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ISSUES OF UNINTENDED CONSEQUENCES OF ELECTRONIC MEDICAL RECORDS: A PROPOSED STUDY FRAMEWORK

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Abstract

While Electronic Medical Records (EMR) or prominent features within EMR have been hailed as an important step for advancing healthcare, a number of studies have noted that its introduction also brings unintended consequences (UCs) to healthcare organizations. According to the literature, the most disruptive type of unintended consequences is related to workflow issues, in that its occurrence will impede work efficiency. Existing literature defines UCs inconsistently and identifies discrepancies in the results addressing UCs, particularly those related to workflow issues. This paper first proposes an integration and systematization of the existing literature on the unintended consequences of EMR (including its various definitions and classifications), and then constructs a framework of studying UCs associated with workflow issues using a mixture of qualitative and quantitative approaches. The main outcomes of a research based on this framework are: (1) a comprehensive understanding of workflow issues constituting the UCs pertaining to the study context, (2) a redesigned workflow addressing the workflow problems arising from the EMR implementations, and (3) suggested mitigation strategies addressing these issues The framework captures a series of phases for studying UCs relating to workflow issues. Our intended study will select a number of hospitals in a developing country as field sites and we also provide justification for our choice of the field sites.

Keywords: Electronic Medical Record, Medical Errors, Unintended Consequences, Health Information Systems.

1 INTRODUCTION

This paper identifies and discusses the issues of unintended consequences (UCs) in the use of Electronic Medical Records (EMR). EMR have been promoted for its ability to improve the performance of medical processes, practitioners and services as their design incorporate clinical guidelines. However, their impacts on health practices are not unanimous. Both the Computer Physician Order Entry (CPOE) and the Clinical Decision Support System (CDSS) are integral parts of EMR (Garets and Davis 2006). For example, the CPOE has been found to be associated with an increase in infant mortality rate (Han et al. 2005). It was also not reported to reduce adverse events in medication processes (Colpaert et al. 2006). Therefore with the use of EMR, medical errors persist. The emergence of reported medical errors may be associated with cognitive overload, loss of awareness to clinical situations, errors in data entry and retrieval, excessive reliance on IT, and disruptions of established workflows. These new risks are classified as the unintended and unanticipated consequences related to the use of EMR (Ash et al. 2004, 2007a,b, and Campbell et al. 2006).

There are several types of UCs in which the most disruptive concerns workflow issues (Ash et al. 2007a, 2007b, Campbell et al. 2006). Studies also reveal "new kind of errors" as one type of UC, not previously addressed. Interestingly, UCs are not always considered as errors (Ash et al. 2007a, 2007b), but may lead to errors (Campbell et al. 2006). On the other hand, there is also a discrepancy in the results of studies of UCs. While a number of qualitative studies have found the presence of negative UCs (e.g. "workflow issues" and the occurrence of "additional work for physician"), EMR have not been shown to significantly create workflow issues or additional work for the clinician, quantitatively. These results question the conditions under which the use of EMR would in fact cause UCs in healthcare. If there are UCs, are they associated with medical errors or adverse events? The American Medical Informatics Association (AMIA) Meeting 2009 indicated the demand to find and list several risk factors which correlate to UCs which aid in the development of predictive models for predicting UCs and explaining the extent to which UCs contribute to Health Information Technology (HIT) failure (Bloomrosen et al. 2010). However, progress in this area of research is limited and there is a lack of a structured framework to conduct studies on the UCs of EMR.

This paper proposes a synthesized review of the literature to present a clear structured view to stakeholders of the meanings, nature, classifications, and issues that constitute the UCs of using EMR. We summarize the existing studies that explored the impact of UCs to EMR use. Then, we propose a framework to study the UCs of EMR using mixed approaches within one study design.

2 LITERATURE REVIEW

2.1 Definition of UCs

Our literature search began in the medical informatics field (Medline®/PubMed) from 2000 to 2011. We used keywords "unintended consequences", "Electronic Medical Records", "Electronic Health Records", "Health Information Technology" and "Health Information System". Since "Electronic Medical Record" (EMR) is often considered to be similar to "Electronic Health Record" (EHR), thus this keyword is used to expand the probability of gaining appropriate manuscripts. The keywords "Health Information Technology" and "Health Information System" are also used to frame all the possible articles, as they represent the generic term for IT use in the healthcare field. In total, the literature search included 331 papers addressing UCs of "Health Information Technology", 301 papers of UCs of "Health Information System", 116 papers of UCs of "Electronic Medical Records" and 94 papers of UCs of "Electronic Health Records".

