Final Report

iPASS -Investigating Paediatric Appendicitis Scores Study

Supported by HCF Research Foundation

Dr Mary McCaskill
Sydney Children's Hospitals Network

Contents

Executive Summary

Generous support from HCF Research Foundation funded this study into treatment of children with abdominal pain and possible acute appendicitis. A treatment model was developed based on risk stratification using the previously validated Paediatric Appendicitis Score (PAS). It was used both with and without blood test results.

The aim of the study was to assess the safety of discharging low risk patients home with early follow-up with their GP and the risk of representation within 24 hours. Families were contacted by phone to establish if they had returned to a hospital within the following two weeks. They were also asked their satisfaction with the care given.

In this study, 318 patients with abdominal pain and low risk for appendicitis were enrolled and 278 were available for analysis. Results showed that 24 patients (8%) re-presented to a hospital for care. Five patients (1.7%) needed an operation, and four of these had appendicitis (1.4%). The median time to representation was 23 hours.

These results indicate that it is safe to discharge patients at low risk of appendicitis with early planned review within 24 hours. Availability of transport is important to enable representation. This will reduce the number of admissions to the tertiary hospital and the associated social and financial burdens families experience.

The change in practice at The Children's Hospital at Westmead has created a major shift in the care of these children. The information is being presented at the Australasian College for Emergency Medicine Annual Scientific Meeting in November 2016. A paper will be submitted for publication by the end of the year.

In addition, for patients in district hospitals, the 24 hour window for discharge means that children with low risk of appendicitis can be safely cared for in a district level hospital without paediatric surgical expertise for 24 hours. This will reduce the need to transfer patients between hospitals and reduce the accompanying social dislocation of the child and family. There is significant interest in testing this model in a district hospital settling as our next study.

Application

HCF Health and Medical Research Foundation

HCF Funding application

General Information

Project Title:

Investigating Paediatric Appendicitis Scores Study

Short Title (max 60 characters):

iPASS

Lay project description (100 words)

Appendicitis is the most common reason for emergency surgery in children but is difficult to diagnose. Doctors and parents want certainty about the diagnosis of appendicitis therefore more invasive and expensive investigations are performed and increasingly children are transferred to hospitals where expert paediatric surgical assessment is available. Not all children need these transfers or investigations. We aim to identify a scoring system that will recognise when a patient is at low risk and can safely go home without further investigation. This will reduce the need for some tests and the expense and inconvenience of transfer to a paediatric hospital.

Academic Discipline:	Emergency Medicine/Paediatric Surgery			
List 4 keywords	Appendictitis	Abdominal Pain	Emergency	Children
Amount requested:	$175,505			
Duration of the study:	2 years			
Has work on the project already begun?	Yes – 6 month pilot data complete			

Principal Investigator

Title:	Dr		
First name:	Mary	Last name:	McCaskill
Current appointment:	Medical Director Emergency Department		
Organisation:	The Children's Hospital at Westmead		
Department:	Emergency Department		
Organisation initials:	CHW		
Postal Address:	Locked Bag 4001, Westmead, NSW 2145		
Phone:	02 9845 3519		
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Role*	C		

Application

HCF Health and Medical Research Foundation

Certification

By submitting this application I certify that:

I and my Organisation understand and agree that any experimentation involving human subjects will conform to the general principles set out in the National Health and Medical Research Council (NH&MRC) statement on Human Experimentation,

I and my Organisation have reviewed the draft Research Grant Agreement provided and have no objections to signing the agreement as presented should this application for funding be successful.

And

Certify that the information provided in this application is true, accurate and complete to the best of my knowledge.

Certification by principal researcher

Name:	Dr Mary McCaskill
Current appointment:	Medical Director Emergency Department
Organisation:	The Children's Hospital at Westmead
Signature:	
Date:	27th Sept 2013

Certification by institution representative

Name:	Dr Michael Brydon
Current appointment:	Director of Clinical Operations
Organisation:	The Children's Hospital at Westmead
Signature:	
Date:	30th Sept 2013

Application

HCF Health and Medical Research Foundation

Project administrator details (if different to PI)

The point of contact that The HCF Foundation will use for communication regarding this application

Title:	Dr		
First name:	Mary	Last name:	McCaskill
Postal Address:	Locked Bag 4001, Westmead, NSW 2145		
Phone:	02 9845 3519	Email:	mary.mccaskill@health.nsw.gov.au

Co-investigators

Name	Current appointment	Organisation	Role*	Most relevant qualification	Away for a significant period (Y/N)	Hours/week devoted to this project	Email address
Dr Mary McCaskill	Medical Director Emergency	The Children's Hospital at Westmead	C	FACEM	N	4	mary.mccaskill@health.nsw.gov.au
Dr Sarah Dalton	Paediatric Emergency Physician	The Children's Hospital at Westmead	C	FRACP	Y	2	sarah.dalton@health.nsw.gov.au
Dr Jonathan Karpelowsky	Paediatric Surgeon	The Children's Hospital at Westmead	C	FRACS	N	2	jonathan.karpelowsky@health.nsw.gov.au
Dr Susan Phin	Paediatric Emergency Physician	The Children's Hospital at Westmead	C	FRACP	N	2	susan.phin@health.nsw.gov.au
Dr Ralph Cohen	Head General Surgery	The Children's Hospital at Westmead	A	FRACS	N	1	ralph.cohen@health.nsw.gov.au
Dr Raymond Chin	Director Paediatrics	Campbelltown Hospital	P	FRACP	N	1	raymond.chin@sswahs.nsw.gov.au

* Indicate whether the investigator is **primarily**: *N.B. Choose only one for each investigator.*

A - Academic **C** – Clinical **G** - Government representative **P** - Provider Representative (e.g of hospital or local area service) **O** - Other

Application

HCF Health and Medical Research Foundation

Project

Classification

Is the research **primary** research or **implementation** research	
Will the research enhance knowledge and understanding in health services research?	Yes/No

Does the project address:

Health service costs?	Yes/No
The quality of health services?	Yes/No
Access to and/or equity of provision of health services?	Yes/No
Health services planning and/or organisation?	Yes/No
Relevance and appropriateness of health services to the needs of individuals or communities?	Yes/No
Effectiveness and efficacy of health services?	Yes/No
How health services are experienced?	Yes/No

Will the research lead to improvements in health?	Yes/No
Will the research lead to improvements in health services?	Yes/No
Will the research lead to reduced cost of health services?	Yes/No

Major Diagnostic Category (if appropriate, from DRG system):

Appendicitis

Application

HCF Health and Medical Research Foundation

Project Summary

Background

Children with acute abdominal pain present commonly to emergency departments. Only 10% of children will have acute appendicitis, which can be difficult to diagnose and potentially serious if missed. To avoid missing this, clinicians are performing more investigations and transferring more patients to paediatric centres for expert surgical review, despite limited evidence of better patient outcomes. Clinical decision rules for possible appendicitis are unreliable in predicting appendicitis. There has been little work to investigate the role of scoring systems in risk stratification identifying low risk patients to permit early discharge safely and avoid unnecessary investigations including imaging and transfers.

(Maximum 100 words)

Aims

Describe in lay terms the general aim of the project

To develop a model using a clinical decision rule for abdominal pain to identify children at low risk of appendicitis who may be safely discharged.

(Maximum 25 words)

Is there an intervention?	Yes

Project

If yes, what is the duration of the intervention?

A score is completed in the Emergency Department. Phone contact will establish if the patient had unplanned representation after discharge.

(Maximum 20 words)

What will be measured and how?

Clinicians complete an electronic form for consecutive patients with possible appendicitis including clinical features and blood test results. It is recorded serially for children under observation. The primary outcome measure is safe discharge of patients without appendicitis. Families are contacted regarding unplanned representation to hospital within 2 weeks of discharge.

(Maximum 50 words)

Describe any benchmark or control group that results will be compared against.

Scores from patients with and without appendicitis will be compared to see if the score was predictive. Safety of discharge of patients will be assessed looking at subsequent unplanned representation to hospital or development of appendicitis. These rates will be compared with pilot data of current practice.

(Maximum 50 words)

Application

General

If the study is already being undertaken, describe the work done to date

A pilot study was completed over 6 months on patients presenting to the Emergency Department with possible appendicitis. This established the use of the score by doctors in emergency and surgical teams. The pilot data identified the usual flow of these patients within the Emergency Department, those requiring admission or surgery and those discharged from hospital. With the introduction of the score the average hours spent in the Emergency Department fell from 9.6 hours to 5.4 hours over 6 months. The next step in this project is to develop a model of care at home for patients using the score.

(Maximum 100 words)

Project Background

Acute abdominal pain is a common complaint among children presenting to the emergency department. Approximately one in ten of these children with abdominal pain will have acute appendicitis (1) (2).

As the most common reason for emergency surgery in children, acute appendicitis is an important diagnosis in such patients and a delay in making the diagnosis increases the risk of perforation with consequently increased morbidity (3) (4).

However, due to its often varied presentation and the many potential causes for abdominal pain in children, definitively diagnosing acute appendicitis in this age group can be difficult for all clinicians involved. To avoid missing the diagnosis of appendicitis, clinicians are performing and families are expecting more investigations including abdominal ultrasound. More patients are transferred to paediatric centres for expert surgical review. However, neither symptoms, signs, laboratory investigations, diagnostic scoring systems nor medical imaging can be relied upon to clarify this uncertainty in all cases (5) (6).

Current clinical decision rules for possible appendicitis are unreliable in predicting appendicitis. There has been little work to investigate the role of scoring systems in risk stratification identifying low risk patients to permit early discharge safely and avoid unnecessary investigations including imaging and transfers. A clinical prediction rule which could reliably exclude appendicitis in a significant number of paediatric patients presenting to the emergency department could potentially allow the finite resources of medical imaging and specialist paediatric surgery to be concentrated appropriately.

The full potential of such a score would be realised if it were introduced as part of a defined model of care in emergency departments across the state and similarly in other states across Australia. Once the model is developed and tested at a tertiary paediatric centre this project will look to introduce it into metropolitan and outer metropolitan hospitals in Sydney to reduce transfer of children with abdominal pan overnight to tertiary centres. This allows care to be delivered closer to the patient's home and reduced family disruption. There is a already interest from tertiary paediatric centres across Australia in this concept. This may lead to its introduction in other states of Australia.

(Maximum 500 words)

Aims

To develop a safe model of care for children with abdominal pain which uses an electronic clinical decision rule to identify children at low risk of appendicitis. The effectiveness of the score in identifying low risk patients will be measured. The risk stratification of patients leads to a model of care as an inpatient, an outpatient with early review or discharge for follow up by GP. The safety of the model which maximises the time spent at home will be measured by phone follow up asking for unplanned representation to hospital or diagnosis of appendicitis within 2 weeks of discharge.

