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The Role of Scenarios in Scripting (the Use of) Medical Technology

The Case of Data-driven Clinical Decision Support Systems

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Content

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Abstract

Newly developed medical technology, which is supposed to provide information or support decisions, is increasingly systemically opaque and is thus no longer comprehensible for the physician. It becomes more and more unclear to the clinical user and also to the developers themselves what data sources and what information are the fundaments of these technologies and how the technology is computing its reasoning on this data. In order to better comprehend the reasoning of these technologies for the actors engaged it is not only necessary to understand the inner processes of the technology but also to get more insights into the assumptions the technology is built on. This requires a better understanding of the imaginations and ideas about the ways of use which are inscribed into the technology in the course of its development. It is known that scenarios play a guiding role in this matter. Therefore, it is important to understand more about the role of scenarios (which are concrete ideas about future situations of use) in the development of medical technology and what conclusions can be drawn with regard to the development of systemically opaque technologies in medicine. To answer these questions, the author uses a case study of the development of such a medical technology, namely a so-called Clinical Decision Support System meant to support treatment decisions in cardiology. This system differs from previous versions in that it is data-driven and partly computes this data in a systemically opaque way, for example by using artificially intelligent algorithms or highly complex simulations. In combining and extending the theoretical concepts of situational scenarios in technology development as well as scripts written into technology it becomes clear throughout the work that – due to the different disciplinary backgrounds of the developers – the development of medical technology is often guided by partly disparate scenarios about who the target user is, how the technology should be used, what it should do, how it should look like and how all this is to be achieved best. Accordingly, the building of the prototype and the negotiation about the scenario's components co-evolve, leading to a more dominant scenario apparent in the technology and to specific scripts influencing the envisioned user to use the technology in particular ways. In the case studied it was particularly the engineer's perspective and less the cardiologist's one about the application context that was implemented, which ended in less recognition of the patient's role in the consultation as well as an assumed passivity on the part of the clinician as recipient of information delivered by the technology.

Zusammenfassung

Neu entwickelte Medizintechnik, die Informationen liefern oder Entscheidungen unterstützen sollen, ist zunehmend systemisch intransparent und damit für den Arzt nicht mehr nachvollziehbar. Welche Datenquellen und welche Informationen diesen Technologien zugrunde liegen und wie die Technologien ihre Schlussfolgerungen aus diesen Daten berechnen, wird für den klinischen Anwender und auch für die Entwickler selbst immer unklarer. Um die Funktionsweise dieser Technologien für die beteiligten Akteure besser nachvollziehbar zu machen, ist es nicht nur notwendig, die inneren Prozesse der Technologie zu verstehen, sondern auch mehr Einblicke in die Annahmen zu erhalten, auf denen diese Technologien aufgebaut sind. Dies erfordert ein besseres Verständnis der Vorstellungen und Ideen über die Nutzungsweisen, die der Technologie im Laufe ihrer Entwicklung eingeschrieben werden. Es ist bekannt, dass Szenarien dabei eine leitende Rolle spielen. Deshalb ist es wichtig, mehr darüber zu verstehen, welche Rolle Szenarien (das sind konkrete Vorstellungen über zukünftige Nutzungssituationen) bei der Entwicklung einer Medizintechnik spielen und welche Schlussfolgerungen im Hinblick auf die Entwicklung systemisch opaker Technologien in der Medizin gezogen werden können. Um diese Fragen zu beantworten, verwende ich eine Fallstudie über die Entwicklung einer solchen Medizintechnik, nämlich ein sogenanntes klinisches Entscheidungsunterstützungssystem, das Behandlungsentscheidungen in der Kardiologie unterstützen soll. Dieses System unterscheidet sich von früheren Versionen dadurch, dass es datengetrieben ist und diese Daten teilweise in einer systemisch opaken Weise verarbeitet, zum Beispiel durch den Einsatz künstlich intelligenter Algorithmen oder hochkomplexer Simulationen. Durch die Kombination und Erweiterung der theoretischen Konzepte von Situationsszenarien in der Technikentwicklung sowie von in die Technik eingeschriebenen Skripten wird im Laufe der Arbeit deutlich, dass - aufgrund des unterschiedlichen disziplinären Hintergrunds der einzelnen Entwickler - die Entwicklung der Medizintechnik oft von zum Teil disparaten Szenarien darüber geleitet wird, wer der Zielnutzer ist, wie die Technik eingesetzt werden soll, was sie leisten soll, wie sie aussehen soll und wie all dies am besten zu erreichen ist. Entsprechend entwickeln sich der Bau des Prototyps und die Verhandlungen über die Komponenten des Szenarios gemeinsam, was zu einem dominanteren Szenario führt, das sich in die Technik einprägt, und zu spezifischen Skripten, die den angedachten Benutzer beeinflussen, die Technik auf bestimmte Weise zu nutzen. Im untersuchten Fall wurde vor allem die Perspektive der Ingenieure und weniger die der Kardiologen in Bezug auf den Anwendungskontext umgesetzt, was dazu führte, dass die Rolle des Patienten in der Beratung weniger berücksichtigt wurde und eine Passivität des Klinikers als Empfänger der von der Technologie gelieferten Informationen angenommen wurde.

1.   Introduction

Recently, the German-based management consulting company *Roland Berger Holding GmbH* published a study[1] which concluded that within the next five years up to 20 percent of jobs in the medical sector could be replaced by programs and robots labelled as to some extent artificially intelligent respectively data-driven (Roland Berger 2019: 13). In addition, the field of personalised or individualised decision making and therapy is attributed a major role in near future medical decision-making. According to the study, individualised therapies will be used in about 30 percent of all medical cases by 2025, and so-called digital twins of patients will be used in as many as 40 percent of cases in order to improve medical insights and simulate therapy options before they are actually performed (Roland Berger 2019: 10). The future will show whether these estimates are realistic or rather optimistic. What can indeed be stated is that the promises of artificially intelligent methods, complex simulation as well as the conduction and usage of big amounts of data have also entered the field of medicine and healthcare. They are linked to hopes of for example improving medical decision-making, responding to current challenges (for example demographic change) and personalising medical care. Supporting this perspective but taking a more critical standpoint, in his book *Digital Health and Technological Promise – A Sociological Inquiry* from 2019 the Australian sociologist Alan Petersen investigates a shift towards a new way medicine will likely be delivered and enacted in the future, what he calls "algorithmic medicine" (2019: 44). According to him

> "[i]ncreasingly, policies and programs in healthcare are oriented towards a
> new future medicine, which may be called algorithmic medicine, drawing
> on big data analysis assisted through the use of AI, including machine learn-
> ing, along with data generated by citizens themselves, who increasingly are
> expected to connect with health and medicine via websites, apps and wear-
> able technologies. [It] … presupposes and demands specific selves, social re-
> lations and forms of citizenship, and distinct ways of thinking about and en-
> acting medicine, risk management and care … [as well as] that people will

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[1] The study was conducted in two waves. On the one hand, 400 experts in the healthcare sector were surveyed in a standardised way on questions concerning the digitalisation of the healthcare sector. Secondly, these results were validated by individual interviews with "leading representatives" of the healthcare sector. The selection mainly represents Europe (80%), the rest refers to other countries not specified further (Roland Berger 2019: 7).

> play an active role in collecting, interpreting and acting on data about them-
> selves as well as participating in big data projects." (2019: 44-45)

Petersen looks at the level of policy making and (inter)national project funding. He postulates a change in every aspect of medical care and treatment, aroused by the active push towards the establishment of data-driven medicine into medical contexts. He chooses the macro level as a perspective to critically examine and sociologically reflect far-reaching, society-wide changes.

Keeping this in mind, the author wants to focus on a smaller field, the area of the development and envisioned application of data-driven medical technologies. In particular, in this work a class of medical technology, the so-called Clinical Decision Support Systems serves as an example. They have a long history. While the aim of early examples (mostly in the 1970s and 80s) was to "build a computer program that could simulate human thinking" (Berner/La Lande 2016: 3) and therefore replacing the job of the clinician to figure out the right diagnosis or treatment, recent-developed versions of these systems are connected with a different approach. On the one side they are claimed not to simulate the clinician's brain but to support his or her decision-making and enhance their medical knowledge. This enhancement, on the other side, is not solely based on established medical knowledge but often uses a big amount of heterogeneous data sources, both conventional and non-conventional in medical contexts. This new generation of Clinical Decision Support Systems are called "data-driven" in the context if this work. As such they are to some extent systemically opaque.

In connecting the empirical interest about the way data-driven medical technologies, especially the new generation of CDSSs described, are developed with the aspiration to connect two sociological concepts with each other: the concept of the script firstly established by French sociologist Madeleine Akrich back in 1992 and the concept of situational respectively prototype scenarios recently developed by German sociologists Ingo Schulz-Schaeffer and Martin Meister the aim is to demonstrate how imaginations and envisions of the interrelations between the future medical technology and its assumed application context that underlies scenarios are guiding the developers in building and therefore scripting the medical technology under development. Given the usually multidisciplinary nature of such development teams (Lehoux et al. 2011), which means they bring in different backgrounds and knowledge and therefore see things differently what Lehoux et al. call "lenses". A focus also lies on the negotiation of different scenarios among the team members. Therefore, a case study is used in

which the development of such a data-driven Clinical Decision Support System was the proposed. Relying on interviews with some of the developers and on project publications the author shows underlying assumptions about the envisioned use context, about the data-driven approach used in the project and how these are combined to a dominant scenario which, again, mainly serves as a guidance for the developers inscribing interrelations of the technology, users and use contexts.

Therefore, in the following section (2.) the epistemological interest of the author is further introduced. Thereafter (3.), the perspective from which the subject is approached is brought in: The importance of scenarios in the development process of technology (and medical technology in particular) for this very process of development and, through this, for the potential implementation in practice. Herein, also a connection is made with the STS-research on scripts. Scenarios, regardless of whether they are prototypically realised or exist in another, more implicit, form, always contain field- or discipline-specific scripts, mostly assumptions about the field of application of the technology. These, which then become part of the scenario, are further integrated into the technical artefact by inscription. This is followed (4.) by the subject of study: What exactly are Clinical Decision Support Systems and what is special about the data-driven versions currently under development? Finally, the focus lies on the case study (5.) and the application of what has been worked out in the sections before (6.). Which scenarios played a role in the project, which scripts were used or rather not used? This is followed by a conclusion (7.).

2.   The Epistemological Interest

To start by returning to Petersen, he summarises the changes cited in the introduction under the term "digital health". He asserts that "regardless of whether digital health evolves in ways imagined, related policies and programs are profoundly refashioning conceptions of self, society and citizenship, and impacting on related notions of truth, privacy, trust, rights and responsibilities" (Petersen 2019: 4). In this regard, although Petersen talks about general conceptions in the broader public, the basic assumption he concludes for the level of policy-making and the concept of digital health itself might also be, in a slightly different way, applicable for the development process of new medical technology. That is, imaginations, for example about future medical healthcare supply and also about arrangements of medical work after the application of new technology, are playing an important role in understanding not only changes

in a sociocultural or -political way but also on a smaller level of the development of a new medical technology. On this level one might not use the terms imagination or, what is related: vision. Rather it might be more promising and therefore necessary to look at already more concrete perceptions which can be called scenarios (Schulz-Schaeffer/Meister: 2015). In difference to the former terms, scenarios, especially when they are situational, are more elaborated ideas about specific constellations (Schulz-Schaeffer/Meister: 2015). For example, a possible situation in which the so far developed or supposed to be finalised medical technology could be applied.

Hence, my certain interest lies in how sociotechnical processes of medical decision-making and therapy-planning in the treatment of diseases, that are already established and to some extent routinised, are becoming subject of change during the process of developing a so-called Clinical Decision Support System, which is meant to be an active part in those medical decision processes. To be more specific, empirically of particular importance are the development processes of supposed to be established Clinical Decision Support Systems (CDSS) that are at least partly not based on common medical expert knowledge. Expert knowledge is thereby knowledge that is evidence-based and/or derives from medical experts and mainly is the basis for and thus is represented by clinical guidelines. Instead, to some extent these systems are using other reasoning techniques, for example based on self-learning algorithms or elaborated modelling and simulation, thereby using additional data sources which are not used conventionally. They are supposed to help the clinical practitioner in making the most appropriate medical decision, by supporting the clinical practitioner with more or less artificially processed information. This information derives from a data corpus that usually contains a broad variety of data sources. How and to what extent do processes of artificial intelligence or simulation included vary? They can be an active part of analysing the inputted patient data or be used for example to evaluate what kind of information is likely to be beneficial for decision-making in general. Either way, how the information is processed remains systemically opaque. The developers of such systems usually emphasise the potentiality of saving costs and enhancing the delivery of best-informed medical decisions and therefore improving the quality and efficiency of medical treatment as such. But besides those, more abstract statements about probable improvements that might go along with the application of the proposed CDSS under development, developers are presumably also following ideas about how the imagined technology or prototypically existent parts of it would be a part of specific social situations. As

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mentioned before, these ideas are becoming manifest in scenarios. At the same time, they are subject to change throughout the development process. Thus, they likely influence for what kind of imagined purposes the CDSS is built. Therewith, of interest is the question in which ways a built CDSS would or could be part of medical real-world situations and which role the development process of the CDSS plays in this regard.

Hence, the reason behind picking newly developed Clinical Decision Support Systems that are supposed to help clinicians in their medical decision-making and planning of a therapy as the empirical focus has two reasons. On the one hand, the Clinical Decision Support Systems which are the subject of this thesis should be seen as a part of the outlined future medicine stated by Petersen, that is to say they are (also) developed within the scope of the broader vision of digital health. On the other hand, the development of CDSSs is usually associated with specific fields of medical application, which makes this broad vision more concrete and therefore CDSSs particularly suitable as a research object for my research interests. This both concerns envisioned changes in the decision-making processes of medical professionals, as well as the chosen focus on scenarios in the development process of these systems. So far, no attention has been paid to particular questions of a scenario's role within medical technology development, both by traditional sociology and by Science and Technology Studies (STS). This study is a first step to fill that gap by asking how developers of a Clinical Decision Support System (CDSS) are guided by scenarios in scripting the use of the medical technology.

3. The Perspective: The Role of Scripts and Scenarios in Technology Development

To put the development process as the focus of my work, an important reference are the works of Ingo Schulz-Schaffer and Martin Meister who wrote about the guiding role of what they call situational scenarios (in their narrative, implicit/tacit or prototypical form) for technology development in the field of ubiquitous computing (Schulz-Schaeffer/Meister 2013; 2015; 2017; 2019). As a consequence, their subject of study is technology development carried out by engineers. According to the authors, especially the physical realisations of scenarios, as prototypes in laboratory settings, are of certain importance for constructing sociotechnical constellations, including new sociotechnical arrangements of work. Of special interest for the purposes of this study is that the authors also put a focus on the role of the imagined user (Schulz-Schaeffer/Meister 2019) who is supposed to work together with the new technology in specific

work settings. In their recent publication, Schulz-Schaeffer and Meister differentiate between four ways of how envisaged future users are represented in the development process, particularly in prototypical scenarios: by representatives of the imagined future users, by independent expert knowledge mainly derived from literature, by the developers themselves and/or by everyday notions and common-sense assumptions (Schulz-Schaeffer/Meister 2019: 49-51).

In this regard, the field of medical technology research and development (and even more the subfield of CDSSs) is particular in nature: It is not uncommon that the research or development team is multidisciplinary, for example that medical engineers are working together with clinicians; the team is also confronted with a wide range of national and international directives and regulations that have to be applied with, and it becomes problematic when there is a lack in the regulations, which is currently the case here; and, as previous research suggests, the area of medicine and healthcare is highly professionalised and characterised by sophisticated expert knowledge and well-established practices and routines which have to be taken into account during development. For the field of CDSS development, it should also be noted that in most cases concrete fields of application are established from the outset, that means the intended support of decision-making processes in a specific area of medicine, for example cardiology. It is therefore interesting whether and in which ways the findings of Schulz-Schaeffer and Meister can be helpful in the area of the development of medical technology and CDSS in particular.

Hence, the theoretical concept that is underpinning this work is mainly going hand in hand with the epistemological interest described above. In addition to the works of Schulz-Schaeffer and Meister a second focus lies on the concept of the "script", which I intend to combine with the concept of situational scenarios. Thereby, the conception of inscription firstly developed by Madeleine Akrich (1992) and the approach of user configuration drawn up by Steve Woolgar (1990) serve as the main references here, as well as works done by Nelly Oudshoorn and Trevor Pinch (2003) as well as to the concept of the new production of users by Sampsa Hyysalo et al. (2016), who particularly wrote about user representation in technology development.

