

The Canadian Association of Pharmacy in Oncology

Association Canadienne de Pharmacie en Oncologie



A word from the President

Hello to all CAPHO members.

Summer is here and some of us are either on vacation or thinking about it. Despite that, there are still things happening with your association.

Autumn and NOPS are just around the corner and will be upon us soon in Halifax. The NOPS organizing Committee is working very hard in bringing us a top-notch conference and I would like to take the opportunity to thank all the Committee members for all the energy, time and passion invested in this event. I am sure that it will be a great success!

There is something new at CAPHO that we are very proud of - a bilingual website. We are pleased to announce in the upcoming weeks you will notice that we will have a website in both official languages in Canada. Yes, CAPHO will now have a website "*en français*" for all of our francophone members.

The CAPHO Executive Committee had decided to sponsor five travel grants for CAPHO members to attend the NCIC spring meeting last spring in Toronto. In this newsletter, you will be able to read about their experiences, find out what they learned, and what was of value to them.

I would like to wish to all CAPHO members a pleasant summer, fantastic vacations and I hope to see all of you at NOPS.

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CPhA Honours CAPHO Member Betty Ridell

As part of its Centennial Celebrations, CPhA is recognizing 100 pharmacists who have made significant contributions to leading and building CPhA and the profession of pharmacy in Canada over the past 100 years.

Nominations for this award were received from many individuals and pharmacy organizations across Canada. All facets of pharmacy and all areas of Canada were represented in the nominations received.

Betty Riddell spent 37 years at the Royal University Hospital, concluding her career there as director of pharmaceutical services. An exceptional mentor, she was a professor of pharmacy at the University of Saskatchewan. Ms. Riddell served as president of CSHP and was associate editor of the CJHP. A former president of SPhA, Ms. Riddell joined CPhA in 1949 and served as Speaker of the Council of Delegates as well as board member.

Betty has also served CAPHO in many different capacities including the Secretary for the Executive, spearheading the final development of the Standards of Practice, and currently is the chair of the membership Committee. Thanks Betty for all your hard work and being an inspiration to us all!

NCIC Pharmacist Steering Group Call for Volunteers

Submitted by Colleen Olson, Member at Large

There is currently a vacancy for a Western Canadian Representative on the Pharmacists Network Steering Group of the National Cancer Institute of Canada. We are looking for an oncology pharmacist who is involved in clinical

trials and practicing in either British Columbia, Alberta, Saskatchewan or Manitoba.

We would like to acknowledge Susan Walisser for her years of dedicated work with the group. She was instrumental in the groups inception. Susan will continue to work with the group as a consultant with the workload survey. She will be missed very much.

Anyone who is interested in volunteering please submit your request to the Chair Biljana Spirovski via email at: BSpirovski@HRRH.ON.CA

NCIC Spring Meeting Summaries **Submitted by CAPhO Grant Winners**

Layton Carefoot
Clinical Trials Pharmacist
BC Cancer Agency, Centre for the Southern Interior

This year, I had the good fortune to attend the NCIC Spring Meeting in Toronto, supported in part by a generous grant from CAPhO. As a new CRA, one of my primary objectives was to attend the "New CRA" orientation sessions, which consisted of a series of brief but well presented topics covering issues including "Ethics and Regulatory Affairs", "Pharmacy", "MANGO", "Data Submissions and Queries", "Auditing" and "Study Closure".

As a result of the orientation session, I think I gained a better understanding of the role of the ethics boards, of the other clinical specialists (data coordinators, trial nurses), and the workings of NCIC. This will facilitate our team efforts to efficiently set up and run trials at our centre. One very useful component of the orientation session was the opportunity to meet members of the NCIC staff, which has already improved our communications with the NCIC study coordinators.

