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Responding to Drug Reactions and Reporting Medication Errors Health & Safety Alert

Introduction

Adverse drug reactions are defined by the World Health Organization (WHO) as "*any response that is noxious, unintended, or undesired, which occurs at doses normally used in humans for prophylactic purposes, diagnosis, treatment of a disease, or modification of physiological function*" (4) (7).

Medication errors are considered avoidable, while adverse drug reactions are expected negative outcomes as a result of the chemical reaction from the drug on the body which is not always preventable and can range from mild to severe (1) (4) (7).

Injury experienced as the result of a medication is the definition of an adverse drug event, which increases the disease process and/or even can cause death to occur from a drug, a missed dose, or the wrong dose of a medicine (1) (7).

There is a difference between an adverse drug reaction and an adverse drug event. When an individual receives a drug and experiences negative consequences, (which may or may not be predictable), it is considered an adverse drug reaction. In contrast, an adverse drug event occurs when: 1) a harmful response is experienced from the exposure to a drug in the normal manner; or 2) when a prescribed medication is not received; or 3) when a medication dose is too high or too low (7).

Even when a medication is prescribed and administered correctly some individuals may still experience adverse drug reactions. When harm from a drug happens, the negative effects can be reduced with immediate action and the right first aid response from caregivers (1) (4).

"Medication.

A. All medication shall be securely locked and properly labeled.

B. All staff responsible for medication administration shall have successfully completed a medication training program approved by the Board of Nursing or be licensed by the Commonwealth of Virginia to administer medications before they can administer medication.

C. Staff authorized to administer medication shall be informed of any known side effects of the medication and the symptoms of the effects.

D. A program of medication, including over-the-counter medication, shall be initiated for a individuals only when prescribed in writing by a person authorized by law to prescribe medication.

E. Medication prescribed by a person authorized by law shall be administered as prescribed.

F. A medication administration record shall be maintained of all medicines received by each individual and shall include:

1. *Date the medication was prescribed.*
2. *Drug name.*
3. *Schedule for administration.*
4. *Strength.*
5. *Route.*
6. *Identity of the individual who administered the medication; and*
7. *Dates the medication was discontinued or changed.*

G. In the event of a medication error or an adverse drug reaction, first aid shall be administered if indicated. Staff shall promptly contact a poison control center, pharmacist, nurse, or physician and shall take actions as directed. If the situation is not addressed in standing orders, the attending physician shall be notified as soon as possible, and the actions taken by staff shall be documented.

H. Medication refusals shall be documented including action taken by staff.

I. The provider shall develop and implement written policies and procedures for documenting medication errors, reviewing medication errors and reactions and making any necessary improvements, the disposal of medication, the storage of controlled substances, and the distribution of medication off campus. The policy and procedures must be approved by a health care professional. The provider shall keep documentation of this approval.

J. The telephone number of a regional poison control center and other emergency numbers shall be posted on or next to each non-pay telephone that has access to an outside line in each building in which children sleep or participate in programs.

K. Syringes and other medical implements used for injecting or cutting skin shall be stored in a locked area" (Virginia Code: 22VAC40-151-750).

"Medication errors and drug reactions.

In the event of a medication error or adverse drug reaction:

1. *First aid shall be administered if indicated.*
2. *Employees or contractors shall promptly contact a poison control center, pharmacist, nurse or physician and shall take actions as directed.*
3. *The individual's physician shall be notified as soon as possible unless the situation is addressed in standing orders.*
4. *Actions taken by employees or contractors shall be documented.*
5. *The provider shall review medication errors at least quarterly as part of the quality assurance in 12VAC35-105-620.*
6. *Medication errors and adverse drug reactions shall be recorded in the individual's medication log"* (Virginia Code: 12VAC35-105-780).

"Medication:

A. The provider shall develop and implement written policies and procedures regarding the delivery and administration of prescription and nonprescription medications used by an individual. At a minimum, these policies will address:

1. *Identification of the staff member responsible for routinely communicating to the prescribing physician:*
   a. *The effectiveness of prescribed medications; and*
   b. *Any adverse reactions, or any suspected side effects.*
2. *Storage of controlled substances.*
3. *Documentation of medication errors and drug reactions; and*
4. *Documentation of any medications prescribed and administered following admission"* (Virginia Code: 12VAC35-46-850).

Drug Reactions

Taking any type of drug is risky. All medications have side effects which can range from insignificant to deadly. A drug reaction is defined as one which is damaging or unintentional and occurs as a direct result of receiving a normal dose of the medication. The more medications an individual is receiving, the greater chances of a drug reaction (19) (4) (20) (7).

