Measuring quality of care in the treatment of acute coronary syndrome

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Chapter 1

General introduction

Based on the paper entitled *The year of Transparency: Measuring Quality of Cardiac Care*.

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INTRODUCTION

Medicine changed dramatically during the last decades with the introduction of multiple life-saving solutions and diseases now becoming treatable which were deemed untreatable in the past. In the beginning of 20th century, an acute coronary syndrome was treated with bed rest and 'expectant treatment', as far away for the nurses' station, so that they would not be disturbed by the frequent telephone ringing.[1] In 1975 the treatment evolved to achieve rapid myocardial reperfusion by streptokinase, cardiac surgery or percutaneous coronary intervention.[1] However, many of these new treatment modalities are more complex and request an excellent organisation, which has not always evolved equally.

Meanwhile, many treatments are initiated without a solid risk assessment and thorough clinical evaluation and may even cause harm to the patients. A study in the U.S. suggests that medical errors are the third leading cause of death emphasizing that patient safety is a serious health care issue.[2] Since the To Err is Human report in 1999, different reports raised an increased attention for quality of care and safety.[3,4] After preclinical research (in vitro and in vivo), clinical research (randomised controlled or large observational trials), this thesis focusses on the next phase: retrospective quality of care studies and whether all research and guidelines do work in real clinical practice.

What is quality of care?

'*Primum Non Nocere*', or '*First, Do No Harm*', is the well-known sentence from the Oath of Hippocrates, which doctors swear at the start of their career.[5] These ethical standards are still considered to be a main priority in health care and form the basis of quality of health care. The second layer which defines 'what is good care' are the professional standards or guidelines of the Royal Dutch Medical Association (*Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst, KNMG)* or the Scientific Societies (*Wetenschappelijke Verenigingen*). This is anchored in laws concerning health care, like the Individual Health Care Professions Act (*Beroepen in de Individuele Gezondheidszorg, BIG*) and Medical Treatment Act (*Wet op de Geneeskundige Behandelingsovereenkomst, WGBO*), which are known to be the third layer. The measurement of quality indicators is the fourth and final layer and the modern way of defining good quality of care. The measurement of quality of the care, both on a local and national level, is the focus of this thesis.

Quality of care has various definitions. The National Academy of Medicine, formerly called the American Institute of Medicine defined quality of care as '*the degree to which health service for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge*'.[6] In 2003, quality of care has been defined by the Agency for Healthcare Research and Quality of the United States as *doing*

the right thing, at the right time, in the right way, for the right person—and having the best possible results.[7] In The Netherlands, the definitions on quality of care were translated into six aspects; Safety, Effective, Patient centered, Timely, Efficient and Equitable.[8]

PART ONE – QUALITY OF CARE ON A LOCAL LEVEL

Patient Safety

Patient safety is defined as the prevention of harm to patients and forms the cornerstone of high quality of care. Measuring patient safety at a local level constitutes the focus of the **first part of this thesis**. In 1999, the National Academy of Medicine, published a report called '*To Err is Human*', which drew attention to the fact that a significant number of patients suffered from injuries or even had died as a result of care delivered in hospitals.[4] Subsequently, various studies in different countries reported that 2.9–16.6% of in-hospital patients experienced one or more adverse events and that in 5–13% of the adverse events the patients died.[9-19] A recent report by Makary et al. showed that adverse events are still the third leading cause of death in the United States.[2] This formed the basis of an increased focus on the assessment and management of patient safety.

The conceptual framework of patient safety is based on the causal chain of Donabedian (differentiating between structure, process and outcome) and Reason's Swiss cheese model (differentiating between latent errors on an organisation level and active errors of human interaction).[20, 21] (**Figure 1**) In the assessment of events, a difference is made between (unintended) events during the process of care (i.e. incidents or errors) and in the (unintended) outcome of events (i.e. complications or adverse event). Furthermore, a causal relationship was assessed between the process and outcome. As an example, if someone who should have been vaccinated against influenza contracts the prevalent strain of the disease, it is quite possible that this could have been prevented. On the other hand, the reoccurrence of acute coronary syndrome in an individual patient might not have been prevented by b-blockers, even if at a population level the benefits are clear.[22] A detailed description of the used definitions is noted in **Box 1**.

