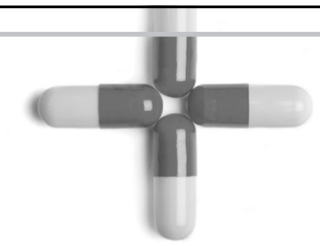


Medication Safety: The Role of the Pharmacy Buyer

Katrina Kagler Harper, PharmD, MBA, BCPS, DPLA

vizient

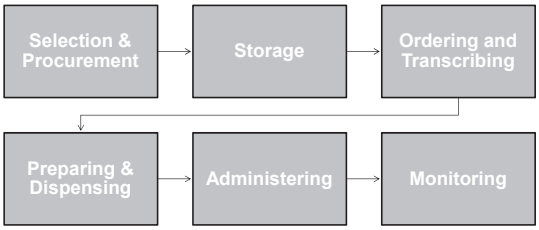
Learning Objectives

- Describe strategies for preventing adverse drug events during the pharmacy procurement, storage and distribution process.
- Summarize current and upcoming regulations applicable to the role and responsibilities of the Pharmacy Buyer
- Summarize current accreditation standards (i.e. The Joint Commission) applicable to the role and responsibilities of the Pharmacy Buyer
- Discuss the specific role of the Pharmacy Buyer in ensuring a safe medication use process

Disclosure Information

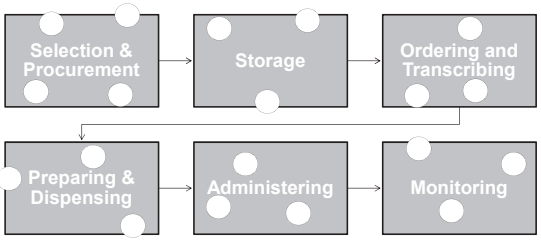
Katrina Harper has no relevant financial or nonfinancial relationships to disclose.

The Medication Use Process



Chapter 5. Principles and Practices of Medication Safety. DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. *Pharmacotherapy: A Pathophysiologic Approach, 8e*; 2011. Available at: https://accesspharmacy.mhmedical.com/content.aspx?bookid=462&sectionid=41100771 Accessed: July 23, 2018

Swiss Cheese Model



Ann Intern Med. 2007;147:755-765., Reason J. Managing the Risks of Organizational Accidents. 1st ed. Aldershot, UK: Ashgate; 1997

Medication Errors vs. Adverse Drug Events

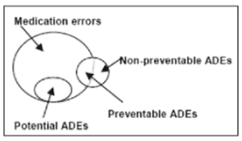
No consistent definition

Medication Error (ME)

- Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.
- It is not necessary for an adverse outcome to occur for an action or decision to be an error

Adverse Drug Event (ADE)

- An injury from a medicine or lack of an intended medicine



J Gen Intern Med. 1995;10:199-205.

Prevalence of ADEs

In 1999, the IOM Issued a Report on Medical Errors

- 8th Leading Cause of Death in the U.S.
- At Least 98,000 Americans Die Each Year Due to Preventable Errors
- Cost Associated With These Errors as much as $29 Billion Annually

In 2006, the IOM released the report "Preventing Medication Errors"

- 1.5 million Americans are injured each year by medication errors
- 1 medication error occurred per patient day in hospital care

In 2012, a study published in American Health & Drug Benefits

- Preventable ADEs associated with injectable medications
- Impact 1.2 million hospitalizations annually

To Err Is Human: Building a Safer Health System. Washington, DC: National Academies Press; 2000. Preventing Medication Errors: Quality Chasm Series. Washington, DC: National Academies Press; 2007. Am Heath Drug Benefits. 2012;5(7):413-422

Cost of ADEs

May cost up to $5.6 million each year per hospital depending on hospital size

- This estimate does not include ADEs causing admissions, malpractice and litigation costs, or the costs of injuries to patients.

National hospital expenses to treat patients who suffer ADEs during hospitalization are estimated at between $1.56 and $5.6 billion annually.

