

CJHP JCPH

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Le Journal canadien de la pharmacie hospitalière

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**36th Annual
Professional
Practice
Conference**

**36e Conférence
annuelle sur
la pratique
professionnelle**

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5-9 février 2005

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Canadian Society of Hospital Pharmacists
Société canadienne des pharmaciens d'hôpitaux

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Caution should be exercised in severely hypercholesterolemic patients who are also renally impaired, elderly, or are concomitantly being administered digoxin or CYP 3A4 inhibitors.

Liver function tests should be performed before the initiation of treatment, and periodically thereafter. Special attention should be paid to patients who develop elevated serum transaminase levels, and in these patients, measurements should be repeated promptly and then performed more frequently.



Clinical research program

Aiming beyond.

- EFFICACY** > † A powerful demonstrated effect across key lipid parameters¹
- EXPERIENCE** > More than 57 million patient-years of experience²
- EVIDENCE** > Demonstrated delayed time to first ischemic event in stable CAD patients^{3v} (n=341, p=0.03)

‡ The Atorvastatin Versus Revascularization Treatments (AVERT) study examined the effect of intensive lipid-lowering in patients with stable coronary artery disease and LDL-C at least 3.0 mmol/L in patients referred for percutaneous transluminal coronary angioplasty (PTCA). Patients were randomized for 18 months to LIPITOR 80 mg daily or to PTCA with usual medical care which could include lipid metabolism regulators. The results of the AVERT study should be considered as exploratory since several limitations may affect its design and conduct. In the medical-treated group with LIPITOR there was a trend for a reduced incidence of ischemic events and a delayed time to first ischemic event. The results also suggest that intensive treatment to target LDL-C levels with LIPITOR is additive and complementary to angioplasty and would benefit patients referred for this procedure.³



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PAAB
 (Pg. 1)

*TM, Pfizer Inc./Pfizer Pharmaceuticals, Pfizer Canada Inc., Toronto

Dear Colleague:

On behalf of the Officers, Council and staff of the Canadian Society of Hospital Pharmacists, it is my pleasure to welcome you to CSHP's 36th Annual Professional Practice Conference.

The 2005 conference promises to be phenomenal! Over the last 10 months, CSHP's Educational Services Committee has worked to assemble an impressive faculty of pharmacy specialists and develop a program of exceptional educational value.

This conference is designed to maximize your opportunities for professional development, networking and socializing with practitioners from across the country. It is our hope that you are able to take full advantage of the 2005 offerings – and enjoy yourself in the process.

At any time throughout the conference, the Officers and staff of CSHP are available to you. Please let us know if we can answer any of your questions, address any of your concerns or be of assistance in any way. Be sure to take a few minutes and stop by the CSHP booth during the exhibits program and say hello.

We look forward to welcoming each of you to another spectacular conference.

Thank you for your ongoing support of CSHP.



Régis Vaillancourt
CSHP President

Chers (ères) collègues,

Au nom des membres du Bureau, du Conseil et du personnel de la Société canadienne des pharmaciens d'hôpitaux, je suis heureux de vous souhaiter la bienvenue à la 36e Conférence annuelle sur la pratique professionnelle de la SCPH.

La conférence 2005 promet d'être formidable. Au cours des dix derniers mois, le Comité des services éducatifs de la SCPH s'est affairé à rassembler un groupe impressionnant d'enseignants spécialisés en pharmacie et à élaborer un programme d'une valeur éducative exceptionnelle.

Cette conférence est destinée à maximiser les possibilités de perfectionnement professionnel, de réseautage et de rencontre avec d'autres praticiens de toutes les régions du pays. Nous espérons que vous pourrez tirer pleinement profit de ce que vous offre la Conférence de 2005 et que vous prendrez le temps de vous divertir.

Nous vous rappelons qu'au cours de cette conférence, les membres du Bureau et le personnel de la SCPH seront à votre entière disposition. Nous pourrions répondre à vos questions, discuter des sujets qui vous intéressent ou vous aider au besoin. Pendant le programme d'exposition, assurez-vous d'effectuer un arrêt au stand de la SCPH et de nous dire bonjour!

Nous sommes impatients de vous accueillir à cette autre conférence exceptionnelle et vous remercions de votre appui soutenu à la SCPH.



Régis Vaillancourt
CSHP President



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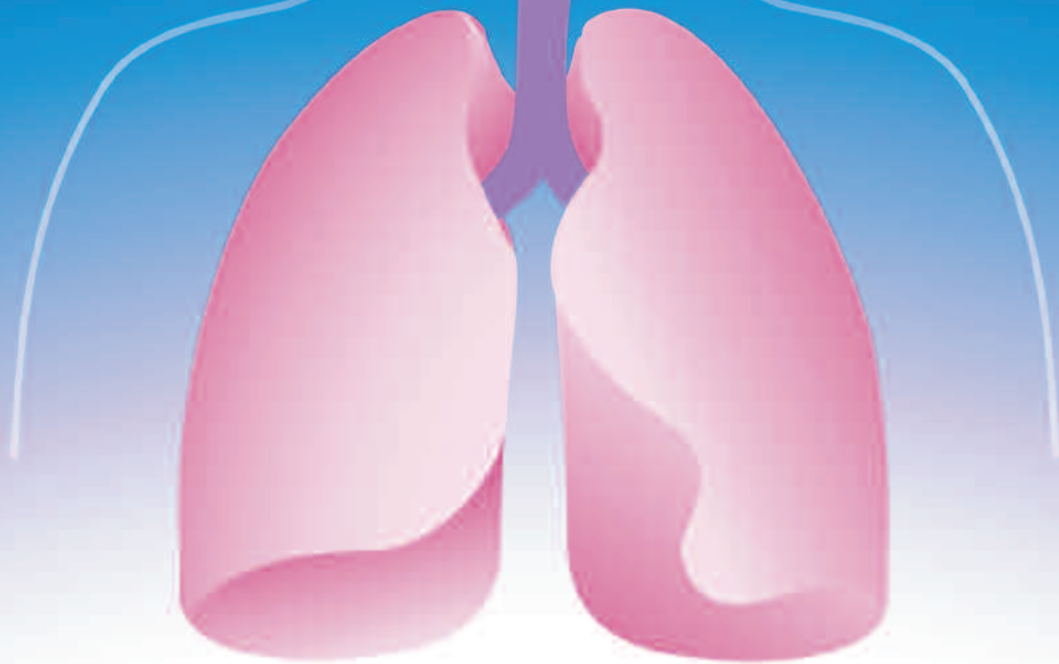
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(at time of printing)

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The following list reflects all CSHP sponsorship received from July 1, 2004 to time of printing.

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Aventis Award

Specialty Practice in Cardiology
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Baxa Award

Innovative Practitioner
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New Programs in Patient
Counselling
\$1,500

Pfizer Award

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\$2,000

Pharmascience Award

Patient Care Enhancement
\$1,000

Distinguished Service Award

Presented by Janssen Ortho Inc.
\$1,500

Outstanding Achievement in
Hospital Practice

Individuals are nominated by their peers

Past Winners

1967 Michael J.V. Naylor
1968 Jacqueline McCarthy
1969 Isabel E. Stauffer
1970 Gordon Brown
1971 Paule Benfante
1972 Edwin J. Smith
1973 Leonard Gibson
1974 Anne O'Toole
1975 Muriel Hale
1976 Orest Buchko
1977 Phyllis Yagi
1978 Douglas J. Stewart
1979 Jack L. Summers
1980 Betty C. Riddell
1981 Brian A. Dinel
1982 J. Glen Moir
1983 Mary T. Gannon
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1986 William R. Foltas
1987 Jack Dancey
1988 Bruce R. Schnell
1989 Alan Samuelson
1990 Reta Fowler
1991 C. Brian Tuttle
1992 William Wilson
1993 Pauline Beaulac
1994 William McLean
1995 James L. Mann
1996 Kevin Hall
1997 Rosemary Bacovsky
1998 Scott Walker
1999 Bonnie Salsman
2000 James Blackburn
2001 Charlie Bayliff
2002 Glen Brown
2003 Robert S. Nakagawa
2004 Garry King

Isabel E. Stauffer Meritorious Service Award

Presented by Pharmaceutical
Partners of Canada
\$1,500

Prolonged Service and
Involvement in CSHP, primarily
at the branch and chapter level

Individuals are nominated by their peers
primarily at the branch and chapter level

Past Winners

1986 Herbert A. Dixon
1986 A.W. Stanley Garvin
1987 Alan Samuelson
1988 D. Bryce Thompson
1989 Fred Rumpel
1990 Doris A. Thompson
1991 David Windross
1991 Louanne Twaites
1992 Cecilia Laskoski
1992 John Iazzetta
1993 No candidates this year
1994 Rosemary Bacovsky
1994 Roy A. Steeves
1995 Kristina Wichman
1995 Donna Pipa
1996 Robert S. Nakagawa
1996 Dennis Leith
1997 No candidates this year
1998 Larry Legare
1998 Emily Somers
1999 Kenneth McGregor
1999 Linda Poloway
2000 Kelly Babcock
2001 No candidates this year
2002 Margaret Colquhoun
2003 Margaret Gray
2004 Nancy Roberts

New Hospital Pharmacy Practitioner Award

Sponsored by Sabex Inc.
\$1,500 x 2

Outstanding achievement in
hospital pharmacy practice for
two pharmacists who have
practiced in an organized health
care setting since licensure as a
pharmacist within the past 5
years or less.

Individuals are nominated by their peers

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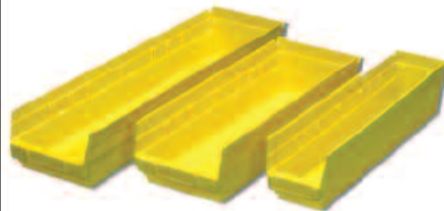


Safety products

Acetaminophen 120 mg with Codeine Phosphate 12 mg
 Lot: 02251126 Mfg: MILTCO

 005910737018
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2004/2005 Awards Program

Sincere appreciation is extended to the Awards Committee and to our 2004/2005 Award Appraisers.

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Rosemary Zvonar

Tribute to the Appraisers of the 2004/2005 Awards Program

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Many thanks to the appraisers of this year's award submissions. We are very grateful to you for sharing your time and expertise in support of the CSHP Awards Program. Without your dedicated efforts on the Society's behalf, the program would not exist.

Mark Edlund

Carmine Nieuwstraten

Mark Friesen

Cali Orsulak

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Linda Poloway

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If you are interested in becoming an appraiser for the 2005/2006 Awards Program, please contact Gloria Day at the National office. Tel.: (613) 736-9733, ext. 231 or email: gday@cshp.ca

PORTRAIT OF A FAMILY HISTORY

HISTORY DOESN'T HAVE TO REPEAT ITSELF



Roger,
History of
angina.

Died age 57
of MI.

Help Reduce the
Risk of CV Death
by **26%**¹
($p < 0.001$; 6.1% vs. 8.1%)

Alice,
History of
diabetes and
high total
cholesterol.

Died age 62
of stroke.



ALTACE 10 mg
ramipril

GUARDING AGAINST CV DEATH

ALTACE is indicated in the treatment of essential hypertension, normally when beta-blockers and diuretics are inappropriate. It may be used alone or in association with thiazide diuretics. ALTACE is indicated following acute myocardial infarction in clinically stable patients with signs of left ventricular dysfunction to improve survival and reduce hospitalizations for heart failure.

Results from the HOPE study showed that ALTACE improved survival in patients by reducing the risk of CV death by 26% ($p < 0.001$; 6.1% vs. 8.1%). ALTACE may be used to reduce the risk of MI, stroke, or CV death in patients over age 55 who are at high risk of CV events because of a history of CAD, stroke, peripheral artery disease, or diabetes accompanied by at least 1 other CV risk factor such as hypertension, elevated total cholesterol levels, low HDL levels, cigarette smoking, or documented microalbuminuria.

Like other ACE inhibitors, ALTACE is not recommended for pregnant or lactating women and should be used with caution in patients with renal insufficiency. The most frequent adverse events occurring in clinical trials with ALTACE monotherapy in hypertensive patients who were treated for at least 1 year ($n=651$) were: headache (15.1%); dizziness (3.7%); asthenia (3.7%); chest pain (2.0%). Discontinuation of therapy due to clinical adverse events was required in 5 patients (0.8%).

The reasons for stopping treatment were cough (ramipril 7.3% vs. placebo 1.8%); hypotension/dizziness (1.9% vs. 1.5%) and edema (0.4% vs. 0.2%).

ALTACE is the most prescribed ACEI among cardiologists.*

*IMS Health Canada: Canadian CompuScript Audit, Moving Annual Total ending June 2004, Total Prescriptions.



Product Monograph available to physicians and pharmacists upon request.

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Upcoming Events/ Événements à venir

Professional Practice Conference (PPC)

February 5 - 9, 2005
Westin Harbour Castle
Toronto, Ontario
Exhibits – yes
Attendance: 1000 – 1200

Annual General Meeting (AGM)

August 13 - 16, 2005
The Westin Ottawa
Ottawa, Ontario
Exhibits – yes
Attendance: 250 - 300

Professional Practice Conference (PPC)

January 28 to February 1, 2006
Westin Harbour Castle
Toronto, Ontario
Exhibit – yes
Attendance 1000 – 1200

Annual General Meeting (AGM)

August 12 – 15, 2006
Le Centre Sheraton
Montreal, Quebec
Exhibits – yes
Attendance 250 – 300

Professional Practice Conference (PPC)

January 27 to January 31, 2007
Westin Harbour Castle
Toronto, Ontario
Exhibits – yes
Attendance 1000 – 1200

Annual General Meeting (AGM)

August 11 – 14, 2007
TBA
Regina, Saskatchewan
Exhibits - yes
Attendance 250 - 300

Professional Practice Conference (PPC)

February 2 - 6, 2008
Westin Harbour Castle
Toronto, Ontario
Exhibits – yes
Attendance 1000 – 1200

Annual General Meeting (AGM)

August 9 – 12, 2008
TBA
Saint John, New Brunswick
Exhibits - yes
Attendance 250 - 300

Professional Practice Conference (PPC)

January 31 to February 4, 2009
Westin Harbour Castle
Toronto, Ontario
Exhibits – yes
Attendance 1000 – 1200

Annual General Meeting (AGM)

August 15 – 18, 2009
TBA
Winnipeg, Manitoba
Exhibits - yes
Attendance 250 – 300

Professional Practice Conference

January 30 to February 3, 2010
Westin Harbour Castle
Toronto, Ontario
Exhibits – yes
Attendance 1000 - 1200



For further information, please contact Desarae Davidson, CSHP National Office.

Tel.: (613) 736-9733, ext. 229

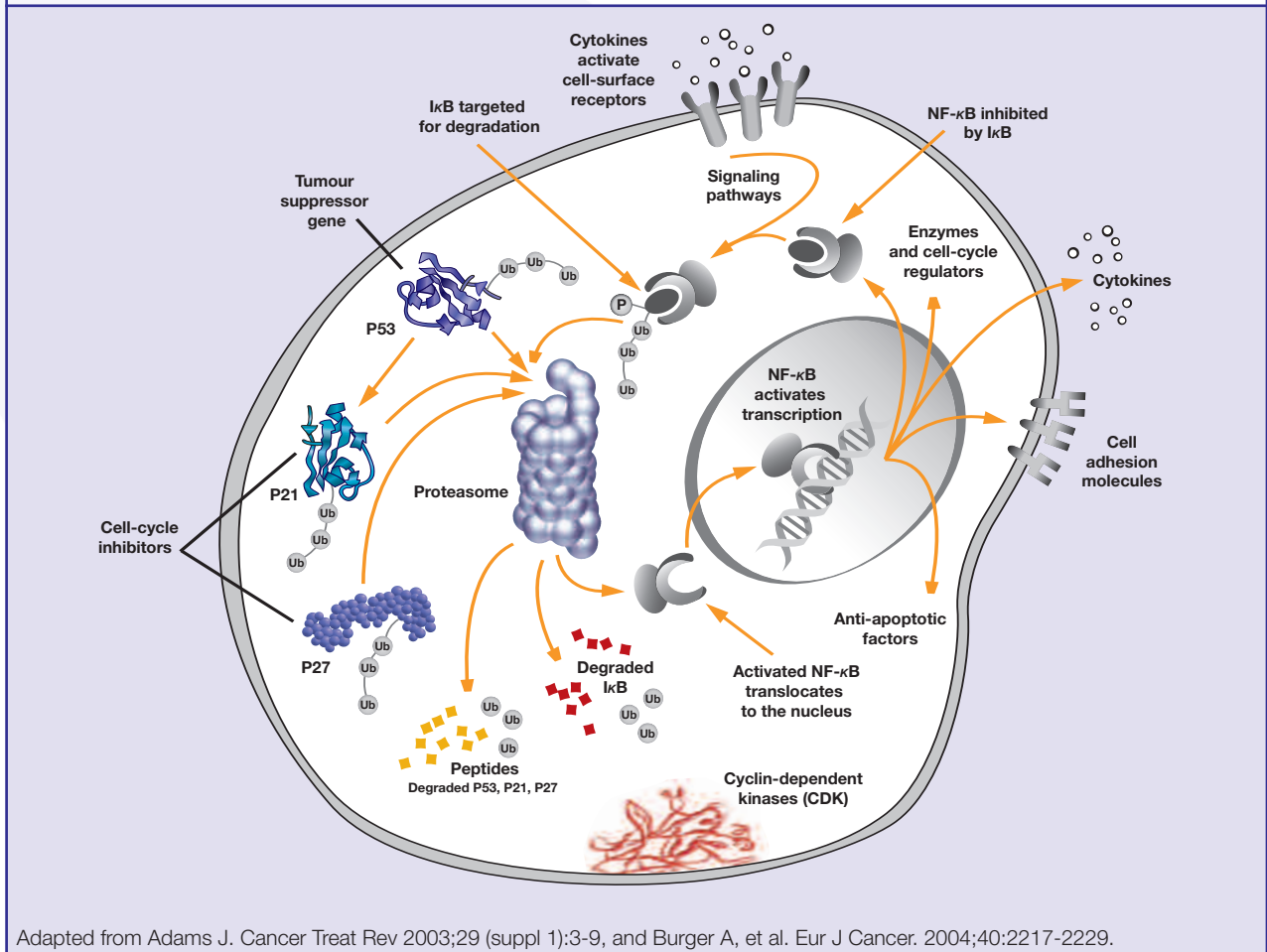
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AT ORTHO BIOTECH WE ARE CURRENTLY CONDUCTING RESEARCH IN THE AREA OF PROTEASOME INHIBITION

The proteasome affects many important regulatory proteins thought to be involved in cancer growth.¹⁻⁵

Proteasome Pathways



Adapted from Adams J. Cancer Treat Rev 2003;29 (suppl 1):3-9, and Burger A, et al. Eur J Cancer. 2004;40:2217-2229.

As shown in non-clinical studies

References: 1. Adams J. Cancer Treat Rev 2003;29(suppl1):3-9. 2. Shah S, et al. Surg Oncol 2001;10:43-52. 3. Loda M, Cukor B, Tam S, et al. Nat Med 1997;3(2):231-234. 4. Lloyd R, Erickson L, Jin L, et al. Am J Pathol 1999;154(2):313-323. 5. Burger A and Seth AK. Eur J Cancer 2004;40:2217-2229.

Continuing Education Credits/ Crédits de formation continue



Canadian Council on Continuing Education in Pharmacy
Conseil canadien de l'éducation permanente en pharmacie

The Educational Services Committee

The Educational Services Committee (ESC) of CSHP has been working for approximately 10 months on the content and format of PPC 2005. They also work on the Annual General Meeting, in conjunction with the local host committee and the national office. The ESC is comprised of a core committee of 10 hospital pharmacists as well as 8 corresponding members from the CSHP branches.

Goal and objectives for the 2005 PPC Program

Goal:

To provide registrants with quality educational sessions

Objectives:

- To provide registrants with educational sessions which inform, educate and motivate clinical practitioners and managers
- To provide leadership in hospital pharmacy practice by presenting sessions on innovative pharmacists' roles, pharmacy practice and pharmacy programs
- To promote life-long learning skills through active participation in problem-based workshops
- To provide registrants with networking and sharing opportunities through the exhibits program, poster sessions and round table discussions
- To promote excellence in pharmacy practice through oral and poster presentations on original work and award winning projects
- To provide an opportunity to Pharmacy Specialty Networks to meet

But et objectifs du programme de la CPP 2005

But :

Présenter des conférences éducatives de qualité aux participants.

Objectifs :

- Présenter aux personnes inscrites des conférences éducatives susceptibles d'informer, d'instruire et de motiver les cliniciens et les gestionnaires.
- Orienter la pratique de la pharmacie d'hôpital en présentant des conférences sur les nouveautés touchant le rôle du pharmacien, la pratique de la pharmacie et les programmes de pharmacie.
- Favoriser des aptitudes d'apprentissage permanentes par une participation active à des ateliers de formation centrés sur des problèmes.
- Donner aux participants l'occasion d'établir des réseaux et de partager grâce au salon des exposants, aux séances d'affichage et aux tables rondes.
- Promouvoir l'excellence dans la pratique de la pharmacie par des présentations orales et des séances d'affichage sur des travaux originaux et des projets primés.
- Donner l'occasion aux réseaux de spécialistes en pharmacie de se réunir.

Program/Programme

Saturday, February 5 • Samedi le 5 février

15:00 – 17:00 Registration/Inscription

Queen's Quay 2

Sunday, February 6 • Dimanche le 6 février

07:30 – 17:00 Registration/Inscription

Metropolitan Foyer

08:45 – 09:00 Opening Remarks/
Remarques préliminaires

Frontenac Ballroom

09:00 – 10:00 **Pharmaceutical Care Practice:
25 Years and 25,000 Patients Later**

Frontenac Ballroom

Linda Strand, PharmD, PhD
University of Minnesota
Minneapolis, MN

10:00 – 10:45 **Break/Posters/Pause/Affiches**

Frontenac Foyer

10:45 – 11:30 **Concurrent Sessions/
Sessions concomitantes**

1. The Role of an ICU Pharmacist

Queen's Quay

Clarence Chant, PharmD
St. Michael's Hospital
Toronto, ON

2. Cardiovascular Secondary Prevention Drug Benchmarks: Can We Reach Them? Yes We Can!

Pier 2/3

Derek Jorgenson, PharmD
Health Quality Council & Saskatoon
Health Region
Saskatoon, SK

3. Privacy Legislation and its Impact on Hospital Pharmacy Practice

Pier 4/5

Anthony Caldwell
Fogler Rubinoff LLP
Toronto, ON

11:40 – 12:25 **Concurrent Sessions/
Sessions concomitantes**

1. Medical Myths

a. Methadone is only for treating opioid addiction

Queen's Quay

Carlos DeAngelis, PharmD
Sunnybrook and Women's HSC
Toronto, ON

b. Acetaminophen vs. Ibuprofen: Not Sure What to Take, Should we alternate?

Queen's Quay

Angela Trope, MSc, MRPharmS
Hospital for Sick Children
Toronto, ON

c. Spironolactone does not cause hyperkalemia

Queen's Quay

Alice Hogg, BScPhm
University Health Network
Toronto, ON

2. Role of Pharmacists in Primary Care

Pier 2/3

Natalie Kennie, PharmD
St. Michael's Hospital
Toronto, ON

3. The Use of Colloids for Fluid Resuscitation in Critical Care

Pier 4/5

Chantal Manoukian, BPharm, MSc
Sir Mortimer B. Davis Jewish General
Hospital
Montréal, QC

12:30 – 14:00 **Satellite Symposiums (luncheon included)/ Symposiums satellites (déjeuner inclus)**

a. Immunonutrition in the ICU

Harbour A

hosted by: Novo Nordisk Canada Inc.

b. Bridging the Care Gap between Clinical Practice and Evidence- Based Medication in Atherothrombosis

Harbour B

hosted by: The Canadian
Cardiovascular Pharmacists Network
on behalf of Sanofi-Synthelabo &
Bristol-Myers Squibb Canada

c. The Role of Thromboprophylaxis to Improve Patient Safety

Harbour C

hosted by: Aventis Pharma Canada

14:10 – 14:55 **"White Paper": Pharmaceutical Care Panel**

Frontenac Ballroom

Margaret Ackman, PharmD
Capital Health
Edmonton, AB

Régis Vaillancourt, PharmD
Canadian Forces Health Services
Ottawa, ON

Debbie Kwan, BScPhm, MSc
University Health Network
Toronto, ON

15:00 – 17:00 Workshops/Ateliers

**1. Different Modes of Dialysis –
The Impact on Drug Therapy**

Queen's Quay

Lori MacCallum, PharmD
St. Michael's Hospital
Toronto, ON

Bill Perks, BScPhm
St. Michael's Hospital
Toronto, ON

**2. Optimizing Personal Digital
Assistant (PDA) use in your
Pharmacy Practice: A look at
What's New, What's Useful and
Future Implications**

Pier 2/3

Robert Balen, PharmD
Vancouver General Hospital
Vancouver, BC

3. Time Management – A Misnomer

Pier 4

Monica Olsen, MHRD, BScN, BA
Olsen and Associates Consulting Inc.
Richmond Hill, ON

**4. Enteral Feeding the Adult –
The Art and the Science**

Pier 5

Jan Greenwood, BSc, RD
Vancouver General Hospital
Vancouver, BC

**5. Professional Writing – Papers and
Abstracts**

Bay

Heather Kertland, PharmD
St. Michael's Hospital
Toronto, ON

Scott Walker, MScPhm, FCSHP
Sunnybrook and Women's College HSC
Toronto, ON

**15:00 – 17:00 PSN Session – Critical Care/
Session RSP – Soins en phase
critique**

**Advances in Critical Care
Therapeutics: Beyond Sepsis**

Pier 7/8

Glen Brown, PharmD, BCPS, FCSHP
Providence Health Care
Vancouver, BC

**Current Trends in the Management
of Ventilator-Associated Pneumonia**

Pier 7/8

Sharon Yamashita, PharmD, FCSHP
Sunnybrook and Women's College HSC
Toronto, ON

**17:00 – 18:00 Wine and Chat/
Vin et causette**

Harbour C

**17:30 – 19:30 Career Opportunities Evening/
Soirée de perspectives d'emploi**

Harbour A/B

Monday, February 7 • Lundi le 7 février

07:30 – 17:00 Registration/Inscription

Metropolitan Foyer

**08:30 – 09:30 Organizational Culture and
Patient Safety**

Frontenac Ballroom

Jack Davis, President & CEO
Steve Long, BScPhm, MBA
Calgary Health Region
Calgary, AB

**09:30 – 10:00 Awards Presentation/
Remise des prix**

Frontenac Ballroom

**10:00 – 10:30 Break/Exhibits/Posters/
Pause/Kiosques/Affiches**

Metropolitan Ballroom

**10:30 – 11:15 Concurrent Sessions/
Sessions concomitantes**

**1. Medication Error Events in a
Sample of Ontario Hospitals:
Learning from an ISMP Canada
Study**

Harbour A

Joan A. Marshman, BScPhm, MSc, PhD
University of Toronto
Toronto, ON

**2. Quality Improvement and Patient
Safety: Living with "Smart"
Infusion Devices**

Harbour B

Mark Duffett, BScPhm
McMaster University Medical Centre
Hamilton, ON

11:25 – 12:10	3. Challenges Associated with Heparin Induced Thrombocytopenia	14:00 – 14:45	Canadian Initiatives in Patient Safety
	Harbour C		Frontenac Ballroom
	Peter Thomson, PharmD Winnipeg Health Sciences Centre Winnipeg, MB		Bonnie Salsman, BScPhm, FCSHP BMS Consultants Halifax, NS
	Concurrent Sessions/ Sessions concomitantes		David Rosenbloom, PharmD David Rosenbloom Consulting Inc. Campbellville, ON
	1. Oral Presentations/ Présentations orales	14:15 – 16:15	Workshop/Atelier
	Queen's Quay 1		1. Time Management – A Misnomer
	2. Oral Presentations/ Présentations orales		Pier 4
	Queen's Quay 2		Monica Olsen, MHRD, BScN, BA Olsen and Associates Consulting Inc. Richmond Hill, ON
	3. Round Tables/Tables rondes	14:45-15:00	Recognition of New Fellows, Board of Fellows/ Reconnaissance des nouveaux associés, Conseil des associés
	a. The When, What, Who and How of Antibiotic Prophylaxis in Surgical Patients		Frontenac Ballroom
	Harbour A		15:00 – 17:00
	Barrie McTaggart, BScPhm McMaster University Medical Centre Hamilton, ON		Workshops/Ateliers
	b. Challenges with Potassium Chloride Storage		2. Different Modes of Dialysis – The Impact on Drug Therapy
	Harbour B		Queen's Quay
	Brian Beven, BScPhm Hospital for Sick Children Toronto, ON		Lori MacCallum, PharmD St. Michael's Hospital Toronto, ON
	c. Beyond BScPhm		Bill Perks, BScPhm St. Michael's Hospital Toronto, ON
	Harbour C		3. Optimizing Personal Digital Assistant (PDA) use in your Pharmacy Practice: A Look at What's New, What's Useful and Future Implications
	Susan Alderson, PharmD, MBA William Olser Health Centre Brampton, ON		Pier 2/3
	Emily Musing, BScPhm, MHSc University Health Network Toronto, ON		Robert Balen, PharmD Vancouver General Hospital Vancouver, BC
	d. HIT Protocols – Challenges in Managing Patients		4. Enteral Feeding the Adult – The Art and the Science
	Pier 2/3		Pier 5
	Tracey Lawson, PharmD St. Joseph's Health Centre Toronto, ON		Jan Greenwood, BSc, RD Vancouver General Hospital Vancouver, BC
	Reem Haj, BScPhm St. Michael's Hospital Toronto, ON		5. Professional Writing – Papers and Abstracts
12:15 – 14:00	Lunch/Exhibits/Posters/ Déjeuner/Kiosques/Affiches		Bay
	Metropolitan Ballroom		Heather Kertland, PharmD St. Michael's Hospital Toronto, ON

Scott Walker, MScPhm, FCSHP
Sunnybrook and Women's College HSC
Toronto, ON

**15:00 – 17:00 PSN Session – Geriatrics/
Session RSP – Gériatrie
Assessing Medication Management**

Pier 7/8

Beth Bryles Phillips, PharmD, BCPS
University of Iowa
Iowa City, IA

Karen B. Farris, BScPhm, PhD
University of Iowa
Iowa City, IA

**17:00 – 19:00 Satellite Symposium
(dinner included)
Symposium satellite (dîner inclus)
New Advances in the Treatment of
Fungal Interactions**

hosted by: Pfizer Canada Inc.

Harbour A

Tuesday, February 8 • Mardi le 8 février

07:30 – 17:00 Registration/Inscription

Metropolitan Foyer

**08:30 – 09:30 Emerging and Pandemic Infectious
Diseases – Should we be
Concerned?**

Frontenac Ballroom

Andrew Simor, MD, FRCPC
Sunnybrook and Women's College HSC
Toronto, ON

**09:30 – 10:00 Awards Presentation/
Remise des prix**

Frontenac Ballroom

10:00 – 10:30 Break/Exhibits/Pause/Kiosques

Metropolitan Ballroom

**10:30 – 11:15 Concurrent Session/
Sessions concomitantes**

**1. Clostridium difficile: New Twists
to an Old Story?**

Harbour A

Daniel Thirion, MSc, PharmD, BCPS
Hôpital du Sacre-coeur de Montréal
Montréal, QC

**2. Management of Diabetic Patients
during Acute Illness: Insulin
Sliding Scales and Beyond**

Harbour B

Doret Cheng, PharmD
Mount Sinai Hospital
Toronto, ON

3. Equity and Cultural Competence

Harbour C

Shakil Choudhury, M.E.S., B.Ed., B.P.E.
Brown Book Productions
Toronto, ON

**11:25 – 12:10 Concurrent Sessions/
Sessions concomitantes**

**1. Oral Presentations/
Présentations orales**

Queen's Quay 1

**2. Oral Presentations/
Présentations orales**

Queen's Quay 2

3. Round Tables/Tables rondes

a. Antimicrobial Protocols

Harbour A

Sandra Taylor, PharmD, FCSHP
Sunnybrook and Women's College HSC
Toronto, ON

**b. Developing a Hospital Policy
on the use of Medical
Marijuana**

Harbour B

Peggy Ruytenbeek, BScPhm
Southlake Regional Hospital
Newmarket, ON

**c. Internet Surfing for
Pharmacists: Navigating the
Seas for HIV Information**

Harbour C

Alice Tseng, PharmD, FCSHP
University Health Network
Toronto, ON

d. Thrombosis Service

Pier 2/3

Bill Bartle, PharmD, FCSHP
Sunnybrook and Women's College HSC
Toronto, ON

Mary Kwan, BScPhm
The Scarborough Hospital
Scarborough, ON

**12:15 – 14:00 Lunch/Exhibits/Posters/
Déjeuner/Kiosques/Affiches**

Metropolitan Ballroom

**14:00 – 14:45 E-Health and Disease State
Management**

Frontenac Ballroom

Jon Rasmussen, PharmD, BCPS
Kaiser Permanente – Colorado Region
Aurora, CO

- 14:45 – 15:00** **Research Grants Presentation, Research & Education Foundation/ Remise des bourses de recherche, Fondation pour la recherche et l'éducation**
- 15:00 – 17:00** **Workshops/Ateliers**
- 1. Fluid and Electrolytes: A Practical Approach**
- Queen's Quay
- Sharon Yamashita, PharmD, FCSHP
Sunnybrook and Women's College HSC
Toronto, ON
- 2. The Apprentice: You're Hired... to Develop Patient Education Materials!**
- Pier 2/3
- Elaine Chong, PharmD, BCPS
Network Healthcare
Vancouver, BC
- Trish Rawn, PharmD
Mount Sinai Hospital
Toronto, ON
- 3. Putting Advocacy Theory into Practice**
- Pier 4
- Marlo Palko
Fleishman-Hillard
Toronto, ON
- 4. Understanding Clinical Evidence and its Implications on Clinical Practice and Public Health**
- Pier 5
- Muhammad Mamdani, PharmD, MA, MPH
Institute for Clinical Evaluative Sciences
Toronto, ON
- 15:00 – 17:00** **PSN Session – ID/ Session RSP – Infectiologie**
- Hospital-Acquired Pneumonia: New Guidelines and Ongoing Controversies**
- Bay
- Richard Slavik, PharmD
Vancouver General Hospital
Vancouver, BC
- Development and Evaluation of Antimicrobial Intervention Programs – A Practical Approach**
- Bay
- B. Joseph Guglielmo, PharmD
University of California San Francisco
San Francisco, CA
- 17:00 – 19:00** **Satellite Symposiums (dinner included) Symposiums satellites (dîner inclus)**

"Fragile as it is" NOT JEOPARDIZING Your Febrile Neutropenic Patient's Health

Harbour B

hosted by: Merck Frosst Canada Ltd.

