Maintaining patient safety with new surgical and invasive methods

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Maintaining patient safety with new surgical and invasive methods

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Our investigation concerns the transanal total mesorectal excision (taTME) method, which was implemented at seven Norwegian hospitals in the period from 2014 to 2018. It was used as the primary surgical tecnique for rectal cancer at these hospitals.

The taTME operations were eventually halted when it emerged that the 157 patients operated on using the new method had elevated complication and recurrence rates compared to patients who underwent surgery by the established method, i.e. total mesorectal excision (TME).

Development of new treatment methods is important for the continuous quality improvement of the health and social care services. The goal is to provide increasingly more accurate treatment. New treatment methods must have an improved effect on the disease being treated and limit the risks of the actual treatment. Before a decision is made to introduce a type of treatment as a new method, the method undergoes a research and trial phase. Legislation, national guidelines and established decision-making processes must ensure that new treatment methods are introduced safely and are consistent with national priorities.

Our investigation shows that the introduction of new surgical and invasive methods has traditionally been far less systematic than in the case of e.g. new drug treatments. Trial of a new treatment requires careful monitoring of the individual patient within a standardised framework. This is particularly important in the cancer area, so as not to inflict an increased risk of recurrence and death on patients.

Our report is based on review of documents, as well as interviews with a number of informants in the specialist health service, administration and professional and interest organisations. In this investigation we have not had any opportunity to present an individual patient story. None of the hospitals involved reported recurrences or complications in taTME-operated patients as serious adverse events related to patient treatment. The patient perspective of the investigation is safeguarded through dialogue with patient and user organisations.

The story of taTME in Norway is an important reminder that there should be a low threshold for new surgical techniques, the use of new technical equipment or new organisation of a procedure to be deemed to constitute trial of a new method. As a general rule, trial of a new method should adhere to clinical research principles.

Our investigation should be of interest to all professional disciplines in the specialist health service that develop and adopt new treatment techniques, even though the starting point and the event investigated are from the gastrointestinal surgical field. The report should be studied in particular by responsible professional managers at our hospitals, as the report presents some key learning points that can help ensure wider safeguarding of quality and patient safety when new surgical and

invasive methods are adopted.

2 Background to our investigation

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A new surgical method for rectal cancer, called transanal total mesorectal excision (taTME), was adopted at seven Norwegian hospitals in the 2014-2018 period.

The professional surgical communities in Norway suspended use of the method in autumn 2018 as a consequence of concerns related to complications and recurrences. A national review was then conducted under the auspices of the Norwegian Gastrointestinal Cancer Group (NGICG-CR). The review showed that the use of taTME in Norwegian hospitals has an elevated complication and recurrence rate compared to the standard surgical method of total mesorectal excision (TME).

NGICG and NGICG-CR

The method was subsequently also assessed in the Norwegian National System for Managed Introduction of New Health Technologies (New Methods) by the interregional medical directors meeting, which in April 2020 decided that the method would not be introduced, due to inadequate documentation.

Ukom (Statens undersøkelseskommisjon for helse- og omsorgstjenesten), hereinafter referred to in English as NHIB (the Norwegian Healthcare Investigation Board) initiated an investigation into the introduction of this surgical method as a serious patient safety issue. The aim is to identify risk areas associated with the introduction of new surgical methods on the basis of the process for using taTME. The report will also point to key learning points that could help improve patient safety related to the introduction of new surgical methods.

Due to the scope of the report, we will not further consider the technical surgical details or professional discussions concerning the taTME method itself. For the same reason, we do not make any assessment of various drivers for the introduction of new surgical methods.

This report has become even more relevant due to the recent media reports on the Norwait study, which also concerns the treatment of rectal cancer. The Norwait study is not discussed in our investigation.

3 The history of taTME in Norway

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Rectal cancer is a serious disease for which treatment methods have developed considerably over the past 50 years. Survival rates have improved significantly. Rectal cancer is treated with surgery, but some patients also receive additional radiation therapy, with or without chemotherapy. The total mesorectal excision (TME) surgical method, which is the standard treatment, was introduced in Norway in 1993. Following the introduction of keyhole surgery (laparoscopy), TME became a more difficult procedure for some patients, due to anatomical conditions. A new method was therefore developed internationally around 2010, called transanal total mesorectal excision (taTME). The method was considered to be promising and, based on early trials, drew interest in many countries. The aim of taTME was to improve the treatment of the cancer disease, and to avoid a permanent colostomy bag for the patient. In Norway, a total of 157 patients were subject to the taTME procedure, before the method was suspended in autumn 2018.

TaTME is considered to be a complex procedure that requires structured training and sound quality assurance. A total of seven Norwegian hospitals (five university hospitals and two local hospitals) implemented or trialled this technique from 2014. In the National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer from 2017 (5th edition), it was stated that the method was in a development phase and that it should therefore be used within the framework of prospective clinical trials, to provide more knowledge of results. Participating patients were also to receive thorough information about their treatment. This recommendation was only followed to a small extent during trial of the method. Only one of the hospitals stated in their response to NHIB that they began the introduction of the method as part of a clinical trial. Two hospitals stated that they viewed the introduction as a quality project. Therefore, they registered the taTME data in their respective local quality registries.

In 2018, preliminary findings were available from Norway, with worrying results in the form of elevated complication and recurrence rates related to the taTME method. The topic was first addressed at the oncosurgical spring meeting under the auspices of the Norwegian Gastro Intestinal Cancer Group (NGICG) in April 2018. Here, the negative results after taTME surgery were presented. At the surgical autumn meeting in October 2018, the concern about taTME was addressed further in a symposium. Here, the professional community agreed that use of the technique had to be suspended. There was also agreement on the need for a national review of all patients who were subject to the taTME surgical method and that the findings needed to be shared internationally. The National Quality Registry for Colorectal Cancer had no separate checkbox to register which patients had received taTME surgery. In the review, data therefore had to be obtained from each individual hospital where the method had been implemented.