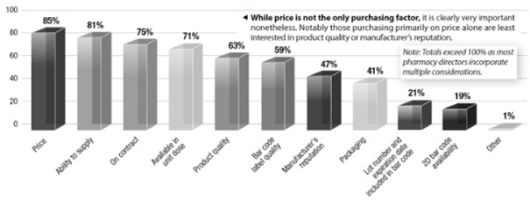
- Patients who experienced ADEs were hospitalized an average of 8 to 12 days longer than patients who did not suffer ADEs
- Patients who experienced ADEs cost of hospitalization were $16,000 to $24,000 more than patients who did not suffer ADEs

Injectable related ADEs cause and increase of $2.7 to $5.1 billion in annual cost to US healthcare payers

- $600,000 in extra annual cost per hospital
- $72,000 per hospital in medical professional liability

 JAMA 1997;277(4):307-11., JAMA 1995;274(1):29-34., Reducing and Preventing Adverse Drug Events To Decrease Hospital Costs. http://www.ahrq.gov/qual/advpaper/jamia.htm. Accessed Dec. 2011. Am Health Drug Benefits. 2012;5(7):413-422

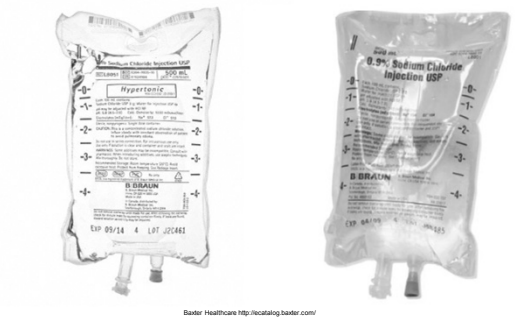
Selection & Procurement Considerations



Pharmacy Purchasing & Products . 2013:10 (9): S2

Strategies for preventing ADEs

Medication Error



Baxter Healthcare http://ecatalog.baxter.com/

High Alert Medications

- **Bear a heightened risk for causing significant patient harm**
- **Although mistakes may or may not be more common with these medications, the consequences of an error can be more devastating to patients.**
- **Examples include opioids, anticoagulants, neuromuscular blocking agents, concentrated electrolytes, magnesium sulfate, insulin, chemotherapy, and lipid-based medications.**

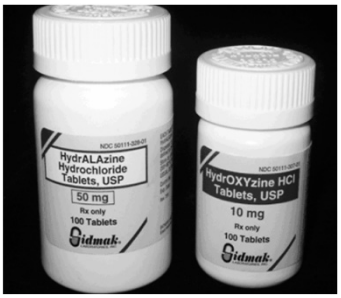
https://www.ismp.org/recommendations/high-alert-medications-acute-list

List of Confused Drug Names

Drug Name	Confused Drug Name
Abelcet	*amphotericin B*
Accupril	Aciphex
acetaZOLAMIDE	*acetoHEXAMIDE*
acetic acid for irrigation	*glacial acetic acid*
acetoHEXAMIDE	*acetaZOLAMIDE*
Aciphex	Accupril
Aciphex	Aricept
Activase	Cathflo Activase
Activase	TNKase
Actonel	Actos

https://www.ismp.org/recommendations/confused-drug-names-list
https://www.ismp.org/sites/default/files/attachments/2017-11/tallmanletters.pdf

Tall Man Lettering



Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities For Change. ISMP 2009.

Avoid Salads

Sound Alike Look Alike Drugs (SALADs)

- Similar medication pairs that may lead to a medication error
- Look Alike: Drug Packaging

Examples of SALADs

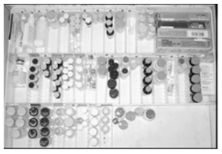
ISMP Medication Safety Alert! Acute Care Edition. September 22, 2011 Issue

Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities For Change. ISMP 2009.

Examples of SALADs

ISMP Medication Safety Alert! Community/Ambulatory Care Edition. 2010;9(7):1-3.

Storage



Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities For Change. ISMP 2009.

Targeted Medication Safety Best Practices for Hospitals

ISMP 2018-2019 TMSBPs for Hospitals include 3 new practices and 2 revised practices.

