Rare Blood Disorder Clinic
BUSINESS CASE

Draft
June 2004
Executive Summary

This proposal is to request approval and funding for a Comprehensive Provincial Program for the Treatment of Rare Blood Disorders. A variety of patients fit within this broad category, including, but not limited to, patients with: Hereditary Angioedema, Primary Immunodeficiency, Sickle cell disease, Thallasemia, (?a1antitrypsin deficiency) and Aplastic Anemia. Patients reside throughout Alberta, as well as in eastern BC, and Western Saskatchewan. Their treatment is for the most part outpatient based, but requires access to blood products for home use, other home intravenous treatment such as chelation therapy, tracking of blood products kept in patient homes and monitoring of blood results. Management is currently a “hit or miss” affair, by specialists in hematology and immunology. This project aims to provide an evidence based, coordinated approach to investigation, treatment, and tracking of these rare but complicated patients.

Revenues will not likely be generated and costs have been thoroughly evaluated. Kathryn Martin is a Patient Care Manager in the Dr. John Akabutu Bleeding Disorder Clinic and she will be responsible for the administration of the pilot project. Dr. Bruce Ritchie, and Dr. Nancy Dower are the medical staff persons who will be jointly responsible for this project.

Project Definition

PROBLEM STATEMENT

Patients with rare blood disorders have in common:

- the rare nature of their condition
- the complicated nature of their investigations and treatment
- requirement for specialized monitoring and care,
- requirement for blood products, and other intravenous products which are commonly used at home,
- requirement for monitoring of these products, as outlined by Justice Horace Krever,
- requirement for attention to the complications of treatment with these products.

Home treatment is almost entirely outpatient based, but requires access to blood products, home intravenous treatment, tracking of blood products for home use and monitoring of clinical outcomes, both beneficial and adverse. This is currently done in a “hit or miss” approach by specialists in hematology and immunology. As patients commence home treatment, it is expected that, as in the case of hemophilia, a large percentage of the national inventory of IVIg, and C1INH will move to patient homes. This must be monitored to avoid outdated, to facilitate recalls, and to track beneficial and adverse outcomes. Although many blood products are being replaced with recombinant products, it is extremely unlikely that this will ever occur with IVIg, since it must be made by humans through exposure to many pathogens or antigens during their lives. Primary ImmunoDeficiency Patients will always be in a “double jeopardy” position - at risk for blood borne pathogens, and not able to be tracked with the usual antibody testing for these pathogens, since they do not make their own antibodies.
CURRENT RESOURCES

There are Comprehensive Bleeding Disorder Clinics in Edmonton and Calgary, which means that some sharing of resources (eg data managers, and secretarial support) is possible.

Blood product tracking program (CHARMS) is available in the hemophilia clinics, as recommended by Justice Horace Krever.

National Blood Borne Pathogens surveillance program established in Edmonton, as recommended by Justice Horace Krever.

Provincial representatives from national societies including: CIPO, CHAES, Aplastic Anemia Society, Thallasemia Society, Sickle Cell Society.

Pilot Project in chelation by the Home IV therapy program.

Home Chelation Program run by Ron Marcinkoski

GOALS AND OBJECTIVES

The goals for this project:
1. Improve diagnosis, and management of patients with rare blood disorders
2. Increase patient satisfaction with level of care received through safe, effective Home infusion of appropriate blood products
3. Decrease Hospital costs through reduced visits to emergency and outpatient clinics, and reduced complications in patients.
4. Enhance education of staff and primary care treaters.
5. Promote a network environment.

Upon completion of this project, the desired outcome is to provide a higher standard of care for Rare Blood Disorder patients.