The concerns about taTME were further addressed at the Norwegian Gastrointestinal Cancer Group-Colorectal's (NGICG-CR) meetings in September and December 2018. At the December meeting, NGICG-CR formally decided to notify the regional medical directors. In the letter that was sent, they discouraged use of the method until requirements for systematic training of surgeons and a clinical trial that included all taTME patients were in place. It was also decided to conduct a national scientific review (audit) under the auspices of NGICG.

The regional medical directors notified the taTME method to the Norwegian National System for Managed Introduction of New Health Technologies (New Methods) at the Bestillerforum (Ordering Forum) in June 2019. The Ordering Forum asked the Norwegian Institute of Public Health (FHI) to conduct a literature search to identify available documentation. Prior to this, NGICG-CR was requested by the regional medical directors to notify the method themselves, but they refused this.

NGICG-CR justified their refusal, because the method had already been suspended, the knowledge base was deficient, and that the national scientific audit was still ongoing.

In December 2019, results from the national audit were published in the British Journal of Surgery. The audit showed higher complication and recurrence rates among patients who had undergone taTME surgery compared to those treated by the standard TME method.

Most of the 157 patients who underwent taTME surgery only received oral information that taTME was a method that was subject to development. The hospitals stated that all patients who underwent taTME surgery were contacted subsequent to the operation, after it was discovered that the method presented an increased risk of complications and recurrence.
The Norwegian Health Minister at that time, Bent Høie, was not satisfied with the information provided by the hospitals and required the regional health authorities to issue more comprehensive patient information that included clear information about patients' rights. This took place in January 2020.

On 23 April 2020, the interregional medical directors meeting decided that the taTME method should not be introduced, as the documentation was deficient. In the decision, it was also indicated that if a new assessment of the method was required, this had to take place via a new request to the National System for Managed Introduction of New Health Technologies (New Methods). The decision was based on a memo from FHI which concluded that data was mainly available from non-randomised trials with limited long-term survival and recurrence data. The decision of the interregional medical directors meeting is recorded in the minutes of the Decision Forum for new methods on 25 May 2020.

4 Treatment of rectal cancer in Norway

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Around 1,100 cases of rectal cancer are diagnosed annually in Norway (2). The diagnosis is made on the basis of tissue samples via scopy examination of the intestine. Once the diagnosis has been made, it is assessed how far the cancer has spread and whether surgery to attempt to remove the cancer is relevant. In principle, all patients with newly diagnosed rectal cancer must be assessed for surgery, either for curative or life-prolonging purposes, unless the patient will not be able to cope with this or the disease is very far advanced (3). The survival rate for rectal cancer has improved over the last 50 years. The five-year relative survival rate has increased from approximately 15 per cent to 70 per cent (4).

In Norway, we have a national cancer treatment strategy (2006-2009) whereby various expert medical groups have contributed to professional recommendations for the diagnosis and treatment of various different types of cancer. These recommendations have been continued and formalised through national action programmes for which the Norwegian Directorate of Health is responsible. The first Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer was published in 2010. So far, a total of eight editions have been published, the most recent in December 2020. The national guidelines are “not directly legally binding, but to a great extent govern the choices made” in the health service, including to ensure professional soundness (3). The cancer treatment action programmes must contribute to public-sector cancer care of good quality, with equal access across Norway.

The Norwegian Directorate of Health sets up its own working groups for each action programme, based on input from the four regional health authorities (RHA). The Norwegian Directorate of Health leads the work and is the responsible publisher. NGICG and NGICG-CR have contributed to the work of revising the content of the action programme relating to colorectal cancer (3).

The TME method

The total mesorectal excision (TME) method was first described in professional communities internationally in 1979 (5). The method was adopted internationally as the standard treatment in the 1990s (6). In Norway, TME became the standard treatment for rectal cancer as from 1993 (6). The technique has contributed to reducing local rectal cancer recurrence rates from well over 20 per cent to around 4 per cent today (7.8).

For some patients with low tumours down towards the anus, TME is not a complete solution, however. In these cases, a rectum amputation is still necessary – which means removing the entire area with the rectum and pelvic floor, with a good margin to the tumour. However, this operation entails permanently opening the bowel.

TME (total mesorectal excision)

The taTME method

When keyhole surgery (laparoscopy) was introduced, ordinary TME became more difficult to perform for some patients, due to cramped pelvic conditions and difficult access at the bottom of the pelvis. This applies especially to men, in particular if they are overweight. As a consequence, a new method with access through the anus, called transanal total mesorectal excision (taTME) was presented by Sylla and Lacy in 2010 (12). Treatment using the taTME method could, give patients a very low splicing of the rectum, giving better opportunities to avoid a permanent colostomy bag (stoma) (3, 6).

TaTME (transanal total mesorectal excision)

However, the method is debated in the international gastrointestinal surgical community. Some have considered the method to be promising, based on results from early trials (14-16). Others expected that the method might lead to fewer postoperative complications, and believed that the method provided a safer splicing (6,17). From the professional community there were also early objections to the method for violating safe TME surgery and for being used for tumours that did not need a low splicing (6,18). TaTME was implemented in e.g. the UK, the Netherlands, Denmark, the USA and China, while other countries waited. At the time of writing, the National Institute for Health and Care Excellence (NICE) in the UK has put the method on hold (19), while the Netherlands has limited taTME surgery to a single centre (20).

The detailed course of the introduction of taTME in Norway is described in the timeline in the next chapter. In brief, the method was adopted at seven hospitals in Norway from 2014 to 2018. The first hospital already started up taTME in October 2014, while the last hospital adopted the method in January 2018. All use of taTME was suspended by the gastrointestinal surgical professional community in Norway in autumn 2018, due to elevated complication and recurrence rates. The method was subsequently also assessed by the National System for Managed Introduction of New Health Technologies (New Methods), where the interregional medical directors' meeting in April 2020 made the decision that the method could not be approved due to insufficient documentation. This shows that the documentation was no better when the method was adopted in Norway in 2014.

