The haemophilia certification system in Canada

Davide Matino[1], Jerry Teitel[2], David Page[3], Arun Keepanasseril[1], Alfonso Iorio[1,4], Irwin Walker[4]

[1]Health Information Research Unit, Department of Clinical Epidemiology and Biostatics, McMaster University, Hamilton; [2]St. Michaels Hospital, Toronto; [3]Canadian Haemophilia Society, Montreal; [4]Division of Hematology, Department of Medicine, Hamilton, Canada

Introduction

Inherited bleeding disorders are caused by the deficiency or dysfunction of plasma proteins required for the development of a physiological hemostatic process[1,2]. Von Willebrand disease (vWD), haemophilia A and haemophilia B are the most common inherited disorders of hemostasis. In their severe forms, these disorders are life-threatening. However advanced treatment modalities have enabled even severely affected patients to reach the same life expectancy of the general male population at least in high-income countries[3,4] . Indeed, after the dramatic events of widespread blood-borne virus transmission in the 1970s-1980s in haemophilic patients, leading to a 35-to-40-year reduction in life expectancy in Canadian patients[5], there has been a strong drive towards continuous improvement, primarily in the safety of replacement therapy[6] .There is now a very high degree of safety from risk of blood borne transmission of pathogens as evidenced by the absence of reported transmission of blood-borne viruses in persons with haemophilia since the late 1980s to date[7]. The safety of current replacement therapies was recently confirmed by a prospective surveillance program ongoing since 2008 and based on regular monitoring of 22,242 European patients (European Haemophilia Safety Surveillance System; www.euhass.org). Regular factor prophylaxis as a therapeutic regimen has been proven effective in preventing haemophilic arthropathy[8]. Even in the presence of neutralizing antibodies (inhibitors) directed against the deficient clotting factor, particularly in haemophilia A, bleeding can usually be treated successfully using activated variants of coagulation factors[9]. Moreover, immune tolerance induction (ITI), based on the long-term intravenous infusion of large doses of FVIII, eradicates inhibitors in as many as two-thirds of patients[10]. Therefore, improving quality of life has become the primary objective of care in developed countries; thus multiple modalities (psychosocial support, physiotherapy, integration into community life, etc), not just the infusion of the deficient factor, are made available to the patient and his family, to allow them to fully experience good health.

The haemophilia care in Canada

Canada is a very large country geographically. With a total of 9.98 million square kilometres, Canada is the world's second-largest country by total area consisting of 10 provinces and 3 territories. Provinces have a great deal of power relative to the federal government, with jurisdiction over many public goods such as health care (but also education, welfare, and intra-provincial transportation). Current Canada's total population estimate (http://www.statcan.gc.ca/) is 35,295,770. The Canadian Hemophilia Registry identified a total of 2,966 haemophilia A patients, 690 haemophilia B patients, 3,963 patients affected by vWD and 1,740 patients with other bleeding disorders, including rare platelet disorders (http://fhs.mcmaster.ca/chr/data.html). Factors usage from 2007 to 2012 is reported in Table I. In 2012 a total of 190,189,628 FVIII IU were used and the mean per capita FVIII usage was 5.39 IU while a total of 45,772,681 FIX IU consumption was registered with a mean per capita FIX usage of 1.29 IU. Some patients live many hundreds of kilometers from the nearest Haemophilia Treatment Centre (HTC). A number of strategies are used to provide care to them. Home infusion is encouraged where feasible. Specialists in the HTC create links with local practitioners to coordinate care in distant locations. Telemedicine is used to communicate with patients and their caregivers. Nurse coordinators connect extensively with patients by telephone. Some centre teams conduct outreach clinics to smaller centers where a concentration of patients reside. Programs funded by government or the local chapter of the CHS provide financial support for families to travel to the HTC for annual assessments. Electronic infusion reporting systems are used to report product use. Distribution of the 24 Haemophilia Treatment Centers (HTCs) in Canada is shown in Figure 1.

The standard of care for haemophilia in Canada

A functional, efficient, and accountable system of haemophilia care has been developed in Canada mostly at the initiative of the comprehensive care centers, without acting official mandates. However, several Canadian provinces have since designated provincial haemophilia programs in specific centres (e.g. British Columbia, Saskatchewan, Manitoba and Quebec). The existing system is thus an eloquent testimony to the goodwill and constructive collaboration among patients and their families, health care providers and funders. The idea that

Table I - Reported use of factor concentrates in Canada from 2007 to 2012.

