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.

CHARMS Update CHARMA Current v3.0.1 Copyright	IS Update
AHARMS.	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.

Locate MDB	File My Documents	i 🖸 🔁	?× 1
My eBook My Music My Picture WebPage	s s	find HMIS97d.mdb	
		once found and select Open button to attach	ed, click on the it to CHARMS
File <u>n</u> ame:	HMIS97D.MDB		<u>O</u> pen
Files of <u>type</u> :	Listing Files of type MDB	•	Cancel
your HMIS9	7d.mdb is on your ho ation by using the dro	spital server, you must pdown arrow above in	locate and 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
CH, the	ARMS will upgrade your existing application V3.0.4 to new version V3.1.0.
Dur you 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

CHARMS Up	grade Sucessful Message
You will be di indicating wh upgraded. If t CHARMS su	splayed the Upgrade status message, ether your CHARMS has been sucessfully he Upgrade failed, please contact your oport.
Upgrade •	Completed X
	<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 Rest Password: ******	ographic ecurity ricted Access
Change Password>>>	Login assword is :
ouning this initial apgrade, your login p	and type in as
'password" , donot include the quotes owercase. Now you can click on the	Login button.
'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.	Login button. remember to WRITE IT

ΟK

CHANGING YOUR DATA ACCESS SECURITY PASSWORD

CHARM	IS Demographic
Data A	ccess Security
2011111-20	in the second
	(
Old Password:	******
Old Password:	××××××××
Old Password: New 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
	OK.

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.

	Dationt Uni	aug Identifier A	ecianment Progress	<u>1</u>
	Fatient On	que lucilarier A	ssignment riogres:	
	19%			
			P	
		<u><u>S</u>top</u>		
This new s	oftware version is des	signed to create an and	onymous but unique identifie	r for each
appropriate	product notifications	a. This will assist with t to Patients as they mo	racking product usage and ove from one home base Clir	providing hic to another.
The III ass	ignment process use:	s Web server technolo	ou to assign patient identifie	rs and is hence
governed b	y your Internet conne	ection speed. This proc	cess may take some time to	complete and
oan be inte	rrupted by clicking th	e Stop button at any til	me. The Assignment proces	s will
automatica	ly restart the next time	e vou enter LHARMS.	until all batient records have	e been assigned

	CHAR	M S	or accidemont	X
	?	Unfortunately there ar preventing their assign Would you like to view	e 57 Patients with inco ment of a Unique Ider w/print the patient list?	mplete data htifier.
This new sof CHARMS Pa appropriate p		Yes	<u>N</u> o	or each viding to another.
The UI assignr governed by yo	ment proce our Interne	ss uses Web server te t connection speed. Th	chnology to assign pat	ient identifiers and is her ome time to complete an

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.

Patient Detai	I						
Patie	nt Detail yright © 1999-2003 AHCDC						
	Last Name	First Name	Hosp.Id: 9	B1	Valid	Provid	ers
Nam Salutatio	e: A2TestPerson n: Mir → Estraid	A2Test	Clinic Id: 8	888888888	? 🔽	Belatives/C	ontacts
Patient Statu	s Active		L.H.H.#: 8	888	_		NO. 10
Languag	e English		MedAlert: 8	888888888		<u>U</u> linic Sur	nmary
Gende	er: M 🗾 Date of Birth: 26	-Sep-1946		888	8888 1	Treatment F	Protocol
Alias Nam	e: Frankie		ew UI was Ger	nerated! er B	Excluded: 🗖	¥isit Asse	ssment
Home Addre	ss			ier E			
Stree	456 Somewhere Ave			/e /	Contact:	Laboral	tory
City/Prov	SOMEOTHERCITY ON	📩 Postal:	UK	38		Hospital Ad	Imission
Mailing -	atient Detail		13.7 141/0		10000		
Str	Datiant Date						
City/P Bleeding I	v3.1.0 Copyright © 1999-2003						
Diagnosi	Last Name	First Nar	ne	Hosp.Id: 981		Valid	Providers
Factor D	Name: A2TestP	erson A2Test		Clinic Id: 888	8888888	Hospid ? ✓	
	Salutation: Mr. 💌	Extra Id.: STON		C.H.R.#: 888	8		Belatives/Contacts
Please Note	Patient Status: Active	UI: HM10146	67	MedAlert 888	8888888		<u>C</u> linic Summar y
Entered: 1 Modified: 1	Language: English	×	Age 57	Health Card #: ON	- 888888	38888 1	<u>Treatment Protocol</u>
Becord: 14		ste of billing 20-3eb-1340	-	Category	DI 1 1		
Kecoru: IN	Allas Name: [Frankle Home Address			Carrier	Carrier I	Excluded: [¥isit Assessment
	Street 456 Somew	here Ave	-		Relative /	Contact:	Laboratory
	City/Prov: SOMEOTH		12K 315	Phone		-	
	Mailing Same or Alt	ernate		Work# (888) 888-8888) 888-8888	× 8888	Hospital Admission
	Street: 456 Somew	here Ave		FAX # (888	1 888-8888	-	Bleed Diary
	City/Prov: SOMEOTH	RCITY ON - Postal: F	12K 3J5	EMail: a2te	stperson@ne	t.ca	Patient Inventory
	Bleeding Disorder		125	First	Encounter: 10-	Apr-2004	12110100
	Factor IX	Z Mod	- -				Consent
							Print Patient
	Please Note: All dates must be	entered with separators / c	or - Date displa	yed depends on	your Windows	Regional Dat	e Settings.
	Entered: 10-Apr-2004 Modified: 10-Apr-2004				Note	Edit A	ldd Delete <u>E</u> xit
					<u>[</u>]		

