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Designing better medicines delivery in the UK National Health Services (NHS)

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RESEARCH

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Abstract

Background
Prescribed medicines are delivered through a variety of routes to patients in the UK National Health Service (NHS) and are regulated by a host of health and trade related policy and law. These ensure the efficient and safe supply of medicines of appropriate quality from the pharmaceutical manufacturer through to the end-user, the patient. However, persisting medication errors and the recent discovery of counterfeit medicines in the bona fide supply chain have meant there are growing concerns about the timely, accurate and safe supply of medicines in the NHS.

Methods
This study undertakes a systems design approach to process modelling and understanding three key supply routes from the manufacturer through to the patient, across both primary and secondary care. A systems design approach was deployed to investigate complex interactions between professionals, products and processes to improve patient safety in collaboration with twenty five clinical and non-clinical stakeholders across the supply chain and six end-user patients.

Results
Several system process models were developed from the literature, field observations and alongside the interviewees. The results reveal that risk to medication safety is perceived as occurring most at the patient-end of the medicines supply chain: the pharmacy and the ward. There are differences observed in the responses of interviewees when they engage with system models.

Conclusions
This paper reflects on the use of a systems design, a mainly engineering approach, to understanding a health care domain problem of medication errors. The approach provided an enhanced insight into the complex set of system factors and interactions involved in generating medication errors. This study is among the first to develop a systems-wide view of the medicines supply process 'as-is' and identify opportunities for re-design to improve patient safety.

Background
Medication errors and the recent discovery of counterfeit medicines in the bona fide supply chain have meant there are growing concerns about the timely, accurate and safe supply of medicines in the NHS [1, 2]. A systems design approach, *Design for Patient Safety*, is advocated by Clarkson et al to consider complex interactions between professionals, products and processes to improve patient safety [3]. Prescribing errors have been described as the "single commonest cause of medical errors" and present a significant patient safety challenge for modern healthcare systems as they continue to persist despite policy and organisational interventions [4]. There are various definitions of what constitutes as a medication error, but there is consensus that it is essentially "a failure in the [medicine] treatment process that leads to, or has the potential to lead to, harm to the patient" [5]. This definition therefore includes errors of omission (absence of medication required to treat a patient) and commission (medication not used appropriately or as intended).

In the UK, the NHS is the sole healthcare provider where approximately 2.3 million medicines are prescribed each day [6]. However, to date the role of the pharmaceutical supply chain in medication error (or the medicines journey from the manufacturer through to the patient) and the associated risk in this process remains largely unexplored in the published literature. Studies have typically focused on aspects of supply namely the hospital pharmacy supply chain and its operational features and more recently on counterfeit medicines entering the bona fide supply chain [7, 8, 9]. Primary care supply routes have seldom been explored and the supply chain in its entirety has been ignored.

There are three main supply routes for prescribed medicines in the NHS, in addition to the growing and emerging supply of medicines through the home care and internet pharmacies path. In primary care, medicines are typically prescribed by a General Practitioner (GP) and taken by the

patient to be dispensed at a community pharmacy, if the GP is not a dispensing doctor (where medicines would have been dispensed at the surgery)[1]. There are two main types of pharmacy in the community, chain or independent pharmacies, but both carry out the same function of supplying and counselling patients about medicines.

In hospital (i.e. secondary care) medicines are prescribed by the doctor and screened by the pharmacist. They are then dispensed and checked in the hospital pharmacy. If the patient is being treated in the ward or other short stay departments, like the medical admission unit, they are sent by pharmacy to be self-administered by patients or administered by a nurse. If the patient is being treated on an out-patient basis then medicines are directly given to patients and they receive counselling on how to use them.

Both community and hospital pharmacies receive medicines from either UK or EU wholesalers or logistic service providers (LSPs) that are wholesalers that supply medicines to pharmacies on behalf of the manufacturer. Wholesalers and LSPs obtain medicines from pharmaceutical manufacturers.

