BC Cancer Agency

Systemic Therapy Update

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Website access at http://www.bccancer.bc.ca/STUpdate/

INSIDE THIS ISSUE

EDITOR'S CHOICE

DRUG UPDATE – NON-PVC BAG AND TUBING FOR ETOPOSIDE INTRAVENOUS SOLUTIONS

Beginning **October 1, 2005**, all etoposide infusions at the BC Cancer Agency will be prepared in non-PVC bags and administered through non-PVC tubings to minimize additional patient exposure to DEHP. Treatment protocols and pre-printed doctor's orders will reflect this change.

Background:
The practice at the BC Cancer Agency has been to prepare etoposide intravenous (IV) infusions in polyvinyl chloride (PVC) bags and administer them through PVC tubings. PVC bags and tubings contain a plasticizing agent, diethylhexyl phthalate (DEHP), which is potentially hepatotoxic and carcinogenic.[1]

Etoposide injectable contains polysorbate 80 which extracts (leaches) DEHP[2,3] from PVC. Recent research suggests that the DEHP extraction may be more substantial than previously assumed. It varies with etoposide concentration,[4] the amount of polysorbate 80 in the solution,[2-5] the amount of DEHP in the PVC equipment, and the contact time of the etoposide solution with the equipment.[4,5] Leaching of DEHP from PVC bags is increased with increased etoposide concentration and longer storage.

The evidence for using non-PVC administration tubing is less compelling. DEHP has been shown to leach from PVC tubing, albeit when etoposide was infused at a slow rate (30-90 mL/h).[4] It is probable that leaching may be more significant when etoposide is given as a continuous infusion, on consecutive days or via longer tubings.

A 500 mL bag of etoposide 0.4 mg/mL, infused over 1 hour, may contain up to 4000 mcg of DEHP 4 hours after preparation.[3,5] A daily intake that one can be exposed to over their lifetime without harmful effect is approximately 3300 mcg (0.44 mcg/kg).[1]

Avoidance of PVC bags or tubings is not currently mentioned in etoposide monographs.[6,7] Bristol Myers Squibb's Medical Information has stated that the use of non-PVC bags for etoposide remains a matter of choice.[8] However, since individuals are exposed to daily DEHP intakes from other sources, it is reasonable to minimize their exposure to additional amounts during etoposide treatments.

Other centers surveyed in Canada, US and Europe use or plan to use non-PVC equipment for etoposide infusions.[9-16]

Pharmacy Implications:
Effective October 1, 2005, all etoposide infusions prepared by BCCA Pharmacies will be in non-PVC, non-DEHP bags.

Nursing Implications:
Effective October 1, 2005, all etoposide infusions will be infused through non-filtered, non- PVC tubings. These tubings are the same as those used for docetaxel infusions. The infusion will be set up exactly as the docetaxel infusion, with the non-PVC tubing as the primary line and with a second, regular IV tubing connected to the lowest side port of the non-PVC tubing.

A diagram of the comparable setup for taxanes is available at
http://www.bccancer.bc.ca/HPI/Nursing/References/NursingBCCA/P-040.htm

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Edmonton Alberta 2005.
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DRUG UPDATE – L-ASPARAGINASE RECONSTITUTION AND CONCENTRATION STANDARDS

The product monograph for L-asparaginase (Kidrolase®, Aventis) states that vials of 10 000 IU should be reconstituted with 4 mL SWI, to yield 2 500 IU/mL.[1] This has traditionally been the BCCA standard. However, in 2001, a 5% overfill in each vial led us to question whether the final concentration would be 2 500 IU/mL or 2 625 IU/mL. At that time, BCCA adopted the policy that reconstitution of 10 000 IU vials with 4 mL SWI would be considered to yield 2 625 IU/mL.

The latest information from the manufacturer states that the overage is needed to ensure that the entire 10 000 IU may be withdrawn from the vial. Given filling precision and loss of potency during shelf life, the vial is

considered to have 10 000 IU ± 10%.[2] Consequently, the BCCA standard has been changed back to the original: the concentration yield of a 10 000 IU vial, reconstituted with 4 mL SWI, is considered to be 2 500 IU/mL.