Older individuals and individuals who have numerous secondary physical and mental health conditions are at greatest risk of experiencing a drug reaction. Women experience more drug reactions than men due to their differences in hormones and immunity to infections and toxins (7) (1) (4) (6).

Medications are processed either through the kidneys or the liver. Individuals with kidney and liver conditions will have more drug reactions because their bodies are unable to process the medications efficiently. Individuals who take medications which require regular blood testing and/or lab work to maintain therapeutic levels within the body are also at increased risk for drug reactions (7) (1) (4) (8).

In order to reduce injury to an individual during medication administration caregivers should be aware of possible drug reactions, and common side effects of medications an individual is receiving and be prepared to respond if they occur (7) (8) (3) (21).

Medications and classes of drugs at highest risk for drug reactions and 50% of all emergency room visits are:

- Anticoagulants such as aspirin, warfarin, and heparin.
- Steroids such as prednisone and hydrocortisone.
- Opioids such as codeine, fentanyl and hydromorphone.
- Digoxin which is typically given to reduce fast heartbeats (tachycardia) and irregular heartbeats (atrial fibrillation).
- Insulin which is typically given to manage type 2 diabetics.
- Dilantin which is typically given to manage seizures (1) (4) (10).

Knowledge of possible medication side effects help caregivers to address issues before they become serious problems. Some examples might include:

- **Constipation.** Many medications have the side effect of constipation which can be reduced by requesting a prescription/order from the individuals primary care provider (PCP) for a regular fiber supplement, or stool softener before it develops into a bowel obstruction or bowel blockage (7) (3) (4) (21).
- **Minor pain relief.** Individuals who have reduced kidney function may need to take alternative pain reliefers to non-steroidal anti-inflammatory drugs (NSAIDs) due to the negative side effects NSAIDs can have on kidney function (4).
- **Lessened effect of anticoagulants.** Individual's taking an anticoagulant may need a special diet for the drug to work properly within the body, because spinach and other green leafy vegetables interact with some anticoagulant medications (25).

Caregivers administering medicines to non-verbal individuals must use their visual observation skills to recognize and respond to adverse drug reactions experienced by these individuals (14) (13). Document any changes observed and collaborate with other caregivers to see if they have noticed any changes. Report any changes observed to your supervisor and the individual's PCP. Observation of drug reactions requires a good understanding of the drugs being administered (5).

It is very important for caregivers to ask lots of questions about the medicines they are assisting to administration. Open and direct communication with the individual's PCP, the pharmacist, and a nurse has been shown to reduce harm (17). Whenever a caregiver is in doubt about any medication, they should ask questions and or educate themselves ***prior to administering the drug*** (18) (17).

The use of a current drug book, or a reputable drug website for caregivers to look-up each medication and learn about common side effects, drug reactions, inappropriate drug use, and drug-to-drug interactions ***prior to administering medications*** is considered best practice in reducing harm (20).

Many electronic health recorders (EHRs) have a formulary of drug information listed within their software databases. Drug information sheets are typically included with each medication dispensed by the pharmacy which is a good resource for medication information. Also, prescription drug information is available on the FDA's Drugs@FDA website and FDA's FDA Label database (20).

Experts analyzing best practices to reduce drug reactions recommend caregivers do the following:

- Complete regular medication reconciliation.
- Maintain an accurate and up-to-date list of medications for all individuals.
- Administer medications within the prescribed limits (6) (4) (18).
- Regular pharmaceutical medication reviews for individuals taking 5 or more medications.
- Regular medication checks with the individual's PCP to evaluate:
  - If all medications are necessary.
  - If dosages or time given need to be adjusted.
  - If each prescribed drug is doing what it is intended to do to improve the individual's health (13).

Responding to Drug Reactions

Increasing caregivers knowledge and education about the medications they are assisting to administer is the best way for them to recognize and deal with drug reactions and medication side effects (7) (8) (3).

Best practice indicates persons who are trained and approved to administer medications should also be proficient in responding with first aid to drug reactions and medication errors (7) (3) (22) (23).

Virginia Code requires caregivers to call the local poison control center whenever a drug reaction or medication error occurs for next step guidance to ensure an individual's health and safety (22).

The poison control center phone number and any other needed contact information should be easily accessible to caregivers when needed.

The National Capital Poison Control Center phone number is 1-800-222-1222 or use their website webPoisonControl for guidance.

