CAPhO ACPhO




The Canadian Association of Pharmacy in Oncology presents the
National Oncology Pharmacy Symposium
PATIENTS FIRST!

L'Association cannadienne de pharmacie en oncologie présente le
Syposium National de Pharmacie en Oncologie
LES PATIENTS D'ABORD !

October 25-28 | Du 25 au 28 octobre
Sheraton Cavalier Hotel, Saskatoon, Saskatchewan

Saskatoon 2012

Onsite Program
Programme

www.capho.org **www.acpho.org**

NOPS 2012 Sponsors

PLATINUM

AMGEN Oncology
Janssen
Baxter
LEO
BD
Lundbeck Oncology
Celgene
NOVARTIS ONCOLOGY
Lilly
Pfizer Oncology Oncologie
Hospira
Roche

GOLD

Eisai
icumedical human connections
MERCK
PPC A Company of the Fresenius Kabi Group
SANOFI

SILVER

Bayer
Boehringer Ingelheim
TEVA

BRONZE

astellas Astellas Pharma Canada, Inc.
omega
Takeda

Table of Contents / Table des matières

Canadian Association of Pharmacy in Oncology (CAPhO)
L'Association canadienne de pharmacie en oncologie (ACPhO)

Association Management Office / Bureau de gestion de l'association
E: info@capho.org
T: 1-778-338-4142
F: 1-604-984-6434

W: www.capho.org

NOPS 2012 Secretariat / Secrétariat du NOPS 2012

Sea to Sky Meeting Management Inc.
Suite 206, 201 Bewicke Avenue
North Vancouver, BC, V7M 3M7
E: nops@capho.org
T: 1-604-984-6455
F: 1-604-984-6434

W: www.seatoskymeetings.com

BD

Helping all people live healthy lives

BD PhaSeal™ – Closed drug transfer from vial to patient

The BD PhaSeal closed-system drug transfer device builds on two unique features: its double membrane technology, which creates a dry, leakproof connection, and its airtight expansion chamber, which contains all aerosols, particles and vapours as well as equalizes the pressure in the vial.

With BD PhaSeal, your safety is never compromised. To help maximize that safety, we have designed BD PhaSeal to both operate simply and fit easily within your existing oncology healthcare procedures.

BD Medical
2100 Derry Road West, Suite 100
Mississauga, ON L5N 0B3
www.bd.com

Welcome Message from the CAPhO President

On behalf of the Executive Committee of the Canadian Association of Pharmacy in Oncology (CAPhO), welcome to Saskatoon and NOPS 2012.

This year's program is an outstanding collection of plenaries, breakout sessions, posters and symposia. I especially hope to see you at the two social events on Saturday: the Exhibit and Poster Viewing Reception followed by dinner at the Delta Bessborough (get ready to laugh!).

Many of you are "annual NOPS attendees"; please take a minute during a networking break to welcome any new faces in the crowd. CAPhO's membership is growing and we really look forward to engaging our new members. On that note, our AGM is scheduled for Saturday at noon, the Townhall for Sunday at 8:30am, and the Executive will be at the CAPhO booth located in the Exhibition area to discuss any Association questions you may have.

We would also like to thank our generous sponsors for their continued support of this important symposium. We encourage you to take the time to visit the exhibits, as this is a great opportunity to learn about new services and products that may benefit your patients.

Lastly, I would like to thank Kathy Gesy and the NOPS 2012 Organizing Committee members who have planned an outstanding program in this beautiful city.

On behalf of the CAPhO Executive, we hope you enjoy NOPS 2012!

Jennifer Jupp

CAPhO President

Mot de bienvenue de la présidente de l'ACPhO

Au nom du comité directeur de l'Association canadienne de pharmacie en oncologie (ACPhO), je vous souhaite la bienvenue à Saskatoon et au Symposium national sur la pharmaco-oncologie (NOPS) 2012.

La programmation de cette année est riche en séances plénières, ateliers, présentations d'affiches et colloques. J'espère particulièrement vous voir aux deux activités sociales du samedi : la réception d'exposition et de visualisation des affiches, suivie d'un dîner au Delta Bessborough (préparez-vous à rire!).

Bon nombre d'entre vous sont des habitués du NOPS. Veuillez prendre quelques minutes pendant la pause-contact pour souhaiter la bienvenue aux nouveaux visages. L'effectif de l'ACPhO grandit et nous avons hâte de travailler avec nos nouveaux membres. À ce sujet, notre assemblée annuelle aura lieu le samedi à midi, la séance de discussion ouverte le dimanche à 8 h 30, et les membres de la direction se trouveront au stand de l'ACPhO dans la salle d'exposition pour répondre aux questions des participants sur l'association.

J'aimerais remercier nos généreux commanditaires pour leur appui soutenu à cet important symposium. Par ailleurs, n'oubliez pas de visiter les stands d'exposition pour connaître les nouveaux produits et services pouvant profiter à vos patients.

Enfin, j'aimerais remercier Kathy Gesy et les membres du comité organisateur du NOPS 2012, qui ont créé une programmation exceptionnelle dans la magnifique ville de Saskatoon.

Au nom de la direction de l'ACPhO, je vous souhaite un bon symposium!

Jennifer Jupp

Présidente de l'ACPhO

Welcome Message from the NOPS 2012 Chair

On behalf of the NOPS 2012 Planning Committee, we would like to extend a warm prairie welcome to our beautiful City of Saskatoon. During your visit to one of Canada's 'sunniest cities', we hope you can make time to get outside and enjoy a walk along our extensive riverbank trail system situated at the doorstep of our conference hotel. We are proud of our city, its agricultural, academic and resource-based economy and we included a special presentation in our program highlighting the Canadian Light Source, the national synchrotron research facility located in Saskatoon.

NOPS 2012 is an important event to oncology pharmacists, technicians and pharmacy assistants. We chose the theme of ***Patients First!*** to reflect our responsibility to provide patient-centered care. It is important to hear the patients' perspective on their desire for safe care and their thoughts on the ever changing landscape of access to cancer drugs and the drug review process. Our patients want us to be competent providers of cancer care and an important foundation of NOPS has always been about presenting current cancer treatment information, partnered with how we provide oncology pharmacy services in a safe and efficient manner.

As you peruse the program, you will see a full agenda with presenters from across the country. We wish to thank all the presenters for the time and effort they have put into their presentations. We also wish to thank our industry partners for the support and educational content they bring to NOPS.

On a personal note, I would like to thank the members of the NOPS 2012 Planning Committee who have made assembling this symposium a rewarding experience, and the Executive Committee members for their support of NOPS 2012.

We hope that NOPS 2012 will be an energizing and educational experience for each of you and that you will take the opportunity to network with your colleagues and have some fun. Saskatoon is a fantastic city and we hope you enjoy your weekend with us!

Kathy Gesy

NOPS 2012 Chair

Mot de bienvenue de la présidente du NOPS 2012

Au nom du comité de la planification du Symposium national sur la pharmaco-oncologie (NOPS) 2012, nous sommes heureux de vous accueillir à Saskatoon, l'une des villes les plus ensoleillées au Canada. Durant votre séjour ici, nous espérons que vous aurez l'occasion de marcher le long des sentiers riverains situés à quelques pas de l'hôtel où a lieu le symposium. Nous sommes fiers de notre ville, de son agriculture, de ses établissements d'enseignement et de son économie fondée sur les ressources. Dans notre programme, nous avons inclus une présentation spéciale du Centre canadien de rayonnement synchrotron, centre de recherche établi à Saskatoon.

Le NOPS 2012 constitue un événement important pour les pharmaco-oncologues, les techniciens et les assistants en pharmacie. Nous avons choisi le thème ***Les patients d'abord!*** pour témoigner de notre engagement à offrir des soins axés sur le patient. En effet, il est primordial de tenir compte du point de vue des patients en ce qui a trait à la sécurité des soins, à l'accès – constamment changeant – aux médicaments contre le cancer et au processus d'examen des médicaments. Nos patients veulent que nous soyons des fournisseurs compétents de soins contre le cancer. Ainsi, la présentation d'information actuelle sur les traitements et les discussions sur la façon dont nous pouvons offrir des services de pharmaco-oncologie sécuritaires et efficaces ont toujours été au cœur du NOPS.

Vous trouverez dans le programme la liste complète des présentateurs venant des quatre coins du pays. Nous tenons remercier ces derniers pour le temps et les efforts consacrés à la préparation de leurs exposés. Nous remercions également nos partenaires du secteur pour leur appui et leur contribution au contenu du NOPS.

Sur une note personnelle, j'aimerais remercier les membres du comité de la planification du NOPS 2012, grâce à qui l'organisation de l'événement a été une expérience enrichissante, ainsi que les membres du comité directeur pour leur appui.

Nous espérons que le NOPS 2012 se révélera une expérience stimulante et éducative pour chacun de vous, et que vous profiterez de l'occasion pour échanger avec vos collègues et vous amuser. Saskatoon est une ville fantastique!

Espérant que vous aimerez votre séjour parmi nous, veuillez agréer mes salutations distinguées.

Kathy Gesy

Présidente du NOPS 2012

Hospira

COMMITTED TO YOUR SAFETY

Date
Friday, October 26, 2012

Time
2:30-4:00 P.M.

Location
Meeting room:
Top of the Inn

NOPS 2012 Satellite Symposium

Update on Minimizing the Risk of Contamination in the Oncology Pharmacy Setting: What is the Evidence

Guest Speaker

Dr. Paul J.M. Sessink, Ph.D., President of Exposure Control B.V., Netherlands

Moderator

Kathy Gesy, Provincial Leader, Oncology Pharmacy Services
Saskatchewan Cancer Agency

Participants need to RSVP through the official CAPhO registration site

Hospira
Advancing Wellness™

CAPhO / L'ACPhO

The Canadian Association of Pharmacy in Oncology (CAPhO) is the national forum for oncology pharmacy practioners and other health care professionals interested in oncology pharmacy.

CAPhO, a voluntary organization, promotes the practice of oncology pharmacy in Canada by conducting educational events, maintaining appropriate professional practice standards, facilitating communication between oncology pharmacists, technicians, pharmacy assistants and other interested health care professionals, and developing oncology pharmacy as an area of specialty practice.

L'Association canadienne de pharmacie en oncologie (ACPhO) est un forum national canadien destiné aux praticiennes et praticiens de la pharmacie en oncologie et aux autres professionnels de la santé qui s'intéressent à ce domaine.

L'ACPhO est un organisme bénévole qui fait la promotion de la pratique de la pharmacie en oncologie au Canada en organisant des événements éducatifs, en établissant des normes de pratique professionnelle appropriées, en facilitant la communication entre les pharmaciens en oncologie, les techniciens, les assistants en pharmacie et les autres professionnels de la santé intéressés et en mettant de l'avant la pharmacie en oncologie comme un domaine de pratique spécialisé.

Become a CAPhO Member / Devenir membre de l'ACPhO

We invite you to join CAPhO as a member. Visit www.capho.org/membership to learn more and to apply.

Why join? Besides being a member of an association that represents your professional interests, benefits from belonging to CAPhO include:

- The online **Member Forum** (a discussion page where you can participate in issue discussions, pose questions and provide answers)
- **Continuing education** opportunities, including access to CAPhO's **online education programs** - "Oncology Basics" is the first of four Oncology Practice Essentials modules and is available only to members
- A **network of professionals** to support you and **advocate** on your behalf
- **Executive, Committee and Task Force positions**
- An invitation to NOPS at a substantially discounted registration rate ($100 off if paid six months prior to the NOPS start date)
- The opportunity to participate in the CAPhO **Awards and Grants Program**

Nous vous invitons à devenir membre de l'ACPhO. Visitez le site www.capho.org/membership pour obtenir plus d'information sur les modalités d'adhésion.

Pourquoi devriez-vous vous joindre à notre association? L'ACPhO défend vos intérêts professionnels et vous offre :

- un **forum des membres** en ligne (une page où vous pouvez participer à des discussions, poser des questions et donner des réponses);
- **Possibilités de formation professionnelle continue**, dont l'accès aux **programmes de formation en ligne** de l'ACPhO. « Oncology Basics » est le premier des quatre modules du cours Oncology Practice Essentials, lequel est uniquement offert aux membres.
- un **réseau de professionnels** vous représentant et **défendant vos droits**;
- des postes au sein de l'équipe de direction, des comités et des équipes de travail;
- une invitation au NOPS à un tarif préférentiel (réduction de 100 $ si vous payez six mois avant la date de l'événement);
- la possibilité de participer au **Programme de bourses et subventions** de l'ACPhO.

THALOMID®
thalidomide capsules
capsules de thalidomide

Revlimid®
lenalidomide capsules
capsules de lénalidomide

Vidaza®
azacitidine for injection
azacitidine pour injection

Abraxane®
for Injectable Suspension
(paclitaxel powder for injectable suspension)
(nanoparticle, albumin-bound (nab®) paclitaxel)
pour suspension injectable
(paclitaxel en poudre pour suspension injectable)
(paclitaxel en nanoparticules lié à l'albumine (nab®))

CAPhO Awards / Prix de l'ACPhO

Distinguished Service Award / Prix de reconnaissance pour services exceptionnels

The Distinguished Service Award is presented to a member of CAPhO in recognition of outstanding achievement and contribution to the Assocation and for long-term service. The award consists of an engraved plaque and cash prize of $1,000 given annually to a member of CAPhO in recognition of outstanding achievement and contribution to the association.

Remis chaque année à un membre de l'ACPhO pour souligner les réalisations et la contribution exceptionelles d'un membre de l'association, ce prix de reconnaissance comprend une plaque gravée et une récompense en argent de 1 000 $.

Merit Award / Prix d'excellence

This award consists of a certificate and a cash award of $1,000 given to a practicing oncology pharmacist(s), pharmacy technician(s) and/or pharmacy assistant(s) and member(s) of CAPhO in recognition of a project/innovation in oncology pharmacy aimed at improving patient care and outcomes. Up to two awards may be granted. Many pharmacy departments have initiated exciting programs in their centres, and this award is aimed at recognizing them.

Ce prix d'excellence, qui comprend un certificat d'excellence et une bourse de 1 000 $, sera remis à un ou plusieurs praticiens et/ou techniciens de la pharmacie en oncologie et membres de l'ACPhO en reconnaissance de leurs projets ou innovations visant à améliorer les soins aux patients et les résultats qui en ont découlé dans leur sphère d'activité. Deux prix pourront être attribués au besoin. De nombreuses équipes pharmaceutiques ont instauré des programmes intéressants dans leur établissement, et ce prix a pour but de les récompenser pour leurs initiatives.

Poster Awards / Prix pour les affiches

During NOPS, a Committee reviews the new posters and awards a certificate and a cash prize of $500 in each of the three poster awards will be awarded in the categories of Research, Pharmacy Practice and Administration. Each award consists of a certificate and cash prize of $500.

Dans le cadre du NOPS, un comité examinera les nouvelles affiches et remettra un certificat et un prix en argent de 500 $ dans chacune des catégories de recherche, de pratique de la pharmacie et d'administration.

OPTIMIZING BONE HEALTH in ADVANCED CANCER

PLAN TO ATTEND

Friday, October 26, 2012
9:15 a.m. – 10:45 a.m.
Sheraton Cavalier, Saskatoon
Centre Room

As advanced cancer patients are surviving longer, these individuals are more likely to develop skeletal-related events (SREs). SREs have a significant effect on quality of life.

The role for bone-targeted agents in advanced cancers is established, and pharmacists will increasingly be involved in the care of these patients. This session will be designed to address practical, clinical questions regarding the evidence in support of bone health management and the day-to-day care of patients. Ample time will be allotted for questions from the audience.

Plan to attend this session that will allow participants to:

- Discuss normal bone remodelling and mechanisms of bone destruction in advanced cancer
- Discuss the clinical and health-related quality-of-life impact of SREs
- Review the latest evidence on SRE prevention
- Discuss toxicities associated with bone-targeted agents

Chair:

Michael LeBlanc, BSc (Chem), BSc (Pharm), PharmD
Clinical Manager, Pharmacy Services
Clinical Pharmacy Specialist, Oncology
Horizon Health Network
The Moncton Hospital
Moncton, NB

Guest Speaker:

Alan So, MD, FRCS(C)
Associate Professor
Department of Urologic Sciences
University of British Columbia
Research Scientist, Prostate Centre
Vancouver General Hospital
Vancouver, BC

How to register:

Contact Caitlin Cousins at ccousins@scimedcan.com or 905.762.0772, ext 254.

Sponsored by: AMGEN

Thank you / Merci

To the CAPhO Executive / Aux membres de la direction de l'ACPhO

Jennifer Jupp, President / Présidente

Joan Fabbro, President-Elect / Présidente désignée

Carlo De Angelis, Past President / Président sortant

Lori Emond, Treasurer / Trésorière

Victoria Kletas, Awards Committee Chair / Présidente du comité des prix

Christopher Ralph, Communications Committee Chair
Président du comité des communications

Tara Leslie, Education Committee Chair Pharmacist
Présidente du comité de la formation des pharmaciens

Yvonne Dresen, Education Committee Chair Technician / Pharmacy Assistant / Présidente du comité de la formation des techniciens et assistants en pharmacie

Betty Riddell, Membership Committee Chair / Présidente du comité d'adhésion

Biljana Spirovski, Research Committee Chair / Présidente du comité de la recherche

To the NOPS Planning Committee Members / Aux membres du comité de planification du NOPS

Darryl Boehm
Saskatchewan Cancer Agency, Regina, SK

Flay Charbonneau
Odette Cancer Centre, Toronto, ON

Carlo De Angelis
Sunnybrook Health Sciences Centre, Toronto, ON

Gabriel Gazze
Royal Victoria Hospital, Montreal, QC

Kathy Gesy
Saskatchewan Cancer Agency, Saskatoon, SK

Michelle Koberinski
Cancer Centre for the Southern Interior, Kelowna, BC

Julie Melmoth
Alberta Health Services, Spruce Grove, AB

Mark Pasetka
Sunnybrook Health Sciences Centre, Toronto, ON

Biljana Spirovski
Humber River Regional Hospital, Toronto, ON

Colleen Thurber
Saskatoon Cancer Centre, Saskatoon, SK

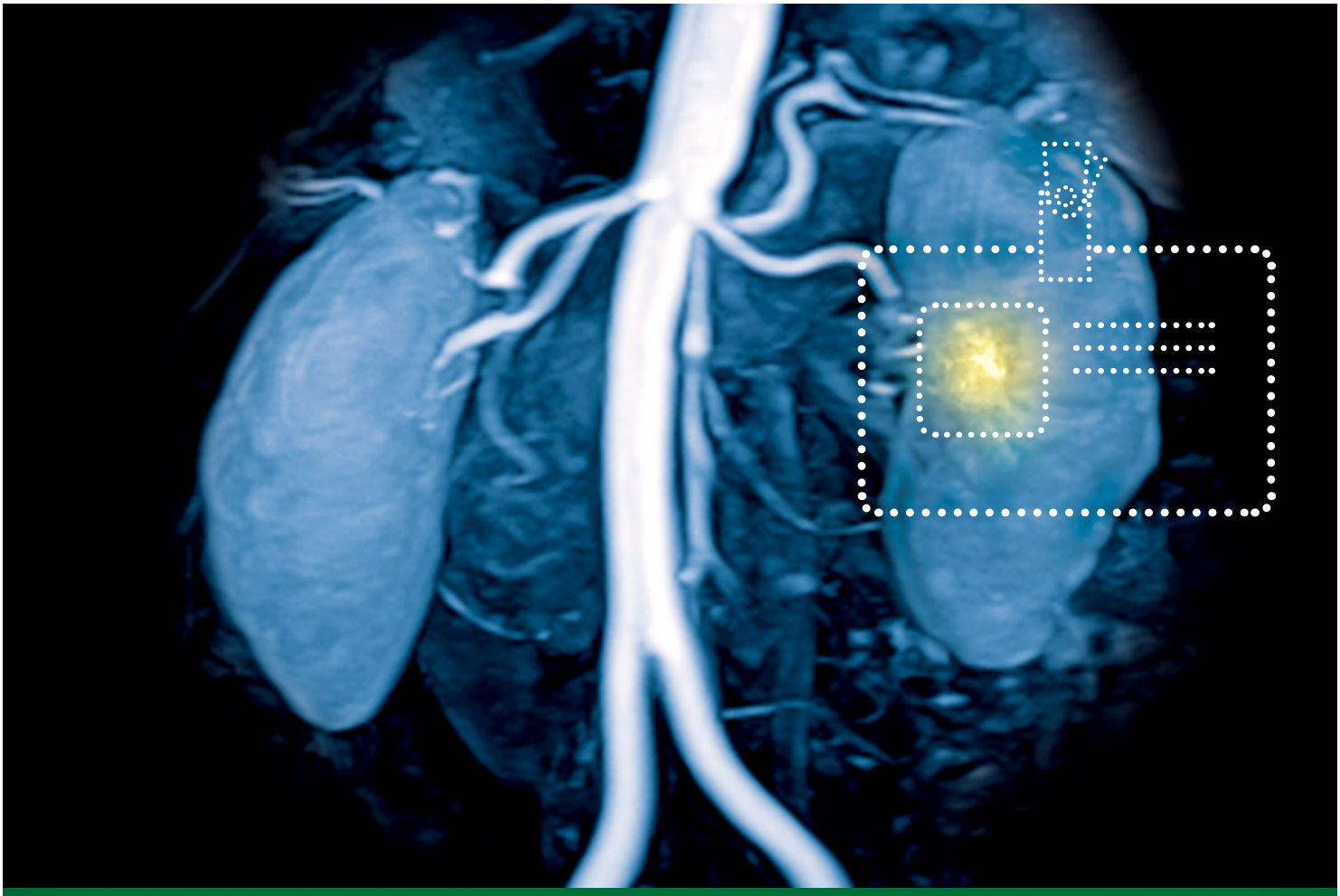
Thanh Vu
Health Canada, Burnaby, BC

Ian Holliday
Sea to Sky Meeting Management Inc., Vancouver, BC

Volunteers / Bénévoles

We would like to thank those who have volunteered their time to assist NOPS 2012 attendees and organizers. We really appreciate the assistance you provide to ensure attendees have everything they need to participate effectively in NOPS 2012.

Nous tenons à remercier tous ceux et celles ayant offert leur temps pour assister les participants et les organisateurs du SNPO 2012. Nous vous sommes reconnaissants d'avoir permis à chacun d'entre eux de vivre une expérience positive.



Personal

Tumours have specific characteristics and behaviours. We're focused on transforming treatment by providing the right drug for the right patient at the right time.

Focused on what truly matters.

Pfizer Oncology

PAAB Member R&D

PrUROMITEXAN

Mesna Injection
100 mg/mL

The first detoxifying agent that offers a prevention of urotoxic side effects associated with oxazaphosphorines

Now also available in 10 mL and 50 mL multi-dose vials

Offering efficiency and convenience

To learn more, come and visit us at booth no. 8

Baxter

Accreditation / Accréditation

The Canadian Council on Continuing Education in Pharmacy (CCCEP) is a national organization established to accredit continuing pharmacy education programs intended to be delivered to pharmacy professionals from more than one province or nationally. CCCEP accreditation is recognized by the pharmacy regulatory authorities in all provinces and territories of Canada. NOPS 2012 is accredited for 10.75 continuing education credits (CEUs).

Letters of Accreditation are available at the Registration Desk, located in the Conference Foyer, Main Level.

Le Conseil canadien de l'éducation permanente en pharmacie (CCCEP) est une organisation nationale dont le mandat est d'accréditer les programmes d'éducation permanente en pharmacie offerts aux professionnels du secteur dans plus d'une province ou à l'échelle du pays. L'accréditation du CCCEP est reconnue par les organismes de réglementation en pharmacie dans toutes les provinces et tous les territoires du Canada. Le NOPS 2012 est accrédité pour 10,75 crédits d'éducation permanente.

Les lettres d'accréditation sont remises au bureau des inscriptions, situé dans le hall d'accueil du congrès, au niveau principal.

Pharmacists/ Pharmaciens: #1152-2012-611-C-P 7 – Pharmacy Technicians / Techniciens en pharmacie: #1152-2012-612-C-T

Presentations / Séances

Recorded presentations (voice and slides) from NOPS 2012 will be available in November at www.capho.org.

Les exposés enregistrés (audio et diapositives) du NOPS 2012 pourront être consultés en novembre sur le site www.acpho.org.

LEO Pharma Symposium

at NOPS 2012

Oct. 26th
7:30 am to 9:00 am

Please register for the Symposium on the CAPho website at
http://www.capho.org/nops-2012/satellite-symposia

VTE in Cancer Patients: What you don't know

Carlo De Angelis, RPh, ACPR, Pharm D.
Clinician Scientist Oncology Pharmacy
Department of Pharmacy
Sunnybrook Health Science Centre
Sunnybrook Odette Cancer Centre
Toronto, ON

VTE Simplified Oncology Protocols: Filling the Practice Gap

Bonnie Kuehl, PhD
Scientific Insights Consulting Group Inc.
Mississauga, ON

Agenda & Learning Objectives:

7:30 am: Carlo De Angelis
Recognize the increased risk of VTE in cancer patients

Q&A

8:30 am: Bonnie Kuehl
Review and discuss the VTE oncology prevention and treatment protocols to address the care gap in cancer patients.

Q&A

Supported by an unrestricted educational grant by LEO Pharma Inc.

PROGRAM AT A GLANCE

THURSDAY, OCTOBER 25

18:30 - 20:00
SATELLITE SYMPOSIUM: *Eli Lilly*
Top of the Inn, 8th Floor

FRIDAY, OCTOBER 26

07:30 - 09:00
SATELLITE SYMPOSIUM: *Leo Pharma*
Top of the Inn, 8th Floor

09:15 – 10:45
SATELLITE SYMPOSIUM: *Amgen*
Centre Room, Main Level

11:00 - 12:30
SATELLITE SYMPOSIUM: *BD Medical*
Top of the Inn, 8th Floor

12:45 - 14:15
SATELLITE SYMPOSIUM: *Celgene*
Centre Room, Main Level

14:30 - 16:00
SATELLITE SYMPOSIUM: *Hospira*
Top of the Inn, 8th Floor

16:15 - 17:45
SATELLITE SYMPOSIUM: *Pfizer*
Centre Room, Main Level

18:00 - 19:30
SATELLITE SYMPOSIUM: *Baxter*
Top of the Inn, 8th Floor

SATURDAY, OCTOBER 27

06:30 - 08:00
SATELLITE SYMPOSIUM: *Lundbeck*
Top of the Inn, 8th Floor

07:30 - 08:15
CONTINENTAL BREAKFAST
Exhibit Hall, Main Level

All sessions take place at the Sheraton Cavalier Hotel, except the Dinner on Saturday

08:15 - 10:00
WELCOME & PLENARY SESSIONS
Centre-East Room, Main Level

10:00 - 10:30 – BREAK
Exhibit Hall, Main Level

10:30 - 12:00
PLENARY SESSIONS
Centre-East Room, Main Level

12:00 - 13:00
CAPHO ANNUAL GENERAL MEETING
Centre-East Room, Main Level

13:00 - 14:00 – LUNCH
Exhibit Hall & Centre-East Room, Main Level

14:00 – 15:20
BREAKOUT SESSIONS 1,2,3
Technician (Top of the Inn, 8th Floor)
Clinical (Centre-East Room, Main Level)
Administrative/Research (Starlight Room, Lower Foyer)

15:20 - 15:50 – BREAK
Exhibit Hall, Main Level

15:50 - 16:35
BREAKOUT SESSIONS 4,5,6
4 (Centre-East Room, Main Level)
5 (Top of the Inn, 8th Floor)
6 (Starlight Room, Lower Foyer)

16:35 - 18:30
EXHIBITS AND POSTERS VIEWING RECEPTION
Exhibit Hall, Main Level

19:00 - 22:30
DINNER & CAPHO AWARDS
Delta Bessborough

SUNDAY, OCTOBER 28

07:00 - 08:30
SATELLITE SYMPOSIUM: *Novartis*
Top of the Inn, 8th Floor

08:00 - 08:30
CONTINENTAL BREAKFAST
Exhibit Hall, Main Level

08:30 - 09:45
CAPHO TOWN HALL MEETING
Centre-East Room, Main Level

09:45 - 10:15
AWARD WINNING POSTERS
Centre-East Room, Main Level

10:15 - 10:30 – BREAK
Exhibit Hall, Main Level

10:30 - 12:40
PLENARY SESSIONS & CLOSING
Centre-East Room, Main Level

13:00 - 14:30
SATELLITE SYMPOSIUM: *Eisai*
Top of the Inn, 8th Floor

REGISTRATION

Conference Foyer, Main Level

Thursday, October 25, 17:00 – 19:00
Friday, October 26, 07:00 – 18:00
Saturday, October 27, 06:00 – 16:30
Sunday, October 28, 07:00 – 12:30

EXHIBIT & POSTER HALL

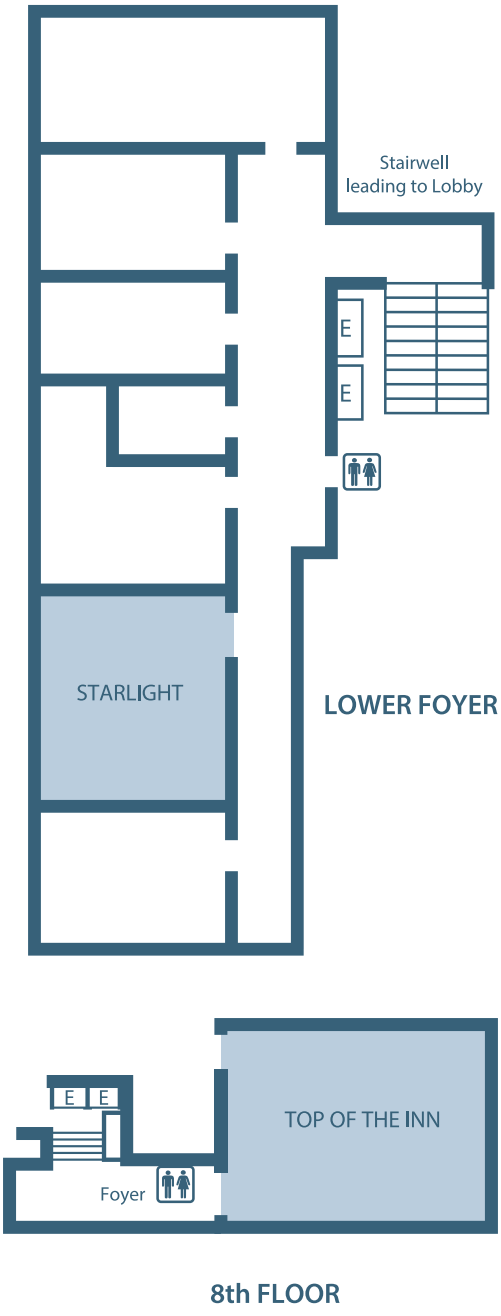
Exhibit Hall, South-West Room and Conference Foyer, Main Level

Saturday, October 27, 07:30 – 18:30
Sunday, October 28, 07:30 – 10:30

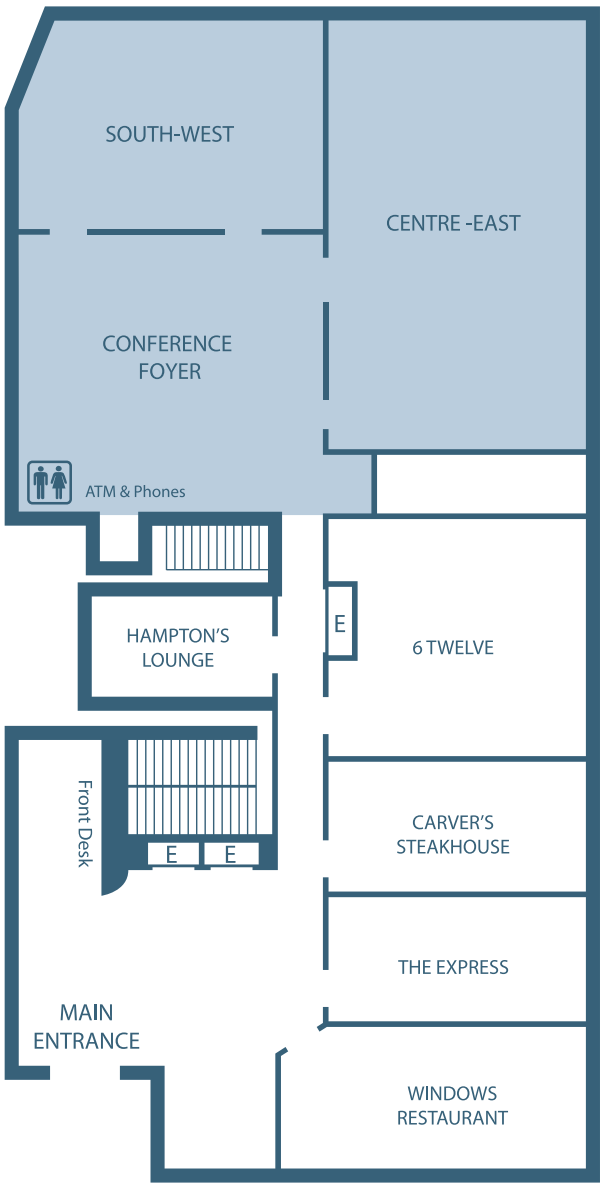
Hotel Floor Plan

Sheraton Cavalier Saskatoon Hotel
612 Spadina Crescent East
Saskatoon, Saskatchewan

T: 1-306-652-6770
W: sheraton.com/saskatoon



8th FLOOR



MAIN LEVEL
Conference Centre

Find out more, contact Lundbeck at 1 800 586-2325.