References

1. Aventis Pharma Inc. Kidrolase Product Monograph. Laval, Quebec; 4 June 2003.
2. Robert Sarrazin, B Pharm. Personal communication. Consultant, OPi Inc. February 2005.

FOCUS ON FATIGUE AND ANEMIA

"*I just ran out of starch" – nothing to hold me up. Feeling blah and drained AND guilty because I expected to be able to keep up with working full time*."

Signed "Droopy" (Breast Cancer Survivor)

What is cancer related fatigue?

Cancer related fatigue (CRF) is a common, persistent and *subjective* sense of tiredness related to cancer or to treatment for cancer that interferes with usual functioning. It is the most common side effect of cancer treatment (Mock, V. et al, 2000, Stasi, R. et al, 2003) It differs from the fatigue of everyday life, which is usually temporary and is relieved by rest. CRF is more severe, more distressing and is usually *not relieved* by rest.

CRF occurs in an estimated 50-70% of cancer patients, 80-96% of those undergoing chemotherapy and 60-93% of those undergoing radiotherapy. It has a profound effect on quality of life (QOL), including physical, psychosocial and economic/occupational aspects. It is often unrecognized or overlooked by health professionals.

There are treatment related and disease related factors associated with the development of CRF. While the exact mechanism of pathophysiology of CRF is not well understood, it has been suggested that other additional physiologic and psychological factors contribute to the severity of the problem. Anemia, hypothyroidism, infection, malnutrition, dehydration, chronic pain and use of centrally acting opioids, sleep disorders, chronic stress, hormonal changes, depression and anxiety are examples of these contributing factors.

What can we do?

Management of cancer related fatigue **begins by careful screening and assessment.** National Comprehensive Cancer Network (NCCN) guidelines for the initial evaluation of cancer-related fatigue use a 0 – 10 scale, 0 = no fatigue, 10 = severe fatigue. Early screening for fatigue can be done by using this scale.

- Mild fatigue 0-3
- Moderate fatigue 4-6
- Severe fatigue 7-10

Screening should identify the presence, as well as the severity, of fatigue. A focused history and physical exam must be conducted as a primary evaluation. It is important to treat reversible medical conditions; for example, anemia, hypothyroidism, pain etc.

Patients may be reluctant to discuss their fatigue for a variety of reasons, so it is incumbent on the oncology health care professional to evaluate this symptom at ongoing intervals during treatment and follow up appointments. Educating patients about fatigue is of critical importance. Strategies such as energy conservation, promotion of healthy sleep habits, ensuring adequate nutrition, learning to manage pain and stress, and engaging in mild exercise programs can contribute to successful management of mild to moderate fatigue. (Refer to: **www.nccn.org** for Clinical Practice Guidelines for Cancer Related Fatigue, version 1.2005).

What is Anemia?

Anemia is a condition characterized by a decrease in the hemoglobin (Hgb) level or circulating erythrocytes. It occurs when a loss or destruction exceeds production of red blood cells (RBCs). It can be acute (more than 30% loss of blood volume usually associated with hemorrhage, trauma or surgery) or chronic (underlying problems such as colitis, cancers, absorption issues, hemorrhoids, menstruation etc.) The common causes of anemia are bleeding, iron deficiency, nutritional deficiency (folate or Vitamin B 12) and kidney disease. As well, inherited

RBC disorders, abnormal or increased RBC destruction and bone marrow disorders or bone marrow failure can cause anemia.

The presence of anemia in cancer patients may affect physical and emotional/cognitive symptoms and can increase tumour hypoxia. Patients may report tiredness/fatigue, shortness of breath, palpitations, headaches, cold or exercise intolerance, anorexia, chest pain, dizziness/fainting and inability to concentrate

In cancer patients there are multiple causes of anemia. These include chemotherapy and/or radiation therapy, bone marrow transplantation, blood loss, tumour infiltration of the bone marrow and/or anemia of chronic disease (ACD). Anemia of chronic disease (ACD) is common in kidney disease, heart disease, diabetes, infectious or malignant conditions and inflammatory diseases like rheumatoid arthritis. In the case of cancer, inflammatory cytokines secreted by the tumor impair precursor red blood cell development. There is an abnormality of iron utilization resulting in decreased haemoglobin synthesis. It is characterized by low serum iron, decreased transferrin (TIBC) and either *normal or increased* serum ferritin (Garner & Benz, 2000).

