Implementing the head and neck oncology e-pathway with structured and standardized documentation - Improving quality and efficiency using the electronic health record

Ebbers, T.

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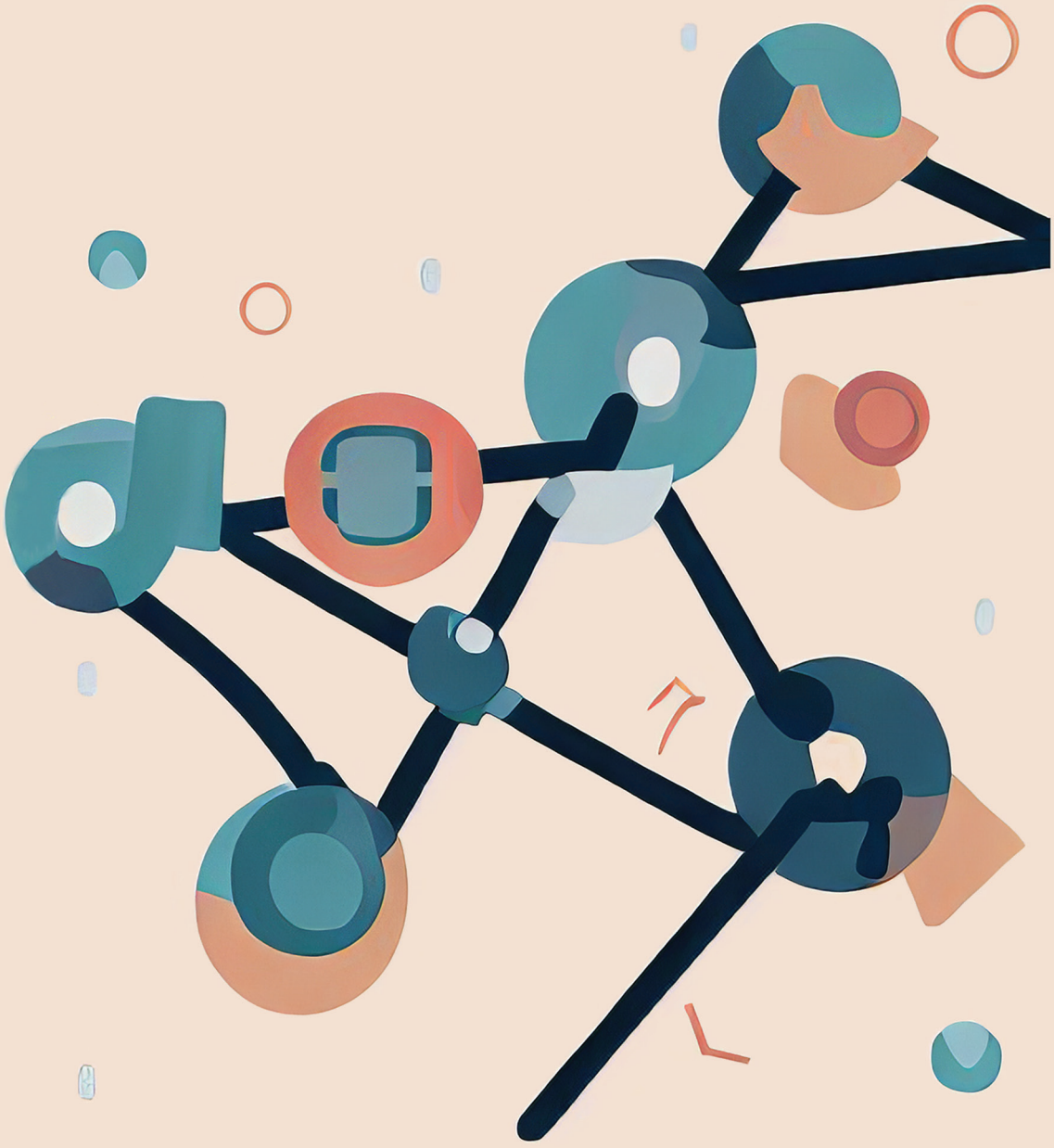
IMPROVING QUALITY AND EFFICIENCY USING THE ELECTRONIC HEALTH RECORD



TOM EBBERS

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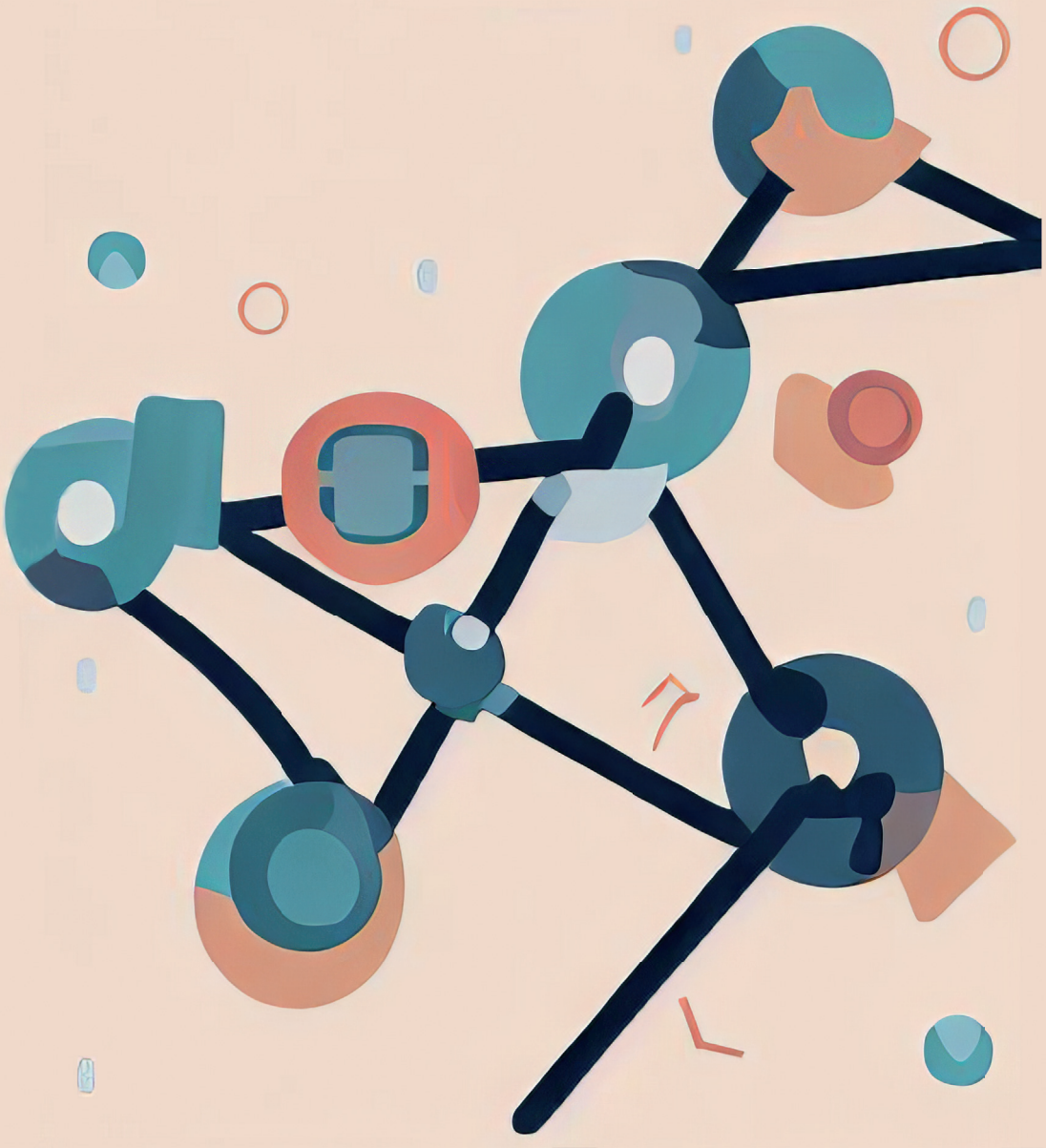


Chapter 1

General Introduction

This dissertation addresses several aspects of healthcare data registration and reuse. In the introduction of this thesis, I will guide the reader through a short history of data recording in healthcare. I will discuss the rise of the (electronic) patient record and the current administrative burden among healthcare providers. I also outline how reuse of EHR data could be achieved and describe why structured recording is closely related to working with care pathways. Lastly, I present the main research questions and the studies that have been conducted to answer these questions.

History of medical documentation

The first medical documentation dates back to the year 1600 BC when several surgical cases were described on an Egyptian papyrus(1). More than a thousand years later, the case histories of Hippocrates of Cos and, subsequently, the Hippocratic School had significant influence in the West and had a more patient-oriented view(2). Hippocrates introduced many medical terms still used by physicians, such as symptoms, diagnosis, therapy, and trauma(3). During the medieval period, the Hippocratic Corpus and other Greek scientific texts were translated into Arabic(4). As a result, medieval Islamic physicians continued the development of case histories for didactic use. Multiple examples show that education would remain the primary purpose of medical documentation for centuries. In the late 18th century, more detailed medical data recording started, containing identifiable, basic medical and legal information.

The first 'modern' patient-related medical records in Europe date back to the early 19th century. They were usually retrospective, free-form narratives based on what a physician wrote in a personal notebook(5, 6). However, such records had no format and were still not used for patient care. Subsequently, administrators tried to supervise content and quality when records became important as legal documents. At the end of the 19th century, some important changes were introduced in hospitals in the US. A transition from retrospective to real-time recording of cases and the imposition of a fixed chart structure through the use of forms dramatically reduced the narrative dimension of these records(6). However, information was often missing or scarce, as these table-oriented forms left no room for narrative. Therefore, physicians no longer recorded their thinking, just short observations(6). Additionally, information was still highly scattered, as medical, surgical, inpatient, and outpatient information were kept in separate volumes. These problems made retrieval of information highly difficult.

To address these problems, innovations based on business and industry models were introduced in 1907, ensuring every patient had a clinic number and combining all information on one patient in a single record(7). This meant that records were no longer time-oriented (one chronological record with information on multiple patients) but patient-oriented (all information on a patient in one record). However, only a minority of

physicians kept adequate records, which ultimately led to requirements to record basic clinical data in a standard format(8). Hospital records grew in volume and complexity and still suffered from unreliable availability of records, illegibility, and lack of ready availability of records from other hospitals or physician offices(9). Furthermore, Lawrence Weed proposed the transition from patient-oriented (information per patient in one file, but chronologically ordered) to problem-oriented records (information per patient, ordered per problem), which would prove to be the basis for the modern organized medical record(10, 11). He advised keeping a numbered past and present problem list, discussing each problem separately, keeping graphs of moving parameters, and linking all progress notes, orders, and plans to a specific problem on the numbered list. In 1967, Weed started a project to build PROMIS (Problem Oriented Medical Information System), a computer system that would store and retrieve all relevant information he described in his earlier publications, therefore overcoming the insurmountable distribution and time barriers present when using paper records(12). This project had four goals (1) to facilitate good patient care, (2) to enable epidemiological studies, (3) to enable medical audits, and (4) to enable business audits. While other research groups chose to enter dictated or written words of physicians into the computer system, Weeds group decided that physicians should interact with the computer system themselves. This decision had a significant impact and ultimately put the responsibility of healthcare data recording in the hands of the healthcare provider.

Purpose of the Electronic Health Record

Initially, Electronic Health Records (EHRs) had limited functionality and use. In 1992, the Institute of Medicine in the US advocated a shift from paper-based to electronic medical records(13). However, poor acceptance by physicians, high costs, and lack of tangible incentives delayed the widespread adoption of the EHR for years(14). Furthermore, the high costs of completely replacing paper charts with an EHR also led to the view that only essential information should be recorded in EHRs, resulting in EHRs complementing instead of replacing paper charts. For example, a diagnosis was recorded in the EHR, but the corresponding treatment plan was still written in the paper chart. Nevertheless, the amount of healthcare data recorded has increased to massive amounts since then. Furthermore, numerous additional functionalities were developed within EHR systems. Currently, the modern EHR has eight core functionalities(15). These are shown in box 1.

Box 1. Functionalities of the EHR

Health information and data
Having immediate access to key information, such as patients' diagnoses, allergies, lab test results, and medications, improves a caregiver's ability to make sound clinical decisions on time.

Result management
The ability for all providers participating in the care of a patient in multiple settings to quickly access new and past test results increases patient safety and the effectiveness of care.

Order management
The ability to enter and store orders for prescriptions, tests, and other services in a computer-based system enhances legibility, reduce duplication, and improve the speed with which orders are executed.

Decision support
Using reminders, prompts, and alerts, computerized decision-support systems helps to improve compliance with best clinical practices, ensure regular screenings and other preventive practices, identify possible drug interactions, and facilitate diagnoses and treatments.

Electronic communication and connectivity
Efficient, secure, and readily accessible communication among providers and patients improves the continuity of care, increase the timeliness of diagnoses and treatments, and reduce the frequency of adverse events.

Patient support
Tools that give patients access to their health records, provide interactive patient education, and help them carry out home-monitoring and self-testing improves control of chronic conditions, such as diabetes.

Administrative processes
Computerized administrative tools, such as scheduling systems, could greatly improve hospitals' and clinics' efficiency and provide more timely service to patients.

Reporting
Electronic data storage that employs uniform data standards enables health care organizations to respond more quickly to federal, state, and private reporting requirements, including those that support patient safety and disease surveillance.

Documentation burden

While the benefits of EHRs are evident, the rise of the EHR has also had some unintended consequences. Over the years, EHRs have increased documentation times for healthcare providers(16, 17). Furthermore, an increased cognitive burden is reported due to various factors, such as the increased requirement for multitasking(18, 19). Furthermore, physicians report an increase in workday length and after-hour documentation (20-22). These can contribute to poorer work-life balance and lower job satisfaction. Also, the reduced available time for patients and the disruptions to patient-physician interaction have negatively influenced the physician-patient relationship(23). Multiple studies have linked the abovementioned factors to the increasing burn-out rate among healthcare providers(24, 25). Therefore, the balance between the effort and time that is asked from physicians to documentation healthcare information and the benefits of other purposes of EHR data should be carefully considered.

Secondary use of EHR data

When considering the key functionalities of the EHR in box 1, supporting high-quality patient care is thought to be the most important goal. However, besides supporting care, EHR data could be used for various other purposes, which is referred to as secondary use. Secondary use is defined as "the application of personal health information (PHI) for uses outside of direct health care delivery"(26). The data can be used for various purposes, such as scientific research, quality and safety measurement, public health, payment, provider certification or accreditation, and marketing and other business including strictly commercial activities.

Secondary use of patient data and quality measurement

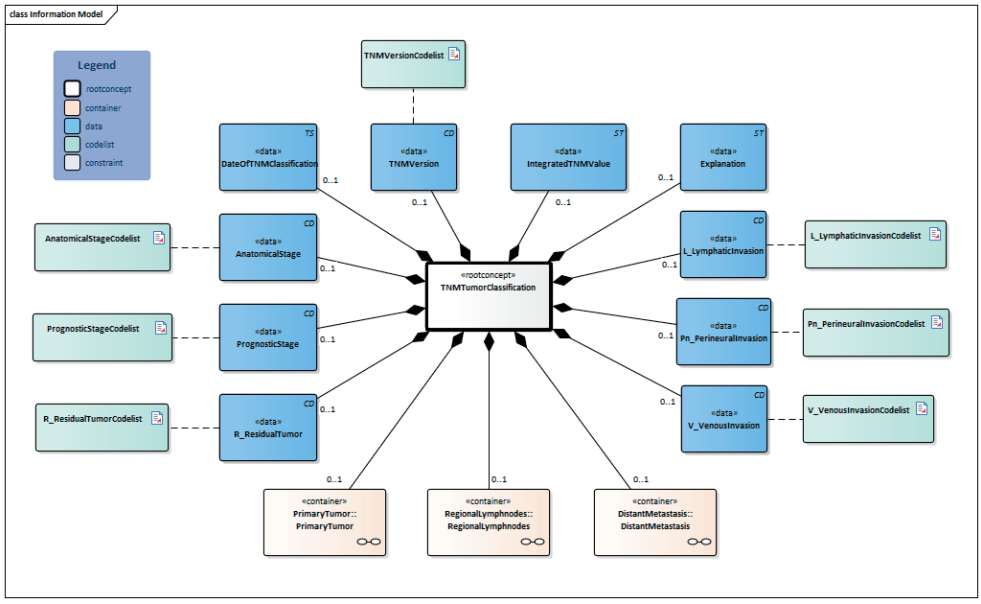
Currently, the use of patient data for secondary purposes is widespread. One of the secondary purposes is quality measurement(27, 28). Since Weed proposed that data within PROMIS should also be used to enable medical and business audits, the use of EHR data for quality measurement purposes has gradually increased. Quality in healthcare is measured by indicators. An indicator is a measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality of care(29). An example of an indicator is: The percentage of patients with a primary head and neck malignancy discussed in a multidisciplinary team (MDT) meeting before treatment. This is relevant because of the multidisciplinary treatment and treatment options available

for head and neck tumors. It is important that all specialties are involved in discussing a treatment plan, which occurs during the MDT meeting. Indicators are used in quality registries, which usually concern a specific patient population. Indicators are grouped as structure-, process- and outcome indicators, and are preferably developed by using a method involving multiple stakeholders(30). By reviewing the results, planning an intervention, and subsequently evaluating the results of an intervention, the quality of care can be improved. However, with the ever more rising healthcare expenditures, reducing costs is becoming more and more relevant. In value-based healthcare, both costs and outcomes are considered(31). To improve value, costs need to be reduced while keeping outcomes at the same level, or outcomes are improved while keeping costs the same. Currently, measuring quality in healthcare is not time-efficient and has high costs(32). Furthermore, insight into the financial aspects of care is often still limited. It is therefore important to develop efficient, sustainable methods to evaluate quality and costs of care. By automating quality measurement, quality insight will be real-time and in the long-term it will reduce costs as time-intensive, manual data collection will be obsolete.

Structured data

Historically, most data within EHRs was recorded in an unstructured format. Unstructured data is data that cannot be easily organized using pre-defined structures. Examples include radiology images, or text files such as physician's free-text notes in the electronic health record (EHR). To optimally develop EHR functionalities that support high quality patient care and facilitate the electronic secondary use of data, information recorded within the EHR needs to be recorded as structured data(33). Structured EHR data is perceived to support clinical care processes, facilitate new technologies for increasing patient safety and care quality, and enable quality monitoring of health processes and evidence-based management by enhancing collection of statistical information(34). Structured data is "organized into specific fields as part of a schema, with each field having a defined purpose". Furthermore, when standardized, the scheme used to store the data is pre-defined (e.g., when documenting gender, "male" and "m" are both stored as '1'). Standardization ensures that data from different sources can be compared, combined, or interpreted similarly. The structure and standardization schemes used for documenting medical concepts are described using health information models *(figure 1)*.

Figure 1. TNM health information model



These models describe the data elements, their structure, form, relation, and the terminology used in structured documentation of medical data. For example, a health information model for documenting temperature would define that each measurement has a value, a unit, a date, and a time. Each element has a specific data type (e.g. number, date, yes/no, or a value list). Furthermore, a code from a terminology system identifies each data element or value, such as SNOMED-CT. This 'identifier' code can be attributed to the data element at the moment of documentation or added later, both of which result in standardized data. For the abovementioned reasons, structured and standardized data is unambiguous, and easily accessible and interpretable by computers. This enables automated secondary use of EHR data for quality measurement, financial insight, or research, but can also be utilized for real-time clinical decision support or robotic process automation within the workflow of health care providers (e.g., automatically generating orders or referral letters).

Structured data recording by healthcare providers

Since Weed proposed that the physician should be responsible for entering information into the electronic health record, the majority of clinical information is entered by healthcare providers. As described, there are many advantages to capturing this clinical information as structured data. However, busy physicians generally value flexibility and efficiency over the requirements for data reuse. As described, there is rich literature describing a negative impact that the implementation of EHRs, often still inflexible

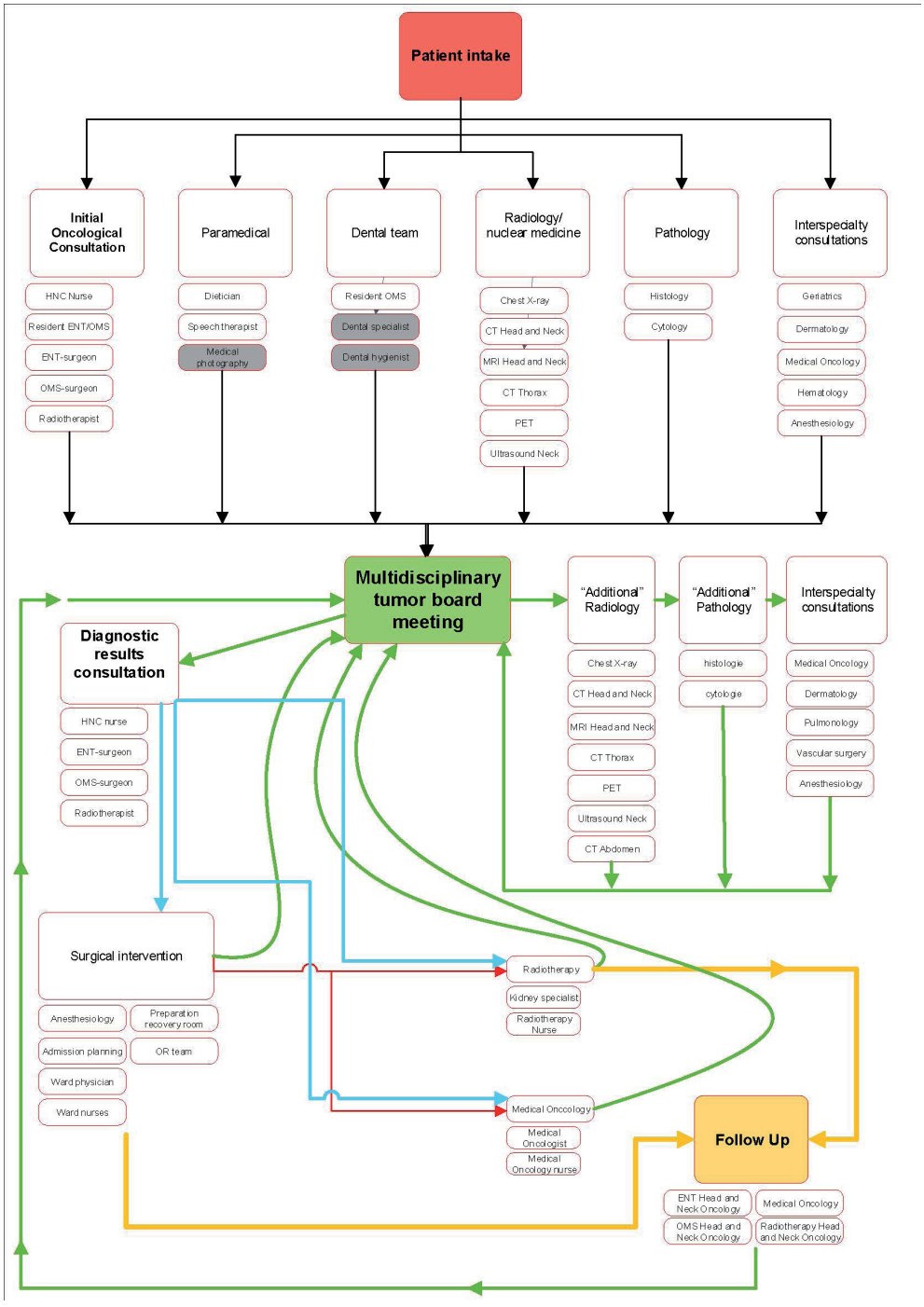
systems, had on documentation time, physician well-being, and their contribution to physician burnout(16, 17, 35). When a rigid EHR system does not offer the flexibility that a complex and variable task as providing patient care needs, problems arise(36). For example, free text registration allows the healthcare provider to document exactly what is relevant for that particular situation. When the same information needs to be recorded in a structured way using a structured data capture (SDC) form, and this form has too much emphasis on completeness, it can result in extensive forms that cover every possible option. This could lead to much of the information displayed on the screen not being relevant to the healthcare provider at that specific moment, leading to frustration, cognitive overload and increased documentation burden(36). Furthermore, it is highly likely that physicians will resort to free-text documentation when a structured documentation system adds additional burden to their workload(37). This leads to missing data in the structured database of the EHR. Furthermore, there is a difference between the data that has to be documented in the context of medical documentation (for providing care), and the data registration required for other purposes, such as medicolegal purposes, billing, and quality measurement purposes. It is highly important to separate the two and ensure that physicians are not burdened with the task of 'additional registration' on top of medical documentation.

It can be concluded from the abovementioned examples that when implementing structured documentation, it is crucial to analyze what has to be documented in specific situations and for what purpose, and to use this knowledge when developing the structured documentation forms. In other words, aligning the process of structured data capture with the care process. A care process for a specific, well-defined group of patients is known as a care pathway.

Care pathways

Care pathways are a methodology for the mutual decision-making and organization of care processes for a well-defined group of patients during a well-defined period(38). Defining characteristics of care pathways includes (1) An explicit statement of the goals and key elements of care based on evidence, best practice, and patient expectations; (2) The facilitation of the communication, coordination of roles, and sequencing the activities of the multidisciplinary care team, patients and their relatives; (3) The documentation, monitoring, and evaluation of variances and outcomes; and (4) The identification of the appropriate resources. Figure 2 shows an overview of the Head and Neck Oncology care pathway. Developing a care pathway is a complex process, which requires input from all involved healthcare providers.

Figure 2. Head and Neck Oncology care pathway



A growing body of literature describes the advantages that care pathways provide. Several studies show that their implementation leads to improvements in patient safety, patient outcomes, patient satisfaction, and optimization of resource use(39-42).

Electronic care pathways

Initially, care paths were mainly paper-based, but in recent years, the EHR and the tools available within EHR systems are increasingly used to support working according to a care pathway. EHR embedded care pathways ('e-pathways') are care pathways that, besides the defining characteristics, also encompass: (1) the clinical data sets used; (2) the on-screen forms and user interface elements required; (3) the formal model of the roles, tasks, sequencing, and business rules of clinical workflow and (4) the messages to be exchanged between the systems that invoke the pathway(43-45). Thus, an e-pathway includes the clinical workflow, what data is documented and by who, when this data is documented, and how the structured data capture forms are presented to the healthcare provider. In addition, an e-pathway also includes supporting functions that aim to support adherence to the care pathway and improve efficiency, such as standardized order sets and automated documentation. An e-pathway facilitates the recording of the relevant data at the appropriate time. Ideally, maximum harmonization between the documentation and care processes is sought. By implementing an e-pathway that supports structured data recording, reusable, relevant information should be captured at the point of care.

Organizational importance

To reach a consensus on the contents of a care pathway, it is essential to involve all relevant caregivers, both medical and paramedical, in the development of the care pathway. Often, a care pathway is multidisciplinary, as is the case with the head and neck oncology care pathway. Head and neck oncological care in the Netherlands is centralized since decades and the head and neck oncological centers have been collaborating since 1984 within the Dutch Head and Neck Society (NWHHT). This includes representatives of the various specialties involved from all Head and Neck oncological centers in the Netherlands. Throughout the years, the NWHHT has defined the most relevant indicators and data within the field of head and neck oncology. Using this knowledge, in combination with the paper based care pathway, an e-pathway with structured documentation was developed. This longstanding collaboration and consensus on relevant items and indicators result in the Head and Neck Oncology being an ideal use case for this thesis.

Aims and outline

However, much is unknown in the field of structured and standardized documentation and reuse of this data. In this thesis, the research questions are formulated in relation to two main themes.

Aim 1: to evaluate the effects of implementing a head and neck oncology e-pathway with structured documentation on the efficiency of providing care.

As described, there is a high documentation burden among healthcare providers, which should be addressed. How high is this burden currently? What is the impact of implementing structured data capture in the abovementioned way on provider efficiency, and how does this affect perceptions of healthcare providers on the EHR and documentation? Can structured data also be entered by the patient, rather than the healthcare provider?

Aim 2: to investigate the effect of implementing a head and neck oncology e-pathway with structured documentation on quality of documentation and quality of reused data.

Besides efficiency, the second important theme is quality. When the efficiency is influenced, is quality affected? What is the influence of structured documentation on the quality of medical documentation? What is the quality of the EHR data that has been automatically reused? Is automated reuse of data feasible for automated quality measurement?

Chapter 2 describes the administrative burden in a tertiary Head and Neck Oncology center. We evaluate the time and effort spent on tasks within the electronic health record during outpatient consultations. In chapter 3, the implementation of an e-pathway that supports routine, structured data capture is evaluated. The impact on the administrative burden of health care provider is analyzed. Furthermore, change in healthcare providers' perceptions regarding the electronic health record and the documentation process is investigated. Besides the influence of the e-pathway with structured documentation on documentation efficiency, documentation quality is also highly relevant as this supports providing good quality of care. Therefore, in chapter 4, a retrospective multicenter study that evaluated the influence of structured and standardized recording on the quality of documentation is found.

Chapter 5 describes the development of a (near) real-time quality dashboard that uses routinely collected structured data and assesses the quality of the data by comparing it to manually collected data on the same patients. In chapter 6, a qualitative study that explores patient perspectives on an electronic health record integrated app is found.

The app supports the capture of patient-entered structured data and facilitates remote monitoring of patients that were treated for Head and Neck cancer. Chapter 7 provides a general discussion of the results from Chapters 2, 3, 4, 5, and 6.

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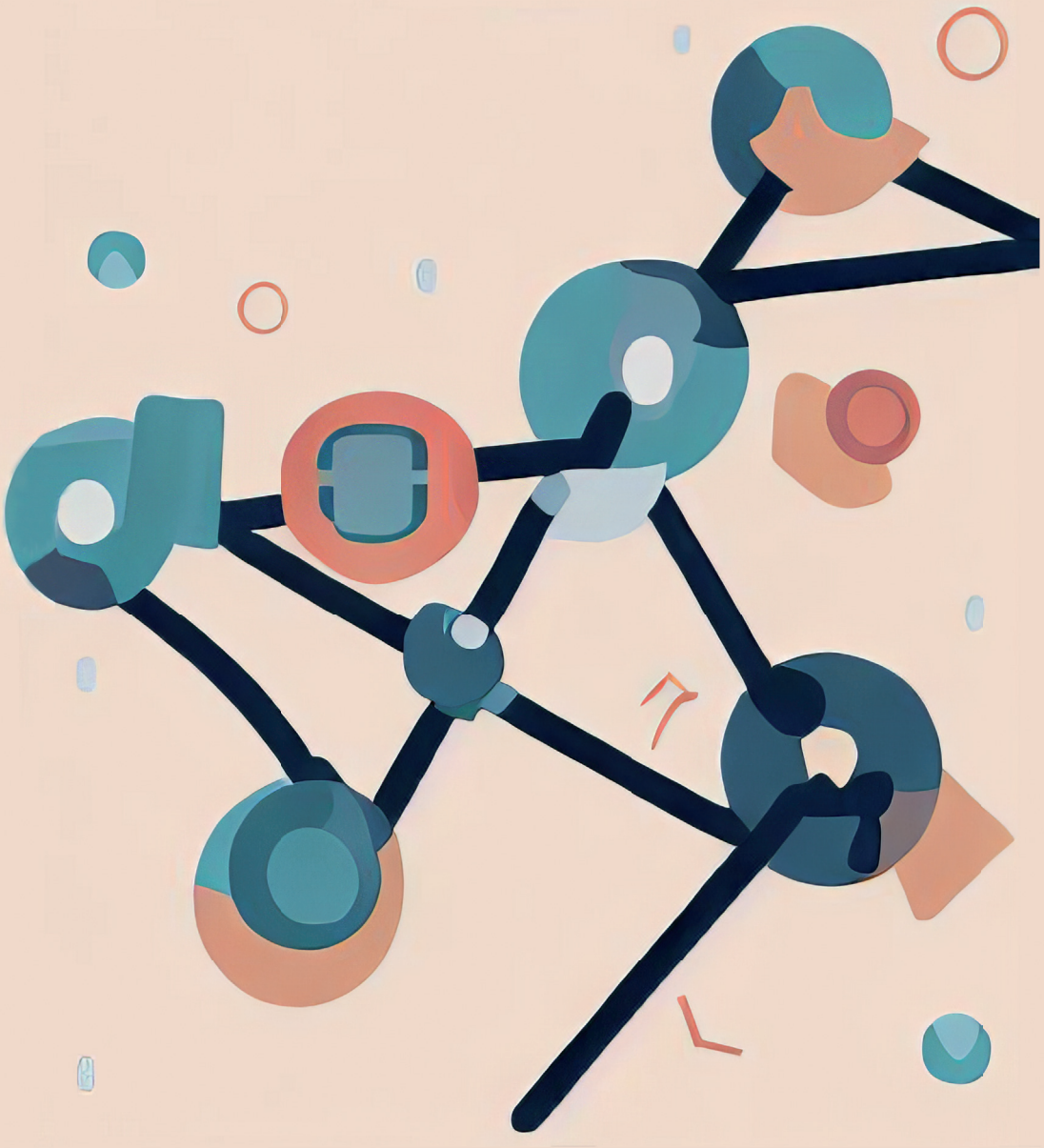

Chapter 2

Quantifying the electronic health record burden in head and neck cancer care

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Background
Although the main task of healthcare providers is to provide patient care, studies show increasing amounts of time are spent on documentation.

