ORIGINAL ARTICLE

Identifying user assistance systems for radiotherapy to increase efficiency and help saving lives

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ABSTRACT

Increasing efficiency and reducing risk in radiotherapy cancer treatment is of high importance. User assistance systems within a digitally connected radiotherapy environment can support all involved professionals to perform their individual tasks faster and better. This paper presents a qualitative analysis of radiotherapy workflows and a corresponding process modelling in order to identify hypothetical user assistance systems for specific process activities. In addition, the results of an empirical study on the identified systems are presented together with derived requirements and design principles for these systems. A structured online survey with 50 medical physicists in Germany has been conducted. Among others the acceptance, the increase of perceived efficiency and the risk reduction while using the assistance systems are analysed and discussed. The results support the creation of value adding user assistance systems for radiotherapy that improve efficiency, reduce treatment risks and reach high user acceptance levels.

ARTICLE HISTORY

Received 7 October 2019
Accepted 24 July 2020

KEYWORDS

User assistance; cancer; radiotherapy; workflow; business process modelling; design science research

1. Introduction

Cancer is the second leading cause of death globally and is responsible for an estimated 9.6 million deaths in 2018 (WHO, 2019). The number of cancer patients is expected to increase by 75% over the next 20 years due to ageing populations and unhealthy lifestyle (GCO, 2019). Percutaneous teletherapy, hereinafter referred to as radiotherapy, often combined with surgery and chemotherapy, is an important treatment method for cancer. Approximately 25% of cancer patients worldwide are treated with radiotherapy, while studies suggest that 50% should be treated with radiotherapy (Atun et al., 2015). Digitalisation helps to make radiotherapy more accessible for patients, pursuing the vision of fully integrated systems and services. (Müller-Polyzou, Reuter-Oppermann, Engbert & Wirtz H, 2019) Today, up to 70% of cancer patients worldwide have no access to radiotherapy while up to 80% have advanced cancer by the time they receive treatment (IAEA, 2019). Emerging technologies, process automation and work simplification can increase the accessibility of radiotherapy by increasing capacities and lowering the required educational level needed for the workforce (IAEA, 2019). In this regard, user assistance systems can support the dissemination of radiotherapy. A prerequisite for well-designed user assistance systems and thereby their acceptance is the in-depth understanding of work processes, occupational user groups, and the overall business

environment. Thus, this paper focuses on the analysis of the radiotherapy work process on the one hand and the identification of value adding user assistance systems on the other hand. We have designed a research project with two parts. In the first part, a qualitative group discussion and interviews are used to derive and model the radiotherapy workflow. In the second part, an empirical study analyses the potential application of assistance systems in the situational context. The systems are analysed in terms of perceived efficiency gains, risk reduction, and foreseen acceptance levels. Increased efficiency and reduced risk in radiotherapy cancer treatment support lower treatment cost and secure treatment quality. Thus, global access to life-saving radiotherapy treatment is improved (Van Dyk et al., 2017). However, emerging technologies will lead to changes of existing work processes and result in new challenges for quality and safety (ASTRO, 2019b). Safety is a decisive aspect in radiotherapy. International organisations keep track on safety issues and solutions to provide best possible recommendations for users (IAEA, 2010; WHO, 2017). In 2011, the American Society for Radiation Oncology (ASTRO) established a national radiation oncology-specific incident learning system (ASTRO 2019a), which provides many educational data reports.

This paper contributes to a more comprehensive understanding of modern radiotherapy work processes and the potential of user assistance systems in

radiotherapy. Additionally, it presents hypothetical user assistance systems to improve efficiency and reduce treatment risks that users would likely accept.

The remainder of the paper is structured as follows. In Section 2 the foundations including the literature and historical, technical, and occupational radiotherapy environment are outlined. In Section 3 radiotherapy processes are modelled following a comprehensive analysis of existing work routines as the result of the first part of our project. In Section 4 an empirical survey as the second part of our project is introduced to gain market information on existing user assistance systems for radiotherapy. The research results are presented, validated, and discussed in Section 5. An outlook on future research projects concludes this paper in Section 6.

2. Foundations

Radiotherapy is a high-technology segment in healthcare. Imaging techniques like Computed Tomography (CT), Positron Emission Tomography Computed Tomography (PET-CT), and Magnetic Resonance Tomography (MRT) are used for diagnostics and precise treatment planning, while Linear Accelerators (LINACs) are used for radiation treatment. Modern LINACs include on-board Cone – Beam Computed Tomography (CBCT) for an accurate tumour localisation just before the treatment. Treatment planning systems are used to calculate treatment plans individually for each patient. Quality assurance of involved solutions is frequently conducted including the verification of the treatment plans. Radiotherapy systems are interconnected, and extensive data are processed mainly in the form of large image files. Digitalisation is already advanced in High Income Countries (HIC).

Nevertheless, even in digitised radiotherapy centres, there are often media discontinuities that lead to efficiency losses and represent risks in terms of patient safety (WHO, 2008).

As LINACs have become the most important tool for radiotherapy treatment, the associated technology has continuously improved into complex 3D irradiation techniques such as intensity modulated (IMRT) and volumetrically modulated (VMAT) therapies. In analogy to developments in the manufacturing industry towards Industry 4.0/IoT, ground-breaking inventions have shaped the development of radiotherapy. Electrification was the prerequisite for the X-ray tubes of Radiotherapy 1.0, while Radiotherapy 2.0 was enabled by the discovery of artificial radioactivity and the increased understanding of radiation physics. Computerisation supported imaging and 3D processing of irradiation plans in Radiotherapy 3.0. Radiotherapy 4.0 stands for a digitalised radiotherapy including intelligent user assistance systems [Figure 1](#). (Müller-Polyzou et al., 2019)

Radiotherapy 4.0 is characterised by integrated systems and services. The interaction of digital solutions is complex, and users are often confronted with several terminals for monitoring and control purposes. Additionally, users have to perform tasks in the radiotherapy work process with a high degree of mobility. In this environment, user assistance systems can help. Overall, the connected environment and availability of structured data in Radiotherapy 4.0 supports the meaningful application of user assistance systems.

