Ministry of Health report for Health Select Committee's inquiry into improving immunisation coverage rates

The report is the Ministry of Health's response to the key themes and issues raised in the inquiry submissions.

To assist the Health Select Committee to make their inquiry recommendations, this report:

- suggests priority areas for improving immunisation coverage
- provides a Ministry of Health response to the key themes raised in the inquiry submissions
- summarises the Ministry of Health's current and planned activities to improve immunisation coverage

Where appropriate, Ministry advice supplied to the Committee throughout the inquiry has been attached to the report as appendices.

Key themes identified from inquiry submissions

The Ministry identified the following key themes from the inquiry submissions. The report addresses each of these themes in turn, and includes Ministry activities for improving immunisation coverage that are relevant to each theme.

- Informed consent and/or communication
- Provider needs and issues
- Improved use of the National Immunisation Register
- Improving the management and monitoring of adverse events
- Vaccine safety and effectiveness
- Other recommendations and issues

Aligning the key themes to the inquiry Terms of Reference

The Health Select Committee's inquiry terms of reference are:

1. To collate current statistics for New Zealand children on timeliness of delivery and completion of immunisation, and how we compare internationally.
2. To assess how well the New Zealand Immunisation Register is working, and the effectiveness of utilisation.
3. To search relevant world literature for optimal methods of how to achieve timely and high immunisation completion rates.
4. To seek up-to-date information on community concerns, informed consent and conscientious objection issues.
5. To seek an analysis of benefits and disadvantages.
6. To define, and make recommendations as to what methods could be applied at minimal cost to improve immunisation in New Zealand, (bearing in mind the first 60 percent are easier to get, the next 20-30 percent require more effort, the next 5 percent lots of effort, and around 5 percent are declines).

This report is formatted to follow the key themes and issues arising in the submissions (and described above). However, the following table matches the first five Terms of Reference with the relevant sections in this report.

Term of Reference	Relevant Section number(s)	Page number(s)
1. New Zealand immunisation coverage statistics	Appendix 2	55-66
2.National Immunisation Register	Section 4	23-25
	Appendix 3	67-69
3.Methods to achieve timely and high immunisation rates	Section 3.1.1.1	15
	Section 7.3	45-46
	Section 7.5	46-47
	Appendix 8	97-102
4.Community concerns, informed consent and conscientious objection issues	Section 2	8-13
	Section 5	26-29
	Section 6	30-43
	Appendix 6	89-96
5.Benefits and disadvantages	Section 1	6
	Section 2.1.1	8-9
	Section 2.1.4	10-11
	Section 6	30-43
	Appendix 4	70-74
	Appendix 5	75-88
	Appendix 6	89-96

Table of Contents

List of Tables

List of Figures

1 Introduction

The immunisation target of 95% of 2-year olds fully immunised by July 2012 is based on the coverage needed across the country to prevent outbreaks of measles, the most infectious of the vaccine-preventable diseases. This target was first adopted in 1995 to be achieved by 2000. Since 1992 the percentage of fully immunised 2-year olds has risen from less than 60% to 87% today (see Appendix 2). About 5% of parents currently oppose immunisation, so achieving 95% coverage means immunising everyone else, while working to improve public confidence.

The Ministry of Health's current focus is to achieve the Immunisation Health Target of 95% of two-year-old children fully immunised by 2012. Once this is achieved, the Ministry may focus on improving immunisation coverage rates in other age groups, such as the 4- and 11- year immunisations, as well as immunisation timeliness (e.g. at 6, 12 and 18 months of age). Further analysis is required to determine optimum immunisation coverage levels for these age groups; levels would depend upon disease risk, population and personal benefits and risks and the current immunisation schedule.

1.1 Priorities for improving immunisation coverage

The Ministry believes that the elements are in place to achieve the target of 95% of children fully immunised by 2012, but that certain aspects could be improved. The immunisation system does not need radical change or restructuring, because that would threaten the basic systems that already achieve almost 90% coverage (see Appendix 1, Figure 7 for a picture of the immunisation system).

The Ministry believes the priorities for immunisation over the next two years are:

1. Get the basic systems right.
2. Differentiate by audience, not by institution

The Ministry's immunisation strategy reflects these two priorities, and is attached as Appendix 1.

1.1.1 Get the basic systems right

The list below identifies some aspects of the immunisation system that limit its success. Some of these aspects were also raised in the inquiry submissions and so are discussed in more detail in this report; the relevant report section numbers are in brackets.

- Ethnicity and poverty are the strongest correlates of low immunisation rates, which suggest there are systemic barriers making some of these people unable, unmotivated, or unwilling to go to a doctor to immunise their children (sections 1.1.2, 2.1.2, 2.1.3, 2.2.1, 2.2.3, 2.3.1, 3.2.2, 7.1, Appendix 2).
- Institutional and funding systems are creating barriers, inefficiency and inflexibility – an example is the division of care between maternity, Well Child, and general practice (section 3).
- Not enough incentives – either for parents or for providers (sections 7.3 and 3.1.1.1).

- Disruption to the immunisation system from changing the immunisation schedule, introducing new vaccines, and responding to outbreaks has diverted time and effort away from improving existing and routine systems.
- The National Immunisation Register could be better used and could be improved (section 4, Appendix 3).
- investigate options to improve the adverse event monitoring system, such as providing increased transparency, and communicating better with parents *(*sections 5.2 and 5.3*)*

Addressing each of these aspects of the immunisation system should contribute to improving coverage, not just for two year old children but for New Zealanders of all ages.

1.1.2 Differentiate by audience, not by institution

"Understanding what motivates parents to immunise their children or not requires much more investigation. To reach the immunisation target of 95% by 2012, we will need a more sophisticated way of finding out why parents make the decisions they do - and more approaches to ensure parents are able to make well informed decisions for themselves and to recognize the benefit for the community." [1]

Previous immunisation strategies are nearly always divided into sections focusing on the different institutions such as the Ministry, District Health Boards (DHBs), Primary Health Organisations, doctors and nurses. Most of these strategies do not differentiate the initiatives for different audiences, though there is a clear focus on the part of the population that is not immunising. The result is that the audience tends to be treated as homogenous, and that all Māori and Pacific are put into one category. This approach creates two risks: interventions are not targeted correctly; and the largest population, those that immunise are ignored.

The Ministry proposes to take a different approach that divides the population into segments based on their behaviours and motivation (see Appendix 1, Table 9), rather than their ethnicity or location, and targets communication and interventions appropriately. The Ministry will advocate and encourage the sector and providers (particularly DHBs) to use this approach in their immunisation strategies and has commissioned audience research to better understand the size of the different groups and their motivations.

[1] Hon. Tony Ryall – Abridged speech notes "Launch of Massey University School of Public Health – Wellington", 24 March 2010

2 Informed consent and/or communication

This section covers the following themes raised in the submissions: informed consent; communication strategies; information sources.

2.1 Informed consent

Some submitters claim that informed consent cannot be achieved as the information provided by the Ministry of Health is not balanced (the benefits are oversold and the risks are undersold) and cannot be trusted; that providers are so focussed on targets that they coerce patients and that those who have chosen not to immunise are considered irrational.

Ministry Response and activities to improve immunisation coverage

2.1.1 Informed consent

The Ministry's role in informed consent is to facilitate the discussion between the parent and the provider by providing science-based, up-to-date information about the vaccines and the diseases they protect against. Although the Ministry is not directly involved in the process, the Ministry acknowledges that its policies and public statements influence both providers and parents.

A comprehensive description of informed consent as it applies to vaccination can be found in Chapter 2 and Appendix 3 of the *Immunisation Handbook* 2006, and includes the legal basis as well as providers' obligations. The *Immunisation Handbook* is the Ministry's main guidance for immunisation providers and is being updated for the change to the national immunisation schedule that is due mid-2011. The Health and Disability Commissioner's office has agreed to review the informed consent sections of the Handbook.

Some of these issues have been raised directly with the Ministry and also through the Health and Disability Commissioner in relation to the human papillomavirus (HPV) immunisation programme. In response, the Ministry amended its HPV consent form in consultation with stakeholders, and developed the following principles for its immunisation programmes.

- People have the right to choose whether to immunise.
- People have a right to know how safe and effective vaccines are, and how long protection lasts for.
- We earn the trust and confidence of the public by being up-front and providing the best information we can.
- We value and listen to feedback about how we can better support the informed consent process for parents and providers.
- We have statutory obligations to ensure the highest level of health for our population.
- The Ministry does not take a neutral role and encourages immunisation because there is a public benefit from having a high proportion of our community immunised (herd immunity and reduced healthcare costs).

- Immunisation is the most cost-effective public health intervention available, next to clean drinking water and sanitation. Promoting immunisation is a proven and effective health intervention and is endorsed by the United Nations and World Health Organization.
- Family doctors, practice nurses and other health professionals are best-placed to answer parents' and individuals' questions about immunisation and ensure they get the information they need to make their decisions. The Immunisation Advisory Centre's 0800 IMMUNE toll-free phone line and website provide back-up information.

2.1.2 Information to support informed consent and parental decision making

Evidence from New Zealand and other countries shows that people do not immunise because of:

- Lack of knowledge – over 50% of parents antenatally state they don't have enough information to make a decision and two-thirds do not feel very confident about their decisions to vaccinate (Petousis-Harris et al 2004)
- Lack of motivation – about 12% of parents do not believe vaccines are effective and around 8% of parents consider the diseases are mild or no longer a threat. Around 20% of parents believe healthy living alone is enough to prevent the diseases, and over 30% of younger mothers believe this (Petoussis-Harris et al 2002a).
- Poor antenatal information – around 80% of parents make their decision to immunise before a child is born. Good decision-making tools improve their confidence and reduce their anxiety about their decision, and significantly increase the timeliness of immunisations for their children (Wroe et al 2004; Wroe et all 2005).
- Fear and distrust – fear of vaccines (pain, reactions, long-term effects), distrust of providers and pharmaceutical companies and biased information (Petousis-Harris et al 2002b; Hamilton et al 2004).
- Lack of opportunity – barriers such as transport, time, pre-existing debts, looking after several other children.

This shows that parents need:

- Access to information that they trust and can understand which gives them the information they need and answers their questions, particularly about the risks and effectiveness of vaccines.
- Opportunities to discuss immunisation with a trusted health provider before birth and soon after.
- Opportunities to immunise at times and places that suit them.
- To be encouraged to immunise.
- To understand the consequences of the diseases and that they have not disappeared.
- To recognise their responsibilities if their children are not immunised.

The Ministry produces a range of resources for parents and providers, including brochures, booklets, consent forms, DVDs, stickers, webpages, e-learning and the *Immunisation Handbook*. Some of the print resources are translated into a range of languages, including Te Reo Māori, several Pacific and Asian languages and Arabic. The Ministry funds vaccinator training courses for providers so they can safely and

confidently deliver vaccines. These courses include information about the diseases, the vaccines, vaccine administration, the cold chain, adverse events, and the informed consent process.

The Ministry receives feedback that its resources contain both too much information and too little information. The challenge for immunisation programmes is to ensure there are sufficient and appropriate resources available to match each of the audiences' needs, without producing so many resources that the audiences are overwhelmed. The Ministry has commissioned a project to identify the behaviours, decision-making processes, attitudes and barriers experienced by those who are not immunising their children. The research results are expected at the end of 2010 and will guide future communication strategies.

Immunisation resources will be reviewed and updated in 2011 as part of the national immunisation schedule change.

2.1.3 Parents who choose not to immunise

The Ministry accepts that a certain proportion of New Zealanders will never choose to immunise, regardless of what information is provided. Research suggests 3-6% of parents fall into this category, though they may not be evenly distributed across the country (see Appendix 2 for decline data from the National Immunisation Register). The Ministry's aim is healthy children so the best strategy for this group is to provide information about how to avoid infections and care for sick children.

The Ministry and providers need to respect the choice that people have made. However most parents of under immunised children have not made a conscious choice not to immunise, they do not immunise because they simply forgot, have other priorities, or it may be too difficult to get to an appointment. Since there are many people in these situations, the Ministry believes it is acceptable to remind people about appointments or offer alternative locations for immunisation.

2.1.4 Immunisation coverage targets

High immunisation coverage is important to protect not only the health of individuals but to protect the community as well, including those who cannot be immunised. However, ensuring informed consent is obtained takes precedence over achieving immunisation targets.

The immunisation target is set to 95% to control the most infectious of the vaccine-preventable diseases, which are measles and whooping cough. Modelling suggests that outbreaks of measles would be prevented if 95% of the population was immune, or if there was sustained 90% coverage for both doses of measles vaccine (at 15 months and 4 years). For whooping cough (pertussis), 80-90% immunisation coverage reduces pertussis notifications to one tenth the level without immunisation, and 95% immunisation coverage reduces pertussis notifications to one hundredth (*Immunisation Handbook* Chapter 6: Pertussis).

The target of 95% coverage allows for those who consciously choose not to immunise, given the research suggesting this group is 3-6% of the population. But it does mean that there may be communities or districts that will not be able to achieve 95% coverage because there are higher than average numbers of people choosing

not to immunise (see Appendix 2 for decline data from the National Immunisation Register). The Ministry considers that the target is still appropriate because it is important to have an aspirational goal and to strive to reach the people least likely to access healthcare. But it is equally important that the consequences of not meeting targets do not override the need for informed consent or to respect peoples' right not to immunise.

2.2 Communication strategies

To build trust and confidence, submitters recommended that multi-layered communication strategies are used. The range of suggestions included using Whānau Ora principles and focusing on achieving equity for Māori; ensuring information is provided during the antenatal period; working to improve health literacy now will enable New Zealanders to make better informed choices in the future.

Ministry response and activities to improve coverage

2.2.1 Multi-layered communication strategies

The Ministry has not mounted a general immunisation promotion campaign for many years. There was a specific campaign for the meningococcal immunisation programme and there are currently communication programmes for the human papillomavirus and influenza immunisation programmes.

Although many parents report that they want more information about immunisation, the Ministry also gets feedback from providers wanting even simpler documents with less text. It is not clear that a public information campaign about immunisation would be effective because the public has such differing needs for information and there are many different reasons for people not immunising. There are also significant financial costs associated with public information and/or social marketing campaigns; any communications activities will need to be funded within the existing budget. There may be opportunities for cost savings (see section 7 "Other recommendations and issues") in vaccine purchase, storage and supply which could be re-directed into communication activities.

The Ministry had mixed results in 2009 in response to immunisation promotion for disease outbreaks: there was a strong public response to the measles outbreak but almost no response to the predicted whooping cough epidemic. Feedback from the sector suggests that media coverage played an important role, but that there is a complex interplay between the immediacy of the disease, parents' attitudes, the threat of children being excluded from school, and media coverage. The Ministry's view is that trust is a critical ingredient and that the Ministry needs to further build trust among parents so that they are confident about the information they get from the Ministry and the decisions they make.

The Ministry intends to mount some targeted communication campaigns using trusted spokespeople, particularly the Ministry's Immunisation Champion but also external people and the chief executives of DHBs, who have put more attention on immunisation since performance against health targets has been published. The target audiences will be:

- the DHBs where immunisation rates are lowest
- parents who haven't made a decision about immunisation
- providers who do not make immunisation a priority.

While some submitters were concerned that a growing proportion of middle-class New Zealanders are actively choosing not to immunise, the Ministry's data shows that although decline rates are higher for NZ Europeans, immunisation coverage drops across the five deprivation quintiles. Poverty and ethnicity are still the highest correlates of low immunisation coverage (see Appendix 2).

The Ministry is using the National Immunisation Register (anonymised data) to analyse the unvaccinated population by ethnicity and level of deprivation (see Appendix 2). This will also include a review of which vaccines are being declined. If there is a particular trend (e.g. measles-mumps-rubella (MMR) vaccine being declined) strategies will be employed to address this, including communication strategies (e.g. refuting the link between MMR and autism).

A key objective of the human papillomavirus immunisation programme was to achieve equity "*in order to enable Māori and Pacific young women to have as equal an opportunity to benefit from the programme as other New Zealanders*"[2]. Funding was made available to DHBs for activities aimed at achieving equity, including community awareness raising activities targeted to Māori and Pacific communities, including whānau engagement. Successful strategies are being shared between the Ministry and DHBs on an ongoing basis and achieving equity in all immunisation programmes remains a priority for the Ministry (also see section 7.1 "Work to close the gap between between Māori and NZ coverage")

An Immunisation Coverage Forum is being established to provide ongoing advice about improving immunisation rates and how the immunisation system is operating for providers (see section 3.2.2 "Sharing best practice"). Whānau Ora principles have been incorporated into the forum's terms of reference.

As described in section 2.1 "Informed consent" above, the Ministry has funded a project to better understand the reasons why parents do not immunise. This research will support improved communication with different audiences.

Some DHBs are undertaking specific projects to engage closely with families who decline immunisation to determine the reason for decline and offer alternate service delivery or immunisation education where appropriate.

2.2.2 Antenatal issues

See Section 3 "Provider needs and issues".

[2] Ministry of Health. 2008. Human Papillomavirus Immunisation Programme: National Implementation Strategic Overview.

2.2.3 Health literacy

The findings of a recent Ministry of Health report[3] on health literacy 'show that overall the majority of New Zealanders are limited in their ability to obtain, process and understand basic health information and services in order to make informed and appropriate health decisions. Furthermore, Māori have much poorer health literacy skills compared to non-Māori, regardless of gender, age, level of education, labourforce status, household income, or rural/urban location, and this is likely to have a negative impact on their health status'. This is an emerging issue and will be explored further by the Ministry in regards to informed consent and immunisation communication.

2.3 Sources of balanced information

Some submitters claimed that information provided by the Ministry of Health is not balanced (the benefits are oversold and the risks are undersold) while others were concerned that misinformation on the internet about immunisation was harmful.

Ministry response and activities to improve coverage

There is a wealth of vaccine information and misinformation available to parents and providers. There are many internet sites that provide useful science based information on vaccine safety but there are many that provide unbalanced and misleading information. This can make it very difficult for people to determine the risks and benefits of vaccination and therefore to make a decision to immunise or not.

The Ministry funds the Immunisation Advisory Centre (IMAC), based in the University of Auckland, to provide a website and an 0800 phone number that parents can call to discuss immunisation and get answers to their questions. The website has recently been recognised by the World Health Organization's (WHO) Global Advisory Committee on Vaccine Safety[4] for meeting their criteria for good information practices. The Centers for Disease Control[5] also has criteria and tips to assist readers in identifying web sites providing information on vaccine safety.

2.3.1 Child health information

Combining the findings of the Ministry's 2006 Review of Well Child/Tamariki Ora Framework and the resulting Parent Information Project, the Ministry has concluded there is a need for a national online child health information service that provides easy access to credible, trusted and high-quality child health information, advice and support for parents, including immunisation. The child health online service should also provide access for parents to telephone and face-to-face child health services. The service will provide information that is appropriate, accessible and acceptable to Māori and Pacific parents, whānau and families, and will meet the needs of Māori and Pacific children.

[3] Kōrero Mārama: Health Literacy and Māori – Results from the 2006 Adult Literacy and Life Skills Survey, Ministry of Health, 2010
[4] http://www.who.int/immunization_safety/safety_quality/vaccine_safety_websites/en/index.html
[5] http://www.cdc.gov/vaccines/vac-gen/evalwebs.htm

3 Provider needs and issues

This section covers the following themes raised in the submissions: funding; coordination; education/information.

3.1 Funding

Submitters argue that the current funding does not meet the needs of and costs to deliver immunisation. Immunisation contracts need to be streamlined to improve efficiency, reduce duplication and to allow flexibility.

Ministry response and activities to improve coverage

3.1.1 Funding

The current immunisation funding levels are unlikely to increase, but they may be rearranged (see immunisation contracts below).

The immunisation benefit is paid when providers deliver national immunisation schedule vaccines. In 2010/11 the benefit is $18.80 excluding GST.

The immunisation benefit is paid by DHBs to primary care providers – usually doctors. However, other medical and nursing council registered providers can claim the benefit, such as lead maternity carers, outreach immunisation service providers and Well Child/Tamariki Ora providers. In order for this to occur, the DHB must agree to set up a contract with the provider and the DHB, and the provider must meet legislative and professional requirements. Many DHBs are unaware of the range of providers that can claim the benefit.

The Ministry is working to make this process as easy as possible for DHBs by changing payment systems and creating contract templates. The Ministry will also better communicate the process to DHBs.

General practitioners have argued for many years that the immunisation benefit is not sufficient to cover the costs of immunising, particularly for the hard-to-reach. Research shows that the costs to general practices vary widely from a first quartile of $14.38 to a third quartile of $32.50 with $25.67 estimated to be the cost of a typical vaccination (Immunisation Advisory Centre 2008).

The research also shows that practices are putting very little time into opportunistic immunisation, recalling, and searching for children who are overdue, and this may be due to the financial loss. The Ministry accepts that it costs more to immunise as rates get higher and considers that a flat fee is not the best mechanism to reimburse the cost of immunising. Rather than increasing the flat fee, the Ministry would prefer to develop staggered payments based on immunisation rates. This is complex to implement because it needs to be integrated into the health payments systems and the contracts between DHBs and primary care.

3.1.1.1 Provider incentives

The Primary Health Organisation (PHO) Performance Programme offers financial incentives to PHOs who improve their performance on clinical indicators against targets. The programme aims to improve the health of enrolled populations and reduce inequalities in health outcomes through supporting clinical governance and rewarding quality improvement within PHOs.

Immunisation is one of these clinical indicators - PHOs have coverage targets for children fully immunised by their second birthday and influenza vaccinations in the over 65 population. Reports from PHO representative organisations are that these incentives have had a positive effect.

From January 2011 the National Immunisation Register will be used to measure the immunisation indicator rather than data from the practice management systems. This is expected to lead to improvements in NIR data quality as providers will have a financial incentive to ensure data is entered correctly and that system upgrades are downloaded.

Australia has successfully used financial incentives to general practitioners to increase its immunisation rates over the last decade, though at high cost.

The Ministry could explore options for changing the way providers are paid, without undermining trust between people and their health provider. Wrongly targeted incentives can create more problems than they solve. The options are:

- A first time payment for undertaking an informed consent process for both providers and parents – incentivising parents to make a choice may improve immunisation coverage and timeliness. The payment would also be made to those who register on the NIR as a conscientious objector and those with medical exemptions.
- A system of staggered payments that start lower than the current subsidy for low immunisation rates but increase as immunisation rates reach certain thresholds.
- Making the immunisation benefit more readily available to other providers.

Further analysis is needed to determine if the above options can be funded from within existing immunisation funding. Consultation with the public and the immunisation sector would also be required.

3.1.2 Immunisation contracts

The Ministry of Health is reviewing the Ministry's current immunisation contracting arrangements (see Appendix 1 for a picture of the New Zealand immunisation system). This project will provide recommendations on how to improve the efficiency and effectiveness of these arrangements. The Ministry estimates that new contracting arrangements will be in place by 1 July 2011.

The project is in response to the Ministerial Review Group's 2009 advice to the Minister of Health to determine what services should be local versus regional or national for planning and funding purposes to enable DHBs to be responsible for planning and funding the lion's share of services, either regionally or locally.

Other reviews of immunisation services have found various problems with current functions and funding, including:

- inefficiency, too many levels of organisation; and we should be able to achieve more for the amount being spent
- overlapping service specifications leading to duplication and role confusion
- fragmented service delivery – responsibility is not linked to resources i.e. DHBs are responsible for the overall outcome but contracts are not managed by DHBs; immunisation services are not integrated i.e. outreach immunisation, National Immunisation Register administration, immunisation coordination
- the reporting burden is too high, and the reports aren't shared or being used to improve performance.

These administrative problems may be contributing to the below target coverage rates in some DHBs.

The Ministry is proposing to consolidate immunisation functions into two levels (national and local), simplify the funding arrangements for the functions and better align funding and accountability with responsibilities. DHBs are being consulted as part of this process about current funding arrangements and whether other options could/should be considered.

The Ministry will also encourage DHBs to build better links with other health and social services, for example the B4 School Check, school based health services, Family Start and Parents as First Teachers programmes. An important link is with midwives and maternity carers because the majority of parents decide about immunisation before a child is born.

The Ministry will also use the Better, Sooner, More Convenient work to consider whether responsibility for immunisation should be devolved to integrated family health care centres. However the decision about who should be covered by each centre will be retained nationally.

Any recommendations should make it easier for DHBs to develop more flexible and tailored services to meet the needs of their population, and form alliances with other DHBs where efficiency gains may be enhanced.

3.2 Coordination

Submitters recommended co-location of immunisation services within the DHB; improving transfer of care between maternity and primary care services and ensuring all babies are enrolled on the NIR, have a primary care and Well Child provider upon discharge from hospital; share best practice; allow a wider range of providers to immunise and ensure culturally appropriate services are available; authorised vaccinator status should be national not just in the DHB it was issued.

Ministry response and activities to improve coverage

3.2.1 Coordination

The immunisation contracts review described in section 3.1.2 above should enable DHBs to co-locate services as appropriate.

