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Measuring quality of care for colorectal cancer care : comprehensive feedback driving quality improvement

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Chapter 1

General introduction and outline of this thesis

Quality of Care

To err is human

Ever since the publication of the Harvard Medical Practice Study (1991)¹ and of the Institute of Medicine report “To Err is Human” (1999),^{2,3} public attention has focused upon patient safety in health care, and the influence of the ‘doctor’ or ‘hospital’ on outcomes of care. A new field of research emerged, describing differences in clinical practice between hospitals and between care providers. Even so, as life expectancy increases, and new treatment options become available, healthcare costs are increasing exponentially, making quality assurance, while limiting budgets, one of the top priorities in health care politics all over the world. In the Netherlands, society’s focus on hospital variations in quality of care resulted a strong call for transparency on hospital ‘quality of care’ for all stakeholders. To answer this call, various initiatives have been taken to measure and improve ‘quality of care’, and to increase transparency. Before we describe these different initiatives, it is helpful to first explain the concept ‘quality of care’.

Quality of care

Various definitions of quality of healthcare have been reported. The Organisation for Economic Co-operation and Development defined 6 aspects of quality of care: *effectiveness* (the degree of achieving desired outcomes), *safety* (the degree of prevention of adverse events), *patient centeredness* (the extent to which healthcare is organized around the patients’ needs, rather than the doctor) *timeliness* (the accessibility of health services, in the Netherlands mostly defined by waiting lists), *equity* (the extent to which the system deals fairly with all concerned and guarantees the highest standards of care for all) and *efficiency* (is the system as productive as possible in terms of input and output).⁴ The American Institute of Medicine defined quality of health care as “... the degree to which health services, for individuals and populations, increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”⁵ This definition includes *safety* and *effectiveness* and *patient centeredness*. Although all aspects are equally relevant, this thesis will mainly focus on *safety* and *effectiveness*.

Initiatives to measure and improve quality of care in the Netherlands

Concentration of care

Due to the overwhelming evidence that a higher hospital procedural volume results in better outcome, the emphasis in quality assessment has shifted from outcome to volume, and procedural volume has become a surrogate measure for quality.⁶⁻⁸ Accordingly, the political and professional focus in the Netherlands is now on concentrating care into high volume centres. Recently, the Association of Surgeons of the Netherlands has set a minimal annual volume standard for a large number of procedures. However, although for most of these

procedures an association between higher volume and better outcome has been proven, an evidence based minimal volume threshold has not been identified.⁹ Moreover, these volume thresholds ignore the fact that low procedural volume does not rule out good quality of care, and high volume does not guarantee good quality. Therefore the Association of Surgeons of the Netherlands recognises that volume thresholds are only a pragmatic first step towards quality control, and that focus should be on quality rather than quantity.

National evidence based guidelines

To reduce variations in treatment patterns and facilitate implementation of new scientific advances, national expert committees have developed evidence- and consensus-based guidelines for diagnosis, treatment and follow-up of different diseases. These guidelines are regularly updated when new evidence emerges. Among the most frequently used guidelines in the Netherlands are the oncological guidelines (accessible on www.oncoline.nl) developed by the Comprehensive Cancer Centres (CCC's). CCC's have a coordinating role in the regional multidisciplinary cancer networks, and are responsible for the implementation of national evidence based guidelines.

Quality indicators

To monitor and improve quality of care and guideline adherence, the Dutch healthcare inspectorate introduced a set of quality indicators in 2003. Quality indicators, "measurable aspects of care, which reflect the quality of care", (www.kiesbeter.nl) have been developed to reveal either substandard or high quality of care.

Types of quality indicators

Based on the Donabedian paradigm, quality indicators are commonly subdivided into three categories; structure, process or outcome indicators.¹⁰ Structure indicators, reflecting 'what is there', or the availability of materials or means relevant for the treatment process, are easiest to measure, but often difficult to link directly to quality of care. Although outcome indicators are often seen as 'the bottom line' of what doctors do, valid outcome information, adjusted for a hospitals' *case-mix*, is not commonly available. Also, outcomes need a minimal event-rate to be *relevant* as an outcome indicator: as the event-rate of most specific adverse outcomes (specific complications or mortality) is rare, event-rates are largely influenced by random variation.^{11,12} Process indicators on the other hand, usually selected from evidence based guidelines, give a fair reflection of what is done for a patient, and are more actionable than outcome indicators.¹³ Moreover, they are less influenced by case-mix and random variation. However, the indicator must concern a process indicated for all selected patients, and have a proven relationship with relevant outcomes.

