

SITE:**CATEGORY:** Archive Process (01)**PREPARED BY:** Trevor Soll**APPROVED BY:****SIGNED (BLUE INK):****DATE SIGNED:**

ADVERSE DRUG REACTION REPORTING PROCESS

INTRODUCTION

This SOP describes how to prepare and complete an Adverse Drug Reaction (ADR) in CHARMS (Canadian Haemophilia Assessment and Resource Management System).

CHARMS is an MS Access Database that is utilized by 26 Haemophilia clinics across Canada. It collects data on product distribution, clinical outcomes, adverse events, genotyping, and has clinical, nursing and study consent modules.

Confirmed ADRs are posted in CHARMS with corresponding data placed in the Health Canada ADR Report. This information is sent out to all intended recipients via the CHARMS webserver.

Responsibilities:

Haemophilia Clinics

- Tracking of patient haemophilia records in CHARMS
 - o Includes product names, lot numbers, quantity, infusion diary, etc.
- Quick response to patient concerns
- Review/update of ADR reporting in patient charts and CHARMS
- Haemophilia physician approves symptoms as ADR

AHCDC

- Notifying clinic of any discrepancies and omissions of ADR submissions
- Notifying the Principle Investigator of all discrepancies and their resolution
- Review of ADR reports

** this documentation reflects the assumption that the user has basic knowledge of the CHARMS program

AMENDMENTS FROM PREVIOUS DOCUMENT

None

DOCUMENTATION REQUIRED

This SOP

Title:

File name:

Version Date: 15 March, 2012

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CHARMS-ADR-1

SOP

1. Master

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ADVERSE DRUG RESPONSE REPORTING

AHCDC

SITE:

CATEGORY:

PREPARED BY: Trevor Soll

APPROVED BY:

SIGNED (BLUE INK):

DATE SIGNED:

MATERIALS

Adverse Drug Reaction details

EQUIPMENT/INSTRUMENTS

PC running the CHARMS program

PRECAUTIONS

- 01) Ensure correct patient data is entered in CHARMS.
- 02) Ensure patient name/PHN matches the Canadian Haemophilia Registry (CHR) Number that is referenced in CHARMS
- 03) It is mandatory that only one designated person at each clinic have the authority to submit this report. It will be up to the Clinic Director to make this choice.

PROCESS

A. Log into CHARMS

- 01) Upon logging into CHARMS, use the Infusion Diary and locate the infusion episode

Bleed Diary
Infusion Diary
v3.1.6 Copyright © 1999-2003 AHCDC

Select Patient: A1 Testperson Andrew
Episode Type: Multiple
Infusion Count: 5

Infusions Occurred
Start Date: 01 Mar 2004
End Date: 31 Mar 2004
Infusion Reason: Various

Hours Till Treated: []
Caused by Injury: []
Days Lost from: School [] Work [] Other []

Infused Lots: [] Bleed Sites: []

Facility	Lot Number	Brand Name	U/V	Exp Date	Total Units	Treatment Site	# Reactions
	A11011	A1 BrandTest	100	10	1000	Home	1
					0		

Use the keyboard ALT-L / ALT-B to select the Infused Lots / Bleed Sites tabs, respectively.

Entered: 19-Apr-2004
Modified: 28-Apr-2004

1 Add a NEW bleed episode, click on the Add button.
2 Add ADDITIONAL Lot# to existing episode, click on Edit button.
3 Delete Lot# from episode, click on Edit, click on record selector (left of Lot#) press Del key on keyboard.

Note Edit Add Delete Exit

- 02) Select the line item of product infused prior to the reaction reported by the patient.

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ADVERSE DRUG RESPONSE REPORTING

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SITE:
CATEGORY:
PREPARED BY: Trevor Soll

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DATE SIGNED:

Infusion Diary
v3.1.0 Copyright © 1999-2003 AHCDC

Select Patient: A1 Testperson Andrew
Episode Type: Multiple
Infusion Count: 5

Infusions Occurred
Start Date: 01-Mar-2004
End Date: 31-Mar-2004
Infusion Reason: Various

Infused Lots
Bleed Sites

Facility	Lot Number	Brand Name	U/V	# of Vials	Total Units	Treatment Site	# Reactions
A1	A1LOT1	A1 BrandTest	100	10	1000	Home	1
				0	0		0

Use the keyboard ALT-L / ALT-B to select the Infused Lots / Bleed Sites Tabs, respectively.

Entered: 13-Apr-2004
Modified: 28-Apr-2004

1. Add a NEW bleed episode, click on the Add button.
2. Add ADDITIONAL Lot# to existing episode, click on Edit button.
3. Delete Lot# from episode, click on Edit, click on record selector (left of Lot#) press Del key on keyboard.

