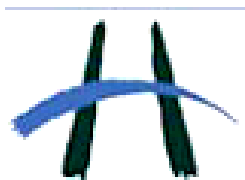


Hamilton – Niagara Regional Hemophilia Program

Procedures

In the Operation of the Regional Coagulation Factor Concentrate
Tracking Program

Affiliated with Hamilton Health Sciences, McMaster University, Canadian Hemophilia Society, Canadian Blood Services, and Regional Hospitals.



Forward

An accurate and verifiable tracking system requires cooperation and active involvement of Canadian Blood Services, the Regional Hemophilia Treatment Centre, Regional Hospitals and individuals who use concentrates, particularly those on home care. This manual describes procedures used by these parties within the regional tracking system in the Hamilton region. The actual tracking system has been described (see Walker, IR et. al. Transfusion 2003;43:556-562).

For further information, contact the Hamilton-Niagara Regional Hemophilia Program (905 521 2348) or MDT Software (905 560 9682).

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Introduction

Purpose

This manual outlines procedures used by the Hamilton-Niagara Regional Hemophilia Program to track factor concentrates throughout its region, describing standard operating procedures for all personnel and methods for validating data. The purpose of the tracking system is to monitor treatment practices and outcomes, record adverse events, manage recalls, minimize wastage, and to monitor utilization and supply particularly during shortages. A tracking system is necessary to fulfil recommendations of the Commission of Inquiry on the Blood System in Canada ('Krever'). We wish to emphasize that these Standard Operating Procedures evolved only after a number of months of planning which involved the hemophilia clinic, the Canadian Blood Services Hamilton Centre, regional hospitals, and the regional branch of the Canadian Hemophilia Society. We strongly advise, before instituting these or similar standard operating procedures, that face-to-face meetings between the involved parties be held. Also to be emphasized is the need for Verification (Reconciliation) of data without which accuracy, and therefore usefulness, will not be maintained. We also emphasize that it is necessary for the clinic as a whole to 'buy in' to the concept of tracking, otherwise the system will fail; all members have a role to play in maintaining the system, the starting point being the patients' records. These must be reviewed frequently, and referred to by medical, nursing and administrative staff, when interviewing patients.

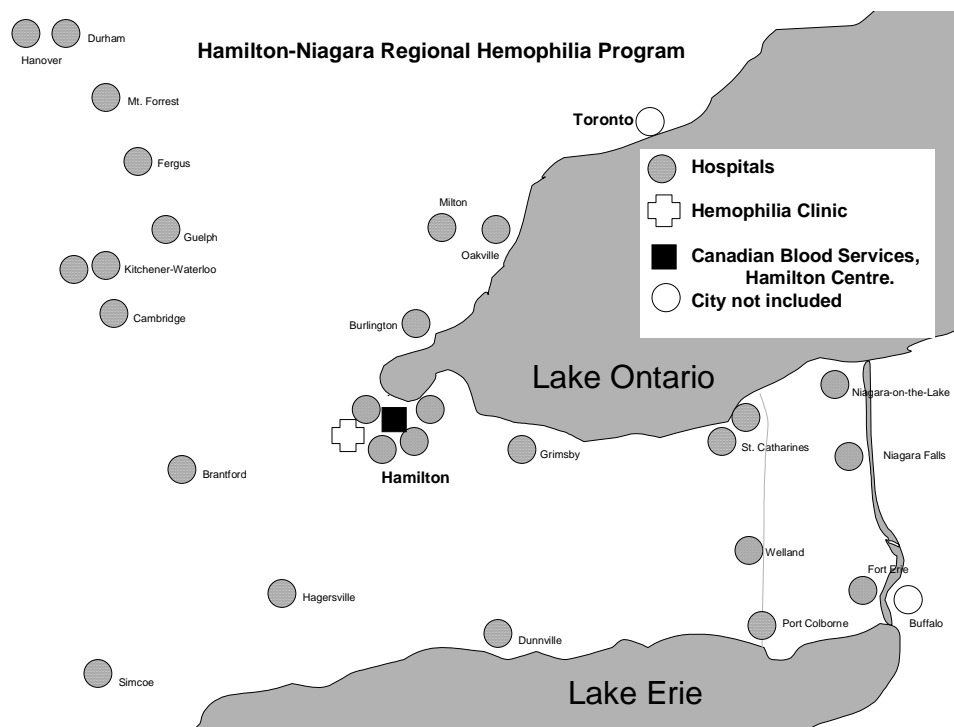
The Hamilton-Niagara Regional Hemophilia Program

The Hamilton-Niagara Regional Hemophilia Program is one of 24 comprehensive hemophilia treatment centres across Canada, providing multidisciplinary service to patients living in the area bordered, approximately, by Niagara Falls, Oakville, Hanover, Kitchener and Simcoe. There is an active home care program. The number of patients with coagulation disorders, and the area serviced, are set out below. The clinic is staffed by adult and pediatric hematologists, a nurse coordinator, a physiotherapist, a social worker, secretary and data coordinator. Key to the tracking system are the nurse coordinator and secretary, who manage the blood products and monitor patient diaries, and the data manager who communicates with, and receives data from, the CBS, regional hospitals and clinic staff, and enters this data into the computer program CHARMS.

Factor	Severity	≤ 18 years	>18 years	Total
VIII	Mild	12	42	54
	Moderate	3	9	12
	Severe	20	28	48
	with Inhibitor	0	9	9
Total VIII		35	88	123
IX	Mild	6	7	13
	Moderate	1	7	8
	Severe	5	11	16
Total IX		12	25	37
Total VIII and IX		47	113	160

Other: VII-3; X-3; XI-12; XIII-3; VWD-54; dysfib.-3; acqu. hemophilia-2

Introduction



Coagulation Factor Concentrates

Used for the treatment of people with disorders of blood clotting, usually hemophilia. Factor concentrates are manufactured either by fractionation of human plasma, or by DNA technology (recombinant type). Factor concentrates are distributed by Canadian Blood Services Hamilton Centre (CBS), to approximately 27 hospital blood banks and the Hamilton Regional Hemophilia Clinic (see figure 1).

Factor Concentrates are given by intravenous infusion to affected individuals, either by health professionals at hospitals, or by themselves when they have been trained to do so. For individuals who bleed frequently, the ready access and injection of factor concentrates in the home leads to less delays and more effective resolution of bleeding.

The Home Care Program

This is a function of the Hamilton-Niagara Regional Hemophilia Program. Individuals or their relatives are trained to infuse factor concentrate individually, paying attention to timeliness, sterility, disposal of used materials, and reporting progress to the clinic. Individuals are subject to regular comprehensive reviews by the multi disciplinary clinic, at least once per year for adults, and more frequently for children.

Introduction

Safety of Factor Concentrates

Factor concentrates are generally very safe; in the past they transmitted hepatitis viruses and HIV; this is no longer the case but there continues to be concern about possible transmission of infectious agents in the future, currently 'new variant Creutzfeld Jacob' (nvCJD) disease. Factor concentrates on occasion cause allergic reactions and, if infused too rapidly, may cause disturbing sensations.

The Commission of Inquiry on the Blood System in Canada ('Krever') found that deficiencies had occurred in the 1980's in the testing, the distribution, the monitoring, and the reporting of side effects of blood products. A tracking system for factor concentrates, involving all of the pathways during distribution and use, are needed. Factor concentrates are distributed to individual's homes, beyond hospitals and beyond the surveillance of the health care system. A validated tracking system requires cooperation between Canadian Blood Services, regional hospital blood banks, the hemophilia clinic and individuals with hemophilia.

Collation of data

Data is forwarded by CBS, regional hospital blood banks, and individuals with hemophilia to the hemophilia clinic which collates the data, entering it into the CHARMS computer program. Briefly, CBS submits data on issues of product to hospitals, hospital blood banks submit data concerning infusions, home care supplies, returns to CBS and breakages, and patients provide infusion (bleed) diaries. Inventories are crossed checked with utilization data.

Computerization

All Canadian hemophilia clinics are provided by the Association of Hemophilia Clinic Directors of Canada with a database program called CHARMS (Canadian Hemophilia Assessment and Resource Management System). This program is specifically designed for hemophilia clinics and is an essential component in a factor concentrate management system. All data received by the hemophilia clinic is entered and analyzed through this program.

Validation

Verification (Reconciliation) is carried out by the data coordinator. The basis for reconciliation is agreement between statements of inventories at hospital blood banks and homes of individuals, on the one hand, with expected inventories as compiled by the clinical computer from the issue and utilization data provided by these same parties over a prior period.

Procedure 1

Hamilton Health Sciences	Department Manual
Posting Date: 2004-04-20	Page 4 of 57
<i>Title:</i> PED-HEMO - CBS Distribution Data: Transfer To Program Data Manager, Data Entry And Quality Control.	

Applies to: Staff of the Product Distribution Department of the Canadian Blood Services, and HHS Data Manager for Factor Concentrate Tracking System in the Hemophilia Clinic, 3F, McMaster site.

1.0 Purpose

- 1.1 To collect distribution data from CBS for factor concentrates in a region, to be entered into the [CHARMS](#) database.
- 1.2 To audit data sent from CBS for accuracy and specificity.

2.0 Equipment

CHARMS software program.

3.0 Procedure

See Table below

4.0 Documentation

Disposition Report: A CBS report summarizing all issues of product over a stated time period, and used by the Factor Concentrate Tracking Program to confirm that all packing slips were received. It indicates the date of issue from the CBS, the facility the product was delivered to, the lot number, unit per vial, and quantity of product sent.

