The Bloody Truth: Exploring the Cost-Effectiveness of Adult Hemophilia in British Columbia

by

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Abstract

Severe forms of bleeding disorders are on the rise across the country and the ability to properly identify, monitor and manage this group is important not only for their future health outcomes, but also to contain the cost of expensive blood products and long-term care. Through policy innovation there is potential to improve the effectiveness of care in British Columbia at modest increase in cost. This study undertakes qualitative interviews, a detailed cost analysis of options and case studies. Findings from interviews suggest concerns over inadequate present human resources in the St. Paul's hemophilia centre, inadequate interaction between patient and staff, and inadequate patient education on prophylactic care. The outcome of the analysis indicates that some increase in human resources would provide benefits at modest incremental cost, and generate some offsetting cost savings.

Keywords: health; bleeding disorders; hemophilia; adults; blood products; costing
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List of Acronyms

CHARMS	Canadian Hemophilia Assessment and Resource Management Information System
CHS	Canadian Hemophilia Society
CHSG	Canadian Hemophilia Standards Group
CIHI	Canadian Institute for Health Information
CTR	Central Transfusion Registry
ER	Emergency Room
FRT	Factor Replacement Therapy
FTE	Full Time Equivalencies
HR	Human Resources
HTC	Hemophilia Treatment Centre
IBRCD	BC Inherited Bleeding and Red Cell Disorders Services
ICHIP	Inherited Coagulopathy and Hemoglobinopathy Information Portal
ITT	Immune Tolerance Therapy
PBCO	Provincial Blood Coordinating Office
PHSA	Provincial Health Services Authority
PK	Pharmacokinetics
SPH	St. Paul's Hospital
VWD	von Willebrand Disease
WFH	World Federation of Hemophilia

Executive Summary

British-Columbia's bleeding disorders programs are facing similar problems to comparable programs across the country. Low staffing levels, difficulty in monitoring use of expensive blood products, issues of centralization, growing numbers displaying bleeding disorders and difficulties with both patient education and management. Given the projected increase in severe forms of hemophilia and the increased life expectancy of Canada's bleeding disorders population, there are legitimate concerns as how to provide adequate management of this population (Fisher et al., 2000, p. 5).

The objective of this study was to address *the potential to improve the cost-effectiveness of the present level of care and potentially improve the quality of care for those suffering from two primary bleeding disorders; hemophilia A and hemophilia B in British Columbia*. The study focuses on the current climate for hemophilia treatment within the local health area of Vancouver; however, due to the centralized nature of care, the study considers the needs of the population as a whole, thus it extends to broader BC and the Yukon which is covered by the hemophilia treatment centre at St. Paul's Hospital in Vancouver.

In order to inform and develop policy options for this issue, the research methodology undertook several separate approaches. First was a literature review and research into climate, costs and clinical practices of bleeding disorders within British-Columbia and Canada. The second approach was informal interviews with administrative and clinical experts in the field to determine the day-to-day issues of patients and clinicians as well as the framework for potential policy options to address these concerns. The third approach was a cost-analysis to determine the total associated costs for hemophilia treatment at St. Paul's hemophilia treatment centre, including: total factor usage based on severity, staffing, emergency ward visits and diagnostic and clinical support services. Finally, a case study analysis was undertaken to determine how the hemophilia treatment centre in BC compares in terms of staffing levels to those of other similar clinics in large Canadian, metropolitan cities. Combined, these approaches uncovered key issues; specifically, there was low patient and staff

interaction due to low staffing and geographical barriers and this resulted in difficulty providing individualized patient care and monitoring the usage of blood products. This was determined to be key as the overwhelming costs of hemophilia care (over $11 of an annual total of roughly $12 million at St. Paul's) are associated with use of factor concentrates. The remaining costs of roughly $800,000 are attributed to all other costs: staffing, diagnostic and clinical support services, etc.

The proposed alternative options to address the policy issue were evaluated on the basis of four criteria: f*inancial cost, implementation complexity, patient acceptability and improving access to comprehensive care team.* The policy options considered were the following: status quo, increasing human resources, mandatory registration with a hemophilia treatment centre and the return to use of plasma-derived factor concentrates over recombinant ones.

Overall, there is a need for increased support for adult hemophilia in BC. This is reflected in the recommendation that, in the short-term, increasing human resources is the most viable option. However, there are long-term considerations: mandatory registration with the hemophilia treatment centre would reduce geographical barriers and improve patient-staff interaction, resulting in decreased costs and better patient health outcomes. Unquestionably, there are many potential cost savings and benefits by improving staffing within clinics: better monitoring of at home factor use, consistent and thorough follow-up of patients, reduction in emergency services, reduction in future program costs, reduction in over-prescription and in use of expired factor. However, realizing these savings and patient benefits requires upfront investment and some high on-going staffing costs.

Chapter 1.

Introduction

British-Columbia's bleeding disorders programs are facing similar problems to comparable programs across the country. Low staffing levels, difficulty monitoring use of expensive blood products, issues of centralization, a growing trend in the bleeding disorders population and difficulties with both patient education and management. There is also the issue of an aging population, while those with bleeding disorders are living as long as the general population, which is certainly positive, they are also developing age related diseases and comorbidities never before seen in the population, such as cardiovascular disease (Mejia-Carvajal et al. 2006). Given the projected increase in severe forms of hemophilia and the increase Canada's elderly population, there are legitimate concerns to provide adequate management of this population (Fisher et al., 2000, p. 5). Thus, there is a need for proper management and quality of care for this population. From the clinical perspective, quality of care for bleeding disorders constitutes several key items: provide appropriate professional care, provide early intervention and follow-up care (to reduce long-term complications); provide 24-hour medical coverage and consultative services and provide education and mentorship services. These standards of care are fully listed by the Canadian Hemophilia Standards Group.

There is also a legitimate concern about the cost of bleeding disorders. Those suffering from bleeding disorders can cost more than an average annual salary and according to CIHI's review of 'circulatory diseases', the estimated cost per patient ranges from $62,000 - >$100,000 per year (Fitch & Pyenson, 2011). British-Columbia faces some unique issues, particularly in terms of catchment areas (the one adult clinic covers the entirety of BC and the Yukon) and comparatively lower staffing than other similarly sized clinics. This capstone will explore the issues surrounding two prominent bleeding

disorders; hemophilia A and hemophilia B, in British Columbia. The goal is to determine if there is the potential to improve the cost-effectiveness of the present level of care and potentially improve the quality of care for those suffering from these forms of hemophilia within the province and the Yukon. The focus of this project is adult hemophilia. The decision to focus on hemophilia A and B is due to their prevalence, severity and my ability to access information related to the diseases. Furthermore, due to similar constraints of access, time and ethics revolving around recovering data from pediatric care, cases attributed to pediatric hemophilia have been excluded from the research.

1.1. Policy Problem

The policy problem explored in this study is *the potential to improve the cost-effectiveness of the present level of care and potentially improve the quality of care for those suffering from two primary bleeding disorders; hemophilia A and hemophilia B in British Columbia*. The study focuses on the current climate for hemophilia treatment within the local health area of Vancouver, however due to the centralized nature of care, the study necessitates consideration to the needs of the population as a whole. Thus it extends to greater BC and the Yukon which is covered by the lone adult hemophilia treatment centre at St. Paul's Hospital in Vancouver.

Chapter 2. Background

This chapter provides an overview of bleeding disorders and their prevalence, specifically Hemophilia A and B, von Willebrand Disease (VWD) and other complications such as inhibitor. This chapter introduces the broad host of complications and varying considerations required by those suffering from these diseases and those health care professionals providing care. Understanding the nature and differences of the disorders allows for a better understanding of challenges for management and quality of care as well as the associated costs. For the purpose of the capstone, VWD and inhibitors are omitted from the analysis.

2.1. Living with Bleeding Disorders

Contrary to popular belief, having hemophilia does not mean that an individual will bleed more quickly or profusely than a non-hemophiliac; instead they bleed for a longer time. An external wound is no more serious for a hemophiliac than for a non-hemophiliac; however internal bleeds (known as hemorrhages) are problematic as they can be spontaneous and can lead to complications. These hemorrhages can be common for those with more severe forms of hemophilia. Bleeds can occur in interstitial tissues and muscles; however they are most often found in joints such as knees, ankles and elbows and they are typically caused by minor injuries such as the twisting of a joint or a bump/minor trauma during sports (World Federation of Hemophilia, 2014). In rare cases the bleeding occurs within vital organs: such as the brain. In these cases the condition quickly becomes life threatening. These bleeds are treated and managed with expensive drugs/blood products called factor concentrates.

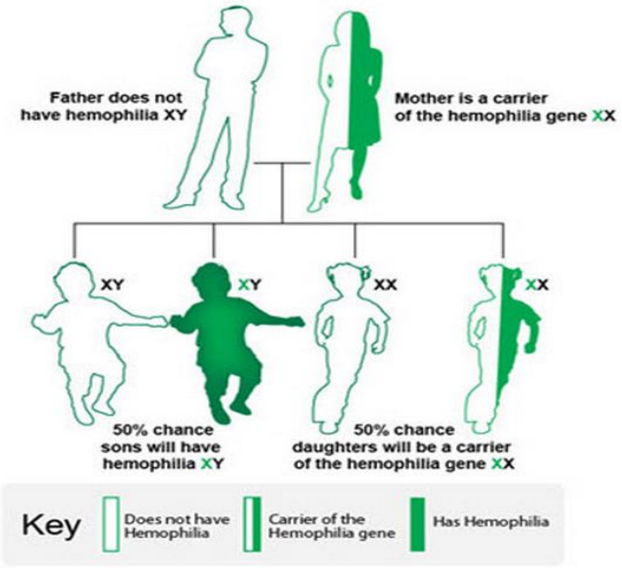
An individual affected with a bleeding disorder may have fewer options when it comes to staying active. The ability to stay active is important for a healthy lifestyle no matter the circumstances. This is also true for those with bleeding disorders: those with

better physical condition show reduced numbers of bleeding episodes (Canadian Hemophilia Society, 2014). Due to the possibility of bleeding into joints and muscle, many contact sports are considered high risk, particularly for those suffering from the more severe forms of the disorder. The reality of living with hemophilia and other bleeding disorders is that a lack of or delay in treatment, as well as minor injuries (such as a sprained ankle) can have serious impacts on the individual's quality of life. A sprained ankle for instance, can cause a bleed, leading to pain and possible long-term joint damage. A full list of sports and their designated levels of risk can be found at the CHS website.

2.1.1. What is Hemophilia?

Hemophilia is a lifelong, hereditary bleeding disorder in which the blood of a person does not clot normally (Canadian Hemophilia Society, 2014). The inability for the blood to clot properly is due to a sex-linked mutation (affecting the X-chromosome) in which an individual has low levels or lack of specific proteins called "factors". Based on the level of factor found in the blood, an individual can be categorized as having mild, moderate or severe hemophilia. A normal, non-hemophiliac individual will have 50-100% of these factor levels in the blood. By comparison an individual with mild hemophilia will have 5-30%, those with moderate hemophilia 1-5% and those with severe hemophilia less than 1% of relevant factor levels (Centres for Disease Control and Prevention, 2013).

Figure 2-1: Hereditary context of hemophilia



Source: CDC http://www.cdc.gov/ncbddd/hemophilia/facts.html

Hemophilia can be divided into several types each with distinct deficiencies in a particular factor protein. These include: hemophilia A, hemophilia B, hemophilia C. Hemophilia A, also known as classic hemophilia, occurs when an individual has low levels or is completely missing factor 8 (FVIII). Hemophilia B arises when the same deficiencies occur with factor 9 (FIX). Hemophilia C occurs when the individual is deficient in factor 11 (FXI). Finally, in very rare cases, hemophilia can develop later in life. This form; called acquired hemophilia, typically involves middle-aged and elderly people or women in the later stages of pregnancy or who have recently given birth (World Federation of Hemophilia, 2014). While the focus will be on hemophilia A and B, it is important to note that there are a wide array of bleeding disorders, all with unique considerations from the perspective both cost and patient outcomes.

2.1.2. Von Willebrand Disease

Von Willebrands Disease (VWD) is caused by a deficiency of von Willebrand factor (VWF). It has three subtypes: type 1, type 2 and type 3. Type 1 occurs when an individual has low levels of VWF and accompanying low levels of factor VIII. This is the

mildest form of von Willebrand disease and also the most difficult to diagnose. Type 2 is more complex and occurs when the VWF itself does not function properly. There are several gene mutations that cause each type (2A, 2B, 2M and 2N) and each is treated differently. Type 3 occurs when people have a complete lack of VWF and low levels of factor VIII. While this is the rarest form of the disease, it is the most serious (National Heart, Lung and Blood Institute, 2011).

The factor protein associated with VWD is linked to hemophilia A. It helps bind the clotting factor in hemophilia A (factor VIII) with platelets in a blood vessel wall, acting like a glue that helps plug bleeds during the clotting process.

Other Types of Bleeding Disorders

While hemophilia A/B and von Willebrand Disease are the primary focus for bleeding disorders in Canada and globally, there remain many other disorders. They can cause abnormal bleeding and affect different factor proteins (FI, FII, FV, FVII, FX, FXIII). Due to ethical considerations, low case occurrence and recommendations from team members at St.Paul's adult hemophilia clinic these much rarer disorders will be omitted from the research. Another omission from this research will be the acquired versions of the bleeding disorders, which also are very rare. Those affected by this form will not necessarily require lifelong treatment as the symptoms can be removed through treatment, something that does not occur with the non-acquired forms of bleeding disorders.

2.2. Diagnosis

When identified and diagnosed, blood disorders are easily classified based on the deficient factor levels found in the blood. Diagnosis of bleeding disorders however, is complex and symptoms are not always obvious. This is particularly true for those with the mild forms of bleeding disorders. Diagnosis can occur either pre or post-natal; early diagnoses are typically made when the family history is known. Later diagnoses are

made evident by a bleeding episode, such as menorrhagia (heavy menstrual bleeding) in women, or after a surgical procedure.

2.3. Epidemiology

Even in its most common form, hemophilia is a very rare disorder. Hemophilia A, the most common form of hemophilia, affects fewer than 1 in 10,000 people. Hemophilia B is even less common and affects 1 in 50,000 people. That is roughly equivalent to 3,000 Canadians being affected by hemophilia A and 650 by hemophilia B (Canadian Hemophilia Society, 2014).

