

# Report of Fact-Finder Tom Closson for Minister of Health and Long-Term Care

Investigation on Handling of Human Tissue at  
Thunder Bay Regional Health Sciences Centre (TBRHSC)

August 9, 2004



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## Introduction

Ontario Health and Long-Term Care Minister George Smitherman asked Tom Closson, President & CEO of University Health Network to conduct an investigation of the incidents at Thunder Bay Regional Health Sciences Centre which involved the mailing of human tissue to three First Nations women.

The mandate of the review was also to include recommendations regarding the handling of human tissue in Ontario's health facilities. As part of the review, Mr. Closson was to consider the views of First Nations communities as well as other communities.

## Investigation on Handling of Human Tissue at Thunder Bay Regional Health Sciences Centre (TBRHSC)

The review of the specific incidents involving Thunder Bay Regional Health Sciences was conducted for Mr. Closson by Dr. Sylvia Asa, Chief of Pathology at University Health Network. In carrying out her review, Dr. Asa spoke with:

- First Nations Regional Chief Charles Fox
- Mrs. Bev Junnila, Technical Director of the Clinical Laboratories at TBRHSC
- Mr. Ron Saddington, President & CEO, TBRHSC
- Mr. Roger Walker, CEO Sioux Lookout Meno-Ya-Win Hospital
- Dr. Joseph Wasielewski, Head of Pathology, TBRHSC

In order to understand more, Mr. Closson spoke with:

- Mr. Ron Saddington, President & CEO, TBRHSC
- Grand Chief Stan Beardy, Nishnawbe Aski Nation
- Ian Potter, ADM - FNHIB - Health Canada
- Al Garman - Regional Director, Health Canada

As Mr. Closson's representative, Ms. Gillian Howard accompanied Mr. Ron Saddington (President & CEO of TBRHSC) and Mr. Ron Nelson (Chair of TBRHSC) to North Caribou Lake First Nation, Eabametoong First Nation and Poplar Hill First Nation at the request of the three Chiefs. Mr. Saddington, Mr. Nelson and Ms. Howard were accompanied by Deputy Grand Chief Alvin Fiddler of Nishnawbe Aski Nation (NAN) on their visits to Poplar Hill First Nation and North Caribou Lake First Nation. Harry Meekins, Health Director, NAN visited all three reserves with the group. They spoke with:

- Councillors of the Poplar Hill First Nation and the woman and her family at the request of Chief Patrick Owen
- Chief Zeb Kenquanash, the Councillors of North Caribou Lake First Nation and the elders of North Caribou
- Chief Charlie O'Keese, two Councillors of Eabametoong First Nation and the woman and her partner

Dr. Asa's interviews determined the sequence of events, the process in place at TBRHSC for the handling of tissue and for the release of tissue to patients and their families, the process in place at Sioux Lookout Meno-Ya-Win Hospital, and also determined the errors that were made in these particular cases. Dr. Asa also provided her opinions and advice as to how all Ontario hospitals should handle human tissue in an appropriate and sensitive manner.

It is evident that a number of regrettable errors were made in these cases. Mr. Closson and Dr. Asa wish to make it clear that in every interview people expressed their regret for the errors that were made and their sorrow for the pain that these errors have caused to individual women, their families and their extended families.

It should also be said that there was a great deal of anger expressed about what had happened, which Mr. Closson and Dr. Asa found completely understandable.

Many people expressed the view that it was completely unacceptable that it should happen to anyone. Mr. Closson and Dr. Asa are in complete agreement with that view.

## The Acts Governing the Handling, Disposal and Release of All Human Tissue

There are a number of laws that deal with the handling, disposal and release of human tissue from health care institutions and the transportation of human tissue between institutions. Mr. Closson received advice in this area from Dr. Asa and from Ms. Bella Martin, General Counsel at University Health Network, with regard to the legal issues involved in the incidents at TBRHSC and in the handling of human tissue in general.

What is very clear to Mr. Closson is that, while laws may provide clarity about the physical handling and disposal of human tissue and fluids, they are silent on the most human element of the subject - how various cultures and traditions govern attitudes, beliefs, and cultural sensitivities about the way human tissue should be handled.

Mr. Closson believes that, because these cases involved the end of pregnancies, the law and legal definitions do not – in fact, cannot – adequately describe or support the loss that women and their families face when dealing with the grief associated with the end of a pregnancy. This belief was underlined time and again in the discussions that took place on the reserves with the families, the band councilors and Chiefs and the elders of Poplar Hill, North Caribou Lake and Eabametoong First Nations.

