Health Canada Santé Canada

Report of the National Consensus Conference on Safety of Organs and Tissues for Transplantation

Canada

Report of the National Consensus Conference on Safety of Organs and Tissues for Transplantation

Published by authority of the
Minister of Health and Welfare

For more information, please contact:
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Health Protection Branch
Health Canada
Tunney's Pasture
Ottawa, Ontario
K1A 0L2

October 29-31, 1995
Ottawa

Our mission is to help the people of Canada
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Health Canada

Aussi disponible en français sous le titre

Rapport de la Conférence consensuelle nationale sur la sécurité des organes et des tissus destinés aux greffes

Cat H49-102/1995E

ISBN 0-662-24153-3

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January 1996

I am pleased to forward to you the *Report of the National Consensus Conference on Safety of Organs and Tissues for Transplantation*. The meeting was sponsored by the Drugs Directorate and was held in Ottawa from October 29 to 31, 1995. This conference was successful in achieving a general consensus on the proposed Canadian General Standard on Safety of Organs and Tissues for Transplantation and in recommending a risk-management framework for compliance and oversight.

I wish to acknowledge the contribution of my co-chair, Dr. Calvin Stiller, of the expert advisors and of the organizing committee for their efforts in planning this meeting. Also acknowledged are the efforts of workshop chairs and rapporteurs, of special guest speakers from Australia, Europe and the United States, and of all invited participants from across Canada.

Special thanks also go to Dr. Keith Bailey and Dr. Wilbert Keon for their successful efforts to facilitate the consensus-building process.

Respectfully yours,

May S.M. Smith MD
Conference Co-chair and
Chair of the Organizing Committee

Executive Summary

To facilitate a consultative approach to addressing the potential risk of disease transmission through organs and tissues in transplantation, the National Consensus Conference on Safety of Organs and Tissues for Transplantation was held in Ottawa from October 29 to 31, 1995.

The goal of the conference was to reach agreement on methods to reduce the risks of disease transmission by organs and tissues intended for transplantation.

The objectives of the conference included obtaining expert guidance on the proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation* and proposing a risk-management framework for oversight and compliance to ensure safety.

The conference was attended by 65 invited participants, who represented a broad spectrum of expertise in fields related to organ and tissue transplantation. Invited speakers from the U.S. Food and Drug Administration (Center for Biologics Evaluation and Research), the Eurotransplant Foundation, and the Australian Therapeutic Goods Administration provided an international perspective.

Conference participants were given background documents that included the proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation*, a report entitled *Safety of Organ and Tissue Transplantation in Canada*, and a paper, *Principles of Risk Management*.

Achievements

- The conference was successful in bringing together a broad range of experts in the field of transplantation and in achieving a consensus.
- The proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation* was accepted in principle.
- A risk-management/regulatory framework was proposed (see Figure 1, page 5).

Recommendations

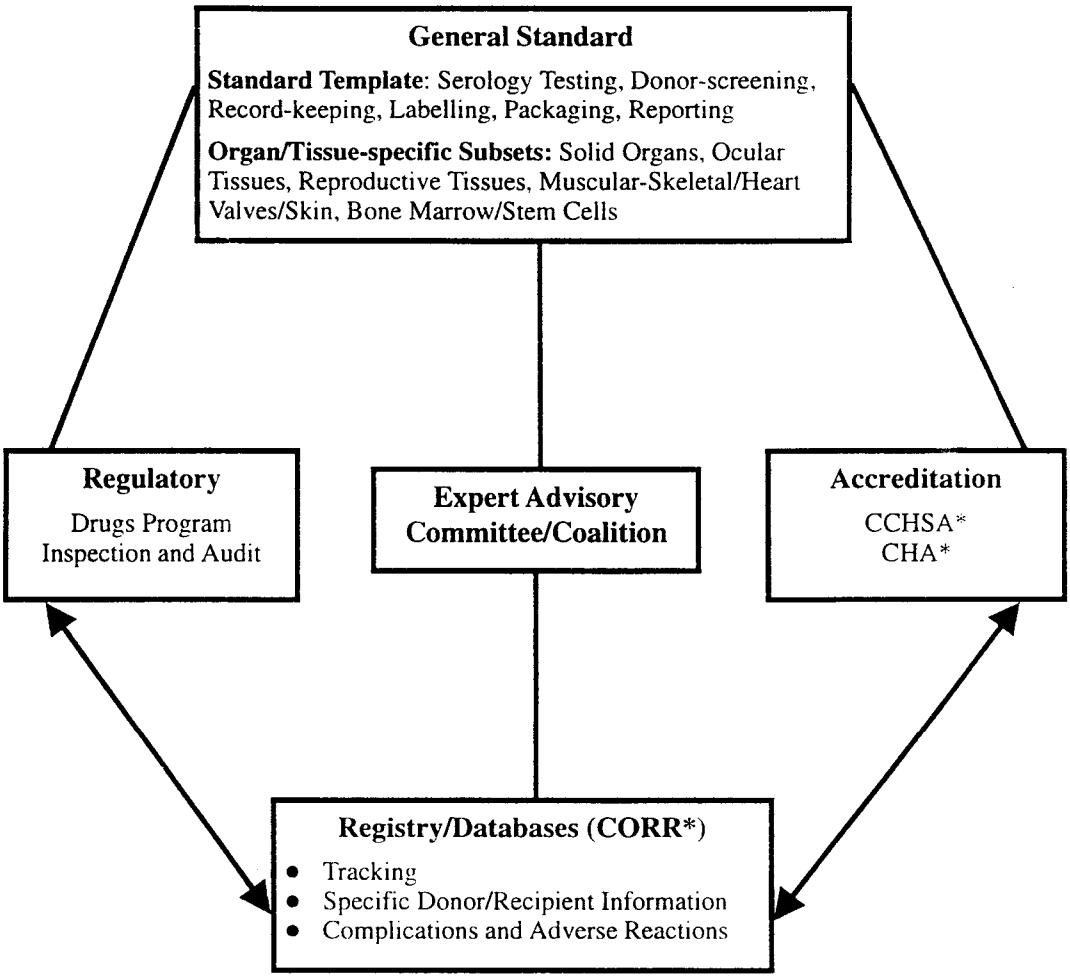
The conference resulted in the following recommendations being made to Health Canada's Drugs Directorate:

- that the proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation* be revised to incorporate input from experts at the conference;
- that the revised *Canadian General Standard on Safety of Organs and Tissues for Transplantation* be accepted as a template for the development of subsets of specific standards for individual organ and tissue types; and
- that the risk-management/regulatory framework proposed by the participants at the conference be adopted for implementation by the Drugs Directorate.

