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Methodology for the Description of Socio-Technical Systems: A Case Study Approach

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Abstract. The ethical implications and regulatory requirements of AI applications and decision support systems are generally the subjects of interdisciplinary research. Case studies are a suitable means to prepare AI applications and clinical decision support systems for research. This paper proposes an approach that describes a procedure model and a categorization of the contents of cases for socio-technical systems. The developed methodology was applied to three cases and serve the researchers in the DESIREE research project as a basis for qualitative research and for ethical, social, and regulatory analyses.

Keywords. bioethical issues, health technology assessment, socio-technical system, privacy, clinical decision support systems, telemedicine

1. Introduction

The digital transformation in healthcare is driven by applications such as telemedicine, clinical decision support systems (CDSS), and novel AI applications [1]. These applications have an impact on the doctor-patient relationship and the patient's social environment [2]. Normative challenges have risen in terms of responsibility, privacy, security, and autonomy. Furthermore, human-machine interaction and professional self-image are concerned. In the DESIREE project (https://www.desiree-forschung.de/desiree/), the ethical and social implications of CDSS were investigated. Three exemplary cases were used: nephrology, surgery, and nursing. The three cases were analysed with the aim of systematically describing the socio-technical and ethical challenges and the "side effects" of these applications. In our research, we tried to be aware, that there are always intended and unintended effects in social action. In our analyses, we focused also on the unintended effects. Then these more grounded descriptions were used by the interviewers for the interviews they conducted with the interviewees: patients, medical students, and nursing students on the impact of digitalisation.

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The aim of this reflected research was to develop a more grounded catalogue of criteria to follow and systematically describe AI, CDSS applications in terms of its socio-technical implications.

2. Method

Criteria underlying decision support systems were identified in an interdisciplinary team consisting of physicians, ethicists, and medical informaticians based on the methods of case study research according to Yin RK (2009) [3]. In the first step we asked the questions "how" and "why" according to the proceeding in case studies [3]. The interdisciplinarity consisted of identifying and analysing the entire socio-technical context. Here, the direct effects of human-machine interaction and indirect effects on professional self-image, legal requirements, and the effect on patients must be considered. Therefore, first, the direct interaction of the system was described and then, second, social effects were identified. In an iterative process, the procedure, the resulting categories, and their items were developed.

3. Results

3.1. Identifying the categories

The structured interdisciplinary procedure resulted in a categorization of cases for socio-technical systems. The following figure 1 shows the process of describing the case studies. The result was a set of categories to be adopted to all the cases:

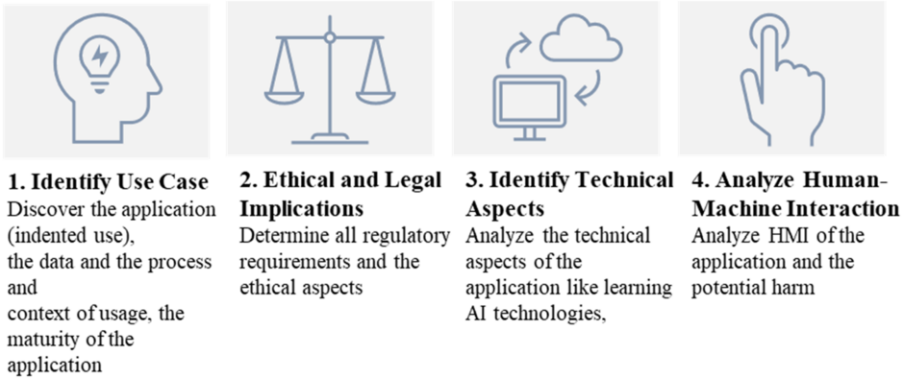

Figure 1. Process of categorization in establishing case studies for socio-technical systems

The figure 1 shows the process of identifying and categorizing the cases. The first step is identifying the application depending on the research question. In the DESIREE project, research projects from different medical domains were chosen. It is crucial to get detailed information about the product/research project. In the second step, all regulatory requirements and ethical implications have to be assessed. In the case of research projects, often there are no regulatory requirements easily to identify yet; here, experts have to classify the system and identify the potential regulatory framework. In

the third step, particularly in the case of AI, a distinction must be made between self-learning systems, data sources, and whether the system could also be implemented at another institution. For example, at another institution it may be dependent on the specification of the hardware. In the fourth and final step, interactions and hazards as well as possible usage errors and failures in the human-machine interaction must be assessed.

3.2. Categories

The category ***Use Case*** describes the overall system with its intended purpose. If it is not a medical device or purely a prototype from research, the intended use in clinical research is often not explicitly given. Here it is helpful to ask the researchers directly.

