in the US and in the developing countries (IOM 1986 in Basch 1994 p12). The report listed three categories of pathogens of importance to global health - high, medium and low - for which vaccines could be developed. The report placed a vaccine against childhood diarrhea in the category of highest importance because of the high burden of this disease in developing countries, not the developed countries, and vaccines for pathogens of lesser significance into category 2 or 3, including hepatits B virus and *Haemophilus influenza* type b virus (Basch 1994 pp12-13). Research and development on vaccines was revitalised in the 1990's because it was recognised that new biomedical technologies might improve the existing vaccines and could be used to create new vaccines for other infectious diseases (Basch 1994 p182). A new globally coordinated effort was initiated to achieve the common goal of Universal Childhood Immunisation (UCI). This brought together national, regional and international development agencies, private foundations, voluntary organisations, academic institutions, and industrial companies. Global and national vaccination programs became a coordinated initiative at this time where the needs of a global

community were established in advance of the development of vaccines. This program could not have been achieved and is not sustainable without significant financial support from the World Bank, the International Monetary Fund, private foundations and developed nations. The program has been promoted by global and national decision-makers on a belief in the value and cost-effectiveness of vaccines and a push for social equity where all populations should have access to the benefits of vaccines. This enabled vaccination to be promoted as a public good, like education, and it was considered unethical to prevent a child from receiving a 'life-saving vaccine'. Thus vaccines were prevented from being framed as a commercial commodity linked to corporate profits (Basch 1994 p182).

Despite the low mortality and morbidity rates in developed countries, achieved by 1950 through environmental and lifestyle reforms, governments globally promoted the idea that 'vaccines prevented infectious diseases' and that 'high participation rates in vaccination programs are necessary to control infectious diseases' (AG IAP FAQ 2013; CDC; Stanley 2001 p380). It has been well established that deaths and illness to infectious diseases were reduced in developed countries *before* the widespread use of vaccines (Stanley 2001 p370). See chapter 2. Therefore, 'vaccine-created herd immunity' was not responsible for the decline in these diseases. Yet in the early 1990's the Australian government decided to increase the vaccination rates in the population on the basis that 'vaccine-created herd immunity is necessary to control infectious diseases' (AG CDIJ 1997). This was in response to WHO directives for global health policies. The Australian government justified this strategy on the premise that it might be possible to eliminate outbreaks of these diseases if vaccination rates were 85-90% (Hawe 1994 p241; Curry 2002 p34). This was despite the Australian College of Pediatricians (ACP) stating in 1991 that the prediction that whooping cough disease could be eradicated by achieving an uptake of the vaccine of 95% was probably wrong (Zeigler et al 1991 p16). This paper (Zeigler et al 1991) was authored by Margaret Burgess who became the founding director of the NCIRS in 1997 and Peter McIntyre who became the director of NCIRS from 2004 until the present time. The risk from these diseases had already been reduced so increased vaccination rates were emphasised in an effort to *prevent* these diseases. Hence the new terminology: *vaccine-preventable diseases.* This was part of a WHO directive that claimed to be 'building on the success

of the smallpox eradication program and ensuring that all children globally benefited from vaccines' (WHO EPI; IOM 1993).

The conclusion that higher vaccination rates would be cost-effective was founded on the theory of *vaccine-created herd immunity*. It was theorised that vaccination rates of 94–97% could interrupt the transmission of the pathogenic organisms and make it possible to eliminate many infectious diseases, particularly measles (Hawe 1994 pp241-2). As measles is a more contagious disease than smallpox it was argued that vaccination rates needed to be much higher than the 50% rate required to eliminate smallpox (Hawe 1994 p241). This theory was based on the observed herd immunity that was obtained after natural infection that resulted in the reduction in the risk of infectious diseases by 1950. The new NIS did not just emphasise higher vaccination rates for measles vaccine but higher vaccination rates for *all* the vaccines recommended on the government schedule; even new ones that had not yet been introduced. It was a 'package deal' (Hawe 1994 p242). In other words, even though the vaccines listed on the national schedule were implemented *after* deaths and illnesses from infectious diseases greatly declined in Australia, the government included all of them (plus new ones) in a new national campaign insisting that 'high participation rates (90%) in vaccination programs are necessary to control infectious diseases.' The NIS was a strategy that was estimated in the 1990's to cost $53 million to operate (Hawe 1994 p242). At this time the infant mortality rates in Australia were low at 8.2 per 1,000 live births and infectious diseases were not considered to be a serious risk.

