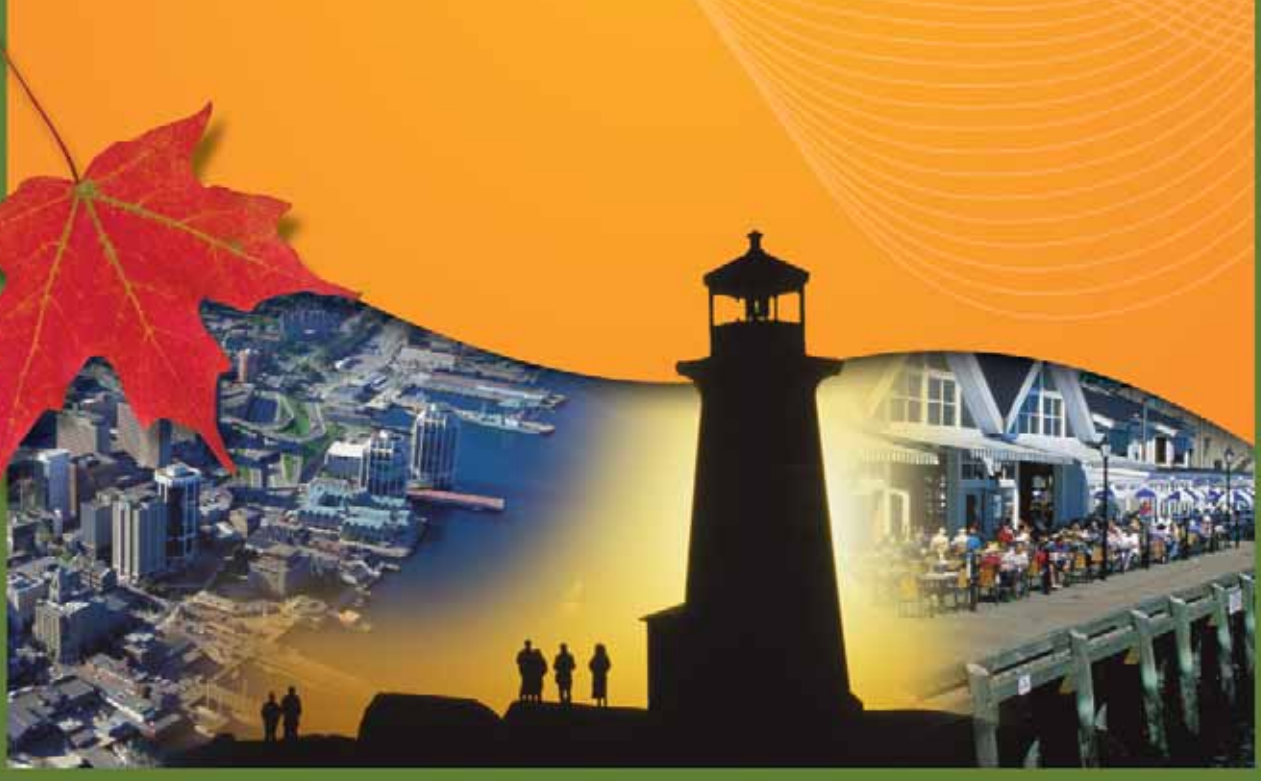
The Canadian Association of Pharmacy in Oncology presents the

2007 National Oncology Pharmacy Symposium

Oncology Pharmacy in Your Community

Onsite Program



OCTOBER 26-28, 2007 | HALIFAX MARRIOTT HARBOURFRONT | HALIFAX, NOVA SCOTIA

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2007 | Message from the Co-Chairs

Ciad Mile Failte! One Hundred Thousand Welcomes to Nova Scotia!

On behalf of the NOPS Organising Committee, it is our pleasure to welcome you to Halifax for the 2007 National Oncology Pharmacy Symposium (NOPS).

The practice of oncology pharmacy involves practitioners from many different walks of life and many different locations. Gone are the days when only a few patients were made to suffer noxious chemotherapy with little or no supportive care. Gone are the days when drug treatment required inpatient admission for most patients. Gone are the days when chemotherapy was only something done in large academic hospitals and specialized cancer centres. Today, we have portable treatments and a population who choose not to commute from home, wherever that may be, to large centres for their specialized chemotherapy treatments. Oncology pharmacy is not limited to just these centres, but is becoming a part of practice for pharmacists in many communities. But care close to home comes with its own challenges- such as maintaining safety and cost-effectiveness. With these challenges in mind, we welcome you to join us as we explore the symposium theme "Oncology Pharmacy in Your Community".

As we learn about many new drugs and treatments, we must also think about how these treatments will ultimately be offered to our shared patients. Are there risks to be considered? How do we communicate within our own sites and from one site to the next, as patients travel between local communities and specialist centres? Do we practices as individuals or as part of a larger community of oncology pharmacists? During the next days, you will have plenty of opportunities to attend educational sessions and to network with colleagues from across the country. Take a few minutes to meet someone new. You may find that you have much in common and lots of things each can learn from the other! And you may simply enjoy the pleasure of making new friends and socializing with each other at the breaks and the gala banquet. After all, a trip to Nova Scotia wouldn't be complete without a lobster dinner.

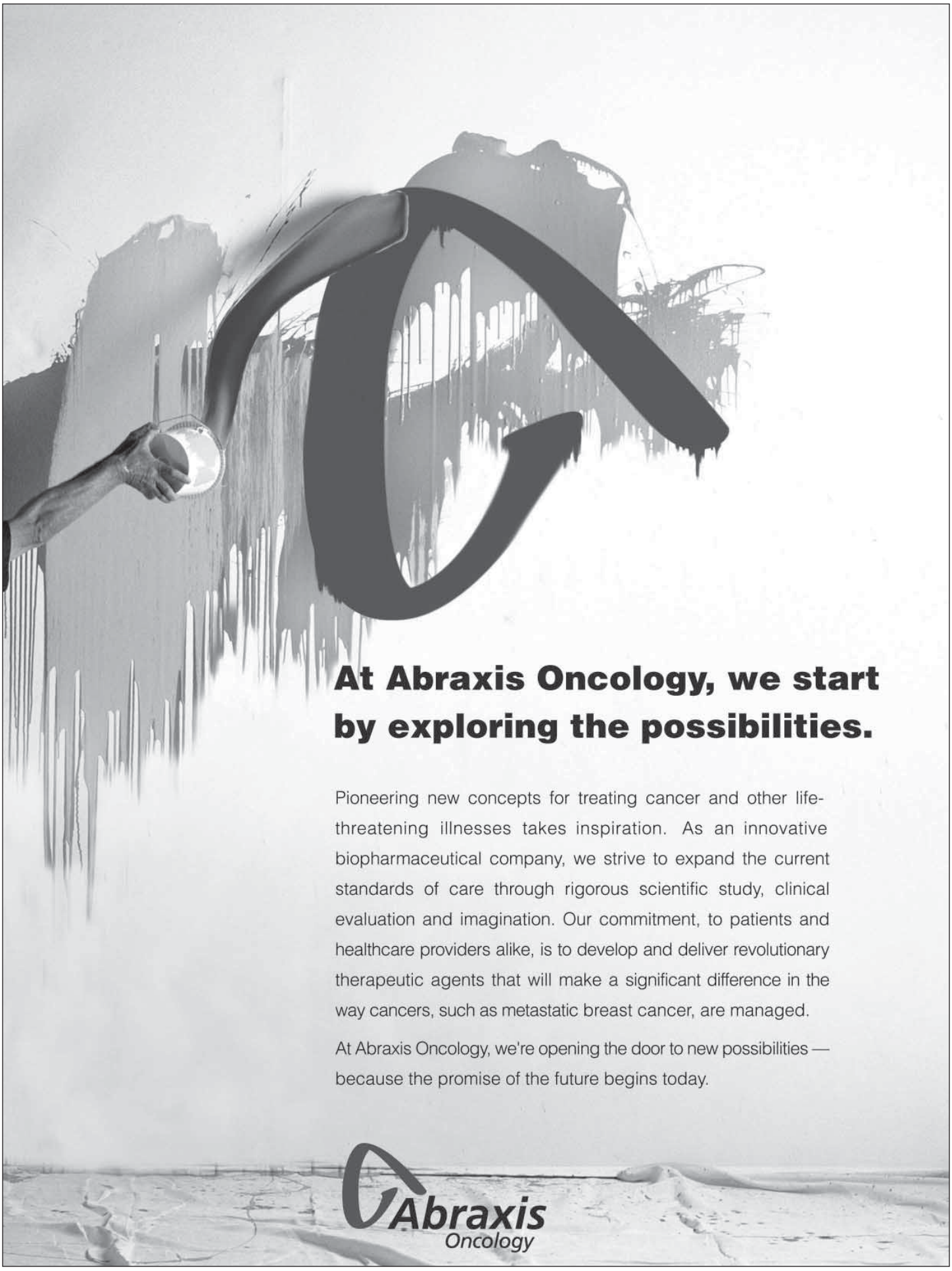
On a serious note, we would like to thank those dedicated individuals on the Organizing Committee who worked all year to bring NOPS 2007 to us all. Take a moment to say Thanks to those people who have worked hard to make this happen. This year, for the first time, we add a local flavour to NOPS, the Host Committee volunteers, who are helping with the tasks of registration, room monitoring, and general greeting to Halifax (they have the Nova Scotia Tartan ribbons). When they welcome you to Halifax, greet them back and tell them about where you practice. We must not forget to thank our pharmaceutical company sponsors as well- without their generous support and contributions, the NOPS meeting could not happen.

Enjoy your experiences at NOPS and in Halifax.

FAILTE! (Gaelic for WELCOME),

Larry Broadfield **Martin Franco** **Roxanne Dobish**

NOPS 2007 Co-Chairs


At Abraxis Oncology, we start by exploring the possibilities.
Pioneering new concepts for treating cancer and other life-threatening illnesses takes inspiration. As an innovative biopharmaceutical company, we strive to expand the current standards of care through rigorous scientific study, clinical evaluation and imagination. Our commitment, to patients and healthcare providers alike, is to develop and deliver revolutionary therapeutic agents that will make a significant difference in the way cancers, such as metastatic breast cancer, are managed.
At Abraxis Oncology, we're opening the door to new possibilities — because the promise of the future begins today.
Abraxis
Oncology

2007 | Message des coprésidents

Ciad Mile Failte! Mille fois bienvenue en Nouvelle-Écosse!

Au nom du comité organisateur, nous sommes heureux de vous souhaiter la bienvenue à Halifax à l'occasion de l'assemblée annuelle de l'Association Canadienne de Pharmacie en Oncologie : le National Oncology Pharmacy Symposium (NOPS), édition 2007.

La pratique de la pharmacie en oncologie implique plus que jamais des professionnels de différents horizons et de différentes régions. L'époque des patients recevant des traitements de chimiothérapie avec peu ou pas de support est maintenant révolue. Terminée également l'époque qui obligeait l'admission d'un patient dans un centre hospitalier universitaire spécialisé pour assurer l'administration d'un traitement de chimiothérapie. Désormais, les patients qui le désirent peuvent recevoir leur chimiothérapie à domicile, et ce, peu importe où ils habitent sans avoir nécessairement recours à de longs déplacements dans les centres hospitaliers urbains. Par conséquent, la pratique du pharmacien en oncologie s'intègre de plus en plus dans les communautés. Ce nouveau virage comporte plusieurs défis, entre autre, la sécurité et le rapport coût-efficacité de la chimiothérapie. C'est donc dans le désir d'explorer ces nouveaux défis que nous vous convions au NOPS sous le thème « **La pratique de la pharmacie en oncologie dans votre communauté** ».

Nous devons déterminer la manière dont les nouvelles molécules et les nouveaux traitements de chimiothérapie seront offerts à nos patients. Quels sont les risques que nous devons prendre en considération? Comment s'assurer que l'information qui concernent nos patients circulent adéquatement entre les centres locaux et les centres spécialisés? Notre pratique doit-elle être individuelle ou s'incorporer à celle des plus grands centres? Au cours des prochains jours, vous aurez la chance de participer à des séances éducatives et d'échanger avec des collègues des quatre coins du pays. Prenez quelques moments pour rencontrer de nouveaux collègues afin d'apprendre et partager vos expériences! Vous aurez la possibilité de nouer de nouvelles amitiés pendant les pauses et bien sûr au banquet, car après tout, votre voyage en Nouvelle-Écosse serait incomplet sans un festin de homards!

Sur une note plus sérieuse, nous aimerions remercier les membres du comité organisateur, qui ont travaillé toute l'année à l'élaboration de l'édition 2007 du NOPS. Prenez quelques instants pour les remercier, car sans eux, cet événement aurait été impossible. Pour la première fois cette année, nous ajoutons une touche locale au symposium puisque des bénévoles de la région s'occuperont de l'inscription, de la surveillance des salles et de l'accueil général à Halifax (on les reconnaîtra à leur ruban traditionnel de la Nouvelle-Écosse). N'hésitez pas à faire leur connaissance! Nous tenons également à souligner la contribution de l'industrie pharmaceutique qui a permis la réalisation de ce symposium. Nous vous invitons, au cours du week-end, à visiter les kiosques des compagnies participantes.

Nous vous souhaitons une expérience et un séjour à Halifax des plus mémorables!

FAILTE! (mot gaélique signifiant « bienvenue »))

Larry Broadfield **Martin Franco** **Roxanne Dobish**

NOPS 2007 Co-Chairs

Looking for a unique and interactive experience? Then join us for:

Navigating the Anemia & Neutropenia Landscape: Optimal Management of Chemotherapy Toxicities

Friday, October 26, 2007
12:00 pm – 2:00 pm
2nd floor, Halifax B/C Ballroom
Halifax Marriott Harbourfront Hotel

Enjoy lunch while interacting with colleagues and experts in small work groups and gain valuable insight into the optimal management of anemia and neutropenia in supportive care oncology.

About the Program

At this unique, interactive luncheon session, participants will rotate, in groups, through various 20-minute work stations during which experts will review: emerging clinical data and guidelines for the use of Erythropoietin Stimulating Agents (ESAs) in chemotherapy-induced anemia; the alignment of neutropenia guidelines to clinical practice; and two patient case studies in the anemia and neutropenia settings.

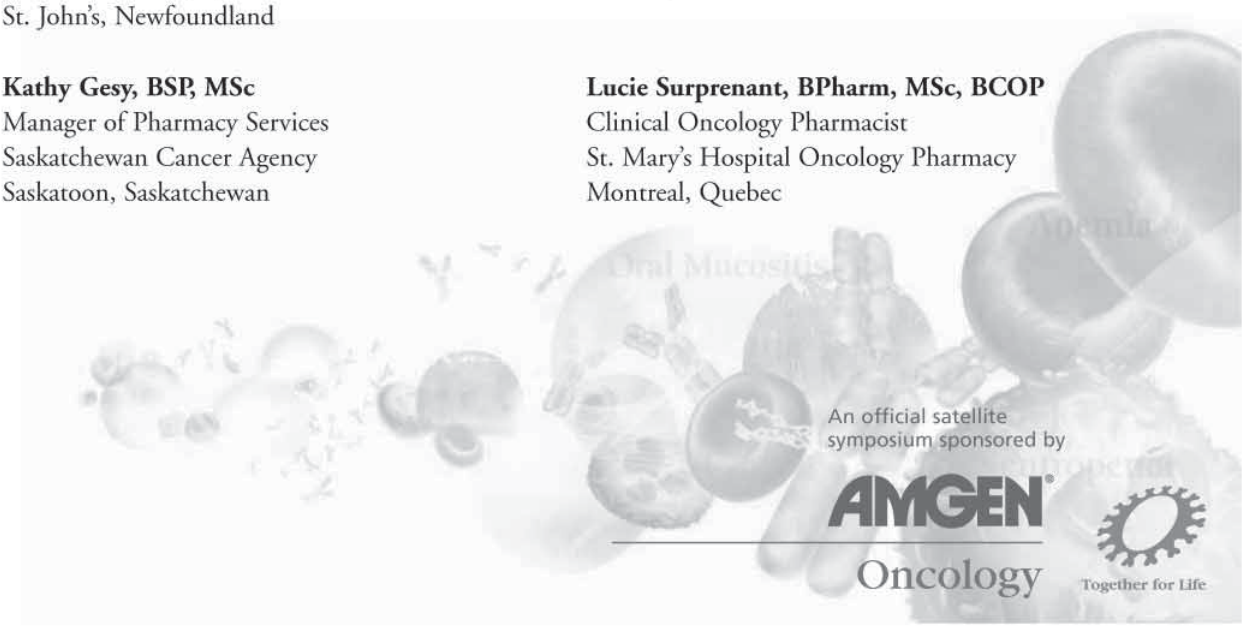
Faculty

Rick Abbott, BScPharm (Chair)
Pharmacy Manager, Provincial Systemic Therapy
Cancer Care Program, Eastern Health
Dr. H. Bliss Murphy Cancer Centre
St. John's, Newfoundland

Sean Hopkins, BSc, BSP, RPEBC, RPh
Clinical Oncology Pharmacist
Ottawa Regional Cancer Centre
Ottawa, Ontario

Kathy Gesy, BSP, MSc
Manager of Pharmacy Services
Saskatchewan Cancer Agency
Saskatoon, Saskatchewan

Lucie Surprenant, BPharm, MSc, BCOP
Clinical Oncology Pharmacist
St. Mary's Hospital Oncology Pharmacy
Montreal, Quebec



2007 | CAPhO Welcome Message and Message de bienvenue de CAPhO

On behalf of the Executive committee of the Canadian Association of Pharmacy in Oncology and the NOPS organizing committee, I would like to welcome you to our annual professional meeting in Halifax.

The Executive committee of CAPhO has decided that NOPS be moved around the country in order to reach as many oncology pharmacists as possible. This has clearly been proven a success and we would like to continue this tradition.

Once again, the NOPS organizing committee has surpassed itself in creating a fantastic educational program. We are also pleased to welcome several of our industry partners, who are sponsoring the event, as well as many very interesting Satellite symposiums. We hope that you will find the time to network with your colleagues from around the country, while at the same time learning all the most up to date oncology pharmacy information.

Many of the CAPhO executive members will be present and will be pleased to discuss the upcoming CAPhO initiatives. On behalf of the CAPhO Executive, we hope that you enjoy this educational event and we are looking forward to seeing you there!

Gabriel Gazzé
CAPhO President 2006-2007

Thank you to our CAPhO Executive: **Dana Cole** | **George Dranitsaris** | **Gabriel Gazzé** | **Kathy Gesy** | **Lynne Nakashima** | **Colleen Olson** | **Kim Stefaniuk** | **Tim VanHelvert** | **Ing Collins** | **Marc Geirnaert**

Au nom du Comité exécutif de l'Association Canadienne de la Pharmacie en Oncologie et du Comité organisateur du NOPS, j'aimerais vous souhaiter la bienvenue à Halifax pour notre congrès annuel.

Le Comité Exécutif de CAPhO avait décidé de déplacer NOPS dans plusieurs villes du Canada afin de rejoindre une plus grande population de pharmaciens qui travaillent en oncologie. Ceci s'est avéré un véritable succès et nous aimerions continuer cette nouvelle tradition.

Le comité organisateur du NOPS s'est, encore un fois, surpassé pour nous fournir un programme éducatif de très grande qualité. Nous sommes très contents de souhaiter la bienvenue à plusieurs de nos partenaires de l'industrie pharmaceutique qui commanditent le NOPS et également de très intéressants Symposiums satellites. Nous espérons que vous trouverez le temps de revoir vos collègues tout en ayant l'occasion de parfaire vos connaissances à propos des nouveautés de la pharmacie oncologique.

Plusieurs membres du Comité exécutif de CAPhO seront présents pour discuter des projets et des nouveautés de votre association. Au nom du Comité Exécutif de CAPhO, nous espérons que vous allez prendre plaisir à cet événement éducatif et nous espérons vous voir là en grand nombre!

Gabriel Gazzé
CAPhO Président 2006-2007

Merci au Comité Exécutif de CAPhO: **Dana Cole** | **George Dranitsaris** | **Gabriel Gazzé** | **Kathy Gesy** | **Lynne Nakashima** | **Colleen Olson** | **Kim Stefaniuk** | **Tim VanHelvert** | **Ing Collins** | **Marc Geirnaert**

2007 | Message from the Honourable Chris d'Entremont, MLA Health Minister of Nova Scotia

On behalf of the Province of Nova Scotia, it is my pleasure to welcome you all to the annual meeting of the National Oncology Pharmacy Symposium. We are proud to have Nova Scotia as the host province to this year's meeting.

I understand this is the first time since you've been meeting that your prestigious members have met in Halifax and I commend you for your commitment to continuously learn from one another and improve health care sectors around the world.

While your annual meeting promises a busy two-day event, I do hope you find some time during your stay in Halifax to discover the beauty, history and fun found throughout our capital city and our beautiful province.

On behalf of all Nova Scotians, I thank you individually for all you do in your specialty of health care. We all know that the field of oncology pharmacy is a very challenging specialty. With many new drugs entering the Canadian market, you play an increasingly important role in ensuring the safe preparation and delivery of these complex therapies.

You should be proud of your hard work and dedication to your profession. Enjoy the annual meeting, the sharing of ideas and procedures with fellow colleagues and, of course, enjoy Nova Scotia!

Sincerely,

Chris d'Entremont
Health Minister

2007 | Message de l'honorable Chris d'Entremont, député d'Argyle et ministre de la Santé de la Nouvelle-Écosse

Au nom de la Nouvelle-Écosse, je suis heureux de vous accueillir au Symposium national sur la pharmaco-oncologie 2007. Nous sommes fiers que notre province soit l'hôte de l'événement de cette année.

C'est la première fois que vos membres prestigieux se réunissent à Halifax à l'occasion de de ce symposium. Je salue votre engagement envers l'apprentissage mutuel et l'amélioration continue des soins de santé offerts dans le monde entier.

Même si cette réunion annuelle s'annonce fort occupée, j'espère que vous trouverez du temps pendant votre séjour ici pour découvrir la beauté et l'histoire de notre capitale et de notre magnifique province.

Au nom des Néo-Écossaises et Néo-Écossais, je remercie chacun d'entre vous pour son travail en soins de santé spécialisés. Nous savons que le domaine de la pharmaco-oncologie comporte des défis de taille. Avec l'entrée sur le marché canadien de nombreux nouveaux médicaments, votre rôle gagne en importance pour ce qui est d'assurer la préparation et l'administration sécuritaires de ces thérapies complexes.

Votre dévouement à votre profession est tout à votre honneur. Je vous souhaite une rencontre annuelle favorable à l'échange d'idées et de procédés avec vos collègues, et bien sûr, un bon séjour en Nouvelle-Écosse.

Veuillez agréer l'expression de mes sentiments les meilleurs.

Chris d'Entremont
Ministre de la Santé

2007 | Thank you to our CAPhO Executive/ Merci au Comité Exécutif de CAPhO

Dana Cole
Prince George Regional Hosptial, Prince George, BC

George Dranitsaris
Self-Employed, Toronto, ON

Gabriel Gazzé
MUHC Royal Victoria Hospital, Montreal, QC

Kathy Gesy
Saskatchewan Cancer Agency, Saskatoon, SK

Lynne Nakashima
BC Cancer Agency, Vancouver, BC

Colleen Olson
Saskatoon Cancer Centre, Saskatoon, SK

Kim Stefaniuk
CancerCare Ontario, Toronto, ON

Tim VanHelvert
NHS - St. Catharines General Site, St.Catherine's, ON

Marc Geirnaert
CancerCare Manitoba, Winnipeg, Manitoba

Ing Collins
Juravinski Cancer Centre, Hamilton, ON

2007 | Thank you to the NOPS Planning Committee Members

Venetia Bourrier
CancerCare Manitoba, Winnipeg, MB

Larry Broadfield
CancerCare Nova Scotia, Halifax, NS

Flay Charbonneau
Sunnybrook Regional Cancer Centre, Toronto, ON

Ing Collins
Juravinski Cancer Centre, Hamilton, ON

Roxanne Dobish
Cross Cancer Institute Pharmacy, Edmonton, AB

Scott Edwards
Dr. H. Bliss Murphy Cancer Centre, St. John's , NL

Martin Franco
Hôpital Maisonneuve-Rosemont, Montréal, QC

H. Lee Gordon
Lethbridge Cancer Center

Victoria Kyritsis
British Columbia Cancer Agency, Vancouver, BC

Sandy Linseman
Grand River Regional Cancer Centre, Kitchener, ON

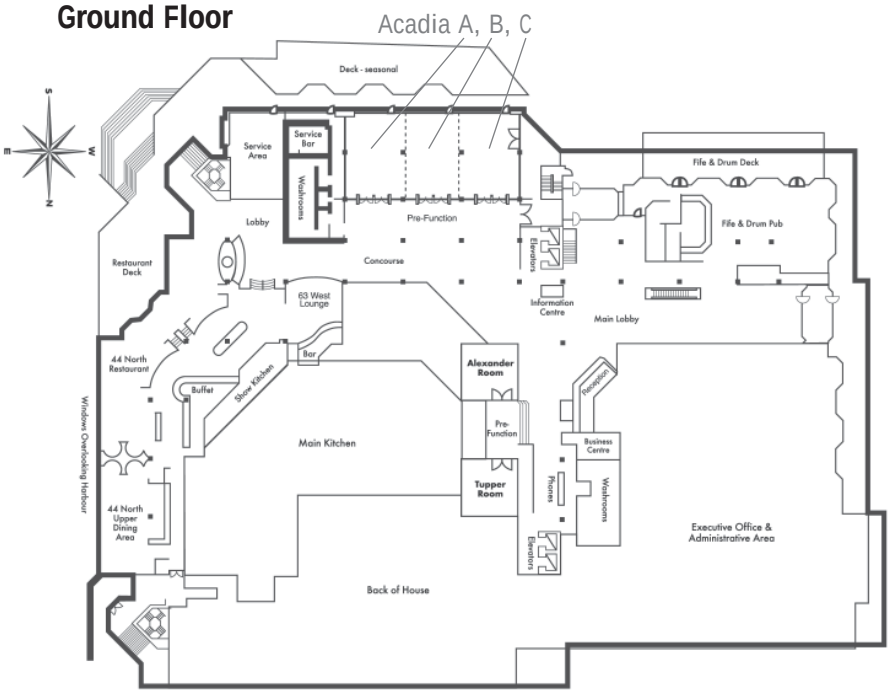
Kimberley Stefaniuk
Princess Margaret Hospital, Toronto, ON

Pat Trozzo
CancerCare Manitoba, Winnipeg, MB

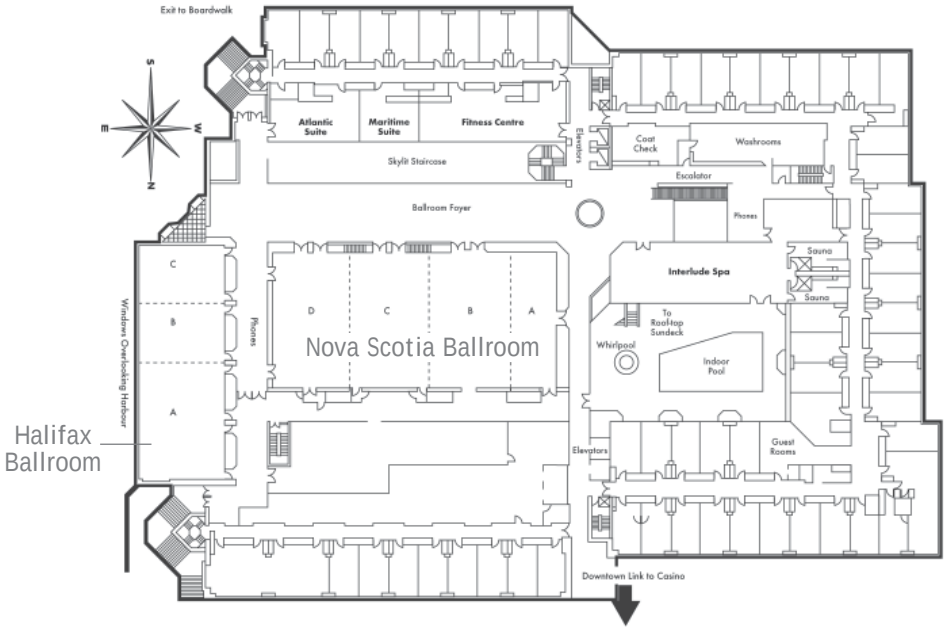
Thanh Vu
British Columbia Cancer Agency, Vancouver, BC

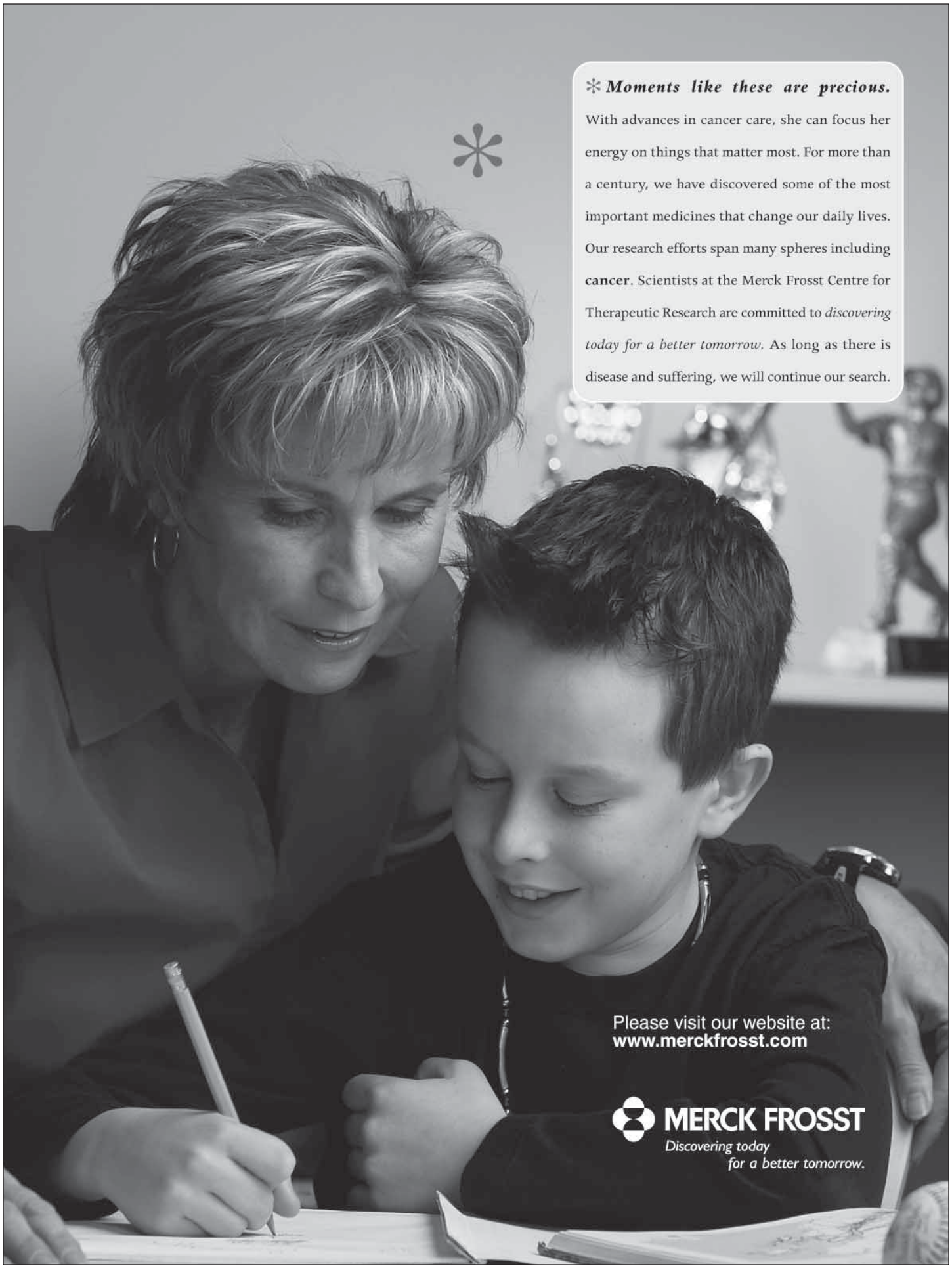
2007 | **Marriott Halifax Floorplan**

Ground Floor



Second Floor




✻ Moments like these are precious.
With advances in cancer care, she can focus her energy on things that matter most. For more than a century, we have discovered some of the most important medicines that change our daily lives. Our research efforts span many spheres including cancer. Scientists at the Merck Frosst Centre for Therapeutic Research are committed to discovering today for a better tomorrow. As long as there is disease and suffering, we will continue our search.
Please visit our website at:
www.merckfrosst.com
MERCK FROSST
Discovering today
for a better tomorrow.

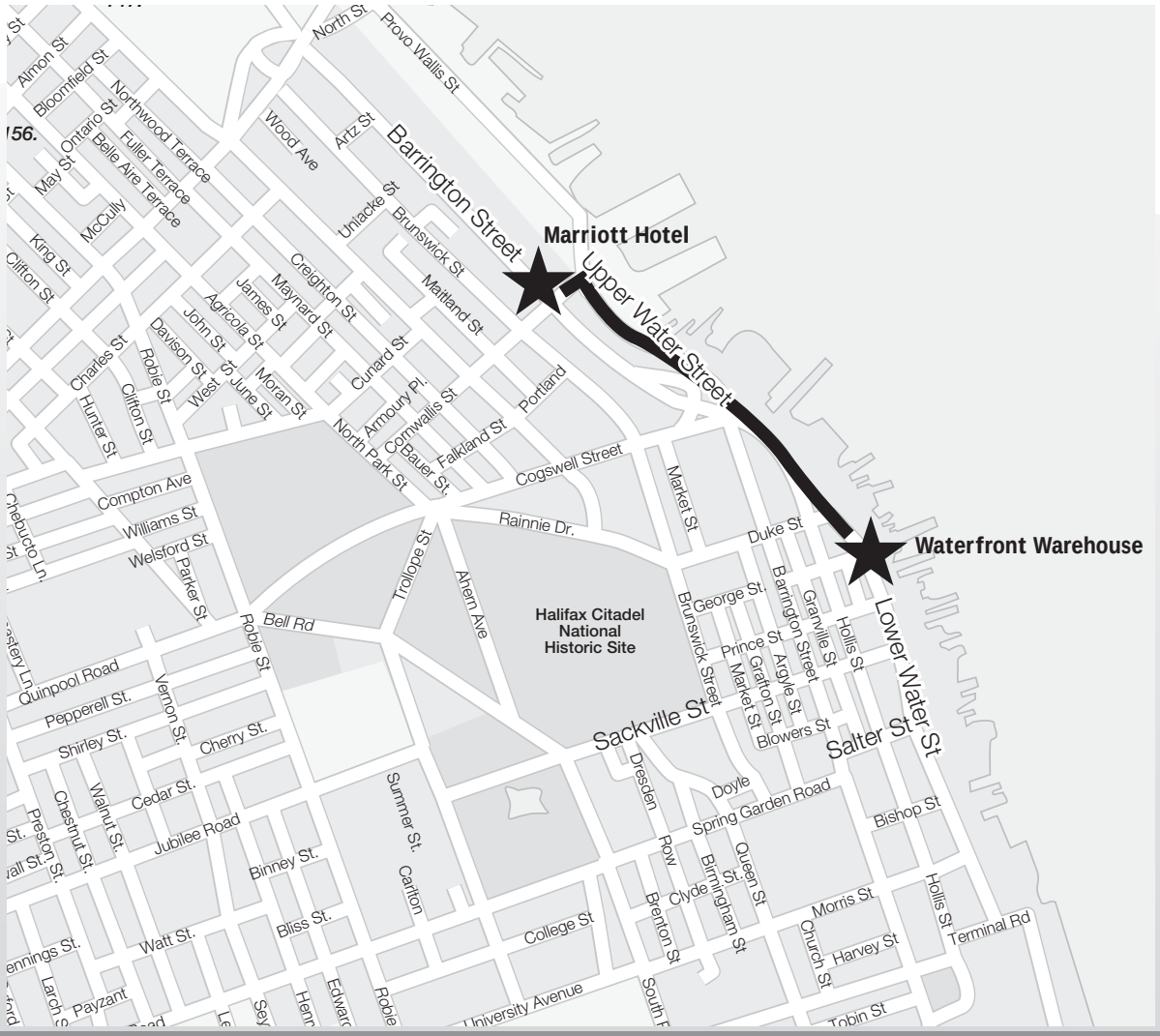
2007 | Walking Directions from the Marriott Hotel to the Waterfront Warehouse

Waterfront Warehouse – Lobster Dinner
1549 Lower Water Street, Halifax, NS
18:30 – 22:30

Within a 10 minute walk from the downtown hotels, the Waterfront Warehouse is easy to find. Just walk down to the harbour front boardwalk anywhere north of Sackville Street, turn right, and look for the outdoor deck and the signs! If you walk down Salter Street, turn left.

Coat check will be available at the Waterfront Warehouse and the dress code is business casual. Please be sure to wear or bring your name badge and dinner ticket to gain entry to this event.

If you have any questions, please see the NOPS registration desk.



2007 | Schedule-at-a-Glance

FRIDAY, OCTOBER 26TH

07:30 – 09:30 *(Halifax B/C)*
SATELLITE SYMPOSIUM
Merck Frosst
APREPITANT FROM NEUROPHARMACOLOGY TO CLINICAL INVESTIGATIONS: ADVANCING PATIENT CARE FOR CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING.

09:45 – 11:45 *(Halifax A)*
SATELLITE SYMPOSIUM
Abraxis Oncology
DOING MORE GOOD THAN HARM IN ONCOLOGY: INTERPRETING ARTICLES ON TREATMENT AND PREVENTION

12:00 – 14:00 *(Halifax B/C)*
SATELLITE SYMPOSIUM
Amgen Canada
NAVIGATING THE ANEMIA & NEUTROPENIA LANDSCAPE: OPTIMAL MANAGEMENT OF CHEMOTHERAPY TOXICITIES

14:15 – 16:15 *(Halifax A)*
SATELLITE SYMPOSIUM
Pfizer
INCREASING THE SAFETY OF ORAL CHEMOTHERAPY AGENTS IN THE COMMUNITY: A NEW TARGETED THERAPY IN MRCC AS TEST CASE

16:30 – 18:30 *(Halifax B/C)*
SATELLITE SYMPOSIUM
sanofi aventis
HOW OLD IS TOO OLD FOR CHEMOTHERAPY TREATMENT?

18:45 – 20:45 *(Halifax A)*
SATELLITE SYMPOSIUM
Celgene
EMERGING USES OF IMIDS IN HEMATOLOGICAL MALIGNANCIES

SATURDAY, OCTOBER 27TH

06:30 – 08:00 *(Acadia Ballroom)*
SATELLITE SYMPOSIUM
Bayer
HEPATOCELLULAR CARCINOMA: CHALLENGES AND OPPORTUNITIES

07:30 – 08:15 *(Nova Scotia Ballroom Foyer)*
BREAKFAST FOR NOPS

08:15 – 08:25 *(Halifax Ballroom)*
WELCOME AND INTRODUCTION

08:30 – 09:00
PLENARY SESSION *(Halifax Ballroom)*
SAFETY ISSUES WITH CHEMOTHERAPY

09:05 – 09:50
PLENARY SESSION *(Halifax Ballroom)*
LEVELS OF CARE FOR DELIVERY OF SYSTEMIC THERAPY

09:55 – 10:25
PLENARY SESSION *(Halifax Ballroom)*
COLORECTAL CANCER SCREENING

10:25 – 10:55 *(Nova Scotia Ballroom)*
BREAK

11:00 – 11:45
PLENARY SESSION *(Halifax Ballroom)*
OXALIPLATIN FOR ADJUVANT TREATMENT COLORECTAL CANCER

11:50 – 12:35
PLENARY SESSION *(Halifax Ballroom)*
MAINTENANCE RITUXIMAB FOR NHL

12:35 – 13:15 *(Halifax Ballroom)*
CAPHO ANNUAL GENERAL MEETING

13:15 – 14:15 *(Nova Scotia Ballroom)*
LUNCH

14:30 – 15:30
BREAKOUT #A1 *(Acadia A)*
NCIC TOPIC- PHARMACIST-INITIATED RESEARCH

BREAKOUT #A2 *(Acadia C)*
MYELODYSPLASTIC SYNDROME- WHAT'S OLD AND WHAT'S NEW

BREAKOUT #A3 *(Acadia B)*
HPV VACCINE

15:35 – 16:35
Breakout #B1 *(Acadia A)*
UNITING PRIMARY CARE AND ONCOLOGY (UPCON): MAKING LINKS FOR BETTER PATIENT CARE

BREAKOUT #B2 *(Acadia B)*
ADVANCES IN THE TREATMENT OF BREAST CANCER- RESULTS OF THE MA.21 STUDY

BREAKOUT #B3 *(Acadia C)*
NEW STANDARDS FOR COMPOUNDING STERILE PREPARATIONS – USP 797 AND CHEMOTHERAPY PREPARATION

16:35 – 18:00 *(Nova Scotia Ballroom)*
WINE AND CHEESE
POSTER AND EXHIBIT VIEWING –
Sponsored by Carmel Pharma
Poster Award Winner Nominations

18:30 – 22:30 *(Waterfront Warehouse)*
EAST COAST LOBSTER DINNER

SUNDAY, OCTOBER 28TH

07:00 – 08:30 *(Acadia Ballroom)*
SATELLITE SYMPOSIUM
Ortho Biotech
MANAGEMENT OF MULTIPLE MYELOMA: FOCUS ON SPECIAL PATIENT POPULATIONS

08:00 – 08:40 *(Nova Scotia Ballroom)*
BREAKFAST FOR NOPS

08:45 – 09:15
PLENARY SESSION *(Halifax Ballroom)*
ORAL SESSIONS
AWARD WINNING POSTERS

09:20 – 10:05 *(Halifax Ballroom)*
PHARMACOGENOMICS 101

10:05 – 10:25 *(Nova Scotia Ballroom)*
BREAK

10:25 – 10:50 *(Halifax Ballroom)*
USE OF THE RECAP FORMULARY SOFT-WARE IN COMMUNITY OUTREACH CLINICS

10:55 – 12:20 *(Halifax Ballroom)*
PANEL SESSION
A DAY IN THE LIFE OF AN ONCOLOGY PHARMACIST

12:20 – 12:30 *(Halifax Ballroom)*
CLOSING REMARKS

SAVE THE DATE!

