



#### The Right Iliac Fossa pain Treatment (RIFT) Audit

Study protocol v3.5 (**Italian Version**) – **Protocollo in Versione Originale** 9<sup>th</sup> January 2017



Protocol release Local audit registration period: Data collection periods: Key Dates

December 2016 December – March 2017 (1) 13 – 26 March 2017, (2) 24 April – 7 May 2017 (3) 5 – 18 June 2017,

In Italy endorsement by

#### WSES ITALIAN CHAPTER



ITALIAN SOCIETY OF COLORECTAL SURGERY







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Further additional resources can be found at the Italian RIFT study online hub: <u>http://itsurg.org/</u>





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## Acknowledgements

We are grateful to the following experts who have supported the design of this protocol.

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## **Project timeline**

1 Dec 2016	Protocol launch (UK version)
9 Jan 2016	Protocol launch (Italian version)
Dec 2016 – Feb 2017	Local pilots Recruitment of participating centres and local teams Local audit registration and local pilots
Feb – July 2017	Local audit registration deadline February 2017 Issue of data collector REDCap logins 1 <sup>st</sup> Data collection period March 13 <sup>th</sup> – 26 <sup>th</sup> 2017 <i>follow up ends April 27<sup>th</sup> 2017</i> 2 <sup>nd</sup> Data collection period April 24 <sup>th</sup> – May 7 <sup>th</sup> 2017 <i>follow up ends June 8<sup>th</sup> 2017</i> 3 <sup>rd</sup> Data collection period June 5 <sup>th</sup> – 18 <sup>th</sup> 2017 <i>follow up ends July 19<sup>th</sup> 2017</i>
	N.B. patients who are not operated on index admission should be followed-up to 30-days post index admission date
May 2017	Data validation protocol released
July 2017	Data validation deadline July 30 <sup>th</sup> 2017 REDCap database locked, final data submission deadline
July – Nov 2017	Data analysis and write up Conference abstract submissions Manuscript submission





## Introduction

**Background:** There is significant variation in the management of patients with right iliac fossa (RIF) pain. Whilst laparoscopy has become first line in many units, the 2012 UK National Appendicitis Audit identified that a third of appendicectomies at that time were being performed using an open approach<sup>1</sup>. The results of this study were widely presented at local units and national meetings as well as being published in several journals.

**New Guidelines:** New guidelines published by the World Society of Emergency Surgery (WSES) in 2016<sup>5</sup> and the European Association of Endoscopic Surgeons (EAES) in 2015<sup>6</sup> provide an opportunity to close the loop on the 2012 audit and to re-audit the modern management of RIF pain.

**Aim**: The primary audit aim is to determine the laparoscopic appendicectomy rate in 2017. The secondary aim is to audit the normal appendicectomy rate. Variation in centres' case mix may influence the normal appendicectomy rate. Patients can be stratified into low, medium, and high risk for appendicitis using the Alvarado or Appendicitis Inflammatory Response (AIR) scores (see Appendix D). Baseline variation will be addressed by adjustment using risk scoring.

## **Audit Standards**

1) An initial laparoscopic approach should be used for appendicectomy unless contraindicated [WSES Statement 5.1]<sup>5-7</sup>.

2) The normal appendicectomy rate should be  $<20\%^1$ . For centres with higher or lower rates, risk stratification data will allow interpretation of this rate in relation to the baseline case-mix.





### Methods

#### 01

#### **Collaborative Teams**

Collection periods: (1)  $13^{th} - 26^{th}$  March 2017; (2) April  $24^{th} - May 7^{th} 2017$  and (3) June  $5^{th} - 18^{th} 2017$ . All consecutive eligible patients within the chosen data collection period should be included. Each centre, should aim to have mini-teams to cover at least 2 among 3 data collection periods but if only one period can be accommodated then the local team can choose which period is preferable to them.

All data collectors, local leads, supervising consultants, data validators, regional leads and steering committee members will be eligible for PubMed-citable collaborative co-authorship.

<u>Steering Committee:</u> a core group of foundation doctors and surgical trainees responsible for protocol design, data handling, analysis and drafting of the paper. The Steering Committee are responsible for use of data resulting from the project.

