Objectives:

- List the common tools of Lean methodology used to evaluate waste and improve efficiency
- Define steps to create a Lean culture in your pharmacy team
- Apply Lean concepts to problem-solving and how this can be used in your pharmacy department

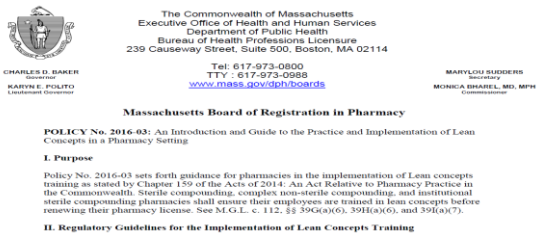
Mass. Board of Pharmacy Policy

- ***New* POLICY No. 2016-03: An Introduction and Guide to the Practice and Implementation of Lean Concepts in a Pharmacy Setting**

- "Sterile compounding, complex non-sterile compounding, and institutional sterile compounding pharmacies shall ensure their employees are trained in lean concepts before renewing their pharmacy license. See M.G.L. c. 112, §§ 39G(a)(6), 39H(a)(6), and 39I(a)(7)."

Mass. Board of Pharmacy Policy

- Effective December 31st, 2017
  - Pharmacist Manager of Record shall attest that their employees have been trained in Lean concepts per recently approved policy



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
239 Causeway Street, Suite 500, Boston, MA 02114

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MONICA BHAREL, MD, MPH, Commissioner

Massachusetts Board of Registration in Pharmacy

POLICY No. 2016-03: An Introduction and Guide to the Practice and Implementation of Lean Concepts in a Pharmacy Setting

I. Purpose

Policy No. 2016-03 sets forth guidance for pharmacies in the implementation of Lean concepts training as stated by Chapter 159 of the Acts of 2014: An Act Relative to Pharmacy Practice in the Commonwealth. Sterile compounding, complex non-sterile compounding, and institutional sterile compounding pharmacies shall ensure their employees are trained in lean concepts before renewing their pharmacy license. See M.G.L. c. 112, §§ 39G(a)(6), 39H(a)(6), and 39I(a)(7).

II. Regulatory Guidelines for the Implementation of Lean Concepts Training

- http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/policy-2016-03.pdf

Mass. Board of Pharmacy Policy

- Individualized to each particular pharmacy practice setting
- Lean training should provide an understanding of:
  1. The definition of Lean concepts
  2. The concepts of waste and value
  3. The benefits of Lean in pharmacy
  4. The basic Lean principles and their use to improve pharmacy processes
  5. The use of the "5S" tools

What is Lean?

- A process improvement methodology focused on eliminating waste in process while increasing value for the customer

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Development of Lean Thinking

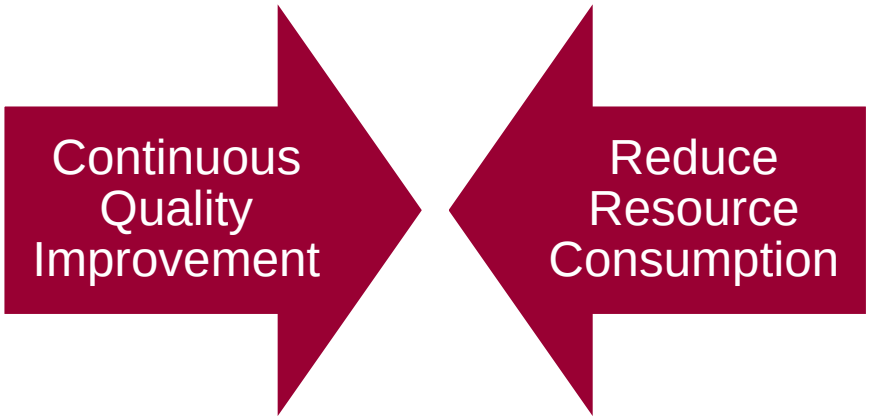
- Term "lean" was created to describe Toyota's business during the 1980s by a research team headed by Jim Womack, Ph.D.