The disorder affects all races and economic groups proportionally; however, men are far more commonly affected than are women. This is true for all forms and severities of hemophilia and is more apparent for the most severe forms of hemophilia (which affect almost only males). By contrast, women who are carries of the disorder often display symptoms of mild hemophilia, particularly during menorrhagia (heavy bleeding during their period). Women can have bleeding disorders, however they are typically only rarely affected by severe forms of hemophilia. This is due to the hereditary aspect of the disease and they will only be severely affected if the mother is a carrier and the father is a hemophiliac. This combination is extremely rare (World Federation of Hemophilia, 2014). Von Willebrands Disease is the most common bleeding disorder and occurs in 1-2% of the population. This is because unlike hemophilia, VWD is inherited from either parent and affects males and women equally. While the most prevalent, it often results in only mild bleeding episodes.

Overall, trends show that the prevalence of hemophilia is increasing. This is particularly true for the prevalence of severe hemophilia (Stonebraker et al. 2010). The reasons for this are not known, however better reporting and expertise is likely a cause.

2.3.1. Prevalence of Hemophilia A

According to 2013 statistics compiled by the Canadian Hemophilia Registry hemophilia A in which people lack the factor VIII protein, affects a total of 2,950

individuals in Canada. There are 2,706 men (91.6%) affected as compared to 244 women (8.2%). The mild form of hemophilia A occurs in 1,798 (roughly 60% of all cases). These cases are divided among the sexes with 233 (13%) women and 1,565 men (87%) affected. Comparatively, this group is the least skewed towards men. [1]

As the severity of the diagnosis increases, the prevalence becomes more heavily skewed towards men. 259 (98%) of 265 moderate hemophilia A cases are men. Finally, 793 (99.4%) of the 798 cases of severe hemophilia A are men. A small group (88 total reported cases), those suffering from inhibitor factor VIII deficiencies was limited to men only.

Hemophilia predominantly affects men; nevertheless there is a single category in which this does not hold true. This is for those with acquired hemophilia. Only 4 cases have been reported and of these cases 3 are women. This is attributed to the fact that the most likely way in which acquired hemophilia develops is through complications in the later stages of pregnancy or having recently given birth. Furthermore, this form of hemophilia is often treated outside the hemophilia treatment centres, meaning that it is also not reported to the Canadian Hemophilia Registry (CHR).

2.3.2. Prevalence of Hemophilia B

Those suffering from hemophilia B, in which individuals lack or are missing the factor IX protein, are less numerous in Canada than those with hemophilia A. A total of 687 cases were reported in 2013. The distribution by gender is very similar to that of hemophilia A, with 598 (87%) being men and 89 (13%) being women. Similar patterns across severities exist as well with a greater percentage of men being affected by the more severe forms of hemophilia B. Mild cases account for 286 (42%) of all reported cases of hemophilia B, 70% of whom are men and 30% women.

Within the moderate hemophilia B category the prevalence data steeply skews towards men as it did in hemophilia A. Of the total of 226 reported cases; which

[1] Full Canadian Hemophilia Registry available at CHR website: http://fhs.mcmaster.ca/chr/data.html

accounts for 33% of all cases, 222 (98%) were men and the remaining 4 (2%) were women. The disparity trend continues with the severe group and those with inhibitor factor IX deficiencies, wherein all but one of the 171 cases (99%) of severe hemophilia B and all four cases of inhibitor hemophilia B, respectively, affect men.

2.3.3. Prevalence of von Willebrand Disease

This is the most common bleeding disorder affecting roughly 1% of the population. It affects men and women equally (Lillicrap & James, 2009). The Canadian Hemophilia Registry reports a total of 3,948 cases of VWD across all types (VWD1, VWD2, VWD3 and acquired VWD).

Due to the difficult nature in identifying the disease; particularly in the mild type 1 form, and because the Canadian Hemophilia Registry was not intended to capture the VWD demographic from the outset (those with VWD were included on an inconsistent basis), there are a total of 808 unknown cases. I have chosen to exclude these cases and base the prevalence statistics on the remaining total of 3,140 cases in which the type was known.

As is the trend with bleeding disorders, the mildest form of von Willebrand Disease Type 1 (VWD1) is the most prevalent, with a total of 2600 cases reported (83% of all cases). The distribution by gender differs from hemophilia A and B. Among von Willebrand cases, 1,675 (64%) are women and the remaining 925 (36%) are men.

The second, moderate form (VWD2), affects a total of 427 individuals (14% of all von Willebrand cases). The prevalence is distributed almost equally between sexes: 230 (54%) women and 197 (46%) men. The most severe and rare form (VWD3) affects a total of 99 individuals (3% of all cases) and is again evenly distributed among the sexes, 54 (54%) women and 45 (46%) men.

2.4. Organizations Tackling Inherited Bleeding and Red Cell Disorders Services

The major player in addressing bleeding disorders in BC is Providence Health Care (PHR). The PHR encompasses 17 facilities, over 6000 staff members and 1000 physicians and an operating budget of roughly $842 million per year[2]. Within this organization, St.Paul's Hospital (SPH) houses the only adult hemophilia clinic in the province (Providence Health Care, 2013). It is a hospital focusing on acute care, teaching and research with 506 beds that serves over 380,000 patients across BC annually. While SPH provides a wide array of services, the bleeding disorders program only recently became part of the BC Inherited Bleeding and Red Cell Disorders Services (IBRCD) program. Prior to March 2012, the program for management and care of these bleeding disorders, including hemophilia A, B and VWD, operated via two separate divisions: the adult program at St. Paul's Hospital (SPH) in Vancouver and a pediatric program at the Children's and Women's Health Centre. Presently (as in the past) the program also covers Yukon and covers approximately 800 patients, making it one of the largest hemophilia programs in Canada

As of March 2012, the BC Provincial Blood Coordinating Office (PBCO) in combination with the Provincial Health Services Authority (PHSA) launched what was then a new program, known as the IBRCD. The goal of the IBRCD is to create a single, coordinated provincial program that covers both children and adults with bleeding disorders. This version allows the program to better meet the national standards of care, ensure that patients maintain proper access levels to resources and that there is better tracking of the expensive blood products being used.

In many ways, this is a step towards a system that mimics that of Quebec. While bleeding disorder clinics vary from province to province, Quebec uses a mandatory registration system to help centralize the process of monitoring factor concentrate consumption, and as a byproduct, patient health outcomes and costs. This mandatory registration is not in effect in BC and the IBRCD initiative has yet to be fully

[2] Three acute care facilities, five residential care facilities, one assisted living facility, one addictions clinic and seven dialysis units

implemented. While mandatory registration has been successful this respect, priorities of government and health authorities often change and there is (particularly in government) a tendency to make decision on four-year cycles. Thus, the potential long-term benefits and cost savings are not fully realized because of these shifting priorities and timelines (Mechtel & Potrafke, 2011).

2.4.1. Central Transfusion Registry (CTR)

CTR is a database operated by the BC Provincial Blood Coordinating Office (PBCO), it contains records of recipients within the jurisdiction of the provincial program who have received blood products. Data sources include[3]:

- Hospitals and clinics in BC and the Yukon - submit recipient and product data electronically to CTR on a monthly basis.
- Canadian Blood Services - provides product (component and plasma protein product) information, including lot number, dose, expiry date, and manufacturer information
- Reporting Facilities - provide surveillance information regarding transfusion reaction
- Screening Physicians - provide IVIG request / approval information

While the CTR is important, the bleeding disorders clinic in BC is currently shifting from one data entry and management system called CHARMS (Canadian Hemophilia Assessment and Resource Management information System) to a new and improved system called ICHIP (Inherited Coagulopathy and Hemoglobinopathy Information Portal). This transition means that electronic health records, data input and data retrieval are not fully operational, making proper management and follow-up with patients more challenging.

[3] Source: PBCO website: http://www.pbco.ca/index.php/data/ctr-data

2.4.2. Adult Bleeding Disorders in BC

As of 2014, British-Columbia has 447 total registered adult patients suffering from bleeding disorders of which 174 are attributed to hemophilia A, 55 to hemophilia B and 127 to VWD. The focus of this study is the 229 with hemophilia A and B. As noted previously, the St. Paul's Hospital team recommended that VWD and the remaining patients who are either unknown (52) or categorized as "other" (38) be excluded. For them available data are limited.

Table 2-1: Prevalence of severity and type of bleeding disorders in BC, 2014

Type	Classification	Number
Hemophilia A	Severe	63
	Moderate	19
	Mild	89
	Inhibitors	3
	Total	**174**
Hemophilia B	Severe	10
	Moderate	19
	Mild	26
	Inhibitors	0
	Total	**55**
VWD	Type 1	101
	Type 2	26
	Type 3	1
	Total	**128**
Other		38
Unknown		52
Total		**447**

While the prevalence of hemophilia continues to rise over time, there is similarly a rise in better lifestyle and healthcare practices (such as the use of long-acting blood products) and the result is that hemophiliacs are living longer. The lifespan of those with mild and moderate hemophilia is approaching that of the general population to the point where they are equivalent (Mejia-Carvajal et al. 2006). Importantly, this increased

lifespan is not limited to simply the mild forms and extends to those with severe hemophilia (Darby et al. 2007). The higher prevalence of hemophilia may be explained in several ways: the increased survival of hemophiliacs, an improved ability to diagnose and classify the disease, improved methods of reporting and/or the effect of immigration of hemophiliacs to Canada.

Undoubtedly living longer is a positive outcome; however with increasing age comes an increased variety and number of complications and co-morbidities. Examples of these age related issues include cancers and cardiovascular disease (Oldenburg et al. 2009). This results in the need for increased frequency and intensity of care.

2.5. Comprehensive Care and the Care-giving Team

According to the BC Provincial Blood Coordinating Office (PBCO), the optimal management of patients with these bleeding disorders is through a comprehensive care setting. This is particularly true for those with the severe forms of the disease, as the patients are more likely to face risk of complications. Comprehensive care is a broad term and World Federation of Hemophilia identifies its key components as the following:

- Accurate diagnosis
- Early and adequate coagulation factor replacement for bleeding episodes
- Prophylaxis[4] to prevent joint bleeding and damage (and the resulting arthropathy)
- Long-term management of joint and muscle damage
- Management of significant complications of treatment (including inhibitors) and;
- The psychosocial support and education required to manage the bleeding disorder

Comprehensive care requires a comprehensive care team. The members of this team should have experience in treating associated bleeding disorders and should be accessible for timely care. Generally, this team should consist of several core members,

[4] Prophylaxis is explained fully under 2.6.2 of the Treatment Practices section

including: a hematologist, nurse coordinator, a laboratory specialist and a psychosocial expert (World Federation of Hemophilia, 2012). In Canada, a set of guidelines set out by the Canadian Hemophilia Standards Group (CHSG) requires a medical director, nurse coordinator, physiotherapist, social worker and administrative assistant. Though not mandated, they are generally accepted by practising clinicians and administrative personnel.

However, across Canada many of these standards are not met and many of the clinics lack other roles such as psychiatry and dentistry as well as physical space to practice. These are access issues that are further exposed in the interview section of this paper. These standards of care are attached in the Appendix D and form the basis for the case study analysis section.

2.6. Treatment Practices

This section explores the composition of the multidisciplinary team required to manage bleeding disorders, current treatment practices associated with each of the previously discussed bleeding disorders based on the type and severity of each, and explanation of prophylaxis and inhibitors as well as technical information related to dosages.

2.6.1. Factor Replacement Therapy

Currently the method for treatment is factor replacement therapy (FRT). The missing factor proteins are replaced via infusions of factor concentrates, either by injections or the use of a catheter. Not every injury or bleeding episode requires that factor concentrates be administered. The general policy in any case is to infuse first and ask questions later, the idea being to prevent avoidable complications.

There are two sources of these factor concentrates: human plasma (called plasma-derived factor) or a genetically engineered cell line (called recombinant factor). The plasma-derived factor comes from plasma donations pooled together and separated through fractionation into different products. The main products from this process are

albumin (to treat burns), immune globulins (for immune system problems), factor VIII and factor IX. Generally plasma-derived products are limited to use for hemophilia B (factor IX), this is due to an individual sensitivities in which they respond better to treatment from a plasma derived source of factor concentrates as opposed to the synthetic version.

Recombinant factor is genetically engineered in a laboratory setting. The gene that creates human factor VIII or IX is isolated and inserted into non-human cells where they eventually produce human factor. Recombinant factor products are considered safer than plasma-derived products due to the history of contamination of plasma-derived products during the 1980's. During this time, HIV and forms of hepatitis infected roughly 2000 individuals in Canada.

2.6.2. Prophylaxis

Prophylaxis is a preventative treatment method administered for moderate and severe cases of hemophilia A/B and VWD. This treatment provides an individual with regular infusions of the corresponding clotting factor concentrates. The goal is to maintain minimum factor levels found in the plasma (around 1%), as doing so will reduce the risk of bleeding and associated joint damage.

There are two main types of prophylaxis: continuous and intermittent. Continuous prophylaxis is the primary form and is provided regularly. Intermittent prophylaxis is essentially short term prevention, typically given prior to engaging in sport or work activity or during or after surgery. Prophylaxis in general has been shown to be effective in reducing bleeds and the associated joint damage, particularly in children (World Federation of Hemophilia, 2013). The alternative to prophylaxis is called episodic treatment, frequently referred to as "on demand" treatment and is given at the time of bleeding. The preference for clinicians, both in terms of patient management and health outcomes, is to use a prophylactic approach as it leads to better long-term outcomes.

2.6.3. Weight Based Dosage Protocols

Whether using prophylaxis, emergency dosage or regular FRT, factor dosages follow a similar formula based on the type and severity of the bleeding episode, the weight of the individual and the volume of plasma in the body. The factor dosage is measured in single units in which each unit is equivalent to the amount of factor activity found in 1 ml of plasma (Canadian Hemophilia Society & Hemophilia Federation of America, 2014).

