CHAPTER 9

PERFORMANCE IMPROVEMENT
HOSPITAL
PERFORMANCE IMPROVEMENT
Introduction to terminology and requirements

Performance Improvement
♦ Required (Board of Pharmacy CQI program, The Joint Commission, CMS – Center for Medicaid/Medicare Services)
♦ Powerful Tool
♦ Systematic Process
♦ Focus on patient safety and optimizing care

1. Medication Errors & introduction of terms
2. CMS Hospital Core Measures
3. Drug Use Evaluation
4. Proactive Risk Assessment
5. Joint Commission Measurement of Success “M”

1. MEDICATION ERRORS
Continuous Quality Improvement Program – required by board of pharmacy to identify quality-related events and to improve patient care (64B16-27.300) ALL PHARMACY PERMITS
- Inappropriate dispensing
  - Variation from the prescription (incorrect drug strength, dosage form, patient, inadequate or incorrect labeling or directions)
  - Failure to identify and manage therapy (under or over utilization, duplication, contraindications, interactions, duration, allergy, or monitoring)
- Requires policy and procedure
- Quarterly meetings with documentation requirements for 2 years
- Includes assessing the impact of staffing levels, work flow, and technical support

Required by Medicare COP §482.25 (b) (6) and 482.21 “the hospital must report drug administrative errors, adverse drug reactions and drug incompatibilities to its hospital-wide QAPI program”. Definition of medication error and ADR should be broad enough to include “near misses”. Program should be non-punitive with the focus on the system and not the involved health care professionals.

Required by Joint Commission (MM.07.01.03) The hospital collects data on significant medication errors and significant adverse drug reactions, adverse events related to moderate or deep sedation or anesthesia, and the use of blood and blood components.
**Sentinel Event with Root Cause Analysis** required since 1995

- **Definition:** “Unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury includes loss of limb or function”
- **Requires** “root cause analysis (RCA)” and voluntary reporting to The Joint Commission. Includes assessment of human factors, equipment factors, controllable environmental factors and uncontrollable external factors, leadership issues such as culture and communication.
- Commonly identified root causes include medication use (formulary, storage/control, labeling, ordering, preparing/distributing, administering and/or patient monitoring) with most having multiple root causes (leadership, communication, human factors, assessment, information management, physical environment, continuum of care, care planning, and patient education)

“**CODE 15**” – state required reporting of significant medical errors. Reported by hospital Risk Manager. Pharmacy Director involved if medication event.

**2. HOSPITAL CORE MEASURES**

**Report card**
- The Joint Commission ORYX requirements – reporting on at least 4 core measures. web page [www.qualitycheck.org](http://www.qualitycheck.org)
- CMS [www.hospitalcompare.hhs.gov](http://www.hospitalcompare.hhs.gov)

**Compliance affects hospital reimbursement**
Heart Attack (Acute Myocardial Infarction or AMI)

- Aspirin at Arrival
- Aspirin at Discharge
- ACE Inhibitor or ARB for Left Ventricular Systolic Dysfunction
- Beta Blocker at Arrival
- Beta Blocker at Discharge
- Fibrinolytic Medication Within 30 Minutes Of Arrival
- Percutaneous Coronary Intervention (PCI) Received Within 90 Minutes of Hospital Arrival
- Smoking Cessation Advice/Counseling

Heart Failure

- Evaluation of Left Ventricular Systolic (LVS) Function
- ACE Inhibitor or ARB for Left Ventricular Systolic Dysfunction
- Discharge Instructions
- Smoking Cessation Advice/Counseling

Pneumonia

- Oxygenation Assessment
- Initial Antibiotic Timing
- Pneumococcal Vaccination
- Influenza Vaccination
- Blood Culture Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital
- Appropriate Initial Antibiotic Selection
- Smoking Cessation Advice/Counseling

Surgical Care Improvement/Surgical Infection Prevention (SCIP)

- Prophylactic Antibiotic Received Within 1 Hour Prior to Surgical Incision
- Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time
- Prophylactic Antibiotic Selection
- Appropriate Venous Thromboembolism Prophylaxis started at the right time
- Appropriate body temperature

Perinatal Care

Venous Thromboembolism (VTE)

Stroke (STK)

Hospital Based Inpatient Psychiatric Services (HBIPS)

Children's Asthma Care
3. **Drug/Medication Use Evaluation**

- Powerful Tool
- Systematic Process
- Focus on patient safety and optimizing care

Collect data *retrospectively* or *prospectively*
Focus on specific drug or treatment

1. **Prescribing examples:**
   - a. appropriate use of vancomycin with goal to reduce resistance and drug related morbidity
   - b. appropriate dosage of drugs
     - i. adjustment for renal function
     - ii. adjustment for patient weight
   - c. appropriate order writing
     - i. PRN orders have clear indication for use
     - ii. No dangerous abbreviations

