

**Report of a Meeting, CHARMS Renewal project  
March 29 and 30, 2008, Toronto Airport Westin**

**Introduction to CHARMS, Goals of the meeting: Bruce Ritchie**

A meeting was held in Toronto on March 29 and 30<sup>th</sup>, 2008 to discuss renewal of CHARMS, the database program developed by the Association of Hemophilia Directors of Canada at the request of the Canadian Blood Agency to track home use of coagulation blood products, particularly recombinant Factor VIII, following its introduction in 1993. Interested parties included the Canadian Association of Nurses in Hemophilia Care (CANHC), The Canadian Association of Physiotherapists in Hemophilia Care (CAPHC), Health Canada, the Public Health Agency of Canada, Canadian Blood Services, Hema Quebec, the Quebec Blood Secretariat and the Pharmaceutical Industry (Baxter, Bayer, Wyeth, NovoNordisk, and CSL). Key to this meeting, all of the parties committed to the renewal of CHARMS and are willing to make significant contributions in time and/or money to a renewed CHARMS.

CHARMS is a distributed database, which means that there are identical copies of the program in 25 centers, collecting similar data. Each centre exports common, anonymized data to a central database, known as CentrePoint. CHARMS was originally developed in MS Access, which was not designed for this sort of work, but which has functioned well for over ten years now. Its strength is in tracking distribution of clotting product for home use, and for facilitating recalls of products when they occur. Less strong is the tracking of product use, which requires patients to provide data from “bleed sheets” documenting their product use and the reason why. Data is entered at each site by data entry clerks, usually working part time and with little training or backup. Data entry quality has suffered as a consequence.

With funding from Baxter, AHDCDC now has the opportunity to improve and enhance CHARMS as a web-based program. This requires a clear vision of what CHARMS should be doing, programming that includes user representation in development to make it “user friendly”, and integration with a variety of other product tracking systems, including those of the blood product distributors - Canadian Blood Services and Hema Quebec, pharmaceutical industry based programs including those from Bayer and CSL, adverse reaction tracking programs of the regulator of the Canadian Blood System – Health Canada, and pathogen tracking systems of the major public health groups including the Public Health Agency of Canada and the Quebec Blood Secretariat.

The Information Systems group at Capital Health, Edmonton’s health region has offered to help with reprogramming CHARMS as a web-based program. They have begun the process by developing a “Requirements Document” outlining what the current versions of CHARMS does with enhancements and changes as requested by the users. The Capital Health IS group has the advantage of being a large, but non-commercial group with a commitment to supporting programs such as CHARMS and the experience with Privacy, hosting, and maintenance required, but at non-commercial rates.

**Legal and Privacy Issues - Elaine Ashfield, Canadian Blood Services**

Elaine Ashfield, BScN, RN, LLB, CIPP/C, Executive Director, Privacy, Records & Information Management at Canadian Blood Services provided background on the privacy environment in Canada. There has been an evolution of privacy that has lagged

behind the technical advances in communication. This means that the internet, (and other technologies such as cellular phones and phone cameras) have provided the ability to quickly and efficiently transmit information, including information that individuals may have wanted kept confidential. Database technologies have become very powerful, providing opportunities to disclose huge amounts of confidential information efficiently and without leaving a trail of this happening. Personal information has been defined as: information about a particular person or that can be used to identify that particular person, with the exception of the name, title, business address or telephone number of an employee of an organization. In the Canadian Charter of Rights and Freedoms, two items pertain to personal privacy:

7. Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.
8. Everyone has the right to be secure against unreasonable search or seizure.

In Canada there is an evolving Privacy Framework at federal, provincial and local levels. At the federal level, Privacy Laws and Regulations include:

Privacy Act and PIPEDA (Personal Information Protection and Electronic Documents Act). The federal Privacy Commissioner is Jennifer Stoddart (1 800 282 1376). The Canadian Standards Association has developed a Model Code for the Protection of Personal Information (CSA Model Code) that provides details of the federal guidelines, and is available upon request. At the provincial level, there is legislation specifically governing Personal Health Information, including: Collection, Use and Disclosure. In addition there are national organizations that have codes of conduct including: Professional Codes of Conduct and other Guidelines, the CMA Code of Ethics and Health Information Privacy Code, and COACH Security and Privacy Guidelines for Health Information Systems. There are additionally, acts specific to various areas of health care such as the Medicine Act, and the Nursing Act, and provincial laws such as the Ontario Public Hospitals Act.