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		
9.65	Administration Menu	Select <u>R</u> ecall Lot#'s		
Chine N	<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	<u>Exit</u>			

STUDY DETAILS

elect Study: No Name 1 Blood Borne Patho	Click on a Study line item to see/edit det Status Category ogens Study External Commercial-Regu	atis below. Start Date End Date latory 01-Jan-2001 01-Jan-2005
Study No:1	itudy Name: Blood Borne Pathogens Study	
Full Name Blood Borne Pathogens Duration Consent Ir	ivestigators Sponsor	
Status: External C	ategory: 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					_ 0
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	e Study Name	Consent To1	YN1 Sample Is	Entered	Modified
8-Apr-2004 01 Lon 200	External Study	ond Bathagan auruaille	No Retained		
Consent Agreeme	nt Record				
Consent Agreeme Study No: 1 Blood I	nt Record Date Borne Pathogens St	of Consent: 18-Apr udy	-2004		
Consent Agreeme Study No: 1 Blood I Consent to 1: Pathog	Int Record Date Borne Pathogens St en surveillance	of Consent: 18-Ap udy	-2004	_ ● Yes	C No C Unk
Consent Agreeme Study No: 1 Blood I Consent to 1: Pathog Consent to 2: Genetic	nt Record Date Borne Pathogens St en surveillance cs analysis	of Consent: 18-Ap udy	-2004	Yes	O No O Unk
Consent Agreeme Study No: 1 Blood I Consent to 1: Pathog Consent to 2: Genetic Date Sample Taken: 0 In event of death, wish m C Destroyed	nt Record Date Borne Pathogens St en surveillance cs analysis I-Jan-2004 y samples: © Retained	of Consent: 18-Apr udy	-2004	 Yes Yes 	C No C Unk C No C Unk

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.

Name'		First Name	Hosp.Id: 99999999999	Valid	Providers
Calutation	Allestperson	Andrew Are You Sure?		? 🗸	Relatives/Contacts
Salutation:					
l		Are you sur	e the Patient has died?		<u>Clinic Summary</u>
Language:	English 💌			1	Treatment Protocol
Gender:	Date of Birth;	- Yes			
Alias Name: ome Addres	: Handy Andy is			r Excluded: [<u>¥</u> isit Assessment
Street	123 Somewhere Ave	L_	New On the Octoor		
City/Prov:	HAMILTON	N - Rostal: 11K 1.J1	- P dd	tom coult	
	ame or Alternate		Date Of Death: 18	4 2004	Autopsy:
lailing — S			Course(1)		
Street	123 Somewhere Ave		Lause(1):		
Street: City/Prov:	123 Somewhere Ave	N T Postal I 1K 1.11	Cause(1):		
Street: City/Prov:	123 Somewhere Ave HAMILTON 01	N 🗾 Postal: L1K 1J1	Cause(1): Cause(2): Double	e Click in Details	to Zoom in
Street: City/Prov: City Disc Citynosis	123 Somewhere Ave HAMILTON 01	Postal: L1K 1J1	Cause(1): Cause(2): Details:	e Click in Details	to Zoom in
Street: City/Prov: leeding Disc liagnosis actor VIII	123 Somewhere Ave HAMILTON 01 order	N Postal: L1K 1J1 Severity Mod	Cause(1): Cause(2): Details:	e Click in Details	• to Zoom in
Street: City/Prov: City/City/City/City/City/City/City/City/	123 Somewhere Ave HAMILTON 01 order	N V Postal: L1K 1J1 X Severity 1 Mod V	Cause(1): Cause(2): Details:	Click in Details	▼ • to Zoom in

