**BACKGROUND**

National organizations are driving health systems to place greater emphasis on performance improvement. Organizations such as the Joint Commission, National Quality Forum (NQF), and Centers for Medicare and Medicaid Services (CMS) have developed clinical quality and patient safety standards and measures to help promote acceptable levels of performance. CMS also ties reimbursement to performance according to required reporting of hospital quality data and will no longer pay for “preventable” complications. Reductions in hospital pharmacy staffing and drug budgets call for greater emphasis on achieving operational efficiency.

ASHP 2015 Goals 3 and 4 mention applying evidence-based methods to improving medication therapy and emphasize the significant role of pharmacists in improving the safety of medication use.

Many improvement opportunities are the result of fragmented communications, non-“error proof” systems, and poor workflow surrounding complex care processes. There is a growing trend for pharmacists to assume leadership roles in improvement projects that are designed to create the ideal “patient experience”: namely what the Institute of Medicine in its crossing the Quality Chasm report defined as “care that is safe, effective, patient centered, timely, efficient, and equitable.” Improvement opportunities exist in the following areas:

1. Clinical care quality (e.g., myocardial infarction, heart failure, pneumonia, the Surgical Care Improvement Project [SCIP] measures, hospital acquired infections),
2. Patient throughput and workflow efficiency (e.g., time spent searching for forms, equipment, waiting, longer length of stay) and,
3. Patient safety (e.g., medication errors, adverse drug events, mislabeled specimens).

To be successful in these endeavors, pharmacists will need to be “armed” with methods and tools that will result in improved sustainable outcomes.

**ISSUE BRIEF**

LEAN Healthcare is a production practice that takes into account the expenditure of resources for everything and eliminates all the waste. It is one improvement methodology that is becoming more prominent in healthcare and has been used effectively for years in Japanese manufacturing companies. LEAN means using less time, money, inventory, and space to increase value from the patient’s perspective. The goal of the use of LEAN is to remove waste from the process (process= set of actions or steps) so that every step in the process adds value from the patient’s perspective. Patients should not be expected to pay for activities that use resources but create no value.

Examples of waste in the medication use processes include:

- **Waste of Correction:** adverse drug events, hospital-acquired infections, medication errors.
- **Waste of Overproduction:** drugs returned to pharmacy.
- **Waste of Material/Information Movement:** multiple STAT sterile preparations runs.
- **Waste of Motion:** poor pharmacy layout.
- **Waste of Waiting:** imbalanced workload, low productivity.
- **Waste of Inventory:** excess forms, low inventory turns.
- **Waste of Processing:** multiple signatures required, multiple information systems entries, reports distribution.
- **Waste of Not Using the Creativity of All Employees:** any ideas not considered and implemented.
The LEAN methodology is most effective when there is a corporate culture that fosters interdisciplinary teams, front line staff who know just how to improve a process are involved, and the main focus is on the patient.

The LEAN process is comprehensive and studies the whole process from beginning to end. The following are examples of how the LEAN methodology might be applied:

- From hospital dock to controlled substances received in safe.
- From physician order written/entered to receipt in pharmacy.
- From patient arrival in the anticoagulation clinic to consultation by a pharmacist.
- From drug arrival on a unit to administration to patient.

**Applying the LEAN Methodology**

As Figure A shows, the process usually begins by defining a Project Charter based on input from staff and others (e.g. voice of the customer). It includes a problem statement, the desired goal, the gap between actual and desired outcomes, and the extent or impact of the problem. A Project Charter designed to improve clinical care quality for SCIP-3 might read as follows:

**Problem Statement:** Our compliance with the SCIP-3 measure (discontinuation of antibiotics within 24 hours post-op) is currently 65% and our goal is 90%. A continuing compliance gap of 25% may result in emergence of antimicrobial resistance and may impact our hospital’s Medicare reimbursement.

**Goal Statement:** To increase compliance with the SCIP-3 measure from 65% to greater than 90% for all surgical patients within 6 months.

**Project Scope:** From end of surgery until the patient’s prophylactic antibiotic is discontinued by the nurse.

**Deliverables:** Pilot implementation project to increase compliance with SCIP-3 measure with control plans to monitor for changes in antimicrobial resistance and infection rates.
After the problem is defined, the next step involves developing a baseline of the current process (Process Map). The process under review is mapped taking into account each step (process). As the team walks the process, any “waste” the patient might perceive is documented. Next, the team envisions the future state based on how the process should be changed to move towards perfection. Differences between the current and future states involving patients presenting to a pharmacist managed anticoagulation clinic might be mapped as Figure B illustrates.

In the improved process or “future state,” the patient signs in and goes directly to the pharmacist thereby deleting the time spent in steps 3–8 under the existing process. Steps deleted include time spent waiting in line to register and time spent in the waiting room. Note that steps 11 and 15 add value from the patient’s perspective since the patient’s laboratory work is completed in step 11 and the patient is counseled in step 15.

The mapping process identifies opportunities for improvement and these opportunities should be prioritized based on patient risk and problem frequency. Root causes for each improvement opportunity may be identified using a “5 Why’s” approach, which involves asking Why? multiple times in descending order. A root cause analysis of intravenous medication turnaround time might read as follows:

**Problem:** delays in medication turnaround time.

**Why?** Need to wait for deliveries to unit.

**Why?** I.V. preparation of first doses takes too long.

**Why?** Time is wasted time in work area.

**Why?** Excessive walking is required.

**Why?** The work area layout is inefficient.

Of the five questions, the primary root cause is identified as being the work area layout. Once the root causes are properly identified, solutions become more evident. Evaluating the effectiveness of proposed solutions involves use of Plan-Do-Study-Act (PDSA) cycles in which small tests of change are planned (P), implemented on a small scale (D), performance-measured compared to current state (S), and changed to adjust the process (A).

Process and outcome measures are used to determine if a change results in an improvement and to provide regular feedback to staff. These measures are also used for ongoing monitoring to assure process stability and sustainability.
Example process and outcome measures that can be used to determine if a change resulted in an improvement are listed below:

- **Productivity**: unit of work measure such as the number of orders processed per hour (are more orders processed per hour?)
- **Lead time**: total time for all process steps such as the time from when order written to drug administration to patient (is the total process time reduced?)
- **Inventory**: supply, material, or resources in excess of customer requirements such as the par levels for drugs stocked in automated dispensing cabinets (are par levels reduced?)
- **Floor Space**: amount of space occupied by materials and staff performing steps in the process, taking into account the full-time equivalents (FTE's) per square foot, inventory per linear foot (has the space required been reduced?)

After the process and outcomes measures have been identified, the next step is to evaluate the outcome measures to determine if the quality of the process output improved. Using the above example, these outcome measures might include the following:

- Number of medication errors;
- Returns to the emergency department per 100 patients;
- Number of hospital acquired infections;
- Number of incomplete registrations per 100 patients;
- Patient, physician, and staff satisfaction;
- Cost reductions (FTE, inventory, space); and
- Enhanced revenue (improved productivity, reduced lead time).

Finally, process and outcome measures are included in a Process Control Plan which outlines tasks and metrics used to move from the current process to the ideal future process. See example Process Control Plan for SCIP-3 in Figure C.

**CONCLUSION**

Pharmacists involved in performance improvement initiatives should use tools and methods designed to assure improved outcomes that are sustainable. LEAN Healthcare is one improvement methodology that is effective in reducing or eliminating “waste” in the pharmacy.