Lundbeck Oncology

NOPS 2012 Program

Thursday, October 25

18:30 - 20:00
Satellite Symposium: **ELI LILLY** *(Top of the Inn, 8th Floor)*
LUNG CANCER 2012: WHERE ARE WE AND WHERE ARE WE GOING
Ronald Burkes, *Professor of Medicine, University of Toronto, Toronto, ON*

Friday, October 26

07:30 - 09:00
Satellite Symposium: **LEO PHARMA** *(Top of the Inn, 8th Floor)*
VTE IN CANCER PATIENTS: WHAT YOU DON'T KNOW
Dr. Carlo De Angelis, *Clinician Scientist Oncology Pharmacy, Sunnybrook Odette Cancer Centre, Toronto, ON*

VTE SIMPLIFIED ONCOLOGY PROTOCOLS: FILLING THE PRACTICE GAP
Bonnie Kuehl, *Scientific Insights Consulting Group Inc., Mississauga, ON*

09:15 - 10:45
Satellite Symposium: **AMGEN** *(Centre Room, Main Level)*
OPTIMIZING BONE HEALTH IN ADVANCED CANCER
Alan So, *Assistant Professor, Department of Urologic Sciences, University of British Columbia, Vancouver, BC*

11:00 - 12:30
Satellite Symposium: **BD MEDICAL** *(Top of the Inn, 8th Floor)*
USP 797 - WHAT DOES IT MEAN FOR CANADIAN PHARMACIES?
Stephen F. Eckel, *Assistant Director of Pharmacy, University of North Carolina Hospitals, Chapel Hill, NC*
Flay Charbonneau, *Pharmacy Manager, Odette Cancer Centre, Toronto, ON*
Kathy Gesy, *Provincial Leader, Saskatchewan Cancer Agency, Regina, SK*
Rick Abbott, *Regional Pharmacy Manager, Dr. H. Bliss Murphy Cancer Centre, St. John's, NL*

12:45 - 14:15
Satellite Symposium: **CELGENE** *(Centre Room, Main Level)*
PADDLING TOGETHER: THE PATIENT'S TEAM
Brian Price, *Men's Eight Coxwain Olympic Medalist and ALL Survivor, Victoria, BC*

14:30 - 16:00
Satellite Symposium: **HOSPIRA** *(Top of the Inn, 8th Floor)*
UPDATE ON MINIMIZING THE RISK OF CONTAMINATION IN THE ONCOLOGY PHARMACY SETTING: WHAT IS THE EVIDENCE?
Dr. Paul J.M. Sessink, *President, Exposure Control, B.V., Netherlands*

16:15 - 17:45
Satellite Symposium: **PFIZER** *(Centre Room, Main Level)*
THE EMERGING ROLE OF TARGETED THERAPY IN LUNG CANCER MANAGEMENT
Shantanu Banerji, *Medical Oncologist, CancerCare Manitoba, Winnipeg, MB*

18:00 - 19:30
Satellite Symposium: **BAXTER** *(Top of the Inn, 8th Floor)*
DON'T FALL SHORT! SHARING DRUG SHORTAGE MANAGEMENT SOLUTIONS
Flay Charbonneau, *Pharmacy Manager, Sunnybrook Health Sciences, Toronto, ON*
Rick Abbott, *Regional Pharmacy Manager, Dr. H. Bliss Murphy Cancer Centre, St. John's, NL*
Wallace Lam, *Practice Leader, Princess Margaret Hospital, Toronto, ON*

Saturday, October 27

06:30 - 08:00
Satellite Symposium: **LUNDBECK** *(Top of the Inn, 8th Floor)*
CLL AND iNHL IN CANADA: CURRENT TREATMENT STANDARDS AND NEW OPTIONS
Harry Hopkins, *Clinical Specialist-Pharmacy, Member Blood and Marrow Transplant Program, Ottawa, ON*

07:30 - 08:15 CONTINENTAL BREAKFAST: *(Exhibit Hall, South-West Room and Conference Foyer, Main Level)*

08:15 - 08:30
Plenary: **WELCOME** *(Centre-East Room, Main Level)*
Kathy Gesy, *NOPS 2012 Chair*

08:30 - 09:15
Plenary: **THE POWER OF PARTNERSHIP** *(Centre-East Room, Main Level)*
Donna Davis, *Patients for Patient Safety Canada, Carievale, SK*

09:15 - 10:00
Plenary: **BODY COMPOSITION AND CLINICAL PHARMACOLOGY ADVENTURES IN CHEMOTHERAPY TOXICITY** *(Centre-East Room, Main Level)*
Dr. Michael Sawyer, *Alberta Health Services - Cancer Care, Edmonton, AB*

10:00 - 10:30 BREAK *(Exhibit Hall, South-West Room and Conference Foyer, Main Level)*

10:30 - 11:15
Plenary: **PATIENT INPUT INTO THE pCODR REVIEW PROCESS** *(Centre-East Room, Main Level)*
Dr. Josephine Nanson, *Saskatoon Exceptional Learner's Centre, Saskatoon, SK*

11:15 - 12:00
Plenary: **THE BIOMEDICAL IMAGING AND THERAPY RESEARCH FACILITY AT THE CANADIAN LIGHT SOURCE** *(Centre-East Room, Main Level)*
Dr. Dean Chapman, *University of Saskatchewan, Saskatoon, SK*

12:00 - 13:00
Meeting: **CAPHO ANNUAL GENERAL MEETING** *(Centre-East Room, Main Level)*
Jennifer Jupp, *CAPhO President*

13:00 - 14:00 LUNCH *(Exhibit Hall and Centre-East Room, Main Level)*

14:00 - 15:20
BREAKOUT SESSIONS #1, #2, #3

Breakout #1: **TECHNICIAN STREAM: EXPANDED ROLE OF THE TECHNICIAN** *(Top of the Inn, 8th Floor)*

14:00 - 14:40
Part 1: **ADHERENCE TO USP <797> STANDARDS IN BC**
Michelle Koberinski, *Cancer Centre for the Southern Interior, Kelowna, BC*

14:40 - 15:20
Part 2: **HELPING HANDS: PHARMACY TECHNICIANS HELPING IN A CLINIC SETTING**
Aynsley Bell, *Cancer Care Manitoba, Winnipeg, MB*

Breakout #2: **CLINICAL STREAM: SUPPORTIVE CARE** *(Centre-East Room, Main Level)*

14:00 - 14:40
Part 1: **ANAEMIA MANAGEMENT IN THE ONCOLOGY SETTING: A REVIEW AND UPDATE**
Dr. Mark Pasetka, *Sunnybrook Health Sciences Centre, Toronto, ON*

14:40 - 15:20
Part 2: **OPTIMIZING PAIN RELIEF FOR YOUR PALLIATIVE CANCER PATIENTS**
Lori Gagnon, *Alberta Health Services Cancer Care, Edmonton, AB*

Breakout #3: **ADMINISTRATIVE / RESEARCH STREAM** *(Starlight Room, Lower Foyer)*

14:00 - 15:20
Part 1 and Part 2
SIFTING THROUGH THE PAST, PAVING THE FUTURE
Dr. Dalyce Zuk, *Alberta Health Services, Calgary, AB*

15:20 - 15:50 BREAK *(Exhibit Hall, South-West Room and Conference Foyer, Main Level)*

15:50 - 16:35
BREAKOUT SESSIONS 4, 5, 6

Breakout #4: **IMPROVING CHEMOTHERAPY PREPARATION SAFETY THROUGH PROCESS CHANGES: WORKLOAD AND WORKFLOW IMPLICATIONS** *(Centre-East Room, Main Level)*
Rachel White, *University Health Network, Toronto, ON*

Breakout #5: **WHAT DID THE PHARMACIST JUST SAY TO ME?** *(Top of the Inn, 8th Floor)*
Dr. Carlo De Angelis, *Sunnybrook Health Sciences Centre, Toronto, ON*

Breakout #6: **UPDATE ON TREATMENT OF GYNECOLOGIC MALIGNANCIES** *(Starlight Room, Lower Foyer)*
Nathalie Letarte, *University of Montreal, Montreal, QC*

16:35 - 18:30 *(Exhibit Hall, South-West Room and Conference Foyer, Main Level)*
Exhibits and Posters Viewing Reception

19:00 - 22:30 *(Delta Bessborough, across the street from the Sheraton Cavalier Hotel)*
Dinner & CAPhO Awards Program & Entertainment

Saturday Social Events

This year's Saturday afternoon and evening events will provide great opportunities to network with old and new friends.

16:35 - 18:30
(Exhibit Hall, South-West Room and Conference Foyer, Main Level)
Exhibits and Posters Viewing Reception

The Exhibits and Posters Viewing Reception will take place amongst the Exhibits. Participation is included in your registration fee.

19:00 - 22:30
(Delta Bessborough, across the street from the Sheraton Cavalier Hotel, at 601 Spadina Crescent East)
Dinner & CAPhO Awards Program & Entertainment

You will be entertained after dinner with music from the musical trio The Chemostatics and laughter with comedian Big Daddy Tazz.

> It was high school that Big Daddy Tazz realized his natural ability to make people laugh. After falling on his face, his teacher asked what he was trying to prove. Tazz quickly answered, "Gravity!" Laughter erupted, and thus the saga began. Tazz is able to do what he loves both on and off stage, which is to make people laugh! His off-the-cuff style brings the audience together, making them feel like they are part of his family, sitting around the kitchen table playing crib.

Participation is included in your registration fee. Guest tickets for the Dinner Event can be purchased at the Registration Desk, located in the Conference Foyer, Main Level, depending on availability.

Delta Bessborough

Sunday, October 28

07:00 - 08:30
Satellite Symposium: **NOVARTIS** *(Top of the Inn, 8th Floor)*
ADHERENCE TO ORAL MEDICATIONS: WHAT'S IN IT FOR THE ONCOLOGY PATIENT?
Ferid Rashid, *Brampton Civic Hospital, Brampton, ON*
Dimitris Polygenic, *McKesson Pharmaceutical Solutions, Toronto, ON*

08:00 - 08:30 CONTINENTAL BREAKFAST *(Exhibit Hall, South-West Room and Conference Foyer, Main Level)*

08:30 - 09:45
Meeting: **CAPHO TOWN HALL MEETING** *(Centre-East Room, Main Level)*
Jennifer Jupp, *CAPhO President*

09:45 - 10:15
Plenary: **ORAL SESSIONS - AWARD WINNING POSTERS** *(Centre-East Room, Main Level)*
Victoria Kletas, *CAPhO Awards Committee Chair*

10:15 - 10:30 BREAK *(Exhibit Hall, South-West Room and Conference Foyer, Main Level)*

10:30 - 11:15
Plenary: **BONE TARGETED THERAPY IN CANCER** *(Centre-East Room, Main Level)*
Dr. Michael LeBlanc, *The Moncton Hospital, Moncton, NB*

11:15 - 12:00
Plenary: **ENGAGING PRIMARY CARE PROVIDERS DURING ACTIVE CANCER TREATMENT**
(Centre-East Room, Main Level)
Dr. Monika Krzyzanowska, *Princess Margaret Hospital, Toronto, ON*

12:00 - 12:30
Plenary: **EFFECT OF INTERRUPTIONS ON CHEMOTHERAPY ORDERING AND THE IMPACT OF CLINICAL PHARMACISTS ON MEDICATION ORDER QUALITY** *(Centre-East Room, Main Level)*
Dr. Patricia Trbovich, *University Health Network, Toronto, ON*

12:30 - 12:40
Plenary: **CLOSING REMARKS** *(Centre-East Room, Main Level)*
Kathy Gesy, *NOPS 2012 Chair*
Dr. Carlo De Angelis, *NOPS 2013 Co-Chair*
Dr. Mark Pasetka, *NOPS 2013 Co-Chair*

13:00 - 14:30
Satellite Symposium: **EISAI** *(Top of the Inn, 8th Floor)*
AN UPDATE ON THE CURRENT MANAGEMENT OF CHEMOTHERAPY INDUCED NAUSEA AND VOMITING (CINV) & AN INTRODUCTION TO A PILOT PROJECT WITH ALOXI (PALONOSETRON HYDROCHLORIDE) IN THE SASKATOON CANCER CENTRE
Sean Hopkins, *Professional Practice Coordinator, Ottawa Hospital Cancer Centre, Ottawa, ON*
Colleen Olson, *Senior Pharmacist, Saskatoon Cancer Centre, Saskatoon, SK*

Every door opened could be a discovery made.

Lilly Oncology

No two cancer patients are alike. That's why Lilly Oncology is committed to developing treatment approaches as individual as the people who need them. We've made many contributions toward improved patient outcomes and - with each door we open - we take another step forward. But helping today's cancer patient isn't enough. Even with over 40 drug targets in development, our quest to help you provide tailored therapy is just beginning.

Making science personal.

To find out more, visit www.lilly.ca or call 1 888 545 5972.

www.lilly.ca

Lilly
Answers That Matter.

Think What's Possible!

Novartis Oncology is dedicated to answering unmet medical needs. Our priority is to discover, develop and make broadly available novel therapies that may improve and extend the lives of patients.

NOVARTIS ONCOLOGY

Novartis Pharmaceuticals Canada Inc.
Dorval, Quebec H9S 1A9
www.novartis.ca
(514) 631-6775 (514) 631-1867

PAAB Member R&D

Speakers & Session Descriptions

Saturday, October 27

The Power of Partnership

DONNA DAVIS
Patients for Patient Safety Canada, Carievale, SK
Saturday 08:30 - 09:15 • Centre-East Room, Main Level

Biography

Donna Davis comes from the tiny village of Carievale in Southeast Saskatchewan. She is married with four children, including her son who died due to medical error. She is a nurse whose career has spanned 36 years working in rural facilities in Saskatchewan and Manitoba. She is a WHO Patient Safety Champion and Co-chair of Patients for Patient Safety Canada, a program of the Canadian Patient Safety Institute, bringing the patient voice to the conference as she tells the account of the multi-system breakdown that claimed the life of her only son and the lessons to be learned from it.

Synopsis

Learning Objectives

- The real life account of a patient safety incident will reach the hearts and minds of the audience heightening their awareness of patient safety
- The audience will understand the effect a harmful patient safety incident has on patients, families and providers
- The audience will learn what actions they can take to improve patient safety in their practice and workplace
- The audience will learn how effective partnerships with colleagues, patients and families can facilitate the sharing of ideas that leads to policy changes and program improvements leading to quality, safe care for all
- Resources and tools available to assist with improving patient safety policies and processes will be identified

Abstract

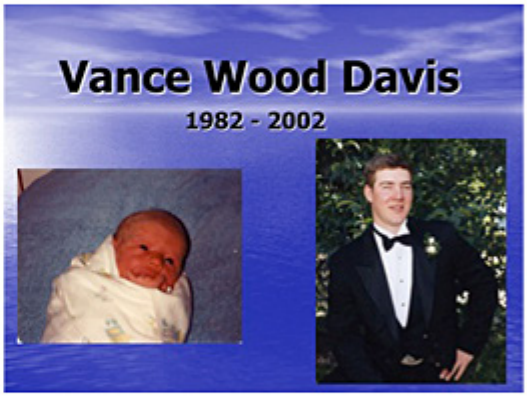
Canadian patients and family members who have experienced adverse events have been able to influence change by sharing stories and leveraging their experiences to promote learning and change at institutional, provincial, regional, national and international levels.

In this presentation, Donna Davis will tell the story of her son's unnecessary death from medical error and the effect this event had on all involved: the family, the providers and the organization. The multi-system breakdown in communication, handover, stereotyping and teamwork will be discussed. Ms Davis tells of lessons learned and those yet to be. With insight derived from this tragic event, Ms Davis will identify resources and tools that will assist attendees in taking action in their practice to improve patient safety.

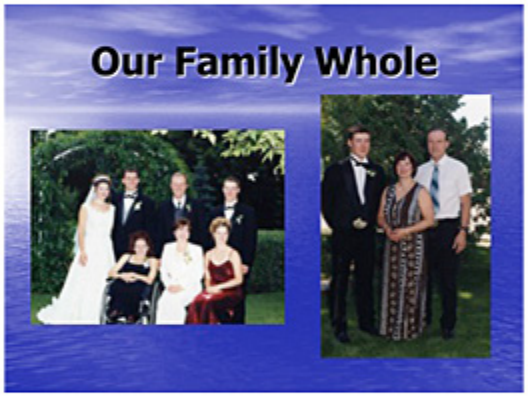
Attendees will learn about Patients for Patient Safety Canada, a patient led program of the Canadian Patient Safety Institute, whose vision is "Every Patient Safe" and mission is "We champion the patient voice to advance safe healthcare."

By drawing from patient / family personal experiences and lessons to be learned, providers and health care organizations can make patient safety issues real because it attaches quality and safety to real people not statistics.

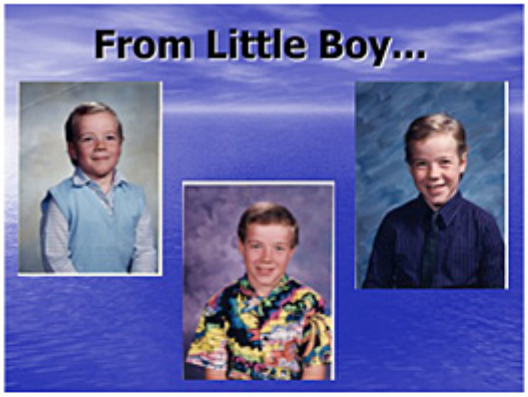
Donna Davis | Presentation Handouts Pg1

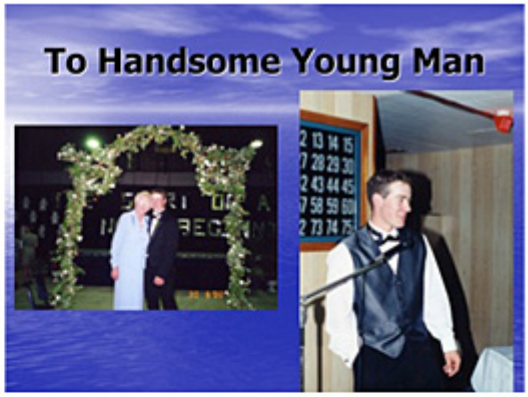


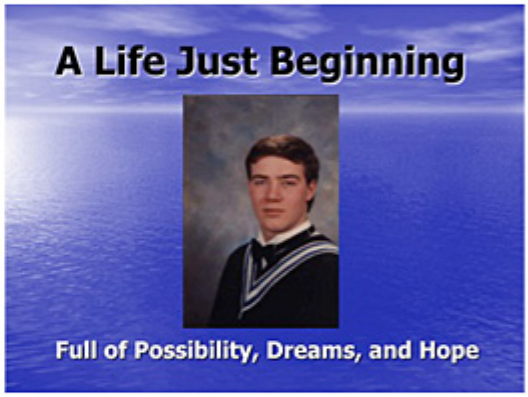
Donna Davis | Presentation Handouts Pg2



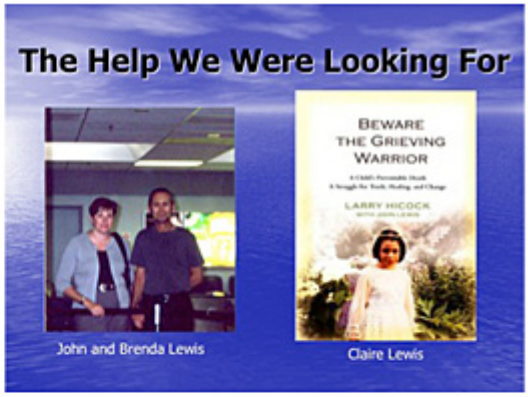
Donna Davis | Presentation Handouts Pg3

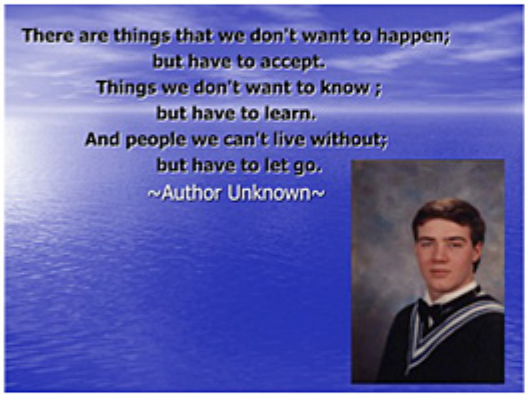


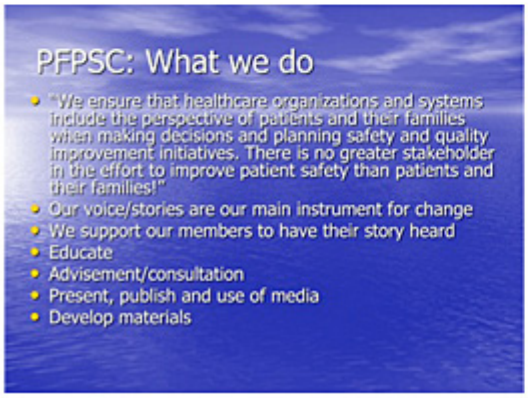




Donna Davis | Presentation Handouts Pg4







Donna Davis | Presentation Handouts Pg5

Body Composition and Clinical Pharmacology Adventures in Chemotherapy Toxicity

DR. MICHAEL SAWYER
Alberta Health Services – Cancer Care, Edmonton, AB
Saturday, 09:15 - 10:00 – Centre-East Room, Main Level

Biography

Dr. Michael Sawyer is an associate professor in the Department of Oncology of the University of Alberta, and a medical oncologist and a clinical pharmacologist for Alberta Health Services, Cancer Care. He obtained his Bachelor of Science in Pharmacy and his MD from the University of Toronto. He completed his fellowship in Medical Oncology at the University of Western Ontario and completed his training in drug development and clinical pharmacology at the University of Chicago Cancer Center under Dr. Mark J. Ratain.

The major theme of his research is the cause of interpatient variability in terms of efficacy and toxicity to cancer chemotherapy. In order to understand these causes his research is focused in several areas such as drug transporters, body composition, nutrition, tyrosine kinase inhibitor pharmacology and metabolomics. He is funded by the Alberta Cancer Foundation, Alberta Innovates Health Solutions, the Canadian Institutes of Health Research and by several investigator initial studies with the pharmaceutical industry. He is Head of the Phase I Program of the Cross Cancer Institute.

Synopsis

Learning Objectives

- Learn about the current image-based methods of body composition
- Describe the effects of lean body mass on cytotoxic chemotherapy toxicity and efficacy
- Learn effects of targeted tyrosine kinase inhibitor therapy on lean body mass
- Appreciate effects of variation of lean body mass in cancer patients and its effects on estimation of renal function

Abstract

Historically cancer chemotherapy has been dosed using body surface area to personalize the dose of chemotherapy and more recently with the introduction of tyrosine kinase inhibitors the concept of flat dosing has been used for tyrosine kinase inhibitors. Applying new techniques that allow clinical CT and MRI scans we have found that neither BSA nor flat dosing may be the preferred way to dose chemotherapy. Modern techniques of body

composition using image analysis will be explained and studies of cytotoxic and targeted chemotherapy with regards to both efficacy and toxicity using body composition analysis will be reviewed. The impact of targeted cancer therapies on muscle wasting and its possible relationship to fatigue will be discussed. The clinical impact of muscle mass variation in the inaccuracy of estimating renal function using current methods and potential solutions to this will problem will be reviewed.

Dr. Michael Sawyer | Presentation Handouts Pg1

Body Composition and Clinical Pharmacology Adventures in Chemotherapy Toxicity Efficacy and Dosing

Michael Sawyer MD B.Sc. Phm FRCPC FACP FACCP
Associate Professor, Dept of Oncology University of Alberta
Medical Oncologist/Clinical Pharmacologist

Cross Cancer Institute

Outline

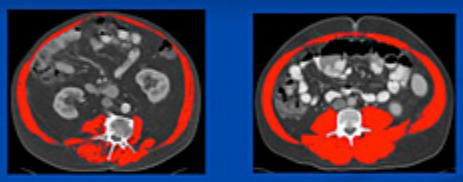
- Imaging methods of body composition
- Effects of lean body mass on 5FU toxicity
- Effects of lean body mass on capecitabine
- Sorafenib and effects of lean body mass and vice versa
- Not all TKIs are the same
- Random number generators aka the Cockcroft-Gault and MDRD equations in cancer patients

Methods

- 3rd lumbar vertebrae (**L3**) was chosen as a standard landmark
- Cross-sectional areas (cm^2) of the sum of all muscles were computed for each image
- Image analysis: Slice-O-matic software V4.3 (Tomovision, Montreal, QC, Canada)

I Had Eyes But I Did Not See

Same BSA = 2.07 and BMI = 30.3



MUSCLE IS COLORED IN RED

Body composition of cancer patients represents a wide spectrum that can not be depicted using body weight, body mass index (BMI) and body surface area (BSA) alone.

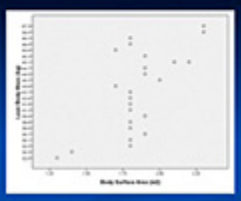


Figure 1. A. Relationship between lean body mass (LBM) and BSA. N = 24 breast cancer patients receiving epirubicin.

Body composition as an independent determinant of 5-fluorouracil-based chemotherapy toxicity

Prado *et al. Clinical Cancer Research* 2007, v.13 p. 3264-68

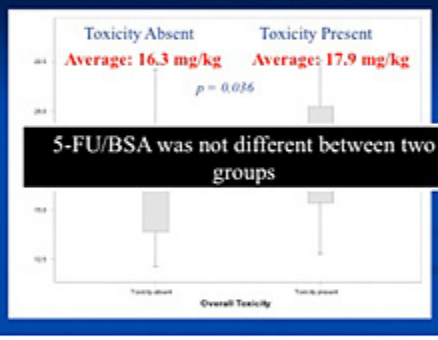
- N = 62
- 67% of women and 56% of men presented with toxicity
- Patients had a wide range of body composition

Results

DOSE of 5-FU

Kg LEAN TISSUE (LST)

DOSE/LST - 12 to 33 mg/kg LST



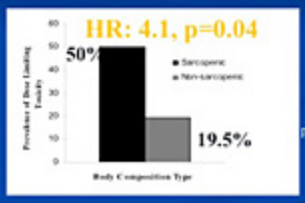
Sarcopenia as a determinant of chemotherapy toxicity and time to tumor progression in metastatic patients with breast cancer receiving capecitabine treatment

Prado *et al.* Clin Cancer Res. 2009 Apr 15;15(8):2920-6.