<u>Regional leads:</u> a network of collaborators across Italy responsible for co-coordinating teams at local hospitals. The regional leads act as a link between local teams and the steering committee. They are the first point of contact for local collaborators. To qualify for authorship, regional leads must recruit at least eight mini-teams.

<u>Mini-teams</u>: each local centre requires one supervising consultant and up to two mini-teams. Each mini-team should be made up of 1-3 collaborators. Collaborators are responsible for identifying eligible patients and collecting baseline and follow-up data. One collaborator should be selected to act as the 'local lead'.

A maximum of 3 (junior doctors or medical students) collaborators per 14-day data collection/ follow-up period will be listed as 'PubMed' citable authors unless otherwise agreed in advance by the RIFT committee. In exceptional circumstances where local teams anticipate a very high volume of patients being eligible for inclusion in RIFT, they may contact the RIFT committee for permission to add an additional collaborator to their team.

## Two mini-teams can participate at each centre, each collecting data during distinct data collection periods.

Local leads: each centre will require 1 collaborator to act as the "local lead". The lead is responsible for: 1) ensuring the RIFT audit is registered locally; 2) making contact with the supervising consultant; 3) sending the steering committee the contact details of the mini-team collaborators from their centre; and lastly, 4) making sure all deadlines are met and data submitted from their centre. These individuals will be listed in the final authorship as local leads, in recognition of their contribution.

<u>Data validator</u>: one junior doctor may act as an independent data validator at each site. They should not have participated as part of the original 'mini-team'. Their role is to assess if all eligible patients were included from their centres. These individuals will be listed in the final authorship as data validators.

<u>Consultant surgeon</u>: one consultant per centre is eligible for collaborative PubMed citable coauthorship if they meet the following criteria: 1) Supports local audit registration; 2) Circulates information about the audit and the audit protocol to consultant colleagues; 3) Facilitates presentation of local audit results at a departmental audit meeting; 4) Completes workplacebased assessments for trainees, if asked. Consultants should ensure collaborators act in





accordance within governance guidelines and should facilitate implementation of post-audit interventions, if required.

<u>International collaboration</u>: in parallel with similar networks in the UK and in the Netherlands, a surgical network (ItSurg) in Italy will roll out this protocol and this group will be responsible for all aspects of running the study.

#### 02

#### **RIFT: A Closed Loop Audit**

RIFT will re-audit the findings of the 2012 National Appendicectomy Audit. The results of this audit have been disseminated in Europe's highest impact surgical journal<sup>1</sup> (*British Journal of Surgery*) and presented at both local and national surgical meetings (including *Association of Surgeons of Great Britain and Ireland*). This dissemination of results provides an intervention following the initial audit, with enough time passing to now re-audit and close the loop. New European guidelines published this year by the European Association of Endoscopic Surgeons (EAES) and the World Society of Emergency Surgery (WSES) provide an additional opportunity to audit against published standards<sup>5, 6</sup>. The results of the closed loop audit will be disseminated through:

- Local presentations teams at all centres will need to provide the contact details of the local consultant supervisor and the local audit officer.
- Publication in a major surgical journal.
- Presentation at regional and national meetings.

Publications and national presentations will not identify individual hospital performance.

#### 03

#### Centres

- Any hospital that performs emergency appendicectomy may participate.
- All participating centres are required to register the RIFT audit according to local regulations. Confirmation of successful registration will be required prior to issue of REDCap logins.
- Two permanent contacts at each hospital are required (consultant and audit officer) to return hospital specific results.

Providing feedback on the audit's findings to your department's clinicians is an
 essential step in the audit loop. Presenting local results will help collaborators develop analytical and presentation skills and will boost their CVs.

#### 04

#### **Inclusion Criteria**

- All consecutive patients referred to general surgeons with undifferentiated right iliac fossa pain or suspected appendicitis.
- All patients who undergo an appendicectomy during the study period.