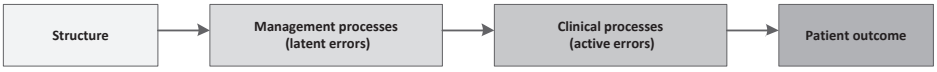

Figure 1: Structure, process and outcome indicators, including latent and active errors.

After finding a substantial number of preventable deaths, the project of EMGO+/NIVEL called 'Zorggerelateerde Schade' (literally Health Care related Injuries) in 2004, 2008 and 2012, raised the attention on Patient Safety Management in Dutch hospitals. As a

result, a national safety program for hospitals '*Voorkom schade, werk veilig'*, started in 2007.[23] This was based on nationwide research on adverse events by EMGO+/NIVEL, in which retrospective patient records review and database algorithms were assessed. The report raised awareness significantly in The Netherlands with respect to patient safety.[24] However, due the general hospital-wide approach, this report provided hardly any insight into causal relations on a departmental level. The development of specific interventions

Box 1: Definitions in the field of patient safety.

Adverse event is (1) an unintended injury (physical and/or mental) which results in (2) temporary or permanent disability, death of prolonged hospital stay and (3) that is caused by health care management rather than by the patient's underlying cardiac disease.

Calculated Risk is a balanced risk or calculated side effect of a treatment described in literature, in which the intended effect of the treatment is considered of greater importance than the severity of the injury or the chance of an injury.

Causation refers to injury caused by health care management including acts of omission (inactions) i.e. failure to diagnose or treat, and acts of commission (affirmative actions) i.e. incorrect diagnosis or treatment, or poor performance.

Complaint is any objection raised to the action or functioning of a health care provider, coming from the user of the health care which is provided.

Complication is any unintended and undesired injury during or after receiving health care, which requires treatment or leads to temporary or permanent injury.

Disability refers to temporary or permanent impairment of physical or mental function attributable to the adverse event (including prolonged or strengthened treatment, prolonged hospital stay, readmission, subsequent hospitalisation, extra outpatient department consultations or death).

Error is failure of performing a planned activity (failure of performance) or a wrong plan to achieve its intended outcome (failure of planning).

Health care management includes the action of individual hospital staff as well as the broader systems and care processes. Health care management is any care related activity that involves the delivery of care or monitoring of health which is provided by individuals or a team of professionals.

Incident is any unintended or unexpected event which could have or did lead to harm for one or more patients receiving health care.

Near Miss is a unintentional event that (1) does not cause harm to the patient because their consequences are recognized and corrected on time, or (2) whose effects do not affect the physical, psychological or social functioning of the patient.

Preventable adverse event is an adverse event resulting from an error in management due to failure to follow accepted practice at an individual or system level. Accepted practice was taken to be 'the current level of expected performance for the average practitioner or system that manages the condition in question'.

Process deviation was defined as every operation or treatment that differentiated from the MISSION! Protocol, such as additional procedures (a pacemaker implantation or second PCI), prescription of extra medication other than described in the protocol (use of antiaritmica, anticoagulation, inotropics or diuretics) or omission of a procedure (no diagnostics performed).

Unintended injury refers to any disadvantage for the patient that leads to prolonged or strengthened treatment, temporary or permanent (physical and/or mental) impairment or death.

Based on Wagner [66] and Langelaan [67, 68].

at each department in order to improve patient safety appeared even more challenging, particularly in cardiology, being a department with a high intervention rate and a large number of patients with life-threatening illnesses. High-risk industries, such as the aviation and chemical industry, are required to perform structured assessments of all processes contributing to a particular activity, which allows them to make a reasoned claim regarding safety. Inspired by high-risk industries and best-practice hospitals, the aim of the **first part of this thesis** is to provide a methodology to review patient safety on a local level and to define if our *work process is sufficiently safe*.[25]

The **second chapter** analyses process deviations and the correlation with adverse events in hospitalised patients who are treated for an acute coronary syndrome according to the protocolised care pathway, called MISSION!, in the Leiden University Medical Center. The definition of an acute coronary syndrome and the description of the MISSION! Protocol is explained in **Box 2**. The **third chapter** describes the results of a retrospective patient record review study concerning incidence, type, nature, and preventability of AEs among hospitalised acute coronary syndrome-patients in The Netherlands. The **fourth chapter** focusses on the treatment of female and their higher risk on adverse events.

Box 2: Acute myocardial infarction and the MISSION! Protocol.