Objective
To quantify the time and effort spent on the Electronic Health Record (EHR) in head and neck cancer care.

Methods
Cross-sectional time-and-motion study. Primary outcomes were the percentages of time spent on the EHR and the three main tasks (chart review, input, placing orders); number of mouse events, and keystrokes per consultation. Secondary outcome measures were perceptions of healthcare providers regarding EHR documentation and satisfaction.

Results
44.0% of initial oncological consultation (IOC) duration and 30.7% of follow-up consultations (FUC) duration is spent on EHR tasks. During 80.0% of an IOC and 67.9% of a FUC, the patient and provider were actively communicating. Providers required 593 mouse events and 1664 keystrokes per IOC and 140 mouse events and 597 keystrokes per FUC, indicating almost 13 mouse clicks and close to 40 keystrokes for every minute of consultation time. Less than a quarter of providers indicated there is enough time for documentation.

Conclusions
This study quantifies the widespread concern of high documentation burden for healthcare providers in oncology, which has been related to burnout and decrease of patient-clinician interaction. Despite excessive time and effort spent on the EHR, healthcare providers still felt this was insufficient for proper documentation. However, the need for accurate and complete documentation is high, as reuse of information becomes increasingly important. The challenge is to decrease the documentation burden whilst increasing the quality of EHR data.

Background and significance

The widespread use of Electronic Health Records (EHRs) has increased substantially and dramatically changed modern medical care. The use of EHRs could lead to many advantages such as improved access to data, improved data quality, and faster documentation(1, 2). However, most healthcare providers are not yet experiencing these benefits of EHR use(3). Whereas the most important task of health care professionals is to deliver patient care, the transition from paper-based to computerized documentation has led to increased documentation time(4). This might be caused by the increased need to fulfill regulatory, reimbursement, and quality measurement requirements(5). Consequently, increased EHR time can result in less time for direct patient care, decreased physician job satisfaction, and increased burnout rates among physicians(6-8). Moreover, the time spent on desktop medicine is increasing at the expense of face-to-face visits, with time currently evenly split between both categories(9). On the other hand, benefits of EHR use, such as improved access to and quality of information, have also been reported(10).

Some papers have quantitatively described how much time and effort physicians spend on the EHR during consultations in the outpatient clinic. A time-motion study (TMS) investigating documentation time in 14 different specialties reported a mean percentage of documentation time per consultation of 33%, whilst another TMS describing time allocation in four specialties reported similar results with 37% spent on the EHR (7, 11). A study that used EHR activity logs found that the EHR is used for an average of 16 minutes and 14 seconds per encounter, with chart review (33%), input (24%), and ordering (17%) accounting for most of the time(12). One study revealed that daily EHR time can vary significantly between surgical (45.6 min), medical (85.7 min), and primary care specialties (115.0 min)(13). These studies consistently show a high percentage of time spent on the EHR. However, detailed data on EHR activity measures such as mouse clicks, keystrokes, and mouse movement is limited. These data might give insight into where the usability of EHRs can be improved. Additionally, physicians make significantly less eye contact with patients when using an EHR than a paper chart(14). Patients are also less likely to actively participate in consultations when a physician is physically engaged with the computer (e.g. keyboard activity) than when a physician is merely gazing at the EHR(15). This implies that less effort required for documentation during consultations could be beneficial to doctor-patient interaction. Besides, a survey study investigating the relationship between EHR design and use factors with high stress and burnout identified interference with the patient-clinician relationship and excessive data entry as significantly associated factors with high stress and burnout(16). The findings of these studies suggest that not only the amount of time spent on the EHR is relevant for the experienced documentation burden, but also the actual effort put in by the health care professional is an important factor, which is also stated in a recent

scoping review by Moy et al.(17). The authors discussed the clinical documentation burden among health care providers and identified time and effort as the two main concepts that underly the documentation burden in EHRs. The study concluded that the documentation burden remains understudied and undermeasured in both inpatient and outpatient settings, indicating that further research is warranted. As stated, time spent on the EHR can vary depending on specialty or setting. Little is known about the documentation burden in the more specific, oncological setting.

Objectives

This study investigated the current state of the documentation burden within the EHR during consultations in a tertiary oncology center. Furthermore, we assessed perceptions of Head and Neck Cancer (HNC) care providers on various aspects regarding EHR documentation and EHR satisfaction.

Methods

A cross-sectional time-and-motion study was conducted at the Department of Head and Neck Oncology at the Antoni van Leeuwenhoek Cancer Centre in Amsterdam, Netherlands. In the outpatient clinic, patients were routinely seen and examined by a HNC care provider. These consultations were recorded and analyzed with video-analytic software Morae version 3.1 (Techsmith. Michigan). Furthermore, providers were invited to complete an online questionnaire regarding various concepts underlying the documentation process and system satisfaction. Data were collected between April and July 2020. The procedures of this study were approved by the Antoni van Leeuwenhoek Cancer Center local ethics committee (IRBd19-312).

We included patients scheduled for an initial oncological consultation (N=47) or a follow-up consultation (N=50). Participating providers were Head and Neck surgeons, fellows, residents, and physician assistants. Providers with less than three months of experience with the EHR (Chipsoft HiX, custom build, version 6.1), which was implemented in 2012, were excluded. After obtaining informed consent, Morae Recorder was used to capture the routine workflow during outpatient consultations. A consultation was defined as the time that a patient was present in the consultation room. Furthermore, the wrap-up time, defined as the time providers need to complete tasks after a patient has left the room, was recorded. The software simultaneously captured the screen of a provider, generated usability metrics, e.g. mouse clicks and keystrokes, and used a webcam to record audio as well as video recording of the mouse and keyboard. Recordings started at the beginning of a consultation and stopped when the provider finished the consultation including the wrap-up. At the end of a consultation, recordings were password protected and stored in a secured folder, ensuring a double layer of protection. Subsequently, recordings were imported into the video-analytic software program

Morae Manager. Following this, detailed video analysis was performed while using time-motion methodology. During playback of the recordings, time spent on various tasks during consultations was measured by a single, independent researcher using the app Time Motion Study version 2.3 (Graphite Inc), which is similar to the TMS capture tool TimeCAT, but available on mobile devices(18). The categories and subtasks used (table 1) were based on a similar study conducted by Joukes et al.(7). When a provider was multi-tasking, both subtasks were measured simultaneously.

Table 1

Categories and subtasks used in measurement app

Category	Subtask	Explanation
1. EHR	Chart review	When the physician is looking for or reading information from the patient record.
1. EHR	Input	When the physician is entering information into the patient record.
1. EHR	Ordering	The physician orders tests, e.g. imaging, laboratory or medication.
1. EHR	Other	Used when the observer cannot discern whether the task falls in one of the four other (more specialized) EHR tasks.
2. Communication	Physician-patient communication	All communication between physician and a patient.
2. Communication	Discussion with colleague	All communication between the physician and a colleague.
3. Other	Other computer tasks	All tasks on the computer that are not in the EHR program (e.g. reading mail).
3. Other	Other activities	All tasks that do not fit in one of the other categories.

Furthermore, the number of mouse clicks, scrolls, keystrokes and EHR mouse path length in meters, consultation duration and supervision time were extracted from the recordings. Subsequently, data from the recording software, the time motion capture tool, and data extracted from the EHR regarding order entry were combined in a database.

A validated questionnaire was used to assess perceptions of HNC care providers on concepts regarding EHR documentation and EHR satisfaction(19). All questions were answered on a 5-point Likert scale, ranging from strongly disagree (1) to strongly agree (5). The questionnaire can be found in *Appendix A*. All HNC care providers working at the department were invited by mail to complete this questionnaire in the online environment of the electronic data capture tool CasterEDC. Twenty-two (84%) providers completed the questionnaire, of which 14 (64%) were supervising staff, 5 (23%) were residents, and 3 (14%) were physician assistants.

Continuous variables are presented as median and quartiles, mean and standard deviation, and categorical variables as numbers and percentages. Descriptive statistics were performed using IBM SPSS Statistics software version 25.0 (IBM Corp).

RESULTS

After excluding three incomplete recordings, a total of 97 valid outpatient consultations were used for analysis, of which 47 were initial oncologic consultations (IOC), and 50 were follow-up consultations(FUC). Provider and patient demographics are shown in table 2.

Table 2

Physician and patient demographics and details of the observed consultations

Physician characteristics	**Initial oncological consultation**	**Follow-up consultation**	**All**
Total HNC care providers	8 (66.6%)	4 (33.3%)	12 (100%)
Physician assistant	2 (16.6%)	0 (0.0%)	2 (16.6%)
Resident	4 (33.0%)	0 (0.0%)	4 (33.3%)
Fellow	2 (16.6%)	0 (33.0%)	2 (16.6%)
Head and neck Surgeon	0 (0.0%)	4 (33.0%)	4 (33.3%)
Patient characteristics			
Age (mean)	67,6	64,6	66,1
Sex (n)			
Male	30	26	56
Female	17	24	41
Observations			
Number of consultations	47	50	97
Total recording time	44h:19m	13h:01m	57h:20m
Total duration of consultations	41h:18m	09h:26m	50h:44m

The median duration of an IOC with a patient present was 52:38 (43:43-62:05) and 54:27 (47:04-63:45), including wrap-up time. The median duration of a FUC with a patient present was 09:54 (06:12-15:14) and 11:55 (07:40-17:21), including wrap-up time. During an IOC, a resident or physician assistant usually consults with a supervisor outside of the room. In most cases, this provider has to wait for the supervisor. The median duration for this supervision time during an IOC was 07:29 (05:15-13:50). The clean consultation duration, in which the supervision time outside of the room is subtracted from the total consultation duration, was also calculated. This was 42:51 (36:55-48:51) with patient present and 43:59 (38:20-52:15) including wrap-up time. Table 3 shows how much time

was spent on each of the main categories. The median percentage of time spent on a specific task relative to the total consultation time is also shown. Because some tasks are regularly conducted simultaneously, such as communicating with the patient and EHR tasks, the total percentage exceeds 100%. Furthermore, not all subtasks were used in every consultation.

Table 3

Time spent on tasks during consultations

Initial oncologic consultation	**N**	**Median**	**(Q1-Q3)**	**Mean**	**(SD)**	**Median % of consultation spent on task**
Consultation duration (including wrap-up, excluding supervision time)	47	43:59	(38:20-52:15)	45:56	(12:25)	100%
EHR tasks – total	47	19:16	(14:42-24:02)	19:20	(07:15)	44.0%
EHR tasks – chart review	47	01:36	(00:37-02:32)	01:57	(01:46)	3.1%
EHR tasks – Input information	47	11:10	(07:40-14:28)	11:06	(04:23)	24.7%
EHR tasks – Placing orders	44	05:59	(04:08-09:10)	06:37	(03:51)	12.2%
EHR tasks – Other	16	00:05	(00:04-00:24)	00:14	(00:15)	0.2%
Other computer tasks	20	00:46	(00:18-01:54)	01:08	(00:46)	1.8%
Physician-patient communication	47	31:47	(28:02-40:09)	34:48	(11:14)	80.0%
Peer communication	43	01:37	(00:48-02:25)	02:32	(03:37)	3.1%
Other tasks	15	00:12	(00:05-00:19)	00:13	(00:10)	0.4%
Follow-up consultation	**N**	**Median**	**(Q1-Q3)**	**Mean**	**(SD)**	**Median % of consultation spent on task**
Consultation duration (including wrap-up)	50	11:55	(07:40-17:21)	13:18	(06:34)	100%
EHR tasks – total	50	03:45	(02:28-05:32)	03:56	(01:57)	30.7%
EHR tasks – chart review	49	01:12	(00:33-01:48)	01:23	(01:00)	9.8%
EHR tasks – Input information	47	01:49	(01:13-02:19)	01:57	(00:57)	14.9%
EHR tasks – Placing orders	47	00:24	(00:12-01:18)	00:42	(00:39)	3.7%
EHR tasks – Other	16	00:11	(00:08-00:16)	00:12	(00:06)	2.0%
Other computer tasks	12	00:36	(00:14-01:31)	01:04	(01:06)	4.9%
Physician-patient communication	50	07 :29	(04:23-13:01)	08:56	(05:37)	67.9%
Peer communication	29	00:58	(00:35-02:00)	01:34	(01:43)	8.4%
Other tasks	9	00:17	(00:11-00:28)	00:22	(00:17)	1.8%

The time spent on EHR tasks had a median duration of 19:16 (14:42-24:02) for IOC and 03:45 (02:28-05:32) for FUC. Furthermore, during IOC, 44.0% of the total consultation time was spent on EHR tasks, and during FUC, 30.7%. The input of information into the EHR was the most time-consuming EHR task, with 24.7% (IOC) and 14.9% (FUC) of total

consultation time. When comparing time spent on EHR tasks by residents, physician assistants and fellows, no significant differences were found. Table 4 summarizes the usability metrics measured within the EHR during consultations.

Table 4

Usability metrics required per consultation

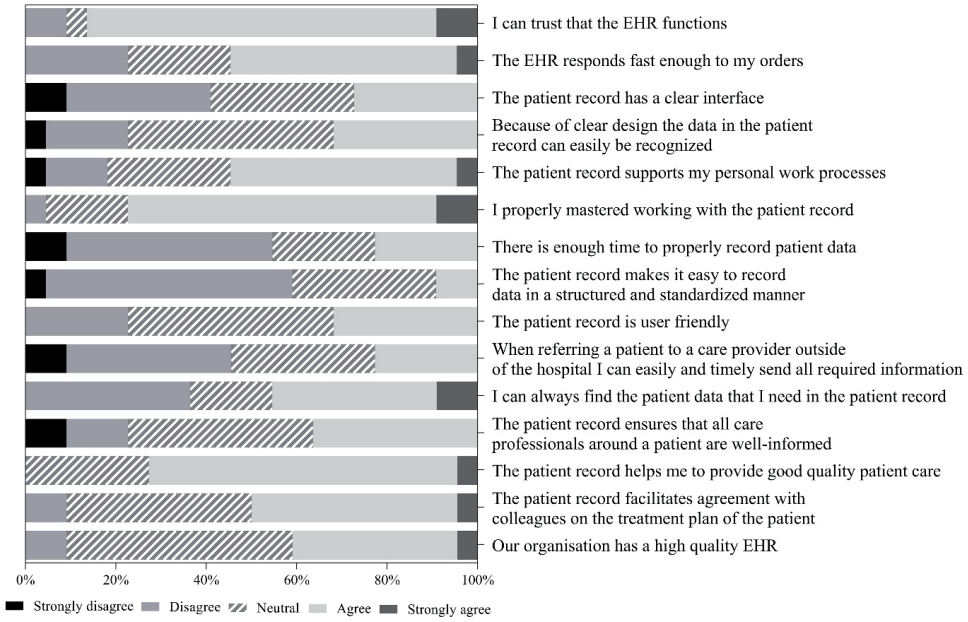
Metric	Initial oncologic consultation including wrap-up		Follow-up consultation including wrap up	
	Mean SD		Mean SD	
Total mouse events - Mean (SD)	593	(300.0)	140	(89.3)
Mouse clicks - Mean (SD)	215	(91.6)	55	(28.4)
Scrolling - Mean (SD)	378	(233.9)	86	(67.0)
Keystrokes - Mean (SD)	1664	(896.3)	450	(290)
Mouse travel distance in meters - Mean (SD)	55	(25.9)	14	(8.2)
Other				
Orders per consultation – Mean (SD)	6.9	(3.4)	1.6	(1.1)
Time per order – Mean (SD)	00m:53s	(00m:20s)	00m:20s	(00m:17s)

This table shows that providers required 1664 (SD = 896) keystrokes and 593 (SD = 300) mouse events per IOC, and providers required 450 (SD = 290) keystrokes and 140 (SD = 89) mouse events per FUC. Table 4 also displays the number of orders placed per consultation, the mean time per order and the time to complete all orders after consultation.

Perceptions of HNC care providers on different aspects regarding EHR documentation and EHR satisfaction were measured using the validated questionnaire. Relevant results are displayed in figure 1. Most respondents (78%) felt that they properly mastered working with the electronic health record, while 4% disagreed with this statement and 18%, all attendings, were neutral. Over half of respondents (55%) said that the EHR supports their personal work processes, 44% indicated that they can always find the information they need in the EHR, and 50% agreed that the EHR facilitates agreement with colleagues on the treatment plan of the patient. However, only a minority indicated that they thought the EHR was user-friendly (32%) and had a clear interface (27%). Furthermore, less than a quarter of respondents (23%) agreed that there is enough time to properly document patient data in the EHR, and that they can easily and timely send all required information when referring a patient (23%). Despite this, over two-thirds of respondents said that the EHR helps them provide good quality patient care (73%), a vast majority indicated that they can trust that the EHR always works (86%), and only

9% disagreed with the statement that their organization has a high quality EHR. The full questionnaire results can be found in appendix B.

Figure 1. Perceptions of HNC care providers on EHR documentation and EHR satisfaction



DISCUSSION

This study aimed to quantify the time and effort currently spent on the EHR by providers in an outpatient clinic of a Head and Neck Oncology care center. Our analysis shows that a significant proportion of time is spent on EHR tasks during consultations. We found that 44.0% of the time during an IOC and 30.7% of the time during a FUC is spent on the EHR. In contrast, during 80.0% and 67.9% of the IOC and FUC, respectively, there was active communication between patient and provider. On average, providers require 593 mouse events, 1664 keystrokes, and 56 meters of mouse travel distance during an IOC and 140 mouse events, 597 keystrokes, and 14 meters of mouse travel distance during a FUC. Additionally, despite that over one-third to just under half of the available time during consultations is spent on the EHR, a majority of providers still feel there is not enough time for proper documentation.

5.1 Comparison with previous literature and interpretation

Our results on time spent on the EHR in Head and Neck Oncology during consultations are consistent with findings of earlier studies. A study conducted at an ophthalmology department found similar results regarding documentation time during consultations, reporting 27% of time during consultations spent on EHR use(20). A study conducted at four different departments reported 37% of consultation time spent on the EHR(11). Another study investigating physician time allocation in various specialties during a whole day, found percentages for documentation tasks ranging from 11% to 39%, stating that the distribution of time spent by providers using EHRs varies between specialties(12). Furthermore, de Hoop et al. reported that 37.1% of time during consultations was spent on the EHR(21). In this study, physicians reported that the spread of patient information, poor integration of information into workflow, and limited information exchange were problematic. Only a few studies investigated usability measures such as keystrokes and mouse clicks. One study describing how physician EHR activity influences patient participation reported similar results, with a mean of 216 (SD =174) mouse events and 729 (SD =768) keystrokes required in consultations lasting 20.3 (SD =10.5) minutes on average(14).

Our results suggest that whilst already spending a large proportion of their time on the EHR, providers are also actively engaged with the EHR. Based on our results, a provider requires almost 40 keystrokes and 13 mouse clicks or scrolls for every minute of consultation time. In contrast, we found that during a large proportion of the consultations, there is active communication between provider and patient, which is beneficial to the provider-patient relationship. However, based on our results, we cannot determine whether the provider was actually talking or listening. It could also mean that the patient is talking and the provider is multitasking and conducting an EHR task while listening. While this is common practice, a high level of multitasking adds to the experienced documentation burden(22, 23).

Healthcare providers mainly had concerns regarding the available time for recording data, timely sending referral information, and finding relevant information within the EHR. All of these factors can contribute to spending additional time on the EHR and therefore cannot be spent on direct patient care. Additional concerns were expressed regarding the extent to which the EHR supports structured data capture. Lack of structured data capture can impede data reuse(24). Surprisingly, only one respondent disagreed with the statement that they properly mastered working with the EHR. This indicates that the vast majority considered themselves skilled with the EHR. This could be either the result of proper training, but overestimating their own efficiency with the EHR could also contribute to this result. Furthermore, our survey results suggest that whereas most providers are optimistic regarding the usefulness of the EHR, most

also think that the usability (e.g. ease of use) of the EHR should be further improved. This suggests the EHR as a solution, rather than consider it the primary reason for the documentation burden.

Comparing our results to other studies must be done with caution because of various factors, such as differences in consultation types and complexity, different EHR vendors, EHR maturity, and study methods. Nevertheless, this study further corroborates that the high documentation burden is widespread.

5.2 Strengths and limitations

The main strength of this study is that this study evaluated the time spent on the EHR combined with EHR usability measures. It also quantifies the time and effort required to document and review information in the EHR while also describing provider perceptions regarding EHR satisfaction and the documentation process. This allows for comparison between quantitative data and the opinion of health care providers on this topic. Another strength is the chosen methodology for our study. While time-consuming, time-motion studies are still generally considered the gold standard methodology for accurately measuring a process.

A limitation of this study is that, as expected, we found variation in consultation duration and usability metrics between consultations in both IOC and FUC. This can probably be attributed to differences in various factors, such as patient complexity and provider variation. Another limitation is that, due to the chosen methodology, we did not investigate time spent on the EHR outside of consultation hours, which is also a construct underlying the documentation burden. However, only a minority of providers indicated that they felt that the amount of time they spent on the EHR outside of consultation hours is high (14.3%), whereas most providers rated this as acceptable (61.9%). Nevertheless, this does not rule out that healthcare professionals still spent a considerable amount of time on the EHR outside of consultation hours. Lastly, as stated in the introduction, a high level of interaction with the computer can negatively influence the doctor-patient relationship. In this study, measure patient satisfaction was not measured. However, it can be expected that patient satisfaction can increase when EHR time decreases, as more time can be spent on the patient, which was also established by Marmor et al.(25)

5.3 Implication for practice

While our results indicate that the burden of documentation during consultations is already high, accurate and complete documentation is becoming increasingly important as information recorded by providers is increasingly reused for other purposes, such as research, quality registries, and other improvements that rely on structured data,

such as clinical decision support. However, policy makers should be critical as to which information should be recorded by healthcare providers while providing care. If information is not relevant for providing care and solely documented for secondary purposes, it is better to minimalize the burden for providers and collect it in different ways. For example, by employing coding staff, or by using patient-entered before-visit questionnaires that are automatically integrated into provider documentation, could be a solution that increases data collection and also reduces documentation burden by relieving physicians(26). The challenge is to reduce the documentation burden while simultaneously increasing the accuracy and completeness of recorded data in the EHR. For this reason, a national program, ''Facilitating Clinical Documentation at the Point of Care'', has started in the Netherlands. This program urges hospitals and EHR vendors to optimize EHRs to support unambiguous, single registration of data during the care process. It also stimulates that data is stored as discrete, coded data to enable reuse for various purposes. This should lead to a decrease of the documentation burden for health care providers and simultaneously increase the accuracy and completeness of data in EHRs. Furthermore, streamlining workflow and aligning the documentation process with clinical workflow might also be effective in reducing the documentation burden(23, 27). Lindsay et al. found that this can result in an 18.5% reduction in documentation time(27). Minimizing interruptions of workflow, for example, by being critical of which decision support alerts should and which should not be used, can also contribute to reducing the burden(28). Other solutions that have been suggested are, for example, telehealth expansion, changing compliance rules and performance metrics, and EHR optimization sprints(29).

The optimal strategy to reduce the burden could differ based on the primary underlying reason. This might vary based on region or setting. A recent study evaluated the difference in EHR use between US and non-US clinicians and found that US clinicians daily spent over 50% more time using the EHR(30). This might be attributed to additional documentation requirements for billing or administrative functions. Policy makers could also consider such nontechnical aspects when developing a strategy. Future studies should focus on implementing and evaluating innovations and developments within EHRs that aim to decrease documentation burden while increasing the quality of EHR data. Providing evidence is important in identifying the best practices that should be implemented(31). To make this type of research more scalabe, it might be better suitable to use EHR log studies instead of time-motion studies(32). However, the process of turning raw audit logs into insights is still complex and can result in largely under- or overestimating of time spent on the EHR(33). It might be helpful to conduct more studies in which audit log data is compared to time-motion data to further validate the reliability of audit log studies and define validated standards.

6. Conclusion

This study found that HNC care providers spent up to 44.0% of consultation time on EHR tasks. During these consultations, providers require up to 40 keystrokes and 13 mouse clicks for every minute of consultation time. These results quantify the widespread concern of high documentation burden for healthcare providers, which is known to lead to potential burnout and decrease of patient-clinician interaction. Despite the significant amount of time spent on documentation, most providers still feel this is insufficient for proper documentation. The challenge is to decrease documentation burden whilst increasing the quality of EHR data.

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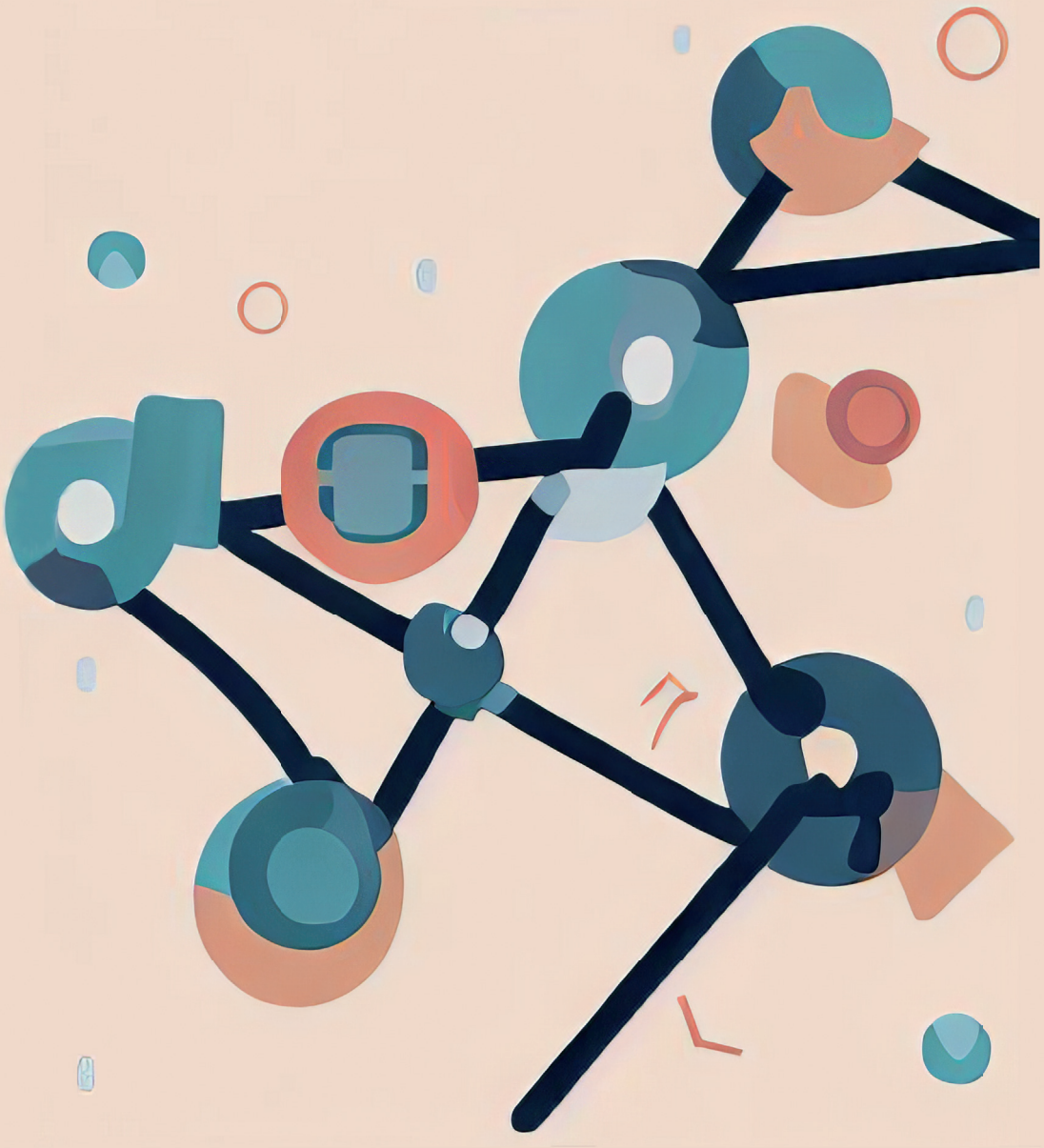

Chapter 3

The implementation of a multidisciplinary, electronic health record embedded care pathway to improve structured data recording and decrease electronic health record burden; a before and after study

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Introduction

Theoretically, the added value of electronic health records (EHRs) is extensive. Reusable data capture in EHRs could lead to major improvements in quality measurement, scientific research, and decision support. To achieve these goals, structured and standardized recording of healthcare data is a prerequisite. However, time spent on EHRs by physicians is already high. This study evaluated the effect of implementing an EHR embedded care pathway with structured data recording on the EHR burden of physicians.

Materials and Methods

Before and six months after implementation, consultations were recorded and analyzed with video-analytic software. Main outcome measures were time spent on specific tasks within the EHR, total consultation duration, and usability indicators such as required mouse clicks and keystrokes. Additionally, a validated questionnaire was completed twice to evaluate changes in physician perception of EHR system factors and documentation process factors.

Results

Total EHR time in initial oncology consultations was significantly reduced by 3.7 minutes, a 27% decrease. In contrast, although a decrease of 13% in consultation duration was observed, no significant effect on EHR time was found in follow-up consultations. Additionally, perceptions of physicians regarding the EHR and documentation improved significantly.

Discussion

Our results have shown that it is possible to achieve structured data capture while simultaneously reducing the EHR burden, which is a decisive factor in end-user acceptance of documentation systems. Proper alignment of structured documentation with workflows is critical for success.

Conclusion

Implementing an EHR embedded care pathway with structured documentation led to decreased EHR burden.

INTRODUCTION

Despite the rapid rise and improvement of technology making everyday life more convenient, the healthcare sector seems to lag behind. Whilst the electronic health record (EHR) is widely implemented, it has not yet delivered on the promise of making the job of physicians easier(1). Physicians complain about a high administrative burden due to various reasons, including poor usability of the EHR, inefficient workflows, and poor interoperability between EHR systems leading to re-entering information multiple times(2, 3). Furthermore, much healthcare information is currently still exchanged by mail or fax. One of the reasons for these problems is that when EHRs became available, data recording was digitalized but not automated; pen and paper were replaced by computer and keyboard, but data was still stored in free-text format. Therefore, using the EHR effectively to improve efficiency by automating parts of the care process has proven difficult. As a result, EHRs have led to an average increase of 12% in documentation time for physicians(4).