#### **Exclusion Criteria**

- Previous appendicectomy or right hemi-colectomy.
- Previous abdominal surgery in the last 90 days.
- Pregnancy.
- Patients aged less than 18 years should not be included.
- You should collect data on <u>all</u> consecutive patients who are referred to general surgeons for RIF pain or suspected appendicitis.





Strategies to identify consecutive patients could include:

- Daily review of patients seen in the surgical assessment unit.
- Daily review of handover sheets/ emergency admission and ward lists.
- Daily discussion with the surgical assessment or on-call team.

#### 05

#### **Outcome Measures**

The primary outcome measure is the rate of laparoscopic appendicectomy. The audit standard is provided by the World Society of Emergency Surgery's Jerusalem Consensus Guidelines (WSES, 2016, Statement 5.1.1) which states that "laparoscopic appendectomy should represent the first choice where laparoscopic equipment and skills are available, since it offers clear advantages in terms of less pain, lower incidence of surgical site infection, decreased length of stay, earlier return to work and overall costs<sup>2</sup>.

#### Secondary outcome measures

The secondary outcome measure will be the normal appendicectomy rate. The National Appendicectomy Audit (2012) reported the rate as 20.6% for the UK<sup>1</sup>. Centres should have a normal appendicectomy rate <20%. Risk stratification data using Alvarado/ AIR score (see Appendix D) will allow interpretation of individual centres' rates in light of their baseline casemix.

#### 06

#### **Data Collation**

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. Collaborators will be given secure REDCap project server login details, allowing secure data storage on the REDCap system. **No** patient identifiable information will be collected. Collaborators may wish to first record data on a paper version of the data collection pro-forma. Paper copies of any data should be destroyed as confidential waste within the centre once uploaded to REDCap.

#### 07

#### Follow Up

Patients who do not undergo appendicectomy on index admission, should be followed-up to 30-days following index admission date, reviewing the hospital data systems (e.g. pathology results systems, new admissions) in order to facilitate follow-up and collection of histology data at 30 days.

80

#### Local Project Registration & Data Governance

It is the responsibility of the local team at each site to identify a local supervising consultant surgeon and to ensure that RIFT is registered appropriately.

- RIFT will measure current practice against established standards.
- RIFT closes a national audit loop.
- No changes to normal patient pathways/ treatment will be made.
- RIFT is a national audit.

REDCap accounts will <u>not</u> be issued until evidence is sent to the RIFT Study Group showing the successful registration of RIFT according to the local rules.





You **must** have confirmation of successful audit registration prior to commencing data collection. If you encounter difficulties with registering the study, seek advice from your supervising consultant, your local lead, or the WMRC steering committee.

#### 09 Quality Assurance

#### Protocol

This protocol was produced with guidance from an expert advisory group. Audit standards and audit methodology were refined following extensive discussion at WMRC meetings. ItSurg group approved the protocol, realizing a version adequate for the italian context.

#### Pilot

Participating centres may pilot patient identification and the initial stages of data collection, including use of REDCap, for <u>one day</u> in the week leading up to their data collection start date. Any problems identified should be addressed by discussion with the steering committee.

#### Data completeness

Following data collection, only data sets with  $\geq 95\%$  data completeness will be accepted for pooled national analysis. Centres with  $\geq 5\%$  missing data points will be excluded and collaborators from those centres withdrawn from the published list of citable collaborators.

#### Validation

At each participating hospital centre, the local lead will identify a collaborator not involved in data collection to act as an <u>independent validator</u>. The validator should be a qualified doctor.

The validator will use hard copy and/or electronic resources to ensure that all eligible patients for RIFT during the study period(s) were included at their centre. A detailed data validation protocol will be released in May 2017.

#### 10

#### Sample Size

Sample size is projected to include approximately 150 centres in all participating countries. It is expected that not every site will take part in each data collection period. We estimate that each hospital will see an average of ten patients with RIF pain each week. We estimate that an average of 80 centres will take part in each data collection period. Using the estimate of 20 patients per hospital per data collection period, we expect to recruit approximately 4800 patients.

