CJHP JCPH

The Canadian Journal of Hospital Pharmacy
Le journal canadien de la pharmacie hospitalière

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37th ANNUAL PROFESSIONAL PRACTICE CONFERENCE
37e CONFÉRENCE ANNUELLE SUR LA PRATIQUE PROFESSIONNELLE

JANUARY 28 - FEBRUARY 1, 2006
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Publications Mail Agreement 40036323 / PAP 9787

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

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LIPITOR® offers up to 50% LDL-C reduction at starting doses of 10, 20 and 40 mg[1¥]

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Power

AND is indicated to reduce the risk of MI in hypertensive patients without CHD but with 3 or more cardiovascular risk factors[1]

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10 mg 20 mg 40 mg 80 mg

LIPITOR is an HMG-CoA reductase inhibitor (statin). LIPITOR is indicated as an adjunct to lifestyle changes, including diet, for the reduction of elevated total cholesterol (total-C), LDL-C, TG and apolipoprotein B (apo B) in hyperlipidemic and dyslipidemic conditions (including primary hypercholesterolemia, combined [mixed] hyperlipidemia, dysbetalipoproteinemia, hypertriglyceridemia and familial hypercholesterolemia) when response to diet and other pharmacological measures alone has been inadequate.

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 IIa and IIb dyslipidemia).

LIPITOR is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥55 years, male sex, smoking, type 2 diabetes, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminuria or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥6, or premature family history of coronary heart disease.

Very rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria, have been reported with LIPITOR and with other HMG-CoA reductase inhibitors.

Patients who develop any signs or symptoms suggestive of myopathy should have their CK levels measured. LIPITOR therapy should be discontinued if markedly elevated CK levels are measured or myopathy is diagnosed or suspected.

See Prescribing Information for complete warnings, precautions, dosing and administration.

Less than 2% of patients discontinued therapy due to adverse experiences. Most common adverse effects vs. placebo occurring in patients at an incidence ≥1% were constipation (1% vs. 1%), diarrhea (1% vs. 1%), dyspepsia (1% vs. 2%), flatulence (1% vs. 2%), nausea (1% vs. 0%), headache (1% vs. 2%), pain (1% vs. <1%), myalgia (1% vs. 1%) and asthenia (1% vs. <1%). The adverse events reported in ≥1% of boys and postmenarchal girls (10-17 years of age) were abdominal pain, depression and headache.

LIPITOR is contraindicated: During pregnancy and lactation; active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal; hypersensitivity to any component of this medication.

The dosage of LIPITOR should be individualized according to the baseline LDL-C, total-C/HDL-C ratio and/or TG levels to achieve the recommended target lipid values at the lowest dose needed to achieve LDL-C target.

Caution should be exercised in severely hypercholesterolemic patients who are also severely 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.

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, as well as other HMG-CoA reductase inhibitors, should be used with caution in patients who consume substantial quantities of alcohol and/or have a past history of liver disease.

£ A patient-year represents the total time of exposure to LIPITOR as defined by the sum of each patient's time on LIPITOR.[3]

PAAB Member R&D

Pfizer

Life is our life's work

References: 1. LIPITOR (atorvastatin calcium) Product Monograph, Pfizer Canada Inc., May 2005. **2.** IMS Health, IMS MIDAS™ (Standard Units: Year 1997 through to April 2005. **3.** Simon Day. Dictionary for Clinical Trials, 1999, John Wiley & Sons Ltd. 137-38.

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 37th Annual Professional Practice Conference.

The 2006 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 2006 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.

Emily Lap Sum Musing
CSHP President

Chers (ères) collègues,

Au nom des membres du Bureau de direction, du Conseil et du personnel de la Société canadienne des pharmaciens d'hôpitaux, je suis heureuse de vous souhaiter la bienvenue à la 37e Conférence annuelle sur la pratique professionnelle de la SCPH.

La conférence 2006 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 2006 et que vous prendrez le temps de vous divertir.

Nous vous rappelons qu'au cours de cette conférence, les membres du Bureau de direction et le personnel de la SCPH seront à votre entière disposition. Nous pourrons 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.

Emily Lap Sum Musing
Présidente de la SCPH

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(at time of printing)

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Pharmascience

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Contributions importantes 2005/2006

CSHP is pleased to thank the following companies for their sponsorship of specific CSHP programs, services and events. The dollar value of these initiatives is included in the calculation of sponsorship levels.

AstraZeneca Canada Inc.
Research & Education Foundation

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AGM 2005 General Sponsorship
AGM 2005 R&E Golf Event
PPC 2006 General Sponsorship

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Research and Education Foundation

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AGM 2005 R&E Golf Event
AGM General Sponsorship
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Sandoz Canada Inc.
AGM 2005 General Sponsorship
AGM 2005 Research & Education Foundation
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PPC 2006 General Sponsorship

At Novopharm, we're making great strides in Hospital Pharmacy, because we know how important it truly is.

With the recent acquisition of Sicor Pharmaceuticals, Novopharm now has access to the largest number of injectable products on the market as well as new dosage forms and innovative IV delivery systems. As a result, Novopharm has several new exciting product launches on the horizon, the first of which is the release of Novopharm Propofol. Propofol is an established product in the Sicor product line resulting in a consistent supply to the Canadian market. With our Diamond Support of the CSHP and our renowned customer service, our commitment to hospital pharmacy has never been stronger.

Introducing new Novopharm Propofol, available in 20, 50 and 100 mL.

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Distinguished Service Award

Presented by Janssen Ortho Inc.
$1,500

This award recognizes 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
1984 Sister Grace Sauvé
1985 Donna M. Shaw
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
2005 Bill Bartle

Isabel E. Stauffer Meritorious Service Award

Presented by Pharmaceutical Partners of Canada
$1,500

This award recognizes prolonged service and Involvement in CSHP, primarily at the branch and chapter levels

Individuals are nominated by their peers.

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
2005 Donna Wheeler-Usher

New Hospital Pharmacy Practitioner Award

Sponsored by Sandoz Canada Inc.
$1,500 x 2

This award recognizes new hospital pharmacy practitioners worthy of acknowledgment for innovative practice in direct patient care, research or education. They exhibit dedication and commitment to the profession and hold promise as future practice leaders.

Individuals are nominated by their peers.

Past Winners

2005 Stephanie Ong
2005 Kerry Wilbur

Hospital Pharmacy Student Award

Sponsored by the Canadian Society of Hospital Pharmacists
$500

This award recognizes pharmacy students who show promise as future hospital pharmacy practitioners through their student activities or their experiential training in direct patient care, research or education. The candidates exhibit keenness, dedication and excellence towards the academic learning, the profession and the practice of hospital pharmacy.

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2005/2006 Awards Committee

Sincere appreciation is extended to the Awards Committee and to our 2005/2006 Award Appraisers.

Chair

Frances Hall

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Rosemary Zvonar

Tribute to the Appraisers of the 2005/2006 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.

CSHP 2005/2006 Awards Program

Apotex Award
Management Issues in Pharmaceutical Care
$1,500

Baxa Award
Innovative Practitioner
$1,500

Baxter Award
Innovation in Safe Medication Practices
$1,500

Bristol-Myers Squibb Award
Clinical Pharmacy Program
$1,500

Hoffmann-La Roche Award
Specialties in Pharmacy Practice
$1,500

Mayne Pharma Award
Oncology
$1,500

Merck Frosst Award
Rational Drug Use
$1,500

Novartis Award
Pharmacoeconomics
$1,500

Novopharm Award
New Programs in Patient Counselling
$1,500

Pfizer Award
Long Term Health Care
$2,000

Pharmascience Award
Patient Care Enhancement
$1,000

Sanofi-Aventis Award
Specialty Practice in Cardiology
$1,500

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Upcoming Events/ Événements à venir

Professional Practice Conference (PPC)
January 28 - 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 - January 31, 2007
Westin Harbour Castle
Toronto, Ontario
Exhibits – yes
Attendance 1000-1200

Annual General Meeting (AGM)
August 11 - 14, 2007
Delta Regina
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
Hilton Saint John
Saint John, New Brunswick
Exhibits - yes
Attendance 250-300

Professional Practice Conference (PPC)
January 31 - February 4, 2009
Westin Harbour Castle
Toronto, Ontario
Exhibits – yes
Attendance 1000-1200

Annual General Meeting (AGM)
August 8 - 11, 2009
TBA
Winnipeg, Manitoba
Exhibits - yes
Attendance 250-300

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

Annual General Meeting (AGM)
August 7 -10, 2010
TBA
Halifax, Nova Scotia
Exhibits - yes
Attendance 250-300

For further information, please contact Desarae Davidson, CSHP National Office.
Tel.: (613) 736-9733, ext. 229 ▪ Fax: (613) 736-5660
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History Doesn't Have to Repeat Itself

Roger,
History of angina.

