

Parent/Caregiver Information Sheet

Title of Research Project: Rural & Urban Appendicitis Complications (RURAL Study).

Investigator(s):

Co-ordinating Investigator: Dr Brodie Elliott - brodie.elliott@northlanddhb.org.nz

Local Lead Investigator: name - email address

Local Lead Telephone Number: xxxxxx

You are invited to take part in a study on appendicitis in children and how easily families can access surgical care. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you and your child will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. If your child is aged 7 or above they will also be asked to sign an Assent form and have their own Participant Information Sheet. This document is 4 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

What is the Purpose of the Study?

You and your child are invited to take part in a national research study looking at the severity and outcomes of appendicitis in children in New Zealand. We are looking at outcomes of children across the country from both rural and urban families. This is part of a series of research being undertaken for a Master of Health Sciences with University of Auckland.

Appendicitis is the most common emergency surgical disease in children. Because appendicitis can get worse the longer it goes on before you get treatment, children from families who are required to travel longer or have less reliable access to transport could be at risk of worse outcomes. This can lead to staying in hospital longer, being admitted to the intensive care unit or needing to come back to hospital for more treatment. This was the case when we looked at children just in Northland.

The RURAL study aims to evaluate the outcomes of appendicitis in children from rural backgrounds or those who cannot access hospital quickly. We want to study the health and outcomes of this large group of children in order to identify if there is something we can help change in the future.

Why are you being asked?

Parents/caregivers like you and your child at participating hospitals across New Zealand are eligible to take part. Your child is aged 16 or under and is being treated in hospital for suspected/proven appendicitis. This makes you and your child eligible candidates for this study, should you wish to participate. Please note that your participation or non-participation in this study will **not** have any effect on your child's care, recovery, or the time you spend in hospital. It is an observational study, and you are free to withdraw from this study at any point.

What will my Participation in the Study Involve?

As this is observational, there are no extra procedures or tests for your child because of this study. Study collaborators will record routinely collected data from your child's hospital notes about **this** admission for appendicitis. We will also review your child's records at thirty days after discharge to check if there are any further hospital presentations because of problems related to the appendicitis

In order to learn more about your journey before arriving to hospital will ask you several brief questions regarding your child's current illness and the events that led up to arriving to hospital. Including this chat, it shouldn't take more than 20-30 minutes of your time.

Benefits & Risk

There will be no direct benefit to you by participating in this study. However, the information we obtain from this study will benefit scientific knowledge, and may help improve care for future patients with appendicitis. There are no major risks associated with participation in this observational study. There will be no change to the length of your child's hospital stay, their postoperative recovery, or the quality of care they receive whether you choose to participate or not.

Who pays for this study?

This study is funded by the Auckland Medical Research foundation and Northland District Health Board. Participants will not bear any financial costs because of this study.

Ethical Approval

This study has received ethical approval from the Northern B Health and Disability Ethics Committee (xxxx, approved xxxx)

Confidentiality & Protection of Privacy

No information which could personally identify you or your child will be used in the reporting of this study. To ensure we don't include families twice and to know who to ask to participate, we need to initially record basic demographic data of your child like age, ethnicity, address and NHI in a secure database. Your address will only be used to calculate your travel distance and the rural/urban/socioeconomic classification of the area you live in. Your demographic information **NOT** be used for any further purposes and will be safely stored in a password protected server and any only accessible by the coordinating investigator and the data manager.

Data will then be de-identified, meaning it cannot be traced back to you, your family or your child. Study participants will be allocated a participant number, with the data related to your child's appendicitis attached to this number. Data will be recorded either electronically or using a paper form while you are in hospital. De-identified data will be uploaded to a secure online trial database to enable data analysis. Paper consent forms will be uploaded to this database and then destroyed. De-identified data will be kept for a period of 10 years, after which it will be destroyed. This de-identified data may be used in further research on appendicitis and children's health.

Accident Compensation Corporation (ACC)

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC. If you have any questions about ACC, please contact your nearest ACC office.

ADHB Cultural Support:

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324. If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by telephoning 09 4868920 ext 3204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

General Information

Please take all the time you need to think about this study. You are welcome to have friends or whānau support you through the duration of this study if you wish. If you would like more detailed scientific information on this study please contact the national study investigators.

The Health and Disability Commission Consumers' Code of Rights applies at all times during this research study. If you have any questions or concerns about your rights as a participant in a research study you can contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act. Their phone number is 0800 555 050 and their email is advocacy@hdc.org.nz.

Thank you for making the time to read about, and consider taking part in this study. Please feel free to contact us if you have any questions about this study.

Local Lead: name; email

Local Consultant Lead: name; email

National Co-ordinating Investigator (CI): Dr Brodie Elliott; Brodie.elliott@northlanddhb.org.nz

Parent/Caregiver Consent Form

RURAL: Rural & Urban Appendicitis CompLications Study

- I am the parent or legally acceptable guardian of the child participant of this study.
- I consent to the research staff collecting and processing my child's information, including information about their health.
- I understand the medical data collected will only be regarding admissions relating to appendicitis and any subsequent problems directly occurring because of this. Information from other services will not be accessed or recorded.
- I have read and I understand the study information sheet dated 21st November 2019.
- I have had this project explained to me in detail by a study collaborator.
- I have had the opportunity to discuss this study and ask question and am satisfied with the answers I have been given.
- I have had the opportunity to use family/whānau support or a friend to help me ask questions and understand the study.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time, and this will in no way affect my child's on-going health care.
- I understand that my participation in this study is confidential and that no material which could identify me or my child will be used in any reports.
- I understand that my address will be used to determine my Statistics New Zealand rural/urban area classification and travel distance to hospital.
- I know who to contact if I have questions about the study.
- I understand that the Health and Disability Consumers' Code of Rights applies at all stages during this research.
- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I agree that the de-identified data collected as part of this study may be used again for further research on appendicitis in children in the future.
- I understand my responsibilities as a study participant

Name of Child: _____

Parent/Guardian Name: _____

Signature: _____

Relationship to Child: _____

Date: _____

Investigator Name: _____

Signature: _____

Date: _____

I would like a copy of the final results once available: YES / NO

How would you like to receive this report? EMAIL / POST

Postal Address: (required) _____

Email Address: (optional) _____

RURAL (Rural vs Urban Appendicitis CompLications) Version 1.2 (21st November 2019)
BM Elliott, C Harmston, on behalf of the CTANZ Collaborative
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