Managing Vascular Access Thrombosis in the Hemodialysis Population: Things to Know for Better Flow

Harbour A

hosted by: Hoffman-La Roche Ltd.

Wednesday, February 9 • Mercredi le 9 février

07:30 – 15:00 Registration/Inscription

Metropolitan Foyer

08:30 – 9:30 Antidepressants and Suicide in Kids: Weighing the Evidence

Frontenac Ballroom

Adil Virani, PharmD
IWK Health Centre
Halifax, NS

09:30 – 10:15 A Practical Overview of Drug-Drug Interactions

Frontenac Ballroom

David Juurlink, M.D.
Sunnybrook and Women's College HSC
Toronto, ON

10:15 – 11:00 Break/Posters/Pause/Affiches

Frontenac Foyer

11:00 – 11:45 Concurrent Sessions/ Sessions concomitantes

1. Prostate Cancer – A General Approach

Queen's Quay

Mario de Lemos, PharmD
BC Cancer Agency
Vancouver, BC

2. Aldosterone Antagonists in the Treatment of Heart Disease

Pier 2/3

Stephanie Young, PharmD
Health Care Corporation of St. John's
St. John's, NL

3. A Duty to Warn

Pier 4/5

Julie Greenall, BScPhm
Sylvia Hyland, BScPhm, MHSc
ISMP Canada
Toronto, ON

- 11:55 – 12:40 Concurrent Session/
Sessions concomitantes**
- 1. Cardiac Toxicity in Oncology:
Why and When**
- Queen's Quay
- Sean Hopkins, BSP
The Ottawa Hospital
Ottawa, ON
- 2. COPD and Tiotropium Use**
- Pier 2/3
- Lawrence D. Jackson, BScPhm
Sunnybrook and Women's College HSC
Toronto, ON
- 3. Acute Coronary Syndromes –
An Update**
- Pier 4/5
- Patrick Robertson, PharmD
Saskatoon Health Region
Saskatoon, SK
- 12:40 – 14:10 Satellite Symposiums
(luncheon included)
Symposiums satellites
(déjeuner inclus)**
- a. Managing Dyslipidemia:
Perspectives from Different
Specialties**
- Harbour A
- hosted by: Merck Frosst/Schering
Pharmaceutical Group
- b. Cardiovascular Update:
Metabolic Syndrome and
Opportunities for Pharmacists**
- Harbour B
- hosted by: AstraZeneca Canada Inc.
- c. The New MDRD Equation to
Assess Renal Function: How Does
it Compare?**
- Harbour C
- hosted by: Renal Pharmacist Network
and sponsored by Ortho Biotech
- 14:15 – 15:00 Prostate Cancer: A Patient's
Perspective**
- Frontenac Ballroom
- Mark Dailey
CityTV
Toronto, ON
- 15:00 – 17:00 Workshops/Ateliers**
- 1. Fluid and Electrolytes: A Practical
Approach**
- Queen's Quay
- Sharon Yamashita, PharmD, FCSHP
Sunnybrook and Women's College HSC
Toronto, ON
- 2. The Apprentice: You're Hired...
to Develop Patient Education
Materials!**
- Pier 2/3
- Elaine Chong, PharmD, BCPS
Network Healthcare
Vancouver, BC
- Trish Rawn, PharmD
Mount Sinai Hospital
Toronto, ON
- 3. Putting Advocacy Theory into
Practice**
- Pier 4
- Marlo Palko
Fleishman-Hillard
Toronto, ON
- 4. Understanding Clinical Evidence
and its Implications on Clinical
Practice and Public Health**
- Pier 5
- Muhammad Mamdani, PharmD, MA, MPH
Institute for Clinical Evaluative Sciences
Toronto, ON
- 15:00 – 17:00 PSN Session – Cardiology/
Session RSP - Cardiologie**
- Bay
- Failed Thrombolysis after Acute
Myocardial Infarction: So Now
What?**
- Claudia Bucci, BScPhm
Sunnybrook and Women's College HSC
Toronto, ON
- Tricky CHF Case Study**
- Glen Pearson, PharmD, FCSHP
University of Alberta
Edmonton, AB
- Complex Coagulopathy Case: DVT,
PE, CVA, GI Bleed, etc.!**
- Wendy Leong, PharmD, MBA, BCCPS
Burnaby Research
Burnaby, BC
- 17:00 Close of the 36th Professional
Practice Conference/
Clôture de la 36^e Conférence
annuelle sur la
pratique professionnelle**

Sunday, February 6 • Dimanche le 6 février

Pharmaceutical Care Practice: 25 Years and 25,000 Patients Later

Linda M. Strand, Pharm.D., Ph.D., D.Sc.(Hon), Distinguished Professor, Peters Institute of Pharmaceutical Care, College of Pharmacy, University of Minnesota, Minneapolis, Minnesota

This presentation is a personal reflection on 25 years of work in pharmaceutical care practice. Ten of these years have been spent developing the practice and 15 years have been devoted to developing practices of pharmaceutical care. There have been many successes along the way and many mistakes were made as well. However each mistake was used to learn more about what is required to successfully provide pharmaceutical care to patients.

This presentation focuses on three observations that reflect a personal perspective on the development of pharmaceutical care practice. First the magnitude of change required to provide pharmaceutical care is much greater than anticipated. And, the type of change that is required is very different than originally imagined. Second, the positive impact that this practice is able to have on individual patients and the health care system in general is much greater than anticipated. This impact can be measured clinically and economically. And, finally pharmacists can now be confident about how to create this impact and achieve the change needed to provide pharmaceutical care to patients on a daily basis.

Data from over 5,000 patients cared for in pharmaceutical care practices will be presented to illustrate each of these points in detail. The knowledge and skills required and the experienced needed to practice, teach and understand pharmaceutical care are now available for all who are interested.

Goals and Objectives

1. To provide pharmacists with an understanding of what is required to successfully provide pharmaceutical care to patients on a daily basis.
2. To understand the practice of pharmaceutical care, its impact, and its acceptance by evaluating data gathered in practice.

Self-Assessment Questions

1. Why is it not possible for pharmaceutical care to be "added on" to the activities currently performed by dispensing pharmacists?
2. What is the most common drug therapy problem identified in pharmaceutical care practice?

3. What level of acceptance of recommendations do pharmaceutical care practitioners experience from physicians?

The Role of an ICU Pharmacist

Clarence Chant, BScPhm, PharmD, BCPS, St. Michael's Hospital and Leslie Dan faculty of Pharmacy, Toronto, ON

The goal of the session is to provide the audience with an understanding of the various roles an ICU pharmacist can and should play within the multidisciplinary clinical team.

Patients in the ICU are at high risk of experiencing drug-related problems owing to the complexity of their underlying illness, invasiveness of the treatment modalities, and the frequent use of numerous therapies with potential for interactions and toxicities. ICU pharmacists can significantly impact pharmacotherapy for these patients. At the fundamental level, retrospective medication order review at a centralized pharmacy should occur to account for altered drug elimination in these patients. At the optimal level, ICU pharmacists should proactively participate in pharmacotherapy decision making at the bedside as part of a multidisciplinary team as well as provide independent educational programs and conduct research. Critical care pharmacists can also play a vital role in the prevention, detection and correction of medication errors to improve patient safety.

The Society of Critical Care Medicine has recently published guidelines on critical care unit services and personnel as well as a position paper on critical care pharmacy services. The recommendations and implications of these papers will also be discussed in the context of current pharmacy manpower shortage.

Goals and Objectives

1. To provide a framework of activities consistent with the role of an ICU pharmacist.
2. To understand the evidence supporting the need of an ICU pharmacist.
3. To discuss the current status/recommendations from professional organization and future needs of pharmacists within the ICU.

Self-Assessment Questions

1. Which 2 documents recently published by the Society of Critical Care Medicine directly discussed clinical pharmacy services?
2. What level of published evidence supports the need of an ICU pharmacist?

- List 10 different services considered by SCCM to be fundamental activities of a critical care pharmacist.

Cardiovascular Secondary Prevention Drug Benchmarks: Can We Reach Them? Yes We Can!

Derek Jorgenson, BSP, Pharm.D., Health Quality Council / Saskatoon Health Region, Saskatoon, SK

The evidence supporting beta-blockers, ACE-inhibitors, ASA, and statins in the secondary prevention of cardiac events is compelling, dramatic, and in some cases decades old. Although the elegance with which this evidence is applied in specific clinical scenarios continues to emerge, guidelines have changed little over the years. The vast majority of post-MI patients will benefit from this cocktail of medications. Despite this abundance of now antiquated evidence, recent analyses from within Canada and abroad suggest that many patients are not receiving these life-saving medications.

This presentation will summarize the results of a recent analysis, by the Saskatchewan Health Quality Council (HQC), on dispensing rates of beta-blockers, ACE-inhibitors, and statins in post-MI patients in Saskatchewan. It is not the results of this report that are interesting, but the reaction of Saskatchewan providers that makes this story worth telling. The HQC designed the analysis in a way that attempted to create a culture of change within the province before the results were released, so that significant quality improvement would be the end result. This presentation will share the strategies utilized by the HQC to foster this culture of change. It will also provide a glimpse into the resulting post-MI quality initiatives and collaboratives that are currently at work across the province, with a focus on how pharmacists continue to be integral agents of change in this process.

Goals and Objectives

- To summarize the results of a recent analysis, by the Saskatchewan Health Quality Council (HQC), on dispensing rates of beta-blockers, ACE-inhibitors, and statins in post-MI patients in Saskatchewan.
- To describe the strategies utilized by the HQC to ensure that this analysis would result in significant provincial quality improvement.
- To summarize the resulting quality improvement initiatives in Saskatchewan that has resulted from this analysis, focusing on the role of the pharmacist.

Self-Assessment Questions

- In 2002, what percentage of post-MI patients in Saskatchewan was taking all three study drugs (statins, beta-blockers, ACE-inhibitors) 90 days post-discharge?
- What is the most important strategy utilized by the HQC to foster a culture of change in Saskatchewan?
- Describe one post-MI quality improvement initiative in Saskatchewan where pharmacists have played a key role?

Acetaminophen vs. Ibuprofen: Not sure what to take, should we alternate?

Angela Trope, MSc, The Hospital for Sick Children, Toronto, ON

The goal of this session is to examine the literature on the emerging practice of combining antipyretics in the treatment of fever in children.

Fever is a common pediatric complaint. The literature is replete with studies evaluating the efficacy of either acetaminophen or ibuprofen alone in the treatment of fever. However, evidence is lacking for the safety and efficacy of combination antipyretic therapy. What is the driving force? Is it fever phobia?

Goals and Objectives

- To update pharmacists knowledge on the role, if any for combination antipyretic therapy
- To enable pharmacists to advise physicians and caregivers on the role, if any for combining antipyretics

Self-Assessment Questions

Should acetaminophen be alternated with ibuprofen in a febrile child?

Spirolactone Does Not Cause Hyperkalemia

Alice Hogg, BScPhm, University Health Network, Toronto, ON

The goal of this session is to provide pharmacists with an understanding of the risk of hyperkalemia with the use of aldosterone antagonists such as spironolactone.

Two studies evaluating the aldosterone inhibitors spironolactone and eplerenone for the treatment of heart failure have been published. The Randomized Aldactone Evaluation Study (RALES) demonstrated the spironolactone significantly improves outcomes in patients with severe heart failure. Similarly the Eplerenone Post-Acute Myocardial Infarction Heart

Failure Efficacy and Survival Study (EPHESUS) investigators concluded that the addition of eplerenone to optimal medical therapy reduced morbidity and mortality among patients with myocardial infarction complicated by left ventricular dysfunction and heart failure.

Although the rate of hyperkalemia was not increased with the use of spironolactone in RALES, an increased incidence of hyperkalemia with eplerenone compared to placebo was observed in EPHESUS. In addition, a population-based time series analysis identified an abrupt increase in the rate of prescriptions for spironolactone and in hyperkalemia-associated morbidity and mortality after the publication of RALES.

Patient characteristics that increase the risk of hyperkalemia with the use of aldosterone antagonists and strategies to prevent and manage hyperkalemia caused by inhibition of the Renin-Angiotension-Aldosterone System will be discussed.

Goals and Objectives

1. To enable pharmacists to identify patients at risk of developing hyperkalemia while taking aldosterone antagonists.
2. To provide pharmacists with strategies to manage hyperkalemia caused by Renin-Angiotension-Aldosterone System inhibitors.

Self-Assessment Questions

1. Which patients are at the greatest risk for developing hyperkalemia on aldosterone antagonists?
2. Which drugs should be used cautiously in combination with aldosterone antagonists?
3. How should patients who present with hyperkalemia be managed?

Role of Pharmacists in Primary Care

Natalie Kennie, BSc(Pharm), PharmD, St. Michael's Hospital, Department of Family and Community Medicine, Toronto, Ontario

The goal of this session to provide pharmacists with an overview of the different potential roles that pharmacist can perform in primary care and in family practice.

As noted in the literature, pharmacists have been practicing in primary care and specifically in family practice settings for over 20 years. Many different roles have been described, and the identification of drug-related problems and the impact of pharmacists on patient outcomes have been reported. Recently a number of initiatives have been launched in Ontario to further investigate the pharmacist's role in various primary care sites.

Several major reports on the Canadian health care system have highlighted the need for alternative approaches to primary health care, specifically how to create teams of health care professionals who can collaborate to provide high level of patient care. Therefore in primary care there is a need to continue to study and further describe the pharmacist's role in medication management and how this role relates to the other members of the health care team and patient. The presenter will discuss recent work related to the description of the primary care pharmacist's role in supporting medication-prescribing practice, medication-taking practice and medication-dispensing practice.

Goals and Objectives

1. To briefly review the history of pharmacists and their roles in primary care settings and including ongoing primary care initiatives in Canada.
2. To outline the various roles that pharmacists have fulfilled in primary care and evidence to date of the benefit of pharmacy services.
3. To outline a framework for describing the pharmacist's role in supporting medication management in the primary care setting.

Self-Assessment Questions

1. What roles have been described for pharmacists in the primary care setting?
2. What initiatives are currently underway to document the role of pharmacists in the primary care setting?

The Use of Colloids for Fluid Resuscitation in Critical Care

Chantal Manoukian, B.Pharm., M.Sc.(Pharm), Sir Mortimer B. Davis – Jewish General Hospital, Montreal, QC

The goal of this session is to review the pharmacology of colloid solutions and provide a framework for their appropriate use.

Fluid resuscitation, also referred to as volume replacement therapy or plasma volume expansion, remains one of the most common therapeutic interventions performed in the intensive care unit. Adequate plasma volume is essential in maintaining tissue perfusion.

When selecting volume expanding agents, the choices are categorized as crystalloid or colloid solutions. Factors that may influence the choice of fluid include individual physician's preferences, safety considerations and cost.

Crystalloids are electrolyte solutions such as lactated Ringer's and 0.9 percent sodium chloride. Colloids are large and complex molecules. The colloids

currently in clinical use worldwide are albumin, hydroxyethyl starch (HES), dextran and gelatin solutions. Only albumin and HES solutions are available for use in Canada. Albumin is a natural colloid. Its use has become controversial especially since the publication of the Cochrane Collaboration findings in the late 1990s. However, the recently reported Saline versus Albumin Evaluation Study (SAFE) has provided evidence regarding the safety of albumin for fluid resuscitation in critically ill patients. Hydroxyethyl starches are synthetic colloids. A variety of different HES solutions exist worldwide. In Canada, 2 types of HES solutions are approved for volume expansion, pentastarch 10% (Pentaspan®) and hetastarch 6% (Hextend®). They widely differ with regard to their physicochemical properties. Knowledge of their basic pharmacology is essential in understanding their physiological, clinical and adverse effects.

Goals and Objectives

1. Review the characteristics of crystalloid and colloid solutions.
1. Review the pharmacology and physicochemical characteristics of colloid solutions.
3. Increase pharmacists' current knowledge with respect to comparative differences of colloid solutions.
4. Describe some of the current clinical conditions in which use of these agents is appropriate.

Self-Assessment Questions

1. What are the limitations to the use of hydroxyethyl starch solutions?
2. What are the appropriate uses of plasma volume expanding agents?

“White Paper” Pharmaceutical Care Panel

Margaret L. Ackman, Debbie Kwan, Régis Vaillancourt

The concept of Pharmaceutical Care (PC) in Canada is supported in the mission statements of numerous pharmacy departments and professional organizations. There are currently a number of programs in place to provide pharmacists with the necessary knowledge, skills and tools to implement PC in their areas of practice.

It is important to assess the impact of this PC practice change on measurable health outcomes in order to validate the PC concept. Due to current study limitations and the poorly defined use of the term PC, examination of PC outcomes is difficult. Nonetheless PC is associated with the resolution of an increased number of drug related problems. There is also evidence to support the effectiveness of patient centered pharmacy services and

interventions. There is evidence to support the pharmacoeconomic benefits of clinical pharmacy services, but the paucity of data does not allow extension of this to PC.

The implementation of PC in Canadian hospitals remains a challenge. Innovative multi-disciplinary collaborative practice models incorporating an increased responsibility for the pharmacist in relation to patient care need to be created. In their creation, these opportunities will allow pharmacists to provide more complete and comprehensive patient care.

Goals and Objectives:

1. Examine the support for Pharmaceutical Care in Canada
2. Review the Evidence Supporting the efficacy and cost-effectiveness of Pharmaceutical Care
3. Discuss the Challenges of implementing Pharmaceutical Care in hospital pharmacy

Different Modes of Dialysis – The Impact on Drug Therapy

Bill Perks BScPhm and Lori MacCallum BScPhm, PharmD, St. Michael's Hospital, Toronto Ontario

Dialysis allows the removal of uremic toxins from the body and is standard treatment for patients with acute and chronic renal failure. Dialysis also affects the removal of many drugs. In addition to affecting drug removal, dialysis impacts on drug therapy in terms of route of administration, need for anticoagulation, adjustment of antihypertensives, and insulin requirements. Different types of dialysis may affect drug therapy differently. Therefore, it is important that pharmacists understand the differences between various types of dialysis so they are better able to interpret dosing guidelines and optimally manage drug therapy.

Goals and Objectives

1. To provide pharmacists with an understanding of the different modes of dialysis including conventional hemodialysis, nocturnal hemodialysis, peritoneal dialysis and continuous venovenous dialysis/hemofiltration.
2. To enable pharmacists to formulate rational drug regimens and dosages depending on the type of dialysis therapy and patient factors.

Self-Assessment Questions

1. Is it necessary to avoid nephrotoxic agents in patients receiving peritoneal dialysis?
2. Is drug dosing for patients receiving nocturnal hemodialysis the same as for patients receiving conventional hemodialysis?

3. What factors affect the choice of circuit anticoagulation for the various modes of dialysis?

Optimizing Personal Digital Assistant (PDA) Use in your Pharmacy Practice: A Look at What's New, What's Useful and Future Implications.

Robert M. Balen BSc(Pharm), PharmD., Informatics Coordinator, Clinical Services Unit - Pharmaceutical Sciences, Vancouver General Hospital, Vancouver B.C.

Personal digital assistants (PDA's) are hand-held tools that provide users with portable computing and communication abilities. These devices can provide a rapid and effective means of accessing, retrieving, analyzing, collecting, sharing and storing large volumes of research or clinical data that is pertinent to patient care. PDA use is becoming ubiquitous in healthcare and the information stored these devices can be accessible at the point of need. Pharmacists should be aware of the capabilities of this technology, determine its potential utility in their specific practice areas and familiarize themselves with strategies for incorporating these devices into their practice.

This session will assume that the participants possess a basic understanding of PDA operating procedures. An overview and demonstration of some PDA resources that are currently available to aid pharmacists in their patient care; research, teaching and other activities will be provided. The potential impact of continued advancements in PDA technology on pharmacists work processes will be discussed.

Goals

1. To demonstrate currently available PDA software for:
 - Clinical practice
 - Drug and disease information
 - Clinical decision support
 - Research data base development
1. To demonstrate how these devices can be integrated into clinical practice to improve point-of-care information processing.
2. Provide answers to commonly asked questions about PDA use in pharmacy practice
3. To share experiences and tips for using PDA's in pharmacy practice and deploying PDA's for use within a pharmacy department.

Objectives

By the end of this session participants should be able to:

1. State 3 examples of how a PDA can be practically integrated into their practice setting
2. Name specific software applications that can help clinicians with the following tasks:
 - Point of care access to disease, drug, and decision support information
 - Research database development and data collection
 - Clinical calculations

Self-Assessment Questions

1. What are the benefits and risks of integrating PDA's into the patient care process?
2. How can a PDA augment your practice or research project effectiveness?

Time Management – A Misnomer

Monica L. Olsen, MHRD, BScN, BA (Psychology), Olsen and Associates Consulting, Richmond Hill, ON

Time is a finite commodity – there are still only 24 hours in a day or 1440 minutes. The challenge is not to manage time, but rather to manage yourself. Your life will not change until you recognize that the number of items competing for your attention is increasing at an unyielding pace. The only sane option to managing your day, your week, your career and your life is to recognize that you have to make key choices – choices as to what is important and thus where you will focus your precious time and energy! The first step though is to create a heightened sense of awareness as to how you are currently using that age-old resource of time. The guiding principle of “doing more things faster is no substitute for doing the right things” underscores the key message in this experiential workshop.

Goals and Objectives

1. To help pharmacists learn an organizing process that helps them categorize their tasks and focus on what is important and not just what is urgent.
2. To equip pharmacists with five common tips for managing themselves with respect to time and determine the most applicable ones.
3. To create a supportive forum for discussion of present situations, feedback and suggestions of strategies.

Self-Assessment Questions

1. What are the four key ways we spend time?
2. What approach is at the heart of effective personal mastery?

Enteral Feeding the Adult – the Art and the Science

Jan Greenwood, BSc, RD, Vancouver Coastal Health Authority - Vancouver General Hospital

The goal of this session is to provide the pharmacist with an understanding of the science and the art behind the practice of delivering timely, safe, efficacious enteral nutrition (EN) in a variety of clinical settings.

In the hospitalised patient, specialized nutrition support may be indicated as a preventative approach to the development of malnutrition. In critically ill patients, malnutrition is associated with impaired immune function, impaired ventilatory drive and weakened respiratory muscles, leading to prolonged ventilator dependence and increased infectious morbidity and mortality. The benefits of specialised nutrition support includes improved wound healing, improved clinical outcomes, and shorter hospital length of stay.

Evidence supports the superiority of EN over parenteral nutrition (PN) in maintaining gut structure and function. Additionally EN is associated with less complications (mechanical, metabolic, infectious) when compared to PN.

Although superior to PN, EN is not benign. In addition to concerns of increased risk of pulmonary aspiration and increased risk of diarrhea, recent literature has documented chronic suboptimal energy delivery in tube fed patients.

The delivery of safe, timely, efficacious EN is dependant on a sound knowledge base. This includes an understanding of macronutrient and micronutrient needs, delivery routes, tube placement methods, delivery techniques, metabolic complications (the refeeding syndrome), mechanical complications (tube dislodgement and tube occlusion), and gastrointestinal complications (elevated gastric residual volumes and diarrhea) in a variety of clinical settings.

Goals and Objectives

1. To provide the pharmacist with an understanding of the key concepts of nutritional assessment and to be able to identify patients who would benefit from EN.
2. To enable the pharmacist to select the optimal feeding route, feeding solution, and delivery method in a variety of clinical settings.
3. To enable the pharmacist to identify and resolve various metabolic, mechanical, and gastrointestinal complications that may arise during the delivery of EN.

Self-Assessment Questions

1. Is it reasonable to deliver feeding formula via the nasogastric route in any patient in whom EN is required?
2. Should all tube fed patients experiencing diarrhea have the tube feeding formula changed to a higher fiber alternative and an antidiarrheal agent prescribed?
3. What should be the approach to the initiation of EN in a patient diagnosed with marasmus?

Professional Writing – Papers and Abstracts

Scott Walker, MSc and Heather Kertland, PharmD

Publication, either in internal or external publications, is an expectation of a hospital pharmacist. While it may be an expectation, most of us avoid it like the plague. Understanding the process and key activities that need to occur to ensure acceptance of your writing will be highlighted in this workshop, both for a written manuscript and also for abstract submission. Pharmacists will be given an opportunity to initiate their own manuscript/abstract.

Goals and Objectives

1. Provide pharmacists with an understanding of the planning and writing of common modes of professional writing (e.g., case report, review article, research manuscript, abstract submission)
2. Identify common areas that require specific consideration when writing articles/abstracts.

Self-Assessment Questions

1. When planning to write a review article list three activities that you should consider prior to starting to write.
2. When writing an abstract for a poster or oral presentation at a meeting, list three common errors that are made.

Advances In Critical Care Therapeutics: Beyond Sepsis

Glen Brown, PharmD, FCSHP, BCPS, Providence Healthcare, Vancouver, BC

Many advances in the care of the critically ill patient have occurred over the last 2 years. Better understanding of the epidemiology, pathophysiology, and response to therapies have allowed for better selection of drug regimens for critically ill patients. Many of these advances have focused on the treatment of septic shock. However, other advances have been made in the optimization of therapy for sedation, infection eradication, respiratory function, and metabolic control.

Goals and Objectives

1. To provide pharmacists with new information on therapeutic strategies to utilize in the care of critically ill patients
2. To enable the pharmacist to adopt these strategies into their ICUs.

Self-Assessment Questions

1. What are three proven benefits of daily interruption of sedatives?
2. What are three strategies for minimizing excessive antibiotic use?

Current Trends in the Management of Ventilator-Associated Pneumonia

Sharon Yamashita Pharm.D., FCSHP, Sunnybrook & Women's College HSC, Toronto, ON

Ventilator-Associated Pneumonia (VAP) is the most common nosocomial infection in the intensive care unit, contributing to significant morbidity and mortality in critically ill patients. Management difficulties include differentiating between colonization and infection as well as choosing appropriate empiric management in the face of increasing antimicrobial resistance. Current trends in the management of VAP have been directed at preventative strategies, early aggressive antimicrobial therapy followed by de-escalation, antibiotic rotation and strategies aimed at reducing the duration of therapy.

While many of the preventative strategies are nonpharmacologic in nature, pharmacologic measures aimed at preventing the aspiration of contaminated secretions include choice of stress ulcer prophylaxis, prevention of gastric overdistension with promotility agents and avoiding unnecessary antibiotic administration. Another preventative strategy is Selective Decontamination of the Digestive Tract (SDD).

Despite an abundance of supportive literature, SDD has not gained widespread acceptance in North America, primarily due to concerns regarding longterm microbial resistance and lack of availability of commercial products. Similar concerns regarding longterm resistance have also prevented widespread application of antibiotic rotation techniques.

Recognizing the difficulties in the diagnosis of VAP, and concerns regarding worse outcomes associated with inappropriate initial choice of antibiotics, current strategies aimed at limiting the duration of antibiotics have recently emerged. The use of the Clinical Pulmonary Infection Score is one such strategy, which aids in the diagnosis and management of VAP.

Goals and Objectives

1. To familiarize the audience with pharmacologic strategies to prevent the development of ventilator-associated pneumonia
2. To review the current literature on the management of ventilator-associated pneumonia including early aggressive therapy, antibiotic rotation and limiting the duration of therapy.

Self-Assessment Questions

- a. Name 3 pharmacologic strategies to prevent ventilator-associated pneumonia
- b. What are the components of selective decontamination of the digestive tract and does the literature support its use in the prevention of ventilator-associated pneumonia?
- c. What is the Clinical Pulmonary Infection Score and how can it be used to manage ventilator-associated pneumonia?
- d. What is the ideal duration of therapy for ventilator-associated pneumonia?

Monday, February 7 • Lundi le 7 février

Organizational Culture and Patient Safety

Jack Davis, President and Chief Executive Officer, and Steve Long, BSc (Pharm), MBA, Director, Pharmacy Services, Calgary Health Region, Calgary, Alberta

In February/March 2004, two patients of the Calgary Health Region (CHR) died as a result of hyperkalemia, while undergoing continuous dialysis. An error in the preparation of the dialysis solutions within the Region's Pharmacy Department contributed to these deaths. With the support of the patient's families the CHR chose to disclose the

deaths and to implement system changes to reduce the risk of similar events occurring. As a result of this and other errors, the CHR is committed to adopting a just and trusting culture to support patient safety.

The just and trusting culture is supported by a number of underlying principles. The CHR is working to make it safer for individuals to proactively identify and report safety deficiencies and occurrences. When deficiencies are identified the intent is to foster an accountable and responsible culture. It will not be blame free, nor will

individuals carry the burden of system flaws over which they had no control. Reporting will require thorough investigation of the event, identification of system contributions and support learning and implementation of appropriate system changes. There will be timely disclosure to patients and families and ongoing evaluation to assure system improvement. The evolving culture will be influenced by societal values as expressed by patients, families, members of the general public, the media and government.

Two perspectives on the changing culture will be presented, the perspectives of the Chief Executive Officer and the Director, Pharmacy Services.

Goals and Objectives

Following this presentation, you will be able to:

1. Describe the principles for a just and trusting culture.
2. Outline the linkage between reporting and the risk of medication errors.
3. Describe events and reactions that can result from public disclosure of a fatal medication error.

Self-Assessment Questions

1. What actions could I take to encourage reporting of medication errors and near misses?
2. Do I support a just and trusting culture when medication errors are reported to me?

Medication Error Events in a Sample of Ontario Hospitals: Learning from an ISMP Canada Study

Joan A. Marshman, BScPhm, PhD, University of Toronto, Toronto, ON; David K. U, MScPhm, Robert W.K Lam, B.Sc(Pharm), Sylvia Hyland, B.ScPhm, MHSc., ISMP Canada

This session is designed to provide pharmacists with an introduction to ISMP Canada's Analyze-ERR, software, and to review what was learned from its application in a sample of acute care hospitals in Ontario.

Individual hospitals have their traditional criteria, procedures, and formats for internal reporting of medication error events. Often the number of events in a single hospital is too small to permit identification of patterns of contributing factors. The ISMP Canada project was designed to assess the feasibility of hospitals using the Analyze-ERR, software to standardize the content fields of such reports and to transmit the reports in a standard format electronically and anonymously to ISMP Canada for compilation in a common database.

Analysis of the 4,243 reports from 14 hospitals provided insights into the proportion of errors that reached the patient and had the potential to cause patient harm, and the human and system factors perceived as contributing to the error events.

Goals and Objectives

1. To provide pharmacists with an introduction to ISMP Canada's Analyze-ERR, software
2. To increase pharmacists' awareness of human and system factors reported, in a compilation of Analyze-ERR,-formatted error reports, as contributors to medication errors in Ontario hospitals.

Self-Assessment Questions

1. What are the information elements that should be included in a medication error event report, in order to provide a sound basis for quality improvement initiatives?
2. Based on the error event reports submitted to ISMP Canada, where should acute care hospitals consider focusing their attention in attempting to reduce the frequency of medication errors?

Quality Improvement and Patient Safety: Living With "Smart" Infusion Devices

Mark Duffett, BSc(Pharm), Hamilton Health Sciences, Hamilton, Ontario

"Smart" infusion devices have been identified by organizations including The Institute for Safe Medication Practices (ISMP) and the Institute for Healthcare Improvement (IHI) as important ways to prevent medication errors. These devices incorporate software designed to catch ordering and programming errors and allow increased tracking of errors and near misses.

Hamilton Health Sciences, a multi-site tertiary-care teaching hospital, was an early adopter of "smart" infusion technology. Using the example of the adoption and use of "smart" infusion technology at this presentation will examine:

- Implementing a "smart" infusion system.
- The role of the pharmacist in the use of "smart" infusion technology.
- Measuring the effects of a "smart" infusion system on error prevention and patient safety.
- Using "smart" infusion systems as a tool for quality improvement and practice change.
- "Smart" infusion technology as a component of a larger patient safety system.

Goals and Objectives

The goal of this presentation is to provide pharmacists with an understanding of some of the issues associated with:

- Implementing a “smart” infusion system.
- The effects of a “smart” infusion system on patient safety.
- Using “smart” infusion systems as a tool for quality improvement.
- “Smart” infusion systems as a part of a larger patient safety system.

Self-Assessment Questions

1. What is the pharmacist’s role in implementing and maintaining a “smart” infusion system?
2. How can a “smart” infusion system fit into a hospital’s patient safety system?

Challenges Associated with Heparin Induced Thrombocytopenia

Peter Thomson, BSc(Pharm), PharmD, Health Sciences Centre, Winnipeg MB

Heparin induced thrombocytopenia (HIT) is one of the two most common serious adverse effects associated with the use of heparin. HIT involves the development of a pathologic antibody following exposure to heparin and is associated with two major sequelae: thrombocytopenia and hypercoagulability.

There are a few agents on the market that can provide alternate anticoagulation in patients with HIT. Each agent has its own set of advantages and disadvantages. In selecting which agents to stock as well as which one to use in a specific clinical situation requires an assessment of a variety of factors. Cost, reversibility and required monitoring are an example of some of the factors to consider.

Over the past 4 years we have conducted three projects at the Health Sciences Centre that have examined different aspects of HIT. Each of these projects has identified different barriers that result in less than optimal recognition and treatment of HIT at our institution. It has become clear to us that in order to properly identify and treat HIT many different care providers need to be involved.

Goals and Objectives

1. To review when a clinician should suspect HIT and what appropriate treatment measures should be considered.
2. To exemplify how HSC has reviewed its practices to identify barriers that impact on both the in diagnoses and treatment of HIT.

Self-Assessment Questions

1. When should I question if someone might have HIT?
2. What factors should I keep in mind when deciding which alternative anticoagulant to recommend?
3. What barriers impact on my ability to identify and treat HIT? Have we limited these at our institution?

