A method for patient inclusion for audio and video recordings in healthcare studies

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Abstract

With the increasing administrative burden and shortage of healthcare staff, there is a growing need for an intelligent solution. Care2Report is such a solution that aims to automatically report a medical consultation with the help of speech recognition by audio (and video) recording a consultation. To train and improve the Care2Report system, much more data from different healthcare domains is needed. There is no suitable existing method to gather such recordings ethically and concisely. This research proposes a method to gather informed consent for audio and video recordings in healthcare studies called the PaCAR method. The PaCAR method was constructed by using a design science framework and is presented by means of a Process Deliverable Diagram and multiple Business Process Models. The problem environment was investigated by means of a literature review and observations. We designed the treatment based on observations and a case study including two protocols from Nivel and Monash University. The treatment was then validated and improved during a case study at the University Medical Center of Utrecht at the Pre Operative Screening outpatient clinic where patients come to get a screening when they will undergo surgery in the not-too-distant future. During two months, 143 recordings were made with a 90% consent rate. It was found that the number of days patients had to consider their participation had a significant relationship with their willingness to participate ($p=0.035$). Before starting with the case study, a number of agreements needed to be made and courses needed to be completed, this research extensively elaborates on those. All responsibilities and the ownership of the different deliverables are explained. The PaCAR method can be used to obtain audio and video recordings from a research point of view.

Keywords: PaCAR method, AV recordings, Informed Consent, Patient Inclusion, Case Study, Process Deliverable Diagram.

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List of Acronyms

AI	Arti cial Intelligence
ASA	American Association of Anesthesiologists
ASR	Automatic Speech Recognition
AV	Audio and Video
BPMN	Business Process Modeling Notation
CBS	Central Bureau of Statistics
CIP	Central Introduction Program
CP	Care Provider
C2R	Care2Report
DoH	Declaration of Helsinki
DPIA	Data Protection Impact Assessment
DVF	Vital Functions Division
ECG	Electro Cardio Gram
EMR	Electronic Medical Record
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
GP	General Practitioner
GVL	Health Questionnaire
HiX	Healthcare Information eXchange
IC	Informed Consent
IEC	Independent Ethics Committee
ICH	International Conference for Harmonization
IRB	Institutional Review Board
LTC	Long Term Care
METC	Medical Ethics Review Committee
MRQ	Main Research Question
OR	Operating Room
PaCAR	Patient Consent for AV recordings
PIF	Patient Information Form
POA	Practice Assisting Doctor
POS	Pre Operative Screening
RFS	Research Folder Structure
RQ	Research Question
SLR	Systematic Literature Review
TC	Telephone Consultation
UMCU	University Medical Center Utrecht
UU	Utrecht University
WER	Word Error Rate
WKZ	Wilhelmina Childrens Hospital
WMO	Law on Medical-Scienti c Research with Humans

1 Introduction

With the increasing administrative burden and shortage of healthcare sta , there is a growing need for intelligent solutions. The administrative burden in healthcare is de ned as \the perceived burden an individual has with the implementation of the policy" [1]. Within the healthcare sector, medical documentation is an important part of a health professional's working day, it has several important functions within the treatment process of a patient [2]. A large part of medical documentation and one of the sources of the huge workload is the reporting on care provided to individual patients. This includes activities such as recording data from the anamnesis, drawing up care plans, writing reports, and making transfers. Most of these actions take place in the patient's Electronic Medical Record (EMR) [3].

An EMR is an organizational system that contains longitudinal electronic records of a patient's health information generated by one or more encounters in a medical setting [4], [5]. These EMRs have been developed with the intent to improve the communication between Care Providers (CPs) and to capture medical history, treatment, and observations [6]. An EMR typically includes information such as patient demographics, problems, progress notes, vital signs, past medical history, medications, immunizations, laboratory data, electrocardiograms (ECGs), and radiology reports. The EMR is designed to automate and streamline the clinician's work ow [4]. Documentation in the EMR is critical for patient care coordination, as well as for hospital revenue and clinician reimbursement [6]. Data appearing in the patient's documentation, theoretically, are required for making an accurate diagnosis and optimally to treat the patient [7].

Documenting all this information consumes a lot of time, healthcare professionals spend 3 to 4 hours up to 65% of their working day creating medical reports [2]. Despite all the improvement initiatives, this burden has only increased in the past decades [8]. Writing notes in a patient's EMR ranges from simple and quick, to complex and time-consuming. The complexity and length of time it takes a CP to document a patient encounter depends on what the patient is being seen for, when they were last seen, the prior relationship between the patient and CP, and even the experience of the CP [9].

In England, for example, 84% of General Practitioners (GPs) described their administrative workload as excessive, and only one in ten stated their workload is manageable and allows them to guarantee safe care of good quality. This caused 38% of primary care partners to consider closing their practice [9].
In a study on Dutch Long-Term Care (LTC) it was found that 82% of respondents experienced their administrative tasks as a burden, and only one out of ten indi-

cated that they did not experience an increase in their administrative workload [10]. The administrative task that CPs spend the majority of their time on was most commonly identi ed as the EMR, and even though this is part of the care process, it can be organized more e ciently [10].

In addition to being time-consuming, manual reporting in the EMR has other disadvantages. Patients have expressed concerns about CPs potentially becoming distracted by the computer during consultations and have been observed to stop talking whenever the CP was typing into the EMR. CPs reportedly spend approximately 43% of consultation time interacting with the computer. This time cannot be spent on interaction with the patient and can lead to a loss of emotional and psychosocial elements critical to the patient-doctor relationship [11], [12]. This results in challenges for CPs who need to interact with the EMR during consultations and highlights the need for a more e cient and less time-consuming method of reporting medical consultations [13].

1.1 Gap in knowledge

The challenges in the section above, ask for a better method to report patient consultations in the EMR. The amount of information that can be logically processed by humans within a limited time, is limited. This amount can be extended by the introduction of Arti cial Intelligence (AI) systems [7]. Willis and Jarrahi [9] propose a list of documentation tasks that are best performed by CPs and AI technology. This builds on human-AI symbiosis, suggesting that humans and AI serve complementary roles based on their unique and irreplaceable capabilities [14]. This implies that more e ective healthcare practices will most likely disclose a complementary partnership between medical professionals and AI technology [9]. Automatic Speech Recognition (ASR) is the use of AI technology or Machine Learning to process human speech into readable text [15].

In healthcare, speech recognition involves using speech input or dictation software as an alternative to typing medical notes. This allows spoken words to be converted directly into continuous text on an EMR or word processing program [2]. Speech recognition software signi cantly decreases the time taken to complete medical reports and already results in substantial savings in transcription costs in the radiology department [2]. Although speech recognition is faster, it is less accurate than using a transcription device. The mean word error rate (WER) of speech recognition software was higher than when medical notes were typed. Speech recognition was 66% less e cient than using a transcription service and, when the licensing fee was

included, costs considerably more annually. But, most of these studies are over 15 years old and ASR technology has developed signi cantly over this time [2].

The automatic subtraction of clinical meaning consists of extracting relevant medical information from the conversation between the doctor and the patient. This information can be used for automatic reporting into the EMR. The adoption of speech recognition in healthcare has been lacking speed due to the interference with doctors' normal way of holding consultations, the lack of support by hospitals, and nancial limitations [13].

According to Zuchowski and Geller [2], speech recognition software was found to be faster and more accurate than typing for completing medical documentation. The average completion time for a whole form was 5.11 minutes with speech recognition software, compared to 8.9 minutes with typing, resulting in a 43% greater time e - ciency. Additionally, the average error rate per line was 0.15 with speech recognition software, compared to 0.3 with typing. Despite these advantages, most respondents (55%) preferred to type their medical notes. They also found that users had low con dence in the accuracy of speech recognition software, with an average rating of 4.07 out of 5 from regular users, compared to 4.53 out of 5 from regular typers. Many respondents suggested that improvements, such as a mobile application, faster learning system, or medical-speci c vocabulary, would increase their acceptance of speech recognition software for medical documentation [2]. Speech recognition software has not yet been trained with the according medical-speci c vocabulary to support CPs in their medical documentation. To train ASR software with the right vocabulary, training data is needed. Recordings of medical consultations are used as training data. There is no usable method that can be used to gather these Audio and Video (AV) recordings. Therefore, a method is needed that explains all steps in detail so that researchers can follow this step-by-step resulting in training data in the form of consultation recordings.

1.2 Problem statement and objective

A solution that meets these requirements is Care2Report (C2R). C2R is a research program from Utrecht University (UU) led by prof. dr. Sjaak Brinkkemper from UU and prof. dr. Sandra van Dulmen from Nivel, the Dutch Institute for healthcare research [16]. C2R aims to develop a software platform for automated medical reporting to remove writing and typing to make notes during or after consultation or during interaction with a patient. With the help of speech recognition technology, an attempt is made to automate medical reporting [17]. As a solution to the well-known issue of the administrative burden in healthcare, C2R strives for automated

reporting in healthcare. The goal is to automatically generate medical reports of patient-doctor interactions in compliance with medical guidelines without disrupting the current way of working [18]. The C2R research program is executed by Ph.D., Master's, and Bachelor's students from UU. Every thesis helps to gain new insights and knowledge for the platform.

The current prototype of C2R is based on one case study on External Otitis. More research and experiments in di erent medical domains are needed to extend the prototype. There is no proper way to conduct this kind of research including recordings of medical consultations, and therefore a method will be developed to propose a method for future research . This method is called the PaCAR method (Patient Consent for A V R ecordings). The method is based on a case study in the University Medical Center Utrecht (UMCU) at the Pre Operative Screening outpatient clinic in collaboration with the Digital Health department. We will look into the process of recording Pre Operative Screening (POS) consultations and propose the rst version of a method based on the procedures of this clinic.

2 Research Questions and Method

This section describes the Research Questions (RQs) and the research design and methods used to provide an answer to the RQs. This includes design science, a literature study, case studies, observations, and hypotheses testing.

2.1 Research Questions

In order to address the knowledge gap and accomplish the research objective, the following Main Research Question (MRQ) was formulated:

MRQ: How can patients be included in medical consultation studies to obtain patient-consented recordings for research?

The answer to the MRQ will propose an integral method for the procedures of upcoming studies that include the recording of medical consultations to expand C2R's scope.

The MRQ was decomposed into the following RQs. An overview of the RQs and how they are positioned in the process is presented in Figure 1.

RQ1: How can patients be included in medical consultation studies?

The first step of executing a medical consultation study is the inclusion of patients. The procedures of including patients in medical trials and observational studies are studied and literature about the most effective ways to include patients and Informed Consent is combined to compose a complete answer to RQ1.

RQ2: What are the procedures in the case study environment for performing medical consultation studies at a hospital?

The first RQ concludes the beginning of the study process. It is important to explore the whole process and what the procedures in our case study environment are for conducting such medical observation studies in hospitals. We investigated all procedures at the POS outpatient clinic.

RQ3: How can patient groups be identified for inclusion in medical consultation studies?

Subsequently, it is important to know which patients can be included in the study. Eligibility criteria in previous similar studies that researched ASR in medical trials were explored and the specific characteristics of patients that regularly visit the concerned department of the hospital were investigated.

RQ4: What factors determine a patient's willingness to participate in a medical consultation study involving AV recordings?

During the informed consent process, a lot of factors can contribute to a patient's willingness to cooperate in a study. We investigated which factors had a significant relation with patient willingness.

RQ5: How can patient-consented recordings obtained during medical consultation studies be processed?

The process will be concluded with the processing of the recordings. It is important to examine the guidelines for this, if there is a standard way, which stakeholder is responsible, and how privacy is guaranteed.

An answer to these RQs will be constructed with the help of design science, a literature review, a case study, observations, and hypotheses testing. These methods will be further explained in Section 2.2.

Figure 1: Research Questions.

2.2 Design Science Framework

Design science is the design and investigation of artifacts in context. An artifact can be a method, technique, conceptual framework, or algorithm that is designed to improve the problem context. The problem context consists of a design problem where it is not yet known which solution is useful in a certain situation [19]. The design problem that we will tackle in this study is the fact that there is no good

method for executing a study that includes the recording of patient consultations in a hospital.

Design science consists of multiple phases, as can be seen in the engineering cycle in Figure 2 by Wieringa [19]. The design cycle can be decomposed into three activities: the problem investigation, the treatment design, and the treatment validation. The treatment can eventually be implemented but this is not always part of the design cycle. The problem domain must be investigated, the goal is to examine what needs to be improved before designing the artifact. This phase will be concluded with the identi cation, description, explanation, and evaluation of the problem that needs to be treated. This is the input for the next phase, the treatment design. In the treatment design phase, one or more artifacts are designed that could treat the problem. In the treatment validation phase, the design is validated to see if it would e ectively address the investigated problem. Does the design contribute to the goals of the stakeholders if it is implemented? This iterative cycle forms the base of every design science project. The result is a validated treatment that can be used in the real world. The transfer of a validated treatment to the real world to evaluate the treatment that is captured in the treatment implementation phase forms the engineering cycle [19].

Figure 2: The engineering cycle [19].

2.2.1 Problem investigation

To investigate the discovered design problem, we started by investigating the problem in the problem investigation phase. Here, knowledge questions about the artifact were asked, the problem context, and the interaction between these two. This returns knowledge to the design problem-solving activity [19]. To investigate the problem that there is no suitable method for executing a study that includes the

recording of patient consultations in a hospital or care institution a literature study and observations were conducted to give a good overview.

Literature A Systematic Literature Review (SLR) and an Integrative Review were conducted to give answers to respectively RQ1 and RQ2.

Systematic Literature Review An answer to RQ1 has been opposed by an SLR. The search process was executed by performing a manual search in di erent databases. The databases used were Google Scholar and PubMed. Titles and abstracts were initially screened, and then the results were consulted to decide whether to include a certain study. The rst criteria were that studies must have been written in English, must be about the informed consent process, and preferably be published after 2010 and before 2023. To give a more holistic overview of the history of informed consent, a few earlier studies were also included.

Articles were included if they reported on the e ectiveness of a certain informed consent form, if they studied the informed consent processes of studies in the healthcare sector, and preferably if they had something to do with audio and video (AV) recording within the medical studies that the informed consent process was for. The last criterion was not realistic, since there is not a lot of research about this, therefore it was a preference.

As can be consulted in Figure 3, 67.000 articles were found in the initial search of PubMed and Google Scholar. This gure has been based on Farshidi et al. [20]. After re ning the search terms and scope, 1013 articles were left. After ltering on relevance, 223 articles were screened on the title, leaving 85 articles to screen on the abstract. These screenings resulted in 25 studies with which the literature review was conducted.

Figure 3: SLR diagram.

Integrative Review A partial answer to RQ2 has been opposed by an integrative review. An integrative review can be used to assess, critique, and synthesize the

literature on a certain topic in a way that enables the creation of a new theoretical framework. This is usually done to address new, emerging topics and create a preliminary conceptualization or theoretical model. This kind of review results in the advancement of knowledge, rather than a simple overview or description of a research area [21], [22]. The search process was a manual process in Google Scholar. A broad review of bias in ASR was conducted. The focus of the review was on medical text and healthcare, and on the Dutch spoken language.

Observations To investigate the current situation at the UMCU at the POS outpatient clinic, an initial observation was performed by each of the four involved researchers. Each researcher observed two or three consultations. When a patient has to undergo a surgical operation an anesthetist has to determine which sort of anesthesia the patient will receive. This has to be established during a conversation in which the patient will be asked a number of questions about their health and preferences. This conversation will be referred to as the POS consultation.

The consultations were observed to get a better idea of how these screenings are done in practice. A consultation can be done either by phone as a Telephone Consultation (TC) or as a physical consultation at the outpatient clinic. Both were observed by the researchers and multiple doctors were observed to get the full picture of how POS screenings are performed.

On top of observing a number of consultations, multiple informal conversations and meetings were held with the head of the outpatient clinic, drs. M. Marsman, about their processes and procedures with regard to clinical studies performed at the UMCU and the POS clinic. She gave feedback on the documents that were created and several matters were discussed in order to create a good method for this study.

2.2.2 Treatment design

To design the treatment to propose a solution for the investigated problem in the previous phase, we started by conducting a case study that consisted of two cases other than the UMCU. This proposed a method that then could be complemented with the observations performed at the UMCU to then propose a treatment that was validated.

Case Study To ll the gap in the literature on the informed consent process for medical studies including AV recordings, two documents were studied in an exploratory case study. This complemented the answer to RQ1 and the MRQ.

Nivel's Privacy Protocol

Nivel is the Dutch Institute for Research in Healthcare located in Utrecht. They focus on contributing to the quality and e ectiveness of healthcare in the Netherlands and Europe. In 1985 it started out as the Dutch Institute of General Practitioners and has since expanded its scope to cover the entire healthcare sector. Nivel collaborates with various stakeholders, including universities, patient organizations, and professional associations, to conduct independent and dedicated research. Nivel aims to answer a wide range of healthcare-related questions through its research and welcomes inquiries from organizations seeking answers to healthcare questions and strives to translate those questions into suitable research that is both useful and scienti cally rigorous. The organization consists of approximately 190 employees, including 110 researchers. Nivel's annual turnover in 2021 was 15.8 million euros. Nivel's mission is `Knowledge for better care.' The organization's core values include mission-driven research, digital innovation, and strengthening international networks and partnerships. Nivel's research is aimed at continuous improvement and innovation of healthcare, promoting participation in society, and ensuring a reliable healthcare system [23], [24].

The Nivel Healthcare Communication Database consists of around 18.000 video and audio recordings of consultation room conversations, recorded in both primary and secondary care, collected since 1975. These recordings aim to show the progress of communication between healthcare providers and patients and identify areas for improvement. The recordings provide valuable information for healthcare providers, patients, and policymakers. Improving communication in healthcare is a key objective of the database, as it enhances the patient's role and position in their own care. By analyzing the video recordings, healthcare policies can be evaluated and re ned to better re ect the actual communication dynamics in the consultation room. Strict privacy measures are followed when collecting the recordings. Written permission is obtained from all participants, and the recordings are stored securely and never shown publicly. The database covers a wide range of consultations across various healthcare professionals and includes everyday interactions, shared decision-making, and more. The anonymized observations from the database serve educational, informational, and supportive purposes for healthcare providers and policymakers. Nivel emphasizes the protection of privacy and ensures that all data received is anonymous and cannot be traced back to speci c individuals. Their privacy policy described exactly which data is used and how it is handled. On top of that the organization adheres to the Good Behavior Code, demonstrating its commitment to ethical data handling [25].

This privacy policy is the first document that was included in our exploratory case study. This document entails regulations describing the different responsibilities of parties, who administers the database, the purpose and contents of the database, how data from the database is processed, the rights of data subjects, the complaints procedures, the duration of the database, which measures are in place for database security, and which employees have access to which part of the database. This document does not go into detail about recruiting and informing patients. Nivel's privacy policy is publicly available, but they implicitly gave us permission to use the document for our research with the aim to generate a more general method.

Monash University's ECLIPSe project

ECLIPSe stands for Exploring Consultations with Low-Income Patients with Obesity and is a research project initiated by Monash University, Australia. The project investigates what makes an ideal consultation from the perspective of low-income patients who are living with obesity. ECLIPSe aims to unravel the inner workings of GP consultations by video-taping consultations between patients and exemplary GPs. Patients are then interviewed using a video-prompted technique that has been used in the Netherlands already. The research informs clinician training, particularly in the area of communication skills, and is the first step in making an Australian library of primary care consultations. Patients are asked if their consultation with their GP may be recorded. The camera will be situated so as to not show the patient's face in the video. Patients who consent prior to the consultation will be asked to complete a short survey before and after their consultation. The research team may contact the patient afterward for an interview about the consultation. They would watch the consultation and discuss elements that went well. The video recordings will be stored in highly secured computers that can only be accessed by the Primary Investigator (PI) and research staff that require access. The research team consists of seven people. Each patient is given a unique identifying code that will be kept on an electronic file that is maintained on a secure, password-protected network drive. Only the PI will have access to this code. For any future research, ethical approval will be needed to access the database of consultations [26].

The ECLIPSe documents consist of two parts. The first part contains ethical documents such as consent forms and explanatory statements for GPS as well as for patients. The second part contains the procedures for executing the project. These documents get into more detail about how to get consent from the doctor as well as from the patient that is being recorded. They also provide information about the instructions for recording and what equipment is needed. The researchers from the project have shared their documents with us to compare them with Nivel's policy.

