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Model for Evaluating the Implementation of a Third Generation EHR System

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Abstract. Most theoretical approaches to evaluate implementation of EHR systems origins from the time when EHR systems replaced paper records. When staff and management have many years' experience in use of EHR, the approaches to implementation is different. In this protocol paper we review the main implementation theories and discuss the adequacy for planning and evaluation of implementation of third generation EHR. Finally, we present a model to understand relations between leadership, the implementation of the EHR system in the individual clinical departments, the perception of the staff and the quality of care. The model is used to outline five hypothesis that can be tested in a specific evaluation project.

Keywords. Evaluation, Electronic Health Record, Implementation, Management

1. Introduction

The Region of Southern Denmark has decided to introduce a new Electronic Health Record (EHR) system at the hospitals in the Region in 2020 [1]. The hospitals in the region were among the very first hospitals to implement EHR systems to replace the paper record in the late 1980's. Different systems have been used, and the new system may be described as the third generation EHR system in the Region of Southern Denmark. The new system is intended to be characterized by a stronger collaborative model between vendors and users, improved semantic interoperability, and an increased emphasis on the problems, work tasks and needs of the users in a specific context [2]. It will be the primary IT tool for about 22,000 doctors, nurses, secretaries and other staff at the region's hospitals, consisting of the core elements:

- Clinical notes and record management
- Medication
- Requisition and answers from laboratory and imaging systems,
- Patient administration
- Booking.

Reviews about the impact of EHR systems have shown that good leadership and management, infrastructure support, staff training and focus on workflows and usability is important for the outcomes of implementing EHR [3].

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Hospitals consists of a large number of clinical departments each with its own management team. Often a department includes more than 200 employees and is an organizational unit with its own local management, even though all departments have a superior management in the directors of the hospital. Studies of the implementation of quality management systems and IT systems in Denmark and other countries have shown that the management of the individual departments are quite diverse and can make a huge difference to the implementation process in terms of variations in management skills, management goals, organizational tasks and responsibilities [3, 4]. A Danish case study of an EHR development process in the North Denmark Region also found differences between wards in the implementation and use of EHR systems [5].

Thus, the implementation of the EHR system in each of the clinical departments can be expected to vary with regard to the focus and importance that the management puts on the implementation and the amount of resources that is allocated during the process to make it a success. These differences between leadership styles in clinical departments in the same hospitals can be used to study the impact of management on the outcomes of implementation of a new EHR system.

In the hospital sector as well as in many other sectors, there have been massive challenges associated with the implementation of major information and communication technologies, ICT systems. It applies internationally in both the private and the public sectors and examples are abundant. Significant difficulties were encountered when large scale ICT systems were implemented in Massachusetts General Hospital in USA, Cambridge University Hospital in England, Copenhagen University Hospital in Denmark, and numerous other hospitals [4, 6].

There are many reasons why such implementation processes often go wrong, and the aim of this project is to develop scientifically sound knowledge of the different reasons for failures and to enable planning and actions that will increase chances of success.

2. Status of knowledge and theoretical approaches

The theoretical approaches to study implementation processes fall in three main research traditions:

- Change management literature
- Literature on diffusion and implementation of innovations
- Literature on the implementation of EHR systems

The first and oldest tradition has elaborated and tested general theories concerning how to lead change processes and took off with the work of Kurt Lewin in the late 1940s [7-9]. The second tradition is really a merger of the diffusion of innovations literature [10] and the implementation literature [11] which began in the 1960s and 1970s. This tradition has elaborated and tested theories concerning factors that generally tend to enhance or inhibit the adoption and implementation of innovations.

While the two first traditions have uncovered more or less general theories, the third and newest tradition took off in the 2000s and has focused on the implementation of EHR systems [3]. Thus, in the latter tradition the ambition is to uncover the drivers, enhancers and inhibitors of this specific type of change processes.

We have chosen to deliberately triangulate between the very specific research in EHR implementation and the more general theories of change management and the

diffusion and implementation of innovations. Combining and synthesizing these traditions, the research project can embrace the complex context of a hospital organization and thus develop important new insights. The three traditions represent decades of research and thousands of research projects and here we can only present the most conspicuous characteristics of the three traditions.