Even though the possible added value of EHRs is theoretically extensive, accurate and accessible data within the EHR is essential for reaching this goal. Currently, most documentation in EHRs is still unstructured and unstandardized, although structured and standardized documentation, hereafter referred to as structured documentation, is key to increasing the added value of EHRs. Furthermore, because healthcare data is mostly unstructured, data reuse possibilities are impeded. Data reuse is becoming increasingly important due to the increased requirements for quality measurement, reimbursement purposes, scientific research, and decision support(5). Nonetheless, replacing the free-text note with long and detailed multiple-choice lists to achieve structured data capture is not a complete solution to the problem of unstructured data. It is crucial to ensure that the EHR is aligned with the clinical workflows of physicians(6, 7). Optimizing a clinical workflow and ensuring that the EHR supports this workflow can be achieved by implementing care pathways.

A care pathway is a complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period(8, 9). Care pathways are standardized to reduce variability between physicians and aim to enhance the quality of care and reduce costs by improving risk-adjusted patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources(9-11). The next step is embedding care paths into the EHR. If designed and implemented appropriately, this will support adherence to the care pathway and help document all relevant information efficiently. EHR embedded care pathways ('e-pathways') are care paths that describe: (1) the clinical data sets used; (2) the on-screen forms and user interface elements required; (3) the formal model of the roles,

tasks, sequencing, and business rules of clinical workflow and (4) the messages to be exchanged between the systems that invoke the pathway(12-14). After implementing an e-pathway, the EHR supports the standardized workflow and therefore assists the physicians in reviewing, documenting, and placing orders. Relevant information is recorded at the point of care, and stored as reusable data. As a result, data elements required for calculating quality indicators or registry purposes are collected routinely, eliminating the need for time-consuming, manual data collection at a later stage.

Studies have shown that the success of information technology implementation is decided by the acceptance of healthcare providers (15). For example, when a new system increases the time required for recording clinical data during a consultation, less time is spent on patient care(16). Ultimately, this will lead to resistance in healthcare providers, resulting in implementation failure. However, complete, accurate, and structured recording of healthcare information is becoming increasingly important, given the increased requirements for data reuse. This study evaluated the impact of implementing an e-pathway with structured documentation. The main research question of this study was whether implementing an e-pathway with structured documentation influenced the documentation burden of physicians in outpatient Head and Neck Cancer (HNC) care.

MATERIALS AND METHODS

Setting

This study was conducted in a tertiary oncology center in the Netherlands. A custom build version of HiX EHR (Chipsoft, Amsterdam) is used in this center. The Head and Neck Oncology e-pathway with structured documentation was formally launched in July 2021. The e-pathway was developed in a process which involved multiple healthcare providers from various specialties. For every phase of the care process, agreements were made regarding when and which healthcare providers should perform specific tasks and record specific information. It was also considered which orders are required for providing optimal care, and when these orders are placed. Furthermore, it was also ensured that space was available in relevant schedules to plan these orders. Following this, the e-pathway implementation included (1) structured documentation templates including discrete data storage for every phase in the multidisciplinary care path, including but not limited to the initial oncology consultation, multidisciplinary tumor board meeting, diagnostic result consultation, and follow-up consultation. Template content and format were explicitly designed to ensure optimal alignment with the work process of the physician; (2) specific smartphrases, autotexts, and content importing technology to automate and standardize documentation as much as possible; (3)

prefilled, standardized ordersets that invoke the care pathway during every phase of the care process for every specific care path. Care pathways were categorized by tumor localization and tumor stage (e.g., hypopharynx stage I-II, oral cavity stage III-IV); (4) automatic capture of all relevant discrete data during the care process for quality measurement and other registry purposes, eliminating the need for manual data collection at a later stage. During the development phase, end-users were involved in multiple testing sessions. All physicians were provided with the opportunity to be instructed in using the optimized EHR.

Study design

We used a before and after study design (17). After obtaining informed consent, initial oncology consultations (IOC) or follow-up consultations (FC) of patients seen by HNC care providers in outpatient Head and Neck Oncology were recorded with specialized recording software, which has functionalities for extraction of usability metrics(Morae, Techsmith). Subsequently, these recordings were analyzed using video-analytic software and studied using time-motion methodology. Time spent on specific categories and tasks *(table 1)* by physicians was measured using Time Motion Studies app (Graphite Inc). The number of mouse clicks, mouse scrolls, keystrokes, EHR mouse path length, and consultation duration were extracted from the recordings. Moreover, data from the video-analytic software, the time motion capture tool were combined with data extracted from the EHR.

Table 1

Categories and tasks used in measurement app

Category	Task	Explanation
1. EHR	Chart review	When the physician is looking for or reading information from the patient record.
1. EHR	Input	When the physician is entering information into the patient record.
1. EHR	Ordering	The physician orders tests, e.g. imaging, laboratory or medication.
1. EHR	Other (documentation)	Used when the observer cannot discern whether the task falls in one of the four other (more specialized) EHR tasks.
2. Communication	Physician-patient communication	All communication between physician and a patient.
2. Communication	Discussion with colleague	All communication between the physician and a colleague.
3. Other	Other computer tasks	All tasks on computer that are not in the EHR program (e.g. reading mail).
3. Other	Other activities	All tasks that do not fit in one of the other categories.

Additionally, HNC care providers were invited to complete the adoption of structured data recording questionnaire previously validated by Joukes et al.(18). This questionnaire can be used to measure and evaluate change in perception on the EHR system and EHR documentation process factors. The explanation of all 29 concepts measured and the full questionnaire can be found in Appendix A and B. The questions were answered on a Likert scale ranging from 'strongly disagree' to 'strongly agree'. The invitations were sent before and six months after implementing the e-pathway.

All data collection was conducted before implementing the e-pathway with structured documentation and at least six months after implementation, ensuring providers had time to adjust to the adapted system. Both data collection periods had a duration of twelve weeks. The procedures of this study were approved by the local ethics committee of Antoni van Leeuwenhoek Netherlands Cancer Institute(IRB d19-312).

Analysis

Statistics were performed using IBM SPSS Statistics software version 25.0 (IBM Corp). For IOC, all analyses were performed on the observed time during the actual consultations, i.e., when the patient and the physician were present in the consultation room. For the FC, analyses were performed on observed time during the actual consultations, including the wrap-up time after the patient left the room. For FC, most physicians only use the EHR after the patient has left the room in contrast to IOC, for which physicians usually conduct all EHR tasks with the patient still present.

For the primary outcome variables, general linear models were defined. Seperate models were created for the two consultation types. Independent variables were the primary variable of interest which was a dichotomous variable indicating whether the consultation took place before or after implementation. Furthermore, the physician was added as a fixed effect and the age of the patient as a covariate. For IOC, a variable indicating whether the tumor was benign or malignant and a variable grouping skin tumors and mucosal tumors were added to the model. Similar regression models were defined for secondary outcome measures, which were the usability metrics that were measured during the consultations, such as mouse clicks and scrolls, keystrokes and mouse movement. Furthermore, interactions between the independent variable that indicated the moment the consultation took place and the other independent variables were checked during analysis and were non-significant and therefore excluded from the models. To evaluate the change in physician perception of the EHR and documentation process, mean factor scores were calculated for concepts measured by the questionnaire. The difference before and after implementation was compared using a Wilcoxon-signed-rank test. A p-value of < 0.05 or a 95% confidence interval excluding 0 was considered significant.

RESULTS

196 consultations were recorded during the study period, of which 97 were IOC and 99 were FC, with a total duration of over 113 hours. The case mix remained comparable before and after the implementation. Estimated marginal means of consultation times are shown in table 2. A non-significant reduction of 3.4 minutes in consultation time (p = 0.145) after implementation is observed in IOC, decreasing from 33.7 (95% CI 28.6 - 39.1) to 30.4 (95% CI 24.4 to 36.4). For FC, consultation duration was 2.4 minutes less in the period after implementation (p = 0.044), decreasing from 13.52 (95% CI 11.81 to 15.23) to 11.09 (95% CI 9.33 to 12.85).

Table 2

Regression coefficients of e-pathway implementation on EHR time

	Regression coefficient B (p-value) for period after implementation	EEM in minutes (95% CI) before implementation	EEM in minutes (95% CI) after implementation
Initial Oncologic Consultation			
Total EHR time*	**- 3.69 (p = 0.003)****	13.91 (11.29 to 16.53)	10.2 (7.20 to 13.23)
Chart review	- 0.62 (p = 0.133)	0.97 (0.04 to 1.89)	0.34 (-0.76 to 1.44)
Input*	- 1.36 (p = 0.075	7.54 (5.87 to 9.20)	6.18 (4.26 to 8.09)
Orders*	**- 1.80 (p = 0.013)****	6.37 (4.61 to 8.12)	4.47 (2.50 to 6.44)
Physician-patient communication*	- 0.67 (p=0.770)	26.86 (21.91 to 31.82)	26.2 (20.50 to 31.91)
Follow up consultation			
Total EHR time*	- 0.53 (p = 0.219)	4.12 (3.51 to 4.74)	3.58 (2.95 to 4.23)
Chart review	- 0.08 (p = 0.776)	1.40 (1.00 to 1.80)	1.32 (0.90 to 1.74)
Input*	- 0.19 (p = 0.369)	2.03 (1.72 to 2.34)	1.84 (1.52 to 2.16)
Orders*	- 0.11 (p = 0.484)	0.82 (0.63 to 1.01)	0.71 (0.46 to 0.96)
Physician-patient communication*	-1.19 (p = 0.220)	9.42 (8.01 to 10.83)	8.23 (6.78 to 9.68)

* Regression equation significant (p < 0.05)

** parameter estimate significant (p < 0.05)

Abbreviation: EEM: estimated marginal mean

The results of the analysis on the influence of the e-pathway with structured and standardized documentation on the total EHR time and the three main tasks are shown in table 2. Relevant interactions terms, which were interactions between the independent variable that indicated the moment the consultation took place and the other independent variables, were not significant and therefore excluded from the model. For IOC, the period after implementation was associated with a 3.69 minute reduction in time spent on the EHR (p = 0.003), a 27% decrease. For FC, we found no significant effect on total EHR time. The analysis showed a 0.53 minute difference (13%) (p = 0.219).

As can be seen from the data in table 2, the highest reduction in EHR time is found in the task placing orders. The mean time required per order decreased from 59.79 to 37.89 seconds ($p < 0.000$), a 36% reduction. Additionally, the total number of orders per consultation increased from 6.94 to 10.08 after implementation ($p < 0.001$).

Table 3 shows the results of the regression analysis conducted on usability metrics. In IOC, the number of mouse scrolls decreased significantly by 66%. In contrast, the number of physical keystrokes, which does not include auto-entered keystrokes, increased by 24%. Additional analysis showed that the automated keystroke entry into the EHR increased by 102.49 ($p = 0.013$) characters per consultation. In FC, mouse scrolls were significantly reduced by 85% and mouse clicks were reduced by 37%.

Table 3

Regression coefficients of e-pathway implementation on usability metrics

	Regression coefficient B (p-value) for period after implementation	**EEM (95% CI) before implementation**	**EEM (95% CI) After implementation**
Initial Oncologic Consultation			
Mouse clicks*	- 20.94 (p = 0.184)	136.46 (101.97 to 170.95)	115.52 (75.80 to 155.24)
Mouse scrolls*	**- 207.40 (p = 0.000)****	313.36 (249.17 to 377.56)	105.97 (32.04 to 179.87)
Mouse movement (meters)*	- 3.72 (p = 0.388)	39.876 (30.42 to 49.34)	36.156 (25.26 to 47.05)
Keystrokes*	**+ 372.06 (p = 0.021)****	1141.39 (792.76 to 1490.01)	1513.45 (1111.95 to 1914.94)
Follow up consultation			
Mouse clicks*	**- 20.1 (p = 0.001)****	54.06 (45.23 to 62.88)	33.90 (24.78 to 43.01)
Mouse scrolls*	**- 69.03 (p=0.001)****	80.67 (65.87 to 95.46)	11.64 (0.00 to 26.91)
Mouse movement*	**- 3.20 (p = 0.039)****	14.90 (12.71 to 17.08)	11.70 (9.45 to 13.96)
Keystrokes*	- 84.78 (p = 0.127)	428.80 (351.65 to 505.96)	344.02 (260.69 tot 427.36)

* Regression equation significant ($p < 0.05$)
** parameter estimate significant ($p < 0.05$)
Abbreviations: EEM = Estimated marginal mean

Survey

Sixty-two questionnaires were sent out to 32 HNC care providers, of which 41 were returned, resulting in a 66.1% response rate. Because of personnel changes, not all HNC care providers could be invited during both study periods. After excluding physicians who did not complete both questionnaires, 26 questionnaires were used for analysis. The results are shown in table 4.

Table 4

EHR system and documentation process factors, their factor scores before and after implementation and significance of Wilcoxon-signed-rank test.

	Mean factor score before implementation	Mean factor score after implementation	Wilcoxon-signed-rank test
System factors			
Information Reliability	3.56	3.83	0.205
Completeness	3.15	3.69	0.131
Accuracy	**2.81**	**3.65**	**0.006***
Format	**2.81**	**3.69**	**0.012***
Currency	3.00	3.54	0.053
System Reliability	3.69	4.00	0.395
Flexibility	3.23	3.85	0.084
Integration	3.19	3.00	0.265
Accessibility	3.85	4.15	0.157
Timeliness	3.23	3.38	0.527
Information Satisfaction	3.15	3.69	0.083
System Satisfaction	3.31	3.46	0.595
Documentation process factors			
Compatibility	**3.08**	**3.92**	**0.031***
Awareness	3.31	3.74	0.028
Perceived Usefulness	**3.08**	**3.63**	**0.016***
Perceived Ease Of Use	**2.77**	**3.46**	**0.036***
Interpersonal Influence	2.62	3.23	0.099
Governmental Influence	2.62	2.92	0.102
Self-Efficacy	3.85	3.69	0.480
Facilitating Conditions	**2.69**	**3.46**	**0.039***
Situational Normality	2.69	2.92	0.257
Structural Assurance	3.92	3.62	0.206
Attitude	**3.81**	**4.00**	**0.021***
Subjective Norm	3.15	3.38	0.584
Perceived Behavioural Control	3.38	4.00	0.054
Institutional Trust	**4.31**	**4.00**	**0.046***
Perceived Risk	3.73	3.15	0.108
Intention To Act	4.08	4.00	0.557
Behaviour Full	3.32	3.45	0.506
Behaviour Physician	3.50	3.63	0.646

It can be seen from the data in table 4 that significant increases in perceived usefulness and perceived ease of use of the EHR were observed, which are important end-user acceptance criteria(19). Furthermore, facilitating conditions, which indicates whether there is enough time for proper documentation, increased significantly. Compatibility, which means whether the EHR supports the personal work process of physicians, improved as well.

DISCUSSION

To our knowledge, this is the first study to investigate the impact of an e-pathway with structured documentation on objective measures of physician efficiency, which is of vital importance in end-user acceptance. This study showed that reducing administrative burden while enabling structured, reusable data capture at the point of care is feasible. Our results show that in IOC, the period after implementation was significantly associated with a 3.69-minute reduction ($p = 0.003$) total EHR time per consultation, a 26.7% decrease. These objective findings are corroborated by significant increases in the perceptions of HNC care providers on perceived ease of use of the EHR and facilitating conditions for proper documentation.

Our results showed a non-significant 3.4 minute reduction in IOC duration. Presumably, physicians reinvest the spare time from EHR tasks in other tasks such as direct contact with the patient. This would indicate that a reduction in EHR time does not always result in a reduction in consultation duration, but also possibly adds to the quality of the communication with the patient. Another explanation could be that our sample was not large enough to demonstrate significance on the effect on total consultation duration. Additionally, appointments often have a reserved time slot, which means the potential reduction in consultation duration is limited, because physicians might simply use the allocated time.

The largest reduction in time spent on the EHR was achieved by reducing the time required for orders. The time required per order decreased by 36.6%. In contrast, the mean number of orders per consultation increased, probably due to using standardized order sets. Presumably, in the pre-implementation period, some orders might be forgotten or placed at a later time. These results indicate that the efficiency and the completeness of placing orders were improved. Additionally, the time required for input of information decreased by a non-significant 1.36 minutes. The analysis result on time spent on chart review was not significant, which can be attributed to this task being conducted prior to the start of an IOC.

When considering the results of the analysis on the usability metrics per consultation, the most striking finding is the 66% decrease in the number of mouse scrolls per consultation. It is highly likely that this is the result of the improved format and usability of the EHR, which is also supported by the results of the validated questionnaire. Therefore, this probably contributes to the reduced time spent on the EHR. In contrast, the number of keystrokes required per consultation increased by 25%. Due to the technology used for automated text entry, the analytical software used measured every automated character as an individual keystroke. However, it was also possible to calculate how many characters were entered automatically. Therefore, it can be concluded that the increase in automated character entry partly explains the increase in total keystrokes. Another contributing factor could be that because the documentation process has become more efficient, notes are now mostly completed during the consultation, whereas prior to the implementation, notes might have had to be completed after hours.

A significant decrease in follow-up consultation duration was found in the period after implementation. However, our results showed that the reduction in total EHR time per consultation was not significant. Therefore, it is likely that the reduction in EHR time cannot fully explain the decrease in total consultation duration. The consultations might have been shorter due to less complex cases. Moreover, this also means that the reduction in the number of required mouse clicks, mouse scrolls, and mouse movement is most likely only partially caused by the improved usability and format of the EHR .

Comparison with previous research

Current literature describing documentation time so far predominantly evaluated the difference between paper-based and EHR-based documentation(20). Whereas there is research on implementing clinical pathways supported by health information technologies, these studies reported improvements in patient outcomes, quality of care, and healthcare resource utilization(21). Decreased waiting times were observed in cancer care and neurology after implementing a pathway-based EHR(22, 23). However, little research objectively describes the effect of embedding care pathways and structured documentation on physician efficiency or EHR burden. Most studies related to this topic only evaluated perceptions of healthcare providers and lack objective measures of efficiency(24-26). One study found that physician satisfaction with standardized reporting in oncology is high when the information reported is clinically relevant and timely available(27). Nevertheless, the efficiency of entering the information into the EHR is a highly important factor because it also influences end-user acceptance, which is a decisive factor when implementing a health information technology(15). Several factors are essential when implementing structured documentation. Firstly, the EHR must have the ability to capture data in a structured and standardized manner. This is often measured by a maturity level, such as the HIMSS classification(28). EHR maturity

depends on the level of functionality and the extent to which there is support for structured and standardized data capture. When a high level of maturity is reached, the second important factor in transitioning from free text to structured data recording is the extent to which physicians have the intention to record data in a structured and standardized way(18, 29). If physicians have a positive perception towards structured data recording, this will contribute to changing their actual documentation behavior to structured documentation. This intention is influenced by various factors, such as the perception that structured recording can reduce freedom of expression or takes more time(16, 30, 31). Moreover, end-users are unlikely to accept any electronic documentation system that adds a significant burden to their workload(32). Therefore, the efficiency and ease of use of a documentation method should be superior to the situation before implementation.

Strengths and limitations

To our knowledge, this is the first study to objectively investigate the impact of an e-pathway with structured and standardized documentation on measures of physician efficiency. Thhe detailed analysis regarding tasks and usability metrics enabled us to gain insight in how the reduction in documentation time was achieved. Our conclusions based on the objective outcomes were supported by the subjective outcomes of the questionnaire. The perceptions of HNC care providers towards the EHR system and documentation process improved, which supports the conclusions reached based on the results of the objective outcomes.

Several limitations are recognized. Due to the chosen methodology that enabled more detailed analysis of documentation burden, time spent on the EHR outside regular consultation times could not be measured. This might have led to underestimating or overestimating the effect on EHR time per consultation, because EHR tasks that were previously performed after a consultation may now be performed during the consultation due to increased efficiency, or vice versa. However, because a positive influence on the perceptions of physicians was observed, underestimating the effect is more likely than overestimating the effect.

Another limitation is that this study was not randomized because it was impossible to concomitantly use the old and new versions of the EHR due to technical reasons. Whereas the design used in this study is common in e-health intervention studies, this is not an optimal design to establish causality. However, this risk was minimized by controlling for confounders in the analysis. Therefore, we are confident that our intervention is the reason for the observed effects. Lastly, while the methods of this study enable a detailed analysis, time-motion methodology and video analysis are highly time-consuming. As studies on this topic will be more common in the future, it

might be more realistic to focus on using and validating EHR system logs to measure the impact of health information technology on physician and organization efficiency. However, studies on this topic have shown that it is difficult to draw valid conclusions from EHR logs(33). Therefore, time-motion methodology currently remains the gold standard for accurately measuring time spent on tasks.

Implications for practice

This study shows that it is possible to collect relevant information for quality measurement through structured data recording. All relevant data-elements for the Dutch Head and Neck Audit quality registry are routinely and structurally captured at the point of care. Therefore, manual data extraction for quality registries will no longer be necessary. Essential conditions for this are that the care pathway is properly integrated into the EHR, and supports the work process of the physician. This decreases documentation time for care providers and improves perceived ease of use, both essential prerequisites for the end-user acceptance. The increased efficiency likely extends beyond actual consultations. Other benefits, such as automatically computing referral letters and more efficient handover of information to colleagues, will also increase efficiency and quality of care. To ensure that implementing a standardized care pathway does not force a physician to use a workflow unsuitable for their setting, it is important to involve healthcare providers in the e-pathway development or adaptation process. If it contains elements that are not feasible for that setting, adjustments can be made if necessary.

The influence of structured data recording on the quality of documentation, which is highly important in providing good quality care, is currently being investigated in another study. The structured data capture offers many reuse possibilities besides automated data extraction and data exchange with quality registries, such as (1) development of internal quality dashboards, (2) reuse for scientific research purposes, and (3) development of clinical decision support tools. These applications can also lead to more efficient care, increased quality of care, and reduced costs. Furthermore, to ensure that abovementioned benefits are not specific to one hospital, a project aiming to implement the HNC care pathway in other hospitals in the Netherlands is currently being conducted. Nevertheless, extracting high-quality structured data from the EHR has proven difficult(34, 35). Priority should be given to developing ways to extract and validate high-quality structured data from the EHR. Furthermore, future studies should focus on developing and validating more time-efficient methods to measure the effect of similar interventions, as research in this field will become increasingly common.

CONCLUSION

This study assessed the effect of implementing an EHR embedded care pathway (e-pathway) with structured and standardized documentation on the EHR burden of healthcare providers, as this is a decisive factor in end-user acceptance of health information system implementation. Nearly 30% reduction in total time spent on the EHR during consultations can be achieved. These results show that it is possible to record data in a structured way at the point of care, thus enabling reuse of healthcare information while simultaneously decreasing the EHR burden for healthcare professionals.

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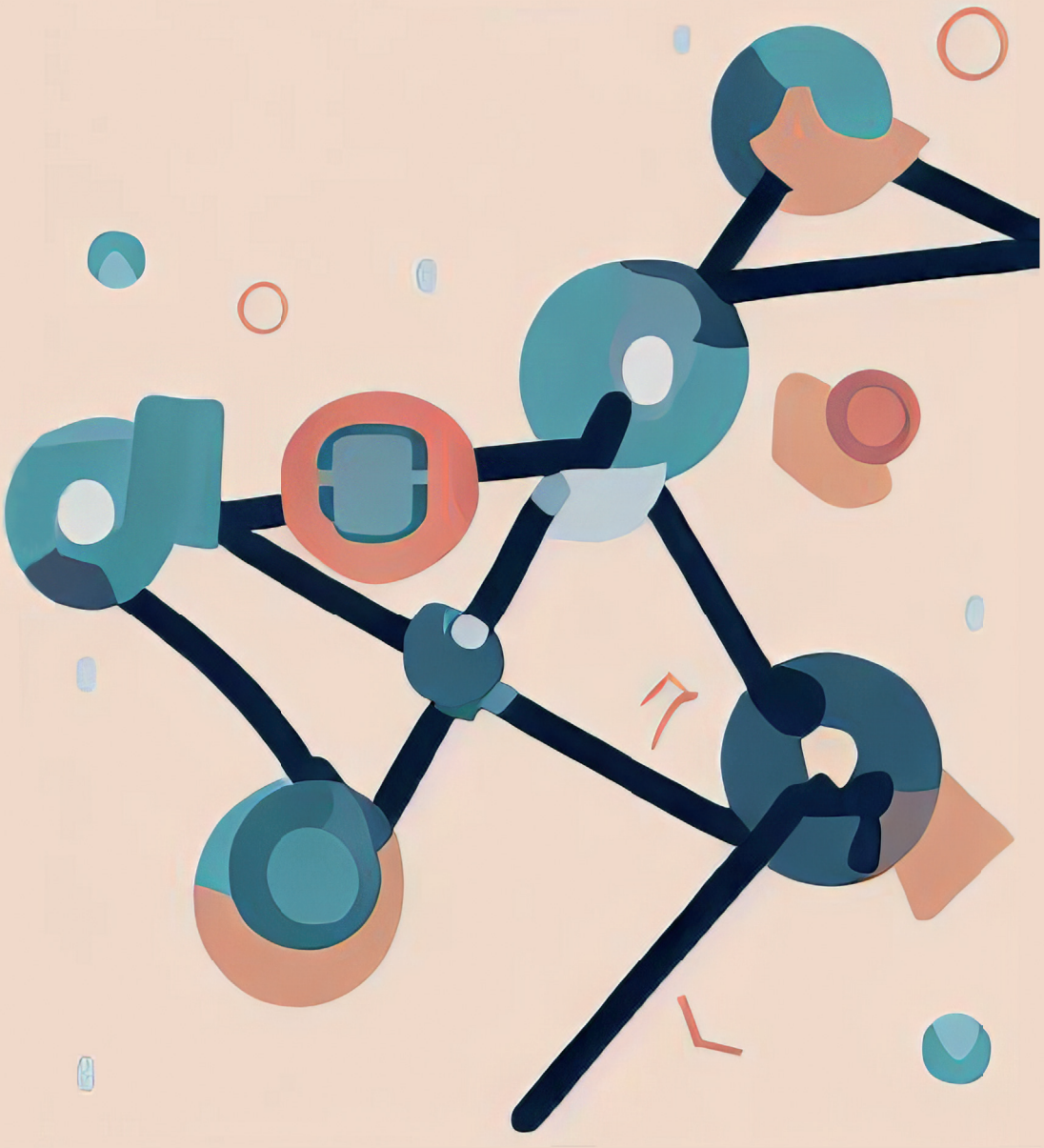

Chapter 4

The impact of structured and standardized documentation on documentation quality; a multicenter, retrospective study

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Introduction

The reuse of healthcare data for various purposes will become increasingly important in the future. To enable the reuse of clinical data, structured and standardized documentation is conditional. However, the primary purpose of clinical documentation is to support high-quality patient care. Therefore, this study investigated the effect of increased structured and standardized documentation on the quality of notes in the Electronic Health Record.

Methods

A multicenter, retrospective design was used to assess the difference in note quality between 144 unstructured and 144 structured notes. Independent reviewers measured note quality by scoring the notes with the Qnote instrument. This instrument rates all note elements independently using and results in a grand mean score on a 0-100 scale.

Results

The mean quality score for unstructured notes was 64.35 (95% CI 61.30–67.35). Structured and standardized documentation improved the Qnote quality score to 77.2 (95% CI 74.18–80.21), a 12.8 point difference ($p<0.001$). Furthermore, results showed that structured notes were significantly longer than unstructured notes. Nevertheless, structured notes were more clear and concise.

Conclusion

Structured documentation led to a significant increase in note quality. Moreover, considering the benefits of structured data recording in terms of data reuse, implementing structured and standardized documentation into the EHR is recommended.

INTRODUCTION

Clinical documentation is the process of creating a text record that summarizes the interaction between patients and healthcare providers during clinical encounters(1). The quality of clinical documentation is important as it impacts quality of patient care, patient safety, and the number of medical errors(2-4). Furthermore, clinical documentation is increasingly used for other purposes, such as quality measurement, finance, and research. Additionally, regulatory requirements regarding documentation have increased(5, 6). Consequently, physicians are spending more and more time on documentation(7).

In recent years, various tools and techniques have been developed to increase documentation efficiency and decrease the time physicians need to spend on documentation. These techniques are known as content importing technology (CIT). Examples of CIT are copy and paste functions (CPF), automated data import from other parts of the electronic health record (EHR), templates, or macros. These tools seem to have multiple benefits, primarily faster documentation during patient visits. However, Weis and Levy described that the use of CIT has multiple risks. Incorrect insertion of data from other parts of the record, or excessively long, bloated notes can distract a reader from key, essential facts and data(8). However, when used correctly, it should be possible to limit these risks.

In addition to the need to increase documentation efficiency, documentation needs to be accurate. Cohen et al stated that variation in EHR documentation between physicians impedes effective and safe use of EHRs, emphasizing the need for increased standardization of documentation(9). However, some studies have suggested that structured and standardized documentation *(hereafter: structured documentation)* can impede expressivity in notes. Rosenbloom explored this tension between flexible, narrative documentation and structured documentation and recommended that healthcare providers can choose how to document patient care based on workflow and note content needs(1). This implies that structured documentation is preferred when reuse of data is desirable. On the other hand, narrative documentation can be used when reuse of information is not required.

Research has shown that structured documentation can improve provider efficiency and decrease documentation time(10). Unfortunately, little is known about the effects that a transition from primarily unstructured, free-text EHR documentation to structured and standardized EHR documentation has on the quality of EHR notes. To date, research on this topic has mainly focused on the difference between paper-based and electronic documentation(11-13). Although reuse of data, for which structured documentation is

essential, will become increasingly important, the primary goal of EHR documentation is supporting high-quality patient care(14). Therefore, the primary objective was to investigate the effect of increased standardized and structured documentation on the quality of EHR notes.

METHODS

Since 2009, the Radboudumc Center for Head and Neck Oncology developed and implemented a highly structured care pathway. A care pathway is a complex intervention for the mutual decision-making and organization of care processes for a well-defined group of patients during a well-defined period(15). In 2017, for all stages of the care pathway (e.g. first visit consultation, multidisciplinary tumor board, diagnostic results consultation, treatment, follow-up consultation) the patient information that had to be entered into the EHR was defined. Structured and standardized forms using different types of CIT, automated documentation and standardized response options were developed in Epic EHR (EPIC, Verona Wisconsin). These forms allowed physicians to enter all patient information efficiently into the EHR. This resulted in structured and standardized notes while simultaneously storing structured data elements into the EHR database. These data elements can be reused in other stages of the care pathway, automatically compute referral letters, trigger standardized ordersets, or other tools to make the care process more efficient. Ultimately, this data is used to populate real-time quality dashboards. Furthermore, data can be extracted from the EHR and sent to third parties, such as quality and cancer registries or other health care centers when referring patients. Besides structured data recording, these forms support additional narrative documentation if needed or preferred. Recently, a similar highly structured care pathway with structured documentation based on the previously developed care pathway in Radboudumc, was implemented at the Head and Neck Oncology department in Antoni van Leeuwenhoek. In this center, HiX EHR (Chipsoft, Amsterdam) is used. Because of the difference in EHR vendor and the resulting variation in technical possibilities of the EHRs, there were slight differences in structured forms and notes in both centers. However, the structured forms that were built in center B remain highly similar to the forms used in Center A, as the forms and notes of Center A were shared with center B and were subsequently used in the development phase.