Died age 57 of MI.

Alice,
History of diabetes and high total cholesterol.

Died age 62 of stroke.

Help Reduce the Risk of CV Death by 26%[1]

(p<0.001; 6.1% vs. 8.1%)

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 in Canada and the ACEI most prescribed by cardiologists.*

*IMS Health Canada: Canadian CompuScript Audit, Moving Annual Total ending March 2005, Total Dispensed Prescriptions.

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Product Monograph available to physicians and pharmacists upon request.

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Conseil canadien de l'éducation permanente en pharmacie

Educational Services Committee

The Educational Services Committee (ESC) of CSHP has been working for approximately 10 months on the content and format of PPC 2006. 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 2006 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 2006

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, January 28
Samedi le 28 janvier

08:30-16:30 Train the Trainers Research Workshop/
Atelier de recherche pour la formation des formateurs

Regatta

(By invitation only. If interested contact your Branch President.)

15:00-17:00 Registration/
Inscription

Top of Escalators – Hotel Side

17:30-20:00 Awards Ceremony/
Opening Reception
Cérémonie de remise des prix/
Réception d'ouverture

Regatta

Everyone welcome

Sunday, January 29
Dimanche le 29 janvier

07:30-17:00 Registration/
Inscription

Metropolitan Foyer

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

Metropolitan West

09:00-10:00 Exploring the Impact of Cultural Differences on Hospital Pharmacists

Metropolitan West

Lionel Laroche, PhD, PEng
MCB Solutions
Toronto, ON

10:00-10:45 Break/Posters/
Pause/Affiches

Harbour Foyer

10:45-11:30 Concurrent Sessions/
Sessions concomitantes

1. **Post-Operative Nausea & Vomiting**

   Pier 2/3

   Peter Loewen, PharmD
   Vancouver General Hospital
   Vancouver, BC

2. **"Medical Internet" Resources and Implications for Future Practice**

   Pier 7/8

   Muhammad Zuberi, BScPhm
   University Health Network
   Toronto, ON

3. **Cardiac Diagnostic Testing – A Primer for Pharmacists**

   Pier 4/5

   Glen Pearson, PharmD, FCSHP
   University of Alberta
   Edmonton, AB

11:40-12:25 Concurrent Sessions/
Sessions concomitantes

1. **Clinical Pearls**

   Pier 2/3

   a. **The Role of Ipratropium in Combination with Tiotropium**

      Charles Bayliff, PharmD
      London Health Sciences Centre
      London, ON

   b. **Practical Considerations with Glargine Insulin**

      Henry Halapy, PharmD
      St. Michael's Hospital
      Toronto, ON

   c. **IV Quinine – Do You Know How to Get It?**

      Carolyn Bubbar, BSP
      University of Toronto
      Toronto, ON

2. **What is USP Chapter <797> and how do I Implement it?**

   Pier 7/8

   Carolyn Bornstein, BScPhm, ACPR
   Southlake Regional Health Centre
   Newmarket, ON

3. **ASA Resistance: Laboratory or Clinical Phenomenon?**

   Pier 4/5

   Jeff Nagge, PharmD
   University Health Network
   Toronto, ON

12:30-14:00 Satellite Symposium (luncheon included)/
Symposium satellite (déjeuner inclus)

Practice Solutions to Cardiac Dilemmas: Three Case-Based Examples

Harbour B

Hosted by Canadian Cardiovascular Pharmacists Network

Thrombosis – Anticoagulation in Special Populations

Harbour A

Hosted by LEO Pharma Inc.

USP Chapter 797 Guidelines: The Implementation Experience

Harbour C

Hosted by Baxter Corporation

14:10-14:55 Pharmaceutical Care Practice – What's New?

Metropolitan West

Lalitha Raman-Wilms, PharmD, FCSHP
University of Toronto
Toronto, ON

15:00-17:00 Workshops/ Ateliers

1. **Racism in the Health Care System: Uncovering Bias and Developing Cultural Competency Skills for Pharmacists**

   Pier 9

   Shakil Choudhury, MES, BEd, BPE
   Brown Book Productions
   Toronto, ON

2. **Practical Tips in Stroke Management**

   Pier 2/3

   Tania Mysak, PharmD
   Capital Health
   Edmonton, AB

3. **In-Hospital Management of Diabetes**

   Pier 5

   Wendy Gordon, PharmD
   Royal Columbian Hospital
   New Westminster, BC

4. **Highs, Lows & Everything in Between: Interpreting Liver & Kidney Function in the Acute & Chronic Setting**

   Regatta

   Lisa Burry, PharmD
   Mount Sinai Hospital
   Toronto, ON

   Séadna Ledger, BScPhm, ACPR
   London Health Sciences Centre
   London, ON

5. **Using the Acute Myocardial Infarction (AMI) Guidelines to Improve the Care of Your Patients: Taking Evidence to the Bedside**

   Pier 4

   Ann Thompson, BScPhm
   Capital Health
   Halifax, NS

15:00-17:00 PSN Session – Geriatrics/ Session RSP – Gériatrie

Pier 7/8

Osteoporosis and the Elderly – The Use of Bisphosphonates and Parathyroid Hormone

Thomas Brown, PharmD
University of Toronto
Toronto, ON

Risks and Benefits of Atypical Antipsychotics in the Elderly

Suaad Ibrahim, BScPhm
Regional Mental Health Care
London, ON

Controversies in the Management of Dementia

Allan Mills, PharmD
Trillium Health Centre
Mississauga, 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, January 30
Lundi le 30 janvier

06:15-08:00 Satellite Symposium (breakfast included) Symposium satellite (petit déjeuner inclus)

ChAT: Chemotherapy Adjuvant Treatment for Breast Cancer in Young Women

Harbour C

Hosted by Pfizer Canada Inc.

07:30-17:00 Registration/ Inscription

Metropolitan Foyer

08:30-10:00 Medication Reconciliation – Safer Healthcare Now!

Metropolitan West

Edward Etchells, MD, MSc, FRCP
Sunnybrook and Women's College HSC
Toronto, ON

Recognition of New Fellows, Board of Fellows/ Reconnaissance des nouveaux associés, Conseil des associés

Metropolitan West

10:00-10:30 Break/Exhibits/Posters/ Pause/Kiosques/Affiches

Metropolitan Centre/East

10:30-11:15 Concurrent Sessions/ Sessions concomitantes

1. **Learning from Medication Incident Data: The Role of the Canadian Medication Incident Reporting and Prevention System (CMIRPS)**

   Pier 4/5

   Michael Hunt, BScPhm
   Canadian Institute for Health Information
   Ottawa, ON

Sylvia Hyland, BScPhm, MHSc
Institute for Safe Medication Practices Canada
Toronto, ON

Lili Loorand-Stiver, BScPhm
Health Canada
Ottawa, ON

2. Atrial Fibrillation – Shocking New Discoveries

Pier 2/3

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

3. A Practical Approach to Managing HIV Drug Interactions

Pier 7/8

Debbie Kelly, PharmD
Memorial University of Newfoundland and Eastern Health
St. John's, NL

11:25-12:10 Concurrent Sessions/ Sessions concomitantes

1. Oral Presentations/ Présentations orales

Pier 2/3

2. Oral Presentations/ Présentations orales

Pier 7/8

3. Round Tables/ Tables rondes

(Limited to 25 participants per round table)

a. Medical Directives

Pier 4/5

Lee Dupuis, BScPhm, MSc, FCSHP
Nadya Nalli, BScPhm
The Hospital for Sick Children
Toronto, ON

b. Leadership Opportunities in Pharmacy

Pier 4/5

Emily Musing, BScPhm, MHA, FCSHP
University Health Network
Toronto, ON

c. Clinician and Physician Order Entry (CPOE)