3.1. Users and Use Contexts in Technology Development – The Concept of the Script

With the SCOT model of social construction of technology (Pinch/Bijker 1984) we have learned, at the latest, that although technology development is a more or less open process, the technology developed nevertheless has an obviously restrictive character (and indeed is in another way also action-enabling). What can be done with a certain (medical) technology is relatively fixed by technical inscriptions. These inscriptions are determined primarily in the course of the development process, as suggested by earlier works (for example see Akrich 1992). Madeleine Akrich was the first to write about inscriptions, which according to her are ideas of the designers about a context of application including what is done with the device, into what she calls the script, meaning inscriptions of these ideas into a material thing. Of central importance for her argument is that, in doing so, designers of technology also envision the users together with imagined situations of use. In her own words, what the designers do becomes quite far-reaching:

> "Designers thus define actors with specific tastes, competences, motives, aspirations, political prejudices, and the rest, and they assume that morality, technology, science, and economy will evolve in particular ways. A large part of the work of innovators is that of 'inscribing' this vision of (or prediction about) the world in the technical content of the new object […] Thus like a film script, technical objects define a framework of action together with the actors and the space in which they are supposed to act." (Akrich 1992: 208)

It can be derived from this statement, that the process of inscription of the designer's imaginations of users and use contexts into the developed technical artefact is not a rather vague understanding about probable application arrangements. Rather, it can become strikingly detailed and wide-ranging. This can be claimed, like Akrich does, for technology development in general. Thus, it indeed counts for the development of medical devices as well.

But it would be rather simple and only half the way if it stopped here. Instead of being too deterministic and overestimating the power of inscription, Akrich (1992: 208-209) conceptualises the development process as a continuous back and forth "between the designer and the user, between the designer's projected user and the real user, between *the world inscribed in the object* and *the world described by its displacement*." Whereas the developers of a certain technology inscribe their imaginations into the object it is in turn the user who is describing the script of the object in its actual use environment. When developing a Clinical Decision Support

System, for example, the developers may have in mind a well-trained and generally innovation-friendly physician in a particular medical field who knows how to interpret the data presented. They therefore develop it relatively presuppositional. The actual user, on the other hand, might not be as well-versed as imagined. Limited in their possibilities to use the system, however, they sometimes develop evasive strategies and deviating actions, so-called descriptions. That means, and its going in line with other approaches emphasising the importance of the practices and handlings in real situations outside the laboratory, the object's script is nothing pre-fixed. On the contrary, Akrich (1992: 207) underlines that the scripts are nevertheless "open to question and may be resisted." Together with Bruno Latour (Akrich/Latour 1992: 261) she developed the concepts of 'de-inscription' and 'antiprogram' to meet the approach of technology development as a co-constructive process. Whereas the former explicates the user's reactions towards the developer's inscriptions, for example that they underwrite, reject or re-negotiate those; and the latter captures "the users' program of action that is in conflict with the designers' program" (Oudshoorn/Pinch 2003: 11) meaning that the proper use of the system is failing.

Steven Woolgar follows a similar but slightly different approach. In contrast to Akrich and Latour he is not putting the same focus on the real user in the process of technology development. At the same time, however, he cannot be accused of exaggerating the power of the developers. Instead, he speaks in terms of the 'configuration' of the user. In so doing, he is partly following the same line stating that, by constructing the technology, the developers are also constructing the potential users and their possible actions. Expressed with the words of Woolgar (1991: 61): "Consequently, it is better to say that by setting parameters for the user's actions, the evolving machine effectively attempts to *configure* the user." To put it into the terms of Akrich, the prescriptions are not only written into the technology, the technology reveals the script or its purpose to the user, it is setting delimitations. The user is therewith always able to flexibly interpret the script, but the developers bound or delimit this flexibility. Hence, also in the understanding of Woolgar it is more accurate to consider the developers as setting a frame that contains possibilities and restrictions about, for example, potential ways of application, interaction, intervention or collaboration between the developed technology and envisioned users. Woolgar exemplifies his approach with a case study in which he took part in the development process of microcomputers in a company where multiple professions and department members were participating in the construction of the technology. This is a peculiarity that

Woolgar also encounters in his analyses. The multidisciplinary and multiperspectively collaboration within the company concerns in particular the forms of technology development and thus also the ways in which users and contexts of use are represented in (or inscribed into) the technology. In other words, what the script looks like. How the technology was built in the company is described by Woolgar as follows, using the metaphor of writing and reading a text[2]:

> "Certain characters become central to the story and others peripheral; groups of actants join forces while others disperse; the activities and achievements of some are highlighted, while others are relegated to the background, silenced and unnoticed. The reader […] of the text is invited to join with certain groups and disassociate herself from others." (Woolgar 1991: 69)

At another paragraph he adds:

> "These different groups and individuals at different times offered varying accounts of 'what the user is like'. Knowledge and expertise about the user was distributed within the company in a loosely structured manner, with certain groups claiming more expertise than others in knowing what users are like." (Woolgar 1991: 69)

What we can capture from these two remarks is that the prescriptions about the expected characteristics or attributes of the user, the way the technology shall 'correctly' be used and how the context of use is supposed to be are subject of complex negotiations and discussions between various contributors throughout the course of development. Who or which group is more or less engaged in this matter varies during a project, as well as does the kind of engagement. Who has the interpretative authority or power associated with knowledge and expertise about users (which is claimed by different actors to be better or worse) is thus not stable beforehand, but a negotiation process over time and among different actors. These remarks (as well as Akrich's) have been very important for the establishment of critical approaches regarding the way technology is constructed, first and foremost the role of users in the process of technology development. Anyway, Woolgar is underestimating the extent up to which users

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[2] Throughout the article, Woolgar uses the metaphor 'machine as text': "My strategy […] is the exploration of a metaphor: the machine as text. The idea is to begin with the supposition that the nature and capacity of the machine is, at least in principle, interpretively flexible. This then sets the frame for an examination of the processes of construction (writing) and use (reading) of the machine; the relation between readers and writers is understood as mediated by the machine and by interpretations of what the machine is, what it's for, what it can do." (Woolgar 1991: 60).

can play an active role in these processes. Akrich and Latour gave an early answer to this omission in emphasising that scripts or inscriptions are of a non-deterministic character (although Woolgar never claimed that). Later on, this was elaborated further by others. For example, by a group of Berlin-based social scientists (Gläser et al. 2017) who call themselves, in citing Akrich's script concept, "The Berlin Script Collective"[3]. As well as by Sampsa Hyysalo and colleagues (Hyysalo et al. 2016) who take the notion of the co-construction of technology and users and state that we now face a significant change in how the users a co-produced in technology development:

To start with the latter work, a specific focus on the role of users in the technology development process is provided by Hyysalo et al. (2016). The authors' thesis is that their role is undergoing a significant change in the course of the early 21st century. This is characterised on the one hand by the fact "[that u]sers will develop new forms of innovative collectives that enable their engagement with products and technologies" (Hyysalo et al. 2016: 2) and on the other hand - and this is of particular interest here - by "creative managers, designers and producers who will develop new strategies for involving and analyzing users." (Hyysalo et al. 2016: 2). According to the authors, they use a multitude of methods and resources, on the one hand to analyse the user in a variety of forms and, on the other hand, to involve the user in new ways (Hyysalo et al. 2016: 3-4). In their concept of user representation, Sampsa Hyysalo and Mikael Johnson (2016: 76) take a closer look at the role of these user analyses for the development process. From their specific composition the user(s) are conceptualised and represented as "envisioned users", as future users represented in the present of product development. This process of conceptualisation and representation of the later users of a technology is mainly done in an explicit way, but happens in many ways unconsciously, too. Besides more strategic, explicit ways, for example the active inclusion of (future) users, consumer studies and needs analyses or the consideration of cultural habits and characteristics, ideas from

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[3] The Berlin Script Collective follows the aim to theoretically capture technologically mediated influences on human practices. This in order to put influence that is technologically mediated on an equal level with other social influences (through interaction or social structures) within social theory. They do this by rendering the agency of different technologies and their function as a medium of influence on human behaviour comparable. For this they use the script concept from Akrich and, thereby, they come to insights that are also relevant for this work.

implicit and thus rather less reflected sources usually flow into the imagination about users as well. For example, the developers incorporate their own everyday experiences and assumptions or preferences from past projects or they are using already established technical concepts. In the same way, aspects of regulatory requirements such as security standards can also have an impact on the assumptions and ideas about future users (Hyysalo/Johnson 2016: 83). The specific interaction between all these sources is essentially responsible for the way the user and possible use cases are represented in the design and development process of a technology or technical device and, thus, how the technology looks like and how it operates.

A particular focus on the concept of the script is provided by Jochen Gläser and colleagues, who gave themselves the acronym 'The Berlin Script Collective'. They concretise why technological scripts are (usually) not coercive but merely influential (Gläser et al. 2017: 14). Besides Dewey-informed notions of pragmatic means-at-hand that challenge the developers envisaged instrumental means in shaping users' ends and users' subversive power in adopting and challenging 'the' script, in referring to Paula Jarzabkowski and Trevor Pinch (2013) they stress the too simplistic view of the idea that there is just one single script inscribed by the constructors of a technology. Rather, a "technology usually contains multiple scripts, which address different interactions with devices and may be more or less overt" (Gläser et al. 2017: 14). Above all, the last notion on the restrained execution of technological scripts is particularly crucial. This is, because it addresses a two-sided key point in technology development, which becomes especially visible in multidisciplinary development projects. As stated in reference to Woolgar – can also be seen in the chapter about situational scenarios in medicotechnological development – users and use contexts might likely change throughout the course of the construction of a technology. Different professions have disparate images and ideas in mind about who the target user is, how the technology should be used, what it should do, how it should look like and how all this is to be achieved best. As a consequence, it is very implausible that a technology contains and executes just one script. Instead - to use the technology example in this thesis once again - a technology like a Clinical Decision Support System should be seen as a hybrid structure of material and immaterial components containing different scripts. Both, scripts with respect to different contexts of use, and different anticipated users. With regard to my case study, these would classically be, for example, the attending physician or the medical assistant and also medical technicians.

While following the aim to provide a framework for comparatively studying technologically mediated influence Jochen Gläser et al. establish seven dimensions that need consideration in an analysis of this kind of influence. Their main argument is that

> "it is the way in which influence is materially inscribed that produces a specific accessibility to users, specificity of purpose, distribution of control, kind and strength of influence used, homogeneity of distribution of control, visibility of the script and embeddedness in situations." (Gläser et al. 2017: 29-30, italic letters in the original)

The first four (or five) of the seven dimensions are particularly suitable for a closer look at technology development itself. These focus on (1) which behaviours the imagined users might typically enact, (2) in what direction this behaviour should be influenced, (3) in which manner and with what level of enforcement this should take place, and (4 (5)) how the distribution of control between the user and the technology should be designed – also in the course of use. In addition, there may well be perceptions about (6) how visible the inscriptions should be, and perhaps even (7) the embeddedness in social situations is taken into account. So, if one looks only at the development process and here especially at the conceptions of the developers themselves, the interest would lie in how these two dimensions appear in this process of development.

Transferred to the field of medical technology development, it is important to ask the question about what role this "frame-working" of future users and use cases plays here. This is because, it is very likely going along with real consequences for how actual (medical) work (with the supposed technology) will or might be performed in the future, outside the laboratories. In order to understand what imaginations about future applications, including the users as such as well as the work situations, are envisioned and are used to develop (partly) artificially intelligent and simulation-based CDSSs and how exactly this is done, it is promising to take a closer look at the development processes of medical technology and devices, which might not be so surprising at this stage of my argumentation.

For this purpose, a main focus lies on an approach of the technical sociologists Schulz-Schaeffer and Meister, who have exemplified in the engineering field of ubiquitous computing how so-called scenarios influence the progress of the development process of a technology. A connection between the research on scripts and the leading role of scenarios in technology development does not yet exist. This is somewhat surprising since the term "scenario" and the concept of development guidance behind it are capable of capturing the actions, practices, and

processes behind the assumptions that are written into the scripts of a technology much more precise and comprehensive than terms such as imagination or envision. This is, because it is in these scenarios where the images, perceptions and concepts about the interrelations between the technology, assumed users and use contexts come into being as subjects under negotiation. By definition, scenarios are very concrete formulations about the way the technology under construction will operate. Often, they are situational, which means concrete users and use contexts are envisioned as well. It therefore can be attributed to them that they play a substantial role in guiding technology development regarding the scripts inscribed into the constructed technology. A scenario is in this sense anything but a synonym for a script, as Akrich implied in her influential article in 1992. Instead, in development processes where scenarios play a significant role (Schulz-Schaeffer and Meister show this for engineering, it is also apparent in medical technology development) it is them giving the developers guidance in deciding towards which direction to construct the technology or to script the technologies performance and appearance in connection with particular social situations of use. In these cases, scenarios are the basis for scripts. This does not mean that one script is connected to exactly one scenario apparent during development, or that a script could be deduced directly from a scenario, one-to-one. This is particularly the case for scenarios not explicated but guiding the developers implicitly or tacitly in technology building. But the same applies to scenarios as to imaginations: They appear in the technology and its application in the form of scripts, which, as Gläser et al. (2017: 14) note, are often even overtly visible. Consequently, it is about replacing relatively loose imaginations with more concrete scenarios. These scenarios play a central role in the empirical part. Finally, a perspective is given to combine them with the script concept. Not just theoretically reflective, but based on an empirical case. But for now, let us continue setting the theoretical foundations.

3.2. The Guiding Role of Scenarios in Technology Development

As we have seen, the process of technological development is very much intertwined with the real application, its environment and its users. Often, this interrelation of the laboratory site and the real environment "out there" manifests itself in envisions and imaginations about situations or contexts where the technology in development is or could be part of. These envisions can take many different forms. They might be of a merely abstract and broad kind, only giving a rough idea about the ways the target technology is supposed to be part of social

situations. Therefore, they are mainly referring to already established future concepts and related associations. Schulz-Schaeffer and Meister label them as visions (Schulz-Schaeffer/Meister 2013). Let us take a closer look into them:

Visions: Visions are everything else but uncommon. One can find them in all those places where the future is being thought about or decisions about future developments are made, be they more social or more technological in nature. However, they play a particularly important role where the imagined changes are of a radical type, whether they are of a society-wide scope or for sub-areas of social life. According to Schulz-Schaeffer and Meister (2013: 3) "[e]specially the fields of technology, which currently are (or in the near past have been) considered as key future technologies, are highly affected by visions." They do not use this term to refer to concrete technical objects. Rather, they point to broader or general terms for technological concepts or so-called core technologies. These core technologies can manifest themselves in a wide variety of technical objects. To give an example: the core technology "artificial intelligence" is associated with innumerable ideas about how societies or societal sub-areas like the medical sector will or would probably look like if the *principle(s)* of artificial intelligence would become common reality. But here, artificial intelligence itself is not an object under concrete development. Of course, one can think of a project where the main goal is the creation of a new self-learning algorithm in order to solve a certain problem or open up new possibilities. Then, indeed, this supposedly intelligent algorithm is a real object or is meant to be real in the future. Nevertheless, artificial intelligence as such is much more abstract and subsumes numerous approaches and technical solutions under one term laden with images and vague ideas about its societal impact. For this reason, the authors attribute three main effects to visions in innovation processes (Schulz-Schaeffer/Meister 2013: 4-7): firstly, mobilising and coordinating related actors, interests and resources; secondly, guiding activities in research and development in a broader sense; as well as, thirdly, functioning as means for prospective technology assessment.

But envisions can also be more detailed. That means they can contain relatively concrete ideas of application or about the characteristics of a target user. Schulz-Schaeffer and Meister (2015) call these more concrete forms scenarios, or rather said: situational scenarios. In contrast to the previously mentioned forms, which they refer to as visions, situational scenarios are characterised by "specifying for imagined typical situations of use of the new technology how the components of these situations - the features of the technology, the users with their interests,

preferences and capabilities, other persons, objects or structures of relevance for the situation - would (or might) interact." (Schulz-Schaeffer/Meister 2015: 166). Thus, situational scenarios are not just about the technology. Rather, they are about the nature of the context as such, although the technology plays an important and prominent role within these scenarios. Let us therefore also look closer into them:

(Situational) Scenarios: Thus, it can be stated that "though visions undoubtedly affect public and private decisions to engage in technology development, they do not provide pictures of the future detailed enough to guide specific research and development activities." (Schulz-Schaeffer/Meister 2013: 7). In order to be able to have an effect on research and development processes, concepts of the future have to be very specific in nature. This is what scenarios do. They tell something about what parts the future technology would be made of, what those parts or components would be able to do, how they would perform and how they are connected to each other. They serve as a tool for future research in specifying and describing a possible future. In technology development the future technology and its forms of use. By referring to Steinmüller (2003: 3), they state that "scenarios act out fictional realities by elaborating coherent chains of cause and effect, which include aims and consequences of human action and constraints exposed by circumstances" (Schulz-Schaeffer/Meister 2013: 8). Furthermore, if a scenario would be situational in nature, which means it says something about ideas of future states of affairs, it usually also includes more information about the envisioned context of its application (Schulz-Schaeffer/Meister 2015: 166). Not only the components of the technology play a role here but also possible users and further elements of the imagined situation that might be of relevance to the developers. As scenarios are results of imaginations and ideas of the researchers, they are of a rather fictional kind. Therefore, they do not represent the current reality. But neither do they represent just the envisioned near or far future. Instead, they can be seen as hybrids of the present and future – or as containing present and future components. That is because (not only) in engineering research and development "images of the future rely on explicit or implicit assumptions about similarities between the imagined future situations and corresponding present situations." (Schulz-Schaeffer/Meister 2019: 41) Schulz-Schaeffer and Meister argue that this is the case, because especially in engineering projects the scope of an envisioned future technology under development is normally not more than a few years. In building up a scenario, to a certain degree engineers rely on conditions that are currently the reality. This could be components of the social context their supposed

technology would be part of or components of the technology which will be set in and shape not yet real social situations. Therefore, they finalise that "situational scenarios that are employed in technology development represent always a combination of components from current situations and of components that will come into existence only as part of the imagined future." (Schulz-Schaeffer/Meister 2019: 40)

More than visions scenarios can take many forms. As narratives they describe a sometimes more, sometimes less detailed context of use of the technology to be developed. These are usually found in published papers or deliverables of the researchers. In its narrative form, the scenario is apparent directly and provides an explicit picture of imagined applications. In the form of implications, they are much more difficult to capture. They are usually revealed indirectly through verbalisations or technical realisations, but mostly remain on a mental level. Beyond this, these implications could also be not reflected at all. That means they are tacitly applied and taken as given. Finally, situational scenarios can take the form of prototypes. Schulz-Schaeffer and Meister (2015: 169) write that a physical or virtual prototype, together with a testbed, "embodies a particular idea about how the technology […] and the users, and other relevant components and circumstances […] should interact in typical future situations of use." Prototypes thus also embody a scenario. They serve as a physical implementation or scripting of the scenario(s) and are therefore more explicit than the narrative form.

