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for health professionals who care for cancer patients Website access at http://www.bccancer.bc.ca/STUpdate/

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INSIDE THIS ISSUE

- Editor's Choice: New Treatment Protocols
- Highlights of Revised Protocols
- Cancer Drug Manual Carmustine
- <u>Patient Education</u> Prevention of Osteoporosis in Women with Breast Cancer; Update on Unconventional Cancer Therapies Manual
- Continuing Education BC Cancer Agency Annual Cancer Conference; Managing Pain: A Continuing Challenge
- Focus on Pharmacy Procedures Pharmacy Procedures for Sterile Product Preparation: A Video Review
- List of New and Revised Protocols:
- List of New and Revised Pre-Printed Orders:
- Website Resources: Reimbursement and Forms;
 <u>Patient Education; Cancer Management Guidelines;</u>
 <u>Provincial Systemic Therapy Policies;</u> Unconventional Cancer Therapies Manual

FAX request form and IN TOUCH phone list are provided if additional information is needed.

EDITOR'S CHOICE

NEW TREATMENT PROTOCOLS

The **Breast** Tumour Group has introduced a new protocol using **goserelin** with **tamoxifen** (BRAJGT). This is a combination endocrine adjuvant therapy in pre-menopausal hormone receptor positive early breast cancer in women who turn down adjuvant chemotherapy. This new indication is partly based on recent randomized controlled data showing the equivalence (and possible superiority) of this combination endocrine therapy to CMF chemotherapy regimen.

The **Lymphoma** Tumour Group has introduced a new protocol using **rituximab** in combination with **fludarabine** (LYFLUDR) for chronic lymphocytic leukemia (CLL). This new combination regimen is partly based on recent randomized controlled data involving a total of 104 patients with previously untreated CLL. Patients were randomized to either 6 monthly courses of fludarabine concurrently with rituximab followed 2 months later by 4 weekly doses of rituximab for consolidation therapy or sequential fludarabine alone followed 2 months later by rituximab consolidation therapy. With a median follow-up of 23 months, the concurrent regimen was associated with higher rate in overall response (90% vs. 77%) and complete response (47% vs. 28%).

The **BCCA EPO Committee** has introduced guidelines on the use of **epoetin alfa** (**erythropoietin**) in the management of cancer-related anemia (SCEPO). This provides information on patient selection, dosing and monitoring parameters for patients who are to be treated with epoetin. Note that epoetin alfa is not a BC Cancer Agency benefit drug and is not covered by any BCCA program. Patients being treated with this agent should have prescriptions filled at a community pharmacy and must arrange their own payment for the drug. Some assistance in this regard is available through the Eprex Assistance Program at 1-877-RX-EPREX (1-877-793-7739).

HIGHLIGHTS OF REVISED PROTOCOLS

The **Breast Tumour Group** has revised a number of chemotherapy protocols to specify baseline and routine bloodwork for platelet count. This is to facilitate the dosing adjustment of the agents for various severity of thrombocytopenia. See under the List of New and Revised Protocols to find out which protocols are affected.

The **Lung** Tumour Group has revised a number of cisplatin-based protocols to provide dose modification based on creatinine clearance. Creatinine clearance is expected to be a more accurate reflection of renal function, thus it is preferred over the use of serum creatinine. See under the List of New and Revised Protocols to find out which protocols are affected.

CANCER MANAGEMENT GUIDELINES

Prevention of Osteoporosis in Women A patient guideline has been developed by the Breast Tumour Group for the prevention of osteoporosis. Postmenopausal women have an increased risk of osteoporosis. This risk can be increased further by factors such as family history, smoking, diet, early menopause, chemotherapy, long term corticosteroids and some hormonal therapies that lower estrogen. The new patient guideline provides information regarding diet and lifestyle modifications for breast cancer patients and survivors to help with the prevention of osteoporosis.