Although the WHO stated in 1989 that measles 'was not eradicable' the new NIS was promoted by the Australian government on the claim that 'measles could be eliminated'. This was defined as meaning 'constant vigilance could prevent outbreaks' and measles could be controlled (Hawe 1994 p243). The Australian Government claimed that highly contagious diseases such as whooping cough and measles could be *eliminated* if very high vaccination rates were achieved. However, the strategy in the early 1990's also involved introducing new vaccines to the schedule and ensuring that the uptake of these vaccines was also above 90% (Hawe 1994 p242), for example, the triple antigen MMR vaccine, *Haemophilus influenza* type b (Hib) and hepatitis B (AG CDIJ 2007). When the NIS was implemented in 1993 infectious diseases were re-named *vaccine-preventable diseases* and the public was informed through the media that high

participation rates were needed for all vaccines to prevent death and illness from infectious diseases (AG IAP 2004).

In the early 1990's a new pertussis vaccine was developed using novel technologies. This was an acellular pertussis formula developed without thimerosal (a mercury compound and preservative) to reduce the adverse events that were associated with whole-cell pertussis vaccination (Basch 1994 p196). The acellular pertussis vaccine was introduced into Australia's national program in 1999 and the whole-cell pertussis vaccine phased out over a number of years. The measles vaccine was reformulated to enhance the immunogenic quality in younger infants because maternal antibodies neutralise the live vaccine virus as well as the 'wild' disease-causing virus (Basch 1994 p15). New biotechnology was also used to improve the oral polio vaccine by increasing its tolerance to heat. These vaccines had an assured market because they were approved for universal use in all populations.

3.11 Australia's National Immunisation Program (NIP) (1997-2012)

In 1997 the initiative to increase vaccination rates was formalized and re-named the Immunise Australia Program (IAP) (AG IAP 2004). This strategy had been gradually implemented since 1993 and aimed to coordinate activities across many areas in order to control epidemics through higher childhood vaccination rates. This included an emphasis on a range of different strategies to attract parents to vaccination and on building infrastructure to improve access and delivery of vaccines. Essentially it required more cooperation between public and private sector interests with the removal of financial barriers to vaccination (Hawe 1994 p241). A 'Seven Point Plan' was implemented to attract parents to vaccination and encourage the uptake of the recommended childhood vaccines. It was believed that the reason vaccination rates weren't high enough was because parents were complacent (Hawe 1994 p242). The vaccines recommended on the NIP schedule were subsidized by the government because they were claimed to be essential for community health. Vaccines to prevent 9 diseases were listed on the NIP in the early 1990's and were provided free of charge in the public and private sector from 1997-2000 in all jurisdictions (AG CDIJ 2007). Vaccination was promoted to parents as being a safe and effective way of protecting children against targeted diseases. It was also stated that the risks of these diseases are far greater than the very small risk of vaccination (AG IAP FAQ 2013).

3.12 Strategies Adopted in the Seven-Point Plan

The strategies adopted in the Seven Point Plan (1997–2013) include initiatives for parents to increase the timeliness and coverage of vaccination as well as education campaigns for the general public and health professionals. The following points have been referenced from the Australian Government's Immunise Australia Program (IAP) website.

1. Central features of this strategy include a contribution from the Commonwealth Government to provide subsidised childhood vaccines, improved standards of maintaining vaccine quality and improved surveillance and reporting of vaccine preventable diseases.

   Although contraindications to vaccines are a significant area of concern for health providers (Obomsawin 1998; Hawe 1994 p242) the focus of the government's concern when the new initiatives were introduced was more about 'marginal cost and marginal benefit' (Hawe 1994 p242). In other words, the contraindications due to genetic predisposition were secondary to economic considerations from a 'one size fits all' policy.
2. A General Practice Immunisation Incentive Scheme (GPII) was established to encourage doctors to participate in the program. Until 2013 the GPII scheme offered a Service Incentive Payment (SIP) to medical practitioners who notified the ACIR of children who had completed the vaccination schedule according to the National Immunisation Program. This payment changed in May 2013 and it is now paid to medical practices that monitor, promote and provide appropriate immunisation services to children under 7 years of age. A service provider education strategy is also provided in the seven-point plan. This is aimed at increasing the service provider's commitment to actively promoting age appropriate childhood immunization.
3. An Outcomes Payment was introduced in 1997 to practices that achieved 90% or greater vaccination coverage of children less than seven years of age who attended their practices. This is now called the GPII described above.
4. There was also an Immunisation Infrastructure Fund that provided funding for divisions of general practice, state-based organisations and funding for a

National GP Immunisation Coordinator to increase the proportion of children who are vaccinated at local, state and national levels.