Currently, the pharmaceutical supply process is regulated by the NHS and various supporting regulatory agencies such as the Medicines and Healthcare products Regulatory Agency (MHRA) and the NHS Purchasing Supply Agency (PASA) to ensure the safe, efficient and timely supply of medicines.

The aim of this study is to apply a systems design approach to understand the role of the pharmaceutical supply chain in medication error. This study is novel in using this to understand medication errors by modelling the journey that medicines make from the manufacturer through to the patient in the NHS. The power in this approach, advocated by Clarkson et al (2004), is that it engages both the researcher and stakeholders to consider the complex interactions between professionals, products and processes. Dieter and Schmidt (2009) argue that systems design facilitates the "evaluation of the performance of parts, products and systems" that can be considered as a central activity of engineers and systems designers to ensure the safe and efficient operation of organisations [10].

A series of systems models of this supply chain have been developed and used to investigate whether all parts arrive where they are needed at the required time, where the most risk lies, and how any changes in the process can reduce medication error from respondents across the supply chain. According to Pidd (2004) the main advantage of systems models is that they "make things explicit in such a way that understanding and change can occur" [11]. Therefore it can be argued that the systems design approach uses modelling to elicit an understanding of problems and provide answers/solutions to solve system problems.

[1] These tend to exist in rural communities where there are few pharmacies

This study is particularly timely as three major pharmaceutical companies have extended their control of medicines in the supply chain, by choosing to directly supply pharmacies with medicines, without traditional intermediary wholesalers. Instead, logistics service providers are contracted to distribute medicines on behalf of the company. It is likely that other pharmaceutical companies will follow suit in changing their supply arrangements. Although, the Office of Fair Trading (OFT) has considered the competition and cost implications of this scheme to the NHS [12], until this study, no formal risk assessment has been taken to understand the consequences of this change for patient safety.

Methods

Study Design

This study employed qualitative methodology mainly semi-structured interviews. Field observations of most parts of the supply chain (general practitioner practices, dispensing doctor practices, community pharmacies, hospital wards and hospital pharmacies) were undertaken to help develop accurate system models.

Participants

A combination of purposive and snowball sampling techniques were employed to identify participants. An informal stakeholder analysis was performed whereby participants were asked at the interview who they thought should be interviewed.

Twenty-five semi-structured interviews were conducted with a variety of stakeholders from the medicines supply chain, including pharmacists, wholesalers, pharmaceutical industry representatives, regulators and policy-makers. Fourteen of these respondents were healthcare professionals with clinical roles and eleven were regulators, industry and policy-maker representatives.

Six patients were also recruited in the study after ethical approval by Cambridge Local Research Ethics Committee was granted. Patient participants were recruited with the help of a local general practitioner who wrote to patients on behalf of the researcher. The first six patients who made contact with the researcher were interviewed.

Data Collection

Each interview was divided into two parts: a conventional semi-structured interview followed by a graphic elicitation session (method described in Crilly, 2006) [13]. In the first part of the interview, respondents were asked to comment on their awareness of medication errors, where they occurred, how they were managed and could be prevented. In the second part, a graphic elicitation session, interviewees were presented with system models of the supply chain. These models (developed from the literature and field observations) not only facilitated an interactive in-depth discussion about the current system (as respondents sketched or altered parts of the models) but also elicited the interviewees' perceptions of risk in the system as they used the models to identify or consider the most risk to medication safety in the process.

Analysis

Interviews were transcribed verbatim and analysed using the software N-Vivo (version 7). The models of the supply chain were edited to incorporate the interviewees' responses and a final top-level map depicting the supply chain in the NHS was developed by the researcher.

Results

Results overview

Healthcare professionals reported more awareness of medication errors and had tended to come across more potential errors than actual errors. One respondent commented that they had come across *"many* [errors] *but you know, one is enough in our book so, you tend to work along the principle that, you know, one is unacceptable"* (R14 Nurse).

In contrast, non-clinical interviewees reported anecdotal awareness or official notification of errors and some acknowledged that this was far from an accurate reflection of reality. *"I think there's a lot more goes on than we know, again I think it's been like an iceberg…the bit that is visible we know about. Unfortunately an enormous amount we don't know about"* (R1 Regulator).