Anemia potentially impacts multiple systems, producing the following signs and symptoms:

- Central nervous system - cognitive functioning and mood,
- Cardio respiratory system - tachycardia, weakness, dyspnea with/without exertion
- Renal system - reduced perfusion, fluid retention
- Gastrointestinal functioning - irregular bowel movements
- Genital tract - menstrual changes, loss of libido and impotence
- Skin - reduced perfusion, coldness and pallor

The National Cancer Institute uses a grading scale for anemia:

- 0 – Within Normal Limits
- 1 - Hgb 100 g/L – Lower Limit of Normal (mild)
- 2 – Hgb 80 -99 g/L (moderate)
- 3 – Hgb 65 – 79 g/L (serious – severe)
- 4 – Hgb < 64 g/L (life-threatening)

Treatment Options for cancer-related anemia

There are various treatment options available for cancer-related anemia. The choice will depend on a variety of factors, including the patient's hemoglobin level, symptoms of anemia, risk of anemia worsening during chemotherapy and the patient's treatment history.

Nutrition:

Patients may need to modify their diet to increase iron, vitamin B12 or folic acid intake. A vitamin/iron supplement may be appropriate or the patient may be referred to a nutritionist.

Red Blood Cell (RBC) transfusions:

This is the standard treatment of choice for patients with symptomatic moderate or severe anemia However, it is important to remember that the indication for transfusion is dependent on activity level and this remedy should be reserved for patients exhibiting symptoms (eg: shortness of breath). RBC transfusion is associated with risks, for example, transfusion reactions, allergic reactions, and the small risk of transmission of infectious agents (e.g., hepatitis B).

Drug options: Epoetin alpha (Eprex ®) or Darbopoetin alpha (Aranesp ®)
Erythropoietin is a naturally occurring hormone, secreted by the kidneys, which regulates the production of red blood cells. Epoetin alpha and Darbopoetin alpha are synthetic versions of erythropoietin, and can stimulate the body to produce more red blood cells. They are both given as a subcutaneous self-injection.

Darboepotin alpha is a new erythropoiesis-stimulating protein. Its long acting pharmacokinetics allow for subcutaneous injections to be given every 14 days. The use of Darboepotin alpha(Aranesp ®) in the oncology setting in Canada is relatively new (January 2005).

Focus on Epoetin alpha and SCEPO:
Epoetin alpha is a recombinant human erythropoietin, a synthetic version of erythropoietin. It is approved for use in Canada for cancer-related anemia. Epoetin alpha is given as a subcutaneous self-injection at either one of the following dosing regimens as recommended by the BCCA protocol SCEPO "BCCA protocol summary guidelines for selecting and monitoring oncology patients for Epoetin Alpha (erythropoietin) therapy":
1) 10,000 units sc three times weekly, or
2) 40,000 units sc once weekly

The target Hgb level is 120g/L (as per SCEPO protocol) but this can take weeks to achieve. Epoetin alpha is effective in increasing hemoglobin levels in some but not all patients, and for those responsive patients, it can decrease the need for blood transfusions. If an initial response is not seen within 4 weeks, the dose can be increased but it should be noted that there are some patients who just do not respond.

Epoetin alpha is generally well tolerated but side effects can include redness, pain and tenderness at the site of injection, as well as flu-like symptoms (weakness, fever, muscle and joint pain). The flu-like symptoms usually disappear on their own. Patients can also experience diarrhea, headaches, and high blood pressure. In rare cases, patients can develop an allergic reaction manifested by dizziness, fast heartbeat, face swelling or breathing problems.

Two other rare adverse effects that can occur are: blood clots and an immune reaction.
- Blood clots: if the patient's hemoglobin is on the high-normal side, the risk of developing thrombo-embolic complications is significant. Adjusting the dose of erythropoietin to maintain the hemoglobin level between 120 and 130 g/L reduces the risk of thrombo-embolic complications.
- Immune Reaction: in these rare cases, patients develop an immune reaction that leads to destruction of red blood cell precursors, causing the anemia to worsen.