5 Timeline for use of taTME

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Timeline for use of taTME

Time	What happened
1979	The TME method is described for the first time (5).
1980s	The TME method becomes known internationally (21)
1993	TME is introduced in Norway as the standard treatment for rectal cancer (22)
2010	TaTME is implemented internationally (12)
October 2014	TaTME is used for the first time in Norway, at a local hospital
2015	A further three Norwegian hospitals adopt taTME (two university hospitals and one local hospital)
2015/2016	NGICG-CR discusses and revises text on the taTME method for the National Action Programme for Diagnostics, Treatment and Follow-up of Colorectal Cancer, 5th edition.
February 2017	TaTME is mentioned for the first time in the National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer (5th edition), which is published by the Norwegian Directorate of Health, with the following wording in chapter 9.1.5 Laparoscopic transanal access: “The technique is in the development phase and although there are good results from individual centres, a systematic review in 2015 concludes that the oncological safety has not yet been adequately documented. The method should therefore be used within the framework of prospective clinical trials, with sound information for participating patients, to provide greater knowledge of outcomes.” (23)
May 2017	One university hospital implements taTME, but stops after one operation due to complications.
	One more university hospital uses the taTME method on two patients, but the planned

January 2018	operation on patient number three is stopped due to concerns from the Radium Hospital relating to early local recurrences. This hospital thus suspends taTME surgery before the national “stop order” is issued.
February 2018	Another university hospital implements TaTME, but stops after three operations.
March 2018	The Section for Oncological Pelvic Surgery of the Radium Hospital, which has a regional function for the treatment of recurrence of cancer in the South-Eastern Norway Regional Health Authority, identifies three patients with complicated (multifocal) local recurrences. Closer scrutiny identifies that these patients were operated on using the taTME method at hospitals in the regional health authority. This is notified to the clinic manager of the Division of Surgery, Inflammatory Medicine and Transplantation at Oslo University Hospital HF (OUS) and to the head of NGICG and NGICG-Colorectal.
April 2018	Oncosurgical spring meeting under the auspices of the Norwegian Gastro Intestinal Cancer Group (NGICG) – taTME results from two hospitals and notices of concern from the professional community at the Radium Hospital are presented.
May 2018	Concerns about taTME are addressed at an NGICG meeting.
June 2018	A member of NGICG writes a letter to the others within NGICG and to operating surgeons at the taTME hospitals about concerns relating to taTME,
September 2018	New discussion in NGICG. The Section for Oncological Pelvic Surgery of the Radium Hospital presents figures for five known recurrences after taTME.
October 2018	Autumn surgical meeting under the auspices of the Norwegian Association for Gastroenterological Surgery (NFGK) – preliminary results that included just over 100 patients were presented. Contributions from gastrointestinal surgeons at two hospitals were presented concerning recurrences after taTME for five and two patients, respectively. The method is discussed. The professional community decides to suspend the use of taTME in Norway, and NGICG is thereafter notified. There is agreement at the meeting to conduct a scientific audit of all taTME procedures that have been carried out in Norway. The agreement to suspend use of the method in Norway must be communicated internationally as quickly as possible.
December 2018	NGICG decides to recommend health authorities to put the taTME method on hold. They also decide to send letters about this to the medical directors of the four regional health authorities (RHA).
	14.01.19: Letters from NGICG-CR are sent to the medical directors of the regional health authorities to notify them about concerns regarding elevated complication and recurrence rates after taTME (Appendix 3). As a consequence, NGICG-CR discourages the use of taTME in the surgical treatment of rectal cancer in Norway until the following measures are established: "a national programme for systematic instruction and training of surgeons in this technique. A national prospective study that includes all of the patients to be treated

January 2019	using this technique." **24.01.-25.01.19**: The 9th Ahus Colorectal Symposium is held. For the first time, results are posted publicly, including to the international community. The symposium has participants from the USA and Europe. The preliminary results of the autumn surgical meeting are presented once again, but with updated data: nine patients with recurrences are known at this point. In addition, the special types of local recurrences observed are noted. The Norwegian results are commented on in a “Letter to The Editor” by Americans Gachabayov et al. in the international journal Updates in Surgery. (24).
March 2019	The first media reports about taTME in Norway and the recurrence rate appear. Minister of Health Bent Høie expects a thorough review of what has happened and the consequences it has had for the patients in question (25).
April 2019	NGICG-CR is encouraged by the medical directors of the regional health authorities to notify the method to the National System for Managed Introduction of New Health Technologies (New Methods). National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer, 6th edition, is published with a minor text change from the 5th edition (the change is marked by NHIB in bold). In Chapter 9.1.5 Combined laparoscopic and transanal access, the following is stated: “The technique is in the development phase and although there are good results **from an international registry, the introduction of the technique requires structured training and randomised trials.** The method should therefore be used within the framework of prospective clinical trials, with sound information for participating patients, in order to gain greater knowledge of outcomes.” (26) It should be noted that the chapter on laparoscopic rectal surgery, Chapter 9.1.4, is expanded with a concern: “It gives grounds for concern, however, that recent studies show uncertainty regarding the oncological quality of the surgical preparation by laparoscopic access. Even though the laparoscopic technique for rectal cancer is increasingly gaining acceptance, it is important to impose requirements for training and quality assurance of the procedure. The individual hospital performing this type of intervention therefore has a special responsibility for itself documenting competence, safety and results.” However, when the 6th edition of the National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer is published, the taTME method has already been suspended in Norway.
May 2019	NGICG-CR declines to register the taTME method with the National System for Managed Introduction of New Health Technologies (New Methods) on the grounds that the knowledge base concerning the method is insuffisient and that further results are needed

