Measuring quality of care in the treatment of acute coronary syndrome

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Summary, conclusion and future perspectives

Samenvatting, conclusie en toekomstperspectieven

SUMMARY, CONCLUSION AND FUTURE PERSPECTIVES

The introduction (**chapter 1**, based on the published article 'The year of transparency: measuring quality of cardiac care') of this thesis describes the measurement of quality in the Dutch cardiac health care system. The definition of 'Quality', is described in four layers; 1. the ethical layer; 2. the professional standards and guidelines; 3. the legal layer and 4. quality indicators. This thesis focusses on the measurement of quality of care by quality indicators in patients treated for acute coronary syndrome and is separated in two parts: measuring patient safety on a local level (**Part I**) and measuring quality indicators on a national level (**Part II**).

The first part of the introduction describes the theoretical framework of patient safety. This thesis focusses on process deviations and the prevention of adverse events in patients treated for acute coronary syndrome and to define if our work process is sufficiently safe. In **chapter 2 to 4** this will be explained further.

The second part of the introduction describes the theoretical framework concerning measuring quality of care. The different types of indicators (structure-, process-, and outcome indicators) and stakeholders (patient, caregiver, health care insurance companies, supervisory boards and government) are discussed. Furthermore, the different mechanisms of actual improvement in health care by quality indicators are explained. Several (clinical) registries and quality indicators in daily cardiac care are described. The introduction concludes with defining the criteria of a good quality indicator (importance, reliable, valid, feasible, usable). **Chapter 5 to 8** of this thesis elaborates on the use of national claims data to measure quality of care in patients with acute myocardial infarction and evaluates patient's privacy the use of claims data.

Furthermore, the structure and content of the individual chapters will be discussed.

Part One - Quality of Care on a Local Level

Chapter 2 describes the development of a new valid instrument to objectively assess and monitor the occurrence of process deviations and adverse events in patients with acute myocardial infarction treated in a predefined care track. All 879 patients with a suspicion for an acute coronary syndrome and warranting coronary angiography in 2012 and 2013 were studied. All medical and nursery records were checked for process deviations (phase I) and whether any harm that occurred which was caused by (or due to inactivity of) the healthcare provider or the healthcare organisation (phase II). This was done by an adjusted version of the Harvard Medical Practice Study. A process deviation is defined as every operation or treatment that differed from the MISSION!-protocol, such as additional pro-

cedures, prescription of extra medication other than described in the protocol or omission of a procedure. An adverse event is defined as an unintended injury that results in disability at the time of discharge, death or prolonged hospital stay and is caused by healthcare management rather than by the patient's underlying disease process. Of all patients, 40% had a process deviation. One third (n = 116) of these had actually an adverse event during admission. The described method could be used as a template for developing a quality instrument of a patient record to objectify and monitor process deviations and potentially predicting and preventing adverse events.

Chapter 3 investigates the causal pathway of adverse events in patients with an acute coronary syndrome. The method is similar to the one used in chapter 2. Aim of this study was to assess the cause and the effect of adverse events in. In 13% of the 879 patients an adverse event occurred, of which 24% was preventable. Especially elderly, female patients and patients with an impaired renal function have a higher risk on experiencing an adverse event.

Chapter 4 describes why female patients more often experience adverse event in the treatment of an acute coronary syndrome and whether a 'risk-treatment-paradox' exists. The 'risk-treatment-paradox' is a situation in which patients at high risk for adverse events receive less intensive treatment compared to patients with a lower risk.[1] Again a patient record review of 879 patients is used. Of all 626 male patients, 10% had an adverse event, whereas in the group of 253 female patients, 21% had an adverse event ($P \leq 0.001$). Gender is an independent predictor of adverse events after adjustment for lifestyle factors, medication, comorbidities and treatment characteristics (odds ratio 2.4, $P \leq 0.001$). Furthermore, the 'risk-treatment-paradox' seems to exist. Women are less often treated according to international guidelines compared to man (less percutaneous coronary interventie (PCI) and longer symptom-to-needle-times), in which the increased risk for female patients is possibly underestimated.