- **New**
  - BEST PRACTICE 14: Seek out and use information about medication safety risks and errors that have occurred in other organizations outside of your facility, and take action to prevent similar errors.
- **Revised**
  - Ensure that all oral liquid medications that are not commercially available in unit dose packaging are dispensed by the pharmacy in an oral or ENFit syringe.
  - Segregate, sequester, and differentiate all neuromuscular blocking agents (NMBs) from other medications, wherever they are stored in the organization.
- **Older**
  - Purchase oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale.
  - Eliminate all 1,000 mL bags of sterile water (labeled for "injection," "irrigation," or "inhalation") from all areas outside of the pharmacy.

Standardize 4 Safety Initiative

https://www.ashp.org/Pharmacy-Practice/Standardize-4-Safety-Initiative/Proposed-Standard-Concentrations

Standardization Of Oral Concentrations

http://www.mipedscompounds.org/standard-formulations

Recalls

Three types

- **Class I**
  - "situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."
- **Class II**
  - "situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."
- **Class III**
  - "situation in which use of or exposure to a violative product is not likely to cause adverse health consequences."

Drug Shortages

- **Monitoring your resources**
- **Team approach**
  - Standardizing treatments
  - Analyzing products
    - Supply chain security
- **Communication**
  - IT team
  - Champions
- **Error mitigation**
  - Concentrations
  - SALADs
  - Compounding
    - FDA Guidance: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities
  - Report any medication errors related to drug shortages https://www.ismp.org/report-medication-error

Regulations

DSCSA timeline – important dates

2015	2017	2019	2020	2023
Jan. 1 **(FDA begins enforcement May 1)** **Manufacturer**: Provide TH, TS & TI to distributor **Distributor**: Ship to authorized trading partner Provide TH, TS, TI to dispenser **Dispenser**: Quarantine and investigate suspect products **July 1 (FDA begins enforcement Mar. 1 2016)** Begin 6 year retention of TH, TS TI	Nov. 27 **Manufacturer**: 1 **(FDA begins enforcement Nov 26, 2018)** Serialization of product begins with unique product identifier TH, TI, TS electronic format Verification of unique product identifiers	Nov. 27 **Distributor**: Receive product with unique identifiers Accept returns only with TI, TS	Nov. 27 **Dispenser**: Accept only serialized products (two dimensional barcode identifiers) Verification of unique product identifiers	Nov. 27 **Manufacturer:** Participate in package level traceability system **Distributor:** Participate in package level traceability system **Dispenser**: Participate in package level traceability system

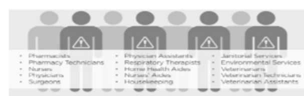
Drug Compounding

http://www.usp.org/compounding/updates-on-standards

USP General Chapter <800>: *Hazardous Drugs – Handling in Health Care Settings*

http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

USP <800>



http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

More Hazardous Drugs (HDs)

Table 4. Drugs Proposed for Placement on the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings* (Category 1 -- Special Handling Information & Category 5 -- Drug Meets the NIOSH Definition of Hazardous Drug)

Generic Drug Name		
Bevacizumab	**Formulation**ª ... IV **Dosage** ... 5-15 mg/kg **AHFS Class**ᵇ ... Antineoplastic **New Drug**ᶜ ... Yes **Special Handling Information**ᵈ ... No **2018 Update Table No.**ᵉ ... 1	**Rationale for Proposing Placement on the List** *Reproductive toxicity and Teratogenicity or other developmental toxicity*: ovarian failure in patients in clinical trials, embryo-fetal toxicity in rabbits **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=939b5d1f-9fb2-4499-80ef-0607aa6b114e
Blinatumomab	**Formulation** ... IV **Dosage** ... 9 mcg/day **AHFS Class** ... Antineoplastic **New Drug** ... Yes **Special Handling Information** ... No **2018 Update Table No.** ... 1	**Rationale for Proposing Placement on the List** *Organ toxicity at low doses*: neurotoxicity at low doses in patients in clinical studies **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=38b482a8-900b-4591-9857-5031ecb830aa
Botulinum toxins, all forms including abobotulinimtoxinA and onabotulinumtoxinA	**Formulation** ... IM **Dosage** ... 1-1000 units **AHFS Class** ... Neurotoxin **New Drug** ... No **Special Handling Information** ... No **2018 Update Table No.** ... 2	**Rationale for Proposing Placement on the List** *Organ toxicity at low doses and Teratogenicity or other developmental toxicity*: spread of toxin effects, reductions in fetal body weight and decreased fetal skeletal ossification at human dose **Package Insert** https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=botulinum+toxin+type+A&pagesize=200&page=1"
Ceritinib	**Formulation** ... Capsule **Dosage** ... 750 mg **AHFS Class** ... Antineoplastic **New Drug** ... Yes	**Rationale for Proposing Placement on the List** *Teratogenicity or other developmental toxicity*: embryo-fetal toxicity at low doses in rats and rabbits **Package Insert**

