



ANTIBIOTIC ADVERSE DRUG EVENTS (ADE) TEMPLATE

2018 Abridged Guidance for the
Post-Acute Long-Term Care Team

Abstract

Nearly half of adverse drug events (ADEs) are preventable and account for about 11% of hospital admissions. ADEs are more likely to occur in adults older than 65 years, recently started on a new medication, and receiving 5 or more chronic medications. About 40% of harm noted in skilled nursing facilities is associated with ADEs. Antibiotics are used frequently in post-acute and long-term care settings and cause a high rate of ADEs.

This guidance document outlines recommendations for using the antibiotic ADE template to improve identification, reporting, and documentation of antibiotic ADEs. The application of this approach to antibiotic monitoring is fundamental to improving antimicrobial stewardship in post-acute and long-term care facilities as ADEs relate directly to patient safety.

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Find more information at: <https://www.pharmacy.umaryland.edu/centers/lamy/antimicrobial-stewardship/>

OPTIMIZING MEDICATION SAFETY THROUGH THE USE OF AN ANTIBIOTIC ADVERSE DRUG EVENTS (ADEs) TOOL

The Antibiotic ADE Tool is annotated on the next several pages to demonstrate the recommended use of the tool. For the purposes of illustration, the following case has been created. Appendix 1 contains a blank, non-annotated version of the ADE Tool for your use.

CASE

Ms. MK is a 92 year old female who was sent from her long-term care facility to the hospital for completion of treatment for a complicated urinary tract infection (UTI). In addition to the UTI she has a history of heart failure, dementia, and chronic obstructive pulmonary disease (COPD). Her medications are listed in the table below.

Medications

<u>Medication</u>	<u>Dose</u>
Digoxin	0.125 mg p.o. every other day
Furosemide (Lasix)	40 mg p.o. daily
Lisinopril	10 mg p.o. daily
Metoprolol Succinate (Toprol XL)	50 mg p.o. daily
Donepezil (Aricept)	10 mg p.o. daily
Vitamin D ₃	2,000 iu p.o. once daily
Tiotropium Handihaler (Spiriva)	18 mcg (2 puffs) once daily by inhalation
Albuterol Inhaler (ProAir HFA)	180 mcg (2 puffs) by inhalation as needed for shortness of breath
Ciprofloxacin (Cipro)	500 mg p.o. every 12 hours x 10 days

She received 7 days of ciprofloxacin I.V. in the hospital and then was transferred back to the nursing home on all of the same medications, but the ciprofloxacin was changed from intravenous to oral administration.

On day 7 of ciprofloxacin (Cipro) therapy her nurse observes new, extensive watery diarrhea. The diarrhea occurs every couple of hours causing abdominal pain. The only new medication she started was the ciprofloxacin. The nurse looks back 7 days at her laboratory results and finds a positive test for *C. difficile*. He/she begins to complete an antibiotic ADE and calls her doctor for instructions.

The Antibiotic ADE is completed with annotations on the next several pages.

Sample Annotated ADE Tool

Optimizing Medication Safety 4.0 Annotated 11/23/2018

Client: _____ Location: _____

A. ASSESSMENT
1. Demographics
a. Allergies

Known allergies should be documented before administration of any new medication, particularly antibiotics.

b. Active Diagnoses (from most recent history/physical)

Active diagnoses are helpful to prevent confusing new signs and symptoms with a change in an underlying condition. These should be taken from the most recent history and physical

Date of Birth: 07/06/1926 (DD/MM/YYYY) Age 92

Most Recent Weight: 49 kg Scale: _____ Date: 10/1/2018

Most Recent Height: 5'2" Method: _____ Date: _____

Creatinine Clearance: 30.9 mL/min Date of Creatinine: 10/18/2018

New or Change in Signs and Symptoms

A. If this is an emergency, take immediate action and notify **PRESCRIBER**.

Emergencies should be handled first as emergencies.

B. Assessment of possible anti-infective related adverse event observed (select all that apply):

- Nausea Vomiting Diarrhea Abdominal tenderness/pain
 Distended abdomen Increased bowel sounds Infectious diarrhea (*C. difficile*)
 Other

1. Possible Gastrointestinal Event

Provide details:

C. difficile suspected based on watery diarrhea and presence of positive *C. diff* test.

Date Observed _____

- Decreased urine output Painful urination Blood in urine Other

2. Possible Renal Event

Provide details:

Date Observed _____

Basic demographic information is needed to calculate creatinine clearance and determine if the antibiotic dose is correct.