Results

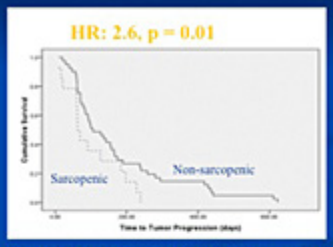
- N=55 female patients

Prevalence of Toxicity between Sarcopenic and Non-sarcopenic patients (n=55)



Dr. Michael Sawyer | Presentation Handouts Pg3

Comparison of Time to Tumor Progression between Sarcopenic and Non-Sarcopenic Patients (p = 0.05)



Sarcopenic patients: 62 days CI 47.3 – 76.7
Non-sarcopenic patients: 105 days CI 52.3 – 157.7

Prevalence and clinical Implications of Sarcopenic Obesity in Patients with Solid Tumors of the Respiratory and Gastrointestinal Tracts: A Population Based Study
Prado et al.
Lancet Oncology, 2008

Study Design

- From Jan 13, 2004 to Jan 19, 2007 2115 patients with solid tumors of the respiratory and GI tracts treated at the CCI
- Of these 325 patients were obese (BMI≥30), of these 250 had CT scans
- Patients completed the Patient Generated Subjective Generalized Assessment
- Assessed performance status
  - Carved in stone clinical assessment

Patient Characteristics

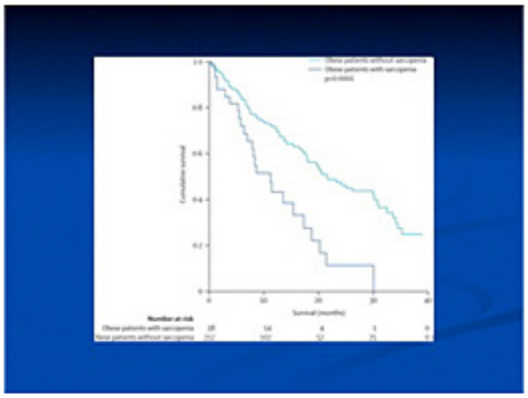
		MALES	FEMALES	TOTAL
AGE (years)	X±SD	64·6 ± 10·2	63·2 ± 10·5	63·9 ± 10·4
	Range	35-88	41-85	35-88
BMI (kg/m²)	X±SD	33·9 ± 4·4	34·7 ± 4·3	34·3 ± 4·4
	Range	30·0-52·7	30·0-53·0	30·0-53·0
Lumbar total muscle cross-sectional area (cm²)	X±SD	180·2 ± 30·4	123·1 ± 22·3	155·3 ± 38·4
	Range	89·4 - 271·5	79·2 - 264·5	79·2 - 271·5
Estimated total appendicular skeletal muscle/ height² (kg/m²)	X±SD	7·47 ± 1·06	6·10 ± 0·93	7·11 ± 1·16
	Range	5·39 - 11·2	4·45 - 10·6	4·45 - 11·2
Estimated Total fat free mass (kg)	X±SD	60·1 ± 9·2	43·4 ± 6·7	52·4 ± 11·6
	Range	36·2 - 87·3	29·8 - 64·5	29·8 - 87·3
Body surface area (m²)	X±SD	2·24 ± 0·2	1·9 ± 0·19	2·2 ± 0·2
	Range	1·61 - 2·88	1·3 - 2·8	1·3 - 2·9

Sarcopenic Obese vs. Obese

	Sarcopenic obese N=87 (32·4%)	Non-sarcopenic obese N=183 (77·2%)	p-value*
Muscle cross-sectional area (cm²) - Mean, SD and Range	170·4 ± 32·9 79·2 - 195·5	159·8 ± 39·0 93·6 - 271·5	p < 0·001
Estimated whole body fat free mass (kg) - Mean, SD & Range	47·9 ± 9·9 29·8 - 64·7	54·0 ± 11·7 34·7 - 87·3	p < 0·001
Sex:			
Males	44 (77·2%)*	92 (47·7%)*	p < 0·001
Females	13 (22·8%)*	101 (52·3%)*	
Age:			
< 65 years old	22 (38·6%)*	107 (55·4%)*	p = 0·0434
≥ 65 years old	35 (61·4%)*	86 (44·6%)*	
Cancer diagnosis:			
Respiratory tract	4 (7·0%)*	56 (29·0%)*	p < 0·001
Colorectal	44 (77·2%)*	99 (51·3%)*	
Other*	9 (15·8%)*	38 (19·7%)*	
Third stage of malignant disease:			
I	3 (5·8%)*	19 (9·8%)*	
II	11 (19·3%)*	47 (23·3%)*	p = 0·869
III	19 (33·3%)*	55 (28·5%)*	
IV	22 (38·6%)*	74 (38·3%)*	
Weight change (over preceding 6 months)*:			
≥10% loss	6	3 (1·7%)*	p = 0·127
No change*	37 (64·9%)*	141 (78·8%)*	
≥10% gain	17 (31·5%)*	35 (19·6%)*	
Functional Score:			
0-1	34 (59·6%)*	142 (73·6%)*	p = 0·043
2-4	23 (40·4%)*	51 (26·4%)*	

Survival Analysis

Variable	Coefficient	Standard error	Relative Risk	95% Confidence Interval	p value
Sarcopenic -obesity	0·76	0·27	2·1	1·3 - 3·6	0·004
Functional status score	0·99	0·22	2·7	1·8 - 4·1	<0·001
Respiratory tract cancer*	1·21	0·27	3·3	2·0 - 5·6	<0·001
Other can cer diagnosis*	0·73	0·27	2·1	1·2 - 3·5	0·007
Stage IV disease*	1·26	0·42	3·5	1·6 - 7·9	0·002

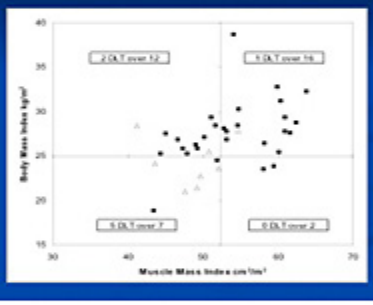


The association of skeletal muscle wasting with treatment with sorafenib in patients with advanced renal cell carcinoma: results from a placebo controlled study.

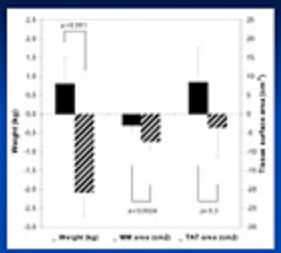
Antoun et al. JCO, 2010

- Metastatic renal cell cancer (RCC) patients resistant to standard therapy (n=80) received sorafenib 400 mg BID or placebo in a randomized, double blinded clinical trial.

Relationship Between Sorafenib DLT and Body Composition

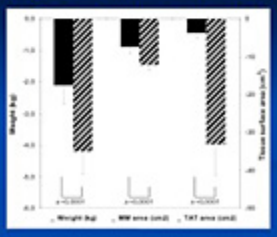


Evolution Of Body Weight, Skeletal Muscle And Total Adipose Tissue During 6 Months Of Treatment With Sorafenib Versus Placebo



Overall change in body weight (kg), total lumbar skeletal muscle (MM) and adipose tissue (TAT) cross-sectional area (cm2) during 6 months treatment with placebo (n=32) ( ) and sorafenib (n=48) ( ). Statistical indications unpaired Student's t-test for body weight : 0.8±0.7 vs -2.1±0.6 (p<0.001) ; skeletal muscle area : -3.1±1.3 vs -7.4±1.7 (p=0.024).

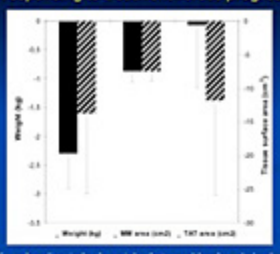
Long term loss of body weight, skeletal muscle and total adipose tissue during 6 and 12 months of sorafenib treatment.



Overall change from baseline in body weight (kg), total lumbar skeletal muscle (MM) and adipose tissue (TAT) cross-sectional area (cm2) in patients treated with sorafenib for 6 months (mean 162 days) ( ) and 1 year (mean 366 days) ( ). Statistical indications are for paired Student's t-test : weight loss (Δ Weight, kg) -2.1±0.6 vs -4.2±0.7 ; skeletal muscle (Δ muscle area, cm2) -7.4±1.7 vs -12.1±1.5, adipose tissue (Δ adipose tissue area, cm2) -3.7±7.8 vs -33.1±8.1.

Dr. Michael Sawyer | Presentation Handouts Pg5

Change of body weight, skeletal muscle and total adipose tissue in patients responding to treatment versus progressive disease

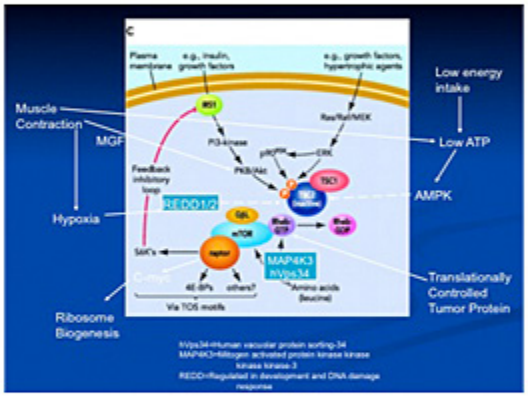


Overall change from baseline in body weight (kg), total lumbar skeletal muscle (MM) and adipose tissue (TAT) cross-sectional area (cm2) in patients with stable disease or partial response to treatment ( ) or progressive disease ( ). No statistically significant differences were noted, p>0.05 unpaired Student's t-test.

- Why are patients who are responding to treatment losing muscle mass

Skeletal muscle proteins

- 1-2% turnover per day
- Synthesis stimulated by
  - Essential amino acids (leucine)
  - Resistance exercise
- Synthesis regulated at multiple steps
  - Translation initiation governed by mTOR
    - Blocked by rapamycin (ie. mTORC1)
    - Regulates muscle size, not fibre type



Other Targets that Make Cause Muscle Wasting

- PI3 Kinase
- IGF1-R
- mTOR
- VEGFR TKI
- bRAF

Other Tyrosine Kinase Inhibitors

- Done with collaborators at Institute Gustav Roussey
  - Everolimus vs placebo
  - Sunitinib vs placebo
  - Sorafenib vs placebo
- Number of patients in total 147
- 78% male
- No differences in weight or muscle surface area at baseline

Dr. Michael Sawyer | Presentation Handouts Pg6

Other Tyrosine Kinase Inhibitors

- Placebo patients had no significant change in weight or muscle surface area mean change in weight 0.9 ± 3.7 kg
- Everolimus patients lost 3.5 ± 5.6 kg
- Sunitinib patients lost 2.5 ± 3.8 kg

- Loss of muscle surface area for everolimus was 3% ± 8 (p=0.1)
- Loss of muscle surface area for sunitinib was 4% ± 5 (p=0.001)
- Rate of loss for everolimus was 0.042 cm^2/day, sorafenib 0.045 cm^2/day, and sunitinib was 0.044 cm^2/day

Cholangiocarcinoma

- Two major types
  - Intrahepatic & bile duct (2500 - 3000)
  - Gallbladder (6000-7000)
- Presents at a late stage
- Only recently has a therapy been introduced
- Experience at the Cross
  - Severe fatigue
  - Weight loss
  - Hypercalcemia
  - Hyper coaguable

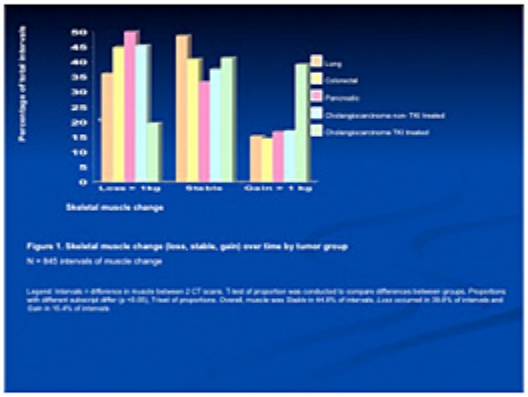


Figure 1. Skeletal muscle change (loss, stable, gain) over time by tumor group

N = 845 intervals of muscle change

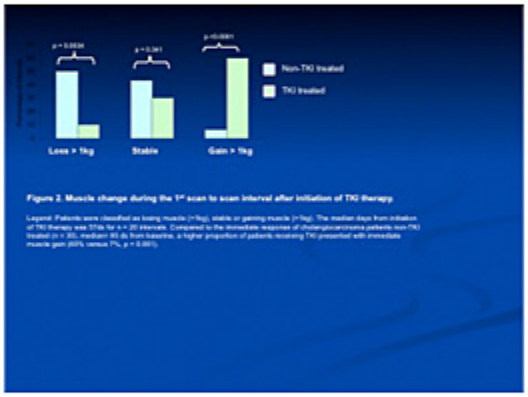


Figure 2. Muscle change during the 1st scan to scan interval after initiation of TKI therapy

What is Happening

- The TKI is selumetinib a MEK inhibitor but shutting down this pathway inhibits IL-6 production and secretion
- IL-6 is a major player in cancer cachexia
- Elevated levels of IL-6 in cholangio
- Chinese liver flukes cause an inflammatory reaction and production of IL-6

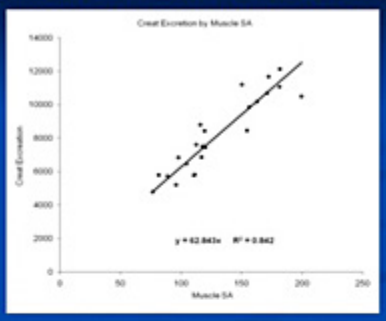
Difficulties in Using Creatinine or Cockcroft-Gault in Patients Who are Sarcopenic

- Cockcroft-Gault equation developed at McGill in early 1970s
- Developed in a general medical population
- Not in a cancer patient specific population
- Based on statistical analysis of common patient demographics

Metabolomic Study of Cancer Cachexia

- Patients did a 24 hour urine collection and had a concurrent CT scan
- 24 patients had a complete urine collections
- The median age was 67 with a range of 49 to 80
- All patients had metastatic disease

Creatinine Excretion Related to Muscle Surface Area



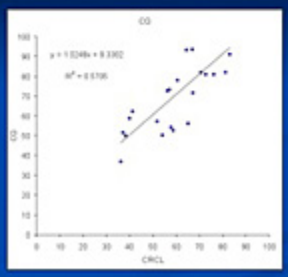
Metabolomic Study of Cancer Cachexia

- Creatinine Clearance = 24 hr Creatine Excr/ Plasma Creatinine
- Creatinine Clearance = (1000*24 hr Creatine Excr)/ (Plasma Creatinine*24*60)
- Creatinine Clearance = (1000*62.84*Muscle SA)/ (Plasma Creatinine*24*60)
- Creatinine Clearance= (44*Muscle SA)/(plasma Cr)

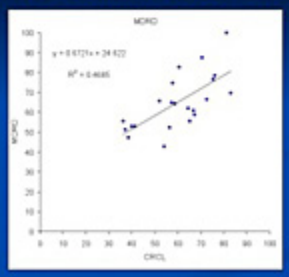
Mean Absolute Percent Error

Equation to Predict GFR	Mean	Median	Min	Max
LBM	9.0	5	1	23
Wright	11.5	10	0	30
CG	22.6	15	1	60
CKD-EPI	18.2	17	1	47
MDRD	19.8	19	2	53

Cockcroft and Gault Formula vs Measured CrCl

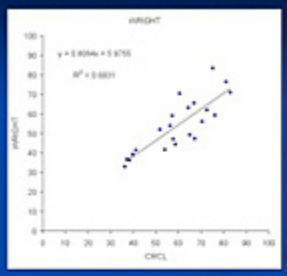


MDRD Formula vs Measured CrCl

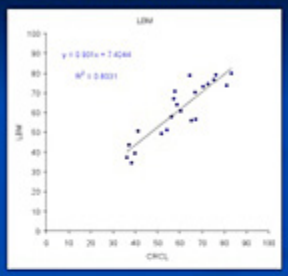


Dr. Michael Sawyer | Presentation Handouts Pg8

Wright Formula vs Measured CrCl



LBM Formula vs Measured CrCl



Future Directions

- Collaboration with Eisai to study E7080 and its effects on lean body mass and fatigue
- Collaboration with Johnson and Johnson on studying siltuximab CNTO 328 in castleman's
- Studying effects of MEK126 on muscle wasting in cholangiocarcinoma
- Collaboration with Norwegian Cancer group to study sarcopenia in lung cancer patients
- Collaboration with BMS in studying brivanib and lean body mass

Acknowledgements

Dr. Vijaya Damaraju
Dr. Carla MM Prado
Dr. Vickie Baracos
Dr. Sami Antoun
Larissa McCaw
Cynthia Stretch
Stephen Petryk
Michelle Kuzma
Cancer Care Alberta Health Services

Patient Input into the pCODR Review Process

DR. JOSEPHINE NANSON
Saskatoon Exceptional Learner's Centre, Saskatoon, SK
Saturday, 10:30 - 11:15 – Centre-East Room, Main Level

Biography

Dr. Josephine Nanson is a registered doctoral psychologist currently in private practice. Her interests are in child and family assessment and therapy. She has a Bachelor of Arts in Psychology, a Master's of Arts in Psychology and in 1988, she received her Ph.D. in Psychology, all from the University of Saskatchewan. She currently provides neuropsychological assessment to children and adolescents from the Saskatoon Cancer Centre and has contributed neuropsychological data to several pediatric clinical trials. She is a member of the Children's Oncology Group (COG). In 2010, she became a survivor of breast cancer. In 2011, she was appointed as one of two patient representatives on the Expert Review Committee of the pan-Canadian Oncology Drug Review (pERC).

Synopsis

Learning Objectives

- To summarize how cancer drugs are funded in Canada
- To provide an overview of the pCODR process
- To discuss how patient advocacy groups can provide useful input on a drug submission to pCODR
- To discuss personal experiences as a patient representative

Abstract

Patient representation on decision-making committees in health is rare, but is emerging as a trend towards greater transparency and accountability, particularly in a climate of decreased resources. The pan-Canadian Oncology Drug Review (pCODR) process requires two patient representatives on the Expert Review Committee (pERC), and grants these representatives voting privileges, the same as the health economists, pharmacists, and oncologists who make up the remainder of the Committee. The patient representatives are responsible for presenting information submitted by the relevant patient advocacy group to pERC, and for representing a patient perspective during the deliberations. This seminar will review the process that pCODR follows, the role of the patient advocacy groups in contributing to the review process, and will discuss the experience of being a patient representative on pERC during its first year of operation.

Dr. Jo Nanson | Presentation Handouts Pg1

pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

Patient Input into the pCODR Review Process

National Oncology Pharmacy Symposium
October 27 2012
Jo Nanson, Ph. D., R. D. Psychologist

Objectives of Presentation

- To summarize how cancer drugs are funded in Canada
- To provide an overview of the pCODR process
- To discuss how patient advocacy groups can provide useful input on a drug submission to pCODR.
- To discuss personal experience as a patient representative.
- Cannot comment of a specific drug review or patient group submission.
- No conflicts of interest, no outside funding.
- Questions at the end please.

Who is Responsible for Cancer Drug Funding in Canada?

	Hospital	Cancer Agencies	Provincial or Territorial Drug Plan
BC		x	
AB		x	x
SK		x	
MB		x	x
ON	x	x	x
NB	x		x
PEI	x		x
NS	x		x
NL	x		x

Drug Access–>Who Does What in Canada

Health Canada (federal)
Reviews for safety, effectiveness & efficacy
Approves new drugs for sale in Canada
Monitors safety in "real" usage

CDEC (CDR)
- All F/P/T Plans (except Quebec)
- Reviews for clinical & cost effectiveness of non-cancer drugs
- Recommends listing on public drug plans

pCODR
- All P/T ministries of Health (except Quebec)
- Assesses clinical evidence and cost effectiveness of new cancer drugs
- Recommends funding in public drug plans & provincial cancer agencies

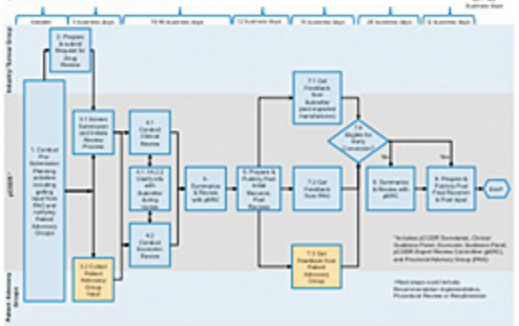
Quebec
- INESS conducts Clinical & financial / cost effectiveness reviews
- Recommends to Minister of Health

P/T Ministries of Health and Provincial Cancer Agencies
- Decide what is covered, who is eligible & extent of coverage
- Pay for the drugs

About pCODR

- Assesses cancer drugs and makes funding recommendations to provinces and territories to guide their drug funding decisions; final decision whether to add an oncology drug to a formulary remains responsibility of each participating jurisdiction.
- Designed to bring consistency and clarity to assessment of cancer drugs by looking at clinical evidence, cost-effectiveness and patient perspectives
- pCODR's partners:
  - provinces and territories (with the exception of Quebec)
  - provincial cancer agencies
  - Canadian Partnership Against Cancer (CPAC)
  - Canadian Agency for Drugs and Technologies in Health (CADTH)
- Committed to transparency and the need to be accountable to patients and public, and responsive to industry

pCODR Review Process



Dr. Jo Nanson | Presentation Handouts Pg2

pCODR

Inputs into pERC Recommendations

pCODR

pERC Deliberative Framework

- Outlines elements to be considered during pERC deliberations
- Reinforces that no single element over-rides another, rather it is sum of all elements that pERC must use
- Can be applied to all oncology drugs and situations, including rare cancers or end of life drug treatments
- Reinforces there is no threshold that must be met for any single element in the review
- It is the individual drug, disease and context that determine pERC's information needs for each element of the framework

pCODR

Detailed Description of Each Element of the pERC Deliberative Framework (1)

Criteria	Sub-Criteria	Sub-Criteria Definitions
Overall Clinical Benefit	Effectiveness (systematic review in the Clinical Guidance Report)	The potential health impact of the drug compared to the other drug and non-drug alternatives, measured in terms of relevant patient outcomes such as mortality, morbidity, quality of life. Magnitude, direction and uncertainty of effect should be considered.
	Safety (systematic review in the Clinical Guidance Report)	Frequency and severity of adverse effects associate with the new drug compared to other drug and non-drug alternatives.
	Burden of Illness (Clinical Guidance Report, patient advocacy group input)	Incidence, prevalence or other measure of disease burden on the population.
	Need (Clinical Guidance Report, patient advocacy group input)	Availability of an effective alternative to the drug technology.

pCODR

Detailed Description of Each Element of the pERC Deliberative Framework (2)

Criteria	Sub-Criteria	Sub-Criteria Definitions
Alignment with Patient Values	Patient Values (patient advocacy group input)	Patient based values which bear on the appropriate use and impact of the drug.
Cost effectiveness	Economic Evaluations (Economic Guidance Report and pharmaco-economic model review)	A measure of the net cost or efficiency of the drug and companion technology compared to other drug and non-drug alternatives. The uncertainty of results should be considered.
Feasibility of Adoption into Health Systems	Economic Feasibility (evaluation of budget impact assessment in Economic Guidance Report)	The net budget impact of the new drug on other drug and health system spending, including companion testing technology.
	Organizational Feasibility (Provincial Advisory Group Input)	The ease with which the new drug can be adopted, with an assessment of health system enablers and barriers to implementation, inclusive of all elements: operational, capital, human resources, legislative and regulatory requirements

pCODR

pERC Funding Recommendations

- pERC recommendations will help guide funding decisions; final funding decisions remain responsibility of each participating jurisdiction
- Funding recommendations are not static - they are context specific, such as:
  - Evidence available at that point in time
  - Existing programs and policies - who is covered, what is/is not covered
  - Basket of currently available and/or funded treatment options
  - Current pricing arrangements
- Almost all cancer drug funding bodies (ministry or agency) in Canada already identify specific patient populations or context for use (e.g., protocols) within their funding criteria for cancer drugs

pCODR

pERC Patient Members

- Jo Nanson
  http://www.pcodr.ca/idc/groups/pcodr/documents/webcontent/pcodr-perc-jnanson.pdf
- Bryson Brown
  http://www.pcodr.ca/idc/groups/pcodr/documents/webcontent/pcodr-perc-bbrown.pdf
- Carole McMahon (Patient Member Alternate)
  http://www.pcodr.ca/idc/groups/pcodr/documents/webcontent/pcodr-perc-cmcmahon.pdf

pCODR

How is the patient perspective incorporated?

- Input from patient advocacy groups received early in review process and allows pCODR to establish the plan (protocol) by incorporating outcomes and issues that are important to patients
- Input is used by pERC in their deliberations and recommendation, to understand patient values
- Shared with provincial and territorial ministries of health, and cancer agencies that participate in pCODR, to use in their decision-making
- Feedback from patient advocacy groups on an initial recommendation allows pERC to further consider outcomes and issues that are important to patients and to improve the clarity of its recommendations

pCODR

pCODR's Approach to Transparency

- pCODR has committed itself to transparency and the need to be accountable to patients and the public, and responsive to industry
- pCODR considers it essential that the evidence upon which pERC recommendations are based be publicly available
- pCODR posts review related documents publicly:
  - Initial pERC recommendation with key messages, a summary of pERC deliberations and relevant background information
  - Full clinical guidance report
  - Summary of economic guidance report
  - Final pERC recommendation with key messages, a summary of pERC deliberations and relevant background information
  - All feedback submitted on an initial recommendation

pCODR

How can patients participate in pCODR review process?

- Registered patient advocacy groups can provide written comments at two points in pCODR review process:
  - early in process for use in preparation of reports used by pERC to develop its recommendations (Step 3.2)
  - later in the review after pERC makes its initial recommendation (Step 7.3)
- Patient advocacy groups can only provide feedback on an initial recommendation if they first provided input in the early stages of review
- Only one input per patient advocacy group per review is accepted

pCODR

What kind of information to include?

- Real world information - patients experience with disease, current therapy and drug being reviewed
  - Patient stories / vignettes may be helpful when trying to illustrate a particularly common or relevant patient experience, but they are often just one source of information
  - Patient surveys can help illustrate the broader patient experience
- Patient advocacy groups are encouraged to look at how to address the questions posed in the input template as succinctly as possible - think key messages
- Scientific evidence is not required - unless it speaks directly to the patient experience. Published studies are rigorously reviewed by the clinical guidance panel and summarized in the Clinical Guidance Report.

pCODR

Personal Observations

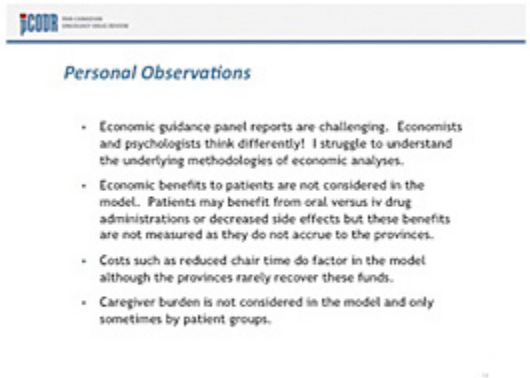
- Patient Representatives seen well accepted by other committee members. This had been a concern prior to the start of PERC. (Savage, 2009-2010, Vogel, CMAJ, 2010).
- Work load is fairly heavy. I typically spend 8-12 hours preparing for each meeting, more if I am leading the discussion of the patient submission. Travel and meeting time is another 1 ½ days.
- No direct mechanism for feedback to PERC from provincial agencies or from patient groups.
- Tight time lines are a concern for each step in the process, yet the total time for work through the process also seem long. There are additional waits for provincial funding approvals.

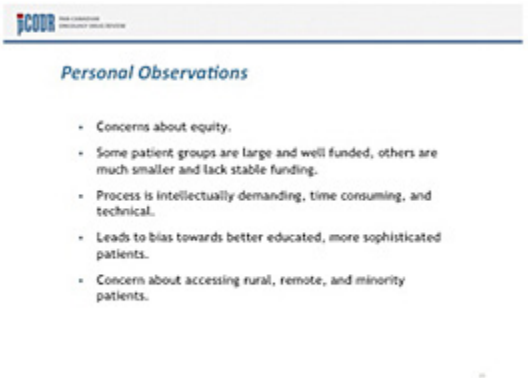
pCODR

Personal Observations

- Patient group submissions are well received by PERC.
- Real-world experience with actual drugs is helpful. If clinical trials have been conducted in Canada or exceptional drug status has been granted, then there may be patients available who have actual experience with the drug. Their perspective is valuable.
- Patient groups routinely indicate a willingness of tolerate significant side effects if there is a perceived benefit, even temporarily.
- Drug funding varies a great deal across the country. Its much simpler in Saskatchewan. This variability frustrates patient groups.