Epoetin alpha is available as pre-filled syringes (10,000 units or 40,000 units) or in a multi-use vial (20,000 units/vial). The medication needs to be stored in the refrigerator. Once the patient has obtained the drug, the patient (or family member) can be taught how to self-inject. If this is not an option, the injection can also be administered by the family physician or community home care nurse.

Epoetin Alpha and Darbopoetin Alpa require a prescription from the physician but are **not BCCA benefit drugs** and must be filled at a community pharmacy. The patient is responsible for the cost of the drug. This is expensive, so it is advisable for the patient to have a financial assessment done prior to filling the prescription. Patient and family counselling departments within the BCCA can answer questions about this process. Patients can also call the Ortho-Biotec Eprex Assistance program (RxEPREX toll free number: 1-877-793-7739) or for Darbopoetin Alpha (Victory Program 1-888-706 4717) These services are available 24 hours a day, 7 days a week. Reimbursement specialists are available to help patients explore options for financial assistance.

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Useful Links:

1. Oncology nursing society (USA) http://www.cancersymptoms.org.
2. American Cancer Society: http://www.cancer.org.
3. BC Cancer Agency website: www.bc.cancer.bc.ca
   - http://www.bccancer.bc.ca/HPI/Nursing/Education/BCCA/JIT/Fatigue.htm.
   - http://www.bccancer.bc.ca/HPI/DrugDatabase/DrugIndexPt/epoetinalfa.htm
   - http://www.bccancer.bc.ca/PPI/PSMPC/Fatigue/default.htm
   - http://www.bccancer.bc.ca/HPI/CancerManagementGuidelines/SupportiveCare/Epoetin+for+Anemia.htm
5. Anemia Institute for Research and Education, www.anemiainstitute.org
6. "Biobehavioral and Sociocultural Dimensions of Cancer – Related Fatigue" Case Study found at: http://www.ons.org/publications/journals/ONF/Volume32/Issue2/3202237.asp
7. CANO Webcast "Anemia & Fatigue: More than just "pale" and "tired". Available at www.cos.ca/cano.
8. ONS resource area: http://onsopcontent.ons.org/Toolkits/Fatigue/ce.shtml
9. ONS patient information: http://www.cancersymptoms.org/fatigue/index.shtml
10. NCCN Fatigue clinical practice guidelines, 2005 @ www.nccn.org

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Editor's note:

Here are some other resources on this area which are available from the BC Cancer Agency Library:

For healthcare professionals:

1. **Recombinant human erythropoietin (rhEPO) in clinical oncology: scientific and clinical aspects of anemia in cancer** / Nowrousian, M. R
2. **Therapeutic approaches to anemia** / Oncology Interactive Education Series | Jack Digital Productions | Princess Margaret Hospital
3. **Fatigue in cancer: a multidimensional approach** / Winningham, Mary L | Burke, Margaret Barton
4. **Fatigue in patients with cancer: analysis and assessment** / Glaus, A

For patient or public:

1. **Your bank to energy savings: how people with cancer can handle fatigue** / Canadian Association of Nurses in Oncology (CANO) this is in the reference list
2. **To be or not to be fatigued** / Northwestern Ontario Regional Cancer Centre

CANCER DRUG MANUAL

Several drug monographs and patient information handouts have been revised.

Dexrazoxane Monograph and Patient Information

This is a new drug monograph and patient information handout. Dexrazoxane is a BCCA benefit drug for pediatric patients with metastatic osteosarcoma treated on the Children's Oncology Group study. It is

occasionally used as a cardioprotectant against doxorubicin-induced cardiotoxicity via undesignated indication request.

Cyclophosphamide Monograph and Patient Information
This has been completely updated.