POISON EMERGENCY? CALL 1-800-222-1222 OR VISIT POISONHELP.ORG

When calling the Poison Control Center caregivers should be prepared to answer a few questions. Such as:

- The name of medication given.
- The amount of medication given.
- Time the medication was given.
- The age of the individual.
- The weight of the individual.
- Your name and phone number, in case the call gets disconnected.

After notifying the Poison Control Center, caregivers should notify the individual's PCP and/or the pharmacist who filled the medication, after a medication error or adverse drug event occurs. They will do a quick medication review and give instructions on the individual's continued care (12) (10).

It is vital for caregivers to follow all directions given by poison control, the PCP and/or the pharmacist in order to address the situation quickly, and lower risk of harm to the individual (12).

Medication Errors

There is no universally accepted definition of a medication error which everyone in the healthcare industry can agree upon. This leads to caregiver confusion about when and how to report them (17).

The National Coordinating Council for Medication Error Reporting and Prevention 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 healthcare professional, patient, or consumer"* (17).

Another definition is simply a medication error, or mistake, either by elimination or addition, within the processing of a drug, beginning with the licensed providers prescription and ending with the individual receiving the actual medicine (1).

Medication errors are considered avoidable. When they happen the risk of harm to the individual is greatly increased. Medication errors can negatively affect the quality of life of individuals and can potentially lead to their death (16).

A medication error is seen as a break-down in the “Rights of Medication Administration” which includes:

- The wrong route.
- The wrong dose.
- The wrong time.
- The wrong drug.
- The wrong patient.
- Incorrect frequency.
- Drug not administered at all.
- Documentation error (8) (6).

Medication administration errors may occur due to:

- A lack of knowledge.
- Caregiver carelessness.
- Poor medication administration routines.
- Incomplete procedural skills.
- Outdated practices (6).

Several personal and system barriers have been identified related to the under reporting of medication errors. Some common obstacles experienced by persons who administer medications are:

- Poor reporting systems which can be time consuming, adding paperwork to an already heavy and tiresome schedule.
- Organizations blaming the person passing meds instead of looking at the system’s processes.
- Staff not receiving feedback or recommendations after reporting a medication error.
- Staff receiving negative responses from supervisors when reporting a medication error.
- Fear of a colleague finding out a medication error was the result of their actions and the resulting stigma, shame, and criticism they may receive.
- Lack of a clear definition of what a medication error actually is. This factor adds to the confusion regarding what types of medication errors need to be reported.
- Fear of reprimand, punishment, job loss, and personal liability (9) (2).

In a study conducted by Lee and Lee in 2021, it was determined 47% of all medication errors go unreported in the U.S. When medication errors go unreported it can be difficult to conduct a root cause analysis to learn the reason behind the mistake and/or to put a correction plan into action (9).

Medication errors are required to be reported and documented when they occur within a provider agency as stated in Virginia Code. It is best practice for medication errors to be reviewed after they happen, in order to analyze the cause behind the inaccuracy and to allow for procedural improvements to be implemented (6) (16) (22).

If the wrong medication is given to the wrong person, caregivers should not attempt to deal with the situation on their own. Caregivers should not try to make the individual vomit or throw-up the medicine. This action could lead to an aspiration into the lungs and increased harm to the individual. Neither should caregivers take a wait and see approach.

When a medication error happens, caregivers should administer first aid as needed, and should call the local poison control center, the individual's PCP, the pharmacist, and/or a nurse if available, for immediate guidance on how to care for the individual (21).

It is best practice for caregivers to document drug reactions and medication errors when they happen. Both a paper MAR and an EHR have space in which to write a short note regarding drug reactions and medication errors. More extensive notes can be added to an individual's medical record (23).

Documentation regarding medication errors can include:

- The facts about what happened without personal opinions using non-bias language.
- The actions the caregiver took to address the situation and get the individual help.
- The specific help given to the individual.
- Who, specifically, the caregiver called to notify, such as poison control, the PCP, the pharmacist, the nurse, the family, or guardian, etc.
- The exact name of the person the caregiver spoke to when the call was made.
- The date and time each call notification was completed.
- What type of notification was made such as email, fax or message sent through a medical portal system.

Licensed agency providers in the Commonwealth are required to be knowledgeable and have a clear understanding of when medication errors and adverse drug reactions are required to be reported to DBHDS Office of Licensing (15).

October 2016 - Reporting a Serious Incident as a Medication Error Office of Licensing Standards

Purpose: This document is intended to offer Providers clarification as to their role of reporting serious incidents/events that are the result of a medication error to the Office of Licensing.