Dr. Jo Nanson | Presentation Handouts Pg4





The Biomedical Imaging and Therapy Research Facility at the Canadian Light Source

DR. DEAN CHAPMAN
University of Saskatchewan, Saskatoon, SK
Saturday, 11:15 - 12:00 – Centre-East Room, Main Level

Biography

Dean Chapman obtained his Ph.D. in Physics from Purdue University (1981), worked at Brookhaven National Laboratory (1982-1995) and in 1995 moved to the Illinois Institute of Technology to direct the synchrotron efforts (three beamlines) at the Advanced Photon Source at the Argonne National Lab. He and colleagues developed the diffraction enhanced imaging for imaging soft tissue. In 2003, he came to the University of Saskatchewan where he leads the Biomedical Imaging & Therapy (BMIT) project, founded a research group on synchrotron imaging of gene expression, is the Canada Research Chair in X-ray Imaging, and is a professor of Anatomy and Cell Biology.

Synopsis

Learning Objectives

- Basics of how a synchrotron works and what it can be used for
- Learning how the synchrotron can be used to image biological systems in unique ways that cannot be done with conventional modalities
- Understanding the basics of how synchrotron biomedical imaging methods work: K-Edge Subtraction, Phase Contrast Imaging, Diffraction Enhanced Imaging and an emerging technique Grating Interferometry
- Examples of the various synchrotron imaging methods being used to visualize biological systems
- Information on how one accesses the Biomedical Imaging and Therapy facility

Abstract

The synchrotron source provides a unique opportunity for biomedical research in both imaging and therapy research and applications. A general purpose biomedical research facility has been built at the Canadian Light Source in Saskatoon, Saskatchewan. The Biomedical Imaging and Therapy (BMIT) beamline complex at the Canadian Light Source is transitioning from construction to operations. The bend magnet beamline has been producing some results for over a year and we are now entertaining users in a Letter of Intent phase. The insertion device beam has been delivered into the experimental hutches.

The BMIT facility has two beamline complexes; an insertion device source beamline at which the bulk of the imaging and therapy research on humans, animals, and plants will be carried out, and an ancillary bend magnet source beamline which will serve as a proof-of-principle facility and research tool for new methods of imaging and therapy. The bend magnet beamline is now being used for first experiments using conventional imaging and diffraction enhanced imaging.

Several imaging methods (absorption-edge subtraction imaging, diffraction enhanced imaging / analyzer based imaging, phase contrast imaging, and absorption imaging) in projection and computed tomography modes as well as monochromatic beam and filtered white beam therapy methods will be available. Plans are underway to incorporate Grating Interferometry to complement the existing modalities.

The beamline overview and status along with examples of the types of research that are and can be carried out will be given. These examples will include a number of biomedical programs such as investigating lung function, a number of bone studies, tissue scaffold imaging, prostate cancer imaging, radiation therapy, and cardiac imaging. Special attention will be given to the ability of the beamline to use the unique imaging methods for following the progression of disease and the response to therapies for animal and possibly human subjects.

Our plans in progressing toward large animal imaging and human research programs will be presented as well as some discussion on the challenges we face in realizing the full potential of the facility.

Finally, a perspective of where the BMIT facility fits in world-wide will be discussed to provide some context of the types of programs that are carried out at other synchrotron facilities.

Adherence to USP <797> Standards in BC

MICHELLE KOBERINSKI
Cancer Centre for the Southern Interior, Kelowna, BC
Saturday, 14:00 - 14:40 – Top of the Inn, 8th Floor
Technician Stream Breakout #1, Part 1

Biography

Michelle Koberinski works at the BC Cancer Agency as the Chemotherapy Certification Pharmacy Assistant. In 2010, Michelle began working towards becoming a regulated pharmacy technician. Since 2007, Michelle has been working to develop, implement and maintain a chemotherapy certification program for the pharmacists, pharmacy technicians and pharmacy assistants in BC who prepare and dispense oral and parenteral chemotherapy medication. In 2010, Michelle received a Merit Award from CAPhO for her work on the BCCA Pharmacy Practice Standards for Hazardous Drugs Manual. Michelle is a member of CAPhO, ISOPP and CSHP where she works with committee members researching and developing national and international safe handling standards and educational programs.

Synopsis

Learning Objectives

- Introduce the College of Pharmacists of BC's Hospital Pharmacy Inspection Report
- Review USP <797> sterile compounding standards to which hospital pharmacies in BC are mandated by the College adhere by 2015
- Describe how hospitals are able to meet these standards
- Indicate how hospitals that are not due for renovations before 2015 can meet the minimum standards set out in the Hospital Pharmacy Inspection Report

Abstract

Many hospital pharmacies across Canada are looking to the United States Pharmacopeia (USP) <797> for guidance on pharmaceutical compounding of sterile preparations. The College of Pharmacists of BC is conducting site inspections of each hospital and Cancer Agency pharmacy in BC. The inspections are designed to ensure that pharmacy standards of practice are being met and comply with legislative requirements. Tools that guide the site inspections include, but are not limited to: HPA, USP<797>, CSHP, PODSA, and WorkSafeBC. Hospital and Cancer Agency pharmacies in the Province have until 2015 to comply with these standards. The College of Pharmacists will give direction, including limitations of compounding, to any sites that may be unable to comply by 2015.

ADHERENCE TO USP<797> STANDARDS In BC Hospital Pharmacies

Michelle Koberinski
Chemotherapy Certification Pharmacy Assistant
BC Cancer Agency, SAH Centre for the Southern Interior, Kelowna, BC

Consultant: Jonathan Lau, Hospital Inspector/Practice Consultant, College of Pharmacists of BC
October 27, 2012

Disclosure

Michelle Koberinski has no real or apparent conflicts of interest to disclose

Learning Objectives

- USP <797>
  - Beyond Use Date
  - CSP Microbial Contamination Risk Levels
- College of Pharmacists of BC's Hospital Pharmacy Inspection Report: Section 14 – Sterile Compounding
- How hospitals in BC can meet the standards set out in Section 14 of the Inspection Report by 2015
- Provisions the College has made for sites unable to meet USP<797> standards by 2015

USP<797>

- The first set of enforceable sterile compounding standards issued by the United States Pharmacopeia (USP)
- Outlines the guidelines, procedures and compliance requirements for compounding sterile preparations
- Sets the standards that apply to all settings in which sterile preparations are compounded

Beyond-Use Date (BUD)

- Not to be confused with Expiration Dates
  - Expiration Date refers to commercially manufactured products, in their original form and container, stored according to the package insert, and based on manufacturer's vigorous scientific testing
- Beyond-Use Date (BUD)
  - Date and time beyond which the CSP should not be used or stored
  - Assigned by person or facility doing the compounding

Old BUD and New BUD

- Old BUD Paradigm
  - Found on the drug monograph, based on drug's chemical stability
  - Assumes the CSP is sterile, prepared under sterile conditions
  - Difficult to prove CSP remains sterile during compounding
- New BUD Paradigm
  - Recognizes CSP may have been contaminated via human transfer of microorganisms and poor aseptic technique
  - Based on drug's *chemical stability in conjunction with microbiological limits, whichever is shorter*

CSP Microbial Contamination Risk Levels

- Assigned according to the potential for microbial contamination during the compounding process, and
- The corresponding probability of contaminating a CSP with:
  1. microbial contamination (i.e. microbial organisms, spores, endotoxins)
  2. chemical and physical contamination (i.e. foreign chemicals, particulate sources)
     - particulate sources (i.e. people, products, and processes)

- Increased # of manipulations → increased microbial contamination risk
- How and where CSP is prepared helps determine risk level
- Determining risk level:
  - No single "iron-clad" determination
  - Use professional judgment
  - Exception: non-sterile raw materials always high risk
  - Responsibility of the person doing the compounding (or Pharmacy)

- USP <797> defines 5 risk levels of microbial contamination:
  - Low Risk
  - Low-Risk with 12-hr or less BUD
  - Medium-Risk
  - High-Risk
  - Immediate Use

Microbiological Limits

Calculated Microbial Growth:

Time (hours)	Microbial Count (CFU per mL)
6	10
9	640
12	41,000
18	17,000,000
24	6,900,000,000

Cundell AM, USP Committee on Analytical Microbiology, Pharmacopeial Forum 2002;28(6):Stimuli on the Revision Process

Low-Risk CSPs

- Personnel shall follow *Personnel Cleansing and Garbing* procedures
- Use of aseptic manipulations within a certified ISO Class 5 or better PEC (Primary Engineering Control) in an ISO Class 7 environment (clean room)
- Use only sterile ingredients, products, components and devices
- No more than 3 commercially manufactured packages of sterile products
- Limited to basic manipulations

Low-Risk CSPs with 12 hour or Less BUD

- The PEC is not located in an ISO Class 7 clean room
- Only non-hazardous drugs are prepared in the PEC
- The preparation is prepared pursuant to physician's order for a specific patient
- Administration must begin within 12 hours or as recommended in the manufacturers' package insert, whichever is less

Low-Risk CSPs with 12 hour or Less BUD

- PEC shall be certified and maintain ISO Class 5
- PEC shall be in a segregated compounding area restricted to sterile compounding activities
- The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors
- Sinks shall not be located adjacent to the ISO Class 5 PEC

Medium-Risk CSPs

- Same criteria as *Low-Risk* except one or more of the following conditions exist:
  1. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered to one or more patients (i.e. batching)
  2. Compounding process includes complex aseptic manipulations other than the single-volume transfer and requires unusually long duration (i.e. TPNs)
  3. Compounding process requires unusually long duration

High-Risk CSPs

CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated:

High-Risk CSPs

1. Use of non-sterile ingredients, devices, or equipment
2. Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour:
   - sterile ingredients of commercially manufactured products
   - CSPs that lack effective antimicrobial preservatives, and
   - Sterile surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs
3. Compounding personnel are improperly gloved and garbed
4. More than 6 hour delay from compounding to sterilization (by filtration, steam or dry heat)

Immediate-Use CSPs

- Intended only for those situations where there is a need for emergency or immediate patient administration of a CSP
- The patient could be subjected to additional risk due to delays in therapy
- Such situations may include:
  - Cardiopulmonary resuscitation
  - Emergency room treatment
  - Preparation of diagnostic agents
  - Critical therapy
  - ❖Does not include hazardous drugs

Immediate-Use CSPs

- Exempt from the requirements described for *Low-Risk Level* CSPs only when <u>all</u> of the following criteria are met:
  1. Compounding process involves simple transfer of not more than 3 commercially manufactured packages of sterile non-hazardous products and not more than 2 entries into any one container
  2. Compounding procedure is a continuous process that does not exceed 1 hour
  3. Aseptic technique is followed
  4. Administration begins within 1 hour of the start of preparing the CSP
  5. Discarded promptly if administration is not started within 1 hour of the start of preparing the CSP

Microbiological BUDs of CSPs

In the absence of passing a sterility test, storage periods cannot exceed the following time periods before administration:

Risk Level	Controlled Room Temp (20°C to 25°C)	Refrigerator (2°C to 8°C)	Freezer (-25°C to -10°C)
Low	48 hrs	14 days	45 days
Low w/12-hour or less BUD	12 hrs or less (see drug monograph)	12 hrs or less	N/A
Medium	30 hrs	9 days	45 days
High	24 hrs	3 days	45 days
Immediate Use	1 hr	1 hr	N/A

CAI and CACI as PECs

- Compounding Aseptic Isolators (CAI) and Compounding Aseptic Containment Isolators (CACI) shall be placed in an ISO Class 7 clean room unless they meet ALL of the following conditions:
  1. The isolator maintains ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during compounding
  2. Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding
  3. No more than 3520 particles per m^3 are counted during material transfer
     - the particle counter probe is located as near to the transfer door as possible

Hazardous Drugs as CSPs

- The potential therapeutic benefits of sterile hazardous drug preparations generally outweigh the risks of their adverse effects in ill patients
- Exposed healthcare workers risk similar adverse effects with no therapeutic benefit
- Occupational exposure to hazardous drugs can result in:
  - Acute effects, such as skin rashes
  - Chronic effects, including adverse reproductive events
  - Possibly cancer

Hazardous Drugs as CSPs

- Prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas from exposure
- Many hazardous drugs have sufficient vapor pressures that allow volatilization at room temperature
  - Storage is preferably within a negative pressure room
  - The storage area should have sufficient general exhaust ventilation, at least 12 ACPH, to dilute and remove any hazardous drug contaminants

Hazardous Drugs as CSPs

- All hazardous drugs shall be prepared in an ISO Class 5 PEC placed in an ISO Class 7 area that is:
  - physically separated from other preparation areas
  - Optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas
  - The PEC optimally should be 100% vented to the outside through HEPA filtration
- If the PEC is a CACI that meets the requirements for placement outside of an ISO Class 7 clean room, the compounding area shall maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 ACPH

Why comply with USP<797>

- The absence of an ISO Class 7 clean room in a general uncontrolled environment increases the potential of microbial contamination
- Administration duration of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization, and thus for patient harm, especially in critically ill or immunocompromised patients

- Parenteral products have the greatest risk of contamination and must be compounded in an area of the lowest level of risk to the products
- When parenteral products contain bacterial endotoxins, they are potentially hazardous to patients
- The greatest level of control over compounding must be evaluated, implemented, and enforced

College of Pharmacists of British Columbia

Hospital Site Visit Inspections

Sterile Compounding

Authority?

- Under the Health Professions Act (HPA), the College of Pharmacists of BC is given the authority to regulate both the registrant and the practice site
- The HPA provides the College with the authority to inspect pharmacies
- Inspections are designed to ensure that pharmacy standards of practice are being met and comply with legislative requirements

Hospital Pharmacy Inspection Report

Covers standards that all hospital pharmacies in British Columbia are expected to meet by 2015

The following legislations are incorporated into the inspection process and are referenced in the report:

USP<797>	PPP
FDA	FPP
CDSA	ISMP
PODSA	ACQP
HPA	ACROP

Hospital Pharmacy Inspection Report

The Inspection Report is divided into 2 sections

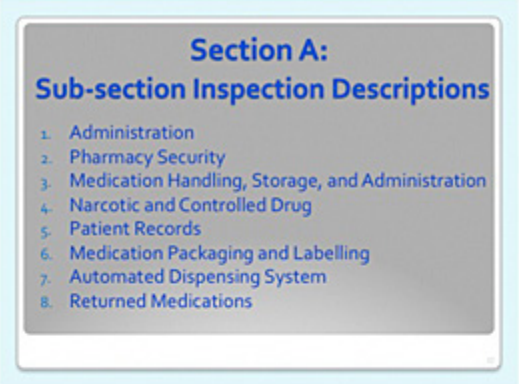
- Section A: Inspection Form consists of 17 sub-sections
  - All sub-sections are linked to the relevant legislations, policies or standards of practice
  - Not all sub-sections are inspected in a single visit
- Section B: Summary Form
  - Summarizes areas from the Inspection Form that requires corrective actions to address the noted deficiencies
  - The pharmacy manager must complete and sign the Summary Form to confirm that all action plans will be carried out as indicated
  - The completed form must be e-mailed or faxed back to the College Inspector within 90 days of the receipt of the report

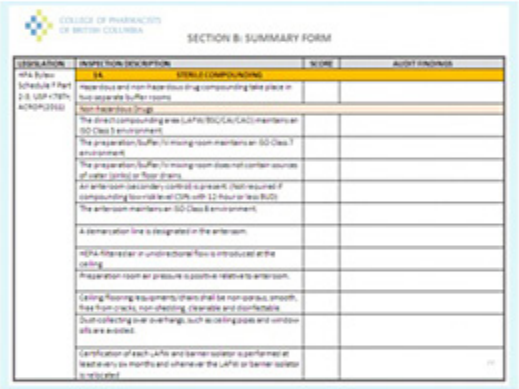
Section A – Inspection Form

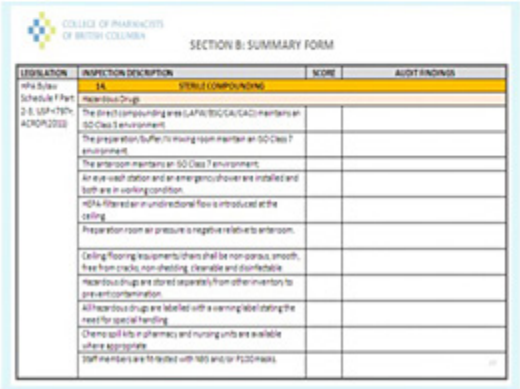
The following notations are used under "SCORE":

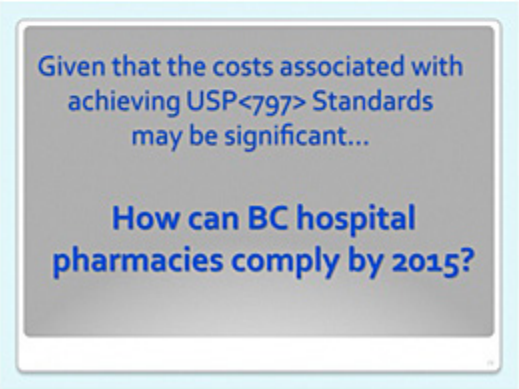
3 = Meet Standards	Practice consistently meets minimum standards
2 = Partially Meets Standards	Practice inconsistently meets minimum standards; an opportunity for improvement exists in this area
1 = Does not meet standards	Practice does not meet minimum standards
N/A	Not Applicable to this facility
N/I	Not Inspected during visit
Unknown	Answer to the question is unknown to the registrant being interviewed, require follow-up if indicated as such under "Observation/Issues" in Section B

Michelle Koberinski | Presentation Handouts Pg6



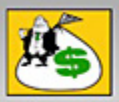






- Non-monetary deficiencies should be corrected without delay
- Guidance from qualified persons who have experience with clean rooms should be sought
- A timetable for implementing full compliance with legislation should be established

What if BC hospital pharmacies are unable to comply with USP<797> standards by 2015?



Remember Me?

Low-Risk CSPs with 12 hour or Less BUD

- The PEC is not located in an ISO Class 7 clean room
- Only non-hazardous drugs are prepared in the PEC
- The preparation is prepared pursuant to physician's order for a specific patient
- Administration must begin within 12 hours or as recommended in the manufacturers' package insert, whichever is less

So....

- Sites will be required to alter their practice while waiting for facility renovations
  - Sites that have a LAFW but no IV room can continue to compound IV products, as long as the site complies to the *Low Risk Level CSPs with 12-Hour or Less BUD* contamination category
  OR
  - Perform sterility testing on CSPs according USP<71> - and pass!

Before Renovations Begin

- The start of renovations is out of *our* control
- A lot can be done to improve the quality and safety of CPS's that is under *our* control
  - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/ Disinfection Procedures
  - Strict adherence to established practices for garbing and sterile preparation techniques
  - Validation
- It is critical to not wait for pharmacy renovations to implement safe and aseptic control practices!
- Remember – Facility Renovation ≠ Compliance

Why comply with USP<797>

The absence of an ISO Class 7 clean room in a general uncontrolled environment increases the potential of microbial contamination... and thus for patient harm, especially in critically ill or immunocompromised patients

It's all about putting

Patients First!

Helping Hands: Pharmacy Technicians Helping in a Clinic Setting

AYNSLEY BELL
Cancer Care Manitoba, Winnipeg, MB
Saturday, 14:40 - 15:20 – Top of the Inn, 8th Floor
Technician Stream Breakout #1 - Part 2

Biography

Aynsley Bell graduated from the Winnipeg Technical College as a certified pharmacy technician in June 2003. She worked for seven years as a pharmacy technician at various internet pharmacies. In October 2010, she started working in the Department of Pharmacy at CancerCare Manitoba. In October 2011, she was assigned to a pilot project of a clinical pharmacy technician assisting the pharmacist and team in the Multiple Myeloma Clinic. She also works in the Investigational Drug Services (IDS) area of the Pharmacy Department.

Synopsis

Learning Objectives

- Why the role of clinical technician was created
- Roles, responsibilities and expectations of the technician
- Integration of a technician into the clinic – pros and cons
- Benefits achieved from the placements of a technician in a clinic setting
- Other non-traditional roles Cancer Care Manitoba offers its technicians

Abstract

The amount of new agents used in hematological malignancies has increased significantly over the past few years. In order to access these medications, the clinical pharmacy technician assists the clinical team with the many documents that are required to ensure accrual and safe delivery of these agents.

As with anything new, there are challenges but as a whole the clinical pharmacy technician role was well received from the hematological clinics. The technicians assist with tracking drug approvals, assist the hematologists in the preparation of non-formulary and restricted drug requests, and assist the pharmacist in ensuring that RevAid registration forms are completed and medication calendars are prepared for pharmacist review.

The implementation of the clinical pharmacy technician role in hematological malignancy clinics was successful and expands the pharmacy technician's role at our cancer centre.

Helping Hands

Pharmacy Technicians Helping in a Clinic Setting

Aynsley Bell
Pharmacy Technician
Cancer Care Manitoba

Why the Role of Clinical Technician was Created

The role of the pharmacy technician was developed as part of a multi-disciplinary team working in the Multiple Myeloma and Lymphoproliferative Disorders (CLL and Lymphomas) Clinic

Roles, Responsibilities and Expectation of the Clinical Technician

- Keeping track of patients on restricted medications, medications requiring Non-formulary approval or Special Access approval and preparing the appropriate requests and renewals for the physician to review and sign
- Entering orders for Physician review and approval, based on directions from Physician and/or Pharmacist
- Photocopying, faxing and printing desired documents at the request of Physician or Pharmacist
- Distributing chemotherapy orders and out patient prescriptions to appropriate departments/pharmacies
- Preparing medication calendars for Pharmacist review
- Assisting in the application for Manitoba Pharmacare and the Manitoba Home Cancer Drug Program

Keeping track of patients on restricted medications, medications requiring Non-formulary approval or Special Access approval and preparing the appropriate requests and renewals for the physician to review and sign

- **Lenalidomide**: Non-Formulary approval, Revaid Application, Pharmacare, and Home Cancer Drug Program
- **Thalidomide**: Non-Formulary approval, Revaid Application, Pharmacare, and Home Cancer Drug Program (for supportive medications)
- **Bortezomib**: Non-Formulary approval, Pharmacare and Home Cancer Drug Program (for supportive medications)
- **Bendamustine**: Non-Formulary approval, Special Access Program request, Pharmacare, and Home Cancer Drug Program (for supportive medications)

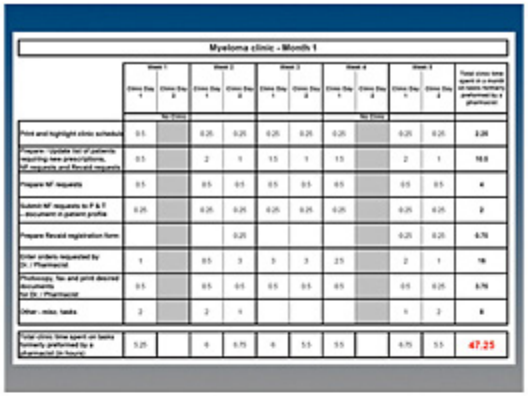
Roles, Responsibilities and Expectation of the Clinical Technician

- Keeping track of patients on restricted medications, medications requiring Non-formulary approval or Special Access approval and preparing the appropriate requests and renewals for the physician to review and sign
- Entering orders for Physician review and approval, based on directions from Physician and/or Pharmacist
- Photocopying, faxing and printing desired documents at the request of Physician or Pharmacist
- Distributing chemotherapy orders and out patient prescriptions to appropriate departments/pharmacies
- Preparing medication calendars for Pharmacist review
- Assisting in the application for Manitoba Pharmacare and the Manitoba Home Cancer Drug Program

Integration of a Technician into the Clinic
Pros vs. Cons

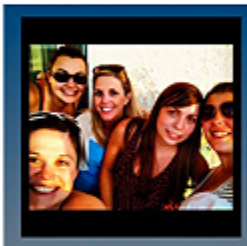
- Helps create an efficient work flow
- Reduces errors discovered at a pharmacy level, resulting in less time spent tracking down the physician to correct it
- Allows pharmacist to focus their time on direct patient care
- Expectation to perform Pharmacist duties when Pharmacist unavailable
- Clinic / Physician becomes dependant on the Technician and less self sufficient
- Clinic Staff / Physician not making use of a technicians full potential / skills
- Lack of clinic space

Aynsley Bell | Presentation Handouts Pg2



Integration of a Technician into the Clinic
Pros vs. Cons

- Helps create an efficient work flow
- Reduces errors discovered at a pharmacy level, resulting in less time spent tracking down the physician to correct it
- Allows pharmacist to focus their time on direct patient care
- Clinic Staff / Physician not making use of a technicians full potential / skills
- Expectation to perform Pharmacist duties when Pharmacist unavailable
- Clinic / Physician becomes dependant on the Technician and less self sufficient



The Multiple Myeloma Team

Benefits achieved from the Placement of a Technician in a Clinical Setting

- Improved efficiency
- Improved accuracy
- Expanded the Pharmacy Technician's role at our Cancer centre
- Freed up Pharmacist time
- Overall success

Other Non-Traditional Roles Cancer Care Manitoba Offer their Technicians

- Neupogen and Smoking Cessation Programs
- Anticoagulation Program
- Regimen building, development and maintenance
- Investigational Drug Studies

Anaemia Management in the Oncology Setting: A Review and Update

DR. MARK PASETKA
Sunnybrook Health Sciences Centre, Toronto, ON
Saturday, 14:00 - 14:40 – Centre-East Room, Main Level
Clinical Stream Breakout #2 - Part 1

Biography

Dr. Mark Pasetka graduated from the University of Manitoba's School of Pharmacy in 2004 and spent three years in a variety of practice settings. After having finished his Doctor of Pharmacy degree at the University of Toronto (2009), Mark went on to complete a two-year post-doctoral fellowship in Oncology at the Odette Cancer Centre in Toronto, Ontario (2011) and now serves as the Clinical Pharmacy Coordinator. Mark is a member of both national and international oncology organizations and has publications in a number of recognized journals. His areas of interest include supportive care, health technology and education, and clinical research.

Synopsis

Learning Objectives

- The attendee will be able to describe the pathophysiology of anaemia in the oncology setting and how iron metabolism can be involved when teaching patients and colleagues
- The attendee will be able to identify signs and symptoms of anaemia and interpret relevant laboratory parameters when assessing oncology patients for anaemia
- The attendee will be able to apply current treatment guidelines and therapeutic options for the management of anaemia in the oncology setting

Abstract

Anaemia is a frequent occurrence in the oncology setting. Many patients will, at some point in the course of the disease or treatment, develop some degree of anaemia. The signs and symptoms associated with anaemia are multiple and can impact on a patient's quality of life, and the condition itself can potentially affect his or her prognosis. Of the various causes of anaemia, patients with cancer may be affected by more than one of these during their disease experience, either separately or in conjunction, which may make treatment of this condition more challenging.

Current guidelines recommend the use of appropriate assessment and treatment of this condition in order to optimize patient quality of life. Identification of all contributing factors for anaemia may better aid the clinician in managing the patient.

Limited treatment options exist for patients with anaemia in the oncology setting. Choices include surveillance, supplementation, transfusion, and erythropoiesis stimulating agents (ESAs) or a combination of these.

This presentation will highlight the pathophysiology of anaemia of cancer and the role of iron metabolism. Patient assessment and interpretation of laboratory values related to anaemia, the use of clinical guidelines, and treatment options will be discussed.

Optimizing Pain Relief for Your Palliative Cancer Patients

LORI GAGNON
Alberta Health Services Cancer Care, Edmonton, AB
Saturday, 14:40 - 15:20 – Centre-East Room, Main Level
Clinical Stream Breakout #2 - Part 2

Biography

Lori Gagnon is a licensed pharmacist with over 20 years of diverse clinical experience most recently in Oncology and Palliative Care. She has been a vital member of interdisciplinary health care teams, providing pharmaceutical care to inpatient and outpatient populations. Currently, Lori practices at the Cross Cancer Institute, specializing in the area of palliative care. She is a team member of both the Rapid Access Palliative Radiotherapy program and the Pain and Symptom Control Team. Her role within these clinics includes patient assessment, best possible medication history, review of drug related problems, collaboration with other team members to solve problems and determine an appropriate care plan, and educate and follow up with patients/families regarding new medications or changes to medication regime. Lori also liaises with other community and hospital pharmacies ensuring medication requirements are fulfilled. She is involved in a variety of research initiatives within the Rapid Access clinic and provides education and expertise to a variety of health care professions. Lori is a guest lecturer at the University of Alberta's Faculty of Pharmacy in Oncology and Pain Modules. She has mentored pharmacy residents, second and fourth year pharmacy students in her area of specialty as well students and residents from other health care professions. Lori is currently in the process of obtaining prescribing privileges in the Province of Alberta and will be able to have signing authority on prescriptions.

Synopsis

Learning Objectives

- Increase understanding, skills and knowledge in order to perform a comprehensive pain assessment
- Provide an overview of basic pain pathophysiology
- Provide a basic overview of principles for opioid and non-opioid analgesics
- Explore reasons for opioid rotation
- Approach `Breakthrough Pain' (BTP)

Abstract

Pain, or the fear of pain, is one of the most common symptoms your cancer patients will experience. It is unfortunate that many cancer patients experience uncontrolled pain. Pharmacists in the cancer care and/or palliative care settings can play a vital role on the interdisciplinary health care team. Pharmacists may complete comprehensive pain assessments, perform best possible medication history, review drug related problems, collaborate with other team members to solve problems and develop an optimal pain management plan.

Sifting Through the Past, Paving the Future

DR. DALYCE ZUK
Alberta Health Services, Calgary, AB
Saturday, 14:00 - 15:20 – Starlight Room, Lower Foyer
Administrative / Research Stream Breakout #3 - Part 1 and Part 2

Biography

Dr. Dalyce Zuk graduated with her Undergraduate Degree in Pharmacy from the University of Alberta in 2005, and then completed a general practice residency with the former Capital Health Region, Edmonton (now Alberta Health Services) before venturing to Vancouver to complete her PharmD program at UBC. Upon returning to Alberta, she completed a two-year Post-doctoral Clinical Pharmacotherapy Practice Fellowship in Solid Organ Transplant at the University of Alberta. She is currently the Pharmacy Ambulatory Services Manager with Alberta Health Services – Calgary Zone. In addition, she guest lectures within the Pulmonary and Transplant & Immunology Modules within the Undergraduate Pharmacy Program at the University of Alberta and within Course 1 (GI, blood and heme) within the Undergraduate Medical Program at the University of Calgary. In her spare time, Dr. Zuk is President of the CSHP-AB Branch and is a member of both the Awards and Education Committees for the Canadian Society of Transplantation. She enjoys quilting, reading, skiing and hiking and is currently enjoying the new adventures that "mommyhood with a toddler" brings.