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.

ssigning 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	Providers
Salutation: Mr. 🔽 Extra Id.: ONON	Clinic Id: 88888888888888888888888888888888888	<u>Belatives/Contacts</u>
Patient Status: Active _ UI:	MedAlert: 888888888	<u>Clinic Summary</u>
Language: English Cender: M Date of Birth: 01-Jan-194	B8888888 1	<u>Treatment Protocol</u>
Alias Name: alias name	New UI was Generated! eder Excluded:	<u>V</u> isit Assessment
Home Address	rrier Excluded:	
Street: 123 Somewhere Ave		Laboratory
City/Prov: HAMILTON ON - Postal	388	Hospital Admission
Patient Detail		
City Patient Detail Bleedi v3.1.0 Copyright © 1999-2003 AHCDC		
Diagn Last Name First N	Hosp.Id: 88888888888	Valid Providers
Iracto Name: A2TestPerson Bob Salutation: Mr. Extra Id.: ONON	Clinic Id: 88888888888888888888888888888888888	? ✓ <u>Belatives/Con</u>
Patient Status: Active VI: HM101	470 MedAlert: 8888888888	<u>Clinic Summ</u>
Language: English 🚽	Age Health	

PATIENT CLINIC SUMMARY – WHAT'S NEW.

ationt Clinic Summe	Select: A1Testpersor	Andrew	Che
Copyright © 1999-2003 AHCDC	Patient: Qwik Find CHR	#	Pg1 Pg2 Add
Blood Group: A Pos v Bleeding Disorder Diagnosis: FVIII Level % 1 (for <1	× enter 0) Severity: Mod ×	LastReview Date: Review Freq.(mnths); Followup Freq.(mnths); Last Encounter, Date:	01-Jan-2000 6 6 01-Jan-2000
Home Care: Yes 💉 Prophyl. Prog.: 🗖	Home Care Start Date: 01-Jan-2000	Last Visit Type: Last Visit Purpose: Wallet Card Issued Date:	Review Review 01-Jan-2000
INHIBITOR Human Level (Max): 1000 Human Level (latest): 1000 Porcine (latest): 1000	Units Date 0.0 BU 0.0 BU	00 VWF:Ag: 00 VWF:Rcof: 00 BleedTime:	1 1 1 mins.
DESMOPRESSIN Bleed VIII0 Time PRE: PRE: PRE: Post[1]: 1 mins. Post[2]: 2 mins. Post[3]: 3 mins. Post[3]: 3 mins. Post[3]: 1 Post[3]: 1	WWAg WWRCOF 10 10 10 1 1 1 2 2 2 3 3 3	Date: 01-Jan-2000	Update Lab Results Intered: 21-Mar-2001 Iodified: 18-Apr-2004
o View Pg1 or Pg2, Click on Page buttons, at the	e top righthand side of this form.	Note Edit	Delete Exit
vik Find CHR : You will see this Qwik fin your patient by CHR# and will also work rsor has to be in the Qwik Find CHR field	o on some of the selected screer with your HandHeld Scanner if a first if you are using the scanner	is in CHARMS. This a CHR Barcoded # is s r.	nows you to sear canned. Note, yo

PATIENT CLINIC SUMMARY – WHAT'S NEW.

atient	Summary Clinic Su R © 1999-2003 AHCDC	ummary ^{Sel} Pati	ect: A1Testperso ent: Qwik Find CHI	on Andrew	Pg 1 Pg 2	Chec Addi Infor
Immuniza	tion Allergies He	eight/Weight Medicate	e AIDS Illness Re	actions Mortalit	vl	
Immunized	I Immunization	Date Vaccine Code	Entered Modifi	ed]	
				3	New Add	
VIROLOGY	Latest Result and	Date Latest Resu	It and Date	Latest Result a	and Date	_
Hej	🗚 Neg 💽 01-Ja	n-2000 HIV: Neg	▼ 01-Jan-2000	HepC: Neg	01-Jan-2000	
HCVr	r: Neg 💽 01-Ja	n-2000 HBsAg: Neg	• 01-Jan-2000	HBsAb: Neg	01-Jan-2000	
HOVE		huttons, at the ton righthend	d side of this form.	Note	Edit Delete	Exit
o View Pg1 o	or Pg2, Click on Page k	satoris, at the top right one		5	<u>></u>	1 H

