

Contract Communication Study Documents

A - Recruitment training evaluation form

****Before/after feedback on CONTRACT Feedback Session – July 2017 ****

"CONservative TReatment of Appendicitis in Children – a randomised controlled Trial (Feasibility)"

Please complete the questions below AFTER the end of the session. Your answers will be kept confidential and will help us to improve the sessions for staff in the future.

Gender: *Male / Female* (please circle)

Role: Surgeon / Research Nurse / Other (please circle)

1. Do you have previous experience of recruiting participants to clinical research: Yes / No (please circle)

2. Do you have any previous experience of recruiting participants to clinical trials? Yes / No

3. Have you so far approached any patients to join CONTRACT? Yes / No

4. Please rate these statements 1-5 with 1= strongly disagree, 2=mildly disagree, 3= neutral, 4= mildly agree, 5= strongly agree

- a. The session has helped me to feel confident about explaining the CONTRACT study to families
- b. The session has helped me feel confident about explaining randomisation to families
- c. The session has helped me to feel confident about exploring families' views about CONTRACT
- d. The session has helped me to feel confident about balancing families' treatment preferences
- e. I feel confident about dealing with families' questions about CONTRACT

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4. What aspects of today's session have you found particularly useful, and why?

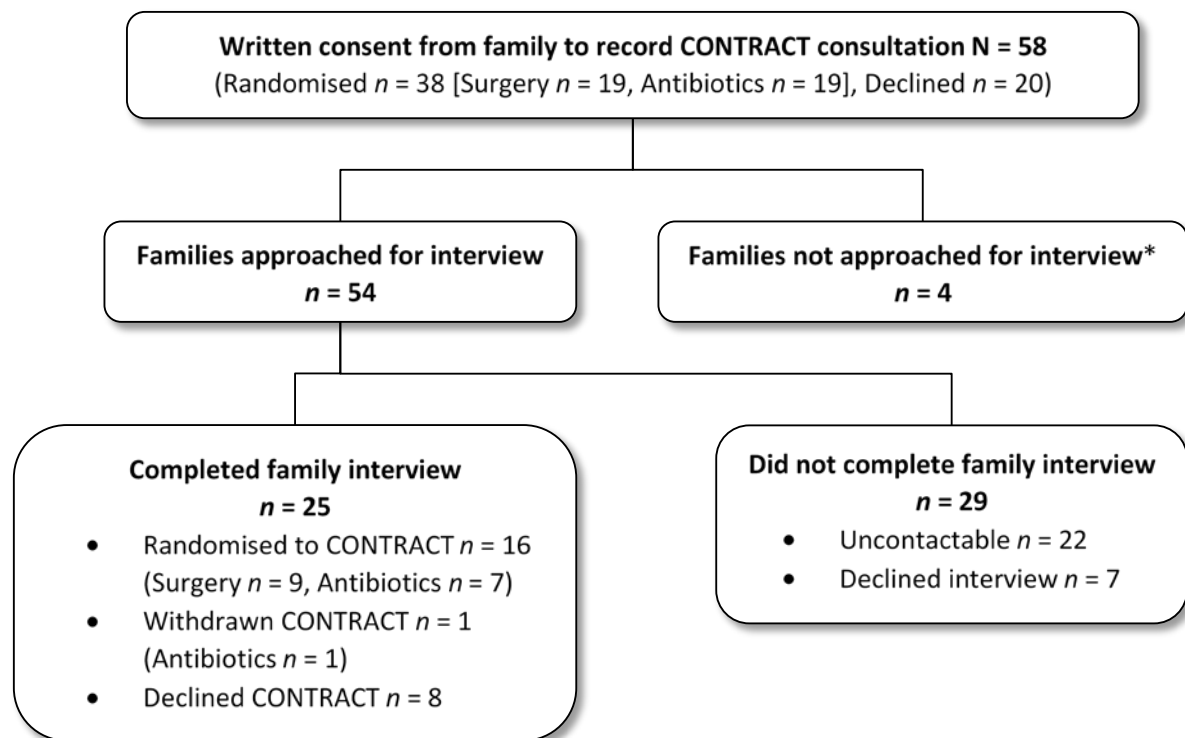
5. How could we improve the session?

6. If there's anything else you would like to share with us about CONTRACT/this session or anything that would help to make the study a success please use the space overleaf to let us know.

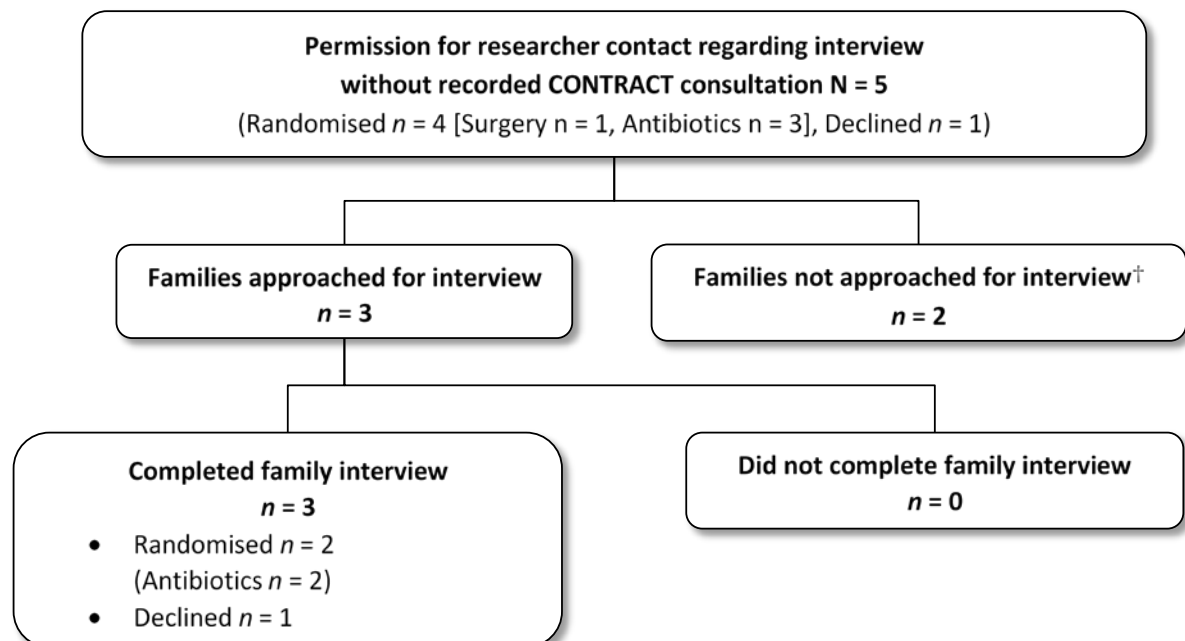
Thank you very much for your feedback

B - Recruitment of families into communication study

(a)



(b)



(a) Recruitment of families with recorded CONTRACT consultations, showing families trajectories through CONTRACT and The Communication Study. *Due to either not consenting for researcher contact ($n = 1$) or the study having reached data saturation ($n = 3$).

(b) Recruitment of families without CONTRACT consultations, showing families trajectories through CONTRACT and The Communication Study. †Due to the study having reached data saturation. Uncontactable families included those with invalid contact numbers, those who did not respond after three telephone attempts, and those who arranged interviews but cancelled and then did not respond to attempts to rearrange.

C - Hints and tips for recruiters (revised final version)



Hints and Tips for Recruiters

This sheet offers a few suggestions that may help with recruitment and consent to CONTRACT.

Before discussing the study with families

- Consider the best time is to discuss the study with the family.
- Out of hours you may not want to have detailed discussions about the study. However, families might have questions about treatment, even in the middle of the night. In discussing treatment a brief mention about CONTRACT may be helpful.

CHECKLIST - What do I need?

- ☒ Digital recorder
- ☒ iPad with video
- ☒ CONTRACT information sheet
- ☒ CONTRACT consent form

Audio-recording the discussion(s)

- Please audio-record all discussions with patient/family (including all stages of the discussions where there are several with the same family, and also when the allocated treatment is revealed), providing they are happy for you to do so. This gives us an insight into what works so we can help you and others to recruit effectively.
- In previous research, over 90% of families were willing to have their consultation recorded. Many forget the recorder is there whilst speaking and families often feel happy that they have contributed towards research.
- Families can initially provide verbal consent for the recording, and written consent to keep the recording can be sought at the end of the discussion(s). **Please say your name and the date at the beginning of each recording.**

Introducing the study to families

'I've got a research study I'd like to tell you about that is open to children like (child's name) with appendicitis. (Child's name) is eligible because he/she has suspected non-complicated appendicitis. As part of the research study, we'd like to record our discussion about the study. It's completely confidential and we use the recording to inform future communication with families about health research. Would you mind if we did that? You can also tell me at the end whether you're OK for us to keep the recording or not and I'll ask you to sign a consent form.'

Discussing the study with families

- Show families the iPad video - this is a really clear and consistent way to communicate the message.
- Present the study in a positive way - it is an opportunity for the family to take part in a study that could contribute towards improving paediatric treatment in future. The treatments being compared are both good treatments.

Key steps...

After explaining the condition...

1. **Reassure** the family that there are **two treatment routes** that can be used to treat acute appendicitis in children - antibiotics and surgery – and studies have shown they are both effective.
2. Establish that there is **current uncertainty**: 'We want to find out whether children/young people with appendicitis are better off being treated with antibiotics or with surgery.'

Current evidence

Antibiotics: Using a non-operative approach, the child would avoid the trauma, physiological stress, psychological distress and physical scarring of an operation. Based on the research that has been done so far, we believe the risk of recurrence is low; for every 100 patients, we estimate around 14 will have a recurrence in the first year (or 1 in 7 children). The potential benefit of antibiotic treatment is that your child may avoid an operation and general anaesthesia altogether.

Appendicectomy: Although appendicectomy avoids recurrence, it carries several risks. For every 100 patients who undergo surgery, up to 25 (1 in 4 people) will experience complications (including wound infection, intra-abdominal abscess, and adhesional small bowel obstruction), 4-5 will be readmitted to hospital (1 in 20-25 children), and 10 patients may show a healthy appendix, which means that the surgery was not necessary for 1 in 10 people.

