

Immunisation adverse reaction monitoring through the use of parent-held diaries

Nicola M Turner FRNZCGP, Claire J McLachlan-Smith PhD and Shelley Yip, Medical Student, Goodfellow Unit, Department of General Practice and Primary Health Care, Faculty of Medicine and Health Science, University of Auckland

ABSTRACT

Aim

To trial a methodology of actively monitoring reactions to routine childhood vaccinations through the use of parent-held diaries.

Method

Thirty-four mothers were recruited through General Practices and given a diary to complete for a week prior to, and a week following, a routine infant vaccination. Two styles of diaries were used, one with an open-ended style, and one that included suggested symptoms.

Results

The percentage increase in all reported symptoms post-vaccination was 57.2%, similar in both groups al-

though the group given a prompt list had an overall much higher rate of symptoms reporting than the other group. Frequently reported symptoms included local vaccine-site reactions (41% for the DTPH, and 17.6% for the Hepatitis B vaccination), persistent or unusual crying (29.5%), grizzly or unsettled (22%), fever (25%). There were no severe reactions reported.

Conclusion

The rate and types of reactions post-vaccination were similar to internationally reported figures for these vaccinations. This methodology offers a positive approach to active monitoring of vaccination reactions with good support from participating parents.

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Introduction

Immunisation is the greatest public health success story in history.¹ However, in New Zealand, there are current concerns over the immunisation programme, which has low and possibly declining coverage rates for immunisation.² The only New Zealand national coverage survey in 1992 found that less than 60% of all children were fully immunised by their second birthday.³ Recent data suggests that immunisation coverage in New Zealand may have dropped by 10% since 1996.⁴ While the reasons for low immunisation rates are multifactorial, it has been recognised that

there is significant parental concern about the side effects of immunisation. There is often more concern over the side effects of the vaccines than the diseases in a population which has little first-hand experience of the diseases.⁵

New Zealand does have a monitoring mechanism for adverse reactions occurring following vaccinations. This has been in place since 1965 and works on a voluntary reporting system. Adverse reactions can be notified to the Centre for Adverse Reaction Monitoring (CARM) in Dunedin.⁶ This monitoring mechanism has several limitations: notifications are volun-

tary; they are mostly made by health professionals; it is not readily understood and used by the public, and it is reliant on the enthusiasm and response of the notifier. There is no known New Zealand research looking at active methods of monitoring adverse reactions. Hence all quantifiable adverse reaction information in New Zealand is reliant on international data.

There are difficulties in developing sound methodology for assessing adverse reaction monitoring, particularly because it is difficult to get a matched unimmunised control group for comparison. It is also dif-

difficult to create an open-ended, non-leading assessment of all recognised and possible reactions following an immunisation event. The concept of a parent-held diary arose as a tool so that all possible reactions could be recorded by the most involved observer, i.e. the parent. The self control could be recording in the diary in the time prior to the immunisation event. Results can both be compared with internationally known expected rates of adverse reactions, while also looking for unexpected reported events that may not be considered in international data. Internationally, parent-recorded diaries⁷ and reporting cards⁸ have been a recognised part of vaccine-reaction monitoring. The strongest use of baby diaries has been in the area of

child psychology, particularly in psycholinguistics.⁹ This study was designed as a pilot to assess the methodology of using parent-held diaries as a tool for actively measuring the amount, type and frequency of occurrence of adverse reactions to immunisations in New Zealand.

Method

Two different styles of diary were prepared. The Group One diary consisted of a list of the most commonly encountered vaccine reactions,¹⁰ commonly encountered minor illnesses, and a question on illness in any other family member. The Group Two diary comprised a single page per day headed with an open ended-question: "Describe any

changes in your child's health or behaviour that you have noticed today." Parents who were recruited to the study used either Group One or Group Two diary method, and in both cases would complete the diary for seven days prior to and seven days following the vaccination. Fifty parents of infants who were due for their six-week, three-month or five-month immunisation were recruited to take part in the study. Recruitment was achieved by one of the researchers approaching practice nurses in the urban Auckland region, and asking practice nurses to identify eligible parents and infants. The practice nurse contacted parents (all mothers) and recruited them for the study. The practice nurses chosen were known personally to the Goodfellow Unit staff or the local immunisation coordinators, or contacts of the researcher. The decision of whom to approach to participate was left to each practice nurse, based on her per-

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Table 1. Symptoms reported per number of infants pre- and post- vaccination
Total number of children reported with symptoms:

	Group 1 (n=20)			Group 2 (n=14)		
	Pre-vaccination	Post-vaccination	Difference in symptoms from pre- to post-vaccination	Pre-vaccination	Post-vaccination	Difference in symptoms from pre- to post-vaccination
Loss of appetite	8	9	1	0	5	5
Fever	0	5	5	0	0	0
Grizzly/unsettled/irritable	13	16	3	8	12	4
Persistent/unusual crying	9	15	6	4	8	4
Vomiting/spitting	3	1	-2	0	1	1
Diarrhoea	2	6	4	2	2	0
Runny nose	2	4	2	6	2	-4
Cough	1	3	2	4	1	-3
Sleepy/drowsy	1	7	6	4	8	4
Local reaction DTPH site		10	10		4	4
Local reaction HepB site		5	5		1	1

