**Study Title:** Prehospital Patient Factors in Paediatric Appendicitis – A Rural New Zealand Perspective

**Short title:** Rural Patient Experiences in Accessing Acute Paediatric Appendicectomy

**Ethics Ref:** To be obtained

**Date and Version No:** 12th June 2019

**Universal Trial Number:** U1111-1235-1917

**ANZCTR Trial ID:**

|  |  |
| --- | --- |
| **Chief Investigator:** | Dr Brodie Michael Elliott, General Surgical Registrar, Northland District Health Board |
| **Investigators:** | Dr Christopher Harmston, Consultant General & Colorectal Surgeon, Head of Department General Surgery, Northland District Health Board.  Dr Henry Witcomb Cahill, House Officer, General Surgery, Northland District Health Board |
| **Funder:** | Northland District Health Board |

There are no potential conflicts of interest to declare.

**TABLE OF CONTENTS**

[1. SYNOPSIS 3](#_Toc531851600)

[2. ABBREVIATIONS 3](#_Toc531851601)

[3. BACKGROUND AND RATIONALE 4](#_Toc531851602)

[4. AIM AND OBJECTIVES 5](#_Toc531851603)

[5. STUDY DESIGN 5](#_Toc531851604)

[6. PARTICIPANT IDENTIFICATION 6](#_Toc531851605)

[6.1. Study Participants 6](#_Toc531851606)

[6.2. Inclusion Criteria 6](#_Toc531851607)

[6.3. Exclusion Criteria 6](#_Toc531851608)

[7. STUDY ACTIVITIES 7](#_Toc531851609)

[7.1. Recruitment 7](#_Toc531851610)

[7.2. Informed Consent 7](#_Toc531851611)

[7.3. Subsequent Visits 7](#_Toc531851612)

[7.4. Discontinuation/Withdrawal of Participants from Study 7](#_Toc531851613)

[7.5. Definition of End of Study 8](#_Toc531851614)

[8. ANALYSIS & DATA MANAGEMENT 8](#_Toc531851615)

[8.1. The Number of Participants 8](#_Toc531851616)

[8.2. Data Analysis 8](#_Toc531851617)

[8.3. Access to Data 8](#_Toc531851618)

[8.4. Data Recording and Record Keeping 8](#_Toc531851619)

[9. QUALITY ASSURANCE PROCEDURES 8](#_Toc531851620)

[10. ETHICAL AND REGULATORY CONSIDERATIONS 9](#_Toc531851621)

[10.1. Declaration of Helsinki 9](#_Toc531851622)

[10.2. Approvals 9](#_Toc531851623)

[10.3. Reporting 9](#_Toc531851624)

[10.4. Participant Confidentiality 9](#_Toc531851625)

[10.5. Expenses and Benefits 9](#_Toc531851626)

[10.6. Other Ethical Considerations 9](#_Toc531851627)

[11. FINANCE 10](#_Toc531851628)

[11.1. Funding 10](#_Toc531851629)

[12. PUBLICATION POLICY 10](#_Toc531851630)

[13. REFERENCES 11](#_Toc531851631)

[14. APPENDIX C: AMENDMENT HISTORY 11](#_Toc531851632)

# SYNOPSIS

|  |  |  |
| --- | --- | --- |
| **Study Title** | Prehospital Patient Factors in Paediatric Appendicitis – A Rural New Zealand Perspective | |
| **Internal ref. no. / short title** | Rural Patient Experiences in Accessing Acute Paediatric Appendicectomy | |
| **Study Design** | Qualitative – Thematic Analysis via Semi-Structured Interviews | |
| **Study Participants** | Family or caregiver(s) who cared for and enabled a child to interact with health care services during an episode of acute appendicitis and the subsequent acute appendicectomy at Whangārei Base Hospital. | |
| **Planned Sample Size** | 20 | |
| **Planned Study Period** | July-August 2019 | |
|  | **Objectives** | **Outcome Measures** |
| **Primary** | To investigate pre-hospital experiences of family and/or caregivers in their journey accessing acute surgical services in Northland. | Documentation of common themes and experiences that affect patient presentation and subsequent interaction with healthcare services |
| **Secondary** | To explore what rural living means in the context of families of acute paediatric surgical service consumers in Northland, New Zealand. | Identification of potential links or common themes seen between rural living and interactions with acute surgical services. |

