Appendices to the report

Ukom

MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

14 Appendices to the report

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Appendix 1

Template for information from HF to patients (PDF)

Appendix 2

Introduction of other surgical and invasive methods (PDF)

Appendix 3

Letter from NGICG-CR to the regional medical directors (PDF)

Appendix 4

Process chart – New methods (PDF)

Appendix 5

Questions from NHIB to the seven relevant hospitals
Below are the questions NHIB sent to the relevant hospitals.

Topic	Question
1. Introduction of taTME	What was the decision-making process on the introduction of taTME? When was the first patient operated using taTME? When was the last patient operated using taTME? What was the reason that you suspended use of this procedure?
2. Training	How was the training and guidance of surgeons in the taTME method arranged? Was there a proctor scheme at the hospital in connection with implementation of the method? How was this carried out?
3. Clinical trial	Were the patients who underwent taTME surgery included in a clinical trial? Attach documentation/protocol Was any data sent to foreign trials? Attach documentation/protocol Was the trial registered in REK? Was it also registered anywhere else? Attach documentation Was the trial reported to the data protection officer (DPO)? Attach documentation
4. Information for patients	Did the patients who underwent surgery using the taTME method receive information that this is a technique in a developmental phase? Attach documentation Did the patients receive an information letter and/or consent form about this? Attach documentation Were the patients who underwent surgery using taTMe at your hospital subsequently informed that the method had been suspended due to complications and oncological results? Attach documentation Did patients have a choice between surgery using taTME or the traditional method? Was it registered in the medical records that the patients were informed that they were to be operated on using a new technique that is subject to development?

5. Quality improvement	Did the hospital perform an internal review/internal scrutiny of the introduction of the taTME method after it was suspended? Attach documentation If the patients you operated on were among those who suffered a recurrence or complications after the taTNME surgery – was notification of this sent to the supervisory authorities?

Statens undersøkelseskommisjon
for helse-og omsorgstjenesten

Postboks 225 Skøyen
0213 Oslo
E-post: post@ukom.no
Org nr: 921018924