Title: Vaccine-preventable child deaths in New South Wales 2005 to 2014: how much is preventable?
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Figure 1

¹Refers to recommendations in the Australian Immunisation Handbook as at August 2016
 (<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home>)

²Child eligible under the NIP or vaccine available prior to the time of the child's death (<http://www.immunise.health.gov.au/>)

Figure 2

Figure 3

Figure 3

Figure 4

Figure 5

ABSTRACT

Aim: To identify and describe potentially vaccine-preventable child deaths in New South Wales (NSW).

Methods: Child deaths in NSW from 2005 to 2014 potentially preventable by vaccination were identified from the NSW Child Death Register (CDR; maintained by the NSW Ombudsman) and the Notifiable Conditions Information Management System (NCIMS; NSW Health). Medical and post-mortem records were reviewed. Cases were classified as vaccine-preventable based on the strength of evidence for the relevant infection causing death and likelihood that death was preventable through vaccination. A two-source capture-recapture method was used to estimate the true number of deaths. Age-specific mortality rate and number of deaths by disease, area of residence and comorbidity were analysed. Deaths were classified as preventable based on vaccine availability, eligibility under the National Immunisation Program (NIP), age and presence of any contraindications.

Results: Fifty-four deaths were identified as definitely or probably due to diseases for which a vaccine was available, with a total average annual mortality rate of 0.33 per 100 000 children and 2.1 per 100 000 infants. Two thirds of deaths occurred in children with no identified comorbidities. Twenty-three deaths were classified as preventable or potentially preventable by vaccination, with influenza (12 deaths) and meningococcal disease (5 deaths) most common. An additional 15 deaths would be potentially preventable as of August 2016 due to immunisation recommendation changes including maternal vaccination.

Conclusions: Maternal vaccination along with increased uptake of childhood influenza vaccination could reduce child deaths, particularly from influenza.

Key words: Child, Australia, influenza vaccines, immunisation programs, vaccination, death

What is already known on this topic?

- Deaths from vaccine preventable diseases in children are now rare in Australia.
- There is a lack of recent, comprehensive assessment of such deaths.

What this paper adds?

- Deaths preventable or potentially preventable by vaccination continue to occur in Australian children.
- There is scope to prevent further deaths, particularly due to influenza, meningococcal disease and pertussis.
- Increased uptake of childhood vaccination in children with and without underlying medical conditions, particularly for influenza, could reduce residual child deaths.

MAIN TEXT

Introduction

Deaths due to vaccine preventable diseases in Australia have declined significantly despite substantial increases in the population.[1] The current National Immunisation Program (NIP) Schedule, funded for all children, protects against 16 infectious diseases; a small number of additional doses or vaccines are also funded for specific high-risk groups.[2] Some vaccines, although registered for use and recommended in the Australian Immunisation Handbook, are available only through private purchase.[3]

Although vaccine preventable deaths among children are now rare, reported cases often cause considerable public interest and distress. Ascertaining complete and accurate identification about such deaths can be problematic, as data from death certificates and notifications to the National Notifiable Diseases Surveillance System may be divergent and incomplete.[1] This study was conducted on behalf of the Child Death Review Team (CDRT) of the New South Wales (NSW) Ombudsman, who review all child deaths in NSW and provide annual reports to Parliament. It aimed to provide a detailed description of deaths among children residing in Australia's largest state and to identify missed opportunities for vaccination. A report and recommendations based on this work were tabled in NSW State Parliament by the NSW Ombudsman.[4]

Materials and Methods

Deaths among live born children from diseases of interest were investigated. Diseases of interest were defined as those caused by a pathogen for which a vaccine is currently available on the NIP (excluding human papillomavirus), regardless of disease subtype. Specifically, this included diphtheria, *Haemophilus influenzae* infection, hepatitis A and B, influenza, measles, meningococcal disease, mumps, pertussis, pneumococcal disease, poliomyelitis, rotavirus, rubella, tetanus and varicella. Cases were identified from two independent sources of routinely collected data over the period 2005 to 2014: the Child Death Register (CDR), maintained by the CDRT, and the Notifiable Conditions Information Management System (NCIMS) maintained by NSW Health.

