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THE NEW NATIONAL REGISTRY FOR GASTROINTESTINAL SURGERY IN NORWAY: NORGAST

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ABSTRACT

Background and Aims: **There is an increasing demand for high-quality data for the outcome of health care. Diseases of the gastro-intestinal tract involve large patient groups often presenting with serious or life-threatening conditions. Complications may affect treatment outcomes and lead to increased mortality or reduced quality of life. A continuous, risk-adjusted monitoring of major complications is important to improve the quality of health care to patients undergoing gastrointestinal resections. We present the development of the Norwegian Registry for Gastrointestinal Surgery, a national registry for colorectal, upper gastrointestinal, and hepato-pancreato-biliary resections in Norway.**

Materials and Methods: **A narrative and qualitative presentation of the development and current state of the registry.**

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Results: **We present the variables and the analysis tools and provide examples for the potential in quality improvement and research. Core characteristics include a strictly limited set of variables to reflect important risk factors, the procedure performed, and the clinical outcomes.**

Conclusion: **A registry with the potential to present complete national cohort data is a powerful tool for quality improvement and research.**

Key words: prospective; national registry; cohort; gastrointestinal surgery; observational

INTRODUCTION

The demand for high-quality data for the outcome of health care increases rapidly. Patients, health professionals and authorities, hospital administrations, and owners now expect core quality indicators to be available for any care provided. While the ultimate goal is to improve the quality of health care, different stakeholders may define quality in different ways. If surgeons expect to inform policy makers, influence the development of health care provided, and participate in its improvement, they must actively supply the community with relevant outcome data.

For many patients, surgical resection is the only available treatment option and often offers cure. However, treatment outcomes may be seriously hampered by complications leading to increased mortality or reduced quality of life. Thus, a continuous monitoring of serious complications is important to describe and improve the quality of health care to patients undergoing gastrointestinal (GI) resections. Such a registry must allow for adjustment for major risk factors (case mix) on an institutional and national level in order to provide the necessary data for continuous improvement of patient care.

We present the development of the Norwegian Registry for Gastrointestinal Surgery (NoRGast): a national registry for colorectal, upper GI, and hepatopancreato-biliary (HPB) resections in Norway.

METHODS

In 2010, a group of surgeons from the five university hospitals in Norway agreed on key features for a unified registry for all GI surgery departments in Norway. These were as follows:

- Optimal data quality and complete cohorts;
- A focus on surgical resection—not disease;
- A generic set of variables: identical for all types of resections.

To achieve this, the following strategy points were established:

- An absolute minimum number of variables;
- Variables needed to be clinically important and reproducible;
- A report function for instant feedback to participating departments.

OPERATIONS AND VARIABLES

Eligible operations are grouped according to whether their entry into the database is to be mandatory or voluntary (Table 1).

A large number of variables were discussed, primarily divided into three groups: the patient

TABLE 1
List of operations and NCSP codes.

Mandatory	
Colorectal resections	JFB 20–64 (segmental and hemicolectomies) JFH[a] (subtotal and total colectomies) JGB[a] (rectal resections and amputations)
All esophageal resections	JCC[a]
Gastric resections	JDC[a] (subtotal gastrectomies) and JDD[a] (total gastrectomies)
All liver resections	JJB[a]
All pancreatic resections	JLC[a]
Bile duct resections	JHC 10–99
Other abdominal operations that can be entered on a voluntary basis are:	
Small bowel resections, appendectomies, cholecystectomies, stoma surgery without colorectal resection, and hernia repairs	

[a]Denotes all subclasses.

TABLE 2
List of variables.