The Ministry expects all DHBs to have an immunisation steering group and immunisation plan to drive strategies and actions for achieving the immunisation coverage target.

A workshop is scheduled in September 2010 to engage with the DHB immunisation champions, public health units, and lead maternity carers to workshop the following issues and develop a strategy for ensuring that 95% coverage becomes routine:

- What will immunisation provision look like in 2013? (The 95% health target is expected to be achieved in 2012.)
- What will the balance of services look like?
- Issues or barriers that need to be resolved.

3.2.2 Share best practice

The Ministry's Immunisation Champion and Immunisation Team's Senior Relationship Manager regularly meet with DHBs and link them together to share successful strategies for improving immunisation coverage. Workshops and conferences are also used to highlight successful immunisation strategies.

The Ministry is establishing an Immunisation Coverage Forum, as recommended by the Ministerial Review Group, to provide ongoing advice about improving immunisation rates and how the immunisation system is operating for providers. Members of the forum will have the following skill sets:

- Practice Nursing
- General Practice
- Midwifery
- DHB immunisation coordination
- NIR administration
- Outreach Immunisation
- Māori immunisation provision
- Pacific immunisation provision
- Immunisation sector and education/training
- Public health (Medical Officer of Health or public health nurse) provision
- Well Child/Tamariki Ora service provision

The Coverage Forum will meet twice a year and will complement the Immunisation Technical Forum that advises the Ministry about vaccines, vaccine strategies, and the immunisation schedule.

Formed in May 2010, the Immunisation DHB Forum meets quarterly so that DHBs can share information and resources and the Ministry shares information about its work programme and immunisation strategies. DHB representatives include Medical Officer of Health and/or Immunisation Steering Group Chair, a Funding and Planning decision maker and other members as delegated by the DHB.

3.2.3 Transfer of care

See table 1 below for an overview of child health services, including timing of services, who provides them and their roles and responsibilities.

At the Health Minister's request, the Ministry is working on developing standardised maternity information/clinical records that can be shared electronically. The ability to electronically share key clinical information will facilitate communication between practitioners. This will include situations where a woman is referred or transferred from one health professional to another such as between lead maternity carers and general practice, and between lead maternity carers and Well Child/Tamariki Ora providers. The National Health IT Board is leading this work, which is part of developing a broader IT solution to deliver a shared care record for health services. See section section 4 "Improved use of the National Immunisation Register" for more information about the National Health IT Board.

Table 1**:** Overview of Child Health Services

Timing	**Provider**	**Roles and responsibilities**
Pre-conception	General Practitioner	Advice on maternal health, contraception and preparation for conception, lead primary health provider for woman and family
General Practitioner to provide summary of woman's medical notes to the Lead Maternity Carer on booking with the Lead Maternity Carer		
Up to 40 weeks gestation	Lead Maternity Carer	Provide lead maternity antenatal services as specified in the Section 88 Notice
	General Practitioner	Provide ongoing medical and primary health care services to woman and family
Birth to 4 weeks	Lead Maternity Carer	Provide lead maternity labour, birth and postnatal services as specified in the Section 88 Notice
	General Practitioner	Provide ongoing medical and primary health care services to baby and family
Lead Maternity Carer to provide a referral and initial summary of the maternity notes to the nominated Well Child Provider by four weeks		
4 to 6 weeks	Lead Maternity Carer	Provide ongoing lead maternity postnatal services as specified in the Section 88 Notice
	Well Child Provider	Initiate contact with the family and conduct the 4-6 week Well Child core contact
	General Practitioner	Immunisations and address any health issues for the mother and baby at six weeks and provide ongoing medical and primary health care services to the baby and family
Lead Maternity Carer to provide final summary of maternity notes to the Well Child Provider and General Practitioner by six weeks		
6 weeks to 3 ½ years	Well Child Provider	Provide Well Child services to infant and family as specified in the Well Child/Tamariki Ora Schedule and Framework including 8-10 week, 3-4 month, 5-7 month, 9-12 month, 15-18 months and 2-3 year core contacts and additional contacts as required
	General Practitioner	Provide ongoing medical and primary health care services to the infant and family, including the 3, 5 and 15-18 month immunisations
Well Child Provider to provide summary of Well Child notes to the B4 School Check provider and General Practitioner by three and a half years		
4 to 5 years	B4SC provider	Provide the B4 School Check to the child and family and follow up on any resulting referrals
	General Practitioner	Provide ongoing medical and primary health care services to the child and family, including the 4 year immunisation
B4 School Check provider to provide summary of B4 School Check to the General Practitioner by five years		
5 years and beyond	General Practitioner	Provide ongoing medical and primary health care services to the child and family, including the 11 year old immunisation event (South Island DHBs only, excluding Nelson Marlborough DHB), human papillomavirus immunisations, influenza and other immunisations.
	Public Health Units	Provide school based immunisation programmes – Year 7 immunisation (North Island and Nelson Marlborough DHBs only), human papillomavirus immunisations, and other immunisation programmes as required.

3.2.4 Authorised independent vaccinator status

The existing legislation (Medicines Regulations 1984, clause 44A) provides authorisation of independent vaccinators for a two year period.

Medical Officers of Health authorise the vaccinator – and they can only authorise vaccinators for the district for which they are designated (Health Act 1956). Any changes to this would require consultation and legislative review.

3.3 Education/information

Submitters argue that immunisation information is crucial during the antenatal period. They recommend all antenatal providers receive immunisation education so they are confident to discuss immunisation with parents; and that there should be requirements to provide evidence and science-based information to parents. All immunisation providers should receive immunisation education; authorised immunisers should have annual updates and their authorisation status should be national; understand why families decline.

Ministry response and activities to improve coverage

The commitment and effort of nurses, midwives and doctors are essential for immunisation. Several factors have been shown to encourage immunisation[6]:

- Confidence and commitment of the provider, more than their knowledge.
- A trusting relationship between the parent and health provider, preferably established before a child is born.
- Early enrolment in a practice or PHO.
- Pre-call and re-call, which means active following up and reminding parents whose children are due or overdue for immunisations.

Like parents, there are a range of attitudes among general practitioners, nurses, midwives and other health providers to immunisation. Overall, providers need:

- Good information about immunisation, the diseases they prevent, vaccines, and safety.
- Accurate and up-to-date information about which vaccines to give to each child.
- Information about their own practice's immunisation rates.
- A simple immunisation programme that is not changed too often.
- Time to spend managing informed consent and chasing the hard-to-reach, among the other priorities facing providers.
- Benefits (financial and non-financial) for achieving high immunisation rates.
- Accurate contact details for children who are due for immunisations.
- Links with other health and social service providers who interact with the same children.

[6] Guide to Community Preventive Services. Vaccinations for preventable diseases: universally recommended vaccines. www.thecommunityguide.org/vaccines/universally/index.html. Last updated: 18/03/2010

3.3.1 Information provided for parents during the antenatal period

DHBs are required to fund pregnancy and parenting education for at least thirty percent of their population of pregnant women. The Ministry is planning to revise its service specification for DHB provided/funded pregnancy and parenting education. The Ministry is carrying out a review of best practice education, which will be used to inform the revision of the service specification. The extent of change and implications for service providers is not yet known. These will be examined during the revision of the service specification.

The Primary Maternity Services Notice 2007[7] contains clauses about the provision of Ministry of Health immunisation information during the third trimester of pregnancy. DHB midwives are not covered by this legislation.

Further work is required to determine who is best placed to deliver immunisation education during the antenatal period. Some DHBs are developing innovative solutions to this. For example Bay of Plenty DHB has employed a "Lay Advocate" who discusses immunisation postnatally with mothers prior to discharge and at mothers' groups.

3.3.2 Immunisation education for providers

The Ministry hosts an Immunisation eLearning programme for Midwives, undergraduate nurses and childbirth educators on the immunisation webpage[8]. Providers had asked for an online resource that could be readily accessed and updated. The programme is designed to help midwives, undergraduate nurses and childbirth educators to quickly and easily find useful information and resources about immunisation in New Zealand. The eLearning web resource may also help parents and caregivers make an informed decision about immunising their child.

The Ministry contracts the Immunisation Advisory Centre and the Well Women's Nursing Service to provide vaccine education for vaccinators, community health workers/promoters, Well Child/Tamariki ora providers, child birth educators, non vaccinators and midwives. Attendance at these courses is also a pre-requisite for vaccinators to obtain authorised independent vaccinator status.

The Immunisation Advisory Centre also provides online learning for providers, through the iCOMET platform[9]. These courses contribute towards continuing medical education for providers, and include vaccinator update courses (to maintain authorised independent vaccinator status), vaccine administration information, influenza pandemic planning and human papillomavirus vaccine training. The development of these courses was part-funded by the Ministry of Health.

3.3.3 Review experiences

As discussed in section 2.1.2 "Information to support informed consent and parental decision making" the Ministry is undertaking an audience research project to identify the behaviours, decision-making processes, attitudes and barriers experienced by

[7] pursuant to section 88 of the New Zealand Public Health and Disability Act 2000
[8] http://www.moh.govt.nz/moh.nsf/indexmh/immunisation-elearning
[9] http://icomet.org.nz/

those who are not immunising their children Ministry also share results of audience research with DHBs. These results will be shared with DHBs.
Hawkes Bay DHB is planning a similar project – their methods and results could be shared with other districts.

4 Improved use of the National Immunisation Register

Three subthemes were raised in the submissions: system; quality assurance; access.

4.1 System

Submitters stated the NIR needs to be more user friendly; child health information systems should be integrated to include all well child preventative services.

Ministry response and activities to improve coverage

The NIR is an extremely powerful tool and there is no doubt that it is critical for delivering a better immunisation service and improving immunisation coverage. The DHBs and practices that understand the NIR and use it effectively have higher immunisation coverage. See Appendix 3 for background information about the NIR.

The NIR itself is a simple database of immunisation records, but it interacts with the practice management system (PMS) software in each clinic, the payments system used by all health providers, and a reporting module that calculates the denominators of eligible populations for each district, clinic, or school. Because immunisation records are private medical records, there are important security measures to protect the information but which make the transfer of data between multiple systems more complicated.

The complexity of this nexus means that NIR-related problems can be difficult to diagnose, and changes in one place can create unexpected problems in another. The rules around immunisation schedules and eligibility also change frequently, and managing these changes has been very challenging. One of the strengths of the NIR is that it is built into the PMS software used by providers so they do not have to use a different system. But this also makes the system much harder to change when the vaccine schedule changes, mainly because of the multiple different PMS systems in use across the country.

The Ministry has made significant improvements to the NIR over the last two years that have made it much more user friendly, though there are still some aspects that could be improved. Newer technologies and the new National Health IT Plan are providing some opportunities to improve how the system works. The Ministry is reviewing the policies and design of the NIR to make it better value for money; more user-friendly for health providers; provide easier access to immunisation information; and better able to meet individual and parent needs.

The Ministry of Health supports the recommendation that children's health should be able to be tracked better though a robust information system. The 2003 Child Health Information Strategy supported the incremental development of linked information systems built on existing systems, knowledge and current practice – for example all WellChild/Tamariki Ora services would have linked databases. The NIR was the first system to be developed; and the strategy has yet to be fully implemented. The B4 School Check is the next system to be developed. The Ministry is currently working with IT providers and the National IT Health Board to explore opportunities to use this system for further child health initiatives.

By 2014 however, the National Health IT Plan is expected to be in place. This plan is driven by the eHealth vision '*New Zealanders will have a core set of personal health information available electronically to them and their treatment providers regardless of the setting as they access health services*'. The eHealth Vision is based on the assumption that over the next five to ten years, a shared care record will be available that is complementary to the health IT solutions already used by healthcare organisations.

More information about the National Health IT Plan, including its purpose, key focus areas, objectives and timeframes can be found at: http://www.ithealthboard.health.nz/content/draft-national-health-it-plan.

4.2 Quality Assurance

Submitters recommended that data integrity and quality would be achieved if providers had a better understanding of their importance and received ongoing training. The GP2GP project needs to be implemented so patient data can be electronically transferred between practices. National data should be analysed to determine if immunisation targets are appropriate.

Ministry response and activities to improve coverage

4.2.1 NIR data quality and training

NIR user training and data cleansing has made a significant contribution to the increase in immunisation coverage as recorded on the NIR over the last 18 months (see Appendix 3). The NIR coverage data initially reported in July 2009 improved by three percentage points once the reports were re-run due to NIR system upgrades, data cleansing and better use of the NIR by providers.

The Ministry has had dedicated relationship managers working across all DHBs looking at how they are using the NIR to target unimmunised populations; the level of training for the users of the NIR; and solving data cleansing issues.

NIR user training is an integral part of the success of the NIR to accurately record immunisation data. The Ministry is establishing the core training requirements of NIR users and the tools available to users and looking at how training is best carried out across the country.

The Ministry has identified best practice models on how some DHBs are using the NIR to improve coverage and have shared this information through a variety of forums including: buddying up of successful DHBs with poor performers; holding national workshops to identify and mitigate issues; and the sharing of reports that drive improvement in immunisation coverage.

The National Immunisation Register is now able to produce coverage reports for practices and clinics and the Ministry is working with the sector to use this information. Making this data available to PHOs and practices should encourage

them to improve their immunisation rates, and to ensure that data is entered correctly and efficiently. The Ministry does not publish this data.
Aligning the PHO performance payments with the NIR will assist with data quality as providers will not receive payments unless the immunisation event data is correctly and efficiently entered.

The work resulting from the National Health IT Plan will improve NIR data quality.

4.2.2 GP2GP project

The Ministry will contract with General Practice New Zealand (formerly the IPA Council of NZ and the General Practice Nursing Alliance) to implement the GP2GP project. This project will mean Patients can electronically move their complete health record between any GP in NZ. This project will be completed in November 2010.

4.2.3 Review immunisation targets

See section 2.1.4 “Immunisation coverage targets” for an explanation of why they are set at 95%.

4.3 Access

Submitters recommend more providers have access to the NIR.

Ministry response and activities to improve coverage

NIR access is determined by the privacy and access policies. If providers meet the policies’ criteria and they have appropriate IT systems, NIR access can be obtained. An example of this is the Family Planning Association which obtained NIR access as part of the human papillomavirus immunisation programme. Part of the Ministry’s review of the NIR will be to update the purposes of the NIR and align access policies to those purposes, while maintaining appropriate privacy controls.

5 Improving the management and monitoring of adverse events following immunisation

This section responds to concerns raised about New Zealand's vaccine safety monitoring systems, publication of adverse event data and providers' responses to adverse events.

5.1 Systems

Several submissions recommended that New Zealand should generate its own data about vaccine safety, using the National Immunisation Register (NIR). This would involve redesigning the NIR to capture health status at registration and health outcomes thereafter. The data would then be reviewed by an independent body 'with no vested interests in vindicating vaccination'.

Ministry Response and activities to improve coverage

Most countries have a vaccine safety monitoring system which includes voluntary spontaneous reporting. New Zealand's safety monitoring system is managed by Medsafe, and is aligned with international best practice. Information about vaccine development and regulation is in Appendix 4 and information about New Zealand's vaccine safety monitoring system and a summary of vaccine adverse event reports, is in Appendix 5.

5.1.1 Using the NIR to monitor health status

If the NIR was redesigned to record all health status information or linked to other health databases, the benefit would be limited by New Zealand's relatively small population size. The number of people being vaccinated in New Zealand would not be high enough to identify any adverse events that are rarely associated with the vaccine; these are usually found after millions of doses have been given.

The NIR could in theory be linked to other health databases. This is because each individual is identified by the National Health Index (NHI) number; a unique identifier used in all of the national health databases and in primary and secondary health care systems. Some other countries have developed linked databases (see 5.1.2 below) but these were developed for that purpose.

There would however be several barriers to using the existing NIR design to monitor the population's health status. Firstly, the NIR only records data when a person has been vaccinated. It would require major changes to record other types of information or information from providers using different systems (e.g. hospitals). Secondly, the NIR is not a comprehensive dataset for the whole population (vaccinated versus unvaccinated). The NIR only records data for children born after the NIR was started in their area (between 2004/05), for those who received the meningococcal B vaccine and for those who received the human papillomavirus vaccine.

Significant financial investment would be required to redesign the NIR or to link it to other databases to capture health status data, including studies into the best way to design and monitor such databases[10]. In order for comparisons to be made, there would need to be a comprehensive collection of a person's health history and circumstances (these are usually checked in major epidemiological studies). New laws may also been needed, if it was compulsory for the entire population's data to be recorded.

5.1.2 International examples of linked databases

The Vaccine Safety Datalink project is a collaborative effort between the United States Center for Disease Control's Immunization Safety Office and eight managed care organizations that hold medical information and immunisation records for over 5.5 million people annually[11]. The project was established in 1990 to monitor immunisation safety and address the gaps in scientific knowledge about rare and serious events following immunisation. This database was used in demonstrating the association of a rotavirus vaccine with intussusceptions (where a bowel obstruction can occur) (Griffin et al 2009).

The United Kingdom's General Practice Research Database holds data on consultations, referrals, prescriptions and vaccinations for more than 4 million patients from 500 practices throughout the UK[12]. This database was used to show no evidence of an increased risk of Guillain-Barré syndrome after seasonal influenza vaccination (Stowe et al 2009).

5.2 Publication

Submitters recommended that vaccine adverse events reports be published.

Ministry response and activities to improve coverage

The Ministry intends to regularly publish adverse event information. Regular publication will put the data into context and promote increased transparency for the immunisation programme. In the future, adverse event publication may improve the public's trust in vaccine safety monitoring and vaccines in general.

At present vaccine adverse event information is usually published reactively rather than proactively. Medsafe published seasonal influenza vaccine adverse event reports in February 2010[13], and the Centre for Adverse Reactions Monitoring published human papillomavirus vaccine (Gardasil) adverse events in April 2010[14].

Adverse event information for vaccines and medicines is published in other jurisdictions. The United States publishes unidentifiable data from their Vaccine

[10] World Health Organization information about the types of studies and levels of evidence required to assess whether an adverse event is causally related to a vaccine http://www.who.int/vaccine_safety/causality/en/.
[11] http://www.cdc.gov/vaccinesafety/Activities/vsd.html
[12] http://www.gprd.com/home/
[13] http://www.medsafe.govt.nz/profs/PUArticles/SeasonalFluVaccine.htm
[14] http://carm.otago.ac.nz/index.asp?link=news

Adverse Event Reporting System[15]. The United Kingdom publishes medicine adverse event reports from their Yellow Card Scheme as Drug Analysis Prints[16]. Swiss adverse event data reported between 1991 and 2001 was recently published in the *Vaccine* journal (Schumacher et al 2010).

5.3 Providers' responses to adverse events

Submitters claim that doctors rarely report vaccine reactions to the Centre for Adverse Reactions Monitoring. Vaccine problems are dismissed and treated as if they happened by chance, and doctors believe that vaccines can never be the cause of ongoing problems.

Ministry response and activities to improve coverage

The Ministry does not agree that New Zealand doctors ignore or dismiss vaccine reactions as a general rule, although there may be instances where it does happen. The Ministry accepts that communication around adverse events could improve.

Evidence shows that New Zealand doctors report vaccine adverse events at a higher rate than other countries and do take them seriously. Data published by the World Health Organization shows that New Zealand has the highest medicine adverse event reporting rate per capita in the world (this includes vaccines and other medicines). Depending on medicines reporting rates between 25 to 50 percent of all reported adverse events in New Zealand are related to vaccines, most are non-serious. Of the 1,000 to 1,500 vaccine reports received each year about 80 percent are reported by doctors (Tatley 2010). Adverse event report data is summarised in Appendix 5.

The Ministry is not responsible for the interaction between doctors and patients but is responsible for ensuring there are systems in place to manage any risks, monitor vaccine safety, analyse reports to check for safety signals, and respond to individuals who experience adverse events. This also includes providing information about vaccine risk and benefits, and educating providers about adverse events and what to do when they happen (reporting and treatment).

The response in April 2010 to febrile convulsions in children from one of the three brands of seasonal influenza vaccine shows that New Zealand's systems can pick up safety signals and that the Ministry will act quickly when there is sufficient justification. New Zealand's data on adverse events is also being used by other countries to inform decisions about influenza vaccines.

The Ministry acknowledges that aspects of the system may not meet parents' needs and expectations, including the time taken to investigate and respond.

[15] http://vaers.hhs.gov/data/index

[16] http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/Druganalysisprints/index.htm

Firstly, vaccine reactions expected by medical professionals may be different from what parents expect. Secondly, the Ministry considers it is appropriate to make decisions based on robust evidence and to thoroughly investigate causal links between vaccines and reactions, even though this can take time when parents are looking for answers. Thirdly there is a tension between the risks and benefits when viewed from an individual perspective as opposed to a population perspective. The balance of risks and benefits across a population may still be positive even when some individuals have adverse reactions. The Ministry's challenge is protect individuals while also ensuring benefit for the whole population.

Some other systems such as Coronial inquests into deaths or Health and Disability Commissioner's investigations may also lead to delays in reporting of adverse outcomes following vaccinations.

The Ministry will further investigate options to improve the monitoring system, such as providing increased transparency, and communicating better with parents.

6 Vaccine safety and effectiveness

Three subthemes were prominent throughout the submissions: vaccines induce disease; vaccines are not effective; the science is distorted/wrong.

To respond to the above issues, this section is divided into the following parts:

- the science is distorted
- vaccines do not work
- vaccines are unsafe
- vaccines cause [chronic] diseases or injuries

6.1 The science is distorted or wrong

Submitters alleged undue influence by pharmaceutical companies on scientific research and national and international vaccination programmes. Some claim that governments and the medical establishment are in an alliance with vaccine manufacturers to hide the real facts about immunisation.

The Committee also asked for a Ministry view on the New England Journal of Medicine Amicus Brief.

Ministry response

The Ministry of Health strongly refutes these claims in the New Zealand context.

The New England Journal of Medicine Amicus Brief was submitted as part of a case heard by the US Supreme Court in 2008[17]. The Supreme Court was hearing evidence against the pharmaceutical company Wyeth, about inadequate drug labelling leading to injury, and the Food and Drug Administration's national drug regulatory role versus individual state law requirements. The Amicus Brief was submitted by a group of high profile doctors, who are current or recent editors of the prestigious New England Journal of Medicine. The Amicus Brief alleges a series of wrongdoings by pharmaceutical companies, including suppression of evidence and obstruction of regulatory bodies, 'costing tens of thousands of lives'. The Amicus Brief also argues that the Food and Drug Administration's systems for drug licensure and post-market safety monitoring in the US are flawed.

The Ministry has reviewed the Amicus Brief. While the alleged wrongdoings are very serious, none of them involved vaccines.

Pharmaceutical companies fund most research on vaccines, including their development. This funding does not mean that the research is biased, as much of it is undertaken by independent researchers operating under international standards of good clinical practice. Nevertheless, the potential for bias is real, leading many

[17] Amicus Brief: http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/06-1249_RespondentAmCuNEJournalofMed.pdf; the Supreme Court's decision: http://www.abanet.org/poladv/preemption/2009mar04_wyethvlevine.pdf

medical journals to require statements of the funding source and all potential conflicts of interest to be declared and published with any scientific studies. There is evidence that disclosure does not always occur and that the research can be compromised. Usually however this is discovered, as in the case of Dr Andrew Wakefield, whose publications and research career in the area of Autism has been discredited following a General medical Council review of his failure to disclose significant conflicts of interest in his articles on measles-mumps-rubella vaccine and autism.

6.2 Vaccines are not effective

Some submissions cast doubt on the contribution of vaccination to reductions in disease. They argue that mortality from vaccine preventable diseases was reducing before vaccines were introduced, and that vaccines are not effective.

The Committee also requested information about when vaccines were introduced in New Zealand and their effect on disease, along with vaccine risks and benefits.

Ministry response

The scientific data show that while improvements in living standards, in particular clean water, have had a great impact on health; immunisation has played an important role as well.

Improvements in living conditions, nutrition and medical care have reduced the chance of people dying from infectious disease such as measles, but without immunisation most people would still acquire some vaccine preventable diseases.

Deaths from pertussis (whooping cough), diphtheria and measles started to decline in industrialised countries prior to the introduction of mass immunisation. The initial decline was due to fewer deaths in those who caught the disease, rather than fewer people becoming infected (i.e. a reduction in mortality not morbidity). More detail about specific diseases follows.

6.2.1 Measles

Measles spreads through the air, and transmission is largely unaffected by improvements in living conditions other than by reducing overcrowding. Healthy children living in ideal conditions remain at risk of death and disability from contracting measles. A proportion of people with measles have severe complications, including pneumonia (6%) and more rarely inflammation of the brain (encephalitis; 0.1%).