2. **Dispensing examples:**
   - a. turnaround time for STAT orders
   - b. accuracy of dispensing
   - c. appropriate auxiliary labels
     - i. storage requirements: refrigerate, do not refrigerate
     - ii. expiration dating
     - iii. special precautions such as hazardous handling, do not shake

3. **Administration examples**
   - a. patient education about medications
   - b. appropriate use of infusion pumps
   - c. compliance with giving medications on time
   - d. eMAR scanning rates
   - e. arm band checks

4. **Monitoring examples:**
   - a. iNR is assessed prior to administration of warfarin
   - b. pain assessment and reassessment for pain medications
   - c. incidence of hypoglycemia or hyperglycemia

4. **Proactive risk assessment** - Required by The Joint Commission & Medicare COP (§482.25 (b) (6)).

- Used to prioritize performance improvement efforts.
- The assessment should include medication errors, adverse drug reactions, and the medication management system (MM 08.01.01).
- An accepted methodology involves Failure Mode and Effects Analysis (FMEA) Requires clarifying the process (e.g., flow chart), assigning severity and risk scores to each process. The scores are used to prioritize performance improvement.
5. **Periodic Performance Review with Measurement of Success** – required by The Joint Commission (discussed in Survey process chapter): Describes which standards must have measurement data to demonstrate compliance.

Measurement of Success is required for some Evidence of Performances (EP) to demonstrate compliance with the standard and is indicated by a “M” icon in the manual.

Measurement sample size guidelines:

<table>
<thead>
<tr>
<th>Population Size</th>
<th>Sample size</th>
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</thead>
<tbody>
<tr>
<td>Fewer than 30 cases</td>
<td>100% of available cases</td>
</tr>
<tr>
<td>30-100 cases</td>
<td>30 cases</td>
</tr>
<tr>
<td>101-500 cases</td>
<td>50 cases</td>
</tr>
<tr>
<td>Greater than 500</td>
<td>70 cases</td>
</tr>
</tbody>
</table>
EXAMPLE PERFORMANCE IMPROVEMENT PROGRAM

Plan Performance Improvement/MUE Activities

<table>
<thead>
<tr>
<th>Non-formulary drug use</th>
<th>Medication variances</th>
<th>Adverse drug reactions</th>
<th>Target drug/drug-class/disease medication use evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>High risk, High volume, Problem prone, New formulary, Request from health care practitioner</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Other performance improvement</td>
</tr>
</tbody>
</table>

Collect data aggregate quarterly

Review at Drug Safety Team and P&T Committee

Make recommendations to improve performance

<table>
<thead>
<tr>
<th>Targeted education</th>
<th>Newsletter</th>
<th>Development of policies, protocols, forms, procedures</th>
<th>Formulary action</th>
<th>Other</th>
</tr>
</thead>
</table>

9.7
Standards of Practice - Continuous Quality Improvement Program.

(1) “Continuous Quality Improvement Program” means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) “Quality-Related Event” means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber’s prescription order, including, but not limited to:
   1. Incorrect drug;
   2. Incorrect drug strength;
   3. Incorrect dosage form;
   4. Incorrect patient; or
   5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:
   1. Over-utilization or under-utilization;
   2. Therapeutic duplication;
   3. Drug-disease contraindications;
   4. Drug-drug interactions;
   5. Incorrect drug dosage or duration of drug treatment;
   6. Drug-allergy interactions; or

(3)(a) Each pharmacy shall establish a Continuous Quality Improvement Program which program shall be described in the pharmacy’s policy and procedure manual and, at a minimum shall contain:

   1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, registered pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager or the consultant pharmacist of record;
   2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality Related Events at least every three months.
   3. A planned process to record, measure, assess, and improve the quality of patient care; and
   4. The procedure for reviewing Quality Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

(4) Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the pharmacist. Documentation of a Quality-Related Event shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacists shall maintain such records at least until the event has been considered by the committee and incorporated in the summary required in subsection (5) below.

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the provisions of Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for two years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

TITLE: ADVERSE DRUG REACTION REPORTING

POLICY:

Reporting adverse drug reactions (ADRs) is an important component of monitoring and evaluating activities of patient care. The ADR program was developed to comply with The Joint Commission on Accreditation of Healthcare Organizations (THE JOINT COMMISSION) standard, to facilitate reporting of significant events to the Food and Drug Administration (FDA), and to improve the quality of patient care. Several organizations have developed definitions for ADRs. At our institution, the definition of an ADR is derived in part from the World Health Organization’s (WHO) definition and is provided below.

Definition: An ADR is any undesirable or unexpected event to a drug (used at normal human doses for prophylaxis, diagnosis, or therapy) that requires discontinuing a drug, modifying a dose, prolonging hospitalization, or providing supportive treatment.