Table 2-2: Approximate dosage protocols for hemophilia A and B

Type	Hemo A (FVIII)	Hemo B (FIX)
Mild	10-15 U/kg	20-30 U/kg
Moderate	20-25 U/kg	40-50 U/kg
Severe	35-50 U/kg	70-100 U/kg

Source: http://www.ahcdc.ca/index.php/membership/practice-guidelines/86-hemophilia-and-vwd-clinical-practice-guidelines-management

The observed variance in dosage ranges for hemophilia A and B are due to the differences in the amount of factor required to raise one kilogram of weight to the normal activity levels. Factor VIII products requires 50 units (0.5 IU/kg) and factor IX products required 100 (1 IU/kg). Thus, an individual weighing 100kg, who has moderate hemophilia A will require approximately 2000-2500 units of factor VIII. Comparatively, if this same case was for hemophilia B, it would require 4000-5000 units of factor FIX.

2.6.4. Pharmacokinetic Dosages (PK)

There has been criticism of weight based dosages as this method is not the most efficient method due to variances in body composition and activity levels. Today, bleeding disorder specialists are relying more on pharmacokinetic (PK) dosages which address the individual's ability to absorb, distribute and metabolize a given drug. The result is more consistent drug delivery and reduced peak and trough in plasma levels. Essentially, this method provides more stability for both the patient and the clinician. The benefits of PK are well noted in studies ranging from angiotensin (for hypertension) to antipsychotics, and while this allows for improved management of drug usage it has drawbacks (Israili, 2000 and McEvoy, 2006). Primarily, to determine appropriate dosage protocols for patients using PK requires increased time and resources from clinic staff an issue that has yet to be overcome across the country.

2.6.5. Inhibitors

This is a very rare yet serious complication of hemophilia in which the body rejects the infused factor concentrate. This renders treatment ineffective as the clotting factor is eliminated and the bleeding cannot be stopped (Canadian Hemophilia Society, 2014).The widespread use of recombinant factor VIII (rFVIII) has led to the development of inhibitors against factor VIII. For patients with severe hemophilia A these inhibitors develop in 20 to 30 percent of all severe cases and effectively render treatment with FVIII useless. This puts an already high-risk population at even higher risk of morbidity and mortality (Franchini, 2010). A positive note is that 2 out of 3 inhibitor cases are resolved on their own or by treatment. In the case of inhibitors, treatment is performed through immune tolerance therapy (ITT) as opposed to factor replacement therapy (FRT).

Considering the prevalence, nature and severity of the disorder, the potential treatment options and the high cost of the disease, this research seeks to more accurately determine the costs of care and the mechanisms to improve the management of these costs. Doing so will be challenging. From a policy perspective, nothing like this

has been done before. Furthermore, the research will determine what possible alternatives there are for improved management of factor usage and the overall health outcomes of patients in the short and long term.

Chapter 3. Methodology

In order to determine which policy options will do the best in addressing the policy problem that *there is potential to improve the cost-effectiveness of the present level of care and potentially improve the quality of care for those suffering from bleeding disorders (hemophilia A/B and VWD) in British Columbia* the research methodology includes expert interviews and a cost analysis. The overall purpose of the research is to explore how to improve these outcomes through policy recommendations.

3.1. Research Approach

The research methodology for this project, excluding literature review and research for the background, is comprised of three components:

- Interviews with key stakeholders who provide professional care to those suffering from bleeding disorders or who work from an administrative side for SPH, CHS and other organizational bodies related to hemophilia and other bleeding disorders

- Cost Analysis of the available relevant direct and ancillary costs associated with hemophilia care. These include: factor utilization, HR/staffing based on current and recommended FTE, ER visits, diagnostic services and non-labour costs.

- Case study analysis highlighting and comparing current practices and support mechanisms for those suffering from bleeding disorders (particularly related to human resources in clinics) across several jurisdictions

3.1.1. Interview with key stakeholders

Eight interviews were conducted in a semi-structured manner with healthcare professionals from St. Paul's Adult Hemophilia Clinic in Vancouver, British Columbia and those in administrative roles both within and outside of the institutional setting of the hospital. Specifically, the professionals interviewed included the following : program directors, physicians, nurses, nurse coordinators, SPH administrations and the national executive director of the CHS. Each interview was recorded and lasted one hour on average. These interviews were conducted between December 2014 and February 2015 to discover the issues faced by the hemophiliac population and management of care. Determining key themes was accomplished through the use of thematic analysis, a qualitative analysis tool (Braun & Clarke, 2006).

3.1.2. Cost Analysis

This section explores the costs associated with the treatment of hemophilia: clotting factor utilization and staffing, as well as ancillary costs associated with diagnostic services (imaging services, lab tests, consultation fees, etc.) non-labour costs (consultations, equipment maintenance, travel, etc.) and emergency room visits. This analysis used data provided by SPH staff and uses staff estimates of the implications from reforms.

3.1.3. Case Study Analysis

The case study analysis section uses an exploratory comparative case study to compare St. Paul's Hospital in Vancouver with clinics/cases along current staffing levels of several key positions including: nurses, physiotherapists, administration, data management, social workers and physicians. It will also compare these cases across levels of clotting factor concentrates used. To be used as a comparison to the SPH hemophilia treatment centre, other clinics needed to be adult clinics, of similar size in large metropolitan cities. With the help of the national executive director of the Canadian Hemophilia Society, four comparator clinics were selected. For reasons of confidentiality, these clinics could not be identified and are listed as Case A through Case D. The

comparisons are analyzed based on the total average staffing levels of each clinic as compared to the average; results are summarized at the end of the section.

All necessary ethical approvals were obtained prior to conducting research; these are detailed in Appendix C. The section that follows details the summary and discussion of the findings that resulted from the research methodology.

Chapter 4. Interviews with key stakeholders

After conducting interviews with bleeding disorder specialists, core team members of a comprehensive bleeding disorders program, hospital administration and a high level executive at the Canadian Hemophilia Society a number of common themes emerged (see Appendix A for descriptions of participants). Themes were determined using a five-step process within thematic analysis. These included becoming familiar with the data via transcription, generating initial codes, searching for themes, reviewing themes and finally, defining and naming said themes (Braun & Clarke, 2006). The key theme that arose was a present lack of human resources, leading to low levels of patient interaction and patient education and empowerment. These are highlighted in the following section.

4.1. Lack of Human Resources

Lack of HR seemed to be the overriding theme identified by the interviewees. It creates a broad range of issues in regards to management of bleeding disorders and creates a domino effect leading to decreased clinic time and poor patient data.

> Our biggest challenges are not fancy or unique, they all boil down to resources. Space and staff….it takes time and effort to set the stage, to get the patient in to see us and it's not a one shot thing, you know. You have some discussions, you make some changes, but the follow-up is really key and the follow-up is where we really fall down because we're always scrambling. (Deb Gue, interview, 2015, February)

Respondents noted that the generally low FTE for key roles meant misuse of time. Nurses for example, have roughly nine hours per week of professional time shifted toward menial tasks that ultimately take away from the care giving role. The cyclical nature of this issue causes an increased likelihood of unresolved issues in managing

factor usage. Interviewees noted that the incidence of specialized staff being pulled away from their designated duties to perform more menial tasks was increasing.

> It's about maximizing the skill set of the individuals…sometimes what happens is that you have very highly skilled people doing menial filing or menial tasks…there's no thought into having enough of a body or enough of an FTE to take care of some of those things. So for example we have some of our nurses doing word processing stuff and you know they are putting together clinic notes and dealing with the font and the look and you know what it's such a waste of their time and skill set (Dr. Shannon Jackson, interview, 2015, February)

> One of the reasons I'm under time constraints today, that I wasn't when I planned this, is that our secretary is sick today and there's no replacement. So, you're looking at the secretary, in addition to everything else (Deb Gue, interview, 2015, February)

The noted lack of HR is not a problem specific to SPH or British-Columbia. Reports from the CHS and CHSG noted that across the nation, hemophilia clinic staff have identified similar issues in terms of inadequate staffing resources. Concerns related to the negative consequences of inadequate staffing however, remain consistent.

> We've known [about under-staffing] for about a decade…especially since the standards of care were developed and the self-assessment was done by the centres themselves. They identified major shortcomings in terms of staffing in centres and we've known about this in anecdotes for a long time. (David Page, interview, 2015, February)

There was a sense of disconnect between hospitals and what the specialized health care providers faced on a daily basis. David Page spoke of the 'behind the scenes' work done on a regular basis by hemophilia centre staff that is of great importance for follow-up, factor use management and health outcomes.

> One of the problems I think for hospitals is they don't see [hemophilia centre staff] at the ER; they don't see [hemophilia patients] even in outpatient. When things go well, [hemophilia patients and centre staff] are out of sight out of mind. [Other hospital staff] don't realize all the work that's being done in terms of follow-up, telephone follow-up, support, the research behind it, all these things that allow [hemophilia patients] to live for a whole year and not have to go in and see anybody (David Page, interview, 2015, February)

4.2. Patient/Staff Interaction

Almost all interviewees noted that interaction between patient and staff was viewed as being critical for proper management of patient factor use and health outcomes. Not surprisingly, the respondents and literature noted that in general the more frequent the interaction between patients and healthcare professionals, the better the care. At the hemophilia treatment centre at SPH however, staff are only currently scheduled to meet patients once per year where a consult will last roughly 10-20 minutes with necessary team members. Respondents acknowledged that some patients may resist meeting with specialists due to logistics, negative experiences in the past or the feeling that they are adequately managing the disorder via home infusions, but the general consensus was that the current allotted time is insufficient. To some degree this is a symptom of the lack of HR, but is also attributable to low clinic time (4.5 hours per week), minimal physical space and geographical challenges.

> The more chances you get to connect with people the better the care goes. This goes back to staffing I think…Investment in HR [would allow us] to be a bit more proactive in connecting with patients. [This] always pays off…When you are limited in your staff, but have unlimited factor you can guess what happens: patients just use more factor (Dr. Shannon Jackson, interview, 2015, February)

Geography was a concern in regards to patient/staff interactions. The large catchment area for the centre and consequent high travel times greatly affects the ability for staff to interact with patients on a more frequent basis. Furthermore, high travel times can result in additional costs to the patient (travel, accommodations, services, etc) causing them to disassociate from the specialized treatment offered by HTC clinicians

> Over half of our population lives beyond what would be considered a reasonable commute to get into Vancouver…. there is a whole host of other issues that come up and we need to come up with [new strategies] to connect with these patients. And that's where a lot of the HR goes in. [We spend] a lot of phone time trying to connect (if possible) with TeleHealth. We recognize that any opportunity to talk with these patients is good because you're not necessarily going to see them in person. This is definitely a case where more is better. (Dr. Shannon Jackson, interview, 2015, February)

While consult times, clinic hours and staff availability are concerns, one interviewee emphasized the importance of the interaction with the entire core team in helping

patients manage their bleeding disorder. Given the low FTE for the roles it was not simply a matter of increasing a single role. A patient being able to access his or her physician more often is helpful, but it does not provide the well-rounded care required. This well-rounded or comprehensive care requires the input from a specialized team of caregivers (nurses, physicians, social worker, physiotherapists and administration/data management) who have the knowledge, experience and expertise to adequately manage these complex disorders.

> Whether it's getting people to come to their visit regularly or helping with their financial side, there are a lot of issues that people struggle with when they have this chronic disease. And so I think it really truly is [expanding] the team that we need to address. Treatment really is a team effort. It's not about just adding physician resources (Sandra Barr, interview, 2015, February)

Interviewees echoed the importance of team based care in managing bleeding disorders, noting that each individual brings valuable expertise and experience to the team and combined, they are able to provide optimal care through the clinic at SPH.

4.3. Patient Education and Empowerment

While lack of staff, patient interaction and concerns over the complexity of the disease were noted, the interview process led to the idea of patient education and empowerment. This is not a new theme (see Mazzuca, 1982) and at SPH interviewees viewed empowerment and education not only as a way to improve patient self-management but also as an excellent risk management tool for clinicians.

> We're not shooting for the moon here. But to really work with these patients, to team up with them, to educate them, to partner with them…when we do that, we've really been able to execute some very significant changes. (Deb Gue, interview, 2015, February)

Without proper education of the disease patients are more likely to have self-management issues. Dr. Shannon Jackson noted that patient education and empowerment also mitigates problems arising during emergency visits. A triage nurse may, due to the rarity of the disease, never have seen bleeding disorders and incorrectly

identify them. Dr. Jackson also pointed out that in some extreme cases, this has led to patients being moments away from unnecessary surgery, which she was forced to call in and cancel. Another interviewee (David Page), noted that the trend of patient education has improved self-management and has led to many benefits for both patients and clinicians.

> Really the objective is to make patients autonomous in their care. Put care in their own hands, educate them so they can be very knowledgeable about taking care of themselves. We've witnessed a lot of improvements in care from the clinical side in terms of provision of care and pharmaceuticals over the last 20 years, but a good deal of that improvement is from patient education and their ability to self-manage effectively. (David Page, interview, 2015, February)

The education of patients, which is currently done through the HTC and online materials, allows patients to be more confident when dealing with self-management and also with emergency situations. The benefits are not only in terms of better health outcomes but also in terms of costs from avoided ER visits and surgeries.

Overall, the resulting issues related to inadequate human resources are echoed by the interviewees as being pervasive and problematic. The issues overlap into other areas of work such as patient/staff interaction which is vital given the chronic and individualized nature of the disease. According to the interviewees personal experiences and data from patient reports provided by the CHS and CHSG, patients are likely to see better outcomes if they have access to the full array of specialized team members at an HTC. The ability to attain better health outcomes by improving communication and interaction between patients and clinicians is echoed by several studies on clinician-patient communication and health outcomes (Street et al. 2009). Furthermore, the interviews reveal that taking the necessary steps to improve clinic time (which would require an increase HR and the current physical space of the clinic) is key for improving the clinical services provided and the associated health outcomes.

Finally, while clinics and health authorities have pushed self-management as a means to better patient outcomes, it lacks the consistent education from bleeding disorder specialists that it requires to function at an optimal level. When self-regulation is properly implemented it allows for the patient-clinician encounters to provide more

favourable patient responses and adherence as well as reductions in health care utilization in general (Clark et al. 2004).

Chapter 5. Cost Analysis of Reforms to Accommodate CHS Audit

Below is an excerpt from findings of the audit of St. Paul's Hospital hemophilia treatment centre, undertaken in 2014 by the Canadian Hemophilia Society (CHS). It highlights key issues that will be explored in this chapter through a cost analysis of reforms to accommodate the CHS audit.