Part Two - Quality of Care on a National Level

Chapter 5 evaluates whether claims data of the Dutch Insurance Companies, managed by Vektis B.V. is useful for quality measurement. National claims data are validated by comparison to local patient records in four representative hospitals in The Netherlands. The data were compared at three stages: 1) validation of diagnosis and treatment coding; 2) validation of the hospital where follow-up has taken place; and 3) validation of follow-up medical treatment, 365 days after the acute myocardial infarction (aspirin, P2Y12-inhibitor, statins, beta-blocker and angiotensin-converting-enzym/angiotensine-2-inhibitor). The claims data were proven to be highly accurate. This offers an opportunity for the use of claims data in quality assessments of acute cardiac care.

Chapter 6 evaluates the secondary prevention care in The Netherlands, one year after acute myocardial infarction. Claims data of all acute myocardial infarction patients in The Netherlands from the national Hospital Information System of 2012 and 2013 are analysed and connected with the national Pharmacy Information System. In total, 59,534 (67 ± 13 year, 66% male) patients were included of whom 52,672 (88%) patients were analysed for one-year medical therapy adherence. STEMI (ST-segment elevation myocardial infarction) patients more often achieved optimal medical adherence than NSTEMI (non-ST-segment elevation myocardial infarction) patients (60% vs. 40%, $p \leq 0.001$). In both STEMI and NSTEMI, use of all five indicated drugs was higher in male patients compared to female patients (STEMI male 61% vs. female 57%, $P \leq 0.001$; NSTEMI male 43% vs. female 37%, $P \leq 0.001$). With increasing age, a gradual decrease was observed in the use of aspirin, P2Y12-inhibitors and statins.

In **Chapter 7**, claims data are used to analyse the 'weekend-effect' in the treatment of acute myocardial infarction. The 'weekend-effect' is a term used for a difference between patients admitted with an acute myocardial infarction on weekends when compared to weekdays, attributable to a lower quality of care (e.g. lower use of medical procedures). All STEMI and NSTEMI patients in the Hospital Information System in 2012 and 2013 were included (59 534 patients, 57% NSTEMI). In STEMI patients, no differences in one-year mortality rates were observed between admission on weekdays or weekends. However, STEMI patients admitted during weekends were more often treated with PCI (weekdays 77% versus weekends 81%, $P \leq 0.001$). In NSTEMI patients, one-year mortality was higher in those admitted during weekends (weekdays 11% versus weekends 13%, $p < 0.001$). Potentially this is related to a lower use of PCI's in NSTEMI patients admitted during weekends (weekdays 35% versus weekends 32%, $P \leq 0.001$). More research is necessary to explain the lower mortality rate for NSTEMI patients, admitted during weekend.

Chapter 8 concludes with the potential conflict of patient privacy and the collection of patient data in quality-of-care registries. While fully acknowledging the importance of re-using already available data for medical research purposes and improving quality-of-care, concerns about the way the registries deal with the applicable privacy legislation do exist. Based to the new (2018) European law, the General Data Protection Regulation, the advice is to explicitly inform patients about the possible re-use of their data stored in quality-of-care registries for medical research (and providing the opportunity to opt-out) and ask every patient their specific informed consent in the near future. In the patients' survey of 361 respondents, the majority agreed with sharing data with healthcare professionals or healthcare researchers. Similar results can be expected when permission is requested for a quality register within cardiology and cardiothoracic surgery.

