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Intervention for reducing the overuse of upper endoscopy in patients <45 years: a protocol for a stepwise intervention programme

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ABSTRACT

Utilisation rates for healthcare services vary widely both within and between nations. Moreover, healthcare providers with insurance-based reimbursement systems observe an effect of social determinants of health on healthcare utilisation rates and outcomes. Even in countries with publicly funded universal healthcare such as Norway, utilisation rates for medical and surgical interventions vary between and within health regions and hospitals.

Most interventions targeting overuse and high utilisation rates are based on the assumption that knowledge of areas of unwarranted variation in healthcare automatically will lead to a reduction in unwarranted variation. Recommendations regarding how to reduce this variation are often not very detailed or prominent.

This paper describes a protocol for reducing the overuse of upper endoscopy in a Norwegian health region.

The protocol uses a combination of digital tools and psychological methods targeting behavioural change in order to alter healthcare workers' approach to patient care.

The aim of the planned intervention is to evaluate the effectiveness of a multifaceted set of interventions to reduce the overuse of upper endoscopy in patients under 45 years. A secondary aim is to evaluate the specific effect of the various parts of the intervention.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ During the last decades, several approaches such as 'Choosing wisely' and the 'Evidence-Based Intervention programme' have aimed to reduce overuse and unwarranted variation in the healthcare service and have so far shown marginal results on utilisation rates.

WHAT THIS STUDY ADDS

⇒ This study protocol describes a practical approach to reduce overuse and unwarranted variation in the use of healthcare services by using a learning healthcare approach.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The protocol adds to the current approaches in quality improvement describing an intervention that combines a 'bottom up' with a 'top-down' approach, both at the hospital level and the regional/national level.

INTRODUCTION

Healthcare utilisation is a field of complexity, as utilisation can be appropriate or inappropriate, of high or low cost, value or quality. From a patient perspective, unwarranted variation in healthcare utilisation can result in both delayed diagnosis and treatment, possibly affecting both outcome and prognosis (primarily related to under-utilisation), or to over-diagnosis and over-treatment, with inherent suboptimal risk-benefit rates for the healthcare services provided. Both from a healthcare system-level and individual physician perspective, over-utilisation is particularly challenging since the total treatment capacity can be overwhelmed, putting undue work stress on physicians, and potentially delaying diagnosis and treatment for more severely afflicted patients due to overall constraints in treatment capacity.

Utilisation rates vary widely both within and between countries. A systematic review of medical practice in the Organization for Economic Cooperation and Development (OECD) countries from 2014 including 836 studies found large variations across regions, hospitals and physician practices for almost every condition and procedure studied.[1] Countries with insurance-based healthcare systems such as the USA consistently document the effect of social determinants of health on healthcare utilisation and outcomes.[2] However, even in countries with publicly funded universal healthcare such as Norway, utilisation rates for medical and surgical interventions vary within and between health regions and hospitals.

The specialist healthcare system in Norway is predominantly a publicly funded universal health coverage system designed to care for

5.4 million citizens (2022). Four regional health authorities are responsible for delivering specialist healthcare in their regions. The South-Eastern Norway Regional Health Authority (HSO) provides specialist healthcare for approximately 3.1 million inhabitants (2023) representing 57% of the population in Norway. HSO is divided into six hospital catchment areas, serving a population of 200 000–500 000 each. The local hospital trusts within the region (seven trusts and two private non-profit hospitals) are legal entities governed by independent boards with an overall responsibility for the clinical services they provide. All inpatient and most outpatient clinical services are provided by the hospital trusts themselves, although independent, privately employed specialists, contracted and reimbursed by the regional health authorities,[3] conduct one in four outpatient visits. In Norway, primary care physicians (PCPs) refer patients to the specialist healthcare services provided by the hospital trusts and the privately employed publically funded specialists. Specialists categorise the referrals based on the provided information. Patients will either be (1) accepted for examination/treatment, (2) declined for examination/treatment or (3) the PCP will receive an individualised letter advising further patient treatment. From a healthcare-system perspective, patients accepted for examination/treatment will use more healthcare resources than the latter two groups. However, from a specialist perspective, it is often quicker just to accept the referral rather than writing a time-consuming letter of advice to the PCP—thereby increasing the chances of over-utilisation of provided healthcare.

