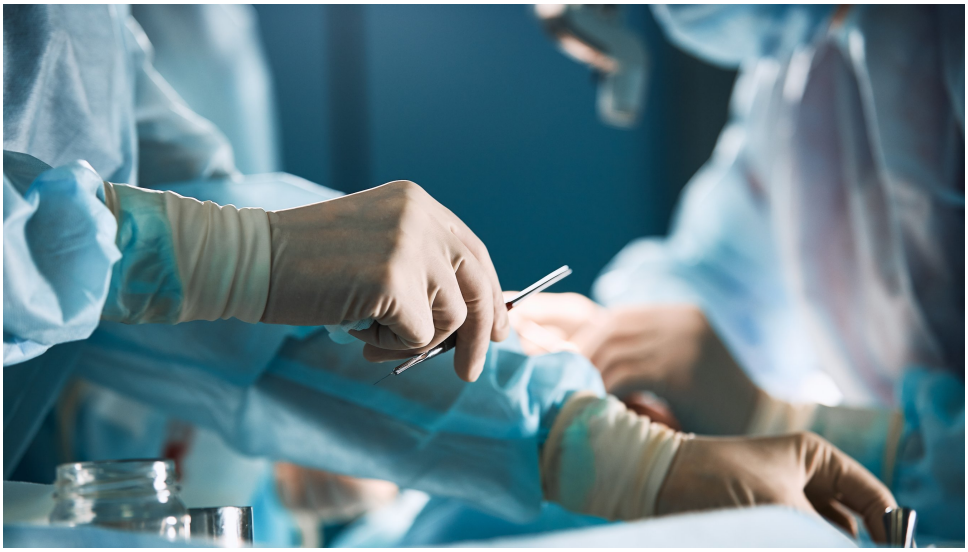
Background to our investigation



Ukom



MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

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 Norwegian Gastrointestinal Cancer Group (NGICG) was established on 11 March 1991 due to the wish for stronger national collaboration for more uniform treatment provision for gastrointestinal cancer, as well as the performance of national /multi-regional prospective studies. NGICG was re-organised as an umbrella organisation in 2007, with overall responsibility for relations with authorities and the Cancer Registry of Norway. As from 2008, three professional forums were created for upper gastrointestinal (NGICG-ØV), middle gastrointestinal (NGICG-HPG) and lower gastrointestinal (NGICG-CR) cancer. NGICG drew up national guidelines for colorectal cancer in 1999. This was the precursor of the current national action programmes, which are published by the Norwegian Directorate of Health. Editing of the action programmes has been an important part of NGICG's activity (1). NGICG-CR is also the professional council for the National Quality Registry for Colorectal Cancer.

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.

Statens undersøkelseskommisjon
for helse-og omsorgstjenesten

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