



PharmaNet Adverse Drug Event (ADE)

Cheat Sheet

Created with information provided by the PharmaNet ADE Project Team

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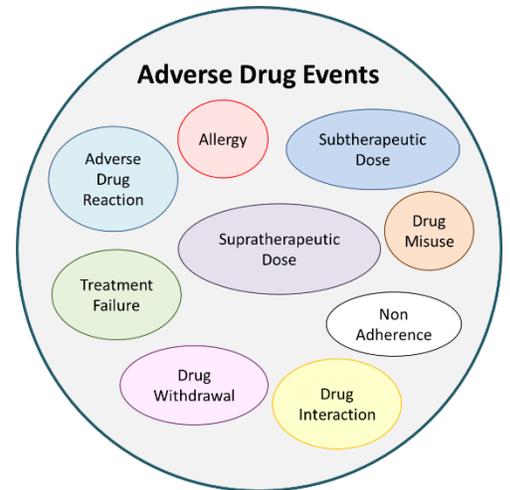
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Introduction

An Adverse Drug Event (ADE) is ‘Harm caused by appropriate or inappropriate use of a drug whereas adverse drug reactions are a **subset** of these events, where harm is directly caused by a drug under appropriate use (i.e. at normal doses). Adverse drug events may include cases of provider error, non-adherence, or incorrect dosages. (Nebeker, Barach, & Samore, 2004).

Information recorded by acute care providers in PharmaNet will include a broad range of ADEs, including as a subset ADRs. As the PharmaNet system will flag these ADEs for review upon subsequent dispensations of the medication, it is important for community pharmacists to review the information contain in the comments of recorded ADE/ADRs to determine the most appropriate action.

The ActionADE research team have completed significant research into what details of an ADE should be recorded to accurately, but succinctly inform other care providers of the event. As ActionADE is a research project there will be limited patients with ADE records, Pharmacists will still record ADRs as per the usual process in PharmaNet. For more information on ActionADE you can visit their [web page](#).



Display of ADE information in a Patient’s PharmaNet Profile in Kroll Service Pack 20

Look for the ***ADE** in the Clinical Conditions tab of the patient profile, it denotes an “ADE” record. When you see *ADE you must look for additional ADE details under the culprit drug in the Adverse Reaction tab of the patient’s profile.

Example:

CLINICAL CONDITION (ZPB1)	*ADE_1450_Deep vein thrombosis
Clinical Condition Comment: INR=1	
ADVERSE REACTION (ZPB2)	Warfarin - DIN 2240205
Adverse Reaction Comment: *ADE_1450_Subtherapeutic Dose_Certain_Hospital extended_3mg_daily	

NOTE: Kroll Service Pack 21 introduces new functionality to improve the users experience of ADE information and brings this information together in a new ADE tab.

The following ADE information will be recorded in the PharmaNet record:

CLINICAL CONDITIONS TAB		
Data element	What it contains & allowed values	Comments
ADE Identifier	*ADE	Flags that this condition is associated with an ADE and its impact to therapy should be considered in the context of the ADE. The pharmacist must look for further details of the ADE in the 'Adverse Reaction' tab. This can be done by matching the *ADE identifier.
Time Stamp	hh=hour (00 - 23) / mm=minutes (00 - 60)	Where a patient has multiple ADEs recorded, permits the matching of symptoms experienced in clinical conditions tab to the correct ADE information recorded in the adverse reaction tab.
Clinical Condition	Name of condition or symptom	Primary symptom/condition experienced as part of the ADE.
Comment Detail	Up to two further conditions/symptoms or lab value	Provides further details of symptoms experienced as part of the ADE, may also include a relevant lab value (eg. INR)

