

Evaluation of the National Rotavirus Immunisation Program FINAL REPORT

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Council immunisation program managers (n=2)

General practitioners (GPs) (n=3)

Practice nurses (PNs) (n=3)

Remote area immunisation providers (n=3)

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Acronyms

ABS	Australian Bureau of Statistics
ACIR	Australian Childhood Immunisation Register
ACSOM	Australian Committee on Safety of Medicines
ADRAC	Australian Drug Reactions Advisory Committee
AEFI	Adverse event following immunisation
AGPN	Australian General Practice Network
AIA	Australian Immunisation Agreements
AIHW	Australian Institute of Health and Welfare
AMS	Aboriginal Medical Service
APSU	Australian Paediatric Surveillance Unit
ARSP	Australian Rotavirus Surveillance Program
ASCOM	Advisory Committee on the Safety of Medicines (Australia)
ATAGI	Australian Technical Advisory Group on Immunisation
CDC	Centres for Disease Control and Prevention (United States)
CHO	Chief Health Officer
CI	Confidence interval
DGP	Division of General Practice
DoHA	Australian Government Department of Health and Ageing
DTP	Diphtheria, tetanus & pertussis vaccine
EIA	Enzyme immunoassay
GACVS	Global Advisory Committee Vaccine Safety
GP	General practitioner
GPII	General Practice Immunisation Incentive
ICD-10-AM	International Statistical Classification of Diseases and Related Health Problems
IRR	Incidence rate ratio
IS	Intussusception
NCCH	National Centre for Classification in Health
NCIRS	National Centre for Immunisation Research and Surveillance

NIC	National Immunisation Committee
NIP	National Immunisation Program
NNDSS	National Notifiable Diseases Surveillance System
PAEDS	Paediatric Active Enhanced Disease Surveillance
PHAA	Public Health Association of Australia
PHU	Public Health Unit
PN	Practice nurse
RACP	Royal Australasian College of Physicians
RFDS	Royal Flying Doctor Service
SBO	State-based Organisation
TGA	Therapeutic Goods Administration
UCI	Understanding childhood immunisation (brochure)
VAERS	Vaccine Adverse Events Reporting System (United States)
VPD	Vaccine preventable disease
WHO	World Health Organization

Executive summary

Background

Rotavirus is a leading cause of hospitalisation in Australia, particularly for those under 5 years of age. The national rotavirus immunisation program commenced in July 2007 with babies born from 1st May 2007 eligible for vaccine. Two different brands of the vaccine (Rotarix[®], GSK and RotaTeq[®] CSL/Merck) were added to the National Immunisation Program (NIP) schedule at the existing 2, 4 and 6 month* schedule points. This program was evaluated by the National Centre for Immunisation Research and Surveillance in 2010.

* RotaTeq[®] only.

Aim

To understand the strengths and weaknesses of program implementation, measure vaccine coverage and adverse events following immunisation (AEFI), and assess the impact of this program on rotavirus disease epidemiology.

Methods

This evaluation was based on the standard NCIRS immunisation program evaluation framework which has been used for previous immunisation program evaluations undertaken by NCIRS. This framework consists of five major components: process evaluation, system description, immunisation coverage, adverse events following immunisation, and disease epidemiology.

Interviews with a sample of key informants who have been involved in program implementation formed the basis of the process evaluation. Immunisation coverage was assessed using data from the Australian Childhood Immunisation Register (ACIR) for two cohorts, children born: 3–9 months and 15–21 months following the commencement of the national rotavirus immunisation program. Adverse events recorded by the Therapeutic Goods Administration January 2006 to December 2009 were used to determine the rates and type of AEFI following rotavirus vaccine, and rates of hospitalisations coded as intussusception were examined to detect any change following rotavirus vaccine introduction. Disease impact was assessed using hospitalisation data for rotavirus and non-rotavirus coded acute gastroenteritis, covering the period from July 2001 to June 2009 with published evidence also included.

Results

Process evaluation

Key informants felt that rotavirus vaccine was successfully integrated into the NIP in Australia, however, they identified a number of strengths and challenges related to the implementation of this program.

There were no reported issues with vaccine supply or management with either brand of vaccine. The two different in brands, which have different schedules, caused confusion among some providers and made program implementation in border regions between jurisdictions using different brands more challenging. The oral administration method was a challenge for some providers: however, education, experience, support from Divisions of General Practice and/or Public Health Units and changes to the presentation of one brand of the vaccine have overcome this. All participants were pleased that there was no catch-up program for rotavirus vaccine, but providers found it challenging to communicate this to parents.

Those responsible for program management at a jurisdictional and local level felt there were delays in the availability of program information and national resources. Providers felt they were well supported to implement the program and that it was relatively easy to put into practice. There was strong stakeholder collaboration reported across all sectors which facilitated the delivery of the program in a short timeframe and concurrently with the national human papillomavirus (HPV) immunisation program.

System description

The surveillance systems available in Australia for the evaluation of immunisation programs provide vital information for measuring outcomes and the impact of the programs on disease burden. However, many of these systems have limitations that either restrict or affect the quality, scope or appropriateness of outputs for program evaluations.

Rotavirus gastroenteritis is notifiable in most but not all jurisdictions but notification criteria vary. The Australian Rotavirus Surveillance Program (ARSP) has provided important strain typing data to inform the formulation of rotavirus vaccines, assess the suitability of the current vaccines and track outbreaks caused by novel serotypes. Rotavirus-related hospitalisation data coded using the ICD-10-AM system is reasonably specific, but misclassification of hospitalisations due to rotavirus by using incorrect or less specific coding is common.

There are a diverse range of approaches to passive surveillance of adverse events following immunisation (AEFI) employed by jurisdictions across Australia. This leads to differences in the quality, accuracy and timeliness of AEFI reports, which needs to be taken into account when interpreting aggregated data. Active surveillance has provided critically important data for monitoring the impact of the national rotavirus immunisation program. An important new initiative of active surveillance for intussusception via the Paediatric Active Enhanced Disease Surveillance (PAEDS) has contributed important data on this AEFI, however, this system is not fully nationally representative, and data from additional jurisdictions would be valuable. Although active surveillance for intussusception is in place, it is often under-reported with limited surveillance data from the vaccine era.

Coverage estimates from the ACIR are consistently high but modestly underestimate of actual levels of coverage (by approximately 3% by a study done in 2001). The under-reporting rate has not been specifically determined for rotavirus vaccine.

Immunisation coverage

Rotavirus vaccine was rapidly and swiftly incorporated into the NIP with coverage recorded by the Australian Childhood Immunisation Register (ACIR) reaching 80% in less than a year. Coverage has been maintained at just below 85% nationally. This is lower than other vaccines given at the same schedule points, likely due to strict upper age limits on the administration of doses. The timeliness of rotavirus vaccination is good, with more than 95% of non-Indigenous children and 90% of Indigenous children receiving the vaccine before the upper age limits. Strict application of the upper age limits appears to have had an impact on improving the timeliness of other vaccines given at the same schedule points by 10% for non-Indigenous and 7% for Indigenous children. Indigenous children have substantially lower coverage than non-Indigenous children for all rotavirus vaccine brands and doses recommended by 12 months of age. This may be related to less timely presentation for vaccination as children get older, which occurs more in Indigenous children than non-Indigenous children as they are most probably more affected by the strict upper age limits. Coverage is higher for Rotarix[®] than RotaTeq[®], possibly due to fewer doses required to complete the schedule. In general, rotavirus vaccine coverage in Australia is high by international standards.

Adverse events following immunisation (AEFI)

The majority of AEFI reports following rotavirus vaccination were of mild, transient events similar to those reported in clinical trials. The overall reporting rate for the 2007–2009 period was 41.6 per 1,000 doses which was comparable to rates observed in Europe. There was a substantial increase in AEFI reported in 2008 partly due to increases usually seen in the first full year after the program commenced as well as the start of enhanced passive surveillance in Victoria. The types of events most commonly reported at national level were vomiting, abdominal pain and diarrhoea. Cases of intussusception were reported to the Therapeutic Goods Administration (TGA) at a rate of 2.8 per 100,000 doses of rotavirus vaccine with the majority (60%) of cases in infants 2–3 months of age after dose 1 of either vaccine. This is similar to the reporting rate observed in the United States. At the national level, hospitalisations coded as intussusception increased slightly in the first two years following rotavirus vaccine introduction compared to the pre-vaccine period both overall (aged <24 months; IRR 1.6, 95% CI 1.07-1.26) and in the younger age group (1-<3 months; IRR 2.15, 95% CI 1.55-2.91). The increase was significant in infants aged 1 to <3 months (IRR 2.15, 95% CI 1.55-2.91), but not in the other age groups. This finding should be interpreted with caution, but is consistent with more rigorous studies showing that there is a possible elevated risk following the first dose of both of the rotavirus vaccines. However, there was no evidence for any excess risk following dose 2 of either vaccine, and a lower than expected number of cases following dose 3 of

RotaTeq[®]. On the basis of these findings, the TGA commissioned a study using ICD-coded hospitalisations for IS (non chart-reviewed) from NSW (Rotarix[®]) and Victoria (RotaTeq[®]) which found a similar risk of IS post dose 1 for both vaccines.

Disease epidemiology

The most recent hospitalisation data from states and territories (to mid-2009) was utilised for the analyses. Hospitalisations coded both as rotavirus and as all-cause acute gastroenteritis (excluding rotavirus) have been included in these analyses. The rationale for this was the known lack of sensitivity of rotavirus-specific coded hospitalisations, reported differences in coding and or testing practices, and the lack of national notifications and up-to-date mortality data. As rotavirus gastroenteritis is not a nationally notifiable disease, it has also been difficult to estimate vaccine effectiveness from a national perspective.

Since the introduction of the national rotavirus immunisation program, there have been marked declines in hospitalisations for rotavirus coded and non-rotavirus coded gastroenteritis in Australia. These declines were particularly evident in children aged <5 years. In those aged <1 year and those 1 to 2 years of age, there were reductions of 74% and 77% in rotavirus-coded hospitalisation rates, respectively, in the post- vaccine period, July 2008 to June 2009 compared with the pre-vaccine period of July 2001 to June 2006. Hospitalisation rates for all-cause acute gastroenteritis (excluding rotavirus) also declined in children aged <5 years, to between 24% to 41% in the post-vaccine period compared with the pre-vaccine period. Overall, there were more than 7000 hospitalisations prevented in children less than 5 years of age in the post-vaccine period of July 2008 to June 2009 compared with the pre-vaccine period. There was also evidence of a decline in rotavirus and gastroenteritis not coded as rotavirus hospitalisations in those aged between 5 to 19 years following vaccine introduction suggesting a herd immunity effect. However in adults aged >20 years there were increases in both rotavirus and gastroenteritis not coded as rotavirus hospitalisations. These were unlikely to be associated with rotavirus vaccine, as the numbers coded as rotavirus were very small, and most had non-gastroenteritis primary causes of hospitalisation. There were differences in hospitalisation rates for rotavirus gastroenteritis across jurisdictions. Hospitalisation rates were higher in people who were identified as Aboriginal and Torres Strait Islander compared with non-Indigenous people. Decreases in hospitalisations seen in Indigenous children were similar to or slightly less than that seen in the general population, in NSW, Queensland, Victoria, South Australia and Western Australia. However, in the Northern Territory hospitalisation rates in indigenous children were markedly higher and exhibited more year-to-year fluctuation, although lower rates were evident in the post-rotavirus period. Surveillance of rotavirus serotypes by jurisdiction showed fluctuations and discernable variations in serotype distribution since vaccine introduction, but no consistent pattern by vaccine type was found.

Other published studies from a number of Australian jurisdictions have demonstrated declines in rotavirus laboratory tests, notifications (Queensland) and emergency department presentations (Victoria, New South Wales). In addition, there has been demonstrated high vaccine effectiveness against hospitalisation (Queensland) although this has not been consistently seen in studies of Indigenous infants in rotavirus outbreaks in central Australia.

There was also a change in the dominant serotype of rotavirus strain from G1P[8] to G2P[4] in 2008–2009; however G1P[8] was again the dominant type in 2009–2010 similar to that observed in 2006–2007 and 2007–2008.

Conclusion

Rotavirus vaccine was successfully integrated into the NIP in Australia with the implementation process being viewed as successful by the majority of key stakeholders. There have been marked reductions in rotavirus and non-rotavirus coded gastroenteritis in the first 2 years following the commencement of the national rotavirus immunisation program. This decline was predominantly seen in children <5 years of age which included the target group for vaccination (children aged 2–6 months). Uptake of the vaccine has been rapid with coverage sustained at relatively high levels despite the strict upper age limits. The reported AEFI were mainly mild and transient in nature, however, active surveillance has suggested a moderate increased risk of IS following the first dose of either vaccine. The impact of this vaccination program on hospitalisations and strain shift is comparable to that observed overseas; however, coverage achieved in Australia is better than that documented in other countries. Continued monitoring of coverage, AEFI and disease epidemiology is required to determine if these results can be sustained or improved in the future.

Stakeholder comments/recommendations

Participant's recommendations for enhancing the implementation of future national immunisation programs are listed below along with recommendations for enhancing surveillance for rotavirus disease which are drawn from review of existing systems.

Planning

Representatives from a wide variety of provider groups should be involved in all stages of the planning process at all levels of government. A minimum of 6 months lead time between program announcement and commencement is desirable. Inclusion of new vaccine onto the ACIR prior to program commencement is desirable and associated national guidelines (i.e. Due and Overdue Rules) should be available prior to the commencement of any new national immunisation program.

Measures to promote updates of patient management software linking to the ACIR being available prior to the commencement of any new national immunisation program should be investigated.

Communication

A national communication plan is needed to streamline the type, content and release of communication materials. Such a plan should provide a framework for timely provision of information to key stakeholders prior to program commencement and ensure key messages are reiterated when the program begins. Timely and ongoing advice to jurisdictions about the national implementation plan, in particular, plans for the development of resources is required to minimise the duplication of effort. State-based organisations (SBOs) and Division of General Practice (DGPs) should be included on national/state/territory direct distribution lists for relevant program resource materials.

With the introduction of any new vaccine onto the NIP, the importance of immunisation in general and reporting of AEFI should be promoted nationally and/or by states/territories. When targeting providers, communication is received better when it comes from a well-known, unbiased health expert.

Consider providing SBOs with quarterly vaccine-specific ACIR coverage reports which include all vaccines introduced onto the NIP since 1993. Mechanisms to improve the availability of local coverage data for those vaccines not included in the ACIR assessment of 'fully immunised' should be explored.

Resources

Consider developing a package of national marketing materials (e.g. template advertisements, brochures, posters) targeting both providers and the public. National resources/communication materials should ideally be distributed prior to or at the time of program commencement. Collaborate with relevant Aboriginal and Torres Strait Islander and multi-cultural groups to develop program resources relevant for these communities. Where vaccine brand differs by jurisdiction, resources should be tailored to the specific brand as much as possible.

Education

Provider workshops/seminars should be standardised to at least the jurisdictional level, funded appropriately and delivered through a number of mechanisms, such as online or face-to-face. Education for providers should be accredited as continuing professional development (CPD) with relevant professional colleges.

Vaccine

Providers who are supported by state/territory infrastructure (i.e. councils) should be consulted about appropriateness of existing funding models when an additional vaccine is introduced onto the NIP.

Surveillance systems

Rotavirus gastroenteritis should be considered for addition to the list of nationally notifiable diseases. The representativeness and sensitivity of the Australian Rotavirus Surveillance Program (ARSP) could be enhanced, as should methods for transferring data between this program and jurisdictional health departments. Further studies are needed to assess the validity of ICD-10-AM codes for rotavirus and non-rotavirus coded gastroenteritis. The coordination and uniformity of AEFI reporting, coding and collation could be improved, as could the timeliness, completeness and analysis of AEFI data reported to the TGA. Support for active surveillance of AEFI, specifically for intussusception should continue. Validation studies of the reporting of rotavirus vaccines to the ACIR should be considered.

CHAPTER 1. Introduction

Rotavirus is a non-enveloped RNA virus in the family Reoviridae that is the major cause of severe diarrhoea in young children and infants. Infection can be asymptomatic, cause mild to moderate gastroenteritis, or severe gastroenteritis with dehydration requiring hospitalisation.¹ Rotaviruses are primarily spread through the faecal-oral route by contact or respiratory spread.² Infection with rotavirus confers some protection against subsequent serious disease.^{1,3} Rotaviruses are typed based on two surface viral proteins (VP): VP7, a glycoprotein (G) and VP4, a protease-cleaved (P) protein.¹ Viruses that contain either G1, G2, G3, G4 or G9 (and either P1a or P1b) are the five most common virus types currently circulating in Australia.⁴

Rotavirus infection is a leading cause of death in children aged <5 years in developing countries resulting in over half a million deaths each year.^{5,6} By the age of 5 years, most children worldwide have been infected with rotavirus, but severe disease occurs commonly in those aged 6 months to 2 years.^{5,6} Rotavirus-related deaths do occur in Australia though to a much lesser extent than in developing countries, and have been recorded as the cause of death in a small number of elderly adults.⁷ Rotavirus gastroenteritis is responsible for a large number of hospitalisations in Australia (18.0 per 100,000), especially in children aged <5 years (254.5 per 100,000). In Indigenous children <12 months of age hospitalisation rates are approximately five times that for all children <12 months of age.^{7,8}

Two rotavirus vaccines have been licensed in Australia since May 2006: Rotarix[®] (GlaxoSmithKline Biologicals [GSK]) and RotaTeq[®] (CSL Biotherapies/Merck & Co).⁹ Both vaccines are oral live attenuated vaccines for use in infants; however, there are differences in their dosing schedules. Rotarix[®] (a live attenuated human rotavirus vaccine) is given in a 2-dose course administered at 2 and 4 months of age. The first dose should be given between 6 and 14 weeks of age with the second dose no less than 4 weeks after the first. The 2-dose course should be completed by the age of 24 weeks as safety has not been assessed in older children.¹⁰ RotaTeq[®] (a pentavalent human-bovine reassortant rotavirus vaccine) is a 3-dose course administered at 2, 4 and 6 months of age. The first dose should be administered at 6–12 weeks of age; the subsequent doses at a minimum interval of 4 weeks. All 3 doses should be administered by 32 weeks of age as safety has not been demonstrated in older children.¹¹ Pre-licensure studies estimated that vaccination would prevent around 85%–100% of cases of severe gastroenteritis in immunised children.¹²⁻¹⁷

The Northern Territory (NT) was the first jurisdiction to implement a funded vaccination program for rotavirus, commencing in October 2006 for all children born from 1 August 2006.¹⁸ From July 2007, both vaccines were included in the NIP for all children born from 1st May 2007.¹⁹ The vaccine used varied by jurisdiction with Rotarix[®] used in the NT, New South Wales (NSW), the Australian Capital Territory (ACT) and Tasmania (TAS) and RotaTeq[®] in Victoria (VIC), South Australia (SA), and Queensland (Qld). In Western Australia (WA), Rotarix[®] was used until May 2009, and RotaTeq[®]

thereafter. This geographic split results in approximately one-half of the birth cohort receiving each vaccine.

Since 2006, RotaTeq[®] has been licensed in more than 90 countries and included in at least seven national vaccination schedules, while Rotarix[®] is licensed in more than 125 countries and incorporated into the universal vaccination programs of 24 countries.²⁰ Australia was one of the first developed countries to introduce a nationally funded rotavirus vaccination program. In light of this, there is considerable international interest in the impact of the program in Australia. In late 2009, the World Health Organization (WHO) recommended that rotavirus vaccine for infants should be included in all national immunisation programs and strongly recommended the vaccine be introduced in countries where diarrheal deaths account for $\geq 10\%$ of mortality among children aged <5 years.²¹

Evaluation of the national rotavirus immunisation program

The National Centre for Immunisation Research and Surveillance (NCIRS), as part of its responsibilities under a funding agreement with the Australian Government Department of Health and Ageing (DoHA), has the lead role in evaluations of national immunisation programs. Evaluations are conducted according to a standard protocol agreed with DoHA, consisting of a process evaluation, system description and an analysis of impacts (adverse events following immunisation and vaccination coverage) and outcomes (morbidity and mortality data). Evaluations are conducted in liaison with key stakeholders, in particular the National Immunisation Committee (NIC). The evaluation of the national rotavirus immunisation program was conducted during 2010.

NCIRS has previously submitted to DoHA several evaluation reports on national immunisation programs in Australia which are unpublished. These include; the national Indigenous Pneumococcal and Influenza Immunisation (NIPHI) Program in 2004,²² the Q fever Immunisation Program (2004),²³ the Meningococcal C Program (2007),^{24,25} the Adolescent Pertussis Immunisation Program (2009)²⁶ and the Childhood and Adult Pneumococcal Programs (2009)^{27,28} as well as a published report on the National Measles Control Campaign.²⁹

CHAPTER 2. Process evaluation

Aims

To describe the implementation processes and identify strengths and challenges of the national rotavirus immunisation program.

Methods

The evaluation focused on program implementation and involved a review of publicly available documents and those provided by key stakeholders. These included media releases, provider and parent resources, health department websites, and internal reports. Documents were reviewed to obtain information about the planning and implementation of the program.

In addition, key informant interviews were conducted between June and September 2010 to gain an in-depth understanding of program implementation as well as strengths and weaknesses of the approaches taken. Purposive sampling was used to recruit a representative sample across key stakeholder groups and jurisdictions using each brand of rotavirus vaccine. A sampling matrix (**Appendix A**) was used to ensure representativeness across these areas and set the quota of participants required for each stakeholder group (quota sampling). Participants working at a national or jurisdictional level were approached directly while providers and local program coordinators were referred by other participants (snowball sampling).

A structured interview questionnaire was developed by NCIRS staff based on previous national immunisation program evaluations (see **Appendix B**).²⁴⁻²⁸ The questionnaire contained both open and closed questions and sought information about:

- program development and infrastructure, including funding
- communication
- implementation of the program including vaccine supply and distribution
- data collection methods and outcomes
- participants' views regarding the strengths and weaknesses of the program.

A Likert scale³⁰ was used to rate participants' views at the time of interview about the overall quality and usefulness of four nationally produced resources and level of agreement with six statements about factors which the investigators felt had impacted on the delivery of the national rotavirus immunisation program.

The questionnaire was piloted with four key informants from outside the study frame. Feedback from this process contributed to enhanced content, altered survey structure and modified wording.

Prior to the interview, key informants were sent the questionnaire by email to allow collation of relevant information to inform their responses. All interviews were audio-digitally recorded with consent of the respondent. Responses were transcribed and drafts sent back to participants for comment with amendments and additions incorporated into the final interview transcripts.

Data analysis

Content analysis was conducted on interview transcripts to identify prominent themes with respect to implementation process, strengths and challenges of delivering the program and recommendations for future program implementation. Ratings of the overall quality and usefulness of four nationally produced resources were analysed by combining the two upper and two lower categories from the psychometric scale to give four categories for analysis. For each resource, participant ratings were calculated as a proportion of those who rated that particular resource. A similar process was used to analyse participants' level of agreement with six statements about factors impacting on the delivery of the program.

Results

Twenty-five key informant interviews were undertaken across nine stakeholder groups. Jurisdictional immunisation program managers from NSW, QLD, WA and the NT were interviewed however those from VIC, SA, TAS and the ACT were not included in the sampling matrix thus were not interviewed. Interviews were also conducted with State-based Organisation (SBO) immunisation coordinators from QLD, WA, ACT and VIC as well as Division of General Practice (DGP) immunisation coordinators from SA, TAS and NSW. In addition, 11 immunisation service providers from various jurisdictions were interviewed, including general practitioners (GPs), practice nurses (PNs), council immunisation coordinators, remote area immunisation nurses, nurses from Aboriginal Medical Services (AMS) and a technical expert on rotavirus. The majority (88%) of key informants were in their current roles when the program commenced in their jurisdiction.

Key informant responses were predominantly of a general nature; some specific examples from a jurisdiction or stakeholder group are included where relevant. The results represent the collective views of those who were interviewed with individual opinions included where applicable. Results are presented in four parts. Parts 1 to 3 outline how the program was implemented from the perspective of those interviewed. Part 4 is a critical analysis of the implementation process from the interviewee perspective from which recommendations are drawn.

Part 1: Program planning and infrastructure

This section summarises key features of funding, program roles and responsibilities, infrastructure and planning.

Funding

Federal

In the media release of 28 March 2007, the Acting Minister for Health and Ageing, Christopher Pyne, announced that the Australian Government would provide \$124.4 million over 5 years for the national rotavirus immunisation program.¹⁹ Under the Australian Immunisation Agreements (AIA) funds were made available to states and territories for the purchase of rotavirus vaccine for 105% of the eligible age-cohort, which included 95% coverage target and 10% for wastage and leakage. The following funding formula was used:

Funding = cohort x cohort % funded x number of doses x nationally negotiated vaccine price

Funding for the first year of the program (1 September 2007 – 30 June 2008) totaled \$24,370,000 and increased to \$36,196,000 in the second year of the program (1 July 2008 – 30 June 2009). In the third year of the program (1 July 2009 – 30 June 2010) funding remained similar at \$35,480,000 however this funding was provided under the National Partnership Agreement on essential vaccines for rotavirus which superseded the AIA's.

As this funding was not allocated for program management or service delivery, state/territory governments funded these aspects of the program through existing core funding of their immunisation program. The considerable one-off investment required to implement a new vaccination program was predominantly borne by the state and territory governments, as per previous vaccines included on the NIP.

Jurisdictional

On 23 August 2006, the NT Government announced it would provide \$480 000 to implement Australia's first rotavirus vaccination program in the NT from October 2006.³¹ This funding was provided to the NT Communicable Disease Control Directorate to purchase vaccine and establish the program; with existing core funding used to manage and coordinate the program. The vaccine manufacturer GSK, provided financial assistance to produce educational materials for the NT program. From July 2007, Australian Government funding was used to implement the program in the NT along with all other jurisdictions.

State-based Organisations/Divisions of General Practice

SBOs and DGPs did not receive program-specific funding for this program. These organisations receive ongoing funding under the General Practice Immunisation Incentive Scheme (GPII) to support providers to implement the NIP. DGP immunisation program coordinators in SA were also supported by funding from the SA Government which ceased as of 30 June 2010. Some DGPs received funding from vaccine industry to deliver local education events for general practice

providers though no such funding was provided to SBOs. In the ACT, competitive grant funding for provider education was provided by ACT Health to ACT Division of General Practice (ACTDGP), though this was not specific to the national rotavirus vaccination program.

Roles and responsibilities

The Australian Government Department of Health and Ageing (DoHA) are responsible for the overall coordination of the program at a national level. Their role in initial implementation was to amend national immunisation policy, coordinate funding for the states and territories, develop national communication materials and promote the program through national communication channels. This involved a number of Australian Government departments as well as various sections within DoHA with overall coordination being provided by the Immunisation Branch. Technical support was provided by the Australian Technical Advisory Group on Immunisation (ATAGI), the National Immunisation Committee (NIC) and NCIRS.

The immunisation sections of state and territory health departments were primarily responsible for implementing this program in their jurisdiction. This included tendering for the vaccine, vaccine purchase and distribution, amending state/territory policy, updating and distributing the jurisdictional vaccination schedule, and developing resources/information for local public health units (PHUs), DGPs and immunisation service providers.

Some jurisdictions developed education programs, primarily targeting nurse immunisers and general practitioners (GPs). For several jurisdictions this was routine practice for any new vaccine introduced onto the NIP but for others this was done specifically for the rotavirus program due to legislative requirements. For example, in NSW, the Policy Directive Immunisation Services Authority for Registered Nurses³² links vaccines recommended by the National Health and Medical Research Council (NHMRC) as listed in the current edition of *The Australian Immunisation Handbook*.³³ As rotavirus vaccine was not listed in the Handbook at the time the program commenced, NSW Health developed a training program for nurse immunisers as an interim measure so they could administer the vaccine under this policy directive.

In general, SBOs worked at a jurisdictional level to disseminate all available information to DGPs and immunisation providers in their jurisdiction with most assisting with the coordination and delivery of education for these groups. In the ACT, information and continuing immunisation education organised by ACTDGP was targeted at both private and public immunisation service providers. In addition, participating SBOs identified that every SBO had a responsibility to meet with the Australian General Practice Network (AGPN) regularly to collaborate and discuss program implementation activities.

DGPs worked locally, often in collaboration with the local PHU and/or local government to disseminate information, deliver education and be a 'point of call' for providers.

All providers interviewed identified that nurses working for various providers (i.e. GPs, councils, remote providers) are the main administrators of vaccine in this program and are also responsible for vaccine ordering and cold chain management. In jurisdictions where councils provide childhood immunisation services, these activities were also undertaken by the council immunisation clinic coordinators, some of whom were not nurses. Most stakeholders felt that GPs usually recommended vaccines but do not frequently administer them; this was the role of the PN.

Participating stakeholders felt that the implementation of the national rotavirus immunisation program was a collaborative effort involving all key stakeholder groups. All key informants reported collaboration with at least one other organisation when implementing this program. For example, ACT Health and ACTDGP collaboratively planned, produced and co-branded resources and education sessions for the national rotavirus program. This was the first time such a collaborative approach was taken to implement a new vaccine on the NIP in the ACT.

