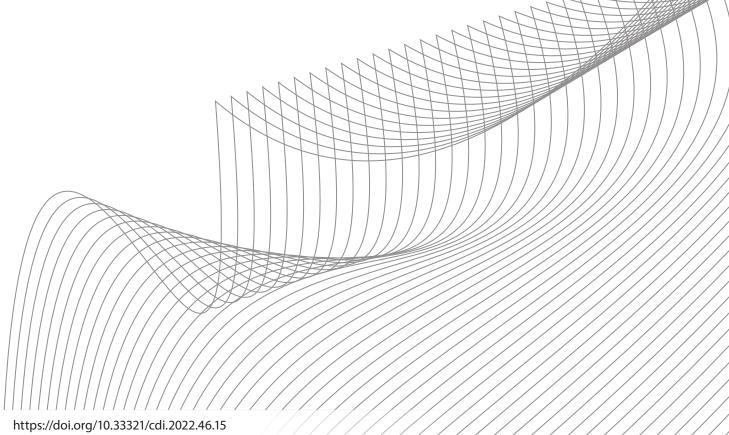# Communicable Diseases Intelligence

SMS reminders to improve the uptake and timeliness of the primary immunisation series in infants: a multi-centre randomised controlled trial

Kerry-Ann F O'Grady, Michelle Kaus, Lee Jones, Gary Boddy, Sheree Rablin, Jack Roberts, Daniel Arnold, Sarah Parfitt, Renee Johnston, Kerry K Hall, Sallyanne Le Gros-Wilson, Kaley Butten, Maree Toombs, Stephen B Lambert

Original article

SMS reminders to improve the uptake and timeliness of the primary immunisation series in infants: a multi-centre randomised controlled trial

Kerry-Ann F O'Grady, Michelle Kaus, Lee Jones, Gary Boddy, Sheree Rablin, Jack Roberts, Daniel Arnold, Sarah Parfitt, Renee Johnston, Kerry K Hall, Sallyanne Le Gros-Wilson, Kaley Butten, Maree Toombs, Stephen B Lambert

Abstract

Background

Immunisation timeliness continues to present challenges to achieving optimal vaccine coverage in infancy, particularly in disadvantaged groups and Australian First Nations infants. We aimed to determine whether a tailored, educational SMS reminder improves the timeliness of immunisation in infants up to seven months of age.

Methods

A pragmatic, three-arm, parallel-group, randomised controlled trial of immunisation reminders was conducted in two First-Nations-specific primary health care centres and two public hospital antenatal clinics in South East Queensland, Australia. Live-born infants of mothers enrolled during pregnancy were randomised at birth and followed to eight months of age. One group received a simple SMS reminder at two weeks before, the week of, and two weeks after the due date for immunisation at two, four and six months of age. The second group received a tailored SMS with an educational message at two weeks before and on the date immunisations were due; those not immunised two weeks following the due date were offered support to immunise the baby. Controls received no intervention or contact until the baby turned seven months of age. The primary outcome was the proportion of infants age-appropriately vaccinated at seven months of age as recorded on the Australian Immunisation Register. Secondary outcomes included vaccination status at three and five months of age.

Results

Between 30 May 2016 and 24 May 2018, one hundred and ninety-six infants (31% First Nations infants) were randomised. At seven months of age, 54/65 (83.1%) infants in the educational SMS ± additional support group (ESMS±S) were age-appropriately immunised, compared to 45/64 (70.3%) in the simple SMS group and 45/67 (67.2%) in controls. Differences were most marked at five months of age: ESMS±S 95.5%; simple SMS 73.4%; controls 75.8%. The difference between the ESMS±S group and the other two groups at seven months of age was no longer apparent when those who received additional support beyond the SMS were assumed to have not been vaccinated if that support had not been received.

Discussion

A tailored SMS reminder system using an educational message and with provision of additional support to mothers is more effective in improving immunisation timeliness in infants at three and five months of age than a simple message and no intervention. The additional support was required at seven months of age in order to achieve higher coverage in the ESMS±S group.

Trial Registration: ACTRN12616000204448

Keywords: *immunisation; timeliness; children; short messaging service; randomised controlled trial*

Introduction

Disparities exist in immunisation coverage in Australia, particularly for Australian First Nations children and those living in socio-economic disadvantaged communities.[1,2] While the reasons for these gaps are multifactorial, the lag in timely receipt of vaccine at each milestone has been identified as a potential contributor to the discrepancies in disease burden.[3,4] The need to address the gap in timeliness has been highlighted numerous times.[2,3,5,6]

Mobile phones are increasingly used in health settings, with impacts on behavioural change in some hard-to-reach groups.[7–9] Studies describing the use of short messaging service (SMS) strategies to improve immunisation uptake and timeliness in Australian First Nations people, in regional areas, and in communities with relatively high levels of socio-economic disadvantage are scarce. Identifying simple and cost-effective interventions to improve timeliness is therefore a priority.[5]

Our primary objective was to evaluate the effectiveness of a targeted SMS with an educational message with or without additional support (ESMS±S) to carers in improving the timeliness of the primary immunisation series in infants. Our primary hypothesis was that ESMS±S was more effective than a simple SMS only, or no SMS, in increasing the proportion of infants considered age-appropriately immunised at seven months of age. Our secondary objectives were a) to evaluate the effectiveness in improving coverage at three and five months of age; and b) to compare time to vaccination at each milestone between groups.