#### 11

#### Data Analysis

The statistical methodology for this national audit have been discussed with expert statisticians. The data will be analysed using descriptive methods, multi-logistic regression models and will be used to produce the sensitivity, specificity, negative predictive value and positive predictive value for the Alvarado and AIR scores.

Non-operative management of appendicitis will be defined as patients with CT proven appendicitis who undergo first line therapy with antibiotics with no plan for surgery. Patients who do not undergo appendicectomy within the subsequent 30 days will be classed as successfully managed non-operatively. Patients who require appendicectomy within 30-days of index date of admission despite initial planned non-operative management will be defined as having failed non-operative management.





## **Appendix A: Data Definitions**

	Data Criteria	Data Options	Data Definition
	graphics and clinical findin		
1	Patient sex	<ul><li>Male</li><li>Female</li></ul>	
2	Patient age	Enter age (years)	Anyone over 5 years old
3	Previous abdominal surgery	<ul><li>No</li><li>Yes</li></ul>	
4(a)	Previous acute inpatient admissions with RIF pain	<ul><li>No</li><li>Yes</li></ul>	Any previous hospital presentation with RIF pain or generalised abdominal tenderness
4(b)	How many previous admissions for RIF pain?	Number	Branching question which will only appear if 4(a) is "yes"
5 (a)	Day of admission	<ul> <li>Monday</li> <li>Tuesday</li> <li>Wednesday</li> <li>Thursday</li> <li>Friday</li> <li>Saturday</li> <li>Sunday</li> </ul>	
5 (b)	Time of admission to SAU	<ul> <li>0800 - 1700</li> <li>1701 - 2200</li> <li>2201 - 0759</li> </ul>	
5 (c)	Duration of symptoms	<ul> <li>0 days (&lt;24hr)</li> <li>1 day</li> <li>2 days</li> <li>3 days</li> <li>4 days</li> <li>5 days</li> <li>6 days</li> <li>7+ days</li> </ul>	Time from onset of symptoms to presentation at hospital on this admission.
5 (d)	Was this patient referred to this unit from another centre?	<ul><li>No</li><li>Yes</li></ul>	Did this patient attend another centre that was unable to manage them and then referred them to the current centre for acute management?
6	Was an appendicitis risk score used by clinical team?	<ul> <li>None</li> <li>Alvarado</li> <li>AIR</li> <li>Other</li> </ul>	
7	Urinalysis	<ul> <li>Not tested</li> <li>Positive</li> <li>Negative</li> </ul>	Positive urinalysis if either leucocytes <b>or</b> nitrites are detected - any quantity above 'trace' should be taken as a positive finding.
8	Nausea	<ul><li>No</li><li>Yes</li></ul>	Documented in A&E or surgical clerking prior to investigation or operation
9	Vomiting	<ul><li>No</li><li>Yes</li></ul>	Anorexia is defined as a loss of appetite or
10	Anorexia	■ No ■ Yes	reduced oral intake
11	RIF pain	■ No ■ Yes	
12	Migration of pain to RIF	■ No ■ Yes	
13	Rovsing's sign positive	<ul><li>No</li><li>Yes</li></ul>	If palpation in the left lower quadrant increases the pain felt in the right lower quadrant, then the patient is "Rovsing's sign positive".
14	RIF tenderness on examination	■ No ■ Yes	
15	Rebound tenderness or guarding	<ul> <li>None</li> <li>Mild</li> <li>Moderate</li> <li>Severe</li> </ul>	Mild: tender but soft Moderate: tender +/- local guarding Severe: very tender +/- generalised guarding/ peritonism