Planning

Following the addition of rotavirus vaccine on the NIP, DoHA developed a communication plan which identified the target and secondary audience, key messages and proposed campaign elements. Stage 1 involved the development and distribution of specific guidelines for providers as well as parents and guardians.³⁴⁻³⁶ Stage 2 saw the revision of the existing Understanding Childhood Immunisation brochure to include an additional insert on rotavirus vaccine,³⁷ the formulation of a NIC working party and development and dissemination of a letter from the Chief Medical Officer to immunisation providers. The National Health (Immunisation Program – Designated Vaccines) Determination and associated explanatory statement were also updated to include rotavirus vaccines.³⁸

There was just over 3 months lead time between the Australian Government notifying the jurisdictions of their decision to fund the program and the date of commencement. In the NT, this was considerably less with only 6 weeks between the NT Government notifying the health department of their decision to fund the program and territory-wide implementation. In this time jurisdictional health departments had to advise the state/territory health minister and parliament of the program; tender and purchase vaccine; develop and disseminate media releases; update state/territory websites; update, reprint and distribute the state/territory immunisation schedule; amend relevant state/territory legislation; develop resources and training materials for service providers; liaise with the vaccine manufacturer to supply relevant support material; develop/amend vaccine order forms; distribute relevant amounts of vaccine prior to the date of commencement; and disseminate information via email, fax and face to face meetings to all key stakeholder groups and immunisation providers. Around the same time, these activities were also taking place for the national HPV immunisation program which had similar timelines to the national rotavirus immunisation program. The short lead time and concurrent roll out of the National HPV

immunisation program was reported by program coordinators to have resulted in a stressful and hasty planning process which delivered less polished resources, than was usually the case.

The majority of these activities were undertaken by the immunisation section in each jurisdictional health department. Other sections of government involved in program planning varied between jurisdictions though in general included communicable diseases; surveillance; procurement, purchasing and logistics; and communication/media. Some jurisdictions also had independent committees who inform the implementation of their immunisation programs.

Most of the SBOs had input into planning by their state/territory health department and informed national activities through liaison with the AGPN. They all assisted DGPs with local level planning and held jurisdictional immunisation workshops to inform DGPs and other provider groups (i.e. councils) about the program and its requirements.

Planning activities undertaken by DGPs were limited by the amount of information available prior to the commencement of the program. DGPs were reliant on information from DoHA as well as state/territory health departments, which was initially minimal given the short lead time to develop communication materials. Despite this, DGPs had forewarning from the AGPN that the program was commencing soon, and advised providers a month or two before the program commenced as this was thought to maximize provider recall. As more detailed information became available, mostly in the week leading up to program commencement, DGPs disseminated a lot of information to their providers, including some of their own resources.

A minority of providers undertook planning activities within their organisations, with types of activities varying by organisation. Most of these activities were led by nurses and included informing all staff about the program through written notices and staff meetings; changing the layout of the vaccine fridge; displaying posters about the vaccine; and providing information brochures to parents. All participating GPs felt that a large amount of planning was not required to implement this program;

'....just read the information that we (GPs) received and just contacted the Division and/or PHU if there were any issues/questions. We already had a system for childhood vaccination so just incorporated this into existing practice. There have been so many changes to the childhood schedule in the past few years that we (GPs) just knew what to do and with the nurses doing most of it nowadays it was easy.'

Part 2: Program implementation

Due to the high disease burden caused by rotavirus, particularly among Indigenous infants,^{39,40} the NT Government implemented a government-funded rotavirus vaccination program from October 2006 for all babies born from 1 August 2006.¹⁸ This highlighted the importance of introducing this vaccination program and provided almost 1 year of program implementation experience and coverage data prior to the commencement of the national program.

Rotavirus vaccine was added to the NIP for all Australian babies born from 1 May 2007 and the program commenced simultaneously across all other jurisdictions in July 2007.¹⁹ All jurisdictions incorporated this program into the existing infrastructure and processes used to deliver the NIP in their state/territory. The program was implemented in accordance with the agreed overall strategy but differed in service delivery models due to differences in existing immunisation infrastructure. GPs provide the majority of vaccinations in most jurisdictions. However, one of the main differences between jurisdictions is the role of local government and community health in the provision of immunisation. A substantial proportion of vaccination is provided by local governments in SA, TAS and VIC, with the latter two having a legislative responsibility to do so. Local governments also provide some services in WA and QLD. In contrast, area health services and community health are the main providers in the ACT, NSW and the NT.

This program prompted some jurisdictions to supply NIP vaccines to maternity hospitals to vaccinate premature babies and infants who remain in hospital at the relevant schedule points. Other jurisdictions had been doing this prior to the program.

Aside from the short lead time to prepare for the program, key informants didn't identify any significant differences in service delivery between this and the existing childhood NIP. However, the following unique aspects of the national rotavirus immunisation program were highlighted by key informants:

- oral vaccine
- no catch-up program
- restrictions on timing of doses and upper age limits
- vaccine available on the private market prior to the national program giving some provider familiarity prior to the commencement of this program
- increased time to administer the oral vaccine, new and not as straight forward as an injected vaccine
- high level of community awareness of the disease as many parents had spoken with providers about a child they knew who had rotavirus disease
- the need to address concerns of parents and providers regarding 'shedding' of the virus from live vaccine and the need to educate parents about the importance of hand hygiene
- multiple changes to the NIP occurring at the same time (introduction of rotavirus and HPV vaccines).

Key informants were asked to rate their level of agreement with a number of statements about factors influencing the implementation of the national rotavirus immunisation program. Their responses are summarised in **Table 1**.

Table 1. Views of key informants about factors influencing the national rotavirus immunisation program (n=24)

	Agree	Neutral	Disagree	N/A
The defined age cut-offs for the rotavirus vaccine created difficulties for parents	70.8%	20.8%	8.4%	-
providers	83.2%	8.4%	8.4%	-
The oral nature of the vaccine has required additional instructional materials to support its implementation.	100%	-	-	-
The oral nature of the rotavirus vaccine has made it more acceptable to parents	95.8%	-	4.2%	-
providers	83.3%	12.5%	4.2%	
The concurrent roll out of the national HPV program made the implementation of the rotavirus program more difficult.	45.8%	12.5%	37.5%	4.2%*

* Key informant (n=1) not involved in HPV program.

There was strong agreement that the oral nature of rotavirus vaccines required additional instructional material to support their implementation as it had been a significant time since an oral vaccine was on the schedule. On one hand participants felt that packaging and communication was not sufficient to prevent mistakes with administration, but on the other oral administration was more acceptable to parents and, to a lesser extent, providers.

‘For a provider to give a vaccine of any sort they still have to go through the education and have the knowledge to explain it all to the parents.....it’s more about the vaccine rather than the way it’s administered.’

Rotavirus was the first vaccine on the NIP with strict age eligibility criteria and no catch-up program. The majority of key informants agreed that this created difficulties for parents more so than providers. Some providers felt this was especially difficult for parents of low socioeconomic status (those who are relatively socially or economically deprived) whom they felt found it more difficult to get to an immunisation provider and achieve timely vaccination. Some providers felt that calculating the eligibility of the child for rotavirus vaccination was both difficult and time consuming and mentioned that they sometimes forget about the defined age cut-offs. Providers also found it a challenge explaining to parents that catch up was not needed and why older children could not receive the rotavirus vaccine.

Program managers on all levels agreed that the concurrent roll out of the HPV program made the implementation of the rotavirus program more difficult.

'It was a timing disaster.'

In contrast, most providers were either neutral or did not feel this had any impact on the implementation of the rotavirus program.

'It was targeting completely different age groups so there was a different mindset about each of them. We (provider) just did it and didn't think about it being too much of an issue.'

The least affected were the remote providers, particularly those from the NT where the program had been running for more than 6 months prior to the commencement of the HPV program.

'It was just a matter of giving another vaccine..... the kids (girls) had younger siblings who were coming in anyway so we just administered HPV when we (provider) saw those who were eligible.'

Vaccine supply and administration

Both Rotarix® and RotaTeq® were available on the private market in Australia from May 2006.⁹ (Amy Choi, CSL Biotherapies Australia. (Personal communication: CSL Biotherapies, September 2010). However, SBOs and DGPs had varying levels of awareness of this. Of those that were aware, most promoted it's availability to providers but didn't drive it, rather making them aware it was available and how to access. The majority of providers were aware of the availability of rotavirus vaccines in the private market very few administered them with cost the major barrier. No remote providers interviewed were aware of the availability of either of these vaccines prior to the commencement of the national program.

Rotavirus vaccine was the first to be assessed by the Pharmaceutical Benefits Advisory Committee for inclusion on the NIP. Following approval of an amended application both rotavirus vaccines were available on the NIP from July 2007. Rotarix® was added to the existing schedule at 2 and 4 months of age and RotaTeq® at 2, 4 and 6 months of age. Each jurisdiction selected one brand of rotavirus vaccine for their state/territory schedule (see **Table 2**).

Table 2. Vaccine brands in Australian states and territories.

Rotarix®	RotaTeq®
New South Wales Australian Capital Territory Tasmania Northern Territory Western Australia (July 2007–April 2009)	Queensland Victoria South Australia Western Australia (May 2009 – current)

As a result of a state-based tender process, WA changed the scheduled brand from Rotarix® to RotaTeq® in May 2009, almost 2 years following the commencement of the national program. Implementing this change involved a strong collaboration between WA Health, Western Australian General Practice Network (WAGPN) and industry but was a relatively seamless transition.

Both rotavirus vaccines are administered orally using different devices, both of which were reported to cause issues with administration. RotaTeq® is presented in a plastic dosing tube with a twist-off cap which is contained in a pouch.¹¹ The presentation of Rotarix® has changed three times throughout the program. The current presentation a squeezable tube containing an oral liquid formulation.¹⁰

The Australian Government provided funding for the purchase of vaccine for the program which is supplied to the jurisdictions based on the forecasts provided by them to DoHA.

Existing ordering and distribution systems were used to disseminate vaccine; but varied by jurisdiction. For example, in QLD there is a one-off delivery 2 weeks prior to program commencement, with vaccine quantity calculated based on use of other NIP vaccines. Following this initial delivery, the new vaccine is incorporated into the routine NIP vaccine ordering process. In contrast, NSW incorporates the new vaccine into the existing NIP vaccine order form which is released prior to program commencement for providers to pre-order the vaccine. In the NT, vaccines are not distributed from a central location; instead providers order vaccines from their nearest regional pharmacy of which there are four throughout the NT. The exact distribution method differs by region based on location (rural/remote); however, these were no different for the national rotavirus immunisation program.

Key informants did not report any vaccine management issues with either rotavirus vaccine. All jurisdictions reported steps were taken to prevent leakage, though further details were not provided.

The availability of two different brands of rotavirus vaccine caused problems for many key informants. The main reported issue was the initial lack of information on the interchangeability between the two vaccines. This caused most problems at the commencement of the program and for those in the border regions where different vaccines could be provided on different sides of the street. This was less of an issue for remote providers, as they reported that they had never come across a child who had commenced the schedule on the non-funded brand. DGPs and providers felt that they knew who to call for assistance when they had a child who commenced the schedule on the non-funded brand, which was most commonly the local PHU.

Initially, each jurisdiction purchased only one brand of vaccine (as per the outcome of the tender process). However, to overcome interchangeability concerns, some jurisdictions (NSW, ACT, WA, NT), purchased a minimal supply of the non-scheduled brand of vaccine to provide to children who had commenced the schedule on the alternative brand. In these jurisdictions, providers were able

to access the non-scheduled brand for an eligible patient (i.e. commenced the course with the non-scheduled brand and was still within the age range for subsequent doses) by contacting the relevant state/territory health authority. Not all providers from these jurisdictions reported that they were aware of this arrangement. In jurisdictions where the non-scheduled brand is not provided by the state/territory health department, patients can choose to obtain the vaccine through a private script. In border regions, there was some sharing of vaccines between jurisdictions; however, this only commenced a few months into the program.

Data collection

Under the AIA, each jurisdiction is required to provide the following information regarding the rotavirus program to DoHA annually: vaccine acquittals, estimates of wastage and leakage and details on program expenditure. In addition, rotavirus vaccine coverage for children aged 1 year is one of the performance indicators on the AIA. This information is provided annually via the ACIR. The state/territory health departments interviewed collected data on the distribution of rotavirus vaccine by brand, provider, geographical area and time. Aside from the NT, this information was collected by each jurisdictions vaccine distribution centre. In the NT, this information is collected from regional pharmacy acquittals. As per national funding agreements all jurisdictions are required to report vaccine acquittals to DoHA on an annual basis. Some jurisdiction health departments shared dose distribution data with SBOs/DGPs to inform their program activities; and others provided vaccine ordering histories to individual providers to assist with forecasting.

As with other childhood NIP vaccines, rotavirus vaccines administered in Australia are required to be reported to the ACIR. In QLD and the NT this is done through the respective jurisdictional immunisation registers. Reports on vaccines administered are available by state/territory from the ACIR as well as the state/territory immunisation registers in NT and QLD. This data is used to measure uptake/coverage as well as calculate wastage and leakage.

Wastage is estimated routinely based on the resident age cohort, numbers of doses administered according to the ACIR, and the numbers of vaccine doses distributed (doses wasted = doses distributed – doses administered). Reports of cold chain breaches and/or expired vaccines are also collected at a jurisdictional level to determine wastage however these reports are an underestimate as they only capture reported wastage.

Leakage is defined as vaccines given outside the recommended target group and these are identified upon entry to ACIR/jurisdictional immunisation registers. In the NT, leaked vaccines are routinely identified from the NT immunisation register and relevant providers are followed up by the NT health department. This information can also be obtained from the Vaccine Information Vaccine Administration System (VIVAS) database in QLD though this is not routinely examined. Other jurisdictions did not specify how leakage data are collected.

Adverse events following immunisation for the rotavirus immunisation program are reported as per the national arrangements for reporting AEFI as outlined in *The Australian Immunisation Handbook* 9th Edition.³³ In addition, a number of enhanced AEFI surveillance activities were commissioned with particular focus on intussusception. A discussion of these is outside the scope of this report. However, more detail on routine reporting and monitoring systems for AEFI is provided in Chapter 5: Adverse events following immunisation.

Participants did not report any program-specific reporting requirements for SBOs, DGPs or providers for this program. However, each of these groups routinely receive coverage estimates from the ACIR calculated using the GPII algorithm which does not incorporate coverage for vaccines introduced on the NIP since 2005 or provide vaccine-specific coverage.

Part 3: Communication and education

The lines of communication across the immunisation network were apparent in the way each stakeholder group first heard about the national rotavirus immunisation program. Most of the SBOs were informed via AGPN (via email or face-to-face meetings) and in turn informed DGPs via email or at face-to-face network meetings. Providers (i.e. councils, GPs, community health) were informed via email or word of mouth from either the DGPs or their relevant jurisdictional health department. The Public Health Association of Australia (PHAA) National Immunisation Conference (2006) was also mentioned by two participants as an initial source of information about the program.

Communication was undertaken at various levels during the national rotavirus immunisation program. In light of this, each key informant was asked about specific communication strategies they employed to reach their target group (i.e. SBOs to DGPs) as well as awareness of strategies targeted at them (i.e. assessment of DoHA materials by SBOs).

National communication

DoHA developed a communication campaign that used a combination of mass media and direct communications to notify the Australian public and health professionals about the national rotavirus immunisation program. Prior to distribution, all DoHA communication materials were circulated to NIC for comment.

Mass media communication strategies included updating national websites, advertising in GP/nurse magazines, a designated campaign launch, media releases and interviews with the Acting Minister for Health.¹⁹ Specific guidelines for parents/guardians³⁶ and immunisation providers³⁵ as well as a public fact sheet³⁴ were posted on the Immunise Australia website. Hard copies of the provider guidelines were mailed with an accompanying letter from the CHO to all GPs

in Australia. The parent/guardian guidelines were distributed in hard copy to providers via DGPs and some PHUs. An updated insert for the *Understanding Childhood Immunisation (UCI) brochure*³⁷ was developed and distributed to providers using similar methods as previously described for the parent/guardian guidelines. Immunisation providers could also order any of these resources directly from the DoHA publications section.

The majority of key informants used these materials to inform the implementation of the program. The *Immunisation provider guidelines* were used by 79% (19/24) of those interviewed and those who did not use it were predominantly state/territory program managers and one GP. Three-quarters of those interviewed (18/24) used *Rotavirus immunisation: information for parents & guardians* and those who did not use were predominantly state/territory program managers and one remote provider. *Understanding childhood immunisation brochure: important update* was utilised slightly less (62.5%, 15/24) and those who did not use it were predominantly state/territory program managers and one each of GP, SBO, council and remote provider.

Following public announcement of the national rotavirus immunisation program there was a lack of information available nationally. Rotavirus vaccine was not included in *The Australian Immunisation Handbook* 8th Edition and the National Centre for Immunisation Research and Surveillance received many questions about the vaccine, particularly interchangeability and recommendations for medically at-risk children. In light of this, the NCIRS fact sheet: *Rotavirus vaccines for Australian children: Information for GPs and immunisation providers* (2006)⁴¹ was developed. This was initially published on the NCIRS website in 2007 and updated in 2009. The fact sheet was used by three-quarters of those interviewed (75%, 18/24). Those who did not use it were either GPs or PNs.

Table 3 contains key informant ratings of the resources developed by DoHA for the national rotavirus immunisation program. The majority of key informants who utilised these resources felt they were good or very good with the same small proportion unsatisfied with all of the DoHA resources.

Table 3. Key informant ratings of national resources developed for the national rotavirus immunisation program

<i>For each of the resources listed below, please mark the box which best reflects your general opinion of the resource.</i>	Good	Average	Poor	Unsure/not used
Rotavirus provider guidelines (n=21)	76.2%	9.5%	4.8%	9.5%
Rotavirus information for parents & guardians (n=21)	85.6%	4.8%	4.8%	4.8%
Update: Understanding childhood immunisation brochure (n=21)	61.9%	14.3%	4.8%	19%
NCIRS fact sheet (n=22)	72.7%	-	-	27.3%

General comments about the resources developed by DoHA for this program were divergent. Some felt they were succinct, clear, well written with easily understandable language while others felt they were too long, too detailed, lacked colour and were not interesting. The DoHA resources were familiar to parents and providers as illustrated by the following comment from a GP:

'I like how they look the same (i.e. purple up the top, green down the side and immunisation emblazoned all over it) as other DoHA immunisation materials that we get – it looks like a page from the Immunisation Handbook. We can clearly identify it as something to do with immunisation. We know where this information has to go in the practice (nurses pigeon hole) and where to find it if we need it. When there are different logos and colours you need to look at it for a while to determine what it's about.'

Program managers acknowledged that developing nationally relevant resources for this program was challenging:

'It was difficult as there were two different vaccine brands so needed all the information on both though each jurisdiction was only interested in the one on their schedule'

Most providers felt that the provider guidelines were a very good resource to advise how and when to use the vaccine. The majority utilised this resource initially to become familiar with the program and its requirements. These guidelines are no longer used routinely but have been kept as a reference if needed. It was felt that the presentation and content of this resource could have been tailored more towards time-poor providers:

'It came in a booklet form (need to give information to providers that is succinct & precise). Main information that they (providers) would have wanted would be around dosage and side effects. It did not pick-up on the timeliness issue. Had more information than was necessary. GPs may not have read it! Could have been shorter.'

In general, providers felt the parent resources were long winded and hence not used at the time of consultation, rather were given to parents to take home and/or supplement verbal advice. The fact sheet for parents and guardians was considered very helpful by most providers as it was presented in a tear off pad and the content answered parents' questions. In contrast, some providers felt that it had too many words and that it was boring, hence parents were not interested in it. Key

informants felt that the UCI insert was a good idea but it was not widely used. This may have been as it was an insert and had the same picture on the front, it was often mistaken for a condensed version of the full UCI booklet. Some participants were concerned that rotavirus vaccine is still not included in the main UCI brochure.

Key informants working in Indigenous communities felt that the DoHA resources for parents were sometimes used with Indigenous clients but not as much as with the non-Indigenous clients. It was felt that this was because it is easier to talk to Indigenous parents, particularly in remote areas where most Indigenous clients won't read print material and rely on word of mouth.

Resources developed by DoHA became available approximately 1 year after the program commenced which was a concern raised by the majority of key informants.

'They were so late, it was almost after the event (hence) they were almost useless. Although they were not available for quite a considerable amount of time after the program commenced, they were sent to providers so will probably have been used, but (jurisdictions) didn't rely on them particularly at the beginning of the program.'

One of the only detailed resources available at the commencement of the program was the NCIRS fact sheet. This was seen by most as timely, comprehensive, critical, factual and concise and all key informants relied heavily on it, as they had for previous NIPs. This was due to it having more information than other resources available at the time and, in the absence of information in *The Australian Immunisation Handbook* (8th Edition), it provided the information that program managers and service providers needed. However, compared to DoHA materials, this resource was not recognised by some providers and was not viewed as reader friendly for busy providers.

'I don't recall seeing this though if I did see it I probably would not have taken the time to read it – it was crammed with text so visually not very encouraging to read for someone working in general practice.....would be more likely to look at it if it were a brief summary as (GPs/PNs) usually look up the detail if needed..... if we had a patient with complications i.e. complicated past medical history, co-morbidities.'

Jurisdictional communication

Communication strategies employed by jurisdictions varied though all states/territories disseminated information through health department websites, media releases, letters from the CHO, direct emails/faxes, inclusion of the rotavirus vaccine on vaccine order forms and face to face education for providers. Less universal strategies included dissemination of vaccine administration information with the vaccine, ministerial briefs for state/territory government and education delivered via video/teleconferences and DVDs. Jurisdictional communication primarily targeted providers and key stakeholder groups (i.e. SBOs, professional groups) although some jurisdictions posted information directly to parents and childcare centres. In other jurisdictions communication to the public was developed by DoHA and industry with SBOs, DGPs, childcare and immunisation providers delivering this to parents.

Given the absence of national resources at the commencement of the program and the need for vaccine-brand specific information, many of the jurisdictions developed their own resources to support initial program implementation. This was particularly the case in the NT, where the program commenced prior to the national roll out and the large Indigenous population required specific resources.

Table 4 illustrates the breadth of resources utilised by health departments. Resources listed are those which were specifically developed for this program by the relevant health department. In addition, jurisdictions updated existing NIP resources including, vaccine order forms, vaccination schedules, pre/post vaccination care advice and websites.

Table 4. Resources developed by specified jurisdictional health departments

Jurisdiction	Resources
NSW	NSW Health GP Immunisation Information Kit (updated to include Rotavirus)
QLD	Letters to immunisation providers (two) Follow-up letter to immunisation providers (August 2007) – advice about missed doses Letter and information sheet – childcare centres Reminder stickers – for child's personal health record 'Ready reckoner' booklet – assist providers to calculate timing of doses Reprinted Personal Health Record (updated) Program information sheet for immunisation providers – distributed with the vaccine
WA	WA Health training package for service providers incl. PowerPoint presentation, an example of the vaccine, a fact sheet. This was developed only for the initial roll out of the program. WA Health Fact sheet – illustrations and steps on how to administer the vaccine. This was developed for Rotarix® initially then for RotaTeq®.
NT	Pictorial administration guide – developed initially though found it was not appropriate DVD guide to administration – for providers, particularly Indigenous health workers PowerPoint presentations – for provider education sessions Dose cut-off calculator (spreadsheet/tables) – to calculate vaccine eligibility Parent letter from NT health minister – to explain the new program and vaccine

State-based Organisation communication

SBOs collated and distributed existing resources and information from a variety of sources to inform immunisation providers about the program and its requirements. ACT DGP and ACT Health collaboratively developed and co-branded a resource package which was disseminated throughout the ACT (see **Table 5**).

Most SBOs used direct email to distribute electronic resources and advise DGPs about the availability of and how to order hard copy resources. Dissemination strategies included posting directly to DGPs, availability at DGP network meetings, discussions at network teleconferences, linking to online information via SBO website, and articles and attachments in routine newsletters for DGPs. In addition, WAGPN included images/PDFs of resources to illustrate what was available and how it may be of use to DGPs and providers. ACT DGP developed a joint media release with ACT Health, whereas other participating SBOs relied on national and jurisdictional media releases. All communication from SBOs was targeted at either DGPs or other providers (i.e. councils).

Divisions of General Practice communication

The primary method of communication to providers used by DGPs was newsletters (which varied in length and frequency) and brief weekly fax and/or email news bulletins. Each DGP had a unique way of collating, analysing and distributing information within their geographical area and frequently manipulated the format of existing material to suit their dissemination strategies and tailor to the needs of time-poor GPs and PNs. One DGP arranged a local GP to be interviewed about the program on a local radio station, though mass media was not used by other DGPs interviewed. **Table 5** illustrates examples of resources developed by DGPs.

Table 5. Resources distributed by Divisions of General Practice

Jurisdiction	Resources
NSW	Newsletter articles – for providers Faxes – weekly for providers Information sheets (1–2 pages) – providers and childcare centres Microsoft Excel spreadsheet ‘Ready reckoner’ – calculate vaccine eligibility and cut-offs
SA	Weekly e-newsletter articles – ‘need to know’ program information for providers SA Immunisation Coordination Unit (SAICU) PowerPoint presentation – provider education, used to develop newsletters/cheat sheet SAICU 1 page ‘cheat sheet’ – summary of key program information for providers.
TAS	Newsletter articles – for providers Radio script – GP presented on local radio station
ACT	ACT Health and ACT DGP collaboratively developed: <ul style="list-style-type: none">• Microsoft Excel spreadsheet ‘Ready reckoner’ – calculate timing of doses• Laminated pictorial administration and reconstitution guide for Rotarix[®]• Letter of introduction for providers – advise about the program and the vaccine• Media release

Hard copy resources were distributed at provider education events and at routine face to face visits to general practices in the DGP area. Participating DGPs felt that when the program commenced a significant proportion of general practices did not regularly utilise the internet and some were poster-free and brochure-free. In light of this, alternative communication strategies were required. As these practices relied heavily on printed information (i.e. faxes, posted letters), some DGPs printed information from the internet and provided demonstrations on how to access relevant information from websites and clinical software packages.

A minority of DGPs promoted the program to parents and childcare centres. Activities targeting these groups included provision of brochures, posters and information sheets; face-to-face education for childcare centre staff; local radio advertisements; and local media releases.

Provider communication

Councils and remote providers reported that they relied on state/territory health departments to advise them about the program. Most developed their own educational materials for staff as well as updated existing materials used in their immunisation clinics. Where available they used industry resources, though these were not always widely disseminated. Resources and information were distributed within the provider's organisation through staff meetings, in-services, centrally located notice-boards and the clinic coordinator.

Participating general practices and AMSs received most of their information from the local DGP and in some jurisdictions via letter or fax from the state/territory health department. DGPs reported that GPs also received a letter from the CHO though this was not mentioned by any providers during the interview, possibly as it was distributed sometime after the program commenced. GPs and PNs recalled utilizing some pharmaceutical company resources and printouts from clinical software.

Some providers had targeted communication strategies for patients, sending letters to parents informing them of the program and eligibility for free vaccines. Others promoted the program in the practice through posters, brochures, telephone 'on-hold' messages, signs developed by the practice for the waiting room, and recommendation of the vaccine in routine childhood vaccination visits. Most providers do not currently use the resources which were distributed at the time of program commencement as rotavirus-specific information for parents has now largely been incorporated into generic childhood NIP resources.

Resources from vaccine industry

The two main companies who provide rotavirus vaccine in Australia are GSK and CSL Biotherapies (CSL). They developed numerous resources to support the implementation of the national rotavirus immunisation program as outlined in **Table 6**. All SBOs and DGPs as well as some jurisdictional health departments reported promoting these resources though the amount of involvement in the dissemination of industry resource materials varied across jurisdictions. QLD

Health and NSW Health distributed industry resources with the vaccine yet in WA and SA, DGPs ordered and distributed these materials locally. There was some collaboration with industry in Qld, the NT and WA to develop specific resources for their jurisdiction, though some of these were made available nationally (i.e. dosing wheel).

In late 2010, CSL commenced a second '2–4–6' blitz campaign in RotaTeq[®] jurisdictions. A letter to providers and a resource order form (fax-back) was distributed with each vaccine delivery to immunisation providers in RotaTeq[®] jurisdictions. In some jurisdictions this promotional campaign was coordinated in conjunction with health departments and/or SBOs. Around the same time GSK introduced a new 'squeeze tube' administration device for Rotarix[®]. An A5 provider information card introducing the new 'Rotarix[®] squeeze tube' was distributed with the vaccine in NSW and accompanied an introductory letter posted to providers in the ACT, the NT and TAS.

Table 6. Rotavirus vaccines resources developed by vaccine industry and distributed in Australia

CSL Biotherapies	GlaxoSmithKline
Rotavirus '2-4-6' campaign materials; <ul style="list-style-type: none"> • RotaTeq[®] Product Information • RotaTeq[®] dosing wheel (developed 2007) • Provider Education kit: PowerPoint presentation, handouts • RotaTeq[®] fridge magnets • RotaTeq[®] brochure for parents • RotaTeq[®] poster for clinic waiting room • RotaTeq[®] 'How to' guide to administration • Print advertisements for RotaTeq[®] in popular parenting magazines Some of the above materials tailored to the Indigenous population	Rotarix [®] Product Information Rotarix [®] dose timeline wheel (developed 2009) Rotarix [®] fridge magnets Rotarix [®] brochure for parents Rotarix [®] brochure for providers Rotarix [®] poster for clinic waiting room Rotarix [®] 'How to' guide to administration (A4 card) Rotarix [®] Q&A brochure for providers and accompanying cover letter Consumer website www.kidsgastro.com.au A5 provider information card introducing the Rotarix [®] squeeze tube Letter to providers introducing the Rotarix [®] squeeze tube

Education

Education was provided in a variety of formats and was widely attended by participants. Participating SBOs and state/territory health departments collaboratively delivered state-wide face-to-face forums attended by DGPs, council immunisation coordinators and some providers. The majority of these were not solely focused on the national rotavirus immunisation program; however, the commencement of the program may have provided some impetus for these events, which are routinely held two to three times per year. In larger jurisdictions (e.g. NSW) regional face-to-face education sessions were run collaboratively by the DGP and local PHU. These were attended by providers and some SBOs attended as observers and/or presenters. In the NT and QLD, immunisation section staff visited remote providers and provided face-to-face education, either

onsite or at a communal event in an easily accessed regional location. As not all providers could attend face-to-face training, other methods of information dissemination to remote providers included videoconference, emails of presentation slides, practice visits, or a 'train-the-trainer' model.