Case-mix/risk factor profile
Age (years)
Gender (male/female)
Pre-morbid weight, self-reported 6 months prior to admission (kg)
Scaled weight on admission (kg)
Height (cm)
Anti-diabetic medication, oral or parenteral (yes/no)
Severe respiratory disease[a] (yes/no)
Severe heart disease[b] (yes/no)
Neoadjuvant chemotherapy latest 3 months (yes/no)
Neoadjuvant radiotherapy to operating field, latest 3 months (yes/no)
CRP and albumin, latest measurement within 3 weeks prior to surgery
ASA-score
ECOG/WHO score, mean during latest 3 weeks predating admission
Primary ICD-10 diagnosis
Derived compound factors
Preoperative weight loss (%)
BMI (kg/m$^{2)}$
Modified Glasgow Prognostic Score[c]
CRP/Albumin ratio
Preoperative risk score (PRS) of mE-PASS[d]
Intervention
Start of surgery (*hour*)
NCSP operation code
Access in abdomen (*open, laparoscopic, converted, robot assisted, and other*)
Access in thorax (if applicable) (*open, thoracoscopic, converted, robot assisted, and other*)
New anastomosis during surgery (yes/no)
New Stoma during surgery (yes/no)
Outcome
Complications Accordion grades III–VI
In case of re-laparotomy/re-laparoscopy, major finding? (*anastomotic leak, bleeding, wound dehiscence, other, and no pathology*)
Discharge to hospital, nursing facility or home
Length of stay (number of nights in hospital)
Unplanned readmissions within 30 days (yes/no)
If unplanned readmission
Complications Accordion grades III–VI
In case of re-laparotomy/re-laparoscopy: major finding?
Derived from link to national population registry:
90 days mortality
Survival

[a]Severe pulmonary disease is defined as any condition with a percentage vital capacity (VC) of less than 60% and/or a percentage forced expiratory volume in 1 s (FEV_1%) of less than 50%.
[b]Severe heart disease is defined as heart failure meeting the criteria of New York Heart Association class III or IV or severe arrhythmia requiring mechanical support.
[c]Abnormal CRP (>10 mg/L) or albumin (<35 g/L) both yields 1 point. Scores 0, 1, or 2.
[d]See reference under "Methods" section.

(case-mix/risk factor profile), the process (intervention), and the outcome. Standard international descriptors were weighed against the need to keep the number of variables at a manageable size to ensure optimal data quality.

The variables chosen are presented in Table 2. Case mix/risk factors include weight loss, use of anti-diabetic medication, the Eastern Cooperative Oncology Group (ECOG) performance score, (1) and the American Society of Anesthesiologists (ASA) score. Some variables are re-calculated into amalgamated risk scores like the Glasgow Prognostic Score (GPS), (2) and its modified version (mGPS), (3) and the preoperative risk score (PRS) of the modified Estimation of Physiologic Ability and Surgical Stress (mE-PASS). (4) Interventions are coded according to the NOMESCO Classification of Surgical Procedures (NCSP; a common Nordic classification system of surgical procedures and interventions) and diagnoses by the International Classification of Disease (ICD, version 10). Operations are characterized also by the hour of initiating anesthesia, by access (open, laparoscopic, converted, or robot-assisted laparoscopy), and

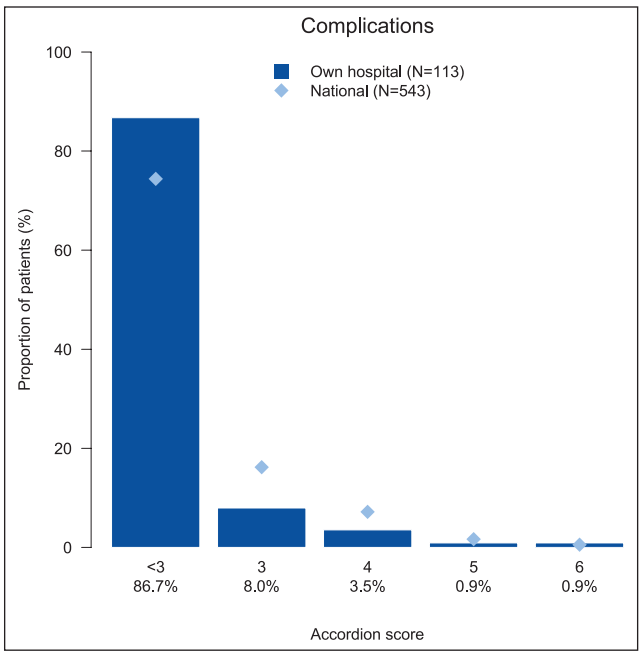

Fig. 1. Proportion of patients with complications according to the Accordion classification. Only the most serious complication is scored. Patients with no Accordion 3 or higher complication are grouped as <3.