Evolution of Lean Thinking

	1980–1990	1990–mid-1990	Mid-1990–1999	2000+
Focus on	Production cell and line	Shop-floor	Value stream	Value system
Approach	Highly prescriptive, using lean tools	Highly prescriptive, imitating lean organizations	Prescriptive, applying lean principles	Integrative, using different management instruments
Industry sector	Automotive—vehicle assembly	Automotive—vehicle and component assembly	Manufacturing in general—often focused on repetitive manufacturing	High and low volume manufacturing, extension into service sectors
Typical activity in this phase	Application of JIT-techniques, 5s, kanban	Emulation of successful lean organizations training and promotion, TQM	Improving flow; process-based improvements, collaboration in the supply chain	Improving customer value to improve organizational alignment. Decrease variability

Liker J. The Toyota Way- 14 Management principles form the World's Greatest Manufacturer. New York, NY: McGraw-Hill; 2004.
Joosten T., Bongers I., and Janssen R. Application of Lean Thinking to Healthcare: Issues and Observations. Int J Qual Health care. 2009 Oct 21: 21(5):341-347.

Lean Thinking



4 Fundamental Rules

- All activities should be highly standardized and specific
- Direct connection must occur between customer ad supplier
- Products and services follow a simple, predetermined path
- Improvement efforts follow a scientific process

Spear S, Bowen HK. Decoding the DNA of the Toyota Production System. Harv Bus Rev, 1999;77:96-108.

Lean in Healthcare

- Similarities to manufacturing, reliant on multiple complex processes
- Many processes and lots of waste
- Operating requirements continue to expand faster than operating budgets
- 20-30% of Healthcare spending is waste
  - Overtreatment of patients, failure to coordinate care, administrative complexities, etc.

Going Lean In HealthCare. Innovation Series 2005. Institute for HealthCare Improvement White Paper. https://www.entnet.org/sites/default/files/GoingLeaninHealthCareWhitePaper-3.pdf. Accessed Feb 2017.
McManus. Application of Lean in Healthcare Processes; A Complex System Perspective. Lean in Health Care. Lean Academy Healthcare. March 2012. Accessed February 2017.

Impact of Lean

Industry Averages	
Direct Labor/Productivity Improved	45-75%
Cost Reduced	25-55%
Throughput/Flow Increased	60-90%
Quality/Safety (Defect) Reduced	50-90%
Inventory Reduced	60-90%
Space Reduced	35-50%
Lead Time Reduced	50-90%

Going Lean In HealthCare. Innovation Series 2005. Institute for HealthCare Improvement White Paper. https://www.entnet.org/sites/default/files/GoingLeaninHealthCareWhitePaper-3.pdf. Accessed Feb 2017.

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Lean in Pharmacy

- Turnaround time for all chemotherapy preparations decreased from 60 to 44 minutes
  - Using lean principles to improve outpatient adult infusion clinic chemo prep (Lamm M, AJHP 2015)
- Increasing the frequency of sterile product batches from 2 to 5 batches per day reduced rework and waste by 64%
  - Use of lean production to reduce waste in sterile compounding (Davis J, Hospital Pharmacy 2009)
- Cost saving of $289,256 due to waste reduction & improvements in workflow
  - Effect of lean process improvement techniques on a university hospital inpatient pharmacy (Hintzen B, AJHP 2009)

Lean: Operational Principles

1. Define Value
   - Define from the standpoint of the patient and customer
2. Identify the value stream
   - Something "flows"
   - Identify all steps in the process
   - Eliminate waste
3. Improve Flow
   - Identify value added steps
4. Establish Pull
   - Provide service only when needed
5. Strive for Excellence
   - Create value
   - Produce a consistent result each time

Rooney S, Rooney J. Lean glossary. Qual Prog. 2005;38:41–7.
Womack J, Jones D. Lean Thinking. New York, NY: Simon & Schuster; 2003.