Pier 4/5

Andrea Ryl, BScPhm
St. Michael's Hospital
Toronto, ON

d. Medication Reconciliation – Sharing, Learning, Progressing

Pier 9

Patti Cornish, BScPhm
Sunnybrook & Women's College HSC
Toronto, ON

Margaret Colquhoun, BScPhm, FCSHP
Institute for Safe Medication Practices Canada
Toronto, ON

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

Metropolitan Centre/East

14:00-14:15 Research Grants Presentation, Research and Education Foundation/ Remise des bourses de recherche, Fondation pour la recherche et l'éducation

Metropolitan West

14:15-15:00 ACEI versus ARB in High-Risk Vascular Patients

Metropolitan West

William Semchuk, PharmD, FCSHP
Regina Qu'Appelle Health Region
Regina, SK

Jennifer Pickering, BScPhm
Hamilton Health Sciences
Hamilton, ON

15:00-17:00 Workshops/ Ateliers

1. Racism in the Health Care System: Uncovering Bias and Developing Cultural Competency Skills for Pharmacists

Pier 9

Shakil Choudhury, MES, BEd, BPE
Brown Book Productions
Toronto, ON

2. Practical Tips in Stroke Management

Pier 2/3

Tania Mysak, PharmD
Capital Health
Edmonton, AB

3. In-Hospital Management of Diabetes

Pier 5

Wendy Gordon, PharmD
Royal Columbian Hospital
New Westminster, BC

4. Highs, Lows, & Everything in Between: Interpreting Liver & Kidney Function in the Acute & Chronic Setting

Pier 7/8

Lisa Burry, PharmD
Mount Sinai Hospital
Toronto, ON

Séadna Ledger, BScPhm, ACPR
London Health Sciences Centre
London, ON

5. Using the Acute Myocardial Infarction (AMI) Guidelines to Improve the Care of Your Patients: Taking Evidence to the Bedside

Pier 4

Ann Thompson, BScPhm
Capital Health
Halifax, NS

15:00-17:00 PSN Session – Cardiology/ Session RSP – Cardiologie Interesting Cardiovascular Pharmacists' Roles

Metropolitan West

The Alphabet Soup of Cardiac Devices

Jenny Chiu, BScPhm, ACPR
Mount Sinai Hospital
Toronto, ON

The Role of the Pharmacist in a Lipid Clinic

William Semchuk, PharmD, FCSHP
Regina Qu'Appelle Health Region
Regina, SK

The Role of the Pharmacist in Cardiac Rehab

Derek Jorgenson, PharmD
Saskatoon Health Region
Saskatoon, SK

Role of the Pharmacist and Pharmacy Technician in the Cath Lab: The Hamilton Experience

Jennifer Pickering, BScPhm
Hamilton Health Sciences Centre
Hamilton, ON

Tuesday, January 31
Mardi le 31 janvier

07:30-17:00 Registration/ Inscription

Metropolitan Foyer

08:30-10:00 Pandemic Influenza-Plan or Pandemonium

Metropolitan West

Susan Poutanen, MD, MPH, FRCPC
Mount Sinai Hospital
Toronto, ON

Recognition of New Fellows, Board of Fellows/ Reconnaissance des nouveaux associés, conseil des associés

Metropolitan West

10:00-10:30 Break/Exhibits/Posters Pause/Kiosques/Affiches

Metropolitan Centre/East

10:30-11:15 Concurrent Session/ Sessions concomitantes

1. Do Bugs Need Drugs? A Community Program for Wise Use of Antibiotics

Pier 4/5

Edith Blondel-Hill, MD, FRCP
British Columbia Children's Hospital
Vancouver, BC

Susan Fryters, BScPhm
Capital Health
Edmonton, AB

2. Meeting the Challenges of Medication Reconciliation in Elective Surgery Patients: Verify, Clarify and Reconcile

Pier 2/3

Virginia Carvalhana, PharmD
Mount Sinai Hospital
Toronto, ON

3. Pharmacist's Role on Medical Mission to Guyana

Pier 7/8

Reshma Dole, BScPhm
Lakeridge Health Corp.
Whitby, ON

11:25-12:10 Concurrent Sessions/ Sessions concomitantes

1. Oral Presentations/ Présentations orales

Pier 2/3

2. Oral Presentations/ Présentations orales

Pier 7/8

3. Round Tables/ Tables rondes

(Limited to 25 participants per round table)

a. Issues & Challenges Faced by Pharmacists in the Emergency Department

Pier 4/5

Christine Howe, BScPhm, ACPR
Mount Sinai Hospital
Toronto, ON

Amita Patel, PharmD
Toronto General Hospital
Toronto, ON

b. Medication Shortages

Pier 4/5

Edward Winkle, BScPhm
Sunnybrook & Women's College HSC
Toronto, ON

c. Innovative Retention and Recruitment

Pier 4/5

Thomas Paton, PharmD
Sunnybrook & Women's College HSC
Toronto, ON

d. Bridging the Gap: Strategies/Forms for Ensuring Medication Reconciliation

Pier 9

Claudia Bucci, PharmD, ACPR
Sunnybrook & Women's College HSC
Toronto, ON

Olavo Fernandes, PharmD, ACPR
University Health Network
Toronto, ON

12:15-14:15 Lunch/Exhibits/Posters/ Déjeuner/Kiosques/Affiches

Metropolitan Centre/East

14:15-15:00 What Strategies can Pharmacists use to Effectively Impact Prescribing Practices? An Evidence-Based Review

Metropolitan West

Janet Martin, PharmD
London Health Sciences Centre
London, ON

15:00-17:00 Workshops/Alteliers

1. How to Integrate Evidence-Based Medicine into Your Daily Practice: Help for the Busy Clinician

Harbour A

Trudy Arbo, PharmD, ACPR
Fraser Health Authority
Burnaby, BC

Aaron Tejani, PharmD
Fraser Health Authority
Burnaby, BC

2. Measuring Your Department's Progress in the Advancement of Pharmacy Practice and Patient Safety

Harbour C

Patricia McGregor, BScPhm
The Scarborough Hospital
Scarborough, ON

Nancy Roberts, BScPhm, FCSHP
South-East Regional Health Authority
Moncton, NB

3. The ABC's of RBC's: An Interactive Talk about Anemia in Chronic Kidney Disease

Harbour B

Jenny Ng, BScPhm
Sunnybrook & Women's College HSC
Toronto, ON

Stephanie Ong, BScPhm
University Health Network
Toronto, ON

4. Efficient Prescription Triage

Pier 4/5

Christine Davis, PharmD
Grace Hospital
Winnipeg, MB

15:00-17:00 PSN Session – Infectious Disease/ Session RSP – Infectiologie

Pier 2/3

Community-Acquired MRSA: An Emerging Pathogen

Gerald Evans, MD
Kingston General Hospital
Kingston, ON

Infective Endocarditis – New Guidelines and Old Questions

Linda Dresser, PharmD
Mount Sinai Hospital
Toronto, ON

Wednesday, February 1
Mercredi le 1er février

07:30-15:00 Registration/ Inscription

Top of Escalators – Hotel Side

08:30-9:30 Drug Metabolizing Enzymes: Putting Pharmacogenetics to Practice

Metropolitan West

Mary H. H. Ensom, PharmD, FCSHP
Children's & Women's Health Centre of BC
Vancouver, BC

09:30-10:15 Drug Toxicity, Pharmacovigilance and Tailored Therapy

Metropolitan West

Sunita Bond Stenton, PharmD
Children's & Women's Health Centre of BC
Vancouver, BC

