

Rheumatic Fever Prevention Programme:
Antibiotic Adherence Trial



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Summary

Key Results

- The most effective intervention to improve antibiotic adherence was directly observed therapy (DOT), which significantly improved the number of children who successfully completed their 10 days of antibiotic treatment.
- To administer DOT in a school based clinic, an additional 127.9 minutes of nursing time per child was required.
- Blister packs and daily text message reminders were well received in primary school students and their whānau but they did not help to improve antibiotic adherence and made no difference to the number of children successfully completing their antibiotic treatment.
- Intramuscular (IM) bicillin was an acceptable treatment option to children and whānau in the South Auckland community. The majority of parents were happy with IM bicillin and would choose to have it again. Using a distraction device with lignocaine was an effective pain management strategy to manage pain associated with the injection.
- More work needs to be done to determine whether the administration of an intramuscular penicillin affects self-identification of future sore throats.
- A number of children who received the IM bicillin were children with repeat sore throats and some of these children still had a GAS positive throat swab following the IM bicillin. There is some confusion in parents and nursing staff around the management of these children and clear guidelines are currently being produced by the Rheumatic Fever Prevention Programme.



1. Introduction

Acute Rheumatic Fever (ARF) is largely preventable disease and the associated factors are well documented in the literature and Ministry of Health publications.^[1,2] Improved living conditions and reduced transmission of the bacteria that causes GAS pharyngitis, along with improved access to antibiotics, have reduced ARF prevalence in most countries.^[2] There is a strong association between socioeconomic deprivation and, ARF and rheumatic heart disease in New Zealand. ARF is associated with substandard housing conditions, overcrowding, and lack of recognition and treatment of GAS infections. Furthermore, analysis of the distribution of cases across NZ shows a concentration in areas where low socioeconomic status is more prevalent, fundamentally identifying ARF as a disease of poverty with the highest incidence being in young people aged between 5 and 14 years of age who are Māori and Pacific.^[1]

Acute Rheumatic Fever (ARF) is an autoimmune response to an untreated group A streptococcus (GAS) infection, usually in the upper respiratory tract. The resulting transitory, generalised, inflammatory response may affect the heart, joints, central nervous system and skin. The chief concern is the inflammation of the heart (carditis), as this may cause cardiac valve stenosis. ARF occurs mainly in children aged five to 14 years, peaking around age eight.^[1]

Rates of ARF are particularly high in Tairāwhiti, Northland and Counties Manukau. In Counties Manukau, the rate for 2014 was 10.0 per 100,000 (Figure 1.1).^[3]

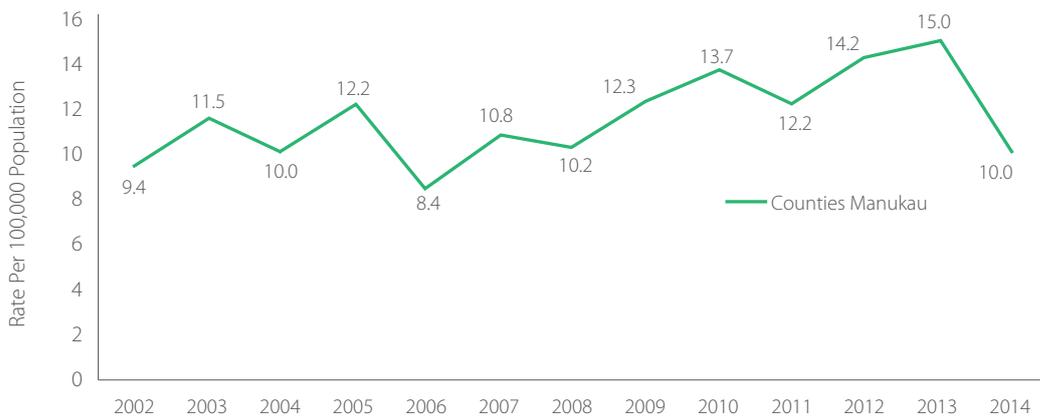


Figure 1.1 | First episode rheumatic fever hospitalisation rate (per 100,000 total population) in Counties Manukau, 2002-2014. ^[3]

The standard treatment for group A streptococcus (GAS) infection is 10 days of oral amoxicillin, 10 days of oral penicillin V or a single dose of intramuscular benzathine penicillin (Table 1.1).^[4] Completing a full course of antibiotic treatment is important to effectively treat GAS infections and prevent rheumatic fever.

Antibiotic	Route	Dose		Duration	IDSA GRADE 2012*,9
Penicillin V	PO	Children <20kg:	250mg two or three times daily	10 days	Strong, high
		Adolescents & Adults >20kg:	500mg two or three times daily		
Amoxicillin	PO	Once daily:	50mg/kg dose once daily <i>Max dose 1000mg per day</i>	10 days	Strong, high
		Or:	Weight <30kg: 750mg once daily Weight >30kg: 1000mg once daily		
		Twice daily:	25mg/kg dose twice daily <i>Max dose 1000mg per day</i>		
Benzathine penicillin	IM	Children <30kg:	450mg (600,000 U)	Single dose	Strong, high
		Children & Adults >30kg:	900mg (1,200,000 U)		
If concern about allergic (IgE mediated\$ or anaphylactic) response to beta lac tams, use:					
Roxithromycin <i>Pending Pharmac decision</i>	PO	Children: Adults: Or:	2.5mg/kg dose twice daily 300mg once daily 150mg twice daily	10 days	Unavailable in the USA
Erythromycin ethyl succinate	PO	Children & Adults:	40mg/kg/day in 2-3 divided doses <i>Max adult daily dose 1000mg</i>	10 days	
For people on benzathine penicillin IM prophylaxis who are GAS positive:					
Treat with a 10 day course of oral penicillin or amoxicillin. Check adherence to prophylaxis programme. Serum penicillin levels will be falling by week three and four post IM long acting benzathine penicillin injection.					

Table 1.1 | Standard treatment for a patient's first or second case of confirmed GAS pharyngitis.^[4]

International research suggests that as many as 40% of patients fail to adhere to the recommended treatment regimen.^[5] There is anecdotal evidence from within the national Rheumatic Fever Prevention Programme that indicates that adherence to the recommended treatment regimen is poor. A review of 77 rheumatic fever cases from 2013 found that less than one third of the children and young people who received antibiotics completed the full course (Personal communication, Ministry of Health, 2013).

Antibiotic adherence, defined as ‘the extent to which the patient’s behaviour matches agreed recommendations from the prescriber’^[6] has been identified as an area for improvement within the national Rheumatic Fever Prevention Programme. Adherence is problematic in most populations and not unique to the national Rheumatic Fever Prevention Programme, but is however a key driver to the success or failure of the programme.

Poor adherence has a number of impacts that concern us;

- Adverse outcomes
- Higher cost of care
- Potential for antibiotic resistance

The reasons for adherence (or non-adherence) are complex and result from a number of factors. Table 1.2 outlines a number of examples of why patients do not adhere to particular regimens.^[7]

Adherence is typically best when medication is;

- taken for a short period of time
- taken once a day
- does not have side effects
- inexpensive

The current regimen in the Rheumatic Fever Prevention Programme in Counties Manukau has been devised to maximise adherence with the standard treatment of 10 days of once daily oral amoxicillin. The reasons for poor medication adherence are often multifactorial (Table 1.2). Non-adherence to medications can be intentional or non-intentional. Intentional non-adherence is an active process whereby the patient chooses to deviate from the treatment regimen. This may be a rational decision process in which the individual weighs the risk and benefits of treatment against any adverse effects. Unintentional non-adherence is a passive process in which the patient may be careless or forgetful about adhering to the treatment regimen. Most deviations in medication taking are due to omissions of doses or delays in taking doses.^[7]

Drugs don’t work
in patients that
don’t take them.

C. Everett Koop, MD

Categories of non-adherence	Examples
Health system	Poor quality of provider-patient relationship; poor communication; lack of access to healthcare; lack of continuity of care
Condition	Asymptomatic chronic disease (lack of physical cues); mental health disorders (e.g. depression)
Patient	Physical impairments (e.g. vision problems or impaired dexterity); cognitive impairment; psychological/behavioural (including forgetfulness); younger age;
Therapy	Complexity of regimen; side effects; perceived benefit
Socioeconomic	Low literacy; higher medication costs; poor social support

Table 1.2 | Reasons for medication non-adherence (adapted from Ho et al, 2009).^[7]

Four pilot interventions were selected to test whether they had an impact on antibiotic adherence within the Rheumatic Fever Prevention Programme. These were;

- directly observed therapy (DOT),
- blister packs to improve medication adherence,
- daily text message reminders, and;
- intramuscular bicillin.

Directly observed therapy (DOT), involves a healthcare professional administering medication daily and has previously been shown to be effective in improving medication adherence in studies of tuberculosis.^[9] This intervention removes a number of the barriers to adherence by shifting much of the responsibility of adherence to the health professional.

Daily text message reminders to patients have previously been shown to be effective in improving medication adherence in studies of compliance of paediatric cataract treatment^[10] and in antiretroviral therapy adherence.^[11] Regular reminders to a patient's (or the parent/guardian responsible for medication management) mobile device is thought to increase adherence by negating forgetfulness and any lack of perceived benefit.

Blister packs have been shown to improve treatment regimen adherence and treatment outcomes in patients receiving daily medication for hypertension^[12] and have successfully been used in regimes for tuberculosis.^[13]

Intramuscular bicillin removes antibiotic adherence issues by treating patients with a single injection. The aim of this part of the trial was to assess whether this was an acceptable option to children, parents and whānau and to ascertain workforce development requirements for a wider implementation.

Each of these pilot interventions was tested in a range of sites across the Rheumatic Fever Prevention Programme in Counties Manukau, in collaboration with providers who are directly engaged with communities targeted by the Rheumatic Fever Prevention Programme to ensure that the interventions developed are the most effective for Māori and Pacific children, young people and their whānau.

Mana Kidz: NHC is the lead agency for the school-based Rheumatic Fever Prevention Programme in Counties Manukau with a robust alliance of ten community health and primary care providers delivering the services to more than 24,000 children across 61 schools.

Rapid response initiative: NHC is the lead agency for the rapid response initiative in Counties Manukau, working with ProCare Health Ltd, Alliance Health Plus and East Health to deliver free sore throat clinics in 28 primary care clinics as well as 17 secondary schools.

Findings

2. Directly observed therapy in a school based setting to improve medication adherence

2.1 Aim

To evaluate the feasibility of directly observed therapy (DOT) in a school based health clinic and its impact on medication adherence within the school community. Specifically;

- the impact on the health team's workload i.e. hours spent arranging and administering DOT;
- the acceptability of the process for stakeholders i.e. health teams, providers, students and their families, school communities;
- any other unknown factors which may influence a wider implementation.

2.2 Protocol

Protocols described in the Mana Kidz Manual of Operations were used to identify patients tested positive for GAS pharyngitis following a throat swab. The intervention group was those who have been offered, and accepted DOT in place of a standard 10 day course of self (or parent) administered oral antibiotics. All treatment options were based on current Heart Foundation Guidelines and recommended best practice. DOT was administered during school days and weekend dosages were given to parents to administer over the weekend.

An education package was developed for health professionals, which included: administration of DOT within the school environment; cultural competence; identification of patients for the study; informed consent; and processes for the measurement of outcomes and data management (Appendix I).

- All registered nurse (RN) and whānau support worker (WSW) time that was considered 'over and above' usual time spent on administering antibiotic treatment was recorded on the time tracking sheets.
- Any additional costs incurred due to administration of DOT including mileage, extra medication, blister packs etc. were monitored and recorded.
- Any unanticipated issues or outcomes were recorded in a daily diary by the RNs.
- Parental acceptability was assessed by brief parent questionnaire (Appendix I), and completed by the parent within 1 week of completion of DOT.
- Post-treatment swabs were carried out on all participants within 72 hours of completing antibiotic treatment by a RN or WSW.