A number of rotavirus-specific education events for health professionals were hosted by industry. These half day sessions involved presentations by an international speaker and/or Australian rotavirus experts and were usually held in capital cities. The PHAA National Immunisation Conferences (2006 and 2008) were attended by some key informants and noted as important educational opportunities.

Part 4: Strengths, challenges and recommendations

Key informants were asked to provide their own opinions about the strengths and challenges of the national rotavirus immunisation program. Opinions varied widely, with many factors seen as both strength and a challenge. Summaries of the strengths and challenges as identified by participants are presented in **Table 7** and their recommendations in **Table 8**. Both are discussed in more detail below.

Planning

Strengths:

- *Stakeholder collaboration*

Challenges:

- *Insufficient lead time*
- *Concurrently introducing two new vaccines onto the NIP*
- *Delay in adding new vaccines to provider software programs and updating ACIR guidelines.*

The lead time provided prior to the commencement of the national rotavirus immunisation program was insufficient for both program managers and providers. Implementing any new vaccine on the NIP takes a considerable amount of time, resources and finances. This program has highlighted that adequate lead time is imperative to enable information to filter out to all involved. All participating program managers felt a minimum of 6 months should be provided to jurisdictional program managers and similar for SBOs/DGPs. It was felt providers needed less though sufficient time to become familiar with the vaccine as well as the program and its requirements.

'A short timeframe to inform, educate and deliver resources to providers places a significant burden on everyone. There needs to be sufficient lead time to enable information to filter out to providers prior to program starting.'

The catch-up component of the national HPV program commenced in the same month as the national rotavirus immunisation program (July 2007) with the school-based program commencing 2–3 months prior. Participants identified competing priorities here. On the one hand it was felt that vaccines which have demonstrated public health benefit and are approved for inclusion on the NIP should not be withheld but on the other concurrently implementing two new vaccination programs creates additional stress on the implementation process and often leads to inequitable execution.

'This is the biggest issue as it confuses people and they just panic.'

Many participants commented that detailed and equitable planning as well as a sufficient lead time would assist in alleviating some of the issues which arose in the concurrent implementation of these two immunisation programs.

Consultation and collaboration across all key stakeholder groups were also viewed as important when implementing national immunisation programs. Although key informants detailed numerous collaborative relationships, it was felt collaboration at a national level could be improved. Those working in various roles within Indigenous communities felt that it was important that Indigenous immunisation providers are involved in program planning on all levels.

'Seek the advice of those who are going to be implementing the program about what's required to implement the program. Prior negotiation with program implementers about appropriate start times is especially important. For example: the 1st July not a good time to start a program.'

DGPS, SBOs and primary care providers felt there was considerable delay in adding rotavirus vaccine to many provider software programs. This pertains not only to parent information sheets but also the sections where vaccination data is entered onto the patient record and subsequently transferred to the ACIR. It was reported that The National Due and Overdue Rules for Childhood Immunisation⁴² were only updated to include rotavirus vaccine after the commencement of the program. Prior to implementation of any new program participants felt it is imperative that the Australian Government take a lead role in updating national reporting mechanisms and guidelines to allow streamlined notification of the new vaccine. This includes adding the new vaccine on the ACIR, amending the National Due and Overdue Rules and incorporating the new vaccine into provider reporting mechanisms (i.e. paper forms, practice management software).

Summary of respondents comments/recommendations

- A minimum of 6 months between program announcement and commencement is desirable.
- Representatives from all provider groups should be included in the program planning process at all levels.
- Inclusion of new NIP vaccines on the ACIR from program commencement is desirable and associated national guidelines (i.e. Due and Overdue Rules) should be available prior to program commencement.

- Measures to promote updates of patient management software which links to the ACIR being available prior to the commencement of any new national immunisation program should be investigated.

Communication

Strengths:

- *DGP support and education for providers, DoHA resources clear and consistent*

Challenges:

- *Communication was delayed, not suitably detailed, inconsistent and not nationally coordinated*
- *DGPs received national/jurisdictional materials after providers*
- *Communication on uptake was limited*
- *Communicating the upper age limits and ‘no catch-up’ messages to parents.*

Participants reported that initial communication about the program was rapid and utilised existing channels however, was not suitably detailed. It was felt that subsequent information including some technicalities of program implementation was considerably delayed. When the program commenced, there was no nationally coordinated approach to public communication or a national media campaign. Many jurisdictions and DGPs disseminated their own media releases and, as a result, local media was well utilised in some areas but not others. Remote providers felt that given its prominence in rural/remote areas, local media should be included in any national health promotion campaign.

‘It’s important that people know locally that it’s (vaccine) available. Advertising through the paper is a great way to let people know about it – they (Government) did this for HepB but not rotavirus.’

Most providers felt they should have been notified about the program earlier; however, DGPs felt they were hamstrung by a lack of suitably detailed information.

‘Organisations who provide information to providers need to maintain a credible reputation by providing quality, accurate and timely information to providers. Lack of materials and sudden changes in recommendations leads to confusion amongst providers and lack of respect for the groups who support them. You can’t go out to the practices until you have all the information together.’

Providers felt that communication targeted at them should be available prior to any public promotion of the program allowing sufficient time for them to become familiar with the program and its requirements and feel capable of answering questions from patients.

'Need to recognise that we (nurses) are a great mechanism for vaccination promotion and that we need the information about a new vaccine in a timely fashion. We are finding that the GPs refer the parents to us for vaccination more now.'

DGPs identified their key role was informing and educating providers about a new vaccine program and felt they did this successfully in this program. However, half of the DGPs advised that they did not receive national or jurisdictional communication materials and only became aware of these when providers starting asking about them. In light of this they wanted to be assured that all DPGs were included on direct distribution lists for national and jurisdictional communication to ensure they can promote these materials as well as avoid wasting time and duplication of effort.

'We (providers) get such great support from the local Division – over the phone and face-to-face training – this needs to continue. Divisions hold regular immunisation updates – work with them to provide education and information to providers.'

A number of consistent, clear letters and information sheets from the Australian Government were distributed to providers but participants reported that they were often delayed and not widely read. One provider felt it was important that communication came from a credible source a well-known health expert and/or prominent local health figure as it would have more impact than generic national communication.

'It's very important to have an authoritative person (like the) public health physician from the local PHU to speak on the advantages of the vaccine.....there is always a feeling that if there is a known person recommending it, it's stronger than just getting the letter from the health minister.'

All participants in program implementation roles felt that communication about this program was not streamlined and was limited by the availability of information at a national level. Developing a communication plan and having all necessary information ready prior to or shortly after the public announcement of the program would assist key stakeholders in their communication process and providers in becoming familiar with the program. However, it should be recognised that information needs across implementation timelines vary between stakeholders. For example, jurisdictional health departments require more detailed information in the planning phase than DGPs/providers. Communication should be ongoing leading up to commencement and general program information re-iterated when the vaccine is distributed.

'Once we (providers) get wind of a new vaccine program, it's important to get some scientific information first then the basic overview just at the time of the release. Once the media get hold of it, patients start asking questions so it's important to have the scientific information so we can field their questions about the new program. As the vaccine hits the practice it's important to send out either the same information again or just a bit more information especially if this is more than a few weeks after we (providers) got the initial

information it may have been lost – important to give more detail on how to administer rather than just the technical stuff at this point.'

SBOs and DGPs also felt that communication on uptake of the rotavirus vaccine was limited. The total numbers of vaccines administered to children <7 years of age is available by vaccine and dose number via the Medicare Australia website.⁴³ The Australian Government and jurisdictional immunisation program managers receive confidential quarterly ACIR coverage reports which report coverage by vaccine, dose number, Indigenous status and health area. National coverage data is also published in peer reviewed journal articles.⁴⁴ However, due to data delays, these are not timely or suitably detailed to inform program implementation at a local level. SBOs/DGPs reported that they rely on quarterly GPII coverage reports to inform local program implementation. These have several limitations including no vaccine-specific coverage, cohort coverage only includes those vaccines added to the NIP prior to 1993, and algorithms for calculating coverage differ between ACIR and GPII. In light of this, participating DGPs and SBOs felt that consideration should be given to making quarterly ACIR coverage reports available to SBOs, investigating mechanisms of improving the availability of local level coverage data for all childhood vaccines, and improving the timeliness of existing coverage reports currently provided to jurisdictions.

Summary of respondents comments/recommendations

- A national communication plan is needed to ensure timely provision of information to key stakeholders prior to program commencement and to ensure key messages are re-iterated when the program begins.
- Jurisdictions should receive ongoing and timely advice about the national implementation plan, in particular plans for the development resource material to minimise duplication of effort.
- Communication targeting providers is best received when coming from a well-known, unbiased health expert.
- Inclusion of SBOs and DGPs on national and jurisdictional provider distribution lists for relevant program materials would aid dissemination.
- Consider providing SBOs with quarterly vaccine-specific ACIR coverage reports which include all vaccines introduced onto the NIP since 1993.
- Investigate mechanisms to improve the availability of local coverage data for those vaccines not included in the ACIR assessment of 'fully immunised'.
- With the introduction of any new vaccine onto the NIP, take the opportunity to promote the importance of immunisation in general and encourage reporting of AEFI.

Resources

Strengths:

- *DoHA resources accepted by the majority of key informants*
- *Large number of resources available from a variety of sources.*

Challenges:

- *There was considerable delay in the dissemination of national resources*
- *Resources were not tailored to specific brand of vaccine*
- *Duplication of effort across stakeholder groups.*

There were a considerable number and variety of resources developed to implement and support this program. The program-specific resources developed by DoHA were accepted by the majority of key informants. The strengths and weaknesses of these resources are discussed in more detail in *Part 3*.

The majority of participants felt that resources needed to be tailored to the funded brand of vaccine on each jurisdictional immunisation program schedule due to significant differences between the two brands of rotavirus vaccine and that there was substantial duplication of effort in resource development. Participants felt that the following should be considered when developing national resources to support introduction of vaccines onto the NIP in the future.

- Present information in varying levels of detail

'.....have plenty of different information handouts at the beginning – basic and scientific, for both parents and providers. One with the bare bones facts and the other with more scientific facts.'

- Tailor materials to meet a variety of learning styles

'It's important to tailor communication/promotion materials to various types of learners i.e. visual, auditory.'

- Develop resources for the Indigenous community

'For us (provider) to give a resource out in our community it has to be Indigenous specific – that's not a maybe, it's a have to be. It makes them feel more comfortable and helps them as the language is often different. For Indigenous clientele, verbal communication and picture stories work. Written words don't work for them.'

- Develop a standard marketing package targeting both providers and the public which can be adapted by jurisdictions

'A complete 'marketing package' is required with each change to the NIP – target both consumers & service providers. This should include a variety of resources, such as;

media releases, radio scripts, banners, logos etc all promoting the same key messages.....should be developed at a national level though able to be tailored by each jurisdiction.'

- Work with the Australian General Practice Network to develop and disseminate resources for providers and the public.

'Centrally develop resources to decrease burden on DGP staff who should primarily be out informing/interacting with service providers. More coordinated approach to what information is provided to service providers – not have each DGP/PHU developing own materials' (SBO-22)

Summary of respondents comments/recommendations

- Consider the development of a national resource package (including marketing materials) targeting both providers and the public.
- If developed, distribution of national resources prior to or at the time of program commencement is desirable. Such resources should include an overview of the program and the vaccine.
- Collaborate with relevant Aboriginal and Torres Strait Islander and multicultural groups to develop program resources relevant to these communities.
- Where vaccine brand differs by jurisdiction, resources should be tailored to the specific brand as much as possible.

Education

Strengths:

- *Sufficient education provided which was well attended and of high quality*

Challenges:

- *Tailoring education to the specific vaccine brand*
- *Duplication of effort across stakeholder groups.*

Program managers reported that education is a major component of any new vaccination program. The face to face education provided for the national rotavirus immunisation program was well attended and highly regarded by providers. The majority of education provided by DGPs had continuing professional development (CPD) points for relevant medical and nursing colleges (i.e. RACGP) which reinforced its quality and allowed medical professionals to have their attendance recognised. Participants felt it was important that in the implementation of future immunisation programs organisations delivering provider education should be well supported and that education is delivered via a number of mediums, is accredited with relevant professional colleges and is widely promoted.

'Education is really important – If I (nurse) had seen the Rotarix® in the plunger/syringe without reading the product information or without any education my initial instincts would have been to inject it. It's important that staffs are educated so they can answer the questions from parents as they always ask lots of questions. So it's really important that before they (Government) introduce a new vaccine that providers are familiar and comfortable with it.'

Most participants felt that education for this program needed to be tailored to the funded brand of vaccine in each jurisdiction due to significant differences between the two brands. This resulted in a lot of duplication of effort in the development of educational material as well as the need for additional education when providers moved jurisdictions. The availability of the non-funded brand in some jurisdictions also required additional education, however, providers reported that this was often provided by peers or the local PHU. Much of the brand-specific educational material was supplied by industry with key experts in the field and jurisdictional program managers adding jurisdictional-specific content. Participants felt that the complexities of educating providers about two different brands of vaccine and the vital role of industry in supporting brand specific education should be kept in mind when implementing future childhood immunisation programs.

Summary of respondents comments/recommendations

- Provider workshops/seminars should be standardised to at least the jurisdictional level, funded appropriately and delivered through a number of mediums.
- Provider education should be accredited as continuing professional development with relevant professional colleges.

Vaccine

Strengths:

- *Vaccine added to existing schedule points on the NIP*
- *No catch-up component*
- *Oral nature of the vaccine*
- *Short dose intervals*
- *Program easy to implement.*

Challenges:

- *Communicating the 'no catch up' message to parents*
- *Strict upper age limits and short dose intervals*
- *Two different brands of the vaccine*

- *Oral vaccine took longer to administer*
- *Presentation of Rotarix®*
- *Uncertainty about re-administration guidelines.*

All providers felt that it was easier to implement a new immunisation program where the vaccine was added to existing NIP schedule points compared with introducing a new vaccine to a new schedule point. It was felt that this adds complexity to implementation processes, and requires increased provider support, resources and increased promotion of the schedule to both parents and providers.

All participants were grateful that there was no catch-up component of the program, particularly jurisdictional immunisation program managers who felt that this would have resulted in the need for significantly more resources to support providers to calculate catch-up schedules, as many providers have difficulty with this. Providers felt that communicating the 'no catch-up' message to parents was a particular challenge as it was different to other vaccinations and was not emphasized in parent information.

'As there was no catch-up component for this vaccine it was sending a different and difficult message to parents about timing of vaccination.....Couldn't say 'it was never too late to start' had to change it so convey 'can't start after the end of the 12th week.'

All participants felt that adhering to the strict age eligibility criteria was one of the most challenging aspects of the program. Calculating the age eligibility was complex and time consuming for providers though it was felt that the development of tools to calculate dose intervals made this easier. As parents and providers are familiar with the 'it's never too late to start' slogan, all participants felt that communicating the rationale for the strict upper age limits was difficult. In light of these issues, there were known instances where older children were administered the rotavirus vaccine and it's likely that such instances were not reported to relevant health authorities as providers may not have been aware of the age eligibility criteria.

Almost all participants felt that the oral nature of the vaccine was well accepted by both parents and providers; however the vaccine took longer to administer compared with other vaccines administered by injection. This created difficulties for those managing appointment schedules, particularly local government and community health providers, some of whom would require additional clinic time and staff. These providers felt that in future they should be consulted about such concerns to determine if any amendments to funding models are required.

'Consider length of time to administer the vaccine – if a new program is going to impact on session times there should be consideration of increased costs to providers to administer an additional vaccine, educate parents etc.'

Despite the vaccine being oral, most participants reported that administration was a challenge for some providers. This was most prominent with Rotarix® which caused issues including recurring spillage prior to administration, difficulty removing the top off the first time, and some confusion about reconstitution which led to instances of the vaccine being administered without proper reconstitution. The most frequently reported administration issue was babies spitting out the vaccine. This occurred predominantly with the initial presentation of Rotarix® as well as RotaTeq® as they both had a larger volume of liquid (2mL+). There was also some confusion amongst providers about guidelines for re-administration.

'The advice was not to re-administerdespite the child spitting the majority of the vaccine out. This was different to the OPV recommendation to re-administer if spat out or vomited up within 15 minutes of administration. We (providers) usually had to counsel parents about this as they often wanted us to re-administer it.'

Irrespective of the brand of vaccine used, almost all jurisdiction immunisation program managers reported hearing about instances of the vaccine being injected. This was more of a concern with Rotarix®.

'Originally the oral administration device for Rotarix® looked like a syringe – the packaging didn't look different enough from an injectable vaccine.'

Anecdotally these participants also conveyed that such instances have been reported in other countries though due to the sensitive nature it is likely that the injection of rotavirus vaccine is under reported. All jurisdictional program managers advised the relevant vaccine manufacturing company of any such occurrences and there were no report of long-term side effects for affected children though counseling of several providers was required.

Program managers were aware of these administration issues and ensured that administration guidelines were disseminated widely, even after the program commenced, and that provider resources and education emphasised the correct method of administration. Feedback from providers was continually sought and provided to vaccine industry which provided the impetus for a review of administration devices. Participants from WA felt that the changeover from Rotarix® to RotaTeq® in WA removed some of the issues with administration of Rotarix® and simplified interchangeability guidelines. The rationale for this change was not disclosed but was viewed positively by key informants from WA and was much more controlled and coordinated than the initial implementation of the program. The WA experience was viewed as a useful model for other jurisdictions who may implement schedule changes in the future.

Providers also mentioned that media reports of porcine circovirus type 1 (PCV1) in the vaccine could damage public confidence in the program. In addition, they were cautious of the new rotavirus vaccines as there could be a risk of intussusception too.

Summary of respondents comments/recommendations

- Providers who are supported by state/territory infrastructure (i.e. councils) should be consulted about the appropriateness of existing funding models when an additional vaccine is introduced onto the NIP.

Table 7. Summary of strengths and challenges identified by respondents.

Strengths	Challenges
<p><i>Scheduling</i> – in line with the current schedule</p> <p><i>Timing of doses</i> – short so people remembered to come back again sooner</p> <p><i>Oral vaccine</i> – less crying and pain for the babies, parents more accepting</p> <p><i>Resources</i> – sufficient and clear, easy to access, lots available on the internet, stressed the importance of correct administration and timeliness</p> <p><i>Administration</i> – relatively easy method, no counting drops</p> <p><i>Providers well supported</i> – education and information from the DGPs and local PHUs, knew about the program before it was implemented</p> <p><i>Parents were educated about the disease</i> – happy and accepting of the vaccine</p> <p><i>No catch-up program</i> – less complexity, single target cohort</p> <p><i>Improved timeliness of vaccine administration at 2/4/6mths</i></p> <p><i>Commencing the program early in the NT</i></p> <p><i>Stakeholder collaboration</i> – ‘made it happen’ in short timeframe</p> <p><i>HPV program</i> - may have overshadowed any substantial media interest in the program</p> <p><i>Impact on disease</i> – there is some published evidence supporting reduction in gastrointestinal disease</p> <p><i>Easy to implement</i> – oral vaccine, well accepted by parents, at existing schedule points, providers well supported</p>	<p><i>Two different brands of vaccine</i> – different schedules, cross border issues increased complexity for providers, tailored education materials</p> <p><i>Timeliness of program information/resources</i> – national information came too late</p> <p><i>Insufficient lead time</i> to prepare for implementation</p> <p><i>Oral vaccine</i> – reintroduced onto NIP, providers less familiar with oral vaccines, takes longer to administer</p> <p><i>Concurrent roll out of HPV program</i> – overshadowed rotavirus program, more work to implement two programs at once, no national campaign</p> <p><i>Presentation of Rotarix®</i> – reconstitution, needle-like initial presentation, consistently changing</p> <p><i>Timeliness</i> – parents and providers don’t adhere to strict dose timings</p> <p><i>No catch-up program</i> – challenge in communicating to parents and providers ‘now or never’</p> <p><i>Storage space</i> – more vaccines in the fridge</p> <p><i>Spitting</i> – children spitting vaccine out, uncertainty around re-administration</p> <p><i>Providers cautious of new rotavirus vaccine</i> – risk of intussusception</p> <p><i>Educating parents</i> – new vaccine, viral shedding</p> <p><i>Porcine circovirus type 1 (PCV1)</i> – some damage to public confidence</p> <p><i>Coverage and availability of this data</i> – could be improved</p> <p><i>Provider software</i> – frequently late including new vaccines</p>

Table 8. Summary of respondent's recommendations.

Planning

- A minimum of 6 months between program announcement and commencement is desirable.
- Representatives from all provider groups should be included in the program planning process at all levels.
- Inclusion of new NIP vaccines on the ACIR from program commencement is desirable and associated national guidelines (i.e. Due and Overdue Rules) should be available prior to program commencement.
- Measures to promote updates of patient management software which links to the ACIR being available prior to the commencement of any new national immunisation program should be investigated.

Communication

- A national communication plan is needed to ensure timely provision of information to key stakeholders prior to program commencement and to ensure key messages are re-iterated when the program begins.
- If all jurisdictions received ongoing and timely advice about the national implementation plan, in particular plans for the development of resources, information sheets and educational materials duplication of effort would be minimised.
- Communication targeting providers is best received when coming from a well-known, unbiased health expert.
- Inclusion of SBOs and DGPs on national and jurisdictional provider distribution lists for relevant program materials would aid dissemination.
- Consider providing SBOs with quarterly vaccine-specific ACIR coverage reports which include all vaccines introduced onto the NIP since 1993.
- Investigate mechanisms to improve the availability of local coverage data for those vaccines not included in the ACIR assessment of 'fully immunised'.
- With the introduction of any new vaccine onto the NIP, take the opportunity to promote the importance of immunisation in general and encourage reporting of AEFI.

Resources

- Consider developing a national resource and marketing package targeting both providers and the public.
- If developed, national resources should ideally be distributed prior to or at the time of program commencement and include an overview of the program and the vaccine.
- Collaborate with relevant Indigenous groups to develop program resources for the Indigenous community.
- Where vaccine brand differs by jurisdiction, resources should be tailored to the specific brand as much as possible.

Education

- Provider workshops/seminars should be standardised to at least the jurisdictional level, funded appropriately and delivered through a number of mediums.
- Provider education should be accredited as continuing professional development with relevant professional colleges.

Vaccine

- Providers who are supported by state/territory infrastructure (i.e. councils) should be consulted about the appropriateness of existing funding models when an additional vaccine is introduced onto the NIP.

Limitations

This evaluation has a number of limitations. An evaluation component was not incorporated into the planning of the national rotavirus immunisation program; hence, this evaluation was designed after the initial implementation of the program. As a result, many program implementation materials were developed solely to implement the program and were not retained for the purposes of program evaluation.

This process evaluation was conducted from June to September 2010, 3 years after the program commenced in July 2007. Key informant interviews are limited by sample and recall bias as it was a challenge to locate appropriate people who had worked in key positions during the planning and implementation phases of the program.

Conclusions

The national rotavirus immunisation program was successfully implemented across Australia from July 2007. It was incorporated into the NIP at the existing 2, 4 and 6 month schedule points, with no catch-up program and was reportedly well accepted by most providers and parents.

The brand of vaccine included on the state/territory immunisation schedules varied by jurisdiction; however, there were no reported issues with vaccine supply or management with either brand. The oral administration method was a challenge for some providers, but education, experience, support from DGPs/PHUs and changes to the presentation of one brand of the vaccine have overcome this. There were delays in the availability of program information and national resources; however, providers felt they were well supported to implement the program and that it was relatively easy to put into practice. There was strong stakeholder collaboration across all sectors which allowed the program to be delivered in a short timeframe and concurrently with the national HPV program.

Participants felt that communication, education and resources could be improved with a nationally coordinated approach to development and timely dissemination to all key stakeholder groups. It was emphasized that longer lead time is needed prior to program commencement in order to undertake the large amount of planning required to implement such programs. These and other key lessons from the implementation of this program will serve to inform the processes of implementing national immunisation programs in the future.

CHAPTER 3. System description

Aims

To describe the surveillance systems and data sources used in the evaluation and review their quality and completeness.

Disease notifications

The National Notifiable Diseases Surveillance System (NNDSS) was established in 1990 and coordinates the surveillance of more than 60 communicable diseases reported by laboratories and health workers to state and territory authorities under their current public health legislation.

Rotavirus is not currently on the national notifiable diseases list though is currently pending national notifiable status.⁴⁵ However, it is notifiable in several states/territories. **Table 9** outlines rotavirus notification activities by jurisdiction (Personal communication: Nicolee Martin, Department of Health and Ageing, 2010).

Table 9. Rotavirus notification activity by jurisdiction.

	ACT	NSW	VIC	TAS	SA	WA	NT	QLD
Notifiable in jurisdiction	NN ^a	Dec 2009	NN ^a	Dec 2008	May 2008	July 2006	1994	Dec 2005
Data first received by NNDSS	NDP ^b	May 2010	NDP ^b	2009	June 2010	July 2006	NDP ^b	2007

a. NN = rotavirus disease not notifiable

b. NDP = no data provided to the Department of Health and Ageing

Lab definitive evidence is required in Qld, NT, NSW, TAS, SA with both lab definitive and clinical evidence required in WA. Lab definitive criteria are the detection of rotavirus by antigen assay or NAA or EM or isolation of rotavirus.⁴⁶ Clinical notification criteria used in WA are a gastrointestinal illness clinically compatible with rotavirus infection, characterized by vomiting and/or diarrhoea, with or without fever.⁴⁷ Notification details collected vary by jurisdiction though generally include a unique record number; state or territory identifier; disease code; serotype; dates of onset, notification, diagnosis and birth; sex; Indigenous status; patient death; and immunisation status.

The NT has been routinely conducting disease surveillance for rotavirus since 1994. This data was useful in providing background epidemiological data in support of funding rotavirus vaccine on the NIP, especially in the NT. Notification data is stored on the NT Notifiable Diseases Database and reported quarterly in the *Northern Territory Disease Control Bulletin*.⁴⁸ With the commencement of

the NT rotavirus vaccination program in October 2006 notified cases included details on hospitalisation (including admission and discharge dates), rotavirus vaccination date and vaccine type (either on ACIR or NT Immunisation database), serotype (where known), and Indigenous status. Although there has been no formal evaluation of completeness of Indigenous status recorded on the NT notifiable diseases database, it is estimated that recording of Indigenous status is complete for at least 90% for what are considered 'priority diseases' and, for rotavirus, it is consistently above 95% (98.5% in 2009). (Personal communication: Heather Cook, NT Department of Health and Families, 2010)

Quality and completeness of notification data

Rotavirus is not notifiable in all states and territories and not all notified data is forwarded to NNDSS. Notification criteria vary between jurisdictions; hence, there is irregularity in the completeness of data fields in the NNDSS. Introducing national surveillance of rotavirus will improve the quality and completeness of notification data collected and reported as well as increase the value of serotyping data.

Rotavirus strain surveillance

The Australian Rotavirus Surveillance Program (ARSP) conducts a laboratory-based rotavirus surveillance program in conjunction with a number of Australian laboratories and has been reporting the changing annual pattern of dominant rotavirus serotypes in the Australian population since 1999.⁴⁹

Participating laboratories detect rotavirus using enzyme immunoassay (EIA) or latex agglutination tests. Samples of stool (0.05–1.0 mL) containing rotavirus are sent to the ARSP with a unique sample code, sex and age of the case from which it was obtained. This code allows samples to be linked to hospital data by the sending laboratory if needed. Upon receipt, the ARSP confirm that rotavirus is in the stool sample using an in-house monoclonal antibody (MAb) EIA, which also identifies common serotypes G1–4 and G9. If rotavirus is not identified in the stool by this method, there is no further testing. If rotavirus is detected but common serotypes are not identified, samples are serotyped by reverse-transcriptase polymerase chain reaction (RT-PCR). If the serotype is not identified using EIA or RT-PCR, the RNA of the virus is analysed.^{49,50}

Annual reports from ARSP have been published in *Communicable Diseases Intelligence* since 1999.⁵¹

Quality and completeness of strain surveillance data

As of 2008, six of the eight jurisdictions contributed to ARSP, this is an increase from 2004/2005 when only five jurisdictions participated.^{49,50} As ARSP does not record residential address or Indigenous status, representativeness of rural and remote locations and Indigenous populations

cannot be assessed. However, stool specimens of cases occurring in rural and remote areas may be less likely to be tested as participating laboratories are mainly located in larger towns and cities. The majority of samples are obtained from patients hospitalised with gastroenteritis though samples have been sent from non-hospitalised cases in outbreaks, predominantly from the NT.⁵⁰

In 2007, ARSP and the Australian Government Department of Health and Ageing undertook a collaborative evaluation of the ARSP.⁵⁰ Results from this showed that in the pre-vaccine era, the ARSP has provided baseline data on the serotypes of rotavirus causing hospitalisation in children in Australia in a sufficiently timely, flexible and sensitive manner. In the vaccine era, ARSP will provide valuable national serotype surveillance data, identifying the effects that each vaccine has on circulating strains, particularly whether changes occur in serotype incidence and whether increased proportions of rare or uncommon types result.⁵² However, a more representative sample is required to assess the impact of Australia's national rotavirus immunisation program, which, coupled with complete national notification data, would allow the assessment of the impact of vaccination, rate of vaccination failures, changes in rotavirus epidemiology, and the emergence of replacement serotypes.⁵⁰

Hospitalisations

The Australian Institute of Health and Welfare (AIHW) National Hospital Morbidity Database was developed in 1993 and collects and manages administrative, demographic and clinical information about patients admitted to public and private hospitals in Australia. AIHW receive data by financial year of separation. Hospitalisation data is classified based on the International Statistical Classification of Diseases and Related Health Problems (ICD). In 1998/1999, most states and territories began using the 10th revision (Australian modification) of this (ICD-10-AM) and, from 1999/2000, all jurisdictions were using this classification. The National Centre for Classification in Health (NCCH) updates the ICD-10-AM every 2 years, under the guidance of the Australian Coding Standards Advisory Committee.^{53,54} ICD-10-AM codes pertinent to rotavirus are presented in **Table 10**.

