John Lambert,
We believe this belongs to your division. Yes!

Aug 29
Moira to have discussion with John A re: Appt for response

Eastern HEALTH

CODE # EXE-3215
C.C. 1. CJ 4. ____
2. ~~EH~~ 5. ____
3. ____ 6. ____
REGISTRY ✓

26 July 2005

Mr. John Abbott, Deputy Minister
Department of Health and Community
P.O. Box 8700
St. John's, NL
A1B 4J6

Dear Mr. Abbott:

You will recall from earlier conversations and certainly from extensive media reporting that advances in the treatment of various forms of cancer is resulting in extreme pressure from both patients and providers to introduce new medications to our drug formulary as well as new diagnostic tools. It is clear that all Provinces are facing the same issues and it is becoming evident that many are deciding to allocate the funding required.

I am attaching correspondence from our clinical experts for your review. The financial implications of keeping in step with the rest of the country are staggering. I would appreciate hearing from you as to how we need to approach this issue.

Sincerely,

George Tilley
President and Chief Executive Officer

cc. Patricia Pilgrim, COO
Dr. Robert Williams, VP
Beverley Clarke, COO

Attachment

RECEIVED
JUL 28 2005
DEPUTY MINISTER'S OFFICE

Newfoundland
Cancer Treatment and
Research Foundation

FEED DOCUMENT THIS DIRECTION

IMPORTANT FAX MESSAGE

TO Faxed to Colleen
COMPANY Moncton
FAX NO.
FROM
NO. OF PAGES Sept 19
RE

July 25, 2005

Mr. George Tilley
C.E.O.
Eastern Regional Integrated Health Authority
Corporate Office
Waterford Site
Waterford Bridge Road
St. John's, NL A1E 4J8

Dear Mr. Tilley:

RE: ADDITIONAL FUNDING FOR PROVINCIAL SYSTEMIC THERAPY BUDGET

We are writing to request additional funding to our Provincial Systemic Therapy budget. Several recent advances in oncology have led to a change in the adjuvant therapy of breast cancer, adjuvant and metastatic therapy of colorectal cancer and the treatment of multiple myeloma. These advances are the result of the new clinical research in oncology and are becoming the standard of care. This will necessitate an increase in our budget for the 2005-2006 fiscal year to incorporate these new standards into practice for cancer patients of Newfoundland and Labrador. As you are aware, our drug budget for 2005-2006 is approximately $6.3 million dollars. This represents a $1 million dollar increase from 2004-2005; however, this amount of funding equals our expenditure for the 2004-2005 year. Cancer centers across the Country anticipate an annual growth in expenditure of approximately 20% per year. This 20% is based on a number of factors, such as, an increase in incidence of cancer, an increase in the number of patients being treated, increased cost of medications, etc. As we have not received an increase in funding over the last three years, we expect the 20% increase on 2004-2005 expenditures to be in range of $7.5 million dollars. However when we submitted our request for the 2005-2006 budget, this new clinical data was not available and, therefore, this necessitates a request for additional funding.

The first area that requires additional funding is in the adjuvant therapy of breast cancer. Three large randomized clinical trials have reported efficacy data at the American Society of Clinical Oncology (ASCO) meeting in May 2005. These have shown a significant benefit in terms of disease free survival and overall survival with the addition of adjuvant Herceptin for one year in breast cancer patients who are known to be HER2/ *neu* overexpressors. We are in the process of writing a guideline in conjunction with our colleagues in Atlantic Canada that will outline the indications for this treatment. On average, we see 350 new breast cancer patients/year and approximately 15%-20% of those will be HER2/ *neu* overexpressors. Factoring in patients who would not be eligible for this treatment because of age or cardiac toxicity, we are anticipating approximately 40 patients per year. The cost has been estimated to be $50,000 per patient per year; therefore, we will require an additional $2,000,000 per year to fund this drug. For the remainder of the 2005-2006 fiscal year, we are requesting an additional $1,000,000 dollars to pay for adjuvant Herceptin.

In addition, we will now need to test all new breast cancer cases for HER2/ *neu* overexpression using immunohistochemistry. Those patients with an equivocal result will need to go on for confirmatory tests using florescence in situ hybridization (FISH).