HOPA/ISOPP 2008 Joint Annual Conference

Wednesday-Saturday • June 18-21, 2008
Anaheim Marriott • Anaheim, California
www.hoparx.org • http://isopp.org

HOPA's 4th Annual Conference has combined with ISOPP's 11th Annual Conference for a 2008 Joint Conference extravaganza! We are planning nearly 40 hours of educational activities over 4 days, so mark your calendars for the biggest hematology/oncology pharmacy meeting of the year!

- Special features this year include a technical track with 6 total hours of programs, 4 platform presentation awards, 3 different poster sessions, 7 concurrent workshops, and a gala social event on Saturday evening to end the meeting.
- Premeeting activities will begin Wednesday morning and the General Sessions will open on Wednesday at 3:00 PM.
- The Anaheim Marriott is the preferred hotel for HOPA/ISOPP 2008; all programming will take place at the Marriott. A limited number HOPA/ISOPP rooms will be available at a discounted rate of
  $165 USD per night plus taxes (single, double, triple, or quad).
- Registration fees will be approximately $450 USD for ISOPP or HOPA members and $550 USD for nonmembers. There will also be an optional Saturday evening social event with an additional fee to be determined.

ONLINE REGISTRATION

E-mail info@hoparx.org with "HOPA/ISOPP 2008 Registration" in the subject line and receive a notification e-mail as soon as online registration becomes available.

ABSTRACT DEADLINES

There will be two abstract deadlines this year, an earlier one in January for completed research and a later one in March for research that will not be complete until the time of the meeting in June. Only pharmacy trainees (residents, fellows, or students) may use the later deadline. A call for abstracts with more details will be available at www.hoparx.org and http://isopp.org.

Check for more meeting details at
www.hoparx.org or http://isopp.org
or call toll free at 001-877-467-2791 (local: 001-609-524-2317)

2007 | FRIDAY, OCTOBER 26 SCHEDULE

07:30 – 9:30
SATELLITE SYMPOSIUM: MERCK FROSST (*Location:* HALIFAX B/C)
APREPITANT FROM NEUROPHARMACOLOGY TO CLINICAL INVESTIGATIONS: ADVANCING PATIENT CARE FOR CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING.
Carlo De Angelis, PharmD, Clinical Pharmacy Coordinator

09:45 – 11:45
SATELLITE SYMPOSIUM: ABRAXIS ONCOLOGY (*Location:* HALIFAX A)
DOING MORE GOOD THAN HARM IN ONCOLOGY: INTERPRETING ARTICLES ON TREATMENT AND PREVENTION
Biljana Spirovski, BScPhm, RPh
George Dranitsaris, M.Pharm, FCSHP

12:00 – 14:00
SATELLITE SYMPOSIUM: AMGEN CANADA (*Location:* HALIFAX B/C)
NAVIGATING THE ANEMIA & NEUTROPENIA LANDSCAPE: OPTIMAL MANAGEMENT OF CHEMOTHERAPY TOXICITIES
Rick Abbott, BSc. Pharm (Chair)
Kathy Gesy, BSP MSc
Sean Hopkins, BSc, BSP, RPEBC, RPh
Biljana Spirovski, BScPharm
Lucie Surprenant, BPharm, MSc, BCOP

14:15 – 16:15
SATELLITE SYMPOSIUM: PFIZER (*Location:* HALIFAX A)
INCREASING THE SAFETY OF ORAL CHEMOTHERAPY AGENTS IN THE COMMUNITY: A NEW TARGETED THERAPY IN MRCC AS TEST CASE
Dr. Scott Edwards, Clinical Pharmacy Specialist

16:30 – 18:30
SATELLITE SYMPOSIUM: SANOFI AVENTIS (*Location:* HALIFAX B/C)
HOW OLD IS TOO OLD FOR CHEMOTHERAPY TREATMENT?
D. Scott Ernst, MD, FRCPC
Mark D. Vincent, MD, FRCPC, MRCP(UK)

18:45 – 20:45
SATELLITE SYMPOSIUM: CELGENE (*Location:* HALIFAX A)
EMERGING USES OF IMIDS IN HEMATOLOGICAL MALIGNANCIES
Darrell J. White, MD, MSc, FRCPC
D. Scott Ernst, MD, FRCPC

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2007 | SATURDAY, OCTOBER 27 SCHEDULE

06:30 – 08:00
SATELLITE SYMPOSIUM BAYER INC. *(Location:* ACADIA BALLROOM*)*
HEPATOCELLULAR CARCINOMA: CHALLENGES AND OPPORTUNITIES
Mark Walsh, MSc, MD, FRCSC

07:30 – 08:15
BREAKFAST FOR NOPS *(Location:* NOVA SCOTIA BALLROOM FOYER*)*

08:15 – 08:25
WELCOME AND INTRODUCTION *(Location:* HALIFAX BALLROOM*)*
Larry Broadfield

08:30 – 09:00
PLENARY SESSION *(Location:* HALIFAX BALLROOM*)*
SAFETY ISSUES WITH CHEMOTHERAPY
Julie Greenall
Roxanne Dobish

09:05 – 09:50
LEVELS OF CARE FOR DELIVERY OF SYSTEMIC THERAPY *(Location:* HALIFAX BALLROOM*)*
Larry Broadfield

09:55 – 10:25
COLORECTAL CANCER SCREENING *(Location:* HALIFAX BALLROOM*)*
Barry D. Stein

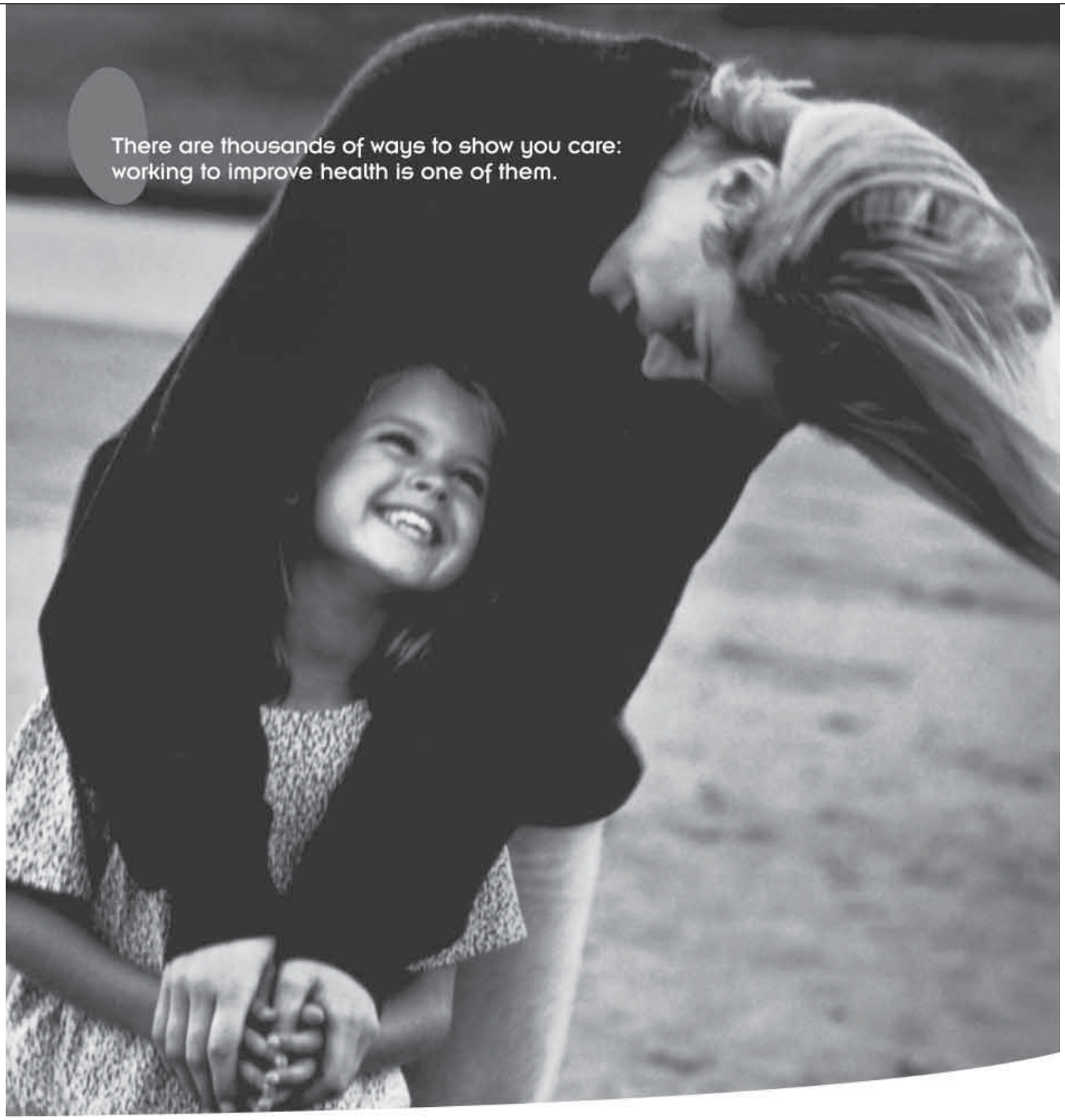
10:25 – 10:55
BREAK *(Location:* NOVA SCOTIA BALLROOM*)*

11:00 – 11:45 *(Location:* HALIFAX BALLROOM*)*
OXALIPLATIN FOR ADJUVANT TREATMENT COLORECTAL CANCER
Pat Trozzo

11:50 – 12:35 *(Location:* HALIFAX BALLROOM*)*
MAINTENANCE RITUXIMAB FOR NHL
Lynne Nakashima

12:35 – 13:15
CAPhO ANNUAL GENERAL MEETING *(Location:* HALIFAX BALLROOM*)*

13:15 – 14:15
LUNCH *(Location:* NOVA SCOTIA BALLROOM*)*



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2007 | SATURDAY, OCTOBER 27 SCHEDULE Continued

14:30 – 15:30
BREAKOUT #A1 *(Location:* ACADIA A)
NCIC TOPIC- PHARMACIST-INITIATED RESEARCH
Carlo DeAngelis

BREAKOUT #A2 (*Location:* ACADIA C)
MYELODYSPLASTIC SYNDROME- WHAT'S OLD AND WHAT'S NEW
Dr Sandra Cohen

BREAKOUT #A3 (*Location:* ACADIA B)
HPV VACCINE
Rob Grimshaw

15:35 – 16:35
BREAKOUT #B1 (*Location:* ACADIA A)
UNITING PRIMARY CARE AND ONCOLOGY (UPCON): MAKING LINKS FOR BETTER PATIENT CARE
Dr. Pat MacCormackSpeak

BREAKOUT #B2 (*Location:* ACADIA B)
ADVANCES IN THE TREATMENT OF BREAST CANCER- RESULTS OF THE MA.21 STUDY
Dr. Margot Burnell

BREAKOUT #B3 (*Location:* ACADIA C)
NEW STANDARDS FOR COMPOUNDING STERILE PREPARATIONS – USP 797 AND CHEMOTHERAPY PREPARATION
Carolyn Bornstein

16:35 – 18:00 (*Location:* NOVA SCOTIA BALLROOM)
WINE AND CHEESE, POSTER AND EXHIBIT VIEWING
Sponsored by Carmel Pharma
Poster Award Winner Nominations

18:30 – 22:30 (*Location:* WATERFRONT WAREHOUSE)
EAST COAST LOBSTER DINNER

2007 | SUNDAY, OCTOBER 28 SCHEDULE

07:00 – 08:30
SATELLITE SYMPOSIUM ORTHO BIOTECH *(Location:* ACADIA BALLROOM*)*
MANAGEMENT OF MULTIPLE MYELOMA: FOCUS ON SPECIAL PATIENT POPULATIONS
Pamela Rudkin, PhC, Pharmacotherapuetic Specialist Hematology-Oncology
Darrell J White, MD, MSc, FRCPC

08:00 – 08:40
BREAKFAST FOR NOPS *(Location:* NOVA SCOTIA BALLROOM*)*

08:45 – 09:15
ORAL SESSIONS - AWARD WINNING POSTERS *(Location:* HALIFAX BALLROOM*)*
CAPhO Award Winning Poster – Pharmacy Practice
CAPhO Award Winning Poster – Research

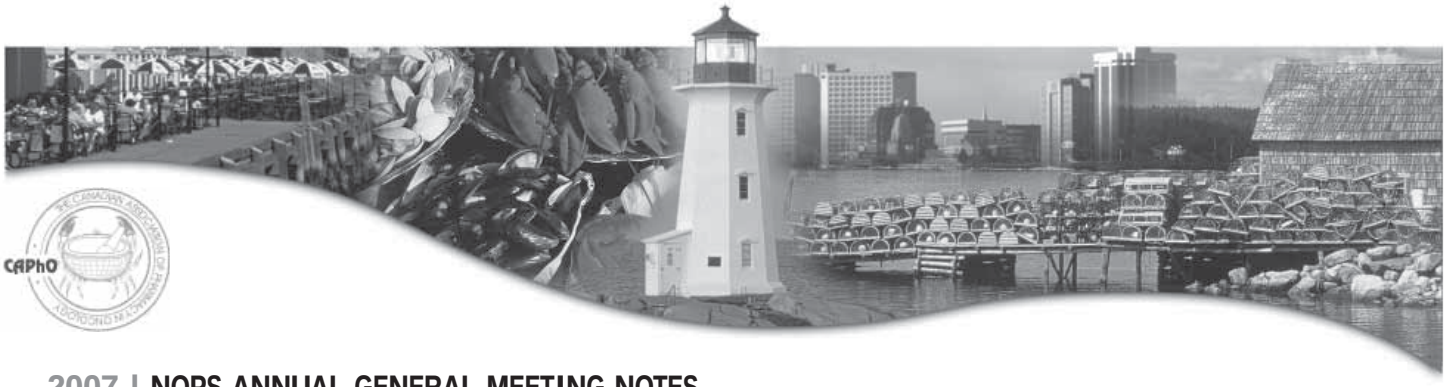
09:20 – 10:05 *(Location:* HALIFAX BALLROOM*)*
PHARMACOGENOMICS 101
Jacques Turgeon

10:05 – 10:25
BREAK *(Location:* NOVA SCOTIA BALLROOM*)*

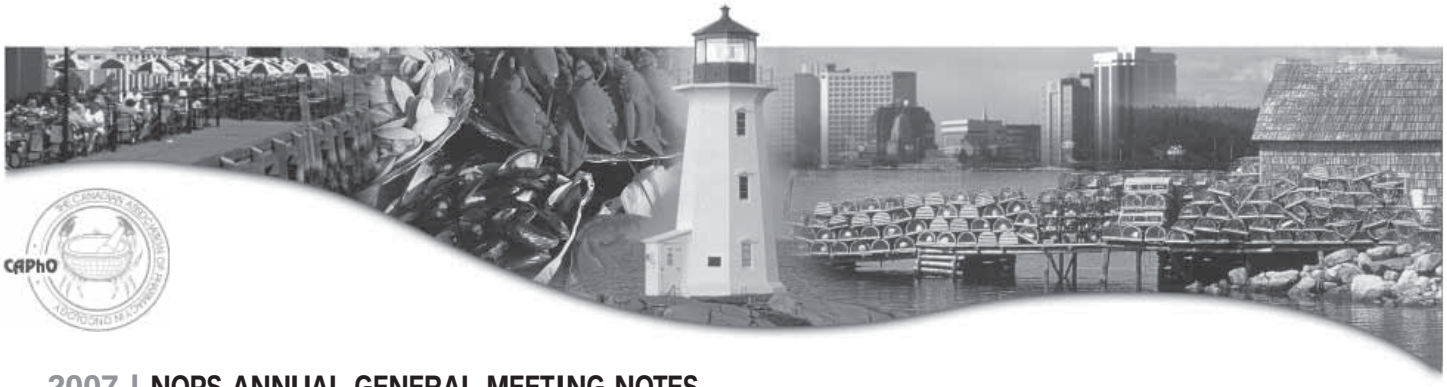
10:25 – 10:50 *(Location:* HALIFAX BALLROOM*)*
USE OF THE RECAP FORMULARY SOFTWARE IN COMMUNITY OUTREACH CLINICS
Sharon Meeke

10:55 – 12:20
PANEL SESSION *(Location:* HALIFAX BALLROOM*)*
A DAY IN THE LIFE OF AN ONCOLOGY PHARMACIST
Jackie Moulton, Burin, NL
Nancy Hallé, Moncton, NB
Darryl Boehm, Saskatoon, SK

12:20 – 12:30
CLOSING REMARKS *(Location:* HALIFAX BALLROOM*)*



2007 | NOPS ANNUAL GENERAL MEETING NOTES



2007 | NOPS ANNUAL GENERAL MEETING NOTES

2007 | NOPS SPEAKER

JULIE GREENALL

RPh, BScPhm, MHSc (Bioethics), FISMPC

ROXANNE DOBISH

Bachelor of Science Degree in Pharmacy from the University of Alberta. Assistant Director of Pharmacy, Alberta Cancer Board; currently seconded to position of Chemotherapy Safety Project Leader for a one year time period

BIOGRAPHY

Julie joined ISMP Canada in 2004 to complete the first Canadian Fellowship in Safe Medication Management and is now a Project Leader with responsibility for analysis of medication incidents.

Julie holds a Bachelor of Science in Pharmacy degree (1981) and a Masters of Health Science in Bioethics (2006) from the University of Toronto. Julie has more than 25 years of experience in pharmacy practice, in both clinical and administrative roles. She has worked in community and hospital pharmacy settings, with the majority of her career spent in small community hospitals. Prior to joining ISMP Canada, Julie was Manager, Pharmacy for the North Simcoe Hospital Alliance in Midland/Penetanguishene, Ontario, where she continues to work as a staff pharmacist on an occasional basis.

Julie is a co-author of the Canadian Root Cause Analysis Framework, as well as several medication safety-related articles published in Canada

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Roxanne worked in oncology pharmacy for over 19 years in a variety of roles including as a staff pharmacist, involvement in the community cancer program implementation, and various management positions

Roxanne's areas of interest and specialization include medication safety, community cancer network, chemotherapy handling and certification, policy and procedure development

She is involved with projects related to medication safety such as provincial policy development and implementation, development of medication error prevention tools for staff and staff training, multidisciplinary presentations, lectures to pharmacy students, and most recently in position of Chemotherapy Safety Project Leader

SYNOPSIS

OUR SYSTEMS ARE SAFE.....AREN'T THEY?
LEARNING FROM ROOT CAUSE ANALYSIS

Saturday, October 27th, 08:30 - 09:00

Objectives of presentation:

- Brief synopsis of fluorouracil incident
- Overview of systems and human factors theory
- Review of RCA findings relevant to pharmacy
- Summary of Alberta Cancer Board actions to date

This presentation will provide an overview of learning relevant to pharmacists from the root cause analysis (RCA) of a medication error with fluorouracil that resulted in a fatality. A key finding from the RCA was that the system failures that were identified in this event exist in other cancer treatment centres. ISMP Canada research found 7 previous similar cases in which patients died. In addition, a usability test conducted at another cancer treatment centre supports the reproducibility of programming the incorrect rate into the pump, given the same information. Learning from this incident has broad applicability to other cancer treatment centres and may be applicable to management of other chemotherapy agents and other high alert medications. Pharmacists have the opportunity and responsibility to provide leadership to enhance the safety of the medication use system.

NOPS October 26-28, 2007

You are cordially invited to attend a satellite symposia entitled:

Emerging Uses of IMiDs in Hematological Malignancies

HALIFAX A Room
Halifax Marriott Harbourfront Hotel,
Halifax, NS

October 26, 2007
Registration & Dinner: 6:45 - 7:30 pm
Symposia to follow

Celgene

Our systems are safe…..aren't they?

Learning from Root Cause Analysis

Roxanne Dobish, RPh, BScPharm, Alberta Cancer Board
Julie Greenall, RPh, BScPhm, MHSc, FISMPC, ISMP Canada
NOPS, Halifax, NS October 27, 2007

Objectives

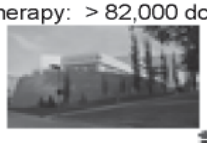
- Brief synopsis of fluorouracil incident
- Overview of systems and human factors theory as it pertains to this incident
- Review of RCA findings relevant to pharmacy
- Summary of Alberta Cancer Board actions to date

ISMP Canada

- Independent, not for profit organization
- Established to review and analyze medication incident reports and develop recommendations to enhance patient safety
- Collaborates nationally and internationally to advance safe medication use
- Works collaboratively with practitioners, institutions, academia, professional organizations, manufacturers and governments
- A key partner in the Canadian Medication Incident Reporting and Prevention System (CMIRPS) with the Canadian Institute for Health Information and Health Canada

Alberta Cancer Board (ACB)

- Mandate to coordinate cancer control and research activities for all of Alberta
- 2 tertiary centres – Edmonton, Calgary
- 4 associate & 11 community cancer centres
- > 40,000 patients treated annually
- Annual IV chemotherapy: > 94,000 doses
- Annual oral chemotherapy: > 82,000 doses



Medication Safety Initiatives

- Training; checklists; learning modules
- Annual chemotherapy certification process
- Medication Error Prevention Policy and annual survey
- Preprinted chemotherapy orders and electronic regimens
- Provincial Pharmacy QA Team; Medication Error Prevention Readings
- Medication Reconciliation
- MSSA Survey
- Participation with Health Quality Council of Alberta

but….

The incident….

"A woman in her 40s died last week after she was mistakenly given a lethal overdose of a standard chemotherapy drug while undergoing treatment at the Cross Cancer Institute. Instead of receiving the intravenous drug continuously over four days, the woman received the dose over four hours on July 31 from a pump that had been programmed in error. She died Aug. 22 at the University of Alberta Hospital from complex causes, including a failure of multiple organs, as well as widespread internal bleeding."

From: Sinnema J. We cannot eliminate human error. Edmonton Journal, Thursday, August 31, 2006.

The root cause analysis....

- Institute for Safe Medication Practices Canada (ISMP Canada) contracted to conduct a root cause analysis (RCA) of the incident
  - 16 causal factors identified
  - 40 recommended actions
    - 27 for local implementation with widespread applicability
    - 13 require assistance from outside agencies
- Full copy of the report is available at:
  http://www.cancerboard.ab.ca/NR/rdonlyres/2FB61BC4-70CA-4E58-BDE1-1E54797BA47D/0/FluorouracilIncidentMay2007.pdf

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More analysis....

Health Quality Council of Alberta (HQCA) conducted a system-wide review and developed leading practice recommendations

- System-wide quality improvement perspective based on 6 dimensions of quality
- 17 recommendations
- Report available at http://publications.hqca.ca/preview/78

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What is RCA?

Goals:

- What happened?
- Why did it happen?
- What can be done to reduce the likelihood of recurrence?

True root causes are the earliest points where action could have been taken to enhance the support system to prevent the event or mitigate the harm from the event.

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Why is there a need for RCA?

- Errors occur at all levels of healthcare.
- All staff, even the most experienced and dedicated professionals can be involved in preventable adverse events.
- Accidents result from a sequence of events and tend to fall in recurrent patterns regardless of the personnel involved.
- New technologies can introduce new opportunities for error.

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Reality of Health Care Environments

- Cognitive overload
- Workload
- Multi-tasking
- Interruptions
- Complexity
- Technology limitations
- Look-alike packaging and labelling
- Sound-alike medication names

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Canadian Adverse Events Study

Baker GR, Norton PG, Flintoft V, et al. CMAJ. 2004;170(1):1678-1686. Available at www.cmaj.ca

- 3745 charts reviewed from 5 provinces
- 360 adverse events identified
- 24% of adverse events were related to medication or fluid administration
- 37% of adverse events were determined to be preventable.

Extrapolation:

- 7.5% (or 187,500) patients in Canadian hospitals were seriously harmed by their care.
- As many as 9,250 to 23,750 people died in a Canadian hospital as a result of medical errors.

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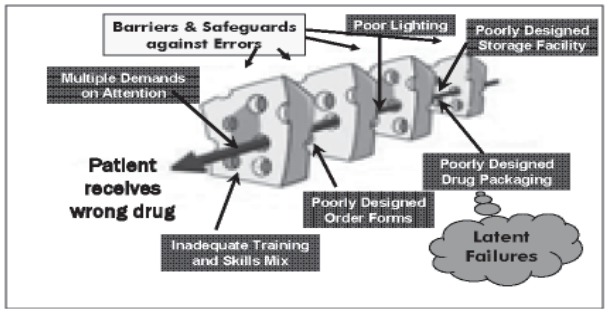
Swiss Cheese Model

adapted from James Reason, 1991



Human Factors Engineering (HFE) 101

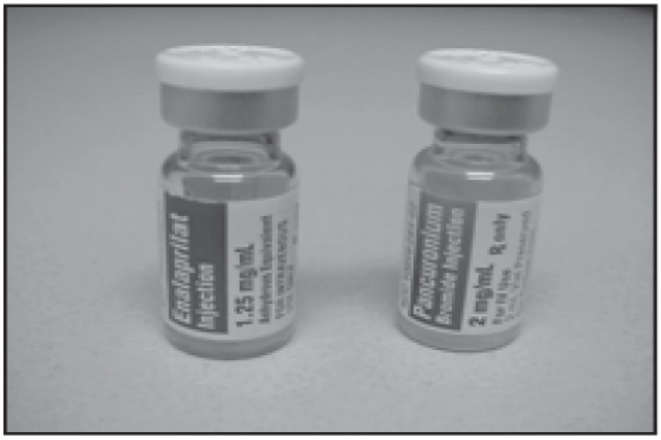
HFE: a discipline concerned with design of systems, tools, processes, machines that takes into account human capabilities, limitations, and characteristics

Confirmation Bias

It leads one to "see" information that confirms our expectation rather than to see information that contradicts our expectation.

The pweor of the hmuan mnid

Aoccdrnig to a rscheearch at Cmabrigde Uinervtisy, it deosn't mttaer in what oredr the ltteers in a wrod are. The olny iprmoetnt tihng is taht the frist and lsat ltteer be at the rghit pclae. The rset can be a total mses and you can sitll raed it wouthit porbelm. Tihs is bcuseae the huamn mnid deos not raed ervey lteter by istlef, but the wrod as a wlohe.
Amzanig huh?



Safety Strategies

- **Eliminate** - Remove the hazard
- **Control** - Provide safeguards
- **Accept** - Not an option – if a serious hazard is identified, the minimum safety strategy is a *control* measure

Hierarchy of Effectiveness (in order of effectiveness)

- Forcing functions & constraints
- Automation / computerization
- Simplification / standardization
- Reminders, checklists, double checks
- Rules and policies
- Education & information

The *Systems* Approach

"...though we cannot change the human condition, we can change the conditions under which humans work"

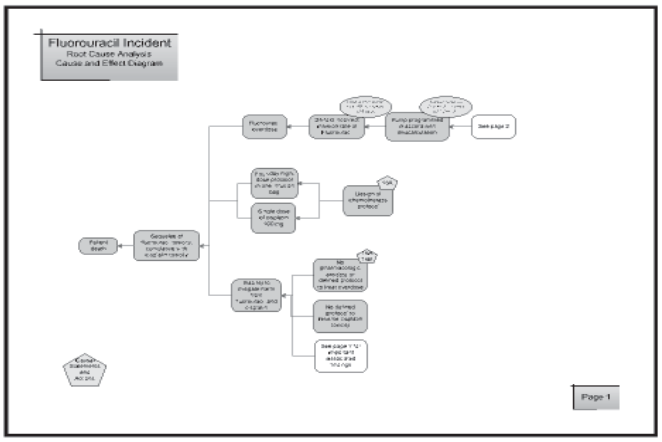
Reason J. (2000). Human error: models and management. *BMJ*, 320(7237): 768-770. Retrieved from: http://www.bmj.com/cgi/content/full/320/7237/768

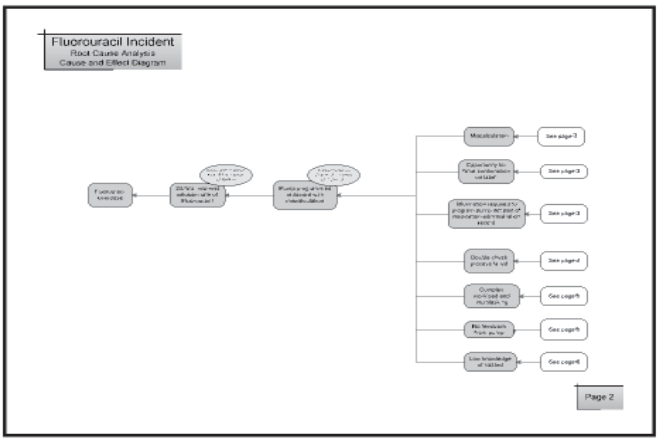
RCA Methodology

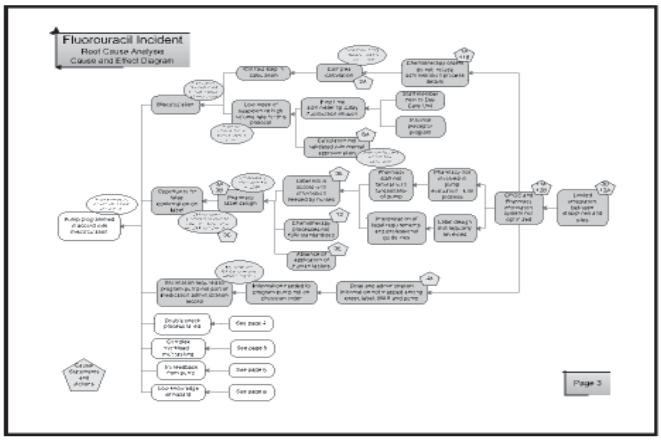
a) Team selection / off-site preparation:
- Pharmacists with oncology and medication safety expertise, oncology nurse, physician/human factors engineer
- Site visits to other cancer treatment centres in Canada and US

b) On-site information gathering
- Interviews / observation of care processes / examination of physical environment

c) Analysis and research
- Usability test of infusion pump and chemotherapy IV bag label
- Final understanding (sequence of events)
- Cause and effect analysis / development of causal statements
- Expert consultation and development of recommended actions







Findings…. Identified causes relevant to pharmacists

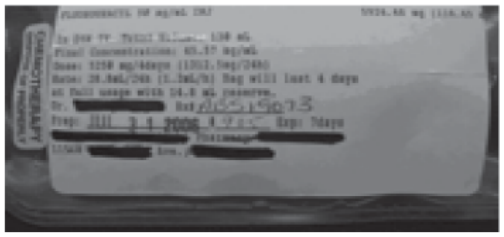
- Information not in physician order or on MAR
- Label format inconsistent with pump programming requirements
- Reliance on calculations at the bedside
- Opportunity for false confirmation on pharmacy label
- Design of the chemotherapy protocol
  - Inability to mitigate harm from fluorouracil and cisplatin
- Lack of coordinated team response

Electronic order

5-Fluorouracil 5,250 mg (at 4,000 mg/m2) Intravenous once continuous over 4 days
Cs_5FU_Part2-HN-CC - Cycle - 1, Day - 1
Substitutions Allowed

Administration Instructions:
Continuous infusion via ambulatory infusion pump
(Baseline regimen dose = 1000 mg/m2/day = 4000 mg/m2/4 days)

Pharmacy label



Pump

Priority Recommendations for Pharmacy

- Include critical information required for medication administration as part of standardized order sets (e.g., total volume and rate of infusion)
- Standardize communication of orders to eliminate use of "mL per 24 h" – **use "mL/h"**
- Standardize administration protocols for high dose fluorouracil
- Design medication orders, MARs and labels to ensure that critical information is available in a logical sequence using consistent terminology
- Use pumps with safeguards such as controlled rate delivery (e.g., elastomeric pumps)

ACB Progress

- Dedicated resources for implementation of recommendations
  - Chemotherapy Safety Project Leader in place June 1, 2007 for one year

ACB Progress

- Provincial Pharmacy & Therapeutics Committee July 2007 reviewed a number of key items:
  - ACB decision / mandate / philosophy on pumps
  - Identification of multidisciplinary teams to work on specific recommendations
  - Incident response
    - draft policy: Clinical Management of a Critical Medication Event

ACB Pump Decision

Consideration given to:
- Safety strategies: eliminate / control / accept
- Hierarchy of effectiveness

Decision:
- Until smart pump technology for ambulatory infusion pumps becomes available for assessment, move to use of elastomeric pumps for all fluorouracil protocols and recommend standardizing to minimize selections.

ACB Pump Decision

Review other drugs (bleomycin, cladribine, doxorubicin) that are currently administered with electronic pumps to determine whether protocols require continuous home infusion and if so whether can be prepared in elastomeric pumps.

ACB Pump Decision

Where protocols require continued use of an electronic ambulatory infusion pump:
- Prepare no more than one day's dose in the container
- Standardize volume and rate of administration to decrease need for complex calculations.
- Eliminate any electronic pumps within ACB centres which require programming in mL/24h.
- Implement changes to policies, procedures, staff training and orientation and patient teaching for electronic pumps currently in use to incorporate ISMP Canada recommendations

ACB Pump Decision

- Participation in a particular clinical trial will be dependent on ability to utilize the pumps in standard use in the ACB centre.
- Continue to evaluate electronic infusion pumps for potential future purchase as smart pump technology becomes available with the aim of standardizing to an ACB standard pump (with ACB after hours support).

ACB Pump Decision

- Implementation will be rolled out provincially once:
  - Chemotherapy order forms and electronic regimens revised
  - Pharmacy calculation sheets and standard label templates developed
  - Nursing orientation to Baxter pumps standardized
  - Patient teaching materials standardized

Clinical Management of Critical Medication Events Policy

- Assessment of medication incidents as potential critical events
- Notifications
- Patient assessment and documentation in health record
- Rapid Response Team
- Disclosure
- Administrative management/follow-up

Publication / Research

- Posting of RCA on external ACB website
- ISMP Canada and ISMP US Safety Bulletins
- Safe Medication Practices article in CJHP
- Publication of case report

Additional activities

- National Systemic Therapy Working Group of Canadian Association of Provincial Cancer Agencies (CAPCA)
- Poison and Drug Information Service (Alberta)

Safety Promotion

Denise Melanson Bursary established for ACB staff to attend patient safety focused conferences or education opportunities

In summary….

- This can happen in other cancer treatment centres
  - When the circumstances were re-created in a different cancer centre using the same information and infusion pump, the same incorrect rate was entered into the pump
- Nursing care is complicated enough, without the need for complex calculations at the bedside
  - Chemotherapy orders can be designed to include information needed to program the infusion pump
- Design of processes, technology and equipment can be improved to ensure safe administration and management of chemotherapy

"We should not all have to learn the same lessons by making the same errors"

Society of Academic Emergency Medicine Patient Safety Task Force

Alberta Cancer Board ismp

"Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has."

Margaret Mead
(as quoted by Hellweg, 1995)

Alberta Cancer Board ismp

2007 | NOPS SPEAKER

LARRY BROADFIELD
Manager, Provincial Systemic Therapy Program with Cancer Care Nova Scotia

BIOGRAPHY

Larry Broadfield is Manager of the provincial Systemic Therapy Program with Cancer Care Nova Scotia (CCNS). Responsible for the creation and management of this provincial program, Larry has developed and maintained a Systemic Therapy Manual for Cancer Treatment and standard Medication Info Sheets for patients on cancer drugs. In close collaboration with Cancer Site Teams, the Guidelines Resource Team, and various other health care professionals, Larry is very active in development of guidelines for individual new drugs, as well as cancer disease management and symptom management. Larry is also the Clinical Co-ordinator for the oncology clinical pharmacists and co-ordinator of pharmacy support for oncology clinical trials at the QEII Health Sciences Centre in Halifax, and practices clinical pharmacy on consultation with the Palliative Care Team at the same site. Larry is appointed as Adjunct Professor by Dalhousie University, where he teaches oncology therapeutics to undergraduate pharmacy students.

SYNOPSIS

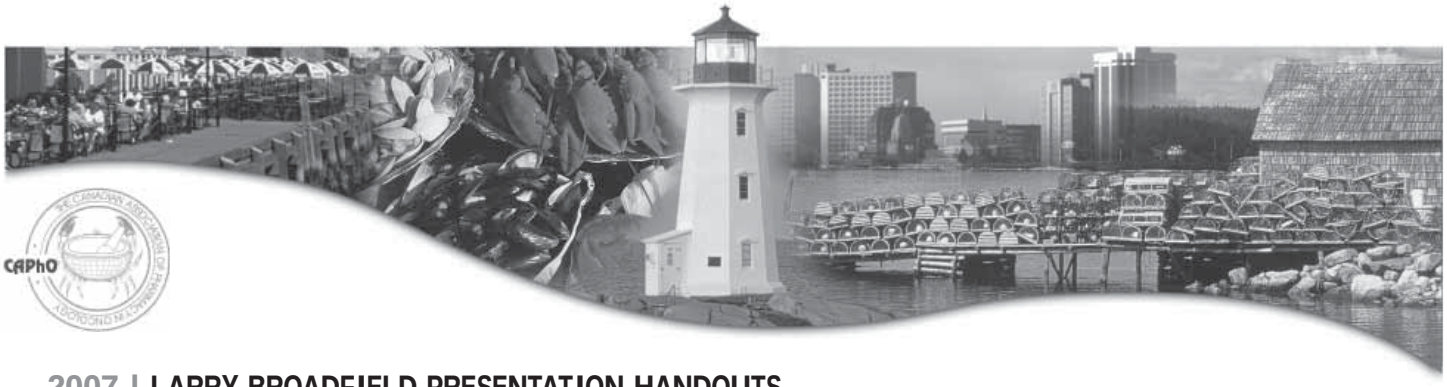
LEVELS OF CARE FOR DELIVERY OF SYSTEMIC THERAPY *Saturday, October 27th, 09:05 – 09:50*

In Nova Scotia, cancer care is delivered in all communities, large and small. Systemic therapy, including all cancer chemotherapy, has historically been offered in most hospital settings, regardless of physical resources or expertise. It was often said "We have a hood, so we can do chemo". This was a concern to the new cancer agency, Cancer Care Nova Scotia, when considering the mandate to establish and monitor standards for safe and effective care.

A model was developed for ranking systemic therapy by degree of risk, and to determine what degree of resource, expertise, physical facility and other factors would be appropriate for treatments of varying risk. The model is called Levels of Care. In this model, each drug or regimen was ranked as Basic, Intermediate, Advanced, or Specialized by an expert panel of clinicians. Criteria for ranking included the probability for harm associated with administration (i.e. things that could happen while administering the drug), the need for urgent or emergent support should an incident occur (e.g. ready access to emergency rooms, ICU), the linkage between systemic treatment and other site-limited services (e.g. concurrent chemotherapy and radiation therapy), and the need for on-site sub-specialists or dedicated facilities (e.g. neuro-oncologist, stem cell transplant unit, etc.). The model then identified the criteria for individual institutions to qualify for delivery of drugs or regimens at each Level. Regimens and drugs were matched to institution levels, to determine which treatments could safely be offered at which institutions. This is now used for planning and delivering patient care.