5. Further incentives to increase the vaccination rates included the establishment of the Australian Childhood Immunisation Register (ACIR). This is a national register that is administered by Medicare Australia to monitor children's vaccination status and to notify parents when a vaccine is required. It also provides a database to inform the government who is eligible for immunisation welfare benefits.

   The ACIR is used to administer the GPII effectively. The GPII is an incentive payment to GP practices to encourage all practices to fully vaccinate at least 90 per cent of children under seven years of age that attend their practices. By registering children on the ACIR the vaccination status of children can be followed and the required amount can be paid to GP practices when the target vaccination rates are achieved. GP's are also expected to consider each consultation with a child as an opportunity to update vaccination status. Medicare Australia subsidizes private consultations that involve vaccination.

6. Children's vaccination status is linked to the eligibility for family assistance payments to remind parents to keep up-to-date with vaccination. In 1997 this payment was called the Maternity Immunisation Allowance (MIA) and it was paid to parents when a child was aged between 18 months and 24 months of age. Parents of unvaccinated children could still receive this benefit if they filled out a conscientious objector's form signed by a doctor. Exemptions were provided for medical, religious or philosophical reasons. Since 2009 the MIA has been provided to parents in two payments. The first payment ($129) is when the child is aged between 18–24 months old and the second payment ($129) is between 4-5 years old. This benefit ceased on 1 July 2012 and was replaced by the *Family Tax Benefit Part A supplement*.

   This benefit was increased to $2,100 and from July 2012 has been paid to parents in three installments of $726 (AG IAP 2013). In order to obtain this welfare benefit parents are required to have their children assessed by the Family Assistance Office (FAO) at one, two and five years of age. Children must be either fully vaccinated, be on a recognised vaccination catch up schedule, or have a signed exemption form for parents to be eligible to claim this benefit. The assessment of the vaccination status of children must take place during the

financial year that each child turns one, two and five years of age in order to receive the benefit.

After increasing the welfare payment linked to vaccination in 2012 the government added *three more vaccines* to the recommended schedule for a child to classify as 'fully vaccinated'. The three new vaccines were meningococcal C, pneumococcal and varicella (chickenpox). Although these vaccines were available to parents for several years prior to 2012 they were not recommended on the NIP. These diseases are a low risk to the majority of children in Australia, however as of 1 July 2013 these vaccines are required for children to be described as 'fully vaccinated' in order to obtain the government welfare benefit. The definition of 'fully vaccinated' in 2013 means inoculation against 11 diseases before a child is 12 months of age. See Appendix 3.

Another welfare payment that was introduced in 1997 was the Child Care Benefit. This payment is to assist with the cost of day care centres and other childcare facilities. Again the benefit applies to children who are fully vaccinated or have an approved exemption from vaccination. The Childcare Rebate was worth approximately $7,500 per child in 2014. This benefit is to assist with childcare and is adjusted according to family income. In 2015 the Australian government proposed removing the right to philosophical and religious exemptions to vaccination. This would be implemented from 1 January 2016 and it means that vaccination will no longer be a choice for parents who depend on welfare payments or childcare benefits for their livelihood (AG DHS 2015). Vaccination with the full schedule of vaccines would be mandatory to receive childcare and welfare payments in 2016. Only medical exemptions will be accepted if this legislation is passed.

7. Regulations have been introduced to require parents to present evidence of their child's vaccination status when they enroll in schools. The regulation requires that a child that is not vaccinated due to medical or conscientious objections can be asked to stay home during outbreaks of an infectious disease. In NSW in 2013, the Public Health Act of 2010 was changed to ban unvaccinated children from childcare centres if parents do not provide an up-to-date certificate of vaccination or a valid exemption form signed by an approved doctor (Gerathy

2013). Exemption forms are allowed for medical, religious or philosophical reasons but they must be signed by an approved doctor.