Acute coronary syndrome

Acute coronary syndrome is a high-risk manifestation of coronary artery disease, ranging from unstable angina pectoris, non-ST-segment elevated myocardial infarction (NSTEMI) to ST-segment elevated myocardial infarction (STEMI). Although rupture or erosion of a vulnerable atherosclerotic plaque frequently leads solely to progression of plaque volume, due to an unfortunate turn of event it might give rise to a cascade of inflammation, thrombus formation and partial or complete occlusion of the coronary artery resulting in acute ischemia or necrosis of the myocardium. A patient with a NSTEMI or STEMI shows elevated level of cardiac biomarkers (Creatine-kinase or Troponine) due to ischemia.

MISSION!

The MISSION!-protocol contains a prehospital, in-hospital, and outpatient framework for clinical decision making and treatment for the different diagnosis in acute coronary syndrome (STEMI, NSTEMI, UAP or another diagnosis like and old ambulatory infarction). This study is focussed on the in-hospital program (early reperfusion, same diagnostic trajectory like 2D-echocardiography, structured medical therapy, and disease education). Generally, patients are planned for discharge 12 hours after a coronary angiography, or 48 hours after a percutaneous coronary intervention. The MISSION!-protocol is based on the evolving guidelines of the European Society of Cardiolog.[63,64,65]

PART TWO – QUALITY OF CARE ON A NATIONAL LEVEL

The different perspectives in the assessment of Quality of Care.

After the assessment of patient safety on a local level, the second part focusses on quality of care on a national level. The quality of care assessment or indicators are used to assess the quality of care and to compare hospitals or caregivers. The assessment of quality of care is becoming increasingly important in healthcare, both globally and in The Netherlands. With the transition into a regulated healthcare market system in 2006, insurance companies received a central role and the shared legal responsibility for the quality of cost-effective care.[26] This responsibility created the legal need to develop a system in which quality of care can be measured and monitored.[27] Currently, hospital accreditation is already based on quality measurements and in the future, reimbursement will most likely also be based on quality instead of price and volume only.[28] The Dutch Minister of Health had declared the year 2015 to be the year of transparency, thereby stressing the need to improve the reporting of quality of care.[29] With the increasing importance of transparency, knowledge on quality measurements will become vital in daily clinical cardiac care.

The aim of measuring quality of care differs depending on the different stakeholders involved in the healthcare system.[30] Patients aim for the best possible clinical outcome, patient-cared-care approach and need quality measurements to be able to take informed decisions. Healthcare professionals aim for the best possible outcome for a maximum number of patients and, additionally, need quality measurements to benchmark results with other healthcare professionals in order to identify improvement opportunities. Healthcare insurance companies aim for the best possible (long-term) value for the money spent on behalf of their customers (insured patients). The government aims to achieve the best possible public health at a stated budget, while guaranteeing financial and physical accessibility and affordability for all inhabitants.[31](**Figure 2**)

How to assess Quality of Care?

The previously mentioned causal chain of Donabedian, is also used in the assessment of measurable indicators for quality of care: structure, process and outcome indicators.[21] (**Table 1**)

Structure indicators reflect the system and setting in which care is delivered and relate directly or indirectly to staff expertise, the organisation logistics or capacity. For cardiac care, examples are PCI volume, availability of a catheterization laboratory and the educational level of the nursing staff. Structure indicators are less likely to be influenced by medical professionals and therefore less useful to monitor programs for quality improvement. They reflect the average results for a large group of providers, not for individual providers. The