<u>Chemotherapy-Induced Diarrhea</u> A management guideline has been developed for the management of chemotherapy-induced diarrhea (CID). Patients receiving chemotherapy or radiation are at high risk for developing diarrhea, particularly with chemotherapeutic drugs like irinotecan or 5-fluorouracil (5FU). This side effect often leads to delay in treatment, dose reduction or discontinuation of treatment as well as a small but significant mortality, especially when it occurs concomitantly with mucositis and neutropenia. Prompt management of CID is therefore important for cancer patients.

CANCER DRUG MANUAL

Limited Revision of Carmustine Monograph The monograph has been revised to provide the option of preparing the agent in either glass or polyolefin containers. The previous recommendation was to prepare carmustine in glass containers only. However, there is evidence showing that the rate of loss of carmustine in D5W at room temperature is similar between glass and polyolefin containers (10% in 7.7 hours and 10% in 7 hours, respectively), and is less than in PVC containers (18.5% in 1 hour). Details on this additional option have been added to the carmustine monograph.

PATIENT EDUCATION

Unconventional Cancer Therapies (UCT) The patient information monographs for Antineoplastons, Chaparral Tea, Livingston Therapy and Vitamin A have been updated in the BCCA Unconventional Cancer Therapies Manual, online at www.bccancer.bc.ca/uct.

Prevention of Osteoporosis in Women Information on how to prevent osteoporosis in breast cancer patients and survivors is now available (see under Cancer Management Guidelines for more details).

CONTINUING EDUCATION

BC Cancer Agency Annual Cancer Conference 2004: You can now register for this year's conference, which will be held from **November 25 - 27th**, **2004** at the Westin Bayshore Hotel in Vancouver. Registration fees are: \$150 (until November 24th) and \$200 (25-27 November).

The theme of this year will be "BC: A Living Laboratory - Enhanced Care Through Research at the BCCA", which will focus on new approaches to maintaining the strong cancer control program of the BC Cancer Agency while evolving into a high-performing translational research organization.

The *Partners in Cancer Care* meeting and the *Scientific Fair* will be held respectively on the morning and afternoon of Thursday, November 25th.

The *Clinical Scientific Symposium* will be held on Friday, November 26th. This is open to all healthcare professionals and is an academic, evidence-based exploration of new scientific insights that hold potential to advance cancer care.

In addition, there will be *Provincial Oncology Professionals* education and business meetings held on selected dates on November 25 - 27th for the disciplines listed below.

November 25 th	November 26 th		November 27 th		
Partners in Cancer CarePathologyScientific Fair	Clinical-Scientific Session Nursing Nutrition	 Psychosocial Oncology Pain & Symptom Management Palliative Care 	Family PracticeRadiation TherapyPublic Education Open Session	 Surgical Oncology Oral Oncology Dentistry Symposium Pediatric Oncology Medical Oncology Retreat 	

Other programs will include the *Poster Presentation* and *Clinical Scientific Banquet* (November 26th) and the new *Public Open Education Session* (November 27th).

For more information on the conference, please visit the BC Cancer Agency website www.bccancer.bc.ca.

Managing Pain: A Continuing Challenge. This conference will be held on **November 5th and 6th**, 2004, at the Sheraton Guildford Hotel, Surrey BC. Supported by the Fraser Health Authority and the BC Cancer Agency, this conference is designed for physicians, nurses, pharmacists, social workers, and other interested health professionals who provide care and support to patients/clients and families.

For information and registration, contact Wood and Associates Inc., phone (604) 688-3787, fax (604) 688-5749.

FOCUS ON PHARMACY PROCEDURES FOR STERILE PRODUCT PREPARATION: A VIDEO REVIEW

Pharmacy staff at BCCA's Vancouver Centre (VC) has recently reviewed a video entitled "Pharmacy Procedures for Sterile Product Preparation" and found it to contain useful and well presented information that would make it a valuable training tool. However, the video contains several recommendations and procedures which differ from those of BCCA Pharmacy. The purpose of this review is to identify and explain some of these differences. Please note that the video's recommendations are in italics; BCCA practise and rationale follow.

