Quality Excellence and Emergency Preparedness: How Canadian Blood Services is meeting the challenge

Dr Graham D. Sher
Chief Executive Officer
Canadian Blood Services

“Breakfast with the Chiefs”
December 1st 2005, Toronto
“Only two things are infinite, the universe and human stupidity, and I'm not sure about the universe.”

– Albert Einstein
Theoretical physicist

“If we don't change direction soon, we'll end up where we're going.”

– ‘Professor’ Irwin Corey
American satirist
Outline

- History and background
- Introduction to Canadian Blood Services
- National service delivery model
- Quality system
- Emergency preparedness
- A model for other parts of healthcare?
Canadian Blood Services

• Founded in 1998 as the successor organization to the Canadian Red Cross Society

• For over 50 years, CRCS operated Canada’s blood supply system

• Early 1980s to mid 1990s:
  – tainted blood scandal
  – largest public health crisis in the history of Canada

• Culminated in the Krever Commission of Inquiry on the Blood System in Canada
Legacy of Failure and Scandal
Krever recommendations set the change agenda

- More openness and transparency
- Clear accountability
- Informed decision-making
- A national system under a single operator
- Sufficient funding and contingencies to eliminate risks from financial compromise
- Improved regulation and regulatory framework
- Better transfusion practices
- Enhanced research and development
…all to ensure that blood safety is paramount

• Krever Commission report emphasized the Canadian blood supply should be governed by five basic principles:
  – blood is a public resource
  – donors of blood and plasma should not be paid for their donations
  – whole blood, plasma and platelets must be collected in sufficient quantities in Canada to meet domestic needs
  – Canadians should have free and universal access to blood components and products
  – safety of the blood supply is paramount
The 1989 Ministerial Principles

• Voluntary system should be maintained and protected
• National self-sufficiency in blood and plasma collections should be encouraged
• Adequacy and security of supply … … for Canadians should be encouraged
• Safety should be paramount
• Gratuity of all blood and plasma fractions … … should be maintained
• A cost-effective and cost-efficient supply program should be encouraged
• A national blood supply program should be maintained
The 1995 interpretive descriptions

- The aforementioned principles were clarified by the Ministers of Health in 1995:

  #3: “Adequacy and security of supply”
  - This principle is important in preparing for national emergencies in peace and wartime

  #4: “Safety should be paramount”
  - This principle refers to the quality and safety of all aspects of the supply chain and therapeutic use

  #7: “National blood supply program”
  - The blood supply program in Canada is uniquely national, with products collected in any region of Canada being used by individuals in any region needing them. National policies and inter-provincial / territorial funding maintain this program
Canadian Blood Services

• Created as a new agency, with the mandate to:
  – rebuild the blood system in Canada
  – regain the trust of Canadians in their blood supply
  – create risk management programs aimed at preventing future catastrophes

• and governed by the principles:
  – safety of the blood supply is paramount
  – fully integrated approach is essential
  – accountabilities must be clear
  – renewed blood system must be transparent

Conference of Health Ministers, April 25th, 1997
Outline

• History and background
• Introduction to Canadian Blood Services
• National service delivery model
• Quality system
• Emergency preparedness
• A model for other parts of healthcare?
Canadian Blood Services

- Mission:

  Canadian Blood Services operates Canada’s blood supply system in a manner that gains the trust, commitment and confidence of all Canadians by providing a safe, secure, cost-effective, affordable and accessible supply of quality blood, blood products and their alternatives.
### Components of the Canadian Blood System

