CHARMS

Canadian Hemophilia Assessment and Resource Management Information System

Version 3.1.0 - April 2004

UPDATE GUIDE



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CHARMS V3.1.0 – OVERVIEW OF ENHANCEMENTS

There are four major enhancements in CHARMS V3.1.0. In addition, numerous changes and added functionality has been implemented. The following pages will show most if not all of these.

1. Splitting the demographic and clinical components into separate database files.

The purpose was to ensure greater security of patient data and to enable the technical support team to trouble shoot without having access to confidential patient demographics.

In addition to the usual CHARMS login username/password, an additional security access password has been added. This new password is encrypted and is required after the initial login to CHARMS. Access without this security password will only allow the user to view the clinical information and no demographics. The clinical information will only be identified by a numerical combination of a system key identifier and the CHR#.

2. Patient "Unique Identifier" assignment.

Every registered active patient that has a CHR# will now be assigned a new Unique Identifier. This UI# will identify each patient uniquely but anonymously throughout the CHARMS system of databases in Canada. It is this UI# that will be used to register patients in the Pharmaceutical databases that track bleed events and product infusions.

UI#'s will automatically be assigned with the initial upgrade of CHARMS. For those patients that have missing information, which will prevent CHARMS from auto assigning a UI, a report will be available to print. The UI# that are assigned, will remain the same if the patient moves from one clinic to another, providing that the qualifying information remains the same.

- 3. Adverse Event Reporting: A new, more detailed form has been added to capture any reactions that a patient reports to the HTC. It is specifically linked to product infused and is recorded via the Infusion Diary. The process in brief is as follows; the reaction record is first captured in CHARMS. The HTC administrator is given the capability to view the information, as it would look on an actual Health Canada Adverse Event form prior to submitting the report. Once the HTC administrator has approved the local previewed report, they may then request CHARMS to submit the report to the web server. CHARMS web services are hosted by Hamilton Health Sciences Hospital. No submission of an Adverse Event is allowed without the appropriate HTC assigned password. The HTC password is authenticated and will only be provided to one person at any HTC and only to the administrator of that HTC. After a successful submission, an automatic notification will be sent to the pre designated parties via email. The Adverse Event Report will be available to only the parties that received the notification and have security access to view it.
- 4. **Research Studies and Patient Consents:** A master Study form has been added to enable the HTC's the capability to record any study that will require patient consents to be recorded. The Master Study module captures the details for each specific study along with any specific consent agreements. The Patient Consent module will record the patient as a participant in a specific study.

CHARMS UPGRADE MANUAL – What to Expect

1. How to get the New CHARMS V3.1.0

The UPDATE CHARMS Icon on your desktop will get the new version of CHARMS for you. You will be notified either by email or telephone that CHARMS V3.1.0 is ready to download. For those HTCs that have their data portion of CHARMS on their hospital servers, you need not worry, as CHARMS will prompt you for the location of your data files. For those HTC's that have their data still stored on their local PC's, the update will automatically upgrade CHARMS without the prompt to locate the data. One important note; All HTC's should have their data tables on their hospital servers. For security reasons as well as proper nightly backups. If you are unsure whether your data tables are on your hospital server, please contact CHARMS Support to investigate and make arrangements to have this done.

2. CHARMS-Upgrade Process: Patience is a Virtue.

Once you have initiated the process, the upgrade should proceed without any problems. You must be connected to the internet in order to activate the upgrade process. CHARMS upgrade will be processing many functions and we hope that you will be patient during this process. You may see some system messages in the bottom left hand corner during the upgrade that will indicate the progress. At the completion of the upgrade you will be displayed a message indicating whether the Upgrade was successfully completed or otherwise. Should you get the "otherwise" message, please contact CHARMS Support to trouble shoot.the process for you.

3. Security Access Screen : Initial default password is "password".

You will have to change this password as the security of your patient data depends on it. Once you change the password, IMPORTANT....write it down and store it in a safe place. It is this password that will give you access to the patient's demographic information. If you forget it, call your CHARMS Support but please be aware it will take more time to return the password to you then in the past. This password is encrypted and will not be easily retrieved.

4. UI# assignments: New unique identifiers (UI#) will be automatically assigned.

The automatic assignment of the new UI's will be initiated with each access to CHARMS if the user is connected to the internet. CHARMS will attempt to assign the UI# for all registered patients that have pre-qualifying information in the database as not missing.

The pre qualifiers are: Date of Birth (DOB), Extra Identifier (EXID), Gender, CHR#. The information screen, which will be displayed to you, will provide more detail of this process. Any patients that CHARMS is unable to assign a UI#, will be listed and available to print. You may then edit these records to fill in the missing information and manually individually assign a UI#.

5. CHARMS Main Menu – when all upgrade processes have completed, the CHARMS Main Menu will be displayed. At this point you are ready to access your patient data and proceed with your normal work activities.

It is suggested that you take a few minutes to view the different menu options and screen changes that we show in this upgrade manual.

Additional remarks for What to Expect: We have tried to ensure that most of your requested changes were included in this release and that all previous problems have been fixed. If you have any problems or get any unusual error messages, please record them and forward to the CHARMS Support Team.

CHARMS UPGRADE MANUAL

CHARMS Upgrade V3.1.0 – How to get it.



Use your desktop Icon as above to get the latest version of CHARMS V3.1.0. You will be prompted to enter in the username and password for this utility application.

Username : DBA Password : (as you know it) This password will be the same one that you use to access your CHARMS application.

	S Update
CHARNS.	Server: Username: Username: Username: Ugdate: Close

Using the CHARMS Utility program to download CHARMS V3.1.0.

The above Server and Username will be pre filled for you. Just click your mouse pointer on the Update button and the download process should start.

A series of system information messages will be displayed. If you encounter any error messages during this process, please contact your CHARMS Support Team.

LOCATING THE CHARMS DATA TABLES

Once you have initiated the upgrade process, CHARMS will check your local computer for the CHARMS data tables. If your data tables are on the hospital server, you will be prompted for the location on the server where the data tables reside.

Use the dropdown arrow to find the drive letter that has been mapped CHARMS on your hospital server.

-	My Documents	<u>,</u> 🖻 💆	?× 1 1 1 1 1 1
D My eBook My Music My Picture WebPage		find HMIS97d.mdb	
		once found and select Open button to attach	
File <u>n</u> ame:	HMIS97D.MDB		<u>O</u> pen
Files of <u>type</u> :	Listing Files of type MDB	<u> </u>	Cancel
	7d.mdb is on your hos ation by using the dro		the item

If you have problems locating your data tables, please call your CHARMS Support Team or contact your local IT department for help. In most cases, you will find the location mapped near the bottom of the list of directories in your dropdown list. Once you locate the location of the HMIS97d.mdb tables, click on it to select and then click on OPEN as above.

CHARMS UPGRADE PROCESS

You will see a series of system messages; just allow the process to continue. If you do not get the message indicating a successful upgrade as below, please contact your CHARMS Support Team.

CH/	ARMS Upgrade Process
	ARMS will upgrade your existing application V3.0.4 to new version V3.1.0.
you	ing this process, please be patient and to verify that r upgrade is in progress, you may see the process on r TaskBar locating on the bottom left of your display.
	Upgrade in progress.
	UPGRADING
	🏽 Start 🛛 💽 🥹 🎦 🀺 隊 📉 🇐 🥖 🥭

CHARMS Up	grade Sucessful Message
indicating wh	splayed the Upgrade status message, ether your CHARMS has been sucessfully he Upgrade failed, please contact your oport.
Upgrade •	Completed Xuccessfully!
	<u>ОК</u>

You will be prompted to enter the new security access password, which will grant you the ability to see the patient demographic information. You will still be able to access CHARMS without this password but you will not be able to see any patient names, address and any other demographic information.

CHARMS Demo Data Access Se Leave Password Blank for Restri Password:	curity
Change Password>>>	
owercase. Now you can click on the	
'password", donot include the quotes : owercase. Now you can click on the You may change your password BUT DOWN and store it in a safe place.	

ΟK

CHANGING YOUR DATA ACCESS SECURITY PASSWORD

a Access Security	
CHARM	IS Demographic
	ccess Security
Old Password:	*****
New Password:	
	and the second sec
Confirm Password:	******

Initial default password = password

Change the default password to something that you will easily remember but consists of upper and lower case characters and/or numbers. Ensure that you WRITE this password down and store in a secure location.

