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Quality Measurement in Neonatal Surgical Disorders: Development of Clinical Indicators

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Abstract

Objective This study aims to develop a set of quality indicators for the measurement of the quality of surgical care for neonates with surgical disorders.

Methods An expert panel of the Netherlands Association of Pediatric Surgeons developed internal (clinical) indicators for neonatal surgery. This included the selection of appropriate care processes, a review of the scientific literature, consensus meetings to establish national guidelines, selection of clinical indicators with independent external evaluation, the setup of a national database, and a pilot study in one of the hospitals to evaluate the defined quality indicators in clinical practice.

Results Seven neonatal surgical care processes were selected. Clinical guidelines to evaluate the care processes were established in six of seven disorders and were based on consensus agreement, which was reached in 81 to 97% of in total 220 relevant items. The expert panel selected a set of 24 indicators to estimate the quality of neonatal surgical care, of which 12 were outcome indicators and 12 process indicators.

Conclusion The development of quality indicators is an important step toward monitoring and, if necessary, improving the quality of neonatal surgical care. Internal or clinical indicators guarantee that the results are only disclosed to the participating center itself and are therefore no threat to individual doctors.

Keywords
- quality
- pediatric surgery
- indicators

Introduction

Assessment and improvement of the quality of care are increasingly seen as an essential part of medical practice.[1–3] Although quality may be improved without measuring it, for example, by the implementation of guidelines, measurement is important for the exact assessment and the continuing improvement of quality of care.[4]

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One method of measuring quality of care is to take a set of collected data and analyze them quantitatively. A well-chosen set of quality indicators may provide an indication of the performance of an individual health care provider, a group of doctors, or even a complete hospital process. Most quality indicators used are external indicators that are used for external appraisal and provide information to patients, health care authorities, or policy makers.[5,6] Clinical or internal indicators are used to monitor and improve health care performance without accountability to outsiders. Internal indicators are not generally available, and rarely used in clinical practice.

Pediatric quality indicators to identify potentially preventable complications in hospitalized children were developed in 2006 by the Agency for Healthcare Research.[7] These included general complications associated with surgery, such as foreign body left in a patient, postoperative hemorrhage, sepsis or wound dehiscence, and did not address disorder specific complications of surgery. Indicators were used to assess how many complications were preventable and did not compare the care processes in individual hospitals. Recently, quality indicators for high acuity pediatric conditions were developed for children treated in emergency departments.[8] The number of quality indicators, which evaluate disease specific health care processes of surgical disorders in children, is limited.[9] Particularly, the quality of care of surgical neonatal disorders representing a heterogeneous group of patients with different surgical care and outcome is unknown. The majority suffers from a variety of complications, which are related to the original disorder or the medical and surgical treatment. A significant number of patients die at young age or sustains lifelong impairment with neurological, intestinal, pulmonary, urogenital, and social problems. Good quality of care may prevent serious and long lasting complications or even death. A monitoring system for quality of care is essential.

The goal of the Netherlands Association of Pediatric Surgeons was to set up a continuous evaluation system of the quality of pediatric surgical care for neonatal surgical disorders. As there were no generally accepted guidelines for good surgical care and no quality indicators, we had consensus meetings and developed specific clinical indicators. We describe the development of a set of clinical indicators for the surgical treatment of neonates with surgical disorders.

Methods

Disorders for which clinical indicators were developed were selected on the basis of a complicated care process with a relatively large mortality and morbidity. These disorders are often associated with an important loss of quality of life over a prolonged period of time and with potentially high cost of health care. A further criterion for selection included the number of children with the disorder, first because as many children as possible should benefit from improved quality of care and second because generally large numbers of patients are necessary to adequately compare the outcome of care. The following congenital anomalies were selected: anorectal malformation, biliary atresia, congenital diaphragmatic hernia (CDH), esophageal atresia, gastroschisis, Hirschsprung disease, and omphalocele.

