**Using Lean Six Sigma to improve controlled drug processes and release nursing time**

Maria Creed, MSc1, Michelle McGuirk, MPSI2, Ruth Buckley, MA3, Aoife De Brún, PhD4 & Marie Kilduff, MSc 5

1 Pharmacy Department, Mater Misericordiae University Hospital, Eccles St., Dublin, Ireland. Email: mcreed@mater.ie

2 Transformation Office, Mater Misericordiae University Hospital, Eccles St., Dublin, Ireland. Email: mmcguirk@mater.ie

3 Quality & Patient Safety Department, Mater Misericordiae University Hospital, Eccles St., Dublin, Ireland. Email: rbuckley@mater.ie

4 School of Nursing, Midwifery & Health Systems, University College Dublin, Dublin, Ireland. Email: aoife.debrun@ucd.ie

5 National Leadership and Innovation Centre for Nursing and Midwifery, Office of the Nursing and Midwifery Services Director, Health Service Executive, Ireland. Email: marie.kilduff@hse.ie

**Corresponding author**: Maria Creed, Pharmacy Department, Mater Misericordiae University Hospital, Eccles St., Dublin, Ireland.

**Running title**: Improving controlled drug processes

**Declaration of Interest:** The authors declare no conflicts of interest.

**Acknowledgements**: The authors would like to thank the Mater Lean Academy for their support of this research.

INTRODUCTION

The use of controlled drugs, such as Morphine and Methadone, is subject to stringent regulations internationally in countries including the UK, France, Germany, Ireland, the USA and Australia.1,2 Given that globally there is an estimated 190,900 premature deaths caused by drugs and that opioid abuse accounts for the majority of these deaths, this stringency is necessary.3 Traditionally, processes to manage controlled drugs in hospital settings were established in adherence to national legislation,1 with little consideration of establishing an efficient process. This project applied quality improvement methods to the controlled drug supply and delivery process to release nursing and pharmacy time in one large teaching hospital in Dublin, Ireland to enable greater efficiency, whilst adhering to national legislation.

It is an on-going challenge in health care to provide cost-effective, high-quality patient care. Quality improvement methodologies, such as Lean and Six Sigma, have been translated from industry with varying degrees of success in an attempt to drive health care improvement.4,5 Lean methods aim to improve organisational processes to reduce waste and improve productivity,6,7 while Six Sigma focuses on reducing variability and errors using data and statistical methods.4 Combined, Lean Six Sigma (LSS) provides organisational problem solving and quality improvement.8,9 Using the five step Define, Measure, Analyse, Improve and Control (DMAIC) approach,10 LSS’s primary outcomes relate to time and cost saving, quality improvement, and increasing patient satisfaction.11-13

The evidence for the efficacy of Lean methods in health care is mixed. In a recent systematic review of Lean approaches in health,5 Moraros et al. assessed the effect of Lean on staff, patient satisfaction, health and process outcomes, and financial costs and found that the evidence to date does not support the claim that Lean interventions lead to quality improvement in health care.

However, there have been several studies of positive outcomes from the application of Lean methods in medication management in health care settings. Green et al. used Lean to evaluate hospital pharmacist activities and categorised 23% as waste because of inefficient work practices.14 This resulting analysis resulted in opportunities for pharmacists to become more process and time efficient. Other studies applying Lean approaches have observed savings in time and cost, increased process efficiencies and consequent improvement in service quality.15,16 LSS approaches have also been employed to improve medication delivery processes, to decrease medication errors, and improve patient and nursing satisfaction, while also reducing nursing wait time for medications.17

Despite progress in this area, there is no published research on the application of quality improvement approaches to improve controlled drug supply processes in hospital settings. This project addresses this gap and seeks to enhance the efficiency of the controlled drug supply in a hospital setting with LSS methods, with the aim of releasing nursing and pharmacy time.