Synopsis

Learning Objectives

- Introduce pharmacists to their role as clinical researchers
- Identify problems in clinical practice that are research opportunities and can be developed into a research proposal
- Review the major steps in the development of a research proposal
    - Clinical question
    - Searching the literature
    - Research methodology
        - Population
        - Intervention implementation
        - Bias
        - Statistical interpretation
- Review the outline of a research proposal for the identified clinical problem

- Identify research funding sources and key strategies to secure research funding
- Discuss accepted ethical principles in the development of research protocols and Research Ethics Board (REB) applications

Abstract

As pharmacists, we are uniquely suited to use our clinical practice experiences to identify relevant questions that need answers. Specifically, we often make interesting observations or encounter compelling problems in our everyday practice. Many of these observations go no further and remain merely as interesting anecdotes. The focus of this session is to help attendees identify specific interesting observations or compelling problems encountered in everyday practice that merit further study. Attendees will be educated in taking these ideas from conception to development of a retrospective research proposal.

Improving Chemotherapy Preparation Safety through Process Changes: Workload and Workflow Implications

RACHEL WHITE
University Health Network, Toronto, ON
Saturday, 15:50 - 16:35 – Centre-East Room, Main Level
Breakout #4

Biography

Rachel White is passionate about making healthcare safer for patients by making environments, processes and technologies more intuitive for clinicians. She has a keen interest in integrating human factors principles into medication safety initiatives, especially those relating to chemotherapy. She has led chemotherapy-focussed research projects on: independent double-checking processes, computerized prescriber order entry systems, barcoded medication administration systems, closed system transfer devices, and pharmacy production processes. Through her research she has gained a strong understanding and respect for the role that clinicians, especially pharmacists, play in patient safety.

Synopsis

Learning Objectives

- Understand the safety benefits to chemotherapy preparation of "one mix at a time" in the biological safety cabinet
- Describe the workload and workflow impacts of switching to one mix at a time for sites with differing resources and practices
- Apply principles learned from these case studies to other practice scenarios

Abstract

The exploratory study Improving the Safety of IV Ambulatory Chemotherapy in Canada made the recommendation in 2010 for oncology pharmacies to conduct "one mix at a time" in the biological safety cabinet. Since the study recommendations were released, many sites have been working to roll out this practice change. However, one concern has been that one mix at a time would require more pharmacy resources. This study was therefore launched to measure the impact of this practice change on workload and workflow.

Two sites in Manitoba participated in the study. Over the course of three days per site, a human factors (HF) specialist observed current mixing practice, measured the amount of time each person spent on specific mixing tasks, and then helped the site modify its workflow to improve preparation safety. After the sites had been using the new workflow for one month, the HF specialist returned and again measured time spent on tasks. Differences in task time were compared before and after the workflow change, and qualitative findings from each site were also assessed.

The study showed that although there were changes to the allocation of tasks between different pharmacy professionals, when sites performed one mix at a time, their practice became more efficient overall. The concept of one mix at a time was also refined, and some additional process safety improvements were noted.

What Did the Pharmacist Just Say to Me?

DR. CARLO DE ANGELIS
Sunnybrook Health Sciences Centre, Toronto, ON
Saturday, 15:50 - 16:35 – Top of the Inn, 8th Floor
Breakout #5

Biography

Dr. Carlo De Angelis earned his Bachelor of Science in Pharmacy from the University of Toronto in 1981 and completed a Hospital Pharmacy Residency at Sunnybrook Health Sciences Centre in 1982. He graduated with a Doctor of Pharmacy from the State University of New York at Buffalo in 1984. From 1985 to the present, Carlo has been the Clinical Pharmacy Coordinator for Oncology at the Odette Cancer Centre, Sunnybrook Health Sciences Centre and has owned and managed a community pharmacy, Panacea Pharmacy since 1994.

Synopsis

Learning Objectives

- Discuss factors which may prevent effective pharmacist-patient communication
- Discuss the implications of ineffective pharmacist-patient communication
- Discuss methods for improving pharmacist-patient communication

Abstract

Patient counseling by pharmacists is one of the cornerstones of medication therapy management. Patient counseling can be defined as "a one-on-one, interactive session designed to modify patient knowledge and behaviour". Oncology is a particularly challenging setting for effective pharmacist-patient communication. Factors which may prevent effective transfer of information and patient understanding of the information may include: the anxiety associated with a diagnosis of cancer, the urgency of decision making, use of multiple medications (for cancer treatment and supportive care purposes), complex treatment plans/regimens (cyclical, sequential/concurrent, oral and/or parenteral administration, dose adjustments/changes during treatment, combined modality (systemic/radiation) therapy, etc.) all layered on top of drug therapy for existing co-morbid conditions. Patients are overwhelmed with the amount of information they are provided, not just by pharmacists but by other healthcare professionals involved in managing their cancer. In addition, there may be inconsistent messaging from these different care providers, which only serves to further confuse patients.

From a pharmacy perspective, the overall goal of patient counseling is to ensure patient understanding of: the treatment plan, the proper use of the medication(s), treatment related side effects that may be experienced (including their assessment and management) and fostering good medication taking behaviour. In the non-oncology setting, effective patient counseling has been demonstrated to improve patient satisfaction, reduce anxiety and promote adherence. However, while principles of effective patient counseling would be expected to be transferable; their use in oncology has been poorly documented and/or studied. Not only do we need to provide the information in a manner consistent with the

patient's learning style and needs but it is imperative to provide the right information at the right time so as to be relevant to the patient's current treatment experience.

Current communication theory suggests that the traditional "sender-message-receiver" model of patient counseling oversimplifies the pharmacist-patient interaction and may actually prevent comprehensive and effective patient centered care. Rather than view counseling as the provision and interpretation of information, we must apply more of a problem-solving approach to pharmacist-patient communication. The prescription label and patient "friendly" drug information sheets are the antithesis of the strategic-inferential model of communication which requires that we go beyond just providing information to the patient. In addition to ensuring an understanding of the instructions/information, it is critical to be aware of and provide context to the patient. An important component of this context is the realization that appropriate medication taking requires a change in patient behavior. The challenge in the oncology setting is that change in patient behavior is typically needed quickly (e.g. to ensure proper taking of antiemetic medication). There are two common models for patient counseling; the Indian Health Services Model (developed for Pharmacy) and the Health Communication Model (most often taught to physicians). The use of these models will be discussed in the context of a cancer patient case to illustrate their use and stimulate conversation as to changes oncology pharmacists must make in their approach to counseling of cancer patients to enable full patient engagement and optimal medication taking behaviour.

Update on Treatment of Gynecologic Malignancies

NATHALIE LETARTE
University of Montreal, Montreal, QC
Saturday, 15:50 - 16:35 – Starlight Room, Lower Foyer
Breakout #6

Biography

Nathalie Letarte is a pharmacist at the Centre hospitalier de l'Université de Montréal and an assistant clinical professor at the Faculty of Pharmacy of the University of Montreal, from which she received her B. Pharm. in 1997 and her M.Sc. in Pharmacy Practice in 1998. She obtained a Board Certification in Oncology (BCOP) in 2007 and completed a Fellowship in Oncology at the University of Illinois at Chicago in 2008. She has been working in oncology for more than ten years and is involved in many provincial and national committees such as NCIC CTG, CEPO, and GEOQ. She is the Co-chair of the Chaire Famille Sabourin en Santé des femmes Faculté de Pharmacie-CHUM.

Synopsis

Learning Objectives

- Discuss the current standard of care of ovarian cancer
- Describe the emerging treatments for advanced ovarian cancer
- Learn about the controversies of adjuvant treatment in endometrial cancer
- Understand the prevention and treatment of cervical cancer

Abstract

Endometrial cancer is the most common gynecologic cancer whereas ovarian cancer is the leading cause of death in gynaecologic malignacies. Advances have been made in the last few years but studies are still ongoing. Cervical cancer is less frequent in western countries and can now be prevented. The presentation will be an overview of the latest updates in the treatment and prevention of ovarian, endometrial and cervical cancers.

Updates in gynecologic cancers

Nathalie Letarte, B.Pharm. M.Sc., BCOP
Pharmacist, Centre hospitalier de l'Université de Montréal
Clinical Assistant professor, Faculty of Pharmacy, Université de Montréal

CHUM

Université de Montréal

Disclosures

- Honoraria
  - Merck, Novartis, Roche
- Reaserch funding
  - Merck

Objectives

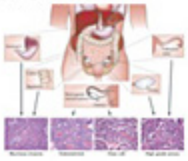
- Discuss the current standard of care of ovarian cancer
- Describe the emerging treatments for advanced ovarian cancer
- Learn about the controversies of adjuvant treatments in endometrial cancers
- Understand the prevention and treatment of cervical cancer

Ovarian cancer

Anything new?

Ovarian cancer

- 5th leading cause of death in Canadian women
  - 1st leading cause of death in gynecologic malignancies
- In Canada, in 2012
  - 2600 new cases
  - 1750 deaths
- Disease of the menopause (65-69 y)
- Combination of endocrinal and environmental causes
  - 10-15% hereditary
- Adenocarcinoma (> 90%)
  - Serous (most frequent)
  - Clear cell (most agressive)
  - Mucinous
  - Endometrioid



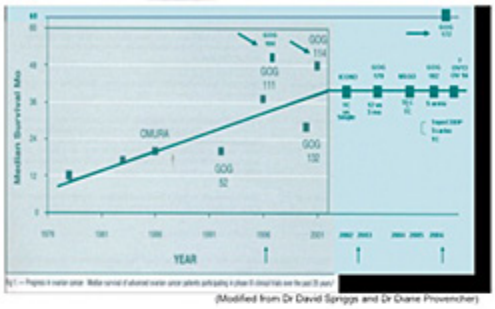
Nature Reviews Cancer 2011;11:719-25.

Staging and usual treatment

Stage I	Limited to ovaries	Ia	Surgery; no further treatment if good prognosis
		Ib	Surgery; no further treatment if good prognosis
		Ic	Surgery; chemotherapy x 6 cycles
Stage II	1-2 ovary(ies) + pelvic metastasis	IIa	Surgery; chemotherapy x 6 cycles
		IIb	
		IIc	
Stage III	1-2 ovary(ies) + pelvic metastasis + nodes	IIIa	Surgery; chemotherapy x 6 cycles
		IIIb	
		IIIc	
Stage IV	Metastasis		Chemotherapy +/- surgery

Nathalie Letarte | Presentation Handouts Pg2

Progress in chemotherapy



(Modified from Dr David Spriggs and Dr Diane Provencher)

Usual adjuvant chemotherapies

Intravenous regimens
Paclitaxel 175 mg/m² + Carboplatin AUC 5-7.5
Docetaxel 60-75 mg/m² + Carboplatine AUC 5-6
Paclitaxel 135 mg/m² /24h + Cisplatine 75 mg/m²
Paclitaxel 80 mg/m² days 1,8,15 + Carbo AUC 6

Is there more than Paclitaxel-Carboplatin?

- Adjuvant / 1st line
  - IP chemotherapy
  - Phase III trials: bevacizumab
- Recurrent / refractory
  - New treatments
  - Trabectedin
  - What to do with the Caelyx shortage ?

IP Chemo : 8 randomised trials

	IV/IP
1986 Zylberberg	10/10
1994 Kirmani	33/29
1996 Alberts GOG 104	279/267
1999 Polyzos	46/44
2000 Gadducci	54/46
2001 Yen	55/63
2001 Markman GOG 114	227/235
2002 Armstrong GOG 172	210/205

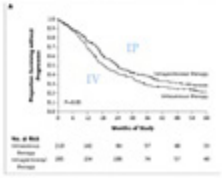
Source: Diane Provencher

GOG-172 PFS

	IV n=210	IP n=205
Median F/U	48.2 mo	52.6 mo
Lost F/U	5 patients	11 patients
PFS	18.3 mo	23.8 mo

HR: 0.80 IC95% (0.64-1.00)

Armstrong, NEJM 2006



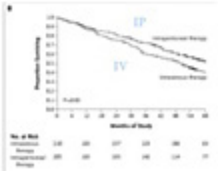
P=0.05

GOG-172 OS

	IV n=210	IP n=205
Median F/U	48.2 mo	52.6 mo
Lost F/U	5 patients	11 patients
OS	49.7 mo	65.6 mo

HR: 0.75 IC95% (0.58-0.97)

Armstrong, NEJM 2006



P=0.03

Only 42% of patients received the planned treatment...

Nathalie Letarte | Presentation Handouts Pg3

Still some questions

- NCI January 2006
  - « All eligible patients should be offered an IP regimen »
- IP day 8 necessary?
- Place of Carboplatin ?
- Doses ? (< 100 mg/m² of cisplatin?)
- Ongoing clinical trial OV-21
  - Paclitaxel 135 mg/m² IV + Carbo AUC 5-6 IV day 1 + Paclitaxel 60 mg/m² IV day 8
  - Paclitaxel 135 mg/m² IV + Cisplatine 75 mg/m² **IP** day 1 + Paclitaxel 60 mg/m² **IP** day 8
  - Paclitaxel 135 mg/m² IV + Carbo AUC 5-6 **IP** day 1 + Paclitaxel 60 mg/m² **IP** day 8

Bevacizumab and 1st line ovarian cancer

ORIGINAL ARTICLE

Incorporation of Bevacizumab in the Primary Treatment of Ovarian Cancer

Robert A. Burger, M.D., Mark F. Brady, Ph.D., Michael A. Bookman, M.D., Gini F. Fleming, M.D., Bradley J. Monk, M.D., Helen Huang, M.S.,

ORIGINAL ARTICLE

A Phase 3 Trial of Bevacizumab in Ovarian Cancer

Timothy J. Perren, M.D., Ann Marie Swart, M.D., Jacobus Pfisterer, M.D., Jonathan A. Ledermann, M.D., Eric Pujade-Lauraine, M.D., Gunnar Kristensen, M.D.,

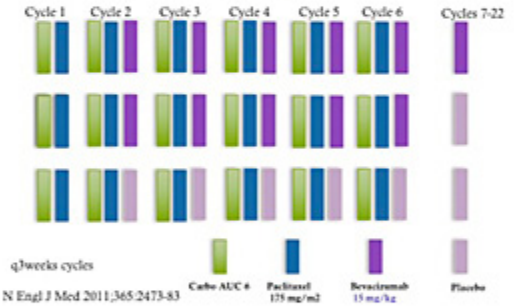
N Engl J Med 2011;365:2473-83 N Engl J Med 2011;365:2484-96.

Bevacizumab GOG-218

- **Stage III** (incomplete resection) and **stage IV** ovarian cancer, never treated
  - Stage III with < 1 cm eligible after amendment
- ECOG 0-2
- Objectives:
  - PFS, **OS**, QOL, adverse events
- Randomisation stratified stage III > 1cm, < 1cm, stage IV

N Engl J Med 2011;365:2473-83

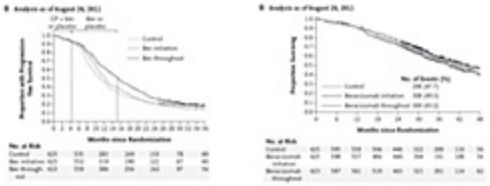
Treatment GOG 218



N Engl J Med 2011;365:2473-83

Results GOG 218

N=1873 patients, 66% stopped due to disease progression, 19% ad all planned cycles



PFS OS

N Engl J Med 2011;365:2473-83

Results GOG218

	PFS	HR	
Control	10,3 mo		
Bev initiation	11,2 mo	0,908	0,795-1,040 p=0,16
Bev throughout	**14,1 mo**	**0,717**	**0,625-0,824 p<0,001**

	OS	HR	
Control	39,3 mo		
Bev initiation	38,7 mo	1,036	0,827-1,297 p=0,76
Bev throughout	39,7 mo	0,915	0,727-1,152 p=0,45

N Engl J Med 2011;365:2473-83

Nathalie Letarte | Presentation Handouts Pg4

Other results GOG-218

- Adverse events
  - Bevacizumab arms
    - Grade 2 or more Hypertension 16,5-22,9%
    - Proteinuria 0,7-1,6%
  - Most events during the chemotherapy portion
- Quality of life
  - Evaluated at cycles 1,4,7,13,22 and 6 mo after
  - Score lower for Bev groups during the chemo portion
  - No differences after treatment

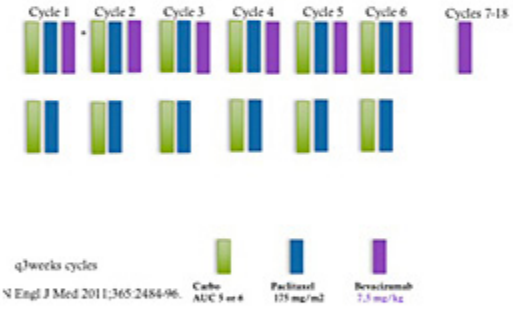
N Engl J Med 2011;365:2473-83

Bevacizumab ICON-7

- **Early Stage I or IIa** and clear-cell or grade 3, or advanced stage **IIb to IV**, epithelial ovarian cancer, primary peritoneal or fallopian-tube
- ECOG 0-2
- Stratification according to stage, residual disease, interval between surgery and chemotherapy
- PFS, OS, biologic PFS, RR, toxicity and QOL

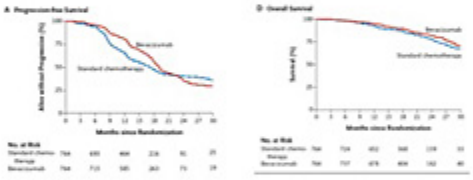
N Engl J Med 2011;365:2484-96.

Treatment ICON-7



N Engl J Med 2011;365:2484-96.

Results ICON-7



PFS
17,4 mo vs 19,8 mo (Bev)
HR=0,87 (0,77-0,99)
P=0,004

OS
Immature data (due 2013)
HR= 0,81 (0,63-1,04)
P=0,098

N Engl J Med 2011;365:2484-96.

Toxicity ICON-7

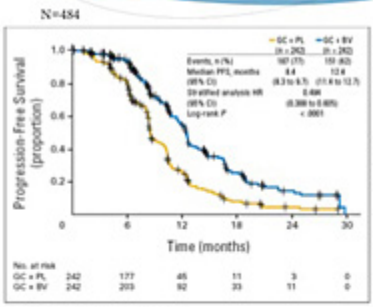
- ≥ Grade 3 events 56% (CTL) 66% (Bev)
- Bevacizumab
  - More bleeding, hypertension, thromboembolic events and GI perforation

Bevacizumab – Oceans Study

- Platinum sensitive (≥ 6 months) **recurrent** ovarian cancer, primary peritoneal or fallopian tube cancer
  - ECOG 0-1
  - No VEGF treatment in the past
- Phase II trial converted to phase III
  - No GI toxicity
- **Carbo AUC 4** Day 1 +**Gem 1000 mg/m²** Days 1,8 + **Bev 15 mg/m²** or **placebo** Q 21 days
  - Chemo x 6 cycles Up to 10 cycles if documented response
  - Bev or placebo continued until PD or toxicity
- Primary outcome: PFS
  - Secondary: ORR, OS, DOR

J Clin Oncol 2012; 30(17):2039-2045.

Results- Oceans



J Clin Oncol 2012; 30(17):2039-2045.

Median #
- 6 cycles chemo
-10 placebo
-12 Bev

ORR
78.5% vs 57.4%
P< 0,0001

DOR
7.4 mo vs 10.4 mo

OS
35.2 mo vs 33.3 mo
HR=1.027 NS

Toxicity OCEANS

- Hypertension
  - grade 3-4 0.4% vs 17.4%
  - Discontinuation of treatment in 3.6%
- Proteinuria
  - 0.9 % vs 8.5%
  - Median Onset > 26.5 mo
  - Discontinuation in 2.4%
- Bleeding and thromboembolic events
  - Bev > Pl
- No differences in FN or neutropenia
- GIP in 2 cases of BEV

Is Bevacizumab a new standard ?

- Improvement in PFS in all trials
  - 11,2-14,1 mo in stage III or IV (0,9-3,8 mo advantage)
  - 19 mo in all stages (2,4 mo advantage)
  - 12,4 mo in recurrent setting (4 mo advantage)
- OS
  - NS or immature data
- Toxicity and QOL
  - QOL data lacking (recurrent)
- PFS has been approved by the Gynecologic Cancer Intergroup consensus conference on ovarian cancer
  - « Valid end-point for recurrent platinum sensitive ovarian cancer »
- Funding ?

Relapsed or recurrent ovarian cancer

Relapsed-recurrent ovarian cancer

- 80% of patients will relapse
- 1st remission is the longest
- Treatment objectives
  - Improve symptoms
  - Improve QOL
  - Response
  - Delay tratments
  - Prolong survival if possible
- No standard treatments
  - Combination vs single agents

Response rates in relapsed

	RR	PFS	OS	Study
Topotecan		7 mo	17,2 mo 59 weeks	Doxil 30-49 JCO 2008
Gemcitabine		20 weeks	51 weeks	JCO 2008
PLD		16 weeks	56-64 weeks	Doxil 30-49 JCO 2008
Carbo-Gem Bev		12.4 mo	33 mo	Oceans
Paclitaxel- Carbo		9.4 mo	33 mo	Calypso
PLD-Carbo		11.3 mo	30.7 mo	Calypso
Epothilones	11-62%			
Cediranib	10-19%			
Pazopanib	46%			
Sunitinib	13%			

Nathalie Letarte | Presentation Handouts Pg6

Trabectedin

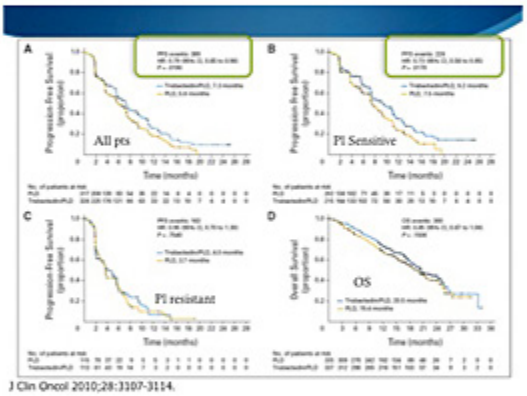
- Antitumoral agent of marine origin discovered int he *Ecteinascidia turbinata*
- Binds to grooves of the DNA and interferes with cell division and gene transcription processes
- Approved in Canada for soft tissue sarcoma and relapsed platinum sensitive ovarian cancer (in association with PLD (Caelyx®))

J Clin Oncol 2010;28:3107-3114.

Trabectedin and PLD

- Recurrent ovarian, fallopian tube or primary peritoneal carcinoma
  - Platinum resistant and platinum sensitive (excluded platinum refractory)
- Open label, randomised phase III trial (OVA-301)
- Primary outcome: PFS
  - Secondary utcomes ORR, OS, safety
  - Tertiary outcome: QOL
- Trabectedin 1.1 mg/m^2 + PLD 30 mg/m^2 q 3 weeks or PLD 50 mg/m^2 q 4 weeks

J Clin Oncol 2010;28:3107-3114.



J Clin Oncol 2010;28:3107-3114.

Trabectedin toxicity

- Worse with combination:
  - Grade 3-4 neutropenia, leukopenia and thrombocytopenia
  - Increase in growth factor use
  - Grade 3-4 AST-ALT elevation
  - Nausea and vomiting
- Worse with PLD
  - Hand-foot syndroome
  - Mucositis

J Clin Oncol 2010;28:3107-3114.

Other analysis

- Time to subsequent therapies
  - Delay of 2.5 months in the combination arm
  - 7.8 mo vs 10.3 mo
- Outcomes in the partially platinum sensitive subpopulation
  - Reduces risk of disease progression or death
  - PFS
  - OS

Ann Oncol 2011;22(1):49-58. Ann Oncol 2011;22(1):39-48.

Caelyx is MIA... what do we do?

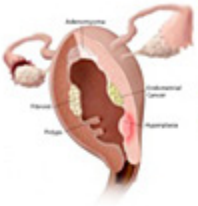
- Paclitaxel-Carboplatin in platinum sensitive
  - Calypso, ICON-4
- Single agents in platinum refractory
  - Topotecan
    - Day1-5 or weekly
  - Gemcitabine
- Clinical trials!!!
- LIPODOX
  - Liposomal doxorubicin from India ?

Nathalie Letarte | Presentation Handouts Pg7

Endometrial cancer

Controversies in the adjuvant setting

Endometrial cancer



- Most frequent gynecologic cancer
- 5300 cases in Canada / 900 deaths in 2012
  - 1/40 women in USA
- Median age at diagnosis: 63 y
- Mortality rate on the rise
  - Longevity
  - Obesity

Types of endometrial cancer

Type 1

- 80-90%
- Prolonged exposition to estrogens
- Low grade (1 or 2)
- Endometrioid
- OR +
- Superficial
- Few nodes metastasis
- More favorable prognosis
- Hyperplasia

Type 2

- 10-20%
- Unclear link to estrogens
- Non-endometrioid histology (serous, clear cell)
- More agressive
- More limited prognosis
- Grade 3
- Nodes involved
- Atrophic
- Older patients

Prognosis factors

- > 50% myometrial envasion
- High grade
- lymphovascular invasion
- non-endometrioid histology

FIGO 2009 Staging

Table II. FIGO endometrial cancer staging system

FIGO stage		Disease extent
I		Confined to uterine corpus
	IA	Limited to endometrium with less than 50% myometrial invasion
	IB	Tumour with 50% or more myometrial invasion
II		Invades cervical stroma
III		Tumour extends beyond uterus
	IIIA	Involves uterine serosa and/or adnexa
	IIIB	Vaginal or parametrial involvement
	IIIC	Pelvic or para-aortic lymph node metastasis
IV	IVA	Invades bladder mucosa and/or bowel mucosa
	IVB	Distant metastasis

FIGO = French Fédération Internationale de Gynécologie et d'Obstétrique.

Radiation: Adjuvant treatment

- Prevents local reccurrence and node metastasis
- No effect on survival
- Early stages and high risk
- External Radiation (pelvic)
- Brachytherapy (internal, vaginal)
  - Complication : vaginal stenosis

Lancet 2000; 355:1404-11.

Nathalie Letarte | Presentation Handouts Pg8

Chemotherapy

- Systemic effect
- Impact on progression-free survival
- OS ? Not clear for early stages

So what do you do ?

- 64 yo woman, stage 1B grade III with worse prognosis factors
- Surgery
- Adjuvant treatment ?
  - Observation ?
  - RT ?
  - RT + brachytherapy ?
  - + Chemo ? Which chemo?