(Maximum 100 words)

Methodology

General

The study will take place in a tertiary paediatric hospital in Western Sydney. Application for ethical approval will be made to the Sydney Children's Hospitals Network Ethics Committee before the study commences.

All patients (2-16 years)who present to the Emergency Department at The Children's Hospital at Westmead with abdominal pain and possible appendicitis will be eligible for inclusion in the study. As part of standard medical

assessment of these patients the Paediatric Appendicitis Score (7) will be completed and recorded electronically. This includes the following elements on history and examination:

Pain	Migration of pain	1	
	Right lower quadrant tenderness	2	
	Cough / hopping / percussion tenderness in RLQ	2	
GI Symptoms	Anorexia	1	
	Nausea or vomiting	1	
Inflammation	Fever >37.2 C		1
Blood tests	White cell count >10,000	1	
	White blood cell count >75% neutrophils	1	

On completion of the initial score consent will be requested from the patient and family to be involved in follow up while in hospital and after discharge by phone. If consent is declined the patient will be treated following current practice.

Patients are discharged home if they have a total score less than 5 unless other pathology is identified or there is significant clinician concern. Surgical referrals are made for children with a total score of 5 or over or if there is significant clinician concern. The surgical team repeats the score during their assessment. They stratify the risk of appendicitis for the patients and decide which of the following risk stratification models of care the patient needs:

- admission for likely appendicitis and surgery,
- ongoing review the following day for possible appendicitis using a home care model or
- discharge home as unlikely appendicitis.

All patients who have consented will be followed up by phone by the project officer to establish if they had an unplanned representation to hospital or developed appendicitis. Satisfaction with the model of care of the child and with the control of pain will also be included. This phone call will follow a script. Queries about medical issues raised in these phone discussions will be referred to one of the paediatric emergency physicians to discuss.

If patients represent with possible appendicitis, they will not be entered into the study a second time and will be referred for surgical review.

The primary outcome measure is safe discharge home without unplanned representation to hospital or unanticipated diagnosis of appendicitis within 2 weeks of initial discharge.
Secondary outcome measures are length of time in the Emergency Department and in hospital length of stay, admission rate and rate of negative appendicectomy.
Satisfaction outcome measures are overall assessment of pain and parent satisfaction with the diagnostic process.

Data will be entered into a Microsoft Excel® spreadsheet and kept securely. Identifying data will not be kept once the data collection is complete.

(Maximum 500 words)

If there is an intervention, describe the tool/technique etc that will be used

The intervention involves:
1. Applying a clinical score when assessing the patient with abdominal pain and using this to identify patients at low risk of appendicitis. The score is developed from the Paediatric Appendicitis Score (7).
2. Phone follow up after discharge identifying unplanned presentation to hospital or diagnosis of appendicitis using scripted phone calls.

(Maximum 100 words)

Analysis and statistics

Analysis will include:
- The predictive value of the score within the defined model of care to identify patients who did not have appendicitis.
- Secondary outcome measures will be compared between risk stratification groups according to the model of care used and also with data from pilot study.
- Satisfaction measures will be compared between risk stratification groups.

(Maximum 200 words)

Application

Describe the study population.

All patients (2-16 years) who present to the Emergency Department at The Children's Hospital at Westmead with abdominal pain and possible appendicitis will be eligible for inclusion in the study.

(Maximum 50 words)

How will participants be recruited?

After initial medical assessment patients and their families will be informed about the study and consent to join will be requested by the treating doctor. Information about the study and the study team will be provided. Families will be assured that if they do not consent they will receive standard care for their child.

(Maximum 100 words)

References

1. O'Shea JS, Bishop M, Alario A, Cooper JM. Diagnosing appendicitis in children with acute abdominal pain. Pediatr Emerg Care. 1988; 4(3): p. 172-176.
2. Reynolds SL, Jaffe DM. Diagnosing abdominal pain in a pediatric emergency department. Pediatr Emerg Care. 1992; 8(3): p. 126-128.
3. Bickell NA, Aufses AH, Rojas M, Bodian C. How time affects the risk of rupture in appendicitis. J Am Coll Surg. 2006; 202(3): p. 401-406.
4. Kwok MY, Kim MK, Gorelick MH. Evidence-Based Approach to the Diagnosis of Appendicitis in Children. Pediatr Emerg Care. 2004; 20(10): p. 690-698.
5. Acheson J, Banjerjee J. Management of suspected appendicitis in children. Arch Dis Child Educ Pract Ed. 2010; 95(1): p. 9-13.
6. Bundy DG, Byerley JS, Liles EA, Perrin EM, Katznelson J, Rice HE. Does This Child Have Appendicitis? JAMA. ; 298(4): p. 438-451.
7. Bhatt, Maala, et al Prospective validation of the Pediatric Appendicitis Score in a Canadian Pediatric Emergency Department. Academic Emergency Medicine, 2009, Vol. 16.
8. Close GR, Rushworth RL, Rob MI Paediatric appendicectomy in NSW: changes in practice over time and between groups. J Qual Clin Pract. 1995 Mar;15(1):29-36..

(Maximum 400 words)

Application

Project Outcomes

Scale

How many people are affected in Australia each year? Australian rate of appendicitis 180/100,00 (8). Australia has 4.1million children <16y.	#	7380 <16y
How many of these people would be reached by implementation of results of this project?	#	2800 NSW
	%	38

Comments

Initial implementation in NSW would focus on metropolitan centres where transfer of children late at night is a frequent occurrence. There is significant interest from tertiary paediatric hospitals around Australia in developing a model of care for these patients.

(Maximum 50 words)

Implementation

How will resulting evidence be translated into changes in practice and scaled up to benefit as many affected Australians as possible?

Because both surgical and emergency teams are involved I this study, once the model of care is shown to be safe and effective it will be introduced into routine practice at The Children's Hospital at Westmead. The Randwick campus of Sydney Children's Hospitals Network will also consider the model of care.
Dr Raymond Chin is head of a district hospital large paediatric units. He is involved in the study to identify how the model would work in that environment. From this step implementation in hospitals across NSW is feasible. Interest from other paediatric tertiary emergency departments across Australia has been shown through the research collaborative PREDICT (Paediatric Research in Emergency Departments International CollaboraTive) and completion of a survey on current practice across Australia.

(Maximum 200 words)

How will it be ensured that any benefits are ongoing?

The NEAT targets are a focus for emergency departments across Australia so if the model delivers reduced length of emergency department stay the NEAT target with encourage ongoing application.
If the model of care delivers parental satisfaction this will ensure that it is used as an ongoing model of care.

(Maximum 200 words)

Are there any policy implications for the results of this project and if so how will they be considered?

To introduce the model of care as routine the internal policy of The Children's Hospital at Westmead would be updated. We would then approach NSW Ministry of Health to review the introduction into the NSW Clinical Practice Guideline for Management of Children with Acute Abdominal Pain.

(Maximum 200 words)

Has there been any stakeholder consultation? Explain.

Discussions have been held with paediatricians at Sydney metropolitan area regarding keeping children as close to home as possible. Discussions have been held with paediatric surgical teams regarding limiting children with abdominal pain needing tertiary paediatric review. As the model progresses this information will be included.

(Maximum 200 words)

Information regarding costs of larger scale implementation provided in the final report:	Yes

Key messages

What are the potential outcomes of the research?

The implementation of a model of care for possible appendicitis based on risk stratification which limits the time a child spends in hospital and maximises care at home while safely identifying children with acute appendicitis. This would reduce cost and length of hospitalisation of children , reduce disruptions and cost to the family unit. It would strengthen the capability of district level hospitals to care for these children without need for transfer to a tertiary paediatric facility.

(Maximum 100 words)

Application

How will the research benefit Australians?

Recent studies have demonstrated significant variation across Australian paediatric Emergency Departments in the management of possible appendicitis. Appendicitis is the most common surgical emergency in children, making consistent guidelines a national priority. This project aims to provide evidence that will inform such a guideline giving significant benefit for Australian children.

(Maximum 50 words)

Timeline

Please provide a timeline for the project.
E.g. Literature review complete; participant recruitment finished; data collection completed, etc.
Assume a starting date of 1 January 2014

Phase	**Objective/goal**	**Planned completion date**
Preparation	Ethics submission	31-Jan-14
Preparation	Ethics approval	30-Mar-14
Preparation	Literature review	28-Feb-2014
Preparation	Development of data collection tool	30-Mar-14
Preparation	Education of clinical staff in use of score	30-Mar-14
Data collection	Begin collection patient data through Emergency	01-Apr-14
Data collection	Audit data for quality and completion rate	01-Jun-14
Data collection	Complete data collection	30-Jun-15
Data analysis	Analysis of data	30-Aug-15
Dissemination	Prepare paper for presentation and publication	30-Sep-15
Dissemination	Discuss potential for change of practice across NSW	30-Dec-15
Dissemination	Discuss potential for change of practice Australia	30-Dec-15

Application

Ethics

Any research on animal or human studies requires approval by an institutional ethics committee. Examples of types of research that may require ethics approval are: trial experiments, clinical or community based interventions, collection of blood or other biological material samples, questionnaires or surveys, reviews of case notes or access to medical records.
If the agency or institution responsible for administering the grant does not itself have an ethics committee set up according to NH&MRC guidelines, **it must arrange for research proposals to be reviewed by a local institution which does have such a committee.**

Ethics application status		Ethics submission underway
If relevant	Date of approval	
	Valid until	

Please forward report from ethics committee.

If not submitting an ethics application, explain why

Ethics submission is underway to SCHN Ethics Committee

(Maximum 100 words)

Risks

Using the risk matrix below please summarise any risks and their level of risk.

Risk		**Consequence**				
matrix		**Insignificant**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Likelihood	**Rare**	Low	Low	Low	Low	Low
	Unlikely	Low	Low	Low	Medium	Medium
	Possible	Low	Low	Medium	Medium	High
	Likely	Low	Medium	Medium	High	High
	Almost Certain	Low	Medium	Medium	High	Extreme

Issue	**Risk level**
Missed appendicitis discharged home –unlikely , moderate consequence. This risk will be minimised by ensuring written and verbal instructions to family to return if symptoms become worse.	Low

Application

Budget

Justification for budget:

The project officer 0.5FTE is vital to the project to allow each case to be contacted after discharge to check for any unplanned representations to a hospital were necessary. The level of this position was chosen to allow experienced HSM or RN to fulfil this role.
Travel was included to allow dissemination of the results to other centres.
The score will be developed as an electronic score.