2.3 Participants

During Term 4 2014, 110 primary and intermediate school students received a 10-day course of oral amoxicillin using DOT. Characteristics of participants in terms of age, ethnicity and gender were similar between the children in the group who received DOT and the control group. DOT was completed by 10 Mana Kidz nurses across 10 schools in the Otara and Mangere areas. To assess the acceptability of DOT from a parent/caregiver perspective, 107 parents/caregivers completed a DOT acceptability questionnaire. To assess the acceptability of healthcare professionals administering DOT, 7 RNs completed a healthcare professional acceptability survey.

2.4 Results

2.4.1 Adherence

Antibiotic adherence was assessed with a post-treatment swab taken by a RN or WSW within 72 hours of completing a 10-day course of oral amoxicillin using DOT (n=110). These results were compared to a control group (n=89), who received a post-treatment swab within 72 hours of completing a 10-day course of self (or parent) administered amoxicillin. Any symptoms were recorded for both groups at the time of the post-treatment swab.

The percentage of post-treatment swabs that returned GAS positive within 72 hours of completing DOT was 4.6% (Figure 2.1). The percentage of post-treatment swabs in the control group that returned GAS positive within 72 hours of completing self-administered antibiotics was 21.4%. A generalised linear mixed model was used to compare the post-treatment swabs results between the control and DOT treatment groups. Explanatory variables include group, age, gender and ethnicity. School was fitted as a random effect. The difference between the percentages of positive swabs in the control group and the DOT group are statistically significant ($P=0.01$; Table 2.1) indicating that DOT was an effective intervention to improve antibiotic adherence.

Depending on which day of the week children started DOT they could have either one or two weekends fall within their 10 days of amoxicillin where parents were required to administer their child's medication at home. All of the children who had a GAS positive post-treatment swab following DOT had only one weekend during the course of their medication.

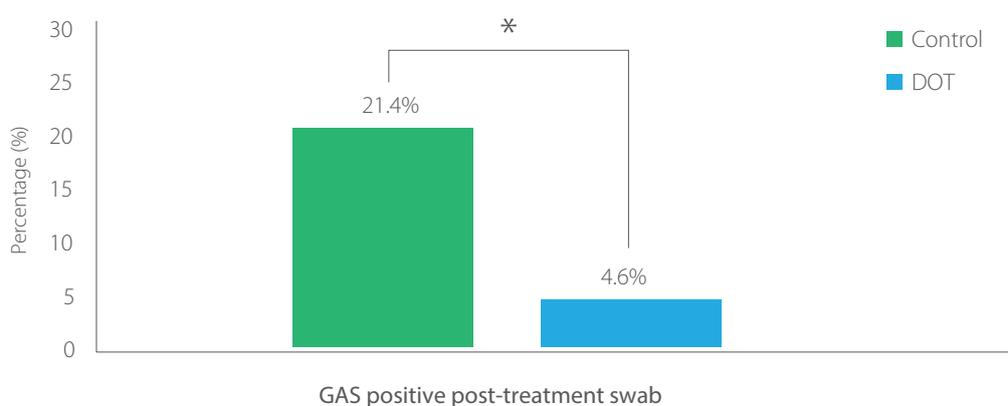


Figure 2.1 | Percentage of GAS positive post-treatment swabs taken within 72 hours of completing 10 days of oral amoxicillin for both the control group (n=89) and the DOT treatment group (n=110). * indicates a statistically significant difference between the control and DOT treatment groups ($P=0.01$; generalised linear mixed model).

Control (n)	DOT (n)	P-value	Odds ratio (95% confidence interval)
89	110	0.01	0.18 (0.05-0.60)

Table 2.1 | Comparison of post-treatment swab results between the control and DOT groups.¹

1. Statistical analysis conducted by the Biostatistics and Epidemiology Department at the University of Auckland.

2.4.2 Impact on health teams workload

To assess the impact of DOT on the health team's workload on administering DOT within the school clinic setting, a time and motion study was conducted. DOT was implemented in 10 Mana Kidz school based clinics and 110 students were treated using DOT. All RN and WSW time that was considered 'over and above' usual time spent on administering antibiotic treatment was recorded on the time tracking sheets. This was broken down into specific DOT related duties and an average time per child was calculated (Table 2.2). The administration of DOT medications (with student) refers to the time taken for the RN to administer the oral antibiotic daily for the next ten days (excluding weekends). DOT medication management refers to time taken to collect medication and then separate into weekend dosages. DOT documentation refers to the time taken for the RN to document daily activities regarding each individual students on DOT. The average time to administer DOT was 127.9 minutes per child and the average additional mileage was 3.1km per child.

For a RN to administer DOT the cost would be \$87.33 per child (Table 2.3). This includes an average RN contract price of \$85,000 per annum for 127.9 minutes per child, \$2.40 mileage per child and \$5 blister pack per child (see below; section 2.4.4). For a WSW to administer DOT the cost would be \$73.90 per child. This includes an average WSW contract price of \$65,000 per annum for 127.9 minutes per child, \$2.40 mileage per child and \$5 blister pack per child (see below; section 2.4.4).

DOT parent/caregiver phone communications	12.3
DOT parent face to face contact (home or clinic)	7.3
Administration of DOT medications (with student)	26.8
DOT medication management	32.5
DOT documentation	27.2
Teacher/school related DOT communications	2.8
Other DOT Related Tasks	6.8
DOT mileage (minutes)	9.1
DOT mileage (kilometre)	3.1
Total additional minutes per child	127.9
Total additional mileage per child (km)	3.1

Table 2.2 | Additional nursing time (minutes) and mileage (km) required to administer DOT per child

By a registered nurse	\$87.33
By a whānau support worker	\$73.90

Table 2.3 | Total additional cost to administer DOT per child by a RN or WSW.

2.4.3 Acceptability to stakeholders

2.4.3.1 Parents/Caregivers

The acceptability of DOT from a parent/caregiver perspective was assessed by a brief questionnaire. There were 107 parents/caregivers that completed the parent questionnaire. Overall the feedback from parents was very positive. The main reason (47.0%) parents chose to have DOT for the treatment of their child's GAS positive sore throat was that remembering to give 10 days of medication is hard (Figure 2.2A). An additional 30.4% of parents selected that 'something else' was the reason. The main reason in this group was that DOT was more convenient as parents find it difficult to administer the 10 days of medication with busy lives including, many children at home and work commitments e.g. shift work.

The majority of parents (99.1%) were happy with the way the medication was given at school. Of the small percentage (0.9%) that were not happy with the way the medication was given at school, the reason given was that they did not know what medication the child was receiving at school and would prefer to administer any medication at home (Figure 2.2B). A high percentage of parents (95.3%) reported that they would be happy to use DOT to treat their child's sore throat again (Figure 2.2C). Of the small percentage (2.8%) that would decline to receive DOT again, the main reason were that they would prefer to administer the medication at home or take the child to the family GP.

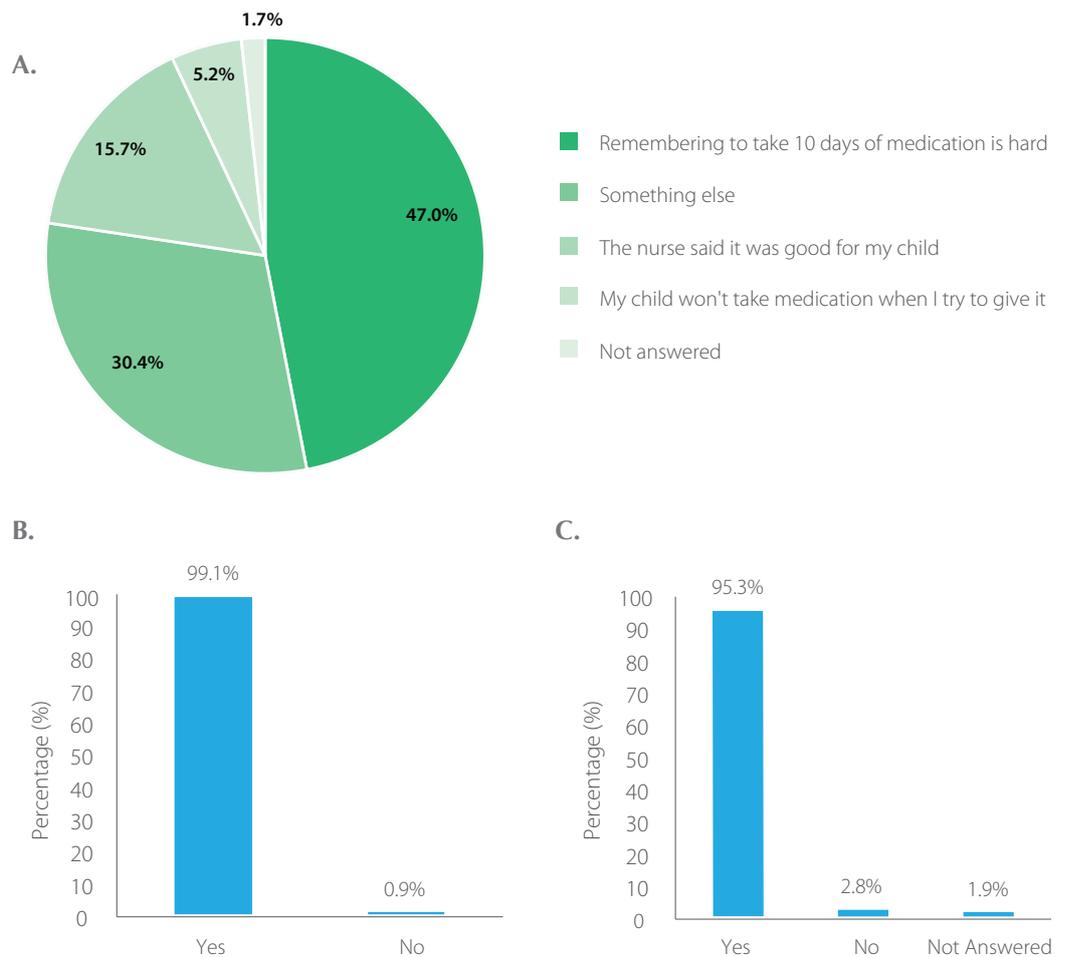


Figure 2.2 | Parent/Caregiver acceptability of DOT. (A) Reasons that parents/caregivers choose to have DOT for treating their child's GAS positive sore throat. (B) Percentage of parents that were happy with the way the medication was administered for DOT at school. (C) Proportion of parents that would choose to have DOT again to treat their child's sore throat.

2.4.3.2 Health professionals

Nurses involved in DOT reported that all of the feedback and comments from the children and whānau they received was very positive. Some of the comments from whānau were that it was more convenient for them as they sometimes forget to give their child the medicine. Nurses reported that the most common reason for whānau declining DOT was that the parent/guardian wanted to remain in control of their child's medication.

The majority of the nurses said they would recommend DOT as a treatment option, however only for the children that previously had poor adherence. They also mentioned DOT was extremely time consuming and if the child was absent from school it meant a home visit. Although DOT impacted the nurses' workload, most nurses (90%) felt the extra workload was worth the effort.

2.4.4 Unknown factors for wider implementation

One of the unexpected issues with DOT, was that the nurses were unable to dispense amoxicillin capsules from the main prescription into a separate container for a child to take home over the weekend. A blister pack could be used to dispense amoxicillin capsules as the nurses are able to separate the weekend days and give this to the parents to administer at home over the weekend. For amoxicillin suspension, an additional weekend bottle could be arranged at the pharmacy in advance.

A number of the children were also given suspension amoxicillin, if this was implemented in schools a number of the clinics may require a fridge for storage of medication, and additional bottles for weekend medication.

2.5 Challenges and Recommendations

- A plan is required for managing doses of antibiotics for non-attendance at school and over the weekends- this may require additional home visits.
- The paperwork needs to be simplified for medication management of individual patients.
- The whānau support worker could be utilised to manage DOT after the nurse has given the first dose of medication. The WSW could undergo a training competency to administer daily medication.
- Not all of the clinics are set up for DOT and some do not have fridges or running water. Additional cost would be required to install fridges and a water cooler (water jug is not suitable for hygiene reasons).
- DOT may not be required for all children (as in the control group 80% had a negative post-treatment swab indicating good antibiotic adherence). DOT could be used for children with adherence issues (i.e. children with 'poor' 5 and 10 day self-reported adherence or repeat GAS positives).
- DOT could be more efficient with the use of a blister pack for children taking capsules, as this would simplify the dispensing of weekend dosages.
- There may be additional pharmacy charges for a blister pack and also an additional weekend bottle for suspension prescriptions.