		2012-2013	2011-2012	2010-2011	2009-2010	2008-2009	2007-2008
Product	**Unit**	**Quantity**	**Quantity**	**Quantity**	**Quantity**	**Quantity**	**Quantity**
Factor Eight Inhibitor Bypassing Activity	IU	14.059.865	14.059.865	12.139.931	11.406.109	9.492.307	7.096.409
Compl.prot.total Octaplex	IU	3.360.500	3.360.500	9.942.500	920.000	12.600	0
Factor IX	IU	42.975.510	42.975.510	43.612.325	39.861.108	37.136.322	33.569.155
Factor VIIa	IU	1.463.400	1.463.400	1.248.000	1.107.000	1.227.000	978.600
Factor VIIa rec. NiaStase®	mg	25.483	25.483	30.502	30.686	34.124	33.740
Porcine FVIII	IU	-	-	0	0	0	249.340
Recombinant Factor VIII	IU	178.234.199	178.234.199	178.792.631	164.791.696	155.487.497	144.129.307
Factor VIII/VWF	IU	28.730.716	28.730.716	26.711.363	24.364.514	20.701.440	18.620.052
Factor XI	IU	35.890	35.890	51.275	74.455	64.575	85.705
Factor XIII	IU	559.000	559.000	533.000	471.750	522.000	444.250
Fibrinogen	g	542	542	933	390	1.188	901

Figure 1 - Distribution of Haemophilia Treatment Centers across Canada

a national standard of care for haemophilia be developed for Canada was first promulgated in the conference "Comprehensive Care for the Canadian Haemophiliac", Winnipeg, May 1978, organised by the Canadian Haemophilia Society (CHS) in close collaboration with its own multi-disciplinary Medical and Scientific Advisory Committee (MSAC).

To analyze the scope of the initiative, we will refer to the definition given in 1998 in the Standards for comprehensive care of haemophilia in Canada, agreed upon during a "second" Winnipeg conference, on April 30 - May 1, 1998.

The Association of Haemophilia Clinic Directors of Canada (AHCDC) and the CHS felt that national standards of care for haemophilia should be developed for the following reasons:

1. to preserve the integrity of the network of Haemophilia Comprehensive Care Programs;
2. to assure equal access and equal standards of care;
3. to establish a reference for discussion of future advances and needs;
4. to be a reference point and unifying force for staff of various organizations that are geographically dispersed and serve a small population;
5. to promote discussion and research regarding optimal ways to deliver care; and
6. to provide the basis for the design of clinics, for accreditation, and for audit and evaluation.

At its Annual General Meeting in Edmonton, the AHCDC appointed a working group on standards of care with two of us (Irwin Walker and Jerome Teitel) as co-chairs. The working group was later expanded to become a multidisciplinary one.

With the aim of developing national standards, a national multidisciplinary committee, including members of the CHS, the Canadian Association of Nurses in Haemophilia Care (CANHC), Canadian Association of Physiotherapists in Haemophilia Care (CAPHC), and the Canadian Social Workers in Haemophilia Care (CSWHC) was initiated to further the initiatives of the AHCDC. The National Standards Committee for Haemophilia Treatment Centres conducted a first conference on April 20, 2005. It was attended by the representatives from the CHS and the AHCDC. An important recommendation from the meeting was that Haemophilia Comprehensive Care should be delivered according to a set of uniform national standards and wherever possible these standards should be needs-based, data-driven and supported by evidence of effectiveness. The meeting also held that generic national standards be developed, but as they would be implemented locally the system must be flexible and adaptable, with the emphasis being the delivery of a uniformly high quality of care.

The meeting also formalised the constitution of a multidisciplinary standards of care working group to develop comprehensive standards of care for haemophilia, led by the AHCDC. All four health care provider groups and CHS were represented in the working group.

Simultaneously, the Ontario clinics were working on provincial standards of care, and they published their document which later became the template for the national standards. This work was spearheaded by the Provincial Haemophilia Coordinator at the time, Julia Sek, and the co-chairs of that group were Jerome Teitel and John Plater. After a series of meetings and deliberations, the first edition of the Canadian Haemophilia Standard of Care was published in 2007 (Canadian Comprehensive Care Standards for Haemophilia and Other Inherited Bleeding Disorders, http://www.haemophilia.ca/en) for use by Haemophilia Treatment Centres, hospital administrations, and provincial Ministries of Health. It has to be acknowledged that this national document was largely based on the Ontario Provincial standards.