(Maximum 400 words)

N.B. Excel spreadsheet with budget must also be included

Other funding

Has funding previously been obtained for this project? No

Funding body	Year	Amount funded	% of project

Is funding currently being or will be sought from another funding body? No

Funding body	Year	Amount sought	% of project

If yes to either of the above questions, please comment on the contribution this funding will make?

(Maximum 200 words)

Application

Reviewers

Please indicate your 3 reviewers. Please note you must contact and ask reviewers if they will review your project and send them your application for review.

Reviewer 1

Name	Prof Les White
Position	NSW Chief Paediatrician
Institution	NSW Kids and Families, NSW Ministry of Health
Email address	lwhit@doh.health.nsw.gov.au
Phone	02 9391 9000

Reviewer 2

Name	Dr Peter Kennedy
Position	Director, Deputy Chief Executive Officer
Institution	NSW Clinical Excellence Commission
Email address	Peter.Kennedy@cec.health.nsw.gov.au
Phone	02 9269 5506

Reviewer 3

Name	Dr Michael Brydon
Position	Director of Clinical Operations
Institution	The Children's Hospital at Westmead
Email address	Michael.brydon@health.nsw.gov.au
Phone	02 9845 0000

Protocol for Ethics submission

Investigating Paediatric Appendicitis Scores Study – iPASS

Emergency and Surgical Departments
The Children's Hospital at Westmead

Investigators

Dr Mary McCaskill Medical Director Emergency
Dr Sarah Dalton Paediatric Emergency Physician
Prof Ralph Cohen Paediatric Surgeon
Dr Jonathan Karpelowsky Paediatric Surgeon
Dr Deepali Thosar paediatric Hospitalist

Background

Acute abdominal pain is a common complaint among children presenting to the emergency department. Approximately one in ten of these children with abdominal pain will have acute appendicitis (1) (2).

As the most common reason for emergency surgery in children, acute appendicitis is an important diagnosis in such patients and a delay in making the diagnosis increases the risk of perforation with consequently increased morbidity (3) (4).

However, due to its often varied presentation and the many potential causes for abdominal pain in children, definitively diagnosing acute appendicitis in this age group can be difficult for all clinicians involved. To avoid missing the diagnosis of appendicitis, clinicians are performing and families are expecting more investigations including abdominal ultrasound. More patients, often inappropriately, are transferred to paediatric centres for expert surgical review despite there being a low likelihood of appendicitis.

Problem

Although abdominal pain is one of the most frequent reasons for presentation of children to an emergency department, almost 90% will not have acute appendicitis. Due to clinician and patient concerns of missing appendicitis children are often over investigated and referred to tertiary centres for paediatric surgical expertise. Various investigations and scoring systems have looked at ways to more conclusively diagnose appendicitis, but little research has been done in risk stratification i.e. defining a low risk group for acute appendicitis that can be discharged without imaging or expert review. A clinical decision rule that can reliably identify low risk patients enabling early and safe discharge could significantly decrease the burden of investigation and utilisation of resources.

The full potential of such a score would be realised if it were integrated as part of an agreed model of care between emergency departments in NSW and similarly in other states across Australia. Once the model is developed and tested at a tertiary paediatric centre there is potential to introduce it into metropolitan and outer metropolitan hospitals in Sydney to guide the transfer of children with abdominal pain to tertiary centres. This allows care to be delivered closer to the patient's home and reduces family disruption. There is considerable interest from tertiary paediatric centres across Australia in this concept, potentially leading to the introduction of this model in other states of Australia.

Aim

To develop a safe and effective model of care for children with abdominal pain which uses an electronic clinical decision rule to identify children at low risk of appendicitis enabling early discharge.

Objectives

- To develop a clinical decision rule for identifying patients with a low likelihood of appendicitis that can be implemented in the Emergency Department by medical staff to minimise length of hospitalisation and facilitate discharge.
- To identify the number of patients with "missed appendicitis" i.e false negative patients included as low risk by this clinical decision rule.
- To identify models of care for follow up of low risk patients outside of a hospital or inpatient model

Population

Inclusion

All patients 5-16 years of age who present to the Emergency Department at The Children's Hospital at Westmead with abdominal pain and clinical suspicion of appendicitis.

Exclusion

- Patients with other causes for abdominal pain felt to be likely on initial examination e.g. gastroenteritis
- Patients who have already had an appendicectomy

Model of Care

Following the 'Guideline for Management of Patients with Clinical Suspicion of Appendicitis, the standard medical assessment in the Emergency Department includes the electronically recorded Paediatric Appendicitis Score (PAS) (7). The initial sub-score (Sub-PAS) is based on history and examination. If this score is 3 or greater blood tests are taken the results of which contribute to a PAS.

The scores include the following elements:

Pain	Migration of pain	1	
	Right lower quadrant tenderness	2	
	Cough / hopping / percussion tenderness in right lower quadrant	2	
GI Symptoms	Anorexia	1	
	Nausea or vomiting	1	
Inflammation	Fever >37.2 C	1	
			Sub-PAS /8
Blood tests	White cell count >10,000	1	
	White blood cell count >75% neutrophils	1	
			PAS /10

Patients are discharged home from the Emergency Department if they have a Sub-PAS of 2 or less or a PAS of 4 or less, unless there is significant clinician concern of appendicitis or an alternative diagnosis requiring admission.

Surgical referrals are made for children with a PAS of 5 or over or if there is significant clinician concern. The surgical team clinically assesses the patient and repeats the PAS during their assessment. They stratify the risk of appendicitis for the patients and decide which of the following risk stratification models of care the patient needs:

- admission for likely appendicitis and surgery,
- ongoing review the following day for possible appendicitis using either a home care model or a short stay (<24 hour) admission model,
- discharge home as unlikely appendicitis,
- admission with another diagnosis.

Consent

After initial medical assessment by the Emergency Department medical staff, the study will be discussed with all eligible patients and families and the information sheet will be provided. Consent will be requested to be enrolled in the study and contacted in follow up. If consent is declined the patient will be treated following current practice and no contact will be made outside the usual clinical care. In patients for whom consent is not requested standard care will be given and consent to follow up will be obtained by phone.

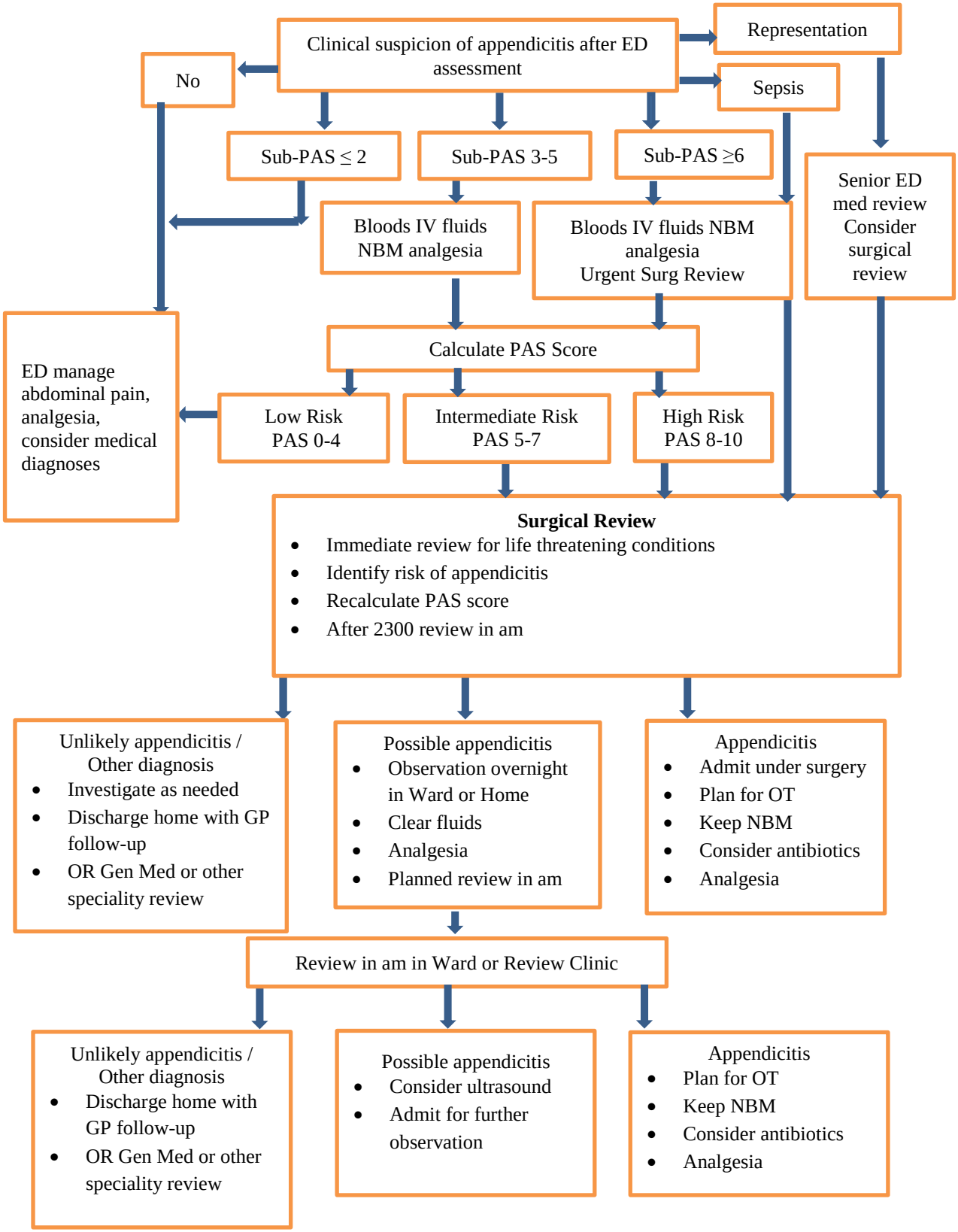
Intervention

All patients who have been enrolled in the study will be followed up with review of their charts to determine treatment given in hospital. They will be called by phone by the project officer to establish if they had an unplanned representation to hospital for abdominal pain or developed appendicitis within 2 weeks of presentation. Parents will be asked their satisfaction with the model of care of the child and with the control of pain. This phone call will follow a script (see Appendix). There will be a separate script for patients in whom concsent was not obtained at the time of the hospital visit.

Data Management

Data will be entered into a Microsoft Excel® spread-sheet and kept securely in a password protected file on the hospital computers. Identifying data will not be kept once the data collection is complete.

