



# PASSPORT to well-being

empowering people with bleeding disorders  
to maximize their quality of life

## CHARTING YOUR COURSE





Canadian Hemophilia Society  
**Help Stop the Bleeding**

The Canadian Hemophilia Society (CHS) exists to improve the quality of life of persons with hemophilia and other inherited bleeding disorders and to find a cure.

The CHS consults qualified medical professionals before distributing any medical information. However, the CHS does not practice medicine and under no circumstances recommends particular treatments for specific individuals. In all cases, it is recommended that individuals consult a physician before pursuing any course of treatment.

The CHS would like to acknowledge those people who contributed to the development of *Charting Your Course*.

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*Note: Bleeding disorders affect both men and women.  
The use of the masculine in this text refers to both.*

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## Introduction

The road to well-being for a person with a bleeding disorder may have detours, roadblocks and wrong turns. Signposts are needed to help find your way... to chart your course.

This module, *Charting Your Course*, describes how those signposts—information gathered at home, patient charts at Hemophilia Treatment Centres, collective Canadian data on care and treatment—can contribute to the well-being of individuals and of the entire bleeding disorder community.

# CHARTING

## Good record-keeping starts at home

### • Before the era of home care

Until the 1970s, a person with a bleeding disorder had to go to the hospital for transfusions of cryoprecipitate or plasma. When a patient was treated in the ER or admitted to hospital, transfusion information was recorded by hospital staff in blood bank records and in the patient's chart.

With the advent of factor concentrates and Hemophilia Treatment Centres (HTCs) in the 1970s, it became possible for a person with hemophilia to receive treatments at home. This revolutionized care by allowing rapid infusions as soon as a bleed started.

*Home care and factor concentrates changed everything. I could control my bleeds myself. I was free from the hospital. I could travel. It was the beginning of a normal life.*

Over time, record-keeping for factor concentrates was transferred from hospital blood banks to HTCs. The patient on home care was given new responsibilities. Accurate tracking from manufacturer to patient became a new challenge.

### • Record-keeping in the 21<sup>st</sup> century

It has been over 30 years since the first patient with a bleeding disorder started home care. In the 1980s, HIV and hepatitis C infected blood and blood products. As factor concentrates were made safer, and recombinant products

introduced in the 1990s, their cost skyrocketed. More importantly, the need to do increased surveillance was recognized.

HTCs had to become more sophisticated in tracking products. In 1998, the CHARMS computer system was introduced to all HTCs in Canada. (See page 8.) The lot numbers of all products dispensed to patients are entered into this system. Then, as *home infusion records*—also called *bleed sheets* or *treatment diaries*—are received from a patient, they are entered into this electronic chart. This gives HTCs information so that the health care providers can:



### **Chart the clinical course**

CHARMS records various test results important to the care of a person with a bleeding disorder. These include:

- joint status
- the specific gene mutation causing the disorder
- inhibitor status
- hepatitis status
- liver and kidney function
- HIV status.

All of this information was previously collected on paper in the HTCs.

### **Prevent the development of a target joint**

Repeated bleeds into one joint can result in the development of a target joint. This can be seen at the patient's annual assessment visit when health care providers review the records for the entire year and see the pattern of bleeding. However, this may be too late; the joint may already have suffered permanent damage.



Good home infusion records, sent frequently to the HTC by the patient, and reviewed just as frequently by the health care team, can prevent this.

### **Monitor proper dosage**

Dosage is usually determined at the annual assessment visit when each patient is weighed. This is most important for children, as they grow so quickly. If a patient on home infusion is not responding to treatment, home infusion records can be checked to see if the patient is using the correct dosage.

### **Identify the development of an inhibitor**

HTCs request that the patient call the nurse coordinator if repeated treatments are needed for the same bleed. There are, however, times when the patient may try to get such a bleed under control without help from the HTC. Accurate records and timely reporting are very important to identify such a situation. The poor response to treatment could be due to the development of an inhibitor.

