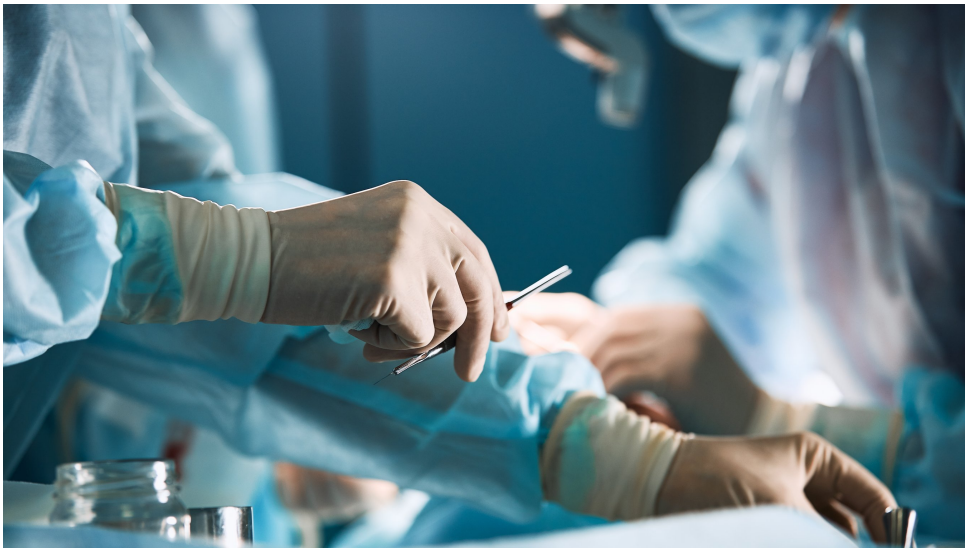
Lack of a national overview of patients who underwent taTME



Ukom



MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

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In the National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer from 2017, it was found that the oncological safety of taTMe was not adequately documented. The method should therefore only be used within the framework of prospective clinical trials and with sound information for the patients involved (23).

Our investigation shows that only one of the hospitals created a local trial protocol with patient information letters and written consent from the patients when they started up taTME surgery. Two hospitals stated that they considered the new surgical method to be a quality project that they followed up through quality registries, including the Norwegian National Registry for Gastrointestinal Surgery (NoRGast).

NoRGast

The Norwegian National Registry for Gastrointestinal Surgery was established on 1 January 2014. The aim is to safeguard the quality of gastrointestinal surgery at Norwegian hospitals. The registry will contribute to identifying areas of failing quality in order to drive targeted quality improvement work. Continuous quality assurance at national and departmental level will also form the basis for treatment-related research. In the longer term, it will also contribute to improving the treatment that patients receive. The University Hospital of North Norway HF (UNN) holds the administrative responsibility, and the professional council is responsible for the professional content. The members of the registry's professional council are elected from all the regional health authorities. The members have doctoral degrees as a minimum and support from their own professional community (48).

Our investigation shows that at six of the seven hospitals, no clinical trial was established and that it was considered unnecessary to submit an application to REK. The hospital that created a trial on testing taTME did not send an application to REK either. This was decided after discussion with the local data protection officer, who advised on the collection and processing of personal data relating to taTME for internal quality assurance. This was also the only hospital where the data protection officer was involved. In addition, three hospitals shared data with an international registry study in England, without the patients being informed of or consenting to this.

Furthermore, the National Quality Registry for Colorectal Cancer, which is one of several quality registries in the Cancer Registry, did not have the opportunity to register which patients had undergone the taTME procedure. The reason was that the registry did not have a separate checkbox for this information. According to our informants, the possibility of registering such information had been requested by elements of the gastrointestinal surgical professional community.
The Cancer Registry was also aware of this issue. It was therefore not possible to use this registry to monitor outcomes of the taTME method. However, the Cancer Registry may be used for comparison (benchmarking) of new methods against established methods. It will not be possible for a national quality registry to have an overview of new methods that are started up in hospitals as local initiatives and which have not been approved through, for example, the New Methods system. When the national review (audit) of all taTME procedures was initiated, data had to be obtained from each of the hospitals via surgeons at the relevant departments.