The documents from the ECLIPSe project contain instructions for gathering informed consent and how medical consultations can be recorded. The policy from Nivel provides information about the processing recordings and the security and privacy aspects database containing such recordings. The documents complement each other and together provide a complete overview of all aspects we needed to consider in the method. Both documents in the case study were selected because we already had existing connections with Nivel as well as with the researcher team from the ECLIPSe project. We chose to perform an exploratory case study because this enabled us to gather information about existing methods as a prelude to further, more in-depth research and develop hypotheses while identifying a new method [27]{[29]. Both documents were studied and the di erent steps and contents were compared and complemented with each other. Meetings with the authors provided a good insight into the performance of the concepts and activities A Process Deliverable Diagram (PDD) was then created to propose a method for including patients in medical consultation studies. A PDD is a technique used to model activities and artifacts of certain processes [30].

2.2.3 Treatment validation

The treatment that was designed in the previous phase has to be validated, this is done with the help of observations and an hypotheses testing at the UMCU POS outpatient clinic.

Observations To give an answer to the question: 'What will be the e ects of the artifact in the problem context?' [31], the problem context was observed while testing the treatment design. The treatment is the designed artifact that proposes a method for recording medical consultations in the setting of conducting research.

To observe this, recordings will be made of patient consultations at the UMCU POS outpatient clinic. We intended to make AV recordings at the clinic, but due to privacy concerns and time constraints, this was not feasible for this project. Therefore we continued the project with audio recordings only. These recordings will be made according to the steps that are outlined in the designed method. The goal of this study is to make at least 100 recordings and store these in a secure and structured way that complies with guidelines and regulations. In order to train the model of C2R's software system, we were hoping to gather 300 recordings. This is a guideline based on 200 recordings to train the model, 50 recordings to validate the model, and 50 recordings to test the model [32].

After two weeks of recording and applying the method, the way of working was evaluated by the researchers and the head of the outpatient clinic. Based on this

evaluation, the method was improved and tested again. If needed, more evaluation sessions could have been done to keep improving the method. This was continuously done by open discussions and contact between the researchers while they applied the method.

Hypotheses Testing An essential part of the method consists of the informed consent process. This is the process of including patients in a study and informing them about the study. Based on the literature and UMCU guidelines, an informed consent form was made and used. This form could not be altered because it has to meet the requirements of the UMCU which are strict. Before a patient gives consent, they had to be called to ask whether or not they wanted to receive the Patient Information Form (PIF) to consider participating in the study. The PIF was, normally, sent by email. It was tested whether it makes a di erence in a patient's willingness to participate whether a male or female researcher approaches the patient.

These data have to be maintained by the researchers in speci c les in the Research Folder Structure (RFS) and are readily available after the recordings are nished. Hypotheses were tested to see if there are di erences in the willingness of the patient to participate in the study based on a number of independent variables. No variables were manipulated in these tests. The dependent variable is the patient willingness, which is represented by the fact that they do not (0), or do (1) give consent for recording their POS consultation. There were multiple independent variables that could in uence whether a patient gives consent. A few of these are the researcher's gender, the number of days the patient had to consider if they wanted to participate, the patient's gender, the patient's age, the type of consultation, and the patient's complexity. For these independent variables named above, the following null hypotheses have been drawn up:

H1 : There is no relation between the gender of the researcher who approaches the patient and their willingness to participate.

The research team consists of two males and two females. For each patient that we approached, it was noted who reached out over the phone and sent an email to the patient. The researcher's gender is either male (0) or female (1).

H2 : There is no relation between the gender of the patient and their willingness to participate.

The patient's gender is either male (0) or female (1) and was consulted from the EMR.

H3 : There is no relation between the age of the patient and their willingness to participate.

Age was grouped into six categories based on the literature. These are 18-29 years, 30-39 years, 40-49 years, 50-59 years, 60-69 years, and 70+ years. To see if there would be a di erence if broader categories are used, the categories 18-39- 40-59 and 60+ were also tested [33]. We decided to use the smaller categories because of the relatively high average age of the sample population. When using smaller categories, we could better interpret the results and draw meaningful conclusions.

H4 : There is no relation between the number of days a patient had to consider their participation and their willingness to participate

According to the literature, it is important to inform people beforehand so they have adequate time to actually think their decision over and to properly understand everything they are consenting to [34]. To test if the number of days the patient had to consider if they wanted to participate in our study had an e ect on the patient's willingness, we noted the day of approach and the day of consultation for each participant. With this information, the number of days was calculated.

H5 : There is no relation between the form of consultation and the willingness of the patient to participate.

A patient can have either a consultation over the phone (TC)(0) or a physical consultation (1). Consultations of admitted patients were excluded. The type of consultation is based on the patient's complexity but also on the patient's ability to visit the hospital.

H6 : There is no relation between the ASA classi cation of a patient and the willingness of the patient to participate.

Patient complexity is given by the doctor in the EMR and could be consulted by the researchers. This complexity is classi ed according to the ASA classi cation, ASA stands for American Society of Anesthesiologists [35]. This classi cation is split up into six classes that describe the overall physical condition of a patient as described in Table 1.

Table 1: ASA classi cation [35].

ASA 1	Normal healthy patients
ASA 2	Patients with mild systematic disease that does not have in uence on their daily functioning
ASA 3	Patients with severe systemic disease that does have in uence on their daily functioning
ASA 4	Patients with severe systemic disease that is a constant threat to life and life-threatening during surgery
ASA 5	Moribund patients who are not expected to survive without surgery
ASA 6	A declared brain-dead patient whose organs are being removed for donor purposes

For this test, only classi cations 1 to 4 were relevant. Patients with either classi - cation 5 or 6 will not be visiting the outpatient clinic but the doctor will visit them at the clinic where they are staying. There were more independent variables that we did not expect to be signi cant or relevant, but they are noted and will also be tested to rule them out at the request of the clinic. These variables are the type of doctor (general and speci c categories), and the day of the week the consultation took place.

Data were analyzed with SPSS. Descriptive statistics were used to summarize the participant's data and the hypotheses were tested using binomial logistic regression and Chi-Squared. Based on these tests a prediction was done for future informed consent processes. The hypotheses are visualized in Figure 4.

Figure 4: Hypotheses testing.

The research methods and design cycle phases are summarized in Table 2.

Table 2: Research methods within design science.

Method	Problem Investigation	Treatment Design	Treatment Validation
Literature	X		
Observations	X	X	X
Case Study		X	X
Hypotheses Testing			X

2.3 Threats to validity

There are several threats to the validity of this research.

2.3.1 Conclusion validity

Conclusion validity demonstrates that the operations of a study such as the data collection procedure can be repeated, with the same results [36]. For this study, a protocol was made that had to be strictly followed by the researchers. The resulting data can be assumed to be valid as well as the findings. A threat to the conclusion validity was the extent to which the researchers would adhere to the protocol and how well they were informed about the protocol. Apart from that, the study was conducted in a limited environment where the context of each independent result is comparable.

2.3.2 Internal validity

Internal validity seeks to establish a causal relationship, whereby certain conditions are believed to lead to other conditions [36]. For your conclusions to be valid, you need to be able to rule out other explanations for the results [37]. A threat to the internal validity was the selection of the participants. The patients were selected based on the researchers' planning and had a consultation at the outpatient clinic of an academic medical center which is not a general hospital. To counter this threat, the sample size had to be rather large so that any variability in the results was less likely to suffer from the sampling bias.

2.3.3 Construct validity

Construct validity is concerned with how well the operational measures for the concepts being studied are identified [36]. Since the concepts that are measured for this study are observed directly and are not operational, there are no threats to the construct validity [38].

2.3.4 External validity

External validity is the extent to which a study's findings can be generalized to other situations, people, settings, and measures [36], [39]. Threats to the external validity of this study were the sampling bias and the situation effect. The sample of this study is patients of the POS outpatient clinic of the UMCU. Different kinds of patients visit this clinic, but the clinic is only slightly comparable to other disciplines in healthcare. The outpatient clinic is part of an academic hospital, which is not a regular hospital and it could be that the patients visiting the UMCU have more complex health conditions. Apart from this, the UMCU is a rather large hospital, so it can be assumed that all healthcare disciplines are represented.

3 Background

This section gives some necessary background information about the administrative burden, the C2R research project, and Automatic Speech Recognition to better understand the following sections of this thesis.

3.1 Administrative burden

Healthcare professionals in all sectors experience a high administrative burden. They spend more than 40% of their working time on administrative tasks. Despite all the improvement initiatives, this burden has increased in the past decades [8], [10]. The main purpose of administrative tasks within a healthcare setting is related to accountability, quality of care, epidemiology, and scienti c research [40]. Administration can be de ned as the systematic collection, recording, and processing of data aimed at providing information to achieve desired purposes or objectives [41], [42]. The administrative burden involves the collection, processing, registration, storage, and provision of information required by a central government [8], healthcare providers, administrators, and sta spend excessive time and resources on this administration that is not directly related to patient care [43]. There are two types of administration in healthcare: patient-related administration and non-patient-related administration. Patient-related administration is, for example, writing reports, writing a care plan, or completing checklists. Non-patient-related administration is, for example, recording hours worked or recording reports of incidents. Tasks that are not directly patient-related are the processing of insurance claims, compliance with regulations, and using EMRs [8].

Various studies indicate that this is an international issue, for this thesis, the focus will be on the Netherlands. The Dutch Ministry of Healthcare indicates that the administrative burden is due to the interpretation of legislation and regulations by healthcare institutions and their employees. The legislation and regulations themselves can provide additional registrations in the actual time spent, but the experienced burden cannot be attributed to the legislation [8]. The Dutch population is aging, and the number of care recipients is subsequently increasing, therefore it is important that healthcare professionals can spend their time on patient care, instead of on administrative tasks [10]. In a Dutch study from 2019 where they investigated the administrative burden in LTC, professionals indicated that they think spending 23% of their time on administrative tasks is acceptable. Six out of ten respondents indicated that they experienced an increase in the administrative workload and 82% state that they experience their administrative tasks as a burden [10].

In a study by Christino et al. [44] it was found that out of 1515 respondents, 92% reported that documentation obligations are excessive, that the time spent with patients has been compromised by this (90%), and that the amount of clinical documentation has had a negative e ect on patient care (73%). Most respondents reported feeling rushed and frustrated because of the documentation demands. Respondents reported spending signi cantly more time on clinical documentation than on direct patient care [44]. It was found that 88% of the respondents reported that they could provide better quality care if clinical documentation demands were reduced and 93% reported feeling frustrated with the amount of documentation they were expected to complete. 78% of respondents estimated spending more than 41% of their working time on clinical documentation and 43% reported that the EMR negatively a ected direct patient care by reducing time with patients [44]. Professionals with 0-4 years of working experience in healthcare, experience the least time spent on administrative tasks (33%), this is possibly due to their age and better digital skills within this relatively new group of employees [10].

Although the burden is increasing, the acceptance rate of this burden by healthcare professionals is also increasing. This issue has a severe impact on the functioning and job satisfaction of healthcare sta and appears to be one of the reasons for resigning and the high turnover rate of healthcare personnel [10], [41]. The administrative responsibilities may also contribute to burnouts. In a survey of 2000 physicians, 87% of respondents reported that the leading case of work-related stress and burnouts was paperwork and administrative concerns [45]. The administrative burden is seen as one of the main reasons that less time is available for primary care and leads to decreased e ciency and increased costs [43]. Additionally, it can make healthcare less accessible and less a ordable for patients [41], while the volume of care is expected to continue to increase [46].

Respondents mostly named the EMR as the administrative task on which they spent most of their time. Even though this is part of the care process, it can be organized more e ciently. The following suggestions for improvements were made by respondents: less search and click work in the EMR and fewer double actions in the EMR. There are a lot of double items in the EMR and some things have to be done both on paper as well as digitally [10].

3.2 Care2Report

As stated before, C2R is a research program from UU led by prof.dr. Sjaak Brinkkemper from UU and prof.dr. Sandra van Dulmen from Nivel [16]. C2R aims to develop a software platform for automated medical reporting to remove writing and typing

during or after consultation or during interaction with a patient. With the help of speech recognition technology, an attempt is made to automate medical reporting [17]. The goal is to automatically generate medical reports of patient-doctor interactions in compliance with medical guidelines without disrupting the current way of working [18]. Some recent projects are working on reducing the Word Error Rate (WER) in transcripts [47], and signaling yellow flags in transcripts [48].

3.2.1 Technical details

The current approach encodes the core information of the patient-doctor dialogue as a set of semantic triples. Natural language generation techniques are then used to convert a selected subset of triples into natural language text. This two-stage approach allows an accurate representation of the consultation by combining the information in the dialogue with the objects and actions recognized by other system components [49].

The C2R process consists of three stages which are pictured in Figure 5. These are [49]:

1. Multimodal recording
2. Formal interpretation
3. Report generation

In the first phase, the audio, video, and sensor input data are preprocessed and then transformed into text, using speech and action recognition technology and a domotics analyzer. Then, in the interpretation phase, a formal representation of conversations, measurements, and treatments based on inputs is combined with semantic technology. In the third, and last phase, a generation of medical reports based on the medical domain practices, followed by report completion, checking by the CP, and uploading through a generic EMR interface is done [49].

Figure 5: Functional Architecture C2R [49].

3.3 Automatic Speech Recognition

ASR, also known as speech-to-text, converts spoken language into written language [50]. The development of ASR started with Audrey, the Automatic Digit Recognition machine, created at Bell Labs in the early 1950s. Audrey could recognize spoken digits between zero and nine with great accuracy [51]. In the following decade, IBM added six words to their Shoebox recognizer, enabling the machine to perform mathematical calculations. In 1976, the Harpy system was developed at Carnegie Mellon University, which could recognize over a thousand words. IBM's Tangora, developed in the mid-1980s, had a vocabulary of twenty thousand words. Dragon Systems developed DragonDictate, a dictation software that required users to pause after every word, which later evolved into Dragon NaturallySpeaking [50]. The subsequent decades witnessed rapid developments in ASR technology. In 2002, Microsoft introduced dictation in O ce and Google introduced voice-automated business search, followed by voice input for Google Maps and Google Search in 2008. In 2011, Apple introduced Siri, a voice assistant integrated into iOS, paving the way for other voice assistants such as Google Now, Microsoft's Cortana, Amazon's Alexa, and Google Home [50].

The basic components of most ASR systems are presented in Figure 6 adapted from Pervaiz et al. [52](p. 3).

Figure 6: Generic model of an ASR system. Adapted from [52].

To evaluate the accuracy of an ASR system, the Word Error Rate (WER) is commonly used as a metric. The WER is calculated by dividing the number of words in the reference transcript that do not match the words in the ASR output by the total number of words in the reference transcript. This calculation provides an estimation of how many words were incorrectly recognized by the ASR system [53]. The WER is calculated as follows [53]:

$$WER = \frac{(S + I + D)}{N} \quad 100$$

Where:

- S is the number of substitutions at word level.
- I is the number of insertions at word level.
- D is the number of deletions at word level.
- N is the total number of words in the reference.

4 Informed Consent

This section gives a comprehensive overview of the informed consent process and its origin. This overview provides an answer to RQ1: How can patients be included in medical consultation studies?

4.1 History of informed consent

One of the fundamental principles in healthcare law is informed consent, which requires that patients give their permission for medical treatment or participation in a medical study. Without this consent, there is a breach of the patient's autonomy and integrity [54]. Medical studies can be divided into two main categories: trials, in which the researcher intervenes to treat or prevent a disease, and observational studies, in which the researcher does not intervene and treatment is decided by the patient's healthcare provider [55], [56]. Participation in medical studies is voluntary and may involve testing of medical interventions, surgical procedures, and behavioral treatments [55].

The modern view of informed consent in scientific research has been greatly influenced by the atrocities committed during the Second World War under the Nazi regime in the context of scientific experimentation. The crimes committed against humanity at that time have permanently altered the way in which humans are involved in scientific research [57]. In 1947, the Nuremberg trials against the Nazis resulted in the formulation of ethical guidelines for research known as the Nuremberg Code [58]. This code contains the first written guidelines for scientific research and emphasizes the principles of voluntary participation and informed consent [58]. However, the Nuremberg Code was soon seen as inadequate, leading to the development of the Declaration of Helsinki (DoH) in 1964, which specifically addressed clinical research [59], [60]. Since then, the declaration has undergone several revisions to keep it up to date [59]. In 1979, the U.S. Department of Health, Education, and Welfare issued the Belmont Report, which acknowledges the existence of other codes but asserts that they may not be sufficient to address complex ethical questions. The Belmont Report's primary principles for ethical research are respect for persons, beneficence, and justice, and these principles are upheld through the use of informed consent, risk-benefit analysis, and appropriate patient selection [58].

Individual scientists were motivated by the DoH to write publications on informed consent. Beecher [61] was the first and most influential of these authors, emphasizing the need for informed consent but also warning that different forms of information are appropriate for different types of research [60]. He believed that while certain

rules and regulations may be necessary at times, they often do more harm than good. In contrast, Papworth was a strong supporter of principles and rights in research [62]. In 1972, the anthology of Katz et al. [63] was published, just before the notorious Tuskegee Syphilis Study was revealed [64]. In this experiment, patients were not informed about their condition and were withheld from e ective treatment. This and other instances of informed consent violations led to a shift in the discussion of codes regulating human biomedical research from private settings to the public sphere, resulting in a complex interplay between scienti c publications, journalism, public outcry, and legislation [60].

In recent years, there have been many misconceptions and lawsuits related to the informed consent process for medical research. For example, a plastic surgeon was found to have insu cient Dutch language skills to communicate e ectively with a patient about their desired results, leading to the determination that informed consent was not obtained. Because the care provided was closely tied to the patient's personal wishes, the board ruled that the surgeon had an increased duty to provide information [65]. In another case, an orthopedic surgeon was accused of performing an operation without obtaining informed consent, having insu cient experience to perform the operation properly, and causing the patient signi cant pain and limitations after the surgery. However, the regional disciplinary committee declared the complaint unfounded, stating that the surgeon had acted with due care by discussing the procedure with the patient. This decision was upheld by the Central Disciplinary Court [66].

In order for a patient's consent to be valid, they must be provided with adequate information. Therefore, before seeking a patient's permission, a medical specialist or researcher must provide the patient with information about the intended study or treatment. This obligation to provide information, along with the requirement of a consent form, make up the concept of informed consent [54].

Informed consent is the autonomous authorization by a patient or test subject to ensure their right to autonomy. The laws and regulations in the Netherlands adequately protect the rights of patients involved in scienti c research [60].

The informed consent process can take di erent forms, as Beecher noted [61]. We will explore this further in the following sections looking into the informed consent process in medical studies. Some medical elds have recognized the need for digitization in the informed consent process due to the administrative burden in healthcare [67]. Many hospitals and healthcare institutions around the world face challenges related to administrative burden in general. Marsman and van Klei found that in many cases, patients can independently give consent for anesthesia through digital

means, which saves time and e ort for doctors and patients [68]. This is particularly relevant given the overall shortage of healthcare sta [69].

4.2 Informed consent types and e ectiveness

Informed consent should be seen as a process, rather than just a document. There are multiple ways to conduct this process. Historically, the conventional informed consent process uses an information document, which lists all necessary information for a study. The study participants can then read this document, and discuss it with one of the study's experts who can provide clari cations. There are multiple guidelines for creating such an informed consent document [70]. More recently, other types of informed consent have gained popularity.

One of the rst studies to use a non-standard informed consent process was done in 1997 [71]. This study evaluated the e ect of a patient information video during the informed consent process of a medical study. Interestingly, no di erences in knowledge about the study were found initially, but 2 to 4 weeks later, more knowledge had been retained by the participants who had watched the video. The results suggest that a combination of a patient information video and an information sheet may result in greater participation in a research study and may increase knowledge of a speci c health problem and the related research study. A study by Hamajima [72] in the same year studied the rst use of video to assist the informed consent process in Japan. The use of video informed consent is tested against the use of a human explaining the informed consent (in this case a physician) for a clinical study. The results were inconclusive, though videos may be the preferable method of acquiring informed consent.

The use of video-assisted informed consent was also compared with a conventional informed consent document by Lin et al. [73]. The video-assisted method consisted of an educational video that illustrated the informed consent information, whereas the control group read an information document. The result of this was that patients who watched the video had a higher knowledge score, which means they had a higher level of comprehension of the provided information. Furthermore, there were signi cant correlations between video education and patient satisfaction [73].