whether a new anastomosis or a new stoma is fashioned. Outcome measures consist of major complications within 30 days. Only the most serious complication was scored using the Expanded Accordion Classification. (5) The cut-off for "major" was set at complications causing at least a percutaneous intervention (Accordion grade III). The other major groups of complications are either single-organ failure or reoperation in general anesthesia (each one Accordion grade IV) or both of them together (Accordion V) and multi-organ failure (also Accordion grade V). For patients undergoing re-laparotomy or re-laparoscopy, the major finding at reoperation is scored. Length of stay (LoS) at index-hospital is recorded and aggregated LoS (including transfer stays and readmissions within 30 days after index surgery; a-LoS) is extracted from the Norwegian Patient Registry (NPR). Ninety-day mortality and survival is calculated indirectly via links to the National Population Registry (Folkeregisteret). No data for cancer stage (tumor size, nodes or metastases) are requested as these are collected by the National Cancer Registry of Norway (Kreftregisteret). The NoRGast datasets can be coupled to cancer stage information from the cancer registry.

ETHICS AND REGULATIONS

The director of the University Hospital Northern Norway has the judicial responsibility for data safety and ethical conduct with necessary approvals for safe storage of sensitive patient information. The registry has approval from The National Data Protection Authority and from the Regional Board of Research Ethics. Written consent is necessary for patient inclusion. Any research publication presenting data from the registry must nevertheless have a dedicated project approval from the Regional Board of Research Ethics.

The registry interface is only available through an encrypted web access run by the Norwegian Health Authorities.

REGISTRY INTERFACE

Specially assigned nurses in each participating unit enter data on a web-based registry interface developed by the Regional Health Authority North's Division for Information and Communication Technology (HN-IKT: www.helsenordikt.no) on an OpenQReg platform (Uppsala Clinical Research Center, Sweden, UCR; www.ucr.uu.se). Each department's registry nurse or local coordinator accesses the web interface through an encrypted and protected line only available on hospital set-up computers. The patients' official 11-digit national identity number identifies data entered. Drop-down menus, pop-up explanatory notes, and tab-to-jump ensures rapid and user friendly data entry.

ASSESSMENT OF COMPLETENESS

To achieve complete series and avoid risk of selection bias, a non-dependent source of data is used to assess whether hospitals enter all their patients. The NPR is made for reimbursement purposes, and surgical procedures are generally coded with a high degree of accuracy as they form the basis of the hospitals' activity-based financial platform. We have approvals to extract the number of the mandatory resections for each hospital and compare with the registry data to establish a "patient coverage rate." Because some patients will have several procedures, the rate will never reach 100%. As an example, a resection of the right colon for a T4 tumor involving an atypical resection of the liver would be classified as a colon resection (i.e. the resection with the highest risk of complications) and not as a liver resection even if the hospital will register both for reimbursement purposes. Information about coverage rate is fed back to the departments to aid them in monitoring the completeness of their registration.

ASSESSMENT OF DATA QUALITY

Poor data quality might result from erroneous scoring of risk factors or outcomes or from missing values. The former is not evident from the read-outs and requires dedicated control of data quality. To check for consistency and reproducibility, two models will be employed: First, de-identified patient files with sham identity numbers will be circulated to all units on a regular basis and registry variables will be scored by the participating centers. The results will be compared across centers to check for consistency. Second, real patient identity numbers will be fed back to the operating units after a delay of about 6 months from