CDR data are based on death certificates and coroners' reports coded using the International Statistical Classification of Diseases (ICD) system, 10th revision, modified for Australia (ICD-10-AM), for all deaths under 18 years of age in NSW. The CDRT provided a dataset containing all deaths potentially due to infectious diseases; deaths potentially due to diseases of interest were identified through ICD-10-AM coding for cause of death and associated cause of death, and from free text in any field. A triage system was used to narrow case selection to those cases specifying a disease of interest or relevant pathogen. Clinical syndromes (such as pneumonia, sepsis or gastroenteritis) without reference to a disease of interest or

relevant pathogen were not further analysed. From NCIMS, we identified notified cases of diseases of interest under the age of 15 years where a death was also recorded. Data from the two sources were matched using personal identifiers including date of birth and surname. Data were also requested from neighbouring jurisdictions (Queensland, Victoria and the Australian Capital Territory) on deaths in children normally residing in NSW.

For each case, all available medical records, post-mortem examination reports, coronial findings and laboratory results were reviewed. A standardised set of demographic, clinical and laboratory information were collected. Vaccination history was obtained from clinical notes and/or NCIMS. All cases of diseases of interest were included, regardless of whether the pathogen subtype was included in the vaccine available at that time or whether the child was eligible for the vaccine under the NIP.

Cases were classified as *confirmed*, *probable* or *uncertain* using a rating scale for the strength of evidence for the disease as having caused death, developed for the study (Table 1). Uncertain cases were excluded from the main analysis.

Table 1 (see separate file)

Confirmed and probable cases were further classified as to whether they were likely to be preventable through vaccination (Figure 1); non-preventable cases were assessed as to whether they would be preventable as of August 2016. Vaccines available, recommended and funded from 2004 to 2016 are shown in Table 2. In classifying deaths as preventable, 100% vaccine efficacy was assumed.

Figure 1 (see separate file)

Table 2 (see separate file)

Data were analysed using STATA (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP) and Microsoft Excel (2010). Mortality rates were presented as annual average rates per 100,000 child population. Postcode data were linked to the Australian Standard Geographic Classification (ASGC) Remoteness Structure data provided by the Australian Bureau of Statistics (ABS) in order to classify deaths by remoteness.[5] Population data by remoteness were obtained from the Centre for Epidemiology and Evidence, NSW Ministry of Health.

Based on the assumption of independence of the two data sources, a capture-recapture method was used to estimate the total number of deaths. This estimation is based on the formula $N = [(a+1)(b+1)/(c+1)] - 1$, where “N” is the total estimated cases, “a” is the total number of cases ascertained from the primary source (CDR), “b” is the total number ascertained from the secondary source (NCIMS) and “c” is the number of cases common to both sources.[6]

The CDRT reviews all deaths of children in NSW under the auspices of the NSW Ombudsman. This study was commissioned by the CDRT on behalf of the NSW Ombudsman and conducted under the *Community Services (Complaints, Review and Monitoring) Act 1993*. Ethics committee review was not required under this Act. Both data sources used in this study are statutory collections and the CDRT provided all data to the research team under their appointment as expert advisor within the Act.

Results

Cases of death due to diseases of interest

Seventy-three cases of death potentially related to a disease of interest were identified (Figure 2). Sufficient data was available to assess deaths among NSW residents who died in two out of three neighbouring states. Fifty-four of the 73 included cases were considered confirmed or probable according to the case definition in Table 1. Case vaccination status for the disease was documented in the clinical notes or NCIMS for around half of the cases. Where vaccination status was not documented in the clinical notes or NCIMS, it was not possible to ascertain this information from the Australian Childhood Immunisation Register (ACIR) as ACIR records are not available for deceased children. No child was documented to have been vaccinated for the disease of interest except for one case of invasive pneumococcal disease due to serotype 19A, who had received three doses of 13-valent pneumococcal vaccine (13vPCV). This case was considered a vaccine failure and not further classified. In almost all cases not vaccinated for the disease of interest, the family was not documented as specifically objecting to vaccination.