Role of quality indicators in the Dutch Health Care System

After the introduction of quality indicators by the Dutch Health Care Inspectorate, many organisations followed, and by 2013 hospitals are overwhelmed by external requests for extensive lists of quality indicators, on various aspects of the care delivered. Nowadays, quality indicators are often used as hospital performance data and play a large role in the purchase policies of insurance companies. In addition, they are – sometimes carelessly - used by popular media to rate and rank hospitals in order to inform patients choosing their health care provider.

However, as quality indicators were designed only as ‘signalling’ measures to detect substandard care, their reliability and validity for these new purposes (for rating and ranking of hospitals, and as a basis for pay-for-performance) remains uncertain.^{14,11}

Reliability and validity of quality indicators

If quality indicators are used to assess and compare quality of care, it is important that they are both *reliable* and *valid*.

First, *reliability* of data is important. *Reliability* means that data are reproducible and that all patients concerned are included. Therefore, a uniform and valid data collection system for information on quality of care is vital for transparency of hospital quality. Currently, reliability of data used for quality indicators is insufficient, as for most quality indicators there is no clear, uniform definition, and data sources and methods for data collection differ between Dutch hospitals. Moreover, there is no data quality control system. Last, process and outcome indicators are often used regardless of relevance or case-mix.¹⁵ It is therefore not surprising that hospital data on quality indicators often conflict with other sources, and result in unreliable and inconsistent hospital rankings.¹⁶ These rankings and ratings result in unjustified negative publicity on quality of care, damaging societal and most importantly, patient’s trust in the Dutch healthcare.

Second, a careful definition of quality indicators is important to assure *validity*. *Validity* means that the quality indicator measures what intends to measure. Presently, validity of the quality indicators used is uncertain: most indicators currently used are process indicators; ratio being that a good process will lead to good outcome. However, for most process indicators, a clear association with good hospital outcomes of care has not been established. In addition, in most cases a single indicator, only giving information on a small part of the care process, is used to assess the quality of the whole process of diagnostics, treatment and outcome of a specific disease. The use of such indicators bears the risk of a ‘perverse incentive’ leading to ‘indicator driven practice’: the focus being on optimization of results on a single indicator, rather than the quality of the whole care process. Also, good results on a single indicator can give a reassuring picture of the quality of care in a hospital, while reality may be different. The most striking example being the Staffordshire scandal, where the overall results on quality indicators were acceptable, while in fact quality of care was appalling.¹⁷

With the increasing societal call for data on hospital performances, there is a need for a new monitoring system and a new methodology for looking at hospital performances from a broader perspective, integrating the various aspects of quality of care. Therefore, a nation-wide database is needed, compiled by uniform data collection in all participating hospitals, with clear definitions, and with sufficient information to monitor structure, process as well as (case-mix adjusted) outcome at hospital level: a Clinical Audit.

The introduction of Clinical Auditing

In 2009, the Dutch Cancer Society published a report on 'the quality of cancer care' in the Netherlands.¹⁸ Main conclusions of this report were that quality of cancer care in the Netherlands was high, but large variations in treatment and outcome between Dutch hospitals existed. The reports' recommendations for improvement of quality of cancer care in the Netherlands were

- to develop quality standards describing the minimal requirements of infrastructure, volume and available medical specialties in a hospital to safely treat a disease,
- to centralize treatment into hospitals meeting these basic structural requirements, and
- to monitor the performance of these hospitals by the implementation of *clinical auditing*: the registration and feedback of detailed information on patients, processes and outcomes of care.