2.1. User assistance literature

User assistance in radiotherapy is based on the information exchange between prevailing systems for data

Figure 1. Historical development of radiotherapy. (Reference blinded for review.)

processing, mining and management [Figure 2](#). The data is provided by data sources and sent to data sinks, for example, for control purposes. On the top of the pyramid are management systems such as user assistance systems supporting employees in radiotherapy departments with dashboards, data evaluation and control. The overall aim of user assistance in radiotherapy is to support the employees in the execution of their tasks described in the underlying core and assistance processes.

Several classifications of user assistance systems have been developed in Information Systems (IS) and engineering domains. Some classify by the nature of assistance or level of information provided. Others classify by the degree of autonomy, interactivity, or intelligence.

Reinhart (2017), for instance, distinguish between execution, perception and decision assistance. Execution assistance systems such as lifting aids assist in physical tasks. A lifting aid in radiotherapy can be used to position immobile patients on the LINAC couch. In contrast, perception and decision systems are classified as cognitive assistance. Cognitive perception assistance supports the five human senses, as for instance, a microscope in cancer pathology. Cognitive decision assistance supports complex decision making. Examples in radiotherapy are decision making systems used in treatment planning and quality assurance processes. This study focuses on cognitive decision assistance systems.

Aehnelt and Bader (2015) differentiate between five types of information assistance: (a) raising awareness by providing information about occurrences within the work environment, (b) operational guidance which filters complex information to a required minimum, (c) monitoring for the purpose of identifying quality issues, (d) documenting process steps and quality issues including tracking back functionality, and (e) guarding users from overload by balancing the level of information. Raising awareness, monitoring of quality issues and process documentation are important for the radiotherapy environment as it is

considered to be a high-risk area. The control of the treatment room with the LINAC is an example of such a system. Operational guidance and guarding the users are already used in treatment planning systems. According to Ludwig (2015) user assistance systems can be classified into three categories depending on their degree of autonomy: (a) automatic or background assistance, (b) assistance by supporting the user with an appropriate bundling of functions, and (c) assistance through decision support. This study considers all three types of autonomy. The classifications of Aehnelt and Bader (2015) and Ludwig (2015) can be applied to commercial radiotherapy systems. Systems such as room control and patient movement control provide a high degree of automation. They raise awareness, monitor quality and document the corresponding work process. Systems such as automatic tumour contouring and segmentation, bundle functions, while some of them additionally provide decision support. They provide operational guidance and balance the level of information for the users.

Morana et al. (2017) define user assistance in Healthcare Information Systems (HIS): “... as a people-, activity- and context-dependent augmentation of task performance by bridging the gap between technology and people’s capabilities to positively influence task outcomes.” They utilise the level of interactivity and intelligence of assistance systems according to Mädche et al. (2016) and define three corresponding modes based on the level of activity between the user and the system.

- Supportive mode: The system provides some information, but the user performs primarily the task. Such systems show low interactivity and intelligence.
- Cooperative mode: The system and the user perform parts of the task. Such systems are characterised by high interactivity and medium intelligence.
- Notifying mode: The system performs a major share of the tasks and the user is only notified on

Figure 2. Radiotherapy pyramid.

the progress and the results. Such systems have low to medium interactivity but high intelligence.

The classification of Morana et al. (2017) is applied in this study. The people-, activity-, and context-dimensions support the process-oriented analysis of the technology dominated radiotherapy. Despite the already existing user assistance systems, there is a continuous demand to improve efficiency and quality in radiotherapy. The understanding of the different occupational groups in radiotherapy (people dimension) is a prerequisite for the following analysis.

2.2. Occupational groups in radiotherapy

Approximately 20 employees of different occupational groups are recommended for a basic radiotherapy centre (IAEA, 2017). Radiation oncologists are responsible for the clinical evaluation, therapeutic decision making, treatment planning, execution, and assessment. Medical physics experts are responsible for the specification, commissioning, and quality assurance of technical devices. They also supervise and optimise treatment planning and assure the compliance with radiation protection legislation. Radiation Therapy Technologists (RTT), medical radiation therapists, medical imaging and therapeutic equipment technicians manage daily the treatment units, operate imaging devices (CT, MRT, PET-CT) and report patient's condition, oncology nurses, nursing professionals, nursing associate professionals, and healthcare assistants support radiation oncologists. They also assist patients during diagnosis and treatment. Further occupational groups such as biomedical engineers, radiation experts, environmental or hygiene experts, and administrative staff ensure the smooth operation of radiotherapy centres (WHO, 2017). The different occupational groups can be supported by user assistance systems. However, individual backgrounds, constraints and demands must be considered when designing these systems (Stephanidis et al., 2019). The design of user assistance systems also requires a profound understanding of the specific radiotherapy work processes and the situational context therein, while also taking into consideration the cancer patients with their individual health and stress situation.

3. Design Science Research

For the overall aim of designing user assistance systems for radiotherapy, we follow the Design Science Research (DSR) paradigm as an overall research design and already apply it in this work. DSR has proven itself to be an important and legitimate research design in Information Systems (IS) research (Gregor & Hevner, 2013). Furthermore, DSR allows

the consideration of practical components (March & Smith, 1995), which is especially relevant in practice-oriented research problems. The aim of a DSR project is to build new innovative artefacts that address unsolved problems or that are more effective or efficient than previous solutions (Hevner et al., 2004, Winter, 2008) and it is characterised by three inherent phases, namely the rigour, relevance and design phase (Hevner & Chatterjee, 2010). Rigour is included in DSR projects by following established research methods and incorporating existing theoretical knowledge. As Design Science Research project should be initiated with a relevance phase that provides the application context (Hevner & Chatterjee, 2010), we focus on the aspect of relevance in this work and present design requirements and design principles for assistance systems in radiotherapy. Benbasat and Zmud (1999) stress the importance of relevance in IS research and give a definition for relevance as “potentially useful for, as well as accessible by, its intended audience”. According to Hevner and Chatterjee (2010), a DSR project should identify design requirements from an application context for the design and the evaluation of an artefact. Based on the design requirements, design principles can be derived. With Design Science Research authors have proposed different frameworks on how to actually structure the project. Prominent examples include the ones by Kuechler and Vaishnavi (2008) as well as Peffers et al. (2012).