In social science, UCs (sometimes referred to as unanticipated consequences or unforeseen consequences) are outcomes that are not intended by purposeful action (Merton 1936). They are grouped into three categories: (1) Positive UCs are unexpected benefits which are not originally intended. (2) Negative UCs are unintended detriments occurring in addition to the previously intended effect of the policy or action. (3) Unintended consequences are also those effects which are contrary to the intended outcomes or negative outcomes.

UCs of IT in the healthcare are defined as silent errors related to information systems in patient care (Ash et al. 2004) that are not obvious. Campbell et al. (2006) defined UCs of IT (CPOE) as unanticipated positive or negative goals. They are not uniform errors/mistakes but are surprises that can span a spectrum from lucky to unfortunate. Ash et al. (2007a) distinguished between "unintended" and "unanticipated" consequences. "Unintended consequences" lack purposeful action, while "unanticipated consequences" refers to their inability to forecast eventual outcomes. A collection of varying definitions of UCs are presented in Table1. In this paper, we propose a working definition of UCs as "the unexpected outcomes that arise as a result of EMR introduction; these outcomes may either be positive/neutral (e.g. increase/maintain efficiency) or negative (e.g. silent errors). In either case, the consequences were never pre-planned." This working definition elaborates all previous definitions, considering that UCs can be negative or positive outcomes of using EMR which are silent, initially unexpected, and previously unknown.

Definition	Sources
Unintended outcomes of purposeful action (of healthcare IT)	Merton (1938)
Silent errors related to healthcare IT	Ash et al. (2004)
Unanticipated negative goal due to the use of healthcare IT	Campbell et al. (2006)
Lack of purposeful action of healthcare IT	Ash et al. (2007a)

Table 1. The Definitions of Unintended Consequences (UCs) of Healthcare IT

2.2 Types of Unintended Consequences (UCs)

There are at least nine types of UCs found by Campbell et al. (2006) and Ash et al. (2007a) (see Table 2). They found three common types of UCs: (1) extra work for clinicians (19.8%), (2) work flow issues (17.8%), and (3) never-ending system demands (14.8%). In subsequent studies (Ash et al. 2007a,b), workflow issue was rated important by the highest number of respondents. They listed several types of UCs of CDSS which exhibited elimination or shifting of the human role in work. Workflow issues, is an important and common example of UCs reported in the literature. Both Ash et al. (2007a) and Campbell et al. (2006) proposed new kinds of errors/risks as a category of UCs. Errors reflect the non-purposeful actions of a computer.

UCs of CDSS (Ash et al. 2007b) N= 95 Clinicians	**UCs of CPOE**	**% Frequency N= 324 Campbell et al. (2006)**	**Sample size Ash et al. (2007a)**
<u>Related to content:</u> Elimination or shifting of human roles Currency of CDSS Content Wrong/misleading CDSS Content <u>Related to presentation:</u> Rigidity of System Alert Fatigue Sources of Potential Errors	More/new work for clinicians	19.8	125
	Workflow issues(e.g. change or elimination of working steps)	17.6	149
	Never-ending system demands	14.8	143
	Paper persistence	10.8	N/A
	Changes in communication patterns and practices	10.1	146
	Emotions (e.g.feeling of anxiety or displeasure)	7.7	140
	New kinds of errors	7.1	82
	Changes in the power structure	6.8	61
	Overdependence on technology	5.2	138
	Total	**100**	**984**

Table 2 .Research Findings on the Type and the Importance of Unintended Consequences (UCs)

The types of UCs by Campbell et al. (2006) and Ash et al. (2007a,b) have been used as referential types of UCs in the following studies to date. The types of UCs had already been classified previously (Ash et al. 2007a,b, Campbell et al. 2006) using qualitative approaches (interviews of physicians about their EMR experience). In addition, a quantitative approach is needed in order to develop an empirical model to assist with the mitigation of these negative consequences. On the other hand, quantitatively, the occurrences of UCs were not proven to exist, especially the UCs related to workflow issues, which in qualitative findings were proven to be most important. Below, we will raise the inconsistencies in the existing literature.

