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Electronic Health Record implementation in a large academic radiotherapy department: Temporarily disruptions but long-term benefits



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ABSTRACT

Purpose: To study the number of disruptions in patient processes in a radiotherapy centre after the replacement of an Electronic Health Record (EHR), integrating information tools for patient care and billing.

Mathods: Our self-made Electronic Medical Record was replaced by a pay EHR, including clinical path and

Methods: Our self-made Electronic Medical Record was replaced by a new EHR, including clinical path and workflow-management. A social-technological approach was used to reduce complexity. We measured disruptions in patient processes by the number and type of EHR related root causes and EHR-related incidents that reached patients, in our patient safety system 12 months before implementing the new EHR, 6 months after implementation (transition period) and 24 months after the transition period. We used Mann-Whitney U and X^2 tests to compare data before and after implementation.

Results: An increase of disruptions occurred only temporarily during 6 months. After this period, the number stabilized to the level before implementation while having more functionalities and benefits. Neither the number nor the severity of incidents reaching patients increased.

Conclusions: Disruptions in patient processes are considered as a main barrier for implementing an EHR. Using a social/technical approach, the increase in disruptions did only temporarily occur and did not reach patients. We think it is important to share this insight with physicians because literature shows that their long-term opinion regarding the usefulness of the EHR is often based on the experience in the first months after implementation. Management of expectations is recommended.

Advances in knowledge: This study is the first of its kind measuring long-term effects of EHR on patient processes in radiotherapy.

1. Introduction

Implementing an Electronic Medical Record (EMR) or an Electronic Health Record (EHR)¹ into a hospital is usually a very disruptive and complex process [1,2]. Nevertheless, in the Netherlands, hospitals have to implement an EHR/EMR to be compliant to law and regulations and to communicate digitally with partners in the care path. The EHR is viewed as the backbone supporting the integration of various information tools e.g. in radiotherapy the treatment planning system, the record and verify system, the document management system, the workflow system, the billing system etc [3]. However, hospitals can

make a choice to what extent they integrate all tools within the EHR. Gartner introduced a frequently used model describing different generations of EHR systems with different levels of functionality and integration. [4] This model is presented (simplified) in Table 1 [5].

In the Netherlands 4th and 5th generation EHRs with integrated decision-support systems have not yet been implemented. If we look specifically at the 20 Dutch radiotherapy centres we see that many of them do not have an EHR that integrates many information tools in patientcare in a coherent enterprise-IT-architecture model. Possibly this is because of expected complexity, or expected limited benefits of such an integrated configuration.

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¹ In this paper we use the definitions of the International Organization for Standardization (ISO) for EHR and EMR: an EHR is defined as a repository of patient data in digital form, stored and exchanged securely, and accessible by multiple authorized users [9,10]. The EHR contains retrospective, concurrent and prospective information and its primary purpose is to support continuing, efficient and high-quality integrated health care. An Electronic Medical Record (EMR), which is restricted to the medical domain, is according to the ISO included in this description as a type of EHR.

Table 1 EHR generations according to Gartner.

EHR generations

The first generation EHR systems combine data from different ancillary systems into a single integrated view

The second generation adds clinical documentation capabilities

The third generation adds order management, limited workflow capabilities, alerts and reminders

Fourth generation EHRs include full clinical workflow with decision support and knowledge management to develop an evidence-based care pathway

Fifth generation adds to this advanced interoperability, to take into account the capabilities and certifications of all resources involved in the provision of care

Implementation of integrated EHRs is complicated because a range of organizational and technical factors should be addressed to enhance the EHR's success. This includes human skills, organizational structure and culture, technical infrastructure, financial resources and coordination [1,6]. It is moreover challenging because of the complexity of medical data, data entry problems, security and confidential concerns, complicated and highly varied structures and processes, and workforce characteristics such as medical professionals with high levels of expertise, power and autonomy [2,7,8].

