OPERATIONAL DEFINITION
MEASUREMENT: Adverse Drug Events (ADE) per 1000 Patient Days

I. Description and Rationale

This measure answers the question: How often do we cause harm to a patient due to the drugs we give them?

Adverse drug events (ADEs) are measured as the rate of adverse drug events per 1000 patient days. This rate is estimated using a "trigger" tool on a random sample of 20 inpatient medical records per month. The trigger tool was developed from an existing tool used in adult healthcare that was tested and modified by a 14-site collaborative conducted by the Child Health Accountability Initiative (CHAI). This tool consists of 15 triggers that emerged as critical indicators for pediatric ADEs (e.g., Diphenhydramine is frequently used for allergic reactions to drugs). Triggers are defined as occurrences, prompts, or flags found during the review of a medical record that trigger further investigation to determine the presence or absence of a medication error.

We report two ADE measures: 1) Total (or Overall) rate; and 2) Preventable rate. Preventable ADEs are distinguished most readily by noting what is non-preventable. Examples of non-preventable ADEs include the following:

- Dermatological reactions from unknown allergens;
- Known side effects without identified mitigation strategies;
- Known side effects that are accepted for the benefit of the drug (i.e. nausea with chemo-therapy).

In addition, the following general definitions apply:

Preventable: Events where a breach of standard professional behavior or technique was identified, or where necessary precautions were not taken, or where the event was preventable by modification of behavior, technique or care.

Non-Preventable: Events where no obvious breach of standard professional behavior or technique occurred, and where necessary precautions were taken, and where no clearly known alteration in method or care exists to prevent the event.

Events that are not clearly preventable or non-preventable according to the definitions above are classified as "possibly preventable." For some purposes, these events may be counted as preventable. However, our reported measure of Preventable ADEs includes only those ADEs actually identified as preventable.

II. Population Definition (Inclusions/Exclusions)
All inpatients with a length of stay greater than 2 days, regardless of age.

III. Data Source(s)
Clinical Effectiveness retrospective chart review

IV. Sampling and Data Collection Plan
20 randomly selected inpatients per month with a length of stay greater than 2 days

V. Calculation
Numerator: The number of adverse drug events (either all ADEs or Preventable ADEs) identified using the trigger tool for the 20 randomly selected inpatients. (Note: For some purposes, "possibly preventable" events may be counted as preventable. However, the reported measure of Preventable ADEs includes only those ADEs actually identified as preventable).

Denominator: The total number of patient days represented by the sample population. Length of Stay is calculated by subtracting the admission date from the discharge date. For example, a person admitted on the 4th of the month and discharged on the 10th will represent a length of stay of 6 days. We do *not* count both the day of admission and the day of discharge, which would yield an LOS of 11, instead of 10. The lengths of stay are then summed over the 20 patients on whom the chart reviews were performed.

This is reported as a ratio per 1000 patient days ((numerator/denominator)*1000)

VI. Analysis Plan and Frequency of Reporting
Data is collected monthly. It is reported quarterly for the CCHMC hospital scorecard and monthly for the Patient Safety team and Inpatient CSI dashboard. Monthly data is plotted on a control chart.

VIII. Limitations

IX. Experts/Resources
- www.chca.com

- Classen DC, Pestotnik SL, Evans RS, Burke JP. Computerized Surveillance of Adverse Drug Events in Hospital Patients. *JAMA* 1991;266(20):2847-2851

- Holdsworth MT, Fichtl RE, Behta M, Raisch DW, Mendez-Rico E, Adams A, Greifer M, Bostwick S, Greenwald BM: Incidence and impact of adverse drug events in pediatric inpatients. Arch Pediatr Adolesc Med. 2003. 157(1): 60-5

- Rozich JD, Haraden CR, Resar RK: Adverse drug event trigger tool: a practical methodology for measuring medication harm. Qual Saf Health Care. 2003. 12:194-200.

X. Revision History

Version	Primary Author(s)	Description of Version	Date Completed
Draft	KR		06/02/2004
Final	AMA	Reformatted/Additional information regarding venues	02/08/2005
Rev 1	TAW	Include “Preventable ADE” measure	11/02/2006
Rev 2	TAW	Changed denominator from Doses to Patient Days	02/27/2008