



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



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Blood. It's in you to give.

“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



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Blood. It's in you to give.

Outline

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



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Canadian Blood Services

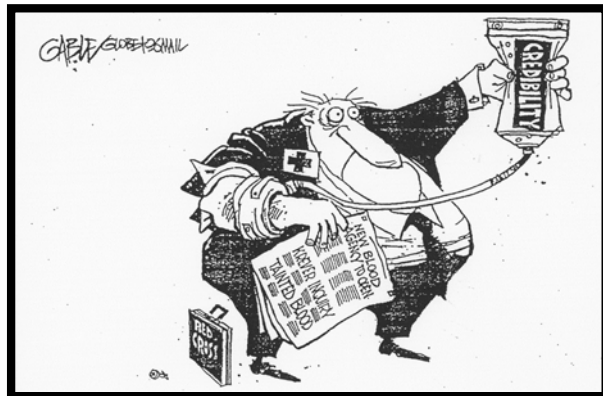
- Founded in 1998 as the successor organization to the Canadian Red Cross Society
- For over 50 years, CRCS operated Canada's blood supply system
- Early 1980s to mid 1990s:
 - tainted blood scandal
 - largest public health crisis in the history of Canada
- Culminated in the Krever Commission of Inquiry on the Blood System in Canada



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Legacy of Failure and Scandal



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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



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...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



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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



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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



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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



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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*



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Components of the Canadian Blood System

Federal Government

Through the Minister of Health:

- establishes standards
- imposes regulation
- licenses blood operators
- inspects establishments

P / T Governments

P/T Ministers of Health are the corporate Members of CBS:

- responsible for funding, defining mission and mandate, and assessing performance
- CBS is not an agent of any government; operates at arm's length from its Members

Blood Operators

- Canadian Blood Services owns and operates system in 9 provinces and 3 territories
- 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

Canadians

Multiple levels of interaction:

- donors
- volunteers
- hospitals, h/care providers
- recipients
- stakeholders



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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



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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



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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



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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



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CBS Governance Model

Corporate Members (Ministers of Health)

“Shareholders” of the corporation

Appoint the Board of Directors

Approve annual corporate plan and budget

Board of Directors

Chair; 4 regional ; 2 consumer and 6 business / medical / technical representatives

Internal Board committees and external liaison committee

Hire the CEO

Chief Executive Officer

Responsible for day-to-day operations

Authority to appoint independent advisory committees

Personal authority to expense contingency funds and borrow commercially to respond to urgent safety concerns



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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



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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



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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



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Opportunities for economy of scale and best practices

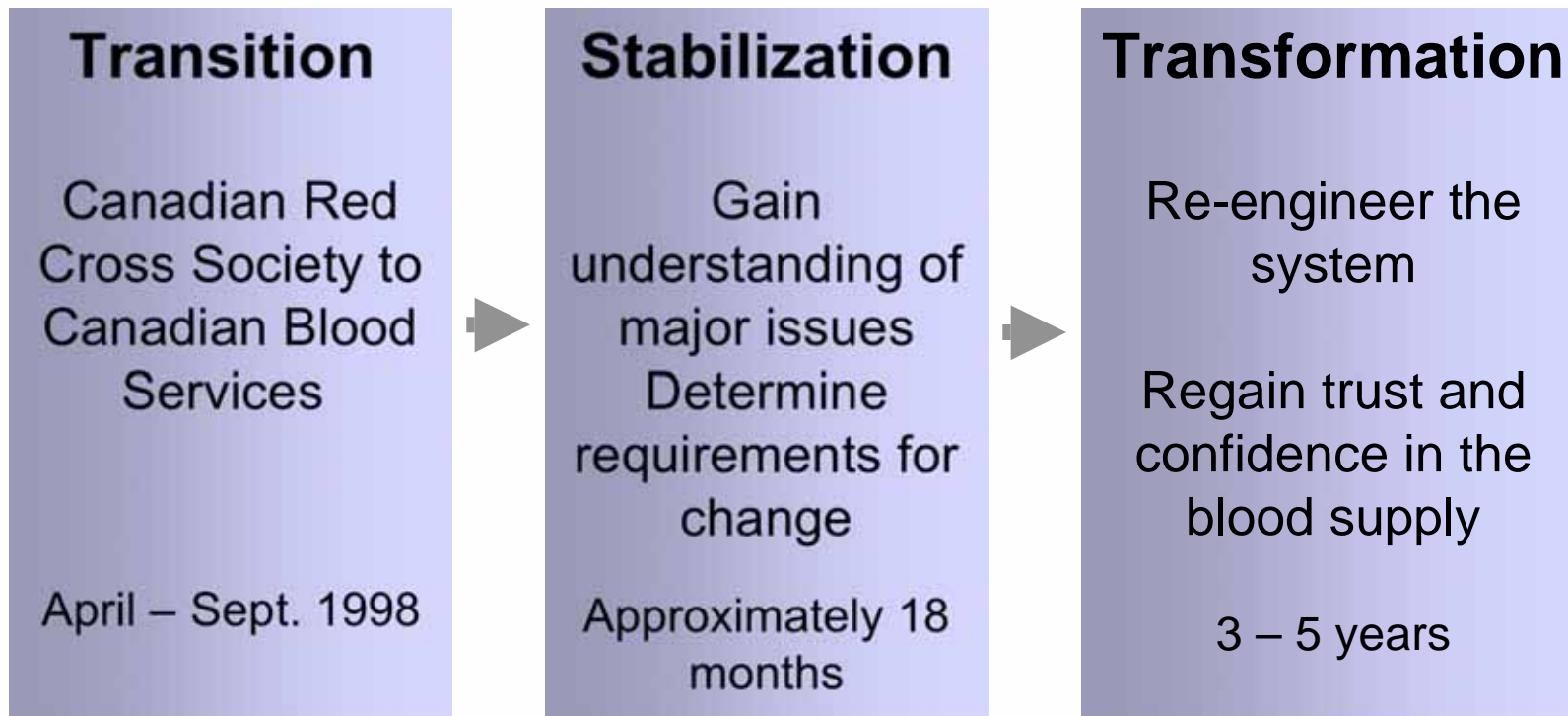
- Inherited a highly decentralized operation with multiple areas of service duplication and redundancy
- Previous “system” operated in a geographically siloed environment
- Ability to negotiate national contracts for supplies and products affords huge savings opportunities
- Opportunity to interact with local, regional, provincial and federal components of healthcare system
- Substantial opportunity for international collaboration and best practice sharing



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Seizing the opportunity: CBS' Transformation



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Seizing the opportunity: CBS' Transformation

Phase 1 (1998 to 2003)

Phase 2 (2003 to ongoing)

Crisis Management

- Restore trust
- Restore safety
- Rebuild core operations
- Stabilize facilities
- Manage crises
- Tactical management

Strategic Management

- Become model for health care delivery in Canada
- From blood manufacturers to "stewards" of the blood system
- Embed strategy across organization



