

Safe Entry and Quality Standards for Gynaecological Laparoscopy Clinical Guideline

V2.0

March 2023

Summary

This document provides guidance for staff on the safe entry and quality standards for gynaecological laparoscopy

Patients undergoing laparoscopic surgery should have been fully counselled and have agreed to the procedure, demonstrating they understand the risks

The theatre must have the appropriate equipment for safe laparoscopic surgery

The surgeon must be trained in the techniques being undertaken, or be being supervised by a trainer with the required skills

The surgeon should ensure that the required surgical assistance is present to complete the procedure safely

Patients at the extremes of size present additional challenge and are therefore at the more risk. Techniques to accommodate these characteristics need to be considered and planned prior to starting the surgery

1. Aim/Purpose of this Guideline

- 1.1. This document provides guidance for staff on the safe entry and quality standards for gynaecological laparoscopy.
- 1.2. This version supersedes any previous versions of this document.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

- 2.1. Patients undergoing laparoscopic surgery should have been fully counselled and have agreed to the procedure, demonstrating they understand the risks by signing a departmental standardised consent form. Occasionally it may be unavoidable to use a handwritten consent form, but a pre-printed consent form is to be recommended or digital.

Careful planning of entry technique and meticulous attention to detail during the process can reduce the risk of complications and improve patient safety. Secondly, achieving high quality images in a standardised way will improve the transfer of information about the findings to the patient and to other clinicians. This guidance addresses these issues.

There are a variety of methods of laparoscopic entry and all carry a low risk of serious complication (circa 1 in 1,000); the low prevalence of serious complications make a valid comparison of every technique impossible. This does not mean that all entry methods are equally safe, it merely reflects the lack of powered data to provide definitive evidence. However, some data exists, and national guidance also exists. The most hazardous part of the procedure is the first port insertion, as this is usually a blind procedure. All subsequent ports should be inserted and removed under direct vision. The factors which must be considered are described below.

2.1.1. Theatre environment

The theatre must have the appropriate equipment for safe laparoscopic surgery:

- High quality monitors; ergonomically sited and preferably ceiling mounted.
- Reliable CO2 supply, preferably piped supply.
- High quality camera and laparoscope with no optical defects.
- Operating table which facilitates 22° Trendelenberg tilt with sufficient low height.
- Patient's legs in adjustable gas strut leg supports; feet enclosed in supportive boots.

2.1.2. Surgeon's experience

The surgeon must be trained in the techniques being undertaken, or be being supervised by a trainer with the required skills. Any concern about ability to perform the procedure should be made clear at the first possible opportunity, to prevent unnecessary patient risk. Selection of entry method should be made on the basis of surgeon experience and learning of a repeatable safe technique.

2.1.3. Surgical assistance

The surgeon should ensure that the required surgical assistance is present to complete the procedure safely.

2.1.4. Patient's physical characteristics

Patients at the extremes of size present additional challenge and are therefore at the more risk. Techniques to accommodate these characteristics need to be considered and planned prior to starting the surgery.

Patients at risk of intra-abdominal adhesions present a raised risk, and strategies to adjust technique in these cases needs to be considered prior to surgery commencing. Specific examples of patients with likely adhesions are those with:

- Multiple abdominal scars.
- Midline laparotomy scar.
- Poor, or keloid scarring.
- History of peritoneal sepsis from any source.
- Umbilical hernia surgery.

2.1.5. Entry Techniques

In the uncomplicated patient most gynaecologists will use a Verres needle to insufflate the abdominal cavity. General surgeons favour an open entry technique (Hasson or similar), however the risk of bowel injury has not been shown to be different between these approaches. There is no high quality evidence to advise one entry method over another. Direct entry and open entry are associated with a lower failed entry rate, and direct entry is associated with a lower vascular injury rate based on very low quality evidence, but blind direct entry (ie: without prior insufflation) is a technique that is not recommended in our unit