Educational materials for doctors and other immunisation providers are supplied by the Immunisation Action Coalition (IAC) (IAC 2012). This is a non-profit organization set up by the US CDC with health professionals to distribute information globally on vaccination. The IAC assists in raising vaccination rates globally by facilitating communication about the safety, efficacy and use of vaccines to health professionals and the public (IAC 2012). The IAC receives funding from pharmaceutical companies in the form of 'educational grants' (IAC 2012). In 1997 the seven-point plan was promoted through an 'Immunise Australia' media campaign that targeted parents of children aged 0-6 years of age. The campaign aimed to raise awareness of participating in vaccination programs to control infectious diseases. Other sources of funding for this program, apart from the government, include the pharmaceutical companies. Vaccine manufacturers are providing funding to health professionals to increase the number of children they vaccinate. One example of this type of funding was the Infanrix Immunisation Awards that were presented at the National Public Health Association of Australia in 2006 (PHAA 2006). GlaxoSmithKline, the manufacturer of the Infanrix combination vaccine for diphtheria, tetanus and acellular pertussis vaccine, offered $10,000 to commend professionals who had implemented programs to successfully achieve the following outcomes:

- An increase to 90% coverage in the 4 year old cohort
- An increase in vaccination coverage in populations of hard-to-reach children and/or adolescents

3.13 The Reason for Increased Incentives in 2012

The government believes vaccination is the safest and most effective way to protect against infectious diseases. It is stated that vaccination reduces the spread of the disease so that individuals who are not vaccinated will also be protected by the vaccine through the establishment of 'vaccine-created' herd immunity. The government states that 'immunization rates in 2012 are at the highest on record and as a result notification rates of vaccine-preventable diseases are low' (AG IAP 2012). Sixty-six cases of measles in children under 10 are cited as the reason for the need to increase incentives for

vaccinating (AG IAP 2012). The government has not provided supportive information on the vaccination status of these measles cases, their severity or the context (e.g. socioeconomic status) in which these cases occurred. This is significant for understanding the factors contributing to the risk from measles that exists in Australia for the majority of children.

This evidence is also inconsistent with the epidemiological literature that indicates there are significant problems with the vaccination campaigns to control measles in the developing countries. Despite high measles vaccination coverage in many countries due to the EPI there are regular epidemics of measles in these countries (Obomsawin 1998). Australian parents are informed by the government that 'measles can have serious consequences including death' (AG IAP 2012). This is the reason provided for the increased incentives to vaccinate in 2012. This statement does not represent comprehensive information about the risk of measles to the majority of children in Australia. Poverty and nutritional status influence the risk of this disease and these factors need to be considered when designing public health policies for the good of the *majority* of the population.

In addition, the government claims parents who do not vaccinate their children are risking their child's health as well as the health of other children. Again the government does not quantify or even identify all the factors contributing to the risk from infectious diseases, yet the statement has been used to justify increasing the incentives for parents to vaccinate. In addition, the government has not provided a risk/benefit assessment for each vaccine to justify implementing strategies that make vaccination the default position for *all* the diseases for which there is a vaccine. This default position is enforced by requiring parents to get a vaccine exemption form signed by a healthcare provider in order to choose not to vaccinate.

3.14 The National Immunisation Program (NIP) Since 2012

Whilst the Australian government states 'vaccination is not compulsory', the recommended schedule of vaccines has now been linked to government welfare benefits, some workplace requirements and school entry. Many Australians feel pressured to vaccinate their children because they are required to get a doctor's signature to refuse a vaccine. Participation is further emphasised by encouraging the

public to believe that it is their responsibility for the 'community good'. See chapter 7. This has the effect of increasing the vaccination rate of the Australian population. The NIP schedule since 2013 now includes vaccines against 16 diseases. See Appendix 3. This is an increase from 7 at the program's inception in the early 1990's**.** Children are now recommended to have 7 vaccines by 2 months of age and 14 vaccines by 4 years of age. This results in approximately twenty-four inoculations/doses to complete the full vaccination schedule at four years of age. Varicella became available in a new combination vaccine - Priorix-Tetra - at 18 months of age from July 2013 in Australia. This vaccine includes measles, mumps, rubella and varicella combined in one vaccine. The vaccines that have been introduced into the NIP schedule since 1990 are for diseases that at the time posed only a low risk to the majority of children. Therefore it is incorrect to claim that high-participation rates are needed to protect community health for these vaccines. See chapters 4 and 7.