Flow Sheet



Outcomes

The primary outcome measure is discharge from ED without unplanned representation to hospital or unanticipated diagnosis of appendicitis within 2 weeks of initial discharge.
The proportion of patients who are identified in the Emergency Department as having clinical suspicion of appendicitis and are admitted to hospital overnight.

Secondary outcome measures are:

- Overnight admission rate
- Length of time in the Emergency Department
- Hospital length of stay
- Rate of negative appendicectomy <10% (current level).
- Parental satisfaction with model of care and pain control

Sample Size

Low risk – unplanned medical review within 2 weeks for same illness in <10% patients
Medium risk - defined adverse events such as admission requiring IV antibiotics within 2 weeks in <5% patients.

To detect a problem with a power of 80% and a confidence level of 0.05.

Analysis

- The predictive value of the PAS and sub-PAS score within the defined model of care to identify patients who did not have appendicitis.
- Secondary outcome measures will be compared between risk stratification groups according to the model of care used and also with data from historical practice.
- Satisfaction measures will be compared between risk stratification groups.

Problem management

- Queries about medical issues raised during phone discussions will be referred to one of the paediatric emergency physician investigators to discuss.

References

1. O'Shea JS, Bishop M, Alario A, Cooper JM. Diagnosing appendicitis in children with acute abdominal pain. Pediatr Emerg Care. 1988; 4(3): p. 172-176.
2. Reynolds SL, Jaffe DM. Diagnosing abdominal pain in a pediatric emergency department. Pediatr Emerg Care. 1992; 8(3): p. 126-128.
3. Bickell NA, Aufses AH, Rojas M, Bodian C. How time affects the risk of rupture in appendicitis. J Am Coll Surg. 2006; 202(3): p. 401-406.
4. Kwok MY, Kim MK, Gorelick MH. Evidence-Based Approach to the Diagnosis of Appendicitis in Children. Pediatr Emerg Care. 2004; 20(10): p. 690-698.
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Appendices

Data Collection Sheet-iPASS

Patient details

Field	Details	
Study ID	Number	
MRN	Number	
DOB	Date	
Age-Completed years	Number	
Sex	Female=1, Male=2	

Presentation details

Field	Details	
Date of presentation	Date	
Time of presentation	24 hour clock	
Date seen by clinician	Date	
Time seen by clinician	24 hour clock	
PAS • Migration of pain • Right lower quadrant (RLQ) tenderness • Cough / hopping / percussion tenderness in RLQ • Anorexia • Nausea or vomiting • Fever >37.2 C • White cell count >10,000 • White blood cell count >75% neutrophils		
Consent	Yes=1, No=2, Not asked=3	
First surgical review Date seen Time seen Indication PAS (If done)	Yes=1, No=2 Date 24 hour clock Text Number	
Outcome Date of discharge(From ED) Time of discharge(From ED) Date of discharge from Hospital Time of discharge from Hospital	Discharged =1 Admitted to ward=2 Admitted to EMU=3 Date 24 hour clock Date 24 hour clock	
Surgery Theatre booking Date Time Surgery Date Time Histopathology	 Date 24 hour clock Date 24 hour clock Appendicitis=1, No=2	

Follow up

Field	Details	
Date of follow up phone call	Date	
Time of follow up call	24 hour clock	
Unplanned return to hospital with abdominal pain *If yes* Date Time Hospital Outcome	Yes=1, No=2 Date 24 hour clock Text Yes=1, No=2	
Overnight admission to hospital *If yes* Date Time Hospital Related to abdo pain	Yes=1, No=2 Date 24 hour clock Text Yes=1, No=2	
Surgery for possible appendicitis *If yes* Date Time Was it Appendicitis?	Yes=1, No=2 Date 24 hour clock Yes=1, No=2, Unknown=3	

Parental satisfaction on follow up

Field	Details	
Assessment	Number 1 to 5	
Pain management	Number 1 to 3	
Confidence about level of care	Number 1 to 5	

Script for phone calls - consented

Prompt sheet for calling families for whom consent to call was obtained at ED presentation

This form is designed to prompt follow up phone call for collecting information from families within 2 weeks of the presentation.

Prior to call

- Check the current contact details for the parent/guardian from the 'Contact details' in PowerChart/"Health-e-care"
- Before calling ensure that you know and are able to pronounce both the child's and parents' names.
- Ensure that you have read a synopsis of the medical history so that the parents don't need to explain the history again. Parents will assume that the you have knowledge of the history, interventions received in hospital and the plan of follow up
- Do not call the parents if the patient died in hospital - check for all patients. If patient died in hospital do not undertake follow up call.

- If you discover that the patient died once discharged communicate empathy for their loss. You may ask if the child's death was related to the abdominal pain/appendicitis but stop the interview after this point and thank parent**.**

Good morning/afternoon. My name is _____ I am a research assistant at the Children's Hospital at Westmead. I would like to speak to you about a research study we are doing at the hospital.
Is this _____ (parent name) mother/father of _____ (child name)?
If no, thank respondent for their time and end call.
We saw your child _____ (child name) in the emergency department at the Children's Hospital at Westmead on _____ and you consented for your child to be part of the study. We would like to ask you some questions about how your child has been since then. This will take less than 5 minutes.

Script for phone calls – not consented

Prompt sheet for 'cold calling' families for whom consent to call was not obtained at ED presentation.
This form is designed to collect information from a 'cold call' made to families within 2-4 weeks of the presentation.
Prior to call

- Check the reason that consent to call was not obtained. If 'parent patient refusal' is indicated DO NOT CALL
- Check the current contact details for the parent/guardian from the 'Contact details' in PowerChart/"Health-e-care"
- Before calling ensure that you know and are able to pronounce both the child's and parents' names.
- Ensure that you have read a synopsis of the medical history so that the parents don't need to explain the history again. Parents will assume that the RAs have knowledge of the history, interventions received in hospital and the plan of follow up.
- Do not call the parents if the patient died in hospital - check for all patients. If patient died in hospital do not undertake follow up call.
- If you discover that the patient died once discharged communicate empathy for their loss. You may ask if the child's death was related to the abdominal pain/appendicitis but stop the interview after this point and thank parent**.**

Good morning/afternoon. My name is _____ I am a research assistant at the Children's Hospital at Westmead. I would like to speak to you about a research study we are doing at the hospital.
Is this _____ (parent name) mother/father of _____ (child name)?
If no, thank respondent for their time and end call.
If yes
We are conducting a research study to try to determine how to best look after children with abdominal pain/possible appendicitis.
We saw your child _____ (child name) in the emergency department at the Children's Hospital at Westmead on ___ _____ and we would like to ask you some questions about how your child has been since then. This will take about 5 minutes.

Your participation is voluntary and you do not have to be part of the study if you don't want to.
Will you agree to answer some questions as part of the study?
If no, thank respondent for their time and end call.

If yes
Information to collect on follow up

1. Did you and your child have unplanned return to hospital with abdominal pain?
    a. If YES: Date, Time, Hospital, and Outcome
2. Was there a need for overnight admission to hospital?
    a. If YES: Date, Time, Hospital, and was it related to abdominal pain?
3. Was there a need for surgery for possible appendicitis
    a. If YES: Date, Time, Hospital, and was it Appendicitis?
4. During your visit to the emergency department
    a. What did you think of the way the doctors assessed your child
        1. Excellent
        2. Good
        3. OK
        4. Poor
        5. Very Poor

b. Did you think staff did everything they could to manage your child's pain?
        1. Definitely
        2. Somewhat
        3. No

C. How confident did you feel about the level of care provided by the doctors at the Children's hospital at Westmead?
        1. Very Confident
        2. Pretty confident
        3. Slightly confident
        4. Not confident at all
        5. Not sure

(Adapted form sample questions for patient/parent survey on CGU resources)

If you have any further questions regarding this study please feel free to contact me or the principal investigator, Dr Mary McCaskill [Give number at request: 9845 3519]

Thank you very much for your help. I hope your child is feeling better.

At any time during the interview, be prepared to respond to questions or requests for information with information from the PARENT INFORMATION Statement e.g.

The purpose of the review…

Your answers will stay confidential…

If you do not want to answer the questions it will not affect your care …

At conclusion of call:

Offer to send parent an information sheet about the study (this may be offered at any time during the interview)

If you have any further questions regarding this study please feel free to contact me or the principal investigator, Dr Mary McCaskill [Give number at request: 9845 3519]

Thank you very much for your help. I hope your child is feeling better.

How to deal with Distressed parents

- Try to calm parents down and reassure parents that all possible help will be provided.
- Find out about the exact reason of parents' concerns.
- Discuss the options with parents if concerns in relation to child's health
  Child can be reviewed in the Emergency Department if the child needs urgent medical attention or by the local medical officer if non-urgent.
  (Please inform the admitting medical officer of the day if parents choose to present to emergency)
  The project officer can offer to discuss the case with one of the investigators or a follow up phone call from one of the investigators to address the concerns raised by distressed parents.
- If parents are unhappy with the management or wanting to complain, please note the parents' concerns and reassure parents that their concerns will be dealt with seriously.

Ethics approval

The Sydney children's Hospitals Network
care, advocacy, research, education

Contact for this correspondence:
Research and Development
Ethics & Governance Administration Assistant
Phone: (02) 9845 1253
Facsimile: (02) 9845 1317
Email: ethics.schn@health.nsw.gov.au

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and Hainsworth Street
Locked Bag 4001
Westmead NSW 2145
Sydney Australia
DX 8213 Parramatta
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http://www.schn.health.nsw.gov.au/
ABN 53 188 579 090

31 July 2014

Dr Mary McCaskill
Emergency
The Children's Hospital at Westmead

Dear Dr McCaskill,

HREC Reference: **LNR/14/SCHN/209**

Project title: **Investigating Paediatric Appendicitis Scores Study**

Sites Listed: **The Children's Hospital at Westmead**

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Executive committee of the Sydney Children's Hospitals Network Human Research Ethics Committee (HREC) at its meeting held on 29 May 2014. This HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that after receiving further information required for this project on 18 July 2014, the HREC Executive granted ethical approval of this research project. Your approval is valid from the date of this letter.

Document Reviewed	*Version*	*Date*
LNR Application, Submission Code: AU/6/0C89116		
Study Protocol		Undated
Data Collection Sheet		Undated
Participant Information Sheet		Undated
iPASS, Follow Up Prompt Sheet for call (Consented)		Undated
iPASS, Follow Up Prompt Sheet for Cold Call		Undated
Cover Letter		14 July 2014

Please note the following conditions of approval:

1. The co-ordinating investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
   -Unforeseen events that might affect continued ethical acceptability of the project.

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2. Proposed changes to the research protocol, conduct of the research, or length of HREC approval, will be provided to the HREC for review in the specified format.