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
	Infusion Date Time Infused Epi-# Reason
Select Patient: A1Testnerson Andrew	01-Mar-2004 0 Various 01-Jan-2004 01:00 PM 2 BleedSpontaneous
	01-Jan-2004 10:00 AM 1 BleedSpontaneous
Episode Type: Single	
New New	Days Lost from
Infusion Date Time Epi-# Infusion Reason	Treated by Injury School Work Other
01-Jan-2004 (24:00): 10:00 1 BleedSpontaneous 💌	
Infused Lots Bleed Sites	
Facility Lot Number Brand Name	U/V # of vials Total Units Treatment Site # Reactions
Allori Allori AlbrandTest	100 1 100 Clinic/Hosp 1 <u>Beaction</u>
OutOfRegion Any Clinic/Hosp not in your Region	
A1 A1 Test Hospital	
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 A1Testnerson Andrew	UT-Mar-2004 U Various ↓ 01 Jan-2004 01:00 PM 2 BleedSpontaneous
Entered 21-Mar. Entered Type: Single	01Jan-2004 10:00 AM 1 BleedSpontaneous
Modified: 19-Apr-2	
Infusion Occurred	New Days Lost from
Infusion Date Time Epi-# Infusi	on Reason Treated by Injury School Work Other
New 01-Jan-2004 (24:00): 13:00 2 Blee	dSpontaneous 🔹 🔹
Infused Lots Bleed Sites	
Facility Lot Number Brand	Name U/V # of vials Total Units Treatment Site # Reactions
▶ A1 ▲ A1LOT1 AAA A1Bra	ndTest <u>100 1 100 Clinic/Hosp 1 Beaction</u>

INFUSION DIARY - WHAT'S NEW

Bleed Diary					
Infusior	1 Diary		All Blee	ed Episodes for this	patient. Click to select
	J		Infusion Date	Time Infused Epi-#	Reason
Select Patien	e: Multiple	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	Various	HoursTill Treated	Caused by Injury	Days Lost from School Work Other
Infused <u>L</u> ots	Bleed Sites		·		
Facility	Lot Number	Brand Name		Vials Total Units Trea	tment Site # Reactions
*	AILUTI	AIBrandlest	- 100 1		E I Heaction
	Use the keybo	ard ALT-L / ALT-B to select the Infu	ised Lots / Bleed S	Sites Tabs, respectively	×
Entered: 19-Apr- Modified: 20-Apr-	2004 2004 2004	leed episode, click on the Add butt NAL_Lot# to existing episode, clic rom episode, click on Edit, click on ress Del kev on kevboard.	on. sk on Edit button. n record selector	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
linusion Dial j	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
Enisode Type: Multiple	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 #or vials Total Units Treatment Site # Reactions
A1LOT1 🚧 A1BrandTest -	100 10 1000 Home - 1 <u>R</u>eaction
* •	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.	ecord selector

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	Pain Row1=1,2,3; Row2=4,5,6; Row3=7,8,9 ✓ 2 Pain ✓ 3 Stiffness ✓ ✓ 5 Warmth ✓ 6 ✓ ✓ 8 ✓ 9 ✓
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. ecord selector

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 Reacti	on							×
Adverse	Drug R	Reaction	v3.1.0 Copyri Select Patio	ght © 1999-2003 AHCDC ent Name: A1T	estperson And	lrew		·
1.Patient ID: HM1	D0995 Chart Nu	umber:	2. Age: 44	DOB: 01-Jan-196	50 3. Sex: M	4. Height	:157 5. V cm	Veight: <mark>73</mark> kgs
Death Date of Death Date of Reaction:	th LifeThr	atcome attributed to adv eat Hospitilized Prol ate of Report: 18-A	verse reaction (check onged Stay Disa	all that apply) bility Congenital In] on Type:	itervention Othe	er If Other Plea	ase Specify	• hrs
L. Suspected D Prima Lot #: A1 Frequency: Route: Therapy From: 01-4	ug Product(s) ary LOT1 Apr-2004	Cose: 100 Cose:	ndary Expiry:[01 ndication of use o Read stop	Jan-2005 Pr f Suspected Drug Pr stion abated after use ped or dose reducer	oduct:FactorVIII oduct:BleedTrau e d:N/A	-A1BrandTest- ma Reaction rea after reintr	A1Testmanuf ppeared oduction: N/A	
B.4 Reaction	B.5 Tests	B.6 History	C.9 Drugs	C.10 Treatmen	nt]
D. Reporter Health Professional G Reported to Manuf. G Entered: 18-Apr-200 Modified:	Hospital: Phone: Entered By:) [] E	Ext.:	Address1: Address2: City Date Sent			Add	Елік