Without this additional security password, you will not be granted permission to see any demographic information in CHARMS.

Passwor	d Changed 🛛 🔀
٩	New Password Change has been accepted
	<u>OK</u>

After you have successfully logged in, CHARMS will start the automatic assignment of UI#'s for all patients that are registered in CHARMS. Qualifiers for a UI# assignment is as follows;

Must have : Date of Birth(DOB), Gender, Extra Identifier(EXID) and a CHR#.

The assignment process will be initiated with each login till all qualified people have been assigned a UI#. The following screen dialogue will be displayed, you have the option to stop it if need be. For those records that did not get an assignment, a report will be available at the end of the process to be printed.

o ration	UI Generator	ique Identifier Assignment Prog	
		que luenailer Assignment Prog	1655
	19%		
		<u>S</u> top	
		signed to create an anonymous but unique ide	
		Ia. This will assist with tracking product usage to Patients as they move from one home bas	
the second			
		s Web server technology to assign patient ide ection speed. This process may take some tin	
		e Stop button at any time. The Assignment pr	
can be inte		e you enter CHARMS until all patient records	

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	F IS	reventing their assign	e 57 Patients with inc ment of a Unique Ide wprint the patient list	entifier.
This new sof CHARMS Pa appropriate p		Yes	<u>N</u> o	or each viding to another
The UI assignm governed by yo can be interrup	our Internet of ted by clicki	s uses Web server te connection speed. Th ng the Stop button a	chnology to assign pa his process may take t any time. The Assign	itient identifiers and is he some time to complete ar

UI #'s may be individually assigned from the Patient Demographic Screen. The same qualifiers apply. The following is the UI# assignment sample.

Note: the UI field is empty on the 1st form. The Globe button when clicked will initiate the request process for the UI# assignment. Once a UI# has been assigned to a patient, it may not be changed or deleted.

ki daga	Last Name	First Name	Hosp.Id:	981	Valid Hospid	<u>P</u> rovid	lers	
Name Salutation	A2TestPerson	A2Test		888888888	B ? ✓	Relatives/0	Contacts	
atient Status		UI:	C.H.R.#:	88888888888888888888888888888888888888	8	Clinic Su		
Language	English 💽			00000000	B888888E 1			
Gender	. M 💽 Date of Birth:	26-Sep-1946		X	000000c 1	Treatment I	Protocol	
Alias Name		<u> </u>	New UI was G	enerated!	ler Excluded: 🥅	<u>¥</u> isit Asse	ssment	
ome Addres	456 Somewhere Ave	V			ier Excluded: 🔽 ve / Contact: 🗖	Labora	tors	
	SOMEOTHERCITY	N T Pastal	Í OK	1				
lailing —			1 s. 2 r. 4 r.		<u>88</u>	Hospital A	Imission	
Str P	atient Detail							
liagnosi	v3.1.0 Copyright © 1999-20	ne First	Service and a service of the service	- Hosp.Id:	981	Valid	Provid	ders
actor I2	Name: A2Test		2.2.2		8888888888	Hospid ? 🗸		
ase Note		Extra Id.: STON		C.H.R.#:	8888		Belatives/C	Contac
	Patient Status: Active		1467	and the second second	8888888888		<u>C</u> linic Su	mmary
intered: 1 odified: 1	Language: English	×	Age 46 57	Health	ON - 888888	38888 1	<u>Treatment</u>	Protoc
ord: I	Gender: M	Date of Birth: 26-Sep-19	46 37	Category				
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	Street: 456 Som	ewhere Ave			Relative .	/ Contact: 🕅	Labora	tory
	City/Prov: SOMEOT	HERCITY ON Posta	al: H2K 3J5	- Phone Home#:	(888) 888-8888	-	Hospital A	dmissie
	Mailing — <u>Same</u> or	<u>A</u> iternate			(888) 888-8888	x 8888	-	
	Street: 456 Som				(888) 888-8888		Bleed	Diary
Ļ	1	HERCITY ON Post.	al: H2K 3J5	EMail:	a2testperson@ne	t.ca	Patient In	ventor
	Bleeding Disorder Diagnosis	% Sev	verity		First Encounter: 10	Apr-2004	Cons	ent
	Factor IX	• 2 Mo					- CQUA	en.
							Print Pa	atient

CHARMS MAIN MENU - STUDY AND PATIENT CONSENT SCREENS

1. Select Study Details – records any internal or external Studies. For local studies, you may enter the Study details as provided by your Clinic Director.

For External studies that your clinic may participate in, you will be provided with the Study Details, which you may then enter.

2. Select Consent Agreement - records patients that are participating in a Study previously recorded in the Study Details.

Study and Consent Forms					
Clinic Information Menu					
Canadian Hemophilia Assessment and Resource Management System					
	Clinic Information Menu				
	Clinic Menu	Select <u>P</u> atient			
	<u>R</u> eporting Menu	Select <u>A</u> rea			
		Select Lot <u>L</u> ocator			
9105	Administration Menu	Select <u>R</u> ecall Lot#'s			
Chine No	<u>Maintenance Menu</u>	Select <u>C</u> onsent Agreement			
ARM	Password Change	Select <u>S</u> tudy Details			
Copyright © 1999-2003 AHCDC v3.1.0	Exit				

STUDY DETAILS

elect Study: No Name 1 Blood Borne Pathog	Click on a Study line item to see/edit d Status Category ens Study External Commercial-Rep	Start Date End Date
	udy Name: Blood Borne Pathogens Stud	y
Full Name: Blood Borne Pathogens St Duration Consent Inv	udy vestigators Sponsor	
Status: External Car	egory: Commercial-Regulatory 💌	Start Date:
Description.		Duration: 5 (Months)
]

To enter a new study record, you must enter a unique Study number to identify the Study. Selecting the tabbed headers may enter the details for; (Duration, Consent Agreements, Investigators and Sponsor) some of this detail is optional.

PATIENT CONSENT SCREEN

From the dropdown selection, you may select any registered patient that is to participate in an existing Study. A patient may be registered as participating in more than 1 study.

Study details are pre filled from the master Study Details that you select by using the dropdown arrow in the Study No item field.

Calendar buttons have been provided and may be used to select the date(s) for the date fields.

Consent Agreement	·				
Consent Ag	greement A1Testperson Andr	ew			
II Consent Agree	ments for above	patient ^{Click}	on a line item to Select	Consent Agr	eement
ConsentDate Sample Dat		Consent To1	YN1 Sample Is	Entered	Modified
8-Apr-2004 8-Apr-2004 01-Jan-2004	External Study	Dathanan unaille	No Retained		
Consent Agreeme	nt Record				
Study No: 1		of Consent: 18-Ap	-2004		
Study No: 1 Blood E	▼ Date Borne Pathogens St		-2004		O No O Unk
<u></u>	Date Borne Pathogens St en surveillance		-2004		C No C Unk C No C Unk
Study No: 1 Blood E Consent to 1: Pathog	Date Borne Pathogens St en surveillance cs analysis I-Jan-2004 y samples:		·2004		

Patient Detail - What's New

Patient Status: If the patient status is changed to Deceased, you will be prompted to enter in the Date of Death and any other related information.

	Last Name	First Name	Hosp.Id: 999999999	9 Valid Hospid	Providers
Salutation	A1Testperson	Andrew Id Are You Sure?		2 ? V	Relatives/Contacts
	Deceased +	п —	e the Patient has died?		
Language	English 💌	Are you sur	e the Fatient has died?	1	
Gender	: 📕 💽 Date of Birth:	01			<u>Treatment Protocol</u>
	Randy Andy	- Yes		der Excluded: 🥅	<u>¥</u> isit Assessment
lome Addres			New	frier Excluded: 🔲	
	123 Somewhere Ave		📲 🔠 Patient Death	Details	
		N 🗾 Postal: L1K 1J1	H Date Of Death: 18	mm ccyy 4 2004	Autopsy:
	ame or <u>A</u> lternate		Cause(1):	4 2004	
	123 Somewhere Ave		- Cause(2):		
S Dies and an official		N 🗾 Postal: L1K 1J1		uble Click in Details	to Zoom in
Bleeding Dis	order		Details:		
		X Severity			
Diagnosis Eactor VIII					
Factor VIII					

Patient Detail – What's New. – Assigning a UI# to a new patient.