Methods

Design

We undertook a single-blind, parallel-group (1:1:1 allocation), multi-centre randomised controlled trial (RCT) with women enrolled during pregnancy and their infants randomised at birth to one of three study groups

(Figure 1): simple SMS; ESMS±S; or controls. Infants were followed until eight months of age with immunisation status confirmed at one month post each milestone (two, four, and six months of age) on the Australian Immunisation Register (AIR) and/or by the infant's primary healthcare provider. The trial was registered with the Australia and New Zealand Clinical Trials Register (ACTRN12616000204448) and was approved by the Human Research Ethics Committees of Queensland Children's Hospital and Health Services, Queensland University of Technology, and The University of Queensland.

Setting

The study was conducted in Caboolture, Toowoomba and Warwick in South East Queensland between June 2016 and June 2018. Caboolture is a satellite town north of Brisbane and Toowoomba and Warwick are rural towns west of Brisbane. Participants were recruited through three primary health care services with predominantly First Nations clients, and through two public hospital antenatal clinics.

Participants

Mothers were eligible if they were: ≥ 12 weeks gestation at enrolment; not planning to move from the study area until the infant turned eight months of age; had access to a mobile phone (either own phone or family member's); were willing to adhere to the study protocol, had provided written informed consent; and were intending on vaccinating their newborn. Entry into the RCT component required a live birth. Women were excluded if they had a previous infant enrolled. Trained research assistants approached women on presentation for antenatal care, provided a detailed study explanation and obtained written consent. Following birth, participants provided verbal consent for their infant's ongoing participation.

Data collection

Data were collected via interviewer-administered questionnaire at each time point; these

were face-to-face at enrolment and either face-to-face or by phone at consecutive timepoints for all study groups. The birth interview could be undertaken up to 41 days post-birth. Data collected included demographics (reviewed for any changes at each time point), cultural factors, pregnancy factors, perceptions of immunisation, access to and sources of immunisation information, and usual source of healthcare. Immunisation status at each milestone was confirmed via the infant's medical record and/or from the AIR. Data were entered into a Filemaker Pro V14 database.

Intervention

Simple SMS: At two weeks before, the week of, and two weeks after each age milestone due date (two, four, and six months), an SMS was sent, as presented in Box 1, to the carer's nominated mobile number. If a carer responded "Yes" at any fortnight for that milestone, no further messages were sent until the next age milestone.

ESMS±S: At two weeks before and the week of each age milestone due date a more detailed SMS was sent to the carer's nominated mobile number (Box 1). Two weeks after the second SMS had been sent, staff checked immunisation records to determine if the infant had been vaccinated. If no record was found, vaccination status was confirmed with the primary carer and, if not vaccinated, they were offered either a home visit or active support for the carer to get the infant to a healthcare provider for immunisation prior to one month past the milestone due date.

For the simple SMS and ESMS±S groups, whether or not a response was received was recorded at each contact timepoint.

Controls: No contact with parents/carers was undertaken until the infant turned seven months of age. At one month after each immunisation milestone, AIR and/or the infants's usual health care provider were checked to determine whether the infant had been immunised.

All infants not age-appropriately immunised at seven months of age were offered support to the parent/carer, including home visits, to complete outstanding vaccinations.

Outcome

The primary outcome was medical record/AIR confirmed immunisation status at seven months of age; final checks were undertaken at eight months to allow time for the record to appear on the AIR. Infants with no record of vaccination were classified as unvaccinated. As the immunisation schedule changed during the study, vaccines that contributed to immunisation status were those that were on the Queensland Immunisation Schedule at the time the infant reached that age-milestone. Secondary outcomes were immunisation status at three and five months of age and time to vaccination in days for each of the three age milestones.
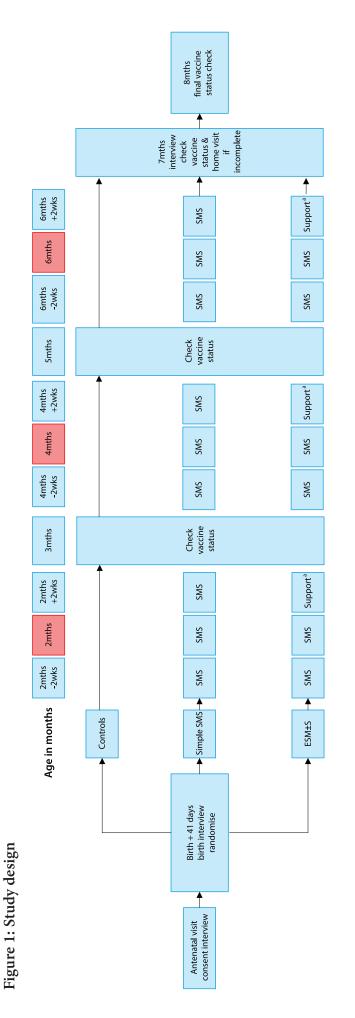
Box 1: Content of SMS messages sent to simple SMS group and ESMS±S group

> **Simple SMS**
>
> *"This is a reminder that your child's <age in months> immunisations are/were due on <date>. Please make an appointment with your doctor. Please reply 'Yes' if these baby needles have already been given or 'No' if not".*
>
> **ESMS±S**
>
> *"Dear <carer name>, this is a reminder that <baby's name> <age in months> baby needles are/were due on <date>. It is important that <he/she> gets these on time so <he/she> doesn't get sick from the diseases that these immunisations protect against. Please make an appointment with your doctor. Please reply "Yes" if these baby needles have already been given or "No" if not".*

Figure 1: Study design

a   Support: immunisation status checked and, if incomplete, the parent/carer was offered a home visit or other support to have the baby vaccinated.

