Redesigning cardiovascular healthcare: patient and professional perspectives on value

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CHAPTER I
GENERAL INTRODUCTION

The Setting

"Cardiovascular disease" includes diseases involving the blood vessels (major- and minor arteries) and the heart with its anatomical structures (myocardium, valves, coronary vessels)(1-4). Myocardial infarction, valvular disease and aneurysms of the aorta are the most frequent encountered pathologies today(5-11).

A plethora of risk factors contribute to the chance of becoming affected by these diseases in a human life-time. Although some are fixed, such as gender, age or genetic profile, others are modifiable such as diet or daily exercise. In particular, life-style related habits such as smoking or poor dietary intake combined with inactivity leading to obesity, are important modifiable risk factors of the 20th and 21st century among others(1, 12, 13). Despite these risk factors becoming increasingly present in modern society, past discoveries on pharmaceutical and technical levels advanced cardiovascular healthcare to new heights, drastically improving survival of patients.

The introduction of clinical electrocardiography by Willem Einthoven in 1901, the use of cardioprotective medication, cardiovascular surgery and percutaneous interventions have decreased mortality roughly from 50% in the 1950's, down to 2% in 2020 in myocardial infarction patients alone(14, 15).

The evaluation of novel treatments on clinical end-points has been studied in numerous retrospective-, prospective-, randomized- and meta-analytic studies over the years. Randomized- and meta-analytic study outcomes are perceived as the highest achievable level of scientific evidence in clinical care, and for that reason, used as the foundation of many clinical practice guidelines in daily cardiovascular care(16-18).

The *value* of clinical care- and outcomes, as observed by the professional, can be defined through (for example) low mortality rates, fewer adverse events such as post-procedural bleeding, or medication-related side effects. Although important for patients' survival and general health, this definition of *value* is rather one-dimensional in character, only seen from the professional's point of view. It is questionable if a sole focus on this one-dimensional view of value is enough to improve clinical care further. And more importantly; is the professional view equal to the *patients'* perspective on value and health?

Value of Health(care)

The definition of "health" by The World Health Organization (WHO) is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." Three aspects of health are interchangeably linked; physical-, mental and social aspects of health(19).

First, *physical* health reflects the ability of individuals to maintain physiological homeostasis during changing conditions ("allostasis"), for instance an increase in heart rate when ascending stairs. Illness develops when physiological mechanisms fail during harmful circumstances, such as an increased thrombotic risk due to smoking, resulting in myocardial infarction. Second, *mental* health comprises of how individuals coherently manage and adapt to changing circumstances to improve their subjective well-being. And third, *social* health projects both physical and mental health aspects of life in general; how does one manage life when there is interaction with other living objects and environments(19).

Healthcare interventions for patients, preventive or curative, have outcomes across all these aspects of health, establishing a personal level of 'health'.

Health(care) outcomes as stated by Porter, are equally multi-layered(20). The result of an intervention is not only 'dead or alive' (Tier 1) but also the occurrence of complications or return to daily life after clinical care (Tier 2) and the sustainability of health during life in general (Tier 3)(20).

Healthcare professionals (both physicians and non-physicians) define "value" of an outcome, by comparing patient's outcome to evidence-based studies (i.e. LDL-cholesterol levels lowered by 25% after one year of statin treatment). However, whether an outcome is positive or negative or deemed valuable, should be a combination of both the professional-, and patient's perceived sense of 'value' regarding treatment and outcome. Although extensive treatment options have increased patient survival, the true challenge for cardiovascular science of the 21st century lies not merely in improving clinical outcomes as seen by the professional but equally the patient perspective on value across all three tiers.

Value Based Healthcare

The focus on value in healthcare is embedded in the concept of 'Value Based Healthcare' (VBHC) as described by Porter and Teisberg, which has become a subject of growing interest in healthcare related research(20-24). In general, it attempts to transform care to become more 'patient-centered' and actively pursue the input of the patient in the development and design of healthcare.

VBHC attempts to prioritize the patients' perspective of healthcare by "the creation and operation of a health system that explicitly prioritizes health outcomes which matter to patients, relative to the cost of achieving this outcome"(25, 26).
Research in this domain questions foremost the relevance of certain evidence-based interventions and outcomes in regard to patient-specific health aspects and personal preferences.

This approach differs greatly from cost-effectiveness studies, which primarily focus on costs and benefits of healthcare outcomes on a societal-, and healthcare sector level. VBHC studies asses outcomes on a patient-clinician level and adopt the patient perspective regarding health into the healthcare experience and what matters during the care process(27).

The assessment of a patient's perception of 'health' is crucial in VBHC research, primarily done via qualitative methods such as observations, interviews and questionnaires. The three C method is an example of this, which proposes that healthcare related outcomes consist of three personal dimensions; capability, comfort and calm(28). First, *capability* describes the ability of a patient to be themselves and do the things that define them as individuals. Second, *comfort* is the level of relief from physical and emotional suffering that often accompany illnesses. This not only encompasses physical pain but equally emotional distress or anxiety. And lastly, *calm* includes all that enables the ability to live normally while getting care, such as the freedom of 'experienced chaos' while getting extensive treatment regimens(28). By addressing the impact of an outcome on such personal levels, can ultimately increase the efficacy of experienced healthcare by creating a better understanding of the patient's view on what is valuable during care(24).