ADVERSE REACTION TAB

Data Element	What it contains	Comments
Drug Name and DIN	Drug name and DIN of the drug associated with the ADE.	This is often referred to as the culprit drug. PharmaNet will check any future dispenses against this DIN and flag as a prior ADR where a <u>potential</u> cross sensitivity exists. The pharmacist must review the ADE record to determine the appropriate action.
ADE Identifier	*ADE	Flags that this record should be treated as an ADE versus ADR.
Time Stamp	hh=hour (00 - 23) / mm=minutes (00 - 60)	Where a patient has multiple ADE recorded, permits the matching of symptoms experienced in clinical conditions to the ADE information recorded in the ADR section
Adverse Drug Event Type	Adverse Drug Reaction	Defines the type of Adverse Drug Event. This informs a pharmacist of the most appropriate clinical intervention. For example, a patient arrives in the ER experiencing seizures due to not taking their phenytoin. This would be documented as an ADE due to non-compliance, the expectation is that the pharmacist will encourage the patient to take their medication as prescribed to prevent a repeat of the non-adherence ADE.
	Allergy	
	Subtherapeutic dose	
	Supratherapeutic dose	
	Treatment failure	
	Drug Withdrawal	
	Drug Interaction	
	Non-Adherence	
	Drug Misuse	
Certainty	Certain	The level of certainty the acute care provider has that the culprit drug caused the associated symptoms/diagnosis. 'Refuted' indicates that the providers has determined that the drug did not cause this ADE. For example, for 'Refuted', allergy testing reveals that a rash subsequent to amoxicillin was likely attributed to use during a viral infection not a true allergy.
	Likely	
	Possible	
	Unlikely	
	Refuted	

ADE Outcome	Death	The outcome of the ADE event, it provides some insight to the severity of the ADE.
	Permanent Disability	
	Worsen Preexist Cond	
	Fetal Defect	
	Hospitalization	
	Hospital Extended	
	Emergency Visit	
	Life Threatening	
Dose with Units	free text	Included where applicable, eg. Subtherapeutic and Supratherapeutic dose.
Frequency	free text	
The information in the ADR comment is in the above order with each data element separated by an underscore. Comment: *ADE_hhmm_Adverse Drug Event Type_Certainty_ADE Outcome_Dose_Frequency		

Recording your Clinical Decisions

The ActionADE research is dependent upon pharmacists recording in PharmaNet their clinical decisions based upon the ADE information presented to them.

The PharmaNet Drug Use Evaluation (DUE) will alert on an ADE as part of the claim process. As these are ADEs versus ADRs, **do not** assume the medication should be discontinued or replaced. In some cases, it is appropriate to ensure the patient takes their medication as in the case of an ADE due to non-adherence. Depending on your Kroll software version this ADE information will be presented differently.

In Kroll SP 20, the user must review the comment details of the ADR and match to the associated Clinical Condition, via *ADE_hhmm identifier, to assess how the ADE alert should be managed clinically. To record the clinical decision in response to ADE information subsequent to the DUE alert, a pharmacist must manually reverse and resubmit any further claim with the appropriate reversal and rationale codes

In Kroll 10 SP 21 the software will merge the information together in a unified alert and provide appropriate option buttons to the user which will pre-populate the reversal and rationale intervention codes for you.

If an issue is noted prior to submission of a claim via review of the patient's PharmaNet profile, the pharmacist can enter the rationale intervention code on the initial claim submission.

PharmaNet Intervention Codes for Reversals due to ADE

Code	Description
RA	Due to ADE alert.
RD	Defer clinical decision.
RO	Override alert.

PharmaNet Intervention Codes to indicate a decision to proceed with the dispense despite the ADE information

Code	Description
AA	Fill despite prior substance use.
AB	Benefit outweighs risk.
AE	ADE report erroneous.
AI	ADE alert inappropriate.
AK	ADE acknowledged and prescription changed.
AR	ADE refuted.
AT	ADE resolved/treated.

PharmaNet Intervention Codes to indicate a therapeutic change as a result of ADE information.

Code	Description
AK	ADE acknowledged and prescription changed.

** See Appendix 1 – Workflow to record pharmacist clinical decisions in PharmaNet

Display of ADE information in Kroll version 10.20 and prior Clinical Conditions Tab

The screenshot shows the PharmaNet Patient Profile interface. The patient is Civies, Precessing, Male, DOB: 09-Jul-1992, PHN: 9735387315. The Clinical Conditions tab is active, showing a list of conditions. The condition ***ade_1553_toxic Epidermal Necrolysis** is highlighted with a red box. A purple arrow points from this box to a pop-up window titled "Condition Details". The pop-up shows the following information:

- Patient Condition: *ade_1553_toxic Epidermal Necrolysis
- Chronic: No
- Reported By: AE
- Date Reported: 20-Feb-2020
- Comment: Trichiasis_skin Hyperpigmentation
- Pract Ref: 91
- Pract ID: Xxanr
- Date Entered: 20-Feb-2020

Buttons for "OK", "Cancel", and "Next" are visible at the bottom of the pop-up.