We have seen that situational scenarios are extremely various in nature and always mediated through carriers. They can be quite obvious, printed in papers, they can hide inside the brains of the involved developers, hide from extern parties as well as from the cautious reflection of the researchers themselves or they can be built into materiality or virtual models and become simulated reality the way envisioned. But regardless whether the scenario is of a narrative, implicit or prototypically realised form, according to Schulz-Schaeffer and Meister (2015: 170) most scenarios that are represented in these ways are of a certain type: They are called *generic scenarios*. With generic scenarios they refer to those kinds of scenarios which represent a to some extent unspecified context of application. Or the scenario transports a certain generality whose intended purpose is merely to demonstrate the usefulness of the functionalities of the technology under development. This by conceiving a social situation (or several), a context of apply. Here, the imagined social context is not particular. Rather, it is more universal in respect of those segments of the situation which would be influenced directly by the technology. However, if there are generic scenarios, of course another category must be distinguished from

them: specific scenarios. While Schulz-Schaeffer and Meister are more interested in the generic type of scenarios they just spend one paragraph on the specific counterpart and characterise it as mainly going along with a newly developed technology that is developed for a particular use-case. For this reason, they do not consider this type of scenario to be equally relevant in regards of their role in guiding the research and development activities. They write:

> "Specific scenarios are about how new technology might be of use within one particular setting. Thus, they are interested only in the components, relations, and circumstances which define this particular setting and address only the interactions that should or might occur between the new technology and these factors. The representations of specific scenarios are self-sufficient. They address what their authors are actually interested in: a particular new technology for a particular application situation." (Schulz-Schaeffer/Meister 2015: 170)

Apparently, in specific scenarios the application context is already known and a technology is developed in order to influence this context in a certain manner. Thus, possible retroactive effects by the scenarios on the continuation of the project might be less strong. Yet, very often specific scenarios can also point to underlying generic scenarios. For this reason, they may become important. That means, because or although the developers do not have a specific application context in mind, they construct relatively specific scenarios in order to exemplify the functions of the technology in a social setting. These may then influence research. For example, when components that are actually only required for a specific scenario remain part of the development which was less specific in the first place. This then might lead to a narrowing or specifying of the development under the scenario. Hence, the following should be noted:

> "[A]ssumptions about the imagined situation of use imply technological requirements, and vice versa, assumptions about technical features affect the question for which contexts of use the new technology might be useful […] this characteristic of technological situational scenarios is the crucial reason why they become a source of cognitive guidance for engineers." (Schulz-Schaeffer/Meister 2015: 172)

To come back to the earlier mentioned hybrid character of scenarios, their nature as being a composition of present and future, this guidance in cognition takes the form of a certain process of negotiation between the components which represent the present and those which represent the future. This applies most to situational scenarios in their prototypically realised

form as well as the connected social setting or testbed.[4] That is because they are physical reality, though just in a laboratorian sense. As such they are objects of actual manipulation and testing. Here, the intertwining and cooperation of the scenario's present and future components can be specified, evaluated and demonstrated – and therefore become subject of negotiation (Schulz-Schaeffer/Meister 2017: 207-212). In applying the concept of "arena" as spaces of negotiation developed by Anselm Strauss (1993: 226-227) Schulz-Schaeffer and Meister (2017, 2019) call these processes of negotiating between actual and fictional reality components of scenarios "negotiation arenas". They are these in two ways: Firstly, they "root the imagined elements of a future application in a working present realisation of this application, and thus in present technological possibilities and use practices." (Schulz-Schaeffer/Meister 2017: 213) Secondly, they act as a rearrangement of these elements from the present and the imagined future. As such they are always the subject matter of debates and consensus building in order to, for example, specify the technology and/or its application and guide the engineers through the development process.

But as sociologists we should ask the question of who is taking action in this process, who is negotiating? According to the authors (Schulz-Schaeffer/Meister 2019: 63), generally speaking it takes the form of "a negotiation of different perspectives related to the different social worlds[5], which are present in the negotiation arena." In the development process these social worlds (mainly the scientific disciplines of the developers and the application contexts) are represented by so-called spokespersons (Schulz-Schaeffer/Meister 2019: 47). They differentiate between four types: imagined future users, independent expert knowledge, the developers themselves and everyday notions or common-sense assumptions (Schulz-Schaeffer/Meister 2019: 49-52). The spokespersons can hold different negotiation positions, mainly as proponents of present or future components and are endowed with varying degrees of negotiation power

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[4] But nevertheless, they can also be seen in their narrative or even their implicit form.

[5] With the term social worlds Schulz-Schaeffer and Meister refer to a concept developed mainly by Adele Clarke and expanded to a whole framework by her together with Susan Leigh Star. It "assumes multiple collective actors – social worlds – in all kinds of negotiations and conflicts, committed to usually ongoing participation in broad substantive arenas. The framework is relentlessly ecological, seeking to understand the nature of relations and action across the arrays of people and things in the arena, representations (narrative, visual, historical, rhetorical), processes of work (including cooperation without consensus, career paths, and routines/anomalies), and many sorts of interwoven discourses." (Clarke/Star 2008: 113)

in order to influence which components will be part of and how "to interrelate the components that make up the scenario." (Schulz-Schaeffer/Meister 2019: 62) For the purposes of this work it is more appropriate not to use the term social world but to specify it to scientific disciplines and connected logics, practices and professional cultures, because those are the "social worlds" that matter here. With this in mind, three subject-specific additions are discussed below: the direct representation of multiple scientific disciplines, the specificity of medical regulations and guidelines and last but not least the specific schemes of medical work arrangements.

3.3. Scenarios in Context of Data-driven Clinical Decision Support – Three Additions

The field of medical technology research and development (and especially the CDSS sub-sector) is of a special nature: firstly, it is not uncommon for the research or development team to be multidisciplinary. For example, medical engineers often work together with clinicians, but also with nurses, mathematicians, computer scientists et cetera. Secondly, the development team is also confronted with a national and international regulatory environment that must be taken into account respectively reflected upon. The special situation here is that there is a lack of regulations in this field of medical development. And, as previous studies have shown, the medical and healthcare sector is highly professionalised and characterised by sophisticated expert knowledge and well-established practices and routines, which has consequences regarding the imagined schemes and conceptions about the probable applications of the developed technology. What is more, for the area of CDSS development it should also be noted that in most cases (like the one discussed here), specific medical applications are determined very early or right at the beginning of the development process, which also affects the schemes about the medical work arrangements, or rather presumably concretises them in their manifestations as scenarios. Therefore, the third addition is the concreteness or specificity of the schemes of medical work arrangements in the technology development process. Let us take a closer look on these particularities in the following.

3.3.1. Direct Representation of Multiple Scientific Disciplines

Not much research has been conducted about the particularity of medical technology development processes. The circumstance of the involvement of many participants from variant

fields and disciplines is, indeed, acknowledged. But, as Lehoux and colleagues (2011) point out, less is known about the actual engagement of multidisciplinary project members in the design or development process of a medical technology or device. Thus, they investigated "how […] heterogeneous design participants actually combine their expertise to develop a medical device" (Lehoux et al. 2011: 313). Although their conceptual focus lays on the traditions of design (design studies) and they focus on the development (or design) of medical devices in companies, therefore taking a different perspective, Lehoux et al. are able to show two things important for this work. The first is, that particularly in medical technology development project members are not only specialists in the systematic construction and design of a technical artefact, that means representatives of engineering disciplines. But also, representatives of other disciplines as well as later users are almost always involved in the construction process of the medical device. They are "intimately involved […] in the design process of a given innovation." (Lehoux et al. 2011: 315) In Lehoux et al.'s study it was physicians, nurses but also computer scientists. In my own case study, they were, besides medicotechnological engineers, cardiologists, mathematicians and computer scientists, whereas the cardiologists have had the position of contributing the medical expertise and being spokespersons of the imagined future users at the same time. According to Lehoux et al. (2011: 313) the different contributions of the project members "vary in content and intensity over the course of a project – for instance, identifying clinical needs, testing prototypes, or commenting on a product's usability – but they all influence how the design process unfolds and what the 'final' technology will look like and accomplish". Which perspectives and contributions the project members build and "what each design participant sees about the innovation to be designed […] is framed through a particular 'lens'" (Lehoux et al. 2011: 316). This lens is filled with the developers' knowledge and expertise representing their discipline, their tasks and responsibilities within the project as well as their own motivations and interests. Transferred to the perspective of the situational scenario as an arena of negotiation about the nature of the technology-application nexus, the following can be adopted: the different representatives of multiple disciplines and probable user groups contribute to the development of the medical device in different ways and with changing intensity. They are doing this by putting on a certain lens that mainly consists of their scientific discipline (their social world), but in connection with their individual role within the project as well as own interests and motivations.

This leads me back to the role of power in those development projects, where multiple disciplines are directly represented by spokespersons. Lehoux et al. are not addressing it. But when we take another look at Wagner's early case study, we can see that power is important to consider. This is, because in directly represented multidisciplinary projects, for example a CDSS becomes likely another shape: Wagner (1998a: 103) proposes that in projects where medical expert systems are (partly) developed by medical practitioners the guiding principle would be the construction of an advising, supporting and assisting expert system, rather than an expert-replacing one. And Weingarten (1998: 182) emphasises that it is necessary to consider the tensions between the different logics of the (medical) expert and the (medical) engineer within these processes of development.

3.3.2. Specificity of Medical Regulations and Guidelines

In the case discussed later, the following point had no direct influence on the development. This is due to the circumstance that the development of the decision support system here had the character of grounding research and its declared aim was not to necessarily develop the system to market maturity. This is a step that some of the project partners may want to take in the future. Nevertheless, as mentioned earlier and becoming apparent later, regulations and guidelines played a reflective role throughout the project. To know them is therefore essential in the development process, regardless whether they are to be followed or not. Furthermore, they set (or in the case of artificial intelligence and simulation do not set) some requirements, which is quite interesting for this work. For example, as Alex Faulkner (2009: 38) points out, the European regulations[6] do "not necessarily require evidence of efficacy in clinical trials, or even the performance of new clinical trials. Evidence of mechanical performance in laboratory tests is sufficient for many new devices. [The regulations are therefore] designed to assess whether a product is safe to use and 'fit for purpose'." It is less designed to evaluate whether a new medical device is 'better', for example more efficient et cetera.

This is particularly true for the efforts starting to meet the 'new' challenges of software-based and especially data- and machine learning-based medical devices. In section three it is already

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[6] In the following reference is made mainly to the regulations set by the European Union (EU). The reason behind it is that the project was researching within this European framework and therefore just these regulations played, although a rather subsidiary, role in the project.

emphasised the circumstance that until now there are no certain established guidelines (globally) which try to define the development process of simulation- and machine learning-based medical devices. But regarding the European regulations of Software as a Medical Product (SaaMP), it can be seen that also here only the safety and the usability of the device as claimed by the developer are tested or defined. To what extent the devices really improve the medical practices in the targeted medical field seems to be of secondary importance or not relevant at all. For example, let us take a look at the key guideline IEC 62304:

> "IEC 62304 defines the software development and verification activities which medical device manufacturers must comply with. Such activities include software development planning, requirement analysis, architectural design, software design, unit implementation and verification, software integration and integration testing, system testing and, finally, software release" (Carroll/Richardson 2016: 188).

Here as well: What is regulated is mainly the frame of the development process itself. Clinical trials are not necessarily required. Therefore, developers of such medical devices are, firstly, building technology under a high degree of uncertainty. Secondly – and more important for the question of this thesis – the developers might likely incorporate the logic of the regulations and may thus reflect less on medical implications of the developed technology or device. Instead they might rather refer more to scripts already established in the respective scientific field or discipline, for example 'healthcare/treatment is improving with the help of new technical possibilities', 'the physician should be able to concentrate on the medically essential' or 'ss long as the device is safe and operates the way it should, it makes sense to deploy it'. Some of them we rediscover in the case study.

3.3.3. Specific Schemes of Medical Work Arrangements

When medical technology developers develop a medical technology, they usually have a relatively or even very concrete application context in mind. In my case study, for example, it is the treatment of cardiovascular diseases, that is problems of the heart valves. This does not mean that there are no ideas about other possible applications, but for the purposes of the development project there is almost always one particular context of use imagined, which the technology at stake is developed for. Often, the intended use context is defined at the very beginning of the project, usually already in the research proposal and it is also not subject of bigger changes during the development phase itself. Therefore, it can be said that in medical device development scenarios are commonly specific in nature. Additionally, they are also

more often of an implicit or even tacit[7] kind, rather than formulated explicitly. As medical technology is mostly developed with a particular purpose in mind and, as we have seen, medical experts in the corresponding field of application are part of the research process, there is often no need to explicate in more detail about probable situations of use. They are either considered to be obvious or they are more likely to be circulated internally, as they are quite specific to one field of application. This means that here the intentions to demonstrate or justify the development of a device are not very strong.

But how, then, is it possible to get to know about these scenarios? Schulz-Schaeffer and Meister (2015: 168-169) are proposing two ways: Firstly, they can be communicated verbally. In interviews, for example, they can be brought to the surface. Another way would be to get to know implicit scenarios mediated through prototypes and the corresponding testbeds. They write that "in test situations […] the prototype represents the new technology […], while the testbed represents the envisaged context of use […]. Consequently, every constellation of technological prototypes and corresponding testbeds embodies an underlying […] scenario." In analysing the prototype and testbed scenario(s) can be made visible. These are the two paths followed in this work. The findings from the interviews serve to find out about what imaginations represented in situational scenarios are brought forward and then use both the interviews and the prototype developed in the end of the project for showing how the scenarios are scripted into the technology.

But first, let us introduce the subject of study: What exactly are Clinical Decision Support Systems, under which regulatory frame are they developed and what is special about the data-driven versions?

4.   The Subject: Data-driven Clinical Decision Support Systems

When doing social scientific research about new medical devices that involves their technical development, one thing should not be lost sight of: the regulation of medical devices as well as their development. Although complying with regulations played a minor role in the course

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[7] The term 'tacit' means, that the scenarios are not only not articulated (for example, written down or verbally communicated) but also not actively reflected. But still, they are present during development (Schulz-Schaeffer/Meister 2015: 168).

of the development of the CDSS developed in the project that serves as the case study[8], the regulatory environment is nevertheless relevant, because the regulatory standards are, to a certain point, putting the development of the medical product under a frame with certain demands that have to be complied with when developing the device towards becoming a medical product. Thus, let us take a short look at the current regulatory environment developers of Clinical Decision Support Systems with a component that uses machine learning or simulation currently face. In particular at the difficulty of regulating machine learning and simulation in medical contexts.

4.1. Software as Medical Product and the Current Regulation of Machine Learning and Simulation in Medical Devices

As is stated on the website of the German Johner Institute[9] "t]here are currently no laws or harmonized standards that specifically regulate the use of artificial intelligence in medical devices" (johner-institute.com: 19.11.2019). The same can be stated for simulations. These circumstances of a lag of regulatory standards are leaving developers of such medical software alone with a significant degree of uncertainty regarding the standards they should rely on. While this "leads to risks for patients (medical devices are less safe) and for manufacturers (audits and approval procedures seem to reach arbitrary conclusions)" (johner-institute.com: 19.11.2019), it also makes it less clear how developers are engineering medical devices with machine learning or simulation components, respectively, what basic standards and frameworks have to be met during development.

Whereas in Europe there is yet not even a statement towards medical software based on machine learning or on simulation, in 2019 the US-American Food and Drug Administration (FDA) published a document promoting a detailed recommendation for a "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based

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[8] The aim of this project was to find out how a CDSS for use in the cardiovascular field could look like. During the public funding phase under investigation, medical and medicotechnological regulations were not directly addressed, but they were certainly reflected in the course of the project with regard to how these regulations would have to be addressed (in the future).

[9] The Johner Institute claims itself as a major provider of medical device regulatory services in Europe and USA.