Canadian Initiatives in Patient Safety

David Rosenbloom, Pharm.D., David Rosenbloom Consulting Inc., Campbellville, ON, and Bonnie Salsman, BScPhm, FCSHP, BMS Consultants, Halifax, NS

Recent studies and publications in numerous jurisdictions, including the Canadian Adverse Events Study, have focused attention on the issue of errors in health care. Pharmacists have recognized the risks associated with medication use for decades, but other health care providers and the public are developing an enhanced awareness of the important role that medication systems and clinical pharmacy services can play in reducing the occurrence of harmful medication-related events.

Various Canadian initiatives are underway to examine issues and possible remedies related to the occurrence, reporting and prevention of medical errors, including medication errors. The Canadian Coalition on Medication Incident Reporting and Prevention (CCMIRP) was convened in Feb 2001, and established a business plan for the development and implementation of a Canadian Medication Incident Reporting and Prevention System (CMIRPS). In September 2002, the National Steering Committee on Patient Safety released its report “Building a Safer System- A National Integrated Strategy for Improving Patient Safety in Canadian Healthcare.” A key recommendation of this report was the establishment of a Canadian Patient Safety Institute (CPSI). Funding for both CPSI and CMIRPS was provided in the federal budget of Feb 2003. CPSI was incorporated in Dec 2003 and CMIRPS is currently under development through a collaborative partnership of ISMP Canada, the Canadian Institute for Health Information and Health Canada.

The goal of this session is to provide an overview of current Canadian patient safety issues and initiatives, and to review advocacy opportunities and challenges for Pharmacy.

Goals and Objectives

1. Discuss initiatives related to patient safety in Canada.
2. Review key areas where pharmacists can play a unique role in improving patient safety.

4. Review opportunities for pharmacists and pharmacy organizations to contribute to the improvement of patient safety.

Self-Assessment Questions

1. Why is the development of an effective Canadian medication incident reporting system of critical importance to improving medication safety?
2. Discuss key attributes of an effective medication incident reporting system.
3. What distinguishes a “culture of safety” and how can the Canadian Patient Safety Institute contribute to the development of such a culture?

Assessing Medication Management

Beth Bryles Phillips, B.S.Pharm. Pharm.D., BCPS, Clinical Pharmacy Specialist, Ambulatory Care, University of Iowa Hospitals and Clinics; Assistant Professor (Clinical), University of Iowa College of Pharmacy, Iowa City, IA

Karen B. Farris, B.S.Pharm., Ph.D., Associate Professor, University of Iowa College of Pharmacy, Iowa City, IA

The goal of this session is to review instruments/strategies to assess medication management capacity and abilities, including the Medication Management Test, and to obtain hands-on experience using some of the instruments.

Medication management is a self-care activity that requires cognitive and psychomotor skills in order to take medications as prescribed or directed. However, cognitive impairment short of dementia places thousands of elderly individuals living in the community at risk of mismanaging their medications. No quick-to-use, single, validated screening tool exists to identify individuals with poor capacity to manage medications by primary care providers.

The most important skills and behaviors required in managing medications among older adults will be linked to assessments of medication management that are currently available. We will identify the strengths and weaknesses of a number of instruments/strategies used to assess medication management and practice using several of them. For example, Farris et al. used the Medication Management Test (MMT) as an objective assessment of medication management capacity. Individuals with good and poor MMT scores scored 12.8 ± 1.5 and 11.4 ± 2.6 on CLOX1 (a measure of executive control function), respectively ($p=0.10$). The results were in the expected direction. Drs. Farris and Phillips are currently using the Medication Management Test as a tool to measure medication management capacity in a larger study, and working to identify predictors of capacity. The results from their research thus far and future work will be presented.

Goals and Objectives

The purpose of this workshop is to:

1. use a consensus approach to identify the most important behaviors in managing medications;
2. review instruments/strategies to assess medication management capacity and abilities, including the Medication Management Test;
3. review cases and interpret the findings for selected instruments; and
4. practice administering selected instruments (if time allows).

Self-Assessment Questions

1. What are the strengths and weaknesses of the current instruments in assessing medication management skill and/or capacity including, for example, the Medication Management Test, DRUGS tool and Ruscin/Semla?
2. What is the appropriate interpretation of CLOX1 and CLOX2 scores?

Tuesday, February 8 • Mardi le 8 février

Emerging and Pandemic Infectious Diseases – Should We Be Concerned?

Andrew E. Simor, MD, FRCPC, Sunnybrook & Women's College Health Sciences Centre, Toronto, Ontario

Emerging infectious diseases may be defined as those that are increasing in incidence in the recent past, or those that are threatening to increase in the near future. Recent examples have included West Nile Virus, Severe Acute Respiratory Syndrome (SARS), avian influenza, “mad cow disease”, and severe nosocomial *Clostridium difficile*-associated

diarrhea. Factors that may contribute to the emergence and spread of these diseases include: microbial adaptation, human susceptibility, environmental changes, societal events, and human behaviour. This presentation will review issues related to the epidemiology and impact of emerging and pandemic diseases in Canadian hospitals.

Goals and Objectives

1. To appreciate factors determining the emergence and spread of new infectious agents capable of causing pandemic disease

2. To understand the changing epidemiology of infectious diseases
3. To determine the impact emerging infectious diseases may have on the provision of healthcare in Canadian hospitals

Self-Assessment Questions

1. What factors contribute to the spread of pandemic infectious diseases today?
2. What should healthcare providers including pharmacists be aware in order to be able to identify and properly manage new or emerging infectious diseases?

Clostridium difficile: New Twists to an Old Story?

Daniel J. G. Thirion, B.Pharm., M.Sc., Pharm.D., BCPS, Hôpital du Sacré-Coeur de Montréal, Faculté de pharmacie, Université de Montréal, Montreal Qc.

The goal of this session is to provide pharmacists with an understanding of the critical issues in treatment and infection control of Clostridium difficile associated diarrhea (CDAD).

Clostridium difficile is the most important cause of nosocomial diarrhea in adults. Disease is usually limited to watery diarrhea but can lead to life-threatening colitis in 1-2% of affected cases. Prolonged hospitalization and readmission also carries an important economic burden for the patient and the health care system. The reported incidence over the past decade has ranged between 35 and 95 cases per 100 000 patients. However, recent incidence in certain areas of southern Quebec has increased to 150 cases per 100 000 patients (and over 800 cases per 100 000 patients in the elderly). Severity is also increasing, as complications and mortality rates have more than doubled over the past decade according to one report.

The reason for increased incidence and severity are unknown at this time. This change in epidemiology has prompted investigations of this condition. A working group has been created to determine the true incidence and the rate of serious complications of CDAD, as well as to identify specific interventions which may have an impact at the hospital and community level. Meanwhile, infection control practices are being modified and implemented, treatment recommendations are being established, and alternative options such as probiotics and transplantation are being sought. The phenomenon is also receiving public attention, and is now under political scrutiny for reallocation of resources to

address the problem. A review of current changes in practice will be presented.

Goals and Objectives

1. Understand critical issues of treatment and infection control of Clostridium difficile associated diarrhea (CDAD).
2. Identify opportunities for pharmacist' intervention in the prevention and management of CDAD.

Self-Assessment Questions

1. What are the most important interventions in preventing or controlling CDAD
2. Which pharmacy driven interventions seem to have an impact in antibiotic utilization?
3. Do probiotics have a role in the management of CDAD?

Management of Diabetic Patients during Acute Illness: Insulin Sliding Scales and Beyond

Doret Cheng, BScPharm, PharmD, Mt Sinai Hospital, Toronto, ON

Diabetes remains a major cause of morbidity and mortality in Canada. Hospital length of stay is on average 2.8 days longer for diabetic patients. Despite more and more evidence supporting the importance of better glycemic control in patients hospitalized for myocardial infarction, cardiac surgery, stroke and patients in intensive care, glycemic control in the hospital setting is often suboptimal. One of the culprits is the widespread use of insulin sliding scales as the sole treatment of hyperglycemia and the lack of evidence regarding optimal glucose control in the average general medicine patient and fear of hypoglycemia. Previously, no established standards have existed for caring for people with diabetes in the hospital. Guidelines and position statements have been published recently to provide standards for diabetes management in the hospital. Pharmacists can play a central role by providing education, consultation and bridge the care gap to improve quality of care in the acutely ill diabetic patient.

Goals and Objectives

1. To identify and review some evidence supporting normoglycemia in hospitalized patients
2. To review the pros and cons of insulin sliding scales
3. To identify the various strategies to improve glycemic control in the acutely ill diabetic patients

Self-Assessment Questions

1. How important is inpatient glycemic control?
2. What are the glycemic target/goals for patients who are admitted to hospital with acute illness?
3. Should insulin sliding scales be eliminated from practice?

Equity, Cultural Competence and Leadership in the Workplace

Shakil Choudhury, M.E.S., B.Ed., B.P.E., Toronto, Canada

The goal of this session is to help pharmacists understand and counteract the ways in which cultural bias – often subtle and unconscious – can negatively impact clients, colleagues, co-workers and can lead to the creation of negative, and sometimes hostile, work environments.

September 11th; The War On Terrorism; Legalizing gay marriage; Welfare reform; Child Poverty. These terms evoke some type of internal response in all Canadians, including agreement, disagreement, disappointment, fear, anger or despair. The response, whatever it may be, is not neutral and is reflective of our personal bias. It is our bias, for both good and bad that plays an essential role in creating the tone of our workplace.

Cultural competence can assist in uncovering our personal bias and creating positive working relationships and environments. Cultural competence suggests the importance of understanding and navigating the myriad of social identities that we all bring to our workplaces; this includes our ethno-cultural backgrounds, gender, ability/disability levels, socio-economic backgrounds and sexual orientation. Relationships are the foundations upon which pharmacists – essential members of the health care team – do their work. Understanding principles of equity and inclusion are essential for culturally competent leaders in creating positive, safe, supportive workplace relationships. Research indicates that inclusive work environments are linked to increased productivity and greater trust between client and health team member.

Goals and Objectives

The goal of this session is to help pharmacists understand and counteract the ways in which cultural bias – often subtle and unconscious – can negatively impact clients, colleagues, co-workers and can lead to the creation of negative, and sometimes hostile, work environments.

To assist pharmacists in understanding how equity and cultural competence can positively impact the creation of their workplace environments.

Self-Assessment Questions

1. What is my social identity? What do I see as culturally “normal” when it comes to ethno-cultural background, gender, class, sexual orientation, and ability/disability? What are my biases?
2. What is the tone of my workplace? What are the biases when it comes to treatment of employees? Conflict resolution? Hiring practices? Salary scales?

E-Health and Disease State Management

Jon Rasmussen, Pharm.D., BCPS, Kaiser Permanente – Colorado, Aurora, Colorado

The goal of this session is to provide pharmacists with an understanding of potential uses of E-Health in disease state management (DSM) programs. There are a number of ways to define E-Health, but this session will specifically examine electronic medical records, disease registries, patient tracking systems, and outcome management tools and their use in disease state management.

Disease state management programs offer pharmacists an opportunity to participate in a population-based approach to delivering care. By identifying patients at risk and applying systems-based programs of care, specifically medication management and monitoring, pharmacists can help deliver on the promise to improve patient safety and clinical outcomes.

Kaiser Permanente – Colorado is a group-model, integrated health maintenance organization in the Denver, Colorado metro area serving over 400,000 members. Over the last decade, the Pharmacy Department has developed a number of pharmacist-managed DSM programs, including the Clinical Pharmacy Cardiac Risk Service. This session will provide a description of operations and outcomes of a variety of these programs.

Goals and Objectives

1. To explain the use of E-Health in disease state management.
2. To describe potential roles of pharmacists in disease state management.
3. To provide examples of pharmacist-led disease state management services.

Self-Assessment Questions

1. Which disease states are most appropriate for disease state management programs?
2. What services can a pharmacist provide in a disease state management program?

3. How can E-Health enhance a pharmacist's role in disease state management?

Fluids and Electrolytes: A Practical Approach

Sharon Yamashita Pharm.D., FCSHP, Clinical Coordinator, Critical Care Department of Pharmacy, Sunnybrook & Women's College Health Sciences Centre

Laboratory abnormalities are common in hospitalized patients. It is important, however, to assess the clinical significance of each abnormality and determine whether management is indicated. The following approach will be applied to several common laboratory abnormalities:

- Is the value abnormal?
- Does it make sense?
- Is management necessary?
- If high, is the cause due to "too much in" or "not enough out"?
- If low, is the cause due to "not enough in" or "too much out"?

Disorders of sodium, potassium, calcium, magnesium and phosphate will be discussed.

Goals and Objectives

1. To provide a general, practical framework for the assessment of common electrolyte abnormalities
2. To discuss several common clinically relevant electrolyte disorders which require therapeutic intervention
3. To apply the above principles using clinical cases to illustrate the approach

Self-Assessment Questions

The following statements are TRUE or FALSE:

1. Disorders of sodium are actually disorders of sodium AND water
2. Hypomagnesemia may contribute to refractory hypokalemia
3. Renal Failure is associated with hypernatremia, hyperkalemia, hyperphosphatemia, hypercalcemia and hypermagnesemia
4. The chloride salt is preferred for the management of diuretic induced hypokalemia
5. Rapid administration of magnesium results in increased renal losses

The Apprentice: You're Hired ... to Develop Patient Education Materials!

Elaine Chong, BSc(Pharm), ACPR, PharmD, BCPS – Network Healthcare, Vancouver, BC; Trish Rawn, BSPHm, PharmD – Independent Consultant and Mount Sinai Hospital, Toronto, ON

Patient education materials have long been a "Trump" card for pharmacists – good information at the right time can make all the difference. But do our written patient education materials make the grade?

Written education materials must be targeted to meet the needs of the patient population. Research studies suggest that there is a mismatch between what patients want to know, and what health care professionals think they need to know. It is a challenge to explain the benefit versus risk ratio clearly and with the proper context. A fair balance must be struck between providing patients with the information they need to make a decision versus causing unnecessary anxiety and confusion. Other considerations include language level; design and layout; tailoring the message to the medium (electronic vs. printed formats); and promoting a healthy call-to-action to the patient.

Similar to the popular reality TV show "The Apprentice," workshop participants will work in teams on a challenging task and then receive feedback on their efforts. In this workshop, the teams will be actively engaged in developing appropriate patient information materials. They will learn how to apply theoretical concepts in the practical development and evaluation of written patient education materials.

Goals and Objectives

1. To understand the mismatch between what patients want to know, and what health care professionals think that patients need to know.
2. To appreciate the factors to consider when developing relevant written patient education materials.
3. To demonstrate how the principles learned in this workshop can be applied to the practical development and evaluation of written patient education materials.

Self-Assessment Questions

1. How adverse effect information do patients really want to know? How much is too much?
2. What are the factors to consider when developing written patient education materials?

3. With the proliferation of the Internet, what are the differences in providing patient education materials in electronic formats versus the traditional printed format?

Putting Advocacy Theory into Practice

Marlo Palko, Fleishman-Hillard, Toronto, ON

Advocacy means I can make a difference. But the pharmacist as advocate is an all-too familiar theoretical tune. How do I put this theory into practice? Where do opportunities really exist? And how do I take advantage of these opportunities when they present themselves?

The goal of this session is to highlight some of the opportunities pharmacists regularly encounter within their daily professional environments to develop and deliver strong and proactive messages with the potential to impact their own scope of practice, the Canadian healthcare environment and, ultimately, the care of patients. The session will explore basic tools of effective communication and the real-life application of advocacy theory.

Goals and Objectives

1. To provide an overview of some basic communications tools and how they can be used to develop effective communications messages and strategies.
2. To identify common opportunities for pharmacists to deliver their key messages within their local and professional communities.
3. To demonstrate the impact of simple, proactive advocacy initiatives on professional and community development.

Self-Assessment Questions

1. What are some basic communications tools I can use in my own environment?
2. What is one opportunity I have on a regular basis to communicate as an advocate for my profession?

Hospital-Acquired Pneumonia: New Guidelines and Ongoing Controversies

Richard S. Slavik, B.Sc.(Pharm.), Pharm.D., Vancouver Coastal Health Association – Vancouver General Hospital Site, Vancouver, BC

Clinical practice guidelines (CPGs) are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. New evidence-based guidelines for the management of hospital-acquired pneumonia (HAP), healthcare-associated

pneumonia (HCAP), and ventilator-associated pneumonia (VAP) by the American Thoracic Society (ATS) and the Infectious Diseases Society of America (IDSA) will soon be published. Key treatment recommendations include early, appropriate, broad-spectrum antibiotic therapy prescribed in adequate doses based on the time of onset of pneumonia, and risk factors for multi-drug resistant (MDR) pathogens. Empiric therapy should include agents from a different antimicrobial class than the patient has recently received, and should cover suspected organisms based on local microbiological data. Combination therapy for a specific pathogen should be used judiciously, and consideration should be given to short duration (5 days) of aminoglycoside therapy when used in combination with a beta-lactam to treat *Pseudomonas aeruginosa* pneumonia. Negative lower respiratory tract cultures can be used to stop antibiotic therapy in patients with cultures in the absence of an antibiotic change in the past 72 hours. De-escalation of antibiotics should be considered once lower respiratory tract cultures results are available and based on clinical response. Shorter duration of antibiotic therapy (7-8 days) is recommended for patients with uncomplicated infections who have received initially-appropriate therapy, have had a good clinical response, and have no evidence of non-fermenting gram negative bacilli. This session will review the methodology and validity of the ATS/IDSA Guidelines, provide an overview of key therapeutic recommendations, and discuss the application of portions of this CPG to everyday practice.

Goals and Objectives

1. To review the methodology, validity, key recommendations, and application of portions of the ATS/IDSA Guidelines for HAP, HCAP, and VAP;
2. To review principles and recommendations for early appropriate, broad-spectrum antibiotic therapy, in adequate doses for empirical therapy;
3. To review ongoing therapeutic controversies such as the optimal management of *Pseudomonas aeruginosa* and MRSA pneumonias, shorter duration antibiotic therapy and antibiotic cycling for VAP.

Self-Assessment Questions

1. What are some methodological strengths and weaknesses of the new ATS/IDSA guidelines for the management of adults with HAP, HCAP, and VAP?
2. What are the key principles to consider to design an appropriate empirical antimicrobial regimen for a patient with HAP, HCAP, or VAP?

3. What are the key controversies in antimicrobial agent selection and dosage regimen for the management of *Pseudomonas aeruginosa* and MRSA pneumonias, and evidence for shorter duration antibiotic therapy and antibiotic cycling for VAP.

Development and Evaluation of Antimicrobial Intervention Programs: A Practical Approach

B. Joseph Guglielmo, PharmD, Department of Clinical Pharmacy, University of California San Francisco, San Francisco, California

The goal of this session is to provide pharmacists with a practical perspective regarding the development and evaluation of an antimicrobial intervention program.

Antimicrobial intervention programs vary, ranging from traditional formulary management and restriction systems to the use of multidisciplinary teams. While antimicrobial intervention programs are relatively widespread, patient- and institution-specific benefit associated with these programs is not well documented. In those instances in which associated outcomes have been reported, problems in study design greatly limit the interpretation of these results.

The most commonly documented outcomes are economic-based and include IV to PO switch, automatic substitution, and restriction systems

limiting the use of high acquisition cost agents. While more difficult to prove, antimicrobial intervention programs have been shown to reduce the rate of antimicrobial-associated adverse events. The impact of antimicrobial intervention programs, such as cycling, upon antimicrobial resistance is logistically difficult to prove, considering the multiple risk factors which impact upon hospital and community bacterial resistance.

Despite these limitations, intervention programs are accepted mechanisms toward the appropriate use of antimicrobials. However, in evaluating the scope of potential programs, human resources, computer database capabilities and institution-specific practices must be considered.

Goals and Objectives

1. To provide pharmacists with an overview of the proven benefit of antimicrobial intervention programs, specific to reduction in cost, adverse events and antibacterial resistance.
2. To identify key barriers toward the establishment of the benefit of antimicrobial intervention programs.

Self-Assessment Questions

1. What outcomes are logistically most difficult to link with antimicrobial intervention programs?
2. What are three potential barriers toward the evaluation of the benefit of antimicrobial intervention programs?

Wednesday, February 9 • Mercredi le 9 février

Antidepressants and Suicide in Kids: Weighing the Evidence

Adil Virani, BSc. (Pharm), Pharm D, IWK Health Centre, Halifax, NS

Recent concerns regarding the use of antidepressants have prompted health professionals to re-evaluate their treatment and monitoring of mood and anxiety disorders in children and adolescents. Since June 2003, researchers and clinicians have analyzed the available published and unpublished data to determine if newer antidepressants actually increase the risk of suicide. Though no suicides occurred in the clinical trials in over 4000 pediatric patients, a small increase in 'suicidal behaviours' was detected in some patients receiving an antidepressant compared to placebo.

In September 2004, the US Food and Drug Administration (FDA) concluded that all newer

antidepressants were associated with an increased risk of "suicidality" (suicidal thoughts and actions) in pediatric patients. Based on this conclusion, the FDA issued a black box warning on the use of all antidepressants in children and adolescents. While some feel the FDA should have contraindicated the use of some antidepressants, many researchers and clinicians argue that the current evidence does not support FDA's conclusion. This presentation reviews the recent warnings regarding the use of antidepressants in pediatric patients and highlights the available evidence related to their associated suicidal risk.

Goals and Objectives

This presentation reviews the recent warnings regarding the use of antidepressants in pediatric patients and highlights the available evidence related to their associated suicidal risk.

1. Describe the recent warnings regarding antidepressants in pediatric patients
2. Discuss the evidence regarding the risk of suicidal ideation associated with antidepressants in pediatric patients
3. Discuss the current role of antidepressants in pediatric patients

A Practical Overview of Drug-Drug Interactions

David, Juurlink, M.D., Sunnybrook and Women's College Health Sciences Centre, Toronto, ON

Drug-drug interactions are a common yet preventable cause of harm. This presentation will provide a general overview of several common DDIs using a case-based approach to highlight their clinical relevance. Included will be interactions mediated by inhibition or induction of cytochrome P450 isoenzymes and drug transporters, as well as some clinically important pharmacodynamic DDIs. The discussion will conclude with some suggested strategies to help overcome the barriers that hamper avoidance of DDIs in clinical practice.

Self-Assessment Questions

1. Describe the role of P-glycoprotein in the genesis of DDIs, and list some common medications that induce or inhibit it.
2. Hepatic cytochrome P450 isozyme 3A4 (CYP 3A4) is often implicated in the development of DDIs. What is the role of extrahepatic CYP 3A4 in drug interactions, and how is it influenced by the bioavailability of the 3A4 substrate?

Prostate Cancer: A General Approach

Mário L. de Lemos, B.Sc.(Hons)(Pharm), M.Sc.(Clin Pharm), Pharm.D., M.R.Pharm.S., M.Sc.(Oncology) candidate, British Columbia Cancer Agency, Vancouver, BC

The goal of this session is to provide the pharmacists with a general approach of the drug therapy of prostate cancer, with particular emphasis on the treatment of metastatic disease.

Prostate cancer is the most frequently diagnosed cancer in Canadian men, with one in 8 men developing the disease during his lifetime. On average every day, 12 men would die of prostate cancer and 55 new cases are diagnosed in Canada. Since the role of androgen stimulation in prostate cancer has been recognized more than 50 years ago, management of this disease has largely evolved to improve the mode of hormonal therapy. Over the past decade or so, however, this has expanded to increased screening, potential for

primary prevention, and prolongation of survival in metastatic disease.

Given that the incidence of prostate cancer increases in age and the general ageing of our population, it is expected that the pharmacists will see more and more patients or survivors of this disease in the near future.

Goals and Objectives

At the end of the session, the participant should be able to advise patients on:

1. The current status of primary prevention of prostate cancer.
2. Role of adjuvant LHRH agonist for localised disease.
3. Role of androgen suppression for advanced disease, including:
 - a. when to initiate treatment,
 - b. the response rate and duration of response,
 - c. the roles of LHRH agonist and nonsteroidal antiandrogens, and
 - d. the adverse effects of androgen suppression.
4. Treatment options for disease progression after androgen suppression.

Self-Assessment Questions

1. Give two reasons why prostate cancer is an important disease.
2. Describe two commonly used diagnostic tools in prostate cancer.

Aldosterone Antagonists in the Treatment of Heart Disease

Stephanie Young, BSc(Pharm), PharmD, Health Care Corporation of St. John's, NL

The goal of this session is to provide pharmacists with an understanding of the role of aldosterone in the pathophysiology of heart disease and the clinical evidence behind the use of aldosterone antagonists as a treatment modality.

Half a century after its discovery, aldosterone is generating renewed interest in cardiology. Scientific evidence has identified aldosterone as a key hormone influencing cardiovascular disease, including hypertension, myocardial infarction and heart failure. Emerging data now indicates that aldosterone affects not only sodium handling in the renal tubules of the kidney, but it also plays a multi-factorial role in the physiology of the brain, vasculature, and heart. Initially, it was assumed that angiotensin converting enzyme (ACE) inhibition and angiotensin II receptor blockade would significantly and sufficiently limit the production of aldosterone in cardiovascular disease states.

However, there are other mediators that regulate the production and release of this hormone and allow for considerable aldosterone escape.

In addition to the pathophysiology of aldosterone, clinical trials examining the use of aldosterone antagonists will be reviewed, with an emphasis on trials that have examined the effects of aldosterone blockade in patients with heart failure or developing heart failure.

Goals and Objectives

1. To provide pharmacists with an understanding of the role of aldosterone in the pathophysiology of heart disease.
2. To review the clinical trial evidence for the use of aldosterone antagonists in the treatment of heart disease.

Self-Assessment Questions

1. What pathophysiologic effects does increased aldosterone have in patients with heart disease?
2. Where do aldosterone antagonists fit in the treatment algorithms for heart failure and myocardial infarction?

A Duty to Warn

Julie Greenall, BScPhm; Sylvia Hyland, BScPhm, MHSc Bioethics, ISMP Canada

With a better understanding of how systems can fail and the recognition that error prevention or mitigation of harm from error requires system design with integrated safeguards, there is increased awareness of the need to warn others when incidents occur. We know that “a major force for improving patient safety is the intrinsic motivation of health care providers, shaped by professional ethics, norms and expectations.”¹ The goal of this session is to discuss ethical issues related to medication incident reporting, and to provide techniques for effective reporting, review, analysis and follow-up of incidents.

Bioethical principles suggest that in addition to disclosing information about preventable adverse events to patients, there is a responsibility to warn others and to seek system improvements. Analysis of error in complex systems requires a multi-pronged and multi-level approach. Working together in the early stages of error analysis can identify improvement opportunities that exist both within and outside the immediate workplace.

A recently released Canadian adverse events study concluded that “Efforts to make patient care safer will require leadership to encourage the reporting of AEs [adverse events].”² The next challenge is translating the learning into actions that will make a difference.

Goals and Objectives

1. To provide pharmacists with a brief overview of ethical issues that arise from our new understanding of medication system failures and error.
2. To provide pharmacists with guidance for effective reporting, review and analysis of medication incidents.

Self-Assessment Questions

1. Describe ethical issues that arise as a result of a new understanding of the nature of error and medication systems.
2. Describe techniques for translating the learning from medication incidents into action for system change.

Cardiac Toxicity in Oncology: Why and When

Sean Hopkins, B.Sc., B.S.P., The Ottawa Hospital – Integrated Cancer Program, Ottawa, Ontario

The goal of this session is to provide information on the cardiac risks of chemotherapy and the various agents that are associated with cardiac dysfunction.

With the myriad of new chemotherapy agents that are being developed and brought into practice, new side effects are being observed as greater numbers of patients are being exposed to chemotherapy. One common side effect that can occur with chemotherapy is cardiac dysfunction. This side effect is most commonly associated with breast cancer chemotherapy that incorporates anthracyclines (doxorubicin, epirubicin) but can occur in other settings (e.g. colorectal cancer, sarcomas). Newer agents such as trastuzumab are primarily used in metastatic disease but are under investigation for adjuvant use.

The risks of developing cardiac dysfunction vary between drugs and protocols (drug combinations). Schedule and administration method may influence risks of developing cardiac toxicity. In addition, cardiac toxicity tends to be idiosyncratic, and it is very difficult to predict who will develop cardiac toxicity. While there is one medication that has been shown to reduce the risk of developing cardiac toxicity (dexrazoxane), it does not provide 100% protection. Treatment of the toxicity is common to non-chemotherapy related cardiac dysfunction but can remain a long-term morbidity.

Goals and Objectives

1. To provide information on the cardiac risks of chemotherapy and the various agents that are associated with cardiac dysfunction.

2. To provide pharmacists with examples of the various chemotherapy regimens that are associated with cardiac toxicity and their efficacy, along with their role in therapy.
3. To introduce newer agents and combinations that are under investigation for cancer treatment.

Self-Assessment Questions

1. What is adjuvant chemotherapy? What are the relative benefits?
4. What is the definition of cardiac toxicity in oncology?
3. What are some of the patient risk factors for developing cardiac toxicity?
4. What can be done to prevent cardiac toxicity in oncology?

COPD and Tiotropium Use

Lawrence Jackson, BScPhm, Sunnybrook & Women's CHSC, Toronto, ON

The goal of this session is to provide pharmacists with an understanding of the pathophysiology of COPD and the evidence supporting the role of bronchodilator therapy, with a focus on tiotropium bromide.

Chronic obstructive pulmonary disease (COPD) is a common cause of disability and death in Canada. Small airway fibrosis and bronchoconstriction contribute to airflow limitation. Destruction of alveoli with loss of elastic recoil limits lung emptying with each breath and contributes to air trapping (lung hyperinflation).

The limited success in improving lung function (FEV1) with bronchodilator therapy has led to therapeutic nihilism. A shift in outcome measurement to include measures such as degree of dyspnea, exercise tolerance and quality of life together with the introduction of long-acting b₂-agonists (LABA) and the long-acting anticholinergic agent, tiotropium bromide, have created renewed interest in the benefits of bronchodilator therapy.

The use of long-acting b₂-agonists have been shown to improve dyspnea and quality of life. Tiotropium bromide has been shown to improve exercise tolerance, reduce dyspnea, improve quality of life and prevent exacerbations and hospitalizations. The proposed mechanism by which it achieves these effects is thought to be through reduced lung hyperinflation.

The Canadian Thoracic Society (CTS) COPD guidelines recommend optimizing bronchodilator therapy through regular use of either a LABA or tiotropium bromide or both agents together as symptoms dictate. In those with moderate to severe

COPD and frequent exacerbations, an inhaled corticosteroid may be added to therapy.

Goals and Objectives

1. To provide pharmacists with an understanding of the pathophysiology of COPD that results in lung hyperinflation.
2. To enable pharmacists to promote the bronchodilator therapy recommendations from the 2004 CTS COPD Guidelines and improve patient outcomes.

Self-Assessment Questions

1. What is the primary consequence of COPD on lung mechanics?
2. What outcome measures should be considered when assessing response to bronchodilator therapy?
3. What combination of bronchodilators is recommended for optimal therapy?

Acute Coronary Syndromes – An Update

Patrick Robertson, B.S.P., PharmD, Saskatoon Health Region, Saskatoon, SK

The goal of this session is to review the early management of acute coronary syndromes. The session will focus on the management of unstable angina and non-ST (NST) elevation myocardial infarctions. At the end of the session, the pharmacist will have an understanding of the current treatments of non-ST elevation acute coronary syndromes. The strength of the supporting evidence and the controversies regarding the treatment will also be reviewed.

The evidence of early invasive treatment will be compared with conservative treatment strategies for ACS patient. All patients require treatment with ASA and heparin. The role of LMWH versus UFH will be discussed. High risk patients require glycoprotein IIb/IIIa inhibitors (GPI). The current evidence of which GPI agents are beneficial and when to initiate them will be reviewed. The role of direct thrombin inhibitors, focusing on bivalirudin, will be compared with GPIs.

Goals and Objectives

1. To review the terms, definitions, and pathophysiology of acute coronary syndrome.
2. Review risk-stratification and outline management strategies for high, moderate and low risk patients presenting with NST ACS.
3. Summarize the results of clinical trials comparing medical therapy versus early interventional therapy for patients with NST ACS.

4. Describe the rationale, the pharmacologic differences and compare the effectiveness and adverse effects of antithrombotic agents (i.e., heparin, LMWH, ASA, clopidogrel) for treatment of NST ACS.
5. Review the long-term strategies for secondary prevention.

Self-Assessment Questions

1. What are three therapies that are essential to the acute treatment of ACS patients?
2. What are the high-risk indicators that prompt an early invasive strategy in ACS patients?
3. What are the benefits versus concerns with the use of LMWH rather than UFH for the ACS patients?
4. Does early GPI use in the high-risk ACS patient provide a mortality benefit?

Prostate Cancer: A Patient's Perspective

Mark Dailey, Anchor/Reporter, Citypulse News, City TV, Toronto, Ont.

Prostate cancer is the most common internal cancer killer of men. One in Eight men will get the disease in Canada. 20 thousand news cases are diagnosed in 2003, and more than four thousand men died from metastatic forms of the disease. It is also one of the most easily detected, treatable and even curable cancers.

This session will bring a first person patient's perspective to the issue from a long time popular Toronto broadcast journalist. Mark Dailey was diagnosed with an early stage prostate cancer in June of 2003 and took his television audience on his "journey to a Cure" in a five part news serial. The stories dealt with the common reactions, and stigma associated with the disease detection, treatment options and an up close look at the actual procedure he chose, radioactive brachytherapy. His public sharing of his very personal cancer story has touched many families dealing with the same emotions and decisions.

Goals and Objectives

1. To raise awareness of prostate cancer screening and detection
2. To highlight the improving treatment options
3. To raise awareness of the critical lack of research support for prostate cancer compared to other popular diseases

Failed Thrombolysis after Acute Myocardial Infarction: So Now What?

Claudia Bucci, BScPhm, Sunnybrook & Women's College Health Sciences Centre, Toronto, ON

The goal of this session is to provide pharmacists with an understanding of the various treatment strategies and pharmacotherapeutic considerations involved in the treatment of acute myocardial infarction patients who have failed thrombolytic therapy, using an interactive case-based workshop.

