

Applying DEMO To Electronic Prescribing and Regulatory Compliance Within The English NHS: A Case Study*

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Abstract

Healthcare systems in most developed nations are dynamic, complex, and heavily regulated because of the nature of its activities and the implication for patient safety. In the UK, the National Health Service (NHS), a publicly funded health organisation is one such heavily regulated system, paid for by taxpayers' contributions and designed to ensure care is free and should be provided at the point of need. Since the 1990's there has been an increase in the regulatory requirements of the English NHS arising from systemic institutional failures as well as medication error, which have often led to the adverse effects for patients. Healthcare organisations thus have a duty of care and a legal obligation towards patients, while patients on the other hand have a legitimate expectation that an agreement reached between the patient and the healthcare organisation in the pursuit of a course of treatment will progress safely and achieve the agreed outcome. The paper summarises the current state of my thesis and how design and engineering methodology for organisation (DEMO) can be applied to electronic prescribing within the English NHS for the purpose of reducing the prevalent medication error as widely reported during prescribing and administration.

Keywords: Medication Error • Electronic Prescribing • Business Process Compliance Management.

1 Introduction

The many healthcare regulations in western economies can seem overwhelming to those whose task it is to provide care. The UK healthcare organisation is an example of a heavily regulated system designed to ensure that patients receive the level of care required for their safety and wellbeing. Since the 1990's there has been an increase in the regulatory requirements of the English NHS arising from systemic institutional failures, many of which have often led to the death of patients [19]. These institutional failures have led to an increase in the number of regulatory bodies, some with statutory powers, others as best practice with the sole purpose of placing a spotlight on the patients care throughout the journey [32]. However, there is also evidence of a disparate level of regulatory body all of whom play a role in the enforcement of patient safety standard. These organisations typically work in silos with little or no coordination thereby creating confusion of what is required of them [32]. The recent research by [32] suggests that there is no integrated approach to identify the many uncoordinated regulatory actors by which the NHS are required either by law, convention, and practice to comply with. This has often led to ineffective improvement efforts, overlapping of responsibilities and challenges with compliance efforts. To avoid compliance problems with the regulatory bodies, enterprises are putting more efforts into the compliance related activities and employ several compliance reporting strategies namely: design-time, run-time and auditing [25]. The design strategy is preventive and thus the focus of this thesis. In this stage, the compliance requirements are captured through a logic-based requirements modelling framework and propagated into business processes. Any non-compliant issues

can be detected in the early stages, thus saving an enterprise's efforts, time, and financial resources. [25]

2 Business Process Compliance Management

In complex high-risk industries such as healthcare, compliance is important. Healthcare compliance is the process by which service providers follow the rules and practices within healthcare. Business Process Compliance ensures that business processes are in accordance with relevant compliance requirements [35] such as the Human Medicines Regulations 2012, GDPR, Medicine Act 1968, Regulation 22 of the Health and Social Act, HIPPA and HITECH etc. While some observers believe that a form of oversight is needed because human lives and health are involved [17], others believe it has become too burdensome.[14]. Since its creation in 1948, the NHS is on record to have taken on numerous technological transformational projects with the aim of ensuring patient safety. However, the NHS digitization process has not always been successful. For example, the failure of the NHS to successfully implement the National Programme for IT (NPFIT) is an example [29]. This has been described as one of the biggest information technology failures in modern times [29]. The digitization project was designed to be the first NHS nationally implemented electronic health record (EHR) across NHS hospitals and General Practitioners. In 2011, the NPFIT was dismantled due to its failure to achieve its objective at a cost of over £12billion [6]. Not to be deterred by the failings of the NPFIT, the NHS currently has a five year forward review plan [27],[23] put together by various stakeholders(actors). Amongst the stakeholders are the Care Quality Commission, Public Health England and NHS Improvement, patient groups, clinicians and independent experts. The five year forward review plan is designed to digitize the health service by introducing the use of technology within the NHS. Among the technology being introduced within the healthcare sphere is electronic prescribing. This should not come as a surprise as reports suggest that there are a myriad of documents highlighting medication error as one of the major causes of medical errors [2].

2.1 Medication Error

The WHO [33] defines medication error as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, pack-aging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.”

Other authors have defined medication error as ‘a failure in the treatment process that leads to or has the potential to lead to harm to the patient [2].