https://www.cdc.gov/niosh/docket/review/docket233b/pdfs/233-BRevisedNIOSHTable42-14-18.pdf

HD Receipt & Storage

Receipt

- **Anti-neoplastic HDs and all HD active pharmaceutical ingredient (API) must be unpacked in an area that is neutral/normal or negative pressure relative to the surrounding areas.**
- **HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.**
- **HD identification**
- **Protocol**
  - Designated area
  - Appropriate PPE if HDs (Group 1 or others per risk assessment) are not received in bag
  - Supplies needed
  - Inspect inventory
  - Transport to storage area
  - Inventory into system

Storage

- **Anti-neoplastic HDs requiring manipulation (including refrigerated anti-neoplastic HDs) and any HD API must be stored separately from non-HDs.**
- **These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).**
- **Non-anti-neoplastic, reproductive risk only and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy.**

USP <800> Supplies

- **Closed system drug transfer devices**
- **IV administration tubing**
- **Cleaning agents**
- **Spill kits**
- **Crushing pouches**
- **Transport bags**
- **Respirators**
- **Personal protective equipment (PPE)**

https://www.cdc.gov/niosh/topics/respirators/default.html

Personal protective equipment

PPE	Specifications
Gloves	• ASTM-tested (Standard D6978) • Two pairs for compounding, administering, managing a spill, and disposal
Gown	• Disposable • Long-sleeved/cuffed • Solid front/ Back closure • Polyethylene-coated polypropylene or other laminate material • ASTM F739-12 tested
Eye and face protection	• Goggles • Face shields in combination with goggles

Table 5 (Continued). Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings*

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
Oral liquid drug or feeding tube	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes†
	Administration	yes	yes	yes, if vomit or potential to spit up†	no	N/A
Topical drug	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes‡, BSC or CACI (Note: carmustine and mustargen are volatile)
	Administration	yes	yes	yes, if liquid that could splash†	yes, if inhalable form potential	N/A

NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161 (Supersedes 2014-138).

Accreditation Standards

CMS Conditions of Participation	The Joint Commission	Det Norske Veritas	Healthcare Facilities Accreditation Program
Hospital Pharmaceutical Services Condition of Participation 42 CFR 482.25	MM.05.01.07 Preparing medications	MM.1 Management Practices SR.3 and SR.4	Standard 25.01.02 Supervision of Pharmacy Activities
Nursing Services Condition of Participation 42 CFR 482.23	Comprehensive Accreditation Manual for Home Care "Medication Compounding" (MC) standards chapter		Standard 16.01.01 Preparation and Administration Drugs
Critical Access Hospitals Condition of Participation 42 CFR 485.635	Medication Compounding Certification		

Implications Of Guidance Related To Compounding Of Medications

Use of compounding pharmacies

Compounded medications from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility

- Hospital must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs and applicable State or Federal laws or regulations.