As mentioned before, bringing existing theories and knowledge into a DSR project is also of great importance. Another way of doing so is the integration of a so-called kernel theory into a DSR project. Walls et al. (1992) first defined the term kernel theory as “theories from natural science, social sciences and mathematics. In Gregor and Hevner (2013) “kernel theory refers to any descriptive theory that informs artefact construction”. For our research, we identify Business Process Management (BPM) as a relevant kernel theory. Van der Aalst et al. (2003) define BPM as “supporting business processes using methods, techniques, and software to design, enact, control, and analyse operational processes involving humans, organizations, applications, documents and other sources of information”. In addition, the authors define a business process management system as “a generic software system that is driven by explicit process designs to enact and manage operational business processes”. In a BPM project, one of the first steps is to clarify the business processes that are to be improved (Dumas et al., 2013). Therefore, we are first modelling the radiotherapy work process in this paper and then identify needs and opportunities for the integration and application of assistance systems. BPM has been successfully applied to healthcare process, e.g., in (Reichert, 2011), (Müller & Rogge-Solti, 2011), (Thabet et al., 2020) or (Lenz et al., 2012).

4. Part 1: radiotherapy work process

Based on the BPM life cycle as presented by Dumas et al. (2013), in order to be able to analyse and later improve a process, first the as-is process needs to be modelled.

The basic principle of radiotherapy is based on a process consisting of 3D imaging, therapy planning, and the treatment at the LINAC Figure 3. The associated work processes are not standardised, and specific variants are being used in hospitals and radiotherapy centres worldwide. Therefore, a detailed work process for modern radiotherapy must be modelled first so as to serve as a basis for the subsequent identification of value-adding user assistance systems.

Identifying the different work steps for the above-mentioned user groups is a prerequisite for relating user assistance systems to the potential sources of risks and inefficiency. Thus, the user assistance systems were selected on the basis of whether they address the weak points within the radiotherapy work process.

4.1. Radiotherapy work process modelling

In the past, flow chart process modelling was well suited for radiotherapy process modelling due to the sequential nature of radiotherapy activities. However, the number of interconnected digital systems and parallel activities has increased over time. (Reference blinded for review.) Furthermore, the different roles and responsibilities in radiotherapy need to be considered. Therefore, we have analysed the environment of modern radiotherapy with special emphasis on the involved occupational groups and the technical system environment. The goal was to represent the relation between people, data and equipment involved in the process of radiotherapy. The analysis was conducted in three qualitative interviews and one interactive group discussion with two medical physicists. After having analysed the process, it was divided into categories. In each of them the exact process steps were discussed and refined. Afterwards, the processes were

modelled in swim lanes reflecting the involved systems and users.

The process and its sub-processes were modelled using Microsoft Visio (MS VISIO, 2019). Finally, the processes were verified with the head of a medical physicist's team of an advanced private radiotherapy centre in Germany. As a result, we have modelled a comprehensive workflow for radiotherapy that represents the current state of art and can act as a denominator for the many individual workflows existing in radiotherapy cancer treatment. The radiotherapy process consists of one main process Figure 4 and five sub-processes (see Appendix). It starts with the cancer treatment workflow and the patient being sent to the radiological diagnostics department for diagnosis. Depending on the type of cancer, doctors' offices, or departments in different hospitals might be involved. Radiation oncologists, along with other specialised physicians, take an important role in tumour board discussions, where the final decisions about the therapy are taken. The following radiotherapy process provides an overview of the patient's journey within the radiation therapy department or centre Figure 4. Additional methods of treatment such as chemotherapy have not been considered, although they might be conducted in parallel. Consequently, this study focuses on radiotherapy and the corresponding procedures. The workflow has been divided into patient admission, imaging, treatment planning, verification, treatment and follow-up care. The identification of hypothetical user assistance systems focuses on these steps.

4.2. Areas of user assistance

Following the process modelling, the radiotherapy workflow was analysed. The goal was to identify potential improvement areas in terms of efficiency increase and risk reduction by the application of user assistance systems. Information from an interactive group discussion and reported incidents from the Safety in Radiation Oncology (SAFRON)

Figure 3. Basic principle of radiotherapy – work process.

Figure 4. Overview radiotherapy process.

database were considered in the analysis (IAEA, 2020). SAFRON is an international database which aims to show and draw attention to high-risk process steps. Although process workflows may vary between the radiation therapy departments, the risks are similar. In total, seven improvement areas were identified in the structured group discussion with medical physicists and healthcare engineers. The radiotherapy process served as a basis for the discussion and the result was summarised in a list describing each improvement area together with a brief description of the hypothetical user assistance system. In a following step, the seven hypothetical user assistance systems were discussed and verified in a qualitative interview with a medical physicist of a private radiotherapy centre in Germany. An additional user assistance system was identified in the discussion. Consequently, a risk management system for assessing the individual risk for patients was added to the list. Thus, in total eight user assistance systems were described and classified according to their interactivity, intelligence and activity mode as presented by Mädche et al. (2016) and Morana et al. (2017) Table 1. The classification provides general guidance for the development of artefacts according to the DSR paradigm.

5. Part 2: empirical study

The empirical study investigates the potential impact of the described user assistance systems in radiotherapy. It answers questions regarding the acceptance, the expected increase in efficiency, and risk reduction in the radiotherapy context. In the following, the study design, the sample group selection process, and the implementation concept are outlined. Afterwards, the questionnaire structure and the limitations of the study are explained.