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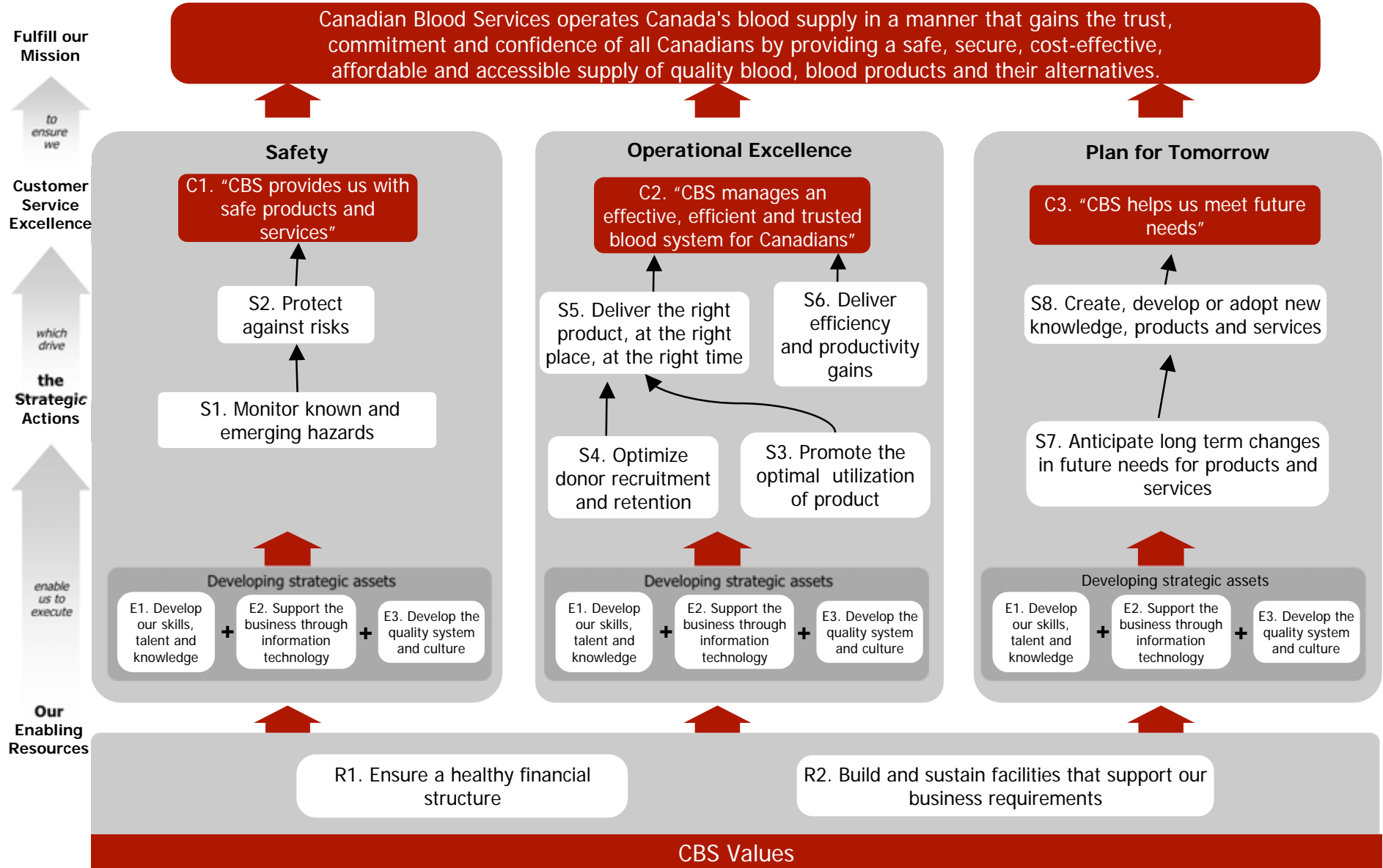
CBS is using a Balanced Scorecard to help execute our business strategy



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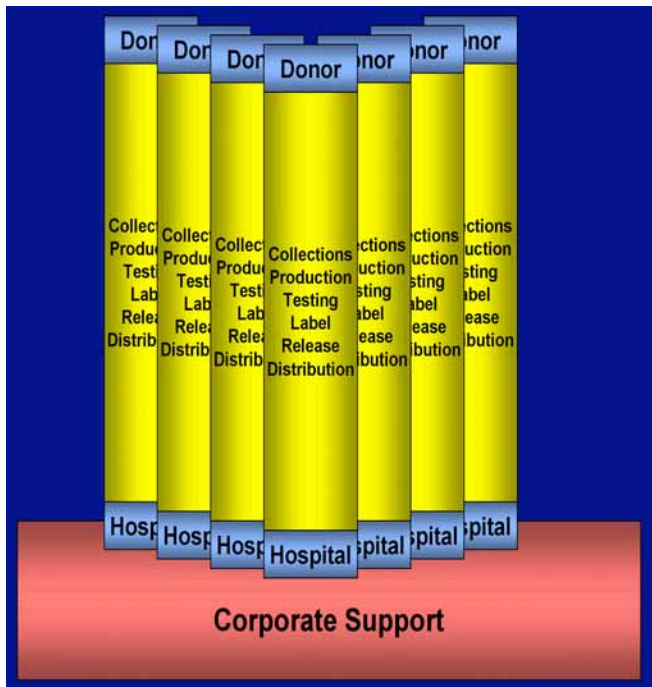
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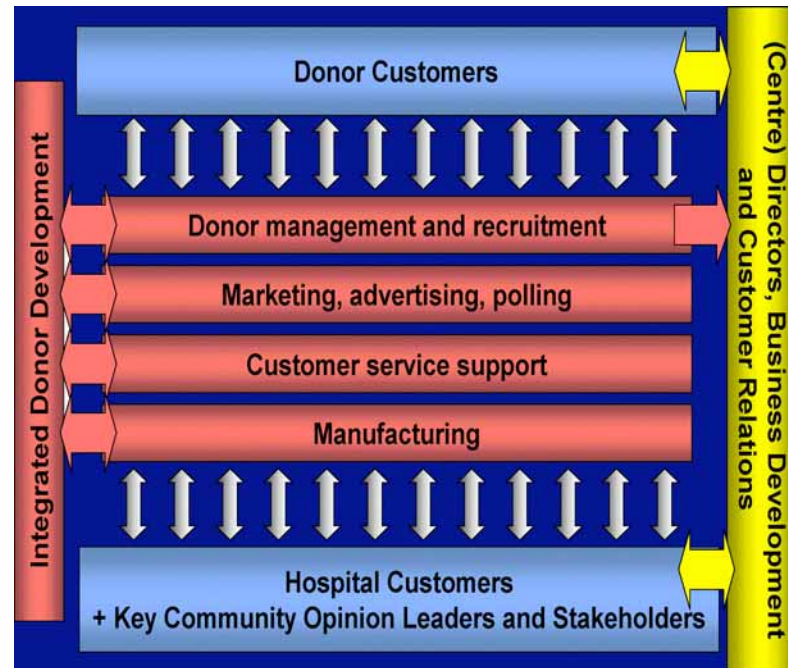