PROCEDURE:

1. Possible ADRs (fitting the above definition) are identified through three sources:
   A. Spontaneous reports: Suspected ADRs can be reported by any healthcare professional. The healthcare professional discovering the ADR should contact a pharmacist to review the ADR and complete an ADR Report Form (See Appendix A). The ADR Hotline is also available to facilitate spontaneous reporting of ADRs. After notification and provision of a patient name, unit number, location in hospital, and a brief description of the ADR, a pharmacist will evaluate the ADR and complete an ADR Report Form.
   B. E-codes: E-codes are ICD-9-CM codes that retrospectively identify any patients admitted or whose hospitalizations were prolonged because of ADRs.
   C. Medication variances: Medication variances are used to report incidents involving medications, including ADRs, that occur within the hospital. Medication variances may be retrospective or spontaneous.

2. ADRs will be compiled by the Department of Pharmacy with the following information documented: a) patient initials, b) patient age, c) source of ADR, d) method of reporting (spontaneous or retrospective), e) type of ADR (dose-related or non-dose related), f) time of occurrence, g) suspected medication, h) ADR description, i) preventability, j) medical service, k) patient care group, l) outcome, and m) FDA notification.

3. The Department of Pharmacy will forward ADRs meeting the criteria below to the FDA via the MedWatch Report (Form 3500):
   A. The suspected drug has been on the market for less than 2 years.
   B. The reaction is not listed in the package insert.
   C. The reaction is attributed to an investigational drug.
   D. The reaction contributes to the death of the patient.
   E. The reaction was life-threatening or permanently disabling.

4. ADRs will be evaluated and reported during the Department of Pharmacy Performance Improvement meeting and to the members of the Department of Pharmacy on a monthly basis.

5. Quarterly ADR data will be summarized and reported to the Medication Use Analysis Subcommittee, the Pharmacy and Therapeutics Committee, and to the Performance Improvement Council.

6. Quarterly ADR data will be distributed to medical Department Chairs and Quality Coordinators along with other medication use indicators.
**ADR** is any undesirable or unexpected event to a drug (used at normal human doses for prophylaxis, diagnosis, or therapy) that requires discontinuing a drug, modifying a dose, prolonging hospitalization, or providing supportive treatment.

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Age (or DOB)</th>
<th>Sex</th>
<th>Allergies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit #</td>
<td>Room # or Clinic</td>
<td>Date of Reaction</td>
<td>Service</td>
</tr>
</tbody>
</table>

Describe the Reaction:

Suspected Drug(s): ____________  Dose/Frequency/Route: __________________________

Indication for Use: ____________  Therapy Dates (from-to): __________________________

Pertinent Laboratory or Diagnostic Data:

Treatment of Reaction:

Drugs Taken Concomitantly:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose &amp; Frequency/Rate/Route</th>
</tr>
</thead>
</table>

Describe other Relevant Medical History:

Submitted by: ________________________  ρ M.D.  ρ R.Ph.  ρ R.N.  ρ Other  Date: ____________

**IMPORTANT:** Please complete reverse side
### Reason for Reporting the ADR

(please ✓ all that apply)

- ✓ The patient died
- ✓ The reaction was life-threatening
- ✓ The reaction was the cause of hospitalization
- ✓ The reaction was permanently disabling
- ✓ The reaction is a teratogenic effect
- ✓ The suspected drug causing the reaction has been on the market for less than 2 years
- ✓ The reaction was the result of a drug-drug interaction
- ✓ The reaction was the result of a drug-food interaction
- ✓ The reaction was attributed to an investigational drug
- ✓ The reaction prolonged hospitalization
- ✓ The reaction was not listed or identified as rare in the package insert (or PDR)
- ✓ The reaction was the reason for discontinuing the suspected medication
- ✓ The reaction prompted additional drug therapy or procedures
- ✓ The reaction was the result of an iatrogenic overdose
- ✓ An increased cluster (or frequency) of the reaction has occurred

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To assess the adverse drug reaction, please answer the following questionnaire and give the appropriate score.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Do Not Know</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are there previous conclusive reports on this reaction?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2. Did the adverse reaction appear after the suspected drug was administered?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4. Did the adverse reaction reappear when the drug was re-administered?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?</td>
<td>-1</td>
<td>+2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>6. Did the reaction appear when a placebo was given?</td>
<td>-1</td>
<td>+1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>9. Did the patient have a similar reaction to the same or similar drug in any previous exposure?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>10. Did any objective evidence confirm the adverse reaction?</td>
<td>+1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Total Score

Naranjo’s Algorithm. Reprinted with permission.

<table>
<thead>
<tr>
<th>Possible (1-4)</th>
<th>Probable (5-8)</th>
<th>Highly Probable (≥ 9)</th>
</tr>
</thead>
</table>

- Doubtful (≤ 0)
- Could the reaction have been prevented?  ρYes  ρNo  ρUnable to Determine
- Discussed with physician?  ρYes  ρNo
- Documented in Chart?  ρYes  ρNo

Send forms to the Department of Pharmacy