It is difficult to obtain a comprehensive view on 'valuable outcome' for both the patient and professional in the clinical context of cardiovascular healthcare; a complex environment with multi-layered treatment options, extensive care tracks and outcomes across multiple tiers of personal health. Individual and subjective perspectives on the value of treatment and outcome are ever present among patient and professional, but it can be worthwhile to investigate these patterns systematically, to improve clinical care.

Value of Cardiovascular Healthcare

This thesis aims to systematically assess clinical cardiovascular care on a national and local-hospital level, to increase the understanding of patterns of 'value' from both the patient,- and professional perspective. Ultimately to provide suggestions to modify and improve daily clinical care further.

First, cardiovascular patients are assessed on a *national level* using claims data. This data enables insight into clinical care patterns, but more importantly helps unravel if that which is perceived as valuable by the professional (i.e. guideline evidence), is truly applied in daily practice. Second, cardiovascular care on a *local hospital level* is qualitatively assessed via Human Factors (HF) science.

As a novelty in clinical research and in line with VBHC, it helps to understand how the patient and professional experience healthcare within a certain context.

Claims Databases

After receiving in-hospital treatment, patients' financial claims are sent to healthcare insurance companies and subsequently collected in central databases. Extensively validated, this 'real-world' data is a unique and accessible source to analyze healthcare usage patterns in cardiovascular patients(29-32). It uncovers which real world, evidence based choices are made by professionals treating patients.

Part I of this thesis describes how this type of data was used to understand treatment of myocardial infarction patients on a national level, regarding two paramount therapeutic pillars; revascularization and secondary preventive medication use. The goal is to gain perspective of national treatment patterns of ST elevation myocardial infarction (STEMI) and non-ST elevation myocardial infarction (NSTEMI) patients in regard to common treatment guidelines. A key question is, if recommended evidence based treatments (=value) are equally found in real world patterns?

Chapter II describes a study using claims data which aimed to find modifiable factors in the treatment of Dutch NSTEMI patients in 2015 by assessing revascularization- and secondary preventive medication patterns in these patients.

Chapter III describes a study which aimed to find modifiable factors in STEMI-, and NSTEMI care regarding revascularization and secondary preventive medication use among patients of different socioeconomic classes by combining claims data with governmental data on income and education.

Human Factors Science

Human Factors (HF) science, at the intersection of psychology, biology and engineering, poses an interesting field to shape VBHC research in cardiovascular care. It assesses human performance on the physical and cognitive level in complex systems to promote safety and efficiency(33). HF science originally emerged during the second world war. As a theoretical discipline developed by the United States Navy, it provided a framework to assess crew performance and the effect of it on naval warfare and air-combat(34). Following this, HF science found its way into industries heavily relying on human performance such as aviation and off-shore industries.

As of the early 2000's, HF science has become an accepted discipline in healthcare, providing a systems approach to design healthcare, improve patient safety and quality of care(35). First described in the 'To Err is Human' manifest of 1999 by Kohn(36), HF research has evolved over the past 20 years into a theoretical and practical framework to understand healthcare work and the effect on outcomes(37-39). In healthcare, HF science is applied for two purposes: i) reducing the cognitive and physical load of professionals and ii) promoting safe, efficient and high quality care to patients(33, 39). To improve care, it focusses on the concept that patient care is more than just a single encounter or task, but a journey/experience across multiple care-givers and organizations(40, 41). The core method involves a human centered design approach or; assessment of humans (patient and professional) in healthcare through series of extensive observations and interviews, understanding daily work, stakeholders' roles and their key interactions with tools and environments (42). Eventually visually mapping this as a patient and/or professional experience(38, 43). Importantly, it highlights patient-professional interaction to the organizational level and vice versa.

As this provides direction to improve safety of clinical care, the World Health Organization (WHO) added elements of HF science to the foundation of the Patient Safety Curriculum(44). HF science provides an interesting addition to VBHC research to understand what is valuable for a patient in the healthcare experience. It structurally assesses the patient within the healthcare environment and the patient-professional interaction with attention to personal aspects of delivered care on outcomes. This enables an empathic understanding of how a patient perceives a certain care track when treated for specific disease(24).

In this thesis, it is discussed how HF science with a focus on the patient-professional experience/journey, can contribute to cardiovascular research by evaluating the patient and professional perspective of value in clinical care. Ultimatly to improve this further in a meaningful way. To illustrate this novel approach, several example studies are discussed in **Part II** of this thesis.

Chapter IV is an editorial which addresses the potential benefit of HF science in clinical cardiovascular research of myocardial infarction patients. **Chapter V** focusses on interprofessional collaboration during complex aortic surgeries.

A HF aviation questionnaire was used to assess teamwork and the perceived safety climate during these procedures among physicians and support personnel, ultimately to improve patient safety and care during surgery.

Chapters VI and VII give an overview of the utilization of a HF design approach to tackle a clinical problem; educating myocardial patients on the importance of statins. The development, design and implementation of a Mixed Reality (MR) statin education model is described with a focus on patient participation and statin education. **Chapter VIII** utilizes a similar HF design approach with patient participation to assess the acceptability and feasibility of a Virtual Reality (VR) pre-cardiac catheterization application for patients in the outpatient setting. Finally, **chapter IX** provides a summary of this thesis, as well as a discussion of the results and an appraisal of the future perspectives regarding Value Based Healthcare in cardiovascular research.

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