*Our HTC recently saw a teenage patient who complained of pain in his hip. His home infusion records had not been sent recently. His mother told us about all the problems he had been having. It became clear that he had been treating the same bleed on and off for months. We did an inhibitor screen and found a low titre inhibitor. We were then able to increase his dosage for each treatment in order to overwhelm the inhibitor. His treatments have been working ever since and his home infusion records are now always up to date.*

### **Accurately monitor product usage and home inventory**

It is important for HTCs to receive home infusion records monthly or more frequently. In addition to providing up-to-date information on product usage useful in detecting problems, this tells HTCs how much a patient has used and how much remains in home inventory.

*In 2001 and 2002 there was a serious world shortage of recombinant factor VIII. I remember how my nurse coordinator worked to make sure that nobody ever ran out. Good records in the clinic and at home really helped.*

For various reasons a patient may not be on home care. Instead, he receives his infusions at the ER of the local hospital. In this case, it is up to the medical personnel at the hospital to record and report all of the information including the product, lot number, dosage and bleed site to the HTC.

In addition, when factor concentrates are delivered to a patient through a local hospital blood bank, it is essential that the blood bank personnel report the same information to the HTC.



### **Find out about and report adverse reactions**

The quick reporting of adverse reactions, either through a telephone call to the HTC or immediate electronic transmission of the information, is crucial. Reporting such reactions on paper bleed diaries, even if they are sent frequently to HTCs, causes delays.

The reporting of adverse reactions allows the HTC to take the necessary steps for patient care and to avoid that particular lot being used again by the same patient. If the reports are properly reviewed, the information can be passed to blood product manufacturers and government safety regulators.

### **Do recalls**

HTCs know which lot numbers of factor concentrate were dispensed to a particular patient. In the event of a recall, they can contact the patient and ensure that any remaining product is not infused. When such records are computerized at the HTC, it can be even quicker for staff to contact patients. (For more information on recalls, quarantines and withdrawals, see page 12.)

### **• Methods of reporting (charting)**

The following methods do not take the place of a phone call. The nurse must be called if a patient has a breakthrough bleed when on prophylaxis, or one that is not responding to treatment.

### **Paper**

All HTCs have a form for recording home infusion records. They request the same basic information:

- patient's name
- date of the infusion
- site of the bleed / or prophylaxis
- name of the particular product
- amount infused in IUs (International Units)
- lot number
- adverse reactions.



This information is recorded by the patient at the time of each treatment and the report is handed in, mailed or faxed to the HTC at the end of each month or when the patient comes to pick up more product. The records are then reviewed by the nurse with the patient.

### Electronic data transmission systems

There are various types of electronic data transmission systems but they all serve the same purpose—to send the patient's home infusion record to the HTC more easily, more accurately and—most important—more quickly.

They have the following characteristics:

- They are based on personal computer or PDA (Personal Digital Assistant) technology.
- They use telephone lines or Internet connections.
- Their use is voluntary.
- Information is secure and confidential.
- Personal health information can be accessed only by the health care providers at the patient's HTC.



All patients go through a training session prior to being given access to the software.

In 2004, three systems were in use in Canada.

- ADVOY<sup>®</sup>, introduced by BAXTER BIOSCIENCE
- DIALOG<sup>®</sup>, introduced by BAYER BIOLOGICS
- HemoNet<sup>®</sup>, introduced by NovoNordisk

People who track their treatments carefully, and transmit that information regularly to their HTCs, are likely to get quicker attention to problems and, in the long run, better treatment. Information transmitted infrequently is out of date and much less likely to be useful.

### Summary

- Good record-keeping helps patients and health care providers:
  - chart the clinical course
  - prevent the development of a target joint
  - monitor proper dosage
  - identify the development of an inhibitor
  - accurately monitor product usage and home inventory
  - find out about and report adverse reactions
  - do recalls.
- Treatment information needs to be communicated and reviewed frequently.
- Different charting systems exist.
  - Paper
  - Electronic
- In 2004, three systems to electronically transmit information from home to HTC were in use.