3. Give a **balanced view** of each **treatment** (refer to “Current evidence” box)
 - People often associate studies with experimental treatments so it may help to emphasise to families that both treatments in CONTRACT are currently used widely and well understood.
 - Present **balanced information** about both treatments and **spend equal time** discussing the benefits and drawbacks of each. So far, we’ve found that the drawbacks of surgery are sometimes not prominent in the discussions, whereas, the drawbacks of antibiotics are very prominent.
 - If parents / families do not voice these spontaneously, try to elicit their concerns/preferences with an open question, *‘What are your initial thoughts now you’ve heard about the study?’*
 - Gently find out the reasons why a patient/family prefers/is concerned about one option over the other with an open question, *‘What makes you think that’s the best treatment?’* Exploring families’ treatment preferences and the beliefs underlying these will enable you to correct any misunderstandings and ensure they understand both treatments well enough to make an informed decision.
 - Exploring treatment preferences also allows you to tailor so that information is balanced in a personalised way.
 - It is completely fine to gently challenge preferences e.g. if someone has a preference for surgery then the potential benefits of antibiotics can be emphasised. Similarly, if someone has had negative experiences of appendicitis in the past, it is OK to explore this. Negative experiences of complicated appendicitis in an adult, or a case that happened many years ago, may not be relevant to the child’s current situation.
4. Explain the **study procedures**, providing the family with time to discuss CONTRACT among themselves, read the leaflets and come back to you with any questions. These are some key points to cover:
 - They will be asked to sign a consent form - avoid emphasising this as a burden.
 - Randomisation (including rationale – please see below for tips).
 - Treatment procedures (e.g. children may want to know how will the antibiotics be administered)
 - Follow-ups (no detail at this stage, just that they will have them)
 - Data protection – all details are kept confidential
 - Request for discussion with CONTRACT Communication Study Researcher – **we are particularly interested in speaking with families who have declined CONTRACT**
 - Remind the patient that regardless of which treatment they are allocated to, they will receive the best possible care and the health professional treating them will be experienced in the treatment provided.
5. Explain the **study purpose**: ‘CONTRACT is a feasibility study to help us do a larger study comparing surgery and antibiotics. We need evidence from large studies before we can change how children with appendicitis all over the UK are treated in future.’

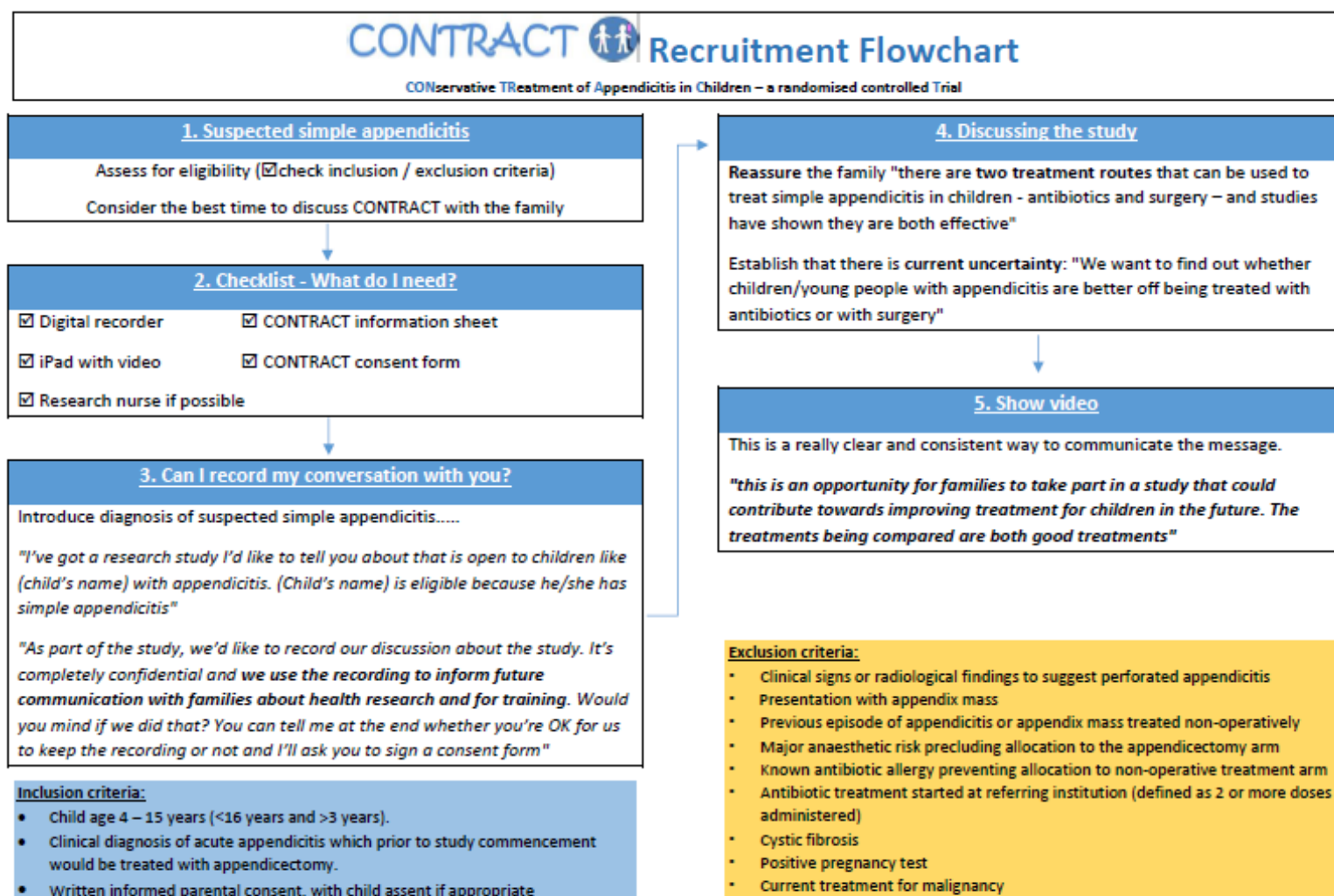
Describing randomisation

- Avoid terms such as ‘toss of a coin’ or ‘decided by a computer’ to explain randomisation. Instead explain that if the patient were to join the study, they would have an equal chance of having an operation or the antibiotics.
- Explain the rationale for randomisation (only way to avoid bias). Cover the key points: we need a fair comparison between the two treatments/groups. The only way to do this is to use randomisation to produce similar groups.

‘We know both treatments are good but want to know which is better. To do this we need to compare the two treatments in similar groups of patients. The only way to make sure that the groups are as similar as possible is to put people into groups by a process called randomisation. This means that if you and [name] take part in CONTRACT, you will have an equal chance of having the operation or the antibiotics. It is important that you only agree to take part if you are prepared to consider either treatment.’

Language/terms: Try using the word ‘study’, rather than ‘trial’. Avoid loaded terminology (e.g. ‘gold standard’, ‘experimental’, ‘the first/second treatment’). It’s helpful to refer to antibiotics or surgery to emphasise equipoise.

D - Recruitment flowchart



6. Elicit any concerns / questions about treatments

If parents / families do not voice these spontaneously, with an open question:

"What are your initial thoughts now you've heard about the study?"

"What are your thoughts about these treatments?"

Gently find out the reasons why a patient/family prefers/is concerned about one option with an open question:

"What makes you think that's the best treatment?"

- Exploring treatment preferences also allows you to tailor so that information is balanced in a personalised way.
- You are not persuading, but ensuring families are fully informed
- [\[see current evidence below & hints and tips doc\]](#)

7. A negative experience of perforated appendicitis?

It is OK to explore this. Negative experiences of complicated appendicitis in an adult, or a case that happened many years ago, may not be relevant to the child's current situation.

"we do not think [name] has a perforated appendicitis but simple appendicitis otherwise he/she would not be eligible for CONTRACT"

"All patients in CONTRACT are very closely monitored and anyone who is allocated to antibiotics who is not improving as we would expect will be offered an appendicectomy"

8. Describing randomisation

- *"We know both treatments are good but want to know which is better. To do this we need to compare the two treatments in similar groups of patients"*
- *"In order to do a comparison, what you need is two groups and for them to be selected not by us saying, oh this patient should have surgery, that patient should have antibiotics"*
- *"The only way to make sure that the groups are as similar as possible is to put people into groups by a process called randomisation"*
- *"What that means is that there's an equal chance of either having antibiotics as the treatment or surgery as the treatment"*

9. Explain the study procedures

- ☒ Follow-ups 6wk, 3mth, 6mth
- ☒ Data protection – all details are kept confidential
- ☒ Request for discussion with sub-study Researcher – particularly families who decline CONTRACT

"CONTRACT is a feasibility study to help us do a larger study comparing surgery and antibiotics. We need evidence from large studies before we can change how children with appendicitis all over the UK are treated in future"

"All patients in CONTRACT are very closely monitored....."

10. Give them time to consider the information

Give the family time to discuss CONTRACT among themselves, read the leaflets and come back to you with any questions.

"Regardless of which treatment [name] is allocated to, they will receive the best possible care and the health professional treating them will be experienced in the treatment provided"

11. Obtaining consent

Please ask the parent/guardian to initial each box they are happy with and to sign the consent form.

- Boxes 1-8 are linked to the CONTRACT Feasibility Study.
- Boxes 9-10 are linked to the CONTRACT Communication Study.

Families can participate in the CONTRACT Communication Study *only*, the CONTRACT Feasibility Study *only*, *both studies*, or *neither study*.

12. How to randomise a patient

You will need your TENALEA username and password and:

- the age of the child
- duration of symptoms (onset of pain until now)
- gender
- patient initials

Once the consent form is signed log in to: <https://prod.tenalea.net/stn/dm/>

Click on CONTRACT study on left hand side

Then click on your local PI name

Then click on add patient

Complete the details and click 'SUBMIT'

If you can, print out the next page or at least note down the randomisation number

Current evidence

Antibiotics:

Using a non-operative approach, the child would avoid the trauma, physiological stress, psychological distress and physical scarring of an operation.

Based on the research that has been done so far, we believe the risk of recurrence is low; for every 100 patients, we estimate around 14 will have a recurrence in the first year (or 1 in 7 children).