CONCLUSION AND FUTURE PERSPECTIVES

Attention for vulnerable groups

The female heart

Although ESC guidelines for the treatment of an acute myocardial infarction are similar in male and female, there are differences in the treatment. Additionally, patients experience more adverse events.[2-8] Other patient characteristics, such as age and frailty, only partly explain these differences (chapter 3 and 4). Furthermore, female patients receive optimal medical treatment less often after an acute myocardial infarction, specifically in NSTEMI patients (chapter 6). In the future, it is important to pay more attention to gender differences regarding disease presentation and under-treatment. The underlying reason for this may be the "risk-treatment paradox": patients with a higher risk for adverse events receive less-intensive treatment (chapter 3 and 4). Since recently, the Dutch Society for Cardiology and the Dutch Heart Foundation pay more attention to the female heart by supporting scientific research and stimulating the participation of women in studies. [9] The causes of adverse events in female patients should be studied, particularly in bleeding-related incidents. Although the ESC guidelines do mention the differences between male and female, currently no difference exists in the approach to diagnosis and treatment.[7, 8]

NSTEMI

NSTEMI patients are mentioned as an undertreated patient population. STEMI and NSTEMI share the same pathologic process to evolve to an acute myocardial infarction and have the same treatment to prevent arteriosclerosis and a recurrent acute coronary syndrome.[10, 11] Due to the acute course, STEMI requires rapid therapeutic treatment. Because of this acute course, a higher mortality rate is expected in STEMI compared to NSTEMI patients. However, an increased mortality is observed in NSTEMI patients compared with STEMI patients, in particular on the long term.[12-15] This is partly attributed to the higher age at admission and the occurrence of co-morbidities in NSTEMI patients. [16-18] Differences in treatment and thus a 'risk-treatment paradox' could play a role as well. Despite the increased mortality risk, chapter 6 shows an under-treatment regarding the use of secondary drug prevention after admission for NSTEMI compared to STEMI. These results emphasize the importance of following the guidelines, especially in NSTEMI patients and female patients.

Elderly patients

Elderly receive secondary prevention less often (chapter 6) and have a greater risk of adverse events (chapter 3). It is expected that this will become even more important in the future, with the increase of the elderly population. In the hospital, attention is already being paid to this vulnerable group by means of the "Senior Friendly Hospital" quality

mark.[19] This quality mark focuses on quality criteria such as the deployment of a geriatric team, attention for the elderly patient on the Emergence Care Department and care after discharge from hospital.

The assessment of quality of care

Local focus

Ideally, a setting could exist where high-risk moments in healthcare are identified on time, in order to adjust processes and prevent poor outcome. The importance of focusing on processes instead of focusing on outcome can be compared to a glass that falls due to a child playing too wildly. When focusing on the outcome, the child would only be corrected if a glass falls over during play (leading subsequently to an undesirable outcome). When focusing the process, one would correct the child's play, which automatically reduces the chance of an undesirable outcome. An increase in poor outcomes can be a trigger to investigate processes; it will be checked if children played too wild, when a striking number of glasses are broken. Therefore, analysing care data through structure, process and outcome indicators are of great importance and data-driven healthcare will become important in clinical practice on local and national level. Chapter 2 and 3 showed a method for process observation within the acute coronary syndrome care pathway. By observing the process deviations, an undesirable outcome can be predicted and ultimately prevented. In the future, real-time monitoring of risky processes can play a role in proactively controlling processes. In this, a patient with known risk factors for adverse event (e.g. female gender, higher age and poor kidney function) can be given a warning when planning a risky procedure. This requires specific attention for risk groups in education for physician assistants and cardiologists.

Furthermore, a cultural change on an entire department is important to regard quality and safety (First, do no harm!) as top-priority for all involved healthcare professionals. On a hospital department, attention is paid to incident analysis through incident reports, complaint procedures, Morbidity and Mortality Conferences and calamity reports. Using a traditional concept, called 'Safety-I', the goal of these meetings is to find solutions in order to prevent all future incidents and accidents ('Freedom from unacceptable risk'). However, complex work processes can go right or wrong. During these situations, the human adaptive power tries to compensate for the fact that clinical practice is always imperfect and variable.[20, 21] 'Safety-II' assumes a resilient work environment ('Resilient healthcare') that adapts to changed systems and observes why it usually goes well. This fits with 'Just Culture' ideas of Sidney Dekker, in which everyone's role is taken into account without any judgement, but by clarifying everyone's responsibility. Anchoring a broader safety culture in a department is therefore a major challenge.