Therefore, several studies of EHR implementations have been performed to evaluate the effect of EHR implementation, with diverging effects. Viswanath et al. found that overall satisfaction among physicians, 3 and 20 months after implementation of an EHR, was lower than their pre-implementation expectations [11]. Other research findings also showed less satisfaction by physicians after implementing a new EHR [12]. Furthermore, several studies addressed actual output effects. These show a mixed picture of both advantages and disadvantages [13-15]. Some studies question the value of an EHR and their impact on quality of care and some even have found empirical evidence that health IT reduces clinical quality through workflow disruption or poor interface design [16,17]. Many EHR implementation studies have however been criticized because of data limitations and deficiencies in the used econometric estimation methods [15,16]. For example, there are only a few studies on EHR's workflow effects with a longitudinal design [11]. A disadvantage of short-term studies, is that it remains unclear if effects associated with mastering the new technology are confounding the results. In addition, despite the fact that radiotherapy is heavily data/IT based, only a few studies have been performed regarding the implementation of an EMD/EHR in a radiotherapy setting. These studies addressed only indirect consequences such as waiting time or conditions such as the need of support from senior health system management, corporate IT, vendors and guidelines [3,18-20].

In this study, we focus on the long-term (30 months) impact on patient processes of replacing a self-made EMR by a fully integrated EHR, i.e. integrating all existing systems used in patientcare, in a large academic radiotherapy institute in the Netherlands (300 employees and 4500 treatments, 54.000 radiation fractions, and more than 100 publications each year). The aim of the study is to evaluate disruptions in patient processes as a consequence of the implementation of a 3rd generation EHR, until 30 months after implementation. The secondary aim is to investigate which of these disruptions reached the patient.

2. Methods

2.1. Intervention: implementing the EHR

2.1.1. Implementation strategy

A new EHR (Hospital Information Exchange (HiX) version 6.0, Chipsoft, Amsterdam, The Netherlands) was selected, customized and implemented in 2015, using an integrated social/technical approach (Table 2).

Social aspects were included in the implementation process, since

Table :

Social aspects of the integrated selection, customization, and implementation process.

Social aspects integrated implementation approach

Radiation oncologist in a project leadership position together with an information manager to involve all physicians in all decisions

Broad involvement of all departments, both patient care and supporting departments Leading principle for all decisions: a fit between work practices and technology (Top)Management 's active involvement in the project and active support Establishing an interdisciplinary project organization with developers, vendors, employees, IT department and end-users

Identifying "champions" in the patient process who can function as a key user Transparent issue-list which also addresses the concerns of end-users Training and education program for every user and administrator (see 2.1.5)

these have been mentioned to reduce organizational complexity [2,8,21]. Obviously, EHR implementation is not only related to technical features of the system but also to the way it is implemented and how it affects processes, power, culture and finance. It is essential to pay attention to stakeholders and their expectations and attitudes towards the system. Therefore, we did not only take into account technological but also social aspects, such as assigning ownership of the implementation to physicians, because this allows close integration in the clinical care-path [8,21].

2.1.2. Selecting and customizing the EHR

The project was identified as a high priority project with appropriate resourcing

(€1, 3 million project costs: €650.000 licenses, €450.000 consultancy, €200.000 additional personnel costs), and led by a radiation oncologist and an information manager. A project organization was established consisting of a steering committee, a project team and several working groups with a broad participation of every department. Key users were appointed and a transparent issue list with concerns of the users was discussed on a weekly base within the project team to be decisive in solving problems. Fig. 1 shows how workgroups of the vendor and our institute were linked and worked together, module for module.

The vendor first adapted their existing module according to the requirements of the previous made agreement between the department and the vendor. Successive review days were organized during which a working group of the department assessed module progress. Finally, integration and acceptance tests were performed in a dedicated acceptance environment.

2.1.3. Characteristics of the EHR

The EHR consisted of 26 modules: The most important modules were: medical record, order communication, workflow with intelligent planning for the complete treatment process, medication, integration with the record & verify system at the linear accelerators, radiation treatment planning system to calculate 3D dose distributions, a connectivity platform including linked medical services, and finance & control (see Fig. 2 for the Enterprise IT architecture with EHR and connected systems).