In addition, some of the legal and / or medical language used in these cases has hindered all parties' ability to work with each other to a productive and supportive resolution for all concerned. However, when the staff of TBRHSC and the people of the First Nations met and spoke with each other, it was evident that everyone was interested ensuring that an incident such as this never happens to another woman or her family.

Mr. Closson believes that TBRHSC complied with the letter of the law in these cases with regard to the transport of tissue, but failed to meet the needs of the individual patients with regard to cultural sensitivity, a respect for traditions and beliefs, and a humane and compassionate handling of human tissue.

It is evident to Mr. Closson that all human tissue associated with a pregnancy is regarded as human remains by First Nations peoples. Regrettable errors certainly occurred in the handling of the tissue and they were compounded by a failure, initially of TBRHSC, to acknowledge views of individuals and the First Nations communities involved.

Mr. Closson does not believe that the events in the cases at TBRHSC would have been acceptable to any cultural group or individual and several recommendations in this report are about the sensitive release of human tissue, which must become the standard in all Ontario hospitals.

There are a number of statutes and regulations that deal with the handling of human tissue. The Ontario Public Hospitals Act refers to how surgeons must deal with surgically removed tissue samples. The Ontario Environmental Protection Act deals with the safe disposal of all human tissues and fluids. The federal Transportation of Dangerous Goods Act governs the packaging, labeling and transportation of human tissue – whether by mail, by hand or by vehicle. The Vital Statistics Act defines a stillbirth.

Ontario hospitals routinely move tissue samples around the province by courier, mail or other means. This is done for example, where one facility does not have the resources or expertise to properly analyze tissue samples. That facility might send the tissue to another facility that does have the necessary resources and expertise. Provided that these transfers are done appropriately (i.e., in accordance with the law) and with sensitivity, there is nothing improper about such transfers. In fact, to stop the movement of human tissue via couriers and / or mail, would compromise the health status of hundreds of thousands of Ontarians.

Knowledge and compliance with all of these laws are requirements of every pathologist practicing in Ontario's hospitals. Pathologists are the professionals who must ensure that hospitals are in compliance with all laws that govern this area, while meeting the diverse needs of patients and their families.

The Vital Statistics Act defines a stillbirth as “the complete expulsion or extraction from its mother of a product of conception either after the 20<sup>th</sup> week of pregnancy or after the product of conception has attained the weight of 500 grams or more. Where a stillbirth has occurred, the products of conception are required by law to be analyzed, and there are regulatory requirements imposed on the institution involved in this analysis in terms of the appropriate packaging, labeling and transportation to a funeral home. Thereafter, the funeral director is subject to a number of regulations with respect to the appropriate registration and burial or cremation of the stillbirth. Similar regulations apply to the transportation and burial or cremation of all human bodies. There are not any similar regulatory requirements with respect to the transport or disposition of other human tissue.

## Details of the Occurrences at TBRHSC

- It was confirmed that tissue was inadvertently sent to patients. The tissue was boxed and wrapped appropriately and labeled with biohazard forms, as required by law. The intent was to send the tissue back to Sioux Lookout Meno-Ya-Win Hospital, however in at least three cases, the packages were mistakenly sent to patients.
- According to the pathology reports in the cases examined, these cases were the products of conception. Placental tissue was identified in the reports but no fetal parts were identified.
- It was confirmed that some specimens from patients treated at Sioux Lookout Hospital are routinely sent to the Department of Pathology at Thunder Bay Regional Health Sciences Centre for examination, since Sioux Lookout Meno-Ya-Win Hospital does not have a department of Pathology. In the case of tissues that are requested for return for burial or other appropriate handling, the usual protocol is to return the tissue to the originating hospital - in this case, the Sioux Lookout Hospital, which then has a mechanism in place to return the tissue to a funeral home for burial.
- In the cases in question, a clerk from TBRHSC who was responsible for mailing did not have an address for the originating hospital within the paperwork. The clerk identified the patient's name and address on the consent form and sent the tissue directly to the patient. This was an error in process and judgment.
- It is confirmed that three incidents were identified within a 5-day period in April 2004. All three involved products of conception that were formalin-fixed and contained no identified fetal parts. All were from First Nations women who had signed consent forms at Sioux Lookout Meno-Ya-Win Hospital indicating that the tissues were to be returned for burial. After completion of the pathology examination at TBRHSC, the specimens were washed of formalin, wrapped in gauze and saline, and packaged in either a plastic specimen container or a plastic biohazard bag as required by law. These containers were sealed and wrapped as per the instructions and regulations of shipping companies. Usually such specimens are accompanied by a signed consent for return of tissue with patient identification and a stamp or written notice of the hospital of origin (Sioux Lookout Meno-Ya-Win Hospital) and the specimens are then returned to the hospital. In three known instances, the clerk at TBRHSC had no identification of the source hospital; instead there was only a signed consent for return of tissue with patient identification (name and address) and the clerk elected to send the specimens to the patients.
- Individuals at TBRHSC indicated that they were not aware of other cultural groups that request tissue for burial. Experience at TBRHSC has included requests for release of tissue such as foreign bodies, gallstones, etc. and there has been release of such specimens to patients after obtaining signed consent.