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

Harbour Foyer

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

1. Trastuzumab Therapy for Early Breast Cancer

Pier 2/3

Flay Charbonneau, BScPhm
Sunnybrook & Women's College HSC
Toronto, ON

2. Self-Management Support: A Pharmacist's Journey from "Sage on the Stage" to "Guide on the Side"

Pier 7/8

Elaine Chong, PharmD, BCPS
Network Healthcare
Vancouver, BC

3. Ventilator-Associated Pneumonia

Pier 4/5

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

11:55-12:40 Concurrent Session/ Sessions concomitantes

1. Challenges of NIOSH Guidelines for Pharmacy

Pier 7/8

Carolyn Bornstein, BScPhm, ACPR
Southlake Regional Health Centre
Newmarket, ON

2. Review of Articles That Will Change Your Practice

Pier 4/5

Kerry Wilbur, PharmD, ACPR
Vancouver General Hospital
Vancouver, BC

3. Update on Pediatric Immunizations

Pier 2/3

James Tjon, PharmD
The Hospital for Sick Children
Toronto, ON

12:40-14:00 Satellite Symposiums (luncheon included) Symposiums satellites (déjeuner inclus)

a. Sepsis, New Data, New Insights – Pulling the Evidence Together

Harbour A

Hosted by Critical Care Pharmacists Network
Sponsored by Eli Lilly Canada Inc.

b. Dyslipidemia in Chronic Kidney Disease

Harbour B

Hosted by Renal Pharmacists Network
Sponsored by Ortho Biotech

14:00-15:00 Ethical Conduct – Point and Counterpoint

Metropolitan West

Moderator: Thomas Paton, PharmD

Robin Ensom, PharmD, FCSHP
Vancouver Coastal Health
Vancouver, BC

Kevin Hall, PharmD
Winnipeg Regional Health Authority
Winnipeg, MB

15:00-17:00 Workshops/ Ateliers

1. How to Integrate Evidence-Based Medicine into Your Daily Practice: Help for the Busy Clinician

Harbour A

Trudy Arbo, PharmD, ACPR
Fraser Health Authority
Burnaby, BC

Aaron Tejani, PharmD
Fraser Health Authority
Burnaby, BC

2. The ABC's of RBC's: An Interactive Talk about Anemia in Chronic Kidney Disease

Harbour B

Jenny Ng, BScPhm
Sunnybrook & Women's College HSC
Toronto, ON

Stephanie Ong, BScPhm
University Health Network
Toronto, ON

3. Efficient Prescription Triage

Pier 4/5

Christine Davis, PharmD
Grace Hospital
Winnipeg, MB

15:00-17:00 PSN Session – Critical Care/ Session RSP – Soins critiques

Pier 2/3

Methodological Issues in Critical Clinical Care Trials

Damon Scales, MD, FRCPC
Sunnybrook and Women's College HSC
Toronto, ON

Use of Recombinant Factor VIIa in Critically Ill Patients

Marc Perreault, PharmD
Montréal General Hospital
Montréal, QC

15:00-17:00 PSN Session – Informatics/ Session RSP – Informatique

Pier 7/8

The Anatomy and Physiology of CPOE

Jeff Barnett, BScPhm, FCSHP
BC Cancer Agency
Victoria, BC

Anatomy and Physiology of CPOE – Patient Safety Issues

Michael Ritchie, BScPhm
Sunnybrook and Women's College HSC
Toronto, ON

The University Network Experience in Implementing Computerized Physician Medication Order Entry: Lessons Learned

Monique Pitre, BScPhm
University Health Network
Toronto, ON

17:00 Close of the 37th Professional Practice Conference/ Clôture de la 37e Conférence annuelle sur la pratique professionnelle

Sunday, January 29 ▪ Dimanche le 29 janvier

Exploring the Impact of Cultural Differences on Hospital Pharmacists

Lionel F. Laroche, Ph.D., P.Eng., MCB Solutions, Toronto ON

The goal of this session is to provide hospital pharmacists with an understanding of the impact of cultural differences on their professional activities and to suggest approaches that will enable them to overcome the challenges resulting from cultural differences. It will also suggest approaches to seize the opportunities offered by cultural differences.

The recent increase of immigration to Canada brings pharmacists in contact with many culturally different people, since both the staff and the client base of hospitals are becoming increasingly diverse. These cultural differences result in misunderstandings in many situations, because people who come from different cultural backgrounds may have different objectives (because they value different things) or may try to achieve the same objectives in completely different ways.

Using many anecdotes derived from the real-life experience of many pharmacists, this presentation analyses specific situations where people from different cultural backgrounds react in very different ways. This presentation explains how these differences in reaction lead to misunderstandings and demonstrates how misunderstandings may occur even when all the parties involved have positive intentions towards one another. Finally, this presentation suggests ways in which pharmacists can modify their approaches to work more effectively with culturally different colleagues and service more effectively culturally different clients.

Goals and Objectives

1. To provide pharmacists with an understanding of the impact of cultural differences on their professional activities
2. To give pharmacists practical suggestions and tips so they can work more effectively with culturally different colleagues and clients

Self-Assessment Questions

1. Does the staff of your pharmacy include a significant percentage of people who were educated and trained in countries other than Canada?
2. Have you worked outside of Canada?
3. Have you worked in a language other than English?

"Medical Internet" Resources and Implications for Future Practice

Muhammad Zuberi, BScPhm, University Health Network, Toronto ON

The "Medical Internet" incorporates websites and services that focus primarily on health. These websites and services may be geared towards the patient, the health-care provider, or both. They are often supported by universities, medical societies, pharmaceutical manufacturers, or commercial organizations.

Patients who access the "Medical Internet" face the challenge of having to locate relevant health information, assess the credibility of the source, and determine the accuracy of the content. In a recent survey by the Health on the Net Foundation, 90% of patient-respondents indicated that health-care providers should suggest trustworthy online sources of health information. This same survey reported that 88% of patient-respondents felt that the provision of medical information was of equal importance as physician consultation. It follows, then, that pharmacists should be proactive in recommending quality, credible sources of health information on the internet.

In general, most websites and services for health-care providers serve to disseminate and improve access to information. These websites are often able to provide a high level of reliable content as they are developed on an enterprise level. At this level, credibility is gained by leveraging the reputation of the sponsoring organization or society.

A new model is emerging within the "Medical Internet" that challenges the notion that patients and health-professionals simply receive content. A deeper level of interaction would be to facilitate the development of websites and services by the user for the user. For pharmacists, this richer experience may be attained by incorporating and customizing existing internet tools for the purpose of improving access to information, collaboration amongst colleagues, and patient care.

Goals and Objectives

1. To identify selected "Medical Internet" resources that may be recommended to patients and/or colleagues as credible and useful sources of health information.
2. To identify selected internet tools and services that may be easily adapted and customized in order to improve access to information, collaboration amongst colleagues and patient care.

Self-Assessment Questions

1. What are some factors that both patients and health-care professionals have identified as being important indicators for quality on the "Medical Internet"?
2. What are some common barriers to developing customized "Medical Internet" resources and how can they be overcome?

Cardiac Diagnostic Testing – A Primer for Pharmacists

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

Cardiovascular disease (CVD) is the leading cause of death in Canada, accounting for 37% of total mortality. Before the principles of evidence-based pharmacotherapy can be applied for patients with CVD, appropriate investigative testing must be undertaken to confirm the diagnosis and/or evaluate the disease process for prognosis and therapeutic stratification. A plethora of cardiac diagnostic tests exist and are commonly employed for these purposes in clinical practice. Each cardiac diagnostic testing modality evaluates and provides data on one or more of the following aspects of the heart's function:

- structural and valvular anatomy;
- electrical activity and conduction;
- myocardial contractility and pump function; and
- myocardial perfusion and/or vascular competence.

While certain testing modalities are more routinely available, certain "gold-standard" tests do exist for the evaluation of various forms of CVD. In addition, there is some degree of overlap in the data provided by some of the different cardiac tests that are commonly utilized in practice.

The goal of this session is to provide pharmacists with an understanding of the common cardiac tests used to provide diagnostic, prognostic, and therapeutic information about various cardiovascular disorders. In discussing each of the cardiac diagnostic testing modalities, the expected data provided by the results of each test will be emphasized for the purpose of illustrating their application to the pharmacotherapeutic management of the patient by clinical pharmacists. In addition, medication indications/contraindications for patients undergoing cardiac testing will be discussed, where applicable.

Goals and Objectives

1. To provide pharmacists with an understanding of the common cardiac tests used to provide diagnostic, prognostic, and therapeutic information about various cardiovascular disorders.
2. To review the potential application of cardiac testing results by pharmacists in the pharmacotherapeutic management of patients with various cardiovascular disorders.