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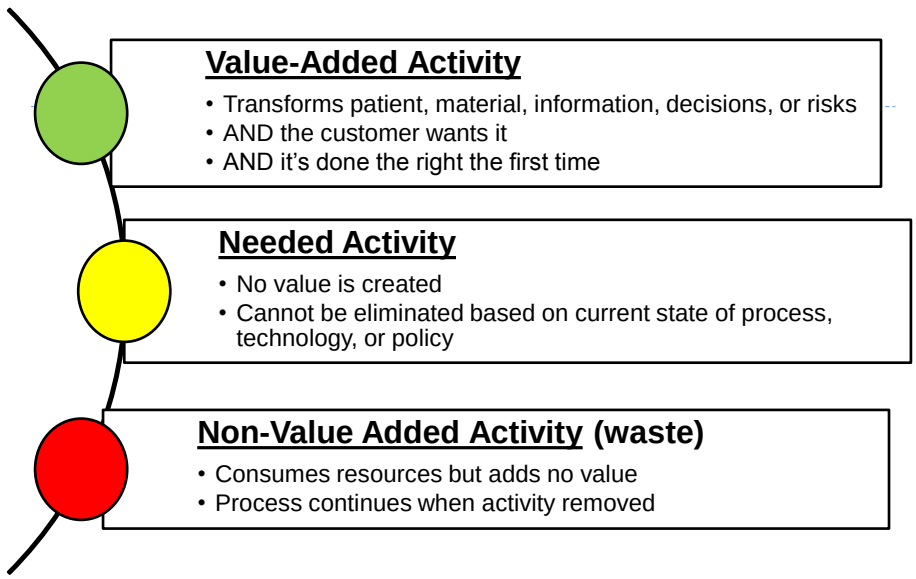
Value

- Determined by the "end" customer, in the case of healthcare, by the patient
  - No unnecessary delays in access to care, particularly no "scheduled waiting"
  - Accurate, consistent and satisfying outcomes
  - Flexible attention to need, change and expectations



Adapted from: McManus. Application of Lean in Healthcare Processes; A Complex System Perspective. Lean in Health Care. Lean Academy Healthcare. March 2012. Accessed February 2017.

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Waste

- Non-value adding activities
  - Mura: Unbalanced workflow
  - Muri: Overburdening people or equipment
  - Muda: Process steps that do not add value

Lean in Pharmacy: 8 Wastes

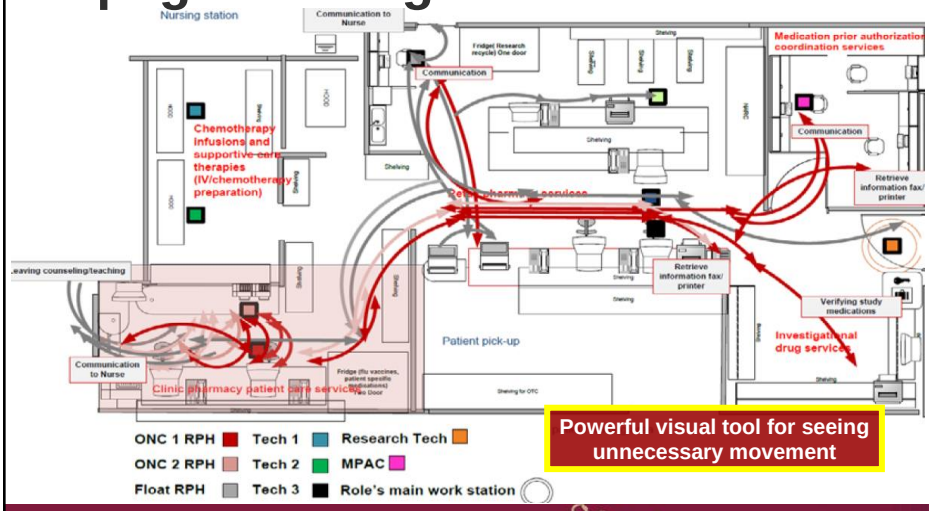
- Defects
- Overproduction
- Waiting
- Transportation
- Inventory
- Motion
- Lack of standardization
- Non-utilized talent

Identify the Value Stream

- Process Maps
  - Document the movement patterns (spaghetti diagrams)or workflows throughout a process
    - An organized visualization of all the interrelated activities

- Value Stream Mapping
  - Identify and eliminate the non-value added activities in each process step

Spaghetti Diagram

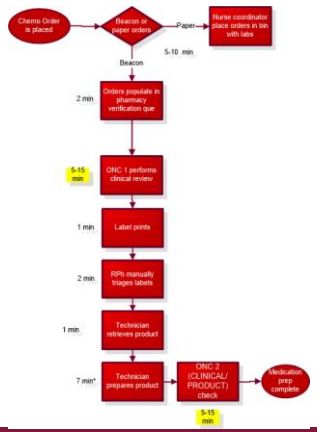


Powerful visual tool for seeing unnecessary movement

Source: Ortega, M. Master's Project: Workflow optimization and redesign for a new oncology clinic pharmacy area at an academic medical center. The University of Wisconsin Hospitals and Clinics. Department of Pharmacy, 2012.