Software as a Medical Device [SaMD]" (FDA 2019: 2). Although it would be too much to give a detailed analysis of what is proposed in the document, it offers some intriguing aspects and directions that bring to light the specialty of machine learning-based medical software. First of all, the authors of the document differentiate between "locked" and "adaptive" algorithms. In doing so, they accentuate the challenges in developing medical devices that are typical when using self-learning algorithms. With locked algorithms they refer to "those [algorithms] that provide the same result each time the same input is provided. As such, a locked algorithm applies a fixed function […] to a given set of inputs." (FDA 2019: 5) Examples given from the authors are static look-up tables or decision trees.

Compared to locked algorithms, adaptive algorithms are changing their "behavior using a defined learning process. The algorithm adaptation or changes are implemented such that for a given set of inputs, the output may be different before and after the changes are implemented." (FDA 2019: 5) These are the kind of algorithms that are designed in currently developed data-driven software, like Ada Dx by the German Start-Up Ada Health or in the project "QuantMed" at the Fraunhofer-Institute for Digital Medicine. Also, the machine learning component of the Clinical Decision Support System developed in the research project about supporting cardiovascular diseases, that serves as a case study, used this kind of dynamic algorithms to distinguish data sources which are relevant for medical decision-making from non-relevant sources. In those cases, what data is used how and when becomes a central role in analysing the development of these medical devices. The use of adaptive algorithms has also implications for the certification and evaluation of the medical device, that is that

> "[t]he power of these AI/ML-based SaMD lies within the ability to continuously learn, where the adaptation or change to the algorithm is realized after the SaMD is distributed for use and has 'learned' from real-world experience. Following distribution, these types of continuously learning and adaptive AI/ML algorithms may provide a different output in comparison to the output initially cleared for a given set of inputs." (FDA 2019: 3)

These changes are categorised into three types, namely changes in performance, in inputs and in the intended use of a medical device. For this reason, the FDA is focusing on how these changes or "modifications" can be met by regulations and proposes a regulation of the total product lifecycle (FDA 2019: 7-15). The document shows some of the special characteristics of medical software that is based on machine learning, regardless of whether this process is implemented using artificial neural networks, genetic algorithms, support vector machines and/or natural language processing (Jiang et al. 2017). These characteristics have serious

implications for imagined/prototyped software currently developed as well as for current devices which are already in use. For that reason, the development process of medical devices which use adaptive algorithms in decision-making and/or simulation of treatments as well as deciding which treatment would be the best for a particular patient (especially when the indication is difficult or complex, like in cardiovascular diseases) is playing an important role.

4.2. Data-driven Clinical Decision Support Systems

Although Clinical Decision Support Systems (CDSS) are only sparsely investigated, their active use in medical contexts goes back almost 50 years in history. They were often based on electronic health records (EHR) collected by the respective medical site itself (Berner/La Lande 2016: 2). The basic idea behind CDSSs can already be derived from the term itself, meaning an expert system that is supposed to help clinicians in making accurate medical decisions, for example about the right diagnosis or the most suitable treatment for a particular patient. While the aim of early examples (mostly in the 1970s and 80s) was to "build a computer program that could simulate human thinking" (Berner/La Lande 2016: 3) and therefore making the job of the clinicians to figure out the right diagnosis or treatment obsolete, currently developed CDSSs are expected to fulfil a different purpose. They do not try to replace the decision-making process of experts by simulating their way of medical reasoning. Instead, it is argued that the system should "assist the clinician in his or her own decision making" and letting the clinician "be active and to interact with the system" (Berner/La Lande 2016: 3). For example, a "CDSS can assist clinicians in decision making by taking over some routine tasks, warning clinicians of potential problems, or providing suggestions for clinician consideration" (Göksu/Lalys 2016: 8). The data sources which build the ground stock of the CDSSs are various, but usually contain established expert knowledge and experiences of past cases from scientific literature with relevance for the regarding medical purpose and/or official clinical guidelines as well as clinical and laboratory data and data from EHR. These data can be related to an individual case by entering specific characteristics of the condition of the particular patient. In the background these individual characteristics are synchronised with the so-called knowledge base of the CDSS, supplied with certain rules for the purposes of correct medical reasoning (Ozaydin et al. 2016: 46). Usually, this is done by a reasoning or inference engine that, in an abstract understanding, "combines the input and other data according to some logical scheme for output." (Spooner 2016: 34) According to Spooner (2016), this can be done for

example with Bayes' rules or a simple IF-THEN-logic combined with Boolean operators. This means that dependent on the input entered by the clinician the CDSS is reasoning on the base of the included medical knowledge and presents an output, for example a list of probable diseases.

This is the case for most of the currently developed and used CDSSs. But there is also a different approach that is getting more attention in recent years. In difference to the described CDSSs which base their reasoning on expert knowledge, those CDSSs can be summarised under the term data-driven CDSSs. The differentiation between knowledge-based and data-driven CDSS differs from the common distinction usually made by the actors in the field, who are not referring to data but to non-knowledge, with which not established medical knowledge is meant (see e.g. Berner/La Lande 2016, Göksu/Lalys 2016, Spooner 2016). This is a bit misleading, because it implies that the last version of CDSSs is not based on any knowledge, which is not the case. Therefore, it is more appropriate to emphasise what they are based on: a big amount of heterogeneous data. According to Bunyamin Ozaydin et al. (2016: 46-48), one of the main differences between these two types of CDSSs lays in the way the respective reasoning engine operates. While a CDSS that is based on expert knowledge operates the way described above, which means that its reasoning is solely derived from established knowledge, facts, rules and guidelines from the medical field it is supposed to be applied to, a CDSS that is not based on this kind of knowledge but uses particular techniques of machine learning or simulation receives its way of reasoning from recognising patterns within the data this engine is operating with. This can possibly lead to new findings and discoveries that are not based on pre-existing knowledge and not represented by clinical guidelines but on (potential) correlations between data points in a data corpus. These differences in reasoning are considered to come along with a changing role of the clinician who is working with the CDSS. Thereto, Ozaydin et al. write that

> "[i]n this sense, the [knowledge-based] decision support system requires a vast amount of a priori knowledge on the part of the decision maker in order to provide the right answers to well-formed questions. On the contrary, the [data-driven] decision support systems […] do not require a priori knowledge on the part of the decision maker. Instead, the system is designed to find new and unsuspected patterns and relationships in a given set of data; the system then applies this newly discovered knowledge to a new set of data." (2016: 46-48)

Thus, it is assumed that there are particular consequences behind integrating principles of data-driven reasoning into CDSSs. A reasoning system that is based on clear, pre-defined rules is replaced by a system that operates more autonomously and, to a certain extent, learns by itself based on a dataset with an outcome that is no longer entirely predictive and is not solely informed by pre-given expert knowledge. They are dynamic in themselves, because they learn continuously (with each new case) and are not only dependent on "external" dynamics, meaning manual updates of the knowledge base, for example medical guidelines. In this respect they are opaquer than the knowledge-based CDSSs.

Regarding the way they operate internally as well as the kind of information they provide, data-driven CDSSs should therefore not be seen as a revival of the knowledge machines (Wissensmaschinen) or expert systems of the 1970s to 90s (for a more detailed characterisation of expert systems as 'Wissensmaschinen' see Rammert et al. 1998). But when the question comes to how situations of medical decision-making with data-driven CDSSs are envisioned, it is intriguing to refer to earlier observations about the development and operations of CDSSs within the context of its application. That means how it is operating in interaction with all the other actors: physicians, nurses, other medical machines etc., in a particular arrangement of medical work. Thus, again, it was the declared goal back then to analyse and extract special knowledge of experts and to build up a model of this knowledge in a computing system. This system should then come to the same conclusions as the human expert but faster and with higher confidence. In other words, what was at stake was the technical replication of actions of medical experts. This in order to relief them from routine work, to backup-control their decisions and, ultimately, to replace or substitute their cognitive work (Rammert 1998a: 16). From today's perspective, it can be claimed that these early projects were more or less unsuccessful. According to Rammert (1998b: 262), expert systems failed because the gap between the development and the application contexts has not been considered and bridged, because differences in the actor's interests were ignored, because divergent views and cultures of practice have been challenged or because a powerful profession felt threatened in its position of power and monopoly by introducing a CDSS. All these potential reasons can be summarised in such a way that knowledge-based expert systems failed mainly due to the way they have been implemented. The mentioned visions connected with them mainly remained visions. German sociologist Gerald Wagner shows this with the example of a knowledge-based expert system that was supposed to help surgeons in intensive care diagnostics in analysing

malfunctions of important vital body functions of intensive care patients. On the basis of certain patient data, it gave a diagnosis with therapeutic suggestions derived from the diagnosis. Again, these outputs have been based directly on input beforehand and the way of algorithmic reasoning operated only along defined paths. After it underwent a one-year trial in a German hospital in 1988, the use of the device was discontinued and filed away as "socially failed" (Wagner 1998a: 101): While some doctors trusted the reliability of the documentation of the expert system, working with it was rejected by the nursing staff - and also by the other doctors on the unit - and the input of patient data was refused. Wagner describes the cause of this rejection as a "competition of memories" (Konkurrenz von Gedächtnissen), a competition between the nursing staff and the expert system. Comparable stories of failed implementation of clinical decision support systems can be found in the literature of the 1980s to 2000s. These followed the hype of the 1970s and 1980s and the hopes and visions of integrating machine intelligence into medical and clinical practice. As a result of the widespread failure of these systems (there are a just few exceptions such as the early support systems MYCIN and INTERNIST), things became very quiet around them in the late 1990s and 2000s. The basic idea, however, did not disappear and is experiencing a revival, as already outlined, in the wider context of machine learning methods, computational modelling and simulation as well as data-driven, personalised medicine. Whereas the earlier knowledge-based expert systems were associated with ideas about being "intelligence enhancers" (Wagner 1998a: 105) of the physician and the patient as "fully instrumented" or "networked" (Wagner 1998a: 98, 101), the systems now developed, which are partly data-driven, are connected with ideas of the "digital or virtual patient" and the system is seen as a supporting system that goes beyond the current physician's practice and knowledge.

In this light, it becomes interesting what Wagner and others (1998a: 91, 119) described over 20 years ago. In contrast to the then prevailing image of the expert system as an artificially intelligent simulation of the expert him- or herself, he characterises the role of earlier knowledge-based expert systems as hermeneutic media in form of a dialogue or communication partner of the physician. Instead of being an autopilot capable of diagnosing the disease and deciding over a therapy, medical expert systems are widening the ample scope of diagnosis and/or therapy planning. This, because they take into account more parameters and variables than the physician would do or would even be capable of. Due to the vast amount of medical knowledge and potentially treatment-relevant information and data, the technical expert

system is intended to be an informative source of insecurity, a meaningful irritant for the human expert. The expert system does not compete with the physician's power of judgement, nor does it relieve the physician of one single decision. It should only be able to contradict, it should be able to tell the physician: You have chosen this diagnosis, but it could be quite different (Wagner 1998a: 119). Expert systems should thus not be left alone. They are social machines whose strengths lie in dialogue (Wagner 1998a: 128). Therefore, according to Wagner, expert systems are not dehumanising medical practice but they privilege the objectively quantifiable and semantically precise form of medical knowledge. However, according to Rüdiger Weingarten (1998: 182) in the same volume, this leads to a conflict in the socio-technical work arrangement between the expert system and the human expert, because (medical) practices on the other side are always opportunistic and situation-specific.

What should data-driven systems be used for in medicine? As can be seen and becomes more apparent in the analysis part of my work, the ideas and conceptions about the work arrangements including an expert system that are present in Wagner's case study in 1988 and the ones within the project serving as a case study in this work do not differ that much in this regard, although over 30 years lie between them. As already outlined, the developers of such systems usually emphasise the possibility of saving costs and improving medical decisions on the best possible knowledge base and thus the possibility to improve the quality and efficiency of medical treatment as such. This has not changed throughout the years and centuries. Besides these rather abstract statements about possible improvements that could be achieved by using the CDSS under development, the developers usually also have ideas about how the envisioned technology or prototypical parts of it could be part of specific social situations. This was already apparent in Wagner's analysis. But what is more, these ideas manifest themselves in the form of scenarios. These in turn influences the kind of imaginary purposes for which the CDSS is developed, manifested as scripts.

In order to exemplify this, let us now concentrate on the empirical case study. To give an introduction into the empirical example, we start with answering the question why the case chosen is suitable for the purposes of this work. After that a focus is set on the methodological approach used for analysing the conducted data (mainly the interviews). In the then following subsections the examined project is described more detailed, starting with the conventional treatment of cardiovascular diseases as stated in project material, followed by the project's concept of the Digital Patient respectively the usage of a big amount of data sources and

completed by the presentation of the technical functionalities of the developed prototype of a Clinical Decision Support System.

5. The Case Study: A Clinical Decision Support System for Decision-making and Therapy-planning of Cardiovascular Diseases[10]

In order to illustrate my approach and to problematise the application of data-driven Clinical Decision Support Systems (CDSS) the author carried out a case study in January and February 2020. The general goal was to get deeper insights into the development process of a data-driven CDSS in order to find out (1) what kind of scenarios have played a guiding role throughout the development, (2) how they were negotiated among the participating research members, as well as (3) to what extent these scenarios have been inscribed into the CDSS. To find a project that meets these requirements, the author conducted a systematic search in November 2019 reviewing scientific publications not older than 2015. This to increase the possibility to find projects that suit the research interests which means that they should have officially ended not too long ago or are at least at a later stage of development. Furthermore, the project should include as a main feature at least a component that uses data-intensive methods, such as self-learning algorithms or simulations of biophysical or -medical processes to support the decision-making processes of clinicians. In addition, two further requirements turned out to be useful for narrowing the range of suitable projects: focusing on realisations in the area of therapy and treatment as well as concentrating on solutions that support medical decisions in the field of specific diseases, sorting out projects that focus on a broader approach. That is, because both intelligent decision support in the field of treatment/therapy and those supporting certain diseases seem to be further developed than the ones used in diagnosis respectively those with the intention to support decisions across medical fields and diseases. To find suitable projects, the search took place on the platform Google Scholar.

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[10] In the following, the quoted interview partners are listed anonymously with ENG (1, 2, 3) for engineers and CAR for cardiologists (1, 2). Publications carry the name of the anonymised project and a number (for example CardioSimu 1 etc.), the same counts for the project website.

Against this background, the project *CardioSimu* (project name is changed) turned out to be particularly suitable, since on the one hand the contents of the project meet the requirements of this work. At the time of elicitation, the project officially *ended half a year ago* and the subject of development was a CDSS that was supposed to support the *therapy-planning* of a *specific group of diseases* and this also partly *via techniques that are data-driven*. Thus, this project could provide a more complete picture of the development process as the development has been at a very advanced stage already. In addition, what made the project particular interesting was that the project members saw the development process more as fundamental research, where things can be tried out. Not all project partners have had the same main goals and interests. This is due to the spatially dispersed members of the project, which also involved respective main tasks in the process of development. As we have seen, this is also typical for projects where several disciplines are represented. But the direct representation of many disciplines (of main interest here are medical engineering and cardiology) in the *CardioSimu*-project let this fact become particular interesting as the negotiations between these disciplines can be retraced directly from the interviews. This is shown in more detail later.

The main aim of the project was to implement, test and validate a CDSS for cardiovascular diseases that allows simulating, comparing and understanding the effects and risks of different treatment strategies. In order to accomplish this goal, the project was a collaboration between different sites across several countries, combining medical expertise with technical knowhow. At the time of data acquisition, a sophisticated prototype of a data-driven CDSS has been developed.

5.1. The Methods of Conducting and Interpreting the Empirical Data

Publicly available materials (reports, scientific papers, videos, the official project-website) served the purpose of getting deeper insights into the project. These documents were then used for two purposes: First, to get a detailed understanding about the general course of the project, with its main achievements and obstacles; how the disease(s) and their treatment(s) are characterised and portrayed; wherein the developers see the benefit of the support system to be developed; and of course, how exactly the developed prototype is designed and how it performs in the end. In other words, on the one hand, the documents simply served as a source of information. Secondly, they served as a source for gaining insights about imaginations, ideas, concepts et cetera that either fulfil the characteristics of situational scenarios or point

towards these. As the main source for the latter aim, the author conducted four face-to-face interviews with five researchers[11] who have been part of the project, from both the medical and the engineering side. These interviews took place in Germany and in the United Kingdom during January and February 2020, whereas the German and one British interview represent the medical and the other British interviews the engineering expertise within the project. The interviews have been based on a guideline that served as an orientation scheme throughout the interview. In order to be able to evaluate them more precisely later, the interviews have also been recorded. The length of the interviews was between 56 and 114 minutes, with an average time of 79 minutes. The Germany-based interview was conducted in German, the ones in the United Kingdom in English. They took place in the working environment of the interviewees, their offices or in meeting rooms.