Recommendations ESMO 2011

Stage	Treatment
Stage IA grades 1-2	Observation
Stage IA grade 3 Stage IB grades 1-2	Observation or brachytherapy If high risk factors, radiation and/or chemo may be considered
Stage IB grade 3	RT If high risk factors, radiation and chemo may be considered
Stage II	RT and brachytherapy Or Brachytherapy High risk : Chemo ± RT
Stages III-IV	Chemotherapy Si ganglions positifs : radiothérapie séquentielle

Recommandations NCCN 2012

Stage	Grade	Traitement
IA (w/o risk factor)	1	Observation
	2,3	Observation or brachytherapy
IA (w risk factor)	1	Observation or brachytherapy
	2,3	Observation or brachytherapy and/or RT
IB (w/o risk factor)	1,2	Observation or brachytherapy
	3	Observation or brachytherapy and/or RT
IB (w risk factor)	1,2	Observation or brachytherapy and/or RT
	3	Observation or RT and/or brachytherapy ± chemo
II	1	Brachytherapy and/or RT
	2	Rt +/- brachytherapy
	3	RT + Brachytherapy +/- chemo
IIIA	1,2,3	Chemo ± RT or RT ± brachytherapy
IIIB, IIIC1, IIIC2	-	Chemo +/- RT
IVA, IVB		Chemo +/- RT

Chemo vs observation following surgery and RT

Study	Treatment	Stages	Grades	Survival	PDS	Comments
GOG 34 Morrow 1990 N=181 (43 excluded)	RT -obs Versus RT fol. Dono 45-60 mg x 8	Stage I-II Ia: 39-33% Ib: 32-42% II:28-23%	All But MI >50% or cervix + or nodes + or adnexes +	NS	Distant recurrence 16% dono vs 23% obs.	Underpowered Unbalanced 25/92 no dono
Kucppala 2008 N=156	RT vs RT followed cisplatin, epi, cyclo	Ia, Ib gr3: 19-16% Ic: 50.46% II:18-25% IIIa:12%	All	5y OS : 81% (chemo) vs 84,7%	Recurrence: 22.4% (chemo) vs 18% P=0,496	Non standard

Chemo vs observation following surgery and RT

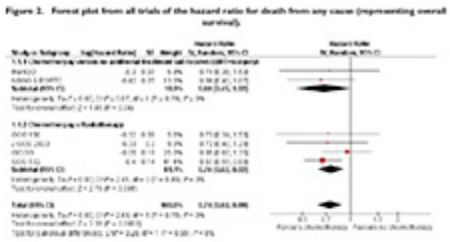
Study	Treatment	Stages	Grades	OS	PFS	Comments
NSGO/ EORTC Hogberg 2010 N=383	RT fol. Obs Vs RT fol. Dono or épi + cisplatin x 4 (Paclitaxel +epi ou dono, dono-carbo ou TC x 4)	Stages I-II Ia:14-9% **Ib:25-33%** **Ic:51-49%** IIa:5%	Mostly grade 2 , 3	HR=0,66 0,4-1,08 P=0,1	HR=0,64 0,41-0,99 P=0,04	Endométrioi d et clear cell Figo 1988 83% cis +dono 10% TC 73% 4 cycles 17% chimio before RT
Mango- Blade III 2010 **N=156**	Rt -obs Vs RT fol. Dono + cisplat x 3	IIb 29-36% IIIa 25-23% IIIc 42-39%	Mostly grade 2 et 3	HR=0,74 0,36-1,52 P=0,41	HR=0,61 0,33-1,12 P=0,1	Endométrioi d only
2 studies combined				HR=0,69 0,46-1,03 P=0,07	HR=0,63 0,41-0,99 P=0,0009	

Nathalie Letarte | Presentation Handouts Pg9

Adjuvant Chemo vs Adjuvant RT

Study	Treatment	Stages	Grades	OS	PFS	Comments
J GOG 2033 N=385 2008	RT versus CAP: cisplatine, doxo, cyclo Q4 w x 3 or more	IC: 68% IIIa: 15% IIIc:12%	1:55% 2:30% 3: 17%	85,3% RT vs 86,7% chemo HR= 0.72 0.40-1.29; P=0.268	5y 83,5% RT vs 81,8% chemo HR=1,07 0.65-1.76; P=0.726).	
GOG 122 Randall N=388 2006	RT versus Cisplatin + doxo q 3 w x 8	Stage III IIIa: 28-18% IIIc:44-51% Stage IV	All	HR = 0,68 0,52-0,89 p = 0.004 5y OS : 42% RT 50% chemo	Recurrence 54% RT, 50% chemo HR = 0,71 0,55-0,9 p = 0,007	Residual tumor < 2 cm
Maggi 2006 N=	RT vs CAP: cisplatine, doxo, cyclo Q4 w x 5 or more	Ic: 26% IIIa: 40% IIIc: 22%	All	HR=0.95 0.66-1.36 P=0.77 OS 3,5,7y 78, 69 and 62% RT et 68, 63 and 60%.	HR= 0.88 0.63-1.23 P=0.45	

Meta-analysis



RR with Paclitaxel-Carbo

	N	CR (%)	PR(%)	ORR (%)
Pittsburgh, 1997	8	25	38	63
Hoskins (BCCA) 2001	22	11	45	56
SWOG 2005	47	8	32	40
MSKCC 2007	53	6	42	47
Athens 2008	47	2	41	62

Ongoing trials

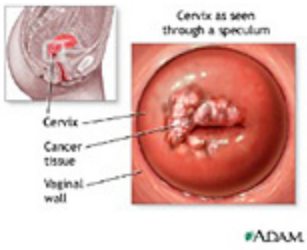
- GOG 249
  - RT only vs brachytherapy followed by chemo (early stage with high risk)
- GOG 261
  - RT + cisplatin followed by TC vs TC (advanced)
- GOG 86p
- CA163-196 (ixabepilone)
- EN-7 (Portec-3)
  - RT+ cisplatin followed by TC vs RT only (stage I,II or III)

Cervical cancer

Cervical cancer

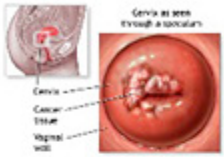
What about prevention?

Cervical cancer



Nathalie Letarte | Presentation Handouts Pg10

Cervical cancer



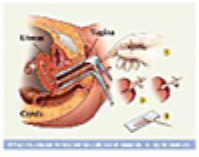
- 3rd most frequent cancer in women in the world (2nd cause of death)
  - 13th in Canada
- 1350 cases and 390 deaths in Canada in 2012
- Death rate reduced by 2,9% since 1998 in Canada
- Linked to HPV in 99,7% of cases!

Risk factors

- HPV
- Early sexual intercourse
- Multiple partners
- Multiparity
- History of sexually transmitted diseases
- Smoking
- Low socio-economic status
- Diet (low vitamin intake)
- Alcohol
- Factor reducing the risks:
  - Nulliparity and abstinence

Screening

- PAP test
  - Observationnal non randomised studies
  - Reduction in invasive cancers
  - Reduction in mortality
- Liquid-based Cytology (LBC)
  - ThinPrep or SurePath
  - Variation of conventional cytology
- HPV DNA
  - Not in all provincial programs



JOGC 2007;29(8)S3.

Health Canada recommendations

- Screening
- Sexually active women ≥ 18 y
  - Annual test x 2 y then q 3 y if normal and same sexual partner, until 69 y
- Women ≥ 67 y without any screening:
  - Test q 6 months and stop if normal
- Each province has a specific program

CMAJ 1995;152(4):483–93.

Prevention of HPV

- Primary prevention
  - Education
  - Abstinence
  - Reducing number of sexual partners
  - Contraception
  - STI preventive measures
- Secondary prevention
  - Reducing the risk of complications of HPV infections
  - Identifying and treatting disease
  - Screening and partner referral
  - Smoking cessation
  - Post exposure prophylaxis

JOGC 2007;29(8)S3.

Gardasil®

- Quadrivalent vaccine VPH Types 6, 11, 16 and 18
  - IM doses at 0, 2 and 6 months
- Indicated for girls and women from 9 to 45 y
- Prevention of:
  - Cervical, vulvar, and vaginal cancer caused by HPV types 16 and 18
  - Genital warts (condyloma acuminata) caused by HPV types 6 and 11
  - And precancerous or dysplastic lesions caused by HPV types 6, 11, 16, and 18:
    - Cervical adenocarcinoma *in situ (AIS)*
    - Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3
    - Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3
    - Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3
    - Cervical intraepithelial neoplasia (CIN) grade 1

GARDASIL®

- is indicated in girls and women 9- through 26 years of age for the prevention of:
  - - Anal cancer caused by HPV types 16 and 18
  - - Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3 caused by HPV types 6, 11, 16,
  - and 18
- GARDASIL® is indicated in boys and men 9 through 26 years of age for the prevention of infection caused by HPV types 6, 11, 16, and 18
  - Anal cancer caused by HPV types16 and 18
  - Genital warts (condyloma acuminata) caused by HPV types 6 and 11
  - And anal intraepithelial neoplasia (AIN) grades 1, 2, and 3 caused by HPV types 6, 11, 16,and 18.

Cervarix ®

- Bivalent vaccine VPH Types 16 and 18
  - IM doses 0,1, and 6 months
- Girls and women from 10 to 25 y
- prevention of cervical cancer (squamous cell cancer and adenocarcinoma) by protecting against the following precancerous or dysplastic lesions caused by oncogenic Human Papillomavirus (HPV), types 16 and 18:
  - • Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3
  - • Cervical adenocarcinoma *in situ (AIS)*
  - • Cervical intraepithelial neoplasia (CIN) grade 1

Vaccines

- Highly effective to prevent CIN2/3 (surrogate for invasive cervical cancer)
- Sustained immunogenicity up to 5 years
  - Time will tell if booster doses are needed
- Will change screening processes once the vaccinated population becomes dominant
- Cost effectiveness
  - 38 000 cases of CIN-1, 12 000 cases of CIN 2/3 = 300 million burden
  - Models estimate a cost of 15 000 – 24 000$ per QALY gained

JOGC 2007;29(8)S3.

References

- Canadian Statistics on Cancer 2012. www.cancer.ca
- Armstrong DK, Bundy B, Wenzel L, et al.; Gynecologic Oncology Group. Intraperitoneal cisplatin and paclitaxel in ovarian cancer. N Engl J Med. 2006 Jan 5;354(1):34-43.
- Stuart GC, Kitchener H, Bacon M, et al. 2010 Gynecologic Cancer InterGroup (GCIG) consensus statement on clinical trials in ovarian cancer: Report from the Fourth Ovarian Cancer Consensus Conference. Int J Gynecol Cancer 21:750-755, 2011
- Burger RA, Brady MF, Bookman MA, et al. Incorporation of bevacizumab in the primary treatment of ovarian cancer. N Engl J Med 365:2473-2783, 2011
- Perren T, Swart AC, Pfisterer J, et al. A phase 3 trial of bevacizumab in ovarian cancer. N Engl J Med 365:2484-2496, 2011
- Aghajanian C, Blank SV, Goff BA et al. OCEANS: A randomised, double-blind, placebo-controlled phase III trial of chemotherapy with ± without bevacizumab in patients with platinum sensitive recurrent epithelial ovarian, primary peritoneal or fallopian tube cancer. J Clin Oncol 2012;30(17): 2039-45.
- Monk BJ, Herzog TJ, Kaye S et al. Trabectedin plus pegylated liposomal doxorubicin in recurrent ovarian cancer. J Clin Oncol 2010; 28: 3107-3114.
- Kaye SB, Colombo N, Monk BJ et al. Trabectedin plus pegylated liposomal doxorubicin in relapsed ovarian cancer delays 3rd line chemotherapy and prolongs the platinum-free interval. Ann Oncol 2011;22(1):49-58.
- Provencher D, Vergote I, Tyulandin S et al. Trabectedin plus pegylated liposomal doxorubicin in relapsed ovarian cancer: outcomes in the partially platinum-sensitive (platinum-free interval 6-12 mo) subpopulation of OVA-301 phase III randomized trial. Ann Oncol 2011;22(1):39-48.

References (2)

- Hill EK, Dizon DS. Medical therapy of endometrial cancer. Drugs 2012;72(5):705-13.
- Colombo N, Preti E, Landoni F, Carinelli S, Colombo A, Marini C, Sessa C. Endometrial cancer : ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol 2011;22(Supplement 6):vi35-vi39.
- Hogberg T, Signorelli M, de Oliveira CF, Fossati R, Lissoni AA, Sorbe B, Andersson H, Grenman S, Lundgren C, Rosenberg P, Boman K, Thalandier B, Scambia G, Reed N, Correa G, Tognon G, Clarke J, Sawicki T, Zola P, Kristensen G. Sequential adjuvant chemotherapy and radiotherapy in endometrial cancer--results from two randomised studies. Eur J Cancer 2010;46(13):2422-2431.
- Kuoppala T, Maenpaa J, Tomas E, Puolitsa U, Salmi T, Grenman S, Loftsverla P, Fors M, Luukkaala T, Sjola P. Surgically staged high-risk endometrial cancer: randomized study of adjuvant radiotherapy alone vs. sequential chemo-radiotherapy. Gynecol Oncol 2008;110(2):190-195.
- Morrow CP, Bundy BN, Homesley HD, Creasman WT, Hornback NB, Kurman R, Thigpen JT. Doxorubicin as an adjuvant following surgery and radiation therapy in patients with high-risk endometrial carcinoma, stage I and occult stage II: a Gynecologic Oncology Group Study. Gynecol Oncol 1990;36(2):166-171.
- Homesley HD, Filiaci V, Gibbons SK, Long HJ, Calla D, Spirtos NM, Morris RT, DeGeest K, Lee R, Montag A. A randomized phase III trial in advanced endometrial carcinoma of surgery and volume directed radiation followed by cisplatin and doxorubicin with or without paclitaxel: A Gynecologic Oncology Group study. Gynecol Oncol 2009;112(3):543-552.

References (3)

- Randall ME, Filiaci VL, Muss H, Spirtos NM, Mannel RS, Fowler J, Thigpen JT, Benda JA. Randomized phase III trial of whole-abdominal irradiation versus doxorubicin and cisplatin chemotherapy in advanced endometrial carcinoma: a Gynecologic Oncology Group Study. J Clin Oncol 2006;24(1):36-44. Calla D, Huang H, Homesley HD, Montag A, Sagae S, Ohi Genet K, Lee R, Spirtos NM. Patient-reported peripheral neuropathy of doxorubicin and cisplatin with and without paclitaxel in the treatment of advanced endometrial cancer: Results from GOG. 184. Gynecol Oncol 2010;118(3):538-542.
- Susumu N, Sagae S, Udagawa Y, Niwa K, Kuramoto H, Satoh S, Kudo R. Randomized phase III trial of pelvic radiotherapy versus cisplatin-based combined chemotherapy in patients with intermediate- and high-risk endometrial cancer: a Japanese Gynecologic Oncology Group study. Gynecol Oncol 2008;108(1):226-233.
- Maggi R, Lissoni A, Spina F, Melpignano M, Zola P, Favalli G, Colombo A, Fossati R. Adjuvant chemotherapy vs radiotherapy in high-risk endometrial carcinoma: results of a randomised trial. Br J Cancer 2006;95(2):266-271.
- Canadian Consensus Guidelines on Human Papillomavirus. J Obst Gynecol Canada 2007;29(8):S3.
- Stephen JH. Cervical cancer. Best Practice & Research Clinical Obstetrics and Gynaecology 26 (2012) 295–309.
- Gardasil Product Monograph. Merck Canada, 2010.
- Cervarix product monograph. GSK, 2010.

Speakers & Session Descriptions

Sunday, October 28

Bone Targeted Therapy in Cancer

DR. MICHAEL LEBLANC
The Moncton Hospital, Moncton, NB
Sunday, 10:30 - 11:15 – Centre-East Room, Main Level

Biography

Dr. Michael LeBlanc is an oncology pharmacy specialist and a clinical pharmacy manager at the Moncton Hospital of Horizon Health Network. He graduated with a BSc (Pharm) from the Memorial University of Newfoundland's School of Pharmacy in 1998 and his PharmD in 2009 from Idaho State University. He has practiced clinically in mental health, palliative care and adult oncology at the Georges L-Dumont Hospital in Moncton, New Brunswick and the H. Bliss Murphy Cancer Centre in St. John's, Newfoundland. He is actively involved in practice-based research, teaching undergraduate and post-graduate pharmacy students and maintains a clinical practice focusing on the prevention and management of treatment-related toxicities.

Synopsis

Learning Objectives

- Discuss the changes to normal bone physiology secondary to cancer and cancer-related therapies
- Discuss the role of bone-targeted therapy for the prevention and management of skeletal-related events
- Identify treatment-related adverse effects and factors associated with high risk of complications
- Review current approaches to the management of ONJ and hypocalcemia
- Discuss the role of the pharmacist in ensuring the safe and effective use of bone-targeted therapies

Abstract

Bone is the most common site of distant metastases for many different cancers. Bone complications often have a significant impact on morbidity and mortality and can develop secondary to bone metastases or bone disease, bone loss associated with malignancy or age, and cancer treatment-induced bone loss. In this session, I will review the clinical consequences of bone loss related to cancer and discuss the therapeutic alternatives for the prevention of skeletal related events. I will also discuss the prevention and management of bone targeted treatment-related toxicities as well as the importance of patient education.

Michael Leblanc | Presentation Handouts Pg1

Update on Bone Health

Michael LeBlanc BSc(Chem), BSc(Pharm), PharmD
Clinical Oncology Pharmacy Specialist
Moncton, Horizon Health Network, NB

Horizon

Disclosure

- Honoraria and/or consultant fees received from:
  - Amgen
  - Novartis
  - Roche Oncology
  - Bristol Myers Squibb
  - Merck Oncology

Learning Objectives

- Discuss the changes to normal bone physiology secondary to cancer and cancer-related therapies
- Discuss the role of bone-targeted therapy for the prevention and management of skeletal related events
- Identify treatment-related adverse effects and factors associated with high risk of complications
- Review current approaches to the management of ONJ and hypocalcemia
- Discuss the role of the pharmacist in ensuring the safe and effective use of bone-targeted therapies

Incidence of bone metastases

- 50% of patients with breast cancer will develop metastases yearly
  - **65-75% of these will be to the bone**
- 85% of men with prostate cancer will develop bone metastases
- 30-60% of patients with lung cancer will develop bone metastases
- Most multiple myeloma patients will have bone metastases (75-90%)
- Also common in other cancers
  - **Thyroid (60%)**
  - **Bladder (40%)**
  - **Melanoma (14-45%)**
  - **Renal (20-25%)**

Normal bone physiology

- Bone remodeling is continuous throughout life
- Balance between osteoblastic and osteoclastic activity
  - **Osteoclasts: cells that break down (Chew) bone to form resorption cavity**
  - **Osteoblasts: cells that Build bone over the resorption cavity**
- Ensures skeletal integrity
- Maintains mineral homeostasis
  - **Including calcium, magnesium, phosphorus**

Normal Physiology Is a Constant Dynamic Process, Balancing Bone Resorption and Formation

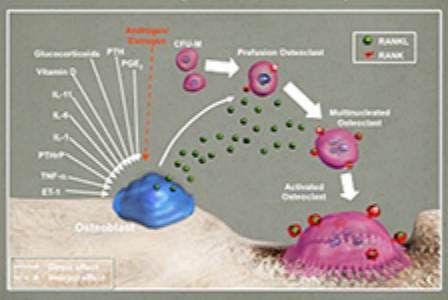
Michael Leblanc | Presentation Handouts Pg2

Effect of cancer on bone structure

- Osteolytic lesions
  - Most common with multiple myeloma
  - Tumour cells activate osteoclasts without activating osteoblastic activity
- Osteoblastic lesions
  - Most likely type of lesion in individuals with prostate cancer
  - Tumor cells stimulate osteoclasts and osteoblasts with the new bone formation being deposited in sites unrelated to the resorption cavities
- Mixed Lesions
  - Other solid tumours

- Excessive bone resorption compromises the integrity of the bone and leads to skeletal complications
  - Tumour cells secrete various factors (autocrine and paracrine) that add to the imbalance of resorption/ formation of bone

Factors Stimulating Osteoblast Expression



Bone Loss/ Destruction in Cancer Patients

Causes

- Cancer treatment-induced bone loss (CTIBL)
- Amenorrhea caused by dysregulation of GnRH
- Premature ovarian failure secondary to chemotherapy
- Prophylactic oopherectomy
- Bone metastases

Each 1 SD decline in lumbar spine BMD was associated with a 2.3-fold increase in the risk of a vertebral fracture

Consequences of bone metastases

- Pain
- Skeletal Related Events (SRE)
  - Fracture
  - Need for radiation therapy
  - Surgery to prevent or treat fractures
  - Spinal cord compression
- Quality of life
  - Loss of mobility
  - Reduced independence
- Societal
  - Cost burden

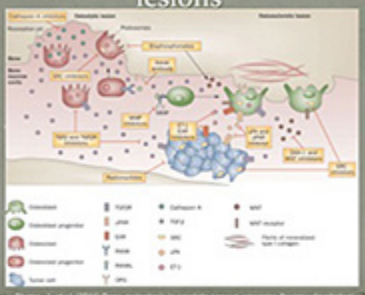
SRE-related Risk Factors Identified in Advanced Cancer Patients

- Smoking
- Nonadenocarcinoma
- Poor performance status (2-3)
- No history of treatment with EGFR TKIs
- Male sex
- Multiple bone metastases (≥osteolytic bone lesions) or bone-only metastases
- Osteoporosis
- Bone metastases with soft-tissue extension
- High pain scores
- History of prior radiation treatments
- Bone and overall disease progression

Therapeutic alternatives

- Radiotherapy
  - External beam radiation therapy (RT)
    - Remains the treatment of choice for single sites
  - Systemic radiopharmaceuticals
    - Concentrate in bone during bone mineralization and deliver short range beta radiation particles to the local area
    - HC approved agents
      - Quadramet (Samarium – ^{153}Sm)
      - Metastron (Strontium – ^{89}Sr)
  - Intensity modulated radiotherapy
  - Hemibody radiotherapy
- Surgical Intervention
  - Fractures or spinal cord compression
- Systemic therapy

Bone-targeted therapy in metastatic lesions



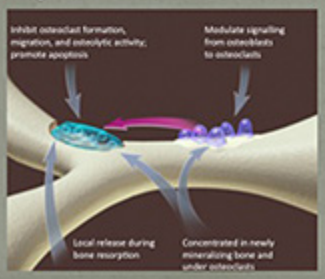
Clinical Guidelines

- NCCN 2012
  - An IV bisphosphonate in combination with oral calcium and vitamin D should be used in women with bone metastasis if expected survival is 3 months or longer and creatinine levels are below 3 mg/dL (category 1)
    - Women with metastatic breast cancer to bone who are candidates for bisphosphonate therapy may also be considered for treatment with denosumab (category 1)
  - In men with castration-recurrent prostate cancer who have bone metastases, denosumab and zoledronic acid have been shown to prevent disease-related skeletal complications, which include fracture, spinal cord compression, or the need for surgery or radiation therapy to bone
  - Bisphosphonate therapy or denosumab can be considered in patients with NSCLC and bone metastasis.
  - The NCCN Multiple Myeloma Guidelines recommend bisphosphonates for all patients receiving myeloma therapy for symptomatic disease (category 1)

Bisphosphonates

- Available as oral and intravenous formulations
  - Non-nitrogen containing
    - Etidronate
    - Clodronate
    - Tiludronate
  - Nitrogen containing
    - Pamidronate – 90 mg IV (2-4 hour infusion)
    - Alendronate
    - Risedronate
    - Ibandronate
    - Zoledronic Acid – 4 mg IV (15 min)
- Useful for the prevention of bone loss (osteoporosis)
- Integral component of management of advanced cancer patients with bone metastases
- Decrease bone resorption and increase mineralization by inhibiting osteoclast activity

Mechanism of Action of Bisphosphonates



Evidence for clinical benefit

- Breast Cancer – prevention of SRE
  - Pamidronate
    - Reduction in skeletal complications in women with bone metastases
      - Hortobagyi 1996 *N Engl J Med*
  - Zoledronic Acid
    - 4 mg more effective than 90 mg of pamidronate for the reduction of skeletal complications
      - Rosen 2004 *Cancer*

Evidence for clinical benefit

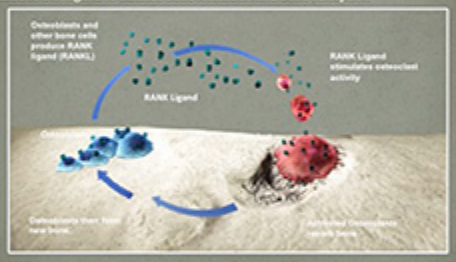
- Prostate Cancer – prevention of SRE
  - **Zoledronic Acid**
    - significant reduction in the frequency of SRE compared to placebo (38 versus 49 percent)
    - median time to develop a SRE was significantly longer with zoledronic acid (488 versus 321 days)
      - Saad F J Natl Cancer Inst. 2002;94(19):1458

Evidence for clinical benefit

- Other cancers – prevention of SRE
  - **Lung – Zoledronic Acid**
    - Significant reduction in the number of SREs (38 versus 47 percent)
    - Significantly longer time to the first event (230 versus 163 days)
      - Rosen LS. J Clin Oncol. 2003;21(16):3150
  - **Multiple myeloma**
    - Prevention of pathological vertebral fractures (relative risk [RR] of 0.74, 95% CI 0.62-0.89)
    - Fewer skeletal related events (RR 0.80, 95% CI 0.72-0.89)
    - Better control of skeletal related pain (RR 0.75, 95% CI 0.60-0.95)
      - Mhankar R. Cochrane Database Syst Rev. 2012;5:CD003188

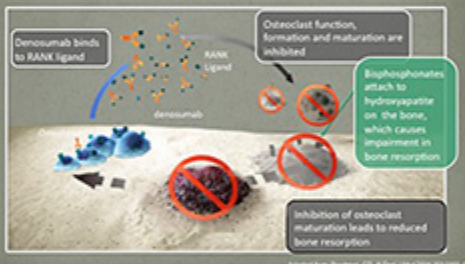
The Role of RANK Ligand in Healthy Bone

- In healthy adult bone, the body NORMALLY regulates the activity of a protein called RANK ligand to balance bone formation and bone resorption



RANKL=receptor activator of nuclear factor kappa B ligand

The Vicious Cycle of Bone Destruction and the Prevention of SREs



Denosumab

- Fully human monoclonal antibody to RANK Ligand
- Administration
  - **120 mg administered as a single subcutaneous injection once every 4 weeks**
  - **All patients, except those with hypercalcemia, should receive at least 500 mg calcium daily and at least 400 IU vitamin D daily.**

Evidence for clinical benefit

- Breast Cancer – prevention of SRE
  - **Denosumab**
    - Greater delay to first on study SREs than zoledronic acid [hazard ratio (HR) 0.82, 95% CI 0.71-0.95, p<0.001 (noninferiority) p=0.01 (superiority)]
    - No difference in overall survival or time to disease progression
      - Stopeck AT. J Clin Oncol. 2010;28(35):5132
- Castration Recurrent Prostate Cancer
  - **Denosumab**
    - Significantly delayed time to first skeletal-related event compared to zoledronic acid (median 20.7 versus 17.1 months, HR 0.82, 95% CI 0.71-0.95)
    - No difference in overall survival or time to disease progression
      - Fizazi K. Lancet. 2011;377(9768):813

Michael Leblanc | Presentation Handouts Pg5

Evidence for clinical benefit

- Lung and other solid tumours – prevention of SRE
  - **Denosumab**
    - Noninferior to zoledronic acid in delaying time to first on-study SRE (hazard ratio, 0.84; 95% CI, 0.71 to 0.98; P = .0007)
    - No difference in overall survival or time to disease progression
      - Henry DH. J Clin Oncol. 2011;29(9):1125

Evidence for clinical benefit

- Denosumab vs Zoledronic Acid
  - Meta-analysis concluded that denosumab significantly delayed:
    - time to a first skeletal event (HR 0.83, 95% CI 0.76-0.90)
    - time to pain worsening (HR 0.92, 95% CI 0.86-0.99)
    - time to multiple skeletal-related events (HR=0.83; 95% CI, 0.76-0.90, P<0.001)
  - No difference for overall survival or disease progression
    - Lei S. Am J Clin Oncol. 2012 Jul

Role of the pharmacist

- Education of patient and providers
- Toxicity prevention
- Toxicity monitoring/management

Bisphosphonates: Adverse Events

- Oral formulations
  - GI disturbance
    - Nausea, heart burn, esophageal irritation/ ulceration
  - Hypocalcemia
  - Increased parathyroid hormone
  - Skin rash
  - Bone pain
  - Subtrochanteric fracture
  - ONJ
- IV formulations
  - Fatigue
  - Nausea/vomiting
  - Bone pain/myalgia
  - Headache
  - Fever
  - Hypocalcemia
  - Increased parathyroid hormone
  - Subtrochanteric fracture
  - Transient leukopenia/anemia
  - ONJ
  - Nephrotic syndrome

Denosumab: Adverse Events

- Adverse events
  - **Fatigue/asthenia**
  - **Hypophosphatemia**
  - **Nausea**
  - **Dyspnea**
  - **Hypocalcemia**
  - **ONJ**

Osteonecrosis of the Jaw (ONJ)

- The persistence of exposed bone in the oral cavity, despite adequate treatment for eight weeks, without local evidence of malignancy and no prior radiotherapy to the affected region
  - American Association of Oral and Maxillofacial Surgeons
- Typically presents as an infection or exposed bone
- Some patients experience prolonged jaw pain, bone enlargement, gingival swelling, and/or sinus tract swelling
  - Results from avascular necrosis and its likely primary mechanism is potent and prolonged inhibition of bone resorption

Michael Leblanc | Presentation Handouts Pg6

Osteonecrosis of the Jaw (ONJ)

Rates of ONJ	Denosumab	Zoledronic Acid
Clinical trials in > 5600 patients with advanced cancer	1.8%	1.3%
Clinical trials in patients with advanced cancer *including 4 month extended double-blind treatment phase*	2.2%	1.6%

Saad F. Ann Oncol. 2012;23(5):1341

Osteonecrosis of the Jaw (ONJ)

- Dental extraction preceded the ONJ event in 62 percent of cases; 82 percent had jaw pain, and a coincident oral infection was present in 48 percent of cases
- ONJ events were documented as early as four months after starting therapy and up to 30 months after first dose of drug; the median time of drug exposure prior to the development of ONJ was 14 months in both groups
- Incidence is higher with longer duration of treatment

Saad F. Ann Oncol. 2012;23(5):1341

Prevention of ONJ

- Conduct baseline oral exam and perform all invasive dental procedures before initiating a bone-targeted therapy
  - **Key history questions**
    - Do you have oral pain?
    - Do you have loose teeth?
    - Are you under the regular care of a dentist?
  - **What to look for in an oral exam?**
    - Loose teeth
    - Dental caries
    - Defective restorations (fillings and crowns)
    - Ill-fitting dentures
    - Ulcers (especially in detecting early cases of osteonecrosis)
    - The presence of bone growths (tori and exostoses) – is important to remove in preventing osteonecrosis BEFORE bone-targeted therapy initiation

Prevention of ONJ

- Refer patients with poor oral hygiene or signs of periodontal disease to a dentist prior to starting therapy
- Thorough dental examination including radiographs should be completed prior to initiation
  - Active oral infections should be treated
  - Sites at high risk for infection should be eliminated
- Consider discontinuation of the drug for three months prior and three months after the dental invasive procedure
- Non-urgent procedures are preferably delayed for 3 to 6 months following interruption of bisphosphonate therapy.
- Counsel patients to adopt healthy dental hygiene
  - Daily flossing
  - Brushing
  - Antibacterial oral rinses
  - Stop smoking

Khan AA. J Rheumatol. 2008;35(7):1391
Ruggiero S, et al. *J Oral Maxillofac Surg* 2009;67:2-12

Treatment of ONJ

- Oral rinses and/or antibiotics alone
- Oral surgeries (40%) including
  - Debridement
  - Sequestrectomy
  - Extraction
- When to interrupt therapy:
  - **Limited evidence and experts differ**
    - European Myeloma Network suggests discontinuation of bisphosphonates until healing occurs, with treatment restarted if there is disease progression
    - Long-term discontinuation of IV bisphosphonates in cancer patients might be beneficial in stabilizing sites of ONJ, reducing the risk of developing new sites, and controlling symptoms (AAOMS)

Saad F. Ann Oncol. 2012;23(5):1341
Ruggiero S, et al. *J Oral Maxillofac Surg* 2009;67:2-12

Management of ONJ

	Pre-ONJ	Stage 1	Stage 2	Stage 3
Clinical features	Patients treated with BP No apparent exposed/ necrotic bone	Exposed/ necrotic bone Asymptomatic No evidence of infection	Exposed/necrotic bone Infection as evidenced by pain, erythema in region of the exposed bone With or without purulent drainage	Exposed/necrotic bone with pain, infection, and one or more of the following: Pathologic fracture Extra-oral fistula or Osteolysis extending to the inferior border
How to manage	Patient education	Antibacterial mouth rinses Clinical follow-up on a quarterly basis Patient education Review indications for continued BP therapy	Sympt. tx with broad-spectrum abx Oral antibacterial mouth rinses Pain control Only superficial debridement to relieve soft-tissue irritation	Antibacterial mouth rinses Abx therapy Pain control Surgical debridement or resection for long-term palliation of infection and pain

Adapted from Ruggiero S, et al. Oral Diseases 2006;12:7-14.