The EHR replaced a self-developed (not integrated) EMR, the system to schedule appointments, the medicine prescription system, the system for reporting to referrers, the document management system and the self-developed billing system. The selection and implementation was based on the following principles (not present in the previous EMR):

- Technological characteristics: Simple architecture with as few as
 possible application interfaces, a uniform user interface and a single
 point of storage for all data. Benefits: less customized connections
 and less manual actions to transport data between IT applications.
- Care paths: Implementation of 12 disease-based care paths with uniform part(s), across care paths, customized care path specific parts and order-communication. Benefits: physicians are guided

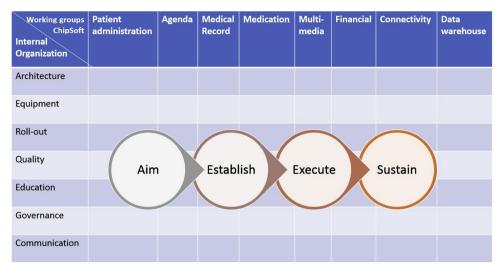


Fig. 1. Working groups vendor (Chipsoft) and internal organization.

through the administrative part of their work.

- Workflow: Workflow steps are incorporated in the EHR only if they are essential for the radiotherapy treatment process and specified in sufficient detail for them to be digitalized (including financial workflow f). Benefits: Variation in treatment, necessary to give patients the best (individualized treatment),is possible. Automated control mechanism for radiotherapy dose and medication prescription and administration. Benefits: less risk for errors, automated registration control and the possibility to pay only attention to deviations.
- Potential to support the research activities of the department. The system sets strict requirements to data capture and includes a single source of truth (SSOT). This is the ability to structure information models and associated data schema such that every data element is stored exactly once. Also integration with an underlying data warehouse is realized. Benefits: easy reporting and data accessibility for research and increased possibilities to capture a large amount of clinical data for prospective trials.
- Compliance to national requirements such as privacy and data exchange. Benefits: less complicated procedures to be compliant.

2.1.4. Management of the implemented EHR

Finally, the IT control organization was changed from IT driven towards business driven, with clearly split responsibilities for technical support (outsourced) and application support (IT department) and functional support (representation of EHR-user groups). The latter ensured a strong connection between IT and all the users of the EHR.

2.1.5. Training

Every user and administrator (150 in total) followed an extensive training program with compulsory classroom-training, E-learning modules and customized on-the-job training. These training activities were scheduled 4 weeks prior to the implementation. De training was given by own employees who were educated according to the "teach the teacher principle" and by the vendor.

2.2. Endpoints

The disruptions in patient processes were evaluated by the number of EHR related root causes of reported incidents and by the number of incidents that reached patients, in our patient safety incident report system [22–24]. Root causes are determined by analyzing all reported

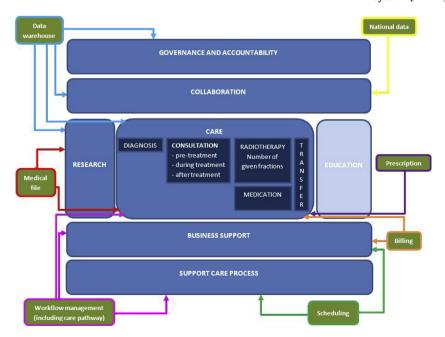


Fig. 2. New enterprise IT architecture. The figure shows the relation between the work domains of the organization (blue rectangles) and the most important functional domains of the EHR (green rectangles). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

incidents down to the source of the incident. EHR related root causes are thus the causes of all incidents that are thought to be related to the EHR. We discriminated two types of EHR related root causes:

- Insufficient communication through EHR between professionals in the treatment team, for example it is not clear in the EHR if the patient needs contrast fluid when making the CT-scan
- Imperfections of the system, for example some protocols are lacking.

An EHR incident in this study is "an unplanned EHR related event that reached the patient but did not result in injury, illness, or hurt of a patient".

We distinguished incidents that reached patients in:

- Incidents regarding medical treatment, for example the protocol for registering data about a pacemaker in the EHR is inadequate with the consequence that the radiation doses in the pacemaker is not sufficient assessed when making the treatment plan.
- Incidents regarding scheduling for example the appointment time in the EHR does not match with the time the patient is invited, with the consequence that waiting time is longer".