As described previously, to assign a new UI#, simply click on the Globe button. You must have access to the Internet in order for the assignment to process.

Assigning a New UI # to a Patient		
Patient Detail		
Patient Detail v3.1.0 Copyright © 1999-2003 AHCDC	New	
Last Name First Name	Hosp.Id: 8888888888 Valid HospId	Providers
Name: A2TestPerson Bob Salutation: Mr.	Clinic Id: 8888888888 ? 🗸	<u>Belatives/Contacts</u>
Patient Status: Active UI: UI:	MedAlert: 888888888	<u>C</u> linic Summary
Language: English 💌 Gender: M 💌 Date of Birth 01-Jan-194	B8888888€ 1	Ireatment Protocol
Alias Name: alias name	New UI was Generated! eder Excluded: 🛙	<u>¥</u> isit Assessment
Home Address	rrier Excluded: ∏ tive / Contact: □	
Street: 123 Somewhere Ave		Laboratory
City/Prov: HAMILTON ON V Postal	B88	Hospital Admission
Patient Detail		
City Patient Detail Bleedi v3.1.0 Copyright © 1999-2003 AHCDC		
	Name Hosp.Id: 8888888888	Valid Provider:
Facto Name: A2TestPerson Bob Salutation: Mr. Extra Id.: DNDN	Clinic Id: 88888888888888888888888888888888888	Pospid ?♥ <u>Belatives/Con</u>
Please N Patient Status: Active VII: HM10		<u>Clinic Sumn</u>
Language: English 💌	Age Health ON - [8888888	0000

PATIENT CLINIC SUMMARY – WHAT'S NEW.

atient Clinic Summa	Select: A1Testperso	n Andrew 🔹	Che
0 Copyright © 1999-2003 AHCDC	Patient: Qwik Find CHR	and the second	Pg1 Pg2 Add
Blood Group: A Pos Bleeding Disorder Diagnosis: FVIII Level % 1 (for <1)	▼ New × enter 0) Seventy: Mod ▼	LastReview Date: Review Freq.(mnths): Followup Freq.(mnths):	6 6
Home Care: Yes 💽 Prophyl. Prog.: 🗖	Home Care Start Date: 01-Jan-2000	Last Encounter Date: Last Visit Type: Last Visit Purpose: Wallet Card Issued Date:	Review _ Review _
INHIBITOR Human Level (Max): 1000 Human Level (latest): 1000 Porcine (latest): 1000	.0 BU 🗾 01-Jan-20	00 VWF:Rcot:	1 1 1 mins.
(WWAg WWRCOF 10 10 10 1 1 1 2 2 2 3 3 3	01-Jan-2000	Jpdate Lab Results ntered: 21-Mar-2001 odified: 18-Apr-2004
o View Pg1 or Pg2, Click on Page buttons, at the		Note Edit	Delete Exit
vik Find CHR : You will see this Qwik find your patient by CHR# and will also work rsor has to be in the Qwik Find CHR field	with your HandHeld Scanner if a	a CHR Barcoded # is s	

PATIENT CLINIC SUMMARY – WHAT'S NEW.

	mary Clinic Summ 99-2003 AHCDC	Select: A1Testpers Patient: Qwik Find Cl	PollUPo2 Ad
Immunization	Allergies <u>H</u> eight/Wei	ight M <u>e</u> dicate AI <u>D</u> S Illness <u>F</u>	Reactions Mortality
Immunized	Immunization Date Va		dified
			New Add New
	est Result and Date	Latest Result and Date	Latest Result and Date
VIROLOGY La		and the second second second	
VIROLOGY La HepA: <mark>N</mark>	leg 💌 01-Jan-2000	HIV: Neg 📩 01-Jan-2000) HepC: Neg 📩 01-Jan-2000
НерА: 🖪	leg \star 01-Jan-2000 leg \star 01-Jan-2000	HIV: Neg 🗾 01-Jan-2000	
HepA: N	leg 丈 01-Jan-2000		

INFUSION DIARY - WHAT'S NEW

The Infusion Diary has been enhanced with the following features;

- 1. Epi-#; you will be able to indicate by using the Epi# the number sequence of infusions that a patient may have had in the same day. If the patient has 2 separate bleed episodes on the same day as the example shows, the first one occurred at 10:00 am and is assigned Epi#1 and the second at 1:00 pm and is assigned Epi#2.
- 2. Facility dropdown selector is now prompted before the entry of the Lot#. This will allow you to indicate whether the infused product came from the Regional Inventory for this infusion or whether the patient used their home inventory for the infusion. When you enter the lot#, the selection process is now quicker as we do not have to check both the inventories to be displayed. You can still however use the binoculars to select the product infused.

Bleed Diary	
Infusion Diary	All Bleed Episodes for this patient. Click to select
v3.1.0 Copyright © 1999-2003 AHCDC	Infusion Date Time Infused Epi-# Reason
Select Patient: A1Testperson Andrew	01-Mar-2004 0 Various 01-Jan-2004 01:00 PM 2 BleedSpontaneous
	01Jan-2004 10:00 AM 1 BleedSpontaneous
Episode Type: Single	
Infusion Occurred New New	
Infusion Date Time Epi-# Infusion Beason	HoursTill Caused Days Lost Holl Treated by Injury School Work Other
01-Jan-2004 (24:00): 10:00 1 BleedSpontaneous 💌	
Infused Lots Bleed Sites	
New Facility Lot Number Brand Name	U/V # of vials Total Units Treatment Site # Reactions
A1LOT1	100 1 100 Clinic/Hosp 🛨 1 <u>Beaction</u>
PatientInv Infused from Patient Inventory OutOfRegion Any Clinic/Hosp not in your Region	
A1 A1 Test Hospital	
A2 Bleed Diary	
Infusion Diary	All Bleed Episodes for this patient. Click to select
•	Infusion Date Time Infused Epi+# Reason
	01 Jan-2004 10:00 AM 1 BleedSpontaneous
New	Dava Loot from
	Hours I III Caused
	dSpontaneous + + +
Infused Lots Bleed Sites	
Facility Lot Number Brand	Name U/V # of vials Total Units Treatment Site # Reactions
A1 A1LOT1 # A1Brar	ndTest <u>-</u> 100 1 100 Clinic/Hosp <u>-</u> <u>1</u> <u>Reaction</u>
Infusion Diary v3.10 Copyright © 1999-2003 AHCDC Select Patient: A1Testperson Andrew Entered: 21-Mar- Modified: 19-Apr-2 Infusion Date Time D1-Jan-2004 (24:00): 13:00 2 Bleed Sites Facility Lot Number Brand	Infusion Date Time Infused Epi-# Reason 01-Mar-2004 0 Various Various 01-Mar-2004 01-00 PM 12 BleedSpontaneous 01-Jan-2004 10:00 AM 1 BleedSpontaneous 01-Jan-2004 10:00 AM 1 BleedSpontaneous on Reason Treated by Injury School Work dSpontaneous Image: State of the

INFUSION DIARY - WHAT'S NEW

Bleed Diary					
Infusion	1 Diary		All Blee	ed Episodes for this	patient. Click to select
3.1.0 Copyright © 1999-2003 AHCDC			Infusion Date	Time Infused Epi-#	
	nt: A1Testperson	Andrew	01-Mar-2004 01 Jan-2004 01 Jan-2004	0 01:00 PM 2 10:00 AM 1	Various BleedSpontaneous BleedSpontaneous
Infu Start Date 01-Mar-2004	sions Occurred End Date 31-Mar-2004	Infusion Reason Various	HoursTill Treated	Caused by Injury	Days Lost from School Work Other
	Bleed Sites				
Facility	Lot Number	Brand Name			tment Site # Reactions
*	A1LOT1	d A1BrandTest	 100 100 	0 1000 Home	• • 1 <u>Reaction</u>
	Use the keybo	ard ALT+L / ALT-B to select the Infu	ised Lots / Bleed S	iites Tabs, respectively	<u></u>
Entered: 19-Apr- Modified: 20-Apr-	2004 3.Delete Lot# f	leed episode, click on the Add butto NAL_Lot# to existing episode, clic from episode, click on Edit, click on ress Del key on keyboard.	on. :k on Edit button.	Note	Edit Add Delete Exit

For Multiple infusion episodes, you can now enter the approximate number of infusions that this bulk entry Is covering for the date range that you have specified.