The Levels of Care model, once developed, was tested with each District Health Authority (DHA) in an impact assessment process. The impact assessment identified a number of issues for successful implementation of the model in individual institutions and across the entire province. The DHAs have used the results from the impact assessment in their business planning cycles, in order to meet the new standard by April 2008. Some things must be resolved at a provincial level for successful implementation. For instance, it was identified that we need to complete common policies and procedures for the ordering, preparation, and administration of chemotherapy (to ensure safe and consistent practice in all sites)- these policies and procedures are nearly complete. It was identified that some practitioners, notably oncology pharmacists and pharmacy technicians have variable levels of knowledge and skills- a common training and education program is needed. The training program for pharmacy technicians (and others), who prepare chemotherapy, is under development, in partnership with the Nova Scotia Community College. Education programs for oncology pharmacists and family physicians who supervise cancer treatments will be the next projects to support local expertise criteria for Levels of Care.

The Levels of Care is supported by provincial resources, such as the Systemic Therapy Manual (listing all drugs/regiments with their respective Level), the Medication Info Sheets, and other CCNS Systemic Therapy resources, for a comprehensive and safe program.



2007 | LARRY BROADFIELD PRESENTATION HANDOUTS

Levels of Care for Delivery of Systemic Therapy in Nova Scotia

Larry Broadfield

Cancer Care Nova Scotia

National Oncology Pharmacy Symposium- 2007

Cancer Care Nova Scotia

What is Levels of Care?

- A model that will define the type of cancer service that can safely and appropriately be provided in a particular location
- Infrastructure standards with pre-defined & objective criteria
- Covers the cancer control & care continuum
- Inclusive of pediatric and adult

What Levels of Care will achieve

- Safe, appropriate care as close to home as prudently possible
- Reduce unnecessary geographic variation in access to services
- Set realistic expectations for all stakeholders
- Manage pressures to provide services in inappropriate locations

Improved Cancer System

History in NS

- Few NS standards for cancer service delivery
- Services based on community demand
- No consistency in services available in similar facilities in different locations

Levels of Care will

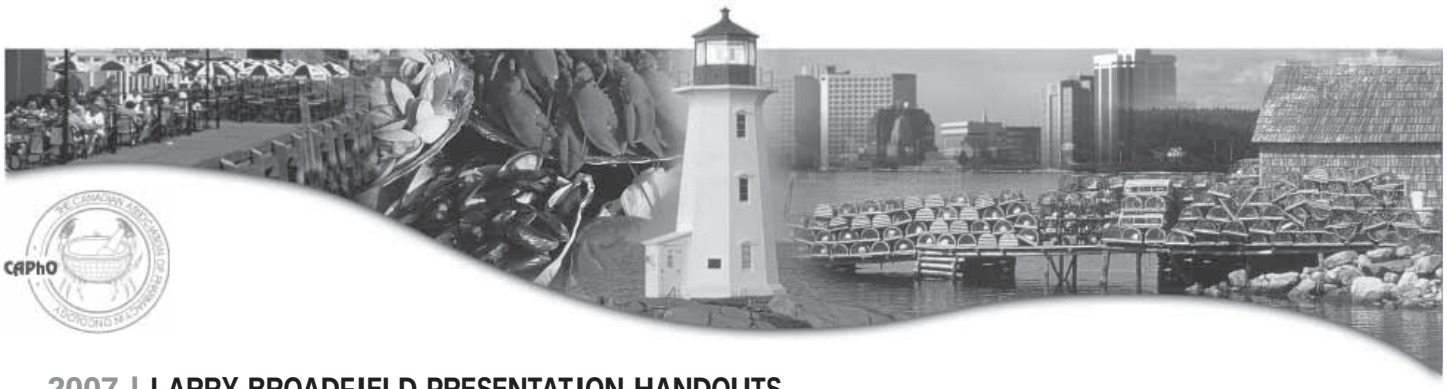
- Balance safety with access
- Balance demand with resources
- Lead to consistency in access to services across province

Why Develop Systemic Therapy Levels of Care?

- Systemic therapy for cancer is high risk
  - Low therapeutic index for most drugs
  - Most health care professionals unfamiliar with these drugs, regimens
  - No system for transfer of care between consultants and local treatment facilities
  - No standards for physical facilities (occupational risks), personnel

Why Develop Systemic Therapy Levels of Care? (2)

- Chemotherapy may be ordered in any hospital, regardless of size, resources
- Many patients seen by oncologists for consultation, drugs administered in local hospital
- Some patients are never sent for oncologist consultation- chemotherapy decision made by local specialist (usu. internist or surgeon)



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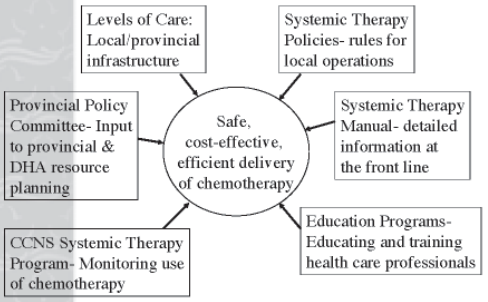
Strategy for Provincial Systemic Therapy Standards

- Multi-faceted approach:
  - Infrastructure (Levels of Care)
  - Policies
  - Information
  - Education
  - Monitoring & Evaluation
  - Resource Planning

Strategy for Provincial Systemic Therapy Standards



Strategy for Provincial Systemic Therapy Standards- Policies

- DHAs accountable and responsible
- Provincial policies & procedures
  - Ordering Cancer Chemotherapy
  - Preparing Cancer Chemotherapy
  - Administering Cancer Chemotherapy
  - Safe Handling of Cancer Chemotherapy
    - Consensus by representative stakeholder groups
    - Self-Assessment of all 9 District Health Authorities (summer 07)- Ordering Chemo, Preparing Chemo

Strategy for Provincial Systemic Therapy Standards- Infrastructure

- Levels of Care- a plan for safe delivery of cancer chemotherapy as close to home as reasonably achievable
  - Planning model for DHAs
  - Medication safety is highest priority
  - Addresses health human resources, credentialing/ training, physical facilities, supportive care, oncologic emergencies

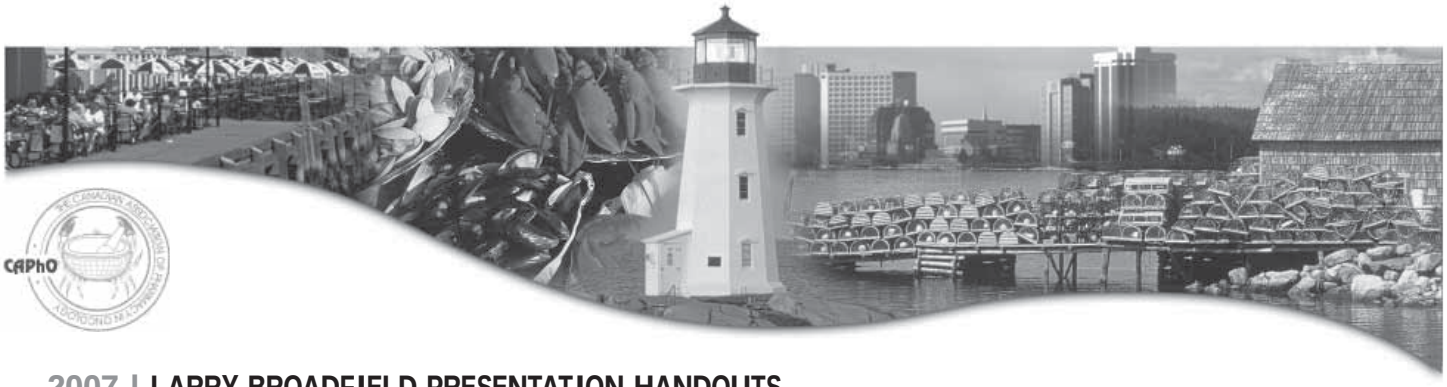
Levels of Care based on

Pre-defined, objective criteria that support the sustainability of the service:

- Patient/procedure volume
- Health professional availability
- Health professional education/ experience (including supportive care)
- Physical space
- Equipment

Systemic Therapy Levels of Care Criteria

- Builds on current components (e.g. Systemic Therapy Manual, Ordering Cancer Chemotherapy P&Ps)
- Benchmarks with other standards (e.g. other provincial cancer agencies, ASCO standards)



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Systemic Therapy Levels of Care Criteria

Concept:

- Match risk acuity of drug/regimen to a facility with 'appropriate' facilities and health professionals
- Make systemic therapy available in local or district facilities, as close to home as possible, without compromising safety

Systemic Therapy Levels of Care Criteria

- Medication risk- the potential for an adverse event **during** the period of administration
  - Adverse events which occur later will happen when patient is home
  - Local resources will be used to manage these events in any case

Systemic Therapy Levels of Care Criteria

Types of Medication Risks Considered

- Vesicant agents
- Agents which require active hydration support
- Agents with a high risk of hypersensitivity reactions or administration-related reactions
- Regimens that require specialist resources (during administration)
  - e.g. Regimens given concurrent with radiotherapy

Systemic Therapy Levels of Care Criteria

Types of Medication Risks Considered

- Vesicant agents
  - Need trained nursing staff with adequate activity for competency (critical mass?)
  - Anthracyclines (e.g. doxorubicin, epirubicin, idarubicin, mitoxantrone)
  - Vinca Alkaloids (e.g. vincristine, vinblastine, vinorelbine)

Systemic Therapy Levels of Care Criteria

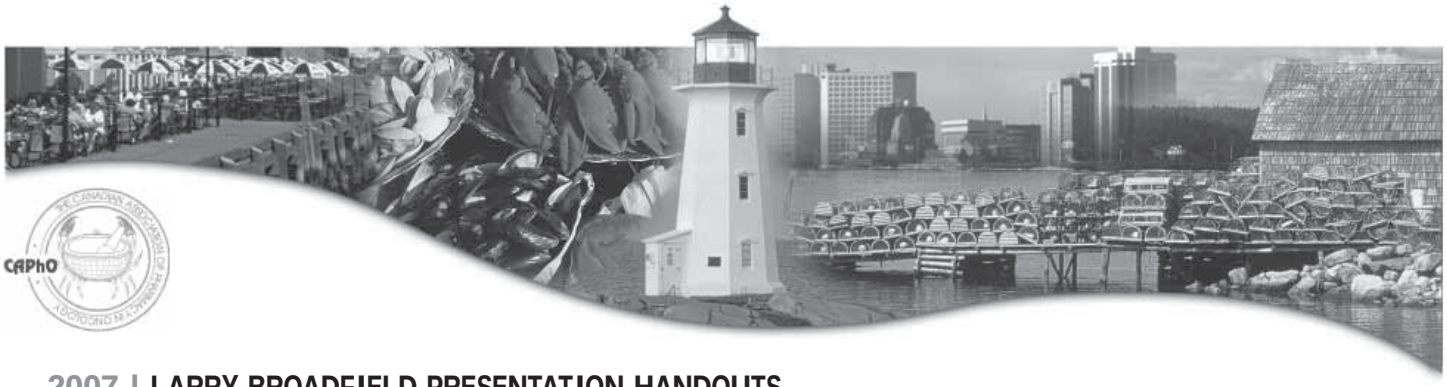
Types of Medication Risks Considered

- Agents which require active hydration support
  - Need active nursing/medical supervision
  - Short-term/long term consequences of inadequate hydration- nephrotoxicity, electrolyte imbalances
  - Platinum salts (e.g. cisplatin)

Systemic Therapy Levels of Care Criteria

Types of Medication Risks Considered

- Agents with a high risk of hypersensitivity reactions or administration-related reactions
  - Taxanes (e.g. palitaxel, docetaxel)
  - Monoclonal antibodies (e.g. trastuzumab, rituximab, alemtuzumab)
  - Biologic agents (e.g. interferon)
  - Irinotecan (cholinergic reactions)
  - Oxaliplatin (neurotoxicities)



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Systemic Therapy Levels of Care Criteria

Types of Medication Risks Considered

- Regimens that should be given under the direct supervision of a medical oncologist, hematologist or urologist
  - Initial cycles of monoclonal antibodies?
  - Initial treatments for hematologic malignancies?
  - On advice from specific CSTs or services/divisions
  - Restricted to Cancer Centre sites

Systemic Therapy Levels of Care Criteria

Types of Medication Risks Considered

- Regimens given concurrent with radiotherapy
  - Only at Cancer Centre (Halifax, Sydney)
  - Only restricted during period of concurrent treatments- cycles given before/after radiotherapy may be given at a different level facility, as appropriate

Systemic Therapy Levels of Care Criteria

Types of Medication Risks Considered

- Regimens that require specialized facility resources
  - Methotrexate levels available from lab for high-dose Methotrexate-containing regimens

Systemic Therapy Levels of Care Criteria

Types of Medication Risks Considered

- Regimens that require multidisciplinary specialist teams (during administration)
  - Acute leukemia service (incl. inpatients)
  - Stem cell transplant service
  - Oral maxillofacial service
  - Neuro-Oncology service

Definitions:

Basic Level Hospital - Basic chemotherapy and other systemic therapies, which do not require complicated adverse effect management. Treatments must be administered within a health care institution

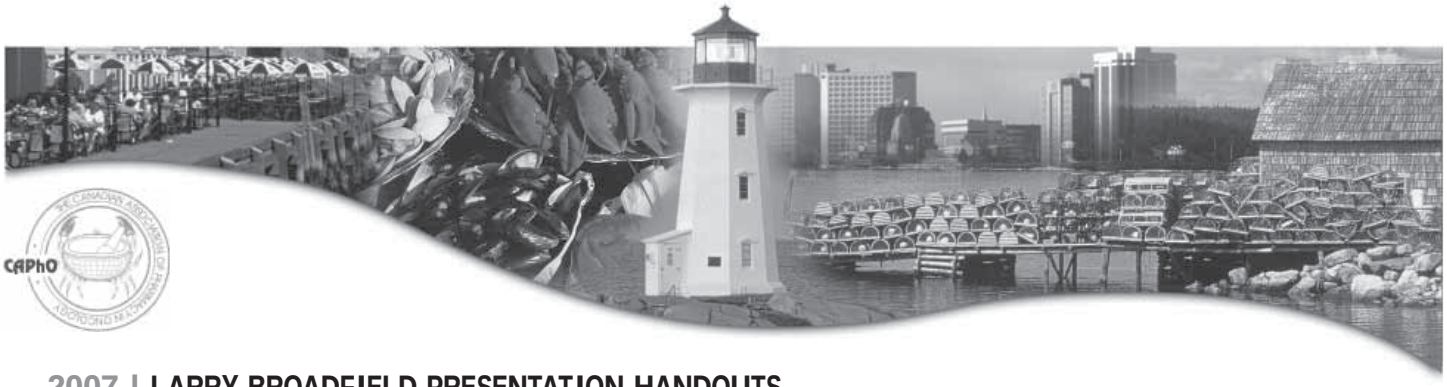
Intermediate Level Hospital - Chemotherapy regimens that include agents where more specialized nursing skills or volume of activity (to maintain competence) are needed

Definitions:

Advanced Level Hospital - Regimens that should be given under the direct supervision of a medical oncologist, hematologist or urologist; regimens given concurrently with radiotherapy

Specialized Level Hospital – Regimens that require specialized facility resources or multidisciplinary specialist teams

Community Level - Systemic therapy which may be self-administered, or given in a community setting (e.g. physician's office) but does not require hospital services



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Systemic Therapy Levels of Care

- Levels of Care Criteria
  - For each 'Level' criteria have been developed for physical facilities, health human resources, organizational support, supportive care and oncologic emergency management
  - The Levels will serve as a planning tool for DHAs to plan their local cancer services, and as a provincial standard to work towards

Physical Facilities

Basic-

- Space for chemo administration
- IV equipment for simple ambulatory treatments
- On-site pharmacy with biological safety
- Access to basic laboratory tests/results

Physical Facilities

Intermediate- (Basic Level, Plus…)

- Dedicated chemo treatment area
- Rapid access to supportive drugs for treatment of extravasation, resuscitation and anaphylaxis equipment/drugs
- Intensive care services available on-site
- Diagnostic imaging and pathology support (If chemo is ordered without consultation by an oncologist)

Physical Facilities

Advanced (Intermediate Level, Plus…)

- Dedicated beds for cancer patients with oncology nurses and oncologists available
- Radiation therapy services on site
- Specialized Diagnostic Imaging and Pathology for cancer diagnosis and staging

Community Level

- Parenteral chemotherapy drugs should NOT be administered in the community setting

Health Professionals

- Training and competence of practitioners
  - Greater training expected for higher levels
- Basic skills and training required for any chemotherapy ordering, preparation or administration
- Education and training may already exist
  - e.g. Interprofessional Core Curriculum (ICC)
- If education does not currently exist, *CCNS* will develop and facilitate delivery of programs and personnel certification

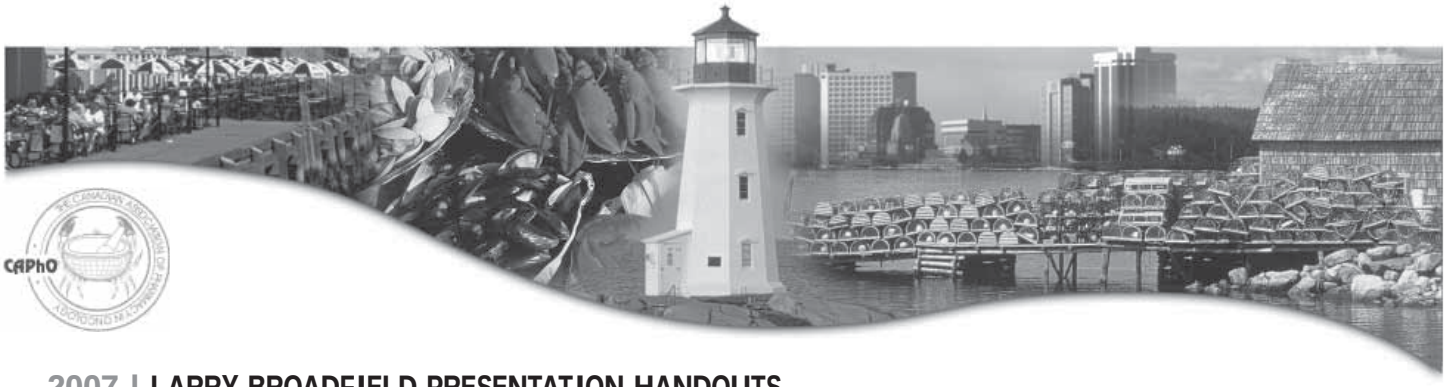
Medical Staff

Community Level-

- Family physicians- supportive care in collaboration with oncology specialist
- Community specialists (e.g. surgeons, internists)- Office procedures for cancer patients within scope of service

Basic-

- At least one ***Community Physician*** to supervise chemo admin, on site or very readily available (within 20 minutes) during administration visits



Medical Staff

Intermediate-

- At least one ***Community Physician*** or ***Community Specialist*** to supervise chemo admin on site during administration visits (may be responsible for chemo treatment unit)
- May have ***Medical Oncology*** outreach support
- At least one ***Community Specialist*** if chemo is ordered without consultation by an oncologist

Medical Staff

Advanced-

- ***Medical Oncologists*** and ***Radiation Oncologists*** on staff & available around the clock; may have ***Hematologists*** and/or ***Surgical Oncologists*** on staff & available around the clock

Specialized-

- Oncologists have developed specific sub-specialized practices

Registered Nurses

Basic-

- At least two ***Nurses with Chemotherapy Certification***- Preferred
  - If only one ***Nurse with Chemotherapy Certification*** is available, chemo to be checked by another nurse, physician or pharmacist-consultation support must be readily available (each order to be verified by pharmacist)
  - If no pharmacists on site, one nurse may prepare and administer the drugs as long as the doses are double-checked by another nurse or physician (see Pharmacy)- NOT preferred

Registered Nurses

Intermediate-

- At least two dedicated ***Nurses with Chemotherapy Certification*** working in chemo unit at all patient care
  - During administration of chemotherapy, the nurse will not be assigned to other responsibilities
- Adequate number of patient treatment visits to maintain competence in managing vesicant administration, hypersensitivity reactions

Registered Nurses

Advanced

- Adequate numbers of ***Nurses with Chemotherapy Certification*** to support all chemo order verification and drug administration
- Adequate numbers of ***Oncology Nurse(s)*** and ***Clinical Nurse Specialists/Nurse Educators*** to provide full service for inpatients & outpatients
- Support to nurses and other health professionals providing Basic and Intermediate Levels (as needed)

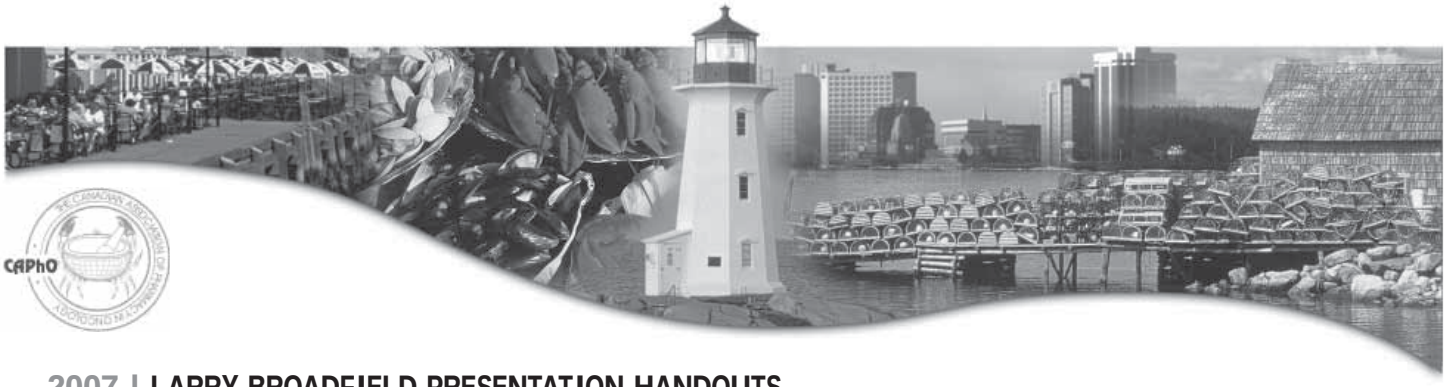
Registered Nurses

Specialized (Same as Advanced Level)

- ***Clinical Nurse Specialists/Nurse Educators*** to support nursing staff in sub-specialized areas

Community Level

- Community or home care nursing (including LTC) in collaboration with oncology specialists
- Supportive care measures during active treatment phase



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Pharmacy

Basic-

- Preferred: On-site pharmacist (& technician trained in chemo preparation, if available) with ***Basic Oncology Pharmacy Training***
- All chemotherapy prepared by a pharmacy service, with at least one pharmacist involved
  - If no pharmacist on site- consider contracting pharmacist coverage with local retail pharmacy or chemotherapy preparation by hospital pharmacy service off-site and transported to Basic Level facility
- Access to pharmacist by phone & fax for consultation and order verification- All chemo orders verified by pharmacist within district

Pharmacy

Intermediate-

- At least one ***Hospital Pharmacist with Oncology Training***
- At least one other pharmacist with ***Basic Oncology Pharmacy Training*** (for back-up) and at least one technician trained in chemo preparation

Pharmacy

Advanced (Same as Intermediate Level, plus)

- Adequate numbers of pharmacists and technicians to support all chemo order verification and drug preparation needs
- At least one ***Oncology Pharmacy Specialist*** and adequate ***Hospital Pharmacists with Oncology Training*** to provide full clinical service for inpatients & outpatients
- Support to pharmacists and other health professionals providing Basic and Intermediate Levels of Systemic Therapy (as needed)

Pharmacy

Specialized (Same as Advanced Level)

- At least one ***Oncology Pharmacy Specialist*** to provide full clinical service for appropriate sub-specialty areas

Community Level

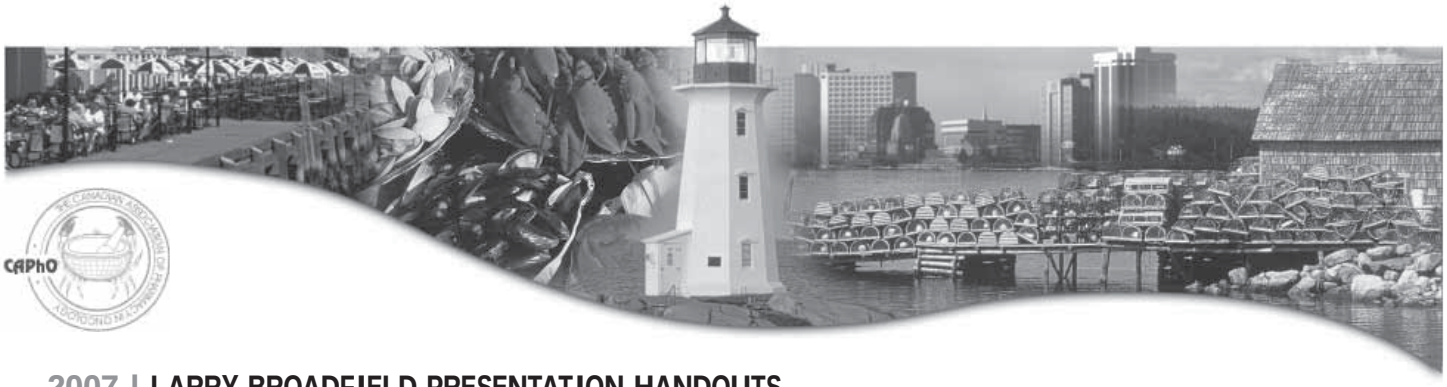
- Retail pharmacists- dispensing systemic and supportive care drugs, as directed in standing orders or other prescription, verification of oral chemotherapy orders, patient counseling on medications

Other Human Resources (Including Supportive Care)

- Clerical support personnel for patient scheduling
- Health records personnel support
- ***Cancer Patient Navigator*** in each district
- Access to psychosocial/spiritual support services within the district
  - May include social work, psychology/psychiatry, psychosocial counselors, dietitians, occupational therapy, physiotherapy, chaplains and others
- Peer and family support groups
- Home caregiver support

Supportive Care

- Supportive care needs most common for systemic therapy patients are identified
  - Divided into 4 major categories:
    - informational needs
    - psychosocial/emotional needs
    - physical needs
    - practical needs
- Cancer patients have many other supportive care needs
  - Beyond the scope of this model to address all of the supportive care needs



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Supportive Care

Information Needs:

- Patient education and reinforcement
- Approved cancer patient information material
- Access to experts for referral of difficult questions

Psychological/Emotional Needs:

- General psychological and emotional support integrated into routine patient care
- Involvement of other supportive care professionals as appropriate and available

Supportive Care

Practical Needs (examples):

- Social work to help resolve practical/financial issues
- Dietitian referral for nutritional problems
- OT/PT for specific rehabilitation problems
- Palliative care team
- Pharmacist help with medication acquisition, insurance coverage, medication counseling
- Integrated care plan by primary oncology team, to access services

Physical Needs:

- Medical care for common symptom management
- Involve family physician for medical care/follow up

Organizational Support

- Systemic therapy is high-risk within DHAs
  - Each district is accountable for the services provided within the district
  - Often a shared responsibility between organizations
- Organizations must operate according to provincial standards that enhance continuity of care
- *CCNS* is mandated to work with each district to assist with training, and standards development and compliance

Organizational Support

Guidance by District Cancer Committee

- Institutions at each level will offer service up to the assigned Level
- Training of personnel supported by DHA DHA ensure physical facilities and staffing for the level(s) assigned
- DHA/*CCNS* will audit sites for compliance with criteria for assigned Level of Care
- Co-ordinate provincial cancer drug formulary; adopt provincial systemic therapy P&Ps
- Adoption of provincial standing orders

Management of Oncologic Emergencies

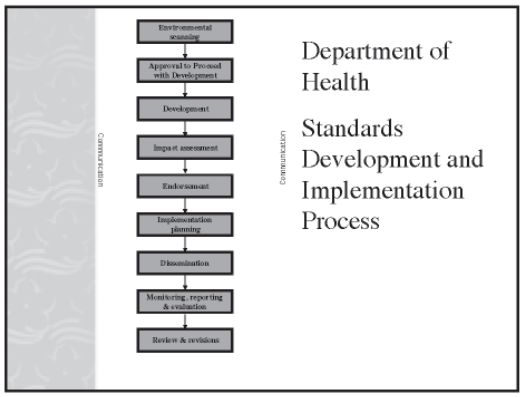
- Not specific to systemic therapy
- Processes to manage oncologic emergencies are mandatory for any institution providing systemic therapy to cancer patients
  - Basic management of emergencies must be available in all Levels of facility

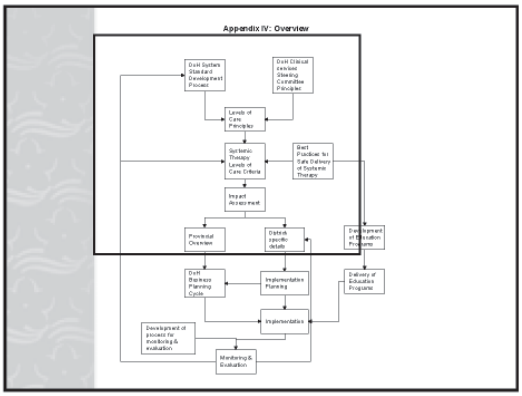
Management of Oncologic Emergencies

- Emergency department staff trained as appropriate for oncologic emergencies-
  - Contact oncologist as needed (strongly encouraged)
- ICC Oncologic Emergencies module, *CCNS* Symptom management guidelines (as available)
  - Febrile neutropenia, empiric antibiotics at nearest Emergency Department according to guidelines
- Emergency surgery and intensive care services, as appropriate for district

Regimen Monographs – Systemic Therapy Manual

- Drugs used alone or in combination are listed in the *CCNS* Systemic Therapy Manual as disease-specific regimens
- Each regimen is assigned a Level of Care designation
  - Usually relative to the drug with the most stringent single agent level
- Regimens should only be delivered in hospitals with a Level of Care rating the same or greater than that assigned to the regimen





IA Overall Impressions

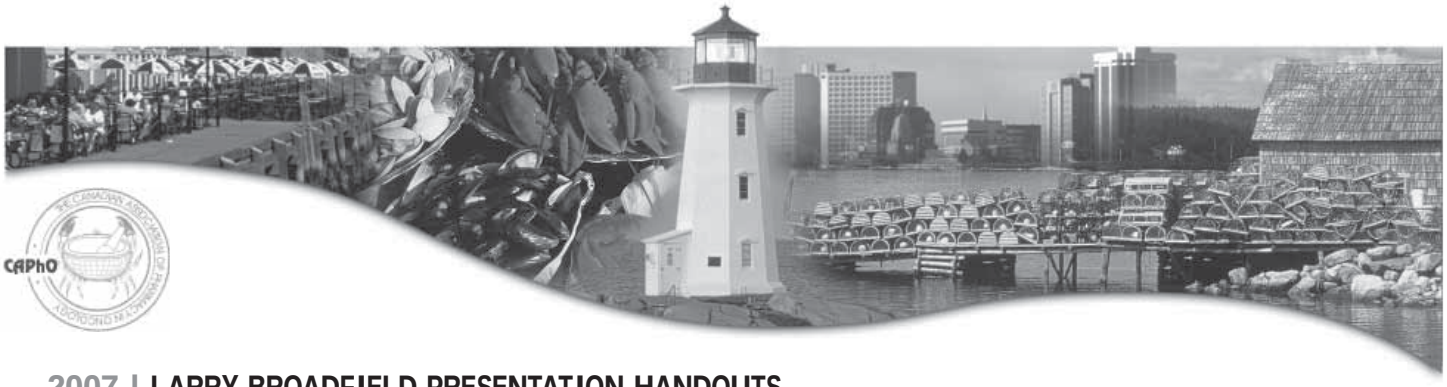
- Not a lot of surprises
- Not a lot of areas of concern
- Facilities often rated themselves lower than *CCNS* would based on info provided
- Progress in area of pharmacy review of chemo orders – all orders now reviewed
- Better congruence in supportive care areas than expected

Priorities as identified by DHAs

- Training/certification (all disciplines) (4)
- Additional staff
  - RNs (3 districts)
  - Pt Navigators (2 districts)
  - Clerical (2 districts)
  - Pharmacy techs (1 district)
- Improved space (2)

Patient Safety Priorities Identified by *CCNS*:

- Minimum numbers of all disciplines able to demonstrate necessary knowledge and skills. (all districts)
- Increased RN staffing to meet minimum requirements (4 districts)
- Identified physician available to respond when chemo is being administered (4 districts)



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RNs- Current HR profile
(excluding tertiary sites)

- 43 (18.4 FTE) RNs currently administering chemo (excluding inpatient RNs from 1 DHA)
- 22 have received formal training in chemotherapy administration
  - Several are currently enrolled or have taken the Cross Cancer Institute distance training

Pharmacists/Techs Current HR profile
(excluding tertiary sites)

- 25 (23.75 FTE) pharmacists verify orders
- 5 (4.5 FTE) prepare chemo
- 23 (22.25 FTE) supervise chemo prep
- 28 (26.5 FTE) technicians prepare chemo
- 22 technicians have received formal training in chemo prep

Non-Pharmacy Chemo Prep

- 2 DHAs
- 4 RNs (3 infrequently when tech not available)
- 2 MDs (none recently – 1 year ago)

Physicians Current HR profile
(excluding tertiary sites)

- 31 family physicians supervise chemo admin
- 38 family physicians order chemo based on orders from consultant oncologist
- 23 specialists supervise chemo admin
- 22 specialists order chemo based on orders from consultant oncologist
- 9 specialists order chemo

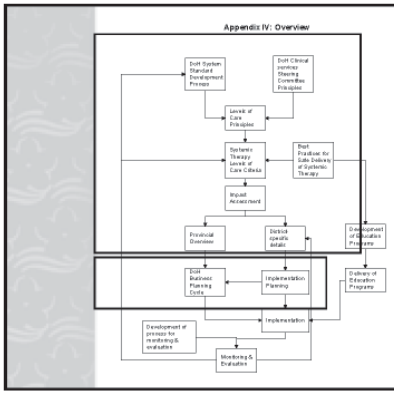
Physician specialities who order chemo independently

7 Internal Med	3 Pediatricians
1 Respirologist	2 Urologists
7 Surgeons	2 Palliative Care
1 Hematologist	

- With recent increases in ***satellite oncology clinics*** in NS, there may be a decrease in specialists ordering chemo w/o consults

Special circumstances

- 2 intermediate facilities may be able to provide some advanced level services
  - Satellite pharmacy in chemo area
  - Oncology trained RNs and pharmacist
  - Medical specialists with advanced training
  - ? Will this change with increased sat clinics
- 1 basic level facility may be able to provide some intermediate level services



Cost

Total Cost	$2,000,000 ($1,943,376 - $2,156,667)
Education Costs (range based on education minimum #s of staff or all involved staff)	$626,646- $839,937
New Positions	$1,316,730

Education Costs

Development/delivery (CCNS)	$453,000
Operational Costs (salary costs) (DHAs) (range based on education minimum #s of staff or all involved staff)	$173,646- $386,937

New Positions

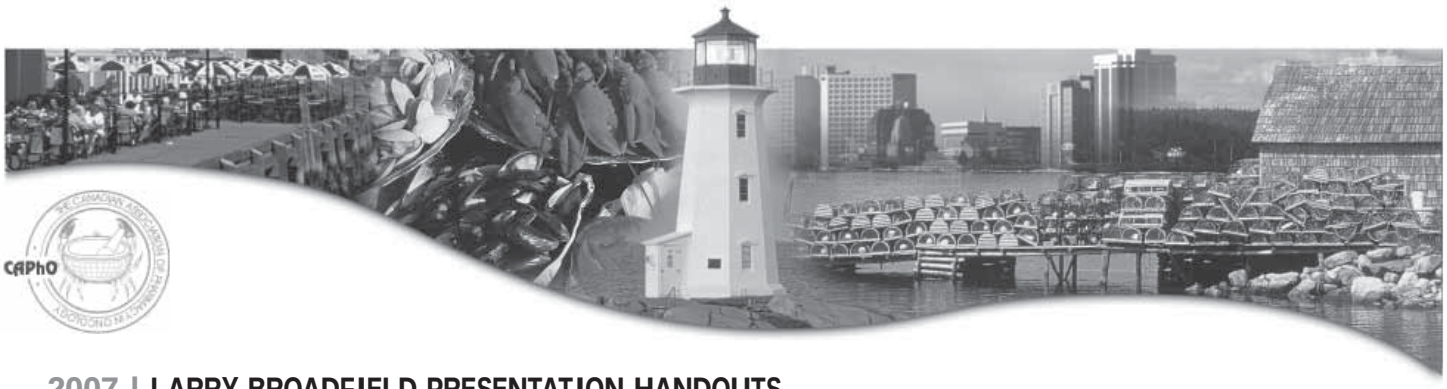
Total number of new positions required (number of district)	Total Cost **$1,316,730**
8.1 FTE RNs (5 districts)	$484,323
4.5 FTE Pharmacists (2 districts)	$314,181
3 FTE pharmacy technicians (3 districts)	$109,983
3.0 FTE Clerical staff (3 districts)	$93,243
5 FTE Cancer Patient Navigators (3 districts)	$315,000

Next Steps – Nova Scotia

- Work with each DHA on an implementation plan
- Monitor each DHA's progress towards implementation and provide support as necessary.
- Develop "certification" process to confirm and communicate the Level for each facility
- Develop a process for monitoring adherence and congruence with the Levels of Care standards
- Develop an evaluation framework

Next Steps- Atlantic Canada?

- Co-CEO NB Cancer Net has expressed interest in meeting with *CCNS* to discuss this approach
- Is there interest/support from other provinces in discussing the possibility of expanding this model into other provinces?



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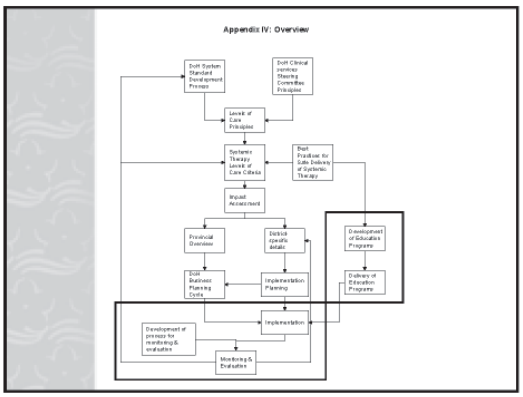


Education

- Interprofessional Core Curriculum
- Specific training for front-line staff
  - Chemo Preparation Course- in partnership with NS Community College
    - On line self-learning with standardized skills assessment
  - Common Chemo Admin Course (beyond tertiary districts)
  - Future plans for: oncology pharmacy, family doctors (GPOs)

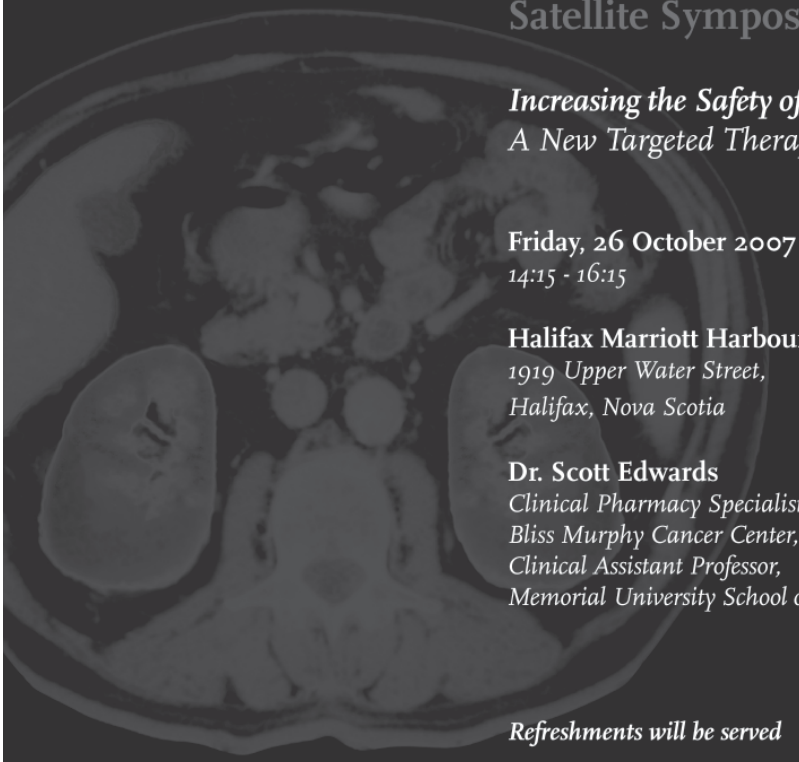
Monitoring and Evaluation

- CCNS has begun holding DHA Site Visits to evaluate local cancer programs across cancer continuum
  - One visit was focused just on systemic therapy delivery
  - Opportunity for input and feedback between CCNS and DHA partners
  - Assist DHAs in ongoing planning

Levels of Care in Systemic Therapy

- Phenomenal progress in just 6 years- from concept to evaluation!
- Reasonable and achievable goals for DHAs based on common objective criteria
- CCNS develops provincial processes and supports (e.g. education programs)
- Covers cancer care from smallest communities to largest tertiary centres

You are cordially invited to attend...