FPMS Products with Lot Numbers: CBS report of current product, lot numbers and their expiry dates

Packing Slips: Forms from the CBS describing product issued

5.0 Definitions

Brand Name: The manufacturers assigned name of a product eg. Kogenate FS, Humate –P, BeneFIX.

Canadian Hemophilia Assessment and Resource Management System (CHARMS): A computer database program designed for Canadian hemophilia clinics.

Canadian Blood Services (CBS): The factor concentrate distributor.

Canadian Blood Services, Product Distribution Department: The division of the CBS

that is responsible for issuing the factor concentrate to the regional facilities.

Expiry Date: The date on which a lot expires.

Factor Concentrate: A lyophilized concentrate of coagulation factor used to treat a factor deficiency (e.g. Factor VII, VIII, IX, XIII, von Willebrand Factor.)

Factor Concentrate Tracking System: A system operated by the hemophilia clinic to coordinate and collect data on distribution, use and side effects of factor concentrate from the CBS, facilities and patients.

Issue: To allocate factor concentrate to a facility or person.

Lot Number: A unique number assigned to a batch (lot) of factor concentrate. Each lot number describes a specific brand name, product name, manufacturer, and units per vial.

Manufacturer: The company that makes the particular Brand Name, eg. Bayer, Baxter.

Product: A general term to describe the factors that are in a concentrate (i.e. Factor VIII, Fibrinogen, Factor IX)

Units Per Vial (UPV): Indicates the content of factor in a vial.

6.0 Cross References

PED - HEMO – Data Entry for the Factor Concentrate Tracking System Database - CHARMS

7.0 External References

none

8.0 Developed By/In Consultation With

Programmer for CHARMS software

9.0 Approved By

Hemophilia Program Co-Directors
Manager, Hemophilia Clinic 3F McMaster site

10.0 Posting Dates

Initial Posting Date: 2004-04-20

11.0 Keyword Assignment	Pediatric, hemophilia,
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12.0 Table

Procedure

*The *CHARMS Data Entry Screen* Column lists sections of CHARMS for data entry, where applicable. There are 3 main sections of CHARMS that are used for the data entry: *Product Master*, *Regional Product Inventory* and *Patient Product Inventory*. *Product Master* lists Manufacturers, Brand Names, product characteristics and available lot numbers; *Regional Product Inventory* lists the products, with lot numbers and amounts, distributed to each of the regional facilities; *Patient Product Inventory* provides details of products distributed to individuals for home (self-) care. This procedure describes the transfer of information from CBS to the Data Manager, data entry into the *Product Master* and *Regional Product Inventory* sections of CHARMS, and the quality control measures which ensure accuracy

Data Source	Work Instructions	CHARMS Data Entry Screen*	Rationale
12.1 CBS Information - Packing Slips	<p>.1 CBS Product Distribution Department duplicates the Packing Slip that accompanies each shipment of factor concentrate to a facility (hospital or clinic).</p> <p>.2 CBS faxes the duplicated Packing Slips to the Data Manager on the same day of the shipment.</p> <p>.3 CBS sends Disposition Report to the Data Manager weekly.</p>		<p>This provides the Factor Concentrate Tracking System with information on all Factor Concentrates that are issued from the CBS to regional facilities.</p> <p>A quality control measure to double check that all Packing Slip information has been received.</p>
	<p>.4 The Data Manager enters the following information from the Packing Slips into the CHARMS database:</p> <ul style="list-style-type: none"> • Facility product was sent to • Brand • Lot Number • Number of vials 	- <i>Regional Product Inventory</i>	<p>This is the starting point for the tracking of Factor Concentrates. The inventory of factor concentrates for each facility is generated from the Packing slips.</p>

	<ul style="list-style-type: none"> • Date product ordered • Date delivered to facility • Shipment ID# • Patient initials for designated lots if applicable. 		
	<p>.5 Data Manager stores Packing Slips for later verification and discrepancy resolution.</p>	<p><i>- Product Master</i></p>	<p>New lot numbers are identified when the software will not accept the entry.</p> <p>Packing Slips and Disposition Reports do not indicate expiry dates, refer to FPMS.</p>
<p>12.2 CBS Information - Disposition Reports</p>	<p>.1 CBS Product Distribution Department generates Disposition Reports at the end of each week and faxes these to the Data Manager. These weekly reports cover a continuous period of time; the start date of the current report is the stop date of the previous report.</p>		<p>Disposition Reports are summaries of information on the individual Packing Slips. Review of Disposition Reports is a check that all Packing Slips have been received.</p>
	<p>.2 Packing Slips for the time period listed on the Disposition Reports, are compiled.</p>		

	<p>.3 The Disposition Reports are checked to ensure each Packing Slip issued has been received. The following discrepancies can be rectified by this process:</p> <ul style="list-style-type: none"> • if the Disposition Reports lists an issue for which the CBS has not faxed a Packing Slips, the Data Manager can enter, the issue data from the Disposition Reports (without a shipment ID#) Data Manager requests a copy of the missing Packing Slip. • if there is a Packing Slip for a factor concentrate that is not listed on the Disposition Reports, the CBS has not sent a complete Disposition Report. CBS Product Distribution Department will be contacted for the missing section of the Disposition <p>.4 Data Manager files Disposition Reports consecutively for further</p>		<p>Data entry errors that arise in further steps can be rectified with</p>
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	discrepancy resolution.		these stored reports.
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Procedure 2

Hamilton Health Sciences	<u>Departmental Manual</u>
Posting Date: 2004-04-20	Page 10 of 57
<i>Title:</i> HEMO – Issuing Factor Concentrate	

Applies to: HHS Transfusion Medicine Laboratory Technologists

1.0 Purpose & Goals Description

1.1 To supply patients on the “Home Care Program” with an “Appropriate” factor concentrate supply as ordered through the Hamilton Niagara Regional Hemophilia Clinic.

1.2 To assure all Factor Concentrate ordered within the region (Central Western Ontario) is appropriate and reasonable.

2.0 Equipment

Fax machine

3.0 Procedure

- 3.1 Receive pending order from the Hamilton-Niagara Regional Hemophilia Clinic.
- 3.2 Receive concentrate from CBS designated for patient named on Order Verification Form.
- 3.3 Compare Order Verification Form with factor product received.
- 3.4 Complete Patient Issue Sheet with the patient name, brand of product, lot numbers, unit size, number of vials and product expiry date.
- 3.5 Dispense order to the patient/family, Patient Issue Sheets to be signed by person picking up order.
- 3.6 Complete Tracking Product form with each dispensed order.
- 3.7 Fax the Tracking Product Form weekly/bi-weekly (as often as required by Hemophilia Clinic for each hospital) to data manager at the Hamilton-Niagara Regional Hemophilia Clinic using the number on the form.

4.0 Documentation

Tracking product forms
Patient Issue Sheet
Order verification form

5.0 Definitions

Factor Concentrate: A lyophilized concentrate of coagulation factor used to treat a factor deficiency (i.e. Factor VII, VIII, IX, XIII, Von Willebrand's Disease).

Home Care Program: A program of the hemophilia clinic that trains patients and/or families to do intravenous infusions of factor concentrates and monitors responses.

Region: The geographical area.

Infusion Diary: A form to document each infusion of factor concentrate, with the date, reason for infusion, type of product, amount of factor and lot number.

Order Verification Form: A clinic form notifying facilities of a homecare supply of a specific patient to be issued by the CBS to that facility.

Tracking Product Form: A form used by facilities to document product supplies that are issued to patient and/or hospital area's (e.g. ward, emergency room).

Patient Issue Sheet: A document used by facilities that list factor, lot number, factor expiry date and number of vials issued to patients, with the patients sign-off.

6.0 Developed By

J. Sek

7.0 In Consultation With

J. Carruthers

T. Almonte

I. Walker

8.0 Approved By

Co-Directors Hemophilia Program

Manager, Children's Health Acute Care

9.0 Posting Dates

Initial Posting Date: 2004-04-20

10.0 Keyword Assignment	hemophilia
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Procedure 3

Hamilton Health Sciences	<u>Departmental Manual</u>
Posting Date: 2004-04-20	Page 12 of 57
<i>Title:</i> HEMO –Factor Concentrate Tracking - Collection of Data from Regional Facilities on Factor Usage and Distribution Procedure	

Applies to: **Data Manager for Factor Concentrate Tracking System and the Regional Facility Blood Banks.**

1.0 Purpose

To collect information on the usage and distribution of [Factor Concentrates](#) from the regional facilities, and enter this into the [CHARMS](#) database.

To audit information sent from regional facilities, for detecting discrepancies between the inventory statements of the facility and that of the [CHARMS](#) database.

2.0 Equipment

[CHARMS](#) software program

3.0 Procedure

3.1 See Table below for Factor Concentrate Tracking procedure

- 3.1.1 *The **CHARMS Data Entry** column lists the section of CHARMS for data entry. There are 3 main sections of CHARMS that are used for the data entry:
- ***Product Master,***
 - ***Regional Product Inventory and***
 - ***Patient Product Inventory.***

4.0 Documentation

none

5.0 Definitions

Canadian Hemophilia Assessment and Resource Management System (CHARMS): A computer database program designed for the Canadian hemophilia clinics.

Canadian Blood Services (CBS): The factor concentrate distributor.

Canadian Blood Services, Product Distribution department: The division of the CBS that is responsible for issuing the factor concentrate to the regional facilities.

Facility: Regional hospital or hemophilia clinic.

Factor Concentrate: A lyophilized concentrate of coagulation factor used to treat a factor deficiency (e.g. Factor VII, VIII, IX, XIII, von Willebrand Factor.)

Factor Concentrate Tracking System: A system operated by the hemophilia clinic to coordinate and collect data on distribution, use and side effects of factor concentrate from the CBS, facilities and patients.

