POTENTIAL ADVERSE DRUG EVENTS (pADEs) DEFINED

Potential adverse drug events (pADEs) have been defined in several ways by several agencies/in several publications. In many definitions, it is implied that pADEs occur due to medication errors or mishaps (several definitions state that pADEs are also known as "near misses" or "close calls"). pADEs are medication-related problems (MRPs)/drug-related problems (DRPs)/ medication-therapy problems, t*hese may include, but are not limited to, medication errors*.

The widely accepted definition of a MRP/DRP is "an event or circumstance involving medication therapy that actually or potentially interferes with the optimum outcome for a specific patient."[1,2]

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines a medication error as follows: "a medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."[3]

The Agency for Healthcare Research and Quality (AHRQ) defines a "near miss" or "close call" as follows: "a near miss is an event or situation that did not produce patient injury, but only because of chance. This good fortune might reflect robustness of the patient (e.g., a patient with penicillin allergy receives penicillin, but has no reaction) or a fortuitous, timely intervention (e.g., a nurse happens to realize that a physician wrote an order in the wrong chart). This definition is identical to that for close call."[4]

Below is a list of definitions of pADEs in a few publications/ by a few agencies:

A. **World Health Organization (WHO):** *a potential adverse event is a "serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted (also called "near miss" or "close call")."*[5]
   - What is contradictory to this definition is that the same document states that, "Adverse events are not always caused by an error. For example, one form of adverse drug event, "adverse drug reaction" is, according to the WHO definition, a complication that occurs when the medication is used as directed and in the usual dosage. Adverse drug reactions are, therefore, adverse drug events that are not caused by errors."[5]

B. **Agency for Healthcare Research and Quality (AHRQ):** *"Medication errors that reached the patient but by good fortune did not cause any harm are often called potential ADEs.* For instance, a serious allergic reaction to penicillin in a patient with no prior such history is an ADE, but so is the same reaction in a patient who has a known allergy history but receives penicillin due to a prescribing oversight."[6]

C. **Bates et al. (*JAMA*.1995):** defined potential ADEs as **"***incidents with potential for injury related to a drug.* An example is a patient who received penicillin despite a known allergy to penicillin, but did not react. Included in this category were drug errors that were intercepted before the order was actually carried out**."**[7]

D. **Kunac et al. (*Pediatric Drugs*. 2009):** "ADEs refer to events of medication-related patient injury, whereas the term medication error encompasses all errors that may occur at any stage of the medication process, with or without patient harm. Some ADEs arise as a result of an error and are therefore considered preventable, whereas others arise from adverse drug reactions, where the medication is used in a proper manner, and are considered non-preventable ADEs. *Potential ADEs are incidents where patient harm could have occurred, but did not either because of chance or intervention."*[8]

E. **VA Center for Medication Safety:** *"Medication errors that are stopped before harm can occur are sometimes called "near misses" or "close calls" or more formally, a potential adverse drug event."*[9]

F. **Poon et al. (*Ann Intern Med*. 2006):** A *Potential adverse drug event (ADE)* is a *"dispensing error that can harm patients if not intercepted before medication administration"* (this study was conducted in a hospital pharmacy).[10]

G. **Nebeker et al. (Ann Intern Med. 2004):** Potential adverse drug events are *"circumstances that could result in harm by the use of a drug but did not harm the patient."* For example, "receipt of a roommate's felodipine but no resulting hypotension."[11]

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3. The National Coordinating Council for Medication Error Reporting and Prevention. About medication errors: what is a medication error? http://www.nccmerp.org/aboutMedErrors.html (Accessed December 5, 2011).
4. http://www.psnet.ahrq.gov/glossary.aspx?indexLetter=N
5. http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf
6. http://www.psnet.ahrq.gov/glossary.aspx
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8. Kunac D, Kennedy J, Austin N, Reith D. Incidence, preventability, and impact of adverse drug events (ADEs) and potential ADEs in hospitalized children in new zealand: A prospective observational cohort study. *Pediatric Drugs*. 2009;11:153-160.
9. http://www.pbm.va.gov/vamedsafe/Adverse%20Drug%20Reaction.pdf
10. Poon E, Cina J, Churchill W, et al. Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy. *Ann Intern Med*. 2006;145:426-434.
11. Nebeker J, Barach P, Samore M. Clarifying adverse drug events: A clinician's guide to terminology, documentation, and reporting. *Ann Intern Med*. 2004;140:795-801.

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PATIENT INFORMATION — **Medication Therapy Intervention & Safety Documentation Form** (version 8, 9/12/11)

Date	Site	MRN	DOB	Gender	Insurance	Ethnicity & Language	Point of Care	Initials	
/ /	☐ A ☐ B ☐ C ☐ D ☐ E		/ /	☐ M ☐ F	☐ None ☐ M-caid ☐ M-Care ☐ Other	☐ Caucasian ☐ Black ☐ Latino ☐ Asian ☐ Other ☐ English ☐ Non-English	☐ MTM / DSM ☐ Med review / pharmacy / dispensary	HC Profess:___ Student:___	☐ Entered in computer database

INTERVENTION: Each row is for an individual intervention (i.e., one MRP per row)