5.1. Study design

A structured online survey was designed and implemented with LimeSurvey (LimeSurvey, 2017). The questionnaire was reviewed by experts and tested. The entire study was optimised for high acceptance by addressees (Schnell, 2019). The required time of ten to fifteen minutes to fill out the questionnaire was measured

beforehand and clearly communicated. A donation of 10 Euros to the German Cancer Aid Foundation for each completed questionnaire was used to increase the motivation (Deutsche Krebshilfe, 2019). Short, positive, and inviting wording was used throughout the questionnaire. The participants were continuously informed about the progress of the survey. Most questions were formulated as closed-ended or semi-open questions. Furthermore, by incorporating the “I don’t know” option, it was avoided that the interviewees felt urged to a specific answer. At the end of the questionnaire, the participants found a concise letter of thanks for their participation.

5.2. Sample group selection

This empirical study targeted medical physicists. Their supervising role in radiotherapy supports the holistic approach of this study. Medical physicists have a good knowledge of the IT environment and workflows, and interact with the personnel in the context of their safety and quality responsibilities. Following Raithel (2008), the random sample was selected from a list of radiotherapy centres in Germany provided by the German Society for Radiooncology (DEGRO). In total, 100 radiotherapy centres were contacted from which 50 ($n = 50$) fully completed the questionnaire achieving an overall response rate of 50%. In total, 58% of the participants were medical physics experts, while 42% were managing medical physics experts.

5.3. Implementation

The medical physicists were contacted individually by telephone in order to achieve a high response rate. This first telephone contact was followed by an Email containing the reference to the online survey. The survey was accessible for a period of three weeks in April 2019. After two weeks, the participants were informed via Email about the status of the study. At the same time, the medical physicists, who had not participated yet, were reminded. In general, the personal contact secured that the invitation Email was received and that only one medical physicist participated for each radiotherapy centre. After closing the survey, the data was imported to IBM SPSS Statistics Ver. 26 for analysis and documentation (SPSS Statistics, 2019).

Table 1. Hypothetical user assistance systems for radiotherapy.

Improvement area	User assistance system	Users	Type of assistance
Digital anamnesis	Patients can enter their anamnesis data digitally on a mobile device.	Patient	High interactivity Low intelligence Supportive
Patient positioning	User assistance with photographic documentation of patient positioning and support of patient positioning at the LINAC.	Radiation therapists, oncology nurses	High interactivity Medium intelligence Cooperative
Patient immobilisation	documentation of patient immobilisation devices at CT/MRT/PET-CT.	User assistance with verification and Radiation therapists, oncology nurses	High interactivity Medium intelligence Cooperative
Imaging information system	User assistance with information about type and location of tumours, displaying diagnostic images and providing information about the CT/MRT/PET-CT scan.	Radiation therapists, medical imaging technician	High interactivity Medium intelligence Cooperative
Patient validation	Patient validation at the LINAC with patient identifying technologies.	Radiation therapists, oncology nurses	Low interactivity High intelligence Notifying
Therapy planning and scheduling	User assistance to coordinate, document and monitor irradiation planning.	Medical physicists	Medium interactivity Medium intelligence Notifying
Appointment application	User assistance with appointment planning functionality.	Patient and administrative staff	High interactivity Medium intelligence Cooperative
	Risk management		
	User assistance that supports the monitoring, recording and archiving of relevant risk parameters.		
	Medical physicists		
	Low interactivity		
	High intelligence		
	Notifying		

5.4. Questionnaire structure

The overall questionnaire is structured in 12 sections. The welcome page introduces the survey and motivates for participation. The second section collects information about the participants regarding their job function, the type of radiotherapy centre

they work at, the number of locations and LINACs as well as the number of patients treated per year. The third section investigates the state of digitalisation. Digitalisation is regarded as a prerequisite for data generation and the corresponding use of user assistance systems. The analysis of the state of digitalisation of radiotherapy centres is based on ten questions that are divided in four categories. The first category pertains the use of an Electronic Health Record (EHR) which is considered to be the basis for digitalisation in healthcare (HIMSS Analytics, 2017). The second category consists of three questions related to the capturing of digital data. The third category includes three questions related to the aggregation and analysis of digital data. The final three questions form the fourth category and refer to the digital integration as such. We interpret the four categories as a digitalisation ladder representing the different levels radiotherapy centres can reach regarding their state of digitalisation. The set of ten questions is followed by one question analysing the perceived state of digitalisation of the own radiotherapy centre. Finally, two questions concern the perceived benefit of the integration of automated processes and cyber security. The following sections four to eleven deal with the hypothetical user assistance systems presented in Table 1. The application of each user assistance system is described. The questions asked are related to the perceived efficiency increase, risk reduction and willingness to use. One question was used to identify eventual technology preferences. The questionnaire ends with section twelve providing contact details and offering a feedback channel for the participants. The complete questionnaire can be found in the Appendix.

6. Research results

6.1. General overview

About 47.6% of the participants state that their centre is a private radiotherapy centre, while 42.9% are part of a public hospital and 9.5% of a private one ($n = 21$). Most of the radiotherapy centres operate in one location only, such as the radiotherapy centres in public or private hospitals that operate solely in one location. However, half of the private non-hospital radiotherapy centres operate in two or more locations Table 2.

On average 3.2 LINACs are operated in radiotherapy centres with a standard deviation of 2.5. The majority of radiotherapy centres in Germany operates two LINACs Table 3 as having a second technically equal LINAC is one accepted option for a failure concept demanded by the authorities (German Commission on Radiological Protection, 2020).

According to the participants ($n = 44$), the average number of patients treated per year and centre is 1.489 with a standard deviation of 1,071.5.

6.2. Digitalisation in radiotherapy

The following section provides empirical data on the state of digitalisation in German radiotherapy centres. The findings are based on ten questions that analyse the degree of digitalisation. About 64% of the participants state that they use a digital patient file in the clinical work process. The digital patient file (EHR) represents the first step on the digitalisation ladder that was developed based on the research results [Figure 5](#). This figure is high compared to the overall implementation of electronic health records in Germany (BertelsmannStiftung, 2018). A further analysis of the category “capturing of digital data” shows that 88% of the participants collect quality assurance data. However, only 34% record digital process data such as the time spent by patients in the waiting room. Also, only 30% of the respondents have a digital risk management system. About 56% of the participants confirmed that they aggregate, analyse and derive measures from aggregated data. However, only 16% of the participants have digital interfaces to patients. About 30% of the participants have digital interfaces to referring physicians or co-handlers and 62% to accounting offices.

