Early connections: effectiveness of a pre-call intervention to improve immunisation coverage and timeliness

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ABSTRACT

INTRODUCTION: Children who have missed or delayed immunisations are at greater risk of vaccine-preventable diseases and getting their first scheduled dose on time strongly predicts subsequent complete immunisation. Developing a relationship with an infant's parents and general practice staff soon after birth followed by a systematic approach can reduce the number of delayed first immunisations.

AIM: To assess the effectiveness of a general practice–based pre-call intervention to improve immunisation timeliness.

METHODS: Clustered controlled trial of general practices in a large urban district randomised to either delivery of pre-call intervention to all babies at aged four weeks or usual care.

RESULTS: Immunisation timeliness for infants receiving the primary series of immunisations among their nominated Auckland general practices was higher than expected at 98% for the six week event. The intervention was statistically but not clinically significant. Coverage was significantly lower among infants with no nominated practice which reduced overall coverage rate for the district.

DISCUSSION: Pre-call letters with telephone follow-up are simple interventions to introduce into the practice management system and can be easily implemented as usual standard of care. Early identification of newborn infants, primary care engagement and effective systems including tracking of infants not enrolled in general practices has the greatest potential to improve immunisation coverage rates even further.

KEYWORDS: Randomized controlled trial; immunization; vaccination; general practice; intervention studies

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Introduction

New Zealand (NZ) historically has mediocre immunisation coverage of children[1] and relatively high rates of vaccine-preventable disease.[2] The risk of vaccine-preventable diseases is greater if childhood immunisations are incomplete, which includes both missed and delayed immunisations. Delays in immunisation puts infants at significant risk of contracting and being hospitalised for diseases such as *Haemophilus influenzae* type b[3–6] and pertussis[4,6–9] and increases the potential reservoir of disease in unvaccinated infants.[5,10]

Receiving the first dose on the vaccination schedule on time is one of the strongest and most consistent predictors of subsequent complete immunisation[11–13] and delays are significantly more likely to result in lower overall coverage.[12,14–16] In our previous study of 124 practices in the Auckland and Midland regions of NZ, median coverage at six weeks for the diphtheria, tetanus and acellular pertussis immunisation was 93%, while timely receipt of this dose was only 40%.[17]

Factors that impact upon immunisation receipt and timeliness are now well established. These

include the knowledge and attitudes of caregivers, particularly antenatally,[18–22] attitudes of health professionals[23,24] and aspects of health care systems such as cost, recall and reminders and cost to provider.[25]

The early establishment of a relationship between general practices and the infant's parents can reduce the number of infants whose first immunisation is delayed.[12] Our prior study demonstrated that early enrolment with a primary care provider was associated with a higher level of immunisation completeness.[17,26,27]

The NZ immunisation schedule from June 2008 for the first six months of life consisted of two combination vaccines: INFANRIX® hexa and Prevenar® given at ages six weeks, three months and five months. INFANRIX® hexa contains antigens from diphtheria, tetanus, and pertussis (DTaP), polio, *Haemophilus influenzae* type b and hepatitis B. Prevenar® (PCV7) is a conjugate pneumococcal vaccine that contains antigens from seven pneumococcal serotypes that are predominant causes of invasive pneumococcal disease.[28] In addition, Bacillus Calmette-Guérin (BCG) is given to infants living in households with people who have, or have had, tuberculosis (TB) or are in immigrant families from countries where TB is common, and HBvaxPRO® (hepatitis B vaccine) is given with hepatitis B–specific immunoglobulin to newborns of mothers who are hepatitis B carriers.