3. Use of blister packs to improve medication adherence

3.1 Aim

To evaluate the effectiveness of blister packs in improving medication adherence.

3.2 Protocol

Any student within a participating Mana Kidz school, who was receiving a 10-day course of oral amoxicillin for the treatment of a GAS positive strep throat was offered the option of a blister pack as a medication delivery option. All students were offered this as an option and only those who agreed to participate were given a blister pack (i.e. this was not randomly allocated).

3.3 Participants

During Term 4 2014, 67 primary and intermediate school students were administered their 10-day course of oral amoxicillin in a blister pack. Characteristics of participants in terms of age, ethnicity and gender were similar between the children in the group who received blister packs and the control group.

3.4 Results

3.4.1 Antibiotic Adherence

Antibiotic adherence was assessed with a post-treatment swab taken by an RN or WSW within 72 hours of completing a 10-day course of oral amoxicillin using a blister pack (n=67). The results were compared to a control group (n=89) who received a post-treatment swab within 72 hours of completing a 10-day course of self (or parent) administered antibiotics. The percentage of post-treatment swabs that returned GAS positive within 72 hours of completing a blister pack was 20.9% compared to 21.4% in the control group (Figure 3.1). A generalised linear mixed model was used to compare the post-treatment swab results between the control and the blister pack groups. Explanatory variables include group, age, gender and ethnicity. School was fitted as a random effect. No statistically significant difference could be demonstrated (P=0.58; Table 3.1), suggesting that the blister pack had no effect in improving antibiotic adherence.

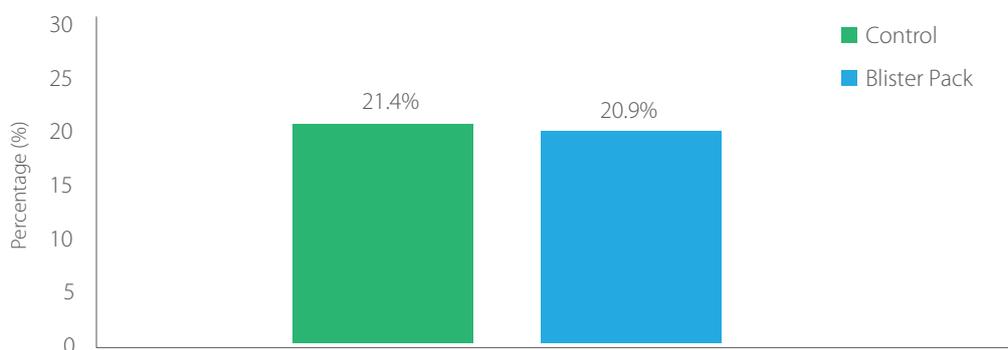


Figure 3.1 | Percentage of GAS positive post-treatment swabs taken within 72 hours of completing 10 days of oral amoxicillin for both the control group (n=89) and the blister pack group (n=67). No statistically significant difference between these groups could be demonstrated (P=0.58; generalised linear mixed model).

Control (n)	Blister packs(n)	P-value	Odds ratio (95% confidence interval)
89	67	0.58	0.76 (0.29-2.0)

Table 3.1 | Comparison of post-treatment swab results between the control and blister pack groups.²

Antibiotic adherence was also assessed by participant reported treatment adherence. This was measured on a scale of good (antibiotics taken correctly), intermediate (missed one or two doses) or poor (missed more than two doses) at two time points (day 5 and day 10). If the participant was unable to be contacted this was recorded as 'not completed'. The blister pack group (n=67) was compared to a control group (n=89). Although self-reported adherence is considered unreliable there was a decrease in the self-reported 'poor' adherence at day 10 in the blister pack group (14.7%) compared to the control group (29.0%; Figure 3.2).

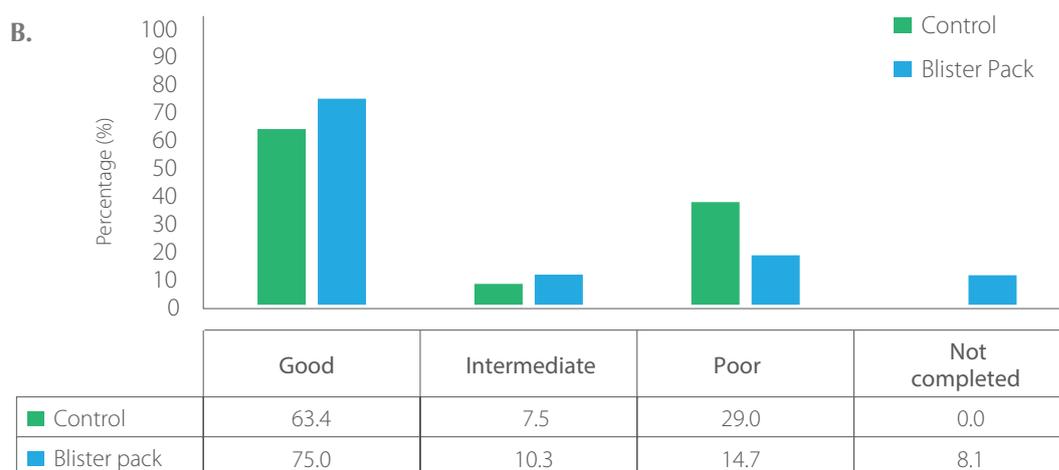
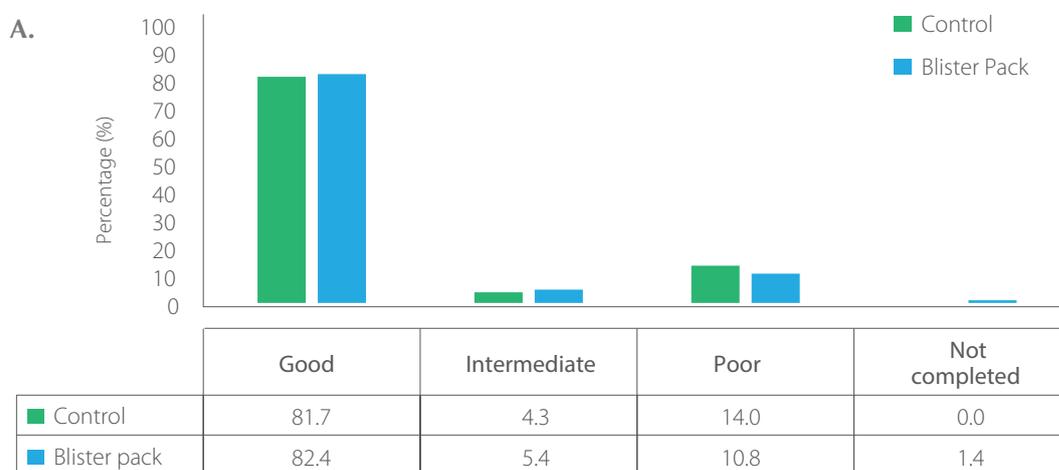


Figure 3.2 | Participant reported treatment adherence. (A) Self-reported adherence at day 5 of amoxicillin treatment in the control and blister pack groups. (B) Self-reported adherence at day 10 of amoxicillin treatment in the control and blister packs groups.

Self-reported adherence is used as a measure of antibiotic adherence across the Rheumatic Fever Prevention Programme with students receiving 10 days of amoxicillin reporting whether their adherence is good (all antibiotics taken correctly), intermediate (missed one or two doses) or poor (missed more than two doses) at 5 and 10 days of treatment. The University of Auckland used the data collected from the AAT to determine if there was a correlation between self-reported adherence and post-treatment swab results. There was no evidence of a significant relationship between self-reported adherence and post-treatment swab results (Spearman correlation=0.0835; P-value=0.2127; Appendix II), suggesting that self-reported adherence is not a reliable measure for determining antibiotic adherence.

3.4.2 Acceptability to stakeholders

3.4.2.1. Feedback from health professionals

To assess the acceptability of using blister packs for medication adherence we asked for feedback from four Mana Kidz RNs who dispensed the blister packs. Overall the RNs had positive feedback regarding the blister pack as an option for children receiving oral antibiotics. They felt it was an excellent tool for children that can take capsules as it ensures the correct dosage and works as a reminder if they had missed any capsules. In addition some of the nurses said it was more convenient for whānau and helped with poor adherence issues. Nurses indicated that whānau reported that blister packs were more convenient than regular packs and that it was a great reminder if children had taken antibiotic or not that day.

3.5 Challenges and Recommendations

- A child friendly pack is required. The blister packs used were large and had mixed feedback, some nurses reported that because they were so large they were harder to lose and parents were reminded they had the medication. Other nurses reported that the children found it shameful to have such a large box of medication dropped off to the classroom.
- Some families found the blister pack confusing if the day they started the medication on was pre-printed halfway through the blister pack and these needed to be manually altered using additional stickers.
- Blister packs need to be available from all pharmacies, nurses and parents are not will to travel further than their local pharmacy to pick up blister packs.
- Blister packs may be more suitable for high school students, as across the arms of the trial where the option of capsules or liquid was given (control, text reminders and DOT), 62.1% of children received suspension antibiotics not capsules.



4. Text communications to improve medication adherence

4.1 Aim

To evaluate the effectiveness of a text based communication service in improving medication adherence.

4.2 Protocol

Any student within a participating Mana Kidz school, who was receiving a 10-day course of oral amoxicillin for the treatment of a GAS positive strep throat was offered (or the parent of student was offered) an automated daily text reminder to remember to take their antibiotics (i.e. this was not randomly allocated). The recipient of the reminder needed an active mobile phone to participate.

4.3 Participants

During Term 4 2014, 72 primary and 14 high school students who were receiving a 10-day course of oral amoxicillin received a daily text reminder for the duration of the course. High school students received the text messages directly to their mobile phone and parents of primary school children received the text messages.

4.4 Text communications

4.4.1 Text messages

A series of 10 daily text messages were developed in collaboration with health literacy experts Workbase. Messages were tailored to either parents or students. An automatic text delivery service was setup-using Vensa Healthcare TXT-2-Remind software.

The messages were developed to be consistent with the medication advice given by health professionals, promote adherence, be clear and concise (text messages were limited to 140 characters), and provide information and support at key times during the 10 day course.

To Parents:

- 1 Antibiotic text reminder to give [name] their antibiotic today. It's important to give it every day.
- 2 Antibiotic text reminder, please remember to give [name] their antibiotic today, 10 days will prevent rheumatic fever.
- 3 Antibiotic text reminder, please remember to give [name] their antibiotic today, it's important to take every dose.
- 4 Antibiotic text reminder, please remember to give [name] their antibiotic today, it's important to take every dose.
- 5 Antibiotic text reminder, Well done when you give [name] their antibiotic today you are half way there.
- 6 Antibiotic text reminder, please remember to give [name] their antibiotic today.
- 7 Antibiotic text reminder, please remember to give [name] their antibiotic today. Contact your school clinic if you have any questions.
- 8 Antibiotic text reminder, you are nearly there! Please give [name] their antibiotic today, not long to go to kill all of the strep germs.
- 9 Antibiotic text reminder, please give [name] their antibiotic today. Talk to your school health team if you have any questions.
- 10 Antibiotic text reminder, well done last dose of antibiotics for [name] today. Remember to get every sore throat checked.
- 11 Antibiotic Adherence Trial, did [name] finish all their antibiotics? Please reply YES or NO. Thank you.