The potential benefit of antibiotic treatment is that your child may avoid an operation and general anaesthesia altogether.

Appendicectomy:

Although appendicectomy avoids recurrence, it carries several risks.

For every 100 patients who undergo surgery, up to 25 (1 in 4 people) will experience complications (including wound infection, intra-abdominal abscess, and adhesional small bowel obstruction),

4-5 will be readmitted to hospital (1 in 20-25 children),

10 patients may show a healthy appendix, which means that the surgery was not necessary for 1 in 10 people.



CONservative TReatment of Appendicitis in Children
- a randomised controlled Trial (Feasibility)



Patient Diary Card

Start the diary on the day your child is discharged home from the hospital. Insert the date of discharge in the date line. Please answer each question with 'Y' for yes, 'N' for no or 'N/A' for not applicable. For example, if your child did not attend school or was not well enough to complete normal daily activities insert 'N' in the relevant line. See examples of normal activity and full activity at the bottom of the page. In the comments please insert the reason why – e.g. pain. Please complete this diary for 2 weeks following discharge.

Study ID: _____

Centre: _____

	Example	Day 0 Discharged home	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Date	1/2/17															
Antibiotics taken?	Y															
Any pain meds taken?	Y															
*Able to do normal daily activities?	N															
Attended school (if applicable)?	N															
*Able to do full activities?	N															
Parent missed work?	Y															
Comments																

*Normal Activity: Sitting down, standing up, walking, running, brushing teeth/hair, showering, dressing, talking with friends / family, making a drink, using an everyday object, lifting, moving or carrying everyday objects such as chairs, bags etc.

*Full activity is all the above plus full activity – e.g. sport, dance, playing with friends or other activity that your child normally takes part in.

Please return this diary card along with the 2 week questionnaire in the prepaid envelope provided.

Thank you for your support with the study!



CONservative TRreatment of Appendicitis in Children – a randomised controlled Trial (Feasibility)

CLIENT SERVICE RECEIPT INVENTORY (CSRI)

This instrument is to be completed by child's parent/guardian

The CONTRACT team is keen to understand the broader impact of appendicitis on children's lives. The following questions therefore mainly ask what health care and other services your child has used since diagnosed with appendicitis and during the past 6 weeks (except otherwise stated).

This questionnaire refers to resource use other than secondary care (related to your child's admission to hospital due to appendicitis).

Child's study number –

Date //

Relationship of interviewee to study child

Section I: HEALTH AND SOCIAL CARE SERVICE USE

Q1. In the last 6 weeks, and since the initial visit to hospital has your child stayed in hospital overnight because of appendicitis problems?

Hospital stay	Name of hospital & ward	Number of nights
1 st hospital stay		
2 nd hospital stay		
Other (specify).....		

Q2. In the last 6 weeks and following discharge from hospital, has your child had any visits to a health care professional?

YES ☐ NO ☐ If no, go to question Q3

CLIENT SERVICE RECEIPT INVENTORY (CSRI)

CONTRACT – Randomised Controlled Trial (Feasibility)

If YES please also state any contact you or your partner has had with any of these services because of your child's health problem.

Health Services	Contacts at home	Contacts at office/surgery	Telephone contacts
	Number of	Number of	Number of
Community nurse/practice nurse			
Health visitor			
General Practitioner/Family doctor			
Community paediatrician			
NHS direct			
Other (specify).....			

Parent's additional notes if

necessary:

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Q3. In the **last 6 weeks**, has your child used any other hospital services?

YES ☐ NO ☐ If no go to question Q4

(Please state outpatient or emergency attendances for the last 6 weeks)

Services used	No. of attendances	Reason of attendance
Accident and Emergency (record if ambulance called)		
Day Hospital Treatment setting		
Other related out-patient visit		
Other (specify).....		
Other (specify).....		
Other (specify).....		

Parent's additional notes if

necessary:

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Q4. In the **last 6 weeks and following discharge from hospital**, has your child used any prescription medication (painkillers, antibiotics or anti-inflammatory drugs)?

YES ☐ NO ☐ If no, go to question Q5

(Please list the prescribed medications following discharge)

<i>Medication (name)</i>	<i>Dose</i>	<i>Duration</i>
Other (specify).....		
Other (specify).....		

Parent's additional notes if

necessary:

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Section II: Family born costs

Family born costs refers to expenses related to the appendicitis or resulting from visits to the family doctor or hospital, including travel costs, lost earnings due to taking time off work, child care costs and “other” expenses.

Q5. In the last 6 weeks, have you bought anything specifically because of your child’s appendicitis?

YES ☐ NO ☐ If no go to question Q6

Please list any medicines (e.g. painkillers, heat or massage oils, herbal or complimentary remedies) that you have bought for your child from the chemist or other shops to help with appendicitis since discharge from hospital.

<i>Expenses</i>	<i>Description</i>	<i>Amount in £</i>
Painkillers or other over the counter medication		

Q6. In the last 6 weeks, have you bought anything specifically because of your child’s appendicitis?

YES ☐ NO ☐ If no go to question Q7

(Please write answers as a sum of the past **6 weeks**)

<i>Expenses</i>	<i>Description</i>	<i>Amount in £</i>
Travel costs including petrol/fuel costs, public transport fares, taxi fares		
Car parking fees		
Child care costs		
Help with housework or care for family’s other children (due to hospital visits)		
Expenses in hospital (e.g. food/beverages)		
Other costs (please specify):		

Section III: Parent's, carer's, partner's employment loss and child's absent from school, etc.

Q7. In the **last 6 weeks**, have your child was absent from school/nursery because of his/her health (appendicitis related)?

<u>If yes:</u> How many days off school?	
	State days (total of 6 weeks)
Date (if remembered)	<input type="text"/> <input type="text"/>
	<input type="text"/> <input type="text"/>
	<input type="text"/> <input type="text"/>
	<input type="text"/> <input type="text"/>
	<input type="text"/> <input type="text"/>

Q8. In the **last 6 weeks**, have you or your partner or anybody else had to take time off work to support your child because of your child's health (related to child's appendicitis)?

YES <input type="checkbox"/> NO <input type="checkbox"/> <u>If no go to question Q9</u>	
(For example your partner, members of your family or your partner's family, or friends).	
<u>If yes:</u> How many days of work?	
Name the person (i.e. you, partner, and/or else)	State days (total of 6 weeks)
	<input type="text"/> <input type="text"/>
	<input type="text"/> <input type="text"/>
	<input type="text"/> <input type="text"/>
	<input type="text"/> <input type="text"/>
	<input type="text"/> <input type="text"/>

Q9. Is there anything else that you would like to tell us about the health or other care received by your child since diagnosed with appendicitis and admitted to hospital? If yes, please give details below.

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Thank you for taking the time to answer these questions.

Your answers are very important on helping us to build a complete picture of how appendicitis affects children, their families and the use of health and community services.

Parent's additional notes if necessary:	
Was the questionnaire easy to complete? YES <input type="checkbox"/> NO <input type="checkbox"/>	Completion time, how long approximately in minutes?

CONTRACT



CORE OUTCOME SET UPDATE AND FINAL STEPS - APRIL 2018

The final survey is coming soon!

- Thank you very much for completing the survey 2 that will contribute to developing a core outcome set for the treatment of acute, non-complicated (or simple) appendicitis in children and young people. Your views are very important to us.
- You will shortly be contacting you to request you to completed the third and **final survey!** In this final survey, we will ask you to re-score each outcome one more time. Like last time, you should score each outcome based on how important you think it is in the treatment of acute uncomplicated appendicitis.
- The survey will use the same 1-9 scale that was used in the other surveys. The more important you think the outcome is, the higher you should score it.

What's different about the final survey?

- In survey 2, you were allocated to one of three groups: (a) young people who have had acute appendicitis; (b) parents of children who have had acute appendicitis, or, (c) paediatric and general surgeons who treat children with acute appendicitis. These groups remain for the final survey.
- For the final survey, we would like you to score each outcome one more time so that we can try to reach agreement across young people, parents, and surgeons on the most important outcomes.
- Last time, we showed you a graph of how other people in your group (young people, parents or surgeons) scored each outcome in the first survey. We then asked you to re-score each outcome based on the scores of other people in your group. **This time, we will show you the scores of everyone in all of the three groups, so young people, parents and surgeons.** We would like you to think about how you scored the outcome last time and how others scored it too. We hope that this will help you to decide whether to stick with how you scored it last time or change it in light of this extra information. It is perfectly fine to stick with your original rating if you do not want to change it.



How will I know how other groups scored the outcomes?

- For each outcome, there will be a graph that shows how young people, parents and surgeons scored the importance of the outcome.
- There is an example graph on the next page and some of the key things you need to know about the graph are explained.
- When you have thought about the score you gave in survey two and the scores the rest of the group gave, you can either leave your score as you originally scored it by clicking on the gold circle or you can change your score by selecting any other number from 1 to 9. The more important you think the outcome is – the higher you should score it.

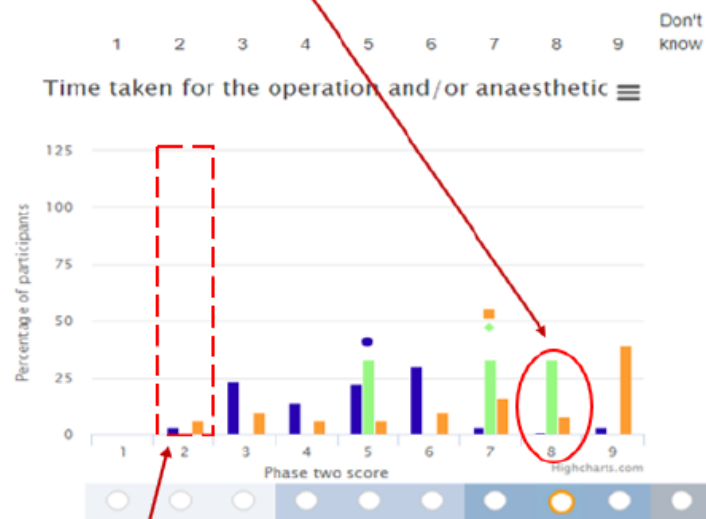
Blue bars show the percentage of **surgeons** who selected that score.
Green bars show the percentage of **young people** who selected that score.
Orange bars show the percentage of **parents** who selected that score.