The 45-minute video (also available as DVD) was developed by the Association des Pharmaciens des Establissements de Sante du Quebec (APES) and the Canadian Society of Hospital Pharmacists. Its production was made possible by Mayne Pharma Canada. It is intended as a reference for Pharmacy staff who prepares cytotoxic, antineoplastic drugs. It assumes previous knowledge of parenteral drug preparation procedures and aseptic techniques. Six common preparation procedures are described in detail, and recommendations are presented on topics such as protective clothing, use and care of the biological safety cabinet (BSC), waste disposal, spill clean-up and accidental self-contamination. Voice-over explanations throughout the procedures are helpful and additional information is provided as text alongside the demonstrations.

Cover gowns:

- wear gowns that are disposable, lint-free, back-closing, long-sleeved, water-repellent at the front, and that have tight-fitting cuffs.

BCCA Pharmacies use gowns that meet the above requirements but, because of its high gown usage, the largest BCCA Centre (VC) uses re-usable cloth gowns with moisture-resistant front and sleeves. A Pharmacy Safe Handling Working Group (PSHWG), composed of BCCA pharmacists and pharmacy technicians, is reviewing gowns used at all BCCA Centres. Its recommendations will be made available to CON hospitals when they are approved.

Gloves:

- double-glove while preparing antineoplastic agents

All BCCA Centre Pharmacies now double-glove, but our written policies and procedures do not yet reflect this change in practice.

Masks:

- wear a surgical mask while handling cytotoxic drugs to prevent contamination of the products being prepared and a respirator mask with a high efficiency filter (e.g. one with an NIOSH N100 rating) while cleaning the BSC

At BCCA, it is not mandatory to wear a mask during drug preparation. Masks are worn while cleaning the BSC, but the type of mask used for this activity is not consistent among all Centres. The PSHWG is reviewing the use of masks in BCCA Pharmacies and their recommendations on this subject will also be made available when approved.

Cleaning the BSC:

- wipe all BSC surfaces with 70% isopropyl alcohol at the beginning and end of each day; wipe the work surface regularly and when a spill occurs ("regularly" is not defined); use detergent and sterile water prior to alcohol during weekly decontamination of the BSC.

At BCCA all inner BSC surfaces are cleaned daily with an aqueous cleaner (e.g. 0.05% chlorhexidine gluconate), then with 70% isopropyl alcohol, since alcohol alone can not adequately dissolve or remove all spills. In addition, the working surface is wiped with a disposable cleansing wipe (e.g. Wet OnesTM) after each dose preparation and with aqueous cleaner and alcohol each time the technician exits the BSC for a work break.

Plastic-backed absorbent pad on BSC work surface:

- place a plastic-backed absorbent pad on the work surface after daily cleaning of the BSC (not indicated how often the pad is to be replaced)

BCCA Pharmacies do not use absorbent pads in the BSC. Any small spills or droplets are more readily seen on the bare surface of a BSC, from which they can be removed immediately. In addition, the working surface of the BSC is cleaned after each preparation and prior to each technician work break (see "Cleaning the BSC" above). Pads create a soft, uneven working surface and may introduce fibres and particles into the BSC. Absorbent pads may be practical in Pharmacies where preparation of cytotoxic drugs occurs at irregular intervals, in which case the pads and used equipment can be bundled up and discarded together after each preparation.

Disinfection of equipment packaging:

The video shows a chemo dispensing pin (CDP) being removed from its outer packaging inside the BSC, apparently without disinfecting the outer packaging surfaces

At BCCA, the outer surfaces of packaged items are sprayed with 70% isopropyl alcohol before the packages are placed into the BSC. Packaged items whose sterile openings are covered by protective caps may be "opened into" the BSC in such a manner that the outer packaging does not enter the work area.

Withdrawal of solution from a vial:

- create and maintain slight negative pressure inside a vial when reconstituting or withdrawing from a vial; exert outward pressure on the syringe plunger while removing the needle from a vial with negative pressure

At BCCA, neutral pressure is maintained inside the vial at all times, by replacing withdrawn solution with an equal amount of air, and withdrawing a volume of air equal to added diluent. We have found that negative pressure inside a vial is as likely as positive pressure to produce aerosols when the needle is removed from the vial. Exerting the precise amount of outward pressure on the syringe plunger while removing the needle from a vial with negative pressure is awkward and difficult, often necessitating subsequent vial re-entry to adjust syringe volume.