To Students:

- 1 Antibiotic text reminder, remember take 10 days of antibiotic medicine for strep throat today.
- 2 Antibiotic text reminder, time to take your antibiotic medicine. It's important to take it every day.
- 3 Antibiotic text reminder, time to take your antibiotic medicine, 10 days will prevent rheumatic fever.
- 4 Antibiotic text reminder, time to take your antibiotic medicine, it's important to take every dose.
- 5 Antibiotic text reminder, well done! When you take your antibiotic today you are half way there, keep going.
- 6 Antibiotic text reminder, time to take your antibiotic medicine. Contact your school clinic if you have any questions.
- 7 Antibiotic text reminder time to take your antibiotic medicine. For any questions you can call Healthline for FREE on 0800 611116
- 8 Antibiotic text reminder, you are nearly there! Please take your antibiotic medicine today, not long to go.
- 9 Antibiotic text reminder, time to take your antibiotic medicine. Talk to your school health team if you have any questions.
- 10 Antibiotic text reminder, well done last dose of antibiotics. Remember to get every sore throat checked.
- 11 Antibiotic Adherence Trial, did you finish all your antibiotics? Please reply YES or NO. Thank you.

4.4.2 Vensa Healthcare TXT-2-Remind system

The TXT-2-Remind Service was installed on the Medtech Server located at ProCare headquarters. Installing on the Medtech server ensures a stable environment which is closely monitored, has an internet connection and less likely to be switched off. TXT-2-Remind clients were installed on 2 helpdesk workstations to monitor the status receipts daily.

Eleven appointment books were setup in Medtech. ProCare nurses based at primary schools were set up to create a reminder for their patient in each of the appointment books over 11 consecutive days. Once set up the reminders go out as per schedule on each consecutive day via the internet to Vensa. This is delivered to the recipients' phone through their mobile phone provider. Recipients can reply to texts only when initiated from the practice. The mobile phone provider delivered the status receipt for the initial reminder and replies back to the TXT2Remind service and client (Figure 4.1).

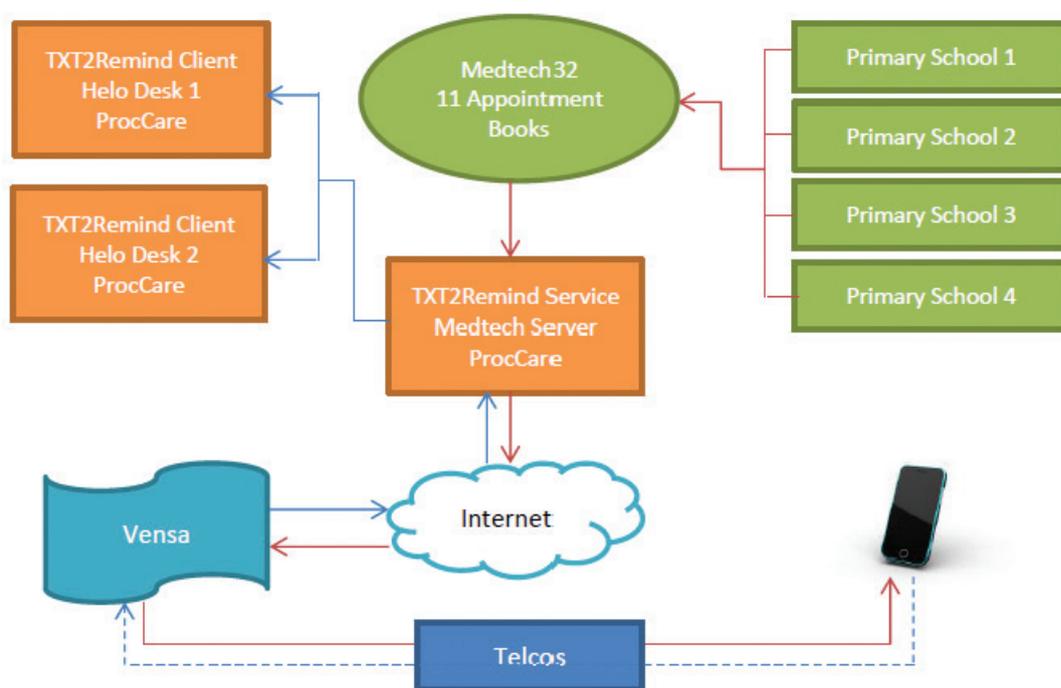


Figure 4.1 | Vensa Healthcare TXT-2-Remind system.

4.5 Results

4.5.1 Primary schools

4.5.1.1. Text messages

There were 72 primary school students that received daily text message reminders. Of the text messages that were sent, 90% were received, 7% had an error status, and 3% were expired (i.e. not received) (Figure 4.2). Parents were also sent a message following the completion of the course of the antibiotics asking if their child had finished the course of antibiotics, only 21% responded either Yes or No to these messages.

Primary School Status Receipts

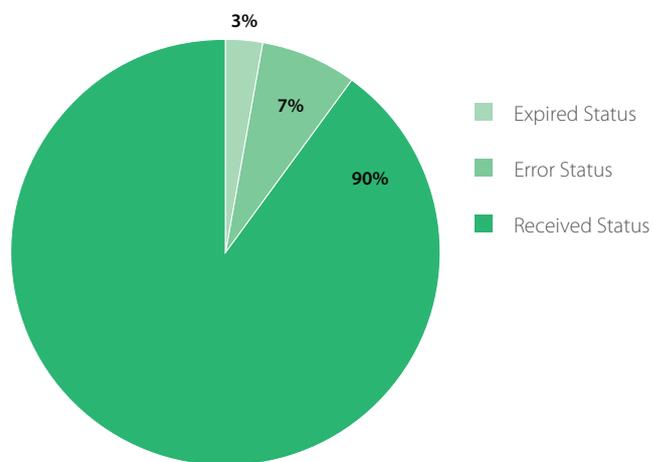


Figure 4.2 | Status of text messages sent to primary school students.

4.5.1.2 Antibiotic Adherence

Antibiotic adherence was assessed with a post-treatment swab taken by an RN or WSW within 72 hours of completing a 10-day course of oral amoxicillin for primary school students whose parents received a daily text reminder (n=72). The results were compared to a control group (n=89) who received a post-treatment swab within 72 hours of completing a 10-day course of self (or parent) administered antibiotics who did not receive a text reminder message. The percentage of post-treatment swabs that returned GAS positive within 72 hours of completing antibiotics with text reminders was 18.1% compared to 21.4% in the control group (Figure 4.3). A generalised linear mixed model was used to compare the post-treatment swab results between the control and the blister pack groups. Explanatory variables include group, age, gender and ethnicity. School was fitted as a random effect. No statistically significant difference could be demonstrated between the groups (P=0.86; Table 4.1), suggesting that the daily text reminders had no effect in improving antibiotic adherence.

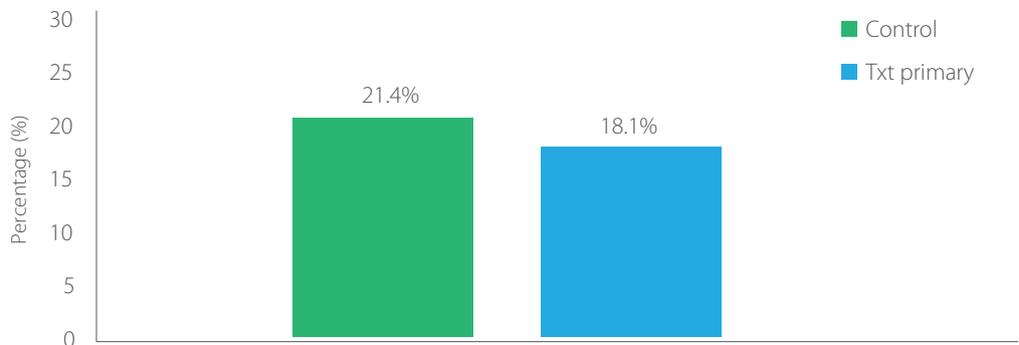


Figure 4.3 | Percentage of GAS positive post-treatment swabs taken within 72 hours of completing 10 days of oral amoxicillin for both the control group (n=89) and the Txt primary group (n=72). No statistically significant difference could be demonstrated between these groups (P=0.86; generalised linear mixed model).

Control (n)	Text primary (n)	P-value	Odds ratio (95% confidence interval)
89	72	0.86	0.90 (0.30-2.73)

Table 4.1 | Comparison of post-treatment swab results between control and text reminders group.³

Antibiotic adherence was also assessed by participant reported treatment adherence. This was measured on a scale of good (antibiotics taken correctly), intermediate (missed one or two doses) or poor (missed more than two doses) at two time points (day 5 and day 10). If the participant was unable to be contacted this was recorded as 'not completed'. The text reminders group (n=72) was compared to a control group (n=89). Although self-reported adherence is considered unreliable there was a reduction in 'poor' self-reported adherence at day 10 in the text reminders group (29.0%) compared to the control group (13.9%) (Figure 4.4).

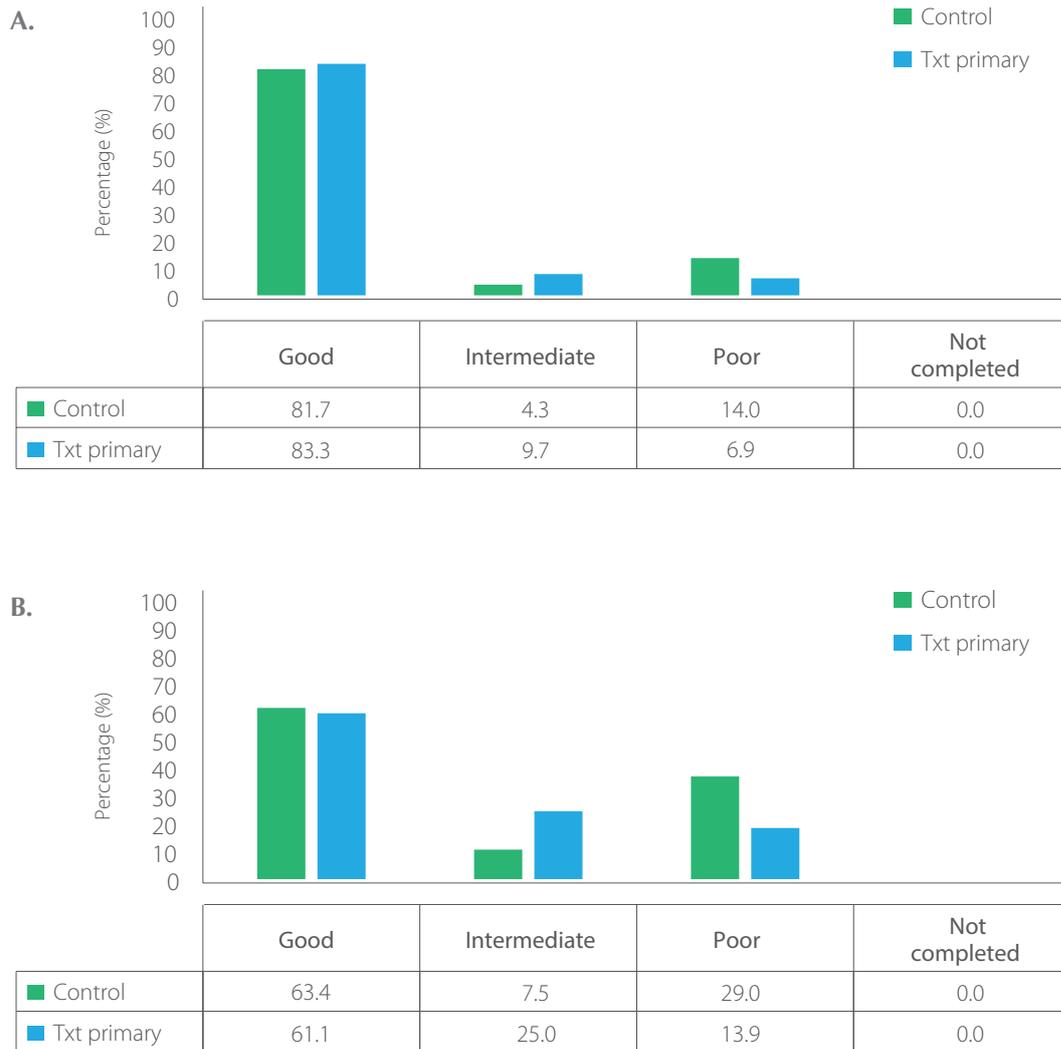


Figure 4.4 | Participant reported treatment adherence. (A) Self-reported adherence at day 5 of amoxicillin treatment in the control and text reminders groups. (B) Self-reported adherence at day 10 of amoxicillin treatment in the control and text reminders groups.