Table 2: Measles disease and measles vaccine risks

Disease	Risks of disease	Risks of vaccine
A highly contagious viral illness causing fever, cough and rash.	• Otitis media (7%) • Pneumonia (6%) • Acute encephalitis (0.1%) • Subacute sclerosing panencephalitis (1 per 100,000) • Case fatality rate of 1-2 per 1000 • Maternal measles associated with an increased risk of premature labour, miscarriage and low-birth weight infants.	• Mild local or systemic reaction (14.2%) • Aseptic meningitis (1 per 100,000) • Encephalitis (1 per million) • Anaphylaxis (<1 per million)

Source: http://www.immune.org.nz/?T=753#me13 downloaded 15/6/10, Immunisation Advisory Centre

If immunisation was stopped, measles would be expected to increase to pre-vaccine levels. According to an Immunisation Advisory Centre estimate[18], over a 10 year period there could be 600,000 measles cases, between 50,000 to 60,000 measles hospitalisations, and 200 to 600 deaths, if measles vaccination was stopped (based on a birth cohort of 60,000).

Measles cases in England and Wales increased sharply in 2008. The majority of cases were in children who were not immunised. Immunisation coverage in the United Kingdom had decreased, partly because of factors such as high population mobility (e.g. in London) and parents' decision not to immunise their children due to the media and public speculation about the [disproved] possible link between autism and the measles-mumps-rubella (MMR) vaccine.

In order to improve immunisation coverage and to prevent an epidemic, a concerted MMR catch-up programme was launched in England in August 2008. Children who were not immunised were offered the vaccine and disease rates have since decreased.

The increase in measles cases in England and Wales show the importance of maintaining a high level of population immunity through measles immunisation.

6.2.1.1 Measles vaccination and disease trend

Recent measles epidemics/outbreaks in New Zealand were in 1991 (estimated 40,000 to 60,000 cases), 1997 (2169 identified cases) and in 2009 there were 253 cases notified, most of which were associated with two outbreaks.

[18] Immunisation Advisory Centre – Submission to Health Select Committee – Supplement 1

The measles vaccine was introduced in 1969 for children between 10 months and five years of age who had not had measles.

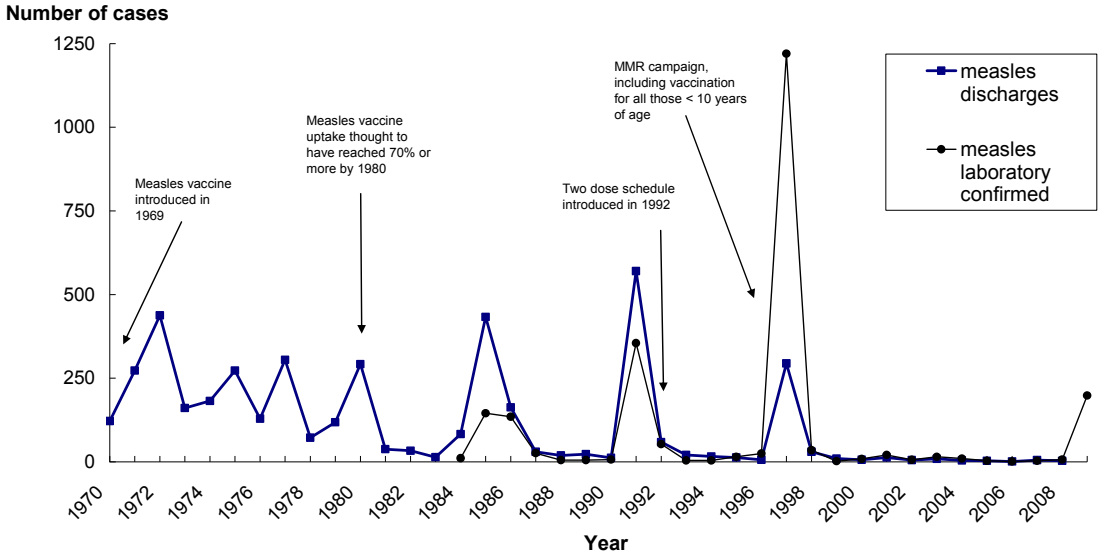
Between 1969 and1980 there were 100 to 300 measles hospitalisations in New Zealand per year. Measles vaccine uptake reached around 70 percent or more by 1980, which resulted in longer periods between epidemics. Measles virtually disappeared between epidemic years.

To improve control a two dose schedule started in 1992, when the first measles-mumps-rubella (MMR) dose was given at 12-15 months, and the second dose at 11 years. There was a measles immunisation campaign using MMR for all children under 10 years of age at the start of the 1997 epidemic.

Since 2001, MMR vaccine has been offered at 4 and 11 years of age; there was also a school catch up programme in 2001 for the second MMR dose for 5 to 10 year olds.

For more information about measles disease and vaccination in New Zealand, see the *Immunisation Handbook*, chapter 9: Measles.

Figure 1: Hospital discharges from measles 1970-2004, and laboratory confirmed cases 1984-2009



Source: Ministry of Health

6.2.2 Rubella

While childhood rubella can have severe complications, immunisation is especially important to prevent maternal rubella. Maternal rubella in the first eight weeks of pregnancy results in foetal damage in up to 85 percent of infants.

Stopping rubella vaccination would reduce population immunity so that rubella would once again infect pregnant women, and cause congenital rubella syndrome in infants.

Table 3: Rubella disease and rubella vaccine risks

Disease	Risks of disease	Risks of vaccine
A highly contagious viral illness causing fever, rash, lympahdenopathy, and foetal malformations	• 85% of infants infected during the first trimester of pregnancy will be born with some type of birth defect, including deafness, eye defects, heart defects, mental retardation, and more. • 1 in 2 adolescents and adults have arthralgia • 1 in 6000 develop encephalitis	• Mild local or systemic reaction (14.2%) • Aseptic meningitis (1 per 100,000) • Encephalitis (1 per million) • Anaphylaxis (<1 per million)

Source: http://www.immune.org.nz/?T=642#rb13 downloaded 15/6/10, Immunisation Advisory Centre

6.2.2.1 Rubella disease trends

New Zealand has experienced several rubella epidemics; in the pre-vaccine era they occurred every six to nine years.

After the 1959/60 epidemic, a survey of ten general practitioners found 89 women who had rubella during pregnancy[19]. Sixty seven viable pregnancies were included in the study (excluded were 15 therapeutic abortions and 7 spontaneous abortions). Of the 67 studied children, two died because of rubella, while ten surviving children had abnormalities attributed to rubella. Eight of these had multiple abnormalities.

During the 1964-65 epidemic "there had been over 350 children diagnosed with hearing difficulties alone (p 208, Day 2008).

There were 44 cases of congenital rubella notified in 1980 and 1981.

The last recorded case of congenital rubella in New Zealand was reported in 1998.

6.2.2.2 Rubella vaccine history

There was a mass rubella immunisation campaign in 1971, when an estimated 95 percent immunisation coverage was achieved through a school based programme for children aged five to nine years, with general practice immunising four year old children (p 180, Day 2008).

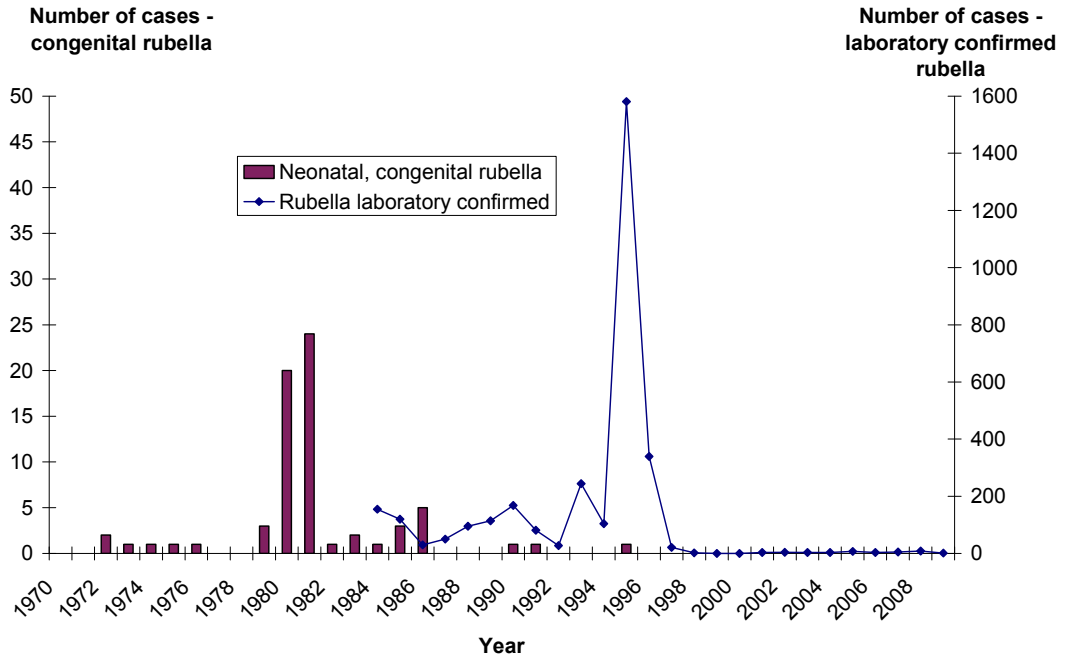
This was followed by a period of low immunisation coverage, with general practice immunising about 40 percent of children aged four years (before school entry). The policy was changed to offering rubella immunisation from 1979 to all girls in year 7 (form 1).

[19] Babies were examined soon after delivery by a paediatrician where possible. Babies were followed up, and were examined by a paediatrician, an ophthalmologist, and an audiometrist, and in some cases by a paediatric cardiologist. The ages of the children at the last examination ranged from 10 to 24 months. Rubella related health problems included deafness (mostly severe; 8 children), cataracts (4), glaucoma (1), mental retardation (marked degree) (1), cardiovascular issues (7 children: 4 patent ductus, 2 aortic stenosis, 1 coarctation pulmonary artery) (Liggins and Phillips 1963).

In 1990, MMR was introduced at 15 months for all children. The second dose of MMR was introduced in 1992 for all children in year 7 (form 1), and replaced the rubella vaccination for girls at that age.

Since 2001, MMR has been offered to children at 15 months and 4 years of age to prevent rubella epidemics, reduce the background incidence of rubella and to continue to protect women before childbearing.

Figure 2: Notifications of congenital rubella, 1970-2009, and laboratory confirmed cases, 1984-2009



Source: Ministry of Health

The 1993 and 1995 outbreaks mostly involved young adult males, who would not have been offered immunisation.

For more information about rubella disease and vaccination in New Zealand, see the *Immunisation Handbook*, chapter 10: Rubella.

6.2.3 Pertussis (whooping cough)

Pertussis can be a severe disease particularly in the very young. For example, a study of children admitted to the national paediatric intensive care unit in Auckland from 1991 to 2003 found that of the 72 pertussis admissions, there were three deaths and six children were left with subsequent respiratory or neurodevelopmental problems (Surridye 2007).

Even with no complications and hospitalisation, pertussis in young children has a high impact on families.

Table 4: Pertussis disease and pertussis vaccine risks

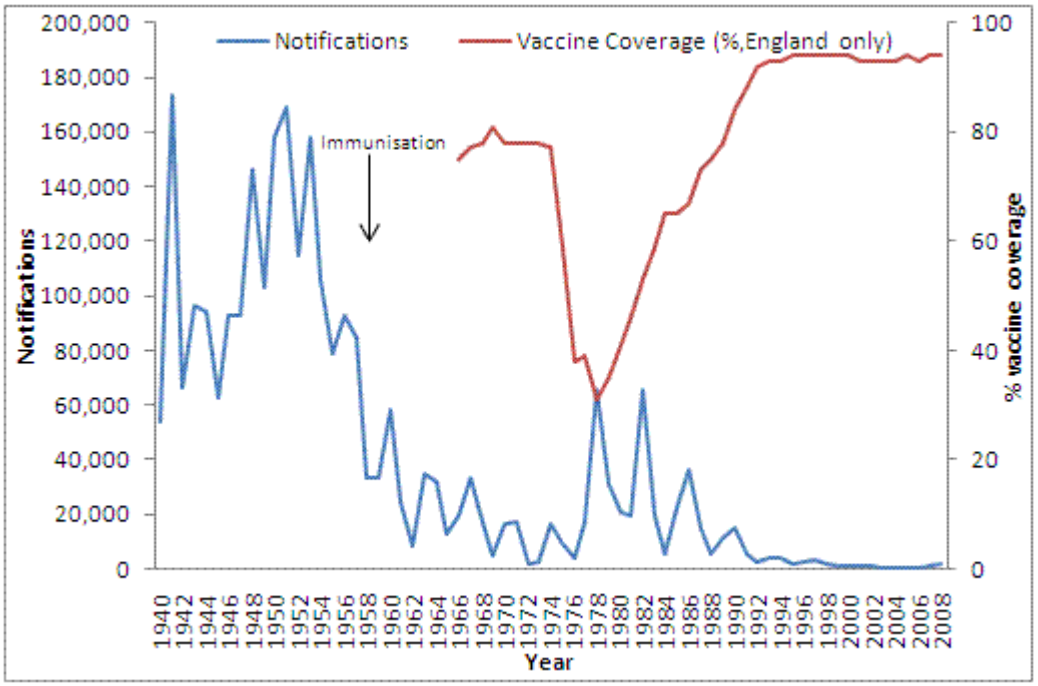
Disease	Risks of disease	Risks of Vaccine
A highly contagious bacterial infection causing whooping cough and vomiting.	• 90% risk of contracting pertussis for non-immune infants. • 20% of all adults and adolescents may be infected at one time. • 0.1-0.3% risk of permanent neurological damage for patients with paroxysmal cough. • Case fatality of 0.05% in hospitalised infants.	• Mild local or systemic reactions (0.8-62%) • Rare serious adverse events: • Severe local reaction (0.8-8.0%) • Convulsions (0.00007%) • Persistent screaming (<0.005%) • Hypotonic hyporesponsive episode (<0.003%) • Anaphylaxis (<0.00001%)

Source: http://www.immune.org.nz/?T=641#pt1 downloaded 15/6/10, Immunisation Advisory Centre

If immunisation was stopped there would likely be a resurgence of pertussis to pre-immunisation levels. Such increases were experienced in Japan, the UK, and Sweden during the 1970s, when immunisation rates decreased because of widespread concerns about the safety of the older whole-cell pertussis vaccine (Gangarosa et al 1998). Sweden stopped the pertussis vaccination programme and a re-introduction of vaccination (using an acellular pertussis vaccine) decreased disease (Olin and Hallander 1999).

The England and Wales data shows the relationship between decline in vaccination coverage and the occurrence of epidemics in 1977-79 and 1981 (see Figure 3 below). When studied from January 1978 and June 1980, the pertussis vaccine was found to be highly effective in protecting against laboratory confirmed disease (93% effectiveness) (Public Health Laboratory Service Epidemiological Research Laboratory 1992).

Figure 3: Pertussis notifications and vaccine coverage, England and Wales, 1940-2008



Source: Health Protection Agency
http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/WhoopingCough/EpidemiologicalData/whoo45VacCover1940to2008/

6.2.3.1 Pertussis vaccination and hospitalisations

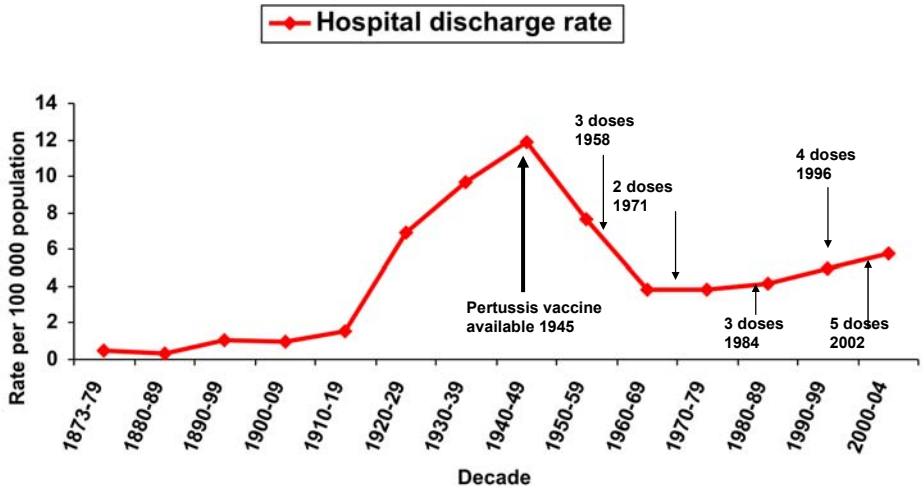
Pertussis is difficult to control even with a vaccine because the vaccine has moderate effectiveness (around 84% in the first two years of life) and protection wears off after about six years. New Zealand has not achieved the high sustained immunisation coverage needed reduce pertussis disease rates. A recent New Zealand Medical Journal notes that the rates of young children hospitalised with pertussis has increased since the 1960s (Grant and Reid 2010).

Pertussis hospitalisation rates declined during the 1950s and 1960s in association with immunisation (Somerville et al 2007). A three dose routine childhood immunisation schedule started in 1960 (at three, four and five months of age).

From 1971 to 1984 a two dose schedule was introduced at three and five months of age. This was to reduce the risk of serious side effects seen with the whole cell pertussis vaccine. However a rise in hospitalisations led to a third dose being introduced in 1984 at six weeks of age. A fourth dose of pertussis vaccine was added in 1996, given at 15 months of age. Acellular pertussis vaccine was introduced in August 2000, replacing the whole cell vaccine used up until then. A fifth dose at four years of age was added in February 2002.

Since 2006, the timing of the pertussis schedule was changed so that three doses of pertussis-containing vaccine are offered in the first year of life, followed by boosters at four and 11 years of age. [The fifteen month vaccination was removed, and vaccination at 11 years introduced.]

Figure 4: Annual pertussis hospital discharge rate per decade per 100,000 person years 1873 to 2004



Source: Somerville et al 2010.

Pertussis control remains an ongoing challenge for New Zealand.

For more information about pertussis disease and vaccination in New Zealand, see the *Immunisation Handbook*, chapter 6: Pertussis.

6.2.4 Polio

Polio causes paralysis that can lead to life-long physical disability.

Table 5: Polio disease and polio vaccine risks

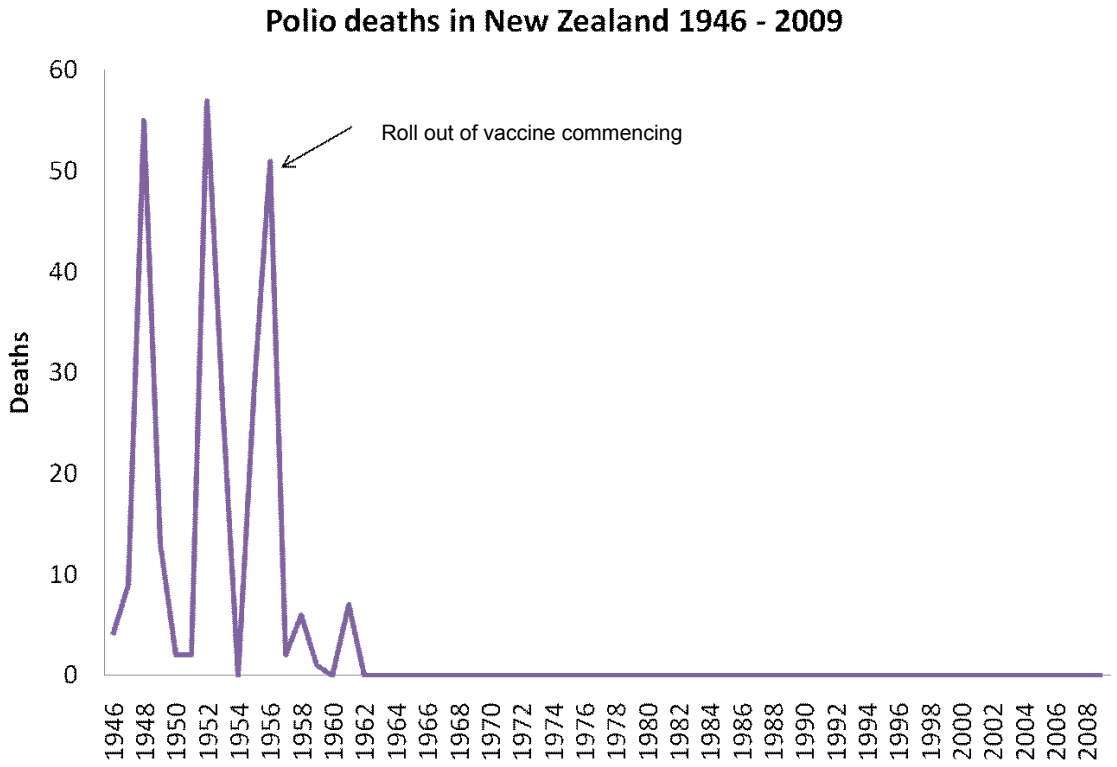
Disease	Risk from Disease	Risk from vaccine
Highly contagious gastrointestinal infection of which humans are the only reservoir.	While many infections cause no symptoms, about 1 in 20 hospitalised patients will die and half of all surviving patients will be permanently paralysed.	• Local redness (1 in 3) • Pain (1 in 7) • swelling (1 in 10) • Up to 1 in 10 has fever, crying and decreased appetite.

Source: Immunisation Advisory Centre http://www.immune.org.nz/?T=755#Po14 downloaded 15/6/10

In the 1950s the incidence of paralytic polio was increasing until the Salk injected vaccine was introduced. The use of the oral vaccine from 1961 led to the elimination of wild polio from New Zealand and most other parts of the world.

If polio vaccination was stopped and a traveller introduced the disease into New Zealand, then unimmunised people would be susceptible to infection.

Figure 5: Polio deaths in New Zealand, 1946-2009



Source: Immunisation Advisory Centre

For more information about polio disease and vaccination in New Zealand, see the *Immunisation Handbook*, chapter 8: Poliomyelitis.

6.2.5 *Haemophilus influenzae* type b (Hib)

Before immunisation was available in New Zealand, Hib was the commonest cause of life threatening bacterial infection, usually meningitis, in children under five years of age. Following introduction of Hib vaccination in January 1994 the disease levels significantly reduced.

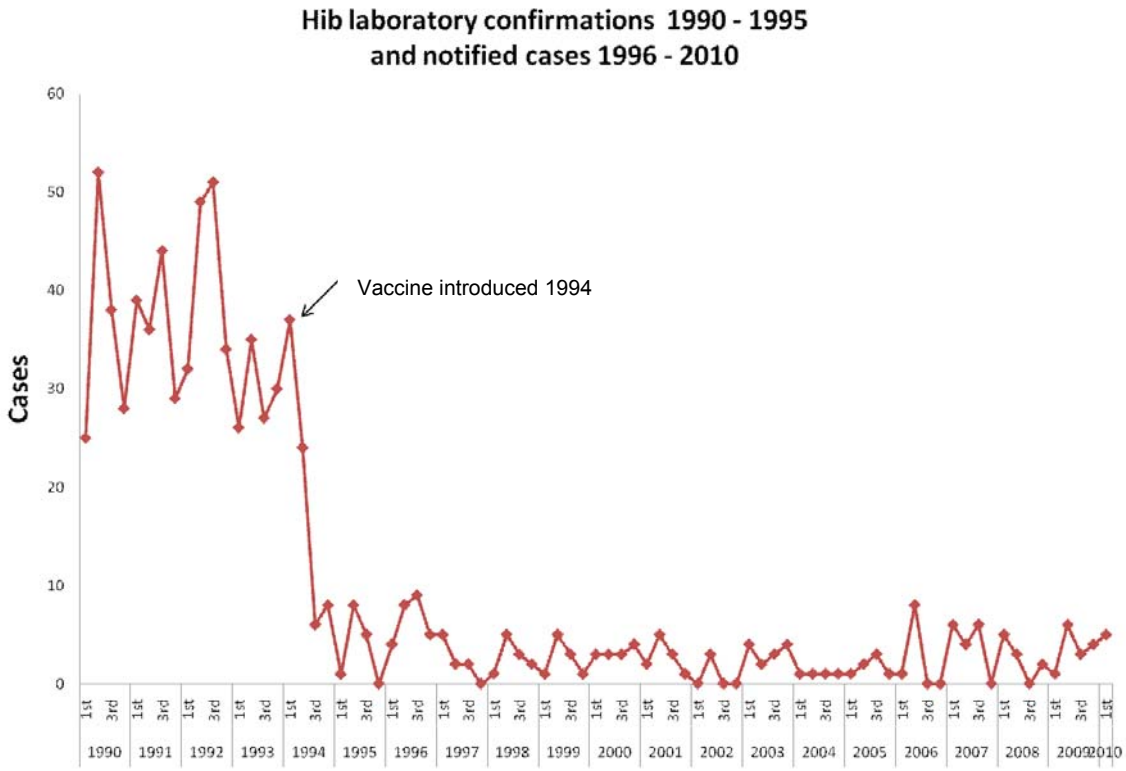
Table 6: Hib disease and Hib vaccine risks

Disease	Effects of disease	Side effects of vaccine
Contagious bacteria spread by droplets, causes meningitis, epiglottitis, septicaemia, osteomyelitis.	• About 5% of meningitis patients die and 1 in 4 survivors have permanent brain or nerve damage. • About 1% of epiglottitis patients die.	• About 1 in 20 have discomfort or local inflammation. • About 1 in 50 have fever. • These side effects disappear usually within 24 hours.