Next Steps

The conference report will be widely distributed for information and comment. The proposed risk-management/regulatory framework will be carefully reviewed and considered by the Drugs Directorate.

Figure 1
Proposed Risk-Management/Regulatory Framework



* Suggested third-party associations

CCHSA	Canadian Council for Health Services Accreditation
CHA	Canadian Hospital Association
CORR	Canadian Organ Replacement Register

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Introduction

Opening Remarks
Mr. Dann Michols, Director General, Drugs Directorate

The mission of the Drugs Directorate is to strive to assure that drugs available in Canada are safe, effective, and of high quality by doing the following:

- effectively, efficiently and continually assessing the benefits and risks of drugs;
- managing the risks appropriately; and
- developing and disseminating information that encourages the optimal use of drugs.

At the moment, tissues and organs are considered drugs and, therefore, fall within the Drugs Directorate's mandate for regulation. The definition of "drug" in the *Food and Drugs Act* includes a substance or mixture of substances sold, manufactured or represented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state, or the symptoms thereof, in humans or animals.

Tissues and organs fit into this definition well. Furthermore, a government decision in 1989 to define blood and blood components as drugs confirms this logical path. The Drugs Directorate is also developing sperm regulations under the act. Tissues and organs may follow similar regulatory reasoning. Concerns have arisen worldwide regarding the potential risk of disease transmission through blood, human tissues and organs. Public interest in Canada has increased as a result of the work of the Royal Commission on New Reproductive Technology and of the Krever Commission. If there is one thing we should learn from the unfortunate events being examined by Justice Krever, it is that if the human mind can ask the question, "Is there a risk?", then it ought immediately to take steps to determine how to mitigate that risk.

The Drugs Directorate believes that there is a potential risk associated with organs and tissues in transplantation and that this risk can best be assessed and managed by applying concepts such as those used in the management of drug risks and benefits. It is this belief that will be explored at this conference.

The regulatory process should be designed to ensure there is sufficient information generated throughout the process to enable effective, timely decisions concerning an intervention and its rational use. It should be designed to efficiently develop knowledge and information and make it available in a timely fashion to all decision-makers. It should also recognize the concept of shared responsibility. Other parties involved – the provinces, health professionals, researchers, industry and the public – each have a responsibility. A constructive regulatory framework defines the responsibilities of each partner to facilitate the free flow of information for informed decision-making. This conference will help identify these decision-makers and advise on their respective responsibilities.

While it continually reviews and learns from the experiences and best practices of other systems, the Canadian regulatory system is designed to meet the needs of Canadians within the context of the Canadian health system, the Canadian way of practising medicine and Canadian values. This expert group is being asked to apply this model as it addresses the challenge of regulating organs and tissues for transplantation.

Goal and Objectives of the Conference
Dr. May Smith, Conference Co-chair

The following are the goal and objectives as presented to the participants prior to the conference.

Goal

- to reach agreement on methods to reduce disease transmission by organs and tissues used in transplantation

Objectives

- to provide a forum to address risk-management and regulatory options;
- to reach agreement on the principal elements to be included in a set of generic national safety standards for donor-screening, serological testing, record-keeping, packaging and labelling, storage, and distribution;
- to reach consensus on mechanisms to ensure compliance with national standards; and
- to reach agreement on a national system for recording organ and tissue transplants to facilitate the follow-up of adverse events.

Background and Format

The conference will provide participants with appropriate background knowledge on the risks in transplantation, risk-assessment and management tools, and international experiences and approaches to ensuring the safety of organs and tissues for transplantation. Background documentation includes the proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation*. Organ-specific, tissue-specific and theme-specific workshops have been designed for participants to review the proposal and reach agreement on the principal elements of a generic standard.

Presentations and discussion will take place on possible mechanisms to ensure compliance with national standards. This will facilitate consensus-building in the development of recommendations for a risk-management/regulatory framework to ensure safety and compliance.

A report of recommendations made at this meeting will be widely distributed for information and comments.

Note: A directory of participants and organizers is attached.

Overview of Transplantation in Canada
Dr. Calvin Stiller, Conference Co-Chair

Transplantation in Canada has had an illustrious history. The first era of transplantation started in 1963 with kidney transplantation in Montreal. These were the post-Barnard, pre-cyclosporin-suppression times, when expectations far exceeded what could be delivered. Then in the 1980s, cyclosporin ushered in T-cell immune-suppressive therapy and the second era of transplantation. This new era also witnessed the initiation and paralleled success of cell and tissue transplantation. Canada notably excelled in both application and outcomes.

Transplantation was established on a centre-by-centre basis, with no national vision of what it could or should be. Transplantation developed to address a bedside need and as a life-saving means. Once established as possible, patients got out of hospital and onto the front pages of the newspaper: transplantation became a *de facto* reality.

This second phase involved establishing credibility and confidence in our work. Outcomes had to be superior to those of other centres. This resulted in the establishment of "risk" categories for donor and recipient pools. During these "risk-aversive" times, donors exceeded the number of recipients. But, as confidence in the outcomes improved, so did the waiting list and referrals of patients who were just outside the limits of the low-risk, good-outcome criteria that had been established.

This was an entrepreneurial phase. Rapid development, no preclinical testing and "ad hockery" were the rule. Common direction and standardization were limited because of competition among centres, with these centres all being at different levels of development. Regional user groups were established based on a need to demonstrate equitable distribution of organs. Each centre was expected to apply safety standards, but no national body was established to ensure that this was done. Tissue-typing became a surrogate for co-operation and sharing of standards. Algorithms were devised to assure the equal distribution of organs. Rudimentary audits, conducted irregularly after the fact, were used to police the application of the algorithms.

The record of Canadian transplantation in this "wild west" era has been quite remarkable. We led the western world in graft and patient survival. We are near the top in terms of the number of donors and transplants per million population. Canada has been a pioneer in lung, small bowel, heart-lung and neural tissue transplantation. Clinical research with new immunosuppressive therapies and implantable parts as a bridge to transplant are also to our credit. Canada is also a leader in the study and application of ethics in transplantation. This is an enviable record in an unorganized era that has depended so much on individual integrity.

Competence is an obvious key to the successes we have experienced. But without trust from all stakeholders, this success cannot be sustained. Trust is the key – for institutions, government and patients, both recipients and donors. Trust is based on integrity combined with expertise and knowledge. While scientific publications and registries of outcomes are essential, a transparent process of audit is both necessary and demanding.

We are now entering the third era of transplantation in Canada. This era centres on the issues of this conference. Effective solutions to the issue of safety will allow us to take advantage of future technological changes.