NOPS 2007 Halifax, Nova Scotia Satellite Symposium

Increasing the Safety of Oral Chemotherapy Agents in the Community: *A New Targeted Therapy in mRCC as Test Case*

Friday, 26 October 2007
14:15 - 16:15

Halifax Marriott Harbourfront – Room: Halifax A
1919 Upper Water Street,
Halifax, Nova Scotia

Dr. Scott Edwards
Clinical Pharmacy Specialist,
Bliss Murphy Cancer Center, St. John's, Newfoundland
Clinical Assistant Professor,
Memorial University School of Pharmacy, St. John's, Newfoundland

Refreshments will be served

Pfizer Oncology

2007 | NOPS SPEAKER

BARRY D. STEIN
B. Com., B.C.L., LL.B

BIOGRAPHY

Barry D. Stein, B. Com., B.C.L., LL.B., graduated from McGill University and has been a member of the Bar of Quebec since 1981. Barry is an accomplished lawyer, with the firm of Spiegel Sohmer Inc. in Montreal, Quebec.

He sits on the Board of Directors of several corporations including on the board of trustees of the Sir Mortimer B. Davis Jewish General Hospital Foundation.

Barry is a member of the advisory board for the Cancer Research Society Environment Cancer Fund and is also a member of the Coalition Priorité Cancer au Québec. He is a founding member of the Screening Action group of the Canadian Partnership Against Cancer.

As the president of the Colorectal Cancer Association of Canada (CCAC), he actively represents the interests of cancer patients and speaks regularly to medical professionals, industry, government, and patient groups across Canada on colorectal cancer.

Under Barry's stewardship, the CCAC has developed national awareness programs, educational programs, support for patients and their families and he has been a key advocate for the bringing about of colorectal cancer screening in Canada as well as for timely access to effective treatment for cancer patients.

As a survivor of metastatic colorectal cancer diagnosed in 1995, Barry was obliged to seek health care out of Canada to fight his disease. His judgement obtained in the Superior Court of Quebec in 1999 serves as a leading precedent in Canada for the reimbursement of out of country health care.

SYNOPSIS

COLORECTAL CANCER SCREENING *Saturday, October 27th, 09:55 – 10:25*

- Helping to make informed decisions
- What is Colorectal Cancer
- How CRC develops
- What is CRC screening
- Benefits of screening
- Limitations of screening
- CCAC initiatives

Colorectal Cancer Association of Canada

National Oncology Pharmacy Symposium

October 27 2007
Halifax ,Nova Scotia

INTRODUCTION

- Helping to make informed decisions
- What is Colorectal Cancer
- How CRC develops
- What is CRC screening
- Benefits of screening
- Limitations of screening
- CCAC initiatives

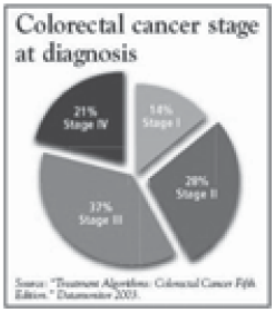
Helping to make Informed Decisions

Should I be screened for CRC?

- We actively invite sub groups of the population (ages 50- 74) **with no known disease** to participate in a medical intervention.
- Essential to advise patients of the benefits and limitations of CRC screening so they can make **informed decisions** by assessing the pros and cons of CRC screening.

Not a new concept - 18th century

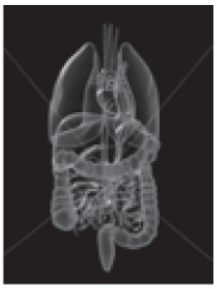
Catching CRC at an Early Stage



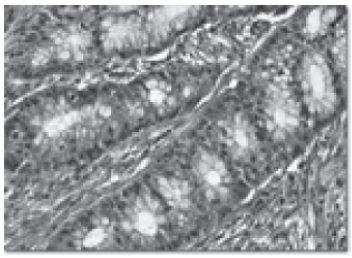
What is Colorectal Cancer?

- Cancer is the rapid creation of abnormal cells which grow beyond their usual cellular boundaries, and which can metastasize to distant organs.
- Colorectal cancer refers to cancer that starts in the colon or rectum.

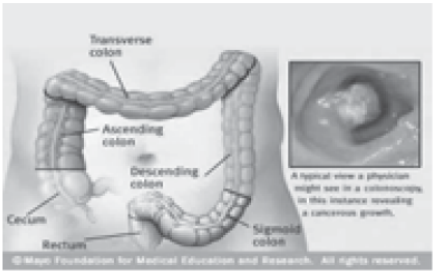
THE COLON



COLON CARCINOMA



Four Sections of the Colon



ascending colon • transverse colon
descending colon • sigmoid colon

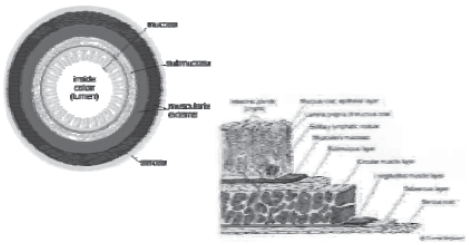
How Colorectal Cancer Develops

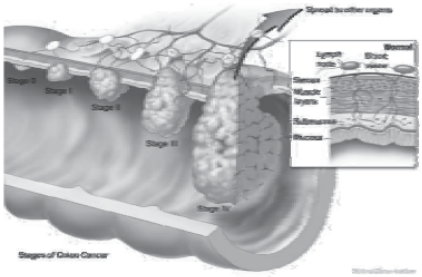
- A growth of tissue or polyp in the center of the colon or rectum.
- Develops slowly over a period of years.
  - Precancerous *adenomas* -changes known as *dysplasia* or *adenomatous polyps increase the risk of cancer in the colon and rectum.*
  - Hyperplastic polyps and inflammatory polyps are not precancerous.

Where Colorectal Cancer Starts

- CRC starts in the innermost layer of the colon and can grow through some or all of the other layers.
- The extent of spread or *stage* of colorectal cancer depends on which of these layers it affects.

The Layers of the Colon





What is Colorectal Cancer Screening

- A preliminary test to decide who should be tested further. ***The participant has no cancer symptoms***.
- ***Screening*** **does NOT** confirm that cancer is present.
- **Only a *Biopsy*** following a positive screening **can confirm** a cancer diagnosis.

Benefits of Screening

- **Screening is effective because**:
  - We can detect pre-cancerous, early stage or small cancers among people who do not show signs or symptoms of cancer.
  - We can confirm and more easily treat CRC cancer in the early stages with more options being available.
- **Screening therefore decreases the participant's risk from dying of cancer.**

Polyp Man arrested!

Incidence rate reduction

- CRC screening reduces cancer rates up to 20%. (15-33%)
- Screening allows for the detection of a pre-cancerous growth that can be removed before they become malignant.

Early detection

- Effective screening can find cancer before it is felt or is in early stages.
- Fecal occult blood test (**FOBT**) can identify polyps, which are pre-cancerous growths.
- Polyps may take 10 years to progress.

Effectiveness

- **Effectiveness explained by three factors:**

Sensitivity –Patients **who have cancer** and who are correctly tested as positive for growth. *FOBTs have a sensitivity ranging from 50 -90%.*

Specificity –Patients **who don't have cancer** and who are correctly tested as negative for growth. *FOBTs have a specificity ranging from 87-98%.*

Positive predictive value –Patients who are positively screened and who have cancer. *FOBTs have a PPV ranging from 2 -30%.*

Psychosocial

- Offer ***peace of mind*** by reducing anxiety and worry among patients –for those who do not have cancer.
- For those at higher risk (i.e. family history), screening allows them to ***take positive steps*** to manage their health.

Simple procedure and Cost effective

- Screening procedures **are easy to administer**, non-invasive and not arduous.
- FOBTs are recommended every at least every 2 years.
- Screening is **cost-effective** as it reduces cost of cancer treatment.

The Faces of Colorectal Cancer

Limitations of Screening

- Procedures can be uncomfortable or embarrassing for participants.
- Preparation is required by patients to ensure accuracy of the test.

For Example:

For FOBT (not FIT) participants are advised not to consume vitamin C, Aspirin, NSAID, red meat, and other red coloured foods.

Limitations of Screening cont'd

- **False Positives**
  - May cause worry and anxiety for patients or result in adverse psychological effects.
  - May lead to unnecessary diagnostic tests or treatment or worse diagnosis/treatment-related side effects and/or death.

Possible Risks

Following a positive FOBT screen test, patients will undergo a colonoscopy to confirm a diagnosis.

- ***Infection/tears in the lining of the colon can occur. 1 in 150 can suffer heavy bleeding .***
- ***5 out of 10,000 to 7 of 10,000 can suffer perforation of the colon.***

False Negatives

- False negative - when cancer is **not** detected even though it **is** present.
- May produce a **false sense of security**. Treatment of cancer is delayed, even when symptoms are present.
- CRC false negatives may be up to **50%**

Do Survival Rates associated with screening tell the whole story?

- *Survival rates may actually be over-inflated* because participants are screened and diagnosed earlier, and are observed for a longer time, but actually they may not be living longer.
- It is possible that an abnormal growth would never have progressed to cancer.

Cont'd

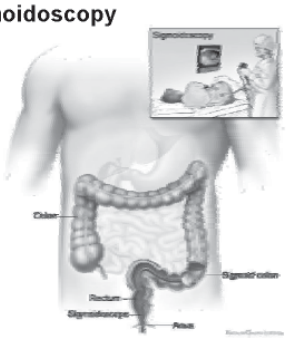
- Some cancers grow extremely slowly and the patient may die of another cause anyways.
- The cancer may never grow or the body's immune system stops the cancer.

Despite Limitations the Benefits are Compelling!

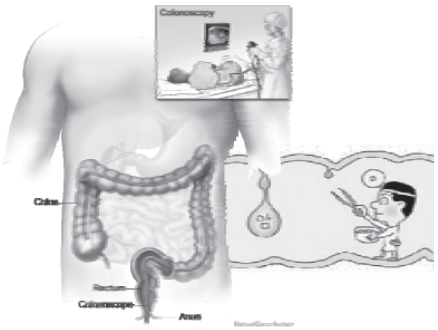
- ***Reduced risk of colorectal cancer mortality has been demonstrated with screening***.
- Health Canada, NCIC, WHO-IARC, CDC and the Colorectal Cancer Association of Canada **endorse CRC screening** as an effective population-based health intervention.

Fecal occult blood test (FOBT)

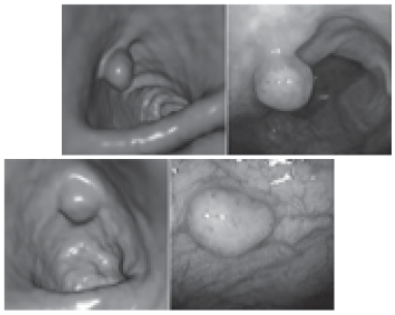
Sigmoidoscopy



COLONOSCOPY



Virtual (CT) vs Optical Colonoscopy



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Advocates for Standards of Care

Awareness and Education of CRC
Support for patients and their families Screening and Timely access to effective treatment

CCAC position on Standards of Care

- 20,800 Canadian men and women were diagnosed with colorectal cancer and 8,700 Canadians will die from it this year.

Equal to about 34 airplane crashes per year…

- Canadians should be outraged knowing that most of these deaths could have been prevented.

CCAC POSITION

- Health Ministries have known they could save lives and improve outcomes since 2002

National Committee on Colorectal Cancer Screening (NCCCS)

Population-based screening <u>at least every 2 years</u> with a fecal occult blood test (FOBT) for those between the ages of <u>50-74</u> years old.

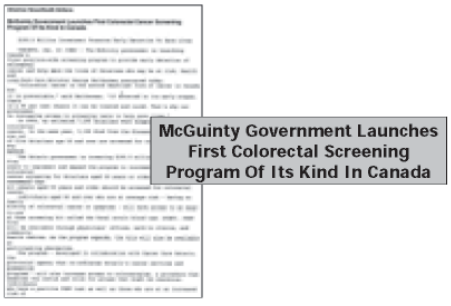
- 3 Provinces introduce population based screening programs & more to come

……Ontario, Manitoba and Alberta..

Why introduce Pop based Screening?

- Failure to implement CRC screening is short-sighted
- Cost of treatment is escalating
- Limits to what Provinces can/will provide
- Patients are being deprived of the standard of care in accordance with treatment guidelines

Ontario Announcement



McGuinty Government Launches First Colorectal Screening Program Of Its Kind In Canada

CMAJ- Low rates of Screening in Canada

- **September 10, 2007** – A study published in the Canadian Medical Association Journal (CMAJ) revealed that ***only 18 per cent of eligible Canadians are receiving colorectal cancer screening within the recommended time frame***, despite the existing guidelines and good access to family physicians.

- Physicians must take on a *more active role in promoting colorectal cancer screening* and so must we all….

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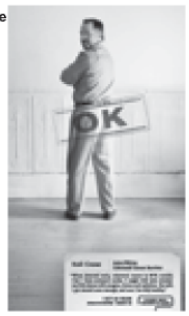
Watch Your Butt

George Thurston -Boule Noire

LOVE LIFE? GET SCREENED!

Neil Crone



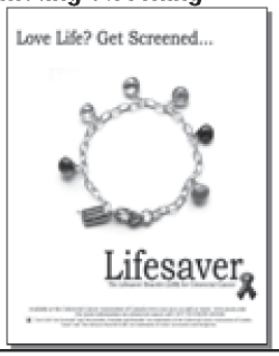
Gilles Renaud

Brad Gushue

Pamela Wallin

Pat Burns

Promoting Screening



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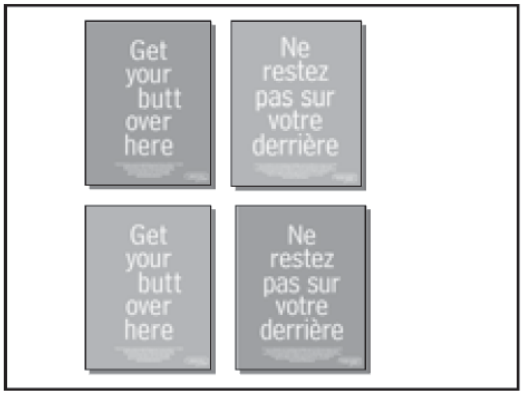


Green Lady

Parliament 2007

Tony Clement Minister of Health

" In November 2006, Prime Minister Stephen Harper announced the Canadian Partnership Against Cancer (CPAC). This new body will be responsible for implementing the Canadian Strategy for Cancer Control, whose objectives are to reduce the number of new cases of cancer among Canadians, enhance the quality of life of those living with cancer, and lessen the likelihood of Canadians dying from cancer.

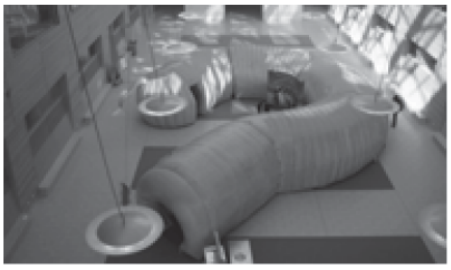
This investment will also help improve screening and prevention, enhance funding for research activities, and help coordinate efforts with the provinces, territories, and cancer care advocacy groups.

I would like to thank the Colorectal Cancer Association of Canada for its dedication to improving the quality of life of colorectal cancer patients and increasing awareness of the disease. We look forward to further collaboration with the Colorectal Cancer Association, as we work together to prevent and control colorectal cancer in Canada."

National Colorectal Cancer Month March 2007

BUTTBOARDS in Action across Canada

Big Awareness Giant Colon Tour



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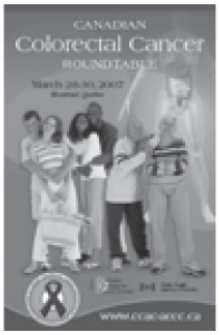
Giant Colon Tour



A couple of guys who I would like to thank..

SEE YOU AT ASCO 2008 CHICAGO

Colorectal Cancer Association of Canada

1 877 50 COLON

www.colorectal-cancer.ca

2007 | NOPS SPEAKER

PAT TROZZO
Site Manager – Pharmacy Program, CancerCare Manitoba

BIOGRAPHY

• Bachelor's degree in Pharmacy and Bachelor's degree in Chemistry from the University of Manitoba

• Board Certified Pharmacotherapy Specialist – American Society of Healthcare Pharmacists

• Site Manager – Pharmacy Program CancerCare Manitoba

• Clinical Assistant Professor – Faculty of Pharmacy, University of Manitoba Teaching oncology and pain & symptom management (Bachelor degree: 2nd, 3rd & 4th year - University of Manitoba)

Pat Trozzo has been working in the field of oncology pharmacy for more than 10 years, focusing primarily on the treatment of breast and gastrointestinal cancers. He has worked as part of a multi-professional pain and symptom team who work with cancer patients to alleviate pain and other issues. He is also involved in the teaching and education of health care professionals in palliative and end of life care.

SYNOPSIS

OXALIPLATIN *Saturday, October 27th, 11:00 – 11:45*
– A NEW STANDARD FOR THE ADJUVANT TREATMENT OF COLORECTAL CANCER

After attending this session, the participant should have a better understanding of:

• The scope of the treatment of colorectal cancer

• The pharmacokinetic features of the drug oxaliplatin

• The key literature addressing the adjuvant treatment of colorectal cancer

• The side effect profile of oxaliplatin and how these can be managed.

2007 | PAT TROZZO PRESENTATION HANDOUTS

Oxaliplatin
"A New Standard for the Adjuvant Treatment of Colorectal Cancer"
NOPS 2007
Halifax, Nova Scotia

Pat Trozzo, B.Sc(Chem), B.Sc.(Pharm), BCPS, FCSHP
Site Manager, Pharmacy Program
CancerCare Manitoba
Pat.trozzo@cancercare.mb.ca

Objectives

- Review the scope of the colorectal cancer problem
- Discuss the history of the adjuvant treatment of colorectal cancer
- The pharmacokinetic features of the drug oxaliplatin
- The trials associated with oxaliplatin as first line adjuvant therapy
- The side effect profile of oxaliplatin and the management of these

Conflict of Interest

- Oxaliplatin has been available through the Special Access Programme by Sigmacon International and from Sanofi-Aventis
- Oxaliplatin (Eloxatin®) is currently marketed by Sanofi-Aventis
- Some slides have been furnished by Sanofi-Aventis
- Advisory board participation
- Unrestricted educational grants to the pharmacy program

Oxaliplatin

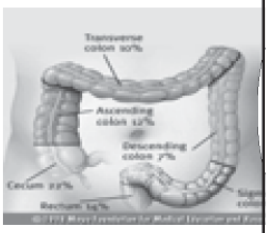
- Oxaliplatin is the focus of today's presentation
- Became available to Canadian patients through the Special Access Programme
- Created a "storm" of controversy
- In some provinces became a "standard of care" prior to having notice of compliance
- As of June 2007, in Canada Oxaliplatin (Eloxatin ®) is indicated for:
  - Use in combination with 5-fluorouracil (5-FU) and leucovorin (LV) as treatment of patients with metastatic colorectal cancer.

Category F5 Tornada
Elie Manitoba
(35 kilometers west of Winnipeg)

Friday June 22, 2007

The colon and rectum

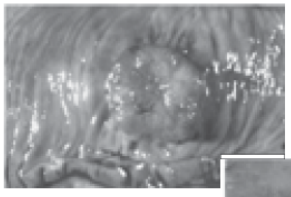
- Approximately 1.5 – 2 meters in length
- Colon:
  - Large intestine
  - From ileum to rectum
  - Functions to absorb water and electrolytes
- Rectum:
  - From sigmoid colon to anus
  - Functions to store stool



Incidence: Colon and Rectum

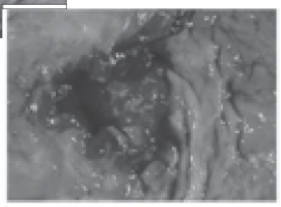
- Incidence: Fourth most common cancer in Canada with 20,800 new cases predicted for 2007
  - 55% male
- Mortality: Second only to lung cancer with 8,700 deaths predicted for 2007
  - 54% male

Canadian Cancer Statistics 2007, NCIC

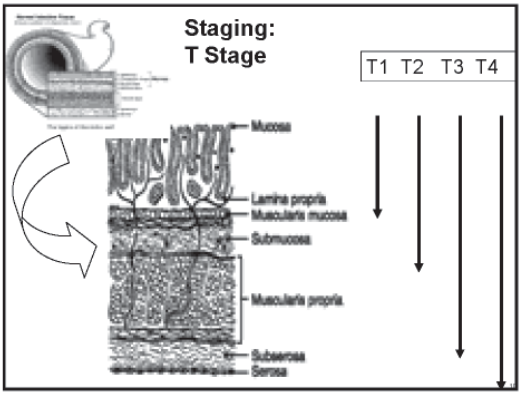


Adenomatous polyp

Carcinoma



Staging: T Stage



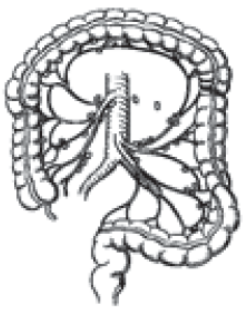
Staging: Nodal Status

Nx – Nodes can't be assessed or insufficient number sampled (< 12 nodes)

N0 – 0 nodes involved

N1 – 1-3 nodes involved

N2 - ≥ 4 nodes involved



Staging and Risk of Recurrence

TNM	Stage	Risk of Recurrence	Frequency at Presentation
T1N0M0 T2N0M0	I	10-15%	23%
T3N0M0 T4N0M0	II	20-25% 40%	30%
TxN1M0 TxN2M0	III	45% 70-75%	26%
TxNxM1	IV	–	21%

Does adjuvant chemotherapy work in colon cancer?

- The Seminal Paper – INT-0035
- 3 arm study including both stage II and III (Dukes B and C); reported separately – accrual 1984-1987
  - 1296 patients – 971 Stage C (42 ineligible), 325 Stage B (7 ineligible)

Moertel et al. NEJM 1990; 322: 352, Ann Intern Med 1995; 122: 321.

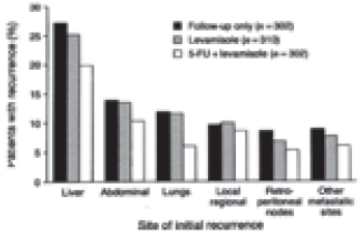
INT-0035

- Observation
- Levamisole – 50 mg po tid x 3 days q2w x 1 year
- Fluorouracil+ Levamisole – Levamisole at same dose/schedule, Fluorouracil 450 mg/m^2 bolus daily x 5, then a break to day 28, and then weekly x 48
- Entered onto study ≤ 5 weeks post surgery

Moertel et al. NEJM 1990; 322: 352, Ann Intern Med 1995; 122: 321

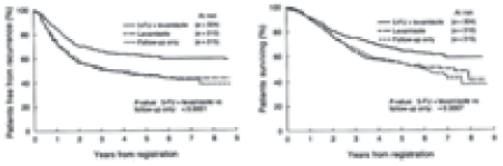
Sites of Recurrence

- No difference between observation and levamisole alone arms



Moertel et al. NEJM 1990; 322: 352, Ann Intern Med 1995; 122: 321.

Relapse Free Survival and Overall Survival



Moertel et al. NEJM 1990; 322: 352, Ann Intern Med 1995; 122: 321.

"MAYO" - Standard of Care 1997-2005

- Intergroup study Feb 88- Aug 89
- High risk II (18%), or III, Median f/u 72 mo.
- Mayo (Fluorouracil 425 mg/m^2 + Leucorovin 20 mg/m^2 days 1-5, q28-35d, x 6), versus observation
- 21-30 days post surgery

	N	5 Yr DFS		5 Yr OS	
Mayo x 6	158	74%	0.004	74%	0.02
Observation	151	58%		63%	

O'Connell et al JCO 1997; 15:246

Oxaliplatin

- Is a stereoisomer diaminocyclohexane carrier ligand-based platinum complex
- First synthesized in Japan in 1969
- Cytotoxicity appears to result from inhibition of deoxyribonucleic acid synthesis
- Steady state plasma platinum concentrations were achieved during the first cycle of treatment with oxaliplatin 130 mg/m^2, and accumulation was not reported after single or multiple dosing
- Large volume of distribution; $t_{1/2}$= 40 hours

Oxaliplatin

- Excretion of oxaliplatin metabolites occurs primarily by the renal route
- Exposure to plasma platinum is increased in patients with moderate renal impairment compared with that in individuals with normal renal function
- However, further deterioration of renal function has not been reported; As well the toxicity of oxaliplatin does not appear to be increased in patients with impaired renal function
- Total body clearance of oxaliplatin metabolites appears to be independent of age, gender and hepatic function

Oxaliplatin

- Poor activity when used as monotherapy
- Combination therapy…

MOSAIC: Study Design

n=2246

Enrollment:
Oct 1998–Jan 2001 (146 centres; 20 countries)

- Completely resected colon cancer
- Stage II, 40%; Stage III, 60%
- Age 18–75 years
- KPS ≥60
- No prior chemotherapy

R

(n=1123) **FOLFOX4** (LV5FU2 + oxaliplatin 85 mg/m^2)

(n=1123) **LV5FU2**

Primary end-point: disease-free survival

Secondary end-points: safety, overall survival

LV5FU2, Leucovorin 200 mg/m^2 iv over 2 hours followed by 5-fluorouracil 400 mg/m^2 bolus and 5-fluorouracil 600 mg/m^2 iv over 22 hours on Days 1 and 2; every 14 days; FOLFOX4, LV5FU2 + oxaliplatin 85 mg/m^2 iv over 2 hours on Day 1

Cut-off Dates for Efficacy Analyses

2003	3-year DFS: primary endpoint [1]
2006	5-year DFS: final update ***(No further updates on relapses)***
2007	Overall Survival: 6-year, final analysis

1. André, et al. N Engl J Med 2004;350:2343–2351

Primary End-Point: Disease-Free Survival

- "DFS allows to make more quickly a decision regarding the efficacy of a new treatment
- Clinical trials can be completed more quickly
- Drug development time can be shortened
- Better therapy can be made available to patients more quickly
- DFS can be considered as an endpoint of its own merit in decreasing the high cost, quality-of life impact and debilitating consequence of recurrent disease"

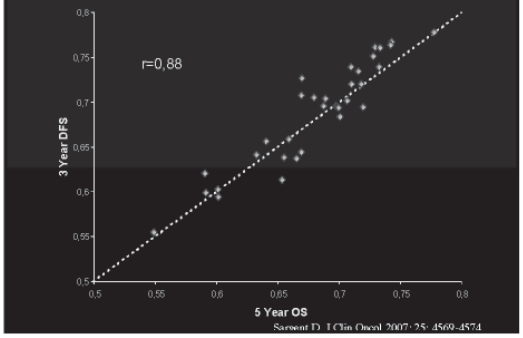
Sargent D. J Clin Oncol 2007; 25: 4569-4574

Methods: Surrogacy of 3-year DFS

- Pooled patients from 18 Phase III randomized clinical trials, with 43 treatment arms, 20,898 subjects
- Median follow-up 8 years – at least 5 years in 89% of patients
  - 66% stage III
  - 55% male
  - 19% > 70 years old
  - 88% received chemo, 12% observation

Sargent D. J Clin Oncol 2007; 25: 4569-4574

3 Year DFS vs 5 Year OS



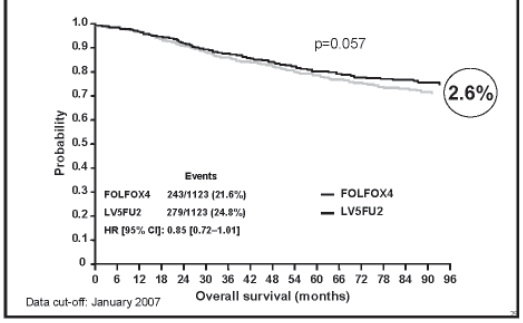
Sargent D. J Clin Oncol 2007; 25: 4569-4574

Summary: Overall Survival

	Probability of surviving at 6 years, %			
	FOLFOX4	LV5FU2	HR [95% CI]	p-value
ITT (overall population)	78.6	76.0	0.85 [0.72–1.01]	0.057
Stage III	73.0	68.6	0.80 [0.66–0.98]	0.029
Stage II	86.9	86.8	1.00 [0.71–1.42]	0.996

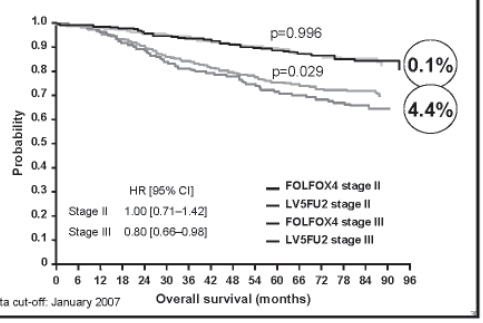
Data cut-off: January 2007

Overall Survival: ITT



Data cut-off: January 2007

Overall Survival: Stage II and Stage III



Data cut-off: January 2007

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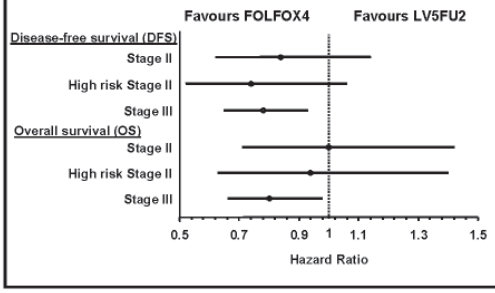
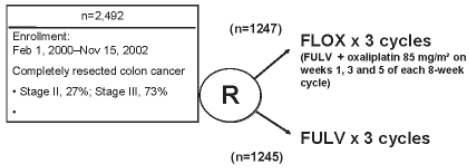
Hazard ratios for DFS and OS by sub group



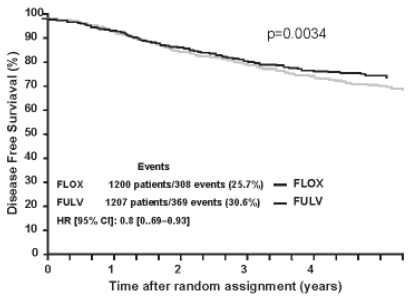
NSABP C-07



Primary end-point: disease-free survival
Secondary end-points: safety, overall survival

FULV: Fluorouracil 500 mg/m² IV bolus weekly for 6 weeks plus leucovorin 500 mg/m² IV weekly over 2 hours for 6 weeks of an 8 week cycle for a total of 3 cycles (6 months of therapy)

Disease Free Survival



Comparison of NSABP C-07 and the MOSAIC trial

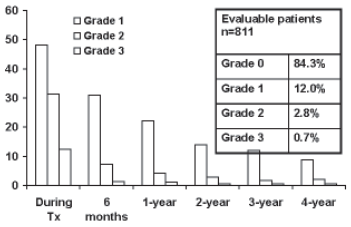
	3 year disease free survival	Benefit over comparator	Hazard ratio
NSABP C-07	73.2 %	6.2%	0.8
MOSAIC	78.2%	8%	0.77

Long-term Safety

Second cancer

	FOLFOX	LV5FU2
(% patients)	5.3	5.7

Peripheral Sensory Neuropathy



Evaluable patients n=811	
Grade 0	84.3%
Grade 1	12.0%
Grade 2	2.8%
Grade 3	0.7%

Data cut-off: January 2007

Oxaliplatin Neurotoxicity Profile

	Acute	Persistent
Incidence	All grades: 56%	Grade 3: 15-18%
Symptoms	Precipitated by cold exposure Paresthesia, dysesthesia hypoesthesia of distal extremities Muscle cramping •Rare: Pharyngolaryngeal dysesthesia (throat discomfort and tightness; jaw pain, sensation of inability to breath or swallow)	Paresthesia, dysesthesia, hypoesthesia Affects fingertips and toes then hands and feet May include proprioception deficits: Interferes with daily activities Persists between cycles Increases in duration and intensity
Onset	Early: 2-48 hours	Late: >14 days After 5 cycles or 850 mg/m²
Recovery	Rapid, complete	Slow, generally complete

Oxaliplatin: Neurotoxicity

- Two types of nerves: motor and sensory
  - Motor nerves - **movement and maintaining muscle tone.**
  - Sensory nerves - **sensation such as pain, touch, temperature, position and vibration.**
- Transient Paresthesias
  - **Numbness and tingling in the fingers, hands, toes or lips**
- Dysesthesias
  - **Unpleasant sensation caused by ordinary stimuli**
  - **Symptoms are enhanced by contact with cold and often regress between cycles.**
- **Both cause functional impairment: increased difficulty with fine motor senses and unsteady gait.**

Oxaliplatin: Persistent Neurotoxicity

- Can impair daily function, decreasing quality of life
- Most important risk factor: total cumulative dose
  - **100% patients experience some sensory neuropathy after 4 cycles**
  - **Some patients experience severe symptoms**
    - **10% patients after 6 cycles**
    - **50% patients after 9 cycles**
    - **75% patients after 12 cycles**

Oxaliplatin: Persistent Neurotoxicity

Management

- Dose reduce Oxaliplatin for Grade 2 peripheral neuropathy
- If symptoms worsen, hold oxaliplatin and/or consider time off in the metastatic setting

Drugs Used

Carbamazepine	Amifostine
Gabapentin	Alpha-lipoic acid
Venlafaxine	Glutathione
Amitriptyline	

Oxaliplatin: Persistent Neurotoxicity

Education

- Discuss likelihood with patient
- Common effect associated with Oxaliplatin treatment
- Describe functional impairment
- Explain the symptoms
  - Usually regress between cycles but tend to last longer with subsequent cycles
  - Usually resolve within 4-6 months
- Describe possible symptoms
- Discuss safety measures

Wilkes GM, *Can J Oncol Nursing* 2005, 9:31-43

Oxaliplatin: Persistent Neurotoxicity

Safety Strategies

- Assess home water temperatures –use tepid water
- Use protective gloves when washing dishes
- Use pot holder when cooking
- Clothing:
  - wear cotton socks and mittens in cold temperatures
- Lighting:
  - ensure well-lit rooms without glare
- Environment:
  - clear walkways; use non-skid showers and tub mats

Almadrones LA. *Advances in Colorectal Care* (newsletter), Meniscus Limited: 2003:8-11

Oxaliplatin: Acute Neurotoxicity

Education

- Avoid cold weather exposure: wear mittens, socks and footwear when going outdoors
- After treatment, have someone else warm up the car before entering
- In hot weather climates, do not use air conditioning at high levels in car or house
- Put on gloves before reaching into the refrigerator or freezer

Wilkes GM, *Clin J Oncol Nursing* 2005; 9:31-43

Oxaliplatin: Acute Neurotoxicity

Acute Laryngopharyngeal Dysesthesias

- **Sensation of respiratory discomfort without any objective evidence of such distress**
  - **Tightness, spasm, difficulty swallowing or speaking, or feeling unable to breathe**
- **Can occur:**
  - **During Oxaliplatin infusion**
    - **Spontaneously or when cold food/beverages are consumed**
  - **Anywhere from several hours to days after infusion**

Oxaliplatin: Acute Neurotoxicity

Management

- **Stop infusion**
- **VSS, SpO_2**
- **Warm compress to throat**
- **Treat symptomatically**
- **Administer Ativan or Morphine to manage anxiety**
- **Subsequent infusions over 4-6 hours**

Oxaliplatin: Acute Neurotoxicity

Education

- Use a straw to drink fluids
- Avoid deep breathing when exposed to cold air outdoors or from an open refrigerator or freezer
- Avoid drinking cold beverages and eating ice cream or other frozen foods
- Avoid sucking ice chips during treatment
- Let Healthcare provider know if you experience discomfort or tightness in the back of the throat or difficulty with breathing or swallowing
  - This sensation will subside in a few minutes
  - Relaxation techniques or therapies may be needed

Wilkes GM, *Clin J Oncol Nursing* 2005; 9:31-43
Barbhaiya RH, *Clin J Oncol Nursing* 2003; 7:453-458
Almadrones LA *Advances in Colorectal Care (newsletter)*, Meniscus Limited: 2003:8-11

Dose Adjustments for Neurologic Toxicity*

Toxicity (Grade)	Duration of Toxicity		Persistent [a] Between Cycles
	1-7 Days	> 7 Days	
Paresthesias/dysesthesias [b] that do not interfere with function (Grade 1)	No change	No change	No change
Paresthesias/dysesthesias [b] interfering with function, but not activities of daily living (ADL) (Grade 2)	No change	No change	65 mg/m^{2**}
Paresthesias/dysesthesias[b] with pain or with functional impairment that also interfere with ADL (Grade 3)	No change	65 mg/m^{2**}	Stop
Persistent paresthesias/dysesthesias that are disabling or life-threatening (Grade 4)	Stop	Stop	Stop
Acute (during or after the 2 hour infusion) laryngopharyngeal dysesthesias[b]	↑ duration of next infusion to 6 hours [c]	↑ duration of next infusion to 6 hours [c]	↑ duration of next infusion to 6 hours [c]

a Not resolved by the beginning of the next cycle.

b May have been cold-induced.

c May also have been pre-treated with benzodiazapines.

*Product Monograph

** Adjuvant setting – reduce to 75 mg/m2, per MOSAIC trial

2007 | PAT TROZZO PRESENTATION HANDOUTS

Alternative strategies

- Ca/Mg no longer recommended – during a planned review by the IDMC of the CONCEPT trial, response rates were significantly lower in ca/mg group vs. placebo group*
- Glutamine, glutathione studies underway
- Xenox – Xaliproden (neuroprotective agent) in patients treated with FOLFOX in 1st line metastatic; 40% reduction in grade 3 NT with RR same between groups
- Xenon – Xaliproden in patients treated with FOLFOX in stage 3 (TSRCC will begin soon)

* JCO correspondence from investigators: volume 25, Sept 2007

Take Home Messages

- Oxaliplatin has considerable activity in the adjuvant setting
- Toxicity is manageable
- Education is key to preventing problems

Questions???

2007 | NOPS SPEAKER

LYNNE NAKASHIMA
Pharmacy Professional Practice Leader, BC Cancer Agency, Vancouver

BIOGRAPHY

BSc Pharm (UBC 1988) PharmD (U of North Carolina at Chapel Hill 1009)
Lymphona Tumor Group Pharmacist

SYNOPSIS

MAINTENANCE RITUXIMAB FOR NHL *Saturday, October 27th, 11:50 – 12:35*

Low grade non-Hodgkins lymphomas, such as follicular lymphomas are generally considered to be incurable, but the natural course of the disease is one of "waxing and waning" and it is managed as a chronic disease. Typically treatment has included a variety of chemotherapy regimens, with a progressive decrease in response rates and relapse-free survival.

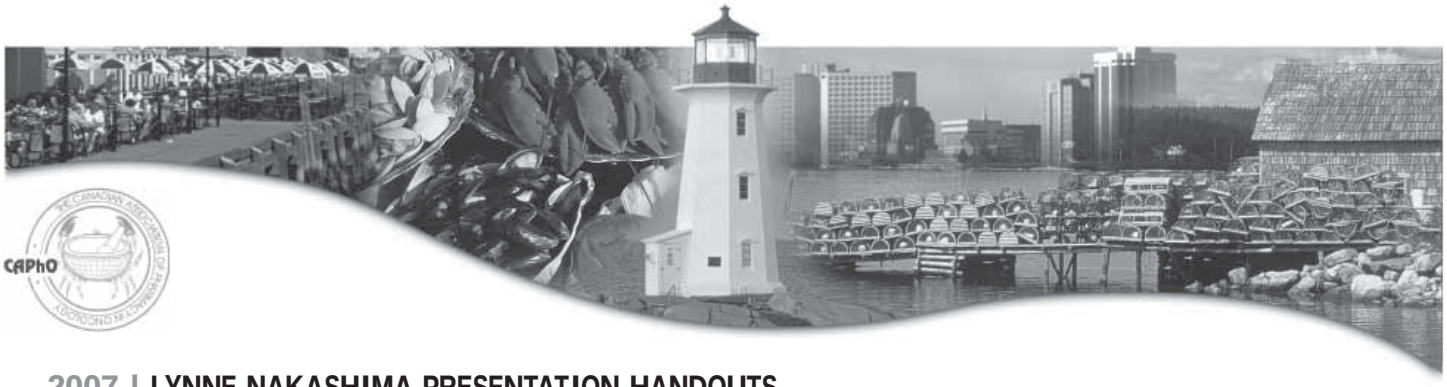
Rituximab has been studied as a maintenance therapy because it is an effective antilymphoma therapy, is very well tolerated and does not negatively impact on quality of life. Data from recently reported studies indicate that maintenance rituximab has a favourable impact on progression-free survival, even when patients have received rituximab as part of their preceding chemotherapy regimen. As a result, rituximab maintenance therapy has been implemented in many treatment centres.