Creating a National Service Delivery Model: *the concept*

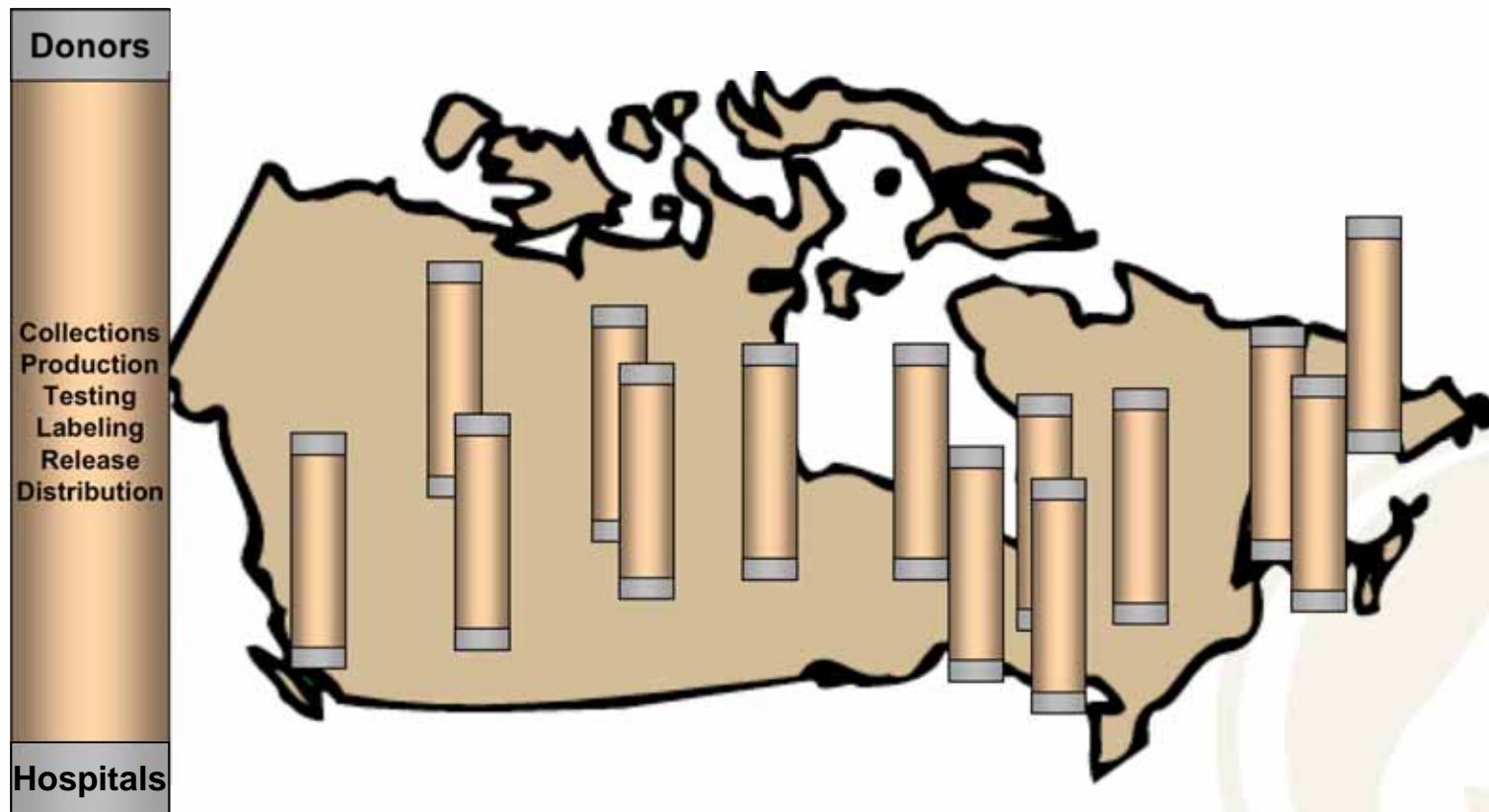
Silo model



Integrated model



Creating a National Service Delivery Model: *the scope of opportunity*



Disconnected “Centres” eroded by cost, time and circumstances into islands of duplication



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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



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Today's effective, efficient national service-delivery model



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



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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

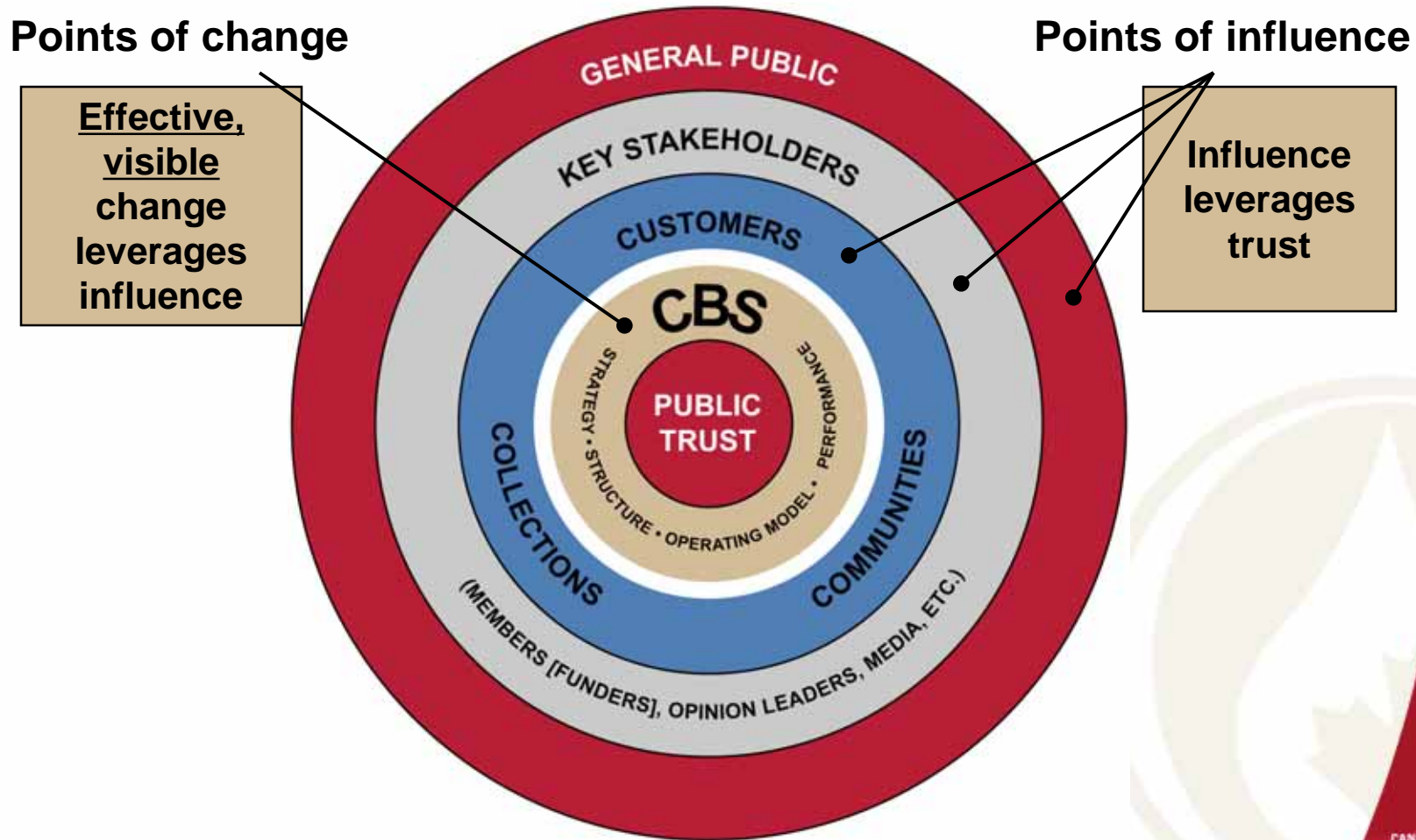
- Donors & Recipients
- Non-governmental organizations
- Advocacy groups
- Health professionals