Multiple di erent consent forms were compared by Glaser et al. [74]. They reported on a multitude of interventions in the standard informed consent process. Audiovisual interventions include videos, visual aids such as PowerPoint, multimedia presentations or anatomical models, posters and diagrams, audio, and video recordings. Fifty-six percent of these interventions improved patient comprehension compared to a standard informed consent document. A combination of standard

informed consent and audiovisual interventions proved to be more e ective, this approach led to 65% more patient comprehension than just standard informed consent. Furthermore, interactive digital interventions were also reported on. This includes computer, tablet, and mobile phone applications that had features that required active patient participation. Of these interventions, 85% resulted in improved patient comprehension compared to standard informed consent [74].

Another study by Rowbotham et al. [75] aimed to investigate the di erence in learning outcomes and time spent interacting with the informed consent artifacts. A standard informed consent paper was compared to an interactive presentation of the same information on an iPad device. The interactive presentation group scored better on a knowledge quiz after completing the informed consent process. Interestingly, this group also spent signi cantly more time on the process than the control group, with 22.7 minutes compared to 13.2 minutes [75].

Gesualdo et al. [76] have conducted a systematic review of digital tools in the informed consent process. They classi ed the tools into three categories: video-only, non-interactive multimedia, and interactive multimedia. Video was de ned as audio-visual content only. Multimedia was de ned as software that provided consent information in various combinations, including images, audio, video, and graphics. They were either navigated by the patient (interactive) or by the researcher as support during the explanation of the study (non-interactive). The studies looked at the understanding of the information, satisfaction with the process, and participation in the study. They found that digital technologies do not negatively a ect any of these outcomes. Furthermore, multimedia tools indicate a higher impact than videos only. Additionally, the presence of a researcher may potentially enhance the e cacy of di erent outcomes in research informed consent processes [76].

Based on these studies, we can conclude that:

- Video-assisted consent, combining patient information videos and written materials, improves knowledge retention and participant engagement.
- Audiovisual interventions (videos, multimedia presentations) and interactive digital tools enhance patient comprehension compared to standard informed consent.
- Interactive presentations on devices like iPads lead to better knowledge outcomes and positively impact understanding, satisfaction, and participation, although they may require more time.
- Multimedia tools show higher e ectiveness than videos alone, and researcher presence can enhance outcomes.

4.3 Informed consent for audio and video recordings in a healthcare setting

Many concerns have been expressed with regard to the patient recording a consultation. Healthcare professionals do not know where this recording will end up and if their privacy is guaranteed [77]. They reported feeling anxious or self-conscious about what they said when being recorded as well as being concerned that the recording would make the doctor-patient communication more formal, factual, or structured [78]. The possible in uence of observation on behavior is referred to as the Hawthorne e ect [79]. This e ect describes the change in behavior of research participants because of the attention they receive, regardless of the experimental manipulation [80].

Gaining informed consent for AV recordings can be done in di erent settings. Baren et al. observed this process in an emergency department [81]. A standard informed consent document was used, and potential participants were given the option to discuss possible questions and concerns. Of the 1609 people that were approached, 1312 (83%) agreed to participate. Of those 1312 participants, only 53% actually read the informed consent document, and only 13% spent more than 2 minutes reading the document. 20% of participants asked questions after reading the document, and 49% accepted a copy of the informed consent document when it was handed to them.

A study by Ram et al. [82] showed that people are often willing to give permission to be recorded during a GP consultation for research purposes. In this study, 85% of patients agreed to be recorded without being o ered any kind of incentive. This high level of participation might be explained by the detailed informed consent procedure, which reduced patients' fears that the recordings would be abused. However, 10% of the GPs that participated considered video recording to be a burden for patients.

This research focuses on recordings done by a doctor or a researcher that are aimed at research purposes. Research involving audio recordings of consultations is both feasible and acceptable [79]. The patient has to give consent for their consultation to be recorded as expressed in Subsection 4.1. Central to the informed consent process for the recordings of consultations are the provision of information, highlighting the purpose of the research, reassurance with regard to security and con dentiality, and clari cation as to what procedures would be recorded [79]. It is important to consider that even if a researcher has obtained a patient's consent, the principle of non-male cence may command the CP at times to decide against recording a consultation if he or she regards the risk for the patient as too great [79].

In a literature study by Themessl-Huber et al. [79] in which they included 16 studies that included the audio recording of consultations, it was found that non-

participation rates for audio recordings ranged from 3% to 83% (mean = 26%; median = 22%). The willingness of patients to consent appears to increase with age and being recruited immediately before the consultation. Moreover, younger, distressed, or embarrassed patients have a reduced likelihood to consent to an audio recording of the consultation. There is no evidence that ethnicity in uences patient consent rates, the evidence on the in uence of sex or gender on consent remains ambiguous. Individual papers argued that patients were more likely to agree to audio than to video recording [79]. Participants in consultation recording studies also show minor variations in age and gender. Non-respondents were signi cantly younger, patient gender did not in uence the change of responding [83].

Patients whose consultation had been recorded felt only slightly or not at all in u-enced by the audio recording (97%) [79]. Another study by Wolderslund et al. [83] supports this nding, less than 10% of participants reported negative e ects of their consultation being recorded. The recording of the consultation was also shown not to increase the length of the consultation [78].

A study by Kumarapeli, Pushpa, and de Lusignan [12] observed 163 recordings of GP pre-surgery consultations. Twelve patients (6.9%) declined to take part in the study, nobody withdrew their consent after the recording was done. It was found that over a quarter of the consultations had an additional person accompanying the patient (28%): mainly children or parents (75,6%). Computer use during the consultation was distributed as follows: 8% in the initial phase, 74% in the core phase, and 18% in the nal phase of the consultation. The presence of an accompanying person increased the length of the consultation (12:22 vs 11:37 min) and less computer use during the consultation (35.1% vs. 42.8%, p=0.003) [12].

Logistical components of supporting recordings of consultations include organized scheduling, informing patients of the bene ts of recordings and their options, ensuring the recording equipment was functioning properly, obtaining consent to record, and ensuring the recording occurred despite time pressures [78].

4.4 Pitfalls of the informed consent process

Several factors in uence the acceptability and feasibility of people giving their consent for being recorded during consultations [34]. The main factors are insu cient time and understanding, lack of opportunity for discussion, lack of clarity on the study purpose, privacy concerns, trust issues, limited understanding of implications, challenges in decision-making capacity, super cial reading of consent forms, and the perception of the informed consent form purpose.

It is important to inform people beforehand so they have adequate time to actually think their decision over and to properly understand everything they are consenting to. Participants should also have the option to discuss their concerns with one of the researchers. Additionally, it is important to clearly state the purpose of the study, so people know what they are contributing to. Furthermore, the distribution of, and access to recordings should be informed on, so participants know their privacy is being respected. Adding to this, lms should be stored securely and should be deleted after use [34].

Mackenzie and Xiao [84] state that it is important to develop trust between the subjects and the researchers. This is especially important when videos of subjects are being recorded. Additionally, they argue that it is not always clear that a subject understands the implications of their consent. Therefore, the informed consent process must be done as best as possible. These ndings are con rmed by Convie et al. [85]. They state that it is di cult to gain true consent, because patients may not have the capacity to comprehend the complexity of the decision they are making. Furthermore, their physical state or anxiety can also impact their decision-making capability. They also argue that trust between the subjects and researchers is important. They state that patients have also stated that feeling informed and understanding was most important to patients [85].

Another problem regarding the informed consent process is study participants spend little to no time reading the informed consent form [81], [86]. This can lead to a poor understanding of what is actually being consented to. A possible explanation for this is that patients may perceive the informed consent form as a document to legally protect the researchers, rather than something to inform or protect themselves [86].

5 Current consultation procedures

This section gives an introduction to our case study environment. We introduce the UMCU and the anesthesiology department where the POS outpatient clinic is located. We describe all procedures we observed. This proposes an answer to RQ2: What are the procedures in the case study environment for performing medical consultation studies at a hospital?

5.1 The UMCU and anesthesiology

The UMCU is an internationally leading medical center in which knowledge about health, illness, and care for patients and society is created, tested, shared, and applied. The UMCU comprises the Academic Hospital Utrecht, the Wilhelmina Children's Hospital (WKZ), and the Medical Faculty Utrecht. The UMCU opts for pro ling on a select number of key points with a national and international reputation, in which top research and top care are integrated. For the region, the UMCU stands for modern acute care, solid specialist expertise, and a wide range of top referral positions. More than 11.500 employees work at the UMCU, including more than 400 residents from all medical specialties. The UMCU has about 1000 beds and annually there are around 30.000 admissions and more than 225.000 patients are treated [87].

The anesthesiology department of the UMCU is part of the Vital Functions Division (DVF). This division has four medical departments: Anesthesiology, the Intensive Care Center, the Emergency Department, and the National Poison Information Center. In addition, the operating room centers and the central sterilization department are also part of DVF. Approximately 65 sta members are attached to the anesthesiology department. All anesthesiological areas of interest are represented. The anesthesiology department provides high-quality pre-operative care for patients of all categories and provides support in the care of vitally endangered patients in the emergency department and other departments of the UMCU. The sub-department of pain medicine provides pain treatments for patients with chronic or oncological pain. Research within DVF is concentrated within the UMCU broad key points `Brain', `Circulatory Health, and `Infection & Immunity', and also actively contributes to research in the eld of medical education. The UMCU has three operating room centers. In total, the UMCU and WKZ, contain 35 operating rooms (ORs) and two hybrid operating theaters. Every year, approximately 25.000 surgical procedures are performed at the UMCU [87].

Figure 7: Map of the POS outpatient clinic at UMCU.

The anesthesiology department is located on the second oor of the hospital near the head entrance. A map of the POS outpatient clinic at the anesthesiology department is shown in Figure 7. This map enhances both the generalizability and ease of interpretation of the method. The method is predominantly designed concerning the environment illustrated in Figure 7. When employing the method in diverse environments and scenarios, researchers can compare those circumstances to the original setting upon which the method was constructed. This is particularly bene cial for researchers who lack medical training or orientation and possess limited familiarity with the layout of hospitals or outpatient clinics.

When a patient comes in, they have to report at the counter of the POS, number 1. The rooms that only employees can enter and have nothing to do with the patient's route will be explained here. The other rooms concerned with the patient's route will be discussed in Section 5.3.

6. O ce of the medical head of the department : This is the o ce of the medical head of the clinic and the team leader of the clinic.
7. POA o ce : This is the o ce of the POA (Practice Assisting Doctor) and where the day start takes place. During this 'day start', the important notices are shared and any particularity is shared. The ongoing research at the clinic, such as C2R, will shortly be mentioned and any other comments are shared with the team of that particular day. In the end, the person who presents the day start will count how many employees of which functions are present, for example, two screeners, one pharmacist, etc.

8. General office space and lockers : Connected to the POA office is a regular office space where anyone can work and where the lockers of the regular staff are also located.
9. Front office medical secretaries : The secretary's office is shared with the pain outpatient clinic. The front office takes care of incoming patients that have a physical appointment at the clinic.
10. Back office medical secretaries : The secretary's office is shared with the pain outpatient clinic. The back office mainly handles incoming calls from patients and other clinics in the UMCU or from other hospitals and takes care of the planning of the screenings at the clinic.
11. Staff canteen : When employees want something to drink or eat or have a small break, they can do this in the staff canteen.
12. Staff toilet : Toilet for staff of the clinic.
13. Storage space : Storage space for employees and belongings of the clinic.

In Appendix A some images are available of the clinic to give a better picture of the clinic.

5.2 Pre Operative Screening

Screening for anesthesia takes place at the POS outpatient clinic. Patients who will receive an operation in the not-too-distant future need to be assessed before their surgery by an anesthesiologist to decide on the anesthesia the patient will receive during the operation. From now on, for the sake of conciseness, we will refer to the anesthesiologist or screener as `doctor'. One of the most important goals of the consultation is to get an impression of the general condition of the patient to be operated on, which is important because the preoperative health status is related to the recovery possibilities after the operation and the occurrence of complications. The second purpose of the screening is to estimate a patient's anesthesia risks. An assessment is made as to whether a patient's state of health permits anesthesia to be performed. The patient's clinical data is noted in the EMR by the doctor, including medication use, information about the operation and admission, specific measures, and any requested consultations to get the patient in optimal condition. Thirdly, the correct anesthesia technique is chosen at the POS in consultation with the patient. The preferences of the patient are taken into account as much as possible. Subsequently, a summary and a conclusion of the pre-operative process are noted in the EMR. The final purpose of the POS is to inform, instruct, and reassure the patient. The doctor informs the patient about the method of anesthesia and

possible related complications and records this in the EMR. Undergoing surgery is very stressful and anxious for some patients. To prevent this, it is crucial to provide clear explanations and instructions for the operation [33].

It is the doctor's responsibility to guide the patient safely and as comfortably as possible through the pre-, peri-, and post-operative or procedural processes. The anesthetist acts immediately if vital functions are threatened. During surgery, but also in intensive care, and in acute situations inside and outside the hospital. In addition, the anesthetist provides the treatment of acute and chronic pain and is part of the palliative team. The anesthetist ensures optimal preparation and supervision of the patient, coordination in the multidisciplinary treatment team, implementation of the appropriate anesthesia technique, pain treatment, and monitoring or support of vital functions [87], [88].

The screening ensures that the operation process is safer because patients know what is expected from them [89]. To proceed safely, for example, the `sober policy' for the operation is explained to patients. When all steps of the POS have been completed, the doctor will consent with the patient and the anesthetist gives their approval for the operation [3]. The above goals and tasks are a guideline, which gives each hospital the freedom to give its own interpretation to the POS.

Concluding, a POS consultation has four main goals:

1. Get an impression of the general condition of the patient to be operated on.
2. Estimate the patient's anesthesia risks.
3. Choose the correct anesthesia technique.
4. Inform, instruct, and reassure the patient.

5.3 POS procedure UMCU

When a patient needs surgery, their primary CP will register them at the POS outpatient clinic. The clinic will estimate in advance whether the patient needs to come to the hospital for an appointment, or whether this can be done via a phone appointment (TC). This depends on the type of procedure and the information known about the patient. A patient follows the following route (Figure 7):

1. Counter POS : When visiting the clinic, patients are seen by di erent employees. When they arrive at the UMCU, they need to report their presence at the counter. The medical secretary of the front o ce checks the patient's details. They check if the patient has lled in the health questionnaire (GVL) yet, if the patient has had their possible additional health checks, and answers any questions the patient has remaining

2. Computers for GVL : If the patient has not lled in the GVL yet, this can also be done at the clinic on paper or on one of the computers. This questionnaire provides the doctor with important information. For some patients, it is necessary to request data from other specialists to get a better assessment of the patient's health. In some cases, the patient needs to see a cardiologist to monitor the heart (ECG), see a pulmonologist, take a blood test, or take an x-ray. This will always be discussed with the patient [90].
3. Waiting room : After a patient has had their possible additional health checks and they have lled in the GVL, they can take place in the waiting room.
4. Pharmacy consultation rooms : Before undergoing the screening, each patient goes to a pharmacist at the clinic to get their medication and allergies veri ed and checked. After this check, the patient can return to the waiting room (number 3).
5. POS consultation rooms : When the patient has their appointment, the doctor has read the patient's EMR and the lled-in GVL. Then the patient will be called out of the waiting room into one of the consultation rooms.

During the screening by a doctor, questions will be asked in response to the questionnaire the patient has lled out. These will be about previous procedures, medication use, diseases, and allergies. The patient is asked to share any previous experiences with anesthesia and ask questions themselves. The heart and lungs will be listened to and the blood pressure will be measured. The doctor will take a look at the mouth of the patient to estimate whether a breathing tube can be easily placed on the patient during anesthesia. The doctor will then tell the patient which form of anesthesia the patient will receive and what the advantages and disadvantages are. Any risks will be discussed. The patient will also be asked for permission to give a blood transfusion. It will be explained how to prepare for the operation, such as how to be sober and which medications you may or may not take on the day of the surgery [90]. The national guideline is to stay sober before surgery, when it comes to drinking, the doctors at UMCU have been considering it ethical to deviate from the national guideline since January of 2023. Patients can continue drinking until they are taken to the operating room [91]. Questions about the operation itself can be directed to the doctor that is treating the patient [68]. The type of anesthesia depends on several factors. The patient's overall condition and the type of procedure are taken into account. The nal choice will be discussed with the patient [90]. When the screening is nished and the patient has no remaining questions, they can leave the clinic.

5.4 Consultation observations

The doctor has to prepare the consultation beforehand. They look at the GVL to see if there are any outstanding matters that need to be discussed with the patient, they look at previous screenings or procedures and if those had any complications. Then, the consultation takes place. It stood out some of the doctors were making quite a lot of notes in the EMR or on paper during the consultation and interacted with the computer frequently. During the consultation, the doctor first explains the goal of the consultation. Then, any ambiguity from the EMR is clarified by asking the patient questions. When needed, the doctor complements the questionnaire with the answers given by the patient. There are several things that are important to discuss during the consultation, these are not discussed in any particular order or step-by-step. If the consultation is at the clinic, the doctor also measures the patient's blood pressure and listens to the heart and lungs, this also needs to be filled in in the EMR immediately while this is also discussed with the patient. When the consultation is done, the doctor writes a conclusion about the patient's status and approves whether or not the patient is ready for their upcoming surgery, the procedure can also be put 'on hold'. This conclusion is the most important part and is used by the doctor on duty during the surgery. After the patient is gone, the doctor has to generate a letter for the patient and either send this via mail or print it out and hand it to the patient.

Other things that were noticed by the researchers during the observations were that the information about a patient can be found in several places in the EMR, this is in line with what we found in literature [10]. For example, information about medication is in the window of the POS screening, but more recent information can be found in the pharmacy window. There are also different tabs with categories that are important during a screening. The GVL in the EMR is also pre-adjusted by means of check marks, the doctor can supplement these during the screening. The doctor does not type that much into the computer but does check the EMR a lot to validate the information with the patient. The typing was mainly done after the patient left the room, in most of our observations.

Overall, the observations showed that everything the doctor types in the EMR is also discussed with the patient. And thus, an ASR system could transmit this information into the EMR while the doctor discusses it with the patient. The doctor would only have to check the information after the screening has ended to see if they want to add any information and to confirm the given information by the ASR system. The system would have to be able to filter by relevance, categorize utterances, and generate a short conclusion, the most important result of the POS consultation.

Concluding, our most important and outstanding observations are:

- The doctor takes notes and consults the EMR frequently during a consultation. This is mostly done to validate the information with the patient.
- The important subjects are not discussed in any particular order.
- Almost everything that the doctor types in the EMR is discussed with the patient during the consultation.
- Information about a patient is in multiple places in the EMR.
- The doctor almost always measures a patient's blood pressure and listens to the heart and lungs in case of a physical consultation.
- When the consultation is done, the doctor writes a final conclusion. This is the most important part of the EMR and the consultation. Thus, typing is mainly done after the patient has left.

The observed screening process is visualized in Figure 8 where we divided the consultation into three phases, the preparation phase, the consultation phase, and the summarization phase. In the preparation phase, the doctor prepares the consultation before the patient is in the room. During the consultation phase, the patient is in the room, and the summarization phase starts when the patient has left.

Figure 8: POS Procedure UMCU.

6 Patient selection

This section gives an overview of which biases exist in Automatic Speech Recognition and which patient groups are identified in hospitals based on literature. This is combined with expert opinions based on which we decided on the eligibility criteria. Then we explain the patient inclusion flow and demographics of our case study sample. This proposes an answer to RQ3: How can patient groups be identified for inclusion in medical consultation studies?

6.1 Literature

6.1.1 Patient groups in ASR

The presence of bias in ASR systems is a growing concern, as the system may perform worse on certain speaker groups. The WER is used for this qualification. Different types of biases can be observed in ASR systems depending on the systems used, the corpora applied, and the methods of training [92]. The following biases can be distinguished:

- Age (age bias)
- Gender (gender bias)
- Region (regional bias)
- Nationality / native language (non-nativeness bias)

Gender bias is the bias that has been under the most scrutiny recently, where male speakers' voices are recognized better in some cases, while female voices have a lower WER in others. Biases against children and the elderly have also been observed in some studies, where certain age ranges have a drastically worse WER [92].

The training set used for the models could account for the gender bias; however, even with a balanced data set, the results for some speakers are consistently worse. Depending on the data that was used to train the ASR system, the acoustics model specifically, speech by certain people tends to be recognized more accurately than speech by others. This difference in accuracy between various (groups of) people is called bias. The contemporary area of research into bias in ASR seeks to uncover sociolinguistic factors that negatively impact the recognition accuracy of ASR systems, and where possible, mitigate the bias [50].