Thrombolytics are the main treatment strategy for acute myocardial infarction. However, 5% of patients who receive this therapy re-infarct or fail to reperfuse. Patients who re-infarct are at high risk for in-hospital and 30 day mortality and hence, early identification and treatment of these patients is important. Despite this, there is limited data evaluating the different treatment strategies available to this population and therefore we must rely on individual patient assessment. Interventional and pharmacologic treatment strategies for patients who have failed thrombolytic therapy may improve clinical outcomes. Rescue Percutaneous Coronary Intervention (PCI) is the preferred treatment modality, however PCI is not readily available in many centres. Additional medications such as glycoprotein 2b/3a inhibitors, clopidogrel, re-administration thrombolytic therapy and other medical therapies may be required. Appropriate timing, dosing and monitoring of these agents is important in order to achieve benefits and minimize risks such as bleeding.

Goals and Objectives

1. To provide pharmacists with an understanding of the various treatment strategies available for acute myocardial infarction patients who have failed thrombolytic therapy.
2. To conduct an interactive, case-based workshop that highlights the common pharmacotherapeutic considerations in patients who receive interventional or pharmacologic treatment after failing thrombolytic therapy.

Self-Assessment Questions

1. When should thrombolytic therapy be re-administered and what are the concerns?
2. What are the issues in patients who go to the cardiac catheterization lab after failing thrombolytic therapy? Should they receive a glycoprotein 2b/3a inhibitor and/or clopidogrel?

Tricky CHF Case Study

Glen J. Pearson, BSc, BScPhm, PharmD, FCSHP, Division of Cardiology, University of Alberta, Edmonton, AB

It is generally well accepted that congestive heart failure (CHF) is a complex clinical syndrome characterized by dyspnea and fatigue secondary to structural and function changes in the heart, which all occur within the setting of an activated neurohormonal system. Patients with CHF who present with acute symptomatology are considered to have acutely decompensated heart failure (ADHF). Hospitalizations for ADHF have increased precipitously over the past few decades. Among patients who present to the hospital emergency room with ADHF, 21% are experiencing their first episode and 79% have established CHF.

While there have been significant advances in our understanding of the pathophysiology of CHF and evidence-based improvements in the pharmacotherapeutic management of chronic heart failure, acute management is inconsistent and less than optimal in many hospitals. This session will focus on the hemodynamic abnormalities and pharmacotherapeutic management of acute decompensated heart failure. In a case study format, the appropriate therapeutic management of ADHF will be reviewed and discussed. The option of heart transplantation for refractory end-stage heart failure will also be addressed, with an emphasis on the non-pharmacological options available to enhance patient survival or bridge them to transplantation.

Goals and Objectives

1. To provide pharmacists with an understanding of the hemodynamic abnormalities and clinical signs involved in the diagnosis of acute decompensated heart failure (ADHF).
2. To discuss the pharmacotherapeutic options and treatment strategies available for the management of acute decompensated heart failure.
3. To review some of the non-pharmacological options available to enhance the survival of patients with refractory end-stage heart failure who are eligible for heart transplantation – “bridge to transplant” modalities.

Self-Assessment Questions

1. What is the level of endogenous B-type (brain) natriuretic peptide (BNP) that is indicative of acute decompensated heart failure?

2. What are the hemodynamic findings of patient who is in cardiogenic shock (Killip Class IV)?
3. Outline the appropriate pharmacotherapeutic plan for the management of the patient with the hemodynamic profile identified in question 2.

Complex Coagulopathy Case: DVT, PE, CVA, GI Bleed, etc.!

Wendy A. Leong (BScPharm, PharmD, BCPS, MBA), Burnaby Research & UBC, Vancouver, BC

The goal of this 30-minute interactive session is to review key concepts in thromboembolic disease management using a real-life case study, and the recently published 7th American College of Chest Physicians (ACCP) Consensus Conference on Antithrombotic Therapy (Chest 2004;126(3)Suppl).

The complex coagulopathy case is the true story of a 25-year old, married Afro-American female with a history of DVT, PE, TIA, CVA and GI bleed; and plans to become pregnant. Participants will learn how to assess her risk of bleeding (using hemorrhagic risk factors) and her risk of recurrent thromboembolic disease (using Virchow's triad). The case study also includes her warfarin dosing and INR response. New recommendations from the 7th ACCP Chest 2004 guidelines will be reviewed, as they apply to this case study.

Goals and Objectives

1. To review a standardized approach for assessing high risk warfarin patients (i.e. risk of bleeding and recurrent thromboembolic events)
2. To discuss the new Chest 2004 Antithrombotic Therapy Guidelines as they pertain to this patient with DVT, PE, TIA, CVA, GI bleed and plans for pregnancy
3. To assess warfarin dosing, INR response and anticoagulation management in a high risk patient

Self-Assessment Questions

1. How can Virchow's Triad be used to assess risk of thromboembolism?
2. Describe the hemorrhagic risk factors.
3. What are the Chest 2004 Antithrombotic Therapy Guidelines for treating thromboembolism in a patient with GI bleed and pregnancy?

Sunday, February 6, 10:00 – 10:45 Frontenac Foyer

1. Trichotillomania Associated with the use of Methylphenidate HCl
2. Effects of Switching Patients from Coumadin, to a Generic Warfarin Product
3. Clinical Outcome of Gentamicin use on Hearing in Neonates
4. Accuracy of Medication Lists Provided by Patients
5. A Multidisciplinary Approach to Improving Parameters of Bone Metabolism and Disease in a Home Dialysis Population
6. Mandatory Reporting of Adverse Drug Reactions
7. Pharmacist-Managed Physician-Directed Management of Allergic Rhinitis in the Canadian Forces – A Trial
8. Computerized Discharge Prescriptions: A Retrospective Survey
9. Assessment of Risk Associated with Short-Term use of Mefloquine in Canadian Forces Members
10. Evaluation of Health Products used by the Canadian Forces Health Lifestyle Information Survey Respondents
11. Evaluation of Caspofungin Use in Fraser Health Authority, British Columbia

Monday, February 7, 13:45 – 14:30 Metropolitan Ballroom

1. Hiring a Pharmacist to Work in Primary Care: Application to Ambulatory and Hospital Pharmacy
2. Strategies Implemented to Reduce Medication Incidents Related to Morphine and Hydromorphone
3. Naive Observation of Medication Administration With and Without Bedside Barcode Scanning Technology
4. Automation Technology Tracks the Use of Unsafe Abbreviations in a Community Hospital
5. Development of a Pharmacy Seamless Care Strategy and Tool for Chronic Renal Failure Patients
6. Interactive Tutorial to Help Pharmacists Better Utilize Drug Information Resources on the Internet
7. Safety Initiative for Medication Swallowing in Dysphagic Patients – Implementation and Evaluation
8. Insulin Nomogram Implementation in the CCU
9. Impact of Using a Person Digital Assistant to Tract Drug Related Problems in a Long-Term Care Facility and an Acute Mental Health Service
10. Prevention of Clostridium Difficile Associated Diarrhea with Saccharomyces Boulardii
11. “MSH Gets Pumped” Implementing Computerized Infusion Pumps at the Markham Stouffville and Uxbridge Cottage Hospitals

Tuesday, February 8, 13:45 – 14:30 Metropolitan Ballroom

1. Assessment of the Educational Needs of Community Pharmacists who Provide Pharmaceutical Care to Renal Transplant Patients
2. Renal Safety with Pamidronate (PAM) 1-hour Infusion for Metastatic Breast Cancer (MBC) and Multiple Myeloma (MM): A Multi-Centred Population-Based Analysis
3. Haemoglobin Response of Cancer Patients with Epoetin alfa: The Ottawa Hospital Integrated Cancer Program Experience (TOH-ICP)
4. Potassium Chloride Medication Safety Initiative between AstraZeneca Canada and the Institute for Safe Medication Practices Canada
5. Implementation of a Program to Convert Renal Disease Patients from Erythropoietin to Darbepoetin
6. Ciprofloxacin: The Impact of a Pharmacist-Managed Dosage Form Conversion Service at a Major Canadian Teaching Hospital
7. Neonatal Withdrawal Syndrome Associated with Fluoxetine and Venlafaxine Use in Pregnancy
8. Probable Cephalexin-Induced Autoimmune Hemolytic Anemia
9. Diclofenac-Induced Hepatitis – A Case Report
10. A Pharmacist-Initiated Hemoglobin Monitoring Program: A Pilot Program Identifying Patients with Chemotherapy-Related Anemia in a Community Oncology Setting
11. Implementation of an Automated Unit-Dose Medication System in a Rehabilitation/Chronic Care Hospital: A Team Approach
12. Measurement of the Effect of Discontinuing Baclofen and Dantrolene Therapy in Long-Term Institutionalized Patients with Spasticity

Wednesday, February 9, 10:15 – 11:00 Frontenac Foyer

1. Improvement in Delivery of Surgical Antibiotic Prophylaxis following a Review and Policy Change
2. Use of a Hospital Information System to Compare Glycemic Alterations Associated with Fluoroquinolone Antibiotics
3. Therapeutic Drug Management Program (TDMP): An Innovative Approach to Optimizing Drug Utilization in University-Teaching Hospitals in Quebec
4. Implementation of a Quality Assurance Program for Unit Dose Cart Filling
5. Trends in Fluoroquinolone Use in Nova Scotia Hospitals and the Effect of Policies on Use
6. Critical Appraisal of the Literature Involving a Pharmacist Intervention in Diabetic Patients
7. Winnipeg Regional Health Authority Pharmacy Summer Student Education Day
8. A Comparison of the Incidence of Urgent Percutaneous Coronary Intervention in Patients Receiving Alteplase or Tenecteplase following Acute ST-Segment Elevation Myocardial Infarction
9. Reconciling Medication Variances: Reducing Medication Errors at Interface of Care

Sunday, February 6 • Dimanche le 6 février

Trichotillomania Associated With The Use Of Methylphenidate HCl

Anwar, M. BScPhm; Sumpton, J. BScPhm; and Bayliff, CD. PharmD, FCSHP, London Health Sciences Centre

Stimulants have demonstrated efficacy in the treatment of Attention Deficit Hyperactivity Disorder (ADHD.) Recently, methylphenidate extended release (XR) tablets (Concerta®) have been introduced to the Canadian market in addition to regular release and sustained release formulations.

We present a case of trichotillomania (the compulsion to pull out one's hair) associated with the use of high doses of methylphenidate XR.

A 10-year-old boy, with a history of ADHD presented to clinic with bald patches. He developed the tendency to pull out his scalp hair approximately 1 month after an increase in dose of methylphenidate XR. The patient had previously been on methylphenidate immediate release tablets without displaying any signs or symptoms of trichotillomania.

The patient was initiated on methylphenidate 10 mg twice daily, which was increased to methylphenidate XR 36 mg in the morning in order to improve behavioural control. Three months later, the dose was increased to methylphenidate XR 54 mg in the morning. After 1 month, the patient developed signs of trichotillomania and methylphenidate XR was discontinued. No other medications were initiated or adjusted during this time. Upon cessation of methylphenidate XR the patient exhibited clinical improvement and was prescribed his previous dose of methylphenidate. When evaluated according to the Naranjo Adverse Drug Reaction Probability Score (APS), a score of 6 was obtained which correlates to a probable adverse drug reaction due to the use of methylphenidate XR.

This case questions the recommended dose conversation from methylphenidate to methylphenidate XR and the need for gradual dose increases.

Effects of Switching Patients from Coumadin™ to a Generic Warfarin Product

Chole Campbell, BSc Pharm, Pharmacist, Ottawa Hospital, Ottawa, ON; Geoff Lewis, MSc Pharm Clinical Pharmacy Specialist, Ottawa Hospital, Ottawa, ON, Kirsten Woodend, RN, MSc, PhD, Director of Research, Canadian Pharmacists Association, Ottawa, ON, Phil Wells MD, Chief, Division of Hematology, Ottawa Hospital, Ottawa, ON

Abstract

Background:

On June 7, 2001, two generic warfarin products, Taro-Warfarin and Apo™-Warfarin were designated as interchangeable with Bristol-Myers Squibb brand warfarin, Coumadin™, in Ontario. Currently, no trials, either randomized or observational have been conducted in Canada to determine the effect on International Normalized Ratio (INR) value, dosage, and/or frequency of INR testing in patients changed from Coumadin™ to a generic warfarin product. The primary objective was to determine if a switch from Coumadin™ to a

generic warfarin product results in a significant change in average weekly oral anticoagulant dose.

Methods:

A retrospective database review was conducted. Patients who were switched from Coumadin® to a generic warfarin product and who fit the selection criteria were included in the study (n=94). The eight-week period before the warfarin brand switch was compared to the eight-week period after the brand switch. We compared average weekly oral anticoagulant dose, frequency of INR monitoring and proportion of out-of-range INR values.

Results:

The mean difference in average weekly dose was 0.14 mg per week (95% CI -0.43, 0.72; p=0.62). The mean difference in the number of INR tests was -0.075 (95% CI -0.36, 0.22; p=0.61). The mean difference in proportion of out-of-range INR values was 0.013 (95% CI -0.058, 0.083; p=0.722).

Interpretation:

Switching patients from the Bristol-Myers Squibb brand warfarin product Coumadin® to a Canadian generic brand of warfarin (Apo™ or Taro) does not require a change in dose or frequency of monitoring.

Clinical Outcome of Gentamicin Use on Hearing in Neonates

Eric Lui, Barrie McTaggart, Shari Gray, Pui-Yi Tam, Mark Duffett, Dale Cochrane, Brenda Head, Hamilton Health Sciences, Hamilton, Ontario

Rationale and Objective:

Gentamicin is commonly used to treat infections in neonates. In our institution, gentamicin is routinely dosed at 2.5 mg/kg/dose. Serum trough levels are monitored, and dosing intervals are adjusted to keep the level <2.0 µg/mL. This study examines the effect of this clinical practice on hearing.

Methods:

All babies admitted to the neonatal intensive and intermediate care nurseries over an 8-month period were included. Clinical information was collected prospectively, including gentamicin use and other potential risk factors for hearing loss. Hearing tests were performed using Automated Auditory Brainstem Response (AABR) prior to hospital discharge. Chi-square test and multiple regression were used for risk factor analysis.

Results:

A total of 355 neonates were included (gestational age: 35±4 weeks, birth weight: 2549±1048g). Gentamicin was given to 259 babies. Total duration of treatment was 4.5±4.5 (range 0-29) days. Serum trough level pre-3rd or pre-4th dose was 1.7±0.7 (range 0.4-7.2) µg/mL. Dosing intervals were adjusted in 84 (33%) babies. Forty-one babies (11.5%) did not pass the hearing test. The rate of failure was not significantly higher in those whose dosing interval was adjusted (p=0.95) or in those who received ≥7 days of therapy (p=0.20). Gentamicin

use was not found to be a significant independent risk factor for hearing loss in neonates (odds ratio 1.4(0.5-4.4), p=0.53).

Conclusions:

Close monitoring is important when using ototoxic drugs such as gentamicin. Clinical use of gentamicin with a target serum trough level of <2 µg/mL is not associated with an increased risk of ototoxicity in neonates.

Accuracy of Medication Lists Provided by Patients

Lori MacCallum, Diabetes Comprehensive Care Program, St. Michael's Hospital, Toronto, Ontario

Background:

Maintaining accurate medication records which are essential to ensure safe prescribing and optimal care of patients poses unique challenges in an ambulatory setting. For example, changes may have been made by family practitioners and/or specialists in between clinic visits. In addition, patients may make changes on their own that may be unknown to their care providers.

Objective:

To compare medication lists provided by patients to a medication history obtained following a one-on-one interview with a pharmacist.

Methods:

All patients attending the Progressive Renal Disease Clinic at St. Michael's Hospital completed a questionnaire which included providing a list of current medications at each clinic visit. All patients were seen by the clinic pharmacist who conducted a formal medication history with the patient. Comparisons were then made between the two methods.

Results:

Medication histories were completed on 122 patients over four months. Thirty-four percent of patients provided a list of their medications that was either incomplete or listed something different from what they were taking. Sixteen percent of patients were unable to complete the list at all because they did not know the names of the medications they were taking. Only 50% of medication lists provided by patients were complete and accurate. Common omissions included injectables, over the counter medications, and medications that were given 2-3 times weekly.

Conclusion:

Having patients provide a list of current medications provides a good starting point for obtaining an accurate history but should not replace a formal discussion between the patient and pharmacist.

A Multidisciplinary Approach to Improving Parameters of Bone Metabolism and Disease in a Home Dialysis Population

Lori MacCallum, St. Michael's Hospital, Toronto, Ontario

Background:

Disturbances in mineral and bone metabolism are common in patients with chronic kidney disease and are associated with significant morbidity including bone pain, fractures, and bone deformities. There is a growing body of evidence demonstrating that these disturbances can lead to vascular calcification and increased mortality. A multidisciplinary continuous quality improvement initiative (CQI) coordinated by the clinic pharmacist was designed to improve these parameters.

Methods:

Baseline data was collected for serum calcium, phosphorus, albumin and parathyroid hormone. The clinic pharmacist presented a series of educational sessions to the multidisciplinary team and staff nephrologists. In addition, the percentage of patients not at nationally recommended targets was presented. Each of the five disciplines involved in the clinic identified and implemented ways to improve patient outcomes. Data was collected nine months later to assess effectiveness of the interventions.

Results:

Peritoneal dialysis population (n=45): at baseline, serum phosphorus, corrected serum calcium, calcium/phosphorus product and parathyroid hormone were at target for 60%, 57.8%, 57.8% and 22.2% of patients respectively. Following the interventions, these parameters were at target for 58.7%, 71.7%, 60.9% and 28.3% of patients respectively.

Home hemodialysis population (n=12): at baseline, serum phosphorus, serum calcium, calcium/phosphorus product and parathyroid hormone were at target for 66.7%, 75%, 66.7% and 16.7% of patients respectively. Following the interventions, these parameters were at target for 78.6%, 93%, 78.6% and 21.4% of patients respectively.

Conclusion:

In this population, improvement in parameters of bone metabolism and disease requires a multidisciplinary approach to successfully improve the care of these patients. Such an approach can be successfully led by a pharmacist.

Mandatory Reporting of Adverse Drug Reactions

Régis Vaillancourt, Directorate of Medical Policy, Pharmacy Policy and Standards, Canadian Forces Health Services, Ottawa, ON, Alan Gervais, Directorate of Medical Policy, Pharmacy Policy and Standards, Canadian Forces Health Services, Ottawa, ON, Claire Gauthier, RPT Directorate of Medical Policy, Pharmacy Policy and Standards, Canadian Forces Health Services, Ottawa, ON

Rationale:

The benefits of reporting adverse drug reactions (ADR) became evident in two studies completed by the Canadian Forces (CF). The results of these studies influenced the implementation of the present procedure. A health professional must report an ADR to a drug on the CF drug benefit list to the Canadian Forces Drug Exception Centre (CFDEC) if the patient subsequently requires a drug not listed on the CF drug benefit list.

Description:

The program was implemented in November 2003. Between November 2003 and August 31st 2004, the CFDEC has received 79 requests for drugs that are not on the CF drug benefit list as a result of an ADR to a benefit drug. An ADR form has been completed for each of these cases and a copy forwarded to the Canadian Adverse Drug Reaction Monitoring Program where these case reports are reviewed and entered into a database that is constantly monitored for signals. Since the knowledge of drug risk evolves over the lifetime of the drug, the CF contributes to the risk assessment that must continue beyond the pre-market evaluation phase. Although not all ADRs are captured, it is an improvement over the underreporting documented in the literature

Conclusions:

As the results of the previous two studies assisted in managing the formulary to promote positive patient health outcomes and to minimize adverse reactions, the forthcoming documented adverse reactions will continue to assist in assessing the risk of drugs on the CF drug benefit list in the CF population.

Pharmacist-managed, Physician-directed Management of Allergic Rhinitis in the Canadian Forces – A Trial

Régis Vaillancourt, Directorate of Medical Policy, Pharmacy Policy and Standards, Canadian Forces Health Services, Ottawa, ON, Mark Kearney, Directorate of Medical Policy, Pharmacy Policy and Standards, Canadian Forces Health Services, Ottawa, ON, Jeff Taylor, College of Pharmacy and Nutrition, University of Saskatchewan, Saskatoon, SK

Background:

According to the 2000 Canadian Forces Health and Lifestyle Information Survey, 21% of male and 32% of female Canadian Forces (CF) members suffered from allergic rhinitis (AR).

Objective:

To evaluate the impact of pharmacist-managed care on the quality of life of AR patients in the CF.

Study Design:

CF members with a confirmed diagnosis of AR who presented to sick parade, physician appointments or a base pharmacy at 4 CF bases between September 2003 and December 2004 were included in the study. Patients at the 2 control bases received standard care from pharmacists. Patients at the 2 treatment bases received enhanced care from pharmacists including monthly follow-up consultations to assess the patient, provide detailed counselling and modify medication therapy via a collaborative prescribing protocol. As the primary outcome, study participants completed the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ(S)) at 4 week intervals, these were then mailed submitted to the study coordinator. Patients were followed for 12 weeks.

Results:

Eighty two patients have been recruited to date. Results suggest a trend whereby CF members receiving enhanced care from pharmacists report an improvement in allergy

symptoms and related RQLQ(S) scores at week 12, while CF members receiving usual care report worsening allergy symptoms and related RQLQ(S) scores.

Conclusion:

Regular interaction with a pharmacist over a 12-week period, where counselling can be provided and pharmacotherapy adjusted, appears to positively impact AR symptoms and quality of life.

Computerized Discharge Prescriptions: A Retrospective Survey

Régis Vaillancourt, Directorate of Medical Policy, Pharmacy Policy and Standards, Canadian Forces Health Services, Ottawa, ON, Geneviève Goulet, University of Laval, Quebec, QC, Yanic Péan, Montfort Hospital, Ottawa, ON, Sonia Dallaire, Montfort Hospital, Ottawa, ON, Christopher Sorfleet, Montfort Hospital, Ottawa, ON

Objective:

To determine the acceptability of a computerized hospital discharge prescription program.

Method:

A retrospective survey to evaluate satisfaction on a numerical scale from 0 to 10 the computerized discharge prescription (CDP) pilot project survey was distributed internally to physicians, ward clerks and nurses and externally to community pharmacists. Community pharmacies within 6 km of the hospital and selected pharmacies in Orleans were visited and surveyed.

Results:

Internal: 34.8 % of the physicians (15/43), 67 % (8/12) of the clerks 0% of nurses responded to the survey. The overall satisfaction of physicians was of 95 ± 13.2 %. Physicians evaluated the estimated time required to complete the process at 4 ± 3.22 minutes and the time gained at 5 ± 5.11 minutes. Physicians did not find any mistakes on the CDP. The clerks' overall satisfaction was of 92 ± 6.41 %. The time required to print the CDP was of 3 ± 1.16 minutes.

External: Fifty-nine community pharmacies were visited with a response rate of 78%(n=46).

Of the respondents, 39.1 % had already received CDP from the hospital and reported an overall satisfaction of 83.3 ± 9.73 %, with 61% indicating that CDP reduced the number of calls needed for clarification and 67% reporting no mistakes on these prescriptions.

Of the respondents, 60.9% had not yet received a CDP but reported an overall satisfaction of 87.7 ± 17.4 %, with 68% indicating that CDP would reduce the number of calls needed for clarification.

Assessment of Risks Associated with Short-Term use of Mefloquine in Canadian Forces Members

Régis Vaillancourt, Directorate of Medical Policy, Pharmacy Policy and Standards, Canadian Forces Health Services, Ottawa, ON, John Sampalis, JSS Medical Research, Montreal, QC, Janice Ma, Directorate of Medical Policy, Pharmacy Policy and Standards, Canadian Forces Health Services, Ottawa, ON

Objective:

To investigate the short-term health effects associated with the use of Mefloquine in Canadian Armed Forces personnel.

Design:

All Regular Force personnel who served in Somalia between 1992-1993 were eligible for inclusion in this descriptive, cross-sectional study. Individuals not prescribed Mefloquine for antimalarial prophylaxis were excluded.

Methods:

Data was extracted from CF medical documents, all events, including injuries, symptoms and signs reported during Mefloquine treatment were identified and classified according to the Canadian Enhancement to the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10-CA). For each event, severity either minor/major as well as causal relationship to Mefloquine was noted.

Results:

The study involved 1413 individuals, 554 (39.2%) of whom reported one or more adverse events (AE) related to Mefloquine for a total of 2030-recorded AE. The most frequently reported AE were: non-infective gastroenteritis and colitis (N=343,24.3%); non-specific signs involving the digestive system and abdomen (N=272,19.2%); abdominal and pelvic pain (N=204,14.4%); nausea and vomiting (N=203,14.4%); sleep disorders (N=152,10.8%); malaise and fatigue (N=147,10.4%); headache (N=135,9.6%), symptoms and signs concerning food and fluid intake (N=122,8.6%); fever of unknown origin (N=106,7.5%) and rash or non-specific skin eruption (N=102,7.2%). Of the total AE, 13 were major, with 12 cases of dizziness and 1 case of cardiac arrest. The reported AE related to Mefloquine per individual were distributed as follows: 1AE (N=114,20.6%), 2AE (N=101,18.2%), 3AE (N=82,14.8%), 4AE (N=82,14.8%), 5 AE (178,32.1%).

Conclusion:

This study shows that the majority of the adverse events were mild with a low rate of major events.

Evaluation of Health Products used by the Canadian Forces Health and Lifestyle Information Survey Respondents

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Objectives:

To identify the patterns of natural health product (NHP) use among Canadian Forces (CF) members. The secondary objective was to compare NHP use with first language (English/ French), gender, age, marital status, education, rank, duration of service, Non NHP medication use, chronic conditions, weight (Body Mass Index BMI), and self reported health status.

Methods:

A cross-sectional survey of CF members was performed and all 6,841 respondents to version B of the CF 2000 Health and Lifestyle Information Survey (HLIS) were included in the study. Descriptive statistics, using SPSS software, were determined for the demographics of the study sample and the frequencies of health products use. Odds ratios and 95% confidence intervals were determined for the association between the independent and dependent variables. A logistic regression analysis was done for independent characteristics associated with health products use.

Results:

Data from the 6,841 respondents was analyzed: mean age was 37.2 years (7.52) with the majority of respondents rating their health status (41.3%) as very good. Of the respondents, 44.1% used health products on a regular basis and 2134 (31.2%) used a NHP in the previous two days.

Conclusions:

CF members, in common with the general population, utilize the full range of NHP. All CF health care providers need to be knowledgeable about NHP and be able to provide accurate information to their patients. Further follow up studies should be conducted to determine where CF members obtain their NHP and from whom they obtain information on NHP.

Evaluation of Caspofungin Use in Fraser Health Authority, British Columbia

Tina Hara, Fraser Health Authority, Surrey, British Columbia, Anisha Lakhani, Fraser Health Authority, Surrey, British Columbia

Purpose of report:

Caspofungin, a novel, broad spectrum intravenous antifungal, received formulary approval in May 2003 as a second or third line agent for the treatment of invasive candidiasis, candida esophagitis or invasive aspergillosis. Due to its reduced frequency of adverse effects and relative ease in dosing, the potential exists for overuse. A drug use evaluation was recommended by the Pharmacy & Therapeutics committee.

Objectives:

Determine if caspofungin use was appropriate in the Fraser Health Authority based on its indication and duration of therapy. Patient characteristics, outcomes and treatment cost information were also collected.

Design and Methods:

Retrospective chart review. Appropriateness of use was based on indication and duration.

Results and Cost Analysis:

Twenty-eight patients received caspofungin over 14 months with a total of 31 courses of therapy. Indication was found to be appropriate in 21 (68%) of the courses; duration was appropriate in all treatment courses. Cost of appropriate use was \$141,053 and inappropriate use was \$49,837. Patient risk factors included chronic heart disease, renal failure, diabetes, broad spectrum antibiotics, and corticosteroids. Overall mortality was 46%.

Conclusion and Implications:

Caspofungin use was appropriate in 68% of courses of therapy in FHA; the indication criteria were appropriate in 68% of the courses and duration criterion was appropriate in 100% of the courses. All patients receiving caspofungin were

critically ill with multiple underlying diseases and risk factors for a fungal infection. Implications of the results for the Fraser Health Authority and the future of pharmacy practice will be outlined.

Monday, February 7 • Lundi le 7 février**Hiring a Pharmacist to Work in Primary Care: Application to Ambulatory and Hospital Pharmacy**

Kelly Babcock, SCO Health Service and Elisabeth Bruyere Research Institute, Ottawa, Ontario, Barbara Farrell, SCO Health Service and Elisabeth Bruyere Research Institute, Ottawa, Ontario, Connie Sellors, Centre for Evaluation of Medicines and Department of Family Medicine, McMaster University, Hamilton, Ontario, Lisa Dolovich, Centre for Evaluation of Medicines and Department of Family Medicine, McMaster University, Hamilton, Ontario

Rationale:

Tailoring a hiring process to identify pharmacists suitable for different practice environments is a challenge. Elements of a successful process used by the Integrating family Medicine and Pharmacy to Advance primary Care Therapeutics (IMPACT) project are described.

Description of Situation:

Qualified pharmacists were required for seven, 1 year part-time contracts. Our objective was to utilize an effective hiring process, transparent, equitable and attractive to the best candidates under tight timelines and a recognized pharmacist shortage.

Steps taken:

A job description and advertisement were distributed to pharmacists in identified markets. Applicants submitted a curriculum vitae, 2 structured references and a candidate letter expressing their qualifications.

A selection committee independently reviewed applications using a structured evaluation tool and interviewed preferred candidates with 2 person teams. After a matching process, some candidates were interviewed by practice site physicians. Applicants were informed of the results and added to our mailing list. Successful candidates participated in a mandatory structured formative training program prior to starting practice.

Results:

The two month process had over 100 application packages requested, 24 applicants and 13 interviews. Seven pharmacists were hired with a variety of experience and training (7/7 community pharmacy, 5/7 hospital pharmacy, 2/7 nursing home). One pharmacist had a Pharm D degree. Four pharmacists graduated 6 or more years ago. The ranking system could discriminate among applicants.

Usefulness to practice:

This complex, interdisciplinary approach was feasible. The structured process and numerous tools developed have general application for hiring pharmacists into advanced positions in ambulatory or hospital practice.

Strategies Implemented to Reduce Medication Incidents Related to Morphine and Hydromorphone

Kelly Babcock, Sylvie Corbeil, Louise Patrick, SCO Health Service, Ottawa, Ontario

Reason:

Medication incident analysis over 1 year showed our 482 bed multi-site hospital had a significant number of incidents related to administration of morphine and hydromorphone including 3 sentinel events.

Description:

Strategies listed below were implemented through a newly formed interdisciplinary Corporate Patient Safety Working Group, following discussion with the Shared Nursing Governance committee, in an attempt to prevent further incidents:

- A verification process for administration of these medications that involves 2 nurses.
- Standardization of terminology across the MAR, the narcotic sheet and the product label.
- Expansion of pharmacy created MAR dose calculations to palliative care unit for narcotics (eg. 2 mg = 1 ml)
- Removal of concentrated narcotic injectable products (i.e. morphine >10mg/ml and hydromorphone > 2 mg/ml) from the normal narcotic drawer.
- Publishing of 2 Medication Safety Alerts on the topic.

Evaluation:

Strategies were implemented across all nursing units (rehabilitation, palliative care and complex continuing care). A verification process audit revealed a 94-98% compliance rate across the nursing units despite the extra workload. Medication incident data analysis revealed an average of 10.8 incidents / month involving these medications over the one year prior to strategy implementation. After strategies were implemented, medication incident analysis revealed an average of 0.8 incidents/month for the first 5 months. No further sentinel events have occurred.

Usefulness to pharmacists:

Collaboration between pharmacy and nursing to improve narcotic policies and procedures can result in improved patient safety. Detailed examples of each strategy will be presented.

Naive Observation of Medication Administration With and Without Bedside Barcode Scanning Technology

Feng Chang, St. Joseph's Health Care, London, ON, Paul Churchman, University of Georgia College of Pharmacy, GA, USA, Randy Carver, PPMH, GA, USA

Purpose:

Medication administration is the last step in medication processing. Point-of-care barcode scanning is being used to improve patient safety. This project assesses administration errors with and without implementation of such technology in a real-time work environment.

Methods:

The setting is an acute care unit of 50 beds using Admin-Rx as the bedside scanning system. Admin-Rx was piloted on some patients while others received standard care. A pharmacy observer recorded the administration processes and verified the information afterwards with a retrospective chart review. The nurses were not aware of the purpose of the observations.

Results:

204 administrations were observed, 15 using Admin-Rx and 189 in the standard group. Admin-Rx significantly increased the number of patients who received a wristband identification check before administration, 14 (93%, $p < 0.01$) vs 34 (18%). For the right route, all 15 (100%, $p < 0.01$) in the Admin-Rx group matched the order. The standard group had 25 (13%) that could not be verified and 1 error. 11 (73%, $p = 0.04$) of the medications in the Admin-Rx group were opened at the bedside versus 93 (49%) in the standard group. The Admin-Rx group also had a higher percentage of properly recorded administrations (93% vs 83%) and on-time administrations (87% vs 60%, $p = 0.03$).

Conclusion:

Barcode technology is promising in reducing administration errors, particularly in patient identification, right route, on-time administrations and opening meds at the bedside. However, errors still occurred so technology does not guarantee an error-free system. The best guard would still be staff training and policies encouraging good practice.

(This project has been submitted for presentation at the 2004 ASHP Mid-Year Clinical Meeting)

Automation Technology Tracks the Use of Unsafe Abbreviations in a Community Hospital

Feng Chang, St. Joseph's Health Care, London, ON, Randy Carver, PPMH, GA, USA

Purpose:

Patient safety is important in institutional practice. As a part of its 2004 National Patient Safety Goals, the US Joint

Commission on Accreditation of Healthcare Organizations (JCAHO) approved a list of abbreviations not to use in medication order writing. This project assesses the extent these potentially unsafe abbreviations are currently used.

Methods:

The setting is a community acute care hospital of 450 beds. A randomized sample review was conducted for inpatient medication orders written over 13 weeks. The orders were retrieved using MedDirect, an automated medication order communication system. Orders were randomly selected for review against JCAHO's unsafe abbreviation list. Any non-medication orders were excluded.

Results:

From a total of 79114 pages, 1336 pages (1.7%) were reviewed. 1668 unsafe abbreviations were found, approximately 1.25 per page. SICU had the highest incidence, possibly related to workload and faster patient turnover. The use of apothecary symbols (37%) was most common, followed by "qd" instead of "daily" (27%), and the use of "c" or "s" instead of "with" or "without" (16%). Only 2 (<1%) orders were clarified and properly re-written. 299 (17.9%) of the unsafe abbreviations were found on pre-printed order sets. These order sets have been identified for future revision.