On the following day, one of the highlights was the Pharmacist Network meeting, providing the opportunity to meet the members of the Pharmacy Committee steering group and diseases site representatives. At this meeting I was introduced to a number of features available on the NCIC web-site that will be very useful, including the updated Pharmacists Network

Manual, and the dispensing procedures template project. The very lively discussion regarding possible pharmacy initiated clinical trials was interesting, and provided background that will be useful when future trials incorporating these ideas are initiated. Other useful bits of information included discussions of temperature monitoring, and of increased documentation of trial supply destruction. Both of these have been incorporated into updated procedures at our centre. I would have preferred there to be more occasions for the pharmacists to meet as a group for discussion of mutual concerns, if possible within the confines of a very busy meeting schedule.

The spring meeting was also the venue for introductory technical and scientific meetings for possible participants in the upcoming OV.19/ICON7 trial. There are a number of interesting logistical considerations to this trial. I felt it very useful to learn details of the trial in advance, with the opportunity to voice concerns and clarify procedures while the protocol is still being finalized. Our initiation of this trial, should we participate, should be much easier based on information gained at these meetings.

Finally, the spring meeting was an opportunity to attend a number of the tumour group "open" site committee meetings. I was able to attend portions of the "Brain", "Breast", and "Lymphoma" Site meetings, all of which provided background information on the status of trials that are either ongoing at our centre, or likely to be carried out at our centre.

Overall, the NCIC spring meeting was a total immersion into clinical trials, and the bits and pieces of information garnered over the period of several days will help me to be a more informed and contributing member to our clinical trial team.

Editor's Note: The updated Pharmacists Network Manual mentioned by Layton is now available in the Pharmacists Network section of the NCIC website.

Carol Davis, Clinical Trials Pharmacist
BC Cancer Agency - Vancouver Island Centre

I attended the NCIC Spring Meetings in Toronto April 26-29, 2007, assisted by the generosity of

CAPhO which made grants available to help enable CAPhO members involved in Clinical Trials to attend the meetings.

April 26, I attended the CAMO Symposium. This year's topic was "Targeting Therapy - From Discovery to Diagnostics, Imaging and Clinical Application". These presentations all served as a reminder of the complexities of using targeted therapies, where the interplay of several mechanisms makes the leap from theory to clinical application very difficult.

April 27, I attended the Pharmacists Network Open Meeting. The organization and commitment of the Pharmacy Steering Group to developing standards of pharmacy practice with regard to Clinical Trials is very evident. A few things stood out at this meeting:

- A reminder of the useful information available in the Pharmacy Network section of the NCIC website: the Pharmacy Network Manual (includes standards and guidelines for pharmacists involved in Clinical Trials), pharmacy procedures, and various templates and logs which can be used to help standardize procedures as well as minimize duplication of work. Coming soon to the Pharmacy Network will be information on how to prepare for an audit.
- Carlo DeAngelis discussed research projects the Committee might like to consider, particularly with regard to patient adherence to study medication regimens. He pointed out studies which had looked at patient adherence and it did not paint a rosy picture. He asked everyone to consider areas where pharmacists could be more involved, such as measuring non-compliance, identifying patients at high risk of non-compliance, and development of strategies to improve compliance in study patients, as well as other factors, such as how drug information is presented on the consent form and drug interactions which may play a big part in patients stopping medication.
- Much discussion ensued about the current CE.5 and upcoming CE.6 trials which are difficult for patients to manage due to multiple strengths of temozolomide dispensed to a population who may find this very confusing. It was agreed that where a study protocol dictates a dispensing process which is felt to

be below the usual standard of care, we write a Note to File to override a study procedure that does not make sense or that we feel puts patients at increased risk of a dosing error. This was a very helpful discussion for me, as our centre did not do CE.5, but will be doing CE.6 so I was able to hear what the problems were and what was learned from CE.5 which we can use to ensure CE.6 goes more smoothly, with increased safety for patients.