New immune-suppressive agents, resulting in a more immune-tolerant host, expansion of the pheno-types of donors, and manipulation of donor-derived cells *in vitro* to modify the rejection process (as with combined marrow/solid-organ transplants) are examples of future options available and ones that will mean that safety issues will become even more pertinent to transplantation. The use of organs from non-perfusable donors will shorten the time of predonation observation and will emphasize the surveillance that we need to put into place both locally and nationally.

How do we maintain the trust that Canadians have placed in us? How do we continue our enviable record? How do we adapt to the extraordinary changes that face us? It is our view that we must have a framework for safety and risk management. We deliver life, either enhanced or extended, to our recipients. But we must do so at the least risk that is compatible with these extraordinary circumstances and with the full knowledge of that risk.

The background work has been done. The individuals in this group represent the key players and expertise necessary. Our patients, our colleagues and our nation reasonably expect us to propose the elements to be contained in a set of national safety standards, to achieve a consensus on methods of verification and, having devised these outlines, to propose the skeleton of a simple workable system.

Conference Proceedings

General Plenary Session – Risk Assessment and Management

Report on Risk Assessment
Dr. Paul Greig

The transplantation of human organs (heart, lung, liver, kidney, pancreas and intestine) and tissues (cornea, heart valve, bone, bone products, dura, fascia, skin, reproductive tissues, bone marrow and stem cells) is a common activity in Canada. The transplantation of these organs and tissues is expected to increase, but is currently limited by the critical shortage of donated organs and by further advances in technology, which are anticipated to improve the results of transplantation and expand the potential for this therapy.

Transplantation of this wide variety of organs and tissues has many features that deserve national consideration. One of these is the safety of the process. There are risks associated with every medical/surgical activity; however, transplantation brings a number of unique risks. These include those associated with donor maintenance, donor-screening, organ allocation, organ retrieval, organ storage and transplantation, organ implantation, rejection, adverse effects of immune-suppressive or other drugs, and the risk of the transmission of disease from the donor to the recipient.

Transplantation of organs and tissues as performed in hospitals and clinics throughout Canada is considered to be exemplary. The results that are reported are equivalent to those reported by the national transplantation organizations in other countries. There is, however, no national organization in Canada to establish and maintain standards of practice, enforce these standards, ensure equitable organ allocation through sharing, promote organ and tissue donation, audit and report the results of transplantation, investigate and manage transplant-related problems, and ensure that transplantation is performed to the highest technical and ethical standards.

To begin to address the need for national standards for organ and tissue transplantation, Health Canada's Bureau of Biologics approached Organ Sharing Canada (OSC – a joint initiative of the Canadian Transplantation Society and the Canadian Association for Transplantation, which was launched in 1992 to establish national equity in transplantation through organ-sharing and standards) to produce a working document that addresses the risks and current standards and practices of transplantation in Canada. In October 1994, OSC organized a working group of transplant professionals from across Canada who researched and authored a document entitled *The Safety of Organ and Tissue Transplantation in Canada*, which was delivered to the Bureau of Biologics in December 1994. This document, a copy of which was provided in the preregistration package for this conference, details Canadian transplantation activity, potential risks associated with transplantation, the incidence of occurrence of these risks in Canada, when known or documented, current standards of practice, and a proposal for establishing, maintaining and enforcing national standards.

The speaker reviewed the findings of the working group as a starting point for the National Consensus Conference on Safety of Organs and Tissues for Transplantation.

Principles of Risk Management
Mr. Dave Blaker

From the risk-management-systems perspective, there are a number of essential elements that must be included in the development and operation of a risk-management process.

In considering the various risk-management options, the following questions must be addressed:

- What are the pros and cons of each option?
- Is there a thorough, clear understanding of the workings of the option?
- What are the costs and consequences of selecting the option?
- Can the option be enforced?
- What is the likelihood of compliance with the option?
- Does the option provide timely resolution of problems?
- Can the effect of the option be tracked and evaluated?

Once the risk-management option is put in place, it must contain a process for increasing the understanding of the actual risks of disease transmission via tissues and organs. The risk-management option must be capable of reacting to new hazards and to new risk estimates.

General Plenary Session – International Perspectives

U.S. Approach to Assuring the Safety of Human Organs and Tissues for Transplantation
Dr. Thomas Arrowsmith-Lowe

Regulatory responsibility for human organs and for human tissues intended for transplantation in the United States resides in the Health Resource and Service Administration (HRSA) and the Food and Drug Administration (FDA), respectively. These two agencies of the U.S. Public Health Service have slightly differing approaches to regulation. HRSA focuses primarily on the availability of organs for transplantation. In response to a disparity between the number of organs available for transplantation and the number of patients requiring transplantation, HRSA strives to increase the number of donors and to match donors with recipients. FDA focuses its efforts on enforcing a federal regulation that requires that tissue available for transplantation is from donors who were adequately screened and tested for HIV and Hepatitis. Many of the organizations that procure organs in the U.S. also procure tissue for transplantation. The lack of a single donor-screening approach for both organs and tissues has the potential to be problematic.

The speaker discussed the approach to donor-screening that the FDA is recommending for human-tissue donors, related this approach to the recommendation on organ and tissue transplantation made by the Centers for Disease Control, and explored the feasibility of such an approach being employed for donors who provide both organs and tissue for transplantation.

The Australian Regulatory Approach: Organs and Tissues for Transplantation
Ms. Carolyn Woodruff

Tissues for transplantation have been regulated under the *Therapeutic Goods Act, 1989*. Prior to that date, tissues and organs for transplantation were regulated only under state or territory legislation, which was concerned with such factors as consent, payment (none allowed) and medical determinations of death.

The national legislation regulates therapeutic goods through premarket evaluation, postmarket surveillance and licensing of manufacturers. With respect to tissues, those that have not undergone any alteration in physical, mechanical or biological properties are regulated solely on the basis of the evaluation and licensing of the tissue-banking facilities.

In the last two years, a code of good-manufacturing practice for tissue banks has been drawn up. This code sets out the minimum requirements of a quality system for tissue banks. It is intended that the style of the code should not restrict innovation in tissue-banking practice, nor should it inhibit the use of new, as yet non-commercial, tests for infectious agents.

Current Regulation and Practices in Europe
Dr. Huibert A. Tjabbes

In the field of transplantation, cooperation in the European Union is not yet very extensive. In most countries, no formal regulation concerning safety exists and the field has had to organize itself. Each organization has developed its own method for achieving safety. Tissue-banking organizations in general are more strict in their screening than organ-exchange organizations.

At the European level, there are some initiatives: voluntary guidelines have been published by tissue-banking associations; the Council of Europe is preparing voluntary guidelines on serological testing; and the European Commission published a report stressing the importance of European regulation. Regulation at the European level will, however, take a long time, and it is not yet clear if all forms of transplantation will be regulated the same way.

