

Estimating immunisation coverage: is the 'third dose assumption' still valid?

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Abstract

Immunisation coverage is calculated from Australian Childhood Immunisation Register (ACIR) data using the 'third dose assumption'. This assumes that if the third in a series of vaccine doses has been recorded on the ACIR, the previous two doses have been received, whether or not they are recorded. The objectives of this study were to validate the 'third dose assumption', and measure the impact of the assumption on immunisation coverage estimates at 12 months of age. A sample of children born in 1999 and assessed as fully immunised at 12 months of age by applying the 'third dose assumption' were selected from the ACIR. Parents were interviewed by telephone to obtain information about vaccinations not recorded on the ACIR. Based on the survey results, the impact of the 'third-dose assumption' on national coverage estimates at 12 months of age was estimated. Of 219 surveyed children assessed as up-to-date at 12 months of age only by applying the 'third dose assumption', 212 (96.8%) met study criteria of 'definite' immunisation for all unrecorded first and second vaccine doses. Of the remaining seven, six believed all doses had been received, while one confirmed that one dose had been missed. The 'third dose assumption' overestimated coverage by 0.2 per cent, based on criteria for 'definite' immunisation. If the assumption were not used, immunisation coverage at 12 months of age in Australia would have been underestimated by 7 per cent. The 'third dose assumption' is valid and important to use in calculating immunisation coverage from the ACIR. Although ACIR reporting and coverage levels continue to improve, under-reporting of vaccine doses due at two and four months of age persists. The 'third dose assumption' may be applicable to comparable immunisation registries in other countries. *Commun Dis Intell* 2003;27:357–361.

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Introduction

The Australian Childhood Immunisation Register (ACIR), managed by the Health Insurance Commission (HIC), is a national population-based register that records immunisations given to children under the age of 7 years.¹ ACIR data are used to estimate and report quarterly immunisation coverage at state and national levels, at the 12 month, 24 month and 6 year milestones. Immunisation coverage is calculated using the cohort method² and definitions of coverage based on the Australian Standard Vaccination Schedule.^{2,3} The most controversial of the immunisation coverage assessment rules is the 'third dose assumption'. This assumes that if the third dose in a vaccine series is recorded on the ACIR, all previous doses in that series have been given, whether or not they are recorded.²

The assumption was considered appropriate when reporting of immunisation coverage from the ACIR first commenced in 1998 because the ACIR is based on the Medicare database and a delay in Medicare registration was likely to affect recording of the first and second vaccine doses due at 2 and 4 months of age. Without the 'third dose assumption', the underestimation of coverage by the ACIR, related to incomplete reporting by providers and delayed Medicare registration, would be substantially greater.^{4,5}

Since 1998, incentives to general practitioners to notify vaccinations to the ACIR have been introduced and there has been a significant reduction in delays in Medicare registration.⁶ As the ACIR has matured and coverage has increased substantially,^{7,8} continued use of the 'third dose assumption' in calculating and reporting immunisation coverage has been questioned. No direct validation of this assumption has been undertaken. This study aimed to assess the validity of the 'third dose assumption' and to estimate its impact on current immunisation coverage at 12 months of age.

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Methods

Approval for the study was obtained from the Commonwealth Department of Health and Ageing Ethics Committee.

Study design and population

The study used a cross-sectional survey design. Children were eligible for inclusion if they were born between 1 October and 31 December 1999 and at 4 May 2001 were recorded as fully immunised for vaccines due before 12 months of age only after applying the 'third dose assumption'. That is, one or more of the first or second vaccine doses of diphtheria-tetanus-pertussis (DTP) vaccine, poliomyelitis (polio) vaccine or *Haemophilus influenzae* type b (Hib) vaccine was not recorded. The number of children eligible was approximately 4,500 children of a total three-month birth cohort of approximately 63,000 children. Using the assumption that 90 per cent of eligible children had actually received all first and second doses of DTP, polio and Hib vaccines, the estimated sample required to detect this proportion with 99 per cent confidence and a precision of 5 per cent was calculated to be 226 children.

Recruitment

Based on a previous study using similar methodology,⁹ NCIRS anticipated a response rate of approximately 40–60 per cent. The HIC were asked to randomly select from the ACIR, 400 children from the 4,500 eligible children. Information letters were sent to the parents of 394 eligible children to advise them that their child had been selected for the study and that they may be contacted by telephone. Six children were excluded because they were one of a set of twins. Electronic telephone directory searches were conducted to identify numbers corresponding to addresses listed in the ACIR. Up to 10 attempts were made to contact each family at different times of the day.