<table>
<thead>
<tr>
<th><strong>Federal Government</strong></th>
<th><strong>P / T Governments</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Through the Minister of Health:</td>
<td>P/T Ministers of Health are the corporate Members of CBS:</td>
</tr>
<tr>
<td>• establishes standards</td>
<td>• responsible for funding, defining mission and mandate, and assessing performance</td>
</tr>
<tr>
<td>• imposes regulation</td>
<td>• CBS is not an agent of any government; operates at arm’s length from its Members</td>
</tr>
<tr>
<td>• licenses blood operators</td>
<td></td>
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<tr>
<td>• inspects establishments</td>
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<table>
<thead>
<tr>
<th><strong>Blood Operators</strong></th>
<th><strong>Canadians</strong></th>
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<tbody>
<tr>
<td>• Canadian Blood Services owns and operates system in 9 provinces and 3 territories</td>
<td>Multiple levels of interaction:</td>
</tr>
<tr>
<td>• Hema-Quebec (set up by an Act of Quebec parliament) is an arm of the QC Ministry of Health; is subject to same Federal regulation</td>
<td>• donors</td>
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<td>• volunteers</td>
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<td></td>
<td>• hospitals, h/care providers</td>
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<tr>
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<td>• recipients</td>
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<td>• stakeholders</td>
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</table>
Canadian Blood Services

Through the 1997 MoU, Ministers of Health ascribed to CBS the “core operational” functions:

- donor recruitment and management
- whole blood and plasma collection
- testing and laboratory work
- processing
- storage and distribution
- inventory management

as well as the following “key” functions:

- standard, policy and guideline setting
- national program of research & development and transfusion medicine
- surveillance and monitoring
- professional and public education
- health risk management
Canadian Blood Services

- **Blood operations:**
  - Recruit donors, collect blood, manufacture components, test, distribute to hospitals

- **Plasma program:**
  - Collect plasma, custom fractionation, acquire plasma derivatives, recombinant proteins and synthetic equivalents

- **Related Programs:**
  - Education, research & development, clinical consultation

- **Unrelated Bone Marrow Donor Registry & Stem Cell Programs:**
  - Linked to 53 other registries worldwide

- **Diagnostic laboratories:**
  - “patient services” in certain provinces

- **Insurance Captive:**
  - Wholly owned subsidiary company to underwrite catastrophic loss

- **CBS Foundation:**
  - To support and extend the mission of CBS
CBS Governance Model

- Arm’s length, not-for-profit agency independent of Member governments
- Regulator: Health Canada
  - blood classified as a drug under Schedule D, Food & Drugs Act
- Exclusively serve 9 provinces and 3 territories
- Funded by all Provinces and Territories (except QC)
- Global budget; no charge to hospitals
- CBS’s operating budget FY2006 = C$865 million
CBS Governance Model

• Seeks to balance:
  – the need for ministerial responsibility and accountability for spending public monies and for setting health policy objectives with
  – the need for CBS to have necessary autonomy and accountability to ensure a safe, secure and effective blood supply system

• Explicitly addresses the issues of roles, responsibilities and accountabilities raised in the Krever Commission report
### CBS Governance Model

<table>
<thead>
<tr>
<th>Corporate Members (Ministers of Health)</th>
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</thead>
<tbody>
<tr>
<td>“Shareholders” of the corporation</td>
</tr>
<tr>
<td>Appoint the Board of Directors</td>
</tr>
<tr>
<td>Approve annual corporate plan and budget</td>
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<table>
<thead>
<tr>
<th>Board of Directors</th>
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<tbody>
<tr>
<td>Chair; 4 regional; 2 consumer and 6 business / medical / technical representatives</td>
</tr>
<tr>
<td>Internal Board committees and external liaison committee</td>
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<tr>
<td>Hire the CEO</td>
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<tr>
<th>Chief Executive Officer</th>
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<td>Responsible for day-to-day operations</td>
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<td>Authority to appoint independent advisory committees</td>
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<tr>
<td>Personal authority to expense contingency funds and borrow commercially to respond to urgent safety concerns</td>
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</table>
Outline

• History and background
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• National service delivery model
• Quality system
• Emergency preparedness
• A model for other parts of healthcare?
Unique features & opportunities

- Creation of a new, independent organization with a clear mandate and a burning platform for change, afforded CBS the opportunity to exploit:
  - benefits of a national approach
  - benefits of clear roles and accountabilities
  - opportunities for economies of scale and best practices
Benefits of a national approach

• Every patient and every institution across the country would have:
  – products and services of consistent standards and quality
  – equal access to supply of all products at all times, irrespective of geography
  – benefit of simultaneous introduction of novel technologies or safety enhancements
Benefits of clear roles and accountabilities

