Canadian Hemophilia Assessment and Resource Management information System (CHARMS)

A tool for Coagulation Product Tracking, Electronic Medical Chart, and clinical research in Canada
Disclosure of Conflicts of Interest

Advisory Boards: Talecris, Baxter, Bayer, Wyeth, Dyax, 

Travel Support: Bayer, Baxter, Astra-Zeneca, Novo-Nordisk, Pharmacia, Pharming, Dyax, CSL Behring, Talecris

Research Funding: Bayer, Baxter, Canadian Hemophilia Society, Public Health Agency of Canada,

Funding for Summer Studentships for students in my laboratory: Pharmacia, Baxter, Sanofi, Novo-Nordisk, Bayer

Honoraria and consulting fees are donated to the University of Alberta to fund research students. I have been given honoraria to speak at meetings of the following organizations: Canadian Hemophilia Society, Alberta Association of Radiologists, Canadian Society of Transfusion Medicine, Canadian Anesthesiologists Society, Bayer Biologics. I have been given honoraria for work for the Canadian Blood Service.
Players in Hemophilia Care in Canada

- World Federation of Hemophilia
- Canadian Hemophilia Society
- Association of Hemophilia Clinic Directors of Canada
- Canadian Association of Nurses in Hemophilia Care
- Canadian Physiotherapists in Hemophilia Care
- Social Work group

Others

- Canadian Blood Services, Hema Quebec, Quebec Blood Secretariat, National Advisory Committee on Blood, MPTAP
- Health Canada - the regulator
- Public Health Agency of Canada, Prévention clinique et biovigilance
AHCDC

- Incorporated in Ontario, 1993
- 42 members +/-
- 25 comprehensive hemophilia clinics
- >8,000 bleeding disorder patients registered in CHR
- Blood product tracking & clinical data (CHARMS)
- 18 year history of comprehensive surveillance of inhibitors following the introduction of rFVIII
- >20 year history of collaborative research
HIV & pooled Blood Products in Canada

![Graph showing the trend of HIV & pooled Blood Products in Canada from 1974 to 1984.](image)
Canadian Hemophilia Registry (CHR)

• Comprehensive registry of bleeding disorder patients for:
  – Tracking outcomes
  – Coagulation product tracking

• Barcoding of Registry Numbers, and lobbying for barcoding of products
REQUEST FOR APPROVAL OF
RECOMBINANT FACTOR VIII PRODUCTS

SUBMITTED BY THE CANADIAN
HEMOPHILIA CLINIC DIRECTORS GROUP

MARCH 1993
CHARMS

• 25 clinics tracking of coagulation factor distribution for recall, reports to funders, …

• Clinical module
• Nursing module
• Consent module
• AE reporting module
• Future
  – Physio therapy module
  – Genetic module
  – Barcoding, …
CHARMS

CHARMS module
• MS Access Database
• Identical program on identical computers in 26 clinics
• Collects data on product distribution, clinical outcomes, adverse events, genotyping
• Automated electronic data export to CentrePoint Module

CentrePoint Module
• collects data exports from clinics to server in Hamilton
• collects summary (aggregate) data only
• summary data transferred to AHCDC head office, CBS, (Quebec Ministry of Health, Public Health Agency of Canada)
Canadian Hemophilia Assessment and Resource Management information System (CHARMS)

Product distribution (CBS)
Clinical outcomes (clinic)
Genotyping (AHCDC)
Sample archive

CenterPoint server, Hamilton

Drug Company Palm Pilot systems
CBS, HQ
Provincial Governments
Health Canada Manufacturers
?CBS, QBS

Adverse events
Product use/outcomes

Canadian Hemophilia Assessment and Resource Management information System (CHARMS)
## Pharma tracking systems

<table>
<thead>
<tr>
<th>Company</th>
<th>Product</th>
<th>System</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bayer</td>
<td>EZ Log</td>
<td>PDA</td>
<td>Active, except Quebec</td>
</tr>
<tr>
<td>Baxter</td>
<td>Advoy</td>
<td>Web, PDA</td>
<td>Abandoned</td>
</tr>
<tr>
<td>Novo Nordisk</td>
<td>HemoNet</td>
<td>Web</td>
<td>Abandoned</td>
</tr>
<tr>
<td>CSL Behring</td>
<td>Helitrax</td>
<td>Cell phone</td>
<td>Active</td>
</tr>
</tbody>
</table>
Goals for CHARMS Renewal

- Establish Privacy plan for CHARMS
  - Privacy Officer
  - Privacy Statement
  - Privacy Policy
  - Privacy Impact Assessments
- CHARMS renewal
  - Web-based
  - Open source vs proprietary approaches
- Review Requirements Document
- RFP
- CHR renewal
## CHARMS Summary

<table>
<thead>
<tr>
<th>Registry</th>
<th>Overview</th>
<th>Funding</th>
<th>Privacy/Security</th>
<th>Governance</th>
<th>Major Issues or Challenges with this Registry (or during its development)</th>
<th>Example Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHARMS</td>
<td>CBS / Hema Quebec / PHAC</td>
<td>Anonymized Registry (CHR) Central Server (CentrePoint)</td>
<td>- how is personal data protected? - how do you protect from loss of data? - intrusion?</td>
<td>CHARMS committee</td>
<td>Renewal Privacy Security Networking</td>
<td>Recalls rFVIII use rFVIIa use</td>
</tr>
</tbody>
</table>
RESEARCH INSTITUTE

UNANSWERED QUESTIONS

UNQUESTIONED ANSWERS