Applying lean methodology to improve parenteral chemotherapy and monoclonal antibody documentation processes based on Normalisation Process Theory

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ABSTRACT

Objective To determine the impact of lean thinking on the original time required to prepare the necessary documentation in relation to the preparation of parenteral chemotherapy/monoclonal antibodies.

Method Four pharmacists and one pharmacy technician from the oncology hospital (Malta) all participated in eight focus groups linked to the different constructs of Normalisation Process Theory (NPT): coherence, cognitive participation, collective action and reflexive monitoring. The value stream documentation process was mapped by analysing all steps in the process where each activity must add value for the patient; tools of lean thinking were applied. Points causing delay in processing were considered critical; possible changes to minimise time waste were discussed and implemented. Time spent on critical points was measured by timing in minutes each step of the process 1 month before and after the changes had been implemented and calculating the mean±SD. An audit was performed comparing the process with standard operating procedures to determine whether any steps required quality improvement.

Results Three critical points were identified: time required to search for pharmacy patient medication records for chemotherapy/monoclonal antibodies required on the day; time to generate preparation labels; and time to generate worksheets. Overall, a total of 122 ±8.6 min (p=0.06) were saved per day, a 37% decrease from the original documentation time. Five deficiencies were identified in the documentation process audit; corrective action was proposed.

Conclusions By applying lean thinking, non-value-added steps leading to time waste in the documentation process were eliminated. This concept could be implemented by using NPT as part of a strategic system to reduce waste.

number of implications including medication waste and increase in patient waiting times among others.³ In view of the multistep nature of the documentation process, the chemotherapy reconstitution environment is an ideal scenario for lean methodology.³

Lean methodology, a management philosophy originating from Toyota manufacturing, encourages service providers to place emphasis on value as defined by the customer and the elimination of waste that hinders the flow of value.⁴ There are five principles of lean thinking (box 1).⁵

Lean thinking has in recent years been applied in healthcare to enhance patients' experience by minimising non-value-added steps (such as time waste and waste of human resources), thereby providing safer, streamlined visits. Therefore, in healthcare, lean thinking focuses on the value stream, where each activity must add value for each stakeholder (mainly healthcare professionals and other staff) and consequently the patient, flow (service delivery without work stoppage or backflows), pull (delivery of the service when it is needed) and perfection.^{6,7} Lean thinking has been studied in various settings/conditions, including oncological ones, such as in patients with bone/brain metastasis,⁸ uro-oncology⁹ and gynaecological-oncology clinics.¹⁰ It has also been applied in scenarios in relation to medication, ranging from application of lean sigma (a rigorous system for identifying and preventing defects in manufacturing and service-related processes¹¹ to aid in medication error reporting¹²) to systems mapping and analysis to understand and reduce medication-delivery waste.¹³

Interventions that are developed through lean thinking should be easily implemented and provide definitive assessments of effectiveness. Normalisation Process Theory (NPT) provides a framework that can aid the successful implementation and integration of interventions into routine work (normalisation). NPT comprises four components¹⁴:

1. Coherence: meaning/sense-making of an intervention by the people using it
2. Cognitive participation: commitment to/engagement with an intervention by the people using it
3. Collective action: the work the people using the intervention will perform to make it function
4. Reflexive monitoring: the people using the intervention reflect on or appraise the intervention.

INTRODUCTION

Good documentation for preparation of parenteral chemotherapy/monoclonal antibodies (MABs) is a critical step in a quality system to ensure compliance with good manufacturing practice requirements.¹ Documentation of parenteral reconstitution involves a multistep, interdisciplinary process² with communication between doctors, pharmacists, nurses and couriers. This multistep process can result in delays in chemotherapy reconstitution, errors and work that needs to be redone, with a

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Box 1 Principles of lean thinking⁵

1. Identify value: the value is specified from the standpoint of the end customer.
2. Map the value stream: all the steps in the value stream are identified, eliminating whenever possible those steps that do not create value.
3. Create flow: the value-creating steps are made to occur in tight sequence so the product will flow smoothly toward the customer.
4. Establish pull: as flow is introduced, customers are allowed to pull value from the next upstream activity.
5. Seek perfection: as value is specified, value streams are identified, wasted steps are removed, and flow and pull are introduced, the process should begin again and continue until a state of perfection is achieved in which perfect value is created with no waste.