Figure 2 (see separate file)

All confirmed and probable cases

The overall mortality rate was 0.33 per 100 000 child population (95% confidence interval 0.25-0.43) and 2.1 per 100 000 infants under 12 months of age (95% confidence interval 1.29-3.25). The highest number of deaths in any one-year age group was in children under 12 months of age (Figure 3). Male children were over-represented (39 of 54 cases). The highest number of deaths occurred in major cities ($n=31$), but the rate of death was highest in inner regional areas (0.63 compared to 0.31 in major cities and 0.4 deaths per 100 000 child population in outer regional, remote and very remote areas). Children from inner regional areas were twice as likely to die ($RR=1.99$, 95% CI 1.03-3.71) compared with children from major cities. There was no statistically significant difference in the risk of death in children in outer regional, remote and very remote areas compared to major cities ($RR=1.29$, 95% CI 0.33-3.64).

Figure 3 (see separate file)

Meningococcal deaths appeared to decrease over the study period, while influenza deaths appeared to increase (Figure 4). Meningococcal serogroup B accounted for eight of the 12 meningococcal deaths and influenza A was identified in 14 of 15 influenza deaths, with H1N1 identified in 5 cases. Two thirds of deaths classified as confirmed or probably due to diseases of interest were in children without known comorbidities (n=36). Of the 18 children with comorbidities, 12 were eligible for NIP-funded vaccine (including all influenza cases) or additional vaccine doses (including all pneumococcal cases) due to their risk category. None of these children were documented as having been vaccinated for the disease of interest.

Figure 4 (see separate file)

Preventable and potentially preventable deaths

Among the 54 confirmed and probable cases of death due to diseases of interest, 23 were considered preventable (n=5) or potentially preventable (n=18), most commonly influenza (n=12) and meningococcal disease (n=5) [Table 3]. Five influenza deaths considered preventable or potentially preventable occurred in children with comorbidities who were eligible to receive funded vaccine. A further seven potentially preventable influenza deaths occurred in children without known comorbidities, most (n=5) in children aged from 6 months to less than 5 years of age, where influenza vaccine was recommended but not funded under the NIP.

Five meningococcal deaths and four pneumococcal deaths were considered preventable or potentially preventable. Preventable deaths occurred in children eligible for catch up programs (n=3), including the NIP-funded meningococcal C vaccine and 7-valent pneumococcal conjugate vaccine (7vPCV) catch-up programs. Potentially preventable meningococcal deaths were due to serogroups (B, C and Y) for which an unfunded vaccine was available for the relevant age-group at the time of death.

Table 3 (see separate file)

Non-preventable deaths

Thirty deaths were not considered preventable by vaccination (Table 3). Nine were in children too young to be vaccinated (aged two months or less) including deaths due to pertussis and influenza (n=4). Although not preventable through vaccination of the child, these deaths may have been preventable through maternal vaccination during pregnancy.

Deaths occurred where the subtype of the pathogen was not covered by the relevant available vaccine, and these were considered non-preventable. These included deaths due to 13vPCV pneumococcal serotypes which were not included in the 7vPCV available at the time, and H1N1 influenza deaths prior to availability

of the H1N1 pandemic vaccine. Seven deaths due to meningococcal B disease (six aged under 12 months) occurred before a meningococcal B vaccine was available (most would have been old enough to be vaccinated). Several varicella deaths in immunocompromised children were also considered non-preventable due to vaccine contraindications. Deaths from untyped *H.influenzae* were not considered preventable due to the low likelihood that the infecting strain was type b (Hib), given the very low proportion of invasive *H. influenzae* of known serotype due to type b.[7]

Of the 30 deaths classified as non-preventable, half would now be potentially preventable through maternal vaccination (infant influenza and pertussis deaths (n=4)) and vaccines incorporating new disease subtypes (meningococcal B, pneumococcal and influenza (n=11)) (Table 3).