Self-Assessment Questions

1. What is the gold-standard cardiac test used to evaluate the anatomy of the coronary arteries and myocardial perfusion?
   a. exercise-stress test
   b. cardiac angiogram
   c. echocardiogram
   d. chest x-ray
2. A maximum oxygen uptake (VO2 max) test is a special form of exercise testing with gas exchange analysis which can provide an accurate assessment of a patient's exercise capacity and cardiopulmonary reserve.
   a. True
   b. False

The Role of Ipratropium in Combination with Tiotropium

Charles Bayliff, BScPhm, PharmD, London Health Sciences Centre, London, ON

Chronic Obstructive Pulmonary Disease (COPD) is the 4th leading cause of death in Canada. It is also a very expensive disease to manage both in terms of resources required and costs incurred most of which are due to hospitalization costs.

The Canadian Thoracic Society (CTS) has published guidelines for the management of COPD and updates these guidelines on a regular basis. The CTS recommends anticholinergic bronchodilators as a primary therapy for the management of COPD. While most of the information provided in these guidelines deals with the chronic disease management, there is some information provided on the management of the patient with an acute exacerbation requiring hospitalization. What information is available is usually based on consensus rather than controlled trials.

Often COPD patients also have comorbidities including coronary artery disease, congestive heart failure and diabetes mellitus and this may complicate selection of drug and dose as well as their overall management, and these aspects as well as the severity of disease need to be considered.

The role of various bronchodilators in a patient with an exacerbation of COPD requiring hospitalization will be reviewed with the focus of maximizing benefit while minimizing risk.

Goals and Objectives

1. To provide pharmacists with an overview of the role of anticholinergic bronchodilators in the management of hospital based COPD exacerbations.
2. To provide pharmacists with an understanding of the benefits and limitations of various aerosol devices so as to meet specific needs of an individual patient.

Self-Assessment Questions

1. What is the optimal dose of ipratropium for a patient experiencing an acute exacerbation of COPD?
2. Which of the following drugs aggravate V/Q mismatch?

   a. prednisone

   b. tiotropium

   c. salbutamol

Practical Considerations with Glargine Insulin

Henry Halapy, BSc(Pharm), PharmD, St. Michael's Hospital, Toronto ON

The goal of this session is to provide pharmacists with an understanding of some of the practical considerations with the novel insulin glargine and its dosing.

Glargine is a novel insulin analogue with unique pharmacokinetic properties. Its lack of peak levels and its long-acting duration of action make insulin glargine ideal to be used as a basal insulin in diabetic insulin regimens. Insulin glargine has found use in patients with both type one and type two diabetes and appears to be as effective as NPH insulin. However, some trials have shown that insulin glargine produces comparatively less hypoglycemia than NPH insulin1. Therefore, practical experience has demonstrated that patients experiencing frequent episodes of hypoglycemia or have blood glucose levels that swing easily have found benefit from using insulin glargine as a basal insulin.

Given that insulin glargine is relatively new, dosing practices have been emerging as clinical experience with its use accumulates. For example, when converting a patient from basal NPH insulin to an insulin glargine regimen, it has been noted that a reduction in the starting dose of insulin glargine (often a 20% reduction is used) is helpful to prevent hypoglycemia. Titration of glargine can be accomplished by increasing the dose by 1 unit every few days until fasting blood sugars of 4-7 mmol/L are achieved. Ongoing practical considerations of insulin glargine dosing remain to be determined as more practical experience accumulates with this medication.

Goals and Objectives

1. To provide pharmacists with an understanding of some of the practical dosing issues with the novel insulin glargine.
2. To enable pharmacists to better make recommendations regarding insulin glargine dosing and titration.

Self-Assessment Questions

1. What pharmacokinetic principles allow for insulin glargine?
2. How should one convert from an insulin regimen containing NPH insulin as the basal insulin to glargine insulin as the basal insulin?

IV Quinine – Do You Know How to Get It?

Carolyn Bubbar BSP, ACPR, PharmD Candidate (University of Toronto)

Malaria is a tropical disease caused by four species of the genus Plasmodium. Malaria is transmitted primarily through the bite of an infected Anopheles mosquito. Patients with severe malaria caused by the species P.falciparum may progress rapidly to develop end organ failure within 24 to 48 hours. Patients who develop severe malaria have a mortality rate of approximately 20% and therefore, this infection should be treated as a medical emergency. The Canadian guidelines for the treatment of severe malaria recommend the use of intravenous quinine for patients with severe malaria. This drug is not marketed in Canada and can only be accessed through the federal government's Special Access Program. This program is called the Canadian Malaria Network which consists of a group of depots for intravenous quinine across the country. This program was established to facilitate storage and rapid distribution of the drug allowing 24-hour a day access. The Canadian Malaria Network also provides access to expert guidance in the management of this severe infection and collects surveillance data for Health Canada.

Goals and Objectives

1. To provide pharmacists with a brief review of malaria.

2. To increase awareness of the Canadian Guidelines for the Diagnosis and Management of Malaria and how to access them.
3. To review the recommendation for the use of IV quinine for the treatment of severe malaria.
4. To discuss the current process in place to access IV quinine in Canada through the Special Access Program (the Canadian Malaria Network).

Self-Assessment Questions

1. What is the definition of severe malaria?
2. What is the treatment regimen recommended for the treatment of severe malaria?
3. If I had a patient in my institution requiring IV quinine, what steps would I follow to access it? Would this change after-hours?

What is USP Chapter <797> and how do I Implement it?

Carolyn Bornstein, BScPhm, RPh, Southlake Regional Health Centre, Newmarket, Ontario

The goal of this session is to introduce pharmacists to USP Chapter <797>, the first practice standards in U.S. history for sterile pharmacy compounding.

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

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

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

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

Resources for facility assessment and implementation planning will be provided.

Goals and Objectives

1. To introduce pharmacists to USP Chapter <797>, the first practice standards in U.S. history for sterile pharmacy compounding.
2. To teach pharmacists how to determine the contamination risk levels of the sterile preparations provided by their facilities.
3. To facilitate the analysis of a pharmacy's sterile preparation practices and the preparation of an action plan to implement USP Chapter <797> standards, based on contamination risk levels.

Self-Assessment Questions

1. What is the hard-fast definition of a High Risk level sterile preparation?
2. What is a beyond-use date and how does it differ from an expiration date?
3. Name 3 resources for USP Chapter <797> implementation.

ASA Resistance: A Laboratory or Clinical Phenomenon?

Jeff Nagge, University Health Network, Toronto, ON

The term "aspirin resistance" has been used to describe both a reduced antiplatelet effect of aspirin, and the occurrence of vascular events in patients treated with aspirin. The extent to which these two phenomena are related is a hotly debated topic.

Goals and Objectives

By the end of the session, participants will be able to:

1. Differentiate between biochemical aspirin resistance and clinical aspirin resistance
2. Describe the strength of association between biochemical aspirin resistance and recurrent cardiovascular events
3. Develop a therapeutic plan for a patient with suspected aspirin resistance

Pharmaceutical Care Practice – What's New?

Lalitha Raman-Wilms, PharmD, University of Toronto, Toronto, ON

The goal of this session is to highlight the developments which have occurred in better defining the practice of Pharmaceutical Care, based on the work of Dr. Linda Strand and others.

Pharmaceutical Care has been incorporated in the teaching of undergraduate students and pharmacists from the early 1990s. Much of this was based on the original development of this practice model and included the nine steps in providing pharmaceutical care. These steps included the establishment of a patient relationship, information gathering, identifying drug-related problems, establishing pharmacotherapeutic outcomes, assessing alternatives, designing therapeutic and monitoring plans, and follow-up care to measure success. Since its inception, Pharmaceutical Care has been provided to many thousands of patients in various settings. Based on practice experience in over 20,000 patients, this care has become better understood and thus better defined. Pharmaceutical Care, as described now, makes it more practical and is consistent, in process and terminology, with the care provided by other health care professionals.

This session will focus on the current practice of pharmaceutical care and outline the steps and activities integral to this process.

Goals and Objectives

To provide pharmacists with an overview of the developments in Pharmaceutical Care, based on the work of Drs. Cipolle, Strand and Morley.

To provide pharmacists with an understanding of the steps and activities associated with this care.