To strengthen conclusions, we measured twelve months before implementation (June 2014 to June 2015) and 30 months after implementation (July 2015 to December 2017). Because of the expected learning curve we counted a transition period of 6 months (July 2015 to January 2016).

2.3. Statistical analysis

We compared the period before implementation (T0) with the transition period (T1) and with the period after the transition period (T2) for both the number of EHR-related root causes and the number of EHR-related incidents that reached patients. All comparisons were made using the Mann Whitney U test. To study changes in the categories of root causes and incidents we used X^2 tests.

3. Results

3.1. EHR related root causes

Prior to the implementation of the EHR, we counted on average 52 reports per month (SD 14), with EHR as related root course. In the first 6 months after implementation, this figure showed a significant increase to on average 70 reports per month (SD 15; p=0.041) (Table 3).

Thereafter, the reported reports decreased again, to 61 per month (SD 35). The number of reported reports in the last period (T2) was not significantly different from the number reported prior to the implementation (T0).

The two outliers (T2, March and May 2017) were related to the implementation of the workflow for brachy treatments within the EHR (March 2017) and due to problems in the connection between the PACS and the treatment planning system when sending diagnostic images (May 2017). The latter problem was solved through an upgrade of the transferring software package.

As presented in Table 4, concerning root causes, the number of imperfections of the system increased significantly, relative to communication issues through EHR.

3.2. Incidents reaching the patient

The absolute numbers of EHR-related reported incidents reaching the patient did not show significant changes over time: prior to the implementation (T0) on average 7 reports/month were counted, in the transition period (T1) on average 9 reports/ months were counted, whereas in the latter period (T2) on average 5 reports/ month were

found (Table 3). None of these incidents resulted in injury, illness or hurt of a patient. Also proportion between the categories did not change significantly (Table 5).

4. Discussion

We showed that the implementation of an integrated EHR (3rd generation) in our large academic radiotherapy department, providing much more functionalities/ benefits than the previous self-made EMR, only temporarily caused more disruptions in patient processes during a limited transition period. There was no increase in incidents that reached patients. As root cause of incidents, imperfections of the system were reported relatively more frequently than communication issues through the EHR, whereas the type of reported incidents itself did not change over time. The implementation approach was characterized by considering a technological enterprise architecture with clinical path and workflow management, in combination with social aspects.

4.1. The importance of including social aspects

Research shows that organizational culture that supports collaboration and teamwork fosters the efficient and effective implementation of an EHR [2]. This is unsurprising as it is a general principle in literature regarding successful organizational changes [25]. Multi-disciplinary teams to deal with the EHR–related issues can, for example, prevent conflict and stimulate collaboration [2]. In our project, collaboration and teamwork was realized by the interdisciplinary project-organization, the integral management of both a physician and a business manager, and by a broad involvement from departments and senior management.

Also in our project, a leading principle for all decisions was the fit between work practices and technology. Previous findings show that this is crucial and that this requires an initial acknowledgement that an EHR implementation is not just a technological project but changes existing work practices [26]. This principle is covered in our study by the introduction of a transparent issue list with concerns of the users, the appointment of key users but above all by facilitating our healthcare professionals to develop their own future work system (clinical paths and workflow management).

Research also notes the important role that senior management plays in EHR implementation [8]. On the one hand it is argued that it helps if the implementation is led by physicians who can deal with medical dominance aspects that hinder collaboration, and to make sure that clinical staff participates at all levels and in all steps. On the other hand, it is important to have competent and experienced project leaders who are familiar with EHR implementation [2]. Our project management with both a physician and an experienced manager in the lead is in accordance with this principle.

In our approach, there was also a lot of focus on training and education. In research is often argued that this importance is underestimated and that inadequate training will create a barrier to successful implementation [27].

4.2. Benefits

Interventions in healthcare are meaningful if they contribute to more quality, or efficiency or safety or possibilities to be compliant to regulations.

The described benefits of the new EHR as described in the methods section can all be traced back to more functionalities and better technological infrastructure than the previous self-made EMR, in order to be able to improve output (quality, efficiency, safety or compliance.). We did not actually measure the improvement as output factors. In other studies this is sometimes (fragmented) done by medical errors, documentation time or other administrative tasks, guideline adherence, adverse drug effects, waiting time and so on with ambiguous

Table 3 Disruptions in the patient process at 3 different timepoints.