Value Stream Mapping

Process: Medication Stream (Chemo Prep)



Sort: Value- Added Activities (by Role)

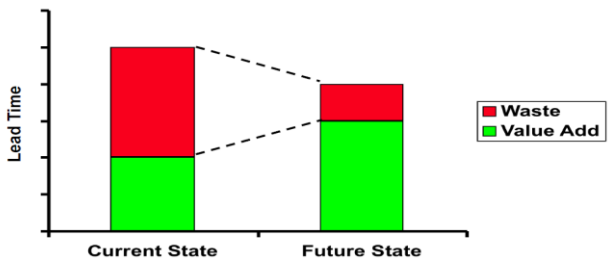
Oncology Pharmacist 1 n=126 (10%)

Number	Activity	%
1	Clinical intervention/ clarification/ reconciliation	8%
2	Patient interview: Medication history/ Gathering patient information	1%
4	Phone Call: Drug Information	1%
6	Face to Face: Drug information resource for MDs/RNs/Patient	2%
6	Patient counseling/	1%
7	Order verification of Treatment Plan	21%
8	Order Entry	8%
9	Profile Review	3%
10	Product checking and dispensing	11%
11	Verifying Retail Prescription Order	8%
13	Cash register (check out)	1%
20	Insurance Audits	4%
24	Prior Authorizations	1%
30	Clinical Review	1%
38	Managing Inventory	3%
40	Credit order in system in healthlink	2%
45	Aoudose and/or Inventory Restocking	1%
17% of Workload in Area 71% Workload by Role		

Source: Ortega, M. Master's Project: Workflow optimization and redesign for a new oncology clinic pharmacy area at an academic medical center. The University of Wisconsin Hospitals and Clinics. Department of Pharmacy, 2012.

Value Stream Map Equation

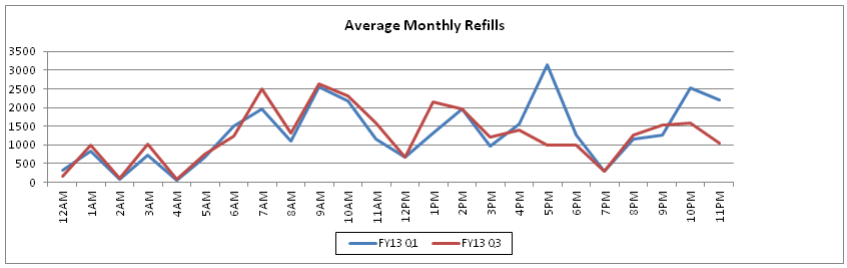
- Increase % Value and reduce % Waste
  - Increase Throughput
  - Lower Cost
  - Improve Quality



Adapted from: McManus. Application of Lean in Healthcare Processes; A Complex System Perspective. Lean in Health Care. Lean Academy Healthcare. March 2012. Accessed February 2017.

Customer Pull in Pharmacy

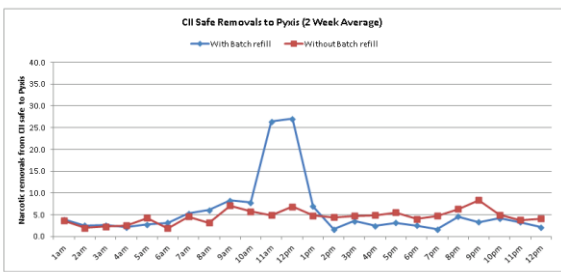
- Batch refilling versus critical low refilling
- Can we control our work?

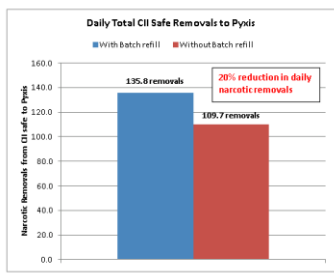


Source: Umass. Department of Pharmacy Process Improvement Project: A3 Batch Refilling versus Critical Low Refilling. September 2013

Leveling Workload

- Batch refilling of control substances to automatic dispensing cabinets
- Single-piece workflow based on stock low





Source: Umass. Department of Pharmacy Process Improvement Project: A3 Batch Refilling versus Critical Low Refilling. September 2013