Table 10. International Statistical Classification of Diseases and Related Health Problems (ICD) codes for rotavirus gastroenteritis and acute gastroenteritis not coded as rotavirus

Rotavirus gastroenteritis ICD-10 code A08.0 (rotavirus enteritis)
Acute gastroenteritis (AGE) not coded as rotavirus K52 and ICD10 codes A01 – A09 (excluding A08.0)

Quality and completeness of hospitalisation data

Overviews of Australian hospitalisation statistics, including details of the number of hospitals reporting and any documented data problems, are published regularly.⁵⁵ The AIHW performs logical validations on the ICD-10-AM coded data for example, for sex- and age-specific diagnoses. Coding audits are also variously performed at hospital level or state/territory level using software such as PICQ (Performance Indicators for Coding Quality) developed by the NCCH.⁵⁶ Variations in hospital access, admission practices and record coding may occur between regions and over time and impact upon the use of hospitalisation data for monitoring disease trends over time and between jurisdictions. There are also limitations associated with the use of ICD codes to identify cases. Errors that cause the ICD code to differ from the true disease include both random and systematic measurement error and may occur either along the patient pathway (e.g. level of detail documented in medical records, clinician experience) or along the paper trail (e.g. transcribing errors, coder errors such as miss-specification, unbundling [assigning codes for all the separate parts of a diagnosis rather than the overall diagnosis] and upcoding [using reimbursement values to determine the order of coding]).⁵⁷ In the National Clinical Coder Workforce Survey, most Australian coders nominated incomplete medical record content as the factor most likely to affect coding quality, followed by the principal diagnosis not being identified, complications/comorbidities not being identified, illegible medical record entries, and pressure to maintain coding throughput.⁵⁸

Validation studies from Australia comparing ICD-10-AM codes for hospitalised rotavirus cases with laboratory testing data have shown that between 89% and 98% of rotavirus-coded hospitalisations are supported by laboratory confirmation.^{59,60} This is comparable to international studies which estimate 91% – 100% of rotavirus-coded hospitalisations are supported by laboratory evidence.^{61,62} Validation studies of ICD-10-AM coding of non-rotavirus AGE-coded hospitalisations in Australia show that approximately 26% of hospitalisations coded as non-rotavirus AGE had laboratory definitive evidence of rotavirus.^{59,60} In light of this, rotavirus-related hospitalisation data from Australia can be considered as reasonably specific; however, misclassification of hospitalisations due to rotavirus by using incorrect or less specific coding is common.

Mortality

Information on individual cause of death is routinely reported to the Registry of Births, Deaths and Marriages in each state and territory on a Standard Medical Certificate of Cause of Death completed by a medical practitioner or coroner. The person completing the certificate must nominate the underlying (principal) cause of death and any associated conditions.⁶³ Since 1997, the International Classification of Diseases, 10th Revision (ICD-10) has been used to identify the cause of death. Deaths recorded on the Registry of Births, Deaths and Marriages in each jurisdiction are supplied via the Australian Bureau of Statistics (ABS) annually to the AIHW Mortality Database, which is the main repository of death data in Australia. Where relevant, deaths from nationally notifiable diseases are also recorded on NNDSS, however this data is not used in this report.

Quality and completeness of mortality data

The concerns associated with the accuracy of the ICD-10-AM codes used for hospitalisation data could also apply to mortality data. The accuracy of the ascertainment of the cause of death may vary according to the experience of the practitioner, the complexity of the disease process and the circumstances of the death. Evidence suggests that, compared to the gold standard of autopsy findings, death certification is largely inaccurate⁶⁴⁻⁶⁷ with estimates that around one-third of deaths may be misclassified on death certificates.⁶⁸ This is of concern given the declining rate of hospital autopsy.⁶⁹ Therefore, despite comprehensive mapping algorithms, which attempt to take into account changing disease classification over time, caution is required in interpreting mortality trends.

There is a delay in reporting of mortality data in Australia. Annual reports on causes of death in Australia are currently available up until 2008. Data from the current (2008) report is preliminary and are pending the results of a new review process for coroner certified deaths registered after 1 January 2007. This process aims to increase the specificity of the assigned ICD-10 codes over time.⁷⁰

Adverse events following immunisation

Passive surveillance

In Australia, AEFI are notified to the TGA by state and territory health departments, health professionals, vaccine manufacturers and members of the public. All reports are assessed using internationally consistent criteria⁷¹ and entered into the Australian Adverse Drug Reactions System (ADRS) database.

Reported AEFI are assigned a causality rating, based on the level of certainty that reported vaccines caused the reaction. Factors that are considered in assigning causality ratings include the timing (minutes, hours, etc) and the spatial correlation (for injection site reactions) of symptoms

and signs in relation to vaccination, and whether one or more vaccines were administered.⁷² AEFI are defined as 'serious' or 'non-serious' based on information recorded in the ADRS database and criteria similar to those used by the World Health Organization (WHO)⁷¹ and the United States Vaccine Adverse Events Reporting System (VAERS).⁷³ 'Serious' events are those where the record indicates the person had recovered with sequelae, been admitted to a hospital or hospitalisation was prolonged, experienced a life-threatening event, or died. Reactions are re-coded from the reporter's description into standardised terms using the Medical Dictionary for Regulatory Activities (MedDRA®).⁷⁴ Individual AEFI reports often list multiple vaccines that were given simultaneously and multiple reactions that occurred following receipt of those vaccines. Also, multiple reports may be received for AEFI following the same vaccination(s).

De-identified AEFI surveillance data from ADRS collected since 1972 is regularly released to NCIRS for analysis. Annual national AEFI surveillance summaries have been published in *Communicable Diseases Intelligence* since 2002. These include all reports received by TGA of adverse events that occurred after the receipt of a vaccine, which contain enough basic information to be a valid report, and where the vaccine cannot be excluded as the cause due to biological implausibility.

Active surveillance

The Australian Paediatric Surveillance Unit (APSU) was established in 1993 to undertake national active surveillance of rare diseases of childhood, including communicable and vaccine preventable diseases. The APSU is a unit of the Division of Paediatrics and Child Health, Royal Australasian College of Physicians (RACP).

Each month clinicians on the APSU database (~1,250) are asked to report children newly diagnosed with any of the conditions listed on the APSU report 'card' which is posted or emailed to them. APSU investigators are informed weekly of new cases reported by APSU contributors and follow up with clinicians with a brief questionnaire requesting further de-identified information. Investigators are responsible for collation, analysis and publication of this data. Study findings are reported every two years in the APSU Biennial Research Report⁷⁵ with results of surveillance for communicable and vaccine preventable diseases reported annually since 2004 in *Communicable Diseases Intelligence*.^{75,76}

Intussusception (IS) has been recognised as a potential complication of rotavirus vaccination.^{77,78} Just prior to the introduction of rotavirus vaccination onto the NIP, the APSU commenced surveillance for IS. Ongoing APSU surveillance will provide information on the diagnosis and clinical management of IS and any temporal association between rotavirus vaccination and intussusception.⁷⁹ Additional data collected through the Paediatric Active Enhanced Disease Surveillance (PAEDS) system supplements APSU data and together may inform any potential temporal association between IS and rotavirus vaccination.⁸⁰

PAEDS is a pilot project initiated in 2007, coordinated by the APSU and NCIRS and funded by the Australian Government Department of Health and Ageing. The primary aim of PAEDS is to actively identify hospitalised cases and capture detailed clinical data not readily available from routine sources, such as diagnosis and outcome, immunisation status, background medical history, and biological samples where relevant. The focus of the PAEDS pilot is on the following four conditions of public health and clinical interest: acute flaccid paralysis, varicella requiring hospitalisation, IS and seizures requiring hospitalisation in infants aged 1–8 months.⁸¹

PAEDS involves a network of clinicians and public health researchers from four tertiary paediatric hospitals: The Children's Hospital at Westmead Sydney, Royal Children's Hospital Melbourne, Women's and Children's Hospital Adelaide and Princess Margaret Hospital Perth. Each has a dedicated part-time surveillance nurse with the centralised database, data management procedures, and communication strategies managed by the APSU.⁸²

The unique aspects of PAEDS include its capacity for:

- Ascertainment of cases unlikely to be detected through existing surveillance systems
- Timely case ascertainment and data review with weekly uploads into a central database
- Collecting data not obtained by other means, e.g. vaccination, presentation, treatment and outcome
- Collection and analysis of biological samples linked to clinical data for the same patient
- Flexibility and responsiveness to urgent or emerging conditions outbreaks or epidemics
- Population-based studies where populations around a reporting hospital are well defined
- Potential for verification of conditions included in data linkage initiatives, e.g. adverse events.⁸²

Hospital-based surveillance for intussusception commenced in June 2003 at Royal Darwin Hospital and Alice Springs Hospital in the NT. Data from the pre and post-vaccine era has been published in the *Northern Territory Disease Control Bulletin*.^{83,84}

Quality and completeness of AEFI data

Reported AEFI represent only symptoms that manifest after vaccination, which may or may not have been caused by vaccination. While there are attempts to assign causality to individual reports by expert review, in the vast majority of cases the causative role of a vaccine cannot be definitively confirmed or excluded. Therefore, the information collated in the ADRS database is primarily intended for signal detection and hypothesis generation. Reporting rates of AEFIs can be estimated using appropriate denominators such as the number of vaccine doses administered. However, they cannot be interpreted as incidence rates due to under-reporting and biased reporting of suspected AEFIs, and the variable quality and completeness of information provided in individual AEFI notifications.^{72,85}

Passive surveillance methods for AEFI have been found to differ between states and territories.^{72,86} For example, AEFI are notifiable conditions in NSW, the NT, Qld and WA. In TAS, AEFI are reported directly to the TGA. This was also the case in VIC prior to 2007. Since this time in Victoria, AEFI have been reported to the Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) service at the Royal Children's Hospital who then forward them to the TGA and provide quarterly reports to the health department. In all other states and territories, AEFI are reported to the health departments who then forward them to the TGA. These jurisdictional differences compound inherent constraints with passive surveillance systems including under-reporting and biased reporting.⁸⁷

A national workshop was held in 2006 to review current post-licensure vaccine safety practices in Australia and to work towards developing a national vaccine safety strategy. A clear set of recommendations to improve surveillance of AEFI in Australia were developed; however, many of these have not yet been met.⁸⁶

Active surveillance methods of the APSU have been evaluated twice.^{88,89} On both occasions the APSU has met the relevant Centres for Disease Control and Prevention (CDC) criteria⁹⁰ for the evaluation of surveillance systems: usefulness, simplicity, acceptability, representativeness, timeliness and data quality. Potential for under-ascertainment of cases was recognised as a limitation; however, it was acknowledged that lack of alternative national data makes it difficult to determine sensitivity of case ascertainment.^{88,89}

PAEDS has proven the feasibility of conducting hospital-based surveillance for uncommon, serious, vaccine-related childhood conditions in Australia and has demonstrated the capacity to respond rapidly and to provide timely detailed data on emerging severe vaccine-related conditions occurring in childhood.⁸² PAEDS should be seen as providing additional surveillance infrastructure in Australia, rather than a project with a limited life-span. National representativeness could be improved by expanding to tertiary paediatric hospitals in other jurisdictions.

As there is under-reporting of IS cases and limited surveillance data from the vaccine era, data are needed from ongoing active surveillance programs for IS to further explore any possible relationship between IS cases, and the age at vaccination, dose and type of vaccine.

Vaccine coverage

Currently, the only national source of information on immunisation coverage in children is the ACIR. Established in 1996, the ACIR is a population-based register of greater than 99% of Australian children, administered by Medicare Australia for the Australian Government Department of Health and Ageing.⁹¹ The ACIR only records details of vaccines administered to children before their 7th birthday. Notifications of vaccination events are sent by providers to Medicare Australia.

NCIRS plays a pre-eminent role in the analysis and reporting of data from the ACIR and the use of

these data for research, surveillance and evaluation. NCIRS receives regular downloads of de-identified ACIR data on a quarterly basis from Medicare Australia for analysis and reporting purposes.

Quality and completeness of vaccine coverage data

Vaccination information recorded on the ACIR has been validated in studies that compared ACIR records with information provided by parents or carers by telephone interview while referring to written records.^{86,92} Studies have shown that although ACIR reporting and coverage levels continue to improve, under-reporting of vaccines due at 2 and 4 months of age persists.⁹³ ACIR coverage estimates are mostly high but underestimate actual coverage.

An assessment of 'fully immunised' status according to the ACIR does not include all NIP vaccines. Rotavirus vaccine is excluded from this assessment.⁹⁴ In addition to annual immunisation coverage reports, jurisdictional program managers and the NIC receive quarterly coverage reports for individual vaccines recorded on the ACIR. However, these reports are not publicly available.

Discussion

The surveillance systems available in Australia for the evaluation of immunisation programs provide vital information for measuring outcomes and the impact of the program on disease burden. However, many of these systems have limitations that either restrict or affect the quality of output for program evaluations. The following recommendations have been developed when considering the national rotavirus immunisation program.

Disease impact

- Notification of rotavirus is not nationally consistent with variable notification criteria across jurisdictions. Ensuring that rotavirus is added to the list of nationally notifiable diseases and subsequent establishment of a single national dataset that is updated by all jurisdictions in a timely way should be a priority.
- The ARSP has provided sensitive strain typing data to inform the formulation of rotavirus vaccines and forecast the extent of outbreaks caused by novel serotypes. In the future, the ARSP will be able to monitor changes in rotavirus serotype epidemiology and identify probable vaccination failures in the vaccine era. However, in order for this data to remain useful, enhanced representativeness and sensitivity of the system are needed as well as methods for transferring data between the program and state and territory health departments.
- Rotavirus-related hospitalisation data coded using the ICD-10-AM system is reasonably specific; however misclassification of hospitalisations due to rotavirus by using incorrect or less specific coding is common. More work assessing the validity of ICD-10-AM codes is required.

AEFI

- There are a diverse range of approaches to passive surveillance employed by jurisdictions across Australia. This leads to differences in the quality, accuracy and timeliness of AEFI reports leading to discrepancies in aggregated data. There is a need to develop a nationally coordinated, uniform approach to AEFI reporting, coding and collation and improve the timeliness, completeness and analysis of data reported to the TGA.
- Active surveillance mechanisms have provided critically important data for monitoring the impact of the national rotavirus immunisation program. However, current systems (APSU and PAEDS) lack sustainability, national representativeness and data completeness. These need to be addressed in order for such systems to continue to provide vital surveillance data.
- Active surveillance for intussusception is in place. However, it is often under-reported with limited surveillance data from the vaccine era. Data are needed from ongoing active surveillance programs for IS to further explore any possible relationship between IS cases and the age at vaccination, dose and type of vaccine.

Coverage

- Coverage estimates from the ACIR are consistently high though under estimate actual levels of coverage. Although there is evidence that some vaccines are under reported, this has not been determined for rotavirus vaccine. Validation studies of reporting of rotavirus vaccine to the ACIR could be considered.

CHAPTER 4. Immunisation coverage

Aim

To examine impact of age cut-offs and different dose numbers on coverage for rotavirus vaccine, the timeliness of rotavirus vaccines and impact of this vaccine on timeliness of other vaccines given at the same schedule points.

Methods

Immunisation data were obtained from the ACIR.⁹⁵ Analyses of ACIR data, as at 30 June 2009, were undertaken on two birth cohorts of children. The first cohort, children born between 1 October 2007 and 31 March 2008, are a birth cohort born from 3–9 months after rotavirus vaccine was introduced onto the NIP schedule. The second cohort, children born between 1 October 2008 and 31 March 2009, are a birth cohort born 15–21 months after introduction of rotavirus vaccine on the NIP. A comparison of coverage by jurisdiction and Indigenous status was also made. Coverage and the timeliness of the administration of 1, 2 and 3 doses of rotavirus vaccine was assessed, depending on which rotavirus vaccine was used in a particular jurisdiction. An assumption was made that children residing in Rotarix[®]-using jurisdictions only received the Rotarix[®] vaccine and children residing in RotTeq[®]-using jurisdictions only received the RotTeq[®] vaccine.

Using the cohort born between 1 October 2007 and 31 March 2008, a thematic national map of coverage for 2 doses of rotavirus vaccine assessed at 12 months of age by ABS-defined Statistical Subdivisions (SSD)⁹⁶ was produced to describe any variations in rotavirus vaccine coverage across Australia. ABS-defined SSD was chosen as the mapping area because each is small enough to show differences within jurisdictions but not too small to render maps unreadable.

Timeliness of immunisation with respect to the upper age cut-offs that apply to both rotavirus vaccines was assessed by jurisdiction. The first dose of Rotarix[®] should be given by the end of the 14 week of age, and the second dose given by the end of the 24th week of age. The interval between the 2 doses should not be less than 4 weeks. The first dose of RotaTeq[®] should be given by the end of the 12th week of age, the second dose should ideally be given by the end of the 28th week of age though both the 2nd and 3rd doses should be given by the end of the 32nd week of age. The interval between doses should be 4 to 10 weeks.³³

Indigenous status on the ACIR is recorded as 'Indigenous' (Aboriginal and Torres Strait Islander), 'non-Indigenous', or 'unknown', as reported by the child's carer to Medicare, or by the immunisation provider to the ACIR. For this report we considered two categories of children: 'Indigenous' and 'non-Indigenous', combining children with unknown Indigenous status and those

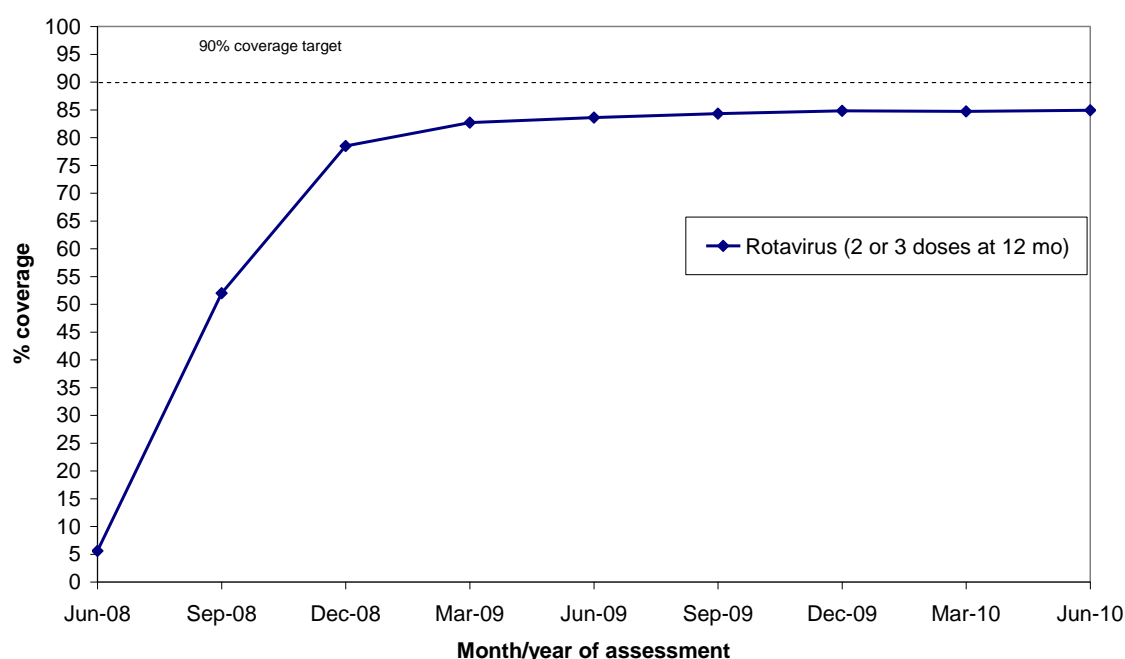
recorded as 'non-Indigenous' for the latter category. The completeness of Indigenous status recording has progressively improved since 2002.⁹⁷

Results

National program

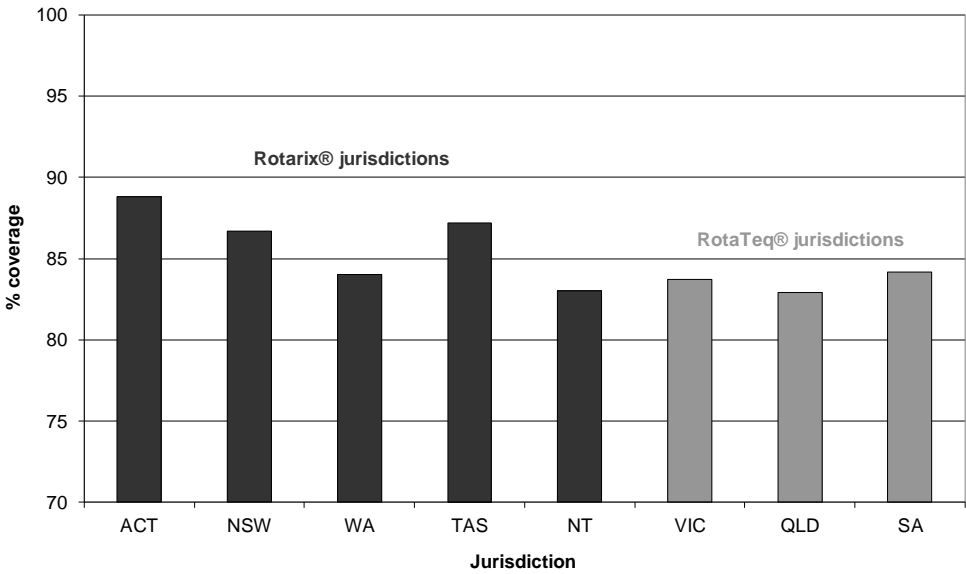
Vaccination uptake for the national rotavirus immunisation program was rapid with 80% of children aged 12 months receiving 2 or 3 final doses (depending on brand) of rotavirus vaccine by the third eligible 3-month cohort. However, due to the strict upper age cut-offs in place for this vaccine, a ceiling has been reached in coverage at just below 85%. The trend in final dose rotavirus vaccine coverage is shown in **Figure 1**.

Figure 1. Trends in rotavirus coverage



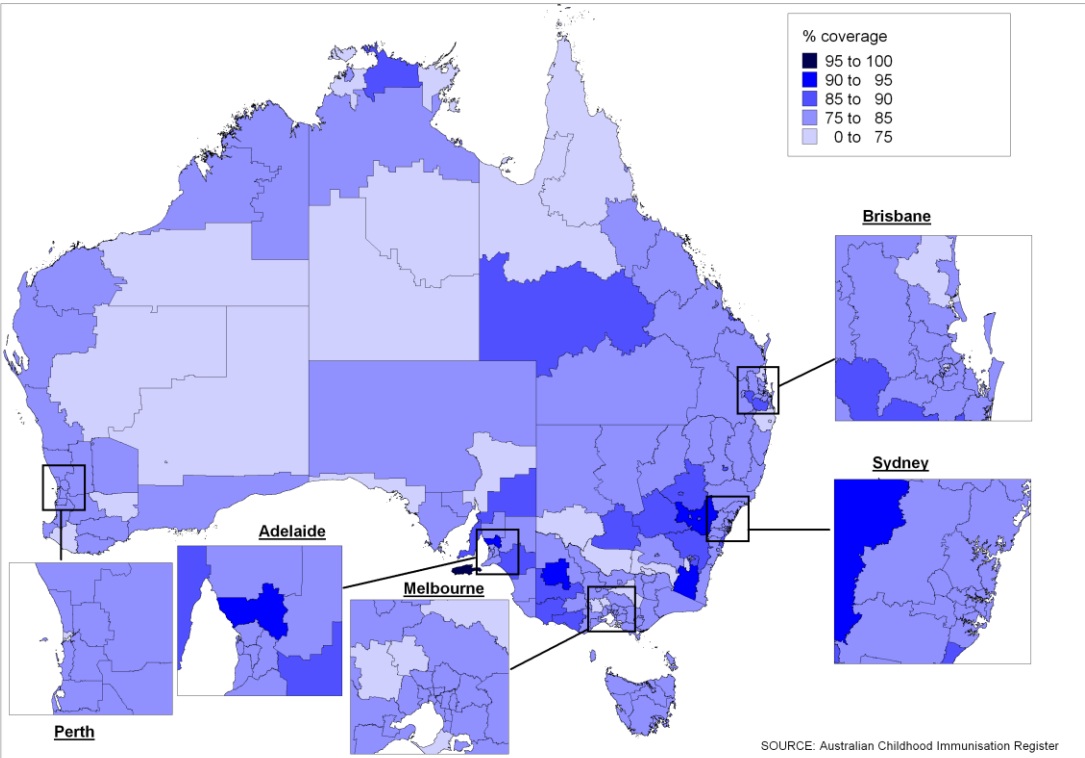
Final dose vaccination coverage estimates (as at June 2010) for rotavirus vaccine at 12 months of age by jurisdiction for the cohort born 1 October 2008 to 31 March 2009 are shown in **Figure 2**. Final dose rotavirus coverage in RotaTeq[®] jurisdictions was slightly lower than coverage in Rotarix[®] jurisdictions in all but one jurisdiction. This was to be expected with RotaTeq[®] requiring 3 doses to complete the schedule, while Rotarix[®] only requires 2 doses. The average final dose coverage for Rotarix[®] jurisdictions is 86% which is slightly higher than that for RotaTeq[®] jurisdictions at 84%.

Figure 2. Final dose rotavirus coverage by jurisdiction, cohort born October 2008 – March 2009



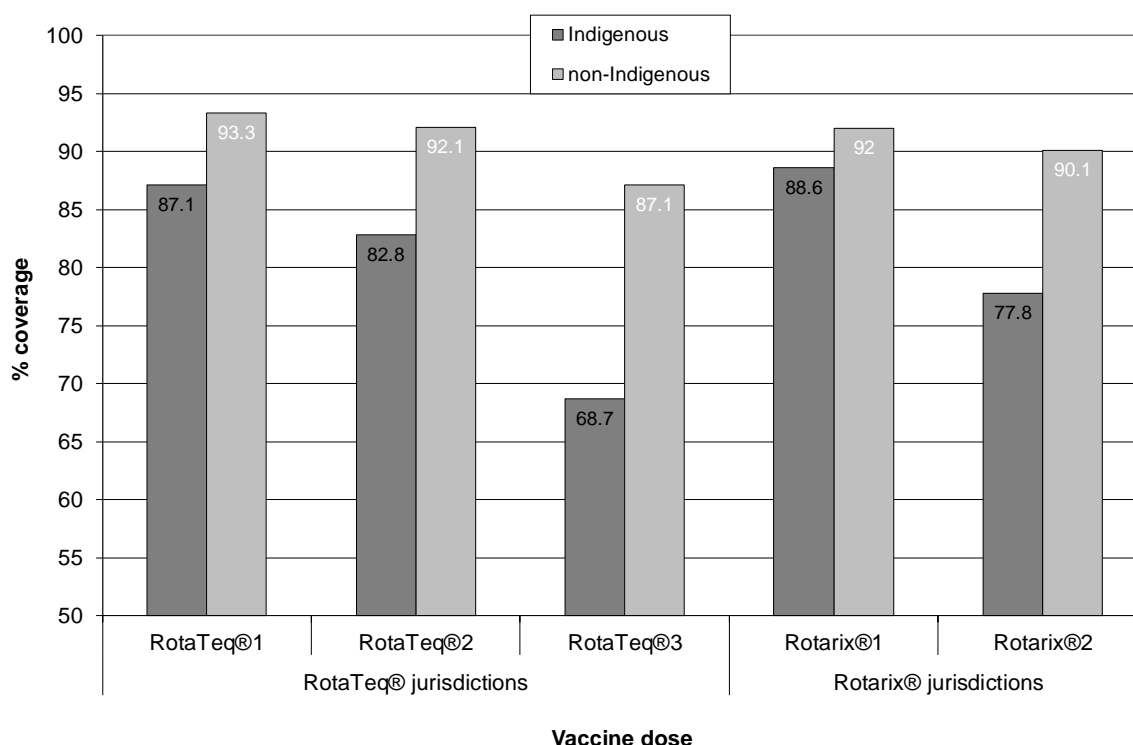
The spatial distribution of vaccination coverage for at least 2 doses of rotavirus vaccine by 12 months of age for the ‘post-rotavirus’ cohort is shown on the map in **Figure 3**. It demonstrates that there is variation in rotavirus coverage across Australia and within states and territories and it appears that areas of low coverage exist within capital cities of Australia.