An intervention that appears to affect one individual may require a successful chain of interactions with other individuals; NPT can help to identify how these interactions may be affected by the intervention and if the intervention needs to be modified to support these interactions.¹⁴ NPT has been applied in different areas of healthcare such as: development, testing and evaluation of a delirium-prevention programme that would be sustainable in acute care¹⁵; to understand the barriers/facilitators to implementing nutrition guidelines for elderly in residential care homes¹⁶; and to help describe components of treatment burden among 47 patients with congestive heart failure managed in primary care.¹⁷ Another study that used focus groups with community pharmacists and semistructured interviews with individual patients by telephone used NPT to explore the perspectives of patients receiving, and pharmacists delivering, an enhanced pay-for-performance community pharmacy heart failure service.¹⁸ No study applying lean thinking with NPT has been identified.

Aim of the study

The aim of this research was to determine the impact of lean thinking application on the original time required to prepare necessary documentation in relation to the preparation of parenteral chemotherapy/MABs.

Ethics approval

Ethics approval was not required for this study since it was considered to be an exercise to minimise time waste as part of the reconstitution unit's duties and was approved by the hospital management.

METHODS

Design

This was a mixed-methods study using focus groups, observation methods and quantitative methods.

Setting

This study was conducted at the aseptic reconstitution unit in the main oncology hospital in Malta between January and August 2015. During the 7 months, focus groups were held and critical points were identified; interventions were then implemented and time measurements as well as an audit were carried out. The unit comprised one principal, three senior and two

basic pharmacists, and one senior and two basic pharmacy technicians, with a workload of 1500 preparations per month at the time of the study. Documentation at the unit includes the following steps, which are mandated by in-house standard operating procedures (SOPs): (1) checking of prescriptions by a first pharmacist; (2) accessing the patient medication record (PMR) for each patient by the same pharmacist; (3) inputting patient/treatment data in an electronic logbook by the same pharmacist; (4) generation of a worksheet and product label for each patient by the same pharmacist; (5) double-checking of all steps for any errors by a second pharmacist.

Inclusion criteria

Participants were purposively selected staff from the pharmacy aseptic reconstitution unit who had a senior or higher post and at least 1 years' experience working in the unit, or were carrying out a course in quality assurance or lean thinking at the time of the study. Five staff out of a total of nine fulfilled the inclusion criteria and were contacted via email by the principal researcher (the principal pharmacist of the section was the principal researcher) who requested participation. Other staff (doctors/nurses) were excluded because of logistic limitations in organising the focus groups.

Lean thinking process

Participants engaged in all eight focus groups, each lasting 120 min, in the principal pharmacist's office. All focus groups were facilitated by the principal pharmacist who took notes on what the participants said. The topic guide was a semistructured discussion, to align with usual lean thinking meetings, based on the SOPs of the unit and the principles of NPT. The questions in the topic guide were adapted from the paper by Murray *et al*¹⁴ (box 2).

During the focus groups, participants applied techniques of lean thinking⁵:

1. Direct observation by the principal pharmacist and direct discussion during two focus groups of the entire documentation process.

Box 2 Topic guide applying Normalisation Process Theory to develop and implement an intervention

Coherence

- ▶ Is the intervention easy to describe?
- ▶ Do participants have a shared sense of its purpose?
- ▶ What benefits will the intervention bring to the staff and patients?

- ▶ Are these benefits likely to be valued by potential users?
- ▶ Will it fit with the overall goals and activity of the unit?

Cognitive participation

- ▶ Will staff easily see the point of the intervention?
- ▶ Will they be prepared to invest time, energy and work in it?

Collective action

- ▶ Will the intervention promote or impede their work?
- ▶ Will staff require extensive training before they can use it?

Reflexive monitoring

- ▶ How did the aseptic reconstitution unit staff perceive the intervention?
- ▶ What are the perceived advantages of the intervention?
- ▶ What are the perceived disadvantages of the intervention?
- ▶ Could the intervention be adapted or improved further?

2. Process mapping during two focus groups: participants mapped the value stream, which is the mapping of information flow in order to identify the components that add value to the process,¹¹ as part of the quality-improvement exercise from the use of lean methodology.
3. Root-cause hypothesis techniques applied during another three focus groups: root-cause hypothesis is as an educated guess as to the root cause of a problem in a process.¹⁹ Using the Fishbone method, participants identify areas in the process that, in their opinion, were causing delay in the documentation process. The Fishbone method is a brainstorming exercise to guess different causes of problems related to man, machine, materials and methods, without using statistical methods.⁹ Participants aimed to decrease time waste by at least 30%.
4. Data collection: NPT was applied to implement interventions and collect data as described below.
5. Reflexive monitoring during one final focus group was used to appraise the intervention.

