NCCMERP
National Coordinating Council for Medication Error Reporting and Prevention

Questions About NCC MERP and Medication Errors
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Contemporary View of Medication–Related Harm. A New Paradigm

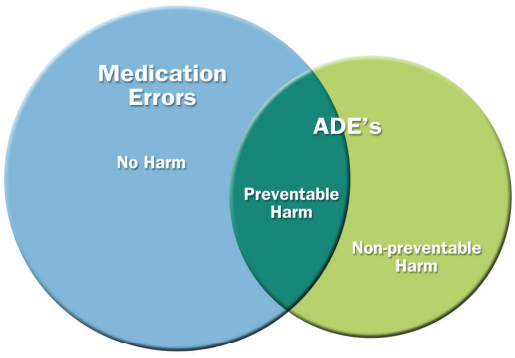
Introduction

The NCC MERP has frequently been asked to help healthcare professionals distinguish among Adverse Drug Events (ADEs), Adverse Drug Reactions (ADRs) and Medication Errors. The Council notes several definitions for these terms in the literature, research reports, and by various organizations. The terms ADE and ADR have been used when patient harm has occurred as a result of a drug (see definitions). To further clarify, an ADR has been defined as harm that results from a medication dose that is "normally used in man." An ADE has been defined as harm associated with any dose of a drug, whether the dose is "normally used in man" or not. An ADR, therefore, is a subtype of an ADE (i.e., all ADRs are ADEs, but not vice versa). By definition, all ADEs are associated with patient harm, but not all ADEs are caused by an error. Significant confusion exists regarding these terms.

The Council proposes new terminology to clarify the terms and the relationships among them and encourages consistent adoption across the medication safety community (see Figure 1 for a graphical depiction with no intended meaning to size of circles[1]):

- "Preventable ADE" is harm caused by the use of a drug as a result of an error (e.g., patient given a normal dose of drug but the drug was contraindicated in this patient). These events warrant examination by the provider to determine why it happened.
- "Non-Preventable ADE" is drug-induced harm occurring with appropriate use of medication (e.g., anaphylaxis from penicillin in a patient and the patient had no previous history of an allergic reaction). While these are currently non-preventable, future studies may reveal ways in which they can be prevented.

Figure 1: Relationship between medication errors and ADEs



[1]Adapted from Figure 1 in Qual Saf Health Care 2004;13:306–314. doi: 10.1136/qshc.2004.010611

Scenario/Case Studies

Medication error resulting in no harm

Case 1. A 25 kg child with no prior history of penicillin allergy was prescribed 250 mg orally of amoxicillin suspension twice daily (morning and evening) for 7 days. On the seventh day, the child inadvertently received a morning dose of 500 mg instead of 250 mg. The child did not suffer any negative consequences from the error.

A preventable ADE (medication-related harm due to error)

Case 2. A 74 year old female with acute leg pain presented to the emergency department. She has a history of sleep apnea. She has no previous history of opioid use. Prescriber ordered hydromorphone 2 mg IV. Patient found unresponsive in respiratory distress with SP O2 at 70. Naloxone administered.

A Non-preventable ADE (medication-related harm not due to error)

Case 3. A 37 year old patient diagnosed with an infection for which amoxicillin and clavulanate potassium is a clinically reasonable choice. Patient has used amoxicillin and other antibiotics in past without adverse effects. Prescriber ordered amoxicillin and clavulanate potassium 500 mg every 12 hours. After taking 3 doses, patient experienced rash and facial swelling. He was transported to the emergency department and treated.

Case 4. A 19 year-old male presented with a severe infection for which treatment with a beta lactam antibiotic is the drug of choice with no good clinical alternative. In the past, this patient developed a maculopapular rash to penicillin. The prescriber, with input from an infectious disease expert, considered the risk-benefit of using a beta lactam antibiotic and concluded that it was the best choice in spite of the previously reported ADE. An order for a beta lactam antibiotic was initiated with close monitoring of the patient to quickly identify an allergic reaction if one manifested. On day 3 of therapy, the patient developed a maculopapular rash and the decision was made to provide symptomatic treatment of the rash and continue therapy with the beta lactam antibiotic. NOTE: this last case is a little tricky. According to our algorithm, the ADE (i.e., maculopapular rash) was known and considered to be an acceptable risk given the severity of the infection and limited therapeutic options. In this case, the ADE was "not preventable" given this difficult clinical situation.