Bleed Diary	
Infusion Diary	All Bleed Episodes for this patient. Click to select
	Infusion Date Time Infused Epi-# Reason
v3.1.0 Copyright @ 1999-2003 AHCDC	01-Mar-2004 0 Various
Select Patient: A1Testperson Andrew	01-Jan-2004 01:00 PM 2 BleedSpontaneous
Episode Type: Multiple • (nfusion Count: 5)	01-Jan-2004 10:00 AM 1 BleedSpontaneous
Infusions Occurred	HoursTill Caused Days Lost from
Start Date End Date Infusion Reason	Treated by Injury School Work Other
(01-Mar-2004 31-Mar-2004) (Various)	
Infused Lots Bleed Sites	
Facility Lot Number Brand Name	U/V #of Vials Total Units Treatment Site # Reactions
A1LOT1 🚧 A1BrandTest 🔹	100 10 1000 Home - 1 <u>Beaction</u>
* •	0 - <u>R</u> eaction
Use the keyboard ALT-L / ALT-B to select the Infuse	ed Lots / Bleed Sites Tabs, respectively
1.Add a NEW bleed episode, click on the Add button.	n Note Edit Add Delete Exit
Entered: 19-Apr-2004 Modified: 20-Apr-2004 (left of Lot#) press Del key on keyboard.	on Edit button.

In the above example, the patient had approximately 5 infusion episodes for the period covering March 1 to March 31. Infusion reason indicates for Various reasons (previously Bulk Entry) and that there was 10 vials over this period that were infused.

INFUSION DIARY – WHAT'S NEW

Bleed Diary	
Infusion Diary v3.1.0 Copyright © 1999-2003 AHCDC Select Patient: A1Testperson Andrew Episode Type: Single	All Bleed Episodes for this patient. Click to select Infusion Date Time Infused Epi+# Reason 01.Jan-2004 01:00 PM 2 BleedSpontaneous 01.Jan-2004 10:00 AM 1 BleedSpontaneous
Infusion Occurred Infusion Date Time Epi-# Infusion Reason 01-Jan-2004 (24:00): 10:00 1 BleedSpontaneous -	HoursTill Caused Days Lost from Treated by Injury School Work Other
Infused Lots Bleed Sites	
Bleed Site(s) During above Episode Infused Bleed Site Grp Bleed Site Side Anatomical Sympton Muscle - Forearm - Right - HandRight - 1 New 4 Swelling 7	2Pain3Stiffness
Use the keyboard ALT-L / ALT-B to select the Infuse	New
Entered: 18-Apr-2004 Modified: 18-Apr-2004 Ileft of Lot#) press Del key on keyboard.	on Edit button.

Bleed Site Details have now include the Bleed Site Group. You may now specify the group that the bleed site belongs to as indicated above under "Bleed Site Grp".

Infused Anatomical; you may indicate where the patient infused the product. Symptoms now allow up to 9 possible different entries for each infusion episode to be recorded.

ADVERSE REACTION REPORTING - WHAT'S NEW

When a patient reports to the HTC that he/she has had a reaction, such as fever or palpitations, etc. The HTC administrator will record this reaction in CHARMS. In addition, the HTC administrator can now submit this report electronically on Health Canada's Adverse Event report form.

The pre-defined recipients for notification of an Adverse Event will be notified by email that an Adverse Event report has been submitted and that they may view this report on the CHARMS web server.

Only the intended recipients will be allowed to view the specific reports that were intended for them.

The recipients are: Health Canada, Canadian Blood Services, Quebec Blood Secretariat and the Manufacturer of the specific product that was linked to the reaction reported by the patient.

Access to these reports is by specific usernames and passwords, which are assigned to all recipients and are authenticated at time of request to view the report. Each request is logged and the requestors IP address is recorded.

The Adverse Reaction form in CHARMS has a lot of detail that must be filled out. Some of the information is pre-filled from information already captured, such as latest weight, age and infusion details. Some of the information required to be reported may be selected from dropdown options such as Lab results. The user may may select any available lab results which will populate the form and can be edited to only include the the applicable test results.

There are additional options on the CHARMS Reaction form, such as ; Links to the web site with reference to reporting of Adverse Events and other useful information. Preview of what the Adverse Event form will look like before submission and finally the capability to submit the Adverse Event Report for distribution to the designated recipients.

Who Should Submit the Adverse Event Report ?

Each HTC administrator will be provided with their clinic's username and password. 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. The HTC administrator will be notified and assigned a username and password, which will be required to submit the report via CHARMS.

Once a report has been submitted, it may not be submitted a second time. It is important that the designated person who will be authorized to submit, reviews the report and preferably prints it to get final authorization from the Clinic Director or the reporting Health Professional before submitting.

ADVERSE REACTION REPORTING - WHAT'S NEW

To record an Adverse Event, use the Infusion Diary and locate the infusion episode, then select the line item of product infused prior to the reaction reported by the patient. Click on the Reaction button and proceed to fill in the Adverse Event report.

📰 Product React	ion							×
Adverse		leaction	v3.1.0 Copyrig Select Patie	nt Name: A1	o Testperson An	drew		<u>.</u>
1.Patient ID: HM1 B. Adverse Rea	00995 Chart Nu	umber:	2. Age: 44	DOB: 01-Jan-19	960 3. Sex: N	4. Heigh	t: <mark>157 </mark> 5. W	/eight: <mark>73</mark> kgs
Death Date of De Death Date of De Date of Reaction:	eth LifeThr 18-Apr-2004	atcome attributed to adve eat Hospitilized Prolo	inged Stay Disab	ility Congenital I		er If Other Ple		hrs
L. Suspected D Prim Lot #: A1 Frequency: Route:		Secor	Expiry: 01 Indication of use of	Suspected Drug F		uma		acturer
Therapy From: 01-	Apr-2004 B.5 Tests	To: 01-Apr-2004 B.6 History	C.9 Drugs	tion abated after u bed or dose reduce C.10 Treatme	ed: N/A	Reaction rea after reintr	oduction: N/A	
		Enteryo	ur descriptive inform	ation in the box belov	P			
D. Reporter Health Professional ⁷ Reported to Manuf. ⁷ Entered: 18-Apr-200 Modified:	Phone:	 Ex	st.:	Address1: Address2: City: Date Sent:			Add **	Exit

Note: In the above example, some of the items have been pre-filled where data in CHARMS was available. Such as the UI#, last recorded weight, age , date of birth. The Infusion date and the product infused prior to the reaction.

The Primary product tab records the product infused as selected from the Infusion Diary to initiate this report. If there is a need to report a secondary product infused, then you may enter this information by selecting the Tab Secondary.

ADVERSE REACTION REPORTING - WHAT'S NEW

B Product Reac	tion						
Adamana	Davis T		1. 19 Mar 19	yright © 1999-2003 AHCI			
		Reaction	Select Pa	tient Name: A	1Testperson A	ndre w	-
A. Patient Info	12						
1.Patient ID: HM	and the second se	umber: C1234	2. Age: 44	DOB: 01-Jan-	1960 3. Sex:	M 4. Height: 157 cm	5. Weight: 73 kgs
B. Adverse Re	action)utcome attributed to ad	verse reaction (ch	ock all that apply)			
Death Date of D	eath LifeTh	reat Hospitilized Pro	longed Stay Di	sability Congenital	Intervention Ot	her If Other Please Spe	cify
		.] [
		ate of Report: 18-A	pr-2004 Rea	ction Type: Palpita	itions 🗾	Reaction Length: >1	 hrs
C. Suspected I	Drug Product(s)						
Prir	nary	Seco	ondary				
Lot #: A	1LOT1		Expiry:	01-Jan-2005	Product: Factor V	III-A1BrandTest-A1Testr	manufacturer
Frequency:			Indication of use	of Suspected Drug	Product: BleedTra	auma	
Route:			Be	action abated after	use	Reaction reappeared	4
Therapy From: 01	1-Apr-2004	To: 01-Apr-2004		opped or dose reduc		after reintroduction	n: N/A 💌
B.4 Reaction	B.5 Tests	B.6 History	C.9 Drugs	C.10 Treatm	nent		
		Enteru	our descriptive infi	ormation in the box belo	ow		
Free Text notes	may be entered her	e which will appear o		Chevrolite and a state of the	and the second second		
1							
							-
D. Reporter							
	•			Address1: Address2:			
Health Professional	I? Hospital: Phone:		Est.:	City:			
Reported to Manul	f.? 🔲 Entered By:			Date Sent:		Edit Add	Exit
Entered: 18-Apr-20	104			8 3	•	►> +*	
Modified:							

Note: Section C – Tabbed items, B.4 Reactions, B.5 Tests, B.6 History, C.9 Drugs and C.10 Treatment These items of information may be accessed and entered by clicking on the appropriate TAB.