Of interest, is the differing schedule of treatment. The dose has remained consistent at 375 mg/m2, but schedules have varied from 4-weekly infusions every 6 months, one infusion every 2 months or one infusion every 3 months. The duration of treatment also varies from 8 months to 2 years.

Side effects with rituximab are generally modest, but long term toxicity is unknown and needs further follow-up.

At the BC Cancer Agency, we are currently recommending maintenance rituximab for patients who have responded to initial therapy, and are currently recommending the every 3 month for 2 years dosing schedule.

Further follow-up is needed, but maintenance rituximab is an exciting addition to the treatment of low grade non-Hodgkins lymphoma patients.



Maintenance Rituximab for Low Grade Lymphomas

Lynne Nakashima, BSc(Pharm), Pharm.D
BC Cancer Agency, Vancouver Centre
NOPS
Oct. 27, 2007

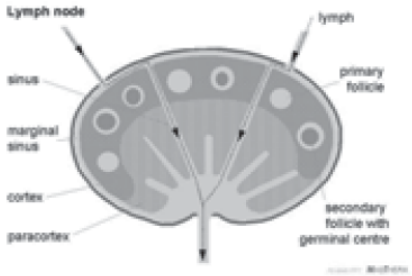
BC Cancer Agency, Vancouver

At Work?

Outline

- Overview of lymphoma and current standard of care
- Rituximab
- Rationale for Maintenance Therapy
- Clinical Results
- Optimal Schedule
- Toxicity profile
- Summary

Sites of Origin of Lymphomas



Classification of Lymphoma

Grade	B-cell	T-cell
Indolent	Small lymphocytic* Lymphoplasmacytic** Follicular, grade 1, 2 or 3 A	Mycoses fungoides
	Marginal zone	
	MALT***	
	nodal	
	splenic	
Aggressive	Follicular, grade 3 B Mantle cell Diffuse large cell*, any type Burkitt-like (small noncleaved cell)	Peripheral T cell, unspecified Peripheral T-cell, specified Angioimmunoblastic (AIL) Nasal T/NK cell Subcutaneous panniculitic Enteropathy associated Anaplastic large cell (CD30 positive) including null cell
Special	Burkitt	Lymphoblastic

Low Grade Lymphoma

- Low grade = indolent
- Most common: follicular lymphoma
- Usually diagnosed in advanced stage
- Waxing and waning course
- Median survival 8-10 years

Management of Low-Grade Lymphoma

- Limited Stage:
  Involved field radiation therapy (IFRT)
- Advanced Stage:
  Asymptomatic - close follow-up under continued observation
  Symptomatic - CVP + rituximab

Localized irradiation can be useful for local symptoms

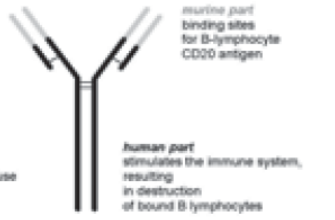
CVP-Rituximab

- Vincristine 1.4 mg/m² on day 1 (no maximum dose) IV push
- Cyclophosphamide 1000 mg/m² on day 1 IV in 100 – 250 mL NS over 20-60 minutes
- Prednisone 100 mg starting on day 1 PO daily in am with food x 5 consecutive days
- Rituximab 375 mg/m² on day 1 or 2 whenever possible but not later than 72 h after CVP IV in 250 mL NS over 90 minutes-8 hours*

Rituximab

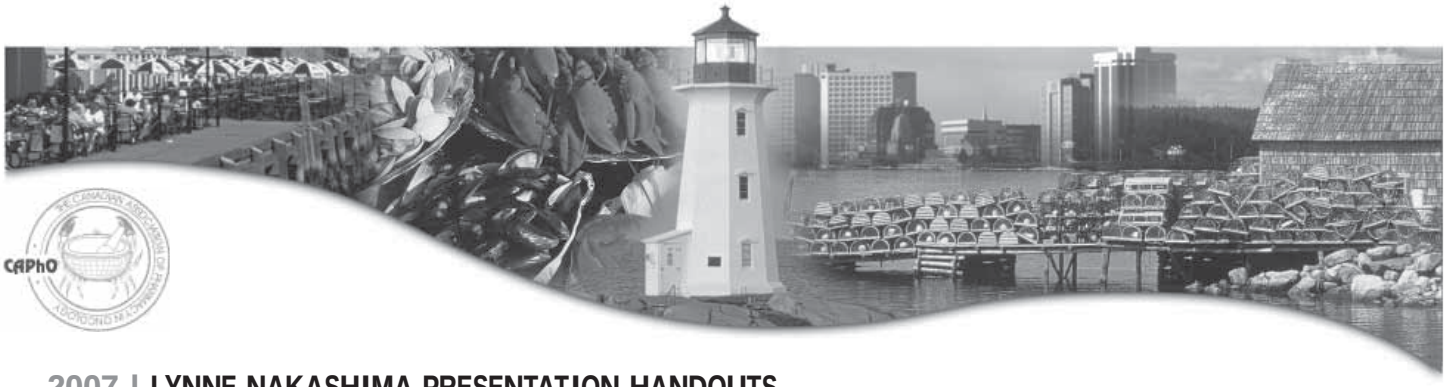
- Chimeric anti-CD20 monoclonal antibody
- Targets CD20 which is expressed by B cells
- Mechanism of action: complement-dependent cytotoxicity, antibody-dependent cytotoxicity and direct apoptosis

Rituximab Antibody



Rationale for Maintenance Therapy

- Effective anti-lymphoma therapy
- CD20 target generally persists on lymphoma cells
- Minimal acute toxicity (ie dose reduction and delay is uncommon)
- Long half-life allows for infrequent treatment but long-term drug exposure
- Maintain quality of life



Studies in Follicular Lymphoma

Hainsworth et al Minnie Pearl Blood 2003; 102:411a-412a

- Phase II after rituximab monotherapy
- 62 patients
- 4 x once-weekly rituximab at 6 month intervals for up to 2 years
- Median PFS = 37 months
- 5 year PFS = 34%

Studies in Follicular Lymphoma (2)

Ghielmini et al Swiss Group (SAKK) Blood 2004;103;4416-4423

- Phase III after Rituximab monotherapy
- 151 patients
- 4 single Rituximab infusions administered at 2 month intervals
- Median event-free survival = 23 mo (vs 12 months for no further treatment)

Studies in Follicular Lymphoma (3)

Hochster et al ECOG 1496 JCO 2004; 22(Suppl):6502

- Phase III following CVP induction
- 305 patients
- 4 one-weekly doses repeated at 6 month intervals for up to 2 years
- PFS = 4.2 years (versus 1.5 years for no treatment arm)

Studies in Follicular Lymphoma (4)

Van Oers et al EORTC 20981 Blood 2006; 108:3295-3301

- Phase III following CHOP or CHOP-R
- 375 mg/m2 infusion once every 3 months for up to 2 years
- Estimated OS = 51.5 months (versus 14.9 months for the observation arm

Studies in Follicular Lymphoma (5)

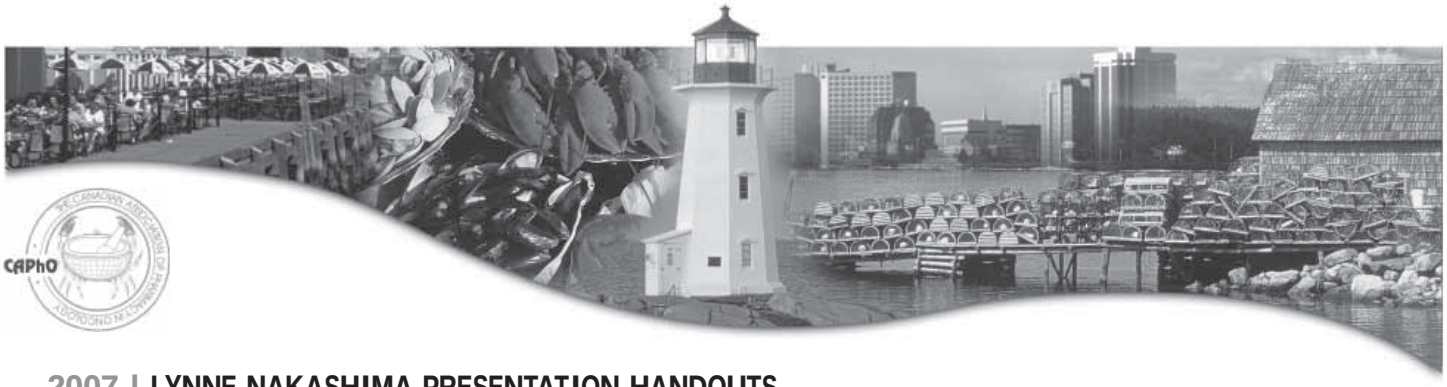
Forstpointner et al. GLSG Blood 2004; 104:3064-3071

- Phase III following Fludarabine, cyclophosphamide, and mitoxantrone (FCM) +/- Rituximab
- 4 one-weekly doses at 3 months and 9 months after induction vs observation
- Median PFS = 27 months (vs 15 months on observation arm)

Maintenance vs Retreatment

Minnie Pearl JCO 2005; 23:1008-95

- Maintenance (4 x one-weekly doses repeated at 6 month interval for up to 2 years) vs Retreatment at disease progression
- Median PFS = 31.3 mo vs 7.4 mo for observation arm
- OS = 72% vs 68%



Dose and Schedule

- Dose in all trials: 375 mg/m2
- 4 weekly infusions every 6 months
- 1 infusion every 2 or 3 months for 2 years

Gordan et al JCO 2005;23:1096-1102

- 4 weekly infusions given then serum levels assessed monthly. Re-treatment given when levels below 25 mcg/mL
- Median time to repeat infusion = 3 months

Optimal Duration of Treatment

- Duration ranges from 8 months to 2 years
- But ongoing trials propose 5 years or until progression
- Complicated by progression while on treatment
- Unknown optimal duration

Toxicity Profile

- More than 700,000 patients treated
- Generally very well tolerated

Infusion-Related Reactions

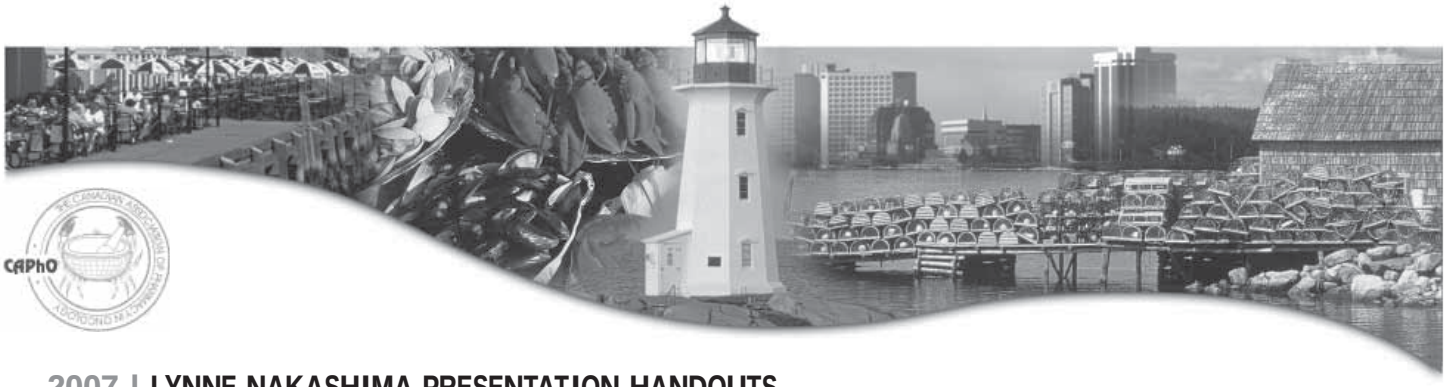
- May be related to release of cytokines and/or other chemical mediators
- Hard to distinguish from true hypersensitivity
- Death has been reported
- hypotension, wheezing, rash, flushing, alarm, pruritus, sneezing, cough, fever or faintness
- Consider withholding anti-hypertensives x 12 hours
- Slow rate of infusion; visually observe

Fatal Cytokine Release Syndrome

- Should be rare as no circulating lymphoma cells or bulky disease
- severe dyspnea (often with bronchospasm and hypoxia) in addition to fever, chills, rigors, urticaria and angioedema starting 1-2 hours after starting infusion
- Stop infusion and evaluate; may re-start at ½ infusion rate

Mucocutaneous Reactions

- Rare, but reported with Rituximab
- Similar to Stevens-Johnson Syndrome
- Hold Rituximab



Hepatitis B Reactivation

- Prior to starting treatment, patients should be tested for HBsAg and HBcoreAb
- If positive, treat with Lamivudine 100 mg orally for duration of treatment and 6 months following

Progressive Multifocal Leukoencephalopathy

- Rare, progressive , demyelinating disease of the CNS, often resulting in death
- Caused by activation of the JC virus

Long Term Toxicity

- Not extensively studied
- Increase in immature and transitional B cells and decrease in memory B cells
- ? Reduced response to vaccination
- Some reports of viral infections (cytomegalovirus, varicella zoster)

BCCA Protocol

- Available on BCCA website: www.bccancer.bc.ca
- Requires at least a partial response to the preceding chemotherapy
- Uses Rituximab 375 mg/m2 every 3 months for 2 years (8 doses)
- Discontinue if lymphoma progresses

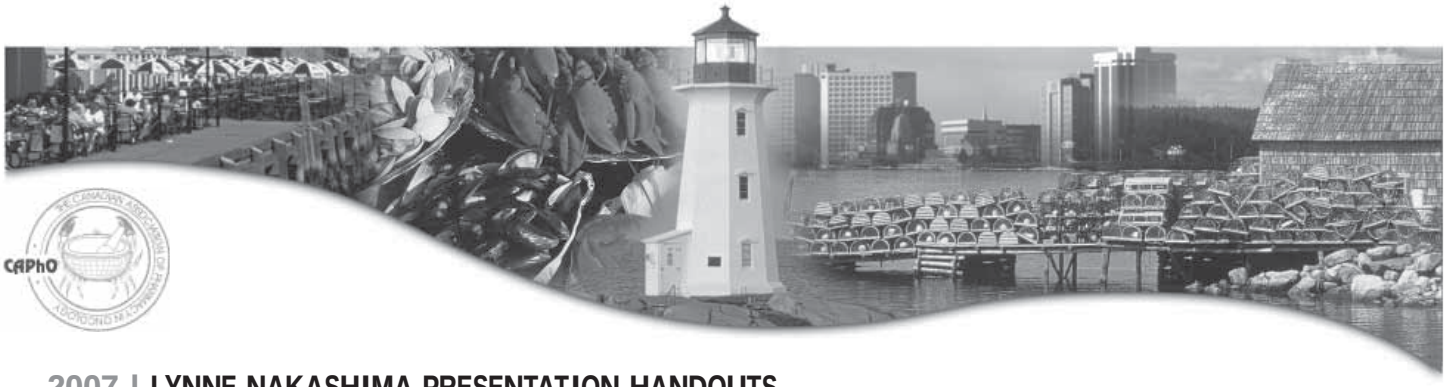
Prophylaxis Orders

PREMEDICATIONS:

Diphenhydramine 50 mg PO prior to Rituximab and then q 4 h if the infusion exceeds 4 h
Acetaminophen 650 mg PO prior to Rituximab and then q 4 h if the infusion exceeds 4 h
Prednisone 50 mg PO prior to Rituximab PRN

Rituximab Orders

- Rituximab 375 mg/m2 x BSA = _____ mg IV in 250-500 mL NS over 90 minutes.
- Infuse 50 mL (or 100 mL of 500 mL bag) of the dose over 30 minutes, then infuse the remaining 200 mL (or 400 mL of 500 mL bag) over 60 minutes.
- For maintenance dose # 1, patients are to be under constant visual observation during all dose increases and for 30 minutes after infusion completed. For all subsequent maintenance doses (# 2-8), visual observation is not required. Vital signs are not required unless symptomatic.
- If flushing, dyspnea, rigors, rash, new pruritus, vomiting, chest pain or any other new acute discomfort occurs, stop infusion and page physician.
- Patient may leave if stable when infusion completed.



Summary

- Rituximab maintenance is the new standard of care for low grade lymphomas
- A standard dose of 375 mg/m2 is used, but the optimal schedule is unknown
- Rituximab is well tolerated, but the long-term toxicity profile is unknown

2007 | NOPS SPEAKER

DR. CARLO DE ANGELIS

Clinical Pharmacy Coordinator – Oncology, Sunnybrook and Women's College Health Sciences Centre; Associate Professor, Clinical Pharmacy, Faculty of Pharmacy, University of Toronto; Pharmacy Owner, Panacea Pharmacy

BIOGRAPHY

Carlo De Angelis received his Bachelor of Pharmacy from the University of Toronto in 1981. He did his Hospital Pharmacy Residency at Sunnybrook and Women's College health Sciences Centre in 1982; and he received his Doctorate of Pharmacy from the State University of New York at Buffalo in 1984. Carlo specializes in cancer treatment symptom prevention and management; education and training in Oncology Pharmacy Practice; and, practice based research to support Oncology Clinical Pharmacy activities.

SYNOPSIS

NCIC TOPIC- PHARMACIST-INITIATED RESEARCH *Saturday, October 27th, 14:30 - 15:30*

PRESENTATION

Speaker handouts for this presentation will be available onsite.

2007 | NOPS SPEAKER

DR SANDRA COHEN
Director, Clinical Unit, Hematopoietic Stem Cell Transplant Program, Maisonneuve-Rosemont Hospital, Montreal

BIOGRAPHY

Dr Sandra Cohen is the director of the clinical unit of the Hematopoietic Stem Cell Transplant Program at Maisonneuve-Rosemont Hospital in Montreal, Canada and an assistant professor at the University of Montreal.

She received her medical degree from Sherbrooke University and did her Internal Medicine and Hematology residency at McGill University. She completed a Bone Marrow Transplant Fellowship at City of Hope National Cancer Institute, Duarte, California and then practiced as a haematologist/transplanter at the City of Hope. Since 2003 she has been working in the field of stem cell transplantation at Maisonneuve Rosemont Hospital.

Dr Cohen participates in many clinical trials notably in chronic lymphocytic leukemia, acute lymphoblastic leukemia, GVHD, stem cell mobilisation, fungal infections, venoocclusive disease, etc… She participates in the teaching of medical students, residents as well as transplant fellows at the University of Montreal.

SYNOPSIS

MYELODYSPLASTIC SYNDROME: WHAT'S NEW AND WHAT'S OLD? IS THERE A THERAPEUTIC LIGHT AT THE END OF THE TUNNEL? *Saturday, October 27, 14:30 - 15:30*

The treatment of MDS remains challenging for several reasons. First, patients with this disorder are likely to be elderly with comorbid diseases. Second, the disease is heterogeneous, making therapies for one type of MDS less optimal than those for others. Finally, there is no widely accepted standard of care in that very few, if any, modalities have been definitively proved to change the natural history of this disease.
The educational objectives:

1) Characterize the current state of MDS treatment, including stem cell transplantation as the only potential curative option
2) Compare the currently available treatment options in patients with myelodysplasia
3) Discuss the role of newer drug treatments that are currently unavailable in Canada
4) Establish a treatment algorithm for MDS patients taking into account their prognosis

PRESENTATION

Speaker handouts for this presentation will be available onsite.

2007 | NOPS SPEAKER

DR ROB GRIMSHAW

BIOGRAPHY

Dr Grimshaw is Head of Division of Gynecologic Oncology at Dalhousie University in Halifax Nova Scotia. He is the Medical Director of the Cervical Cancer Prevention Program of Cancer Care Nova Scotia, and is acting as Interim Medical Advisor to Cancer Care Nova Scotia at present.

SYNOPSIS

HPV VACCINE *Saturday, October 27th, 15:35 - 16:35*

Cervical cancer, the Human Papilloma Virus (HPV), its epidemiology and role in cervical carcinogenesis, the role of vaccine against HPV, and ongoing contrioversies regarding public vaccination programs will be reviewed.

PRESENTATION

Speaker handouts for this presentation will be available onsite.

2007 | NOPS SPEAKER

search - speak

DR. PAT MACCORMACK-SPEAK
RN, MBA, Program Manager, UP

BIOGRAPHY

Pat McCormack-Speak (pms) has been a Registered Nurse for 30 years. She received her bachelor's degree in nursing from St. Scholatica, Duluth, Minnesota and a MBA from the Kotz Graduate School of Management, St. Thomas University, St. Paul, Minnesota.

She LOVES working on innovative projects and over her career she has worked in patient care at the primary health care to tertiary care level and in the capacity of a direct care provider to administrator.

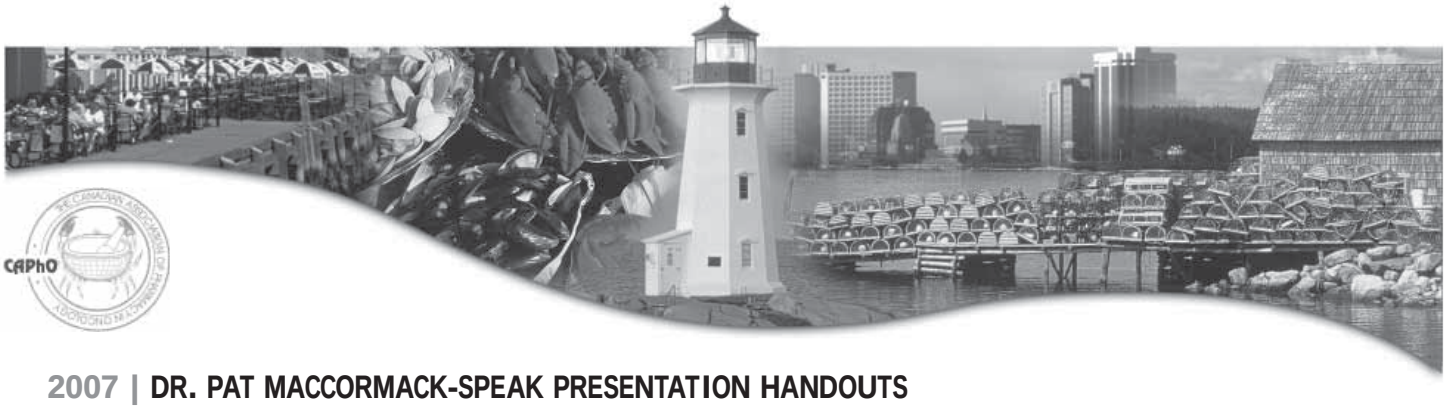
During her career in Winnipeg, she has worked with the VON, Lions Place for Health, and the Alzheimer Society of Manitoba. Before coming to Cancer Care Manitoba in 2003, Pat was a Lecturer (Gerontology), Clinical Practice Coordinator undergraduate programs, and Program Coordinator for the Baccalaureate Programs for Registered Nurses in the Faculty of Nursing, at the University of Manitoba.

SYNOPSIS

UNITING PRIMARY CARE AND ONCOLOGY (UPCON): MAKING LINKS FOR BETTER PATIENT CARE

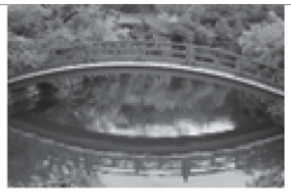
Saturday, October 27th, 15:35 - 16:35

With the pressures of fee for service practice, the shortage of primary care practitioners and the increasing burden of chronic illness in our aging population, the provision of care for the complex and less frequent diagnosis of cancer provides Family Physicians (FPs) and Nurse Practitioners (NPs) with a challenge. Patients benefit from having FP/NPs with disease-specific knowledge; information to help them navigate the cancer care system; and excellent communication with cancer specialists in all disciplines. Despite the challenges that our partners in primary care face daily in practice, it is clear: primary care clinicians are instrumental in improving cancer-related health outcomes from prevention to survivorship to end of life care.



2007 | DR. PAT MACCORMACK-SPEAK PRESENTATION HANDOUTS

Bridging the Gap…
Uniting Primary Care and Oncology (**UPCON**)
…Making Links for Better Patient Care



Today's Presentation

UPCON
Uniting Primary Care Oncology Network

- Why did we do this?
- What did we do?
- What did we achieve?

UPCON
Uniting Primary Care and Oncology

Why did (do) we do this?

- Burden of cancer is rising steadily in the population
- Cancer patients believe we talk to each other regularly
- FPs feel that patients disappear in the cancer system; the "black box"

Leadership is needed to build relationships and improve integration of care

The problem in cancer care is...

- The cancer system is poorly integrated with primary care
- Cancer is infrequent in a FP's practice and poorly taught
- FPs often feel like "outsiders"

Leadership is needed to build relationships and improve integration of care

AND…there is/are

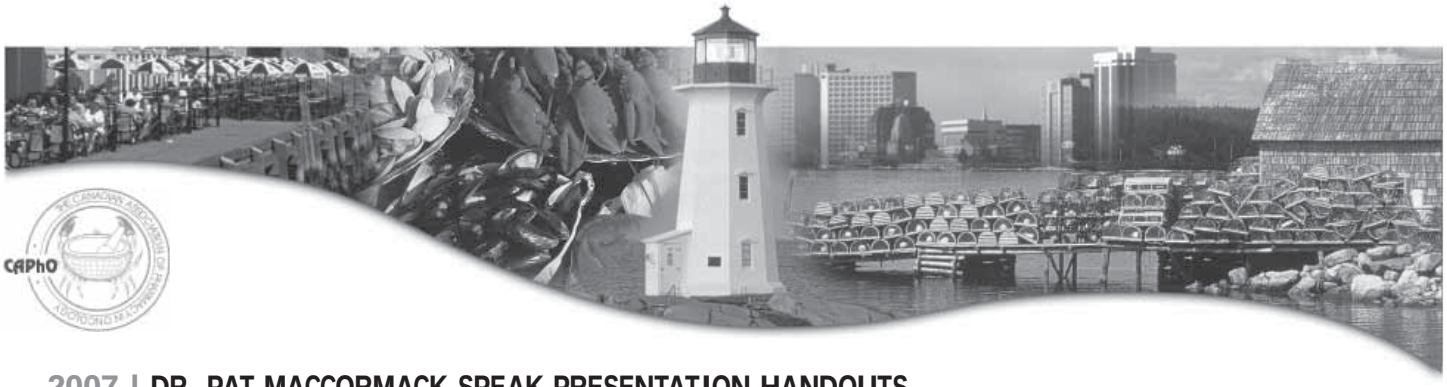
- Increase in cancer d/t aging population
- HR shortages
- More treatments
- More effective treatments

Leadership is needed to build relationships and improve integration of care

As well as…

- Higher profile of FPs & primary care in shared care
- In primary care, growth of service around:
  - screening,
  - prevention,
  - follow-up care
- Evidence that FPs provide high quality follow-up care

Leadership is needed to build relationships and improve integration of care



Outcome: Better Patient Care

Specific goals to ensure:

- Achieve better integrated care for **patients**
- Improve information sharing for **physicians**
- Enhance cancer care knowledge of FPs
- Build relationships
- Promote role of primary care cancer diagnosis and treatment

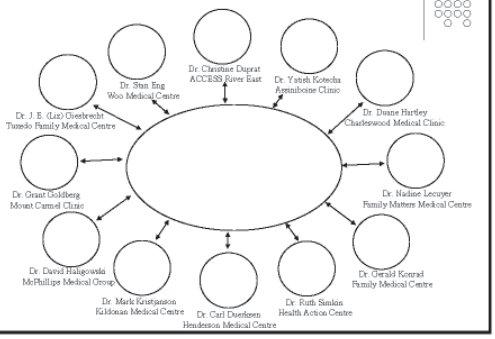
Leadership is needed to build relationships and improve integration of care

Recruiting for the Lead Physician Model

- **Enhance knowledge (individual level)**
- **Translate knowledge (clinic level)**
- **Impact patient care (system level)**

Leadership is needed to build relationships and improve integration of care

Recruitment… The UPCON Network



Back to the Basics

Education

Information

Relationship

Education
Lead Physicians (Individual level)

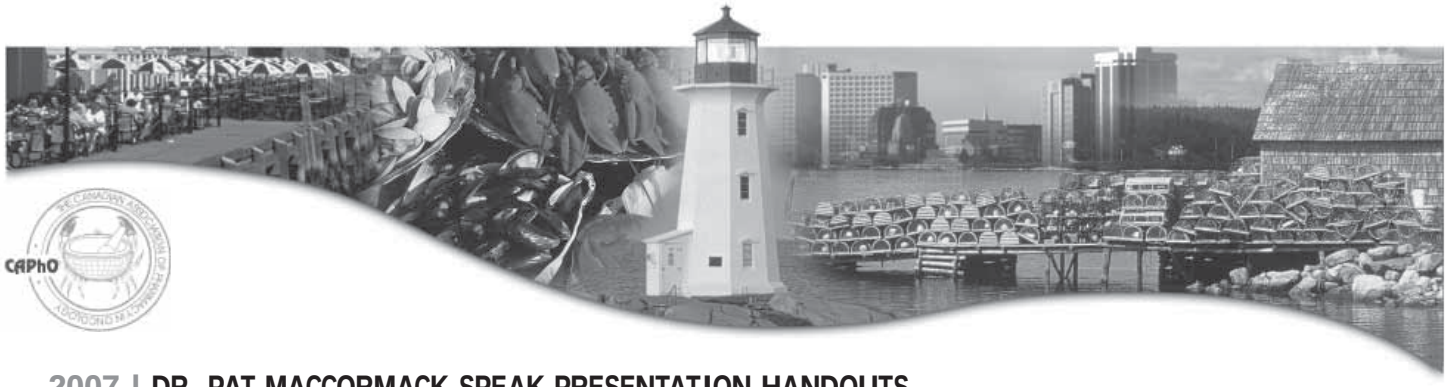
- **Orientation and assessment**
  - Why are we here?
  - Navigating the system
- **14 small group learning sessions**
  - Mainpro-C accreditation
  - Case based sessions – FP and Guest Expert
- **Clinical Exposure**
  - ½ day clinical partnerships

Leadership is needed to build relationships and improve integration of care

Education
UPCON Clinics (Clinic level)

- **UPCON Pearls**
- **Lunch 'n Learn Sessions**
- **Annual full day symposia for FPs & RNs**
- **UPWords newsletter**
- **Easy access to CancerCare specific contacts**

Leadership is needed to build relationships and improve integration of care



Sharing VMO / OpTx
Information Sharing (System level)

- Supplied hardware and internet
- Trained 75 UPCON clinic staff
- Linked 3000 patient charts with UPCON clinics:
  - **Makes a difference in care**
  - **2/3 report access as beneficial**
    - **Notes, labs, meds**

Relationship
Creating new ground

- **Surveys about shared care**
- **Bear Pit Sessions June 05 & March 07**
  - **UPCON Fax sheets**
  - **Accessibility Initiative**
    - UPCON FPs
    - Oncologists
- **Marketing at CCMB**

Leadership is needed to build relationships and improve integration of care

Marketing & Relationships at CCMB

- **Two campaigns**

  Who's your family doctor?
  2003 - 42% charts
  2006 - 81% charts

  Seen your family doctor lately?
  Placed >155 patients with new FPs
- **UPWords newsletter**
- **Use of Guest Experts**

Promoting Shared Care
Communicating with each other

Sample note excerpt:

The patient will return in two weeks for a further discussion of her treatment options.

Dr. Sri Navaratnam
Medical Oncology
Phone 787-3595
Fax 786-0196
If urgent 931-2824

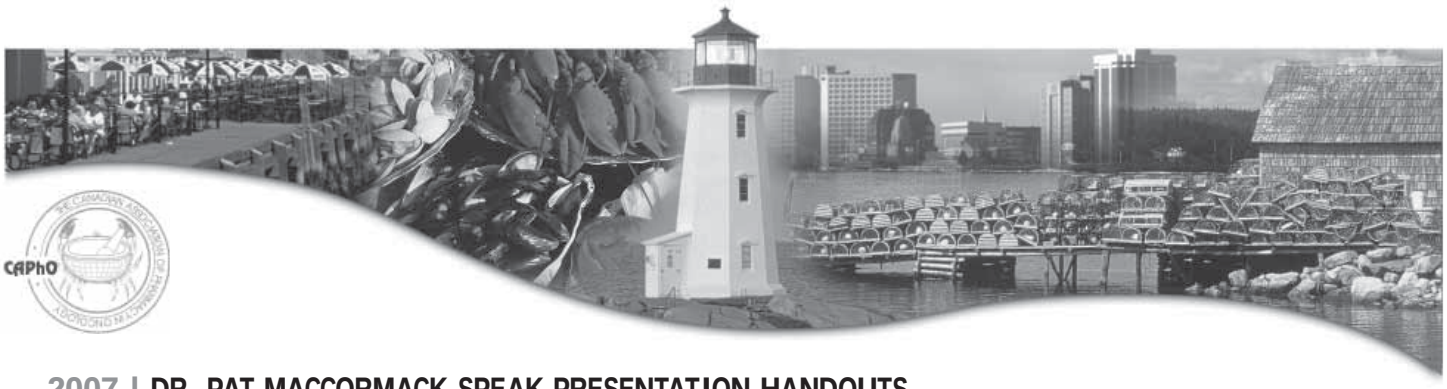
Leadership is needed to build relationships and improve integration of care

Supporting our Relationships

- **New website for physicians & PHC providers**
- **CCMF Scholarships in Primary Care Oncology**
- **CancerTalk - our provincial newsletter**

How Did We Do???
Program Evaluation

1. **UPCON Clinic Physician Survey**
2. **FP Comparison Survey**
   UPCON and non-UPCON FPs



UPCON Clinic Physician Survey

Survey Methodology

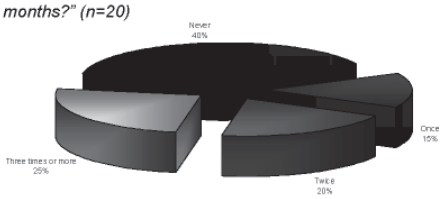
- Probe Research surveyed FPs in 12 UPCON medical clinics
- Phone interviews in the summer of 2006
- In total 29/86 physicians (34%) completed the survey
  - 8 Lead Physicians
  - 21 Non-Lead Physicians

Respondent Profile

	Respondents (n=29) %
Physician Status	
Lead Physician	28
Non-Lead	72
Familiarity with UPCON	
High	52
Medium	21
Low	28
Received OpTx Training	
Yes	55
No	45

Seeking Help from Lead Physician

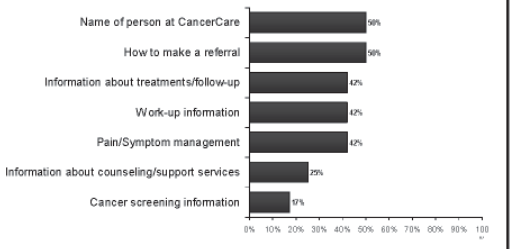
"How many times have you sought information or advice regarding cancer-related issues and treatments from your UPCON lead physician over the past 12 months?" (n=20)



Base: Non-Lead Physicians

Information Sought from Lead Physicians

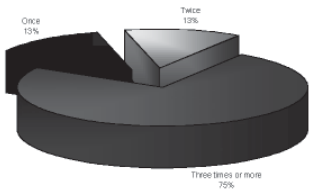
"Which of the following types of information or advice were you looking to obtain?" (n=12)



Base: Non-Lead Physicians

How Lead Physicians See It

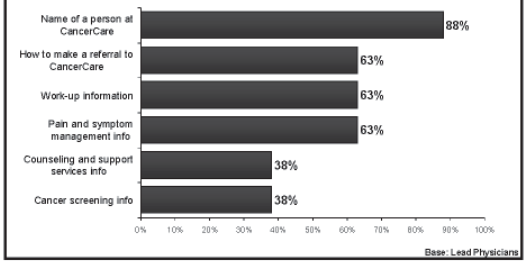
"How many times have colleagues sought you out for information or advice regarding cancer-related issues and treatments over the past twelve months?" (n=8)



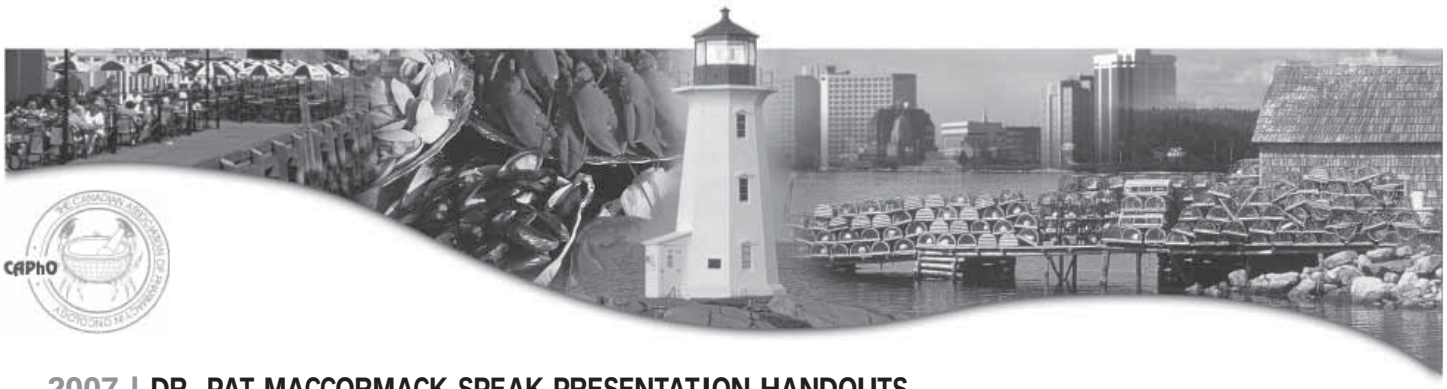
Base: Lead Physicians

Information Sought from Lead Physicians

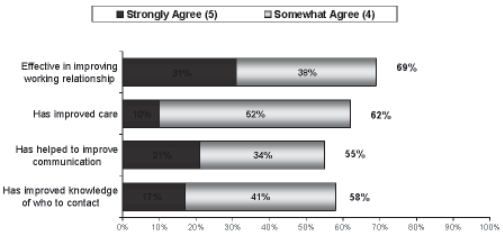
"Which of the following types of information or advice were they looking to obtain?" (n=8)



Base: Lead Physicians



Overall FP Evaluation of UPCON

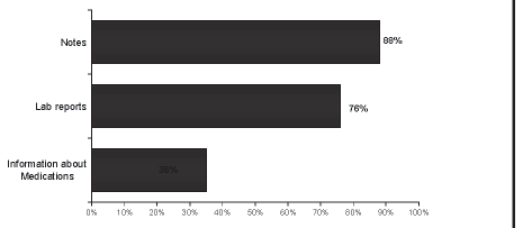


Use of Cancer EHR - OpTx

2006 usage

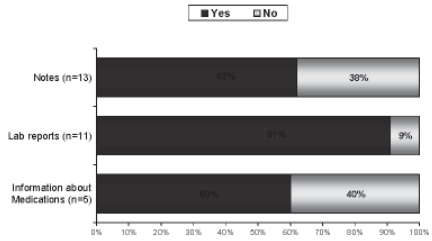
- Nine of 13 clinics use
- Range 2-61 log-ins per clinic
- Mean
  - 25 log-ins per year or
  - 2 per month in clinics using
- Median
  - 12 log-ins per year or
  - 1 per month in clinics using
- 56% of log-ins by Lead FPs

Information Sought from the OpTx System



Base: N=17 Used OpTx in Past 12 Months

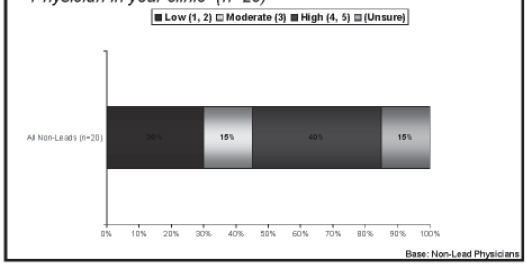
Difference Made to Patient Care?



