

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

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- 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:

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CHARMS-ADR-1

SOP

1. Master

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ADVERSE DRUG RESPONSE REPORTING

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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

Infusion Diary
v3.1.6 Copyright © 1999-2003 AHCDC

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

All Bleed Episodes for this patient. Click to select

Infusion Date	Time Infused	Epi #	Reason
01-Mar-2004		0	Vanous
01-Jan-2004	01:00 PM	2	BleedSpontaneous
01-Jan-2004	10:00 AM	1	BleedSpontaneous

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

Hours Till Treated: Causd by Injury: Days Lost from School Work Other

Infused Lots | Bleed Sites

Facility	Lot Number	Brand Name	U/V	Lot Vols	Total Units	Treatment Site	# Reaction
	A1101	A/BlandTest	100	10	1000	Home	1
*				0	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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Infusion Diary
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Select Patient: **AITestperson Andrew**
Episode Type: **Multiple** Infusion Count: **5**

Infusion Date	Time Infused	Epi #	Reason
01-Mar-2004		0	Various
01-Jan-2004	01:00 PM	2	BleedSpontaneous
01-Jan-2004	10:00 AM	1	BleedSpontaneous

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

Facility	Lot Number	Brand Name	U/V	For Vols	Total Units	Treatment Site	# Reactions
	A110T1	A1BrandTest	100	10	1000	Home	1
					0		0

Buttons: Note, Edit, Add, Delete, Exit

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

Adverse Drug Reaction
v3.1.0 Copyright © 1999-2003 AHCDC

Select Patient Name: **AITestperson 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** kgs

B. Adverse Reaction
Outcome attributed to adverse reaction (check all that apply)
Death [] Date of 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 #: **A110T1** Dose: **100** Expiry: **01-Jan-2005** Product: **Factor VIII-A1BrandTest-A1Testmanufacturer**
Frequency: [] Indication of use of Suspected Drug Product: **BleedTrauma**
Route: []
Therapy From: **01-Apr-2004** To: **01-Apr-2004** 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
Hospital: [] Health Professional? [] Phone: [] Reported to Manuf.? [] Entered By: []
Address1: [] Address2: [] City: [] Date Sent: []
Entered: **18-Apr-2004** Modified: []

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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ADVERSE DRUG RESPONSE REPORTING

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The screenshot shows the 'Adverse Drug Reaction' form with the following details:

- A. Patient Information:** Patient Name: ATTestperson Andrew, Patient ID: HMT00995, Age: 44, DOB: 01-Jan-1960, Sex: M, Height: 157 cm, Weight: 73 kg.
- B. Adverse Reaction:** Date of Reaction: 18-Apr-2004, Date of Report: 18-Apr-2004, Reaction Type: [blank], Reaction Length: [blank].
- C. Suspected Drug Product(s):** Primary: Lot # AT10T1, Dose: 100, Expiry: 01-Jan-2005, Product: Factor VIII A1BrandTestAT1Testmanufacturer, Indication: Bleed/Trauma.
- B.4 Reaction:** This tab is highlighted with a blue arrow and contains a text area for descriptive information.
- D. Reporter:** Fields for Health Professional, Hospital, Address, City, Date Sent, and Entered (18-Apr-2004).

B.4. Reaction

This close-up shows the 'B.4 Reaction' tab with a text area for entering descriptive information. The text area contains the instruction: "Free Text notes may be entered here which will appear on the Health Canada 'Adverse Reaction Form'".

Enter patient reaction details here.

B.5. Tests

This close-up shows the 'B.5 Tests' tab with a dropdown menu for selecting tests. The 'Coag' option is selected and circled in red. Below the dropdown is a text area for lab results with the following text: "Coagulation-Date: [01-Jan-2000] LabNo: [1] INR: [1] PT: [1] Coagulation-Date: [01-Jan-2000] LabNo: [1] INR: [1] PT: [1] PTT: [1] TCT: [1] VWMult [Normal] VWFRCOF: [1] FXI: [1] FXII: [1] FXIII: [1] FXIII-U: [1000] Inh(P): [1000] DNA: [Uncertain] ProteinC: [Normal] Pr".

Edit and submit on the lab results that are applicable.

B.6-10

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The screenshot shows a web-based form with five tabs: B.4 Reaction, B.5 Tests, B.6 History, C.9 Drugs, and C.10 Treatment. The B.6 History, C.9 Drugs, and C.10 Treatment tabs are circled in red. Each tab contains a text area for a description. Below the tabs is a 'D. Reporter' section with fields for Name (A1FAA1FA), Hospital (A1 Test Hospital), Phone (305) 111-1111, and Date Sent (18-Apr-2004). There are also buttons for 'Edit', 'Add', and 'Exit'.

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.

This screenshot is identical to the previous one, but a red arrow points to the magnifying glass icon in the bottom right corner of the form, indicating the 'Report Preview' function.