• Health Canada is the regulator, and has no funding involvement
  – ensures its ability to fulfill its functions independently and without conflict of interest

• PT Ministers (Members) have role in funding and setting broad public health policy; elected officials and bureaucrats not permitted to serve on Board

• Operator (CBS) is a sole purpose entity with governance autonomy, operational independence and capacity for rapid response
Opportunities for economy of scale and best practices

• Inherited a highly decentralized operation with multiple areas of service duplication and redundancy

• Previous “system” operated in a geographically siloed environment

• Ability to negotiate national contracts for supplies and products affords huge savings opportunities

• Opportunity to interact with local, regional, provincial and federal components of healthcare system

• Substantial opportunity for international collaboration and best practice sharing
Seizing the opportunity: CBS’ Transformation

**Transition**
Canadian Red Cross Society to Canadian Blood Services
April – Sept. 1998

**Stabilization**
Gain understanding of major issues
Determine requirements for change
Approximately 18 months

**Transformation**
Re-engineer the system
Regain trust and confidence in the blood supply
3 – 5 years
Seizing the opportunity: CBS’ Transformation

**Phase 1**
(1998 to 2003)
- Restore trust
- Restore safety
- Rebuild core operations
- Stabilize facilities
- Manage crises
- Tactical management

**Phase 2**
(2003 to ongoing)
- Become model for health care delivery in Canada
- From blood manufacturers to “stewards” of the blood system
- Embed strategy across organization
CBS is using a Balanced Scorecard to help execute our business strategy
Canadian Blood Services operates Canada's blood supply in a manner that gains the trust, commitment and confidence of all Canadians by providing a safe, secure, cost-effective, affordable and accessible supply of quality blood, blood products and their alternatives.

**Safety**
- C1. “CBS provides us with safe products and services”
- S1. Monitor known and emerging hazards
- S2. Protect against risks

**Operational Excellence**
- C2. “CBS manages an effective, efficient and trusted blood system for Canadians”
- S1. Deliver the right product, at the right place, at the right time
- S3. Promote the optimal utilization of product
- S4. Optimize donor recruitment and retention
- S5. Deliver efficiency and productivity gains

**Plan for Tomorrow**
- C3. “CBS helps us meet future needs”
- S8. Create, develop or adopt new knowledge, products and services
- S7. Anticipate long term changes in future needs for products and services

**CBS Values**

**Fulfill our Mission**
- R1. Ensure a healthy financial structure
- R2. Build and sustain facilities that support our business requirements

**Customer Service Excellence**
- which drive the Strategic Actions

**Our Enabling Resources**
- enable us to execute

**Developing strategic assets**
- E1. Develop our skills, talent and knowledge
- E2. Support the business through information technology
- E3. Develop the quality system and culture
Creating a National Service Delivery Model: the concept

Silo model

Integrated model

Donor Customers

Donor management and recruitment

Marketing, advertising, polling

Customer service support

Manufacturing

Hospital Customers
+ Key Community Opinion Leaders and Stakeholders

Corporate Support

Integrated Donor Development

(Centre) Directors, Business Development and Customer Relations
Creating a National Service Delivery Model: 
the scope of opportunity

Disconnected “Centres” eroded by cost, time and circumstances into islands of duplication
Traits of the silo model

- Operations consisted of 14 disconnected “silos” across Canada
- No coherent strategic approach to the business
- No big picture of problems and solutions
- Process and structural duplication
- Error-prone manual systems
- Obsolete IT infrastructure
- Lack of operating metrics
- Many inconsistencies
- No consistent operational look and feel
- Major management skill-deficits
Today’s effective, efficient national service-delivery model

- Manufacturing
- Testing
- Head Office

> 15,000 clinics / yr
Features of the new service-delivery model

- Fully integrated national network of:
  - collections, testing, production, labeling, distribution
- Capacity for rapid response to emerging threats (e.g. WNV)
- Flexibility and scalability to manage demand shifts (e.g. 9/11, Aug 2003 blackout, labour disruptions)
- Comprehensive use of information technology to improve safety and quality
  - e.g. MAK Progesa, advanced modular testing
- Single national inventory
  - improved supply-demand alignment
- Fully integrated donor management to improve supply
  - national marketing and communications, national/local branding, advertising, media relations, proactive National Contact Centre, intensified donor development with a strong community focus
- Improved hospital relations
Clear roles & accountabilities