Note: Copies of overheads from the presentations are available upon request.
Please contact Dr. May Smith, Bureau of Biologics, Drugs Directorate – tel.: (613) 952-0237, fax: (613) 941-5481.

Workshops – Organ-specific and Tissue-specific

Summary of Organ-specific and Tissue-specific Workshops
Dr. May Smith

Participants in each organ-specific and tissue-specific workshop were asked to discuss all of the questions listed below, and to present their deliberations under the following headings: Areas of Consensus and Unresolved Issues. (Note that a general summary of the organ-specific and tissue-specific workshops is possible because each workshop addressed the same questions. The theme-specific workshops addressed area-specific questions and their findings are presented separately.)

Question 1: What are the specific risks in this organ/tissue group (i.e. Which are the transmittable diseases specific to this group of tissues?)?

General consensus was reached on the transmittable diseases as listed in the Canadian General Standard with a few additions.

Question 2: What are the standards to be followed nationally?

Some special guidelines and/or standards specific to each group, and other examples of serological testing and screening, should be included in the generic standards.

Question 3: Is the proposed Canadian General Standard acceptable?

All groups agreed that the Canadian General Standard was acceptable in principle as a template.

Question 4: In the context of risk management, are there any specific additional criteria or exceptions to this standard for a specific organ or tissue group?

Consensus was reached that risk-management issues are identifiable and should be included in the Canadian General Standard (i.e. experience and training of medical directors), and that standards should apply to end users as well. Moreover, standards should include disease-transmission risk to medical personnel.

Question 5: Can the proposed standard and future standards be applied retroactively to all banked tissues?

The consensus was that, when possible, appropriate or feasible, the archiving of sera is recommended. The issues here tend to centre on problems of logistics and limited resources.

Question 6: Which risks does your group wish to see audited or tracked?

Consensus was reached that receiving feedback on recipient information, infection, complications and diseases, as well as genetic information, was desirable for tracking and auditing.
There is consensus that the proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation* is acceptable as a template for developing and refining specific standards relevant to each organ and tissue group. There is a need, though, to define absolute and

relative screening criteria for each group. All groups agree that auditing and tracking of disease and infection is essential to ensuring safety.

Solid Organs
Chair: Dr. Wilbert Keon
Rapporteur: Mrs. Gail Werner

Areas of Consensus

1. Risks to solid organs are viral, bacterial, fungal, malignancy, genetic, high-risk screening, past and current medical history and organ function.

2. Tests: HIV 1/2, HTLV 1/2, Hepatitis B (Surface Antigen and Core Antibody), Hepatitis C, Syphilis, CMV and EBV (Toxoplasmosis at program's discretion).

3. History: documented past and present history, cancer and disease – each case must be assessed according to CDC guidelines, but HIV-positive recipients must not be rejected on the basis of them. Physical exam, lab tests, operative findings post mortem.

4. The only absolute contraindication is cancer in the specific organ. All other contraindications are relative.

5. Assess all as potential donors.

6. Proposed standards need extensive revision, especially contraindications for donation.

   Organs cannot be banked or quarantined. Serum is, in most cases, already banked or quarantined, and could be tested retrospectively for newly identified organisms. Quarantine to minimize risk does not work for this category, given the time-related constraints associated with solid-organ transplantation.

Tracking

- use of organs from any donor with relative contraindications in relation to outcome;
- any development of cancer in recipients; and
- any development of transmittable or infectious disease especially Hepatitis B, Hepatitis C, EBV and HIV.

Unresolved Issues

The following issues from the proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation* were raised but not resolved.

Pg	Proposed Standard	Comment or Suggested Revisions
11	All donor, processing, storage and distribution records must be maintained indefinitely.	Concern about feasibility.
12	Hepatitis B vaccination shall be offered free of charge to all non-immune personnel whose job-related responsibilities involve the potential exposure...	The organ procurement organization shall be responsible for ensuring appropriate vaccination be offered to all non-immune personnel whos related responsibilities involve the potential exposure...
13	Informed consent includes notification of all possible risks, harms and tests to be performed.	Informed consent includes notification of all reasonable risks, harms, tests to be performed.
13	...requirement for virological testing, especially HIV and HBsAG.	...requirement for virological testing, especially HIV, HBsAG and H(
13	Procurement from living persons incompetent to consent should be limited to donors and recipients of the same family and involve an independent third party (i.e. court or review board).	Delete. Dealt with legally on a provincial basis.
14	...except for reimbursement of costs directly associated with the donation, *including compensation for the donor's time.*	Delete: *including compensation for the donor's time.*
15	Donor Age – Donor age criteria for each kind of donation shall be established and documented.	Delete
15	CONTRAINDICATIONS	**ADD** (Absolute) 1) Those donors who may have a malignancy that n transmissible by tissues or organs. 2) HIV-positive donor when the tis organ is to be transplanted into an HIV-positive recipient.
16	...presence or clinical suspicion of neurologic degenerative disease or dementia (such as Alzheimer's or multiple sclerosis).	...presence or clinical suspicion of multiple sclerosis.
16	...congenital rubella ...Reye's syndrome	...presence or clinical suspicion of genetic disease that is transmissibl
16	...active septicaemia (bacteremia, fungemia, viremia)	...untreated systemic infection.
16	...active leukemias ...active disseminated lymphomas	Delete
16	HIV-seropositive donors	HIV-seropositive donors, unless recipient is HIV-positive.
16-17	...persons with repeatedly reactive screening ...*TO END OF SECTION*	CDC Guidelines — if recipient is HIV-positive.
17	Screening tests that have complied with Canadian regulations for certain viruses shall be performed on donor blood.	Screening tests that have complied with Canadian regulations for cert infectious agents shall be performed on donor blood.
18	For cadaveric donors, the donor's physician and/or the physician who signed the death certificate must be notified.	Should the family of the cadaveric donor be notified?
19	HTLV-I and HTLV-II screening is not required.	HTLV-I and HTLV-II screening is required.

19	In case of immunosuppressed recipients, cytomegalovirus (CMV) testing should be performed.	In case of immunosuppressed recipients, cytomegalovirus (CMV) an testing should be performed.
19	AUTOLOGOUS DONORS *Whole Section*	Delete
24	Maximum storage periods should be established for each organ or tissue.	Maximum recommended storage periods should be established for ea organ or tissue.

Ocular Tissues
Chair: Dr. Paul Dubord
Rapporteur: Mr. André La Prairie

Areas of Consensus

Note: There is a real shortage of tissues, especially corneal tissue, so restrictions cannot be tightened until there is sufficient tissue to meet requirements.