Dr. H. Bliss Murphy
Cancer Centre
300 Prince Philip Drive
St. John's, NL A1B 3V6
Tel: 709.777.6480
Fax: 709.753.0927
http://www.nctrf.nf.ca

Currently, the FISH testing is sent out of province. We will also require funding to allow for this testing to be done in an efficient manner and we are asking that this money be given directly to the Cancer Care program to oversee this testing. Collaboration will have to take place with the Pathology program to determine the financial impact of this testing. Unfortunately, we are not able to provide an approximate costing for these procedures at this time. A process is currently underway to determine the financial impact of these additional tests.

The other area in which there has been quite a lot of progress is the treatment of colorectal cancer. New adjuvant therapies are now available for these patients. FOLFOX-4 (Oxaliplatin, 5-FU, folinic acid) chemotherapy that is currently used in the metastatic setting has now been shown in clinical trial to be of benefit in the adjuvant setting for patients with colorectal cancer. Many of our colleagues across the Country are already offering adjuvant FOLFOX-4 chemotherapy to patients as a standard of care and we would like to be able to start offering this treatment in the Fall 2005 once we have the necessary infrastructure available to expand our infusional home chemotherapy program.

On average we see approximately 300 new stage II and III colon cancers patients per year. We will be treating our high-risk stage II and stage III patients with FOLFOX-4 if they are eligible to receive this treatment based on clinical practice guidelines. We anticipate treating 180 patients with this regimen per year. This regimen will cost approximately $24,000 per patient, therefore, we will require an additional $4,300,000 dollars per year to fund this treatment. In the 2005-2006 fiscal year we expect to spend $2,000,000 on the treatment of adjuvant colorectal cancer with adjuvant FOLFOX-4 chemotherapy. However, as previously stated, the utilization of this treatment will depend upon the full implementation of the Home Infusion Program.

The other area of advancement in the treatment of colorectal cancer adjuvantly is the use of oral Capecitabine (Xeloda) for elderly patients. This drug has been shown to be equivalent to 5-FU and folinic acid and much less toxic. Several of our patients treated with intravenous 5-FU and folinic acid chemotherapy develop severe complications necessitating long hospitalizations. Results of recent clinical trials has led to a move in Canada to use oral Capecitabine for these patients instead of bolus intravenous 5-FU and folinic acid. Unfortunately, our Provincial Systemic Therapy Drug Program does not cover oral chemotherapy. This issue MUST be addressed immediately to ensure that we are able to provide our elderly patients with the appropriate adjuvant therapy with oral Capecitabine. We estimate that there will be 45 patients per year at a cost of $5,770.00 per patient. Annually this will require an additional $260,000. For the 2005-2006 fiscal year we will require an additional $130,000 to provide the standard of care with oral Capecitabine for this population as well.

We have previously written to the Government looking for funding for two new agents in the treatment of metastatic colorectal cancer. These include Bevacizumab (Avastin) and Cetuximab (Erbitux). Both are used in the treatment of metastatic colorectal cancer. We are anticipating Health Canada approval of both of these drugs in the last quarter of 2005. Previously, we had anticipated that approximately 120 patients per year would be treated with Avastin and 60 patients with Erbitux. However, due to expanding clinical evidence on the toxicities of these two agents, we now anticipate 95 patients per year to be treated with Avastin and 36 patients per year to be treated with Erbitux. We estimate Avastin will cost the province $2,430,000 per year and Erbitux will cost us $1,000,000 per year. For the 2005-2006 fiscal year, we will require an additional $600,000 for Avastin and an additional $250,000 for Erbitux depending on Health Canada's approval of these agents.

There have also been exciting new advances in the treatment of multiple Myeloma with the use of an agent called bortezomib (Velcade). This agent has been reviewed and approved by the HCCSJ and NCTRF

Pharmacy and Therapeutics committee and it is estimated that approximately 10 patients per year will require treatment. The annual cost of this treatment is approximately $35,000 per patient. Therefore, we will anticipate an annual cost of approximately $350,000. Until we gain more clinical experience with using this new agent it is expected that most patient will be treated within the HCCSJ during the first year. The budget impact of this treatment for 2005-2006 will be approximately $175,000. Currently, hematology drugs given in St. John's are not funded under the Provincial Systemic Therapy Program; however, with the amalgamation of services under Eastern Health this will likely become encompassed under the Provincial Systemic Therapy Program budget.

