BC Cancer Agency

Systemic Therapy Update

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Website access at http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate.htm

INSIDE THIS ISSUE

EDITOR'S CHOICE

HAVE YOU COMPLETED THE SYSTEMIC THERAPY UPDATE SURVEY?

We need to know if the Systemic Therapy Update is meeting your needs. Please click on the link below which takes you directly to an online survey. It will take you ***only 5 minutes*** to complete and will help us make necessary improvements to the newsletter. You may answer anonymously or enter your email address for a chance to win a prize.

And here is the survey!
http://www.surveymonkey.com/s.asp?u=380522327729

NEW ADJUVANT TRASTUZUMAB PROTOCOL OPTION

The BC Cancer Agency Breast Tumour Group has recently introduced a new adjuvant trastuzumab (HERCEPTIN®) protocol (**BRAJDTFEC**). The protocol and pre-printed order are posted on the website (www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Breast), and a protocol-specific patient handout is in preparation.

There are some key differences between this regimen and other existing adjuvant trastuzumab protocols:

- trastuzumab is given weekly, for 9 weeks only
- trastuzumab is given with docetaxel, *before* anthracyclines
- FEC dosing is different from our existing regimen, ie:

	BRAJDTFEC	**BRAJFEC**
Epirubicin	60 mg/m^2	100 mg/m^2
Fluorouracil	600 mg/m^2	500 mg/m^2
Cyclophosphamide	600 mg/m^2	500 mg/m^2
Number of cycles	*3*	*6*

The new protocol is identical to the regimen tested in the FinHer trial.[1] This trial compared docetaxel vs. vinorelbine for 9 weeks, with each arm followed by 9 weeks of FEC. In the subset of Her2/neu overexpressing

cancers (N=232), it also compared the same two arms with or without weekly trastuzumab during the first 9 weeks only. This brief treatment with trastuzumab produced the same relative benefit in relapse-free survival as the larger North American Intergroup, BCIRG, and BIG (HERA) trials, all evaluating a full year of trastuzumab (hazard ratio for recurrence or death 0.42).

It is not recommended that this new protocol supplant use of the 1-year trastuzumab regimens in most patients with Her2/neu overexpression, given the smaller number of patients studied. However, it may be reasonable for individuals with otherwise relatively low risk tumours: e.g., T1a or T1b, node negative, +/- ER positive, and without significant lymphovascular invasion (LVI), who might not otherwise have been recommended chemotherapy, prior to the adjuvant trastuzumab era. Another group that may be appropriate are those for whom one year of trastuzumab may pose excessive cardiac risks or severe logistical difficulties due to geography or other reasons.

It should be noted that all doses have been maintained as reported in the published clinical trial, and therefore deviate slightly from our existing protocols. Differences in FEC dosing are noted in the table above. Docetaxel dosing for the new protocol is given as a range of 80-100 mg/m^2. In the clinical trial, the initial docetaxel dose tested was 100 mg/m^2, but due to excessive toxicity in many patients, this was amended to 80 mg/m^2. The treating oncologist should exercise discretion in selecting an initial dose, depending on patient status.

For more details about this new protocol, please contact Dr. Susan Ellard (sellard@bccancer.bc.ca).

Reference:
1. Joensuu H. et al. Adjuvant docetaxel or vinorelbine with or without trastuzumab for breast cancer. New Engl J Med 2006;354:809-20.

CANCER DRUG MANUAL

2006 Acknowledgements As we begin a new year, the Cancer Drug Manual staff would like to extend sincere appreciation to the Editorial Board and the expert reviewers for sharing their time and expertise in support of the Cancer Drug Manual throughout the year.

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The multidisciplinary and multi-centre nature of our board ensures the quality and usefulness of the Cancer Drug Manual for health professionals across the province. Quorum for our monthly meetings requires the presence of

at least one nurse, one physician, and one pharmacist. If you are interested in knowing more about the Cancer Drug Manual Editorial Board, please contact:

- Mário de Lemos: Cancer Drug Manual Editor, 604-877-6098, local 2288, mdelemos@bccancer.bc.ca

Currently, we are looking for **two nurses** to serve on the Board. If you are interested, please contact either Mário de Lemos (see above) or Karen Janes: Regional Professional Practice/Academic Leader, Nursing, 604-877-6098, local 2622, kjanes@bccancer.bc.ca.