The premises of the Canadian comprehensive care standards for haemophilia and other inherited bleeding disorders are that:

- improved quality of life is the ultimate goal of care, with an emphasis on measurable outcomes and independent living;
- inherited bleeding disorders are rare and therefore collaboration among HTCs and networks needs to be encouraged;
- bleeding disorders and their treatments are associated with a number of complications - medical, psychological and social-that may affect quality of life of affected individuals and so care needs to be comprehensive;
- evaluation and documentation of clinical outcomes are essential components of a comprehensive program;
- standards of care are measures that HTCs can adhere to and which can be used for auditing. Key indicators are signals that demonstrate whether a standard has been attained. They provide a way in which to measure and communicate the impact or result of the standard, as well as the process.
- accountability for utilization of factor replacement product is necessary due to its potential to cause adverse events and its high cost; this is equally true for products used in centres and at home in supervised home therapy programmes;
- HTCs have a responsibility to participate in research, education and innovation to the degree that they are capable. Regional differences within the province or region must be acknowledged in the provision of care for people with bleeding disorders.

Future perspective and conclusions

The vision is to provide comprehensive care to all individuals with inherited bleeding disorders, guided by clear standards, facilitated by engagement with stakeholders, and driven by needs and best practice, resulting in best outcomes. The focus of these standards is on the structural and resource requirements necessary for a HTC to effectively provide care, and on its functions and responsibilities.

In 2009 in response to a request from the AHCDC executive, the Standards group initiated a self assessment survey among Canadian Haemophilia Treatment Centers according to the specific standards (Table II, III, IV) and key indicators (see appendix 1) proposed. Standards of care are measures that Haemophilia Treatment Centres can adhere to and which can be used for self-evaluation and auditing. Key indicators are signals that demonstrate whether a standard has been attained. They provide a way in which to measure and communicate the impact or result of the standard, as well as the process. The goal was to validate the Canadian clinic standards by assessing acceptability and adherence. The average adherence by all clinics to all standards was 92% (standards being adhered to by an average of 22 of 24 HTCs). Adherence levels below 83% (20 of 24 HTC) were observed for only 4 standards; for two of these standards the low adherence was due to a lack of core team members, particularly social workers and physiotherapists and possibly administrative staff as well. As indicated by

Table II - Standards - 1. Scope of care

The HTC will:

1. Establish correct diagnoses.
2. Establish and maintain a full complement of core team members
3. Develop visibility in the bleeding disorder and medical community.
4. Strive to enrol all members of the target population in its region.
5. Establish a collaborative relationship among core team members
6. Establish a routine for patient access to regular and emergency care.
7. Establish a process for referring patients to services not provided within the programme.
8. Register patients in CHARMS (Canadian Haemophilia Assessment and Resource Management System) and CHR (Canadian Haemophilia Registry) databases.
9. Provide the patient with documentation that identifies his/her bleeding disorder and recommended treatment.
10. Provide education to affected individuals, family members, health care givers and others as necessary.
11. Have a home infusion program, in which patients and families are instructed in home therapy, including prevention and recognition of bleeds and correct practices.
12. Provide primary and secondary prophylaxis regimens as appropriate (all pediatric patients with severe haemophilia should be considered).
13. Provide early intervention and follow-up care to reduce long-term complications.
14. Network with outside agencies creating formal linkages to provide efficient access to their services.
15. Encourage and facilitate eligible members to participate in activities of AHCDC, CANHC, CPHC, CSWHC and other relevant HTC working groups.

Table III - Standards - 2. Quality Measures[1]

The HTC will:

1. Maintain health records according to legislation, which must include:
   - history and physical examination;
   - diagnosis and treatment recommendations;
   - operative/special procedure notes and records;
   - interdisciplinary progress notes;
   - medication records;
   - consent forms;
   - adverse events/allergies;
   - records of home therapy program (teaching, home visit to initiate program, and annual certification);
   - records of telephone communications.
2. Participate in data collection and submission to CHARMS including:
   - i. patient demographics;
   - ii. factor utilization.
3. Submit anonymous data to the Centre Point module of CHARMS and to the CHR, as required by AHCDC. AHCDC will pool and collate factor concentrate utilization data and make it available to the operators of the blood system to plan purchases, flag inconsistencies, outliers and adverse events and to conduct efficient recalls and advisories as necessary. AHCDC will also use data for research planning, and various administrative and political purposes.
4. Adhere to provincial health information privacy protection acts.
5. Be supported by its host hospital and the provincial Ministry of Health.
6. Accept accountability for the appropriate use of all factor concentrates distributed within its catchment area to registered patients with inherited bleeding disorders. This excludes cryoprecipitate and fresh frozen plasma, but includes all plasma derived and recombinant concentrated clotting factors distributed by Canadian Blood Services and Héma-Québec.
7. Participate in a formal accreditation and evaluation process once it is established.
8. Mentor, where possible, students and trainees in the health professions.
9. Establish mechanisms to acknowledge and review compliments, complaints and special requests. These compliments and complaints are documented and reviewed periodically.