We think that it is important for us to realize that these increased expenditures are the result of advancements in the care of cancer patients. These treatments have become standard of care across the Country and it is essential that we obtain the necessary funding to ensure optimum treatment for cancer patients of Newfoundland and Labrador. Adjuvant therapy is used to cure cancer patients and, therefore, it is essential that we have this funding to offer the best care to our patients. In total we will require $10,034,000 annually to fund these new treatments, and an adjustment of $4,155,000 for the 2005-2006 fiscal year. In addition to this new funding, an annual budget increase of 20% on the previous years expenditures must be built into the budget process to stay current with the ongoing growth in incidence, duration of treatments, and inflationary costs of medications. Appendix I clearly outlines this information in table and graphic format.

We would be more than pleased to meet with you at any time to discuss these further, and we look forward to an opportunity to present this information to your Board and to the Government as needed.

Thank you for your attention to this matter and we look forward to talking to you about this in the new future.

Yours sincerely,

For Dr. Laing Kara Laing M.D. FRCP(C)

Kara Laing, M.D., F.R.C.P. (C)
Director, Medical Oncology
The Dr. H. Bliss Murphy Cancer Center
Assistant Professor, Faculty of Medicine
Memorial University of Newfoundland

Rick Abbott, BSc. Pharm., RPEBC
Provincial Pharmacy Director
Systemic Therapy

KL/dpr

Cc Mr. G. Butt
Ms. P. Pilgrim
Mr. J. Parsons
Ms. C. Power
Dr. P. Gardiner

Appendix I.

Graph I: PSTP Budget vs Expenditures, 2001/02 to 2004/05

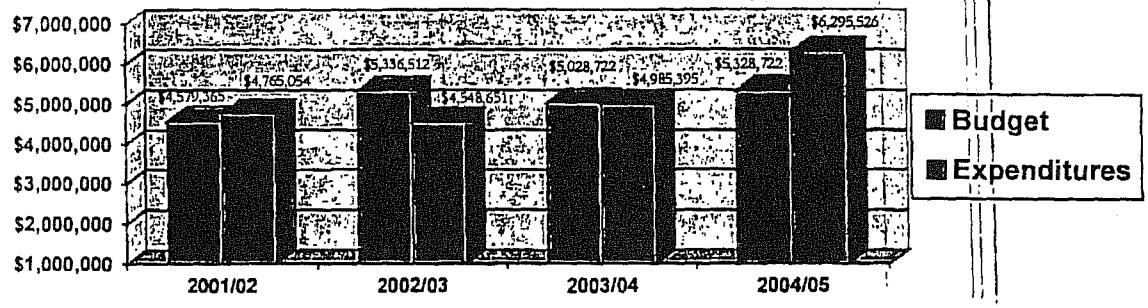

Table I: Overview of Budget & Expenditures, 2003/04 to 2005/06

YEAR	Budget	Budget ↑ from Previous Year	Expenditure	Expenditure↑ fr Previous Year	Projected Deficit
2001/02	$ 4,579,365	N/A	$ 4,765,054	N/A	N/A
2002/03	$ 5,336,112	16%	$ 4,548,651	(- 4.5%)	N/A
2003/04	$ 5,028,722	(- 5.8%)	$ 4,985,395	9.6%	N/A
2004/05	$ 5,328,722	6%	$ 6,295,526	26%	N/A
2005/06	$ 6,368,233	19.5%	***$ 7,550,000*** ***(Projected)***	***20%*** ***(Projected)***	**($ 1,180,000)**

Table II: Overview of Expenditures for New Treatments In addition to the Current Budget Allocation

Treatment and Intent	Treatment Regimen	# pts annually	Annual Cost	# pts 05/06	Additional Funding 05/06	Increased Funding 06/07
Adjuvant Breast Cancer	Herceptin	40	$ 2,000,000	20	**$ 1,000,000**	**$ 2,000,000**
Adjuvant Colorectal Cancer	FOLFOX-4	180	$ 4,300,000	83	**$ 2,000,000**	**$ 4,300,000**
Adjuvant Colorectal Cancer	Capecitabine	45	$ 260,000	22	**$ 130,000**	**$ 260,000**
1st line Metastatic Colorectal Cancer	Bevacizumab (Avastin)	95	$ 2,430,000	23	**$ 600,000**	**$ 2,430,000**
2nd line Metastatic Colorectal Cancer	Cetuximab (Erbitux)	36	$ 1,000,000	9	**$ 250,000**	**$ 1,000,000**
Multiple Myeloma	Bortezomib (Velcade)	10	$ 350,000	5	**$ 175,000**	**$ 350,000**
TOTALS		**406**	**$ 10,340,000**	**162**	**$ 4,155,000**	**$ 10,340,000**

Cost of new drug only.