Data collection

Computer-assisted telephone interviews were conducted in July 2001. Parents were encouraged to read from a provider-completed written vaccination record to answer whether their child had received all first and second doses of DTP, polio and Hib vaccines and the dates each dose had been received.

Data analysis

Data were analysed using SAS version 8¹⁰ and Epi Info version 6.04b.¹¹

Assessment of response bias: demographic information and immunisation histories recorded on the ACIR were compared for surveyed children and those for whom contact was attempted but an interview not achieved.

Assessment of immunisation status: information provided by parents was used to determine immunisation status. A child was defined as 'definitely' immunised if the parent provided at least the month and year of vaccination for all six first and second vaccine doses, either from a provider-completed written record or by recalling vaccination dates, at least one of which could be verified from the ACIR (as most children had at least one of the six vaccines recorded on the ACIR). A child was defined as 'possibly' immunised if the parent recalled that the particular vaccine doses had been received but was unable to provide vaccination dates, or none of the dates recalled could be verified from the ACIR. Children were defined as 'under-immunised' if the parent confirmed that the child had not received one or more of the six vaccine doses.

Children who met the study definition of 'definitely' immunised were also assessed to identify the age at which they received the specified vaccines and the type of immunisation provider who gave the vaccines.

Impact of the 'third dose assumption' on coverage at 12 months of age

Immunisation coverage for the entire birth cohort at 12 months of age was re-calculated to correct for the proportion of surveyed children for whom the 'third dose assumption' had been applied inappropriately. Coverage was calculated using the formula: $(c-a)+(b*a)$

where: *a* was the percentage of the entire birth cohort assessed as fully immunised at 12 months of age due only to the application of the 'third dose assumption' (7.02%), i.e. those missing first or second vaccine doses but recorded as having received all third doses used to assess coverage;

b was the proportion of surveyed children at interview who had received all first and second vaccine doses;

c was the percentage of the birth cohort assessed as fully immunised at 12 months of age from ACIR data (91.18%).

Sensitivity analyses, using more and less stringent definitions of 'immunised' for all first and second vaccine doses, were also conducted in order to assess the assumptions used to define 'definite' immunisation status for the surveyed children.

Results

Response to survey

In all, 225 interviews were completed, a response rate of 57 per cent (Table 1). The majority of those not surveyed were not contactable, presumably because the address recorded on the ACIR was not current. There were no statistically significant differences

between the 225 surveyed and 169 unsurveyed children in gender, rural versus metropolitan residence, or vaccine doses recorded on the ACIR (data not shown).

Evidence of immunisation status of surveyed children

Of the 225 surveyed children, 219 were assessed as fully immunised before 12 months of age, by applying the 'third dose assumption' (i.e. 6 children were up-to-date at 4 May 2001, the date the sample was drawn, but not before their first birthday). The parent of only one of these 219 children confirmed that their child had missed one of the six vaccine doses in question. As shown in Table 2, the 'third dose assumption' appears to have been correctly applied for at least 212 (96.8%) of the 219 children and up to 218 (99.5%) if those defined as 'possibly immunised' are included.

Impact of the 'third dose assumption' on immunisation coverage estimates

Coverage at 12 months of age for the whole birth cohort, using the 'third dose assumption', was assessed by the ACIR as 91.2 per cent.⁷ The 'third dose assumption' was applied to 7.02 per cent of the whole birth cohort. If it had not been used, and only those children with all first, second and third doses recorded on the ACIR had been defined as fully immunised at 12 months, coverage would have been 84.2 per cent (Table 3). Based on the 212 surveyed children who met the study criteria of 'definitely' immunised with all first and second vaccine doses, the 'third dose assumption' had been correctly applied for 96.8 per cent (95% CI 94.5–99.1) of the 7.02 per cent of children in the entire birth cohort who were missing first or second doses from their ACIR record. Correcting for inappropriate application of the 'third dose assumption' lowered immunisation coverage at 12 months of age by 0.2 per cent, to 91.0 per cent (Table 3). Sensitivity analyses using more or less stringent study definitions of 'immunised' gave a range of coverage estimates at 12 months of 90.2–91.2 per cent (Table 3).