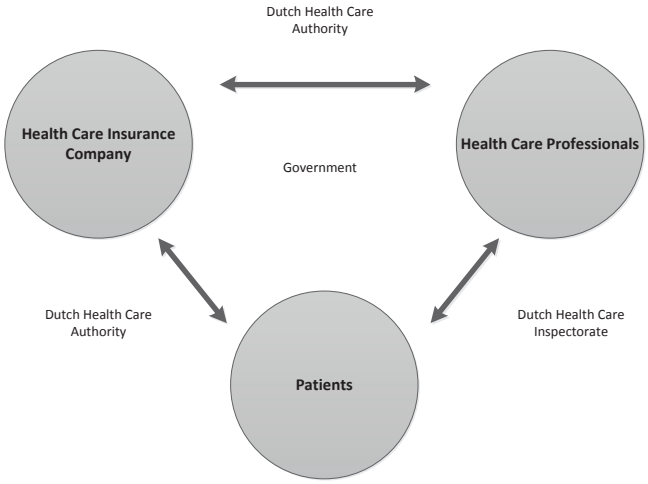

Figure 2: Different positions in the health care system in the Netherlands

Table 1

	Structure Indicators	Process Indicators	Outcome Indicators
Example	PCI-volume a year Availability of cathlab Education level of the nurses	Medical prescription according to guidelines Door-to-balloon-times	Morbidity and mortality rates Functional health status Patient Statisfaction Costs
Advantages	Appropriate. If associated with outcome, inexpensive proxies of cardiovascular outcomes.	Reflect care that patients actually receive. Actionable from provider perspective. Clear link to quality improvement activities.	The 'bottom-line" of cardiology Outcomes measurement alone may improve outcomes.
Disadvantages	Most variables not actionable from provider perspective. Imperfect proxies for outcomes reflect average results for large groups of providers, not individuals.	Little information about which processes are important for specific procedures.	Numbers too small to measure with adequate procedure-specific outcomes for most hospitals and procedures. Outcomes measures that are not procedure-specific less useful for purposes of quality improvement.

Based on Birkmeyer et al. which is applied on examples in the field of Cardiology.

advantage of these structure indicators is that they are expedient and relatively inexpensive to collect and can be used in plain hospital comparisons. Structure indicators are in general of limited use in clinical practice although a large study (n = 457,498) was published in which a relationship was found between increased operator/institutional volume of PCI procedures and a decrease in adverse outcomes and costs of hospitalisation.[32] However, other studies demonstrated that an increase of volume above a certain threshold is not

related to improved outcomes. Hence, some of these structure indicators may be useful to define minimal requirements.

Process indicators describe the care patients actually receive. Examples for cardiac care are door-to-balloon-times in patients with a ST-segment elevation myocardial infarction and medication prescription according to the guidelines.[33, 34] The usefulness of process indicators and the association with clinical outcome measures has been thoroughly established. In patients with an acute myocardial infarction, Peterson et al. showed a correlation between processes of care and outcome. With every 10% increase in process adherence (for example medication use according to clinical guidelines) there was an associated 10% decrease in in-hospital mortality.[33] Another study demonstrated that 6% of hospital-level variation of 30-day mortality rate could be explained by the performance on process measures.[35] In heart failure, the relationship between process and outcome is however modest. In the OPTIMIZE-HF study, none of the process measurements were associated with a decrease in 60- or 90-day mortality.[36] In case of a proven association, process indicators can be useful to monitor if aspects of clinical practice are likely to result in an improvement of the quality of care. A limitation, however, is that there is a lack of evidence on which processes are important for specific procedures. Importantly, although the use of process indicators is known to be effective in general, they are not able to not mark the quality of care provided to individual patients since it can be necessary to deviate from the normal care process in order to provide optimal care for that specific patient. For example, prescribing beta blockers after an acute myocardial infarction is considered common practice. However, patients with symptomatic bradycardia after an acute myocardial infarction should not receive a beta-blocker, thereby stressing the need for a connection with clinical data, which are more time-consuming to require.

Quality of care is most effectively measured by clinical outcome measures, referring to the effect of the provided care on the health status of patients. These outcome measures can be translated to *outcome indicators.* Examples of these are overall mortality rate, hospital readmission rate, functional health status and patient satisfaction. Outcome measurement is considered the most important measurement of quality of care but has to be acquired per patient and is therefore relatively time-consuming and expensive. In 2013, the Court of Audit (Algemene Rekenkamer) concluded that the quality of most indicator sets is limited and that only 7 % of the indicators collected by hospitals were outcome indicators.[37]

The relationship between registration of quality indicators and patient outcomes

Since registration is a time-consuming process, it is important to ascertain whether the used quality indicators actually provide the desired effect of improving quality of care.