Base: Successfully found specific types of information in OpTx

Usefulness of Having an UPCON Lead Physician in the Clinic

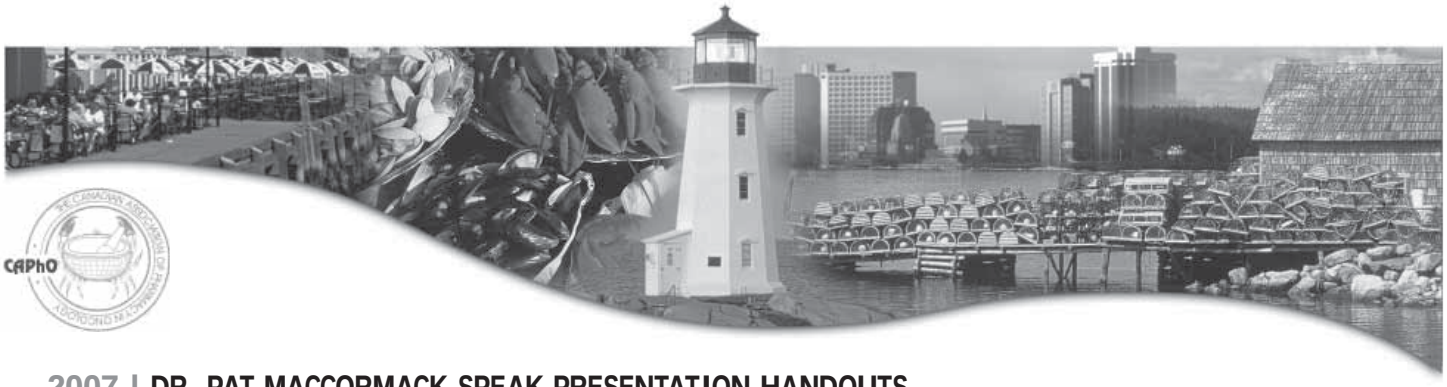
"On a scale of 1 to 5, with 5 being very high, please rate how useful it has been to have an UPCON Lead Physician in your clinic" (n=20)



Base: Non-Lead Physicians

Physician Mail Survey

- Purpose:
  - Track perceptions about collaborative care of cancer patients over time
  - UPCON vs non-UPCON FPs in Winnipeg
  - Sept 2004, Sept 2005, May 2007
- Survey adapted from
  - Picker Institute
  - Client Perception of Coordination of Care



Methods

- Sample Population
  - 82 FPs in UPCON clinics
  - 228 other FPs (in Winnipeg only) randomly selected from CP&S register
- Four mail contacts with respondents
- Approved by U of Manitoba REB

Response rate

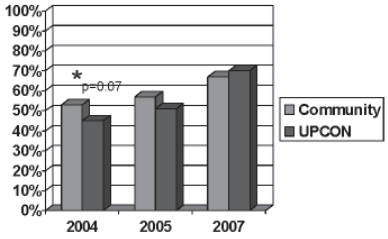
- Baseline survey (2004)
  - 44% Response n=133 [48 UPCON + 85 Other]
- Second survey (2005)
  - 32% Response n=86
- Third survey (2007)
  - 37% Response n= 114 [38 UPCON + 76 Other]

Results

UPCON respondents as a group are

- Less likely to work fee for service
- More likely to be in community health centres or academic teaching units
- Have fewer years in practice
- **More critical of CCMB-FP collaboration at baseline**

I feel my FP role is valued by the care providers at CCMB

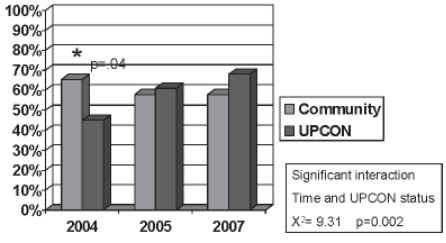


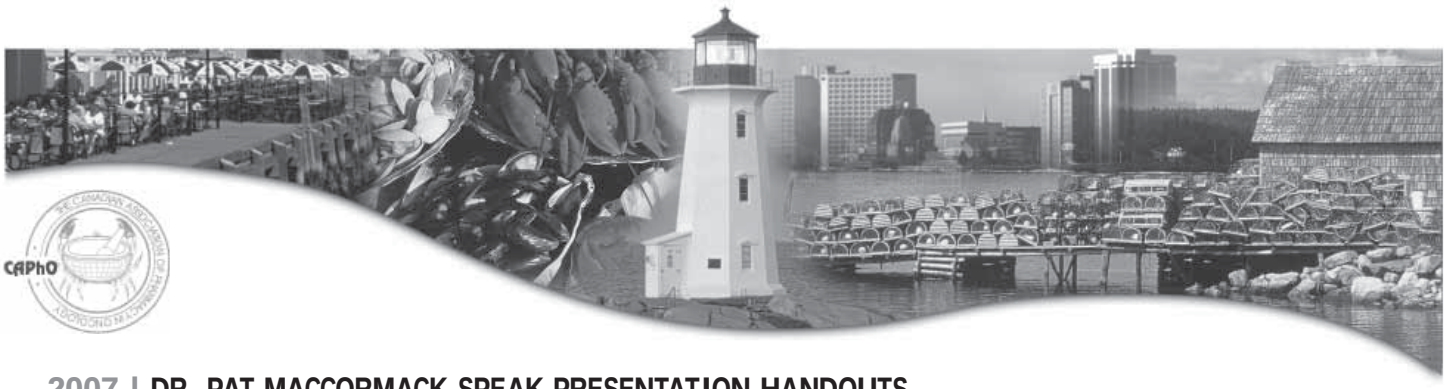
Scale Development: Collaboration

- Felt informed about changes made at CCMB in meds or treatments
- *Aware of the results of tests done at CCMB*
- Felt informed about changes in pts' health status
- *Clinical notes available when needed*
- Clear about who's responsible for what
- *Good overall coordination of care*

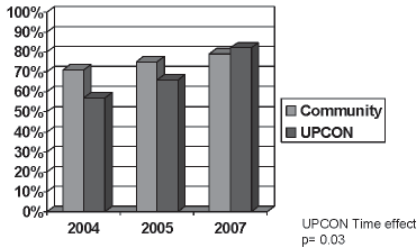
- All factors loaded at 0.50 or more
- Alpha for scale 0.82

Clear about who is responsible for what aspects of care





Good coordination of care between CCMB and my clinic



UPCON Time effect
p= 0.03

Results

- UPCON clinics were significantly more critical at baseline-perhaps why the project interested them in the first place
- UPCON had real impact on FPs perceptions of coordination of care and communication
- The intervention succeeded only in making their views the same as control FPs!

Limitations

- Survey does not clarify which UPCON interventions in particular were effective
- Response rate of 40% is low
- Contribution of Lead UPCON FPs to improvements seen not yet analyzed: they may account for a good part of the change

Where do we go from here?

- **What do we know from our experience?**
- **How do we take what we know and use it?**
- **Do the needs of primary care differ substantially from region to region?**
- **Who needs to do this?**

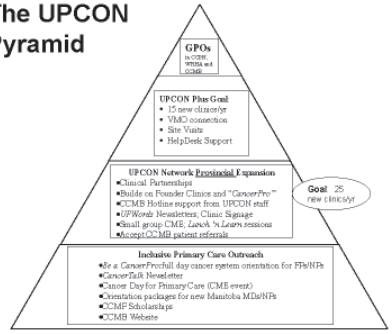
Leadership is needed to build relationships and improve integration of care

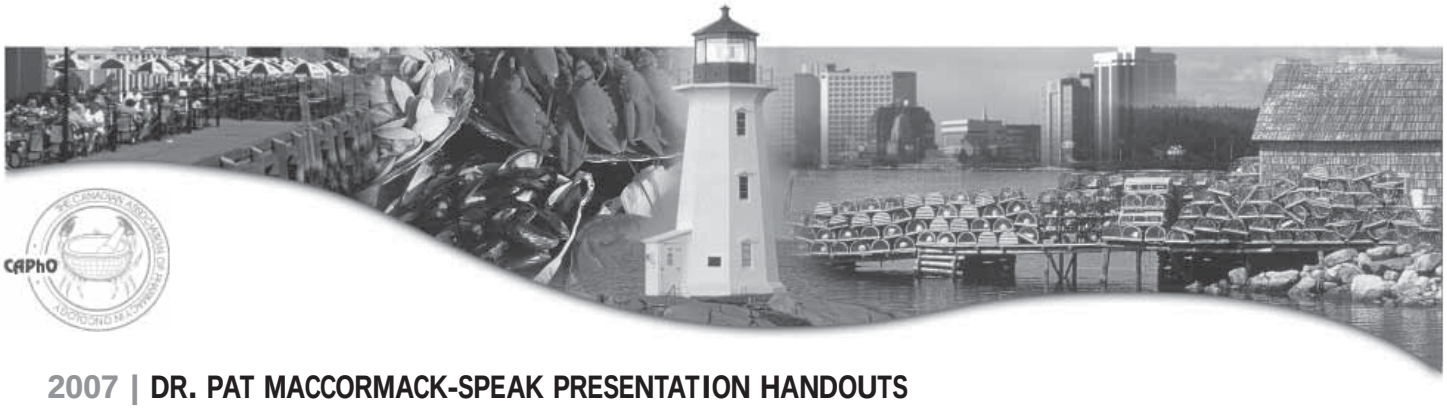
Building a Foundation for Expansion

- Community Outreach Strategy
  - **GO sessions 3 x year**
  - **25 FP/NPs per session**
  - **Rural/Northern focus**
  - **Focus on cancer system & navigation; Early diagnosis, referrals, follow-up**

Leadership is needed to build relationships and improve integration of care

The UPCON Pyramid





2007 | DR. PAT MACCORMACK-SPEAK PRESENTATION HANDOUTS

2007 | NOPS SPEAKER

DR. MARGOT BURNELL
Medical Oncologist, Saint John Regional Hospital

BIOGRAPHY

Dr. Margot Burnell is a medical oncologist practising in the Department of Oncology at the Saint John Regional Hospital in Saint John New Brunswick. She obtained her medical degree from the University of Western Ontario and did her residency in Internal Medicine and Medical Oncology at the University of Toronto. Upon completion she did a Fellowship in Medical Oncology at the Royal Marsden Fulham Road London UK. She has been practicing in Saint John for 20 years and is actively involved in both clinical practice as well as clinical research. She is currently a member of the NCIC-Breast Site Committee and the NCIC Clinical Trials Committee. She is a Co-Principal Investigator of MA-21.

SYNOPSIS

ADVANCES IN THE TREATMENT OF BREAST CANCER: RESULTS OF THE MA.21 STUDY

Saturday, October 27th, 15:35 - 16:35

Objectives:

1. To review the background of adjuvant breast cancer chemotherapy .
2. To review the design and results of NCIC CTG MA21. A PHASE III ADJUVANT TRIAL OF SEQUENCED EC + FILGRASTIM + EPOETIN ALFA FOLLOWED BY PACLITAXEL VERSUS SEQUENCED AC FOLLOWED BY PACLITAXEL VERSUS CEF AS THERAPY FOR PREMENOPAUSAL WOMEN AND EARLY POSTMENOPAUSAL WOMEN WHO HAVE HAD POTENTIALLY CURATIVE SURGERY FOR NODE POSITIVE OR HIGH RISK NODE NEGATIVE BREAST CANCER.
3. To discuss the management of side effects related to each of the chemotherapy regimens.
4. To provide an overview of clinical decision making in the adjuvant setting.
5. To discuss the clinical relevance of MA21.

PRESENTATION

Speaker handouts for this presentation will be available onsite.

2007 | NOPS SPEAKER

CAROLYN BORNSTEIN
BScPhm, RPh, ACPR, FCSHP

BIOGRAPHY

Carolyn is a staff pharmacist at Southlake Regional Health Centre in Newmarket, Ontario. Two years ago she was project leader for the complete review and revision of the Pharmacy Department's policies and procedures for Compounding Sterile Preparations and Chemotherapy with respect to USP Chapter 797, the NIOSH Alert 2004, CAPhO, ASHP and CSHP standards and guidelines. The project included a certification program for pharmacy staff on sterile IV preparation. Carolyn has presented on these topics at National and Provincial conferences and in hospital pharmacy departments across Canada.

Carolyn graduated from the Faculty of Pharmacy, University of Toronto, completed a residency at Mount Sinai Hospital and has worked in hospital pharmacy ever since. She is currently the President of the Canadian Society of Hospital Pharmacists and was recently granted the CSHP Fellow designation.

SYNOPSIS

NEW STANDARDS FOR STERILE PRODUCTS- 797 AND BEYOND... *Saturday, October 27th, 15:35 – 16:35*

The goal of this session is to introduce pharmacists to USP Chapter <797>, the first practice standards in U.S. history for sterile pharmacy compounding and the how they can be incorporated into the procedures for the preparation of chemotherapy.

Recommended standards using evidence-based knowledge now exists for sterile pharmacy compounding. Compliance with the chapter's standards will control contamination in aseptic processing of compounded sterile preparations. Everything from preparation, labelling, dispensing, storage and delivery are addressed.

All standards are based on the microbial contamination risk levels assigned to the sterile preparations prepared in your facility. The designations of Low risk (level 1), Medium risk (level 2) and High risk (level 3) are based on the complexity of the procedure (number of manipulations), the sterility (or absence of) of the components, the physical facilities where preparation takes place and the duration of storage.

Risk level will then dictate the physical layout/requirements of the sterile preparation area (including the frequency and degree of cleaning/disinfection), garbing requirements, the training of personnel, the frequency of environmental monitoring, the aseptic technique media-fill verification, end-preparation evaluation testing and the beyond-use date assigned.

Critical quality assurance includes personnel education, training, evaluation and validation, environmental monitoring, process validation/verification and end-preparation testing.

But considering the risks of handling and preparing chemotherapy, can the standards of USP Chapter 797 be applied to the oncology pharmacy? What are the unique challenges of incorporating these recommendations into this specialized area?

Goals and Objectives of the Presentation:

1. To introduce pharmacists to USP Chapter <797>, the first practice standards in U.S. history for sterile pharmacy compounding.

2. To teach pharmacists how to determine the contamination risk levels of the sterile preparations provided by their facilities.

3. Suggestions for how to incorporate USP Chapter <797> standards into the chemotherapy preparation area without compromising the safety of the staff and patients.

Self – Assessment Questions:

1. What is the hard-fast definition of a High Risk level sterile preparation?

2. What is a beyond-use date and how does it differ from an expiration date?

3. What is the most significant impact of implementing USP 797 standards in the preparation of chemotherapy/hazardous drugs?

4, What is USP Chapter <797> and how do I implement it?

FOR CCCEP – References for presentation

1. USP Pharmacists' Pharmacopeia, 2005

2. Buchanan EC, Schneider PJ. Compounding Sterile Preparations, 2nd edition (2005), ASHP

3. Introduction to USP Chapter 797 http://www.ashp.org/bestpractices/Chapter797-SterileCompounding.pdf

4. Discussion Guide for Compounding Sterile Preparations, American Society of Health Systems Pharmacists, 2004. Accessed at: http://www.ashp.org/SterileCpd/797guide.pdf

5. ASHP Guidelines for Quality Assurance for Pharmacy prepared Sterile Products. Am J Health –Syst Pharm. 2000;57:1150-69. Accessed at: http://www.ashp.org/bestpractices/drugdistribution/Prep_Gdl_QualAssurSterile.pdf

6. An update on USP Chapter 797, The New National Standard for Sterile Preparation, L. Trissel accessed at: http://www.ashp.org/SterileCpd/USP797_Update_Trissel.pdf

7. ASHP Self-assessment Tool for Compounding Sterile Preparations, An online primer for determining compliance with USP Chapter 797, 2004. ASHP website. The link is: http://www.ashpbestpracticessat.com/Print_Version_ASHP_797_Assessment.pdf

8. USP Chapter 797: Establishing a Practice Standard for Compounding sterile Preparations in Pharmacy, KastangoES, Bradshaw BD. Am J Health-Syst Pharm.2004;61:1928-38 Accessed at: http://www.ajhp.org/cgi/reprint/61/18/1928.pdf

9. A Primer on USP Chapter <797> "Pharmaceutical Compounding – Sterile Preparations" and "USP Process for Drug and Practice Standards, Newton DW. Trissel LA. IJPC 2004;8(4):251-263 accessed at: http://www.nhianet.org/docs/usp_797_primer.pdf

10. Proposed revisions to USP Chapter 797 Pharmaceutical Compounding - Sterile Preparations. Accessed at: http://www.usp.org/healthcareInfo/pharmInfo/revisions797.html

11. Blueprint for Implementing USP Chapter 797 for Compounding Sterile Preparations, Kastango ES. Am J Health-Syst Pharm. 2005;62:1271-88 accessed at: http://www.ajhp.org/cgi/reprint/62/12/1271.pdf

12. ASHP, 797 Compliance Advisor, Kastango ES. Accessed at http://www.797complianceadvisor.com

2007 | CAROLYN BORNSTEIN PRESENTATION HANDOUTS

New Standards for Compounding Sterile Preparations – USP Chapter 797 and Chemotherapy Preparation

Carolyn Bornstein BScPhm, ACPR, FCSHP

SOUTHLAKE

NOPS October 2007

Goals and Objectives

1. To introduce you to USP Chapter 797, the U.S. practice standards for sterile pharmacy compounding
2. To describe how to determine the contamination risk levels of sterile preparations and their subsequent beyond-use dating (BUD)
3. To review the unique challenges of implementing USP Chapter 797 standards in the Oncology Pharmacy

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Pre-existing *Voluntary* Standards for Sterile and Nonsterile Compounding in Pharmacies

- 1970s – National Coordinating Committee on Large Volume Parenterals (NCCLVP)
- ASHP – Technical assistance bulletins (90's)
  - QA when compounding sterile preparations; revised 2000
- 1995 - USP Chapter 1206 – Sterile Drug Products for Home Use
- 2000 – Health Products and Food Branch Inspectorate – Manufacturing and Compounding Drug Products in Canada – currently awaiting final revision

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Despite all these standards, there is poor compliance!

- 2 U.S. surveys (1995 and 2002) revealed few equipped pharmacies and even less performing critical quality assurance
- 2002 survey revealed only 5.2% compliance with garbing

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Perception:

Recommendations are unnecessary, excessive, costly, time-consuming and lack evidence to support them

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USP Chapter 797 provides…

- A uniform code of practice using evidence-based knowledge
- Quality controls necessary for patient safety in the compounding of sterile drugs

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USP Chapter 797

- The United States Pharmacopeia and The National Formulary Service (USP)
- Independent, science-based public health organization
- USP Chapter 797 - released Jan 2004
- First practice standards for sterile pharmacy compounding in US history
- 1-999 are standards, 1000+ are guidelines

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Impact of USP Chapter 797

- JCAHO – requires gap analysis and action plan with reasonable timelines (Jan 2008)
- FDA enforcement is debatable (legally)
- Pharmacy State boards considering
- Legal counsel of the hospital - lawsuits
- Significant costs of compliance a major issue

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USP Chapter 797 REVISIONS*

http://www.usp.org/USPNF/pf/generalChapter797.html

- USP <797> Expert Review Committee
- Revisions released Aug 2006
- 2500 pages of comments from 300 stakeholders
- Official 797 Revisions - 14 to 23 sections (soon)
- To include: hazardous drugs and radio pharmaceuticals, environmental design and control, immediate use, garbing
- Still remaining: sections on disinfectants, cleaning and environmental monitoring

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Where can I find USP Chapter 797?

- ASHP website www.ashp.org
- USP website www.usp.org
- $210 USD
- 4 supplements in 2005

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What is the Purpose of 797?

- To protect patients by regulating facilities, equipment, work practices
- To ensure the **sterility and accuracy** of extemporaneously CSP's
- **Patient safety**
- Combining **scientific knowledge and professional skill**

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Compounded Sterile Preparations (CSPs)

- Proper preparation, labelling, storage, dispensing and delivery (cold chain)
- Contamination control
- Aseptic processing
- Critical Quality assurance – environmental monitoring, process validation/verification and end-preparation testing

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When does USP 797 apply?

- Applies to ALL pre-administration manipulations (eg. RNs, MDs, Pharmacy)
- Every pharmacy that compounds sterile preparations (product vs preparation)
- Whether you prepare ONE per MONTH or 100 per DAY, you MUST COMPLY (US)
- Hazardous drugs/chemotherapy was not in the original Chapter 797, but was included in the proposed revisions of Aug 2006

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Where do you start?

- Review the sterile preparations you compound and determine their RISK LEVEL
- Then you can determine which USP Chapter 797 standards apply
- Plan for highest risk level you prepare
- Perform GAP analysis then action plan (self-assessment tool on ASHP website)

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Chapter 797 Sections

1. Responsibilities of Compounding Personnel
2. Microbial contamination Risk Levels
3. Verification of compounding accuracy and sterility
4. Personnel training and evaluation of aseptic manipulation skills
5. Environmental quality and control
6. Suggested topics for SOPs
7. Verification of automated compounding devices

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Chapter 797 Sections...

8. Finished-preparation release checks and tests
9. Storage and beyond use dating
10. Maintaining product quality and control after preparation leaves the pharmacy
11. Patient or caregiver training
12. Patient monitoring and adverse-event reporting
13. Quality Assurance Program

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Responsibilities of Compounding Personnel

- Educated, trained, skilled (certified)
- Ingredients – identity, quality, amount
- Open/partial vials stored appropriately
- Minimize bacterial endotoxins
- Proper and adequate sterilization (within 6hr)
- Equipment: clean, accurate, validated
- Consider potential harm from added substances (handling precautions)

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Responsibilities of Compounding Personnel

- Packaging – appropriate for sterility, stability
- Maintain sterility of pre-sterilized items
- Labels: appropriate, complete
- Beyond use dating: appropriate, scientific criteria based
- Compounding procedures correct
- Compounding deficiencies – identified, corrected
- Separate compounding from quality evaluation

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Chapter 797 RISK LEVELS

- Based on the potential for microbial contamination
- Affected by:
  - Complexity of the preparation/procedure
  - Environment/physical facilities
  - Storage period – time until administration

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The RISK LEVEL then dictates,

- Compounding environment (physical facilities)
- Personnel training
- Personnel garbing (PPE)
- Frequency of environmental monitoring
- Aseptic technique media-fill verification
- Type of end-preparation evaluation tests
- Beyond-use date (expiration dates) – chemical stability AND microbial sterility

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RISK LEVEL - DEFINITIONS

Risk Level 1 (LOW)	Risk Level 2 (MEDIUM)	Risk Level 3 (HIGH)
- Usually a 1:1 preparation stored at RT and used within 28 hours - Unpreserved and sterile for ONE patient or for more than one patient WITH preservatives - Closed system, basic, simple aseptic transfers and manipulations (phaseal considered a closed system)	- Batch prepared without preservatives for more than one patient or to be administered over several days - Pooling multiple sterile commercial products for use by multiple patients or one patient multiple times - Complex or numerous aseptic manipulations of sterile ingredients or takes significant time to prepare	- Nonsterile ingredients components, containers, or equipment before terminal sterilization Combining multiple ingredients (sterile or nonsterile) by using an open system transfer before terminal sterilization Contaminated or considered high risk for becoming contaminated More than 6 hrs between compounding & sterilization

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RISK LEVEL - EXAMPLES

Risk Level 1 (LOW)	Risk Level 2 (MEDIUM)	Risk Level 3 (HIGH)
- Reconstituting and transferring Cefazolin to a minibag Preparing single drug in less than 25 doses Most chemo? Batching?	- any IV with more than 3 additives - Batching 25 or more doses - using an ACD Ambulatory infusion devices Protocols with 3 drugs in same bag	- Morphine infusions prepared from morphine powder - Alum bladder irrigation - Nuclear pharmaceuticals (requiring terminal sterilization)

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RISK LEVEL - FACILITIES

	Risk Level 1 (LOW)	Risk Level 2 (MEDIUM)	Risk Level 3 (HIGH)
LAFH	ISO Class 5 (previously 100)* Chemo - BSC	ISO Class 5 (previously 100) Chemo - BSC	ISO Class 5 (previously 100) Chemo - BSC
Clean room	Not required (Chemo – ISO Class 7* neg pressure)	ISO Class 7* (positive pressure) (neg pressure - chemo)*	ISO Class 7* (positive pressure) (neg pressure – chemo)*
Ante-room	Not required (chemo – ISO class 7*)	Preferred but separate room not required – ISO Class 8* (chemo - ISO Class 7*)	Separate anteroom required – ISO Class 8* (chemo – ISO Class 7*)

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IMMEDIATE USE*

- 3 or fewer ingredients (including diluent) prepared outside of ISO Class 5 environment
- eg. RN on nursing unit
- To be administered within 1 hour
- No direct contamination occurs
- **NOT a hazardous drug**
- Must be labelled if administered by someone else

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Beyond-Use Dating (BUD)

DEFINITION:

The date (or time) beyond which the sterile preparation MUST NOT be used

- Manufactured vs pharmacy sterile preparation
- based on RISK LEVEL
- All SOPs or worksheets MUST include BUD
- Base the BUD on the drug's chemical stability in conjunction with microbiological limits for patient safety (whichever is SHORTER)

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Beyond-Use Dating

- In absence of sterility testing use 797 BUDs (applies to most chemo)
- If you perform sterility testing on the batch, you can use chemical stability dating (N/A)
- To extend BUD YOU MUST HAVE SUPPORTING DATA (document references)
- Remember to consider stability of IV solution once overwrap is removed
- Exception: prepackaging lipids has 12 hr limit

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Beyond-Use Dating

- Multidose vials with preservative = 28 days* (unless mfr says less)
- Single use vial = 6 hours* (implications for chemo)
- What do we do with chemo partial vials that do not contain preservatives??
- ADD-Vantage and Mini-Bag Plus, attached and activated system – currently Chapter 797 considers them Risk Level 1 vs mfr FDA labelling (a revision issue – may revert to mfr recommendations)

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Beyond-Use Dating

	Risk Level 1 (LOW)	Risk Level 2 (MEDIUM)	Risk Level 3 (HIGH)
Room temp	48 hours	30 hours	24 hours
Fridge	14 days	7 days (9 days*)	3 days
Freezer	45 days (-20C)	45 days (-20C)	45 days (-20C)

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PARTICLES = CONTAMINATION

- Particles are both non-viable and viable (eg. carry bacteria)
- Particles generated by:
  - Materials (ceiling tiles,clothing)
  - Movement (air, traffic, people)
  - Electrical static (electronics)
  - AND…..

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… PEOPLE!!!

Generated from:

skin, hair, nails, cosmetics, clothing

Sitting still = 100,000/minute

Sit/stand = 250,000/minute

Walking 2 mi/hr = 5 million/minute

1 billion skin flakes shed per day

AN OPEN DOOR = billions per minute

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Personnel Restrictions??

Staff MUST NOT PREPARE CSPs if they have:

- Respiratory symptoms (masks are not impermeable)
- Serious rashes or sunburn (high skin shedding)
- Artificial nails/nail polish
- Makeup ("flaking" makeup*)

MUST be able to cover All facial hair

For Chemo prep area NO Contact lenses

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Personal Protective Equipment
PPE = Garbing

- Determined by RISK LEVEL
- Add-on as RISK LEVEL increases
- Scrubs, gowns, gloves, masks, hair bonnets, shoe covers – NO jewellery
- Sequence specified*(bottom up):
  - Scrubs, wash hands, shoe covers, hair bonnet, mask, 30 second handscrub, gown, gloves
  - Different PPE re: chemo (eg double gloves)

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Anteroom – ISO Class 8*

- separate room preferable
- If one room – demarcation line
- Chemo - separate and ISO Class 7*
- NO cardboard, or paper/particle shedding materials (eg. paper towels)
- Garbing area – NO food/drink
- Wipe all product with 70% ISA prior to entering clean room/buffer zone

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Clean room – ISO Class 7*

- Uncluttered, preferably separate
- Seamless, nonporous, washable materials (ceiling tiles, windows, doors, flooring, paint)
- All materials resistant to sanitizers (eg. chairs)
- Positive pressure HEPA filtered air (99.97%) TYPE C preferred (Chemo neg pressure)*
- Engineering controls: air flow (at least 12 exchanges/hr), velocity, humidity, temperature
- NO sinks or floor drains
- NO fridges, computers, printers

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Cleaning the CSP areas – SOP

- Germicidals recommended (virucidal preferred) – alcohol won't get spores
- DON'T REFILL alcohol/detergent bottles
- Rotate agents - q3months
- Similar to cleaning the O.R.s
- Dedicated mops, buckets – must GARB
- DAILY: cleanroom and anteroom floors
- WEEKLY: cleanroom walls, work surfaces
- MONTHLY: cleanroom ceiling, storage area/shelving in both rooms, fridge interior

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Environmental Monitoring

- Processes, environmental controls, sanitation practices working?
- Air Quality– q6months (ISO Class testing)
- Air Sampling – monthly (LOW & MED Risk), weekly for HIGH Risk
- Surface Sampling/Fingertip - plates, slides, paddles, swabs – freq based on volumes and risk
  - **(Low/med)<100/mo= q6mo, 101-300=q3mo, >300=qmonth; (HIGH risk) >3/mo = qmonthly**
  - **Revision suggesting q6months x4 drugs/tracers**
- Baseline - monitor (alert levels Chapter 1116)
- Can be done in chemo – desktop tests available

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CSP Worksheets – Include:

- Risk level designation
- Sterility testing, if required
- Ingredients, Equipment, Procedure
- Manufacturer and corresponding DIN
- WHMIS/MSDS information
- Beyond Use Dating
- Storage information
- Sample label
- For nonsterile ingredients – cert of analysis info
- References

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Staff Training - CERTIFICATION

- All pharmacy personnel working in CSP area
- Didactic and experiential training
- Competency – written and practical testing
- Media fill testing recommended to validate
- Frequency/evaluation depends on risk levels
  - **Level 1&2 – q6-12mos, Level 3- monthly**
- Certification of aseptic technique
- Document all training and retraining
- All chemo personnel should do this first!
- **Inservice housekeeping personnel too!**

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Training Tools & Techniques

- ASHP Compounding Sterile Preparations manual, 2nd edition (incorporates USP Chapter 797) ($75 ASHP members)
- A.P.E.S. – videos on CSHP website (www.cshp.ca) aseptic technique
- Onsite training – eg. Baxter

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ASHP Compounding Sterile Preparations 2.0 multimedia Training – online testing and documentation (CD demo) $750 USD ashp.org

- Module One
  - Focuses on technicians and pharmacists who prepare sterile preparations
- Module Two
  - Discusses supervisors' responsibilities for quality control
- Module Three
  - Covers quality assurance practices

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ASHP Basics of Aseptic Compounding Technique Video Training Program (NEW!) $280 USD ashp.org

- For entry level pharmacy technicians working in a lab setting. This program is a basic how-to demonstration of aseptic technique.
  This program focuses on such fundamentals as:
- - Proper washing
- - Gloving
- - Gowning
- - Proper syringe drawing techniques
  ...and more!

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Valiteq – Aseptic Technique 5 Part Video (DVD or VHS) $450 CDN

The video parallels the Compounding Manual, and is designed to reinforce the training concepts and procedures presented in the manual. The Training Video is available either as a 3 VHS set, or a fully authored 2 DVD set. Total program run time is 1 hour, 53 minutes.

www.valiteq.com

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Certification/Training Tools

- Updated and is now **fully compliant** with the new USP <797> and JCAHO standards. This program demonstrates procedures for cytotoxic and hazardous drug preparation, administration, spill cleanup, and waste management, in order to help reduce risk.
- DVD and workbook included
- $250 USD for ASHP members

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Training Tools & Techniques

- Review of training tools by Clyde Buchanan (Dec 2005) online – Midyear presentation on Personnel Training, at: http://www.ashpadvantage.com/website_images/pdf/2006_mcm_handouts/USP797_Steps_to_Compliance.pdf
- Powerpoint presentations on proper garbing, aseptic technique, etc. (inhouse with photos)

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Validating Aseptic Technique

1. Repeat procedure with growth media (eg. TSB) as the component instead of additives
2. Incubate an entire sample of CSP
3. Sample drawn from one or more of batch and add to growth media, then incubate

WHEN?

- **Test at "busiest" time of day; repeat x 3 days**
- **Incubate 14 days at 25C OR 7 days 25C followed by 7 days 35C (FDA recommended)**

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Media Fill Validation - annually

- LOW Risk
  - 3 sets of 4 – 5 mL aliquots into 3 – 30 mL sterile glass vials. Seal. Incubate 14 days
- MEDIUM Risk
  - 6 x 100 mL into each of 6 empty viaflex bags
  - Then 2 x 5 mL from one into other
  - 5 mL from each bag into sterile vial. Seal. Incubate 14 days

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Media Fill Validation – HIGH Risk – semi-annually

- Use non-sterile dry powder microbial growth media
- Dissolve 3g in 100 mL water
- Draw up 25 mL into 3 x 30 mL syringes
- Transfer 5 mL from each into sterile vial (Control)
- Affix 0.2micron filter and needle
- Transfer 10 mL into separate sterile vials
- Seal. Incubate 14 days

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Media Fill Test Kits

- Tryptic soy broth kits available (eg. Healthmark, QI Medical, Valiteq, Baxter)
- Powders to reconstitute, ampoules, vials and minibags
- Replicate multiple manipulations
- Frequency based on Risk levels prepared
- Sample size recommended 5%

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Other Chapter 797 Activities

Validation of Storage Conditions
- Monitoring fridge temps – daily, record

Sterilization – filter, autoclave
- Validate: bubble testing, filter integrity, biological indicators

Finished preparation testing
- Visual, weight, sterility, pyrogen testing, analysis

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Quality Assurance is CRUCIAL

- Is everyone doing what they're supposed to be doing?
- Validate changes in procedure (eg. cleaning routine – is it really clean?)
- Valuable information if there's a breach – eg. microbial growth – must examine entire environment/activities, not just the preparation and LAFH

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Special Considerations

- Preparation of hazardous drugs (chemotherapy) is not covered indepth by USP Chapter 797 – in revisions*
- Refer to the NIOSH Alert, Sept 2004 – accessed at: http://www.cdc.gov/niosh/docs/2004-165/
- Also refer to CSHP and ASHP websites for Guidelines on Handling Hazardous Drugs

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What USP 797 does not cover

- Receival and storage of HDs
- Drug preparation
- Drug administration
- Ventilating cabinets (BSC's vs compounding aseptic isolators)
- Decontamination and hazardous waste disposal
- Spill control
- Medical surveillance

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Taking USP 797 into the Oncology Pharmacy....

- Personnel training/certification in aseptic technique
- Maintain a clean, separate, uncluttered and functional sterile prep area to minimize the possibility of contamination
- Visually inspect integrity of all final CSP's
- Review cleaning procedures
- Housekeeping personnel eg. training, PPE, procedures

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Taking USP 797 into the Oncology Pharmacy....

- Review worksheets for completeness
- Review BUD vs stability
- Validate what's being done
- Consider environmental monitoring
- Document workload
- **CLEAN is preferred, but SAFETY COMES FIRST!**

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USP Chapter 797 References

- Resource: ASHP Compounding Centre at http://www.ashp.org/SterileCpd/
- Introduction to USP Chapter 797 http://www.ashp.org/bestpractices/Chapter797-SterileCompounding.pdf
- The ASHP (American Society of Health Systems Pharmacists) Discussion Guide for Compounding Sterile Preparations. Accessed at: http://www.ashp.org/SterileCpd/797guide.pdf
- ASHP Guidelines for Quality Assurance for Pharmacy prepared Sterile Products. Accessed at: http://www.ashp.org/bestpractices/drugdistribution/Prep_Gdl_QualAssurSterile.pdf

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USP Chapter 797 References

- An update on USP Chapter 797, The New National Standard for Sterile Preparation, L. Trissel accessed at: http://www.ashp.org/SterileCpd/USP797_Update_Trissel.pdf
- ASHP Self-assessment Tool for Compounding Sterile Preparations, An online primer for determining compliance with USP Chapter 797, 2004. ASHP website. The link is: http://www.ashpbestpracticessat.com/Print_Version_ASHP_797_Assessment.pdf
- USP Chapter 797: Establishing a Practice Standard for Compounding sterile Preparations in Pharmacy, Kastango and Bradshaw (AJHP 2004) The link is: http://www.ajhp.org/cgi/reprint/61/18/1928.pdf

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References/Resources

- A Primer on USP Chapter <797> "Pharmaceutical Compounding – Sterile Preparations" and "USP Process for Drug and Practice Standards, D. Newton and L. Trissel IJPC 2004;8(4):251-263 accessed at: http://www.nhianet.org/docs/usp_797_primer.pdf
- Blueprint for Implementing USP Chapter 797 for Compounding Sterile Preparations, ES Kastango, AJHP 2005;62:1271-88 accessed at: http://www.ajhp.org/cgi/reprint/62/12/1271.pdf
- ASHP, 797 Compliance Advisor, Kastango ES. Accessed at www.797complianceadvisor.com
- Q&A on Proposed USP Chapter 797 Revisions with E. Clyde Buchanan http://www.ashp.org/s_ashp/docs/files/CRC_FAQ_Proposed_797.pdf

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2007 | NOPS SPEAKER

JACQUES TURGEON
B.Pharm., Ph.D.

BIOGRAPHY

Since spring 2007, Dr. Jacques Turgeon has been appointed Director of Research at the Centre hospitalier de l'Université de Montréal. From 2005-2007 he was Vice-Rector – Research, Université de Montréal and from 2000-2005, he has served as Dean of the Faculté de Pharmacie, Université de Montréal He received his Bachelor degree in Pharmacy in 1983 from Laval University in Quebec City followed by an M.Sc. degree in pharmacokinetics and a Ph.D. degree in drug metabolism from the same institution in 1985 and 1988, respectively. He completed post-doctoral studies from 1988 to 1990 in the department of Clinical Pharmacology, Vanderbilt University in Nashville, USA, under the supervision of Dr. Dan M. Roden. He joined the Faculty of Pharmacy of Laval University in 1990 as an assistant professor. He was promoted to the rank of associate professor in 1993 and full professor in 1998. From March 1999 to May 2000, he was Senior Director of the Pharmacokinetics department at Phoenix International Life Sciences.

SYNOPSIS

PHARMACOGENOMICS 101 *Sunday, October 28th, 09:20 – 10:05*

Dr. Jacques Turgeon, Director of Research, Centre hospitalier de l'Université de Montréal. He received his Bachelor degree in Pharmacy (1983) from Laval University followed by an M.Sc. degree (1985) in pharmacokinetics and a Ph.D. degree (1988) in drug metabolism from the same institution. He completed post-doctoral studies in the department of Clinical Pharmacology, Vanderbilt University (1988-1990).

He has developed expertise in the role of pharmacogenetics in cardiovascular drug actions. He has integrated in his research approaches in vitro (patch-clamp technique, in vitro metabolism and molecular biology) models as well as designed and performed studies in healthy volunteers and patients.

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The National Oncology Pharmacy Symposium 2007

Pharmacogenomics 101

Jacques Turgeon, B.Pharm., Ph.D.
Director, Research Center CHUM

October 28, 2007

CHUM

Genetics/omics & pharmacogenetics/omics: definitions

- OMICS vs ETICS
  - OMICS refers to the study of phenomena taking place at the level of the genome. These phenomena can explain various aspects of intersubject variabilities.
  - ETICS refers to the study of phenomena related to various aspects of intersubject variabilities. These phenomena can be explained by variations at the genome level.
- Genetics is the study of intersubject variability in the presentation of a phenotype (risk for disease, color of the eyes, response to a drug, etc…)
- Pharmacogenetics is the study of intersubject variability in the response to a drug or treatment.

Genomics

- Pertaining to the genome, all of the genetic information possessed by any organism.
- There are, for instance, the human genome, the elephant genome, the mouse genome, the yeast genome, etc. Humans and many other higher animals have two genomes, namely:
  - A chromosomal genome which is in the nucleus of the cell; and
  - A mitochondrial genome which is outside the nucleus in the cytoplasm of the cell.
- Together these two genomes make up the total genome.
- The study of a genome is called genomics.

Genetics

- The scientific study of heridity. Genetics pertains to humans and all other organisms.
- Human genetics today comprises a number of overlapping fields, including:
  - Classical or formal genetics -- the study of the transmission of single genes within families and the analysis of more complex types of inheritance.
  - Clinical genetics – the diagnosis, progonosis and, in some cases, the treatment of genetic diseases.
  - Genetic counseling -- an important area within clinical genetics involving the diagnosis, risk assessment, and interpersonal communication.
  - Cytogenetics -- the study of chromosomes in health and disease.
  - Biochemical genetics – the biochemistry of nucleic acid and proteins including enzymes.
  - Pharmacogenetics -- how genes govern the absorption, metabolism and disposal of drugs and untoward reactions to them.
  - Molecular genetics -- the molecular study of genetics including particularly DNA and RNA.
  - Immunogenetics -- the genetics of the immune system including blood groups, HLA, and the immunoglobulins.
  - Behavioral genetics -- the study of genetic factors in behavior in health and disease including mental retardation and mental illness.
  - Population genetics -- the study of genes within populations including gene frequencies, the gene pool, and evolution.
  - Reproductive genetics -- the genetics of reproduction including genes and chromosomes in germ cells and the early embryo.
  - Developmental genetics -- the genetics of normal and abnormal development including congenital malformations (birth defects).
  - Ecogenetics -- the interaction of genetics with the environment.
  - Forensic genetics -- the application of genetic knowledge, including DNA, to legal matters.