For example, if we look at who scored the below outcome '8' in the last survey, we can see that very few surgeons scored it 8, however, a much higher proportion of young people and parents scored it 8.

• The **blue circle** shows the **average score** that **surgeons** gave the outcome overall.

◆ The **green diamond** shows the **average score** that **young people** gave the outcome overall.

■ The **orange square** shows the **average score** that **parents** gave the outcome overall.



If you want to find out exactly what proportion of each group selected each score in the last survey, just hover over the space on the graph above the score you're interested in and a pop-up box will appear with more detail. For example, if you wanted to find out what proportion of parents scored this outcome '2', you could hover your mouse over the highlighted section above and a text box will pop up with more information.

Like last time, the gold circle on the 1-9 score at the bottom is the score you gave the outcome in survey 2. You can either score the outcome the same or decide whether you want to change it having considered how all the other groups scored the outcome.

We'd like you to join us at our CONSENSUS MEETING!

- The 'consensus meeting' will bring young people, parents and surgeons together to finalise the core outcome set.
- By meeting face-to-face, we can discuss reasons for or against prioritising certain outcomes as more or less important. We can also decide together on the most important appendicitis outcomes for young people, parents and surgeons. This will allow us to finalise the core outcome set and improve the quality of research and treatment in future!
- The consensus meeting is an interactive day. Young people, parents and surgeons will each be provided with an electronic voting device. You will be able to vote on which outcomes are important to you but no one else will know how you vote except you. We will discuss as a group which of the outcomes are most important for everyone involved so everyone gets a say. You will get to see what young people and surgeons also think about the different outcomes.

When: 10.00-16.00 Saturday 30th June

Where: The Priory Rooms Meeting and Conference Centre,
40 Bull Street, Birmingham, B4 6AF.

Expenses: We will be able to reimburse any travel costs.
Lunch and refreshments will be provided.

We really hope that you can make it! We will be in touch after the final survey to provide you with more details on the consensus meeting.



Thank you very much for joining us at the **CONTRACT**

Core Outcome Set Consensus Meeting!

Thank you so much for completing the online surveys for the core outcome set for children and young people with acute uncomplicated appendicitis and for attending this consensus meeting.

What's in this pack?

This pack contains information you will need for the meeting. It provides details of what will happen during the meeting and tells you the results of the final online survey you completed back in April.

The aim of this project and a reminder of what a core outcome set is:

This project aims to finalise a core outcome set for the treatment of acute appendicitis in children and young people. If all research studies in a particular health condition used the same outcomes, they could all be compared and combined. This would reduce waste by making best use of all the research, which would help to progress treatments and care for patients. When a set of main outcomes has been agreed for a health condition, it's called a 'core outcome set'. The core outcome set we develop together will be used by researchers to improve the quality of research that is done among children and young people with acute uncomplicated appendicitis.

What have we done so far?

Overall the project involves three online surveys and a consensus meeting. We are nearly at the end of this process.

So far, we asked you to complete three surveys:

1. Survey 1 asked you to rate the importance of appendicitis outcomes based on your own, individual experience.
2. Survey 2 asked you to rate the importance of appendicitis outcomes again, whilst taking into account how other participants in your group (young people, parents or surgeons) rated the outcomes in survey 1.

3. Survey 3 (the last survey) asked you to rate the importance of appendicitis outcomes again, whilst taking into account, not only how other participants in your group (young people, parents or surgeons) rated the outcomes, but also how other participants from all three groups rated the outcomes in survey 2.



Whilst this may seem a complicated process, the aim of asking you to complete all three surveys was to take into account both your views and experiences, as well as the views and experiences of others. By doing this, we aimed for participants to reach consensus (or agreement) on the most important and meaningful outcomes for the treatment of children and young people with acute appendicitis.

Finalising the core outcome set

The consensus meetings are the final stage in the project. We are holding a consensus meeting midweek with surgeons and a consensus meeting at the weekend with young people and parents. By representing all groups, we will ensure that the final core outcome set is meaningful and relevant to everyone involved in the treatment and care of children and young people with acute appendicitis. The remit of the consensus meeting will be to refine the final results from the surveys, no new outcomes will be considered at this stage and the results of the surveys will be paramount when finalising the core outcome set. The survey results show which outcomes are considered important, but this meeting now allows us to consider the core outcome set as a whole. In particular the following issues will be considered:

- Are these the outcomes that we would expect all future research studies about acute uncomplicated appendicitis in children and young people to measure as a minimum?
- Do any of the outcomes in the core outcome set contain closely similar outcomes to each other i.e. unnecessary duplication?

Of note we are not at this stage focussing on *how* an outcome should be measured nor *when* it should be measured. We are just interested in confirming *if* it should be measured or not.

What will happen during the consensus meeting?

During the meeting we review all the outcomes that were included in the survey process. We will rescore those that have been identified as being most important and there will be opportunity to discuss others if any participants feel it particularly important to do so.

- Using the same 1-9 scale that was used in the online surveys, if more than 70% of participants at the meeting score an outcome at 7-9 (very important) and less than 15% of participants score the same outcome 1-3 (less important), the outcome will be classed as 'consensus in' and can be included in the core outcome set.
- We will discuss the outcomes that have already been identified as important from the results of the surveys.
- We will also discuss outcomes that have been identified as less important overall but still of particular importance to at least one participant group.
- After discussing an outcome, we will ask each participant to electronically score the outcome using a device we will provide you with. This is the same scoring system as used in the online surveys. All of your answers will be completely private and confidential.
- We will review any remaining outcomes that have not been identified as being important to any of the participant groups. We will discuss these but we will only rescore them if participants feel strongly that we should.

Who can I ask for help at the consensus meeting?

If there's anything you're unsure of during the meeting, please ask one of the study team who will be happy to help out!

Final results of Survey 3

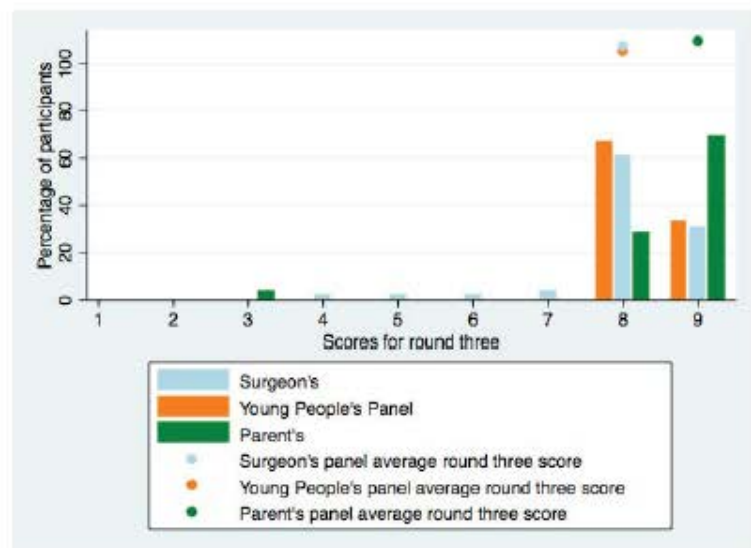
In Survey 3 participants were asked to vote one final time on the importance of each outcome. In this third survey everyone was able to take into account the views of other people in their participant group (surgeons, parents, or young people) as well as people from the other 2 participant groups. The results of Survey 3 are shown in the table below.

In each cell the percentage of each participant group that scored each outcome 7-9 in the third round is presented. Where the percentage of participant groups is over 70% the cell has been coloured green. As you can see, over 70% of people in all three groups scored 5 of the outcomes 7-9. This will be the order that we discuss the outcomes today.

Outcome	Young people	Parents	Surgeons	All groups
Intra-abdominal abscess	100	97	95	96
Re-operation	100	87	98	94
Bowel obstruction	100	94	95	94
Major or minor complication	100	97	87	91
Readmission to hospital	100	87	87	88
Total healthcare visits	0	13	24	19
Any unplanned imaging	0	16	18	17
Total cost of treatment	0	3	24	16
Duration of antibiotics	0	28	9	15
Duration of home healthcare	0	7	6	6
Death	67	97	96	96
Quality of life	67	97	95	94
Recurrent appendicitis	67	87	96	92
Antibiotic failure	100	90	69	77
Blood Loss	67	84	73	77
Unplanned Central Venous Catheter	100	69	78	75
Wound infection	75	84	54	65
Wound complication	75	84	52	64
Radiology procedure	50	52	82	71
Patient stress	67	84	55	66
Length of stay	50	41	63	54
Pain score	100	75	36	52
Fever after treatment	100	72	21	41
Duration of drainage	100	65	35	47
Time away from school	100	45	40	44
Negative appendectomy	100	35	33	35
Other infectious complication	100	55	18	33
Blood markers of inflammation	100	59	14	33
Analgesia	100	53	11	29
Bacterial peritoneal cultures	100	50	13	28
Wound healing time	100	45	13	27
Cosmesis	100	23	26	26
Time away from full activity	100	19	13	18
Psychological effects	33	53	37	43
Cost effectiveness	50	36	44	41
Conversion to open operation	67	59	25	39
Unplanned CT scan	50	19	36	31
Time to ambulation	50	38	23	29
Operation time	50	47	13	26
Recovery of bowel function	50	31	20	25
Parental stress	50	32	13	21
Parent time off work	67	26	13	19
Time to normal diet	50	16	13	15

Intra-abdominal abscess

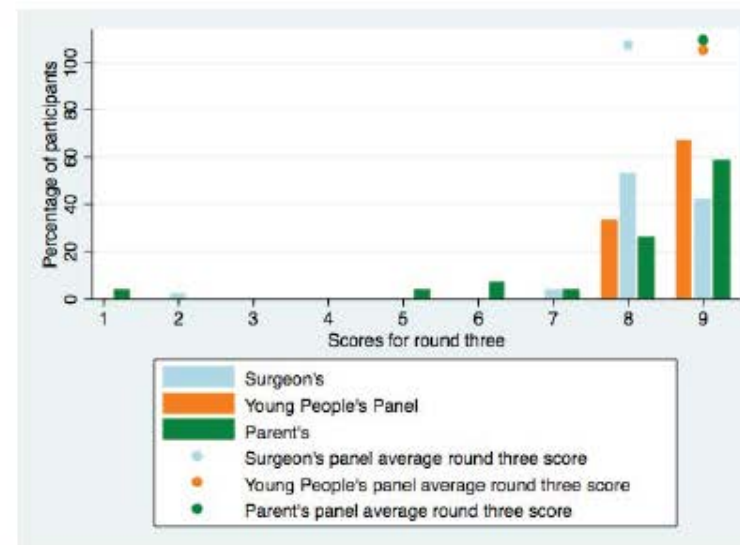
A pocket of infected fluid or pus deep inside the tummy that may occur after appendicectomy or treatment with antibiotics and may require another procedure or more treatment with antibiotics.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	97%	95%

Re-operation

Having another operation that was not planned.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	87%	98%

Bowel obstruction

A blockage of the intestine that would require treatment in hospital on may require an operation to treat it.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	94%	95%

Major or minor complications

Any type of complication classified as a minor or major (excluding readmission to hospital, bowel obstruction and recurrent appendicitis).