Infusion: An intravenous injection of factor concentrate.

Home Care Program: A program of the Hemophilia Clinic that trains patients and/or families to do intravenous infusions of factor concentrates and monitors responses.

Issue: To allocate factor concentrate to a facility or person.

Prophylactic Treatment: The infusion of factor concentrate to prevent a bleed.

Brand Name: The manufacturers assigned name of a product, e.g. Kogenate FS, Humate –P, BeneFIX.

Product: A general term to describe the factors that are in a concentrate (e.g. Factor VIII, Fibrinogen, Factor IX).

Manufacturer: A company manufacturing factor concentrates, e.g. Bayer, Baxter.

Units Per Vial (UPV): The content of factor in a vial.

Lot Number: A unique number assigned to a batch (lot) of factor concentrate. Each lot number describes a specific brand name, product name, manufacturer, and units per vial.

Data Manager: The person responsible for coordinating data flow from the CBS, facilities and patients, and for entry into CHARMS.

6.0 Cross References

Audit Discrepancy Report: Lists a history of a product lot number that has failed reconciliation.

Audit Reply: A report indicating full agreement between a facility inventory report and the CHARMS database.

Facility Audit Log: A log of dates of correct and fully reconciled facility inventories of factor concentrate.

Facility Checklist: A report documenting the receipt of Tracking Logs from facilities.

Facility Inventory Report : A statement of a facility's current inventory of factor concentrate.

Factor Concentrate Tracking Log: A log maintained by each facility in the region indicating the disposition of factor concentrates, the date of issue, the brand, the lot number, the quantity (# of vials), who it was issued to and the purpose of the issue.

7.0 External References

Cecilia Stiles, programmer for CHARMS software

8.0 Developed By/In Consultation With

Theresa Almonte
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9.0 Approved By

Co-Directors Hemophilia Program
Manager, Children's Health Acute Care

10.0 Posting Dates

Initial Posting Date: 2004-04-20

Review/Revision Posting Date: yyyy-mm-dd

11.0 Keyword Assignment	Blood, CBS
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12.0 Table - Factor Concentrate Tracking

Data Source	Work Instructions	CHARMS Data Entry Screen	Rationale
12.1 Factor Concentrate Tracking Log	.1 Facilities enter the following information in the Factor Concentrate Tracking Log each time Factor Concentrate is issued, either to a patient for home care or to a clinical area for infusion: <ul style="list-style-type: none"> • Date of issue • Patient name • Brand name • Lot number • Number of vials • Purpose for issue (Homecare, Bleed and site of bleed, Surgery, Prophylaxis) 		The Data Manager is provided with all information on all issues and uses of concentrate from or at all facilities.

	<p>.2 If a product is disposed of, returned, transferred or discarded by a facility the following information will be listed in the "Discarded/Returned/Transferred" section of the Factor Concentrate Tracking Logs:</p> <ul style="list-style-type: none"> • Date • Brand Name • Lot number (s) • Quantity removed • Reason for removal (discard, returned, recalled, disposed, transferred) • Location product was transferred to if applicable <p>.3 The regional facilities fax the Tracking Log to the Data Manager weekly. Facilities that issue product infrequently may fax this report only when they issue product, but in the absence of any issues the status of inventory needs to be confirmed at intervals, either by faxing a blank Tracking Log, or by phone (as arranged with the Data Manager)</p> <p>The Factor Concentrate Tracking Log is faxed to the Data Manager for entry into the database.</p>	<p>- Regional Product Inventory or Patient Product Inventory (issues for Home Care), and Bleed Diary (for infusions at facility).</p>	<p>The Tracking Log is used also to record changes in inventory other than by distribution to patients e.g. returned to CBS, outdated, damaged.</p> <p>The Factor Concentrate Tracking Logs cover a time period that is continuous. The stop date of a previous report is the start date for the next report.</p> <p>Data Manager enters data from the Tracking Log into CHARMS: Issues to patients (home care), issues for infusion at the facility (E.R., ward etc.), disposals, and returns to CBS.</p>
<p>12.2 Facility Inventory Report</p>	<p>.1 Every 2-3 months, facilities are asked to provide to the Factor Concentrate Tracking System a Facility Inventory Record listing all factor concentrates on site at that time. Data includes:</p> <ul style="list-style-type: none"> • Product Name • Brand Name • Lot number • Number of vials <p>The report is faxed to the Data</p>		<p>The inventory provided by each facility is compared with that generated by the CHARMS database from previously received packing slips (from CBS) and Factor Concentrate Tracking Logs (from facilities). The Facility Inventory Report and</p>

	<p>Manager.</p> <p>.2 The Facility Inventory Report is compared with the inventory generated by the CHARMS database. If discrepancies between the two inventories are identified, see 12.3. If there are no discrepancies between inventories, see 12.4.</p>		CHARMS should match exactly.
12.3 Audit Discrepancy Report	<p>.1 If a facility's Facility Inventory Report and the CHARMS database inventory don't match an Audit Discrepancy Report is generated. This report lists the following information:</p> <ul style="list-style-type: none"> • Facility name • Date of audit • Date of previous audit (which acts as a baseline for current audit) • Product Name and Lot Number involved. • Number of vials present in current inventory (from Facility Inventory Report) and number of vials calculated by CHARMS database • History of CBS issues to that facility (as provided by CBS), including dates, and quantity issued • Detailed history of issues to patients, transfers, discards and returns for that facility (as provided by the facility on Tracking Logs). • A calculation of the values in the CHARMS database, for the time period, including totals for each lot, as follows: <p>CBS issues – Issues from Facility (including transfers, discards etc) = Current Inventory</p> <p>.2 This report is then faxed to the facility.</p> <p>.3 The facility will then forward corrections to the Data Manager either by fax or phone.</p>		The Audit Discrepancy Report informs the facility that an error has occurred, thereby starting a process of correction and reconciliation.
12.4 Audit	.1 Once a correct Facility		The Audit Reply

Reply	<p>Inventory Report is received by the Data Manager the Audit Reply is generated and faxed to the facility.</p> <p>.2 When Facility Inventory Report is correct, the date of the audit and the facility name is recorded in the Facility Audit Log.</p>		<p>informs the facility of agreement between their Facility Inventory Report and CHARMS calculated inventory, thus verifying the information on the Tracking Logs, with corrections if any.</p> <p>The Facility Audit Log is a record of each facility's past reconciliations.</p>
12.5 Facility Checklist	<p>.1 The Facility Checklist records the contact information for each facility, past phone calls, past submissions of Tracking Logs and past audits. The following information is recorded for each facility:</p> <ul style="list-style-type: none"> • Name of facility and number (assigned by Data Manager). • Phone number. • Name of contact. • Recommended frequency of phone calls for this facility (usually every two weeks) • Dates of calls • End date of last Factor Concentrate Tracking Log submitted (the start date of the current Log) • Date of previous audit (Facility Inventory Report) <p>.2 Phone calls to facilities using the checklist:</p> <p>Facilities that issue product regularly submit Factor Concentrate Tracking Logs weekly whether product is issued or not. They are phoned on approx the 15th and 30th of each month whenever Factor Concentrate Tracking Logs have not been received.</p>		<p>Phone calls by the Data Manager to the facilities ensure that facilities are keeping their Tracking Logs updated and submitting them regularly. It is very important to keep data as close to current as possible, to be able to cross-check patient inventories, and to facilitate error correction.</p>

	<p>Facilities that issue product infrequently only submit the Factor Concentrate Tracking Logs when they have issued, transferred, discarded or returned product (low volume facilities). These facilities receive a phone call on the 30th of each month, and will usually give a verbal confirmation that they have not issued product since the last submission or phone call. (this must be arranged by the facility and the Data Manager).</p> <p>If a facility has not issued product since the last Factor Concentrate Tracking Logs date, they can verbally tell the Data Manager that they have not issued product for that time period. However, if the facility has issued product since the last phone call or Factor Concentrate Tracking Log submission, they are asked to submit a current Factor Concentrate Tracking Log.</p>		
12.6 Storage of Reports	<p>.1 The Data Manager stores the Factor Concentrate Tracking Logs, Facility Inventory Report, Audit Discrepancy Report and Audit Replies by facility, then chronologically.</p> <p>.2 The Facility Checklists are filed separate from the above reports, and chronologically.</p>		The stored reports are often useful in compiling a history when solving complicated discrepancies, and inventories in the Facility Inventory Reports can be used as baseline in subsequent Audit Discrepancy Reports.

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Procedure 4

Hamilton Health Sciences	<u>Departmental Manual</u>
Posting Date: 2004-04-20	Page 19 of 57
<i>Title:</i> HEMO – Ordering Factor Concentrate	
Applies to: HHS Hemophilia Nurse Coordinator or Delegate	

1.0 Purpose

1.1 To supply patients on the “Home Care Program” with an Appropriate Factor Concentrate supply as ordered through the Hamilton Niagara Regional Hemophilia Program.

1.2 To assure that all Factor Concentrate ordered within the region (Central Western Ontario) is appropriate and reasonable.

2.0 Equipment

Treatment guidelines/ standing orders for factor doses

Telephone

Fax machine

E-mail

CHARMS software

3.0 Procedure

3.1 Patient/family telephones or emails hemophilia clinic to request factor concentrate (clinic requires 3 business days to complete order).

3.2 Hemophilia Nurse Coordinator or Delegate checks with the patient/family and CHARMS data that monthly diary submission is current and checks current factor inventory remaining in patient’s home against CHARMS data. If not current, diary must be submitted when factor concentrate is picked up by patient/family.

3.2.1 [insert next number] Each order will be documented (including date and product quantity) under patient name in the Tracking Binder.