Box 2: Sample sizes required for primary outcome

			80% power	90% power
	Baseline coverage	Target coverage	n per group	n per group
3 months of age	79%	95%	81	103
5 months of age	61%	90%	40	51
7 months of age	53%	85%	38	43

Sample size

We planned a three-group study with 104 weeks accrual time and seven months follow-up in the infant cohort. At the time this study was planned, there were no existing data in this population with which to inform potential effect sizes for time-to-event analyses. For the proportion vaccinated on time, we chose coverage targets based on the desired outcome from a public health perspective. Immunisation status at each time point prior to the study was derived from our previous cohort study of First Nations children in Caboolture.[6] Sample sizes required for the outcomes of the proportion vaccinated are presented in Box 2.

For the time-to-immunisation analyses, Cox proportional hazards modelling was planned to evaluate intervention effectiveness by calculating hazard rate ratios (HRR) and their corresponding 95% confidence intervals (95% CI). This included a frailty model with a random effects approach to account for recurrent events and sibling effects, if applicable. We powered the study to detect a failure HRR of 1.4 in the control group compared to the ESMS±S group at seven months of age with 80% power and an alpha of 0.05. As above, the HRR estimate was based on what would be considered a public health impact. This required 142 infants per group. Accounting for a 20% loss to follow-up over the seven-months, we aimed to recruit 510 participants (170 per Group). However, given slower-than-anticipated recruitment and a high loss to follow-up between enrolment and birth, study recruitment was terminated in May 2018 given inadequate remaining funds. Applications for further funding were not successful. Thus, the proportional hazards modelling was not undertaken and only descriptive data relating to time to vaccination are presented.

Randomisation and blinding

Randomisation codes were computer-generated by an independent biostatistician in permuted block sizes of six, stratified by study site. Codes were concealed in opaque envelopes until randomisation and checked by two people. Double-blinding was not feasible; however, participants were not informed that the infant would be randomised. They were informed the study will follow children to evaluate immunisation uptake and that at various time-points they may receive reminders that their infants' immunisations are due. Limited disclosure involving active concealment to participants is consistent with the NHMRC National Statement,[10] if participants are not exposed to an increased risk of harm and a full explanation of the study aims is provided to participants at the end of the study.

Statistical methods

Descriptive statistics were calculated for the study population overall and by infants randomised and expressed as proportions and/or means and medians (if not normally distributed) of the selected characteristics with the corresponding 95% confidence intervals. Differences between groups were performed using Anova for comparisons of means and χ^2 test for comparisons of proportions, conditional on test assumptions for each being satisfied. Medians and interquartile ranges (IQR) were calculated for non-parametric data and compared with the Kruskall-Wallis test.

Differences in the proportions of infants age-appropriately immunised at three, five, and seven months of age were calculated using the χ^2 test. Relative risks (outcome vaccination status) and their 95% CIs were calculated to compare the simple SMS group to controls and the ESMS±S group to controls. Baseline variables with a *p*-value of < 0.1 in univariate models were included in binomial regression models to assess for independent predictors of vaccination uptake; site and First Nations status were retained in all models irrespective of statistical significance.

Results

Between 30 May 2016 and 24 May 2018, there were 883 women screened, with 322 enrolled (Figure 2); 442 were ineligible. Amongst those eligible, 109 refused, and ten were not enrolled for other reasons. There were twelve screen failures (failure to complete the baseline interview after consent), leaving 310 participants for baseline analysis. Due to loss to follow-up following baseline (n = 96) and withdrawal of consent either before or after infant birth (n = 18), a total of 196 babies were randomised to one of the three study groups (Figure 2).

Of the infants randomised, 61/196 (31.2%) identified as First Nations; 38/196 (19.4%) were the mother's first-born child. The baseline characteristics of mothers are presented in Appendix A and the characteristics of randomised infants are presented in Table 1. Baseline differences existed despite the randomisation process; however, although the analysis was limited by sample size, none were independently associated with study outcomes in binomial regression models (data not shown).

At seven months of age, 144/196 infants (73.5%) were age-appropriately immunised; the corresponding proportions at three and five months of age were 171/196 (87.2%) and 160/196 (81.6%) respectively. For First Nations infants, the corresponding proportions at three, five, and seven months of age were 54/54 (100%), 48/54 (88.9%) and 35/54 (64.8%), and for other infants, 125/134

(93.3%), 116/134 (86.6%) and 102/134 (76.1%); the differences at each time point were not statistically significant. The median times in days to vaccination at each age milestone, overall and by group, are presented in Table 2. There were no statistically significant differences between the groups at any timepoint.

Figure 2: Consort diagram

a   LTFU: loss to follow-up.