National focus

Furthermore, there is a national need for an inexpensive and efficient way of measuring quality of care. Various stakeholders in the healthcare sector (Inspectorate of Healthcare and Youth, health care insurers, National Healthcare Authority, audits (such as Q-mentum)) ask the hospitals and health care provider to justify the care provided and to deliver various indicators. A survey of the Federation Medical Specialists, Association of Arts and Auto and the general practitioners' initiative 'Het Roer Moet Om' in 2017, observed that physicians spend 40% of their time working on administration such as keeping medical records, checking diagnosis-treatment codes or acquiring data for quality and safety registries.[22] Solely 36% of these actions are considered useful by physicians. The use of registered claims data to gain insight in care processes and quality of care plays an important role. This thesis proofs that claims data from acute myocardial infarction patients and associated pharmacy claims data are very useful for efficient and valid quality measurement (chapter 5).

This national claims data can be used to gain insight into national financial flows. Furthermore, it can be used within quality-of-care measurements for more transmural insight. By linking various data registries, a patient can be monitored throughout the entire care process: from the first presentation with thoracic complaints at the general practitioner, followed by a treatment for acute myocardial infarction in the hospital, up to results about cardiac rehabilitation and long term follow-up. In addition, it offers the possibility of comparison of hospitals or regions. By analysing ambulance regions, postal code regions or hospital regions, regional variation can be mapped. As an example, the regional variation in preventive medication in the Netherlands by postal code is presented in Figure 1.[23] Regional analysis are useful for a targeted regional approach, in which care providers in one region (hospitals, general practitioners, Municipal Health Service (Gemeentelijke Gezondheidsdienst, GGD) and all paramedics in a region, pharmacists) are responsible for the health of patients living in that region. This is comparable to *Accountable Care Organizations*, in which healthcare providers and health insurers are jointly responsible for the health care costs and health of a population (for example a municipality or region). Furthermore, national (claims) data are already being used for Value Based Healthcare, with the aim to maximize value for the patient while minimizing healthcare costs.[24]

The use of registered data such as claims data for quality of care assessments will increase in the future. A number of pitfalls must be mentioned here. With a large volume of data (big data), formulating a good research question in advance is important in order not to get lost in the amount of data. Additionally, it is important to collaborate with a data manager *and* a physician from the clinical field to develop a relevant quality analysis. At last, performing these analyses is expensive. Luckily, experience is gained on how claims