Funding for the NIP is provided by the Australian Government and industry sponsors to establish the following services (AG IAP 2013; PHAA 2006):

1. Free vaccines recommended in the NIP
2. The Australian Childhood Immunisation Register (ACIR) that records details of vaccines given to children under seven years of age
3. Notification payments to immunisation providers that report vaccines administered to the ACIR
4. The General Practice Immunisation Incentives (GPII) Scheme to provide financial incentives for monitoring, promoting and providing immunisation services to children (ended May 2013).
5. A facilitation and reward payment to states and territories to deliver the NIP in their jurisdictions.

3.15 Vaccination in the Australian Workplace

In 2006 the Federal government implemented a new Policy Directive requiring students studying health at tertiary institutions to be fully vaccinated before commencing or completing their practical work (NSW DH 2005). This was a mandatory directive requiring the updating of vaccination status against 10 diseases. The policy directive states that all health students who are affiliated with the hospital system or with NSW

Health are required to be vaccinated. In 2007 this initiative was extended to include all health professionals and employees of the NSW health system and in 2008 this was extended to other Australian States (AG IH9 2012). See Appendix 3. The Australian Government recommends that employers in occupations where workers are at significant risk of infectious diseases should implement a vaccination program. This program should include a vaccination policy, current staff vaccination records, provision of relevant information about infectious diseases and the management of employees who refuse vaccination (AG IH9 2012). The government emphasizes that this policy should include reducing the risk of a healthcare worker transmitting disease to a patient (AG IH9 2012). It is recommended that employers should take all reasonable steps to encourage unvaccinated workers to be vaccinated and if an unvaccinated person is exposed to a vaccine-preventable disease then they should be given any agent (prophylaxis) that prevents the development of the disease (AG IH9 2012).

The reason for extending vaccination programs to healthcare workers, childcare centres, schools and emergency services is the belief that individuals are at greater risk from infectious diseases in these occupations (AG IH9 2012). There has been no evidence provided of a heightened risk of these diseases to Australian workers in these occupations. However, it is stated that these professionals have greater capacity to transmit these diseases to other individuals because they work in close contact with communities. Public policies are based on 'best judgment' and the current thinking is that individuals in some workplaces are at greater risk from infectious diseases therefore vaccination policies should be enforced. Academic institutions are insisting that health students be vaccinated to complete their courses, even though the Australian Government policy states that vaccination in Australia is not compulsory and that these directives are recommendations, not regulations or legislation (AG IH9 2012). Since 2012 some childcare centres, schools and institutions have been discriminating against healthy individuals by selecting against their enrolments or by preventing their placement in clinical situations in the workplace because they are not fully vaccinated. Parents and health professionals are losing welfare benefits and work/school placements if they do not follow the recommended procedures and several court cases have arisen due to the pressure placed on individuals to vaccinate (Hansen 2012).

3.16 The Evidence for Workplace Vaccination Policies

I have relied on Sepkowitz 1996 and Sepkowitz and Eisenberg 2005 for this information because these are the only sources cited by the government in the Australian Immunisation Handbook to support this policy.

The Australian Government has based its vaccination policy for the Australian workplace on evidence that has been collated from US workplaces and not Australian workplaces (AG IH9 2012). Statements about this policy in the Immunisation Handbook are based on evidence provided in two documents:

1) An analysis of occupationally acquired infections in healthcare workers in the US in 1996 and
2) The recommendations that were provided by the US Advisory Committee on Immunisation practices (ACIP) in 1997 (AG IH9 2012).

With reference to occupationally acquired infections in the US, the literature states that the last assessment of this issue occurred in 1986 (Sepkowitz 1996). There are few historical studies that have examined the incidence, prevalence or exposure-associated rates of infection in any country. Prior to 1996 the issue of preventative measures to improve worker safety had not been a matter for consideration (Sepkowitz 1996). Although there is a recognised risk to healthcare workers, a system to track fatal, occupationally acquired infections to determine an accurate estimate of the risk to healthcare workers had not been established in any country by 2005. Consequently, the actual occupational death rate from infections acquired in the workplace in any country was unknown when this policy was introduced (Sepkowitz and Eisenberg 2005).