2.1.6. Guidance on Verres needle insertion

- 2.1.6.1. Patient should be lying flat and an intra-umbilical vertical incision from the base upwards should be made through the skin and cuticle down to the fat layer. The wound should accommodate the external diameter of the chosen port size; namely 12mm for a 10mm port and 7mm for a 5mm port. This is important as a slightly small incision can hold back the primary port requiring the surgeon to apply unnecessary force; when this resistance is overcome the port rapidly shoots into the abdomen risking viscus or vascular injury. A slightly over-large wound is safer.
- 2.1.6.2. The abdomen should be stabilised in such a way that the Verres needle can be passed vertically through the base of the umbilical wound, just far enough to penetrate the fascia and peritoneum. Two audible clicks are usually heard, or felt. Note that using this technique, the tip of the Verres needle will only need to travel a very short distance (about 3-8mm) in any size patient, because at the base of the umbilicus, there are no muscle layers, the abdominal wall structures are fused and the peritoneum is fixed.
- 2.1.6.3. The intra-abdominal pressure is now observed, and should be 8mmHg or less. The flow rate of gas should be close to the flow rate tested in open air prior to start, and the rise in abdominal pressure should be smooth and controlled. If these criteria are not met, stop the procedure and re-evaluate, as it is likely the Verres needle is incorrectly sited. Repeat the procedure once an understanding of the problem is clear. After two failed attempts a trainee should allow the trainer to take over this part of the procedure. If a fully trained surgeon has two failed attempts then a careful evaluation of further similar attempts, or an alternative entry method, need to be considered.
- 2.1.6.4. The abdominal pressure should continue until 20-25mHg is reached. At this point the surgeon should judge whether the findings are consistent with appropriate space being available to insert the primary trocar. Be aware that the

pressure may be falsely elevated if the patient is not fully paralysed, if in doubt discuss the issue with the anaesthetist. Be aware that the diaphragmatic muscles are the last muscle group to be paralysed and their contraction could falsely elevate the intra-abdominal pressure. Do not insert a primary trocar if the abdomen is insufficiently inflated.

2.1.7. Primary trocar entry

- 2.1.7.1. The primary trocar should be inserted in a suitable splinted abdomen at 90° to the skin surface at the base of the intra-umbilical incision.
- 2.1.7.2. A bladed blind trocar should be firmly pressed into the adequately sized wound and twisted between 10 'o' clock and 2 'o' clock position whilst continuing the forward pressure. There will be an initial click as the shield is retracted and the blade exposed. The controlled twisting motion will allow the blade to cut 1mm at a time through the tissues. The trocar only needs to travel a short distance, for the reasons explained above. Once through the peritoneum there will be a second click confirming the shield has moved forward to cover the blade and make the trocar blunt. It can now be safely introduced into the abdominal cavity as it is blunt. Non-bladed trocars are used in the same way but do not produce audible clicks.
- 2.1.7.3. Optical primary ports are available in bladed or non-bladed versions. These allow vision through the laparoscope as the trocar passes through the abdominal wall. They require experience in their use, to familiarise the surgeon with the views of safe passage through the abdominal wall.
- 2.1.7.4. There is no definitive evidence of improvement in safety reported between optical and blind trocar entry, but there are cost differences. Selection of trocar should be made on the basis of surgeon experience and learning of a repeatable safe technique.

2.1.8. Initial laparoscopy and secondary ports

- 2.1.8.1. Once the laparoscope is in place, and confirms normal positioning of the primary trocar, a 360° view of the abdominal cavity should be performed. This is to check for any visceral injury or bowel adhesions. The liver and diaphragm should be inspected and photographed for the record.
- 2.1.8.2. The position of the origin of the inferior epigastric vessels (not to be confused with the obliterated umbilical arteries) should now be mapped by pressing a finger on the abdomen in the appropriate place. These vessels arise on

the medial aspect of the internal inguinal ring, which can be seen where the round ligament enters the inguinal canal. Working up the abdomen with the same finger a line of potential hazard can be marked out. This line of hazard needs to be avoided by secondary trocars.

- 2.1.8.3. Port placement is a matter of surgeon choice and relates to the procedure planned. However, if the patient has endometriosis, any future surgery will be performed using secondary ports placed lateral to the inferior epigastric vessels and level with the umbilicus on each side. So, if such surgery is a future possibility, placing ports in this area will allow the incisions to be re-used thus reducing scarring for the patient. For similar reasons a fourth port in the midline would be ideally placed midway between the symphysis pubis and the umbilicus.