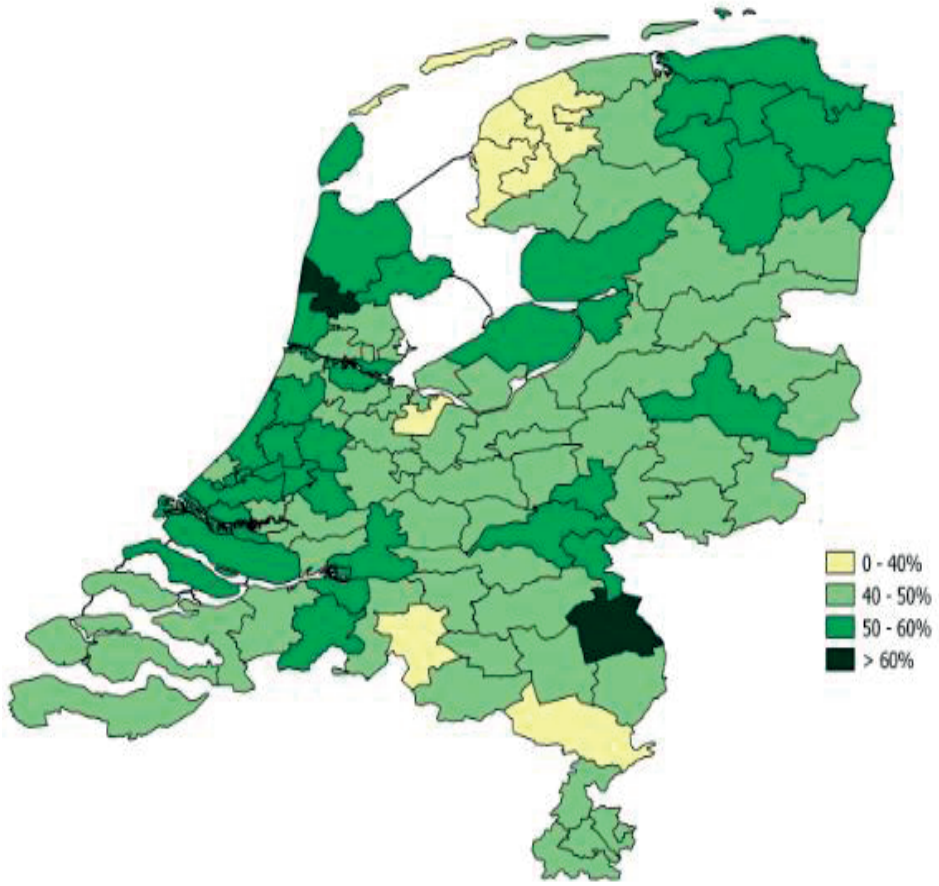

Figure 1: Optimal medical treatment in the Netherlands in 2012 and 2013.
Caption: Optimal medical treatment is defined as the use of acetylsalicylic acid, P2Y12 inhibitor, statin, beta-blocker and an ACE inhibitor one year after acute myocardial infarction.

data can be used for quality analyses (analysis per patient and process) in addition to financial analyses (analysis per procedure and volume), which may lead to a cost reduction in the future.

Publishing data

In the Dutch profession of Cardiology, a great reticence exist to publish quality data which can be traced back to individual centers or healthcare providers. In other professional groups in the Netherlands and in other countries, people are less negative about this. In Sweden, transparency on the quality of care based on outcome results contributed to an increase in quality and a decrease in costs.[25] Sweden, in particular SWEDEHEART (a cardiovascular clinical registry), has years of experience in publishing quality data (example in **figure 2**). The public health care organization ensures uniform criteria and specific

budget is available per county for the registration of clinical data.[26] The Swedish registries exist since 1987 and currently explores the possibilities of using registries for conducting scientific research by Registry-Randomized Controlled Trials.[27] Also in The Netherlands, several professional groups use national data for comparing the quality of care. The Dutch Society for Surgery has noticed positive results from the publication of national clinical data in the Netherlands.[28] Furthermore, linking clinical data and claims data in colorectal cancer surgery proofed that an increase in the number of complications in hospitals was associated with an increase in costs, and vice versa. [29]

An important step in the comparison of quality of care within cardiology in the Netherlands is the Dutch Heart Registry, in which the various clinical registrations in cardiology (Meetbaar Beter, NCDR and BHN) are combined and use uniform criteria. This offers great opportunities to link national (claim) registries with detailed clinical information.[30] The national claims data of the insurers, as described in this thesis, can be used on a scientific level for the generation of outcome data and the transmural follow-up of the acute myocardial infarction patient. The clinical data from the Dutch Heart Registry can be linked with claims data, in order to gain more insight into underlying processes and possible options for improvement. The number of clinical variables per patient which are relevant to include in the registry could be discussed. A small dataset with basic elements, determined by the members of the Dutch Cardiac Society (Nederlandse Vereniging voor Cardiologie), can be registered annually and nationally.