Chatterjee et al. have described three mechanisms by which registrations can help to improve patient outcomes.[38]

First of all, *reporting about quality of care among cardiology departments itself* can lead to more awareness and an incentive for hospital leaders and clinicians to improve the care that is provided. In order to achieve this, it is important that results can be shared safely. Studies show that departments that pay explicit attention to quality of care, show improved outcomes in care. This is called the Hawthorne effect.[39]

Public reporting can also be a powerful incentive for clinicians and hospital leaders to improve. In addition, public reporting provides transparency in quality of care and can thereby increase the confidence of patients in the healthcare system. However, public reporting of quality indicators in the United States also demonstrated some disadvantages. First of all, states that publicly report on quality of care did not show differences in outcome compared to states that did not report.[40] A further concern of public reporting is that it will lead to risk aversion among physicians, deferring patients with more complex pathology, as is demonstrated in the literature. For example, in the United States, the majority (89 %) of interventional cardiologists have reported that the decision to intervene in critically ill patients was influenced by the fact whether or not they participated in the reporting of quality measures.[40] A registry confirmed this trend in practice, showing that patients in reporting states (e.g. New York) were less likely to undergo a PCI procedure if they were in shock.[41] Public reporting of CABG mortality in New York led to an increase of sicker patients being referred to the adjacent state Ohio.[42] Although transparency in quality indicators is increasing in The Netherlands, the results are currently not linked to individual caregivers. The Society for Cardiothoracic Surgery in Great Britain and Ireland, in collaboration with the National Health Service, provide open access information on treatment results of all individual cardiothoracic surgeons.[43] In The Netherlands, the aim of the Dutch government is to publish results of quality of care measurements at a national website for patients in order to improve transparency and to help patients in making informed decisions (www.kiesbeter.nl).

Pay-for-performance is the newest quality improvement mechanism, which is gaining attention from healthcare leaders and healthcare insurance companies as a strategy for maximizing quality while controlling costs. Pay-for-performance implies a shift in paying for quality healthcare instead of volume of care, which can be a strong stimulus to improve quality.[38, 44]

Registration of quality of care in The Netherlands.

National quality measurement

National quality measurements are initiatives from government, supervision institutions, insurance companies and patient organisations. From the perspective of the individual hospital and/or cardiology department these initiatives can be interpreted as external requests for accountability. The Dutch Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg en Jeugd, IGJ*) has an important task, as described in Article 36 of the Healthcare Insurance Act, to verify if hospitals meet the minimum level of quality according to general healthcare acts and the professional standards as defined by the professional organization of the different medical specialists.[26] Verification of the data is achieved by surveillance of compliance to the law, regulations, professional standards and guidelines. The Dutch Healthcare Inspectorate focuses on surveillance of the highest risks by mostly collecting process and structure indicators. For ST-segment elevation myocardial infarction, outcome, structure and process indicators (number of PCI procedures, in-hospital or 30-day mortality, door-to-needle time or door-to- balloon time and the percentage of patients referred for cardiac rehabilitation) are acquired. For pacemaker and implantable cardioverter defibrillator implantations the number of procedure-related complications within 90 days has to be registered.[45]

Hospitals use external accreditation programs to prove and objectify a certain level of quality of care as well as maintenance of quality of care to outsiders. The Q-Mentum, formerly known as The Netherlands Institute for Accreditation in Healthcare (*Nederlands Instituut voor Accreditatie in de Zorg, NIAZ*) or Joint Commission International aim to assure and improve Dutch healthcare by using an international accreditation program. Besides quantitative quality indicators, the accreditation systems comprise explicit quality policies and quality instruments, such as incident reporting and audits.

To reduce rising health care costs while improving quality of care, the Dutch healthcare system has changed in 2006 towards a regulated health care market. In order to achieve this, two important acts were introduced: the Healthcare Insurance Act (*Zorgverzekeringswet*) and the Act of Regulation of Healthcare (*Wet Marktordening Gezondheidszorg*).[26, 46] In the new system the health insurance companies play a central role, positioned between patients and caregivers, with a shared responsibility to ensure good quality and cost-effective care. For the first time it became possible for the insurance companies to selectively contract care based on the quality of the provided care. Additional to the responsibility in limiting the rising healthcare costs, insurance companies are required to analyse and interpret quality of care provided by caregivers. Article 14 of the Healthcare Insurance Act, and the general directorial derived from this act, states that insurance companies share

the responsibility for efficient and timely healthcare of good quality, based on professional standards defined by the scientific professional organisations and healthcare providers. The explanatory memorandum of the act states that more information on outcome of caregivers will be available in the future.[47] Currently, however, more attention is given to the volume and cost agreement than to the provided quality of care.[48,49] The Dutch Healthcare Authority (*Nederlandse Zorgautoriteit, NZa*), who has the task of overseeing the regulated healthcare market, is positive about the increased attention to quality of care in contracting during recent years.[50] A report of the Council for Public Health and Healthcare (*Raad voor de Volksgezondheid en Zorg, RVZ*) concluded that health insurance companies have to be more transparent about the criteria used for contracting care, which caregivers are contracted and how patients were involved in the process of contracting care.[51]

Quality Indicators used in a cardiology department.