16	Highest recorded temperature	Enter value (°C)	Documented in A/E or surgical clerking or on observation sheets or nursing notes prior to investigation or operation
Preop	erative blood tests		
17(a)	Highest preoperative white blood cell count	Enter value (x10 <sup>9</sup> /L)	Documented in clerking or electronic laboratory
17(b)	Neutrophil count at the time when highest WBC count recorded	Enter value (x10 <sup>9</sup> /L)	results prior to investigation or operation
17(c)	Highest preoperative CRP	Enter value (mg/L)	
	erative imaging		
18(a)	What pre-operative imaging was performed?	<ul> <li>Ultrasound scan</li> <li>CT scan</li> <li>MRI</li> <li>None performed</li> </ul>	Leave blank if none performed
18(b)	Ultrasound: appendicitis	<ul> <li>Appendicitis confirmed</li> <li>Equivocal</li> <li>Appendicitis ruled out</li> </ul>	Branching logic, this will appear for each imaging modality selected in 18(a)
18(c)	Ultrasound: other pathology	Options will mirror diagnostic categories in Q21	
18(d)	CT: appendicitis	<ul> <li>Appendicitis confirmed</li> <li>Equivocal</li> <li>Appendicitis ruled out</li> </ul>	
18(e)	CT: other pathology	Options will mirror diagnostic categories in Q21	
18(f)	MRI: appendicitis	<ul> <li>Appendicitis confirmed</li> <li>Equivocal</li> <li>Appendicitis ruled out</li> </ul>	
18(g)	MRI: other pathology	Options will mirror diagnostic categories in Q21	
Manag	gement and follow up		
19	Planned first line non- operative management of appendicitis with <b>no</b> <b>initial plan</b> for surgery	<ul> <li>No</li> <li>Yes – discharged having not had surgery</li> <li>Yes – but required inpatient operation on index admission</li> </ul>	Planned non-operative management: the patient was treated for a <b>diagnosis of appendicitis</b> with <b>antibiotics</b> with <b>no</b> plan for surgery. If antibiotics were started at the time that a decision for surgery was made or after the decision was made, this should not be recorded as planned non-operative management. If planned non-operative management failed and a decision was later made to operative, record this as 'required inpatient operation'.
20	Was an operation performed on index admission?	■ No ■ Yes	
21	Discharge diagnosis following index admission	<ul> <li>Appendicitis</li> <li>Colorectal cancer</li> <li>Crohn's</li> <li>Gastroenteritis</li> <li>Hernia</li> <li>Intra-abdominal abscess</li> <li>Meckel's diverticulum</li> <li>Mesenteric adenitis</li> <li>Mesenteric thrombosis</li> <li>Other GI diagnosis</li> <li>Ectopic pregnancy</li> <li>Endometriosis</li> <li>Ovarian cyst</li> <li>Pelvic inflammatory</li> </ul>	Documented in discharge summary





	1		
22	Length of stay of the	disease <ul> <li>Other gynaecological</li> <li>Urinary tract infection</li> <li>Renal calculi</li> <li>Other urological</li> <li>Non-specific findings/ abdominal pain</li> </ul> Enter value (days)	From time of referral to the general surgeons to
22	index admission	Line value (uays)	the time of discharge.
23(a)	30 day follow up: Was this patient readmitted with ongoing symptoms related to the RIF pain?	<ul><li>No</li><li>Yes</li></ul>	Branching logic, this will only appear for patients who were not operated on index admission Documented in electronic records Do <b>not</b> include readmission with unrelated presentations (eg chest pain)
23(b)	If readmitted, did they undergo surgery?	<ul><li>No</li><li>Yes</li></ul>	
Appen	dicectomy		
24	If underwent surgery on	ndex admission or re-admission, b	oranching logic for 24(a)-(i)
24(a)	What was the highest grade of surgeon who made the decision to operate?	<ul> <li>Consultant/ post CCT fellow</li> <li>SpR/ middle grade</li> <li>CT/ SHO equivalent</li> <li>FY1</li> </ul>	The most senior surgeon or trainee who is documented as making the final decision to operate.
24(b)	At which point was the decision made to operate?	<ul> <li>&lt;1h</li> <li>1 - 6h</li> <li>6 - 12h</li> <li>12 - 24h</li> <li>24 - 48h</li> <li>&gt;48h</li> </ul>	Time from admission to SAU to the decision being made to operate
24(c)	When was the operation performed?	<ul> <li>&lt;1h</li> <li>1 - 6h</li> <li>6 - 12h</li> <li>12 - 24h</li> <li>24 - 48h</li> <li>48 - 72h</li> <li>72 - 96h</li> <li>&gt;96h</li> </ul>	Time from admission to SAU to the start of the operation
24(d)	Operative approach	<ul> <li>Laparoscopic</li> <li>Laparoscopic converted to open</li> <li>Open RIF incision</li> <li>Open midline incision</li> </ul>	Documented in operation note or discharge summary. Please select the most appropriate option with regards to operative technique
24(e)	If open approach, what was the reason for the open approach?	<ul> <li>Patient preference</li> <li>Previous surgery</li> <li>Local policy for adults</li> <li>Local policy for children</li> <li>Consultant preference</li> <li>Trainee preference</li> <li>Theatre capability/ equipment availability</li> </ul>	Documented in the operation note or discharge summary.
24(f)	Procedure completed	<ul> <li>Diagnostic procedure only</li> <li>Appendicectomy</li> <li>Other procedure</li> </ul>	
24(g)	If other procedure performed, what was it?	<ul> <li>Right hemicolectomy</li> <li>Meckel's Diverticulectomy</li> <li>Small bowel resection</li> <li>Other bowel surgery</li> </ul>	