3.3 A four (4) week factor supply (see definition of ‘appropriate’ above) will be ordered on the Canadian Blood Services Product Distribution Fractionation Order Form (F3411) then faxed to the local CBS office. In some circumstances, e.g. when bleeding is rare, or when diaries are not being received reliably, a smaller supply may be ordered.

3.4 Complete the Order Verification Form and forward to the facility which is to receive the order from CBS (only when homecare supplies are picked up from a facility other than the clinic).

3.4.1 [insert next number] Each dispensed order to be documented on Tracking Product Form when homecare supplies are picked up at the clinic.

4.0 Documentation

Tracking Product Form

Product Distribution Fractionation Order Form (F3411)

Order Verification Form

Tracking Binder

5.0 Definitions

Factor Concentrate: A lyophilized concentrate of coagulation factor used to treat a factor deficiency (e.g. Factor VII, VIII, IX, XIII, von Willebrand's Disease.)

Home Care Program: A program of the hemophilia clinic that trains patients and/or families to do intravenous infusions of factor concentrates and monitors responses.

Region: The geographical area.

Infusion Diary: A form to document each infusion of factor concentrate, with the date, reason for infusion, brand of product, amount of factor and lot number.

Order Verification Form: A hemophilia clinic form notifying facilities of a homecare order for a specific home care patient to be issued by the CBS to that facility.

Product Distribution Fractionation Order Form (F3411): A CBS form used by facilities to order concentrates from CBS.

Tracking Binder: A binder maintained by hemophilia clinic staff that houses patient names, their factor deficiency, product of choice, the facility where the product is picked up from (by patients) and current year's order.

Tracking Product Form: A form used by facilities to document product supplies that are issued to patients and or different hospital areas (i.e. ward, emergency room).

Appropriate Factor Concentrate Supply: A quantity which meets patients needs, which minimizes inconvenience, which takes into account individual requirements and current national and regional supply. The quantity will vary among individuals and will fluctuate from time to time. A reasonable supply under normal circumstances is about one month.

6.0 Developed By

Julia Sek

7.0 In Consultation With

Theresa Almonte
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Irwin Walker

8.0 Approved By

Co-Directors Hemophilia Program
Manager, Children's Health Acute Care

9.0 Posting Dates

Initial Posting Date: 2004-04-20

10.0 Keyword Assignment	Hemophilia
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Procedure 5

Hamilton Health Sciences	<u>Departmental Manual</u>
Posting Date: 2004-04-20	Page 21 of 57
<i>Title:</i> HEMO – Infusion Diary Completion by Patients	
Applies to: HHS Patients on Hemophilia Home Care Program	

1.0 Purpose

To document the process by which patients on the home care program order their home care supply of factor concentrate and document their factor infusions.

2.0 Equipment

Handheld Computers

3.0 Procedure

- 3.1** The patient or the patient's guardian determines that he will require restocking of his home supply of Factor Concentrate. In most cases this will occur when the patient is left with enough Factor Concentrate for one or two infusions.
- 3.2** The patient or the patient's guardian will call either the Program Secretary or the Hemophilia Nurse Coordinator to place the Factor Concentrate order. The patient is required to give the hemophilia clinic three working days notice for his Factor order.
- 3.3** The Program Secretary or the Hemophilia Nurse Coordinator will advise the patient of when his factor order will be ready for pick up.
- 3.4** The Hemophilia Nurse Coordinator will order the patient's Factor Concentrate from CBS and have it delivered to either the Hemophilia Clinic or the patient's local regional hospital, as negotiated between patient and clinic.
- 3.5** The patient will go to either the Hemophilia Clinic or their local hospital to pick up their Factor Concentrate where they will be required to sign the Patient Issue Sheet for the product they are picking up.
- 3.6** The patient will bring his product home and refrigerate it for proper storage.
- 3.7** The patient will infuse himself with Factor Concentrate as directed by the clinic based on either a predetermined prophylactic regimen or when the patient has experienced injury or a bleed.
- 3.8** Once the treatment is complete the patient will document his/her infusion. The patient has the option of using either the pre-existing paper Infusion Diary or electronically via a handheld computer. Regardless of the means by which the data is documented the patient must provide the following information:
 - 3.8.1 NAME-** The name of the patient for which the data is being documented.
 - 3.8.2 DATE OF INFUSION –** The date the infusion took place.
 - 3.8.3 REASON FOR TREATMENT-** The patient must indicate if the treatment was a prophylactic infusion or for treatment of a bleed or injury.
 - 3.8.4 SITE OF BLEED-** If the patient has treated for a bleed or injury, the site of the bleed must be indicated. (e.g. right elbow)
 - 3.8.5 PRODUCT NAME-** The brand name of the Factor Concentrate used for treatment (e.g. Kogenate FS or BeneFIX).
 - 3.8.6 LOT NUMBER-** The lot number(s) of the Factor Concentrate used.

- 3.8.7 **NUMBER OF VIALS USED** – The number of vials of each Lot Number used.
- 3.8.8 **ADVERSE REACTION**- If the patient experiences a reaction to the infusion such as a rash, they must indicate that on their diary. (They are to contact the clinic as soon as possible if such an event occurs).
- 3.9 There is other data that the patient can also add to the diary that is not required, but up to the discretion of the patient and Hemophilia Nurse Coordinator:
- 3.9.1 **DAYS OFF WORK/SCHOOL**- The number of days the patient is absent from work or school as a result of a bleed or injury.
- 3.9.2 **SWELLING**- If the patient has noticed that the site of bleed or injury is swollen, they can indicate the amount of swelling (mild, moderate or severe).
- 3.9.3 **REASON FOR BLEED**- Why the bleed occurred (trauma or spontaneous)
- 3.9.4 **PAIN** – The amount of pain the patient is experiencing (mild, moderate or severe).
- 3.9.5 **SITE OF CARE** – Where the treatment took place (e.g. home or emergency department).
- 3.9.6 **SITE OF INFUSION** – Where the Factor Concentrate was injected (i.e. hand, elbow).
- 3.10 The patient will keep a continuous log of all infusions on a monthly basis. After his last infusion for the month, the patient will list the amount of Factor Concentrate remaining in his/her possession, on the designated area of the paper diary, including the brand name, the lot number(s) and the corresponding number of vials per lot number. This is referred as the Patient Inventory.
- 3.11 The Infusion Diary must be submitted to the Hemophilia Clinic monthly. These can be mailed, faxed, e-mailed or hand delivered. The patients who use handheld computers must transmit their data via a telephone modem within a week of each infusion.
- 3.12 Once delivered, the program secretary will date the Infusion Diary and begin the reconciliation process.

4.0 Definitions

Brand Name: The manufacturers assigned name of a product, e.g.. Kogenate FS, Humate –P.

Expiry Date: The date on which a lot number expires.

Infusion Diary: A form to document each infusion of factor concentrate, with date, reason for infusion, type of product, amount of factor and lot number of product.

Factor Concentrate: A lyophilized concentrate of coagulation factor used to treat a factor deficiency (e.g. Factor VII, VIII, IX, XIII, von Willebrand's Disease.)

Factor Concentrate Tracking System: A system operated by the hemophilia clinic to coordinate and collect data on distribution, use and side effects of factor concentrate from the CBS, facilities and patients..

Home Care Program: A program of the Hemophilia Clinic that trains patients and/or families to do intravenous infusions of factor concentrates and monitors responses.

Infusion: An intravenous injection of factor concentrate.

Issue: To allocate factor concentrate to a facility or person.

Lot Number: A unique number assigned to a batch (lot) of factor concentrate. Each

lot number describes a specific brand name, product name, manufacturer, content in units per vial, and expiry date.

Manufacturer: The company that makes the particular Brand Name, e.g. Bayer, Baxter.

Nurse Coordinator: The nurse who manages nursing activities and the home care program.

Patient Inventories: The number of vials of concentrate, with lot numbers, in patients' possession.

Patient Issue Sheet: A document used by facilities that list factor, lot number, factor expiry date and number of vials issued to patients, with the patients sign-off.

Product: A general term to describe the factors that are in a concentrate (e.g. Factor VIII, Fibrinogen, Factor IX).

Program Secretary: An individual who works for the Hemophilia Clinic in an administrative capacity.

Prophylactic Treatment: The infusion of factor concentrate to prevent a bleed.

Units Per Vial (UPV): Indicates the content of factor in a vial.

5.0 Documentation

Infusion Diary (formerly Bleed Diary)
Patient Issue Sheet

6.0 Developed By

T. Alimonte

7.0 In Consultation With

J. Sek
I. Walker
J. Carruthers

8.0 Approved By

Co-Directors Hemophilia Program
Manager Children's Health - Acute

9.0 Posting Dates

Initial Posting Date: 2004-04-20

10.0 Keyword Assignment	hemophilia
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Procedure 6

Hamilton Health Sciences	<u>Departmental Manual</u>
Posting Date: 2004-04-20	Page 24 of 57
<i>Title:</i> HEMO – Data Collection, Validation, and CHARMS Entry of data from Infusion Diary	
Applies to: Hemophilia Nurse Coordinator, Program Secretary, Data Manager for Factor Concentrate Tracking System and Patients who are on the Home Care Program	

1.0 Purpose

1.1 To describe the collection and audit of data from Infusion Diaries.

1.2 To describe documentation of the collection and audit process.

2.0 Equipment

CHARMS software program

3.0 Procedure

For procedure, please see Table below

4.0 Definitions

Audit: Examine and check the validity of data.

Brand Name: The manufacturers assigned name of a Product, (most commonly used). i.e. Kogenate FS, Humate –P, BeneFIX.