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	97%	87%

Readmission to hospital

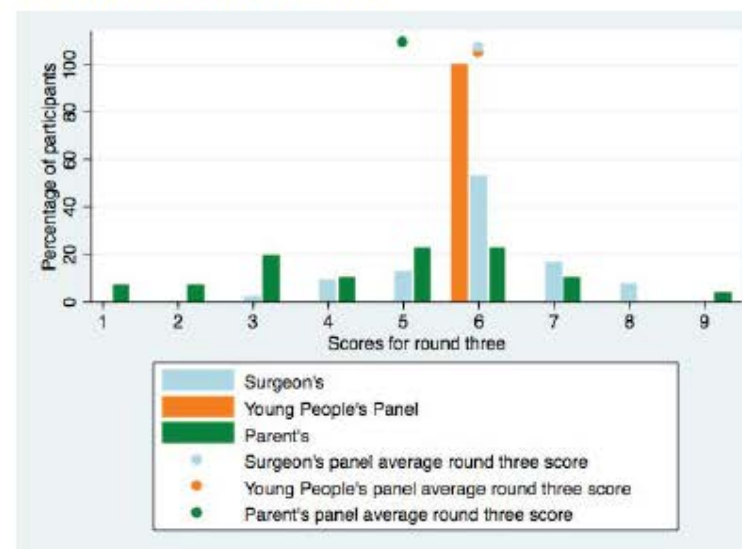
Needing to be readmitted to hospital with a stay at least one night.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	87%	87%

Total healthcare visits following discharge

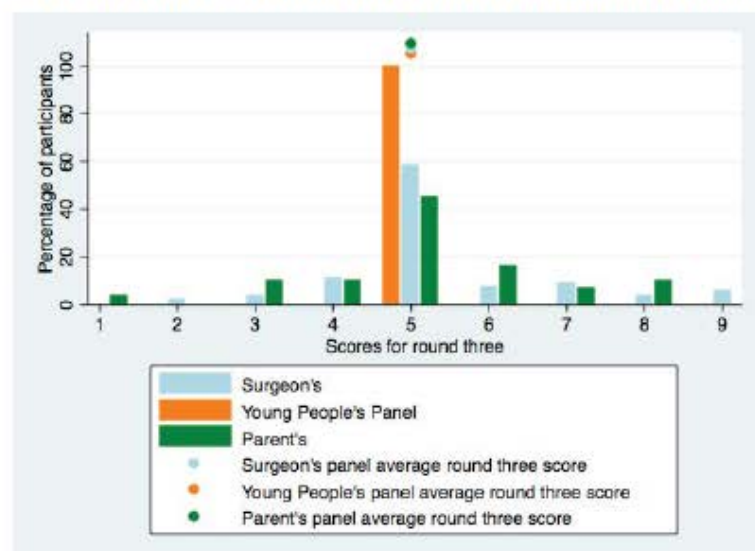
How many times the child visits a healthcare professional after they go home following their initial hospital treatment.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	0%	13%	24%

Any unplanned imaging

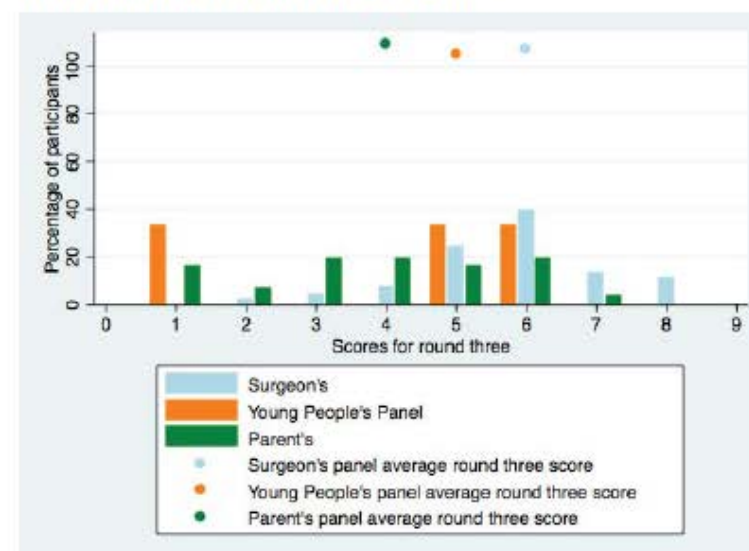
Having any type of x-ray or ultrasound test (other than CT scan) after treatment.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	0%	16%	18%

Total cost of treatment

The total cost of treatment for the health service.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	0%	3%	24%

Duration of antibiotics

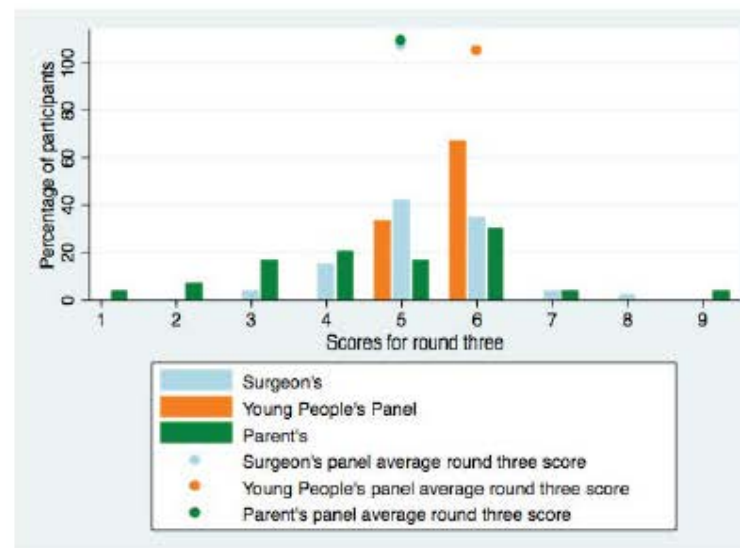
How long a child is treated with antibiotics for.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	0%	28%	9%

Duration of home healthcare

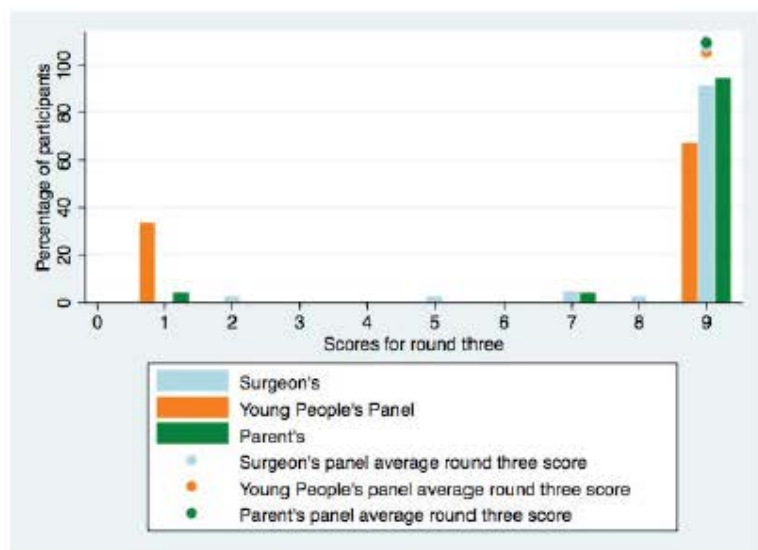
How long additional healthcare is needed at home after the child's initial hospital treatment.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	0%	7%	6%

Death

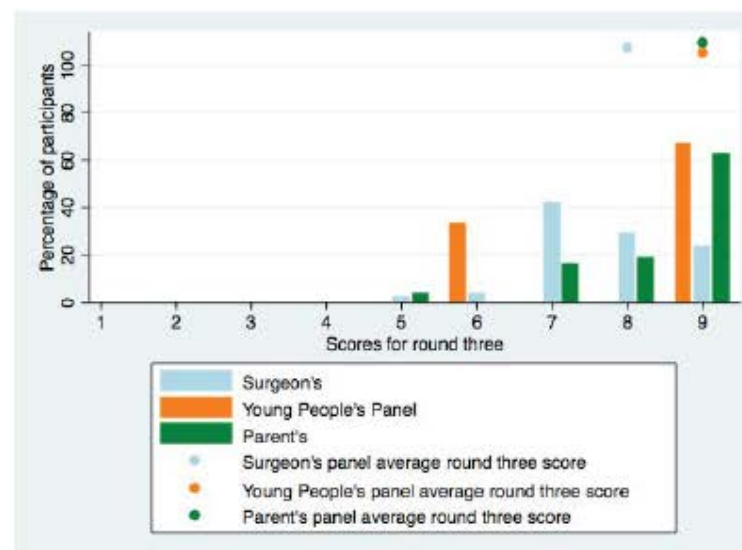
Dying (please bear in mind that the risk of dying from appendicitis is very low, but it may still be important to measure this as an outcome in studies).