April 28 and 29, I attended several Disease Site meetings, to hear reports on existing trials as well as new and upcoming trials. It is a challenge at these sessions to attend the ones pertinent to practice at your centre, while several disease site meetings run concurrently. One can only do one's best. Thank you again to CAPhO for your support!

Mary-Jane Doornik R.N., C.Ph.T.
Clinical Trials Pharmacy Technician
Juravinski Cancer Centre, Pharmacy Dept.
Hamilton, ON

In April, I had the privilege of attending my first NCIC Spring Meeting in Toronto. As a Clinical Trials Pharmacy Technician, I am involved with many NCIC Clinical Trial Studies on a daily basis.

At the NCIC Spring Meeting, I attended the CRA (Clinical Research Associate) Orientation and CRA workshops offered. Also attending these sessions were clinical trial nurses, CRA data managers, and pharmacy staff from other NCIC study sites. This was a great opportunity to network with colleagues from other sites across Canada.

I attended workshops in "Ethics & Regulations" relating to clinical trial research thus increasing my knowledge of the legal and ethical procedures pertaining to the conduct of clinical trials in Canada. I also learned more about the conduct of trials affiliated with the U.S. and the laws associated with these (Pharmaceutical Management Branch of the NCI). Teamwork and "Good Clinical Practice Guidelines" were highlighted at many of these sessions as well. Each component of a clinical trial involves many team members from physicians, to trial nurses, to CRA's, to lab technicians, to pharmacy staff, and

finally the patients involved in the research. It was informative to learn and understand what each team member's role and responsibilities were, and therefore improve communication and teamwork.

Other sessions that I attended included "Preparing for an NCIC Site Monitoring Visit", and a poster presentation that also included booths set up highlighting several disease site groups. As well I attended a start-up meeting for a study that our clinical site will be participating in.

Overall, I learned how many professionals are involved in clinical trials research and how exciting it is to be a part of the team. Upon returning to my workplace I am more aware of the importance of clear and concise drug accountability, better prepared for monitoring and audit visits, and the need for good communication and close teamwork. There are many resources available to support our practice e.g. study coordinators, monitors and sponsors. The staff at NCIC encourage all clinical trial staff to contact them to answer any questions relating to these trials.

**Lorna Pederson,
Allan Blair Cancer Centre Pharmacy, Regina,
Sask.**

I was pleased to attend the NCIC Meeting in Toronto, Ontario April 26-29, 2007. As a pharmacist, I have been involved with clinical trials for some time but I was unaware of the scope of activity required for their development and implementation at NCIC. It was most interesting to meet with the NCIC Pharmacy Network and to receive updates on trials in various stages of development.

NCIC is the research arm of the Canadian Cancer Society, receiving funds from this charity and the Terry Fox Foundation as well as an operating grant from U.S.A. NCIC was established in 1980 at Kingston, Ontario under the leadership of Dr. Joe Pater. NCIC's mission is to develop and conduct clinical trials, aimed at improving prevention and treatment of cancer with the goal of reducing morbidity and mortality from this disease group. NCIC was first involved in IND studies for Investigational New Drugs.

Later it joined the trials of other research groups and other groups were allowed to join NCIC studies. NCIC also works with industry to conduct their trials.

In 1988 NCIC first received funds from the National Institute of Health, an American government body. NCI U.S. gives a grant to NCIC every five years which averages \$1,000,000.00 annually. NCI U.S. monitors trials done through NCIC in collaboration with U.S. Trial groups. NCIC has a seat at the table for trials done in the U.S.A. and internationally. It is most important that NCIC have voice on international committees.

NCIC Clinical Trial committee is made up of faculty from Queen's University, medical oncologists, radiation oncologists and lay representatives. They review policy and evaluate new trial proposals. Approval of a new trial is based on scientific priority and the importance of the study to NCIC CTG. The process of collaboration is increasingly explicit and is begun in the concept stage.