An audit was also carried out by the principal pharmacist over a 1-month period by observing the process carried out by staff in the unit over three randomly chosen days and comparing it with a compiled checklist derived from the unit's SOPs to determine whether any steps required quality improvement—that is, the combined and unceasing efforts of everyone working in the unit to make the changes that will lead to better system performance in this case.²⁰ This is a baseline audit which is carried out annually by the department. The checklist already in use by the department was used for this exercise in view of the experience gained in using this tool, which was derived from the SOPs. The audit was carried out during the first month of the study—the period when the first two focus groups were held.

NPT application to implement the interventions

Designing and implementing interventions were discussed by all focus group participants based on the four principles of NPT.¹⁴

Participants ensured coherence by giving interventions a clear purpose during focus groups and by discussing the benefits that interventions could bring in the unit. When designing interventions, focus group participants considered implementation issues, including quality assurance aspects.

Cognitive participation was then discussed during focus groups. The intervention was defined and refined and focus group participants engaged other staff in the unit to understand the interventions and their benefits.

Through collective action all aseptic reconstitution staff were given training by focus group participants on how to use the new interventions and the sharing of responsibilities. A 1-month analysis of the interventions was carried out by focus group participants to determine the impact on the original documentation time and to ensure that the interventions did not impede their work flow. Time spent measuring the interventions was noted by two focus group participants to ensure reliability using a stop watch every day 1 month before and after implementation of the interventions.

Through reflexive monitoring, focus group participants met in a final focus group 2 months after implementation of the interventions to reflect on the interventions (box 2). A 2-month time frame was a practical but adequate time span for the interventions to be normalised into staff daily routine.

Data analysis

Analysis for focus groups was carried out using the framework approach,²¹ with the coding frame developed and applied

independently by two researchers to promote confirmability and described using a narrative approach. Time spent on the critical points for each step of the process was inputted into SPSS V21 and analysed using descriptive statistics; mean±SD was calculated. t-Test calculations were performed to assess whether the decrease in time was statistically significant. p Values ≤0.05 were considered significant.

Main outcome measures

The main outcome measures were change in time waste and quality improvement steps.

RESULTS

Participant demographics

One principal pharmacist with 15 years' experience, two senior pharmacists with 14 and 9 years' experience, one basic pharmacist following a course in lean thinking with 2 years' experience and one pharmacy technician pursuing a postgraduate degree in quality assurance with 2 years' experience participated in the study.

Root-cause hypothesis of parenteral chemotherapy/MAB reconstitution documentation process identified during focus groups

During focus groups, participants identified four key themes (critical areas) that were causing delays in the documentation process (table 1).

Since each key theme requires extensive discussion of the original workflow, possible interventions that are required, implementation of the interventions and follow-up, and workflow changes to minimise time waste were discussed for 'Process' only during focus groups (table 1).

The current work practices that participants, during focus groups, felt were causing major delays within 'Process' were the excessive number of steps required to prepare documentation:

At the reconstitution unit we have to input all patient details into a Logbook on an Excel[®] spreadsheet. Then we re-insert the same details in a patient's worksheet. Details are re-inserted for a third time to issue a set of three labels that are used on the chemotherapy preparation. The process is therefore too lengthy.

(Senior pharmacist, 9 years' experience)

Participants also stated that there were frequent changes in brands of drug products with no information communicated by the Central Procurement Office (CPO) to the aseptic reconstitution unit:

Table 1 Key themes and sub-themes identified during root-cause hypothesis analysis of parenteral chemotherapy/monoclonal antibody reconstitution documentation process

Documentation takes too long to prepare

Process	Chemotherapy prescription types
▶ Excessive number of steps in preparation of documentation	▶ Missing details in prescriptions
▶ Frequent change in brands with no information communicated to reconstitution unit	▶ Complex protocols impeding checking
Place	People
▶ Lack of organised office area	▶ Short-staffed office
	▶ Delay in prescription delivery by couriers
	▶ Delay in issuing of prescriptions by doctors
	▶ Miscommunication

There are too often changes in brands of chemotherapy and MABs and no one informs us. This translates into last minute preparation of worksheets for the specific brand with a resultant further delay in the documentation process.