- **Intended purpose**: The intended purpose is a regulatory term from the Medical Device Regulation (MDR 745/2017).
- **Medical Domain:** This category describes in a nutshell the overall CDSS
- **Matureness** If the CDSS is not a medical device it could be an idea or a prototype from research
- **Goal of the System:** high level description of the purpose if there is no intended purpose described

The ***Ethical implications*** are ethics and social aspects to be discussed:

- **Ethical dimension**, e.g. responsibility, autonomy, transparency, trust, privacy, justice/fairness, caring
- **Decision and data transparency** raise the question of whether the decisions of the applications are clear and transparent to the user. Does the user know on which data basis the application is relying? Does the user know with which rules and above all reliability the system works, and the final results are achieved?
- **Impact on role and self-perception** bring up the question of whether CDSS change self-perception in terms of competence and self-image through applications that may be "better" than human decision making.
- **Impact on doctor-patient relationship** raises the question of whether CDSS change the doctor-patient relationship in terms of competence of the application and how it is perceived in the doctor-patient relationship.
- **Educational Impact** Are CDSS changing the way we need to educate doctors and nurses?
- **Impact on employment structures**: Will CDSS change the way we work in health facilities?

Legal implications refer to the legal and regulatory requirements.

- **Regulatory Aspects** (e.g. Medical Device Regulation): The development of medical devices is subject to regulatory requirements. The general safety and performance requirements must be fulfilled (addresses patient safety).
- **Privacy**: Are personal data (mostly those of the patient) sufficiently protected according to the law?
- **Performance** means the ability of a product to fulfil the intended aim or stated goal of the CDSS;
- **Risks**: What risks can the CDSS pose to humans, animals, and the environment? How high is the harm and the occurrence of an adverse event caused by the CDSS?

The ***technical aspects*** describe everything about the technology of the CDSS.

- **Method** describes the methodological basis on which the CDSS was developed. Whether it is a self-learning AI or contains a guideline-based rule set.
- **IT-Security, Data Protection** describes whether the data is safe e.g. from attacks.
- **Used Technology** describes whether the CDSS is an app or a desktop application (e.g. webservice) and whether there are other technological aspects that are relevant.
- **Components** such as hardware or additional systems that interact with or are included.
- **Users:** the ones who interact directly with the system. (e.g. medical staff, patients)

Human-machine interaction is a relevant category because ethical aspects and e.g. risks can be derived from the interaction.

- **Representational Layer**: the GUI but also the presentation of the data and the design are shown here.
- **Use Scenarios/User Story** describes the process of interaction in steps to clarify the interaction.
- **Use errors, Risks, Hazardous situations**: Based on the use scenarios, use errors and their effects can be determined.

3.3. Conclusions out of the three case studies

In the DESIREE project there were three cases, where we applied the developed categories: Case 1 describes the MeSiB system to give people in home ventilation more security through a safety box in case of disconnection of the ventilation tube or power failures. Case 2 describes an app to help physicians create personalized treatments for patients with kidney disease (https://ckdn.app/). Case 3 "Surgery of the future" is a support system designed to assist the surgeon in making the correct incision during an surgery.

All three cases were research projects. In order to work on all criteria, direct contact with the researcher or manufacturer is needed. Since all contacts to the researchers were available in this project, it was possible to apply all categories. Without this contact or a real user, the concrete description of the human-machine interface and underlying technology is not possible. Moreover, the impact of these systems is so diverse that an interdisciplinary team should work on the cases. Otherwise, there is a danger that a certain bias will occur. Not only interviewees, but, also interviewers (from different scientific fields) tend to stress risks, e.g., concerning data privacy and data protection.

4. Discussion

The systematic case study of three cases in the DESIREE project aims to describe the use of a CDSS more grounded in the context of regulation, ethics, and human-machine interaction. The methodology for the description should promote the understanding of the CDSS and serve as a basis for the development of a vignette for scientific investigations in the fields of social research, ethics, and innovation research.

The ethical aspects are a central part of this research. The regulatory aspects address many ethical dimensions such as responsibility or autonomy. Furthermore, it could be possible to include other ethical assessments such Meestar [4].

The legal and regulatory aspects such as the Medical Device Regulation (MDR), patient safety, and risks were considered crucial for a comprehensive picture of a socio-technical system. The legal frameworks are deeply linked to the ethical considerations.

This interaction is often safety-critical and is closely linked to acceptance criteria but also contain hazards for users. These hazards often relate to use errors, which should indicate what happens in the event of an error. But, often products only show the "happy path" and in research projects, there is often no risk management according to ISO 14971 and DIN EN 62366.

This research looked into three different cases resulting in a more in-depth view of the respective CDSS or AI application. Thus it should serve as a basis for further socio-technical research.

Contributions of the authors

ML: conception, design, writing, data analysis and interpretation, ADK: data collection, analysis and interpretation, revision, RR: data interpretation, revision. The DESIREE study group are from Fraunhofer-Institut für System- und Innovationsforschung ISI, Karlsruhe Tanja Bratan, Heike Aichinger, Nils Heyen, Diana Schneider. Institut für Ethik, Geschichte und Philosophie der Medizin, Medizinische Hochschule Hannover Sabine Salloch, Florian Funer. Evangelische Hochschule Rheinland-Westfalen-Lippe Martin Langanke, Wenke Liedtke

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