The second step included a review of the scientific literature and a review of existing quality indicators for the selected anomalies. We also searched for evidence-based guidelines of good surgical practice. As there were no appropriate high-level evidence-based guidelines, we initiated national consensus meetings to develop our own national guidelines. These were developed with the iterated consensus procedure including evaluation of the standard of care in all pediatric surgical centers with questionnaires about preoperative policies and diagnostics, perioperative management, postoperative care, and follow-up.[4,10] In the consensus meetings, representatives of all pediatric surgical centers compared the care processes, discussed the level of evidence of standards of good care and combined the information to reach consensus and to establish national guidelines for the selected disorders. Finally, these guidelines were approved by the general assembly of the Netherlands Association of Pediatric Surgeons.

For the third step of the development of quality indicators a Quality Indicator Board (QIB) was selected, a 10-member expert panel of representatives of the six pediatric surgical centers and representatives of the executive board of the Netherlands Association of Pediatric Surgeons. A balanced set of indicators was defined to adequately monitor the care processes of the selected neonatal disorders with process and outcome indicators. Indicators were defined in two steps. First, for every care process potential indicators were suggested by subgroups of the QIB. Potential indicators were chosen based on their support by scientific evidence or professional expert opinion, on their potential ability for improvement and fulfillment of the so called SMART criteria. SMART is an acronym for specific, measurable, acceptable, relevant and realistic, and time-bound, which is used for quality monitoring in industry.[11] The initial selection criterion, that the indicator should be extractable from existing registration systems, could not be applied, as almost none of the information required was part of any dataset of existing hospital databases. Potential indicators were reviewed and selected after consensus of the QIB. As a result, two independent experts in quality management evaluated them. For every indicator, a standardized report was defined including the type of indicator, the quality target, the definition of selected and excluded patients, and a way of data reporting with a well-defined nominator and denominator. Eventually, the selected indicators and indicator reports were approved by the general assembly of the Netherlands Association of Pediatric Surgeons.

The next step was the construction of a national database. For each of the six selected care processes, checklists were defined with information about patient characteristics, operations and other treatment, pre- and postoperative investigations, complications, and follow-up. All checklists were tested in clinical practice for applicability and completeness in one of the participating pediatric surgical centers. Finally, the databases were transferred

Table 1 Number of items to evaluate the care processes of six disorders and the number of items on which consensus was reached

	Consensus items	Consensus agreement (%)
Anorectal malformation	36	29 (81)
Biliary atresia	35	30 (86)
Esophageal atresia	61	59 (97)
Gastroschisis	45	42 (93)
Hirschsprung disease	43	41 (95)
Omphalocele	45	42 (93)

into web-based databases, which are presently applied in all participating hospitals.

Results

Screening of the Cochrane library and the PubMed database at that time showed no appropriate studies with level-1 or level-2 evidence, according to the Oxford Centre for Evidence-Based Medicine, that could be used to define optimal care processes of the selected disorders, with the exception of CDH.[12]

In 11 national consensus meetings, various treatment parameters for six of the seven care processes were scored. The percentage of eventual consensus for the evaluated items of the selected disorders is shown in ►Table 1. For CDH, it was decided that children with a head-to-lung ratio below 1.4 on the prenatal ultrasound would be antenatally referred to one of the two extracorporeal membrane oxygenation (ECMO) centers. Therefore, details for the care processes of CDH were not addressed during the consensus meetings.

In the first round of the selection of the quality indicators, 36 potential indicators were defined. Of the 36 potential indicators, 19 were selected by the expert panel on the basis of consensus of the participating experts, potential for improvement, and the SMART criteria. Five potential indicators were selected after a substantial change. In total, 12 outcome indicators and 12 process indicators were chosen and defined exactly (►Table 2). An example of a quality indicator report is shown in ►Table 3. To register patients' characteristics and variables that are relevant for the outcome and for the quality of care, checklists were compiled. After the checklists had been tested in practice in one center, they were slightly modified where necessary, and consequently introduced into a web-based registration of the Dutch Institute on Clinical Auditing (DICA).[13] The registration has been implemented in all pediatric surgical centers. This enables the centers to collect their data and compare these with the other centers. Data are periodically analyzed and compared anonymously by DICA, so that each hospital will obtain information about its performance compared with the benchmark of the other participating centers. Other European pediatric surgical centers may join this neonatal surgical quality of care monitoring system in the future.