	to assess whether the method can be recommended in Norway, due to, inter alia, uncertainty concerning the local recurrences (relapses) detected in several Norwegian patients.
June 2019	TaTME is notified by the regional medical directors themselves to the Ordering Forum, as they consider the method to be technically demanding with a considerable training need on any introduction. The Norwegian Institute of Public Health (FHI) is commissioned to conduct a literature search to identify available documentation of the method. Media reports that Norwegian Health Minister Bent Høie is not satisfied with the information the hospitals have provided to the 157 patients who underwent taTME surgery. The Minister requires the regional health authorities to issue more detailed patient information (27).
July 2019	Editorial by Norwegian gastrointestinal surgeons on behalf of NGICG-CR concerning preliminary observations in Norway after the introduction of taTME is published in the British Journal of Surgery based on pending results from the national audit (Larsen et al.) (28).
September 2019	The scientific results from Norway are presented internationally for the first time at the annual “European Society of Coloproctology” (ESCP) meeting, 25.09-27.09.19, in Vienna (29). National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer, 7th edition is published with the following update in Chapter 9.1.5 Combined laparoscopic and transanal access: “The procedure is considered to be highly complex and requires structured training and sound quality assurance before it can be implemented in standard patient care. In an earlier edition of the National Action Programme on Colorectal Cancer (6th edition), it was recommended that the method should not be used as part of standard patient treatment, but solely be used within the framework of prospective clinical trials. Preliminary reports on the use of this technique in some Norwegian hospitals give cause for concern in terms of complications and oncological outcome. Against this background, the use of taTME in the surgical treatment of rectal cancer is not recommended in Norway until there is more knowledge about this procedure.” (30).
December 2019	NGICG publishes results of the national audit in the British Journal of Surgery for all patients (n=157) operated on using taTME in Norway (Wasmuth et al.) (6).
January 2020	The Health Minister, in collaboration with the regional medical directors, has created a common template for a new letter to the patients, which is sent from the hospitals that have used the taMTME method (Appendix 1).
April 2020	The interregional medical directors meeting makes the following decision based on FHI’s documentation assessment of taTME: “Transanal total mesorectal excision (taTME) may not be introduced. The documentation is deficient. If the method is required to be assessed once again, a new order must be submitted to the National System for Managed Introduction of New Health Technologies (New Methods).” (31).

May 2020	Decision by the interregional medical directors meeting in April 2020 is registered in the minutes of the new methods Decision Forum (31).
December 2020	National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer, 8th edition is published with the following update in Chapter 10.1.5 Combined laparoscopic and transanal access: “Preliminary reports on the use of this technique in some Norwegian hospitals give cause for concern in terms of complications and oncological outcome. The method may not be used in Norway following the decision of the RHA medical directors on the basis of letters from NGICG-CR in January 2019. The decision is valid until there is more knowledge about the procedure and the reasons for the poor results in Norway.” (3).

6 Trial of new surgical and invasive methods

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Innholdsfortegnelse

It has been established that the scientific burden of proof (evidence) associated with the taTME method was deficient, both at the time when the first hospital started up in 2014, and later via FHI's literature review (2019). The taTME method must therefore be considered to be a trial treatment.

The white paper Meld. St. 10 (2012–2013) Good Quality – Safe Services – Quality and Patient Safety in the Health and Care Service, the term trial treatment was used about "all treatment where efficacy, risks and adverse reactions are not sufficiently documented for the treatment to be included in the ordinary treatment provision. This means that trial treatment concerns both treatment subject to clinical trials and undocumented treatment given outside clinical trials." It is furthermore stated that the rapid developments in medical technology in recent times, such as keyhole surgery, have contributed to more effective and less invasive treatment for patients. However, it is a major challenge for both the health service and health authorities that these new methods are implemented without sufficient documentation of the method's safety, or adequate testing in clinical trials. The report also highlights the variation in practice in terms of how the health service adopts new methods, both between hospitals in the same region, and between regions. There is too little awareness of the divide between standard treatment, and what should be considered to be development work. Within surgery, there has been a tradition of developing the profession to ensure patients access to ever better treatment options. This has usually functioned well for minor adjustments to established methods. For wider adjustments, this approach presents greater risk to

the patient, because the patient may then be offered treatment that is neither approved nor safe enough. The fact that new methods are adopted following local initiatives also contributes to the failure of the health authorities to have sufficient oversight of the types of treatment options offered at the individual hospitals. The white paper Meld. St. 10 (2012–2013) also describes a need for a national method assessment system, as well as national principles for trial treatments, to ensure the development of safe treatment methods for patients (32). A national guideline with principles for trial treatment was published by the Norwegian Directorate of Health in November 2019. In the guide, there is a precise definition of trial treatment:
“Trial treatment is any treatment of which the efficacy and safety are not sufficiently documented for the treatment to be included in the normal treatment provision. This means that trial treatment concerns both treatment subject to clinical trials and treatment given outside clinical trials.” (33).

There are several examples up through history of how new surgical and invasive procedures have led to unexpected or serious consequences for patients after implementation (28). Examples of invasive methods that have been temporarily or permanently suspended after they were taken into use in Norway include TAVI (catheter-based implantation of heart valves in patients with aortic valve narrowing) and Essure (new sterilisation method for women), see Appendix 2.

NGICG and NGICG-CR

Introduction of TME in Norway as a national project

During the 1980s, reports were published from individual departments in England showing good treatment outcomes with fewer local recurrences (relapses) for rectal cancer using the TME operating technique (22). In Norway too, TME was taken into use at individual departments in Norwegian hospitals, with good results (34). This gave reason to believe that the TME method could improve rectal cancer survival rates. There were gradually also reports that rectal cancer surgery should be performed by fewer, specialist surgeons who were specially trained in the method. In order to assess whether these measures worked, a national registry for rectal cancer was needed. In Norway, the introduction of the TME surgical method in 1993 was organised as a national project (the Rectal Cancer Project), and a number of courses were arranged for the training of surgeons in Norway. In this way, hospitals could compare themselves with a national average, correct their own practice and ensure the necessary quality improvement. Pathologists also received training aimed at a quality improvement in and standardisation of the descriptions of the pathological samples, so that these could also be evaluated. An evaluation of the introduction of TME in Norway in the 1993-1999 period showed that surgery using the TME technique reduced the frequency of local recurrences (relapses) from 28 per cent to 8 per cent, while the five-year survival rate increased from 55 per cent to 71 per cent for patients under 75 years of age (22). In order to monitor patients with rectal cancer who had received TME treatment, in collaboration with the Cancer Registry a quality registry for rectal cancer was created in 1996. In addition to registering data relating to the use of TME, there was also prospective registration of rectal cancer in Norway.
Registration of colon cancer was included in this registry as from 2008, and the registry gained the status of official National Quality Registry for Colorectal Cancer (1).