> "…despite committed, experienced and well-trained staff, the Hemophilia Program at St. Paul's Hospital fails to respect the Canadian Comprehensive Care Standards for Hemophilia and Other Inherited Bleeding Disorders in several important ways. Patients with an acute bleed are often unable to go to the Hemophilia Treatment Centre for assessment and treatment during regular working hours. This situation is unheard of in any comprehensive care centre in the Developed World. Moreover, a lack of clinic time means that patients do not receive their regular assessments annually, as prescribed in the Standards of Care. Avoidable joint damage may occur, leading to long-term poor outcomes, increased factor concentrate use and joint surgery.
>
> While patient feedback was extremely positive with relation to the skill, experience and professionalism of the care team members, it confirmed the problems with relation to access to Program staff and clinic scheduling.
>
> A patient population that has almost quadrupled in a decade and increasing demands for services are putting a severe strain on human resources, thus limiting delivery of optimal care in certain circumstances.
>
> Approximately 95% of the total cost of hemophilia care can be attributed to the cost of clotting factor concentrates and only 5% to the delivery of care (Centre staff, clinics, diagnostic testing, research, measurement of health outcomes…). A small investment in human and physical resources would help the St. Paul's Hemophilia Program respect Standards of Care and lead to better"

A 2005 study by the Canadian Institute for Health Information (CIHI) gives a sense of the costs of acute diseases. Disease of the circulatory system (which include

hemophilia) have the second-highest annual unit cost of $11,260 and the third highest number of in hospital stays with 292,562 (CIHI, 2005). Narrowing the field to CIHI's 'circulatory diseases', the estimated cost per patient rises sharply, ranging from $62,000 - >$100,000 per year[5](Fitch & Pyenson, 2011). Clearly, these are large groupings and are not appropriate estimates of cost for the hemophiliac population.

The expected cost of a hemophiliac's care varies with: age, activity levels and body composition (more muscle mass means higher doses of factor concentrate to achieve desired plasma levels). This paper gives a clearer picture of actual costs in the case of the hemophilia treatment centre at St. Paul's Hospital. The following section explores the direct costs associated with factor use and ancillary costs. The latter include: costs of professional care (by doctor, nurse, physiotherapist, social worker and administration/data manager) and hospitalization/ER visits.

5.1. Direct Costs

This section will explore the more visible costs associated with the treatment of hemophilia, particularly the cost of factor concentrates for hemophilia A and B. This is highlighted in Table 5-1 below. Following will be a breakdown of key considerations, based on this table (including important limitations).

Costs of Factor Concentrates

Factor concentrates have varying costs based on the manufacturer and whether the factor concentrate is for hemophilia A or hemophilia B. Due to issues of confidentiality it is not possible to divulge costs associated with individual manufacturers, nor the cost associated with either plasma-derived or recombinant factor concentrates as standalone products. On the advice of David Page (National Executive Director of the Canadian Hemophilia Society) I used a "blended" cost for factor VIII clotting factor

concentrates ($0.60 per IU) and $0.88 per IU for factor IX clotting factor concentrates cost. Plasma derived factor, which currently is only used for cases of hemophilia B, was determined to be $0.71 per IU[6].

Table 5-1: Estimated Annual Factor Consumption and Costs, SPH, 2012-14

Hemophilia Classification	St. Paul's # of patients	3 year total, 2012-2014	annual average per category	annual average per patient	annual average cost per category	annual average cost per patient
	(count)	*(units)*	*(units)*	*(units)*	*(dollars)*	*(dollars)*
FVIII Severe	63	40,035,826	13,345,275	211,830	$8,007,165	$127,098
FVIII Moderate	19	2,026,176	675,392	35,547	$405,235	$21,328
FVIII Mild	89	981,353	327,118	3,675	$196,271	$2,205
FIX Severe	10	7,237,884	2,412,628	241,263	$2,123,113	$212,311
FIX Moderate	19	1,765,412	588,471	30,972	$517,854	$27,255
FIX Mild	26	229,004	76,335	2,936	$67,175	$2,584
Total FVIII	171	43,043,355	14,347,785	83,905	$8,608,671	$50,343
Total FIX	55	9,232,300	3,077,433	55,953	$2,708,141	$49,239
Total FVIII & FI	226	52,275,655	17,425,218	77,103	$11,316,812	$50,074

source: Deb Gue, SPH annual factor consumption 2012-2014

Over a three year period, hemophilia A patients at SPH consumed an annual average of 14.3 million IUs of factor VIII, costing roughly $8.6 million per year in factor VIII. $8.0 million of annual factor VIII cost (93%) is attributable to the 63 cases of severe forms of hemophilia A. The average annual distribution of factor IX for hemophilia B is 3.1 million IUs costing $2.7 million. $2.1 million (78%) of this total cost is attributable to 10 severe hemophilia B patients.

The annual cost per severe hemophilia B patient is almost twice that of a severe hemophilia A patient. However, type B is rarer than A and the total annual factor cost for hemophilia B patients is roughly one third that for hemophilia A. The costs of clotting

factor per patient also vary based on the individual characteristics of the patient. Recall that the dosages of clotting factor required to raise a patient plasma levels to the normal activity levels are based on the total weight and plasma levels of the individual. The larger the plasma volume or the more severe the form of hemophilia, the more clotting factor required and thus the higher the associated costs. This highlights the positive impact that an individualized treatment plan could have. Tailoring consumption to the needs of each individual requires better data on an individual's factor usage trends and the ability to monitor them to make appropriate changes. This promotes more efficient use of clotting factor concentrates and better health outcomes.

Staff Salary Distribution

Table 5-2: Annual salary costs based on current FTE at SPH (assuming 20% benefits)

Role	Current FTE	Current Salary
Physician	0.2	$88,767.84
Nurse	1.3	$136,982.04
Physiotherapist	0.4	$35,138.88
Social Worker	0.4	$31,904.64
Data Management/Administration	0.7	$32,096.40
	Total	**$324,889.80**

Currently, the annual salary costs for the core HTC team members total approximately $325,000. The current FTE are substantially below the recommended levels set out by the Canadian Hemophilia Standards Group (this is discussed in subsequent sections). The rationale for increased staffing numbers is to shift to forms of care that allow for better management of factor usage (eg, weight based dosages and a more individualized form of care such as pharmacokinetic dosages (PK)). These individualized approaches/practices of care require either increasing the total number staff and associated clinic space or by increasing the time current staff spends in the clinic.

There are some important limitations to consider. First, due to the transition from CHARMS to the ICHIP (essentially a patient outcome monitoring database) and the variable quality of patient self-reports, the data recorded may not capture the complete picture of factor use by hemophiliacs in BC. Second, staff at SPH work on a plethora of diseases and often take on roles outside their job description (sometimes going so far as volunteering additional time). The focus of this study is on hemophilia, the major bleeding disorder at SPH. The omission of other bleeding disorders such as von Willebrand Disease (VWD) underestimates the complexities faced by staff and the burden that a lack of adequate FTE creates.

Nevertheless, the key point made in this cost analysis is that factor use is the overwhelming cost component of hemophilia care. For both hemophilia A and B the vast majority of clotting factor consumption and therefor cost, is attributable to patients with severe forms of hemophilia. Data from literature and interviews show that this group is the fastest growing among the hemophilia population (Stonebraker et al. 2010). Thus, appropriate management of patients is a key cost consideration in terms of potential cost savings.

5.2. Ancillary Costs

Ancillary costs include many less visible items. They include: non labour costs, cost of hospitalization diagnostic and clinical support services as well as cost associated with emergency ward visits. While this is not a comprehensive list, it provides a sense and a baseline of the costs that might be included with care for hemophilia in BC.

Non-Labour Costs

These include costs related to administrative expenses, travel and accommodation, supplies, equipment maintenance, etc. The list and associated costs were provided by SPH for a five-year period (and are not comprehensive).

Cost of Hospitalization

There are many considerations in the calculations for hospitalization costs[7]. Not only do they vary from one location to another; they depend on the type of care needed (cardiology vs hematology), the patients state current state of health, type of visit (planned vs emergent), whether patients were under the care of their own family physician or the care of another family physician[8]. What follows is a representative sample of SPH costs allocated to hemophilia patients. The list is by no means exhaustive.

Hospitilization

The daily hospitalization cost for acute inpatient care was determined to be $1,280 (cost provided by Providence Healthcare – Patient Rate Summary). Cost per outpatient emergency visit not elsewhere calculated was estimated to be $500. Based on interviews, I estimated roughly two thirds of ER visits were handled on an outpatient basis; one third required a one-day hospitalization. Based on these assumptions I estimated the average cost of hospital services not elsewhere included was $957 per visit. Hemophiliac patients visiting an emergency ward received an estimated additional factor dosage of 4000 units. Based on the overall distribution of SPH patients between hemophilia A and B, the average cost of this additional factor is $2,673 per ER visit.

Cost of diagnostic services

Diagnostic services are another major cost, specifically for imaging services such as MRI and X-Rays, which are needed to identify and monitor current and future long-term issues such as joint damage and arthritis. Due to the chronic nature of the disease, the dangers of internal bleeds and potential long-term damage to joints, hemophiliacs will need more frequent use of imaging services than the average in-patient.

[7] According to a 2005 study of acute care hospital stays published by CIHI, the average cost per stay in a hospital across all diseases is roughly $7,000 ($6,983)

[8] This is similarly reflected in a report in 2008 by Dr. Chuck K. Wen of McMaster University who noted an average cost of between $6,500 and $6,800 per stay

Imaging

Four primary imaging services were costed. With unit cost in parentheses, these included: X-rays ($110), CT Scans ($630), MRI ($686) and ECG ($25). I sampled 30 visits and, based on the sample frequencies, estimated the expected cost of imaging services to be $268 per ER visit.

Diagnostic tests

Tests include a wide array of services such as: renal profile, urinalysis, coagulation screen, rapid metabolic panel, anti HIV, hepatitis and many more. However, on average, bleeding disorder team members noted roughly 6 services are used per patient (this is confirmed in my tabulations using ER visits). The cost of these services is difficult to determine on an individual basis, however an average cost of $288 was provided for these services by administration at SPH.

Average cost of an Emergency Ward Visit

Given this information, the average cost of an ER visit is determined to be $4,186. SPH estimate of the total emergency visits for the year 2014 was 84.[9] This equates to slightly over $352,000 in a single year for emergency visits. Naturally, this can shift dramatically from year to year given that rare cases can cost upwards of $500,000 for factor alone (Dr. Shannon Jackson, interview, February, 2015).

Table 5-3: Average cost of an Emergency Room (ER) visit

Services, diagnostics, drugs	**Avg Cost**
Clotting factor	$ 2,673
Diagnostic tests	$ 288
Imaging (see unit costs and probabilities below)	$ 268
ER and hospital costs not otherwise counted	$ 957
TOTAL	**$ 4,186**

[9] Total number of ER visits may not be entirely accurate due to the transition from CHARMS to ICHIP (as noted earlier)

5.3. Room for Improvements

There is a need to determine adequate staffing and the effect this will have on the use of factor as well as the use of diagnostic and clinical support services such as imaging and lab tests. To this end, I present two cases for increases in staffing. Both are rooted in recommendations made by the CHS and CHSG. One uses CHS's loftier recommendations for staffing (Case 1) as opposed to the more conservative recommendations by SPH administration (Case 2). Table 3.2 shows the cost of compliance between CHS recommendations and SPH recommendations for staffing. Included are estimated costs of physical space, of ER visits and of ancillary costs. Note that factor cost is divided between a relatively small quantity distributed in the course of ER visits (roughly $225,000) in the status quo, and the residual $11.1M distributed elsewhere.

Table 5-4: Cost of Compliance with recommendations of Audit by Canadian Hemophilia Society vs. St. Paul's Hospital

Category	Status Quo	Reform		Incremental cost (+), saving (-)	
Direct Costs		Case 1	Case 2	Case 1	Case 2
- Factor	$ 11,092,000	$ 10,619,000	$ 10,852,000	$ (473,000)	$ (241,000)
- Staff	$ 325,000	$ 857,000	$ 590,000	$ 532,000	$ 265,000
- Space	$ 27,000	$ 41,000	$ 41,000	$ 14,000	$ 14,000
ER visits (including factor distributed in the ER)	$ 352,000	$ 246,000	$ 281,000	$ (105,000)	$ (70,000)
Ancillary Costs					
- Diagnostic	$ 114,000	$ 125,000	$ 125,000	$ 11,000	$ 11,000
- Non-labour	$ 213,000	$ 234,000	$ 234,000	$ 21,000	$ 21,000
TOTALS (excluding factor distributed outside the ER)	**$ 1,030,000**	**$ 1,503,000**	**$ 1,270,000**	**$ 473,000**	**$ 241,000**
TOTALS (including all factor)	**$ 12,122,000**	**$ 12,122,000**	**$ 12,122,000**	**$ 0**	**$ 0**
Factor cost/ total (%)	**93.4%**	**88.9%**	**91.0%**		

Reform can be expected to lower overall use of factor, SPH staff have made estimates of approximately 10 percent. I have constructed Table 5.4 on a break-even basis: what percentage reduction is required to generate zero net cost of reform? In Case 1 the necessary reduction is 4.3 percent; in Case 2 it would require a smaller 2.2 percent reduction. If factor cost reduction is greater than these thresholds, there will be net savings from the reform; if less, there will be net financial cost increases. While both cases exhibit varied increases in staffing levels, the effects of this increase on the break-even analysis means that Case 1 requires an increase of $532,000 to reach desired staffing levels as compared to the status quo, whereas the more conservative Case 2 requires an increase of only $265,000.

It is important to note that in each case, there would be a necessary increase in clinic space to be effective. This increase is space was laid out in the SPH 2015 business case which provided an increase in the number and size of the exam rooms. The increase would include doubling of exam room size and increasing the number of exam rooms from three to five. The current clinic space is about 600 square feet, which translates to a cost of $27,000 (assuming an annual opportunity cost of rent at $45 per square foot). The 50% increase in clinic space would increase the cost for space to $40,500, a total increase of $13,500.