Figure 3. Vaccination coverage for the final dose of rotavirus vaccine* by 12 months of age by Statistical Subdivisions, post-rotavirus cohort, Australia



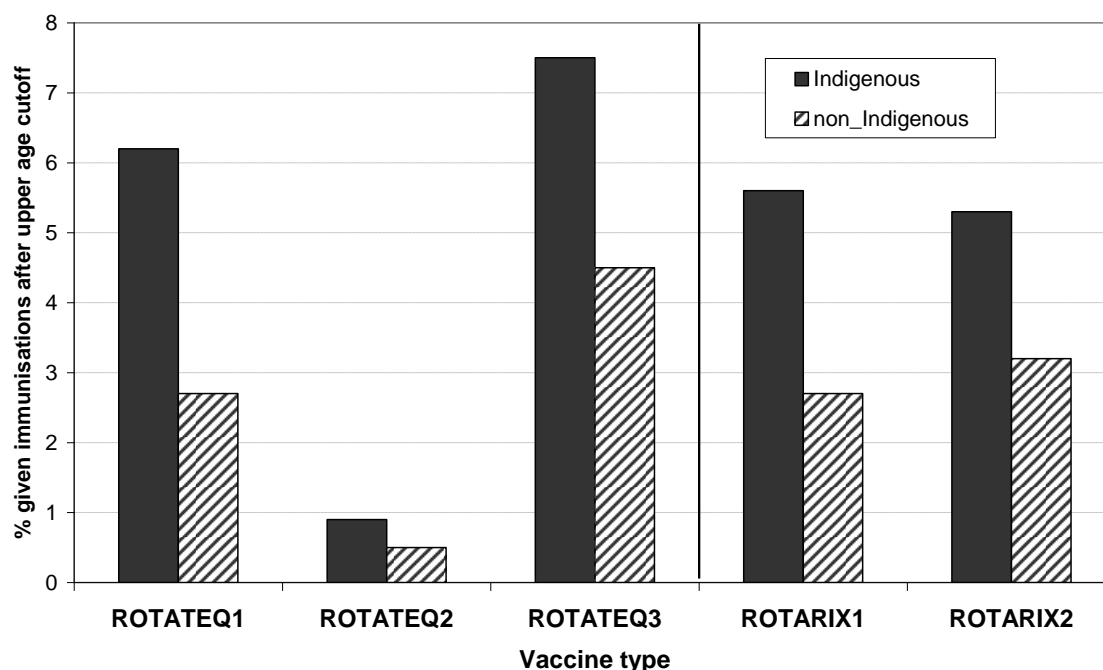
For all doses of rotavirus vaccine, coverage is lower for Indigenous children than non-Indigenous children with the difference greatest for the third dose of RotaTeq® vaccine, at 18% (**Figure 4**). Coverage of the first dose of either brand of vaccine is similar for Indigenous and non-Indigenous children; however, disparities between the two groups increase with subsequent doses. This may be due to a less timely presentation for vaccination as children get older and due to the upper age limits for rotavirus vaccine, where older children who present late may not be eligible to receive this vaccine.

Figure 4. Coverage for rotavirus vaccine by dose number and Indigenous status



The percentage of children given rotavirus vaccination after the upper age limit by Indigenous status is shown in **Figure 5**. For all rotavirus doses, the percentage of children given vaccination after the upper age limit was considerably greater for Indigenous children than non-Indigenous children. For both Indigenous and non-Indigenous children, the percentage given rotavirus vaccine after the upper cut-off was greatest for the third dose of RotaTeq® vaccine (**Figure 5**). However, our data also show that rotavirus vaccine are being administered after the upper age limits, especially to Indigenous children.

Figure 5. The percentage of children given rotavirus vaccination after upper age limit by vaccine type, dose and Indigenous status



A comparison of timeliness of the third dose of paediatric diphtheria, tetanus, pertussis (DTP) vaccination between the 'pre-rotavirus' cohort and the two 'post-rotavirus' cohorts is shown in **Figure 6**. It shows that timeliness at 7 months of age improved 2.7 percentage points from pre to post introduction of rotavirus vaccine. A similar improvement was seen for the third dose of 7vPCV vaccine (not shown). There was little difference in the timeliness of the third dose of DTP vaccine between the 'pre-rotavirus' cohort and the 'post-rotavirus' cohort for RotaTeq[®] states and territories versus Rotarix[®] states and territories, 2.8 percentage points and 2.3 percentage points, respectively (not shown). The impact on timeliness of the third dose of paediatric DTP vaccination on two categories of vaccination delay: delay of 1-6 months; and delay greater than 6 months is depicted in **Figure 7**. It shows that a higher proportion of Indigenous children experience vaccine delay than non-Indigenous children, especially long delay greater than 6 months. However, these levels did decrease substantially from the pre to the post rotavirus introduction period for both Indigenous children and, to a lesser extent, non-Indigenous children.

Figure 6. Comparison of the timeliness of the third dose of DTP, pre-rotavirus introduction versus post-rotavirus (includes non-immunised children in denominator)

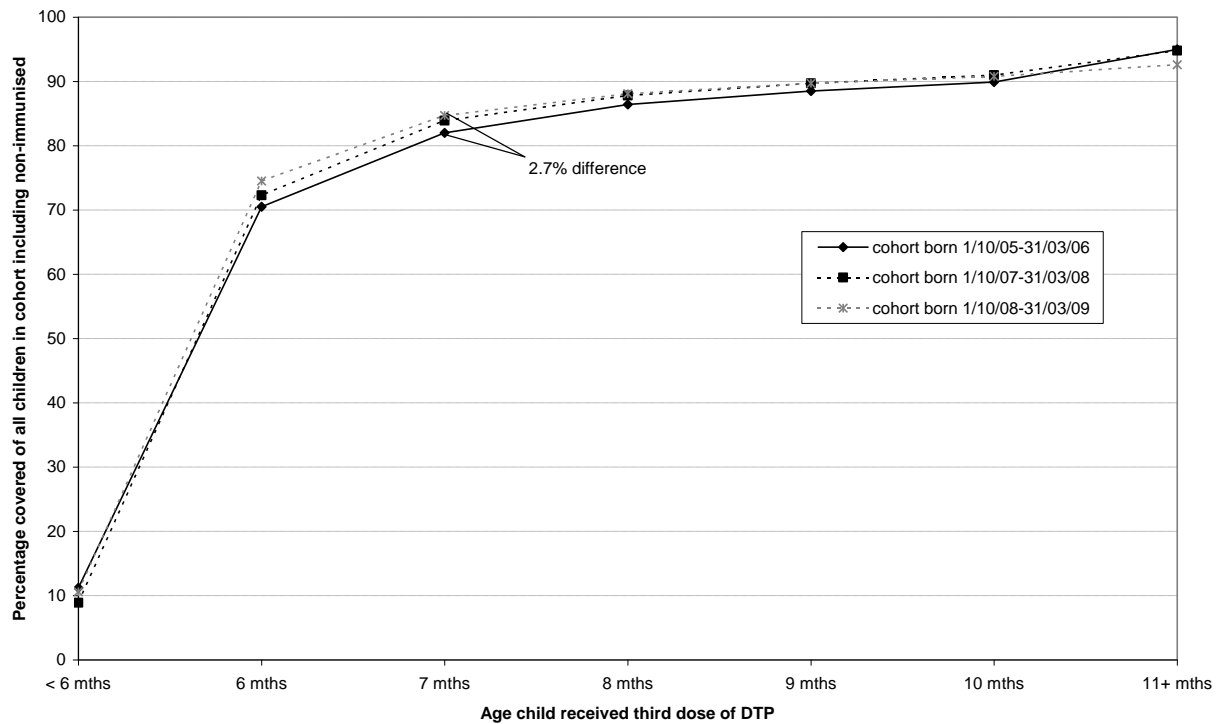
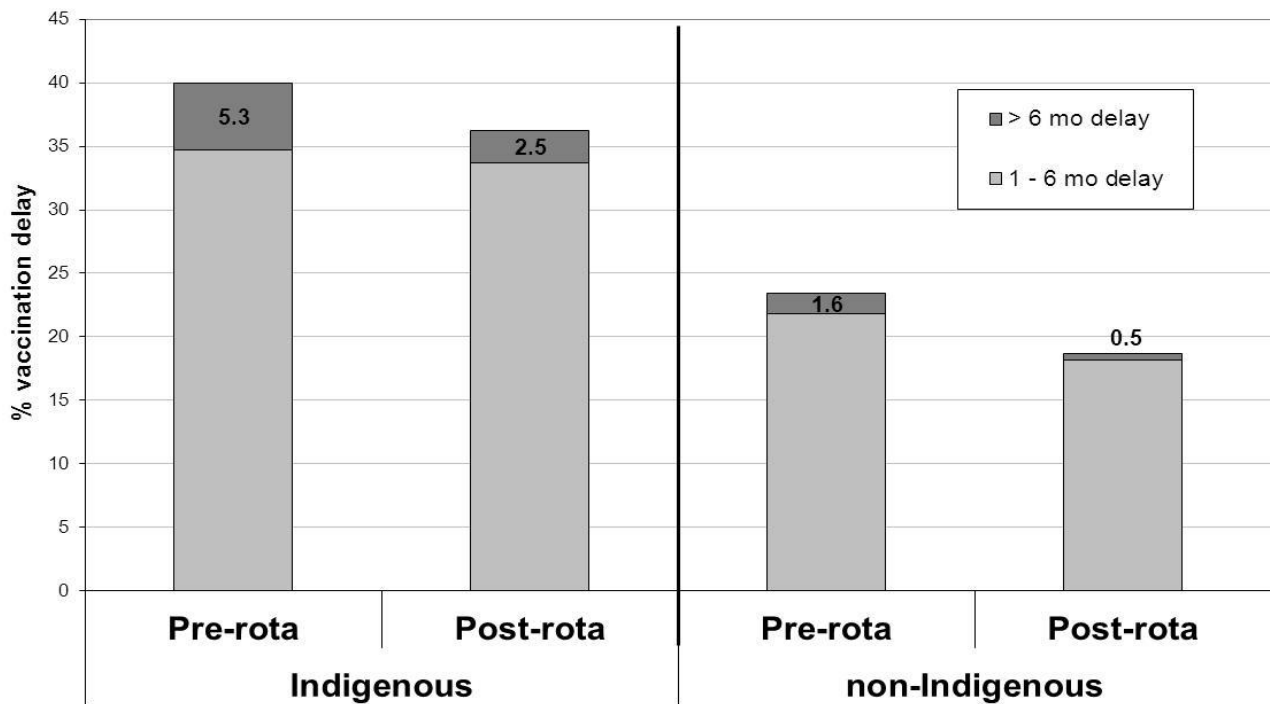


Figure 7. The percentage of all children with vaccination delay for DTPa-containing vaccine by Indigenous status, pre and post introduction of rotavirus vaccination



International programs

Since 2006, rotavirus vaccine has been introduced in a small number of developed countries and a considerable number of developing countries as recommended by the WHO.²¹

The WHO-UNICEF estimates annual final dose rotavirus coverage (2006–2009) for 19 countries including Australia.⁹⁸ There is considerable variation in coverage reported which may be due to the funding, service delivery and surveillance mechanisms in each country. However WHO-UNICEF has considered potential biases, and enlisted contributions from local WHO experts in an attempt to determine the most likely true level of vaccination coverage. In general there is a trend of maintenance or increased coverage in countries where the vaccine has been provided for a number of years. In particular, coverage in developed countries in the second or third year of an immunisation program is comparable to or better than that achieved in the first year of these programs.⁹⁸

Table 11 provides a summary of available coverage estimates published by other countries.

Table 11. Rotavirus program implementation and coverage achieved, selected countries.

	Program	Vaccine	Funding	Measures	Cohort/s	Coverage (year)
Belgium ⁹⁹	November 2006 (Rotarix®) June 2007 (RotaTeq®)	Rotarix® RotaTeq®	Government co-payment funds 80% of vaccine cost.	Numerator – estimated from national sales figures with the assumption that all children received full vaccine course. Denominator – number of newborn children in the period.	January 2007 to December 2009	National average – 88.4% of all newborns in the cohort.
United States ¹⁰⁰	February 2006	Rotarix® RotaTeq®	Advisory Committee on Immunization Practices (ACIP) recommended but not government funded in all states.	Site specific coverage with ≥1 dose rotavirus vaccine. Numerator – doses reported to Immunization Information System (IIS) sentinel sites (n=8). Denominator – number of same-aged infants enrolled at each site.	June 2006 to June 2009	Children aged 5 months 72% (average over all IIS sites 2006–2009)
Mexico ¹⁰¹	May 2007	Rotarix®	Ministry of Health purchases vaccine for Mexican infants through various healthcare institutions.	Numerator – annual number of doses administered by CENSIA ^a Denominator – eligible birth cohort receiving vaccine purchased through CENSIA.	February 2006 to December 2007 ^b	Children aged ≤11 months dose 1 – 74% dose 2 – 51% Children aged 12–23 months dose 1 – 4% dose 2 – 2%
Israel ¹⁰²	Late 2007	Rotarix® RotaTeq®	No government funding. Both vaccines available for private purchase through health maintenance organisations (HMOs) with partial reimbursement up to 50% by health insurance.	Data on rotavirus vaccine purchases were obtained including information on vaccine type, number of doses and date of first dose purchase.	Infants aged <12 months during the study period. September 2007 to April 2009	Total doses purchased = 19,108 % total by brand Rotarix® = 92.1% RotaTeq® = 7.9% Coverage with one dose April 2008 = ~10% April 2009 = 55%

a. National Centre for Child and Adolescent Health (CENSIA) purchase vaccine for 50% of Mexican infants.

b. Children aged ≤11 months and 12–23 months at the end of 2007.

Discussion

Rotavirus vaccine was rapidly and swiftly incorporated into the NIP with coverage reaching 80% in less than a year. Although vaccination coverage was good at approximately 85% nationally it was not as high as for existing vaccines due at the same schedule point which have reached levels greater than 90%.¹⁰³ This has also been seen in the United States, where coverage in children aged <5 months estimated from Immunization Information System sentinel sites was 72% for rotavirus, 13% lower than coverage for both DTPa and 7vPCV.¹⁰⁰

Lower coverage could reflect typical new-vaccine coverage dynamics, the presence of vaccine-specific barriers or both. One such vaccine-specific barrier is the strict upper age limits for the rotavirus vaccine, where vaccination is not recommended for a child who is older than the stated age limits. These strict upper age cut-offs have resulted in a plateau in coverage for rotavirus vaccine at just below 85%. With such limits in place it may be difficult to reach levels of coverage achieved for other vaccines. Timeliness of rotavirus vaccine delivery is very good with 95%–99% of doses given before the upper age limits that apply. Again, the upper age limits in place for rotavirus vaccine is a likely explanation for this result.

The impact that the introduction of rotavirus vaccines may have had on the timeliness of another vaccine given at the same age was also examined. In the period since introduction of rotavirus vaccines onto the Australian NIP a small but consistent 3% improvement in population coverage for receipt of the third dose of DTP vaccine by 7 months of age was demonstrated. In addition, there were decreases in the proportion of children who experienced long vaccination delay for the third dose of DTP vaccine, particularly amongst Indigenous children. Of note, timeliness of vaccination for Indigenous children was still poorer than for non-Indigenous children. Although the study design cannot directly determine if the improvement in both the overall timeliness and percentage of children with delayed administration of this concomitantly administered vaccine resulted from rotavirus vaccine introduction, there were no other changes to the infant schedule, such as vaccine dose variations or changes in combination vaccines, during the two observation periods, that might be postulated to account for the improvement in DTP coverage. In addition, infant vaccine coverage and timeliness had been stable in the six years prior to rotavirus vaccine introduction, including for almost two years following the introduction of hexa- and penta-valent DTPa-containing combination vaccines in 2005 and prior to rotavirus vaccine introduction in 2007.

Although coverage for dose 1 and 2 of rotavirus vaccine obtained from the NT Immunisation Database was thought to be low, it is comparable to the ACIR final dose coverage in other jurisdictions. Dose 1 coverage for NT Indigenous and non-Indigenous children born in 2007 and 2008 is higher than final dose coverage for the NT as measured by the ACIR. However dose-specific coverage from the NT highlighted the gap in coverage between Indigenous and non-Indigenous children, which was also evident in the analysis of ACIR data nationally. This may be due to a less timely presentation for vaccination as children get older, which occurs more in

Indigenous children than non-Indigenous children. Due to strict upper age limits for rotavirus vaccine, older children who present late may not be eligible to receive this vaccine.

Australia was one of the first developed countries to introduce a nationally funded rotavirus immunisation program with a geographical split in vaccine brand used and is one of the only countries with nationally representative coverage estimates.^{95,104} Population-based coverage for rotavirus vaccine has been scarcely reported in the published literature as illustrated in **Table 11**. This may be due to the challenges in gaining representative population estimates of vaccination coverage to measure program impact and allow appropriate comparisons between countries. Of the data available, final dose coverage achieved in Australia is markedly better than other countries with established rotavirus vaccination programs^{98,99,101} including the US where current population-based coverage estimates are well below that seen in any one Australian jurisdiction.¹⁰⁰ It is also comparable to reported coverage in countries where the program is universally funded in part by government (i.e. Belgium) and better than countries where the vaccine is not universally funded by government (i.e. Israel).

Conclusion

Uptake of rotavirus vaccine increased rapidly at the commencement of the national rotavirus immunisation program and has been maintained. However, coverage for this vaccine is lower than other vaccines given at the same schedule point due to strict upper age limits which decrease achievable coverage for rotavirus vaccine. The strict upper age limits for rotavirus vaccine have had a minor impact on improving the timeliness of other vaccines given at the same schedule points with very few rotavirus doses recorded on the ACIR administered outside the strict upper age limits.

Coverage is marginally higher for Rotarix[®] than with RotaTeq[®], possibly due to fewer number of doses required to complete the schedule for Rotarix[®]. Indigenous children have substantially lower coverage than non-Indigenous children, as they are likely to be more affected by the strict upper age limits due to delayed vaccination. However, for the general population, rotavirus vaccine coverage in Australia is high by international standards.

CHAPTER 5. Adverse events following immunisation

Aims

1. To summarise Australian passive surveillance data for adverse events following immunisation reported to the Therapeutic Goods Administration (TGA) for rotavirus vaccine and describe reporting trends.
2. To determine national level of ICD-coded hospitalised cases of Intussusception and provide brief overview of other investigations into AEFI with rotavirus vaccine conducted in Australia,

Methods

De-identified information on all AEFI reports were released to NCIRS from the Office of Medicine Safety Monitoring (OMSM) database by the TGA. AEFI records contained in this database were eligible for inclusion in the analysis if a vaccine was recorded as 'suspected' of involvement in the reported adverse event. That is, sufficient basic information are provided and not excluded as biologically implausible.

AEFI were defined as 'serious' or 'non-serious' based on information recorded in the ADRS database and criteria similar to those used by the World Health Organization⁷¹ and the US Vaccine Adverse Events Reporting System (VAERS).⁷³ In this report, an AEFI is defined as 'serious' if the record indicated that the person had recovered with sequelae, been admitted to a hospital, experienced a life-threatening event, or died.

The causality ratings of 'certain', 'probable' and 'possible' are assigned to individual AEFI records by the TGA. They describe the likelihood that a suspected vaccine or vaccines was/were associated with the reported reaction at the level of the individual vaccine recipient. Factors that are considered in assigning causality ratings include the timing (minutes, hours etc) and the spatial correlation (for injection site reactions) of symptoms and signs in relation to vaccination, and whether one or more vaccines were administered. However, in many instances a causal association between vaccines administered to an individual and events that subsequently occurred cannot be clearly ruled in or out. In addition, children in particular often receive several vaccines at the same time. Therefore, all administered vaccines are usually listed as 'suspected' of involvement in a systemic adverse event as it is usually not possible to attribute the AEFI to a single vaccine.

Data from the National Hospital Morbidity Database provided by the Australian Institute of Health and Welfare (AIHW) were utilised to identify and analyse ICD-coded hospitalised cases of

Intussusception. Hospitalisations coded as K56.1 (intussusception) in any diagnostic code were included in the analysis.

National hospitalisation rates for IS were calculated for children aged <24 months from 1st July 1998 to 30th June 2007 and compared with hospitalisation rates from 1st July 2007 to 30th June 2009. Periods were selected to include only ICD-10-AM coded admissions to avoid potential coding variations with the earlier ICD-9-CM. Incidence rate ratios (IRR) and 95% confidence intervals (CI) were calculated for each IRR.

Hospitalisations were also compared by birth-cohorts. The cumulative incidence of hospitalisations in children aged <12 months were grouped into three pre-vaccine cohorts (born 1 July 1999 – 30 June 2003, 1 July 2003 – 30 June 2005, and 1 July 2005 – 30 June 2007) and compared to one post-vaccine cohort (born 1 July 2007 – 30 June 2008). Data on the later post-vaccination cohort (born 1 July 2008 – 30 June 2009) were not complete and not included.

All analyses were performed using SAS software version 9.1.3.¹⁰⁵ The distribution of AEFI records was analysed by age, gender and jurisdiction. Average annual population-based reporting rates were calculated for each state and territory and by age group using population estimates obtained from the ABS. AEFI reporting rates per 100,000 administered doses were estimated using data from the ACIR.

Results

Australian passive surveillance data reported to the TGA

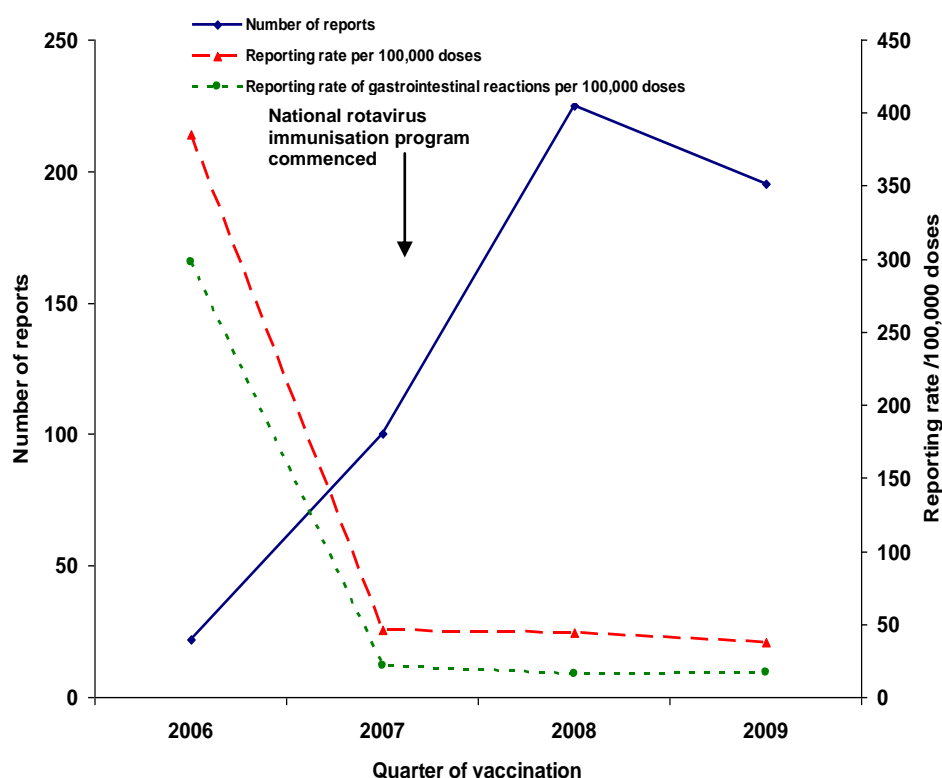
There were a total of 553 reports of adverse events following receipt of rotavirus vaccine during the 2006–2009 period. The overall reporting rate for the 2006 – 2009 period was 41.6 per 1000 doses. The majority (98%, n=542) of these reports were from children aged <1 year, while only 2% (n=11) were for children aged 1 to <7 years. As expected, the majority (85%) of the AEFI following rotavirus vaccine also listed other vaccines as suspected of involvement in the reported adverse event, as most infants receive rotavirus vaccine at the same time as other scheduled vaccines at 2, 4 and 6 months of age.

A total of 21% (n=116) of records listed outcomes defined as ‘serious’ (i.e. recovery with sequelae, hospital admission or prolonged hospitalisation, life-threatening event or death). These included reports of life-threatening events (n=5), hospital admissions (n=111) although there were no reported deaths. The five reports of life-threatening events following vaccination included three reports which resulted in intussusception and where the child received only rotavirus vaccine; one report vaccinated with hexavalent (DTPa/Hib/HepB/IPV), 7vPCV and rotavirus resulting in apnoea, bradycardia and seizures; and one report vaccinated with DTPa/IPV, 7vPCV and rotavirus resulting in hypotonic-hyporesponsive episode (HHE).

Six per cent of all records had causality ratings of either 'certain' (3%) or 'probable' (3%), while 94% were coded as 'possible'.

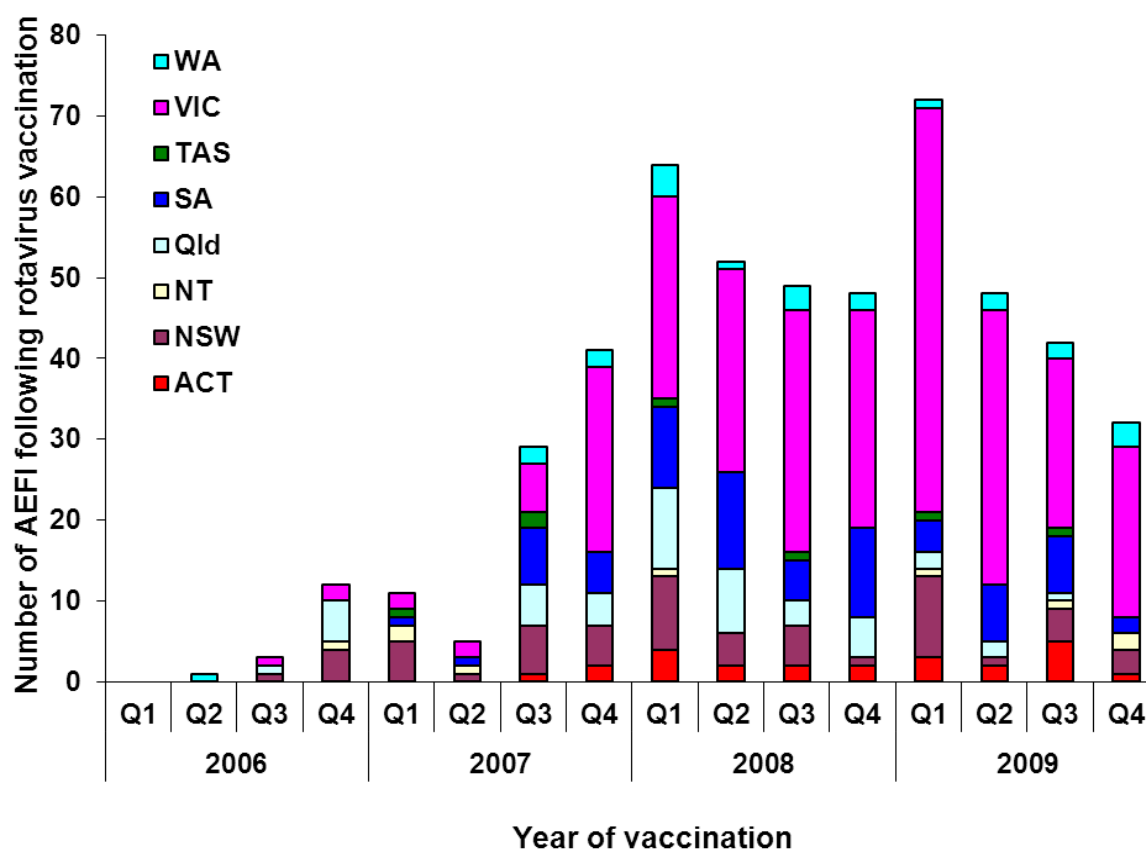
Figure 8 shows trends over time in the number of AEFI reported following rotavirus vaccine. The number of reports for children <1 year of age peaked in 2008 (n=225) following the commencement of funded rotavirus vaccination in October 2006 in the NT and in July 2007 nationally. Hence, the peak in 2008 appears to be partly due to the first full calendar year of rotavirus vaccine use after its inclusion in the NIP, as well as the first full year of enhanced passive surveillance in Victoria. **Figure 9** shows the total number of adverse events following rotavirus vaccination in various jurisdictions for <1 year olds. The majority of the cases (49%) were reported from Victoria, followed by South Australia (13%) and NSW (11%). The increased reporting from Victoria is congruent with the implementation of enhanced surveillance in Victoria from April 2007.

Figure 8. Reports of adverse events following rotavirus vaccination for <1 year olds, TGA database, 2006 to 2009, by quarter of vaccination



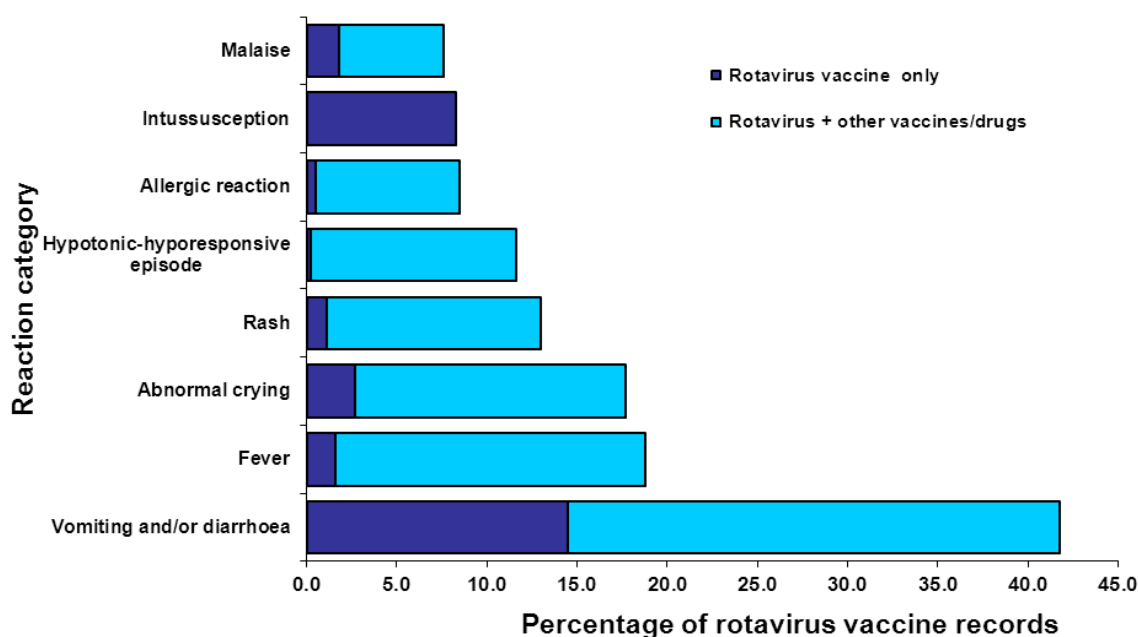
* The arrow indicates the commencement of the funded national rotavirus immunisation program in July 2007.