The CSA Model Code in particular covers:

1. Accountability
2. Identifying Purposes
3. Consent
4. Limiting Collection
5. Limiting Use, Disclosure and Retention
6. Accuracy
7. Safeguards
8. Openness
9. Individual Access
10. Challenging Compliance

From a practical point of view, the starting point is to first decide the purpose for which you are collecting and sharing the information and recipients of the information must agree that they will only use the information for those purposes. If you are using de-identified or anonymous information (aggregated data), consider if the purpose is consistent or not

Secondary uses of information are where information is collected for one purpose and in turn used for another purpose. Examples include using patient health information to assess standards of care furnished to patients, improve hospital or medical procedures, compile medical statistics, conduct medical research, conduct health system analysis...

Secondary use poses challenges in the electronic age such as:

What level of de-identification and anonymization is needed, and what level is acceptable. There is an ongoing debate as to whether patients should be informed of secondary uses, even when data de-identified or anonymized.

Oversight and Enforcement requires attention to the multi-level governance in place, including: provincial and federal privacy commissioners or ombudsman and their Rulings and Guidance. Good intergovernmental Relations clearly benefit successful information sharing. Information Governance Mechanisms include:

- Privacy Policies, Security Policies and Statements of Information Practices
- Privacy Officers/Teams and Information Security Officers/Teams
- Privacy and Security Awareness Training
- Information Guidance for Stakeholders
- Confidentiality Agreements and Guidance for Signatories
- Monitoring Compliance
- Privacy and Security Audit Mechanisms
- Memoranda of Understanding
- Data Sharing Agreement
- Acceptable use agreements

**Coping with a Privacy Audit - Michael Power, Vice President, Privacy and Security Smart Systems Ontario <michael.power@ssha.on.ca>**

Michael Power, vice president for privacy at Smart Systems for Health Agency (SSHA) talked about “Privacy Change Management in a Public Sector Agency”. He described their experience in responding to their failure to pass the first significant privacy audit in Canada. SSHA has a unique mandate in that it operates common IT products and services for the health care system as an Agency of Ontario. SSHA helps providers share personal health information electronically between one or more health care professionals/organizations. SSHA builds on existing system to expand information sharing possibilities.

• Plays a variety of roles:

- HINP (Health Informatics Network Provider)
- Service provider to HINP
- Service Provider to HIC
- Agent of HIC
- Institution under FIPPA (Freedom of Information and Privacy Protection Act)

The scope of activities at SSHA include providing one network for 700 sites with

unique IDs for 13,500 individuals, and email for 80,000 individuals. They have 3 portals including ports for OntarioMD.ca, PublicHealthOntario.ca and eHealthOntario.ca. SSHA sits between the Ministry of Health and the Health Care Sector.

In 2007 SSHA underwent a dramatic reorganization, following an unsuccessful audit by the Ontario Privacy Commissioner. In response, SSHA completely reorganized, replacing their executive, which included hiring Michael as VP Privacy and Security to solve their privacy problems. They focused on building on existing strengths; added corporate capability such as an enterprise architecture; strengthened core functions through project management, and client management; clarified roles, functions, and accountabilities; became more customer focused, and scalable to accommodate growth in scale and complexity of solutions.

SSHA were the first organization to be reviewed by IPC under PHIPA legislation - no other agency in Canada has gone through such an extensive review, which left them with 82 recommendations. Importantly, their findings included no breaches but they did need a detailed plan to improve and update SSHA's program.

The SSHA plan had the following goals:

- Update relevant policies and procedures.
- Embed privacy and security deeper into our organizational culture.
- Improve transparency by making privacy and security solutions available to clients.