Table 1: Characteristics at birth for randomised infants

	Simple SMS	ESMS±S	Controls	Total
Indigenous status of baby				
Non-Indigenous	43 (67.2)	49 (75.4)	43 (64.2)	135 (68.9)
First Nations	21 (32.8)	16 (24.6)	24 (35.8)	61 (31.2)
Birth weight (grams)				
< 2500	3 (4.7)	5 (7.7)	7 (10.5)	15 (7.7)
≥ 2500	61 (95.3)	59 (90.8)	60 (89.6)	180 (91.8)
Declined/missing/unknown	0	1 (1.5)	0	1 (0.5)
Gestational age (weeks)				
< 37 weeks	4 (6.2)	5 (7.7)	5 (7.5)	14 (7.1)
≥ 37 weeks	60 (93.8)	60 (92.3)	62 (92.5)	182 (92.9)
Declined/missing/unknown	0	0	0	0
Birth type				
Singleton	64 (100.0)	61 (93.9)	67 (100.0)	192 (98.0)
Multiple	0	4 (6.1)	0	4 (2.0)
Declined/missing/unknown	0	0	0	0
Length of stay in hospital post birth (days)				
Median (IQR)	2 (1–3)	2 (1–4)	2 (1–3)	2 (1–3)
Infant diagnosed with medical condition post birth				
Yes	13 (20.3)	7 (10.8)	11 (16.4)	31 (15.8)
No	51 (79.7)	58 (89.2)	56 (83.6)	165 (84.2)
Declined/Missing/Unknown	0	0	0	0
Planned use of childcare				
Yes	36 (56.3)	40 (61.5)	40 (59.7)	116 (59.2)
No	21 (32.8)	24 (36.9)	21 (31.3)	66 (33.7)
Unknown	7 (10.9)	1 (1.5)	6 (9.0)	14 (7.1)
Planned age in months for start of childcare if planned use is "Yes"				
0–5 months	1 (2.8)	8 (20.0)	8 (20.0)	17 (14.7)
6–11 months	18 (50.0)	20 (25.0)	12 (30.0)	40 (34.5)
12+ months	14 (38.9)	21 (52.5)	15 (37.5)	50 (43.1)
Declined/missing/unknown	3 (8.3)	1 (2.5)	5 (12.5)	9 (7.8)
Impact of the baby on the family (score of 1–10)[a]				
Mean (SD)	5.0 (3.8)	5.4 (6.1)	5.7 (6.1)	6.6 (5.3)
Internet access at home since birth of baby				
All of the time	55 (85.9)	51 (78.5)	58 (86.6)	164 (83.7)
Some of the time	4 (6.3)	7 (10.8)	4 (6.0)	15 (7.7)
None of the time	1 (1.6)	2 (3.1)	0	3 (1.5)
Declined/missing/unknown	4 (6.3)	5 (7.7)	5 (7.5)	14 (7.1)
Mother has had access to working mobile phone since birth of baby				
Yes	63 (98.4)	63 (96.9)	62 (92.5)	188 (96.0)
No	0	1 (1.5)	1 (1.5)	2 (1.0)
Declined/missing/unknown	1 (1.6)	1 (1.5)	4 (6.0)	6 (3.0)

a   Question asked of mother to rank on a scale of 1 (no impact) to 10 (significant impact): "How much do you think this baby has had an impact on the other members of your family?"

Table 2: Days to vaccination from each age milestone

	Simple SMS	ESMS±S	Controls	Total	*p* value[a]
2 months					
Median (IQR)	-16.5 (-18, -12)	-16 (-18, -12)	-16 (-18, 10)	- 16 (-18, 10)	0.707
Range	-20, 91	-18, 7	-20, 59	-21, 91	
4 months					
Median (IQR)	3.5 (0, 11)	1 (0, 6.5)	5 (1, 10)	3 (0, 10)	0.089
Range	-18, 101	-19, 27	-19, 99	-19, 101	
6 months					
Median (IQR)	6 (1, 13.5)	6 (2, 15)	6.5 (3, 18)	6 (2, 16)	0.412
Range	(-18, 45)	-3, 50	(-13, 57)	(-18, 57)	

a   Kruskal-Wallis rank test.

The proportion of infants age-appropriately immunised and adjusted relative risks (aRR) comparing infants in intervention groups to controls at each age milestone are presented in Table 3. Infants randomised to the ESMS±S group were more likely to be age-appropriately immunised at each time point than infants in the control group, with the strongest effect at five months of age (aRR: 6.9; 95% CI: 1.9–25.3). There were no differences between the simple SMS group and controls at any milestone.

Sixteen mothers in the ESMS±S group met the criteria for additional support on 25 occasions. Offers for support were refused on 12 occasions and the mother could not be contacted on one occasion; the primary reason for refusal was help was not considered necessary. Two home visits for vaccination took place and, at their request, the remaining ten were provided support with accessing their local clinic and/or arranging appointments. One event occurred at the two-month timepoint and one at the four-month timepoint; the remainder were provided at the six-month timepoint. One mother required support at all three milestones. If this support had not been provided to any person in the ESMS±S group at any timepoint and it was

assumed the infant was not vaccinated on time, the proportion of infants in the ESMS±S group who were vaccinated on time was 92.3% at three months, 89.2% at five months and 70.1% at seven months. The differences between groups at seven months were no longer statistically different.

Lack of response to an SMS was highest at the two weeks prior to each age milestone timepoint and progressively declined by the time of the third SMS (Table 4). The proportion of mothers responding that the infant had been vaccinated at the two-week-prior timepoint was highest at the two-month milestone and likely reflects the immunisation schedule recommending vaccines can be given at six weeks of age. Lack of response to the third SMS was lowest for those in the ESMS±S group; however, they also received a phone call from staff if records indicated the baby had not been vaccinated.

Table 3: Proportion vaccinated by randomised group and stratified by age

| Age | Simple SMS (N = 64) | | | | ESMS±S (N = 65) | | | | Controls (N = 67) | |
	n (%)	aRR[a]	95% CI	*p* value	n (%)	aRR[a]	95% CI	*p* value	n (%)	aRR[a]
3 months	57 (89.1)	2.01	0.74, 5.46	0.169	61 (92.4)	3.10	1.03, 9.32	0.044	53 (80.3)	Ref
5 months	47 (73.4)	0.89	0.40, 1.96	0.765	63 (95.5)	6.94	1.91, 25.25	0.003	50 (75.8)	Ref
7 months	45 (70.3)	0.79	0.39, 1.58	0.500	54 (83.1)	2.28	1.05, 4.94	0.037	45(67.2)	Ref

a   aRR: adjusted relative risk (adjusted for variables with p < 0.01 in univariate analyses; site and First Nations status were retained in all models irrespective of statistical significance.