[1] This section describes expected activities of an HTC that contribute to the quality of both the individual centre and the Canadian HTC network.

Table IV - Standards - 3.Therapeutic Services[1]

The HTC will:

1. Provide the appropriate professional care for their patients, recognizing the need for pediatric and adult medical expertise as appropriate.
2. Provide a comprehensive evaluation (including laboratory testing) at least annually for adult patients and semi-annually for children. This frequency is recommended for those with higher bleeding risk; for those with a lower bleeding risk a less frequent schedule will be appropriate. The evaluation will include updating wallet cards (treatment recommendations).
3. Provide assessments from each core team member at least annually. Patients will have additional access to core team members as required.
4. Provide emergency departments and family physicians with diagnosis and treatment recommendations for registered patients, consistent with the PHIPA and the hospital's health records policy. The HTC will arrange for qualified 24-hour medical coverage and consultative services for the target population.
5. Educate patients and families on the best way to advocate for and to access emergency care and other services.
6. Utilize, as appropriate, clinical practice guidelines published by AHCDC and other expert bodies for the management of bleeding episodes, inhibitors and special or surgical procedures.
7. Establish formal links to provide access to special hemostasis testing, genetic testing, and treatment for haemophilia and its complications.
8. Work in collaboration with patients and their families to promote health and to enhance ability to cope with a chronic health condition.
9. Provide education and recommendations to other community professionals who provide services to patients with inherited bleeding disorders.
10. Provide prophylaxis (primary and secondary) to patients in accordance with AHCDC recommendations and best practice.
11. Provide a home therapy program to all appropriate patients and monitor its effectiveness for each individual. The home therapy program will include comprehensive training in intravenous technique and procedures for both care givers and patients themselves, as appropriate, safe and responsible handling and storage of factor concentrates and safe disposal of used equipment and supplies.
12. Maintenance of home therapy records will be encouraged and routinely reviewed, to help in making treatment recommendations.
13. Provide injection equipment and other supplies to patients.
14. Provide management for patients with inhibitors with reference to guidelines issued by the AHCDC and other expert bodies.
15. Be located in a facility that should be readily accessible to people with disabilities.
16. Be located within an Ambulatory Clinic area to facilitate prompt assessment and treatment of acute bleeding episodes.
17. Be located in a facility that has or is linked with an Emergency Department where patients can obtain treatment outside of regular hours.

[1]This section describes the actions required of an HTC in the direct delivery of therapeutic services.

statements from the World Federation of Haemophilia and by the Canadian standards, a lack of any of these team members is particularly serious considering their importance. Lack of complete adherence to other standards was due to a variety of reasons, in most cases either easily explainable or spurious.

No correlation was found between the level of adherence to the standards and any one of a variety of HTC descriptors. The general level of acceptability of the standards was high; most clinics (20 of 24, 83%) thought the standards were useful and 22 of 24 clinics (92%) expressed their willingness to participate in evaluation and accreditation processes once these are established.

To fulfill the proposed standards of care a full audit process, modeled on the Ireland and UK experience, has been planned by the AHCHC-led Canadian Haemophilia Standards Group, but has been slowed down by unexpected privacy issues encountered early in the process.

Complementarily to this process, and in order to gather information that can be used to advocate for adequate resources in clinics, a CHS task force led by Past-President, Pam Wilton, has developed a Haemophilia/Bleeding Disorder Clinic evaluation process to be led by CHS to roll out in 2013. The proposed process, which is supported by the Executive Committee of the AHCDC, consists of an assessment of the services and resources in Haemophilia/Bleeding Disorder Clinics through interviews with clinic personnel and a patient questionnaire. This survey is evaluating the adequacy of the physical, material and human resources in Canada's 24 HTC. The overall goal is to identify any gaps in resources that may prevent Haemophilia/Bleeding Disorder Clinics from delivering care and treatment according to the Canadian Comprehensive Care Standards for Haemophilia and Other Inherited Bleeding Disorders and that may lead to sub-optimal patient outcomes (see Table I, II, III).

The primary objectives are:

- to conduct a thorough assessment of the services and resources in Haemophilia/Bleeding Disorder Clinics in each province;
- to prepare a detailed report and recommendations for hospital administrators and/or Ministry of Health officials in each province;
- to identify and meet key decision-makers in each province with the goal of maintaining and improving the care for people with inherited bleeding disorders;
- to follow up support implementation of recommendations.

Interviews with clinic personnel and patient questionnaires (see appendix 2, 3) are used in the evaluation.