5.1.1. The Challenge of Anonymisation

In order to provide a high degree of anonymity, the names of the interview partners and also the title of the project have changed. These measures follow in general the Code of Conduct "Guidelines for Safeguarding Good Research Practice" of the German Research Foundation (Deutsche Forschungsgemeinschaft DFG) (DFG 2019) and particularly the Ethics Code of the German Sociological Association (Deutsche Gesellschaft für Soziologie DGS) (DGS 2017). Despite these measures, there is a problem regarding the successful anonymisation of the interviewees. This results from the use of publications which have been published in the context of the project and contain some of the names of the project members (because they are the authors of these publications). In order to find a feasible way, the author follows the procedure that Schulz-Schaeffer and Meister (e.g. 2015) have already established in their project on ubiquitous computing: In order to provide at least a certain level of anonymity project-related publications are cited in a way that makes them difficult to identify, although not totally unidentifiable, as this is not possible to achieve. Therefore, instead of citing the names of the authors these

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[11] One interview was conducted with two researchers together. The reason behind this decision was due to the inflexible schedule of the author, as the visit of the Sheffield site was only for one day. However, as it was important to talk to both interview partners, the author decided to conduct a double interview. There are limitations, especially regarding the mutual influence of the interview partners on each other. This was taken into account in the interpretation of the interview.

publications are given numbers. This encryption can only be decrypted by me, so it remains principally assignable. These measures should provide an acceptable level of anonymity, even though in this particular case it cannot be guaranteed entirely.

5.1.2. Combining Qualitative Content Analysis and the Grounded Theory Method

The evaluation or interpretation of both the publications and the interviews is done in a focused way. The material was specifically examined for statements and indications that provide or could provide an answer to my research question. The focus lied on preconceived categories that are theory-driven. In this case - not surprisingly - the evaluation of the empirical material was based on the theoretical background of situational scenarios and on scripts, the concepts introduced before. Nevertheless, this does not mean that the interpretation was made blindly and just in the mission of pregiven categories. Instead, a special focus was put on the specific, already elaborated, context of this case. This means the focus was on aspects that came out from the case itself and have proven to be important. This is shown more detailed in the analysis section (chapter 6). Hence, in analysing the material the author follows a middle way of the methods of Qualitative Content Analysis based on the understanding of Philipp Mayring (2019) and Grounded Theory Methodology, firstly developed by Anselm Strauss and Barney Glaser (1967).

To briefly outline the first, Mayring describes the approach of Qualitative Content Analysis as follows, emphasising the creation and application of (pregiven) categories as the main advantage compared to other approaches: The characteristic of being guided by categories is the central criterion that distinguishes Qualitative Content Analysis from other text analysis approaches. Categories express aspects of analysis in a short form, are more or less closely oriented to the source material and can be organised hierarchically. The category system (as the compilation of all categories) is the essential instrument of analysis. It is used to analyse the material and only those parts of the texts that refer to the categories are taken into account. (Mayring/Fenzl 2019: 634). What Mayring describes as the approach of Qualitative Content Analysis is a procedure in which categories are generated primarily from already existing knowledge about the object of study. What the researcher wants to find out is usually already known beforehand and thus are also most of the questions that the text shall answer. Once the categories have been established, they serve, as the quote shows, as analytical tools and the

text is scanned for relevant material. This ensures a high level of intersubjectivity, but there is also the risk of ignoring or missing interesting facts that are not covered by the categories.

this approach was not applied in a strict way but combined with the methodological approach of Grounded Theory, which particularly focuses on the creation of in vivo codes, that means codes that are developed directly from the material. Here - while reflecting own prior knowledge – the in vivo codes are generated in the form of open coding of the material. If necessary, these codes are supplemented by so-called borrowed codes, codes that originate from the background knowledge of the interpreting person (Strauss et al. 1996: 50). However, in the spirit of the approach this should be avoided as much as possible.

Since this bears the risk of theoretical blindness, also this approach was not applied in its most consequent understanding. Instead, a pragmatic approach was used. The categories used to analyse the source material for this study are partly theory-driven and partly derived from the characteristics of the case. This means, during the content analysis the author was informed and guided by theoretical assumptions and perceptions. These were used as a loose frame. Therefore, the search was conducted within and also without the framework.

For a more detailed explanation, on the next pages an overview of the project is given, putting the focus on three aspects: the specifics of the disease and its conventional ways of treatment as portrayed in the project; the concept of the so-called Digital Patient, that is the underlying database of the development and the operation of the support system; and the ways the support is supposed to be technically provided by the CDSS. Here, the main focus lies on documents and project deliverables. This is followed by a section about the primary research question about how scenarios guide developers in constructing and scripting a medical technology. In the last part a reflection is given upon the special empirical case of data-driven Clinical Decision Support Systems. It is argued that these are not only systemically opaque in nature, but are also scripted in this way. An end is set with the open question about possible implications for medical practice.

5.2. The Disease and Its Conventional Treatment

The project locates itself in a specific medical subdiscipline, namely the treatment of the diseased heart valve within the field of cardiology. According to the project description, the field of cardiovascular or valvular heart diseases is dominated by two conditions, aortic stenosis and mitral regurgitation, both of which are associated with significant morbidity and

mortality, yet which pose a truly demanding challenge for treatment optimisation. The medical term of aortic stenosis describes the condition where the aortic valve opening becomes narrow (stenotic), limiting the amount of blood pumped by the heart. The term mitral regurgitation refers to the medical state where the mitral valve does not close completely, meaning that blood can flow backward, reducing the heart's ability to pump blood (EC 2019: 1). Thus, in the project these two conditions were the subject of matter, whereas in the end of the project in January 2019 only the developed models for aortic stenosis have been already integrated into a CDSS (EC 2019: 2). After an individual got diagnosed with aortic stenosis and/or mitral regurgitation that is severe enough to consider a surgical intervention it becomes the main challenge for the clinician to decide over the timing and nature of interventional treatment. Regarding the right timing of operational intervention, the clinician has to reason and decide whether it is not too early or too late to operate, because operating on patients too late carries the risk of development of irreversible heart failure. Operating too early exposes patients to unnecessary risks and adverse events, conceivably causing short- or long-term sequelae. Currently, the way cardiologists are reasoning over the perfect timing of intervention is by (manually or with the help of technical tools) analysing relevant clinical symptoms (usually measured via echocardiography in the process of diagnosing), the blood pressure pre and post the aortic and/or mitral valve, the ejection fraction rate as well as the size of the relevant ventricular chamber. This is the common standard according to the corresponding clinical guidelines of the European Society of Cardiology (ESC).[12] Concerning the type of intervention, the whole replacement of the aortic valve is still the standard treatment as it is for the mitral valve, although recently there are also approaches to repair the respective valve, for example by implanting a transcatheter. These are becoming more widely used but are still less common. According to the project website, there is a consensus among cardiologists that different types of valve prosthesis (size, shape) or repair techniques will have different functional results. Deciding which option of treatment would be the indicated one, that means having the most

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[12] For example, whether a surgical intervention is indicated or not is recorded in respective guidelines of the European Society of Cardiology (ESC), a non-for-profit organisation which, among many other activities, publishes clinical practice guidelines on a regular base that "present relevant evidence to help physicians weigh the benefits and risks of a particular diagnostic or therapeutic procedure" (www.escardio.org) in the field of cardiovascular diseases. Their observance is therefore not mandatory, but in the spirit of evidence-based medicine they are generally used as standards that should be followed.

promising outcome, is therefore a highly complex and complicated process, as this includes the planning of the whole therapy procedure.

Keeping this in mind, the approach of the project consortium is to considerably enhance the process of the clinician's decision-making and therapy-planning in this specific medical field. This by using technological means: The planned CDSS is supposed to go clearly beyond parameters conventionally used by looking at the cardiovascular system at a more "holistic" and multi-scaled way. In addition, the CDSS shall allow for better personalisation of treatment strategies. This approach is connected with the idea of the so called Digital or Virtual Patient[13], a concept that transports a broader vision as well as real data-based manifestations. In the following let us elaborate on this in more detail.

5.3. The Underlying Concept of the Digital Patient – Using Big Amounts of Data

In the summary section of the project's website the project members state that the major advance of this CDSS over current practice is that it integrates and interprets all heterogeneous data available about the patient, integrates population data where needed, and provides a consistent, repeatable, quantitative and auditable record of the information that contributes to the decision process. Behind this formulation lies a concept that takes the name "the Digital Patient" (CardioSimu 2). It was supposed to underpin the whole project. The Digital Patient is not the actual human patient itself or a medical version of the person. Rather it is a corpus of data about the patient, that derives from many different sources and constitutes the patient inside the CDSS. As this is the case, the scores of many of these input data points are, like the patient itself, not stable but subject to change. In addition, the degree of representation would become denser with each additional data point that is added to the system. Or, according to a project deliverable, the Digital Patient data on any particular individual evolves over time, becoming an increasingly accurate representation of the individual, as new data is available (CardioSimu 2). This data corpus was meant to be a main part of the CDSS. It is supposed to

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[13] The term of the concept is not stably used within the project and among the project members. In order to avoid confusion, the term "Digital Patient" is used when referring to the underlying data concept of the project.

be interpreted by a computational model partly based on machine learning. This in order to enable a more effective quantitative characterisation of the disease state and to predict the effect of intervention (CardioSimu 2). In a deliverable that was published at the beginning of the project (CardioSimu 2) the developers present a list of the data that was supposed to constitute the Digital Patient. They are listed in the following:

- Meta data (about the current medical state of the patient)
- Demographics
- Medication
- Risk factors
- Diagnoses
- Physiological and laboratory measurements
- Echocardiographic measurements (the main tool to diagnose cardiovascular diseases)
- Computer tomography measurements
- Operative data
- Computational measures and concepts.

As can be seen, the data corpus was meant to contain basic medical health records (demographics, medication, diagnoses etc.) as well as data that is of particular importance to the cardiologist in order to make informed decisions about the need, time and nature of the medical intervention. The latter is mainly measured during the course of diagnosing, that means before the planning of a particular therapy option. It primarily consists of data from medical imaging, meaning echocardiographic and computer tomographic images as well as magnetic resonance imaging of the heart and the heart valves.

The above listed sources and types of medical data contain more information than is required for therapy planning, referring to the clinical guidelines mentioned earlier. In addition – and not mentioned in the cited early project deliverable – the project partners decided to measure and wanted to include the patients "Quality of Life", in doing so referring to variables established by the World Health Organisation (WHO), in short WHOQOL. These measures are meant to capture the overall quality of life of individuals as well as populations. It includes a wide range of measurements about physical health, psychological health, the level of independence, social relations, measures about the broader environment of the individual as well as information about personal beliefs, including spirituality and religion (www.who.int). But this has not been undertaken at the time of conduction, according to one interview partner

(CAR 2). Furthermore, during the project the researchers also decided to conduct the activity rate of the treated patients before and after the therapy, this with wearable devices which constantly measure their physical activity in their everyday environments (for example meters walked within a day). At the same time some data sources have been excluded or made less important in the CDSS itself. This out of different reasons, for example because certain data was not available or not easy to collect from all participating hospitals. Or they turned out to be of less or no additional advantage compared to the data conventionally used.

In the end of the project the final prototype of the developed CDSS contained five different sources of information which represent the Digital Patient. That is, firstly, the current guidelines which bear reference to the treatment of cardiovascular diseases, secondly the already established risk scores, thirdly the method of case-based reasoning, fourthly the activity rate of the patients and fifthly a whole visual simulation of the patient's heart valve functions (CardioSimu 3). The next chapter is going to expand on the individual functions.

5.4. The Prototypical CDSS and how it Operates

At the final stage of the project a prototype of the CDSS has been developed, including the components described before. After typing in all the relevant information that constitute the Digital Patient inside the CDSS it processes them in a particular way. In the end, the system presents more abstract data of information, those that make up most of the accessible components of the CDSS. As the fifth component in the actual prototype of the CDSS, the simulation of the individual heart valves of a patient is based on all or most of the other information. This was seen as the main innovative component supporting the cardiologist's decision-making within the project. The components give information with different levels of abstraction. The interpretation work remains on the clinician's side. And still it is up to the physician to decide over the further course of the therapeutic treatment. The types of information which are delivered and displayed to the clinician by the system are the following. Let us take a closer look into them as some of them play a bigger role in the analysis part:

Clinical guidelines: These are shown to the user of the system first. This component is rather simple, as it offers the possibility for the user to click through all the relevant clinical guidelines that matter for the therapy of the disease. This part of the system (as is the next one) cannot be claimed as being data-driven. Rather, it represents, as

a component of the bigger system, the knowledge-based approach. The function only lies in presenting the guidelines as such, without further interpretation or (hidden) computation. The primary benefit is seen in putting the guidelines back to the mind of the user, at the time when their exact content can become important – directly in the situation of therapy planning. Additionally, the system shows the relevant guidelines to the user in a condensed way, which means with the system it is possible to access all the guidelines that might be important at one point.

Risk scores: The second component is also an already established functionality. In cardiology so-called risk scores exist. These are scores that calculate the risk of a patient regarding their morbidity and mortality. Several risk score systems have been established. Examples are the euroSCORE and the STS-Score developed by the Society of Thoracic Surgeons (STS). In both these scores a certain number that represents the weight of the particular risk within the system is assigned to every single risk factor. Filled in with data of individual risk factors the system will calculate the overall mortality risk of an individual patient if an operative procedure is applied. Just like the guidelines, the functionality of the risk score system is implemented into the CDSS without any changes.

Case-based reasoning: In contrast, the component of case-based reasoning was developed within the project, although the general idea is well-known in cardiovascular treatment. The function of this component is the reasoning of the patient's risk regarding particular operative procedures. But conversely to the component of the risk scores, this is based on the comparison of individual cases. A cardiologist, who was part of the project, describes this function as follows: On the basis of a patient who is recorded with all the components that have been classified as important at some stage, a comparison is made between how similar this patient is to

patients who have already been recorded in the database (CAR1, 55). Basically, the aim is therefore to find cases within a database which are similar to the case at hand. Often this involves distinct characteristics of the anatomy of the patient's heart or other factors that might influence the short- or long-term outcome of an individual patient. This is put into a similarity score ranging between 'zero' and 'one', where 'one' is the case of total similarity. The most similar cases within the database can then be studied in more detail, regarding characteristics of the patient, operative procedures, outcome for the patient, remaining symptoms et cetera.

Activity rate: The (significant change of the) physical stamina of an individual with a heart valve disease is considered as an important indicator for the right timing of an operative intervention. Therefore, conventionally the patient has to absolve tests that measure their physical stamina. This on a regular base. An example is the six-minute walk test. Here, the patient has to walk on a self-paced level for six minutes in order to simulate the movements in their everyday environment. The comparison between several tests over a longer period thus might show signs indicating a worsening of the disabilities of the heart valve(s). Within the project, another approach has been followed. Instead of using data from for example the walk tests, patients have been equipped with mobile health devices (health watches) which were measuring their heart frequency rate (and other activity data as well). The patients were supposed to use or wear these in their actual everyday environment. The idea behind using wearable devices instead of established methods was to find out, whether these data can predict the results of standardised tests that would otherwise be done by study nurses or performed by nurses in the outpatient clinic (CAR1, 59). As this proved to be the case according to

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	statements from the interviews, the activity rate was included as a component in the CDSS.
Heart valve simulation:	According to the project members, this component is meant to be the core functionality of the CDSS. Here, a part of the heart valve is simulated using data from imaging procedures usually made during the diagnosing process. This includes, for example, images from magnetic resonance imaging (MRI) or computed tomography (CT), as well as echocardiography (an ultrasound of the heart). The CDSS creates a virtual image of the relevant area of the heart and the clinician can then analyse this image and also manipulate it accordingly by importing data records. Or, for example, the clinician can insert a laser-scanned model or geometry of various artificial heart valves into the virtual model and is then able to try out different placement angles of these. This can be combined with patient-specific flow profiles of the blood inside the patient's heart[14], as measured by the MRI. In combination with the heart valve models, the respective surgical result (e.g. would aneurysms occur or not) can be simulated or predicted. To figure out which parameters are important to be included in the simulated model a machine learning approach was used. One cardiologist (CAR1) described it as a "holistic" approach, meaning the approach was to include not only data that is conventionally used but also using new sources.

6.   The Analysis: An Implicit Scenario under Negotiation

In what now follows the example of the development of a prototype of the described Clinical Decision Support System created in the course of the project CardioSimu, is taken as a case. It is particularly shown what assumptions about the reality of the social situation at stake have

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[14] This is called pressure volume loop and it shows how and how much blood is pumped by the heart at a certain volume.

been part of the project and in which ways they found their way, as scripts, into the CDSS. To give a first note, let us start with wherefrom the members got their knowledge about what cardiologists usually do when they decide over and plan a treatment (6.1.). Thereafter, we separate the assumptions into assumptions about the decision-making and therapy planning work cardiologists conventionally do (6.2.), implications about the integration and application of big amounts of data – the so-called Digital Patient (6.3.) – and imaginations about how the work of cardiologists would look like if they would work together with a decision support system like the one developed in the project (6.4.). For the last a dominant scenario is unveiled that lies behind the imaginations brought forward in the interviews and scientific articles and is inscribed into the CDSS. After this main part of the analysis, a final conclusion is given (7.).