Source: Immunisation Advisory Centre http://www.immune.org.nz/?T=640#hb14 downloaded 15/6/10

Stopping Hib vaccination is likely lead to an increase in Hib cases to similar numbers experienced before 1994.

Figure 6: Hib notifications - 1990 to 31 March 2010



Source: Immunisation Advisory Centre

For more information about Hib disease and vaccination in New Zealand, see the *Immunisation Handbook*, chapter 7: Hib.

6.3 Vaccines are unsafe

Some submitters question vaccine safety.

Ministry response

Every country in the world has a national immunisation schedule based on the internationally accepted evidence about the need for, the safety, and the effectiveness of certain vaccines. New Zealand's immunisation schedule is reviewed every three years and may change as new, more effective vaccines become available for control of vaccine preventable diseases.

For more information about vaccine development and regulation and the schedule review process, see Appendices 4 and 7, respectively. New Zealand vaccine adverse event reports between 2005 and 2009 are summarised in Appendix 5.

In New Zealand, the vaccine safety and effectiveness issues are regularly debated in the media by parents and by anti immunisation groups. All vaccines have the potential to generate debate along the general themes described below, and which are discussed in more detail in Chapter 20 of the *Immunisation Handbook 2006*.

- Vaccines cause idiopathic illness – many illnesses of unknown cause are blamed on vaccines
- Unholy alliance for profit – doctors, pharmaceutical companies and governments collude for the sake of profits made from the sale of vaccines
- Poisonous chemical cocktails
- Cover up
- Towards totalitarianism – governments use the law to force immunisation as the first step towards increased state control
- Immunity is temporary/ vaccines don't work
- Healthy lifestyle alternatives

Organisations and national programmes (including New Zealand) produce material to address public concerns and misconceptions about vaccine safety and effectiveness. Links to a few are below.

- Ministry of Health – *Immunisation Handbook* 2006, Chapter 20: Vaccination questions and concerns: http://www.moh.govt.nz/moh.nsf/pagesmh/4617/$File/2006-20questions.pdf
- Immunisation Advisory Centre – *Rebuttals to anti-immunisation material* http://www.immune.org.nz/?T=938
- World Health Organization – *Six common misconceptions about immunisation* http://www.who.int/immunization_safety/aefi/immunization_misconceptions/en/index.html
- Immunise Australia *Immunisation Myths and Realities – responding to arguments against immunisation* http://www.health.gov.au/internet/immunise/publishing.nsf/Content/uci-myths-guideprov
- US Centers for Disease Control and Prevention – *Common questions parents ask about infant immunizations* http://www.cdc.gov/vaccines/spec-grps/infants/parent-questions.htm

6.4 Vaccines cause [chronic] disease or injuries

Submitters state vaccinated people are less healthy than unvaccinated i.e. that certain chronic diseases (e.g. asthma, autism, diabetes etc) have increased since vaccines became widely used; that vaccine ingredients are not tested for safety; and that concerns about vaccine safety are the main reasons why parents don't vaccinate.

Ministry response

Table 7 below summarises the conclusions of the United States' Institute of Medicine safety panel on several recent vaccine safety controversies; these refute claims that vaccines cause certain chronic diseases or death. More information is contained in Appendix 6.

Table 7: Events judged not to be linked to vaccines*

Exposure	Events judged not to be causally linked with exposure	Year reviewed and National Academies Press site address for specific citation
Multiple immunisations	• Increased susceptibility to infection • Type 1 diabetes mellitus • Sudden infant death syndrome	2002 http://fermat.nap.edu/catalog/10306.html 2003 http://fermat.nap.edu/catalog/10649.html
Measles-mumps-rubella vaccine	• Autism	2004 http://fermat.nap.edu/catalog/10997.html
Thiomersal containing vaccines	• Autism	2004 http://fermat.nap.edu/catalog/10997.html
Haemophilus influenzae type b (Hib) conjugate vaccines	• Hib infection shortly after immunisation	1994 http://fermat.nap.edu/catalog/2138.html
Hepatitis B vaccine	• Incident cases/relapses of multiple sclerosis in adults	2002 http://fermat.nap.edu/catalog/10393.html
Influenza vaccine	• Relapses of multiple sclerosis	2004 http://fermat.nap.edu/catalog/10822.html
Diphtheria and/or tetanus toxoid containing vaccine	• Acute/chronic encephalopathy • Sudden infant death syndrome • Infantile spasms (hypsarrhythmia)	2003 http://fermat.nap.edu/catalog/10649.html 1994 http://fermat.nap.edu/catalog/2138.html
Whole cell pertussis vaccines	• Sudden infant death syndrome	2003 http://fermat.nap.edu/catalog/10649.html

*Based on a review of scientific evidence by an expert safety panel of the Institute of Medicine (see www.iom.edu or the specific citation in the Table).

Source: Canadian Immunization Guide, 7th edition, 2006. http://www.phac-aspc.gc.ca/publicat/cig-gci/p02-01-eng.php

Population level evidence shows that vaccinated populations are healthier than unvaccinated populations. A number of countries including New Zealand have noted dramatic reductions in mortality and morbidity in general, and reductions associated with specific diseases following the introduction of immunisation campaigns (see section 6.2 “Vaccines are not effective”). This has been shown for most vaccines in use today. The trend is more pronounced in the Third world, for example a paper by Gakunju (2003) from Kenya estimated that a 0.11% increase in immunisation coverage led to a 1% reduction in infant mortality.

At an individual or small group level there are few studies of the general health status of immunised versus unimmunised children. The ability to find similar groups of children that have no confounding factors (e.g. sociodemographic, lifestyle) is likely to be a major reason why. The New Zealand Cot Death Study (Mitchell et al 1995) showed that unimmunised infants had higher rates of sudden infant death syndrome (SIDS) than those who were immunised. (This case control study adjusted for confounding variables.)

A recently published study showed that vaccinating children on time (according to the immunisation schedule) during infancy had no effect on neuropsychological outcomes 7 to 10 years later, compared to children who had were vaccinated late or not at all (Smith and Woods 2010). The study used publicly available data on 1,047 children from the United States' Vaccine Safety Datalink project, and analysed 42 neuropsychological outcomes. For some outcomes, vaccination on time was associated with better performance; no statistically significant differences favoured late or no vaccination.

With respect to specific diseases, there are claims that atopy (the asthma, eczema and hay fever triad) is more common in children who are immunised than those who are not. There is conflicting evidence from a small number of studies on this topic. Many of the studies use sampling methods with a high probability of bias, such as parent recall in groups of parents who choose not to immunise their children. One of the largest and best conducted studies was a longitudinal cohort study of 167,240 children followed up prospectively (DeStefano 2002). In this group there was no evidence of a relationship between asthma and immunisation status.

7 Other issues and recommendations

7.1 Work to close the gap between Māori and NZ coverage; take a Whānau Ora approach

Ministry response and activities to improve coverage

The Ministry's Statement of Intent 2010-2013[20] gives clear indication that Whānau Ora is now a priority and this will be a key driver in consideration of immunisation strategies for Māori.

Whānau Ora places families in the centre and in control of achieving their own outcomes. While whānau will be self-managing, there will also be expectations on government services to deliver better results for New Zealand families.

The Ministry will be contracting for integrated family health centres which will align to concept of whānau ora. They will facilitate the one door concept in that people will have a single entry point for all health and social services.

The Ministry used the lessons learned from the MeNZB[21] programme during the rollout of the HPV[22] immunisation programme. Both of these programmes had objectives to achieve equity for both Māori and Pacific peoples.

See also sections 2.2. "Communication strategies" and 3.2.1 "Immunisation contracts review".

7.2 Legislation

Submitters recommend the requirements around immunisation certificates for entry into early childhood education centres and schools need to be strengthened. They argue that certification of declines would reinforce this decision (i.e. an active decision to decline is made and documented). For those declining immunisation to be eligible for school enrolment and WINZ benefits, one submitter recommended that parents be required to state their philosophical objection to immunisation.

Ministry response

The Health (Immunisation) Regulations (1995)[23] contain requirements for:

- parents to present an immunisation certificate (completed at 15 months and 4 years of age) upon enrolment to early childhood and primary school
- early childhood centres and primary schools to maintain registers of immunisation status.

[20] http://www.moh.govt.nz/moh.nsf/pagesmh/10104/$File/soi1013.pdf
[21] CBG Health Research Limited. 2006. Meningococcal B Immunisation Evaluation Final Report
[22] Ministry of Health. 2008. Human Papillomavirus Immunisation Programme: National Implementation Strategic Overview.
[23] Pursuant to Section 117 of the Health Act 1956

The Education Review Office audits the existence of the education provider's immunisation register as part of their regular reviews but there is no requirement for the provider to put additional vaccinations on the register. It remains as a "historic" record of the situation when the child first attended the early childhood centre or was enrolled at primary school.

The electronic National Immunisation Register will provide more complete information for all children born after December 2005 and so in time it will replace the need for the school based registers.

Requiring parents to make a formal immunisation decision or linking immunisation with social service entitlements may require legislation, but could be considered as part of a process to explore parent incentives (see section 7.3 below).

7.3 Parent incentives

Some submitters recommended incentives for parents who immunise their children, while others believed these could be perceived as coercion or bribing parents to immunise.

Ministry response

Incentives have improved immunisation rates in other countries. In Australia, parents receive A$123 if their child is fully immunised by 2 years old and another A$123 if they are fully immunised by 5 years old. This used to be a general maternity allowance that was later tied to immunisation. Conscientious objectors who make a formal declaration declining immunisation and those with medical reasons for not immunising also receive the payments.

While immunisations are fully subsidised, there is no positive financial incentive for parents. It could be argued that because parents who choose to immunise their children contribute to herd immunity in their communities, this contribution should be recognised in some manner.

Options for financial incentives for parents could be explored, but with care to ensure that incentives do not undermine trust or the process of informed consent. Wrongly targeted incentives can create more problems than they solve. Some options are:

- A first time payment for undertaking an informed consent process for both providers and parents – incentivising parents to make a choice may improve immunisation coverage and timeliness. The payment would also be made to those who register on the NIR as a conscientious objector and those with medical exemptions.
- A payment for parents whose children are fully immunised by two years old. The payment would also be made to those who register on the NIR as a conscientious objector and those with medical exemptions.
- Linking an existing benefit or service to immunisation, for example parents could only claim the 20 hours Early Childhood Education Funding if their child was fully

immunised, The payment would also be made to those who register on the NIR as a conscientious objector and those with medical exemptions.

Note that the Task Force on Community Preventive Services immunisation recommendations found insufficient evidence to recommend parent incentives on their own as a means to increase community demand for vaccinations (see Table 8 below).

7.4 Government and Ministry leadership and action is required to achieve the immunisation target

Ministry response and activities to improve coverage

The Government and Ministry are working to establish stronger leadership and decision making throughout the health and disability system.

Monitoring performance, such as quarterly publication of DHB's progress towards the health targets, will continue to drive accountability, improved service performance and innovation within the health and disability system. The immunisation contracts review project will also help to align accountability with funding.

The Ministry acknowledges the importance of this Select Committee inquiry into improving immunisation coverage. The results of the inquiry will help to shape the Ministry's immunisation strategy.

7.5 Increase community demand for immunisation

The Task Force on Community Preventive Services' recommendations[24] to improve immunisation coverage were frequently mentioned in the submissions.

Ministry response and activities to improve coverage

The Task Force on Community Preventive Services' recommendations are provided below. The recommendations are based on a systematic review of interventions designed to improve immunisation coverage.

To raise immunisation rates of two-year olds fully immunised to the target of 95%, the Ministry has two overall strategies for improving the immunisation system and reaching more people:

- Differentiate by audience, not by institution
- Get the basic systems right.

These strategies incorporate many of Task Force's recommended interventions. See Appendix 1 for more detail about the Ministry's immunisation strategies.

[24] www.thecommunityguide.org/vaccines/universally/index.html. Last updated: 18/03/2010.

Table 8: Task force on Community Preventives Services - recommended interventions to improve immunisation coverage

Intervention	Task Force Findings
Enhancing Access to Vaccination Services	
Expanded access in healthcare settings when used alone	Insufficient Evidence
Home visits to increase vaccination coverage	Recommended
Multicomponent interventions for expanding access in healthcare settings	Recommended
Reducing client out-of-pocket costs	Recommended
Vaccination programs in schools and organized child care centres	Recommended
Increasing Community Demand for Vaccinations	
Client or family incentives	Insufficient Evidence
Client reminder and recall systems	Recommended
Client-held medical records	Insufficient Evidence
Clinic-based education when used alone	Insufficient Evidence
Community-wide education when used alone	Insufficient Evidence
Multicomponent interventions that include education	Recommended
Vaccination requirements for child care, school and college attendance	Recommended
Provider- or System-based Interventions	
Provider assessment and feedback when used alone	Recommended
Provider education when used alone	Insufficient Evidence
Provider reminder systems when used alone	Recommended
Standing orders when used alone	Recommended

7.6 Some submissions contained DHB strategies and plans for improving local coverage rates

Ministry response and activities to improve coverage

The Ministry will share these documents nationally at the DHB Forum.

7.7 To protect the very young, immunisation timeliness should also be a focus, not just fully immunised at 2 years of age

Ministry response and activities to improve coverage

The Ministry agrees that on-time immunisation is important, particularly to protect young babies. Once the immunisation health target is achieved for two-year olds, the Ministry will place a greater focus on ensuring babies and children receive their vaccines on-time, according to the national immunisation schedule.

7.8 Work with other social service providers

Ministry response and activities to improve coverage

The Ministry is working with the Ministry of Social Development's Family Start team to look at ways in which the Ministry can support them to increase immunisation coverage for families in their care, while ensuring privacy and health information rights are upheld.

The Health and Education ministries worked together in the planning stages of the human papillomavirus immunisation programme. This was to ensure schools and their boards received appropriate and timely information about the programme to enable them to make a decision whether to allow vaccination at their schools or not.

7.9 Public-private partnerships

Ministry response and activities to improve coverage

The Ministry welcomes these partnerships – but acknowledges any relationships with vaccine manufacturers would need to be transparent and on the public record so that trust and confidence can be maintained.

There is already one established partnership – the National Influenza Strategy Group – that has two industry members alongside doctors, immunisation providers, and influenza experts. The companies participate in promoting the influenza immunisation programme to health professionals, especially to encourage uptake among healthcare workers.

7.10 Opportunities for cost savings in immunisation

Submitters recommended that strategic purchasing for vaccine supply, storage and distribution services would mean significant cost savings for the Government.

Ministry response and activities to improve coverage

The Ministry is working to achieve cost savings in immunisation through three mechanisms:

- long-term strategies to improve value for money in vaccine prioritisation and procurement;
- Vaccine purchase and supply for the current tender round;
- Reviewing current immunisation contracts.

7.10.1 Long-term strategies

In response to the 2009 Ministerial Review Group report[25], the Government considered a range of options to improve the quality and performance of the public

[25] http://www.beehive.govt.nz/sites/all/files/MRG%20Report%20Meeting%20the%20Challenge.pdf

health system. This included long-term strategies to improve value for money in vaccine prioritisation and procurement as well as PHARMAC's possible role in the process[26]. The Ministry of Health will report back to Cabinet with proposals later in the year.

7.10.2 Vaccine purchase and supply for the current tender round

A tender process is underway for supply of National Immunisation Schedule vaccines from 2011-2014. There may be opportunities for cost savings as tenders will be evaluated not only on the ability to supply vaccines to New Zealand, but also on their value for money and value added services. PHARMAC is providing some assistance with economic analysis to support decision-making.

7.10.3 Reviewing current immunisation contracts

See section 3.1.2 ''Funding" for a description of this project.

[26] http://www.moh.govt.nz/moh.nsf/pagesmh/10114/$File/moh-decision-summary-26may2010.doc

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Appendix 1 – Immunisation Strategy

Immunisation aims to:

- prevent diseases through vaccination and achieving coverage that prevents epidemics

The immunisation system is working well when it provides:

- good service (safe, effective, trusted, efficient, timely, high quality)
- equity of outcomes for high risk populations
- value for money

The Ministry of Health's approach to immunisation is based on:

- keep it simple, and focus on getting the basics right
- immunisation is one of the six headline health targets
- there have been lots of reviews of immunisation, don't need a major new piece of work
- don't need radical change to the immunisation system, but need to make existing systems work more efficiently and smoothly
- audience/patient-driven approach, rather than institution-driven
- assume no new funding so need to find savings from within the system to spend where it's most effective

The Ministry's Immunisation Team will:

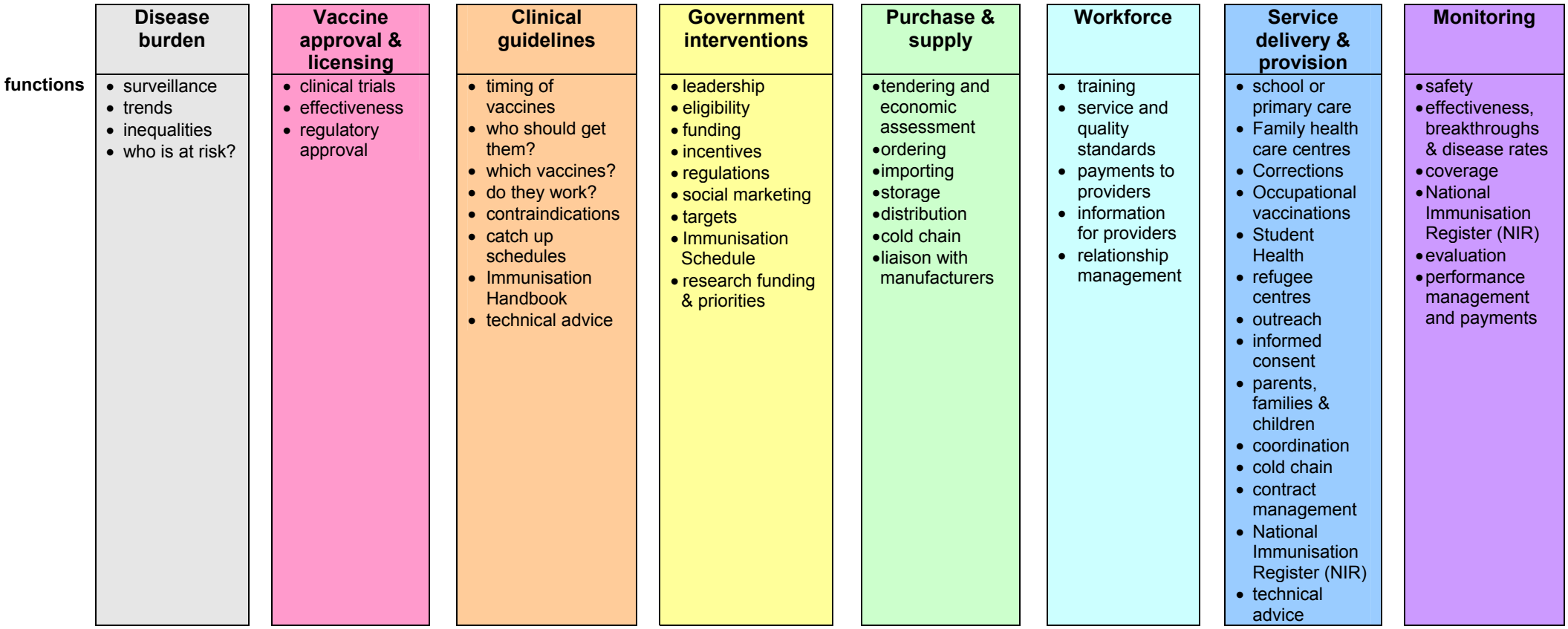
- provide leadership and guidance to the sector and to the public through
  - short, simple documents in plain English
  - more certainty and cohesion for the sector
  - clearly describe what is happening, when, and who is doing it
  - a few focused priorities – do a few things well
  - sound and timely advice from the Immunisation Technical Forum
  - establish an Immunisation Coverage Forum, to get advice from and coordinate with service providers
  - quality and timely surveillance data to inform the programme and the sector
  - measured responses to outbreaks
- advocate for immunisation, rather than take a neutral stance, because there are proven public health benefits
  - earn the trust of the public and the sector by being honest, responsible, competent, fair, and accountable
  - encourage immunisation while allowing individuals to choose
- get the National Immunisation Register working well and review its design for the future
- postpone next Immunisation Schedule change from 2010 to 2011 and 3-yearly from then, allowing 12 months from budget decisions to implement any changes
- sort out the Ministry's own contracts and funding for immunisation services by clarifying national versus local functions, aligning those that go together, rationalising the number of contracts, and allowing more flexibility but also accountability
- take an audience-driven approach rather than one based on the different health institutions:

- get some good audience research about what influences immunisation choices and behaviours
- divide the population into groups that require different actions and services:

Table 9: Audience Segments

audience segment	what they need	comment
do immunise	• good service and a good overall experience • positive encouragement • maintain trust (no nasty surprises)	don't overlook this group or take them for granted
willing to but unable	• remove the barriers or disincentives • better information, including about how to access services, maybe in another language	easiest way to improve coverage?
unmotivated	• clear responsibilities/consequences for complacency • make the diseases relevant or personal • make it easy to do the right thing	find out what's important to them and try to link into it
distrusting	• earn their trust (they probably don't trust us) • address their concerns • more facts and less "hard sell"	it is hard to change attitudes
opposed to immunisation	• leave them alone • support them to keep their own children healthy • tell them how to prevent diseases spreading to others	unlikely to convince this group to immunise

Figure 7: A picture of the immunisation system



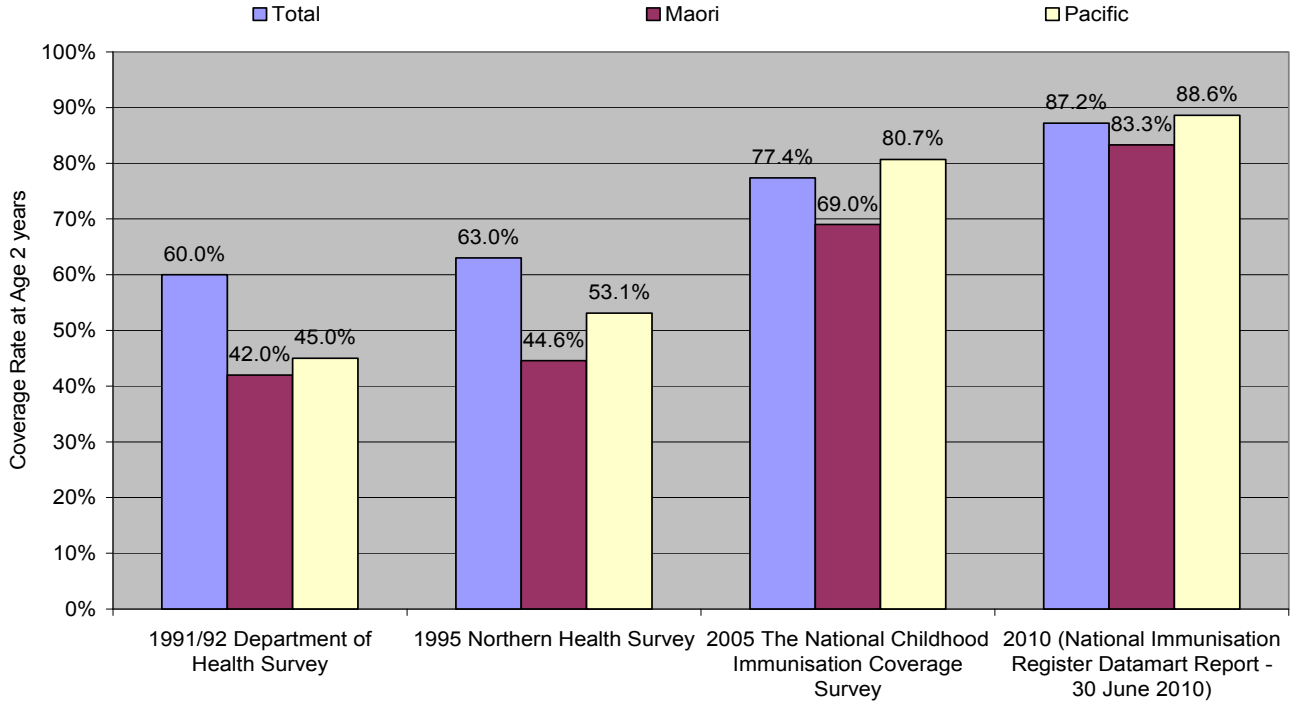
Appendix 2 – Immunisation coverage data

Changes in national immunisation coverage for 2 year old children over time

Figure 8 shows New Zealand's immunisation coverage for two-year old children by ethnicity over time. Data for this graph is sourced from national and regional coverage surveys and the National Immunisation Register (NIR).