Immunisation provider of surveyed children

General practitioners (GPs) were the main providers of first and second vaccine doses (Table 4). A higher proportion of surveyed children received these vaccinations from a GP (81%) than was recorded on the ACIR for all vaccinations given to children as at May 2001 (70%). The proportion of surveyed children who usually received vaccinations at hospital clinics

Table 1. Contact and interview rates of the children selected for the study

	Children selected for study n	%
Total in sample	394*	
Contacted	237	60.2
Not contactable [†]	157	39.8
Contacted		
Eligible	231	97.5
Ineligible [‡]	6	2.5
Eligible		
Interviewed	226	97.8
Refused	5	2.2
Interviewed		
Included	225	57.1 [§]
Excluded	1	

* Eligible children sent letters.

† All contact attempts were unsuccessful.

‡ Ineligible to participate in the study as the parent was unavailable during the survey period (n=3) or unable to participate in an English-language interview.

§ Response rate: (number interviewed/total in sample)*100.

|| Excluded: wrong age (ascertained at interview).

Table 2. Parent report of whether six vaccine doses* due at 2 and 4 months of age had been received (n=219)

Immunisation status	Number	%	Cumulative frequency	%
Definitely immunised [†]	212	96.8	212	96.8
Possibly immunised [‡]	6	2.7	218	99.5
Under-immunised	1	0.5	219	100.0
Not sure/refused to answer	0	0.0	219	100.0

* The six vaccine doses were the first and second doses of DTP, Hib, and polio vaccines.

† Includes those where at least one recalled vaccination date could be validated from the ACIR.

‡ Includes those where none of the dates provided could be validated from ACIR records.

was similar (3.3% versus 2.9%) and at council clinics, somewhat lower (7.6% versus 18.9%) than recorded for all children in the cohort.

Discussion

This study is the first national, population-based study to attempt to validate the 'third dose assumption' used in calculating immunisation coverage in Australia. The main finding of the study is that the 'third dose assumption' is valid and should continue to be used for estimating coverage at 12 months of age from ACIR data. The level of overestimation caused by using the assumption is negligible (less than 0.5%) compared with the level of underestimation of coverage if it was not used (6–7%). This is particularly important when, despite significant improvements, the ACIR continues to underestimate coverage because of provider under-reporting.¹²

The range of estimates of the impact of the 'third dose assumption' on immunisation coverage at 12 months of age, calculated from survey data, were robust due to the high proportion of survey respondents who read from provider-completed written records. The parent of only one child confirmed that one of the doses in question had been missed. The parents of the six children defined as 'possibly' immunised for all six first and second vaccine doses were certain that all doses had been received. For most of these children, dates were verified from the ACIR for at least three of the vaccine doses. Thus it is likely that most were fully immunised.

A previous study in 1999, in which NCIRS examined changes in the impact of the 'third dose assumption'

on coverage estimates, showed that if the 'third dose assumption' was not applied, national and state or territory immunisation coverage estimates fell by 11 per cent, with little change over an 18 month period.⁵ The study presented here demonstrates that the reduction in coverage that occurs if the 'third dose assumption' is not applied has reduced (7% versus 11%), but is still significant. The previous study also showed that the impact of the 'third dose assumption' varied by jurisdiction and was more significant in areas where a high proportion of vaccinations were administered by GPs and notified to the ACIR by scannable forms. The present study confirms that GPs are over-represented as vaccination providers

Table 4. Providers from whom the surveyed children* usually received vaccinations

Provider	Number	%
Doctor's surgery	173	81.6
Hospital clinic	7	3.3
Local council	16	7.6
More than one of the above	6	2.8
Overseas	5	2.4
Child health or community clinic	5	2.4
Total	212	

* Includes only those defined as 'definitely immunised' with all first and second vaccine doses.

Table 3. Impact of the 'third dose assumption' on estimates of coverage at 12 months of age for children born between 1 October and 31 December 1999

Evidence	Coverage* % (95% CI)	Difference % (95% CI)
With third dose assumption	91.18	–
Without third dose assumption*	84.16	7.02
Adjusted for 'definite' survey group [†]	90.96 (90.8–91.1)	0.22 (0.06–0.39)
Adjusted for 'possible' survey group [‡]	91.15 (91.1–91.2)	0.03 (0.00–0.10)
Adjusted for written record + date [§]	90.22 (89.9–90.5)	0.96 (0.64–1.28)

* Children defined as up-to-date at 12 months of age only if all first, second and third vaccine doses were recorded in the ACIR.