(Pharmacist, 2 years' experience)

Interventions identified during focus groups that were implemented to minimise time waste

During the focus groups, participants proposed interventions that could reduce the number of steps required to prepare documentation. During discussion, participants identified ways using Excel to decrease time to prepare labels and issue worksheets directly from the logbook, by amalgamating three steps into one, thereby decreasing the original average time of 326 min required for this procedure. This, however, also meant that further details had to be inputted in the logbook, which took a few more minutes to compile each day. Participants also put the PMRs, which were previously stored in an archive room, in the unit's office, which reduced the time to retrieve them. Figure 1 shows the minutes taken to carry out the process for the critical points before and after the intervention. This resulted in a total of 122 ± 8.6 min saved per day, a 37% decrease from the original documentation time of 326 minutes ($p=0.06$).

The CPO was also approached and requested to provide information to the unit on changes in brands for chemotherapy/MABs before supplying the unit with the medicine. However, this information could not be provided for a number of logistical reasons, such as a very short delivery period, and therefore there was no improvement in time waste from this intervention.

Steps requiring quality improvement

Following the audit, five steps were identified that required quality improvement (table 2).

Reflexive monitoring during focus group

During the final focus group (reflexive monitoring), participants praised the intervention:

The change was overall welcomed by the whole unit; however, the time saved has not been utilised for other purposes as yet but chemotherapy is now delivered to the wards more on time.

(Senior pharmacist, 14 years' experience)

In-depth discussion on how the system could be adapted further and how time that was saved could be utilised more efficiently provided the output described in box 3.

DISCUSSION

Minor interventions in the original documentation process resulted in a total of 122 ± 8.6 min saved per day, a 37% decrease from the original documentation time, which, although not statistically significant, was considered to be significant in practice. This study therefore confirms the usefulness of applying the lean concept and highlights the importance of engaging staff to come up with solutions for the problems they encounter. Lean methodology, although relatively new to the Maltese healthcare system, has been applied in different healthcare settings, with the resultant delivery of excellent and efficient care in a safe environment, which benefits patients, employees and tax payers.^{22 23}

The concept of lean is synonymous with simplicity and efficiency²⁴ and is mostly used in healthcare as a process-improvement approach. This study is proof that minor changes to simplify the process increased the efficiency of individuals, by reducing the total documentation time by ~2 hours. Minimisation of time waste, although not as extensive, has also been shown in another oncology pharmacy setting.²⁵ The quality improvement study in an outpatient oncology pharmacy²⁵ showed the elimination of six non-value-added steps and an overall turnaround time of 70 min compared with 90 min at baseline, as opposed to the present study which provided further time improvement. Lean six sigma quality improvement tools applied in a study that analysed the process for prescription of oral chemotherapy practice found a lack of pharmacist review of oral chemotherapy prescriptions. Following this deficiency, pharmacists reviewed all oral chemotherapy prescriptions ordered over a 7-month period and carried out 22 interventions.²⁶

Individuals are set in routines without recognising the number of unnecessary steps they execute on a daily basis. While amelioration and implementation of change is imperative, maintenance of an improved system is fundamental. Therefore, this study should not be considered as a standalone, one-off exercise that has resolved time waste issues; sustainability of

Figure 1 Number of minutes to carry out process for the critical points pre- vs post-intervention.

Table 2 Number of deficiencies and corrective action required following audit

Procedure	Deficiency	Corrective action
1. Procedure for prescription verification of aseptic preparations	<ul style="list-style-type: none"> ▶ Signature of doctor on prescription does not belong to the name of the doctor written on prescription ▶ Patients' weight not always included in prescription ▶ Rubber stamp by releasing pharmacists not always used; kept in office or in preparation area to avoid respraying 	<ul style="list-style-type: none"> ▶ Signature and name should tally; doctor to use rubber stamp ▶ 'Last weighed/weight' to be included in the comments section ▶ Second rubber stamp for releasing pharmacists made available
2. Procedure for preparation of worksheets and labels from approved master documents	<ul style="list-style-type: none"> ▶ Worksheets not standard and are outdated. Some contain mistakes 	<ul style="list-style-type: none"> ▶ Data to be extracted from logbook directly into latest template of worksheet
3. Procedure when medicines are privately purchased by the patient or other private entity	<ul style="list-style-type: none"> ▶ No transfer note when stock is transferred from one unit to another 	<ul style="list-style-type: none"> ▶ Transfer note from one unit to another signed at both ends and copy filed at both ends