NZ practices typically have recall systems set up in their electronic practice management systems (PMSs) to remind parents that their child's immunisations are overdue. All childhood scheduled immunisations should be recorded on the National Immunisation Register (NIR) at the time of delivery, with data directly transmitted from the practices. The NIR sends reminder messages to practices if information about immunisation events is delayed. The overdue times for NIR are set outside those for the PMS so that the practices have time to follow up before they start receiving overdue messages from the NIR. The PMS will generate a recall for a child at eight weeks if the six week doses have not been given, whereas the NIR will consider that immunisation event overdue when the child is aged 10 weeks. Similarly, PMS and NIR timeliness 'windows' for the three month vaccines are aged four and four and a half months respectively, and again for the five month event aged six and six and a half months.

From our previous work, we hypothesised that the enrolment of children with a general practice soon after birth, and parents being actively invited when their baby is four weeks old to attend the practice for their first (six week) set of vaccines, followed up with early phone calls if they do not respond, would improve immunisation timeliness. We therefore aimed to conduct a randomised controlled trial (RCT) of a general practice–based pre-call intervention. Our objectives were to assess the effectiveness of this enhanced practice system on coverage and timeliness of the six week, three month and five month immunisations.

Methods

Study design

This was an RCT of a multicomponent intervention compared with usual care. Randomisation was at the level of the general practice. The study was registered with Australia New Zealand Clinical Trials Registry (00082892) and ethical approval was obtained from the Ministry of Health Auckland Regional X Ethics Committee (Reference NTX/08/08/072).

Setting and study population

The setting was practices in the Auckland District Health Board (ADHB) catchment area and the study population was babies born in the ADHB region and/or those whose parents nominated practices in the ADHB region as their general practice. The study took place between 1 November 2008 and 20 April 2010. The NIR is notified of the nominated general practice for all newborns and the practice then is informed by the NIR that they are the baby's nominated practice. Children are tracked using the unique National Health Index (NHI) number assigned at birth.

Intervention

Our intervention consisted of a brief letter of welcome and invitation to attend when the baby

was six weeks, plus simple information on immunisation. This was sent by the practice to the baby's caregiver when the baby was four weeks old (see appendix in the web version of this paper for this pre-call material). A follow-up phone call was made to the baby's caregiver when the baby was five weeks old if an appointment had not already been made for the six week vaccinations and, if the caregiver did not present the baby for immunisation, a further attempt at contact (early recall) was made to the caregiver when the baby was seven weeks old. Phone calls were the preferred method of pre-call/recall although a text message, email or letter could also be used. Practices were given a $15 shopping mall voucher per baby to acknowledge the time and effort required to administer the intervention, to be claimed irrespective of whether or not it resulted in immunisation of the baby.

WHAT GAP THIS FILLS

What we already know: Children who have delayed or missed immunisation events are at greater risk of vaccine-preventable diseases. Getting their first scheduled dose on time strongly predicts subsequent complete immunisation, and developing a relationship between the general practice staff and a baby's parents soon after birth can reduce the number of delayed first immunisations.

What this study adds: Immunisation coverage and timeliness for infants receiving the primary series of immunisations among their nominated Auckland general practices is extremely high, with no clinically relevant room for improvement. A pre-call intervention made a statistically significant improvement in timeliness of immunisation, but only by one day. Coverage was significantly lower among infants with no nominated practice and this reduced the overall coverage rate for a district. Targeting both the systems and services that can identify and track infants who are not engaged with primary care at birth has the greatest potential to improve immunisation coverage rates even further.

Inclusion/exclusion criteria and practice allocation

A database of all 148 general practices operating in the ADHB region was created by combining general practice databases held by the Immunisation Advisory Centre and the Department of General Practice and Primary Health Care. Telephone directories were cross-referenced to ensure all practices in the ADHB region were included. All practices were assigned a number (practice code). Practices identified as not involved in delivering infant immunisations were excluded. Following consent, block randomisations were conducted of recruited practices using a computer random number generator to assign each practice to either the intervention or control group. The research team other than the project manager were blind to the identity of practices in the intervention and control groups. Intervention practices were assisted to adjust their PMS to automatically send out pre-call and recall letters to their patients in the study.