The objectives of this project:
1. Establishment of a Clinic for Rare Blood Disorders
2. Patients will be accurately diagnosed, including genotyping
3. Patients will be registered on a national registry
4. Patients with primary immunodeficiency and hereditary angioedema will be trained and will commence home treatment with the specialized blood products used to treat their diseases.
5. Patients with sickle cell disease, thallasemia, and aplastic anemia will continue to have blood transfusions in the Medical Outpatient departments, but will be trained and will commence home treatment with chelation therapy, to prevent the complications of iron overload.
6. Specialized blood products, (and chelation therapies) stored in the patient homes will be monitored, and tracked, as outlined by Justice Horace Krever.
7. Rare blood disorder patients will benefit from assuming control of their treatments.
8. Rare blood disorder patients will benefit from consistent investigation, treatment, and monitoring of their condition.
9. Number of emergency visits, and medical outpatient visits for rare blood disorder patients will be decreased through home treatment.
10. Patients will express a higher level of satisfaction with the care they receive.

Solution Description

DESCRIPTION OF PROPOSED PROJECT

Development of a Rare Blood Disorder Clinic:
A nurse coordinator, secretary data entry clerk will be hired, trained in the teaching of home treatment, and in the use of the patient registry and computerized blood product tracking programs. A nurse with expertise in these disorders will be vigilant for recognized complications of these diseases and their treatments. She will train the patients and their families in the home treatment and monitoring of their diseases, train primary care providers in the community, and counsel patients and their families over the telephone. The secretary will schedule patient visits, maintain the paperwork for the distribution of blood products to patient homes, maintain patient records, type letters to physicians and patients, and generally assist in the day to day management of the clinic. A 1/2 time data entry clerk will maintain the electronic record of product distribution and use to facilitate monitoring of product use and outcomes and to facilitate recalls. A part time (1/5) social worker will counsel the patients at annual comprehensive visits and between visits as necessary. Consultants in Infectious Disease, Respiratory Medicine, and Ear, Nose and Throat will come to the annual clinics and will be familiar with the patients for follow-up between visits. Dentists?

Standard Operating Procedures (SOPs) are currently being developed for the Bleeding Disorder Program and are available from national organizations in Canada, the US and UK for investigation and treatment of all of the Rare Blood Disorders and will be used as a template for the Rare Blood Disorder Program. These are based on published guidelines, and will be placed in a home page for the clinic on the CHA website.

Patients with Hereditary Angioedema, Primary Immunodeficiency, Aplastic Anemia, Sickle Cell Disease, Thallasemia and other hemoglobinopathies will be registered with the clinic, than assessed in a yearly basis in once monthly clinics in WMC 2E2. Patients may choose not to be followed by the clinic, but registration with the clinic and the national registry will be mandatory for patients to have Home Treatment. This will facilitate tracking of products, their use, and outcomes of their use.

Home Treatment:
Patients with Primary Immunodeficiency will be trained in the home use of weekly, subcutaneous 14% SCIg. By using once weekly SCIg, or every two weeks IVIg at home, vs every 4 weekly IVIg in hospital, we expect to achieve better control of infections with less IVIg. We will also unload the Medical Outpatient Department, allowing it to be used for other things. IVIg will be monitored similar to current monitoring of product distribution and use in Hemophilia with CHARMS.
IMPACT ON STAKEHOLDERS

Stakeholders include patients with rare blood disorders currently looked after through the Medical Outpatient Department of the University Hospital, their families and medical staff. The expected benefits to patients, families and medical staff include:

- Improved diagnosis and care
- Improved control of their health by the patients
- Enhanced coordination of care and communication between the patient and doctors based in Edmonton and Calgary.

CRITICAL SUCCESS FACTORS

Factors critical to the successful implementation of this application include, but are not limited to:

- A preliminary conference with all stakeholders, including the Pediatric and Adult Hematology Physicians in Calgary and Edmonton, CHA administrative staff, including Kathryn Martin and Debbie Gordon, as well as the patient groups, including the Canadian Hereditary Angioedema Society (CHAES), the Canadian Immunodeficiency Patient Organization (CIPO), the Aplastic Anemia Society, the Thalassemia Society, the Sickle Cell Society and with input from the Alberta branch of the Canadian Hemophilia Society.
- Physician acceptance of this process.
- Patient acceptance of this process.
- Patients made aware of their rights and responsibilities. As pioneers in this process, we will require their contribution in data gathering.
- Adequate staffing
- Office Space
- Communication between all parties to evaluate and modify the clinics as needed.
- Administrative Support for scheduling, preparing and organizing sessions

ALTERNATIVE COURSES OF ACTION

Alternatives to using specialty clinics and home treatment include continued treatment of patients in hospital outpatient departments and emergency wards, incomplete monitoring of product use, and incomplete monitoring of outcomes of treatment. There is a chronic shortage of hematologists and immunologists in Alberta, so that investigation, treatment and monitoring of rare blood disorders is “hit and miss”, and home treatment is not feasible.