The Council believes the standardized use of this terminology will focus attention on efforts aimed at eliminating preventable harm. The following algorithm (Figure 2) distinguishes between "Preventable ADEs" and "Non-Preventable ADEs."

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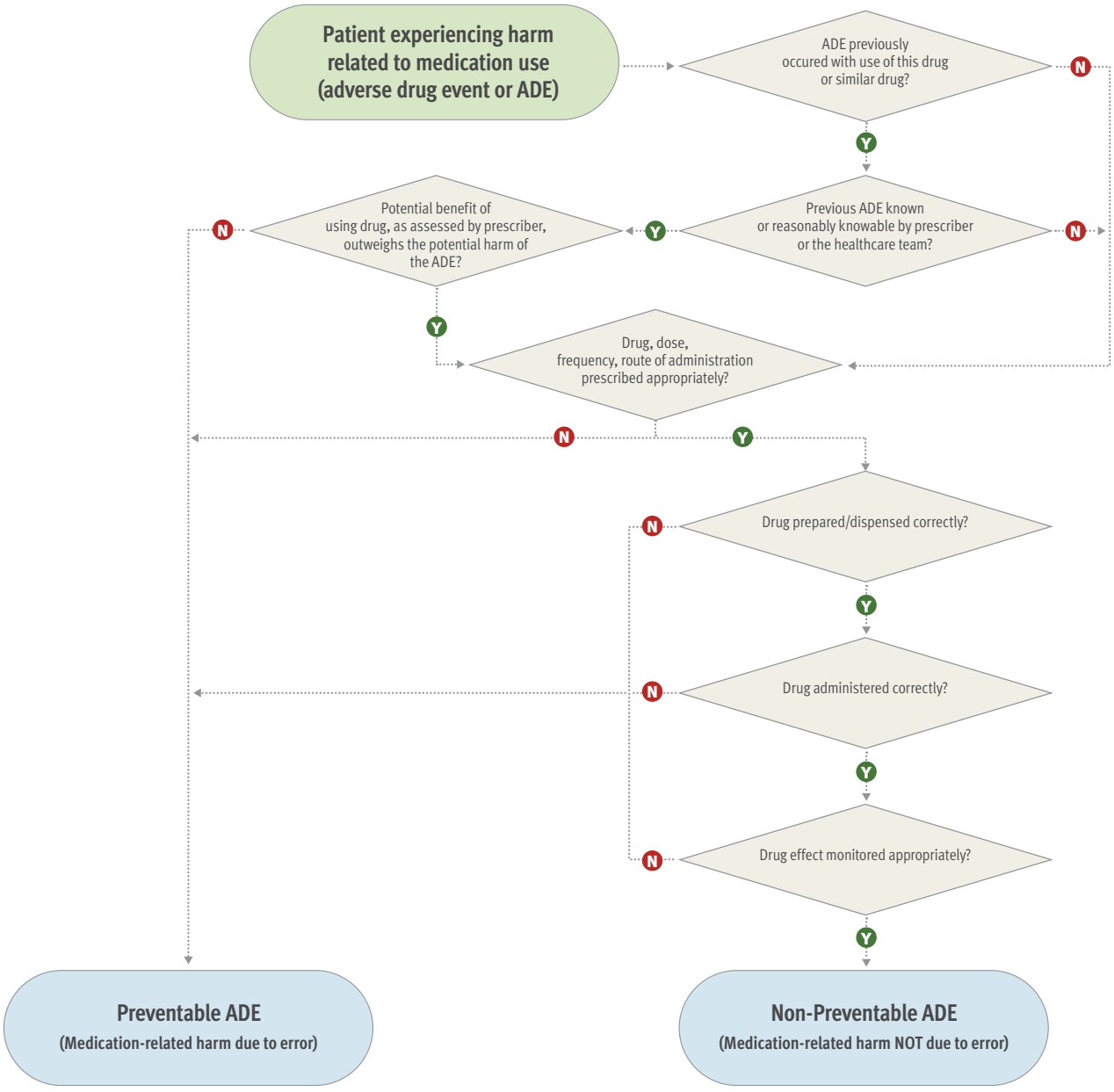

Appendix

Relevant Definitions

Harm: Impairment of the physical, emotional, or psychological function or structure of the body and pain or injury resulting therefrom. (NCC MERP)

Adverse Drug Event (ADE): An injury resulting from medical intervention related to a drug. Source: Institute of Medicine (IOM)

Medication Error (ME): 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. Source: National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).

Adverse Drug Reaction (ADR): Any response to a drug which is noxious and unintended which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function. Source: World Health Organization (WHO)