	Drug(s) involved)	Indication	Intervention Codes (see table below): I* MRP: (if #5-17 →)	II** For pADE/ADE: (if A-D →)	III** For pADE:	IV*** Intervention/ Recommend.:	Intervention Accepted? (optional) ****	Resolved? (optional)	Description of event- MUST complete for Severity ii or iii pADEs & all ADEs: Problem	Recommendation	Outcome
1.				A B C D E F G H I	i ii iii	101 102 103 104 105 106 107 108 109 110 111 112 113 114 115	☐ Yes ☐ Modified Yes ☐ No	☐ Yes ☐ No ☐ FTR			
2.				A B C D E F G H I	i ii iii	101 102 103 104 105 106 107 108 109 110 111 112 113 114 115	☐ Yes ☐ Modified Yes ☐ No	☐ Yes ☐ No ☐ FTR			
3.				A B C D E F G H I	i ii iii	101 102 103 104 105 106 107 108 109 110 111 112 113 114 115	☐ Yes ☐ Modified Yes ☐ No	☐ Yes ☐ No ☐ FTR			

I. MEDICATION-RELATED PROBLEM (MRP)[1]

Appropriateness and Effectiveness
1. Untreated medical problem
2. Drug dosing not adequate for treatment goals (dose, interval, or duration)
3. Treatment not optimal based on current evidence / guidelines
4. Monitoring standards not being followed

Safety (pADE / ADE)
5. Drug dosing excessive for treatment goals (dose, interval, or duration)
6. Incomplete / improper directions
7. No indication for medication prescribed
8. Polypharmacy (Rx not needed) / duplication
9. Contraindication
10. Adverse drug reaction (ADR)
11. Allergy
12. Drug interaction
13. Lab/diagnostic test indicated, not ordered
14. Abnormal lab result not addressed
15. Pharmacy / dispensing error
16. Medication overuse or misuse
17. Dose discrepancy between patient use & prescribed therapy
18. Using expired medication(s)

Nonadherence and Patient Variables
19. Medication underuse / poor adherence
20. Dosage form is not reasonable for patient
21. Inadequate patient self-management of lifestyle and other non-drug variables
22. Patient dissatisfied or refuses treatment, no rational reason given

Miscellaneous
23. Drug not available in prescribed strength
24. Inadequate refills between scheduled visits
25. Nonformulary / not cost effective drug choice
26. Illegible prescription
27. No follow-up appointment with PCP
28. Other

II. ADE / pADE CLASSIFICATION[2]

Potential Adverse Drug Event (pADE)
A. No med error / event, but potential for ADE identified
B. Med error/event DID NOT reach patient
C. Med error/event reached patient, but no harm
D. Med error/event reached patient, monitoring or intervention required to confirm no harm

Adverse Drug Event (ADE)
E. Event occurred, resulting in temporary harm and requiring intervention
F. Event occurred, resulting in temporary harm and requiring hospitalization
G. Event occurred, resulted in permanent harm / disability
H. Event occurred, life-threatening
I. Event occurred, resulted in death

III. pADE SEVERITY RATING[3]
i. Potential for minimal (would require patient self-management) or no harm
ii. Potential for moderate harm (would require healthcare professional intervention or hospitalization to resolve)
iii. Potential for severe harm (permanent disability or death)

IV. INTERVENTION / RECOMM.
101. DC drug(s)
102. Substitute drug(s)
103. Add drug(s)
104. Change dose/dose interval
105. Change duration of tx / qty
106. Change PRN to schedule
107. Change schedule to PRN
108. Order lab / dx'tic test
109. Educate patient
110. Refer to other service
111. Clarify Rx
112. Substitute dosage form
113. Make appt w/ provider
114. Provide Rx compliance box
115. Other

*Select 1 code if possible, 2 max. ** Circle 1 only ***Circle all that apply **** Document acceptance status if approval from provider is required; "Modified Yes" applies if provider agrees with problem but changes recommendation

Adapted From: (1) From Patient-Centered Primary Care Collaborative (http://www.pcpcc.net/files/medmanagepub.pdf); (2) From NCC MERP (http://www.nccmerp.org/medErrorCatIndex.html); (3) From Medicare Nursing Home Levels of Harm categories, http://www.medicare.gov/NHCompare/static/related/incdrawlevelofharm.asp?language=English&version=default

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Medication Management Services: Resource-Based Relative Value Scale					
Level of Service Provided	**Level #1**	**Level #2**	**Level #3**	**Level #4**	**Level #5**
Assessment of Drug-Related Needs	Problem-Focused 1 Medication	Expanded Problem 2 Medications	Detailed 3–5 Medications	Expanded Detailed 6-8 Medications	Comprehensive ≥9 Medications
Identification of Drug Therapy Problems	Problem-Focused 0 Drug Therapy Problems	Expanded Problem 1 Drug Therapy Problem	Detailed 2 Drug Therapy Problems	Expanded Detailed 3 Drug Therapy Problems	Comprehensive ≥4 Drug Therapy Problems
Complexity of Care Planning and Follow-Up Evaluation	Straight-forward 1 Medical Condition	Straight-forward 1 Medical Condition	Low Complexity 2 Medical Conditions	Moderate Complexity 3 Medical Conditions	High Complexity ≥4 Medical Conditions
CPT Codes	99605 Initial Encounter With New Patient (or 99606 for All Follow-Up Encounters)	99605 (or 99606) and 99607	99605 (or 99606) and 2 X 99607	99605 (or 99606) and 3 X 99607	99605 (or 99606) and >4 X 99607
Face-to-Face Time	15 Minutes	16–30 Minutes	31–45 Minutes	46–60 Minutes	>60 Minutes
Payment Amount	$	$$	$$$	$$$$	$$$$$

SOURCE: Minnesota Department of Human Services, MHCP Provider Manual, Medication Management Therapy Services, HIPAA–Compliant MTMS CPT Codes, Revised 1/5/2010.

www.pcpcc.net/files/medmanagepub.pdf Appendix p20.