# ELECTRONIC CHARTING

## The Canadian Hemophilia Registry, CHARMS and Centre Point

- **A brief history of electronic databases in hemophilia**

**1991** – A survey of the Canadian hemophilia population becomes the basis for the Canadian Hemophilia Registry (CHR).

**1993** - The Canadian Blood Agency (CBA) asks the newly incorporated Association of Hemophilia Clinic Directors of Canada (AHCDC) to develop an electronic system to track the use of recombinant factor VIII (rFVIII).

**1996** - An agreement is signed between the CBA, McMaster University and the AHCDC to develop the Canadian Hemophilia Assessment and Resource Management information System or CHARMS.

**1998** - After testing in 8 centres, CHARMS is formally rolled out in all 24 HTC's. A central module, called Centre Point, is introduced to collect anonymous data on product use in all clinics.

- **The Canadian Hemophilia Registry (CHR)**

The CHR is an anonymous registry of patients with congenital bleeding disorders (hemophilia, von Willebrand Disease, other factor deficiencies, platelet function disorders) registered in HTC's in Canada. Each patient is issued a CHR number. For reasons of confidentiality, the only link between the individual and his registry number is kept in the patient's HTC. Data collected in the registry includes...

- type of bleeding disorder
- severity
- presence or absence of an inhibitor
- exposure to blood borne pathogens and
- mortality.

Information in the CHR is stored on a server at the Hamilton Health Sciences Centre. A website (<http://www.chr.ca>) describes the CHR and publishes summary data on the bleeding disorder population.

Patient records can be labelled with a CHR number without breaking confidentiality. This number is also used to identify

blood samples in the archive of the Blood Borne Pathogens Project. Results of testing are decoded in the HTC and communicated to the appropriate individuals.

### • Centre Point

Information on product distribution and use is transmitted anonymously from the CHARMS database in each clinic to the Centre Point module once a month. This information is linked only to a CHR number, and so cannot be used to identify individuals. It is compiled in Centre Point to study trends in use. Data from Centre Point has been made available to the Canadian Blood Services (CBS) and the Quebec Blood System Secretariat since 2000 for planning product purchases.

### • Canadian Hemophilia Assessment and Resource Management Information System (CHARMS)

CHARMS serves as a paperless, electronic chart for patients registered in HTCs. This system has many benefits for individual patients. (See pages 3-5.) Through the gathering of collective, anonymous information, CHARMS also provides other benefits to the entire bleeding disorder community.

#### **Recording and communicating adverse drug reactions**

Adverse drug reactions still occur with clotting factor concentrates and other drugs used to treat bleeding disorders. People react to these products for reasons which are not always well understood. Uncommon adverse drug reactions may not occur with sufficient frequency in a single centre to be identified as a problem. However, when brought together in a national database, such as CHARMS, significant problems become more obvious. This information is made available to the manufacturer of the product implicated, Health Canada, the Canadian Blood Services, and the Quebec Blood System Secretariat. All of these groups are notified by e-mail of the reaction. A secure website at the Hamilton Health Sciences Centre allows them to see this anonymous information. Visitors to the website are logged.

#### **Collecting research data**

People who consent to taking part in AHDCDC research projects run through the HTC may have their data collected through CHARMS.

### Tracking trends in use to predict future purchase needs

The distributors of blood products in Canada, the CBS and Héma-Québec, are responsible for buying, importing and supplying clotting factor concentrates to Canadian hospitals. The use of these products is increasing, caused, in part, by increasing use of FVIII for immune tolerance and prophylaxis in children newly diagnosed with hemophilia. Both of these strategies have dramatically improved the health of people with hemophilia, but have also posed difficulties for the distributors who need to plan for a changing market. “Real-time” data on product use, collected through CHARMS, can more quickly alert treaters and distributors to changes in product demand.

### Dealing with disasters and shortages

A global shortage of FVIII occurred in 2001. Conservation guidelines were introduced including very low home inventories. Elective surgery and immune tolerance inhibition protocols on new inhibitors were delayed. Many users of FVIII were inconvenienced. Since a large percentage of Canadian factor concentrates are kept in patients’ homes, a more accurate view of inventory could limit the inconvenience experienced if such a situation arises again.