Data source comparison

Confirmed cases were more likely to have been identified from both data sources (Figure 5). Of the 54 confirmed and probable cases, 47 were identified from the CDR, 40 from NCIMS and 33 matched from both sources. The capture-recapture analysis estimated a total of up to 57 confirmed and probable cases (95% CI 53-61), indicating that three additional cases may have been captured if case ascertainment had been complete.

Figure 5 (see separate file)

Discussion

We identified influenza as the most common cause of childhood death preventable or potentially preventable by vaccination. Influenza was the confirmed or probable cause of 15 deaths in NSW children over the ten year period of our study. As 14 of 15 influenza deaths occurred from 2009 onwards, identification may reflect increased testing following the pandemic year, with an increase in all-age influenza notification rates also noted nationally over this time period.[8]

An excess of influenza deaths (7 of 15) occurred in children with comorbidities. While influenza vaccination is recommended and funded under the NIP for children with specified medical conditions,[2] low vaccination coverage has been well documented.[9, 10] Another seven influenza deaths occurred in children over six months of age with no documented comorbidities and all influenza cases who died before arrival at hospital were previously healthy children under five years of age. Previously healthy young children with influenza have been shown to have high hospital admission rates[11] and may be more likely to die before hospital admission or within three days of symptom onset, compared to those with underlying medical conditions.[12] While influenza vaccination is recommended in Australia for all children between 6 months and five years of age, it is only funded under the NIP for those at higher risk [2] and coverage is very low.[13,

14] Coverage recorded in ACIR was less than 2.5% in children aged 6 months to less than 5 years of age between 2005 and 2014 (excluding Western Australia, where a funded seasonal influenza immunisation program for children commenced in 2008).[14] A number of other high income countries provide free influenza vaccination for all young children.[15, 16]

Influenza deaths in young infants were rarely confirmed as the cause of death in our study. Several deaths were classified as uncertain and attributed at post-mortem to sudden unexplained death in infancy (SUDI). SUDI is multifactorial, and although signs of infection are often found at autopsy, minor respiratory infections in infants are common and in many cases not believed to be the primary factor contributing to death.[17] Despite a lack of clarity around the cause of death, these infants may have been protected by maternal vaccination, recommended for pregnant women and funded under the NIP since 2010,[2] although the duration of neonatal protection following vaccination in pregnancy is uncertain.[18] In addition, this study only investigated deaths among live born children and did not examine the burden of stillbirth, which may also be potentially preventable through maternal immunisation.[19]

We identified 12 deaths due to meningococcal disease over the ten year study period, substantially less than the 26 deaths identified in NSW in children less than 15 years between 2000 and 2007.[20] There has been a dramatic decline in meningococcal C disease since the introduction of the meningococcal C immunisation program in 2003.[21] The meningococcal C deaths in our study occurred between 2005 and 2007, with most children eligible for meningococcal C vaccine catch-up programs under the NIP. Although meningococcal C vaccination coverage has been high (93%), coverage is lower in catch-up cohorts (70%).[21] Most meningococcal deaths in our study were due to meningococcal B disease; most occurred before the meningococcal B vaccine (which is now recommended but not funded under the NIP for young children, particularly those aged <24 months, adolescents aged 15-19 years, and those with specific medical conditions[2]) became available in 2014. While serogroup B was predominant in Australia over the study period, its incidence has declined concurrently with the decline in serogroup C disease.[21]