In response to the report, SSHA:

- Conducted analysis of recommendations.
- Identified owners and high level approach.
- Established Privacy Change Initiative Project Management Office (PCIPMO).
- Completed detailed planning and resourcing exercise.
- Began implementation phase.
- Emphasized continuous improvement.
- Mapped each recommendation to one of 9 different policy areas and 24 different sub-streams.

The PCIPMO Governance and Reporting Structure was specifically developed to make change quick, effective and efficient. They were 100% complete by 31 March 2008 - an independent review by IPC in October 2007 generated the David Flaherty Report, <http://www.ipc.on.ca/index.asp?navid=53&fid1=7776>

Key pieces of their Continuous Improvement effort: included

- Policy for PIAs and reviews refreshed and finalized
- PIA procedures finalized.
- Privacy and security aspects of procurement documentation finalized
- Privacy & Security Standard of Conduct revised.
- Data removal and media disposal process and procedures finalized.
- Privacy Impact Assessments updated for generally available products and services including Network Refresh and ONE OfficeNET.
- Online Learning Management System (LMS) with two modules for Privacy and Information Security launched.

- Enterprise Security and Privacy Incident Management Program launched.
- Information Classification and Handling Guidelines finalized as an Agency standard.
- Longer term privacy culture strategy in development.

#### Next Steps

- Continue implementing as planned.
- Continue to work with IPC.
- Continue to consult with client stakeholders.
- Expand on the implementation work and build a best practice program.
- Deepen our privacy culture.

In September 2007 SSHA launched a staff awareness campaign, to make staff aware of:

- Updated Privacy and Security Standard of Conduct.
- Updated Information Security Policy.
- Strengthened document management practices
- Mandatory staff training.
- Enterprise Security and Privacy Incident Management Planning.

The goals of the Staff awareness program were to raise the profile of Privacy and Security staff and function: through a “Desk tour”, poster campaign (Get Caught) and telephone hotline and central e-mail. They rewarded positive actions defined in Standard of Conduct. They developed an online Privacy Training program using web-based training software. They decided on the role of their Privacy and Security Team. The core mandate was to protect sensitive information from unauthorized or accidental access, use or disclosure.” A strategic objective was to ensure SSHA products, services and processes are well designed., meet obligations under government legislation, and properly protect rights of patients and health care providers. They did this through conducting PIAS, TRAs and SPAs; managing incidents; and advising on policy and architecture Their role within SSHA is evolving. They want to become health care sector’s IT provider of choice through building and keeping trust. They plan to continue to evolve and innovate to protect information entrusted to Agency. They will be transparent to learn from and leverage our experiences.

Communications – SSHA have a newsletter at [www.ssha.on.ca](http://www.ssha.on.ca)

#### **Patient Registries – Irwin Walker**

Irwin described in detail a meeting he had with Anne-Louise Cruikshank, South Africa, Charles Hay, U.K, Fritz Rosendaal, Netherlands, and Irwin Walker, Canada. (chair). He described registries using the joint WHO/ WFH Statement “In order to allow for the proper planning and development of health services, the establishment of a national registry of people with hemophilia is essential. It is therefore a recommendation that priority be given to identification and diagnosis of affected people and their families and to the central registration of individuals with hemophilia and related disorders. In order to be successful, such a scheme must guarantee confidentiality and respect for human rights.” Bruce Evatt, while he was at WFH, developed a guide to registries, describing key principles as follows:

- Determine type and amount of data - Accuracy, simplicity, completeness.
- Confidentiality and ethical issues - Who owns the data? How to maintain confidentiality?
- Registry Management - Who runs it?
- Method of data collection
- Registry Maintenance - Assigned responsibility, Periodic review of data, Sharing of data, Keeping registry user-friendly