In The Netherlands, the quality of cardiac care is measured by different stakeholders and the different quality indicators are provided by the cardiology departments or on a hospital level. In July 2017, The Netherlands Heart Registration (Nederlandse Hart Registratie, NHR) is founded, which is a fusion between three Dutch registries in cardiology and cardiothoracic surgery: 1) National Cardiovascular Data Registry (NCDR), 2) the Supervisory Committee for Heart Interventions in The Netherlands (Begeleidingscommissie Hartinterventies Nederland, BHN) and 3) Meetbaar Beter. Recently, examples from clinical practice show the downside of too many quality indicators. Registration of clinical parameters are known to be a laborious and time-consuming task, resulting in less time for actual patient care.[52-54] Fraud with quality indicators is seen when hospitals struggle to meet the quality criteria or to measure the quality indicators.[55] In The Netherlands, around 3,500 indicators for quality assessments in general hospitals exist. The majority, around 96%, is requested by the insurance companies and patient representatives. The remaining 4% is requested by the Dutch Health Care Inspectorate, which composes around 3,500 variables and resulted in 250 indicators in 2017.[56] The QUASER study, in which the development of quality improvement of the different health care systems in European hospitals was compared, showed an excessive amount of indicators and external audits in The Netherlands.[57] Moreover, the indicators in the six countries were comparable, but not similar due to the use of different definitions for the numerators and denominators.

Criteria for a good Quality Indicator

As addressed before, the results of any measurement must be relevant for the different stakeholders in healthcare. For the use and development of quality indicators it is also important to take into account that indicators are scientifically acceptable. This means the indicators should be reliable and valid.[58] *Reliable* means that the indicator provides the same result on repeated measures and that the dataset is as complete as possible with

uniform datasets which are collected in a uniform way. Also, the Dutch Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra, NFU) points out in their report the importance of a central vision on registration of care and the value of a uniform standardised dataset. They aim to develop a uniform structure of elementary data elements and the use of a unified medical language based on international standards.[59] The use of universal definitions is encouraged by the International Consortium for Health Outcomes Measurement (ICHOM), an international non-profit organisation with the aim of transforming healthcare systems by measuring and reporting patient outcome.[60]

Validity means that the indicator measures what it is intended to measure. This requires a good methodological quality, taking into account potential differences in casemix and random variation. A common remark heard by healthcare providers is that they are concerned about the lack of a proper case-mix correction and that a negative outcome compared with others can be explained by the increased complexity of their patient population compared to other hospitals. A good casemix correction applied in crude data could change the compared clinical outcome and is important to avoid unintended consequences.[42, 61, 62] Furthermore, it is important to remember that quality indicators are merely a proxy of the actual quality of care. Therefore, the indicators should give appropriate coverage of the quality of care of a department and be in line with the crucial aspects of current strategies to improve quality of care.

Claims data

With the growing importance of quality assessment and the search for efficient data collection, routinely collected claims data are being used more frequently and studied for cardiac outcome measurements. Benefits of the claims data are the automatic and continuous data acquisition which makes it less laborious for health care professional to gather care outcome measurements. Claims data have the advantage to cover nationwide, do not depend on hospital participation and are useful for chain of care evaluation (including connection with external datasets). However, claims data are collected for billing purposes rather than for research. **Chapter 5** shows the validation of claims data in the assessment of medical treatment in the first year following acute coronary syndrome. **Chapter 6** uses the claims data to clarify if there are differences in medication use during one year following acute coronary syndrome, stratified for type of infarct, age and gender. In **chapter 7**, claims data is used to analyse the 'Weekend-effect' in patients with an acute myocardial infarction. Previously, several studies have shown that patients admitted with an acute myocardial infarction during the weekends have a higher mortality rate than those admitted during weekdays, possibly attributable to less trained personnel available and a lower use of medical procedures.[5-10] **Chapter 8** concludes with the potential conflict

between patient privacy and the collection of patient data in quality-of-care registries and the impact of the new European law, the General Data Protection Regulation.

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