Of the pertussis deaths identified in our study, most were less than 2 months of age. Similarly, 10 of 11 pertussis deaths reported nationally between 2006 and 2012 were in infants less than 2 months of age.[22] Such deaths are likely to be preventable through pertussis vaccination during pregnancy,[23] which was recommended in the Australian Immunisation Handbook in April 2015 and provided free of charge by all states and territories from mid-2015.[2, 22]

Our analysis assumes deaths were preventable or potentially preventable when a vaccine was available and/or funded under the NIP. However, our conclusions are limited by the efficacy of the vaccines available for each disease. The estimated effectiveness of influenza vaccine in prevention of hospitalised influenza was 55.5% in a recent Australian study.[13] Vaccine effectiveness against death was 65% (95% confidence

interval 54% to 74%) among children aged 6 months to 17 years in a recent US study, and 51% (95% confidence interval 31% to 67%) in a subgroup of children with high-risk conditions.[24] Acellular pertussis vaccines in infants are estimated to have an efficacy of 84% against hospitalisation,[25] and the effectiveness of maternal pertussis vaccination against early infant death from pertussis is estimated as 95%.[26] Meningococcal B vaccination protects against 73-88% of strains in the UK, where it has been introduced into the routine national program.[27]

Capture-recapture analysis estimated that three additional confirmed or probable cases would have occurred due to the diseases of interest. Capture-recapture methodology allows estimation of the total number of deaths in the population based on two independent data sources and has been previously used to estimate the incidence of congenital rubella syndrome[28] and acute flaccid paralysis in Australia.[29] This study was enhanced by the use of two independent data sources, although it is limited by the potential for underestimation of child deaths due to absence of specific pathogen information in some CDR records, which were excluded for review by our triage process. While this study was limited to one state in Australia, it provides detailed review of ten years of data from all children in a state contributing 32% of the Australian child population (aged up to 19 years)[30] and the findings are likely apply nationally.

Conclusion

While the number of deaths in children from infectious diseases has decreased markedly since the pre-vaccine era, we identified an estimated 23 deaths potentially preventable by vaccination in a ten year period in NSW, particularly in young infants. There is scope to reduce child deaths, particularly from influenza, meningococcal B and pertussis. In particular, increased uptake of currently funded influenza vaccination for children with comorbidities, as well as maternal vaccination for influenza and pertussis, may reduce child deaths. This study quantifies influenza attributable deaths among children without underlying medical conditions, which would be a key component of cost-effectiveness analysis required to consider funding of universal childhood influenza vaccination under the NIP.[31] Further, more detailed, recommendations to reduce the number of vaccine preventable child deaths are described in the report of this study tabled in the NSW State Parliament.[4]

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TABLE LEGENDS

Table 1
Case definition for deaths due to pathogens/diseases of interest

Table 2
Australian National Immunisation Schedule (as implemented in NSW), 2005 to 2014

Table 3
Confirmed and probable cases of death due to disease of interest and potential for prevention by vaccination

FIGURE LEGENDS

Figure 1
Framework for assessing potential for prevention by vaccination

Figure 2
Process for assessing cases of disease of interest and final included cases

Figure 3
Number of confirmed & probable cases of death due to diseases of interest by age group, 2005-2014

Figure 4
Rate of deaths due to diseases of interest over time by disease (number of deaths above bars)

Figure 5
Case classification by data source for all cases of death due to diseases of interest, 2005-2014

Table 1 Case definition for deaths due to pathogens/diseases of interest

	Laboratory & Epidemiological evidence		Clinical & Post-mortem evidence
Confirmed	Laboratory definitive evidence [†] of pathogen of interest from a clinical specimen	AND	Post-mortem or clinical evidence of severe disease consistent with the disease of interest
Probable	Laboratory suggestive evidence [†] of pathogen of interest from a clinical specimen OR Laboratory evidence of a pathogen of interest from a post-mortem specimen OR Epidemiological link to a case of disease of interest	AND	Post-mortem or clinical evidence of severe disease consistent with the disease of interest
Uncertain	Laboratory evidence (clinical or post-mortem specimen) of a pathogen of interest OR epidemiological link to a case of disease of interest	AND	<i>Absence</i> of post-mortem or clinical evidence of severe disease consistent with the disease of interest
Not a case	No laboratory evidence of pathogen of interest		

