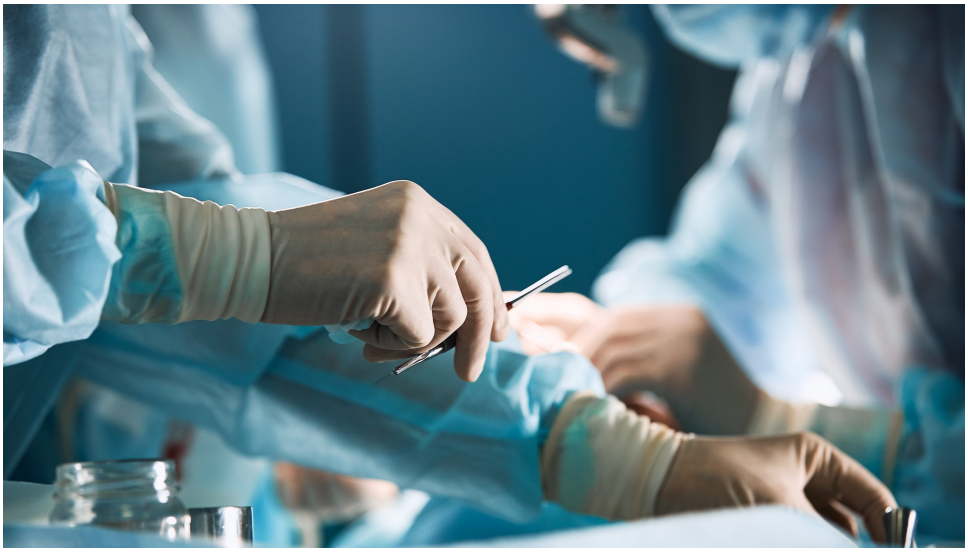
The patient’s right to be involved and to receive information



Ukom



MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

The patient’s right to be involved and to receive information

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How were patients informed?

The Norwegian Regulations for Management and Quality Improvement in the Health and Social Care Services define the management's responsibility for ensuring that the enterprise’s activities are in line with current legislation and that employees have the necessary knowledge and expertise concerning, applicable regulations, policies and guidelines (53).

In the National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer, 5th edition, it is referred to how the taTME technique is in a developmental phase and that its oncological safety has not yet been adequately documented. It was therefore recommended that the method should be used within the framework of prospective clinical trials in order to gain more knowledge of treatment outcomes. The recommendation also includes sound information for participating patients (23).

If the trial of new surgical procedures takes place as part of a clinical trial, this may help to ensure that the choice of treatment method is based on the patient’s informed consent. The trial must include procedures for verbal and written information on both new and established methods, documentation of this in the patient’s records, and information on how patient data will be used. This will also ensure that the rights described in the Norwegian Patient and User Rights Act are safeguarded:
“The patient shall have the information that is necessary to obtain an insight into his or her health condition and the content of the health care.” (Section 3-2 of the Norwegian Patient and User

Rights Act.) With regard to patient information, we also refer to the national guide with principles for trial treatment (33).



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Methods introduced as part of clinical trials will also be subject to the Norwegian Health Research Act. This includes requirements for approval by Regional Committees for Medical and Health Research Ethics (REK), in addition to informed consent from the patient.

Relevant legislation

Norwegian Patient and User Rights Act (Pbrl)	Sections 3-1 to 3-6 of the Norwegian Patient and User Rights Act describe patients' rights to be involved and to receive information. For treatment which is not generally recognised, i.e. trial treatment, there is a stricter obligation to provide information. (Norwegian Appeal Board for Health Personnel 02/169) (54).
Norwegian Health Research Act	Chapter 4 of the Norwegian Health Research Act contains provisions regarding consent. The main rule is that participants' consent is required for health information to be used in a research project (55).
Norwegian Healthcare Personnel Act (Hpl)	The duty of healthcare professionals to provide information is stipulated in Section 10 of the Norwegian Healthcare Personnel Act. The duty of healthcare professionals to document the healthcare is stipulated in Chapter 8 of the Norwegian Healthcare Personnel Act. What is to be documented is further described in the Norwegian Patient Record Regulation (56). An important aim of the documentation obligation is that it must be possible to subsequently verify the healthcare, and which information was provided (57).
Norwegian Management and Quality Improvement Regulation	The regulation aims to contribute to professionally sound health and care services, improvement and patient and user safety, and compliance with other requirements in health and care legislation (53). The regulation came into force on 1 January 2017 and specifies senior management's responsibility for planning, execution, evaluation and correction of the activity.
Norwegian Patient Record Regulation	The regulation aims, among other things, to contribute to the patient's right to information and involvement, and that healthcare can be verified retrospectively (56).

