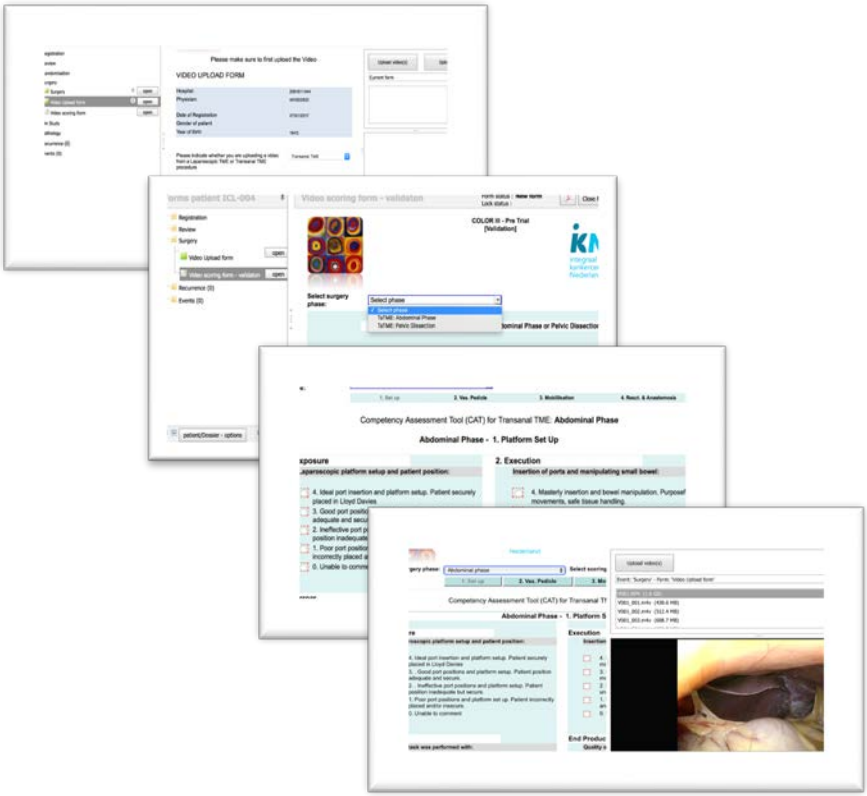
Surgical **Q**uality **A**ssurance in COLOR III Trial



Competency **A**ssessment **T**ool

Surgical Quality Assurance (SQA)

1.WHAT IS SURGICAL QUALITY ASSURANCE (SQA)?

Variations of the surgical technique and surgeon's competency are the most criticised components in a surgical RCT. It is crucial to control for the heterogeneity amongst the surgical practices.

SQA is a protocol that addresses the issue of heterogeneity by:

(i) Standardisation of the operation
(ii) Evaluate the surgeon's performance against the agreed standard.

2. HOW DOES SQA WORK IN COLOR III?

Extensive work has been done alongside the main COLOR III trial design.

(i) **Standardisation** of TaTME with experts' consensus; operation manual is written.

(ii) **Competency Assessment Tool (CAT)** development for TaTME for objective and reliable video analysis

(iii) **Before entering** the trial, each centre is invited to submit operative videos**,** which are assessed using CAT.

(iv) **During the trial,** video analysis is used to investigate incidences and adverse events.

Competency Assessment Tool (CAT)

1. WHAT IS A COMPETENCY ASSESSMENT TOOL (CAT)?

CAT is a marking sheet for the evaluation of surgical skills for an operation. It is designed to ensure standardised technical performance through robust methodology.

2. HOW is CAT USED IN SQA of COLOR III TRIAL?

CAT is used in video analysis, measuring and monitoring the compliance to the agreed operative standard in COLOR III.

Each centre who wishes to participate are asked to submit 2 TaTME and 1 Lap TME unedited, full length videos. The videos are assessed by 2 independent assessors trained to use CAT to decide whether the surgical performance is compliant.

Feedback is given to either start enrolling patients or explore the areas where standards are not met.