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Expanding the circle of public trust



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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



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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%

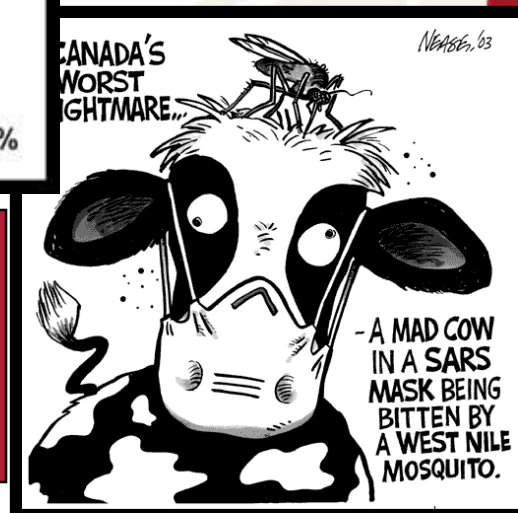
I trust CBS to do what is best for the blood system

79%

Source: Ipsos-Reid National Poll, August 2005

0 20 40 60 80 100%

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.



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ou to give.

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



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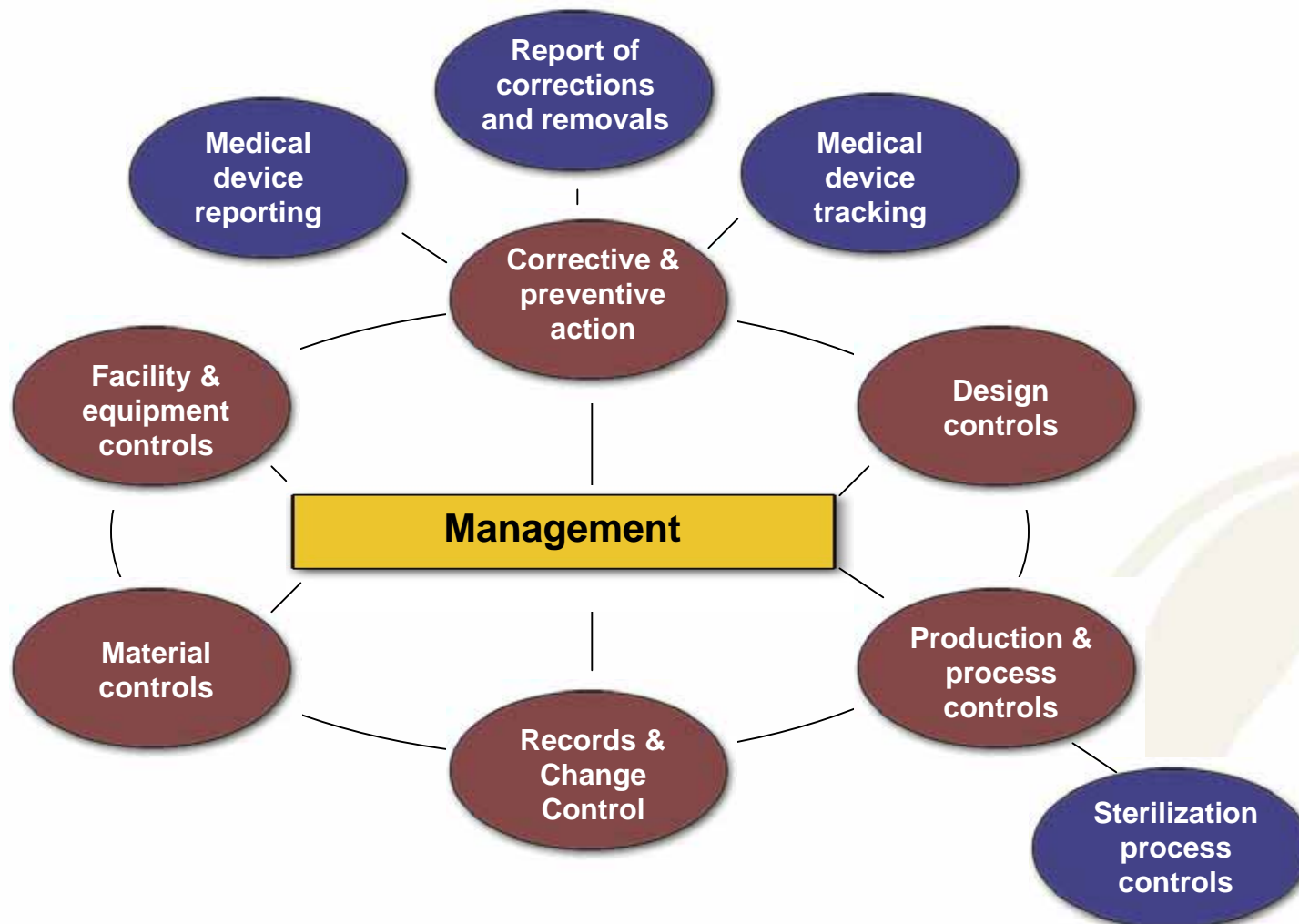
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Quality System

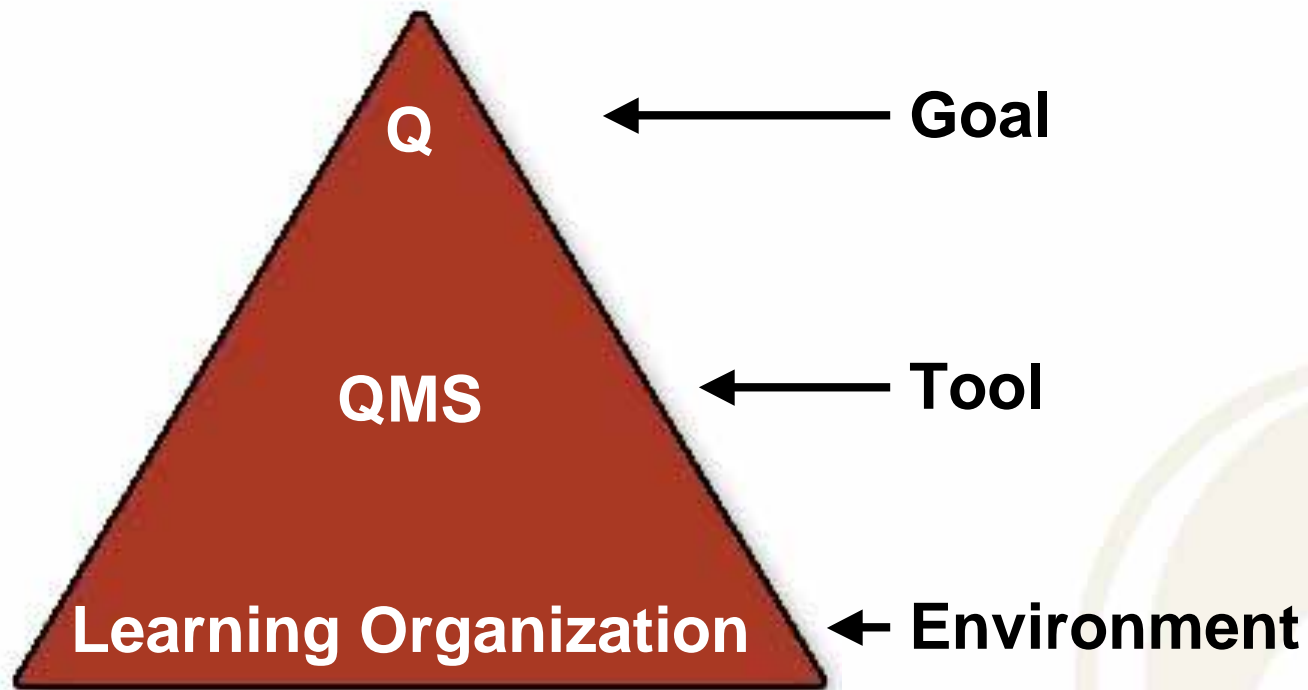
- **Quality system** (CSA, FDA (QSR), AABB, ISO 9000:1994): the organizational structure, responsibilities, procedures, instructions, processes, and resources for implementing quality management
 - **Quality management** (CSA, ISO): coordinated activities to direct and control an organization with regard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