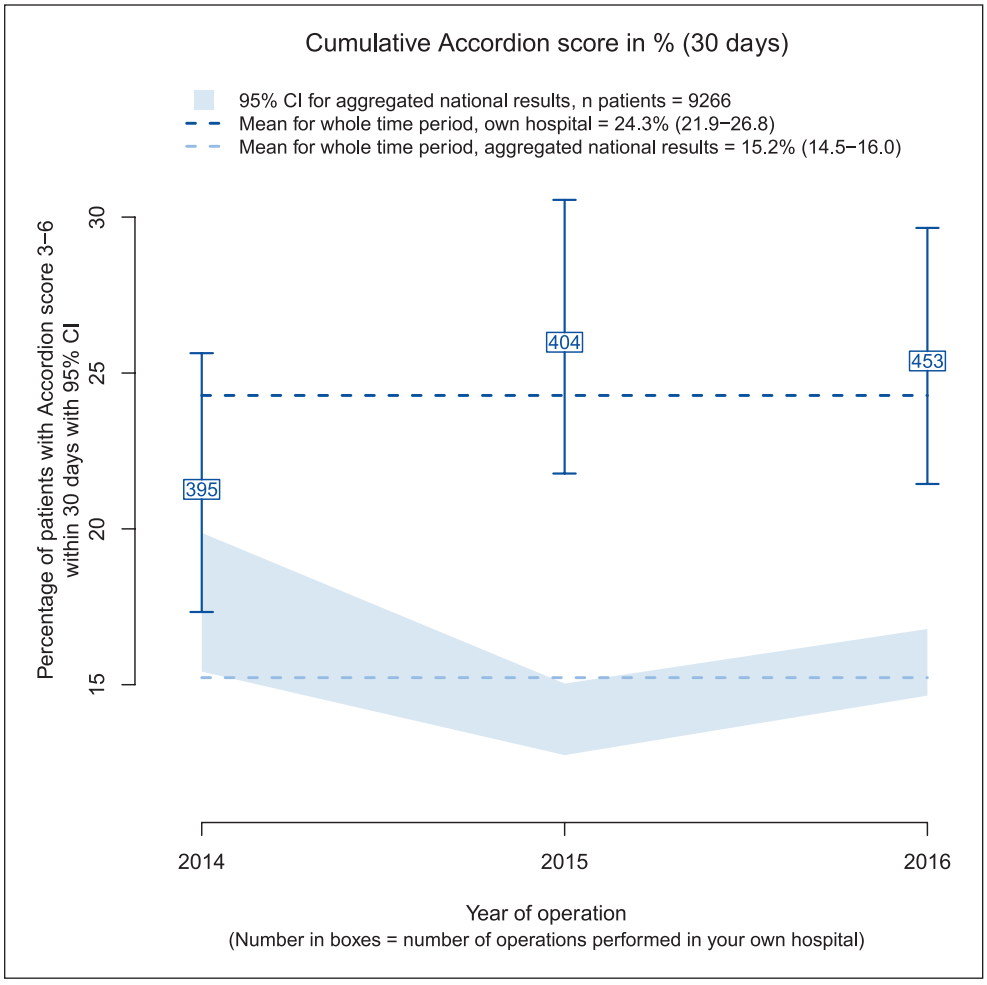

Fig. 2. Percentage of patients with at least one major complication defined as Accordion 3-6. Whiskers are 95% CI for own hospital and numbers in boxes are number of cases own hospital in the period.

original data entry. The centers will then be asked to score the variables anew, allowing for control of reproducibility within each center.

ANALYSIS AND WEB-BASED REPORT DESK

The information and technology division of Northern Norway Regional Health Authority (Helse-Nord IKT) has developed an online "report desk" for presentation of results/reports from NoRGast and other Norwegian medical quality registries, built around an instance of JasperReports Server (Jaspersoft®, San Francisco, CA, USA). Crucially, the server has been set up with an integration to the statistical software R, (6) thus making its rich tools for data visualization and analysis available. Samples are provided in Figs 1 and 2. Each participating hospital can view own results at any time set against an aggregated mean of all the other hospitals put together.

WRITTEN CONSENT AND LINK TO OTHER REGISTRIES

Following the national regulations in Norway, a signed consent is mandatory to allow for patient-identifiable registries like NoRGast to harvest data from all hospitals and to link datasets with other major health and population registries in the country. Patients receive information about the registry at the outpatient clinic and upon arrival at the hospital for surgery. Signed consent forms are scanned and stored in the hospital's protected area.

RESULTS

A three-center version was released in September 2013 and tested locally for 4 months. In January 2014, the registry was officially approved and running, and signed consent was mandatory. In May 2015, the registry was acknowledged with the status of a National Quality Registry. The registry was introduced to the surgical community by written information, by presentation at national conferences, and by personal contacts in the various health regions.