Outcome measures

Our primary outcome measure was receipt of six week immunisations and age at which these were delivered as recorded on the NIR for all the babies in our study in intervention, control and non-participating practices. Secondary measurements were receipt of three month and five month immunisations and age at which these were delivered. Pre- and post-trial surveys were also conducted for participating practices to establish their practice population and their pre-call/recall practices before, during and after the trial.

Power calculations

This was a clustered randomised trial with each enrolled practice being a cluster. Because receipt of all three primary series doses is important to most effectively reduce risk of vaccine-preventable diseases, the trial was powered on receipt of three month and five month immunisations. Our previous study had shown that the inflation effect could be between 20 and 40 (see Table 1).[17] A significant contributor to this large inflation effect was the fact that at that time some practices were not enrolling pre-school children in their practices for pragmatic reasons which led to a large inter-practice variability in immunisation timeliness and coverage rates. At the time of this current study, this problem had largely been addressed with the introduction of the NIR plus the introduction of children being fully vaccinated by their second birthday as a performance indicator as part of the Primary Health Organisation Performance Management Programme. With most or all children being enrolled with practices

Table 1. Summary of sample size calculations

Immunisation doses	Timely immunisation coverage			
	Current %	Desired %	Sample size required DE = 20	Sample size required DE = 10
6 weeks	88	98	4000	2000
3 months	75	94	2000	1000
5 months	60	85	2000	1000

DE = Design effect

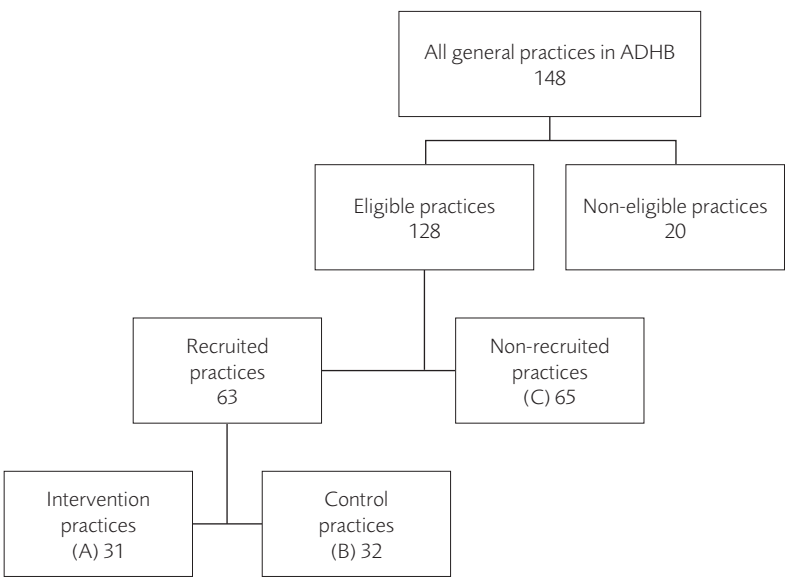
soon after birth, the design effect was expected to be significantly smaller. We planned to deliver 1000 interventions. This sample size was calculated to be sufficient to have 80% power at the 0.05 level of statistical significance to detect an increase in the timely immunisation coverage from 75% to 94% at the three month and from 60% to 85% at the five month immunisations.

Analysis

The variables in the NIR dataset consisted of NHI number (converted to a unique identifier), date of birth, dates when six week, three month and five month immunisations given (vaccines coded v1 for INFANRIX® hexa and v2 for Prevenar®), nominated practice at birth, practice(s) giving immunisation for all children born in the ADHB catchment area for the study period (1 November 2008 to 20 April 2010). At this date all intervention babies were aged six months or older. Immunisation events identified as BCG vaccine were deleted.