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	67%	97%	96%

Quality of life

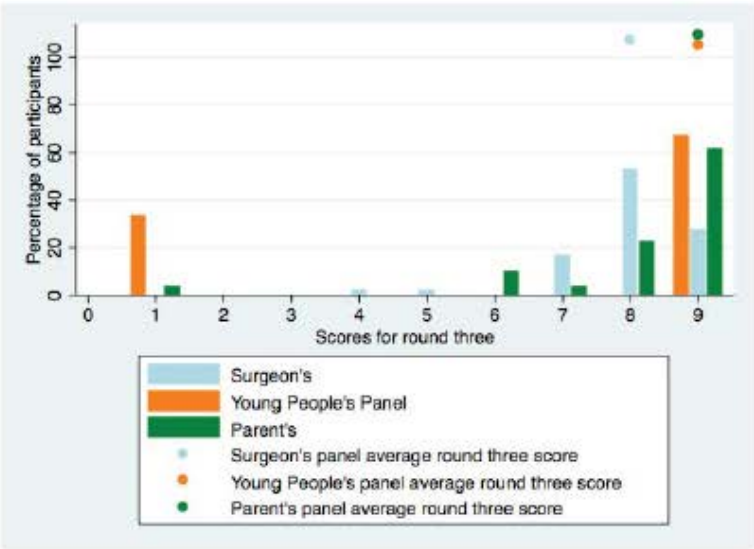
The child's quality of life that is measured using a specifically designed questionnaire.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	67%	97%	95%

Recurrent appendicitis

Getting appendicitis again.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	67%	87%	96%

Antibiotic failure

Operation to remove the appendix, due to antibiotic failure.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	90%	69%

Blood loss

Blood loss during the operation – losing lots of blood during an operation is unusual but you might think it is important to measure this.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	67%	84%	73%

Unplanned central venous catheter

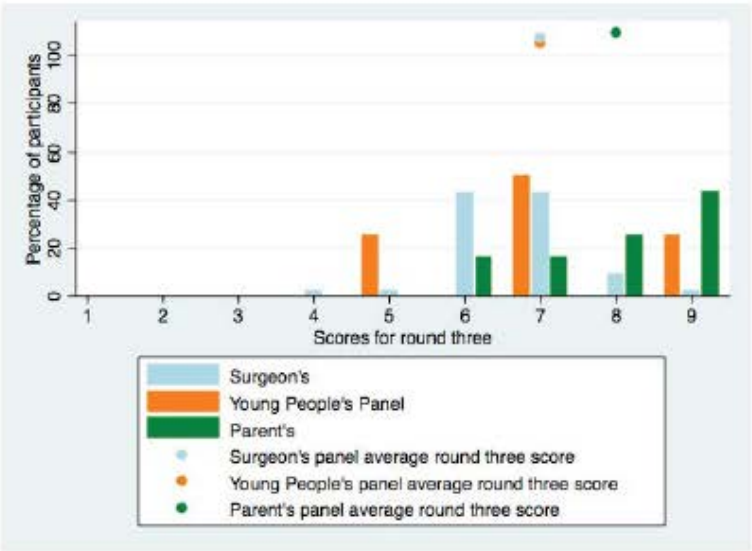
Having a central venous catheter or not. A catheter is a fine tube inserted into a large vein to give medicines and usually used when medicines in to a vein are likely to be needed for over a week.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	69%	78%

Wound infection

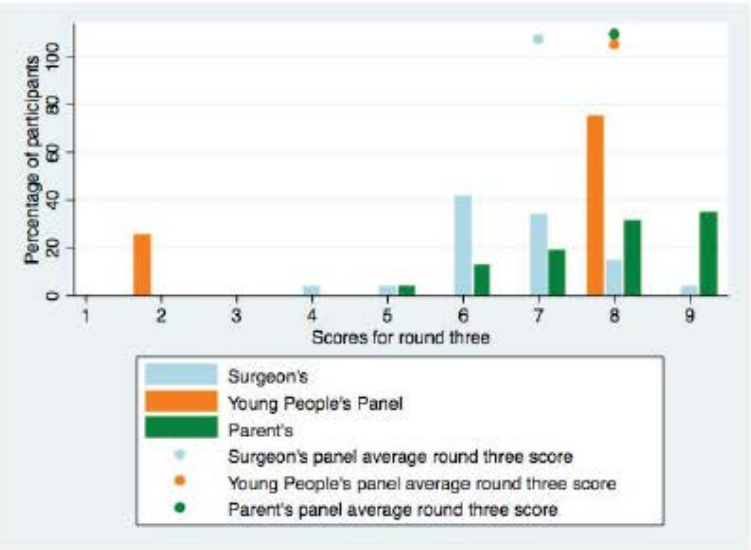
An infection at the site of the operation that requires treatment with antibiotics.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	75%	84%	54%

Wound complication

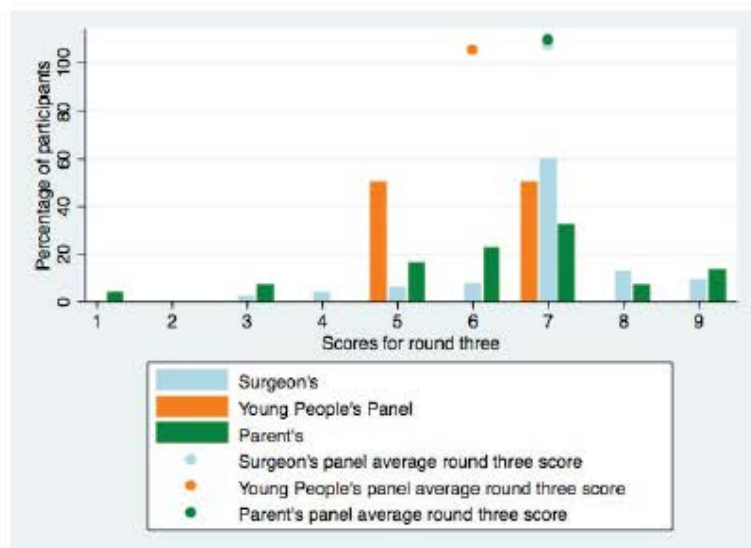
A complication with the surgical wound, such as the wound opening up before healing, or bleeding. This may need treatment with medicine or another procedure.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	75%	84%	52%

Unplanned radiology procedure

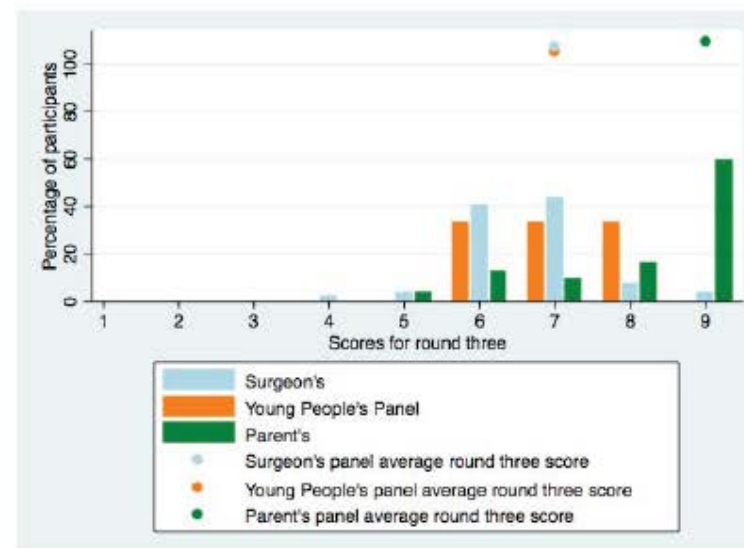
Whether a child needs an interventional radiology procedure or not. An interventional radiology procedure is where an x-ray doctor puts a tube inside the tummy to drain pus, using an x-ray for guidance.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	50%	52%	82%

Patient stress

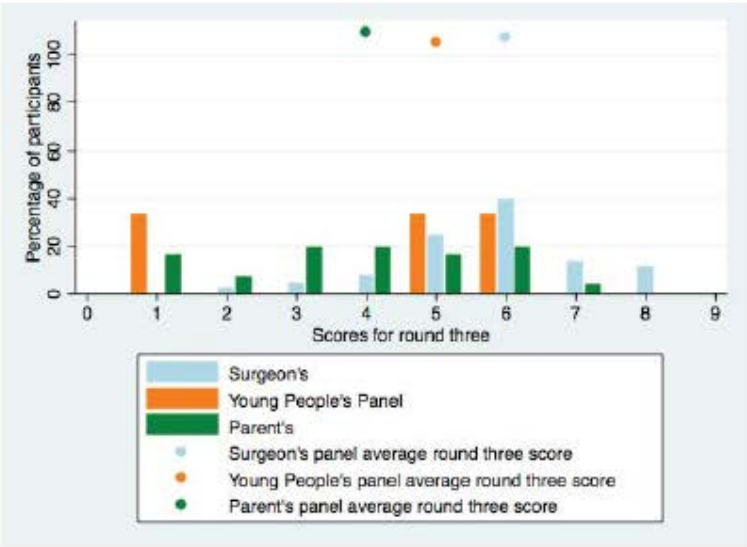
A measure of stress in the child that would be measured using a specifically designed questionnaire.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	67%	84%	55%

Hospital length of stay

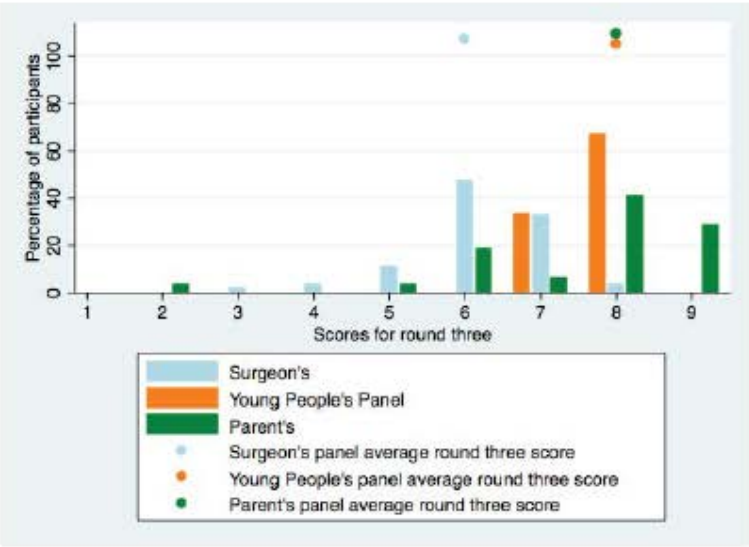
How long a child has to spend in hospital.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	50%	41%	63%