Studies have shown that there are differences in performance between speakers of different ages, genders, regions, and native versus non-native speakers. In a study conducted by Feng et al. [93], a Dutch ASR model was found to have a bias against

gender, age, regional accents, and non-native accents. Female speech was better recognized than male speech and teenager's speech was the best recognized, followed by senior people's (over 65 years old), while children's speech was the words. The speech of native Dutch speakers was much better recognized than that of non-native speakers, irrespective of age. This can be caused by the fact that non-native speakers typically have an accent, meaning that the match with the Acoustic Model is worse than that of native speakers. Furthermore, no correlation was found between Dutch pro ciency level and ASR performance for non-native speakers. The speech of Flanders obtained the worst ASR performance and was worse than all regions in the Netherlands. Additionally, regional accents seemed to be stronger for older people than children and teenagers [93]. In a study by Chen et al. [94] results were found that support these ndings. They found that slight di erences exist in the recognition of voices from di erent racial groups, although the properties are similar and adequate for voice biometrics viewed from the nature of voice properties. They found signi cant di erences in voice characteristics in gender subgroups but found that for commercial ASR systems male speakers' performance was higher than for female speakers, and in open source ASR systems female speakers' voice was better recognized [94].

The speaking style was also found to in uence the size of the bias in ASR systems. Human-Machine Interaction speech was consistently worse recognized than read speech, which may be due to the fact that HMI speech allows for more speaker-dependent articulations and di erences in word usage, causing problems for the ASR system [93].

6.1.2 Patient groups in POS

Screening for anesthesia takes place at the POS. Patients are screened who will be operated on in the not-too-distant future [33]. In the Netherlands, over 1 million patients undergo surgery each year. The most recent numbers are from 2010 from the Central Bureau for Statistics (CBS) and can be consulted in Figure 10. In 2010, over 1.4 million surgeries were performed in the Netherlands. Since 1995, this number has been increasing over the years. In 2010, 43% of surgeries in the Netherlands were performed on males and 57% on females. Most surgeries were performed in the age category 45-65 (29.5%) [95].

In 2022, the UMCU had 235.433 unique patients and executed 29.847 OR treatments [96]. In 2021 they had 7.163 fewer patients, but 881 more OR treatments [97]. Compared to 2019, the year where there were no COVID-19 restrictions yet, there were 4% more patients in 2022 at the UMCU, and 42% more surgeries or OR

treatments [96], [98]. This shows that the number of surgical procedures at UMCU is growing over the years, which is in line with the data from the CBS in Figure 9.

Figure 9: Number of surgeries 1995-2010 [95].

Figure 10: Surgeries by age and gender in 2010 [95].

A thesis study by Hobert and Jannink [33] investigated the POS screening process at the Deventer Hospital in the Netherlands, which is a medium-sized hospital. They showed that for a patient between 40 and 60 years, a doctor schedules 10 minutes, for a patient over 60 years, 15 minutes are scheduled. Planning is based on age because the general rule is based on: the older the patient, the more complex the patient. However, this statement does not always apply, since patients spend an average of 39 minutes in the consulting room. This study included patients that were 18 years or older. Exclusion criteria were so-called readmission patients, these are patients for whom a valid screening still exists, which can be taken over. Patients undergoing eye surgery are also excluded, as they undergo a shortened screening. Per measurement day, the time of 25 patients is measured that they are present at the POS, which results in 250 measurements after 10 measurement days [33].

There is a list of factors based on literature from different Dutch hospitals that are patient-dependent that influence a POS consultation. These factors have an influence on the processing time and contents of patient consultations. These are the following factors [33]:

1. Medication - This extends the consultation time.
2. Heart conditions - Ten sub-questions must be asked about the heart condition, which extends the duration of the consultation.
3. Vascular diseases - Sub-questions need to be asked.
4. Coagulation problems - If they occur repeatedly and the patient takes medication for this, this is of importance.
5. Lung diseases
6. Diabetes - There is a special protocol for Diabetes patients that needs to be followed.
7. Kidney diseases - If the patient undergoes dialysis or is undergoing a transplant this influences the consultation.
8. Allergies or hypersensitivity
9. Nausea - If a patient is easily nauseous, they may be given additional medication to prevent nausea after surgery. This also requires additional explanation.
10. Muscle diseases - This often concerns complex patients with a lot of medication, which means that more data has to be processed in the EMR.
11. Back problems/Joint complaints/Rheumatism - These patients often object to a spinal anesthetic, which requires more explanation to the patient.
12. Sleeping problems - Patients with sleep apnea syndrome are often obese patients, which makes them more complex.
13. Bad experience with anesthesia -When patients have bad experiences with anesthesia, this requires more consultation time. The patient receives additional information to reassure them. In the EMR, the CP can see if the patient has had previous surgery, if so, they ask whether the patient has had bad experiences with these previous operations.
14. Used corticosteroids in the last six months - This prolongs the consultation as there is a protocol attached to this use.
15. Brain disorder - Patients with brain disorders are often more complex because of medication.
16. Nervous system disorders - Patients with nervous system disorders are often more complex due to medication.

17. Cor/heart disease - The doctor listens to the patient's heart to check whether there is a heart murmur, if so, it is necessary to schedule an extra consultation for the patient to make an ECG.
18. Pulmones - The patient's lungs are also listened to, if the doctor hears something strange, an extra consultation for a lung examination needs to be arranged.
19. Syndromes - These patients are often more complex and require additional care.
20. Wheelchair - These patients are often more complex and require additional care.
21. Loneliness - Lonely Patients often require more consultation time because they want to tell their stories. Loneliness is measured using the Loneliness scale that was developed by de Jong Gierveld and van Tilburg [99].
22. Dutch language - When a patient does not speak Dutch, it is more di cult to communicate with the patient, which requires extra consultation time.
23. Illiteracy - When a patient is illiterate, this takes extra time as all information has to be given orally, requiring letters to be explained.
24. Nervous/afraid of the operation - To reassure patients who are very afraid of the operation, extra consultation time is needed.
25. Many questions/curious - When patients have many questions or are very curious the consultation can take extra time to answer this patient's questions.
26. Education level - There may be a di erence in consultation time due to education level, this results in the eld of knowledge, information that needs to be explained, and asking questions. For example, when a patient works in a hospital, less information has to be explained to them.

Seven of these factors were found to signi cantly in uence consultation time according to Jannink and Hobert [33]:.

1. Medication
2. Diabetes
3. Muscle diseases
4. Bad experience with anesthesia
5. Cor/heart diseases
6. Pulmones
7. Many questions/curious

The UMCU POS outpatient clinic provided us with data they gathered in 2019. Throughout this year the clinic analyzed over 15.000 health questionnaires from all patients that had a screening at the clinic. This data was not published but was only used for internal planning purposes. This data provided us with the subjects that occur the most often in the clinic. In discussion with the head of the clinic about the di erent subjects, we came to a conclusion about several frequently occurring subjects during a POS consultation that complies with the list above. For example, 41.54% of the sample had visited a cardiologist before (N=4851), 86.01% had surgery before (N=10.615), and 39.64%)was under treatment by another specialist than the one the POS was meant for (N=4787).

6.2 Case study

6.2.1 Patient inclusion

Subjects were drawn from patients that visited the UMCU POS outpatient clinic for a screening consultation between the 7th of March and the 26th of April of 2023. It is not known how big the total population was. Inclusion criteria were that the patient had to be 18 years or older and they had a screening consultation planned at the POS outpatient clinic. The patient also had to speak Dutch. Patients were included based on the presence and planning of the researchers. Patients were excluded if they were under the age of 18, if they were mentally retarded, if they lived in an institution or had a supervisor, if the patient was deaf, or if the patient was admitted to the ward. The doctor will then visit the patient at that speci c department, so we cannot record them at the POS outpatient clinic. These eligibility criteria have been established in discussion with the medical head of the clinic and the medical secretaries of the back- and front o ce. Based on these criteria we ended up with a total population of 247 patients that could be approached by the researchers for inclusion in our case study.

All 247 patients were approached by the researchers by phone. After talking to the patients over the phone, four patients were excluded because their EMR was not up-to-date, and in deliberation with the patient, we concluded that the patient did not comply with our criteria. These patients were going to reschedule their surgery, did not master the Dutch language well enough, or had a supervisor that answered the phone. Twenty-eight patients could not be reached after multiple attempts by the researchers or due to a network error, these were also excluded. This left us with a sample population of 215.

Of these 215 patients, 199 gave permission to receive the PIF via mail (N=192), or through the post and the patient portal (N=7). Sixteen patients did not want to

receive the PIF and thus did not want to participate. Most patients did not give an explicit reason for not wanting to participate. Some reasons that were given were that the approach was too short before the consultation (N=2), that medical consultations are emotional matters (N=2), that the patient felt nervous and that a lot of things were unclear still (N=2), or that the patient did not feel able to understand what the study was about (N=2). For example, someone stated that \Consultations are an emotional matter, this cannot be done by a computer", and \I do not know what is coming at me, this is my rst screening and I think that is exciting enough". One patient did want to receive the PIF but reached out via mail to one of the researchers that they did not want to participate due to the fact that the study was performed by external people and that they would only want to participate when the study was carried out by hospital sta themselves.

We ended up with 198 patients that gave permission to ask them for their consent to record their consultation. Fifty- ve recordings did not go through due to di erent reasons. The doctor needed to call for the researcher so they could set up the microphones, nineteen times the doctor forgot to do this so the recording could not go through. Other reasons why the consultation could not be recorded were that the consultation was canceled or moved to another date outside of our presence (N=18), that the doctor did not give consent for recording the consultation (N=5), a technical failure (N=3), language barrier (N=2), the patient was admitted at the time of the consultation (N=1), the consultation was very di cult so in discussion with the doctor it was decided to not ask the patient for their consent (N=1), other reasons (N=1). One recording was made, but lost due to unclear reasons, this patient did give consent for the recording. For the other four recordings, it is unclear why they did not take place. The patient selection and inclusion process is presented in Figure 11, which is based on [100], [101].

This leaves us with 143 recordings. One patient was recorded twice and was also asked for consent twice. They did not receive the PIF twice, in agreement with the medical head this was not necessary.

Figure 11: Patient inclusion owchart.

6.2.2 Patient demographics

This resulted in a population of 247 individuals, we will discuss the demographics of the 160 patients that gave their consent or did not give their consent. Of this sample, 80 individuals were male (50%) and 80 were female (50%). The mean age of the sample was 55.64 (SD=16.37, Mdn=58). Age ranged from 19 to 83, with 65% of the individuals being over the age of 50. The birth country of the sample was 93.8% Dutch (N=150), 2.5% other European countries, 1.9% American, 1.3% Asian, and 0.6% African. See Figure 12 for the distribution of the sample population by age and gender. ASA score was measured from 1 to 6, our sample ranges from 1 to 4 and has a median score of 2. There were 15 missing values, for these patients, the score was not lled in in the EMR. Fifteen patients had an ASA score of 1 (10%), 76 patients has an ASA score of 2 (52%), 51 patients had an ASA score of 3 (35%), and four patients had an ASA score of 4 (3%).

Figure 12: Number of patients by age and gender.

7 The PaCAR method

This section provides the core part of the PaCAR method which mainly answers the MRQ: How can patients be included in medical consultation studies to obtain patient-consented recordings for research?

7.1 Process Deliverable Diagram

This subsection will highlight the informed consent process for studies that include AV recordings at Nivel, combined with the informed consent procedure for the ECLIPSe study at Monash University in Melbourne, Australia as explained in Section 2.2.2. For this purpose, a PDD was created, which can be consulted in Figure 13. A detailed explanation of the activities and concepts can be found in Appendix B.

The model starts with the Preparing phase . First, the research documentation needs to be created. This documentation consists of a non-WMO declaration, a Medical Ethics Review Committee (METC) Request, a Data Privacy Impact Assessment (DPIA), a Data Transfer Agreement (DTA), a Data Management Protocol (DMP), a Cooperation Agreement, a Research Protocol, and a Patient Information Form (PIF). These documents are explained in detail in Section 9.1.1. When the research documentation has been created, ethical approval can be given. This is necessary for the research to be able to start. The ethical approval contains the goal of the study, the research ID, and the ethical approval code. When the documentation is created and approval has been given, an Informed Consent Form needs to be created. This form is then adapted for the research at hand, the healthcare provider names, the goal of the recording, the research identi cation number, and the ethical approval code are added. Before the researchers can recruit participants, the eligibility criteria have to be determined. These result in exclusion and inclusion criteria. Then, the researchers can start creating the participant population, these are all participants that meet the eligibility criteria. This results in a list of participants, including their Patient ID, email address, and phone number that can be approached by the researchers.

In the next phase, the Performing phase includes the actual contact with the participants. Researchers can start approaching the potential participants. The speci cs of the study are discussed with each participant over the phone, and any concerns or uncertainties the participant has can be discussed with the researchers. If the patient agrees to receive the PIF, the researcher sends an email. This email contains the PIF for the participant to read so they can consider their participation

well-informed. When the participant has their consultation, they either do or do not give consent by signing the informed consent form. The signed informed form is then stored in the Research Folder Structure (RFS), speci cally the signed informed consent forms part. Since these forms contain personally identi able information, this part of the database has restricted access. Then, the recordings can be made. First, the consultation is performed and recorded.

Then we enter the*Storing phase* in which the recordings are stored in the consultation recordings part of the RFS. As with the signed informed consent forms, these recordings also contain personally identi able information, so this part of the database has restricted access as well. The researchers update the randomization key in which the recording can be led back to the corresponding patient by their patient ID.

The last phase is the*Processing phase* , in which, in no particular order, the recordings are processed into transcriptions and the EMR of the corresponding patient is extracted from HiX so that the transcription can be compared to the notes the doctor took during the consultation. And the transcriptions need to be masked so that all personally identi able information is removed and the transcripts cannot be led back to the patient anymore. These transcripts are stored in the anonymously coded consultation part of the RFS. Since these anonymized transcripts do not contain personally identi able information, third parties can request access to these recordings. These requests can be approved or denied at the discretion of the data controller. The last action is to remove the original recording stored in the consultation recording part of the RFS.

Figure 13: Method for patient consent for AV recorded consultations.

7.2 Execution case study

Before the researchers could start approaching patients, a number of things needed to be done. All researchers needed to become an intern or an employee at the UMCU in order to get access to patient data and records. The introduction program needed to be ful lled including a course on general safety measures in the hospital. Apart from this course, the researchers also had to complete a Good Clinical Practice (GCP) course. Researchers and other employees who are directly involved in a clinical study involving human subjects must hold a GCP certi cate [102]. The contents of this course are described in detail in Section 9.1.2. All researchers also needed access to HiX (Healthcare Information eXchange), in order to view patient EMRs and the planning of the clinic. All researchers received the medical secretary role in order to get these rights.

In order to make sure patients were informed well enough, everything was discussed and tuned with the medical head of the clinic. The processes of all consultation options and approaching patients were modeled with the help of the Business Process Modeling Notation (BPMN) to give a better overview of what the researchers needed to do and all possible options. These were checked multiple times with the medical head and improved so that all possible options would be accounted for. One of the process models will be discussed in the next section (Section 7.3), and the models can be consulted in Appendix C.

The recording days were planned in consultation with the outpatient clinic and the availability of the medical head of the clinic that wanted to be present on the first day. The availability of the researchers was checked and a schedule was made so that on every recording day there was at least one, preferably two, researchers present at the clinic.

A document was prepared with all the necessary information for the researchers (Appendix C). Including which information needed to be told to the patient over the phone. The things that at least needed to be discussed with the patient were:

1. Confirm that the patient has a consultation at the POS outpatient clinic
2. Give a short explanation about the study
3. Ask if the patient would consider participating in the study
4. Emphasize that the study does not influence the consultation
5. Emphasize that the recording is anonymized and explain this in simple language
6. Emphasize that the recording is stored safely
7. Ask for permission to mail the PIF
8. Explain that the patient can decide on the day of the consultation if they want to participate in the study

An example conversation was written out so that the researchers could keep that alongside the conversation to have something to hold onto (Appendix C, activity B). An example email was also written out so that the researchers could copy and paste this email when sending it to a patient (Appendix C, activity B). The PIF was also created. The UMCU had a standard PIF for this that, with some slight adjustments, was ready to be used for this study. The PIF can be consulted in Appendix D.

The researchers made use of the trial and favorites list function in HiX. This list enables users to collaborate on a list of patients and can make notes for every patient. In this list, we included the patients we were going to call based on a standard

format and codes. This format was: code, date, time, type of consultation, and which doctor. The codes used were NB (yet to call), BB (call back), BT (called and consent for recording and mail), and BM (called and only consent for mail). So this could look like `BT, 15/4, 12:45, TC, Screener 1'. Or `BB, 13/3, 10:15, Phys, Sta doctor'. After calling a patient, the researchers adjusted the note in the trial and favorites list with the corresponding code and the trial needed to be added to the patient's EMR. Screenshots of the HiX environment can be found in Appendix E.

All doctors and other employees were also informed about the study. A document was prepared for this and all sta received an email a few weeks beforehand with all information (Appendix C, Sub appendix 2). When a doctor had patients scheduled for that day that could be recorded, they were contacted by the researchers at the beginning of the day and asked if they were okay with recording the consultation. Once given consent, this was noted and the doctor did not have to give consent again. To help remind the doctor of which patient was approached for the study, we put a `C2R' comment in the notes of the consultation of those patients. This could then be seen in the agenda of the doctor.

All researchers spent a day before starting with the recordings testing out the microphones and putting the audio les on the UMCU computers. The decision of which microphones were bought was made by the whole C2R team based on their experiences. On this day, a document was created with step-by-step instructions about how to use the microphone. This guide can be consulted in Appendix F.

Everything that was done during this case study needed to be in line with the daily functioning of the clinic. Therefore, we adjusted some details during the execution of the study to be in line with the clinic's business as usual.

7.3 Patient Inclusion Process

Figure 14: BPMN Informed consent process.

This section will dive into the patient inclusion process for studies that include AV recordings. This process is visualized using BPMN, a modeling language to create graphical models of business process operations which include activities and ow controls that de ne the order of performance [103].

The patient inclusion process involves several steps that researchers follow to identify potential participants who meet the study's eligibility criteria and include them to participate in the study. The process begins with screening potential participants. The researcher screens patients preferably 1 up to 3 working days prior to the day of their consultation and determines who may be approached for participation. If a patient meets the eligibility criteria, the researcher calls the patient to inform them about the study, including its purpose, procedures, potential risks, and bene ts. If the patient agrees to receive more information, the PIF is sent to the patient.

On the day of the patient's appointment, the researcher checks with the doctor that they will notify the researcher when they will get the patient out of the waiting room. When the patient is called into the consulting room, they are reminded of the study they were approached for, asked if they had any remaining questions and if they have been able to make a decision. If the patient declines to participate, the process ends here. If the patient still wishes to participate, the researcher starts the recording. If the patient's consent has not yet been recorded in the EMR, the researcher must do so. Finally, after the consultation is done, the recording can be terminated and should immediately be transferred to a secured server. This ensures that the patient's personal information is protected and kept con dential throughout the study process.

The process for consultation over the phone and the process for a patient that comes to the clinic last minute are written out in Appendix C. The most important di erences are that in case of a consultation over the phone, the patient does not visit the clinic, and has to be reminded over the phone of the study. Because patients

often do not answer the phone immediately, the doctors often call them at other times than was planned. This makes it a challenge to schedule the recordings of TCs. Patients that come in last minute cannot be approached in advance, and thus need to be informed immediately before their consultation, this is also a challenge due to time pressure at the clinic.

There are a number of things that need to be taken into account. Not all patients' email addresses are in their EMRs, or it could occur that the email address in the EMR is not correct. It was discussed with the secretary that the researchers could adjust the email address in the EMR. If the patient did not want to receive an email but wanted to receive the PIF through the post, we decided to also send the PIF through the patient portal. This assured that the patient would receive the information before the consultation took place and reassured their rights.

7.4 Validation of the method

In this section, the validation of the PaCAR method will be discussed by addressing its execution at the UMCU and the experiences of the researchers that applied the method at the UMCU. The factors that in uence the outcomes of the method are discussed in Section 8.

7.4.1 Case study

The designed method was applied as described above by four researchers at the UMCU POS outpatient clinic during a time span of two months. All researchers were Master's students of UU from either Business Informatics of Human-Computer Interaction with no medical background. The research team consisted of two male and two female researchers. All researchers completed the required courses described in Section 7.2 and Section 9.1.2.

