

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

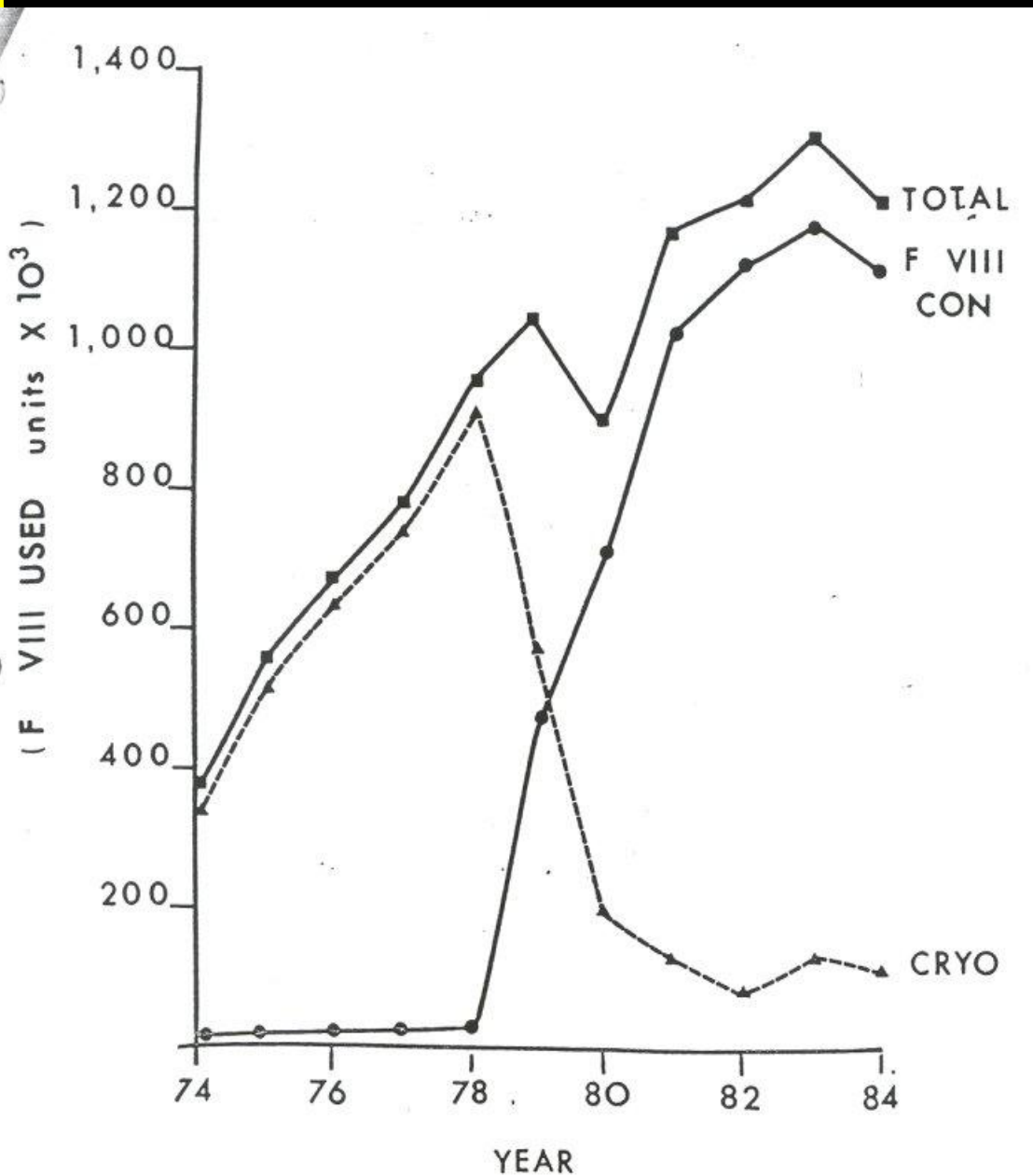
Others

- 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

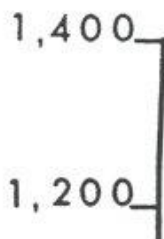
HIV & pooled Blood Products in Canada



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





Hemophilia & HIV

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



Drug Company
Palm Pilot systems

CenterPoint
server,
Hamilton

Product
use/outcomes

CBS, HQ

Provincial
Governments

Adverse
events

Health Canada
Manufacturers

?CBS, QBS

Pharma tracking systems

| Company | Product | System | Status |
|-----------------|----------|------------|-----------------------------|
| Bayer | EZ Log | PDA | Active, except Quebec |
| Baxter | Advoy | Web, PDA | Abandoned |
| Novo Nordisk | HemoNet | Web | Abandoned |
| CSL Behring | Helitrax | Cell phone | Active |