Data Manager: The person responsible for coordinating the data flow of information from the CBS, facilities and patients for entry into the CHARMS database.

Canadian Hemophilia Assessment and Resource Management System (CHARMS): A computer database program designed for the Canadian hemophilia clinics.

Expiry Date: The date on which a lot number expires.

Factor Concentrate: A lyophilized concentrate of coagulation factor used to treat a factor deficiency (i.e. Factor VII, VIII, IX, XIII, von Willebrand's Disease.)

Factor Concentrate Tracking System: A system operated by the hemophilia clinic to coordinate and collect data on distribution, use and side effects of factor concentrate from the CBS, facilities and patients.

Home Care Program: A program that educates and trains patients/families to prepare and do intravenous infusions of factor concentrate, make decisions about when to treat, carry out correct documentation and storage and handling of product, and, as well, monitors patients' responses to treatments.

Infusion: An intravenous injection of factor concentrate.

Issue: To allocate factor concentrate to a facility or person *v.* or a defined allotment of factor concentrate *n.*

Lot Number: A unique number assigned to a batch (lot) of factor concentrate. Each lot number describes a specific brand name, Product name, manufacturer, and units per vial.

Nurse Coordinator: The nurse who manages nursing activities and the home care program.

Program Secretary: The individual who works for the Hemophilia Clinic in an administrative capacity.

Product: A general term to describe the factors that are in a concentrate (i.e. Factor VIII, Fibrinogen, Factor IX).

Units Per Vial (UPV): Indicates the content of factor in a vial.

Reconciled/Reconciliation: To account for all products issued.

5.0 Documentation

Diary Discrepancy Log: A log to record incorrect inventory or any other discrepancy in patient diaries.

Patient Audit Log: A log of dates of correct/fully reconciled patient inventories.

Infusion Diaries (formerly Bleed Diaries): A form to document each infusion of concentrate, with the date, reason for infusion, type of product, amount of factor and lot number.

Patient Inventory: The quantity of concentrate currently held in stock by the patient.

Patient Log: A month-by-month log of the current status of individual's patient diaries.

6.0 External References

Cecilia Stiles, programmer for CHARMS software

7.0 Developed By

Julie Carruthers

8.0 In Consultation With

Theresa Almonte
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Irwin Walker

9.0 Approved By

Co-Directors Hemophilia Program
Manager, Children's Acute Care

10.0 Posting Dates

Current Posting/Review Date: 2004-04-20

Initial Posting Date: 2001-01-01

Review Date: 2002-10-04

11.0 Keyword Assignment	hemophilia
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12.0 Table.

*The *CHARMS Data Entry Screen* Column lists sections of CHARMS for data entry, where applicable. There are 3 main sections of CHARMS that are used for the data entry: ***Product Master, Regional Product Inventory and Patient Product Inventory.*** There are also more specialized sections of the program for Lot Number location (***Lot Locator***), Patient Demographics, Lab Testing, Reporting etc.

Procedure Steps	Work Instructions	CHARMS Data Entry Screen	Rationale
12.1 Infusion Diary submission (<i>Patients</i>)	<p>.1 Patients on Home Care Treatment are required to submit an Infusion Diary. The required frequency of submission is once per month for those using paper diaries and within one week of each infusion for those who using handheld computers.</p> <p>.2 Patients send Infusion Diaries to the Hemophilia Nurse Coordinator or Program Secretary at the Hemophilia Clinic, either by mail, e-mail, fax or hand delivery. Electronic diaries are submitted via a telephone modem.</p> <p>.3 Patients record the infusion in the Infusion Diary each time they infuse Product. The required information recorded includes:</p> <ul style="list-style-type: none"> ▪ Date of infusion ▪ Reason for infusion ▪ Location of bleed ▪ Product Name, ▪ Lot Number 		<p>Infusion Diaries provide the Factor Concentrate Tracking System with documentation of infusions by patients on Home Care.</p> <p>Documentation of usage of Product by patients outside of the facilities, provides information for future reports.</p>

	<ul style="list-style-type: none"> ▪ Number of vials infused <p>.3 The patient includes a current home inventory with each diary submission. Each inventory statement includes the number of unused vials and the corresponding lot numbers at the time of last infusion on the diary.</p>		
<p>12.2 Infusion Diary Audit <i>(Program Secretary and Hemophilia Nurse Coordinator)</i></p>	<p>.1 The Hemophilia Nurse Coordinator date stamps the diary upon receipt, reviews the diary for errors and omissions and compares the treatments with the recommendations.</p> <p>2. The Hemophilia Nurse Coordinator inscribes the reason for each Infusion even when this has been done, to verify adherence to definitions.</p> <p>.3 The Hemophilia Nurse Coordinator contacts the patient if there are any questions or concerns regarding accuracy or practices.</p> <p>.4 The Hemophilia Nurse Coordinator forwards the Infusion Diary to the Program Secretary.</p> <p>.5 The Program Secretary reviews the Infusion Diary and its inventory.</p> <p>.6 The Secretary audits diaries</p>	<p>Report D5 for previous reconciled inventory minus usage since that date</p>	<p>The diaries are reviewed to ensure that the records are accurate, that the patient is infusing himself correctly and to monitor Product usage.</p> <p>This is to verify that the patient has submitted the correct information in the Infusion Diaries. If the stated inventory matches the inventory calculated from infusion records received, it is assumed that the documentation of patient's home infusions (Infusion Diary) is correct. Discrepancies must be identified and resolves as quickly as possible.</p>

	<p>utilizing the CHARMS D4 and D5 report, according to formula: Submitted inventory = Previous submitted inventory + current issues - infusions. If there are discrepancies with this Audit, the patient is phoned to discuss and resolve.</p> <p>.7 When the Infusion Diary Inventory matches the CHARMS inventory for that patient the Program Secretary will initial the diary and indicate, "reconciled" on the diary.</p> <p>.8 A copy of the Audited diary is forwarded to the Data Manager for data entry into the CHARMS database.</p>	<p>according to diary records = calculated inventory = submitted inventory statement.</p>	<p>Copies are made to ensure that both the Hemophilia Nurse Coordinator /Program Secretary and the Data Manager have identical copies of every submitted and Audited Infusion Diary.</p>
<p>12.3 Infusion Diary Reconciliation <i>(Program Secretary and Hemophilia Nurse Coordinator)</i></p>	<p>If the patient has forgotten to include an inventory (A), or if the Audit reveals any discrepancies (12.2.6), (B), the Program Secretary will phone the patient to rectify the problem.</p> <p>A) Infusion Diary Inventory Missing: The Program Secretary will indicate on the diary if the inventory is missing and the date when the patient is called.</p> <p>B) Infusion Diary Discrepancy: If the</p>		<p>Each submitted Infusion Diary is initially Audited by the Program Secretary and Hemophilia Nurse Coordinator. Once the Infusion Diary is reconciled, it can be forwarded to the Data Manager for data entry.</p>

	<p>patient's Infusion Diary inventory does not match the calculated inventory, the Program Secretary will write on the diary the date the phone call was made to the patient to identify a solution to the discrepancy.</p>		
<p>12.4 Data Entry of Infusion Diaries (Data Manager)</p>	<p>.1 The Data Manager will enter the usage information from the Infusion Diary into the CHARMS database.</p> <p>.2 The submitted Infusion Diary Inventory is rechecked (see 12.2.7) with the Inventory in the CHARMS database. If there is a discrepancy with the inventory, the Hemophilia Nurse Coordinator/Program Secretary is contacted for resolution action.</p> <p>.3 When the Infusion Diary inventory is identical to the inventory in the CHARMS database, the Data Manager records the reconciliation in the Patient Log, and in the Patient Audit Log.</p> <p>.4 The patient diary with correct inventory is filed in the patient file by the Data Manager.</p>	<p>Patient Product Inventory (& Bleed Diaries)</p>	<p>Once the Infusion Diary had been Audited by the Hemophilia Nurse Coordinator/Program Secretary (see 12.2 and 12.3) it can be entered into the CHARMS database.</p>

<p>12.5 Data Entry Infusion Diary Reconciliation (Data Manager)</p>	<p>If the submitted inventory does not match the inventory in the CHARMS database after data entry:</p> <ul style="list-style-type: none"> • The data entry is double checked. • The Hemophilia Nurse Coordinator/ Program Secretary are emailed with detailed documentation of the error. • A paper copy of the email will be filed with the diary in the patient file. <p>When the discrepancy has been resolved with the patient, the Data Manager is informed of the changes to be made to diary.</p>		<p>The Infusion Diary is Audited again at the data entry level after the Infusion Diary has been entered into the CHARMS database.</p>
<p>12.6 Patient Log (Data Manager)</p>	<p>.1 As Infusion Diaries are received by the Data Manager and entered into the CHARMS database, the monthly status is logged into the Patient Log.</p> <p>If the patient submits a complete Infusion Diary for the month, a "C" will be placed in the month column. If the patient submits a partial Infusion Diary for the month, a "P" will be placed in that month column.</p> <p>When a patient submits an Infusion Diary with an incorrect inventory a "/ I" is placed beside</p>		<p>The Patient Log is used to identify which patients need to be contacted to resolve incorrect inventories, which patients have to submit a current inventory and which patients need to submit current diaries to the Factor Concentrate Tracking System.</p> <p>The Patient Log is a chart set up as patients versus month for each year.</p> <p>C = Complete P = Partial I = Inventory Incorrect A = Inventory</p>

	<p>the "C" or "P" for that month. (When the inventory is reconciled, the "I" is changed to an "A".) If the inventory is submitted correct, a "/A" is placed beside the "C" or "P" in the month column</p> <p>If an inventory is not submitted, the "C" or "P" stands alone.</p>		<p>Correct, Infusion Diary fully Audited.</p> <p>e.g. C/I = complete diary for that month, inventory submitted but incorrect.</p>
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Procedure 7

Hamilton Health Sciences	Factor Concentrate Tracking System
<i>Issue Date:</i> 2004-01-27	Page 32 of 8
<i>Title:</i> Data Entry for the Factor Concentrate Tracking System Database – CHARMS	

Applies to: Data Manager for the CHARMS database (Hemophilia Clinic, 3F, McMaster Site)

1.0 Purpose:

Information is recorded in the Factor Concentrate Tracking System database (CHARMS) to:

- 1.1 Produce distribution and utilization reports, summaries for reporting reactions to products, patient specific treatment summaries, reports to aid product recalls and, with the CBS, facilitate rational distribution of product to facilities and individual patients.
- 1.2 Verify data.