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

🗄 Product Reac	tion							
Adamana	Davis T		v3.1.0 Coj	oyright © 1999-2003 AF	ICDC			
Aaverse	e Drug H	ceaction	Select Pa	tient Name:	A1Testperso	n Andrew		•
A. Patient Info	imation				1000 0 0			
1.Patient ID: HM	100995 Chart N	umber: C1234	2. Age: 4	4 DOB: 01-Jar	n-1960 3. 9	ex: M	4. Height: 157	5. Weight: 73 kgs
B. Adverse He	action)utcome attributed to ad	verse reaction (ch	eck all that apply)				
Death Date of D	eath LifeTh	reat Hospitilized Pro	longed Stay D	isability Congenita	al Intervention	Other If C)ther Please Specify	ý
Date of Reaction:	18-Apr-2004 C	ate of Report: 18-A	pr-2004 Rea	action Type: Palpi	tations	 React 	ion Length: >1	 hrs
C. Suspected I	Orug Product(s)							
Prir	nary	Seco	ondary					
Lot #: 🗛	1LOT1		Expiry:	01-Jan-2005	Product: Fac	tor VIII-A1Br	andTest-A1Testma	nufacturer
Frequency:			Indication of us	e of Suspected Dru	ug Product: Blee	dTrauma		_
Route:			в	eaction abated afte	ar use	Bea	ction reappeared	
Therapy From: 01	1-Apr-2004	To: 01-Apr-2004	s	topped or dose red	luced: Y	a	fter reintroduction:	N/A 🗾
B.4 Reaction	B.5 Tests	B.6 History	C.9 Drug	s C.10 Trea	tment]
		Enter	our descriptive in	formation in the box b	elow			
Free Text notes	may be entered her	e which will appear c	n the Health Ca	anada "Adverse Re	eaction Form''			
1								
								-
D Benerter	01780			60				
D. meponter				Address	:1:			
Health Professional	I? Hospital:		Est	Address	:2: tu:		T	
Reported to Manul	f.? 🔲 Entered By:			Date Ser	nt:		Edit Add	Exit
Entered: 18-Apr-20	004				100 C			

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 AHCDC 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: [>1 hrs C. Suspected Drug Product(s) Primary Secondary Lot #: [AILD11 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 Too [01-Apr-2004 Reaction abaled after use Therapy From: [01-Apr-2004 Too [01-Apr-2004 Reaction abaled after use Therapy From: [01-Apr-2004 Too [01-Apr-2004 Reaction abaled after use Therapy From: [01-Apr-2004 Too [01-Apr-2004 Reaction abaled after use Therapy From: [01-Apr-2004 Too [01-Apr-2004 Reaction abaled after use Reaction reappeared after reintroduction: N/A Select Tests: Blood Chem Code after Phino Print [1] FTT[1] TTT[1] TTTT[1] TTT[1] TTTT[1] TTTT[1] TTT[1] TTT[1] TTT[1] TTTT[1] TTTT[1] TTT[1] TTT[1] TTT[1] TTT	Product Reaction	
A. Patient Information I. Patient I. Patie	Advance Dung	Departien v3.1.0 Copyright © 1999-2003 AHCDC
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In the section of the section is a set of the sectore set of the set of the set of the set of the	A. Patient Information	Munter [1124] 2 Act M DOD 01 In 1000 2 ComM A United [57] 5 Multicle [70
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B.4 Reaction B.5 Tests B.6 History C.9 Drugs C.10 Treatment Select Tests: Blood Chem Cogg Imm Virol Imm Coagulation-Date: [01 Jan-2000] LabNo: [1] INR: [1] PT: [0] Jan-2000] LabNo: Imm Virol Imm Coagulation-Date: [01 Jan-2000] LabNo: [1] INR: [1] PT: [1] PT: [1] INR: [1] PT: [1] PT: [1] INR: [1] PT: [1] PT: <td>Therapy From: 01-Apr-2004</td> <td>To: 01-Apr-2004 stopped or dose reduced: Y - after reintroduction: N/A -</td>	Therapy From: 01-Apr-2004	To: 01-Apr-2004 stopped or dose reduced: Y - after reintroduction: N/A -
D.4 Headthoff D.5 Focks D.6 Fiscury 1.5 Didgs C. To Treadment Select Tests: Blood Chem Cogg Cogg Imm Virol Coagulation-Date: (01 Jan-2000) LabNo: (1) INR: IN	P.4. Departies B.5. Tests	B C History C O Durge C 10 Trestment
Select Tests: Blood Corp Corp<	D.4 neaction D.5 rests	
Coagulation-Date: [01 Jan-2000] LabNo:[1] INR:[1] PT. Obsolutator Date: [U1 Jan-2000] LabNo:[1] INR:[1] PT. [U1 D RU VW MULE(Normal] Pr WVFRCDF:[1] FX:[1]	Select Tests: Blood	
	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]
D. Reporter Address1: Health Professional ? Phone: Ext: City: Bate Sent: Edit Entered By: Date Sent: Entered: 18-Apr-2004		() FXIL[1] FXIL[1] FIII[F0], [1000] FIII[F],[1000] FIXA.[0ficeitain] Fixeina.[Noimai] Fi
D. Reporter Address1: Health Professional ? Hospital: Phone: Ext: City: City: Bate Sent: Edit Entered: 18-Apr-2004		
Health Professional ? Hospital: Address2: Phone: Exit: City: Reported to Manuf.? Entered By: Date Sent: Entered: 18-Apr-2004 Image: Control of the sent:	D. Reporter	Address1:
Reported to Manuf.? Entered By: Date Sent: Edit Add Exit Entered: 18-Apr-2004 % Image: Control of the sent: Image: Contro	Health Professional 2	Address2:
Entered: 18-Apr-2004	Benorted to Manuf 2 Februard Par	Ext. City:
	Entered 18-Anr-2004	
Modified:	Modified:	