FEDERAL (HEALTH CANADA)
• Regulation (Food and Drugs Act)
• Establishment Licensure
• Compliance and enforcement
• National Disease Surveillance

PROVINCES/ TERRITORIES
• Funding of Blood Operators
• Regulate Health Professions
• Medical practice (hospitals)
• Public Health

SAFETY

OPERATORS (CBS)
• Donor recruitment
• Product collection, manufacture
• Acquisition, distribution of derivatives
• Bone Marrow Donor Registry

OTHERS
• Donors & Recipients
• Non-governmental organizations
• Advocacy groups
• Health professionals

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Expanding the circle of public trust

Points of change

Effective, visible change leverages influence

Points of influence

Influence leverages trust
Public involvement & transparency

- Board of Director meetings open to public
  - board minutes at http://www.bloodservices.ca

- National Liaison Committee
  - 6 Community Liaison Committees

- Consensus Conferences

- Advisory committees:
  - Scientific & research committee
  - donor Advisory Panel
  - hospital Advisory Panel

- Stakeholder involvement in plasma products RFP
Maintaining public trust is constant challenge

The numbers continue to validate progress...

- I trust CBS to act in the best interests of the public: 80%
- I trust CBS to do what is best for the blood system: 79%

Source: Ipsos-Reid National Poll, August 2005

But... while progress continues, CBS is ever mindful that maintaining trust is a never-ending endeavor. Any incident – real or imagined – can set-back years of diligence, effort and progress.
Benefits of a single national system

- National inventory
  - ability to supply all institutions and patient need with product from any part of country

- Capacity to deal with surges to the system
  - enhanced WNV testing in height of epidemic each season

- A “national pharmacare” program
  - CBS is sole purchaser of plasma protein products, recombinant clotting proteins and similar agents
  - $450 million purchases annually
  - single largest customer worldwide of major US plasma fractionator
  - least impact during global shortages of IVIG and fVIII
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Quality Excellence at CBS

• Premise of CBS’ Transformation is to create a *high quality organization*, delivering safe products and services in the most efficient manner possible

• This is about much more than quality assurance, quality control, quality compliance or quality policies

• Quality is to be a core competency of CBS and central to the culture of the organization
  – compliance is simply the cost of entry into the business
  – quality simply makes good business sense

• Objective is to become the “*Toyota of blood manufacturers*” worldwide
Quality System

• **Quality system** (CSA, FDA (QSR), AABB, ISO 9000:1994): the organizational structure, responsibilities, procedures, instructions, processes, and resources for implementing quality management
  
  – **Quality management** (CSA, ISO): coordinated activities to direct and control an organization with regard to quality

• **Quality management system** (ISO 9000:2000): management system (set of interrelated or interacting elements) to direct and control an organization with regard to quality
  
  – **process**: set of interrelated or interacting activities which transforms inputs into outputs
FDA Quality System Regulations

- Medical device reporting
- Corrective & preventive action
- Report of corrections and removals
- Medical device tracking
- Facility & equipment controls
- Design controls
- Material controls
- Production & process controls
- Records & Change Control
- Sterilization process controls
Simply put… …
Frequent, detailed communications using a variety of mediums
Roadmap to CBS’ quality maturity

1. Baseline
   - Requirements and performance relative to requirements not understood

2. Improve
   - Root causes to key operational problems are identified and solutions are implemented

3. Standardize
   - Execution follows standard design using documented procedures supported by training and verification programs

4. Manage
   - Process execution monitored by system of outcome based metrics and managed by system of predictive metrics

5. Optimize
   - Continuously improving capability, minimizing waste and increasing adaptability

- Level 0: Unknown
- Level 1: Understood
- Level 2: Stabilized
- Level 3: Repeatable
- Level 4: Capable
- Level 5: Efficient

Requirements and or performance relative to requirements are understood as basis for targeting improvements.
Requirements and performance relative to requirements are understood as basis for targeting improvements.
Root causes to key operational problems are identified and solutions are implemented.
Execution follows standard design using documented procedures supported by training and verification programs.
Process execution monitored by system of outcome based metrics and managed by system of predictive metrics.
Continuously improving capability, minimizing waste and increasing adaptability.