Definitions:

(1) "Medication error" means an error in administering a medication to an individual and includes when any of the following occur:
(i) the wrong medication is given to an individual,
(ii) the wrong individual is given the medication,
(iii) the wrong dosage is given to an individual,
(iv) medication is given to an individual at the wrong time or not at all, or
(v) the wrong method is used to give the medication to the individual.

(2) "Serious incident" means any incident or injury resulting in bodily damage, harm, or loss that requires medical attention by a licensed physician, Doctor of Osteopathic Medicine, physician assistant, or nurse practitioner while the individual is supervised by or involved in services, such as attempted suicides, medication overdoses, or reactions from medications administered or prescribed by the service.

(3) "Medications" (adapted from CMS & Licensing Regulations): Medications refers to all prescription and over-the-counter medications taken by the resident, including dosage, frequency of administration, and recognition of significant side effects that would be most likely to occur in the resident. This information must be in the resident's clinical record.

Recording and Reporting Requirements:

- All medication errors should be recorded and dealt with through the provider's administrative processes. Refer to12VAC35-105-780, for additional regulatory requirements. Providers should remember that the state's incident reporting system is not designed to be used to capture all staff inaccuracies or all behaviors of persons receiving services. There are more appropriate methods of doing this.
- Current DBHDS Licensing standards indicate that medication errors should only be reported to licensing when it results in adverse outcomes, which is defined as a serious incident in the licensing regulations.
- Licensing requires that a serious incident is reported within 24-hrs. Medication Errors become serious incidents when they lead to adverse reactions or outcomes.

Reference to DBHDS Standards:

12VAC35-105-160. Reviews by the department; requests for information. Each instance of death or serious injury shall be reported in writing to the department's assigned licensing specialist within 24 hours of discovery and by phone to the individual's authorized representative within 24 hours. Reported information shall include the following: the date and place of the individual's death or serious injury; the nature of the individual's injuries and the treatment received; and the circumstances of the death or serious injury. Deaths that occur in a hospital as a result of illness or injury occurring when the individual was in a licensed service shall be reported.

(General Steps Regarding Medication Errors) 12VAC35-105-780. Medication errors and drug reactions.

1. First aid shall be administered if indicated.
2. Employees or contractors shall promptly contact a poison control center, pharmacist, nurse or physician and shall take actions as directed.
3. The individual's physician shall be notified as soon as possible unless the situation is addressed in standing orders.
4. Actions taken by employees or contractors shall be documented.
5. The provider shall review medication errors at least quarterly as part of the quality assurance in 12VAC35-105-620.
6. Medication errors and adverse drug reactions shall be recorded in the individual's medication log.

Caregiver Considerations

Preparing, double checking, administering, observing, documenting, and reporting observations are all part of the complex process of medication management (6).

Administering medications involves:

- Knowledge on how to communicate with the physician and pharmacy when medications are ordered.
- Properly storing medicines.
- Accurate preparation for medication use.
- Understanding administration instructions.
- Correctly documenting medication administration.
- Following disposal instructions of old medications and or discontinued medicines.
- Knowing when to, and who to report observed side effects and responses to medications (11).

Assisting with administration of medications is a high-risk skill which is an important responsibility that can consume a large amount of time during a shift (8) (5). Reducing interruptions when handling medications has been shown to reduce medication errors (16).

It is best practice to have a written policy outlining the process for handling medications which aligns with Virginia Code, and the Virginia Board of Nursing approved 32-hour medication aide curriculum (6) (23). Written policies increase caregiver confidence and ensures consistency in delivering quality care (14).

Each caregiver is to successfully complete the Commonwealths required 32-hour training and pass an administration competency to be verified by supervisors before any caregiver can be responsible for handling medications within a licensed provider agency in Virginia (6) (23).

Medication errors have been shown to increase in comparison to the length of the time between a caregivers last training, review and/or refresher (6) (16).

Caregivers responsible for the management of medications who received annual medication administration reviews and/or refreshers, at minimum every two years, have been shown to make fewer medication errors than those who do not receive additional reviews or refreshers (6) (14) (16).

The caregiver who uses the double check method prior to administering medicines has fewer medication errors than those who do not use this method (16).

Caregivers responsible for managing medications should have a good understanding of how medication administration impacts the individuals human rights.

Such as:

- An individual has the right to be informed as to why they are taking each medication being administered to them. When a caregiver is administering a drug, they should communicate the diagnoses for each medicine to the individual weather the caregiver believes the individual understands or not.