2.1.9. Laparoscopy – pelvic survey

- 2.1.9.1. The risk of performing a laparoscopy is only justifiable if a comprehensive examination of the pelvic anatomy is performed.
- 2.1.9.2. The pelvic survey needs to be recorded in clear photographs of the relevant areas. To achieve this, the patient should be in Trendelenberg tilt to approximately 22°.
- 2.1.9.3. The small bowel needs to be gently lifted out of the pelvis with bowel graspers and any fluid in the pouch of Douglas removed. This can be done by using suction if opened, but if not it can be achieved by using the gas pressure to expel the fluid up the metal suction tube present in all the gynaecology laparoscopy sets.
- 2.1.9.4. The uterus should be manipulated so clear views and in focus photographs of the following areas are obtained:
- Overall picture of pelvis with uterus in centre.
 - Left ovary and fallopian tube.
 - Left ovarian fossa and pelvic side wall.
 - Right ovary and fallopian tube.
 - Right ovarian fossa and pelvic side wall.
 - Pouch of Douglas showing both uterosacral ligaments.
 - Rectal surface and rectovaginal septum.
 - Retrovert the uterus to view the uterovesical pouch.

- 2.1.9.5. Additional photographs of the liver and the appendix from the initial survey complete the set.
- 2.1.9.6. Specific photographs of any pathology found should be in focus and at a distance that makes it clear where the pathology is sited.
- 2.1.9.7. A layout of six photographs per page gives a good level of detail whilst limiting excessive photo paper use.
- 2.1.9.8. It is good practice to video all operative laparoscopy, for training, transfer of information and future review in the case of complication.

2.1.10. Removal of ports

- 2.1.10.1. All secondary ports must be removed under direct vision to ensure that any obscured vessel injury can be checked for and any bleeding controlled.
- 2.1.10.2. Secondary port sites over 7mm should be closed with a suture using a port closure device, or similar intra peritoneal closure method.
- 2.1.10.3. Consideration should be given to peritoneal closing at the umbilical wound to prevent herniation, or subsequent omental adherence.

2.1.11. Obese patients BMI >30

The same technique described above for Verres needle insufflation can be used with obese patients, as the distance from the base of the umbilicus to the peritoneum is not greatly increased. However, there is a greater risk of extra peritoneal gas insufflation if the needle is angled as the distance to travel is greatly increased. Therefore, the Verres needle must be placed 90° to the skin to take advantage of the shortest route into the abdominal cavity. Initial abdominal pressure readings may be above 8mmHg with a very heavy abdominal wall. However, if raising the abdominal wall reduces the pressure this is a sign that the needle is correctly sited. Secondary ports that are cuffed may be an advantage in obese patients. Alternatively, a Palmer's point (see below) entry may be considered.

2.1.12. Very thin patients BMI <18

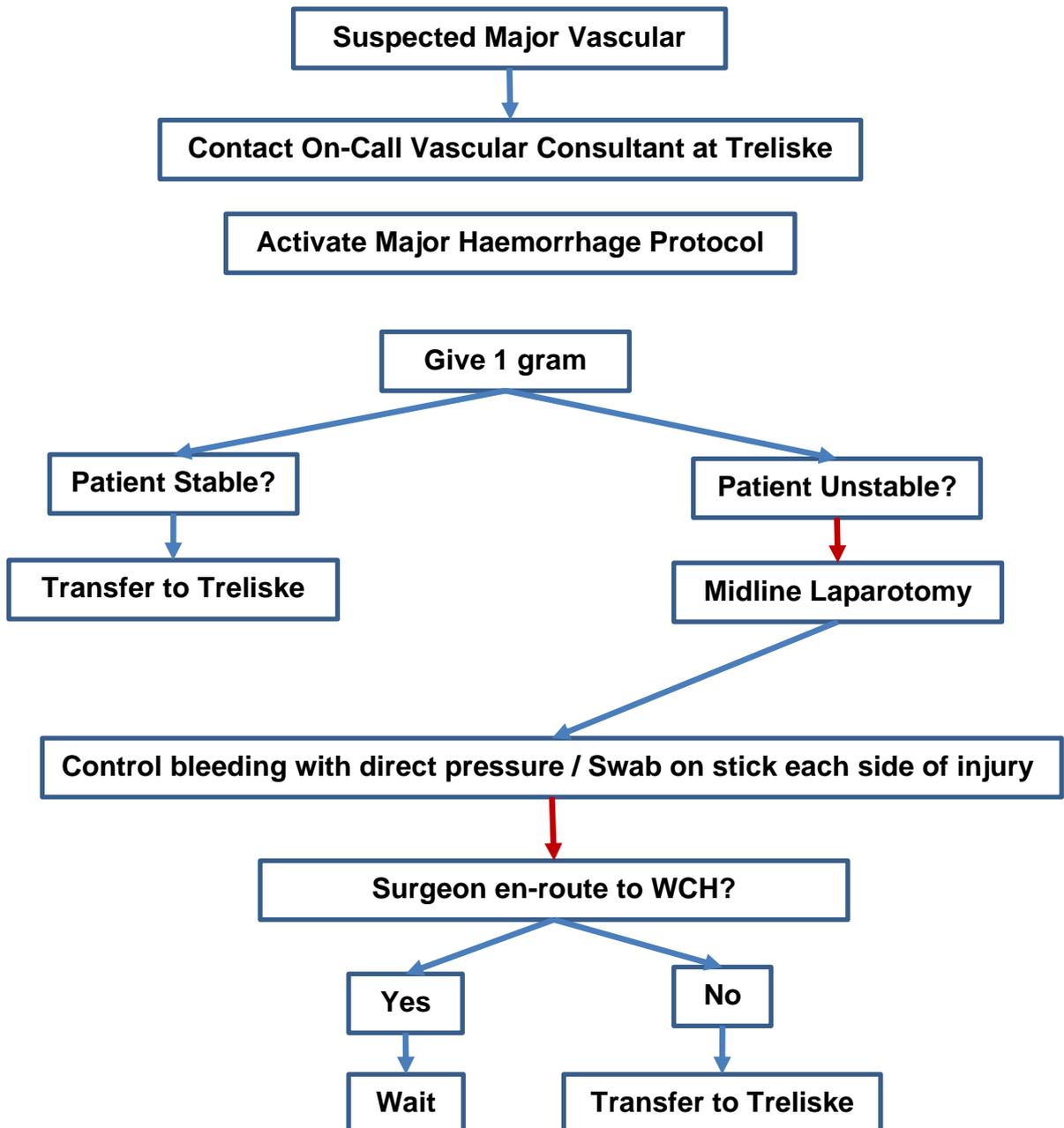
In the very thin patient there is less abdominal wall thickness and less bulky intra-abdominal organs, so the distance from the skin surface to the posterior abdominal wall major vessels is reduced. Controlled entry is essential as the margin for error is lessened. In such cases the open entry technique (Hasson, or its variants) may be more controlled. However, currently there are no robust data to show that open entry reduces the risk of bowel injury or major vascular injury. Palmer's point entry (see below) may also be considered as the entry site is further away from the major midline vessels.

