

# Core outcome set for surgical innovation



## Modifications

Includes modifications to the

- procedure,
- concomitant interventions or
- which patients were offered the procedure during the study

NB: excludes abandoning or changing to another procedure at any point (eg, laparoscopic approach converted to open)



## Procedure completion success

Describes the procedure completion success, either with or without modifications (eg, planned innovative procedure was abandoned or changed, all technical steps were completed as planned)



## Problems with device working

Whether any problem(s) with the device working occurred, if applicable (eg, new stapler misfired)



## Surgeons' experience

Surgeons'/operators' emotional, psychological, or physical experience of the procedure (eg, ergonomic comfort during the operation)



## Intended benefits

Refers to any intended benefit(s) of the procedure that occurred

- before,
- during or
- after

the procedure (eg, fewer tests needed before surgery, less operative time, better recovery)



## Expected & unexpected disadvantages

Includes any of the following:

*expected* disadvantages that occurred

- before,
- during or
- after

the procedure (eg, more tests needed before surgery, longer operative time, more patients required intensive care)

*unexpected* disadvantages that occurred

- before,
- during or
- after

the procedure (eg, unexpected instrument clashing, inadvertent injury to nearby tissue and/or organs)



## Overall desired effect achieved

Whether the overall desired effect (overall aim) of the procedure/device was achieved (eg, tumour successfully excised)



## Patients' experience

Patients' emotional, psychological, or physical experience relating to the procedure being innovative (eg, anxiety because of the procedure being new)