A further consideration is the estimated reduction in ER visits. There were an estimated 84 ER visits in 2014. The current estimated cost per ER visit is approximately $4,200.[10] This translates to an estimated cost of $352,000 per year. While there is uncertainty as to the effect of reform the bleeding disorder team members estimated that Case 1 would reduce ER visits by about 30% and Case 2 by about 20%. Case 1, ER costs would decrease by approximately $107,000 in Case 2, there would be a decrease of approximately $70,000. Finally, there is an estimated increase of 10% in ancillary costs (primarily for imaging and lab tests) due to the ability of staff to process more patients in the hemophilia centre. This would increase the ancillary costs by $32,000.

[10] $4,200 per emergency visit includes a list of parameter values and assumes a per day cost. The annual cost assumes that each ER visit is a single day. This is a conservative estimate given the probability that a number of cases are multiple days, meaning the total cost for ER visits (and the potential avoided costs) would be significantly higher.

Chapter 6. Case Study Analysis

This section explores the relationship between staffing levels across key roles by comparing St.Paul's Hospital to four other hemophilia clinics. The five key roles include the following: nursing, physiotherapy, social work, physicians and a combination of administration and data management. Recall that the cases presented have been selected by the National Executive Director of the Canadian Hemophilia Society (CHS), David Page. All are adult clinics of similar size and are located in large metropolitan areas across Canada. Due to need for confidentiality, the clinics other than St. Paul's have been anonymized (Case A through Case D) and thus comparators will be void of explicit information related to roles and factor usage. Comparisons in terms of what constitutes adequate staffing is based on requirements set out by the CHSG standards which include: scope of care, quality measures and therapeutic services[11].

6.1. Comparative Staffing Levels

The five clinics vary in their base FTEs across measured roles, reflecting the distinct needs of each. While differences are expected based on the number and size of clinics, the cases also displayed concerning similarities: all are below recommended FTE levels suggested by the CHS. This is detailed in Table 6-1 below

[11] For more information on CHSG standards see: Canadian Comprehensive Care Standards for Hemophilia and other Inherited Bleeding Disorders, First Edition, June 2007 in Appendix D.

Table 6-1: Clinic Comparison of Current FTE vs. FTE Recommended by CHS

Centre	Staff Resource	Current FTEs	Recommended FTEs	Gap
St. Paul's, (Vancouver)	Nursing	1.3	2	0.7
	Physiotherapy	0.4	0.8	0.4
	Social Work	0.4	0.8	0.4
	Admin/Data Management	0.7	1.5	0.8
	Physician	0.2	1	0.8
Case A	Nursing	1.5	2	0.5
	Physiotherapy	0.4	0.6	0.2
	Social Work	0.1	0.2	0.1
	Admin/Data Management	0.8	1	0.2
	Physician	0.9	1	0.1
Case B	Nursing	1.6	2.2	0.6
	Physiotherapy	0.2	0.4	0.2
	Social Work	0.2	0.4	0.2
	Admin/Data Management	1	1.5	0.5
	Physician	2	2	0
Case C	Nursing	0.8	1	0.2
	Physiotherapy	0	0.2	0.2
	Social Work	0	0.2	0.2
	Admin/Data Management	0.4	0.4	0
	Physician	0.1	0.1	0
Case D	Nursing	0.7	1	0.3
	Physiotherapy	0	0.2	0.2
	Social Work	0.1	0.2	0.1
	Admin/Data Management	0.1	0.2	0.1
	Physician	0.25	0.3	0.05
Average Gap (by role among five clinics)	Nursing	0.46		
	Physiotherapy	0.24		
	Social Work	0.2		
	Admin/Data Management	0.32		
	Physician	0.19		

The SPH gap for each role is larger than the average. Particularly evident are gaps in nursing and administration/data management. Given the importance of nursing in bleeding disorders discussed previously, this gap will result in decreased touch-points, poorer management of factor usage, and lower patient health outcomes. Similarly, findings suggested that another important gap identified is in relation to the

administration and data management role (gap of 0.8 at SPH as compared to 0.32 across other cases)[12]. Administration and data management play a vital role in maintaining accurate records, research, monitoring, follow-up with patients and generally providing support services for the health care providers. With such low levels in this role, records are less likely to be maintained properly. Thus, inadequate staffing for data management and administration decrease the likelihood that expensive blood products are properly and efficiently documented. Currently, the problem is compounded as records and data are transitioning from the Canadian Hemophilia Assessment and Resource Management Information System (CHARMS) to ICHIP.

The gap in this administration/data management is concerning because it has wide-spread effects on other roles within the program. This role has a wide array of duties, from managing phone calls to maintaining accurate transfusion records. Due to the gap in FTE for this role, these duties often fall to the other already time-constrained team members, often nurses. The result is less time with patients, invariably causing difficulty managing factor usage and poorer health outcomes which disregard the standards of care that are required by the CHSG.

Proper staffing in social work is important, particularly in considering the transition period from pediatric to adult hemophilia care. Inadequate FTE in social work means that the clinic is less capable of providing proper support for these patients. This has serious implications because it can cause young adults to disengage from the necessary active care. From a long-term perspective, this can potentially lead to joint damage and the need for what would have otherwise been avoidable surgeries. The final result is increased costs associated with poor management of acute and chronic conditions.

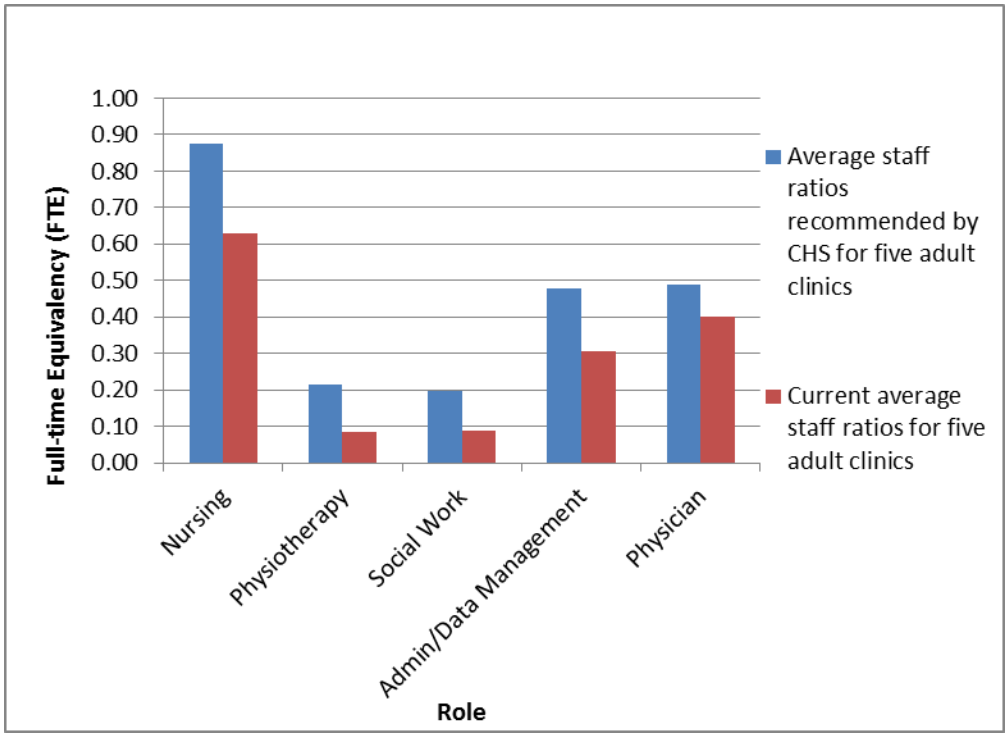
[12] This is the second highest gap at SPH across assessed roles only behind physicians. Though Physicians have the highest gap, it is not the most concerning. The physician FTE data may be subject to different reporting methods in different clinics.

Table 6-2: Staff ratios per 100 patients

Clinic	Nursing	Physiotherapy	Social Work	Admin/Data Management	Physician
St. Paul, Vancouver	0.60	0.19	0.19	0.33	0.09
Case A	0.37	0.10	0.02	0.20	0.22
Case B	1.13	0.14	0.14	0.71	1.42
Case C	0.43	0.00	0.00	0.22	0.05
Case D	0.59	0.00	0.08	0.08	0.21
5 Clinics					
Average	0.63	0.09	0.09	0.31	0.40
Average (as required by CHS)	0.88	0.22	0.2	0.48	0.49
Average Gap	-0.25	-0.13	-0.11	-0.17	-0.09

At first glance, it would seem that SPH does relatively well in terms of staffing per 100 patients, only with nursing and physicians FTEs is SPH below the comparative average ratios for the five clinics. While this is true, the problem is that collectively; all five clinics are understaffed based on the CHS guidelines in every role. The largest and most obvious gap is for the role of nursing. While any gap can be viewed as serious, as discussed previously nursing plays a vital role in both patient management and outcomes. There is a need to clarify that each clinic works under different provincial guidelines, has different populations and do not necessarily operate under the same circumstances. A clearer view of the current deficiencies in FTE for key roles across the five clinics is detailed in Figure 6-1 below.

Figure 6-1: Comparing Current Five-Clinic Average FTEs per 100 patients to Staff Ratios Recommended by the Canadian Hemophilia Society



While there are many considerations in making comparisons between bleeding disorder clinics in different jurisdictions, the goal of Figure 6-1 is to show that the average staffing of the five centres falls short of the guidelines set out by the CHS and CHSG in every measured category.

Chapter 7. Criteria & Measures

To properly develop an appropriate response to the needs of those affected by bleeding disorders, the potential policy options are evaluated based on the following criteria: financial cost, implementation complexity, patient acceptability and access to comprehensive team members from HTC. Together, these criteria are measured on a value system in which the highest score indicates the perceived overall effectiveness of the option. Table 6-1 below provides a summary of the criteria and measures.

Table 7-1: Criteria and Measures

Criteria	Description	Methodology	Measurement	Value
Financial Cost	What is the financial cost to implement the policy relative to the status quo? What are the potential cost-savings of implementing the policy?	- Stakeholder evaluation - Confidential reports and academic literature	Low/minimal financial investment required to implement policy. High cost recovery possible	High = 3
			Moderate financial investment required to implement policy. Moderate possibility for cost recovery	Medium = 2
			High financial investment required to implement policy. Poor cost recovery	Low = 1
Implementation Complexity	What is the degree of administrative complexity required	- Stakeholder evaluation	Low/minimal amount of administration	High = 3

	to implement the policy? How long will the policy take to implement?	- Supported by literature, grey literature and government reports	required to implement policy	
			Moderate amount of administration required to implement policy	Medium = 2
			High amount of administration required to implement policy	Low = 1
Acceptability	To what extent will the policy be accepted by patients, staff, hospital administrators and government	- Supported by literature and interviews - Stakeholder evaluation	Very likely to be accepted/supported	High = 3
			Likely to be accepted/supported	Medium = 2
			Not likely to be accepted/supported	Low = 1
Access to comprehensive care team members of HTC	To what extent does the policy improve patient access/touch points with specialized care	- Supported by literature and interviews - Stakeholder evaluation	Directly improves access to comprehensive care team	High = 3
			Indirectly improves access to comprehensive care team	Medium = 2
			Does no improve access to comprehensive care team	Low = 1

Financial Cost

Given the ever-constrained budgets for health care, the cost is important. This criterion is concerned only with operating and capital costs of the policy options. If minimal costs are required to implement and maintain a policy option, the option scores favourably. Conversely, a high operating and capital cost means the option scores unfavourably.

Implementation Complexity

How much time will a policy need to take effect and be of service to hemophiliacs and those with other bleeding disorders? Are public consultations required? Because implementation complexity is tied to acceptability (particularly from patients) a key question is, will there be resistance to change? Identifying and defining the complexities associated with implementation of the policy options is crucial given the dark history associated with poor management of factor products in Canada during the 1980's. A policy option scores well on this criterion if there is minimal change in management required.

Acceptability

The willingness of patients, staff, hospital administrators and government to accept the policy is important. The emphasis will be on patients and government, as the interviews have revealed that staff and hospital administration would generally be accepting of improvements to staffing as it would allow for better patient outcomes and overall management. Patients have at-home infusions and high levels of self-management. A policy that requires major lifestyle changes would have low adherence levels resulting in poor outcomes for both the patient and the hemophilia treatment centre and thus, would score unfavourably. A policy that has minimal changes to patient lifestyles, does not oppose patient values and can promote health outcomes will score highly.

Access to comprehensive care team members of HTC

This study has shown that improving communication and in-vivo meetings between patients and the comprehensive care team members provides better potential monitoring and follow-up of factor use and patient outcomes. A policy that produces additional opportunities for patients to access the expertise of the comprehensive care team members at the hemophilia treatment centre will score highly, whereas a policy that does not create these opportunities will score poorly.

Chapter 8. Policy Options

Given the research findings from the interview process with key stakeholders, the costing analysis, case studies and literature review, four distinct policy options are proposed. The first is the status quo, followed by three alternatives identified and developed through the investigative process and literature review. These options are described below.

8.1. Status Quo

This option represents the current state of affairs. However moving forward, endorsing this option would reflect a decision that concerns related to hemophilia and other bleeding disorders were not of sufficient severity to warrant reallocation of budgets.

8.2. Increase in Human Resources

Currently there is a lack of staffing (as demonstrated in Figure 6-1 and Table 6-1) and the importance of adequate staffing across key roles cannot be underestimated. Because with adequate staffing comes the ability to manage the use of expensive clotting factor products, improve follow-up care and improve the long-term health outcomes for hemophiliacs by reducing chronic issues such as joint damage. Thus an increase in staffing is proposed. However, this option is made up of two sub-options for increases in FTE's across all roles. Case 1 follows the CHS recommendations for more comprehensive staffing increases across all key roles, while Case 2 follows the more conservative staffing increases proposed by the SPH business case.

8.3. Mandatory registration with Hemophilia Treatment Centre (HTC)

Creating a mandatory registration with the HTC, similar to the current system used in Quebec and Manitoba, means that the provision of factor concentrates is restricted to those who are registered with the HTC. Note that the goal is not to centralize care as in Quebec, but to have patients register while allowing them to seek care at a location of their choosing. This has two primary effects: firstly, it serves to provide increased touch-points for HTC members with patients, which can help minimize the geographical issues faced by patients. Secondly, mandatory registration would result in patients being far more likely to contact bleeding disorder specialists. This provides greater opportunity for individualized treatment which can mitigate safety issues associated with under prescription and cost issues associated with better monitoring of factor use.