Survival curve analysis was used to measure delay in immunisation. For each infant participant the days from their ideal immunisation date (i.e. 42 days for six week vaccine) to the actual day they received vaccine were counted. For this analysis, second and third dose assumptions were made, i.e. if the three- and/or five month vaccines had been given it was assumed that the child had previously received the earlier doses. We compared total scores (i.e. number of delayed days) using survival analysis (Kaplan-Meier and Cox proportional hazards) for (1) intervention versus control group (intention to treat analysis), (2) pre-call versus non-pre-call in the intervention group, and (3) pre-call in the intervention group versus control group to test if there was any significant differences. This allowed analysis by continuous rather than dichotomous data (i.e. defining an immunisation event as either on time or delayed). This provided greater statistical power and allowed for graphic representation of results plotting number of delayed days over time for both groups. Adjustment for clustering effect was conducted.

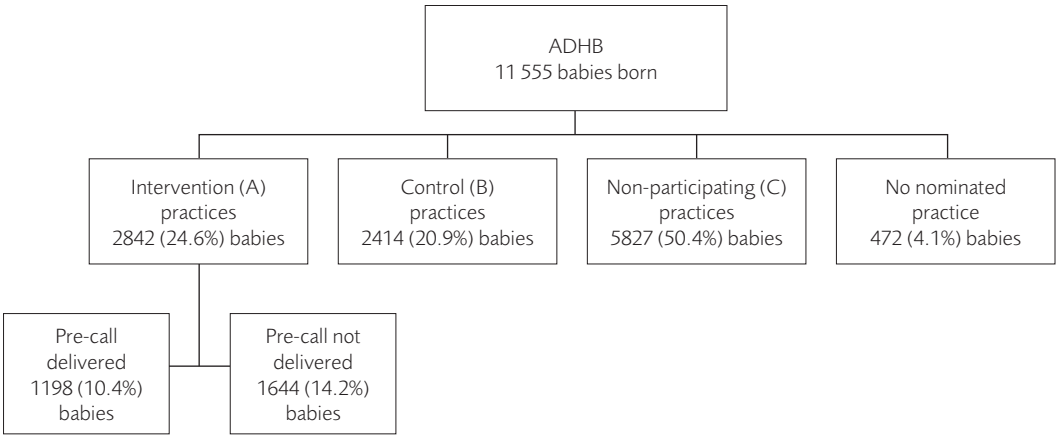
Figure 1. Recruitment of practices in ADHB



Results

Practice recruitment is presented in Figure 1. From 128 eligible practices, 63 were recruited with 31 randomised to the intervention group (A) and 32 to the control group (B). Groups A, B and C (non-recruited practices) were similar with respect to the socioeconomic status of the practice locations and the average practice size. The num-

Figure 2. Babies born in practice groups during the study period



ber of babies born in the ADHB between 1 November 2008 and 20 April 2010 (a one year 5.75 month period) was 11 555 (see Figure 2). This is 7834 babies per calendar year, which was close to our estimate of 8000 babies per year for the 128 eligible general practices. Half of the eligible practices (63) were enrolled in the study, and close to half (46%) of the babies were nominated to these practices. There were slightly more babies born to the control (B) than the intervention (A) practices. A small number of infants (n=472, 4%) had no nominated practice.

Only 1198 of the 2842 babies in the A practices received pre-call interventions (42%). The reasons for these not being delivered included practices not receiving or being aware of the notification from the NIR in time, practice nurses stopping the intervention for periods of time (for example during the summer period when there were locum nurses), plus one A practice failed to deliver any interventions at all. In many instances details were not recorded as to whether or not the intervention included a five-week pre-call or seven-week recall as well as the four-week pre-call mail-out, so sub-analyses of how often these were required was not possible.