2.1. The change management literature

The change management literature is the oldest of the three research traditions. It has been characterized by a number of stage models more or less resembling and elaborating on Lewin's early unfreeze-transition-refreeze model [12]. The most influential has been Kotter's eight-stage model [13], which claims that successful change management follows eight steps: 1) Establish a sense of urgency; 2) Form a powerful guiding coalition; 3) Create a vision; 4) Communicate the vision; 5) Empower others to act on the vision; 6) Plan for and create short term wins; 7) Consolidate improvements and produce more change; 8) Institutionalize the new approaches. Very few studies have applied the change management perspective to EHR implementation processes. There is a review chapter relating this literature to health information systems [14] and two recent PhD dissertations based on qualitative interviews and using Kotter's and Lewin's framework [15, 16].

2.2. The innovation diffusion and implementation literature

While the change management literature focuses on leadership and management factors influencing processes of organizational change, the innovation diffusion and implementation literature has a broader focus on the factors that tend to influence the adoption and implementation of innovations across contexts [10, 17]. Thus, change management is seen as only one among many factors that influence successful implementation. In that respect, it resembles the EHR implementation literature presented below. Since this tradition is older than the EHR implementation literature and tries to generalize across the implementation of many different types of innovations, it has produced general theoretical frameworks, theories and concepts that are useful for the interpretation of the EHR implementation literature. The following list indicates the type of factors that hundreds of studies have found to be important to most implementation processes [17]: 1) Historical background of the intervention; 2) Design of the intervention; 3) Implementation actors; 4) Addressee response; 5) Other simultaneous interventions; 6) Issue networks and other environments.

2.3. The EHR implementation literature

The newest tradition is a specific EHR implementation research. Numerous studies have since the late 1990s examined factors related to success, failure and implications of EHR system implementations. This EHR implementation literature has been reviewed recently [3] and they organize their findings from 117 studies conducted between 1999 and 2017 in three categories: 1) Barriers to successful implementation; 2) Factors associated with successful implementation; and 3) Studies reporting on efficiency and productivity pre- and post-EHR implementation. The review reports empirical findings under these headings, but there are no or very little theoretical considerations and there are no attempts to relate the findings to the literatures on change management and adoption and

implementation of innovation presented above. However, among the studies in the three categories we have identified a number of areas that will be relevant to study.

2.3.1. Impact of EHR on productivity

Productivity is defined as the ratio between the output produced (e.g. number of admissions or surgical procedures) to the resources (e.g. number of medical doctors) used in production of health care [18]. Thus, productivity is equal to the number of outputs produced per input unit. EHR may have impact on the productivity of hospitals because EHR, on the one hand, may result in more accurate documentation, reduction in medical errors, improved quality of care and improved reimbursements [19]. On the other hand, there may be unintended consequences of implementation of new EHR systems that can have impact on the productivity, e.g. increased documentation time, interruption in clinical workflow and system errors in patient care [20].

2.3.2. Impact of EHR on clinical outcomes and safety

EHR may have impact on the clinical outcomes of the patients treated at the hospital and the safety of the patients. The review by Priestman et al. [3] describes a number of studies of the impact of EHR systems on clinical outcomes and point out that clinical impact depends on the setting. Whereas some studies have found positive improvements in clinical outcomes and safety others have found negative results. Similar to the effects on hospital productivity, studies have also found that impact on safety and clinical outcomes may return to baseline over 6-18 months.

2.3.3. Impact of EHR on patient satisfaction and perception

The introduction of the new EHR system in the Region of South Denmark will include a patient portal, where patients have online access to their own record. In addition, the patients will get the possibility to change their bookings for e.g. outpatient visits. Many of these features already exist in the national health portal "sundhed.dk" and if they replicate what already exist, it is relevant to evaluate the impact of the new system on the patients' perception of and satisfaction with the hospital services. A review by de Lusignan et al. [21] shows that the online access EHR services most utilised by patients are prescriptions, viewing the test results, messaging with their clinician, arranging referrals and rescheduling appointments. The review also describes that 16 studies have reported how patient experience and satisfaction with having online access to their EHR was high. The patients' perception of this service is mostly studied by use of interview or questionnaire to patients.

2.3.4. Impact of EHR usability on satisfaction and use

The Region of South Denmark envisions that clinical workflows are to be adapted to the solution to the largest extent possible in order to ensure most effective utilization of the new EHR, and to enable a fast implementation. This also emphasizes a streamlining of speciality specific workflows across hospital units. Such standardization offers long term benefits, but potentially amplifies the risk of alienating users by imposing changes to work and acceptance of a new information system simultaneously.