During the implementation period, the number of participating hospitals has gradually increased. By the end of 2015, 9 hospitals participated rising to 16 hospitals by the end of 2016. By August 2017, a total of 29 out of the 32 hospitals performing more than 20 GI resections per year have entered more than 13.500 operations

into the database. The cumulative number of operations entered was 1565 in 2014, 3965 in 2015, and 5192 in 2016. Among the formal resections are some 3.900 colonic, 1.500 rectal, 390 pancreatoduodenectomies, 850 liver, 300 gastric, and 200 esophageal.

Coverage (completeness) by April 2017 varied between less than 30% and up to 93%. The variation is both between hospitals in the implementation phase versus hospitals with a 3-year run-time, but it also varies somewhat within participating centers year by year. The rate of missing values varied between variables and operation groups and ranged from zero for several variables and up to 52% for preoperative weight loss in colonic resections. Data quality has yet to be independently assessed.

DISCUSSION

A prospective, protocol-based registry comprising all patients undergoing a procedure is the optimal way of establishing the magnitude of effect from an intervention. To organize this on a national level is the only way to avoid the bias created by patient selection and selective publication that to some degree will affect most interventional trials and patient series.

The principal aim of NoRGast is to improve the quality of the surgical treatment by providing each operating unit with their own core quality metrics to allow for quality improving measures. This is achieved by the report desk system that provides real-time results against a backdrop of national average figures. The main tool for quality improvement is hence to actively feedback the detailed data showing sub-optimal outcome and thereby setting off measures within the department in question. The same data will show top performing centers and point to where important lessons can be learnt. Our experience from the first 3 years clearly shows both the potential and the challenges pertaining to a national registry. While almost all the hospitals performing GI resections in Norway have begun to enter their patients, the cohorts are not complete. The challenge remains to achieve complete series for all hospitals and this is a chief ambition. To spur enthusiasm, frequent feedback to participating centers show how much they lack for complete coverage and the authorities show increasing interest in demanding outcome metrics.

Registry data will primarily not address cause-and-effect relationships under ideal conditions, but instead focus on what is achieved under everyday conditions across the nation, and thus reflect the real world of surgical services. A prospective registry with good coverage (completeness) ensures that data from all patients are secured, even for the frailest and those with risk factors usually precluding inclusion into interventional trials.

To ensure optimal and lasting data quality, we have kept the number of variables at a minimum. Case mix is calculated on the basis of 11 variables and the intervention is described by six variables. A scoring of Accordion III and higher and a description of major findings in case of re-laparotomy/laparoscopy describe outcome. Mortality at 90 days, survival, failure-to-rescue, and length-of-stay are calculated automatically from these data.

The present regulations in Norway make informed consent necessary. This introduces a potential bias, as it is almost impossible to validate the decision to decline participation, that is, that some patients are actively omitted on a basis of poor risk profile presented officially as a lack of consent. This challenge is well recognized in the field. (7) This will to some extent be neutralized as numbers become very large.

The choice of variables and hence how quality is defined is clearly dependent on viewpoint. We considered it pivotal that the definitions of quality should reflect the view of the surgeons and the interests of our patients: the surgeons, as our attitude is vital to the success of the registry; and the patients, as their well-being is our ultimate goal.

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Construction of registry platform and data analysis: T.G., K.T., L.S.N., and K.L.
All authors participated in writing, careful revision, and approval of manuscript.

AVAILABILITY OF DATA AND MATERIALS

The registry interface is only available through a dedicated and encrypted web access, "Norwegian Health Web," run by the Norwegian Health Authorities. Even for testing purposes, access can only be made via log-ins at protected computers connected to this web.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The registry has all the necessary approvals from National Data Protection Authorities and Board of Research Ethics. Subsequent publications presenting real patient data will necessitate a dedicated approval by the Research Ethics Board. All patients provide written consent.

CONSENT TO PUBLISH

This paper does not contain clinical data.

DECLARATION OF CONFLICTING INTERESTS

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