2.1.13. Alternative entry sites

- 2.1.13.1. Whilst several alternative entry sites have been reported, the only alternative recommended site for Verres needle insufflation is 3cms below the left costal margin in the mid clavicular line (Palmer's point). This is an area where adhesions are less likely and in the absence of major splenomegaly, or previous surgery in this quadrant, is a relatively safe entry point. It is an ideal alternative site in the following situations:
- Multiple abdominal scars.
 - Midline scar.
 - Previous umbilical hernia repair.
 - Extremely thin patient.
 - Morbidly obese patient.
- 2.1.13.2. The stomach should be emptied by a naso, or oro-gastric tube and aspiration prior to needle insertion to reduce the risk of gastric injury.
- 2.1.13.3. After appropriately sized skin incision the Verres needle is placed perpendicular to the abdominal wall and introduced through the layers. Four clicks will be heard, or felt, as the needle passes through the layers and into the peritoneum. Intra-abdominal pressure should be 8mmHg or less and rise slowly with insufflation.
- 2.1.13.4. Once in place a 5mm port, and laparoscope, can be used to inspect the umbilicus from underneath and umbilical port placement achieved under direct vision, if free from adhesions.
- 2.1.13.5. If present, adhesions can be divided followed by port placement. Alternatively, if appropriate the laparoscopy can be completed with the 5mm laparoscope in the Palmers point position throughout.
- 2.1.13.6. In some situations a high point of visualisation is required (TLH for large fibroid uterus, common iliac and para aortic node dissections, multiple bowel adhesions etc.) For TLH in a uterus greater than 18 week size, sometimes a high secondary port is placed alongside the Falciform ligament (Lee-Huang point) under direct vision. Also in some situations an optical trocar as primary port in Palmers point, or in areas above the umbilicus can be used for the similar reasons, provided the surgeon is skilled in these techniques.

2.2.