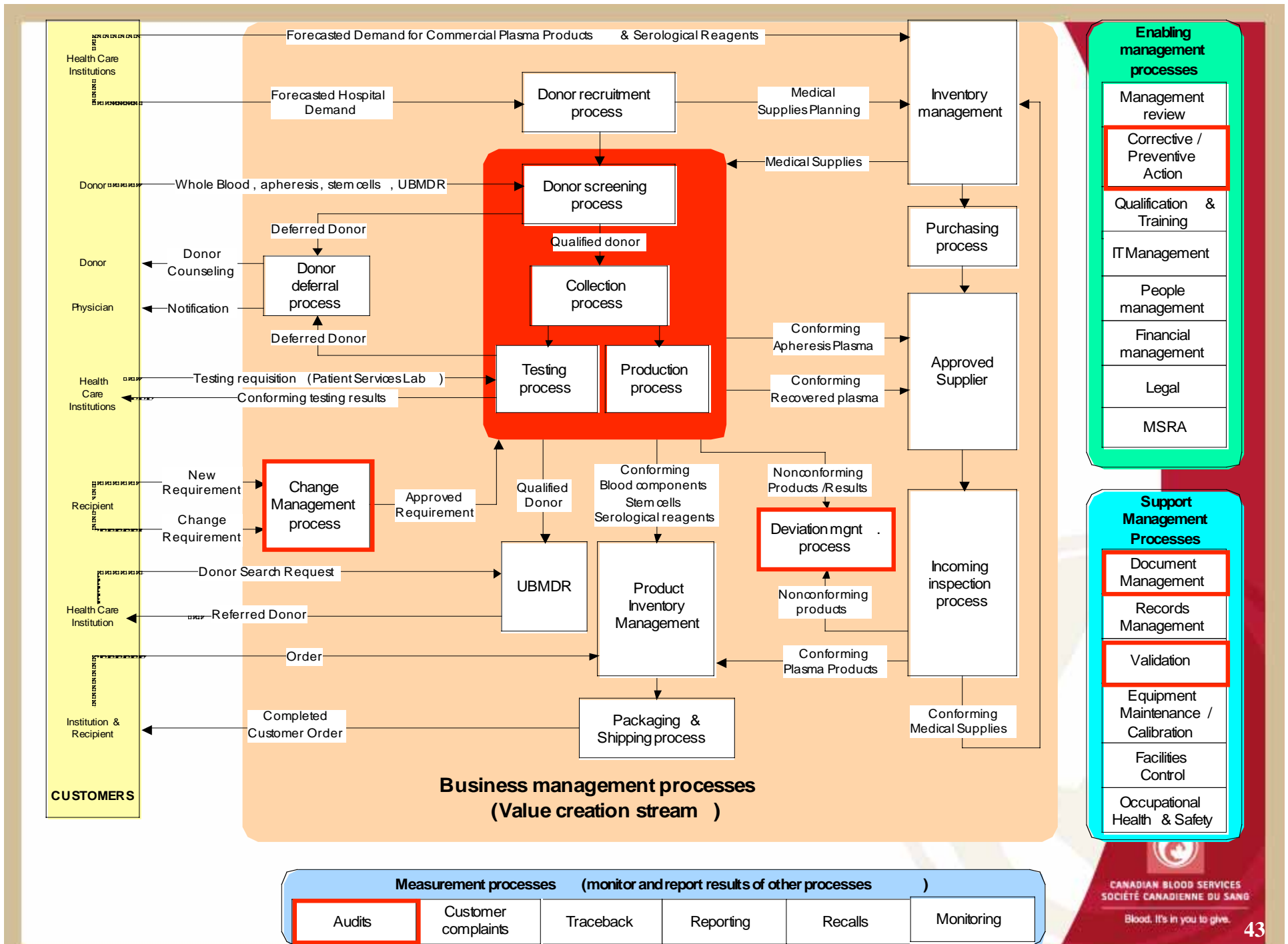


Simply put... ..



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CBS' QMS Spelled Out . . .



On Target

Vol. 5, No. 4, July 2005 Canadian Blood Services' Internal Corporate News Bulletin

QMS Spelled Out
From the desk of Graham Sheg, Chief Executive Officer

Reflecting over the last several years, it is fair to say that we have created confusion around what a Quality Management System (QMS) is in relation to our business. Back in 2001, when we launched our Change Control "system", we did so under the framework of what we were calling a QMS. Then in 2003, we launched the QMS Transformation Project under the Quality Assurance & Regulatory Affairs division (then Safety & Performance Management) with the mandate to automate all of our "quality systems".

The truth is QMS is much more than this, and does not need to be so confusing. To really understand what a QMS is one must first understand what "quality" is. In simple terms, one can say that quality means "doing the right thing right, the first time, and doing it better and better". In other words, quality is compliance to regulations, and meeting specified requirements, and customer service excellence, and continuously improving, and—the list goes on. Most importantly, quality is not something owned by the "Quality" division of an organization—it is owned and pursued by every division and every person. As such, the QA&RA division does not own quality—we all do!

So what then is a QMS? First and foremost, a QMS is a tool used to help an organization in its pursuit of quality. It is the collection of purpose, policies, processes, procedures, work instructions, forms and records which define what, why and how it does what it does. Most importantly, it is a single, integrated "system".

Like "quality", a QMS does not belong to QA&RA. It is owned by a partnership of all divisions and employees at CBS. While some parts of the QMS are owned by QA&RA, an equal number of parts are owned by each of the other divisions. For example, QA&RA happens to be the owner of processes such as Change Control, Validation, Document Management and Audits. Similarly, each of the other divisions owns a piece of it as well. For example, the collection process is owned by Operations, the training process is owned by Human Resources, the TD testing process is owned by Medical, Scientific & Research Affairs, supply management is owned by Corporate Services and our strategic management process is owned by the Office of Strategic Management. Our QMS then, is the integration of all of these.

In May we made the decision to no longer house QMS under a project structure. Why? First, there was the realization that we weren't ready to automate these processes—much work still needs to be done by the division and CBS as a whole in the development, implementation and improvement of these processes. But more importantly, by its very name there was a perception and thus confusion that the processes being automated by the project defined our QMS. In fact, they represent only a small part of it.

As I'm sure many of you have heard me say on one occasion or another, quality is not a "destination"—it is a journey. QMS is a very important tool which will help us on that journey, and as such it will change, improve and mature over time. Some might feel that in making the decisions of the past months, we have taken a step back. While it is true that we have delayed the automation of these processes, I truly believe that as an organization we have taken a very important step forward in our understanding of what a QMS is and how it will ultimately help us on our Quality journey. ■

Graham Sheg

Building a better blood system for Canadians.