Being asked for their estimation on the state of digitalisation of their radiotherapy centre, 36% of the participants believe that their centre is fully/a lot digitalised. An additional 54% believe that their centre is partially digitised. Only 10% regard their radiotherapy centre as little digitised. The reason could be that medical physicists relate digitalisation to the processing of quality assurance data. In total 74% of the participants see a benefit in the integration of automated processes. Only 12% do not see a benefit while 14% are undecided. Furthermore, a majority of 98% of the respondents say that cyber security is important/very important for radiotherapy. Cyber security can therefore be regarded as a prerequisite for user assistance systems in radiotherapy. The understanding of digitalisation in radiotherapy serves as a basis for the analysis of

Table 3. Number of LINACs in radiotherapy centres.

	Frequency	Percent	Cumulative Percent
Valid	1	5	10.0
	2	23	46.0
	3	11	22.0
	4	2	4.0
	5	3	6.0
	6	1	2.0
	7	2	4.0
	10	1	2.0
	12	2	4.0
Total	50	100.0	

the previously identified user assistance systems. The digitalisation ladder can be used in practice to determine the level of digitalisation of an individual radiotherapy centre and to identify the next reasonable step. For example, a centre that does not use a digital patient file should first implement one before investing into digital interfaces towards patients.

6.3. Digital anamnesis

Anamnesis is the collection of potentially relevant information in order to record the medical history of the cancer patient. About 76% of the respondents state that they document anamnesis data digitally and 22% document patient data on paper. In comparison to the 64% of the respondents using digital patient files, one can assume that a certain number of digital anamnesis forms are stored outside the digital patient file. A user assistance system is described that allows patients to enter their anamnesis data using a mobile device. About 10% of the respondents state that they would definitely use such a system. About 54% would consider using such a system. About 22% would not want to use the system and 14% are undecided. Therefore, a total of 64% of the respondents would consider using such a system. About 6% of the participants believe such a system would save a lot of time. About 40% believe it would save time and 20% state that it would save little time. Therefore, a total of 66% of the respondents believe that the user assistance system for digital anamnesis increases process efficiency. About 12% state that the system would not save time and finally 22% do not know. About 36% of the respondents believe that digitalisation of the anamnesis will reduce errors. About 18% believe it will reduce few errors,

Table 2. Cross table type of radiotherapy centre and number of locations.

			Number of locations			Total
			One	Two	> Three	
Type of RT centre	Part of a public hospital	Count	9	0	0	9
		% within type of RT centre	100.0%	0.0%	0.0%	100.0%
	Part of a private hospital	Count	2	0	0	2
		% within type of RT centre	100.0%	0.0%	0.0%	100.0%
	Private radiotherapy centre	Count	5	4	1	10
		% within type of RT centre	50.0%	40.0%	10.0%	100.0%
Total	Count		16	4	1	21
	% within type of RT centre		76.2%	19.0%	4.8%	100.0%

Figure 5. Digitalisation ladder of radiotherapy.

Figure 6. Radiotherapy process overview.

Figure 7. Admission process.

while another 18% say it will not reduce errors. Therefore, a total of 54% of the respondents believe that a user assistance system that allows patients to enter their anamnesis data using a mobile device will reduce errors.

6.4. Patient positioning assistance

Cancer patients are prepared at the CT, MRT, PET-CT for the radiotherapy treatment. Movable lasers project coordinates onto patients in order to mark them with

Figure 8. Imaging process.

Figure 9. Treatment planning process.

a waterproof pencil or a medical tattoo. The position of the patient at the CT, MRT, PET-CT has to be exactly reproduced for the treatment at the LINAC. The exact position has to be secured for every radiation fraction, up to approximately 30 times. First the participants were asked with regard to the overall meaningfulness of photographic documentation of the patient's position at the CT, MRT, PET-CT. About 54% of the respondents believe that it is very helpful. Another 44% believe it is helpful, thus

reaching an overall degree of consent of 98%. In the survey a user assistance system is described that documents the patient positioning using cameras installed at the patient table. The information is afterwards stored in the patient file and the images can be viewed on a mobile device in order to position the patient at the LINAC. In total 64% of the respondents would consider using such a system Table 4.

Understanding the underlying motivational factors, 66% of the respondents agree that the system will save

Figure 10. Radiation treatment part 1.

Figure 11. Radiation treatment part 2.

time and ease processes (22% agree, 44% agree partially). 12% agree less, while 16% believe it would not make documentation faster and easier. 6% are undecided regarding this question. 48% of the respondents express that the system would reduce errors, 20% state it would reduce few errors. 20% of the respondents believe it would not reduce errors and 12% are undecided.

6.5. Immobilisation device assistance

Repeatable immobilisation of patients and accurate patient positioning are a prerequisite for effective radiotherapy. A user assistance system is described that ensures that patient positioning at the CT, MRT, PET-CT, and the LINAC are congruent while automatically documenting the immobilisation devices

used. Cumulative 80% of the respondents state that they would use such an assistance system [Table 5](#).

Additionally, the participants were asked if the automatic documentation of the immobilisation devices reduces errors. About 4% of the respondents say it would reduce many errors. About 70% of the respondents believe that it would reduce errors. About 18% believe it would reduce few errors. Only 6% believe it would not reduce errors while 2% do not know. Therefore, a total of 92% of the respondents believe that the system will reduce errors.

6.6. Patient validation

In radiotherapy, it is of utmost importance to secure that patients are treated with the correct treatment

Figure 12. Radiation treatment part 3.

Figure 13. Follow-up care process.

Table 4. Stated usage of the patient positioning assistance system.