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 Treatmen	t]			
Select Tests: Bloc	id 💽 Chem	💽 Coag Co	ai 🕶 Hemo	💌 Imm 💽 👻	Virol 💽			
Coagulation-Date:	[01Jan-2000] FII:[1] FV:[1] FVII:[1] FVI	II-C:[1] VWFAg:[1]	ProteinC:[Normal]				
D. Reporter		-10						
Lineble Destaurional	Hospital:		1	Address1: Address2:			10	
Reported to Manuf.	? Phone: ? Entered By:	E	Ext.:	City: Date Sent:		Edit	Add	Exit
Entered: 18-Apr-200 Modified:	D4		9	3 🖪	•	5	•*	

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

.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 descrip	tion may be entered	here that will appear	on the Health Ca	nada "Adverse Reaction Form"
	<i>.</i>	v (
.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 descrip	tion may be entered	here that will appear	on the Health Ca	nada "Adverse Reaction Form"
				-
	A material contract	5		
.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:
Ma Drafa sianal	Hospital: A	Test Hospital	11	Address2:
eaim Froressional	Phone: 🧐	05) 111-1111 E	st.: 1111	
eported to Manul	. ? 🗹 Entered By: Sa	illy HeadNurse		Date Sent: Edit Add Ex
			1.12	
ntered: 18-Apr-20	104		6	ן און אים איד

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:

See revers La version est dispon verso pour	Health Canada se for return ad française de c ible sur deman connaître le c	Santé Canada Idress. e document de. Voir au entre à contac	Canadian Adv Rep due to	ort of suspected drug products (Vaccines	action Monito d adverse reaction marketed in Can excluded)	oring Pro on ada	gram	Health Products and Food Branc Direction générale des produits d santé et des aliments
A. Patien 1. Patient ide HM100 Chart Numb 1234 B. Adver	nt Information entifier 2. Age read 2995 Date DD MM 1 I rse Reaction	at time of tion 44 or of birth t YYYY 1960	3. Sex 4. Height ✓ Male or Female 157 cm	5. Weight Ibs 1. or <u>73</u> kgs	Suspected of (See "How the Name (give labeled street #1 Factor VIII-A11) *2 Dose, frequency 8	Irug pro o report ngh & manufac BrandTest-A	duct(s) * section turer, / known AlTestman 3. Therapy	n on reverse)
1. Outcome Death Life-thr	attributed to ad 	verse reaction dd / mm / yyyy)	(check all that apply) Disability Congenital malforma Required intervention damage / permanent	tion	#1 540,, #2		#1 From 02-02-2 #2	(dd / mm / yyyy) - To (dd / mm / yyyy) IMNI - 02-02-2004
Hospit: DD M 18 4. Describe r	d time of reaction d time of reaction M 2004 eaction or prob	ged Y 4 Iem	Other:	4. YYYY 2004	Indication for use o product #1 BleedSpontaneo #2	f suspected	drug	5. Reaction abated after use stopped or dose reduced #1 Yes No 🖌 Doesn't apply #2 Yes No 🖌 Doesn't apply
Reaction T Free text m Canada "A	ype:Palpitation ay be entered I dverse Event"	is Length of R here which wil form.	eaction:Hrs I be entered onto the He	alth 6.	Lot # (if known) #1 <u>A1LOT2</u> #2	7. Exp. dat #1 (dd / mn #2	e (if known) 1 / yyyy) 	8. Reaction reappeared after reintroduction #1 Yes No 🖍 Doesn't apply #2 Yes No 🖌 Doesn't apply
5. Reievant 1	ests / laborator	y data (includin	g dates (dd / mm / yyyy)	9.	Concomitant drugs (dd / mm / yyyy) (excl "Adverse Event")). Treatment of adv (dd / mm / yyyy) Free text may be e "Adverse Event"	(name, dose ude treatmen ntered here form. erse reaction ntered here form.	e, frequency at of reaction which will n (drugs and which will	and route used) and therapy dates be entered onto the Health Canada / or therapy), including dates be entered onto the Health Canada
Coagulatio VWFAg:[1	n-Date: [01-Ja] vant history, im	n-2000 FII: [1	The sting medical conditions	C:[1] 1. /sfunction)	. Reporter (See "Confid Name, address & pl Dr. Al Familydoc A Al Test Hospital	ientiality tone numbe Al Familydo	" sectio r.	on on reverse)
Free text n Canada "/	iny be entered adverse Event"	here which wi form.	ll be entered onto the He	alth 2.	Health professional	? 3.Occupa	tion	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	eaction	v3.1.0 Copyri	ght © 1999-2003 AHC			
A Patient Infor	mation	eaction .	Select Path	ent Name: P	All lestperson An	drew	_
1.Patient ID: HM	100995 Chart Nu	mber: 1234	2. Age: 44	DOB: 01-Jan-	1960 3. Sex: N	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	sath LifeThre	eat Hospitilized Prolo	onged Stay Disa	bility Congenital	Intervention Oth	er If Other Please Spe	ecify
		Submit It Now?				×	
Date of Reaction:	18-Apr-2004 Da		u sure uou want h	submit it pow?		action Length:	+ hrs
C. Suspected D	rug Product(s)	You ca	an't change the in	formation once it	has been submitted	II	
Prin	nary	I .					
Lot #: 🗛	1LOT2	_			ĩ	BrandTest-A1Test	tmanufacturer
Frequency:		=	<u>es</u>		_	neous	<u> </u>
Houte:	2.Eeb.2004	To: 02-Eeb-2004	Read	tion abated after		Reaction reappeare	
Therapy From: 102	.1 60-2004	10.021002004		ped or dose redu		arter reintroductio	
B.4 Reaction	B.5 Tests	B.6 History	C.9 Drugs	C.10 Treat	nent		ı
-		Enter yo	our descriptive inform	nation in the box bel	ow		
Free text may be	entered here which	will be entered onto	the Health Canad	a "Adverse Even	it'' form.		
			10 MMA	<u> </u>			
D. Reporter	.1FAA1FA 💽 Dr.	A1Familydoc	A1Familydoc	Address			
Health Professional	?	Test Hospital	st · [1111	Address2	<u> </u>		
Reported to Manuf	.? 🗹 Entered By: Sus	an HeadNurse		Date Sent		Edit Add	Exit
Entered: 18-Apr-20	04		4			**	
Nounea: 18-Apr-20							
					Send Adver	rse Reaction Rpt via th	ne internet

Product Reaction Adverse Drug Rea A Patient Information	v3.1.0 Copyright © 1999-2003 AHCDC Select Patient Name: ATTestperson An	drew _
1.Patient ID: HM100995 Chart Number:	1234 2. Age: 44 DOB: 01-Jan-1960 3. Sex: M	4. Height 157 5. Weight 73
B. Adverse Reaction		om kgs
Death Date of Death LifeThre	ta Access Security	f Other Please Specify
	CHARMS	i outer riedae opeony
Date of Reaction: 18-Apr-2004 Da	Data Web Login	action Length: hrs
C. Suspected Drug Product(s)		
Primary	please enter your Clinic's Login Username and Password in	
Lot #: A1LOT2	helds below then click UK.	BrandTest-A1Testmanufacturer
Frequency:	Llinic Username: HAM	neous 👻
Route:	Password:	eaction reappoared
Therapy From: 02-Feb-2004		after reintroduction: N/A
P 4 Penation P 5 Teste	<u>QK</u> <u>C</u> ancel	J
D.4 Heaction D.5 Tests	Factor and developing information in the term below.	
Free text may be entered here which will be	e entered onto the Health Canada "Adverse Event" form	
The less may be entered here when will be		
A1FAA1FA - Dr. A	1Familydoc Alfamilydoc Address1:	
Health Professional ?	Address2:	
Reported to Manuf. ? V Entered By: Susan He	adNurse Date Sent	Edit Add Exit
Entered: 18-Apr-2004		
Modified: 18-Apr-2004	<u> </u>	

Only HTC authorized personnel may submit Adverse Reaction Reports.