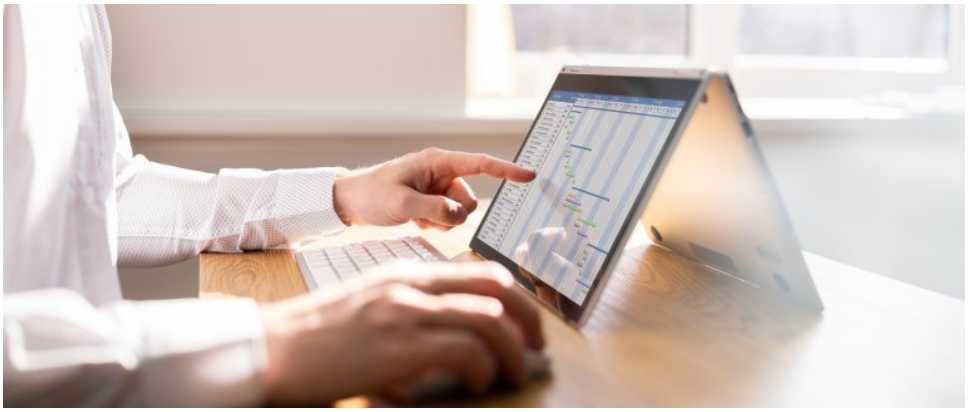


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National quality registries

National quality registries are tools for quality assurance of health services and patient safety. In Norway, 51 national medical quality registries have so far been established. Among these, there are registries for several different cancers, including colon and rectal cancer (49). The National Quality Registry for Colorectal Cancer (the Colorectal Cancer Registry) was established in 2007 when the National Quality Registry for Rectal Cancer (the Rectal Cancer Registry) was expanded to include colon cancer (50). The Rectal Cancer Registry was already started in 1993, at the same time as the introduction of TME as the standard surgical treatment for rectal cancer in Norway (50). The aim was a clinical registry with data quality that was good enough for the quality of treatment at Norwegian hospitals to be assessed (50, 51). The idea was that harmonising and modernising patient treatment would improve treatment outcomes by reducing local recurrences and increasing five-year survival rates after TME (50, 51), which has proved to be the case (50). The Rectal Cancer Registry has been a measure to improve quality and patient safety within Norwegian cancer treatment (50, 52).

We have previously referred to how the recommendation was made in the National Action Programme for Treatment of Colorectal Cancer, 5th edition, that taTME should be used within the framework of prospective clinical trials (23). In practice, the introduction in hospitals nonetheless took place at the decision of the local professional communities, without any clinical trials being started up. There was no opportunity either for the National Quality Registry for Colorectal Cancer to capture which patients were operated on using the new method. There was thus no national overview of how the recommendation was followed in the hospitals in question.

The letter sent to patients on behalf of the Norwegian Minister of Health and the regional medical directors in 2020 states that “In Norway, operations for cancer tumours in the rectum and results after surgery are recorded in a common registry. The registry provides a good overview of the treatment outcomes” (Appendix 1).

This wording in the letter gives the impression that it was through a common registry that the severe complications and early local recurrences were discovered. The reason that a connection between the taTME surgical method and the severe outcomes was discovered was, however, that treatment of recurrences of rectal cancer was centralised at the Radium Hospital. In the South-Eastern Norway Regional Health Authority, where most taTME procedures were performed, all patients with a recurrence of rectal cancer are referred to this leading cancer hospital. Individual

patients from other regions with particularly complicated cases of the disease are also referred to this hospital. Through this centralised scheme, surgeons at the Radium Hospital became aware that several of the patients with severe recurrences had been operated with the taTME surgical method relatively shortly before the recurrence. The surgeons raised this issue at the 2018 spring meeting for the gastrointestinal surgical professional community, as further described in the timeline. It was thus almost a coincidence that the link between taTME surgery and early local recurrence was discovered.

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