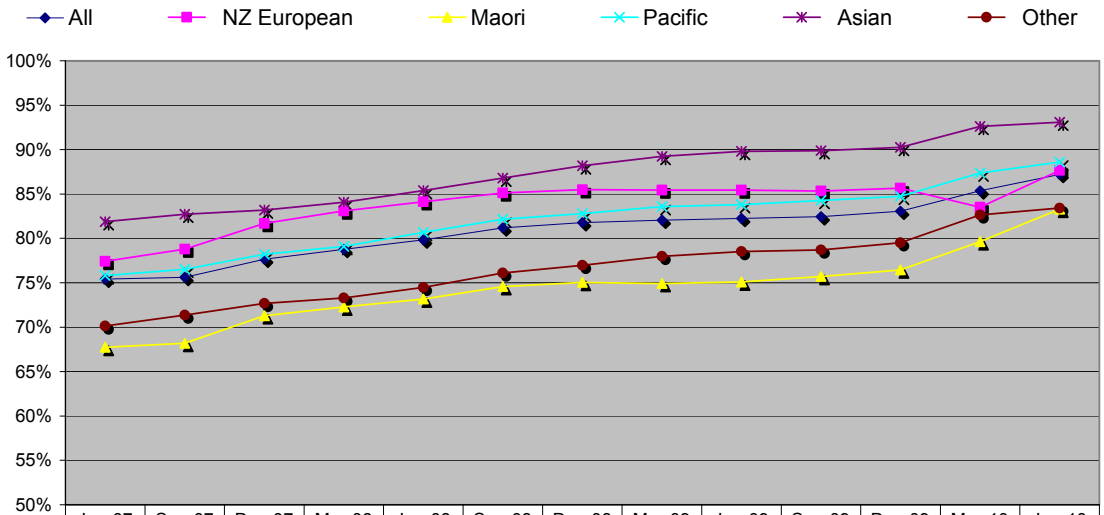
Figures 9 and 10 show 2 year old immunisation coverage by ethnicity and level of deprivation between 2007 and 2010. Data is sourced from the NIR.

Figure 8: Immunisation coverage for 2 year old children by ethnicity (1991-2010)



Figures for Māori and Pacific peoples were not presented in the 1992 report but were presented in subsequent articles without confidence intervals because the survey was not designed to provide good estimates for ethnic coverage levels. Caution should therefore be exercised when using these figures.

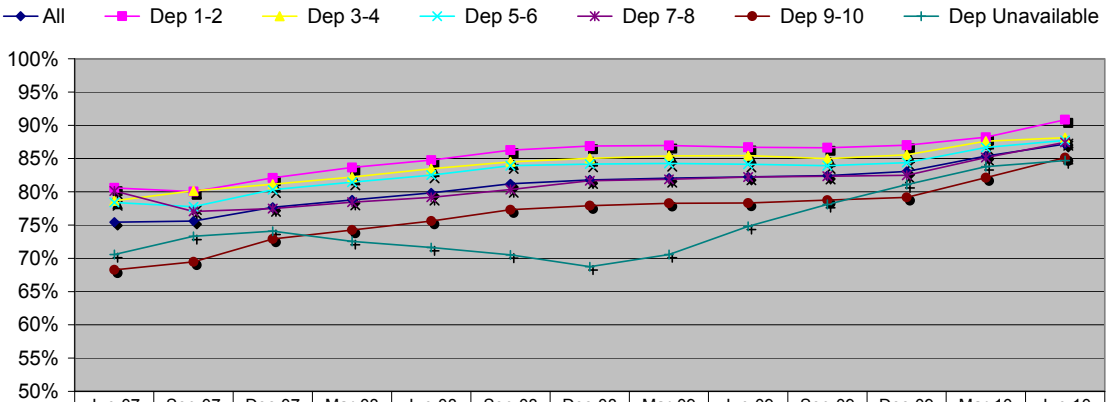
Figure 9: National immunisation coverage for 2 year old children by ethnicity - June 2007-June 2010



	Jun-07	Sep-07	Dec-07	Mar-08	Jun-08	Sep-08	Dec-08	Mar-09	Jun-09	Sep-09	Dec-09	Mar-10	Jun-10
All	75%	76%	78%	79%	80%	81%	82%	82%	82%	82%	83%	85%	87%
NZ European	77%	79%	82%	83%	84%	85%	85%	85%	85%	85%	86%	84%	88%
Maori	68%	68%	71%	72%	73%	75%	75%	75%	75%	76%	76%	80%	83%
Pacific	76%	77%	78%	79%	81%	82%	83%	84%	84%	84%	85%	87%	89%
Asian	82%	83%	83%	84%	85%	87%	88%	89%	90%	90%	90%	93%	93%
Other	70%	71%	73%	73%	74%	76%	77%	78%	79%	79%	80%	83%	83%

Source: National Immunisation Register

Figure 10: National immunisation coverage for 2 year old children by level of deprivation - June 2007-June 2010



	Jun-07	Sep-07	Dec-07	Mar-08	Jun-08	Sep-08	Dec-08	Mar-09	Jun-09	Sep-09	Dec-09	Mar-10	Jun-10
All	75%	76%	78%	79%	80%	81%	82%	82%	82%	82%	83%	85%	87%
Dep 1-2	81%	80%	82%	84%	85%	86%	87%	87%	87%	87%	87%	88%	91%
Dep 3-4	79%	80%	81%	82%	83%	85%	85%	85%	85%	85%	86%	88%	88%
Dep 5-6	78%	78%	80%	81%	83%	84%	84%	84%	84%	84%	84%	87%	88%
Dep 7-8	80%	77%	77%	78%	79%	80%	82%	82%	82%	82%	83%	85%	87%
Dep 9-10	68%	69%	73%	74%	76%	77%	78%	78%	78%	79%	79%	82%	85%
Dep Unavailable	71%	73%	74%	73%	72%	71%	69%	71%	75%	78%	81%	84%	85%

Source: National Immunisation Register

Immunisation timeliness

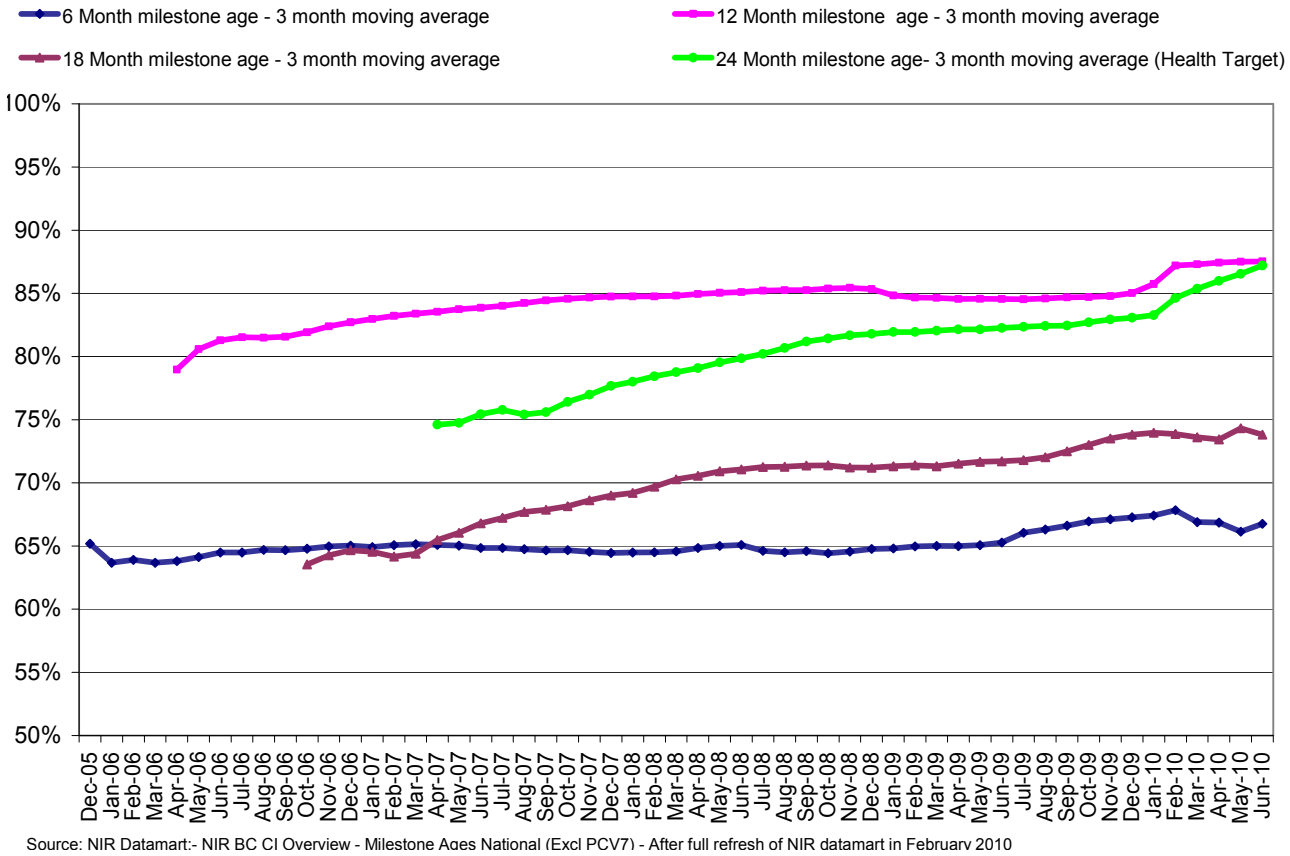
Immunisation timeliness means children receive their immunisations on time, according to the immunisation schedule. One measure of immunisation timeliness is the number of children who are fully immunised at each of the six-monthly milestone ages.

Table 10: Immunisations measured at each milestone age

Milestone Age	Immunisations included in measurement
Six months	6 weeks, 3 months, 5 months
12 months	as above
18 months	as above PLUS 15 months
24 months	as above

Immunisation coverage increases between six and 12 months as no immunisations are scheduled during this time and children have time to catch up. Coverage usually decreases slightly at 18 months due to the 15 month immunisation event. Coverage increases again at 24 months as no further immunisations are scheduled and children have time to catch up. See figures 11 and 12 below.

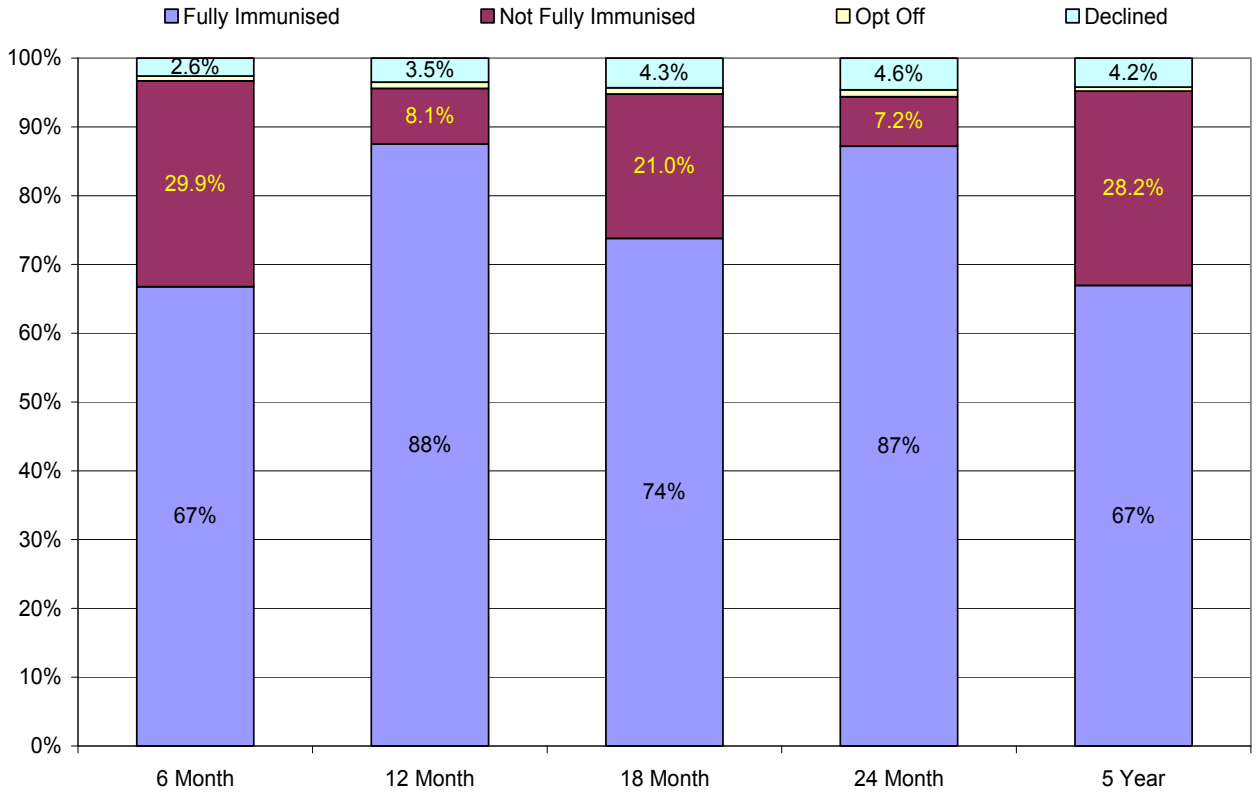
Figure 11: National immunisation coverage by milestone age - December 2005 to July 2010



Source: NIR Datamart:- NIR BC CI Overview - Milestone Ages National (Excl PCV7) - After full refresh of NIR datamart in February 2010

Source: National Immunisation Register

Figure 12: Immunisation coverage by milestone age - fully immunised, not fully immunised, opt off and declined
(n=16102; children who the milestone age between 1 April and 1 July 2010)

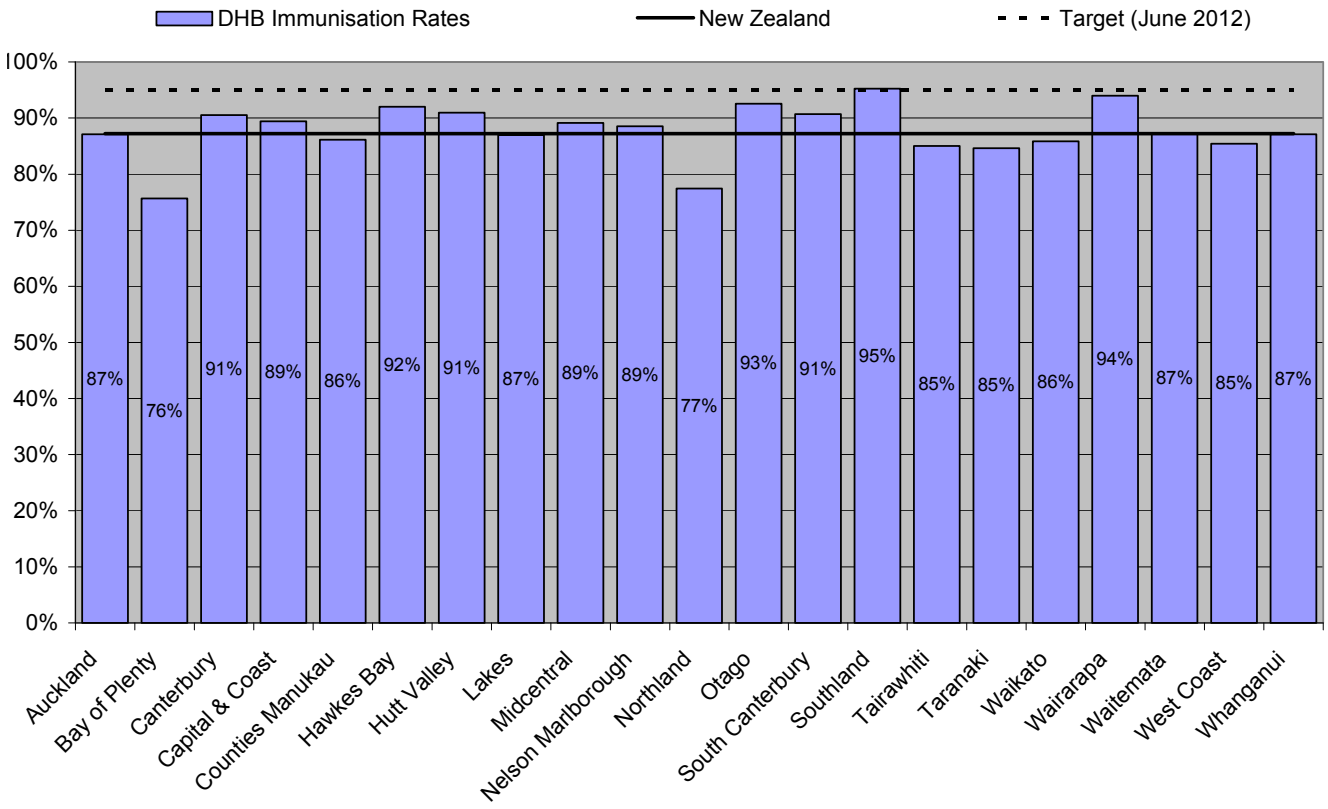


- Fully immunised – received all immunisations by the milestone age according to immunisation schedule
- Not fully immunised – has not received all immunisations by the milestone age according to immunisation schedule
- Opt off – decision made not to record immunisations on the NIR (may be immunised or not)
- Declined – decision made not to receive scheduled vaccine(s)

District Health Board immunisation coverage data

Figure 13 and tables 11 and 12 below show the percentage of fully immunised 2-year old children by DHB, ethnicity and level of deprivation. Only those children who turned 2 years of age between 1 April and 1 July 2010 are included, which is why in some DHBs the number of eligible children is low.

Figure 13: Immunisation coverage by DHB for 2 year old children
(children who turned 2 years of age between 1 April and 1 July 2010)



The table below shows the number of children who turned 24 months of age between 1 April 2010 and 1 July 2010 and who have completed their age appropriate immunisations by the time they turned 24 months of age.

Table 11: Immunisation coverage by DHB and prioritised ethnicity for 2 year old children

DHB Area	Total			NZE			Maori			Pacific			Asian			Other		
	No. Eligible	Fully Immunised for Age	%	No. Eligible	Fully Immunised for Age	%	No. Eligible	Fully Immunised for Age	%	No. Eligible	Fully Immunised for Age	%	No. Eligible	Fully Immunised for Age	%	No. Eligible	Fully Immunised for Age	%
Auckland	1,580	1,376	87%	443	398	**85%**	202	160	**79%**	344	293	**85%**	316	287	**91%**	275	238	87%
Bay of Plenty	768	581	**76%**	335	260	**77%**	299	217	**73%**	18	12	**67%**	42	38	**90%**	74	54	**73%**
Canterbury	1,691	1,531	91%	953	883	90%	257	229	89%	86	75	**87%**	130	121	93%	265	223	84%
Capital & Coast	984	880	89%	421	380	89%	204	179	88%	104	90	**87%**	114	106	**93%**	141	125	89%
Counties Manukau	2,229	1,920	**86%**	296	272	91%	654	503	**77%**	766	684	89%	290	272	94%	223	189	85%
Hawkes Bay	587	540	92%	232	211	91%	280	258	92%	27	27	100%	12	12	100%	36	32	89%
Hutt Valley	621	565	91%	248	224	88%	159	145	91%	82	76	93%	56	52	**93%**	76	68	89%
Lakes	460	400	**87%**	129	118	91%	262	221	84%	13	12	92%	22	22	100%	34	27	**79%**
Midcentral	599	534	89%	290	260	88%	190	164	86%	26	24	92%	29	28	97%	64	58	91%
Nelson Marlborough	436	386	89%	265	238	**88%**	86	78	91%	n/s	n/s	**86%**	19	18	95%	59	46	**78%**
Northland	603	467	**77%**	204	168	**80%**	321	239	**74%**	12	12	100%	n/s	n/s	100%	60	42	**70%**
Otago	498	461	93%	327	304	92%	69	65	94%	18	18	100%	19	19	100%	65	55	85%
South Canterbury	161	146	91%	120	110	92%	18	15	83%	n/s	n/s	100%	n/s	n/s	100%	18	16	89%
Southland	398	379	95%	272	258	95%	72	69	96%	14	14	100%	12	11	**92%**	28	27	96%
Tairawhiti	200	170	**85%**	36	32	89%	148	126	85%	n/s	n/s	100%	n/s	n/s	100%	n/s	n/s	**43%**
Taranaki	436	369	**85%**	255	214	**84%**	119	102	86%	n/s	n/s	100%	15	15	100%	41	32	**78%**
Waikato	1,435	1,232	**86%**	629	544	**86%**	513	433	84%	42	39	93%	91	86	95%	160	130	**81%**
Wairarapa	133	125	94%	78	75	96%	38	36	95%	n/s	n/s	**50%**	n/s	n/s	100%	12	11	92%
Waitemata	1,932	1,684	87%	741	654	**85%**	296	243	**82%**	232	207	89%	273	252	**92%**	390	328	84%
West Coast	103	88	**85%**	61	56	92%	18	16	89%	n/s	n/s	100%	n/s	n/s	100%	17	n/s	**53%**
Whanganui	240	209	87%	101	92	90%	91	83	91%	10	n/s	**80%**	n/s	n/s	100%	33	21	**64%**
National	**16,102**	**14,043**	**87%**	**6,438**	**5,751**	**88%**	**4,299**	**3,581**	**83%**	**1,826**	**1,618**	**89%**	**1,460**	**1,359**	**93%**	**2,079**	**1,734**	**83%**

The orange shaded area shows districts with immunisation coverage below the national average.

N/S – Data not shown to protect privacy – less than 10 children in the group.

The table below shows the number of children who turned 24 months of age between 1 April 2010 and 1 July 2010 and who have completed their age appropriate immunisations by the time they turned 24 months of age.

Table 12: Immunisation coverage by DHB and level of deprivation for 2 year old children

DHB Area	Dep 1-2			Dep 3-4			Dep 5-6			Dep 7-8			Dep 9-10			Dep Unavailable		
	No. Eligible	Fully Immunised for Age	%	No. Eligible	Fully Immunised for Age	%	No. Eligible	Fully Immunised for Age	%	No. Eligible	Fully Immunised for Age	%	No. Eligible	Fully Immunised for Age	%	No. Eligible	Fully Immunised for Age	%
Auckland	239	215	**90%**	236	211	89%	272	239	**88%**	314	274	87%	395	331	**84%**	124	106	85%
Bay of Plenty	57	46	**81%**	114	86	**75%**	113	85	**75%**	132	98	**74%**	217	164	**76%**	135	102	**76%**
Canterbury	326	303	93%	349	314	90%	384	333	**87%**	308	276	90%	190	175	92%	134	130	97%
Capital & Coast	311	287	92%	181	155	**86%**	144	127	88%	127	114	90%	158	138	87%	63	59	94%
Counties Manukau	176	162	92%	216	197	91%	185	163	88%	318	281	88%	870	726	**83%**	464	391	**84%**
Hawkes Bay	58	52	**90%**	68	59	**87%**	115	103	90%	98	91	93%	211	201	95%	37	34	92%
Hutt Valley	124	116	94%	88	80	91%	114	105	92%	105	96	91%	147	131	89%	43	37	86%
Lakes	41	39	95%	51	47	92%	58	50	**86%**	87	71	**82%**	153	131	86%	70	62	89%
Midcentral	66	60	91%	99	88	89%	124	105	**85%**	133	119	89%	120	108	90%	57	54	95%
Nelson Marlborough	59	55	93%	88	79	90%	95	84	88%	80	76	95%	36	31	86%	78	61	**78%**
Northland	23	22	96%	81	67	**83%**	82	64	**78%**	127	96	**76%**	213	163	**77%**	77	55	**71%**
Otago	85	79	93%	108	103	95%	113	108	96%	93	85	91%	63	58	92%	36	28	**78%**
South Canterbury	25	22	**88%**	43	38	88%	37	33	89%	32	31	97%	15	14	93%	n/s	n/s	89%
Southland	100	92	92%	77	72	94%	78	75	96%	54	53	98%	65	63	97%	24	24	100%
Tairawhiti	11	10	91%	n/s	n/s	100%	19	16	**84%**	26	24	92%	124	103	**83%**	17	14	**82%**
Taranaki	38	36	95%	97	82	**85%**	88	73	**83%**	100	85	**85%**	75	64	85%	38	29	**76%**
Waikato	176	152	**86%**	237	205	**86%**	221	198	90%	231	205	89%	376	316	**84%**	194	156	**80%**
Wairarapa	20	19	95%	14	13	93%	22	22	100%	46	42	91%	26	24	92%	n/s	n/s	100%
Waitemata	302	266	**88%**	336	295	**88%**	382	338	88%	337	293	**87%**	182	154	**85%**	393	338	86%
West Coast	n/s	n/s	**89%**	15	15	100%	19	16	**84%**	47	38	**81%**	12	10	**83%**	n/s	n/s	100%
Whanganui	24	22	92%	33	25	**76%**	46	42	91%	54	46	**85%**	81	72	89%	n/s	n/s	100%
National	**2,271**	**2,063**	**91%**	**2,534**	**2,234**	**88%**	**2,711**	**2,379**	**88%**	**2,852**	**2,494**	**87%**	**3,732**	**3,177**	**85%**	**2,002**	**1,696**	**85%**

The orange shaded area shows districts with immunisation coverage below the national average.

