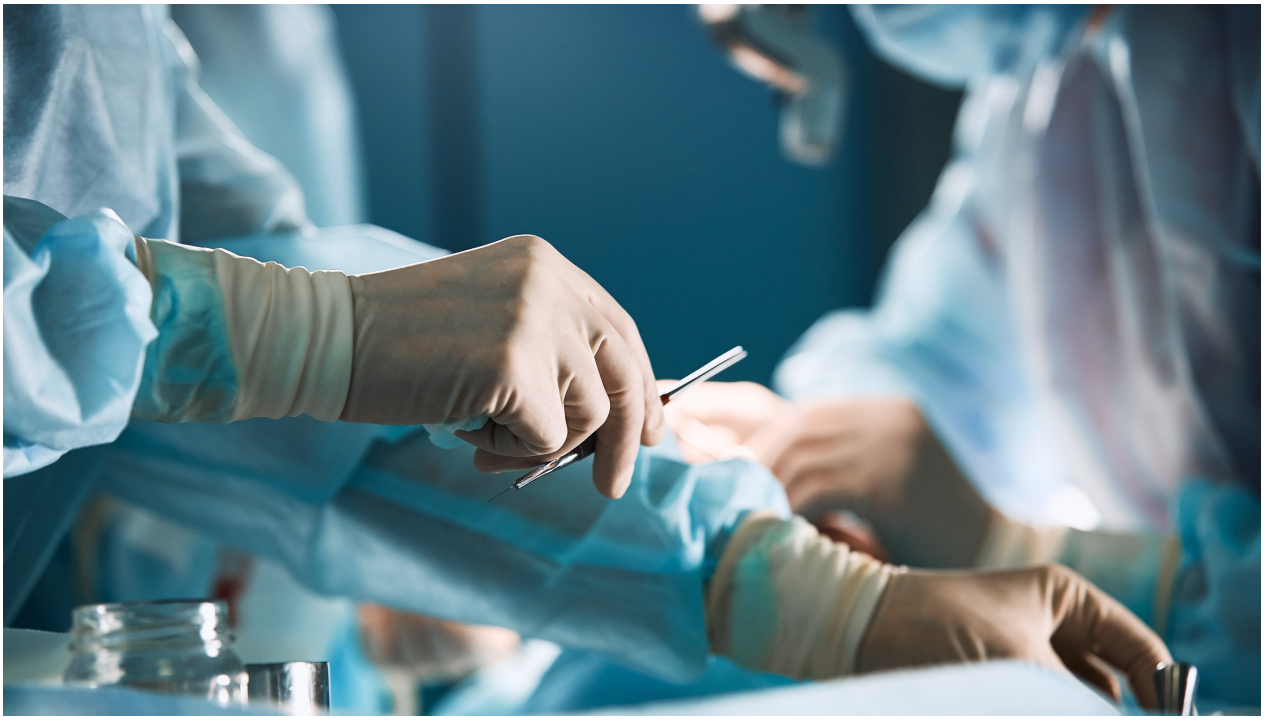
Learning points



MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

10 Learning points

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Our investigation shows that there was no overall national governance when taTME was introduced, but that the method was started up as a local initiative. Decisions on start-up were taken at departmental level, and the senior professional management of the hospitals was not involved.

The scientific documentation level related to the safety and efficacy of taTME surgery was limited throughout the period in which the method was in use. Only one hospital responded that they conducted one mini-method assessment, but this took place after the taTME method was adopted. The assessment did not concern the method itself, but rather the need for new equipment. One in seven hospitals established a clinical trial in conjunction with the start-up of the method. The national recommendations with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer relating to the use of taTME (the National Action Programme), were not followed.

Patients did not receive sufficient information about the taTME method, nor about the uncertainty and risks associated with it. Patient information was sent to a registry abroad without patients being informed of or consenting to this.

Four years passed from the first hospital starting up taTME operations in 2014 until concerns about the new surgical method were raised by some surgeons in the gastrointestinal surgical community. It was not until 2018 that the work commenced to achieve a national overview of how the patients were doing after their operations. The National Quality Registry for Colon and Rectal Cancer did not have check options for taTME surgery, so there was no national overview of adverse treatment effects.

Responsibility for safe organisation with new surgical and invasive methods

The responsibility for safe health services is a management responsibility, and the organisation of the surgical provision must be included in the hospital's overall governance system to ensure patient safety and quality. It is a management responsibility to ensure that all treatment offered by the hospital is in accordance with health and care legislation, and in line with professional and research ethical guidelines. On the trial of new surgical and invasive methods, the national guidelines with principles for trial treatment must be adhered to.

NHIB points to the following learning points that can help improve quality and patient safety when new surgical and invasive methods are adopted.

- There should be a very low threshold to acknowledge changes associated with a surgical or invasive procedure as a new method and secure implementation in the conduct of a clinical trial. A change may comprise the adjustment of a technique, the use of new equipment, or a change in the organisation concerning the procedure.

- There is often a lack of knowledge base, for example from randomised controlled trials, when new surgical methods are trialled. New Methods' national decision-making system is not suitable for assessment of new surgical methods that are being trialled. Methods with limited documentation will lead directly to a negative decision. Hospitals can make local decisions on the introduction of new methods following their own method assessments, and in line with current legislation and national recommendations. There must be expertise at hospitals to conduct mini-method assessments. The decision-making process must be documented.

- There is a need for more robust organisation of decisions locally, regionally and nationally for the trial of methods where the knowledge base is limited. The decision on the trial of a new method should be made at senior overall level in the hospital and not only at departmental level. This is to better ensure that the introduction adheres to prioritisation guidelines and principles of investigative treatment, and is in line with legal and research ethical guidelines. This can provide better opportunities for regional and national governance and the dimensioning of treatment provision. The medical directors of hospitals and regional health autorities should be included in the decision-making loop in order to achieve a regional overview of new methods and/or the introduction of new methods.

- The general rule for the trial of new surgical and other invasive methods with a limited knowledge base must be that this should take place as part of a clinical trial in accordance with

current legislation, and in line with national principles of investigative treatment. Quality assurance via quality registries is not sufficient, but may provide a supplement as a basis for comparison concerning the new method. The use of quality registry data in registry-based randomised trials (R-RCT) may be a relevant type of randomised clinical trial.

- Introduction of new surgical methods that are subject to development should take place at hospitals which have the research resources and expertise to follow up new methods with the necessary research. It will often be necessary for the trial to take place as an element of research collaboration within the regional health authority or nationally. In research design, it should also be assessed whether to draw up a nationally monitored deployment plan for the trial.

- Hospitals must have procedures for decision-making processes that are in line with national principles for trial treatment when a new method is adopted outside a clinical trial. This would ensure, among other things, good patient information and informed consent.

Patient information and involvement

- It must be a general rule that a standard patient information letter is prepared for all types of planned treatment. In the case of trial treatment, there are tighter patient information requirements, and the patient must not be in any doubt that the treatment may be associated with uncertainty and increased risk. The information must be in writing, and the patient should also be given the opportunity to ask questions. Verbal information alone is not sufficient. The patient must give informed consent to trial treatment.

- Patients have a right to be involved in deciding which treatment they receive. The co-choice method should be used when there are two or more relevant treatment options. Through shared decision making, the patient must receive adequate and correct information about all available and appropriate options, whereby the benefits, drawbacks and uncertainties associated with the various treatments are clearly communicated. A shared decision making process will also give the patient better opportunities to be able to ask questions.

- The information process associated with the trial of a new surgical or invasive method must be documented in the patient’s records.

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