Implementation

SCHEDULE OF CLINICS
Hiring of staff
- December 2004

Patient registration
- Ongoing from Dec 2004

Home Treatment of Primary Immunodeficiency, Hereditary Angioedema, and chelation therapy
- Ongoing from Jan 2005

Risks

PROJECT RISKS

- Patients may not wish to register with the clinic
- Patients may not wish to participate in home treatment
- Physicians may not wish to participate in home treatment

The following actions will be taken to minimize risks:
1. Patients and Physicians will take part in an educational conference to bring them up to date on management protocols, and the advantages of home treatment.
2. Patients and Physicians have been consulted throughout the development of this project, and will continue to be consulted through an oversight committee.
3. Patients will undergo a documented training program prior to commencing Home Treatment.
4. Patients will sign a consent form prior to partaking in the registration and home treatment.
5. Staff will not be asked to do anything that is outside their current scope of practice.

Budget

REVENUE & COSTS

Possible sources of revenue include:
Genotyping – cost recovery from other provinces.

It is not expected that revenue will be generated from this project. It is anticipated that significant cost savings for patients and physicians will occur, based on less emergency treatment, and emergency room visits (need costs from Brian Holroyd). Staff training and educational costs will be also reduced by decreasing the need for travel to these sites. The costs associated with the implementation of this project, including patient registration and provision of two education sessions, is estimated to be $25,208.00. Physicians will bill the government directly for their services.

Operating Costs:
See Appendix 1,

Evaluation

EVALUATION PLAN

Stakeholders will be asked for feedback and evaluation on an ongoing basis. Data collection will be through questionnaires, log records of clinics, evaluation of patient clinical outcomes. All stages have a comprehensive evaluation conducted by a third party, assessing both program-specific and system-level parameters.

PERFORMANCE INDICATORS

1. Patient, Hematologist/Immunologist and Registered Nurse Satisfaction
2. Quality of care and health outcomes (clinical indicators)
3. Evaluation of access to services and ease of use for all stakeholders
4. Emergency visits (compared to historical data)
5. Evaluation of costs avoided for patient, staff, and physicians

Appendix: Project Management Team

The key players for this pilot project include (but are not limited to):

CHA Staff

Key Contact/Administrator:
• Kathryn Martin, Patient Care Manager, Dr. John Akabutu Center for Bleeding Disorders

Nurse coordinators:
• Wilma McClure, Nurse Coordinator, Dr. John Akabutu Center for Bleeding Disorders
• Leslie Logi, Nurse Coordinator, Home IV therapy program

Physicians:
• Dr. Bruce Ritchie, Hematologist; CHA, University Hospital Site
• Dr. Nancy Dower, Pediatric Hematologist; CHA, University Hospital Site
• Dr. Robert Turner, Hematologist; CHA, University Hospital Site
• Dr. Kent Stobart, Pediatric Hematologist; CHA, University Hospital Site
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Social Worker:
• Sylvia, Hematology Social Worker; CHA, University Hospital Site
Pharmacists:
• Brent Gotas, Pharmacist, Outpatient Pharmacy, Capital Health
• Ron Marcinkoski, Pharmacist, Market Drugs Medical

Secretarial staff:
• Dena Allen, secretary, Dr. John Akabutu Center for Bleeding Disorders
• Melanie Peters, data entry clerk, Dr. John Akabutu Center for Bleeding Disorders

Non CHA Staff

Physicians:
• Dr. Tom Bowen, Immunologist, Calgary Health Region
• Dr. Man-Chiu Poon, Hematologist; CRHA, Foothills Hospital Site