Lean Tools: Problem Solve

- PDCA / PDSA
- Ishikawa (Cause-and-Effect) Diagram
- 5 Whys

PDSA cycles

- Useful tool when you when you understand why something is happening
- Develop a plan
- Test the plan (Do)
- Review the result (Study)
- Where many fail -
  - Act upon the results

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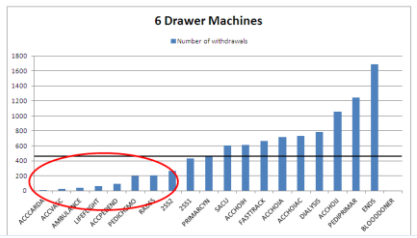
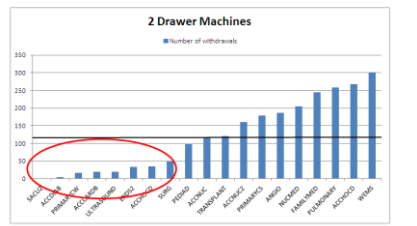
PDSA cycles

- Plan
  - Review ADCs
- Do
  - Remove devices
- Study
  - Impact on service
- Act
  - No action needed

Machine name	Number of withdrawals
ACCCARDA	7
ACCVASC	23
AMBULANCE	35
LIFEFLIGHT	58
ACCPEDEND	95
PEDICHEMO	199
RAD55	208
2552	268
2551	433
PRIMARCYN	460
SACU	604
ACCHOIH	613
FASTTRACK	661
ACCHOIA	718
ACCHOIAC	734
DIALYSIS	782
ACCHOIJ	1056
PEDIPRIMAR	1244
ENDS	1685
BLOODDONER	-

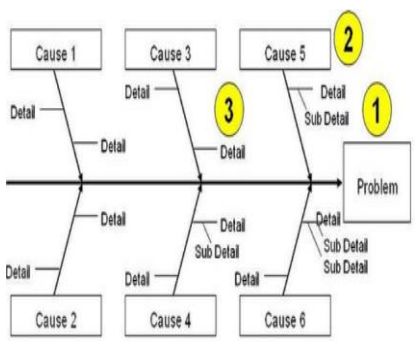


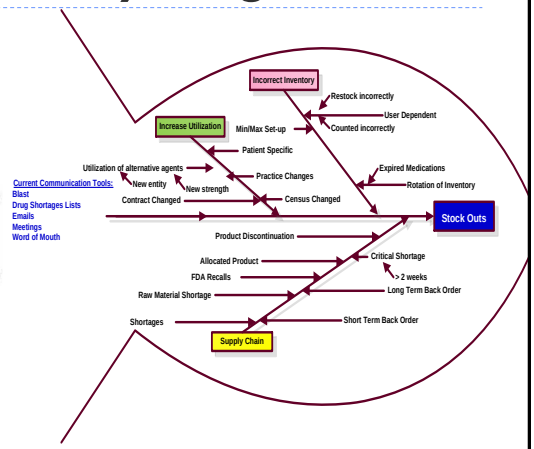
Machine name	Number of withdrawals
SACU2	1
ACCDIAB	4
PRIMARYCW	17
ACCCARDB	19
ULTRASOUND	20
ENDS2	33
ACCHOCD	34
SURG	50
PEDIAD	98
ACCNUC	118
TRANSPLANT	121
ACCNUC2	161
PRIMARYCS	179
ANGIO	187
NUCMED	205
FAMILYMED	244
PULMONARY	259
ACCHOCD	268
WEMS	301



Source: Umass. Department of Pharmacy Process Improvement Project: A3 Pyxis Optimization. June 2014.

Ishikawa (Fishbone) Diagram





Source: Tufts Medical Center. Department of Pharmacy: Drug Selection Committee.

Lean Tools: Control Strategies

- To insure long term sustainability of process improvement and spread adoption
  - 5S
  - Standardized Work
  - Audit Tools

5S Methodology

- Five step methodology aimed at creating and maintaining an organized visual workplace
- This system aids in organizing , cleaning , developing , and sustaining a productive work environment

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5S – IV Storage Area

- Sort → Set in Order → Shine → Standardize → Sustain

Source: Umass. Department of Pharmacy Process Improvement
Project: 5S IV Storage Area. March 2014

5S – Pediatric Vaccine Fridge

- Are your work areas organized?
- How do we sustain?

