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Lean Pharmacy

Technical Paper

Using time-tested manufacturing process tools to achieve efficiencies in pharmacy operations

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Introduction

Healthcare seems to take a long time to accept and adopt techniques and practices known for years to revolutionize other businesses. One of those techniques has been given the name "Lean." While the name certainly conjures up the healthcare reality of having to do more with less, lean actually represents an orientation to production of goods and services that emphasizes just a few basic principles:

- *Lean transformation* is a process in which the efficiency, cost and quality of a process are improved by the application of lean principles, principally the reduction of waste.
- Work adds value to a process only if it generates a transformation of the product (the object of the work) at a cost the customer is willing to pay; and if it is done right the first time. Any other work creates waste.
- Human beings (e.g., workers) are at the core of all successful work-process transformations.
- The human beings that know most about work processes are those who perform the work.
- Work cannot be assessed, critiqued or improved without observing it *in situ* (what the Japanese call the *gemba*).
- Work processes that result in rework, or that require activities that do not directly contribute value, or that delay or prevent productive work create waste. Waste (*muda*) is the enemy of an efficient and productive work environment.
- Quality is a key factor in eliminating waste. Quality cannot be inspected in to a process at the end; it must be built into each step of the process.
- The transformation process involves looking at the current state, imagining and describing the ideal state (according to lean principles) and then creating and implementing the plan to transition toward the ideal state.
- Efficiency gains within a department are not meaningful if they result in waste in the overall work flow; analysis of a process for lean transformation requires that the effect of any change is measured against the upstream and downstream effects of the transformation. It may be preferable to add a person to a work flow if the result is reducing work load or expense elsewhere in the overall system.
- Quality improvement is a continuous process. Lean transformations are not once-and-done activities, but represent an ongoing quest for improving the way work is performed. There is always something else that can be improved in a process[i].

As healthcare organizations look to lean in an effort to do more with less, some have applied lean principles to the operations of departments within hospitals, and more widely to hospital operations as a whole, with some success; including the application of lean principles to pharmacy operations.

Sources of Waste

According to lean philosophy there are several sources of waste in processes:

1. **Overproduction**. Production of unnecessary goods and materials that consume space and cost that may eventually have to be discarded as expired. Lean processes feature just-in-time production of just what is needed.

2. **Lack of standardized work**. Standardization is a key component of consistent quality.
3. **Queue (waiting) time**. Time spent waiting for someone else to complete their step in a process. Note that this is different from more-generic idle time. In the lean philosophy, it is better for workers to be idle, than busy with work that produces no value.
4. **Transportation (handling).** The need to move goods, services or people about to produce value. This is most frequently seen in terms of excessive walking being necessary to accomplish a value-added task.
5. **Inventory.** This is related to overproduction, but may also represent overstocking of component parts needed for production.
6. **Unnecessary motion**. Performing tasks that do not transform the product or service in a way that adds value.
7. **Defective products.** Waste occurs when products are defective in a variety of ways, including creating the need for subsequent inspection for defects.
8. **Underutilized skills**. The use of highly skilled (and expensive) workers to perform tasks that could be performed by individuals with lesser skill at lesser cost.[1]

In addition, some Lean Experts discuss an additional waste; inadequate or defective information management tools (e.g., ERP Systems that don't provide appropriate data / info).

Examination of pharmacy practice in hospitals reveals these sources of waste in a variety of areas:

- **Order transmission and management.** In many hospitals, the receipt of medication orders to process in the pharmacy is a batch feed activity, where staff in a patient-care area accumulates new medication orders and then transmits them to the pharmacy. The flow of work to the pharmacy is therefore uneven and episodic.

  Orders are then reviewed when they are received in the pharmacy by a pharmacist who must contact the physician if there are concerns or problems with the order. This communication is non-productive for several reasons:

  - It is displaced both in time and location from the order creation. The order fulfillment is delayed because of the process of transmission and review. (Transportation and handling)
  - The review is made without adequate context regarding the patients, their current condition and any decisions that may have been made on the patient care unit. (Inadequate information)
  - The review may further delay implementation of therapy. (Queue time)
  - The clarification process creates an adversarial relationship between the pharmacist and the physician, because the physician is now involved in the care of another patient, and because the physician realizes that therapy has been delayed. (Queue time, Defective Products)
- **Inventory Management.** Inventory systems in hospital pharmacies tend to operate on the honor system; the person who takes the last of an item becomes responsible for ensuring its replacement. While inventory turnover is probably acceptable, based on the ability of wholesalers to deliver frequently, the lack of good visual clues that something needs to be reordered and the lack of individuals who are responsible for

ensuring that needed items are ordered results in the need to perform exceptional (non-value-added) work to handle the shortfalls. The lean alternative is to use highly visible indicators that a reorder is needed, coupled with clear assignment of the reordering responsibility so that the need to reorder is clear and is communicated to the person invested with the responsibility of reordering. (Inventory, Overproduction)