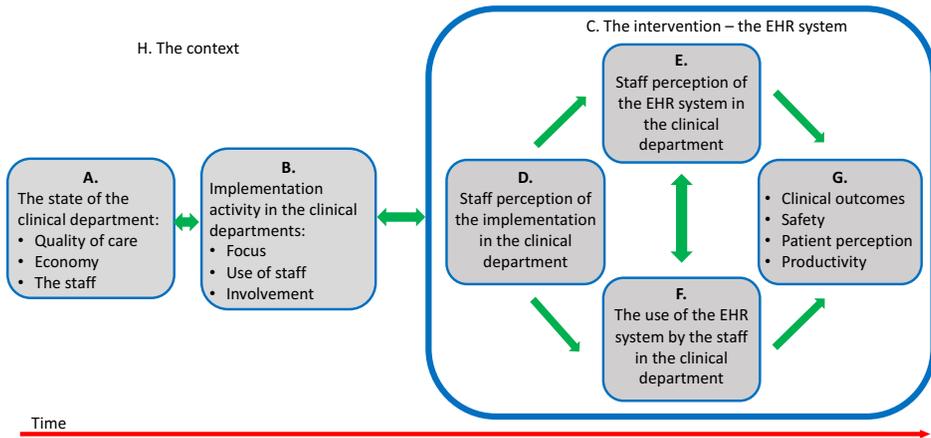


Figure 1. Relations between leadership, the implementation of the EHR system in the individual clinical departments, the perception of the staff and the quality of care examined in the study.

Several models for evaluation of the relationship between intention to use, and actual use are used in research today. DeLone and McLean’s “Information Systems Success Model” [22] includes elements of systems quality, information quality, intention to use, satisfaction, actual use, individual and organizational impacts, and has been deployed to evaluate EHR implementations in multiple studies [23]. The Technology Acceptance Model (TAM) by Davis [24] has been widely used to evaluate acceptance and use of new technology with an analysis of how the users believe the new system would enhance job performance, and the degree to which it would be easy to use. However, like any other widely used explanatory model, TAM has received its share of critique. Consequently, several modified models have been proposed, most noteworthy are TAM2 by Venkatesh and Davis [25] and the Unified Theory of Acceptance and Use of Technology (UTAUT) [26], both of these seek to improve social influences and facilitation conditions in the model. Holden and Karsh reviewed the use of TAM in a number of studies and reported that although the model predicts a substantial part of use and acceptance of health IT, several aspects relating to the healthcare challenge the use of acceptance models [27]: e.g., essentially information system usability permeates all models as an abstract level construct, rather than focusing on tasks and challenges specific to clinicians. Consequently, a more implementation-oriented approach may yield better insight into specific issues of the EHR system in question.

3. Conceptual model for studying implementation of third generation EHR

Based on the three research traditions and the four identified impact areas, we have elaborated a conceptual model to guide research in implementation of third generation EHR systems (Figure 1). The implementation and change management activities at the level of the clinical departments (B) and its impact on the staff’s perception of the EHR system (E) and, in the end, the impact on the quality of care, safety and productivity (G) is the central relation in our model. But the model also considers the impact of the state or point of departure within the clinical department with regard to the economic situation, quality of care and the state of the staff (A), the functionalities of the EHR system (C), the

perception of the implementation of the EHR (D), the use of the EHR among the members of the staff in the department (F), and the overall context of the health care system (H).

Based on the Hansen and Nørup approach [4], we will test five hypotheses:

- (1) **Hypothesis 1:** There is a positive association between initial support for an ICT innovation before the implementation and the perceived performance of the ICT innovation after the implementation.
- (2) **Hypothesis 2:** There is a positive association between higher levels of directive leadership of the employees during the implementation process and the perceived performance of the ICT innovation after the implementation.
- (3) **Hypothesis 3:** There is a positive association between levels of participation in the implementation process and the perceived performance of the ICT innovation after the implementation.
- (4) **Hypothesis 4:** There is a positive association between an implementation strategy that has been adapted to the specific department and the perceived performance of the ICT innovation after the implementation.
- (5) **Hypothesis 5:** There is a positive association between clinicians' use and satisfaction with the current EHR system, and the perceived usefulness and usability of the replacement EHR system.

Based on the literature we know however that the process will be influenced by a number of other factors than the leadership styles of managers at the clinical departments. A number of structural factors at the departmental level such as their resources and their staff (B) will determine the point of departure. It is also evident that the overall context (F) is important, and rises questions such as: How is multilevel governance practiced? How much support is given and how? What are the temporal characteristics of the implementation (e.g. who implements first and who last?)? And, of course, all theoretical approaches emphasize basic characteristics of the intervention (the EHR system to be implemented (G)) as an important factor to be considered. We are not only interested in the perceived outcome according to the users of the new EHR system (C and D), but also in the quality of care and in the patient's satisfaction with the system (E).

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