The Joint Commission's (TJC) survey process

TJC Top Challenging Clinical Standards 2017

Standard	Issues
IC.02.02.01	Medical devices
PC.02.01.03	Patient orders
PC.01.03.01	Plan of care
IC.02.01.01	Implementation of the IC plan
RC.01.01.01	H&Ps and timing orders
MM.03.01.01	**Medication storage**
MM.04.01.01	Therapeutic duplication
PC.02.01.11	Resuscitation services

Medication Management & Pharmaceutical Services (CMS 23.CFR.482)

TJC MM.03.01.01 - Medication storage

Stored according to manufacturer's recommendations

- Temperature management
- Unrefrigerated succinylcholine
- Vaccines
- Removal of external protective covering on intravenous (IV) bags
- Do not use date
- Multi dose vials
- Secured and authorized access
  - Diversion risk?
  - Anesthesia cart medications unsecured
- EP 10: Medications in patient care areas are available in the most ready-to-administer forms commercially available or, if feasible, in unit doses that have been repackaged by the pharmacy or a licensed repackager.

Medication Management & Pharmaceutical Services (CMS 23.Cfr.482)

MM.01.01.03 The organization safely manages high-alert and hazardous medications.

- EP1. The organization identifies, in writing, its high-alert and hazardous medications
- EP 2. Policies and procedures for segregating easy-to-confuse (e.g., look-alike or sound-alike) medications.

MM.05.01.09 Medications are labeled

- TJC National Patient Safety Goals (NPSG) 03.04.01 - Labeling of medications and containers
  - Medication Labeling in Peri-operative and Procedure Areas
    - Items labeled, i.e., syringes, containers, basins

Packaging Size

- Multi-dose Vials (MDV) vs. Single Dose Vials (SDV)

LD.04.03.09 - Oversight of care provided through contractual agreements

Revisions Related To Medication Management

Effective January 1, 2018

EC.02.05/03 EP 14 implement a policy to provide emergency backup for essential medication dispensing.

EC.02.05/03 EP 15 implement emergency backup for refrigeration for essential medications.

MM.03.01.01 EP 4 "Wasting" was added to the requirement for a written policy addressing the control of medication between receipt by an individual health care provider and administration of the medication.

MM.08.01.01 EP 16 Implement a policy describing the type of medication overrides that are to be reviewed for appropriateness and the frequency of review when automated dispensing systems are used. (100% review of overrides is not required)

Quick Safety #39 – Supporting Second Victims

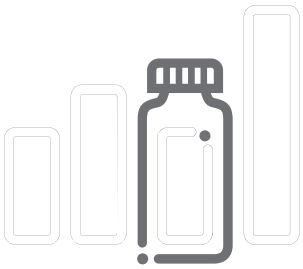
Who's affected by an adverse event

- Patient
- Family
- Health care providers
  - Effects on health providers:
    - Reduced job satisfaction
    - Guilt and anxiety
    - Sleeplessness
    - Signs of post traumatic stress disorder
    - Fear of litigation
    - Fear of job loss
    - Burnout
    - Suicide ideation

Potential safety actions to support second victims:

- Just culture – lessons learned
- Debrief sessions for all involved
- Education on how to provide peer-to-peer support
- Policies addressing protections for the support program
- Support services for those involved in litigation

Ensuring a safe medication use process



Culture Of Safety

- **Promote a culture of safety to lower medication errors.**
  - Just Culture model
    - Creating an environment of internal transparency around risk
    - Striving to understand why human errors occur within the organization
    - Striving to understand why at-risk behaviors occur within the organization
    - Learning to see common threads in order to prioritize risk and interventions
    - Working with staff to design systems that reduce the rate of human error and at-risk behavior or mitigate their effects
    - Learning when to console and when to coach employees
    - Limiting the use of warnings and punitive actions to the narrow circumstances where such use benefits organizational safety
    - Avoiding traditional organizational biases by focusing on the risks inherent in systems and behavioral choices, not the actual outcomes of events
    - Using data to build both unit and organizational models of risk
    - Learning to measure risk, at both the unit and organizational levels

Medication Error Reporting

Increase detection and reporting of medication errors and potentially hazardous drug-use situations.

- FDA MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- National Coordinating Council for Medication Error Reporting and Prevention
- ISMP National Medication Errors Reporting Program (MERP)
- ISMP National Vaccine Errors Reporting Program (VERP)

Recommend methods to facilitate the implementation of organization-wide, system-based changes to prevent medication errors.