A multicenter, retrospective design was used to assess the difference in note quality in two tertiary HNC care centers. In center A, structured documentation has gradually increased in recent years. Therefore, the EHR notes of patients seen between January and December 2013 were compared with those of patients seen between January and December 2019. The transition to structured documentation in center B was more

immediate due to implementing an EHR embedded care path that supports structured documentation. Therefore, the notes of patients seen between March and July 2020 were compared with those seen between January and April 2021. This shorter interval added to internal validity because it is less likely that other, time-related factors influenced the outcome. Notes of consultations of adult patients that completed at least one initial oncological consultation (IOC) or follow-up consultation (FUC) during the study period were eligible for inclusion. In both centers, a list of eligible notes was extracted from the EHR and for each consultation type and each documentation method, 36 notes were randomly drawn. In total, 288 notes were included. Subsequently, notes were carefully anonymized. All names, dates, and other identifying information were replaced with <name>, <date>, or otherwise masked. A translated example of a structured note is available as Electronic Supplementary Material *(Online Resource 1)*. HNC care providers from center A were recruited to rate the notes collected in center B, and HNC care providers in center B were recruited to rate notes from center A to minimize bias. Each physician was assigned a random group of notes. However, unstructured and structured notes were evenly distributed among raters. Subsequently, notes were scored in a secured digital environment created in CastorEDC (Castor, Amsterdam), an electronic data capture platform.

The quality of the notes was assessed using the Qnote instrument, a validated measurement method for the quality of clinical documentation(16). This instrument rates every element of a note individually, by using one or more of seven components *(table 1)*.

Table 1

Elements and components of Qnote instrument

Elements	Components
Chief complaint	Sufficient information
History of present illness	Concise
Problem list	Clear
Past medical history	Organized
Medications	Complete
Adverse drug reactions and allergies	Ordered
Social and family history	Current
Review of systems	
Physical findings	
Assessment	
Plan of care	
Follow-up information	

The primary outcomes of this study were the quality of notes and note elements, measured by the Qnote instrument on a 100-point scale. Secondary outcomes included length of notes in words, mean component scores per note, and subjective quality measured by a general score given on a scale of 1-10.

Data were notated and analyzed using SPSS version 25 (IBM Corp, Armonk, NY, USA). Two-way ANOVA was used to assess differences in note quality between before and after implementation of structured documentation. The Qnote grand mean score and element scores were outcome variables. The type of note, the originating center, and a dummy variable indicating the period in which the note was written were added as fixed factors. Two-tailed significance was defined as $p < 0.05$ or a 95% CI not including zero.

This study was approved by the Institutional Review Boards at Antoni van Leeuwenhoek Netherlands Cancer Institute and Radboud University Medical Center.

RESULTS

The grand mean score of all 144 EHR notes written before implementing structured documentation was 64.35 (95% CI 61.30–67.35). When comparing this score to all 144 EHR notes written with structured documentation, a 12.8 point difference ($p<0.001$) was found. Structured documentation improved the grand mean score to 77.2 (95% CI 74.18–80.21). Subsequently, additional analysis was conducted on all element scores. The results are shown in table 2.

Table 3 shows descriptive results of element scores displayed per type of note. What can be observed from the data in table 3 is that for structured documentation, the standard deviation decreases in most elements scores, indicating the variability in quality seems to be lower in structured notes. Furthermore, when comparing the grand mean score for IOC and FUC notes separately, an increase for both types of notes was found (figure 1). IOC Qnote score increased by 14.9 (95% CI 11.3-18.5) points from 67.3 to 82.3. FUC Qnote score increased by 10.8 (95% CI 4.6-17.0) from 61.3 to 72.1.

Subsequently, analysis was conducted on data from both centers separately to determine whether structured documentation led to increased quality in both centers. In center B, an increase of 14.59 was found (95% CI 7.22-21.96) in IOC note quality, and a 16.36 point increase (95% CI 8.99-23.73) in FUC note quality was found. A significant improvement in IOC Qnote score by 15.10 (95% CI 8.26-22.10) was observed in center A. The 5.3 point increase in FUC note quality was not statistically significant (95% CI -1.61-12.14).

Table 2

Estimated marginal means of Qnote scores and main effect of structured documentation

Element	Qnote score Unstructured documentation	Qnote score Structured documentation	Mean difference (95% CI)	p-value of difference
Chief complaints	84.0	93.3	+ 9.3 (4.0 to 14.7)	0.001*
HPI	71.6	87.1	+15.4 (7.8 to 23.1)	0.000*
Problem list	23.3	39.0	+15.7 (3.9 to 27.6)	0.009*
Past medical history	38.8	47.0	+8.2 (0.0 to 16.4)	0.050*
Medications	29.5	42.0	+12.6 (-3.3 to 28.4)	0.120
Adverse reactions	25.6	84.7	+59.1 (47.2 to 71.0)	0.000*
Social and family history	72.5	88.3	+15.8 (6.3 to 25.5)	0.001*
Physicial findings	82.8	85.3	+2.5 (-2.2 to 7.2)	0.293
Assessment	74.5	85.9	+11.4 (5.1 to 17.7)	0.000*
Plan of Care	74.5	80.1	+5.7 (-2.3 to 13.7)	0.162
Follow-up information	72.5	86.9	+14.4 (7.9 to 20.9)	0.000*
Grand Mean	**64.4**	**77.2**	**+12.8 (8.7 - 17.0)**	**0.000***

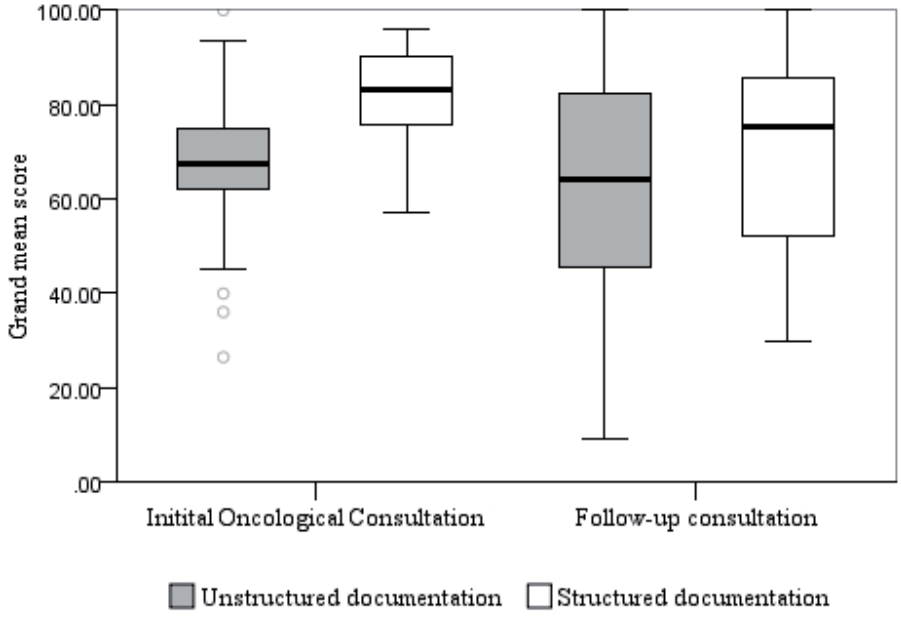
Table 3

Descriptive results of Qnote element scores, per note type

	Initital Oncological Consultation				Follow-up consultation			
	Unstructured		Structured		Unstructured		Structured	
	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)
Chief complaints	89,4	(22,2)	97,2	(11,5)	78,6	(30,2)	89,4	(23,8)
HPI	87,4	(27,7)	97,4	(8,6)	55,8	(46,4)	76,7	(36,3)
Problem list	33,8	(46,6)	46,5	(49,0)	12,7	(33,1)	31,5	(45,8)
Past medical history	73,7	(41,5)	85,2	(31,6)	4,7	(19,1)	8,0	(26,6)
Medications	29,5	(45,3)	42,0	(49,5)	*			
Adverse reactions	25,6	(40,0)	84,7	(31,1)	*			
Social and family history	72,5	(36,2)	88,3	(19,4)	*			
Physicial findings	87,3	(15,5)	87,0	(16,4)	78,2	(26,5)	83,6	(20,6)
Assessment	83,3	(20,6)	88,3	(18,7)	65,8	(39,3)	83,6	(23,5)
Plan of Care	80,1	(25,1)	89,6	(17,3)	69,3	(41,0)	69,9	(43,4)
Follow-up information	63,9	(32,1)	88,0	(22,0)	81,0	(27,9)	85,7	(27,1)
Grand Mean	67,4	(12,6)	82,3	(8,7)	61,3	(25,4)	72,1	(20,2)

* grey marked elements were not evaluated for this note because these elements were considered not relevant in this type of consultation

Figure 1. Boxplot of grand mean score per note type.



Analysis of secondary outcome measures showed a significant increase in note length for structured documentation in both note types. IOC notes increased from 442.1 to 639.6 words, with a mean difference of 197.5 (95% CI 146.9-248.1), translating to a 44.7% increase. A significant 53.3% increase was found in FUC notes, increasing with 46.5 words (95% CI 31.7-61.2) from 86.9 to 133.4. To evaluate whether this increase in note length led to unnecessary long notes containing excessive non-essential information, all scores for a given component were averaged. For example, the component concise was used to rate 9 of the 11 elements used to rate a note. The mean of all conciseness scores was calculated to get an overall indication of the conciseness of the note. Table 4 shows the difference in mean component scores. As can be seen from the data in table 4, the mean conciseness score, indicating whether note elements were focused and brief, increased significantly. Furthermore, the mean clearness score, indicating whether note elements were understandable to clinicians, also increased significantly.

When analyzing the scores of the general instrument that rated the notes on a scale of one to ten, a significant increase in documentation quality was also found. Mean scores increased from 6.83 to 7.52, which was an 0.68 increase (95% CI 0.44–0.94).

Table 4

Mean component score difference between unstructured and structured documentation

Component (number of elements for which component was used)	Explanation of component	Mean difference (95% CI) of mean component score	p-value of difference
Sufficient information (7)	Enough information for purpose	+14.3 (10.2 – 18.4)	< 0.001*
Concise (9)	Focused and brief, not redundant	+10.7 (6.5 – 14.9)	< 0.001*
Clear (8)	Understandable to clinicians	+14.8 (10.6 – 18.9)	0.009*
Organized (3)	Properly grouped	+14.5 (7.8 – 21.2)	< 0.001*
Complete (3)	Adresses the issue	+7.9 (1.61 – 14.3)	0.014*
Ordered (1)	Order of clinical importance	+16.2 (4.5 – 27.9)	0.007*
Current (3)	Up-to-date	+24.5 (17.3 – 31.7)	< 0.001*

DISCUSSION

The study offers some important insights into the impact of increased structured and standardized documentation on EHR note quality in outpatient care. In this retrospective multicenter study, our results show that structured documentation is associated with higher quality documentation. In summary, our results show a 20.0% increase measured on a 0-100 scale. Furthermore, our results showed that structured notes were significantly longer than unstructured notes, but were more concise nevertheless.

This study showed an overall increase in documentation quality after the implementation of structured and standardized recording. In 8 of the 11 elements measured with the Qnote instrument, a significant increase in quality was found. This result may be explained by the fact that relevant elements and items that have to be documented are presented to the health care provider in an intuitive, uniform way. Therefore, clinicians are less likely to forget certain elements and items within the note. Furthermore, repeatedly recording in the same format ensures the physician is trained to record properly and completely. The medication element showed a minor, insignificant increase. This might be because medications were not included in notes in one center and therefore did not contribute to the observed results on this element. Additionally, minor, insignificant increases were found in physical examination and plan of care. This could be explained by the fact that the score for these elements was already high in unstructured documentation.

A recent study found variation in the quality of documentation between healthcare providers(9). This variation could lead to inefficient documentation and the risk of patient harm from missed or misinterpreted information. Therefore, reducing this variability

may also be considered relevant. The descriptive data on element scores in this study showed a trend indicating that the variation in documentation quality decreases when using structured documentation. However, some elements still showed significant variation. Therefore, implementing solutions that reduce variation in documentation quality between encounters and healthcare providers should be encouraged.

In addition, when the notes were analyzed differentiated by center, a significant increase in the quality of IOC notes was observed. This was also the case for follow-up notes in one of the two centers. This supports the conclusion that structured and standardized recording increases documentation quality, independent of a specific center or EHR vendor.

The results also show notes were longer when structured documentation was used. This could be because structured documentation contributes to including all relevant elements, or because health care providers are more reliant on CIT. CIT can be a problem if it leads to unnecessary, unorganized, or unclear information in a note and distracts the reader from the essential information buried within the note. This is known as note bloat. When considering the results of this study, there is no evidence that the longer notes were the result of note bloat. Firstly, an increase in quality in almost all elements where CIT is mainly used (problem list, past medical history, adverse reaction, social and family history) was observed. Secondly, the analysis on components used to assess the individual elements showed significant increases in clearness and conciseness. Therefore, it is safe to assume that in this study, the longer notes were not associated with note bloat and are most likely the result of more complete, and therefore higher quality, documentation.

The reports in the literature to date have mainly focused on the effect of electronic documentation versus handwritten documentation. Some studies have shown a perceived decrease in quality after implementing EHRs, identifying copy-paste functions (CPF) and note clutter as the main reasons for this quality decrease(17). Others claim that EHRs increase note quality compared to manual recording in inpatient and outpatient care(11-13, 18). A small number of studies have evaluated semi-structured templates that mainly use free-text documentation, comparing them to traditional templates or fully unstructured free-text notes. A small (n=36) trial comparing outpatient notes written using a traditional template with an optimized template found mixed results, with no difference in overall quality(19). However, the intervention notes were inferior in accuracy and usefulness, although better organized. Another study evaluating a quality improvement project to improve clinical documentation quality found no increase in quality(20). A third, larger study did find a significant increase in inpatient documentation quality using a semi-structured template(21). The abovementioned

studies indicate that further research on this topic is warranted. However, our findings show compelling evidence that structured documentation can improve documentation quality.

This study has several strengths. This is the first study to use a validated measure instrument for outpatient notes to examine the impact of structured and standardized recording on outpatient note quality. Given the rising demand for reuse and exchange of healthcare data, structured and standardized data recording will become increasingly important. This study proves that structured documentation can also improve the quality of EHR notes. Furthermore, the increase in quality was found in two centers with different EHRs. These factors contribute to the generalizability of the results.

Another strength of this study is the method used to assess the quality of the notes. Of the instruments available in the literature that are used to assess the quality of documentation, most focus on the absence of data or only assess the global quality of the note, such as the PDSI-9(22). However, the Qnote instrument is based on a qualitative study in which relevant elements of an outpatient clinical note were identified(23). Therefore, it is possible to rate the quality of all note elements independently and subsequently calculate a total score. This structured approach is likely to be more objective than other, more general rating instruments. Besides, rating elements individually benefit from being able to identify specific deficits in note quality. Because of this, improving the quality of clinical EHR notes can be conducted in a more targeted and effective way.

This study also has some limitations. Firstly, the main limitation of the retrospective nature of this study is that a causal relationship between the implementation of structured and standardized documenting cannot be established with certainty. In one center, the interval between the two study periods was several years. Therefore, the influence of other factors cannot be eliminated. In the other center, the interval between study periods is shorter, making it highly likely that implementing the standardized care pathway with structured documentation is the primary reason for the increase in note quality. Moreover, analyzing the data differentiated by center resulted in similar outcomes. Secondly, the Qnote instrument has been validated on a population of diabetic patients and not for oncological patients. However, the elements used are general and not disease- or setting-specific. Moreover, the general score given by the raters in this study showed similar or marginally lower scores than the Qnote instrument. This conclusion was also stated in the initial Qnote validation study(16). Lastly, due to the visual similarity of structured and standardized notes, the complete blinding of study notes for raters was impossible. This might have led to an unconscious bias. However, the risk was minimized by recruiting note raters employed at another hospital.

The findings of this study support the assumption that structured documentation positively influences documentation quality. This is an important finding, given that the need for structured documentation will only increase in the near future because structured data is key in enabling the reuse of healthcare data. Data reuse will become increasingly important in health care, for various purposes, such as automated quality measurement, information exchange when referring patients to other health care centers, and less time-consuming data collection methods for scientific research. Furthermore, the use and implementation of decision support tools also require structured recording of healthcare data. The abovementioned applications of data reuse in healthcare can lead to increased efficiency and quality of healthcare. Nevertheless, there could be a concern that as data reuse becomes more important, healthcare providers are required to capture more data while providing care. This, in turn, might lead to an increased administrative burden. This should be avoided, as healthcare providers are unlikely to accept a documentation method that adds a significant burden to their workload(24). Efforts should be made to to implement structured documentation methods within EHRs to enable data reuse while reducing the administrative burden. The results of this study raise further questions about the benefits and pitfalls of structured documentation systems, on which future studies should focus. These include the effect of the structured documentation systems on documentation time and effort, how physicians' perceptions regarding the documentation process and the EHR are influenced, and how these factors affect adoption, and how these factors affect adoption. As a result, we have started another study to answer such questions.

CONCLUSION

This study demonstrated that structured and standardized recording led to an increase in the quality of notes in the EHR. Additionally, a significant increase in note length was found. Moreover, the results showed that the longer notes were also considered more clear and concise. Considering the benefits of structured data recording in terms of data reuse, it is recommended to implement structured and standardized documentation into the EHR.

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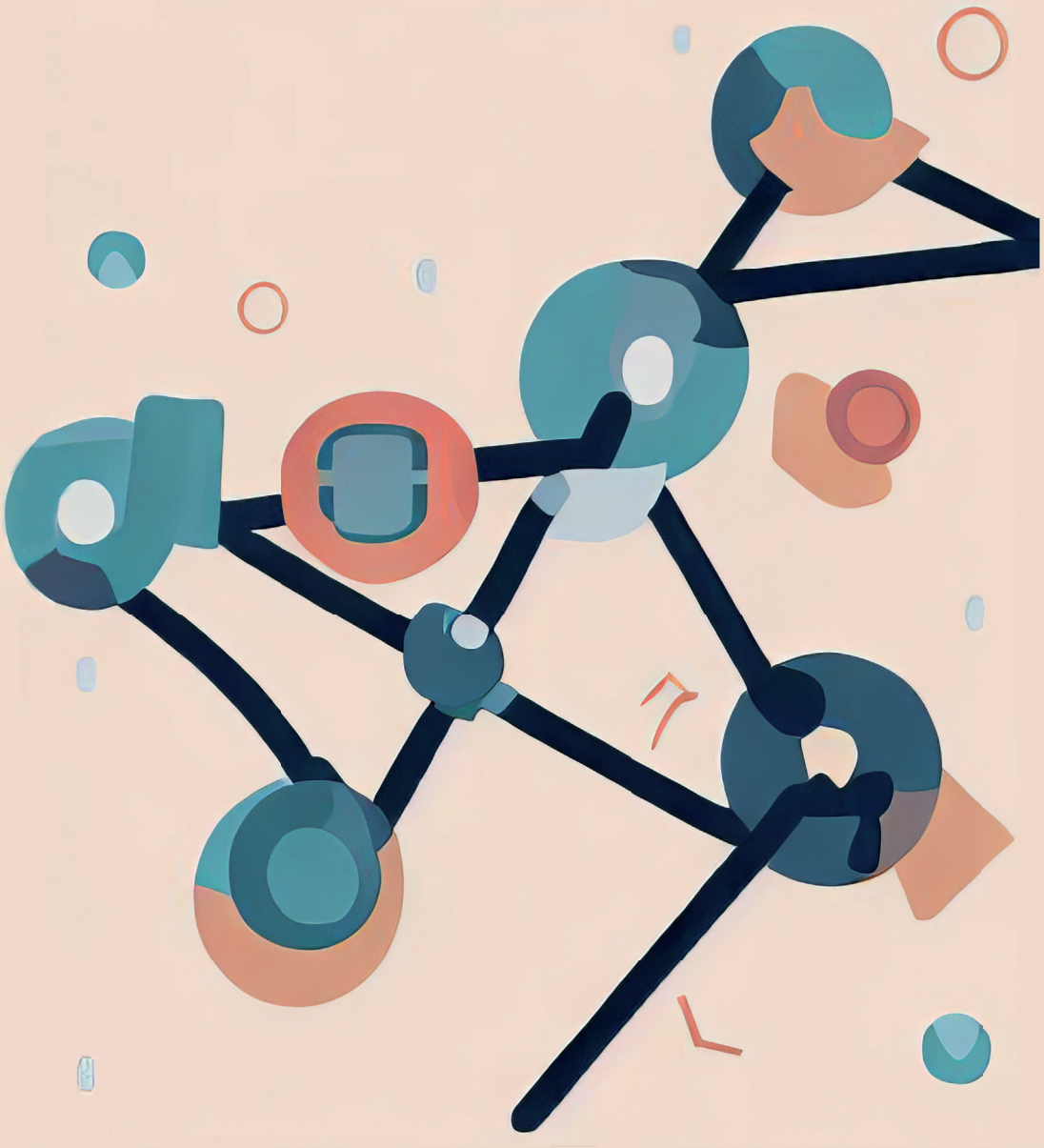

Chapter 5

Development and validation of automated electronic health record data reuse for a multidisciplinary quality dashboard

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Objective

To describe the development and validation of automated electronic health record data reuse for a multidisciplinary quality dashboard

Materials and methods

Comparative study analyzing a manually extracted and an automatically extracted dataset with 262 patients treated for HNC cancer in a tertiary oncology center in the Netherlands in 2020. The primary outcome measures were the percentage of agreement on data elements required for calculating quality indicators and the difference between indicators results calculated using manually collected and indicators that used automatically extracted data.

Results

The results of this study demonstrate high agreement between manual and automatically collected variables, reaching up to 99.0% agreement. However, some variables demonstrate lower levels of agreement, with one variable showing only a 20.0% agreement rate. The indicator results obtained through manual collection and automatic extraction show high agreement in most cases, with discrepancy rates ranging from 0.3% to 3.5%. One indicator is identified as a negative outlier, with a discrepancy rate of nearly 25%.

Conclusions

This study shows that it is possible to use routinely collected structured data to reliably measure quality of care in real time, which could render manual data collection for quality measurement obsolete. To achieve reliable data reuse, it is important that relevant data is recorded as structured data during the care process. Furthermore, the results also imply that data validation is conditional to development of a reliable dashboard.

Abstract

INTRODUCTION

Quality measurement in healthcare is crucial to improve quality of care. However, the process is currently highly time-consuming, because it relies on manual data collection by data extraction employees or healthcare providers. Implementing electronic health records (EHRs) has increased the amount of available data and the opportunities for use of this data for quality measurement. The problem is that most of this data is captured in an unstructured format, which means that the data is not arranged according to a pre-set data model. Therefore, EHR data is currently difficult to reuse for secondary purposes, such as clinical decision support, scientific research, and quality measurement[1]. In most cases, data entry clerks still manually collect data from an EHR to enter into a specific quality measurement database.

To enable automated EHR data reuse for quality measurement, structured data capture is considered critical [1, 2]. Modifying the documentation process is often required to ensure that clinicians document relevant information as structured data. Therefore, the EHR must be adapted to support structured and standardized recording of relevant data at the point of care[3]. A prerequisite for such a successful transition is that healthcare practitioners are motivated to record data in this structured manner. This can be influenced by various factors, such as perceived ease of use of the EHR and the time required for documentation[4, 5]. Furthermore, several factors can contribute to improving clinician documentation, and therefore structured data recording[3]. These include sufficiently educating clinicians regarding documentation, standardization of the documentation process to reduce variability, improvement of clinical workflow, and ensuring minimal documentation burden by properly aligning structured data capture of the EHR with the clinical workflow.

Once data is recorded in a structured format, the information can be extracted and reused, for example, in quality measurement. However, using automatically extracted data from the EHR is still challenging because of data quality problems[2, 6]. Firstly, these can be caused by problems on the input side of the EHR; this includes a lack of or inconsistent provider documentation, data entry errors (human or computer), or missing coding (such as ICD terminology). Inconsistent provider documentation can have multiple reasons, such as limited skills, insufficient training, time pressure, or insufficient user-friendliness of the EHR[7]. Secondly, the extraction process can cause data quality problems, such as the existence of different places where information is stored (which can also be an input problem), missing coding, and incorrect extraction rules. The successful use of EHR-extracted data to calculate reliable quality measures is still challenging, and limited evidence on this topic [8-10].

In our hospital, a large academic medical center in a metropolitan area, Epic EHR (Epic, Verona Wisconsin) was implemented in 2012. It is the central EHR used by healthcare providers in the hospital. At the Head and Neck Oncology department, with approximately 500 head and neck cancer (HNC) patients per year, the EHR was adapted in 2017 to support routine structured data capture. In the following years, the routinely collected data was used to populate a real-time quality dashboard. This study describes the development of this dashboard in the Head and Neck Oncology department. It also validates the routinely collected structured data used within the dashboard by comparing the EHR-extracted data to manually extracted data. This study aimed to explore whether automated and reliable quality measurement is feasible. We hypothesized that if certain conditions are met, it is possible to use routinely collected data to reliably calculate quality indicators and render manual data collection for quality measurement obsolete. We hoped to gain insight into the quality of the data in the dashboard and whether data quality influences the indicator results. Additionally, this study aimed to learn how data validation can be used to implement data quality improvement cycles.

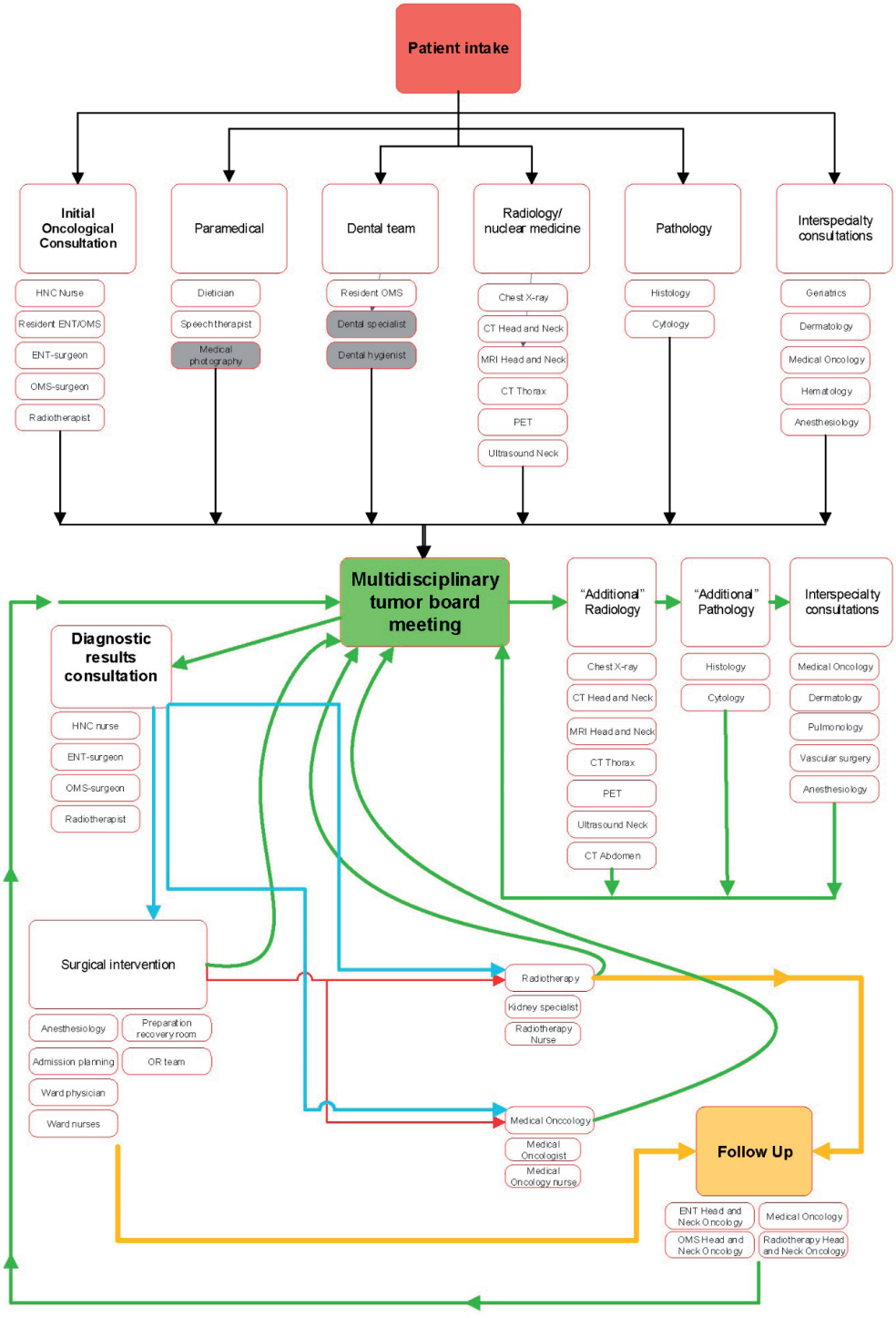
METHODS

Automation of data collection and population of the dashboard

The first step in the development of the dashboard was to determine which clinical variables and indicators should be shown within the dashboard. For this purpose, relevant indicators and clinical variables used in the Dutch Head and Neck Audit (DHNA) were chosen[11]. The DHNA is the Head and Neck Oncology quality registry in the Netherlands. After reviewing the selected indicators and variables, we defined which data elements were required to calculate these indicators. An indicator consists of a numerator and a denominator and usually has multiple conditions. Therefore, multiple data elements are required for calculating a single indicator. For each data element required, it was considered whether this information was clinically relevant and should be routinely documented by healthcare providers while providing care. If not, this data element should either be captured automatically by the EHR, or should not be recorded because this would add to the physician documentation burden. Standardized and structured documentation forms (smartforms) that capture relevant data elements were built and implemented in various phases of care. Care path phases included but were not limited to; triage, diagnostic phase, various treatment phases, and follow-up (figure 1).

These phases usually consist of multiple stops. For example, the diagnostic phase can contain an initial consultation, additional tests, and a multidisciplinary tumor board. A smart form was developed for every stop in which relevant data should be recorded. The

Figure 1. Overview of the Head and Neck Oncology care pathway



forms were developed in combination with tools such as automated documentation and standardized, prefilled order sets. As a result, relevant data elements were recorded routinely at the point of care in a structured format and administrative burden was decreased.

This routinely collected structured data was then used to auto-populate the dashboard. The data was extracted daily from the EPIC EHR database using an extraction algorithm. This preliminary data underwent a refinement process using using Medimapp Analytics, a third-party business intelligence software (Soulve Innovations, Utrecht, The Netherlands). To illustrate, the software employed specific logic rules to assign specific appointments as the start for various stages in the patient care pathway. For instance, the first radiation treatment appointment code would signal the onset of the therapeutic phase, provided there was no preceding surgical procedure for a specific patient. Additionally, the algorithm was designed to handle situations where multiple multidisciplinary team meetings (MDT) concerning a specific patient were extracted. In these instances, the software, using pre-established logic, identified and selected the correct MDT necessary for the calculation of quality indicators.

Patients were included in the dashboard based on ICD-10 diagnosis codes. For every indicator that was added, extraction logic had to be defined. For example, this included what data elements are required for a specific indicator, their location or locations in the EHR database, and which procedure codes are used in the EHR to indicate relevant appointments, office-based procedures, or surgical procedures. Furthermore, the calculation logic for indicators was defined. Because the Head and Neck Oncology care pathway is a complex pathway with many possible variations for a specific patient journey, multiple data validation cycles were conducted by a physician in collaboration with an IT specialist whenever indicators were added to the dashboard. After every cycle, extraction logic and calculation logic were improved. As an example, appendix A shows the relevant data elements and extraction logic required for one indicator. Appendix B shows a screenshot of the dashboard (available online).