† Adjusted for the proportion of surveyed children up-to-date at 12 months of age defined as 'definitely' immunised with all first and second vaccine doses.

‡ Adjusted for the proportion of surveyed children who were up-to-date at 12 months of age defined as either 'definitely' or 'possibly' immunised with all first and second vaccine doses.

§ Adjusted to include only children who were up-to-date at 12 months of age defined as 'definitely' immunised where a written record was used and the full date was provided for all the first and second vaccine doses (189/219; 86.3% 95% CI 81.7–90.9).

for children missing first and second doses from their ACIR record (81%) compared with other children in the same birth cohort (70%). This supports the view that non-notification of first and second dose vaccine encounters, while an important issue for all categories of immunisation provider, is more important among GPs.

There were several limitations to the study, although none is likely to substantially alter key results. It is difficult to achieve true random sampling from the ACIR because of both confidentiality requirements and intrinsic limitations of the Medicare database. In this study, disadvantaged or highly mobile families may have been less likely to be contacted and surveyed, and also less likely to be immunised.¹³ However, the surveyed and unsurveyed children did not differ significantly in demographic or recorded immunisation histories. ACIR still represents the best available method of obtaining a representative sample of the population.

The study relied on parent's report from provider-completed written immunisation records, with the full date of immunisation accepted as a proxy for confirmed receipt. Parents without written records were asked if they were certain all doses had been received. Our ability to validate parental report within the sample, by comparison with dates for vaccine doses recorded on the ACIR, adds considerable weight to the conclusions.

Conclusions

The 'third dose assumption' is valid and it is appropriate that it be used to calculate official immunisation coverage for children at 12 months of age from the ACIR, in order to minimise the degree to which the ACIR underestimates coverage. We know from a previous study that one of the main contributing factors for underestimation of coverage by the ACIR, and also the need for the 'third dose assumption', is under-reporting of immunisations by providers.¹² This may be best addressed by measures aimed at improving notification of vaccinations to the ACIR through Divisions of General Practice.

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References

1. Hull BP, McIntyre PB, Heath TC, Sayer GP. Measuring immunisation coverage in Australia. A review of the Australian Childhood Immunisation Register. *Australian Family Physician* 1999;28:55–60.
2. O'Brien ED, Sam GA, Mead C. Methodology for measuring Australia's childhood immunisation coverage. *Commun Dis Intell* 1998;22:36–37.
3. National Health and Medical Research Council. *The Australian Immunisation Handbook*, 7th edition. Canberra: Australian Government Publishing Service, 2000.
4. McIntyre PB, Heath TC, O'Brien ED, Hull B. National immunisation coverage—interpreting the first three quarterly reports from the ACIR. *Commun Dis Intell* 1998;22:111–112.
5. Hull BP, McIntyre PB. Immunisation coverage reporting through the Australian Childhood Immunisation Register—an evaluation of the 'third dose assumption'. *Aust N Z J Public Health* 2000;24:17–21.
6. Human Capital Alliance. Evaluation of the Australian Childhood Immunisation Register. Report prepared for the Commonwealth Department of Health and Aged Care. Canberra: April 2000.
7. Department of Health and Ageing. Communicable Diseases Surveillance—additional reports. *Commun Dis Intell* 2001;25:94.
8. Department of Health and Ageing. Communicable Diseases Surveillance—additional reports. *Commun Dis Intell* 2000;24:324.
9. National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases. Measles Control Campaign 1998. Evaluation report. Canberra: Department of Health and Ageing, 1999. Available from: <http://immunise.health.gov.au/metadata/measeval.htm>
10. SAS version 8 (computer software). Win98. Cary, NC: SAS Institute Inc., 1999.
11. Dean AG, Dean JA, Coulombier D, *et al.* Epi Info version 6: a word processing, database and statistics program for epidemiology on microcomputers. Atlanta, Georgia, USA: Centers for Disease Control and Prevention, 1994.
12. Hull, BP, Lawrence GL, MacIntyre CR, McIntyre PB. Immunisation Coverage: Australia 2001. 2002. Canberra, Commonwealth Department of Health and Ageing. Available from: <http://immunise.health.gov.au/report.pdf>
13. Bond L, Nolan T, Lester R. Home vaccination for children behind in their immunisation schedule: a randomised controlled trial. *Med J Aust* 1998;168: 487–490.