8.4. Return to use of Plasma-derived Factor Concentrates

This option explores the use of plasma-derived products as opposed to the widely used lab made recombinant products and emphasizes the potential to reduce the total cost of factor below the current 93%. While the history of plasma-derived factor use leading to human immunodeficiency virus (HIV) infections cannot be overlooked, the introduction and application of virus inactivation methods and more rigorous screening of donors has led to remarkable improvements in the safety of plasma-derived factor concentrates. Currently, plasma-derived factor must go through a rigorous five-step process that includes: heat treatment, microfiltration, chromatography, pasteurization and the use of a solvent/detergent (Hemophilia of Georgia, 2012). These processes have greatly improved the safety of the plasma-derived products. The fact that there have been no new cases of product-transmitted hepatitis virus or HIV infection in the last 25 years only further demonstrates the safety of plasma-derived products (Gringeri A, 2011).

Chapter 9. Analysis of Policy Options

The policy options are evaluated based on the criteria and measures discussed. Each option is given a score and summed in the following section. The scores are colour-coded (red is given a value of 1, yellow a value of 2 and green a value of 3).

Table 9-1: Policy Evaluation Table

Criteria	1. Status Quo	2. Increase HR	3. Mandatory registration with HTC	4. Return to plasma derived factor
Financial Cost	1	3	2	3
Implementation Complexity	3	2	3	1
Acceptability	2	3	3	1
Access to comprehensive care team members	2	3	2	2
Total Scores	8	11	10	7

9.1. Status Quo

9.1.1. Financial Cost

The key managerial distinction in costing is between factor usage and all other costs: staffing, ancillary, non-labour, diagnostic and clinical support services. The overwhelming majority of these costs of roughly $11.3 million (93%) are attributed to factor usage, while roughly $1.0 million (7%) is attributed to all other costs. The estimate of factor cost share for the total program is estimated to be above 95% with the inclusion of factor VIIa and inhibitor patients. There are two key points to be made here. First is that current staffing levels are considered inadequate by both the CHS and SPH. Second is that improved staffing can lead to better health outcomes, improved monitoring/management of factor use and probably savings in factor use sufficient to offset the costs of increased service intensity.

While some emergencies are unavoidable, many patients are forced to go to ER due to low clinic times (currently only 4.5 hours per week available for clinic time). The team in the hemophilia centre estimated a reduction in these ER cases between 20 and 30 percent. These reductions imply annual savings between $70,000 and $105,000. Finally, there is a potential for greater consequences to long-term outcomes at SPH. Reduction of bleeds and chronic long-term issues such as joint damage and arthritis improve the future outlook of patients. Consequently, reduction in long-term issues also reduces the financial burden to the healthcare system (Kendall, 2010). Thus the cost of the status quo is rated as poor (red) primarily due to the missed potential cost savings.

9.1.2. Implementation Complexity

Because the status quo is already implemented, it receives a rating of 3 (high/green) in terms of its complexity level. There are no new complexities to address.

9.1.3. Acceptability

While patients are currently accepting present accessibility level services, many have voiced concerns over emergency care and accessing bleeding disorder team

members. There can also be a lack of education for some patients due to poor management through the ER or scheduled visits. This can negatively impact daily living, result in poorer health outcomes and reduce their overall quality of life. These concerns justify a patient rating of 2 (moderate/yellow).

9.1.4. Access to Comprehensive Care Team Members

Voluntary evaluations of clinics across Canada performed in collaboration with the CHS reveal variations in patient satisfaction with access to services. At SPH 65% of the responding patients were satisfied with access to their clinic. However, when asked about ability to access their health care providers, the numbers change (example: 50% were satisfied with their access to physiotherapy). More concerning, for those who needed to see a bleeding disorder team member due to urgent problems (without an appointment) only 36% were satisfied with the care they received. Generally, patients accept the status quo in terms of general accessibility, but are less accepting of the difficulty with emergency situations and low access to individual team members. This is also likely a symptom of generally low clinic time. For these reasons, patient acceptability receives a yellow (moderate) rating.

9.2. Increase Human Resources

There are several possibilities for increasing HR, however the focus is on two cases. One is the recommendation from the CHS report (Case 1), which increases the staffing levels significantly across all roles. Alternatively, the recommendation from the 2015 SPH business case (Case 2) would provide more moderate increases to HR, specifically increases to physician, nursing and administrative/data management roles. Naturally each case would yield different results in terms of effectiveness, cost and feasibility. This option also works synergistically with option #3, mandatory registration with an HTC. Both cases provide the necessary staffing levels which in turn allow for the increase in patient/staff interaction and improved monitoring of factor usage. This is explored in more detail in section 8.3.

9.2.1. Financial Cost

On the surface, the cost of increasing human resources appears to be high. Currently the cost of the members of the hemophilia treatment centre at SPH (which includes physician, nursing, physiotherapy, social worker and administration/data management) is $325,000 per year. Using the CHS recommendations (Case 1) would amount to a total staff cost of roughly $857,000, an increase of $532,000 over the status quo. In comparison, the more conservative Case 2 (as recommended by the SPH business report) would increase staffing costs from the current $325,000 to roughly $589,000. This is an increase of $265,000 from the status quo. While these staffing cost increases seem significant in comparison to present staffing costs, they are comparatively small given the potential savings in factor utilization and ER visits.

First, an increase in staffing is estimated to provide a significant reduction in over-prescription and better patient management. Clinicians noted that the potential for more “touch-points” is key. An increase in staffing provides opportunities for enhanced monitoring, education, follow-ups and management of factor use. The other major benefit would be a reduction of undesired crossover between roles (as exemplified by nursing time used to complete data management tasks)[13]. The impact of increasing the FTEs in other roles is not as clear; however it would likely lead to further reductions in factor use.

In sum, despite the initial costs attributed to increasing HR, the future benefits of reduced emergencies and factor usage results in this policy scoring high (3 or green) in terms of financial cost.

9.2.2. Implementation Complexity

Currently, SPH and all provincial hospitals face tight provincial budget constraints. There are also inherent complexities for hiring within SPH as the request first goes from Providence Health Care to the Provincial Blood Coordinating Office and

[13] Estimated 9 hrs/week nurses spent on data management tasks. Given the per hour cost difference between roles, this results in an annual cost of roughly $10,750.

finally to the Provincial Health Services Authority (PHSA) for approval. Historically, hemophilia has been given a low priority in terms of the total services available at SPH and competing to secure an increase is likely to be challenging – in part because the savings in factor utilization fall under a different health ministry line (eg. Canadian Blood Services, Provincial Blood Coordinating Office and Hospital Blood Banks). Furthermore, given that the current annual operating budget is $437,000 for staffing and supplies, the process for increasing staffing beyond this mark is tied to increasing patient visits. [14] Thus, the increase in staffing would need approval by the PHSA funding sub-committee.

According to hospital regulations, an increase in FTE of 0.2 or below is fairly straight forward. The hiring process needs only to follow collective agreements and first determine if the existing staff are willing to increase their workload. If the increase in FTE is greater than 0.2, the position must be reposted, meaning that the unions associated with that role as well as anyone qualified can apply and a potentially extensive hiring process must take place. In Case 1 (using CHS recommendations for comprehensive staffing) every role has an increase over 0.2 FTE. In Case 2 there are also increases greater than 0.2 FTE. Due to these complexities, this option scores a 2 (moderate/yellow).

9.2.3. Acceptability

The proposed increase in HR (for either Case 1 or Case 2) as well as the increase in clinic space would significantly improve access of patients to bleeding disorder specialists at the hemophilia treatment centre at SPH. The increased staff would alleviate issues related to patients who require urgent care but who do not have an appointment. Currently only 47% of patients are satisfied with the availability of the clinic team and only 36% are satisfied with the care they receive. While the increase in HR does not resolve issues related to geography and the need to travel large distances to reach SPH, patients noted that visits were often worthwhile and that other hospitals

[14] Provided by finance and administration at SPH

did not have enough knowledge about their problems. The proposed increase to staffing would facilitate more frequent interactions with a greater number of patients and improve the outlook for hemophiliacs in BC. For these reasons, this option scores a 3 (high/green) in terms of patient acceptability.

9.2.4. Access to Comprehensive Care Team Members

An increase in HR would greatly increase the accessibility of patients to comprehensive care team members. First, the addition of team members would naturally enable processing more patients in a given year. The second reason for increased access would be due to minimizing role overlap. Clearing the lines between roles and having more designated FTEs for specific roles enables team members to function more efficiently in terms of managing patients and also in terms of valuable clinical research. For these reasons, access to the comprehensive care team members' scores highly with a 3 (green).

9.3. Mandatory registration with a HTC

Registration by hemophilia patients is not currently mandatory in BC and in fact is mandated only in Quebec and Manitoba. Experts noted that mandatory registration has been considered an effective means to enhance support for clinicians and patients alike. This was due to registration David Page supported this option, referring to successes demonstrated in Quebec. If implemented, when a patient arrives at a hospital or clinic that lacks a comprehensive bleeding disorder team, the information is accessible and available to a clinic that does have such a team. Registration enables healthcare providers at satellite clinics to be more readily supported by bleeding disorder experts at an HTC. Not only is there the potential for real-time follow-up, registration allows for more systematic monitoring and reviewing of infusion logs. Unsurprisingly (as mentioned in section 8.2) this option works synergistically with an increase in HR.

9.3.1. Financial Cost

The financial cost of this as a standalone policy is low. Once the option is mandated through the province (Provincial Blood Coordinating Office) and the blood banks comply mandatory registration will move forward with negligible costs. However, this option's success depends to some degree on the ability of the HTC to manage the patients. Mandatory registration means more patients will be in the system. As the number of patients registered grows, there is a need to properly manage their needs. For the clinic to have a successful outreach program, it would need adequate staffing levels. Hence, it has value only in conjunction with increase in human resources. Therefore, for these reasons, this option scores a 2 (moderate/yellow) in terms of financial cost.

9.3.2. Implementation Complexity

Implementation of this option is fairly straight forward. The PCBO would need only to instruct the Canadian Blood Services (CBS) and the hospital blood banks that patients must be registered with the hemophilia treatment centre. There is already the legal/governmental apparatus in place to implement this option. Furthermore, this option is consistent with the objectives of the BC Ministry of Health which seeks to "align workforce, infrastructure, information management and technology resources to achieve patient and service outcomes" (Ministry of Health, 2014). Once ICHIP has been fully implemented, this option would greatly improve electronic records. Considering this information, this option scores high with a 3 (green).

9.3.3. Acceptability

This option scores high in terms of patient acceptability with a 3 (green). For the most part, patients would approve as it would allow them to go to other clinics or hospitals with a greater chance of receiving proper care.

This option would also enhance the use and credibility of the Factor First initiative. It essentially works like an I.D. card. It makes other non-specialized clinicians aware of the hemophiliac's status improves patient confidence (particularly in

emergencies). A final reason for the acceptability of this option is that it would reduce somewhat the travel and accommodation costs of having to see a specialist in Vancouver, which is important considering the HTC covers both BC and the Yukon. These are important considerations with regards to patient engagement and helps ensure they do not disassociate from the program.

9.3.4. Access to Comprehensive Care Team Members

This option does not improve access to comprehensive team members directly as it does not change the clinic time or the frequency of clinical visits and for this reason it receives a moderate score (2/yellow). However it would require that other clinics or hospitals without bleeding disorder specialists interact with members of the HTC. Patients have recounted experiences in which they receive care from someone who is not knowledgeable about their needs. This can cause patients to disassociate from the program, resulting in poor long-term outcomes. Clinicians predict that for those who do not live close to Vancouver and cannot easily access specialized care, this option would improve patient management and health outcomes.

9.4. Return to Plasma-derived Factor Concentrates

The use of recombinant factor concentrates is currently the norm in Canada, primarily due to their availability and improved safety. While there are safety concerns for plasma-derived factor concentrates related to infection from contaminated blood products (Hepatitis C and HIV/AIDS), these products go through rigorous safety measures and there have been no reported cases of communicating these illnesses in over 25 years. Moreover, the widespread use of recombinant factor has led to a serious and challenging complication in which 20 to 30 percent of severe hemophiliac patients develop inhibitors, in which the body rejects the blood products, thus, rendering treatment ineffective (Franchini, 2010). In such cases, use of bypassing products such as anti-inhibitors are necessary.

9.4.1. Financial Cost

This option would be more cost-effective in several ways. First, for hemophilia B patients, plasma-derived factor is cheaper ($0.70 per IU compared to $0.88 per IU of recombinant). Second, treatment of patients with inhibitors can have significant benefits. While small in number, this group is far more costly per capita than those without inhibitors. Inhibitor products are significantly more expensive ($1.46 per IU for anti-inhibitors). In some cases, the prices of these products is astronomical (over $1,100 per IU for FVIIa), meaning that a patient that develops inhibitors from widespread use of recombinant factor can cost over $500,000 annually.[15] Due to the lower costs and reduction of inhibitor cases, this option scores high (3/green) in terms of financial cost.

9.4.2. Implementation Complexity and Acceptability

The implementation complexity is inextricably tied to patient acceptability and the complexity of implementing this policy is significant. This is because in the 1980s, blood-products were contaminated with blood-borne disease such as hepatitis and HIV. Roughly 2,000 Canadian became infected with HIV through the use of plasma-derived products (Norris, 2008). This has soured the relationship between the Canadian Blood Services (CBS), bleeding disorder clinics and those with bleeding disorders (Norris, 2008). Presently, there remains high resistance and thus low patient acceptability to using plasma-derived treatment options in Canada. Clinicians are also concerned that implementation of this option would cause patients to disassociate from the program due to this fear or anger which would have a negative impact in the long-term.

Another consideration is that presently, the major pharmaceutical companies such as Bayer, Baxter, Octapharma and Novo Nordisk invest very little resources into the research and development of plasma-derived products. As noted previously, this policy option would require these companies to alter their focus from recombinant factor concentrates to plasma-derived products, which is likely to result in a temporary

[15] From interviews with Dr. Shannon Jackson and CHS's David Page

reduction or cessation of the funding provided for research and clinical trials. These projects (once funded) often allow for the addition of staffing and resources for the HTC.