		Frequency	Percent	Cumulative Percent
Valid	Yes, definitely	4	8.0	8.0
	Yes, I would consider using it	32	64.0	72.0
	No, I would not want to use it	11	22.0	94.0
	Don't know	3	6.0	100.0
	Total	50	100.0	

plan. One can imagine demented patients who cannot verify themselves their identity to the treating personnel onsite. Patient validation is the process of securing the correct treatment by various means. About 22% of the respondents state that they already use a commercial system for patient validation ($n = 75$).

Table 5. Stated usage of the immobilisation device assistance.

		Frequency	Percent	Cumulative Percent
Valid	Yes definitely	11	22.0	22.0
	Yes, I would consider using it	29	58.0	80.0
	No, I would not want to use it	6	12.0	92.0
	Don't know	4	8.0	100.0
	Total	50	100.0	

About 68% of the respondents would consider using a patient validation system. Only 4% would not use such a system. Face recognition with camera (29.3%) and a patient card with printed barcode (24%) are the preferred technologies for patient validation Table 6. About 20% of the respondents believe that a system for

Table 6. Technology preferences for patient validation.

		Responses		Percent of Cases
		N	Percent	
Patient validation technology	RFID bracelet	3	4.0%	6.0%
	Barcode bracelet	8	10.7%	16.0%
	Patient card with printed barcode	18	24.0%	36.0%
	Fingerprint sensor	13	17.3%	26.0%
	Face recognition with camera	22	29.3%	44.0%
	Do not know	7	9.3%	14.0%
Others		4	5.3%	8.0%
Total		75	100.0%	150.0%

patient validation during imaging and therapy at the LINAC would save time. About 32% believe it would save little time.

6.7. Scheduling the therapy planning

Radiotherapy treatment planning is the process in which the medical physics experts, radiation oncologists and therapists create an individual treatment plan for a patient. The treatment planning process consists of different steps, so that the tasks for the involved staff members need to be scheduled. A user assistance system is described that schedules the tasks in terms of coordination, documentation and work monitoring. Cumulative 86% of the participants would use the described assistance systems [Table 7](#).

6.8. Appointment application

Due to the high costs, LINACs should be highly utilised. It is therefore important that patients keep their appointments and arrive on time. About 14% of the respondents state that they often experience unnecessary idle times at the LINAC. About 84% state that they do not. An intelligent user system is described that informs patients about upcoming appointments. The system could request confirmations and offer the option of integrating appointments into private calendars. Patients could communicate directly with the reception at the radiotherapy centre for appointment rescheduling. Cumulative 62% of the participants would use the patient appointment application [Table 8](#).

Table 7. Stated usage of the therapy planning scheduling system.

		Frequency	Percent	Cumulative Percent
Valid	Yes, definitely	24	48.0	48.0
	Yes, under certain conditions	19	38.0	86.0
	No, I would not want to use it	6	12.0	98.0
	Don't know	1	2.0	100.0
	Total	50	100.0	

Table 8. Stated usage of the patient appointment application.

		Frequency	Percent	Cumulative Percent
Valid	Yes, definitely	4	8.0	8.0
	Yes, under certain conditions	27	54.0	62.0
	No, I would not use it	15	30.0	92.0
	Don't know	4	8.0	100.0
	Total	50	100.0	

Furthermore, 59% of the respondents believe that the mobile communication with the patient before arrival helps to avoid delays or idle times at the LINAC.

6.9. Risk management

Risk management deals with the identification, analysis, evaluation, control, and monitoring of risks. In radiation therapy, risk management has gained importance due to new regulations (Official Journal of the European Union, 2013). A user assistance system is described that monitors, records and archives relevant risk parameters in radiotherapy. About 24% of the respondents believe that the use of digital process data is necessary for comprehensive risk management. An additional 38% of the respondents agree partially with this statement. About 18% agree less, while 8% do not agree. About 6% do not know. About 14% would definitely use such a system.

6.10. Discussion and validation

The goal of the research project was to identify improvement areas in terms of efficiency increase and error reduction by the application of user assistance systems in the complex radiotherapy environment. The hypothetical user assistance systems reach overall high values of expected efficiency increase and error reduction. Furthermore, all user assistance systems are accepted by the participants shown by values above 60% for the considered usage [Table 9](#).

The described hypothetical user assistance systems are in their specific context integrated into the work process. The results confirm the statement that 74% of the participants see a benefit in the integration. However, only 36% of the participants estimate their state of digitalisation as fully digitalised/a lot digitalised. The digitalisation of the radiotherapy centre is a prerequisite for the described systems. They need to be integrated into the core and assistance processes of radiotherapy. Their interactivity and intelligence depend to a great extent on data mining and processing capabilities of the radiotherapy pyramid [Figure 2](#). Only 16% of the participants have digital interfaces to patients. Digital interfaces to patients are a prerequisite for the appointment application system.

Table 9. Overview efficiency increase, error reduction and considered usage of the user assistance systems.

Improvement areas	Efficiency increase (save lot of time, save little time)	Error reduction (reduce many errors, reduce few errors)	Would use it (Definitely use it, consider using it)
Digital anamnesis	66%	54%	64%
Patient positioning assistance	66%	68%	72%
Immobilisation device assistance	–	92%	80%
Imaging information system	–	72%	64%
Patient validation	52%	– but 98% say it is helpful	90% – includes users already using it 86%
Therapy planning scheduling	–	–	–
Appointment application	58%	–	62%
Risk		management	–
–	76%		

Also, the value-add of the digital anamnesis system can be increased utilising connectivity outside the radiotherapy centre. Only 30% of the participants state that they have a digital risk management system, but 76% say they would use a risk management user assistance. The COVID-19 pandemic is likely to accelerate the development and deployment of risk management systems in radiotherapy.