Validation of automated collected data

To validate the data used in the dashboard, analysis was conducted by comparing the automatically extracted dataset (AED) with the manually extracted dataset (MED) on the same population. The MED was routinely collected by data entry clerks, who routinely collect patient data for the Netherlands Cancer Registry (NCR) and the DHNA[11, 12]. All data used in the dashboard was extracted to create the AED. The inclusion criteria were; (1) patients that had an initial consultation for their HNC in 2020; (2) were treated for first primary Head and Neck Squamous Cell (HNSSC) carcinoma (oral cavity; oropharynx; nasopharynx; hypopharynx; larynx; nasal cavity and paranasal sinuses; malignant

salivary glands and lymph node metastases of squamous cell carcinoma of unknown origin), and (3) were treated with curative intent. Exclusion criteria were; (1) carcinoma in situ; (2) patients diagnosed with a second primary HNSCC carcinoma; (3) a residual or recurrent disease; (4) mucosal melanomas, thyroid tumors, skin tumors, sarcomas, neuroendocrine tumors and hematological malignancies. The MED was requested at the NCR, and the AED was extracted from the dashboard. In- and exclusion criteria were applied to select the study population. Subsequently, records in both datasets were linked based on a unique patient identifier. A linkage indicator was added to the database, which indicated three groups of records: linked records, records uniquely registered in the dashboard, and records uniquely registered in the NCR.

Statistical analysis

Data were notated and analyzed using SPSS version 25 (IBM Corp, Armonk, NY, USA). Percentages were used to assess the level of agreement per variable. Calculations for levels of agreement of the two databases were standardized and therefore applicable on all items, either nominal, categorical or numeric. For date variables, the difference in days between the two datasets was calculated and added as an extra variable. Then, the numerator and denominator of the quality indicators included in this study, the levels of agreement of the results, and the difference in percentage were calculated. Additionally, the kappa statistic was calculated if applicable. Two-tailed significance was defined as $p < 0.05$.

This study did not fall under de scope of the Medical Research Involving Human Subjects Act, which was confirmed by the Institutional Review board East-Netherlands (2021-13111).

RESULTS

For both datasets, the total number of patients was counted. The MED contained 330 patients. The unfiltered AED contained 625 patients. After filtering out patients that did not visit the HNC department, 325 patients could be linked, resulting in coverage of 98.48%. After in- and exclusion criteria were applied to both datasets, 262 linked records were included for analysis. Table 2 shows the tumor localization of included patients in both datasets, which was based on ICD-10 coding. This variable showed near-perfect agreement with a kappa statistic of 0.96 ($p = 0.001$).

Subsequently, analysis was conducted on the date variables that indicate the start and end of the primary care path phases (triage, diagnostic, and various treatment phases) within the Head and Neck Oncology care pathway. The results are shown in table 3.

Table 2

Tumor localization based on ICD-10 codes for manual and automatically extracted datasets

Localization	Manual N (% of total)		Automatic N (% of total)	
Oral cavity and lip	82	(31.3%)	85	(32.4%)
Oropharynx	66	(25.2%)	60	(22.9%)
Nasopharynx	4	(1.5%)	4	(1.5%)
Hypopharynx	14	(5.3%)	13	(5.0%)
Larynx	60	(22.9%)	61	(23.3%)
Nasal cavity and paranasal sinuses	16	(6.1%)	16	(6.1%)
Salivary glands	17	(6.5%)	18	(6.9%)
Unknown primary tumor	3	(1.1%)	5	(1.9%)
Total	262	(100%)	262	(100%)

The difference in days between the manually extracted date and the automatically extracted date were calculated for records that did not show agreement. Figure 2 shows the distribution of the number of days that the manually extracted date differed from the automatically extracted date for three of these variables. A negative number indicated that the manually extracted date was earlier than the automatically extracted date. A positive number indicates that the automatically extracted date was a date prior to the manually extracted date.

The results of comparing other relevant variables required in calculating the quality indicators, such as treatment modalities, are shown in table 4.

After comparing the variables in the datasets, the numerator and denominator of the selected set of indicators included were calculated and compared. The results are shown in table 5.

DISCUSSION

This study described the development and validation of automated reuse of routinely collected structured data within a Head and Neck Oncology care pathway for a real-time quality dashboard. The results show that it is possible to automatically extract highly reliable data from the EHR and use it to calculate quality indicators reliably. The outcomes of these indicators were, in most cases, consistent with results based on manually collected data. This study provides evidence that it is feasible to transition from manual to automatic quality measurement. However, this requires effort to implement

Table 3

Date variables relevant in mapping the care pathway

Variable	Records with data present		Records in agreement	Level of agreement
	Manual	Electronic	(if data present in both sets)	
Date of referral	261	257	138/256	**53.9%**
Date of initial visit	262	258	228/258	**88.4%**
Date of MDT before treatment	255	259	210/252	**83.3%**
Date of surgery	132	137	120/122	**98.3%**
Start date of radiotherapy	199	205	182/197	**92.4%**
End date of radiotherapy	199	188	172/180	**95.6%**
Start date of systemic therapy	50	53	39/46	**84.7%**
End date of systemic therapy	50	53	28/46	**60.9%**

structured data recording within a care pathway, enabling electronic extraction and further data reuse. Additionally, continuous data validation is required to improve the quality of the structured data used.

Interpretation

The coverage of the dataset was nearly 100%. Only five patients were present in the MED while not in the AED. The dashboard used specific ICD-10 codes recorded within Epic EHR to include patients. It was evident that the initial AED contained more patients than the MED. This was because the MED included all patients who met the inclusion criteria of the National Cancer Registry, while the AED was compiled based on the registration date of a subset of ICD-10 diagnosis codes within the EHR. This raw selection of patients requires filtering using additional structured data to get the desired set of patients. Considering the high coverage, this method is feasible, provided that adequate recording of the ICD-10 code is achieved within the care pathway. However, additional filtering should be conducted to obtain reliable denominator of the quality indicators.

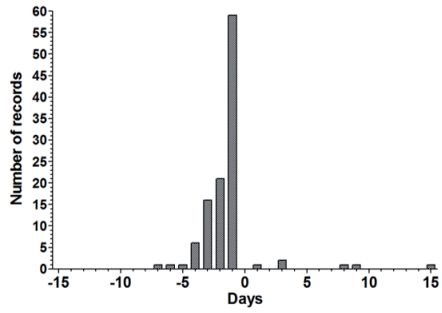
The date variables required to map patient care pathways were found to be in substantial agreement, with a rate of up to 98.8%. These variables are primarily used to compute process indicators, specifically waiting times.

Two variables stood out negatively. The date of referral was in agreement in only 53.9% of cases. An explanation might be that during the manual data collection by data entry clerks, the date of referral is found in the referral letter from the general practitioner. This letter is scanned into the EHR as a PDF. Therefore, there is no way to extract the referral date from the EHR automatically. For this reason, during the dashboard development,

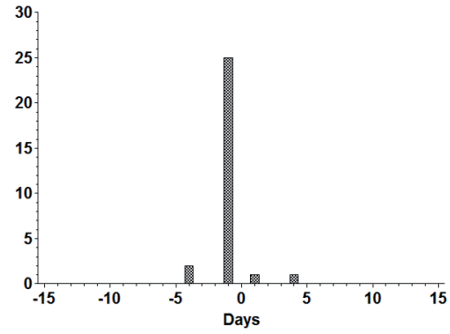
Figure 2

Distribution of calculated difference in manual vs automatically extracted date variables

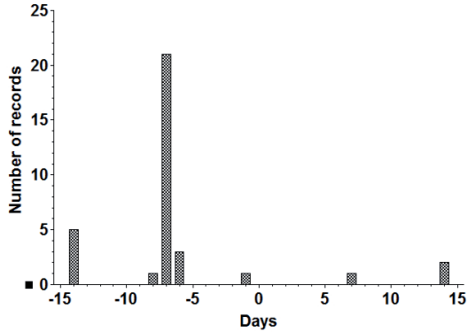
Referral date (n=118)



Initial visit (n=30)



Pre-treatment MDT (n=42)



the administrative assistant's first action, which is the order of scheduling the appointment, was chosen as the referral date. The histogram of the difference between the manually and automatically collected date also shows that there is only one to three days difference in most cases. This is likely dependent on the day of referral. As a result of this problem, process indicators which include the referral date in the calculation, showed a median difference of one day compared to the MED. Therefore, to increase the agreement on this variable and the indicators using this variable, the EHR should be modified to enable the electronic extraction of the actual referral date, preferably without requiring additional documentation.

For the date of the first consultation, mostly one-day differences are found. Because there were no apparent explanations for the majority of these one-day differences, a sample of these patients was checked. The date within the EHR was congruent with the

Variable	Records with data present		Records in agreement (if data present in both sets)	Level of agreement
	Manual	Electronic		
Treatment intent	261	262	250/261	**95.8%**
Tumor localization	262	262	254/262	**96.9%**
Surgical treatment	262	262	234/262	**89.3%**
Neck dissection	132	262	115/132	**87.1%**
Radiotherapy treatment	262	262	248/262	**94.7%**
Systemic treatment	262	262	251/262	**95.8%**
Dental team consultation	189	262	183/189	**96.8%**
Date of dental team consultation	175	179	167/169	**98.8%**
Physical therapist consultation	43	262	23/43	**55.8%**
Date of physiotherapy consult	40	22	4/20	**20.0%**
Surgical complications	132	262	118/132	**89.4%**
Unplanned reoperation	132	262	128/132	**96.7%**

manually extracted date. Subsequently, by consulting with the IT-specialist, an error in the extraction logic was found, resulting in the one-day differences.

For the pre-operative MDT, it was found that the manually extracted date was often seven days prior to the automatically extracted pre-operative MDT date. In our hospital, the MDT is conducted weekly and some patients are repeatedly discussed in multiple MDTs. Therefore, it might be assumed that an additional MDT often occurs before treatment starts, which is automatically extracted and marked as the last MDT before treatment. This additional MDT might be missed during manual extraction. Determining which MDT should be used is relevant for specific indicators, such as the median time from first consultation to the pre-operative MDT. Moreover, the definition of existing quality indicators is not always entirely unambiguous and detailed enough, which can result in interpretation differences. Therefore, it is advisable that when transitioning from manual to automatic quality measurement, the definition of existing quality indicators should be revised if necessary, to ensure complete and unambiguous definitions that are computer-interpretable.

Another variable that showed lower agreement was the end date of systemic therapy. Significant differences between the manual and automatically extracted dates were found. In these cases, the extraction logic seems to select systemic treatment end dates of a second round of systemic treatment, probably due to recurrence or residual tumor. This can be attributed to insufficient extraction logic. A solution could be to define a cut-off point in weeks, after which the logic would consider the date part of another round of treatment. For the other relevant variables, a high agreement was found in most variables. However, agreement on whether or not there was a physiotherapy

Table 5

Indicator results (Dutch Head and Neck Audit) - manual vs automatically extracted

Indicator	Manual Clinical Quality Measurement (N=262) Numerator/Denominator (%)		Electronic Clinical Quality Measurement (N=262) Numerator/Denominator (%)		% difference
Percentage of patients that has been discussed in a MDT prior to curative treatment	242/250	(96.0%)	250/261	(95.7%)	- 0.3%
Percentage of patients that started with treatment within 30 days after initial appointment	230/249	(92.4%)	232/261	(88.9%)	- 3.5%
Percentage of patients that started adjuvant therapy within 6 weeks after surgical treatment	53/75	(70.6%)	59/80	(73.8%)	+ 3.2%
Percentage of patients that has had a initial appointment within 7 days after referral	226/248	(91.1%)	232/252	(92.1%)	+ 1.0%
Percentage of (curative) patients seen by a dental team prior to the start of radiotherapy treatment	167/194	(86.1%)	178/204	(87.3%)	+ 1.2%
Percentage of (curative) patients seen by a physiotherapist after a neck dissection	40/68	(58.8%)	22/63	(34.9%)	- 24.9%
Percentage of (curative) patients that underwent an unplanned re-operation after surgical treatment	9/132	(6.8%)	7/136	(5.1%)	+ 1.7%
	Manual Clinical Quality Measurement (N=262) days		**Electronic Clinical Quality Measurement (N=262) days**		
Median time - initial consultation until MDT	2.0		2.0		=
Median time - referral until MDT	6.0		7.0		+1 days
Median time - referral until initial consultation	5.0		6.0		+1 days

consultation was low. The calculation logic determining whether a physical therapy consultation occurred is based on whether the physical therapist used a specific form. This form is only available for inpatient care, not in the ambulatory setting or when referred to an external physical therapist. This was considered a problem on the input side. On the other hand, when using manual abstraction, data extraction personnel could review a patient record to determine whether they were seen in the outpatient setting, or were referred to an external physical therapist. Consequently, this resulted in low agreement on the indicator using this variable, which was the percentage of patients seen by a physiotherapist after neck dissection. There is a 24.4% difference, with the indicator based on the MED showing 58.8% and the indicator based on the AED only 34.9%. Similarly, multiple studies have shown that automatically extracted EHR data can miss care events[10, 13].

The abovementioned results and examples illustrate that when transitioning to electronic extraction of EHR data and automated quality measurement, the data and the extraction logic should be checked, validated and subsequently improved. Basic validation rules that a manual data extraction employee unconsciously applies are not always incorporated into the extraction logic. Both initial validation sessions during the development phase and subsequent periodic, targeted validation sessions are recommended. Continuing these validation sessions will help improve EHR extraction logic and quality indicator definitions but will also help identify problems or gaps in the structured documentation process. Additionally, clear and unambiguous definitions of quality indicators used are required to ensure reliable and comparable results.

Comparison with previous research

There is evidence that implementing quality dashboards that provide immediate access to information for clinicians can improve adherence to quality guidelines and may help improve patient outcomes[14]. However, the quality of data used in these dashboards can be a concern, and calculating reliable quality measures based on EHR data can be challenging[8, 9, 15]. Therefore, continuous effort and refinement of all aspects of a dashboard, including data quality, are required to develop a useful dashboard[6, 16]. Studies that compared manually extracted data to automatically extracted data from the EHR found mixed results. One study comparing quality measures based on automatically extracted data from the EHR to manually collected data found low to modest agreement (kappa = 0.36) and an overall disagreement of 30%[10]. A particular reason was that automatically extracted data frequently missed care events. As a result, some automatically extracted indicators underperformed compared to manually extracted indicators. This is similar to our results regarding the numerator of the indicator physiotherapy consultation after neck dissection, in which the automatically extracted data missed care events and, therefore, the indicator underperformed compared to

the manually collected indicator. These findings were supported by a retrospective study stating that workflow and documentation habits can profoundly impact EHR-derived quality measures, and automatically extracted indicators often underperform compared to manually extracted indicators[13]. Another study investigating the quality of specific automatically extracted variables recorded in preterm births and comparing them to manually extracted variables found relatively high agreement, with discrepancy rates ranging from 3.2 to 12.8%[17]. A study investigating the relative change of four indicators results based on EHR-extracted data compared to manually extracted data found percentages ranging from 2.4% to 7.2%[18]. The results of these studies are similar to the results of the variables and indicators compared in this study. Furthermore, these percentages are comparable to discrepancy rates in manual database creation[19, 20]. However, comparison to this study should be made with caution. The quality of data EHR-extracted data and indicators based on EHR-extracted data also varies depending on the characteristics of the data extracted[21]. For example, structured data such as inpatient medications can be fairly reliably extracted from the EHR, with a median kappa of 0.75 compared to manually abstracted data[22]. However, when extracting and combining data from different places of the EHR, or data that has been recorded at various points in time is more challenging. Additionally, unstructured data is difficult to reliably extract, and therefore, the quality of automatically extracted data highly depends on the use of structured fields[10]. Furthermore, data is recorded in the same structured fields over time. When extracting data from a specific field, effort is needed to develop extraction logic that determines the correct value in a specific context. This also influences quality of extracted data. Successful data extraction using natural language algorithms has also been reported, but should mainly be used to enrich structured sources [23, 24]. Overall, a growing body of literature describes that it is feasible to extract structured data from the EHR and use it to calculate reliable quality indicators. Our study confirms these findings and proves it is also possible by extracting routinely collected structured data within multidisciplinary care.

Strengths and limitations

This study has multiple strengths. We have shown that it is possible to extract structured data in real time from the EHR and use it for automated quality measures. By comparing this with manually collected data on the same patient group, we can more reliably determine data quality than using other validation methods[25]. Furthermore, the direct comparison between the manual and automatically extracted data ensured that disagreements could be evaluated. As a result, specific errors in the extraction logic and the structured documentation process can be identified and improved, leading to higher data quality. Lastly, by comparing not only variables but also the results of the quality indicators, it is also possible to gain insight into how significant the impact of disagreement in specific variables is on the result of a quality indicator. Dependent

on the indicator, the difference can be considered relevant or irrelevant, which in turn helps to prioritize where the focus of improvement cycles should be, or to determine for which indicators data no longer needs to be collected manually.

This study also has some limitations. In this study, we did not conduct a patient-by-patient review of the EHR when a disagreement was found. However, in the development phase of the dashboard, we conducted regular manual validation sessions, cross-checking the automatically extracted data to the EHR. Validation sessions are conditional to data quality improvement in data extraction from EHRs, especially in the initial phase[26]. In time, targeted, automated validation reports that could show anomalies in the data will be developed and implemented. These will further improve the extraction logic and, if necessary, the documentation process. Another limitation of this study predominantly focused on variables relevant to calculating process- and structure indicators, such as date variables for care events. However, when these care events can be reliably extracted for these care event variables, adding clinical variables that are documented during these care events should be possible with minimal extra effort.

Implications for practice

Current literature describes that measuring quality of care can lead to improved care. Currently, manual data collection for Head and Neck Oncology quality measurement in the Netherlands can take up to two hours per patient, and is collected months to even years after initial treatment. Implementing structured and standardized recording and using this data to calculate quality indicators in real-time can speed up the process of quality improvement and reduce costs by making manual data collection obsolete. Furthermore, as more quality indicators and case-mix variables will be added, manual data abstraction of the rising amounts of data will become increasingly time-consuming in the future. However, to use routinely collected data to calculate reliable indicators, the results of our study imply that it is important to standardize the care pathway and the corresponding documentation process[3]. This reduces variability in documentation practices among different employees, increases the use of standardized vocabulary, and reduces the possibility of the same information being recorded in different places in the EHR. These are the main reasons for low data quality when reusing data[2]. In addition, by periodically reviewing the extracted data and the results in the dashboard, insight can be obtained as to where the gaps in the primary registration process or workflow are, and how the extraction logic and the indicator definitions can be improved. This will increase the data quality within the EHR and the information shown by the quality dashboard. In the future, other functionalities can be developed, such as a signalling function that notifies healthcare providers when a patient is in danger of failing to adhere to process indicators, which is known as a textbook process[27]. Alternatively, a provider-specific dashboard could be developed that shows the current status of

their patients, and where they currently are in their patient journey. Moreover, further steps should be taken to accomplish digital healthcare information exchange with other organizations, such as national quality registries or other healthcare centers. Other clinical information, such as TNM-staging information, should be added to the automatically extracted data from the EHR. Furthermore, To achieve digital information exchange, even more data standardization is needed by using terminology systems and interoperability exchange standards and instrastructures such as HL7 FHIR. Future studies should focus on implementing such infrastructure and validating the data that has been digitally exchanged between institutions.

It is likely that the number of hospitals aiming to implement reusable data capture in the forthcoming years will increase. Currently, the transferability of content to hospitals associated with different EHR vendors presents a challenge. However, our team has contributed to the creation of an implementation manual, a valuable tool for guiding other hospitals in developing and implementing similar care pathways with reusable data capture. It is important to note that healthcare institutions considering similar initiatives should recognize the significant commitment and thorough understanding required to carry out these implementation projects. This includes tasks like mapping out the care pathway, building structured data capture environment within the EHR, defining the extraction logic, data point validation and a multitude of other associated activities. Therefore, a project-based approach is recommended, encompassing healthcare providers, IT specialists, and a project leader. Additionally, it would be beneficial to include staff from other relevant areas such as administrative roles and quality assurance personnel. Quantifying the exact human and time resources required for similar projects presents a challenge, given that the process represents a long-term, multifaceted endeavor, engaging various stakeholders over a period of several years. However, the insights gained from this study should provide valuable guidance to other researchers and colleagues who might be undertaking similar initiatives.

CONCLUSION

This study provides evidence that it is possible to transition to automatic quality measurement with routinely collected structured data. In most cases, our results showed high levels of agreement between manual and automatically extracted variables and indicator results, but also suggest that continuous validation of data and extraction logic is a prerequisite for reliable results and further improvement of data quality. In addition, the definitions of quality indicators should be unambiguous. The findings of this study should contribute to the development of future EHR-driven quality dashboards.

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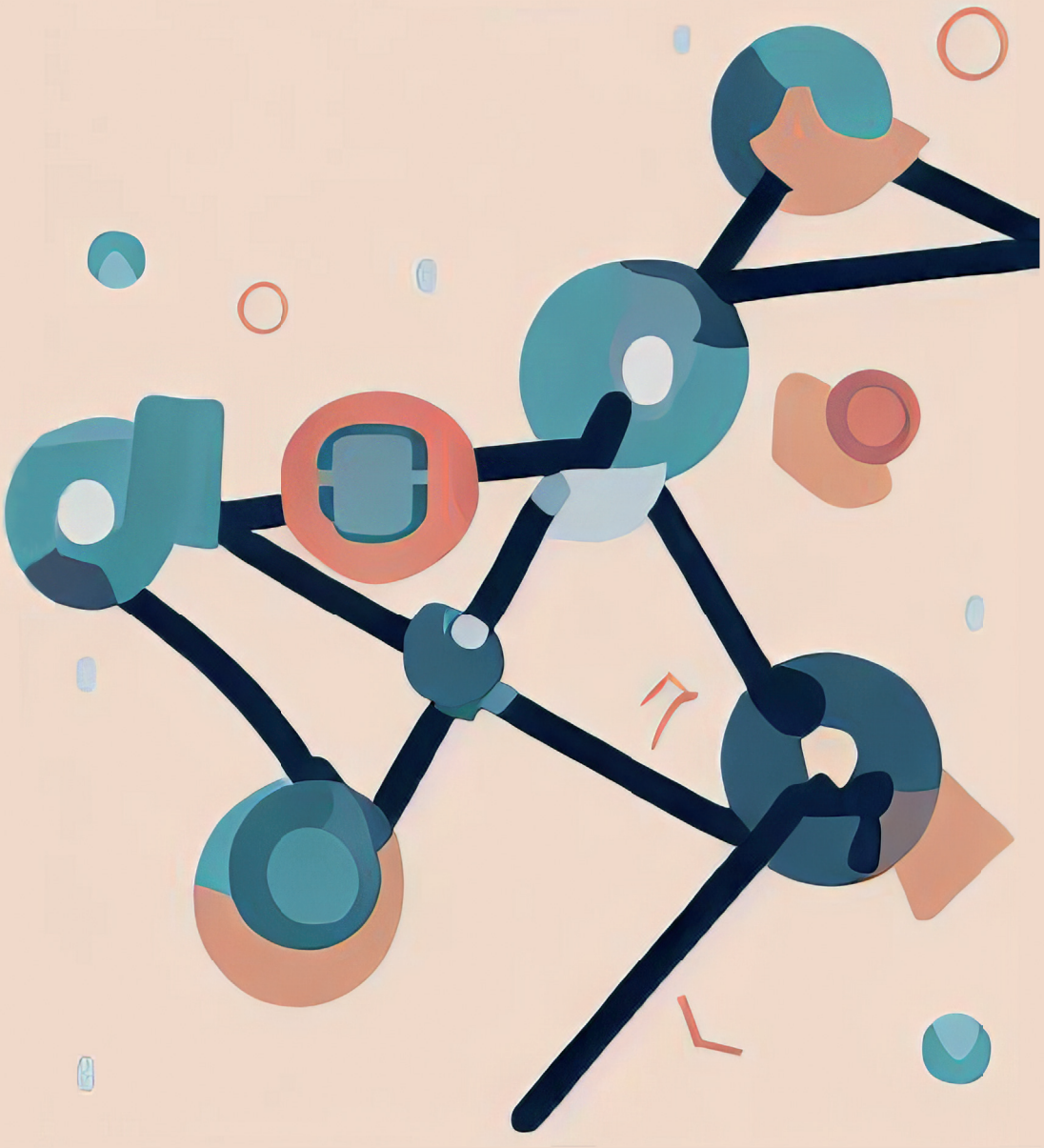

Chapter 6

Evaluation of a remote monitoring app in head and neck cancer follow-up care

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Background

A remote monitoring app was developed for head and neck cancer (HNC) follow-up during the Sars-Cov-2 pandemic. This mixed-methods study provides insight in the usability and patients' experiences with the app to develop recommendations for future use.

Methods

Patients were invited to participate when they were treated for HNC, used the app at least once and were in clinical follow-up. A subset was selected for semi-structured interviews through purposive sampling considering gender and age. This study was conducted between September 2021 – May 2022 at a Dutch university medical center.

Results

135 of the 216 invited patients completed the questionnaire, resulting in a total mHealth usability score of 4.72 (± 1.13) out of 7. Thirteen semi-structured interviews revealed 12 barriers and 11 facilitators. Most of them occurred at the level of the app itself. For example, patients received no feedback when all their answers were normal. The app made patients feel more responsible over their follow-up, but could not fulfill the need for personal contact with the attending physician. Patients felt that the app could replace some of the outpatient follow-up visits.

Conclusions

Our app is user-friendly, makes patients feel more in control and remote monitoring can reduce the frequency of outpatient follow-up visits. The barriers that emerged must be resolved before the app can be used in regular HNC follow-up. Future studies should investigate the appropriate ratio of remote monitoring to outpatient follow-up visits and the cost-effectiveness of remote monitoring in oncology care on a larger scale.

INTRODUCTION

Approximately 560.000 patients are diagnosed with head and neck cancer (HNC) each year worldwide (1). Follow-up protocols prescribe clinical follow-up for three years to lifelong after curative treatment, consisting of several outpatient follow-up visits per year (2). Patients have stated that the current follow-up regimen is intensive (3). Some report that the frequency of visits is excessive and that they prefer a less rigorous follow-up schedule (4, 5). In addition, not all follow-up visits are essential from a medical point of view – some are mainly intended to reassure the patient (3, 6, 7). Not only patients, but also healthcare professionals are willing to de-intensify HNC follow-up, provided that the doctor-patient relationship is adequately maintained (8). Finally, the current follow-up schedule pressures healthcare systems and contributes to high costs (9, 10).

Using a remote monitoring application (RMA) within HNC follow-up might actively engage patients in their care, optimize patient information delivery, reduce the number of required outpatient follow-up visits and thereby reduce healthcare costs (11). RMAs are designed to collect patient-entered data such as patient-reported outcome and experience measures, which can be received and interpreted by the hospital involved. We specifically developed an RMA for HNC patients during the Sars-Cov-2 pandemic and used it as an alternative to outpatient follow-up visits since the pandemic led to a significant decrease in outpatient capacity at hospitals all over Europe (12). Our RMA remained available as an add-on to regular follow-up care when outpatient follow-up visits were resumed.

Before further implementation into clinical practice, the RMA had to be evaluated and optimized. Therefore, this study aimed to investigate patients' experiences with remoting monitoring using our RMA during the Sars-Cov-2 pandemic. Our primary objectives were to evaluate the app's usability from a patient's perspective and to gain insight into the barriers and facilitators for using the RMA. In addition, we aimed to evaluate differences between patients over and under 65 years of age, as there is limited knowledge about the older oncology patient's experiences with and use of digital health services (13).

METHODS

Study design and setting

This study used a mixed-methods methodology, starting with a survey among HNC patients, followed by in-depth interviews among a subset of these patients. This study was performed at the Radboud university medical center in Nijmegen, The Netherlands.

This is one of the largest Dutch head and neck oncology centers, with approximately 500 newly diagnosed patients annually. The local ethics committee considered the study exempt from further review (dossier number 2020-6941). The consolidated criteria for reporting qualitative research (COREQ) checklist was used (14) (Appendix available online).

Study population

Patients were eligible to participate in this study if they were treated for HNC and were currently in HNC follow-up. According to the Dutch guidelines, this follow-up consists of five years of prescheduled visits after treatment with decreasing frequency (15). Other criteria were that they were fluent in Dutch and 18 years or older. HNC patients who used the RMA at least once were invited to complete the mHealth App Usability Questionnaire (MAUQ), a validated questionnaire that objectively evaluated the usability of mHealth apps (16). Subsequently, qualitative interviews among a subset of participants were used to explore barriers and facilitators for using the RMA.

The Remote Monitoring Application (RMA)

Our RMA is designed to monitor HNC patients at home. The RMA is developed using EPIC MyChart (EPIC EHR, Verona, Wisconsin) and therefore integrated within the Electronic Health Record (17). Patients receive automatic monthly notifications for self-monitoring, which is achieved by completing a short questionnaire and examining the head and neck area using video instructions by themselves or a relative. Case managers, who are supportive healthcare professionals coordinating HNC care, are automatically notified by a message from the electronic health record in case of potential abnormal findings. These include that the patient experiences symptoms consistent with possible disease recurrence, requires psychosocial support, has a question, or uploaded a photo or video that needs to be checked. The case manager reviews the patients' results, and decides whether the treating physician needs to be consulted and if the patient needs to visit the outpatient clinic.

Data collection

mHealth App Usability Questionnaire (MAUQ)

The MAUQ consists of 21 questions and is developed to evaluate the usability of a mobile health app by statements on ease of use and satisfaction, system information arrangement and usefulness, which can be answered using a 7-point Likert scale (strongly disagree – strongly agree) (16). To translate the English version of the MAUQ to Dutch, translation guidelines for validated questionnaires were followed. Multiple forward- and backward translations were conducted by two independent professional translators from the Radboud University, department Radboud into Languages.

Discrepancies were discussed and resolved by previous mentioned translators, TE, RK, and GB (18). The final version of the Dutch MAUQ and the original English version are included in the Appendix, A1 and A2. All eligible patients received an invitation to complete the MAUQ through CastorEDC, an electronic data capture platform (19). After completing the MAUQ, patients were asked if researchers could contact them for an in-depth interview. The quantitative data was collected between September and November 2021. All answers were processed anonymously.

Interviews

Patients were selected through purposive sampling based on gender and age from the population who completed the MAUQ and agreed to participate in the interview (20). A semi-structured interview guide was developed by two researchers (CW, TE) based on literature published about usability of m-Health applications and the questionnaire results. Two experts in qualitative research (RK, RH) reviewed the interview guide. The interview guide covered four topics: (1) use of the RMA, (2) content of the RMA, (3) influence of remote monitoring on perceived care, and (4) future perspectives on remote monitoring in HNC care. Questions were open-ended and were optionally followed by questions to expand on each topic. See the Appendix A3, for the interview guide.

After two interviews, three researchers (CW, DS, TE) reviewed the interview guide and made minor adjustments accordingly. Interviews were conducted until data saturation, the point at which no new information was mentioned in the interviews, was reached (21).

Two researchers (CW, DS) were trained in interviewing and conducted the interviews in January and February 2022. No one was present besides the interviewer(s) and the participant. Participants were informed about the role of the researcher and the study goals. There was no relationship between the participants and the researcher, nor did the researcher benefit from certain outcomes. Written and verbal informed consent was achieved before each interview. Participation was voluntary, and patients could withdraw from the study at any moment without consequences.