The method was applied between March 7 and April 26 of 2023. During these two months, there were twenty-seven recording days on which the researchers made recordings and approached patients. Due to some holidays and the researchers' availability, we could not make recordings each workday. Beforehand, the month of May was also taken into account to make recordings, but this was not necessary since we had already exceeded our objective of 100 recordings in April.

A total of 143 recordings were made during those 27 recording days. Forty-two percent of these recordings were made in March (13 recording days), and 58% were made in April (14 recording days). In March, there were an average of 4.6 recordings per day and in April there were 5.9 recordings on average each day. In Figure 15 the

number of recordings on each day in March and April are visualized. Here, you can clearly see that in March the number increased over time due to a learning e ect, and in April the number of recordings stabilized due to a stabilization e ect. In total, there was an average of 5.3 recordings each day throughout the whole period.

Figure 15: Number of recordings per day in March and April.

There were eight weeks in which we recorded during the period of the case study. On average, we had 3.4 recording days each week due to some holidays. We were not able to do recordings on Mondays. The rst week was the week with the least recordings, namely three, this can be explained by the starting phase of the case study where we rst needed to call patients before we could start recording. The week with the most recordings was week 4 with 28 recordings. On average, we made 18 recordings each week. In Figure 16 the number of recordings each week is visualized. On the right, the numbers are weighted with the number of recording days of each week.

Figure 16: Number of recordings per week.

7.4.2 Lessons learned

All four researchers involved in the case study that applied the PaCAR method shared their thoughts about the method and its processes. Each researcher shared their positive points and points of improvement and these were categorized. We

identi ed three categories with positive points and four categories with points of improvement.

The PaCAR method
Positive points:

- The method was clearly described step by step with the help of several process models which made everything clear.
- The standard documents for mailing and calling patients were helpful and gave a good head start.
- The calling schedule was a good way to make sure you could call consecutively instead of having to check in between which patients could be included and called.

Points of improvement:

- The method needs a lot of getting used to and training. After a while, it became easier to know what to say to patients and where everything could be found.
- The example conversation could be a little bit more concise. We experienced that the less information you tell the better. Apart from the obligatory information you have to provide to the patient.

Facilities
Positive points:

- The research team was well received and guided at the clinic by the managers and secretariat.
- The microphones were easy to use and work with.

Points of improvement:

- It took some time before the researchers received the accurate HiX rights, for future projects we now know which kind of rights are needed.
- We were not allowed to store multiple recordings on one iPhone, this made it hard to record consecutive consultations due to the working pressure of the clinic.
- Picking up and bringing the microphones often felt like a burden. Fixed microphones in every consultation room would be better if we want to scale the method.

Working with HiX
Positive points:

- The codes we used in the trial and favorites list in HiX to keep track of which patient was called or not or had to be called back were handy. It was also useful that we could work together on this list. The list also made it easy because you could directly access a patient's le out of the list.
- The C2R comment in the consultation appointment in the doctors' agendas was helpful for them not to forget to call us.
- The dragging map in HiX was helpful so we could see where patients were, but this only works if doctors adhere to this.

Points of improvement:

- There is lots of administration in di erent places which was sometimes unclear. Many les hold the same information, this could be organized better.
- Manually typing phone numbers out of the EMRs was very sensitive to errors. It would be nice to have a calling software program with which you can call patients straight out of their EMR in HiX.

Medical
Points of improvement:

- Sometimes it was di cult to decide for ourselves whether a patient could participate due to the fact that the researchers did not have a medical background.
- Some doctors were a bit critical, some more support from the management would have been nice. Because the sta changes almost every day it was very hard to inform everyone. Maybe it would be nice to choose enthusiastic employees beforehand as a sort of stakeholder and mainly work with them to record consultations.

8 Factors for patient consent rate

This section investigates all factors that possibly in uence a patient's willingness to let researchers record their medical consultation. This gives an answer to RQ4: hat factors determine a patient's willingness to participate in a medical consultation study involving AV recordings?

8.1 Results hypothesis testing

8.1.1 Data preparation

Prior to the analyses, all personal data was removed, and all variable values were coded into numeric values instead of string values. Age was calculated from the birth date, and the days a patient had to consider were calculated by distracting the day of approaching them from the day of the consultation. All collected data were checked for missing values and possibly extreme values. This showed that the data did contain a number of missing values. The data did not contain any extreme values. Since we did not want to lose the valuable data of the patient if any of the variables of that patient were missing, we decided to keep the missing values in the data. All missing values were coded as '99'.

Then, we recoded some of the variables into di erent categories. First, age was grouped into the following categories: 18 to 29 (1), 30 to 39 (2), 40 to 49 (3), 50 to 59 (4), 60 to 69 (5), and 70 or older (6). The days the patients had to consider were categorized into: 1 to 3 days (1), 4 to 6 days (2), and 7 or more days (3).

8.1.2 Results

The hypotheses were tested by means of cross-tabulation and Chi-Squared. This is the most suitable test because we mostly have categorical variables and independent groups. This test shows us whether there is a relationship between two variables [104]. Not all requirements were met due to the expected counts being below ve in a number of cases. We decided to go through with the tests because our goal was to achieve a consent rate as high as possible. Thus, the number of patients that did not give their consent was expected to be low beforehand. We will discuss the results per hypothesis.

Hypothesis 1

There is no relation between the gender of the researcher who approaches the patient to participate in a study and the willingness of the patient to participate.

The researcher's gender was either male (0) or female (1). Ninety-four patients were approached by a female researcher (58.75%) and 66 patients were approached by a male researcher (41.25%).

Table 3: Distribution of patients Hypothesis 1.

	Patient consent		
Researcher gender	No	Yes	Total
Male	5 (29.40%)	61 (42.70%)	66 (41.25%)
Female	12 (70.60%)	82 (57.30%)	94 (58.75%)
Total	17	143	160

Five of the seventeen patients that did not give consent were approached by a male researcher (29.40%), and twelve were approached by a female researcher (70.60%). The distribution of patients by male and female researchers, as well as consent and no consent is presented in Table 3.

The results show that there isno signi cant di erence between patients that were approached by a male researcher and patients that were approached by a female researcher and their willingness to participate: $\chi^2(1, N = 160) = 1.100$, $p = 0.294$. None of the expected values were under the required value of 5.

This suggests that our study did not nd enough evidence to support a signi cant association between the researcher's gender and the patient's willingness to participate. According to the available data and analysis hypothesis 1 is not rejected, the gender of the researcher does not appear to have a relation with the patient's willingness to participate in our study .

Hypothesis 2

There is no relation between the gender of the patient and the willingness of the patient to participate.

The gender of the patient was either male (0) or female (1). Eighty patients were male (50%) and eighty patients were female (50%).

Table 4: Distribution of patients Hypothesis 2.

	Patient consent		
Patient gender	No	Yes	Total
Male	12 (70.59%)	68 (47.55%)	80 (50%)
Female	5 (29.41%)	75 (52,45%)	80 (50%)
Total	17	143	160

Twelve of the seventeen patients that did not give consent were male (70.59%) and ve were female (29.41%). The distribution of patients by gender, as well as consent and no consent, is presented in Table 4.

The results show that there is no signi cant di erence between male and female patients and their willingness to participate: $X^2(1, N = 160) = 3.225$, $p = 0.073$. None of the expected values were under the required value of 5.

This suggests that our study did not nd enough evidence to support a signi cant association between the patient's gender and the patient's willingness to participate. According to the available data and analysis hypothesis 2 is not rejected, the gender of the patient does not appear to have a relation with the patient's willingness to participate in our study .

Hypothesis 3

There is no relation between the age of the patient and the willingness of the patient to participate.

Patient age was categorized into 18 to 29 years (1), 30 to 39 years (2), 40 to 49 years (3), 50 to 59 years (4), 60 to 69 years (5), and 70 or older (6). Fourteen patients were between 18 and 29 years (8.75%), seventeen patients were between 30 and 39 years (10.63%), twenty-four patients were between 40 and 49 years (15%), twenty-nine patients were between 50 and 59 years (18.13%), thirty-eight patients were between 60 and 69 years (23.75%), and thirty-eight patients were 70 years or older (23.75%).

Table 5: Distribution of patients Hypothesis 3.

	Patient consent		
Patient age	No	Yes	Total
18-29	2 (11.76%)	12 (8.39%)	14 (8.75%)
30-39	1 (5.88%)	16 (11.19%)	17 (10.63%)
40-49	4 (23.53%)	20 (13.99%)	24 (15%)
50-59	1 (5.88%)	28 (19.58%)	29 (18.13%)
60-69	3 (17.65%)	35 (24.48%)	38 (23.75%)
70+	6 (35.29%)	32 (22.38%)	38 (23.75%)
Total	17	143	160

Two of the seventeen patients that did not give consent were between 18 and 29 years (11.76%). One patient was between 30 and 39 years (5.88%). Four patients were between 40 and 40 years (23.53%). One patient was between 50 and 59 years (5.88%). Three patients were between 60 and 69 years (17.65%). Six patients were

70 years or older (35.39%). The distribution of patients by age, as well as consent and no consent, is presented in Table 5.

The results show that there isno signi cant di erence between the age of patients and their willingness to participate: $X^2(5, N = 160) = 4.667$, $p = 0.458$. Six of the expected values were under the required value of 5.

This suggests that our study did not nd enough evidence to support a signi cant association between the patient's age and the patient's willingness to participate. According to the available data and analysis hypothesis 3 is not rejected, the age of the patient does not appear to have a relation with the patient's willingness to participate in our study .

Hypothesis 4

There is no relation between the number of days before a patient's consultation when they are approached for the research and their willingness to participate

The number of days the patient had to consider participating in the study was categorized into 1-3 days (1), 4-6 days (2), and 7+ days (3). Forty-seven patients were approached 1 to 3 days before their consultation (29.40%), 76 patients were approached 4 to 6 days before their consultation (47.50%), and 37 patients were approached 7 or more days before their consultation (23.10%). On average, patients were approached 5.06 days before their consultation (SD=2.14, Min=1, Max=12, Mdn=6).

Table 6: Distribution of patients Hypothesis 4.

	Patient consent		
Number of days	No	Yes	Total
1-3	3 (17.60%)	44 (30.80%)	47 (29.40%)
4-6	13 (76.50%)	63 (44.00%)	76 (47.50%)
7+	1 (5.90%)	36 (25.20%)	37 (23.10%)
Total	17	143	160

Table 7: Cross-tabulation Hypothesis 4.

		Patient consent		
Number of days		No	Yes	Total
1-3	Observed	3	44	47
	Expected	5	42	
	Contribution to Chi ²	0.800	0.095	
4-6	Observed	13	63	76
	Expected	8.1	67.9	
	Contribution to Chi ²	2.964	0.354	
7+	Observed	1	36	37
	Expected	3.9	33.1	
	Contribution to Chi ²	2.156	0.254	

Three of the seventeen patients that did not give consent were approached 1 to 3 days before their consultation (17.60%), thirteen were approached 4 to 6 days before their consultation (76.50%), and one patient was approached 7 or more days before their consultation (5.90%). The distribution of patients by the number of days they were approached before their consultation, as well as consent and no consent, is presented in Table 6.

The results show that there is a signi cant di erence between patients that were approached 1 to 3 days, 4 to 6 days, or 7 or more days before their consultation and their willingness to participate: $X^2(2, N = 160) = 6.697$, $p = 0.035$. Two of the expected values were under the required value of 5. The number of patients that did not give consent and had 4 to 6 days to consider was much higher than expected (13 versus 8.1), contributing 2.964 to Chi², and the number of patients that did not give consent that had 7 or more days to consider was much lower than expected (1 versus 3.9), contributing 2.156 to Chi². The patients that did give consent and had 1 to 3 days to consider and 7 or more days to consider contributed the least tho Chi² (0.095 and 0.254 respectively).

This suggests that our study found enough evidence to support a signi cant association between the number of days the patient had to consider and the patient's willingness to participate. According to the available data and analysis hypothesis 4 is rejected, there appears to be a relation between the number of days a patient has to consider and their willingness to participate in our study .

Hypothesis 5

There is no relation between the form of consultation and the willingness of the patient to participate.

Consultations were either over the phone (TC)(0), or physical (1). 97 consultations took place over the phone (60.63%) and sixty-three consultations took place at the physical outpatient clinic (39.38%).

Table 8: Distribution of patients Hypothesis 5.

	Patient consent		
Consultation form	No	Yes	Total
TC	9 (52.94%)	88 (61.54%)	97 (60.63%)
Physical	8 (47.06%)	55 (38.46%)	63 (39.38%)
Total	17	143	160

Nine of seventeen patients that did not give consent had a TC (52.94%) and eight had a physical consultation (47.06%). The distribution of patients by the type of consultation, as well as consent and no consent, is presented in Table 8.

The results show that there is no significant difference between patients that had a TC and a physical consultation and their willingness to participate: $\chi^2(1, N = 160) = 0.470$, $p = 0.493$. None of the expected values were under the required value of 5.

This suggests that our study did not find enough evidence to support a significant association between the type of consultation and the patient's willingness to participate. According to the available data and analysis hypothesis 5 is not rejected, the type of consultation does not appear to have a relation with the patient's willingness to participate in our study .

Hypothesis 6

There is no relation between the ASA classification of a patient and the willingness of the patient to participate.

A patient's ASA score can be 1, 2, 3, 4, 5, or 6. Fifteen patients had an ASA score of 1 (10.27%). Seventy-six patients had an ASA score of 2 (52.05%). Fifty-one patients had an ASA score of 3 (34.93%). Four patients had an ASA score of 4 (12.74%). The median ASA of the sample is 2, this means that at least 50% of the patients had an ASA score of 2 or lower. None of the patients had an ASA score of 5 or 6.

Table 9: Distribution of patients Hypothesis 6.

	Patient consent		
ASA Classi cation	No	Yes	Total
1	0 (0%)	15 (11.19%)	15 (10.27%)
2	8 (66.67%)	68 (50.75%)	76 (52.05%)
3	3 (25%)	48 (35.82%)	51 (34.93%)
4	1 (8.33%)	3 (2.24%)	4 (2.74%)
5	0 (0%)	0 (0%)	0 (0%)
6	0 (0%)	0 (0%)	0 (0%)
Total	17	143	160

None of the seventeen patients that did not give consent had an ASA score of 1 (0%). Eight had an ASA score of 2 (66.67%). Three had an ASA score of 3 (25%). One had an ASA score of 4 (8.33%). The distribution of patients by ASA score, as well as consent and no consent, is presented in Table 9.

The results show that there is no signi cant di erence between patients with a low or high ASA score and their willingness to participate: $\chi^2(3, N = 146) = 3.742$, $p = 0.291$. Four of the expected values were under the required value of 5.

This suggests that our study did not nd enough evidence to support a signi cant association between the patient's ASA score and the patient's willingness to participate. According to the available data and analysis hypothesis 6 is not rejected, the ASA score of the patient does not appear to have a relation with the patient's willingness to participate in our study .

Other variables

A number of other variables were tested for which we had not formulated any hypotheses in advance. We identi ed three additional variables during the case study that we were interested in to see if they would have a relation with a patient's willingness to participate in our study. These are the type of doctor and on which day of the week the consultation took place. For these variables, the following hypotheses were formulated during the case study:

H7: There is no relation between the type of doctor the patient has a consultation with and the willingness of the patient to participate.

H8: There is no relation between the weekday of the consultation and the willingness of the patient to participate.

Hypothesis 7

The type of doctor was categorized in two di erent ways: into general categories

and more speci c categories. This was discussed with the medical head who was interested to see if this would make any di erence.

Doctor (general)

The type of doctor (general) is either Resident (0), Screener (1), or Sta doctor (2). Forty-seven patients were seen by a resident (29.38%), Ninety-nine patients were seen by one of the screeners (61.88%), and fourteen patients were seen by a sta doctor (8.75%).

Table 10: Distribution of patients Hypothesis 7a.

	Patient consent		
Doctor (general)	No	Yes	Total
Resident	8 (47.06%)	39 (27.27%)	47 (29.38%)
Screener	9 (52.94%)	90 (62.94%)	99 (61.88%)
Sta doctor	0 (0%)	14 (9.79%)	14 (8.75%)
Total	17	143	160

Eight of the seventeen patients that did not give consent were seen by a resident (47.06%), nine were seen by a screener (52.94%), and none of the patients that were seen by a sta doctor did not give consent. The distribution of patients by the type of doctor, as well as consent and no consent, is presented in Table 10.

The results show that there isno signi cant di erence between the type of doctor patients were seen by and their willingness to participate: $\chi^2(2, N = 160) = 3.935$, $p = 0.140$. Two of the expected values were under the required value of 5.

This suggests that our study did not nd enough evidence to support a signi cant association between the general type of doctor and the patient's willingness to participate. According to the available data and analysis hypothesis 7 is not rejected, the type of doctor does not appear to have a relation with the patient's willingness to participate in our study .

Doctor (speci c)

The type of doctor (speci c) is either Youngest resident (0), Eldest resident (1), Screener 1 (2), Screener 2 (3), Screener 3 (4), or Sta doctor (5). Twelve patients had a consultation with the youngest resident (7.50%). Thirty- ve patients with the eldest resident (21.88%). Forty-six patients had a consultation with screener 1 (28.75%). Forty- ve patients with screener 2 (28.13%). Eight patients with screener 3 (5%), and fourteen patients with the sta doctor (8.75%).

Table 11: Distribution of patients Hypothesis 7b.

	Patient consent		
Doctor (speci c)	No	Yes	Total
Youngest resident	4 (23.53%)	8 (5.59%)	12 (7.50%)
Eldest resident	4 (23.53%)	31 (21.68%)	35 (21.88%)
Screener 1	5 (29.41%)	41 (28.67%)	46 (28.75%)
Screener 2	4 (25.53%)	41 (28.67%)	45 (28.13%)
Screener 3	0 (0%)	8 (5.59%)	8 (5%)
Sta doctor	0 (0%)	14 (9.79%)	14 (8.75%)
Total	17	143	160

Four of the seventeen patients that did not give consent had a consultation with the youngest resident (23.53%), four patients had a consultation with the eldest resident (23.53%), ve patients that did not give consent had a consultation with screener 1 (29.41%), and four patients had a consultation with screener 2 (25.53%). The distribution of patients by the type of doctor, as well as consent and no consent, is presented in Table 11.

The results show that there isno signi cant di erence between patients that were screened by for example the youngest resident or the sta doctor and their willingness to participate: $X^2(5, N = 160) = 9.301$, $p = 0.098$. Six of the expected values were under the required value of 5.

This suggests that our study did not nd enough evidence to support a signi cant association between the speci c type of doctor and the patient's willingness to participate. According to the available data and analysis hypothesis 7 is not rejected, the type of doctor does not appear to have a relation with the patient's willingness to participate in our study .

Hypothesis 8

No researchers were available on Mondays, so the days of the week on which patient consultations were included were on Tuesday (0), Wednesday (1), Thursday (2), and Friday (3). Forty-eight patients that were included had their consultation on a Tuesday (30%). Forty-two patients had their consultation on a Wednesday (26.25%). Thirty-nine patients had their consultation on a Thursday (24.38%), and thirty-one patients had their consultation on a Friday (19.38%).

Table 12: Distribution of patients Hypothesis 8

	Patient consent		
Weekday	No	Yes	Total
Tuesday	9 (52.94%)	39 (27.27%)	48 (30%)
Wednesday	3 (17.65%)	39 (27.27%)	42 (26.25%)
Thursday	4 (25.53%)	35 (24.48%)	39 (24.38%)
Friday	1 (5.88%)	30 (20.98%)	31 (19.38%)
Total	17	143	160

Nine of the seventeen patients that did not give consent had their consultation on a Tuesday (52.94%). Three patients had their consultation on a Wednesday (17.65%). Four patients that did not give consent had their consultation on a Thursday (25.53%), and one patient had their consultation on a Friday (5.88%). The distribution of patients by which day their consultation was, as well as consent and no consent, is presented in Table 12.

The results show that there is no signi cant di erence between patients that had their consultation on, for example, a Tuesday, or a Thursday and their willingness to participate: $X^2(3, N = 160) = 5.666$, $p = 0.129$. Three of the expected values were under the required value of 5.

This suggests that our study did not nd enough evidence to support a signi cant association between the weekday of the consultation and the patient's willingness to participate. According to the available data and analysis hypothesis 7 is not rejected, the day of the week does not appear to have a relation with the patient's willingness to participate in our study .