Submitted by:
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Tanya Leduc (Writer)
Anne Dar Santos (Writer)
Gigi Concon (Editorial Assistant)
Sarah Jennings (Assistant Editor)
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Cancer Drug Manual Staff
BC Cancer Agency

Sunitinib Monograph and Patient Handout These have been developed for this new agent. Expert review was provided by Dr. Christian Kollmannsberger (Genitourinary Tumour Group). Sunitinib is currently licensed for use in the treatment of gastrointestinal stromal tumour (GIST) after failure of imatinib, and for metastatic renal cell carcinoma after failure of cytokine therapy. At present, sunitinib is not on the benefit list of the BC Cancer Agency. Physicians must obtain approval via the BC Cancer Agency Compassionate Access Program (CAP), after which the First Resource program can assist patients with financial coverage for sunitinib (see special ordering process on our website www.bccancer.bc.ca/HPI/ChemotherapyProtocols/sapchart). Also see **DRUG UPDATE** in the September 2006 issue of Systemic Therapy Update for a brief summary on sunitinib.

Asparaginase Monograph and Patient Handout have been completely revised. Expert review was provided by Dr. Kevin Song (Leukemia/BMT Program of BC). The three formulations, asparaginase, Erwinia asparaginase and pegaspargase were combined into one monograph and handout. The important distinction among the three is hypersensitivity potential. Asparaginase therapy can be continued despite an asparaginase allergic reaction with the substitution of Erwinia asparaginase or pegaspargase. There are differences in other side effects as well, and in general, pegaspargase toxicities occur later and are less severe than with the other two formulations. Both Erwinia asparaginase and pegaspargase are available through the Health Canada SAP, while asparaginase is once again marketed in Canada (from Opi). All three formulations have been included in the BC Cancer Agency Chemotherapy Preparation and Stability Chart.

Imatinib Monograph and Patient Handout A drug interaction with levothyroxine has been added. Imatinib may increase thyroid-stimulating hormone (TSH) levels and/or increase hepatic clearance of levothyroxine. Monitor thyroid function and adjust levothyroxine dose as appropriate when starting or changing imatinib therapy.

Pegylated Liposomal Doxorubicin (CAELYX®) Monograph Dosing recommendations have been added for patients with hepatic dysfunction.

CLINICAL TRIALS RESEARCH: PILOT STUDY OF ON-LINE SUPPORT FOR BREAST CANCER PATIENTS

A new BC Cancer Agency pilot study will provide breast cancer patients with training to learn new coping skills and to participate in counsellor-led online support groups from their home computers. The goal of the study is to increase support, and improve the quality of life for young breast cancer survivors post-treatment. The study is suitable for patients living in smaller centres, and patients reaching the end of their primary treatment. To be eligible for the study, participants must fit the following criteria:

- women 45 years or younger,
- living in British Columbia or the Yukon, particularly outside of large urban areas,
- within 3 years of diagnosis for invasive breast cancer, and

- have completed primary treatment.

Participants will be randomly selected to join one of two groups:
1) self-directed at-home coping skills program consisting of a workbook and instructional CD teaching problem solving, goal setting, communication and relaxation techniques,
2) self-directed at-home coping skills program plus 10 sessions of an online support group led by a counsellor.

The study begins in February 2007 and groups will be offered over two years. To obtain study flyers for your clinic or for more information, please contact:
- Principle Investigator: Dr. Joanne Stephen at 604-930-4000 ext 4505 or jstephen@bccancer.bc.ca.
  Or
- Study Coordinator: Jennifer Macdonald at 604-930-4000 ext 4589 or jmacdonald3@bccancer.bc.ca.

HIGHLIGHTS OF CHANGES IN PROTOCOL AND PRE-PRINTED ORDER

The ***Gastrointestinal Tumour Group*** has introduced several changes:

- *New Adjuvant Regimen for Colon Cancer*: the **GIAJFL** protocol is based on the de Gramont fluorouracil (5FU) regimen (bolus/infusional 5FU plus leucovorin, given every two weeks) and replaces the GIFFAD protocol ("Mayo" daily bolus 5FU/leucovorin). GIAJFL is the third option for adjuvant treatment of colon cancer and may be used for patients intolerant of oral capecitabine (GIAJCAP) or FOLFOX therapy (UGIAJFFOX), or patients more suitable for IV rather than oral therapy.
- *New Regimen for Advanced Colorectal Cancer*: the **GIAVFL** protocol is also based on the de Gramont 5FU regimen. It is an additional option to the weekly infusional 5FU regimen (GIFUINF) for patients who are not candidates or intolerant of capecitabine or "doublet" chemotherapy regimen.
- *Leucovorin Infusion Time Revised*: this has been shortened from 120 to 90 minutes for FOLFIRI-based regimens (**GIFOLFIRI**, **UGIFFIRB**) to facilitate the concurrent infusion of irinotecan and leucovorin.

LIST OF NEW AND REVISED PROTOCOLS, PRE-PRINTED ORDERS AND PATIENT HANDOUTS

The **BC Cancer Agency Protocol Summaries, Provincial Pre-Printed Orders (PPPOs) and Patient Handouts** are revised periodically. New and revised protocols, PPPOs and patient handouts for this month are listed below. Protocol codes for treatments requiring "Compassionate Access Program" approval are prefixed with the letter **U**.