Before implementation EHR (T0)			Transition period (T1)			After implementation EHR (T2)		
Month	EHR related root causes of incidents	EHR related incidents which reach patients	Month	EHR related root causes of incidents	EHR related incidents which reach patients	Month	EHR related root causes of incidents	EHR related incidents which reach patients
Jul 2014	48	4	Jul 2015	72	17	Jan 2016	58	7
Aug 2014	58	8	Aug 2015	90	9	Feb 2016	50	8
Sep 2014	40	5	Sep 2015	63	6	Mar 2016	44	4
Oct 2014	56	11	Oct 2015	83	9	Apr 2016	41	5
Nov 2014	28	5	Nov 2015	62	7	May 2016	33	2
Dec 2014	50	9	Dec 2015	49	5	Jun 2016	42	2
Jan 2015	46	10				Jul 2016	30	4
Feb 2015	38	7				Aug 2016	30	3
Mar 2015	65	7				Sep 2016	37	6
Apr 2015	55	7				Oct 2016	32	3
May 2015	78	8				Nov 2016	43	3
Jun 2015	65	3				Dec 2016	32	2
						Jan 2017	55	0
						Feb 2017	72	5
						Mar 2017	181	4
						Apr 2017	70	8
						May 2017	144	13
						Jun 2017	76	7
						Jul 2017	64	7
						Aug 2017	45	8
						Sep 2017	70	4
						Oct 2017	80	11
						Nov 2017	71	6
						Dec 2017	63	6
Total	627	84		419	53		1463	128
Mean	52.3	7.0		69.8	8.7		61.0	5.4
Median	52.5	7.0		67.5	8.0		52.5	5.0
SD	13.6	2.4		15.0	4.5		35.5	3.0
P-value				T0-T1: 0.041	T0-T1: 0.616		T0-T2: 0.83	T0-T2: 0.078

conclusions [18,21,28,29]. We think this is due to many confounding factors influencing this kind of output. Nevertheless, regarding measurable output in the sense of process disruptions, in our study we found no significant difference before and after implementation, after the transition period.

We did not perform time measures because efficiency was not a goal of our implementation.

4.3. Disruptions in patient processes

Disruptions were measured by analyzing reported EHR-related incidents in of our patient safety system. The clinic has a long history with safety improvement with a high level of willingness to report incidents. Therefore, the reported incidents give a good overview of the disruptions in the patient processes.

Insight into the progress of workflow disruptions over time is necessary because in previous research this was found to be one of the major barriers to EHR implementation [21]. Our research showed that the increase of disruptions was only temporarily. In addition, the

number of incidents regarding medical treatment (80 in 3, 5 year) showed no significant changes over time. Given the 54.000 radiation fractions a year, in 0.04% of the fractions such an incident occurred, independently from the EHR implementation.

After implementation, imperfections of the system were reported relatively more frequently than communication issues as root cause of incidents. Probably this is due to the amount of added functionalities with added protocols that were not always completely worked out in all details when they were implemented. Because of these added functionalities, the stabilization of incidents after the transition period on the level before implementation suggests that the new system may actually reduce the number of "potential" disruptions. We have however no data available to prove that assumption.

It is important to incorporate the awareness of only temporarily disruptions while having more functionalities in the design of the implementation process, because it is empirically found that physician's decisions regarding the usefulness of an EHR are made very early, within the first few months of use of the EHR. These early perceptions then remain stable and become the lens through which subsequent

Table 4EHR related root causes at the different time points, split out in two categories.

EHR related root causes	T0 Before implementation EHR	T1 Transition period	T2 After implementation EHR	T0-T1 Chi square p-value	T0-T2 Chi square p-value
Communication through EHR	548	282	1007	p < 0,001	p < 0,001
	87%	67%	69%		
Imperfections system	79	137	456		
	13%	33%	31%		
Total	627	419	1463		
	100%	100%	100%		

Table 5EHR related incidents at the different time points split out in two categories.