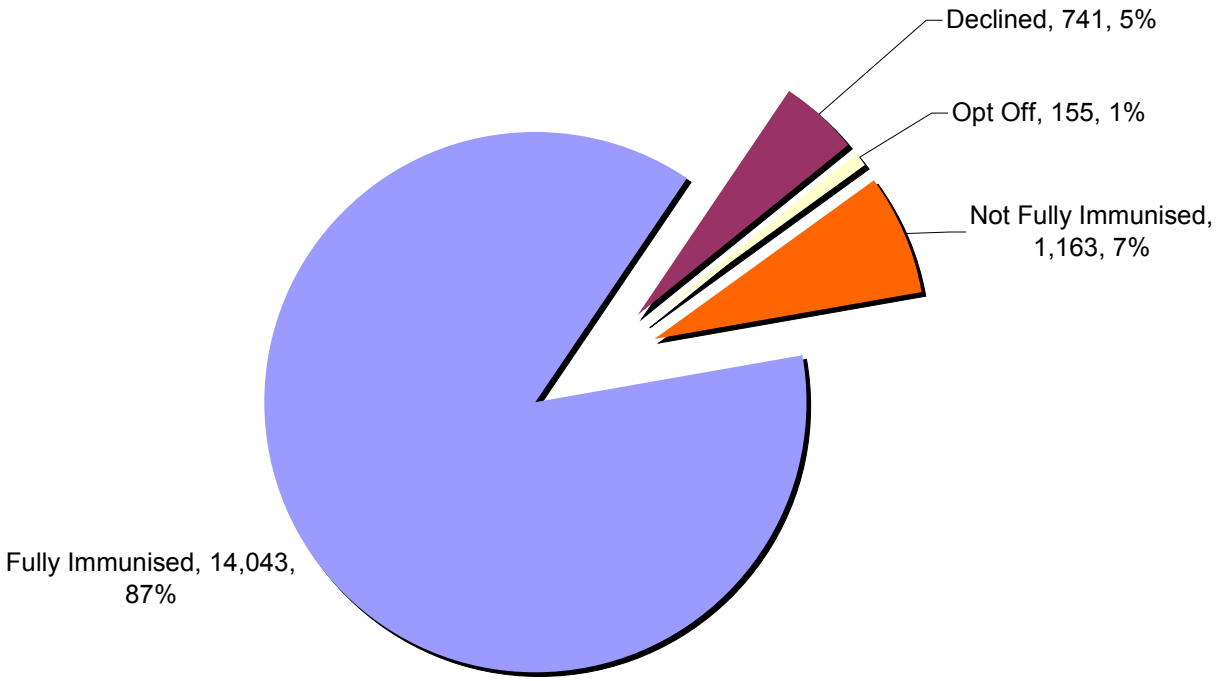
N/S – Data not shown to protect privacy – less than 10 children in the group.

Who isn't being immunised?

Figure 14 shows the proportion of 2 year old children who are fully immunised, not fully immunised, opted off the NIR and declined immunisation.

- Fully immunised – received all immunisations according to immunisation schedule by the time they turned 2 years of age
- Not fully immunised – has not received all immunisations according to immunisation schedule by the time they turned 2 years of age
- Opt off – decision made not to record immunisations on the NIR (may be immunised or not)
- Declined – decision made not to receive the scheduled vaccine(s)

Figure 14: National immunisation coverage at 2 years of age - fully immunised, not fully immunised, opt off and declined
(children who turned 2 years of age between 1 April and 1 July 2010)



Note: "Declined" includes 14 children who declined and then opted off, and have been counted in to both 'declined' and 'opt off'.

Figures 15 to 18 on the following pages provide more data about 2 year old children who are not fully immunised, have declined immunisations or who have opted off the NIR.

Figure 15: Numbers of 2 year old children not fully immunised - by ethnicity and deprivation index
(children who turned 2 years of age between 1 April and 1 July 2010; percentages relative to the total number of children not fully immunised are in brackets)

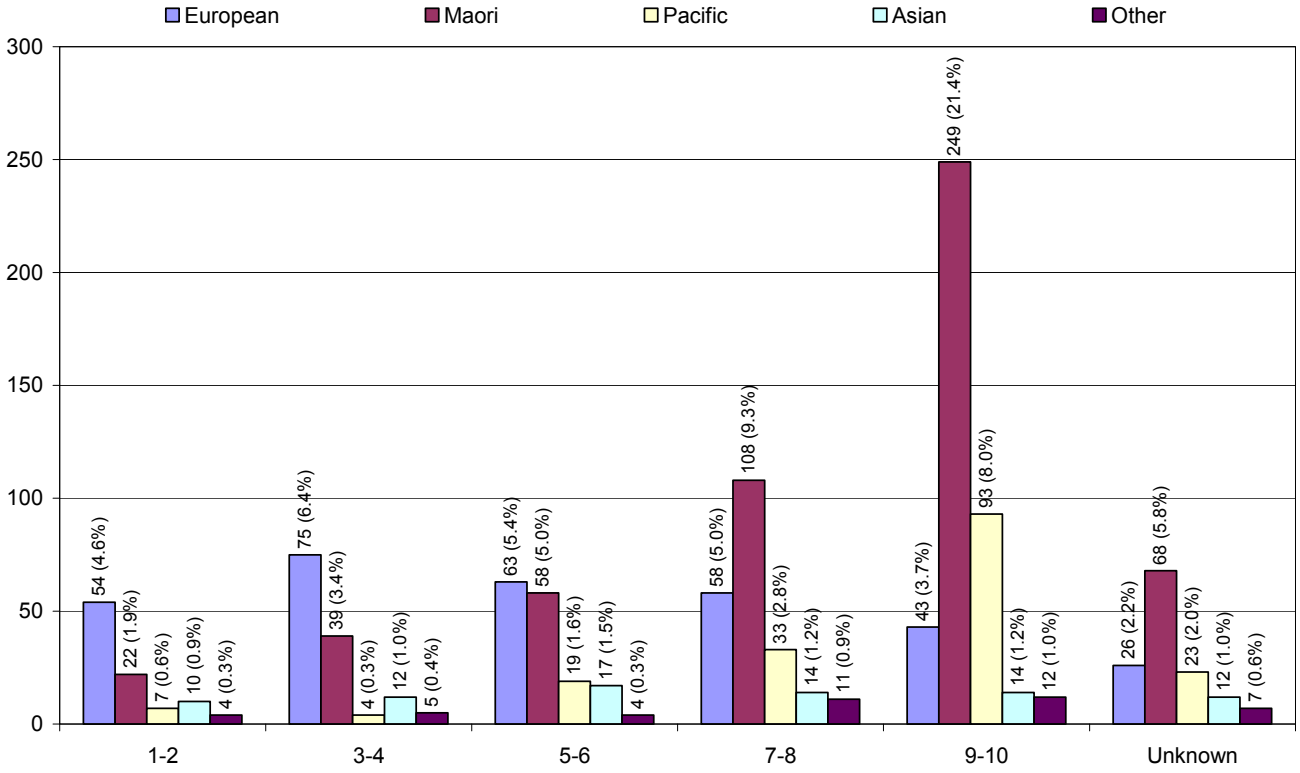


Figure 16: Numbers of 2 year old children not fully immunised by DHB
(children who turned 2 years of age between 1 April and 1 July 2010)

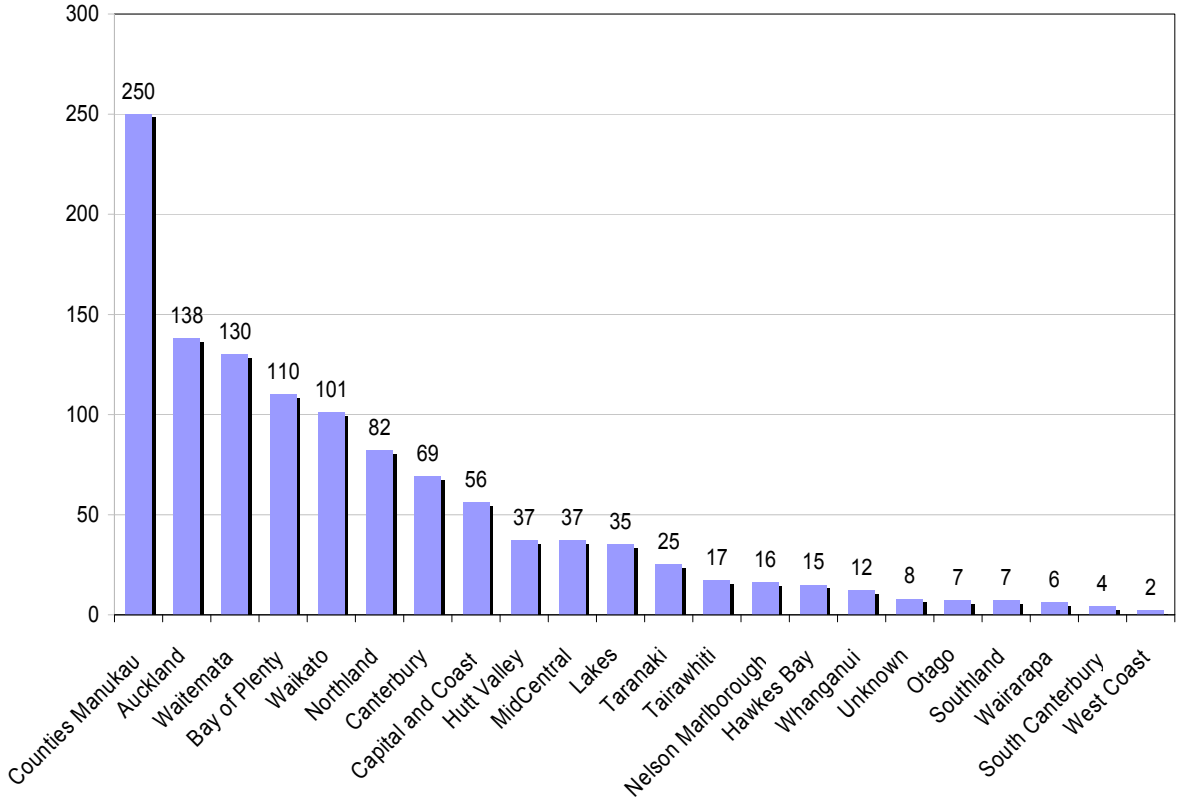
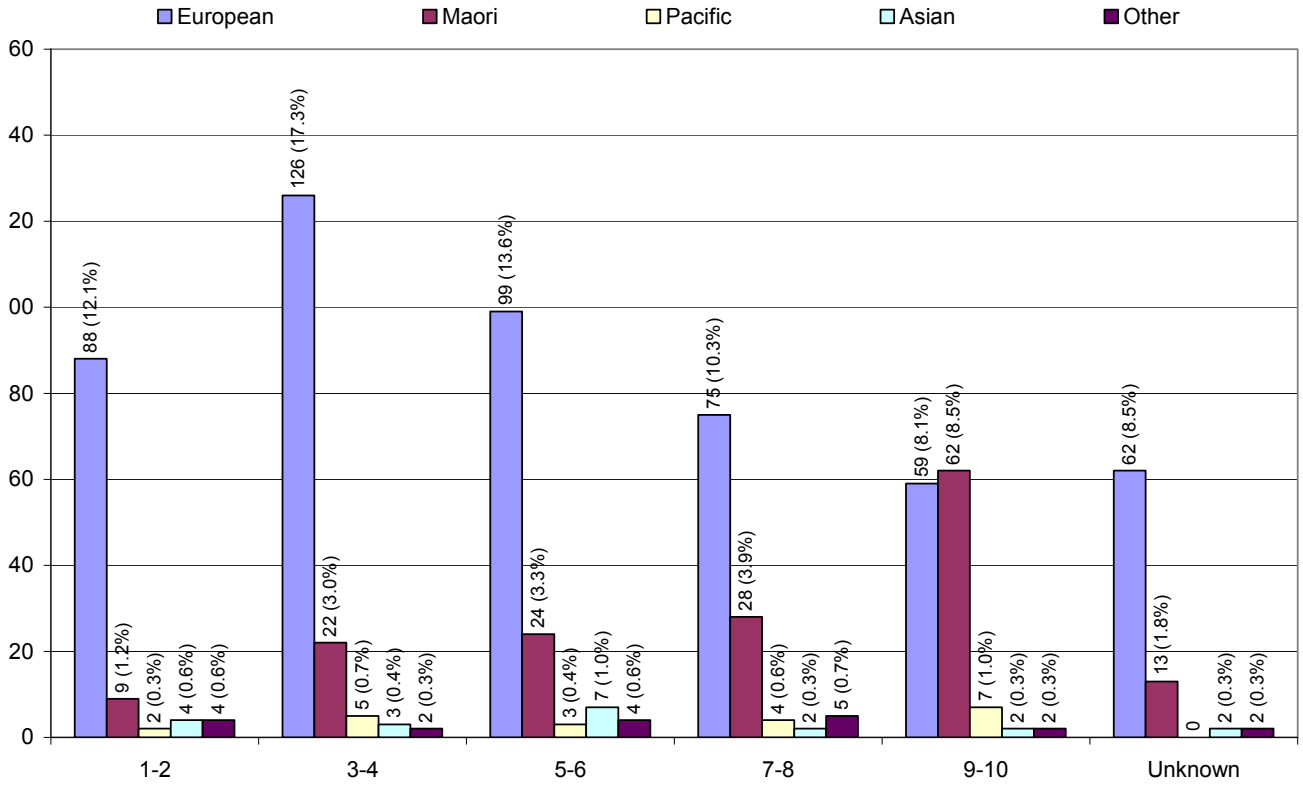


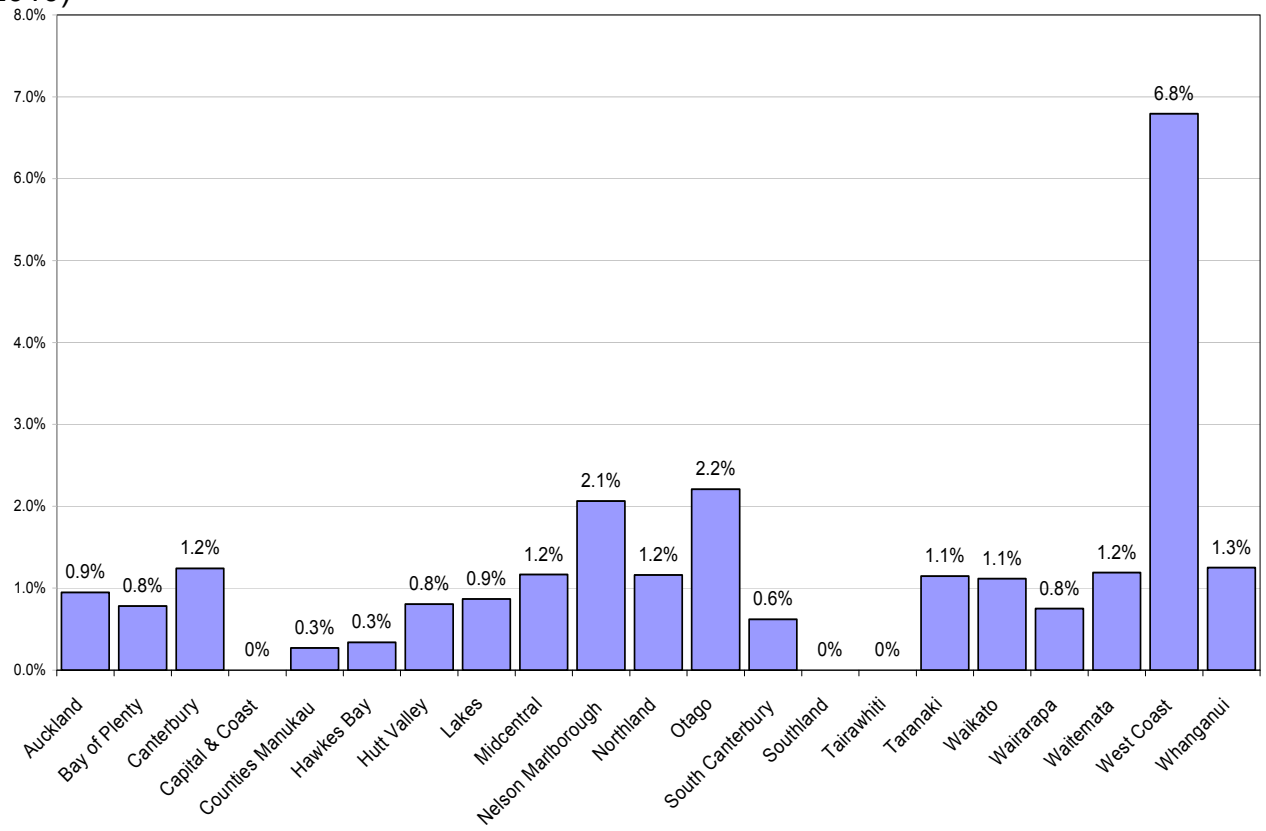
Figure 17: Number of declines by ethnicity and deprivation index
(children who turned 2 years of age between 1 April and 1 July 2010; percentages relative to the total number of declines are in brackets)



(excludes the 14 children who declined then opted off the NIR)

Figure 18 below shows the percent of 2 year old children in each DHB that have chosen not to have their immunisation data recorded on the NIR (opted off). These children may still be fully, partially or not immunised. Nationally, 1% of 2 year old children have opted off the NIR; DHB opt off rates range from 0% to 6.8%.

Figure 18: Opt off rate by DHB
(relative to the DHB's population of children who turned 2 between 1 April and 1 July 2010)



How New Zealand's immunisation coverage compares internationally

Table 13: WHO/UNICEF immunisation coverage estimates by specific vaccine for OECD countries (2008)

OECD Countries	DTP1	Rank DTP1	DTP3	Rank DTP3	HepB3	Rank HepB3	Hib3	Rank Hib3	MCV	Rank MCV	Pol3	Rank Pol3
Australia	97	19	92	25	94	10	94	15	94	17	2	24
Austria	94	28	83	29	83	17	83	26	83	30	83	29
Belgium	99	1	99	1	98	3	98	4	93	19	99	1
Canada	97	19	94	21	14	19	94	15	94	17	90	27
Czech Republic	98	13	99	1	99	1	99	1	97	6	99	1
Denmark	97	19	75	30	-		75	28	89	24	75	30
Finland	99	1	99	1	-		98	4	97	6	97	12
France	98	13	98	9	29	18	87	24	87	26	98	8
Germany	98	13	90	27	90	15	93	18	95	16	96	15
Greece	99	1	99	1	95	9	83	26	99	1	99	1
Hungary	99	1	99	1	-		99	1	99	1	99	1
Iceland	94	28	98	9	-		98	4	96	11	98	8
Ireland	97	19	93	24	-		93	18	89	24	93	22
Italy	98	13	96	17	96	8	96	13	91	23	96	15
Japan	99	1	98	9	-		-		97	6	95	19
Luxembourg	99	1	99	1	94	10	98	4	96	11	99	1
Mexico	99	1	98	9	98	3	98	4	96	11	98	8
Netherlands	98	13	97	14	-		97	10	96	11	96	15
New Zealand	**91**	**30**	**89**	**28**	**90**	**15**	**86**	**25**	**86**	**28**	**89**	**28**
Norway	97	19	94	21	-		94	15	93	19	94	21
Poland	99	1	99	1	98	3	88	23	98	4	99	1
Portugal	99	1	97	14	97	6	97	10	97	6	97	12
Republic of Korea	95	27	94	21	94	10	-		92	21	92	24
Slovakia	99	1	99	1	99	1	99	1	99	1	99	1
Spain	98	13	97	14	97	6	97	10	98	4	97	12
Sweden	99	1	98	9	-		98	4	96	11	98	8
Switzerland	97	19	95	20	-		93	18	87	26	95	19
Turkey	97	19	96	17	92	14	96	13	97	6	96	15
Great Britain and Northern Ireland	97	19	92	25	-		92	22	86	28	92	24
United States of America	99	1	96	17	93	13	93	18	92	21	93	22
Number of Countries		**30**		**30**		**19**		**28**		**30**		**30**
Simple mean	**98**		**95**		**87**		**93**		**94**		**95**	
Median	**98**		**97**		**94**		**95**		**96**		**96**	

DTP1 and 3 – first or third dose of diphtheria, tetanus and pertussis (whooping cough) containing vaccine
HepB3 – third dose of hepatitis B containing vaccine
Pol3 – third dose of polio containing vaccine
Hib3 – third dose of *Haemophilus influenzae* containing vaccine
MCV – measles containing vaccine

Appendix 3 – The National Immunisation Register (NIR) – background information

The following has been extracted from information supplied to the Health Select Committee on 22 March and 14 April 2010.

The National Immunisation Register

The National Immunisation Register (NIR) is a computerised information system developed to hold immunisation details of New Zealand children.

The register enables authorised health professionals to quickly and easily find out what vaccines a child has been given (this includes children whose family has shifted or changed healthcare providers). Primary care providers can follow up on individual children and check their immunisation status in real time. This helps to make sure immunisations are given at the appropriate time.

The register also provides an accurate record of immunisation coverage rates – regionally and nationally. This enables programme planning to target populations with the lowest immunisation rates. The register is also used to track progress towards the national target of 95% of two year olds fully immunised by July 2012.

History of the National Immunisation Register

The development and rollout of the National Immunisation Register was separated into three main parts – a primary care element, schools based system, and a birth cohort and maternity systems element. The first two elements were needed to support the start of the MeNZB meningococcal campaign. The birth cohort and maternity systems element supports the ongoing child immunisation programmes.

Implementation was phased throughout the country, starting in the Auckland region in mid-2004 and finishing in Nelson/Marlborough in December 2005.

Information is collected for children born after the date the register was rolled out in their DHB - at present children up to four and five years old have all their vaccination details recorded on the register. The register also records MeNZB and human papillomavirus (HPV) vaccinations for older children.

Who uses the National Immunisation Register?

The register receives and sends information to several other information systems: multiple maternity systems (to register babies), the five practice management systems used in general practices, and the School Based Vaccination System used by public health nursing for school programmes.

Maternity - Most registrations come from maternity data sent after the baby is discharged from the maternity facility.

Primary care - providers send immunisation event data at the time of immunisation for each registered individual, in addition to demographic and vaccinator information.

This is usually done electronically, through the provider's practice management system which also sends a message to the Ministry's claim centre so that the provider is paid for that immunisation event. Paper-based systems are also available. Authorised providers can also look up an individual's immunisation status.

School based vaccinators – upload data from school-based vaccinations for human papillomavirus to the register.

DHBs – each DHB has a local NIR administrator funded by the Ministry of Health who monitors immunisation coverage for programme planning, liaises with primary care providers and assists with data quality.

Ministry of Health - monitors immunisation coverage to plan programmes and identify issues, assist with data quality, publishes national and DHB data each quarter to monitor progress towards the immunisation coverage target.

Security and privacy of information
The management of health information is governed by the Health Information Privacy Code 1994, which forms the basis of the National Immunisation Register's privacy policy.

The individual (or their parent or guardian) must be informed about the register and be aware that information about them is being recorded and for what purpose. Individuals (or their parents or guardians) can choose not to have immunisation data recorded, even if they still have the vaccine(s).

National Immunisation Register – data quality and integrity
The strength of the National Immunisation Register (NIR) is that it is built into the systems that primary care providers use everyday, that is, the patient management systems. However this also makes it difficult and complex to change the NIR, because if the NIR rules change or a new vaccine is added then there are multiple systems not owned by the Ministry that also need to change.

As part of the NIR update for the 2008 national immunisation schedule change, the Ministry made significant improvements to the NIR which included:

- the development of practice level immunisation coverage reports
- recording human papillomavirus (HPV) immunisations on the NIR – and upgrading non-primary care based data management systems to message HPV immunisation data to the NIR
- improving the completeness of counting children in the DHB's NIR birth cohort, and the inclusion of children who were immunised overseas or have incomplete immunisation records
- data cleansing to remove false entries and data errors.

These changes contributed to recent improvements in immunisation coverage, as the NIR may have been undercounting by up to 3 percentage points. For example in July 2009, 80% of two-year old children were fully immunised. When the

immunisation coverage reports were re-run after the NIR upgrades, immunisation coverage for July 2009 increased to 83%.

Some factors that contribute to data quality and immunisation coverage issues are:

- practice management system / primary care organisation / DHB datasets are different to the NIR dataset
- data entry errors
- data entry delays by immunisation providers
- highly mobile individuals
- individuals registered on the NIR but who are not enrolled on a primary care organisation
- on-time NIR registration by lead maternity carers (where electronic messaging is not available for example home births)
- individuals being registered twice with two unique identifier number (NHI), resulting in duplicate records.

Appendix 4 – Vaccine development and regulation

The following has been extracted from information provided to the Health Select Committee on 4 June 2010.

The development and regulation of vaccines can be divided as follows:

1. development
    a. pre-clinical research and development
    b. clinical research and development
2. approval
3. post-approval.