Most is entered in free text, with the exception of B.5 Tests; On this form, you will be allowed to select the applicable lab tests as well as free text for submission.

ADVERSE REACTION REPORTING - Select and auto fill from CHARMS Laboratory Results

All Copyright © 1999-2003 AHCCC Select Patient Name: ATTestperson Andrew A Patient Information I. Patient ID: [HI1100995] Chart Number: C1234 2 Age: [4 008: [01Jan-1960] 3. Sex: [M] 4. Height: [57] 5. Weight [73] orm Tage B. Adverse Reaction Dutcome attributed to adverse reaction (check all that appl) Death Deteor/Death LifeThreat Hospitized Prolonged Stay Disability Congenital Intervention Other If Other Please Specify Date of Reaction: [B-Apr-2004] Date of Report: [B-Apr-2004] Reaction Type: [Palpitations Reaction Length: [>] hrs C. Suspected Drug Product(s) Primary Secondary Lot #: ALLOTT Dose: [100 Expiry: [01-Anr-2005 Product; Factor VIII-ABrandTest-A1Testmanufacturer Indication of use of Suspected Drug Product; BleedTrauma Route: Reaction: [B-A pr-2004] Reaction abated after use Therapy From: [01-Apr-2004 Too [01-Apr-2004 Reaction abated after use Therapy From: [01-Apr-2004 Too [01-Apr-2004 Reaction abated after use Stopped or dose reduced: Thereathere introduction: N/A B.4 Reaction B.5 Tests B.6 History Cageudation-Date: [01-Jan-2000] Labhor([1] NR;[1] PF froequency (Di Jan-2000] Labhor([1	Product Reaction	
A. Patient Information 1. Patient ID: HM100995 Chart Number: C1234 2. Age: 44 DDB: 01-Jan-1960 3. Sex: M 4. Height: 157 5. Weight: 73 cm kgs B. Adverse Reaction Outcome attributed to adverse reaction (check all that apply) Death Date of Death LifeThreat Hospitilized Prolonged Stay Disability Congenital Intervention Other If Other Please Specify Date of Reaction: 18-Apr-2004 Date of Report: 18-Apr-2004 Reaction Type: Palpitations Reaction Length: >1 if i	Advance Dung	
1. Patient ID: HM 100995 Chart Number: C1234 2. Age: 44 D0B: D1Jan-1960 3. Sex; M 4. Height: 157 5. Weight 73 om kgs B. Adverse Reaction Outcome attributed to adverse reaction (check all that apply) Death Date of Death LifeThreat Hospitilized Prolonged Stay Disability Congenital Intervention Other If Other Please Specify Date of Reaction: 18-Apr-2004 Date of Report: 18-Apr-2004 Reaction Type; Palpitations Reaction Length: >1 1 trist C. Suspected Drug Product(s) Primary Secondary Lot # AlLOT1 Dose: 100 Expiry: 01 Jan-2005 Product: Factor VIII:A1BrandTestA1Testmanufacturer Indication of use of Suspected Drug Product: Beaction reappeared after use Reaction reappeared after reintroduction; N/A Intervention; N/A Intervention; Intervention; N/A Intervention; Intervention; N/A Intervention; Intervention; Intervention;		Reaction Select Patient Name: All estperson Andrew
B. Adverse Reaction Outcome attributed to adverse reaction (check all that apply) Death Dete of Deeth Life Threat Hospitilized Prolonged Stay Disability Congenital Intervention Other If Other Please Specify Date of Reaction: [18-Apr-2004] Date of Report: [18-Apr-2004] Reaction Type: Palpitations Reaction Length: [1] * hrs C: Suspected Drug Product(5) Primary Secondary Lot #: [A1LOT1 * Dose: [100 Expiry: [01-Jan-2005 Product[Factor VIII-A1BrandTest-A1Testmanufacturer Indication of use of Suspected Drug Product[BleedTrauma Route: Route: Reaction B.5 Tests B.6 History C.3 Drugs C.10 Treatment Select Tests: Blood * Chem Cog Cog Cog Hemo * Imm Virol * Cogulation-Date: [01-Jan-2000] LabNo: [1] INR; [1] PT [0.000 LibNo: [1] INR; [1] PT [1]		Munter [1124] 2 Act M DOD 01 In 1000 2 ComM A United [57] 5 Multicle [70
Dutcome attributed to adverse reaction (bleck all that apply) Death Date of Death LifeThread Hospitilized Prolonged Stay Disability Congenital Intervention Other If Other Please Specify Date of Reaction: 18-Apr-2004 Date of Reaction Type: Palpitations Reaction Length: >1 Image: Date of Reaction: 18-Apr-2004 Date of Reaction Type: Palpitations Reaction Length: >1 Image: Primary Secondary		
Date of Reaction: 18-Apr-2004 Date of Report: 18-Apr-2004 Reaction Type: Palpitations Reaction Length: >1 hrs C. Suspected Drug Product(s) Primary Lot #: AlLOT1 Dose: 100 Expiry: 01-Jan-2005 Product: Factor VIII-A1BrandTestA1Testmanufacturer Frequency: Reaction abated after use Reaction abated after use Reaction reappeared After entroduction: N/A ▼ B.4 Reaction B.5 Tests B.6 History C 9 Drugs C.10 Treatment Select Tests: Bod Chem CoaguetornDate: [01-Jan-2000] LabNo:[1] INR:[1] PT: PT: PT: PT: [01-Jan-2000] La		
Date of Reaction: 18-Apr-2004 Date of Report: 18-Apr-2004 Reaction Type: Palpitations Reaction Length: >1 • hrs C. Suspected Drug Product(s) Primary Secondary Lot #: AlLOT1 • Dose: 100 Expiry: 01-Jan-2005 Product Factor VIII-A1BrandTestA1Testmanufacturer Frequency: Indication of use of Suspected Drug Product BleedTrauma Route: Reaction abated after use Therapy From: 01-Apr-2004 To: 01-Apr-2004 To: 01-Apr-2004 Reaction B.5 Tests B.6 History C 9 Drugs C.10 Treatment Select Tests: Blod Coagulation-Date: (01-Jan-2000) LabNo(11)NR:(11)PT(1)PT(1)PT(1)PT(1)PT(1)PT(1)PT(1)P	Death Date of Death Life]	
C. Suspected Drug Product(s) Primary Secondary Lot #: AILOT1 Dose: 100 Expiry: 01 Jan-2005 Product: Factor VIII-A1BrandTest-A1Testmanufacturer Frequency: Indication of use of Suspected Drug Product/BleedTrauma Image: Colspan="2">Indication of use of Suspected Drug Product/BleedTrauma Route: Reaction abated after use Reaction reappeared Therapy From: 01-Apr-2004 To: 01-Apr-2004 Stopped or dose reduced: Y Reaction reappeared B.4 Reaction B.5 Tests B.6 History C 9 Drugs C.10 Treatment Select Tests: Blood Chem Cogg Cog Imm Virol Imm Coagulation-Date: (01 Jan-2000) LabNo: LabNo: (1) INR: I		
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Lot #; AILOT1 Dose: Dose: Display: Display:<		
Frequency: Indication of use of Suspected Drug Product BleedTrauma Route: Reaction abated after use stopped or dose reduced: Reaction reappeared after reintroduction: Therapy From: 01-Apr-2004 To: 01-Apr-2004 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 Select Tests: Blood Chem Cos Hemo Imm Virol Imm Coagulation-Date: [01-Jan-2000] LabNo: Coagulation-Date: [01-Jan-2000] LabNo: Imm Virol Imm Coagulation-Date: [01-Jan-2000] LabNo: [11] INR: [11] PN: [10:00] Inh(P): [10:00] DNA: [UnCertain] ProteinC: [Normal] Pr D. Reporter Address1: Address1: Address1: Address1: Entered Edit Add Esit Reported to Manuf.? Entered By: East: Date Sent: Edit Add Esit Entered: 18-Apr-2004 Phone: Esit Edit Add Esit	Primary	Secondary
Boute: Image: Comparison of the stopped or dose reduced: Reaction reappeared after reintroduction: B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment Select Tests: Blood Chem Cost Image: Hemo Image: Hemo <td>Lot #: A1LOT1</td> <td>Dose: 100 Expiry: 01 Jan-2005 Product: Factor VIII-A1BrandTest-A1Testmanufacturer</td>	Lot #: A1LOT1	Dose: 100 Expiry: 01 Jan-2005 Product: Factor VIII-A1BrandTest-A1Testmanufacturer
Therapy From: 01-Apr-2004 To: 01-Apr-2004 Stopped or dose reduced: Y Reaction reappeared after use after reintroduction: N/A • B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment Select Tests: Blood Chem Cost Cost Hemo Imm Virol • Coagulation-Date: [01-Jan-2000] LabNo: Coagulation-Date: [01-Jan-2000] LabNo: [11] INR: [11] PT: [11] FX: [1	Frequency:	Indication of use of Suspected Drug Product BleedTrauma
Therapy From: 01-Apr-2004 stopped or dose reduced: Y after reintroduction: N/A B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment Select Tests: Blood Chem Cogg Cogg Imm Virol Coagulation-Date: (01-Jan-2000) LabNo: (1) INR: (1) PTTTTTTTTTTTTTTTTTTTTTTTTTTTTTTTTTTTT	Route:	Beaction abated after use Beaction reanneared
Select Tests: Blood Chem Cog Cog Imm Virol Imm Virol Imm Cog	Therapy From: 01-Apr-2004	
Select Tests: Blood Chem Cog Cog Imm Virol Imm Virol Imm Cog	P.4. Departies B.5. Tests	B C History C O Durge C 10 Trestment
D. Reporter Address1: Health Professional ? Phone: Ext: City: Reported to Manuf.? Entered By: Date Sent: Edit Add Exit		
WvFRCOF:[1] FX:[1] FX:[1] FXII:[1] Inh(HU): (1000] Inh(P):[1000] DNA:[UnCertain] ProteinC:[Normal] Pr D. Reporter Health Professional ? Phone: Ext: Date Sent: Entered By: Date Sent: Entered I8-Apr-2004		
D. Reporter Address1: Health Professional ? Phone: Ext: City: Bate Sent: Edit Add Exit	Coagulation-Date: [01-Jan-2000] L	.abNo:[1] INB:[1] PT: Load U. Konnade: U. Van-2000 LabNo[1] INB:[1] PT:[1] PT:[1] PT:[1] VWWULC[Normal]
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Health Professional ? Phone: Ext.: City: Reported to Manuf. ? Entered By: Date Sent: Edit Entered: 18-Apr-2004 Phone: Image: City:	D. Reporter	Address1:
Reported to Manuf.? Entered By: Date Sent: Edit Add Exit Entered: 18-Apr-2004 10 Image:	Health Protocoronal 21	Address2:
Entered: 18-Apr-2004	Phone:	
Modified:	Modified:	8 Là MB N M M M M M M M M M M M M M M M M M