BACKGROUND

Project Context

This project reviewed the controlled drug supply process in a single centre, quaternary referral teaching hospital with approximately 600 in-patient beds and a staff complement of just over 3,000, which includes 1,204 nursing staff. In accordance with national drug legislation, a nurse must request controlled drugs, using hand-written orders. Furthermore, legislation stipulates that a pharmacist must supply controlled drugs using a specified documentation method. In this hospital, a process had been in place for decades, with the most recent review taking place over 10 years ago. However, in that time, the number of commercially available controlled drugs has risen exponentially, along with demand. This increase has impacted on nursing and pharmacy staff time, with increased demands on pharmacy regarding dispensing controlled drugs and, in the current setting, more frequent nurse journeys to pharmacy to collect controlled drugs

A scheduled controlled drug supply process existed, where nurses electronically requested a porter to collect a controlled drug order book from the ward, if required, on scheduled days, at a specific time. The porter transported the order book to the pharmacy and subsequently delivered the controlled drugs to the ward later in the day. However, this process did not efficiently meet user needs. Whilst controlled drugs were prescribed daily, the collection of the drug order book only operated on alternative days at 08:00 during nurse handovers and the drug delivery process required the presence of two members of nursing staff to count the controlled drugs received.

Retrospective data indicated that only 19% of controlled drug orders were processed in this manner. The unscheduled process led to a mean of 17 nurse journeys daily to Pharmacy for controlled drugs. For clarity, when we use the term ‘nurse journey’ we refer to instances where nurses must leave the ward to make an unscheduled visit to the pharmacy to order and collect controlled drugs. This is an important target for improvement, because when nurses must leave the ward in this unscheduled, ad-hoc manner to collect medication, time is taken from direct patient care. In addition, given that controlled drug orders take precedence over other pharmacy orders, pharmacists’ workflow is also interrupted by unscheduled drug requests outside of what was allocated as protected time for controlled drug processing.

Ethical considerations

As this research was considered service improvement work and exempt from ethical review, the project was approved by the hospital’s Chief Executive Officer. The project is reported in line with SQUIRE (Standards for Quality Improvement Reporting Excellence) guidelines.18

METHODS

Data collction and approach

The DMAIC (Define, Measure, Analyse, Improve, Control) framework was employed as follows:10

*Define*

A multidisciplinary team, including representatives from Nursing, Pharmacy, Quality and Administration formed to examine the controlled drug ordering and delivery process. Stakeholder insight and knowledge, along with shadowing of those involved in the process (i.e. ‘Gemba’ - walk in the shoes of those who undertake the work) led to the development of a process map (see Supplemental Digital Content, Figure 1). The team also established the needs and perceptions of nurses, pharmacists and porters, who were all directly involved in the controlled drug process. This list formed the basis of the Critical to Quality (CTQ) requirements. The CTQ is a tool that, along with relevant stakeholders, helps to map the internal critical quality parameters that relate to the wants and needs of those involved in the process. Thereafter, suitable metrics were chosen to effectively identify and evaluate problems.

*Measure*

The CTQ tool and the process map highlighted the non-value (or unnecessary) activity, the data required to identify the magnitude of the problem and pinpointed the key performance indicators. Over a two-week period in July 2014 the following measurements were collected:

* Number of scheduled controlled drug orders/deliveries (via porter)
* Number of unscheduled controlled drug orders/deliveries (via nurse) / number of pharmacy interruptions
* Time of day of unscheduled order/deliveries (via nurse)
* Time taken by nurse for unscheduled order/deliveries (mean)
* Time taken by pharmacist for unscheduled supply of controlled drugs (mean)
* Reason for unscheduled order/deliveries (via nurse)

*Analyse*

The Analyse phase involved critically appraising the baseline data collected, advancing theories on root causes and opportunities for improvement. Critical factors were identified (e.g., mandatory signatures on drug orders) and separated from waste components inherent in the process. Table 1 displays the principal reasons for unscheduled nurse journeys to Pharmacy. The root causes were then organised by the team in order of priority.

*Improve*

In the Improve phase, data were presented to stakeholders in conjunction with a silent brainstorming session for solutions. Silent brainstorming is a technique to enable all participants to reflect and to contribute to the session. It recognises that not all participants may feel comfortable speaking up in the same way and thus enables a democratic contribution process. Potential improvements were graded for ease of implementation and this helped plan the initial pilot study. The solutions agreed for the pilot included to:

* Increase the scheduled porter drug collection and delivery service from 3 to 5 days a week, without affecting porter staffing levels through elimination of waste steps and more efficient distribution of time
* Reorganise porter service times to reflect times of greatest demand
* Reformat delivery documentation
* Remove receipt collection from the porter process and to streamline checking requirements for nurses to one double-check with a colleague on controlled drug receipt in the clinical area

The unscheduled process whereby the drug collection and delivery (undertaken by a nurse) was identified as waste, i.e., a non-value step. Although deemed ‘waste’, it is not possible to eliminate this process as patients may urgently require controlled drugs not on the ward at any time. This necessitates a nurse journey to Pharmacy to retrieve the drug (‘unscheduled’), in a timely manner to ensure quality patient care. The ‘waste’ targeted in the unscheduled process was the depleted ward stock (Table 1).