Source: Umass. Department of Pharmacy Process Improvement
Project: 5S Pediatric Vaccine Refrigerator. November 2014.

Standardized Work

- Documented description of methods, materials, tools, & processing times
  - Recipes
  - Checklists
  - Templates

Tufts Medical Center

Master Formulation Record — DEPARTMENT OF PHARMACY

DRUG NAME	DOSAGE FORM	CONCENTRATION
PROPYLTHIOURACIL	Oral Suspension	5 mg/mL

Date updated: November 2014

Author: Maria Benitez
Reviewer: Hengameh Ansari, PharmD;
Thuy Nguyen, PharmD
Approving Manager: Melissa Ortega PharmD MS

FINAL RECIPE VOLUME: 100 ML

Ingredients	Quantity
Propylthiouracil 50 mg tablet	10 tablets
Ora-Plus/Ora-Sweet (1:1 mixture)	Qs 100 mL

Equipment
- Mortar and pestle
- Stirring rod
- Graduated cylinder

Clothing
- Protective clothing for hazardous agent

Packaging
- 1 x 120 mL amber plastic bottle

Procedure
1. Crush the tablets in a mortar and triturate to a fine powder.
2. Add sufficient vehicle to wet the powder and triturate to a fine paste.
3. Gradually add vehicle:
   a. Add approximately 15 mL of vehicle to the paste, triturate well, and transfer into a graduated measuring cylinder.
   b. Rinse the mortar and pestle with about 20 mL of vehicle and transfer the contents into the measuring cylinder.
   c. Repeat until final volume in the cylinder is 100 mL.
4. Transfer to the 100 mL amber plastic bottle and shake well to mix.
5. Complete standard label, assign appropriate lot number and label final product.

Special instructions: **Hazardous agent. Prepare in IV room with chemotherapy precautions**

Stability: 91 days under refrigeration (4˚C) in amber plastic bottle

Beyond use date: 91 days from date of manufacture, if stored in amber plastic bottle & refrigerator

Sample Bottle Label

Tufts Medical Center
PROPYLTHIOURACIL
5 mg/mL Oral Suspension
100 mL
Date prepared: _____ Prepared by ____
Lot #: _____
Beyond use date: _____ CHK by _____
This is a compounded preparation

Auxiliary Labels: Hazardous Drug, Shake well, Refrigerate.
Final appearance of product: Uniformly suspended product

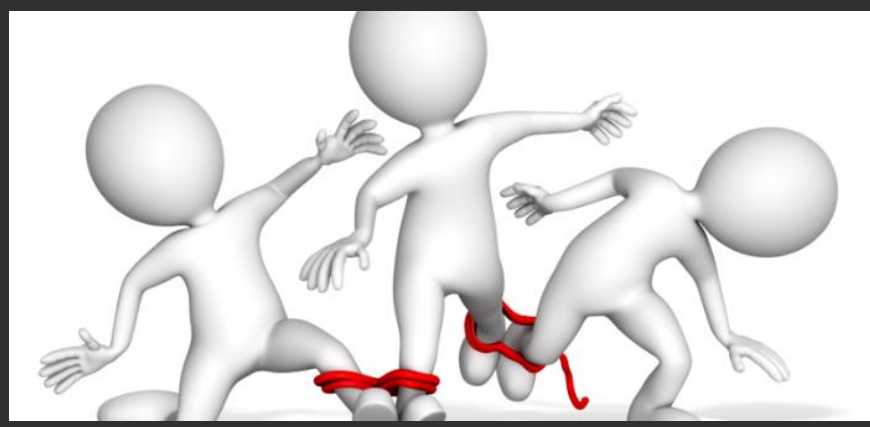
References:
Nahata MC, Morosco RS, Trowbridge JM. Stability of propylthiouracil in extemporaneously prepared oral suspensions at 4 and 25°C. *Am J Health-Syst Pharm* 2000;57:1141-1143.

File Name: Propylthiouracil 5 mg per mL Master Formulation

Source: Tufts Medical Center. Master Formulation Record.