Pharmacogenomics

- The study of how variations in the human genome affect the response to medications.
- The older term "pharmacogenetics" was created from the words «pharmacology» and «genetics» to indicate the intersection of pharmaceuticals and genetics.
- The sequencing of the human genome and the introduction of new technologies have made it possible to analyze multiple genes simultaneously. The newer term "pharmacogenomics" describes such large-scale, often genomewide approaches.
- Pharmacogenomics may permit drugs to be tailor-made for individuals and adapted to each person's own genetic makeup. Environment, diet, age, lifestyle, and state of health all can influence a person's response to medicines, but understanding an individual's genetic makeup is thought to be the key to creating personalized drugs with greater efficacy/safety.
- Pharmacogenomics combines traditional pharmaceutical sciences such as biochemistry with annotated knowledge of genes, proteins, and single nucleotide polymorphisms.

Pharmacogenetics

- The merger of pharmacology and genetics into a field that pertains to the hereditary responses to drugs.
- For example, after the administration of a muscle relaxant drug, a patient may remain apneic for hours due to a genetically determined defect in metabolizing (processing) the muscle relaxant.
- The term "pharmacogenetics" dates to 1962 when Dr. Werner Kalow published "Pharmacogenetics: Heredity and the Response to Drugs."
- Pharmacogenetics is often used interchangeably with the newer term "pharmacogenomics."

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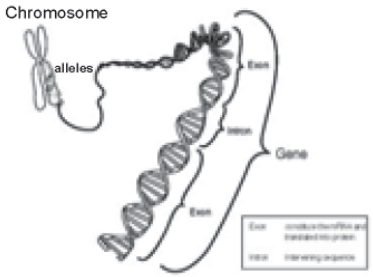
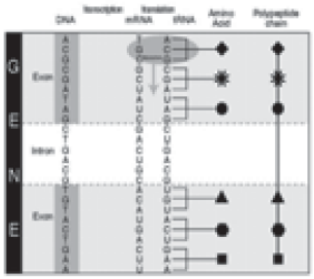
Biotechnologies

- Processes that use biological systems
- Curative *vs* palliative treatments
- Based on DNA information: sequence, use and manipulation

Biotechnologies



Biotechnologies



Biotechnologies

- Recombinant DNA
- Monoclonal antibodies
- Antisense therapy
- Gene therapy
- Rational drug design

Recombinant DNA

- The protein is identified and its amino acid sequence determined.
- The amino acid sequence is used to localize the gene and to isolate it.
- The gene is then incorporated into the DNA of a host cell.
- The host cell is cultured for replication and protein production.
- The protein is collected, purified and formulated for subsequent administration to humans.

Recombinant DNA

Human Insulin	1982	Diabetese
Somatrem	1985	Growth hormone
Interferon alpha	1986	Oncology
Epoetin alpha	1989	Anemia, autologue graft
Alteplase	1990	Myocardial infarction
Oprelvekin	1997	Thrombocytopenia

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Monoclonal antibodies

- A protein is injected in an animal to provoke the formation of antibodies. B lymphocytes are isolated.
- B and T lymphocytes are hybridized and cells obtained put in culture.
- Antibodies produced at their surface are isolated, verified for their specificity, cloned and put in culture again.
- Antibodies produced are purified and formulated for administration to humans.

Monoclonal antibodies

Muromonab-D3	Anti-reject drug
Abciximab	Platelet aggregation
Daclizumab	Anti-reject drug
Anti-HER-2	Breast cancer
Enlimomab	CVA
CenTNF	Rhumatoid arthritis

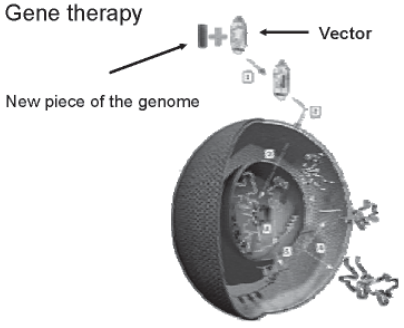
Antisense therapy

- The objective of anti-sense therapy is to block the production of a defective/undesired protein.
- The most frequently used technique consists in the administration of a complementary DNA (cDNA; antisense) to the mRNA of this protein.
- The cDNA and mRNA strongly bind together which prevents the formation of the protein.
- So far, results have been disappointing in HIV, viral infection, cancer, CV disease (restenosis).

Human Genome Project

- To establish a human gene map and DNA structure in cells
- To identify genes involved in several human diseases (Genetics)
- Limitation: To transform this information into drugs or therapies (Pharmacogenetics)

Gene therapy



Biotechnology problems

- Drug preparation
- Drug storage
- Drug administration
- Patient responsability
- Cost
- Reimbursement
- Safety
- Individualized therapy
- Measures of efficacy

Biotechnologies

Pharmacists will skillfully ride the coming biotechnology drug wave into the 21st century, where they will reign as the unchallenged drug therapy experts, designing, dispensing, counseling about and monitoring the effects of medicines in the brave new world of genetic engineering, or,

The biotechnology drug wave will sweep past most pharmacists and biopharmaceuticals, with their short half-lives and unique delivery systems, will largely be dispensed by specialists, most of whom are nonpharmacists.

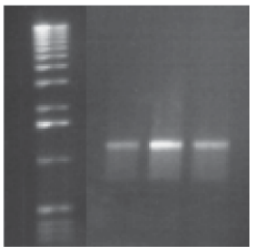
Drug Topics 1992;3:13

Technics in genetic studies

- Blotting
  - Southern
  - Northern
  - Western
- Restriction Fragment Length Polymorphisms
- Polymerase Chain Reaction
- Reverse Transcripase PCR
- Gene chips

Technics in genetic studies: blotting

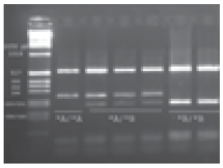
- Blotting
  - Southern (DNA)
  - Northern (RNA)
  - Western (Proteins)



Technics in genetic studies: RFLP

- A restriction enzyme recognizes a specific sequence of nucleotids (GTCT) and cut the DNA or RNA when this sequence is found.

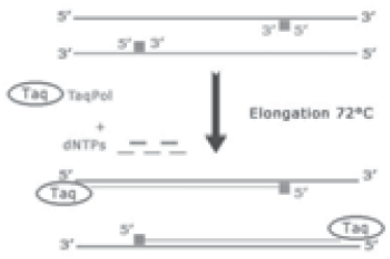
- ACCTCTCTGAAG
- ACGTCTGTGAAG



Technics in genetic studies: PCR

- PCR is a technique for amplifying a specific region of DNA, defined by a set of two "primers" at which DNA synthesis is initiated by a thermostable DNA polymerase.
- Usually, at least a million-fold increase of a specific section of a DNA molecule can be realized and the PCR product can be detected by gel electrophoresis.
- The regions amplified are usually between 150-3,000 base pairs in length.

Technics in genetic studies: PCR



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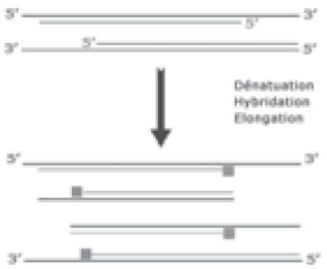
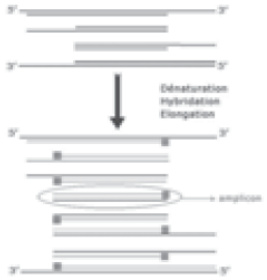
Technics in genetic studies: PCR



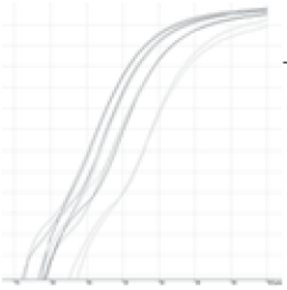
Technics in genetic studies: PCR



Technics in genetic studies: RT-PCR

- RT-PCR (reverse transcription-polymerase chain reaction) is the most sensitive technique for mRNA detection and quantitation currently available.
- Compared to the two other commonly used techniques for quantifying mRNA levels, Northern blot analysis and RNase protection assay, RT-PCR can be used to quantify mRNA levels from much smaller samples.
- In fact, this technique is sensitive enough to enable quantitation of RNA from a single cell.

Technics in genetic studies: RTPCR



This techniques allows for the quantification of RNA present in a cell and could give an indirect measure of the relative expression of a protein.

Technics in genetic studies: GeneChip

- Mutations, or alterations in a gene's DNA, can result in certain diseases.
- It is often difficult to identify and characterize these mutations because most large genes have many regions where a mutation could occur and cause disease.
- Examples of such genes are BRCA1 and BRCA2, which are believed to cause as many as 60% of all cases of hereditary breast and ovarian cancers. In BRCA1 alone, over 500 different mutations have already been discovered.
- The DNA microchip is a revolutionary new tool used to identify mutations in genes like BRCA1 and BRCA2. The chip, which consists of a small glass plate encased in plastic, is manufactured using a process similar to the one used to make computer microchips. On the surface, each chip contains synthetic single stranded DNA sequences identical to a normal gene.

Technics in genetic studies: GeneChip

- DNA from individuals to be tested is labeled with green dye and the DNA containing no mutations is labeled with red dye.
- Both sets of labeled DNA are then inserted into the chip and allowed to hybridize, or bind, to the synthetic BRCA1 or BRCA2 DNA on the chip.
- If the individual does not have a mutation for the gene, both the red and green samples will hybridize with the sequences on the chip.
- If the individual does possess a mutation, the red (normal) DNA will still hybridize perfectly with the DNA on the chip, but the green (individual's) DNA will not hybridize properly in the region where the mutation is located.

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Technics in genetic studies: PCR

Genetics of breast cancer: BRCA1 and BCRA2

- At least five germline mutations that predispose to breast cancer have been identified:
  - BRCA1
  - BRCA2
  - P53
  - Phosphatase and TENsin homolog (PTEN)
  - ataxia telangiectasia mutated (ATM)
- These high-risk mutations account for most of the families with four or more breast cancer cases, 20-25% of familial breast cancer, and 5% of all breast cancers.
- Genotyping strategies can provide information for the establishment of risk for siblings.

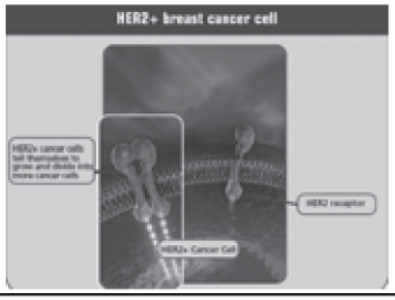
Cancer's hormone receptor and HER2 status

- Hormones such as estrogen and progesterone play a role in the growth of many breast cancers. It is important to know whether the tumor is positive or negative for either of these hormone receptors.
- An estrogen-receptor-positive tumor is called "ER+", and a progesterone-receptor-positive tumor is called "PR+". Tumors that are positive for either of these hormone receptors may benefit from hormonal therapy.
- Similarly, HER2 status can tell a lot about how aggressive the breast cancer is, as well as what treatments may provide the most benefit. HER2 status and hormone-receptor status are not the same thing, and being positive for one does not mean the cancer is positive for the other.

Pharmacogenetics of breast cancer: HER2

- HER2 stands for Human Epidermal growth factor Receptor 2.
- Studies show that approximately 25% of breast cancer patients have tumors that are HER2+.
- HER2+ tumors tend to grow and spread more quickly than tumors that are not HER2+.
- HER2 status is not hereditary.
- Each normal breast cell contains copies of the HER2 gene.
- HER2 proteins help send growth signals from outside the cell to the inside of the cell. These signals tell the cell to grow and divide.
- HER2+ breast cancer cells have an abnormally high number of HER2 genes per cell. When this happens, too much HER2 protein appears on the surface of these cancer cells.

Pharmacogenetics of breast cancer: HER2



Pharmacogenetics of breast cancer: Herceptin

- Herceptin® (Trastuzumab) is a monoclonal antibody designed to target and destroy HER2+ cancer cells.
- Clinical experience with Herceptin for the adjuvant treatment of HER2+, node-positive breast cancer began in 2000.
- In 2006, Herceptin was approved for the adjuvant treatment of HER2+, node-positive breast cancer.Herceptin, as part of a treatment regimen containing doxorubicin, cyclophosphamide and paclitaxel.

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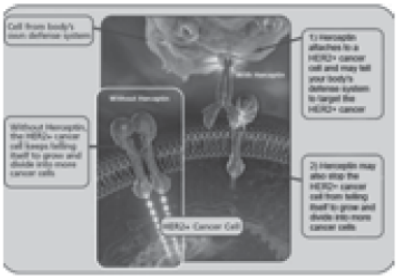
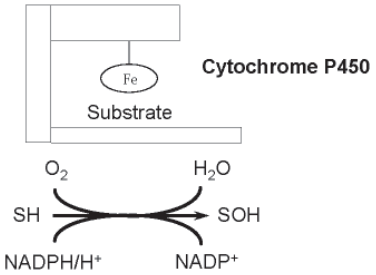
Pharmacogenetics of breast cancer: Herceptin

- Herceptin is designed to target HER2+ cancer cells. Based on laboratory studies, Herceptin is thought to work in 2 ways:
  - 1) Herceptin attaches to a HER2+ cancer cell and may tell your body's defense system to target the HER2+ cancer cell
  - 2) Herceptin may also stop the HER2+ cancer cell from telling itself to grow and divide into more cancer cells
- Herceptin plus chemotherapy for HER2+ breast cancer had a 52% reduction in the risk of breast cancer returning compared to chemotherapy alone.

Pharmacogenetics of breast cancer: Herceptin



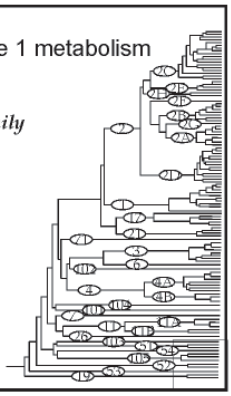
Pharmacogenetics of phase 1 metabolism



Pharmacogenetics of phase 1 metabolism

The cytochrome P450 superfamily

Families 1, 2, 3 and 4
are involved in drug metabolism

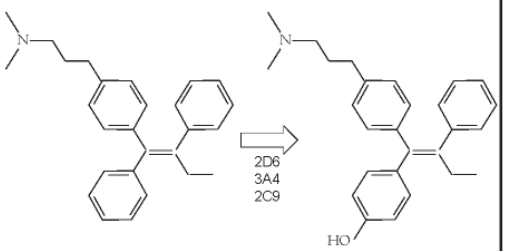


Pharmacogenetics of phase 1 metabolism

CYP2D6

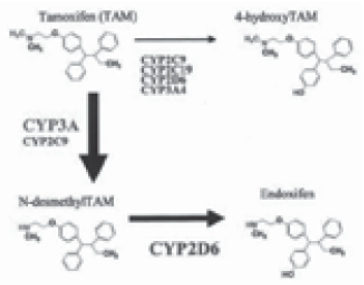
- Genetic polymorphisms (SNPs) in Caucasians
- Enzyme activity is functionally lacking in 5-10% of the population
- SNPs can be detected by RFLP or PCR analyses
- Substrates : debrisoquin, spartein, mexiletine, dextromethorphan, bufuralol, tamoxifen
- CYP2D6 represents 5-10% of all CYP450 in the liver; it is also present in the brain

Pharmacogenetics of phase 1 metabolism



Tamoxifen (TAM) 4-OH TAM

Pharmacogenetics of phase 1 metabolism



CYP2D6 and tamoxifen

- Tamoxifen, a pro-drug, undergoes major metabolism through CYP3A4 and CYP2D6.
- Two active metabolites are formed
  - 4-OH-tamoxifen (CYP2D6)
  - N-desmethyl-4-OH-tamoxifen (CYP3A4/CYP2D6)
- SSRIs (paroxetine, fluoxetine) with high affinity for CYP2D6 decrease the levels of 4-OH-TAM and endoxifen.
- The role of potent antiestrogenic metabolites (30- 100-fold) and efficacy and toxicity (hot flashes).
- The role of genetic polymorphisms and drug-drug interactions in the response to tamoxifen.

Pharmacogenetics of Drug Metabolizing enzymes

ROLE OF GST-A1 IN THE METABOLISM OF BUSULFAN.

P. Bouchard, K. Alain, S. Bilodeau

M Franco, B Vadnais

B. Pronovost, F. Bélanger, V. Michaud, J. Turgeon.

Pharmacogenetics of Phase 2 metabolism

- Busulfan, an alkylating drug, is widely used as a conditioning treatment for patients undergoing bone marrow transplantation.
- This myelosuppressive agent has a narrow therapeutic index:
  - A close follow-up is required to minimize the risk associated with inefficacy (graft rejection) or those associated with toxicity (VOD).
- Wide interindividual variation in busulfan kinetics have been reported, especially after oral administration of the drug and in children.

Pharmacogenetics of Phase 2 metabolism

- Some factors could explain the observed interpatient variability, including; circadian rhythms, age, disease, drug-drug interactions, weight/obesity, busulfan bioavailability (bezoars formation) and elimination pathway (GST).
- Busulfan is extensively metabolized in the liver by Gluthation S-Transferase (GST)-mediated conjugation with gluthation. (Czerwinski et al. 1996)
- GST-A1 is the principal catalyst of busulfan conjugation: this isoform has been shown to be responsible for 80% of the metabolism of busulfan. (Gibbs et al. 1996)

Pharmacogenetics of Phase 2 metabolism

- Expression levels of GST-A1 are associated with the presence of genetic polymorphisms:
  - GST-A1*A/*A>*A/*B>*B/*B. (Coles etal.2001)
- Poonkuzhali et al. have described a correlation between high activity of GST-A1 and decreases in Cmax, Cmin and AUC of busulfan. (DMD 2001)
- Reduced Ke and clearances were observed in patients with GST-A1 *A/*B compared to carriers of *A/*A genotype. (Kusama et al. 2006)
- Relationships between genotypes of GST and phenotypes remain controversial.

Pharmacogenetics of Phase 2 metabolism

Hypothesis:

- Interindividual variability in oral clearance (CLo) of busulfan is related to variability in GST-A1 activities; the major enzyme involved in the metabolism of busulfan.

Objectives:

Primary

- To evaluate the predictive value of GST-A1 genotypes on the oral clearance of busulfan.

Secondary

- To examine the predictive value of busulfan volume of distribution determined after i.v. administration on the AUC of busulfan after oral administration of the drug.

Pharmacogenetics of Phase 2 metabolism

Demographics	Cohort (n=88)
Gender (male:female)	49:39
Age* (years)	48.2±9.8
Weight* (Kg) Adjusted ideal weight* Lean weight*	79.9±15.5 65.3±10.1 63.5±9.6
Oral Clearance* (mL/min)	188.4±42

Pharmacogenetics of Phase 2 metabolism

Pharmacogenetics of Phase 2 metabolism

Population	n	*A/*A	*A/*B	*B/*B
Patients in our study	88	27.2%	45.5%	27.2%
Healthy subjects	116	31.0%	49.8%	19.8%

Pharmacogenetics of Phase 2 metabolism

- Allelic frequency of variant alleles of GST-A1 in our French Canadian population appeared higher than that reported in other populations.
- The frequencies of *B allele found in our population studied were 44-49 % compared to 39%, 38%, 26%, 16% et 12.9% in Hispanic, European Caucasian, Afro-American, Japanese and Chinese populations, respectively.
- Our results demonstrate a significant influence of GST-A1 polymorphisms on the oral clearance of busulfan in Caucasian patients.
  - Homozygous patients for the wild-type allele show a higher oral clearance compared to carriers of two variant alleles (207.3±46.7 ml/min vs 166.4±30.5 ml/min, respectively).

Pharmacogenetics of Phase 2 metabolism

- A greater frequency of GST-A1 *B/*B was observed in our patients than that observed of healthy subjects. Further analyses are needed to assess GST-A1 polymorphisms as a risk factor for haematological malignancies.
- Our data suggest that the volume of distribution of busulfan could predict its oral AUC. However, larger studies are required to evaluate the superiority of the determination of volume of distribution compared to body weight, BSA, BMI.

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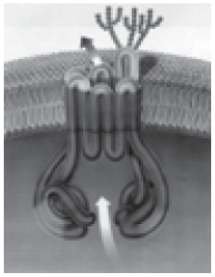
Pharmacogenetics of Drug transporters

P-glycoprotein; MDR1

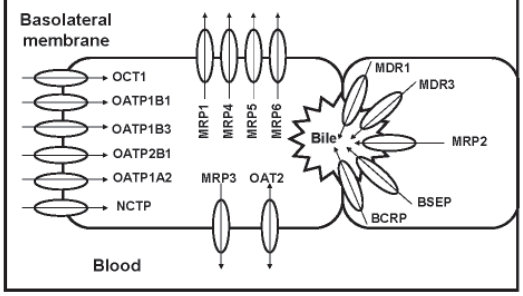
- Pump located in the brush border of the intestinal wall
- Work in synergy with CYP450 to protect the organism
- Blood-brain barrier, kidney, liver, placenta, heart
- Genetic polymorphisms on *mdr1*
- Several CYP3A4 substrates are transported by P-glycoprotein pump.

Pharmacogenetics of Drug transporters



P-glycoprotein; MDR1

Membrane transporters in the hepatocyte



Membrane transporters in the enterocyte

Basolateral membrane

Blood

Pharmacogenetics of Drug transporters

CLIC study

CLINICAL IMPACT OF DRUG INTERACTIONS WITH CHEMOTHERAPY METABOLIZED BY CYP3As

E. Tonietto, S. Cuerrier, M. Boyer

N. Letarte, C. Noël

V. Michaud, J. Turgeon.

CLIC Study

- Patients elective for chemotherapy often present with concomitant diseases requiring chronic therapies.
- These medications may interact with antineoplastic agents and modulate their response as well as their adverse effect profiles.
- The objective of our study was to evaluate the potential drug-drug interactions between substrates of high affinity for CYP3As and/or P-glycoprotein and antineoplastic agents which are substrates of these enzymes or transporters.

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CLIC Study

- A retrospective, observational and transversal study was performed in 387 patients receiving highly emetogenic chemotherapy metabolized by CYP3As:
  - etoposide, cyclophosphamide, anthracyclines, vinca alkaloids
- Treatment of lung or breast cancer.
- Among them, 57 were taking drugs that are substrates of high affinity for CYP3As while on chemotherapy.
  - atorvastatin, lovastatin, simvastatin, diltiazem, verapamil, amlodipine, felodipine, nifedipine
- Prevalence of gastrointestinal and hematologic side effects were compared between these two groups.

CLIC Study

- Patients taking substrates of high affinity for CYP3As tended to have less modification of their anti-emetic therapy due to a poor control of nausea and vomiting than the control group (7,0% vs 16,4%, p=0.072).
- A similar tendency was observed when only women (n=38 and 290, respectively) were compared (5,1% vs 18,2%, p=0.061).
- Patients taking substrates of high affinity for CYP3As had significantly less neutropenia at day 1 of cycle 2 (0% vs 10,6%, p=0.005).

CLIC Study

- Our results suggest that concomitant use of high affinity substrates for CYP3As may improve the side-effect profile of antineoplasic drugs such as etoposide, cyclophosphamide, anthracyclines and vinca alkaloids.
- This could be explained by the modulation of influx/efflux transporter activities as well as that of drug metabolizing enzymes controlling the intracerebral concentrations of antineoplasic agents.

2007 | NOPS SPEAKER

SHARON MEEKE
Pharmacy Manager, Juravinski Cancer Centre
BScPhm, University of Toronto
Specialty: Oncology

BIOGRAPHY

I have worked exclusively in oncology for the last 7 years; as a clinical pharmacist for the first 6 years at the Juravinski Cancer Centre in Hamilton Ontario, followed by the pharmacy manager position.

Previous pharmacy experience has been split between hospitals e.g. Markham Stouffville Hospital, Markham, Ont. and various retail pharmacies, but always connecting with oncology.

SYNOPSIS

USE OF THE RECAP FORMULARY SOFTWARE IN COMMUNITY OUTREACH CLINICS *Sunday, October 28th, 10:25 – 10:50*

The Regional Cancer Program Formulary reflects our vision of standardized cancer care for patients in LHIN 4, Ontario. It contains all of the systemic therapy regimens approved for use for cancer patients. Authorized pharmacy staff maintains it.

The Regional Cancer Program Formulary Software (RECAP-FS®) plays a major role in achieving standardized practice at the Juravinski Cancer Centre and outreach communities.

Objectives:

- To show that an electronic formulary software can increase local and regional access to the latest treatment information.
- RECAP can help ensure that the same high quality treatment will be delivered to patients regardless of location.
- Desktop icons can allow individuals rapid electronic access and provide access for clinical partners within the Region.

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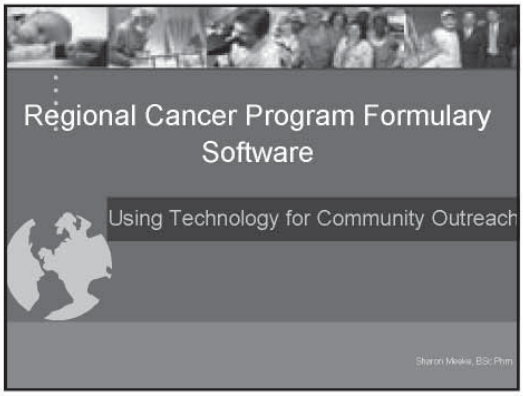

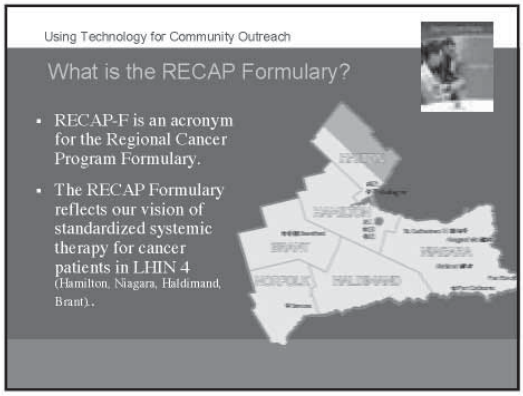

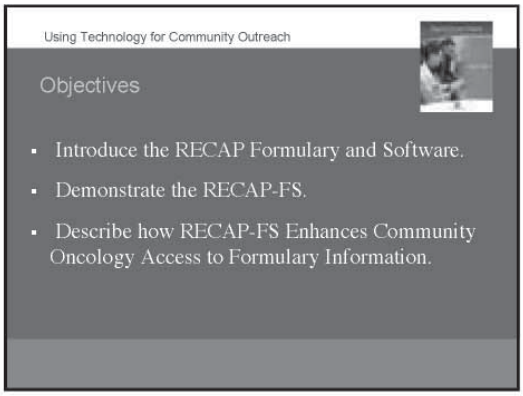

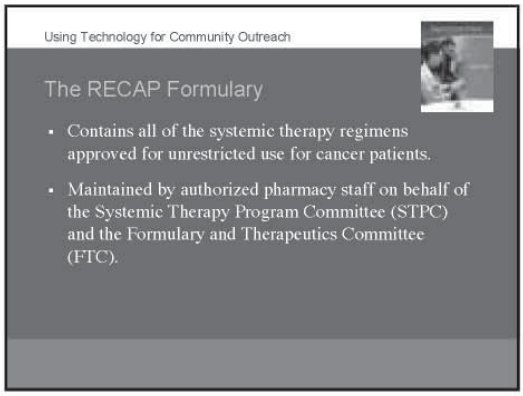

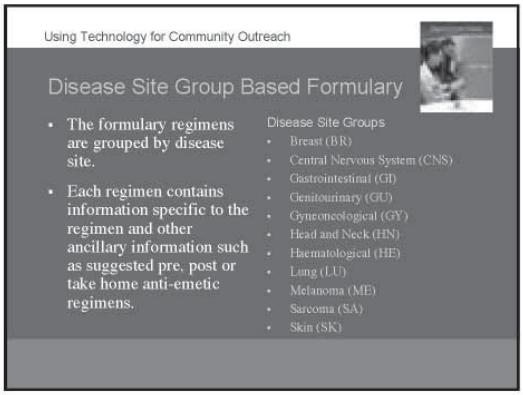

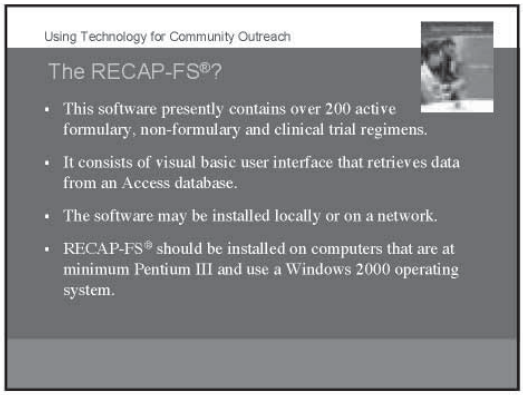

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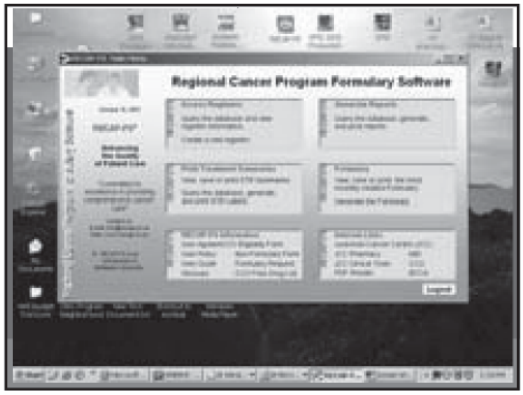
Using Technology for Community Outreach

Why Create RECAP-FS®?

- To automate the process of editing, updating, exporting, archiving and printing chemotherapy regimen information.
- To add efficiency and cost effectiveness to the process of disseminating regimen information in a timely manner.
- To increase the oncology community access to the latest regimen information.
- To enhance patient safety and the quality of patient care.

RECAP-FS® is a tool that facilitates quality clinical processes and outcomes.



Using Technology for Community Outreach

Inside RECAP-FS

Regimen Data Access

- Query the regimen database
- Perform a Multiple Regimen Search or a Single Regimen Search

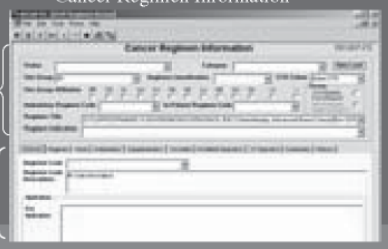
Using Technology for Community Outreach

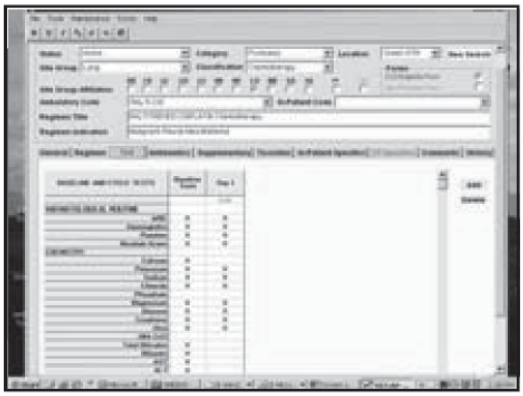
Inside RECAP-FS

Cancer Regimen Information

Standard Regimen Information

Regimen Details in a 10 Tab Format





Using Technology for Community Outreach

Inside RECAP-FS

Generate Reports

- Query regimen database
- Select required fields
- View and edit Crystal report output
- Print report

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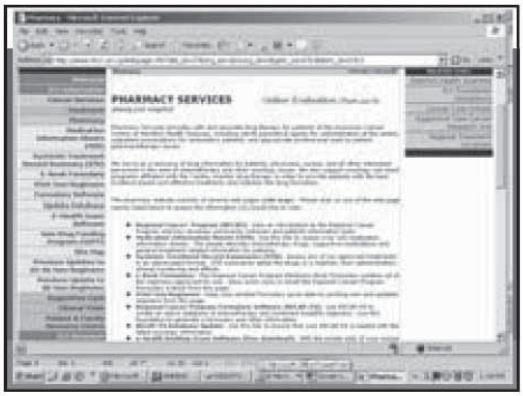

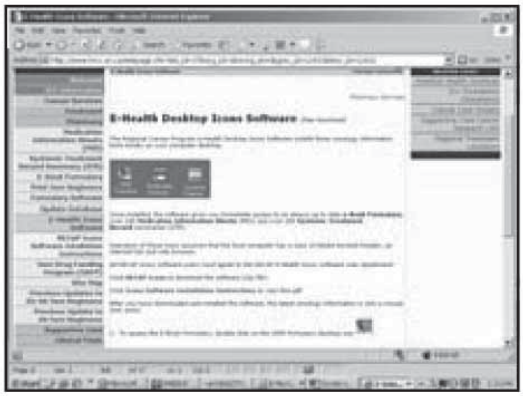

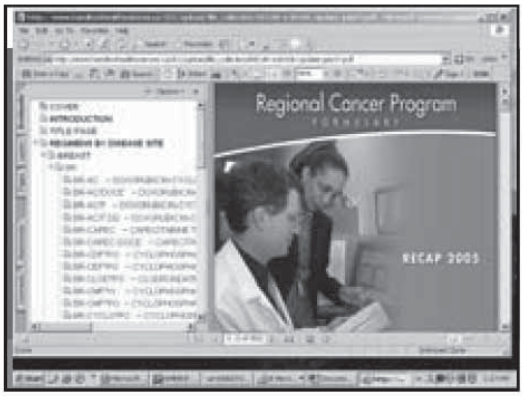

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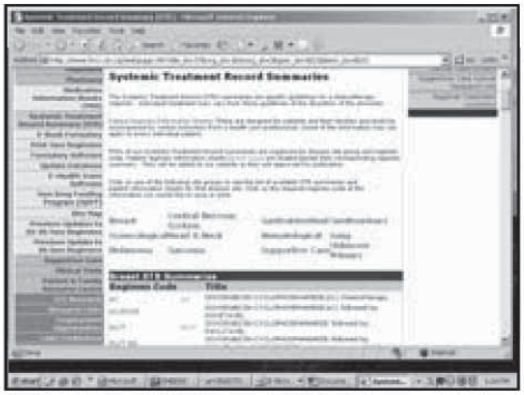
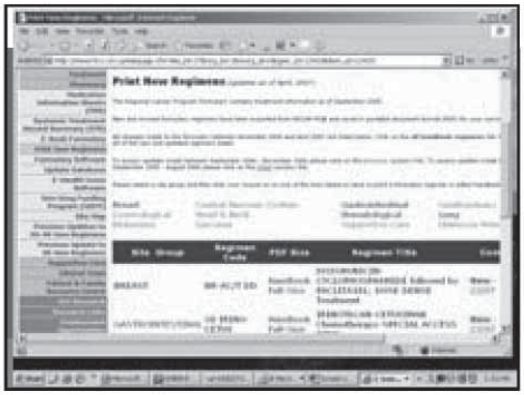
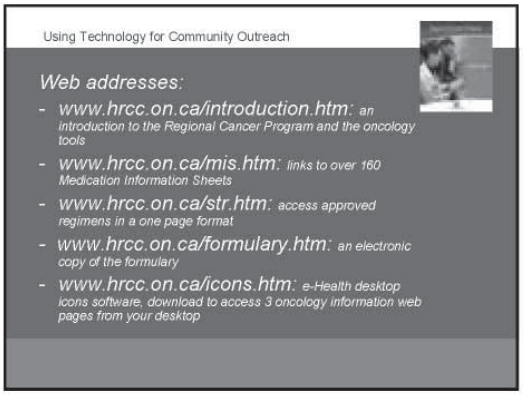
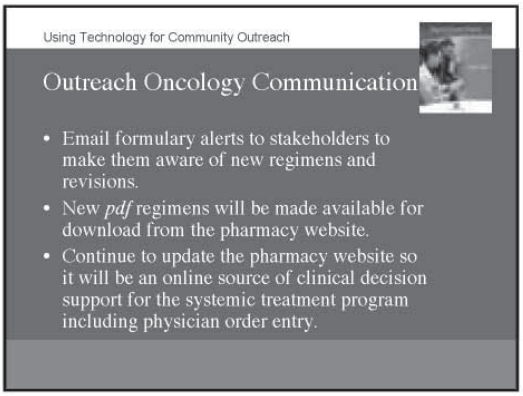
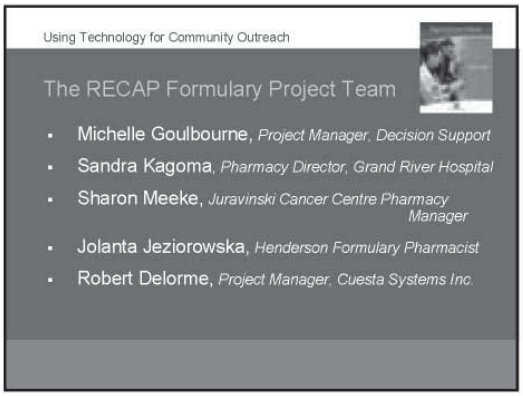










2007 | NOPS PANEL SESSION

A DAY IN THE LIFE OF AN ONCOLOGY PHARMACIST *Sunday, October 28th, 10:55 - 12:20*

PANELISTS

DARRYL BOEHM
Allan Blair Cancer Centre

Darryl graduated with distinction from the College of Pharmacy at the University of Saskatchewan in Saskatooon in 1989. He briefly worked in retail pharmacy before undertaking a residency in oncology pharmacy practice at Royal University Hospital. Since that time, Darryl has worked at both cancer centres in Saskatoon and Regina as a staff pharmacist, project leader for a provincial pharmacy information management solution, and clinical trials pharmacist. He has given numerous cancer related presentations to other health care professionals and the general public, and has several publications in pharmacy and medical journals. Darryl is currently the senior pharmacist and team leader for the pharmacy department at the Allan Blair Cancer Centre in Regina, and is involved in provincial initiatives related to the provision of oncology pharmacy services in Saskatchewan.

NANCY HALLÉ
Dr Léon Richard Oncology Center

Nancy received her pharmacy degree from Université Laval. Since 1993, she has been working as a pharmacist at the Dr Léon Richard Oncology Center. In 2001, she obtained a MBA from the University of Moncton. Nancy received her BPS certification as an oncology pharmacist in 1999 and has been recertified in 2006. She is currently pharmacist coordinator at the Dr Léon Richard Oncology Center.

JACKIE MOULTON
Burin Peninsula Health Care Center

Jackie Moulton graduate from the College of Trades and Technology at St. John's, Newfoundland with a diploma in Pharmacy in 1984.

In 1984, Jackie began her career as a part-time staff pharmacist with Shoppers Drug Mart in Marystown, Newfoundland. She was later hired to full time status. Jackie continued to work in the retail setting until 1990. In July of 1990, she began working with the Burin Peninsula Health Care Center in Burin, Newfoundland as a Clinical Pharmacist. She was later promoted to a Clinical Pharmacist II. To date, Jackie is still employed with the Burin Peninsula Health Care Center.

Working in a rural hospital setting creates a unique and ever expanding working and learning environment. She is constantly learning through continuous education and through enquiries from the medical and nursing staff. To ensure that patients receive safe and appropriate chemotherapy services, Jackie works closely with the Newfoundland Cancer Treatment and Research Foundation.

... Synopses on next page

SYNOPSES

A DAY IN THE LIFE OF AN ONCOLOGY PHARMACIST

Sunday, October 28th, 10:55 - 12:20

Darryl Boehm:

In this presentation, an overview of oncology pharmacy services provided through the two tertiary cancer centres in Saskatchewan will be reviewed. In addition, the presenter will review a typical day for a front line staff pharmacist at a tertiary cancer centre in Saskatchewan.

Nancy Halle:

1. Presentation of the facilities
2. Description of the healthcare team and the services provided
3. Description of the pharmacist's role
4. Identification of the challenges/opportunities for the pharmacist

Jackie Moulton:

Rural oncology pharmacy has different challenges as well as different benefits than oncology pharmacy in larger centers. Through my presentation I hope to enlighten participants as to these challenges and benefits and innovative ways to overcome such challenges.

A Day In The Life Of A…..