Irwin went on to describe the Canadian Hemophilia Registry, where it is, how it works, what data is collected, and how to validate the data against other registries. Collected data includes: Clinic, Province, Date of Birth, Factor Deficiency, Severity/Type, an Extra Identifier (ExID), Sex, Status (Alive/Lost etc.), HIV status, and HCV status. Disorders include Hemophilia A, Hemophilia B, Von Willebrand Disease, Rare Coagulation Deficiencies, and Rare Platelet Disorders. Irwin described the problems the registry faces on an ongoing basis – defining identity in an anonymous system so as to prevent duplicates, and maintaining the registry of mild cases who do not follow up regularly with the clinic. Irwin described a number of benefits from maintaining a registry including: providing a unifying force for the AHCDC, Assist lobbying of government for clinic funding, Federal HIV- and HCV-assistance programs.; providing data for external requests, including: Canadian Hemophilia Society, Provincial and federal governments, Canadian Blood Services, Pharmaceutical companies, WFH; research - Registry related, Interventional, Other, external; and finally it facilitates Confidentiality by providing CHR numbers. There have been a number of publications from the registry including: . He offered some final advice:

1. First think about comprehensiveness, accuracy and sustainability.
2. Set clear objectives BEFORE deciding what data is to be collected.
3. Get agreement from all stakeholders on the design, and on the data which is to be collected.
4. Consider work-load of data collection and input vs. usefulness of data.
5. Keep data collection simple.
6. Collect only data which can be verified.
7. Avoid data creep. Consider collection of core data and research data separately.
8. Investigate privacy laws in your jurisdiction.
9. Share the data with all constituencies.

### **Patient Registries – Bruce Ritchie**

Bruce described the Health Canada planned changes in the regulatory environment that will allow the regulator to compel Pharma to support registries for post marketing surveillance. A couple of national groups may be interested in collaborating on establishing standards for registries. Of these the Canadian Standards Association (CSA) looks most promising.

**Data Standards for Adverse Event Reporting – Heather Sutcliffe, Director  
Marketed Health Products Safety and Effectiveness Information Bureau of Health  
Canada (HC-SC)**

Heather Sutcliffe described the Canada Vigilance program and how they leverage data standards. The Canada Vigilance Program has Existed since 1965 as a spontaneous Adverse Reaction Reporting Program, with voluntary reporting for Health Professionals and Consumers, and mandatory reporting for Market Authorization Holders (i.e. manufacturers) under legislative framework of the *Food and Drugs Act and Regulations* (C.01.016), Access to Information and Privacy Act etc. It is part of the Marketed Health Products Directorate, and collects adverse reaction reports for marketed health products approved for use in humans, including:

- pharmaceutical drugs (prescription and non-prescription)
- biologics (Schedule D, biotechnology products, therapeutic and diagnostic vaccines and fractionated blood products)
- radiopharmaceuticals drugs
- natural health products
- cells, tissues and organs

The vigilance program has to integrate data form a variety of sources, so data standards are key to this. International Sharing of data between Regulatory Agencies requires consistency of data coding and assessment. They use the ICH (International Conference on Harmonization), HL7 (Health Level Seven), and standards from other other organizations: WHO International Drug Monitoring Program and CIOMS (Council for International Organizations of Medical Sciences). The ICH (International Conference on Harmonization)has been in existence since 1989. It provides requirements for the regulation and surveillance of pharmaceuticals through some 60 technical guidelines and a series of electronic standards for the transmission of regulatory data, for the development of good quality, safe and effective medicines that are registered in an efficient and cost-effective manner. Guidelines include:

Q (Quality) , S (Safety), E (Efficacy), and M (Multidisciplinary)

By incorporating ICH in the Guidance Document for Industry, HC provides consistency to Industry by implementing the ICH reporting requirements of post-market safety information, a step towards enabling electronic reporting with required data standards; provides Health Canada with the collection of increased quality of safety information in a more efficient manner; and provides opportunity for Health Canada and other Regulators to continue working towards a harmonized approach in the collection of post-market safety information which is important in information sharing.