The process is based on a successful initiative by the Quebec Chapter of the CHS. Study interviewers met all 37 clinic personnel across Quebec in half-hour meetings. These face-to-face interviews are preferred to a written survey to allow dialogue and clarification of responses. The resulting report is validated by the clinic directors and recommendations are made to the Ministry of Health. The same approach will be applied to all clinics across Canada.

To promote a consistent approach, the interviews are conducted by David Page, CHS National Executive Director, and Michel Long, CHS National Program Manager and, in Ontario, Sarah Crymble, Haemophilia Provincial Coordinator. The patient questionnaire was originally developed for the Irish and U.K. HTC audits, and has been modified by the group preparing the Canadian audit.

The observations, based on the clinic interviews and patient questionnaires, will be assembled in a draft report by the CHS National Office for each clinic and then shared first with the clinic director. Once vetted and approved by the clinic director a final report will be shared with the local chapter Board of Directors. Then, if necessary, a strategy will be developed to approach the appropriate health authorities - hospital administration, regional health authority of Ministry of Health - with a proposal to better meet the standards of care. Up to now, most of the Ontario assessments have been concluded and the visits in Western Canada have been scheduled for winter 2014. We expect that by the end of April 2014 the visits will be completed. Patient questionnaires are actively being distributed by Centres and responses are being received.

In summary, the process of haemophilia centre accreditation in Canada was born with the cooperation of patients and doctors. It will serve as the model to standardize and, where necessary, to improve the care of Canadian haemophilia patients. There is no "end" to such a process. In our opinion, many important results have been achieved, and several important lessons can be learned. As well, we are sure that interesting and actionable results will stem from the ongoing process.

Keywords: haemophilia, comprehensive care, audit, accreditation, certification.

The Authors declare no conflicts of interest.

References

1) Kumar R, Carcao M. Inherited abnormalities of coagulation: haemophilia, von Willebrand disease, and beyond. Pediatr Clin North Am 2013; **60:** 1419-41.
2) Lillicrap D. vonWillebrand disease: advances in pathogenetic understanding, diagnosis, and therapy. Blood 2013; **122:** 3735-40.
3) Darby SC, Kan SW, Spooner RJ et al. Mortality rates, life expectancy, and causes of death in people with haemophilia A or B in the United Kingdom who were not infected with HIV. Blood 2007; **110:** 815-25.
4) Tagliaferri A, Rivolta GF, Iorio A et al. Mortality and causes of death in Italian persons with haemophilia, 1990-2007. Haemophilia 2010; **16:** 437-46.
5) Walker IR, Julian JA. and Association of Haemophilia Clinic Directors of Canada. Causes of death in Canadians with haemophilia, 1980-1995. Haemophilia 1998; **4:** 714-20.
6) Mannucci PM. Treatment of haemophilia: building on strength in the third millennium. Haemophilia 2011; **17** (Suppl 3): 1-24.
7) Blood safety monitoring among persons with bleeding disorders-United States, May 1998-June 2002. MMWR Morb Mortal Wkly Rep. 2003; **51:** 1152-4.
8) Iorio A, Marchesini E, Marcucci M, Stobart K, Chan AK. Clotting factor concentrates given to prevent bleeding and bleeding-related complications in people with haemophilia A or B. Cochrane Database Syst Rev. 2011 Sep 7; (9): CD003429.
9) Iorio A, Matino D, D'Amico R, Makris M. Recombinant Factor VIIa concentrate versus plasma derived concentrates for the treatment of acute bleeding episodes in people with haemophilia and inhibitors. Cochrane Database Syst Rev. 2010 Aug 4;(8): CD004449.
10) Hay CR, Di Michele DM. The principal results of the International Immune Tolerance Study: a randomized dose comparison. Blood. 2012; **119:** 1335-44.

Correspondence: Alfonso Iorio
HIRU CRL-140
Clinical Epidemiology and Biostatistis
McMaster University
1280 Main St. West
L8S4L8 Hamilton, Ontario, Canada
e-mail: iorioa@mcmaster.ca