Adverse Reactions Tab

The screenshot shows the PharmaNet Patient Profile interface. The patient is Civies, Precessing, Male, DOB: 09-Jul-1992, PHN: 9735387315. The Adverse Reactions tab is active, showing a list of drugs. The drug **Sulfamethoxazole/Trimethoprim 400MG-80MG** is highlighted with a blue box. A green arrow points from this box to a pop-up window titled "Reaction Details". The pop-up shows the following information:

- Drug: Sulfamethoxazole/Trimethoprim 400MG-80MG
- DIN: 00445274
- Form: Tablet
- Manufacturer: Apotex Inc
- Reported By: AE
- Date Reported: 20-Feb-2020
- Comment: *ade_1553 adverse Drug Reaction_certain permanent Disability_
- Pract Ref: 91
- Pract ID: XXANR
- Date Entered: 20-Feb-2020

Buttons for "OK", "Cancel", and "Next" are visible at the bottom of the pop-up.

Display of ADE information in Kroll version 10.21

Clinical Conditions and Adverse Reactions tab contain information from pharmacies only.

A new "ADE" tab displays adverse drug event information recorded by acute care sites via ActionADE.

PharmaNet Patient Profile

View

Patient: **Civies, Precessing** Male DOB: **09-Jul-1992** PHN: **9735387315**

Clinical Conditions (2) Adverse Reactions (0) **ADEs (8)** Profile (104)

Drug	DIN	Form	Manufacturer	Date Reported
Sulfamethoxazole/Trimethoprim 400MG-80MG	00445274	Tablet	Apotex Inc	20/02/2020
Cephalexin 500 MG	00768715	Tablet	Apotex Inc	20/02/2020
Oxycodone Hcl 5 MG	00789739	Tablet	Sandoz Canada	20/02/2020
Warfarin Sodium 3 MG	02240205	Tablet	B-M Squibb	20/02/2020
Warfarin Sodium 2 MG	02242681	Tablet	Taro Pharm	20/02/2020
Citalopram Hydrobromide 20 MG	02248010	Tablet	Pharmascience	20/02/2020
Meloxicam 7.5 MG	02248267	Tablet	Pharmascience	20/02/2020
Fentanyl 50MCG/HR	02282968	Patch Td72	Teva Canada Li	20/02/2020

Detail Refresh Extra Functions Cancel Next

Pharmanet ADE Details Form

Pharmanet ADE

Description

Adverse Reaction

Drug **Sulfamethoxazole/Trimethoprim 400MG-80MG**

DIN **00445274** Form **Tablet** Manufacturer **Apotex Inc**

Event Type **Adverse Drug Reaction** Certainty **Certain** Outcome **Permanent Disability**

Dose with Units Frequency/Sig

Condition

Symptoms/Diagnosis **TOXIC EPIDERMAL NECROLYSIS
TRICHIASIS
SKIN HYPERPIGMENTATION**

Chronic **No**

Date Reported **20/02/2020 15:53** Pract Ref **91** Pract ID **XXANR** Reported By **AE**

OK

Information from the Adverse Reaction field and Clinical Condition field have been brought together by the software by matching the *ADE_hhmm identifier

The detailed information from the ADE presented into defined information fields with headers.

Display of ADE information in Kroll version 10.21 continued.

1-(local):Pharmacy10-21BC-Modify Rx for Civies, Precessing

File Edit Rx View Labels Profile Reports Utilities NH Cards Session Help Version 10 LiveChat with Kroll Support

F3 - Patient F5 - Drug F7 - Doctor F9 - Workflow F11 - Drop-off F12 - Save Changes Alt+X - Start

484386 Modify Rx Adjust

PharmanetADEAlertForm

Pharmanet ADE Alert

Description **Grp All to SULFAMETHOXAZOLE/TRIMETHOPRIM DIN 00445274 on 2020/02/20 by AE**

Adverse Reaction

Drug **Sulfamethoxazole/Trimethoprim 400MG-80MG**

DIN **00445274** Form **Tablet** Manufacturer **Apotex Inc**

Event Type **Adverse Drug Reaction** Certainty **Certain** Outcome **Permanent Disability**

Dose with Units Frequency/Sig

Condition

Symptoms/Diagnosis **TOXIC EPIDERMAL NECROLYSIS
TRICHIASIS
SKIN HYPERPIGMENTATION**