Conclusion:

Proper abbreviation use minimizes confusion and improves communication. At present, unsafe abbreviations are still commonly observed. However, imaging technology in the pharmacy department can track, store and analyze medication orders easily. This helps pharmacy to identify trends, track the use of unsafe abbreviations and develop strategies for quality improvement initiatives.

Development of a pharmacy seamless care strategy and tool for chronic renal failure patients

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Rationale

Continuity of care is required when patients move from the care of one pharmacist to another. The appropriate transfer of information to pharmacists as well as to patients at these times is essential in order to prevent drug related problems (DRPs) from occurring. There is currently no formal system or tool that is used consistently by various pharmacists at University Health Network to transfer medication-related information.

Objectives

To develop a strategy and tool to transfer medication-related information between pharmacists caring for chronic renal failure (CRF) patients.

Methods

The project was divided into three phases including data collection, tool design and developmental pilot. The data collection phase consisted of a literature review, collection of patients' drug related problems on admission and a needs assessment of stakeholders. Qualitative research methods were used for data collection and data analysis.

Data collected was used in phase 2 to determine the most optimal tool and strategy for medication information transfer in dialysis patients. In phase 3 the developed tool was tested on various pharmacists to assess feasibility.

Results

Of the total 199 DRPs, 130 are recognized as being related to lack of appropriate information transfer. The electronic Dear Pharmacist Letter created communicates pertinent medication-related information to community or clinic pharmacists including an up to date list of the patient's medications. The tool also creates two different formats of a patient medication schedule to be given to the patient when they are discharged from the hospital.

Conclusion

A large proportion of DRPs occurring in dialysis patients on admission are a result of the lack of appropriate information transfer between health care professionals, as well as to the patient. A stakeholder needs assessment; collection of DRPs on admission, and a literature review can be used to develop a seamless care strategy and electronic tool for CRF patients.

Interactive Tutorial to Help Pharmacists Better Utilize Drug Information Resources on the Internet

Certina Ho, Tommy Cheung, Scott Gavura, Drug Information and Research Centre, Ontario Pharmacists' Association, Toronto, ON

Purpose

The Drug Information and Research Centre (DIRC) receives over 60,000 drug information (DI) requests annually. DIRC has a wide range of resources to support its services, of which, Internet references play a significant role. As more pharmacies become equipped with Internet access, DIRC developed an educational program for practicing pharmacists to better utilize Internet resources for patient care.

Objectives

The program had 4 objectives:

1. Review the basics of using and searching the Internet.
2. Identify web sites pertaining to pharmacy practice.
3. Identify criteria for evaluating web sites.
4. Answer DI requests using Internet resources.

Description

A two-hour program was developed with 75 minutes of lecture, followed by 45 minutes of practice exercises, either with live online demonstration by the presenters, or hands-on activities by the participants, depending on the facilities available.

Evaluation

This program has been delivered to over 300 pharmacists across Ontario. Of the 278 evaluations received, 97% of the participants either strongly agreed or agreed that the content was appropriate and easy to understand; 95% found that the length and format of the program were appropriate; and 99% highly rated the visual aids and handouts.

Importance and Usefulness for Pharmacists

The program provides tools to enhance pharmacy practice and patient care by increasing awareness and utilization of appropriate Internet resources. Since this interactive tutorial was well received, such an approach may be applicable to similar educational events. An online version of this program may be considered to broaden access to pharmacists in remote areas.

Safety Initiative for Medication Swallowing in Dysphagic Patients- Implementation and Evaluation

Jackson L; Little J; Plowman S; Siemiatkowska K; Williams E; Kung E; Holley L; Etchells E, Sunnybrook and Women's College Health Sciences Centre, Toronto, Ontario

Rationale:

Inappropriate oral medication administration to patients with dysphagia was observed, leading to undesirable outcomes of: choking episodes, refusal to take medication, and crushing of sustained release medication products. These occurrences were attributed to miscommunication among the Speech-Language Pathologist (SLP), Nursing and Pharmacy.

Description of the initiative:

Our goals were to design an algorithmic approach to improve communication processes, establish responsibilities for each stakeholder and evaluate the effectiveness of the education program to disseminate the new strategy. A chart audit and caregiver interview performed on 60 patients in two patient care areas in a five hundred bed complex continuing care facility revealed a number of inconsistencies and gaps in communication. The new process calls for the nurse to seek each patient's swallowing preferences, the SLP to write in the Doctor's order sheet using standard phrases to describe medication administration, and the Pharmacy to place this information in the 'Comments' section of the Medication Administration Record (MAR). Each education session involved a knowledge pretest, description of stakeholder responsibilities, instruction on swallowing mechanisms by the SLP, a knowledge posttest and session evaluation.

Evaluation:

Clear stakeholder responsibilities and improved communication procedures were developed. The knowledge test scores increased from 56% to 78%. Satisfaction with the education sessions averaged of 4.4 out of 5.

Importance and usefulness:

This improved communication method has been successfully implemented throughout the hospital increasing the safety of administration of oral medication to dysphagic patients.

Insulin Nomogram Implementation in the CCU

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Rationale:

Observed poor insulin control and the recent Canadian Diabetes Association recommendation of insulin infusions for all patients admitted with acute myocardial infarction lead the CCU team to develop a nurse-managed insulin infusion nomogram.

Description:

The unit pharmacist developed a CCU-specific nomogram by adapting a previously developed intensive insulin nomogram in use in the MSICU setting. After an initial trial period, revisions were made based on feedback from users. The nomogram was adopted into clinical practice in April 2004.

Evaluation:

Initial evaluation revealed that the average insulin infusion was 43 hours. Patients' had an average of 11 blood glucose measurements/24 hours. There were 2 incidents of BG < 4 mmol/L. Patients' glucose levels were maintained within target levels 74% of the time. Assessment and modification of the nomogram to address shortcomings (initial bolus dosing, supplemental dosing for patients that are eating) are on-going.

The nurse-managed insulin nomogram is a protocol developed by the multidisciplinary CCU team that has achieved the goal of better insulin control in acutely ill patients.

Impact of Using a Personal Digital Assistant to Track Drug Related Problems in a Long-Term Care Facility and an Acute Mental Health Service

John Papastergiou, Lawrence Jackson, Sonia Sen-Roy, Artemis Diamantouros, Edward Kung, Sunnybrook & Women's College Health Sciences Centre, Toronto, Ontario

Rationale

A previous paper-based method of documenting drug related problems (DRPs) and drug information (DI) questions was infrequently used. Electronic data collection using the personal digital assistant (PDA) is proposed.

Concept

We anticipate that the use of PDAs will facilitate data entry thereby increasing the number of DRPs and DIs documented and improve ability to analyze data (ie., workload measurement and drug use evaluation, and the type, significance, source and setting of DRPs and DIs).

Methods of implementation

Pharmacists documented DRPs and DI questions prospectively over a three-month period. Predetermined levels of significance were assigned to potential DRPs. An electronic data collection program was created for the Palm OS® using PenDragon Forms 3.2®. Statistical analysis was done using SPSS 10.2®. Pharmacists completed a survey to give subjective feedback on the usefulness of the PDA.

Results

In 411 patients, a total of 408 DRPs were identified, including change in dose (44.6%), addition of a medication (27.0%), discontinuation of a medication (13.5%), and therapeutic substitution (4.9%). Significance was classified as high in 54.3% of DRPs. Physician acceptance rate was 98%. A total 313 DI questions were documented. Nurses and physicians accounted for 59.4% and 31.6% of these, respectively. The pharmacist survey indicated that the PDA was easy to use and facilitated documentation of interventions. Areas for improvement included a greater number of preformatted screens and improved navigation.

Importance to practice

The PDA was easy to use and improved pharmacists' documentation of DRPs and DI questions. Incorporation of additional preformatted screens and improved navigation will facilitate use.

Prevention of Clostridium Difficile Associated Diarrhea with Saccharomyces Boulardii

Jennifer Tung, BSc. (Pharm), Lisa Dolovich, Pharm D, MSc., St. Joseph's Healthcare, Hamilton, ON

Rationale:

Clostridium difficile is a major cause of antibiotic associated diarrhea within the hospital setting. The yeast, *Saccharomyces boulardii*, has been found to have some effect on reducing the risk of *C. difficile* associated diarrhea (CDAD) and its role in preventative therapy has yet to be firmly established.

Objective:

To review the effectiveness of *S. boulardii* in the prevention of primary and recurrent *C. difficile* associated disease. Benefit was defined as a reduction of diarrhea associated with *C. difficile*; risk was defined as any adverse effects of *S. boulardii*.

Methods:

A literature search in Medline, Embase, CINAHL and the Cochrane Library was performed. Included studies were randomized, double-blind placebo controlled trials in English evaluating *S. boulardii* in CDAD prevention.

Results

Four studies were reviewed. Two investigated prevention of recurrence in populations who were experiencing CDAD at baseline. One trial showed a reduction of relapses in patients suffering recurrent CDAD (RR=0.53, p<0.05). The other demonstrated a significant reduction of CDAD relapse in the recurrent treatment group of patients receiving high-dose vancomycin (RR=0.33, p≤0.05). Two other studies examined primary prevention of CDAD in populations who had been recently prescribed antibiotics. These studies lacked power to detect statistically significant differences. Patients on treatment experienced increased risk for thirst and constipation.

Conclusion

S. boulardii may be effective for secondary prevention in some specific patient populations with particular concurrent antibiotic treatment. Its role in primary prevention is poorly

defined and more research will be required before changes in practice are recommended. S. bouldardii seems to be well tolerated.

“MSH Gets Pumped”: Implementing Computerized Infusion Pumps at the Markham Stouffville and Uxbridge Cottage Hospitals

Fockler S, Markham Stouffville Hospital and Uxbridge Cottage Hospital, Markham ON

Moledina S, Markham Stouffville Hospital, Markham ON, Colquhoun M, ISMP Canada, Toronto, ON

True to its vision to “care for our community through partnerships and the pursuit of excellence”, Markham Stouffville Hospital has embraced the importance of medication safety for quality patient care. In June 2002, the Safe Medication Practice Committee was launched and several safety initiatives followed. Since intravenous drugs carry the highest risk for harm, placing protection between patient and drug in the form of a computerized infusion pump became a priority.

Two computerized pumps were evaluated by a cross-section of clinical and management staff. Once a product was chosen, the implementation team was selected. Six weeks prior to implementation, key users and managers from each area were invited to the program launch. Two key pharmacists developed the drug dataset from the literature, with input from nursing and physician representatives. Major policy and practice changes were approved by the Drugs and Therapeutics Committee. The dataset was reviewed by teams of clinical pharmacists and nurses in 3 separate forums and the dataset was revised. Training was provided to nurses over a 2 week period prior to “Go Live.”

After three months of use, quality assurance data was downloaded from the pumps to assess the extent to which rate limits were crossed (lower or higher doses given) and number of times medication incidents were avoided. This data will be available for presentation at the PPC.

Since we were the first community hospital to adopt these pumps in the GTA, our implementation team has many recommendations for those who are considering a similar program.

Tuesday, February 8 • Mardi le 8 février

Assessment of the Educational Needs of Community Pharmacists Who Provide Pharmaceutical Care to Renal Transplant Patients

Salma Bhaloo, Andrea Fox, St. Michael's Hospital, Toronto, Ontario

Purpose:

Community pharmacists are becoming more involved in the care of renal transplant recipients (RTR). To optimally provide care, pharmacists should have a baseline knowledge of transplant therapeutics.

Objectives:

The objectives of this study were to: i) determine community pharmacists' knowledge in the area of renal transplantation therapeutics and other aspects of care; ii) to identify the educational needs of this group.

Methods:

A survey was sent to 62 community pharmacies that provided services to RTR. Respondents were asked to i) rate their level of comfort with various topics in transplantation; ii) rank various methods of education according to perceived usefulness; iii) rank 3 topics of greatest priority.

Results:

Twenty-two completed surveys were received. Pharmacists were most comfortable in the area of reimbursement and billing issues of immunosuppressive medications. All other areas (i.e. therapeutic knowledge of immunosuppressives, co-morbidities in renal transplantation, drug interactions) received a maximum rating of “somewhat comfortable”. None of the pharmacists surveyed had received formal education

in renal transplantation, however 95% believed that they would benefit from education. The preferred mode of delivery of education was didactic-style teaching. The top 3 areas identified for education were therapeutics, adverse effects and drug interactions of immunosuppressive agents.

Implications: Community pharmacists identified that renal transplant therapeutics is an educational need. The transplant team needs to develop educational strategies with the identified topics and methods of delivery to better support community pharmacists as they become more actively involved in the community health care team of RTRs.

Renal Safety with Pamidronate (PAM) 1-Hour Infusion for Metastatic Breast Cancer (MBC) and Multiple Myeloma (MM): A Multi-Centred, Population-Based Analysis

Mário L de Lemos, Suzanne C Malfair Taylor,* Jeff Barnett,* Francis Hu,* Andrea Levin,† Veronica Moravan,* Susan E O'Reilly,* British Columbia Cancer Agency, Vancouver, BC. † British Columbia Renal Agency, Vancouver, BC.*

Background:

ASCO guidelines recommend pamidronate be infused over 2 hours (PAM-2) to avoid renal deterioration (RD), although there are some data to suggest that 1-hour pamidronate infusions (PAM-1) may be safe.

Methods:

Prevalence of RD (> 2 times baseline serum creatinine [SrCr]) with PAM-1 between Jan 2000-Dec 2002 from the BCCA registry and systemic therapy drug database was compared to that with PAM-2 in RCTs. A cost-minimization analysis comparing PAM-1 and PMA-2 and the 15-minute infusion of

zoledronic acid (ZOL) was performed with a sensitivity analysis that varied the opportunity cost of time in the treatment room.

Results:

RD occurred in 7.7% of 169 patients: 15% (12/80) in MM, 1.1% (1/89) in MBC. There is no evidence that this differs from the 10% reported in RCTs (one-tailed binomial test, p=0.3874). The respective costs/dose (drug/labour/supplies) of pamidronate and zoledronic acid are \$325 and \$610. Cost neutrality occurs if the opportunity cost of chair time is \$6.33/min for PAM-1 vs. ZOL and \$2.71/min for PAM-2 vs. ZOL. If a median \$4/min is used, the respective costs of PAM-1, PAM-2, and ZOL become: \$685, \$790, and \$925/cycle.

Conclusions:

Prevalence of RD with PAM-1 from a population database was not different than that with PAM-2 in RCTs. Our findings further support the safety of PAM-1. PAM-1 is less expensive than ZOL.

	MM (n = 80)	MBC (n = 89)
Demographics		
Female	41.3%	100%
Age* (years)	66 + 12.5	57.7 + 12.9
Pamidronate dose* (mg)	median 90	median 90
Pamidronate treatments per patient†	8.3 + 10.7 (2)	8.7 + 10.3 (4)
Baseline SCr† (µmol/L)	125.9 + 133.4 (88)	86.8 + 32 (81.5)

* mean + SD; † mean + SD (median); 1 µmol/L = 0.0113 mg/dL

Haemoglobin Response of Cancer Patients with Epoetin alfa: The Ottawa Hospital, Integrated Cancer Program Experience (TOH-ICP).

Sean P. Hopkins (B.S.P.), Department of Pharmacy, The Ottawa Hospital, Integrated Cancer Program, Paul Bastianelli, Faculty of Science, University of McGill, Wendy W.K. Cheung (Pharm.D.), Department of Medical Affairs, Ortho Biotech, Canada

Rationale:

Epoetin alfa has been used extensively for cancer-related anemia (CRA) over the past decade with proven efficacy. A retrospective chart review was undertaken to evaluate patient’s experience on Epoetin alfa at TOH-ICP.

Objective:

To examine if the Hb response rate at TOH-ICP is consistent with the literature.

Methodology:

A retrospective electronic chart review was performed at the TOH-ICP. Patients who had received Epoetin alfa for CRA during March 2003 to April 2004 were included for the review. Primary and secondary endpoints were early Hb response and overall Hb response respectively, each defined as 10 g/L at week 4 and 20 g/L at week 8 & 12 increase from baseline Hb.

Results:

261 patients were reviewed, and 161 patients had sufficient laboratory data for the analysis. Mean baseline Hb was 91 g/L. At week 4, 8 and 12, mean Hb increase was 15 g/L, 23 g/L and 27 g/L respectively. Sixty percent (60%) of patients were early responders, while 58% of patients had reached a Hb increase of over 20 g/L at week 12. Median Hb increase at week 4 from baseline for the early responders was 23 g/L. Overall responders had median increases of 36 and 39 g/L at 8 & 12 weeks respectively. Wide variability of Hb results was also observed.

Conclusion:

Patients who had received Epoetin alfa at TOH-ICP for CRA had demonstrated comparable Hb results consistent with medical literature. Wide variability in Hb increase could be associated to lack of therapeutic monitoring. A Hb monitoring program has been initiated upon the chart review by the oncology pharmacists, in collaboration with the multidisciplinary team at TOH-ICP.

Potassium Chloride Medication Safety Initiative between AstraZeneca Canada and the Institute for Safe Medication Practices Canada

Fontana P, AstraZeneca Canada Inc., Mississauga, Ontario, Hyland S, Institute for Safe Medication Practices-Canada Toronto, Ontario, U D, Institute for Safe Medication Practices-Canada, Toronto, Ontario

Analysis of medication error reports involving concentrated Potassium Chloride (KCl), reveal a potential for 10mL Potassium Chloride concentrate Polyamp® ampoules to be confused with Sodium Chloride (NaCl) and Sterile Water for Injection (SWI) 10mL Polyamp® ampoules. Consequences of substitution errors may be lethal. To help prevent medication errors, the Institute for Safe Medication Practices (ISMP-Canada) in collaboration with AstraZeneca Canada Inc. explored changes in labelling and packaging of KCl concentrate Polyamp® ampoules.

Over 2 years, a Task Force with representatives from ISMP-Canada and AstraZeneca explored options to reduce the risk of mix-ups and help differentiate the KCl product from other products. As a result, the 10mL volume of KCl in a 20mL size Polyamp® was introduced and new labels were designed. With such changes, the concentrated KCl product looks and feels different from NaCl and SWI. Customers were surveyed on the changes.

Experiments verified the stability of the new product. Ink Permeation studies were also completed. Results of tests were favourable.

The new KCl package format assists healthcare professionals reduce the risk for substitution errors between KCl and other Polyamp® ampoules. In Spring of 2004, the new product was released to market. The outcome of this initiative serves as an example and model for further collaboration between Pharmaceutical Industry and Medication Incident Reporting and Prevention Programs for enhancement of patient safety.

Due to the discontinuation of AstraZeneca sterile manufacturing in Canada, the new KCl product will be available until supply contracts expire.

Implementation of a Program to Convert Renal Disease Patients Stabilized on Erythropoietin to Darbepoetin

Albanese, S RPh B.Sc.Pharm, Haink, G PhD, Chan, J RPh B.Sc.Pharm, Department of Pharmacy, Thunder Bay Regional Health Sciences Centre, Thunder Bay, Ontario

Abstract

Treatment of anemia of progressive renal insufficiency (PRI) and end stage renal disease (ESRD) normally requires the frequent administration of Erythropoietin (EPO), a recombinant human erythropoietin (Eprex, Ortho Biotech). Recently, darbepoetin ((DAR) Aranesp, Amgen Inc) an analogue of recombinant human erythropoietin was introduced onto the Canadian market. Thunder Bay Regional Health Sciences Centre (TBRHSC) is a regional dialysis centre located in Northwestern Ontario. Because of the potential advantages for the use of DAR, a decision was made to switch patients from EPO to DAR. The objective of this study was to assess the implementation, efficacy and cost of converting PRI and ESRD patients, previously stabilized on EPO, to DAR. Initial Dose selection was chosen based on a sliding scale, beginning at 200:1 (EPO:DAR). One hundred eighty eight patients were identified to be converted to DAR. Of these, 186 patients (99%) completed the switch and 158 patients (84%) completed the 6 month follow-up. At the 6 month review following the conversion, the conversion ratio was 207:1 (PRI) and 221:1 (HD) and 155:1 (PD). The average hemoglobin (Hgb) for all patients was 115g/L pre-conversion and 116g/L, post-conversion. One hundred eleven patients (71%) reached target Hgb levels compared to 69% pre-conversion. The projected average annual cost of DAR per PRI, HD, and PD patient was \$3821.00, \$6366.00, and \$4943.00 respectively, as compared to \$3883.00, \$7082.00, \$3854.00 and for EPO. Based on our experience, switching EPO to DAR was safe, effective and resulted in savings.

Ciprofloxacin: The Impact of a Pharmacist-managed Dosage Form Conversion Service at a Major Canadian Teaching Hospital

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Terryn L. Naumann, Pharmaceutical Sciences Clinical Services Unit, Vancouver General Hospital, Vancouver Coastal Health Authority, Vancouver, BC, Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC, Peter J. Jewesson, Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC

Background

Parenteral ciprofloxacin appears to be overutilized at Vancouver Hospital. In November 2003, the Pharmacist-managed IV-PO Dosage Form Conversion Service was implemented, enabling autonomous pharmacist-initiated dosage form conversion for ciprofloxacin.

Objective

To evaluate characteristics of ciprofloxacin use prior to and following implementation of a dosage form conversion service.

Methodology

This was a single-centre, pre/post, unblinded study: Phase I (365 days) and Phase II (120 days). All patients who were ordered and received ciprofloxacin IV were included. Primary endpoint was IV:PO ciprofloxacin use ratio. Secondary endpoints were total number of ciprofloxacin doses, number of inappropriate IV ciprofloxacin doses, duration of hospital stay, and cost of therapy between the two phases.

Results

Two hundred ciprofloxacin IV treatments were included (100/phase). Total number of doses and ratio of IV to total doses across phases were similar ($p=0.2830$). IV:PO ciprofloxacin ratio was 3.03 (Phase I) vs. 3.48 (Phase II). Inappropriate IV doses decreased between Phases I and II (244/521 (47%) vs. 201/554 (36%) ($p=0.0005$), respectively), and number of pharmacist-preventable IV doses lessened (114/244 (47%) vs. 65/201 (32%) ($p=0.0026$). Potential cost avoidance of inappropriate IV use was \$7,172 (43%) (Phase I) and \$6,012 (34%) (Phase II) ($p=0.001$), and pharmacist-preventable costs reduced from \$3,367 (20%) to \$1,975 (11%) ($p=0.001$).

Conclusions

While utilization of ciprofloxacin remained unchanged and the proportion of IV to total doses is stable, the incidence of inappropriate IV doses and its associated costs appear to have declined subsequent to implementation of a Pharmacist-managed IV-PO Dosage Form Conversion Service.

Neonatal Withdrawal Syndrome Associated with Fluoxetine and Venlafaxine Use in Pregnancy

R Law, S Campbell, C Bayliff, London Health Sciences Centre, London, Ontario

Newer antidepressants such as Selective Serotonin Reuptake Inhibitors (SSRI's) and Serotonin and Norepinephrine Reuptake Inhibitors (SNRI's) are often used in the management of depression in pregnancy because of their low teratogenic potential. However, Health Canada issued a warning in August 2004 about possible neonatal complications due to their use in pregnancy. We report a case of neonatal withdrawal syndrome associated with fluoxetine and venlafaxine.

A male infant was born at 32 weeks. Throughout the pregnancy his mother was taking venlafaxine, fluoxetine, and carbamazepine for the management of post-traumatic stress syndrome. Immediately after delivery, the infant experienced respiratory distress requiring intubation for 3 days and sedation with morphine infusion at 1mg/hour for 5 hours which was then weaned over 2 days. After extubation, he was noted to be jittery with high pitched cry, increased respiratory rate and decreased sucking reflex. He received lorazepam in a tapering fashion over 3 days with a marked improvement symptomatically and in abstinence score.

The withdrawal syndrome was felt to be due to fluoxetine and venlafaxine as it was similar to other reported cases.

Morphine was felt to be an unlikely cause given the short duration of use. A Naranjo adverse drug reaction probability scale of 4 suggested a possible adverse drug reaction.

This case highlights some signs and symptoms of neonatal withdrawal syndrome associated with fluoxetine and venlafaxine use in pregnancy to increase awareness among pharmacists of the syndrome.

Probable Cephalexin-Induced Autoimmune Hemolytic Anemia

Ostad, N., Crown, N., Bayliff, C., London Health Sciences Centre, London, Ontario

Generally cephalosporins are well tolerated. There have been reports of hemolytic anemia associated with use of cephalosporins, particularly with cefotaxime and cefotetan. We present a case of hemolytic anemia associated with cephalexin.

A 48-year-old female was admitted to hospital for management of ongoing hemolytic anemia. The patient had undergone a tooth extraction at another centre 8 days prior to admission. Post procedure she had received cephalexin 250mg every 6 hours, cyclobenzaprine, ibuprofen, and ketorolac. Over the next few days she felt progressively unwell and became fatigued causing her to seek care at hospital. Upon admission to hospital she was noted to be hypotensive and jaundiced. Hemoglobin was reduced at 47g/L and bilirubin was increased at levels near 80 umol/L. Coombs test was positive. In the absence of other identifiable causes the hematology consult suggested that this was likely hemolytic anemia due to cephalexin. Cephalexin as well as her other therapies were stopped. Due to hemodynamic instability she was transferred to our facility. At our facility she stabilized hemodynamically and symptoms improved. She was discharged home on cyclophosphamide and prednisone with out-patient follow-up. At the time of discharge her hemoglobin had increased to 58g/L. At follow-up several weeks later she continued to improve. The Naranjo scale indicated that this was a probable adverse effect.

This case illustrates the potential for cephalexin to have severe hematologic sequelae and the need for pharmacists to be aware of this uncommon adverse event.

Diclofenac-induced Hepatitis – A Case Report

Sung M, Dhaliwall S, Deshpande S, Bayliff C, London Health Sciences Centre, London, Ontario

NSAIDs are commonly associated with PUD, but other reactions including pneumonitis, blood dyscrasia and hepatic effects may also occur. These reactions can cause severe morbidity resulting in hospitalization or even mortality. We report a case of severe hepatitis secondary to diclofenac to increase awareness of this infrequently-reported adverse drug reaction (ADR).

A 67-year-old female presented to the hospital with shortness of breath, malaise and anorexia that persisted for 3 weeks. She had noted brown urine, a yellow tinge to her skin and sclera. Patient had no history of hepatic disease and was initiated on twice-daily diclofenac 75mg and misoprostol 200mcg combination 5 months ago for osteoarthritis. Initial laboratory information revealed elevated ALT (1938), AST

(805) and bilirubin (177), accompanied by hypoalbuminemia (25). Diclofenac was discontinued; prednisone was started in query of an autoimmune hepatitis. Workup included negative results for hepatitis A, B and C. Liver biopsy later revealed acute hepatitis with bridging necrosis marked by cholangiolar and canalicular cholestasis. Transaminases declined over the next 2 weeks, while bilirubin and INR remained elevated. This reaction progressed to hepato-renal failure and subsequently resulted in death.

In the absence of other identifiable etiologies, it was felt that this was a case of diclofenac-induced hepatitis. The onset of these symptoms was consistent with those documented in previous case reports. The Naranjo ADR Probability Scale was applied and a score of 6 suggests that diclofenac is a probable cause of this ADR. Pharmacists should be aware of the potential of diclofenac to cause hepatic dysfunction.

A Pharmacist-Initiated Hemoglobin Monitoring Program: A Pilot Program Identifying Patients with Chemotherapy-Related Anemia in a Community Oncology Setting.

Ivan Tyono, Department of Pharmacy, William Osler Health Center (WOHC), Brampton Memorial Hospital Campus, ON, Canada, Catherine Moore, Department of Nursing Medicine/Oncology, WOHC, Brampton, ON, Canada, Ferid Rashid, Department of Pharmacy, William Osler Health Center (WOHC), Brampton Memorial Hospital Campus, ON, Canada, Sue Alderson, Department of Pharmacy, William Osler Health Center (WOHC), Brampton Memorial Hospital Campus, ON, Canada, Wendy W.K. Cheung, Department of Medical Affairs, Ortho Biotech, ON, Canada

Rationale:

Cancer-related anemia (CRA) is highly prevalent, significantly impacts patients' quality of life (QoL) and clinical outcomes, and is often caused by myelosuppressive chemotherapy. Epoetin alfa has demonstrated predictable hemoglobin (Hb) response, QoL improvement, and transfusion reduction. Pharmacists are in a unique position to provide pharmaceutical care (PC) in CRA as they routinely monitor hematological laboratory values during chemotherapy.

Description & Implementation Steps:

Consistent with Pharmaceutical Care (PC) model, a multidisciplinary hemoglobin monitoring program (HMP) was developed and implemented by the oncology pharmacy team. The goal of the program was to enhance overall patient care by increasing the role of pharmacy in CRA.

The concept was presented to the medical oncology team and pharmacy management. An 8-week pilot program was implemented in August 2004. During routine monitoring, pharmacists identified patients receiving chemotherapy with Hb < 100 g/L and referred them to medical oncologists with therapeutic recommendations. Hb was monitored if Epoetin alfa was initiated (for therapeutic evaluation). The number of patient referrals and therapeutic interventions (excluding blood transfusion) were noted.

End Results and Evaluation:

The 8-week pilot program was successful and has been integrated as routine practice. Final results of the program will be shared in the presentation.

Importance of concept & clinical utility: This pilot provided invaluable insights to the oncology team. It illustrated the importance of a multidisciplinary approach and the significant role of pharmacists in CRA. The program was also easy to implement, with minimal impact on pharmacists’ workload. It demonstrated feasibility of implementing PC in a busy community oncology setting, resulting in enhanced patient care.

Implementation of an Automated Unit-Dose Medication System in a Rehabilitation/Chronic Care Hospital: a Team Approach

Marcia Crockett, BScPhm; Patricia Smither, BSP; Pamela Bovan, RN, MScN, St. Joseph’s Health Care, Parkwood Hospital, London, Ontario

Rationale:

It was identified that the existing medication administration system in our hospital was not meeting our patient care needs. Our patient population has become more acute with complex medication regimens requiring frequent changes. The collaboration of Pharmacy and Nursing during the implementation of a new medication system was integral to its success.

Objective:

To develop and implement the processes to support a new automated unit-dose system of medication administration, which would promote an environment of safe and efficient medication practice.

Process:

Using a shared leadership model, a task team comprised of representatives from Pharmacy and Nursing planned the conversion of our 540-bed rehabilitation and chronic care facility. The process to convert from a carded drug system to an automated unit-dose system included: choosing a new medication cart, designing the nursing education program, developing feedback systems, and revising the Medication Manual.

A parallel implementation process was in place within the Pharmacy Department. The physical environment was reorganized and changes to daily operations were developed.

Outcomes:

The automated unit-dose medication administration system has been successfully implemented. The feedback has been positive. In a post conversion evaluation 79.6% of nurses agreed that the system allowed them to administer medications in a safer manner. Overall satisfaction with the new system was reported at 91.5%.

Conclusion:

The conversion has improved our ability to meet the increasing demands of our complex patients in a safe and efficient manner. It has positioned our department for a planned “citywide” Pharmacy computer system implementation.

Wednesday, February 9 • Mercredi le 9 février

Improvement in Delivery of Surgical Antibiotic Prophylaxis Following a Review and Policy Change

Rosemary Zvonar, The Ottawa Hospital, Ottawa, Ontario

Rationale:

Optimal delivery of pre-operative antibiotics is important in the prevention of surgical site infections.

Objective:

A review of quality indicators in the delivery of antimicrobial surgical prophylaxis was performed at The Ottawa Hospital.

Methods:

Two hundred and ninety charts from January to March 2002 for surgical procedures requiring inpatient admission from five surgical divisions were retrospectively reviewed. The quality indicators evaluated were appropriateness of antibiotic selection, dosing, timing, intra-operative dosing, and duration of post-operative prophylaxis.

Results:

The results are shown in the Table. In order to improve practice, a multidisciplinary group was formed and a new Surgical Prophylaxis policy was approved. Changes implemented included administration of pre-operative doses at induction by the anesthesiologist when possible, an automatic substitution for higher doses of antibiotics (e.g. cefazolin 2 gm) for patients with a BMI >30, and a list of recommended surgeries requiring prophylaxis. A follow-up evaluation was conducted May to July 2004, which showed improvements in the timing, dosing and administration of intra-operative doses. (Table) Duration of post-operative prophylaxis was > 24 hours in 90% of the cases in 2002 and was therefore not re-examined.

Year (N)	Approp Agent	Approp Dose	Approp Timing	Intra-Op Dose if Reqd
2002 (N=290)	93.4%	72.4%	36%	39.4%
2004 (N=261)	92.3%	83%	67.7%	54%

Conclusion:

A new policy incorporating administration of pre-operative antibiotics by anesthesiologists resulted in a significant improvement in the timing of delivery of pre-operative antibiotic surgical prophylaxis. Continued efforts will be required for further improvement.

Use of a Hospital Information System to Compare Glycemic Alterations Associated with Fluoroquinolone Antibiotics

Rosemary Zvonar, The Ottawa Hospital, Ottawa, Ontario

Rationale:

A formulary review of fluoroquinolones (FQ) and literature reports of dysglycemia with gatifloxacin (G) precipitated this review.

Objective:

To identify if there is a difference in the risk of hypoglycemia (HOG) or hyperglycemia (HRG) amongst the FQ.

Methods:

Patients prescribed at least 2 doses of G and an equal number prescribed ciprofloxacin (C) between April 1, 2003 to July 30, 2003 at The Ottawa Hospital, General Campus, were included. Following a formulary change from G to levofloxacin (L), patients receiving L during the same period in 2004 were reviewed. The hospital's clinical results reporting system (OACIS) was used to review serum glucose values and the prescription of concomitant hypoglycemic agents. The incidence of HOG (serum glucose < 3.8 mmol/L) and significant HRG (serum glucose ? 18 mmol/L) was compared between FQ.

Results:

	G	L	C
# of Patients	334	301	334
% Pts on Hypoglycemic Agent	14.1	19	19.8
% Pts HOG while on FC	3.6	1	1.7
% Pts HRG while on FQ	1.8	1	4.2

Conclusion:

This review using the information in our results reporting system aided and supported the decision to use levofloxacin as our formulary respiratory FQ.