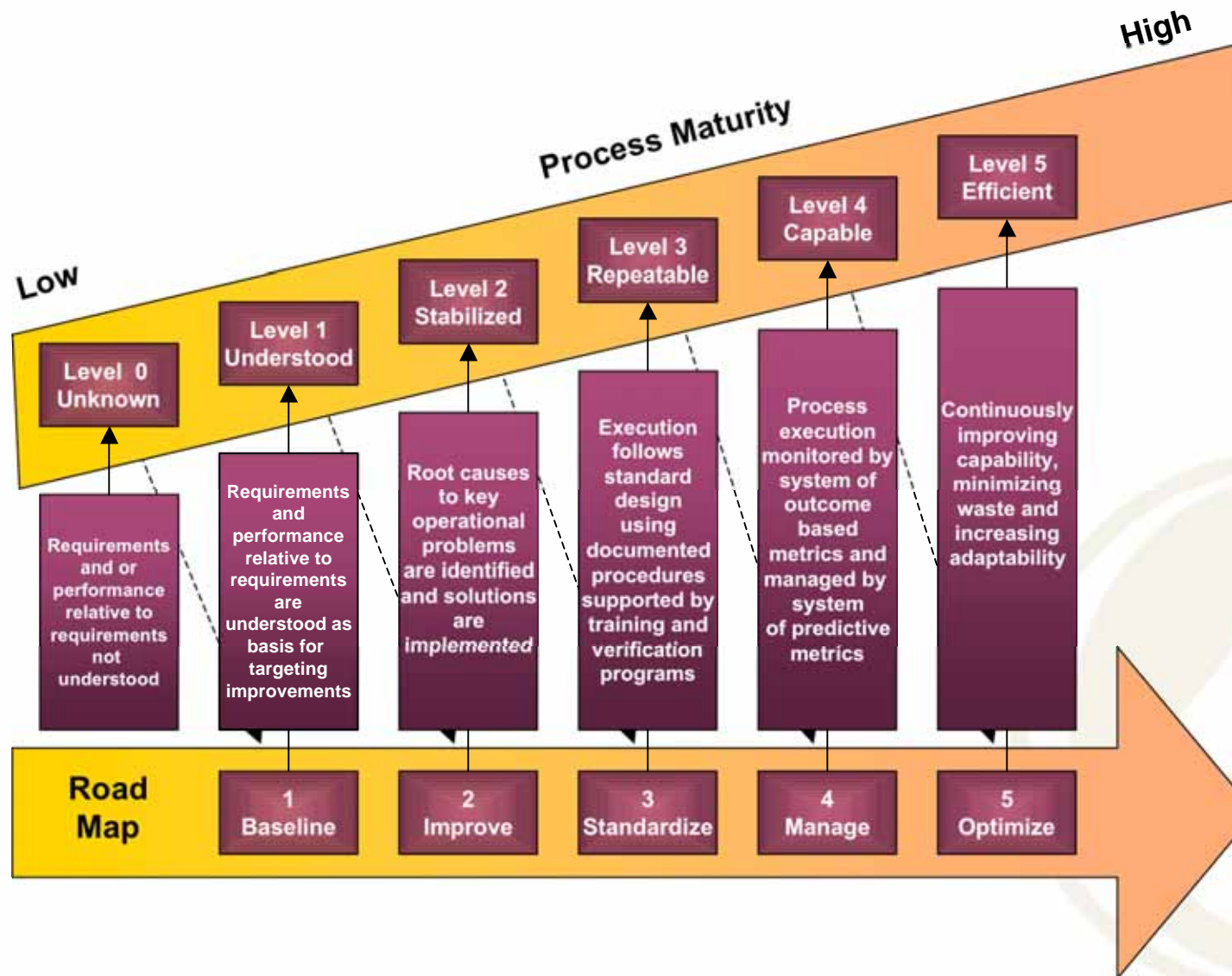
Frequent,
detailed
communications
using a variety of
mediums



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Roadmap to CBS' quality maturity

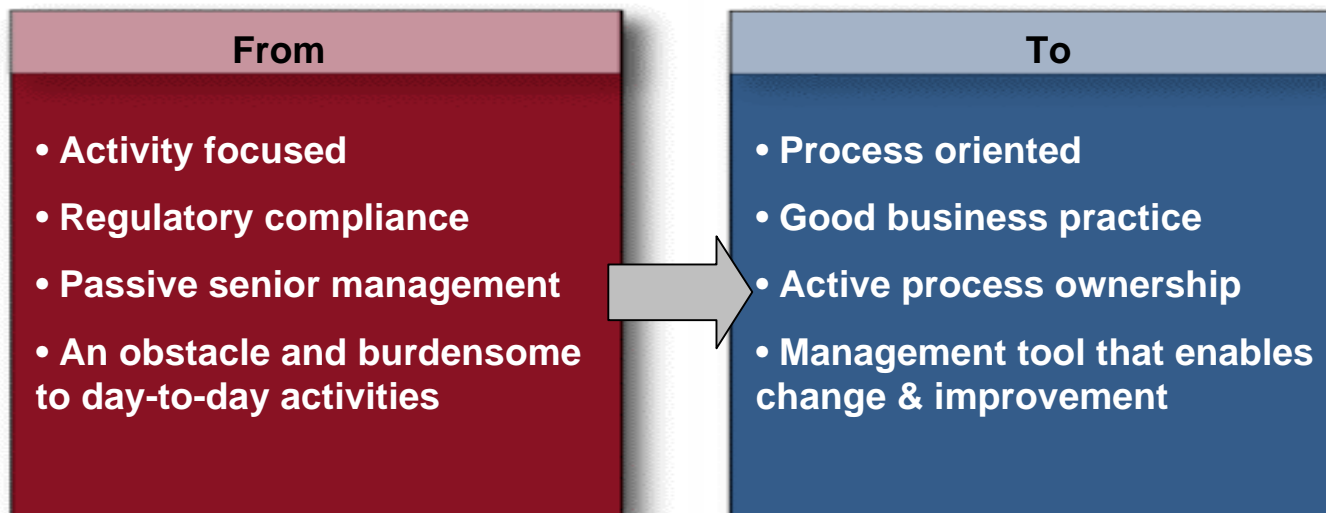


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Challenges to quality system maturity

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



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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)



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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



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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*