Discussion and conclusions

We examined the effectiveness of two forms of SMS reminders in improving the uptake and timeliness of immunisation in infants up to seven months of age in South East Queensland. At each milestone, infants in the ESMS±S group had higher coverage than infants in the simple SMS and control groups, with coverage of 92.4%, 95.5% and 83.1% at three, five and seven months of age. There were no significant differences between the simple SMS and controls at any timepoint. The need for additional support was most common, and accounted for the greatest differences in groups, at the seven-month timepoint.

Our findings are consistent with systematic reviews indicating SMS reminder systems can improve vaccine coverage and timeliness; however, effectiveness varies.[11–13] These reviews also demonstrate that discrepancies persist, including when financial incentives are used. An Australian study of 1,594 infants and children (3.4% First Nations) born between November 2013 and November 2015 in New South Wales and South Australia[14] found small improvements in timeliness only at the 12-month timepoint in children who received an SMS reminder alone (RR: 1.09; 95% CI: 1.01–1.18) or in combination with a personalised calendar (RR: 1.11; 95% CI: 1.03–1.20), and only in children who had a history of previous late doses. A high rate of on-time vaccination was observed amongst control participants in the New South Wales / South Australia study, thought to be related to the introduction of the Australian "No Jab No Pay" policy.[14]

There were no significant differences in our study between the control and simple SMS groups, suggesting additional measures are needed beyond basic SMS reminders to reach desired immunisation timeliness targets. Financial incentives have been effective,[15] but the incremental gains above SMS only are modest. A recent commentary suggested the impact of educational or provoking measures should be further explored,[16] and our findings support that call. We opted for an educational message based on a health belief model,[17] which uses concepts of risk to influence behaviour. Additionally, in the ESMS±S group, those not vaccinated within two weeks of the due date were offered assistance.

Immunisation delay is most marked at the six-month milestone in this and other studies,[2,6] and the educational SMS had no additional effect over a simple SMS or no intervention at

Table 4: Responses to SMS messaging at each age milestone for the two intervention groups

Age milestone	Simple SMS (N = 64)								ESMS±S (N = 65)							
	Yes[a]		No[b]		No response		Not required[c]		Yes[a]		No[b]		No response		Not required[c]	
2 months – 2 weeks	23	35.9%	10	15.6%	31	48.4%	0	0.0%	31	47.7%	6	9.2%	28	43.1%	0	0.0%
2 months	20	31.3%	3	4.7%	18	28.1%	23	35.9%	16	24.6%	0	0.0%	18	27.7%	31	47.7%
2 months + 2 weeks	9	14.1%	0	0.0%	12	18.8%	43	67.2%	7	10.8%	2	3.1%	9	13.8%	47	72.3%
4 months - 2 weeks	0	0.0%	11	17.2%	53	82.8%	0	0.0%	2	3.1%	17	26.2%	46	70.8%	0	0.0%
4 months	17	26.6%	3	4.7%	44	68.8%	0	0.0%	20	30.8%	9	13.8%	34	52.3%	2	3.1%
4 months + 2 weeks	20	31.3%	1	1.6%	26	40.6%	17	26.6%	28	43.1%	9	13.8%	6	9.2%	22	33.8%
6 months – 2 weeks	0	0.0%	11	17.2%	53	82.8%	0	0.0%	2	3.1%	11	16.9%	52	80.0%	0	0.0%
6 months	5	7.8%	8	12.5%	51	79.7%	0	0.0%	9	13.8%	15	23.1%	39	60.0%	2	3.1%
6 months + 2 weeks	21	32.8%	3	4.7%	35	54.7%	5	7.8%	34	52.3%	14	21.5%	6	9.2%	11	16.9%

a   Yes: infant has been vaccinated.
b   No: infant has not been vaccinated.
c   Not required: SMS not required as it was known the infant had been vaccinated.

that timepoint in our study. The difference was due to the additional assistance. Delays at this timepoint potentially reflect additional barriers to timely vaccination, such as mothers returning to work; however there are a lack of studies that address this in detail. Studies in New South Wales and Western Australia[2,18] found predictors of delayed vaccination included: three or more previous pregnancies; young maternal age; prematurity; maternal smoking during pregnancy; and being an Aboriginal infant born in Western Australia. This was similar to our previous study of infants in Caboolture,[6] in which unemployed mothers, families with three or more previous children and premature birth were associated with delayed vaccination.

Coverage in the control group was higher than in our previous study conducted during 2013–2015, which found 48% of infants with were age-appropriately immunised at seven months of age.[6] This suggests other measures have improved timeliness since then. The most obvious would be the introduction of the federal government's "No Jab No Pay" policy in 2016. However, coverage was still suboptimal at the seven-month timepoint in our study, the time at which many infants will enter childcare, and 48.7% of families (76/156) for whom the information was known at the seven-month timepoint did not have government benefits linked to their baby's immunisation status.

As multiple messaging has implications for service providers and potentially risks alienating recipients, we collected data on SMS responses. Non-response was higher at the two-week prior and at the due date of vaccination timepoints than at two weeks post due date. The reasons for this are not immediately apparent, other than possibly more incentive to respond once the infant had been immunised. Our data suggest that more than one message is required in this cohort to facilitate timeliness, consistent with a systematic review which suggested that more than one message was more effective.[13] Of relevance to service providers is that offers for assistance to immunise the baby, including home visits, were declined in 50% of eligible

episodes, primarily because the parent/carer did not consider it necessary. We did not delve into this with participants and future studies could explore this further. Studies of home visiting for at-risk and/or disadvantaged mothers suggest multiple factors influence the decision to engage including trust; functional status; and parenting confidence.[19,20] The quality of the relationship between the service provider and the family are important to the success of home-visiting programs.[21] This may have been a factor in our study, in which the relationship between study staff and participants was not comparable to that with a trusted service provider.