Pain score

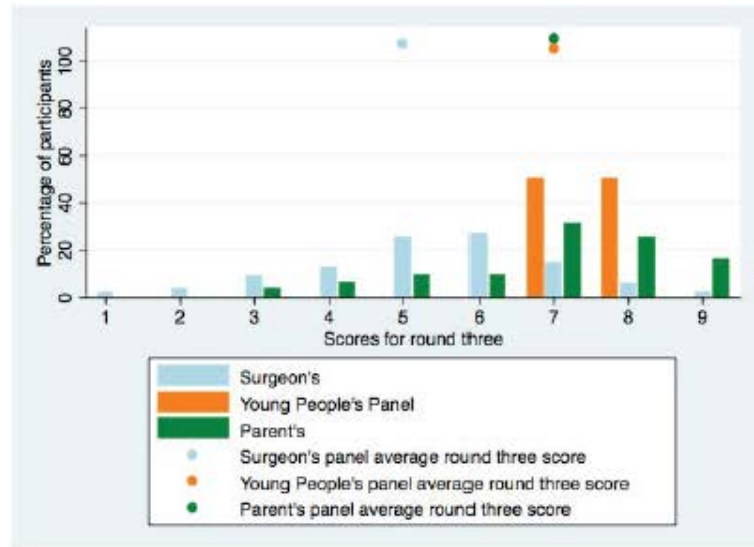
How severe a child reports that pain is, using a pain score.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	75%	36%

Fever after treatment

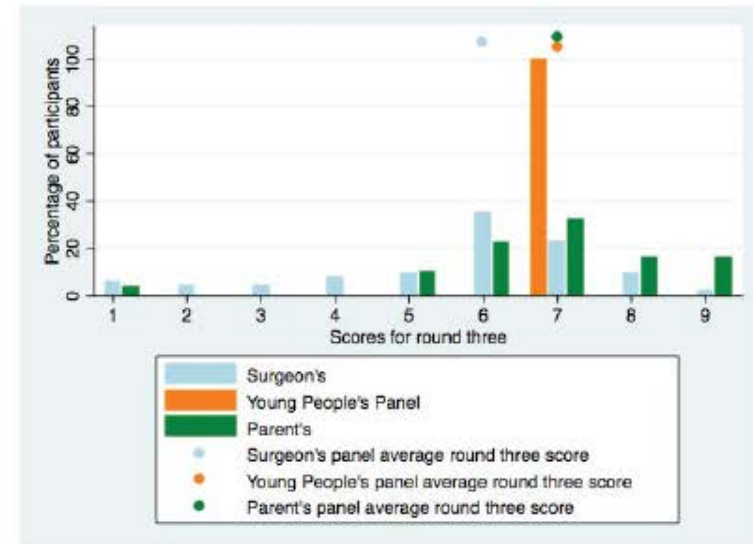
A high temperature after treatment has started.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	72%	21%

Duration of drainage

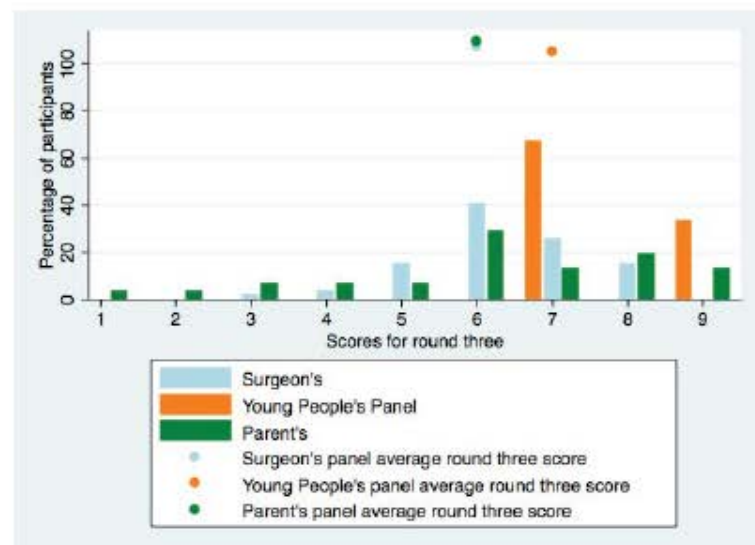
If a small tube (called a drain) is used after an operation or to drain pus from the tummy, the length of time this is needed for. This is unusual after treatment of uncomplicated appendicitis but can sometimes be needed.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	65%	35%

Time away from school

How long a child has to spend away from school or their normal activities.

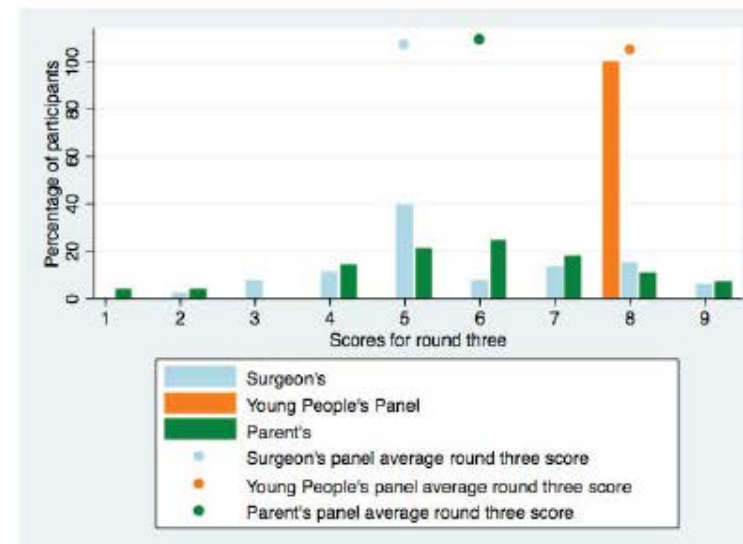


	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	45%	40%

32

Negative appendicectomy

Having an operation to remove the appendix and it turning out that the diagnosis was not appendicitis after all and an operation was not needed.

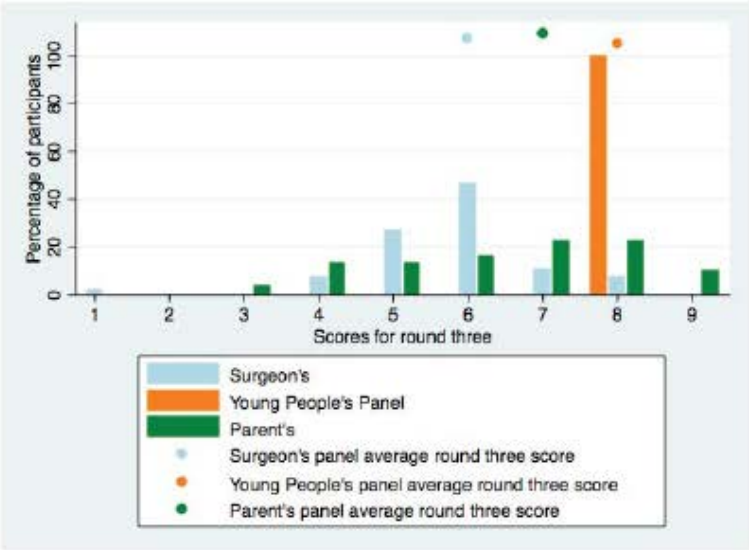


	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	35%	33%

33

Other infectious complication

Other infection during or after treatment that is not related to the appendix or surgical wound. For example, a urine infection or chest infection.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	55%	18%

Blood markers of inflammation

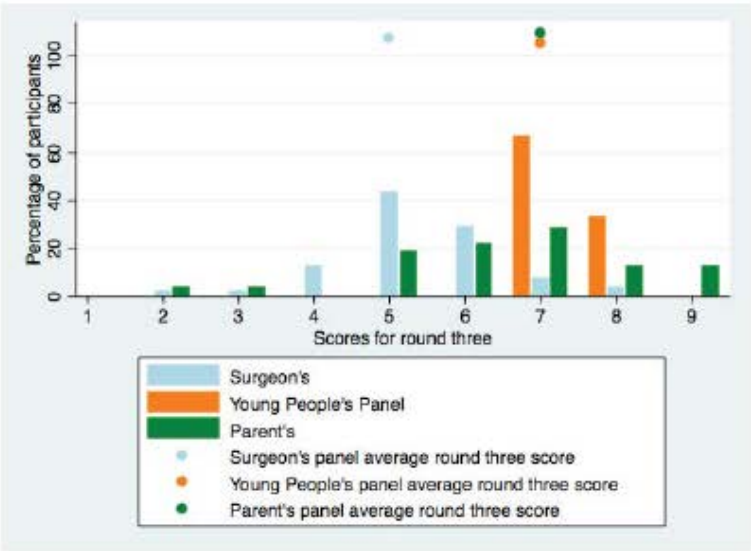
Results of blood tests that indicate how well the child is responding to treatment.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	55%	18%

Analgesia (pain relief)

Number of doses and types of painkiller medicine (analgesia) that are needed.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	53%	11%

Bacterial peritoneal culture

Which bacteria are grown from inside a patient's tummy when fluid is tested.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	50%	13%

Wound healing time

How long the wound takes to heal after an operation.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	45%	13%

Cosmesis

Cosmesis is the neatness of a wound and whether the child or parent is happy with how it looks.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	23%	26%