How taTME was implemented in hospitals

In our investigation, we have seen that there was no equivalent national coordination of the start-up of taTME surgery. The method was used in Norway for the first time in 2014, at a local hospital without any kind of protocol. Common to all seven hospitals that began to perform taTME surgery was that the decision to start up was taken at department level after assessment by the local gastrointestinal surgical community at the hospital. TaTME was implemented by hospitals in three out of four regional health authorities in Norway. At this time, taTME was not mentioned in the National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer. Nor was taTME registered for method assessment in the National System for Managed Introduction of New Health Technologies (New Methods).

Foto: shutterstock

NHIB has obtained information from the gastrointestinal surgical departments of all hospitals that implemented the method. The information we have received shows that it is common practice for the trial of new surgical methods to be decided at department or clinic level. Locally managed trials of new methods has been a tradition within surgery. Today it is most often the case that new methods are introduced as a local initiative, by the individual surgeon on the basis of their own special interests. This is how surgical innovation has been promoted. This constitutes a completely different tradition to the introduction of new drugs, which without exception takes place through trials in research projects.

The hospitals responded that, in connection with the trial of taTME, training and guidance were provided for the participating surgeons. The training varied, with some surgeons receiving training abroad via courses in Spain, the UK, the Netherlands or Belgium. Some hospitals also used Norwegian or foreign proctors (supervisors), but three of the seven hospitals stated that they did not use any such proctor scheme when they started using taTME. There was no standardised strategy

for training Norwegian gastrointestinal surgeons before the method was adopted. The professional communities at the respective hospitals decided for themselves how the training would be conducted for their own surgeons.

Only one of the hospitals in our investigation stated that they undertook taTME as part of a clinical trial. The other hospitals had no ongoing trials at the time of adopting taTME, even though three of the hospitals adopted the method after 2017. The recommendation in the National Action Programme for Colorectal Cancer was that taTME should only be used within the framework of prospective clinical trials, with thorough information for participating patients, in order to gain greater knowledge of outcomes. It was also in this edition of the 2017 Action Programme that taTME was mentioned for the first time. The hospitals that started to use the method, without a clinical trial, stated as a reason that the method was perceived as sufficiently well-documented.
The hospitals believed it was sufficient to monitor patient data in local quality registries.

As the timeline shows, we can see that revising and updating the national guidelines for treatment of colorectal cancer was a protracted process. The Norwegian Directorate of Health has informed NHIB that the national action programmes in the cancer field are now updated and revised regularly and as required, and at least once every year.

In the guidelines published in England by the National Institute for Health Care and Excellence (NICE) in March 2015 regarding taTME, it was stated that the current evidence regarding the safety and efficacy of the method was limited, in terms of both quantity and quality (35). The guidelines therefore required surgeons who wanted to try the method to inform the senior management of this, and also that the patients in question had to be informed in detail and in writing of the uncertainty associated with the procedure. Furthermore, the guidelines required the introduction of the method to be followed up, either with surveillance (monitoring) or research, in order to control patient outcomes (35).

As we have seen in this investigation, no nationally formalised cooperation was established to trial the taTME method in Norway. Nor was a taTME registry created, which would have made it possible to aggregate the results of all seven hospitals and quality assure the results of the method in Norway. A national overview, in the form of a scientific audit, was not in place until the autumn of 2018. This took place after the first notifications of concern had become known in the spring of 2018. So it took around four years from the first hospitals adopting the method until the work commenced of gaining an overview of the outcomes of the taTME procedures carried out in Norway.

In our investigation, three hospitals responded that they fully or partly registered their patient data in the international taTME registry, International taTME educational collaborative (36). One hospital submitted an application to the Regional Committees for Medical and Health Research Ethics (REK) in Norway for assessment and approval of the submission of patient data to this international multicentre study (LOREC). However, this application was submitted in February 2019, long after the hospital had submitted data to the English taTME registry, LOREC. The hospital has informed NHIB that it submitted data from the ordinary patient records, including demographic, tumour-related, intra- and postoperative data (gender, date of birth, date of surgery, preoperative diagnostics with MR and ultrasound, intraoperative data such as blood loss and operation time, and postoperative data such as length of stay on the ward and complications, as well as long-term follow-up). REK assessed that the application concerned quality assurance of treatment provision that already was established, and concluded that the project therefore fell outside the scope of the Norwegian Health Research Act with approval requirements. The other hospitals had no contact with REK in connection with the use

of the method. One of the hospitals received an assessment from the local data protection officer (DPO), who concluded that there was no need for REK's approval. None of the other six hospitals stated that they approached their local data protection officer for an assessment.

Norwegian Regional Committees for Medical and Health Research Ethics (REK)

Introduction of new surgical methods as a trial compared to new drugs in National System for Managed Introduction of New Health Technologies (New Methods)

The introduction of taTME in Norway illustrates how surgical interventions have traditionally been adopted and the challenges this presents, compared to, for example, the introduction of new drug therapy.

In 2013, a national scheme for the introduction of new drugs and methods was established, called the National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway, now New Methods. The regional health authorities are responsible for New Methods. This scheme has mainly been used for the introduction of new drugs, and to a small extent for the introduction of new surgical methods, as the majority of the cases reported for consideration by New Methods relate to drugs (37).

In 2020, a total of 142 proposals and method alerts were reported for assessment in New Methods, distributed as 121 methods for pharmaceutical drugs, 10 methods for medical devices, diagnostics and tests, and 11 methods for procedures and organisational measures (37). From the establishment of the New Methods system in 2013 and up to 2020, a total of 769 proposals and method alerts were submitted for assessment. These comprise 597 methods for drugs and 173 methods for non-medicinal products (such as medical devices, medical and surgical procedures and diagnostic tests) (37).

The fact that assessment of surgical methods is in the minority may be due to several factors. One reason may be that the development of new surgical methods and other non-medicinal methods cannot always take the same course as for the development and introduction of new drugs with randomised trials (38). It is more difficult to conduct randomised trials for surgical methods than for new drugs (38, 39). It is also possible that fewer new surgical methods are actually developed, compared to medicinal products, but this is difficult to quantify.