3. Statistical analysis conducted by the Biostatistics and Epidemiology department at the University of Auckland.

4.5.1.3 Feedback

Mana Kidz nurses involved in text reminders reported that it was well received and that parents appreciated the daily reminders, as they had previously forgotten to give their children the medication. One issue raised was that if a parent had several children receiving antibiotics they found the text messages confusing.

4.6.2 High schools

Recruitment of students to receive daily text reminders in the high schools was very difficult and the numbers were very low (n=14). We were unable to complete the recruitment for high school daily text reminders, due to a number of reasons including a low GAS positive rate in the high schools during Term 4, 2014 and a reduced number of students in the high schools due to Term 4 exams.

We also found that there were additional reasons that students declined the daily text reminders including that they did not want to give out their phone numbers to nurses or that they did not have mobile phones to receive text messages.

We were interested to see if the final text could be used as a way of eliciting self-reported adherence information. However, with a low response rate (21%) this is not a particularly useful method.

We intend to continue to explore the possibility of direct reminders to young people. The NHC will be looking at another cohort of patients over 2015 while presentations to school clinics are higher (during the winter months) to explore the use of text reminders.

4.6 Challenges and Recommendations

- Text reminders require a system that works across all patient management systems, the Vensa system only works with Medtech.
- To be effective the text communication system needs to be efficient for the nurses/WSWs to use in a busy clinic. The Vensa system was very time consuming for the nurses, having to manually enter 10 appointment book reminders and this is not acceptable to a busy school clinic.
- The text reminders should not require any response- only 21% of parents responded when asked if their child had taken their antibiotics.
- Text reminders can be managed by a WSW in the school based clinic.
- In high schools not all teenagers had a phone and not all were happy to receive text messages from the clinic.



5. Use of intramuscular bicillin as a treatment option for GAS positive in schools and primary care settings

5.1 Background

Most of the programmes/studies that have been successful in reducing rheumatic fever have used intramuscular bicillin as a first line treatment option.^[14] It has also been successfully used for many decades for the secondary prevention of recurrence of Rheumatic Fever.^[15] Given the proven success of IM bicillin in both primary and secondary prevention, the real question we sought to answer is whether this is an 'acceptable' option for the South Auckland community. It was thought that given the high rates of Rheumatic Fever in this community and the increasing community awareness around the preventable nature of it, the community will find this to be an acceptable option in situations where completion of 10 days of oral antibiotics is extremely challenging. Another important question this research sought to answer was whether the pain of the injection was significant enough to prevent children re-presenting with a sore throat. This is a challenging question to accurately measure, however the following report has captured some key indicators to inform discussion around this question.

5.2 Aims

- To evaluate the acceptability and feasibility of offering intramuscular (IM) bicillin with (0.25ml of lignocaine 2%) as a treatment option for GAS positive pharyngitis in schools and primary care settings.
- To monitor for any unintended consequences such as reduction in self-identification, following the introduction of IM Bicillin as a treatment option for GAS positive pharyngitis into the test schools.

5.3 Protocol

All protocols, consent forms, nursing competencies, standing orders and documentation for IM bicillin trial are in Appendix III.

5.4 Participants

During Term 4 2014, 41 primary and intermediate school children in Mangere received an IM bicillin (see protocol in appendix III) as a treatment for GAS positive pharyngitis. All parents of children who were GAS positive in Term 4 of 2014 at Turuki Healthcare schools, were offered the option of an IM bicillin to treat their child's GAS positive pharyngitis. If parents consented, the IM bicillin was administered by Mana Kidz nurses at Turuki Healthcare. For each child that received an IM bicillin the following was collected: a consent form, parent acceptability questionnaire, child acceptability questionnaires (at two time points), an 11th day post-treatment swab, a 3 week assessment and any adverse or injection site reactions.

In addition, a focus group on the acceptability of bicillin from a healthcare worker perspective was completed with three nurses and three whānau support workers who were involved in the administration of bicillin.

5.5 Adherence

Antibiotic adherence was 100% as children received a one-dose IM bicillin. However, to enable a comparison to other treatment interventions a post-treatment swab was taken on day 11 (or within 72 hours of day 11). Following bicillin, 36.4% of children had a GAS positive post-treatment swab. Because the majority of children (71.7%) who received bicillin had had multiple (n= 2–8) GAS positive sore throat throughout 2014 we compared the post-treatment GAS positivity between this group and the group of children for whom this was the first GAS positive throat swab. Just over one-third (35.7%) of children who had more than one GAS positive sore throat in 2014 had a positive post-treatment swab compared to 18.2% of those for whom this was the first GAS positive throat swab.

There are a number of possible explanations for a positive post treatment swab in a situation where you know poor antibiotic adherence is not an issue as in this case. These are:

- Treatment failure due to poor quality penicillin (e.g. failure in the cold chain management of the bicillin supply) This explanation is highly unlikely due to the stringent quality assurance processes by Medsafe for the importation of penicillin into New Zealand and strict adherence to storage protocols by the researchers.
- Treatment failure due to the strep bug being resistant to penicillin. This explanation is also extremely unlikely as penicillin resistant strep have never been found in the world.
- The children are GAS carriers with viral sore throats. This is the most likely explanation and is supported by the fact that there was a higher prevalence of post-treatment GAS positive results in those with recurrent sore throats compared to children for whom this was the first GAS positive result.

Other studies have also found that 7–37% of children treated with an appropriate antibiotic for GAS pharyngitis have a positive throat swab at the end of treatment.^[16] Shulman et al (2012) states that in most of these circumstances children who test GAS positive after a full course of appropriate antibiotic are GAS carriers.^[16] The conclusions from this study are limited to its aims and further research and expert advice is required to understand the positive post-treatment swabs.

5.6 Adverse events

There were no known adverse events during this study.

5.7 Acceptability to stakeholders

5.7.1 Acceptability to children

The acceptability of the IM bicillin from a child's perspective was assessed by two brief questionnaires, one on the day of the IM bicillin and 21 days later. There were 35 children that completed the first questionnaire and 28 children that completed the second questionnaire.

In both questionnaires children were asked to rate the pain level from 0 – 10, where 0 was no pain at all and 10 was the worst possible pain (Figure 5.1) On the day of the IM bicillin (after the injection) the average pain rating was 4.1, and one month later when asked the same question the average pain rating was 4.4. In both questionnaires children were asked how afraid of the injections they were on a scale of 0-10, where 0 was not afraid and 10 was the worst possible fear. On the day of the IM bicillin the average rating was 3.4 and 21 days later the average rating was 3.6.

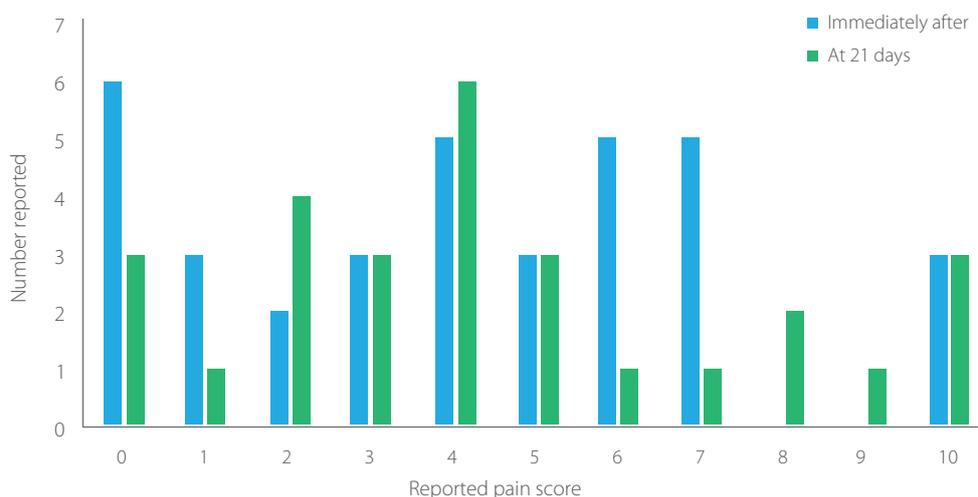


Figure 5.1 | Reported pain level from children immediately following bicillin IM and 21 days later (on a scale of 0-10, where 0 is no pain at all and 10 is the worst possible pain).

In the second questionnaire, children were asked to rate how painful the injection site was the day following the IM bicillin on a scale of 0-10, where 0 was no pain and 10 was the worst possible pain. The average rating was 3.5.

In the second questionnaire, children were also asked whether they still present to an adult when they have a sore throat. 82.1% of children reported that they still self-identify with a sore throat following the IM bicillin, however, 10.7% reported that they do not self-identify when they have a sore throat (Figure 5.2). It is unclear how long this effect will last. In the two months following the trial, 69% of the children in the control group had a new throat swab and 64% of the children in the bicillin group had a new throat swab.

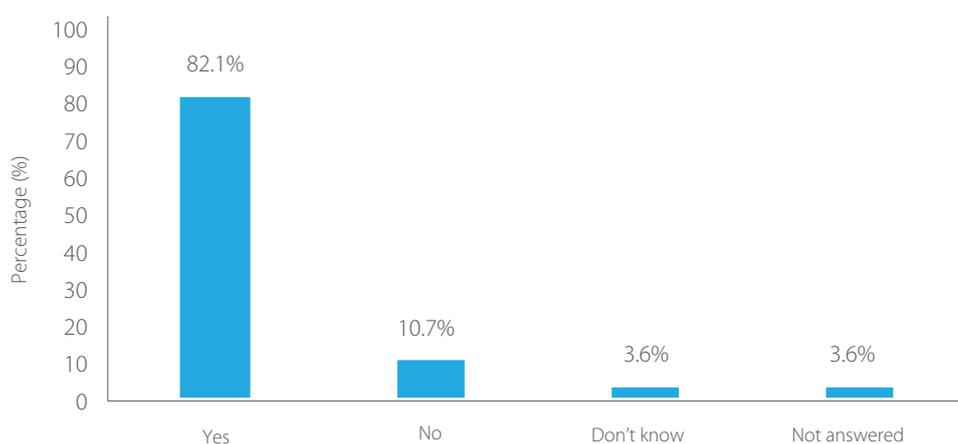


Figure 5.2 | Proportion of children that self-identify when they have a sore throat following IM bicillin.

5.7.2 Acceptability to parents/caregivers

The acceptability of IM bicillin from a parent/caregiver perspective was assessed by a brief questionnaire on the day their child received the IM bicillin. There were 36 parents/caregivers that completed the parent questionnaire. Approximately one third of parents chose to have an IM bicillin for their child because remembering to take 10 days of medication is difficult, one third thought that injections were stronger than oral medication and one third chose to have an IM bicillin for their child because the nurse/doctor said that it would be good for their child (Figure 5.3A). The majority of parents were happy with the way the IM bicillin was administered (82.9%; Figure 5.3B) and would choose to have an IM bicillin again (80.5%; Figure 5.3C).