1. It was agreed that the specific risks identified in the proposed standard were acceptable for ocular tissues, with some modifications for diseases such as neoplasms, which are not contraindications for ocular tissue transplantations. There are almost no diseases, including Syphilis, that have an effect on ocular tissue that would qualify as a contraindication.

2. The Eye Bank Association of America produces the oldest and most internationally recognized standard for ocular tissues. It was agreed that this standard was a good reference document, but that there was merit in also having a Canadian standard.

3. The proposed standard is acceptable as a framework from which to work. It holds many advantages for the Canadian system. The proposed standard should be a document that responds to current scientific knowledge.

4. Risk should include the possibility of disease transmission to retrieval personnel. Appropriate tests for screening using post-mortem blood samples should be addressed.

5. Retroactivity is not an issue for eye transplantation (donors are dead). Storage of sera is not necessary for non-banked tissue.

6. Auditing and tracking should be compulsory with non-compliance penalties for both the bank and surgeon. Outcome analysis is key to determining the risks of tissue transplantation. Accreditation by knowledgeable and neutral parties is ideal.

Unresolved Issues

It was raised that the safety standard must be developed by an appropriate agency from which the standard operating procedures are generated. Still to be better defined is the role and expertise of the medical director.

Reproductive Tissues
Chair: Dr. John Jarrell
Rapporteur: Dr. Robert Casper

Areas of Consensus

Fresh semen should not be used under any circumstances (although the practice is happening in some places in Canada).

1. - three tissues (sperm, oocytes, embryos) need to be handled individually
   - greater burden on reproductive technology to provide stringent screening because of life-enhancing quality of treatment in healthy patients
   - universal precautions for handling all samples
   - six-month quarantine adequate for HIV
   - HIV-positive samples can be handled and stored for cancer patients
   - take culture from the donor, not semen, for gonorrhea and chlamydia
   - no screening needed for ureaplasma

2. Only the current standards – the Canadian Fertility and Andrology Society (Therapeutic Donor Insemination) Standards, 1992-93 – are acceptable.

3. - proposed Canadian General Standard is acceptable
   - compensation of donors is appropriate
   - personnel with serious infection (e.g. HIV-positive) should not be excluded from handling or storing samples. This section should be removed from the Canadian General Standard.
   - section on incompetent donors should be removed

4. - organ-specific experience and training requirements should be listed for medical directors
   - standards of practice should be followed by all end users of donor sperm
   - documentation of donor information should be provided if possible (donors do not have to be anonymous)

5. It is unlikely that future standards can be applied retroactively to currently banked samples, but one possible solution is to begin drawing a serum sample from all donors at the time of banking for freezing and future testing if new technology is available.

6. - expand follow-up past-pregnancy testing to include genetic, infection and efficacy issues
   - also follow recipient-related diseases such as ovarian cancer

Unresolved Issues

Is good medical/genetic history going back three generations as good as karyotyping? **Vote**: four in favour of routine karyotyping of donors, three against.

There is no efficient method of freezing oocytes, therefore, should oocyte donation be stopped because of the problem with HIV-screening? **Vote**: two in favour of not allowing oocyte donation, four against terminating oocyte donation.

Muscular-Skeletal/Heart Valves/Skin (Non-Perfused Tissues)
Chair: Dr. Michael Gross
Rapporteur: Dr. David Howarth

Areas of Consensus

Mission statement: require national standards with guidelines to carry into the future to minimize the risk to recipients.

Risks (* = absolute exclusion criteria)

1.* HIV 1/2, HBsAG, anti-HCV, HTLV-I/II, VDRL-positive (serology)
2.* Donor history
- Jacob-Creutzfeldt, Rabies (i.e. potentially transmittable neurologic disease)
- Malignancy – metastases, Haematologic (selected with respect to tissue, i.e., skin. Heart valves not affected)

–* Infection as per p. 16

–* CDC exclusionary criteria – require a uniform donor history for organs and tissues with respect to the following:

1) lifestyle – drugs, sexual activity, institution (e.g. jail, prison more than 72 hours within the past 12 months) or psychiatric facilities; travel history; body piercing in non-sterile conditions in past 12 months; industrial-chemical exposure (lead, pesticides, arsenic, mercury or defoliants); rape in past 12 months; and
2) previous medical care – medical history; human-pituitary-derived growth hormone; previous transplant recipient; and auto-immune diseases – consensus agreement with p. 15, 16, 17 and CDC exclusionary criteria for donor screening.

There should be retroactive donor history guidelines (for relative contraindications). Serologic tests must be done retroactively, and sera must be stored.

Tissue from living donors should be quarantined for 180 days (may be fewer with newer screens, e.g. PCR-DNA for HIV). Living donors: must have informed consent; patients testing positively must be informed; adverse reactions must be reported to the tissue bank (e.g. infection or failure of tissue), but not tracking of all patients (logistically impossible).

There must be standard appropriate clinical follow-up by the implant surgeon with respect to the efficacy of tissue.

Unresolved Issues

3. Is the proposed General Canadian Standard acceptable? It is felt that this standard is an overview that requires more specificity with respect to individual tissue types and organs.
- examination of lymph nodes from donor (with respect to granulomas, e.g., TB, mets, lymphomas) and blood cultures, bone swab cultures – primary malignant brain tumours should be excluded?

Bone Marrow, Stem Cells (Haematopoietic Cell Transplantation)
Chair: Dr. Hans Messner
Rapporteurs: Dr. Anthony Ridgway and Dr. Armand Keating

Areas of Consensus

Current Status: Canadian transplanters have been actively involved in North American and international organizations to develop standards and guidelines for the practice of bone marrow transplant (BMT), and the procurement, processing, evaluation and administration of the graft. A draft document covering these issues was prepared by the Foundation for the Accreditation of Haematopoietic Cell Therapy (FAHCT) .

1. Testing of the donor or graft for specific diseases: HIV 1/2, HTLV 1/2, Hepatitis B, Hepatitis C, CMV, Syphilis.

2. Current Canadian standards: none currently in use. Most transplant centres follow transfusion-practice guidelines as a minimum. Consensus was reached that the final FAHCT document will serve as a draft for Canadian guidelines and standards.

3. Canadian General Standard is acceptable with the following exceptions:
   a) donor selection: Consent re minors for cord-blood ownership – definition of family to include extended family; list of contraindications to donor selection requires revision to accommodate risk-benefit considerations; procurement/processing – pooling issues need to be addressed in the context of transfusion practice (e.g. pooled platelets); quarantine: not applicable because of need for timeliness of BMT; and
   b) adverse reactions: Reporting of transmissible reportable infections from the laboratory director to the transplant program director and to the appropriate provincial authorities and reporting of established infections arising from the graft by the BMT program director to the laboratory director and, when applicable, to the provincial health ministry. Lists of reportable infections should be forwarded to LCDC for national compilation. Reporting of adverse events should exclude expected BMT-related complications such as Graft Versus Host Disease.