Table 2. Total number of symptoms reported during the 14 days

	Pre-vaccination			Post-vaccination					
	Group One	Group Two	Total	Group One	% relative increase	Group Two	% relative increase	Total	% relative increase
Total number of symptoms	165	85	250	260	57.5	133	56.5	393	57.2
Number of symptoms per infant	8.25	6.07	7.35	13	57.5	9.5	56.5	11.6	57.2

sonal knowledge of the parent, and belief in the parent's level of interest and ability to record a diary for a 14-day period. Parents who had agreed to participate were then contacted via telephone by the researcher. Background information on the family was requested over the telephone. Ethnicity was ascertained by asking the mothers which ethnic group they belonged to. The mother was sent a diary by mail and was requested to fill it out every day starting from seven days prior to the immunisation event, and then for seven days following the immunisation event. The diaries were given out in an alternating fashion to the mothers.

When diaries were completed, diaries were analysed and the results compared. Group Two data were coded according to the symptoms listed in the Group One diary.

Results

Thirty-two General Practices were approached. In total 23 practice nurses agreed to help, but 10 actively recruited mothers for the study in the time period of two months. The other 13 either did not find the time to recruit in the period or did not find suitable candidates. In total 50 mothers were issued with diaries and 34 (68%) completed and returned the diaries.

Twenty parents completed diaries for Group One, and 14 completed diaries for Group Two. Ages ranged from 15–19 to 40–44 with the majority (n=22) in the 30–39 year age range, a total of eleven under 30 years and only one over 40 years. 88.2% were Pakeha

(n=30), with only three Maori and one Indian. 20.6% were community service cardholders (n=7). Most infants monitored were either second (47%) or first (38%) born in the family.

Infants due for the six-week vaccination were more difficult to recruit because they are frequently not

Those mothers who noted the most symptoms pre-vaccination, also noted more symptoms post-vaccination.

seen in General Practices before the six-week visit. In total four diaries were completed for the six-week vaccination (two for each group). Seventeen diaries were completed for the three-month vaccination (11 in Group One, and 6 in Group Two), and 13 diaries were completed for the five-month vaccination (seven in Group One, and six in Group Two). The infants in each of these groups were given the standard immunisation schedule vaccines as per the New Zealand national schedule.¹¹ This comprises the Tetramune (DPTH) from Wyeth Lederle (diphtheria, tetanus, pertussis, haemophilus influenza vaccine), H-BVax 11 from Merck Sharp and Dohme Ltd (Hepatitis B) and Oral Polio vaccine from SmithKline Beecham. The identical regime is given at six-weeks, three-months and five-months.

Twenty out of 25 completed the diaries with the Group One style (prompted) while it was much lower

in Group Two (unprompted) diaries with only 14 out of 25 completed.

Findings

All children were reported to have some form of common symptom both prior to and post vaccination. No severe or life-threatening symptoms were reported in any of the diaries. Symptoms were more likely to be reported by Group One than by Group Two both prior to and following the vaccination.

The most commonly reported symptom that was significantly increased post-vaccination for both groups was a local site skin reaction. The post-vaccination reaction was noted in a total of 14 children at the DTPH site (41%) and in six children at the Hepatitis B site (17.6%). Of note is the much higher reporting of a site reaction when given a prompt in the Group One diaries, with 10 (50%) reporting a site reaction for the DTPH, and five (36%) for the Hepatitis B site. The next most commonly reported symptoms for the Group One diaries were persistent/unusual crying and sleepy/drowsy noticed, with six more children post-vaccination than pre-vaccination, giving a 30% increase. Other symptoms reported markedly more post-vaccination than pre-vaccination were fever, with an increased recording by five children (25%), grizzly/unsettled/irritable with an increase by three children (15%), and diarrhoea with an increase by four children (20%). The most commonly reported symptoms for Group Two were grizzly/unsettled/

irritable with an increase by four children (29%) and persistent or unusual crying with an increase by four children (29%).

The most marked differences between the two groups were in the increased reporting for local reactions in Group One, no reporting on fever at all in any Group Two diaries, an increased reporting post-vaccination for diarrhoea in Group One only, and a decrease noted in vomiting/spitting by Group One as opposed to an increase post-vaccination in Group Two.

A prompt list, such as with the Group One diaries, produces an increase in reporting of all symptoms though the actual percentage increase from pre-vaccination to post-vaccination came out very similar in both groups.

It is noteworthy that those mothers who noted the most symptoms pre-vaccination, also noted more symptoms post-vaccination.