# ABBREVIATIONS/TRANSLATIONS

|  |  |
| --- | --- |
| CI | Chief Investigator |
| CRF | Case Report Form |
| DHB | District Health Board |
| ICF | Informed Consent Form |
| HDEC | Health and Disability Ethics Committees |
| Koha | Gift/Token of appreciation/Repayment for time and participation |
| PIL | Participant/ Patient Information Leaflet |
| SOP | Standard Operating Procedure |
| Whānau | Family – often an extended family when compared to New Zealand European families. |

# BACKGROUND AND RATIONALE

In 2014 almost half of people in Northland, New Zealand, lived outside a main urban or independent urban area.1 Regional centres without dedicated Paediatric Surgical specialists are frequently expected to deal with non-paediatric specific emergencies in paediatric populations. Of these, emergency appendicectomies are the most commonly encountered acute surgery performed on children. A recent retrospective audit of our department demonstrated rural children were much more likely to have more severe appendicitis on presentation (OR 2.04), worse Clavien-Dindo postoperative complication grade (p=0.001) and a longer median length of stay (2.5 days vs 2.2 days; p=0.029).

Rural communities reflect diverse and small populations spread over large geographic areas but in general, rural New Zealand tends to have higher proportions of Māori, more children, and fewer families without dependent children.2 Northland has a higher than average Māori population, particularly in the younger generations. In the 2013 Census, 46% of under 15-year olds identified as Māori.1 This mirrors the local rates of appendicitis where about 42% of Northland paediatric appendicectomies in the last 10 years were on Māori children.

The Royal Australasian College of Surgeons are clear; rural patients have a right to a comparable quality of surgical services to urban populations, especially with regards to non-specialist, emergency surgery.3 Reduced access to healthcare and delays in obtaining surgical treatment have been associated with worse outcomes in patients with acute appendicitis.4–7 Overseas studies have routinely implicated prehospital patient factors with worsening severity of appendicitis.8–11 However, to our knowledge no study has investigated this in the unique New Zealand environment.

This study aims to identify barriers to accessing surgical care that are significant to health care consumers as well as investigate perceptions of rural living by investigating the clients’ family’s journey with accessing acute paediatric surgical care. In order to identify specific local concerns, we will contact the listed primary caregiver of paediatric consumers who underwent surgical treatment for appendicitis. Using a semi-structured interview, a variety of open questions will be asked across main domains or themes that have been identified as potential root causes. This dialogue will have a dynamic element and will be actively guided by our interactions with study participants and local consumer council. The responses will be transcribed and analysed to identify common themes, domains and barriers to care.

No invasive or medical procedures will be undertaken on the participants and their participation will not change their relationship with healthcare providers. The interviewers will all be medical professionals who have a firm understanding of the area and its health needs. The interview will be approached in a safe and considered manner with attention to cultural and socioeconomic needs of our population. The perceived risk to patients is extremely minimal.

# AIM AND OBJECTIVES

|  |  |
| --- | --- |
| **Aim/Research Questions** | **Objectives** |
| **Primary**  To investigate pre-hospital experiences of family and/or caregivers in their interactions with accessing acute surgical services in Northland. | Documentation of common themes and experiences that affect patient presentation and subsequent interaction with healthcare services. |
| **Secondary**  To explore what rural living means in the context of families of acute paediatric surgical service consumers in Northland, New Zealand. | The identification of potential links or common themes seen between rural living and interactions with acute surgical services. |

# STUDY DESIGN

The primary caregiver of a child (aged 16 or under) who has recently undergone an acute appendicectomy at Whangārei Hospital will be identified from electronic Hospital records. They will be contacted in person if the child is still an inpatient or by phone if they have been recently discharged. From here, the survey will be introduced and preliminary consent gained to participate in the interview. The caregiver will be asked a suitable time and location for the interview – ideally in a location they feel comfortable and familiar with, such as their own home. Once there, an investigator will go over the information sheet and formal consent. If agreed, the investigator will undertake the interview which will be recorded and field notes taken on a case report form (CRF). If the child is present, they are of course welcome to participate, and voice their story, but this is not an expectation and their interaction will be determined by family wishes.  
  
Data collection will be undertaken using a semi-structured interview, through a variety of open questions. Prompts for each domain will be provided to investigators that have been derived from pre-existing themes thought to be contributing factors through previous research or clinical practice experience. Each interview is expected to last approximately 30 minutes and no scheduled follow up visits or interactions are planned. Participants will be offered a small renumeration/koha for their time in the form of a local supermarket voucher.