The 2018 strategic document of the Health region of South-Eastern Norway (HSO) named 'Regional Development Plan 2035' defines the reduction of unwarranted variation as one of five prioritised objectives.[4] Unwarranted in this regard is in accordance with Wennberg's original definition: 'there is variation in the utilization of health services that cannot be explained by variation in patient illness or patient preferences'.[5] HSO has developed a dashboard accessible for all hospitals in the region displaying variation in utilisation rates,[6] based on the Nomesco Classification of Surgical Procedures and some radiological procedures[7] that categorise all relevant procedures into a hierarchical system. The dashboard revealed upper endoscopy and endoscopic retrograde cholangiopancreatography as number 10 ranked on cost and volume—combined with a significant unwarranted variation in utilisation rates of gastroscopy within and between hospitals in HSO.

Upper gastrointestinal endoscopy (gastroscopy) is used to investigate and treat conditions affecting the upper gastrointestinal (GI) tract and to monitor conditions affecting the upper GI tract associated with cancer in certain high-risk groups. However, most of the conditions that require a gastroscopy are uncommon in people aged under 55 years. In Norway, oesophageal and stomach cancers are very rare in this age group, and overall incidence rates have decreased significantly in the last seven decades.[8]

The evidence-based intervention (EBI) developed by the Academy of Medical Royal Colleges UK, has defined upper GI endoscopy as an invasive procedure that is not always well tolerated and carries significant risks. According to the recommendations established by the EBI programme, upper endoscopy should accordingly not be used as a first-line indication in all patients and only in patients <55 years of age with the following conditions[9]:

- Any dysphagia (difficulty in swallowing).
- Assessment of upper GI bleeding.
- Investigation of specific symptoms.
- Management of specific cases of *Helicobacter pylori* and associated ulcer and diseases like Barret's oesophagus and coeliac disease.

Unwarranted variations in utilisation rates for upper endoscopy have also been documented in other countries such as in Saudi Arabia, where a retrospective chart review revealed that 31% of the referrals could be categorised as inappropriate.[10] In Italy, a similar review of referrals deemed 74% to be of low priority.[11 12]

There are several known tools available to reduce unwarranted variation, such as guideline improvement, shared decision-making and clinical audits,[13] and several initiatives have been launched to monitor and reduce unwarranted variation in utilisation rates and outcomes of medical and surgical interventions. Both clinician-driven initiatives such as the 'Choosing Wisely' campaign and the more 'top-down' EBI programme launched by National Health Service (NHS) England to improve the quality of care by reducing unnecessary interventions, have shown marginal results on their target to reduce utilisation rates.[14 15] All these tools have a common trait—they are based on the assumption that knowledge of areas of unwarranted variation in healthcare automatically will lead to a reduction in unwarranted variation—and recommendations regarding how to reduce this variation are not very prominent. Heus *et al* recently published a review exploring 121 randomised clinical trials evaluating various deimplementation strategies.[16] While the authors report that 'Most deimplementation strategies achieved a considerable reduction of low-value care', they also note that they 'found no signs that a particular type or number of interventions works best for deimplementation'.

Changing established behaviour is challenging in all complex organisations, and permanent behavioural modulation is demanding. Making the change easy to understand and perform is central to success.[17] Harvesting clinical data from the electronic patient journal systems enables rapid-cycling of continuous improvement measures.[18] The Learning Health System (LHS) framework is targeting the digital, clinical and personal aspects of this method, while combining continuous improvement work with digital dashboards and external support.[19 20]

Studies documenting the effect of interventions to reduce the overuse of various procedures are sparse–both

in a general perspective as well as within this particular area of interest. The aim of the planned intervention is to evaluate the effectiveness of a set of interventions to reduce the overuse of upper endoscopy in patients under 45 years of age. A secondary aim is to evaluate the specific interventions included in the protocol.