Time away from full activity

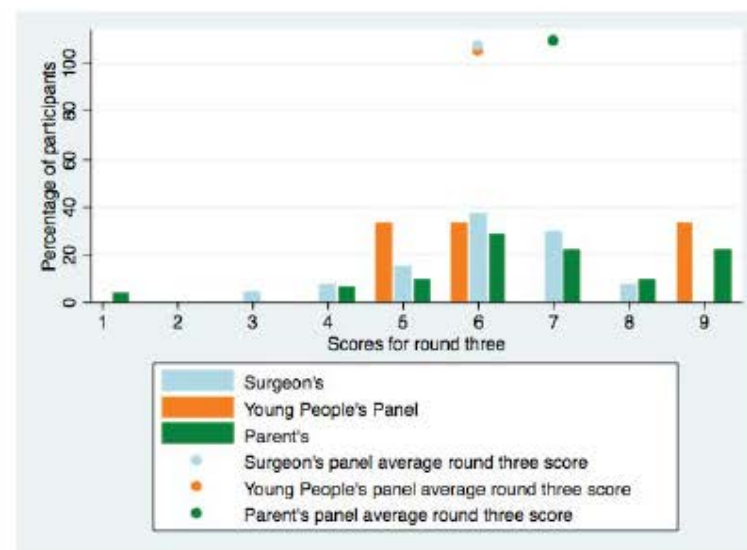
How long a child spends away from full activity, such as sport.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	100%	19%	13%

Psychological effects

Long term psychological effects of the illness, treatment or stay in hospital.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	33%	53%	37%

Cost effectiveness

Cost effectiveness involved working out how much a treatment costs, while also considering whether the treatment worked or not.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	50%	36%	44%

Conversion to open operation

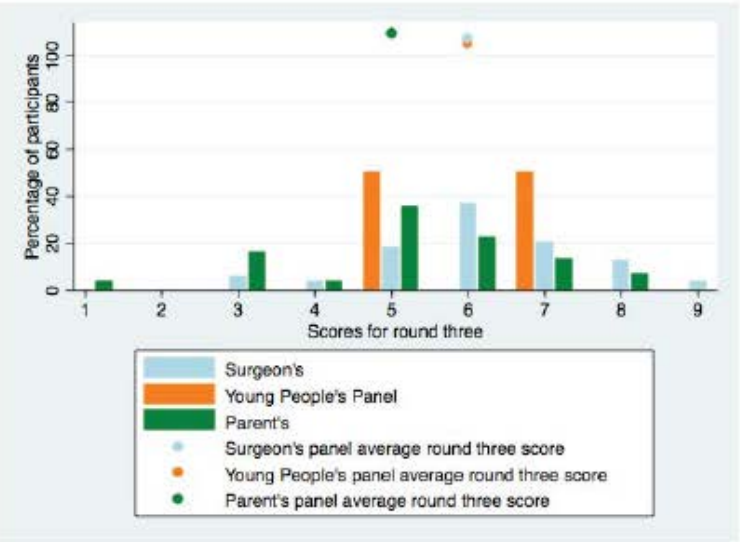
If an operation that started out as keyhole (a few small holes) needs to be converted to an open operation (a larger cut).



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	67%	59%	25%

Unplanned CT scan

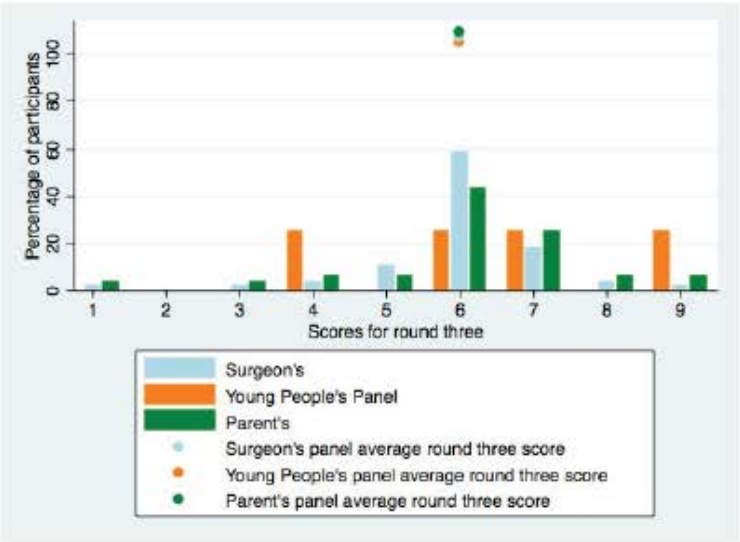
Whether a CT (CAT) scan is needed after treatment or not. A CT scan makes more detailed pictures of parts of your body than an x-ray but uses higher dose of x-rays.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	50%	19%	36%

Time to get out of bed

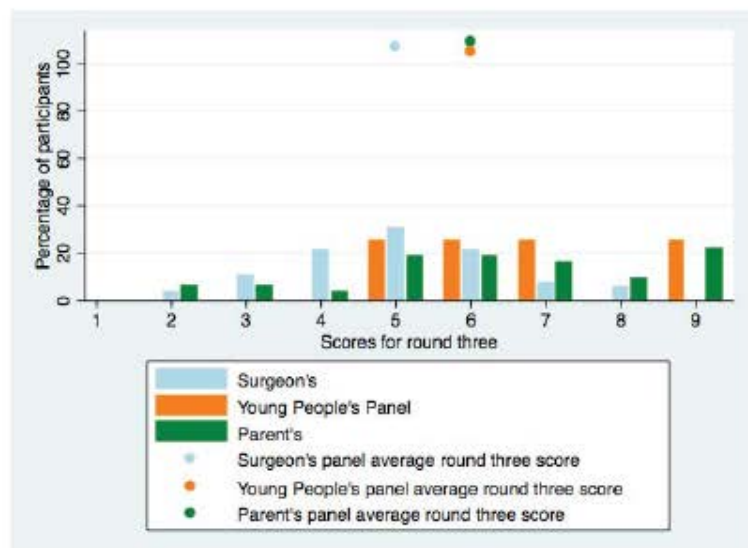
How long before the child can walk around or move normally.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	50%	38%	23%

Operation time

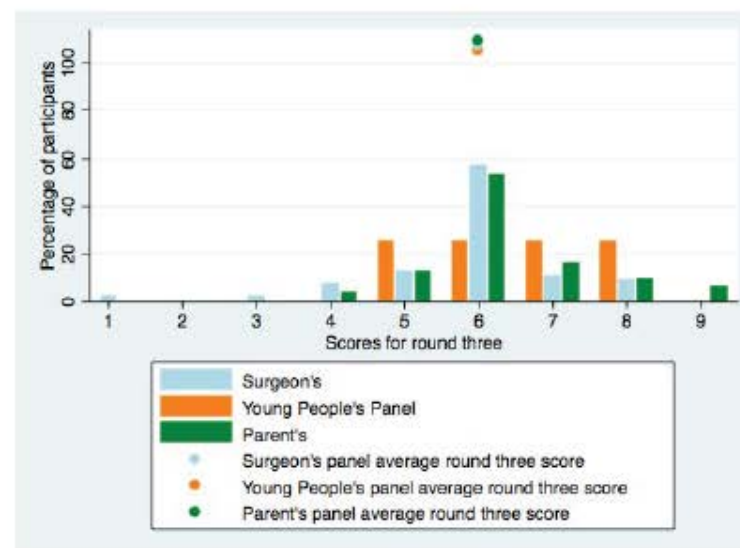
Time taken for the operation including time that the child is asleep for (under general anaesthetic).



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	50%	47%	13%

Recovery of bowel function

How long it takes to be able to eat or pass a stool normally.



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	50%	31%	20%

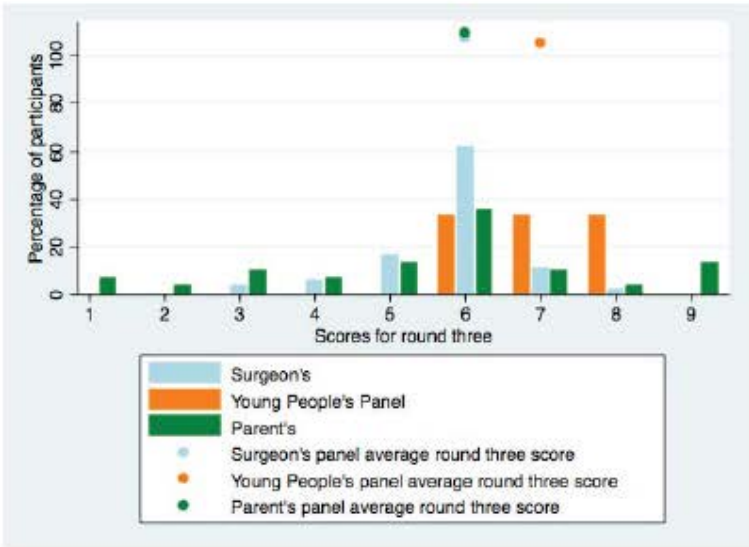
Parental stress

A measure of stress in the parent/guardian that would be measured using a specifically designed questionnaire.



Parent time off work

How long a parent/guardian spends away from work.

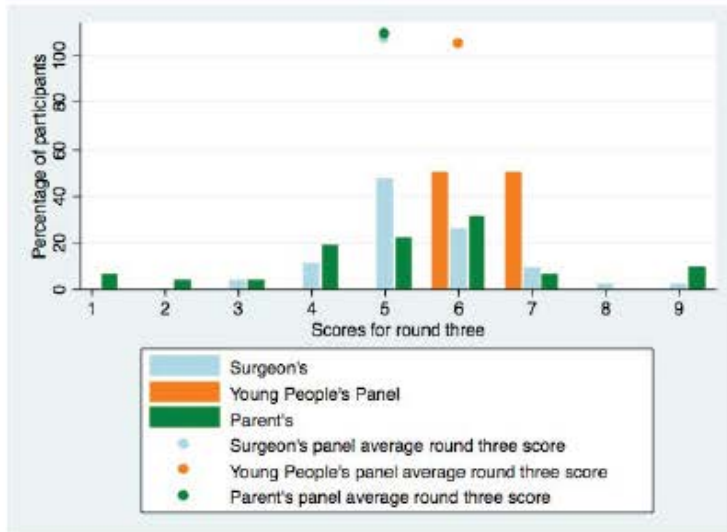


	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	50%	32%	13%

	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	67%	26%	13%

Time to normal diet

Time taken to get back to eating completely normally again.



CONTRACT

Thank you for helping to inform the future of research and treatment in acute appendicitis in children and young people!



	Young people	Parents	Surgeons
Percentage of participants who scored this outcome 7-9 in survey three	50%	16%	13%

CONTRACT Core Outcome Set
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NHS
National Institute for
Health Research