When interviewees were asked where they perceived most medication errors to occur, 15 interviewees identified pharmacy as being more error prone, 7 considered hospital wards to be more risky and 3 felt that wholesalers and manufacturers introduced risk into the supply chain that continued through to the patient. An example response is; *"probably in the pharmacy dispensary. Very occasionally there'll be something, something wrong with the drug when it comes from the manufacturer"* (R13 Dispensing General Practitioner).

The six patients interviewed demonstrated a sophisticated understanding of the various ways they could obtain medicines. The patient cohort comprised of three women and three men aged between 40-80 years old. The average age of patients was 61 years old. Four out of the six patients used a repeat prescription collection service – an arrangement between the pharmacy and their general practitioner to have the medicines ready for collection, usually within 3 days of the patient's request. The remaining two took their prescriptions from the general practitioner to the pharmacy for dispensing. Half of the patients considered the lack of continuity of supply and foreign imports of medicines as a source of risk to medication safety as it could cause confusion when they were taking medicines, but on the whole patients (5 out of 6) were confident in the system, in particular the professionals, of ensuring safety.

Results in more detail

Using the supply chain system models led to a greater understanding of the current system 'as-is' by the researcher as opposed to official descriptions. There were very few comprehensive models or diagrams of parts of the supply chain and therefore asking respondents to help develop this was vital.

Several system process models were developed from the literature, field observations and alongside the interviewees. There were generic models that described the supply process at a high level, such as the model illustrated in Figure 1 and models that were specific to the supply situation such as hospital or community supply as depicted in Figure 2 and 3 consecutively.

There were differences observed in the responses from interviewees about risk in the system with the process models. Interviewees cited risk more widely than in the first interview part without the models. Risk was described as arising from the system and human factors: *"It's multiple factors actually I would say. So in that sense introduction to the physical environment, the introduction to the way that systems actually function in the pharmacy and even the computer, that to me was, was the first big stumbling block I had. I think culminating into that, also the staff that I had, day staff, weekday staff and weekend staff are totally different"* (R7 Pharmacist in response to figure 2). Some commented that risk was at every link: *"Well, the risks are based on the number of links in chain and whether we understand"* (R4 Regulator in response to figure 1). This was in comparison to the interviews where there was a heavy bias on pharmacy and the ward for being the most responsible for medication errors. *"The dispensary [hospital pharmacy] is the main worry because of the errors they bring to the ward"* (R15 Nurse in response to figure2).

Furthermore, interactions between staff, medicines and stages of the supply chain were pinpointed as introducing risk more than at interview alone and respondents tended to give multiple reasons for risk rather than single reasons. Previous interview responses were also expanded so for example if the pharmacy was identified as being more responsible than issues such as imported medicines from Europe, inappropriate medication ordering by the elderly or poor communication with prescribers was described. Similarly for the ward, its layout and multiple locations of medicines, the delay and complexity of the discharge process were recognized.

There were no observed differences in the role of the interviewee to their ability to engage and think about systems design. For example, one patient on seeing Figure 2 (the hospital process model) remarked: *"Gosh that's a long journey for a medicine"* (P1 Patient in response to figure 1).

Collectively interviewees identified that there were a lack of safeguards built into the system, which meant that not only did the detection of medication errors at each step become more difficult but there was concern that as errors made their journey to the patient they were compounded. For example, one pharmacy respondent in hospital noted that *"for every drug we dispense, there is how many administrations? and so you could have the same administration error repeated over and over a time from one supply"* (R6 Pharmacist in response to figure 2 and 3).

Furthermore, most respondents felt that more needed to be done to deal with the threat of counterfeit medicines in the bona fide supply chain, as they noted many possible entry points on the systems models. "I would say it can enter the chain at the wholesaler level and also at the pharmacy level mainly, which is worrying because of high levels of parallel imports" (R3 Manufacturer in response to figure 3)

A reduced amount of medication error from counterfeits and lack of continuity of supply was considered by some non-clinical interviewees by the new changes of supply by manufacturers through logistic service providers. It was argued that the manufacturer had the line of sight of the medicine through to the pharmacy, which conferred greater safety. This was not a view shared by healthcare professionals, who instead on the whole tended to be more cynical about the new supply arrangement as the threat of counterfeits was still posed by parallel imports.