3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

4. The co-ordinating investigator will provide an annual report to the HREC and at completion of the study. The annual report form is available on the Hospital's intranet and internet or from the Secretary.

5. Your approval is valid for 5 years from the date of the final approval letter. If your project extends beyond five years then at the 5 year anniversary you are required to resubmit your protocol, according to the latest guidelines, seeking the renewal of your previous approval. In the event of a project **not having commenced** within 12 months of its approval, the approval will lapse and reapplication to the HREC will be required.

Should you have any queries about the HREC's consideration of your project please contact the Research Ethics Administration Assistant on (02) 9845 1253.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The HREC wishes you every success in your research.

Yours faithfully

Ms Jillian Shute
Executive Officer
Sydney Children's Hospitals Network Human Research Ethics Committee

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Progress Reports

HCF Progress Reports June 2014

HCF Research Foundation

Progress Report

Short Title:	**iPASS**

Progress report #:	1	Progress report date:	21st July 2014
Period covered by report:	1st January	To	1st June 2014

General Information

Project Title:	Investigating Paediatric Appendicitis Scores Study
Lay project description (100 words):	
Appendicitis is the most common reason for emergency surgery in children but is difficult to diagnose. Doctors and parents want certainty about the diagnosis of appendicitis therefore more invasive and expensive investigations are performed and increasingly children are transferred to hospitals where expert paediatric surgical assessment is available. Not all children need these transfers or investigations. We aim to identify a scoring system that will recognise when a patient is at low risk and can safely go home without further investigation. This will reduce the need for some tests and the expense and inconvenience of transfer to a paediatric hospital.	

Principal Investigator

Title:	Dr		
First name:	Mary	Last name:	McCaskill
Current appointment:	Medical Director Emergency		
Organisation:	The Children's Hospital at Westmead		
Department:	Emergency Department		
Organisation initials:	CHW		
Postal Address:	Locked Bag 4001 Westmead NSW 2145		
Phone:	02 9845 3519		
Email:	mary.mccaskill@health.nsw.gov.au		

Signature of applicant:

Date: 21st July 2014

Objectives and Timeline

Do you expect to complete the project as specified, either in the application or the most recent agreement with the HCF Foundation?	Yes
Do you expect to complete the project on schedule, either as indicated in the application or the most recent agreement with the HCF Foundation?	Yes

If the answer to either of the previous 2 questions is no, please provide reasons:

This is the timeline which was submitted for the project in the application. Please indicate how much of each objective has been met. If planned completion dates have changed, please add a new date.

Phase	**Objective/goal**	**Planned completion date**	**% of objective complete.**	**New completion date**
Preparation	Ethics submission and protocol development	31st Jan 14	100%	16th May 14
Preparation	Ethics approval	30th Mar 14	85%	8th Aug 14
Preparation	Literature review	28th Feb 14	100%	28th Feb 14
Preparation	Development of data collection tool	30 Mar 14	100%	30th Apr 14
Preparation	Education of clinical staff in use of score	30th Mar 14	85%	11th Aug 14
Data collection	Begin data collection	1st Apr 14	0%	11th Aug 14
Data collection	Audit data for quality and completion rate	1st Jun 14	0%	15th Sep 14
Data collection	Complete data collection	30th Jun 15	0%	
Data analysis	Analysis of data	30 Aug 15	0%	
Dissemination	Prepare paper for presentation and publication	30 Sep 15	0%	
Dissemination	Discuss potential for change of practice across NSW	30 Dec 15	0%	
Dissemination	Discuss potential for change of practice across Australia	30 Dec 15	0%	

Are there any new objectives?

Phase	**Objective/goal**	**Planned completion date**
	Nil	

If timelines for the project have changed since the last report please provide reasons:
Protocol development and ethics submission have been more detailed than anticipated.

Recruitment

Is recruitment on track?	About to start recruitment

Number of participants recruited:	0
If recruitment is delayed, please provide reasons:	
Awaiting final ethics approval before commencement	

General comments

Please comment on the progress so far:
Progress has been slower than expected but it is anticipated that the project will be completed within expected timelines.

Implementation

Please comment on work towards implementation that will ensure the greatest number of Australians are able to benefit from project outcomes:
Discussion of the project has generated interest in participating in further study and potential use of score within hospitals in metropolitan Sydney, in Melbourne and in Perth.

Work during next phase

Please comment on the work to be completed in the next 6 months of the project:
During the next six months recruitment will commence and audit of data quality. Potential to expand on the study and include other centres will also be explored.

Publication

Please provide details of any publications, presentations or media attention related to this project:	
Reference details	Submitted or Accepted or Publication date
Nil yet	

Expenditure

How much money has been expended in the course of conducting the research so far? Account details still being established to enable tracking of finances.	$

HCF Research Foundation

Progress Report

Short Title:	iPASS

Progress report #:	Interim progress report	Progress report date:	29/06/2015
Period covered by report:	2nd July 2014	To	29th June 2015

Progress Report

General Information

Project Title:	Investigating Paediatric Appendicitis Scores Study

Lay project description (100 words):

Appendicitis is the most common reason for emergency surgery in children but is difficult to diagnose. Doctors and parents want certainty about the diagnosis of appendicitis therefore more invasive and expensive investigations are performed and increasingly children are transferred to hospitals where expert paediatric surgical assessment is available. Not all children need these transfers or investigations. We aim to identify a scoring system that will recognise when a patient is at low risk and can safely go home without further investigation. This will reduce the need for some tests and the expense and inconvenience of transfer to a paediatric hospital.

Principal Investigator

Title:	Dr		
First name:	Mary	Last name:	McCaskill
Current appointment:	Medical Director Emergency		
Organisation:	The Children's Hospital at Westmead		
Department:	Emergency Department		
Organisation initials:	CHW		
Postal Address:	Locked Bag 4001 Westmead NSW 2145		
Phone:	02 9845 3519		
Email:	mary.mccaskill@health.nsw.gov.au		

Signature of applicant: 

Objectives and Timeline

Do you expect to complete the project as specified, either in the application or the most recent agreement with the HCF Foundation?	Yes
Do you expect to complete the project on schedule, either as indicated in the application or the most recent agreement with the HCF Foundation?	Yes

If the answer to either of the previous 2 questions is no, please provide reasons:
--

This is the timeline which was submitted for the project in the application. Please indicate how much of each objective has been met. If planned completion dates have changed, please add a new date.

Phase	**Objective/goal**	**Planned completion date**	**% of objective complete.**	**New completion date**
Preparation	Ethics submission and protocol development	31st Jan 14	100%	
Preparation	Ethics approval	30th Mar 14	100%	
Preparation	Literature review	28th Feb 14	100%	
Preparation	Development of data collection tool	30 Mar 14	100%	
Preparation	Education of clinical staff in use of score	30th Mar 14	100% Repeated when junior doctors start work in ED	
Data collection	Begin data collection	1st Apr 14	100% Commenced on 11/11/2014	
Data collection	Audit data for quality and completion rate	1st Jun 14	50% Audit 19th Dec 2014 Plan for a further audit in August.	August 2015
Data collection	Complete data collection	30th Jun 15	45%	November 2015
Data analysis	Analysis of data	30 Dec 15	10% Plan for analysis complete	
Dissemination	Prepare paper for presentation and publication	30 Dec 15		
Dissemination	Discuss potential for change of practice across NSW	30 Dec 15	15% -Discussion with paediatricians at NSW District Paediatric Unit meeting. -Interest from other Sydney hospitals in participating.	

Are there any new objectives?

Phase	Objective/goal	Planned completion date
	Involvement of two other two Sydney Metro district hospitals –Mt Druitt Hospital and Liverpool Hospital in the study to confirm safety in their setting. There has been interest from a number of paediatric units but these two are linked closely with The Children's Hospital at Westmead and would impact on a significant number of children to avoid transfer.	-Engagement May 2015 complete -Local ethics Sept 2015 -Data collection commence Dec 2015 2016 -Analysis Dec 2016

If timelines for the project have changed since the last report please provide reasons:
Ethics approval at The Children's Hospital at Westmead took longer than anticipated. Data collection is now progressing excellently.

Recruitment

Is recruitment on track?	Yes
Number of participants recruited:	140
If recruitment is delayed, please provide reasons:	

General comments

Please comment on the progress so far:
Progress on track so far. Enthusiastic recruiting team members. Good phone follow up rates and positive responses overall from families.

Implementation

Please comment on work towards implementation that will ensure the greatest number of Australians are able to benefit from project outcomes:
There has been discussion in a number of forums and a lot of interest about the potential for this approach to be followed across the country. Two Sydney metropolitan hospitals agreed to participate in the study – Mt Druitt Hospital and Liverpool Hospital. Princess Margaret Hospital in Perth has also asked to participate in the study.

Work during next phase

Please comment on the work to be completed in the next 6 months of the project:
- Continued recruitment of patients and phone followup –this includes patients with mild, moderate and high risk of appendicitis. - Interim internal data audit check - Support metropolitan hospital ethics submission and data collection.

Publication

Please provide details of any publications, presentations or media attention related to this project:	
Reference details	Submitted or Accepted or Publication date
Not at this stage	

Expenditure

How much money has been expended in the course of conducting the research so far?	$ 69 500 salaries

HCF Research Foundation

Progress Report

Short Title:	iPASS

Progress report #:	Final report	Progress report date:	August 2016
Period covered by report:	Final report	Project ID	SDCHW201316

General Information

Project Title:	Investigating Paediatric Appendicitis Scores Study

Lay project description (100 words):

Appendicitis is the most common reason for emergency surgery in children but is difficult to diagnose. Doctors and parents want certainty about the diagnosis of appendicitis therefore more invasive and expensive investigations are performed and increasingly children are transferred to hospitals where expert paediatric surgical assessment is available. Not all children need these transfers or investigations. We aim to identify a scoring system that will recognise when a patient is at low risk and can safely go home without further investigation. This will reduce the need for some tests and the expense and inconvenience of transfer to a paediatric hospital.

Principal Investigator

Title:	Dr		
First name:	Mary	Last name:	McCaskill
Current appointment:	Medical Director Emergency		
Organisation:	The Children's Hospital at Westmead		
Department:	Emergency Department		
Organisation initials:	CHW		
Postal Address:	Locked Bag 4001 Westmead NSW 2145		
Phone:	02 9845 3519		
Email:	mary.mccaskill@health.nsw.gov.au		

Signature of applicant: 

Date: 22nd Aug 2016

Objectives and Timeline

Do you expect to complete the project as specified, either in the application or the most recent agreement with the HCF Foundation?	Yes
Do you expect to complete the project on schedule, either as indicated in the application or the most recent agreement with the HCF Foundation?	Completed

If the answer to either of the previous 2 questions is no, please provide reasons:

This is the timeline which was submitted for the project in the application. Please indicate how much of each objective has been met. If planned completion dates have changed, please add a new date.