Self-Assessment Questions

1. What are the components of the Patient Care Process?
2. What are the activities associated with each step in the Patient Care Process?

Racism in the Health Care System: Uncovering Bias and Developing Cultural Competency Skills for Pharmacists

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

Over the last five years, a number of studies have rocked the health care sector by demonstrating that that minority populations in the North America consistently suffer from disparities in all aspects of health care services, treatment and care. From advanced cancer treatment and renal transplant surgery right through to history-taking, laboratory tests, or adequacy of pain medications, differentials exist for members of non-white and Aboriginal communities.

Voices from within the profession of pharmacy, such as Bruce A. Berge (PhD), Professor and Head Pharmacy Care Systems at Auburn State University, Betsy Sleath (PhD, RPh) as well as others are urging pharmacists to heed the call of these findings and critically examine themselves and their work environments in order to advance a patient-centred practice.

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

Cultural competence can assist in uncovering our personal bias and creating positive working relationships and spaces. 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 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?

Practical Tips in Stroke Management

Tania Mysak, BSP, PharmD, Capital Health, Edmonton AB

The goal of this session is to provide pharmacists with practical information and

evidence that may be applied to both acute and sub-acute stroke patients.

Stroke is the 4th leading cause of death in Canada accounting for over 16,000 deaths per year. Aside from being a significant contributor to mortality, the economic costs of stroke account to over $2.7 billion a year. After the acute event, stroke continues to be a significant contributor to morbidity as patients may be left with deficits such as hemiparesis or aphasia as well as loss of driving privileges or inability to return to work.

There have been some advances in recent years to aid in the management of acute stroke, however evidence suggests these therapies have not been broadly implemented. As well, many of the risk factors for stroke are modifiable such as hypertension, diabetes mellitus, hypercholesterolemia and smoking. Finally, the sequelae of stroke make patients susceptible to infection or depression and require appropriate monitoring and management.

Using a case-based format, this presentation will illustrate areas in which a pharmacist can contribute to the care of stroke patients.

Goals and Objectives

1. To provide pharmacists with an understanding of the current evidence regarding management of stroke patients.
2. To enable pharmacists to apply the information learned to the pharmacotherapeutic management of stroke patients.

Self-Assessment Questions

1. What is the appropriate antithrombotic therapy for secondary prevention of stroke?
2. What is the optimal strategy for managing hypertension in the acute and sub-acute stroke patient?

In-Hospital Management of Diabetes

Wendy Gordon, PharmD, Royal Columbian Hospital, New Westminster, BC

Diabetes is associated with an increased risk of mortality after an acute coronary syndrome. Even in patients without a history of diabetes, hyperglycemia identified on admission correlates to higher mortality in the acute myocardial infarction patient.

Hyperglycemia has several deleterious cardiovascular effects. These include impaired ischemic preconditioning, increased infarct size, cardiac myocyte death through apoptosis and hemodynamic fluctuations.

The DIGAMI trial evaluated the use of insulin infusions in patients presenting with a myocardial infarction1. Based on this study the current Canadian Diabetes Association Guidelines recommend2:

All patients with acute MI with BG > 12 mmol/L should receive insulin-glucose infusion therapy to maintain BG between 7-10 mmol/L for at least 24 hours, followed by multidose SC insulin for at least 3 months (Grade A Level 1A)

Recently two new trials have been published evaluating insulin and glucose-insulin-potassium infusions in patients with acute myocardial infarction3,4,. This has lead to new debate over the use of insulin in the cardiac patient.

Goals and Objectives

1. To evaluate the current literature relating to the glycemic management of patients admitted with a diagnosis of acute myocardial infarction.
2. To develop a therapeutic plan for both diabetic patients and patients with hyperglycemia in the setting of an acute myocardial infarction.
3. To review the use of subcutaneous insulin sliding scales and insulin infusions for the hospitalized patient.

Self-Assessment Questions

1. Should all patients with a diagnosis of acute myocardial infarction be placed on an insulin infusion?
2. What factors would you take into account when developing an insulin sliding scale?
3. A patient with Type I diabetes is NPO for a procedure. What would you recommend for glycemic management?

Highs, Lows, & Everything in Between: Interpreting Liver & Kidney Function in the Acute & Chronic Setting

Lisa Burry, BScPharm, PharmD, FCCP Mount Sinai Hospital, Toronto, ON, Séadna Ledger, BScPharm, London Health Sciences Centre, London, ON

This session is designed to provide pharmacists with the skills necessary to interpret common laboratory parameters used in the assessment of the liver and kidney function. It is particularly important for pharmacists to understand the general principles of laboratory monitoring and the implication of abnormal values on drug therapy.. Furthermore, the focus of assessment should be on trends instead of isolated abnormal values, always taking into account patient-specific clinical information.

The presence of renal and/or liver failure, either as acute onset or chronic disease, has significant impact upon the provision of pharmaceutical care such as pharmacotherapy selection, dosing, and monitoring. An understanding of general physiology of the liver and kidney, factors that alter organ function, and how to assess function are essential for hospital pharmacy clinicians to appropriately manage a patients' pharmacotherapy.

Goals and Objectives

The intent of this session is not to make the pharmacist a diagnostician, but rather to improve upon the pharmacist's basic understanding of laboratory value interpretation and assessment of liver and kidney function. To achieve the objectives listed below, the workshop will consist of both didactic and case-based learning opportunities:

1. To understand the general principles involved in laboratory monitoring.
2. To review basic physiology of the liver & kidney.
3. To become familiar with the various methods for interpreting liver & kidney function & understand the advantages/limitations of each.
4. To work through examples of interpreting liver & kidney function and subsequently altering drug therapy based on the assessment of organ function.

Self-Assessment Questions

1. What is the definition of acute renal failure? Chronic renal failure?
2. List the methods for assessing a patient's renal function? What are the advantages and disadvantages of each?
3. What is the definition of acute liver failure? Chronic liver failure?
4. List the methods for assessing a patient's liver function? What are the advantages and disadvantages of each?

Using Acute Myocardial Infarction (AMI) Guidelines to Improve the Care of Your Patients: Taking Evidence to the Bedside

Ann Thompson, BScPharm, Capital Health, Halifax, Nova Scotia

The treatment of myocardial infarction has become increasingly complex as many pharmacologic agents emerge with new indications. Moreover, the combined use of multiple antiplatelet and anticoagulant therapies places an increased emphasis on safety in the acute and chronic setting.

Evidence supports specific therapies in the AMI setting to reduce morbidity and mortality. Clinical practice guidelines are then developed by many experts to convey a sound treatment approach, based on the best evidence. While national trends demonstrate improved use of evidence-based therapies, there is still opportunity for improvement as therapeutic gaps remain. A number of Canadian tools have been developed (Safer Healthcare Now! Campaign and the Canadian adaptation of the ACC/AHA guidelines) to help improve our overall management.

This workshop will focus on the application of evidence-based pharmacotherapies in the clinical setting of acute myocardial infarction and its post-discharge management for secondary prevention. The foundation of this will be discussed with participants around a variety of clinical scenarios.

Goals and Objectives

1. To provide pharmacists with an evidence-based treatment approach to the management of acute myocardial infarction
2. To provide case-based examples of therapeutic dilemmas in the treatment of acute myocardial infarction
3. To emphasize appropriate therapies that should be considered before discharging patients after they have had an AMI
4. To increase awareness of the Safer Healthcare Now Campaign

Self-Assessment Questions

1. What is the role of beta-blocker therapy in the treatment of AMI?
2. Should every patient who has an MI be started on atorvastatin 80mg?
3. Should all patients receive clopidogrel in the setting of AMI? If so, how should it be dosed?

Osteoporosis and the Elderly – The use of Bisphosphonates and Parathyroid Hormone

Thomas ER Brown, PharmD, University of Toronto and Sunnybrook and Women's College Heath Sciences Centre

The goal of this session is for pharmacists to understand some of the challenges in preventing and treating osteoporosis in elderly patients.

The prevention and treatment of osteoporosis has significantly changed in the last two years for three reasons:

Hormone replacement therapy is no longer used routinely as a first line agent due to the results of the Women's Health Initiative trial.

Parathyroid hormone the first agent that builds bone is available in Canada.

The role of combination therapy and its effect on bone density and fracture risk is controversial.