24(h)	If appendicectomy performed, <u>macroscopic</u> intraoperative appearance of appendix	<ul> <li>Gynaecological procedure</li> <li>Urological procedure</li> <li>Other</li> <li>Simple appendicitis (non-perforated)</li> <li>Complex appendicitis</li> <li>Normal appendix</li> </ul>	Documented in operation note Simple appendicitis: injected/ inflammed appendix that does not have 'complex' features Complex appendicitis: perforated, purulent or necrotic appendix Normal appendix: may be described 'lily white'
Histold 24(i)	<i>bgy</i> If appendicectomy performed, appendix <u>histology</u>	<ul> <li>Normal histology</li> <li>Simple appendicitis (non-perforated)</li> <li>Complex appendicitis (perforated, purulent)</li> </ul>	Documented in histology report
		<ul> <li>Adenocarinoma</li> <li>Carcinoid</li> <li>Mucocele</li> <li>Crohns</li> <li>Other</li> </ul>	

- 1. Contact your **regional lead** or the Italian steering committee (<u>itsurg.group@gmail.com</u>) about participation in the RIFT study at the centre of your choice. They will connect you to any other interested doctors.
- 2. Form a team of up to 3 collaborators. Agree who will act as the 'local lead'.
- 3. Liaise with supervising consultant.
- 4. Register the audit. See Appendix C for confirmation that RIFT should not be treated as research and may be registered as audit. Ensure that you secure formal audit approval from your hospital's clinical audit department <u>prior</u> to commencing data collection. *This may seem daunting at first* but is in fact quite straight forward. Every hospital has an audit department and it is a simple case of approaching them with the information we have prepared in this protocol, and applying this to the local audit registration form. You will need a consultant surgeon to support you and sign the hospital's audit form. Ensure that the audit department know that this is part of a *national project* and that you will enter anonymised data on REDCap.

It is essential that you begin this process immediately; approval can take up to a month. You may have to contact or even visit the hospital before your placement starts to ensure that you will be ready. If you have any difficulties contact your local lead, regional lead, your supervising consultant or the steering committee.

- 5. Once the study is approved, please forward evidence of this to the Italian steering committee (<u>itsurg.group@gmail.com</u>). REDCap accounts will be issued after communication of ethics approval is received.
- 6. Arrange to **meet** with the other members of your mini-team, including if possible, supervising consultant. Talk through how you will identify patients and collect required data, it will be particularly helpful if the consultant is present to offer guidance regarding this. A "Whatsapp group" may be helpful for organising the team.
- 7. Complete a **practice pilot** audit day: Complete one day of audit at your centre in the week prior to the main start day. This will allow you to become familiar with the best way to identify patients, and data collection methodology. Contact us with any queries from the day. This will allow the steering committee to iron-out any problems.
- 8. Start the 14-day consecutive data collection from: (1) 13<sup>th</sup> March; or (2) 24<sup>th</sup> April 2017; or (3) 5<sup>th</sup> June 2017.
- 9. **Identify** <u>all</u> patients fitting the **inclusion criteria** within your specified two-week window.
- 10. Log data collection on REDCap and keeping a list of patient hospital numbers securely on paper or a trust computer.
- 11. Follow up patients at 30 days and log this data on REDCap. Discuss the best way to follow up patients with the consultant supervising your audit, as this will vary.
- 12. Ensure all data has been uploaded to the **REDCap** system and you have completed all fields, avoiding **missing data points**. If more than 5% of patients at your centre are missing data, your centre cannot be included and your name will be withdrawn from the author list.
- 13. It is a condition of participation in RIFT that following completion of the audit at your centre you <u>must</u> ensure that your local results are presented to your hospital's surgical department and reported back to the audit department.

