

Chapter 8 – Monitoring Medication Use

1. Monitoring medication use is a collaborative interdisciplinary process that ensures the medication therapy is appropriate and effective, while minimizing the occurrence of adverse events. Each patient's response to his or her medications must be monitored according to his or her clinical needs and must address the patient's response to the prescribed medication and actual or potential medication-related problems. All care givers (e.g., physicians, nurses, respiratory therapists, etc.) will document the information obtained from their assessments in the patient's medical record. Individual providers monitor effects of medications in accordance with applicable professional practice guidelines. Additional guidance on patient assessment and reassessment is contained in MEDCEN Memo 40-6, Plan for the Provision of Patient Care Services.

2. Monitoring and assessing the effect of medications includes, but is not limited to:

- a. Direct observation of the patient during assessments, evaluations, or other patient contact;
- b. Gathering the patient's own perceptions of side effects and drug sensitivities, and when appropriate, perceived efficacy; and,
- c. Review of information contained in the patient's medical record (e.g., progress notes, care plans, relevant laboratory results, etc.), clinical response, and medication profile.

3. First doses of new medications. The effects of all doses of medications will be assessed and evaluated, whether the first or last dose. There is a higher likelihood of an adverse reaction to a medication that is new to a patient than to a medication the patient has successfully taken in the past. The extent of assessment, reassessment, or evaluation of a new medication will vary based upon the clinical picture and medication. For example, reassessments of individuals given a penicillin or sulfa-containing antibiotic will include a review for changes in the status of the patient as a response to the care (e.g. resolution of fever) and/or a response to the antibiotic (e.g. rash). Medications for which a test dose is appropriate (e.g., iron injection, amphotericin B) and used will be given the test dose to identify any adverse events, drug allergies or sensitivities. Clinical laboratory studies may also be ordered as appropriate to monitor the patient's response (e.g., aminoglycoside peak and trough levels and serum creatinine).

4. Adverse drug events. Adverse drug events or reactions (ADRs) are frequent complications of drug therapy. WAMC reports, receives, and evaluates ADR reports to assess the safety of drug therapy, educate healthcare professionals, and to identify and measure trends in order to institute corrective actions and or preventative measures designed to improve patient outcomes.

- a. Adverse drug reaction definition. WAMC uses the proposed FDA ADR definition found in the 14 Mar 03 Federal Register. An adverse drug reaction is a noxious and unintended response to any dose of a drug (or biologic) product for which there is a reasonable possibility that the product caused the response.
 - (1) Allergic reaction. Consistent with the above definition, an allergic reaction (e.g., immunologic, hypersensitivity) is considered an adverse drug reaction.
 - (2) Not an adverse drug reaction. The following do not constitute an adverse drug reaction:
 - (a) Accidental poisonings;
 - (b) Drug abuse syndromes;
 - (c) Drug withdrawal; and,
 - (d) Side effects. A side effect is defined as an expected, well-known reaction resulting in little or no change in patient management (e.g., drowsiness or dry mouth due to administration of a tricyclic antidepressant). A side effect occurs with predictable frequency and is often an effect whose intensity and occurrence are dose-related.
- b. Adverse drug reaction surveillance. WAMC will identify, track, and organize adverse drug reaction (ADR) data. ADR surveillance will occur:
 - (1) Prospectively (before drug therapy) – based on the use of drugs associated with greater ADRs, or the use of drugs in patients at greater risk for an ADR (e.g., geriatrics, patients with organ failure, etc.);
 - (2) Concurrent (during drug therapy) – based on real-time reporting of ADRs by the MEDCEN staff, and by monitoring for the use of drugs that are commonly used to treat ADRs (e.g., antihistamines, epinephrine, corticosteroids, etc.) or abrupt discontinuations or decreases in doses of a drug; and,
 - (3) Retrospectively (after drug therapy) – based on the retrospective analysis of coding (i.e., ICD code 282) or the submissions of a new drug request.
- c. Adverse drug reaction reporting.
 - (1) Health care provider. The individual discovering the adverse drug reaction should report the reaction to the patient's health care provider in order for that individual to take any necessary action.
 - (2) Pharmacy. Any individual can submit an adverse drug reaction to the Pharmacy via:

- (a) Microsoft Outlook. Send a message to any of our pharmacy staff members or the WAMC ADR Report mailgroup as an *encrypted* email with a full report, or as a *non-encrypted* email without any patient-specific information to initiate an adverse drug reaction report. In the latter situation, we will contact you to complete the report.
 - (b) CHCS mail. Send an email to g.ADR with pertinent information to initiate a report (e.g., patient name and social security number, date and description of the reaction, suspected drug, etc.) and we will assist you in completing the report.
 - (c) Distribution. Complete a DA Form 4106, FDA MedWatch Form (Form FDA 3500; see Appendix O), VAERS-1 form (see Appendix P), or WAMC Form 2678E (see Appendix Q), and drop it off at Pharmacy or via distribution.
 - (d) Telephone. Call the adverse drug reaction voicemail hotline at 8-ADRS (8-2377; not 907-2377) and provide the pertinent information to initiate the report. Assistance will then be provided in completing the report.
- (3) Pharmacy & Therapeutics (P&T) Committee. A clinical pharmacist will report and trend all adverse drug reactions submitted subsequent to the end of the month preceding each meeting. The Chairperson of the P&T Committee will advise on any specific actions needed for reported ADR, and should be notified immediately of any serious or preventable ADRs.
- (4) Quantifi®. All adverse drug reaction reports will be entered in the WAMC Quantifi® database or a similar database approved to store this information.
- d. Adverse drug reaction documentation.
- (1) The individual who discovers the adverse drug reaction (ADR) should document the ADR in the patient's medical record and initiate documentation of the ADR. Any individual can report an ADR.
 - (2) ADRs are documented using either the Form FDA 3500 (MedWatch form; available on-line at <http://www.fda.gov/MedWatch/SAFETY/3500.pdf>; see Appendix O), Form VAERS-1 (Vaccine Adverse Event Reporting System; available on-line at http://vaers.hhs.gov/pdf/vaers_form.pdf; see Appendix P), DA Form 4106 (Incident Report) or Patient Safety Report, or WAMC Form 2678E (Adverse Drug Reaction Alert; see Appendix Q). ADRs are also documented in Quantifi®.
 - (3) When the ADR involves an allergic reaction (e.g., penicillin or sulfa drugs, etc.), the HCP will complete a DA Form 3365, Authorization for Medical Warning Tag and submit the form to the Patient Administration Division (PAD).

PAD will place a DA Label 162 (Emergency Medical Identification Symbol) on the patient's paper medical record.

(4) Pharmacy will ensure that reported ADRs (allergic reactions and drug sensitivities) are documented in the patient's allergy field in CHCS/AHLTA.

e. Adverse drug reaction evaluation. The Pharmacy will evaluate all adverse drug reactions (ADRs) for likeliness using the Naranjo Algorithm (see Appendix R). The reaction will also be evaluated for severity and preventability (see Appendix S).

f. Adverse drug reaction education. WAMC will periodically conduct educational activities to reinforce the need to report adverse drug reactions and the benefits of such reports. This may include formal lectures or publishing information in the medical staff newsletter, informal discussions, or case presentations.

5. Medication errors. AR 40-3 defines a medication error as 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. The US Army and WAMC use the Patient Safety Report (PSR®) as its electronic medication error reporting system, or DA Form 4106, if hand written version is temporarily necessary.

a. Medication error surveillance. WAMC will identify, track, and organize medication data. Medication surveillance will occur:

(1) Prospectively (before drug therapy) – for circumstances or events that have the capacity to cause medication errors (i.e., near miss reporting);

(2) Concurrently (during drug therapy) – for errors detected after the medication is dispensed or administered while under WAMC's care; and,

(3) Retrospectively (after drug therapy) – for errors detected after the medication is dispensed or administered after the patient has departed WAMC (e.g., errors reported by patients, errors caught during refills, etc.).

b. Medication error reporting. Medication errors should be communicated to:

(1) Health care provider. The individual discovering the medication error should report the error to the patient's health care provider in order for that individual to take any necessary action.

(2) Pharmacy. Any individual can submit a medication error report involving any pharmacy to the Pharmacy via:

- (a) Microsoft Outlook. Send any pharmacy staff member an *encrypted* email with a full report, or a *non-encrypted* email without any patient-specific information to initiate an incident report. In the latter situation, the reporting person will be contacted to obtain the information to complete the report.
 - (b) Distribution. Complete a DA Form 4106 and drop it off or send it via distribution to the Pharmacy.
 - (c) Telephone. Call Pharmacy for assistance in completing a DA Form 4106.
 - (d) On the WAMC computer desktops there is an icon button labeled Med Error, which will direct the patient to the online error reporting system.
- (3) Patient Safety Officer. The medication error reporting individual must also provide the WAMC Patient Safety Officer a copy of the completed DA 4106.
- (4) PSR (Patient Safety Reporting)®. All medication errors will be entered in the WAMC PSR® database.
- c. Medication error documentation.
- (1) The individual who discovers the medication error should document the error. Any individual can report errors.
 - (2) Medication errors are documented using DA Form 4106 (Incident Report), which is available on the WAMC desktop or in FormFlow, and in PSR®.
- d. Medication error evaluation.
- (1) The staff (and associated performance improvement committees) assigned to the location where the medication error report originated should evaluate their medication errors.
 - (2) Medication errors entered into the USP PSR® database can be evaluated using the PSR® evaluation tools.
 - (3) Medication errors classified as category I (see AR 40-3) will be evaluated by root cause analysis.
- e. Medication error education. WAMC will periodically conduct educational activities (e.g., patient safety training) to reinforce the need to report medication errors and the benefits of such reports.
6. Drug-nutrient interactions. Policies and procedures related to monitoring for, and preventing, drug-nutrient interactions are maintained by Pharmacy (see Appendix Z) and are posted on the intranet and/or provided upon request.