METHODS AND ANALYSIS

This protocol describes a step-wedged intervention study conducted in the Norwegian Healthcare system. The routinely collected data from the Norwegian Patient Register (NPR)[21] combined with individual hospital trust data sets will be used to identify the study population, apply eligibility criteria, generate the interventions and analyse outcomes.

The study will be performed in four hospital trusts within the South-Eastern Regional Healthcare Authority in Norway, selected based on the higher-than-average volumes of upper endoscopy in the 18–44 year population (data from NPR). The remaining hospital trusts in the region will serve as the control group. The hypothesis to be tested is that a complex intervention as described below will lead to less specialist time spent on referrals and upper endoscopies in the 18–44 year population, with the following aims:

a. The main aim of this study is to reduce the annual number of endoscopies performed by specialists in gastroenterology in the hospital trusts in the 18–44 age group.
b. Secondary aims are to reduce the number of referrals from PCPs to specialists in gastroenterology for individuals in the 18–44 age group and further, to improve the efficacy of referral response by decreasing individualised replies for this age group.

Based on these aims, the primary endpoint of the study is a total number of upper endoscopies performed in the hospital trusts in the 18–44 age group. Secondary endpoints are a number of referrals from PCPs for this age group, the proportion of referrals managed with individual replies to the PCP and the estimated aggregate clinical time spent on referrals and endoscopic examinations for this patient group. Individuals with blood tests suggesting coeliac diseases need to undergo endoscopy according to Norwegian guidelines. Due to these indications for the use of endoscopy for patients less than 45 years old, a goal of zero endoscopies is not viable.

Intervention

The protocol will be implemented at the hospital that initiated and designed the intervention. The stepped wedge design is used as described in table 1. The intervention will take place at each individual healthcare trust level and at the regional trust level, as described below. In addition to following a change of utilisation rates in the included hospitals where the intervention will be implemented, the remaining hospitals in the region will serve as a control group.

The multidimensional intervention is divided into two collaborative arms at both regional and hospital trust levels.

LOCAL HOSPITAL TRUST

The intervention in the hospital trust is based on a mixed method intervention divided into stages as described in table 1. The intervention is following the LHS framework together with traditional quality improvement strategies.[19]

Initial data capture will be performed by the local intervention team gathering information on the number of referrals from individual PCPs to departments of gastroenterology, the outcome of the referrals (individualised reply, rejection or examination). Furthermore, the referral, reply and rejection rates for the PCPs in the area will be collected and analysed.

Transforming the data to knowledge will be performed in close collaboration with the clinicians in the field, in order to identify areas of improvement. Planned combined interventions include:

1. The development and use of a standardised rejection letter (to reduce time spent writing rejection letters to PCPs and patients.
2. Educating PCPs with regards to which patients are not in need of an examination by a specialist in gastroenterology. This will be done by reaching out to all PCPs with an information letter.
3. Improving patient knowledge of upper GI symptoms by creating updated patient information on symptoms, treatment and when to seek medical care. This will improve health-literacy and self-efficacy and reducing the demand for clinically inappropriate specialist referrals.

These efforts all aim at minimising the change at hand, thus making it easier for the involved healthcare personnel to alter the behaviour.

Table 1 Timeline of intervention phases in a stepped wedge design

	Q2-3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024
Hospital A	Analyses	Intervention	LHS-cycle	LHS-cycle	LHS-cycle	End
Hospital B		Analyses	Intervention	LHS-cycle	LHS-cycle	End
Hospital C+D			Analyses	Intervention	LHS-cycle	End

This table describes the timeline of intervention phases for all four participating hospitals.
LHS, Learning Health System.

Furthermore, the referral profile of each PCP will be analysed. PCPs will be benchmarked on individual referral rates for the 18–44 years old population. The general physicians with highest referral ratest (top 20 individuals) will be informed by mail and encouraged to change their referral practices in line with benchmark statistics. Training within gastroenterology through short internships at the department of gastroenterology will be offered to this group, as well as the possibility of clinical guidance.

