	The Johns Hopkins Hospital	*Policy*	MDU 000
	INTERDISCIPLINARY CLINICAL PRACTICE MANUAL	*Effective Date*	DRAFT 8/13/01
	Subject	*Page*	1 of 9
	REPORTING AND ANALYSIS OF MEDICATION EVENTS	*Supersedes*	N/A

PHILOSOPHY
It is the philosophy of The Johns Hopkins Hospital (JHH) that:

- Medication events are inevitable despite the best efforts of conscientious professionals and the institution of systems to prevent them.
- Medication events are not necessarily viewed as incompetence or misconduct on behalf of the practitioner(s) involved. We consider that practitioners do their best to provide safe patient care. We acknowledge that systems-related issues account for the majority of medication events.
- All healthcare professionals and trainees have an obligation to report medication events as a means to improve the medication use system and to provide a safe environment for patient care by making it difficult for similar events to occur in the future.
- Prompt and thorough reporting of medication events in good faith by practitioners or staff will not result in disciplinary action by the hospital against individuals involved.   (***Wording related to non-punitive reporting is still being developed. Concerns relate to cases where a practitioner continues to make multiple medication errors despite systems analysis and multiple attempts at remediation. Cases that require mandatory reporting should also be considered.***)
- It is the right of the patient, and the obligation of the JHH and its employees and staff, to disclose clinically relevant medication events to the patient in a prompt, clear and honest manner (see ICPM, Patient Error Disclosure Policy).

SCOPE/INDICATIONS FOR USE

- This policy applies to all aspects of the medication use system (prescribing, dispensing, administration and monitoring) at JHH.
- The purpose of this policy is to provide a standardized mechanism for identifying, reporting and analyzing medication events in order to improve the medication use system.

CONTENTS	

DEFINITIONS

Medication Use System
The medication use system begins when an authorized prescriber obtains the necessary information to prescribe drug therapy. The process then proceeds through order communication, dose preparation, product dispensing, medication administration, and monitoring of drug effects. The process is completed when changes to previous medication orders are considered with regard to clinical response to therapy. The intended functioning of this process is described by policies and procedures.

Medication Event
Medication event is a medication error or adverse drug reaction as defined below.

Medication Error
A medication error is a deviation from the intended functioning of the medication use system. In this context,

medication errors generally result from flaws within the system (by definition, medication errors are preventable).

> **Potential Medication Error -** A process deviation in the medication use system intercepted before it reaches the patient.

> **Actual Medication Error -** A process deviation in the medication use system that reaches the patient.

> **Significant Medication Error -** An actual medication error that results in a significant adverse drug reaction as defined below.

> **Near Miss -** Used to describe any process variation which did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome. A near miss can be either an actual error or a potential error. (*Examples*: a patient did not suffer adverse consequences following a ten-fold overdose of a medication, a pharmacist or nurse stopped a ten-fold overdose from being administered, etc)

Adverse Drug Reaction (ADR)
Any adverse clinical event associated with medication use.

> **Significant ADR** - An ADR resulting in; a) hospitalization, b) unplanned treatment, c) actual or probable increase in hospital stay, d) a life-threatening event, or e) death or permanent disability.

> **Preventable ADR** - An ADR that could reasonably have been identified and avoided based upon existing policies and procedures, patient data, medical literature or accepted medical practice.

RESPONSIBILITIES (SEE ALSO APPENDIX I)	
NURSES, PHARMACISTS, PHYSICIANS, AND OTHERS INVOLVED IN THE MEDICATION USE SYSTEM	▪ Reports medication events using established procedures (Appendix II). ▪ Identifies potential strategies for system improvements, in collaboration with departmental/unit management.

PHYSICIAN ADVISORS, NURSE MANAGERS/ NURSING CLINICAL PERFORMANCE IMPROVEMENT (NCPI) REPRESENTATIVES AND PHARMACY ASSISTANT DIRECTORS	▪ Physician Advisors, Nurse Managers/NCPI representative and Pharmacy Assistant Directors collaborate, in a timely manner, on the review and reporting of significant medication events, near misses, general trends and performance improvement strategies to the Functional Unit Performance Improvement Committee.
	   ▪ The initial review of near misses is completed by the:
	      ▪ Physician Advisor if it involves prescribing.
	      ▪ Pharmacy Assistant Director if it involves dispensing.
	      ▪ Nurse Manager if it involves administration.
	   ▪ Nursing and Pharmacy, reporting is accomplished by the completion of the Performance Improvement Follow-up Form (Appendix IIIa and IIIb), for all significant medication administration events or near misses. In nursing, a copy of the form is forwarded to the NCPI representative.
	▪ Physician Advisors, Nurse Managers/NCPI representative and Pharmacy Assistant Directors are responsible for providing feedback related to significant medication events, near misses and performance improvement strategies to all appropriate staff.