ICH guidelines include:

ICH: E (= Efficacy) - Guidelines related to Adverse Reaction Reporting:

- E2B – Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
- E2C – Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs
- E2D – Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
- E2E – Pharmacovigilance Planning

ICH: M (= Multidisciplinary)

Guidelines related to Adverse Reaction Reporting

- M1 – MedDRA: Medical Terminology
- M2 – ESTRI: Electronic Standards for the transfer of Regulatory Information
- M5 – Data Elements for Drug Dictionaries

MedDRA refers to the Medical Dictionary for Regulatory Activities , and has been implemented with Canada Vigilance. It uses standardized terminology for classification, retrieval, presentation and communication of medical information (ICH standard). The scope includes: symptoms, signs, diseases and diagnoses, investigations and tests, therapeutic indications, surgical and medical procedures, & medical, social and family history: medication error related terms

MedDRA has been implemented with Canada Vigilance. Sharing of data requires consistency of data coding and assessment. MedDRA facilitates standardized electronic transmission of medical information

HL7 (Health Level 7/ Health Language 7) refers to a standards development organization working in the Health Care and Patient Safety Environment and provides for electronic interchange of clinical, financial and administrative information among independent healthcare-oriented computer systems, including: health Information Systems, Clinical Laboratory Systems, Enterprise Systems and Pharmacy Systems. The HL7 Standard is an interoperable standard for the electronic exchange of information in the healthcare area, with mechanisms to allow variations world-wide. Technical Committees of HL7 focus on particular areas such as Pharmacy, Patient Safety, Government, Laboratory, Health Care Devices etc.

ISO has standards for health informatics as well - TC215/WG6 (Health Informatics) provides standardization in the field of information for health to achieve compatibility and interoperability between independent systems. Individual Case Safety Report (AR reporting) and Medical Product Terminology have been added to the current work items. They have developed International Standards to reflect both ICH and HL7 requirements. Canada is represented by Canadian Advisory Committee of the Standards Council of Canada

Registries are important to Health Canada and are included in the proposed changes to the Canadian regulatory framework. They are a tool that can be used in surveillance of patients and products. They require development in accordance with privacy act, and are established by a variety of organizations (Manufacturers, CIHI). Examples of registries include: Clozapine (manufacturer), Hip Implants (CIHI). Health Canada does not establish or fund registries, but the Progressive Licensing Project will include regulatory requirements for post-market commitments depending on the information available in the pre-market phase which could include a registry

Progressive Licensing is part of the new strategy of Health Canada for approval of products. The primary goals are expressly tied to public safety. They should be met in a

way that reflects best practices for regulating in the Canadian context. They plan to align the Progressive Licensing Framework with the system of health care in Canada to achieve positive health outcomes and ensure that the new regulatory structure enables Health Canada to implement best international regulatory practices and maintain appropriate oversight without unduly increasing regulatory burden; and encourage and make best use of evolutions in the science of drug development and regulation.

Proposed Elements: Progressive Licensing include 5 main elements:

Element 1: Scientific and regulatory advice meetings

Element 2: Submission Requirements

Element 3: Authorization

Element 4: Post-Authorization

Element 5: Re-evaluation

All elements will work together in an integrated system, building knowledge of the benefits and risks of a drug.

**Barcode standards – Alicia Duval, Vice President, Healthcare Sector/Vice-présidente, Secteur des soins de santé, GS1 Canada**

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Alicia Duval from GS1 Canada presented background on an initiative between GS1 and the ICCBBA to standardize the barcodes on blood products. GS1 Canada is a Not-for-profit, industry-led association that promotes and maintains global standards for the identification of goods, locations and related e-commerce communication. Their Mission is “To take a leadership role in establishing, promoting, and facilitating implementation of global multi-industry standards for collaborative commerce”. As a GS1 Member Organization they represent Canada’s voice in the development and maintenance of global collaborative commerce standards.

GS1 is an integrated organization of national member organizations collaborating on standards for electronic commerce. They have over 30 years of experience, and have 108 GS1 Member Organizations (MOs) representing all points in the supply chain, and over 1 million companies doing business across 149 countries. They have approximately 2,000 staff worldwide. GS1 covers over 20 sectors (including consumer goods, foodservice, healthcare, transportation and defence) and over 5 billion transactions a day. GS1 Standards are used across industries. The GS1 Healthcare Initiative focusses on supporting Healthcare. GS1 Canada’s Healthcare Sector Initiative is aiming to lead the healthcare industry to the effective utilization and development of global standards to enable efficiencies and improve patient safety.