The information from these clinical audits can be used to reduce hospital differences in practice and outcome, to analyse national practice and to identify and implement best practices. Also, clinical audits can serve as a platform for the implementation of new techniques into clinical practice. Additionally, data from clinical audits can be used for hospital transparency in quality of care: to provide proof of adequate care to other stakeholders.

The History of Clinical auditing

The idea of a clinical audit dates from the times of Florence Nightingale, who kept strict records of the mortality rates of injured or ill soldiers. After she implemented strict sanitary rules, and ensured that they were carried out, mortality dropped from 40 to 2%.¹⁹ Another famous person who pioneered auditing in the medical profession was dr. Ernest Armory Codman (1869-1940). Codman, a surgeon in Massachusetts (USA), kept notes on all of his and his colleague's patients, treatments and their outcomes.²⁰ He suggested that '*every hospital should follow every patient it treats long enough to determine whether or not the treatment has been successful, and then to inquire, "If not, why not?" with a view to preventing similar failures in the future.*' However, confronting his peers with their failures and mistakes made him very unpopular in the medical society, and finally forced him to give up his medical practice.²¹

It was almost a century later that the value of clinical auditing was recognized in a broader medical audience. In 1975, the first national clinical audit for knee arthroplasty was implemented in Sweden. This example was quickly followed by many other audits in Sweden, but also internationally. Renowned examples are the Norwegian and Danish audits,

the National Quality Improvement Project (NSQIP) in the United States, and the various audits in the United Kingdom.

Clinical auditing: process and requirements

Clinical auditing is a continuous process, often described as the '**audit cycle**', which consists of

1. systematic, uniform registration of patient, treatment and outcome of all patients in a population, by those involved in the care process.
2. frequent comprehensive and meaningful feedback of information on performances.
3. improvement projects and identification of best practices to improve outcomes.
4. adjusting benchmarks and goals.

Basic requirements are

- a limited but meaningful dataset, including all relevant processes and outcomes, and all case-mix factors needed for risk-adjustments.
- full participation of all hospitals involved.
- a timely and frequent feedback system.
- involvement of professionals to realize meaningful feedback and case-mix adjustments.

The Dutch Surgical Colorectal Audit

In 2009, a group of dedicated colorectal surgeons initiated the Dutch Surgical Colorectal Audit (DSCA): the first nationwide population based surgical outcome registration in the Netherlands. The aim of the DSCA is to monitor and improve outcomes of colorectal cancer resections in the Netherlands, by registering patient, diagnostic, treatment and outcome information and reporting this information back to the hospitals.

The dataset was developed by an expert committee and based on national evidence based guidelines. Data are entered by participating surgeons through a web-based interface in a highly secured database. In each participating hospital a single surgeon is appointed who is responsible for the data-entry. To secure data quality, hospitals receive data quality reports throughout the year, summing all patients with inconsistent or unusual data combinations, identified by a total of 70 queries. The responsible surgeon is asked to verify the data of these patients and to correct the data when indicated. Weekly feedback information on the number of registered patient files, and overall completeness of patient files combined with benchmarked performance indicators are placed online on a secured Internet page, accessible for the hospital only. Each year, outcomes of colorectal cancer care in the Netherlands are reported in an annual report, which is presented during an annual conference. Completeness and reliability of the data are cross-checked with the data from the Netherlands Cancer Registration.

Colorectal Cancer treatment

Colorectal cancer is the third most common cancer in males and the second most common cancer in females. In the Netherlands, every year, 12,000 new patients are diagnosed with colorectal cancer, of which 8,600 with colon cancer, and 3,400 with rectal cancer.²² Of these patients, 11,000 undergo a surgical resection of the tumour, or a Transanal Endoscopic Microsurgical (TEM) excision. Average 30-day mortality after colorectal cancer resections is 4.7%.²³ Complications occur in 34% and 11% of patients undergo a re-intervention. Long-term prognosis (5 year survival) for patients with colorectal cancer depends on tumour stage at diagnosis. Recent advances in treatment opportunities have increased survival, especially for rectal cancer patients. Overall 5-year survival is 59% for colon cancer and 61% for rectal cancer.²² Evidence based guidelines describe the preferred treatment for each tumour stage, based on the latest scientific advances, in order to increase the likelihood of long-term disease-free survival.