The study's strengths are the high proportion of First Nations participants, inclusion of regional communities and assessment of an alternative message to a simple reminder SMS which is commonly used in recall systems. Messages and information addressing vaccine effectiveness, vaccine safety and disease severity that drew on key theoretical frameworks were acceptable in a small study of Australian pregnant women.[22] However they were one part of a broader package of support with participants indicating more information from their midwife was wanted.[23] In our study, less than half of the participants at baseline had received or sought information about infant immunisation during their pregnancy (Appendix A, Table A.1).

The main limitation of the study was that the target sample size was not reached, preventing detailed modelling of time to vaccination and predictive factors. The high loss to follow-up of mothers between enrolment and birth may have introduced a selection bias in that those who agreed to continue in the study may have been more or less likely to immunise on time than did those who did not agree to continue, and this impacts on the generalisability of our study. Further, the characteristics of mothers of infants not randomised (Appendix A, Table A.1) suggested a higher proportion of these women may be experiencing disadvantage; were more often First Nations women; and more commonly reported having three or more other children at home. As those mothers did

not reconsent to continue participation in the study at the infant's birth, we were unable to confirm the infant's immunisation status on the AIR; such confirmation would have provided some indication of whether selection bias was present. Finally, there were some baseline differences between study groups that are difficult to explain given the randomisation process; they are likely due to the small sample size in each group. We examined the effect of these differences in regression models and none were independently associated with study outcomes (data not shown).

Larger studies are needed to support our findings. The high loss to follow-up needs to be addressed. Enrolling women at earlier stages in their pregnancy may have been a factor. We maintained contact with participants regularly up to birth (via SMS and/or phone and/or speaking to them at later antenatal visits); congratulations cards were sent at birth; up to six weeks were allowed after birth for the interview to be done; and interviews were scheduled at days and times that suited the participants. Amongst those who withdrew consent, the primary reason was lack of time. This study was designed taking into account translation to primary care where interventions would need to be easily incorporated into existing systems and not require excessive resources. Further studies evaluating more intensive interventions would need to consider long-term feasibility.

In our setting, simple SMS messaging alone is not effective in improving immunisation timeliness, even if delivered multiple times. Improving immunisation timeliness requires multi-faceted approaches, particularly amongst families most at risk of delay. Active support for parents/carers can play an important role; however, this is likely dependent on relationships with service providers.

Acknowledgements

Author details

A/Prof Kerry-Ann F O'Grady, Senior Research Fellow,[1]
Ms Michelle Kaus, Research Officer,[1]
Ms Lee Jones, Biostatistician,[1]
Mr Gary Boddy, Principal Program Officer,[2]
Ms Sheree Rablin, Research Manager,[1]
Mr Jack Roberts, Research Officer,[1]
Mr Daniel Arnold, Data Manager,[1]
Ms Sarah Parfitt, Clinical Research Nurse,[1]
Ms Renee Johnston, Research Officer,[1]
Dr Kerry K Hall, Lecturer,[3]
Mrs Sallyanne Le Gros-Wilson, Research Officer,[1]
Dr Kaley Butten, Research Fellow,[1,4]
Prof Maree Toombs, Associate Dean Indigenous Engagement,[5,6]
A/Prof Stephen B Lambert, Medical Epidemiologist.[2,7]

1. Australian Centre for Health Services Innovation@Centre for Healthcare Transformation, Queensland University of Technology, Kelvin Grove, Queensland, Australia

2. Communicable Diseases Branch, Queensland Health, Herston, Queensland, Australia

3. First Peoples Health Unit, Griffith University, Southport, Queensland, Australia

4. Australian eHealth Research Centre, CSIRO, Herston, Queensland, Australia

5. Faculty of Medicine & Biomedical Sciences, The University of Queensland, Herston, Queensland, Australia

6. Carbal Health Services, Toowoomba, Queensland Australia

7. National Centre for Epidemiology and Population Health, Australian National University, Canberra, Australia

Corresponding Author

A/Prof Kerry-Ann O'Grady
L7, Centre for Children's Health Research
62 Graham Street
South Brisbane, Qld, 4101, Australia
P: +61 0439 933 777
E: kerryann.ogrady@qut.edu.au

References

1. Hull B, Hendry A, Dey A, Macartney K, Beard F. Immunisation Coverage Annual Report 2019. *Commun Dis Intell (2018)*. 2021;45. doi: https://doi.org/10.33321/cdi.2021.45.18.

2. Moore HC, Fathima P, Gidding HF, de Klerk N, Liu B, Sheppeard V et al. Assessment of on-time vaccination coverage in population subgroups: a record linkage cohort study. *Vaccine*. 2018;36(28):4062–9. doi: https://doi.org/10.1016/j.vaccine.2018.05.084.

3. O'Grady KA, Krause V, Andrews R. Immunisation coverage in Australian Indigenous children: time to move the goal posts. *Vaccine*. 2009;27(2):307–12. doi: https://doi.org/10.1016/j.vaccine.2008.09.096.

4. Naidu L, Chiu C, Habig A, Lowbridge C, Jayasinghe S, Wang H et al. Vaccine preventable diseases and vaccination coverage in Aboriginal and Torres Strait Islander people, Australia 2006–2010. *Commun Dis Intell Q Rep*. 2013;37(Suppl):S1–95.