9.4.3. Access to Comprehensive Care Team Members

Implementation of this policy would have widespread effects. The switch to less costly factor concentrates would translate into significant cost-savings for the HTC. These savings can be used to fund research, improve staffing and in the long-term management of factor use and overall health outcomes. However, because this option would mandate use of plasma-derived products, there would be a temporary short-term decrease in funding from pharmaceutical companies for research and clinical trials. This is due to their research and development being targeted at recombinant factor. A shift away from this would take time and resources. In terms of access to the comprehensive team this would cause issues as these funds provide additional resources, often the hiring of temporary staff for studies. Lack of this funding would therefore result in more role overlap. Finally, from the patient perspective, implementation of this option would not increase access to the comprehensive team and could have the opposite effect and reduce access if patients abandon the program due to concerns over the use of plasma-derived products. No patients and no funding for research would hurt the clinics budget and would result in downsizing of an already depleted roster. For these reasons, this option would not increase access to comprehensive care team members and scores moderately with a 2 (yellow).

Chapter 10. Recommendations

As indicated in Table 8-1, the highest rated policy option according to the four measured criteria is increasing human resources. It is recommended that the more conservative increases in staffing proposed in Case 2 be implemented. The rationale for selecting the more conservative alternative is the significant difference in terms of staffing cost between these sub-options (where Case 2 is more cost-effective) and because the resulting cost-savings associated with improved staffing are not yet fully known. Securing funding can be challenging, particularly given the current government imposed budget constraints for healthcare. This challenge grows more difficult with a larger requested staffing cost and uncertain benefits.

While the cost of increasing staffing ranked high (due to comparatively low cost of staffing as compared to the potential factor cost savings), there is a concern that the initial cost to SPH of expansion may be difficult to manage. From expert interviews, a number of professionals spoke about ideal staffing increases and potential compromise solutions. Ultimately, the minimal needed additional staff boiled down to nursing and administration/data management; increases here will yield the "biggest bang for our buck". Assuming that government or associated non-profits do not run campaigns to improve funding, Case 2 allows SPH to increase staffing in these key roles while also staying within the parameters of its current budget. This sub-option represents an initial investment for SPH and additional funding form Providence Health Care and the Provincial Health Services Authority (PHSA) would be required for this policy to take effect. Thus, taking the approach of a pilot project would allow for comparisons in terms of measured outcomes of factor usage, ER visits and patient health outcomes. Such a study would likely provide a more substantive basis on which to estimate future costs and health outcomes but would delay improvements.

It is important to note that the reform options discussed are not mutually exclusive. The option to increase HR focuses on the more pressing short-term concerns; however in the long-term, there is great benefit to implementing mandatory patient registration with an HTC. This option works synergistically with the increase in HR: it would require higher staffing levels to function effectively. Mandatory registration has the potential to mitigate problems of geographical barriers and increase patient/staff interactions (touchpoints). Reducing these barriers means patients are less likely to disassociate from the program. Furthermore, this option aligns well with the need to extend access to comprehensive services to hemophiliacs across British Columbia and the Yukon as well as 2016 objectives set out by the Ministry of Health (Ministry of Health, 2014).

It is also important to re-emphasize some limitations regarding this study and its findings. First, there is generally very little data related to such a rare disease, particularly in terms of assessing policy alternatives and the problem is further compounded by the lack of staff to keep good quality records up to date. Second, in regards to interviews, several voices were noticeably absent, primarily those of patients and to a lesser degree those of mid to high-level policy officials. Third, these findings are not comprehensive or exhaustive and the findings are not necessarily generalizable to different jurisdictions. While the case study analysis provides a glimpse of how other clinics do comparatively in terms of staffing, the cross jurisdictional comparison is challenging because of difficulty in gaining access to health-related information. Finally, there are limitations in terms of access to information even at SPH. The hemophilia treatment centre at St. Paul's Hospital did an excellent job of granting permissions and providing access where possible; however there remain many confidentiality issues in terms of patient data and funding models.

Chapter 11. Conclusion

Bleeding disorders are nuanced and require specialized care from a knowledgeable and experienced comprehensive bleeding disorders team. While bleeding disorders are rare, they have a very high cost associated with consumption of blood products. To effectively manage the use of these products there is a need for adequate staffing. Due to inadequate staffing levels across Canada the hemophilia treatment centres have difficulties maintaining up-to-date infusion logs, optimally managing factor usage or follow-up with patients via phone or clinic time. These issues can have significant costs from a financial aspect as well as from the standpoint of overall patient health outcomes. Patients have echoed this sentiment, noting challenges regarding accessibility to the comprehensive team and that often times the care provided in other hospitals or clinics is inadequate as the healthcare providers are often not sufficiently knowledgeable about the complexities of the disease. This is particularly true when making unscheduled visits to other hospitals or clinics for emergencies.

Unquestionably, there are many potential cost savings by improving staffing within clinics: better monitoring of at home factor use, consistent and thorough follow-ups of patients, reduction in emergency services, reduction in future program costs, reduction in over-prescription and in use of expired factor. However, they require some upfront investment and not all savings are captured in the short-term. The research supports the view that an initial investment in staffing would have many benefits for hemophilia from both the clinical and patient perspective in both the short-term and long-term. Overall this research provides insight into hemophilia in BC and strengthens findings in the existing literature. It provides a well-grounded model for the costing of ER visits and hemophilia services at SPH. It is anticipated that the proposed policy recommendation will improve overall cost-effectiveness and health outcomes.

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Appendix A.

Description of Primary Interview Participants

Dr. Shannon Jackson

Dr. Jackson is a general hematologist and the medical director of the adult hemophilia program at St.Paul's Hospital in Vancouver B.C. She is the medical lead responsible for liaising with hospital services and clinic operations as well as with the Provincial Blood Coordinating Office.

Deb Gue

Deb is a Clinical Nurse Specialist at St.Paul's Hospital in Vancouver. She is a jack of all trades and a stable figure at SPH responsible for the nursing care of the inherited bleeding disorders population in B.C and the Yukon.

Sandra Barr

Sandra is the program director for medicine and ambulatory care at Providence healthcare. She oversees several programs at Mount Saint Joe's and St. Paul's Hospital including the HTC at SPH. Sandra is responsible for ensuring that the program operates from a quality and safety perspective, but also from a financial and strategic planning side.

David Page

David is a hemophiliac who is also the National Executive Director of the Canadian Hemophilia Society. David was involved with CHS in developing the Standards of Care (set out in 2007). He is also in charge of staff and supports the board of directors in implementing their strategic planning and making any recommendations for the future.

Dr. Jerry Teitel

Dr. Teitel served as division head of Hematology and Oncology at St. Michael's Hospital for 15 years, and he continues as the Medical Director of the Specialized Complex Care Program. He has been president of the Canadian Hematology Society and the Hemophilia and Thrombosis Research Society of North America, and he was the first elected president of the Association of Hemophilia Clinic Directors of Canada. He has written or co-authored approximately 100 peer-reviewed articles and book chapters in the field of coagulation and bleeding disorders.[16]

[16] Source: St. Michael's website:
http://www.stmichaelshospital.com/programs/hemophilia/team.php

Appendix B.

Sample Interview Schedule: Bleeding Disorder Specialists

Example Interview Schedule

This interview will take approximately 1 hour. You have the right to give honest answers. There are no right or wrong answers. You can choose to stop or withdraw at any time. I will be taking notes and the interview will be recorded. If you feel uncomfortable both recording and note taking can cease upon request of you (the interviewee). You have the right to ask for the interviewer to explain a question. Your information is not confidential, but can be anonymized upon request. Do you consent to taking part in this interview (FYI – this is verbal consent).

- *What is your job description/title*
- *What does that encompass?*
- *What role do you play in regards hemophilia at SPH?*
- *If role is limited generalize the following questions*
- *What are some of the differences with planned care management and emergency care?*
- *Associated costs?*
- *Why do these emergencies happen (management issue? Lack of HR? Poor follow-up? etc)*
- *What are some standard costs associated with care at SPH?*
- *Average cost of a stay?*
- *What are costs associated with hemophilia? (primary costs)*
- *Specifically hemoA/B and based on the associated severities*
- *Direct costs vs ancillary costs*
- *What are primary issues faced by SPH in terms of:*
    - *Costs*
    - *HR (specifically admin/data management)*
- *What policies are currently in place generally for SPH to accommodate these issues*

- *Research points to several possible recommendations, such as creating mandatory registration with an HTC to provide factor, how would this benefit the clinic?*
- *How hard would this be to implement?*
- *What are some possible drawbacks?*
- *Who pays for the high costs associated with hemophilia*
- *Breakdown of BC health insurance/coverage for the disease*
- *What is the outlook for hemophilia?*
- *What are the avenues for the most effective changes to take place?*

Appendix C.

Detailed Case Study Analysis

This section includes in-depth examination of staffing levels for the comprehensive team members across five comparative clinics within Canada. The staffing levels were then compared to recommended standards set out the Canadian Hemophilia Standards Group and Canadian Hemophilia Society. For confidentiality reasons, these clinics have been de-identified.

11.1. St. Paul's Hospital

Current State of Human Resources

With one of the largest hemophilia programs in the country, the adult division of hemophilia managed through St.Paul's Hospital has inadequate human resources across key positions. These deficiencies in human resources (HR) create substandard access to services needed by those suffering from bleeding disorders. An example that highlights this issue is in regards to those patients referred due to a possible von Willebrand disease. Due to lack of time and clinic space, these diagnoses can no longer be assessed at the Centre.

Table 11-1: Staff Resources at St. Paul's Hemophilia Treatment Centre

Role	Current FTE	Recommended FTE
Nursing	1.3	2
Physiotherapy	0.4	0.8
Social Work	0.4	0.8
Administration/Data Management	0.7	1.5

Physician	0.2	1

Based on standards for comprehensive care in hemophilia set out by the Canadian Hemophilia Standards Group (CHSG) in 2007- which focus on structural and resource requirements for a hemophilia treatment centre (HTC) to effectively provide care – these full-time equivalencies (FTE) are completely inadequate and is a primary reason for which services such as diagnosing potential cases of VWD are no longer being assessed at this clinic. FTE are the ratio of total number of paid hours during a period (part time, full time, contracted, etc) by the number of working hours in that period (Monday-Friday). The following sections will explore and explain the staffing issues associated to each position.

Current Staffing – Nurses

Nurses provide expert support to health care providers, particularly to those who are unfamiliar with the special needs of individuals with bleeding disorders. This is particularly true for those patients who undergo surgery. There are approximately 96 to 120 surgeries a year and each surgery requires anywhere from 1 to 8 hours of nursing time to keep factor levels stable and promote proper clotting (called hemostasis). Clearly, monitoring is a key responsibility of the nurse; however, it is time consuming and requires that the nurse be on site and given the time commitment (particularly for post-surgery), it requires adequate staffing at the position to be effective.

The hemophilia program at St.Paul's currently has lower levels of staffing in nursing than in other programs of similar size in Canada. The 1.3 full-time equivalencies (FTE) are considered inadequate for their current needs (Canadian Hemophilia Standards Group, 2007).

Current Staffing – Physiotherapist

The role of physiotherapists is important in managing those with bleeding disorders, particularly considering the prevalence of chronic joint disease and the ageing population. The current FTE for physiotherapists is 0.4 (Canadian Hemophilia Standards Group, 2007). While this is not stated as "inadequate" the introduction of new ultrasound

technology will allow for better diagnosis of bleeds, likely meaning an increase on the demand for physiotherapist's time and expertise.

Current Staffing – Social Work

Social workers are designated only 0.4 FTE, this too is considered inadequate according to the Canadian Hemophilia Standards Group. The role of social workers in hemophilia is an important one, particularly considering the transition period for patients. This period is the time in which children become adults; that is to say, they transition from the pediatric division to the adult division. This period is vital as without proper support many teenagers and young adults will disengage from actively caring for their bleeding disorder. This suggests that they will likely neglect preventative measures and care (such as prophylaxis) which can lead to long term damage to joints and other complications which can incur higher costs for follow-up or emergency treatment.

Current Staffing – Administration and Data Management

With the introduction of ICHIP (Inherited Coagulopathy and Hemoglobinopathy Information Portal); a web-based application that allows patients to monitory and track their use of factor infusions at home, the need for proper levels of staffing in administrative and data management roles will be vital (Provincial Blood Coordinating Office, 2014).

This system requires significant resources to function effectively. This is due in part to the idea that while patients will be tracking infusions at home, their entries will have a need to be validated through the clinic to ensure quality and consistency. There is also the assumption that patients will be well disciplined and complete entries fully and regularly. There is also a need for this validation of other data related to lab results, physiotherapist joint scores, annual assessment visits, imaging and consultant reports. The ICHIP system, when properly implemented, is able to accurately report provincial utilization and inventory which can allow for better management of treatment and reduce overall complications.

Given these considerations, the 0.7 FTE in administration (0.5) and data management (0.2) are considered completely inadequate and will not allow for

appropriate booking and confirmation or for the maximization of the ICHIP system (Canadian Hemophilia Standards Group, 2007). The results of inadequate supporting roles is often poorer health outcomes for patients, decreased education opportunities for patients and a decreased ability to capture empirical data on factor usage levels. This can result in increased risk/likelihood of mismanagement of clotting factor usage, particularly for at home infusions, all of which are well documented

Current Staffing – Physician

Physicians play another key role in the clinic. Time is often split between clinic and lab work. In the case of SPH, one of the physicians is also the coordinator and much of the available time in clinic is done on a volunteer basis. The 0.2 FTE for this role are completely inadequate given the importance of specialized knowledge of care that the role brings to the clinic. Increased FTE would naturally increase the workload potential of the clinic and provide minimal wait lists and improved turnover time with lab work. (CIHI, 2012)

11.2. Case A

Current State of Human Resources

Table 11-2: Staff Resources at Case A HTC

Role	Current FTE	Recommended FTE
Nursing	1.5	2
Physiotherapy	0.4	0.6
Social Work	0.1	0.2
Administration/Data Management	0.8	1
Physician	0.9	1

Current Staffing – Nurses

With such a large volume of patients at this clinic (317 patients with hemophilia A and 87 with hemophilia B) the current level of staffing for nurses of 1.5 FTE is considered insufficient. Due to city sprawl, the clinic is witnessing a large influx of new patients which is placing a heavy demand on nursing time as these patients need to be processed.