- Sioux Lookout Meno-Ya-Win Hospital has no pathology laboratory on site and sends some pathology specimens to TBRHSC. In cases of products of conception, including the placenta of normal deliveries, Meno-Ya-Win Hospital has a flow chart and procedure manual for handling of the tissue. A consent form and request to return the specimen is stamped with the hospital name or it is hand written on the form. Sioux Lookout Meno-Ya-Win Hospital, on return of the tissue, packages the material appropriately, sends the box to a local funeral home where it is placed in a coffin and sent to the home community with notification of the Chief and / or family of the method of delivery and expected date of arrival.

### Summary of Investigation at TBRHSC:

- In at least three instances, the staff at Sioux Lookout Meno-Ya-Win Hospital apparently failed to properly identify the origin of specimens from their hospital on paperwork that is used for return of specimens to the originating hospital.
- The staff at TBRHSC does not have a complete written protocol for handling the release of tissues. In at least three instances where there was uncertainty concerning the appropriate recipient of tissue, the decision was made by a clerk.
- Familiarity with the traditions and sensitivities of First Nations and / or other cultural / religious / ethnic needs for burial of surgically resected human tissues is not included in TBRHSC's written procedures and protocols.

## Recommendations:

Some of the recommendations in this report are specific to Thunder Bay Regional Health Sciences Centre and Sioux Lookout Meno-Ya-Win Hospital but most of the recommendations apply to all hospitals in the Province of Ontario. Health care professionals need to ensure that humanity, dignity and compassion are used in the application of the law as it applies to the release of human tissue.

1. The Sioux Lookout Meno-Ya-Win Hospital must implement a system to ensure that all requests for return of tissue sent to TBRHSC have clear identification of the hospital of origin.
2. All Ontario hospitals, which send tissue samples to another site for a pathology workup, must ensure that samples are clearly marked with hospital of origin and the desired disposition of the tissue. That is – should the tissue sample be returned to hospital of origin or disposed of by the receiving hospital following the completion and delivery of the pathology report?
3. The TBRHSC Department of Pathology must create and implement a complete written protocol for release of all human tissues that are not disposed in the usual fashion. In the event that there is a request to release tissue to someone other than a hospital or funeral home – for example, to the patient, relative or other designate – the request should be considered as outside of usual protocol and require approval by a senior manager or medical staff member.
4. TBRHSC management must ensure that clerks who do the mailing of tissue specimens receive the appropriate information with regard to protocol and the need for approval by senior staff or medical staff if a mailing seems outside the normal practice.
5. All Ontario hospitals must ensure that they have such a written protocol and incorporate the approval by senior management or medical staff for release of tissue outside of normal protocol.
6. All hospitals in Ontario must ensure that their staff members have a clear understanding of the nature of sensitive specimens that require special handling. This will ensure that all hospital employees involved in handling human tissues are aware of areas of special need.
7. TBRHSC and the First Nations involved with these cases should work together to develop a written protocol for the release of human tissue on compassionate and / or cultural grounds. A successful protocol would respond to the needs of the First Nations peoples and any other person or groups of persons who may have special needs around the handling of human tissue.

8. Once developed this written protocol for the release of tissue on compassionate / cultural grounds should be shared with all Ontario hospitals by TBRHSC and the First Nations involved in its development.
9. TBRHSC, with other hospitals in Northwestern Ontario, should develop a program to educate their staff on the handling of specimens in relation to cultural sensitivities with a particular focus on the traditions, beliefs and needs of First Nations peoples.
10. The TBRHSC program to educate health care providers on the culturally sensitive and compassionate handling and release of human tissue should be made available to all Ontario hospitals.