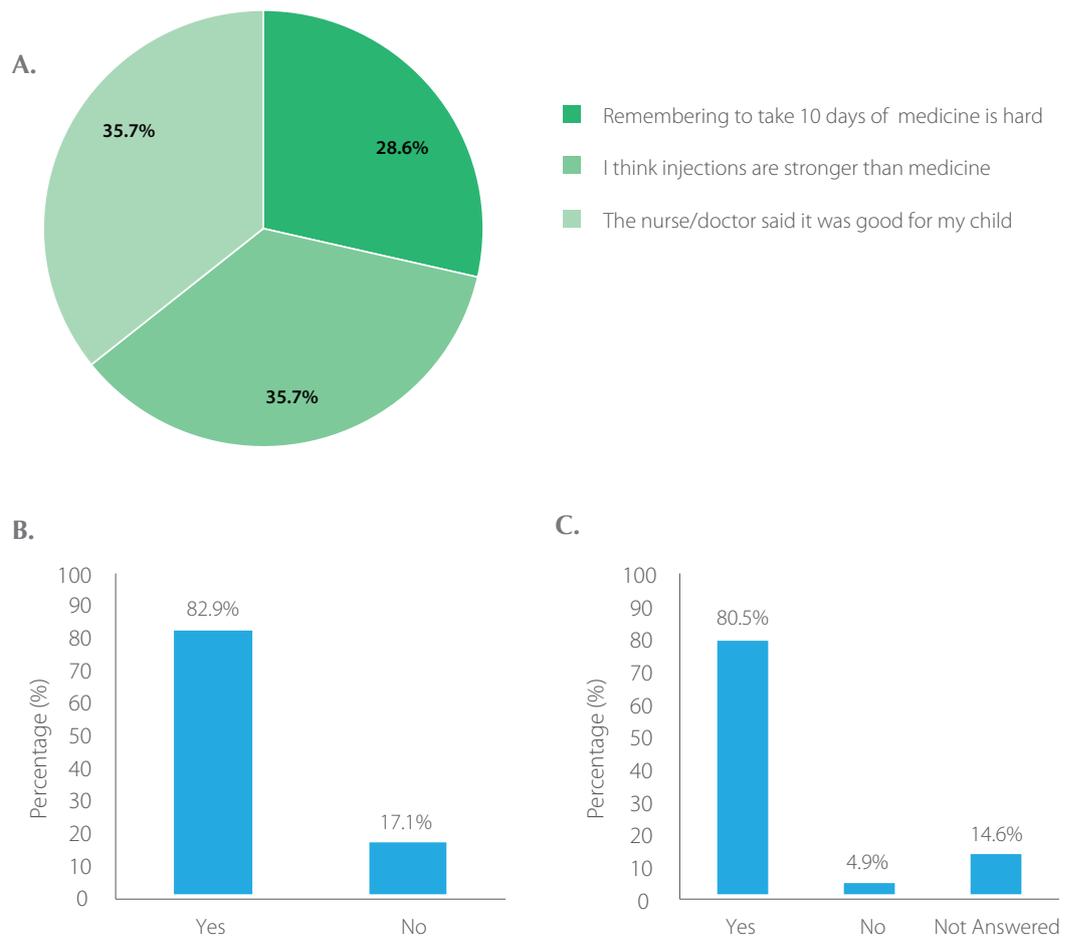


Figure 5.3 | Parent/Caregiver acceptability of IM bicillin. (A) Reasons parents/caregivers chose to have an IM bicillin for the treatment of their child's GAS positive throat. (B) Proportion of parents/caregivers that were happy with the administration of the IM bicillin. (C) Proportion of parents/caregivers that would choose to have an IM bicillin to treat their child's GAS positive sore throat again.

5.7.3 Acceptability to health professionals

To assess the acceptability of IM bicillin as a treatment option from a healthcare professional perspective, a focus group that consisted of four RN's and three WSW's from Turuki healthcare in Mangere was conducted. The overall feedback from the RN's was very positive suggesting they all felt confident to administer the IM bicillin. The majority (85.7%) felt confident to recommend IM bicillin as a treatment option. One nurse felt the injection was a concern for young children. Other comments indicated that the use of the 2% lignocaine along with the buzzy distraction device with the IM bicillin had a positive outcome in the treatment of pain management.

RNs reported that most of the whānau had positive responses when offered IM bicillin as a treatment option. However, a small proportion of parents still felt an oral antibiotic was more appropriate for first time GAS positive treatment and they would only choose IM bicillin as a treatment option if their child had multiple GAS positives.

RNs reported that the majority of children were apprehensive when the injections were offered but were more inclined to agree once the nurse had thoroughly explained the process. The feedback post IM bicillin was very positive from both the whānau and the children suggesting they would chose IM bicillin as a treatment option in the future. One of the key issues that the healthcare professionals found was that transportation was a real issue for many of the whānau and it would be more convenient if the child could have the injection at the school clinic or at home.

The majority of the healthcare professionals stated that there was no change in the behaviour of the children self-identifying following the IM bicillin injection. However, all of the healthcare professionals were concerned with the high proportion of GAS positives following IM bicillin. Many of the whānau who had children that were GAS positive post IM bicillin were reluctant to receive a second IM bicillin.

All of the healthcare professionals accepted IM bicillin as a good treatment option for children that had been multiple GAS positive throughout the year. They also felt IM bicillin was more convenient for whānau that had previously poor adherence with oral antibiotics. Approximately half (57%) of the healthcare professionals would recommend IM bicillin in the school clinic if the clinic was fully equipped to handle intramuscular injections as it would be more convenient for whānau.

The majority of the healthcare professionals were happy to recommend IM bicillin as a treatment option in general practice sore throat clinics. The majority (71.4%) suggest IM bicillin would have a better uptake if it was offered in school health clinic or homes, as it is a more convenient option for whānau. They also suggest that the IM bicillin as a treatment option would help improve adherence issues and follow up time for the healthcare professionals and is ultimately more convenient for whānau.

5.8 Challenges and Recommendations

- Transport to a clinic may be an issue for some families, and some families would have preferred to have the option of the IM bicillin at school or home.
- Clear guidance is required for the clinical management of children that have a GAS positive throat swab following IM bicillin.
- If IM bicillin was to be more widely used there is a need for a comprehensive guideline to support its use, including administration guidelines for the addition of lignocaine, the correct site for administration and use of distraction and pain reduction measures.
- The conclusions from this study are limited to its aims and further research and expert advice is required to understand the positive post-treatment swabs.

Conclusions and Recommendations

- Directly observed therapy was an effective intervention to significantly improve antibiotic adherence. If the process of DOT could be improved and the time managed more effectively, the estimated cost (\$87.33 per child) and the registered nursing time (127.9 additional minutes per child) to administer oral antibiotics daily could be reduced.
- Although blister packs and daily text reminders did not improve antibiotic adherence in primary schools, they were both well received by children and whānau. However, both of these interventions could be investigated in high school students, where a higher proportion of students take capsules rather than suspension amoxicillin.
- Intramuscular bicillin was an acceptable treatment option for children and whānau, in particular for whānau had previously had antibiotic adherence issues. Using the lignocaine and distraction device 'buzzy' worked well to manage pain associated with the injection.
- A number of children who received the IM bicillin were children with repeat sore throats and some of these children still had a GAS positive throat swab following the IM bicillin. There is some confusion in parents and nursing staff around the management of these children and clear guidelines are currently being produced by the Rheumatic Fever Prevention Programme on the management of children with repeat sore throats.

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Appendix I:

Directly observed therapy

DOT Parent/Caregiver Questionnaire

Kia ora. Talofalava. Malo E Lelei. Kia Orana. Fakalofa Lahi Atu,

Mana Kidz Nurses have been helping with giving the medicine for your child at school to treat the strep germ that has given them a sore throat. This questionnaire will help us understand if this is a good way to help kill the strep bug for you. Thank you for your help.

1. Which (if any) of the following influenced you to choose to have the nurse help give medication to treat your child's sore throat at school?

- Remembering to give 10 days of medicine is hard
- My child won't take medicine when I try and give it
- The nurse said it was good for my child
- Something else

2. Were you happy with the way the medicine was given at school?

- Yes
- No (please tell us why you ticked no)

3. Would you choose to do this again to treat your child's sore throat?

- Yes
- No (please tell us why you ticked no)

4. Is there anything else you would like to say about the nurse giving the medicine at school for sore throats? (optional)

Guideline: Direct Observation of Therapy (DOT) – Antibiotics for the Treatment of Group A Streptococcal (GAS) and Skin Infections

Purpose

The purpose of this guideline is to outline the specific requirements for students who require antibiotics for the treatment of GAS and skin infections utilising DOT safely and effectively. DOT within the school setting will ensure that the student is supported to successfully complete the full course of antibiotics.

Responsibility

This guideline applies to all Registered Nurses (RN) and Public Health Nurses (PHN) working in Mana Kidz involved in the management of DOT. RNs and PHNs who manage DOT are accountable both legally and professionally for their own practice.

Guideline

This guideline promotes best practice. The RN/PHN must always exercise clinical judgement within the domains of professional accountability.

Step	Action
1.	<p>It is the responsibility of the RN/PHN to be accountable for their own practice and therefore needs to be aware of:</p> <ul style="list-style-type: none"> ■ the main pharmacological actions of the antibiotic ■ the dose ■ frequency ■ route of administration ■ potential side effects and interactions ■ storage and stability of medication <p>This includes appropriate observation of the student i.e. observing them swallow their antibiotic.</p>
2.	<p>The RN/PHN co-ordinates an agreed process of DOT with the student and parent/caregiver and will:</p> <ul style="list-style-type: none"> ■ Discuss medication adherence in relation to the prevention of Acute Rheumatic Fever ■ Explain the rationale and the need for DOT in their specific case ■ Confirm the student's willingness to adhere to DOT
3.	<p>The RN/PHN/Whānau Support Worker (WSW) collects the antibiotic from pharmacy. Antibiotics may be accessed from the clinic stock utilising the practitioner supply order (PSO) option if this is available.</p>
4.	<p>At every visit the RN/PHN:</p> <ul style="list-style-type: none"> ■ Ensures that there is clean drinking water available ■ Confirms student's identity (name, NHI, Date of birth) ■ Verifies that the antibiotic to be taken is as per medication request/standing order ■ Instructs the student to swallow the antibiotic (with some water if tablet/capsule being taken) ■ Observes the student swallowing the antibiotic ■ Document this event on the students clinical record ■ Report any observed side effects as soon as possible to the GP/Mana Kidz clinical leader as appropriate

5.	<p>The “five rights” of medication administration should be applied for each student encounter:</p> <ul style="list-style-type: none"> ■ The right medication ■ The right student ■ The right dosage ■ The right route ■ The right time
6.	<p>If the student is absent from school, the RN/PHN/WSW contacts the parent/caregiver:</p> <ul style="list-style-type: none"> ■ Discusses the period of absence and the plan for how student will take antibiotics ■ RN/PHN will home visit if necessary/as agreed with parent/caregiver to administer antibiotics ■ Leave antibiotics with parent to continue administering this whilst student is away from school ■ Maintain daily contact (phone or home visit) with parent/caregiver to monitor medication adherence until completion of antibiotics ■ Notify Clinical Leader of any significant issues ■ Document all interventions in student's clinical record
7.	<p>Antibiotics will be supplied to parent/caregiver during weekends and school holidays:</p> <ul style="list-style-type: none"> ■ RN/PHN discusses the importance of medication adherence with parent/caregiver ■ Provides the appropriate amount of antibiotics for the duration of the time the student will be away from school ■ Provides education (as per step 1) ■ Where possible the RN/PHN/WSW will contact parent/caregiver to follow up on medication adherence (daily or as able)

School

Class

Patient Sticker



Student Medication Record for DOT

Medication: Amoxicillin	Dose: mg, od, 10/7	Caps / Liquid (circle)
--------------------------------	---------------------------	------------------------

Medication Administration Record

Date and Time	Comments	Signature and Designation
Day 1: ___/___/2014, ___:___ hrs		
Day 2: ___/___/2014, ___:___ hrs		
Day 3: ___/___/2014, ___:___ hrs		
Day 4: ___/___/2014, ___:___ hrs		
Day 5: ___/___/2014, ___:___ hrs		
Day 6: ___/___/2014, ___:___ hrs		
Day 7: ___/___/2014, ___:___ hrs		
Day 8: ___/___/2014, ___:___ hrs		
Day 9: ___/___/2014, ___:___ hrs		
Day 10: ___/___/2014, ___:___ hrs		

Medication sent home on days: _____ and _____ Additional Days: _____

Empty container sighted Y /

Post-treatment swab result (circle): GAS Positive / GAS Neg / Other

Example of a DOT diary: September 2014

Sun	Mon	Tue	Wed	Thu	Fri	Sat	Directly Observed Therapy – Daily Time Record Sheet	
	1	2	3	4	5	6	School:	
7	8	9	10	11	12	13	PHN/WSW Name:	
14	15	16	17	18	19	20	Students offered DOT today (no's):	
21	22	23	24	25	26	27	Accepted:	Declined:
28	29	30						Unsure:

Record in minutes for each episode		Day Total
DOT Parent/caregiver telephone communications:		
DOT Parent face to face contact (home or clinic):		
Administration of DOT medications (with student):		
DOT Medication Management:		
DOT Documentation:		
Parent Questionnaire:		
Teacher/School related DOT communications:		
Other DOT Related Tasks:		
DOT Mileage:		

Appendix II: Correlation for adherence

Statistical analysis provided by the Biostatistics and Epidemiology department at the University of Auckland.