In all of section B, the nurse should identify any new, relevant signs and symptoms, provide details of the ADE(s) and the date observed and take appropriate follow-up action. The focus is on a change that occurred after starting the antibiotic(s).

Sample Annotated ADE Tool

Optimizing Medication Safety 4.0 Annotated 11/23/2018

Client: _____ Location: _____

In all of section B, the nurse should identify any new relevant signs and symptoms, provide details of the ADE(s) and the date observed and take appropriate follow-up action. The focus is on changes from baseline that occurred after starting the antibiotic(s).

Fatigue Bleeding Delayed clotting Bruising Other

3. Possible Blood Event

Provide details:

Date Observed _____

Abdominal tenderness/pain Nausea/vomiting Decreased appetite
 Yellow skin or eyes Other

4. Possible Liver Event

Provide details:

Date Observed _____

Dizziness Confusion Hypoactive, difficulty arousing Delirium Delusions
 Hallucinations Spasmodic jerky muscle movements (myoclonus) Peripheral numbness & tingling
 Seizure(s) Other

5. Possible Neurological Event

Provide details:

Date Observed _____

Hallucinations are a sensory experience without a stimulus.
Delusions are fixed false beliefs held despite evidence to the contrary.

Muscle pain Muscle weakness Tendon pain Other

6. Possible Muscle Pain/Muscle Weakness/Myositis

Provide details:

Date Observed _____

Tendon pain – for example, Achilles tendon.

Sample Annotated ADE Tool

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Client: _____ Location: _____

In all of section B, the nurse should identify any new relevant signs and symptoms, provide details of the ADE(s) and the date observed and take appropriate follow-up action. The focus is on changes from baseline that occurred after starting the antibiotic(s).

- Fast heart rate Low blood pressure QTc interval > 500 msec
 Palpitations Dizziness Syncope (fainting) Other

7. Possible Arrhythmia Event

Provide details (including onset of ADE relative to drug administration, actions taken):

Date Observed _____

- Rash Hives/wheal/flare Erythema (skin redness) Pruritis (itchiness) Other

8. Skin/Dermatological Event

Provide details:

Date Observed _____

- Hives, wheal and flare Labored breathing
 Systolic BP < 90 mm Hg Other

9. Possible Anaphylaxis

Provide details (including onset of ADE relative to drug administration, actions taken):

Date Observed _____

10. Other Event

Provide signs and symptoms noted:

Date Observed _____

Sample Annotated ADE Tool

Optimizing Medication Safety 4.0 Annotated 11/23/2018

Client: _____ Location: _____

3. Laboratory Values

A. Current (within the past 14 days) laboratory values (related to ADE):

Renal Event ←	<input type="checkbox"/> 1. Serum creatinine	Date Obtained _____
Blood Event ←	<input type="checkbox"/> 2. WBC	Date Obtained _____
	<input type="checkbox"/> 3. Hemoglobin	Date Obtained _____
	<input type="checkbox"/> 4. Platelets	Date Obtained _____
Liver Event ←	<input type="checkbox"/> 5. Total bilirubin	Date Obtained _____
	<input type="checkbox"/> 6. AST/ALT	Date Obtained _____
Muscle Event ←	<input type="checkbox"/> 7. Creatinine phosphokinase (CPK)	Date Obtained _____
<i>C. difficile</i> Infection ←	<input checked="" type="checkbox"/> 8. <i>C. difficile</i> test	Date Obtained <u>10/18/2018</u>
	<input type="checkbox"/> 9. Other	Date Obtained _____

Renal, blood, liver, and muscle ADEs and *C. difficile* infections are likely to have laboratory values available that will help make the diagnosis. If they are not available, it is likely that the prescriber will order the relevant laboratory test(s) corresponding to the suspected ADE event.

4. Current anti-infectives resident is receiving (anti-infective may have been started in the hospital):

Brand Name	Generic Name	Start Date	Stop Date
<u>Cipro</u>	<u>ciprofloxacin</u>	<u>10/18/2018</u>	<u>10/28/2018</u>

It is common for residents to receive two or more antibiotics at the same time. All antibiotics, and their start and planned stop dates, should be recorded.

5. Discussion with Prescriber

Recommendation to the Prescriber:

- Discontinue suspected anti-infective Replace with alternative medication Change dose/frequency/route of administration Other

No further action at this time

Provide details, including follow-up plan (if applicable):

Has had 7 days of ciprofloxacin. Should another antibiotic be used instead to complete the 10 day course?