[†]Consistent with national notifiable diseases case definitions, where available

Table 2: Australian National Immunisation Schedule (as implemented in NSW), 2005 to 2014

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Notes
DTP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	
Polio	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	
MMR	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	
Varicella	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	Also recommended from 2003
Hib	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	
Meningococcal C	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	
Meningococcal ACWY	R-SRG	R-SRG	R-SRG	R-SRG	R-SRG	R-SRG	R-SRG	R-SRG	R-SRG	R-SRG	R-SRG	R-SRG	For high-risk medical conditions and travel*
Meningococcal B										R	R	R	For infants & young children < 2 yrs; adolescents 15-19 yrs
Hepatitis B	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	
Hepatitis A*	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	Funded under NIP for Indigenous children 12-24 months in some states (not NSW). Also recommended for travelers ≥ 1yr to endemic areas (unfunded).
Rotavirus		R	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	NIP	
Influenza^													
Individuals > 6m at risk of severe influenza & pregnant women	R	R	R	R	R	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	Funded under NIP in 2010 but previously subsidized under PBS. List of underlying medical conditions expanded in 2013
Indigenous people ≥ 15y yrs	A	A	A	R	R	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	
Indigenous children 6 m - 5 yrs	A	A	A	A	A	A	A	A	R	R	NIP - SRG	NIP - SRG	
Children >6m to ≤ 5yrs	A	A	A	A	A	A	A	A	R	R	R	R	Funded in Western Australia from 2008 (not NSW)
Pandemic H1N1 2009					NIP								
Pneumococcal													
7-valent PCV	NIP	NIP	NIP	NIP	NIP	NIP							Catch-up for all children < 2 yrs; replaced 23-valent PPV as booster for high risk children at 12 months of age from 2005
13-valent PCV							NIP	NIP	NIP	NIP	NIP	NIP	Replaced 7-valent PCV July 2011; NIP-funded catch-up for children 12-35m (additional dose); booster for children with high-risk medical conditions from 2013 if dose of 13-valent PCV not previously received (in addition to 23-valent PPV).
23-valent PPV	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	NIP-SRG	Funded dose for Indigenous children in some states (not NSW) at 18-24m from 2001 to 2011; booster for children with specified underlying medical conditions at 12m from 2001 (replaced by 7-valent PCV in 2005) and 4-5 yrs from 2003 (second dose in 5-10 years recommended from 2013).

Abbreviations: NIP - Funded under National Immunisation Program; NIP-SRG - Funded under National Immunisation Program for special risk group only; R - recommended; R-SRG - recommended for special risk groups only; A - available; yrs - years; m – months; PCV – pneumococcal conjugate vaccine; PPV – pneumococcal polysaccharide vaccine.

*Adolescent programs funded by some States and Territories in 2017.

Source <http://www.ncirs.edu.au/provider-resources/vaccination-history/>

Table 3 Confirmed and probable cases of death due to disease of interest and potential for prevention by vaccination[†]

Disease	Total	Number preventable or potentially preventable[†]	Number not preventable[†]	Number not preventable that may be preventable in 2016
Influenza	15	12	3	3
Meningococcal	12	5	7	6
Pneumococcal[‡]	15 [§]	4	11	3
Others[¶]	11	NR	9	3
Total	53	23	30	15

[†] As determined by the assessment framework in Figure 1

[‡] Eight of these deaths were classified based on samples obtained post-mortem (five were untyped).

[§] One additional pneumococcal death occurred due to a vaccine strain (19A) in a fully vaccinated child and was considered a vaccine failure; the case was not classified regarding potential for prevention by vaccination.

[¶] Amalgamated data due to small cell sizes. NR: not reported due to small cell size

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