The interviews and notes will be transcribed, deidentified and anonymised through means of a study identification number. A dynamic thematic analysis method12 will be used with the gathering and analysis of data occurring concurrently as to add depth and quality to these processes. Thematic analysis involves the search for and identification of common threads that extend across an entire interview or set of interviews and is suitable for answering questions such as the aims of this study.12

# PARTICIPANT IDENTIFICATION

## Study Participants

20 “study participants” will be interviewed. These participants will be defined as the one or more individuals who cared for and enabled a child to interact with health care services during an episode of acute appendicitis and the subsequent acute appendicectomy at Whangārei Base Hospital in three months prior to the date of the interview.

The actual number of individuals in each interview will be dynamic and decided on by the family to maximise participant comfort and a full discussion to be had. In some cases, we envision an extended whānau being present – a possibility that we will encourage.

## Inclusion Criteria

* Participant is willing and able to give informed consent for participation in the study.
* Aged 18 years or above.
* Is a caregiver or family member of a child who was directly involved in the child’s accessing of healthcare in which the child has undergone an acute appendicectomy at Whangārei Base Hospital in the last three months.
* Either open or laparoscopic appendicectomy.
* Was involved in the child’s journey and access to healthcare during this time.

## Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

* The listed caregiver contacted wasn’t involved in the child’s accessing of healthcare services leading up to and including their acute appendicectomy.
* The child was transferred to another District Health Board pre-operatively – for example to Starship Childrens Hospital, a Tertiary service in Auckland for definitive treatment.
* The appendicectomy was an elective procedure.
* The child underwent an interventional radiologic or percutaneous procedure.
* The child and their family doesn’t usually reside in the Northland District Health Board catchment area.
* Family decline consent.

# STUDY ACTIVITIES

## Recruitment

Participants will be identified from hospital records of acute theatre events for appendicitis in patients under the age of 16. This will identify all potential study participants. If the patient is a current inpatient at Whangārei hospital, then the caregiver will be contacted by a study investigator, in person during appropriate day-time hours (0700-1700 or other acceptable time as defined by the family). If the family has been discharged from hospital, then the listed primary caregiver of the client will be contacted by phone for the purpose the project introduced and preliminary consent gained to participate in the interview. If no contact is made after a maximum of three attempts by the investigating team then the family will be withdrawn from participating in this study.

## Informed Consent

The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific activities are undertaken.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site.

## Subsequent Visits

Further to the initial interview, there will not be any subsequent visits or investigator led interactions with participants.

## Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. (In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

* Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
* Significant protocol deviation
* Significant non-compliance with study requirements
* Withdrawal of Consent
* Loss to follow up

Depending on the stage of data processing, when a participant voices their wish to withdraw from the study, it may not be possible to destroy all records of the interview pertaining to that participant.   
The participant will be offered the choice between having any data that is identifiable as belonging to them removed or allowing it to continue to be used. However, once the findings have been produced, removal of data may not be possible.

If feasibly possible, withdrawn participants will be replaced to ensure an adequate study population. The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in a study file.

## Definition of End of Study

The end of study is the date of the last interview of the last participant.

# ANALYSIS & DATA MANAGEMENT

## The Number of Participants

This study will aim to involve approximately 20 direct participants.

## Data Analysis

A dynamic thematic analysis method12 will be used with the gathering and analysis of data occurring concurrently as to add depth and quality to these processes. Investigators will deeply familiarise themselves with the data, transcribe interviews and consider both latent and manifest content in data analysis. Subsequently open coding will involve collecting codes under potential subcategories/subthemes or categories/themes, and comparing the emerged coding’s clusters together and in relation to the entire data set classifications. Several investigators will be involved in generating initial codes, defining and naming themes, reviewing themes, and searching for themes.

## Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

## Data Recording and Record Keeping

The interview audio file will be transcribed and it, along with any notes will be deidentified and allocated a generic study ID. Common themes, quotes and responses will be taken from the pooled data. Patient data, anonymised or otherwise will only be kept on encrypted DHB memory sticks, password locked DHB computers and secure DHB webmail during data collection and analysis.

# QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, relevant regulations and standard operating procedures.

# ETHICAL AND REGULATORY CONSIDERATIONS

## Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

## Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted for Locality Assessment with the Northland DHB and HDEC. In addition to this, the draft semi-structured interview domains and script will be submitted for local cultural assessment with the Kaunihera Kaumatua and also ease of understanding and palatability by the local DHB consumer council.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

## Reporting

The CI shall submit on completion, or on request, a progress report to the HDEC (where required) and host organisation. In addition, an End of Study notification and final report will be submitted to the same parties.