8.1.3 Binomial Logistic Regression

We used a binomial logistic regression to test the hypotheses in a multivariate analysis. A binomial logistic regression is used when the dependent variable is dichotomous (yes or no), and there are multiple independent variables that are categorical [105], [106].

A logistic regression was performed to assess the e ects of all independent variables on the likelihood of a patient giving consent [107]. The logistic regression model was not statistically signi cant: researcher gender (p=0.141), patient gender (p=0.161), patient age (p=0.093), number of days (p=0.158), consultation form (p=0.856), ASA score (p=0.949), general type of doctor (p=1.000), speci c type of doctor (p=0.657), and weekday (p=0.383). Therefore, we looked at the variables individually by means

of Chi Squared to further investigate the possible relationships between any of the independent variables and the patient's willingness to consent.

8.1.4 Conclusion hypotheses testing

Based on these experiments we can conclude that the only variable that has a relationship with a patient's willingness to participate in our study and let us record their consultation is the number of days the patient had to consider participating. This was also expected according to the literature. It is important to inform people beforehand so they have adequate time to think their decision over and to properly understand everything they are consenting to [34]. Most of the tested variables have a high coherence and none of them are self-contained. This conclusion gives us an answer to RQ4: What factors determine a patient's willingness to participate in a medical consultation study involving AV recordings?

9 Accountability and processing of the recordings

This section describes how the patient-consented recordings need to be processed according to legal requirements and how the privacy of patients is obtained throughout the process. This section composes an answer to RQ5: How can patient-consented recordings obtained during medical consultation studies be processed?

9.1 Requirements from the UMCU

9.1.1 Applications and agreements

There are a number of application forms and agreements that needed to be filled in and signed in order to start the case study at the UMCU. We will not go into the different documents in too much detail but we listed them including a summary of their purpose to give an idea.

1. nWMO:
   If an applicant is unsure whether a study falls under the Medical Research Involving Human Subjects law (WMO), a so-called non-WMO Declaration can be requested from a recognized METC (Medical Ethics Review Committee). An nWMO advisory committee can also advise an applicant to submit this to an METC if it has reason to believe that an investigation may be subject to a WMO obligation [108].
2. METC request
   Research that falls under the WMO must be reviewed in advance by an independent committee of experts. The research may not start without a positive decision from this committee. To submit an application to the committee, the following documents need to be submitted [109]:
   - METC Regulations
   - Annual reports from the past three years (if available)
   - Justification for the expectation that the committee will meet the ten-protocol requirement
   - Completed and signed application form
   - Completed and signed mutation form for each (alternate) METC member
   - Signed declaration of interests and (side) functions (explanation)
   - Signed confidentiality agreement
   - Signed Curriculum Vitae (CV)
   - Confidentiality agreement signed by each adviser (if fixed advisors are used)

3. Data Protection Impact Assessment (DPIA)
   This is an instrument to identify the privacy risks of data processing in advance so that the organization can take measures to reduce these risks [110].
4. Data Transfer Agreement (DTA)
   This is a legal contract that outlines the terms of sharing personal data, including its use and protection, between organizations. It ensures compliance with privacy policies and laws and protects the interests of the data provider [111].
5. Data management plan (DMP)
   This is a digital document in which you outline what data you will gather during your research project, how you are going to store and manage the data during the project, and what will happen to the data after the project is nished [112].
6. Cooperation contract
   All involved parties sign a cooperation contract in which all agreements are stated.

Furthermore, an RFS request needed to be done by the data managers of the UMCU. They create a folder structure on the internal server on which all les and data can be stored. A Research Protocol needs to be created so that everyone concerned with the study has the same idea of the study and works towards one goal and the same deliverables according to a schedule. The informed consent form and PIF were also created in this stage.

9.1.2 Mandatory Prerequisite Courses

Central Introduction Program

The researchers had to complete a number of courses in order to start with the study at the UMCU. First, all researchers had to pass the Central Introduction Program (CIP). All new employees, trainees, and external sta have to follow this program. After the CIP, each employee follows a training program speci c to their function and department. A standard element of the CIP is an E-introduction on general quality and safety in the UMCU. Parts of this course were an introduction to the di erent locations of the UMCU, and a tour through the hospital and di erent departments: for example the the ORs and the laboratory. Most of the course was about what you would need to do in certain situations, how to ensure personal hygiene, your workplace, and calamities. These were explained with a lot of examples and videos. After completing the CIP, there was a speci c training program for the researchers to learn the basics about HiX. This course was also online and contained the basics:

what do you use HiX for, patient safety and privacy, and care registration. The following contents were covered: logging in, the screen layout, patient selection and les, examples, orders, the patient portal, and how you can personalize HiX. Lastly, it was explained where you could go for support when you experienced problems with HiX. Apart from the basic introduction to HiX, the researchers also needed to follow an extra physical introduction course about HiX applied to their speci c role. During this lecture-like course, the teacher took the attendees through the program and explained multiple tasks after which exercises followed which the attendees had to carry out successfully by themselves.

Good Clinical Practice

Before conducting research in a clinical environment, researchers need to pass a GCP course. GCP stands for Good Clinical Practice and is an international ethical and scienti c quality standard for designing, recordings, and reporting trials that involve the participation of human subjects [102]. This course was o ered by a third party and made possible by the UMCU.

Compliance with GCP is a legal obligation in the Netherlands since 2004 that is regulated by the Medicines law and the WMO [102], [113]. These laws outline the requirements for conducting clinical trials and ensure the protection of human subjects participating in research. Compliance with GCP guidelines, also known as ICH-GCP (International Conference for Harmonization) implies that \freely given informed consent should be obtained from every participant prior to clinical trial participation"[102].

All researchers involved with the study and who needed to have direct contact with patients, completed the GCP course. The course gave information about the laws and regulations that are in place to ensure that clinical trials involving human subjects are carried out integer and reliably and that the rights, safety, and well-being of human subjects are ensured. The course shows how you can apply the content of the guidelines in your daily practice. Regulatory authorities, such as the ICH, have developed GCP guidelines that are widely accepted and implemented. These guidelines provide a framework for researchers, sponsors, investigators, and ethics committees to conduct clinical trials in a consistent, ethical, and scienti cally rigorous way [102].

The course starts with some examples of historical tragedies to emphasize the importance of the guidelines. The ICH-GCP is developed out of the Nuremberg Code and the DoH. Therefore, both codes are explained shortly. The Nuremberg Code contains ten principles and was created as a result of war crimes during the Second World War. The DoH followed this code [102].

During the 1970s and 1980s a lot of countries had their own GCP guidelines with di erent standards that led to delays in getting products to the market and created an increase in pharmaceutical costs. As a solution, a series of conferences were held to unify these di erent codes. These meetings became known as the International Conference on Harmonization of Good Clinical Practice (ICH-GCP), all codes were formed into one internationally recognized, uniform standard to which all countries could commit at the end of the 1990s. The guideline has been revised a few times after that [102].

GCP is an international ethical and scienti c quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the DoH, and the clinical trial data are credible.

The ICH-GCP guideline has thirteen principles, but was developed with two main purposes in mind:

1. Protect the rights, safety, and well-being of trial subjects, consistent with the principles that have their origin in the DoH.
2. Assure the credibility of the clinical trial data.

The thirteen key aspects of GCP are discussed, these are [102]:

1. Ethical Principles
   Clinical trials should adhere to ethical principles derived from the DoH, GCP, and applicable regulatory requirements.
2. Risk-Bene t Assessment
   The anticipated risks and bene ts should be evaluated to determine whether a trails' bene ts justify the potential risks to individual participants and society.
3. Participant Rights and Safety
   The rights, safety, and well-being of the participants should be prioritized over the interests of science and society.
4. Adequate Information
   Su cient non-clinical and clinical data on the investigational subject should be available to support the proposed trial.
5. Scienti cally Sound Protocols
   Clinical trials should be scienti cally sound and described in clear and detailed protocols.
6. Protocol Compliance
   Clinical trials should be carried out in accordance with protocols that have

been previously approved by an Institutional Review Board (IRB) or Independent Ethics Committee (IEC).

7. Quali ed Medical Care
   Quali ed physicians should be responsible for any medical care and decisions related to trial participants.
8. Quali ed Personnel
   All persons involved in conducting the trial should possess the necessary quali cations, education, training, and experience for their respective roles.
9. Informed Consent
   Prior to participating in a trial, participants should provide their informed consent voluntarily.
10. Accurate Recording and Reporting
    All clinical trial information should be captured, handled, and stored in a manner that facilitates accurate reporting, interpretation, and veri cation.
11. Con dentiality and Privacy
    The con dentiality of records that could identify participants should be protected, respecting their privacy and con dentiality according to the applicable regulatory requirements.
12. Good Manufacturing Practice (GMP)
    Investigational products should be produced, handled, and stored in compliance with applicable GMP standards and used as in the approved protocol.
13. Quality Assurance
    Systems and procedures should be implemented to ensure the quality of all aspects of the trial.

After the principles are explained, the di erent roles in a clinical trial are highlighted. These are the investigator, the sponsor, and the monitor. The investigator is the owner of the advertisement for subject recruitment (if used), the signed informed consent forms, the source documents, the (completed) subject identi cation code list, the subject enrollment log, and the nal report by the investigator to the IRB/IEC. The sponsor is the owner of the sample of the label(s) attached to the investigational product, the master randomization list, the pre-trial monitoring report, monitoring visit reports, the nal trial close-out monitoring report, the certi cate of analysis of the investigational product(s), the Audit Certi cate, and the treatment allocation and decoding information. The course also focuses on the informed consent process of clinical trials. The guidelines state that \you cannot include a human being as a subject in a trial unless you have obtained informed consent" [114].

9.2 Responsibilities

In this section, we describe the document flow of the UMCU case study we did in which we obtained audio recordings and the EMRs of consultations. The action responsibility for each deliverable is also presented. To present the responsibilities of different stakeholders we make use of the PASCI matrix. This is a derivation from the RACI matrix. This is a Responsibility Assignment Matrix that is used to provide a way to plan, organize and coordinate work. Each activity is assigned a different degree of responsibility [115]. The rows represent activities undertaken in the project, the columns of the matrix are resources, and each cell contains zero or more PASCI initials indicating the type of responsibility of such a resource on such an activity [115].

The initials in the cells are different functions, called roles in PASCI [115], [116]:

- Perform (P): Person who must carry out the work and is responsible for the activity until the work is finished and approved by the accountable.
- Accountable (A): Person who must approve the work performed by the person responsible for an activity, and who becomes responsible for it after approval.
- Support (S): Person who may assist in completing an activity. Unlike Consulted, who may provide input to the activity, Support will actively contribute to the completion of the activity.
- Consulted (C): Person whose opinion and expertise are sought while performing the work, and with whom there is two-way communication.
- Informed (I): Person who is kept updated on the progress of an activity and/or the results of the work, and with whom there is just one-way communication.

The different resources presented in the columns of Table 13 are:

- Medical Department (Med. Dept.) The medical department at the medical institution. In this case study this is the POS outpatient clinic of the UMCU.
- Medical ICT Department (Med. ICT): The ICT department of the medical institution. In this case study these are the data managers of the UMCU.
- Medical Research Institution (Med. Res.): Medical Research institution interested in performing additional research on the consultation transcript and EMR beyond the reporting, for example, Nivel and Julius Center.
- Utrecht University C2R (UU C2R): The Care2Report research program based at Utrecht University.
- Business C2R (Bus. C2R): The Care2Report private company and startup.

Table 13 presents the PASCI matrix based on the UMCU case study.

Table 13: PASCI matrix.

	Action	Result	Med. Dept.	Med. ICT	Med. Res.	UU C2R	Bus. C2R
1	Select Patients	Patient list	S/C/I			P/A	
2	Approach and Inform Patients	Patient list	C/I			P/A	
3a	Obtain Informed Consent	Signed Informed Consent Form	P/I			A/I	
3b	Store signed Part Informed Consent	Stored Informed Consent Form	I			P/A	
4	Consultation		P/A/C			I	
5a	Record Consultation	Original Audio	I			P/A	
5b	Store Original Audio	Stored Audio	I			P/A	
6	Obtain Patient EMR	Patient EMR	C/I	P/A		C/I	
7	Completeness Check	Checked Patient List	S/C	I		P/A	

There are a number of deliverables following the actions presented in Table 13. All deliverables have an Owner, a Creator, a party that is responsible for the Storage, a User, and a Remover. Since all deliverables in Table 14 contain patient information the Medical Department at which the study is performed is the Owner of the deliverables and is responsible for Removing the deliverables when this is required according to the guidelines.

For this research, we only consider the deliverables up to the delivery of the original audio and the corresponding patient EMR for transcription and anonymization. When the original audio is transcribed and anonymized, the anonymous transcript may be transferred to C2R.

The Patient Information Form (PIF) is created in collaboration with the Medical Department and the researchers of C2R. It is stored by the researchers in the RFS which is prepared and under maintenance by the Medical ICT department. The researchers use the PIF to send it to potential participants of the study.

The Signed Informed Consent is created by the patient. It is stored by the researchers in the RFS and used by the Medical Department and researchers to prove that patients were informed and voluntarily approved to participate in the study. In this case study, the informed consents were not signed on paper but consent was given orally to the doctor.

The Patient ID list is created by the researchers of C2R and they also keep it updated. The list is stored in the RFS or in HiX and used by the researchers of C2R to check whether a patient has already been approached or not.

The Randomization Key: ID & Audio is created by the researchers and stored in the RFS. This randomization key connects the original audio to the patient ID. The Medical ICT department uses this key to extract the correct EMRs from HiX.

The Original Audio Recording is created by the researchers and stored in the RFS. It is also used by the researchers of C2R.

The Original Patient EMR , with which we mean the elds out of the patient's EMR that comply with the original audio for comparison of the transcript with what the doctor wrote in the EMR. The EMR is created by the Medical Department, the Medical ICT department will create an excerpt with only the necessary data. It is stored by the Medical Department in HiX and the excerpt is stored by the Medical ICT Department in the RFS for the researchers to access and use.

The Randomization Key: EMR & Audio is created by the Medical ICT department to connect the extracted EMRs to the original audio recordings. This key is used by the researchers of C2R to check whether C2R's transcript complies with what the doctor wrote in the EMR.

Table 14: Ownership of the deliverables.

Deliverable	Owner	Creator	Storage	User	Remover
Patient Information Form	Med. Dept.	Med. Dept. / UU C2R	UU C2R	UU C2R	Med. Dept.
Signed Informed Consent	Med. Dept.	Patient	UU C2R	UU C2R	Med. Dept.
Patient ID List	Med. Dept.	UU C2R	Med. ICT	UU C2R	Med. Dept.
Randomization Key: ID & Audio	Med. Dept.	UU C2R	Med. ICT	Med. ICT	Med. ICT
Original Audio recording	Med. Dept.	Med. Dept. / UU C2R	UU C2R	UU C2R	Med. ICT
Original Patient EMR	Med. Dept.	Med. ICT	Med. ICT	UU C2R	Med. Dept.
Randomization Key: EMR & Audio	Med. ICT	Med. ICT	Med. ICT	UU C2R	Med. ICT.

9.3 Secure research data access in STS-ml

As several roles are involved, we analyze the security and privacy perspective regarding the conduction of performing research around medical consultations. To do so, we created an STS-ml model [117] that describes the privacy consents, the execution and recording of the consultation, and the analysis of the data. The STS-ml model consists of three sub-models: the *social view* that highlights actors, their goals, documents, and interactions; the *information view* that shows information ownership and which documents reify which information entities; and the *authorization view*, represented in Figure 17, which highlights permissions and prohibitions for information.

The model shows the *Research Data Controller* as a central role in this context, as many authorizations are granted to this actor and are then propagated to other actors such as the *Healthcare provider*, the Research Assistant, etc. Importantly, the Patient and the Healthcare provider have shared ownership of two pieces of information: the Consultation content, and the Identifying information, these both are personal identi able information. The model decouples the two to denote that the consultation content exists irrespective of information on the identity of the patients. The Patient permits the Research Data Controller to read documents that contain Identifying information in the context of the goal Research conducted, but

prohibits the production or transmission of documents that make that information tangible.

Regarding the Consultation contents, the Patient grants permissions to read and transmit documents, as the de-identified consultation contents need to be shared for their analysis, but modification or production of documents that include that information is prohibited. Only the research assistant who acts as an observer is permitted to produce documents that include the Consultation content and Identifying information, but only in the context of recording the consultation.

The diagram shows commitments to participate in research by all the involved actors. In addition to the patient, also the research assistants, the healthcare provider, and the external data processor all own a piece of information called Commitment that denotes their promise to treat private data confidentially in accordance with GCP. Permissions for these commitments are granted to the Research Data Controller, which are then transferred to the research assistant who acts as a manager, which is the only other actor who is entitled to read documents that make that commitment tangible, only for the purpose of verifying the consents.

Figure 17: STS-ml authorization view, representing permissions (green ticks) and prohibitions (red crosses) in the analyzed setting for Read, Modify, Produce, and Transmiss actions.

10 Dicussion and Conclusion

This research contributes to the C2R research program and start-up by proposing the first version of the PaCAR method that can be used to inform and include patients in AV recording healthcare studies. However, there are several limitations to this study that provide some improvements for future studies and projects. In Section 2.3 the potential threats to validity were already discussed, we will now reflect on these threats and other limitations.

First, there are some limitations regarding the sample size of the case study. Patients were selected based on the researchers' planning and availability resulting in a convenience sample which is a threat to the internal validity. All patients in our sample have undergone a POS screening at the UMCU, which is an academic hospital. This kind of care in such a hospital is only partly generalizable to other healthcare institutions. Because the UMCU is a rather large hospital we assumed that all healthcare disciplines are represented in our sample and give a good basis for further research on the PaCAR method. Due to these circumstances, we aimed for a rather large sample to counter a sampling bias. Starting the collaboration with the UMCU, we encountered a lot of administrative work that held us back from starting with the case study. If we would have been more aware of these administrative duties, we could have started earlier with the progress of starting the case study so we could have had more time to include patients and could have had a bigger sample size. In spite of these limitations, we achieved a sample size of 143, which was bigger than the target size.

The protocol the researchers needed to strictly follow to ensure conclusion validity was evaluated during the case study and slightly improved when necessary. We improved the protocol to make sure every researcher could still adhere to the same process of approaching and including patients. Because we continuously improved the protocol and made sure that every researcher followed the protocol to the best extent possible, we made sure the conclusion validity was not an issue.

Another point of discussion is the fact that we tried to investigate whether the weekday of the consultation has a relation to a patient's willingness to participate in our study. We did not include and approach any patients on Mondays due to the researchers' availability, therefore we also can not fully disclose that our conclusion for this factor is valid.

Many of the improvements of, for example, the protocol and the PIF were done in consultation with experts from the POS outpatient clinic and Digital Health department. Most of these discussions were informal meetings in which feedback was given. We could have structured this kind of feedback better by conducting

expert interviews in which we would have better kept track of which feedback was given and which improvements were made at which moments. On the other hand, we did not want to interfere too much with the normal way of working of the personnel at the UMCU since we did not want to interrupt their work and just observe their processes.

The SLR also has a limitation, we, unfortunately, did not keep track of the search terms when studying the literature. Therefore we cannot guarantee the reproducibility of our literature protocol. Because we did not want to make up the search terms afterward, we decided to keep this part out of the study. This is de nitely a point of improvement for future work.

Overall, we tried to research many di erent objectives within one study with limited time. This may have resulted in not being able to keep track of every step and discussion in detail. This might have an impact on the external validity and reproducibility of this study. For future studies, we would advise focusing on fewer objectives at once or including more researchers so that the tasks can be distributed better.

We managed to propose a validated and tested method for patient consent for AV recordings in healthcare studies. We call this method the PaCAR method (Patient Consent for AV Recordings). The PaCAR method was applied and tested in a real-life case study at the UMCU POS outpatient clinic. This method serves as an answer to the MRQ of this thesis: How can patients be included in medical consultation studies to obtain patient-consented recordings for research?

To construct an answer to this question, multiple RQs were de ned. The answers to those will shortly be discussed before concluding on the MRQ. The ndings presented in this section provide a comprehensive understanding of the key outcomes and their implications for future research and application of the PaCAR method.