Road Map

Low

High

Process Maturity
Challenges to quality system maturity

- Resistance to change
- Priority given to quality system implementation vs other strategic initiatives
- Ability to demonstrate benefits
- Cultural shift:

**From**
- Activity focused
- Regulatory compliance
- Passive senior management
- An obstacle and burdensome to day-to-day activities

**To**
- Process oriented
- Good business practice
- Active process ownership
- Management tool that enables change & improvement
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Emergency Preparedness

• Multiple aspects:
  – business continuity planning:
    • labour disruption
    • adverse weather conditions
    • loss of systems
  – disaster recovery planning:
    • manmade (e.g. 9/11, Aug 2003 blackout)
    • natural
  – emergency preparedness:
    • bioterrorism
    • emerging transmissible harmful agents (e.g. WNV)
    • public health threats (e.g. SARS, Pandemic influenza)
Definition of a “Disaster”

• A “disaster” at CBS includes:
  – any domestic disaster, act of terrorism or other event that:
    • suddenly requires a much larger amount of blood than usual; OR
    • temporarily restricts or eliminates CBS’ ability to collect, process, and distribute blood; OR
    • creates a sudden influx of donors, requiring accelerated activities to meet an emergent need elsewhere
Business Continuity Management

• A management process that:

  – identifies potential impacts that threaten an organization and provides a framework for **building resilience** and the capability for an **effective response** that safeguards the interests of its key stakeholders, reputation, brand and value creating activities’

  – *Business Continuity Institute (BCI), 2003*
Key Program Objectives

- Ensure the safety of staff, volunteers and donors
- Maximize the defense of CBS’ reputation and brand image
- Minimize the impact of business continuity events (including crises) on our customers
- Demonstrate effective governance to our members, stakeholders, media and to the general public
- Assist CBS to meet regulatory, legal and insurance requirements
- Risk based decisions regarding redundancy of operations, timeliness to response, level of preparedness etc.
CBS’ Business Continuity Management Program

- Key external organizations
- Crisis communication plan
- Site evacuation plans
- Crisis management plan
- Information technology DRPs
- BCPs and SIRPs
- Executive on-call manual

BCMP
Technology recovery plan

- Develop Disaster Recovery Plan
- Identify Business Requirements for recovery
- Identify gaps and develop strategies to address the gaps
- Assess Current Recovery Capabilities
- Emergency Preparedness
- Keep Disaster Recovery Plan up to date
User recovery priority dictates recovery capability strategies

- < 1 day recovery time
- Facility and technology ready for use before disaster is declared
  - Hot Site

- > 14 days recovery time
- Facility and technology acquired at time of disaster

- 1 – 14 days recovery time
- Facility and some technology ready for use before disaster is declared
  - Warm site
CBS uses a combination of Pre-stage and Subscribe recovery strategies to provide 100% of the critical services within the user priority timeframes.