Interferon Patient Information for Bladder Instillation
On June 1, a new protocol using combination intravesical BCG and interferon was introduced (GUBCGIFN) for palliative therapy of bladder cancer. Single-agent intravesical interferon has been used rarely in the treatment of bladder cancer, since it is less effective than single-agent BCG. With the advent of combination therapy, increased use of intravesical interferon and a need for patient information are anticipated. There will now be two patient handouts for interferon: "interferon injection" and "interferon for bladder." The side effects sections of the handouts differ significantly, as patients treated with intravesical interferon experience less systemic toxicity.

Interferon Monograph
This has been updated to include information related to the GUBCGIFN protocol. Ready-to-use interferon contains preservatives that may inactivate BCG; this drug interaction has been noted in the monograph, along with instructions to use only the lyophilized powder formulation of interferon for combination therapy. Intravesical administration and dosing information has been added to the monograph.

Trastuzumab Monograph
This has been revised to clarify administration and observation time. The previous monograph stated that trastuzumab should be given "over 90 min for loading dose and over 30 min for subsequent doses." It should be noted that this applies to weekly trastuzumab only. For 3-weekly trastuzumab, all doses are given over 90 minutes. Also, the observation period is not required after 3 treatments with no reaction (i.e.,not after cycle 2).

PATIENT EDUCATION

Patient Information Handouts for several cancer drugs have been introduced. These include ***dexrazoxane*** (new), ***cyclophosphamide*** (completely updated), ***interferon*** (new handout for bladder instillation).

CANCER MANAGEMENT GUIDELINES

The ***Lung Tumour Group*** has revised the management guidelines for adjuvant chemotherapy of non-small cell lung cancer and palliative treatment of malignant mesothelioma.

Non-Small Cell Lung Cancer This now includes recent evidence to recommend platinum-based adjuvant chemotherapy in the management of completely resected (stage IB, II, IIIA) non-small cell lung cancer. The BCCA protocols used for this indication are the combination regimens of ***carboplatin*** and ***paclitaxel*** (LUAJCAT) and ***cisplatin*** and ***vinorelbine*** (LUAJNP).

Malignant Mesothelioma This now includes recent evidence to support the use of ***pemetrexed*** with ***platinum*** (protocol LUMMPPEM). This combination regimen has been shown to prolong survival.

LIST OF NEW AND REVISED PROTOCOLS

The **BC Cancer Agency Protocol Summaries** are revised on a periodic basis. New and revised protocols for this month are listed below. Protocol codes for treatments requiring “Undesignated Indication” approval are prefixed with the letter **U**.

New protocol:

- **(U)LUAVERL** new: Treatment of advanced non-small cell lung cancer (NSCLC) with erlotinib (Tarceva®)

Revised protocols:

- **BRAJACTT** revised (observation time removed): Adjuvant therapy for breast cancer using doxorubicin and cyclophosphamide followed by paclitaxel and trastuzumab
- **BRAJTR** revised (observation time removed): Adjuvant therapy for breast cancer using trastuzumab (Herceptin®) following the completion of chemotherapy (sequential)
- **BRAVTPC** revised (observation time removed, GFR clarified): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®), paclitaxel and carboplatin as first-line treatment for recurrent breast cancer
- **BRAVTR** revised (observation time removed): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®)
- **BRAVTRAD** revised (observation time removed): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and docetaxel as first-line treatment for recurrent breast cancer
- **BRAVTRAP** revised (observation time removed): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and paclitaxel as first-line treatment for recurrent breast cancer
- **BRAVTRNAV** revised (observation time removed): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and vinorelbine
- **BRJACTTG** revised (observation time removed): Adjuvant therapy for breast cancer using dose dense therapy: doxorubicin and cyclophosphamide followed by paclitaxel and trastuzumab
- **BRLAACDT** revised (observation time removed): Treatment of locally advanced breast cancer using doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab

LIST OF NEW AND REVISED PRE-PRINTED ORDERS

The **INDEX to BC Cancer Agency Pre-printed Orders** are revised on a periodic basis. New and revised pre-printed orders for this month are listed below.