ADVERSE REACTION REPORTING - Edit and submit only the lab results that are applicable.

B.4 Reaction	B.5 Tests	B.6 History	C.9 Drugs	C.10 Treatme	nt			
Select Tests: Bloc	d 🔄 Chem	Coag Co	aj 🕶 Hemo 🗌		• Virol 💽			
Coagulation-Date:	(01-Jan-2000) FII:(1] FV:[1] FVII:[1] FVI	II-C:[1] VWFAg:[1]	ProteinC:[Normal]				▲ ▼
D. Reporter	Hospital:		1	Address1: Address2:				
Health Professional Reported to Manuf.	Phone:	E	Ext.:	City: Date Sent:		Edit	Add	Exit
Entered: 18-Apr-20 Modified:)4		9	3 🖪		5	•*	

ADVERSE REACTION REPORTING - Enter in free text format any other applicable data.

3.4 Reaction	B.5 Tests	B.6 History	C.9 Drugs	C.10 Treatment
		Enter yo	ur descriptive inform	nation in the box below
Free text descript	tion may be entered	here that will appear	on the Health Ca	nada "Adverse Reaction Form"
	I.	K. (*		
8.4 Reaction	B.5 Tests	B.6 History	C.9 Drugs	C.10 Treatment
		Enter yo	ur descriptive inform	nation in the box below
Free text descript	tion may be entered	here that will appear	on the Health Ca	nada "Adverse Reaction Form"
1298				
				-
1.4 Reaction	B.5 Tests	B.6 History	C.9 Drugs	C.10 Treatment
		Enter yo	our descriptive inform	nation in the box below
Free text descrip	tion may be entered	here that will appear	on the Health Ca	nada "Adverse Reaction Form"
	-			
). Reporter	1FAA1FA	. A1Familydoc	A1Familydoo	Address1:
	Hospital a	Test Hospital	HATT anniyood	Address2:
ealth Professional	Phone: (9	05) 111-1111 E	st.: 1111	City:
eported to Manuf	.? 🗹 Entered By: Sa	lly HeadNurse		Date Sent: Edit Add Ei
ntered: 18-Apr-20	04		4	8 🖪 🔊 👀
odified:				

History, Drugs and Treatment Tabs, will allow the Clinic administrator to enter in free text to describe each section in detail. This information will then be displayed on the Health Canada "Adverse Reaction" Report Form.

D. Reporter: This information is partially filled in from the master Providers form. i.e. Address, City..etc. Entered By: This item would hold the name of the person filling out the form on behalf of the Doctor submitting the Adverse Reaction form. ADVERSE REACTION REPORTING - Web site links to FAQ's

Web links to Health Canada's FAQ's on Adverse Reaction. Link to these sites can be accessed from within CHARMS by clicking on "Question" symbol button in the Adverse Reaction form.



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ADVERSE REACTION REPORTING - PRE VIEW OF THE REPORT.

You may preview the report as it will look to the recipients after submission. It is recommended that this Report be reviewed by the Clinic Director or the reporting Health Professional before it is submitted. To view this report, use the button on the form that looks like this:

La version est disponi	Canada le for return ad française de c ble sur deman connaître le c	e document de. Voir au	Re due te	port of suspecte o drug products	eaction Monito d adverse reaction marketed in Can s excluded)	on	gram	Health Products and Food Branc Direction générale des produits d santé et des aliments
1. Patient ide HM100 Chart Numb 1234 B. Adver	er Date DD Mil 1 1 se Reactio	at time of tion 44 or of birth 1 YYYY 1960	3. Sex 4. Height ✓ Male feet Female or 157 cm	5. Weight t lbs 1 or <u>73</u> kgs	C. Suspected ((See "How t Name (give labeled stre * ¹ Factor VIII-A1) * ² Dose, frequency 8 (o report ingh & manufac BrandTest-A	section durer, i known	· · · · · · · · · · · · · · · · · · ·
	eatening		(check all that apply) Disability Congenital malform Required interventio damage / permanen	ation	#1 500., #2	ioute used	#1 From	(dd / mm / yyyy) - To (dd / mm / yyyy) 2014 - 02-02-2004
2. Date and DD M 18 4 4. Describe r	dization - prolon time of reaction M 2004 eaction or prob	on Y Lem	Other: 3. Date of this DD MM 18 4	1	Indication for use o product #1 BleedSpontaneo #2	0.00	drug	5. Reaction abated after use stopped or dose reduced #1Yes No Doesn't apply #2Yes No Doesn't apply
Free text m	epe:Palpitation ay be entered l dverse Event"	here which wil	eaction:Hrs I be entered onto the H	ealth 6	Lot # (if known) #1 AILOT2 #2	7. Exp. dat #1 (dd / mn #2	e (if known) n / yyyy)	8. Reaction reappeared after reintroduction #1 Yes No 🖍 Doesn't apply #2 Yes No 🖌 Doesn't apply
5. Relevant t	ests / laborator	v data (includin	g dates (dd / mm / yyyy)		(dd / mm / yyyy) (exc Free text may be e "Adverse Event" 0. Treatment of adv (dd / mm / yyyy)	lude treatmer intered here form. erse reaction intered here	which will (drugs and	and route used) and therapy dates be entered onto the Health Canada i / or therapy), including dates be entered onto the Health Canada
Coagulatio VWFAg:[1	n-Date: [01-Ja] vant history, in:	n-2000) FII:[1	J FV:[1] FVII:[1] FVIII sting medical conditions	1	D. Reporter (See "Confid Name, address & pl Dr. A1Familydoc / A1 Test Hospital	hone numbe	r.	on on reverse)
Free text n	10 E 10	here which wi	ll be entered onto the H	lealth	Health professional	12 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	45 m m	4. Also reported to

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the adverse reaction.