EHR related Incidents	T0 Before implementation EHR	T1 Transition period	T2 After implementation EHR	T0-T1 Chi square p-value	T0-T2 Chi square p-value
Medical treatment	26	12	42	p = 0,290	p = 0,777
	31%	23%	33%		
Scheduling	58	41	86		
	69%	77%	67%		
Total	84	53	128		
	100%	100%	100%		

experience with the EHR is assessed [11]. We think dissatisfaction affects the further development of IT systems and the general work climate. To avoid this, we think it is very important to inform physicians in advance about the transition period of approximately 6 months with significantly more disruptions and the recovery afterwards. It is also important to not only communicate on the use of the technology but also frequently on its value, its fit and its necessity [11,30,31]. We think that rationalizing the usefulness of the EHR by evaluation on the base of jointly selected performance criteria is desirable.

4.4. Strengths and limitations

The main limitation of this study is its single-center character, which may affect the generalizability of the results. It is necessary to continue this study in other centers to investigate if our approach is reproducible. Nevertheless, because we measured during a long period, we think our conclusions are robust.

It is also a limitation that in this study, that real quality improvement for the patient is not measured because there are a lot of confounding factors, which cannot be eliminated. However, our described benefits to enable improved quality are crystal clear and we found that the number of incidents reaching the patient did not change.

Another limitation is that we did not investigate other large barriers such as time-efficiency by using an EHR. In previous research was found that documentation time could also be a barrier [32]. However, in the same study was concluded that an EHR can generate time savings in other activities such as accessing a patient chart or maintaining patient report forms.

The strength of this study is long term follow-up. We found that one of the largest barriers for EHR implementation, disruptions in the patient process, only temporarily occurred in our department, and did not reach patients while there is literature that the perceptions of physicians about the usefulness of the EHR are based on this period and do not really change after recovery.

5. Conclusions

The implementation of an EHR integrating various information systems, such as the treatment planning, workflow, billing etc. is complex because a range of organizational and technological issues must be addressed. A barrier for implementation of such an integrating EHR is the expected number of disruptions in patient processes. An approach, which focusses on both technological, and social aspects as well, can help reduce complexity and an increase of disruptions. We found in our study, using this approach that the mentioned increase of disruptions occurred but only temporarily. Furthermore, this increase was not present when looking to incidents reaching patients. We think it is important to share this insight with physicians because literature shows that physicians base their opinion on the usefulness of the EHR on their experience in the first months after implementation and often assess further decisions regarding the EHR through this negative lens. Because support of physicians is crucial for the performance of the EHR, management of expectations and dialogue about the benefits of the system needs continuous attention.

Summary points

What was already known on the topic:

- Implementing an Electronic Health Record (EHR), integrating all information tools for patient care and billing, is a complex process.
- An implementation approach, which focusses on both technological and social aspects as well, can help reduce complexity.
- An important barrier for the implementation of such an integrating EHR is the expected number of disruptions in patient processes.
- Overall satisfaction among physicians, 3 and 20 months after implementation of an EHR, is lower than their pre-implementation expectations.
- Physicians base their opinion on the usefulness of the EHR on their experience in the first months after implementation and often assess further decisions regarding the EHR through this negative lens.

What this study adds:

- This study is the first of its kind measuring long-term effects of an integrated EHR on patient processes in radiotherapy, which is a heavily data/IT based medical specialty.
- Long-term measurements showed no negative effects of EHR on patient processes. Using a social-technological approach, the increase of disruptions in patient processes after implementation occurred only temporarily during the transition period of six months.
- No increase in incidents reaching patients was observed.
- We recommend to use this information to manage expectations, in order to take full advantage of the increased benefits of an integrated EHR.

Contributions

All authors have made a substantial and direct contribution. M. Jacobs: main author, study design, literature review and coordination of the research. R. Mannens: data analysis, R. Swart: statistics, figures and tables. L. Boersma, A. Dekker, F. van Merode: critical revision of the manuscript for important intellectual content, B. Reijmen, F. Körver: important contributions to the methods section as former project leaders EHR. All authors contributed to writing the manuscript.

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