Michael Leblanc | Presentation Handouts Pg7

Electrolyte Abnormalities

- Osteoclast inhibition significantly affects calcium homeostasis
  - Hypocalcemia
  - Hypophosphatemia
- Compensatory mechanisms may be blocked
  - prior parathyroidectomy
  - low vitamin D levels
  - hypomagnesemic hypoparathyroidism
  - renal failure

Blair HC. Biofactors. 2011 May;37(3):159-67. Epub 2011 Jun 14

Electrolyte Abnormalities

- Incidence of hypocalcemia (any grade)
  - 9.6% denosumab
  - 5.0% zoledronic acid
- Severe hypocalcemia (including fatal cases)
  - 3.1% denosumab
  - 1.3% zoledronic acid
- Risk of severe hypocalcemia increases with denosumab in the presence of renal impairment (<30mL/min)
- Educate patient and monitor for signs of hypocalcemia
  - Altered mental status
  - Tetany
  - Seizures
  - QTc prolongation

Denosumab Product Monograph, Amgen Canada Inc. May 2011

Prevention of hypocalcemia

- Pre-existing hypocalcemia must be corrected prior to initiating therapy
- All patients, except those with hypercalcemia, should receive at least **500 mg calcium daily** and at least **400 IU vitamin D daily**
- Calcium and vitamin D levels should be monitored at baseline and regularly
- Calcium, magnesium, and vitamin D should be administered as necessary
- If hypocalcemia occurs while receiving denosumab, additional short-term calcium supplementation may be necessary

Renal toxicities

- Bisphosphonates
  - Nephrotoxicity is both dose- and infusion time-dependent
  - Renal deterioration with either drug can progress to renal failure and the need for dialysis
  - Prevention
    - Dose reduce in renal failure for zoledronic acid
    - Longer infusion times for pamidronate
    - Avoid concomitant nephrotoxic agents
- Denosumab
  - Limited evidence in patients with impaired renal function (<30mL/min)
  - Increased risk of electolyte abnormalities

Panzella MA. Kidney Int. 2008;74(11):1365

Other toxicities

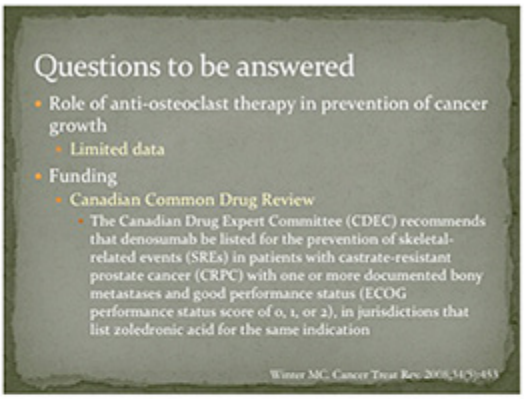
- Acute phase reactions
  - transient fever and an influenza-like syndrome (bisphosphonates)
- Bone, joint, or muscle pain
  - Does not always resolve post d/c
- Increased risk of infections (denosumab)
  - Has not been proven in clinical studies

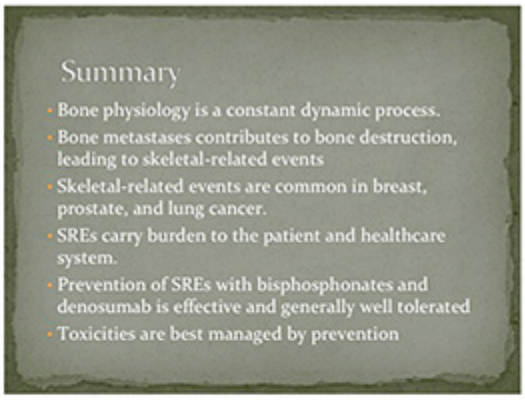
Practical Comparison of Zoledronic Acid and Denosumab

	Zoledronic Acid	Denosumab
Route of administration and logistical considerations	IV, chair time and nursing support required	SC injection with 27-gauge needle
Dose/Frequency	4 mg over 15 minutes, Q3-Q4 wks	120 mg Q4 wks
Monitoring	Serum calcium Renal function	Serum calcium
Adverse events of interest	ONJ Deterioration in renal function Acute phase reactions	ONJ Hypocalcemia
Cost	$354.08 per vial Approximately $736 per dose when consider Nursing administration, pharmacy preparation, kidney function and creatinine level monitoring and chair time	$536.45 per vial

Novartis Pharmaceuticals Canada Inc. Zometa® Product Monograph. Date of Revision: Oct 26, 2011
Amgen Canada Inc. Xgeva® Product Monograph. Date of Authorization: Oct 14, 2011.
Data from independent analysis conducted by Saskatchewan Cancer Agency

Michael Leblanc | Presentation Handouts Pg8





Engaging Primary Care Providers during Active Cancer Treatment

DR. MONIKA KRZYZANOWSKA
Princess Margaret Hospital, Toronto, ON
Sunday, 11:15 - 12:00 – Centre-East Room, Main Level

Biography

Dr. Monika Krzyzanowska is a medical oncologist and health services researcher at Princess Margaret Cancer Centre and the University of Toronto. The overarching goal of her research program is to improve the quality of care received by cancer patients treated in routine care settings across the continuum of care from screening through end-of-life. She is the Clinical Lead for Quality Care and Access within the Systemic Treatment Program at Cancer Care Ontario and the Chair of the American Society of Clinical Oncology Quality of Care Committee.

Synopsis

Learning Objectives

- What we know about engaging primary care givers (PCPs) during the active cancer treatment phase
- What the knowledge gaps are
- How we can improve the integration between PCPs and the cancer system with a specific focus on cancer patients receiving chemotherapy

Abstract

Cancer is a unique chronic disease in that cancer-directed treatment is almost exclusively delivered by specialists. However, prior studies demonstrate that cancer patients continue to see their primary care providers (PCPs) throughout their cancer journey including during the active treatment phase. Potential PCP roles during this phase in the cancer journey include assistance with treatment decision-making, emotional support, symptom management and management of comorbid conditions. Previous surveys indicate that many PCPs want to be actively involved during the active treatment phase of their patients with cancer, but little is known about the preferences of oncologists or successful models that integrate primary and specialist care during the active treatment phase.

Effect of Interruptions on Chemotherapy Ordering and the Impact of Clinical Pharmacists on Medication Order Quality

DR. PATRICIA TRBOVICH
University Health Network, Toronto, ON
Sunday, 12:00 - 12:30 – Centre-East Room, Main Level

Biography

Dr. Patricia Trbovich is the Research Lead within the Health Technology Safety Research Team at the University Health Network. She is Assistant Professor of Clinical Engineering in the Institute of Biomaterials and Biomedical Engineering, and of Health Informatics in the Department of Health, Policy, Management and Evaluation, Faculty of Medicine, University of Toronto. Her areas of expertise include human factors engineering and patient safety. Her current research focus includes improving patient safety in outpatient chemotherapy environments, assessing the risks associated with intravenous medication administration, and providers' compliance with evidence-based guidelines. She has also conducted extensive research on Mitigation of Interruptions on Delivery of High-Risk Medical Procedures.

Synopsis

Learning Objectives

- Identify the nature of interruption patterns during medical oncologists' ordering practices
- Describe circumstances when interruptions are a necessary form of communication and discuss strategies to increase physicians' resiliency to interruptions
- Discuss the benefits to quality of ordering when integrating pharmacists into oncology clinics

Abstract

Interruptions are causal factors in medication errors. Although researchers have assessed the nature and frequency of interruptions during medication administration, there has been little focus on understanding their effects during medication ordering. Further, although pharmacists are highly involved in medication ordering and quality control processes, the impact of integrating a pharmacist in a clinic setting is not well understood.

The current study is aimed at assessing: 1) the frequency and nature of interruption patterns during medical oncologists' ordering practices; and 2) the impact of presence of clinical pharmacist on frequency of interruptions and oncologists' medication ordering performance.

Direct observations were conducted at a Canadian cancer treatment facility to: 1) document the nature, frequency, and timing of interruptions during medication ordering; 2) quantify the number of interruptions received by oncologists as a function of pharmacist presence in clinic; and 3) quantify the number of corrections required to medication orders once received by triage pharmacists as a function of pharmacist presence in clinic.

Results showed the main reasons for interruptions in oncology clinics were communication events (e.g. asking questions

related to patient assessments, patient history, and medication orders). We therefore have concluded that completely eliminating sources of interruptions is neither feasible nor recommended. Instead, efforts should be made to minimize the impact of interruptions occurring during safety-critical tasks and/or increase oncologists' resiliency to interruptions.

Furthermore, results revealed that pharmacists in clinic play an important role in communication and medication order quality, particularly in resolution of potentially serious medication order quality issues. Thus, we recommend that integration of pharmacists in clinic should continue to be supported, and interdisciplinary communication between oncologists and pharmacists should be further encouraged.

Our purpose:
Make a difference

As a member of the Janssen Pharmaceutical Companies of Johnson & Johnson, Janssen Inc. is dedicated to addressing and solving the most important unmet medical needs of our time. Driven by our commitment to the passionate pursuit of science for the benefit of patients, we work together to bring innovative ideas, products and services to patients across Canada and around the world.

Nous mettons la science **au service des patients**

À titre de membre du groupe des entreprises pharmaceutiques Janssen de Johnson & Johnson, Janssen Inc. s'emploie à répondre aux besoins non satisfaits les plus importants de notre temps. Poussés par notre passion de mettre la science au service des patients, nous collaborons à de nouvelles solutions, produits et services pour le bien des patients dans le monde entier.

Betsy Gross, *Lilies and Carp*
Artwork from The Creative Center
Janssen is proud to feature artwork created by people affected by the illnesses and diseases we are committed to treating and preventing.

Œuvre créée au *The Creative Center*
Janssen présente avec fierté les œuvres de personnes affectées par les maladies que nous cherchons à traiter et à prévenir.

Janssen Inc.

Member R&D Member
19 Green Belt Drive
Toronto, Ontario
M3C 1L9

vx12003BEF

www.janssen.ca

Janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Exhibition & Posters

Opening Hours

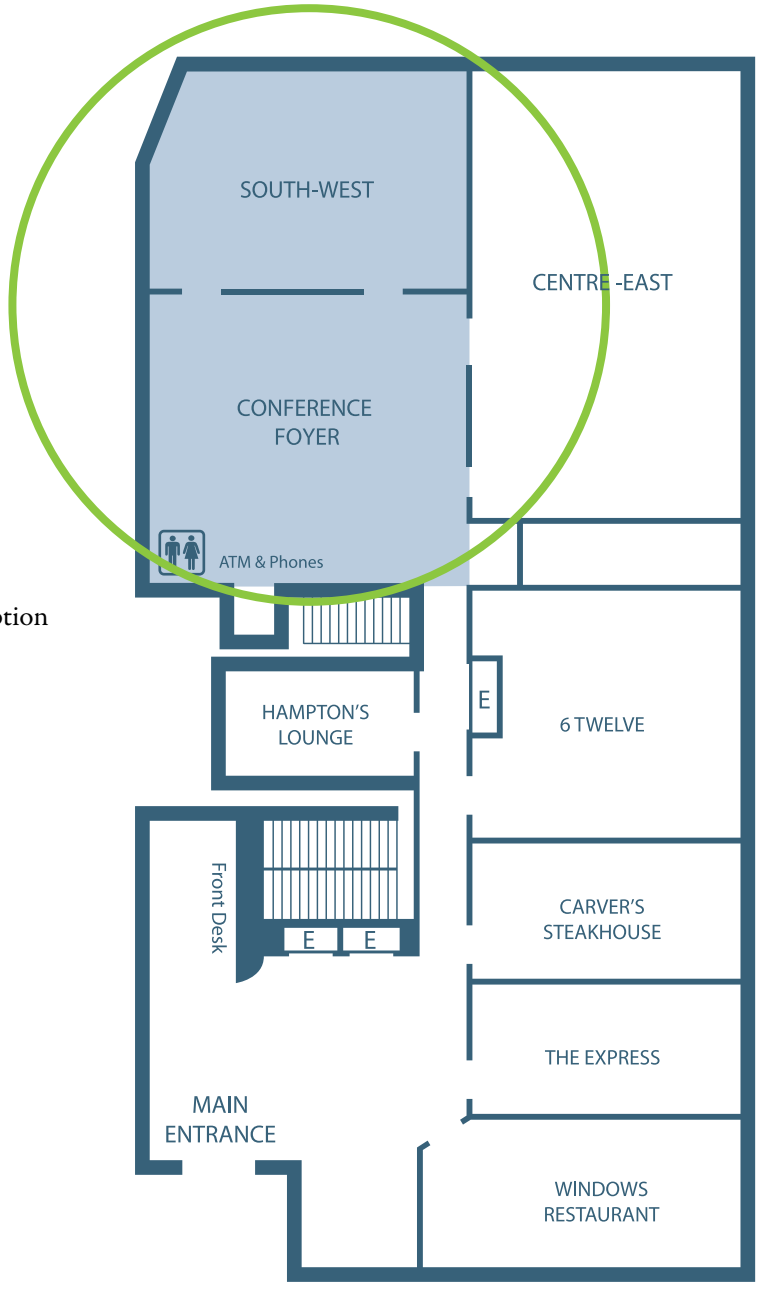
The following events will take place in the Exhibit & Poster Hall, located in the Exhibit Hall, South-West Room and Conference Foyer, Main Level).

Saturday, October 27 07:30 - 18:30

07:30	Hall opens
07:30 - 08:15	Continental Breakfast
10:00 - 10:30	Refreshment Break
13:00 - 14:00	Networking Lunch
15:20 - 15:50	Refreshment Break
16:35 - 18:30	Exhibits and Posters Viewing Reception
18:30	Hall closes

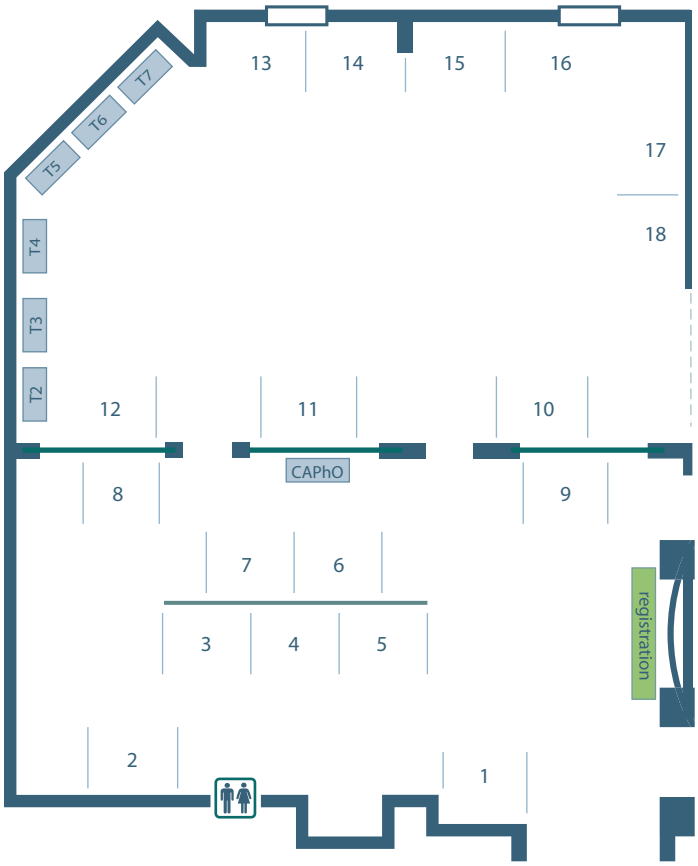
Sunday, October 28 07:30 - 10:30

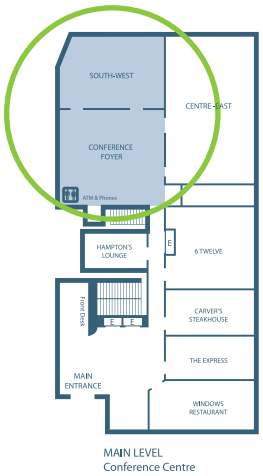
07:30	Hall opens
08:00 - 08:30	Continental Breakfast
10:15 - 10:30	Refreshment Break
10:30	Hall closes



MAIN LEVEL
Conference Centre

Exhibitor Listing





Company	Booth #
AMGEN ONCOLOGY	5
BAXTER CORPORATION CANADA	8
BD MEDICAL (Carmel Pharma Canada Inc)	3
CELGENE	4
EISAI	17
ELI LILLY	9
GSK	18
HOFFMANN-LA ROCHE LIMITED	14
HOSPIRA HEALTHCARE CORPORATION	1
ICU MEDICAL, INC.	12
JANSSEN	15
LEO PHARMA	7
LUNDBECK	6
MERCK	16
NOVARTIS PHARMACEUTICALS CANADA INC.	11
PFIZER ONCOLOGY	2
PHARMACEUTICAL PARTNERS OF CANADA INC.	13
SANOFI	10

	Table #
ASTELLAS PHARMA CANADA	T5
BAYER INC.	T2
BOEHRINGER INGELHEIM (Canada) LTD.	T3
CAPhO	T1
OMEGA	T6
TAKEDA CANADA INC.	T7
TEVA CANADA LIMITED	T4

An investment in research is an investment in hope.

Roche is a leader in the research and development of pharmaceutical and diagnostic solutions that look beyond today's horizons and make a profound difference in people's lives.

Working in partnership with healthcare practitioners from across the country, we have opened the door to countless new possibilities in the discovery, treatment and management of acute and long-term disease.

Roche

We Innovate Healthcare

www.rochecanada.com

Poster Listing

Administration

Pharmacy Practice

Research

SYMPOSIUM: *An Update on the Current Management of Chemotherapy Induced Nausea and Vomiting (CINV) & An Introduction to a Pilot Project with ALOXI® (palonosetron hydrochloride) in the Saskatoon Cancer Centre*

Date: October 28, 2012 from 1:00 pm to 2:30 pm
Location: "TOP OF THE INN"; 8th floor Sheraton Cavalier Hotel

Eisai Ltd. is pleased to invite you to a Symposium on the Management of Chemotherapy Induced Nausea and Vomiting (CINV) being held on Sunday October 28th at 1:00 pm. Please register online as early as possible Lunch will be provided. Two speakers will present as detailed below.

Speaker 1: Sean Hopkins, Professional Practice Coordinator, The Ottawa Hospital Cancer Centre, Ottawa, Ontario

Title: Current Advances in the Management of Chemotherapy Induced Nausea and Vomiting (CINV)

Description: An overview of Chemotherapy Induced Nausea and Vomiting (CINV) with an update on the latest therapies available for the prevention of CINV.

Speaker 2: Colleen Olson, Senior Pharmacist, Saskatoon Cancer Centre

Title: Clinical Experience with Aloxi® (palonosetron hydrochloride) in Saskatchewan

Description: Information will be shared on the use of Aloxi® (palonosetron hydrochloride) within a clinical experience pilot program in Saskatchewan.

Administration

USE OF TELEHEALTH TECHNOLOGY IN PROVIDING ONCOLOGY PHARMACY SERVICES

OBJECTIVE: To establish a permanent telehealth pharmacy program for Cancer Centres to allow for the real-time verification by a pharmacist of intravenous chemotherapy||preparation by a technician in another location.

DESIGN: An equipment deployment and training schedule was established. Training sessions were held via the telehealth equipment for each of the pharmacy sites. A data collection tool was developed to track the number of patients served and number of intravenous chemotherapy doses prepared using the technology.

RESULTS: Deployment of equipment was completed to 21 sites between October 2011 and March 2012. Training sessions were completed for all 21 sites utilizing the telehealth technology. Between October 1, 2011 and July 31, 2012, a total of 3008 chemothearpy preparations representing care for 1747 patients had been completed using the telehealth technology.

CONCLUSION: Policies and procedures were developed in the initial project to ensure that all safety checks and balances were maintained when use of telehealth technology was employed and approval from the Alberta College of Pharmacists was obtained. Deployment of permanent equipment to each of the pharmacies allows for increased flexibility to utilize the technology.

Contact Author

Robin Burns, Alberta Health Services - Pharmacy, Edmonton, AB

Co-authors

Roxanne Dobish, Alberta Health Services, Edmonton, AB

Lee Gordon, Alberta Health Services, Edmonton, AB

Asela Peiris, Alberta Health Services, Edmonton, AB

Administration

QUALITY IMPROVEMENT INITIATIVES IN CHEMOTHERAPY ORDERING AND PROCESSING

OBJECTIVE: The introduction of new anticancer agents and increasing use of multiple lines of treatment together with increasing cancer patient numbers and limited healthcare budgets demands evaluation and optimization of workflow processes. We review and evaluate the impact of various process improvement initiatives in chemotherapy ordering and preparation on pharmacy workflow.

DESIGN: Over the past several years chemotherapy ordering and preparation has been evaluated and processes changed. The effect of these changes on workflow and pharmacy chemotherapy processing were documented.

RESULTS: Implementation of non-same-day chemotherapy scheduling and the requirement for orders to be entered in advance by midday the day before treatment have lead to efficiencies in order review and verification. Verifying orders in advance lead to minimal improvements in chemotherapy preparation time. Putting an order on hold while clarification is sought has a significant impact on preparation time. Queuing of preparation based on the patient appointment time has lead to improvements in workflow and preparation time.

CONCLUSIONS: Chemotherapy ordering and preparation is a complex process. Changes to components of the process have varying impact on pharmacy workflow and preparation time. Optimizing the pharmacy process requires changes to pharmacy specific components as well as processes occurring outside the pharmacy.

Contact Author

Flay Charbonneau, Sunnybrook Odette Cancer Centre, Toronto, ON

Co-authors

Ben de Mendonca, Sunnybrook Health Sciences Centre, Toronto, ON

Tiffany Leung, Sunnybrook Odette Cancer Centre, Toronto, ON

Carlo De Angelis, Sunnybrook Odette Cancer Centre, Toronto, ON

Administration

BEST PRACTICES FOR COMPUTERIZED PRESCRIBER ORDER ENTRY SYSTEMS (ST CPOE) IN SYSTEMIC CHEMOTHERAPY DELIVERY – IMPLICATIONS FOR PATIENT SAFETY AND PHARMACY PRACTICE

OBJECTIVES: CPOE has been consistently shown to reduce medication errors and adverse drug events in various settings. An evidence-informed guideline was developed to identify the key features, functionalities and components of a ST CPOE system required to ensure safe, high quality systemic treatment.

DESIGN: This interdisciplinary evidence-based guideline and concordance indicators were developed by an expert panel of IT specialists and clinicians, including pharmacists. A systematic review was conducted on available clinical and technology literature and input sought from content experts.

RESULTS: This guideline contains two distinct yet interconnected sections: Clinical and technological. Areas of interest to pharmacy practice include inter-professional roles, error reduction, unanticipated benefits/ consequences, impact on practice, clinical decision supports (CDS), alerts, audits, effective regimen build/ modification features, and systems integration. Indicators such||as near miss and error rates are vital for evaluating medication safety.

CONCLUSIONS: Pharmacist and clinician engagement are important from design, change management, implementation, to monitoring of ST CPOE systems. Pharmacy order verification and CDS within ST CPOE reinforce patient safety and quality of care. Current literature focuses mainly on CPOE systems' role and impact on prescribers in non-oncology settings; the impact of CPOE on oncology pharmacy practice should be considered for future research.

Contact Author

Annie Cheung, Cancer Care Ontario, Toronto, ON

Co-authors

Vishal Kukreti, Cancer Care Ontario, Toronto, ON

Roxanne Cosby, Cancer Care Ontario, Toronto, ON

Sara Lankshear, Cancer Care Ontario, Toronto, ON

Administration

DETERMINANTS OF INTRAVENOUS CHEMOTHERAPY PHARMACY PROCESSING TIME

OBJECTIVE: We set out to identify factors which significantly affect the pharmacy processing time for intravenous chemotherapy.

DESIGN: Six months of data extracted from a patient scheduling and communication program used at our centre was used identify and determine the time to complete various steps in the chemotherapy preparation process. Evaluation of chemotherapy "specific" determinants of turnaround time included type of chemotherapy (clinical trial versus not), number of agents in the regimen, reconstitution required versus not, and final product type (syringe, minibag, large volume bag). External factors such as blood work turnaround time, number of patients in the queue, need for order clarification and order in on time were also evaluated.

RESULTS: The median overall pharmacy turnaround time is approximately 1 hour. The median time to actually prepare the chemotherapy (processing time) is 45 minutes. There appears to be no single chemotherapy specific factor which significantly impacts processing time. External factors significantly impact on the overall pharmacy turnaround time. Data analysis is ongoing.

CONCLUSIONS: Chemotherapy preparation time is less variable than the overall pharmacy turnaround time. The ability to prepare chemotherapy in a specified period of time can be significantly impacted by factors external to pharmacy.

Contact Author

Carlo De Angelis, Sunnybrook Odette Cancer Centre, Toronto, ON

Co-authors

Ben de Mendonca, Sunnybrook Health Sciences Centre, Toronto, ON

Tiffany Leung, Sunnybrook Odette Cancer Centre, Toronto, ON

Flay Charbonneau, Sunnybrook Odette Cancer Centre, Toronto, ON

Administration

DEVELOPMENT AND IMPLEMENTATION OF A PROVINCIAL ONCOLOGY PHARMACY RESIDENCY PROGRAM IN AN AMBULATORY CARE SETTING

OBJECTIVE: The goal of the BC Cancer Agency (BCCA) Pharmacy Practice Residency Program is to equip the resident with the necessary skills and knowledge to provide competent and quality care to cancer patients in an ambulatory care setting.

DESIGN: To develop and implement a 12-month, post-baccalaureate residency program at the BC Cancer Agency. This program provides experiential training through general and tumour group-specific rotations at various regional cancer centres across British Columbia. A comprehensive preceptor development program was developed to support preceptors in the development and facilitation of residency rotations.

RESULTS: In June 2012, the inaugural residency program was implemented at the BC Cancer Agency. It includes 7 non-direct patient care rotations, 8 direct patient care rotations, and a longitudinal Pharmacy research project. All direct patient care rotations, except 2, are conducted in the ambulatory care setting.

CONCLUSION: Implementation of a provincial pharmacy residency program in oncology ambulatory care requires strong collaboration, buy-in and support at all levels of the institution – from pharmacy staff and leadership to other health disciplines and administration. The traditional pharmacy resident training model cannot be easily adapted into the ambulatory care setting, requiring innovation and creativity in the program design

Contact Author

Sally Man, BC Cancer Agency, Vancouver, BC

Co-authors

Susan Walisser, BC Cancer Agency, Vancouver, BC

Pharmacy Practice

A RETROSPECTIVE REVIEW OF THE IMPACT OF GRANULOCYTE COLONY STIMULATING FACTORS ON THE OUTCOMES OF METASTATIC COLORECTAL CANCER IN AN OUT PATIENT SETTING

BACKGROUND: Delays in chemotherapy due to neutropenia may be associated with poorer outcomes. The purpose of this study is to examine the effect that granulocyte colony stimulating factors (G-CSF) have on survival.

METHODS: A chart review of all outpatients diagnosed with metastatic colorectal cancer and treated with FOLFIRI chemotherapy at Mount Sinai Hospital between 2007 and 2012 was conducted. Multivariable Cox proportional hazards were used to compare survival of neutropenic patients treated with G-CSF to patients not treated those without neutropenia.

RESULTS: Ninety-three patients were identified, 31 of whom did not experience a neutropenic event and 62 who did: 18of whom were managed with G-CSF support and 44 with reductions in dose intensity. Patients treated with G-CSF had a non-significant increase in time to event (progression or death) compared to patients with a neutropenic episode and no G-CSF (Hazard Ratio [HR] 1.26; 95% CI 0.65, 2.43), but had a significant increase in time to event (HR 2.26; 95% CI 1.11, 4.60) over patients without neutropenic episodes.

CONCLUSION: GCS-F did not have a statistically significant impact on survival in patients who experienced neutropenia. Time to event was prolonged in G-CSF treated patients compared to those patients who did not experience neutropenia.

Contact Author

Anthony Amadio, University of British Columbia, Vancouver, BC

Co-authors

R. Burkes, University of British Columbia, Vancouver, BC

T. Bailie, University of British Columbia, Vancouver, BC

M. McLean, University of British Columbia, Vancouver, BC

B. Coleman, University of British Columbia, Vancouver, BC

Pharmacy Practice

IMPACT OF PHARMACIST INTERVENTIONS ON 5HT3 ANTAGONIST PRESCRIBING AND OVERALL MANAGEMENT OF CHEMOTHERAPY INDUCED NAUSEA AND VOMITING (CINV)

AIM: Ondansetron usage increase to 70% in our institution. A/c to literature, Ondansetron has same efficacy as that of other 5HT3 antagonist but has higher cost. In our formulary another 5 HT3 antagonist also available i.e Granisetron, so we started restricting Ondansetron use, and switched to Granisetron wherever possible. The primary aim was to evaluate impact of RPh intervention on Ondansetron prescribing and cost saving. Whereas second aim was to evaluate overall antiemetic prescribing based on NCCN guidelines.