Introduction of new drugs

Randomised controlled trials compared to observational trials

Registry-based randomised trials (R-RCT)

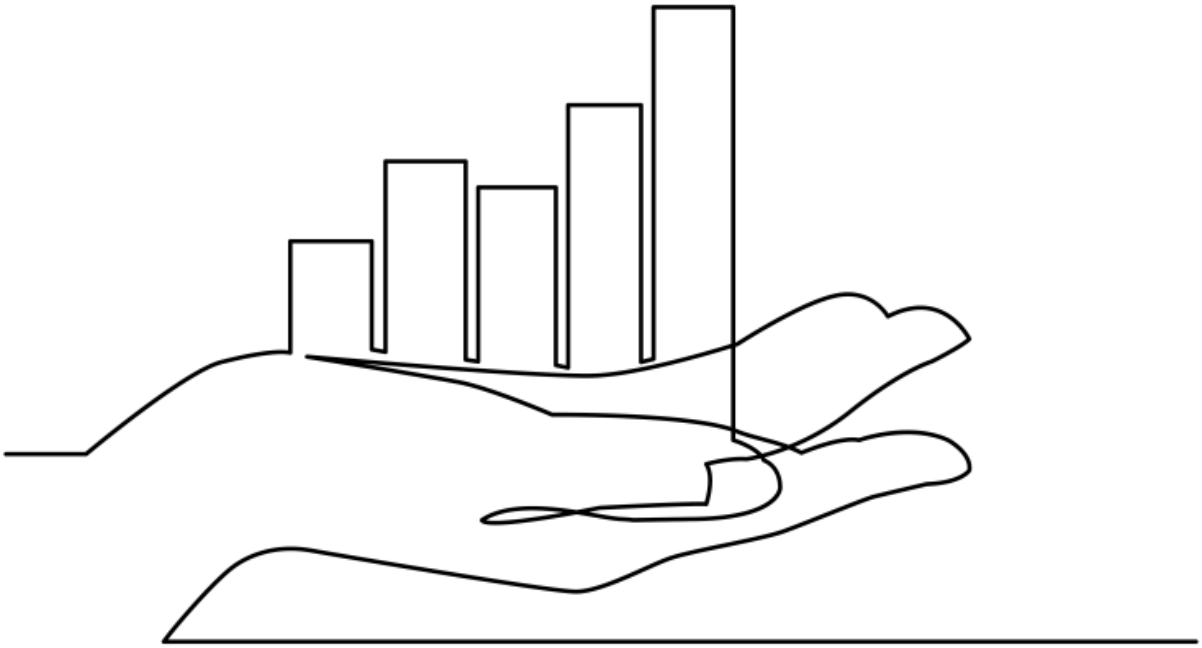
The introduction of the taTME method in Norway is a good example of challenges related to the introduction and implementation of new surgical techniques, compared to the introduction of new medical products. When introducing new drugs, there are strict rules and requirements for testing in clinical trials before the drug can be approved for clinical use. For new surgical methods, there is no equivalent tradition of adhering to regulations or requirements prior to implementation (28).

For example, the existing TME method was gradually adopted as the standard surgical treatment for rectal cancer, based on observational studies rather than randomised, controlled trials (28). TME subsequently proved to be a method that reduced local recurrence of rectal cancer, both in Norway and internationally.

The learning curve on the introduction of new methods

Another challenge associated with surgical innovation is learning curves. The introduction of a new surgical method requires the surgeons to receive training before they can perform the procedure independently in a responsible way (28). This means that there is a learning period during which the individual surgeon has limited experience from using the method, and where there is a greater risk of adverse outcomes. Nevertheless, it is not acceptable for the learning curve period to affect the safety of patients (7). If there is a risk of patient injury, compensatory measures must be taken in advance.

On the trial of taTMe in Norway, there was great variation in training and guidance (proctor scheme) at the seven hospitals. Some members of the Norwegian gastrointestinal surgical community state that the learning curve was of less significance on the introduction of taTME in Norway. The reason given is that the local recurrences occurred not only after the earliest treatments performed, but also after experienced surgeons had used the method at several of the hospitals (6, 7). The learning curve is nevertheless referred to internationally as an important factor to take into account when using this method (43).



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Mini-method assessment for new treatment methods

A mini-method assessment is a simplified assessment that can be used by hospitals before a new treatment method is adopted. Mini-method assessment includes a literature search and critical assessment of research literature on the method, with main emphasis on efficacy and safety. In addition, the organisational, economic and ethical implications of introducing the method (44) are assessed.

The Norwegian Institute of Public Health (FHI) is the national resource group for mini-method assessments, and competence resources have been established in all of the four regional health authorities, to assist the clinical professional community with the preparation of these assessments. On FHI's website it is stated (in Norwegian) that
“Mini-method assessments reveal the consequences of introducing new methods at hospitals, contribute to knowledge-based and transparent decisions, and help to increase patient safety” (45).

FHI also operates the national database for mini-method assessments with an overview of commenced and approved mini-method assessments. In the database of completed mini-method assessments, methods approved in 2020 and 2021 show that Oslo University Hospital is responsible for almost all of these assessments (46).

When trying out new surgical methods, the fact that there will be limited access to randomised trials represents a challenge. A mini-method assessment may nevertheless, in some cases, be a useful tool for raising awareness of the basis of evidence concerning a new method.

In connection with the introduction of taTME, only one hospital responded that they undertook a mini-method assessment. However, this was performed after the procedure had been introduced and was related to the need for resources for the necessary equipment.

The Intervention Centre at Oslo University Hospital HF as a national resource

The Intervention Centre at Oslo University Hospital HF (OUS) was established by the Storting in 1996 as a common, national resource. The Intervention Centre is a provider for all entities in the health service concerning:

- Development of new treatment methods
- Development of new treatment strategies
- Comparison of new and established methods
- Studies of the social, economic and organisational consequences of new methods.

Training of healthcare professionals in new treatment methods is an integral aspect of this (47). When the Intervention Centre collaborates with clinical communities on the development of new methods, trials created must show what needs to be documented in order to introduce the method in the clinic.

In our interviews, we received feedback that the Intervention Centre’s provision is little known in the gastrointestinal surgical professional community with which we were in contact in conjunction with this investigation.