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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Product Reaction v3.1.0 Copyright © 1999-2005 AHDCDC

Adverse Drug Reaction

Select Patient Name: AT1Testperson 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

Date of Reaction: 18-Apr-2004 Reaction Length: hrs

C. Suspected Drug Product(s)

Are you sure you want to submit it now?
You can't change the information once it has been submitted!

Primary

Lot #: A11012

Frequency: Brand Test: AT1Testmanufacturer

Route: Reaction abated after use stopped or dose reduced: N/A Reaction reappeared after reintroduction: N/A

Therapy From: 02-Feb-2004 To: 02-Feb-2004

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

Free text may be entered here which will be entered onto the Health Canada "Adverse Event" form.

D. Reporter AT1FAA1FA Dr. AT1Familydoc AT1Familydoc

Health Professional? Hospital: AT1Test 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

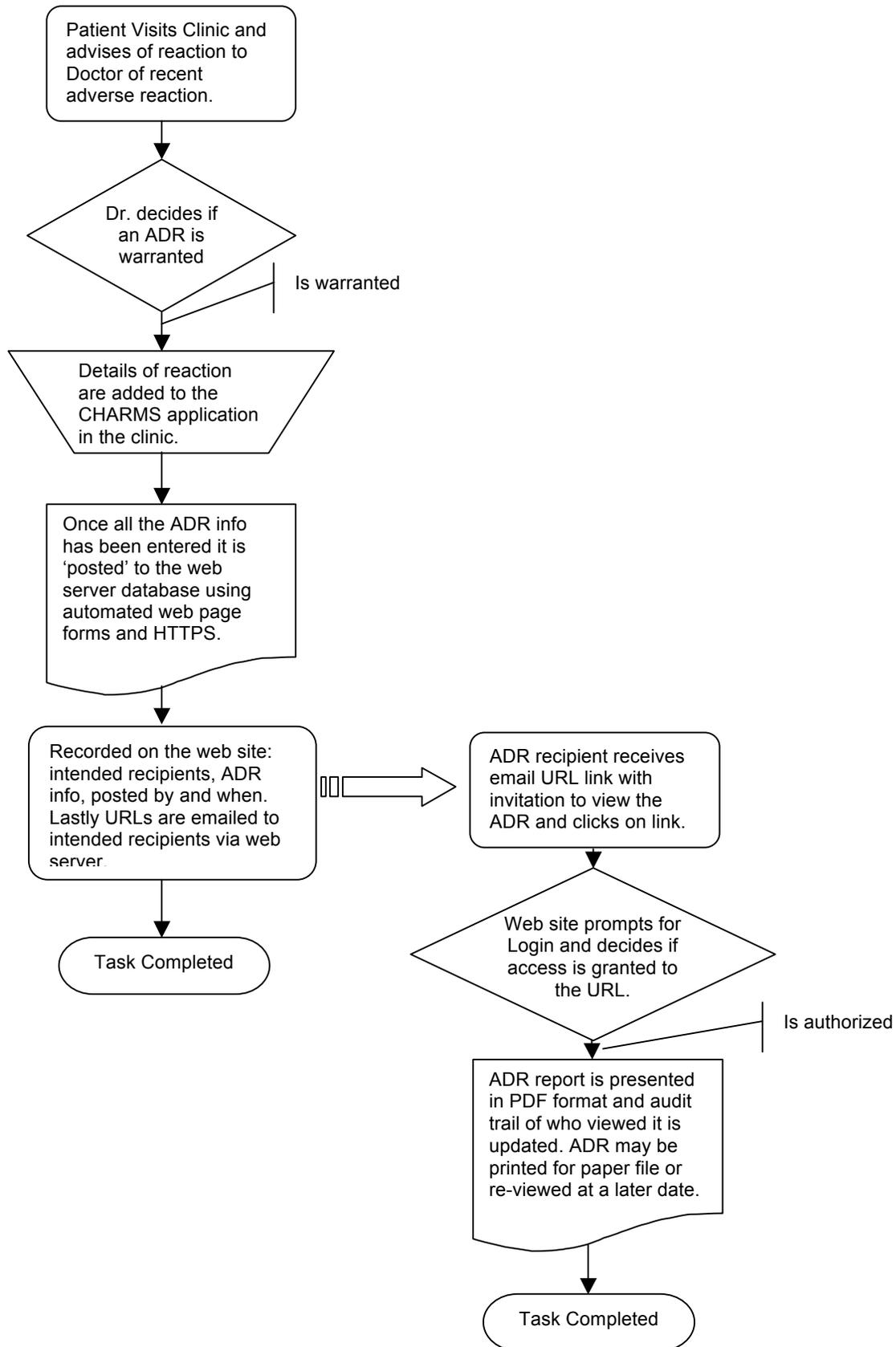
END OF SOP

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CHARMS Adverse Reaction Reporting Process Data Flow Diagram



CHARMS ADVERSE EVENT REPORTING MODULE

EMAIL FLOWCHART