Note Edit Add Delete Exit

03) Click on the Reaction button and proceed to fill in the Adverse Event report.

Product Reaction
v3.1.0 Copyright © 1999-2003 AHCDC

Select Patient Name: A1 Testperson Andrew

A. Patient Information
1. Patient ID: HM100995
Chart Number:
2. Age: 44
DOB: 01-Jan-1960
3. Sex: M
4. Height: 157 cm
5. Weight: 73 kg

B. Adverse Reaction
Outcome attributed to adverse reaction (check all that apply)
Death ☐ Life Threat ☐ Hospitalized ☐ Prolonged Stay ☐ Disability ☐ Congenital ☐ Intervention ☐ Other ☐ If Other Please Specify
Date of Reaction: 18-Apr-2004
Date of Report: 18-Apr-2004
Reaction Type:
Reaction Length: hrs

C. Suspected Drug Product(s)
Primary
Lot #: A1LOT1
Dose: 100
Expiry: 01-Jan-2005
Product: Factor VIII-A1 BrandTest-A1 Testmanufacturer
Frequency:
Route:
Therapy From: 01-Apr-2004
To: 01-Apr-2004
Indication of use of Suspected Drug Product: Bleed Trauma
Reaction abated after use stopped or dose reduced: N/A
Reaction reappeared after reintroduction: N/A

B.4 Reaction **B.5 Tests** **B.6 History** **C.9 Drugs** **C.10 Treatment**

Enter your descriptive information in the box below

D. Reporter
Health Professional? ☐ Hospital:
Phone:
Reported to Manul? ☐ Entered By:
Entered: 18-Apr-2004
Modified:
Address1:
Address2:
City:
Date Sent:
Add Exit

A. Some cells may be pre-populated with existing data (ie UI#, last recorded weight, age, date of birth). Please review to ensure all is correct.

B. 'Primary' product tab. This tab records the product infused as selected from the Infusion Diary to initiate the report. If there is a need to report a secondary product infused, enter the details by selecting the 'Secondary' tab.

04) Complete 'Section C' sub-tabs (B4. Reaction, B5. Tests, B6. History, C9. Drugs, C10. Treatment).

Note: Most information is to be entered manually with the exception of B5. Tests where you can select the applicable test results as well as add text. All information inputted in each section will be added on the Health Canada 'Adverse Reaction Form'

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Product Reaction v3.1.0 Copyright © 1999-2003 ANCD

Select Patient Name:

A. Patient Information

1. Patient ID: Chart Number: 2. Age: DOB: 3. Sex: 4. Height: cm 5. Weight: lbs

B. Adverse Reaction

Outcome attributed to adverse reaction (check all that apply)

Death ☐ Life Threat ☐ Hospitalized Prolonged Stay ☐ Disability ☐ Congenital ☐ Intervention ☐ Other ☐ Other Please Specify

Date of Reaction: Date of Report: Reaction Type: Reaction Length:

C. Suspected Drug Product(s)

Primary	Secondary
Lot # <input type="text" value="A1LOT1"/> Dose: <input type="text" value="100"/> Expiry: <input type="text" value="01-Jan-2005"/> Product: <input type="text" value="Factor VIII-A1Brand t-est A1Testmanufacturer"/> Frequency: <input type="text"/> Route: <input type="text"/> Therapy From: <input type="text" value="01-Apr-2004"/> To: <input type="text" value="01-Apr-2004"/>	Indication of use of Suspected Drug Product: <input type="text" value="Bleed/Trauma"/> Reaction abated after use stopped or dose reduced: <input type="text" value="N/A"/> Reaction reappeared after reintroduction: <input type="text" value="N/A"/>

B.4 Reaction **B.5 Tests** **B.6 History** **C.9 Drugs** **C.10 Treatment**

Enter your descriptive information in the box below

D. Reporter

Health Professional? ☐ Hospital: Address1:
 Reported to Manual? ☐ Phone: Address2:
 Entered By: City:
 Date Sent: Add Edit
 Modified:

C. Suspected Drug Product(s)

Primary: Lot #: Dose: Expiry: Product: Frequency: Indication of use of Suspected Drug Product: Therapy start: To: Reaction abated after use stopped or dose reduced: Reaction reappeared after reintroduction:

B.4 Reaction **B.5 Tests** **B.6 History** **C.9 Drugs** **C.10 Treatment**

Enter your descriptive information in the box below

Free text notes may be entered here which will appear on the Health Canada "Adverse Reaction Form"

D. Reporter

Health Professional? ☐ Hospital: Address:
 Phone: City:
 Reported to Manuf.? ☐ Entered By: Date Sent:
 Entered: Edit Add
 Modified: ? [Icon] [Icon] [Icon]