Exercise

Standardized Work



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Standard Work Exercise

- Take 2 minutes and draw a football
- Share your drawing with the person next to you
  - Does it look the same or is their variation?
  - What contributes to your drawings looking different?
    - Skillset, memory, application, etc

Standard Work Exercise

- Take 2 minutes and draw a football
- Draw 2 lines from the left to right
  - Use the red dots on the paper to draw
- Draw 5 laces on the football
- Draw two lines at each of ball
  - Use the green dots on the paper to draw

Standard Work

- Do your team members know what to do at each workstation?
- Do you observe variation in the work being done at different workstations?
- Where does standard work supplement what exists in policies and procedures?
- Application to cross training

ADC vs CII Safe Comparison Standard Work			
Date: 4/2016		Team Leader:	Supervisor: Example, PharmD
Area: Pharmacy CII Safe		Job: Narcotic CPhT	Written By: Example, RPh
Step	Major Step	Key Points	Reason for Key Point
1	Print the "Pyxis vs. CII safe compare report" for the previous 24 hrs	1. In the CII safe console, go to: Report → Quality Assurance → Pyxis vs. CII safe compare 2. Enter previous day's date in date fields	
2	Remove keys from CII safe and access the Narcotic Return Safe/Box	1. In the CII safe console, go to: Access Inventory → Meds → vault key 2. Access the Narcotic Return Safe/Box with key	
3	Retrieve the Narcotic Return Reconciliation Form and medications from the Narcotic Return Safe/Box		
4	Reconcile each med in the safe with what is listed on the Reconciliation form	1. Match drug, location, quantity 2. Check for expired medications	
5	Re-count each medication to ensure it matches log		
6	Review Pyxis vs. CII Safe Compare report for unloads and outdates from pyxis	1. Reconcile unloads and outdates with the Narcotic Return Reconciliation Form	
7	Pharmacist verifies returned medications	1. Pharmacist compares returned medications to the Return Form and also reviews the Pyxis vs. CII Safe Compare Report	
8	Report any discrepancies to pharmacy manager or designee		
9	Return in-date controlled substances to the CII safe	1. Log expired/waste controlled substances in the Waste/Expired Controlled Substances Reconciliation Log 2. Place expired/waste controlled substances in the appropriate CII Safe compartment	
10	File signed report	1. Both the pharmacist and pharmacy technician must sign and date	

Source: Umass. Department of Pharmacy Standard Work. ADC vs CII Safe Comparison Standard Work.

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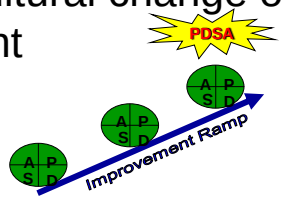
Lean Tools: Test Concepts

- Small tests of change offer quick simulations of change concepts
  - Waste Walk/Gemba
  - Kaizen Event

Lean Culture

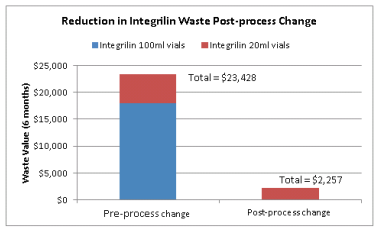
- Requires cultural change of continuous improvement



- Emphasis on customer satisfaction, a clean, safe, and orderly environment as well as teamwork, cooperation in problem solving, and employee empowerment

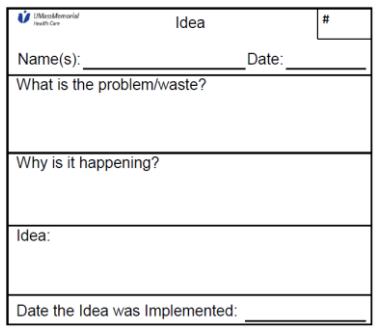
Idea Board Systems

- Create opportunities for staff to share their ideas that leaders may not see
- Elimination of integrilin drips in from each cath room to central cath hall eliminated $42,000 in waste per year and 90% of waste eliminated



Idea Board Cards

- Everyone can identify a problem
- Train staff at all levels to think about root causes
  - 5 Whys
- Engage employee ideas
- Utilize PDSA cycles



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How to make LEAN successful in your team

- A team that utilizes LEAN methodology effectively embraces the culture of transparency
- The culture must be open to new ideas and accept the question WHY?

Key Points

- Lean is a set of principles not just tools, and the application of these principles can improve pharmacy processes
- Tools of Lean can help you understand your systems, problem solve, improve efficiency, and add value
- The strive for excellence requires strong leadership and persistence over time

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