- **Work Allocation.** Work flows often result in pharmacists performing jobs that could and should be performed by technicians. Pharmacists are more highly trained, more expensive and less plentiful than technicians, making this use of their time and talent wasteful. (Underutilized skill)

  In a recent commentary describing a technology-enabled pharmacy practice, the American Society of Health-System Pharmacists Section on Pharmacy Informatics and Technology (SOPIT) has proposed that the role of the highly trained pharmacist should be to guide the choice of drug therapy for patients directly; that there is nothing involved in the direct preparation and distribution of medications that requires a pharmacist's expertise[ii].

- **Batch Processes.** Pharmacy processes tend to occur in batches that send work through the system in large groups rather than continuously. The resulting workload experiences peaks and valleys that produce waste in several ways:
  - During peak times, the work is frantic, sometimes resulting in lapses in quality. Since the only quality control on the process is an end-process pharmacist check, the risk of rework (non-value added work) becomes higher, resulting in waste. (Queue [waiting] time)
  - During the valleys, workers may be idle, especially if they are waiting for someone else to finish processing the batch before they can work on it. For example, pharmacists must wait for the technicians to complete preparation of a batch of doses before they can check them. Typically, in the manual environment, checking cannot occur until the technician completes some batch of doses that must all be checked together. (Queue [waiting] time)
  - The batches represent groups of doses being prepared/distributed in advance. The less frequent the batches, the more time it takes to prepare the batch, and the farther in advance doses need to be prepared. Since these doses represent medication orders that may change, or be discontinued, the risk increases that doses will be prepared that will subsequently be returned unused, requiring crediting (non-value-added work) and potentially discarding. (Overproduction)

  From a lean perspective, a different way of processing that would produce doses just-in-time would minimize the opportunity of preparing doses that will not be used, would even out the work flow so that workers stay busy at an acceptable pace and would result in work that was of generally higher quality.

- **Walking.** Walking to perform one's work tasks is only value-added work if that walking is the task that is to be performed (such as in delivery of medications to their points of use). Walking that occurs because inventory is not properly distributed for the work to be done is not value-added work and therefore waste. Observation of the steps required to perform a task within the pharmacy will often reveal that both pharmacists

and technicians spend large amounts of time walking to different inventory locations to fulfill their tasks.

- **Other activities that do not add value.** Pharmacists spend a significant amount of their time in hospital pharmacies reviewing and approving orders and the medication doses used to fulfill them. From a lean perspective, this is not a value-added task since it only exists because the process of ordering medication therapy, and the process of providing doses to fulfill that therapy, can produce output of poor quality (inspecting in quality). From a lean perspective, a more productive activity would be to provide in-process assurance that mistakes do not get made. (Underutilized skills)

  As previously described, pharmacist participation in the generation of those orders (getting them right the first time) and the creation/validation of in-process checks to ensure that those orders are properly fulfilled (fulfilling them correctly the first time) would be value-added activities, even if they made the act of fulfilling each order slightly slower.

  Even in this regard, clinical activities can suffer from waste when a significant amount of the clinical pharmacist's time is spent locating and transcribing patient data rather than in rendering judgment and advice about the application of medications to specific patient conditions. (Transport and handling) Ideally, technology support would bring that data to the pharmacist[ii].