Qualitative studies (Ash et al. 2004, 2007a,b, and Campbell et al. 2006) have shown that there are UCs of EMR of which workflow issues are the most disruptive type. Workflow issues (measured as time expenditures (Zheng et al. 2010)) are commonly indicated by the additional working sequences, elimination of specific processes, or change of working sequences. The use of EHR did not extend the time spent by a physician with patients (Pizziferri et al. 2005). Average times spent in patient care and administrations after EHR implementation were lower than pre-implementation periods by 0.5 minutes. This study found that EHR (an upgraded/integrated EMR) improved time efficiency. Hollingworth et al. (2007) showed that the use of e-prescribing (a feature of EMR) did not increase the combined computer and writing time for prescriber. Its use prolonged the time spent in computer tasks by 5.4 minutes/hour. E-prescribing tasks took marginally longer than handwritten prescriptions. If carefully implemented, e-prescribing will not disrupt workflow (Hollingworth et al. 2007). Further, the use of EHR increased the time spent in patient care across the specialty by 0.94 minutes (Lo et al. 2007) However, the time extension from using EHR was not significant (Lo et al. 2007).

EMR did not increase time in patient care but it changed the sequence of works and time allocation in every working step (Zheng et al. 2010). Finally, depending on implementation characteristics (e.g. workstation location, or mobile device capability), these changes may potentially disrupt workflow significantly (Zheng et al. 2010). Such studies used physicians' time in dealing with the patient as the unit of analysis. They were conducted using time and motion analysis by examining work sequences and time spent in each working step and they compared the results of pre and post EMR implementations. Their results showed that workflow issues and the emergence of additional work and time were not statistically significant as a result of EMR use. Furukawa (2010) used an efficiency perspective (measured by time spent in patient care) to find the impact of EMR sophistication level in a large scale study (N=364) of US Hospitals' Emergency Departments (ED). ED Length of Stay (EDLOS) was the unit of analysis. The level of EMR sophistication was associated with lower EDLOS. This research did not focus on the UCs specifically but rather on the impact of EMR to efficiency. Since extended time of patient care is considered as an UC, it was relevant for our literature review. In most cases, EMR definitely had a positive or negative impact on the time spent in patient care. However, there is no quantitative evidence on the existence of workflow problems which contradict the qualitative findings.

2.3 Literature Review Summary

Table 3 presents a summary of the relevant literature. The lack of clarity in the definition of UCs makes the operationalization of variables difficult. Since there is a discrepancy as to whether UCs are in fact medical errors or rather that they refer to events which lead to medical errors, it seems that the definition of UCs cannot be properly clarified by eliciting issues from clinical incident reports alone. These issues also need to be qualitatively verified by expert(s) for identification, confirmation, and further elabloration if needed. One type of UC is "new kind of errors". The addition of "new errors" indicates that UCs are medical errors or have possibilities which lead to medical errors, but there has been a lack of studies to explore whether UCs are medical errors or lead to medical errors. UCs are unexpected outcomes (positive, neutral or negative) that arise as a result of EMR introduction. Negative UCs are silent errors, or errors which are not obvious (Ash et al. 2004). "New kinds of

errors" are errors which are unpredictable or have not been found, they are unanticipated negative goals due to the use of health care IT (Campbell et al. 2006).

The most prominent type of UCs of EMR relates to "workflow issues". Workflow represents the sequences of work or steps in conducting work. They may need to be flexible depending on the medical guidelines (Lenz and Reichert 2007). EMR are designed to follow medical guidelines rigidly in terms of patient care which may impede the flexibility of a real clinical setting (Koppel et al. 2005).The implementation of EMR in a hospital will always have an impact on the workflow of the organization. The scale of the impact depends on the scope and complexity of the IT system itself (Ouvry et al. 2002) and the impact can be either positive or negative. Negative impact occurs when the EMR impede working progress, and decrease the performance and efficiency of work. Existing studies have only reported workflow issues qualitatively from the physicians' perspective reported from their experiences in using EMR, but they have not been proven quantitatively to be unfavourable workflow issues when measuring the efficiency/performance of work using EMR.

Source	**EMR Impacts on Workflow Issues**	**Research Methods**	**Variable(s) measured**
Pizziferri et al. (2005)	No association of EMR with additional work No association of EMR with extended time in patient care EMR does not change the time allocation significantly	Quantitative - case study, time and motion analysis comparing Pre-Post EMR	Time expenses in patient care, administration time
Hollingworth et al. (2007)	No association of EMR with additional work No association of EMR with extended time in prescribing EMR change the time allocation/sequences	Quantitative - case study, time and motion analysis comparing pre-post EMR	Time expenses in prescribing.
Lo et al. (2007)	No association of EMR with extended time in patient care significantly.	Quantitative - case study, time and motion analysis comparing pre-post EMR	Time expenses in patient care
Zheng et al. (2010)	No association of EMR with additional work/time. EMR change the time allocation/sequences.	Quantitative - case study time and motion analysis comparing pre-post EMR	Time expenses in patient care
Furukawa et al. (2010)	EMR sophistication level associates with time spending in patient care	Quantitative - survey regression	Length of stay (wait time and treatment Time), level of EMR sophistication.
Ash et al. (2007a)	EMR (CPOE) creates work flow issues and additional work for clinicians	Qualitative - case study respondents' perspective	N/A
Ash et al. (2007b)	EMR (CDSS) eliminates and changes work sequence.	Qualitative case study respondents' perspective	N/A
Campbell et al. (2006)	EMR (CPOE) creates workflow issues and additional work for clinicians	Qualitative - case study respondents' perspective	N/A