Goals and Objectives

1. To provide pharmacists with an understanding of the challenges in preventing and treating osteoporosis in the elderly.
2. To discuss the role of various therapeutic agents and strategies in the prevention and treatment of osteoporosis

Self-Assessment Questions

1. When should combination therapy for osteoporosis be used?
2. What is the role of parathyroid hormone in elderly patients with osteoporosis?
3. What are therapeutic endpoints in monitoring patients with osteoporosis?

Risks and Benefits of Atypical Antipsychotics in the Elderly

Suaad Ibrahim BSC (Pharm), Regional Mental Health Care, London, ON

Older patients are more sensitive than younger adults to the side effects of antipsychotics.The aim of pharmacotherapy in dementia is to improve the disturbing behavioral and psychological symptoms without causing unacceptable side effects or exacerbating underlying cognitive impairment. Antipsychotics are used to control psychosis and aggression in the later stages of dementia. However, evidence of their efficacy in BPSD, is supported by few, small and short term randomized controlled trilas (RCTs). Atypical antipsychotics are considered to be associated with less neurological side effects than typical (conventional) antipsychotics. Thus, there is less need for anticholinergic drugs, which is particularly important in the elderly with dementia who are at high risk for confusion.

There is documented evidence that atypical antipsychotic induce non-neurological side effects such as weight gain in younger adults, but few data address this liability in the elderly. As well, data from some RCTs found that the use of atypical antipsychotics in elderly with dementia increases risk of mortality from all causes, mostly, cardiovascular events and infection. Metanalyses, systematic review and cohort studies question the significance of these findings and suggest presence of confounding factors at baseline. Larger long term RCTs are needed to provide concise, evident-based recommendations on the use of atypical antipsychotics in the elderly with dementia.

Goals and Objectives

To discuss the clinical effectiveness and safety of atypical antipsychotics in treatment of behavioral and psychological symptoms of dementia (BPSD) in the frail elderly.

Self-Assessment Questions

1. What is the safety profile of atypical antipsychotics in the frail elderly with dementia?
2. When and how should atypical antipsychotics be used to control behavioural and psychotic symptoms of dementia?

Controversies in the Management of Dementia

Allan Mills, Pharm.D., Trillium Health Centre, Mississauga, ON

As we continue to care for patients with dementia and gain experience in using the acetylcholinesterase inhibitors more and more questions arise around the optimal method to prevent and control dementias.

Research is showing that there are differences in the pathophysiology of the various types of dementias leading to questions regarding the optimal way to approach each type of dementia. In particular, multiple subtypes of vascular dementia (VD) have been articulated which calls in questions the general approach to vascular dementia. Should we be looking for specific preventative and treatment strategies for each subtype or is the current strategy of treating VD sufficient?

As we continue to use acetylcholinesterase inhibitors we are also faced with questions of how long should we use these agents and at what point is treatment no longer warranted. There is significant controversy around using these agents in severe dementia (MMSE <10) and limited data around the effect of stopping these agents. With the current measurement tools frequently used in clinical practice (MMSE) it is difficult to determine adequate response and just as difficult to predict the effect of withdrawal. Switching to another agent has been proposed as an option but this is not always effective.

The identification of mild cognitive impairment (MCI), a transitional stage between normal aging and Alzheimer's Dementia, has generated interest in trying to prevent or control the symptoms of

dementia at the highest level of functioning. Currently there is no agreed upon classification system or subtype definition which leads to many clinicians wondering how to optimally treat these patients and if specific subtypes (language, memory) predict different dementias. Also some study data does not support long term benefit using donepezil causing others to wonder if this strategy is effective in MCI. Superimposed on these questions is the addition of memantine to our armamentarium and where it stands as a treatment option.

Goals and Objectives

At the end of this session the participants will be able to:

1. List the different types of vascular dementia and relate how this may or may not affect treatment options
2. Describe the current state of the literature surrounding mild cognitive impairment and contrast these results to that of Alzheimer's Dementia
3. Demonstrate an understanding of the difficulties around long term use of acetylcholinesterase inhibitors for Alzheimer's Dementia including switching, stopping and using the agents at low MMSE scores (<10) as well as the role of memantine.

Monday, January 30 ▪ Lundi le 30 janvier

Medication Reconciliation – Safer Healthcare Now!

Edward Etchells, M.D., MSc, FRCP, Sunnybrook and Women's College Health Sciences Centre, Toronto, ON

Reconcilable Differences: Can Safer Healthcare Now! Reduce Adverse Drug Events in Canadian Hospitals?

Goals and Objectives

The goal of this session is to review the epidemiology of medication errors at times of transition (admission, transfer, and discharge), and evidence of effectiveness of medication reconciliation, and to review the objectives of the Safer Healthcare Now! Medication reconciliation project.

Self-Assessment Questions

1. What are unintended medication discrepancies?
2. What are undocumented intended medication discrepancies?
3. What proportion of patients admitted for general medical problems have at least one unintended medication discrepancy at the time of admission?

Learning from Medication Incident Data: The Role of the Canadian Medication Incident Reporting and Prevention System (CMIRPS)

Michael Hunt, BScPhm, Manager Pharmaceuticals, Canadian Institute of Health Information, Ottawa ON, Sylvia Hyland, RPh BScPhm MHSc, Vice President, Institute for Safe Medication Practices Canada, Toronto ON, Lili Loorand-Stiver, BScPhm, Patient Safety Analyst, Health Canada, Ottawa ON

The goal of this session is to provide pharmacists with an overview of the CMIRPS initiative, and its current status.

CMIRPS is a medication incident reporting and prevention system, currently in the development stages, that will strengthen the Canadian healthcare system's capacity to report, analyze and manage medication incident data on a national basis, with a view to understanding why these events happen and how they can be prevented in the future. It will promote an open, "blame-free" system that encourages healthcare practitioners to voluntarily share their experiences with medication incidents.

CMIRPS, a collaborative effort of the Canadian Institute for Health Information (CIHI), Health Canada and the Institute for Safe Medication Practices Canada (ISMP Canada) has the objective of reducing preventable medication incidents in Canada. Ultimately, data reported and shared through the CMIRPS initiative will support lessons learned in one jurisdiction being available to reduce the risk of similar incidents occurring elsewhere. Annual reports, information bulletins and root cause analyses will contribute to the overall picture of patient safety by identifying areas for system/process improvement.

Funding for this initiative is being made available by Health Canada.

Goals and Objectives

1. To provide pharmacists with an overview of the CMIRPS initiative, and its current status.

2. To provide an overview of the roles of the collaborating organizations involved in the development of CMIRPS.
3. To highlight the benefits of participating in the CMIRPS initiative.

Self-Assessment Questions

1. Who are the collaborating organizations in the CMIRPS initiative, and what are their respective roles?
2. Identify critical factors for a successful medication incident reporting program.
3. How can a national system for reporting medication incidents improve patient safety at the local level?
4. What types of data will be collected and analyzed through CMIRPS?

Atrial Fibrillation – Shocking New Discoveries

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

Atrial fibrillation remains the most common arrhythmia in hospitalized patients, impacting pharmacists irrespective of their practice site. There have been several recent advances in the understanding of the pathophysiology of atrial fibrillation. This has led to several new treatment modalities. Atrial fibrillation remains one of the dysrhythmias that medications are still used, both in the conversion to and maintenance of sinus rhythm. New drugs are being developed and will be discussed. As well, old medications are used, often inappropriately.

In 2004, the Canadian Cardiovascular Society released a consensus statement on the treatment of atrial fibrillation. This document can help the pharmacist in the choice of goals of therapy and medication selection.

Goals and Objectives

By the end of the session the attendee should be able to:

1. List the recommendations from the CCS A Fib consensus conference that affects a hospital pharmacist
2. List new antiarrhythmic agents for the treatment of atrial fibrillation
3. List effective agents for the prophylaxis of post-op atrial fibrillation

Self-Assessment Questions

1. List the target ventricular response rate for an individual in atrial fibrillation.
2. Describe the benefits of using a fib prophylaxis in a patient undergoing open heart surgery
3. Describe two new therapies for individuals with atrial fibrillation.