Data analysis

mHealth App Usability Questionnaire (MAUQ)

The mean and standard deviation (SD) for each subscale and the total usability score were calculated according to the MAUQ instruction guide (16). A Mann-Whitney-U test was used to compare the total scores of patients under 65 to those of 65 years and above. Two-sided p-values of <0.05 were considered statistically significant. IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, N.Y., USA) was used for all analyses.

Interviews

Thematic analysis as described by Braun & Clarke in 2006 was used as follows to analyze the data that emerged from the interviews. The interviews were recorded to be anonymously transcribed by an independent third-party company. Participants did not receive the transcripts for corrections because they were transcribed verbatim. Two researchers (CW, DS) read and labelled the interviews by open-ended coding using Atlas.ti (Scientific Software Development GmbH, Berlin, Version 9). Coding differences were discussed by four members of our team (CW, DS, TE, RK) until consensus was reached. There were three moments of reflection during the coding process. The codes were compiled into subthemes. Two researchers (CW, DS) merged these subthemes into the six levels of the barriers and facilitators framework published by Grol and Wensing (22). Again, differences were discussed until a consensus was reached. Afterwards, results were discussed with a fifth researcher (RH) and adjusted accordingly.

RESULTS

Participants

In total, 216 patients who at least used the RMA once were invited to complete the MAUQ. After three reminders, 135 patients completed the questionnaire, resulting in a 63% response rate. The mean respondent age was 66.2 (± 9.7). Thirteen semi-structured interviews were conducted for the qualitative part of this study. The interviewees' ages ranged from 54 to 71 years, with a mean of 63.8 (± 5.0). The majority (n=8) were male. Other participant characteristics are shown in table 1.

mHealth App Usability Questionnaire

The total mHealth usability score as measured by the MAUQ was 4.72 (± 1.13) on a scale from 1 to 7. The subscale scores for ease of use and satisfaction, system information arrangement, and usefulness were 5.0 (± 1.23), 4.74 (± 1.15), and 4.42 (± 1.24), respectively. The statements "the app was easy to use" and "it was easy to learn to use the app for me" scored the highest: 5.39 and 5.47, respectively. Patients also felt confident that the RMA sent the information they entered to their healthcare provider (score: 5.27). The statements "I had many more opportunities to interact with my healthcare provider" and "the app helped me manage my health effectively" scored the lowest: 4.06 and 4.15, respectively. The results of all statements are shown in table 2. Patients younger than 65 scored 4.63 (± 1.16) and patients of 65 years or older scored 4.72 (± 1.20). There was no significant difference between the two groups (p=0.627).

Interviews

Due to the Sars-CoV-2 regulations, interviews were performed by telephone, with a mean duration of 31 minutes (range 16 – 51). Data saturation was reached after 11 of the 13 interviews. A total of 12 barriers and 11 facilitators emerged and were classified into five levels of Grol and Wensing's framework. The innovation level covered nine of the 23 barriers and facilitators (22). No barriers or facilitators that fit the economic and political context, and this level was therefore omitted. The results are shown in Table 3.

Innovation

The interviewees indicated that the RMA was easy to use. The questions were straightforward and focused on detecting possible cancer recurrence. However, patients would like to provide more nuanced answers and suggested adding a free-text field to elaborate on the answer or having more answer options than 'yes' and 'no'.

> *'The questions are fully focused on my situation, on throat cancer. I think they are adequate.' – Patient #9*

Interviewees encountered some problems while conducting self-examination of the head and neck. The instruction video could not be saved or rewound. In addition, some interviewees pointed out that the self-examination explained in the video did not specifically address the investigation of their tumor localization.

> *'You cannot save the video or watch it again. So, you cannot stop the video and be like, "what should I do now?" – Patient #4*

> *'The video only demonstrates how to examine the outside area. My type of cancer was in my mouth, and sometimes I thought, "should I not look in my mouth?" […] Not everyone has the same thing, it is very personal. – Patient #7*

An advantage of using the RMA was that it is less time-consuming than a hospital visit. Interviewees also stated that follow-up by the RMA could reduce the frequency of hospital visits by extending the time between visits. When patients answer 'yes' to questions within the RMA, a notification reaches the case manager, who contacts the patient to verify the results. When patients answer 'no' to each question, all results are

normal, and they receive no feedback from the RMA. Patients who always had a normal result indicated that they were unaware of what happened with their data.

'So, if I enter "no" in every question, I'll get "You have completed all your assignments again", but I won't get, after two days, "We've looked into it, glad it's going so well"." – Patient #3

'They can't see it in the hospital, whether I filled it out correctly or not. I can say "everything is fine", but they can't tell if that's the truth.' – Patient #10

Individual professional

Healthcare professionals clearly demonstrated how to self-examine the head and neck area in the video. However, patients also reported that an explanation of interpreting the findings was lacking.

'If they had explained something in the video like "look for a bump or look for hard parts or whatever", it would have been clearer. The video does explain very clearly where to examine, but not what to examine.' – Patient #7

Patient

Patients reported not having to learn new things to use the RMA. Besides, the RMA allowed patients to be more involved with their illness and symptoms. Patients felt more self-responsibility when using the RMA compared to outpatient hospital visits. Some considered this positive, as it gave them more control over their follow-up. Others reported a negative effect, as they sometimes felt unnecessarily preoccupied with their symptoms.

'The RMA signals: listen up, you need to check yourself. Because the RMA reminds me of that, I also sometimes perform the self-examination when I sit quietly for a while, without having received a notification from the RMA.' – Patient #7

'Imagine; it's beautiful weather and you go for a walk. You get home, and you get that notification again. You have to do another one of those examinations. Then I feel all kinds of things again. It makes me insecure.' – Patient #4

One barrier mentioned was the difference in how physicians and patients examine the head and neck. Some patients expressed less confidence and knowledge in their way of examining than that of a physician.

'The doctors know what to feel, but I don't. I don't feel that, I don't know what to feel, what to look for. They do explain it in the video, but I can't do anything with that.' – Patient #2

Social context

Some patients needed help from a relative to complete the self-examination as a barrier to using the RMA. A facilitator was that the RMA made patients feel more connected to the hospital.

'I do think it's a good thing to keep using the RMA, because it also reminds people again of: "the hospital is still thinking about me, they read the answers I give and want to know how I am doing". – Patient #12

Patients reported missing personal contact with healthcare professionals when using the RMA. The RMA could not offer the personal attention that they experienced during a physical visit.

'I do miss being able to go back to the hospital. They call and then they ask, "How are you?", and that's it. I can examine my neck, but I don't think that's the solution.' – Patient #8

Organizational context

The RMA made it easier for patients to contact the hospital when needed. Patients also stated that the RMA allowed them to monitor their complaints at their preferred time.

'I can complete the RMA at the time I prefer. The notification can come in spontaneously sometime during the day. Once I have seen it, I will fill it out in the evening when I have the time.' – Patient #7

The RMA was introduced during the Sars-CoV-2 pandemic. Patients received an email with information about the RMA. According to some patients, this introduction was incomplete and unclear. Some patients reported the lack of flexible endoscopic examination as a shortcoming.

'*When do you get a notification? When do you not? It was a bit off now, which is understandable during Covid, but the context was a bit lacking.' – Patient #6*

'At a checkup appointment at the hospital, they will look down the throat with a tube to keep a close eye on everything. That is something that cannot be replaced by the RMA.' – Patient #13

Discussion

This mixed-method study provides insight into the usability of an RMA developed by a Dutch University Medical Center during the Sars-CoV-2 pandemic and patients' experiences with this RMA in HNC follow-up care. The overall usability of the RMA assessed with the mHealth Usability Questionnaire was good, particularly in terms of ease of use. The fact that there were no significant differences in MAUQ scores for patients over and under 65 years of age supports the assumption that our RMA is suitable for patients of all ages. Semi-structured interviews revealed 12 barriers and 11 facilitators for use in daily practice from patients' perspectives. Self-responsibility and the ability to perform checkups at their preferred time were mentioned as facilitators of using the RMA. Barriers were the interpretation of self-examination of the head and neck area and the lack of personal contact with their treating physician.

Patients felt that the RMA provided quick communication with their healthcare providers in case they filled out that they were experiencing physical symptoms. Van den Brink et al. also concluded that an electronic health system allowed for early detection of problems in HNC care that required direct intervention (23). They hypothesized these

problems could have led to adverse events had they been discovered during later outpatient visits. This could also be the case in our study, although we did not review individual reported symptoms. The MAUQ showed that patients were confident that information sent through the RMA would be received by their healthcare providers. The interviews revealed that patients received no feedback from the RMA in case all their answers were normal. During the development process of the RMA, we chose to only review abnormal patient answers to keep the automated monitoring process as efficient as possible. An explanation on when healthcare providers will review answers should be added to the RMA to better inform the patient.

The MAUQ did not cover all topics that emerged from the interviews. First, patients reported that the RMA made them more alert to symptoms of possible cancer recurrence in daily life and gave them a higher sense of self-responsibility. Bouaoud et al. also concluded that mHealth applications enable the early detection of health problems and improve HNC patients' self-management (24).While our patients felt the instructions on examining the head and neck area were clear, directions on interpreting their findings were missing. A solution might be to practice the self-examination with a healthcare provider before starting remote monitoring to increase patients' confidence in distinguishing normal from abnormal findings. However, Addeo et al. described a number of reasons for non-optimal patient communication, including a lack of time or staff.(25) Time for patient education should therefore be scheduled. Also, the reliability of patient-examination in comparison to physician-examination could be studied in the future. Second, some patients clarified that the RMA did not fully apply to every HNC localization. For example, the instruction video does not cover examining the oral cavity. Duman-Lubberding et al. also reported that patients felt that Oncokompas, an e-health application for self-management after cancer treatment, was not tailored to their individual needs (26). Our RMA could be personalized more by adding specific instruction videos for various HNC localizations. The RMA's complexity should be considered, as this could negatively affect the overall usability. Finally, patients felt that remote monitoring could not replace personal contact with their treating physician. Chen et al. reported clinicians' willingness to de-intensify HNC surveillance and also expressed the importance of maintaining the patient-physician relationship (8). Therefore, we suggest that our RMA could be used to reduce the frequency of routine visits in individualized follow-up care, but not fully replace outpatient visits. Furthermore, shared decision-making on whether or not to use this tool in follow-up is essential because some patients could benefit significantly from the RMA, while others could be negatively affected due to increased preoccupation with their disease. Future studies should also focus on integrating remote monitoring into HNC follow-up care while adequately maintaining the patient-physician relationship, and meeting the need

for supportive care for cancer patients. Another aspect that needs further investigation is the cost-effectiveness of integrating remote monitoring in cancer follow-up care.

The main strength of this study is the mixed-methods design. Other studies have also investigated the feasibility and usability of remote monitoring in head and neck oncology using quantitative methods (27, 28). The results showed that remote monitoring of symptoms is feasible and that the applications were useful, which is consistent with our findings. However, through our qualitative analysis, additional barriers and facilitators were found, which can be used to optimize our RMA further.

This study also has some limitations. We cannot completely exclude selection bias. Patients with a higher educational level or more affinity with technology could be more likely to use the RMA and more inclined to participate in this study. One patient who had used the RMA once decided not to continue it because he was not satisfied with it. Unfortunately, this patient was not willing to participate in this study. There may be more patients who feel the same way. It would be interesting to study patients who chose not to start or continue using the RMA to understand the barriers for use better. Unfortunately, patients who started using the RMA during the pandemic did not agree to participate in a research study nor for researchers to extract information from their medical records, making it difficult to compare patients who used the RMA with a general HNC population. Also, we did not have access to detailed demographic and clinical data of patients that solely agreed to complete the MAUQ because of privacy reasons. Therefore, we could not investigate whether certain characteristics such as HNC-site or -stage were related to differences in MAUQ-scores. Finally, the response to the MAUQ was 63% after sending thee reminders. One could argue that a considerable amount of patients did not respond. However, our response rate was higher than the average email-survey response rate of 51% among surgical patients recently described in a systematic review by Meyer et al. (29)

It should be noted that our RMA focusses on changes in physical function that may indicate recurrence. Although disease surveillance is one goal of cancer follow-up care, monitoring of functional and psychosocial status is also important. Dutch HNC patients routinely receive symptom-related questionnaires focusing on these domains through the Dutch Head and Neck Audit.(30) Therefore, surveillance of other areas is beyond the scope of our RMA and this study.

CONCLUSION

This study shows that our RMA is user-friendly and makes patients feel more connected to the hospital and more alert to new symptoms. The RMA can be improved by following patient suggestions, such as explaining how to interpret self-examination of the head and neck and giving patients feedback when the monitoring results are normal. Patients indicate that remote monitoring could reduce the frequency of outpatient visits, providing that the physician-patient relationship is adequately maintained. As such, the RMA could help to relieve the pressure on HNC follow-up care in the future. Since detecting recurrences or second primary tumours is an important goal of HNC follow-up, the next step would be to study the effectiveness of disease detection through our RMA.

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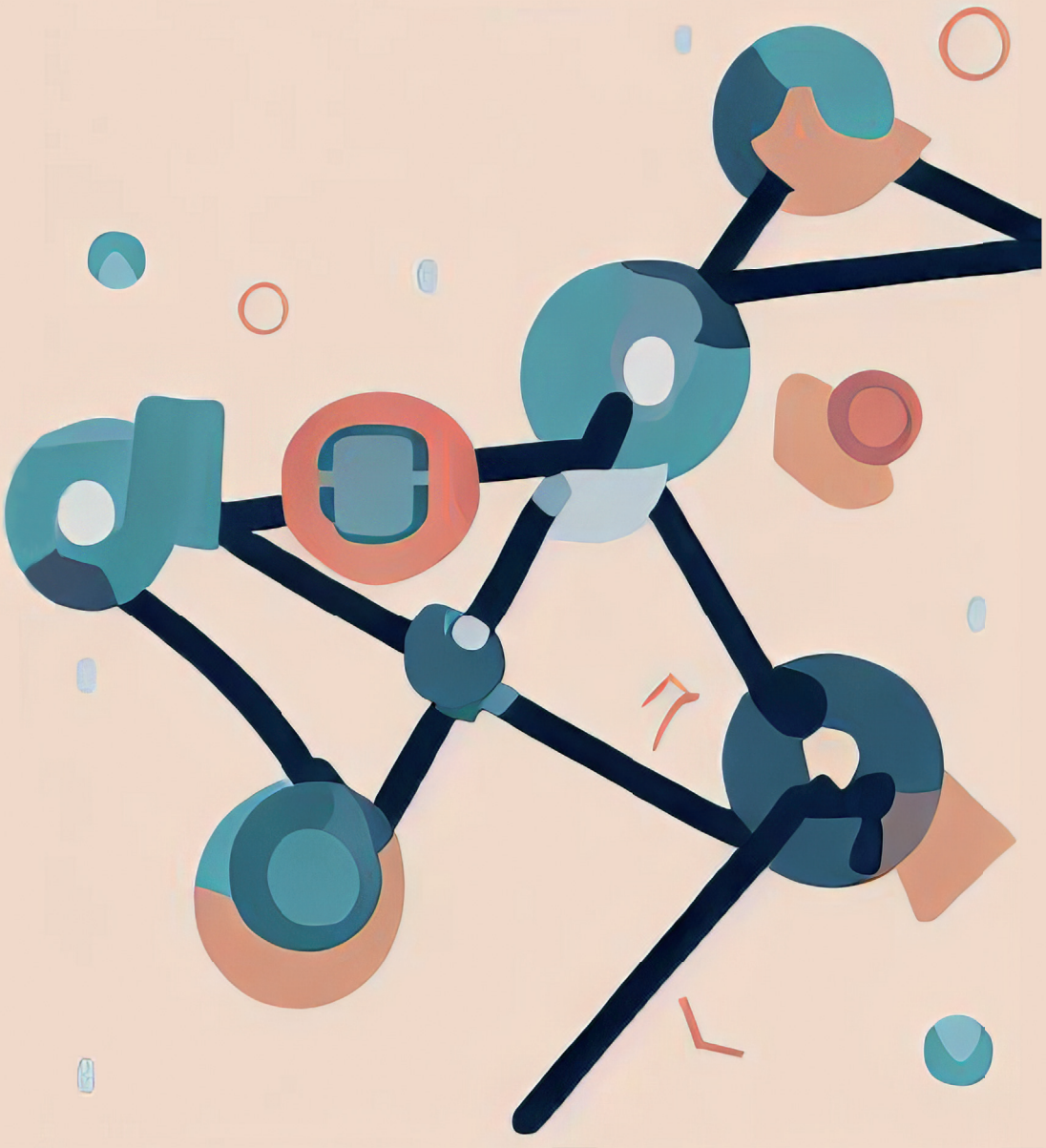

Chapter 7

General discussion

Research on data-driven healthcare is emerging. Data-driven healthcare starts with structured data recording and the reuse of EHR data. This dissertation studies various aspects relevant to this subject. The studies incorporated within this thesis have been conducted to meet the aims outlined in Chapter 1. Below, the most important lessons learned are discussed to provide the reader with insights into key aspects to implementing structured data recording and automated data reuse.

Key findings

Aim 1: to evaluate the effects of implementing a head and neck oncology e-pathway with structured documentation on the efficiency of providing care.

It was found that healthcare practitioners experience a significant administrative burden, up to 44.0% of consultation time. However, introducing a structured documentation system led to a promising reduction of up to 27.0% in EHR documentation time during outpatient consultations, offering a potential solution to reduce the high documentation burden. These findings were corroborated by significant increases in the perceptions of HNC care providers on perceived ease of use of the EHR and facilitating conditions for proper documentation. Finally, it was demonstrated that patients have predominantly positive perceptions towards a remote monitoring application facilitated by patient-driven structured data collection.

Aim 2: to investigate the effect of implementing a head and neck oncology e-pathway with structured documentation on quality of documentation and quality of reused data.

Implementing structured documentation has shown a substantial improvement of up to 20% in documentation quality compared to unstructured formats, emphasizing increased comprehensiveness while maintaining concise notes. Furthermore, the development of a real-time quality dashboard utilizing routinely collected structured data demonstrated the reliability of automatically extracted EHR data to compute relevant quality indicators of the Dutch Head and Neck Audit. The results of the automatically computed indicators aligned with manually indicators based on manually collected data, confirming the feasibility of automated data extraction and automated quality measurement.

Implementing structured data recording

In the second chapter of this thesis, the growing issue of increased administrative burden is discussed. Over recent years, healthcare providers have been dedicating an increasingly more significant proportion of their time to administrative duties. Literature reports suggest that in since the implementation of EHR's, documentation times range between 11-39%, with an average of 28%, as compared to 16% in the pre-EHR era(1). Moy et al., in a more recent study, stated that alongside time, effort is another pertinent factor contributing to the perceived documentation burden(2). Several constructs contribute to the perceived effort of documentation, such as cognitively demanding work, (e.g., multitasking), workflow fragmentation, after-hours EHR usage, and the impact on the doctor-patient relationship. Various solutions have been proposed over the years to tackle the issue of documentation burden. The utilization of medical scribes, for instance, could alleviate the burden experienced by physicians. However, this solution merely transfers the burden without effectively reducing it. Other suggested solutions encompass altering the data entry requirements, redesigning the documentation process, enhancing system usability, and improving training on EHR usage. It can be argued that a comprehensive strategy incorporating these aspects should be sought.

The same care information is frequently recorded multiple times in the EHR(3). If healthcare data could be efficiently exchanged between institutions, it would likely reduce some data-entry requirements by minimizing the need for manual data re-entry. However, this necessitates redesigning the documentation process to capture data in a structured, reusable format. This documentation redesign could lead to improved ease of use and reduced workflow fragmentation, contributing to a reduced perceived administrative burden. However, there persists a perception among healthcare providers that structured documentation is more time-consuming than free-text documentation and may impede freedom of expression(4). These negative perceptions among healthcare providers towards structured data recording present an obstacle to successful transitioning from free text to structured data recording(5). If healthcare providers harbor positive perceptions towards structured data recording, this could potentially change their actual documentation behavior towards structured documentation. Moreover, end-users are unlikely to accept any electronic documentation system that significantly adds to their workload(6). Therefore, it was crucial to demonstrate that structured and standardized documentation can actually contribute to a reduction in administrative burden.

Chapter 3 evaluated the effect of implementing an electronic care pathway featuring structured and standardized documentation on documentation time. This method essentially combined the redesign of the documentation process with improvements

in system usability. This chapter demonstrates that implementing an electronic care pathway with structured data capture reduced the administrative burden of the healthcare provider during consultations. The enhanced efficiency is likely to extend beyond individual consultations, although this was not measurable with the design used in this study. For instance, it can be expected that by documenting in a structured and standardized way, exchanging information with colleagues both within the hospital and outside might become more efficient. In addition, other healthcare providers who reuse previously recorded data while providing care, may also experience time savings. Utilizing and sharing structured and standardized data could yield improvements in efficiency across various levels of the organization. Evaluating these improvements requires a broader view than focusing solely on individual user efficiency and demands a broader consideration of the organization's overall efficiency. This should be considered when conducting future studies on this topic.

It can be anticipated that implementing e-pathways with structured documentation might also contribute to improving quality of care and potentially reduces costs. For example, widely implemented reusable data capture should contribute to making data more findable and accessible. This may result in avoiding redundant histories being taken and a reduction in reconducting previously performed tests and examinations. This, in turn, might reduce costs and possibly shorten turnaround times. Moreover, it can be suggested that utilizing an electronic pathway with customized standardized order sets might reduce the likelihood of healthcare providers unintentionally omitting particular orders for appointments or examinations. Therefore, by employing this approach, adherence to clinical guidelines might be improved. Omitted orders would necessitate subsequent requests, thereby consuming additional time. Furthermore, standardized, tailored order sets should contribute to reducing instances of both overdiagnosis and underdiagnosis, which is important when considering optimal value-based healthcare.

Quality of structured documentation

A common perception associated with structured and standardized documentation is that it can reduce expressiveness and therefore, impede the quality of EHR notes. However, in Chapter 4 of this thesis, we demonstrated that implementing an e-pathway with structured documentation can enhance the quality of documentation. The results also indicated that notes generated with structured and standardized documentation were lengthier than unstructured notes but were nonetheless more understandable, focused, concise, and better addressed the issue.

Therefore, it can be concluded that concerns about reduced expressiveness can be refuted, and that structured documentation does not objectively lead to diminished quality of documentation. However, it is essential to emphasize that implementing structured and standardized documentation does not imply that all medical information must be entered using dropdown lists and checkboxes (4). When information reuse is unnecessary or healthcare providers objectively state that certain information is not suitable for recording using structured documentation, free-text documentation should be used. Also, free-text fields can be utilized to clarify and describe details, if necessary. When this free-text information is consistently stored as free-text in a specific place or field, the data is semi-structured. This could facilitate future data analysis, for instance, by utilizing natural language processing, a type of artificial intelligence.

Practical implications and recommendations – implementing structured documentation

While several positive effects and benefits of implementing reusable data capture have been discussed above, reports in the literature show that efforts to implement structured data capture have not always yielded successful results. Below, we will discuss why it might be that the projects studied within this thesis were successful. Studies on implementing health information technologies in hospitals indicate that multiple socio-technical factors influence the outcome of similar implementation(7). In addition to concerns about efficiency, other aspects have been mentioned, such as caregiver/patient relationships, fear of office staff, time required for implementation, quality of care, and financial aspects. However, the study also suggests that sound project management, leadership, and staff training could address most of these concerns.

From the perspective of this thesis, several prerequisites for a successful implementation of structured data capture have become apparent. Firstly, it is imperative to have a mature Electronic Health Record (EHR) that supports the necessary functionalities(8, 9). Secondly, it is equally critical to predefine what must be documented within a care pathway and also consider why it must be documented. For instance, considerations could involve the indicators of quality registration and the requisite data elements. However, the main priority should be to consistently fulfill the essential information requirements to deliver high-quality patient care. Any information that is not relevant for healthcare providers during the primary care process should be omitted from the documentation requirements within the electronic care pathway.

One of the critical elements to successful implementation is persuading the end-user, which in this case is the healthcare provider. Therefore, it is essential that the

EHR documentation process aligns with the healthcare provider's work process, thus minimizing workflow interruptions. Meeting this principle should turn the EHR into a tool that enables the healthcare provider, instead of obstructing the healthcare provider while providing care. This optimization should be achieved by not merely implementing structured data entry forms but deploying the structured documentation system as a component of an entire electronic care pathway. Hence, structured documentation implementation should encompass mapping all consultations and contacts in a care process. Subsequently, all potential pathways should be outlined. Furthermore, it should involve the development of corresponding order sets that trigger these potential routes.

Furthermore, it is highly important that an implementation project is carried out by a cohesive team. This team should consist of motivated healthcare providers, someone with project management knowledge and experience, information management personnel, and potentially other stakeholders such as administrative staff. Studies indicate a correlation between successful implementation outcomes and having a physician lead the project(7). This was also the case in both implementation projects studied within in this thesis, which were both spearheaded by motivated healthcare providers with a keen interest in health informatics. A common issue in similar projects is that an informatics department or EHR vendor commences a project with good intentions, but the healthcare provider is insufficiently involved during the developmental process. This then results in a new system that does not align with what the healthcare providers had envisioned or does not function in clinical practice.

One might argue that it is crucial to involve healthcare providers with expertise on the medical contents of the care pathway. When developing an e-pathway, these healthcare providers can reliably determine what the end-user needs from the EHR to provide optimal care. However, sometimes conflicts may arise due to data reuse requirements. For example, relevant information should be recorded in a standardized manner in a specific location in the EHR from a reuse perspective. But this is sometimes not feasible in practice because it disrupts the healthcare provider's workflow excessively. If this is the case, a thorough discussion might be needed to decide whether to opt for a different method. This could be free-text recording, which eliminates reuse possibilities, or might be to accept the workflow disruption but with an advantage in reuse. However, excessive workflow disruptions will contribute to an increase in both perceived and objective administrative burden, leading to dissatisfaction among end-users. This, in turn, could lead to the end-user not correctly using the new documentation system, causing missing data as the healthcare providers do not enter the data discretely but elsewhere in free text, for instance. Ultimately, it could even lead to the end-user not using the system, essentially resulting in implementation failure.

It can be concluded from this that while reusable data capture should be aimed for, it is crucial to keep the multiple conditions in mind. During implementation, emphasis should be given to end-user satisfaction and ensuring immediate benefits such as a reduced administrative burden and improved workflow. Furthermore, providing healthcare providers and other involved parties, such as support staff, with comprehensive training on using a new system should also enhance acceptance and integration. Indirect benefits, such as better insight into the quality of care, or better collection of data for research, can help motivate the end-user, but immediate, noticeable improvements within the consulting room are likely to be more effective in convincing healthcare providers. Providing an immediate benefit might contribute to getting all healthcare providers in a department to commit to structured documentation. The new system should be more convenient or faster, or healthcare providers will likely not alter their documentation behavior(10). Following an implementation project, effective data governance should be prioritized. Clear consensus on the ownership, quality oversight, and decision-making concerning alterations in foundational datasets is crucial for the sustained success of the achieved outcomes.

Practical implications and recommendations – extraction and reuse of structured data

Initially, it was believed that if healthcare information were documented in the EHR using structured documentation, extracting this data for reuse purposes, e.g., quality measurement and research, would be straightforward. Unfortunately, literature has shown that extracting high-quality data from the EHR is challenging(6). The reasons behind this poor data quality when extracting EHR data are not always clear. To gain insight into these reasons, EHR data should be validated after the initial EHR extraction process.

In this thesis, structured EHR data was reused within a multidisciplinary quality dashboard. This dashboard calculated the quality indicators of the Dutch Head and Neck Audit using routinely collected structured data. In Chapter 5, the development process of the dashboard was described, and the quality of this reused data was analyzed. During the initial phase and during the development process, several problems with data extraction from the EHR emerged. For instance, certain information was not recorded as structured data but in free text, even though structured capture was possible. It was also found that some information could be recorded as structured data in multiple places within the EHR. Initially, this led to missing data and, therefore, inaccurate information in the dashboard. Another specific issue arose in that not all data was accessible as structured data. For example, the calculation of some indicators requires a date field. However, in

some cases, the date was not available as structured data. For instance, a date of referral is only available in free text within a PDF file accessible using the EHR. Nevertheless, healthcare providers should not be burdened with documenting such dates during consultations, and similar data should preferably be automatically extractable from the EHR database.

An additional issue with the extraction of data documented within more complex care pathways is that patients often pass through certain parts of the pathway multiple times. For example, patients are frequently discussed more than once within the multidisciplinary tumor board. Furthermore, some patients complete a pathway several times, for example, because they are diagnosed with a second primary tumor. In both instances, information is recorded multiple times in the same data field within the EHR database. It must then be defined within the extraction logic which 'version' of a certain data field in the EHR database should be used. Moreover, presumed data relationships are not always present. For instance, a complication, 'wound infection,' could be recorded in the EHR, but there is no relation to the corresponding specific surgical procedure.

Challenges were also discovered when deriving indicators from automatically extracted data. For instance, the definition of indicators initially designed for calculation based on a manually collected dataset are not always entirely unambiguous. In Chapter 5, we discussed some of these examples. A simple, yet illustrative example is the indicator considering whether a physiotherapy consultation has taken place after a neck dissection. When collecting the data manually, a human will verify whether a physiotherapy consultation has occurred and whether this was within a reasonable time post-surgery. If this process is automated, a definitive maximum time limit after the surgery must be established within the extraction logic. Thus, it is recommended to revise indicator definitions to ensure machine interpretability.

Despite the difficulties in data extraction described in this chapter, Chapter 5 has provided evidence that it is possible to extract valid data from the EHR and use it to reliably calculate quality indicators. One of the main reasons why this study was successful could be that multiple data validation sessions were conducted during the dashboard development process. These data validation sessions, in which the information in the dashboard was compared at patient level to the source information in the EHR database, are critical in advancing toward reliable data extraction. Besides improving the extraction logic, data validation can also lead to insights into missing data, which can help identify the gaps within the structured documentation process. This, in turn, will also improve data quality within the EHR.

Based on the results of Chapter 5, it could be advisable to periodically validate the automatically calculated quality information through targeted comparison with the EHR. It might also be beneficial to discuss the results with colleagues. Discussing automatically calculated quality information can improve the quality of care if Plan-Do-Check-Act (PDCA) cycles are conducted accordingly, similar to manual quality measurement. Additionally, reviewing the automatically computed results can improve confidence in the validity of the data. Physicians often exhibit a degree of skepticism toward the assistance of data-processing machines during their work((11). This might also be the case for machine-extracted data instead of human-extracted data. This highlights the need to build trust in machine-extracted data in the future. Furthermore, discussing automatically collected quality information can also provide insight to other healthcare providers about the consequences of insufficient registration, such as lack of, or incorrect, quality information.

Future perspectives

As highlighted before, prioritizing the reduction of administrative burden for healthcare providers should take precedence over the capture of reusable data. Currently, EHRs have limited flexibility in terms of usability and structured data entry capabilities, meaning switching between various tabs in the EHR is often required. To address this concern, future development should prioritize a more adaptable EHR in which structured data entry modules can be shown within a single user interface or workflow. By developing the EHR in a more modular manner and facilitating the seamless integration of these modules, it is possible to construct optimal EHR workflows without disruptions with greater ease. Furthermore, adjustable data entry forms that adapt to known information could also contribute to streamlining the documentation process. In an ideal situation, all relevant health information is stored in a single, comprehensive database. However, the current landscape often involves various data sources besides the EHR, for example separate pathology and radiology systems. To optimize the functionality of adaptable data entry forms, integration or linkage of these data sources is paramount, necessitating solutions like clinical data repositories.

The integration or linkage of these various sources can also contribute to improved clinical decision support tools, which are usually dependent on structured data. In the future, we could see the utilization of real-time AI prediction models within the EHR, which could recommend the most appropriate treatment for a patient based on the information that was entered. AI models could potentially offer predictions on treatment success rates, complication risks, or disease recurrence at each stage of the

care pathway. These forecasts can provide valuable insights to patients, aiding them in making more informed and appropriate decisions.