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Key Program Objectives

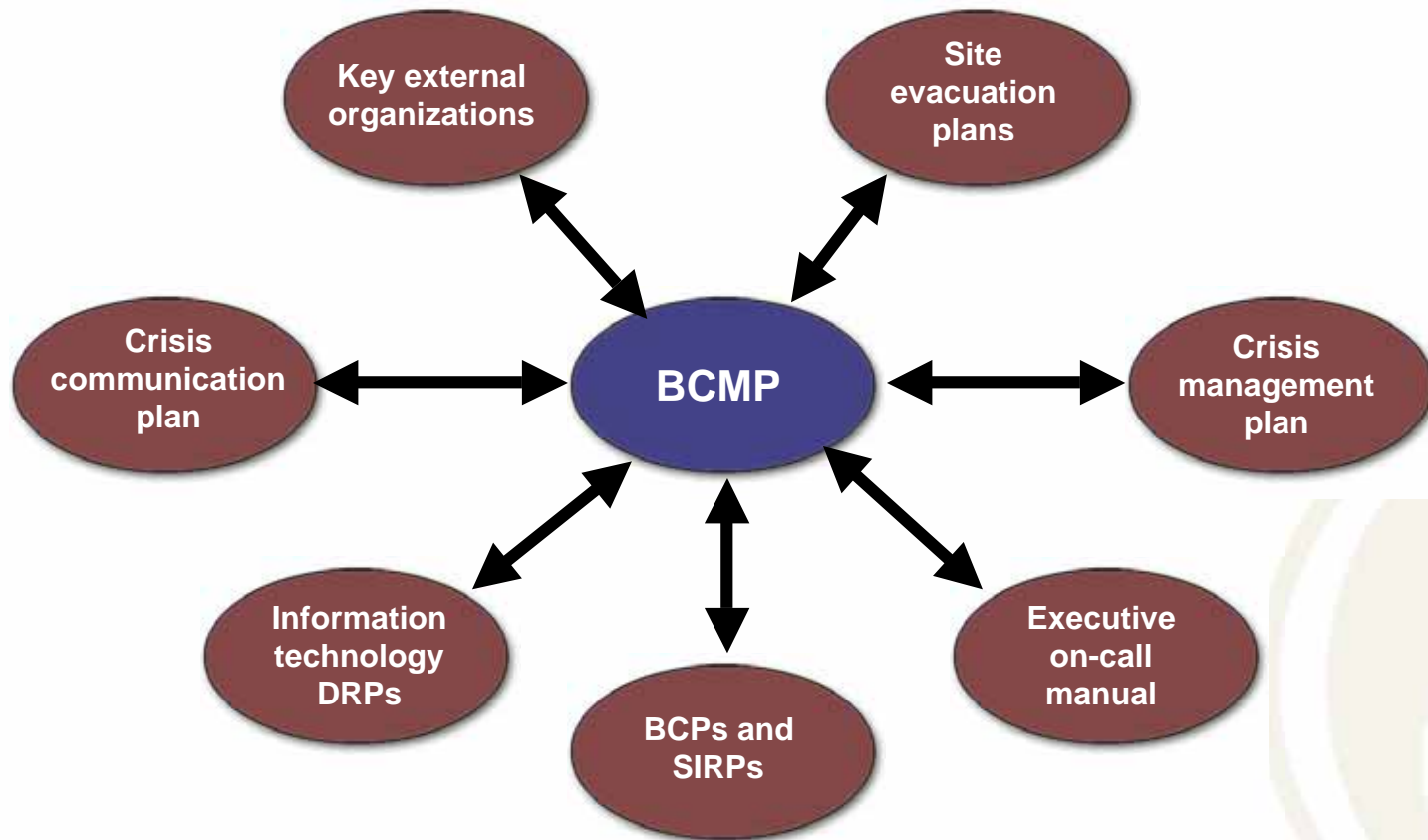
- Ensure the safety of staff, volunteers and donors
- Maximize the defense of CBS' reputation and brand image
- Minimize the impact of business continuity events (including crises) on our customers
- Demonstrate effective governance to our members, stakeholders, media and to the general public
- Assist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



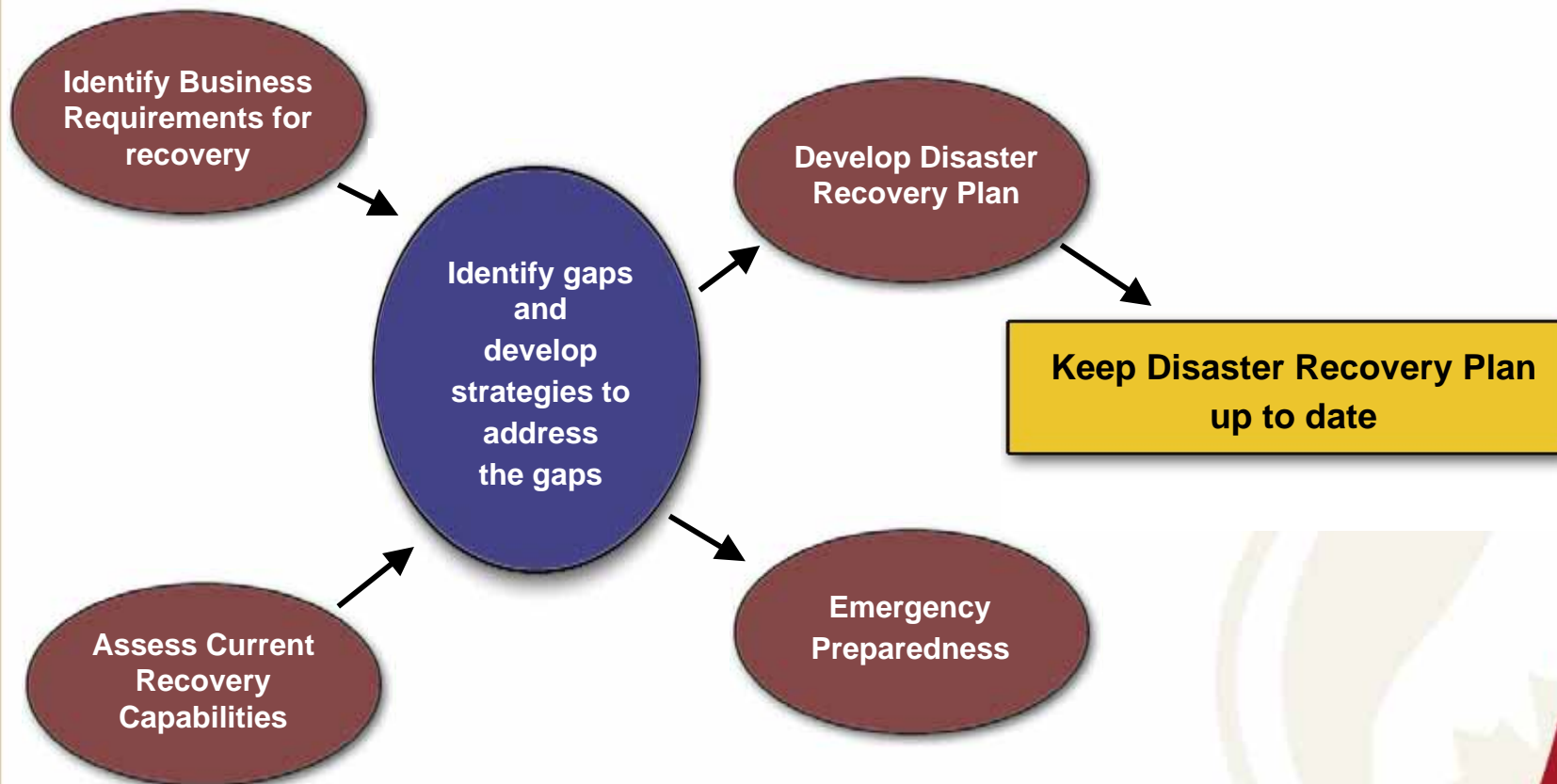
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CBS' Business Continuity Management Program