2.0 Definitions:

Brand Name: The manufacturers assigned name of a product, e.g.. Kogenate FS, Humate –P.

Canadian Hemophilia Assessment and Resource Management System (CHARMS): A computer database program designed for Canadian hemophilia clinics.

Canadian Blood Services (CBS): The sole distributor of factor concentrates in Canada..

Canadian Blood Services, Product Distribution Department: The division of the CBS that is responsible for issuing the factor concentrate to the regional facilities.

Data Manager: The person at the hemophilia clinic responsible for coordinating the data flow of information from the CBS, facilities and patients for entry into the CHARMS database.

Expiry Date: The date on which a lot number expires.

Factor Concentrate: A lyophilized concentrate of coagulation factor used to treat a factor deficiency (e.g. Factor VII, VIII, IX, XIII, von Willebrand’s Disease.)

Factor Concentrate Tracking System: A system operated by the hemophilia clinic to coordinate and collect data on distribution, use and side effects of factor concentrate from the CBS, facilities and patients..

Home Care Program: A program of the Hemophilia Clinic that trains patients and/or families to do intravenous infusions of factor concentrates and monitors responses.

Infusion: An intravenous injection of factor concentrate.

Issue: To allocate factor concentrate to a facility or person.

Lot Number: A unique number assigned to a batch (lot) of factor concentrate. Each lot number describes a specific brand name, product name, manufacturer, content in units per vial, and expiry date.

Manufacturer: The company that makes the particular Brand Name, e.g. Bayer, Baxter.

Nurse Coordinator: The nurse who manages nursing activities and the home care program.

Product: A general term to describe the factors that are in a concentrate (e.g. Factor VIII, Fibrinogen, Factor IX).

Program Secretary: An individual who works for the Hemophilia Clinic in an administrative capacity.

Prophylactic Treatment: The infusion of factor concentrate to prevent a bleed.

Units Per Vial (UPV): Indicates the content of factor in a vial.

3.0 Related Internal Documents:

Audit Discrepancy Report: Lists a history of a product lot number that has failed reconciliation.

Audit Reply: A report that is generated by the Data Manager and sent to facilities to confirm agreement between that facility's inventory report and the CHARMS database.

Diary Discrepancy Log: A log to record incorrect inventory or any other discrepancy in patient diaries.

Disposition Reports: A summary report issued by CBS that lists all the issues within a given time frame. It indicates the date of issue from the CBS, the facility the product was delivered to, the lot number, unit per vial, and quantity of product sent. The Disposition Report is used to verify that all individual packing slips were received, and hence that all issues have been recorded.

Facility Audit Log: A log of dates of correct and fully reconciled facility inventories of factor concentrate.

Facility Checklist: A form used to document the receipt of Tracking Logs received from the facilities.

Facility Inventory Report: A statement of a facility's current inventory of factor concentrate.

Factor Concentrate Tracking Logs: A log of issues recorded by each facility in the region indicating the date they issued a product, which product was issued, the lot number and quantity of product (in vials), who it was issued to and the purpose of the issue.

FPMS Products with Lot Numbers: CBS report of current products, lot numbers and their expiry dates.

Patient Audit Log: A log of dates of correct/fully reconciled patient inventories.

Patient Infusion Diaries (formerly Bleed Diaries): A form in which to document, for each infusion, the date, reason for infusion, type of product, amount of factor and lot number of product.

Patient Inventories: The number of vials of concentrate, with lot numbers, in patients' possession. Patients are asked to send a summary of their inventory at specified intervals.

Patient Log: A log of patient diaries received.

Packing Slips: Forms from the CBS describing each individual issue of product.

4.0 Equipment:

CHARMS software program

5.0 Action/Decision-making Framework:

The procedure is outlined in the table below. The column headed **CHARMS Data Entry Screen** lists the areas in CHARMS where data, coming from the sources listed in the column headed **Data Source**, is entered. The procedure to be followed is under **Work Instructions** and the **Rationale** is explained in the last column. There are three main areas in the CHARMS database for entering data, **Product Master, Regional Product Inventory and Patient Product Inventory**. These are all accessible from the Area screen, via Main Menu> Clinic Menu> Select Area>. These three areas reflect the movement of products, from CBS (**Product Master**) to regional facilities (**Regional Product Inventory**) and then to patients (**Patient Product Inventory**). The latter, which includes the Bleed Diary, is also accessible from the individual patient Directory Screen (Main Menu> Clinic Menu> Select Patient> Directory).

Elsewhere there are specialized sections of the program for a) locating lot numbers via **Lot Locator** – Report Menu> Miscellaneous Report E2 or Main Menu> Clinic Menu or **Lot # Recall** - Main Menu> Clinic Menu> Select Area, b) listing lot numbers for each product issued in the region (**Product Master Lot #'s** - Report E3 or Main Menu> Clinic Menu) and, c) listing various region and patient summaries (Reports Menu – Diary (D) reports).

Data Source	Work Instructions	CHARMS Data Entry Screen	Rationale
5.1 CBS Information – Packing Slips – Disposition Reports – FPMS Reports.	5.1.1 Enter Brands and Lot Numbers from the Packing Slips into the Product Master. If already entered go to Regional Product Inventory (below).	Product Master	Packing Slips describe the Brands, Lot Numbers and quantity of product issued to facilities; these are sent by CBS Product Distribution Department to the Data Manager every time products are issued.
5.1 CBS Information continued.....	5.1.2 New products (Brands) are entered in the Product Master		The Product Master lists, once, the Brand Names, Lot numbers and expiry

Summary of Tracking System

	<p>under the appropriate manufacturer.</p> <p>5.1.3 New lot numbers are entered under the appropriate Brand.</p> <p>5.1.4 Expiry dates are entered from the CBS FPMS report.</p>		<p>dates of all products issued. The quantities of each issue of product, and facilities to which the issued products are sent, are listed in the Regional Product Inventory (see later).</p> <p>CBS provides a monthly report (FPMS) listing all the current expiry dates.</p>
<p>5.1 CBS Information continued – data validation.</p>	<p>5.1.5 Packing slip data is also entered into the Regional Product Inventory, thereby assigning a quantity of product to a specific facility.</p> <p>5.1.6 Cross-check the Packing Slips against the Disposition Report.</p> <p>5.1.7 Correct errors. If data is missing, it can be entered from the Disposition Reports. If there is a Packing Slip for a product not listed in the Disposition Reports, the CBS Product Distribution Department must be contacted for clarification.</p>	<p>Regional Product Inventory</p>	<p>CBS Product Distribution Department sends the Data Manager a weekly Disposition Report of all factor concentrates that have been issued within the week. The CBS Disposition Report is used to check that all Packing Slips sent from the CBS Product Distribution Department to the Factor Concentrate Tracking System have been received.</p>
<p>5.2 Facility Information</p> <p>– Factor Concentrate Tracking Logs.</p>	<p>5.2.1 Enter Tracking Log data into appropriate modules (see next column).</p>	<p>A) Patient Product Inventory for issues of factor concentrate for Home Care (Patient Products tab) and hospital-based</p>	<p>Facilities enter data on all products, whether issued, used, returned or discarded, into the Factor Concentrate Tracking Log, which is sent at</p>

Summary of Tracking System

	<p>Facility Audit Log (both are separate from CHARMS).</p> <p>5.2.5 Fax an Audit Reply to the audited facility to inform the facility that there are no discrepancies with the Facility Inventory Report.</p>		<p>the next audit.</p>
<p>5.3 Patient Information</p> <p>– Patient Infusion Diary</p>	<p>5.3.1 The Nurse Coordinator reviews the diaries both for clinical purposes and to ensure that the information is appropriate for data entry into the CHARMS database.</p> <p>5.3.2 Data from the Patient Infusion Diary is entered into CHARMS. Infusions are entered into the Bleed Diary while returns and discards are entered into Product Returns.</p>	<p>- Patient Product Inventory</p>	<p>The Patient Infusion Diary informs the Factor Concentrate Tracking System of all infusions that are performed in the home and all transfers, returns and discards of product.</p> <p><u>Note:</u> Data on infusions at facilities differ from those on home infusions in being recorded by facilities on the Factor Concentrate Tracking Logs rather than Patient Diaries – see section 5.2. Both, however, are entered in the Bleed Diary.</p>
<p>5.3 Patient Information continued – data validation.</p>	<p>5.3.3 The patient submits a summary of his/her current inventory with each Infusion Diary, or once/month if using an electronic diary.</p> <p>5.3.4 The dates that the diaries cover, and the status of the inventory (if provided) is logged into the</p>		<p>To ensure the patient has submitted complete and correct information, the patient’s stated inventory is compared with that calculated by CHARMS from Patient Infusion Diaries.</p> <p>This is a means of checking on deficient diary entries and inventory statements.</p>

	<p>Patient Log/Checklist.</p> <p>5.3.5 The patient's inventory is compared with that in CHARMS.</p> <p>5.3.6 The Nurse Coordinator or Program Secretary resolves discrepancies between the stated inventory and that calculated by CHARMS from Patient Infusion Diaries. Amendments are then given to the Data Manager for correction in the CHARMS database.</p>		<p>If a discrepancy in the diary is identified the previous data entry is double-checked. If the discrepancy still exists one or more of the possible causes should be considered:</p> <p>a) An incorrect Inventory has been submitted by the patient, or,</p> <p>b) there is an error in the Patient Infusion Diary.</p> <p>For both situations, the Nurse Coordinator or Program Secretary contacts the patient for discrepancy resolution.</p>
	<p>5.3.7 When the inventory submitted by the patient matches the inventory in CHARMS the audit is documented on the Patient Log and the Patient Audit Log.</p>		
<p><u>Calculation of Inventory in CHARMS</u></p>			
<p><u>Facility:</u> CBS Issues – Facility Issues to patient – Transfers of Product Out to Other Facilities + Product Transferred In From Other Facilities – Discards/Returned Product = Facility Inventory</p>			
<p><u>Patient:</u> Facility Issues to Patient – Infusions – Discards/Returns - Transfers to Other Patients + Transfers From Other Patients = Patient Inventory</p>			

6.0 Documentation:

As described, and assured by validation procedures.