- Process improvement

Process Improvement

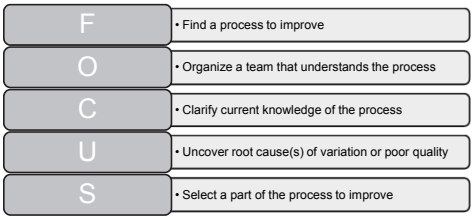
The job of examining the processes used in a company, department, project, etc. to see how they can be made more effective

- The proactive task of identifying, analyzing and improving upon existing business processes within an organization for optimization and to meet new quotas or standards of quality

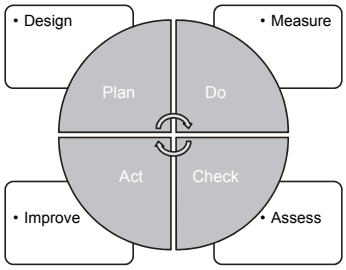
Quality improvement (QI) consists of systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups

- **Root Cause**
  - Explore and understand the root causes of medication errors.
- **Fishbone (Ishikawa) Diagram**
  - Cause and Effect Diagram
  - The fishbone diagram identifies many possible causes for an effect or problem.
  - It can be used to structure a brainstorming session.
  - It immediately sorts ideas into useful categories.

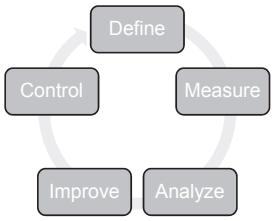
FOCUS-PDCA Model



FOCUS-PDCA Model



DMAIC



Six Sigma methodology

- Used to ensure quality within an existing process
- A data driven improvement cycle
- An easily managed systematic process to deliver measurable results and accelerate change

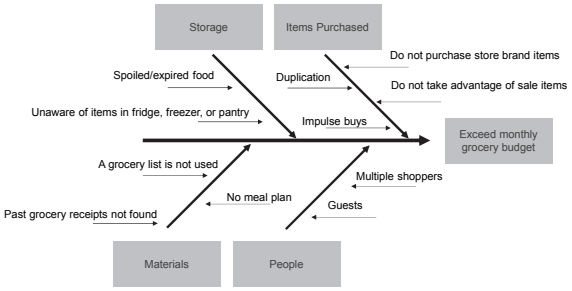
Process Improvement In The Pharmacy

- **Identify the problem you want to solve or process you want to improve**
- **Gain support from management and individuals willing to join the team**
- **Create a team**
  - Create a team based on the anticipated workload of the project
- **Become intimately knowledgeable about the current work process**
  - Conduct a gemba walk
  - Understand the value stream
- **Keep the customers in the forefront**
- **Brainstorm potential solutions**
  - Choose solutions based on predicted high impact
- **Implement changes**
- **Ensure that there are measures for accountability**
- **Promote continued quality improvement**

Example

Problem: Monthly grocery bill is over budget by $100
FOCUS-PDCA Model
Find a process to improve
• Exceeding Monthly Grocery Budget
Organize an effort to work on improvement
• Team: Family members
• Schedule Family meeting
Clarify current knowledge of the process
• Process mapping – Create a flowchart of current practice
Understand process variation and capability
• Root cause analysis
Select a strategy for continued improvement
• Limit number of grocery shoppers
• Limit number of trips to the grocery store
• Shop according to grocery list
• Use coupons/weekly ads

Example



Example

Goal

SMART: specific, measurable, achievable, results-focused, and time-bound.

Aim: By December 31, 2017, the monthly grocery bill will be within the allotted amount of $500 per month.

FOCUS-PDCA Model

Plan: Limit number of grocery shoppers

Do: Only the mother will do the grocery shopping

Check: The bill for the month of May was over by $90 ($590) per collected receipts

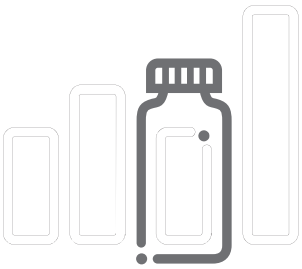
Act: Introduce a new element of change into the plan

Repeat

Plan

- Limit number of trips to the grocery store
- Shop according to grocery list
- Use coupons/weekly ads/ price matching

Questions?



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