### • Electronic transmission of treatment diary data from home to HTC

Recently electronic systems have been developed to make it quicker and easier to transmit home treatment diary data. (See page 6.) The CHARMS programmers have worked hard to integrate these systems so that data can be captured without the need to re-enter it into CHARMS.

### • Security

An individual’s identity and contact information are kept on the HTC computer in an encrypted file, separate, but linked to the data in CHARMS. The CHARMS data itself is kept on hospital mainframe computers wherever possible for regular back-up and to control access. Transmission of confidential data outside the clinic is carefully controlled to prevent inadvertent access.

Security is critical to the success of CHARMS and electronic tracking of bleeding disorders. Without assured security, the system will fail quickly and completely. Critical features are...

- state-of-the-art encryption of data
- secure transmission

- access control on data files on hospital mainframe computers
- regular security tests
- regular back-up
- password protection on the mainframe computers, servers and CHARMS
- logging of access.

### Summary

- An electronic charting system requires accurate, complete and timely input of data.
- Such a system saves time by cutting down on the number of times information needs to be recorded.
- It allows faster search and review of data.
- An electronic charting system does not rely on computers; it relies on people: patients, family members, nurses, physicians.
- No one can be forced to keep good records, but when you do—when we all do—we create an effective tool to improve care for individuals and for the entire bleeding disorder community.

## AN EFFECTIVE SURVEILLANCE SYSTEM FOR FACTOR CONCENTRATES



### Making Sure Products Are Safe and Effective

Rarely does a week go by without a report of adverse reactions to a particular drug or medical device.

Thalidomide for pregnant women in the 1960s, blood products in the 1980s, and breast implants in the 1990s are three well-known examples.

Thus, a surveillance system to make sure products are safe and effective after they are marketed is crucial. This applies not only to plasma-derived factor concentrates but also to recombinant products and, indeed, all drugs.

The goal of *post-marketing surveillance* is to learn quickly of any potential problem with a product and then take action, including removal of the product from inventory and notification of the patients.

This document provides an overview of the different parts of an effective surveillance system and how they work.

## • The players

- The manufacturers of factor concentrates
- The regulators responsible for safety and efficacy: Health Canada
- Provincial public health authorities
- The distributors of factor concentrates: the Canadian Blood Services (CBS) and Héma-Québec
- The staff at the hospital blood bank where factor concentrates are often stored
- The health care providers at the Hemophilia Treatment Centres (HTCs)
- The patients and their families

## • Keeping track of products

Any surveillance system is doomed to failure if the system cannot keep accurate records of where products are.

- The manufacturers keep records of the source of material for their products and where the finished products are delivered.
- The distributors—the CBS and Héma-Québec—keep records of where they purchase products and where they send them.
- The HTCs and hospital blood banks keep records of the products they stock and the ones they send to patients for home care.
- Patients and their families keep records of the products they use.

## • Adverse drug reaction reporting

Patients occasionally suffer unexpected symptoms after treatments. There are different kinds of adverse drug reactions.

- Some adverse reactions are experienced immediately. They include headache, fever, chills, flushing, allergic reactions, etc.
- In other cases, for example, an inhibitor to FVIII or FIX, they are noticed later after tests administered by the personnel at the HTC.
- In the past, viruses such as HIV and hepatitis C were transmitted by blood products. Today, factor concentrates, both recombinant and plasma-derived, are considered safe from transmitting these viruses. Nevertheless, adverse reaction reporting is essential to identify any new diseases quickly.

No matter what the adverse reaction or its possible cause, it is essential to report it. This allows those responsible to investigate, find the cause and take action.

For the system to work, all these steps must be in place.

- The patient or his caregiver reports the reaction to the HTC.
- The personnel at the HTC collect information on the reaction and then report it to the manufacturer and to the regulator. In some provinces, they also report to provincial public health authorities.
- Each year, the manufacturer submits a report on all adverse reactions related to its products to Health Canada and to distributors. In the event of a serious adverse drug reaction, it must report within 48 hours.