6.1. Wherefrom Do the Developers have the Assumptions?

First of all, as this project was a collaboration of multiple disciplines, the knowledge base of the technical members on the one side and the medical members on the other was quite different. This is rather obviously the case as these members represent very different disciplines. Therefore, it was mainly the technical members within the project who were interviewing the cardiologists being part of the development team, as the quote of an engineer shows:

> "[T]he information that I have about the process [of diagnosing and therapy planning] is from cardiologists. So, we were looking at the data that we had that were routinely gathered, and what was not routinely gathered, what we needed to ask for extra. And [for this reason we were] talking to cardiologists from [the participating hospitals] about what they are doing." (ENG3, 32)

Throughout the project several meetings and discussions took place where the cardiological work was the subject matter broadly discussed among the project members. In these meetings it was the main goal to find out about key issues cardiologists are currently facing in order to get an idea about how a CDSS could possibly be helpful for the clinician: "I think what we did get, it was a long discussion with the clinicians, was an idea about what their challenges were. You know, what are the difficulties in diagnosing the patient and deciding where to go" (ENG2, 61). The outcome or the conclusion drawn from these discussions have been described as "a general feeling", for example about "that the tendency was to overtreat, perhaps treat too soon" (ENG2, 61). Furthermore, the intuition of the cardiologists, which means their experience-based knowledge, played an important role in evaluating the data and the outcome of the systems computation. One technical developer told a story about a clinician who was

involved in the project and was not believing the numbers presented to him by an earlier version of the support system. It is said that this cardiologist knew the patient by himself and had much more information about him than the system got. So, the technical developers tried to make more use of the experiences and knowledge of the clinicians who were part of the project (ENG3, 52), for example by putting more effort on the case-based reasoning component of the system. As a consequence, among the technical team(s) within the project the knowledge about cardiological decision-making and therapy planning was bounded, or like one technical developer explicated it, they "had limited access to the information about what actually the cardiologists do" (ENG3, 32). Hence, to say it with Schulz-Schaeffer and Meister (2019) the knowledge about the cardiologist (and other clinicians) as users and about cardiological decision-making mainly derived from the professional knowledge of the involved cardiologists as potential users themselves as well as from everyday notions or common-sense assumptions of the involved engineers.

6.2. Assumptions about how Cardiologists Conventionally Decide

Among the project members many assumptions existed about how cardiologists actually decide over a treatment and plan a therapy. As already mentioned in the section about the disease and its current treatment the members of the project CardioSimu explicate a clinical motivation behind their approach of developing a technology. They see their motivation in the need of assisting the cardiologist in making the right decision regarding whether they should do an intervention or not and claim two aspects as particularly important in making these decisions: It is the timing and the nature of the intervention (CardioSimu website). The cardiologist is the one making the final decision and is planning the treatment and is therefore also the main reference or "target user" (CardioSimu website) addressed by the project members.[15] It is the clinician's work which is supposed to be supported by the developed system. So, besides the broad understanding of the main difficulties currently apparent in cardiological

[15] Whereas one interview partner contradicted this assumption that was brought forward by everyone else and also stated in the documents: This person put the healthcare assistants to the frontstage and claimed them as the main or target user, the ones who have to be able to understand the whole system, the input as well as the output, because "the clinician him- or herself simply receives the additional information which they seek to assimilate into their process" (ENG1, 64). The one the clinician receives the information from is the professional health staff.

decision-making, how is the cardiological work assumed or imagined among the project members? Firstly, it is important to divide between the technical and the medical members, as the clinicians who took part in the development have been cardiologists themselves. This is also apparent in the interviews. Different assumptions or estimations about the actual work cardiologists are doing have been stressed and brought to the surface by medical and the technical interviewees.

Assumption one: *Cardiologist's decision-making is characterised by an interplay between previous experiences and clinical guidelines*

What is stressed by every interview partner is that cardiologist's decision-making is characterised by an interplay between previous experiences of the clinicians and the guidelines counting for cardiological interventions. Although this is not exclusively the case for cardiological decision-making, it was mentioned most often by the interview partners and therefore deserves attention. Among the interviewees both sides, the personal experience of the clinician and the following of the guidelines that are evidence-based, are seen as important resources for the decision-making of the cardiologist. The predominant view is that of a complementary relationship they have for the decision-making process, as treatment decisions vary "from person to person", as one cardiologist explains. Further he states that "[w]e are guided by evidence in guidelines, but a lot of clinical decisions are guided by our own previous experience. So, if you have managed a similar case, eventually with a positive outcome, you are more likely to do that again" (CAR2, 32). The clinical guidelines are seen more like "a good starting point", however it is assumed that a lot of clinicians "often do follow guidelines blindly" (CAR2, 63). This is considered as counterproductive for the decision-making process and thus for the potential outcome for the patient as well.

But at the same time, it is also supposed that too much reliance on own experience is not advantageous either, turning it into intuition which is considered as risky. An interviewed engineer stated that "throughout the project I got the idea that there is […] too much intuition involved in decision-making" (ENG3, 38). It was concluded that this intuition has to become more robust, which means getting supported by additional data and modelling, in short: by a Clinical Decision Support System. But still, the information from the clinical guidelines as well as the knowledge gained from individual experience are seen as being of considerable importance for decision-making, although the solely reliance should lay on neither of them. Relying too much on the guidelines is seen as losing sight of the individuality of the patient, as

"you [as a cardiologist] are following a path to make a decision for the individual, but they do not take into account […] an individual profile, because they cannot […]. There simply is not the information in analysis that is being done to support that" (ENG1, 53). On the other hand, relying too much on one's own experience is seen as problematic, because for the developers it indicates a lack of reliable, evidence-based and therefore to some extent objectifiable sources for making the clinical decision. Instead, for the engineers, it is associated with randomness. An example is the decision on what measurements to rely on, like one engineer describes as "when we asked, so we have five pressure measurements, which one to take. […] In some cases, it was random, […] the decision […] which one is the most valuable […] was not continuous. […] Through experience they knew […] and for us it was a confusion" (ENG3, 32). For the development team, a path in between had to be found, hence making use of both the knowledge contained in the guidelines and the experience contained in the heads of the cardiologists.

Assumption two: *There are variations in measurements which need to be scrutinised and filled with medical meaning*

Another estimation was mentioned in the interviews: a variation in measurements, for example MRI or CT scans. This was only broad forward by the technical members and not mentioned at all by the medical interview partners. But according to the engineering side "they [the cardiologists] did different measurements of the same parameters at different times and in different states" (ENG3, 32). The measurements can tell the clinician different things at certain times of conduction, which is seen as, to some extent, reflecting a kind of variation in the meaning of measurements. Nevertheless, this variation in measuring body signs is connected to the assumption that cardiologists strongly rely on their own previous experience. The two following statements of two engineers about measuring the heart rate of a patient using different methods explains this connection in more detail:

> "A […] clinically descent concept is measured using different methods and the results are different. So, […] you measure […] with magnetic resonance imaging or measure it with ultrasound and they are just different. So, which is right? Well, probably neither. Which is better? We do not know. It all depends on how you interpret it." (ENG1, 38)

And:

> "There is heart rate measured during CT or MRI scan, which is different, because it is a claustrophobic, stressful environment with loads of things

going on. And there is heart rate measured in some other tests as well. And there is a difference between them. [..] I imagine that the clinicians looking at that see a pattern of what is going on through the experience that they had with other patients and much better understanding their physiology." (ENG3, 34)

Here, the assumption about cardiological work is that there is a connecting item or action needed between the variation in the meaning of measurements and a reliance on previous clinical experiences, and this is the act of interpreting the data. This "interpretational work" (Mort et al. 2005: 2033) is considered to have an important position in applying the experience a clinician made throughout their carrier and the fact that measurements taken are not speaking for themselves but need some analyses to become meaningful. Even whether the running of certain tests and the conduction of particular clinical measurements are "relevant to the conditions under which your symptoms would be manifest" (ENG1, 26) or not has to be taken into account. Thus, what kind of tests the clinician and their medical staff are deciding to run and under what condition the patient is during these tests (for example the process of MRI as claustrophobic and stressful) is therefore assumed to have a significant influence on decision-making and it is seen that it needs to be scrutinised and filled with medical meaning by medical experts derived from the interplay of experience and guideline knowledge mentioned above.

Assumption three: There are differences between routine and borderline cases and the last are the ones that matter

Another assumption that was relatively prominent, but only stressed in the interviews with the cardiologists, is that there is a difference between the clinical routine and those cases that are at the borderline of deciding if and how to intervene. On the one side there are plenty of cases that are "in between" (CAR2, 68) which means clinicians connected them neither with good nor with bad memories. These cases have not been difficult in a medical sense, "they are just routine" (CAR2, 68). These routine cases are mainly treated following clinical guidelines which tell the clinician what to do. Everything that can be done with the patient and what the clinician should do is classified there. This is divided into degrees of evidence with regard to how evident the guideline already is or which data basis is used. These are the standard approaches (CAR1, 40). Cases that appear as routine can thus easier be treated by following a guided path presented in guidelines. On the other side there are borderline cases. These are cases which show inconsistencies or ambiguities (in the measured data or the broader medical

appearance of the patient) and might therefore not be represented by clinical guidelines. In cardiology, these cases involve a meeting of several clinicians from different professions working in the field of cardiological medicine, the so-called *heart team*. In the words of a cardiologist: "[U]sually when it is about borderline decisions in cardiology, we sort of consult a heart team. We have different specialties, we also have different interests, that may have an opinion about how a patient is managed." (CAR2, 36) The heart teams have an outstanding importance for the decision-making. The experience of the cardiologists plays a main role here, too,

> "because […] you are influenced by your own previous experience, which why the heart team is so important, really, in cardiology. You have sort of different cardiologists, different surgeons, people have different experience. And then […] they come up with that sort of hopefully more holistic sort of management plan for that patient" (CAR2, 36).

These so-called heart team conferences about borderline cases are an established institution in cardiology. Both interviewed cardiologists emphasise its significance in cardiological decision-making and in a widely noticed paper from 2013 David Holmes et al. claimed that "this […] approach will become the standard of cardiovascular care" (903). In these heart teams all measures taken are considered and discussed by a multidisciplinary team. According to one cardiologist these team conferences are the place where also less conventional information and more uncommon measures are part of making a decision. But there is no standardisation (CAR1, 70). This lack of standardisation is supposed to be addressed by the developers.

Assumption four: The cardiologist has to deal with too much medical information

Although not mentioned as prominent as the other assumptions, there is still the idea of the clinician who has to deal with too much information to make a wholly informed decision. Deciding about the positioning of the valve, meaning where to position the artificial valve optimally and how to turn it best in terms of the angle; what are the optimal hemodynamic adjustments after valve replacement; is it possible to optimise the blood flow; is an avoidance of extra turbulences and calcification possible; and when is the best time to perform the procedure? These are all questions that are seen to be particularly relevant for the decision-making and the therapy planning afterwards. It is assumed that there is too much information to be able to easily decide about these and other medical questions, as this citation of an engineer shows:

> "The big problem they [the cardiologists] have now is that they cannot assimilate all the information they need. So, there must have been a sweet spot

some time in history where clinicians […] were exposed to the amount of information they can sort of integrate in their heads. But now it is increasing. They got huge piles of information papers that are coming in every day from journals, clinical trials, et cetera. Some of them are very conflicting results. They have got to integrate a lot in their heads and then remember all the patients they have ever seen." (ENG2, 67)

This widely and well-known image of the clinician (here the cardiologist) who has to deal with too much information and who is not able to retrieve all of it in the process of decision-making played a major role for the engineering side of the development team. Because of the complexity and sheer quantity of the information that is needed under best circumstances, it is a widely accepted assumption that "nobody can make a clear decision. That is definitely right, everybody agrees on" and in the project this was the main reason "why we wanted to provide more data to make that decision", whereas "it is a complex task […], because how do you know that your opinion is the best opinion" (ENG3, 43), reflecting the huge amount of information and therefore possible facts not included in the decision made respectively the data provided to support making the decision.

6.3. Implications of the Digital Patient Concept

We have already seen that the concept of the Digital Patient is represented in the CDSS in the form of various data from different sources, conventionally and non-conventionally used in cardiological decision-making and therapy planning. But the Digital Patient also comes along with a broader vision about the influence of newly added and newly combined data and data sources affecting the process of decision-making of clinicians respectively cardiologists. The vision behind the Digital Patient concept can be deduced from the following statement in an early deliverable of the project:

> "The [concept of the] Digital Patient […] will develop new ways of combining rich patient information in a highly visual, coherent and meaningful way. In the short-term, this will enable new clinical information to be generated by the blending and fusing of existing data but, ultimately, it will lead to the creation of a powerful 'patient avatar' capable of supporting the medical professional by producing the new clinical knowledge which will emerge from the integration of patient-specific and population-specific information. These innovative information technologies will impact how medical professionals can access simulations of the progression, treatment, and outcome of a disease to support diagnosis, prognosis, and choice of treatment" (CardioSimu 2).

What can be deduced from this statement? First of all, the concept of the Digital Patient means the combination of big amounts of data that contains traditionally measured data and newly conducted data sources. These data are "rich", which means having a potential that can be brought to light by (intelligently) combining them with each other and thereby generating new, not to say better, information to serve medical decision-making. This combination can mean using simple algorithms or statistical methods operating along pre-given standards and weightings, like statistical regression. But it also includes the usage of artificially intelligent methods combining the various data in an opaque way and the process of simulating based on a model with inputted individual data, whereas for the user of the system a direct relation between the inputs and the output is difficult to spot. For the developers this, consequently, leads to a digital version of an individual patient inside of a model. With this digital version it is possible to run, or simulate, treatment strategies which would not be possible with the real patient him- or herself. The following quote explains and exemplifies this a bit further: "[Y]ou can do whatever you want to that virtual patient. You can perform an intervention and see what would be the outcome or you can make the virtual patient perform exercises which would be too dangerous because of the state of the [real] patient" (ENG3, 26). That means, with the simulation of an individual patient, turning them into a virtual version, it is possible to also simulate, and therefore predict, possible treatment strategies as well as probable outcomes and thus supporting the decision-making process of cardiologists. The combination of information of the individual patient and information abstracted on a population level makes this possible, so it is stated by the developers. Implied is a possibility to extensively represent the real patient by the virtual avatar using at least partly intelligently combined data and simulations that are built on this data. The potential opacity behind it is only modestly reflected, although the usage of artificial intelligence and simulation in general is partly seen critically respectively as to be treated with caution: "[T]he question is how do you slow that development down a little bit without hindering innovation. Because I think you do need to not be too ambitious with those things" (ENG2, 27). Nevertheless, the developers mainly connect positive associations with intelligent combinations of big amounts of data. Let us take a closer look into this vision of the Digital Patient and its implications:

Within the project the concept of the Digital Patient is seen as a solution addressing the challenges cardiologists currently face regarding the developer's understanding about cardiologist's work. But, as we have seen in the section before, this understanding is not equally

distributed among the project members. Besides individual differences there are certain assumptions that have been primarily or even exclusively brought forward by either the engineers or the cardiologists. This indicates disciplinary differences within the project. Nevertheless, after we have seen that these disciplinary differences have played a role in the matter of assumptions about the decision-making work cardiologists do, it can be stated that it also appeared regarding assumptions about the Digital Patient concept. The main difference lies in the assumption about in which way and to what extent it is possible to represent the real individual patient in its complexity within the CDSS. Let us exemplify this with two statements. The first one comes from a cardiologist. He describes the concept of the Digital Patient as a tool that makes it possible to represent the patient in an analogous, but a simplified way. For him it will never be feasible to achieve a whole representation of the real patient, because the patient's physiology is too complex, regardless whether the artificial reasoning engine is intelligent or not:

> "[The Digital Patient] will always be a simplified version. Because […] no matter how good the computer model or how complex it can be, it can never truly represent physiology of a patient. […] I mean, the human body is so complex, it cannot represent all, especially when we talk about the patient's outcomes. We cannot represent someone's thoughts in a computer algorithm. […] So, the whole […] changes of blood pressure, heart rate responses, you can try and simulate. But there are so many different influences on that, both physical and emotional, that you could never model in a perfect way. So, I think the idea of the Digital Patient is that it is nice, but you should probably read it as a digital simplification of physiology. So, […] it cannot represent the patient, it can represent maybe some basic principles of their physiology" (CAR2, 46).

Compared to this statement, the engineering side is more optimistic about the possibilities of a data-driven support system like the one developed in the project. The following statement is thus from an engineer. He characterises the concept of the Digital Patient differently. As a virtual representation of a real individual inside the CDSS here the virtual patient gets closer to what is stated in the deliverable: a patient avatar and therefore an adequate representation of the patient. One with which medical procedures can be tried out without harming the real patient him- or herself:

> "So, the Digital Patient, as I understand it, is a computational being inside of data and procedures that represents a specific person. And [because] that being [is] digital, you can do whatever you want to that virtual patient. You can perform an intervention and see what would be the outcome or you can make the virtual patient perform exercises which would be too dangerous,

because of the state of the patient. So, getting it up to higher heart rates and exercising till failure, which you cannot do in reality, what is happening in industry, where you crush cars against walls to make sure that they are safe. So, with the Digital Patient […] you could kill the virtual patient to see, or that is how far it can be pushed and whether that is acceptable or not. And if it is not acceptable, […] how do we need to intervene [so that it] is on an acceptable level" (ENG3, 26).

Whereas the cardiologist emphasises the restrictions that lead to an imagination of the support system, what could be called bounded representativity, the engineer stresses the ability of the support system to be able to represent the patient to an extent detailed enough to do a simulation of interventions or exercises with the virtual surrogate and directly deduce medical knowledge and conclusions out of them in order to help in medical decision-making. The analogy to safety tests in the automotive industry illustrates this idea quite well: Under protected, that means controlled conditions, the automobile respectively the patient can be exposed to influences or pushed to limits that would not be acceptable or feasible in the real-world environment. Findings from this can then be more or less directly incorporated into further decision-making or planning towards which direction to go. This direct transfer of insights from a simulation to the real world is not shared by the quoted cardiologist.