7.0 External References:

CHARMS User Guide, version 3.1, March 2001. Association of Hemophilia Clinic Directors of Canada.

8.0 Developed By:

J. Carruthers

Summary of Tracking System

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8.1 In Consultation With:

J. Sek
T. Almonte
I. Walker

Initial Issue Date: January 1, 2001

9.0 Approved by:

Dr. I Walker – Co-Director Hemophilia Program
Dr. A. Chan - Co-Director Hemophilia Program
Manager Children's Health Acute Care

Summary of Tracking System

FACILITY	DOCUMENTS	CHARMS FUNCTION	PROCEDURE
CBS <ul style="list-style-type: none"> ▪ Receives concentrates from CBS National Centre. ▪ Distributes concentrates to facilities. 	<ul style="list-style-type: none"> ▪ Packing Slips ▪ Disposition Report ▪ FPMS Report ▪ PDF Order Form (F3411). 	Product Master Record: <ul style="list-style-type: none"> ▪ Manufacturer, product details and Lot numbers. 	<ul style="list-style-type: none"> ▪ CBS Distribution Data: Transfer to program Data Manager, Data entry and Quality Control.
Facilities <ul style="list-style-type: none"> ▪ Receive concentrates from CBS. ▪ Distributes concentrates to patients on home 	<ul style="list-style-type: none"> ▪ Tracking Logs. ▪ Patient Issue Sheet. 	Regional Product Inventory Record: <ul style="list-style-type: none"> ▪ Issues from CBS to specific facilities, and returns. • Issues from facility blood 	<ul style="list-style-type: none"> ▪ Issuing Factor Concentrate
Patients <ul style="list-style-type: none"> ▪ Receive concentrates from facilities. ▪ Infuse Products. 	<ul style="list-style-type: none"> ▪ Paper diaries. ▪ Handheld computers. 	Patient Product Inventory Record: <ul style="list-style-type: none"> ▪ Issues from facilities to patients. • Infusions by patients. 	<ul style="list-style-type: none"> ▪ Infusion Diary Completion by Patients
Hemophilia Clinic <ul style="list-style-type: none"> ▪ Receive requests from patients. ▪ Infuse Products. ▪ Order products from CBS. ▪ Manage and audit system. 	<ul style="list-style-type: none"> ▪ Order Verificaton Form ▪ Audit Discrepancy Report ▪ Diary Discrepancy Log ▪ Facility Audit Log ▪ Facility Checklist. ▪ Facility Inventory Report. ▪ Patient Audit Log. ▪ Patient Log. 	Patient Product Inventory Record: <ul style="list-style-type: none"> ▪ Issues from facilities to patients. • Infusions by patients. 	<ul style="list-style-type: none"> ▪ Ordering Factor Concentrate ▪ Data Entry for the Factor Concentrate Tracking System Database - CHARMS ▪ Collection of Data from Regional Facilities on Factor Usage and Distribution ▪ Data Collection, Validation, and CHARMS Entry, of data from Infusion Diaries.

Canadian Blood Services
 LOVEMETENDER, CANADIAN BLOOD SERVICES
 PACKING SLIP

Shipment date: **31-JAN-01**
 Shipment ID: **0000345621**
 Prepaid/Collect:
 Ship Via:
 Req. Delivery Date:
 Order Date: **02-JAN-01**

Bill To: PROVINCE OF ONTARIO
 CANADIAN BLOOD SERVICES
 FRACTIONATION

Ship To: **GRACELAND MEMORIAL**
 1 MAIN ST
 LOVEMETENDER, ON
 L8N 3Z5

Product Description Requested	Qty Requested	Qty Backordered For the Attention of	Patient Initials	Product Description Issued	UPV	Lot #	Quantity Issued
RECOMBINATE FACTOR VIII FS	11810 IU		EP	CRAZY 8	1000	111223AA	6 V

Shipper:
 Verifier: _____

Total # of Pieces:
 Total Weight:

Misc. # of Pieces:
 Misc. Weight:

Acknowledgment: _____
 Signature

 Date

IT IS A GOVERNMENT REQUIREMENT THAT A SIGNED COPY OF THIS VOUCHER INDICATING RECEIPT OF PRODUCTS BE RETURNED AS SOON AS POSSIBLE

PLEASE SIGN AND RETURN TO THE CANADIAN BLOOD SERVICES

Example Disposition Report

Disposition Reports

13-Nov-2001

LOVEMETENDER HAMILTON CANADIAN BLOOD SERVICES
Disposition Report

From: **05-NOV-2001 to 11-NOV-2001**

Centre: 55 LOVEMETENDER HAMILTON CANADIAN BLOOD SERVICES

Product Group: FSB1000 RECOMBINANT FACTOR VIII FS 1000UPV

Date	Disposition Type	Centre/Manufacturer/Customer/Storage Location	Product	Lot Number	Quantity	Discrepant	UPV	Total Units	UOM
05-NOV-2001	ISSUE TO CUSTOMER	JONNY MEMORIAL	FSB1000CU	327K007	30		1181	35430	IU
05-NOV-2001	ISSUE TO CUSTOMER	GENERAL HOSPITAL	FSB1000CU	372K007	6		1181	7086	IU
08-NOV-2001	INTERNAL TRANSFER-RECEIPT	HEAD OFFICE CANADIAN BLOOD SERVICES	FSB1000CU	372K007	60		1181	71860	IU
09-NOV-2001	ISSUE TO CUSTOMER	HOUNDDOG COUNTY GENERAL FACILITY	FSB1000CU	372J052A	12		1139	13668	IU



Strictly Confidential

FPMS Products with Lot Numbers

Example FPMS Report

Product Code: 0FI01.0IM - FIBRINOGEN 1.0 g (FIBRINOGEN) BAXTER BIOSCIENCE						
Lot Number	Lot Creation Date	Lot Expiry Date	REG Date	UOM	UPV	
040895H	1996-02-05	2000-08-16		G		
040897F	1997-10-28	2000-05-31		G		
040899I	2000-03-13	2002-08-31		G		
040902I	2003-02-17	2005-08-31		G		
040999I	2000-03-29	2002-08-31		G		
041002J	2003-01-24	2005-09-30		G		
04109406S	1995-03-27	1999-06-22		G		
041202L	2003-11-10	2005-11-30		G		
041302L	2003-04-28	2005-11-30		G		
04199209S	1994-07-17	1997-09-01		G		
Product Type: AAT - ANTITHROMBIN III KYBERNIN-P				Sequence #:218		
Product Group: AAT1000 - ANTITHROMBIN III 1000 UPV KYBERNIN-P						
Product Code: AAT1000AV - ANTITHROMBIN III 1000 UPV (KYBERNIN-P) AVENTIS BEHRING						
Lot Number	Lot Creation Date	Lot Expiry Date	REG Date	UOM	UPV	
62467111C	2001-07-18	2003-08-31			1000	
Product Type: AC1 - C1 INHIBITOR BERINERT P				Sequence #:225		
Product Group: AC10500 - C1 INHIBITOR BERINERT P 500 UPV (BERINERT P)						
Product Code: AC10500AV - C1 ESTERASE INHIBITOR (BERINERT P) 500 UPV AVENTIS BEHRING						
Lot Number	Lot Creation Date	Lot Expiry Date	REG Date	UOM	UPV	
01961711A	2002-06-26	2004-05-31			500	
02061711C	2002-10-04	2004-09-30			500	
02161711A	2002-09-06	2004-10-31			500	
02661711A	2003-01-24	2004-11-30			500	
02661711C	2002-12-12	2004-11-30			500	
02861711A	2003-03-13	2004-11-30			500	
04161711A	2003-06-12	2005-03-31			500	
05461711A	2003-10-31	2005-10-31			500	
06961711A	2003-12-30	2006-03-31			500	
Product Type: B08 - RECOMBINANT FVIII BAXTER BIO				Sequence #:171		
Product Group: B080250 - RECOMBINANT FVIII 250 UPV (RECOMBINATE) BAXTER BIOSCIENCE						
Product Code: B080250BA - RECOMBINANT FVIII 250 UPV (RECOMBINATE) BAXTER BIOSCIENCE						