It is crucial to report all suspected adverse reactions. A problem that is not reported will not be corrected.

### • Recalls, quarantines and withdrawals

Occasionally, because of adverse reaction reports, or because of information obtained in other ways, it is necessary that products already distributed not be used. In the care of people with bleeding disorders, this is complicated by the fact that most products are in people's homes, and not in hospital blood banks.

These events fall into three categories:

#### **Recalls**

A *recall* is the most serious event and has the following characteristics:

- There is a real concern over the safety or efficacy of the product.
- The manufacturer is obligated to report the recall to Health Canada and to distributors.
- The recall is initiated by the manufacturer and is not optional.
- Health Canada, as the regulator, oversees the recall.
- There is a duty to warn patients. The distributors notify hospitals and HTCs. Physicians in those hospitals and HTCs notify patients, typically within less than 48 hours.

Causes of recalls over the last five years have been the discovery that:

- a particular product had less than 80% of the indicated potency

- bottles of diluent water had cracked, causing a risk of bacterial contamination
- alcohol swabs were not sterile
- someone had tampered with vials of a particular product before distribution.

### Quarantines

A *quarantine* occurs when a product is held back and not used for a short period of time because of a possible problem with its safety or efficacy. If the problem is found to be real, the product is recalled. If it is found there is no problem, the product is released from quarantine.



### Withdrawals

A product *withdrawal* occurs when the manufacturer decides to remove the product from use. Although both the regulator and the manufacturer consider the product to be safe and effective, the manufacturer feels that the product does not meet its own standards.

The decision to withdraw is voluntary on the part of the manufacturer. Once withdrawn, however, staff at distributors, hospitals and HTC's follow the same procedures as in the case of a recall or a quarantine. Patients are contacted and asked to return the product.

*Each recall, withdrawal or quarantine is different. But from the point of view of the patient on home care, they are hard to tell apart. That is why it is important to talk to the staff at the HTC. They can give the full story.*

### • Notification

When there is concern for safety, but the product has already been infused by the patient, it is crucial that the patient be notified.

Typically in such a case, the manufacturer informs Health Canada and the distributors of information that has come to light about a particular product. In recent years this has happened several times with plasma-derived factor concentrates. While the risk to patients from these events was extremely small because of safety measures including viral inactivation, there was nevertheless a duty to

communicate from manufacturer to distributor to physician and, finally, to the patient. It is only through such notification that patients can ask for and receive testing and counselling.

It is the role of the personnel at the HTC to notify patients. If there is a health concern, notification must be conducted rapidly, usually within less than 48 hours.

In an efficient surveillance-notification system, key information about all implicated products reaches all patients concerned quickly.

### **A back-up patient notification system**

In 2003, the CBS and Héma-Québec, in conjunction with the Plasma Protein Therapeutics Association, set up a system to provide product recall information for Canadians using plasma products, including recombinants. Called the Patient Notification System (PNS), this service:

- is free of charge and voluntary
- is completely confidential
- provides information to individuals on product recalls within 24 hours by courier, telephone, fax or e-mail
- does not change the primary and legal responsibility of the treating physician and/or hospital officials to notify patients.

To register, visit the Web site at [www.patientnotificationsystem.org](http://www.patientnotificationsystem.org), call the toll-free phone number (1-888-UPDATE-U), or send an application form by mail to NNC Group, Attention: PNS Manager, 5250 West 76<sup>th</sup> Street, Indianapolis, IN, 46268.

This back-up service may provide information on recalls/withdrawals that some people with bleeding disorders would not otherwise get, especially if they are not registered in an HTC. In addition, some people with bleeding disorders may want to have a secondary source of information on recalls/withdrawals in addition to the primary source in HTCs.

### **Summary**

- Register at a Hemophilia Treatment Centre.
- Keep good home care records.
- Report adverse reactions immediately.
- In the event of a recall, quarantine or withdrawal, return the product immediately for replacement. Find out from your HTC staff what the problem is.