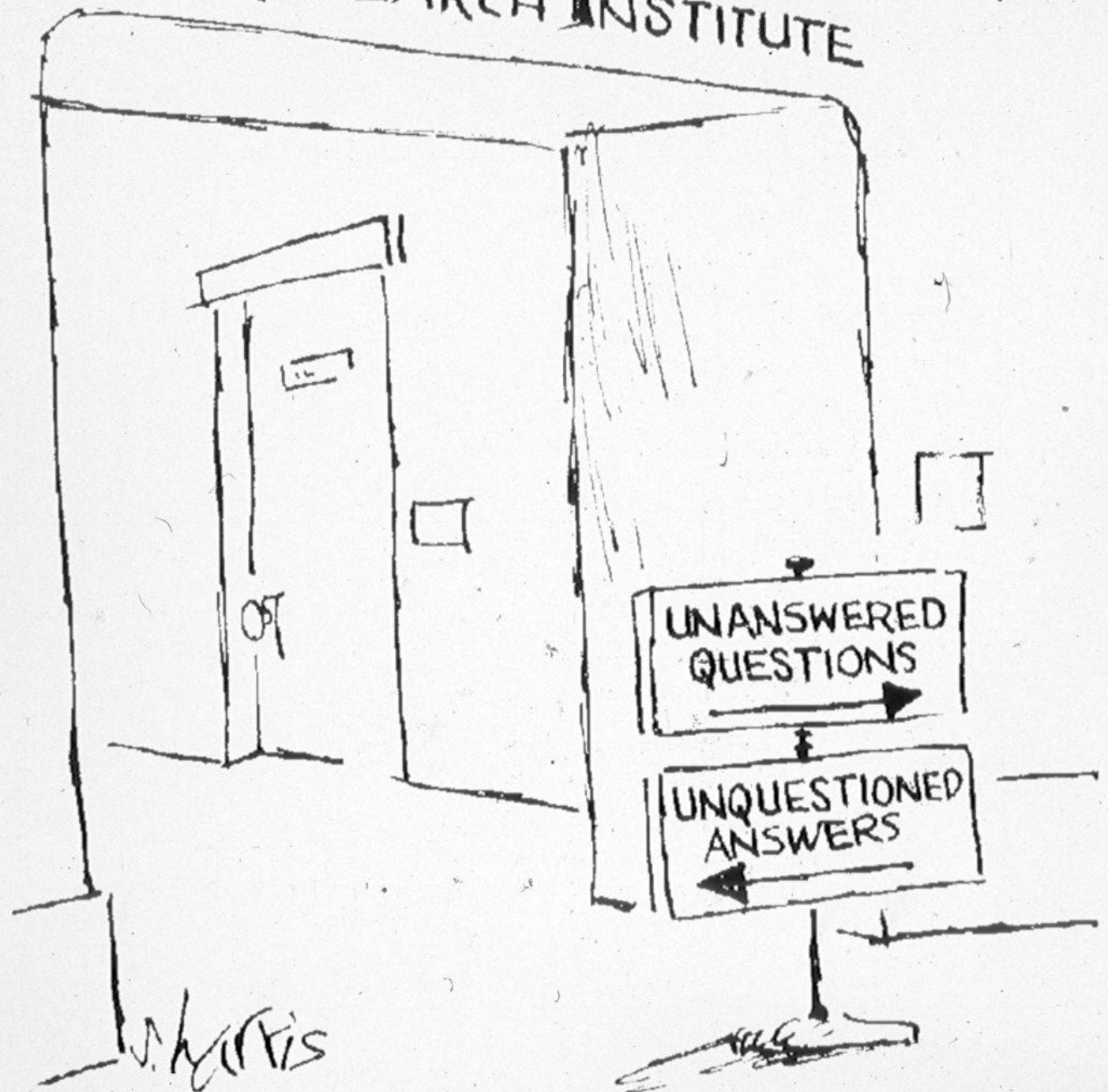
Goals for CHARMS Renewal

- 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

| Registry | Overview | Funding | Privacy/Security | Governance | Major Issues or Challenges with this Registry (or during its development) | Example Outcomes |
|----------|----------|--|--|--|--|---|
| CHARMS | | <ul style="list-style-type: none"> - who is funding? - how much? - how is longevity ensured? - other | <ul style="list-style-type: none"> - how is personal data protected? - how do you protect from loss of data? - intrusion? | <ul style="list-style-type: none"> - describe the oversight board - how are changes/enhancements approved? | <ul style="list-style-type: none"> Renewal Privacy Security Networking | <ul style="list-style-type: none"> Recalls rFVIIa use rFVIII use |

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