Discussion

Systems modelling is a key feature of understanding and improving systems design. Systems modelling with stakeholders means the current performance and behaviour of a system referred to the 'as-is' process model can be understood and evaluated. Furthermore, 'to-be' process models can be created alongside stakeholders and used to guide the implementation of system changes [13]. This paper has reflected on how the systems design approach can be applied to understand a health care domain problem of medication errors. Process models that are powerful in their ability to provide both simple and detail graphical accounts of a system have been used in a hierarchal fashion to uncover system design issues that contribute to medication error.

The iterative modeling approach alongside the participants meant that this approach allowed all those engaged to consider the issues at the heart of a problem more widely and deeply (as has been demonstrated in the responses of interviewees upon reflection with the models in the interview). For example, emphasis was placed on interactions between staff, medicines and stages of the supply chain when participants actively annotated models. One possible reason could be that the process allowed interviewees more time to think and respond or that the system models highlighted previously unexplored interactions or connections in the system. These more detailed responses led to a more sophisticated analysis of why medication error persisted and how these could be minimized without unbalancing the system to improve safety.

The results reveal that risk to medication safety is perceived as occurring most at the patient-end of the medicines supply chain: the pharmacy and the ward. Although this study has attempted to touch on the role of the wider supply chain, risk perception is still focused on administration of medicines by nurses and dispensing by pharmacies. This perhaps reflects an attitude that automation of the processes involved in the earlier stages of the supply chain conferred greater safety. Both for the ward and pharmacy, workload and task issues seem to compound the risk of error revealing that strategies that focus on the pathways leading to the pharmacy and ward should be considered with an equal weight in comparison to previous strategies that tended to focus on the ward or pharmacy in isolation. It is important to consider that the small sample size and purposive and snowballing sampling technique may have introduced bias into the results. A larger study may overcome this.

The risk of counterfeit medicines still continued despite changes in the manufacturer's supply of medicine through logistic service providers owing mainly to sophisticated counterfeiting techniques and parallel import channels of supply. Therefore, more evidence is needed to see if the scheme will improve safety and help deal with supply issues. It is important to point out that the scheme only relates to branded medicines (75% of the medicines market; OFT, 2007), safety related issues with generic and unlicensed medicines are yet to be addressed.

Furthermore, interviewees were concerned by the lack of safeguards present that allowed medication errors to go undetected to the patient. More safeguards that were embedded in the system were called for rather than relying than on checking and vigilance by staff, which under certain circumstances was difficult to maintain at the desired level. Careful re-design is required to truly embed safety in a seamless manner rather than 'add-on' attempts to place more safeguards.

Although not necessary, it is useful for the researcher to possess some technical ability with graphical software programs to help assist with the model drawing process. This may put some researchers off from using this approach. Also the iterative modeling required can be time consuming but the benefits of this approach in eliciting more detailed responses (in comparison to qualitative interviews alone) allows researchers to gain insight into how stakeholders believe the system operates. More specifically, in this study it was possible to understand how medication error arises in the pharmaceutical supply chain.

Conclusion

This paper reflects on the use of a systems design, a mainly engineering approach, to exploring the role of the pharmaceutical supply chain in medication error. The approach provided an enhanced insight into the complex set of system factors and interactions involved in generating medication errors and therefore successful in highlighting opportunities for re-design to improve safety. A wide number of stakeholders were engaged, including patients, demonstrating the flexibility of this approach to health care research.

Patients receive their medicines from a multitude of routes in the medicines supply chain, but the current chain lacks integration. More system safeguards that were seamlessly embedded were called for to minimise the risk from

medication error and counterfeit medicines. Further risk management and systems design research is required to help improve patient safety in delivering medicines in the NHS.