New protocols, PPPOs and Patient Handouts (affected documents are checked):

Code	Protocol	PPPO	Patient Handout	Protocol Name
GIAJFL	☑	☑	☐	Adjuvant Therapy of Colon Cancer using Fluorouracil Injection and Infusion and Folinic Acid (Leucovorin) Infusion
GIAVFL	☑	☑	☐	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using 5-Fluorouracil Injection and Infusion and Folinic Acid (Leucovorin) Infusion

Revised protocols and PPPOs (affected documents are checked):

Code	Protocol	PPPO	Changes	Protocol Name
BRAVGEMD	☑	☑	*Docetaxel administration volumes clarified*	Palliative Therapy for Metastatic Breast Cancer using Gemcitabine and Docetaxel
GIFFAD	☑	☑	*Deleted (replaced by GIAJFL)*	Adjuvant Therapy for Stage III and High Risk Stage II Colon Cancer using Leucovorin and Fluorouracil.

Code	Protocol	PPPO	Changes	Protocol Name
UGIFFIRB	☑	☑	*Leucovorin (folinic acid) infusion time revised*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Fluorouracil, Folinic Acid (Leucovorin) and Bevacizumab
GIFOLFIRI	☑	☑	*Leucovorin (folinic acid) infusion time revised*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Fluorouracil and Folinic Acid (Leucovorin).
GIFUA	☑	☐	*Precautions amended*	Combined Modality Curative Therapy for Carcinoma of the Anal Canal using Mitomycin, Infusional Fluorouracil and Radiation Therapy
GIFURC	☐	☑	*Return appointment orders revised*	Combined Modality Adjuvant Therapy for High Risk Rectal Carcinoma using Fluorouracil, Folinic Acid (Leucovorin), Capecitabine and Radiation Therapy
GOSMCC2	☑	☐	*Carboplatin dosing formula clarified*	Treatment of Small Cell Carcinoma of Cervix using Paclitaxel, Cisplatin, Etoposide and Carboplatin with Radiation (GO 95 02)
LYCDA	☑	☐	*Dose reduction clarified*	Treatment of Hairy Cell Leukemia with Cladribine
LYCODOXMR	☑	☑	*Title clarified, intrathecal methotrexate deleted from PPPO*	Treatment of Burkitt Lymphoma and Leukemia (ALL-L3) with Cyclophosphamide, Vincristine, Doxorubicin, Methotrexate, Leucovorin (CODOX-M) and Rituximab
LYIVACR	☑	☑	*Title clarified, PPPO reformatted*	Treatment of Burkitt Lymphoma and Leukemia (ALL-L3) with Ifosfamide, Mesna, Etoposide, Cytarabine (IVAC) and Rituximab

NURSING RESOURCES OF THE MONTH

Articles of the month:

- Boehmke MM, Dickerson SS. The diagnosis of breast cancer: transition from health to illness. Oncology Nursing Forum 2006;33(6):1121-7.
- Huber C, Ramnarace T, McCaffrey R. Sexuality and intimacy issues facing women with breast cancer. Oncology Nursing Forum 2006;33(6):1163-7. (*This article also poses 6 questions for use in a journal club or discussion group.*)

WEBSITE RESOURCES

The following are available on the BC Cancer Agency website (www.bccancer.bc.ca) under the Health Professionals Info section:

Reimbursement and Forms: Benefit Drug List, Class II, Compassionate Access Program (Undesignated Indication)	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms
Cancer Drug Manual	www.bccancer.bc.ca/cdm
Cancer Management Guidelines	www.bccancer.bc.ca/CaMgmtGuidelines
Cancer Chemotherapy Protocols	www.bccancer.bc.ca/ChemoProtocols
Cancer Chemotherapy Pre-Printed Orders	www.bccancer.bc.ca/ChemoProtocols under the index page of each tumour site
Systemic Therapy Program Policies	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies
Unconventional Cancer Therapies Manual	under Patient/Public Info, Unconventional Therapies

IN TOUCH	www.bccancer.bc.ca	bulletin@bccancer.bc.ca
BC Cancer Agency	(604) 877-6000	Toll-Free 1-(800) 663-3333
Communities Oncology Network	Ext 2744	jvenkate@bccancer.bc.ca
Education Resource Nurse	Ext 2638	nursinged@bccancer.bc.ca
Nursing Professional Practice	Ext 2623	ilundie@bccancer.bc.ca
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	lkovacic@bcancer.bc.ca
Drug Information	Ext 6275	druginfo@bccancer.bc.ca
Library/Cancer Information	1-888-675-8001 Ext 8003	requests@bccancer.bc.ca
OSCAR Help Desk	1-888-355-0355 Fax (604) 708-2051	oscar@bccancer.bc.ca
Compassionate Access Program office (formerly Undesignated Drug Application office)	Ext 6277 Fax (604) 708-2026	cap_bcca@bccancer.bc.ca
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