  In the IV room, technicians take large batches of labels printed at regular intervals, burst and sort those labels, then distribute them as doses to be prepared. Again, this is not value-added work, because it exists only because the work is not presented to the worker ready to be performed. (Transport and handling, Underutilized skills)

  Pharmacist checking of intermediate preparation steps is often required for sterile products that are hazardous or expensive; these checks require that the pharmacist change clothes to enter the cleanroom and perform the check, then change clothes again when they leave the cleanroom. These checks are doubly wasteful, because they are required only because of the opportunities for poor dose quality and because they require the pharmacist to waste time changing clothing. (Transport and handling, Underutilized skills)

  Similarly, technicians may spend time processing returned doses, perhaps crediting them in the patient's bill. From the lean perspective, this is not value-added activity since it occurs only because of the batch-flow process that created and delivered those doses too far in advance. (Overproduction, Transport and handling)

The Lean Pharmacy: A vision of the future state

Any discussion of the desired future state of pharmacy practice must start with the recognition that there is no endpoint. Lean transformation is a continuous process that adapts, as it must, to changes in the requirements of the process. That said, one can envision a form of pharmacy practice that more closely adheres to lean principles:

1) **Clinical Practice.** Clinical pharmacists participate with physicians in reviewing and planning medication therapy. Clinical pharmacists operate at the electronic center of a maelstrom of patient information automatically screened and grouped for their review[ii]. They spend very little time seeking and acquiring data for review. Screening programs

apply monitoring criteria to reported changes in patient condition that alert the pharmacist of the need to intervene on behalf of patients whose therapy requires review.

2) **Order Management.** Order processing is the result of entering medication orders, or changes to medication orders, into an electronic prescriber order entry system. Part of an electronic medical record, it applies clinical decision support algorithms to the newly entered orders, alerting the prescriber to possible problems, while also providing contextually relevant information about the patient's condition and its history as contextual information, while ordering is being performed. The result is that orders are more likely to be correct as prescribed and any issues can be collaboratively addressed during the prescribing process as a constructive conversation between the pharmacist and the physician. Indeed, in this scenario the physician may ask the pharmacist to order the medication therapy.

3) **Drug Product Fulfillment.** Medication products needed for fulfillment of medication orders are prepared and dispensed just-in-time, minimizing or eliminating the preparation and subsequent waste of doses that were changed or discontinued between the time of their preparation and the time of intended use.

   Order fulfillment uses automated supply cabinets, such as medication carousels, that minimize or eliminate walking to secure medication therapies.

   Order fulfillment uses bar coding to verify that the person fulfilling the order has selected the proper medication products and the proper amount(s) of those product(s).

   Where product preparation is required (such as the compounding of an IV admixture), all ancillary products are also barcode-verified, the correct instructions are available electronically during the preparation, necessary computations for the preparation are performed by a software system based on the products actually selected, and a history of the steps performed may be photographically captured.

   Checking of the fulfillment process, where it must be performed, is done by an individual who is trained in that function, but does not require the advanced training and credentials of a pharmacist.

   Pharmacist involvement includes design and oversight of the process, including definition of quality assurance functions and parameters, and regular review of the metrics produced from the fulfillment process.

   Where sterile compounding is required, the steps are automated to minimize or eliminate physical manipulation of the ingredients; to remove potential for touch contamination as far as is physically possible.

   Similarly, automated dispensing cabinets on the patient care areas permit nurses to acquire medications for use without the pharmacy having to prepare them, reducing or eliminating the delay in the provision of therapy, and eliminating the inefficiencies and batch processes associated with delivery from a central location.

   Pharmacist checking, where it is required, is performed based on images taken during the fulfillment process, permitting the technicians to continue working and reducing the amount of walking and clothes-changing the pharmacist must perform to check the technicians' work.

4) **Inventory Management.** Inventory is managed within automated cabinets, such as carousel systems, that keep track of inventory, permit historical review of usage and automatically alert responsible persons to reorder medication if needed. The same systems that reduce the amount of walking for the technicians fulfilling the medication orders also assist the pharmacy purchasing agent by notifying them when supplies reach critical levels and permitting them to look at historical trends and adjust ordering behavior appropriately.

   These same cabinets also use the vertical space within the pharmacy to reduce the amount of physical floor space required for the pharmacy, potentially freeing that space up for other pharmacy functions, or returning that space to the hospital for other uses.

   Medication supplies are ordered in quantities determined to be sufficient to permit continued provision of medicinal care without tying up large amounts of money in inventory or having that inventory expire and become waste.

5) **Continuous Improvement.** Pharmacists and the technicians continually assess the efficiency of the medication fulfillment process and modify that process as those assessments dictate.

Long-Term Changes

Achieving a lean vision for the pharmacy requires some long-term changes to its regulatory environment; including more general and consistent regulation of the pharmacy technician group, changes to pharmacy practice acts that permit those technicians to perform functions currently limited by law to pharmacists, and sufficient education and training for technicians to assume a more significant role in the fulfillment process.