Preclinical Testing

The preclinical testing of a vaccine is a prerequisite for the initiation of clinical trials. The testing may be carried out in *in vitro* (within an artificial environment, eg a test-tube) supplemented with *in vivo* (within a living organism) testing as required. The goal of preclinical testing is to demonstrate that the vaccine is suitable for testing in humans.

These studies are aimed at defining the characteristics of the vaccine including the indicators of safety and immunogenicity (the ability to produce an immune response) in an appropriate animal model.

Adjuvants may be tested here – these are substances that are added to the vaccine to enhance the immune response. Adjuvants must meet certain requirements, including not causing too many reactions.

Clinical Studies

Before the start of clinical trials (particularly phase III trials), a sound understanding of the epidemiology of the pathogen or disease of interest in the intended study population is needed. This requires population-based or outbreak evaluations of individuals exposed to, at high risk of, or suffering from, the disease in question.

Such studies define disease incidence, the proportion of infected persons who develop clinical disease and the risk of transmission. The understanding of the full clinical spectrum of illness and the optimization of diagnostic criteria as well as definition of the high-risk groups frequently defined by age, gender, ethnic or population group membership, social characteristics as well as geography and seasonality of exposure, is essential for accurate vaccine evaluation.

All clinical trials should adhere to the standards described for good clinical practice. However, vaccines demand special consideration because:

- Vaccines are given to healthy individuals, mostly children and infants.
- Vaccines are given to prevent disease; this limits tolerability of adverse events.
- Vaccines are biological products which are highly complex substances derived from living materials, and sometimes comprising living organisms. They require

specialized assays and testing to assure their quality and safety on a lot-to-lot basis.

Consistency of manufacturing for the vaccine lots used in clinical trials should be demonstrated and well documented. These lots should be adequately representative of the formulation intended for marketing. Clinical data may be required to help to demonstrate manufacturing consistency.

Phase I Studies

A Phase I trial primarily seeks information on safety, looking for any vaccine-related side effects. This is done by comparing the vaccine with a control or placebo (an inactive substance, such as normal saline). A Phase I trial can also provide initial data on the dose and administration schedule (the time between vaccinations) that achieve the optimal immune response. Generally phase I studies are small-scale studies to determine clinical tolerance and safety.

Phase II Studies

Once phase I studies have been successfully completed with a satisfactory outcome, a candidate vaccine then undergoes phase II clinical evaluation. The main distinction between phase I and phase II studies is that phase II studies involve larger numbers of subjects, and are often randomized and well controlled. The outcome measures, however, are often similar. Phase II vaccine trials are intended to demonstrate the immune response produced by the active component(s) and the safety profile of a candidate vaccine in the target population.

The phase II studies should define the optimal dose, initial schedule and safety profile of a candidate vaccine before the phase III trials can begin.

Phase III Studies

The phase III studies are large-scale clinical trials designed to provide data on vaccine efficacy and safety. In large scale efficacy studies of this type, that usually enrol many thousands of subjects, serological data are usually collected from at least a subset of the immunised population at pre-defined intervals to evaluate the immune response. It is also important to collect serological data from all persons classified as vaccine failures.

When vaccines containing the same antigens are already in common use and/or the incidence of disease is very low, it may not be feasible to perform a formal study of protective efficacy. In such instances, the phase III trials, although involving larger numbers of persons than previous phases, will be confined to the evaluation of immune responses and comparison with any recognised correlates of protection. Sometimes there are no established and unequivocal immunological correlates of protection. In such cases, it is important that an attempt is made to estimate the effectiveness of the vaccine after its approval and widespread introduction. Phase III trials involve a larger number of subjects than were included in the earlier phases of development and, thus, provide expanded safety assessments.

Production, characterisation and quality assurance of vaccines

The characterisation, standardisation and control of the components, safety and potency of vaccine preparations are key issues during development. The amount of data collected to support clinical studies increases throughout phases I and II, and product characterisation should be completed by the beginning of the phase III stage of development.

In-process testing is performed to ensure adequate control over the manufacturing process and manufacturing consistency. Analytical criteria are established during product development and used subsequently to evaluate new batches and to establish batch-to-batch consistency.

Sufficient stability data is generated to support clinical trials. Further data on stability to support the expiry date of the product for licence is based on long-term, real-time, stability studies under the real conditions of use.

The Approval Process

In New Zealand, once a pharmaceutical company has completed the clinical studies for a vaccine and they believe that they have generated sufficient data to support the quality, safety and efficacy this data is submitted to Medsafe for evaluation. Thus an application to Medsafe includes (but is not limited to) data supporting:

- Preparation of antigen
- Finished product manufacture
- Manufacturing sites
- Development, purity, dissolution, stability
- Pre-clinical toxicology
- Dose determination
- Clinical trials of safety and efficacy

Multiple volumes of data are received by Medsafe and are evaluated by scientists and clinicians. Medsafe evaluates an application against international standardised guidelines that are also used by the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and Australian Therapeutic Goods Administration (TGA).

Medsafe reviews the risks and benefits for each specific vaccine to ensure that the safety profile is acceptable i.e. the benefits of the medicine outweigh the risks. The following factors are taken into consideration.

1. Benefits:
- Has efficacy been demonstrated in the target population (i.e. those who will use the vaccine)?
- Is the vaccine significantly better than placebo (dummy treatment)?
- What is the natural history of the disease that the vaccine is targeted at?

2. Risks:

- What proportion of people taking the vaccine experience an adverse reaction?
- How many of these adverse reactions are considered to be serious?
- How many people stopped treatment because of an adverse reaction?
- Are the adverse reactions reversible, treatable or avoidable (e.g. interactions with other medicines)?

If Medsafe evaluators are not content with the data initially supplied by the applicant requests for further information are made to in order to resolve any deficiencies in the application. Only once Medsafe is satisfied that the vaccine is effective, has an acceptable safety profile and meets the required standards for product quality assurance will a recommendation for approval be made.

Post-approval

Before a vaccine is marketed any experience of its safety and efficacy is limited to its use in clinical trials. However clinical trials do not always reflect the actual use of a medicine or vaccine in real life. The post-approval period is critical for the collection of data on the safety and effectiveness of a vaccine in large numbers of recipients; these data may come from both active and passive modes of surveillance. Following licensing, there is continued surveillance of persons who were vaccinated for adverse events, especially for those rare events that can be detected only in very large numbers of subjects. Pharmacovigilance is the term used to describe post-approval safety surveillance.

Pharmacovigilance involves:

- Monitoring the use of medicines (including vaccines) in everyday practice to identify previously unrecognised adverse effects or changes in the patterns of adverse effects.
- Assessing the risks and benefits of medicines to determine if action is required to improve their safe use.
- Providing information to healthcare professionals and consumers to promote safe use of medicines.
- Monitoring the impact of any action taken and assessing whether further action is required.

Information from many sources is used for pharmacovigilance, including:

- Clinical and observational studies.
- Published medical literature.
- Pharmaceutical companies.
- Other regulatory authorities such as the FDA (America), EMA (Europe) and TGA (Australia).
- Spontaneous adverse reaction reports submitted to the Centre for Adverse Reactions Monitoring (CARM).

The main aim of pharmacovigilance is to identify safety signals.

Medsafe analyses adverse reactions reports in conjunction with other information to determine if the safety signal is real. Medsafe seeks the advice of independent experts, via the Medicines Adverse Reactions Committee or may also form working

groups of experts to provide advice. Medsafe also works closely with other regulatory authorities from around the world.

Medsafe undertakes a risk-benefit assessment on safety signals to assess if action is required.

The majority of safety signals are not supported by any additional information and no action is taken although Medsafe may continue to closely monitor the issue. A small number of possible safety signals are confirmed. In these cases Medsafe takes appropriate action to ensure the safety of these medicines is improved.

What action can Medsafe take if a safety concern is confirmed?

- Provide information directly to healthcare professionals and consumers on safety related issues.
- Require changes to warnings in the product information or on the product label.
- Restrict the conditions that the medicine can be used for.
- Ask the pharmaceutical company to commission a clinical study to investigate a particular safety concern.
- Medsafe can recommend removal of the medicine from the market in circumstances where there is clear evidence that there is a direct risk to the safety of New Zealanders.

Appendix 5 – New Zealand's vaccine adverse event monitoring system and vaccine adverse event reports (2005 to 2009)

Reproduced from information provided to the Health Select Committee on 27 July 2010.

Question
The Health Select Committee has asked about adverse events in association with vaccines, their classification in terms of severity and limitations on the data.

Response – Executive Summary

This document provides information on adverse events following immunisation reported to the Centre for Adverse Reactions Monitoring (CARM) for scheduled vaccines over the past five years (spontaneous reports). It also provides a summary of the reporting process and sets out how vaccine safety is monitored in New Zealand.

Information from spontaneous reports needs to be interpreted with caution. An adverse event reported after someone has an immunisation does not automatically mean the vaccine is responsible.

Between 1 January 2005 and 31 December 2009, 4,757 reports of adverse events following immunisation were submitted to the Centre for Adverse Reactions Monitoring. Data published by the World Health Organization shows that New Zealand has the highest spontaneous reporting rate per capita in the world.

The vast majority of reports describe known and expected reactions such as injection site pain, swelling, redness and itching or raised temperature, headache and general malaise. Expected reactions such as these are estimated from clinical trial information to occur at a rate of between 2 to 10 percent of people immunised.

A small number of reports describe rare or unexpected events. A number of reports describe events considered serious according to internationally defined criteria. Of the 4,757 reports, 174 (3.6%) meet the criteria of a serious report. Included in the 174 reports are four reports of death: one of these deaths is before the Coroner; the second has been before the Coroner although the Centre of Adverse Reactions Monitoring has not received a copy of the findings or any correspondence from the Coroner; the third was attributed by the Coroner to sudden infant death syndrome; the fourth occurred in an elderly patient with a history of heart disease.

There are limitations on what can be interpreted from this data. Further clinical details, investigation and research may be required before events can be considered as having been caused by the vaccine.

The purpose of having a catch-all system where health professionals, parents and anyone who has been immunised can report any adverse event following immunisation is to ensure that any potential warning signals are picked up, assessed and acted on if necessary. The nature of the system means that false signals will be detected.

In most cases, adverse events resolve or are subsequently found to be unrelated to the vaccine Continued analysis of spontaneous reports by Medsafe and the Centre for Adverse Reactions Monitoring does not show any new potential safety signals that are not already outlined in the vaccine data sheets. The balance of benefits and risks for each vaccine remains positive.

Introduction

All medicines and vaccines have risks and benefits.

Before a medicine or vaccine is approved for use it must be tested in clinical trials to determine its effectiveness. Information about potential risks is known from the clinical trial data and assessed before the medicine or vaccine is approved for use.

Known information about each medicine and vaccine is published for health professionals in a data sheet, available on the Medsafe website. Consumer Medicine Information is usually also published.

As the use of a medicine or vaccine increases, more information becomes available on its safety profile. Some adverse reactions are rare and may not be seen until a very large number of people have received the medicine or vaccine. This is one of the reasons why it is important to monitor all medicines and vaccines after they have been approved.

Most countries have a safety monitoring system which includes a voluntary spontaneous reporting scheme to help identify any possible safety concerns. In New Zealand, Medsafe is the medicines regulator responsible for monitoring available information to ensure that approved vaccines remain acceptably safe for use in New Zealand. Vaccine safety is never reviewed in isolation from the expected benefits of the vaccine, but in terms of the benefit risk balance.

In addition, the World Health Organization plays an important role in terms of vaccine safety through its Strategic Advisory Group of Experts on Immunisation and Global Advisory Committee on Vaccine Safety.

Spontaneous reporting

Two terms are used to describe spontaneous reports. Adverse events are undesirable events experienced by a person which may or may not be causally associated with the vaccine. Adverse reactions are undesirable effects from medicines or vaccines, i.e. they are causally associated.

Spontaneous reports are case reports of adverse events that people have experienced while or after taking a medicine or having a vaccine. Medsafe contracts the collection, review and analysis of this information to the New Zealand Pharmacovigilance Centre at the University of Otago in Dunedin.

Healthcare professionals and consumers are encouraged to report adverse events following immunisation to the Centre for Adverse Reactions Monitoring (CARM), which is part of the New Zealand Pharmacovigilance Centre. Pharmaceutical companies also submit adverse event reports.

Data published by the World Health Organization shows that New Zealand has the highest spontaneous reporting rate per capita in the world. It has been estimated that in general only around ten percent of all adverse reactions are reported.

However, it is not necessary for all adverse reactions to be reported for a potential safety signal to be spotted.

What does Medsafe do with this information?

Medsafe and the Centre for Adverse Reactions Monitoring analyse spontaneous reports in conjunction with other information to determine if there are any new potential safety signals. Medsafe seeks the advice of independent experts, through the Medicines Adverse Reactions Committee, or may form working groups of experts to provide advice. Medsafe works closely with other regulatory authorities from around the world.

Medsafe undertakes a risk-benefit assessment on safety signals to decide if action is required. Further information on risk-benefit assessment is provided on the Medsafe website http://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp

Most safety signals are not supported by any additional information and no action is taken, although Medsafe may continue to closely monitor the issue. A small number of possible safety signals are confirmed as real. In these cases Medsafe has a number of regulatory actions it can take, including withdrawing the product.

Advantages and limitations of spontaneous reports

Spontaneous reports have been shown to be a very simple way of finding potential or possible safety signals with medicines and over 90 countries have a spontaneous reporting system. They can be used to monitor the safety of medicines in real life use over the lifetime of the medicine and for all types of people.

The limitations of using spontaneous reports include under-reporting, a lack of reliable information on the extent of use of the medicine and wide variations in the clinical details provided about the event and the history of the patient. Spontaneous reports are heavily subject to reporting bias such as media or other attention on an issue. They are also not very effective at detecting adverse reactions that occur a long time after starting the medicine. For this reason these reports are only used to identify safety signals. These signals require further formal epidemiological study before they can be validated or discounted.

Information obtained from spontaneous reports needs to be interpreted with caution.

Understanding vaccine safety and spontaneous reporting

Spontaneous report patterns can be variable and depend on many factors. Summaries of reported events following immunisation are not lists of known or proven adverse reactions to vaccines, cannot be used to determine the frequency of adverse reactions to vaccines in the whole population, and cannot be used to directly compare the relative safety of vaccines. They must not be interpreted and used as such.

Healthcare professionals and consumers are encouraged to report any *suspicions* that an event they have experienced may have been caused by vaccination. Therefore reports sent to CARM may be:

- real adverse reactions to the vaccine
- anxiety or nervousness about needles or the process of vaccination
- coincidental events that would have occurred anyway

With any vaccine various types of adverse events are expected to be reported.

- Injection site reactions.
- Well recognised reactions such as headaches, dizziness, muscle aches, mild fever and tiredness.
- Mild allergic reactions such as mild rashes and itching.
- Rare but serious allergic reactions called anaphylaxis. This can occur in response to any medicine or vaccine and some foods. Healthcare professionals giving vaccines are trained to spot the symptoms of serious allergic reactions and promptly treat them.
- Events due to anxiety such as fear or anticipation of the needle injection, such as fainting.
- Coincidental medical conditions.
- New adverse reactions i.e. those not already listed in the prescribing information (data sheet).

In New Zealand it is less likely that any new rare side effects to vaccines will be detected as the number of people immunised is usually small compared to the numbers immunised in other countries. Therefore Medsafe uses international data available from the World Health Organization, other regulators and pharmaceutical companies to help assess any reports of rare events following immunisation and to determine if they may be new events linked to immunisation.

There will always be a number of coincidental events reported because vaccines are given to large sections of the population. In some cases vaccines are specifically targeted to people with underlying medical conditions, such as the influenza vaccine. The challenge is to be able to distinguish these coincidental “background” events from those that may have been caused by the vaccine.

The time between immunisation and an event can be important in determining whether the event was coincidental; most reactions to vaccines occur within a very short time frame of immunisation, usually within days. In some circumstances a longer timeframe between immunisation and reaction onset has been considered where there is a scientific basis to support it.[27]

[27] Systemic reactions usually occur within 2 weeks – the longer time frame is to include any possible autoimmune reactions – onset time for these is around 6 weeks. Studies looking at the link between influenza vaccines and Guillain-Barré syndrome used a time period of 8 weeks based on the following ref: Stratton K, Alamario DA, Wizemann T McCormick MCl eds: Immunization safety review committee board on health promotion and disease prevention. Immunization safety review: Influenza vaccines and neurological complications. Washington DC: National Acadamies Press 2004.

Another method is to compare the number of reports for a specific event with the expected background rate for that event. When doing this it is important to ensure that definite diagnoses of the events reported were made and to adjust the background rate for any differences in population groups and seasonal variations.[28] Table 14 shows the number of coincident events that might be expected as background rate events within one day, one week and six weeks after receipt of a hypothetical vaccine[29].

Table 14: Predicted numbers of coincident, temporally associated events after a single does of a hypothetical vaccine, based upon background incidence rates

	Number of coincident events since a vaccine dose per 10 million people			Baseline rate used for estimate
	Within 1 day	Within 7 days	Within 6 weeks	
Guillian-Barré syndrome (per 10 million people)	0.51	3.58	21.50	1.87 per 100,000 person-years (all ages; UK Health Protection Agency data)
Optic neuritis (per 10 million females)	2.05	14.40	86.30	7.5 per 100,000 person-years in US females
Spontaneous abortions (per 1 million pregnant women)	397	2780	16684	Based on data from the UK (12% of pregnancies)
Sudden death within 1h of onset of any symptoms (per 10 million people)	0.14	0.98	5.75	Based upon UK background rate of 0.5 per 100,000 person-years

Source: Black S, Eskala J et al. *Importance of background rates of disease in assessment of vaccine safety during mass immunisation with pandemic H1N1 influenza vaccines*. The Lancet 2009; 374:2115-22

Summary of spontaneous reports in New Zealand

A summary of spontaneous reports associated with vaccines in the National Immunisation Schedule for the past five years follows (table 15).

This five-year time period was chosen to reflect the current safety status since the safety of vaccines has improved over time and the scheduled vaccines change regularly. Data for vaccines which are no longer used is not included.

Overall, between 1 January 2005 and 31 December 2009 more than 1.9 million doses of scheduled vaccines are recorded on the National Immunisation Register. The doses administered are undercounted because not all vaccines given are recorded on the register. For example, seasonal influenza immunisation is not recorded on the National Immunisation Register and in the 2010 season over 1 million doses have been distributed. For childhood immunisations, the register only captures information on the children who were born after the register was started. People can also choose not to have their immunisations recorded on the register.

[28] An example of the application of this approach in NZ vaccine monitoring was utilised at the time of the monitoring of the MeNZB vaccine and a condition known as Henoch-Schönlein Purpura - Sexton, K., et al., *Henoch-Schonlein purpura and meningococcal B vaccination.* Arch Dis Child, 2009. **94**(3): p. 224-6.

[29] Black S, Eskala J et al., *Importance of background rates of disease in assessment of vaccine safety during mass immunisation with pandemic H1N1 influenza vaccines*. The Lancet 2009; 374:2115-22

Between 1 January 2005 and 31 December 2009, the Centre for Adverse Reactions Monitoring received 4,757 reports of adverse events following immunisation of which 174 (3.6%) were considered to be serious, as set out in table 15.

More than one vaccine may be given at the same time. Therefore some reports appear more than once in table 15.

The numbers of reports and the number of events described within those reports may change over time due ongoing quality control by the Centre for Adverse Reactions Monitoring such as the identification of duplicate reports or the provision of follow up information resulting in the addition, removal or change to the events reported.

Table 15: Overview of reports of events following immunisation reported to the Centre for Adverse Reactions Monitoring between 2005 and 2009 for scheduled vaccines

Vaccine	**Trade name(s)**	**Reports – not serious**	**Reports – serious***	**Total Number of reports**
Adult tetanus-diphtheria vaccine	ADT booster	284	5	289
Diphtheria-tetanus-pertussis vaccine	Boostrix	33	2	35
Diphtheria-tetanus-pertussis-polio-hepatitis B-*Haemophilus influenzae* type b vaccine	Infanrix hexa	215	25	240
Diphtheria-tetanus-pertussis-polio vaccine	Infanrix IPV	2114	73	2187
Haemophilus influenzae type b vaccine	Hiberix	195	10	205
Human papillomavirus vaccine	Gardasil	226	10	236
Measles-mumps-rubella vaccine	MMR II	663	25	688
Pneumococcal conjugate vaccine	Prevenar	228	26	254
Influenza vaccines	Influvac, Vaxigrip, Fluvax	589	34	623
TOTAL*		**4547**	**174***	**4757**

* The total number of reports classified as serious is not the sum of the numbers in the table because in some reports more than one vaccine was given.

Non-Serious Reports

The most commonly reported reactions associated with vaccines given to infants and children were*:*

- injection site inflammation, pain, redness and itching
- vomiting
- headache
- fever
- irritability

The vast majority of reports were non-serious.

The most commonly reported reactions associated with vaccines given to adolescents and adults (ADT, Gardasil and Influenza) were:

- injection site inflammation, pain, redness and itching
- arm pain
- fever
- vomiting
- dizziness, fainting

With Gardasil, due to the age group being immunised, a small number of pregnancies have occurred either before immunisation or shortly afterwards. These cases are recorded as drug exposure during pregnancy to enable the pregnancy to be followed up but this does not mean that any ill effects are expected. To date, there has been no evidence here or overseas that there are any adverse effects on either mother or baby as a result of immunisation.

Seriousness of adverse events following immunisation

International convention defines the seriousness of reports based on the outcome or nature of the reported event as documented in the report irrespective of whether there is any association to the medicine or vaccine.

CARM consider a report to be serious based on the international criteria:

- hospitalisation (or prolonged hospitalisation) of the patient
- life threatening event
- persisting disability of the patient
- intervention required to prevent permanent impairment
- congenital anomaly
- death of the patient.

Since a report is defined as serious based on what is reported about a patient, it is possible to have both serious and non-serious reports describing the same event term.

Table 16: Overview of reports classified as serious irrespective of association to the vaccine

Vaccine trade name(s)	Hospitalisation	Life threatening event	Persisting disability	Intervention Required	Congenital anomaly	Death
ADT booster	1	1	3			
Boostrix	2					
Infanrix hexa	22	1				2
Infanrix IPV	67	1	1	4		
Hiberix	7		2	1		
Gardasil	3	1	4	1		1
MMR II	16	3	2	3	1	
Prevenar	22	1	1			2
Influvac, Vaxigrip, Fluvax	18	4	8	3		1
Total*	**132**	**10**	**18**	**9**	**1**	**4**

* The total number of reports classified as serious is not a summation of the numbers in the table as some reports relate to more than one vaccine i.e more than one vaccine was given.

Hospitalisations

In 132 reports the patient was admitted to hospital for observation or treatment for the following categories of events:

- fever (32.5%)
- hypotonic hypotensive episodes (12.9%)
- allergic reactions (10.6%)
- neurological symptoms (8.3%)
- injection site reactions (7.6%)
- convulsions (7.6%)
- febrile convulsions (6.1%)
- gastrointestinal symptoms (3.8%)
- vasovagal (fainting) (3.0%)
- other (8.3%).

Hypotonic hypotensive episodes (HHE) – 12.9% of hospitalisation reports describe an infant experiencing an HHE episode, which is a collapse or shock-like state which occurs within 48 hours of immunisation. No long term effects have been found in infants who have had one of these events. Information on this possible adverse reaction was published by Medsafe in Prescriber Update in July 1998 and is attached on page 86.

Convulsion – the number of reports of convulsions (fits) is well below the expected background rate for convulsions which is estimated at 70 cases per 100,000 people per year.[30] These reports did not raise any safety concerns.

Fever or febrile convulsions are expected in a small proportion of children experiencing fever following immunisation or due to infection. No long term effects are expected in infants who have experienced febrile convulsions.

[30] Black et al 2009 'Importance of background rates of disease in assessment of vaccine safety during mass immunisation with pandemic H1N1 influenza vacines' the Lancet 374: 5115-2122

Life threatening event

The 10 life threatening reports all describe acute onset allergic-type events including three of anaphylaxis and two of cardiac events. The latter two reports were in elderly patients following influenza vaccination.

There is a risk of serious allergic reactions with all medicines, vaccines and some foods. With vaccines, the risk of anaphylaxis is estimated to be around 1 – 3 reactions per one million doses administered. All vaccinators are trained and equipped to treat anaphylaxis if it does occur – this is the main reason people are asked to wait for 15 – 20 minutes following any immunisation and why there are at least two health professionals on site.

Persisting Disability

The 18 reports of persisting disability refer to clinical events that had been present for variable periods of time and were still persisting at the time of reporting. In most cases as further information becomes available other causes of the events are discovered, the patient recovers or is lost to follow-up and the report is never resolved.