Eliminating bubbles and adjusting syringe volume:

- remove a full syringe from the drug vial, attach a needle, eject bubbles into the needle cap, then re-enter the vial if necessary to adjust drug volume

At BCCA, slightly less than the final required volume is first drawn into the syringe then, with the syringe still attached to the vial or CDP, air bubbles are consolidated and injected back into the vial. The vial may continue to be held above the syringe even if a CDP is used, provided that air only, not solution, is injected back into the vial so that the filter is not wetted. The balance of required solution is then withdrawn slowly, avoiding the production of new air bubbles. This one-step, "interim bubble removal" procedure minimizes multiple vial entries and eliminates the need for a needle, thus enhancing both aseptic technique and operator safety.

Dispensing the finished product:

- dispense final products inside sealed plastic bags enclosed within a rigid container.

At BCCA Centres, the large number of doses being dispensed makes the use of rigid outer containers for all doses impractical. Doses are dispensed inside sealed plastic bags, with safety caps on syringes and foil seals over injection ports, and transported over short distances by Pharmacy or Nursing personnel.

The video may be viewed or purchased by contacting Robyn MacKenzie, Territory Manager, Mayne Pharma Canada at 1-800-567-2855, ext. 604, or Robyn.Mackenzie@ca.maynepharma.com).

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BENEFIT DRUG LIST

The following new programs have been funded by the Provincial Systemic Therapy Program effective 1 November 2004:

- Goserelin (class I) and tamoxifen (class I) as adjuvant therapy for breast cancer (BRAJGT)
- Fludarabine (class I) and rituximab (class II) as treatment of chronic lymphocytic leukemia

Where appropriate, a Class II form must be completed and submitted to the Provincial Systemic Therapy Program before the drug will be dispensed at a regional cancer centre or reimbursed to a community hospital.

Ken Swenerton, MD, FRCPC

ACTING PROVINCIAL SYSTEMIC THERAPY PROGRAM LEADER, BC CANCER AGENCY

LIST OF NEW AND REVISED PROTOCOLS

The INDEX to BC Cancer Agency Protocol Summaries is revised monthly (includes tumour group, protocol code, indication, drugs, last revision date and version). Protocol codes for treatments requiring "Undesignated Indication" approval are prefixed with the letter U.

- BRAJGT new: Adjuvant Therapy for Breast Cancer Using Goserelin and Tamoxifen
- **BRAVCAF** revised (baseline and routine bloodwork for platelet): Palliative Therapy for Metastatic Breast Cancer Using Cyclophosphamide, Doxorubicin and Fluorouracil
- **BRAVCAP** revised (baseline and routine bloodwork for platelet): Therapy for Metastatic Breast Cancer Using Capecitabine (Xeloda®)
- **BRAVCMF** revised (baseline and routine bloodwork for platelet): Palliative Therapy for Advanced Breast Cancer using Cyclophosphamide, Methotrexate and Fluorouracil
- **BRAVCMFPO** revised (baseline and routine bloodwork for platelet): Palliative Therapy for Advanced Breast Cancer using Cyclophosphamide (oral), Methotrexate and Fluorouracil
- **BRAVTAX** revised (baseline and routine bloodwork for platelet): Palliative Therapy for Metastatic Breast Cancer using Paclitaxel
- **BRINFCAF** revised (baseline and routine bloodwork for platelet): Therapy for Inflammatory Breast Cancer using Cyclophosphamide, Doxorubicin and Fluorouracil
- **BRLA2** revised (baseline and routine bloodwork for platelet): Therapy for Locally Advanced Breast Cancer using Cyclophosphamide, Doxorubicin and Fluorouracil
- UGOOVCAGE revised (exclusions, tests, treatment dosing, dose modifications): Treatment of Advanced
 Ovarian Cancer in Patients Who Have Progressed or Recurred Following First-line Platinum-based
 Treatment Using Carboplatin and Gemcitabine
- **LUAJEP** revised (dose modification based on creatinine clearance): Adjuvant Cisplatin and Etoposide following Resection of Stage I, II and IIIA Non-Small Cell Lung Cancer
- **LUALTL** revised (dose modification based on creatinine clearance): Therapy for limited stage SCLC using Alternating CAV/EP plus Early Thoracic Irradiation using Cyclophosphamide, Doxorubicin, Vincristine, Etoposide and Cisplatin