In the UK over 273 million medication errors are reported to occur every year [38],[15], [16]. Apart from the financial consequences and burden on the NHS organisation, there is also the issue of litigation, as reports suggested that a 1/4 of all litigation claims in general medical practice were due to medication errors [2] often leading to the death of patients. Reports also suggest that these errors are made at every point of a patients journey with 54 percent made during the administration of the drugs and the other 21 percent made during prescribing and 16 percent during dispensing. The report also suggests that 1/3 of the potentially harmful medication errors are made in primary care during prescribing (GP, pharmacy, dentist, optician services) [15]

These statistics highlight serious concerns and the need for healthcare organisations to ensure compliance with relevant regulatory demands. Healthcare organisations as highlighted by [13], have a duty to build and design a safe business process that ensure that patients are safe from unintended harm. Healthcare organisations are therefore required to demonstrate that their business processes conform with the relevant regulatory demands, conventions or best practice in order to safeguard patient safety. In the UK, patient safety has become a matter of public and regulatory concern [19]. However, evidence suggest that the NHS still has a long way to go in effectively dealing with this problem. [28]

2.2 Purpose And Motivation of The Thesis

The main purpose of this thesis therefore is to investigate how design and engineering methodology for organisation (DEMO) can be applied to electronic prescribing and administration within the NHS for the purpose of reducing the prevalent medication error widely reported and thus assist in medication compliance. It will analyse the administration of medications by nurses, doctors, and their corresponding commitment to patients. In the UK over 273 million medication error are reported to occur every year [38],[15],[16]. This high level of medication error and the need for patient safety has seen the rapid transition from paper prescription to electronic prescribing.[1].

3 DEMO

DEMO is believed to be a methodology for modelling business processes that conceives organizations as social systems, consisting of an interrelated network of people in specific roles acting according to their specific responsibilities and authorities and coordinating their actions by means of communication. DEMO assumes, in line with the Language Action Perspective (LAP), that communication is a kind of action that creates commitments to act between actors” [7] This thesis focuses on the human centric approach to electronic prescribing and business process compliance using DEMO with particular reference to the commitment and transaction among the actors during the prescribing and administration of medication within and acute NHS hospital. To the best of my knowledge DEMO has not been applied within the NHS with reference to electronic prescribing and the reduction of inpatient medication error and will thus make a significant contribution to electronic prescribing and patient safety.

4 Related work

The perspective of DEMO in healthcare has been published in [22][10]. In my opinion, the view of DEMO in the NHS relating to electronic prescribing and business process compliance is yet to be fully researched.

5 Aim Of The Thesis

The overarching aim of this thesis is to apply DEMO to the business process compliance with reference to electronic prescribing within the English NHS healthcare system to avoid medication error and its corresponding adverse effect. DEMO will be applied to effectively capture the business process compliance requirements of medication prescription and administration amongst the stakeholders/actors during the patient journey in an acute foundation trust in the south east of England. Since its creation in 1948, the NHS is on record to have taken on numerous technological transformational projects with the aim of ensuring patient safety. However, the NHS digitization process has not always been successful. For example, the failure of the NHS to successfully implement the National Programme for IT (NPfIT) is an example.[29]

6 Problem Definition

Many studies to date have highlighted the prevalent level of medication error and the need for a stricter compliance framework. [31][26][21][30][30] However, despite continued effort to address this problem, hospitals in the UK and the rest of the world still record yearly cases of medication error thus putting patient lives at risk of possible adverse effect. [12][18] The introduction of electronic prescribing has been identified as a way of addressing medication error by moving from the use of paper prescription and the need to transcribe to electronically prescribing medication[38] [3][34][9][1][8][24] As with the introduction of any information system, the question of capturing the requirements to support the implementation of an information system or ensuring that the business process has been adequately complied with has been highly debated. Practitioners such as [11] are wary of the traditional waiter approach of requirement gathering, while various scholars and practitioners writing in the field of healthcare management have observed that the high level of systems not meeting the objectives of the organisations or the users has been due to sociotechnical factors such as ineffective change management, a lack of stakeholder engagement, unsuitable

software and outdated IT infrastructure [5][39][4], and others believe that sufficient attention has not been paid to the role of agile project management methodology for requirement capturing within the healthcare industry [20] or as cited in [22] that it is only by knowing what people do are we able to develop a system that supports their activities” .