The digital care pathway

Healthcare will likely evolve and become more and more digitalized. Within this digital care pathway, it might be possible to move some of the documentation responsibilities away from the healthcare practitioners. For instance, certain initiatives enable patients to fill out questionnaires at home before consultations, allowing specific issues to be directly addressed during the consultation. A similar method was used in chapter 6 of this thesis, in which patients remotely entered structured data into the EHR, that was subsequently used by an algorithm. It could be feasible to let patients enter their history of present illness at home using an app or website before an appointment. This data could then be automatically reused within the EHR to pre-fill EHR documentation, thus reducing the time required for documentation during the actual consultation. Other advancements that can be incorporated within the digital care pathway include video consultations, of which significant surge was seen during the COVID pandemic. Even self-examinations at home conducted by patients, for example flexible laryngoscopy, could potentially be a part of the future Head and Neck oncology digital careway. However, such innovations should be evaluated thoroughly in future studies, comparing their accuracy and effectiveness to traditional methodologies. Chapter 6 highlighted the generally positive patient perception towards these developments. Still, both patients and physicians emphasize the importance of preserving the doctor-patient relationship. Consequently, careful consideration is required to maintain the balance between digitalizing care and sustaining meaningful, personal interactions between healthcare providers and patients.

Regarding the exchange of structured data with other institutions, such as quality registries, several issues need to be addressed. The infrastructure for data exchange requires further development. In Head and Neck Oncology, developing Fast Healthcare Interoperability Resources (FHIR) messages with embedded Health Information Models (ZIBs) is a crucial step. A significant barrier in this process is the need for data mapping. In manual data extraction, a data clerk can interpret the data within the EHR. However, when data is extracted automatically, a mapping table is often required to translate a certain data element to corresponding items of the quality registry. Developing these mapping tables is time-intensive and registry-specific. Policymakers will have to decide whether quality registries must be revised to correspond with the developed exchange standards, or that the standardized data is mapped to fit the current quality registries data dictionary.

Throughout the various stages involved in achieving structured data exchange from hospital to quality registry, data validation is essential. Hopefully, in the near future, automatic data extraction will be conducted alongside manual data extraction. Initially, rigorous validation of automatically exchanged data will be necessary. Even comparing data on a patient level to EHR data or manually abstracted data might be required. Subsequently, developing intelligent validation reports that highlight inconsistencies in certain data might prove beneficial.

When validation of the automatic extracted data has proven that part of the automatically extracted data is of high enough quality, there might be a transitional period. During this period, specific data is extracted and exchanged automatically, while other data continues to be manually extracted and added to the registry. Through periodic data validation, insight is gained into which data is of sufficient quality to cease manual data collection. Consequently, the current role of a data extraction employee may evolve into that of a validation employee. Ultimately, this process will pave the way for a fully automated exchange of structured data between healthcare institutions, eliminating the need for human intervention.

In conclusion, this thesis on structured data capture and reuse in healthcare yielded valuable insights and showed potential for a significant reduction in administrative burden and improvement in documentation quality. The future of reusable data capture in healthcare should require a focus on user acceptance of structured documentation systems and on reliable extraction of data for reuse. This might be achieved by developing adaptable, more flexible EHRs, improving and streamlining data integration between systems and institutions, and implementing electronic care pathways. Moreover, addressing challenges in structured data exchange among healthcare institutions requires attention to data mapping, validation, and subsequently continuous improvement of data quality. Hopefully, this thesis serves as a foundation, highlighting the essential role of structured data capture and data reuse in enhancing healthcare efficiency and quality, paving the way for future advancements in healthcare informatics.

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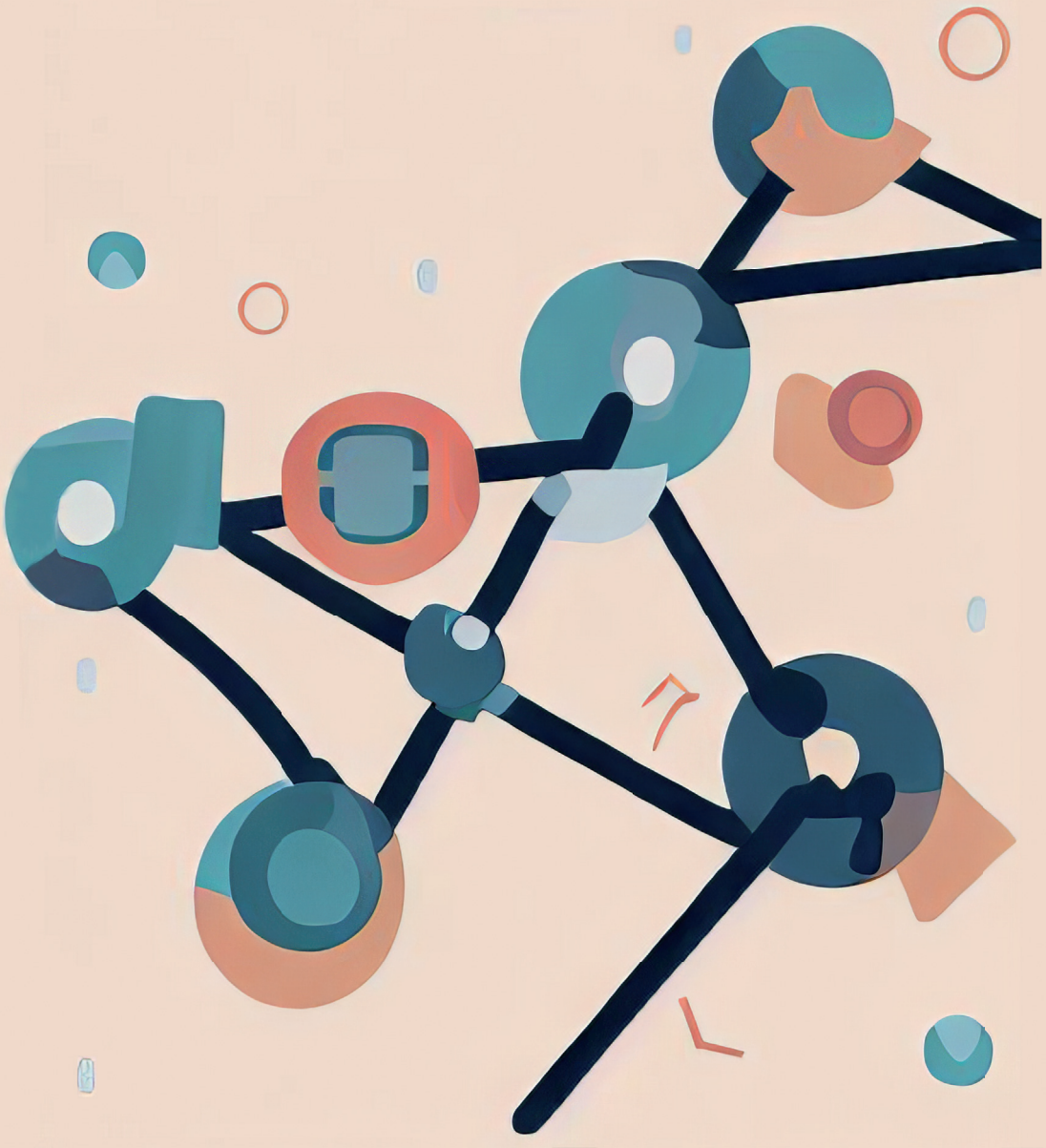


Chapter 8

Summary

A multitude of systematic reviews have shown an escalation in the administrative load on healthcare providers following the implementation of EHRs. In **Chapter 2**, our investigation focused on assessing the present administrative burden imposed by EHRs on providers in the field of head and neck oncology. The outcomes of this study corroborate those reported in the literature. A substantial 44% of a consultation is utilized for administrative tasks within the EHR. Simultaneously, an exchange of communication between the patient and the healthcare provider takes place during 80% of the consultation duration. However, the provider often multitasks, combining patient communication and EHR tasks, or switches back and forth. Switching between tasks and the need for multitasking are factors known to increase the perceived administrative burden.

It was hypothesized that the introduction of e-pathways featuring structured documentation could potentially yield benefits across several domains. **Chapter 3** investigates the impact of a structured and standardized documentation system on the time required for EHR documentation in outpatient Head and Neck Oncology consultations. Time-motion methodology and video-analysis of outpatient consultations demonstrated a reduction in the time dedicated to documentation by up to 27.0%. Considering the outcomes of Chapter 2, and the significant treat of extensive documentation burden in modern healthcare, it is a significant finding that the implementation of structured documentation can help to decrease, rather than increase, the EHR documentation burden.

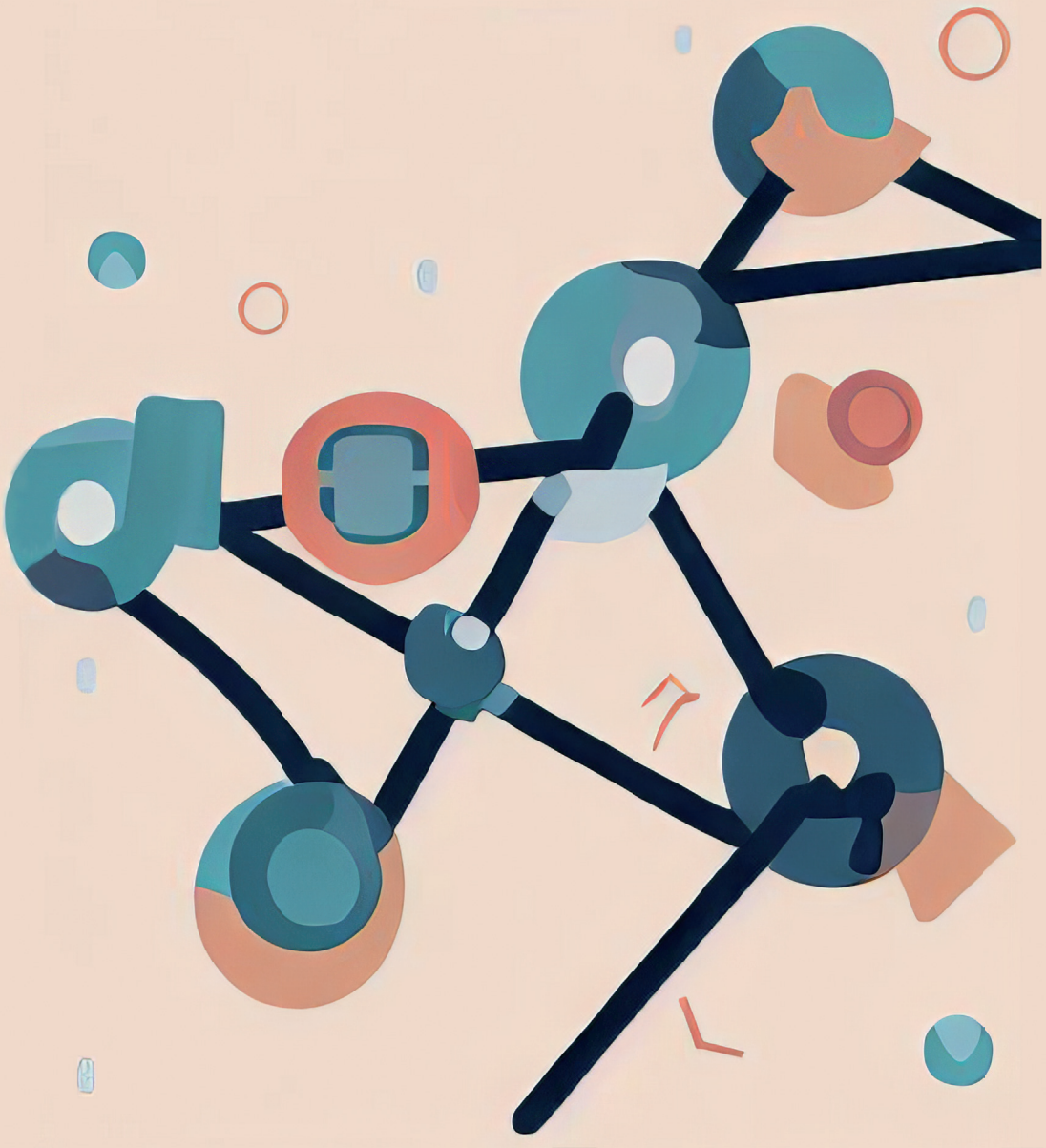
Chapter 6 explores patient perspectives regarding an mHealth application that enables patient-entered structured data collection. This patient-entered structured data was used to support remote monitoring of patients that had been treated for Head and Neck Cancer. The research utilized a mixed-method design to capture the views and experiences of HNC patients using the remote monitoring application (RMA) during their follow-up period. The mHealth Usability Questionnaire indicated a positive response to the overall usability of the RMA. Semi-structured interviews uncovered 12 barriers and 11 facilitators for RMA usage in daily practice, from a patient perspective. The ability to conduct self-checkups at a time of their choosing and increased self-responsibility were identified as facilitators, whereas barriers included difficulty in self-examination of the neck and lack of personal contact with their treating physician.

Chapter 4 focuses on the effect of structured and standardized documentation on the quality of documentation within the EHR. We compared notes recorded prior to and following the implementation of a structured documentation system. In this retrospective multicenter study, our findings illustrate that structured documentation is associated with enhanced documentation quality, with a marked 20% improvement

in quality measured on a 0-100 scale. Additionally, we found that notes recorded with structured formats were significantly more comprehensive than unstructured notes but were nevertheless perceived as more concise.

Chapter 5 describes the development of a near real-time quality dashboard that employs routinely collected structured data, and evaluates the quality of data used in the dashboard by comparing it to manually collected data from the same patients. Furthermore, the results of a set of quality indicators relevant to Head and Neck Oncology were computed for both methods of data collection and compared. The study concluded that extracting highly reliable data from the EHR automatically and using it to reliably compute quality indicators is feasible. In most cases, the outcomes of the indicators were consistent with results based on manually collected data.

In conclusion, the results of the thesis highlighted the potential of structured data capture and data reuse. This encompasses enhancing care efficiency in decreasing administrative burden for healthcare providers, enhancing documentation quality, and confirming the feasibility of automated data reuse within healthcare settings.



Chapter 9

Nederlandstalige samenvatting

Samenvatting

Verschillende onderzoeken laten zien dat de invoering van het elektronisch patiëntendossier (EPD) heeft geleid tot een toename van de administratieve last voor zorgverleners. In **hoofdstuk 2** hebben we ons gericht op het onderzoeken van de huidige administratieve last binnen het EPD voor zorgverleners in de Hoofd Hals Oncologie. De uitkomsten van dit onderzoek bevestigen de resultaten die in de literatuur worden gerapporteerd. Een aanzienlijke 44% van een consult wordt gebruikt voor administratieve taken binnen het EPD. Tijdens 80% van de consultduur vindt er communicatie plaats tussen de patiënt en de zorgverlener. Hieruit blijkt dat zorgverleners vaak multitasken, waarbij communicatie met de patiënt en EPD-taken worden gecombineerd of afgewisseld. Het afwisselen van taken en de noodzaak tot multitasking zijn factoren waarvan is bewezen dat ze de door zorgverleners ervaren administratieve last verhogen.

Het gebruik van elektronische zorgpaden, waarin gestructureerde documentatie plaatsvindt, kan mogelijk leiden tot efficiëntievoordelen. **Hoofdstuk 3** onderzoekt de impact van een gestructureerd en gestandaardiseerd documentatiesysteem op de tijd die nodig is voor documentatie in het EPD tijdens poliklinische consulten in de hoofd- en hals oncologie. Time-motion methodologie en video-analyse van poliklinische consulten lieten een vermindering van de documentatietijd tot 27% zien. Gezien de resultaten van hoofdstuk 2 en de steeds verder toenemende administratielast in de hedendaagse gezondheidszorg is het een belangrijke bevinding dat de implementatie van gestructureerde documentatie kan bijdragen aan het verminderen van administratielast, in plaats van de last te vergroten, wat voorheen vaak werd gedacht.

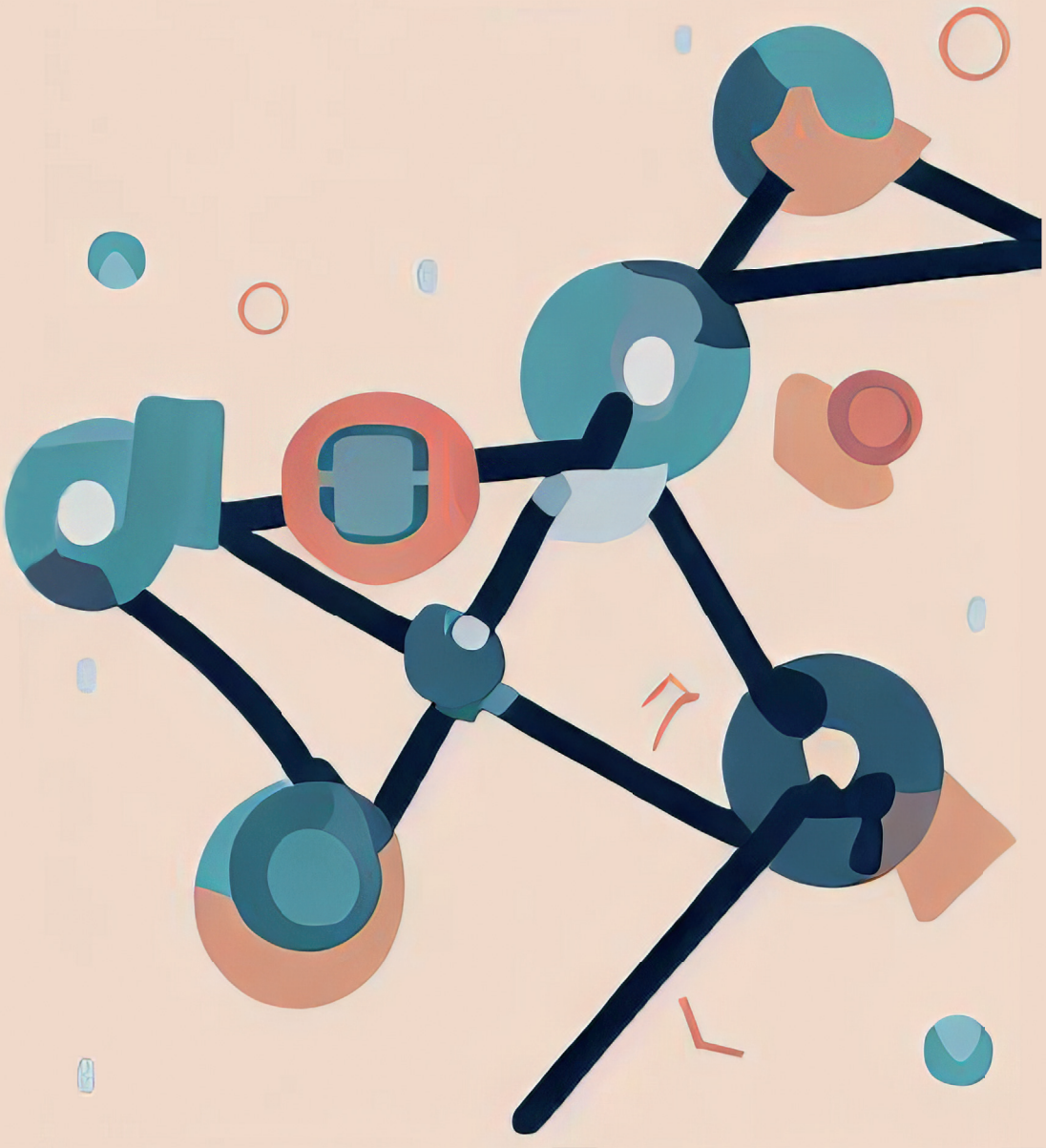
Hoofdstuk 6 onderzoekt de mening van patiënten over een mHealth-toepassing die gestructureerde gegevensinvoer door patiënten mogelijk maakt. Deze door de patiënt ingevoerde gestructureerde gegevens werden gebruikt om het op afstand monitoren van patiënten die behandeld waren voor hoofd- en halskanker mogelijk te maken. Er werd een mixed-method design gebruikt om de visies en ervaringen van hoofd-hals oncologische patiënten te verzamelen die de RMA (Remote Monitoring Application) tijdens de follow-up periode van hun ziekte gebruikten. De analyse van de mHealth Usability Questionnaire liet zien dat patiënten in het algemeen positief stonden tegenover de algehele bruikbaarheid van de RMA. Semigestructureerde interviews leverden 12 belemmerende en 11 bevorderende factoren op voor het gebruik van RMA vanuit het perspectief van de patiënt. De mogelijkheid om zelfcontroles uit te voeren op een door hen gekozen tijdstip en toegenomen zelfverantwoordelijkheid werden geïdentificeerd als belangrijke bevorderende factoren, terwijl onder andere

moeilijkheden bij zelfonderzoek van de hals en gebrek aan persoonlijk contact met hun behandelend arts enkele van de belemmerende factoren waren.

Hoofdstuk 4 richt zich op het effect van gestructureerde en gestandaardiseerde documentatie op de kwaliteit van documentatie binnen het EPD. Notities die voor en na de implementatie van een gestructureerd documentatiesysteem waren geschreven werden met elkaar vergeleken. Deze retrospectieve multicenterstudie liet zien dat gestructureerde documentatie geassocieerd is met verbeterde documentatiekwaliteit, die kon oplopen tot 20% verbetering. Daarnaast toonden we aan dat notities die in middels gestructureerde notities waren geschreven significant langer waren dan ongestructureerde notities, maar desalniettemin als beknopter werden ervaren.

Hoofdstuk 5 beschrijft de ontwikkeling van een bijna real-time kwaliteitsdashboard dat routinematig verzamelde gestructureerde gegevens gebruikt. Daarnaast evalueert dit hoofdstuk de kwaliteit van de gebruikte data in het dashboard door deze te vergelijken met handmatig verzamelde data van dezelfde patiënten. Bovendien werden de resultaten van een reeks kwaliteitsindicatoren relevant voor hoofd- hals oncologie berekend voor zowel de handmatige als de automatisch verzamelde data. De studie concludeerde dat het haalbaar is om zeer betrouwbare gegevens uit het EPD automatisch te ontsluiten en deze te gebruiken om op een betrouwbare manier kwaliteitsindicatoren te berekenen. In de meeste gevallen waren de uitkomsten van de indicatoren consistent met resultaten op basis van handmatig verzamelde data.

Samenvattend tonen de bevindingen van dit proefschrift duidelijk het veelbelovende potentieel van gestructureerde vastlegging en hergebruik van gegevens in de zorg aan. Dit omvat het verbeteren van de efficiëntie van zorg, het verminderen van administratieve last voor zorgverleners, het verbeteren van de documentatiekwaliteit in het EPD, en het bevestigen van de haalbaarheid van automatisch hergebruik van zorggegevens.



Chapter 10

Appendices

Chapter 2 - Appendix A

Variables and questions of Adoption of Structured Data Recording questionnaire

Variable	Question
InformationReliability1	I trust data that a colleague recorded
InformationReliability2	I can trust data that a patient has recorded
InformationReliability3	I trust data that I recorded myself
InformationReliability4	When I change data, I trust that the new data is updated throughout the entire patient record
Completeness1	The patient record contains all the information I need
Accuracy1	The data in the patient record represent reality
Accuracy2	The data in the patient record contain few errors
Format1	The patient record has a clear interface
Format2	Because of clear design the data in the patient record can easily be recognised
Currency1	The data in the patient record are up to date
InformationSatisfaction1	The data in the patient record meet my expectations
SystemReliability1	I can trust that the EHR functions
Flexibility1	In different situations I can use the patient record flexible in my own way
Integration1	I have to use different computer programs to gather all patient data
Integration2	The patient record brings together data that used to be in various places
Accessibility1	I can access the patient data at any desired location
Timeliness1	The EHR responds fast enough to my orders
SystemQuality1	Our organisation has a high quality EHR
Compatibility1	The patient record supports my personal work processes
Awareness1	I know for what purposes the data that I record can be used other than providing care
Awareness2	I understand that data have to be recorded structured and standardised
Awareness3	I know how to record data to enable reuse (e.g. for discharge letters and in research)
PerceivedUsefulness1	When referring a patient to a care provider outside of the hospital I can easily and timely send all required information
PerceivedUsefulness2	The patient record ensures that all care professionals around a patient are wellinformed
PerceivedUsefulness3	The patient record facilitates agreement with colleagues on the treatment plan of the patient
PerceivedUsefulness4	The patient record helps me to provide good quality patient care
PerceivedUsefulness5	Recording data in a structured and standardised manner costs me more time than recording in free text
PerceivedEaseOfUse1	I can always find the patient data that I need in the patient record
PerceivedEaseOfUse2	The patient record is user friendly
PerceivedEaseOfUse3	The patient record makes it easy to record data in a structured and standardised manner

Attitude1	I like recording data in free text
Attitude2	I like working in a structured and standardised manner
Attitude3	It is important that patient data can also be used by managers and researchers
Attitude4	It is important to record patient data directly at the point of care
Interpersonal1	My supervisor stimulates me to register data in a structured and standardised manner
Governmental1	External organisations like the inspectorate emphasize that I should record structured and standardised
SubjectiveNorm1	I record data in a structured and standardised manner because my colleagues expect it from me
SelfEfficacy1	I properly mastered working with the patient record
FacilitatingConditions1	There is enough time to properly record patient data
PerceivedBehavioural1	I can control whether the patient data is properly recorded in the patient record
SituationalNormality1	In my organisation proper data recording goes without saying
StructuralAssurance1	My organisation makes sure the patient record always functions
StructuralAssurance2	My organisation makes sure that patient data cannot be accessed by unauthorised persons
InstitutionalTrust1	I trust that my organisation manages the patient record safely
PerceivedRisk1	Reuse of data I recorded can harm the privacy of the patient
PerceivedRisk2	Reuse of patient data can lead to errors in the care provision
IntentionToAct1	I want to reuse as much available data as possible
IntentionToAct2	I want to record data structured and standardised
Behaviour1	I record many data twice or more (in multiple systems)
Behaviour2	I record as many data structured and standardised
Behaviour3	I reuse as many available data as possible
Behaviour4	I record data in such a way that others can use and reuse my data
Behaviour5	I register an allergy structured and standardised in the patient record as soon as there is new information
Behaviour6	I record medication structured and standardised in the patient record when there is new information
Behaviour7	I record all diagnoses using a standard list instead of in free text
Behaviour8	I record all procedures using a standard list instead of in free text
Behaviour9	I record a pain score structured and standardised in the patient record when there is new information
Behaviour10	I record vital parameters (e.g. pulse, blood pressure, respiratory rate, conscience) structured and standardised when there is new information
Behaviour11	I record risk of falling structured and standardised in the patient record when there is new information

Chapter 2 - Appendix B

Full survey results

Question	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I trust data that a colleague recorded	0%	4%	17%	57%	22%
I can trust data that a patient has recorded	0%	13%	57%	26%	4%
I trust data that I recorded myself	0%	4%	0%	57%	39%
When I change data, I trust that the new data is updated throughout the entire patient record	0%	52%	26%	22%	0%
The patient record contains all the information I need	0%	22%	30%	48%	0%
The data in the patient record represent reality	4%	13%	30%	52%	0%
The data in the patient record contain few errors	9%	26%	57%	9%	0%
The patient record has a clear interface	9%	30%	35%	26%	0%
Because of clear design the data in the patient record can easily be recognised	4%	17%	48%	30%	0%
The data in the patient record are up to date	4%	22%	39%	35%	0%
The data in the patient record meet my expectations	0%	13%	52%	35%	0%
I can trust that the EHR functions	0%	9%	4%	78%	9%
In different situations I can use the patient record flexible in my own way	4%	9%	22%	65%	0%
I have to use different computer programs to gather all patient data	0%	35%	9%	52%	4%
The patient record brings together data that used to be in various places	4%	22%	26%	43%	4%
I can access the patient data at any desired location	0%	9%	4%	83%	4%
The EHR responds fast enough to my orders	0%	22%	26%	48%	4%
Our organisation has a high quality EHR	0%	9%	52%	35%	4%
The patient record supports my personal work processes	5%	14%	27%	50%	5%
I know for what purposes the data that I record can be used other than providing care	5%	45%	27%	18%	5%
I understand that data have to be recorded structured and standardised	0%	5%	9%	59%	27%
I know how to record data to enable reuse (e.g. for discharge letters and in research)	0%	14%	50%	27%	9%
When referring a patient to a care provider outside of the hospital I can easily and timely send all required information	9%	36%	32%	23%	0%
The patient record ensures that all care professionals around a patient are well-informed	9%	14%	41%	36%	0%
The patient record facilitates agreement with colleagues on the treatment plan of the patient	0%	9%	41%	45%	5%

The patient record helps me to provide good quality patient care	0%	0%	27%	68%	5%
Recording data in a structured and standardised manner costs me more time than recording in free text	0%	27%	36%	32%	5%
I can always find the patient data that I need in the patient record	0%	36%	18%	36%	9%
The patient record is user friendly	0%	23%	45%	32%	0%
The patient record makes it easy to record data in a structured and standardised manner	5%	55%	32%	9%	0%
I like recording data in free text	0%	18%	32%	45%	5%
I like working in a structured and standardised manner	0%	9%	14%	68%	9%
It is important that patient data can also be used by managers and researchers	0%	0%	18%	45%	36%
It is important to record patient data directly at the point of care	0%	0%	5%	55%	41%
My supervisor stimulates me to register data in a structured and standardised manner	0%	36%	45%	18%	0%
External organisations like the inspectorate emphasize that I should record structured and standardised	5%	36%	41%	14%	5%
I record data in a structured and standardised manner because my colleagues expect it from me	0%	23%	36%	41%	0%
I properly mastered working with the patient record	0%	5%	18%	68%	9%
There is enough time to properly record patient data	9%	45%	23%	23%	0%
I can control whether the patient data is properly recorded in the patient record	5%	5%	27%	59%	5%
In my organisation proper data recording goes without saying	5%	23%	55%	18%	0%
My organisation makes sure the patient record always functions	0%	0%	14%	68%	18%
My organisation makes sure that patient data cannot be accessed by unauthorised persons	0%	5%	9%	59%	27%
I trust that my organisation manages the patient record safely	0%	0%	0%	68%	32%
Reuse of data I recorded can harm the privacy of the patient	5%	23%	14%	27%	32%
Reuse of patient data can lead to errors in the care provision	0%	18%	27%	41%	14%
I want to reuse as much available data as possible	0%	0%	18%	55%	27%
I want to record data structured and standardised	0%	0%	14%	55%	32%
I record many data twice or more (in multiple systems)	0%	14%	9%	55%	23%
I record as many data structured and standardised	0%	14%	43%	38%	5%
I reuse as many available data as possible	0%	10%	19%	71%	0%

I record data in such a way that others can use and reuse my data	0%	5%	33%	52%	10%
I register an allergy structured and standardised in the patient record as soon as there is new information	0%	19%	14%	48%	19%
I record medication structured and standardised in the patient record when there is new information	0%	14%	14%	57%	14%
I record all diagnoses using a standard list instead of in free text	5%	48%	10%	33%	5%
I record all procedures using a standard list instead of in free text	10%	19%	24%	43%	5%
I record a pain score structured and standardised in the patient record when there is new information	14%	48%	24%	14%	0%
I record vital parameters (e.g. pulse, blood pressure, respiratory rate, conscience) structured and standardised when there is new information	5%	33%	14%	43%	5%
I record risk of falling structured and standardised in the patient record when there is new information	10%	43%	24%	19%	5%

Chapter 3 - Appendix A

Concepts measured by the Adoption of Structured Data Recording questionnaire and their explanation

Concept	Explanation
Information reliability	Whether the information in the EHR is reliable
Completeness	Whether the information in the EHR is complete
Accuracy	Whether the information in the EHR is accurate
Format	Whether the information in the EHR is in an understandable format
Currency	Whether the information in the EHR is up to date
System reliability	Whether the user can trust that the EHR works
Flexibility	Whether the user can use the EHR flexibly in different situations
Integration	Whether the user needs to open multiple computer programs to gather all information on patients
Accessibility	Whether the user can access the patient data in every place in the organization
Timeliness	Whether the system responds to user input in a timely manner
System satisfaction	The overall opinion of the user on the quality of the EHR
Compatibility	Whether the EHR supports the work processes of the user
Awareness	Whether the user knows why it is important that their data are recorded correctly
Perceived ease of use	The overall opinion of the user on the usability of the EHR
Information satisfaction	Whether the user is satisfied with the information that the EHR provides
Perceived usefulness	Whether the EHR aids in the user's daily work
Attitude	What the user thinks of structured and standardised recording
Interpersonal influence	Whether the supervisor promotes correct recording
Governmental influence	Whether the government (i.e. the inspectorate) promotes correct recording
Subjective norm	Whether the user records correctly because colleagues expect this
Self-efficacy	Whether the user is capable of correct recording
Facilitating conditions	Whether there is enough time to record data correctly
Perceived behavioural control	Whether it is within the user's control to record data correctly
Situational normality	Whether it is normal in the organisation to record correctly
Structural assurance	Whether the organisation ensures that data are stored safely and cannot be lost
Institutional trust	Whether the user trusts that the organisation stores the records safely
Perceived risk	Whether the reuse of data can harm the patients' privacy and or safety
Intention to act	Whether the user wants to record data structured and standardised and wants to reuse data
Behaviour	A number of facets that indicate whether the user is already recording structured and standardised data

Chapter 5 - Appendix A

Required data elements and extraction rules required for specific indicator

Has a patient been discussed in a multidisciplinary tumor board meeting prior to the start of curative treatment?