Therapeutic Drug Management Program (TDMP): An Innovative Approach To Optimizing Drug Utilization In University-Teaching Hospitals In Quebec.

Jean-François Bussi eres, Centre Hospitalier Universitaire M ere-Enfant Sainte-Justine, Montr al, Qu ebec, Beno t Cossette, Centre Hospitalier Universitaire de Sherbrooke, Sherbrooke, Qu ebec, Catherine Dehaut, Centre Hospitalier Universitaire M ere-Enfant Sainte-Justine, Montr al, Qu ebec, Sylvie Desgagn e, Centre Hospitalier Universitaire de Qu ebec, Qu ebec, Qu ebec, Van Duong, Centre Hospitalier Universitaire de Montr al, Montr al, Qu ebec, C eline Dupont, McGill University Health Center, Montr al, Qu ebec

Patricia Lefebvre, McGill University Health Center, Montr al, Qu ebec, Nathalie Letarte, Centre Hospitalier Universitaire de Montr al, Montr al, Qu ebec, Michel Th eberge, Centre Hospitalier Universitaire de Qu ebec, Qu ebec, Qu ebec, Marc Vall e, Centre Hospitalier Universitaire de Sherbrooke, Sherbrooke, Qu ebec

Rationale:

The TDMP is an innovative program initiated in 2004 by the five university-teaching hospitals of Quebec to share

expertise, clinician input and information in a health system where increasing drug costs and limited qualified resources are challenging.

Objectives:

Therapeutic drug management is defined as a systematic way of evaluating drugs which integrates systematic reviews of the literature, outcome research and assessment of economic impacts. The TDMP's objective is to achieve optimal drug utilisation by supporting the centres in their missions.

Methods:

The executive committee sets priorities and oversees administrative and legal matters and public relations while the scientific committee develops a methodology for drug evaluations, Drug Utilisation Review (DUR), common databases and canvases for each reports. It also works to identify models for dissemination of information to clinicians.

Results:

Since 2004, the TDMP provided the centres with: 1 preliminary drug evaluation; 3 complete drug evaluations; 1 revision of a therapeutic class, 1 DUR and a functional web site to share information. It also produced a handbook. The documents produced are useful tools integrated to the Pharmacy and Therapeutic committees' decision process.

Conclusion:

The TDMP converts research into innovative tools for clinicians and in doing so, facilitates the transfer of theory into every day practice. In these times of scarcity of professional resources and ever-increasing drug costs, sharing information and expertise is imperative and the TDMP provides a good example of the university-teaching hospitals of Quebec working collaboratively to optimise the pharmacotherapy of patients.

Implementation of a Quality Assurance Program for Unit Dose Cart Filling

Peter Davies, St. Michael's Hospital, Toronto Ontario

Reason for Initiative

In 1995 a redistribution of responsibilities led to the elimination of the second check of unit dose carts filled by pharmacy technicians. A review of medication incident and discrepancy reports for 2001 suggested the need to develop and implement a quality assurance program.

Description of Initiative

The quality assurance program for unit dose cart filling was initiated in July 2002 and consisted of a formal process to delegate technicians to perform this duty. In order to complete the delegation technicians had to demonstrate an accuracy rate of at least 99.8% over a three day period. Weekly random audits to check accuracy of cart filling were performed both before and after the initiation of the program to determine its impact.

Evaluation of Initiative

From July 1st 2002 to April 30th 2003 a total of 25 technicians successfully completed the delegation program. In the 6 months prior the error rate was an average of 0.7% as

measured through weekly random audits. After the initiation the error rate dropped to 0.54% during the 3rd quarter of 2002 and further dropped to 0.14% during the 4th quarter. In 2003, the error rate for the first quarter was 0.10%, 0.22% for the second quarter and 0.28% for the last quarter. Audits were not performed during the third quarter of 2003 due to conflicting priorities.

Importance and Usefulness of Initiative for Pharmacists

An accurate unit dose cart filling process is important both to minimize the time spent by pharmacists investigating missing medication and to ensure the correct medications are available in a timely manner. Quality assurance through a delegation program showed a decrease in the cart filling error rate.

Measurement of the Effect of Discontinuing Baclofen and Dantrolene Therapy in Long-Term Institutionalized Patients with Spasticity

Barbara Farrell, Nikki Pora, Ineke Neutel, Kelly Babcock, SCO Health Service, Ottawa, Ontario

Rationale:

Despite lack of valid trials documenting efficacy, baclofen and dantrolene are widely used to treat spasticity. There is a clinical impression that these drugs are useful, however, their side effects are often overlooked.

Objective:

The purpose of this project was to evaluate the effects of planned withdrawal of baclofen and dantrolene in consenting complex continuing care patients.

Study design and methods:

This descriptive study design collected data before, during and after the withdrawal intervention. A withdrawal protocol was used in which the clinical team made withdrawal decisions and did individualized monitoring. Proportions were used to describe the results.

Results:

Of 69 patients taking either baclofen or dantrolene, 29 were excluded from the withdrawal protocol primarily due to physicians' decisions. Of the 40 eligible patients, 26 (65%) participated in the tapering protocol. Of these 26, 15 (58%) were able to have baclofen or dantrolene discontinued, 6 (23%) were maintained on a lower dose, 4 (15%) were maintained at the same dose and one patient died during tapering. Six (23%) had other changes made to their spasticity treatment, and 4 (15%) had improvements in other symptoms which could have been adverse effects of the antispasticity agents.

Conclusion:

Over half of the patients participating in a tapering protocol were able to have baclofen or dantrolene either discontinued or the dose lowered; a few had adjustments in other medications or therapy made. Targeted Medication Withdrawal programs can be a successful approach to reducing unnecessary medication in long-term institutionalized patients.

Trends in Fluoroquinolone Use in Nova Scotia Hospitals and the Effect of Policies on Use

Andrea Kent, Colchester East Hants Health Authority, Truro, Nova Scotia, Ingrid Sketris, Dalhousie University, College of Pharmacy, Halifax, Nova Scotia, Lynn Johnston, Division of Infectious Diseases, Faculty of Medicine, Dalhousie University, Halifax, Nova Scotia, Ryan Sommers, Dalhousie University, Halifax, Nova Scotia, Susan Pierce, Capital District Health Authority, Halifax, Nova Scotia (currently on a sanctioned LOA)

Background:

Antimicrobial resistance results in increased morbidity and mortality. Evidence suggests an association between antimicrobial use in hospitals and resistance. Fluoroquinolones are useful in the treatment of a variety of infections, unfortunately, overuse and inappropriate use may occur.

Objective:

To evaluate the use of fluoroquinolones in hospitals and determine whether utilization policies affect use.

Methods:

Purchasing Data expressed as drug volume and expenditures were obtained from the Provincial Drug Distribution Program (PDDP) and aggregated using the World Health Organization (WHO)/ Anatomical Therapeutic Chemical (ATC) Defined Daily Dose (DDD) system for the fiscal years of 1997-2003. Fluoroquinolone drug utilization was expressed as DDD/acute-care bed day/year and DDD/hospitalized community-acquired pneumonia event (CAP)/year. Policy data was obtained from surveys mailed to each district.

Results:

All provincial hospitals administering fluoroquinolones were included (n= 31). Total fluoroquinolone use increased over the six years studied; mean DDD/1000 bed days 48 in 1997 to 172 in 2003 (p<0.01). Use of respiratory fluoroquinolones increased from a mean DDD/100 CAP/year of 3.4 to 1747.5 over the study period. Variations in use existed among districts and according to size (small, medium, large). The presence of utilization policies trended toward lower use of fluoroquinolones but was not statistically significant.

Conclusion:

Through the WHO ATC/ DDD methodology we demonstrated a significant increase in fluoroquinolone use over time. The presence of utilization policies trended toward lower use, suggesting that further studies are warranted. Lack of resources for education and follow-up may prevent hospitals from gaining full impact of the interventions.

Key words: drug utilization, antimicrobials, fluoroquinolones, policies

Critical Appraisal of the Literature Involving a Pharmacist Intervention in Diabetic Patients

Karen Leask BSP, Lisa Dolovich Pharm D, St. Joseph's Healthcare, Hamilton, Ontario

Objective:

To determine if diabetic outpatients who experience pharmacist counseling versus no pharmacist counseling on clinic visit have improved glycemic control and quality of life.

Search Strategy:

The PubMed database was searched using terms included under the headings of Diabetes, Pharmacists, Counseling and the Outpatient setting.

Study Selection:

Included studies had pharmacist interventions in diabetic patients in the outpatient setting where the outcomes were those of the patient. Studies where pharmacist involvement was not the main intervention, diabetic patients were not the primary study population, and outcome focus was not on the patient were excluded. Also excluded were review articles and non-English language studies.

Data Extraction:

The studies were appraised consistently using a form that included criteria related to study design, population and sample size, the intervention and the results measured.

Results of the Review:

Three of the studies showed statistically significant decreases in the HBA1c. Four of the studies analyzed changes in fasting blood glucose levels, but only two showed statistically significant improvement. There was no trend between the studies in regards to episodes of hypoglycemia and hyperglycemia. Two of the studies assessed quality of life; one found no difference, while the other showed improved attitudes and perceptions to many different aspects of patient health.

Conclusion:

Through counseling in an outpatient clinic pharmacists can improve glycemic control and quality of life in diabetic patients. These results lead to a new research question of whether or not pharmacist counseling in the diabetes outpatient clinic improves a patient's understanding of their medications.

Winnipeg Regional Health Authority Pharmacy Summer Student Education Day

Colette B Raymond, Donna M.M. Woloschuk, Winnipeg Regional Health Authority, Winnipeg MB

The Winnipeg Regional Health Authority (WRHA) Pharmacy Student Education Day (SED) was designed to give summer pharmacy student employees a forum to share summer work experiences, learn about post-graduate training options, and become better informed about the range of hospital pharmacy career options. We evaluated their perceptions of the SED including: satisfaction, utility, exposure to new career possibilities, and the influence of the SED on consideration of post-graduate study and career options.

The SED program included student presentations (7) of summer employment projects. Guest speakers (4) described Pharmacy Residency and Doctor of Pharmacy Program options. Pharmacists (4) spoke about their varied pharmacy career paths in WRHA tertiary care, community and specialty practice hospital settings.

The mean age of student participants was 22.8 years (7 female, 5 male). Three were entering 2nd, 5 were entering 3rd, and 4 were entering 4th (final) year pharmacy studies. Most students (67%) were employed at a tertiary care site. Students rated the event as meeting expectations, highly useful, and identifying career paths previously unknown to them. SED participation favourably influenced students' intent to consider hospital pharmacy careers and postgraduate education. For future events, students requested a mixed SED program that would both student and pharmacist speakers.

The WRHA SED provided students with a useful forum to share summer project and work experiences, and to engage in informative discussion about hospital career options. Similar educational events would provide novice researchers with a 'non-threatening' opportunity to practice developing survey tools, collecting/analyzing data and communicating research results.

A Comparison of the Incidence of Urgent Percutaneous Coronary Intervention in Patients Receiving Alteplase or Tenecteplase following Acute ST-Segment Elevation Myocardial Infarction.

Nichole Sweeney, Dalhousie University, QEII Health Sciences Centre, Halifax, NS, Chris Gray, QEII Health Sciences Centre, Halifax, NS, Andrea Lavoie, QEII Health Sciences Centre, Halifax, NS, Catherine Kells, QEII Health Sciences Centre, Halifax, NS, Iqbal Bata, Dalhousie University, QEII Health Sciences Centre, Halifax, NS, Danette Beechinor, Dalhousie University, QEII Health Sciences Centre, Halifax, NS

Rationale:

Since changing the formulary thrombolytic from alteplase (tPA) to tenecteplase (TNK), clinicians have developed a subjective impression that the rate of urgent percutaneous coronary intervention (PCI) has increased.

Objectives:

To assess if the rate of urgent PCI with TNK is greater than with tPA at this institution, and to determine if specific patient characteristics influence this rate.

Methods:

A retrospective chart review was conducted of consecutive patients admitted with ST-segment elevation myocardial infarction (STEMI) from October 2002 to June 2003. Univariate analysis was used to determine if specific patient characteristics influenced the rate of urgent PCI.

Results:

There was no significant difference between thrombolytic groups in the requirements for urgent PCI. Of the 158 patients included in the study, 56 received TNK and 102 received tPA. In the tPA group, 26.5% of patients required

urgent PCI vs 32.1% in the TNK group ($p=0.4498$). There was a significant trend to increased urgent PCI ($p=.0079$) in patients with non-therapeutic aPTT measurements within 24 hours after the initiation of thrombolytic. Patients with subtherapeutic aPTT measurements were 4.84 (95%CI 1.58-14.8) times more likely to require urgent PCI.

Conclusions:

The rate of urgent PCI with TNK was no different than with tPA. Revision of heparin dosing to a weight-based nomogram and increased use of enoxaparin with thrombolysis, may decrease the rate of urgent PCI due to sub-optimum anti-coagulation. Continued surveillance of urgent PCI rates, and modifiable risk factors for urgent PCI post-thrombolysis is required.

Reconciling Medication Variances: Reducing Medication Errors at Interface of Care

Tasnim Vira, Markham Stouffville Hospital, Markham, Margaret Colquhoun, Markham Stouffville Hospital, Markham

Rationale for Report

Medication errors at interfaces of care (admission, transfer, and discharge) are common and can lead to adverse drug events and deaths. Medication errors were reduced by 70-99% when medication reconciliation was implemented.

Description of Service

“Medication reconciliation” addresses medication errors at interfaces of care. Reconciliation involves patient interviews, examination of available patient records and medication vials

followed by comparison with orders and interventions with physicians to rectify medication variances. Some variances are intended therapeutic changes, but others are unintended and can be considered medication errors.

Identification of Problem and Implementation of Changes

In 2002, a trial of Medication Reconciliation was conducted ($n=60$). 60% of patients had at least one unintended variance and 18% had at least one clinically important variance; none had been detected by usual clinical practice. Medication Reconciliation addressed most variances before harm occurred. The mean cost of admission Medication Reconciliation was \$64 per clinically important variance, which is favourable compared to the average cost of treating an adverse event.

Beginning June 2004, Medication Reconciliation has been implemented for selected patients on the ICU/CCU and Medicine units.

Evaluation of Initiative

In June and July 2004, Medication Reconciliation was conducted on 84 patients. 109 unintended variances were detected affecting 58% of patients. Medication orders were changed for 67% of the unintended variances upon reconciliation with the physician.

Importance & Usefulness to Clinical Practice

Unintended medication variances at interfaces of care are common and clinically significant. Medication Reconciliation is a cost-effective process to detect and rectify unintended variances in order to minimize patient harm.

CSHP Fellows / Associés de la SCPH

CSHP Fellow status is conferred by the Board of Fellows upon CSHP members who have demonstrated noteworthy sustained service and excellence in the practice of pharmacy in hospitals and related health care settings.

Board of Fellows 2004/2005

Chair: Christopher Judd, FCSHP

Past Chair: Bonnie Salsman, FCSHP

Chair-elect: Jeff Barnett, FCSHP



Venetia Bourrier B.Sc. (Pharm.)

Venetia Bourrier earned her Bachelor of Science degree in Molecular Biology at the University of Winnipeg in 1981 and her Bachelor of Science degree in Pharmacy at the University of Manitoba in 1985. In 1988, Venetia completed a Letter of

Accomplishment Program in Geriatric Pharmacy Practice at the University of Manitoba.

From 1985 to 1988, Venetia practiced as a staff and clinical pharmacist at St. Boniface General Hospital. During this time, Venetia completed a six month study to investigate the feasibility of introducing a rotational clinical pharmacy service to geriatric medicine. Venetia continued her career in Geriatric Pharmacy practice at Tache Nursing Centre from 1988 to 1990.

In 1990, Venetia assumed the position of Director of Pharmacy at the Manitoba Cancer Treatment & Research Foundation, now known as CancerCare Manitoba (CCMB). Over the next 14 years, Venetia developed a comprehensive oncology pharmacy program at CCMB. Major accomplishments include establishment of a chemotherapy ordering process, investigational drug service, a Regional Oncology Pharmacy & Therapeutics Committee, an intravenous admixture pharmacy service, an ambulatory infusion pump program, and electronic prescribing. More recently, Venetia's efforts have been focused on escalating oncology drug costs and the establishment of a Provincial Oncology Drug Program for Manitoba. From this environment, new programs such as a pharmacist-managed anticoagulation program and pharmacists with specialized skills focused on clinical practices in pediatrics, bone marrow transplant, pain and symptom management, and other cancer disease sites have evolved.

Venetia has been actively involved in education at various levels. CCMB has been a clinical practice site for pharmacy students from both Manitoba and Saskatchewan. In 2002 and 2003, Venetia was the Chief Administrator of the Pharmacy Examining Board of Canada (PEBC) Qualifying Examination Part II Objective Structured Clinical Examination (OSCE) at the Winnipeg site. Venetia has delivered numerous therapeutics and administrative presentations and lectures to health professionals and organizations across the province. In addition, education and training have been provided to pharmacists, pharmacy technicians, nurses, and physicians practicing in the 14 community cancer programs (CCPs) in rural Manitoba. A disease site module-based pharmacist

Board Members:

Jean-François Bussi res, FCSHP

David Hill, FCSHP

Peter Jewisson, FCSHP

Lauza Saulnier (ex officio member)

curriculum is near completion for the Community Cancer Programs Network.

Venetia has participated on committees and task forces of numerous professional associations. She is currently President of the Manitoba Association of Pharmacy Directors (MAPD) and a member of a task force of the Canadian Association for Pharmacy in Oncology (CAPhO) to develop oncology pharmacy practice standards. Venetia has been an active member of the Canadian Society of Hospital Pharmacists (CSHP) for 20 years and served as President of CSHP – Manitoba Branch in 1989.

In her non-professional life, Venetia enjoys travelling, dancing, music, and spending special times with her husband Denis and their three children Colin (aged 14 yrs), Mathieu (aged 11 yrs), and Nicole (aged 9 yrs).

Venetia is very honored to receive the status of Fellow of CSHP.



Barbara Farrell B.Sc.Pharm., Pharm.D.

Barbara Farrell earned her Bachelor of Science in Pharmacy at the University of Toronto in 1986, completed a hospital pharmacy residency at Chedoke-McMaster Hospital in Hamilton in 1987, and earned her Doctor of Pharmacy degree from the

University of Toronto in 1994.

Barbara was a staff pharmacist at Victoria Hospital in London, Ontario, from 1987 to 1992 and also worked in local community pharmacies during this time. Following achieving her Pharm.D., she worked as a consultant, developing and providing local, provincial, and national continuing education programs to facilitate the implementation of pharmaceutical care. Barbara joined the Faculty of Pharmacy, University of Toronto in 1995 as part of a team to develop the Structured Practical Experience Program for undergraduate students. From 1995 to 1996, she was a primary care pharmacist at two family practice clinics in Toronto, and then coordinated a seamless care project involving the clinics, local hospital, and neighborhood pharmacies.

Since 1999, Barbara has been the Clinical and Research Coordinator for the Pharmacy Department of SCO Health Service in Ottawa. She is affiliated with the Elisabeth Bruy re Research Institute, is a member of the SCO Health Service Research Ethics Board, and maintains a clinical practice in the SCO Geriatric Day Hospital. Barbara has taken many steps to develop a research program for the SCO pharmacy

department, including participating in the CSHP Research Educator Program, and most recently, acting as a co-principal investigator in the Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics (IMPACT) project (Ontario Primary Health Care Transition Fund, 2004). Barbara's efforts were recognized with the 2004 Michel Bilodeau Award for the Development of the SCO Health Service as a Centre of Excellence.

Barbara has used her expertise in teaching pharmaceutical care skills in presentations, workshops, one-on-one mentoring, articles, and a textbook chapter on effective patient interactions. She currently is an assigned mentor to two pharmacists working in innovative primary care projects funded by the Ontario Primary Health Care Transition Fund.

Barbara maintains active involvement with the Canadian Society of Hospital Pharmacists (CSHP) and other associations. From 1986 to 1987, she was President of the Ontario Pharmacy Residents Association. From 1988 to 1991, she was Vice-chair, then Chair of the Lake Erie Chapter of the Ontario Branch, CSHP. She was a long-time member of the Ontario Branch Education Committee and participated on other task forces and planning committees. Currently, she is Chair-elect for the CSHP Geriatrics Professional Specialties Network. Barbara's expertise in geriatrics has led to involvement in a variety of steering committees and advisory groups. Her practice was featured in the 2002 Canadian Pharmacists' Association (CPhA) video: *Pharmacists: The Next Wave*.

Barbara's community focus includes volunteer work at her son's school and the creation and maintenance of an Ottawa Hospital family lounge in memory of her brother. She enjoys living in Ottawa with her husband, Barry, and her son Aidan. She continues to practice Pilates and recently attained a yellow belt in Taekwondo.



Ruby Grymonpre B.Sc.(Pharm.), Pharm.D.

Ruby Grymonpre graduated from the University of Manitoba with her Bachelor of Science in Pharmacy degree in 1979 and received her Doctor of Pharmacy degree from the University of Minnesota in 1982. Ruby

is currently a professor at the Faculty of Pharmacy, University of Manitoba, and also holds cross-appointments with the Sections of Geriatric Medicine and Clinical Pharmacology, Faculty of Medicine, University of Manitoba. She is a Research Affiliate with the Centre on Aging, University of Manitoba, and the Riverview Health Centre.

Ruby's area of expertise is 'Geriatric Pharmacy'. She shares this expertise with students in the Faculties of Pharmacy, Medicine, Nursing, and Dentistry, and has been involved in developing, coordinating, and teaching a variety of courses in therapeutics, drug information, pharmaceutical care, and geriatrics. Her program of research relates to studying and improving medication use by the aged population. Most recently, Ruby received a 5 year, \$1.25 million New Emerging Team Grant in collaboration with sociology, geriatric medicine, and nursing to study Rural Health and Aging; and a 2-year operating grant of \$150,000 from the Canadian Institutes of Health Research to study medication adherence among older Manitobans.

Ruby is frequently asked to advise on a variety of initiatives in Geriatric Pharmacy at the national and provincial level. In 2003, she was invited to serve as a primary panelist for the Canadian Cardiovascular Society Consensus Conference on Heart Disease and the Elderly. She authored a chapter entitled: *Urinary Incontinence* for the text *Therapeutic Choices* and a chapter entitled *Primary Prevention of Cardiovascular Events in Older Individuals* for the text *Geriatric Issues for Cardiologists*. She has been an Expert Advisor for the Addictions Research Foundation, Toronto; the Canadian Pharmacists Association (CPhA), Ottawa; and the Quebec Research Group on Medication Use in the Elderly. She has been a member of the CPS Editorial Advisory Panel since 1991 and represents the CPhA on the Advisory Committee on Management, Therapeutic Products Directorate, Health Canada.

Dr. Grymonpre has been the recipient of numerous awards and honors for her work. Most notably, she received a University of Manitoba Outreach award and the Parke Davis Award (1995 & 1987) for her role in developing the Medication Information Line for the Elderly; a Centennial Award from the Manitoba Pharmacists Association; and the Glaxo Wellcome Award and a Parke Davis Award from the CSHP for her work relating to community pharmacists' care of older adults (1998, 2000 & 2001).



Denis Lebel B.Pharm., M.Sc.

Denis Lebel graduated from the Université de Montréal in 1992. He completed a hospital pharmacy residency at Centre Hospitalier Universitaire Mère-Enfant Sainte-Justine in 1993 and obtained a M. Sc.

in Hospital Pharmacy Practice the same year.

After graduation, Denis worked as a pharmacist at Centre Hospitalier Universitaire Mère-Enfant Sainte-Justine where he initiated the provision of pharmaceutical care to patients of the Pediatric Intensive Care Unit. In 1999, he became Assistant Director of the Department of Pharmacy. His responsibilities include the coordination of pharmaceutical care, research services, and teaching activities. Denis has also been responsible for the Centre Hospitalier Universitaire Mère-Enfant Sainte-Justine pharmacy residency program since 1999.

Mr. Lebel contributed to the evolution of the pediatric curriculum for pharmacy students at Université de Montréal. He developed the first classes in Pediatric Pharmacotherapy, and in 2000, Denis developed the first elective course in Pediatric Pharmacotherapy. Mr. Lebel is also a reviewer for the Journal of Pediatric Pharmacology and Therapeutics and a moderator of Pedpharm, an electronic mailing list for Canadian pharmacists caring for pediatric patients.

Denis has contributed to the Association des Pharmaciens des Établissements de Santé du Québec (APÉS) as a member of many committees and task forces over the years. From 1996 to 2000, he was editor of *Pharmactuel*. In 1999, he created and programmed the APÉS (www.apesquebec.org) and the *Pharmactuel* (www.pharmactuel.com) websites. He is also the founder and moderator of the APÉS mailing list.

Denis's professional interests have to date included pediatric pharmacotherapy, antibiotic desensitization, ketogenic diet, simulation of costs in a pediatric population, application of information technologies in clinical practice, impact of the Special Access Program on the pharmaceutical care of patients, and interactive pharmaceutical care simulation as a teaching tool. He has been an investigator on several trials.

Mr. Lebel is a seasoned speaker and author of a book chapter and numerous publication and poster presentations. He has received several awards for his pharmaceutical care, teaching, administrative, and research activities.



**Patricia Lefebvre
B.Pharm., M.Sc.**

Patricia Lefebvre graduated from the Université de Montréal with a Bachelor of Pharmacy degree in 1983 and completed a Residency in Hospital Pharmacy at the Université de Montréal in 1984. In 1985, she joined the pharmacy department of

The Montreal General Hospital where she served in various capacities including Clinical Pharmacist, Coordinator of Operational Activities, Coordinator of Special Projects, and Acting Director of the Pharmacy Department.

In 2000, Patricia was appointed the first Pharmacist-in-chief of the McGill University Health Centre. This new position presented many challenges of organizational and clinical practice change following the merger of five institutions. In her current position, Patricia has expanded clinical services, teaching, and research activities, and enhanced departmental computerization. She has developed services in the field of drug formulary management, drug utilization review, and therapeutic drug management. She has expanded the affiliation with the Faculté de pharmacie de l'Université de Montréal with the cross-appointments of three new positions of professeur-adjoint de clinique. She has served as a preceptor for pharmacy students, a supervisor for hospital pharmacy residents, and lecturer at colleges of pharmacy.

Since 2000, Patricia has focused her pharmacy practice in the area of safety. She has served on hospital advisory groups, professional associations, and government committees; published articles; and delivered medication safety presentations to groups and organizations at both the provincial and national level.

Patricia is a Past President of the Association des pharmaciens d'établissements de santé du Québec. In 2002, she received the Prix d'excellence Roger Leblanc in recognition of outstanding leadership, dedication and commitment to practice excellence and professional development. Currently President of the Quebec Branch of CSHP, she also serves on the panel of appraisers for the Canadian Journal of Hospital Pharmacy and the CSHP awards program, and participates on a number of committees and task forces at both the provincial and national level.



**Emily Lap Sum Musing
R.Pharm., B.Sc.Pharm.,
M.H.Sc., ACPR**

Emily Musing graduated with a Bachelor of Science in Pharmacy from the University of Toronto in 1983 and completed a hospital pharmacy residency at Mount Sinai Hospital in

1984. She returned to school from 2001 to 2003 to obtain a Masters in Health Science in health administration from the department of Health Policy Management and Evaluation (HPME) within the Faculty of Medicine at the University of Toronto.

Emily started her hospital pharmacy career in 1983 in the neonatal intensive care unit at Women's College Hospital. She returned to Mount Sinai Hospital in 1985 as a staff pharmacist and subsequently moved into the positions of Drug Information Pharmacist and then Clinical Supervisor. In 1992, Emily became the Education Coordinator in the Wellesley Hospital. She moved to the Toronto Western Hospital in 1996 to take on the position of Clinical Practice Leader and became the Manager of Professional Practice in 1997. Emily is currently the Director of Pharmacy at the University Health Network, where she provides leadership and strategic direction for inpatient and retail pharmacies across three sites: Toronto General Hospital, Toronto Western Hospital, and Princess Margaret Hospital.

Throughout her career, Emily has enjoyed active involvement in many pharmacy-related associations. She has held leadership positions within CSHP, both at the provincial and national levels, including serving as Vice-chair of the Canadian Hospital Pharmacy Residency Board, President of the Ontario Branch, Chair of the Ontario Branch Education and Public Affairs Committees, and is currently serving as President-elect of CSHP. Emily has also been active as an assessor and track coordinator with the Pharmacy Examining Board of Canada, assessor and case writer for the Ontario College of Pharmacists (OCP) Quality Assurance Program, member of the OCP Structured Practical Training Task Force, past-executive on the Pharmacy Residency Forum of Ontario, manuscript reviewer for Longwoods Review, coordinator of IntraCity Rounds for Metro Toronto, and founding member of the Ontario Pharmacy Residents' Association.

As an assistant professor with the Faculty of Pharmacy, University of Toronto, Emily has been involved as a lecturer, co-coordinator, tutor, and examiner in a wide variety of courses over the past fourteen years, including Pharmacy Practice Seminar, Pharmaceutical Care, Ethics workshops, Case Study Seminars, Communications, and Drug Information. Emily is also a tutor for the Health Policy course in the Faculty of Medicine and Health Economics for HPME. She has precepted students linked to the Faculty of Pharmacy, University of Toronto Clinical Clerkship and Hospital Administration courses, OCP Structured Practical Training Program, Hospital Practice Residency Programs for UHN, Wellesley, and Mount Sinai, and the Ohio State Doctor of Pharmacy Program. She has published articles and made numerous presentations at the provincial, national and international level. Her work has been recognized through various awards related to education, pharmacy and healthcare administration.



Shannan L. Neubauer B.S.P., Pharm. D.

Shannan Neubauer earned her Bachelor of Science in Pharmacy degree at the University of Saskatchewan in 1989, completed a hospital pharmacy residency at the South Saskatchewan Hospital Centre in 1991, and earned her Doctor of Pharmacy degree from Wayne State University, Detroit, Michigan, in 1998. Shannan was appointed Assistant Professor, College of Pharmacy & Nutrition, University of Saskatchewan, in 1998 and has served as the provincial Hospital Residency Coordinator since 1999.

Shannan became involved with CSHP – Saskatchewan Branch early in her career and has chaired the Membership Committee, served as branch Treasurer, and has been a member of the Educational Services Committee. She has served as Chair for two inter-organizational provincial committees, the Seamless Care Task Force, and the Pharmacy Coalition on Primary Care. In 2003, she was invited by the Health Quality Council to participate in an interdisciplinary health care professional and health policy maker excursion to the United Kingdom to investigate primary health care organization and quality improvement initiatives in Scotland and England.

Shannan's practice and research interests lie in the area of primary health care. Her practice sites include a family medicine clinic and the Mid-life Women's Health Centre in Saskatoon, Saskatchewan. She was a co-investigator on a study funded by Saskatchewan Health entitled *The Pharmacist in Primary Care: A Comparison of Pharmaceutical Care in Co-located versus Community Pharmacy Practices* and has recently completed a follow-up involving the qualitative aspects of successful team practice. She was also the provincial educator who developed and conducted the workshops to certify Saskatchewan pharmacists to prescribe emergency contraception.



Suzanne Taylor B.Sc.(Pharm.), Pharm. D., BCPS

Suzanne Taylor (nee Malfair), received her B. Sc.(Pharm.) and Pharm. D. degrees from the University of British Columbia (UBC) in 1992 and 1995 respectively. In between, she completed a hospital pharmacy residency at Vancouver General Hospital in 1993. She has since become Board Certified in Pharmacotherapy (BCPS), earned the level one certificate in Health Care Management from the British

Columbia Institute of Technology, and taken several courses in pharmacoeconomics and outcomes research through the American Society of Health-System Pharmacists, the American College of Clinical Pharmacy, and the Harvard School of Public Health. She is also trained faculty for the Bayer Institute's communication workshops: Clinician-Patient Communication to Enhance Health Outcomes, and Difficult Clinician-Patient Relationships. She is licensed in both British Columbia and Washington State.

Suzanne has worked at the B.C. Cancer Agency (BCCA) since 1995 in several positions: Acting Clinical Coordinator, Pharmacoeconomics/Clinical pharmacist, and Pharmacoeconomics pharmacist. She played a key role in the development of the clinical pharmacy program at the BCCA Vancouver Centre and has been a preceptor and lecturer for undergraduate, residency and Pharm. D. students in clinical rotations, directed studies projects, and research rotations. Her clinical practice site was the bone marrow transplant unit for seven years. She developed the Pharmacoeconomics service that is now responsible for provincial population-based economic modeling to ensure sufficient funds are available for the entire province's cancer treatments, pharmacoeconomics and outcomes research, coordinating requests for non-standard cancer therapies, and providing guidance and/or assistance to other healthcare professionals performing drug-related research at BCCA. She also enjoys lecturing in the Faculty of Pharmaceutical Sciences at UBC. In addition, she practiced at Vancouver Hospital and Health Sciences Centre on a casual basis from 1993-2004.

Suzanne is a reviewer for the *Annals of Pharmacotherapy*, part of the editorial review board of the *Journal of Oncology Pharmacy Practice*, and an active member of the International Society of Oncology Pharmacy Practice (ISOPP), the Canadian Association of Pharmacy in Oncology (CAPHO), the Canadian College of Clinical Pharmacy (CCCP), the College of Pharmacists of B.C., the American Society of Clinical Oncology (ASCO), and CSHP. Her roles in CSHP date back to 1992 and have included B.C. Branch Membership Services Committee member and B.C. Branch Treasurer; and currently include B.C. residency common examiner, B.C. residency program ombudsman, B.C. Branch Delegate to the B.C. College of Pharmacists Advanced Credentialing Committee, and member of the National Finance Committee.

Suzanne has been honoured with several local, national, and international awards and speaking invitations, primarily in the areas of communication skills, hematology, oncology therapeutics, and pharmacoeconomics and outcomes research in oncology. She has also published on the same.

Outside of pharmacy, Suzanne loves curling, boating, aerobics, jogging, fishing, and spending time with her family: Cliff, Jensen (born Aug 2002), Chelsea (born Aug 2004), and Bailey dog!

CSHP would like to recognize the generous contributions of the following speakers.