Current Staffing – Physiotherapist

With only 0.4 FTE the physiotherapist can only dedicate time to caring for patients with severe forms of bleeding disorders. Milder forms are not given sufficient attention. More specifically, the physiotherapist spends most of his/her time dealing with acute problems, meaning that there is little opportunity to focus on education and prevention. As such, the services provided by the clinic are in respect to physiotherapy are considered inadequate.

Current Staffing – Social Work

At a glance, 0.1 FTE for social work appears low, however they are deemed to be sufficient as the services provided meet the standards set out by the CHSG. The social worker has flexibility in their schedule and is available to patients as he/she attends clinic on an as-needed-basis. However, CHS and clinic staff still recommend a slight increase in FTE for social work as the influx of new patients means a social worker is likely to see an average of 3-4 patients per week.

Current Staffing – Administration and Data Management

0.8 FTE for administration and data management are insufficient. The clinic's staff at this position manages data entry for CHARMS, home care ordering and monitoring for roughly 200 patients. The lack of human resources results in the charting of factor concentrates utilization and follow-up care for patients being sub-optimal. In considering the trend of increasing patients with severe bleeding disorders, the

administrator/data manager struggle to meet deadlines and data entry generally lags behind by roughly 3 months.

Current Staffing – Physician

The clinic has 0.9 FTE for the physician role. This is meets the needs in terms of medical coverage in the clinic and necessary lab work. The high physician FTE provides the clinic with no wait list and excellent turn-around time with lab work.

Summary Case A

The clinic at CASE A meets almost all the basic standards set out by the CHSG, yet it takes a minimalist approach and barely meets the requirements. While it has a full complement of competent core team members, the concern (as identified by the Canadian Hemophilia Society) is that the combination of low human resources, having nearly double the number of severely affected patients than the other cases and an ever growing number of new patients will force optimal care to shift to severe cases. This would result in those with milder forms of the disease receiving sub-optimal care.

11.3. Case B

Current State of Human Resources

Table 11-3: Staff Resources at Case B HTC

Role	Current FTE	Recommended FTE
Nursing	1.6	2.2
Physiotherapy	0.2	0.4
Social Work	0.2	0.4

Administration/Data Management	1	1.5
Physician	2	2

Current Staffing – Nurses

The clinic in CASE B currently has 1.6 FTE for nursing which is considered inadequate. As noted, nurses in HTCs provide expert support to health care providers, particularly for those unfamiliar with the unique needs of those with hemophilia and other bleeding disorders. This is particularly relevant as the clinic manages over a dozen surgeries per month, each requiring additional hours of instruction, care and support.

Current Staffing – Physiotherapist

Physiotherapy at the clinic is currently listed at 0.2 FTE. This is considered insufficient. The clinic also notes that of these 0.2 FTE, the physiotherapist can only devote half of their time (0.1 FTE) to hemophilia and inherited bleeding disorders.

Current Staffing – Social Work

0.2 FTE for social work is considered inadequate. In practice (much like with physiotherapy), the social worker is only available for half of the designated full-time equivalencies, resulting in poor support for those who require treatment. This is particularly true for those in the transition period between pediatric and adult care.

Current Staffing – Administration and Data Management

The clinic in case B faces inadequate levels of administration and data management (1.0 FTE). The lack of these positions is problematic as scheduling appointments is time-consuming; this problem however, is compounded by the fact that the current version of CHARMS is outdated and not integrated with patient records or home infusion/utilization data. This leads to double entries of data and the system is not

used to its full capacity. Inefficient use and access to data for patient records has led the clinic being unable to fully contribute to national outcome research data.

Current Staffing – Physician

At 2.0 FTE the CASE B clinic has sufficient physician FTE to manage clinical and lab duties necessary for adequate care of patients as recommended by the CHSG.

Summary Case B

This clinic does particularly well in terms of physician FTE, however its deficiencies in social work and administration/data management have resulted in difficulty supporting health care providers. Having an increased FTE for these roles would lead to a need for more accurate and timely home infusion reporting and data collection.

11.4. Case C

Current State of Human Resources

Table 11-4: Staff Resources at Case C HTC

Role	Current FTE	Recommended FTE
Nursing	0.8	1
Physiotherapy	0	0.2
Social Work	0	0.2
Administration/Data Management	0.4	0.4
Physician	0.1	0.1

Current Staffing – Nurses

Nursing currently has 0.8 FTE, however due to demands of the program nurses work closer to full time (1.0 FTE) on a volunteer basis. However, currently the FTE for nursing is considered inadequate.

Current Staffing – Physiotherapist

Officially the clinic does not have a designated physiotherapist. The physiotherapist is loaned to the clinic by another department and attends clinic once a month for urgent cases. Clearly, 0 FTE means that the clinic is not meeting the standards of care in this area.

Current Staffing – Social Work

Much like the physiotherapists, CASE C clinic has no dedicated social worker (0 FTE) and has not had one for more than a decade. This is considered completely inadequate. As noted, the lack of support services for both health care providers and patients impedes optimal health outcomes and program effectiveness.

Current Staffing – Administration and Data Management

0.4 FTE for administration/data management is considered to be barely sufficient. The support that is provided by these roles is focused primarily on patient care, meaning that data entry and record keeping is neglected. Proper data entry is an important component of managing long term impacts and costs.

Current Staffing - Physician

The 0.1 FTE for physician is considered adequate, but minimally so. It suffices for clinical responsibilities but leaves little time for research and the development of clinical policies both of which the CHSG identifies as essential characteristics of an effective program.

Summary Case C

Generally have adequate or near adequate FTE across roles. However the clinic in CASE C lacks a complete multidisciplinary team of health care providers which is at the core of the provisions for optimal care for patients with bleeding disorders as set out by the CHSG.

11.5. Case D

Current State of Human Resources

Table 11-5: Staff Resources at Case D HTC

Role	Current FTE	Recommended FTE
Nursing	0.7	1
Physiotherapy	0	0.2
Social Work	0.1	0.2
Administration/Data Management	0.1	0.2
Physician	0.25	0.3

Current Staffing – Nurses

0.7 FTE for nursing is considered inadequate at the clinic for CASE D. The nurse often brings work home and makes time to work with data clerks to update CHARMS.

Current Staffing – Physiotherapist

The clinic does not have a dedicated physiotherapist but does have access to one who is on call. Unfortunately the time that the physiotherapist can provide for clinical care is insufficient and patients seek private physiotherapists. The concern is that the private physiotherapist will have limited knowledge about bleeding disorders making the required annual joint assessments impossible.

Current Staffing – Social Work

The clinic does have 0.1 FTE for social work, however they are not designated to the hemophilia and bleeding disorders clinic. The social worker is strictly available on an on-call basis and consulted only if absolutely necessary. The current level of FTE is considered inadequate as standards of care are not being met because the clinic is unable to perform the required psychosocial annual assessments.

Current Staffing – Administration and Data Management

Administration/data management currently has 0.1 FTE and much of their time is devoted to basic data entry which is considered adequate. However, the FTE are too low for the clinic to provide consistent support to patients, thus patients report infrequently, resulting in the clinic having out of date patient infusion diaries.

Current Staffing – Physician

Currently there are 0.25 FTE for physicians which are considered inadequate as waiting lists for consultations are very long (roughly 7 months). These lags for consultations are also due in part to the clinic having several new patients per week and nearly a dozen follow-ups. This combination of new patients and a lack of consistent clinical work is magnified by an aging population and increase in severe cases.

Summary Case D

Similarly to CASE C, CASE D has small gaps between the current and recommended FTE for each role. Again, much like in CASE C, CASE D lacks a

complete multidisciplinary team of health care providers which is at the core of the provisions for optimal care for patients with bleeding disorders as set out by the CHSG.

Appendix D.

CHSG Standards - 2007

CANADIAN COMPREHENSIVE CARE STANDARDS FOR HEMOPHILIA AND OTHER INHERITED BLEEDING DISORDERS

First Edition
June 2007

Authored by the Canadian Hemophilia Standards Group[1]

[1] A committee of the Association of Hemophilia Clinic Directors of Canada in collaboration with the Canadian Hemophilia Society (CHS), the Canadian Association of Nurses in Hemophilia Care (CANHC), Canadian Physiotherapists in Hemophilia Care (CPHC), and Canadian Social Workers in Hemophilia Care (CSWHC).

PREAMBLE

Guiding Principles

: Achieving best treatment outcomes
: Treating all people equitably
: Respecting individuals' autonomy and privacy
: Creating an atmosphere of honesty, integrity & trust

Premises

: 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 Hemophilia Treatment Centres (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 Hemophilia Treatment Centres 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 programs.
: 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.

Purpose

The purpose of national standards is to encourage Hemophilia Treatment Centres to adhere to uniform practices that are desirable, accountable, transparent and organized.
Comprehensive care is the recommended method of care delivery, enabling people with inherited bleeding disorders to have access to effective and expert health care. The provision of high quality multidisciplinary care will improve patient outcomes and optimize resource utilization.
Standards will help in:

- Achieving recognition of Hemophilia Treatment Centres by hospital

and provincial authorities, thereby enabling the provision of optimal care according to recognized standards
- Assuring equitable access and quality evidence-based care across Canada
- Establishing a reference for future advances and needs
- Establishing a focus and unifying force for staff of various disciplines that are serving the small and geographically dispersed population of people with inherited bleeding disorders
- Promoting discussion and research regarding optimal ways to deliver care
- Providing the basis for design of clinics, for accreditation, and for audit and evaluation.

Characteristics of effective programs

Effective programs….
: deliver comprehensive care through an integrated, multidisciplinary team.
: partner with patients to foster and facilitate self-management and independence.
: have the capacity to tailor management to the individual's needs and abilities.
: adhere to guidelines and standards.
: regularly participate in quality assurance.
: consult with other programs.
: participate in collaborative research.

STANDARDS

Principles

1. Striving to enrol all individuals with bleeding disorders in the Hemophilia Treatment Centre (HTC) region
2. Making accurate diagnosis.
3. Performing genetic diagnosis and counselling
4. Managing all aspects of bleeding episodes
5. Prevention
6. Diagnosis
7. Treatment
8. Rehabilitation
9. Advocating both for individuals and the patient group
10. Facilitating and maintaining linkages and consultations with other health care practitioners and services
11. Coordinating care for the individual, both within the institution and beyond
12. Preventing and treating complications and enabling rehabilitation
13. Promoting self-fulfillment, self-determination and societal integration
14. Monitoring patients' use of factor concentrate

The Population served includes people with:
1) Hemophilia A & B, both inherited and acquired
2) Von Willebrand disease, both inherited and acquired
3) Rare inherited bleeding disorders
4) Heterozygosity for (carriers of) hemophilia A and B

Core team

Permanent team members with specific expertise and experience in the management of bleeding disorders are required. The following members are essential and should be readily accessible to one another.
: Medical Director (adult or pediatric hematologist or internist)
: Nurse Coordinator
: Physiotherapist
: Social Worker
: Administrative Assistant

Extended team members

These members are important to the successful delivery of quality health care and must be available within each program or on a referral basis, even if only through agreements with other health care institutions.
: Orthopedic surgeon
: Rheumatologist and/or physiatrist
: Hepatologist
: Infectious disease/HIV specialist
: Gynecologist/Obstetrician
: Geneticist/Genetic Counsellor
: Dentist
: Medical experts in pain management
: Psychiatrist/ Psychologist
: Childlife specialist (for HTCs that see children)
: Occupational Therapist

Diagnostic and Therapeutic Principles

1. Care is patient and family centred.
2. Patients and families are partners with the HTC in care decisions.
3. There is universal access of the target populations to the HTC.
4. There is access to prophylactic infusion therapy as appropriate.
5. There is access to home therapy as appropriate.
6. There is choice of treatment product when available.
7. There is choice of HTC and physician when available.
8. Individualized treatment recommendations are developed for all patients.

Services

1. Special hemostasis laboratory
2. Other diagnostic laboratory services
3. Transfusion medicine
4. Diagnostic imaging
5. 24-hour emergency care
6. Home infusion program with appropriate education
7. Access to medical and allied health expertise necessary to satisfy the complex and diverse needs of their patients
8. Factor concentrate utilization management
9. Educational services to other health care services and outside agencies
10. Outreach services

Responsibilities of an HTC

1. Deliver evidenced-based patient care
2. Promoting bleeding disorder care through consultation with other agencies and organizations, in particular CHS, Provincial Governments, CBS, Héma-Québec, Health Canada and Public Health
3. Monitoring product utilization
4. Managing product recalls and notifications
5. Maintenance of patient records
6. Education
a. Patients
b. Families
c. Carriers
d. Other health care workers
e. Community agencies, such as schools, government agencies
f. Emergency rooms throughout the region of the HTC
7. Research
8. Advocacy
9. Surveillance for complications, including inhibitors, adverse drug and transfusion reactions
10. Participation in evaluation and accreditation activities
11. Participation in national databases

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 program.
8. Register patients in CHARMS (Canadian Hemophilia Assessment and Resource Management System) and CHR (Canadian Hemophilia 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.*This is further detailed in "3.11".
12. Provide primary and secondary prophylaxis regimens as appropriate (all pediatric patients with severe hemophilia 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 & facilitate eligible members to participate in activities of AHCDC, CANHC, CPHC, CSWHC and other relevant HTC working groups.

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 nonurgent, 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.
1-10 Policies and procedures for education of newly diagnosed patients are available.
1-10 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 program (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).

STANDARDS – 2. QUALITY MEASURES

The HTC will:
1. Maintain health records according to legislation, which must include:
i. History and physical examination
ii. Diagnosis and treatment recommendations
iii. Operative/special procedure notes and records
iv. Interdisciplinary progress notes

v. Medication records
vi. Consent forms
vii. Adverse events/allergies
viii. Records of home therapy program (teaching, home visit to initiate program, and annual certification)
ix. 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 plasmaderived 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.

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.

STANDARDS - 3. THERAPEUTIC SERVICES

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 hemophilia 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. Maintenance of home therapy records will be encouraged and routinely reviewed, to help in making treatment recommendations.
12. Provide injection equipment and other supplies to patients.
13. Provide management for patients with inhibitors with reference to guidelines issued by the AHCDC and other expert bodies.
14. Be located in a facility that should be readily accessible to people with disabilities.
15. Be located within an Ambulatory Clinic area to facilitate prompt assessment and treatment of acute bleeding episodes.
16. Be located in a facility that has or is linked with an Emergency Department where patients can obtain treatment outside of regular hours.

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 specialized 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.