Phase	**Objective/goal**	**Planned completion date**	**% of objective complete.**	**New completion date**
Preparation	Ethics submission and protocol development	31st Jan 14	100%	16th May 14
Preparation	Ethics approval	30th Mar 14	85%	8th Aug 14
Preparation	Literature review	28th Feb 14	100%	28th Feb 14
Preparation	Development of data collection tool	30 Mar 14	100%	30th Apr 14
Preparation	Education of clinical staff in use of score	30th Mar 14	85%	11th Aug 14
Data collection	Begin data collection	1st Apr 14	100%	11th Nov 14
Data collection	Audit data for quality and completion rate	1st Jun 14	0%	
Data collection	Complete data collection	30th Jun 15	completed	29th Feb 16
Data analysis	Analysis of data	30 Aug 15	Completed	31st Mar 16
Dissemination	Prepare paper for presentation and publication	30 Sep 15	Abstract written and submitted	30th July 16

Are there any new objectives?

Phase	**Objective/goal**	**Planned completion date**
	Additional data collection for patients with moderate to high risk who were discharged without surgery (Appendicectomy)	Completed

If timelines for the project have changed since the last report please provide reasons:

Recruitment

Is recruitment on track?	Completed recruitment
Number of participants recruited:	330 patients in low risk category 100 patients in moderate to high risk who were discharged without surgery
If recruitment is delayed, please provide reasons:	

General comments

Please comment on the progress so far:
The recruitment is now complete and data cleaning and analysis is in progress. The data analysis for the low risk patients has been completed and the writing of the paper for publication is in progress. The abstract for the low risk patients is submitted for oral presentation. Following are the results of the study in the low risk category Out of 330 patients, 290 were included in the final analysis. The rest were lost to follow up or refused consent. Out of the Of 290 low risk children, 7 (2.4%) needed surgery on initial presentation. Out of the 283 discharged patients, 24 (8%) had unplanned return to a hospital, with 5 of them needing unanticipated surgery (1.77%). The median time to representation was 23 hours. Out of the total 12 patients needing laparotomy, there were 7 cases of appendicitis, 3 with histologically normal appendix, 1 case of intussusception and 1 with fallopian cyst torsion. Our conclusion is that if a child has a low Paediatric Appendicitis Score it is safe for the child to go home for 12 hours before the next review.

Implementation

Please comment on work towards implementation that will ensure the greatest number of Australians are able to benefit from project outcomes:
Discussion of the project has generated interest in participating in further study and potential use of score within hospitals in metropolitan Sydney, in Melbourne and in Perth. There have been ongoing discussions with other hospitals. The discussions will be continuing after the final report for dissemination of the results. The data on moderate and high risk patients is still getting analysed and we are intending to prepare a paper for publication in peer reviewed journal. The work towards this paper will continue after the completion of this report.

Publication

Please provide details of any publications, presentations or media attention related to this project:	
Reference details	Submitted or Accepted or Publication date
Australasian College for Emergency Medicine Annual scientific meeting 2016 Risky Business Queenstown (ACEM ASM 2016)	Abstract submitted and attached

Expenditure

How much money has been expended in the course of conducting the research so far? The support has been much appreciated for this important work in the acute care of children.	$ 175,505.49

Outcomes

Clinical Practice Guideline

Possible Appendicitis Management Guideline©

DOCUMENT SUMMARY/KEY POINTS

- The document provides the basic clinical practice guidelines for the acute management of abdominal pain in paediatric patients by Emergency and Surgical teams.
- Model of care includes care in Emergency Department and in the Surgical Ward. It is a trial guideline and will be reviewed in August 2015.
- The guideline aims to care for these children in a streamlined and safe manner minimising undefined waiting and minimising time spent in hospital for the child.

NSW Ministry of Health Policy Directive

Children and Infants with Acute Abdominal Pain – Acute Management

http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_384.pdf

- The above linked document is a NSW Ministry of Health Policy Directive and requires mandatory compliance.
- SCHN contact people: Head of Emergency and Surgical Departments at CHW, NUM of Surgical Ward.

Introduction

Appendicitis is the most common surgical abdominal disorder in children over the age of 2 years[(1)]. Although the classical presentation of appendicitis is well described it can be difficult to diagnose as signs and symptoms often mimic other common but self-limited causes of abdominal pain[(2)]. The early and accurate diagnosis of appendicitis is of primary importance and may lead to decreased perforation rates[(3)].

Appendicitis is a clinical triad of:

1. Abdominal pain
    - Pain is central to the diagnosis
    - This is usually in the right iliac fossa but may be in the lower abdomen or centrally located and is usually a constant pain. It is demonstrated clinically by localised tenderness and rebound tenderness - elicited by pain on percussion or sudden movements e.g. jumping in the child
    - In cases of advanced or perforated appendicitis (i.e. peritonitis) this may be a diffuse constant pain

- The pain is usually associated with localised muscle rigidity when palpating the child's abdomen. This is present even though the child is otherwise distracted

2. Gastrointestinal disturbance
    - Includes anorexia - loss of appetite
    - Vomiting usually follows the onset of pain
    - Diarrhoea - not profuse but rather small frequent mucous-like stools
3. Inflammation
    - Fever - usually low grade especially in the early phase of the illness. Early high grade fever is not a common finding and often represents an alternative diagnosis
    - A high white cell count especially with a high neutrophil count may represent this inflammation in appendicitis but is not diagnostic

Paediatric Appendicitis Score

The Paediatric Appendicitis Score (PAS) is a tool that has been designed to help determine the likelihood of appendicitis in a child presenting with abdominal pain[4]. The total score is out of 10 points. Children who score 8 to 10 are likely to have appendicitis, between 5 and 7 have an intermediate probability and scores of 4 and less are unlikely to be associated with appendicitis[2].

As a local addition, in the initial stages of assessment in the Emergency Department a clinical sub-PAS is calculated comprising of 8 elements before blood tests are taken. Children with a score of 3 or above are thought to be at higher risk and warrant blood tests.

This scoring system has been incorporated into a process detailed in this document to guide management in the Emergency Department but does not replace clinical acumen. All cases for whom there are significant concerns about appendicitis should be discussed with senior Emergency Department or Surgical staff regardless of the PAS.

Table 1: Paediatric Appendicitis Score

Pain		
Migration of pain	1	
Right lower quadrant tenderness	2	
Cough / hopping / percussion tenderness in RLQ	2	
GI Symptoms		
Anorexia	1	
Nausea or vomiting	1	
Inflammation		
Fever >37.2 C	1	
Clinical Sub-PAS		**8**
White cell count >10,000	1	
White blood cell count >75% neutrophils	1	
PAS score		**10**

Risk level	Score
High risk score	Sub-PAS ≥6, PAS ≥8
Intermediate risk score	Sub-PAS 3-5, PAS 5-7
Low risk score	Sub-PAS ≤2, PAS ≤4

The score is calculated by allocating the following number of points for each named symptom or sign at the time of assessment. Initially the clinical sub-PAS is calculated using the first 8 elements out of a possible total score of 8. Blood tests FBC EUC are taken if the score is 3 or above or if there are significant concerns. The full PAS is then calculated out of 10.

All children who are seen in the Emergency Department with a possible diagnosis of appendicitis should be fully assessed and have a clinical sub-PAS calculated by Emergency staff. If the score is 3 or above the child needs blood tests taken. Local anaesthetic cream should be applied early in appropriate cases and bloods sent for analysis as soon as possible. All patients should receive analgesia. Those with a PAS of 5 or more should be referred to the surgical team for review given intravenous fluids and remain nil by mouth. A repeat PAS will be calculated as part of a review by the surgical team. This may point to improvement or deterioration in clinical signs.

Sepsis

If the child is septic on assessment (tachycardic, poorly perfused see Sepsis Pathway) antibiotics, intravenous fluids are given within the hour. This therapy should not be delayed and should occur in conjunction with urgent referral to the surgical team. Surgery will only proceed once the patient is appropriately resuscitated.

Sub-PAS ≥6, PAS ≥8

Children with sub-PAS of 6 or above or a PAS of 8 or above are more likely to have appendicitis. Early referral to the surgical team is needed while bloods are being processed. Decision on intravenous antibiotics and operative management is at the direction of the surgical team.

Sub-PAS 3-5, PAS 5-7

Children with intermediate sub-PAS 3-5 or PAS between 5 and 7 have blood tests taken, are placed NBM with IV fluids and are referred to the surgical team. It is likely they will require a period of observation before the need for appendicectomy become clear. See below for the management plan for these children. This management plan is decided by the surgical team.

Sub-PAS ≤2, PAS ≤4

Appendicitis is unlikely in cases where the sub-PAS is 2 or less or the PAS is 4 or less. These children can usually be managed in the Emergency Department with attention to potential medical diagnoses such as urinary tract infection and do not require early surgical review. The Ministry of Health guidelines on "Children and Infants with Acute Abdominal Pain-Acute Management" provides further advice about managing these patients.

Representations

Children who present twice within the same episode of illness with abdominal pain to CHW, or those who present to the GP, local hospital and CHW require a senior ED medical review to consider a surgical registrar review.

Overnight Surgical Review

Between 2300 and 0700 stable cases are cohorted for review by the surgical team in the morning. The overnight surgical registrar is called at 0630 and informed of the number of patients, type of conditions and likelihood of need for theatre. If they deteriorate at any stage an urgent surgical review is arranged. Patients are not sent to the ward without a surgical team review. The surgical registrar reviews the patients early to decide on disposition and informs ED NUM as well as ED doctor of outcome. This information is relayed to bed manager for 0730 theatre planning meeting.

Observation Period

After the surgical review some children will have an intermediate likelihood of appendicitis and need a period of observation to review the progress of symptoms. For observation the patient is admitted to the Surgical Ward after Surgical Team review. Overnight these children have routine observations done. They are given clear fluids and paracetamol for analgesia. They are reviewed by the surgical team on their morning round.

Morning Review

On review in the morning the child's signs and symptoms are re-evaluated.

- If they have settled the child is discharged home with follow-up by their GP.
- If they have developed signs of acute appendicitis they are placed NBM admitted/ remain admitted under the surgical team for surgery.
- If they require further observation for possible appendicitis, the patient is admitted /remains admitted under the surgical team. If an ultrasound would be helpful in determining the diagnosis the urgent appointments on the weekday ultrasound list at 10am and 10.30am and can be used for possible appendicitis.
- If their symptoms persist but are not of surgical aetiology the General Medical team is consulted.