## **Appendix C: HRA Ethical Approval Tool**



Is my study research?

#### To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

Right Iliac Fossa Treatment (RIFT) audit

IRAS Project ID (if available):

You selected:

- 'No' Are the participants in your study randomised to different groups?
- 'No' Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- 'No' Are your findings going to be generalisable?

#### Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at HRA.Queries@nhs.net. 1. National Surgical Research Collaborative. Multicentre observational study of performance variation in provision and outcome of emergency appendicectomy. Br J Surg [Internet]. 2013 Aug 1 [cited 2016 Sep 23];100(9):1240–52. Available from: http://onlinelibrary.wiley.com/doi/10.1002/bjs.9201/abstract

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Data Point	Alvarado	AIR	AAS	RIPASA	PAS
Nausea Or vomiting	1	1		1	1
Anorexia	1			1	1
RIF Pain	2	1	2	0.5	
Migration to RIF	1		2	0.5	1
Rovsing's Sign				2	
RIF Tenderness			1 - 3	1	2
Rebound or Guarding	1	1 - 3	2 - 4	1(+ 2)	
Temperature	1	1		1	1
wcc	2	1 - 2	1 - 3	1	1
Leukocytosis	1				
Polymorphs		1 - 2	2 - 4		1
CRP		1 -2	1 - 5		
CRP Over 24h			1 - 2		
Coughing					2
Gender				0.5 - 1	
Age				0.5 - 1	
Duration				0.5 - 1	
Negative Urinalysis				1	
Total Score	10	12	23	16.5	10

## **Appendix E: Appendicitis Risk Stratification Scores**

This table has been adapted from the WSES Jerusalem guidance paper<sup>5</sup>, and is a comparison of all the current risk stratification scores, including: the Alvarado score; the Appendicitis Inflammation Response Score (AIR); the Acute Appendicitis Score (AAS); The Raja Isteri Pengiran Anak Saleha Appendicitis (RIPASA); and the Paediatric Appendicitis score (PAS).

# Appendix F: Comparison of data and audit standards Please see the online document for the full list of EAES and WSES audit standards.