In the Pharmacy Sector, GS1 supports the retail and hospital pharmacy sector to advance a safe and efficient pharmacy supply chain. Over 90% of pharmaceuticals and over the counter medications carry a barcode (GTIN - global trade item number). GS1 Canada and CareNET Services, Inc. - signed a strategic alliance to enhance and increase the adoption of global supply chain and e-commerce standards and practices to improve safety and efficiency within the Canadian healthcare community. Over 430 Canadian

hospitals are now members of GS1 Canada. Over 90% of Canada's pharmaceutical and OTC products carry a GS1 bar code. The global focus is on unit dose level.

In August 2006, the world's leading medical device and pharmaceutical companies adopted GS1 as the sole system of standards in healthcare. Why Use Global Supply Chain Standards in Healthcare? Because of the global nature of the healthcare industry today, as well as the worldwide threats of medical errors, counterfeiting and diversion, country-by-country work is neither sufficient nor effective. Global standards shared across the healthcare industry are key to identifying and authenticating products.

GS1 & ICCBBA Sign MOU. On September 4, 2007, ICCBBA and GS1 Healthcare announced they have signed a Memorandum of Understanding to cooperate in the area of automatic identification standards for Healthcare. Two complementary global standards organizations will collaborate to advance global automatic identification standards in Healthcare to reduce medical errors, enable global traceability, and to increase the effectiveness of the healthcare supply chain.

Issue: Plasma Derivatives. There are signs of a growing demand for clarification on the process and assignment of coding for plasma derivative products. Specific recent events illustrate this: The introduction of *ISBT 128* coding of Octaplas as required by the Finnish Red Cross Blood Service, The decision by the Australian National Blood Authority to require GS1 coding for plasma derived, recombinant and diagnostic blood products; The request from the Quebec Professional Association of Transfusion Safety Officers for *ISBT 128* coding of stable products

At the hospital level, these products are handled in two different manners:  
In some locations they are distributed by the Blood Banks that, in general, are standardizing on the use of *ISBT 128* and whose computer systems most readily handle this coding system  
In others, distribution is via the hospital pharmacy where coding compatible with other drugs is preferred, and where the GS1 System of standards is being actively developed.

GS1 and *ISBT 128* Standards are complementary and apply to the specific needs of the healthcare sector. The *ISBT 128* Standard is the recognized and adopted standard for blood products requiring traceability to the donor. GS1's global standards apply to for the identification of pharmaceutical products, medical devices, patients, caregivers, locations and assets.

Unique GTIN at Every Packaging Level, and include Product ID, Batch or Lot number, Expiry Date, Serial Number, Secondary data for specific health industry products, a customer part number, and a variable count for encoding quality.

GS1 Data Carriers include a variety of different barcodes systems, Radio Frequency Identification (RFID) chips. The common element is the data format. GS1 has a standard for identifying blood products. *ISBT 128* Uses « AIs » =α Donation

Identification Number, =% ABO/Rh Blood Groups, => Expiration Date (CYYJJ), &> Expiration Date and Time (CYYJJHHMM), =< Product Code (catalogue #), &) Manufacturer's Lot Number (fixed length) ...but not the same data structures as GS1 and reverse

To find a solution for the plasma derivatives, there will be an Initial Meeting June 20, 2008, King Edward Hotel, Toronto. This is a joint GS1 & ICCBBAA meeting to look at the bar coding of plasma derivative products. The demand for coding of plasma derivative products is increasing and there is a window of opportunity to develop a globally standardized solution. The objectives of consultative meeting are to:

- obtain user requirements - bring stakeholders/users together to identify their needs and concerns from the perspective of identifying and tracking plasma derivative products;
- identify communication and education needs to promote consistency and best practices around the globe; and
- identify concerns of industry, government and healthcare providers.

**Integrating CHARMS with other systems; Rebecca Parke from CBS phoned in, Sylvie Thibault attended for Hema Quebec as well as a member of the IT department by phone,**

Rebecca parke described the efforts to date to integrate product distribution data from CBS with CHARMS. There have been some glitches, but these have gradually been worked out over time. Hema Quebec has a couple of new systems in place – they made a commitment to do the same for their information system.