2.2. Management of Suspected Major Vascular Injury During Laparoscopic Gynaecological Procedures



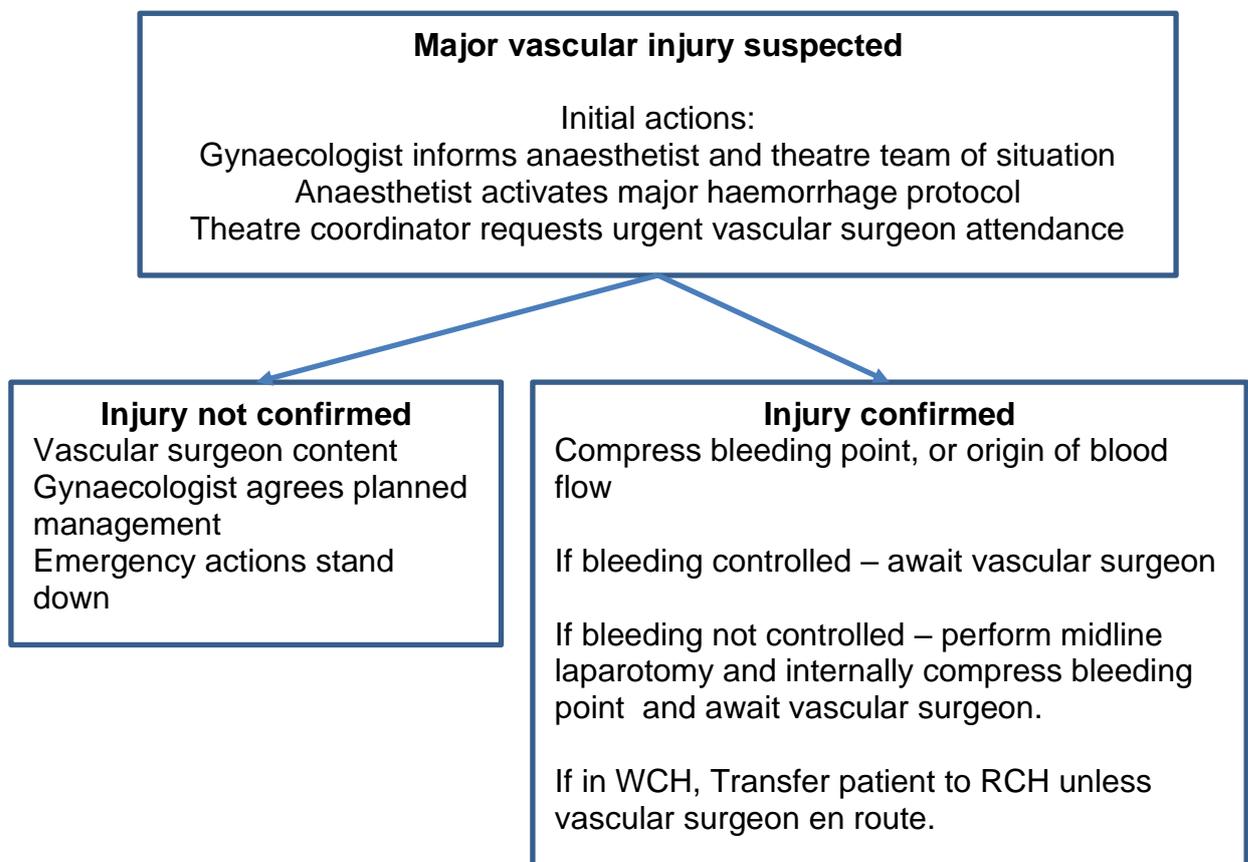
Notes:

Protocol drawn up in consultation with gynaecologists and vascular surgeons from RCHT

2.2.1. Plan includes having a single Debakey type clamp available in WCH for use by vascular surgeon if required. Deliberate decision not to have many instruments in order to reduce complexity and to reduce the temptation to do too much in WCH where facilities are limited and staff inexperienced.

- 2.2.2. Goal is stabilise and transfer, even if this means with an open abdomen and surgeon pressing on a vessel.
- 2.2.3. Availability of blood will be limited, hence recommendation not to attempt repair in WCH.
- 2.2.4. Patient likely to require transfer to Treliske anyway, either for definitive surgery or ICU.
- 2.2.5. Decision not to include radiology in protocol as adds complexity, likely to be too time consuming and imaging quality inadequate. Equally REBOA rejected as expertise unlikely to be available and does not provide definitive repair of injury.

2.3. Major vascular injury at Laparoscopy proforma



Notes:

A major vascular injury is rare and frightening for all concerned. The team must focus on clinical priorities and communicate well. The team lead is the Surgeon who performed the procedure. When the vascular surgeon arrives, a clear agreement may be made to hand team leadership over to him/her, or not, but everyone must be clear who is leading the team at all times.