- **BRAJACTT** revised (observation time removed): Adjuvant therapy for breast cancer using doxorubicin and cyclophosphamide followed by paclitaxel and trastuzumab
- **BRAJTR** revised (observation time removed): Adjuvant therapy for breast cancer using trastuzumab (Herceptin®) following the completion of chemotherapy (sequential)
- **BRAVTPC** revised (observation time removed): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®), paclitaxel and carboplatin as first-line treatment for recurrent breast cancer
- **BRAVTR** revised (observation time removed): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®)
- **BRAVTRAD** revised (observation time removed): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and docetaxel as first-line treatment for recurrent breast cancer
- **BRAVTRAP** revised (observation time removed): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and paclitaxel as first-line treatment for recurrent breast cancer
- **BRAVTRNAV** revised (observation time removed): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and vinorelbine
- **BRJACTTG** revised (observation time removed, labs clarified): Adjuvant therapy for breast cancer using dose dense therapy: doxorubicin and cyclophosphamide followed by paclitaxel and trastuzumab
- **BRLAACDT** revised (observation time removed, trastuzumab dosing schedule clarified): Treatment of locally advanced breast cancer using doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab
- **ULUAVERL** new: Treatment of advanced non-small cell lung cancer (NSCLC) with erlotinib (Tarceva®)

CONTINUING EDUCATION – MARK YOUR CALENDAR

- **2-5 October 2005**: Annual Canadian Association of Nurses in Oncology Conference, Moncton, New Brunswick (www.cos.ca/cano) – registration now open
- **23-26 October 2005**: 1st International Cancer Control Congress, Pan Pacific Hotel, Vancouver, BC (www.cancercontrol.org)
- **28-30 October 2005**: National Oncology Pharmacy Symposium, Sheraton Wall Centre, Vancouver, BC (http://capho.ca/) – registration and poster submission now open

- **3-5 November 2005**: BCCA Annual Cancer Conference, Westin Bayshore 1601 Bayshore Drive, Vancouver, BC (www.bccancer.bc.ca/HPI/AnnualConference/default.htm) – registration and poster submission now open

WEBSITE RESOURCES

Reimbursement and Forms: The current Benefit Drug List, Class II forms and Undesignated Indication Application forms are available on the BC Cancer Agency website under Health Professionals Info, Chemotherapy Protocols, Frequently Used Forms (http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms.htm).

Cancer Drug Manual is available on the BC Cancer Agency website www.bccancer.bc.ca/cdm/.

Cancer Management Guidelines are available on the BC Cancer Agency website (http://www.bccancer.bc.ca/CaMgmtGuidelines/) under Health Professionals Info, Cancer Management Guidelines.

The Cancer Chemotherapy Protocols are available on the BC Cancer Agency website (www.bccancer.bc.ca/ChemoProtocols) under Health Professionals Info, Chemotherapy Protocols.

The Cancer Chemotherapy Pre-Printed Orders are available on the BC Cancer Agency website (www.bccancer.bc.ca/ChemoProtocols) under Health Professionals Info, Chemotherapy Protocols. Pre-Printed Orders are posted at the index page of each tumour site.

Provincial Systemic Therapy Program Policies are available on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Chemotherapy Protocols, Policies and Procedures.

The Unconventional Cancer Therapies Manual is available on the BC Cancer Agency website www.bccancer.bc.ca under Patient/Public Info, Unconventional Therapies.

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Pharmacy Professional Practice	Ext 2247	gconcon@bccancer.bc.ca
Provincial Systemic Therapy Program	Ext 2247	gconcon@bccancer.bc.ca
Communities Oncology Network Pharmacist	Ext 6277	jbarnett@bcancer.bc.ca
Drug Information	Ext 6275	druginfo@bccancer.bc.ca
Library / Cancer Information	1-888-675-8001 Ext 8001	requests@bccancer.bc.ca
OSCAR Hotline	1-888-355-0355	
Update Editor	Ext 2288	mdelemos@bccancer.bc.ca
Centre for the Southern Interior (CCSI)	(250) 712-3900	Toll-Free 1-(888) 563-7773
Fraser Valley Centre (FVCC)	(604) 930-2098	Toll-Free 1-(800) 523-2885
Vancouver Centre (VCC)	(604) 877-6000	Toll-Free 1-(800) 663-3333
Vancouver Island Centre (VICC)	(250) 519-5500	Toll-Free 1-(800) 670-3322