The informed consent process

First, we looked into informed consent, a fundamental principle in healthcare law that originated from the Nuremberg Code and the Declaration of Helsinki (DoH). Informed consent is the autonomous authorization by a patient or test subject to ensure their right to autonomy. This should be seen as a process rather than just a document and can take multiple forms. According to the literature, a combination of conventional or standard informed consent and a patient information video or an audiovisual intervention is the most e ective to get patients to comprehend the contents of the study. Gaining informed consent for recordings of consultations has also been researched. For example, in the emergency department and general practitioner consultations, around 85% of patients agreed to participate and have

their consultation recorded. Both examples used detailed informed consent procedures where patients had the option to discuss questions and concerns. This is an important principle when asking a patient for their informed consent to record their consultation. Other important matters to consider are that even if a researcher obtains a patient's consent, a CP may always decide against recording if they regard the risk for the patient too great. Potential participants should have adequate time to overthink their decision and must be informed beforehand. They should have the option to discuss their concerns, the purpose of the study should be clearly stated, and the distribution of, and access to the recordings should be informed on so that patients know their privacy is being respected. Younger, distressed, or embarrassed patients are less likely to consent to an audio recording of their consultation. There is no evidence for the influence of gender or ethnicity. Overall, patients are more likely to consent to audio than to video recording.

The medical procedures

The procedures and daily way of working at the POS were observed and with the help of literature, we created an extensive understanding of the problem environment as-is. We studied the POS outpatient clinic at the UMCU. The UMCU is an internationally leading medical center with more than 11.500 employees. The anesthesiology department is part of the DVF and has approximately 65 staff members. Screening for anesthesia takes place at the POS, patients who will undergo surgery in the not-too-distant future need to be assessed prior to the surgery by a doctor. A POS screening has the goal to get an impression of the general condition of the patient, to estimate a patient's anesthesia risks, to choose the correct anesthesia technique, and to inform, instruct, and reassure the patient. The screening either takes place at the POS outpatient clinic, over the phone, or at the clinic where a patient is admitted. When a patient reports at the counter, the medical secretary checks whether they have filled in the GVL. If the patient has filled this in, they have a consultation with a pharmacist to verify their medication and allergies. Then, the patient will be screened by the doctor. The screening contains questions about, for example, previous procedures, medication use, diseases, allergies, and previous experiences with anesthesia.

During multiple observations of POS consultations, it stood out that:

- The doctor takes notes and consults the EMR frequently during a consultation.
- The important subjects are not discussed in any particular order.
- Almost everything that the doctor types in the EMR is discussed with the patient.
- Information about a patient is in multiple places in the EMR.

- The doctor almost always measures a patient's blood pressure and listens to the heart and lungs in case of a physical consultation.
- When the consultation is done, the doctor writes a final conclusion. This is the most important part of the EMR and the consultation. Thus, typing is mainly done after the patient has left.

The patient inclusion process

To decide on the eligibility criteria, literature was consulted to give a base and this was later discussed with the experts from the POS outpatient clinic to decide on the final inclusion and exclusion criteria. Patients were excluded if they were under 18 years old, if they did not speak Dutch, if they were mentally retarded, if they lived in an institution or had a supervisor, if the patient was deaf, and if the patient was admitted to the ward. Based on these criteria, we had a patient population of 247 that were approached by the researchers.

Four patients were excluded during the approach and twenty-eight patients could not be reached for various reasons. This leaves us with a sample population of 215 of whom 199 patients gave permission to receive the PIF. Fifty-five recordings could not go through due to various reasons. Seventeen patients did not give consent to record their consultation. This resulted in 143 recordings and a consent rate of 90%. The sample (N=160) contained 50% males and 50% females with a mean age of 56 (SD=16, min=19, max=83). Ninety-four percent of the sample was born in the Netherlands and the median ASA score was 2. Forty percent of the recorded consultations were physical and 60% were over the phone.

The PaCAR method

The PaCAR method was created based on documents provided by Nivel and Monash University. These documents were compared and combined into a PDD that was tested and validated at the POS and improved during and afterward. The method distinguishes four main phases of the process. The first explains the 'preparing phase' where the agreements between the two parties are made and the informed consent form is created. The eligibility criteria are decided and the patient population is created. The 'performing phase' is about gaining informed consent and creating the recording, here patients are approached and asked to sign the informed consent form when their consultation takes place. The 'storing phase' is about storing the recordings and updating the randomization key. The 'processing phase' is about processing and storing the recordings and making sure the anonymization process is conducted. The PaCAR method was tested and validated at the POS outpatient clinic. All possible options for the patient inclusion process were

modeled in BPMN. All extra documents that were needed were created: planning and schedules, example conversations, example emails, microphone and recording instructions, and a doctor information document. During 27 recording days, 143 recordings were made (M = 5.3). The main lessons learned are that participants are willing to participate in these kinds of studies, that it is important to have support from the medical department and management, that a method like the PaCAR method gives good structure, and that it is of importance to have detailed instructions and to work carefully and meticulous.

The (non-)in uential factors

Using cross-tabulation and Chi-Squared, several variables were tested to see if they had a relation with the patient's willingness to participate in our study and let us record their consultation. One variable was found to have a signi cant relation, this was the number of days the patient had to consider their participation. On average, patients were approached 5 days before their consultation. The other variables did not have a signi cant relation according to the available data: researcher gender, patient gender, patient age, consultation form, ASA score, type of doctor, and weekday.

The processing of recordings

To ensure the patients' privacy, several agreements need to be made beforehand. This includes an nWMO, METC request, DPIA, DTA, DMP, and a cooperation contract. Apart from these agreements, the researchers with access to patient data needed to complete some courses. This included the CIP, a GCP course, and two HiX trainings. These courses make sure that the researchers have enough knowledge to protect the rights, safety, and well-being of the patients, consistent with the principles that have their origin in the DoH.

With the help of a PASCI matrix, we assigned the responsibilities to the di erent actions concerning our case study. The medical department is the owner of almost all deliverables concerned with this case study and is also the party that needs to remove these deliverables when necessary. This only does not apply to the randomization key that connects the EMR to the original audio, the medical ICT department is responsible for this deliverable. Most deliverables are created by the UU C2R team, most of these were in collaboration with the medical department and one with the medical ICT department. The storage of the deliverables is divided between the UU C2R team and the medical ICT department. All deliverables are used by the UU C2R team apart from the Randomization Key that connects the patient IDs with the original recordings.

The access to these deliverables was also analyzed. An STS-ml model was created that described the privacy consents, the execution and recording of the consultation, and the analysis of the data. In theauthorization view the permissions and prohibitions for information were presented. In this view, it becomes clear which permissions and prohibitions theResearch Data Controller, the Healthcare Provider, the Research Assistant, the Research Data Controller, and the Patient have.

10.1 Future research

This study presents the first version of the PaCAR method that researchers can apply to get patients' consent for recording their medical consultations. We discovered that the days a patient has to consider has a significant association with their willingness to participate in such a study, so this is something to keep in mind when applying the PaCAR method. In this final section, we will identify possible directions future research could go.

POS recordings

The 143 recordings that were made during the case study at the UMCU POS can be used for future studies. The recordings were automatically transcribed by the C2R system and those transcriptions were anonymized creating anonymous transcripts that may be transferred to C2R. These transcripts provide much information about the contents of POS consultations with which the C2R system can learn how to summarize such consultations into a conclusion paragraph that fits into an EMR.

Further validate the PaCAR method

The PaCAR method was applied to gather audio recordings during this research. The method aims that it can also be used to gather video recordings. To further validate the method it would be a good follow-up study to execute a case study where audio and video recordings are gathered using the PaCAR method.

Apply PaCAR to train the C2R system

To keep improving C2R, the PaCAR method can be used for executing other case studies to gather more recordings and transcripts to train the system with more data so it can learn to summarize medical consultations better. The improvements and feedback gathered during this case study can be applied. Discussed in Section 7.4.2. The C2R system can now be trained with the POS consultation transcripts but still needs training data from other healthcare domains to be able to represent all types of healthcare consultations.

Future collaboration between C2R and UMCU

During this research and case study, a foundation has been laid for a relationship between C2R and the UMCU. This provides C2R with the ability to work more with the UMCU in the future and establish a partnership to test and apply the C2R system in the UMCU. We are looking forward to what projects we can take up there to keep improving C2R.

Application of PaCAR by other researchers

When the PaCAR method will be published it can also be used by other researchers of other projects to gather recordings of medical consultations for healthcare studies. We propose a new method as a solution to a problem that has not been solved by others yet.

Implement PaCAR in C2R

The future goal is to implement a method such as the PaCAR method in the C2R system to capture the whole process in one system instead of having to use multiple systems. The interface of the C2R system would provide the user with an option to select eligible patients and inform the patients about the use of C2R. The system would need to be able to apply the eligibility criteria by itself and maybe send automatic messages to the patients that meet those. If the patient has questions they can answer the message, this will appear in the C2R inbox, where the researcher or doctor can answer them. In the message the patient can indicate whether they do, or do not want to participate, or if they need some time to think about it. The option they select will automatically result in a note with the patient's consultation. The system will also automatically remind the doctor when they need to take action to record the consultation.

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A POS outpatient clinic photos

POS outpatient clinic counter.

POS outpatient clinic counter with Care2Report poster.

POS outpatient clinic hallway with consultation rooms.

POS outpatient clinic POA o ce.

B Activity and concept tables

Activity table of the PDD.

Concept table of the PDD.

C Framework POS recordings for C2R

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Stappenplan Informed Consent procedure patienten

Er zijn drie soorten patienten die een consult kunnen hebben op de POS poli. Patienten die fysiek langskomen op de poli voor een consult (optie 1) en patienten die een belafspraak hebben voor een telefonisch consult (optie 2). Deze twee soorten patienten hebben van tevoren een afspraak gemaakt en staan in de planning. Er zijn ook patienten die op de dag zelf langskomen bij de balie om een afspraak te maken voor dezelfde dag (optie 3). Deze mensen worden bijvoorbeeld vanaf een andere afdeling doorgestuurd.

Het liefst minimaal 2 (werk)dagen dagen voorafgaand aan opname dagen screent een onderzoeker X welke patienten benaderd kunnen worden voor deelname.

Fysieke afspraak

A. Onderzoeker X kijkt of de patient benaderd mag worden voor deelname aan onderzoek.

a Als de patient niet voldoet aan de geschiktheidscriteria, dan eindigt hier het proces.

b Als de patient wel voeldoet aan de geschiktheidscriteria, ga door naar activiteit B.

B. Een onderzoeker belt de patient op en informeert de patient over het onderzoek.

C. Een onderzoeker vraagt om toestemming van de patient om het Patient Informatie Formulier (PIF) te mailen.

a Als de patient hier geen toestemming voor geeft eindigt hier het proces.

b Als de patient wel toestemming geeft, ga door naar activiteit D.

D. Een onderzoeker mailt het PIF naar de patient.

E. Een onderzoeker informeert aan het begin van de dag de arts(en) welke patienten zijn benaderd voor het onderzoek.

F. De patient heeft diens POS afspraak op de polikliniek.

G. De arts vraagt de patient aan het begin van het consult of diegene nog mee wil doen aan het onderzoek.

a Als de patient hier geen toestemming voor geeft, eindigt hier het proces.
b Als de patient wel toestemming geeft, ga door naar activiteit H.

H. De opname kan worden gestart.

I. Een onderzoeker legt de Informed Consent (IC) van de patient vast in de opname en in het patientendossier i.o.m. de polimedewerker die de patient spreekt. De patient moet zijn of haar naam en geboortenaam zeggen, en dat hij/zij toestemming geeft voor deze studie en eventueel gerelateerd toekomstig onderzoek.

a Als de toestemming van de patient nog niet in HiX is vastgelegd, moet de onderzoeker dit doen via het research account. Leg vast dat de patient toestemming heeft gegeven voor het onderzoek en ook of ze toestemming hebben gegeven voor toekomstig onderzoek.
b Als de toestemming van de patient wel in HiX is vastgelegd, ga door naar activiteit I.

J. De opname kan worden beeindigd nadat het consult af is, en moet meteen worden overgezet op de beveiligde server en verwijderd worden van de iPhone.

Informed consent proces fysiek consult.

Belafspraak

A. Onderzoeker X kijkt of patient benadert mag worden voor deelname aan onderzoek.

a Als de patient niet voldoet aan de geschiktheidscriteria, dan eindigt hier het proces.
b Als de patient wel voldoet aan de geschiktheidscriteria, ga door naar activiteit B.

B. Een onderzoeker belt de patient op en informeert de patient over het onderzoek.

C. Een onderzoeker vraagt om toestemming van de patient om het Patient Informatie Formulier (PIF) te mailen.

a Als de patient hier geen toestemming voor geeft, eindigt hier het proces.
b Als de patient wel toestemming geeft, ga door naar activiteit D.

D. Een onderzoeker mailt het PIF naar de patient.

E. Een onderzoeker informeert aan het begin van de dag de arts(en) welke patienten met een TC zijn benaderd voor het onderzoek.

F. Als de polimedewerker de patient belt, dan herinnert een onderzoeker of de polimedewerker de patient aan het begin van het TC aan het onderzoek.

G. Onderzoeker X/Polimedewerker X vraagt of de patient mee wil doen aan het onderzoek.

a Als de patient hier geen toestemming voor geeft, eindigt hier het proces.
b Als de patient wel toestemming geeft, ga door naar activiteit H.

H. De opname kan worden gestart.

I. Een onderzoeker hoort de Informed Consent (IC) van de patient mondeling en legt het vervolgens nogmaals als de opname start en legt de informed consent vast in de opname en in het patientendossier i.o.m. de polimedewerker die de patient spreekt. De patient moet zijn of haar naam en geboortenaam zeggen, en dat hij/zij toestemming geeft voor deze studie en eventueel gerelateerd toekomstig onderzoek.

a Als de toestemming van de patient nog niet in HiX is vastgelegd, moet de onderzoeker dit doen via het research account. Leg vast dat de patient toestemming heeft gegeven voor het onderzoek en ook of ze toestemming hebben gegeven voor toekomstig onderzoek.

b Als de toestemming van de patiëntwel in HiX is vastgelegd, ga door naar naar activiteit J.

J. De opname kan worden beëindigd nadat het TC af is, en moet meteen worden overgezet op de beveiligde server en verwijderd worden van de iPhone.

Fysieke aanloop afspraak

A. Patient komt langs bij de POS balie om een afspraak maken voor diezelfde dag.

B. Secretaresse opent het EPD van de patient en checkt of de patient benaderd mag worden voor deelname aan onderzoek.

a Als de patient hier niet voor in aanmerking komt eindigt hier het proces.
b Als de patient hier wel voor in aanmerking komt ga door naar activiteit C.

C. Secretaresse informeert de patient over het lopende onderzoek.

D. Secretaresse vraagt of de patient het PIF formulier wilt ontvangen.

a Als de patient hier geen toestemming voor geeft eindigt hier het proces.
b Als de patient wel toestemming geeft, ga door naar activiteit E.

E. Secretaresse overhandigt een fysiek exemplaar van het PIF aan de patient.

F. Patient heeft diens afspraak op de poli op de afgesproken tijd.

G. Onderzoeker X vraagt of de patient goed genoeg heeft na kunnen denken over de deelname en of de patient nog vragen heeft. Beantwoord de vragen van de patient. Vraag daarna of de patient mee wil doen aan het onderzoek.

a Als de patient hier geen toestemming voor geeft, eindigt hier het proces.
b Als de patient wel toestemming geeft, ga door naar activiteit H.

H. Een onderzoeker zegt voorafgaand aan het consult tegen de polimedewerker die de patient gaat zien, dat de patient meedoet aan een studie.

I. De opname kan worden gestart.

J. Een onderzoeker legt de Informed Consent (IC) van de patient vast in de opname en in het patientendossier i.o.m. de polimedewerker die de patient spreekt. De patient moet zijn/haar naam en geboortedatum zeggen, en dat hij/zij toestemming geeft voor deze studie en eventueel gerelateerd toekomstig onderzoek.

a Als de toestemming van de patient nogniet in HiX is vastgelegd, moet de onderzoeker dit doen via het research account. Leg vast dat de patient toestemming heeft gegeven voor het onderzoek en ook of ze toestemming hebben gegeven voor toekomstig onderzoek.
b Als de toestemming van de patientwel in HiX is vastgelegd, ga door naar activiteit K.

K. De opname kan worden beëindigd nadat het consult af is, en moet meteen worden overgezet op de beveiligde server en verwijderd worden van de iPhone.

Informed consent proces aanloop patient.

Activiteit A - Patienten selecteren voor inclusie

Voordat je besluit om een patient te bellen, zijn er een aantal redenen om iemand niet te includeren in deze studie. Deze staan hier uitgeschreven.

Geschiktheidscriteria Care2Report:

1. Patient heeft een afspraak voor een screening op de POS tussen 7 maart en 26 april.
2. Patient is 18 jaar of ouder.
3. Patient spreekt Nederlands.

Exclusiecriteria voordat je een patient gaat bellen:

1. Patient is onder de 18 jaar.
2. Patient spreekt geen Nederlands.
3. Patient is mentaal geretardeerd.
4. Patient woont in een instelling en/of heeft een begeleider.
5. Patient is doof.
6. Patient ligt opgenomen op de afdeling (Afdelingspatient - AP)

Activiteit B - Patient informeren

Patienten moeten van te voren geinformeerd worden over het onderzoek waar ze voor worden benaderd. Dit gebeurt telefonisch en kan gedaan worden door de onderzoekers. Daarvoor hebben zij de GCP cursus afgerond en is dit document opgesteld als leidraad.

Extra info:
Patienten mogen niet zomaar gemaild worden vanwege privacy redenen, daarom moet er eerst om toestemming gevraagd worden of we het PIF naar hen mogen mailen.

Ook mogen patienten niet zomaar benaderd worden voor deelname aan (klinisch) onderzoek, hier moeten zij in het algemeen voor benaderd worden door de behandelend arts. Als zij toestemming hebben gegeven dat ze benaderd mogen worden voor deelname aan onderzoek, mogen wij hen benaderen voor deelname aan ons onderzoek. Marije Marsman en onderzoeker X kunnen in HiX kijken of de patient de 'benaderings' toestemmingsverklaring al getekend heeft en/of de patient al deelneemt aan ander onderzoek. Is dit het geval, dan mag patient door onderzoekers gebeld worden.

Dinsdag 7 maart starten we met bellen. Dit kan vanuit het UMCU met een telefoon met een vaste lijn.

Doel van het telefoongesprek:

1. Patient informeren over het onderzoek
2. Patient om toestemming vragen om het PIF te mailen.

Activiteit A - Patient informeren.

Dingen die genoemd moeten worden in het gesprek
Patient heeft een afspraak bij de anesthesie voor een peroperatief screening consult.
Kort uitleg geven over het onderzoek.
Vragen of de patient wil overwegen of diegene wilt deelnemen.
Benadrukken dat het onderzoek geen invloed heeft op de afspraak.
Benadrukken dat de opname wordt geanonimiseerd en dit goed uitleggen in goed begrijpelijke taal.
Benadrukken dat de opname veilig wordt bewaard.
Vragen om toestemming om de informatie te mailen naar de patient.
Aangeven dat de patient op de dag van de afspraak zelf kan laten weten of diegene wel of niet deel wil nemen aan het onderzoek.

Voorbeeld van een telefoon gesprek met een patient:

Goedemorgen/Goedemiddag,

Met f vul naam ing van de afdeling anesthesiologie van het UMC Utrecht. Ik bel u in verband met de afspraak die u binnenkort op de anesthesie poli heeft.

Als het u schikt, wil ik u graag iets vertellen over een wetenschappelijk onderzoek op de anesthesie polikliniek van het UMC Utrecht.

Onderzocht wordt of een computer een opgenomen gesprek tussen u en de arts kan vertalen naar medische tekst. Als de computer dit kan leren, dan hoeft een arts in de toekomst minder in uw dossier te typen tijdens het gesprek, dit gebeurt dan automatisch. Dit heeft als voordeel dat de arts tijdens een gesprek meer aandacht voor u als patient zal hebben.

Wij willen het gesprek tussen u en de arts op de aneshtesie poli opnemen, zodat onze computer kan leren het gesprek te vertalen naar medische tekst

Belangrijk om te weten is dat het onderzoek geen invloed heeft op het gesprek tussen u en de arts.

Uw persoonlijke gegevens worden niet in de medische tekst opgenomen, deze door de computer vertaalde gesprekken zijn anoniem. Na de vertaling van de opname naar de medische tekst, wordt de opname vernietigd.

Naast dat ik u dit vertel, hebben we ook een folder met de informatie die u kunt nalezen. Zouden we deze u mogen mailen?