Ultrasound

If abdominal ultrasound is required, aim to have it done in daylight hours unless the result is needed for urgent surgery. There are urgent ultrasound appointments for 10am and 10.30am each weekday. For the hour leading up to the scan give some intravenous or oral fluid and ask the child not to pass urine. This preparation will reduce the time taken to complete the scan.

Weekdays before 9.30am

- Consultant in ED Acute Obs decides on 2 cases needing urgent ultrasound in ED or Surgical Registrar identifies possible appendicitis case on Surgical Ward.
- Powerchart request completed including contact number for result
- Call Radiologist/ radiology Reg on for ultrasound to confirm need for investigation– Ext 52880
- Fill bladder in preparation
- (Let Sonographer know on Ext 51250 if patient needs to void)
- On weekends or evenings call the radiologist on call.
- Send patient to ultrasound at appointed time
- Radiologist calls Admitting Officer Ext 52454 or Surgical Reg with verbal report
- Check Powerchart for report 30 mins after patient returns to ED if no phone call to Admitting Officer
- If report not on Powerchart call radiologist on for ultrasound to discuss findings

Ovarian Torsion

Torsion of the ovary is an uncommon diagnosis but is an alternative to be considered in abdominal pain especially in teenage girls. If there are signs of peritonitis or guarding then urgent treatment may be required and therefore urgent imaging is indicated. In cases where torsion of the ovary is considered a possibility but signs of peritonitis and guarding are absent it is reasonable to observe overnight and review the following morning. Imaging by ultrasound of these possible cases can be considered in daylight hours.

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1. Clinical outcomes of children with acute abdominal pain. Scholer, S J, et al., et al. s.l. : Pediatrics, 1996, Vol. 98.
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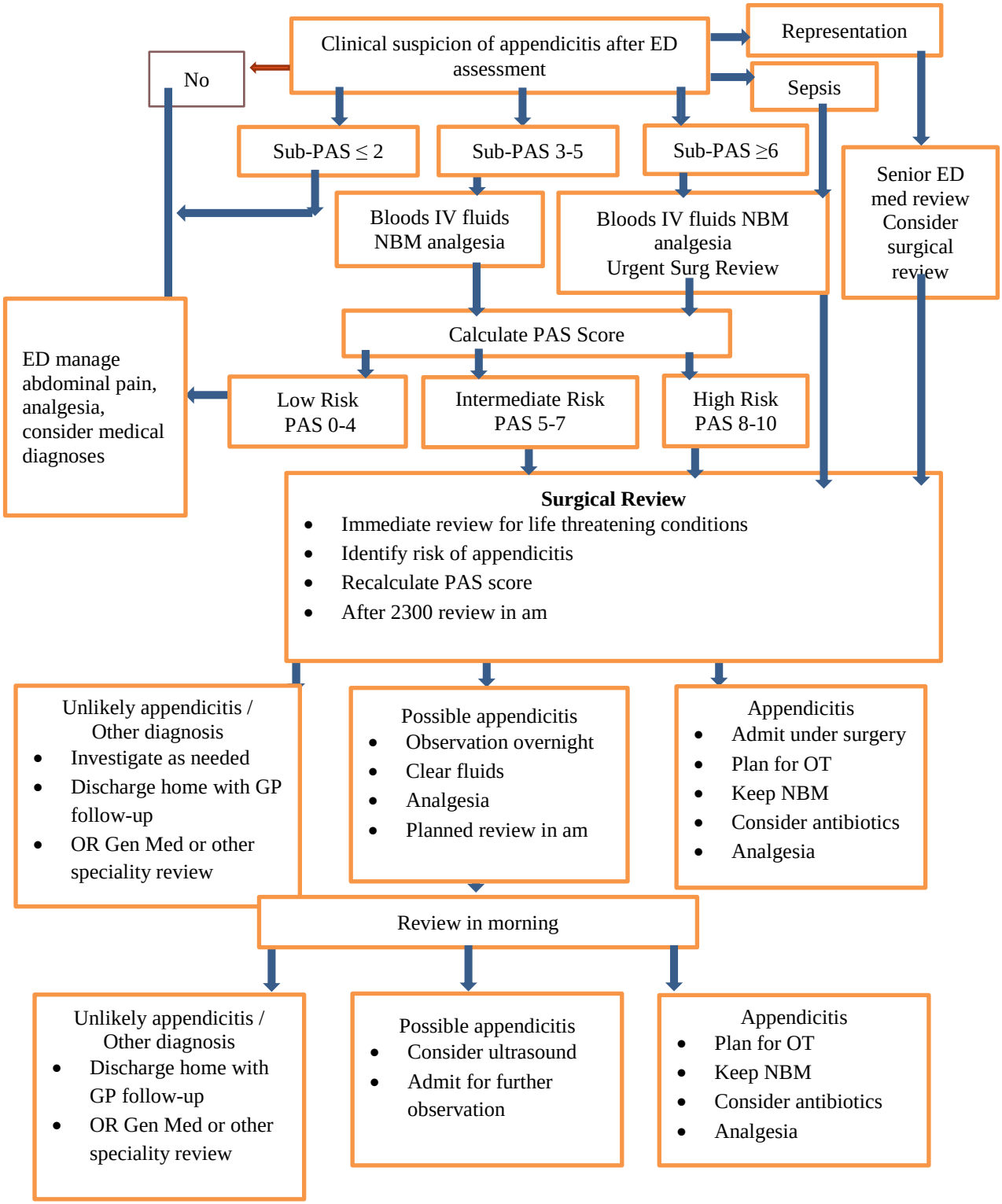
Diagram 1: Process for managing children with possible appendicitis in Emergency Department (ED)



Presentation

Abstract Post Presentation ACEM ASM

Presenter

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Title

Tummy Pain in Children – using a risk assessment tool.

Funding

Supported by HCF Research Foundation

Background:

Acute abdominal pain in children is a common presentation to EDs. These patients receive many investigations, specialist review sometimes requiring transfer. The aim of the study was to include a clinical decision rule to stratify risk and embed that in a model of clinical care.

Objectives

- Facilitate safe discharge of patients at low risk of appendicitis.
- To identify the number of with false negative patients.
- Quantify parental satisfaction of the model of care.

Method:

A prospective observational study of children (5 to 16 years) presenting with abdominal pain with clinical suspicion of appendicitis. Patients were identified as low risk using the Paediatric Appendicitis Score[1]. Primary outcome was discharge from ED without unanticipated diagnosis of appendicitis within 2 weeks. Parents were contacted to check if they had visited another facility and to rate their care.

Results:

Of 290 low risk children, 7 (2.4%) needed surgery on initial presentation. Of the 283 discharged patients, 24 (8%) had unplanned return to a hospital, with 5 of them needing unanticipated surgery (1.77%). The median time to representation was 23hours. Of 12 patients needing laparotomy, there were 7 cases of appendicitis, 3 with histologically normal appendix, 1 case of intussusception and 1 with a fallopian cyst torsion.

Parents were generally confident with the model of care in 174 out of 210 available responses (83%).

Conclusion:

This model of care uses a risk stratification tool and safely identifies children at low risk of appendicitis.

Draft Publication

Introduction

Appendicitis is the commonest paediatric surgical presentation to Emergency Departments. Making a correct and early diagnosis is important because delayed diagnosis of appendicitis can lead to complications and major consequences associated with it. It is also important to recognize benign presentations with acute abdominal pain which settle without intervention, and are unlikely to be appendicitis. These admissions pose the risk of major burden on the health system including unnecessary investigations, long waiting times and possible transfers to tertiary level hospitals for specialist review. Admission of a child also had a significant impact on families.

Though the diagnosis of appendicitis is largely clinical, investigations such as urinalysis, blood tests and imaging may be helpful to make a diagnosis. They also help ruling out other possible diagnoses which may mimic the presentation of appendicitis. Large numbers of studies have shown that there is no way of correctly identifying all patients in need of surgical intervention for appendicitis in an acceptable timely manner.

In recent years, inclusion of clinical decision rules in the standard pathway of assessment has been suggested to address the situation. Again, many different rules exist and their use has been variable. The two best known and most studied decision rules for acute appendicitis are the Alvarado score and the Paediatric Appendicitis Score (PAS). A recent review by Kulik concluded that a high quality, well validated, and consistently high-performing clinical decision rule for acute appendicitis could not be identified. It has been suggested that further research should aim at stratifying the children presenting with possible appendicitis into clinical risk groups to determine the best method of management.

Using this strategy, a model of care was constructed using the paediatric appendicitis scores (PAS) to stratify children presenting with abdominal pain and in whom appendicitis was considered as a differential diagnosis. The focus of this study was on the safety of early discharge of patients at low risk of appendicitis.

Study design

This was a prospective cohort study. We describe the performance of the model of care for patients presenting to emergency department for assessment of possible appendicitis with a low risk of appendicitis as measured by the treating clinician using clinical practice guideline incorporating use of Pediatric appendicitis score as risk stratifying tool.
The medical professionals could deviate from the guidelines as needed based on the clinical judgment irrespective of the risk assessment based on the scores.

The study was reviewed by the institutional review board and ethics approval was granted. The pre-existing electronic template for documenting the PAS was modified to document parental consent for the study.
All junior and senior medical staff were educated about the ED guidelines, the study protocol and the modified template in the ED electronic database (Health-e-care). The information about the appendicitis score and the e-template was displayed in important clinical areas for easy access and as a reminder of the study.

Any patient between the age of 5 and 16 years of age presenting to the Emergency Department at The Children's Hospital at Westmead with abdominal pain with clinical suspicion of appendicitis with a low risk for appendicitis based on

PAS score≤4 was eligible for inclusion in the study. Patients felt to be likely to have other causes for abdominal pain on initial examination such as gastroenteritis and those who already had an appendectomy were excluded. The medical professionals could deviate from the guidelines as needed based on the clinical judgment irrespective of the risk assessment based on the scores. The history, examination and PAS were recorded in the ED database by the medical professional examining the child. The scores were divided into clinical (sub-PAS) and investigational (blood test) components, to give a complete PAS. The children were managed according to the clinical guideline based on the PAS derived risk of appendicitis.
The parents of children who were discharged home as low risk of appendicitis were reassured and educated with verbal and written instructions to present back if deteriorating or experiencing persistant symptoms. Parents were informed of the study and consented for data collection and follow up a phone call. The consent was documented in the electronic template.