	Data Criteria	Related Audit Standard
1	Patient sex	WSES 1.1. 1.2 and EAES Bro On S.1 and B.2
2	Patient age	WSES 1.1 – 1.3 and EAES Pre-Op S 1 and R 2
3	Previous abdominal surgery	
4	Previous acute inpatient admissions with	
	RIF pain	
5	Duration of symptoms	WSES 4.1, 4.2 and EAES Operative Care R 1
6	Appendicitis risk score used by clinical	
	team	
7	Urinalysis	
8	Nausea	
9	Vomiting	
10	Anorexia	WSES 1.1 – 1.3 and EAES Pre-Op S 1 and R 2
11	RIF pain	These guideline recommendations state that ALL
12	Migration of pain to RIF	patients should be risk stratified. The data criteria to
13	Rovsing's sign positive	the left are required for one, or all, of the risk
14	RIF tenderness on examination	stratification scores.
15	Rebound tenderness or guarding	
16	Highest recorded temperature	
17(a)	Highest preoperative white blood cell count	
17(b)	Neutrophil count at the time when highest	
	WBC count recorded	
17(c)	Highest preoperative CRP	
18(a)	What pre-operative imaging was	WSES 2.1 – 2.7 and EAES Pre-Op S1 - 2 and R2 – 6
	performed?	These recommendations are related to the imaging
18(b)	Imaging: appendicitis	of suspected appendicitis patients.
18(c)	Imaging: other findings	
19	Planned first line non-operative	
	management with <b>no initial plan</b> for	WSES 3.1 – 3.2 and EAES Pre-Op R7
20	surgery	WEESE1 EC and EAES Bro On D9 14 and
20	Was an operation performed on index admission?	WSES 5.1 – 5.6 and EAES Pre-Op R8 – 14 and
21	Discharge diagnosis following index	Operative Care R1 - 15
21	admission	
22	Length of stay of the index admission	
~~	Length of stay of the mack dumission	
00()		
23(a)	30 day follow up:	
	Readmission with ongoing symptoms	
23(b)	If readmitted, did they undergo surgery?	
24(a)	What was the highest grade of surgeon	
- · (~)	who made the decision to operate?	
24(b)	Operative approach	
24(c)	If open approach, reason for this	WSES 5.1 – 5.6 and EAES Pre-Op R8 – 14 and
24(d)	Procedure	Operative Care R1 - 15
24(e)	If other procedure performed, what was it?	
	If appendicectomy performed,	
24(f)	macroscopic intraoperative appearance	MOED C.D. C.A and EAED On white One DO
	of appendix	WSES 6.3 – 6.4 and EAES Operative Care R9
24(g)	If appendicectomy performed, histology	WSES 6.1 and EAES Post-Operative Care R1
<u>۲</u> (9/	n apponatootomy performed, <u>mistology</u>	

## Appendix G: Centre Survey

This will be a separate form on REDCap for the local lead and consultant to complete.

	Data Criteria	Options
Centre	e details	· ·
1(a)	Does your unit care for?	<ul> <li>Adults only</li> <li>Children only</li> <li>Adults and children</li> </ul>
2	Does your hospital have an on-site gynaecology service?	<ul><li>Yes</li><li>No</li></ul>
3	Does your centre have 'review clinic' slots for patients to return for further assessment/imaging the following day if a diagnosis is unclear?	<ul> <li>Yes – with ultrasound and clinical review</li> <li>Yes – clinical review only</li> <li>No</li> </ul>
4(a)	How many <b>consultants</b> will be "on call" during the 2 week study period?	Number =
4(b)	How many consultant general surgeons work at your centre?	Number =
4 (c)	Is there a <b>dedicated</b> registrar based on SAU to review patients?	<ul> <li>Yes – 24/7</li> <li>Yes – During the day</li> <li>No – One registrar splits time between theatre and SAU</li> </ul>
5	At weekends, Is ultrasound available?	<ul><li>Yes</li><li>No</li></ul>
6(a)	At weekends, is CT available?	<ul> <li>Equivalent to weekday service</li> <li>Reduced service but available for urgent surgical requests</li> <li>Not available</li> </ul>
6(b)	At night, is CT available?	<ul> <li>Equivalent to weekday service</li> <li>Reduced service but available for urgent surgical requests</li> <li>Not available</li> </ul>
Does	your centre have an agreed policy for:	
7	When to use appendicitis risk stratification scores?	<ul> <li>Yes – use of score recommended</li> <li>Yes – use of score discouraged</li> <li>No policy in place</li> </ul>
8	Which patients should have a CT scan prior to appendicectomy? (e.g. diagnosis unclear, age >50)	<ul> <li>Yes – please detail</li> <li>No policy in place</li> </ul>
9	Whether some patients with appendicitis may be managed non-operatively?	<ul> <li>Yes –conservative management recommended for some patients; please detail</li> <li>Yes – policy discourages conservative management</li> <li>No policy in place</li> </ul>
10	Whether laparoscopic or open appendicectomy should be routinely performed?	<ul> <li>Yes – open surgery recommended</li> <li>Yes – laparoscopic surgery recommended</li> <li>No policy in place</li> </ul>
11	Whether a macroscopically normal looking appendix should be removed or left in situ?	<ul> <li>Yes – removal recommended</li> <li>Yes – recommend it be left in situ</li> <li>No – no policy in place</li> </ul>

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