5. Royle J, Lambert SB. Fifty years of immunisation in Australia (1964-2014): the increasing opportunity to prevent diseases. *J Paediatr Child Health*. 2015;51(1):16–20. doi: https://doi.org/10.1111/jpc.12796.

6. Lovie-Toon YG, Hall KK, Chang AB, Anderson J, O'Grady KA. Immunisation timeliness in a cohort of urban Aboriginal and Torres Strait Islander children. *BMC Public Health*. 2016;16(1):1159. doi: https://doi.org/10.1186/s12889-016-3825-z.

7. Rodgers A, Corbett T, Bramley D, Riddell T, Wills M, Lin R-B et al. Do u smoke after txt? Results of a randomised trial of smoking cessation using mobile phone text messaging. *Tob Control*. 2005;14(4):255–61. doi: https://doi.org/10.1136/tc.2005.011577.

8. Bramley D, Riddell T, Whittaker R, Corbett T, Lin R-B, Wills M et al. Smoking cessation using mobile phone text messaging is as effective in Maori as non-Maori. *N Z Med J*. 2005;118(1216):U1494.

9. Kunutsor S, Walley J, Katabira E, Muchuro S, Balidawa H, Namagala E et al. Using mobile phones to improve clinic attendance amongst an antiretroviral treatment cohort in rural Uganda: a cross-sectional and prospective study. *AIDS Behav*. 2010;14(6):1347–52. doi: https://doi.org/10.1007/s10461-010-9780-2.

10. National Health and Medical Research Council. *National Statement on Ethical Conduct in Human Research (2007)*. Canberra: Australian Government; 2007.

11. Jacobson Vann JC, Jacobson RM, Coyne-Beasley T, Asafu-Adjei JK, Szilagyi PG. Patient reminder and recall interventions to improve immunization rates. *Cochrane Database Syst Rev*. 2018;1:CD003941. doi: https://doi.org/10.1002/14651858.CD003941.pub3.

12. Mekonnen ZA, Gelaye KA, Were MC, Gashu KD, Tilahun BC. Effect of mobile text message reminders on routine childhood vaccination: a systematic review and meta-analysis. *Syst Rev*. 2019;8(1):154. doi: https://doi.org/10.1186/s13643-019-1054-0.

13. Eze P, Lawani LO, Acharya Y. Short message service (SMS) reminders for childhood immunisation in low-income and middle-income countries: a systematic review and meta-analysis. *BMJ Glob Health*. 2021;6(7). doi: https://doi.org/10.1136/bmjgh-2021-005035.

14. Menzies R, Heron L, Lampard J, McMillan M, Joseph T, Chan J et al. A randomised controlled trial of SMS messaging and calendar reminders to improve vaccination timeliness in infants. *Vaccine*. 2020;38(15):3137–42. doi: https://doi.org/10.1016/j.vaccine.2020.02.045.

15. Gibson DG, Ochieng B, Kagucia EW, Were J, Hayford K, Moulton LH et al. Mobile phone-delivered reminders and incentives to improve childhood immunisation coverage and timeliness in Kenya (M-SIMU): a cluster randomised controlled trial. *Lancet Glob Health*. 2017;5(4):e428–38. doi: https://doi.org/10.1016/S2214-109X(17)30072-4.

16. Kazi AM. The role of mobile phone-based interventions to improve routine childhood immunisation coverage. *Lancet Glob Health*. 2017;5(4):e377–8. doi: https://doi.org/10.1016/S2214-109X(17)30088-8.

17. Becker MH. The Health Belief Model and personal behaviour. *Health Educ Monogr*. 1974;2:324–508.

18. Gidding HF, Flack LK, Sheridan S, Liu B, Fathima P, Sheppeard V et al. Infant, maternal and demographic predictors of delayed vaccination: a population-based cohort study. *Vaccine*. 2020;38(38)6057–64. doi: https://doi.org/10.1016/j.vaccine.2019.09.091.

19. McCurdy K, Daro D, Anisfeld E, Katzev A, Keim A, Lecroy C et al. Understanding maternal intentions to engage in home visiting programs. *Child Youth Serv Rev*. 2006;28(10):1195–212. doi: https://doi.org/10.1016/j.childyouth.2005.11.010.

20. Tandon SD, Parillo K, Mercer C, Keefer M, Duggan AK. Engagement in paraprofessional home visitation: families' reasons for enrollment and program response to identified reasons. *Womens Health Issues*. 2008;18(2):118–29. doi: https://doi.org/10.1016/j.whi.2007.10.005.

21. Munns A, Watts R, Hegney D, Walker R. Effectiveness and experiences of families and support workers participating in peer-led parenting support programs delivered as home visiting programs: a comprehensive systematic review. *JBI Database System Rev Implement Rep*. 2016;14(10):167–208. doi: https://doi.org/10.11124/JBISRIR-2016-003166.

22. Kaufman J, Attwell K, Tuckerman J, O'Sullivan J, Omer SB, Leask J et al. Feasibility and acceptability of the multi-component P3-MumBubVax antenatal intervention to promote maternal and childhood vaccination: a pilot study. *Vaccine*. 2020;38(24):4024–31. doi: https://doi.org/10.1016/j.vaccine.2020.04.010.