The treatment process of colorectal cancer is described in the national evidence based guideline, available on 'Oncoline'. For each patient a tailored treatment plan should be made, using the information in the guidelines. However, little evidence is available on how to tailor treatment for specific patient groups such as elderly patients or patients with an emergent presentation.

Hospital variation

Recent evidence has shown that for the treatment of colorectal cancer, there is a large variation between hospitals in adherence to these guidelines.^{24,25} These variations may in part be explained by structural differences such as the availability of Magnetic Resonance Imaging or a radiotherapy department, but also by differences in hospital type, size, resources, organisation and logistics.²⁵ Last, the regional structure of multidisciplinary cancer networks may result in subtle differences in the implementation of guidelines. However, until recently these differences in guideline adherence were not observable for hospitals, doctors, or society, as guideline adherence was not systematically registered. Therefore, the DSCA aims to produce meaningful feedback information on structure, processes and outcomes of care in a hospital, which may be used to

- gain insight in and reduce hospital variations in practice, guideline adherence and outcome, to enable hospitals to **improve** their **outcomes** using the audit cycle, and to identify best practices
- gain more insight in **national practice** and performance, to set benchmarks, and identify aspects that need improvement
- monitor and assure the safe **implementation of new techniques**
- answer the need for **transparency** on quality of care to other stakeholders

Challenges and general outline of this thesis.

The subject of this thesis is how data from clinical audits can be used to produce meaningful feedback information, supporting improvement of quality of care, using the DSCA as an example. It consists of 4 parts, elucidating the 4 different ways of using data from clinical audit to improve quality of care mentioned above: using the audit cycle as an instrument to **improve outcomes** and quality of care, evaluating **national practice** and performance, monitoring **implementation of new techniques**, and last, increasing **transparency** in quality of care.

In Part 1, **Chapter 2** we study the literature for evidence that clinical auditing, the registration and feedback of data on hospital quality of surgical care, indeed results in improvements. **Chapter 3** reports on the results of 3 years of clinical auditing on colorectal cancer treatment in the DSCA, and describes the key elements that led to the successful implementation of the DSCA.

In Part 2 we describe how data from clinical audits can be used to gain more insight in national practices and performances and identify aspects that need improvement, especially for high-risk patient groups. In **Chapter 4** we study the distribution of high-risk patients over the Dutch hospitals, using the 'expected mortality': an integrated measure for the effect of a patients risk factors on the likelihood of an unfavourable outcome. In **Chapter 5** we study the national results of non-elective colon cancer surgery compared to elective procedures in elderly patients.

In Part 3, **Chapter 6** shows how data from clinical audits can be used to monitor the implementation of new techniques, using the introduction of laparoscopic colorectal surgery as an example. We study the hospital variation of use and safety of laparoscopic surgery in the Netherlands.

In Part 4 we focus on how data from clinical audits can be used to evaluate quality of care and to increase transparency in quality of care. We evaluate how various aspects of quality of care cohere and on how these data can be combined into combined measures, which can be used by all stakeholders to evaluate quality of care as a whole. In **Chapter 7** we study the *validity* of available quality indicators to evaluate the quality of care for colorectal cancer, focussing on the construct validity and internal consistency of indicators. In **Chapter 8** process indicators are combined into composite measures reflecting guideline adherence. We study the hospital variation in guideline adherence and the association between guideline adherence and outcomes of care on patient and hospital level. In **Chapter 9** we describe how relevant outcome measures can be combined into a composite measure for a 'textbook outcome', which is valid and usable for all stakeholders, and prevents indicator driven practice. In **Chapter 10** we focus on the *relevance* of indicators. To judge quality of care, a minimal volume is needed. We therefore propose a combined measure for volume

and outcome, which selects hospitals with an acceptable outcome, but also a sufficient sample size to prove that their results are not just a 'lucky streak'.

In **Chapter 11**, the findings and implications of the studies included in this thesis are summarized, discussed and placed in a broader perspective. **Chapter 12** gives a summary of this thesis, translated in Dutch.

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