Fig. 1 Template

The patient has the following score for abdominal pain
0 if feature absent
1 or 2 (as indicated) if feature present

PAIN
- Migration of pain to RLQ ___ / 1
- Right lower quadrant tenderness ___ / 2
- Cough/hopping/percussion tenderness in RLQ ___ / 2

GI SYMPTOMS
- Anorexia ___ / 1
- Nausea or vomiting ___ / 1

INFLAMMATION
- Fever >37.2 C ___ / 1

Clinical Subtotal ____ / 8 (Sub-PAS)

- WCC>10,000 ___ / 1
- Neutrophils >75% ___ / 1

TOTAL ___ / 10 (PAS)

RISK LEVEL
HIGH 6-8/8 clinical subtotal 8-10/10 total score
MODERATE 3-5/8 clinical subtotal 5-7/10 total score
LOW 0-2/8 clincial subtotal 0-4/10 total score

Clinical impression of likelihood of appendicitis (unlikely / likely / very likely / unsure)

Parent/Guardian consent for iPASS data collection and follow up phone call within 2 weeks of presentation (Yes/No/Not asked)

Data was extracted from the ED database into excel sheet each week for abdominal pain as presenting complaint and/or PAS scores documented using the e-template. Data was reviewed by the investigator to confirm the history, clinical findings and PAS scores. The patients who were discharged as low risk for appendicitis were enrolled in the study. Rest of the patients were classified as at high risk (with high scores)/alternative diagnoses/no clinical suspicion of appendicitis/possibly missed.

The charts of individual patients enrolled as low risk of appendicitis were reviewed by one of the investigators using the health-e-care for clinical information and Powerchart for laboratory investigations.

Those parents, who had not been consented but eligible, received a phone call and a verbal consent was requested. The data was included and follow up completed only if consent was obtained.

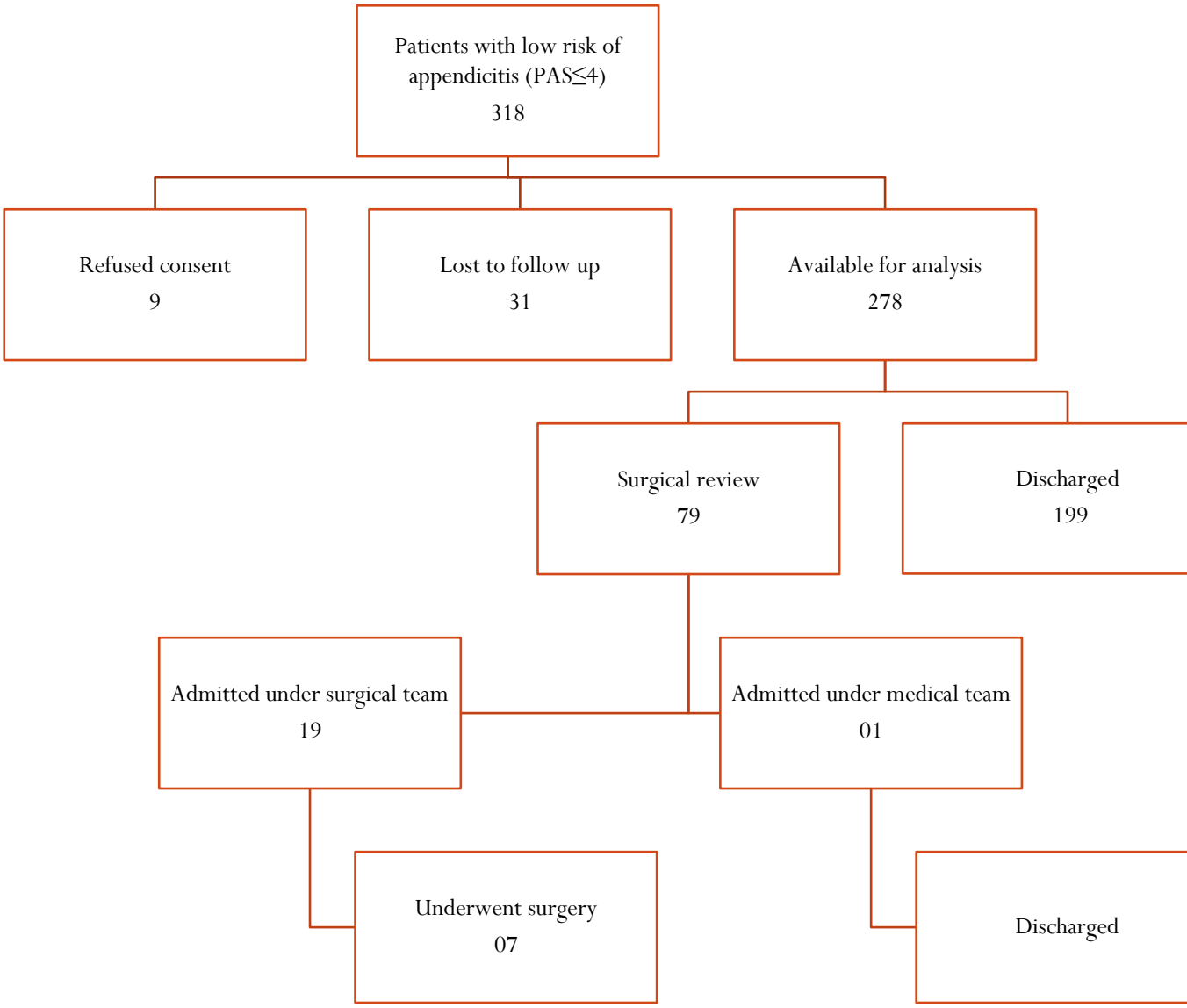
A follow up phone call was made according to the scripted format approved by ethics committee. The phone calls were made after at least 2 weeks of discharge, up to 3 months or maximum of 6 phone call attempts. After this time if no follow up was obtained they were considered lost to follow up. On follow up, parents were asked about the outcome and also requested to rate their experience in pain management, ED medical assessment and confidence on the model of care.

The primary outcome was return to hospital within 24 hours of discharge from the emergency department.

The secondary outcomes were rate of overnight admission, need for IV antibiotics, need for surgical intervention, time to re-presentation and parental satisfaction of the model of care.

Results

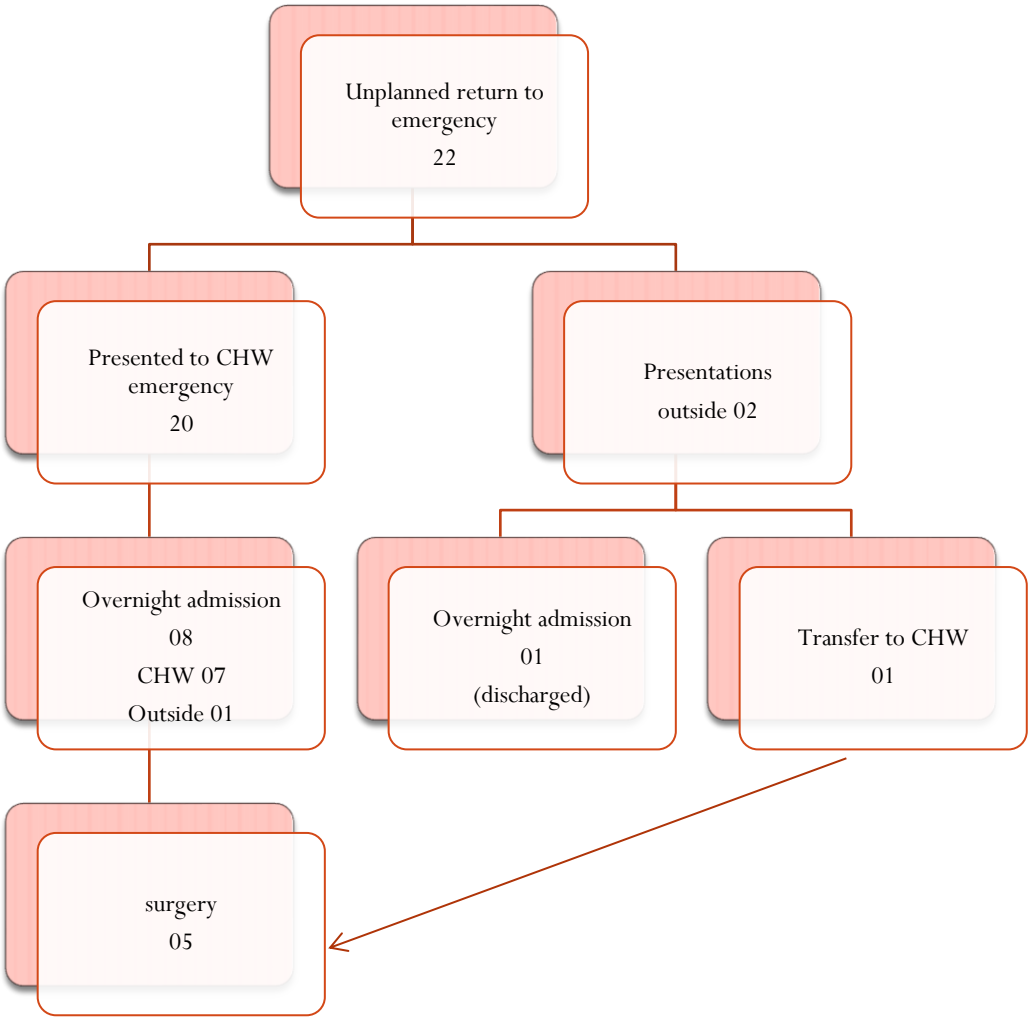
Out of 318 patients with low risk of Appendicitis, 9 refused consent and 36 were lost to follow up, leaving 283 patients' data available for analysis.



Only about 28% patients presenting to Emergency Department needed surgical review and a fourth of those were admitted to Hospital.
7 patients had ongoing signs on surgical review which warranted exploration. 4 of them had acute appendicitis histologically, 1 had torsion of the fallopian cyst and 2 had histologically negative appendectomy.

276 out of the enrolled 283 patients were eventually discharged home without needing surgery.
One patient was advised to return for Ultrasound the next morning (planned return), which was negative for appendicitis and the patient was discharged home. 23 of the patients discharged without surgery had unplanned return to Emergency, 20 to CHW and 3 to peripheral hospitals. 5 of them underwent surgery, 04 for appendicitis and 1 for intussusception. Out of the 4

appendectomies performed, 1 was histologically negative. The shortest time of representation was 9 hours.



About 8 % of the patients discharged from Hospital returned to Emergency for review, about 3% of those needing overnight admission and 1.6% needing surgery.
The times of re-presentations varied from 6 hours, 33 min to 8 days, 10 hours and 15 minutes. The median time of re-presentation was 23 hours.

The times of re-presentations of those who had surgery were 09:20 to 55:47 Hrs.