Appendix 1

Key Indicators - 1. Scope of Care*

1-1 Patients' factor levels are documented in their clinic records.
1-2 The HTC has a complete complement of core team members as listed in the standards.
1-3a The HTC has regular communications with the local chapter or region of the Canadian Hemophilia Society.
1-3b The HTC has a process in which to communicate to outside agencies about current events/workshops and conferences.
1-3c Outside agencies are able to contact team members for information.
1-4 The HTC is aware of the pattern of factor concentrate utilization in the region
1-5a There is evidence of collaboration among all members.
1-5b Core team members contribute to the development of policies, procedures and standards.
1-6a Registered patients can access care and follow-up care for acute bleeds.
1-6b Non life-threatening bleeds in non inhibitor patients are managed in the ambulatory care setting, so that there is a low hospitalization rate for bleeding episodes.
1-6c Policies & procedures are available for the treatment of non-urgent, urgent and emergency bleeding episodes.
1-7a The HTC has a referral list for secondary team members and utilizes their services routinely.
1-7b Secondary team members are extended invitations to team educational workshops and activities.
1-7c The core team is aware of referral procedures to secondary team members.
1-8a CHARMS software is available in the HTC.
1-8b All core team members have access to the CHARMS program.
1-8c Clerical work for data entry is kept current.
1-9 Wallet cards or FactorFirst cards are issued to registered patients and updated as needed.
1-10a Policies and procedures for education of newly diagnosed patients are available.
1-10b A variety of educational resources are available to distribute to patients, families and community.
1-11a Policies & procedures are available on how to administer the home therapy program.
1-11b There are patients registered in the home therapy program and the list of participants is available.
1-11c There is documentation in the patient health record about participation in home therapy programme (including date of certification)
1-12a Prophylaxis therapy is made available to the appropriate patients.
1-12b A current list of patients on prophylaxis is available.
1-13a The HTC has access to a special hemostasis laboratory, transfusion medicine department, and diagnostic imaging department.
1-13b The HTC has a procedure for assigning priority for new patient referrals.
1-14 Contact information for the HTC is current in listings with the Canadian Hemophilia Society, the World Federation of Hemophilia and parent hospital.
1-15a Core team members are members of relevant organizations and / or working groups within the bleeding disorder community and communicate regularly with these organizations.
1-15b Core team members, when able, serve on appropriate committees within the organization (AHCDC, CANHC, CPHC, and hospital).

Key Indicators - 2. Quality Measures*

2-1a Hospital records contain current HTC documentation that may include assessments by core team members stating patient goals, team recommendations, patient issues, and patient progress.
2-1b Hospital records and clinic charts include documentation of telephone calls for patient advice and follow-up.
2-2a Data is routinely exported from CHARMS to Centre Point.
2-2b Factor utilization reports are available from the local CHARMS program.
2-2c The HTC has the ability to monitor expiry dates of factor concentrates within its jurisdiction via the CHARMS program.
2-3a Data is routinely exported from CHARMS to Centre Point.
2-3b Registered patients are assigned a CHR number.
2-4 If the HTC has clinic charts, the charts are stored appropriately to maintain privacy and confidentiality, and are accessible to appropriate team members.
2-5a The HTC participates in hospital or peer evaluation and responds to critical appraisal.
2-5b There is a process to request adjustment in resources and to monitor services available to the patient population.

2-6	Data is routinely exported from CHARMS to Centre Point.
2-7	Centre volunteers to undergo accreditation process or responds to requests to do so.
2-8	HTCs located in academic healthcare institutions provide professional educational opportunities.
2-9	Patients and families have a mechanism in which to communicate concerns and compliments.

Key Indicators - 3. Therapeutic Services*

3-1	The members of the HTC have the appropriate training and qualifications to provide care to the patient population.
3-2a	The number of assessment clinics offered is sufficient to meet the standard of annual and semi-annual patient evaluation.
3-2b	The HTC provides a mechanism for team members to share knowledge with each other to promote best patient outcomes.
3-3	Core team members are available for assessment clinics and urgent care.
3-4a	The HTC has resources available to ER departments regarding treatment and complications.
3-4b	HTC provides treatment recommendations to emergency departments and family physicians.
3-5a	Educational information is offered to patients and family on current issues/events related to bleeding disorders.
3-5b	Each core team member provides education and support to patients and families.
3-5c	Team members ensure that patients have sufficient information to make informed decisions.
3-6	There are reference materials available to team members and students (i.e. AHCDC Clinical Practice Guidelines, journal articles and texts).
3-7	There are formal links to specialised laboratories and Canadian Blood Services
3-8a	When participating in research or clinical trials, team members ensure the safety and well-being of the patient above all other objectives.
3-8b	The HTC has contact information available (e.g. business cards).
3-9a	When a patient moves to a location served by another HTC, the two centres will ensure that a formal transfer takes place promptly, including the forwarding of all relevant medical records, with patient consent.
3-9b	Educational information is offered within the community as requested or needed (i.e. school, daycare).
3-10	There are reference materials available to team members and students (i.e. AHCDC Clinical Practice Guidelines, journal articles and texts).
3-11	The team has a mechanism to evaluate the home therapy program outcomes with participants.
3-12	Patients receive injection equipment and supplies free of charge
3-13	There are reference materials available to team members and students (i.e. AHCDC Clinical Practice Guidelines, journal articles and texts).
3-14	Physical clinic space is appropriate for people with disabilities or mobility aids.
3-15a	There is private clinic space available for acute assessments and treatment.
3-15b	The HTC ensures an adequate stock of factor concentrates is maintained within its institution.
3-16	The Emergency Department affiliated with the HTC has recommended treatment guidelines for registered patients.