Figure 9. Total number of adverse events following rotavirus vaccination by jurisdiction for <1 year olds



AEFI recorded with the TGA and listed in *The Australian Immunisation Handbook* 9th edition are shown in **Table 12** and **Figure 10**. **Table 13** shows AEFI included on the database that are not listed in *The Australian Immunisation Handbook* 9th edition. The top section of the table lists those AEFI comprising more than 1% of reports, and the bottom section those comprising less than 1%, grouped by organ system. The majority of AEFI reported for the rotavirus vaccine were mild transient events. The most commonly reported AEFI were gastrointestinal symptoms predominantly diarrhoea and vomiting (42%), followed by fever (19%), abnormal crying (18%), and rash (13%). Severe AEFI included one report each of anaphylaxis and syncope, 64 reports (12%) of HHE, 43 (8%) of intussusception and 19 (3%) of convulsion (**Table 12**; **Figure 10**).

Figure 10. Most frequently reported adverse events following rotavirus immunisation,* TGA database, 2006 to 2009, by number of vaccines suspected of involvement in the reported adverse event



* Percentage of 553 AEFI records where rotavirus vaccine was listed as suspected of involvement in the reported AEFI.

Table 12. Adverse events following immunisation (AEFI) reported for rotavirus, TGA database, 2006 to 2009, grouped by *The Australian Immunisation Handbook* 9th edition

Reaction	Number	Per cent	age <1 years	age >1 years
Gastrointestinal reaction*	231	42	227	4
Fever	104	19	101	3
Abnormal crying	98	18	95	3
Rash	72	13	70	2
Hypotonic-hyporesponsive episode	64	12	64	0
Allergic reaction†	47	9	47	0
Intussusception	43	8	41	0
Convulsions	19	3	18	1
Anorexia	16	3	16	0
Orchitis	2	0.4	2	0
Anaphylaxis	1	0.2	1	0
Lymphadenitis	1	0.2	1	0
Thrombocytopenia	1	0.2	1	0
Syncope	1	0.2	1	0
Total‡	553	100	542	11

* Gastrointestinal symptoms of vomiting or diarrhoea, with or without other symptoms or signs of an allergic reaction as defined in *The Australian Immunisation Handbook* 9th edition.

† Allergic reaction involving the respiratory and/or circulatory system but not coded as anaphylaxis.

‡ Total number of AEFI records analysed, not the total in each column as categories are not mutually exclusive and an AEFI record may list more than one reaction term.

Table 13. 'Other'* reaction terms reported for rotavirus vaccine, TGA database, 2006 to 2009

Reaction	Number	Per cent	age <1 year	age >1 year
Malaise	42	8	41	0
Resp. rate/rhythm change	39	7	38	1
Somnolence	33	6	31	2
Pallor	26	5	26	0
Erythema	21	4	20	1
Heart rate or rhythm change	8	1	8	0
Oedema	5	1	5	0
Other reactions	88	16	87	1
Gastrointestinal	15	3	15	0
Metabolic and endocrine	13	2	13	0
Cardiovascular	12	2	12	0
Infections	9	2	8	1
Eye or ear	7	1	7	0
General	6	1	6	0
Neurological	6	1	6	0
Respiratory	6	1	6	0
Skin	5	1	5	0
Renal/urinogenital	4	1	4	0
Haematological and immune	2	0.4	2	0
Psychological	2	0.4	2	0

* Reaction terms not listed in *The Australian Immunisation Handbook* 9th edition but included in AEFI records in the ADRAC database. The top part of the table shows reaction terms included in 1% or more of AEFI records; the bottom part of the table shows reaction terms grouped by organ system that were included in less than 1% of AEFI records.

The majority of reports included multiple vaccines, making any association with rotavirus difficult to interpret. Therefore, reports including only rotavirus were analysed separately. They comprised 15% (n=84) of the 553 records, out of which 36 AEFI records described only one reaction. The most frequently reported single reactions following vaccination with only rotavirus vaccine were gastrointestinal symptoms (n=19) and intussusception (n=12); others included rash (n=4), and one report of rectal haemorrhage.

Hospitalisation data on Intussusception

Hospitalisation rates appeared to decline in the pre-vaccine period (**Figure 11**), and increase transiently in 2006/2007 and 2007/2008. These trends were most pronounced in the <12 month age group (**Table 14**). In a comparison of 1998/1999 – 2006/2007 (pre-vaccine) with 2007/2008 – 2008/2009 (post-vaccine), an increased risk of IS hospitalisations was observed in children aged 1

to <3 months, and in all children aged <2 years (**Table 15**). There was no significantly increased risk in the 5-<7 month age group. Restricting the comparisons to single post-vaccination years resulted in a significantly elevated risk at 5-<7 months of age in 2007/2008 (IRR 1.34 (95% CI 1.02-1.74) but not in 2008/2009 (0.89, 95% CI 0.68-1.16). The IRR for the 1-<3 month age group was elevated in both years. The overall IRR for ages <2 years were significant in 2007/08 (1.20, 95% CI 1.06-1.36) but not in 2008/09 (1.06, 95% CI 0.95-1.18).

Figure 11. Intussusception coded hospitalisations in children less than 2 years, Australia, 1998 to 2009 (source: AIHW National Hospital Morbidity Database)

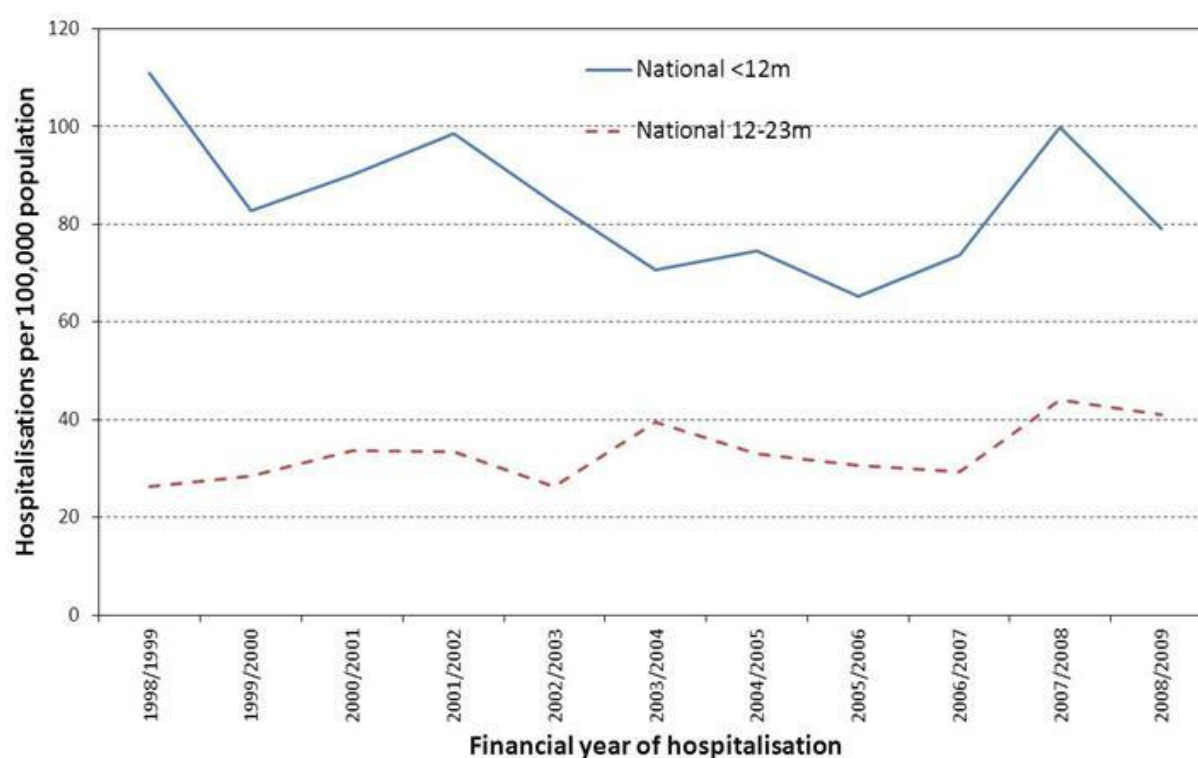


Table 14. Intussusception coded hospitalisations in children less than 1 year (excluding < 1 month), Australia, 1st July 1999 to 30th June 2007 (source: AIHW National Hospital Morbidity Database)

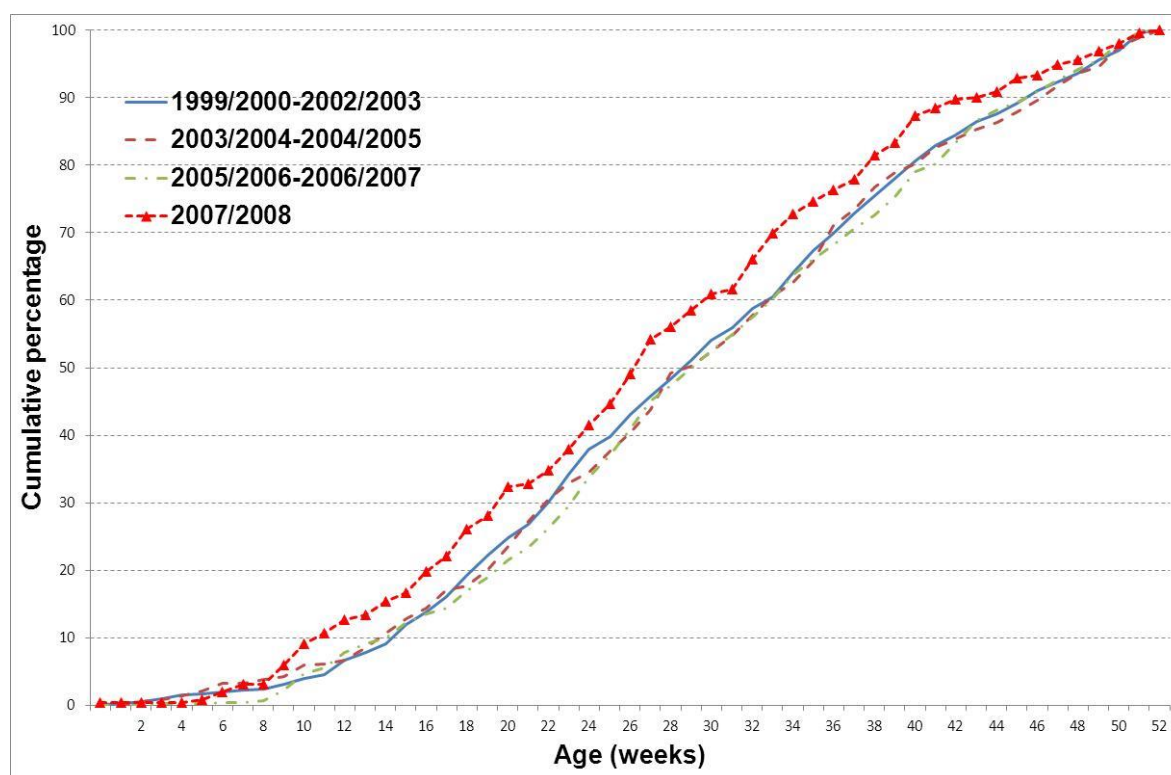
Year	1-<3 months Rate (95% CI)	3-<5 months Rate (95% CI)	5-<7 months Rate (95% CI)	7-<9 months Rate (95% CI)	9-<12 months Rate (95% CI)
1999/2000- 2000/2001	26.2 (16.4 -39.6)	98.7 (78.6-122.4)	149.9 (124.8-178.4)	115.4 (93.6-140.7)	79.3 (64.5-96.4)
2001/2002- 2002/2003	36.3 (24.5-51.8)	111.4 (89.8-136.6)	134.4 (110.5-161.8)	125.9 (102.9-152.5)	92.8 (76.6-111.4)
2003/2004- 2004/2005	23.6 (14.4-36.5)	80.2 (62.3-101.7)	106.2 (85.4-130.6)	113.3 (91.8-138.3)	71.6 (57.6-87.9)
2005/2006- 2006/2007	29.6 (19.5-43.1)	71.4 (55.1—90.9)	115.3 (94.3-139.5)	96.6 (77.5-119.0)	68.8 (55.6-84.2)

Table 15. Intussusception coded hospitalisations in children less than 2 years, Australia, 1998 to 2009 (source: AIHW National Hospital Morbidity Database)

Age group (months)	Pre-vaccine period 1st July 1998 to 30th June 2007	Post-vaccine period 1st July 2007 to 30th June 2009	Post-vaccine/ Pre-vaccine period Incidence Rate Ratio (IRR)	
	Rate per 100,000	Rate per 100,000	IRR	(95%CI)
1-<3	30.4	65.3	2.15	(1.58, 2.91)
3-<5	95.0	97.0	1.02	(0.81, 1.28)
5-<7	130.6	141.9	1.09	(0.90, 1.31)
7-<9	119.2	115.3	0.97	(0.79, 1.19)
9-<12	79.8	76.2	0.95	(0.78, 1.17)
0-<12	83.10	89.3	1.07	(0.98, 1.18)
0-<24	57.13	66.3	1.16	(1.07, 1.26)

The age distributions of IS hospitalisations aged <12 months were similar in three pre-vaccine cohorts. However, the single post-vaccination cohort for which data were available appeared to have a younger age distribution (**Figure 12**). The divergence between pre- and post-vaccination age distributions commenced from 10-12 weeks of age and remained relatively constant from then on.

Figure 12. Intussusception coded hospitalisations in children less than 1 year by birth cohorts, Australia, 1999 to 2008 (source: AIHW National Hospital Morbidity Database)



Discussion

The AEFI reporting rate for rotavirus vaccine was very high in 2008 (43.1 per 100,000 doses) mainly because of reports associated with rotavirus vaccine in the first full calendar year after its inclusion in the NIP as well as the implementation of a new AEFI reporting and evaluation system in Victoria in April 2007.¹⁰⁶ Historical data show that initial high levels of AEFI reporting occur each time a new vaccine is introduced (Meningococcal Conjugate Vaccine in 2003 and HPV in 2007) as immunisation providers are more likely to report milder, less serious AEFIs for vaccines they are not familiar with, followed by a reduction and stabilisation of reporting over time.

The profile of the adverse events reported in Australia following rotavirus vaccination are similar to those reported in Europe¹⁰⁷ with vomiting, abdominal pain and diarrhoea the most commonly reported events. In the years 2006–2009, there were 43 reports of intussusception following rotavirus vaccine to the TGA which was substantially lower than the 53 cases detected in a study by the APSU over a 10-month period.^{108,109} The majority (60%) of intussusception reports were in infants after dose 1 (2–3 months age group). The cases reported to TGA equate to a rate of 2.8 per 100,000 doses of rotavirus vaccine, similar to the reporting rate of intussusception in the US

passive surveillance system (VAERS) of 2.3 per 100,000 administered doses, and the rate in the US Vaccine Safety Datalink system from health care use data of 2.7 per 100,000 doses.¹¹⁰

However, two recent studies in Mexico found an increased risk of intussusception in infants following receipt of Rotarix that was most marked in the first seven days following dose 1 (approximately 4 fold increase in 1 study). Several recent studies in Australia have also found evidence suggestive of a post-rotavirus vaccination risk of intussusception in infants especially after dose 1 of rotavirus vaccines.¹⁰⁹⁻¹¹² The results of the APSU/PAEDS study suggested an increased rate of IS in Australian infants post dose 1 of both Rotarix[®] and RotaTeq[®]. According to this study, in infants 1 to <3 months of age, there was some evidence of an excess of observed cases following receipt of first dose of a rotavirus vaccine, with higher RRs in the 1–7day, compared to the 1–21 days, window for both vaccines. However, there was no evidence for any excess risk following dose 2 of either vaccine, however there was a lower than expected number of cases following dose 3 of RotaTeq[®]. On the basis of findings from APSU/PAEDS study, the TGA commissioned a study using ICD-coded hospitalisations for IS (non chart-reviewed) from NSW (Rotarix[®]) and Victoria (RotaTeq[®]) which found a similar risk of IS post dose 1 for both vaccines using data analysed by the Self Controlled Case Series method (SCCS). Further on, NSW Health commissioned NCIRS to perform a more detailed investigation into the clinical and epidemiological characteristics of infants who had been hospitalised in NSW with an ICD-coded diagnosis of IS, and to conduct statistical analyses to determine the risk of a confirmed diagnosis of IS post Rotarix[®] vaccine.

In September 2010, The World Health Organization (WHO) issued a *Statement on rotavirus vaccines and intussusception* that advised of the possibility of an increased risk of intussusception shortly after the first dose of rotavirus vaccination in some populations but also noted the substantial documented benefits of rotavirus vaccination. The CDC has also issued a *Statement regarding Rotarix[®] and RotaTeq[®] rotavirus vaccines and intussusception* which notes a low level of increased risk in some studies and supports the continued use of both vaccines in the USA.¹¹³

Australian ICD-coded IS hospitalisations should be interpreted with caution. A study in NSW has shown that only 72% of IS-coded hospitalisations in NSW from July 2007-June 2010 were confirmed as IS by chart review and application of Brighton criteria. (NCIRS-NSW Health report; unpublished data). There appear to be transient variations over time unrelated to rotavirus vaccination and the time period of post-immunisation data is limited. It is not possible to draw conclusions on whether or not there is an increase in hospitalisations attributed to rotavirus vaccinations.

Conclusion

There was a substantial increase in AEFI reported in 2008 partly due to this being the first full year of enhanced passive surveillance in Victoria, as well as reports associated with rotavirus vaccine in the first full calendar year after its inclusion in the NIP. This enhanced propensity to report newer vaccines increases the sensitivity of the system to detect signals of serious, rare or previously unknown events. The majority of AEFI reports were of mild, transient and well-recognised vaccine side-effects. It is important to emphasize that various Australian and international studies have found evidence suggestive of a risk of intussusception in infants' post-rotavirus vaccination especially after dose 1 of rotavirus vaccines. However, When compared with the illness prevented by these vaccines, this report demonstrates that the benefits of rotavirus vaccination outweigh the risks. The regular analysis and publication of national AEFI surveillance data collated in the OMSM database remains an important aspect of Australia's immunisation program.

Chapter 6. Disease epidemiology

Preface

This chapter explores the disease outcomes before and after the implementation of the national rotavirus immunisation program. Hospitalisations for rotavirus and non-rotavirus coded gastroenteritis were analysed to ascertain any changes in disease epidemiology following the program. Both rotavirus and non-rotavirus coded gastroenteritis hospitalisations were included since there was reported lack of sensitivity of rotavirus coding for hospital admissions resulting from misclassification of rotavirus hospitalisation by using incorrect or non-specific acute gastroenteritis codes.⁶⁰ The data source used for this analysis was hospitalisations from the National Hospital Morbidity Database from the AIHW. The other data sources (AIHW Mortality Database for deaths; the National Notifiable Diseases Surveillance System for notifications) did not have complete data available to assess the impact of the program. As mentioned in earlier chapters, rotavirus gastroenteritis is not a nationally notifiable disease and hence data from all states/territories were not available to assess the effect of the rotavirus immunisation program nationally. In addition, updated death data for rotavirus gastroenteritis is nationally available only until 2006 (i.e. before the national rotavirus immunisation program was implemented) and hence was considered not useful for determining the impact of the program. Please see Chapter 2: System description for more information.

In view of the constraints of the data sources described above, analysis of the impact of the national rotavirus immunisation program included data on hospitalisations coded as rotavirus and gastroenteritis not coded as rotavirus, and also available published Australian and international studies on rotavirus notifications, hospitalisations and vaccine effectiveness. This analyses was performed to determine any changes to national hospitalisation rates as previous studies in Australia have been from a local perspective and did not look at the national picture. Hence, there was a need to determine the national impact by comparing states and territories that used the two different brands of vaccines.

Aims

1. To review published Australian and international studies on rotavirus notifications, hospitalisations and vaccine effectiveness.
2. To determine any differences in hospitalisation rates of rotavirus and non-rotavirus coded gastroenteritis before and after the implementation of the national rotavirus immunisation program.

Methods

Published studies on vaccine effectiveness and the impact of the rotavirus immunisation programs on notifications, hospitalisations and deaths

Literature searches were done using Medline, Embase, CINAHL, Web of Science and PubMed to identify Australian and international studies on vaccine effectiveness and the impact of the program on hospitalisations, notifications and deaths and only major select studies were included in this evaluation.

Hospitalisations from the AIHW National Hospital Morbidity Database

Hospitalisations for rotavirus and non-rotavirus coded gastroenteritis cases with separation dates between 31 July 2001 and 30 June 2009 with an ICD-10–AM code of A08.0 (rotavirus enteritis), K52 and A01 to A09 excluding A08.0 (non- rotavirus acute gastroenteritis) were analysed. The chosen period of analyses allowed for adequately comparing the pre-vaccination versus the post-vaccination period. Both cases coded as rotavirus and gastroenteritis cases were included because previous Australian research has identified substantial differences in testing practices by states and territories.³⁹

For Indigenous status, data for only New South Wales, Victoria, Queensland, Western Australia, and South Australia was used from 2005 onwards since Indigenous identification was considered 'acceptable'.¹¹⁴ For the Northern Territory, hospitalisation data from 2001 onwards were analysed. The Northern Territory was separated from the other states/territories in analyses of Indigenous status due to an earlier start of the vaccination program and the markedly different rates and trends in the jurisdiction.

Hospitalisation rates were calculated using annual ABS population estimates. Age-specific rates were calculated where appropriate. Incidence rate ratios (IRR) were calculated to compare hospitalisation rates. Ninety-five per cent confidence intervals (CI) and p values were calculated for each IRR using a standard procedure in EpiBasic (University of Aarhus, Denmark). Variables were explored for possible associations using a chi square test for trend; a p value of 0.05 was considered statistically significant.

Results

Part 1: Published studies

International studies

Several studies from the United States, Belgium, Mexico and Nicaragua were identified that focused on the impact of the rotavirus immunisation programs (**Table 16**).^{99,101,115-119} In all the

selected international studies, post-vaccination hospitalisation rates were lower than the pre-vaccination hospitalisation rates for rotavirus gastroenteritis (**Table 16**).^{99,101,115-119} The decline in hospitalisation rates ranged from 35% to 83% across the different settings.

Vaccine effectiveness was also determined in some of the studies.^{99,116,118} The vaccine effectiveness, for preventing hospitalisation, for at least one dose of vaccine ranged between 94% to 97% dependent on the type of control (hospitalised or community controls) used in a case control study based in Connecticut, United States.¹¹⁶ Similarly, another study in Texas, USA, determined that the vaccine effectiveness ranged between 82% and 88% dependent on the source of the control data (immunisation information system or provider records) used for calculation of vaccine effectiveness.¹¹⁸ However, a Nicaraguan study found that the vaccine effectiveness also varied with the severity of rotavirus enteritis (46% to 77%) and found it most effective against very severe rotavirus diarrhoea.¹¹⁷

Australian studies

There were seven relevant Australian studies that reported pre-vaccination and post-vaccination outcomes following the national rotavirus immunisation program (**Table 17**).^{60,120-125} Rotavirus notifications declined by 53% in 2007 and 57% in 2008, compared with 2006, in Queensland.¹²² In addition, rotavirus gastroenteritis hospitalisation rates have substantially declined (75% to 93%) following the rotavirus immunisation program in several states/territories including Queensland, Victoria, New South Wales and South Australia.^{60,121,123,124} Also, hospitalisation rates for non-rotavirus coded AGE declined in the post-implementation period in the same states/territories.^{60,121,123,124} Vaccine effectiveness ranged from 85% to 94% and was dependent on the type and doses of vaccine administered in studies conducted in Queensland and the Northern Territory.^{60,125} Furthermore, only one study specifically assessing non-hospitalised medical presentations (to an Emergency Department) for gastroenteritis and is an area that needs more study.¹²⁰

Rotavirus Strain Surveillance

Notifications data is currently not available nationally. However, since 1989, multi-centre hospital-based rotavirus strain surveillance has been implemented nationally.⁵² Prior to the roll out of the rotavirus immunisation program, from 1997 to 2007, rotavirus strain surveillance has shown that G1[P8] was the dominant serotype identified.⁵² The next common serotype was G9, seen in a quarter of strains characterised, followed by G3 and G4 that represented approximately 9% and 4%, respectively.⁵² The G2 strain had been reported only in a minority of cases in Australia from 1997 to 2007.⁵² In the post-implementation period, from July 2007 to June 2008, G1 still remained the dominant serotype, identified in 52% of all strains characterised, followed by G2, G3 and G9 identified in greater than 10% of specimens.¹²⁶ In the RotaTeq[®] states, G3 strains were more common, and G2 and G9 strains were more prevalent in Rotarix[®] states.¹²⁶ From July 2008 to June 2009, G2P[4] was the dominant serotype (seen in 50.3% of specimens) for the first time

nationally and more prevalent in Rotarix® states, whereas G1P[8] and G3P[8] were more common in states using RotaTeq®.⁴⁹ In the most recent reported period, from July 2009 to June 2010, G1P[8] was the dominant type (49.3%) followed by genotype G2P[4] (21.1%).¹²⁷

Table 16. Selected published international studies on the impact of rotavirus immunisation programs on rotavirus disease

Authors	Source & Year	Location	Study Design	Results
United States				
Evan Anderson, Angela Rupp, Stanford Shulman, Deli Wang, Xiaotian Zheng, Gary Noskin ¹²⁸	Pediatrics, 2011	Chicago, USA	Descriptive study of hospital acquired rotavirus (Ha-RV) and community acquired rotavirus (Ca-RV) infections from 1 Sep 2003 – 31 May 2008.	Ca-RV hospital admissions from 2003–2007 ranged from 1.21 to 1.87/100 admissions (median 1.61) 2007–2008 decreased to 0.28/100 admissions (83% reduction, $p < 0.001$) 2003-2007 rate of Ha-RV/1,000 patient days ranged from 0.46-0.66 (median 0.53). This decreased to 0.16/1,000 patient days in 2007–2008 (70% reduction, $p < 0.001$)
Sachin Desai, Daina Esposito, Eugene Shapiro, Penelope Dennehy, Marietta Vázquez ¹¹⁶	Vaccine, 2010	Connecticut, USA	Matched case-control study of rotavirus vaccine effectiveness Cases (n=42) were vaccine-eligible children 8 weeks–3 years of age, hospitalised due to laboratory-confirmed rotavirus gastroenteritis. They were matched to two control groups: (a) hospitalised controls (n=80): hospitalised for reasons other than RGE, matched to the cases by age and time of presentation (b) community controls (n=73): non-hospitalised children matched by age and medical practice	Adjusted VE against hospitalisation with RGE in vaccine-eligible children receiving at least 1 dose of vaccine was 94.3% (95% CI 55.4%–99.3%; $p = 0.006$) for hospitalized controls and 96.9% (95% CI 59.4%–99.8%; $p = 0.008$) for community controls.