Table 3. EMR Impact Measurement from Previous Studies

3 PRELIMINARY FRAMEWORK FOR RESEARCH

Given the variety of UCs' definitions and contradictory research finding, we propose a multi-phase framework to initiate research in this area (see Figure 1). The purpose of phase 1 is to discover, extract and identify UCs to obtain a formal definition of UCs that can be operationalized for research. We defined UCs as "the unexpected outcomes that arise as a result of introducing EMR; these outcomes may either be positive/neutral (e.g. increase/maintain efficiency) or negative (e.g. silent errors). In either case, the consequences were never pre-planned". We used this definition as the basic understanding of UCs. Next step, we will begin to collect clinical incident reports and other reports associated with incidents, errors and performance of the hospitals. Our objective in this phase is to identify all unplanned events associated with the use of EMR which are either positive or negative. We will limit our elicitation to the events which are only associated with EMR, therefore we will also ask experts to give judgments on our chosen events. We will focus to elicit adverse events (negative outcomes).

Redwood et al. (2011) classified UCs by extracting all socio-technical medication errors from medication incident reports which are routinely collected by clinical risk management system staff.

These occur as a result of interaction between humans and computer. UCs can also be extracted from incorrect rules within a computer system, by reflecting on technical failure and the inability of technicians or users to follow standard procedures, recommendations or guidelines, which can lead to technical violations. These are reported as procedural errors in medication incident reports (Aron et al. 2011). Our proposed initial working definition of UCs (section 2.1) can be used as a starting point for extracting UCs from either clinical incident reports or expert opinions. The definitions of UCs refers to socio technical errors of EMR in which those errors reflecting human-computer interaction are not obvious (silent), and lead to unintended negative outcomes or system failures. This will include UCs of which all actions and interactions involving EMR which are not considered to be deliberate. In the end, we will classify and identify the triggers of all adverse events associated with the use of EMR as listed by Ash et al. (2007a,b) and Campbell et al. (2006).

In phase 2 (a replication of Furukawa 2010), we explore the impact of EMR on workflow. In this phase, we want to hypothesize from the work by Ash et al. (2007a,b) and Campbell et al. (2006), that the prominent type of UCs of EMR is workflow issue. If this hypothesis is not supported, other types of UCs will emerge. Since Zheng et al. (2010) stated that workflow issues are reflected and measured as time expenditures, we will measure the time spent in patient care. The study will also investigate whether EMR are associated with magnitudes of errors, and whether EMR will trigger new medical errors/risks. We hope to provide more insight as to how EMR system affects hospital activities. EMR use can be compared across hospitals using quantitative measures (degree of likelihood of wait time, treatment time and the magnitude of errors). In measuring the magnitude and the frequency of errors, we only focus on the errors and incidents associated with EMR or identified as socio-technical errors as found in phase 1.

In phase 3, we explore whether the use of EMR will trigger new errors/risks. This phase will validate phase 2 if there were evidence that EMR impact efficiency and are associated with the magnitude of medical errors. We will further explore results from the previous phase where there was no empirical evidence that EMR does not impact efficiency and medical errors. This level of study will use the case study approach using several different hospitals. Time and Motion Analysis (T&M) (Zheng et al. 2010) will be used to assess workflow fragmentation of each hospital's department by showing the time allocation of each working sequence and pattern of the work sequencing (what, when and how). T&M is proposed as the best study to observe workflow which is commonly used for exploring business process efficiency. For investigating whether the workflow issues relate to medical errors, fault tree analysis (FTA) is used to graphically analyze the antecedents of medical errors that will result in the occurrence of predefined undesired events (Stamatelatos and Caraballo 2002).