In Germany, currently there is still a lack of data regarding radiotherapy specific errors. Assuming that the workflow in modern radiation therapy is similar in different countries, the collected data can be correlated to the data from the oncology-specific incident learning system RO-ILS of ASTRO (2019a). In the report Q1/Q2 2018, a summary of events occurred during treatment planning is given. It has been identified that 30% of the errors (starting from Q1 2014 until Q2 2018) arose because of errors during the treatment planning process. Mostly Radiation Therapists discovered the error (39%), followed by Physicists (28%) and Dosimetrists (11%). The contributing factors were organisational management (27%), procedural issues (24%), human behaviour (21%), and communication (20%). Often the data was poor, incomplete, unclear or missing (34%), the written documentation in the electronic medical record was incorrect, incomplete or absent (25%), and inadequate communication patterns were designed (23%) or a failure to request needed information occurred (7%). Taking this report into account, it becomes obvious that adequate assistance systems to improve communication, documentation and tracking can have a significant impact on patient's safety.

An empiric study of Kessel et al. (2016) on mobile apps in oncology unveiled that 84.3% of the interviewed health care professionals support the idea of an oncological app providing automatic reminders and timetables. The study also suggests the assessment of side effects and quality of life during therapy as important functions for user assistance systems. In total 75.0% of the health care professionals believed that a mobile app could be beneficial for the hospital.

A limitation of this study was that it was conducted only in Germany. The extension to other countries could produce different results because of national specifics such as occupational groups, the impact of regulations or cultural aspects. However, the technical infrastructure used in radiotherapy worldwide always incorporates digital imaging equipment and at least one therapy device. Therefore, a certain commonality of work processes is already given. Differences are expected in particular for different treatment techniques and specialised radiation machines. Furthermore, the research study was limited to the occupational group of medical physicists. Other occupational groups in radiotherapy might provide more detail on some research items. Furthermore, the research was broad in its set-up analysing with a specific focus the hypothetical user assistance systems along the work process. More detailed questions regarding single user assistance systems, in particular specific human-machine design features and usability aspects that play a vital role in healthcare applications were not analysed in this study.

7. Ensuring practical relevance in the design of assistance systems

The radiotherapy process modelling and survey on user assistance systems secured the relevance and context of application of our Design Science Research project. The hypothetical user assistance systems present new solutions for known problems in radiotherapy – thus, constitutes an improvement according to the classification by Gregor and Hevner (2013). Being currently between the stages of suggestion and development of the proposed artefacts we formulate distinctive common design requirements (DRs) based on the derived insights from the survey Table 10.

In a DSR project, it is the next step to formulate design principles (DP) that address all design requirements. It is good practice to also match them with existing literature as far as possible. Detailed design requirements and principles will be elaborated in subsequent projects and for specific user assistance systems. Associated evaluation criteria must be developed and considered in the further development of the systems. For this work, we formulate first comparatively abstract design principles that implement several of the design requirements DR1-DR10 as shown in Table 11. For the other DRs, individual DPs must be developed in future projects.

Table 10. Distinctive common design requirements.

Design Requirements	Description
DR1	The user assistance systems must increase efficiency in work processes of specific radiotherapy treatments.
DR2	The user assistance systems must reduce the risk for all involved groups in radiotherapy centres.
DR3	The systems must balance intelligence and interactivity for different user groups.
DR4	It must be optimised for usability and acceptance for different cultures and regions worldwide.
DR5	The users should always make the final decisions.
DR6	The system should increase patient comfort and well-being at all times.
DR7	The systems must ensure data privacy in the healthcare context and the integration must consider cyber security standards.
DR8	The system must be integrated into the risk management system, comply with valid standards and should be reliable.
DR9	The systems should be integrated with patients and referring physicians to maximise value.
DR10	The development must be documented for global certification at responsible national authorities.

Table 11. Distinctive design principles.

Design Principles	Description	Design Requirements
DP1	The systems must be integrated into data management, mining and processing systems within the radiotherapy centre.	DR 1
DP2	The system incorporates different user profiles with coordinated functionalities and provision of information. International language support is implemented, and GUI design considers culture specifics.	DR 4
DP3	The system only makes suggestions and the interface offers a choice of accepting the suggestion or making a different decision.	DR 5
DP4	The system implements guidelines according valid national data protection law, in Europe according to the General Data Protection Regulation (GDPR).	DR 7
DP5	The systems incorporate technical redundancy for well-functioning and secure user data in adverse situations. The system provides a secure technical interface for integration purposes.	DR 8
DP6	The system implements well-accepted and utilised standards with regard to IEC 14,971, IEC 62,304 and IEC 62,366, in case they are classified as medical products.	DR 8

8. Conclusions and outlook

In this paper we have analysed and presented the workflow in radiotherapy centres. In order to investigate degree of digitalisation and the use of assistance systems we conducted a study with 50 medical physicists in Germany. The overall project followed the DSR paradigm. Corresponding design requirements and principles were outlined. The findings motivate future research on the design of user assistance systems embedded in the radiotherapy work process to improve efficiency and reduce treatment risks. All suggested hypothetical assistance systems can help to improve the workflow and communication within the radiotherapy department. Due to the new regulations (EURATOM) and the obligation to record incidents and potential risks in radiotherapy, it will be interesting to follow the trend in errors occurring during the radiotherapy process. A further study, correlating the use of assistance systems with the occurring errors, would be informative.

Our detailed analysis of the workflow and the user-specific views collected in this study support healthcare providers to develop value adding user assistance systems for radiotherapy treatment, thereby helping to save lives in cancer treatment. Cancer is a truly global disease. Future research should analyse international aspects of user assistance systems for radiotherapy. In addition, more detailed research is required for the specific systems considering the rapid change of technology in the field driven among others by digitalisation, big data and artificial intelligence. Furthermore, aspects of data privacy and risk responsibility need to

be addressed to increase overall acceptance of the systems. Additional research focusing on the patients and their specific needs in their extraordinary treatment situation would support the design of user assistance systems that add value.