4) Risk Management – quarantine is not applicable (see above). Issues related to graft manipulation are not addressed and should be addressed further elsewhere.

5) Retroactive applicability of banked cells – this is neither applicable to autografts nor possible with allografts since, in the latter, cells are almost never banked, with the exception of cord-blood cells.

6) Tracking and Auditing – graft-related infectious complications, graft effectiveness and development of graft-related genetic diseases should all be tracked and audited.

Workshops – Theme-specific

Serology Testing
Chair: Dr. David Howarth
Rapporteur: Dr. John Spika

1. For what infections should organ and tissue donors be screened?

1.1 Given that the Health Protection Branch, Bureau of Biologics, makes risk-benefit assessment necessary for serological tests for blood donors, should testing requirements for organ/tissue donors be the same as those for blood donors? What are the reasons for and against such requirements?

With the exception of ocular tissues, serologic tests currently recommended for blood donors should also be used for the donors of these tissues; however, the result of a VDRL test is not required before transplantation. For transplantation of ocular tissues, only testing for HIV 1/2, Hepatitis B (Surface Antigen) and Hepatitis C should be required based on a previous evaluation of HTLV 1/2 and VDRL testing in this setting.

1.2 Should there be additional tests used for organ and tissue donors (e.g. CMV)?

Additional serologic tests are required depending on the organ/tissue and patient population (e.g. for CMV – bone marrow transplantation, EBV – paediatric patients, Hepatitis B (Core Antibody) – in liver transplantation, and toxoplasmosis – organs in selected circumstances). Addition of new tests should be based on a scientific assessment of risk. These tests should be mandatory in each area, but the information need not necessarily preclude the use of a specific tissue or organ. The consensus is that the approach should be one of disease detection, and that the standard or guideline should indicate which disease to search for, rather than specify which test to use.

2. Which laboratories should be used for donor testing?

Accredited laboratories should be used for serologic testing. There should be a national defined standard, which doesn't currently exist.

3. What specific serological tests should be carried out to detect disease in donors?

Sera should be stored in the event more effective and efficient tests become available.

3.1 Should specific protocols for testing be required?

Specific protocols (standard operating procedures) should be developed for testing that would define the minimum type/number of tests necessary and ensure that the results of the tests are recorded in the patient's record.

3.2 If, in the future, new types of tests are introduced for blood donors (e.g. HIV-antigen tests and PCR tests), would there be reasons for not introducing these for the testing of organ and tissue donors?

New tests should be introduced following an evaluation of them in a selected number of Canadian laboratories that test specimens from transplantation programs. These Canadian laboratories should be selected on the basis of the volume of specimens processed.

Unresolved Issues

- evaluation of serologic tests on cadaveric blood and in specimens in which hemodilution has occurred
- need for national accreditation standards for laboratories
- need for a national mechanism to evaluate new tests and/or the use of evaluation by other national (non-Canadian) agencies such as the FDA.

Donor Screening
Chair: Dr. Paul Greig
Rapporteurs: Dr. David Colpitts and Dr. Bill Freeland

Questions 1, 4 and 7 were grouped, as were questions 2, 3 and 5. Questions 6 and 8 were dealt with separately.

Areas of Consensus

1. Should organ and tissue donors be asked the same screening questions for high-risk behaviours and high-risk exposures that are asked when screening blood donors?

Yes. Add genetic issues and occupation. The answer will either be a) yes,
b) no, or c) unknown.

4. Should the screening process elements be the same for cadaveric and living donations?

Yes, but acknowledge that living donor information is better.

7. Who is qualified to screen donors?

It is the responsibility of the medical director to decide who is qualified to do donor screening in each region. There should be an established formal training procedure for staff at each centre. Need for confidentiality should be emphasized.

2. Which pre-existing conditions in the donor's history are acceptable and which are not?

A comprehensive medical history should be obtained on each donor. The decision as to the use of any tissue/organ is the responsibility of the transplant physician or the medical director of the tissue bank. He or she would seek lay input to decide which pre-existing conditions in the donor are acceptable.

3. What are the relevant signs that should be noted on physical examination?

Signs of high-risk behaviour (e.g. needle tracks, tattoos, STDs), existing disease
(e.g. jaundice, adenopathy) or previous surgery, or review of medical records. Detail of physical examination will depend on the organ or tissue being donated.

5. What other sources of information about the donor may be useful?

Primary source of information is family, including the family doctor. Other sources should be used at the discretion of the health care professional.

Unresolved Issues

6. Who is responsible for recalling and retesting donors, and for recipient tracking when necessary? How much documentation will this involve and who is responsible for the documentation?

There is agreement that the medical director is responsible for reporting and initiating tracking after being notified by the responsible physician of an adverse reaction. There is also agreement that each organ procurement organization is responsible for maintaining a tracking mechanism.

Unresolved: voluntary versus mandatory regular reporting and national surveillance – auditing.

8. Is the draft Canadian General Standard on donor-screening appropriate and adequate?

Unresolved: duration of storage of donor serum (p. 20 of proposed Canadian General Standard). Query 5 or 10 years storage beyond use of all donated tissue from single source.

Record-Keeping/Labelling and Packaging
Chair: Ms. Prudence Taylor
Rapporteur: Mr. Robert Symons

Areas of Consensus

1. Can a national registry be established with existing resources?

Consensus reached was about the need for a national registry for all organ, tissue and cell groups. Registries do exist, but many are fragmented, and there is no national accountability or standards.

It was thought that existing resources should be explored as a step towards a national registry, understanding the limitations that currently exist.

2. What are the requirements of appropriate packaging?

2.1 What barriers/layers are required to ensure the safety and quality of product?

2.2 Rigid containers versus bags?

2.3 What type and quality of material is suitable for packaging the various organs and tissues?

Standards of packaging need to be developed for each organ, tissue and cell group that will ensure the integrity and sterility of the organ, tissue or cells. The packaging material will be defined by each group and, if possible, meet industry standards for the purposes for which the material is intended.

3. What are the requirements of appropriate labelling?

3.1 What information should be on each package?

3.2 What methods are suitable for labelling?

Comprehensive, complete and uniform standards of labelling need to be developed for each organ, tissue and cell group. These standards should be adaptable and ensure that testing stored samples can be achieved with emerging technology. The mechanism for labelling should use current technology to provide a permanent record of the donor's identity. New labelling technology must be applied to samples in a way that does **not** put stored samples at risk.