Discussion

Methods to quantify the quality-of-care processes have been used for more than 25 years. Most quality indicators monitor the quality of general care processes in primary care or in complete hospitals, and are specific for common medical disorders such as decubitus ulcers, wound infection, or the percentage of glycated hemoglobin (HbAIC) in diabetes.[14] These, and also more specific pediatric quality indicators, are not appropriate to monitor the specific quality of pediatric surgical practice. Therefore, the Netherlands Association of Pediatric Surgeons developed a set of specific quality indicators for the care of infants with surgical disorders.

Indicators are preferably based on scientific evidence including empirical studies.[15] In many areas of health care, such as in pediatric surgery, evidence of good care is limited and often methodologically weak. In these circumstances, indicators have to be developed using expert opinion. Group judgments are preferred to individual opinion, which can be facilitated by consensus meetings.[16] Characteristics of techniques to develop consensus include mailed questionnaires, elicitation of decisions, group feedback on choices, structured meetings and aggregation, which all have been used in our indicator development process.[15]

External or performance indicators are used for external appraisal to patients, parents, health care providers, or policy makers. Internal or quality indicators are for internal quality improvement. With information obtained by internal indicators every center is able to compare its own care with a benchmark of good clinical practice. If the outcome is below the collective standard, a center can analyze its cause (i.e., case mix), improve its care processes, if necessary, or if this is not possible, then it can decide to transfer the care for a certain group of patients to other centers. The outcomes of internal indicators are only disclosed to the participant and are not public. A public outcome would include several potential risks. First, indicators might be chosen that do not differentiate between "good" or "bad" clinical practice, and are no threat to individual doctors or hospitals. Second, results could be polished up to seem to be better than they really are which may intervene with the implementation of a change to improve and optimize the care process. A third potential risk is that a medical specialist may be reluctant to treat patients with complicated pathology and a bad prognosis, as this might jeopardize funding or patient referral.[17] The use of internal indicators is a better guarantee of wide support and participation of health care workers, includes no risks for individual doctors or hospitals, and makes it possible to obtain honest data to monitor and improve quality of care.

Quality indicators can be divided into outcome, process, and structure indicators.[18–20] Outcome indicators give information about the outcome of a complete care process (e.g., death, fecal continence), process indicators give information about the efforts and actions that take place to provide quality

Table 2 Clinical indicators of neonatal surgery

Disorder	Process indicator	Outcome indicator
Anorectal malformation	• Screening associated anomalies (according to protocol)	• Wound infection • Fecal continence score
Gastroschisis	• Patients with line sepsis • Duration parenteral nutrition	• Death
Omphalocele	• Number of reoperations to closure • Consultation clinical geneticist	• Total hospital admission in the first 5 years of life
Congenital diaphragmatic hernia	• Neurological assessment at the age of 1 year	• Recurrent hernia • Death • Death without ECMO
Biliary atresia	• Age Kasai operation • Screening at the age of 1 year (according to protocol)	• Death with native liver • Normalization bilirubin at the age of 6 months
Esophageal atresia	• Ultrasonographic screening kidneys	• Leakage anastomosis • Stenosis anastomosis
Hirschsprung disease	• One stage operation • Number of operations	• Fecal continence score • Enterocolitis

Abbreviation: ECMO, extracorporeal membrane oxygenation.