Margaret Ackman

Capital Health
Edmonton, AB

Susan Alderson

William Olser Health
Centre
Brampton, ON

Robert Balen

Vancouver General
Hospital
Vancouver, BC

William Bartle

Sunnybrook and Women's
College HSC
Toronto, ON

Brian Beven

Hospital for Sick Children
Toronto, ON

Glen Brown

Providence Health Care
Vancouver, BC

Claudia Bucci

Sunnybrook and Women's
College HSC
Toronto, ON

Anthony Caldwell

Fogler Rubinoff LLP
Toronto, ON

Clarence Chant

St. Michael's Hospital
Toronto, ON

Doret Cheng

Mount Sinai Hospital
Toronto, ON

Elaine Chong

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Mark Dailey

CityTV
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Jack Davis

Calgary Health Region
Calgary, AB

Carlos DeAngelis

Sunnybrook and Women's
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Karen B. Farris

University of Iowa
Iowa City, IA

Julie Greenall

ISMP Canada
Toronto, ON

Jan Greenwood

Vancouver General
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Vancouver, BC

B. Joseph Guglielmo

University of California San
Francisco
San Francisco, CA

Reem Haj

St. Michael's Hospital
Toronto, ON

Alice Hogg

University Health Network
Toronto, ON

Sean Hopkins

The Ottawa Hospital
Ottawa, ON

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ISMP Canada
Toronto, ON

Lawrence D. Jackson

Sunnybrook and Women's
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Toronto, ON

Derek Jorgenson

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St. Michael's Hospital
Toronto, ON

Heather Kertland

St Michael's Hospital
Toronto, ON

Mary Kwan

The Scarborough General
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Scarborough, ON

Tracey Lawson

St Joseph's Health Centre
Toronto, ON

Wendy Leong

Burnaby Research
Burnaby, BC

Steve Long

Calgary Health Region
Calgary, AB

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St. Michael's Hospital
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Institute for Clinical
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Chantal Manoukian

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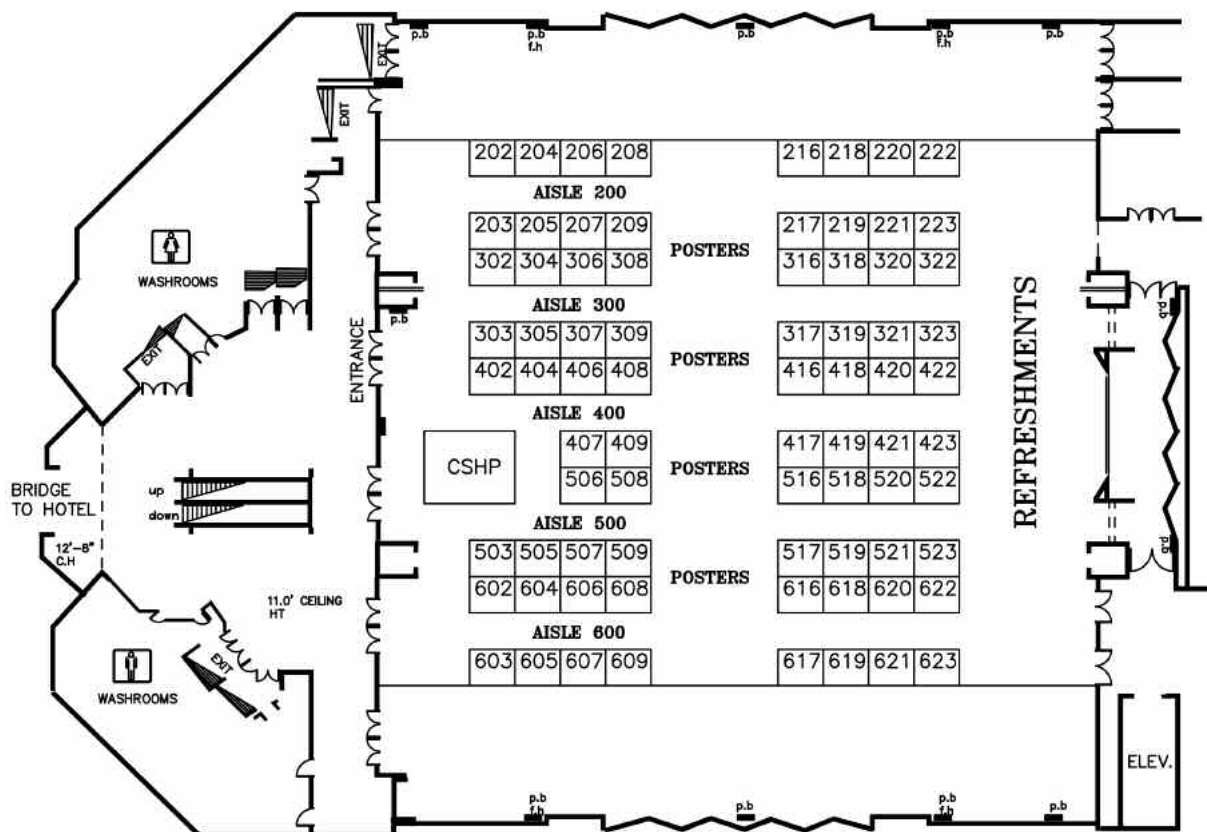
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THERAPEUTIC CLASSIFICATION: Lipid Metabolism Regulator

ACTIONS AND CLINICAL PHARMACOLOGY

LIPITOR (atorvastatin calcium) is a synthetic lipid-lowering agent. It is a selective, competitive inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. This enzyme catalyzes the conversion of HMG-CoA to mevalonate, which is an early and rate-limiting step in the biosynthesis of cholesterol.

LIPITOR lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and by increasing the number of hepatic Low Density Lipoprotein (LDL) receptors on the cell-surface for enhanced uptake and catabolism of Low Density Lipoprotein (LDL).

LIPITOR reduces LDL-Cholesterol (LDL-C) and the number of LDL particles. LIPITOR also reduces Very Low Density Lipoprotein-Cholesterol (VLDL-C), serum triglycerides (TG) and Intermediate Density Lipoproteins (IDL), as well as the number of apolipoprotein B (apo B) containing particles, but increases High Density Lipoprotein-Cholesterol (HDL-C). Elevated serum cholesterol due to elevated LDL-C is a major risk factor for the development of cardiovascular disease. Low serum concentration of HDL-C is also an independent risk factor. Elevated plasma TG is also a risk factor for cardiovascular disease, particularly if due to increased IDL, or associated with decreased HDL-C or increased LDL-C.

Epidemiologic, clinical and experimental studies have established that high LDL-C, low HDL-C and high plasma TG promote human atherosclerosis and are risk factors for developing cardiovascular disease. Some studies have also shown that the ratio of total cholesterol (total-C) to HDL-C (total-C/HDL-C) is the best predictor of coronary artery disease. In contrast, increased levels of HDL-C are associated with decreased cardiovascular risk. Drug therapies that reduce levels of LDL-C or decrease TG while simultaneously increasing HDL-C have demonstrated reductions in rates of cardiovascular mortality and morbidity.

Pharmacokinetics

Atorvastatin is rapidly absorbed after oral administration; maximum plasma concentrations occur within 1 to 2 hours. Atorvastatin tablets are 95% to 99% bioavailable compared to solutions.

Mean distribution of atorvastatin is approximately 381 liters. Atorvastatin is $\geq 98\%$ bound to plasma proteins. Atorvastatin is extensively metabolized by cytochrome P-450 3A4 to ortho- and para-hydroxylated derivatives and to various beta-oxidation products. Approximately 70% of circulating inhibitory activity for HMG-CoA reductase is attributed to active metabolites.

Atorvastatin and its metabolites are eliminated by biliary excretion. Less than 2% of a dose of atorvastatin is recovered in urine following oral administration. Mean plasma elimination half-life of atorvastatin in humans is approximately 14 hours, but the half-life of inhibitory activity for HMG-CoA reductase is 20 to 30 hours due to the contribution of longer-lived active metabolites.

INDICATIONS AND CLINICAL USE

LIPITOR (atorvastatin calcium) is indicated as an adjunct to lifestyle changes, including diet, (at least equivalent to the Adult Treatment Panel III (ATP III) TLC diet), for the reduction of elevated total cholesterol, (total-C), LDL-C, TG and apolipoprotein B (apo B) in hyperlipidemic and dyslipidemic conditions, when response to diet and other nonpharmacological measures alone has been inadequate, including:

- Primary hypercholesterolemia (Type Ia);
- Combined (mixed) hyperlipidemia (Type Ib), including familial combined hyperlipidemia, regardless of whether cholesterol or triglycerides are the lipid abnormality of concern;
- Dysbetalipoproteinemia (Type III);
- Hypertriglyceridemia (Type IV);
- Familial hypercholesterolemia (homozygous and heterozygous). For homozygous familial hypercholesterolemia, LIPITOR should be used as an adjunct to treatments such as LDL apheresis, or as monotherapy if such treatments are not available.

LIPITOR also raises HDL-cholesterol and therefore lowers the LDL-C/HDL-C and total-C/HDL-C ratios in patients with primary hypercholesterolemia and combined (mixed) hyperlipidemia (Fredrickson Type Ia and Ib dyslipidemia). In pooled data from 24 controlled clinical trials, LIPITOR raised HDL-C levels 5%-7% in primary hypercholesterolemia (type Ia) patients and 10%-15% in mixed (type Ib) dyslipidemia patients.

In clinical trials, LIPITOR (10 to 80 mg/day) significantly improved lipid profiles in patients with a wide variety of hyperlipidemic and dyslipidemic conditions. In 2 dose-response studies in mildly to moderately hyperlipidemic patients (Fredrickson types Ia and Ib), LIPITOR reduced the levels of total cholesterol (29-45%), LDL-C (39-60%), apo B (32-50%), TG (19-37%), and increased high density lipoprotein cholesterol (HDL-C) levels (5-9%). Comparable responses were achieved in patients with heterozygous familial hypercholesterolemia, non-familial forms of hypercholesterolemia, combined hyperlipidemia, including familial combined hyperlipidemia and patients with non-insulin dependent diabetes mellitus. In patients with hypertriglyceridemia (Type IV), LIPITOR (10 to 80 mg daily) reduced TG (25 - 56%) and LDL-C levels (23 - 40%). LIPITOR has not been studied in conditions where the major abnormality is elevation of chylomicrons (TG levels > 11 mmol/L, i.e. types I and V).

In an open-label study in patients with dysbetalipoproteinemia (Type III), LIPITOR (10 to 80 mg daily) reduced total-C (40-57%), TG (40-56%) and LDL-C + VLDL-C levels (34-58%).

In an open label study in patients with homozygous familial hypercholesterolemia (FH) LIPITOR (10 to 80 mg daily) reduced mean LDL-C levels (22%). In a pilot study, LIPITOR 80 mg/day showed a mean LDL-C lowering of 30% for patients not on plasmapheresis and of 31% for patients who continued plasmapheresis. A mean LDL-C lowering of 35% was observed in receptor defective patients and of 19% in receptor negative patients (see PHARMACOLOGY, Clinical Studies).

For more details on efficacy results by pre-defined classification and pooled data by Fredrickson types, see PHARMACOLOGY, Clinical Studies.

Prior to initiating therapy with LIPITOR, secondary causes should be excluded for elevations in plasma lipid levels (e.g. poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemias, obstructive liver disease, and alcoholism), and a lipid profile performed to measure total cholesterol, LDL-C, HDL-C, and TG. For patients with TG < 4.52 mmol/L (< 400 mg/dL), LDL-C can be estimated using the following equation:

$$\text{LDL-C (mmol/L)} = \text{total-C} - [(0.37 \times (\text{TG} + \text{HDL-C}))]$$

$$\text{LDL-C (mg/dL)} = \text{total-C} - [(0.2 \times (\text{TG} + \text{HDL-C}))]$$

For patients with TG levels > 4.52 mmol/L (> 400 mg/dL), this equation is less accurate and LDL-C concentrations should be measured directly or by ultracentrifugation.

Patients with high or very high triglyceride levels, i.e. > 2.2 mmol/L (200 mg/dL) or > 5.6 mmol/L (500 mg/dL), respectively, may require triglyceride-lowering therapy (fenofibrate, bezafibrate or nicotinic acid) alone or in combination with LIPITOR.

In general, combination therapy with fibrates must be undertaken cautiously and only after risk-benefit analysis (see WARNINGS, Muscle Effects, PRECAUTIONS, Pharmacokinetic Interaction Studies and Potential Drug Interactions).

Elevated serum triglycerides are most often observed in patients with the metabolic syndrome (abdominal obesity, atherogenic dyslipidemia [elevated triglycerides, small dense LDL particles and low HDL-cholesterol], insulin resistance with or without glucose intolerance, raised blood pressure and prothrombotic and proinflammatory states).

(For the treatment of specific dyslipidemias refer to the Report of the Canadian Working Group on Hypercholesterolemia and Other Dyslipidemias or to the US NCEP Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults [Adult Treatment Panel III], under SELECTED BIBLIOGRAPHY).

When drugs are prescribed attention to therapeutic lifestyle changes (reduced intake of saturated fats and cholesterol, weight reduction, increased physical activity, ingestion of soluble fibers) should always be maintained and reinforced.

The Atorvastatin Versus Revascularization Treatments (AVERT) study examined the effect of intensive lipid-lowering in patients with stable coronary artery disease and LDL-C at least 3.0 mmol/L. In patients referred for percutaneous transluminal coronary angioplasty (PTCA). Patients were randomised for 18 months to LIPITOR 80 mg daily or to PTCA with usual medical care which could include lipid metabolism regulators. The results of the AVERT study should be considered as exploratory since several limitations may affect its design and conduct. In the medical-treated group with LIPITOR there was a trend for a reduced incidence of ischemic events and a delayed time to first ischemic event. The results also suggest that intensive treatment to target LDL-C levels with LIPITOR is **additive and complementary** to angioplasty and would benefit patients referred for this procedure (see SELECTED BIBLIOGRAPHY).

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal (see WARNINGS). Pregnancy and lactation (see PRECAUTIONS).

WARNINGS

Pharmacokinetic Interactions

The use of HMG-CoA reductase inhibitors has been associated with severe myopathy, including rhabdomyolysis, which may be more frequent when they are co-administered with drugs that inhibit the cytochrome P-450 enzyme system. Atorvastatin is metabolized by cytochrome P-450 isoform 3A4 and as such may interact with agents that inhibit this enzyme. (See WARNINGS, Muscle effects and PRECAUTIONS, Drug Interactions and Cytochrome P-450-mediated Interactions).

Hepatic Effects

In clinical trials, persistent increases in serum transaminases greater than three times the upper limit of normal occurred in $< 1\%$ of patients who received LIPITOR. When the dosage of LIPITOR was reduced, or when drug treatment was interrupted or discontinued, serum transaminase levels returned to pretreatment levels. The increases were generally not associated with jaundice or other clinical signs or symptoms. Most patients continued treatment with a reduced dose of LIPITOR without clinical sequelae.

Liver function tests should be performed before the initiation of treatment, and periodically thereafter. Special attention should be paid to patients who develop elevated serum transaminase levels, and in these patients measurements should be repeated promptly and then performed more frequently.

If increases in alanine aminotransferase (ALT) or aspartate aminotransferase (AST) show evidence of progression, particularly if they rise to greater than 3 times the upper limit of normal and are persistent, the dosage should be reduced or the drug discontinued.

LIPITOR should be used with caution in patients who consume substantial quantities of alcohol and/or have a past history of liver disease. Active liver disease or unexplained transaminase elevations are contraindications to the use of LIPITOR; if such a condition should develop during therapy, the drug should be discontinued.

Muscle Effects

Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatinine phosphokinase (CPK) values to greater than ten times the upper limit of normal, should be considered in any patient with diffuse myalgia, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. LIPITOR therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected.

The risk of myopathy and rhabdomyolysis during treatment with HMG-CoA reductase inhibitors is increased with concurrent administration of cyclosporin, fibrin acid derivatives, erythromycin, clarithromycin, niacin (nicotinic acid), azole antifungals or telavancin. As there is no experience to date with the use of LIPITOR given concurrently with these drugs, with the exception of pharmacokinetic studies conducted in healthy subjects with erythromycin and clarithromycin, the benefits and risks of such combined therapy should be carefully considered (see PRECAUTIONS, Pharmacokinetic Interaction Studies and Potential Drug Interactions).

Rhabdomyolysis has been reported in very rare cases with LIPITOR (see PRECAUTIONS, Drug Interactions).

Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has also been reported with HMG-CoA reductase inhibitors. LIPITOR therapy should be temporarily withheld or discontinued in any patient with an acute serious condition suggestive of a myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis (such as severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures).

PRECAUTIONS

General

Before instituting therapy with LIPITOR (atorvastatin calcium), an attempt should be made to control elevated serum lipoprotein levels with appropriate diet, exercise, and weight reduction in overweight patients, and to treat other underlying medical problems (see INDICATIONS AND CLINICAL USE). Patients should be advised to inform subsequent physicians of the prior use of LIPITOR or any other lipid-lowering agents.

Effect on the Lens

Current long-term data from clinical trials do not indicate an adverse effect of atorvastatin on the human lens.

Effect on Ubiquinone (CoQ₁₀) Levels

Significant decreases in circulating ubiquinone levels in patients treated with atorvastatin and other statins have been observed. The clinical significance of a potential long-term statin-induced deficiency of ubiquinone has not been established. It has been reported that a decrease in myocardial ubiquinone levels could lead to impaired cardiac function in patients with borderline congestive heart failure (see SELECTED BIBLIOGRAPHY).

Effect on Lipoprotein (a)

In some patients, the beneficial effect of lowered total cholesterol and LDL-C levels may be partly blunted by a concomitant increase in Lp(a) lipoprotein concentrations. Present knowledge suggests the importance of high Lp(a) levels as an emerging risk factor for coronary heart disease. It is thus desirable to maintain and reinforce lifestyle changes in high risk patients placed on atorvastatin therapy (see SELECTED BIBLIOGRAPHY).

Hypersensitivity

An apparent hypersensitivity syndrome has been reported with other HMG-CoA reductase inhibitors which has included 1 or more of the following features: anaphylaxis, angioedema, lupus erythematosus-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, eosinophilia, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome. Although to date hypersensitivity syndrome has not been described as such, LIPITOR should be discontinued if hypersensitivity is suspected.

Use in Pregnancy

LIPITOR is contraindicated during pregnancy (see CONTRAINDICATIONS).

Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause harm to the fetus when administered to pregnant women.

There are no data on the use of LIPITOR during pregnancy. LIPITOR should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the patient becomes pregnant while taking LIPITOR, the drug should be discontinued and the patient apprised of the potential risk to the fetus.

Nursing Mothers

In rats, milk concentrations of atorvastatin are similar to those in plasma. It is not known whether this drug is excreted in human milk. Because of the potential for adverse reactions in nursing infants, women taking LIPITOR should not breast-feed (see CONTRAINDICATIONS).

Pediatric Use

Treatment experience in a pediatric population is limited to doses of LIPITOR up to 80 mg/day for 1 year in 8 patients with homozygous familial hypercholesterolemia. No clinical or biochemical abnormalities were reported in these patients.

Geriatric Use

Treatment experience in adults 70 years or older (N=221) with doses of LIPITOR up to 80 mg/day has demonstrated that the safety and effectiveness of atorvastatin in this population was similar to that of patients < 70 years of age. Pharmacokinetic evaluation of atorvastatin in subjects over the age of 65 years indicates an increased AUC. As a precautionary measure, the lowest dose should be administered initially (see PHARMACOLOGY, Human Pharmacokinetics; SELECTED BIBLIOGRAPHY).

Renal Insufficiency

Plasma concentrations and LDL-C lowering efficacy of LIPITOR was shown to be similar in patients with moderate renal insufficiency compared with patients with normal renal function. However, since several cases of rhabdomyolysis have been reported in patients with a history of renal insufficiency of unknown severity, as a precautionary measure and pending further experience in renal disease, the lowest dose (10 mg/day) of LIPITOR should be used in these patients. Similar precautions apply in patients with severe renal insufficiency [creatinine clearance < 30 mL/min (< 0.5 mL/Sec)], the lowest dosage should be used and implemented cautiously (see WARNINGS, Muscle Effects; PRECAUTIONS, Drug Interactions). Refer also to DOSAGE AND ADMINISTRATION.

Endocrine Use

HMG-CoA reductase inhibitors interfere with cholesterol synthesis and as such might theoretically blunt adrenal and/or gonadal steroid production. Clinical studies with atorvastatin and other HMG-CoA reductase inhibitors have suggested that these agents do not reduce plasma cortisol concentration or impair adrenal reserve and do not reduce basal plasma testosterone concentration. However, the effects of HMG-CoA reductase inhibitors on male fertility have not been studied in adequate numbers of patients. The effects, if any, on the pituitary-gonadal axis in premenopausal women are unknown.

Patients treated with atorvastatin who develop clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients receiving other drugs (e.g. ketoconazole, spironolactone or cimetidine) that may decrease the levels of endogenous steroid hormones.

Pharmacokinetic Interaction Studies and Potential Drug Interactions

Pharmacokinetic interaction studies conducted with drugs in healthy subjects may not detect the possibility of a potential drug interaction in some patients due to differences in underlying diseases and use of concomitant medications (see also Geriatric Use; Renal Insufficiency; Patients with Severe Hypercholesterolemia).

Concomitant Therapy with Other Lipid Metabolism Regulators: Combined drug therapy should be approached with caution as information from controlled studies is limited.

Bile Acid Sequestrants:

Patients with mild to moderate hypercholesterolemia: LDL-C reduction was greater when LIPITOR 10 mg and colestipol 20 g were coadministered (-45%) than when either drug was administered alone (-35% for LIPITOR and -22% for colestipol).

Patients with severe hypercholesterolemia: LDL-C reduction was similar (-53%) when LIPITOR 40 mg and colestipol 20 g were coadministered when compared to that with LIPITOR 80 mg alone. Plasma concentration of atorvastatin was lower (approximately 26%) when LIPITOR 40 mg plus colestipol 20 g were coadministered compared with LIPITOR 40 mg alone.

However, the combination drug therapy was less effective in lowering the triglycerides than LIPITOR monotherapy in both types of hypercholesterolemic patients (see PHARMACOLOGY, Clinical Studies).

When LIPITOR is used concurrently with colestipol or any other resin, an interval of at least 2 hours should be maintained between the two drugs, since the absorption of LIPITOR may be impaired by the resin.

Fibric Acid Derivatives (Gemfibrozil, Fenofibrate, Bezafibrate) and Niacin (Nicotinic Acid): Although there is limited experience with the use of LIPITOR given concurrently with fibric acid derivatives and niacin, the benefits and risks of such combined therapy should be carefully considered. The risk of myopathy during treatment with other drugs in this class, including atorvastatin, is increased with concurrent administration (see WARNINGS, Muscle Effects and SELECTED BIBLIOGRAPHY).

Coumarin Anticoagulants: LIPITOR had no clinically significant effect on prothrombin time when administered to patients receiving chronic warfarin therapy (see SELECTED BIBLIOGRAPHY).

Digoxin: In healthy subjects, digoxin pharmacokinetics at steady-state were not significantly altered by coadministration of digoxin 0.25 mg and LIPITOR 10 mg daily. However, digoxin steady-state concentrations increased approximately 20% following coadministration of digoxin 0.25 mg and LIPITOR 80 mg daily (see Human Pharmacokinetics). Patients taking digoxin should be monitored appropriately.

Antihypertensive agents (amlodipine): In clinical studies, LIPITOR was used concomitantly with antihypertensive agents without evidence to date of clinically significant adverse interactions. In healthy subjects, atorvastatin pharmacokinetics were not altered by the coadministration of LIPITOR 80 mg and amlodipine 10 mg at steady state (see Human Pharmacokinetics).

(quinapril): In a randomized, open-label study in healthy subjects, steady-state quinapril dosing (80 mg QD) did not significantly affect the pharmacokinetic profile of atorvastatin tablets (10 mg QD) (see Human Pharmacokinetics).

Oral Contraceptives and Hormone Replacement Therapy: Coadministration of LIPITOR with an oral contraceptive, containing 1 mg norethindrone and 35 µg ethinyl estradiol, increased plasma concentrations (AUC levels) of norethindrone and ethinyl estradiol by approximately 30% and 20%, respectively. These increases should be considered when selecting an oral contraceptive. In clinical studies, LIPITOR was used concomitantly with estrogen replacement therapy without evidence to date of clinically significant adverse interactions.

Antacids: Administration of aluminum and magnesium based antacids, such as Maalox, TC Suspension, with LIPITOR decreased plasma concentrations of LIPITOR by approximately 35%. LDL-C reduction was not altered but the triglyceride-lowering effect of LIPITOR may be affected.

Cimetidine: Administration of cimetidine with LIPITOR did not alter plasma concentrations or LDL-C lowering efficacy of LIPITOR, however, the triglyceride-lowering effect of LIPITOR was reduced from 34% to 26%.

Cytochrome P-450-mediated Interactions: Atorvastatin is metabolized by the cytochrome P-450 isoenzyme, CYP 3A4. Erythromycin, a CYP 3A4 inhibitor, increased atorvastatin plasma levels by 40%. Coadministration of CYP 3A4 inhibitors, such as grapefruit juice, some macrolide antibiotics (i.e. erythromycin, clarithromycin), immunosuppressants (cyclosporine), azole antifungal agents (i.e. itraconazole, ketoconazole), protease inhibitors, or the antidepressant, nefazodone, may have the potential to increase plasma concentrations of HMG-CoA reductase inhibitors, including LIPITOR (see SELECTED BIBLIOGRAPHY). Caution should be exercised with concomitant use of these agents (see WARNINGS, Pharmacokinetic Interactions, Muscle Effects; PRECAUTIONS, Renal Insufficiency and Endocrine Function; DOSAGE AND ADMINISTRATION; SELECTED BIBLIOGRAPHY).

In healthy subjects, coadministration of maximum doses of both atorvastatin (80 mg) and terfenadine (120 mg), a CYP 3A4 substrate, was shown to produce a modest increase in terfenadine AUC. The QTc interval remained unchanged. However, since an interaction between these two drugs cannot be excluded in patients with predisposing factors for arrhythmia, (e.g. preexisting prolonged QT interval, severe coronary artery disease, hypokalemia), caution should be exercised when these agents are coadministered (see WARNINGS, Pharmacokinetic Interactions; DOSAGE AND ADMINISTRATION).

Antipyrine: Antipyrine was used as a non-specific model for drugs metabolized by the microsomal hepatic enzyme system (cytochrome P-450 system). LIPITOR had no effect on the pharmacokinetics of antipyrine, thus interactions with other drugs metabolized via the same cytochrome isozymes are not expected.

Macrolide Antibiotics (azithromycin, clarithromycin, erythromycin): In healthy adults, coadministration of LIPITOR (10 mg QD) and azithromycin (500 mg QD) did not significantly alter the plasma concentrations of atorvastatin. However, coadministration of atorvastatin (10 mg QD) with erythromycin (500 mg QD) or clarithromycin (500 mg BID), which are both CYP 3A4 inhibitors, increased plasma concentrations of atorvastatin approximately 40% and 80%, respectively (see WARNINGS, Muscle Effects; Human Pharmacokinetics).

Protease Inhibitors (nelfinavir mesylate): In healthy adults, coadministration of nelfinavir mesylate (1250 mg BID), a known CYP 3A4 inhibitor, and atorvastatin (10 mg QD) resulted in increased plasma concentrations of atorvastatin. AUC and C_{max} of atorvastatin were increased by 74% and 122% respectively.

Patients with Severe Hypercholesterolemia: Higher drug dosages (80 mg/day) required for some patients with severe hypercholesterolemia (including familial hypercholesterolemia) are associated with increased plasma levels of atorvastatin. Caution should be exercised in such patients who are also severely renally impaired, elderly, or are concomitantly being administered digoxin or CYP 3A4 inhibitors (see WARNINGS, Pharmacokinetic Interactions, Muscle Effects; PRECAUTIONS, Drug Interactions; DOSAGE AND ADMINISTRATION).

Drug/Laboratory Test Interactions

LIPITOR may elevate serum transaminase and creatinine phosphokinase levels (from skeletal muscle). In the differential diagnosis of chest pain in a patient on therapy with LIPITOR, cardiac and noncardiac fractions of these enzymes should be determined.

ADVERSE REACTIONS

LIPITOR is generally well-tolerated. Adverse reactions have usually been mild and transient. In controlled clinical studies (placebo-controlled and active-controlled comparative studies with other lipid lowering agents) involving 2502 patients, <2% of patients were discontinued due to adverse experiences attributable to LIPITOR. Of these 2502 patients, 1721 were treated for at least 6 months and 1253 for 1 year or more.

Adverse experiences occurring at an incidence ≥1% in patients participating in placebo-controlled clinical studies of LIPITOR and reported to be possibly, probably or definitely drug related are shown in Table 1 below:

TABLE 1. Associated Adverse Events Reported in ≥1% of Patients in Placebo-Controlled Clinical Trials

	Placebo % (n=270)	LIPITOR % (n=1122)
GASTROINTESTINAL		
Constipation	1	1
Diarrhea	1	1
Dyspepsia	2	1
Flatulence	2	1
Nausea	0	1
NERVOUS SYSTEM		
Headache	2	1
MISCELLANEOUS		
Pain	<1	1
Myalgia	1	1
Asthenia	<1	1

The following additional adverse events were reported in clinical trials; not all events listed below have been associated with a causal relationship to LIPITOR therapy: Muscle cramps, myositis, myopathy, paresthesia, peripheral neuropathy, pancreatitis, hepatitis, cholestatic jaundice, anorexia, vomiting, alopecia, pruritus, rash, impotence, hyperglycemia, and hypoglycemia.

Post-marketing experience: Very rare reports: severe myopathy with or without rhabdomyolysis (see WARNINGS, Muscle Effects; PRECAUTIONS, Renal Insufficiency and Drug Interactions). Isolated reports: thrombocytopenia, arthralgia and allergic reactions including urticaria, angioneurotic edema, anaphylaxis and bullous rashes (including erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis). These may have no causal relationship to atorvastatin.

Ophthalmologic observations: see PRECAUTIONS.

Laboratory Tests: Increases in serum transaminase levels have been noted in clinical trials (see WARNINGS).

SYMPTOMS AND TREATMENT OF OVERDOSAGE

There is no specific treatment for atorvastatin overdose. Should an overdose occur, the patient should be treated symptomatically and supportive measures instituted as required. Due to extensive drug binding to plasma proteins, hemodialysis is not expected to significantly enhance atorvastatin clearance.

DOSAGE AND ADMINISTRATION

Patients should be placed on a standard cholesterol-lowering diet [at least equivalent to the Adult Treatment Panel III (ATP III) TLC diet] before receiving LIPITOR, and should continue on this diet during treatment with LIPITOR. If appropriate, a program of weight control and physical exercise should be implemented.

Primary Hypercholesterolemia and Combined (Mixed) Dyslipidemia, Including Familial Combined Hyperlipidemia

The recommended starting dose of LIPITOR is 10 or 20 mg once daily. Patients who require a large reduction in LDL-C (more than 45%) may be started at 40 mg once daily. The dosage range of LIPITOR is 10 to 80 mg once daily. Doses can be given at any time of the day, with or without food, and should preferably be given in the evening. Doses should be individualized according to the level of risk; the baseline LDL-C and/or TG levels; the LDL-C, TG and/or total-C/HDL-C targets (see the Detection and Management of Hypercholesterolemia, Working Group on Hypercholesterolemia and other Dyslipidemias [Canada] and/or the US National Cholesterol Education Program [NCEP Adult Treatment Panel III]); the goal of therapy; and the patient's response. A significant therapeutic response is evident within two weeks, and the maximum response is usually achieved within two to four weeks. The response is maintained during chronic therapy. Adjustments of dosage, if necessary, should be made at intervals of two to four weeks. The maximum dose is 80 mg/day.

Lipid levels should be monitored periodically and, if necessary, the dose of LIPITOR adjusted based on target lipid levels recommended by guidelines.

The following reductions in total cholesterol and LDL-C levels have been observed in 2 dose-response studies, and may serve as a guide to treatment of patients with mild to moderate hypercholesterolemia:

TABLE 2. Dose-Response in Patients With Mild to Moderate Hypercholesterolemia (Mean Percent Change from Baseline)*

Lipid Parameter	LIPITOR Dose (mg/day)			
	10 (N=22)	20 (N=20)	40 (N=21)	80 (N=23)
Total-C: 7.1 mmol/L ^b (273 mg/dL) ^b	-29	-33	-37	-45
LDL-C: 4.9 mmol/L ^b (190 mg/dL) ^b	-39	-43	-50	-60

a. Results are pooled from 2 dose-response studies.

b. Mean baseline values.

Severe Dyslipidemias

In patients with severe dyslipidemias, including homozygous and heterozygous familial hypercholesterolemia and dysbetalipoproteinemia (Type III), higher dosages (up to 80 mg/day) may be required (see WARNINGS, Pharmacokinetic Interactions, Muscle Effects; PRECAUTIONS, Drug Interactions).

Concomitant Therapy

See PRECAUTIONS, Drug Interactions.

Dosage in Patients With Renal Insufficiency

See PRECAUTIONS.

PHARMACEUTICAL INFORMATION

Drug Substance

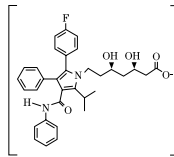
Proper Name: Atorvastatin calcium

Chemical Name: [R-(R*,R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid, calcium salt (2:1) trihydrate

Empirical Formula: C₂₃H₂₆FN₂O₅Ca•3H₂O

Molecular Weight: 1209.42

Structural Formula:



Description: Atorvastatin calcium is a white to off-white crystalline powder that is practically insoluble in aqueous solutions of pH 4 and below. Atorvastatin calcium is very slightly soluble in distilled water, pH 7.4 phosphate buffer and acetonitrile, slightly soluble in ethanol, and freely soluble in methanol.

Tablet Composition:

Each tablet contains either 10 mg, 20 mg, 40 mg or 80 mg atorvastatin as the active ingredient. Each tablet also contains the following non-medical ingredients: calcium carbonate, candellilla wax, croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, hydroxypropyl methylcellulose, polyethylene glycol, talc, titanium dioxide, polysorbate 80 and simethicone emulsion.

Stability and Storage Recommendations:

Store at controlled room temperature 15 to 30°C.