- The individual has the right to refuse medications. The caregiver assisting with the administration of medications is responsible for documenting the refusal and reporting it to the correct persons and healthcare professionals.
- An individual has the right to privacy when receiving their medications unless they have consented to receiving their medications in a public area. The caregiver administering medications should provide a private location to give the individual their medicines such as in the individual's own room, or a private medication room or office.
- An individual has the right to receive only medications which have been prescribed to them. Caregivers who give the wrong medications to the wrong person are committing a medication error along with violating the individual's human rights (24).

Resources

- The DBHDS Office of Licensing: https://dbhds.virginia.gov/clinical-and-quality-management/office-of-licensing/
- The DBHDS Office of Human Rights: https://dbhds.virginia.gov/clinical-and-quality-management/human-rights/
- Virginia Commonwealth regulations for training programs for medication administration by unlicensed persons and immunization protocol: https://law.lis.virginia.gov/admincode/title18/agency90/chapter21/section30/
- Approved VBON Medication Administration Curriculum, Guidance Document: 90-62, Revised: November 14, 2017, Medication Administration Training Curriculum Approved by the Board of Nursing for Various Settings - https://www.townhall.virginia.gov/L/GetFile.cfm?File=C:%5CTownHall%5Cdocroot%5CGuidanceDocs%5C223%5CGDoc_DHP_5592_v9.pdf
- Approved VBON training programs, Contact to verify 32-hour training course is offered - https://www.dhp.virginia.gov/Boards/Nursing/EducationPrograms/ProspectiveStudents/MedicationAideTrainingPrograms/
- Virginia Law, Chapter 34: The Control Drug Act - https://law.lis.virginia.gov/vacode/title54.1/chapter34/
- National Institutes of Health, National Library of Medicine (2019). Medline Plus database - https://medlineplus.gov/druginformation.html
- Drugs.com (2019). Find drugs and conditions database - https://www.drugs.com/
- U.S. Food & Drug Administration (2019). Drugs @ FDA database - http://www.fda.gov/drugsatfda
- Virginia Poison Control Center: https://poison.vcu.edu/

"*Content of medication administration training.*

A. The curriculum shall include a minimum of 32 hours of classroom instruction and practice in the following:

1. Preparing for safe administration of medications to clients in specific settings by:

a. Demonstrating an understanding of the client's rights regarding medications, treatment decisions, and confidentiality.

b. Recognizing emergencies and other health-threatening conditions and responding accordingly.

c. Identifying medication terminology and abbreviations.

2. Maintaining aseptic conditions by:

a. Implementing universal precautions.

b. Insuring cleanliness and disinfection.

c. Disposing of infectious or hazardous waste.

3. Facilitating client self-administration or assisting with medication administration by:

a. Reviewing administration records and prescriber's orders.

b. Facilitating client's awareness of the purpose and effects of medication.

c. Assisting the client to interpret prescription labels.

d. Observing the five rights of medication administration and security requirements appropriate to the setting.

e. Following proper procedure for preparing medications.

f. Measuring and recording vital signs to assist the client in making medication administration decisions.

g. Assisting the client to administer oral medications.

h. Assisting the client with administration of prepared instillations and treatments of:

(1) Eye drops and ointments.

(2) Ear drops.

(3) Nasal drops and sprays.

(4) Topical preparations.

(5) Compresses and dressings.

(6) Vaginal and rectal products.

(7) Soaks and sitz baths.

(8) Inhalation therapy.

(9) Oral hygiene products.

i. Reporting and recording the client's refusal to take medication.

j. Documenting medication administration.

k. Documenting and reporting medication errors.

l. Maintaining client records according to facility policy.

m. Sharing information with other staff orally and by using documents.

n. Storing and securing medications.

o. Maintaining an inventory of medications.

p. Disposing of medications.

4. Facilitating client self-administration or assisting with the administration of insulin. Instruction and practice in the administration of insulin shall be included only in those settings where required by client needs and shall include:

a. Cause and treatment of diabetes.

b. The side effects of insulin.

c. Preparation and administration of insulin.

d. Signs of severe hypoglycemia and administration of glucagon.

5. Facilitating client self-administration or assisting with the administration of auto-injectable epinephrine pursuant to an order issued by the prescriber for a specific client in a facility licensed by the Department of Behavioral Health and Developmental Services under the provisions of subsection D of § 54.1-3408 of the Code of Virginia.

B. Pursuant to subsection L of § 54.1-3408 of the Code of Virginia, the board requires successful completion of the curriculum approved by the Department of Behavioral Health and Developmental Services (DBHDS) for unlicensed persons to administer medication via a gastrostomy tube to a person receiving services from a program licensed by the DBHDS" (Virginia Code: 18 VAC90-21-30).

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