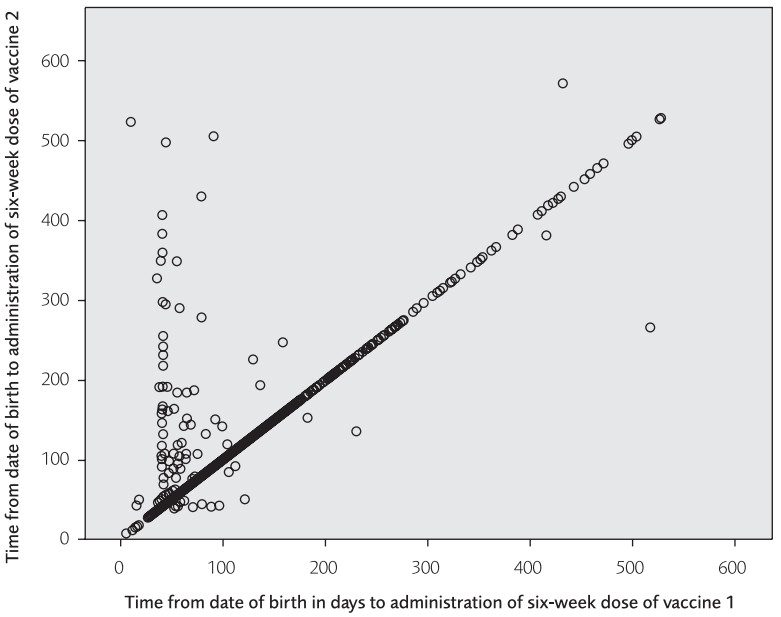
The overall coverage rate for the six week vaccine '1' (INFANRIX® hexa) for A, B and C practices delivered on time by eight weeks of age was 98%—see Table 2. This was also the case for vaccine 2 (Prevenar®). Scatter plots of the difference in timing between v1 and v2 for all cases

Table 2. Overall vaccination rate for six week event for vaccine 1 for intervention, control, non-participating and no nominated practice

Type of practice	Six week vaccine 1 received by age eight weeks	Opted off / Declined	No NIR data	Total	% completed by practice type	% by A, B or C only	% overall
A	2743	53	46	2842	97		
B	2388	26	0	2414	99	98%	94%
C	5744	83	0	5827	99		
D1	32	16	0	48	67		
D2	0	0	424	424	0		
	10 907	**177**	**470**	**11 555**			

Key:
A = Intervention practice
B = Control practice
C = Non-participating practice
D1 = No nominated practice, six week immunisation data available
D2 = No nominated practice, six week immunisation data not available
v1 = INFANRIX® hexa

Figure 3. Differences in timing between vaccines 1 and 2 for six week vaccination event



and then for those in practices A and B showed that these were rarely given separately; hence, separate analyses for v1 and 2 were not required. See Figure 3 for scatter plots for the six week events which shows a straight line when time of delivery of vaccine 1 is plotted against time of delivery of vaccine 2.

When the 472 children with no nominated practice (D) were included in the total, the overall vaccination rate completed by eight weeks of age for the six week vaccination dropped from 98% to 94%. Table 3 shows the average age of receipt of INFANRIX® hexa at six weeks, three months and five months by practice type for children receiving immunisations. It can be seen that non-participating practices (C) consistently had a slightly longer average delay than recruited practices (A and B), but children without a nominated practice who were vaccinated had a much greater average delay. While the majority (88%) of the babies attended the practice their parents nominated at birth, 12% were either vaccinated or declined vaccination at a different practice for vaccine 1 at the six week event.

We analysed data both using the second and third dose assumptions (e.g. if the three month dose was recorded in the NIR, we assumed the six week event had been given) and not making this assumption but categorising these children as having no information on the six week vaccination event. This made a slight difference in coverage rates. When applied to immunisation registers, the third-dose assumption results in an over-estimate of immunisation coverage that is smaller than the underestimate produced by assuming all those with missing data have not been immunised.[29]

When the vaccination times of A and B practices for receipt of the six week vaccine were compared (intention-to-treat analysis), there was no indication of a difference between the groups (Log Rank (Mantel-Cox): Chi-square 0.268, df=1, p=0.605). There also was no difference in days to vaccination for the three month vaccine event (Log Rank (Mantel-Cox): Chi-square 0.540, df=1, p=0.46) nor for the five month vaccine (Log Rank (Mantel-Cox): Chi-square 0.281, df=1, p=0.60).