<table>
<thead>
<tr>
<th>System / Service</th>
<th>Recovery Time Objective</th>
<th>Estimated Time to Recover Outside of Ottawa</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAK PROGESA</td>
<td>1 day</td>
<td>1 day</td>
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<tr>
<td>PDSI</td>
<td>1 day</td>
<td>1 day</td>
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<tr>
<td>MAK Patient Services</td>
<td>1 day</td>
<td>1 day</td>
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<td>SAP</td>
<td>1 day</td>
<td>1 day</td>
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<td>BLIS 2000</td>
<td>2 days</td>
<td>1 day</td>
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<td>FPMS</td>
<td>2 days</td>
<td>&lt; 2 days</td>
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<td>HLA</td>
<td>3 days</td>
<td>&lt; 3 days</td>
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<td>ESS</td>
<td>3 days</td>
<td>&lt; 3 days</td>
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<tr>
<td>Internet WEB Update</td>
<td>3 days</td>
<td>&lt; 3 days</td>
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<tr>
<td>Intranet WEB Services</td>
<td>5 days</td>
<td>2 - 4 days</td>
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<td>Notes – Email</td>
<td>5 days</td>
<td>2 - 4 days</td>
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<tr>
<td>File and Print Services</td>
<td>5 days</td>
<td>2 - 4 days</td>
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<tr>
<td>Notes – Database Access</td>
<td>7 days</td>
<td>2 - 4 days</td>
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<td>UBMDR</td>
<td>7 days</td>
<td>2 - 4 days</td>
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<td>Data Warehouse</td>
<td>7 days</td>
<td>2 - 4 days</td>
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<td>Heat</td>
<td>10 days</td>
<td>2 - 4 days</td>
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<tr>
<td>RIMS</td>
<td>15 days</td>
<td>2 - 4 days</td>
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Emergency Preparedness

• West Nile Virus:
  – from discovery of transmissibility of agent (late 2002) to implementation of DNA-based screening assay (summer 2003) was an unprecedented time of responsiveness
  – mobilized financial and human resources and accessed corporate capacity
    • contingency fund
    • consolidated laboratory environment
  – cooperated with Regulator, manufacturers, public health, funding PT governments, US blood agencies
  – no cases of transfusion transmitted WNV in Canada
Emergency Preparedness

- Pandemic influenza:
  - while agent is unlikely to be transfusion transmissible, impact on blood system could be enormous:
    - loss of staff
    - loss of donors
    - cessation of public gatherings
    - impacts of altered healthcare practices
  - extensive internal preparedness planning
  - cooperation with multiple levels of public health (local, PT, federal)
  - exploring feasibility of transnational movement of blood products

<table>
<thead>
<tr>
<th>‘Flu Planning</th>
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<tr>
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<tr>
<td>- Preparing staff &amp; volunteers</td>
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<tr>
<td>- Hospital needs &amp; utilization</td>
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<tr>
<td>- Command &amp; control</td>
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<tr>
<td>- Fast track processes</td>
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<tr>
<td>- Finished product inventory</td>
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<tr>
<td>- Integrated communications strategy</td>
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<tr>
<td>- HR Management &amp; deployment</td>
</tr>
<tr>
<td>- Public health partnerships</td>
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<tr>
<td>- Logistics strategy</td>
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<tr>
<td>- Alternate sites</td>
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<tr>
<td>- Donor recruitment strategy</td>
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<tr>
<td>- Essential operations</td>
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</tbody>
</table>
“Fate favours the prepared”

Louis Pasteur
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• A model for other parts of healthcare?
Canadian Blood Services has transformed the national blood supply system:

- overcome the legacy of failure and lack of responsiveness that culminated in the tainted blood scandal
- single national system (excluding QC)
- standardized service delivery
- equal access to products and services
- singular focus on quality excellence in every aspect of our business (core operations and support services)
- scalability and flexibility to respond to shifting demands
- demonstrated capacity to deal with disasters or emergencies
Summary

CBS has restored public trust in the blood system by emphasizing product quality and safety, operational transparency and accountability, and customer service.
Summary

- CBS Transformation, while a work in progress, is an unqualified success to date
- CBS revenue flat, tracking overall health spending trends
- CBS completely revamped its service-delivery model AND significantly increased collections
Conclusion

• CBS is a unique entity in the Canadian healthcare system:
  – federally regulated
  – provincially funded
  – nationally managed
  – monopoly service provider in all jurisdictions

• Values of accountability, transparency, public participation are core tenets of the organization

• Experience to date has shown the model to be effective, efficient and trusted by stakeholders

• Model for other services?
  – cord blood bank, tissue banking, organ transplantation, national pharmacare, … …
Conclusion

• “… special purpose organizations … with arms-length governance represent a new way of doing business in Medicare and the Canadian federation. These organizations may be a virtuous answer to the dysfunctional F/P/T process”

  » Michael B. Decter, April 2005