APPHON/ROHPPA NEWSLETTER

Atlantic Provinces Pediatric Hematology/Oncology Network
Réseau d'Oncologie et Hématologie Pédiatrique des Provinces Atlantiques

Winter 2016

Board Changes

The APPHON/ROHPPA Board of Directors is very pleased to announce the position of Chair has been filled by Dr. Lynette Bowes. Lynette is a Pediatric Hematologist/ Oncologist and Head of the Oncology/ Hematology at the Janeway Child Health & Rehabilitation Centre in St. John's, Newfoundland.

Dr. Mark Bernstein has stepped down as Chair effective November 14, 2015 and will stay on the Board as Past Chair until the spring. Many thanks from the Board to Mark for all his hard work during his tenure on the Board.

The position of Vice Chair has been filled by Mickey Daye, MEd, BScN, RN, Manager, Maternal Child Services, Cape Breton Regional Hospital.

The IWK Health Centre's new clinical representative on the APPHON/ROHPPA Board of Directors will be Dr. Conrad Fernandez, Head, Division of Pediatric Hematology/Oncology.

The Janeway Child Health & Rehabilitation Centre's new representative on the APPHON/ROHPPA Board of Directors will be Arlene Scott, Regional Director, Children's & Women's Health Program Eastern Health.

2015 APPHON/ROHPPA Conference

The annual APPHON/ROHPPA conference this year took place on November 12-14th and included an EPEC Education Day. Attendance was at an all-time high with over 100 health care professionals registering.

Our speakers received phenomenal reviews and content wise it was said to be the best ever held. There were a few technical/ process issues which will be addressed to the best of our ability prior to the next conference.

Due to a vote held in 2015, the APPHON/ ROHPPA conference will be moved to the spring starting in 2017. If anyone knows of conflicting conferences in 2017 that we should be mindful of when choosing a date, please let Carol Digout know.

Thank you to all our speakers, organizers and registrants for making the APPHON/ROHPPA conference a huge success.

Processing Initial/Malignant Specimens Found Unexpectedly

….'whenever possible all pediatric malignant specimens should be collected at the IWK for NB, NS, and PEI; and at the Janeway in NL. If a malignant tissue is unexpectedly revealed during another procedure, then follow the APPHON/ROHPPA guideline for **Processing Initial Malignant Specimens Found Unexpectedly** and send the specimen to the IWK lab.

APPHON/ROHPPA Pediatric Chemotherapy Administration Standards and Competencies Documents

Please be aware that the *APPHON/ROHPPA Pediatric Chemotherapy Administration Standards and Competencies* document (May 2015), as well as the corresponding *APPHON/ ROHPPA Pediatric Chemotherapy Administration Competency Checklist (May 2015)* underwent slight wording revisions in December 2015 to add clarity to the definition of the 'Competent Chemotherapy Administration Supervisor' and to the requirements of initial clinical competency.

The revisions do not alter the previous meaning and requirements of the APPHON/ ROHPPA standards and competencies, but rather added clarity. If there any questions please contact Mary Jean Howitt (NS, NB, PE) or Stephanie Eason (NL).

Upcoming APHON Chemotherapy/ Biotherapy Provider Course

The next *APHON (Association of Pediatric Hematology/Oncology Nurses) Chemotherapy and Biotherapy Provider course* is scheduled for April 28 and 29, 2016 at the IWK Health Center. The registration form is now on the APPHON/ROHPPA website under 'Education' and under 'News and Events'. Deadline for registration is March 23/2016.

If you have any questions regarding the course, please forward them to MaryJean.Howitt@iwk.nshealth.ca or Christa.McGuirk@iwk.nshealth.ca.

IWK Pharmacy Changed to Computerized BSA Formula

The IWK Pharmacy has recently switched to using a computerized formula (the DuBois method) to calculate BSAs, in keeping with the goal of having all Nova Scotia health professionals use the same formula. Frontline nursing have used the Mosteller calculation of $\sqrt{[ht(cm) \times wt(kg)]/3600}$ to date and in most cases the results of the two calculations are quite similar (less than 5% variance). However, it has been noted that the DuBois method varies beyond the 5% more frequently than the previous online formula (Haycock). Because of this, the IWK is moving towards making the DuBois method accessible to all team members verifying chemotherapy orders. If you are not using the DuBois method at your facility to determine BSA, you also may find a slight increase in >5% discrepancy and may find it helpful to also make accessible the DuBois method for all those verifying chemotherapy orders. Please note that the DuBois method is not a calculation that can be done easily on a calculator and therefore clinicians will need access to the online formula.