HC/SC 4016 (01-02)

Canada

ADVERSE REACTION REPORTING – SUBMITTING THE ADVERSE EVENT

📰 Product Reac	tion						2
Adverse	Drug R	leaction	v3.1.0 Copyrig	x © 1999-2003 AHCE			
A. Patient Infor		cuction	Select Patie	nt Name: A	l estperson And	Irew	
1.Patient ID: HM	1.7	mber: 1234	2. Age: 44	DOB: 01-Jan-1	960 3. Sex: M	4. Height: 157	5. Weight: 73
B. Adverse Rea	action	itcome attributed to adv	erse reaction (check	all that applu)		cm	kgs
Death Date of De				Contraction of the second	Intervention Othe	r If Other Please Spe	cify
		Submit It Now?				٢	
	18-Apr-2004 Da		u sure you want to	submit it pow2		action Length:	* hrs
12	Orug Product(s)				as been submitted!		
Prin	nary	l					
Lot #: 🗛	1LOT2	2	(Yes	No		BrandTest-A1Test	manufacturer
Frequency:			<u>1. 168</u>	<u>N</u> 0		neous	
Route: Therapy From: 02	2.Eeb.2004	To: 02-Feb-2004	Read	ion abated after u		Reaction reappeared after reintroduction	
Therapy From: 102	.1 60-2004	10.021022004		_1		arter reintroduction	
B.4 Reaction	B.5 Tests	B.6 History	C.9 Drugs	C.10 Treatm	ent		ı
			ur descriptive inform		220		
Free text may be	entered here which	will be entered onto t	he Health Canada	("Adverse Event"	' form.		
				1			
				<u> </u>			
D. Reporter	1FAA1FA 💽 Dr.	A1Familydoc	A1Familydoc	Address 1:			
Health Professional	I?☑ Hospital: A1 Phone: (905		st.: 1111	Address2 Citu:			
	.? 🗹 Entered By: Sus			Date Sent:		Edit Add	Exit
Entered: 18-Apr-20 Modified: 18-Apr-20			6			**	
Nounea: 18-Apr-20						Desetion Detail of	
					Send Advers	e Reaction Rpt via th	e internet

I.Patient (D): HM100995 Chart Number: 1234 2. Age: [44] DDB: (11-Jan-1960 3. Sex: M. 4. Height [57] 5. Weight: 73 B. Adverse Reaction Option Option Option Figure 1000 Figure 10000 Figure 1000 <t< th=""><th>Product Reaction Adverse Drug Rea A Patient Information</th><th>v3.1.0 Copyright © 1999-2003 AHCDC Select Patient Name: AlTestperson And</th><th>Irew _</th></t<>	Product Reaction Adverse Drug Rea A Patient Information	v3.1.0 Copyright © 1999-2003 AHCDC Select Patient Name: AlTestperson And	Irew _
B. Adverse Headlon Out Access Security Death Date of Death Life There Death Access Security I Other Please Specify Data Access Security I Other Please Specify Primary In order to complete your CHARINS Data Weah Instaction Data Access Interpretation Password Prequency: Password: Password: Password: Password: Password: Password: Password: Password: Password: Price text may be entered here which will be entered onto the Health Canada "Adverse Event" form. D. Reporter Attent Hospital Health Professional 7 (Prove Provide Security)		r: 1234 2. Age: 44 DOB: 01-Jan-1960 3. Sex: M	
Date of Reaction IB-Apr-2004 Death CHARMIS Point of Reaction Date of Reaction IB-Apr-2004 Death	B. Adverse Reaction		om kgs
CHARMIS Dete of Reaction 18-Apr-2004 De CHARMIS CS-suspected Drug Product(e) Frimary Lot #: AlLOT2 Frequency: Route: Therapy From: 02-Feb-2004 B.4 Reaction B.5 Tests Enter your decemptive information in the box below Free text may be entered here which will be entered onto the Health Canada "Adverse E vent" form. D. Reporter D. Reporter ThEATFA TO: Alf-amilydoc Aff-amilydoc Address1 Health Professional 7 Prove 1997 How Adverse 1111 Enter 111 Enter 1		ata Access Security	f Other Please Specify
		CHARMS	r outer r lease opecay
C: Suspected Drug Product(s) In order to complete your CHARMS Data Web transaction please enter your CHARMS Data Web transaction Password: BrandTest-A1Testmanufacturer traous eaction reappeared after reintroduction: N/A ■ B.4 Reaction B.4 Reaction B.5 Tests Enter your descriptive information in the box below Enter your descriptive information in the box below Free text may be entered here which will be entered onto the Health Canada "Adverse E vent" form. D. Reporter Hospital Alter Hospital Alter Hospital	Date of Reaction: 18-Apr-2004 Da	Data Web Login	action Length: hrs
Primary please enter your Clinic's Login Username and Password in Tields below then cick OK. BrandTest-A1Testmanufacturer Lot #: A1L012 Clinic Username: HAM BrandTest-A1Testmanufacturer Route: Password eaction reappeared after reintroduction: N/A B.4 Reaction B.5 Tests Enter your descriptive information in the box below Free text may be entered here which will be entered onto the Health Canada "Adverse E vent" form. Dr. A1Familydoc Affeestional ? Proprint Hotels A1Test Hospital Adverse	C. Suspected Drug Product(s)		
Lot #: All OT 2 Clinic Username: HAM BrandTestA1Testmanufacturer Frequency: Password: Percurve Percurve Percurve B: 4 Reaction B: 5 Tests Percurve Percurve Percurve Percurve B: 4 Reaction B: 5 Tests Enter gour descriptive information in the box below Percurve <	Primary	please enter your Clinic's Login Username and Password in	
Bit Password: Possec B.4 Reaction B.5 Tests 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. Price text may be entered here which will be entered onto the Health Canada "Adverse Event" form.	Lot #: A1LOT2		BrandTest-A1Testmanufacturer
Therapy From: 02-Feb-2004 QK Cancel B.4 Reaction B.5 Tests Enter your descriptive information in the box below Free text may be entered here which will be entered onto the Health Canada "Adverse Event" Torm. Image: Constraint of the c	Frequency:		neous 💽
Therapy From: 02-Feb-2004 After reintröduction: N/A * B.4 Reaction B.5 Tests Enter your descriptive information in the box below Free text may be entered here which will be entered onto the Health Canada "Adverse E vent" form. D. Reporter D. Reporter Alf-AntFA * Dr. Alf-amilydoc Address1 Health Professional ? C Horphal Horphal Cury	Route:	Password:	eaction reappeared
B.4 Reaction B.5 Tests Entergour 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 Alf-ambydoc Alf-ambydoc Alf-ambydoc Addresst Addresst Addresst Addresst	Therapy From: 02-Feb-2004		after reintroduction: N/A 💌
	B A Beaction B 5 Tests	<u>OK</u> <u>C</u> ancel	J
Free text may be entered here which will be entered onto the Health Canada "Adverse Event" form. D. Reporter Alf-AntFA Dr. Alf-amilydoc Affersional ? Control Health Professional ? Control	B.4 Headlinh B.5 Tests	Enter your descriptive information in the box below	
D. Reporter A1FAA1FA Dr. A1Familydoc Address1 Health Professional? Hospital A1 Text Hospital Address2 Professional Professi	Free text may be entered here which will t		
AlfFAA1FA ▼ Dr. [A1Familydoc AlfFamilydoc Address1: Health Professional ? ✓ Hospital Lat Text Hospital Address2:			
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AlfFAATFA ▶ 0r. [A1Familydoc Addresst: Health Professional ? Poptial A1 Test Hospital Addresst:	D Reporter		
Health Professional ? Phone: (905) 111-1111 Ext.: 1111 City.	A1FAA1FA Dr. /		
			Edit Add Exit
		9 1 19	
Modified: 18-Apr-2004	Modified: 18-Apr-2004		

Only HTC authorized personnel may submit Adverse Reaction Reports.