- Two reports of injection site pain and one of brachial neuritis, which is inflammation of the nerves in the arm.
- Three reports of diverse generalised symptoms such as headaches, muscle and joint pains, fever symptoms and fatigue.
- One report of alopecia (hair loss) three months after immunisation in a patient taking other medicines.
- One report of persisting constipation and diarrhoea.
- One report of deafness, rash and a fever – the infant had also received cotrimoxazole antibiotic therapy.
- Three reports of transverse myelitis, which is a neurological disorder caused by an inflammation of the nerves. In two of the cases follow-up information reported that other causes had been identified.
- One report describes an ophthalmologic disorder. Follow-up information reported that the event was likely to be due to another cause.
- One report was of persisting injection site reaction.
- One report of persistence of symptoms including a hearing disorder.
- One report of Bells Palsy, which is a paralysis of the face, occurring within one day of immunisation. Bells Palsy is usually considered to be due to a viral infection and the onset of symptoms takes longer than 24 hours.
- One report of Motor Neurone Disorder – this report was still under active investigation by the reporter at the time of reporting.
- Subsequent information showed that two reports were miscoded. One related to a case of hives and the other was a report of fatigue in a patient with a history of chronic fatigue syndrome.

Intervention Required

There are 9 reports of a medical intervention being required.

- Two reports describe injection site abscesses that required draining.
- Five reports were for allergic reactions that required medical management or intervention.
- One report was for a febrile convulsion in which the parents administered supportive intervention.
- One report of a lung abscess of unknown origin that required draining.

Congenital anomaly

There is one report of an early (first trimester) termination of pregnancy in a woman who had received the MMR vaccine as an adult before her pregnancy status was established. This case does not describe an actual congenital anomaly but rather an event which placed the foetus at increased risk of injury due to the administration of a live vaccine during a crucial period of foetal development.

Deaths

There are four reports of death occurring some time following immunisation. This does not mean the vaccine caused the death.

Two deaths of infants were reported; in both cases the infants had been immunised with Infanrix-IPV and Prevenar vaccines. In the first case the Coroner determined that the cause of death was Sudden Infant Death Syndrome (SIDS). The second case has been before the Coroner although the Centre of Adverse Reactions Monitoring has not received a copy of the findings or any correspondence from the Coroner. The peak age for SIDS lies within the 6 week to 5 month range of the first series of childhood immunisations and it is expected that coincidental events will be reported with immunisation. Published evidence suggests that vaccination reduces the risk of SIDS[31,32]. Based on current information neither of these cases have raised any safety concerns with the Infanrix-Hexa and Prevenar vaccines.

There was one report of sudden death six months after immunisation with Gardasil vaccine. The cause of death has not been determined and this case is being reviewed by the Coroner.

There was also a death of an elderly patient following seasonal flu vaccination. The patient had a history of heart disease. It was unclear from the report if the patient experienced a serious allergic reaction or a cardiac arrest. There is no evidence in medical literature supporting an association between immunisation and death in the elderly.

[31] Venneman MMT, Butterfass-Bahloul T, Jorch G et al 2007 'Sudden Infant Death Syndrome: No increased risk after immunisation' Vaccine 25: 336-340.
[32] Venneman MMT, Hoeffgen M, Bajanowski T et al 2007 'Do immunisations reduce the risk for SIDS? A meta-analysis' Vaccine 25: 4875-4879.

Prescriber Update Articles

Hypotonic-Hyporesponsive Episodes to Immunisation
Website: July 1998
Prescriber Update No.16:34-36

Dr Osman Mansoor
Public Health Physician
Public Health Group, Ministry of Health

Dr David Coulter
Acting Medical Assessor
Centre for Adverse Reactions Monitoring (CARM), Dunedin

Hypotonic-hyporesponsive episodes (HHE) are recognised serious reactions to immunisation, especially pertussis-containing vaccine. Management involves checking the airway, breathing and circulation, then hospitalisation as a precaution. In reported cases, full recovery has occurred and there has been no long term sequelae. The paediatrician who assesses the child should also advise on the completion of the immunisation programme.

Since 1992, CARM has received 32 reports of children experiencing hypotonic-hyporesponsive episodes (HHE) following immunisation, all from pertussis-containing vaccines. The WHO database has over 600 reports of HHE, the majority following immunisation of pertussis-containing vaccines.

Serious effects but no long term sequelae reported

HHE is defined as an acute diminution in sensory awareness or loss of consciousness accompanied by pallor and muscle hypotonicity.[1] Variously described as shock, collapse or HHE, onset is within 12 hours after immunisation. Most children are initially irritable and febrile, then become pale, limp and unresponsive or hyporesponsive. Respiration is shallow and cyanosis frequently occurs. The duration of an episode varies from a few minutes to 36 hours.

The initial response should be as in any case of shock (airway, breathing, circulation). Careful clinical observation and documentation of the event are vital for differential diagnosis. Urgent hospital referral is advised for paediatric assessment and to exclude other causes.

A return to normal after the reaction has been reported in all published cases.[1] No long term sequelae have been identified in the small number of children who have had long term follow-up.[2]

HHE not a contraindication for further doses of pertussis vaccine
The *Immunisation Handbook* (pages 67 and 70) advises that HHE is no longer a contraindication to further doses of pertussis vaccine. The benefit/risk ratio should, however, be carefully considered for each child.

Paediatrician to advise on future immunisation options
The paediatrician who sees the child should also advise about future doses of pertussis and other vaccines. The options include:

- continue with normal immunisations, but give the next dose under supervision (e.g. in a day hospital);.
- omit pertussis in future (i.e. use DT plus Hib instead of DTPH). Note that although pertussis is most associated with this reaction, it has been reported with other vaccines including DT[3] and DTaP[4]; or
- use acellular pertussis vaccine (DTaP is available but not funded; DTaPH is not yet available in New Zealand) - limited data suggest a lower rate of HHE with acellular vaccine.[5]

A recently published Dutch study described 101 children who experienced HHE following immunisation, of whom 84 subsequently received further doses of pertussis vaccine.[6] None experienced a recurrence or other adverse event. One of the 17 children who did not continue with normal immunisation experienced severe pertussis.

Wide variation in incidence
Different studies have found an incidence of HHE following immunisation with DTP or its pertussis component varying between 3.5 and 291 per 100,000 injections.[1] This wide variation probably reflects the lack of an ideal case definition and difficult case recognition, as well as different vaccine formulations. The highest rate of 291 per 100,000 was found with plain DTP vaccine as opposed to a rate of 99 per 100,000 for adsorbed vaccines (the type used in New Zealand since 1971).[1] The largest study found a rate of 57 per 100,000,[7] and this is the rate quoted in the *Immunisation Choices* booklet and the *Immunisation Handbook*.

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3. Pollock TM, Miller E, Mortimer JY, Smith G. Symptoms after primary immunisation with DTP and DT vaccine. *Lancet* 1984;2:146-9.
4. Blumberg DA, Mink CM, Cherry JD, et al. Comparison of acellular and whole-cell pertussis component diphtheria-tetanus-pertussis vaccines in infants. *J Pediatr* 1991;119:194-204.
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Appendix 6 – Immunisation concerns – refuting links to chronic diseases or conditions

The following has been extracted from information provided to the Health Select Committee on 4 June 2010.

Chapter 20 of the *Immunisation Handbook* addresses concerns about immunisation. The *Immunisation Handbook* was provided to the Health Select Committee as a PDF document with the initial Ministry briefing documents.

The Immunisation Advisory Centre supplied much of the following information.

Autism
MMR is a combination vaccine offering protection against measles, mumps and rubella. In New Zealand it is given to children at 15 months and 4 years of age. A link between this vaccine and development of bowel inflammation and autism was proposed by some researchers in 1998. There have been many very large population studies since, comparing immunised with unimmunised children and they have all consistently found that the rates of neurological and behavioural conditions are the same regardless of immunisation status.

The possibility of an association between MMR and autism was suggested primarily by a group of researchers in the United Kingdom led by Dr Andrew Wakefield. In 1998 The Lancet medical journal published a small case series of 12 children who suffered from gastrointestinal and behavioural problems. It reported that parents of 8 of the 12 children recall the onset of their child's health problems as occurring following receipt of the MMR vaccine. There was intense media coverage of this study and the author stated in media interviews that he believed that the MMR vaccine was responsible.

The paper was retracted by 10 of the original 13 authors in 2004 and has now (2010) been fully removed from the journal records. Among many shortcomings of the study were major ethical problems as well as a serious conflict of interest of the first author who received a large amount of money from personal injury lawyers acting on behalf of the parents of the children in the study.

Three studies suggested an association between MMR vaccine and the development of autism including Wakefield's Lancet paper mentioned above. All have serious shortcomings and the findings have not been able to be replicated by other investigators.

Studies claiming an association between MMR vaccine and autism:

1. Wakefield AJ, Pittilo RM, Sim R, Cosby SL, Stephenson JR, A.P. D, et al. Evidence of persistent measles virus infection in Crohn's disease. Journal of Medical Virology. 1993;39(4):345-53.

Electron microscopy specimens from Crohn's disease and control patients. The validity has been questioned as the results have not been able to be reproduced by other researchers.

2. Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. Lancet 1998;351:637-41. RETRACTED 2004.
   Study of 12 children with chronic entercolitis and regressive developmental disorder. There have since been several articles on the limitations of this study.
3. Uhlmann V, Martin CM, Sheils O, et al. Potential viral pathogenic mechanism for new variant inflammatory bowel disease. Molecular Pathology 2002;55:84-90.
   91 patients with a gastrointestinal disorder and 70 control subjects.

There have been over 20 major studies whose findings refute the claim that MMR causes autism. Most are large population or cohort studies, some with over a million children. Summaries of a few are below. A range of references follow.

- In 1999, a large population-based study in England looked at the vaccination status of 498 children with autism and control subjects without autism and found no link between the timing of vaccination with MMR and the onset of autism.
- In 2004 another English study looked at the rates of autism in 5,500 children who attended general practice and were immunised with MMR, and found no evidence to suggest a link between the vaccine and autism.
- A study of more than 440,000 Danish children vaccinated in the 1990s compared with 96,000 unvaccinated children provided strong evidence against the hypothesis that MMR causes autism or autistic spectrum disorder.
- A large study in Finland followed almost 600,000 children for 20 years after MMR vaccination and found no evidence for MMR vaccine-associated autism or other neurological disorders.
- A study of the rates of irritable bowel disorder and autism among 6100 French school-aged children found no association between MMR and these diseases.
- A study in Sweden in 1998 looking at the prevalence of autism over 10 years found no change after the introduction of MMR vaccine.
- Two independent groups of researchers in the UK performed epidemiologic studies to determine if there was an association between bowel symptoms /autism, and MMR. Both studies found no evidence for gastrointestinal problems being linked to developmental regression or to MMR vaccination.
- Additional studies in the US and UK found no correlation between trends in early childhood MMR immunisation rates and trends in autism diagnosis. For example, a study done in California, showed that although rates of autism have gone up by 373% over 15 years, the increase in the number of children immunised with MMR has only increased by 14% in that time.
- A study in the United States looked at patients with irritable bowel disorder born over a 32 year period, found that vaccination with MMR or other measles-

containing vaccines, or the timing of vaccination early in life, did not increase the risk for irritable bowel disorder.

- At least 3 laboratory-based studies by different research groups using technical methods similar to those in the Uhlmann study, found no evidence of measles virus in the bowel specimens of patients with irritable bowel disorder.

The following papers refute the association between MMR and autism.

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3. Offit PA, Coffin SE. Communicating Science to the Public: MMR Vaccine and Autism. Vaccine, December 8, 2003, Vol. 22(1):1-6. http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6TD4-497H3XH-1&_user=140507&_coverDate=12%2F08%2F2003&_rdoc=1&_fmt=high&_orig=search&_sort=d&_docanchor=&view=c&_acct=C000011498&_version=1&_urlVersion=0&_userid=140507&md5=85bbf2ab8dd88e0784e0571924afeb4e
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6. Taylor B, Miller E, Lingam R, et al. Measles, mumps, and rubella vaccination and bowel problems or developmental regression in children with autism: population study. British Medical Journal 2002; 324:393-6. http://www.bmj.com/cgi/content/full/324/7334/393?view=long&pmid=11850369
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trend analysis. British Medical Journal 2001;322:460-3.
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http://www.ncbi.nlm.nih.gov/pubmed/19108524

Diabetes
The theory that vaccination is associated with the onset of Type 1 diabetes has been rejected. There is a temporal association between the mass administration of childhood vaccines and onset of diabetes and it is well established that some infections can increase the risk of diabetes. There are two vaccines in particular that have been implicated by some people as causing diabetes.

For an address of issues raised by Classen and Classen about NZ data see: Petousis-Harris H, Turner N. Hepatitis B vaccination and diabetes [letter]. New Zealand Medical Journal 1999;112(1093):303-4.

In 2002 the American Institute of Medicine reviewed immunisation and the potential for immune dysfunction:

The Immunization Safety Review committee reviewed the evidence regarding the hypothesis that multiple immunizations increase the risk for immune dysfunction, with a focus on evidence related to risk for infections, the autoimmune disease type I diabetes, and allergic disorders.

The committee found that evidence favours rejection of a causal relationship between multiple immunizations and increased risk for infections and for type I diabetes. They also found that epidemiological evidence regarding risk for allergic disease, particularly asthma, was inadequate to accept or reject a causal relationship. The committee recommended continued attention in the form of policy analysis, research, and communication strategy development to inform those concerned about these issues and to encourage parents to vaccinate their children.

http://www.iom.edu/Reports/2002/Immunization-Safety-Review-Multiple-Immunizations-and-Immune-Dysfunction.aspx

Additionally there have since been cohort studies including:
1. Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. Childhood Vaccination and Type 1 Diabetes. N Engl J Med 2004 April 1, 2004;350(14):1398-404.
2. Hviid A, Wohlfahrt J, Stellfeld M, Melbye M. Childhood vaccination and nontargeted infectious disease hospitalization.699-705, 2005 Aug 10. http://content.nejm.org/cgi/reprint/350/14/1398.pdf

Cancer
In 2002, the Institute of Medicine produced “Immunization Safety Review: SV40 contamination of polio vaccine and cancer”. The following summarises this report.
“Some of the polio vaccine administered from 1955-1963 was contaminated with a virus, called simian virus 40 (SV40). The virus came from the monkey kidney cell cultures used to produce the vaccine. Most, but not all, of the contamination was in the inactivated polio vaccine (IPV). Once the contamination was recognized, steps were taken to eliminate it from future vaccines. Researchers have long wondered about the effects of the contaminated vaccine on people who received it. Although

SV40 has biological properties consistent with a cancer-causing virus, it has not been conclusively established whether it might have caused cancer in humans. Studies of groups of people who received polio vaccine during 1955-1963 provide evidence of no increased cancer risk.

However, because these epidemiologic studies are sufficiently flawed, the committee concluded in this report that the evidence was inadequate to conclude whether or not the contaminated polio vaccine caused cancer. In light of the biological evidence supporting the theory that SV40-contamination of polio vaccines could contribute to human cancers, the committee recommends continued public health attention in the form of policy analysis, communication, and targeted biological research."

http://www.iom.edu/Reports/2002/Immunization-Safety-Review-SV40-Contamination-of-Polio-Vaccine-and-Cancer.aspx

During the past 50 years there have been significant advances in vaccine development and regulation and this type of viral contamination of vaccines is unlikely to occur again. In 1983 a report was commissioned by the Minister of Health to investigate the safety of poliomyelitis vaccines. The report found no evidence showing any increase in the relevant conditions which could be ascribed to the vaccine and even suggested that what evidence there is, is negative. (New Zealand Special Committee to Investigate the Safety of Poliomyelitis Vaccines, *Report to the Minister of health of the Special Committee to Investigate the Safety of Poliomyelitis Vaccines.* 1983, Ministry of Health: Wellington.)

Sudden Infant Death Syndrome (SIDS)

There have been claims that vaccines cause sudden infant death. However, there are many studies showing that vaccines do not cause sudden infant death; some show an inverse association. A 2007 meta-analysis found that immunisations are associated with a halving of the risk of SIDS.

Vennemann MM, Hoffgen M, Bajanowski T, Hense HW, Mitchell EA. Do immunisations reduce the risk for SIDS? A meta-analysis. Vaccine 2007 21;25(26):4875-9.
http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6TD4-4N8K597-3&_user=140507&_coverDate=06%2F21%2F2007&_rdoc=1&_fmt=high&_orig=search&_sort=d&_docanchor=&view=c&_searchStrId=1303440308&_rerunOrigin=google&_acct=C000011498&_version=1&_urlVersion=0&_userid=140507&md5=ab00d4a7953ee5376a0dd44bff0e12f4

For the review by the Institute of Medicine on vaccinations and sudden unexpected death in infancy:
http://www.iom.edu/Reports/2003/Immunization-Safety-Review-Vaccinations-and-Sudden-Unexpected-Death-in-Infancy.aspx

Allergic Diseases

There is no association between vaccination and increased risk for allergic diseases. If any association is present it appears to be inverse with a slight protective effect offered by vaccination.

1. Immunization Safety Review: Multiple Immunizations and Immune Dysfunction 2002
http://www.iom.edu/Reports/2002/Immunization-Safety-Review-Multiple-Immunizations-and-Immune-Dysfunction.aspx
2. Maitra A, Sherriff A, Griffiths M, Henderson J, Parents ALSo, Team CaS. Pertussis Vaccination in Infancy and Asthma or Allergy in later Childhood: Birth Cohort Study. British Medical Journal 2004 17 April 2004;328:925-6.
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http://pediatrics.aappublications.org/cgi/content/full/119/2/e367
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http://www3.interscience.wiley.com/journal/120174161/abstract
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http://pediatrics.aappublications.org/cgi/content/abstract/123/3/944Vaccine

Encephalitis following vaccination

A 2006 study of more than 2 million children found diphtheria-tetanus-pertussis and measles-mumps-rubella vaccines do not increase the risk of encephalopathy.

Ray Paula, Hayward Jean, Michelson David, Lewis Edwin, Schwalbe Joan, Black Steve, et al. Encephalopathy After Whole-Cell Pertussis or Measles Vaccination: Lack of Evidence for a Causal Association in a Retrospective Case-Control Study. Pediatric Infectious Disease Journal 2006;25(9):768-73.
http://www.ncbi.nlm.nih.gov/pubmed/16940831

Appendix 7 – The process for reviewing and changing the National Immunisation Schedule

The following has been extracted from information provided to the Health Select Committee on 4 June 2010.

The Schedule of publicly funded vaccines (National Immunisation Schedule) is reviewed every three years and may change as new, more effective vaccines become available for control of vaccine preventable diseases.

The Immunisation Technical Forum provides authoritative specialist clinical and technical advice to the Director-General of Health on vaccines and the government's immunisation programme (including vaccine effectiveness, safety and vaccine preventable disease control). The Forum includes expertise in paediatrics, delivery of immunisation services, microbiology, and infectious diseases. Any conflicts of interest are declared at meetings, so that if there are conflicts these can be managed.

The Ministry of Health considers the Forum's technical advice, together with available economic information. The Ministry then prioritises vaccines for funding.

Any amendment or replacement to the Schedule must have the Minister's approval, before it is legally valid and can be interpreted as the "National Immunisation Schedule" as defined in regulation 2 of the Health (Immunisation) Regulations 1995.

The outcome of the current review of the National Immunisation Schedule are expected in late 2010.

Appendix 8 - Immunise Australia: Seven Point Plan and similar New Zealand initiatives

The following has been extracted from information provided to the Health Select Committee on 14 April 2010.

Immunise Australia's Seven Point Plan was launched in February 1997 and Australia's immunisation rates have significantly increased since then. The plan consisted of:

- incentives for parents
- incentives for doctors
- monitoring and evaluation of immunisation targets
- immunisation days
- measles eradication
- education and research
- school entry requirements.

The seven-point plan is described in more detail on the following pages, along with similar New Zealand initiatives, where applicable.

1. Incentives for parents (maternity and childcare benefits)	
Description	**New Zealand comment**
A bonus to parents for ensuring that their child's immunisation coverage was up-to-date for age. Now called the Maternity Immunisation Allowance – not income tested. Two payments of AUD$122.75 each – the first amount is paid for children who meet the immunisation requirements between 18 and 24 months of age; the second for children who meet the immunisation requirements between 4 and 5 years of age. Parents can still receive the payment if they do not immunise their child and meet certain exemption requirements.	Not offered in New Zealand.
Childcare rebates – now called the Child Care Benefit – for children who are fully immunised and attend an approved child care centre. Means tested – between 24 to 50 hours can be claimed for at AUD$3.60 per hour or AUD$180 per week.	Not offered in New Zealand. See section 7 'school entry requirements' regarding attendance at childcare centres and vaccination status.

2. A bigger role for General Practitioners	
Description	**New Zealand comment**
Financial incentives for general practitioners who monitor, promote and provide age appropriate immunisation services to children under the age of seven years. This initiative continues, although it has undergone some revisions since its introduction.	The Primary Health Organisation (PHO) Performance Programme offers financial incentives to PHOs who improve their performance on indicators against targets. The programme aims to improve the health of enrolled populations and reduce inequalities in health outcomes through supporting clinical governance and rewarding quality improvement within PHOs. Immunisation is one of the clinical indicators - PHOs have targets for children fully vaccinated by their second birthday and influenza vaccinations in the over 65 population.
	General practitioners are paid $18.80 +GST per immunisation event to cover the cost of storing and administering the vaccine and any pre- or re-call costs incurred (eg for letters and phone calls to the individual or their parent).
Divisions of General Practice also increased their involvement to ensure GPs follow current immunisation protocols and that proper arrangements were in place locally for vaccine storage and for sending data to the Australian Childhood Immunisation Register. Australia's register is manual; providers must complete forms and send them to the register.	No incentives for data entry onto the National Immunisation Register.
	Primary Health Organisation Cold Chain Accreditation was introduced in 2004 – introduction of primary care standards and an accreditation process for maintaining the vaccine cold chain. This included a one-off quality payment to go towards the purchase of a vaccine refrigerator.

3. Monitoring and evaluation of immunisation targets	
Description	**New Zealand comment**
Data on immunisation rates from the Australian Childhood Immunisation Register are published regularly.	Immunisation coverage data from the National Immunisation Register published quarterly by the Ministry of Health – on the Ministry's website and in major newspapers (as part of the Health Target reporting).
4. Immunisation days	
Description	**New Zealand comment**
The Commonwealth, together with the States and Territories piloted a series of immunisation days to increase immunisation rates in geographical areas of low immunisation in 1997.	No national days; there are local responses to outbreaks - eg measles.
5. Measles eradication	
Description	**New Zealand comment**
A one-off school based measles control campaign in 1998 which offered measles-mumps-rubella vaccination to all primary school aged children.	A measles epidemic was predicted for 1997 so a measles-mumps-rubella vaccination campaign was launched for all children aged under 10 years. Measles outbreaks continue in New Zealand, as immunisation coverage is too low to prevent them. Measles-mumps-rubella vaccine is offered to children at 15 months and 4 years of age, and is also free to adults aged under 40 years.

6. Education and research	
Description	**New Zealand comment**
A major community education campaign was conducted in 1997, including television and magazines and a component targeting people from diverse cultural and linguistic backgrounds.	The Ministry of Health produces vaccine and disease information for children, parent and caregivers as DVDs, print and electronic media. The human papillomavirus and influenza immunisation programmes also include television advertising.
Service provider strategy including distribution of a new edition of the *Australian Immunisation Handbook*, a regular column in *Australian Doctor*, a rural satellite broadcast program and a range of resource materials. Service providers continue to receive program information, resources and copies of the new edition of the Handbook as they are developed.	The Ministry produces the *Immunisation Handbook* for providers, containing information about the vaccines on the national immunisation schedule and the diseases they protect against.
	The Ministry funds vaccinator training for providers.
	The Immunisation Advisory Centre, under contract to the Ministry of Health, offers parent and provider information and education (via training courses, an 0800 phone line, web-based and print resources, and immunisation coordination and facilitation services).
The National Centre for Immunisation Research and Surveillance was established in 1997. The Centre coordinates and conducts research and analysis of epidemiological and sociological aspects of immunisation and vaccine preventable diseases and provides policy information and advice to inform future directions for the national childhood immunisation programme.	There is no direct New Zealand equivalent for Australia's National Centre for Immunisation Research and Surveillance. The Immunisation Advisory Centre does immunisation research, along with some universities and hospitals.
	Between December 2002 and December 2008 the Ministry of Health and the Health Research Council entered into a joint venture to fund immunisation research in New Zealand.

7. School entry requirements	
Description	**New Zealand comment**
The Commonwealth worked with State and Territory Governments on uniform school entry requirements to ensure that parents submit details of their children's immunisation history when they enrolled their children for school. Recommendations for model school entry legislation were developed by the Legislation Reform Working Group and endorsed by the National Public Health Partnership. Legislation was passed in New South Wales, Victoria, Tasmania and the Australian Capital Territory.	Immunisation is not mandatory in New Zealand. An unimmunised child cannot be prevented from enrolling at an early childhood facility or primary school, but may be excluded from attending during disease outbreaks. The Immunisation Regulations (1995) state that early childhood education centres and primary schools must see a child's immunisation certificate (completed at 15 months and 4 years of age) either before or promptly after enrolment at the facility and keep a record of the child's immunisation status against vaccine preventable diseases. The immunisation certificate shows which diseases a child has been immunised against.