Table of _10_day_adherence by _10_day_post_swab			
_10_day_adherence	_10_day_post_swab		
Frequency Percent Row Pct	Negative	Positive	Total
Good	129 54.89 81.13	30 12.77 18.87	159 67.66
Intermediate	26 11.06 81.25	6 2.55 18.75	32 13.62
Poor	31 13.19 70.45	13 5.53 29.55	44 18.72
Total	186 79.15	49 20.85	235 100.00

Spearman Correlation Coefficient	
Correlation (r)	0.0835

Test of H0: Correlation = 0	
Two-sided Pr >= r	0.2127

Sample size = 235

Appendix III:

Intramuscular bicillin

Script for talking to parents/caregivers about using antibiotic injections to treat strep sore throats:

We know that forgetting to take medicine happens a lot and can affect people's health. Remembering to give antibiotics to your child for 10 days for their strep sore throat can be hard.

Instead of taking antibiotic liquid or pills for 10 days, your child could have one antibiotic injection.

The antibiotic injection is a very good way to treat strep sore throats but we haven't used it very often because it is quite painful for children. We are also worried that children might stop telling us when they have a sore throat because they are afraid of having an injection.

The nurses at Turuki Health Care can give an antibiotic injection to a child with a strep sore throat. This is free. The nurses also add a medicine to the injection so it is less painful.

We would like to know if you and your child want to have one antibiotic injection, instead of 10 days of antibiotics to treat their strep sore throat.

We also need your help to answer some questions about why you chose the injection and what you thought about it. Your child will also be asked some questions about having the injection. Your answers to these questions will help us understand why you chose the injection. Your child's answer will help us understand if the injection was okay for them and what they will do if they get another sore throat.

If you are interested we have some more information that you can take with you.

Letter and Information Sheet for Parents:

Kia ora, Talofa lava, Kia orana, Malo e lelei, Fakaalofa lahi atu, Bula vinaka, Namaste, Malo ni, Fakatalofa atu

Your child recently had a throat swab at school which showed Group A Streptococcus (also called strep) germs in your child's throat. This means that your child needs antibiotics to treat their strep/sore throat to stop Rheumatic Fever.

There are three ways your child can have antibiotics. The three ways are shown in the pictures at the bottom of this page.

If you and your child choose to have the injection we would like to ask you to join in a study looking at what families think about using injections to treat strep sore throats. You and your child would have to answer a few questions. Your child can still have the injection if you choose not to be in the study.

There is more information on the next two pages.

If you have any questions or want more information, please talk to our Co-ordinator.

Names:

Phone Numbers:



**Liquid medicine
for 10 days**



Pills for 10 days



One injection

Information Sheet

Short title

Using antibiotic injections to treat strep sore throats

Can you help us with a study being carried out by Turuki Health Care, National Hauora Coalition and the University of Auckland?

Study Outline

This study aims to find out what āāu/families think about using antibiotic injections as a way of treating strep sore throats.

Doctors and nurses know that antibiotic injections are a very good way to treat strep sore throats. But we haven't asked whānau/families if they think they would choose an injection to treat strep sore throats. The nurses at Turuki Health Care will be offering antibiotic injections to children with strep sore throats in some of the Mangere schools in the Mana Kidz Rheumatic Fever Prevention Programme. The results will help us to know if these injections for strep sore throat could be used in other Mana Kidz clinics and in general practices.

We will also be checking that children are still telling people at school when they have a sore throat, and that the pain of the injection is not making children afraid to say when they have a sore throat.

Very rarely injections can cause injury, treatment for this is free under ACC.

What you need to do?

You will be asked to answer some questions about why you chose the injection. Your child will be asked some questions about how they found the injection. Your answers to these questions will help us understand if having the injection was acceptable to you. Your child's answer will help us understand if the injection was okay for your child or if they now will not tell people about sore throats.

Your Rights:

- You do not have to take part in this study and it will not affect your care from Mana Kidz
- You can ask questions about the study at any time
- Your name will not be used in any study report or presentation
- Your child can still have the injection if you choose not to take part in the study
- You can stop being part of the study at any time
- You will be given a short report about the study when it is completed

Concerns

If you have any questions about your rights in this study you can contact Health and Disability Advocate who has nothing to do with this study. This is a free service provided under the Health and Disability Commissioners Act.

Ph 0800 555 050

Fax 0800 2787 7678 (0800 2 SUPPORT)

Email advocacy@hdc.org.nz

Consent Form

Title: Using antibiotic injections to treat strep sore throats

Investigators: Turuki Health Care, National Hauora Coalition, University of Auckland

Request for interpreter

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island / Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	lo	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Sāmoan	Ou te mana'ou ia i ai se fa'amatala upu	loe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	loe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	lo	Ikai

If you are willing to take part in this study, please complete this consent form.

I have read and understood the information sheet	Yes	No
I have been given and read a written explanation of what I need to do	Yes	No
I have had an opportunity to ask questions and to have them answered	Yes	No
I understand I have the right to withdraw from the study at any time and the right to decline to answer any question	Yes	No
I agree to provide information to the researcher on the understanding my name will not be used.	Yes	No
I understand that my consent to take part does not alter my legal rights	Yes	No
I agree to take part as a subject in this study, under the conditions set out in the information sheet.	Yes	No

I hereby consent to myself and my child
(full name)

to take part in this study.
(full name)

Date: Signature:

Full names of researchers:

Contact phone number for researchers:

Project explained by:

Project role:

Date: Signature:

Parent/Caregiver Questionnaire

1. Tick the things that helped you decide to use an injection to treat your child's strep sore throat?

- Remembering to take 10 days of medicine is hard
- I think injections are stronger than medicine
- The nurse/doctor said it was good for my child

Please tell us if you had other reasons

2. Do you think the way the nurse gave the injection was okay?

- Yes
- No (please tell us why you ticked no)

3. Would you choose to have this injection again to treat your child's sore throat?

- Yes
- No (please tell us why you ticked no)

Questionnaire 1

Antibiotic injections for strep sore throat

Kia ora. Talofalava. Malo E Lelei. Kia Orana. Fakalofa Lahi Atu.

Mana Kidz Nurses are offering antibiotic injections to treat the Strep that has given you a sore throat. This questionnaire, and another one after one month, will help us understand if this is a good way to help kill the strep bug for you. Thank you for your help.

How old are you?

1. Which ethnic group do you belong to? Mark the space or the spaces that apply to you.

NZ European Māori Samoan Cook Island Māori

Tongan Niuean Chinese Indian

Other such as Dutch, Japanese, Tokelauan

please state

2. How painful was the injection when it was being injected?

0 1 2 3 4 5 6 7 8 9 10

No pain

Moderate pain

Worst possible pain

3. How afraid are you of these injections?

0 1 2 3 4 5 6 7 8 9 10

Not afraid

Moderately afraid

Worst possible fear

4. How afraid are you of going to the doctors when you are hurt or sick?

0 1 2 3 4 5 6 7 8 9 10

Not afraid

Moderately afraid

Worst possible fear

5. Is there anything you would like to say about the injections?

Nurse record:

Dose: 0.6MU / 1.2MU

Lignocaine Y/N

M/F

Buzzy Bee with cold pack Y/N

Injection site reaction Y/N Details:

Adverse Event Y/N Details:

Thank you for your help.

Questionnaire 2

Antibiotic injections for strep sore throat

Kia ora. Talofalava. Malo E Lelei. Kia Orana. Fakalofa Lahi Atu,

Please think about your penicillin injection, a month ago.

1. How painful do you remember the injection being when it was being given?

0 1 2 3 4 5 6 7 8 9 10

No pain

Moderate pain

Worst possible pain

2. How painful was the place where the injection went in the next day?

0 1 2 3 4 5 6 7 8 9 10

No pain

Moderate pain

Worst possible pain

3. How afraid are you of these injections?

0 1 2 3 4 5 6 7 8 9 10

Not afraid

Moderately afraid

Worst possible fear

4. Do you still put your hand up or tell an adult when you have a sore throat?

Yes No Don't know

5. How afraid are you of going to the doctors when you are hurt or sick?

0 1 2 3 4 5 6 7 8 9 10

Not afraid

Moderately afraid

Worst possible fear

6. Is there anything you would like to say about the injections?

Thank you for your help.

Registered Nurses Process: Intramuscular Injection of Bicillin with Lignocaine (> 30kg)

You will need

- 1.2mu prefilled Bicillin syringe (with Bicillin needle)
- 2% Lignocaine ampoule
- x1 1ml syringe
- 25g 1" needle
- BUZZY® pain management device

Consent

- Check written consent with parent/caregiver
- Obtain verbal assent from student
- Establish rapport/engage with child with an awareness of whānau

Process

Ensure an aseptic non touch technique is used throughout the procedure.

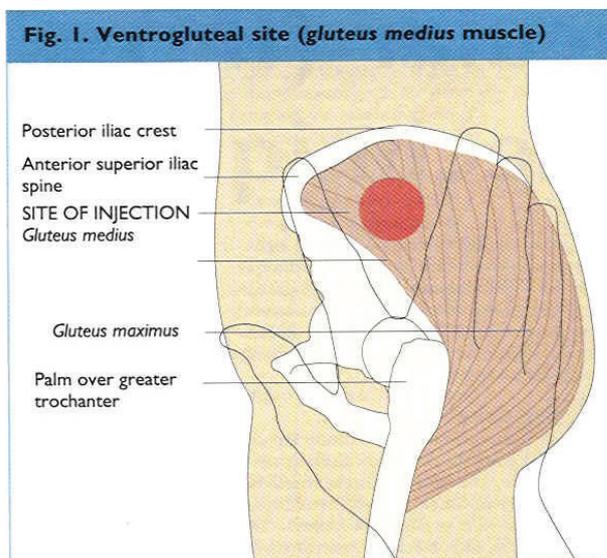
- 2 RNs independently double check the pre-filled Bicillin syringe and Lignocaine ampoule
- Administering RN draws up 0.25ml of 2% Lignocaine into a 1ml syringe
- Checking RN confirms right volume in syringe
- Attach 25g 1" needle to the 1ml syringe containing Lignocaine
- Remove cap from pre-filled Bicillin syringe and draw back plunger to allow space for Lignocaine
- Add Lignocaine to the pre-filled Bicillin syringe
- Discard empty Lignocaine needle/syringe in sharps bin
- Push plunger up gently so there is no air in the Lignocaine/Bicillin syringe
- Attach Bicillin needle (with needle guard) and warm injection with hands
- Locate site for VG injection (see below)
- Press activated BUZZY® directly on injection site and leave for **1 minute**
- Slide BUZZY® 2-5cm proximal to site
- Use distraction while administering (non-procedural talk/eye spy/breathing)
- Administer Lignocaine/Bicillin to client slowly. Give first portion containing Lignocaine and wait a few seconds then give remaining Bicillin (leave BUZZY® vibrating until needle is removed).

Note: Discard unused Lignocaine at the end of the day.

Administration Site

Gluteus Medius Muscle

- This site is recommended in adults and children over seven months old as it is the largest muscle in the young child.
- Potential complications are limited as it is free from nerves and major vascular structures.
- Site is easily palpable and accessible in both thin and obese patients.
- The muscle is accessible in the supine, prone or side lying position.
- Subcutaneous tissue is thinner over this muscle and has a consistent thickness of adipose over it ensuring that the needle will penetrate the muscle.



Documentation

- Document hypersensitivities and weight
- Document consent and assent completed
- Injection administration to include medications given and dose, date, time, route, and signature of nurse (can be electronic)
- Complete documentation of other actions as needed

If Consent/Assent Refused

- The child is not formally assessed and injection is not administered
- Notify referring RN of refusal and need for oral antibiotics

Process: Intramuscular Injection of Bicillin with Lignocaine (< 30kg)

You will need

- 1.2mu prefilled Bicillin syringe (with Bicillin needle)
- 2% Lignocaine ampoule
- x1 1ml syringe
- x1 3ml syringe
- x2 23g 1" needle
- BUZZY® pain management device

Consent

- Check written consent with parent/caregiver
- Obtain verbal assent from student
- Establish rapport/engage with child with an awareness of whānau

Process

Ensure an aseptic non touch technique is used throughout the procedure.