In 2005, the CDC performed another analysis of the risk to US workers and estimated that 17 – 57 per million US healthcare workers die annually from occupational infections and injuries (Sepkowitz and Eisenberg 2005). However, the researchers admit that this figure is an educated guess at best. The figure was based upon 'the projected potential consequences' of only 4 diseases based on the prevalence, transmission rate and natural history rates of these infections (Sepkowitz and Eisenberg 2005). The 4 diseases were hepatitis B, hepatitis C, HIV and tuberculosis. These diseases are relevant to specific environments and the risk characterisation from these studies should not be assumed to represent the risk to all US and Australian healthcare workers. The

risk is dependent upon the social and environmental context in which the diseases are observed. In addition, the risk assessment includes the risk from HIV, which cannot be prevented with a vaccine, and it does not include diseases that present a risk to Australian workers.

This death rate was also based on data with significant limitations so it is impossible to know if the figure was an over- or underestimation of the risk to US healthcare workers (Sepkowitz and Eisenberg 2005). In 2005, there was no national tracking system in any country to define the need for extra measures for healthcare worker protection. This also means that it was not possible to estimate the cost-effectiveness of introducing mandatory vaccination policies for any occupation – either in Australia or the US - at this time. Vaccination polices in Australian workplaces have been implemented *before* the size of the risk that workers face has been quantified, therefore preventative policies for healthcare workers cannot be claimed to be evidence-based practice. These policies have been based on the current belief in the necessity for vaccines as opposed to empirical evidence of risk established by a national tracking system of worker's health. In 2005, the CDC recommended that national organisations introduce nationwide tracking systems to determine the magnitude of the problem resulting from acquired infections and death in healthcare workers (Sepkowitz and Eisenberg 2005). This demonstrates that the introduction of this policy in Australia in 2006 was based upon unrepresentative data from another country, and the Australian government had not quantified the risk that infectious diseases in Australia pose to healthcare workers. The US data uses the example of experiences with SARS and smallpox vaccination in the early 2000's to illustrate the potential risk of infectious diseases to healthcare workers. These are interesting examples to use particularly as the risk of smallpox was greater from the vaccine than from the disease itself (Sepkowitz and Eisenberg 2005). In 2003, the US government was concerned about bioterrorism and implemented a policy requiring all healthcare workers to be vaccinated against smallpox *in case* of a terrorist attack. This program had to be aborted after vaccinating only tens of thousands of workers because of the significant side-effects (including death) caused by the smallpox vaccine.

Healthcare workers were refusing to get this vaccine because of the known fatal reactions. As a result of this harm, the US government extended financial compensation for workers to include those who have become disabled from a vaccine in the line of

duty (Sepkowitz and Eisenberg 2005). A compensation scheme is not available to the Australian public and this represents a safety issue for employees who are harmed by a vaccine in the line of duty. The lack of information regarding the magnitude of risk due to infectious diseases in the workplace has been confirmed by an Australian doctor who commented 'I can't recall a single case of a student or clinician getting tetanus, diphtheria or mumps from a patient. The diseases we do fear catching – HIV, hepatitis C and most viral respiratory diseases – have no vaccines' (Iannuzzi 2012). This doctor also commented that he now gets numerous visits from a 'new category of patient': healthy young adults. These students are visiting doctors to get forms signed and to update with multiple vaccines in order to complete their practical placements for their tertiary courses (Iannuzzi 2012).

In addition to the lack of information on the risk of infectious diseases to healthcare workers there is a lack of information on the magnitude of the risk from the required vaccines for occupational use. Due to the lack of adequate surveillance of post-vaccination adverse events there is no quantitative data on the risk that is imposed on healthy adults by updating with a combination of 10 recommended vaccines. It is known that vaccines present a serious risk to some individuals yet Australia, unlike the US, does not have a vaccine compensation scheme for the victims of vaccine adverse events. Hence, introducing mandatory directives regarding the use of vaccines in the Australian workplace should have been preceded by the collection of evidence of the necessity for this action, a public debate on the pros and cons of this regulation and a compensation scheme for individuals who are harmed by this mandated medical procedure.