Although many authors have highlighted the causes of medication error [9][7][31][21] there is insufficient information about the approach needed to ensure that an electronic prescribing system adequately addresses the prevalent error during prescribing and administration of medication. As part of the NHS digital transformation policy, NHS hospitals are expected to go paperless by 2023 while it simultaneously aims to become one of the safest healthcare systems in the world. The use of electronic prescribing has been identified as a means by which the NHS hopes to reduce medication and pre- scribing errors whilst addressing compliance demands. The NHS Dictionary of Medicine and Device (dm+d) is one aspect of ensuring compliance through e use of codes for standardisation of drug prescription and administration. While the use of technology is believed to improve patient care it is however believed to raise considerable challenges in ensuring patient safety [36] [37]. Digitisation presents unique challenges for compliance and in order to ensure the continuous guaranteed compliance the concept of compliance management needs to be considered during all phases of the patient journey during the administration of medication.

6.0.1 The problem

The high level of medication error and the need to streamline business processes for patient safety and regulatory compliance In the UK, patient safety has become a matter of public and regulatory concerns [20][21]. However, evidence suggest that the NHS still has a long way to go in effectively dealing with this problem [22]

6.0.2 Proposed Solution

The application of DEMO to electronic prescribing to improve the administration and prescription process of an NHS hospital in England to reduce the prevalent level of medication error and ensure compliance.

7 Overview of a prescription process

The process map represents a high-level description of a prescription process in a foundation trust hospital in the South of England.

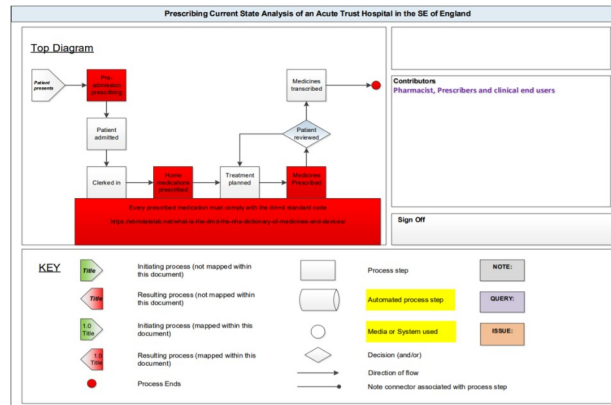


Figure 1: Sample of a prescription process

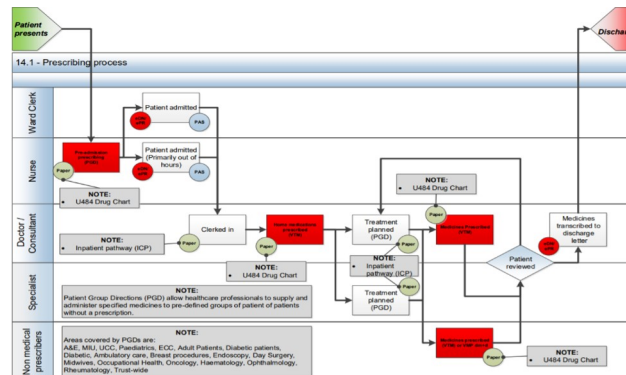


Figure 2: sample of a current prescribing process

8 Research Question

RQ1: The main research question for this thesis is: How can DEMO be applied to electronic prescribing in both outpatient and inpatients so that the electronic prescribing processes can be improved upon to attain business process compliance and a reduction in medication error.

9 Research Objectives

1. Assess the current state of medication error.
2. Assess the current state of regulatory compliance.
3. Identify all the activities that take place from the moment a patient is seen.

by the GP and referred to the hospital, up to the point where they are seen in a hospital, by a doctor, nurse and triaged, admitted, or discharged where medication is prescribed.

4. Identify all actors and their role involved in electronic prescribing along the patient pathway.
5. Define the concept of essential actors for the purpose of this thesis.

10 Research Methodology

The proposed approach takes the form of a literature review that highlights the challenges and issues which lead to medication error and non-compliance. An in-depth action research will be embarked on a major electronic prescribing process improvement effort that emphasizes the transaction and commitment of the identified actors in a healthcare organisation in England.

10.0.1 Data Collection

Desmond Benjamin and Co are a health IT company and owned by me and currently working with an electronic prescribing consulting firm who are currently implementing electronic prescribing at an NHS hospital.

11 Conclusion and state of thesis

I currently work in the healthcare sector where I am the lead technical developer for the implementation of electronic prescribing for one of the largest public sector healthcare organisations in the south east of England. I started my doctoral studies at Unilux three semesters ago as a part time doctoral student with 7 years to complete the programme. The time spent on my studies is aligned with my day-to-day tasks, where I spend 3hrs a week working one way or another towards my research. As part of my role I also ensure the prescribing system is configured and developed to prevent medication error (a focus of my thesis). I am still at the preliminary stages of my thesis and currently undergoing my literature review and will very much welcome feedback from the doctoral consortium.

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