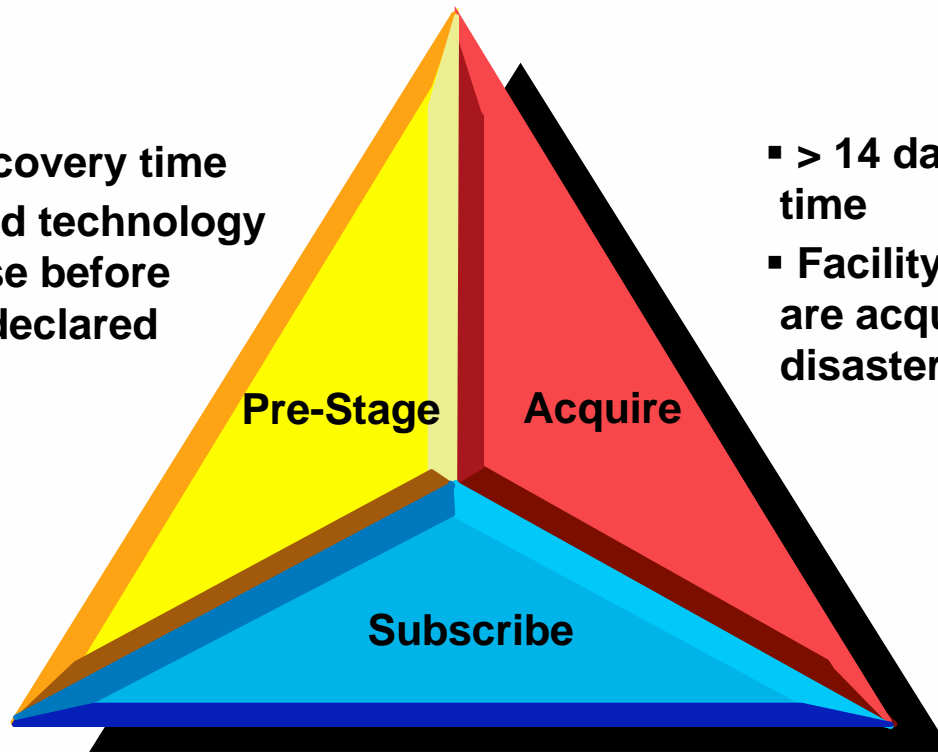


Technology recovery plan



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 are acquired at time of disaster

- 1 – 14 days recovery time
- Facility and some technology ready for use before disaster is declared
- Warm site



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CBS uses a combination of Pre-stage and Subscribe recovery strategies to provide 100% of the critical services within the user priority timeframes.

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



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



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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 trans-national movement of blood products

'Flu Planning

- Preparing staff & volunteers
- Hospital needs & utilization
- Command & control
- Fast track processes
- Finished product inventory
- Integrated communications strategy
- HR Management & deployment
- Public health partnerships
- Logistics strategy
- Alternate sites
- Donor recruitment strategy
- Essential operations



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“Fate favours the prepared”

Louis Pasteur



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Outline

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



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Summary

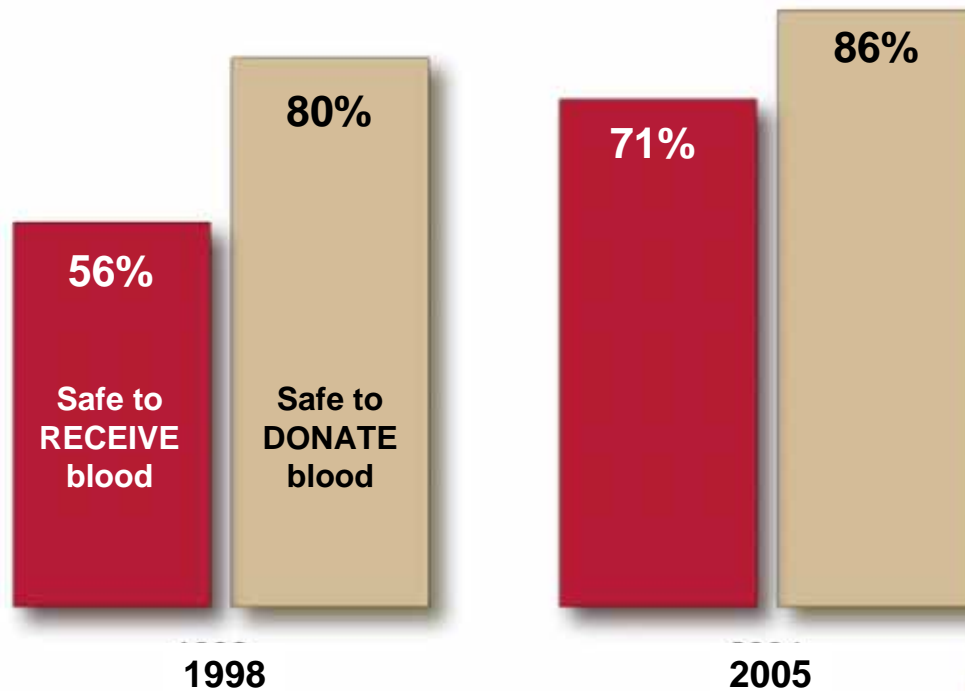
- Canadian Blood Services has transformed the national blood supply system:
 - overcome the legacy of failure and lack of responsiveness that culminated in the tainted blood scandal
 - single national system (excluding QC)
 - standardized service delivery
 - equal access to products and services
 - singular 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



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Summary



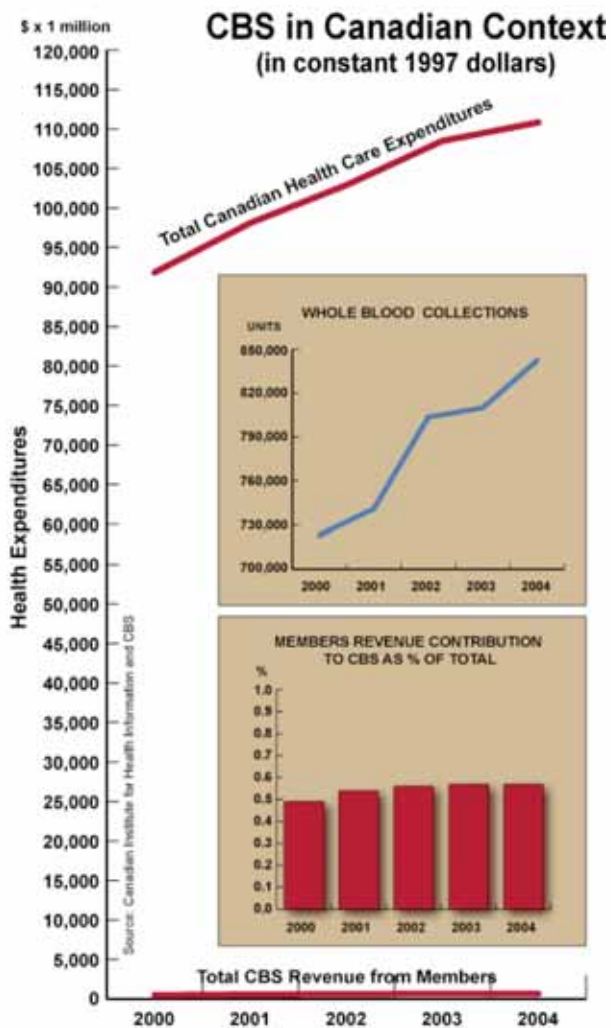
CBS has restored public trust in the blood system by emphasizing product quality and safety, operational transparency and accountability, and customer service



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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



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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,



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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*



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