As this is the case what also becomes quite apparent is that although the cardiologist holds a more critical position towards the extent of representativity of the Digital Patient model, both are rather uncritical regarding the potential non-traceability of the implications of the information displayed in the CDSS. This is evident in all interviews, even though it is acknowledged that at least a basic understanding of simulation should be acquired for a competent use of the CDSS, or at least when using the fifth component.

A difference becomes also apparent when looking at the component(s) of the Digital Patient that are considered as being most important or most influential. On the engineering side it was the simulation part of the system, as this was the component the engineers interviewed have been working on primarily. On the medical side instead, the component that was thought of being most useful was the case-based reasoning, which was also seen as the most useful tool by participants in the cardiological experiment where the development team presented additional information to one group of cardiologists, whereas the other group had to make a decision on cases only using conventional data. What is more, in contrast the simulation component was seen rather sceptical by the medical participants. The explanation for this difference given by the engineering side is the following: The simulation approach is the newest and

therefore the clinicians have less experiences with this component and have been more sceptical about it. This idea was brought forward several times. In the portrayal of the interview partners it reflects remarks by Schulz-Schaeffer and Meister (2019). While the technical developers present themselves as spokespersons of future components of the technology (later we see: of the scenario), the medical test persons and to some extent also the cardiologists involved are given an advocacy for currently existing components, being rather sceptical about unfamiliar parts of the technology.

Not so with the idea of case-based reasoning as the idea of comparing a (difficult) case with similar cases of the past, treated by the clinicians themselves or by others, is already present in the idea of the heart team. This is considered to be significant for the decision-making in borderline cases. Hence, case-based reasoning is assigned a role similar or comparable to that, as the following statement from a cardiologist shows:

> "I am not saying that the clinical support tool sort of replaces that heart team, but some of the features within it sort of did that. So, we had the case-based reasoning decision tools that looked at what other clinicians may have done with similar cases in the past and that would help guide what you may [do now]" (CAR2, 36).

It can therefore be said that both preferences are based on disciplinary interests: The engineers see their field of study, the individual modelling of the heart valves and the connected simulation of heart flows under the influence of different interventions, as the primary innovation promising great benefit and is therefore pushed by the engineering side, while the cardiologists see the main helpful element in the access to experience-based data that would otherwise be far more complicated to obtain, which is represented by case-based reasoning.

However, what is assumed among all members of the project was that the concept of the Digital Patient is, generally speaking, good, which means helpful. It is claimed to be an advancement for the cardiologists making the medical decision and it is assumed to be an improvement for the patient's outcome as well. But whether the representation of the concept of the Digital Patient inside the CDSS is actually helpful for the treated patient is, however, an open question, as this was not a subject matter in the project. Nevertheless, it is imagined this way:

> "Wenn man sich überlegt, ein Patient, der hinterher schwerstbehindert, der hinterher einen Schlaganfall durch diese Operation erleidet, der möglicherweise sehr lange im Krankenhaus ist, hinterher sehr immobil ist, vielleicht hinterher eine deutlich schlechtere Lebensqualität hat als vorher. Da kann man sich vorstellen, dass das nicht nur individuell belastend ist, also dass ein Patient am Alltag weniger teilnehmen kann und dass er sich da

irgendwie schlecht dabei fühlt, das sind ja messbare Faktoren, da kann man irgendwie von ausgehen. Aber es ist natürlich auch, es gibt da mehr Komplikationen, es gibt mehr Krankenhausaufenthalte, es gibt Folgeeingriffe, Folgeaufenthalte in Kliniken, die unnötig wären. Ich denke, das ist erstmal, würde erstmal auf der Hand liegen, zu sagen warum finden wir es besser, eine Intervention mit mehr Informationen zu planen" (CAR1, 82, translated version in footnote 16).[16]

The above statement shows that the added information and the outcome from the combination with one another as well as with conventionally used data is assumed to be better for making an informed decision and are therefore also seen as being an improvement for the patient's outcome and even for the whole patient management in the hospitals and clinics. Accordingly, for the support of the clinician the approach of the developers is considered as being helpful. There is also a consensus among the project members about to what extent the system working with the concept of the Digital Patient can or should be part of the decision-making, which is analysed in detail in the next section. For the developers (the cardiologists as well as the engineers) an algorithm computing big amounts of medical data will not be able to precisely predict medical outcomes or events, for example surgical complications. This means, it is seen that not everything can be captured with data. Also, with a decision support tool the decision should not be "completely binary", it rather should "provide information to the clinician to make their own decision" (CAR2, 42). Or the way an engineer was putting it: "We will not replace all clinicians with big data, because big data is not big enough." (ENG3, 54). This refers back to the statement discussed at the beginning. Although the CDSS provides new information through the application of methods that are in part potentially opaque, it is not intended to replace the clinician in his or her power of decision-making, but to support him or her. How to support them is the subject of the next chapter.

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[16] "If you think about it, a patient who is severely disabled afterwards, who suffers a stroke as a result of this operation, who is maybe in hospital for a very long time, who is very immobile afterwards, perhaps has a significantly worse quality of life afterwards than before. One can imagine that this is not only stressful individually, that a patient can participate less in everyday life and that he feels somehow bad about it. These are measurable factors, so you can somehow assume that. But of course, […] there are more complications, there are more hospital stays, there are follow-up operations, follow-up stays in clinics that would be unnecessary. I think it would be obvious at first to say why we think it is better to plan an intervention with more information."

6.4. Imaginations of Use, the Scenario behind Them and Its Scripting into the CDSS

The two sections before have been about the technology itself and the envisioned context of its application separately. Now it is time to bring them together. This section is about a situational scenario (Schulz-Schaeffer/Meister 2013). One about the imagined application of the CDSS and its context of use. This section is also about what role it played in scripting the form(s) of use of the system. As a reminder, scenarios should tell something about (1) what parts the future technology is made of, (2) what those parts or components are able to do, (3) how they perform and (4) how they are connected to each other. This was shown in section 5.4., but there it was not established as a part of a scenario, which is the aim now. Furthermore, if a scenario is situational in nature, it (5) usually also includes more information about the envisioned context of its application (Schulz-Schaeffer/Meister 2015: 166). Thus, not only the components of the technology play a role but also possible users and further elements of the imagined situation that might be of relevance for the developers. This was also demonstrated showing assumptions about the cardiologist's work.

6.4.1. The Dominant Narrative Scenario

It was not possible to find these imaginations of use sufficiently in the literature published by the developers (except for the vision about the Digital Patient, which remained broad and abstract). This might be due to the assumption made earlier about the nature of situational scenarios. Namely, that they are of an implicit, even tacit kind and thus not easy to find explicated in publications or in other narrative forms like the project's website. Therefore, the following analysis relies mainly on verbalisations from the interviews. Although this needs more interpretation work it unveils (a) scenario(s) which played a role among the project members in scripting the use of the CDSS. After extracting statements that bring to the surface assumptions about the integration and application of the CDSS, its context of use, they were condensed to imaginations about the type of relationship(s) between clinicians and the support system. These imaginations again were combined into a concrete, more complex situational scenario. This procedure involves a greater degree of pre-interpretation and the presented scenario or scenarios have never been formulated in this complexity and do not appear in this condensed form in the project publications. The scenario is supported by statements made by all interview partners in the course of the respective interviews. They represent rather fewer individual

opinions, but can be considered with sufficient certainty as ideas shared among the developers. They also reflect assumptions and imaginations of the two sections before. Nevertheless, there are differences and inconsistencies. At this point, however, only those are mentioned that are significant, i.e. those that occurred several times but were not necessarily shared by everyone. Let us now look at the dominant scenario:

The dominant narrative scenario:

The clinical decision support system in CardioSimu is an additional step in the decision-making and treatment planning process for cardiovascular diseases, after the process of diagnosing and before the beginning of the treatment. During a clinical consultation the cardiologist is sitting together with the patient in the practice and after some minutes, because it has to be time efficient in an already time pressured workplace, receives the condensed individual information based on the patient's and population data in order to make a decision about the treatment. As such the clinical decision support system is a module in already existing clinical imaging systems and can deliver high-level complex information about an individual patient within a few minutes. It serves the cardiologists as a condensation, refreshing and extension of their knowledge, memory and experiences. Based on their knowledge, the decision support system enriches the information and knowledge base for medical decision making with more and newly combined clinical information that digitally represents the individual patient for the cardiologist. The cardiologist can click through five different components: clinical guidelines, risk scores, case-based reasoning, activity data and model-based simulation of the individual heart valve. This relieves the individual cardiologist from the management of the medical information overload and allows him/her to better concentrate on the decision-making process. In other words, the system thus guides, helps and positively influences the cardiologist in his or her decision-making in giving more and more individual-based information. This means, in the decision-making process the former is the deliverer, and the latter is the recipient of information that may or may not be incorporated into the decision-making process. It is up to the cardiologist to decide which components are considered helpful. Where the

decision is considered certain, the system provides additional assurance. Where the decision is considered uncertain, the system helps to find the best decision, as the heart team traditionally does. But it is never the system that decides, but always the cardiologist.

6.4.2. The Different Role of the Patient

It has to be said that the developers never carried out a test situation of this scenario. The only experiment they did was a controlled study about the response of cardiologists to the presented features of the CDSS prototype making a decision with their help. Therefore, the situational part of the scenario, or the envisions behind it, was never really reconciled in an actual testbed (Schulz-Schaeffer/Meister 2013). Thus, the situational scenario can, indeed, be described as implicit. It is even unequally distributed among the developers, although basic images and ideas could be found in every interview. It is the details which matter in this case. For example, what is excluded from the scenario, because it was highly inconsistent among the interview partners, was the role of the patient to be treated. This inconsistency can, again, be drawn along the line of the discipline. Whereas the engineers treat the patient as the subject matter of the decision-making process, cardiologists assign a more active role to the patient, both in terms of receiving the information that is central to the decision-making process and in terms of their own input of and access to the relevant data. Against this background, the patient consultation has a significant importance. The scenario suggests that the clinician is consulting the patient to discuss his or her condition based on the information given by the CDSS. The idea is to type the patient-specific parameters in, which are known by the patient or performed in the process of diagnoses, and to receive the processed information right away. This means in particular similar cases to the patient in front of the clinician and the simulation of the patient's heart valve as well as, if conducted, information from the activity monitoring. Therefore, for the engineers it was important to develop the system's components fast computing, as this statement exemplifies:

> "[I]f you have a situation where a patient presents and you do some imaging and some work and you make a decision and then they will come back in three weeks or three days or whatever it is. And then it is possible to run the very computationally expensive simulations to assist with the decision. But it is often the case, the patient is with you for one hour or five minutes and you have to, if you are going to make use of those processes, you have to do it now. […] So, really you need to think a lot about what your clinical

workflow is and what your timing is. You also need to think a lot about what level of accuracy is adequate" (ENG1, 26).

As can be deduced from this statement, although the engineering position was taking into account the specific situation of the cardiological patient consultation and the ideas about the workflow of the clinician, considered was only the relationship between the doctor and the CDSS. The physical presence of the patient him or herself was only seen as a variable necessitating the computation of the CDSS to be more time efficient. Other considerable questions are mainly medicotechnical in nature (for example level of accuracy), which means reflecting the medical context, but with the lens of their own discipline (Lehoux et al. 2011), what kind of consequences this has for the development of technical components. The imagined distribution of roles in the envisioned situation also becomes important. To whom does the system present the information? Who should be able to read it and how should decisions be made? Who, above all, is involved in the decision-making? For the cardiologists, it is clear that the decision is not just made by the clinician but is made together with the patient, because "essentially, as a good clinician, you are supposed to explain to the patient the risks and benefits of the surgery. So, informing the patient is important. Ultimately, the decision about what treatment they undertake […], they have to consent for it" (CAR2, 38). So, for the cardiologist it is important to be able to discuss the results with the patient during the consultation and make "swift decisions" (CAR2, 50). It is therefore even important that the CDSS is "almost patient-facing" (CAR2, 50). Not only that, but the possibility of greater direct influence by patients is also seen as an improvement for the decision-making process. That this was not taken into account is seen critically: "patient reported measures, patient reported outcomes, we didn't really include that in our decision support tool and that might have been more beneficial." (CAR2, 38) Here, differences regarding estimations about how the real-world situation looks like become apparent. Recalling Schulz-Schaeffer and Meister (2019: 51) "practices, understandings and beliefs constituting […] social worlds guide their members to view and interpret certain components and their characteristics differently". While the engineering perspective is envisioning the situation as follows: *the clinician (and clinician is equated with cardiologist) receives processed information from the CDSS and assimilates these into his or her own decision-making*, the cardiological point of view is including the patient as an active part into the context of application. This can be described as: *the clinician (and clinician can mean cardiologist or general surgeon), with the help of the patient, types in the information needed and receives the processed*

information from the CDSS in order to discuss them and decide over the next treatment steps. What thus comes into light are differences between disciplines. These differences have to be negotiated between the developers, in the terms of Schulz-Schaeffer and Meister (2019): spokespersons representing the different social worlds, in this case mainly the scientific disciplines of medicotechnological engineering and cardiology. This negotiation takes place "in the processes of building, specifying and evaluating scenarios" and entails "which components and features will win through and which will have to be adapted" (Schulz-Schaeffer/Meister 2019: 51). In the project discussed here, the cardiological view of a more active involvement of the patient did not materialise in the prototype, as can be assumed from the interview statements. Consequently, this position has not prevailed. The vast majority of statements consider the cardiologist as the sole target user, who only receives the information and carries out intended manipulations with the displayed material. As already mentioned, the patient basically appears only as a variable to be taken into account – as the subject of the decision and as part of the information basis for calculating the Digital Patient, and not as an active part of the imagined situation of decision-making.

6.4.3. Different Envisions about the Clinical User of the CDSS

The same counts for the envisioned clinical user of the CDSS. For the interviewed cardiologists it is mandatory that the support system is simple to use and its components are easy to comprehend. This is also due to the assumption that the target user of the CDSS would not only be a cardiologist trained in specifics of cardiovascular diseases and open to unconventional methods, but also, for example, surgeons who are not this familiar with cardiological graphs and methods or simply cardiologists working in a more traditional way, which according to the developers view means less catheter-based and more surgical interventions. An example brought forward is the visualisation of pressure volume loops. Not everyone is equally familiar with them. Clinicians who work with a catheter (which is still a minority) may better be able to interpret them than those who primarily do surgery and therefore do not pay as much attention to pressure volume loops. In the case under consideration, it must be noted that the final product of the project was a prototype and not a product the developers thought of being ready for implementation. Nevertheless, it appears that not much attention was paid to the graphical presentation, for example in the pressure volume loop simulation. This was pointed out by an interview partner of cardiology during the presentation of the prototypical software.

And with reference to the randomised experiment with practising cardiologists, another cardiology interviewee states that even the simplified version used in the experiment required at least half an hour to sift through the information in the components and draw conclusions from them, and that "it can [thus] still take a considerable amount of time in an already time-pressured workplace" (CAR2, 54). Even though the developers, across disciplines, agreed from the very beginning that there has to be trust in the system on the part of the clinicians (and, by the way, the cardiologists also emphasise here that system trust must also be there on the part of the patients) in order for the CDSS to be used in a way that is beneficial, in the course of the experiment it became apparent that the respective indication of individual parameters needs to be explained and displayed more clearly. However, as the project officially came to an end at that time, no further action was taken.

6.4.4. The Cardiological and the Engineering Sub-scenario

In addition to these variations in the scenario, the interview data contains indications of further differences. For example, there are some contradictory statements about the general time pressure in cardiovascular work. For example, this work is described by one side as already characterised by time pressure, but by another side as relatively leisurely and in principle without urgency. Furthermore, there also seem to be different views on who actually inputs the patient data into the CDSS. This is described by one of the interviewees (a cardiologist) as a situation in which during the consultation the clinician types the relevant parameters of the patient into the system in order to have the results available a few minutes later. A divergent view (from an engineer) of this situation is that the clinician simply receives the information and remains very passive. The hospital staff is supposed to insert the data (as explained above) before the consultation.

There are therefore two different sub-scenarios concerning the situation of the use of the CDSS. They can be characterised as the cardiological and the engineering sub-scenario. Above, the main part of the engineering perspective is already presented as the dominant scenario. For purposes of comparison, let us again take a look at the first part of the scenario, which is essential:

> The clinical decision support system in CardioSimu is an additional step in the
> decision-making and treatment planning process for cardiovascular diseases, after
> the process of diagnosing and before the beginning of the treatment. During a

clinical consultation the cardiologist is sitting together with the patient in the practice and receives the condensed individual information based on the patients and population data in order to make a decision about the treatment.

What follows is the cardiological sub-scenario that was also envisioned. The changes to the first sub-scenario are in bold letters:

The clinical decision support system in CardioSimu is an additional step in the decision-making and treatment planning process for cardiovascular diseases, after the process of diagnosing and before the beginning of the treatment. During a clinical consultation the **clinical decision maker** is sitting together with the patient in the practice and **types the patient information into the CDSS**. After some minutes, because **it has to be time efficient in an already time pressured workplace**, the condensed individual information based on the patients and population data is displayed and the clinical decision maker can **discuss them with the patient** in order to make a decision about the treatment.