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PEER REVIEW

Not commissioned; externally peer reviewed

CONFLICTS OF INTEREST

The authors have no competing interests to declare.

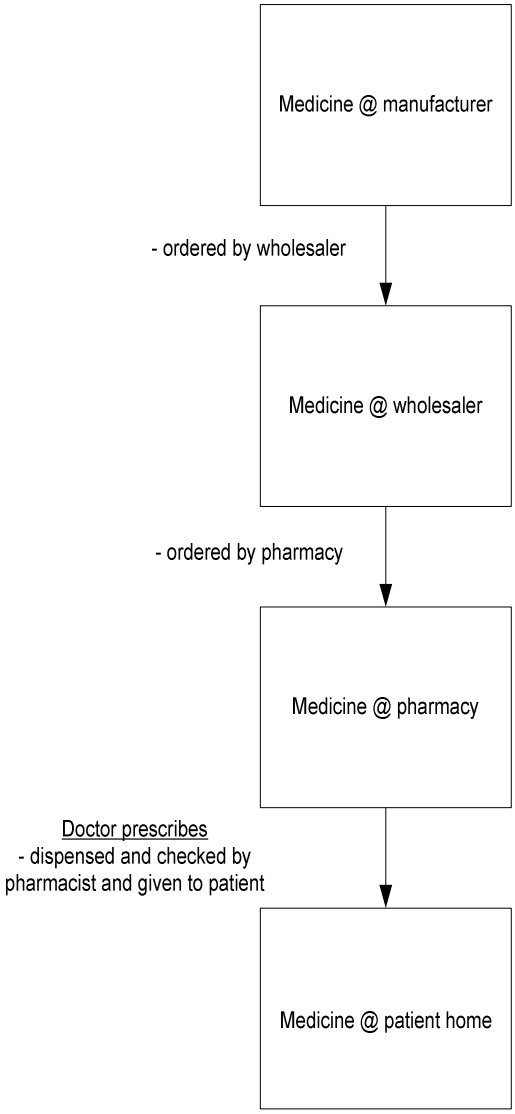