Example Patient Diary

REGIONAL HEMOPHILIA CENTRE

NAME: *Elvis Presley*

YEAR 2001

BLEEDING EPISODE	Date	<i>January 7, 2001</i>	<i>January 10, 2001</i>	<i>January 11, 2001</i>	<i>January 15, 2001</i>	<i>January 20, 2001</i>	<i>January 22, 2001</i>
Site of Bleeding		<i>Prophylaxis</i>	<i>Prophylaxis</i>	<i>Bleed - R Knee</i>	<i>Prophylaxis</i>	<i>Prophylaxis</i>	<i>Precautionary</i>
Cause		-	-	<i>unk</i>	-	-	<i>Skiing</i>
Material Used (specify factor type)							
Total Factor Units Used							
INFUSION SITE <small>(ie. vein used, catheter)</small>		<i>L. wrist</i>	-	-	-	-	-
? Reaction (specify symptoms)							
G E N E R A L E V E N T S	Took Medication <small>(specify type and dose)</small>						
	Days Off <small>(specify location or level of activity)</small>						
	Days Hospitalized						
	Given Physiotherapy						
	Visited Physician						
	Used Crutches or Cane						
	Other Physical Illness <small>(ie. flu, cold)</small>						
IF ON HOME INFUSION							
LOT NUMBER:		<i>111223AA</i>	<i>111223AA</i>	<i>111223AA</i>	<i>111223AA</i>	<i>111223AA</i>	<i>111223AA</i>
		<i>x 1 vial</i>	<i>x 1 vial</i>	<i>x 1 vial</i>	<i>x 1 vial</i>	<i>x 1 vial</i>	<i>x 1 vial</i>
				<i>444568B</i>		<i>444568B</i>	
				<i>x 2 vials</i>		<i>x 1 vial</i>	
REORDER							
WHITE COPY - KEEP							
YELLOW COPY - TO PROGRAM							

Example Facility Checklist

FCTS - Hospital Checklist**Dates of:** *March 1, 2001 to March 15, 2001***Phoned On:** *15-Mar-01*

	Hospital	Phone Number	Long Dist	-CALL NA	Prev Report Date	New Report Dates (Start-Stop)	NPI	Audited A=Asked D=Done	Audit Date
1	Other Hospital 1	555-777-0000	Y	Y	1-Mar-01	15-Mar-01	X	D=Done	Mar-15
2	Other Hospital 2	555-777-0001	N	NA	14-Mar-01				Feb-15
3	Other Hospital 3	555-777-0002	Y	NA	15-Mar-01				Feb-15
4	Other Hospital 4	555-777-0003	N***	Y	3-Mar-01	03-15-01		A	Feb-15
5	General Hospital	555-355-2355	Y***	NA	15-Mar-01				Feb-15
6	Other Hospital 5	555-355-2356	Y	Y	26-Feb-01	03-15-01			Jan-15
7	Graceland Memorial Hosp	555-555-1111	Y***	Y	1-Mar-01	03-15-01	X	A	Jan-15
8	Hemophila Clinic	555-888-5555	N	Y	2-Mar-01	03-15-01			Jan-15
9	Other Hospital 6	555-888-5556	Y	Y	22-Feb-01	03-16-01			Jan-15
10	Other Hospital 7	555-888-5557	N***	NA	15-Mar-01				Feb-15
11	Other Hospital 8	555-888-5558	N***	Y	1-Feb-01	03-15-01	X	D	Mar-15
12	Other Hospital 9	555-888-5559	N***	NA	15-Mar-01				Feb-15
13	Other Hospital 10	555-888-5560	N	Y	3-Mar-01	03-16-01		D	Mar-16
14	Other Hospital 11	555-888-5561	N	Y	1-Mar-01	03-15-01		D	Mar-15
15	Central Hospital	555-555-2222	Y***	Y	1-Mar-01	03-15-01	X	A	Jan-15
16	Other Hospital 12	555-555-2223	Y	Y	2-Mar-01	03-15-01			Jan-15
17	Other Hospital 13	555-555-2224	Y	NA	14-Mar-01			D	Mar-15
18	War Memorial Hospital	555-111-6666	Y***	Y	1-Mar-01	03-15-01	X		Jan-15

*** hospital doesn't have regular patients and rarely issues product - Call end of each month.

Example Facility Inventory Report

**Factor Concentrate Tracking Program
Product Inventory**

- Please submit a hospital product inventory every 3 months

Facility: Graceland Memorial Hospital

Date: March 15, 2001

Hospital Fax Number: 555-222-1111

	Product Name*	Supplier	Brand	Lot #	Expiry Date	# of Vials*
1	<i>Factor VIII</i>	<i>Baxter</i>	<i>Crazy 8</i>	<i>1112223AA</i>	<i>unk</i>	<i>6</i>
2	<i>Factor VIII</i>	<i>Baxter</i>	<i>Crazy 8</i>	<i>444556BB</i>	<i>01/01/06</i>	<i>4</i>
3	<i>Factor VIIa</i>	<i>Novo Nordisk</i>	<i>Niastase</i>	<i>LU1111</i>	<i>01/01/05</i>	<i>2</i>
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						

*required fields, all other field are optional
Please fax to Data Manager at (905) 555-7979 upon completion.

Appropriate Factor Concentrate Supply	A quantity which meets patients needs, which minimizes inconvenience, which takes into account individual requirements and current national and regional supply. The quantity will vary among individuals and will fluctuate from time to time. A reasonable supply under normal circumstances is about one month.
Audit	Examine and check the validity of data
Audit Discrepancy Report	Lists a history of a product lot number that has failed reconciliation.
Audit Reply	A report indicating full agreement between a facility inventory report and the CHARMS database.
Brand Name	The manufacturers assigned name of a product, e.g. Kogenate FS, Humate –P, BeneFIX.
Canadian Blood Services (CBS)	The factor concentrate distributor.
Canadian Blood Services, Product Distribution Department (CBSPD)	The division of the CBS that is responsible for issuing the factor concentrate to the regional facilities.
Product Distribution Fractionation Order Form (F3411)	A form supplied by the “CBS” that lists licensed, available products.
Canadian Hemophilia Assessment and Resource Management System (CHARMS)	A computer database program designed for Canadian hemophilia clinics.
Data Manager	The person responsible for coordinating data flow from the CBS, facilities and patients, and for entry into CHARMS.
Diary Discrepancy Log	A log to record incorrect inventory or any other discrepancy in patient diaries.
Disposition Reports (DR)	A CBS report summarizing all issues of product over a stated time period, and used by the Factor Concentrate Tracking Program to confirm that all Packing Slips were received. It indicates the date of issue from the CBS, the facility the product was delivered to, the lot number, unit per vial, and quantity of product sent.
Expiry Date	The date on which a lot expires.
Facility	An organization to which CBS distributes concentrates. In most areas this is synonymous with “hospital”, but in some regions includes the “hemophilia clinic”.
Factor Concentrate	A lyophilized concentrate of coagulation factor used to treat a factor deficiency (e.g. Factor VII, VIII, IX, XIII, von Willebrand Factor.)
Factor Concentrate Tracking Log	A log maintained by each facility in the region indicating the disposition of factor concentrates, the date of issue, the brand, the lot number, the quantity (# of vials), who it was issued to and the purpose of the issue.

Factor Concentrate Tracking System	A system operated by the hemophilia clinic to coordinate and collect data on distribution, use and side effects of factor concentrate from the CBS, facilities and patients.
FPMS Products with Lot Numbers	CBS report of current products, lot numbers and expiry dates
Home Care Program	A program that educates and trains patients/families to prepare and do intravenous infusions of factor concentrate, make decisions about when to treat, carry out correct documentation and storage and handling of product, and, as well, monitors patients' responses to treatments.
Facility	Regional hospital or hemophilia clinic.
Facility Audit Log	A log of dates of correct and fully reconciled facility inventories of factor concentrate.
Facility Checklist	A report documenting the receipt of Tracking Logs from facilities.
Facility Inventory Report (FIR)	A statement of a facility's current inventory of factor concentrate.
Infusion	An intravenous injection of factor concentrate.
Infusion Diary (Formerly Bleed Diary)	A form to document each infusion of concentrate, with the date, reason for infusion, type of product, amount of factor and lot number.
Issue	To allocate factor concentrate to a facility or person.
Lot Number	A unique number assigned to a batch (lot) of factor concentrate. Each lot number describes a specific brand name, product name, manufacturer, and units per vial.
Manufacturer	A company manufacturing factor concentrates, e.g. Bayer, Baxter.
Nurse Co-ordinator	The nurse who manages nursing activities and the home care program.
Order Verification Form	A hemophilia clinic form notifying facilities of a homecare order for a specific home care patient to be issued by the CBS to that facility.
Packing Slips (PS)	Forms from the CBS describing product issued.
Patient Audit Log	A log of dates of correct/fully reconciled patient inventories.
Patient Log	A log of patient diaries received.
Product	A general term to describe the factors that are in a concentrate (e.g. Factor VIII, Fibrinogen, Factor IX).
Product Distribution Fractionation Order Form (F3411)	A CBS form used by facilities to order concentrates from CBS.
Patient Issue Sheet	A document used by facilities that list factor, lot number, factor expiry date and number of vials issued to patients, with the patients sign-off.
Program Secretary	The individual who works for the Hemophilia Clinic in an administrative capacity.
Prophylactic Treatment	The infusion of factor concentrate to prevent a bleed.

Reconcile	To account for all products issued.
Region	The geographical area.
Tracking Binder	A binder maintained by hemophilia clinic staff that houses patient names, their factor deficiency, product of choice, the facility where the product is picked up from (by patient) and current year's orders.
Tracking Product Form	A form used by facilities to document product supplies that are issued to patient and/or hospital areas (e.g. ward, emergency room).
Units Per Vial (UPV)	The content of factor in a vial.

End of document.