While the nurse is not making the diagnosis, he/she can use their professional knowledge and experience to assess the severity of the ADE and suggest a plan to the prescriber.

B. INTERVENTION

1. Suspected Anti-infective Ciprofloxacin

2. Course of Action and Follow-up

- Discontinue suspected medication
 Replace with alternative medication _____
 Change dose/frequency/route of administration _____
 Other _____
 No further action at this time

This section is generally completed by the prescriber or by the nurse following discussion with the prescriber.

Provide details, including follow-up plan (if applicable):

Rehydrated, supportive measures instituted.

Sample Annotated ADE Tool

Optimizing Medication Safety 4.0 Annotated 11/23/2018

Client: _____ Location: _____

C. ADDITIONAL REVIEW AND EVALUATION

1. Estimated Creatinine Clearance _____ mL/min Date _____

This section is generally completed by the pharmacist or infection preventionist following the course of antibiotic therapy.

2. Other Possible Adverse Anti-infective Events

A. Evaluate if the resident has experienced an anti-infective related ADE:

1. Anti-infective-anticoagulant drug interaction

Document interacting anti-infective(s) and if appropriate action(s) have been taken to address interaction:

Active anticoagulant (select all that apply):

- warfarin (Coumadin)
- rivaroxaban (Xarelto)
- apixaban (Eliquis)
- edoxaban (Savaysa)
- dabigatran (Pradaxa)

2. Multi-drug resistant organism (MDRO) infection(s)

Identify type of MDRO infection(s):

- methicillin-resistant *S. aureus* (MRSA)
- vancomycin-resistant *Enterococci* (VRE)
- carbapenem-resistant *Enterobacteriaceae* (CRE)
- MDR *Acinetobacter*
- MDR *Pseudomonas*
- Extended spectrum beta-lactamase (ESBL) producing *Enterobacteriaceae*
- Other _____

Infection with an MDRO generally occurs later after the first course of antibiotics is finished.

How many anti-infectives has the resident received in the last 90 days?

- 1
- 2
- 3
- 4
- other

Provide details of anti-infectives (i.e., dose, duration, frequency, indication, start and end dates):

Date Observed _____

Sample Annotated ADE Tool

Optimizing Medication Safety 4.0 Annotated 11/23/2018

Client: _____ Location: _____

3. *C. difficile* infectious diarrhea (Compared to baseline; check all that you observe.)

- Diarrhea Abdominal pain Increased bowel sounds Other
 C. difficile test _____ date _____

Provide details:

Date Observed _____

Infection with *C. difficile* generally occurs later and may occur after the first course of antibiotics is finished.

4. Other

Provide details:

Date Observed _____ Suspected Anti-infective _____

This section is available to record any other antibiotic ADE(s) that may be detected by the pharmacist or infection preventionist.

3. Category of Possible Anti-infective Adverse Drug Event

Predictable
Preventable
ADEs

- Allergy
 Anticipated/Expected/Dose-related
 Idiosyncratic/Unanticipated/Unpredictable

The pharmacist or infection preventionist should choose the category of antibiotic ADE. Subsequently, root cause analysis can be performed to identify strategies to minimize allergic reactions and predictable/preventable ADEs.

4. Event Outcome (Hartwig Severity Assessment Scale)¹

The Hartwig scale is a reliable and valid way to categorize event outcomes. This section should be completed by the pharmacist or infection preventionist following the ADE.

- Level 1. Resolved, no residual harm. No change in treatment was needed.
 Level 2. Resolved with suspected anti-infective held, discontinued or otherwise changed.
 Level 3. Resolved with suspected anti-infective held, discontinued or otherwise changed AND/OR an antidote or other treatment was required.
 Level 4. Any Level 3 ADE which causes hospitalization or increases length of stay by at least 1 day.
 Level 5. Any Level 4 ADE which requires intensive medical care.
 Level 6. The ADE caused permanent harm to the resident.
 Level 7. The ADE either directly or indirectly led to the death of the resident.

Resulting Severity of the ADE

- A. Mild Event: Levels 1 and 2
 B. Moderate Event: Levels 3 and 4
 C. Severe Event: Levels 5, 6 and 7

The severity of the ADE is determined by the numerical Level.

5. EMR Documentation

- This adverse event should be documented in the resident's medical record to help avoid future exposure and adverse events.

1.Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions.

Unless the ADE Tool is a permanent part of the resident's medical record, this box should be checked to assure that that ADE is transcribed into the EMR.