Table 3. Average age of receipt of INFANRIX® hexa at six weeks, three months and five months by practice type

Practice type	Average age in weeks of receiving six week v1	Average age in months of receiving three month v1	Average age in months of receiving five month v1
A	7.06	3.40	5.64
B	7.09	3.43	5.65
C	7.26	3.48	5.7
D	8.92	4.49	6.32

Key:
A = Intervention practice
B = Control practice
C = Non-participating practice
D = No nominated practice
v1 = INFANRIX® hexa

However, this analysis did not take into consideration the fact that the 58% of children in the A practices did not receive the intervention.

We therefore conducted a second analysis looking at vaccination in group A, stratifying by actual delivery of the intervention. This showed that babies receiving the intervention were statistically more likely to receive their six week vaccination event earlier (Log Rank (Mantel-Cox): Chi-square 19.187, df=1, $p<0.001$) with mean days to six week vaccination event 49.6 days for those who received interventions compared with 51.2 days for those who did not—see Figure 4. An advantage of this analysis is that it takes into account types of censored data, for example where six week data is missing but the third dose assumption is used. The same pattern was repeated for vaccination coverage stratified by delivery of intervention for A practices for the three month vaccination event (Log Rank (Mantel-Cox): Chi-square 16.527, df=1, $p<0.001$) with mean days 100.1 compared with 103.8, and for the five month event (Log Rank (Mantel-Cox): Chi-square 11.621, df=1, $p=0.001$) with mean days 166.2 compared with 170.1.

A third analysis comparing only those babies in the A practices who had received the intervention with the group B babies found a similarly significant result for the six week vaccination event results (Log Rank (Mantel-Cox): Chi-square 5.969, df=1, $p=0.015$), the three month (Log Rank (Mantel-Cox): Chi-square 10.722, df=1, $p=0.001$) and the five month (Log Rank (Mantel-Cox): Chi-square 6.753, df=1, $p=0.009$).

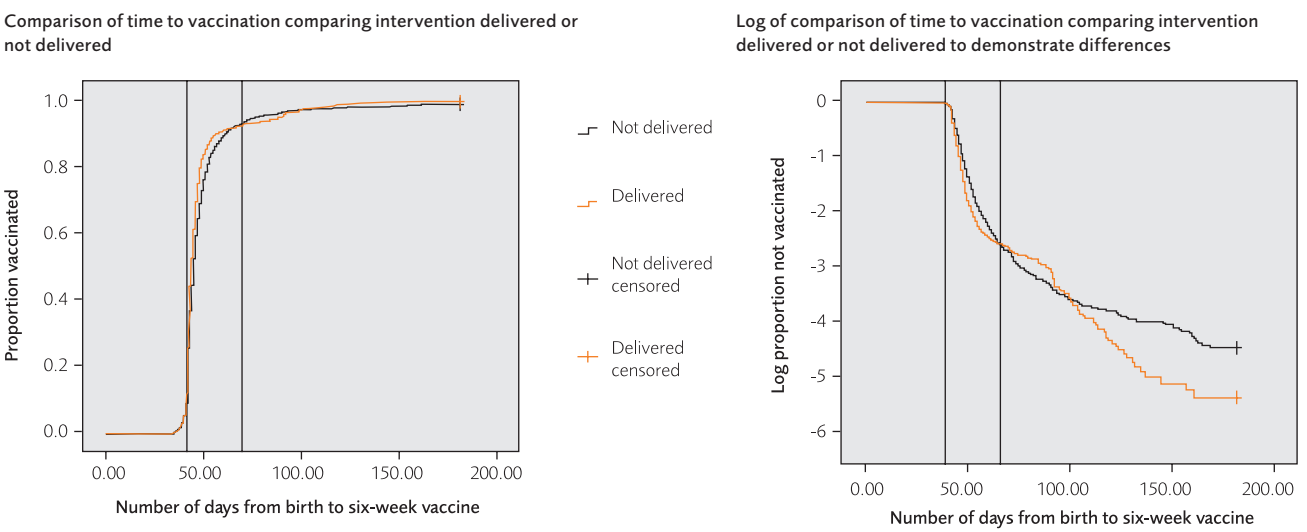
While there was no statistical difference in timeliness between A and B groups, we expected that recruited practices (A and B) would have less delay in immunisation overall than C practices which declined to participate (and may be less focused on vaccination). We therefore repeated the timeliness analysis including group C for the six week vaccine. We found that group C practices had a significantly more delayed vaccine rate for the six week vaccine (Log Rank (Mantel-Cox): Chi-square 14.705, df=1, $p=0.001$).