Solutions were tested over 2 weeks in October 2014 on two wards: a medical oncology ward (characterised by high and varied controlled drug usage), and a surgical ward (where the same controlled drugs are used consistently postoperatively). The data collection outlined in the Measure phase was repeated to compare changes pre-intervention, post-intervention, and at follow-up points. The pilot results indicated a 46% reduction in the number of unscheduled nurse journeys to Pharmacy for controlled drugs, with associated time savings for staff. This presented strong evidence for the wider roll-out of the intervention across the entire hospital.

*Control*

The aim of the Control phase is to maintain improvements and evaluate sustainability. Improvements borne out in the pilot were visible throughout the hospital following the implementation of clear communication processes and the initiation of embedding the changes. Information sessions were provided to each nursing division, with all Clinical Nurse Managers invited to attend. A simple data entry method was established to enable intervention monitoring over time. This involved introducing a new daily metric whereby the Pharmacy Department would record and display the number of unscheduled controlled drug journeys by nurses daily, along with details of the new process. Furthermore, the Pharmacy Department planned quarterly hospital-wide communication with up-to-date data to encourage behaviour change. This process change was implemented hospital-wide in March 2015.

RESULTS

The mean number of controlled drug collections and deliveries over 18 months studied was 458 per month (range 410–496). In the month prior to roll-out (February 2015), porters carried out 199 (44%) of controlled drug collections and deliveries, with nurses carrying out 249 (56%). In the first full month post-intervention (April 2015), this trend reversed, with porters more involved in the controlled drug collection and delivery process (n=321, 68%) than nurses (n=149, 32%). A chi square frequency test confirmed the difference between the two time points was statistically significant, χ2(1) = 53.25, p < .001, indicating that increasing the number of porter-led deliveries resulted in reductions in number of nurse journeys to pharmacy for the controlled drugs.

Follow-up analysis revealed this trend was sustained over time, with porters involved in 351 out of 496 (71%) requests in August 2016, and nurse involvement reduced to 139 occassions (29%) (see Supplemental Digital Content, Figure 2). A chi square test revealed significant difference between February 2015 (baseline pre-intervention) and follow-up (August 2016), indicating the intervention effect had been successfully sustained over time, χ2(1) = 71.46, p *>* .001. This equates to a 48% improvement on pre-intervention data, far exceeding the 25% improvement goal at the outset. Additional changes to the process have resulted in eliminating the need for porters to return to the clinical area for documentation, thus freeing up their time for increased involvement in value added steps of the process.

Impact on nursing and pharmacy time

By reducing the wasteful steps in the controlled drug process, nurses saved 661.5 hours in 18 months (~37 hours per month) releasing an additional 157.5 hours (~9 hours per month) of Pharmacy time, with no increase required in the protected time set aside for controlled drug dispensing. There was no impact on porter time, with the same amount of time allocated to the controlled drug supply process spread more efficiently over 5 days rather than over 3 days. In monetary terms, the cost savings equate to €17,755 (€13,495 for nursing, €4,260 for Pharmacy). These figures, guided by the midpoints on current nursing and pharmacy salary scales, are based on a nurse taking a mean of 21 minutes to obtain controlled drugs from the Pharmacy and the pharmacist occupied for a mean of 5 minutes during each unscheduled drug collection.

DISCUSSION

This project aimed to improve the controlled drug process in a large teaching hospital in Ireland. Whilst it is not feasible to anticipate all ward requirements for controlled drugs in an acute hospital setting, initial exploratory work to map the processes successfully identified non-value activity that could be eliminated or reduced whilst continuing to adhere to national legislation. Specifically, these included the timing and frequency of the scheduled supply, increasing porter involvement with delivery, and use of unnecessary documentation. By applying LSS techniques to the controlled drug process, there was a significant reduction in unscheduled nurse journeys to pharmacy to obtain controlled drugs. Nursing and pharmacy time was released by effectively alleviating the need for nurses to go to the pharmacy and designing processes to better meet periods of greatest need. Moreover, this improvement was maintained 18 months following implementation, indicating that process improvement had been embedded, sustained and controlled over time. This change resulted in increased efficiency for both nursing and pharmacy staff, equating to 46 hours of staff time per month, which can be redirected into patient care.