AVAILABILITY OF DOSAGE FORMS

LIPITOR (atorvastatin calcium) is available in dosage strengths of 10 mg, 20 mg, 40 mg and 80 mg atorvastatin per tablet.

10 mg: White, elliptical, film-coated tablet, coded "10" on one side and "PD 155" on the other. Available in bottles of 90 tablets.

20 mg: White, elliptical, film-coated tablet, coded "20" on one side and "PD 156" on the other. Available in bottles of 90 tablets.

40 mg: White, elliptical, film-coated tablet, coded "40" on one side and "PD 157" on the other. Available in bottles of 90 tablets.

80 mg: White, elliptical, film-coated tablet, coded "80" on one side and "PD 158" on the other. Available in blisters of 30 tablets (3 strips X 10).

References:

1. LIPITOR (atorvastatin calcium) Product Monograph, Pfizer Canada Inc., August 2003. 2. IMS Health MIDAS; March 1997-March 2003. 3. Pitt B, Waters D, Brown WW et al. Aggressive lipid-lowering therapy compared with angioplasty in stable coronary artery disease. *N Engl J Med* 1999;341:70-76. 4. Data on File, Pfizer Canada Inc. 5. Simon Day. Dictionary for Clinical Trials, 1999, John Wiley & Sons Ltd. Pages 137-38.

For a copy of the Product Monograph or full Prescribing Information, please contact:



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Member





PHARMACOLOGIC CLASSIFICATION:
Angiotensin Converting Enzyme Inhibitor

ACTION AND CLINICAL PHARMACOLOGY
ALTACE (ramipril) is an angiotensin converting enzyme (ACE) inhibitor.

Following oral administration, ALTACE is rapidly hydrolyzed to ramiprilat, its principal active metabolite.

INDICATIONS AND CLINICAL USE: *Essential Hypertension.* ALTACE (ramipril) is indicated in the treatment of essential hypertension. It may be used alone or in association with thiazide diuretics. ALTACE should normally be used in patients in whom treatment with a diuretic or a beta-blocker was found ineffective or has been associated with unacceptable adverse effects. ALTACE can also be tried as an initial agent in those patients in whom use of diuretics and/or beta-blockers are contraindicated or in patients with medical conditions in which these drugs frequently cause serious adverse effects. The safety and efficacy of ALTACE in renovascular hypertension have not been established and therefore, its use in this condition is not recommended. The safety and efficacy of concurrent use of ALTACE with antihypertensive agents other than thiazide diuretics have not been established.

Treatment Following Acute Myocardial Infarction
ALTACE is indicated following acute myocardial infarction in clinically stable patients with signs of left ventricular dysfunction to improve survival and reduce hospitalizations for heart failure. Sufficient experience in the treatment of patients with severe (NYHA class IV) heart failure immediately after myocardial infarction is not yet available. (See WARNINGS – Hypotension.)

MANAGEMENT OF PATIENTS AT INCREASED RISK OF CARDIOVASCULAR EVENTS: ALTACE may be used to reduce the risk of myocardial infarction, stroke or cardiovascular death in patients over 55 years of age who are at high risk of cardiovascular events because of a history of coronary artery disease, stroke, peripheral artery disease, or diabetes that is accompanied by at least one other cardiovascular risk factor such as hypertension, elevated total cholesterol levels, low density lipoprotein levels, cigarette smoking, or documented microalbuminuria. The incidence of the primary outcome (composite of myocardial infarction, stroke and death from cardiovascular causes) was reduced from 17.8% in the placebo-treated group to 14.0% in the ramipril-treated group.

GENERAL: In using ALTACE consideration should be given to the risk of angioedema (see WARNINGS). When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury or even death of the developing fetus. When pregnancy is detected ALTACE should be discontinued as soon as possible (see WARNINGS – Use in Pregnancy, and INFORMATION FOR THE PATIENT).

CONTRAINDICATIONS: ALTACE (ramipril) is contraindicated in patients who are hypersensitive to this drug, or to any ingredient in the formulation, or in those patients who have a history of angioedema.

WARNINGS: Angioedema. Angioedema has been reported in patients with ACE inhibitors, including ALTACE (ramipril). Angioedema associated with laryngeal involvement may be fatal. If laryngeal stridor or angioedema of the face, tongue, or glottis occurs, ALTACE should be discontinued immediately, the patient treated appropriately in accordance with accepted medical care, and carefully observed until the swelling disappears. In instances where swelling is confined to the face and lips, the condition generally resolves without treatment, although antihistamines may be useful in relieving symptoms. Where there is involvement of tongue, glottis, or larynx, likely to cause airway obstruction, appropriate therapy (including, but not limited to 0.3 to 0.5 mL of subcutaneous epinephrine solution 1:1000) should be administered promptly (see ADVERSE REACTIONS).

The incidence of angioedema during ACE inhibitor therapy has been reported to be higher in black than in non-black patients. Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor (see CONTRAINDICATIONS).

Hypotension: Symptomatic hypotension has occurred after administration of ALTACE, usually after the first or second dose or when the dose was increased. It is more likely to occur in patients who are volume depleted by diuretic therapy, dietary salt restriction, dialysis, diarrhea, or vomiting. In patients with ischemic heart disease or cerebrovascular disease, an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident (see ADVERSE REACTIONS). Because of the potential fall in blood pressure in these patients, therapy with ALTACE should be started under close medical supervision. Such patients should be followed closely for the first weeks of treatment and whenever the dose of ALTACE is increased. In patients with severe congestive heart failure, with or without associated renal insufficiency, ACE inhibitor therapy may cause excessive hypotension and has been associated with oliguria, and/or progressive azotemia, and rarely, with acute renal failure and/or death.

If hypotension occurs, the patient should be placed in a supine position and, if necessary, receive an intravenous infusion of 0.9% sodium chloride. A transient hypotensive response may not be a contraindication to further doses which usually can be given without difficulty once the blood pressure has increased after volume expansion in hypertensive patients. However, lower doses of ALTACE and/or reduced concomitant diuretic therapy should be considered. In patients receiving treatment following acute myocardial infarction, consideration should be given to discontinuation of ALTACE (see ADVERSE REACTIONS – Treatment Following Acute Myocardial Infarction). **DOSAGE AND ADMINISTRATION – Treatment Following Acute Myocardial Infarction.**

Neutropenia/Agranulocytosis: Agranulocytosis and bone marrow depression have been caused by ACE inhibitors. Several cases of agranulocytosis, neutropenia or leukopenia have been reported in which a causal relationship to ALTACE cannot be excluded. Current experience with the drug shows the incidence to be rare. Periodic monitoring of white blood cell counts should be considered, especially in patients with collagen vascular disease and/or renal disease. **Use in Pregnancy:** ACE inhibitors can cause fetal and neonatal morbidity and mortality when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ALTACE should be discontinued as soon as possible.

PRECAUTIONS: Renal Impairment: As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function have been seen in susceptible individuals. In patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, such as patients with bilateral renal artery stenosis, unilateral renal artery stenosis to a solitary kidney, or severe congestive heart failure, treatment with agents that inhibit this system has been associated with oliguria, progressive azotemia, and rarely, acute renal failure and/or death. In susceptible patients, concomitant diuretic use may further increase risk. Use of ALTACE should include appropriate assessment of renal function. ALTACE should be used with caution in patients with renal insufficiency as they may require reduced or less frequent doses (see DOSAGE AND ADMINISTRATION). Close monitoring of renal function during therapy should be performed as deemed appropriate in patients with renal insufficiency.

Anaphylactoid Reactions during Membrane Exposure: Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes (e.g. polyacrylonitrile [PAN]) and treated concomitantly with an ACE inhibitor. Dialysis should be stopped immediately if symptoms such as nausea, abdominal cramps, burning, angioedema, shortness of breath and severe hypotension occur. Symptoms are not relieved by antihistamines. In these patients consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agents.

Anaphylactoid Reactions during Desensitization: There have been isolated reports of

patients experiencing sustained life threatening anaphylactoid reactions while receiving ACE inhibitors during desensitization treatment with hymenoptera (bees, wasps) venom. In the same patients, these reactions have been avoided when ACE inhibitors were temporarily withheld for at least 24 hours, but they have reappeared upon inadvertent rechallenge.

Hyperkalemia and Potassium-Sparing Diuretics: Elevated serum potassium (greater than 5.7 mEq/L) was observed in approximately 1% of hypertensive patients in clinical trials treated with ALTACE. In most cases these were isolated values which resolved despite continued therapy. Hyperkalemia was not a cause of discontinuation of therapy in any hypertensive patient. Risk factors for the development of hyperkalemia may include renal insufficiency, diabetes mellitus, and the concomitant use of agents to treat hyperkalemia or other drugs associated with increases in serum potassium (see PRECAUTIONS – Drug Interactions).

Surgery/Anesthesia: In patients undergoing surgery or anesthesia with agents producing hypotension, ALTACE may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it may be corrected by volume repletion.

Aortic Stenosis: There is concern, on theoretical grounds, that patients with aortic stenosis might be at particular risk of decreased coronary perfusion when treated with vasodilators because they do not develop as much aortic flow reduction.

Patients with Impaired Liver Function: Hepatitis (hepatocellular and/or cholestatic), elevations of liver enzymes and/or serum bilirubin have occurred during therapy with ACE inhibitors in patients with or without pre-existing liver abnormalities. In most cases the changes were reversed on discontinuation of the drug.

Elevations of liver enzymes and/or serum bilirubin have been reported with ALTACE (see ADVERSE REACTIONS). Should the patient receiving ALTACE experience any unexplained symptoms particularly during the first weeks or months of treatment, it is recommended that a full set of liver function tests and any other necessary investigations be carried out. Discontinuation of ALTACE should be considered when appropriate. There are no adequate studies in patients with cirrhosis and/or liver dysfunction. ALTACE should be used with particular caution in patients with pre-existing liver abnormalities. In such patients baseline liver function tests should be obtained before administration of the drug and close monitoring of response and metabolic effects should apply.

Nursing Mothers: Ingestion of a single 10 mg oral dose of ALTACE resulted in undetectable amounts of ramipril and its metabolites in breast milk. However, because multiple doses may produce low milk concentrations that are not predictable from single doses, ALTACE should not be administered to nursing mothers.

Pediatric Use: The safety and effectiveness of ALTACE in children have not been established; therefore use in this age group is not recommended.

Use in Elderly: Although clinical experience has not identified differences in response between the elderly (>65 years) and younger patients, greater sensitivity of some older individuals cannot be ruled out.

Patient Alertness: ALTACE may lower the state of patient alertness and/or reactivity, particularly at the start of treatment (see ADVERSE REACTIONS).

Cough: A dry persistent cough, which usually disappears only after withdrawal or lowering of the dose of ALTACE, has been reported. Such possibility should be considered as part of the differential diagnosis of cough.

Drug Interactions: Concomitant Diuretic Therapy: Hypotension may result but can be minimized by discontinuing diuretic or increasing salt intake prior to ramipril treatment and/or reducing initial dose. **Agents increasing serum potassium:** Use potassium sparing diuretics with caution and monitor frequently. **Agents causing renal release:** ALTACE antihypertensive effect increased. **Lithium:** Lithium levels may be increased. Administer lithium with caution and monitor levels frequently. **Antacids:** The bioavailability of ALTACE and the pharmacokinetics of ramiprilat were not affected. **Digoxin:** No change in ramipril, ramiprilat or digoxin serum levels. **Warfarin:** The co-administration of ALTACE with warfarin did not alter the anticoagulant effects. **Acenocoumarol:** No significant changes. **Non-steroidal anti-inflammatory agents (NSAID):** The antihypertensive effects of ACE inhibitors may be reduced with concomitant administration of NSAIDs (e.g. indomethacin).

ADVERSE REACTIONS: Essential Hypertension. Serious adverse events occurring in North American placebo-controlled clinical trials with ramipril monotherapy in hypertension (n=972) were: hypotension (0.1%); myocardial infarction (0.3%); cerebrovascular accident (0.1%); edema (0.2%); syncope (0.1%). Among all North American ramipril patients (n=1,244), angioedema occurred in patients treated with ramipril and a diuretic (0.1%). The most frequent adverse events occurring in these trials with ALTACE monotherapy in hypertensive patients (n=651) were: headache (15.1%); dizziness (3.7%); asthenia (3.7%); chest pain (2.0%); nausea (1.8%); peripheral edema (1.8%); somnolence (1.7%); impotence (1.5%); rash (1.4%); arthritis (1.1%); dyspnea (1.1%). Discontinuation of therapy due to clinical adverse events was required in 5 patients (0.8%). In placebo-controlled trials, an excess of upper respiratory infection and flu syndrome was seen in the ramipril group. As these studies were carried out before the relationship of cough to ACE inhibitors was recognized, some of these events may represent ramipril-induced cough. In a later 1-year study, increased cough was seen in almost 12% of ALTACE patients, with about 4% of these patients requiring discontinuation of treatment. Approximately 1% of patients treated with ALTACE monotherapy in North American controlled clinical trials (n=972) have required discontinuation because of cough.

Treatment Following Acute Myocardial Infarction
Adverse events (except laboratory abnormalities) in a controlled clinical trial of post-AMI patients with clinical signs of heart failure considered possibly/probably related to ALTACE and occurring in more than 1% of stabilized patients (n=1,004) were: hypotension (10.7%); increased cough (7.6%); dizziness/vertigo (5.6%); nausea/vomiting (3.8%); angina pectoris (2.9%); postural hypotension (2.2%); syncope (2.1%); heart failure (2.0); severe/resistant heart failure (2.0%); myocardial infarction (1.7%); vomiting (1.6%); headache (1.2%); abnormal kidney function (1.2%); abnormal chest pain (1.1%); diarrhea (1.1%). Isolated cases of death have been reported with the use of ramipril that appear to be related to hypotension (including first dose effects), but many of these are difficult to differentiate from progression of underlying disease (see WARNINGS – Hypotension). **Discontinuation of therapy due to adverse reactions was required in 368/1,004 post-AMI patients taking ramipril (36.7%), compared to 401/982 patients receiving placebo (40.8%).**

Clinical Laboratory Test Findings: increased creatinine; increases in blood urea nitrogen (BUN); decreases in hemoglobin or hematocrit; hyponatremia; decreases of liver enzymes, serum bilirubin, uric acid, blood glucose; proteinuria and significant increases in serum potassium.

DOSAGE AND ADMINISTRATION

Essential Hypertension: Dosage of ALTACE (ramipril) must be individualized. Initiation of therapy requires consideration of recent antihypertensive drug treatment, the extent of blood pressure elevation and salt restriction. The dosage of other antihypertensive agents being used with ALTACE may need to be adjusted.

Monotherapy: The recommended initial dosage of ALTACE in patients not on diuretics is 2.5 mg once daily. Dosage should be adjusted according to blood pressure response, generally, at intervals of at least two weeks. The usual dose range is 2.5 to 10 mg once daily. A daily dose of 20 mg should not be exceeded.

In some patients treated once daily, the antihypertensive effect may diminish towards the end of the dosing interval. This can be evaluated by measuring blood pressure just prior to dosing to determine whether satisfactory control is being maintained for 24 hours. If it is not, either twice daily administration with the same total daily dose, or an increase in dose should be considered. If blood pressure is not controlled with ALTACE alone, a diuretic may be added. After the addition of a diuretic, it may be possible to reduce the dose of ALTACE.

Concomitant Diuretic Therapy: Symptomatic hypotension occasionally may occur following the initial dose of ALTACE and is more likely in patients who are currently being treated with a diuretic. The diuretic should, if possible, be discontinued for two

to three days before beginning therapy with ALTACE to reduce the likelihood of hypotension (see WARNINGS). If the diuretic cannot be discontinued, an initial dose of 1.25 mg of ALTACE should be used with careful medical supervision for several hours and until blood pressure has stabilized. The dosage of ALTACE should subsequently be titrated (as described above) to the optimal response.

Use in Renal Impairment: For patients with a creatinine clearance below 40 mL/min/1.73 m² (serum creatinine above 2.5 mg/dL), the recommended initial dose is 1.25 mg of ALTACE once daily. Dosage may be titrated upward until blood pressure is controlled or to a maximum total daily dose of 5 mg. In patients with severe renal impairment (creatinine clearance below 10 mL/min/1.73 m²) the maximum total daily dose of 2.5 mg of ALTACE should not be exceeded.

Treatment Following Acute Myocardial Infarction:

Initiation of therapy requires consideration of concomitant medication and baseline blood pressure and should be instituted under close medical supervision, usually in a hospital, three to ten days following an acute myocardial infarction in haemodynamically stable patients with clinical signs of heart failure. The recommended initial dosage of ALTACE is 2.5 mg given twice a day (b.i.d.), one in the morning and one in the evening. If tolerated, and depending on the patient's response, dosage may be increased by doubling at intervals of one to three days. The maximum daily dose of ALTACE should not exceed 5 mg twice daily (b.i.d.). After the initial dose of ALTACE, the patient should be observed under medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. If a patient becomes hypotensive at this dosage, it is recommended that the dosage be lowered to 1.25 mg b.i.d. following effective management of the hypotension. (see WARNINGS – Hypotension).

Patients who have been fluid or salt depleted, or treated with diuretics are at an increased risk of hypotension (see WARNINGS – Hypotension). An excessive fall in blood pressure may occur particularly in the following: after the initial dose of ALTACE; after every first increase of dose of ALTACE; after the first dose of a concomitant diuretic and/or when increasing the dose of the concomitant diuretic. If appropriate, the dose of any concomitant diuretic should be reduced which may diminish the likelihood of hypotension (see PRECAUTIONS – Drug Interactions). Consideration should be given to reducing the initial dose to 1.25 mg of ALTACE in these patients.

Use in Renal Impairment: In patients with impaired renal function (creatinine clearance of 20-50 mL/min/1.73 m² body surface area), the initial recommended dosage is generally 1.25 mg of ALTACE once daily. This dosage may be increased with caution up to 1.25 mg of ALTACE twice daily, depending upon clinical response and tolerability.

Insufficient data is available concerning the use of ramipril following acute myocardial infarction in patients with heart failure and severe renal failure. (see ACTION AND CLINICAL PHARMACOLOGY – Pharmacokinetics and Metabolism, PRECAUTIONS – Renal Impairment).

Use in Hepatic Impairment: Insufficient data is available concerning the use of ramipril following acute myocardial infarction in patients with heart failure and hepatic dysfunction. Dose reduction and careful monitoring of these patients is required (see ACTIONS AND CLINICAL PHARMACOLOGY – Pharmacokinetics and Metabolism, PRECAUTIONS – Patients with Impaired Liver Function).

Management of Patients at Increased Risk of Cardiovascular Events: Recommended initial dose: 2.5 mg of ALTACE once daily. Depending on the tolerability, the dose is gradually increased. It is recommended to double the dose after one week of treatment and – after another three weeks – to increase it to 10 mg. Usual maintenance dose: 10 mg of ALTACE daily (see ACTION AND CLINICAL PHARMACOLOGY, WARNINGS, and PRECAUTIONS). Dosage recommendations for special risk groups such as patients with renal or hepatic impairment, or at an increased risk of hypotension (fluid or salt depletion, treated with diuretics) are to be followed as previously described (see WARNINGS and PRECAUTIONS).

DOSAGE FORM

a) Composition
ALTACE (ramipril) capsules 1.25 mg, 2.5 mg, 5.0 mg, and 10.0 mg contain the medicinal ingredient ramipril in quantities of 1.25 mg, 2.5 mg, 5.0 mg, and 10.0 mg respectively. The qualitative formulation for all potencies of ALTACE is: ramipril, pre-gelatinized starch NF (as filler, gliding agent and disintegration agent) and empty gelatin capsules. Empty gelatin capsules for all potencies of ALTACE are composed of gelatin NF and coloring agents specific to each potency (see below).

POTENCY	CAP	BODY
1.25 mg	Yellow iron oxide Titanium dioxide	Titanium dioxide
2.5 mg	Yellow iron oxide FD & C red no. 3 Titanium dioxide	Titanium dioxide
5.0 mg	FD & C blue no. 2 FD & C red no. 3 Titanium dioxide	Titanium dioxide
10.0 mg	FD & C blue no. 2 FD & C red no. 3 Black iron oxide Titanium dioxide	Titanium dioxide

b) Stability and storage recommendations

Store ALTACE (ramipril) in original container at room temperature, below 25°C and not beyond the date indicated on the container.

AVAILABILITY: No. 4 hard gelatin capsules:

- 1.25 mg (white/yellow);
- 2.5 mg (white/orange);
- 5.0 mg (white/red);
- 10.0 mg (white/blue).

ALTACE capsules 1.25 mg, 2.5 mg, 5.0 mg and 10.0 mg are packaged in cartons of 30 (2 x 15 blister-packed) capsules. Bottles of 100 capsules and 500 capsules also available.

Product monograph available upon request.

References:

1. ALTACE Product Monograph. 2. The Heart Outcomes Prevention Evaluation Study Investigators (HOPE) Trial. Effects of an angiotensin-converting-enzyme inhibitor, ramipril, on cardiovascular events in high-risk patients. *N Engl J Med* 2000;342(3):145-53.

Venofer[®]

iron sucrose injection

20 mg elemental iron/mL
Therapeutic Class: Hematinic

DESCRIPTION

VENOfer (Iron Sucrose Injection) is a brown, viscous, sterile, nonpyrogenic aqueous solution containing 20 mg/mL elemental iron in the form of an iron(III)-hydroxide sucrose complex as the active ingredient, and water for injection. NaOH may be used to adjust the pH to 10.5 - 11.1. The sterile solution has an osmolarity of 1250 mOsm/L. Iron(III)-hydroxide sucrose complex has a molecular weight of approximately 43,200 daltons and a molecular formula as follows:



where: n is the degree of iron polymerization and m is the number of sucrose molecules in complex with the iron(III)-hydroxide. VENOfer is available in 5 mL single dose vials. The product contains no preservatives or dextran polysaccharides.

ACTION AND CLINICAL PHARMACOLOGY

VENOfer (Iron Sucrose Injection) consists of polynuclear ferric hydroxide cores surrounded by noncovalently bound sucrose molecules. Following intravenous administration of VENOfer, iron sucrose is dissociated by the reticuloendothelial system into iron and sucrose.

In 22 hemodialysis patients on erythropoietin therapy treated with iron sucrose at 100 mg of iron three times weekly for three weeks, significant increases in serum iron and serum ferritin and significant decreases in total iron binding capacity occurred four weeks from the initiation of iron sucrose treatment.

In healthy adults treated with intravenous doses of VENOfer, the iron component exhibits first order kinetics with an elimination half-life of 6 h, total clearance of 1.2 L/h, non-steady state apparent volume of distribution of 10.0 L and steady state apparent volume of distribution of 7.9 L. Since iron disappearance from serum depends on the need for iron in the iron stores and iron utilizing tissues of the body, serum clearance of iron is expected to be more rapid in iron deficient patients compared to healthy individuals. The effects of age and gender on the pharmacokinetics of VENOfer have not been studied.

In healthy adults treated with intravenous doses of VENOfer, the iron component appears to distribute mainly in blood and to some extent in extravascular fluid. In a study evaluating VENOfer at 100 mg of iron labelled with ⁵²Fe/⁵⁹Fe in patients with iron deficiency, it was found that a significant amount of the administered iron distributes in the liver, spleen and bone marrow. The bone marrow is an iron trapping compartment and not a reversible volume of distribution.

The sucrose component of VENOfer is eliminated mainly by urinary excretion. In a study evaluating a single intravenous dose of VENOfer containing 1510 mg of sucrose and 100 mg of iron in 12 healthy adults, 68.3% of the sucrose was eliminated in urine in 4 h and 75.4% in 24 h. About 5% of the iron was eliminated via renal excretion over 24 h.

INDICATIONS AND CLINICAL USE

VENOfer (Iron Sucrose Injection) is indicated in the treatment of patients with dialysis-associated anemia.

CONTRAINDICATIONS

The use of VENOfer (Iron Sucrose Injection) is contraindicated in patients with evidence of iron overload, patients with known hypersensitivity to VENOfer, and patients with anemia not caused by iron deficiency.

WARNINGS

HYPERSENSITIVITY REACTIONS

POTENTIALLY FATAL HYPERSENSITIVITY OR ANAPHYLACTIC-TYPE REACTIONS CHARACTERIZED BY SHOCK, LOSS OF CONSCIOUSNESS, COLLAPSE, HYPOTENSION, DYSPNEA, OR CONVULSION HAVE BEEN REPORTED RARELY IN PATIENTS RECEIVING VENOfer (IRON SUCROSE INJECTION) (SEE ADVERSE REACTIONS). FATAL IMMEDIATE HYPERSENSITIVITY REACTIONS HAVE BEEN REPORTED IN PATIENTS RECEIVING THERAPY WITH A VARIETY OF PARENTERAL PREPARATIONS CONTAINING IRON CARBOHYDRATE COMPLEXES. FACILITIES FOR CARDIOPULMONARY RESUSCITATION MUST BE AVAILABLE DURING DOSING IN CASE OF SERIOUS ANAPHYLACTOID REACTIONS (SEE ADVERSE REACTIONS). PHYSICIAN VIGILANCE IS REQUIRED WHEN ADMINISTERING ANY INTRAVENOUS IRON PRODUCT.

HYPOTENSION

HYPOTENSION HAS BEEN REPORTED FREQUENTLY IN PATIENTS RECEIVING INTRAVENOUS IRON. HYPOTENSION FOLLOWING ADMINISTRATION OF VENOfer MAY BE RELATED TO RATE OF ADMINISTRATION AND TOTAL DOSE ADMINISTERED. CAUTION SHOULD BE TAKEN TO ADMINISTER VENOfer AS RECOMMENDED (SEE DOSAGE AND ADMINISTRATION).

PRECAUTIONS

General

Because body iron excretion is limited and excess tissue iron can be hazardous, caution should be exercised in the administration of parenteral iron formulations, and treatment should be withheld when there is evidence of tissue iron overload. Patients receiving VENOfer (Iron Sucrose Injection) require periodic monitoring of hematologic parameters, including hemoglobin, hematocrit, serum ferritin and transferrin saturation. Generally accepted guidelines recommend withholding administration of intravenous iron formulations from patients demonstrating a transferrin saturation >50% or serum ferritin >800 ng/mL (see DOSAGE AND ADMINISTRATION and SYMPTOMS AND TREATMENT OF OVERDOSAGE). Transferrin saturation values increase rapidly after IV administration of iron sucrose; thus, serum iron values may be reliably obtained 48 hours after IV dosing.

Local Reactions

Care must be taken to avoid paravenous infiltration. If this occurs, the infusion of VENOfer should be discontinued immediately. Ice may be applied to cause local vasoconstriction and decrease fluid absorption; massage of the area should be avoided.

Oral Iron Use

Oral iron should not be administered concomitantly with parenteral iron preparations. Like other parenteral iron preparations, VENOfer may be expected to reduce the absorption of concomitantly administered oral iron preparations.

Pregnancy

Teratology studies performed in rats at IV doses up to 13 mg iron/kg/day (more than 9 times the maximum recommended human dose for a 70 kg person) and rabbits at IV doses up to 13 mg iron/kg on alternate days (approximately 9 times the maximum recommended human dose for a 70 kg person) have not revealed definitive evidence of impaired fertility. Fetal growth effects at these doses appeared related to low maternal food consumption and low body weight gain. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, VENOfer should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. When iron sucrose was administered at deliberate overdoses to rabbit dams (up to 215 mg/kg/day) marked fetal/placental iron overload was noted. It is unlikely that significant fetal iron overload would occur in iron deficient pregnant women receiving therapeutic doses of VENOfer to correct iron deficiency (see PRECAUTIONS - General).

Nursing Mothers

VENOfer is excreted in the milk of rats. It is not known whether VENOfer is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when VENOfer is administered to nursing women.

Pediatric Use

The safety and effectiveness of VENOfer in pediatric patients has not been established.

Geriatric Use

Clinical studies of VENOfer did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting with lower doses, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Drug Interactions

Drug interactions involving VENOfer have not been studied.

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ADVERSE REACTIONS

The safety of VENOfer (Iron Sucrose Injection) has been documented in 231 chronic renal failure patients exposed to doses of 100 mg iron IV as iron sucrose given up to three times weekly for up to ten doses in three separate clinical trials.

The following adverse events, whether or not related to VENOfer administration, were reported by >5% of those patients: hypotension (36%), cramps/leg cramps (23%), nausea, headache, vomiting, and diarrhea.

Adverse events, whether or not related to VENOfer administration, reported by >1% of these patients are categorized below by body system and ranked in order of decreasing frequency within each body system. Some of these symptoms are seen in dialysis patients not receiving intravenous iron.

Body as a Whole: headache, fever, pain, asthenia, malaise.

Cardiovascular: hypotension, chest pain, hypertension, hypervolemia.

Gastrointestinal: nausea, vomiting, abdominal pain.

Central and Peripheral Nervous Systems: dizziness.

Musculoskeletal: cramps/leg cramps, musculoskeletal pain.

Respiratory: dyspnea, cough.

Skin and appendages: pruritus, application site reaction.

Anaphylactoid reactions were not observed in these clinical studies, but have been reported with iron sucrose, generally at doses higher than 100 mg and/or with fast infusion rates.

Post-Marketing Experience: From the spontaneous reporting system, 46 out of an estimated more than 787,361 patients exposed to VENOfer between 1992 and 2000 reported anaphylactoid reactions, including 15 patients who experienced serious or life-threatening reactions associated with VENOfer administration (see WARNINGS - HYPERSENSITIVITY REACTIONS). Almost all of these patients received single doses greater than 100 mg iron.

Other adverse events, in order of decreasing frequency, reported rarely with VENOfer use, were: hypotension, nausea, headache, edema, metallic taste/taste perversion, vomiting, abdominal pain, phlebitis, urticaria, flushing, dyspnea, pyrexia, rash, dizziness, tachycardia, tachypnea and wheezing. Doses higher than 100 mg are associated with a higher incidence of adverse events. Necrotizing enterocolitis, not necessarily causally associated with VENOfer use, has been reported rarely in very low birth weight premature infants.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Dosages of VENOfer (Iron Sucrose Injection) in excess of iron needs may lead to the accumulation of iron in storage sites, resulting in hemosiderosis. Periodic monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognizing iron accumulation. VENOfer should not be administered to patients with iron overload and should be discontinued when serum ferritin levels exceed usual norms (see PRECAUTIONS - General).

Symptoms associated with overdosage or infusing VENOfer too rapidly include hypotension, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse. Most symptoms have been successfully treated with IV fluids, corticosteroids and/or antihistamines.

DOSAGE AND ADMINISTRATION

The dosage of VENOfer (Iron Sucrose Injection) is expressed in terms of mg of elemental iron. Each 5 mL vial contains 100 mg of elemental iron (20 mg/mL).

The recommended dosage of VENOfer for the repletion treatment of iron deficiency in dialysis patients is 5 mL of VENOfer (100 mg of elemental iron) delivered slowly by the intravenous route during the dialysis session. Frequency of dosing should be not more than three times weekly. Most anemic patients will require a minimum cumulative dose of 1000 mg of elemental iron, administered over 10 sequential dialysis sessions, to achieve a favourable hemoglobin or hematocrit response. Patients may then continue to require therapy at the lowest dose necessary to maintain target levels of hemoglobin, hematocrit and iron storage parameters within acceptable limits. Doses of iron sucrose at 20-50 mg iron have been shown to result in clinically meaningful responses in some patients in the maintenance phase.

Administration: VENOfer must only be administered intravenously, by slow injection or infusion, generally into the dialysis line. **Slow Intravenous Injection:** In chronic renal failure patients, VENOfer may be administered by slow intravenous injection at a rate of not more than 1 mL (20 mg iron) undiluted solution per minute [i.e., 5 minutes per vial] not exceeding one vial of VENOfer (100 mg iron) per injection. Discard any unused portion.

Intravenous Infusion: VENOfer may also be administered by infusion. This mode of administration may be preferable to minimize the risk of hypotensive episodes (see WARNINGS - HYPOTENSION). The content of each vial must be diluted exclusively in a maximum of 100 mL of 0.9% NaCl immediately prior to infusion. Use immediately after diluting in saline. Unused diluted solution should be discarded.

PHARMACEUTICAL INFORMATION

Proper Name: Iron Sucrose

Chemical Names: Iron (III)-hydroxide sucrose complex

Ferric-hydroxide Sucrose Complex

Saccharated Iron Oxide

Structural Formula: Exact structural formula not known.

Molecular Weight: Approximately 43,200 daltons

Reconstitution Table

Vial Size	Volume of Diluent to be Used per Vial	Nominal Concentration per mL
5 mL	Maximum 100 mL 0.9% NaCl	1 mg/mL (when the maximum of 100 mL NaCl is used).

When prepared as an infusion, use immediately. Do not store.

NOTE: Do not mix VENOfer with other medications or add to parenteral nutrition solutions for intravenous infusion. As with all parenteral drug products, intravenous admixtures should be inspected visually for clarity, particulate matter, precipitate, discoloration and leakage prior to administration, whenever solution and container permit. Solutions showing haziness, particulate matter, precipitate, discoloration or leakage should not be used. Discard unused portion.

STABILITY AND STORAGE RECOMMENDATIONS

Store at 15-25°C. Do not freeze. Discard unused portion.

PARENTERAL PRODUCTS

VENOfer must only be administered intravenously by slow injection or infusion (see DOSAGE AND ADMINISTRATION).

AVAILABILITY OF DOSAGE FORMS

VENOfer (Iron Sucrose Injection) is available in 5 mL single dose vials, sold in boxes of 10. Each 5 mL contains 100 mg (20 mg/mL) of elemental iron as an iron(III)-hydroxide sucrose complex in water for injection.

REFERENCES

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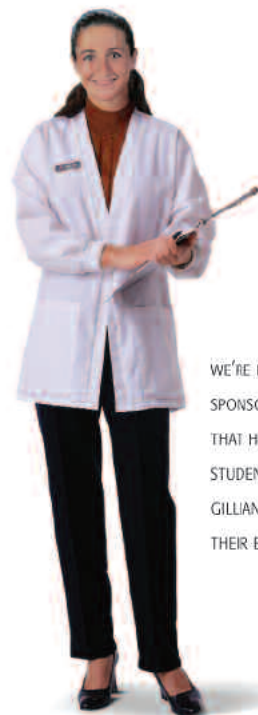
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