Lastly, analysis of practice surveys found that 13 A and 12 B practices used some form of pre-call prior to the trial. All but one A practice (which had failed to use the pre-call intervention) intended to continue using our pre-call intervention post-trial.

Discussion

At the commencement of our study in 2008, NZ immunisation rates were estimated from the NIR data to be 88% for the six week vaccine event, 75% for the three month event and 60% for the

Figure 4. Days to six week vaccination event in Group A stratifying by actual delivery of the intervention



The window for 'timely' six week vaccination is 6–10 weeks (42–70 days)

five month event. We calculated our sample size based on these data. However, we found the coverage rate for enrolled children in all practices in the study was much higher than expected, at 98% for the six week vaccine and dropped off very little for the three month and five month doses.

We did find a statistically significant improvement in timeliness of vaccine receipt at the six week, three month and five month events comparing children who received the intervention with those who had not, but because the coverage rates were so high, this only translated into children receiving the vaccine on average one day earlier (from 49.5 days to 50.5 days for the vaccine due at 42 days), which is not clinically significant.

Given that there were much higher coverage rates across all practices to start with, the lack of clinical significance is not surprising.

While the average coverage among all the ADHB practices was 98%, there was a small percentage of infants without nominated practices (n=472, 4%). Thirty-three percent of infants with no nominated practice for whom there was an entry for the six week vaccination event were not vaccinated. When these infants were added to the total, the overall coverage rate dropped to 94%. This is an important finding. Infants with no nominated general practices are much less likely to get immunised and, if they do, are much more likely to be delayed. This reduces the overall coverage rate significantly for the region (making the general practices look as though they are performing less well than they are). Children who are not getting general practice services including immunisation pre-call and/or recall can be considered to be 'falling through the cracks': Attention needs to be given to this group of children, both encouraging earlier general practice enrolment for them and targeting outreach services for those unenrolled.

We identified a number of places where errors occur in the collection of data in the NIR: the practitioner (usually the practice nurse) may enter incorrect data in the PMS, there may be technical problems with the transfer of data from the PMS to the NIR, the NIR might send back error messages to the practitioners' inboxes that they do not know how to action, a practitioner may not know how to manage entry of complex 'catch-up' schedules when a child is presenting late or has received a different immunisation regime in another country, or the PMS might not have the facility to record these complex immunisation entries accurately. An unvaccinated child presenting at three months may have this immunisation event recorded as the three month rather than the six week vaccination event. Furthermore when patients transfer practices it is usually not possible for their full clinical records to be transferred electronically between practices. This means that the new practice needs to manually enter previous vaccines from paper records or the child well health book, which will not always be available.