If you have further questions about this, please contact Tamara MacDonald. (Tamara.MacDonald@iwk.nshealth.ca).

CAPO Conference – Halifax 2016

The Canadian Association of Psychosocial Oncology Conference is being held in Halifax from May 11th-May13th. The theme is Generation Y to Older Adults: Psychosocial Care Across the Ages. Please visit their website for more information:

http://www.capo.ca/conferenceevents/capo-conference-2016/

Measuring Children Under 2 years

Serial, accurate growth measurement of children is an essential part of assessing a child. In oncology the length, along with weight and head circumference, is used to track growth of the child as well as used for dosing of medications based on calculated body surface area. If the correct equipment isn't used, it can mean an unnecessary nutrition referral or a missed nutrition referral for poor nutrition, improper dosing of medication or parental concern that the child isn't growing. It can also make it difficult to assess the child's overall growth and nutritional status.

When measuring an infant under the age of 2 years, a recumbent length board with a fixed headpiece and movable foot piece that is perpendicular to the surface of the board is the correct equipment. Using a piece of paper and then marking where the head and foot are is not an accurate way to measure. The child must have shoes removed, light clothing and no ponytails, hats, etc. One person must hold the child with eyes looking straight up and head touching the fixed headpiece. Legs should be fully extended with toes pointing up and feet flat against the foot piece. Measurements should be taken to the nearest 0.1cm and then repeated. The average of the 2 measurements is taken as long as the measurements do not vary by more than 0.5cm. Even if the child can stand but is under the age of 2 years, a recumbent length is the correct way to measure.

Patricia MacPherson
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Our Vision

To facilitate access for Atlantic province children and youth to comprehensive, current, effective, evidence-based hematologic/oncologic treatment delivered as close to home as safely feasible.

Research ethics oversight in the Maritimes for regional sites participating in COG studies supplement attached.

Research ethics oversight in the Maritimes for regional sites participating in COG studies
A change is coming….

Background

The Children's Oncology Group is a clinical trials network serving US, Canada and a number of other countries. Roughly 30-40% of children participate in a COG clinical trial or biology and banking study. There are a variety of types of studies conducted by COG - epidemiology, supportive care, phase I, II, III therapeutic trials, and biology and banking studies. The IWK takes part in all of these types of trials (the majority of which are sponsored by the COG). At any one time, we have approximately 60-70 clinical trials and banking studies open for enrollment.

All of these COG studies receive rigorous oversight. They are developed by disease committees who are world experts in the conditions under study, reviewed and approved at the COG scientific council, and approved by the Clinical Trials Evaluation Program (CTEP) of the NIH. They are also subsequently approved by the independent US based Central Institutional Review Board before they are released to the IWK.

Approximately 50-60 children per year are diagnosed with cancer across the Maritimes. As these diseases are rare, it is not uncommon to have significant fluctuations in the number of patients cared for in any one regional center - some years this may be none and some several. In this setting, APPHON/ROHPPA has site specific agreements in place that govern the type of clinical treatment and care that can be provided at each center. This is related to local expertise, training and resources. This is known as the Levels of Care Approach document and the levels are designated as Basic, Intermediate, Advanced or Sub-Specialty centres for care.

To date, children have been treated under the APPHON/ROHPPA Levels of Care agreement with the complexity of care and chemotherapy being dictated by resources indicating the site of care. There is an aim to deliver care as close to home as possible in a safe manner, and with assurance that adequate resources (health care personnel, space, etc.) are in place locally to care for the child. There has not been a distinction between children taking part in a trial and not taking part in terms of determining site of treatment related to regulatory compliance.

Due to regulatory requirements (detailed below), it is acknowledged that the care of children on and off study will need to be differentiated at outside health facilities. We are unaware of any ethical adverse events that have come to children as a result of this practice but we should be in compliance as this adds safety and scientific rigor to the trial delivery. At this point in time, none of the 16 national Canadian sites that treat children with cancer across Canada has a system in place for the regulatory compliance of regional sties.

Research ethics oversight is governed by a number of regulatory bodies, stipulating background and training including; ICH-GCP: International Conference on Harmonization-Good Clinical Practice, Food and Drug Regulations: Division 5, *Drugs for Clinical Trials Involving Human Subjects* and the Tri Council Policy Statement: *Ethical Conduct for Research Involving Humans* (TCPS v2 2014). In addition, the Children's Oncology Group also has specific requirements for study conduct and training (GCP and registration with CTEP, form 1572 and attendant requirements). The IWK has been in compliance with these requirements but because of the complexity this has not happened to date in regional sites.