Let op: als een patient geen mailadres heeft geven we bij aanmelding voor de afspraak bij de POS balie een kopietje mee van het PIF of sturen we het per post op

naar de patient. Check dan aan de telefoon ook even het adres wat in het systeem staat.

Het e-mailadres wat ik in het ziekenhuisadministratie zie staan is vul emailadres in g klopt dat?

Let op: mocht het mailadres dat in het systeem staat niet kloppen:

1. Noteer wat volgens de patient het juiste mailadres is
2. Geef door aan de patient dat je dit door gaat geven aan het secretariaat.
3. Geef het juiste mailadres door aan het secretariaat.

Mijn vraag aan u is, of u zou willen overwegen of dat we uw gesprek mogen opnemen?

Aan het begin van uw afspraak zullen wij u er nog aan herinneren en kunt u laten weten of u heeft besloten om wel of niet mee te doen aan het onderzoek. Als u niet mee wilt doen heeft dit verder geen consequenties en zal het gesprek niet worden opgenomen.

U hoeft niks te ondertekenen, uw toestemming wordt in uw dossier genoteerd.

Dan wens ik u nog een jne dag!

Activiteit D - PIF mailen

Als de patient telefonisch toestemming heeft gegeven om het PIF via de mail te ontvangen kan het onderzoeksteam de patient een mail sturen.

De mailadressen kunnen worden verzameld door de onderzoeker via researchtoegang in HiX.

Het PIF is te vinden in de RFS.

Een standaard mail die gebruikt kan worden is toegevoegd in Bijlage 1.

Informeerprocedure artsen

Alle artsen moeten ook geinformeerd worden over het project, hiervoor is een informatiefolder gemaakt over het onderzoek van Care2Report.

Elke opnamedag start om 8:00 tijdens de dagstart. Hier wordt kort toegelicht dat er die dag opnames worden gemaakt en welke studenten er die dag meelopen. Hier is een planning voor gemaakt te zien in de volgende sectie.

Alle screeners wordt gevraagd of ze akkoord zijn met het feit dat er opnames worden gemaakt die dag, en of er bepaalde consulten zijn die geexcludeerd moeten worden.

Voor de vaste sta hoeft dit niet elke dag gevraagd te worden, maar is het wel goed om in de gaten te houden dat er consulten kunnen zijn die ze liever niet op willen nemen.

Het informatieformulier voor polimedewerkers is toegevoegd in Bijlage 2.

Indeling POS polikliniek

Er kunnen twee opnames tegelijk gemaakt worden, er zijn twee sets om opnames te maken. Hiervoor moeten ook twee onderzoekers aanwezig zijn. Dit kan een fysiek consult en een belconsult zijn, twee belconsulten, of twee fysieke consulten.

Een opnameset bestaat uit

1. 1 iPhone
2. 1 microfoonset met 2 microfoons
3. 1 iXpand USB-stick

Om de opnames te starten zal een onderzoeker aanwezig zijn in de spreekkamer en de opname starten. Dan zorgt de onderzoeker ervoor dat de patient toestemming geeft op de opname voor deelname aan de studie. Hierna verlaat de onderzoeker de spreekkamer. Dit hoeft niet altijd, na een paar keer kan de arts dit waarschijnlijk zelf. De arts kan de opname eindigen. Als de patient de spreekkamer verlaat kan de onderzoeker de spreekkamer in om de iPhone op te halen en de opname over te zetten op de UMCU server.

Een microfoonset bestaat uit een verzender en twee microfoons. 1 microfoon moet aan de kant van de arts geplaatst worden, en 1 microfoon aan de kant van de patient. De microfoons kunnen op tafel neergelegd worden. Om de opname over te zetten op een UMCU computer is er een USB-stick die in de iPhone geplaatst kan worden en in de computer. Hiermee kun je de bestanden rechtstreeks overzetten in de juiste map op de UMCU leserver.

Indeling onderzoekers:

Per opnamedag moet er minimaal 1 onderzoeker aanwezig zijn, het liefst twee. Als er geen beschikbaarheid van de onderzoekers is, wordt er die dag niet opgenomen. Hier moet rekening mee worden gehouden tijdens het benaderen van patienten.

Er is een indeling gemaakt met de beschikbaarheid van de onderzoekers. Deze is hieronder te zien. Deze voorlopige indeling is een uitgangspunt, hier kan mogelijk nog van worden afgeweken.

Planning opnames maart en april.

Tussen de opnames door, kunnen de onderzoekers patienten bellen om ze te benaderen voor deelname. Hierbij moet rekening gehouden worden met de aanwezige onderzoekers op de dag van het consult van de patient. Als er maar 1 onderzoeker aanwezig is die dag, dan kun je geen twee patienten benaderen die op hetzelfde tijdstip of overlappend een consult hebben ingepland enzovoorts.

Na de eerste twee weken met opnames zullen we een evaluatiemoment inplannen om te kijken of er aanpassingen nodig zijn in de planning etc.

- Introductie bij dagstart: dinsdag 28 februari (week 9)
- Start patienten bellen: dinsdag 7 maart (week 10)
- Start opnames: woensdag 8 maart week 10)
- Evaluatiemoment: woensdag 22 maart (week 12)

Bijlage 1. Standaard mail patienten

Geachte heer/mevrouw(weghalen wat niet van toepassing is)

We hebben elkaar zojuist gesproken n.a.v. het onderzoek waarbij we het gesprek tussen u en de anesthesioloog willen opnemen en door een computer willen laten vertalen naar medische tekst.

In de bijlage vindt u het uitgebreide informatie formulier zodat u dit nog een keer rustig kunt nalezen.

U hoeft niet vandaag te beslissen, aan het begin van uw afspraak op de poli zullen we u vragen of u heeft besloten om wel of niet mee te doen.

Met vriendelijke groet,

f vul naam onderzoeker in

Bijlage 2. Informatieformulier voor behandelaren

Informatie voor behandelaren over wetenschappelijk onderzoek

Titel: Care2Report

Geachte polimedewerker,

Met deze informatiebrief willen we u informeren over het wetenschappelijk onderzoek dat uitgevoerd wordt op de POS poli waar u mogelijk bij betrokken kunt worden.

U leest in deze brief om wat voor onderzoek het gaat, bij welke onderdelen u betrokken kunt worden en maakt kennis met het onderzoeksteam.

1. Algemene informatie

De Universiteit Utrecht doet dit onderzoek samen met het UMC Utrecht.

2. Wat is het doel van het onderzoek?

Wij onderzoeken of een computer het gesprek tussen u en de patient kan vertalen naar een medische tekst. Als een computer dit kan leren, dan hoeft u in de toekomst minder in het patientendossier te typen, want dit gebeurt dan automatisch. Dit heeft als voordeel dat u minder tijd aan administratie hoeft te besteden en dus meer tijd overhoudt voor de patient.

3. Wat betekent het onderzoek voor u als polimedewerker

Voor u als polimedewerker betekent dit dat de gesprekken die u met de patient voert opgenomen kunnen worden. Hiervoor wordt bij de dagstart toestemming gevraagd. Mocht er een consult zijn waarvan u denkt, deze wil ik liever niet opgenomen hebben, kunt u dit op dat moment aangeven bij de onderzoekers. Welke patienten in aanmerking komen voor de studie wordt door de onderzoekers bepaald. Patienten worden door het onderzoeksteam benaderd en gevraagd of zij deel willen nemen. Ook zorgen de onderzoekers ervoor dat de opnameapparatuur ter plaatse is en werkt. Het kan dus zijn dat er een onderzoeker bij het consult aanwezig is. De opnames en alle data worden volledig geanonimiseerd.

4. Wat meedoen voor de patient inhoudt

Als de patient meedoet, wordt het gesprek tussen u en de patient opgenomen. Dit wordt gecombineerd met gegevens uit het medisch dossier dat gemaakt wordt door u tijdens het gesprek. Hierdoor kan de computer leren om een gesprek om te zetten naar medische tekst. De patient hoeft niks extra's te doen voor het onderzoek.

5. Wat zijn de voordelen en de nadelen als de patient meedoet aan het onderzoek?

De patient heeft geen voordeel van het meedoen aan het onderzoek. De patient krijgt geen onkostenvergoeding. De deelname draagt bij aan de zoektocht naar

e cientere zorg, waarbij de artsen en verpleegkundigen meer tijd overhouden voor hun patienten.

Moet de patient zich zorgen maken dat de spraakopnames buiten het UMC terechtkomen?

Nee, dit hoeft niet. De opname wordt in het UMC Utrecht op een beveiligde plek bewaard. Nadat de opname omgezet is tot tekst, wordt de opname vernietigd. Voor analyse door de computer wordt het gesprek geanonimiseerd. Dit betekent dat alle woorden, die tot de patient te herleiden zijn, veranderd/verwijderd worden.

6. Wanneer stopt het onderzoek?

Als er 300 gesprekken zijn opgenomen, maar uiterlijk 31 juli 2023.

7. Wat doen we met de gegevens van de patient?

Doet de patient mee met het onderzoek? Dan geeft deze ook toestemming om diens gegevens te verzamelen, gebruiken en bewaren.

Welke gegevens bewaren we?

- geslacht en leeftijd zoals dit in het dossier staat
- het anesthesiologisch dossier dat gemaakt is n.a.v. het gesprek met de anesthesioloog
- het uitgeschreven gesprek (door middel van spraakherkenning)

Bij het verwerken van de gegevens houden wij ons aan de Algemene Verordening Gegevensbescherming, waarbij we de gegevens zoveel mogelijk anonimiseren. Wat dit precies voor de patient betekent kunt u lezen in de bijlage 1 van het PIF. Wij vragen voor het gebruik van de gegevens toestemming van de patient.

8. Heeft u of de patient vragen?

Vragen over het onderzoek kunt u stellen aan het onderzoeksteam (Zie punt 10).

9. Hoe geeft de patient toestemming voor het onderzoek?

De patient wordt van tevoren telefonisch benaderd en kort geinformeerd over het lopende onderzoek. Hierna krijgt de patient het PIF gemaild waar alle informatie nog een keer uitgebreid staat beschreven. Op de dag van het POS consult zelf, zal mondeling gevraagd worden of de patient mee wilt doen of niet. Indien de patient toestemming geeft, moet dit nog een keer mondeling bevestigd worden op de opname. De toestemming wordt in het EPD vastgelegd door de onderzoekers.

Met vriendelijke groet,

Drs. M. Marsman, anesthesioloog, en prof. Dr. S. Brinkkemper, hoofdonderzoeker Universiteit Utrecht, afdeling informatica.

10. Het onderzoeksteam

UMCU

Naam medewerker Hoofdonderzoeker UMC Utrecht Email
Naam medewerker Ondersteuning projectleiding UMC Utrecht Email
Naam medewerker Contract en budgetbeheer UMC Utrecht Email

Medewerkers UMCU.

Universiteit Utrecht

prof. dr. Sjaak Brinkkemper Hoofdonderzoeker Universiteit Utrecht Email
Roos van Vilsteren Projectleiding UU Opnameprocedures, patientinclusie en informed consent procedure Email
Naam student Softwareontwikkeling en eisen van het systeem Email
Naam student Ethische procedures van het onderzoek en het systeem Email
Naam student Gebruiksvriendelijkheid van het systeem Interactie van de polimedewerker met het EPD Email
Naam student Softwareontwikkeling en technische ondersteuning Email

Medewerkers UU.

D Patient Information Form

Deelnemersinformatie voor deelname aan wetenschappelijk onderzoek

Titel: care2report

Geachte heer/mevrouw,

Met deze informatiebrief willen we u vragen of u wilt meedoen aan wetenschappelijk onderzoek. Meedoen is vrijwillig. U krijgt deze brief omdat u een afspraak heeft op de polikliniek anesthesiologie. U leest hier om wat voor onderzoek het gaat en wat het voor u betekent.

1. Algemene informatie

De Universiteit Utrecht doet dit onderzoek samen met het UMC Utrecht.

2. Wat is het doel van het onderzoek?

Wij onderzoeken of een computer het gesprek tussen u en de arts kan vertalen naar een medische tekst. Als een computer dit kan leren, dan hoeft de arts in de toekomst minder in uw dossier te typen, want dit gebeurt dan automatisch. Dit heeft als voordeel dat de arts minder tijd aan administratie hoeft te besteden en dus meer tijd overhoudt voor u als patient.

3. Wat meedoen inhoudt

Als u meedoet, wordt het gesprek tussen u en de anesthesioloog of screenings-verpleegkundige opgenomen. Dit wordt gecombineerd met de gegevens uit het medisch dossier dat gemaakt wordt tijdens het gesprek. Hierdoor kan de computer leren om een gesprek om te zetten naar medische tekst. U hoeft niets extra's te doen voor het onderzoek.

4. Wat zijn de voordelen en de nadelen als u meedoet aan het onderzoek?

U heeft zelf geen voordeel van meedoen aan dit onderzoek. U krijgt geen onkosten-vergoeding. Uw deelname draagt bij aan de zoektocht naar e cientere zorg, waarbij artsen en verpleegkundigen meer tijd overhouden voor hun patienten.

Moet ik mij zorgen maken dat deze spraakopnames buiten het UMC terecht komen?

Nee, dit hoeft niet. De opname wordt in het UMC Utrecht op een beveiligde plek bewaard. Nadat de opname omgezet is tot tekst, wordt de opname vernietigd. Voor analyse door de computer wordt het gesprek geanonimiseerd. Dit betekent dat alle woorden, die tot u te herleiden zijn, veranderd/verwijderd worden.

Wilt u niet meedoen?

U beslist zelf of u meedoet aan het onderzoek of niet.

5. Wanneer stopt het onderzoek?

Als er 300 gesprekken zijn opgenomen, maar uiterlijk 31 juli 2023.

6. Wat doen we met uw gegevens?
Doet u mee met het onderzoek? Dan geeft u ook toestemming om uw gegevens te verzamelen, gebruiken en bewaren.

Welke gegevens bewaren we?
- geslacht en leeftijd zoals dit in uw dossier staat
- het anesthesiologisch dossier dat gemaakt is n.a.v. het gesprek met de anesthesioloog
- het uitgeschreven gesprek (door middel van spraakherkenning)

Bij het verwerken van uw gegevens houden wij ons aan de Algemene Verordening Gegevensbescherming, waarbij we uw gegevens zoveel mogelijk anonimiseren. Wat dit precies voor u betekent kunt u lezen in de bijlage 1. Wij vragen voor het gebruik van uw gegevens uw toestemming.

7. Heeft u vragen?
Vragen over het onderzoek kunt u stellen aan het onderzoeksteam. Heeft u een klacht? Bespreek dit dan met de onderzoeker. Wilt u dit liever niet? Ga dan naar de klachtenbemiddelaars. Deze zijn bereikbaar via tel. 088-75 562 08. Of digitaal via: http://www.umcutrecht.nl/nl/Ziekenhuis/Ervaringen-van-patienten/Een-klacht-indienen.

8. Hoe geeft u toestemming voor het onderzoek?
U kunt eerst rustig nadenken over dit onderzoek. Daarna vertelt u de onderzoeker of u de informatie begrijpt en of u wel of niet wilt meedoen. Wilt u meedoen? Dan kunt u uw toestemming voor deelname, aan dit onderzoek en het gebruik van uw gegevens voor later onderzoek, mondeling aan het begin van uw gesprek met de anesthesioloog of screenings-verpleegkundige geven. Zij zullen uw toestemming in uw dossier noteren. Na uw mondelinge toestemming zal de opname starten en wordt u gevraagd uw toestemming mondeling te bevestigen. Indien u geen toestemming geeft, zal het gesprek niet worden opgenomen. Het gesprek zal dan op de gebruikelijke manier in uw dossier beschreven worden.

Met vriendelijke groet,

Drs. M.Marsman, anesthesioloog en prof. Dr. S.Brinkkemper, hoofdonderzoeker
Universiteit Utrecht, afdeling informatica

Bijlagen: Aanvullende informatie over verwerking van uw gegevens

Bijlage 1: Aanvullende informatie over verwerking van uw gegevens

Hoe beschermen we uw privacy?
Om uw privacy te beschermen geven wij uw gegevens een code. Op al uw gegevens zetten we alleen deze code. De sleutel van de code bewaren we op een beveiligde plek in Het UMC Utrecht. Als we uw gegevens verwerken, gebruiken we steeds alleen die code. Ook in rapporten en publicaties over het onderzoek kan niemand terughalen dat het over u ging.

Wie kunnen uw gegevens zien?
Sommige personen kunnen wel uw naam en andere persoonlijke gegevens zonder code inzien. Dit zijn mensen die controleren of de onderzoekers het onderzoek goed en betrouwbaar uitvoeren. Deze personen kunnen bij uw gegevens komen:

- Een controleur die door het UMC Utrecht of de Universiteit van Utrecht is ingehuurd.
- Nationale en internationale toezichthoudende autoriteiten. Bijvoorbeeld de Inspectie Gezondheidszorg en Jeugd.

Deze personen houden uw gegevens geheim. Wij vragen u voor deze inzage toestemming te geven.

Hoelang bewaren we uw gegevens?
We bewaren uw gegevens 15 jaar in het UMC Utrecht. De geluidsopnames worden verwijderd nadat dit tot tekst is omgezet. Deze tekst wordt 15 jaar bewaard in het UMC Utrecht. De volledig geanonimiseerde gegevens worden uiteindelijk naar de Universiteit van Utrecht gestuurd en dar op een beveiligde omgeving bewaard voor maximaal 15 jaar.

Mogen we uw gegevens gebruiken voor ander onderzoek?
Uw gegevens kunnen na a oop van dit onderzoek ook nog van belang zijn voor ander wetenschappelijk onderzoek op het gebied van de ontwikkeling van spraakherkenning of analyse van gesprekken tussen anesthesioloog en patient. Daarvoor zullen uw gegevens 15 jaar worden bewaard in het UMC Utrecht en de Universiteit van Utrecht. Geeft u hiervoor geen mondelinge toestemming?. Dan kunt u nog steeds meedoen met dit onderzoek.

Kunt u uw toestemming voor het gebruik van uw gegevens weer intrekken?
U kunt uw toestemming voor het gebruik van uw gegevens op ieder moment intrekken. Dit geldt voor het gebruik in dit onderzoek en voor het gebruik in ander onderzoek. Maar let op: trekt u uw toestemming in, en hebben onderzoekers dan al gegevens verzameld voor het onderzoek? Dan mogen zij deze gegevens nog wel gebruiken.

Wilt u meer weten over uw privacy?

- Wilt u meer weten over uw rechten bij de verwerking van persoonsgegevens? Kijk dan op www.autoriteitpersoonsgegevens.nl.
- Heeft u vragen over uw rechten? Of heeft u een klacht over de verwerking van uw persoonsgegevens? Neem dan contact op met degene die verantwoordelijk is voor de verwerking van uw persoonsgegevens. Voor uw onderzoek is dat:
  - Drs. Marsman, anesthesioloog, m.marsman-2@umcutrecht.nl
- Als u klachten heeft over de verwerking van uw persoonsgegevens, raden we u aan om deze eerst te bespreken met het onderzoeksteam. U kunt ook contact opnemen met de Functionaris Gegevensbescherming van het UMC Utrecht gaan via privacy@umcutrecht.nl. Of u dient een klacht in bij de Autoriteit Persoonsgegevens.

Klachten:
Als u klachten heeft kunt u dit melden aan de onderzoeker of aan uw behandelend arts. Mocht u ontevreden zijn over de gang van zaken bij het onderzoek en een klacht willen indienen dan kunt u ook contact opnemen met de klachtenbemiddelaars. Deze zijn bereikbaar via tel. 088-755 62 08. Of digitaal via: http://www.umcutrecht.nl/nl/Ziekenhuis/Ervaringen-van-patienten/Een-klachtindienen.

E HiX Screenshots

When selecting patients, researchers needed to check whether patients already participated in a study or gave permission to be contacted for participating in a study. When opening a patient's EMR, you need to click on the red-marked part.

Study section patient EMR.

You then get to see this screen. Here you can see the details of a patient. This example patient already participated in two studies/trials. At the bottom, you can see that they indicated that they do not have any objections against using their rest material for research and education and that they are ne with their medical personal data being used for research.

Detailed study section patient EMR.

There is another check mark that could be in a patient's EMR, in which they indicate that they give permission to be contacted by researchers.

Permission for research approach.

When patients participated in the study. The study must be added to their EMR. Here you see C2R's research code which had to be added.

C2R research code in HiX.

On the top left (red marked) you can see which patient's EMR you are consulting. In the other red-marked box, you can consult the patient's contact details. The researchers need this to call the patient and possibly mail them afterward.