

*Discussed
with Dr. Cook
July 16, 2005*



July 14, 2005

Dr. Donald M. Cook
Clinical Chief
Laboratory Medicine
Health Care Corporation of St. John's
St. John's, NL A1B 3V6

Dear Dr. Cook:

As per our many recent discussions, I agree with you that our estrogen receptor status reports prior to 2003 require immediate investigation. Our recent examples of sixteen patients converting from estrogen receptor negative for estrogen receptor positive status is quite concerning. Factors identified on those slides clearly show problems with the technique of estrogen receptor testing and the interpretation of same. I have been unable to review paperwork from 1997 – 2003 with regards to protocols, quality practice, and controls. I am therefore eager to review the estrogen receptor status of all patients seen in our laboratory from May, 1997, when immunohistochemical staining for estrogen receptor status first became available up until March, 2004, when analysis and readjustment of the estrogen receptor status protocol was carried out by Dr. G. Ejeckam. I think that it is vital that we expediently review these cases and let patients know as quickly as possible of any change in their estrogen receptor status.

As quickly as possible, I would like to know the estrogen receptor status of every patient tested in our laboratory between 1997 and 2004. From that information, I would also like an estimate of the total of positive cases given out per year. I would need all of the reports pulled from the computer for review. Patient demographics, including name, age, and MCP number, should be collated along with their surgical number, their histologic type of carcinoma and the histologic grade. All of the slides from the cases including the estrogen receptor slides need to be pulled and organized. All slides then need to be reviewed by me, both estrogen receptor negative and estrogen receptor positive patients. Estrogen receptor negative patients should be given priority. Blocks will be pulled from those cases and estrogen receptor / progesterone receptor status reordered. This test should be carried out as quickly as possible. 10% of cases should be randomly selected for outside quality assurance consultation. Dr. Frances O'Malley at Mount Sinai Hospital has agreed to act in this capacity. Problematic cases, as defined by a multiplicity of reasons, should also be sent for outside testing.

St. Clare's Mercy Hospital

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It will be necessary to have a computerized database for this project. This database should include the patient's name, MCP number, surgical number, hospital of origin (please remember that these patients were treated in all hospitals in Newfoundland), results of original estrogen receptor / progesterone receptor testing, presence of control tissues, results of new testing, and any comments about the case. Also included in these computerized report should be the histologic type of cancer as well as the grade of cancer.

As we have discussed in my opinion, the above suggestion should be carried out as quickly as possible.

Yours sincerely,



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c.c. Dr. Bob Williams

July 19, 2005

Dr. Bev Carter
Division of Anatomic Pathology
Laboratory Medicine Program
St. John's Hospitals, Eastern Health
St. Clare's Site
St. John's, NL A1C 5B8

Dear Dr. Carter:

This is to acknowledge receipt of your letter dated July 14, 2005. I certainly accept what's been stated in your letter and will ensure that you obtain the necessary resources to carry out your suggestions.

Sincerely yours,

Donald M. Cook, MD, FRCPC, FCAP
Clinical Chief, Laboratory Medicine Program
St. John's Hospitals, Eastern Health

c.c. Dr. Bob Williams


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