METHOD: RPh reviews pt profiles admitted in ward and evaluate 5HT3 antagonist prescribing. Drs are contacted when necessary & orders switched from Ondan to grani where possible. Interventions logged in the CPOE. Data was collected and analyzed.

RESULT: Interventions data depicted total of 103 Interventions in 1 year. These are as follows: 1. duplication of 5HT3 antagonist 22.3% 2. Addition of other antiemetic 19.4% 3. switch of Ondan to grani 24% 4. no need of antiemetics 22% 5. wrong diluent 6.79% 6. IV to po change 7.7% Overall cost saving in this period was approx RS 59760.

CONCLUSION: Our data shows that RPh intervention has favorable impact on 5HT3 receptor prescribing and leads to more adherence to standard of care practice guidelines.

Contact Author

Nadia Ayoub, Aga Khan University Hospital, Karachi, Pakistan

Co-authors

Salwa Ahsan, Aga Khan University Hospital, Karachi, Pakistan

Shamim Raza, Aga Khan University Hospital, Karachi, Pakistan

Pharmacy Practice

OPIOID ANALGESIC USE AMONG NOVA SCOTIA (NS) CANCER PATIENTS: RESULTS FROM A POPULATION-BASED OBSERVATIONAL STUDY

OBJECTIVES: A systematic analysis of opioid use by cancer patients in Nova Scotia using population-based datasets.

METHODS: Opioid use by NS cancer patients was studied by linking data from two provincial datasets: the NS Cancer Registry (NSCR); and the NS Prescription Monitoring Program (NSPMP) database. Drug use patterns were analyzed for the entire group||and in sub-populations (at diagnosis, at end of life). Usage was also examined by age, sex, urban or rural residence, and cancer type.

RESULTS: Eligible cases from the NSCR (54,000) and the NSPMP (290,000) were linked, resulting in 27,700 cancer patients who received 217,600 opioid prescriptions between mid 2005 to 2010. Opioid use included both short-term (less than 30 days' supply) and chronic use prescriptions. More than half (57%) of all prescriptions were for strong opioids (morphine, hydromorphone, fentanyl), 36.5% for weak opioids (acetaminophen with codeine or oxycodone), and 6.5% for other opioids (meperidine, methadone). A trend towards higher use, expressed as morphine-equivalents/day, was seen in younger patients and those with poorer prognosis cancer types. No differences were apparent by sex or place of residence.

CONCLUSIONS: Strong opioids comprised the majority of prescriptions. Usage differences were noted by several demographics.

Contact Author

Larry Broadfield, Cancer Care Nova Scotia, Halifax, NS

Co-authors

Judith Fisher, Dalhousie University, Halifax, NS

Ingrid Sketris, Dalhousie University, Halifax, NS

Gordon Walsh, Cancer Care Nova Scotia, Halifax, NS

Pharmacy Practice

EVALUATION OF CANCER TREATMENT ORDER ENTRY BY THE CLINICAL SUPPORT PHARMACY TECHNICIAN (ONCOLOGY) IN THE MEDICAL DAY UNIT AT THE QUEEN ELIZABETH II HEALTH SCIENCES CENTRE

OBJECTIVES: To determine whether trained pharmacy technicians can enter chemotherapy orders at least as safely and efficiently as pharmacists. We measured the time needed for order entry, workflow interruptions, and errors with a pharmacist compared to a clinical support technician.

DESIGN: Before and after observational study of oncology order entry for ambulatory hematology patients. Results There were 144 and 128 individual orders timed for the pharmacist (Phase 1) and the technician (Phase 2), respectively. Total mean time to perform order entry was 1:37 min (Phase 1) and 1:20 min (Phase 2). After outliers were removed, there was no difference in the mean time to enter chemotherapy orders (pharmacist 00:45 sec, technician 00:48 sec, p=0.92). There were 33 non-order entry related interruptions (total 39:38 min) in Phase 1, and 25 interruptions (total 30:08 min) in Phase 2. Errors were 3 in Phase 1 and 0 in Phase 2; and rated as having no effect on patient care.

CONCLUSION: Chemotherapy order entry by a pharmacy technician was not inferior to a pharmacist for safety and efficiency. Changes in scope of practice for the clinical support technicians can increase the amount of time for direct patient care by pharmacists in the oncology setting.

Contact Author

Larry Broadfield, Cancer Care Nova Scotia, Halifax, NS

Co-authors

Heather Neville, Cancer Care Nova Scotia, Halifax, NS

Claudia Harding, Cancer Care Nova Scotia, Halifax, NS

Shelley Heukshorst, Cancer Care Nova Scotia, Halifax, NS

Pharmacy Practice

DEVELOPMENT OF A DATA-DERIVED ALGORITHM FOR USE OF PLERIXAFOR FOR PERIPHERAL BLOOD STEM CELL (PBSC) HARVEST IN PATIENTS ELIGIBLE FOR AUTOLOGOUS STEM CELL TRANSPLANT (ASCT)

PBSC mobilization and collection is a prerequisite for ASCT. In up to 35% of patients, initial mobilization attempts fail to harvest sufficient number of PBSC. Plerixafor has been approved on a case-by-case basis by the Saskatchewan Cancer Agency (SCA) for patients eligible for a second harvest. Our objective was to develop an institution specific, preemptive algorithm where patients likely to fail the first mobilization could be identified for use of upfront plerixafor, thus avoiding delays, patient stress and increased risk of interim disease progression.

PATIENTS AND METHODS: The algorithm was developed through literature review and retrospective collection of data from medical records of 31 SCA patients eligible for ASCT during 2011/12.

RESULTS: The algorithm was developed on the basis of an estimated minimum PBSC count for an adequate PBSC collection for multiple myeloma and lymphoma of 20x10^6/L and 10x10^6/L, respectively.

CONCLUSION: The algorithm for preemptive use of plerixafor was approved for funding by the SCA. The success of this strategy in optimizing plerixafor use in patients eligible for ASCT, improving success of first mobilization procedures, and reducing downstream system costs resulting from delays and second mobilization costs will be tracked in a prospective database.

Contact Author

Pat Danyluk, Saskatchewan Cancer Agency, Saskatoon, SK

Co-authors

Kathy Gesy, Saskatchewan Cancer Agency, Saskatoon, SK

Pharmacy Practice

APPLICATION OF LEAN METHODOLOGY TO IMPROVE CHEMOTHERAPY DELIVERY

OBJECTIVE: The early effect of lean process improvements on an outpatient chemotherapy program was evaluated.

DESIGN: A significant increase in the chemotherapy and targeted therapy treatment numbers prompted a lean methods workflow analysis. Mapping the current state value-stream to identify process waste then brainstorming the ideal future state with the voice of the customer in mind generated our action items. The future state model actions were prioritized based on adopting value-added processes. Kaizen events were used to initiate and measure improvements.

RESULTS: All eight major sources of waste were reduced through kaizen implementation. Significant improvements included virtual elimination of patient wait time for treatments by admixing chemotherapy the afternoon prior to treatment and a mean order processing time decrease from 60 to 30 minutes per regimen by creating electronic standardized chemotherapy order sets. Other improvements included focused attention on related tasks/roles for pharmacy staff reducing the potential for interruption-related errors, reduced delivery runs, a more logical workflow and increased job satisfaction for pharmacy personnel.

CONCLUSION: Adopting and implementing lean methodology in a COPS Centre improved the wait time for patients, the efficiency of the program and refocused patient-centered care.

Contact Author

Katherine Diduck, Sunrise Health Region – YRHC Pharmacy, Yorkton, SK

Co-authors

Lorraine Lysak, Sunrise Health Region – YRHC Pharmacy, Yorkton, SK

Shannan Meubauer, Sunrise Health Region – YRHC Pharmacy, Yorkton, SK

Pharmacy Practice

INCIDENCE AND MANAGEMENT OF PACLITAXEL ASSOCIATED HYPERSENSITIVITY REACTIONS FOLLOWING EARLY DISCONTINUATION OF PROPHYLACTIC PREMEDICATIONS

OBJECTIVE: Infusion-related HSRs are a common adverse effect of paclitaxel. Patients at our centre are routinely premedicated with dexamethasone, diphenhydramine and a histamine receptor 2 antagonist (H2RA) for HSR prevention. Ongoing premedication use consumes clinical resources, extends duration of treatment visits, and carries a risk of adverse effects. We report the outcomes of early premedication discontinuation in paclitaxel patients with no history of HSR after the first 2 treatments.

DESIGN: Over a 5 month period, 116 patients were eligible for early discontinuation of premedications after two HSR-free doses of paclitaxel. H2RA premedication was discontinued in 66 patients treated with paclitaxel and carboplatin, and all premedications were discontinued in 50 patients treated with paclitaxel and trastuzumab or paclitaxel monotherapy. During the study period patients received a total of 161 (paclitaxel-carboplatin group) and 142 (paclitaxel-trastuzumab/monotherapy group) non-premedicated paclitaxel doses.

RESULTS: 1/66 (1.5%; 95%CI: 0 - 4.46%) and 2/50 (4%; 95%CI: 0 - 9.43%) patients experienced non-severe HSRs following discontinuation of H2RA premedication or all premedications respectively. All HSRs were managed according to standard practice and patients were able to continue paclitaxel therapy.

CONCLUSIONS: Early discontinuation of paclitaxel premedication is possible in a select group of patients. Monitoring for HSRs should be ongoing.

Contact Author

Chris Folkins, Sunnybrook Odette Cancer Centre, Toronto, ON

Co-authors

Angie Giotis, Sunnybrook Odette Cancer Centre, Toronto, ON

Mark Pasetka, Sunnybrook Odette Cancer Centre, Toronto, ON

Carlo De Angelis, Sunnybrook Odette Cancer Centre, Toronto, ON

Pharmacy Practice

INTERPROFESSIONAL APPROACH TO IMPROVING SAFETY AND ELEVATING THE STANDARD OF CARE OF ORAL CANCER THERAPY USE AT A COMMUNITY TEACHING HOSPITAL

OBJECTIVE: To improve safety and the standard of care in a community teaching hospital for patients initiating oral cancer therapy for solid tumours using an interprofessional approach.

DESIGN: Patients are initially assessed and referred to the drug access facilitator for reimbursement assistance. Orders are entered into a computerized physician order entry system, which are reviewed by the pharmacist. Patients are booked into the chemotherapy clinic for baseline blood work and assessment by the nurse. The pharmacist provides education and evaluation of home medications, with a follow-up phone call one week later. The patient returns to clinic each cycle for interprofessional assessment, including blood work.

RESULTS: A retrospective review between September 1st, 2011 and July 31st, 2012, demonstrated that 40 patients used this process. The majority of patients were treated with capecitabine (63%) and erlotinib (20%). At the initial clinic visit, pharmacist interventions were performed on 15 (38%) patients. The majority of interventions were related to drug interactions (53%) and order changes (27%). Mature data on interprofessional team interventions will be available on the final poster.

CONCLUSION: Our interprofessional process ensures that patients are supplied with comprehensive care, including reimbursement assistance, safety teaching, pharmacist education, and nursing assessment.

Contact Author

Daniela Gallo-Hershberg, North York General Hospital, North York, ON

Co-authors

Edita Dolabchian, North York General Hospital, North York, ON

Katherine Bouris, North York General Hospital, North York, ON

Raymond Ha, North York General Hospital, North York, ON

Pharmacy Practice

CLINICAL PHARMACY TECHNICIAN SUPPORT IN HEMATOLOGICAL MALIGNANCY CLINICS

OBJECTIVE: The role of a clinical pharmacy technician was developed as part of a multi-disciplinary team working in the Multiple Myeloma and Lymphoproliferative Disorders (CLL and Lymphomas) clinics.

DESIGN: The amount of new agents used in hematological malignancies has increased significantly over the past few years. In order to access these medications, the clinical pharmacy technician assists the clinical team with the many documents that are required to ensure accrual and safe delivery of these agents.

RESULTS: The feasibility of a clinical pharmacist technician role was well received from the hematological clinics. The technicians assist with tracking drug approvals, assist the hematologists in the preparation of non-formulary and restricted drug requests, assist the pharmacist in ensuring that RevAid registration forms are completed and medication calendars are prepared for pharmacist review.

CONCLUSION: The implementation of the clinical pharmacy technician role in ematological malignancy clinics was successful and expands the pharmacy technician's role at our cancer centre.

Contact Author

Marc Geirnaert, CancerCare Manitoba, Winnipeg, MB

Co-authors

Aynsley Bell, CancerCare Manitoba, Winnipeg, MB

Barb Hart, CancerCare Manitoba, Winnipeg, MB

Pharmacy Practice

BCG AND BIOHAZARDOUS DRUG SURVEY

OBJECTIVE: The purpose of this survey is to find out what procedures are currently being used to prepare BCG and other biohazardous drugs in Canada.

BACKGROUND: Biohazardous drugs are drugs that contain viable microorganisms; for example, Bacillus Calmette-Guerin (BCG) and some as gene medicines. Cancer patients often have compromised immune systems. They may be exposed to biohazardous drugs if cross-contamination occurs when biohazardous drugs are prepared in the location as chemotherapy. Standardized Safe handling procedures for handling biohazardous drugs do not currently exist in Canada or the U.S.

DESIGN: Canadian health care facilities that prepare biohazardous drugs for cancer patients were surveyed to determine their safe handling procedures for these drugs.

MATERIALS AND METHOD: The survey was delivered online via Survey Monkey. It was distributed by the Canadian Association of Pharmacy in Oncology (CAPhO) to their contacts. Results: The results of the survey, which show there is a large variation in safe handling procedures for biohazardous drugs, will be summarized in the poster.

CONCLUSION: Pharmacies will increasingly be asked to handle biohazardous drugs as newer agents. Standardized Safe handling procedures are needed for biohazardous drugs to prevent cross contamination and nosocomial infections.

Contact Author

Rhonda Kalyn, BC Cancer Agency, Kelowna, BC

Co-authors

Joan Fabbro, BC Cancer Agency, Kelowna, BC

Pharmacy Practice

TEACHING PATIENTS ABOUT THEIR CHEMOTHERAPY (CHEMO) REGIMEN… ANY ROLE FOR A TEACHING-VIDEO? A PILOT SURVEY

OBJECTIVE: Specific teaching for a chemo regimen and how to manage its side effects is currently taught in a one-on-one approach at the Peel Regional Cancer Centre. The objective of this pilot was to determine the patients' acceptance and their needs for a regimen-specific video to replace one-on-one teaching.

DESIGN: Patients started on systemic chemo were approached to participate in a one-on-one interview. The interview contained 32 open-ended or rating questions on current teaching methods, the patients' acceptance of a video and their ability to use different video options (eg., captioning) and formats (eg., iPad or DVD player).

RESULTS: Twenty-five patients participated between Dec 2011 & Feb 2012. Key findings include that most considered a chemo regimen-specific video to be "very useful" or "useful". However, for ease of understanding, information provided in writing or via speech was preferred. Teaching on how to use a video will be required in up to 56%. Despite being multi-ethnic, captioning in their language was not considered useful by patients.

CONCLUSION: Pilot results suggest a video is acceptable for regimen-specific chemo teaching but should not be the only means of providing information. The results will help produce and implement a patient-oriented, regimen-specific chemo teaching video.

Contact Author

Mova Leung, Peel Regional Cancer Centre, Mississauga, ON

Co-authors

Umraan Ahmed, University of Toronto, Toronto, ON

Pharmacy Practice

THE DEVELOPMENT AND EVALUATION OF AN ONCOLOGY PATIENT COMPLIANCE TOOL

OBJECTIVE: The medication regimens that patients take at home as part of their cancer treatment are complex and mistakes can lead to serious consequences. The objective of our cancer program was to develop and evaluate an innovative tool that would enhance patient compliance with their medication regimens.

DESIGN: In 2010, a web-based program was developed for the purpose of generating illustrated medication calendars. The calendar contains pictures of the medications and visually displays when they are to be taken. Patients receiving supportive care medications with their chemotherapy are given||a calendar.

RESULTS: Patients, nursing and pharmacy staff completed a survey to evaluate the program. The response rate for the patients was 75%. The results were very positive with over 80% of patients moderately or completely agreeing that the calendar helped them to better understand their medications and when to take them. While the response rate for staff was lower at 45%, they saw this tool as a tremendous aid. Over 95% agreed that the calendar helped patients better understand what medications they needed to take and when to take them.

CONCLUSION: The results and comments from the evaluations demonstrate the positive impact this innovative tool has had on patient care.

Contact Author

Kelly Smith, London Health Sciences Centre, London, ON

LET'S THINK

IF ONE OF US CAN COME UP WITH AN IDEA TO HELP OUR PATIENTS,
WHAT COULD ALL OF US COME UP WITH?

LET'S WORK

Boehringer Ingelheim

Science For a Better Life — It's our promise and our commitment to all Canadians. Every day, we put science to work to improve the quality of life for people, for animals and for communities.

Our innovations in healthcare lead to breakthroughs that fight diseases and offer healthier alternatives to existing treatments. Our advances in crop science and animal health protect our food supply and improve nutrition. Our high-tech, high-performance materials improve the design and functionality of products we all use regularly.

Who is Bayer? We're Canadians, we're inventors. Together, we're making life better for everyone.

www.bayer.ca

Science For A Better Life

Research

MEDICATION ADHERENCE AMONG ADULTS PRESCRIBED IMATINIB, DASATINIB, OR NILOTINIB FOR THE TREATMENT OF CHRONIC MYELOID LEUKEMIA

BACKGROUND: Oral tyrosine kinase inhibitors (TKIs) are the standard of care for chronic myeloid leukemia (CML). TKIs are administered in an outpatient setting for an||indefinite period which contributes to poor adherence, associated with disease progression.

OBJECTIVES: To evaluate the need for TKI adherence-enhancing intervention and to identify patient characteristics influencing TKI adherence.

DESIGN: Cross-sectional retrospective chart review of patients receiving a TKI from the Tom Baker Cancer Centre. Adherence was evaluated using the medication possession ratio (MPR). Results: 124 patients were included in the study. Thirty-eight (31%) patients were non-adherent to their regimen. Patients receiving no concurrent medications were more likely to be non-adherent (OR 2.33, 95% CI 1.05-5.13, p=0.04). The median MPR was 0.95 (IQR = 0.83-1.07). Median MPR was lower in patients receiving imatinib compared to dasatinib or nilotinib (0.95 versus 1.00, p=0.01) and in those less than 50 compared to those greater than 50 years old (0.92 versus 0.97, p=0.02). No other associations were found.

CONCLUSIONS: In this study, 1 in 3 CML patients treated with a TKI were non-adherent to their regimen. This is a significant obstacle to the optimal treatment of this population. Interventions to improve adherence should be created, implemented and evaluated.

Contact Author

Kristin Anderson, Tom Baker Cancer Centre, Calgary, AB

Co-authors

Patrick Yau, Tom Baker Cancer Centre, Calgary, AB

Carole Chambers, Tom Baker Cancer Centre, Calgary, AB

Nadine Lamb, Tom Baker Cancer Centre, Calgary, AB

Research

A RETROSPECTIVE REVIEW OF THE IMPACT OF GRANULOCYTE COLONY STIMULATING FACTORS (G-CSF) ON THE OUTCOMES OF METASTATIC COLORECTAL CANCER (mCRC) IN AN OUT PATIENT SETTING

OBJECTIVES: The purpose of this study was to examine the effect that G-CSF had on survival of mCRC patients.

DESIGN: We conducted a chart review of all patients diagnosed with mCRC and treated with FOLFIRI between Jan 1,2007 and Dec 31, 2011. We compared survival of patients given G-CSF following neutropenia, to patients not given G-CSF following neutropenia, to patients without neutropenia. 93 patients were identified. 31 did not experience neutropenia 62 did: 18 of these patients received G-CSF support.

RESULTS: Patients treated with G-CSF had a non-significantly lower risk of event (progression or death) than patients with neutropenic episodes (HR 1.26; 95%CI 0.65, 2.43), but had a significantly lower risk (HR 2.26; 95%CI 1.11, 4.60) than patients without neutropenic episodes. Compared to neutropenic patients not receiving G-CSF, G-CSF treated patients had fewer neutropenic episodes (1.83 vs. 2.29), fewer dose reductions (27.8% vs. 45.4%), more infections (0.83 vs. 0.48), shorter treatment delays due to neutropenia (18.9 days vs. 21.4) and the same number of hospitalizations (0.39 vs. 0.39). None were statistically significant.

CONCLUSION: G-CSF did not have a statistically significant impact on survival in patients who experienced neutropenia. Neutropenic episodes and treatment delays were reduced in patients treated with G-CSF.

Contact Author

Toni Bailie, Mount Sinai Hospital, Toronto, ON

Co-authors

Anthony Amadio, Mount Sinai Hospital, Toronto, ON

Marcia McLean, Mount Sinai Hospital, Toronto, ON

Rob Burkes, Mount Sinai Hospital, Toronto, ON

Research

INFLUENCE OF CIPROFLOXACIN ON RATES OF FEBRILE NEUTROPENIA IN BREAST CANCER PATIENTS RECEIVING DOCETAXEL AND CYCLOPHOSPHAMIDE (TC) CHEMOTHERAPY

INTRODUCTION: Published reports on the rates of febrile neutropenia with Docetaxel and Cyclophosphamide (TC) chemotherapy in early stage breast cancer patients range from 4-8% with widespread use of prophylactic antibiotics and without growth factor support during periods of hematologic nadirs. We report on the rates of febrile neutropenia with TC chemotherapy with and without Ciprofloxacin antibiotic prophylaxis in a similar group of patients.

PATIENTS AND METHODS: A cohort of patients with early stage breast cancer receiving standard dose TC chemotherapy (Docetaxel 75 mg/m2 and Cyclophosphamide 600 mg/m2) who did not receive growth factor primary prophylaxis or Ciprofloxacin antibiotic prophylaxis (n=99) were compared with a similar cohort of patients that universally received Ciprofloxacin antibiotic prophylaxis (n=84) following implementation of standardized guidelines and preprinted physician orders. Rates of febrile neutropenia were analyzed for each patient cohort.

RESULTS: In patients who received Ciprofloxacin prophylaxis, the rate of febrile neutropenia was 10.7% as compared to 25.3% in patients who did not receive Ciprofloxacin prophylaxis, a decrease of 14.6% (RR=0.42, 95% CI=0.21-0.86, p=0.017).

CONCLUSIONS: Ciprofloxacin antibiotic prophylaxis during periods of hematologic nadirs significantly decreased the rate of febrile neutropenia associated with TC chemotherapy.

Contact Author

Darryl Boehm, Saskatchewan Cancer Agency, Regina, SK

Co-authors

Kathy Gesy, Saskatchewan Cancer Agency, Regina, SK

Harriette Pituley, Saskatchewan Cancer Agency, Regina, SK

Roberta Ekberg, Saskatchewan Cancer Agency, Regina, SK

Research

PAIN SEVERITY & IMPAIRMENT OF ACTIVITY BETWEEN PEGFILGRASTIM (P) AND FIXED DOSE FILGRASTIM (F) IN WOMEN WITH EARLY STAGE BREAST CANCER RECEIVING CHEMOTHERAPY

OBJECTIVE: To compare the incidence & severity of muscle and/or joint pain (MJP) in patients (pts) receiving P (6mg SC for 1 day) or fixed-dose F (300mcg SC for 7-8 days).

DESIGN: This is a prospective, observational study of women with breast cancer receiving chemotherapy and P or F. Pts were ineligible if they could not complete a pain diary, or had received P or F in the past 6 months. Baseline characteristics were assessed to identify risk factors for developing MJP. Each pt completed a pain diary to record MJP severity, its management & impact on everyday activities.

RESULTS: 140 pts were enrolled. In both P & F groups, MJP peaked in prevalence & severity on days 3 to 6. Pain that increased ≥3 points were reported in 48% of pts. Daily activities were affected in 48% of reporting-days, with 26% reported as moderate or severe impairment. P was associated with lower muscle (p=0.0049) & joint (p=0.014) pain by regression analyses. Use of docetaxel was the sole baseline risk factor for developing MJP.

CONCLUSION: Pts on P or F experience significant MJP & impairment of daily activities but pts receiving P have less pain & burden relating to pain.

Contact Author

Mova Leung, Peel Regional Cancer Centre, Mississauga, ON

Co-authors

Tiffany Marr-Delmonte, Peel Regional Cancer Centre, Mississauga, ON

Jessica Kano, Peel Regional Cancer Centre, Mississauga, ON

Joy Eustaquio, Peel Regional Cancer Centre, Mississauga, ON

Brian Higgins, Peel Regional Cancer Centre, Mississauga, ON

Robert Myers, Peel Regional Cancer Centre, Mississauga, ON

Glenn Jone, Peel Regional Cancer Centre, Mississauga, ON

Research

A RETROSPECTIVE REVIEW OF CANCER PATIENT REFERRALS FOR FILGRASTIM ADMINISTRATION IN THE OUTPATIENT SETTING OF THE PROVINCE OF QUEBEC

BACKGROUND: Centre Local de Services Communautaires (CLSCs) services include administration of G-CSF injections. Using the single-dose per cycle pegylated form of filgrastim (pegfilgrastim) would reduce the number of injections for prophylaxis of chemotherapy-induced neutropenia. Whether this would reduce provincial health care costs depends in part on how many injections are referred to CLSCs.

OBJECTIVE: To estimate the proportion of filgrastim doses referred to CLSCs.

DESIGN: Retrospective chart review of breast cancer (BC) and non-Hodgkin's lymphoma (NHL) patients who received filgrastim between March and June 2010, obtained from 6 hospital cancer clinics representing 13.4% of all Quebec cases.

RESULTS: 116 patients (73% BC; 27% NHL) received a mean (SD) of 4 (1.9) cycles of chemotherapy with a mean (SD) of 7 (2.1) filgrastim injections per cycle. CLSC referral occurred for 67% of filgrastim injections, but was highly variable clinic-to-clinic (18-100%).

CONCLUSION: A majority of filgrastim injections are referred to CLSCs for administration. Replacing 7 filgrastim injections with 1 pegfilgrastim injection per cycle would reduce the number of injections administered at CLSCs by 86% on average. This may produce financial savings for the province of Quebec. Additionally, reduced dosing frequency simplifies patient management, which may confer a compliance advantage.

Contact Author

Tazmin Merali, Drug Intelligence Inc., Toronto, ON

Co-authors

Josée Martineau, Cité de la Santé de Laval, Laval, QC

Visal Uon, Hôpital Charles Lemoyne, Montreal, QC

Catalin Mihalcioiu, Hôpital Royal Victoria, Montreal, QC

Research

STABILITY OF 2.5 MG/ML BORTEZOMIB SOLUTION IN SYRINGES FOLLOWING RECONSTITUTED WITH 0.9% SODIUM CHLORIDE AT 40C AND ROOM TEMPERATURE (230C).

BACKGROUND: Previous publications have demonstrated the stability of 1.0 mg/mL of bortezomib for up to 42 days, recent publications have demonstrated that subcutaneous bortezomib has an improved safety profile. It was the intent of this study to evaluate the stability of bortezomib 3.5 mg vials reconstituted with 1.4 mL of 0.9% sodium chloride (NS).

METHODS: On study day 0, 2.5 mg/mL syringes were prepared. 3 were stored at room temperature and 3 were stored in the refrigerator. Concentration and physical inspection were completed on study days 0, 1, 2, 4, 7, 10, 14, and 21. Bortezomib concentrations were determined by liquid chromatography.

RESULTS: During the study period all solutions retained more than 95% of the initial concentration.

CONCLUSIONS: We conclude that 3.5-mg vials of bortezomib reconstituted with 1.4 mL of NS are physically and chemically stable for up to 21 days at 4C or room temperature. Since subcutaneous bortezomib injections represent a change in practice, the increased concentration represents a potential patient-safety issue if a 2.5 mg/mL solution was inadvertently administered IV. Therefore, we recommend that sites moving to subcutaneous administration of bortezomib eliminate 1.0 mg/mL iv solutions from their site or place significant barriers to iv administration of bortezomib.

Contact Author

Scott Walker, Sunnybrook Health Sciences Centre, Toronto, ON

Co-authors

Flay Charbonneau, Sunnybrook Health Sciences Centre, Toronto, ON

Shirley Law, Sunnybrook Health Sciences Centre, Toronto, ON

Research

STABILITY AZACITIDINE SOLUTIONS IN STERILE WATER FOR INJECTION STORED AT -15C

BACKGROUND: A publication has demonstrated the stability of azacitidne for up to 23 days at -20C. However, many pharmacies use residential refrigerators with an upper freezer with a maximum setting of -15C. It was the objective of this study to evaluate the stability of azacitidine 10 and 25 mg/mL concentrations at -15C.

METHODS: On study day 0, syringes and the original manufacturer's glass vials containing 10 or 25 mg/dL concentrations of azacitidine were prepared. All containers were stored at -15C. Concentration and physical inspection were completed on study days 0, 1, 6, 13, 18, 20, and 23.

RESULTS: During the study period all solutions retained more than 96% of the initial concentration and the estimated time to achieve 90% of the initial concentration was 50 days.

CONCLUSIONS: We conclude that 10 and 25 mg/mL concentrations of azacitidine are physically and chemically stable for up to 21 days at 4C or room temperature. This is statistically similar to -20C data. 90% of the initial azacitidine concentration will be retained if, during the life of the product, storage at 23°C does not exceed 2 h, storage at 4°C does not exceed 8 h, and storage at –15°C does not exceed 4 days.

Contact Author

Scott Walker, Sunnybrook Health Sciences Centre, Toronto, ON

Co-authors

Flay Charbonneau, Sunnybrook Health Sciences Centre, Toronto, ON

Shirley Law, Sunnybrook Health Sciences Centre, Toronto, ON