7 Lack of a national overview of patients who underwent taTME

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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).

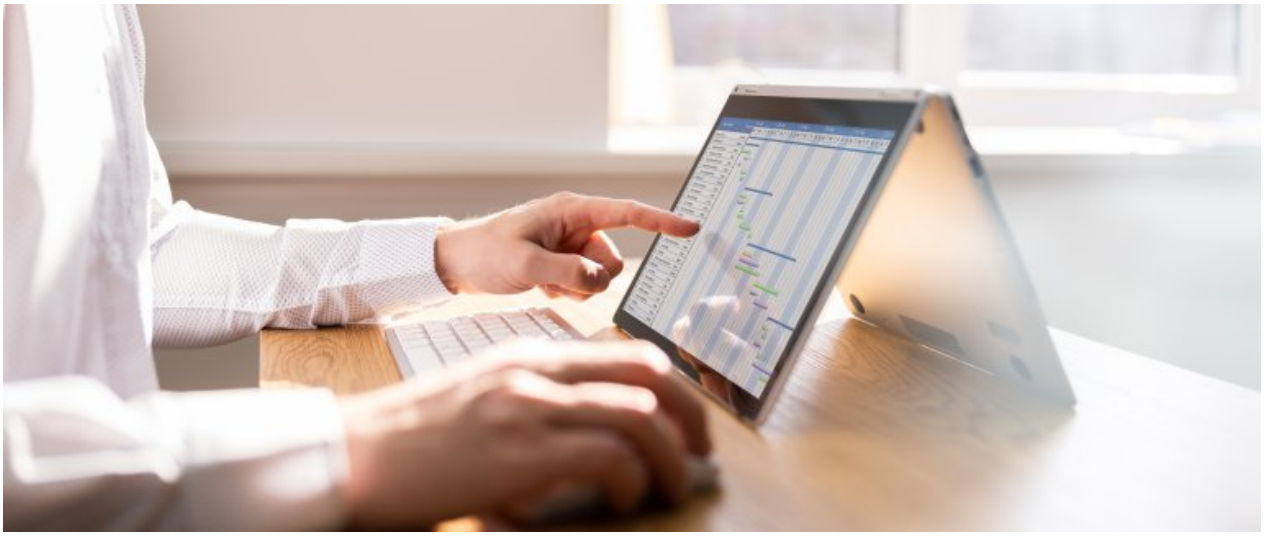
Our investigation shows that only one of the hospitals created a local trial protocol with patient information letters and written consent from the patients when they started up taTME surgery. Two hospitals stated that they considered the new surgical method to be a quality project that they followed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

NoRGast

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

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.

8 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	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

Act (Hpl)	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.

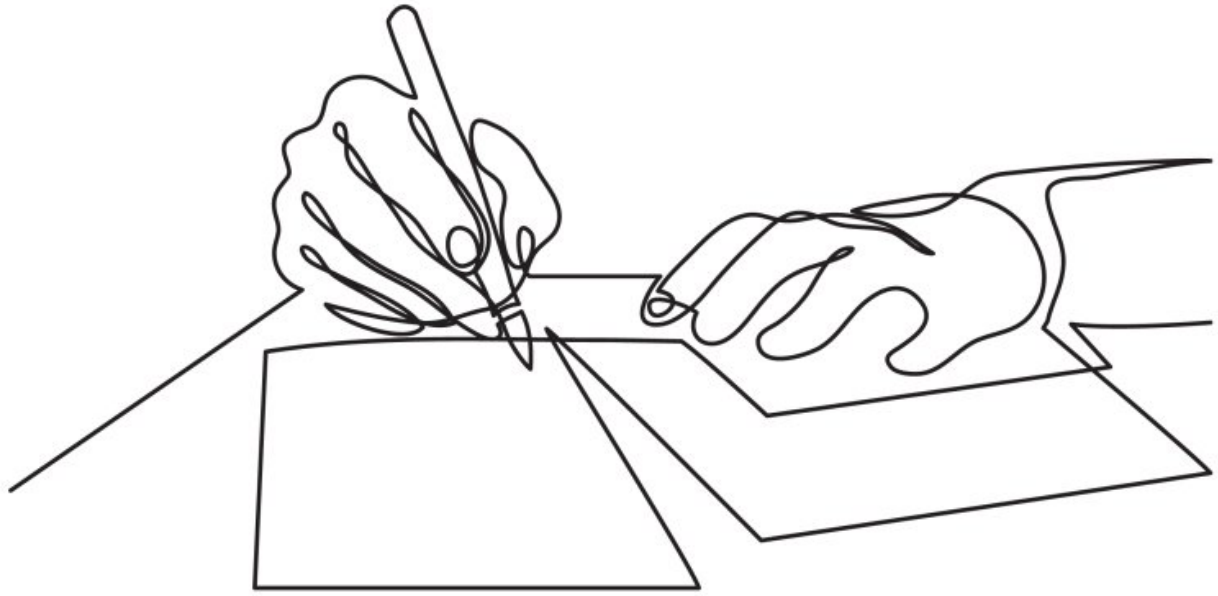
Several of the hospitals responded that they perceived the introduction of taTME as a quality project. Healthcare providers have a duty to quality assure the healthcare they provide. Quality assurance concerns evaluating whether the healthcare achieves the expected results with good quality. It may concern 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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9 Follow-up after the taTME method was suspended

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Subsequent information to patients

The hospitals we investigated stated that all patients who underwent taTME surgery were contacted subsequent to the operation, after it was discovered that the method presented an increased risk of complications and recurrence of rectal cancer. In view of concerns from parts of the gastrointestinal surgical professional community about complications and oncological outcomes in connection with taTME surgery, NGICG-CR sent a letter dated 14 January 2019 to the medical directors of the regional health authorities discouraging the use of taTME surgery in the treatment of rectal cancer in Norway (Appendix 3). NGICG-CR requested that the letter be forwarded to relevant hospitals and departments.