FUNCTIONAL UNIT PERFORMANCE	▪ Reviews all significant Functional Unit medication events, near misses and general trends to determine multi-disciplinary strategies to prevent recurrence

RESPONSIBILITIES (SEE ALSO APPENDIX I)	

IMPROVEMENT (PI) COMMITTEE	through systems improvement.
	▪ Provides the following reports to the Clinical PI Committee, the Pharmacy PI Committee and the Nursing Clinical PI Committee:
	   ▪ monthly report describing significant medication events, near misses and actions taken to reduce the potential for recurrence.
	   ▪ quarterly analysis of trends and actions taken to reduce the potential for recurrence.

CLINICAL PI COMMITTEE, PHARMACY PI COMMITTEE, NURSING CLINICAL PI COMMITTEE	▪ Receive and review reports from Functional Unit PI Committees and provide reports to the Medication Event Reduction Improvement Team (MERIT). Develops multidisciplinary action plans to address areas of improvement. ▪ Make recommendations related to hospital-wide errors with an emphasis on prescribing errors (**Clinical PI**), dispensing errors (**Pharmacy PI**), and administration errors (**Nursing PI**).
MEDICATION EVENT REDUCTION IMPROVEMENT TEAM (MERIT)* *subcommittee of the Pharmacy & Therapeutics Committee	▪ Reviews medication event analysis reports from Nursing, Pharmacy and Clinical PI Committees and medication events reported in the literature with the purpose of suggesting system changes designed to reduce the potential for adverse medication events. ▪ Identifies trends, patterns of performance, significant events and near misses that affect more than one Functional Unit or service and makes recommendations for systems improvement.
NURSE PHARMACY ADVISORY COMMITTEE	▪ Develops and implements performance improvement strategies, as requested.
PATIENT SAFETY COMMITTEE	▪ Supports the establishment, implementation and evaluation of policies, procedures, processes and structures related to patient safety at the JHH. ▪ Reviews and supports the Hospital's programs and progress in furtherance of risk reduction activities as they pertain to patient care, general liability and health, safety and environment.
PERFORMANCE IMPROVEMENT COUNCIL	▪ Monitors status of identified problems and associated corrective action plans. ▪ Establishes integrated priorities for hospital-wide performance improvement strategies. ▪ Establishes and monitors performance improvement committees at JHH.

ANALYSIS OF SIGNIFICANT MEDICATION EVENTS, NEAR MISSES, AND TRENDS

▪ Goal: identification of performance improvement opportunities
▪ A systems approach using the Plan-Do-Study-Act (PDSA) Cycle (see references) is recommended.
I. Plan
   ▪ **Collect Information:**
     - Determine what happened as completely and objectively as possible.
     - Determine the events leading up to the incident.
     - Determine the consequences of the incident.
     - Determine if any other reports or data would be helpful in analyzing the incident.

   ▪ **Identify Potential Causes:**
     - Keep asking "why" to identify the underlying cause of the problem.
     - Brainstorm all possible causes.
     - Identify if anything was unusual, different or changed at the time of the incident.

- Determine what could have prevented the medication event from happening.
- Identify steps in the process that failed.
- Identify barriers that impeded process from being carried out as designed..

- **Process Redesign**
  - Identify what can be done to prevent similar medication events in the future.
  - Develop a new (or re-design an existing) medication process.
  - Determine how to test the new or redesigned process.
  - Identify outcomes that can be used to measure the success of the change and devise a method to collect outcomes data.

II. Do
  - Run the test of the new or redesigned process. Consider a small pilot.
  - Collect data on the outcomes measures.

III. Study
  - Assess pilot results
  - Determine whether change was successful, i.e., will it prevent similar event in the future
  - Identify any lessons learned.

IV. Act
  - Implement change, or modify it and run it through another cycle, or develop a new approach and repeat the PDSA Cycle.

(Items I – IV, Source: Institute for Healthcare Improvement, IHI Quality Improvement Resources: A Model of Accelerating Improvement and JCAHO Root Cause Analysis in HealthCare Tools and Techniques, 2000)

SUPPORTIVE INFORMATION	
DEVELOPER	Reporting and Analysis of Medication Events Task Force
SPONSORS	Patient Safety Committee Medication Error Reduction Improvement Team (MERIT) Nursing Standards of Care

COMPANION DOCUMENTS	ICPM, Patient Error Disclosure Policy
	Nursing Practice and Organization Manual, Volume I, Section V, page 500,
	    Management of Nursing Practice Events.
	Nursing Practice and Organization Manual, Volume II, Section III, page
	    360 U, Medication Administration.