How our findings relate to what is already known

Timeliness of children's vaccination varies widely between and within countries.[30–39] There are a range of factors associated with timeliness reported in these studies. Ethnicity, area of residence[21,40,41] and negative media coverage are all associated with delay in vaccination.[36]

Integrated systems including outreach and recall has been shown to be effective. For example, an extensive programme in Chicago which combined immunisation education at birth with ongoing reminder–recall achieved over 90% on-time adherence for recommended immunisations among inner-city children aged 0–35 months.[42] Having a nurse vaccine manager who is in charge of tracking inventory, training staff, and developing vaccination protocols can improve timeliness of vaccine delivery.[43]

Our study shows that enrolment and early engagement with a general practice is resulting in excellent coverage and timeliness. However the children not enrolled with a general practice fare poorly and represent a small but significant group for whom outreach services should be targeted, and assistance given for the infant to join a general practice.

Strengths and limitations

We piloted the intervention set-up, received early datasets for testing, performed dummy runs, dou-

ble-entered data and performed meticulous data cleaning to ensure we had an accurate dataset to analyse.

However, we recruited fewer practices to the study (63/128, 50%) than the 60% we had intended and we had delays in some practices implementing the intervention. The intervention was only delivered to 42% of the eligible children in the intervention practices, plus some of the practices reported that they were already doing some form of recall; hence, the comparison between intervention and control group had no significant difference. We had incomplete records of whether or not the delivered intervention included five-week pre-call or seven-week recall contacts.

Recommendations

As a result of this study we recommend that NIR notify general practices so that they are aware of all newborns for whom the practice is the nominated provider as soon as possible after birth, and that DHBs follow up newborns with no nominated providers to ensure registration with a provider as early as possible. Different regions will use different strategies to achieve this. We further recommend that practices send a pre-call letter with accompanying information about immunisation when infants are aged four weeks, as a fully automated prompt system followed by telephone contact if the family does not make contact seems to be a cost-efficient and sensible strategy. Because many Auckland practices are already doing some form of pre-call, having a standardised four-week pre-call letter prompt system that all practices could use may have a positive effect on timeliness. It could assist those practices who are not pre-calling and act as a reaffirmation to those practices who are pre-calling that their current commitment is worthy of continuing.

Conclusion

We found immunisation coverage and timeliness for infants receiving the primary series of immunisations among their nominated Auckland general practices to be extremely high, with no clinically relevant room for significant improvement. The intervention trialled in this study made a statistically significant improvement to timeliness of vaccination; however, only by one day. However, coverage was significantly lower among infants with no nominated practice and this reduced the overall coverage rate. Non-enrolment of babies at birth with a general practice is a significant factor in delayed or missed immunisations. Targeting both the systems and services that can identify and track these infants has the greatest potential to improve immunisation coverage rates even further.

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COMPETING INTERESTS
None declared.

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APPENDIX A: Pre-call material

A pre-call letter and information sheet about immunisation was generated by the PMS for four-week-old babies. These were printed on white A5 paper using the practice nurse's standard paper and printer.

Pre-call letter

Dear [name of caregiver],

We would like to welcome your new baby to our practice.

As our babies grow, immunisation is part of the regular care that they are offered. It is nearly time for your baby's first immunisations which are due at six weeks of age.

Having your baby immunised on time is important and offers protection against seven serious diseases early on. Enclosed you will find some brief information about the six week immunisations. Scheduled childhood immunisations are free for all New Zealand children.

Please contact us at the practice to arrange a time to come in. We look forward to meeting you and your baby.

Kind Regards,

[Practice contact]

Information about vaccines at six weeks

Getting your baby immunised on time at six weeks will reduce the chance of contracting vaccine-preventable diseases. Starting on time is important because young babies are particularly at risk of catching these diseases.

At six weeks, two injections are offered to provide protection against seven serious diseases. One injection called INFANRIX® hexa and one called Prevenar® start the important process of protecting your baby against diphtheria, tetanus, whooping cough (pertussis), polio, hepatitis B, *Haemophilius influenzae* type b, meningitis and pneumococcal disease.

As with any health procedure, there are risks and benefits. If you have any questions, please talk with your GP or practice nurse or call 0800 IMMUNE (466863). More detailed information about the immunisations your baby will be offered and the diseases the vaccines protect against can be found at http://www.immune.org.nz/.