A package insert will include such information as deemed critical by each group. Mechanisms must be in place to ensure donor confidentiality and, if possible, anonymity.

3.3 How should shipment containers be labelled?

External containers will be labelled only with exporter and importer identification and contact information. Mechanisms to prevent tampering should be in place.

4. What federal security guidelines will need to be addressed?

Local, provincial and federal regulations should be complied with.

5. What information constitutes basic donor information? Could a standard form be developed for this purpose?

5.1 What information should accompany an organ/tissue to the transplant centre?

The information that constitutes a permanent donor record must be decided upon by each organ, tissue and cell group. All critical donor information will be archived in duplicate to ensure the ability to track and trace outcome.

Note: There seemed to be general agreement on the use of technological labelling (i.e. bar codes) with the assistance/support of the private sector. There were also significant concerns raised about the possibility and ramifications of mislabelled organs/tissues. The importance for standardization and uniformity of labelling was agreed to be critical.

Reporting/Databases
Chair: Dr. Locksley McGann
Rapporteur: Ms. Pauline Copleston

How should information be recorded (i.e. computerized), and at what level should it be recorded (e.g. unit level, provincial stats, national stats)?

Can there be national agreement on the criteria for tests, procedures and recording standards (i.e. same units, code lists, etc.)?

How could a national registry be established with existing resources?

Areas of Consensus

- There must be a mechanism to track organs and tissues from the recipient to the donor, and to all other recipients.
- There must be central reporting of adverse reactions, with reaction times reflecting the urgency of preventing disease transmission.
- Information must be collected and retained at the centre level to demonstrate compliance with regulations and quality.
- Data collected must include mandatory donor information and tests; it would be most useful to have a common standard for the format of data.
- The compliance process should include the mechanism for reporting to the national agency.
- Centres must have a mechanism for tracking complications.
- The national agency should maintain a list of who's transplanting what, and a registry of relevant complications.
- There are existing databases, and these should be utilized whenever possible.

Unresolved Issues

It was recognized that information is needed at different levels, but the linkages and flow of information between the levels has not been defined.

It was also not defined as to who will take responsibility for which segment of the data-tracking procedure, but general recognition was that the bulk will fall on the actual transplant centres.

Note: General consensus was achieved in plenary that there must be a common format for data storage.

Oversight and Compliance – Plenary Session

The session began with five expert presentations followed by a review of the process with the intention of achieving consensus on the critical issues.

Accreditation Process
Dr. John Jarrell

- The driving force of accreditation must be to facilitate professional-patient interaction. The task is to balance accreditation and regulatory requirements.
- The standards have to be exceedingly high because the patients are healthy to begin with, and the technology is one based on "quality of life" issues rather than life-saving issues.
- A third party, such as the CCHSA, is crucial for legitimacy.
- The focus must be on the patient as client.

There is an immense challenge in undertaking a process to respond to the request for patient safety in the field of reproductive technologies. One of the major aspects of reproductive care is the lack of public trust that has been identified by the Royal Commission on New Reproductive Technologies.

Additional environmental factors that are affecting the process of oversight in the field of reproductive tissue transplantation include the absence of standardized guidelines for reproductive technology as well as differing funding mechanisms throughout Canada and a myriad of complex ethical issues.

The presentation focused on a partnership process that has been developed through the Canadian Fertility and Andrology Society, the Society of Obstetricians and Gynaecologists of Canada and the CCHSA. These groups have developed an accreditation process that, it is hoped, will begin to build a return of public trust and standardized care in this very important field of reproductive medicine.

Licensure/Inspection
Dr. Locksley McGann, Dr. Alfonso Del Valle

Dr. Locksley McGann

Organ and tissue transplantation has become routine in many disciplines of clinical medicine, creating an increasing demand for banking services in Canada and elsewhere. As with all clinical services, safety, efficacy, and economy are issues of paramount importance. The organ and tissue-banking community must ensure that safe and effective practices are consistently applied and documented across the country. This requires national standards with mandatory licensing and inspections.

Licensure

This must include all tissues and organs, as well as all sources of those organs and tissues, such as tissues coming into the country from commercial sources, tissues from non-profit sources and tissues recovered in Canada for the purpose of transplantation. All tissues that are designated for transplantation in Canada must fall under the same sets of conditions. These rules must also be consistent across Canada. The first way licensing can be accomplished is by registration, in which the national agency is informed of the activity. The second method is certification, in which the national agency approves of the activity. At the moment, neither system is in place. Many European countries, and Australia, have chosen registration.

Inspections

Inspections should cover all levels of activity, from donor identification to distribution of tissues. The critical issue is safety; however, at some point, the issue of quality must be addressed. Inspections should be performed by a national agency, as opposed to a peer inspection group, because there will have to be a penalty of some sort for non-compliance. The national agency should contract for the expertise it requires for inspections, rather than having all those different areas of expertise itself. The inspections should be periodic (interval to be determined). Should the inspections be announced or unannounced? In the U.S., the FDA is moving towards unannounced inspections, while in most other countries, some period of warning is provided. The rationale is to provide an opportunity for the relevant personnel to be present. It is likely that Canada will choose the "unannounced" route. There must be consequences for non-compliance, which could range from a period of time to meet compliance standards to closure or destruction of current inventory of organs/tissues.

Note: The Bureau of Biologics currently conducts announced and unannounced inspections.

Dr. Alfonso Del Valle

A national regulatory authority in Canada is required to establish and maintain national standards for tissue and organ cryobanks. This regulatory authority should be responsible for the accreditation and licensing of tissue and organ cryobanks. Passing a rigorous inspection of the facilities must be the basis of acquiring accreditation and licensing. Periodic inspection thereafter will ensure compliance with the national standards and, therefore, with accreditation and licensure. Prevention of disease transmission by tissues and organs used for transplantation should always be a major priority when performing an inspection. The inspectors should be selected by the regulatory authority from a group of experts. It is important that the inspector demonstrate knowledge of the tissue-specific issues associated with the tissue or organ cryobank inspected. A tissue-specific inspection allows for a better strategy for the prevention of disease transmission by tissues and organs used for transplantation. The inspection must include the following areas of operations of a cryobank: administration, facilities and equipment, the practices and procedures manual, donor records, and tissue and organ storage, labelling, distribution and tracking.