Appendix A: Supplementary data

Table A.1: Baseline characteristics of enrolled women

Characteristic	Simple SMS (N = 64)	ESMS±S (N = 65)	Control (N = 67)	Infant not randomised (N = 114)
Mother's age at enrolment (years)				
Mean (SD)	29.1 (5.5)	29.4 (5.6)	30.0 (5.7)	27.2 (6.2)
Gestation at enrolment (weeks)				
Mean (SD)	27.5 (8.2)	26.4 (7.6)	26.9 (8.1)	29.2 (14.2)
Mother's Indigenous status				
Indigenous	13 (20.3)	9 (13.9)	15 (22.4)	20 (17.5)
Father's Indigenous status				
Indigenous	11 (17.2)	8 (12.3)	15 (22.4)	19 (16.7)
Mother's relationship status				
Single	7 (10.9)	9 (13.9)	11 (16.4)	18 (15.8)
Married	27 (42.2)	29 (44.6)	18 (26.9)	34 (29.8)
Defacto	22 (34.4)	18 (27.7)	26 (38.8)	54 (47.3)
Separated	1 (1.6)	2 (3.1)	0 (0.0)	6 (5.3)
Declined/missing/unknown	7 (10.9)	7 (10.8)	12 (17.9)	2 (1.8)
Household family type				
Nuclear[a]	57 (89.1)	58 (89.2)	54 (80.6)	97 (85.1)
Number of other children at home				
None	19 (29.7)	17 (26.2)	19 (28.4)	34 (29.8)
1–2	36 (56.3)	35 (53.8)	37 (55.2)	55 (48.2)
3+	9 (14.1)	13 (11.3)	11 (16.4)	25 (22.0)

Characteristic	Simple SMS (N = 64)	ESMS±S (N = 65)	Control (N = 67)	Infant not randomised (N = 114)
Other children at home are up to date with immunisations (mother report)				
Yes	46 (71.9)	46 (70.8)	46 (68.6)	77 (67.5)
No	0	2 (3.1)	1 (1.5)	1 (0.9)
Not applicable	17 (26.6)	17 (26.2)	19 (28.4)	29 (25.4)
Declined/missing/unknown	1 (1.5)	1 (1.6)	1 (1.5)	7 (6.1)
Receive government pension/unemployment benefits				
Yes	24 (37.5)	24 (36.9)	28 (41.8)	60 (52.6)
Mother's education status				
Tertiary degree	8 (12.5)	11 (16.9)	14 (20.9)	10 (8.8)
Diploma/certificate/trade	28 (43.8)	27 (41.5)	26 (38.8)	43 (37.7)
High school	14 (21.9)	9 (13.8)	15 (22.4)	29 (25.4)
Did not finish high school	13 (20.3)	15 (23.1)	12 (17.9)	27 (23.7)
Declined/missing/unknown	1 (1.6)	3 (4.6)	1 (1.5)	5 (4.4)
Total annual household income				
$104,000+	15 (23.4)	17 (26.2)	14 (20.9)	9 (7.9)
$78,000–103,999	12 (18.8)	13 (20.0)	15 (22.4)	12 (10.5)
$52,000–77,999	9 (14.1)	7 (10.8)	10 (14.9)	23 (20.2)
$0–51,999	18 (28.1)	16 (24.6)	16 (23.9)	31 (27.2)
Declined/missing/unknown	10 (15.6)	12 (18.5)	12 (17.9)	39 (34.2)
Mother has regular GP				
No	25 (39.1)	23 (35.4)	16 (23.9)	49 (43.0)
Mother has had the same midwife for antenatal care				
No	33 (51.6)	39 (60.0)	34 (50.8)	56 (49.1)

Characteristic	Simple SMS (N = 64)	ESMS±S (N = 65)	Control (N = 67)	Infant not randomised (N = 114)
Has internet access at home				
Yes	62 (96.9)	52 (80.0)	60 (89.5)	93 (81.6)
Has an email address				
Yes	61 (95.3)	61 (93.8)	63 (94.0)	105 (92.1)
No	2 (3.1)	2 (3.1)	4 (6.0)	5 (4.3)
Declined/missing/unknown	1 (1.6)	2 (3.1)	0	4 (2.6)
Has a smart phone capable of hosting mobile applications[b]				
Yes	63 (98.4)	62 (95.5)	64 (95.5)	112 (98.2)
No	0	1 (1.5)	3 (4.5)	1 (0.9)
Declined/missing/unknown	1 (1.6)	2 (3.0)	0	1 (0.9)
Has received/sought information on infant immunisation during pregnancy				
Yes	35 (54.7)	45 (69.2)	39 (58.2)	59 (51.8)
No	26 (40.6)	19 (29.2)	25 (37.3)	48 (42.1)
Declined/missing/unknown	3 (4.7)	1 (1.5)	2 (4.5)	7 (6.1)
Mother has someone to count on to support decisions she makes				
Yes	63 (98.4)	64 (98.5)	66 (98.5)	105 (92.1)
No	0	1 (1.5)	0	4 (3.5)
Declined/missing/unknown	1 (1.6)	0	1 (1.5)	5 (4.4)
Mother has someone to confide in				
Yes	62 (96.8)	65 (100.0)	64 (95.5)	106 (93.0)
No	1 (1.6)	0	2 (3.0)	3 (2.6)
Declined/missing/unknown	1 (1.6)	0	1 (1.5)	5 (4.4)
Mother has someone she can trust/rely on for help				

Characteristic	Simple SMS (N = 64)	ESMS±S (N = 65)	Control (N = 67)	Infant not randomised (N = 114)
Yes	62 (96.8)	65 (100.0)	62 (92.5)	104 (91.2)
No	1 (1.6)	0	4 (6.0)	2 (1.8)
Declined/missing/unknown	1 (1.6)	0	1 (1.5)	8 (7.0)

a   Nuclear family: parents/carers and children only. The other category was "extended" family.
b   Smart phone, as opposed to a basic phone lacking mobile applications capacity.