Chronic **No**

Date Reported **20/02/2020 15:53** Pract Ref **91** Pract ID **XXANR** Reported By **AE**

Would you like to:

Reverse the dispense

Override and Dispense As Is

Modify Rx

Adapt Rx

Defer the decision

Priority Test

Patient Search

Name **Civies, Precessing**

Address **5618 Stockheld Drive**

City **Falmouth**

Phone **Home (555) 555-5555**

Plan **BCPA** Client ID

Allergies (0)

Conditions (0)

Plans Pricing Dates Co

Rx Plans Plan P

BCPA Not Ad

Cash Not Ad

Next Disp Qty Min In Max Disp Qty

Rx Comments (0)

Add Rx Image

Transfer Rx From Another Store

Transfer Rx To Another Store

Inactivate Rx

Cancel Rx

Call Doctor

Counsel Patient on Pickup

Print Kroll Care

Dispense Quantity

Clinical Interactions

Plan Information

Refill Information

Patient Plan Information

Generic Equivalents

Dispense as it was Filled

Unit Dose Info

Work Order

Counseling History

Workflow

Send Rx to Trouble

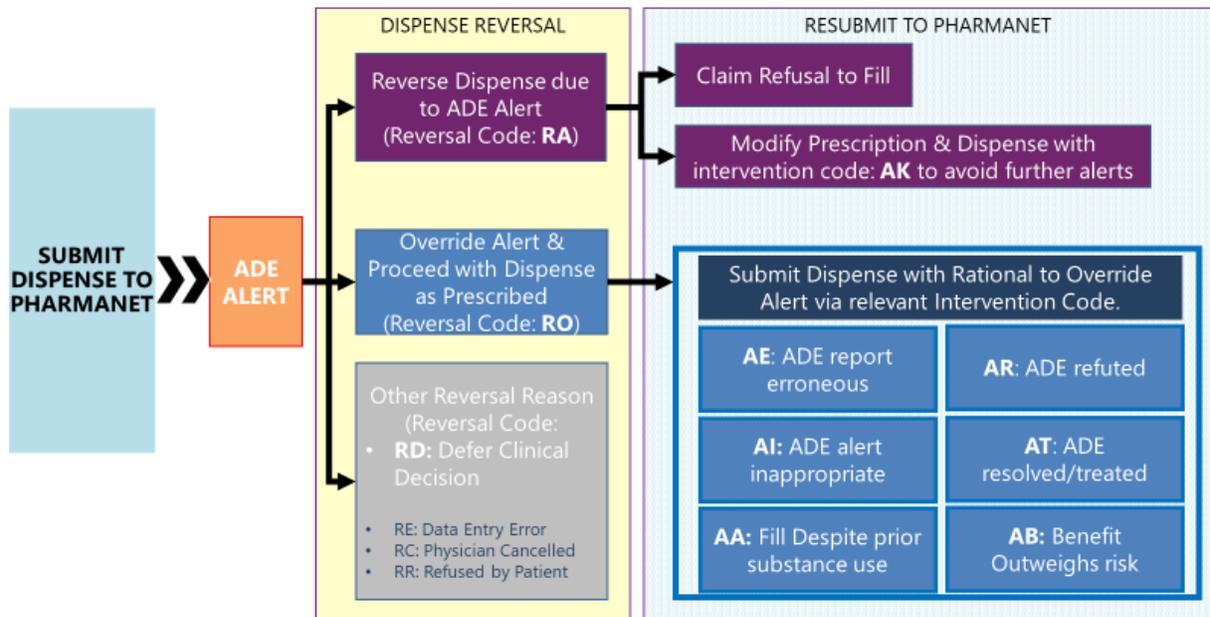
View Workflow Detail

A special ADE alert is created, when relevant, based upon the drug being dispensed and ADE type, and option buttons with automated actions to record the clinical response to the intervention are present.

To record these interventions in previous Kroll versions the pharmacist must manually reverse and resubmit with appropriate PharmaNet intervention codes.

Appendix 1 – Workflow to record clinical decisions due to ADE information by pharmacists in PharmaNet.

A) Workflow if decision made at time of claim adjudication and display of PharmaNet DUE alert



B) Workflow if decision made at time of profile view, prior to submission of claim adjudication.