Figure 1: Process model of generic supply process

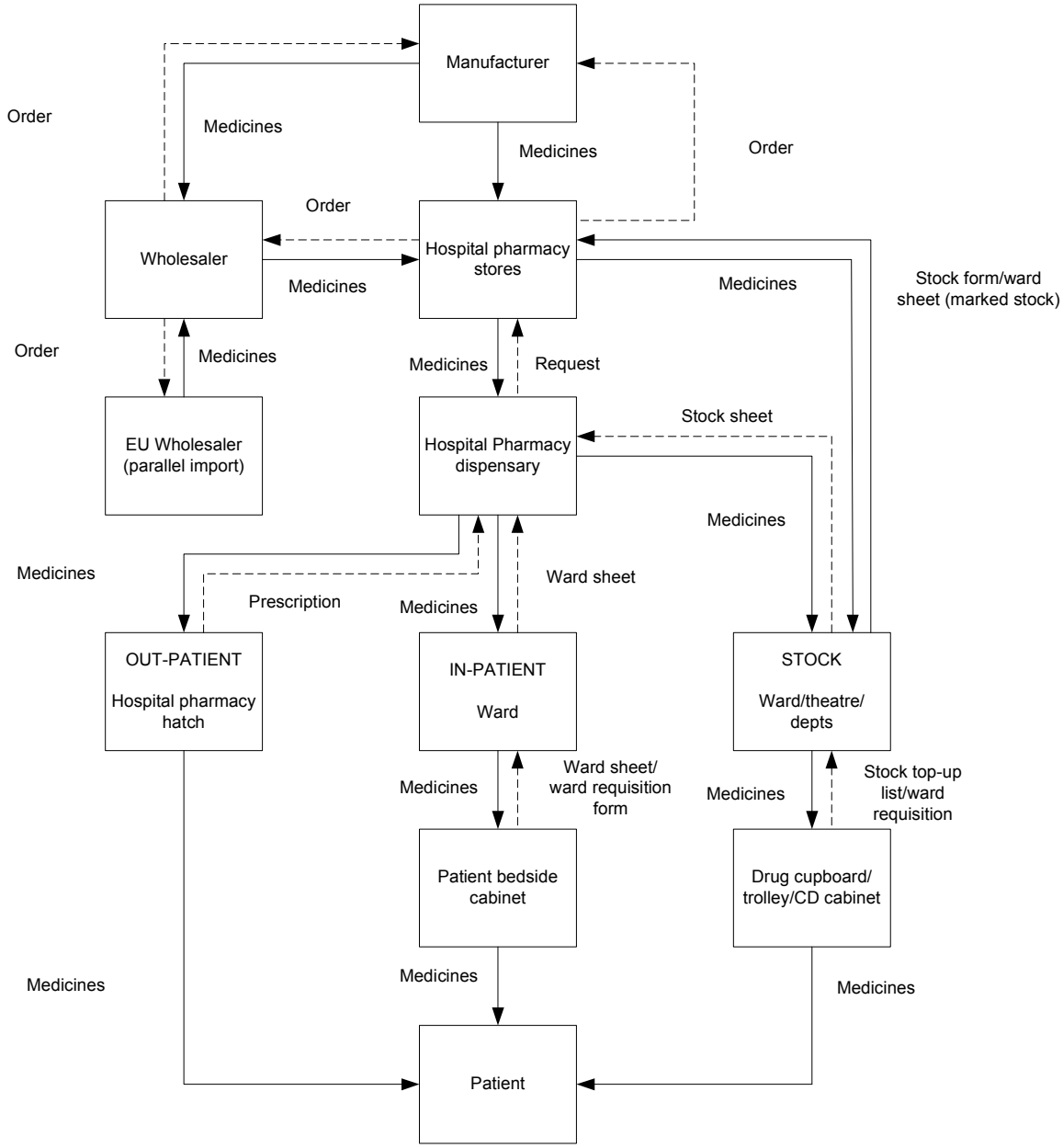

Figure 2: Hospital Supply Process Model
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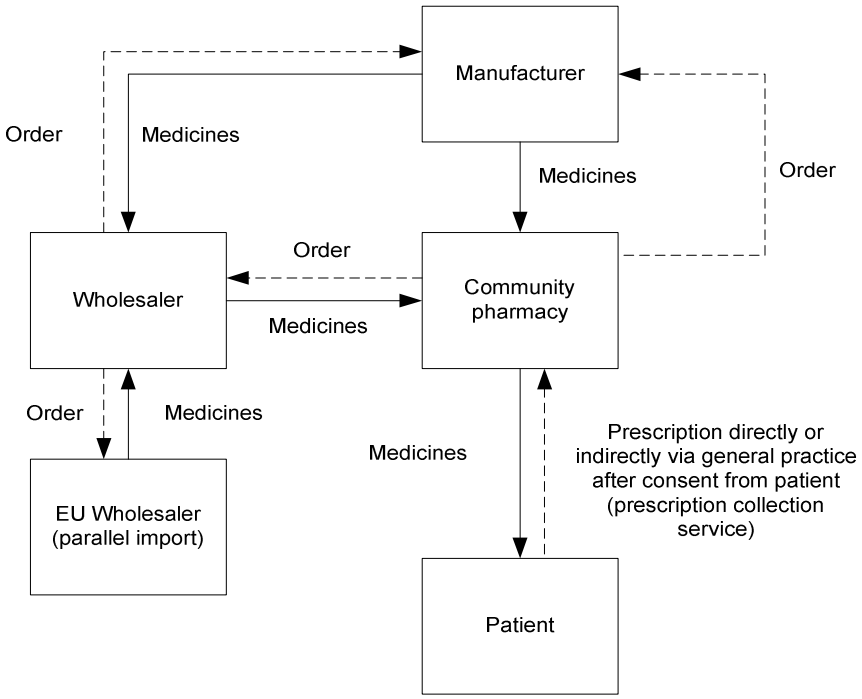

Figure 3: Community Pharmacy Supply Process Model