Information	Data elements Extraction logic	
Diagnosis	- Diagnosis code - Date of diagnosis	ICD-10 code(s) included
MDT	- Multidisciplinary tumor board completed Y/N - Date of MDT	Define appointment code(s) that indicate included MDT(s) Define which MDT should be used if multiple MDT have been conducted
Treatment	- Curative or palliative treatment intent	Smart Data Element (location) that indicates curative or palliative treatment intent.
Treatment	- Surgical procedure - Date of surgical procedure	Define procedure codes that indicate (first) surgical treatment Exclude procedure codes for diagnostic procedures Date should be after MDT date
Treatment	- Radiotherapy treatment Y/N - Start date of radiotherapy treatment	Appointment code(s) that indicate (initial) radiotherapy treatment Date should be after MDT date
Treatment	- Systemic treatment Y/N - Start date of systemic treatment	Appointment code(s) that indicate (initial) systemic treatment treatment Date should be after MDT date

Chapter 6 – Appendix A1

Original English mHealth App Usability Questionnaire (MAUQ)

Ease of use and satisfaction score (MAUQ_E)

1. The app was easy to use.
2. It was easy for me to learn to use the app.
3. I like the interface of the app.
4. The information in the app was well organized, so I could easily find the information I needed.
5. I feel comfortable using this app in social settings.
6. The amount of time involved in using this app has been fitting for me.
7. I would use this app again.
8. Overall, I am satisfied with this app.

System information arrangement score (MAUQ_S)

9. Whenever I made a mistake using the app, I could recover easily and quickly.
10. This mHealth app provides an acceptable way to receive healthcare services.
11. The app adequately acknowledged and provided information to let me know the progress of my action.
12. The navigation was consistent when moving between screens.
13. The interface of the app allowed me to use all the functions (such as entering information, responding to reminders, viewing information) offered by the app.
14. This app has all the functions and capabilities I expected it to have.

Usefulness score (MAUQ_U)

15. The app would be useful for my health and well-being.
16. The app improved my access to healthcare services.
17. The app helped me manage my health effectively.
18. The app made it convenient for me to communicate with my healthcare provider.
19. Using the app, I had many more opportunities to interact with my healthcare provider.
20. I felt confident that any information I sent to my provider using the app would be received.
21. I felt comfortable communicating with my healthcare provider using the app.

Chapter 6 - Appendix A2

Translated Dutch mHealth App Usability Questionnaire (MAUQ)

Gebruiksgemak en tevredenheid (MAUQ_E)

1. De app was eenvoudig te gebruiken.
2. Het gebruik van de app was eenvoudig te leren.
3. De gebruikersinterface van de app bevalt me.
4. De informatie in de app was overzichtelijk, dus ik kon de informatie die ik nodig had gemakkelijk vinden.
5. Ik voel me op mijn gemak als ik de app in het bijzijn van anderen gebruik.
6. De hoeveelheid tijd die benodigd is voor het gebruik van deze app was passend voor mij.
7. Ik zou deze app nogmaals gebruiken.
8. In het algemeen ben ik tevreden over deze app.

Organisatie van systeeminformatie (MAUQ_S)

9. Als ik tijdens het gebruik van de app een fout maakte, kon ik die eenvoudig en snel herstellen.
10. Deze app was een geschikte manier om zorg te ontvangen.
11. De app bevestigde mijn invoer adequaat en gaf op heldere wijze informatie over de voortgang van mijn handeling.
12. De navigatie was consistent bij het wisselen tussen schermen.
13. Met de gebruikersinterface van de app kon ik alle functies gebruiken (zoals informatie invoeren, op herinneringen reageren, informatie bekijken) die de app biedt.
14. Deze app beschikt over alle functies en mogelijkheden die ik ervan verwacht.

Nut (MAUQ_U)

15. De app zou nuttig zijn voor mijn gezondheid en welzijn.
16. De app verbeterde mijn toegang tot de zorg
17. Met de app kon ik effectief aan mijn gezondheid werken.
18. De app maakte het gemakkelijk voor mij om met mijn zorgverlener te communiceren.
19. Dankzij het gebruik van de app had ik veel meer mogelijkheden tot interactie met mijn zorgverlener.
20. Ik had er vertrouwen in dat alle informatie die ik via de app naar mijn zorgverlener verstuurde ontvangen zou worden.
21. Ik voelde me op mijn gemak om via de app met mijn zorgverlener te communiceren.

Chapter 6 - Appendix A3

Interview guide (translated from Dutch)

Introduction

- Can you remember when you first used our remote monitoring app?
- Do you still use the remote monitoring app?

Theme 1: use of the app

Overall, what did you think of using the remote monitoring app?

- What was easy when using the app? Why?
- What was more difficult when using the app? Why?
- Did you have to learn new things before you could use the app? What things?
- Did you need help from anyone else to use the app? At what?
- Did you run into any problems while using the app? Which ones? Did you manage to solve them? How?

Theme 2: content of the app

What do you think of the questions asked in the app?

- What do you think of the clarity of the questions? What was good? What could be better?
- Were there any questions that were difficult to complete? Which ones? Why?
- Do you have any suggestions for improvement of the questions? If so, which ones?

What do you think of the explanation of the self-examination of the neck in the app?

- Was the explanation clear? What was good? What could be better?
- Did the video help you? How? What was good? What could be better?
- Did you manage to perform self-examination? Did you do this by yourself or with someone else? Why?
- Do you have any suggestions for improvement of the self-examination section? If so, which ones?

The app has a link to Oncokompas at the end. Did you click on it?

- If yes: are you using Oncokompas due to this link? Why yes/no?
- Do you think the link to Oncokompas is of added value to the remote monitoring app? Why?

Theme 3: Influence of remote monitoring on perceived care

What do you think of remote monitoring with the app compared to standard follow-up visits at the hospital?

- What do you think are the advantages of remote monitoring with the app compared to hospital checkups? Why?
- What do you think are the disadvantages of remote monitoring with the app compared to hospital checkups? Why?
- What do you miss in remote monitoring with the app compared to hospital checkups? Why?
- Do you trust remote monitoring with the app? Why?
- Has anyone from the hospital ever contacted you because of your answers in the app? What happened? What did you think of that?
- What do you think of the help the hospital offered in using the Home Monitor app? What was good? What could be better?
- How do you feel when you use the app? (Anxious, reassured, etc.) Does this differ from follow-up visits at the hospital?
- Does the app affect how often you are reminded of your illness? Why?

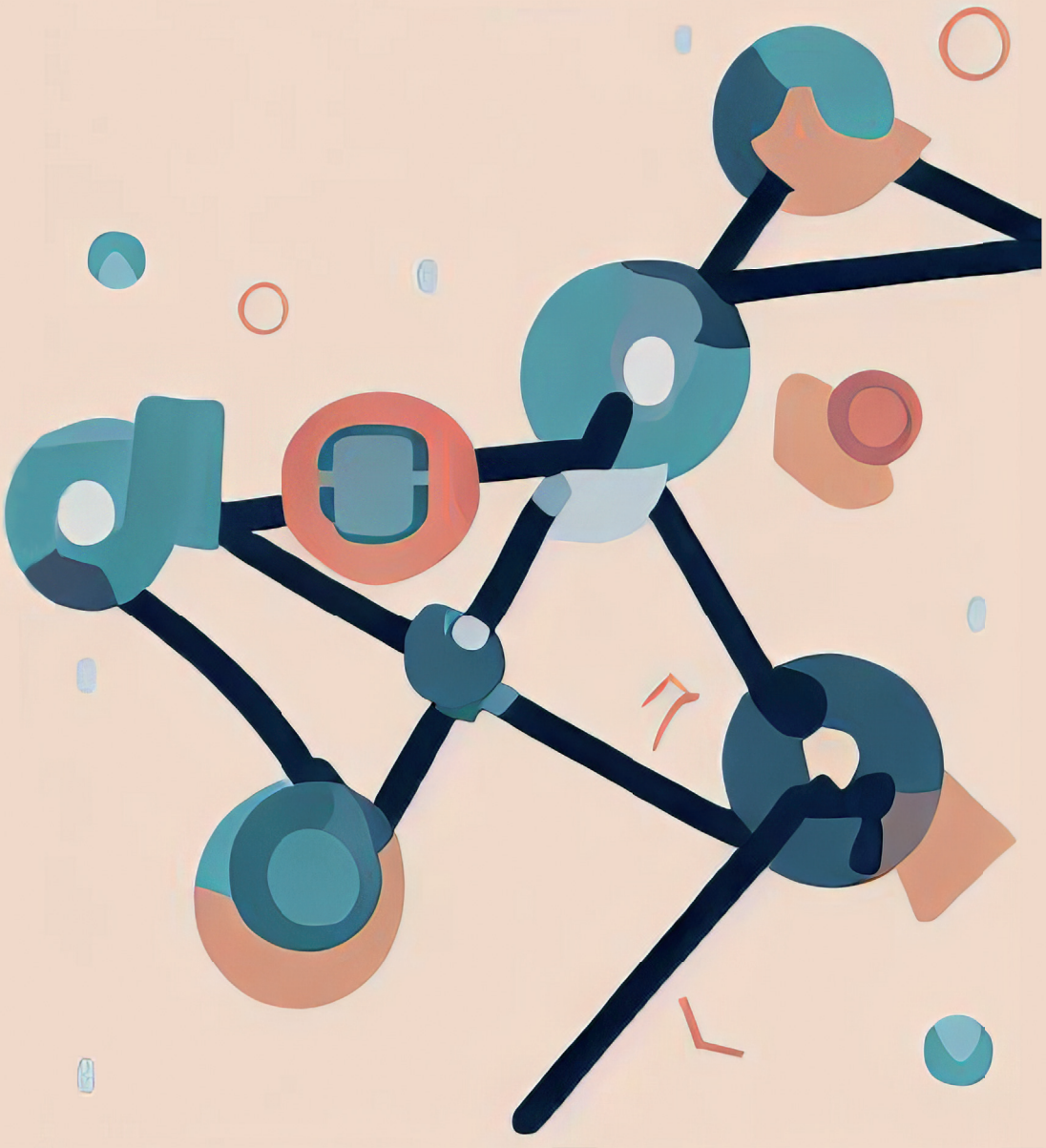
Theme 4: Remote monitoring in the future

What do you think of the app being used more often in the future?

- How would we best introduce the app to patients? And when?
- What do you think of being monitored with the app instead of standard hospital follow-up visits? Why?
- What do you think of a combination of follow-up visits in the hospital and follow-up with the app?
- Would you recommend the app to other patients? Why?
- Are there any areas of improvement for the app that we have not yet discussed? If so, which ones?
- What would you have wanted to know before you started using the app?
- What would you tell a patient who was about to start using the app?
- What would the ideal aftercare look like for you? And what role could the app play in that?

Wrapping up

- Are there any topics that we have not discussed yet and are of importance to you?
- Do you have any remaining questions?



Chapter 11

Data management form

Research data management

The studies in this thesis were conducted in accordance with the principles of the Declarations of Helsinki. All studies were reviewed by either local institutional review boards or regional CCMO and were either exempt from review or ruled as not subject to WMO.

Data collection and storage

In chapter 2 and 3, video consultations were used that were recorded with written consent given by the patient beforehand. Software was used to record consultations and afterward, recordings were saved to a password-protected file, in a secure folder on the participating hospital server. This double layer of protection ensured information safety. After data collection, the password-protected files could only be accessed and opened by the investigator with a licensed software program. The lead investigator is in charge of safeguarding the password. Recordings were coded, and the coded data was saved in a protected database in the lead researcher's department.

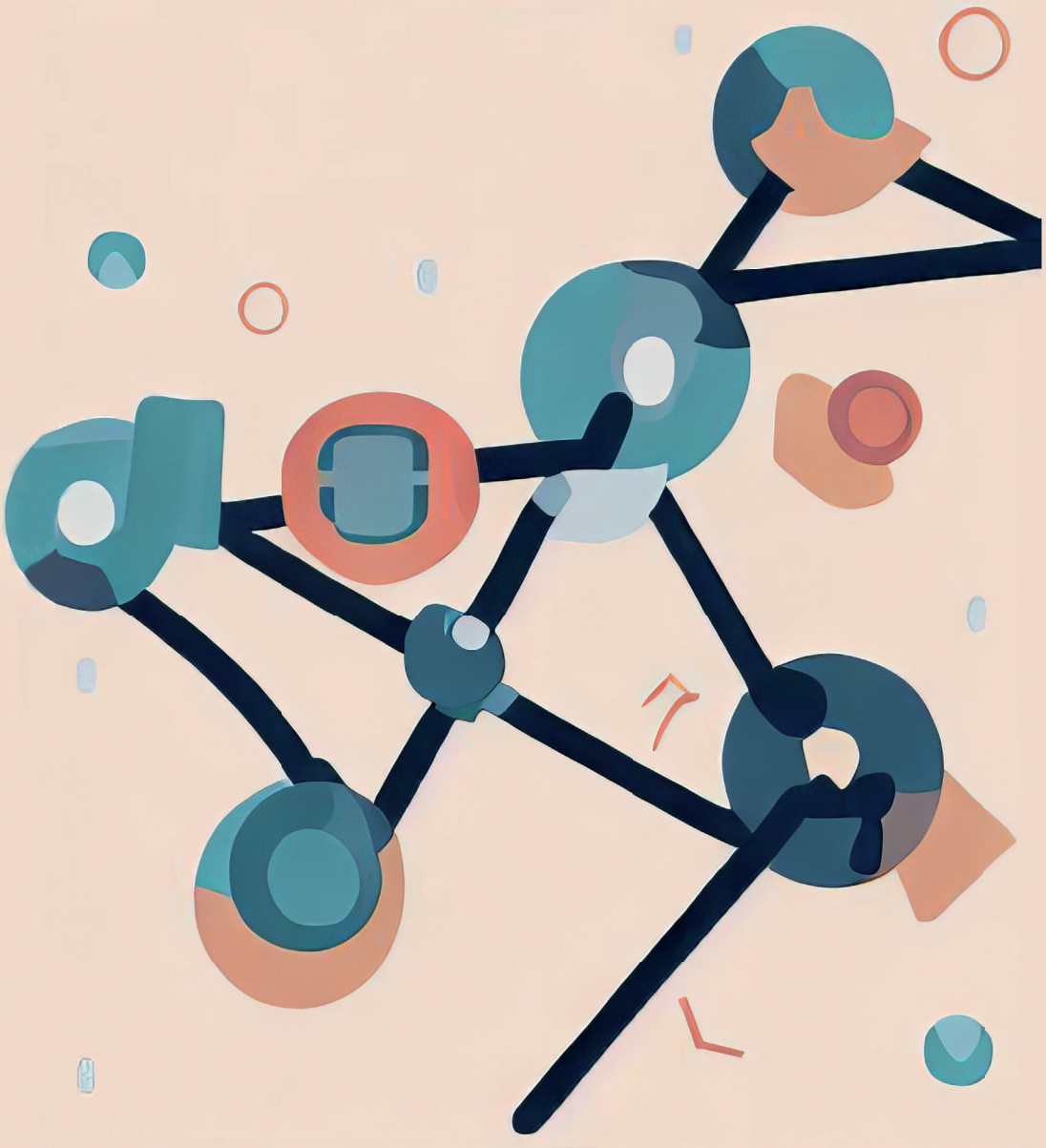
In Chapter 4 and 5, all collected data was de-identified by the lead researcher and stored in a protected database file. In chapter 6, CastorEDC was used to collect quantitative data anonymously. Furthermore, the researchers ensured that the participants' anonymity was maintained in qualitative data collection. Afterward, participants could only be identified by a participant ID number. All quantitative and qualitative data was stored securely and only accessible by the researchers.

All data are stored at the ENT department server (H:\DIVERSE\Ebbers). Paper (hardcopy) data are stored in cabinets in the department.

Microsoft Excel, SPSS, and Atlas.TI were used for anonymous data collection and analyses.

Availability of data

All studies are published open access. The data will be archived for 15 years after termination of the study. Reusing the data for future research is only possible after a renewed permission by the participants. The anonymous datasets that were used for analysis are available from the corresponding author upon reasonable request.



Chapter 12

Portfolio

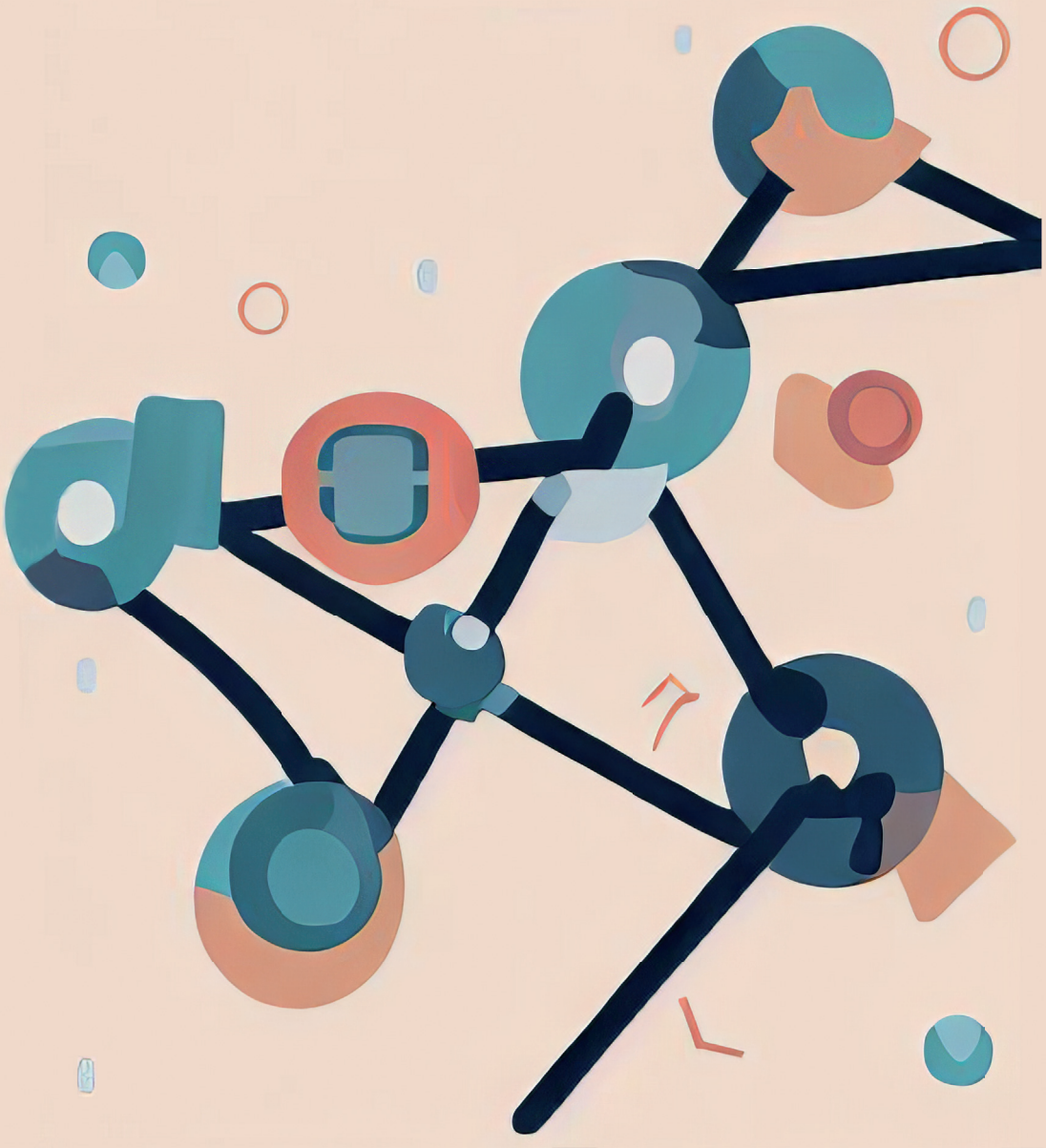
Department: KNO

PhD period: 01-06-2019 – 21-03-2025

PhD supervisor(s) Prof. dr. R.P. Takes, prof. dr. R.B. Kool

PhD Co-supervisor: dr. G.B. van den Broek

Training activities	**Hours**
Courses	
RIHS - Introduction course for PhD candidates (2019)	15.00
Epic physician builder course (2019)	30.00
Radboudumc – eBrok course (2019)	26.00
RU - Cursus kwalitatief onderzoek (2019) Radboudumc - Scientific integrity (2020) RU - Statistiek voor promovendi met SPSS (2020) RU - Scientific Writing for PhD candidates (2021) RU - Projectmanagement for PhD candidates (2021)	84.00 20.00 60.00 84.00 52.00
Conferences – Oral Presentations KNO vergadering, Kameryck: Invloed van de implementatie van een zorgpad in het EPD op administratielast en kwaliteit van dossiervoering (2023)	10.00
Eindevenement Registratie aan de Bron, Utrecht: Eindresultaten project Dataversneller Hoofd-Hals Oncologie (2022)	10.00
Other	
Hercertificering Brok (2023)	5.00
Teaching activities	
Supervision of internships	
Master thesis Healthcare Policy, Innovation and Management (2021)	20.00
Total	416.50



Chapter 13

Dankwoord

Het tot stand komen van dit proefschrift was een intensieve en leerzame reis die ik gelukkig niet alleen heb hoeven afleggen. Ik heb mogen rekenen op de steun, begeleiding en inspiratie van velen. Met dit dankwoord wil ik graag mijn waardering uitspreken voor iedereen die op welke manier dan ook heeft bijgedragen aan dit werk.

Dr. van den Broek, Beste Guido. Toen ik aan het begin af en toe door de bomen het bos niet meer zag, wist jij me altijd in de goede richting te sturen. Onder jouw begeleiding werd ik wegwijs binnen de ICT in de zorg en heb ik me het totaalplaatje en de samenhang van alle verschillende facetten binnen dit onderwerp eigen weten te maken. Jouw visie, aangevuld met alle kennis en kunde opgedaan als Chief Medical Information Officer, was onmisbaar voor het succesvol afronden van mijn thesis. Ik heb mogen profiteren van jouw ontspannen en pragmatische manier van begeleiden, waarin ik mij erg goed op mijn plek voelde. Heel hartelijk dank voor de grote bijdrage die jij hebt willen leveren aan mijn promotietraject, maar ook mijn professionele ontwikkeling!

Prof. dr. Takes, Beste Robert. Met jouw grote ervaring binnen de wetenschappelijke wereld en de Hoofd-Hals Oncologie wist jij altijd het overzicht te houden en passende adviezen te geven over de richting van mijn onderzoek. Ook wist jij met waardevolle feedback mijn manuscripten altijd weer een naar een hoger niveau te tillen. Bedankt voor je begeleiding en de tijd en energie die je hierin hebt gestoken!

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Prof. dr. Smeele, Beste Ludi. Hartelijk dank voor je steun en input met name aan het begin van mijn promotietraject!

Dr. Dirven, Beste Richard. Ik vond onze samenwerking bij de studies in het Antoni van Leeuwenhoek top! Altijd stond je klaar voor vragen of maakte je tijd om ergens te gaan lunchen en onze verdere plannen te bespreken. Jouw informele manier van begeleiden heb ik altijd als zeer prettig ervaren. Ik kijk er naar uit om weer verder van je te mogen leren nu je weer werkzaam bent in het Radboudumc!

Beste leden van de manuscriptcommissie, hartelijk dank voor uw tijd en het beoordelen van mijn proefschrift.

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AIOS en onderzoekers, bedankt voor al jullie gezelligheid, steun, begeleiding, samenwerking, koffiemomentjes, borrels, weekendjes weg, congressen, skivakanties en al het andere wat bijdraagt aan dat ik nergens anders mijn promotie en opleiding had willen doen. Werken in deze groep is een feest en ik kijk uit naar al het moois dat nog gaat komen in de komende jaren!

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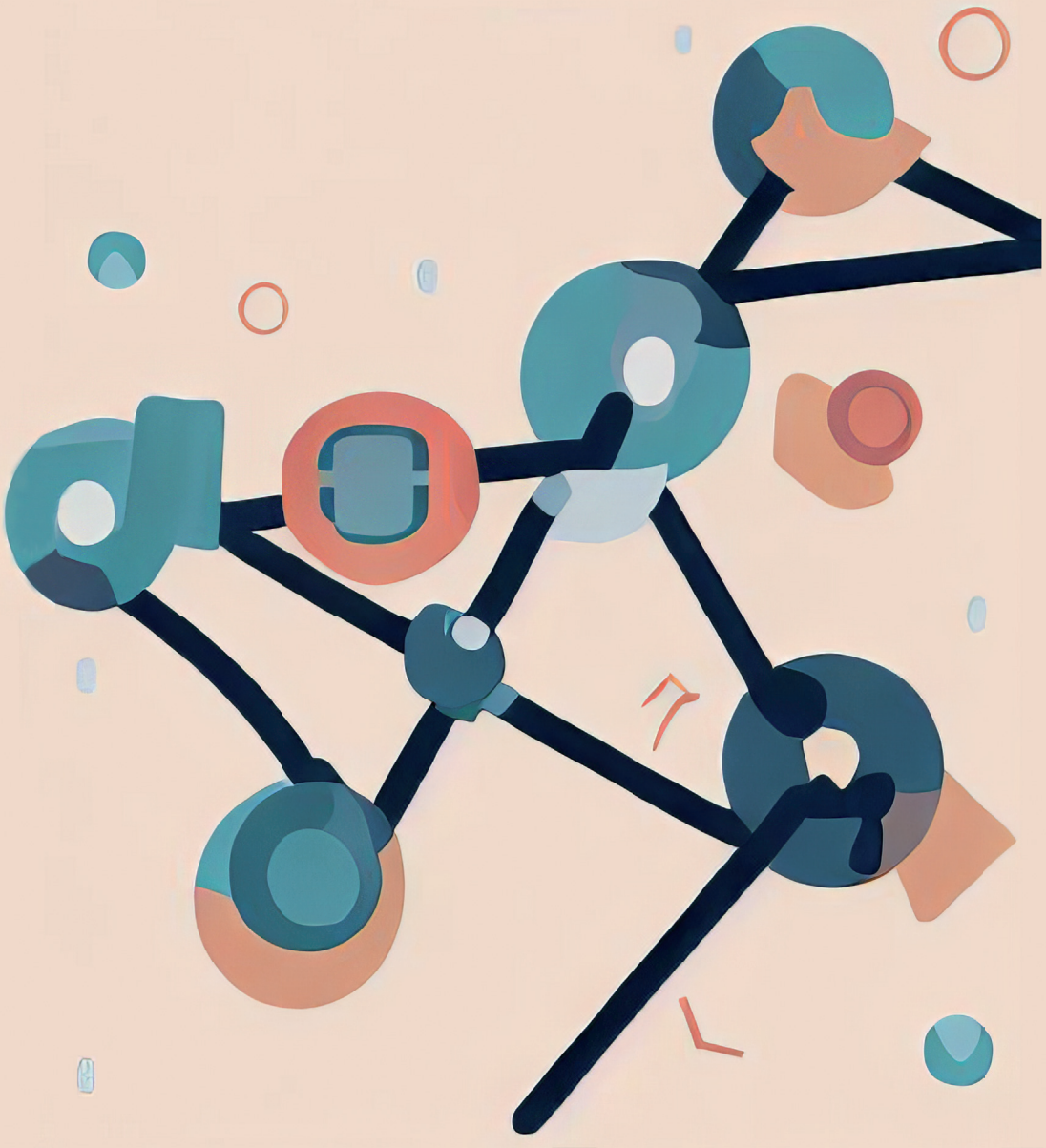
Ik wil mijn paranimfen, Jeroen en Bram, in het bijzonder bedanken. Prachtig om jullie na al die jaren op de laatste dag van mijn promotietraject aan mijn zijde te hebben staan!

Verder aan iedereen die dichtbij mij staat, jullie hebben elk op jullie eigen manier bijgedragen aan wie ik ben en aan wat ik heb kunnen bereiken. Hartelijk dank aan jullie allemaal!

Lieve pap en mam, Lisa en Emma, bedankt voor jullie onvoorwaardelijke steun en vertrouwen in mij, ook toen het moeilijk was. Pap en mam, thuiskomen in een warm nest is voor mij vanzelfsprekend, want ik heb het geluk dat ik jullie als mijn ouders heb. Dank jullie wel!

Lieve Celine, dank je wel voor wie jij bent en hoe gelukkig jij mij maakt. Ik hou van jou!



Chapter 14

Curriculum vitae

Tom Ebbers werd geboren op 8 januari 1993 in een spoorhuisje aan de Zegheweg in Woudenberg. Na zijn basisschooltijd op C.B.S. de Glashorst in Scherpenzeel was de volgende stop het Christelijk Lyceum Veenendaal, waar hij in 2011 het VWO afrondde. Via de decentrale selectie bemachtigde hij een plek op de studie Geneeskunde aan de Radboud Universiteit. Hij vulde zijn bachelorfase aan met met een bestuursjaar bij de Medische Faculteit en de faculteitskroeg, Café de Aesculaaf. Tijdens de masterfase werd zijn interesse in de Keel-, Neus- en Oorheelkunde gewekt en deed hij een onderzoeksstage en een keuzecoschap bij de afdeling KNO van het Radboudumc. Na een goed gevulde studententijd studeerde hij af begin 2019, waarna hij in juni van datzelfde jaar mocht beginnen als promovendus KNO in het Radboudumc in Nijmegen, wat ondertussen zijn thuisstad geworden was. Na 3 jaar onderzoek mocht hij in 2022 beginnen aan de opleiding tot KNO-arts, waarin hij zich op dit moment bevindt in het 3^{e} jaar en tot op heden werkzaam was in het Radboudumc en het Viecuri in Venlo.