LSS methods have been previously applied to medication management in hospitals;4,14 however, this study is novel as it explored how increasing efficiencies in controlled drug ordering and delivery can impact on both pharmacy and nursing time. Similar to previous work,19,20 this research illustrated that by applying LSS in health care increased efficiencies in processes, staff time savings and cost savings can be achieved. Although the evidence base from Lean methods in health care is mixed,5 this study highlights its success in improving process efficiency around medication supply and delivery. Our findings contrast with those of Hartzband and Groopman,21 who describe clinician dissatisfaction with strict adherence to standardised work; a theme echoed by Waring and Bishop who described tensions between clinicians and service leaders around the social organisation of health care.22

The complexities inherent in a large hospital environment with historical layers of power and hierarchy,10 makes change management, and indeed LSS implementation, challenging.23 Upon reflection, the project team identified three factors that proved crucial to successful implementation and in sustaining improvement over time;24 the involvement of stakeholders, identifying and measuring the right indicators, and understanding the culture inherent in the environment. The engagement of all stakeholders from the outset was crucial, as their involvement contributed significantly to the success of the initiative. Working with stakeholders to create the process map and presenting them with the two-week test data served to underline the value of process re-design. The identification of two processes (scheduled and unscheduled) for the collection of controlled drugs enabled a focused discussion on ‘waste’ and opportunities for improvement so that the process would effectively meet the needs of all stakeholders.

A reorganisation of work practices was agreed through the involvement of all stakeholders. For instance, by reducing documentation requirements, porter time was freed up to enable additional days for the porter-led ‘scheduled’ process. Also, the delivery time was changed to meet time of greatest need and relieve pressure on nursing staff to order drugs by a certain time. These solutions, along with education and awareness-raising through data sharing, enabled the new process to be adopted and sustained over time. Frequently, the ‘silo’ mentality of health care professionals can act as a barrier to change and quality improvement. 25 It is important therefore to view quality improvement as a social process, where collaborative approaches to change can promote staff engagement with improvement initiatives and encourage the diffusion, uptake, and sustainability of interventions.26

Secondly, appropriate measurement was crucial in convincing others of the need for and the benefits of change.26 The two-week test data were beneficial in this regard. These data demonstrated a positive gain for the patient, nursing staff and pharmacist, in terms of releasing time for other activities.

Finally, consideration of the local context and cultural insight was crucial to enact change in a complex environment.27 The multidisciplinary project team involved comprised long-standing and recognisable members of hospital staff from pharmacy and nursing backgrounds, with multiple contacts within the clinical and non-clinical environment. This enabled leverage of local knowledge and insight which was instrumental in involving stakeholders and during awareness-raising activities prior to roll-out of the intervention post-pilot. Support and enthusiasm from senior management also helped to ensure the success of the intervention.

This research has contributed to the literature by exploring, measuring and demonstrating the impact of systemic process change on controlled drug processes in a health care setting. This project demonstrates the considerable impact process changes may have on both nurses’ and pharmacists’ time, and on workflow. Observed time savings were equated to cost savings for the organisation as this can prove an effective means of drawing attention of stakeholders to the benefits of quality improvement. However, it is important to acknowledge that cost savings may not necessarily be reflected in the finances of an organisation, but the value added was freeing up time for staff by removing wasteful activities and allowing staff to spend their time on more appropriate activities or by improving workflow of those activities.

Conclusions

This study found that by applying LSS principles and involving all relevant stakeholders, medication management processes can be streamlined to effectively release nursing and pharmacy time. Given the current pressures on health care globally, such initiatives have potential to increase efficiencies when there are limited financial and staffing resources. Though not an aim of the current study, future work should seek to explore the impact of similar process changes on patient and staff satisfaction. This study has resulted in a reduction in nurse journeys to pharmacy for controlled drugs and released nursing and pharmacy time. We would this time is now being utilised for direct patient care, although we cannot conclude this based on this study. Future work should seek to understand how the time saved from such process improvements is utilised. As this was a single centre study, using locally adapted controlled drug processes, the intervention implemented may require adaptation to be successfully employed elsewhere. However, given that many countries impose similar controls, we contend that the methods used are likely to benefit other settings, albeit with some tailoring to accommodate local requirements.

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