An article in Dagens medisin in June 2019 shows that Health Minister Bent Høie was not satisfied with the information the hospitals gave to the 157 patients who underwent taTME surgery, and he therefore required the regional health authorities to send out better information to patients (27). The situation concerning taTME had to be fully disclosed, and opportunities for appeal and to seek compensation from the Norwegian System of Patient Injury Compensation (NPE) had to be made clear. All the hospitals stated that they sent letters to the patients affected to inform them. At this time, the hospitals performing taTME surgery had already been contacted by the regional medical directors on behalf of NGICG-CR (January 2019) with the recommendation to stop using the taTME method, as well as a recommendation for how the patients who had undergone this surgery should be followed up with control.

Quality improvement and learning

In the Western Norway Regional Health Authority and the South-Eastern Norway Regional Health Authority, after the taTME-method was suspended, an internal review about the introduction of the method was conducted. All of the hospitals in question were involved.

Besides this, the hospitals' responses showed that after
the taTME method was stopped, quality improvement and learning were followed up in different ways. Some hospitals stated that internal meetings and discussions were held at the individual hospital and in the professional community after the incident with the taTME method. No minutes were taken of these meetings. One hospital stated that the experience with the taTME method had led to significantly greater awareness concerning the introduction of new methods in general, but did not describe in further detail what this entailed in practice. Another hospital stated that they had

involved the expert director concerning questions about future introduction of new methods and equipment, but this was not concluded. Two hospitals stated that they had created research committees at department-level to assess and approve new methods prior to introduction and to initiate performance monitoring.

Notification to the supervisory authorities

None of the hospitals that had patients with severe local recurrences or complications responded that they notified this to the Norwegian Board of Health Supervision or the county governor (now the state administrator). One hospital stated that they requested a patient who suffered a recurrence to report this to the Norwegian System of Patient Injury Compensation (NPE).

Complaints to the Norwegian System of Patient Injury Compensation (NPE).

In the last five years, the Norwegian System of Patient Injury Compensation (NPE) has paid out over NOK 60 million in compensation to patients with colon cancer. NPE has stated that delayed diagnostics and use of an incorrect treatment technique or method are among the most common reasons stated concerning failed treatment.

NPE has informed NHIB that so far they have received 12 cases concerning use of the taTME method. The first three cases were reported in March and April 2019, respectively. Ten cases have so far been dismissed, while two cases have been partly upheld. NPE states that there are various reasons for dismissal of cases. Some dismissals are, for example, explained by the fact that at the time of surgery it was not known that the taTME surgical method presented an increased risk of recurrence. Other dismissals are explained by the fact that the cases concerning the spread of the cancer disease and local recurrence were not related to the method of surgery.

Norwegian System of Patient Injury Compensation (NPE)

NPE is a government agency under the Norwegian Ministry of Health and Care Services. They consider compensation claims from patients who believe they have suffered an injury following treatment failure in the health service. Cases are considered free of charge (60).
NPE has three regulatory tasks:

1. Determine whether compensation applicants are entitled to compensation and determine the size of the compensation.
2. Contribute with statistical data for quality improvement and injury prevention in the health service.
3. Provide information about the patient injury compensation scheme to patients, the health service and the general public.

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10 Learning points

Publisert 8. februar 2022

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.

11 Our mandate

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The Norwegian Healthcare Investigation Board (NHIB) is an independent government agency with the mandate of investigating serious adverse events and other serious concerns concerning patient and user safety within the Norwegian health and social care services.

NHIB must improve patient and user safety in the health and social care services through investigations of serious adverse events or other serious concerns.

NHIB does not assess civil or criminal liability or culpability.

NHIB itself decides which serious adverse events or circumstances to investigate, the timing and scope of the investigations, and how this will be executed.

Investigations are conducted in dialogue with the parties involved, i.e. employees in the health and social care services, patients/users of health care services and their families.

Reports to NHIB are public, but do not include references to the names or addresses of individuals involved. In each individual investigation it is assessed whether reference may made to the location of the adverse event or the serious circumstances.

NHIB’s activities are regulated by Norwegian Act no. 56 of 16 June 2017 concerning the Norwegian Healthcare Investigation Board.

12 Method

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We undertook the investigation in several phases.

Phase 1

Obtaining information from media reports, literature searches, reports and protocols from the National System for Managed Introduction of New Health Technologies (New Methods). Published reports from other European countries' method assessments of taTME were also reviewed. The survey in Phase 1 was the basis for assessment of the need for further investigations. Based on our findings, we wished to interview a selection of key individuals in order to shed light on the perspectives of the health authorities, the professional gastrointestinal surgical community, and patient and user organisations.

Phase 2

- In this phase, we interviewed key individuals within the professional gastrointestinal surgical community, health administration and other relevant professionals.
- We obtained information from the seven hospitals that had performed taTME.
- Information was also obtained from the Cancer Registry and the Norwegian System of Patient Injury Compensation (NPE)

Phase 3

Systematisation of key findings from our media review, literature searches, interviews and data retrieval from the seven hospital authorities, and further assessment of how this affects patient and user safety when new surgical methods are introduced.

Phase 4

Prior to the completion of the report, we reviewed the draft timeline, findings and learning points with actors relevant to this investigation, for necessary corrections and input:

- Representatives of the gastrointestinal surgery profession in all regional health authorities
- Norwegian Gastro Intestinal Cancer Group (NGICG) and Norwegian Gastro Intestinal Cancer Group – Colorectal (NGICG-CR)
- A member of the Danish Colorectal Cancer Group (DCCG)
- The Norwegian Medical Association represented by the Norwegian Association for Gastroenterological Surgery (NFGK)
- The Cancer Registry

- Centre for Clinical Documentation and Evaluation (SKDE)
- Norwegian Directorate of Health
- Shared decision making centre at the University Hospital of North Norway HF (UNN)
- Norwegian Cancer Society and NORILCO
- Norwegian National System for Managed Introduction of New Health Technologies (New Methods) represented by the Bestillerforum (Ordering Forum)
- Norwegian System of Patient Injury Compensation (NPE)
- The hospitals that performed taTME surgery
- Intervention Centre at Oslo University Hospital HF
- Probo in connection with national evaluation of New Methods,
- Reflection Panel in NHIB

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Publisert 8. februar 2022

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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?

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