*Numbering of Key Indicators refers to the corresponding Standards

Appendix 2

Canadian Hemophilia Society
Help Stop the Bleeding

STANDARDS OF CARE FOR HEMOPHILIA AND OTHER INHERITED BLEEDING DISORDERS

PATIENT QUESTIONNAIRE

The Canadian Hemophilia Society (CHS) and its chapter is asking you to complete this questionnaire on the services you (or your child) receive at your comprehensive care clinic. Completion of this questionnaire is entirely voluntary. Your participation will help us help the clinics to meet the standards of care as defined by the Canadian Comprehensive Care Standards for Hemophilia and Other Inherited Bleeding Disorders. The goal is to improve resources and ultimately your care.

The CHS is also meeting the personnel of the comprehensive care clinic to get their views on how services can be maintained and even improved.

Please complete this questionnaire for yourself (or your child) and return it to the CHS in the enclosed stamped addressed envelope. **This questionnaire is confidential and anonymous.** Your answers will be seen only by the two people compiling the results at the CHS National Office. No individual replies will be revealed to the staff at your comprehensive care clinic.

A summary of the responses will be prepared and used to advocate for optimal care for people with inherited bleeding disorders.

Please indicate your province of residence: _____

Please indicate your comprehensive care clinic and the date of your last visit: _____

_____ / _____
Month Year

1. When you need to be seen by the bleeding disorder team within normal working hours because of an urgent or new medical problem, and have no appointment, are you **satisfied with the availability of the clinic team members** to help you with the immediate problem?
   ☐ Yes ☐ No ☐ Not applicable
   COMMENTS: _____

2. When you need to be seen by the bleeding disorder team within normal working hours because of an urgent or new medical problem, and have no appointment, are you **satisfied with the care** you (or your child) receive?
   ☐ Yes ☐ No ☐ Not applicable
   COMMENTS: _____

3. Does the clinic provide you with a *FactorFirst* or other form of wallet card?
   ☐ Yes ☐ No
   If yes, is it updated annually?
   ☐ Yes ☐ No
   COMMENTS: _____

4. If you (or your child) are on "home infusion", are you satisfied with the arrangements that are in place for your home treatment (for example, telephone access to nurse coordinator, education in home infusion techniques, supply of factor concentrates, supply of infusion equipment)?
   ☐ Yes ☐ No ☐ Not applicable
   COMMENTS: _____

5. If you (or your child) are on "home infusion", are you advised to provide a diary about your home treatment/bleeding events?
   ☐ Yes, and I fill out the diary regularly on paper. ☐ Yes, I am asked to, but NO, I do not provide a diary.
   ☐ Yes, and I fill out the diary regularly on EZ-log, Helitrax or i-CHIP. ☐ No, I am not requested to.
   COMMENTS (If you do not fill out the diary, please provide the main reasons):

6. How often do you go to the comprehensive care clinic for a regularly scheduled check-up?
   ☐ Every 6 months ☐ Every 2 years ☐ Other (please specify) _____
   ☐ Once a year ☐ Never
   COMMENTS (If you are invited but do not attend, please provide the main reasons):

7. At the time of your regular check-up, which clinic members do you meet?
   ☐ Physician ☐ Other (please specify) _____
   ☐ Nurse ☐ Other (please specify) _____
   ☐ Physiotherapist ☐ Other (please specify) _____
   ☐ Social worker ☐ Other (please specify) _____
   ☐ Other (please specify) _____ ☐ Not applicable
   COMMENTS: _____

8. Are you satisfied with the arrangements that are in place for your check-up? (Please consider such things as: appointment notification, length of time in clinic, wait times, preparation instructions, explanation of procedures/tests.)
   ☐ Yes ☐ No ☐ Not applicable
   COMMENTS: _____

9. Are all the questions you have and issues you raise at your regular check-up addressed to your satisfaction?
   ☐ Yes ☐ No ☐ Not applicable
   COMMENTS: _____

10. Are you satisfied with the physiotherapy and orthopedic services that are available for the management of your joint problems?
    ☐ Yes ☐ No ☐ Not applicable
    COMMENTS: _____