	4. Transanal Set Up & Purse String		5. Rectotomy		6. Posterior Mesorectal Dissection	
Exposure	**Transanal platform setup, constant pressure insufflation system**		**Retraction and exposure throughout task:**		**Retraction and exposure throughout task:**	
	4. Ideal	ergonomic platform setup. Optimal pneumorectum, clear operative field for task.	**4. Clearly**	demonstrate the level of dissection with optimal traction and tissue tension	**4. Clearly**	demonstrates fascial planes with versatile traction and tissue tension.
	3. Good	platform setup. Efficient and safe insertion. Good pneumorectum and operative field for task.	**3. Demonstrate**	ment of dissection plane with appropriate traction and tension on tissue.	**3. Demonstrates**	most of the fascial planes with appropriate traction and tension on tissue.
	2. Inadequate	platform setup. Laborious insertion. Suboptimal pneumorectum and view for task.	**2. Ineffective**	exposure of plane. Tractions often in wrong directions. Little tension.	**2. Ineffective**	exposure of planes. Tractions are often in wrong directions. Little tension
	1. Poor	platform set up. Hazardous and unsafe insertion. Poor pneumorectum; unclear view.	**1. Fails**	to demonstrate dissection plane. Lack of traction and no tissue tension.	**1. Fails**	to demonstrate fascial planes. Poor views. Lack of traction and no tissue tension.
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Execution	**Purse string placement with regular intramuscular bites:**		**Circumferential full thickness dissection:**		**Dissection in posterior TME plane close to mesorectal fasia, demonstrating angel's hair.**	
	4. Masterly	suturing with even and intramuscular bites of 8-10. Safe, protective tissue handling.	**4. Masterly**	full thickness dissection, smoothly followed circumferentially. Safe and purposeful movement.	**4. Masterly**	dissection close to mesorectal fascia following established planes. Safe & purposeful movements.
	3. Efficient	with good bites. Occasional uneven spacing or bites, quickly corrected. Rarely unsafe handling.	**3. Efficient**	occasional less than full thickness or too deep, quickly corrected. Rarely unsafe tissue handling.	**3. Efficient**	dissection, occasional loss of plane, quickly corrected. Rarely unsafe tissue handling
	2. Laborious	Uneven/big bites. Frequent loss of level causing some spiralling of suture. unsafe tissue handling.	**2. Laborious**	dissection. Repeated less than full thickness or too deep, corrected. Frequent unsafe tissue handling.	**2. Laborious**	dissection, repeated loss of plane. Inefficient and frequent unsafe tissue handling.
	1. Hazardous	Poor bites/spacing. Loss of level, significant spiralling, uncorrected. Unsafe handling.	**1. Hazardous**	dissection. Mostly less than full thickness or too deep. Uncoordinated and unsafe tissue handling.	**1. Hazardous**	dissection, mostly in the wrong plane. Uncoordinated and unsafe tissue handling
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adverse Events	**This task was performed with:**		**This task was performed with:**		**This task was performed with:**	
	4. No	bleeding. Adjacent structure protected. No collateral injury/mucosal trauma	**4. No**	bleeding. Adjacent structure protected. No collateral injury/perforation.	**4. No**	bleeding/avulsion. Adjacent structure protected. No collateral injury/perforation.
	3. Minimal	bleeding, quickly controlled. No collateral injury/mucosal trauma.	**3. Minimal**	bleeding, quickly controlled. No collateral injury/perforation.	**3. Minimal**	bleeding/avulsion, quickly controlled. No collateral injury/perforation.
	2. Moderate	bleeding, controlled; small rectal wall haematoma. Mild injury/mucosal trauma.	**2. Moderate**	bleeding/avulsion, controlled. Potential collateral injury or rectal perforation.	**2. Moderate**	bleeding/avulsion, controlled. Potential collateral injury e.g. pelvic nerves/perforation.
	1. Significant	bleeding, uncontrolled; large rectal wall haematoma. Significant injury/mucosal trauma.	**1. Significant**	bleeding/avulsion, uncontrolled. Rectal perforation/collateral injury.Purse-string breaking	**1. Significant**	bleeding/avulsion, uncontrolled. Definite Collateral injury e.g. pelvic nerves/perforation.
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End-product Quality	**Quality of pneumorectum and purse string with even radial folds.**		**Quality of Rectotomy before TME dissection begins:**		**Quality of mesorectum and pelvis**	
	4. Optimal	pneumorectum. Tight purse string closure, even radial folds. Ideal position.	**4. Complete**	circumferential full thickness rectotomy before beginning TME dissection.	**4. Smooth**	intact mesorectum. No obvious destruction or visible defects. No mesorectal tissue left in situ.
	3. Satisfactory	pneumorectum. Closed purse string, slightly uneven. Good position.	**3. Satisfactory**	full thickness dissection rectotomy; minor incomplete areas, able to proceed to TME.	**3. Occasional**	minor mesorectal injury to fascia only. No obvious destruction or defects. Minimal tissue left in situ.
	2. Inconsistent	pneumorectum. Loose purse string, uneven. Slight spiralling. Small leak of bowel content.	**2. Sub-optimal**	rectotomy with some incomplete areas, too shallow or too deep with injury to rectal wall	**2. Sub-optimal**	with obvious injury into fat. Some mesorectal tissue remaining in pelvis.
	1 Poor	pneumorectum. Purse string undone. Significantly spiralling position. Large leak.	**1. Poor**	rectotomy largely incomplete, significantly too shallow or too deep. Rectal wall perforation.	**1. Incomplete**	posterior mesorectum with deep injuries into fat. Significant destruction. Tissue left in pelvis.
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Comments						

How do I take Part in SQA?

First of all, thank you for joining us in COLOR III!!

Please see the videos requirements for entering the trial:

1.THREE VIDEOS

2 x TATME – at least one of which needs to be of a **Male** patient.
And
1 x Lap TME of a **Male** patient.

2. FULL-LENGTH UNEDITED

Ensuring both abdominal and transanal operative fields are recorded.
This may require more attention where two separate systems are used – remember to press the recording button for both cameras.

3. EXTERNAL VIDEO RECORDINGS

Certain steps are crucial but difficult to be captured.
Please ensure the following steps are demonstrated by asking your assistant to hold the camera externally:

- Transanal platform setup +/- purse string
- Specimen retrieval
- Anastomosis, especially in second purse-string and hand-sewn coloanal anastomosis.

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