ADVERSE REACTION REPORTING - CHARMS DATA WEB

🗉 Product Reaction 💌
x3.1.0 Copyright 0 1999-2003 AHCDC
Adverse Drug Reaction Select Patient Name: AlTestperson Andrew
1.Patient ID; IMI 10995 Chart Number: 1234 2. Age: 44 DDB: U1Jan-1950 3. Sex; M 4. Height 157 5. Weight: 73 D. A. June Das Start
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 Set your web password first using the web page that will be displayed next.
Primary Once you ve set you te can te submit this report.
Lot # A1LOT2 ast-A1Testmanufacturer
Frequency: OK
Route: Heaction abated after use Heaction reappeared
Therapy From: 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 onto the Health Canada "Adverse Event" form.
D. Reporter
ATFAATFA - Dr. ATFamilydoc Atfamilydoc Addresst
Health Professional ? Phone: (905) 1111 Ext: 1111 City:
Reported to Manuf. ? 🗹 Entered By: Susan HeadNurse Date Sent: Edit Add Exit
Entered: 18-Apr-2004

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>
	Username:
	Password:
	< Login >
	Change Password I Forgot My Password

ADVERSE REACTION REPORTING – CHARMS DATA WEB – CHANGING YOUR PASSWORD

	CHARMS Data Web Login
	Username:
	Password:
E	Enter your old password above then enter a new password below. Enter the new password a second time to confirm the change then lick login as usual to change your password as well as login.
Viicona	When choosing a new password please keep security as paramount mportance and select a password of sufficient complexity so it cannot be guessed. As guidelines: use a minimum length of 8 characters and a combination of upper and lower case letters, numbers and symbols e.g. "MyAcct\$1". Do not use birthdates or iny combination of family member names.
	New Password:
R	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.

A Patient Information 1.93.0 Copyright @ 1999-2003 AHCDC A. Patient Information Image: All Content Name: Conten
A. Patient Information 1. Patient Information 1. Patient ID: HM100995 Chart Number: 1234 2. Age: 44 D0B: 01.Jan-1960 3. Sex: M 4. Height: 157 5. Weight: 73 cm kgs Outcome attributed to adverse reaction (check all that apply) Death LifeThreat Hospitilized Prolonged Stay Disability Concernent Hospitilized Prolonged Stay Disability Date of Reaction: 18-Apr-2004 Concernent Hospitilized Prolonged Stay Disability Date of Reaction: 18-Apr-2004 Concernent Hospitilized Prolonged Stay Submission of your Adverse Reaction report was SUCCESSFUL Primary Disability Disability Lot #: AllOT2 Disability
1. Patient ID: HM100995 Chart Number: 1234 2. Age: 44 DOB: 01.Jan.1960 3. Sex: M 4. Height: 157 5. Weight: 73 B. Adverse Reaction Outcome attributed to adverse reaction (check all that apply) 0utcome attributed to adverse reaction (check all that apply) 0utcome attributed to adverse reaction (check all that apply) 0utcome attributed to adverse reaction (check all that apply) Death Date of Death LifeThreat Hospitilized Prolonged Stay Disability Congenital Intervention Other If Other Please Specify Adverse Reaction: 18-Apr-2004 Adverse Reaction Submission Submission of your Adverse Reaction report was SUCCESSFUL n n Length: n hrs Lot #: A1L0T2 OK OK OK N
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 C. Suspected Drug Product(s Submission of your Adverse Reaction report was SUCCESSFUL Primary Lot #: A1LOT2 DK
Death Date of Death LifeThreat Hospitilized Prolonged Stay Disability Congenital Intervention Other If Other Please Specify Date of Reaction: Adverse Reaction Submission SUCCESS Date of Reaction: Image: Comparison of your Adverse Reaction report was SUCCESSFUL Primary Submission of your Adverse Reaction report was SUCCESSFUL Date #: A1LOT2
Adverse Reaction Submission SUCCESS Date of Reaction: 18-Apr-2004 C. Suspected Drug Product(s Primary Lot #: A1L0T2
Date of Reaction: 18-Apr-2004 Image: mark the section report was SUCCESSFUL C. Suspected Drug Product(s Submission of your Adverse Reaction report was SUCCESSFUL Primary Lot #: A1L0T2
C. Suspected Drug Product(s Submission of your Adverse Reaction report was SUCCESSFUL Primary Lot #: A1LOT2
Primary Image: Constraint of the stream of
Lot #: A1LOT2 ndTest-A1Testmanufacturer
Frequency:
Route: Reaction abated after use Reaction reappeared
Therapy From: 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 onto the Health Canada "Adverse Event" form.
D. Reporter
Hospital Al Test Hospital Al Test Hospital Address2:
Reported to Manuf ? V External Bar Susan Headfalurse
intered: 18-Apr-2004 Contraction Countries and the Country of Coun
odified: 18-Apr-2004

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
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) dick 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 you 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