These statistics will be monitored every 2 weeks by the study team and every month in the LHS learning community during the study period.

Implementing the changes will transform data to knowledge, enabling the LHS-circle to continue. A digital dashboard automatically harvesting data from the electronic patient journal (EPJ) is central to following the change. The variables within the dashboard cover the number of upper and lower endoscopies performed, number of referrals, distribution of the outcome of referrals (percentages of rejection, individualised answers and examinations) and estimated total clinical time spent on this patient group on a departmental level.

To ensure similar interventions within each local hospital trust, representatives from the study group will participate in the LHS cycle in all trusts. The stepped-wedge design will ensure proper use of the LHS-circle, where the intervention in the first hospital trust serves as a pilot, and where the intervention in the following hospital trusts can be tweaked based on the learnings in the pilot hospital trust to maximise the impact of the intervention.

Regional arm

- Analyses of regional and local utilisation rates of gastroscopy without biopsy in persons under 45 years of age. Relevant NOMESCO procedure codes (JUD 02) are collected from the Norwegian patient registry and displayed in the HSO dashboard as previously described.
- Mapping analyses of endoscopy resources (human and equipment).

Currently, whereas the UK guidelines uses 55 years as a target for reduced need of endoscopic procedures in individuals with no alarm symptoms, the Norwegian guidelines uses <45 years. The Norwegian Society of gastroenterology and Directorate of Health will be contacted to revise clinical guidelines in order to safely reduce the overuse of unnecessary clinical procedures.

Statistics

Statistical analyses will be performed with standard methods, including χ^2 tests for categorical data, mean values as a measure of central tendency with SD as a measure of dispersion for normally distributed data and accordingly Mann-Whitney U test and 25th and 75th percentiles for skewed data. Time trends taking into consideration both seasonal variation and changes over time before the intervention will be compared with time trends after the intervention by the use of linear regression, both for the individual hospital trust and HSO as a whole.

Power calculations were performed as follows: We experienced a 23% drop in 'gastroscopy without biopsy' from 2020 to 2022 in Sorlandet Hospital, that is, from 766 in 2020 to 592 in 2022. We thus assume a 10% spontaneous drop in gastroscopy during the study period. According to previous assumptions we want to power the study to be able to detect a 20% drop in gastroscopy procedures, on top of a postulated 10% spontaneous drop.

We thus assume 90% (including the postulated 10% spontaneous drop from 100%) as the baseline gastroscopy activity and want to detect a further drop to<70% 12 months after the intervention. Assuming an alpha (p)<0.05, a power >80% (beta<0.2), a two-sided test and simple superiority, 62 patients are needed according to the clinical calculator (https://clincalc.com/stats/samplesize.aspx).

As the hospitals within this study yearly performs over 500 upper endoscopies without biopsy in the 18–44 age group, patient numbers will be no limitation in this study.

To ensure that changes identified within the study are not a result of national variation, the mean reduction in endoscopy for the 18–44 years old population is calculated for all Norwegian non-participating hospitals during the same time period and will be corrected for in the final calculation according to our '10% spontaneous drop' assumption.

Limitations

This study is performed in Norway, where healthcare is available to all, regardless of income or geography. This might limit the transfer value to other healthcare settings.

Climate effect

At the end of the study, the climate effect of the intervention will be evaluated, based on estimations of the reduction of carbon dioxide emission of patient travel and number of procedures.

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Competing interests None declared.

Patient and public involvement The user boards, or appointed members thereof, of all participating hospitals will be kept informed of the ongoing study and serve as a reference group for study dissemination and patient information.

Patient consent for publication Not applicable.

Ethics approval The design of the study has been discussed with the Regional Ethics Committee of Southern Norway, who, on the basis of the study design, have deemed the study to be not in need of review from an ethical perspective (application ID: 644576).

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