COMMUNICATION & EDUCATION	**INITIAL:** Within two (2) months of the effective date: 1. Policy will be distributed for inclusion into the Interdisciplinary Clinical Practice Manual. 2. Nurse Managers and Pharmacy Assistant Directors will be responsible to train nursing and pharmacy staff. 3. Physician Education: Physician Advisors, Residency Training Coordinators, Department Chiefs, and Medical Staff Newsletter. 4. Department management will be responsible for training appropriate staff. **ONGOING:** 1. Nurse Managers, Pharmacy Assistant Directors, Physician Advisors, Residency Training coordinators, Department Chiefs and Department Management will be responsible for training new employees regarding the policy as appropriate. 1. Policy revisions will be distributed to all manual holders with instructions on manual

SUPPORTIVE INFORMATION		
	updates.	
REFERENCES	1. Institute for Healthcare Improvement, IHI Quality Improvement Resources: A Model of Accelerating Improvement (PSDA Cycle). 2. Institute of Medicine, To Err is Human, Building a Safer Health System, 1999. 1. Institute of Medicine, Crossing the Quality Chasm: A new health system for the 21st century, 2001. 4. JCAHO Root Cause Analysis in HealthCare Tools and Techniques, 2000. 5. JCAHO, Support of Patient Safety and Medical/Health Care Error, 2001. 2. National Patient Safety Foundation Recommendations, Talking to Patients About Health Care Injury, 2000.	
REVIEW CYCLE	Three (3) years	MEDICAL BOARD APPROVAL Date:

Vice President for Nursing and Patient Services   Vice President for Medical Affairs

_____   _____

Date: Date:

APPENDIX I: MEDICATION EVENT REPORTING FLOW DIAGRAM
(TO BE COMPLETED)

APPENDIX II: REPORTING PROCESS

EVENT	PROCESS FOR REPORTING

MEDICATION ERROR	**JHMI ON-LINE MEDICATION EVENT DATA COLLECTION SYSTEM**
	• Access to the on-line data collection system is through the JHMI Forms Repository https://jhmcis.jhmi.edu/WebForms/ available on all clinical workstations.
	• Anyone who can log on to the clinical workstation can enter an event
	• Events should be entered as soon as possible after occurrence and must be entered within 7 days.
	• Complete on-line data collection form:
	  - Enter reporter's first name and last name. Identification of the reporter is requested only in the case that there would be questions surrounding the report.
	  - Enter patient location/unit, patient's first name, patient's last name, patient's history number, date of event, time of event, and service.
	  - Enter up to three drugs involved in the event. Use generic names whenever possible.
	  - Select as many sources of event as are appropriate to identify system-related issues. These include drug prescribing, dispensing, administration, and recording processes.
	  - Select the highest appropriate level of clinical outcome based on whether or not the event reached the patient, and on whether increased monitoring, unplanned treatment, or potential/actual increase in hospital stay results from the event.
	  - Describe the event in the Comments section.
	• Notify treating physician of all drug administration errors as soon as possible.
	• Contact the **JHH Legal Hotline (x5-7949)** if life-threatening event or serious morbidity occurred to which the event may have contributed.

ADVERSE DRUG REACTION	**ADR HOTLINE or JHMI ON-LINE ADVERSE DRUG REACTION DATA COLLECTION SYSTEM**
	• Adverse drug reactions can be reported on the ADR Hotline (24 hours a day, extension 4-4ADR)
	• Access to the on-line data collection system is through the JHMI Forms Repository https://jhmcis.jhmi.edu/WebForms/ available on all clinical workstations.
	• Anyone who can log on to the clinical workstation can enter an event
	• Complete on-line data collection form:
	  - Enter reporter's first name and last name. Identification of the reporter is requested only in the case that there would be questions surrounding the report.
	  - Enter patient location/unit, patient's first name, patient's last name, patient's history number, date of event, time of event, and service.
	  - Enter setting where the drug suspected of causing the ADR was administered.
	  - Select severity (mild, moderate, severe) of the reaction.
	  - Enter up to three drugs involved in the event. Use generic names whenever possible.
	  - Describe the adverse drug reaction.
	• A pharmacy clinical specialist will complete an additional set of questions about the event and will calculate likelihood of causality, severity, and whether or not the reaction was preventable.

APPENDIX IIIA: PERFORMANCE IMPROVEMENT FOLLOW-UP FORM

APPENDIX IIIB: PHARMACY PERFORMANCE IMPROVEMENT FOLLOW-UP FORM

The Johns Hopkins Hospital
Department of Pharmacy
Performance Improvement Follow-up Form for Significant Medication Errors and Near Misses
Privileged and Confidential

Check one: Significant Error ___   Near Miss ___

Date of Error or Near Miss:

Patient's Name: Visit Number:

Patient Location:

Description of the error or near miss:

Description of Corrective Action (Emphasis should be placed on improving the system flaw that led to the error):