**Integrating CHARMS with other systems: Pharmaceutical Industry – Bayer, CSL, Baxter, NovoNordisk, Wyeth**

Baxter has now decommissioned their Advoy system because of privacy concerns. Bayer described EasyLog and their commitment to integrating with CHARMS.

**Integrating CHARMS with other systems: TTISS Cindy Hyson, Nick Karitsiotis**

Nick Karitsiotis from PHAC described the Transfusion Transmitted Injury Surveillance (TTIS) system. They use 2 data integration mechanisms, a Client/Server system, and a Web enabled systems. Nick described 2 typical Data Integration Mechanisms: a Data sharing with client/server systems (ex. Microsoft Access), and a data sharing with web based systems (ex. Microsoft .NET Framework). In Client/server Systems:

- Export function is built into client/server system - Mdb, xls, txt
- Exported file gets 128 bit encrypted (ex. Winzip 11), emailed to PHAC on schedule
- PHAC decrypts file and imports into data warehouse (ex. Dynamic Data Management System (DDMS)) -This would happen for each file sent to PHAC
- PHAC exports master file out of DDMS for analysis
- Examples: Transfusion Transmitted Injuries Surveillance System (TTISS) v3, Enhanced Hepatitis Strain Surveillance System (EHSSS) v4

Whereas, in web based systems, there are 2 ways to integrate data:

- 1. Export function is built into web enabled system as XML file
  - Exported file gets 128 bit encrypted (ex. Winzip 11) and emailed to PHAC on schedule

- PHAC decrypts file and imports into data warehouse (ex. Dynamic Data Management System (DDMS))
- This would happen for each file sent to PHAC
- PHAC exports master file out of DDMS for analysis
- Examples: TTISS v4, Transfusion Errors Surveillance System (TESS), EHSSS v5, Cells, Tissues, & Organs Surveillance System (CTOSS) – in planning
- 2. PHAC account is created on web enabled system
  - PHAC logs into web enabled system and is able to view cases that qualify for data sharing
  - PHAC is able to export data in XML format
  - PHAC imports data into DDMS
  - Examples: TTISS v4, TESS, EHSSS v5, CTOSS – in planning

A web based hybrid system, such as TTISS contains a localized client demographic module, Shared data (based on data sharing agreement) is uploaded to central website in real time; data is viewed and shared through views (user policy driven) and data exports.

**Integrating CHARMS with other systems: Quebec blood surveillance – Yves Jalbert**

Yves Jalbert from the Quebec Blood Surveillance system has recently obtained funding to hire a programmer, and committed to integrating their surveillance work with CHARMS.

**Strategies for Privacy, Bruce Ritchie**

Bruce discussed the protocol for obtaining approval from the Privacy Office in Alberta and differences in Privacy legislation across the provinces as described by Elaine Ashfield. Alberta is the only province that has mandated a Privacy Impact Assessment – the rest of the provinces like to see these, but have not mandated them. The privacy offices in most of the provinces have said that the Alberta PIA template is good and the format will be acceptable to them. Therefore we resolved to fill out the PIA in Alberta and use this as the basis for submitting PIAs in all provinces across the country. This will greatly simplify things, since the hospitals and other agencies are expected to accept PIAs approved by their provincial privacy offices.

**Presentation of the CHARMS Requirements Document: Bruce Lawson, Joanne Szewczuk, Capital Health**

Joanne Szewczuk from Capital Health has reviewed the current version of CHARMS in detail and produced a CHARMS Requirements document (attached). This is a very long document. Key items are described in the first few pages. Joanne has asked for input into the document so as to be able to move forward with the new web-based program. Key additions will be the integration of CHARMS with information systems at Canadian Blood Services, Hema-Quebec, Health Canada, the Public Health Agency of Canada, the Quebec Blood Secretariat, and industry based product-tracking systems (Bayer and CSL).

**Capital Health possibilities, Bruce Lawson, Joanne Szewczuk, Capital Health (see attached)**