In our investigation, only one healthcare provider stated that they informed patients both in writing and verbally prior to taTME surgery that this was a new method subject to development. The other hospitals responded that to a great extent they informed patients verbally that they would be operated on using a new method, but this was not further documented in the patients' records. One provider responded that they did not inform patients that taTME was surgical technique in a developmental phase.

No patient information letter was prepared that in a good way explained to patients what the surgical method concerned. Nor was there any information concerning the extent to which it had been documented that the new method gave a better outcome compared to the traditional method, TME.

Several of the hospitals responded that they perceived the introduction of taTME as a quality project. Healthcare providers have a duty to quality assure the healthcare they provide. Quality assurance concerns evaluating whether the healthcare achieves the expected results with good quality. It may concern evaluating a service (procedure, drug, surgery), a treatment performed by a unit (team, department, hospital), or treatment associated with a particular diagnosis. Quality assurance does not concern trying out new methods and therapies, or developing new knowledge about health and disease. Such purposes are defined as health research (58). The performance of a quality project is not subject to the same stringent requirements for informed consent, provided that only information collected for use in the ordinary healthcare of the person concerned is used. An obligation to give information may nonetheless apply.

Shared decision making

Patients have a right to influence the treatment they receive at Norwegian hospitals. Shared decision making must be the norm when there are two or more real treatment options (59). Shared decision making is a process whereby patients, together with healthcare professionals, make decisions about which examination and treatment methods are best suited for the individual. The patient must receive adequate and accurate information about all available and appropriate options, and about the likelihood of benefits and drawbacks associated with the options available. The hospitals that were investigated were asked whether patients were presented with a choice between taTME surgery and traditional surgery. Most of the hospitals responded that patients were given this choice, whereby taTME was presented, among e.g. as a new method of avoiding a permanent colostomy bag. None of the hospitals stated that they informed patients prior to the surgery that the knowledge base associated with the taTME method was limited. Two hospitals responded that patients were not presented with a choice of surgical methods. Patients thus did not have the opportunity to decline or choose another option.

NHIB has had contact with patient and user organisations during the investigation. These organizations highlight that patients have a high degree of confidence in the treatment they are offered at Norwegian hospitals. Patients trust what doctors say, and it is not common for the patient to ask critical questions. Another factor that was highlighted in connection with bowel cancer is that this is a disease for which there is a strong taboo. This may result in patients not being inclined to question the treatment offer they receive. NHIB believes that by applying shared decision making methods to treatment options, patients will also have better opportunities to ask difficult questions.

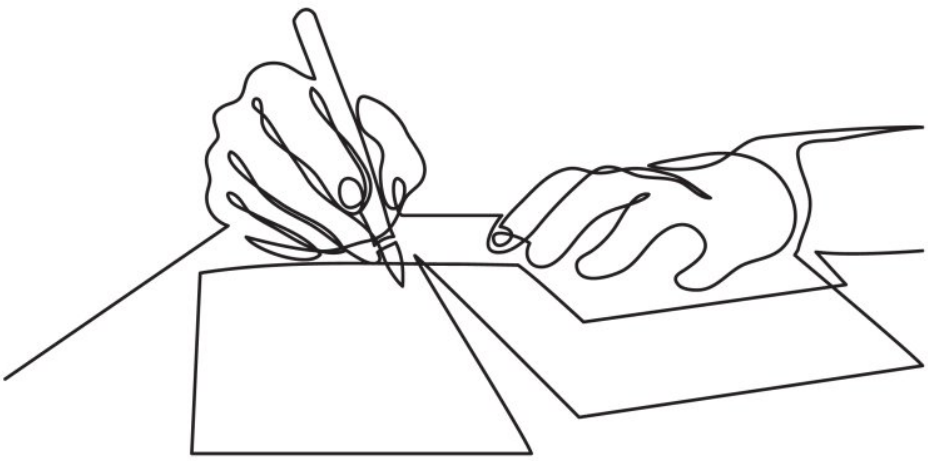


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