## Participant Confidentiality

The study staff will ensure that the participants’ anonymity is maintained. The participants will be identified only by a participant ID number on all trial documents and any electronic database, with the exception of the case report form, where participant initials may be added. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

## Expenses and Benefits

* Small koha (gift/token) to thank the participants involved for their time – this is likely to be a local supermarket voucher for $20-30 dollars and will be finalised after discussion with DHB staff and the consumer council.
* The cost of 2x high quality dictaphones/audiorecorders
* Partial reimbursement of travel costs for investigators travel to rural areas to interview participants in a place of their choosing to maximise comfort and rapport.

## Other Ethical Considerations

Whilst the study is evaluating barriers to the local surgical service for paediatric appendicitis, we aren’t approaching, contacting or altering the care of any paediatric consumer of healthcare. Only families that speak English fluently and consent to the interview will become participants in this evaluation.   
  
Therefore, the true participants of this study is the adult caregiver and/or family of the child who underwent surgery. We will be discussing the family’s perspective of the care they received and the lead up to the child’s presentation to hospital. Because almost half of participants are likely to be of Māori descent, local cultural liaison support from Te Pou Tokomanawa and Kaunihera Kaumatua will be obtained to ensure that vulnerable populations aren’t approached inappropriately or in a culturally unsafe manner.

# FINANCE

## Funding

Funding will be sought from the Northland District Health Board to support the expenses outlined in 11.6.

# PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by Northland District Health Board. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. If indicated by study participants, a copy of the research findings will be provided in their chosen medium -physical copy post vs electronic copy.

# REFERENCES

[1] Subnational Population Estimates [Internet]. Statistics New Zealand. 2017; [Cited 2018 Mar 21]. Available from URL: https://www.stats.govt.nz/information-releases/subnational-population-estimates-at-30-june-2017-provisional

[2] Shoemack P, Holloway L, Tibble M, Chiu K, Bramley D, Barnett P, et al. Rural Health: Challenges of Distance, Opportunities for Innovation [Internet]. Wellington, 2010. Available from URL: http://www.rgpn.org.nz/Network/media/documents/pdfs/rural-health-challenges-opportunities.pdf

[3] Royal Australasian College of Surgeons. Position Paper: Rural and Regional Surgical Services [Internet]. 2014. Available from URL: https://www.surgeons.org/media/21054259/2014-10-29\_pos\_fes-fel-055\_rural\_and\_regional\_surgical\_services.pdf

[4] Paquette IM, Zuckerman R, Finlayson SRG. Perforated Appendicitis Among Rural and Urban Patients: Implications of Access to Care. *Ann Surg*. 2011 Mar; **253**: 534–8.

[5] Hernandez MC, Eric Finnesgaard B, Johnathon Aho BM, Victor Kong BY, John Bruce BL, Stephanie Polites BF, et al. Appendicitis: Rural Patient Status is Associated with Increased Duration of Prehospital Symptoms and Worse Outcomes in High- and Low-Middle-Income Countries. *World J Surg*. 2017; **42**: 1573–80.

[6] To T, Langer JC. Does access to care affect outcomes of appendicitis in children? - a population-based cohort study. *BMC Heal Serv Res*. 2010; **250**.

[7] Kong VY, van de Linde S, Aldous C, Handley JJ, Clarke DL. Quantifying the disparity in outcome between urban and rural patients with acute appendicitis in South Africa. *S Afr Med J*. 2013; **103**: 742–5.

[8] Kearney D, Cahill RA, O’Brien E, Kirwan WO, Redmond HP. Influence of delays on perforation risk in adults with acute appendicitis. *Dis Colon Rectum*. 2008; **51**: 1823–7.

[9] Pittman-Waller et al. Appendicitis : why so complicated ? Analysis of 5755 consecutive appendectomies. *Am Surg*. 2000; **66**: 548–54.

[10] Temple CL, Huchcroft SA, Temple WJ. The Natural History of Appendicitis in Adults. *Ann Surg*. 1995; **221**: 278–81.

[11] Maroju NK, Smile SR, Sistla SC, Narasimhan R, Sahai A. Delay in surgery for acute appendicitis. *ANZ J Surg*. 2004; **74**: 773–6.

[12] Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nurs Health Sci*. 2013; **15**: 398–405.

# APPENDIX C: AMENDMENT HISTORY

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Amendment No.** | **Protocol Version No.** | **Date issued** | **Author(s) of changes** | **Details of Changes made** |
| 1 | 1.1 | 05/02/2019 | Dr Brodie Elliott | Amendment after discussion with peer review – Bronwyn Woodcock |
| 2 | 1.2 | 12/06/2019 | Dr Brodie Elliott | Amended protocol and added UTN and ANZCTR identification numbers. |