Authors	Source & Year	Location	Study Design	Results
Leila Sahni , Julie Boom, Manish Patel, Carol Baker, Marcia Rench, Umesh Parashar and Jacqueline Tate ¹¹⁸	Vaccine, 2010	Texas, USA	<p>Case-control study of vaccine effectiveness of RV5 against rotavirus disease, June 2008.</p> <p>Vaccine effectiveness ((1-OR of vaccination)×100) was calculated using three comparison groups:</p> <ol style="list-style-type: none"> 1.patients with AGE who tested negative for rotavirus 2. patients with acute respiratory infection (ARI) symptoms 3. children selected from Houston-Harris County Immunization Registry (HHCIR). <p>Cases were children with AGE who had laboratory-confirmed rotavirus.</p>	<p>Among the 91% of case and control patients with immunisation records, 49% were in the IIS, and 97% had a provider record. Good agreement was observed across record sources ($\kappa=0.65$).</p> <p>VE was 82% using IIS data compared to 82–88% using provider data.</p> <p>Controls identified through the IIS provided VE estimates similar to hospital control patients.</p>
Catherine Yen , Claudia Steiner, Marguerite Barrett, Aaron Curns, Katherine Hunter, Emily Wilson & Umesh Parashar ¹¹⁹	Vaccine 2010	USA	<p>Descriptive study of racial disparities and hospitalisations.</p> <p>Retrospective analysis of hospitalisations from 2000 to 2008</p> <p>Diarrhoea-associated hospitalisations by race/ethnicity among children aged <5 years pre (2000–2006) and post-(2007–2008) rotavirus vaccine in 5 US states.</p>	<p>Pre-vaccine hospitalisation rates were greater among whites versus blacks and Hispanics. In 2008, racial disparities for children aged 12–35 months resolved, but higher hospitalisation rates among black infants aged <6 months persisted.</p>

Authors	Source & Year	Location	Study Design	Results
Other countries				
Mark Zeller , Mustafizur Rahman, Elisabeth Heylen, Sarah DeCoster, Sofie DeVos, Ingrid Arijis, Luis Novo, Natasha Verstappen, Marc Van Ranst, Jelle Matthijnsens ⁹⁹	Vaccine, 2010	Belgium	Descriptive study of hospitalisations at the Gasthuisberg University Hospital from 1986 to 2009	<p>Average % rotavirus positive cases out of all hospitalised gastroenteritis cases tested between 1986 and 2006 was 19.0%.</p> <p>This % dropped to 12.4%, 9.6% and 6.4% post-vaccine introduction (2006–2009), which is a decline of 34.7%, 49.4% and 66.3% respectively.</p> <p>The prevalence of the G2 serotype sharply increased in the 2006–2007 rotavirus season compared to the previous seasons and remained high (30–40%) in the 2007–2008 and 2008–2009 seasons.</p> <p>It is unclear if the predominance of G2 serotypes is related to the vaccine introduction, or if this is attributable to normal serotype fluctuations.</p>
Vesta Richardson , Joselito Hernandez-Pichardo, Manjari Quintanar-Solares, Marcelino Esparza-Aguilar, Brian Johnson, Cesar Misael Gomez-Altamirano, Umesh Parashar and Manish Patel ¹⁰¹	New England Journal of Medicine, 2010	Mexico	<p>Descriptive study of deaths from diarrhoea</p> <p>Deaths from diarrhoea, regardless of cause, from January 2003 to May 2009</p>	<p>There was a significant decline in diarrhoea-related deaths following rotavirus vaccination program.</p> <p>In 2008, there were 1,118 diarrhoea-related deaths among children <5 years of age, a reduction of 675 from annual median of 1,793 deaths (2003–2006). Diarrhoea-related mortality fell from an annual median of 18.1 deaths per 100,000 children at baseline to 11.8 per 100,000 children in 2008 (rate reduction, 35%; 95% CI 29 to 39; p<0.001).</p> <p>Among infants who were 11 months of age or younger, diarrhoea-related mortality fell from 61.5 deaths per 100,000 children at baseline to 36.0 per 100,000 children in 2008 (rate reduction, 41%; 95% CI 36 to 47; p<0.001).</p> <p>As compared with baseline, diarrhoea-related mortality was 29% lower for children between the ages of 12–23 months.</p>

Authors	Source & Year	Location	Study Design	Results
Manish Patel , Cristina Pedreira, Lucia Helena De Oliveira, Jacqueline Tate, Maribel Orozco, Juan Mercado, Alcides Gonzalez, Omar Malespin, Juan Jose Amador, Jazmina Uman a, Angel Balmaseda Maria Celina Perez, Jon Gentsch, Tara Kerin, Jennifer Hull, Slavica Mijatovic, Jon Andrus, Umesh Parashar ¹¹⁷	JAMA, 2009	Nicaragua	<p>Case–control study of vaccine effectiveness (VE) of RV5* for preventing hospitalisations.</p> <p>For each case, 2 groups of control children were selected – hospital and neighbourhood –individually matched to the case’s date of birth (±30 days)</p>	<p>Of the 285 rotavirus cases, 265 (93%) required hospitalisation; 251 (88%) received intravenous hydration. Among cases and controls, respectively, 18% and 12% were unvaccinated, 12% and 15% received 1 dose of RV5*, 15% and 17% received 2 doses, and 55% and 57% received 3 doses. Vaccination with 3 doses was associated with a lower risk of rotavirus diarrhoea requiring overnight admission or intravenous hydration (odds ratio [OR], 0.54; 95% CI: 0.36 – 0.82).</p> <p>Of the 285 rotavirus cases, 191 (67%) were severe and 54 (19%) were very severe.</p> <p>A progressively lower risk of severe (OR, 0.42; 95% CI: 0.26 – 0.70) and very severe rotavirus diarrhoea (OR 0.23; 95% CI: 0.08–0.61) was observed after RV5* vaccination.</p> <p>VE of 3 doses of RV5 against rotavirus disease requiring admission or treatment with intravenous hydration was 46% (95% CI: 18%–64%); against severe rotavirus diarrhoea, 58% (95% CI: 30%–74%); and against very severe rotavirus diarrhoea, 77% (95% CI: 39%–92%).</p>

* Pentavalent rotavirus vaccine, RotaTeq[®]

Table 17. Published studies from Australia on the impact of rotavirus immunisation program on rotavirus disease.

Authors	Source & Year	Location	Study Design	Results
Emma Field , Hassan Vally, Keith Grimwood and Stephen Lambert ⁶⁰	Pediatrics, 2010	Queensland	Descriptive study of vaccine effectiveness (VE) of RV5 for preventing AGE hospitalisations Gastroenteritis hospitalisations, 2000–2008	RotaTeq®: 3-dose VE (non–rotavirus AGE hospitalisation): 62.3% to 63.9% 3-dose VE (rotavirus AGE hospitalisation): 89.3% to 93.9%
Thomas Snelling , Rosalie Schultz, Julie Graham, Robert Roseby, Graeme Barnes, Ross Andrews and Jonathan Carapetis ¹²⁵	Clinical Infectious Diseases, 2009	Northern Territory	Matched Case-control study of vaccine effectiveness of RIX4414 (Rotarix®) for preventing AGE hospitalisations Outbreak of G9 gastroenteritis from 12 March to 11 July 2007	Rotarix®: 2-dose VE (hospitalisation for gastroenteritis): 77.7% (95%CI: 40.2%–91.7%) 2-dose VE (hospitalisation for rotavirus infection): 84.5% (95% CI: 23.4%–96.9%)
Stephen Lambert , Cassandra Faux, Lisa Hall, Frances Birrell, Karen Peterson, Christine Selvey, Theo Sloots, Michael Nissen and Keith Grimwood ¹²²	Medical Journal of Australia, 2009	Queensland	Descriptive study. Retrospective analysis of rotavirus notifications [2006–2008] and laboratory rotavirus testing data [2000–2008] Notifications and number of laboratory tests	<u>Rotavirus notifications</u> Declined by 53% (2007) and 65% (2008) in children aged <2 years. <u>Laboratory tests</u> The number of laboratory tests performed declined by 3% (2007) and 15% (2008). The proportion of tests positive declined by 45% (2007) and 43% (2008) compared with data collected before introduction of the immunisation program.

Authors	Source & Year	Location	Study Design	Results
Helen Marshall , Michelle Clarke, Geoff Davidson, Michael Gold & Kavita Rasiah ¹²⁴	Conference poster – PHAA National Immunisation Conference and European Society of Pediatric Infectious Diseases, 2010	South Australia	Descriptive study of prevention of rotavirus positive and all-cause AGE hospitalisations by RV5, 2005–2009	<p><u>Vaccinated children</u> <i>All-cause gastroenteritis</i>: 41% reduction in hospitalisations for children aged 0–4 years <i>Rotavirus positive gastroenteritis</i>: 76% reduction in hospitalisations for children aged 0–4 years. Marked decrease in children aged < 1 year from 23% in 2005–2006 to less than 5% during 2008–2009.</p> <p><u>Unvaccinated</u> <i>Rotavirus positive gastroenteritis</i>: reduction in rotavirus admissions post vaccine. The level of reduction for 3, 4 and 5 year olds was 64.6%, 34.5% and 75.0% respectively. <i>All-cause gastroenteritis</i>: reduction of 43.7%, 31.6% and 42.3% in admissions for 3, 4 and 5 year olds, respectively</p>
Kristine Macartney , Mamta Porwal, Dianne Dalton, Terri Cripps, Trish Maldigri, David Isaacs and Alison Kesson ¹²³	Journal of Paediatrics and Child Health, 2010	New South Wales	Descriptive study of hospitalisations at The Children's Hospital at Westmead, 2001–2009	<p>Rotavirus gastroenteritis hospitalisation declined in 2008 and 2009 after vaccine introduction by 75% compared with mean annual hospitalisations from 2001 to 2006. The greatest decline was seen in those <12 months of age (93%). Also, decline in nosocomial rotavirus gastroenteritis from 2007 to 2009.</p>
Daniel Belshaw , David Muscatello, Mark Ferson, Alma Nurkic ¹²⁰	Communicable Disease Intelligence, 2009	New South Wales	Descriptive study Emergency Department (ED) visits and lab diagnosis using data from selected NSW laboratories and ED, 2001–2008	<p>In 2008, the seasonal increase in laboratory confirmed rotavirus gastroenteritis related ED visits declined substantially in children aged <15 months and in older children (aged 15 months to 5 years) compared with earlier years.</p>

Authors	Source & Year	Location	Study Design	Results
Jim Buttery , Stephen Lambert, Keith Grimwood, Michael Nissen, Emma Field, Kristine Macartney, Jonathan D Akikusa, Julian J Kelly, Carl Kirkwood ¹²¹	In press Pediatric Infectious Disease Journal, 2010	Victoria, New South Wales and Queensland.	Descriptive study Hospitalisations AGE January 2000–July 2010	Rotavirus vaccine coverage: 87% of infants receiving at least 1 dose. Hospital admissions for both rotavirus gastroenteritis and non-rotavirus coded gastroenteritis reduced following vaccine introduction in 3 settings: RCH (Vic), CHW (NSW) and Queensland. Also decline in hospitalisations in age groups not eligible for NIP-funded vaccine.

Part 2: Hospitalisations from the AIHW National Hospital Morbidity Database

Rotavirus and gastroenteritis not coded as rotavirus epidemiology following the national rotavirus immunisation program

National trends

Between 1 July 2001 and 30 June 2009, there were 28,139 hospitalisations coded as rotavirus gastroenteritis, with a general decreasing trend in the hospitalisation rate observed over time (**Figure 13**). The median annual number of hospitalisations was higher in the pre– immunisation period, from July 2001 to June 2006 (173 cases), compared with the post– immunisation program period from July 2007 to June 2008 (138 cases) and from July 2008 to June 2009 (106 cases). Overall, the hospitalisation rate decreased significantly from 20.6 cases per 100,000 population in 2001/2002 to 6.2 cases per 100,000 population in 2008/2009 ($p < 0.001$). A 71% decline in rotavirus enteritis hospitalisations in children <5 years of age was observed from 261 per 100,000 in July 2001 to June 2006 to 76 per 100,000 in July 2008 to June 2009. A protective effect was also observed in those aged between 5–19 years but there was an increase in cases in those aged 65 years and older.

For gastroenteritis not coded as rotavirus, between 1 January 2001 and 30 June 2009, there were 1,110,138 hospitalisations, or 98% of total acute gastroenteritis hospitalisations. A 34% decline in non-rotavirus coded gastroenteritis hospitalisations in children <5 years of age was observed from 1419 per 100,000 in July 2001 to June 2006 to 938 per 100,000 in July 2008 to June 2009. However, modest increases in hospitalisations were observed in other age groups (20–44, 45–64 and 65 years and older) in whom absolute rates of hospitalisation remained very low.

Overall, there were 7150 fewer hospitalisations for acute gastroenteritis (both rotavirus coded and non-rotavirus coded) in children less than 5 years in the second year following introduction of rotavirus vaccines to the NIP (2008/2009) compared the period prior to vaccine introduction (2001/2002–2005/2006).

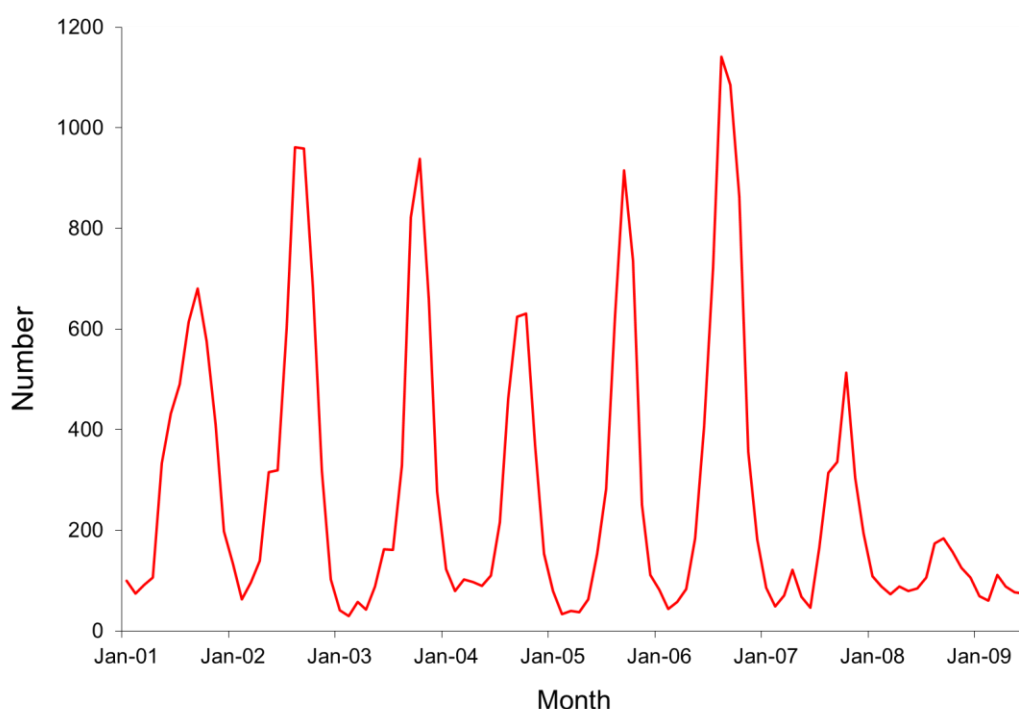
Age distribution

Rotavirus gastroenteritis

The rotavirus hospitalisation rate was highest among children 1 year of age in all years studied, with an annual average of 417 per 100,000 population. Rates were much lower in adults, with all adult age groups having rates <1% of that in children 1 year of age. Hospitalisation rates decreased in the first year of the program (2007/2008) compared to pre-vaccine years, and

decreased further in 2008/2009, for all age groups <20 years (**Figure 14**). The greatest declines by 2008/2009 compared to pre-vaccine years were in the <1 and 1 year age groups, of 74% and 77% respectively (**Table 18**). In addition, a decline of 65% to 67% in rotavirus gastroenteritis hospitalisation rates in children aged between 3 years and less than 5 years of age was observed in the same period. Increases were seen in adult age groups, but rates were much lower than in children (**Table 18**).

Figure 13. Hospitalisations coded as rotavirus enteritis, Australia, 2001 to 2009,* by month of admission



The age distribution of rotavirus hospitalisations changed significantly in the post-vaccination period, with the proportion among children <5 years of age decreasing from 92.3% (95% CI 91.5–93.2) in 2001/2002 to 79.6% (95% CI 77.4–81.7) in 2008/2009. Simultaneously, a significant increase in the proportion of cases aged 65 years and older was observed during the pre-immunisation period from 0.5% (95% CI 0.3–0.8) in 2001/2002 to 1.7% (95% CI: 1.3–2.1%) in 2005/2006, ($z=4.97$, $p<0.001$). There was a further increase to 7% (95% CI: 5.7–8.5%) in 2008/2009. However, data from July 2007 to June 2009 showed that as age increased, the proportion of rotavirus gastroenteritis hospitalisations coded as principal diagnosis decreased (**Table 19**).

Table 18. Rotavirus coded hospitalisation rates before and after the rotavirus immunisation program

Age (years)	PRE	POST			POST		
	2001/2002 to 2005/2006	2007/2008			2008/2009		
	Rate	Rate	IRR	(95% CI)	Rate	IRR	(95% CI)
< 1	387.7	195.3	0.50	(0.46 0.55)	99.8	0.26	(0.23 0.29)
1	483.9	300.1	0.62	(0.58 0.67)	110.2	0.23	(0.20 0.25)
2	250.9	134.3	0.54	(0.48 0.60)	102.3	0.41	(0.36 0.46)
3	122.4	54.5	0.45	(0.38 0.53)	40.9	0.33	(0.28 0.40)
4	67.4	37.3	0.55	(0.45 0.68)	23.6	0.35	(0.27 0.45)
5–19	6.7	3.5	0.52	(0.44 0.61)	2.9	0.43	(0.36 0.52)
20–44	0.2	0.4	1.54	(1.00 2.37)	0.4	1.67	(1.10 2.54)
45–64	0.4	0.6	1.54	(1.02 2.33)	0.6	1.51	(1.00 2.29)
≥65	1.6	4.4	2.73	(2.19 3.41)	3.3	2.04	(1.60 2.59)

Figure 14. Rotavirus coded hospitalisations rates, Australia, 2001 to 2009, by age group and year of separation

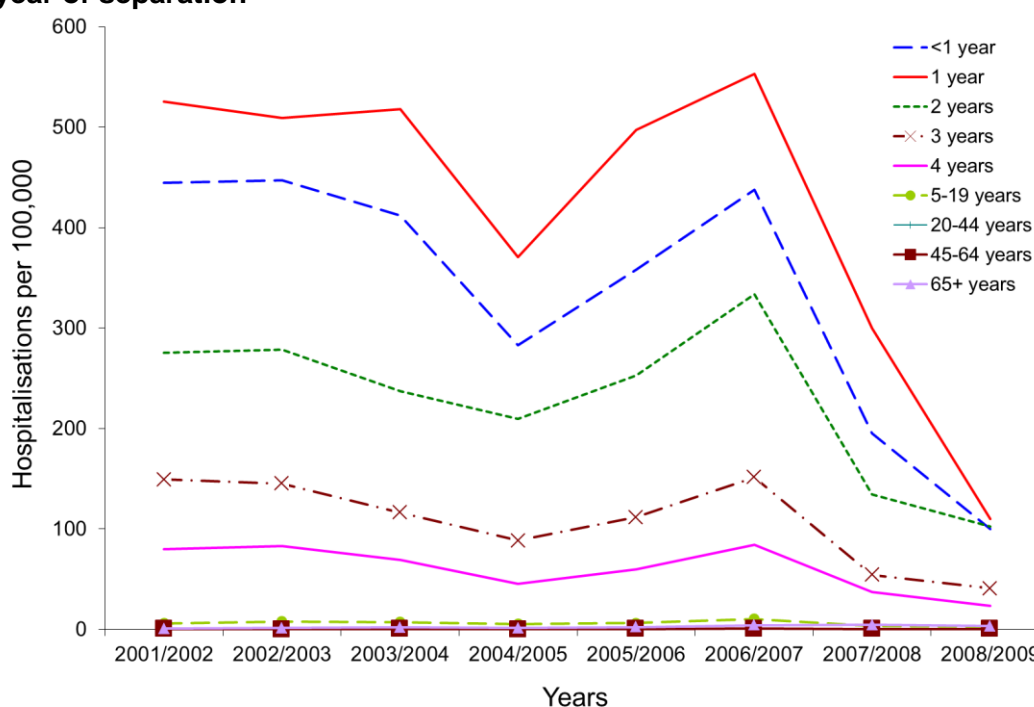


Table 19. Percentage of rotavirus coded hospitalisations by age groups and principal diagnosis ICD codes, 2007 to 2009*

	<1	1-4	5-19	20-44	45-64	65+
2007/2008						
Rotavirus enteritis code (A08.0)	74	87	84	59	60	44
Gastroenteritis not coded as rotavirus (K52&A0x.x)	1	1	2	0	7	0
Non-gastroenteritis codes (Other codes)	25	12	14	41	33	56
2008/2009						
Rotavirus enteritis code (A08.0)	65	86	78	70	50	35
Gastroenteritis not coded as rotavirus (K52&A0x.x)	2	1	1	0	3	0
Non-gastroenteritis codes (Other codes)	33	13	21	30	47	65

* This includes all ICD-coded rotavirus enteritis hospitalisations and it does not include all gastroenteritis not coded as rotavirus enteritis.

Gastroenteritis not coded as rotavirus

The hospitalisation rate for gastroenteritis not coded as rotavirus was highest among children 1 year of age in all years studied, with an annual average of 2,077 per 100,000 population. However, rates in adults were much higher compared to children than was the case for rotavirus, with the pre-vaccine rate in the ≥ 65 year age group being 67% of that in 1 year-old children. Rates decreased over time for all age groups <20 years (**Figure 15, Table 20**) in the post-vaccine compared to pre-vaccine period. The greatest declines were in ages <5 years, of 24% to 41% in 2008/2009, and only 6% in the 5–19 year age group. However, significant increases were seen in all adult age groups, up to 25% in those aged ≥ 65 years.

The age distribution of gastroenteritis not coded as rotavirus hospitalisations also changed, with the proportion of cases that were children aged <5 years decreasing from 17.5% (95% CI: 17.2–17.7%) in 2001/2002 to 9.2% (95% CI: 9.0–9.3%) in 2008/2009. Conversely, the proportion of cases aged ≥ 65 years and older increased during the pre-immunisation period from 29% (95% CI: 28.7–29.2%) in 2001/2002 to 33% (95% CI: 32.8–33.3%) in 2005/2006, ($z=21.45$, $p < 0.001$) and increased further to 37% (95% CI: 37.1–37.6%) in 2008/2009, in the post-immunisation period. This increase was also evident after age standardization (data not shown). However, data from July 2007 to June 2009 showed that as age increased, the proportion coded as principal diagnosis decreased (**Table 21**).

Table 20. Hospitalisation rates for gastroenteritis not coded as rotavirus before and after the rotavirus immunisation program

Age (years)	PRE	POST			POST		
	2001/2002 to 2005/2006	2007/2008			2008/2009		
	Rate	Rate	IRR	(95% CI)	Rate	IRR	(95% CI)
<1	2,094	2,011	0.96	(0.93 0.99)	1,581.3	0.76	(0.73 0.78)
1	2,233	1,874	0.84	(0.81 0.86)	1,334.8	0.60	(0.58 0.62)
2	1,337	935	0.70	(0.67 0.73)	823.8	0.62	(0.59 0.64)
3	849	644	0.76	(0.72 0.80)	507.6	0.60	(0.57 0.63)
4	609	478	0.78	(0.74 0.83)	358.8	0.59	(0.55 0.63)
5–19	246	246	1.00	(0.98 1.02)	232.0	0.94	(0.92 0.96)
20–44	408	466	1.14	(1.13 1.15)	455.8	1.12	(1.10 1.13)
45–64	493	589	1.20	(1.18 1.21)	592.8	1.20	(1.19 1.22)
≥ 65	1,496	1,974	1.32	(1.31 1.33)	1,862.9	1.25	(1.23 1.26)

Figure 15. Hospitalisation rates for gastroenteritis not coded as rotavirus, Australia, 2001 to 2009, by age group (<5 years)

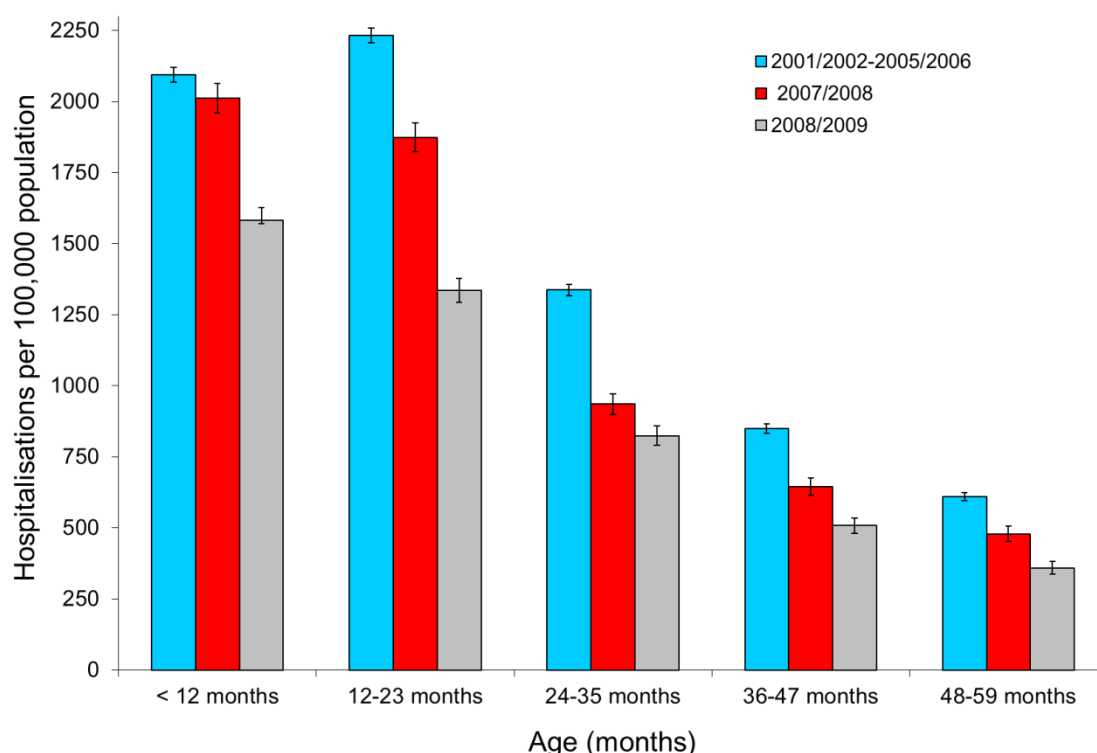


Table 21. Percentage of hospitalisations for gastroenteritis not coded as rotavirus by age groups and principal diagnosis ICD codes, 2007 to 2009*

	<1	1-4	5-19	20-44	45-64	65+
2007/2008						
Gastroenteritis not coded as rotavirus (K52&A0x.x)	70	72	74	60	51	40
Rotavirus enteritis code (A08.0)	7	10	1	0	0	0
Non-gastroenteritis codes (Other codes)	24	17	25	40	49	60
2008/2009						
Gastroenteritis not coded as rotavirus (K52&A0x.x)	71	72	73	61	51	40
Rotavirus enteritis code (A08.0)	4	7	1	0	0	0
Non-gastroenteritis codes(Other codes)	25	20	26	39	49	60

* This includes all ICD-coded gastroenteritis not coded as rotavirus hospitalisations and it does not include all rotavirus coded hospitalisations.

Sex distribution

The proportion of males was higher than females in rotavirus hospitalisations between 2007/2008 and 2008/2009 (53% versus 47%). However, for gastroenteritis not coded as rotavirus hospitalisations, the proportion of females was higher than males (59% versus 41%). Similar proportions of males and females were observed for rotavirus and gastroenteritis not coded as rotavirus gastroenteritis hospitalisations prior to the roll out of the national rotavirus immunisation program. Furthermore, no statistically significant differences in the proportion of males and females

were observed across the years studied i.e. before and after the rollout of the national rotavirus immunisation program.

State and territory trends

The decline in rotavirus hospitalisation rates varied between states and territories. The size of the decline in 2008/2009 compared to the pre-vaccine period (2001/2002–2005/2006) ranged from 42% in the Northern Territory to 77% in New South Wales (**Figures 16 and 17**). In the Northern Territory, there is an overall downward trend since late 2006 following the introduction of the program in October 2006, however, there was an increase of 64% in rotavirus hospitalisation rates in 2008/2009 compared to 2007/2008 (**Figure 16 and 17**). Hospitalisation rates for gastroenteritis not coded as rotavirus declined from between 1% to 19% across states and territories in 2008/2009 compared to 2007/2008.

Figure 16. Rotavirus coded hospitalisation rates, by state and territory, 2001 to 2009.