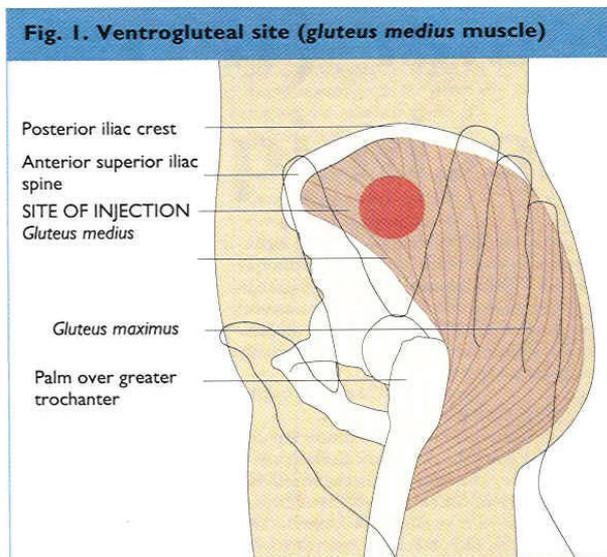
- 2 RNs independently double check the pre-filled Bicillin syringe and Lignocaine ampoule
- Using a 3ml syringe pull the plunger back to 1.15ml
 - Decant the Bicillin from the prefilled syringe into the 3ml syringe using a 23g needle filling from plunger end of 3ml syringe first to avoid air bubbles
- Administering RN draws up 0.25ml of 2% Lignocaine into a 1ml syringe
- Checking RN confirms right volume in syringe
- Attach 23 (or 25)g 1" needle to the 1ml syringe containing Lignocaine
- Add Lignocaine to the 3ml Penicillin filled syringe
- Discard empty Lignocaine needle/syringe in sharps bin
- Push plunger up gently so there is no air in the Lignocaine/Bicillin syringe
- Attach Bicillin needle (with needle guard) and warm injection with hands
- Locate site for VG injection (see below)
- Press activated BUZZY® directly on injection site and leave for **1 minute**
- Slide BUZZY® 2-5cm proximal to site
- Use distraction while administering (non-procedural talk/eye spy/breathing)
- Administer Lignocaine/Bicillin to client slowly. Give first portion containing Lignocaine and wait a few seconds then give remaining Bicillin (leave BUZZY® vibrating until needle is removed).

Note: Discard unused Lignocaine at the end of the day.

Administration Site

Gluteus Medius Muscle

- This site is recommended in adults and children over seven months old as it is the largest muscle in the young child.
- Potential complications are limited as it is free from nerves and major vascular structures.
- Site is easily palpable and accessible in both thin and obese patients.
- The muscle is accessible in the supine, prone or side lying position.
- Subcutaneous tissue is thinner over this muscle and has a consistent thickness of adipose over it ensuring that the needle will penetrate the muscle.



Documentation

- Document hypersensitivities and weight
- Document consent and assent completed
- Injection administration to include medications given and dose, date, time, route, and signature of nurse (can be electronic)
- Complete documentation of other actions as needed

If Consent/Assent Refused

- The child is not formally assessed and injection is not administered
- Notify referring RN of refusal and need for oral antibiotics.

Intramuscular Injection Of Bicillin With Lignocaine Added - Competency

Learning objectives

On completion of this competency the Registered Nurse (RN) will be able to safely and effectively administer intramuscular Bicillin with Lignocaine added for the management of Group A Streptococcal pharyngitis in General Practice.

Pre requisite

- Attended education session on administration of Bicillin with Lignocaine added
- Reviewed NZ Heart Foundation Guidelines for Sore Throat management
- Completed Goodfellow online Quiz on 'Primary Prevention of Rheumatic Fever'
- Completed Essential readings

Learning outcomes

On completion of this competency the Registered Nurse will be able to:

- 1 Describe the pathophysiology of Group A Streptococcus pharyngitis
- 2 Describe the rationale and process of primary prevention programmes and sore throat management
- 3 Describe and access the resources for primary prevention
- 4 Discuss the importance of a family/whānau centred approach to supporting care of the child/young person (including cultural and social factors)
- 5 Explain the process of informed consent/assent of child / young person
- 6 Access and discuss protocol for anaphylaxis management in the community
- 7 Access and discuss CMDHB Procedure for Medication Management
- 8 Discuss the rationale for ventrogluteal intramuscular injection
- 9 Demonstrate the procedure and technique for ventrogluteal intramuscular injection.
First injection is under the supervision of an experienced peer
- 10 Describe Bicillin and Lignocaine contraindications, side effects, adverse reactions, precautions, storage and dosage
- 11 Access and discuss protocol for anaphylaxis management in the community
- 12 Maintains principles of infection control and standard precautions
- 13 Discuss the 'five rights' of medication safety
- 14 Discuss the process of 'refusal of injection'
- 15 Apply the principles of nursing documentation

Essential readings

1. Jarvis, C. (2000). *Physical Examination & Health Assessment*. 2nd Ed. W. B. Saunders Company: Philadelphia.

Optional readings

1. Nursing Council of New Zealand, Code of Conduct for Nurses <http://nursingcouncil.org.nz/Media/Files/Code-of-Conduct-Booklet-full2>
2. Rheumatic fever. The Neglected Disease (2010) Best Practice Journal 32: 15–18. 83- 86
3. New Zealand Guideline for Sore Throat Management (2006), produced by The National Heart Foundation of New Zealand and The Cardiac Society of Australia and New Zealand

Learning Parameters and Audit

	Initial	Comments to support competency
<p>On completion of this competency the Registered Nurse will:</p> <ul style="list-style-type: none"> ■ Shows an understanding of the importance of correct sore throat management ■ Apply knowledge gained from the relevant resources accessed to clinical practice ■ State how cultural and social factors may impact of the care of a child/young person presenting with a GAS. Applies principles of Treaty of Waitangi to clinical practice ■ Collects accurate medical history including recent and current health status and allergies ■ Applies strategies to increase health literacy such as 'Teach Back' and "three steps to health literacy" methods ■ Establishes rapport when obtaining written consent from parent/caregiver and verbal assent from child/young person ■ Demonstrates hand hygiene (five moments of hand hygiene) ■ Utilises the 'five rights' of medication safety and states rationale for this ■ Administers injection according to Injection Administration procedures (using distraction methods if applicable) ■ Explains to child/young person the process of post injection observation ■ Effectively manages the process of 'refusal of injection' including notifying the referring RN 		

Completed on:

Audited by:

Signature:

Designation:



Standing Orders

FOR

Administration of Intramuscular Benzathine Penicillin
with Lignocaine 2% to treat Group A Streptococcal Pharyngitis

For the use of Registered Nurses

Practising under the Direction and Supervision

Dr

DOCUMENT APPROVED BY: National Hauora Coalition

DATE:

(This document will be reviewed within a minimum period of one year)

Standing Orders

A: Medicines:

Intramuscular (IM) Benzathine Penicillin G

IM Lignocaine 2%

Standing Order Definition

A standing order is a written instruction issued by a medical practitioner or dentist. It authorises a specified person or class of people (e.g. paramedics, registered nurses) who do not have prescribing rights to administer and/or supply specified medicines and some controlled drugs. The intention is for standing orders to be used to improve patients' timely access to medicines.

Standing Order Guidelines

Ministry of Health 2012

Reference

Ministry of Health (2012). Guidelines for the Development and Operation of Standing Orders: New Zealand.

Affirmation

I/We, the undersigned Paediatricians / General Practitioners

- 1 Have reviewed the minimum expectations outlined in these Standing Orders.
- 2 Are satisfied that these provide adequate guidelines for a Registered Nurse deemed competent by the Mana Kidz Clinical Team to undertake these practices, who has successfully completed the theory/ clinical component of the speciality.
- 3 Understand that the Registered Nurse has completed a detailed competency assessment before initiating any of these activities. This consists of professional development education sessions on the diagnosis and management of Group A Streptococcal pharyngitis provided by the Mana Kidz Project Team. All Registered Nurses are assessed at the end of the sessions by the Mana Kidz Team Leaders. This education is over and above the requirements that the Registered Nurses will have met for routine nursing duties.
- 4 Understand that the Registered Nurse accepts full accountability (personally and professionally) to practise within the standing orders and is answerable if acting beyond the scope of these orders.
- 5 Understand that I am accountable to provide back up and feedback to the Registered Nurse.
- 6 Agree to an audit of administration records, as a substitute for countersigning requirements.

Signed Date
Dr

Affirmation

We, the undersigned qualified Registered Nurses of the Mana Kidz School Based Programme, accept full accountability (personally and professionally) to practise within the standing orders and are answerable if acting beyond the scope of these orders.

We undertake to submit an annual competency assessment for the administration of medication and relevant procedures.

Signed Date
RN

Signed Date
RN

A. Medicines to be given by the Registered Nurse in the Mana Kidz School Based Programme for the treatment of Group A Streptococcal Pharyngitis.

Only medicines on this list may be given by Registered Nurses under these Standing Orders

The Registered Nurse (RN) may supply administer medicines that have been prescribed in the Standing Orders to be given in the community.

The Registered Nurse is to give medicines only to:

- Persons who have a throat swab positive for group A streptococcus and who are consented to take part in the Mana Kidz School Based Programme.
- Household members (of consenting students at participating schools) who are aged 3 years and up to 18 years of age, are found to have a throat swab positive for group A streptococcus, and have consented to treatment by the RN.

The Registered Nurse must document the assessment and treatment of the child to whom medicines are given under this standing order (including any adverse reaction). Documentation of medicines administered must include the name of the medication, dose, date and time given along with the signature of the individual supplying or administering the medication.

IM Benzathine Penicillin G

Indications for use

- Throat swab culture positive for group A beta-haemolytic streptococcus

Charting and administration:

The medicine should be supplied or administered in accordance with the sore throat management protocol in the Manual of Operations for Mana Kidz School Based Programme and Heart Foundation Guide to sore throat management.

Children less than 30kg

- 600,000 units single IM dose

Children 30kg and over

- 1,200,000 units single IM dose

Contraindications

- Previous hypersensitivity to β -lactams
- Check allergy status first. Do not give if allergic to penicillins (including amoxicillin or cephalosporins)
- Concurrent use of tetracyclines (bacteriostatic agents may reduce the bactericidal effect of penicillin).
- Bleeding disorder (IM administration may cause haematoma).
- Do not inject into or near an artery, vein or nerve (may cause severe and/or permanent damage).

Precautions

- Serious and occasionally fatal hypersensitivity
- Use in caution in patients with a history of significant allergies and or asthma
- Injection near a nerve can result in permanent neurological damage select site with care

Side Effects

The most common side effects are

- Skin eruptions

Less common side effects are

- Antibiotic pseudomembraneous colitis has been reported
- Haemolytic anaemia, leucopenia thrombocytopenia
- Neuropathy, nephropathy

Lignocaine 2%

Indications for use

- Local anaesthetic for use with IM Benzathine Penicillin G

Charting and administration

The medicine should be supplied or administered in accordance with the sore throat management protocol in the Manual of Operations for Mana Kidz School Based Programme.

- Administered IM into ventrogluteal muscle
- All ages 0.25mls of 2% Lignocaine (to be added to IM Benzathine Penicillin)

Contraindications

- Known hypersensitivity to local anaesthetics of the amide type
- Do not inject into an artery or vein

Precautions

- Complete heart block
- Hypovolaemia
- Dosage reduction may be required in patients presenting with impaired hepatic function.

Side Effects

Usually dose related and include: Nervousness, blurred vision, dizziness, bradycardia, hypotension, tremor, nausea, vomiting, drowsiness, speech disturbances, perioral numbness, muscle twitching, confusion, vertigo or tinnitus, psychosis, seizures and respiratory depression.



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National
Hauora Coalition