As a next step, we will further investigate the proposed assistance systems (Table 1) and identify one system that is most promising not only for practical application but also from a research point of view. For that, extended interviews with the involved parties are planned. Once we have identified a system, the aim is to design a prototype as an artefact based on the formulated design principles. Following the DSR framework (Gregor & Hevner, 2013), we will choose the appropriate framework, describe the artefact and evaluate it with practitioners from German centres. Another important topic for future research is an analysis on the transferability of our results to other European countries and worldwide. [Figure 6-13](#)

Disclosure statement

No potential conflict of interest was reported by the authors.

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Appendix Information on radiotherapy

Which function do you have within your radiotherapy centre?

- Managing medical physics expert
- Medical physics expert
- Medical physics expert in training
- Other

Your radiotherapy is ...

- Part of a public hospital
- Part of a private hospital
- Private radiotherapy centre

How many locations do you have?

- 1
- 2
- 3
- >3

How many LINACs do you have?

- 1
- 2
- 3
- Other

How many patients do you treat per year?

State of digitisation

Do you use a digital patient file in the clinical process?

- Yes
- No
- I don't know

Do you record digital process data? (e.g., time patient spends in the waiting room)

- Yes
- No
- I don't know

Do you collect digital quality assurance data? (e.g., measurement data of a LINAC)

- Yes
- No
- I don't know

Do you have a digital risk management system?

- Yes
- No
- I don't know

Do you aggregate the collected data digitally in a central location?

- Yes
- No
- I don't know

Do you evaluate the aggregated data?

- Yes
- No
- I don't know

Do you derive measures from aggregated data?

- Yes
- No
- I don't know

Do digital interfaces to patients exist?

- Yes
- No
- I don't know

Are there any digital interfaces to referring physicians or co-handlers?

- Yes
- No
- I don't know

Are there digital interfaces to health insurance companies?

- Yes

- No
- I don't know

Do you see a benefit in the integration of automated processes?

- Yes
- No
- I don't know

Please estimate the state of digitalisation in your radiotherapy centre.

- Fully digitised
- A lot digitised
- Partially digitised
- Little digitised
- I don't know

How important is cybersecurity for radiotherapy?

- Very important
- Important
- Less important
- I don't know

Digitised anamnesis

The recording of patient data is currently ...

- Digitally documented
- Documented on paper
- Not documented at all
- I don't know

Using mobile devices, patients could digitally enter their data into the anamnesis form themselves.

Would you use such a system in radiotherapy?

- Yes, definitely
- Yes, I would consider using it
- No, I would not want to use it
- I don't know

The digitalisation of the anamnesis ...

- Would save a lot of time
- Would save time
- Would save little time
- Would not save time
- I don't know

The digitalisation of the anamnesis ...

- Would reduce errors
- Will reduce few errors
- Will not reduce errors
- I don't know

Patient validation

Would you use a patient validation system in RT?

- Yes, I am using a commercially available system
- Yes, I would consider using it
- No, I would not want to use it

- I don't know

Which technology would you prefer for the patient validation system?

- RFID bracelet
- Barcode bracelet
- Patient card with printed barcode
- Fingerprint sensor
- Face recognition with camera
- I don't know
- Others

A system for patient validation during imaging and therapy at the LINAC allows ...

- Time savings
- Little time savings
- No time savings
- I don't know

Patient positioning

How helpful is the photographic documentation of the patient positioning at the CT|MRT|PET-CT for the patient positioning at the LINAC?

- Very helpful
- Helpful
- Less helpful
- I don't know

Cameras could be installed at the patient table documenting the patient's position and storing it in the patient file. The images can be viewed on a mobile device in order to position the patient at the LINAC. Would you use such a system?

- Yes, definitely
- Yes, I would consider using it
- No, I would not want to use it
- I don't know

The patient positioning system makes documentation faster and easier.

- I agree
- I partially agree
- I agree less
- I don't agree
- I don't know

Viewing the patient positioning on the mobile device will ...

- Reduce errors
- Reduce few errors
- Reduce no errors
- I don't know

Documentation of the positioning accessories

To ensure that patient positioning at the CT|MRT|PET-CT and at the LINAC is congruent, the immobilisation devices used could be automatically documented. Would you use such a system?

- Yes, definitely
- Yes, I would consider using it
- No, I would not want to use it
- I don't know

The automatic documentation of the immobilisation devices ...

- Will reduce many errors
- Will reduce errors
- Will reduce few errors
- Will not reduce errors
- I don't know

Information about the imaging

How often does it happen that exact information (e.g., size of image area or kind of tumour) about the CT|MRT|PET-CT scan is missing at the imaging device?

- Very often
- Often
- Less often
- Not at all
- I don't know

MTRAs could receive information about the type and location of the tumour via a mobile device. In addition, the mobile device could be used to view diagnostic images and retrieve information on the scan. Would you use such a system?

- Yes, definitely
- Yes, I would consider using it
- No, I would not want to use it
- I don't know

The use of mobile devices helps the user to create CT|MRT|PET-CT scans and helps to avoid unnecessary radiation exposure (e.g., due to multiple scans).

- I agree
- I partially agree
- I agree less
- I don't agree
- I don't know

Radiation planning

Would you use software solutions for the scheduling of irradiation planning?

- Yes, definitely

- Yes, under certain conditions
- No, I would not want to use it
- I don't know

Due to the high costs, LINACs must be fully utilised. It is therefore important that patients keep their appointments and arrive on time. Do you experience unnecessary idle times?

- Yes
- No
- I don't know

An information system could inform patients about appointments. It could request confirmations and offer the option of integrating appointments into calendars. Patients could communicate directly with the reception for rescheduling. Would you use it?

- Yes, definitely
- Yes, under certain conditions
- No, I would not want to use it
- I don't know

The communication with the patient before arrival using mobile devices helps to avoid delays or idle times at the LINAC.

- I fully agree
- I agree
- I partially agree
- I agree less
- I don't agree
- I don't know

Risk management

The use of digital process data is necessary for comprehensive risk management.

- I fully agree
- I agree
- I partially agree
- I agree less
- I don't agree
- I don't know

Would you use such a system in your radiation therapy?

- Yes, definitely
- Yes, I would consider using it
- No, I would not want to use it
- I don't know