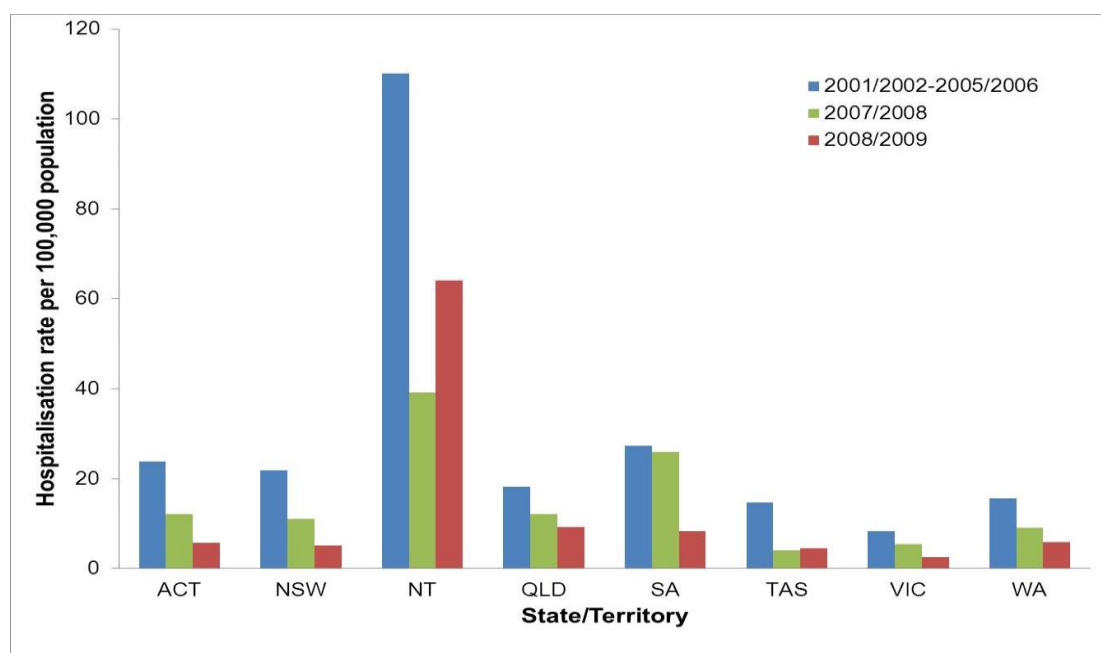
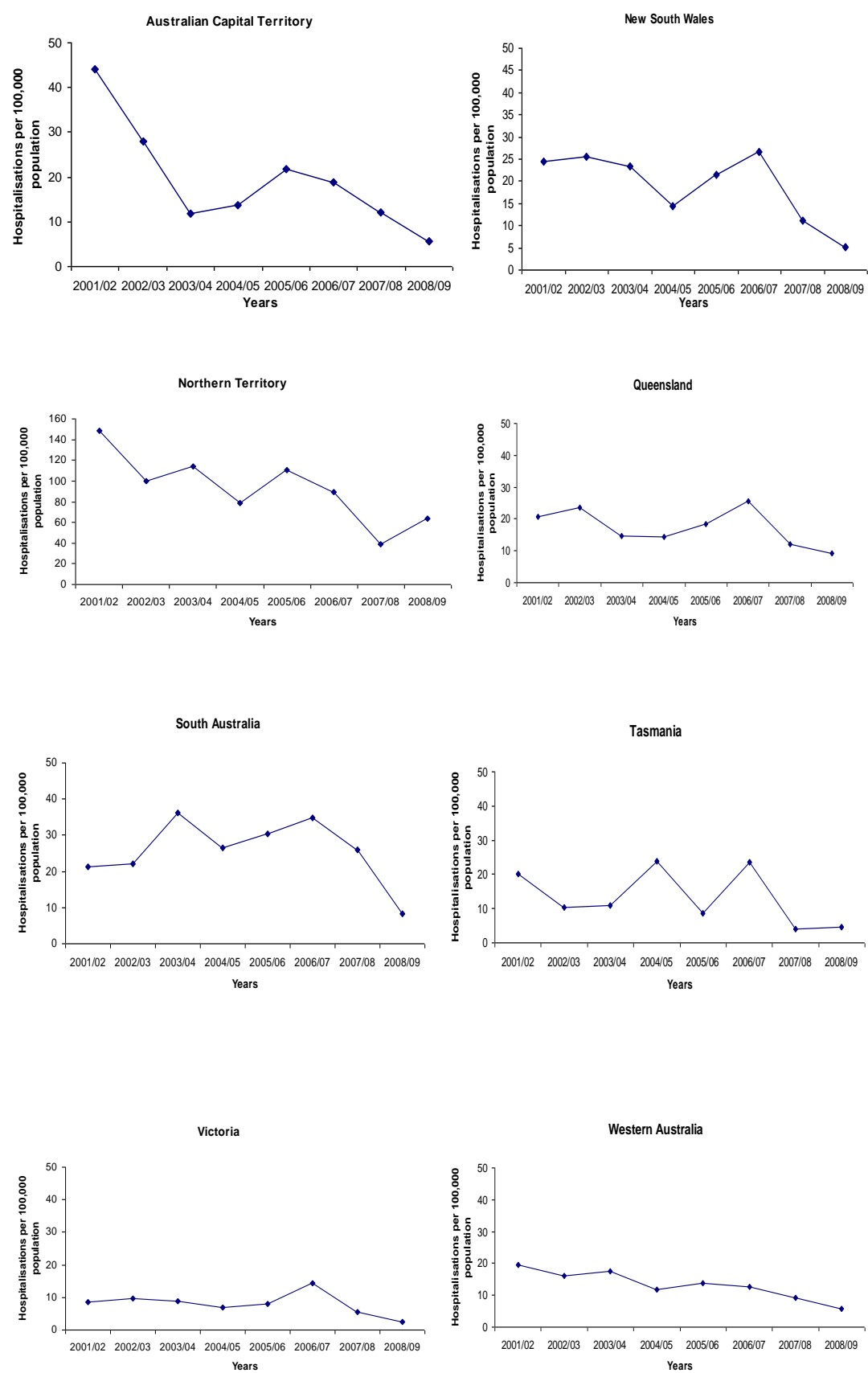


Figure 17. Rotavirus coded hospitalisation rates, by state and territory, 2001 to 2009.



Aboriginal and Torres Strait Islander People

Rotavirus gastroenteritis

In Aboriginal and Torres Strait Islander people, rotavirus gastroenteritis hospitalisation rates declined in the post-vaccination period in New South Wales, Queensland, Victoria, South Australia and Western Australia (**Table 22 and Figure 18**). In children <5 years of age, a 58% decline in rotavirus enteritis hospitalisation rates was observed from 436 per 100,000 in July 2005 to June 2007 to 184 per 100,000 in July 2008 to June 2009. Furthermore, the Indigenous versus non-Indigenous incidence rate ratios indicate that rotavirus hospitalisation rates were 3 to 6 times higher in children less than 1 year of age in children recorded as Indigenous compared to other children (**Table 23**).

In the Northern Territory, a 72% decline was observed in rotavirus gastroenteritis hospitalisation rates in Aboriginal and Torres Strait Islander children <5 years from 3413 per 100,000 in July 2001 to June 2002 to 962 per 100,000 in July 2007 to June 2008 (**Figure 19**) and an overall downward trend observed since the introduction of the program in October 2006. However, an increase of 76% was observed from 962 per 100,000 population in July 2007 to June 2008 to 1688 per 100,000 population in July 2008 to June 2009. In addition, the Indigenous versus non-Indigenous incidence rate ratios were higher than other jurisdictions and indicate that rotavirus hospitalisation rates were significantly higher in children less than 5 years of age recorded as Indigenous compared to other children. The point estimates of the incidence rate ratios were higher in the post-immunisation period and fluctuated between 8 in 2005/2006 to 35 in 2008/2009 although the confidence limits overlapped also reflecting greater decline in the post-immunisation period in non-Indigenous children.

Table 22. Rotavirus coded hospitalisation rates in Aboriginal and Torres Strait Islander people by jurisdictions*, 2001 to 2009

	<1	1-4	5-19	20-44	45-64	65+
New South Wales, Queensland, Victoria, South Australia and Western Australia						
2005/2006	1182	227	2.0	0.7	0	0
2006/2007	1105	274	5.3	0	0	8.4
2007/2008	750	189	2.6	0	1.7	0
2008/2009	381	133	2.0	0.6	0	0
Northern Territory						
2001/2002	11151	1445	5	0	0	0
2002/2003	6729	839	0	4	0	0
2003/2004	8327	1366	5	4	14	0
2004/2005	4975	537	5	0	0	0
2005/2006	6299	1274	0	66	0	0
2006/2007	5853	834	5	4	0	0
2007/2008	2107	668	5	0	0	0
2008/2009	4336	1007	14	4	12	0

*Jurisdictions with acceptable Indigenous status reporting in New South Wales, Queensland, Victoria, South Australia, Western Australia and the Northern Territory

Figure 18. Rotavirus coded hospitalisation rates in children < 5 years by Indigenous status in New South Wales, Victoria, Queensland, South Australia & Western Australia, 2005 to 2009

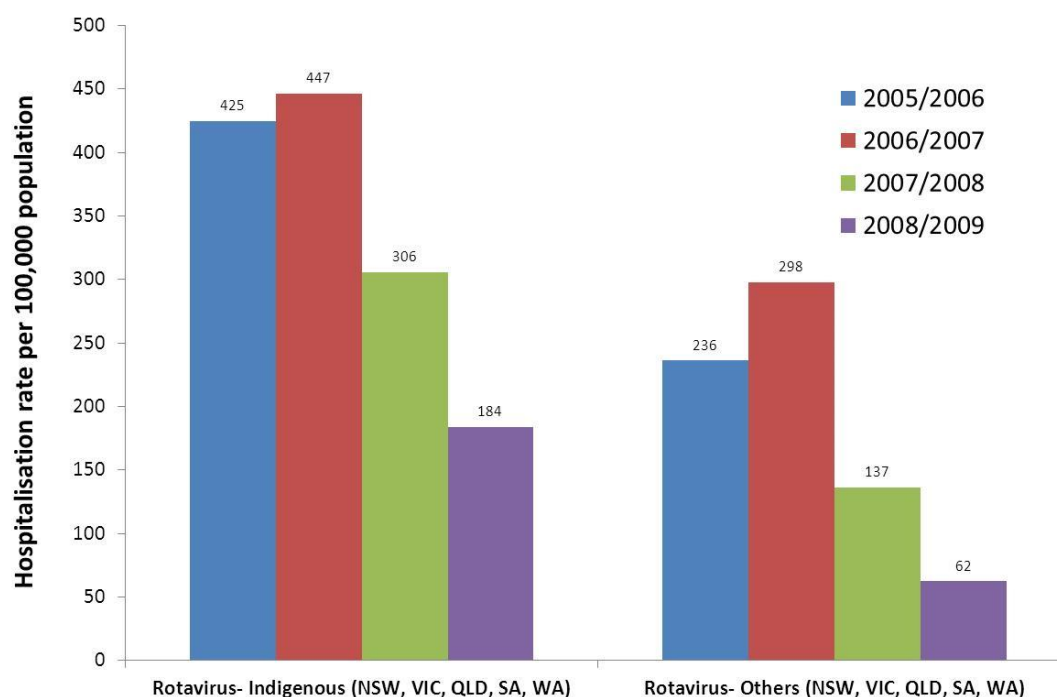


Figure 19. Rotavirus coded hospitalisation rates in children < 5 years by Indigenous status in the Northern Territory, 2001 to 2009

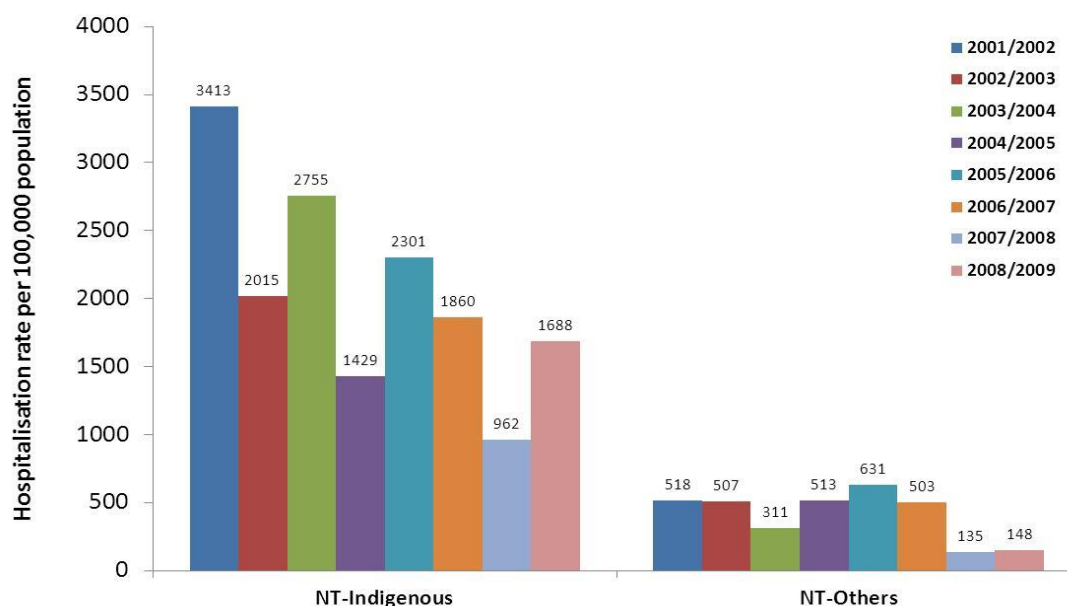


Table 23. Indigenous versus non-Indigenous incidence rate ratios of rotavirus coded hospitalisations in children <1 year by jurisdictions*, 2001 to 2009

	Incidence Rate Ratio (95% Confidence Interval)	
	Indigenous/Non-Indigenous	
New South Wales, Queensland, Victoria, South Australia and Western Australia		
2005/2006	4.1	(3.4, 4.9)
2006/2007	3.0	(2.4, 3.6)
2007/2008	4.6	(3.6, 5.8)
2008/2009	5.8	(4.1, 8.0)
Northern Territory		
2001/2002	12.6	(7.9 20.1)
2002/2003	7.4	(4.6 11.9)
2003/2004	16.2	(8.7 30.1)
2004/2005	9.4	(5.0 17.7)
2005/2006	8.3	(5.0, 14.0)
2006/2007	11.2	(6.1, 20.4)
2007/2008	26.3	(6.3, 110.0)
2008/2009	35.1	(11.0, 111.9)

*Jurisdictions with acceptable Indigenous status reporting in New South Wales, Queensland, Victoria, South Australia, Western Australia and the Northern Territory

Gastroenteritis not coded as rotavirus

Hospitalisations for gastroenteritis not coded as rotavirus in New South Wales, Queensland, Victoria, South Australia and Western Australia, 7153 (3%) were reported in Aboriginal and Torres Strait Islander people in the post-vaccination period (July 2007 to June 2009) and 6994 (3%) in the pre-vaccination period (July 2005 to June 2007). Rates declined in the second post-vaccination year but not in the first (**Table 24 and Figure 20**). Overall, a 37% decline in Indigenous children <5 years of age was observed from 2818 per 100,000 in July 2005 to June 2007 to 1785 per 100,000 in July 2008 to June 2009. The incidence rate ratios indicate that gastroenteritis not coded as rotavirus hospitalisation rates were significantly higher in Indigenous children less than 1 year of age compared to other children from July 2005 to June 2009 (**Table 25**).

In the Northern Territory, 2389 (63%) were identified as occurring in Aboriginal and Torres Strait Islander people in the post-vaccination period compared to 2475 (60%) in the pre-vaccination period. But, a 16% decline was observed in children less than 5 years from 12325 per 100,000 in July 2001 to June 2002 to 10334 per 100,000 in July 2007 to June 2008 (**Figure 21**). However, an increase of 2% was observed from 10334 per 100,000 population in July 2007 to June 2008 to 10572 per 100,000 population in July 2008 to June 2009 in children less than 5 years. In addition, the incidence rate ratios indicate that gastroenteritis not coded as rotavirus hospitalisation rates were significantly higher in Aboriginal and Torres Strait Islander children less than 5 years of age compared to other children in the Northern Territory.

Table 24. Hospitalisation rates of gastroenteritis not coded as rotavirus in Aboriginal and Torres Strait Islander people by jurisdictions*, 2001 to 2009

	<1	1-4	5-19	20-44	45-64	65+
New South Wales, Queensland, Victoria, South Australia and Western Australia						
2005/2006	5449	2097	318	518	865	2521
2006/2007	5376	2184	282	564	885	2151
2007/2008	5283	2008	390	607	1033	3209
2008/2009	3188	1417	249	552	1027	2562
Northern Territory						
2001/2002	25252	8965	255	375	1002	1291
2002/2003	29993	9000	228	385	1283	2143
2003/2004	24057	8746	296	540	1435	2296
2004/2005	142	89	20	17	54	59
2005/2006	28096	9753	289	737	1558	2081
2006/2007	20875	7467	224	694	2046	3090
2007/2008	19031	8100	504	667	2101	4274
2008/2009	18811	8453	299	535	1591	3678

*Jurisdictions with acceptable Indigenous status reporting in New South Wales, Queensland, Victoria, South Australia, Western Australia and the Northern Territory

Table 25. Indigenous versus non-Indigenous incidence rate ratios of gastroenteritis not coded as rotavirus hospitalisations in children <1 year, by jurisdictions*, 2001 to 2009

	Incidence Rate Ratio (95% Confidence Interval)	
New South Wales, Queensland, Victoria, South Australia and Western Australia		
2005/2006	2.6	(2.4, 2.8)
2006/2007	2.5	(2.3, 2.7)
2007/2008	2.9	(2.7, 3.2)
2008/2009	2.2	(2.0, 2.5)
Northern Territory		
2001/2002	12.7	(9.3 17.3)
2002/2003	12.4	(9.4 16.3)
2003/2004	9.2	(6.9 12.2)
2004/2005	1.5	(0.2 10.5)
2005/2006	6.9	(5.5, 8.7)
2006/2007	12.6	(9.0, 17.6)
2007/2008	8.3	(6.3, 11.1)
2008/2009	9.0	(6.6, 12.1)

*Jurisdictions with acceptable Indigenous status reporting in New South Wales, Queensland, Victoria, South Australia, Western Australia and the Northern Territory

Discussion

This current evaluation of the impact of the national rotavirus immunisation program has been conducted more than 3 years after implementation of the program. Declines in hospitalisation rates for rotavirus-coded gastroenteritis and gastroenteritis not coded as rotavirus were observed from the pre-immunisation to the post-immunisation period. These declines were particularly evident in children aged <5 years. In those aged <1 year and those 1 to 2 years of age, there were reductions of 74% and 77%, respectively, in rotavirus-coded hospitalisation rates in the post-vaccine period, July 2008 to June 2009 compared with the pre-vaccine period of July 2001 to June 2006. Hospitalisation rates for gastroenteritis not coded as rotavirus also declined in children aged <5 years ranging from 24% to 41% in the post-vaccine period compared to the pre-vaccine period. There were more than 7000 fewer hospitalisations in children less than 5 years of age in the post-vaccine period of July 2008 to June 2009 compared to the pre-vaccine period. There was also evidence of a decline in rotavirus and gastroenteritis not coded as rotavirus hospitalisations in those aged between 5 to 19 years in July 2008 to June 2009 compared to the pre-vaccine period. These results are similar to findings from recent studies reported in Australia.^{60,121,123,124} Modest increases in hospitalisation rates were observed in the older age groups, particularly those aged ≥65 years, in the post-immunisation period. However, this increase was also observed in the pre-immunisation period and absolute hospitalisation rates for rotavirus-coded gastroenteritis in adults remain very low. Similar findings have been reported in a previous Australian study and could be explained by increased testing for rotavirus gastroenteritis in the older population.^{60,122} In addition, there were differences in hospitalisation rates across states and territories with Victoria reporting the lowest rate. Similar results have been reported in an earlier Australian study, where New South Wales, Queensland and South Australia had twice the hospitalisation rate of Victoria which the authors felt may have reflected variations in coding practices and/or testing practices.³⁹

Changes in rotavirus serotypes causing disease have been reported by the ARSP following implementation of the national rotavirus immunisation program from July 2007 to June 2009.^{49,126} G1P[8] was identified as the dominant strain prior to national roll out of the rotavirus immunisation program and remained as the dominant serotype in the first year of the post-immunisation period (July 2007 to June 2008).¹⁶ However, from July 2008 to June 2009, G2P[4] was identified as the dominant serotype in Australia.⁴⁹ In the most recent reported period, from July 2009 to June 2010, G1P[8] was the dominant type similar to that observed in 2006–2007 and 2007–2008, followed by genotype G2P[4].¹²⁷ Differences between serotypes were also observed between RotaTeq[®] and Rotarix[®] states and territories.^{49,126,127} This demonstrates that there are fluctuations in serotypes and discernable variations across states/territories since vaccine introduction, but there is no clearly consistent pattern or influence by vaccine type. However, the potential for “vaccine

pressure” exerting an influence on serotype selection or emergence of rare serotypes warrants ongoing national serotype surveillance.

The rotavirus immunisation program has also resulted in declining death rates¹⁰¹ and vaccine effectiveness^{60,116-118,125} ranging from 46% to 97% as reported by Australian and overseas studies. The decline in death rate was reported from Mexico¹⁰¹ and difficult to demonstrate for Australia as there is lack of sufficient data. The variation in vaccine effectiveness may be attributed to the differences in the study designs, settings and severity of the disease outcomes assessed.

In people who were identified as Aboriginal and Torres Strait Islander, there was evidence of a decline in hospitalisation rates in the post-immunisation period. Decreases in Indigenous children were similar to or slightly less than that seen in the general population, in New South Wales, Queensland, Victoria, South Australia and Western Australia. However, in the Northern Territory rates in Indigenous children were markedly higher, yearly rates more variable, although lower rates were evident in the post-rotavirus immunisation period. This is despite the high background rates of gastroenteritis occurring in the Northern Territory particularly in central Australia in the pre-vaccine period. However, an increase in hospitalisation rates was observed in the Northern Territory between 2008 and 2009, particularly in Aboriginal and Torres Strait Islander people. This could be attributed to the rotavirus G2P[4] outbreak in the jurisdiction during this period.¹²⁹ A previous study in the Northern Territory also depicted a heavy burden of rotavirus hospitalisations experienced by Indigenous children and a vaccine efficacy of 84.5% (95% confidence interval, 23.4%–96.9%) against confirmed cases of rotavirus infection in a G9P[8] outbreak.¹²⁵ However, a subsequent study has documented lower vaccine effectiveness in this setting of 19% (odds ratio 0.81; 95% confidence interval, 0.32–2.05) for 2 doses compared to none, for preventing all hospitalisations and also 11% (odds ratio 0.89; 95% confidence interval, 0.30–2.64) for preventing severe acidosis in the recent G2P[4] outbreak; suggesting that the issue of vaccine effectiveness in this population needs further investigation.¹³⁰

Limitations

There were several limitations of this evaluation. Rotavirus is not a nationally notifiable disease and therefore, vaccine effectiveness for the national program could not be determined because of a lack of national data on vaccination status. Also, there was limited death data available for the evaluation, and data on ambulatory presentations for rotavirus gastroenteritis (that is GP, clinic or ED presentations) could not be specifically assessed. In addition, the study designs of the current evaluation and most of the studies included were descriptive ecological studies, which may reflect changes due to factors not related to immunisation such as strain variation and coding practices.⁶⁰ Furthermore, using yearly comparisons for hospitalisations could reflect natural fluctuations of

rotavirus activity that occur by year and by location and should be considered as a caveat. However, the impact of the program appears realistic despite these limitations.

Conclusion

This evaluation shows that following the implementation of the national rotavirus immunisation program, there was a marked decrease in hospitalisations for rotavirus coded gastroenteritis and gastroenteritis not coded as rotavirus nationally, particularly in children aged <5 years. Other published studies from a number of Australian jurisdictions have demonstrated declines in rotavirus laboratory tests, notifications (Queensland) and emergency department presentations (Victoria, New South Wales). A protective effect was also observed in the 5–19 year age group, indicating a herd immunity effect. There was also a change in the dominant serotype of rotavirus strain from G1P[8] to G2P[4] in 2008–2009; however G1P[8] was again the dominant type in 2009–2010 similar to that observed in 2006–2007 and 2007–2008. There has been demonstrated high vaccine effectiveness against hospitalisation (Queensland) although this has not been consistently seen in studies of Indigenous infants in rotavirus outbreaks in central Australia.

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Appendices

Appendix A. Matrix of participants in key informant interviews

Stakeholder	National	NSW	ACT	QLD	VIC	TAS	SA	NT	WA
Jurisdictional Immunisation Coordinator (JIC)		X		X X				X	X
General Practice Network State-based Immunisation Coordinator (SBOIC)			X	X	X				X
Division of General Practice (DGP)		X				X	X		
Local council		X			X				
General practitioner (GP)		X		X					X
Practice nurse (PN)			X			X	X		
Remote area immunisation provider				X				X X	
Expert in field from NCIRS	X								

X = One key informant.

Appendix B. Key informant interview questionnaire

Evaluation of the national rotavirus immunisation program Jurisdictional Immunisation Program Managers

The National Centre for Immunisation Research and Surveillance (NCIRS) is currently undertaking an evaluation of the national rotavirus vaccination program. The evaluation will provide information on the processes used to plan and implement the program at a jurisdictional level. The results will be provided to the Australian Government and the National Immunisation Committee to inform future national vaccination programs.

This questionnaire will be the basis for a telephone interview. It is being provided prior to your interview to allow you to reflect on the questions and collect any supporting information to inform your responses. You are not required to respond to this questionnaire now; this will be done at the time of your telephone interview.

All information you provide will be confidential and the final report will contain de-identified, summarised information. Following your interview you will be provided with your interview transcript for approval prior to the inclusion of any de-identified information in the final report.

The interview/questionnaire will cover the following

- ✓ Your role during the program
- ✓ Planning and implementation
- ✓ Communication strategies and resources
- ✓ Service delivery
- ✓ Data
- ✓ Strengths and challenges

1. Participant details

- 1.1. Job title:
- 1.2. Department/Section
- 1.3. Were you in your current position during the implementation of the national rotavirus vaccination program (July 2007/May 2006 NT)?
 - 1.3.i. Yes
 - 1.3.ii. No – what was your previous role?
- 1.4. What was your role and its responsibilities in the implementation of this program in 2007 (NT 2006)?
- 1.5. Is there another person from your jurisdiction who could provide additional information regarding the implementation of the program?

2. Program planning and funding

- 2.1. How much 'lead time' (*approximately*) was provided between program announcement and required implementation?
 - 2.1.i. Was this adequate?
 - 2.1.ii. What activities did your jurisdiction undertake during this period?
- 2.2. In addition to DoHA funding, were there any other contributors of resources/funding to this program in your jurisdiction? (*i.e. state/territory government*). If yes:
 - 2.2.i. Who?
 - 2.2.ii. What was provided?
 - 2.2.iii. What was this used for?
- 2.3. Is there any ongoing funding provided to your jurisdiction specifically for this program? If yes, please describe:
 - 2.3.i. Who?
 - 2.3.ii. Funding formula?
 - 2.3.iii. What is this used for?
- 2.4. Which areas/sections of your state/territory health department were involved in the planning and/or implementation of this program?
- 2.5. Did your jurisdiction develop any policies/guidelines specifically for this program? If so, please describe and indicate if/where available?

3. Communication and resources

- 3.1. What forms of communication did your jurisdiction use in the initial roll out of the rotavirus program? (*media, seminars*)
 - 3.1.i. Who were the target groups? (*parents, providers*)
- 3.2. Please indicate if you used (*e.g. distributed, referenced*) any of the following national resources? (*mark all that apply*)

Note: For your information, these resources are attached.

- Rotavirus Vaccination Program Provider Guidelines ☐
- Rotavirus Immunisation Information for Parents & Guardians ☐
- Understanding Childhood Immunisation brochure insert – Rotavirus update ☐
- NCIRS Fact Sheet: Rotavirus vaccines for Australian children: information for immunisation providers ☐

3.3. For each of the resources listed below, please mark the box which best reflects your opinion of the resource:

	Very Poor	Poor	Average	Good	Very Good	Unsure
Rotavirus Vaccination Program Provider Guidelines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Rotavirus Immunisation Information for Parents/Guardians	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Understanding Childhood Immunisation brochure insert – rotavirus update	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NCIRS fact sheet: Rotavirus vaccines for Australian children: information for immunisation providers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3.4. Please provide any further comments about these resources (*positives/negatives*).

3.5. Has your jurisdiction developed any program-specific resources?

If yes, please describe:

3.5.i. What was developed?

3.5.ii. Why?

3.5.iii. When? (i.e. pre/post program commencement)

3.5.iv. Who was the target audience(s)?

3.5.v. How were they distributed?

3.5.vi. Key messages in these materials?

3.5.vii. Evaluations/feedback obtained?

3.6. Has your jurisdiction used any other communication materials specific to this program? (*i.e. materials from vaccine industry*)

If yes, please describe:

3.6.i. Who developed?

3.6.ii. What was developed?

3.6.iii. Why?

3.6.iv. When?

3.6.v. Who was the target audience(s)?

3.6.vi. How were they distributed?

3.6.vii. Key messages in these materials?

4. Service delivery

- 4.1. Was the program rolled out in stages or simultaneously implemented across the jurisdiction?
 - 4.1.i. Please describe any inconsistencies and rationale for these.
- 4.2. Were there any aspects of service delivery which were different for this program as compared with other national childhood vaccination programs?
 - 4.2.i. If yes, please describe.
- 4.3. What were the arrangements in your jurisdiction for reporting AEFI in this program?
- 4.4. Compared to previous childhood vaccination programs, were there any different provider types (*e.g. paediatrician, hospitals*) used to implement this program?
 - 4.4.i. If yes, please describe who and why?

5. The vaccine

- 5.1. How do providers order rotavirus vaccine in your jurisdiction? Have these changed over time?
 - 5.1.i. Were these different to other national childhood vaccination programs?
- 5.2. How did your jurisdiction supply vaccine for this program? Was this different to other childhood vaccination programs? If so, how?
- 5.3. Please describe any issues with vaccine supply (*i.e. vaccine shortage*) and/or vaccine management (*i.e. cold chain*) which you have encountered in this program?
- 5.4. (*Preamble: two different brands of rotavirus vaccine used in Australia which have strict dosing requirements*). Has using two different brands of rotavirus vaccine had any effect on program planning and/or implementation?
 - 5.4.i. If yes, please describe?
- 5.5. Does your jurisdiction provide access to the non-funded brands of vaccine? If so, please describe the process for accessing this.
- 5.6. Have you received any reports of vaccine administration issues with rotavirus vaccine? If yes, please describe.

6. Data

- 6.1. What routine data is collected by your jurisdiction for this program (*vaccine distribution, coverage, AEFI, wastage/leakage*)?
 - 6.1.i. How was this collected?
 - 6.1.ii. Is there any 'non-routine' data collected for this program? If yes, please describe?
- 6.2. Has your jurisdiction undertaken any internal evaluation or review specific to this program? If yes, is there any reports/information available on these?
- 6.3. Are you able to provide any data/estimations, from July 2007 – current, regarding;
 - 6.3.i. Doses purchased?
 - 6.3.ii. Doses distributed?
 - 6.3.iii. Wastage (estimate)?
 - 6.3.iv. Leakage (estimate)?

- 6.4. Is there any other data available from your jurisdiction which has not been previously mentioned?

7. Strengths and challenges

- 7.1. From your perspective and compared with other childhood vaccination programs:
- 7.1.i. What, if any, are the strengths of the implementation of the rotavirus program?
 - 7.1.ii. What, if any, are the challenges of the implementation of the rotavirus program?
 - 7.1.iii. What, if any, are the issues/problems which you have encountered with this program? Have they been resolved? If so, how? (e.g. vaccine supply, systems/processes)
- 7.2. Has your experience with this program informed how you implement another national childhood vaccination programs?
- 7.2.i. Please describe why/why not?
- 7.3. Based on your experiences with this program, do you have any recommendations for planning/implementing future national childhood vaccination programs?
- 7.4. Any further comments?

8. Program specific factors

8.1. For each of the statements below, please mark the box which best reflects your level of agreement:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
The defined age cut-offs for the rotavirus vaccine created difficulties for;					
parents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
providers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comment:					
The oral nature of the vaccine has required additional instructional materials to support its implementation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comment:					
The oral nature of the rotavirus vaccine has made it more acceptable to:					
parents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
providers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comment:					
The concurrent roll out of the National HPV Program made the implementation of the rotavirus program more difficult.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comment:					