Calm, clear instructions given once are more effective than repeated unclear commands to many people. Use staff wisely and think about priorities. Assign tasks to be as efficient as possible. Many people trying help without direction leads to much noise and duplication of effort, ultimately slowing progress.

2.3.1. Anaesthetist

- Consider senior support
- Ensure adequate blood products ordered and delivered
- Establish appropriate vascular access and stabilise circulation

2.3.2. Gynaecologist

- Stay calm and focused
- Communicate clearly and lead the team
- Think ahead and consider options, as situation changes

2.3.3. Lead of scrub team

- Inform theatre coordinator immediately problem identified
- Ensure adequate members of staff present
- Instruct members of scrub team clearly and concisely
- Arrange additional theatre sets as required

2.3.4. Vascular Surgeon

- Provide a clear assessment of situation to whole team as soon as possible
- Give clear and concise instructions about equipment requirements
- Consider senior support

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with policy/Key changes to practice
Lead	Minimal Access Surgery Lead
Tool	Theatre De-briefs and monitoring via datix incidents
Frequency	De-briefs after each surgery and incidents monitored as they are reported

Information Category	Detail of process and methodology for monitoring compliance
Reporting arrangements	Reporting into the Gynae risk management meeting and via Gynae morbidity and mortality meeting and Obs and Gynae Specialty meetings.
Acting on recommendations and Lead(s)	Gynae risk management consultant with Gynae risk management meeting members and Obs and Gynae Specialty meetings.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 3 months, immediately if required. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant staff/stakeholders

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ['Equality, Inclusion and Human Rights Policy'](#) or the [Equality and Diversity website](#).

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Safe Entry and Quality Standards for Gynaecological Laparoscopy Clinical Guideline V2.0
This document replaces (exact title of previous version):	Safe Entry and Quality Standards for Gynaecological Laparoscopy Clinical Guideline V1.0
Date Issued/Approved:	December 2022
Date Valid From:	March 2023
Date Valid To:	March 2026
Directorate / Department responsible (author/owner):	Mr. Thomas Smith- Walker; Consultant Gynaecologist and Obstetrician
Contact details:	01872 252731
Brief summary of contents:	Guidance for staff on the safe entry and quality standards for gynaecological laparoscopy
Suggested Keywords:	Gynaecology, laparoscopy
Target Audience:	RCHT: Yes CFT: No CIOS ICB: No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Gynaecology Specialty Meeting
General Manager confirming approval processes:	Caroline Chappell
Name of Governance Lead confirming approval by specialty and care group management meetings:	Caroline Amukusana
Links to key external standards:	https://www.bsge.org.uk/wp-content/uploads/2016/03/GtG-no-49-Laparoscopic-Injury-2008.pdf
Related Documents:	None required

Information Category	Detailed Information
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical/ Gynaecology

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
February 2020	V1.0	Initial Issue	Mr Dominic Byrne, Consultant Gynaecologist - Endopelvic Surgeon
December 2022	V2.0	Full review and update to new Trust template. Update to section 2.1. re. digital consent.	Mr. Thomas Smith-Walker; Consultant Gynaecologist and Obstetrician

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team
rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Safe Entry and Quality Standards for Gynaecological Laparoscopy Clinical Guideline V2.0
Directorate and service area:	Gynaecology
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Mr. Thomas Smith- Walker; Consultant Gynaecologist and Obstetrician
Contact details:	01872 252731

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide guidance for staff on the safe entry and quality standards for gynaecological laparoscopy
2. Policy Objectives	To provide guidance for staff on the safe entry and quality standards for gynaecological laparoscopy
3. Policy Intended Outcomes	Safe entry and quality standards in gynaecological laparoscopy
4. How will you measure each outcome?	See section 3
5. Who is intended to benefit from the policy?	Patients and staff

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	<ul style="list-style-type: none"> • Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	Please record specific names of individuals/ groups: Gynaecology Specialty Meeting
6c. What was the outcome of the consultation?	Approved- 16 December 2022
6d. Have you used any of the following to assist your assessment?	National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys: No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	Any information provided should be in an accessible format for the patient's needs – i.e., available in different languages if required/access to an interpreter if required

Protected Characteristic	(Yes or No)	Rationale
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	Those patients with any identified additional needs will be referred for additional support as appropriate - i.e., to the Liaison team or for specialised equipment. Written information will be provided in a format to meet the family's needs e.g., easy read, audio etc
Religion or belief	No	All staff should be aware of any beliefs that may impact on the decision to treat
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Gynaecology Specialty Meeting

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:

[Section 2. Full Equality Analysis](#)