3.17 The Impact of Coercive Strategies in Vaccination Policies

Whilst government welfare benefits are also available for parents who choose not to vaccinate their children, there are certain requirements they must meet in order to receive these benefits. In 2013 these requirements include a certificate from a healthcare provider that states one of the following reasons (Ag IAP 2013):

- 'There is a medical reason why the child should not be vaccinated
- The child has already had the disease or has natural immunity
- A particular vaccine is unavailable'

- Conscientious objection

To obtain the welfare allowance without vaccinating their children parents need to complete the *Immunisation Exemption: Medical Contraindication* form or the *Conscientious Objector's* form that is available on the Health Department website. The *Conscientious Objector's* form can be used by parents choosing not to vaccinate their children for personal, philosophical or religious reasons. To refuse vaccination parents must complete the form with the assistance of an approved healthcare provider. This means the government has set a default position of vaccinating rather than not vaccinating in Australia. The significance of this is that healthy children are now recommended to use multiple vaccines before their first birthday yet doctors are not obliged to inform parents of the ingredients of these vaccines.

The Conscientious Objector's form became known as the 'vaccine refusers' form in June 2013 (Hartley 2013). Many parents experience difficulties in getting GP's to sign refusal forms in order to claim the government welfare benefit of $2,100 (Bradley 2013). One poll found that 54% of doctors would only sign 'vaccine refusers' forms on medical grounds (Bradley 2013). The Australian Medical Association (AMA) has stated there is 'no legal obligation to do so' (Woodhead 2013). Brian Morton, chair of the AMA's Council of General Practice, states that his decision not to sign refusal forms is backed by advice from the medical defence organisations (Woodhead 2013). Although the government's official line is that vaccination in Australia is not compulsory, in reality it results in financial and employment penalties for individuals who choose not to vaccinate.

There is currently confusion over whether doctors are obligated to sign conscientious objector's forms. The government provides a directive to doctors requiring them to counsel parents about the pros and cons of vaccines before signing the forms. The expectation that doctors will sign the forms is also supported by the government's statement that 'vaccination is not compulsory' and the fact that welfare benefits are linked to the signing of this form. However, the Australian Medical Association (AMA) informs doctors that if they do not feel they have adequately explained the risks and benefits of vaccination during the consultation then they are within their rights to not sign a conscientious objector's form (Woodhead 2013). Consequently many parents and employees in Australia feel pressured to vaccinate by doctors who will not sign the

vaccine refusal forms and by employers that require employees to update with the recommended vaccines. This is resulting in discrimination in some aspects of Australian society on the basis of vaccination status, even whilst the government continues to claim vaccination in Australia is not compulsory. As of 2015 the Australian government has proposed removing the conscientious objector's form and the right to refuse vaccines on philosophical and religious grounds. Only medical exemptions will be accepted in the new legislation for social welfare policies to be implemented in 2016 (AG DHS 2015).

3.18 Conclusion

The Australian government's NIP has been set within the framework and directives of the WHO's global health policy. It has not been developed within the specific environmental context of the Australian community but to comply with directives from the WHO on global vaccination policies. These policies have been developed by WHO/UNICEF since the 1970's and inspired by the campaign to eradicate smallpox. Although there was disagreement at this time about the value of vaccination in eradicating diseases, WHO/UNICEF decided to expand the program to many other infectious diseases. This was initiated as the Expanded Program on Immunisation (EPI) and since the 1970's has developed through many phases in all WHO member countries, both developing and developed. The campaign has been promoted on the moral principle of 'saving the world's children with life-saving vaccines'. During the 1980's the influence of neoliberalism resulted in economic and political experts dominating the development of global health policies. Mixed health messages began to be presented through WHO directives as neoliberalism focused public health policies on technology-based interventions such as vaccination. This was done in many developing countries at the expense of primary healthcare programs that targeted the social and environmental determinants of health. In the 1990's the World Bank, the International Monetary Fund and the Rockefeller and Gates Foundations became partners with the WHO/UNICEF to sponsor global vaccination programs. A shortage of funding in the 1990's for the research and development of vaccines led to the development of public-private partnerships that were influential in the direction of global health policies in WHO member countries.