- **ULUCISDOC** revised (dose modification based on creatinine clearance): First-Line Treatment for Advanced Non-Small Cell Lung Cancer (NSCLC) with Docetaxel (Taxotere®) and Cisplatin
- **LUCMT1** revised (dose modification based on creatinine clearance): Combined Chemotherapy and Radiation Treatment for Stage 3 Non-Small Cell Lung Cancer
- LUNAVP revised (dose modification based on creatinine clearance): Treatment for Advanced Non-Small Cell Lung Cancer (NSCLC) with Cisplatin and Vinorelbine
- **LUPAVESE** revised (dose modification based on creatinine clearance): Treatment For Extensive Stage Small Cell Lung Cancer (SCLC) With Cisplatin, Doxorubicin, Vincristine And Etoposide (PAVE)
- LUPAVESL revised (dose modification based on creatinine clearance): Treatment For Limited Stage Small Cell Lung Cancer (SCLC) With Cisplatin, Doxorubicin, Vincristine And Etoposide (PAVE), And Cisplatin And Etoposide (EP) Concurrent With Early Thoracic Irradiation
- LUPE revised (dose modification based on creatinine clearance): Palliative Therapy of Selected Solid Tumours using Cisplatin and Etoposide
- **LUPESL** revised (dose modification based on creatinine clearance): Treatment for limited stage small cell lung cancer (SCLC) with etoposide and cisplatin (EP) and early thoracic irradiation
- LYFLUDR new: Treatment of Chronic Lymphocytic Leukemia with Fludarabine and Rituximab
- **SCEPO** new: Guidelines for Selecting and Monitoring Oncology Patients for Epoetin Alfa (Erythropoietin) Therapy

LIST OF NEW AND REVISED PRE-PRINTED ORDERS

Pre-printed orders should always be checked with the most current BC Cancer Agency protocol summaries. The BC Cancer Agency Vancouver Centre has prepared chemotherapy pre-printed orders, which can be used as a guide for reference. An index to the orders can be obtained by Fax-back.

- **BRAVTPC** new: Palliative Therapy for Metastatic Breast Cancer using Trastuzumab (Herceptin®), Paclitaxel and Carboplatin as First-Line Treatment for Recurrent Breast Cancer Refractory to Anthracycline Chemotherapy
- **GIEFUP** revised (wording to Mitomycin in the CHEMOTHERAPY section): Combined modality therapy for locally advanced esophageal cancer using 5 Fluorouracil and Cisplatin
- UMYBORTEZ revised (requirement for day 8 labs deleted): Treatment of Multiple Myeloma with Bortezomib

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).

Patient information handouts for cancer drugs are available on the BC Cancer Agency website (www.bccancer.bc.ca/DrugDatabasePt/) under Health Professionals Info, Cancer Drug Manual, Drug Information for the Patient. For treatment protocol specific information, go to the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Chemotherapy Protocols, Information for the Patient.

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

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

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

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Protocol Summaries: (also available on our website www.bccancer.bc.ca) Index of Protocol Summaries										
BRAJGT	BRAVCAF	□ BRAVO	:AP	BRAVCMF		BRAVCMFPO				
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LUPAVESL	LUPE	LUPES	L	LYFLUDR		SCEPO				
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☐ Benefit Drug List (01 November 2004) ☐ Class 2 Form (01 November 2004)										
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☐ Jan-Dec 2000	☐ Jan-De	ec 2001	☐ Jan-Ded	2002		Jan-Dec 2003				
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