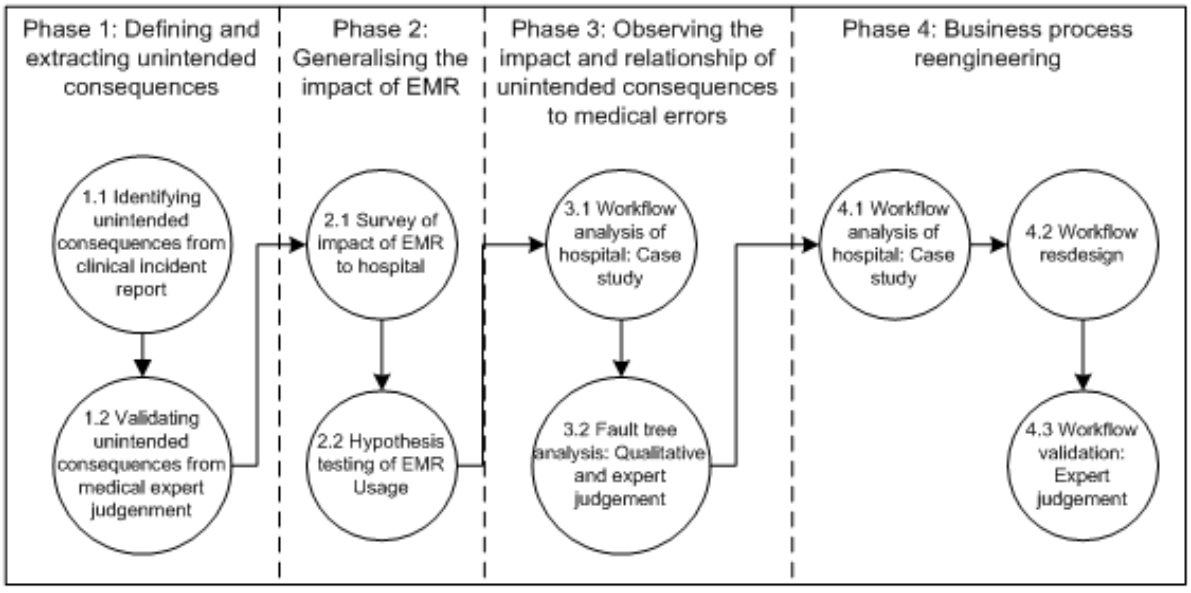

Figure 1.Preliminary Framework of Studying Unintended Consequences

Phase 4 is for solution generation, where we redesign the workflow by considering findings from previous phases. We begin workflow redesign by analyzing workflow for each work sequence in order to design the mitigation strategy in every work sequence. In phase 4, all stakeholders/experts related to those systems (e.g. physicians, hospital director, or departments' heads) will be approached for data collection. The proposed modified work sequences will be validated by experts (e..g. hospital directors and physicians) using the Delphi Method and cross assessment, and they will be represented graphically. Validation may require several continuous iterations by different stakeholders.

To date, studies of UCs were mostly conducted in developed countries setting. We are not aware of studies that have been conducted in developing countries where EMR and other Health IT have been newly introduced and implemented. The timing of such studies is important for practice as it will provide timely feedback to management of the effectiveness of the EMR introduction. This proposed research will be conducted in Indonesia accessible to the first author, where EMR in hospitals are at an early stage of implementation after the enactment of The Constitution in Electronic Information and Trade of The Republic of Indonesia 2008. This new initiative is fuelled by the hope that IT will improve health sector. It therefore encourages extensive use of electronic healthcare in the country. In Indonesia, physician density per 10.000 population is low (2.9), compared to a developed country like Australia (29.9) (WHO 2011). Also, hospital beds per 10.000 head of population are 6, while in Australia the number is 38 (WHO 2011), reflecting a higher hospital workload and demand for hospital care in the former. The conditions in Indonesia are therefore conducive for the study of UCs. Under poorer medical conditions/resources (e.g. facilities and medical personnel are scarce), UCs are more likely to occur, and EMR may ultimately make an impact on ED workflow (positive or negative). This research is scoped to study how we can overcome some of the UCs concerning workflow issues of EMR in Indonesian hospitals' ED setting.

4 CONCLUSION

UCs (e.g. workflow issues) are unexpected outcomes as a result of EMR introduction. We propose a framework for studying the existence and mitigation of unintended workflow issues/problems. We first seek how EMR affects the workflow and how these issues lead to further errors. A large scale quantitative study is employed to measure how EMR impact workflow. A qualitative method captures a deeper insight into how workflow issues lead to errors. The study of UCs will be conducted at both a macro and a case-specific level in order to gain depth and breadth in our understanding of UCs. The result will be a redesigned workflow that will be validated using expert judgment. A mixed method approach will provide a balanced solution to redesigning workflow around EMR implementations. The study will be conducted within a context of scarce resources where UCs will likely be prolific.

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