Cancer Centre Pharmacist

Saskatchewan

- Population: 1 million
  - 65% urban, 35% rural
    - 420,000 in Saskatoon or Regina
  - 15.1% >65 and 29.2% <20 (higher than national average)
  - 13.5% Aboriginal
  - Far north – geographic issues for access to health care
- Economy
  - 8.7% agriculture, 12% manufacturing/construction, 12.3% other industries, 67% service
  - Natural resources: oil, gas, uranium, potash, diamond, gold, forestry
  - Crude oil single largest export commodity
- Many self employed – no private drug plans, or private plans are formulary based (e.g., only cover drugs listed on public plans)

Drug Formularies

Background

- Patients in Saskatchewan with diagnosis of cancer are eligible for drug benefits
  - Registered with Cancer Agency – requires pathology report
  - Prescribed by oncologist or associate
  - Drug formulary/clinical practice guidelines
- Saskatchewan Cancer Agency (SCA) operates 2 publicly funded pharmacies
  - Saskatoon, Regina
  - Provide bulk of oncology pharmaceutical services for entire province

Drugs Listed on SCA Drug Benefit Program

- Parenteral and oral drugs used to treat cancer
  - Chemotherapy, biologics, hormones, targeted treatments
  - Some supportive care drugs with restrictions: Filgrastim, Pegfilgrastim, 5-HT_3 antagonists, Octreotide, Pamidronate
  - Does not include analgesics, antibiotics, etc.
- Outpatient or inpatient
  - Generally, if indication is related to cancer management, public Prescription Drug Plan (e.g., Pharmacare) and hospital defers to Cancer Agency

Saskatchewan Cancer Agency Pharmacy Services (1)

- Administrative
  - Drug contracting and tendering coordinated with SAHO and Cancer Care Manitoba
  - Centralized purchasing
  - Development of provincial policies/procedures (may be adopted by regional health authorities)
  - P&T
  - Budgeting, planning (human, capital)
  - Occupational health and safety
  - Risk management
  - Drug use review/evaluation, pharmacoeconomics
  - Clinical practice guidelines
  - Exception drug coverage requests
  - Various task forces and working groups, accreditation
  - Clinical management system (Varian) – chemotherapy regimen development

Saskatchewan Cancer Agency Pharmacy Services (2)

- Clinical
  - Antiemetic management/prescribing
  - Stem cell transplant
  - Gynecology oncology clinic
  - Imatinib (Gleevec™), Trastuzumab (Herceptin™) monitoring programs
  - Community oncology program of SK (COPS)
  - Disease site/tumor group reps – clinical practice guidelines
  - Medication histories/reconciliation
  - Patient medication teaching
  - Drug information
  - Developing preprinted physicians orders
  - Clinical trials
  - Telephone call back/follow up
  - Public education
  - Insurance assistance
  - Residency and student rotations

Saskatchewan Cancer Agency Pharmacy Services (3)

- Technical
  - Preparation of parenteral cytotoxic treatments for both outpatient and inpatient
  - Dispensing take home prescriptions for SCA funded drugs (e.g., oral chemotherapy, Filgrastim, Ondansetron, Dexamethasone, etc.)
  - Facilitate transportation of Rx's to patients (e.g., mail, courier, bus) for patients who reside outside Regina or Saskatoon and who are not attending those clinics
  - Inventory management – electronic perpetual inventory with barcode scanning
  - Training

Staffing

- Note – service includes pediatric and adult oncology, and both outpatient and inpatient
- Provincial: 1 pharmacy manager, 1.5 FTE technicians for pharmacy purchasing
- Regina: 1 FTE senior pharmacist, 1 FTE clinical trials pharmacist, 5 FTE staff pharmacists, 4 FTE technicians
- Saskatoon: 1 FTE senior pharmacist, 1 FTE clinical trials pharmacist, 6 FTE staff pharmacists, 2 FTE stem cell transplant pharmacists, 2 FTE technicians
- 2 biological safety cabinets at each centre
- 41 physicians b/w both centres: medical, radiation, pediatric oncology, hematologists, gyne oncologists, clinical associates (GPO's)

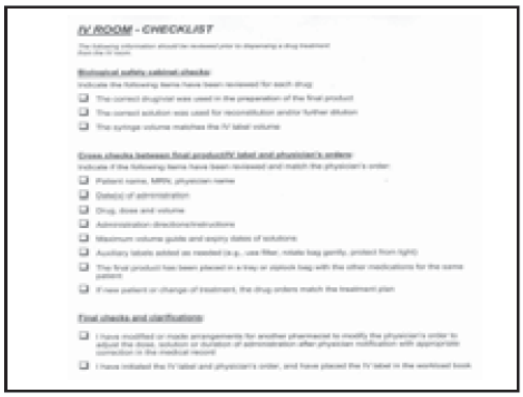
Patients/Workload

- Each centre serves about half the province and has a catchment of approx. 500,000
- 1000-1100 patients/mo
- S'toon: 1700 IV doses/mo, 2200 Rx's/mo,
- Regina: 1900 IV doses/mo, 1600 Rx's/mo
  - 17% of IV workload related to inpatients
    - 40% pediatric, 24% of patients
  - 5% of outpatient workload: pediatrics
- Hours: Mon-Fri 0800-1630h
  - On call after hours and w/e for emergencies

Role as part of health care team

- Help achieve desired therapeutic outcome
- Patient safety
  - Quality assurance, review treatment plans, pathology reports, BSA and dose calculations, organ function tests (CBC, RFT, LFT), drug interactions, etc.
- Patient education and advocate
- Support oncologists and other health care professionals

NEW DRUG ORDERS - CHECKLIST



IV ROOM - CHECKLIST

The following information should be reviewed prior to dispensing a drug treatment from the IV room

Biological safety cabinet checks

Indicate the following items have been reviewed for each drug

- ☐ The correct drug/vial was used in the preparation of the final product
- ☐ The correct solution was used for reconstitution and/or further dilution
- ☐ The syringe volume matches the IV label volume

Cross checks between final product/IV label and physician's orders

Indicate if the following items have been reviewed and match the physician's order:

- ☐ Patient name, MRN, physician name
- ☐ Date(s) of administration
- ☐ Drug, dose and volume
- ☐ Administration directions/instructions
- ☐ Maximum volume guide and expiry dates of solutions
- ☐ Auxiliary labels added as needed (e.g., use filter, rotate bag gently, protect from light)
- ☐ The final product has been placed in a tray or ziplock bag with the other medications for the same patient
- ☐ If new patient or change of treatment, the drug orders match the treatment plan

Final checks and clarifications

- ☐ I have modified or made arrangements for another pharmacist to modify the physician's order to adjust the dose, solution or duration of administration after physician notification with appropriate correction in the medical record
- ☐ I have initialed the IV label and physician's order, and have placed the IV label in the workload book

Community Oncology Program of Saskatchewan (COPS)

- Coordinated by 2 cancer centres in partnership with regional health authorities
- Primary goal to provide treatments in centres closer to home communities
  - Reduces need for traveling
- Cost of oncology drugs still responsibility of SCA
- 16 designated centres in Saskatchewan
- Cancer Centre Pharmacies review all prescriptions/orders and provide directions/medication to community centres
- Annual site visits – education, inspections, team building
  - Pharmacist, nurse, medical oncologist, social worker

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October 26, 2007

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Clinical Trials

- Pharmacy position devoted to managing clinical trials
  - Review trial for feasibility, budget impact, ethics submission, start up visit, pharmacy summary, computer codes, preprinted orders, inventory, patient rosters, ongoing issues, updates, and liaison with other departments, close out visits
- NCIC, NSABP, NCCTG, RTOG, COG, drug company sponsored, investigator initiated
  - Pharmacy generated in house trials – e.g., complementary and alternative medicine survey
- Primarily phase II-III clinical trials
- Regina has been in top 2-3 NCIC centres in Canada for recruiting to some studies (e.g., MA.21)
- Ongoing audits – all cooperative groups, FDA

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Special Drug Supplies

- Health Canada special access programme
  - Thalidomide, Temsirolimus, Gemtuzumab, Pegaspargase…
- Company sponsored compassionate or assistance programs
  - Thalidomide, Sunitinib, Sorafenib, Dasatinib…
    - Pharmacist assisted medication review/drug interaction checks/recommendation, toxicity grading (NCI version 3.0) for anti-VEGF

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Blood and Marrow Transplant Pharmacists

- 2 FTE positions in Saskatoon
- Provide outpatient and inpatient clinical services to patients receiving hematopoietic stem cell transplants
  - Leukemia, lymphoma, myeloma
- Patient education, antimicrobial prophylaxis/treatment, managing chemotherapy toxicities, preprinted orders for conditioning and transplant regimens
- 30 autologous stem cell transplants/year
  - 10-15 allogeneic transplants are followed day 100+
  - Follow other patients on inpatient hematology service

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Pharmacist Antiemetic Prescribing

- Algorithm based, toxicity graded
- Symptom diaries given to patients
  - Nausea, vomiting, diarrhea, constipation, fatigue
- Medical oncologists transfer authority for prescribing antiemetics to pharmacists
  - Pharmacist can still consult or review changes with medical oncologist if needed

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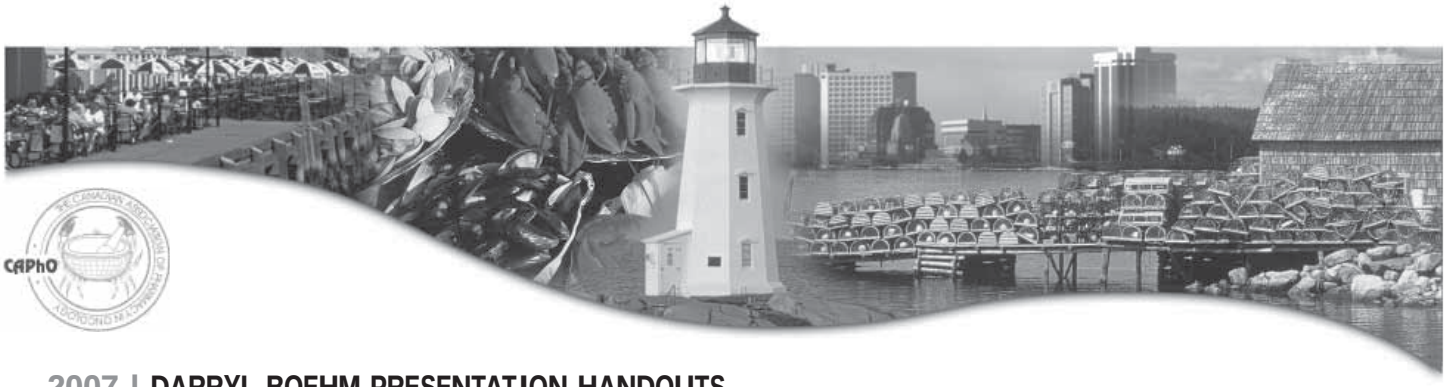


Gynecology Oncology Clinic

- 2 gynecologist oncologists see patients 1-2 days per week
  - Primarily cancer of ovary, endometrium, cervix requiring chemotherapy
- Pharmacist works with physician/nurse team in their clinic
  - Medication histories, patient education on chemotherapy, symptom assessments and suggestions, dose calculations, electronic clinical note documentation

Pharmacy Challenges

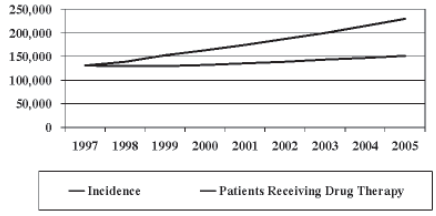
- Recruitment and retention of staff
  - Competition with private sector and hospital
- Formalizing training, (re)certification of both pharmacists and technicians
  - Residency programs
- Demand to provide increased levels of service with limited capacity
- Dealing with pediatric and inpatient oncology units with increasing adult ambulatory workload
- Rapid changes in oncology practice due to research

Provincial Cancer Agency Pressures

- Cancer drug expenditures growing 20% per annum
  - Drug costs will double within 5 years
- Number of new cases increases 2-3% per annum
- Number of patients receiving active treatment growing 6% per annum
  - Expanded indications for previously untreated pts
  - Longer duration of treatment in curative or chronic disease situation

Rate of Growth of Cancer Incidence in Canada vs. Number of Surviving Patients Receiving Drug Therapy

(1997 to 2005) based on NCIC, BC and Ontario data



Best/worst days

- Best
  - When patient is finished treatment (e.g., 1 year of adjuvant Trastuzumab, pediatric ALL)
  - Patients relying on pharmacist for advice or seeking out their "personal" cancer centre pharmacist
  - Camaraderie with physicians, nurses, pharmacists
  - Team building on visits to outlying centres
  - Recognition from senior management of important role of pharmacists and pharmacy
- Worst
  - Getting to know your patient after repeated visits to the centre, only to find out about a recurrence or bad news
  - Not being able to help some patients or provide medication due to funding restrictions
  - Collecting payment from patients (Avastin)
  - Pharmacy medication errors
- Interesting
  - Television interview on short notice, microscopic slide incident

A day in the life of an oncology pharmacist

Presented by Nancy Halle
NOPS 2007
Halifax, October 28th 2007

PLAN

- Presentation of the facilities
- Description of the healthcare team
- Description of the pharmacist's role
- Identification of the challenges/ opportunities

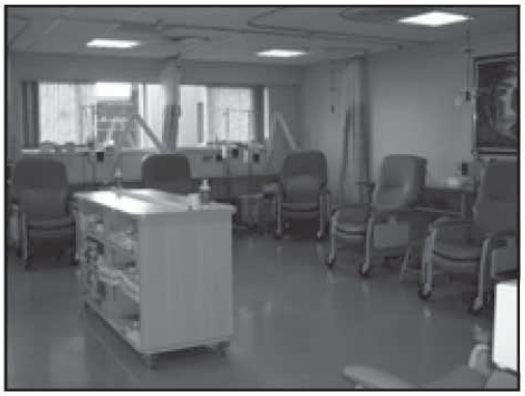
Facilities

- Dr Leon Richard Oncology Center
  - Outpatient Clinic
  - 10 chairs for chemo treatments
  - 3 beds
  - 3 linear accelerators
  - Brachytherapy
- Mgr Henri Cormier Lodge (65 beds)

Facilities

- 4D
  - Inpatient oncology unit
  - 22 beds

  3CS
  - Palliative care unit
  - 6 beds



Healthcare team

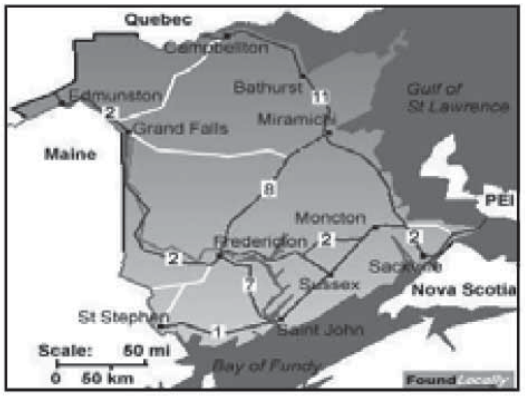
- 1 hemato-oncologist
- 4 radiation oncologists
- radiation therapists
- radiation physicists
- general practitioners
- 1 social worker/dietician/psychologist

Healthcare team

Nurses
- Breast cancer navigators
- Brachytherapy navigator
- Community systemic therapy coordinator
- Educational nurse
- 1 oncology pediatric nurse
- Triage nurse
- 3 CRA

Population

- Mostly adult patients
- Pediatric patients
- Outreach chemo clinics
  - Bathurst
  - Caraquet
  - Campbellton



Statistics

- 4700 outpatient chemo treatments/year
- 800 inpatient chemo treatment/year
- 800 treatments (outreach clinics)
  - 187 referrals

Pharmacy

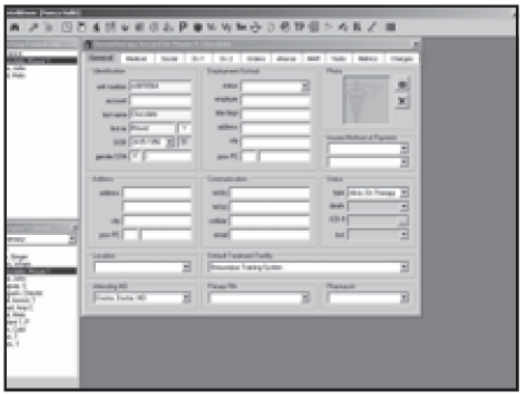
- Staff
  - 2 pharmacists
  - 2 full time tech
  - 2 part time tech
- Opening hours
  - 8:30 am to 6:00 pm
- Pharmacist on call after hours
- CPOE services

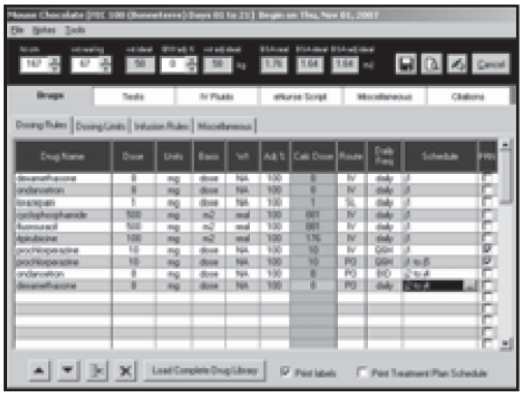
Pharmacist's role

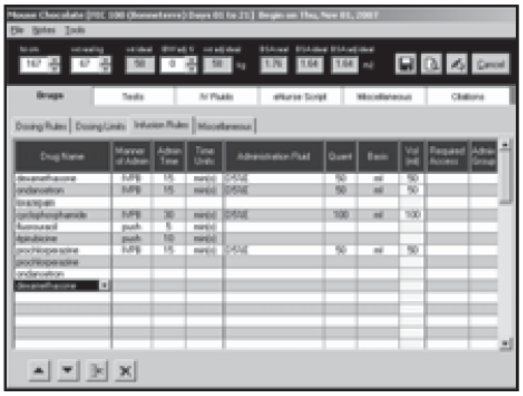
- Verification of chemo prescription
  - for our clinic and outreach clinic
- Verification of chemo preparation
- Patient counseling
- Rounds
  - 4D
  - Pediatrics
  - Teleoncology

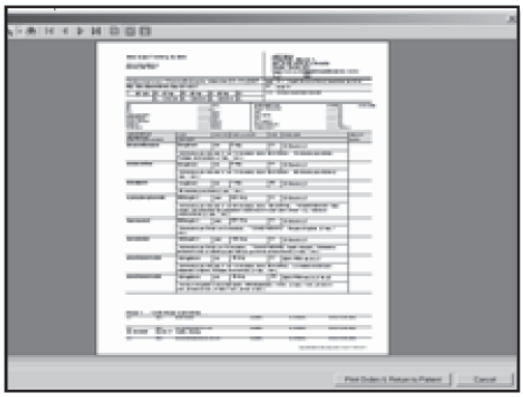
Pharmacist's role

- Drug information
- CPOE
  - Programming of the protocols
  - Resource person
  - Webinar
  - Procedures









Pharmacist's role

- Clinical trials
- Teleoncology
- Education
- Program management
- PTC

Challenges

- $$
- Priorities
- Communication
- Space
- Information Technologies Compatibilities

Opportunities

- Delegation
- Recognition of our role by physicians
- Technology

Conclusion

- Great team
- Rewarding work
- Challenging

It's Better in the Bay!!! Challenges and Opportunities for the Rural Oncology Pharmacist

Jackie Moulton
Clinical Pharmacist II
Eastern Health Care Authority

Learning Objectives

- Challenges of Rural Oncology Pharmacy
- Benefits of Rural Oncology Pharmacy
- Overcoming the challenges
- Opportunities

Learning Objectives

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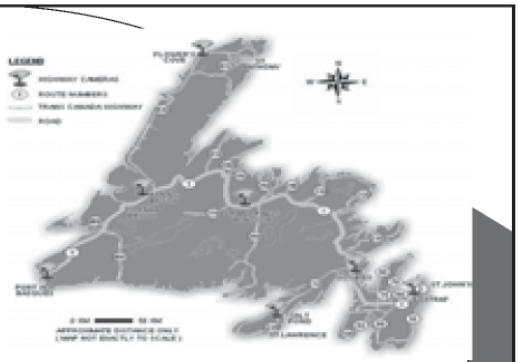


Challenges of Rural Oncology Pharmacy

- Drug availability
- Lack of professional staff/ Recruitment
- Local GP's overseeing chemotherapy treatments
- Lack of specialized Oncology personnel
- Little contact and information with new products

Challenges of Rural Oncology Pharmacy

- Lack of education opportunities
- Patients are seen, accessed and orders written in larger centers
- Storage/stability/sterility issues in transporting chemo preps to more remote centers

2007 | JACKIE MOULTON PRESENTATION HANDOUTS

Learning Objectives

- Challenges of Rural Oncology Pharmacy
- Benefits of Rural Oncology Pharmacy
- Overcoming the challenges
- Opportunities

Benefits of Rural Oncology Pharmacy

- Familiarity with patients and their families
- Patients benefit from receiving chemotherapy close to their home community
- Collaboration easier between physicians, nursing and pharmacist
- Increased role of the pharmacist due to lack of oncology services
- Easier promotion of clinical services

Learning Objectives

- Challenges of Rural Oncology Pharmacy
- Benefits of Rural Oncology Pharmacy
- Overcoming the challenges
- Opportunities

Overcoming the Challenges According to Jackie

- Offer more incentives to encourage pharmacists to rural areas
- Delegate the inpatient physician as the individual to oversee chemo
- Offer training to technicians to enable them to prepare chemo
- Larger centers should increase video and teleconferencing to provide education to rural pharmacist

Overcoming the Challenges According to Jackie

- ACOP/ NOPS– Keeping rural pharmacists in touch with new therapies/ networking
- Create an email/ listserve for Atlantic Canadian pharmacist
- Create an ACOP website where pharmacist can post questions

Learning Objectives

- Challenges in Rural Oncology Pharmacy
- Benefits in Rural Oncology Pharmacy
- Overcoming the challenges
- Opportunities

Opportunities for Clinical Advancement

- Reverse seamless care/Medication Reconciliation
- Supportive Care Medication Management
- Compassionate Release Medication
- Patient counseling program

Reverse seamless care/ Medication Reconciliation

- Change mindset of traditional seamless care programs
- Transfer of information from rural center to larger institution

Supportive Care Medication Management

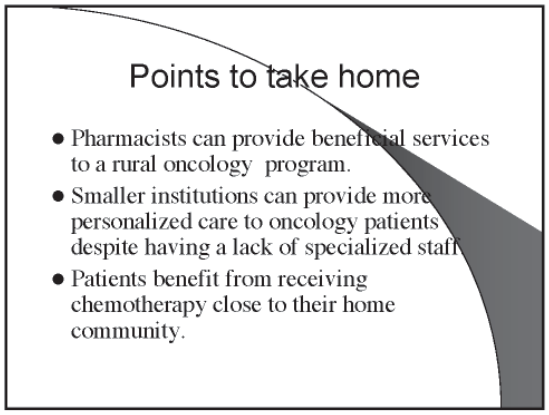
- Pharmacist assessment of chemotherapy induced toxicities
- Pharmacist interview of patient and suggest appropriate therapies

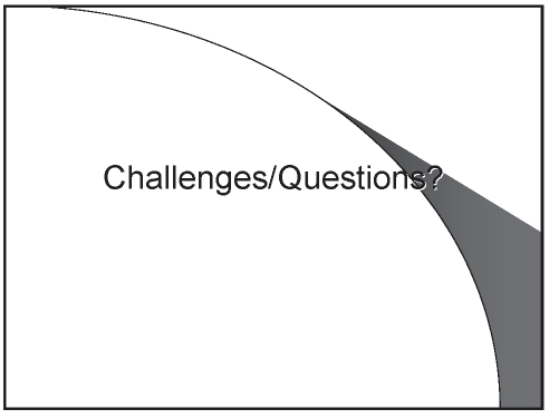
Compassionate Release Medication

- Provision of oncology related drugs for patients in need
- Pharmacist assessment identifies financially challenged patients

Patient counseling program

- Provide counseling and supplement this with patient information handouts to all new chemotherapy patients


Points to take home
Pharmacists can provide beneficial services to a rural oncology program.
Smaller institutions can provide more personalized care to oncology patients despite having a lack of specialized staff
Patients benefit from receiving chemotherapy close to their home community.


Challenges/Questions?


Contact Information
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PHARMACIST NETWORK COMMITTEE

Susan Walisser, Marlene Sellon, Biljana Spirovski, Nathalie Letarte, Rob Whelan, Ing Collins, Colleen Olson, Zoe Koulouris

Introduction: The National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) is a cooperative oncology group which carries out clinical trials in cancer therapy, supportive care and prevention across Canada and internationally. It is one of the national programs and networks of the NCIC, and is supported by the NCIC with funds raised by the Canadian Cancer Society.

History of the Pharmacists Network: In 1986, pharmacists affiliated with the NCIC CTG organized an education symposium held in conjunction with the annual spring meeting, which became the first National Oncology Pharmacy Symposium (NOPS). In 1988, a pharmacist consultant was hired by the NCIC CTG to assist in the development and monitoring of drug handling procedures for symptom control studies. As well, pharmacists were invited to study workshops and start-up meetings with investigators and clinical research associates.

Twenty-five people attended the inaugural meeting of the Pharmacists Network, held in Montreal on November 29, 1992. There was a unanimous decision to form a Pharmacists Network by establishing a Steering Group and developing a formal proposal.

The Pharmacists Network Steering Group holds two meetings a year in conjunction with the Spring and Fall NCIC CTG meetings; as well as teleconferences throughout the year as required. A page for the Pharmacists Network is a part of the NCIC CTG website. The Pharmacists Network Steering Group has recently revised the Pharmacy Manual and provided a number of templates to assist pharmacists at participating centres. Examples of some available templates are illustrated on this display.

Pharmacists Network Mission Statements:

1. To promote the optimum utilization and standardization of oncology pharmacy services in the development and conduct of clinical trials.

2. To improve communication and sharing expertise in oncology issues and information between members, the central office and other professional groups within the NCIC CTG for the ultimate benefit of the cancer patient.

Contact Information:
www.ctg.queensu.ca/members

IMPLEMENTATION OF DOSE BANDING IN BAXTER COMMERCIALLY PREPARED 5-FU INFUSORS WITH SUB-ANALYSIS OF SAFETY AND COST-EFFECTIVENESS

Mr. Rick Abbott, B. Sc (Pharm), Mr. Jonathan Edwards, Pharm Student
Dr. H. Bliss Murphy Cancer Center, Eastern Health Cancer Care Program

Purpose: As the incidence of cancer escalates on an annual basis there is a need to revamp existing hospital oncology services. Pharmaceutical services can be revised to reduce patient waiting times and administration while at the same time promoting safety by utilizing dose banding.

History: Since 2005 the Dr. H. Bliss Murphy Cancer Center (DHBMCC) has utilized a home infusion program for the delivery of 5-FU infusional chemotherapy. All 5-FU infusional chemotherapy is prepared based on an agreed upon dose banding chart. Since May 2007 our center has been dispensing commercially filled infusors. To date, 56 patients are participating in the home infusion program with approximately 85% of these patients receiving their 5-FU chemotherapy from commercially prepared infusors.

Safety: The Institute for Safe Medical Practices has been quoted as saying "use pre-filled syringes/bags/cassettes whenever available commercially." To ensure a quality product the chemotherapy suite has become fully compliant with USP 797 and has implemented many of the National Institute of Occupational Safety and Health (NIOSH) guidelines.

Cost Considerations: The DHBMCC utilizes approximately 1000 infusers per annum. Commercially pre-filled infusors with dose banding is a cost-effective means of providing a home infusion program.

Contact Information:
Mr. Rick Abbott
Dr. H. Bliss Murphy Cancer Center
Eastern Health Cancer Care Program

Sponsor:
Baxter Canada Corporation

THE EVOLUTION OF PHARMACY SUPPORT FOR ONCOLOGY CLINICAL TRIALS

Kim Bruce-Payne, Larry Broadfield, Claudia Harding
Capital District Health Authority, Halifax

Oncology clinical trials are a key component of the comprehensive cancer program at the QE II Health Sciences Centre. Over a period of several years, the participation of the Pharmacy service in support of oncology clinical trials has grown substantively. Continued growth in the number of active clinical trials has driven the Pharmacy service to develop new models for service delivery.

In 2005, shifting responsibilities among the oncology pharmacists necessitated the creation of a full time pharmacy technician position to support oncology clinical trials, and in 2006 another part time position to support Special Access drugs was added. This was in addition to 2 previous pharmacy technician positions for non-oncology trials. Since this time, duties previously carried by the oncology pharmacist have shifted to the technician, including up front preparation of pharmacy procedures, ongoing trial maintenance (e.g. quality control of acquisition and accountability records), and frequent study monitoring visits. Other duties have been retained by the oncology pharmacist (e.g. development of drug information sheets for new agents), and a new function to develop trial-specific Pre-Printed Orders has been added. Examples of each will be illustrated.

Billing for Pharmacy services has been carefully monitored, and the entire cost of the pharmacy technician has been offset against receivables from the trials. This program is cost-neutral for the department. Data will illustrate this success.

As we look to the future, new opportunities may be considered. For instance, the opportunity to conduct pharmacy practice research around clinical trial support is under consideration. Some ideas will be shared for discussion.

MEDICATION SAFETY HUDDLES: REDUCING RISK OF MEDICATION ERRORS AND IMPROVING PATIENT SAFETY

Dr. Scott Edwards, Clinical Pharmacist & Mr. Michael Godsell, Pharmacy Student
Dr. H. Bliss Murphy Cancer Center, Eastern Health Cancer Care Program

Purpose: The primary goal of this trial is to identify potential sources of medication errors or near misses and strategies to prevent these problems in the future at the Dr. H. Bliss Murphy Cancer Centre (DHBMCC) by holding brief meetings or "huddles" among front line oncology staff.

Design: From Sept 2005 to August 2007 a clinical pharmacist met with the oncology nursing staff once weekly for a briefing that had a maximum length of 15 minutes. We utilized a standardized list of three questions to initiate discussion. During the ensuing discussion staff members explored potential sources of medication errors or near errors and strategies to prevent these problems in the future. The clinical pharmacist collected data from each session and accountability for follow-through was assigned.

Results: Over the two-year period the patients identified 5 issues and the nursing staff identified 182 issues. Of the combined 187 issues, 22 (11.7%) were resolved.

Conclusion: The medication huddle has become a standard of practice within the DHBMCC. The pharmacy team is able to efficiently utilize time in identifying critical medication errors that can be rectified to enhance pharmacy services and patient safety.

Contact Information:
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EVALUATION OF THE INDENTIFICATION AND TREATMENT OF HEMATOLOGICAL TOXICITIES AMONG CHEMOTHERAPY PATIENTS AT THE DR. H. BLISS MURPHY CANCER CENTER IN ST. JOHN'S, NL

Erin Schwenger Michael LeBlanc, B.Sc (Pharm), Pharm D (candidate)

Objective: To evaluate hematological toxicities and patient care by implementing a clinical pharmacy service to monitor for neutropenia and anemia among chemotherapy patients, initiate required therapy and collect insurance information for eligible patients.

Design: All patients undergoing chemotherapy at the Dr. H. Bliss Murphy Cancer Center requiring hematology during the 2-month period were included in the review. Hematology was checked the day following treatment with serum creatinine, total billirubin, hemoglobin, hematocrit, absolute neutrophil count (ANC) and platelets being documented. Any patient with Hemoglobin less than 100 g/L, or ANC equal to or less than 1.5 x 109 /L was referred to the clinical pharmacist.

Results: 12.28% of the 288 patients screened presented with hemoglobin less than 100 g/L and 12.72% presented with an ANC less than 1.5 x 109 /L. Of the 29 patients with neutropenia, 14 were being treated with palliative intent, 13 were adjuvant, and 2 were neoadjuvant. 76.9% of the adjuvant patients identified did not currently have therapy initiated.

Conclusions: A clinical pharmacy position dedicated to hematological screening of patients undergoing chemotherapy to identify chemotherapy-induced anemia and neutropenia and to facilitate patient access to medications can improve patient outcomes and ensure the appropriate and timely use of growth factors.

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COST-EFFECTIVENESS ANALYSIS OF OXALIPLATIN (ELOXATIN®) IN THE ADJUVANT TREATMENT OF STAGE III COLON CANCER

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Objective: To determine the incremental cost per Quality-Adjusted Life-Years (QALY) of FOLFOX - oxaliplatin plus 5-fluorouracil/Leucovorin (5FU/LV) compared with 5-FU/LV alone for the adjuvant treatment of stage III colon cancer from the perspective of Ontario's Ministry of Health.

Design: Patients' outcomes were modeled from treatment until death using patient level data from the MOSAIC trial. The data from this trial was extrapolated based on the relationship between the overall survival (OS) and disease-free survival (DFS), and Canadian life tables. Utilities were obtained from the literature. Resource utilization data were derived from the MOSAIC trial and supplemented with data from the literature. Unit costs were obtained from the Ontario Ministry of Health and Long-Term Care documents, a data abstraction at London Health Sciences, and the literature. Results were discounted at 5% annually.

Results: Incremental cost-effectiveness ratios of FOLFOX compared to 5FU/LV from the lifetime analysis were Can$14,266 per disease-free year; Can$23,598 per life year saved and Can$24,104 per QALY. The results were stable for a wide range of inputs, but were most sensitive to assumptions regarding the utility values associated with relapse.

Conclusion: Oxaliplatin/5-FU/LV is a cost-effective treatment for stage III colon cancer, with a cost-effectiveness ratio of Can$24,104 per QALY.

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Category of abstract: Pharmacy practice and administration

HAZARDOUS DRUG SPILL: IN-SERVICE DEVELOPMENT FOR COMMUNITY HOSPITAL PHARMACY STAFF

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Nancy Coady, British Columbia Cancer Agency – Vancouver Island Centre

Objective: To describe the development of a hazardous drug (HD) spill in-service by the British Columbia Cancer Agency (BCCA) Pharmacy Communities Oncology Network (CON) Educators.

Design: The Pharmacy CON Educators developed the HD Spill In-Service based on the HD Spill Control in Pharmacy, BCCA Pharmacy Directive VI-10. The directive incorporates recommendations from the NIOSH "Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings" (Sept.2004) and ASHP Guidelines on Handling Hazardous Drugs (Jan.2006).

Materials and Method: The directive was divided into key learning objectives. Photographs were taken of mock spills. A power point presentation was developed using the objectives and photographs.

Results: Six learning objectives were identified:

- Spill-kit contents
- Procedures for personnel contamination
- Procedures for donning Personal Protective Equipment
- Locations of spills
- Types of spills
- Procedures for cleaning based on location and type of spill

Conclusions: The Pharmacy CON Educators currently use the in-service to educate CON hospital pharmacy staff in HD spill control.

SUPPORT FOR A PROVINCIAL ONCOLOGY DRUG PROGRAM (PODP) VIA ELECTRONIC LINKAGES

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Background: The Provincial Oncology Drug Program (PODP) was funded in May 2006 to provide equitable access to new drugs and treatment for all cancer patients in Manitoba. A crucial component of the PODP was to obtain prospective data on all chemotherapy delivered in all facilities in Manitoba. The Varis MedOncology (VMO) computer program was the electronic linkage that provided the forum for capturing data on systemic therapy delivered in the province.

Objective: To ensure that all sites (hospitals, outpatient sites and community cancer programs) were using the VMO system for the ordering and billing of intravenous chemotherapy.

Design: Site visits were conducted to all the facilities during which a process audit review was completed. Problem solving occurred during the site visits and feedback summaries were distributed to all the sites with suggestions for improvements of the order entry and billing process. First cycles of chemotherapy are now being triaged and entered into the VMO system for all facilities at CancerCare Manitoba MacCharles site.

Results: After five months, all twenty-three sites were utilizing the VMO system to capture systemic therapy data which can be utilized for fiscal drug management, adherence to clinical practice guidelines and criteria for drug use and outcome evaluation.

Conclusion: Cancer patients in Manitoba will benefit from a comprehensive provincial oncology drug program supported by electronic linkages with all facilities delivering systemic therapy.

Treatment of Metastatic Breast Cancer (MBC) with Doxorubicin or Pegylated Liposomal Doxorubicin (PLD): The Development of a Cycle-Based Risk Model to Identify Patients at High Risk for Cardiac Toxicity

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Background: Anthracyclines (ACH) have demonstrated effectiveness for adjuvant and MBC therapy. However cardiac toxicity from ACH can lead to therapy discontinuation or hospitalization, and may progress to congestive heart failure. Since such risk may vary by patient and with each cycle of treatment, we developed and tested a cycle-based risk prediction model for cardiac toxicity in MBC patients receiving chemotherapy with doxorubicin (DOX), either in its traditional form or the PLD formulation.

Methods: Data was obtained (n=509) from a randomized trial of MBC patients assigned either DOX (60 mg/m2 every 3 wks) or PLD (50 mg/m2 every 4 wks) [O'Brien, 2004]. In the cycle-based risk model, disease and treatment factors that were potential predictors of cardiac toxicity were identified for each cycle of chemotherapy. Factors with p-value <= 0.25 with >= grade 2 cardiac toxicity following a cycle were retained and included in a generalized estimating equations (GEE) regression model. Using backward elimination, we derived a risk scoring algorithm (range 0-62) from the final reduced model.

Results: Risk factors for ACH-induced cardiac toxicity included an interaction effect between DOX and cycle count, patient age and weight, previous ACH exposure and poor performance status. A receiver operating characteristic curve analysis had an area under the curve (AUC) of 0.84 (95% CI: 0.79–0.89). A precycle risk score cutoff of >= 30 to < 40 was identified to optimize sensitivity (58.5%) and specificity (89.0%). Prior to each cycle of administration, patients scoring > 30, would be considered at high risk for cardiac toxicity (i.e. >= grade 2). Risk scores < 30, >= 30 to < 40, or >= 40 predict a 0 to < 5%, 5 to <13% and 13%-67% risk of cardiac toxicity, respectively.

Conclusions: Risk of cardiac toxicity varies according to number of cycles administered, cumulative ACH exposure as well as patient factors. Our model may provide patient specific risk information that may be helpful in assessing risks and benefits of anthracyclines in the metastatic setting and to potentially reduce cardiac complications.

NATIONAL CANCER INSTITUTE OF CANADA (NCIC) PHARMACISTS NETWORK WORKLOAD SURVEY – WHAT DOES PHARMACY DO TO SUPPORT ONCOLOGY CLINICAL TRIALS?

Susan Walisser, Marlene Sellon, Biljana Spirovski, Nathalie Letarte, Ing Collins, Rob Whelan, Colleen Olson, Zoe Koulouris

Objective: To gain insight into the work being done within pharmacy to support oncology clinical trials with the aim of enhancing NCIC Pharmacist Network activities and NCIC pharmacy focused clinical trial funding.

Design: The Pharmacists Network Steering Group designed a survey to collect information regarding the number and experience of pharmacy staff actively involved in clinical trials, the types of activities being undertaken and the sources of funding. This on-line survey was advertised to pharmacists known to NCIC. The results were then collated and analyzed.

Results: Completed surveys were received from a representative cross section of centres. There was significant variation in staffing resources across the country but most centres had one pharmacist responsible for clinical trials. The involvement of pharmacy technicians varied greatly. Some centres had no technician involvement. Clinical trials pharmacy staff usually had at least 3 years of oncology experience. A number of core activities were identified. Most pharmacies receive some funding from clinical trials budgets or pharmacy levied fees.

Conclusion: The information collected will be helpful in identifying opportunities for the Pharmacist Network to support oncology pharmacy clinical trials practice and can be used by NCIC to identify reasonable per case funding specifically for pharmacy services.

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VIRTUAL PHARMACY SERVICES TO A REMOTE HOSPITAL WITHOUT AN ON-SITE PHARMACIST

Marianne Moore - BCCA – VC; Nicole Abrahamczik – Mills Memorial Hospital; Greg Atherton - GR Baker Memorial Hospital; Rachel Marshall – Mills Memorial Hospital; Nola Paulin – Mills Memorial Hospital; Janice Reynolds - GR Baker Memorial Hospital

Objective: To provide virtual pharmacy services, including chemotherapy, to a remote hospital in the absence of a pharmacist at the remote site.

Design: After approval of a proposal and draft policies and procedures by the BC College of Pharmacists and the Regional Pharmacy Director, a one-month trial of virtual pharmacy services was undertaken in BC's Northern Health Authority (NHA).

Materials and Methods: A pharmacy technician at the remote site enters orders into the local pharmacy computer, then FAXes related documentation to the supervising site, where a pharmacist checks them and contacts the nurse or physician at the remote site to discuss potential problems. The pharmacist then approves preparation of the drug at the remote site.

After preparation, materials used and the labelled final product are displayed to the pharmacist via videoconferencing equipment. The sharp acuity of the transmission allows the pharmacist to comfortably verify accuracy of preparation and labels on screen. For oral medications, the pharmacist counsels the remote patient on camera.

Results: After a successful trial period, "telepharmacy" has been used in the NHA for over two years, both to extend days of pharmacy service at a remote site and to cover pharmacist absences, thus avoiding chemotherapy preparation at, or patient travel to, another site.

Conclusion: "Telepharmacy" is a safe and practical way to compensate for pharmacist absences in remote communities.

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For more information, or to join the NOPS 2008 Team, please contact me at leegordo@cancerboard.ab.ca. I look forward to hearing from you.

Sincerely,

Lee Gordon, NOPS 2008 Co-chair
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