COG requirements: COG has specific detailed requirements for a site to be designated a COG center. Only the IWK in Halifax and the Janeway in St. John's, Newfoundland have the resources and personnel to be designated a COG center. These sites are subject to a minimum of a 3 year audit by COG, annual audit by C17, and periodic monitoring from Health Canada.

COG stipulates that certain study related procedures must always be conducted at the designated COG center (the IWK and Janeway):

a. Consent for study
b. Enrollment on study
c. Delivery of investigational new drugs (phase I/II and new drugs in phase III trials)
d. Assessment of all protocol response evaluation time points/visits
e. All sampling for research sub-studies (biology, PK, etc.).

We have been compliant with these requirements. COG also stipulates the COG research center (IWK) has a clear plan established for regional centers for:

a. Dose adjustments and deviations from protocol therapy (already in place).
b. Adverse event notification and review (passively in place - could be strengthened)

Requirements ICH - GCP/Division 5 (Pediatrians and Family Physicians

Sub-investigators mean pediatricians and family doctors who are delivering chemotherapy in regional centers. By ICH-GCP requirements, sub-investigators should have completed regulatory training to supervise delivery of protocol treatment for participants in regional sites.
By these regulations, sites and sub-investigators responsibilities include being aware of the study aims, procedures and reporting practices relevant to their responsibilities in the study. Covered under this are any protocol related activities (even if they would normally be delivered as part of clinical care for a patient off study, e.g. physical exams, blood work, delivery of chemotherapy such as vincristine). As these are done under the auspices of the trial, they are considered research related activities even though standard of care. Management of complications of treatment (e.g., fever/neutropenia and transfusions) is considered part of normal clinical care. Evidence of both regulatory training (ICH-GCP) and training on the specific protocol being conducted at the site and updates/recertification, should be available for audit by the responsible ethics board and if necessary by COG, C17 or Health Canada.

There are potential consequences if we remain non-compliant:

a. Suspension of all COG related research at the IWK.
b. Lack of access of COG related protocol delivery in regional centers.
c. If access is limited, then inconvenience for families to travel to IWK to receive therapy or worst case, no access to COG trials in the Maritimes.
d. Investigators receiving sanctions by their local REB or institution for non-compliance.

We have had a number of discussions about this issue with the Nova Scotia Health Authority (NSHA) Research Ethics Board, the IWK Research Ethics Board, IWK administration and APPHON/ROHPPA. The current plans are still evolving but the following is the plan to be implemented over the next 6 months.

The following process has been proposed to support the timely activation of a research protocol in a regional site initiated at the time of the identification that the child is enrolled on study (some of which already occurs):

A. The regional site physician for the child is identified.
B. It is confirmed that the regional physician has completed their regulatory (GCP, etc.) training and that it is up to date. Appropriate free training is available through the IWK Research Ethics website.

C. The IWK provides training slides on the protocol to the physician.
D. The IWK provides access to the site and the pediatrician to the protocol through an online research ethics system called ROMEO. The IWK, pediatrician and site all indicate that they will keep the full protocol confidential.
E. The IWK highlights the aspects of the protocol that will be delivered locally and confirms that the physician is in agreement with their responsibilities.
F. The IWK provides precise guidance for chemotherapy orders.
G. The IWK provides education on reportable Severe Adverse Events specific to the protocol.
H. The regional site provides sign off on the protocol opening locally using regional REB forms (e.g. NSHA has physician, pharmacy and clinical care area forms). The sign off is related to protocol specific tasks and is distinct from having adequate resources to care for a child with cancer. Resource issues will be dealt with per clinical protocols already in place.
I. The IWK maintains a delegation log that confirms the trial related procedures for which the sub-investigators have responsibility.
J. The IWK PI is responsible for the conduct of the full protocol.
K. To support understanding by the research participants, the wording in the standard consent template would provide a more detailed description of the relationships between the IWK REB, regional REB, the sub-investigator and sites.

Plans

a. The IWK COG office is in the process of hiring a coordinator for this process. He/she will be responsible to ensure regional education of the process as outlined above, develop materials that support regional responsibilities, and assist with regulatory compliance.
b. The IWK PI (Conrad Fernandez) will begin contacting all physicians looking after pediatric oncology patients in the Maritimes.
c. The issue is being brought to the APPHON/ROHPPA board to discuss in more detail the implementation of an Atlantic research ethics solution.

Please let me know if you have questions, concerns or suggestions as we implement the solution to this challenging but essential requirement.

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