Box 3 Further possible improvements proposed during the reflexive monitoring focus group

1. Affix one label with all necessary cautionary notes, such as 'refrigerate' or 'vesicant', issued directly from the logbook. This can potentially save time by printing and affixing one label instead of a number of labels and reduce cost by saving on the number of labels.
2. Standardise the diagnosis column in the logbook and attempt to link this to medication entitlement protocol to facilitate searching for appropriate/relevant protocols and thereby saving time on bureaucratic processes.
3. Add another column to the logbook with a link to the original consultant's request and highlight the status of the medication entitlement, indicating its pending approval or approved status.
4. Adapt the system to indicate if there is a mistake in the calculation of doses, thereby reducing errors and enhancing patient safety.

interventions should be seen as an iterative continuous process. Other aspects of the documentation process were identified that, if looked into, could result in further reduction in time waste. Therefore, regular meetings to discuss possible amelioration of processes with a possibility of saving on current limited resources, including staff time, are fundamental. Lean methodology can aid implementation of waste-reduction strategies in a specific healthcare system. However, each system has to be seen in its own context, including the human resources and respective expertise available, as well as the availability of other adequate resources, such as IT systems and equipment. It is therefore imperative to allow individuals working within a system to generate and identify their own strategies, integrate them into practice while exploiting these strategies to fulfil their own needs, and at the same time ensure that core elements of lean thinking are not lost when applied to new contexts.²⁷

Any proposed intervention, even when lean thinking is applied, brings with it challenges and barriers that need to be addressed.⁸ The present study also shows that implementation of some changes is not always as straightforward as others, and hindrances in the system, at times unavoidable, could be encountered. Overcoming hindrances requires closer collaboration and enhanced communication between interdisciplinary

teams, as shown in the study by Belter *et al*,³ which found that enhanced communication between the oncology infusion centre, pharmacy and laboratory translated into a decrease in patient waiting times from 88 to 68 min.³

Adequate education and acceptance of interventions is a prerequisite for their successful implementation. Novel explanatory frameworks, such as NPT, aid in understanding barriers and facilitators for implementation of interventions and inform the implementation. NPT is a theory of action²⁸; in this research it targeted both work that individuals carry out alone and in conjunction with others. This is essential to make an intervention work.¹⁶ Therefore, it targeted implementation of an intervention to bring a practice into action. NPT is concerned with embedding practice into the everyday work of individuals and groups and integration of practice that is sustained within an organisation or institution.²⁸ This requires continuous investment in terms of commitment, effort, meaning and appraisal.²⁹

Strengths and limitations of the study

A mixed-methods approach seemed appropriate for applying lean thinking in the unit. Focus groups helped us to explore stakeholders' experience and expertise in the unit, and the group dynamics generated a number of solutions to minimise time waste. However, although we recruited only key staff, including all staff in the unit may have generated more solutions. This study was carried out in one reconstitution unit only and, although services provided by the unit are similar to those of other healthcare systems, differences in practices make it difficult to extrapolate the results to other units.

Future research

Economic realities and the global impact of the financial crisis call for action and further research in all healthcare sectors to minimise waste. While many areas can benefit from the application of lean methodology, future research could target the whole documentation, as well as reconstitution process, which should also look into the linkage with multidisciplinary professions and processes.

CONCLUSION

By applying the concept of lean thinking, a number of non-value-added steps and wasted time in the original documentation process were eliminated. This concept merits attention and could be further looked into as part of a strategic system to reduce waste.

What this paper adds

What is already known on this subject

- ▶ Lean thinking applied in healthcare enhances the patient's experience by minimising waste and thus providing a safer, streamlined visit.
- ▶ Interventions developed through lean thinking are easily implemented and provide definitive assessments of effectiveness.

What this study adds

- ▶ This research methodology applied principles of lean thinking in the aseptic reconstitution unit of an oncology hospital and implemented interventions based on the Normalisation Process Theory to decrease the original documentation time, thereby impacting positively on patient waiting time.
- ▶ The tools and theory used in this research should be applicable beyond the study setting, affecting global research and practice.

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