NCIC working committees include the IND (investigational new drugs in phase 1 and 2), symptom control, quality of life, economics and ten disease site committees. Disease site committees are responsible for scientific leadership. The chair is external and often has an international role. Disease site groups generate ideas for new clinical trials. Each trial proposal must have an hypothesis. Background rational for the trial, sample size and feasibility must also be determined

When a new trial is initiated, the study chair is appointed and a protocol is developed in collaboration with the central office. If required, a Clinical Trial Application (CTA) is submitted to Health Canada. Member sites are surveyed for interest. On approval from Health Canada, the protocol, sample consent, and applicable documents are posted on the website. All participating sites are notified of central activation. Each site has its own internal activation/trial approval process often consisting of a local impact analysis. Local activation allows the site to start enrolling patients.

The REB (Research Review Board) exists to protect the rights and welfare of human subjects

participating in biomedical research at each institution. The REB assures that the trial meets ethical standards and complies with all regulations pertaining to human research. Each protocol must initially and continuously be reviewed by the REB. Any amendment to the protocol must receive REB approval before implementation. Serious adverse effects are to be reported to the local REB within 30 days of receiving a safety letter.

Clinical Research Assistants (CRA's) have a very important responsibility in all stages of clinical trials including accrual and follow up of patients on trials. It is essential for the CRA to communicate with patients and document all side effects and toxicities. All information must be 100% accurate. It is important that the pharmacist work closely with CRA's on site to assure that all trials proceed in a timely fashion.

Wendy Won, Clinical Trials Pharmacist BCCA-Vancouver Centre

My NCIC Spring Meeting started with an eye-opening visit to Princess Margaret Hospital. I was welcomed by their clinical trials pharmacists, Jane Nagai and Jeff Doi. They gave me a comprehensive tour of the ambulatory care pharmacy, where the intravenous chemotherapy and oral study medications were prepared and dispensed. I was able to observe first-hand the process in which the clinical trials drugs were prepared and dispensed at their centre. We also shared experiences in study drug storage, temperature monitoring, study binder set-up, documentation as well as preparation of various study documents. The visit was both memorable and educational.

After the hospital visit, I attended the new CRA (Clinical Research Associate) orientation. The orientation consisted of various short presentations from NCIC representatives, covering topics from study activation, ethics and regulatory information to audits and monitoring and study closure. All of these lectures were good reviews for me and they further enhanced my knowledge of the different aspects of clinical trials.

The highlight of my second day at the conference was the Pharmacists Network meeting. I was

able to meet and network with pharmacists from other cancer centers. The in-depth presentation given by Carlo De Angelis at the meeting on the topic of oncology pharmacy initiated research within NCIC-CTG was thought provoking. It gave me an insight into what was to come in the future of pharmacy-initiated research with NCIC trials. From the presentation, I discovered the potential areas of interest for pharmacy-related research, which include patient compliance with study medications, trial procedure related to drug therapy, patient information transfer and drug interaction.

I also attended the start-up meeting for OV.19 study, which has already received central activation and was anticipated to open at our centre later this year. On the last two days of the conference, I attended the various disease site meetings to learn new updates on closed, ongoing and upcoming studies.

In summary, the knowledge and experience that I gained from the NCIC meeting will definitely change the way I practice as a clinical trials pharmacist at our centre. The information that I have learned will make me a more knowledgeable and confident pharmacist to meet the growing demands of clinical trials. Since my return from the meeting, I have initiated the use of the NCIC monitoring visit log to document monitor's visits at our site. I have also started a new procedure to keep better documentation and record keeping of our note-to-files for protocol deviations. In addition, I have helped revise our study dispensing procedure template to make it more user-friendly. The other areas which I am planning on improving are to better document our workload stats and to promote pharmacy representation within our clinical trials unit at our centre.

Acknowledgement: special thanks to Jane Nagai and Jeff Doi for their time and experiences and to CAPhO for sponsoring my trip to attend the meeting.