Economics and politics began to dominate the design of public health policies from this time, with health statistics obtained from non-governmental economic models of the cost-effectiveness of implementing vaccination programs. Global health directives were based on industry modeling for global communities instead of the specific ecological conditions of each country. In 2000 the direction of global public health policies changed with the establishment of the Global Alliance for Vaccines and Immunisation (GAVI), a body that consists of public-private partnerships with governments and corporations jointly influencing global health policy decisions. At this time vaccines became the sole focus of global policy: GAVI promoted vaccines to WHO member nations using financial incentives as well as by controlling the supply of vaccines to these countries. This resulted in the 'vaccine paradox' where governments, in alliance with corporations, control the supply and demand of vaccines. This represents a clear conflict of interest that is not transparent to the public. Since 2000 global public health policies have protected industry interests through the sole focus on vaccination programs and many authorities within the WHO, and developed nations, have expressed concern at these technology-based health programs. This has been at the expense of broader primary healthcare needs.

Australia's NIP expanded in the 1980's and 1990's according to WHO goals for achieving high participation rates for all the recommended vaccines. The goals were set to increase childhood vaccination rates to ninety percent for all the vaccines in Australia even though there was no significant threat to the majority of the population from the targeted infectious diseases. The decision to use vaccines for many diseases was a universal directive to both the developed and the developing countries, without risk/benefit assessments for the use of each vaccine in specific countries and populations. In addition, national governments did not provide an adequate surveillance system for the accurate determination of the frequency of causally related adverse events from vaccines. The harm caused by vaccines, either individually or in the combined schedule, has not been included in the economic modeling for the cost-effectiveness of vaccination programs. These programs have been based on the assumption that vaccine-created herd immunity can prevent infectious diseases, if enough people participate in these programs, without causing significant harm to the population. The lack of empirical evidence for these assumptions is discussed in chapters 4 and 7.

During the 1990's government's re-labeled infectious diseases as *vaccine-preventable diseases*, a label that implies vaccines can prevent infectious diseases. The public has been informed through the mainstream media that high participation rates in vaccination campaigns are needed to *prevent* infectious diseases but the empirical evidence to support this claim has not been provided. The evidence the Australian government provides to support vaccination policies is discussed in Chapter 7. The government has introduced many new vaccines since the 1990's and emphasised the need for high vaccination rates for all infectious diseases for which there is a vaccine. New vaccines are continually added to the national recommended schedule. Each vaccine carries a risk to some individuals yet the Australian government does not provide a separate risk/benefit assessment for each disease and vaccine, nor for the combination of vaccines that are recommended in the children's schedule. The vaccines have been added to the recommended schedule without public consultation or participation in policy development, and without informing the public of the ingredients of vaccines. Financial incentives have been used to pressure parents and doctors to use all the recommended vaccines and to assist the government to track the vaccination status of children. These strategies were implemented in 1993 and formalized in 1997 as the Immunise Australia Program (IAP). These coercive practices have increased in 2015 with many employees now being required or expected to vaccinate even though the government continues to claim that vaccination in Australia is not compulsory.

The Australian Government's program does not make any reference to the historical evidence of the control of infectious diseases in Australia or the risk/benefit of using an increasing number of vaccines in children/adults. Mainstream media has been used since the 1990's to influence public behaviour by informing the public that high participation rates in vaccination programs are important in controlling infectious diseases without providing evidence for this claim. In contrast, the media was used in the early 20th century to successfully promote social (ecological) medicine to the public to reduce the threat of infectious diseases through environmental and lifestyle changes. The media message changed in the second half of the century when the focus of public health was directed to vaccination policies. Since this time the mainstream Australian media has emphasised the benefits of vaccines, without providing empirical evidence, and without informing the public of the known risks associated with each vaccine or the long-term health effects of the combined schedule of vaccines.

Overview of later Chapters

Chapter 4 provides a discussion of the implementation of vaccination policy in Australia and the methodology used for assessing environmental health risks in infectious disease law. It examines the way in which health risks for vaccines and infectious diseases are being characterized and framed to the public. Chapter 5 examines the principles that underpin good medical practice and health promotion in public health policy. A description of the influence of corporations in the supply and demand for vaccines in government vaccination policies is provided in chapter 6 and chapter 7 is a discussion of the evidence the government provides to the public on the Immunise Australia Program (IAP) website to support vaccination policies. Chapter 8 describes the concept of undone science and the political framework that increases areas of undone science in public policy. In chapters 9 and 10, I have provided examples of the corporate influence and undone science in two global vaccination programs, the Human Papillomavirus (HPV) vaccine and the 'Swine Flu' 2009 vaccine. In chapter 11 I have drawn conclusions about the development of Australia's vaccination policies and the integrity of the scientific evidence being used to make claims about the safety and efficacy of vaccines.