11. Are dental services offered at or through your clinic?
    ☐ Yes ☐ No ☐ I don't know
    COMMENTS: _____

12. If you use the dental services offered through your clinic, are you satisfied with them?
☐ Yes ☐ No
COMMENTS: _____

13. Are the costs of dental services covered?
☐ Yes ☐ No
COMMENTS: _____

14. Do you have access to a social worker if you (or your child) need one?
☐ Yes ☐ No ☐ I don't know ☐ Not applicable
COMMENTS: _____

15. Do you have access to a psychologist if you (or your child) need one?
☐ Yes ☐ No ☐ I don't know ☐ Not applicable
COMMENTS: _____

16. Are you satisfied with the psychosocial services that are available at or through your clinic?
☐ Yes ☐ No ☐ Not applicable
COMMENTS: _____

17. If you or your child recently moved from pediatric care to adult care, were you satisfied with how the clinics helped with the transition?
☐ Yes ☐ No ☐ Not applicable
COMMENTS: _____

18. Does your clinic team provide information and advice to other health care providers (for example, pediatricians, family physicians, dentists, etc) who care for you (or your child)?
☐ Yes ☐ No ☐ I don't know ☐ Not applicable
COMMENTS: _____

19. Does your clinic team provide information and advice to people in your community (for example, teachers, daycare workers, employers) if you request it?
☐ Yes ☐ No ☐ I don't know ☐ Not applicable
COMMENTS: _____

20. Are you satisfied with the access to your clinic (for example: parking, after-hours entrance, signage, availability of wheelchairs in the building)?
☐ Yes ☐ No ☐ Not applicable
COMMENTS: _____

21. If you (or your child) need to go to your clinic for help between your regularly scheduled appointments for a non-urgent medical reason, is it easy to book an appointment?
☐ Yes ☐ No ☐ Not applicable
COMMENTS: _____

22. How quickly are you usually seen?
☐ Immediately ☐ The same day ☐ The next day ☐ 2 or 3 days later ☐ Not applicable
COMMENTS: _____

23. When your comprehensive care clinic is closed or after hours, do you know whom you should contact for help?
☐ Yes ☐ No ☐ Not applicable

24. When you attend your hospital Emergency Department (ED), are you satisfied with the care you (or your child) receive?
☐ Yes ☐ No ☐ Not applicable
COMMENTS: _____

25. What do you think is very good about your comprehensive care clinic?

26. What do you think is most in need of improvement at your comprehensive care clinic?

27. Have you ever made a complaint about your clinic?
☐ Yes ☐ No
If yes, was the complaint process made clear to you? ☐ Yes ☐ No
If yes, was your complaint handled to your satisfaction? ☐ Yes ☐ No
COMMENTS: _____

28. What other comments would you like to make?

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE.

Appendix 3

Assessment of HTC services and resources

Questions to the clinic:

1. How many patients are registered in your clinic with the following conditions?
   - ___ Severe hemophilia A
   - ___ Moderate hemophilia A
   - ___ Mild hemophilia A
   - ___ Severe hemophilia B
   - ___ Moderate hemophilia B
   - ___ Mild hemophilia B
   - ___ Hemophilia A or B & inhibitors
   - ___ Type 1 VWD
   - ___ Type 2 VWD
   - ___ Type 3 VWD
   - ___ Rare factor deficiencies
   - ___ Inherited platelet disorders

Questions to the healthcare professionals:

1. What proportion of a full-time position do you spend on the care of people with hemophilia and other bleeding disorders? (Consider care and treatment, inter-disciplinary meetings, education of patients and family members, outreach to the community and other health care professionals and continuous medical education.)
2. Is this enough to answer the demand?
   a. If yes, explain.
   b. If not, why?
   c. Do you have data or reports to support your assessment?
3. In your opinion, with regard to respecting the standards of care adopted in 2007, what are the main strengths of your Hemophilia Treatment Centre?
4. In your opinion, with regard to respecting the standards of care adopted in 2007, what are the main failings or weaknesses?
5. In an ideal world, what more could you do to ensure optimal utilization of clotting factor concentrates, including better product tracking, measuring outcomes and avoiding wastage, under-prescription and over-prescription?
6. What would be the principal recommendations you would make to administrators of your hospital or to other health authorities such that you could provide optimal care to your patients?
7. What would be the principal recommendations you would make to administrators of your hospital or to other health authorities such that you could continue to provide high quality care and conserve resources?
8. What other observations would you like to make?
9. What other data can you provide (e.g. % of patients receiving annual or bi-annual assessments on schedule) that demonstrate the HTC's capacity, or lack thereof?