Many components referring to the social context of application apparent in the interviews with the cardiologists have turned out as not being dominant in the development of the prototype. A possible explanation could be the more dominant role the engineering of the technology played in the course of the project. This does not determine less recognition of the medical specifics – in general there was a high consistency in the statements among the disciplines regarding the basic idea of what the CDSS should do and how this can be beneficial for the clinician and the outcome for the patient. The specifics of the disease have been recognised quite thoroughly. Not so regarding the work context of the clinician. Nevertheless, coming to a conclusion that during the development the game of negotiation (Schulz-Schaeffer/Meister 2019) was played only in the arena of the engineers would be misleading. Although several components of the perspectives of the cardiologists got lost in the building of the system, others prevailed, first of all the perspective of time pressure, which was the main reason why a fast computing modelling (physics-based 0D- and 3D-modelling) was chosen. Ultimately, therefore, it can be said that multidisciplinarity was manifest in the project in the form of partial exchange of knowledge, which has been limited primarily to the specifics of the disease and to decision-making as a self-contained process. The wider context of the consultation was considered less important, but seems to be important to the cardiologists involved.

7. Conclusion

What should be concluded after the case analysis? This is done in a three-part step. Firstly, important findings are summarised. Thereafter, they are discussed regarding the question how situational scenarios and scripts are connected. In the end, an outlook is given about how systemically opaque CDSSs (and other medical devices) might change medical decision-making and thereby hypothesise that it leads to a work arrangement of collaborative cognitive co-working between intelligent human and technological actors, a collaboration that is based on different knowledge-bases.

7.1. Summary

As demonstrated, different versions of the scenario presented above could be deduced from the interviews. Building the final prototype of the CDSS can be, in line with the concept from Schulz-Schaeffer and Meister, characterised as an arena of negotiation between representatives (Lehoux et al. 2011) or spokespersons (Schulz-Schaeffer/Meister 2019) of different disciplines, mainly cardiology and medicotechnological engineering, about the shape of the scenario, its components and its situational context. This negotiation took a particular form within the project. First of all, knowledge exchange between the engineering and medical members of the development team, which is strikingly necessary in medicotechnological development, mainly took place during meetings of the project members. As the development was distributed among several sites across Europe, working together, physically, was not possible most of the time. Direct learning from each other was therefore also restricted simply by separation in space and was thus limited in general. Hence, and secondly, the concrete processes of the development of some of the components took place without direct involvement of the cardiologists, although regular updates and discussions took place in the course of the project.

As already stated in the earlier course of this work, the cardiologists had an ambivalent role in the project. They spoke for the developer role as well as for the user role. They were both advocates of change and interested in preserving existing components of the application situation (Schulz-Schaeffer 2019). The engineers were not completely indifferent to this, they saw a need in basing the system on cardiologist's knowledge in order to make it work and to build up trust in the system's operation. But the cardiologists had a specific personal interest in maintaining certain routines, whereas the engineers were mainly advocating the new components of the CDSS (in the interviews mainly the modelling and simulation). This reflects the

tension between experts and engineers in medical technology development mentioned by Weingarten (1998: 182). As stated, it was not possible to counteract this tension sufficiently due to spatial and institutional separation. In the end, as apparent in the interviews and visible in the prototype, it was more the engineer's perspective about the application context that was implemented, especially regarding the patient's role during consultation. Consequently, it was the cardiologists who took a more (self-)critical perspective on the developed prototype and the development process.

7.2. Discussion

Through knowledge exchange, discussions and most notably through building the prototype, not only images about the technical specifications of the CDSS, its performance and the inter-relation of its components have been inscribed into the technology, but also potential users and the use context were inscribed into the CDSS (Akrich 1992). Most of the time the users and the characteristics of the possible use context were not represented by actual users and contexts. They were represented by parts of the development team who also acted as competent users by themselves (Schulz-Schaeffer 2019: 50) informed by own everyday experiences and assumptions whereas both were also influenced by preferences from past projects and preferred technical concepts, like physics-based modelling and case-based reasoning (Hyysalo/Johnson: 83). The inscription did not happen in a determined and straightforward way but in negotiating the components of the scenarios between spokespersons of different disciplines. These practices of negotiating the scenario's components served as a guide for the actual development of the prototype's scripts.

But the dominant scenario has not been the only possible socio-technical arrangement inscribed into and fixed in the technology. Instead, more than one scenario or different versions of a scenario have been present during the project and have been under negotiation. So, the development team was guided by partly disparate scenarios about who the target user is, how the technology should be used, what it should do, how it should look like and how all this is to be achieved best. Accordingly, the building of the prototype and the negotiation about the scenario's components co-evolved, leading to scripts influencing the (envisioned) user to use the technology in certain ways. With Gläser et al. (2017: 14) it can be stated that there will likely be more than one script inscribed into a technology. This can only be assumed for this case, since the developed system could not be studied in use. However, it is very likely to be the

case here as well, since a negotiation process on (components of) scenarios, as in this case, unlikely reaches a final conclusion. Therefore, it would be wrong to assume only one scenario and therefore one script inscribed into the CDSS, although one dominant scenario is present in the finalised prototype.

As Akrich and others point out, an object's script is nothing pre-fixed, but also a co-constructing of inscription and description. The CDSS prototype is defining "a framework of action together with the actors and the space in which they are supposed to act" (Akrich 1992: 208) – the framework that was apparent as an implicit, even tacit, scenario in the course of development. Within this framework actions of de-scription or re-interpretation by users are likely possible. Whereas the developers inscribe their imaginations into the object it is in turn the users who are de-scribing the script of the object in its actual use environment. For example, a cardiologist might develop an antiprogram (Oudshoorn/Pinch 2003: 11) and is still be able to decide explaining the figures and graphs displayed on the CDSS to the patient during consultation, even though the patient was not expected to have a significant role during decision-making. The technology containing the scenario might offer this freedom. However, it becomes more difficult if the measurements and graphical presentations displayed are challenging or at least very unfamiliar for the treating cardiologist (or even when it is a surgeon). The given framework is derived from the scenario in which a well-informed cardiologist aware of for example pressure volume loops is envisioned. Therefore, just loose explanation and a more technical graph is included. The scenario's component of the well-informed cardiologist inscribed into the system could likely be too narrow for the treating clinician. Instead of finding a workaround or a different way of use, non-usage or rejection (Akrich 1992: 208) could be a possible consequence.

Therefore, the following can be stated. The concept of situational scenarios has proven to be helpful in describing and explaining how scripts arise or where assumptions about the internal interdependency of a technology and its embedding in social situations of application come from. With this concept it is possible to understand in detail which assumptions have played a role in the development, have combined to form a scenario and how this process was co-evolutionarily negotiated between multidisciplinary parties during the construction of a technology.

It was also able to show that this process can also be found in medical technology development, although in my case study it became clear that scenarios are sometimes more difficult

to identify because they are implied or only present tacitly. In contexts like these, a lot of interpretation work is needed. Critical reflection is also needed on the fact that the data sources, publications and above all interviews, are retrospective sources, this work is dependent on narratives. However, elaborating implicit or tacit scenarios may well be more successful if process data can be collected, if the project can be followed while the technology is being built. Thus, a lot of effort had to be made to work out leading scenarios, based on post-reflective statements of the interview partners, which might not have been presented in this form in earlier stages of development, but were also shaped by experiences and knowledge exchange during the project. Furthermore, the concrete influence of the regulatory environment on the scenarios could not be taken into account in the intended notoriety, as it did not play a direct role in the project, but nevertheless the circumstance that there is a lack in the regulations of medical devices like Data-driven Clinical Decision Support Systems was reflected upon, and interview statements suggest that it has always played a background role during development, although not taken into account directly.

In order to be able to work this out more clearly for the area of medical technology development, following research should focus empirically on development processes that would follow the situation considered here, namely the further development of the project-based prototype into a medical device. Further interesting questions would arise in this context. What influence do scripts written into the prototype have on the further development? Which actors play a role in market-oriented development? Here, one would therefore consider another stage of development. The experimental phase would be left behind and the real world would be more present. As a follow-up of this work, this would be of great value.

7.3. Outlook

To give a final outlook, it is important to point out the following: Medico-historically seen, medical reasoning became an interplay between medical knowledge a physician develops over time, based on the experiences a physician makes throughout a carrier and on intersharing knowledge with colleagues (*experience-based knowledge*) and medical knowledge that is mainly based on established medical evidence, rules and guidelines, the ones that feed the knowledge-based CDSSs (*rule- or evidence-based knowledge*). Over the last centuries there has been a development towards an increased relevance of the latter, and this to the chagrin of the former. However, with the appearance of data-driven CDSSs classical evidence- and

experience-based medical knowledge is getting company by a third way of creating knowledge. Experience-based knowledge can be located at the level of the individual physician and maybe also at the level of the direct collegial environment (the heart team) and evidence-based knowledge can be seen as standardisation of medical knowledge applying strictly scientific methods. Both are comprehensible to humans. Knowledge generated intelligently by machines is opaque to humans in the process of its generation. It is not completely transparent and cannot be verified by the physician. He or she just sees the output and might know the whole input, but even that is not necessarily the case. The knowledge base of the early expert systems was the same as the knowledge base of the physician, so the traceability of the decision-making process of the CDSS was much easier for the physician, what, in principle, also increased the level of trust in the systems reasoning. What came along even with these earlier versions was a change of the "thinking styles" in medicine, its perceptual apparatus and its criteria of reality (Wagner 1998a: 125). But the new systems are (partly) operating on a different base, so for the physician the systems reasoning is not as traceable as before. This makes it, generally speaking, more difficult to develop trust in the systems operation (e.g. Gretton 2018). Whether this new form could be characterised as a resurface of experience-based medical knowledge in a new, technical form remains to be seen. But nevertheless, this new way of generating knowledge might, again, reshape how medical reasoning and decision-making is done in practice. How the developers and manufacturers of those systems build these becomes therefore a central role.

Therefore, it is very likely that not only the ways of reasoning and decision-making of the medical staff would change but that the whole sociotechnical constellation of medical diagnosis and/or treatment will undergo or is already undergoing changes as well. As the degree of autonomy of the supporting system rises as well as the produced knowledge is different the whole medicotechnological arrangement of planning a therapy or deciding over a treatment – for example deciding over a therapy of a patient with a heart valve disease – might become more a character of *collaborative cognitive co-working* between human and technical actors. This was partly reflected by the interview partners but remained on rather general comments on risks and benefits of artificially intelligent and simulation-based methods in medical workplaces. As this already is and going to be much more relevant in the near future, it is necessary to conduct more critical and social scientific research in this area.

Bibliography

Akrich, M. (1992). The De-Scription of Technical Objects. In *Shaping Technology/Building Society: Studies in Sociotechnical Change* (pp. 205-224). MIT Press.

Berner, E. S., & La Lande, T. J. (2016). Overview of clinical decision support systems. In *Clinical decision support systems* (pp. 1-17). Springer.

Carroll, N., & Richardson, I. (2016). Software-as-a-Medical Device: demystifying Connected Health regulations. *Journal of Systems and Information Technology*, *18*(2), 186-215.

Clarke, A. E., & Star, S. L. (2008). The social worlds framework: A theory/methods package. In *The handbook of science and technology studies. Third edition* (pp. 113-137). MIT Press.

Faulkner, A. (2009). *Medical technology into healthcare and society: A sociology of devices, innovation and governance*. Palgrave Macmillan.

FDA, U. (2019). Proposed regulatory framework for modifications to artificial intelligence/machine learning (AI/ML)-based software as a medical device (SaMD).

Glaser, B. G., & Strauss, A. L. (1967). *Grounded Theory. Von der Methodologie zur Forschungspraxis*. Weinheim/Basel.

Gretton, C. (2018). Trust and Transparency in Machine Learning-Based Clinical Decision Support. In *Human and Machine Learning* (pp. 279-292). Springer.

Holmes, D. R., Rich, J. B., Zoghbi, W. A., & Mack, M. J. (2013). The heart team of cardiovascular care. *Journal of the American College of Cardiology*, *61*(9), 903-907.

Hyysalo, S., & Johnson, M. (2016). User representation: A journey towards conceptual maturation. In *The new production of users: changing innovation collectives and involvement strategies* (pp. 75-100). Routledge.

Hyysalo, S., Jensen, T. E., & Oudshoorn, N. (Eds.). (2016). *The new production of users: changing innovation collectives and involvement strategies*. Routledge.

Jarzabkowski, P. & Pinch, T. (2013). Sociomateriality is 'the New Black'. Accomplishing repurposing, reinscripting and repairing in context. *M@n@gement 16*(5), 579-592.

Lehoux, P., Hivon, M., Williams-Jones, B., & Urbach, D. (2011). The worlds and modalities of engagement of design participants: A qualitative case study of three medical innovations. *Design Studies*, *32*(4), 313-332.

Mayring P., & Fenzl T. (2019). Qualitative Inhaltsanalyse. In *Handbuch Methoden der empirischen Sozialforschung* (pp. 633-648). Springer VS.

Mort, M., Goodwin, D., Smith, A. F., & Pope, C. (2005). Safe asleep? Human–machine relations in medical practice. *Social Science & Medicine*, *61*(9), 2027-2037.

Oudshoorn, N. E., & Pinch, T. (2003). Introduction: How users and non-users matter. In *How users matter: The co-construction of users and technologies* (pp. 1-25). MIT Press.

Ozaydin, B., Hardin, J. M., & Chhieng, D. C. (2016). Data mining and clinical decision support systems. In *Clinical Decision Support Systems* (pp. 45-68). Springer.

Petersen, A. (2019). *Digital Health and Technological Promise: A Sociological Inquiry*. Routledge.

Pinch, T. J., & Bijker, W. E. (1984). The social construction of facts and artefacts: Or how the sociology of science and the sociology of technology might benefit each other. *Social studies of science*, *14*(3), 399-441.

Rammert, W. (1998a). Was sind Expertensysteme? Maschinen, Medien und Mittel der Macht. In *Wissensmaschinen. Soziale Konstruktion eines technischen Mediums. Das Beispiel Expertensysteme* (pp. 15-25). Campus.

Rammert, W. (1998b). Resümee und Ausblick: Von der Funktion zum Funktionieren. In *Wissensmaschinen. Soziale Konstruktion eines technischen Mediums. Das Beispiel Expertensysteme* (pp. 248-265). Campus.

Rammert, W., Schlese, M., Wagner, G., Wehner, J., & Weingarten, R. (1998). *Wissensmaschinen. Soziale Konstruktion eines technischen Mediums. Das Beispiel Expertensysteme*. Campus.

Roland Berger Focus (2019). *Future of Health. Eine Branche digitalisiert sich – radikaler als erwartet*. Roland Berger GmbH.

Schulz-Schaeffer, I., & Meister, M. (2013). *Scenarios as patterns of orientation in technology development and technology assessment. Outline of a research program*. STI-Studies.

Schulz-Schaeffer, I., & Meister, M. (2015). How situational scenarios guide technology development: some insights from research on ubiquitous computing. In *Practices of Innovation and Responsibility. Insights from Methods, Governance and Action. Studies of New and Emerging Technologies*, (pp. 165-179).

Schulz-Schaeffer, I., & Meister, M. (2017). Laboratory settings as built anticipations: prototype scenarios as negotiation arenas between the present and imagined futures. *Journal of Responsible Innovation*, *4*(2), 197-216.

Schulz-Schaeffer, I., & Meister, M. (2019). Prototype scenarios as negotiation arenas between the present and imagined futures. Representation and negotiation power in constructing new socio-technical configurations. In *Socio-Technical Futures Shaping the Present* (pp. 37-65). Springer VS.

Spooner, S. A. (2016). Mathematical foundations of decision support systems. In *Clinical Decision Support Systems* (pp. 19-43). Springer.

Strauss, A. L. (1993). *Continual permutations of action*. De Gruyter.

Strauss, A. L., Corbin, J. M., Niewiarra, S., & Legewie, H. (1996). *Grounded theory: Grundlagen qualitativer Sozialforschung*. Psychologie-Verlag-Union.

Steinmüller, K. (2003). *Szenarien. Instrumente für Innovation und Strategiebildung*. Z_punkt GmbH, www.conspect.de/jonas/PDF/SzenarioWS_Reader_2003.pdf.

The Berlin Script Collective (2017). *Comparing scripts and scripting comparisons: toward a systematic analysis of technologically mediated influence*. TUTS Working Papers.

Wagner, G. (1998). Die Verfertigung des Wissens: Die Konstruktion der Maschinen im praktischen Umgang. In *Wissensmaschinen. Soziale Konstruktion eines technischen Mediums. Das Beispiel Expertensysteme* (pp. 85-128). Campus.

Weingarten, R. (1998). Die Aushandlung von Praktiken: Kommunikation zwischen Fachexperten und Medieningenieuren. In *Wissensmaschinen. Soziale Konstruktion eines technischen Mediums. Das Beispiel Expertensysteme* (pp. 129-188). Campus.

Woolgar, S. (1991). Configuring the user: the case of usability trials. *The Sociological Review*, *38*(1), 58-99.