Administrative inspections should include institutional identity, the mission statement, articles of incorporation and the statement of purpose and scope. A board of trustees, or advisory board, should include lay representatives and persons knowledgeable in the field in which the facility is operating. The hierarchical organization chart of the facility should clearly outline the job descriptions of the key employees, their credentials, and the responsibilities for and delegation of technical work. A critical review of the medical or laboratory director is essential. The integrity of the facility's data, both substantive and physical, must be maintained. The standard operating procedures manual must match the observed behaviour, and that manual must reflect the latest procedures. The existence of an up-to-date file about adverse reactions will give the inspector the assurance that the facility is actively tracking and auditing organs and tissues.

Inspections of facilities and equipment should concentrate on documentation of regularly scheduled maintenance and safety procedures. The facility must comply with occupational safety standards, and be able to demonstrate environmental safety procedures.

Inspections of donor records must involve a review of releases from quarantine, confidentiality, informed consent, quality assurance and control. Accuracy and completeness are essential. Screening practices from the standard operating procedures manual should be obvious in the documentation.

Inspection of the storage facilities should concentrate on the adequacy of inventory control as well as the reliability of the storage equipment.

Labelling should be clear and unambiguous. Tracking mechanisms must be audited, and must be transparent through the entire procedure.

National Standards/Monitoring
Mr. André La Prairie, Dr. Paul Dubord

Mr. André La Prairie

There is currently a plethora (approximately 50) of guidelines and standards for the banking of organs and tissues. Some of these guidelines and standards are organ/tissue-specific, and others are disease-specific. They are produced by a variety of associations and societies and cover all aspects of transplantation: donor-screening, serology-testing, record-keeping and workplace safety.

While all guidelines and standards are recommended, very few have been made mandatory to date. In the U.S., the FDA noted that while the American Association of Tissue Banks published very good standards for tissue-banking and offered inspection and accreditation services, only a very small percentage of tissue banks participated in this process. Solid-organ programs also have seen the need to establish minimum standards as they continue to improve the sharing and allocation of organs between centres. In Europe, Australia and the U.S., tissue banks have been addressing the need for standards, inspection and accreditation as the global market for tissues and other human transplants expands.

The result has been that all countries are now recognizing that the safety of organs and tissues

used for transplantation requires nationally recognized standards, mandatory reporting of transplant activities and an inspection/accreditation process. Moreover, the requirement for an independent or third-party involvement is seen as essential.

Dr. Paul Dubord

The central issue for standards is the care of the patient. Safety concerns reflect both the safety and quality of the organs/tissues used in transplantation. Safety also includes the safety of the medical personnel.

The medical standards have to be dynamic, comprehensive, modified to current scientific knowledge and financially realistic. They must be formulated through a medical advisory board with technical and administrative input, as well as public input.

Oversight and Compliance – Discussion
Dr. Keith Bailey, Dr. Wilbert Keon (Co-chairs)

Introduction

Dr. Keith Bailey

It has become apparent that there is a real need and desire to achieve consensus on the issues being discussed. The integrity and openness of the regulatory process is the means for creating the atmosphere that alleviates public fears. We are looking for a regulatory framework that will work for us.

Dr. Wilbert Keon

The Canadian General Standard must include the subsets that pertain to each different category of organ and tissue transplants. (The presentation and ensuing discussion centred on the figure entitled Proposed Risk-management/Regulatory Framework, see figure 1, page 5).

The working assumption is that a set of standards can be agreed upon. So the question then becomes, "Once we have them, what are we going to do with them?" Some of these standards can be enforced by regulation, but not all of them. The ones that cannot be enforced by regulation could be enforced, on a voluntary basis, by an accreditation process. How would one go about an accreditation process? An existing association (e.g. the Canadian Hospital Association) could assist in the process. The regulatory part of the process could be handled by the Bureau of Biologics, Drugs Directorate, which could handle the responsibilities for inspection and audit.

There must also be a registry, or central repository, for tracking, consensus reports, specific donor/recipient information, and complications and adverse reactions. CORR already handles much of this information, and its capacity could be increased to manage the remaining data requirements. There must also be a feedback loop through an expert advisory committee with the capability of assembling experts, such as those present at the conference, as necessary, until the system is functional. The expert advisory committee could "massage" the information it receives, then feed back into the subsets of the Canadian General Standard to filter back through the system.

Dr. Keon posed the following questions to start the discussion:
- What level of risk-management strategy is appropriate?
- Is inspection and/or accreditation needed?
- What is/should be the consequence for non-compliance?
- What is an appropriate risk-management/regulatory option?

Discussion

The discussion raised several points germane to oversight and regulation. It included the regulatory role of the Bureau of Biologics, Drugs Directorate, "third-party" associations, methods of reporting of organ and tissue activity, and methods of recording adverse reactions and complications.

It was agreed that both the use of existing technologies and data, and the networking of all existing organizations would be cost effective.

The participants in the workshop on bone marrow reiterated their position that there is a need for an independent third party responsible for accreditation.

Important to the accreditation process are the inclusion of lay people and the creation of a mechanism to ensure that results are made public. It was suggested that outcome analysis be addressed and that this be dealt with during the implementation process.

Oversight and Compliance – Summary

There is general agreement on the proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation*. The standard will be a template for the development of subsets of specific standards for individual organ and tissue types.

The Drugs Directorate should facilitate the development of a standard with an expert working group/expert advisory committee. Once developed, assurance of compliance by health professionals can either be monitored by federal regulation and/or the accreditation process.

It was moved by Dr. Calvin Stiller, seconded by Dr. Allan MacDonald, and unanimously carried, that the proposed risk-management/regulatory framework be accepted with the caveat that the expert working group be comprised of those societies and professional bodies that are associated with human tissue/organ transplantation. This group should be brought together to give advice on the science and policy related to the development of guidelines and standards. The proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation* should be referenced and used as a template for the development and refinement of subsets of specific standards for various organs and tissues. It was strongly recommended that the Drugs Directorate, through the Bureau of Biologics, be charged with the responsibility of carrying out this action.

Closing Remarks

Dr. May Smith

This conference was successful in bringing together a broad range of experts in the field of transplantation and in achieving a consensus. The proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation* was accepted in principle, and a risk-management/regulatory framework was proposed.

It has been recommended

- that the proposed *Canadian General Standard on Safety of Organs and Tissues for Transplantation* be revised to incorporate input from experts at the conference;
- that the revised *Canadian General Standard on Safety of Organs and Tissues for Transplantation* be accepted as a template for the development of subsets of specific standards for individual organ and tissue types; and
- that the risk-management/regulatory framework (see figure 1, page 5) proposed by the participants at the conference be adopted for implementation by the Drugs Directorate.

The report of the conference will be widely distributed for information and comment. The proposed risk-management/regulatory framework will be carefully reviewed and considered by the Drugs Directorate.

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Workshop 2: Records/Labelling/Packaging

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