of care (e.g., preoperative ultrasound, number of operations required), and structure indicators address the settings in which a care process takes place and the instrumentalities of which it is the product (e.g., presence of specific multidisciplinary meetings, availability of ECMO). We have not defined structure indicators. All pediatric surgical centers in the Netherlands are organized according to the standard of the National Health Council. There are no structure indicators, which can differentiate between centers and are able to improve the infrastructure. This does not mean that the infrastructure in all pediatric surgical centers is the same. For example, ECMO is a relatively complicated and expensive

Table 3 Example of a quality indicator report

Quality indicator	Death without ECMO therapy
Component	Process indicator, department, and disorder specific.
Quality target	There is consensus to refer patients with CHD to ECMO centers to enable final rescue therapy in respiratory failure. Referral is a measure of good clinical practice.
Nominator	Number of patients with CDH who died without ECMO in the 1st month of life.
Denominator	Total number of patients with CDH who died in the 1st month of life.
Exclusion	None.

Abbreviations: CDH, congenital diaphragmatic hernia; CHD, congenital diaphragmatic hernia; ECMO, extracorporeal membrane oxygenation.

treatment modality, which has been concentrated into two centers. The availability of ECMO is not an appropriate structure indicator as it is not realistic to offer ECMO treatment in every center. "Death without ECMO treatment" has been selected as an outcome indicator for CDH instead, to monitor the adherence to the national agreement to refer patients with CDH to the ECMO centers. There are also other indicators that have been chosen to monitor adherence to the guidelines, such as "ultrasonography of the kidneys" in patients with esophageal atresia and "consultation of a clinical geneticist" in patients with omphalocele. One of the indicators for both anorectal malformation and Hirschsprung disease is fecal continence and constipation. To measure fecal continence, the criteria of the Krickenbeck conference were put into the scoring list, for which every item of voluntary bowel movement, soiling, and constipation was rated with one point.[21]

For most of the selected indicators, there is no benchmark for good clinical practice. Scientific literature often addresses the outcome of a disease or disorder there is less attention for the process, which leads to the outcome of a care process. For example, early routine ultrasonographic evaluation of the urinary tract in patients with anorectal malformation may prevent serious complications later in life and is therefore a good process indicator for this group of patients. Also, for outcome indicators, it is difficult to use the results in the literature as a benchmark as these are often based on selected data, on selected groups of patients, and may be presented in a favorable way. Therefore, results from the literature are generally not suitable as benchmark for quality of care. We decided that the mean or median performance of all participating centers would be a good reflection of the quality of everyday clinical practice and would be an appropriate standard of good quality of care.

Quality indicators have a signaling function. If the results of doctors, group of doctors or hospitals are different from the benchmark, further analysis is mandatory. Reasons for performance outside the range of good practice include differences in case mix. If difficult pathology is referred to specialized centers, the overall performance of these centers could easily fall below the supposed standard.[22,23] We developed a relatively large database in which many variables are registered so that risk adjustment techniques can be used to account for patients characteristics that influence the outcome of the measurement but do not depend on the quality of care of the health care provider. However, risk adjustment is complicated and does not adjust perfectly for all factors. Therefore, health care providers may continue to see quality indicators as a threat if indicators are used for external appraisal.

One of the limitations of the registration system is the relatively small number of patients.[24] These small numbers imply an increased risk of chance variability and false reassurance if results are below the standard but statistical significance is not reached. Chance variability decreases if numbers increase, for instance by a longer period of registration or more participants to a quality-of-care monitoring system.

It proved to be difficult and time-consuming to go from checklists and databases to an actual full registration. The requirements for such a registration included the necessity of a Web-based application, strict anonymity of the data, and analysis by an independent partner, restrictions of the ownership of that data, and the possibility to compare present and newly developed indicators with appropriate feedback. Furthermore, the hospitals and health authorities increasingly enforce precautions for data safety, so that data are stored safely and data cannot be hacked. Our current independent partner meets these requirements.

In the course of time, the value of an indicator may change necessitating its replacement by other indicators, for instance if there is no room for improvement anymore or if the indicator turns out to be nonselective. Moreover, other future participants to the quality monitoring system also may require a change of indicators.

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