B.5. Tests

C. Suspected Drug Product(s)

Primary		Secondary	
Lot #: A1LDT1	Date: 100	Expiry: 01-Jan-2005	Product: Factor VIII-A1BrandTest-A1Testmanufacturer
Frequency:	Indication of use of Suspected Drug Product: Bleed/Trauma		
Rout:			
Therapy From: 01-Apr-2004	To: 01-Apr-2004	Reaction abated after use stopped or dose reduced: Y	Reaction reappeared after reintroduction: N/A

B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment

Select Tests: Blood Chem Coag **Ces** Hemo Imm Virol

Coagulation Date: [01-Jan-2000] LabNo: [1] INR: [1] PT: [] Acquisition Date: [01-Jan-2000] LabNo: [1] INR: [1] PT: [1] TCT: [1] YWMult: [Normal]
 VWFRCOF: [1] FxI: [1] FxII: [1] FxIII: [1] FxIV: [1] FxV: [1] InH: [] F000: [] InnP: [] F000: [] DNK: [UnCertain] ProteinC: [Normal] Pr

D. Reporter

Health Professional? ☐ Hospital: _____ Address1: _____
 Phone: _____ Ext: _____ Address2: _____
 Reported to Manuf? ☐ Entered By: _____ Date Sent: _____
 Entered: 10 Apr 2004
 Modified: _____

Buttons: ? [Icon] [Icon] Edit Add Exit

B.6-10

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B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment

Enter your descriptive information in the box below

Free text description may be entered here that will appear on the Health Canada "Adverse Reaction Form"

B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment

Enter your descriptive information in the box below

Free text description may be entered here that will appear on the Health Canada "Adverse Reaction Form"

B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment

Enter your descriptive information in the box below

Free text description may be entered here that will appear on the Health Canada "Adverse Reaction Form"

D. Reporter

A1FAA1FA Dr. A1Familydoc A1Familydoc Address1: Address2: City: Date Sent: Edit Add Exit

Health Professional ? Hospital: A1 Test Hospital Phone: (305) 111-1111 Ext.: 1111

Reported to Manul. ? Entered By: Sally HeadNurse

Entered: 18-Apr-2004 Modified:

History, Drugs and Treatment tabs will allow all the administrator to describe each section in detail.

05) Report Preview

It is recommended that the report be reviewed by the Clinic Director or reporting Health Professional before it is submitted. To preview the report, click on the magnifying glass. Make any revisions to the form as required.

B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment

Enter your descriptive information in the box below

Free text description may be entered here that will appear on the Health Canada "Adverse Reaction Form"

B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment

Enter your descriptive information in the box below

Free text description may be entered here that will appear on the Health Canada "Adverse Reaction Form"

B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment

Enter your descriptive information in the box below

Free text description may be entered here that will appear on the Health Canada "Adverse Reaction Form"

D. Reporter

A1FAA1FA Dr. A1Familydoc A1Familydoc Address1: Address2: City: Date Sent: Edit Add Exit

Health Professional ? Hospital: A1 Test Hospital Phone: (305) 111-1111 Ext.: 1111

Reported to Manul. ? Entered By: Sally HeadNurse

Entered: 18-Apr-2004 Modified:

06) Submitting the Adverse Event

Click on the Save button to submit the ADR. Click 'Yes' on the popup box to finalize the submission.

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ADVERSE DRUG RESPONSE REPORTING

AHCDC

SITE:
CATEGORY:
PREPARED BY: Trevor Soll

APPROVED BY:
SIGNED (BLUE INK):
DATE SIGNED:

Product Reaction v3.1.0 Copyright © 1999-2000 AHCDC

Adverse Drug Reaction Select Patient Name: A1Testperson Andrew

A. Patient Information
1. Patient ID: HM100995 Chart Number: 1234 2. Age: 44 DOB: 01-Jan-1960 3. Sex: M 4. Height: 157 cm 5. Weight: 73 kg

B. Adverse Reaction
Outcome attributed to adverse reaction (check all that apply)
Death ☐ LifeThreat ☐ Hospitalized Prolonged Stay ☐ Disability ☐ Congenital ☐ Intervention ☐ Other ☐ If Other Please Specify
☐ Submit It Now?

Date of Reaction: 18-Apr-2004 Dial ☐ Are you sure you want to submit it now? You can't change the information once it has been submitted.

C. Suspected Drug Product(s)
Primary
Lot #: A11012 Frequency: Yes No
Route: Reaction abated after use stopped or dose reduced: N/A
Therapy From: 02-Feb-2004 To: 02-Feb-2004 Reaction reappeared after reintroduction: N/A

B.4 Reaction **B.5 Tests** **B.6 History** **C.5 Drugs** **C.10 Treatment**
Enter your descriptive information in the box below.
Free text may be entered here which will be entered onto the Health Canada "Adverse Event" form.