Principal findings

1. Reliability of results

From international findings the expected rate of reactions to the DTPH vaccine formulation used in NZ¹⁰ include the following: redness, swelling and/or pain at the site in up to a half of all cases; high fever (over 38°C) in just under 50%; fretfulness in around 50% of cases; drowsiness in 32%; anorexia in 21% and vomiting in 6%. Rarer, more severe reactions occurring in less than 1% are high pitched, unusual cry (0.1%), convulsions (0.06%) and collapse with shock-like state (0.06%). Allergic reactions have been reported but are rare.

The expected rate of reactions to the Hepatitis B vaccine is a fever or local injection site reaction in 1–6% of cases.¹¹ Allergic reactions have been reported very rarely. Nausea, di-

arrhoea and general malaise have also been reported but more frequently in adults.

While the sample size here is too small to put much significance on the findings generally the results fit with expected vaccine reactions. There were no surprise, unexpected reactions, and no major reactions in either group. Hence we would conclude that within the limitations of this small pilot study, diaries appear to be useful as a reliable means of collecting data on vaccine reactions.

2. Acceptability of the diary to parents

This methodology had enthusiastic support from the parents and practice nurses who participated. However only 68% completed the diaries, and this was from a sample size in a highly selected group decided by the practice nurses. This was a pre-selected group of people and it is difficult to generalise to a wider group. However those that did fill in the diaries did so clearly and accurately. Further consideration needs to be given as to how to improve the participation to obtain a more representative sample if this study is to be developed further.

3. Differences in type of diary

The major differences between the two groups was that Group One overall noted more symptoms pre- and post-vaccination (total 425) than Group Two (total 218). However the percentage increase in overall symptoms following the vaccination came out remarkably similar between the two groups with 57.5% increase by Group One, and 56.5% increase by Group Two.

Differences between the two groups are likely with such small numbers, but it is interesting that in Group Two (unprompted) no one reported fever, and local site reaction

Key points

- Parents are now more concerned about the side effects of immunisation than the diseases protected against.
- Side effects were monitored by parents using diaries covering both before and after immunisation.
- The most commonly reported symptoms were local skin reactions, fretfulness/sleepiness and fever.
- Diaries using prompt lists were more effective than open reporting.
- Prevacination patterns seem to predict postvaccination problems.

reporting was much lower. In particular only one case reported a site reaction to the Hepatitis B vaccination. The divergence of opinion between the two groups on vomiting, runny nose and cough symptoms are more likely to be a reflection on intercurrent illness than vaccine reaction.

Symptoms both pre- and post-vaccination were higher when parents were using diaries with a list of prompts, and lower when using an open-ended question. However the trends pre- to post-vaccination were similar with both groups. Overall this shows a high rate of increased symptom reporting following a vaccination event. While none of these would be considered 'severe' in any medical interpretation, they would certainly have an impact on the family and need to be recognised.

With 80% of parents using the prompted diaries completing the study compared to only 56% completing using the unprompted diaries, we surmise that parents may find a diary with a prompt list easier to complete rapidly than an open-ended style.

We would recommend the use of the prompted diary as it appears to

There is an urgent need to improve confidence in the vaccination programme as immunisation rates are low.

have higher compliance, and gives a higher reporting rate of symptoms both pre- and post-vaccination.

4. Other findings

An interesting extra result of this study is that it may be possible to predict which children will react to a vaccine as a result of the parent's report on the child's health prior to vaccination. There may be symptoms listed in the reported history of some children prior to the vaccination that would suggest that a child is more likely to have a reported reaction to the vaccination. There is no known international data reporting the effect of parental attitudes and awareness of a child's health and behaviour on the outcome of a vaccination reaction, but it is an intriguing possibility to examine further.

Although the methodology has implicit observer bias and interpreta-

tion, using a diary to report on a child's health in the week prior to the vaccination will give some baseline data for comparison post-vaccination. The strength of the methodology is that it is simple, non-intrusive and is completed at the time, rather than relying on parental recall. One weakness of the methodology is that it favours a sample group who are literate and who have enough time.

Conclusions

It is of major concern that there is no active monitoring of adverse reactions to vaccinations in New Zealand. There is an urgent need to improve confidence in the national vaccination programme as immunisation rates are low, leaving children at risk of recurrent epidemics. This pilot study was used to examine whether parent diaries would be a valid and acceptable methodology for examining the type and

frequency of adverse reactions. Although statistical significance can not be reliably drawn because of the small sample size, there is evidence that this could be a methodology with potential to trial with a much larger sample size.

From this study we would conclude that:

- parent-held diaries are an effective tool for active monitoring of vaccine reactions in selected patients;
- the diaries appear to be a reliable and valid means of collecting data on adverse reactions;
- there is no other system in NZ presently that is actively collecting adverse reaction information;
- there needs to be a wider study to gain statistically significant information. Estimates are a study population of at least 300 would be needed.

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