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:

<table>
<thead>
<tr>
<th></th>
<th>BRAJDTFEC</th>
<th>BRAJFEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epirubicin</td>
<td>60 mg/m²</td>
<td>100 mg/m²</td>
</tr>
<tr>
<td>Fluorouracil</td>
<td>600 mg/m²</td>
<td>500 mg/m²</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>600 mg/m²</td>
<td>500 mg/m²</td>
</tr>
<tr>
<td>Number of cycles</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

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:

**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:
Linda Hamata (Writer) Gigi Concon (Editorial Assistant)
Tanya Leduc (Writer) Sarah Jennings (Assistant Editor)
Anne Dar Santos (Writer) Mário de Lemos (Editor)
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, UGIFIRB) 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):

<table>
<thead>
<tr>
<th>Code</th>
<th>Protocol</th>
<th>PPPO</th>
<th>Patient Handout</th>
<th>Protocol Name</th>
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<tbody>
<tr>
<td>GIAJFL</td>
<td>✓</td>
<td>✓</td>
<td>☐</td>
<td>Adjuvant Therapy of Colon Cancer using Fluorouracil Injection and Infusion and Folinic Acid (Leucovorin) Infusion</td>
</tr>
<tr>
<td>GIAVFL</td>
<td>✓</td>
<td>✓</td>
<td>☐</td>
<td>Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using 5-Fluorouracil Injection and Infusion and Folinic Acid (Leucovorin) Infusion</td>
</tr>
</tbody>
</table>

**Revised protocols and PPPOs** (affected documents are checked):

<table>
<thead>
<tr>
<th>Code</th>
<th>Protocol</th>
<th>PPPO</th>
<th>Changes</th>
<th>Protocol Name</th>
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</thead>
<tbody>
<tr>
<td>BRAVGEMD</td>
<td>✓</td>
<td>✓</td>
<td><em>Docetaxel administration volumes clarified</em></td>
<td>Palliative Therapy for Metastatic Breast Cancer using Gemcitabine and Docetaxel</td>
</tr>
<tr>
<td>GIFFAD</td>
<td>✓</td>
<td>✓</td>
<td>Deleted (replaced by GIAJFL)</td>
<td>Adjuvant Therapy for Stage III and High Risk Stage II Colon Cancer using Leucovorin and Fluorouracil.</td>
</tr>
<tr>
<td>Code</td>
<td>Protocol</td>
<td>PPPO</td>
<td>Changes</td>
<td>Protocol Name</td>
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<td>----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>UGIFIRB</td>
<td>☑</td>
<td>☑</td>
<td>Leucovorin (folinic acid) infusion time revised</td>
<td>Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Fluorouracil, Folinic Acid (Leucovorin) and Bevacizumab</td>
</tr>
<tr>
<td>GIFOLIRI</td>
<td>☑</td>
<td>☑</td>
<td>Leucovorin (folinic acid) infusion time revised</td>
<td>Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Fluorouracil and Folinic Acid (Leucovorin).</td>
</tr>
<tr>
<td>GIFUA</td>
<td>☑</td>
<td>☐</td>
<td>Precautions amended</td>
<td>Combined Modality Curative Therapy for Carcinoma of the Anal Canal using Mitomycin, Infusional Fluorouracil and Radiation Therapy</td>
</tr>
<tr>
<td>GIFURC</td>
<td>☐</td>
<td>☑</td>
<td>Return appointment orders revised</td>
<td>Combined Modality Adjuvant Therapy for High Risk Rectal Carcinoma using Fluorouracil, Folinic Acid (Leucovorin), Capecitabine and Radiation Therapy</td>
</tr>
<tr>
<td>GOSMCC2</td>
<td>☑</td>
<td>☐</td>
<td>Carboplatin dosing formula clarified</td>
<td>Treatment of Small Cell Carcinoma of Cervix using Paclitaxel, Cisplatin, Etoposide and Carboplatin with Radiation (GO 95 02)</td>
</tr>
<tr>
<td>LYCDA</td>
<td>☑</td>
<td>☐</td>
<td>Dose reduction clarified</td>
<td>Treatment of Hairy Cell Leukemia with Cladribine</td>
</tr>
<tr>
<td>LYCODOXMR</td>
<td>☑</td>
<td>☑</td>
<td>Title clarified, intrathecal methotrexate deleted from PPPO</td>
<td>Treatment of Burkitt Lymphoma and Leukemia (ALL-L3) with Cyclophosphamide, Vincristine, Doxorubicin, Methotrexate, Leucovorin (CODOX-M) and Rituximab</td>
</tr>
<tr>
<td>LYIVACR</td>
<td>☑</td>
<td>☑</td>
<td>Title clarified, PPPO reformatted</td>
<td>Treatment of Burkitt Lymphoma and Leukemia (ALL-L3) with Ifosfamide, Mesna, Etoposide, Cytarabine (IVAC) and Rituximab</td>
</tr>
</tbody>
</table>

**NURSING RESOURCES OF THE MONTH**

- 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:

<table>
<thead>
<tr>
<th>Resource</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reimbursement and Forms: Benefit Drug List, Class II, Compassionate Access Program (Undesignated Indication)</td>
<td><a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms</a></td>
</tr>
<tr>
<td>Cancer Drug Manual</td>
<td><a href="http://www.bccancer.bc.ca/cdm">www.bccancer.bc.ca/cdm</a></td>
</tr>
<tr>
<td>Cancer Management Guidelines</td>
<td><a href="http://www.bccancer.bc.ca/CaMgmtGuidelines">www.bccancer.bc.ca/CaMgmtGuidelines</a></td>
</tr>
<tr>
<td>Cancer Chemotherapy Protocols</td>
<td><a href="http://www.bccancer.bc.ca/ChemoProtocols">www.bccancer.bc.ca/ChemoProtocols</a></td>
</tr>
<tr>
<td>Cancer Chemotherapy Pre-Printed Orders</td>
<td><a href="http://www.bccancer.bc.ca/ChemoProtocols">www.bccancer.bc.ca/ChemoProtocols</a> under the index page of each tumour site</td>
</tr>
<tr>
<td>Systemic Therapy Program Policies</td>
<td><a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies</a></td>
</tr>
<tr>
<td>Unconventional Cancer Therapies Manual</td>
<td>under Patient/Public Info, Unconventional Therapies</td>
</tr>
</tbody>
</table>