

**Ethics Review**

**Pastoral Care and Ethics Department  
Eastern Health**

May 29, 2007

To: Dr. Robert Williams, MD  
From: Rick Singleton, D. Min. Director  
Re: Ethics Consult, ER PR

Present: Dan Boone, Lawyer; Heather Predham, Risk Management; Dr. Joy McCarthy, Oncologist; Dr. D. Cook, Lab, Dr. N. Denic, Lab, Dr. Natalie Bandeau, Intensives and Ethicist; Rick Singleton, Facilitator

Issue: In the summer of 2005 the Director of Laboratory Medicine for Eastern Health became aware that there may be some problems with testing of samples from breast cancer patients that were processed to determine appropriate follow up with patients. The specific test is for the presence of hormone receptors in the tumour which may impact follow-up treatment (ER /PR).

The problem with the results was rooted in the test procedures used in the time period from 1997 – 2005. In 2005 samples known to have been processed for this batch of patients were forwarded to Mt. Sinai in Toronto for retesting at their lab. In the batch forwarded to Mt Sinai there were 101 samples from deceased patients, 19 of the retested samples produced results that may have resulted in a different care plan and treatment follow-up than that implemented based on the original test results..

Important facts to the history and understand of this case include the following  
There were no mistakes or technical errors at the root of this problem;  
It is impossible to know in any specific case if the outcome for any individual patient would have been different;  
Intervention for post-menopausal women had positive impact by lengthening life in 47 % of patients treated.

The main ethical issue in this case pertains to disclosure. There are several considerations regarding the duty to disclose, the right of families to be informed of results from the retesting at Mt. Sinai, and who should manage the disclosure processes.

The obligation to disclose the information to families is based, from an ethics perspective, on the negative right of families to the information about the deceased. A negative right respects the right of individuals or families to access information, but it does not oblige anyone to make direct contact with individuals or families to provide the information. The obligation to inform is different in this situation than if situations where a mistake had been made, where the information would make a difference or potential difference in the care plan or interventions of a patient.

While legally no one has the right to a deceased person's health record or other health information in the context of the Core Values of Eastern Health and in a spirit of good will it is appropriate that Eastern Health take reasonable steps to inform the community that this problem has occurred and that information is available. This can be done through local media and as part of the follow up from previous media coverage of the issue.

Access to the information or health record must be requested in writing. The request must come from the individual or individuals in line of priority to identify substitute decision-makers according to the Act Respecting Advance Health Care Directives and Substitute Decision-makers. The request would be handled according to the policies and practices pertaining to health records.

Contact with families ought to be managed mainly by the Risk Manager with the assistance of competent staff and the Corporate Communications Department. The ethics consultation had several recommendations in this regard.

1. A press release prepared as this matter is being resolved ought to mention that information pertaining to deceased patients may be available by contacting the appropriately designated office or number.
2. Efforts should be made to ensure information about the retested samples be presented by an individual competent to explain the matters to the family member.
3. If families of deceased patients whose samples have not been retested request the same information then it should be explained that the sample has not yet been retested and it will be retested, if that is the preference of the family, and that the retesting will be done at the site doing this testing procedure for Eastern Health when the request is made.

I thank all who participated in this consultation for their time and attention.

Yours truly,

Rick Singleton  
Facilitator