ADVERSE REACTION REPORTING - CHARMS DATA WEB

😰 Product Reaction
v3.1.0 Copyright © 1999-2003 AHCDC
Adverse Drug Reaction Select Patient Name: AlTestperson Andrew
1. Patient ID: HM100995 Chart Number: 1234 2. Age: 44 DDB: 01 Jan-1960 3. Sex: M 4. Height: 157 5. Weight: 73 B. Adverse Reaction om k </td
Outcome attributed to adverse reaction (check all that apply)
Death Date of Death LifeThreat Hospitilized Prolonged Stay Disability Congenital Intervention Other If Other Please Specify
Set Web Password
Date of Reaction: 18-Apr-20 Sorry, this initial password cannot be used to submit Adverse Reaction reports.
C. Suspected Drug Produ / I Set your web password first using the web page that will be displayed next.
Primary Once you've set you're clinic's password you can re-submit this report.
Lot #: A1LOT2 ast-A1Testmanufacturer
Frequency:
Route: Heaction abated after use Heaction reappeared
Therapy From: 02-Feb-2004 To: 02-Feb-2004 To: 02-Feb-2004 Stopped or dose reduced: N/A 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
Free text may be entered here which will be entered on to the Health Canada "Adverse Event" form.
D. Reporter A1FAA1FA V. A1Familydoc A1Familydoc Address1:
Health Professional ? U Hot Test Hospital Address2: Phone: 10051111111 Etc. 1111 Cite:
Reported to Manuf.? P Entered By Susan HeadMurse Date Sent: Edit Add Exit
Entered 18-Apr-2004
Modified: 18-Apr-2804

CHARMS DATA WEB – The first time you access, you will be required to change your password from the default assignment.

Login Page - Microsoft Internet Explorer	
	CHARMS Data Web.
	Welcome to CHARMS Data Web. All access to this website is secured by user login and recorded for security, including your IP address (206.172.164.4). The information on this web site is intended only for the purposes of the manufacturer, the regulator and the distributor of the product described. By accessing this information, YOU agree to not share this information outside these groups.
	Please enter your assigned login name and password; then click <login> to continue.</login>
	CHARMS Data Web Login
	Username:
	Password:
	< Login >
	Change Password I Forgot My Password
	Change Password I Forgot My Password

ADVERSE REACTION REPORTING – CHARMS DATA WEB – CHANGING YOUR PASSWORD

	CHARMS Data Web Login
	Username:
	Password:
Ent	er your old password above then enter a new password below. er the new password a second time to confirm the change then k login as usual to change your password as well as login.
imp can cha nun	en choosing a new password please keep security as paramount ortance and select a password of sufficient complexity so it not be guessed. As guidelines: use a minimum length of 8 racters and a combination of upper and lower case letters, obers and symbols e.g. "MyAcct\$1". Do not use birthdates or combination of family member names.
	New Password:
Re-e	enter New Password:
	< Login >
	Cancel Change Password I Forgot My Password

ADVERSE REACTION REPORTING – CHARMS DATA WEB – Initial web access established, now You can submit the Adverse Event Report.

Unless you get the SUCCESSFUL submission message, your report has not been submitted. You may Try to submit until you get the SUCCESSFUL message. If you encounter any problems, please contact Your CHARMS Support.

Product Reac	tion					
Adverse	e Drug]		Statis Resolution (1999-2003 AHCDC Name: A1Testpers		
A. Patient Infor		AUGUION	Select Patient	Name. Allestpers	on Andrew	<u> </u>
1.Patient ID: HM		Number: 1234	2. Age: 44 D	0B: 01-Jan-1960 3.	Sex: M 4. Height: 15	
B. Adverse Rea	action	Outcome attributed to adve	rse reaction (check all t	vat anniu)	¢	m kgs
Death Date of De			and the second second second	Congenital Intervention	Other If Other Please S	Specify
	(j	Adverse Reaction S	ubmission SUCCE	SS	×	
Date of Reaction:					n Length:	• hrs
C. Suspected D		Submission	of your Adverse Rea	ction report was SUCCES	SFUL	
Prin	nary					
Lot #: 🗛	1LOT2		OK OK		ndTest-A1T	estmanufacturer
Frequency:					4S	<u> </u>
Route:	D T-1 2004	To: 02-Feb-2004		abated after use	Reaction reappe	ared
Therapy From: 02	2-Feb-2004	10.02-1-60-2004	, stopped	or dose reduced: N/A	 after reintroduc 	
B.4 Reaction	B.5 Tests	B.6 History	C.9 Drugs (C.10 Treatment		
			ur descriptive informatio			
Free text may be	entered here whic	h will be entered onto th	ne Health Canada ''A	dverse Event'' form.		
D. Reporter	1FAA1FA 🔽 D	r. A1Familydoc	A1Familydoc	Address1:		
∟ Health Professional		1 Test Hospital		Address2:		
Reported to Manuf	Phone: [3 .? 🗹 Entered By: S		te <mark>1111</mark>	City: Date Sent:	Edit A	dd Delete Exit
Entered: 18-Apr-20)04		Q			* 🗰
Modified: 18-Apr-20)04					

ADVERSE REACTION REPORTING - EMAIL NOTIFICATION SENT TO RECIPIENTS

The following is a sample of the email notification that will be sent out to the intended recipients notifying Them that an Adverse Event has been submitted.

Each request to view is logged along with the requestor's IP address. Only the people notified will be able to view the report that was intended for them only.

Adverse Reaction Notification (13)
<u>Eile Edit View Go M</u> essage <u>C</u> ommunicator <u>H</u> elp
💱 📎 🤯 🛱 🥰 🧊 🔹 👔 Get Msg New Msg Reply Reply All Forward File Next Print Delete Stop
E TESTING ONLY !!!! - Adverse Reaction Notification (13) CHARMS Web Notifier
Subject: TESTING ONLY !!!! - Adverse Reaction Notification (13) Date: Tue, 20 Apr 2004 03:30:08 -0400 From: <u>"CHARMS Web Notifier" <notifier@charms.ahcdc.ca></notifier@charms.ahcdc.ca></u> To: <u><stilesc@sympatico.ca></stilesc@sympatico.ca></u> CC: <u><stilesc@sympatico.ca></stilesc@sympatico.ca></u> Adverse Reaction Notification (13)
Dear Sir/Madam , This is an automated email notification that a new Adverse Reaction Report has been submitted for your review as of today, Apr 20, 2004.
In order to view or print this Adverse Reaction Report you will need to:
 a) have Adobe Acrobat Reader v4+ installed, b) click on the link below and c) provide your CHARMS Data Web username/password to login on our secure web server.
Click here to retrieve ADR #13.
If you are having any technical difficulties reading this report, please email us at support.charms@ahcdc.ca
If you questions about the content of this report, please contact the Reporter listed on the bottom of the report.
Thank you from the CHARMS Data Web Support Team.
All information in this email should be considered confidential and intended solely for the use of the individual or entity to whom this email is addressed. If yo have received this email in error please notify the sender immediately then delete the message and any attachments.
Had this been real we would have sent it to:
 To: Ontario Regional AR Centre (Blood Services) BCC: walkeri@mcmaster.ca (Reporting Clinic) CC: Andrea Vogel (Andrea Vogel at AHCDC)
Automated Email from http://charms.AHCDC.com

NOTES