D. Reporter A1FAA1FA Dr. A1Familydoc A1Familydoc Address:
Health Professional? ☒ Hospital: A1 Test Hospital Address:
Phone: (805) 111-1111 Ext: 1111 City:
Reported to Manuf.? ☒ Entered By: Susan HeadNurse Date Sent:
Entered: 18-Apr-2004 Modified: 18-Apr-2004

Send Adverse Reaction Rpt via the Internet

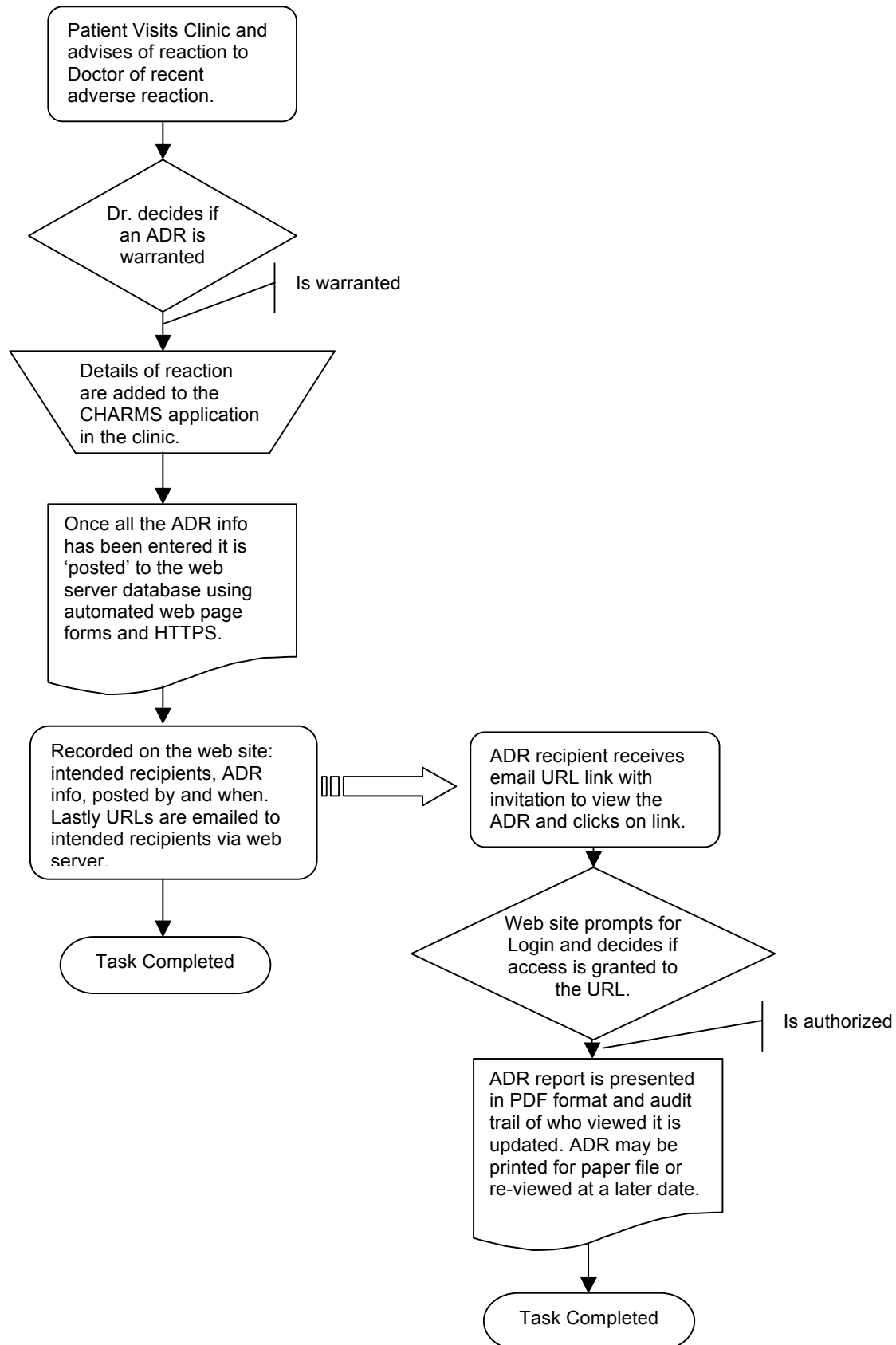
END OF SOP

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CHARMS Adverse Reaction Reporting Process Data Flow Diagram



CHARMS ADVERSE EVENT REPORTING MODULE

EMAIL FLOWCHART