Achieving such a vision also requires some long-term changes in the general medication use process; including wider adoption of electronic medical records (EMR) and computerized prescriber order entry (CPOE), definition of more clinically relevant computerized decision support systems(CDSS), and better research into the proper layout of pharmacies.

Tools for the Lean Pharmacy

Nonetheless, pharmacies can start approaching a leaner work flow today with tools currently on the market, including:

1) A growing number of software systems that complement electronic medical record systems, scan changes to patient condition and alert pharmacists where medication interventions may be required.
2) Order entry systems with at least a rudimentary CDSS that can alert both physicians and pharmacists to potentially inappropriate medication orders. Pharmacists must work with their medical staffs to ensure that such systems provide timely and relevant alerts to potentially problematic medication orders.
3) A variety of tools that can be used to reduce or eliminate the transit time for an order to the pharmacy, including CPOE systems (for which the transmission is nearly instantaneous) and image-based systems that essentially fax written orders to the pharmacy as an image rather than waiting for physical transportation of the orders.

Some of these image systems actually pull up the relevant patient's record for review and adjustment when the user selects an order image to process.

4) Pharmacy information systems that can be configured to support multiple batch refills per day, some as many as a refill batch every hour. These tools can be used to smooth out the flow of refill work to reduce the latency period between fulfillment and use, thereby reducing the opportunity that medication will be prepared and sent only to be returned later.
5) Automated Dispensing Machines placed in patient care areas to reduce or eliminate the need to perform physical deliveries of patient-specific supplies. While these inventories require management in themselves, they can be managed on a less-urgent basis than is typically required from a centralized dispensing system.
6) Where centralized fulfillment is required, automated storage devices such as medication carousels that bring the medications to the technician who is fulfilling the order rather than requiring that technician to walk all over the pharmacy acquiring the needed medication supplies.
7) Bar code scanning equipment to validate the appropriate placement (during stocking) and retrieval (during fulfillment) of medication products, to reduce or eliminate wrong-drug selection error.
8) In compounding, that same technology used to ensure that appropriate diluents and adjuvant supplies are used in the preparation of those medication doses.
9) Automated compounding systems that can automatically perform the appropriate dose calculations, eliminating dose computation errors by the technician during compounding.
10) Those same automated compounding systems used to capture dose preparation steps, reducing the need for pharmacists to stop and change garb to inspect compounded preparations (especially when they are sterile preparations) and potentially eliminating the need for double-checks that are otherwise required for expensive and/or high-risk drugs.

Use of tools such as these, along with careful arrangement of facilities and observation of work flow, can permit a pharmacy to begin its lean journey, transforming itself into an organization of high quality, responsive service and fulfilled providers.

Transitioning to the Lean Pharmacy

As previously described, lean transformation is not a once-and-done phenomenon, nor does such a transition necessarily require dramatic, sweeping change. Observation of the current process, implementation of small, systemic transformations and continuous change to improve those processes that appear to be the most wasteful characterize the lean journey.

Some of the changes may seem counter-intuitive to those who must adopt them. Therefore, change management is important as lean transformations occur[i]. This is especially true where the adoption of automated systems is being considered that may dramatically change the work flow. Planning for staff training and support while transitioning to a new work flow, including preparing them for the sense of discomfort they will feel as they attempt to unlearn old habits

is essential. A tendency to "fall back" into old habits, especially during periods of high work load, should be expected and managed.

Key to this transition, therefore, is consistent management attention to the progress of the transformation, as well as ongoing support for those who must implement it. Without leadership support, the transition is not likely to succeed. This support is needed beyond the pharmacy department; there must be support and involvement from other affected departments (notably Nursing and the Medical Staff) as well as from the hospital senior executives to enable the transformation.

Consistent improvement, involvement of those who must do the work in the planning and execution of the transformations, regular coaching and follow-up will yield a series of changes whose values become increasingly apparent and that become increasingly anticipated by those who have seen the power of their own ideas make their workplace better.

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[i] Graban M ***Lean Hospitals*** CRC Press ©2009 ISBN 13:978-1-4200-8380-4

[ii] Gumpper K et al ***Technology Enabled Practice: A vision statement by the ASHP Section on Pharmacy Informatics and Technology***, Am J Health-Syst Pharm 2009; 66:1573-1577