Patient's privacy

For the patient, the quality records exhibit an improvement in the quality of care on a population level and an improvement in the insight into the quality of care of the various institutions and care providers. However, the privacy aspect of patient data also plays an important role in the use of care data. The owner of the data is initially the healthcare provider or institution, and after transfer of data to financial or clinical records, the owner is the person who manages and maintains these registrations. As long as the data are anonymous or data are linked by a Trusted Third Party, it will not interfere with the right to privacy of the patients. However, anonymous data can be traceable to a patient when a disease or treatment is rare. Therefore, Vektis B.V. maintains a limit of at least 10 patients per postcode area when sharing their data. The new legislation from Europe (General Data Protection Regulation (GDPR), as of May 25, 2018) is stricter regarding privacy. Especially when using quality records for scientific purposes, this requires good informed consent ánd an opt-out arrangement, next to reliable data security.[31] This means that a patient must be informed about the fact that his data could be used for scientific research or quality-of-care analyses that serve the public health and that the patient has the possibility to remove his or her data from the databases at all times.

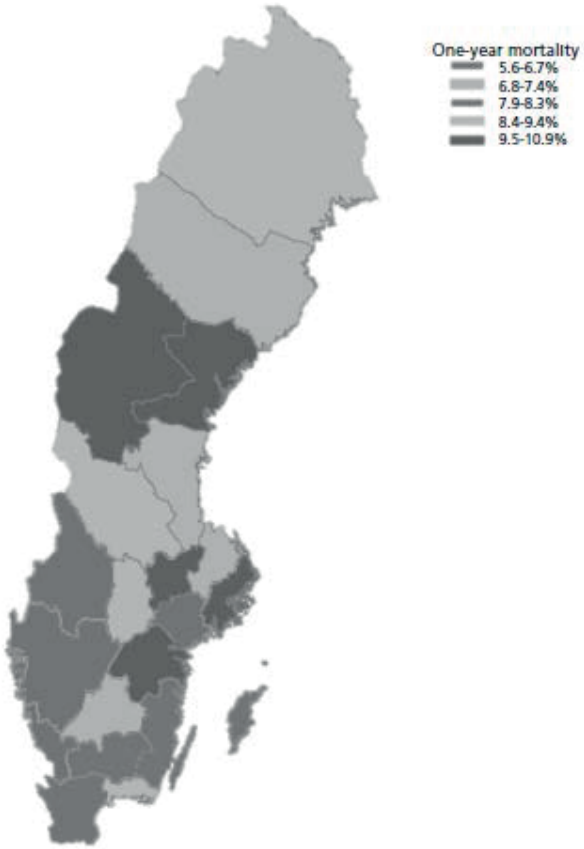

Figure 2: One-year mortality in acute myocardial infarction patients younger than 80 years in Sweden in 2015 – 2016, stratified per home county and per hospital.
Source: Jernberg T. Swedeheart - Annual report 2016. Uppsala, Sweden: Uppsala Clinical Research Center, 2017.[32]

For publication and sharing results from quality-of-care research, the degree of traceability of the used data will always remain a discussion. Transparency of quality of care leads to improvement of care, in which the level of transparency depends on mutual trust of the involved care providers, authorities and patients.

Is our provided care 'sufficiently safe'?

This thesis focused on the question how one can measure the quality of care to assess whether the care provided for the treatment of acute coronary syndrome is sufficiently safe. Two methods were used: local record review study regarding patient safety (Part 1) and national claims data registration for quality-of-care research (Part 2). Claims data lack patient details, record review study research is laborious. The two different methods complement each other and serve a different purpose: safety and quality of care. The

provided care seems *safe*, yet 13% of the patients experience an adverse event. More research is necessary, but what kind of research? Record review study is very laborious and even research within a strict and clear working protocol as the MISSION!-protocol results in heterogeneous answers on the causal pathway of adverse events. Real-time monitoring of process deviations with registered data results in more insight in adverse events.

The provided care seems to have a *good quality of care* and to accord with the guidelines, yet only 49% of all the patients receive all five indicated medications after acute myocardial infarction. Herein there is room for improvement as well. Future analysis with claims data, combined with clinical data and other data sources, can provide more insight in order to continuously improve the quality of care.