A Practical Approach to Managing HIV Drug Interactions

Debbie Kelly B.Sc.(Pharm.), Pharm.D. Memorial University of Newfoundland, and Eastern Health, St. John's, NL

The goal of this session is to provide non-HIV specialist pharmacists with an overview of clinically important drug interactions they may encounter in caring for HIV patients. The focus will be on interactions between antiretrovirals and medications used in general practice.

Interactions with antiretroviral medications are frequent, plentiful and complex. Pharmacists should be aware of this interaction potential as consequences may include significant toxicity or drug failure. Both pharmacodynamic and pharmacokinetic interactions are common. Furthermore, many specific drug combinations have not been studied so interactions must be anticipated based on knowledge of pharmacokinetic and pharmacodynamic parameters.

Pharmacists may feel overwhelmed when providing care to patients with HIV infection, due to the complexity of the illness and drug therapy. This session aims to increase pharmacists' comfort level by reviewing some common interactions between HIV-specific and non-HIV specific therapies, and suggesting a practical approach for anticipating and assessing possible interactions.

Goals and Objectives

1. To review common mechanisms of drug interactions with antiretroviral agents
2. To provide a practical approach for anticipating potential interactions with HIV therapy
3. To illustrate some clinically significant interactions through the use of actual patient cases

Self-Assessment Questions

Consider the interaction potential in each scenario:

1. A patient receiving triple antiretroviral therapy including atazanavir requires PPI therapy to treat esophageal and duodenal ulcers.
2. A patient taking an antiretroviral regimen containing lopinavir/ritonavir receives fluticasone for the treatment of asthma
3. A patient controlled with triple antiretroviral therapy including efavirenz is started on phenytoin for treatment of a generalized seizure.

ACEI versus ARB in High-Risk Vascular Patients

ACEI: Jennifer Pickering, BScPhm, Hamilton Health Sciences, Hamilton, ON

ARB: Bill Semchuk, M.Sc., PharmD, FCSHP, Regina Qu'Appelle Health Region, Regina, SK

The goal of this session is to provide pharmacists with an understanding of the relevant clinical evidence supporting the usage of angiotensin converting enzyme inhibitors (ACEI) and angiotensin receptor blockers (ARB) in the treatment of high risk vascular patients. The two speakers will debate the pros and cons of this group of agents.

There is extensive evidence for the usage of ACEIs for the long- term benefit in high risk vascular patients. Recent evidence with ARBs when compared to ACEI have shown ARBs to be non-inferior but have failed to show their superiority. The clinical debate is whether the two group of agents are equivalent or interchangeable. There have been conflicting publications on this topic, one suggesting increase in myocardial infarction and another showing no increase. This evidence will be reviewed and debated in order to optimize care in the high risk vascular patient.

Goals and Objectives

1. Discuss the evidence pertaining to ACE inhibitors in high risk vascular patients.
2. Discuss the evidence pertaining to angiotensin receptor blockers in high risk vascular patients
3. Pharmacist will be able to apply this evidence in selecting an appropriate agent for their patient.

Self-Assessment Questions

1. What is a high risk vascular patient?
2. Is there a difference between ACEI or ARB in the treatment of a high risk vascular patient?

The Alphabet Soup of Cardiac Devices

Jenny Chiu, BScPhm, ACPR, RPh, Mount Sinai Hospital, Toronto, ON

"PPM, DES, ICD, BiV, CRT, LVAD"—What are the ingredients for the cardiac devices alphabet soup? The goal of this session is to provide pharmacists with the knowledge of the place in therapy of cardiac devices.

More and more, devices are implanted into individuals to complement medical therapy in order to improve their quality of life and in some cases to prolong it. The insertion of PPMs (permanent pacemakers) has been very effective in treating heart block. Bare metal stents and DES (drug-eluting stents) have decreased morbidity outcomes in acute coronary syndromes.

Heart failure therapy remains a challenge. Despite having several drugs which have shown survival benefit (eg. ACE inhibitors, beta-blockers, spironolactone), mortality remains high. Devices may prolong survival, however their insertion can be costly and not without risk. This session will review device therapies available (implantable cardioverter-defibrillator (ICD), biventricular pacemaker (BiV)/cardiac resynchronization therapy (CRT) and left ventricular assist device (LVAD)), criteria for its insertion and possible implications to patients' medical regimens which pharmacists should be aware of.

Goals and Objectives

1. To provide pharmacists the knowledge of devices available to cardiac patients to complement medical therapy
2. To familiarize pharmacists the place in therapy of cardiac devices

Self-Assessment Questions

1. Does my fainting patient require a device?
2. Does my "frequent flyer" patient warrant some "alphabet soup"?
3. Do I need to change my patient's medical regimen post-device insertion?

Role of the Pharmacist in a Lipid Clinic

Wm. Semchuk, M.Sc., Pharm.D., FCSHP, Regina Lipid Clinic, Regina Qu'Appelle Health Region

Vascular risk factors are prevalent in society and large gaps exist between optimal treatment as described by current consensus statements and actual treatment rates and goal obtainment. The reasons for these gaps are not fully elucidated and likely diverse. In order to optimize management for select patients, multidisciplinary clinics have been developed. The Regina Lipid Clinic is a referral clinic that deals primarily with patients who have experienced challenges in obtaining control of their cholesterol as well as those who have suffered an event previously. The clinic is staffed by endocrinologists, dietitians and pharmacists.

The role of the pharmacist within the clinic include both direct patient care activities and non direct patient care activities. The former include: acquisition of complete drug and non prescription product histories, assessment of adherence to therapy, extensive patient education activities, consultation and recommendations on pharmacologic therapy and long term patient monitoring for efficacy and

safety of prescribed therapy. Non direct patient care activities include provision of educational outreach to non clinic physicians, pharmacists, nurses and dietitians, patient educational symposia and editing of a lipid clinic newsletter.

This presentation will overview the various aspects of care provided by the pharmacist in the clinic.

Goals and Objectives

By the end of this presentation, the attendee will be able to:

- Discuss opportunities for pharmacists in a lipid clinic
- Describe challenging situations within a lipid clinic environment
- Utilize knowledge gained to consider a role in a lipid clinic

The Role of the Pharmacist in Cardiac Rehab

Derek Jorgenson, BSP, PharmD, Saskatoon Health Region, Saskatoon, SK

Cardiovascular disease continues to be the most common cause of death in the western world. While primary prevention strategies may ultimately have the greatest impact on reducing the consequences of this disease on our population, secondary prevention will always play an important role in reducing cardiovascular events.

Cardiovascular rehabilitation programs are common tool used across the country to reduce the risk of recurrent vascular events. These programs can take many different forms ranging from exercise-only programs to those that offer intensive education and risk factor modification interventions. The impact of these programs is well documented in the literature; however, it is less clear what the role of the pharmacist should be in this specialty setting.

This presentation will the broad range of potential roles, and the supporting evidence, that a pharmacist can play in the various types of cardiovascular rehab programs that exist.

Goals and Objectives

1. To provide participants with an understanding of the importance of the role of the pharmacist in cardiac rehab programs.
2. To provide participants with an overview of the wide range of roles that a pharmacist can play in cardiac rehab.

Self-Assessment Questions

1. Has one model of cardiac rehab program been proven to be superior over any other?
2. Has the inclusion of a pharmacist on the cardiac rehab team been proven to reduce cardiovascular mortality?

Tuesday, January 31 ▪ Mardi le 31 janvier

Do Bugs Need Drugs? A Community Program for Wise Use of Antibiotics

Edith Blondel-Hill, MD, FRCP, BC Children's Hospital, Vancouver BC, Susan Fryters, BSc.Pharm., Capital Health, Edmonton AB

Do Bugs Need Drugs? is a community education program promoting the wise use of antibiotics. The program focuses on three key messages

- Handwashing is the best way to stop the spread of infections.
- Not all bugs are created equal. Bacteria and viruses are different; antibiotics work against bacteria but not against viruses.
- Use antibiotics wisely. Antimicrobial resistance is a public health problem.

Do Bugs Need Drugs? was initiated in 1997 in Grande Prairie, Alberta and expanded to the Capital Health region in 2000. Currently the program is in use in 7 of 9 Alberta health regions and is currently being implemented throughout the province of British Columbia.

Components of the Do Bugs Need Drugs? program include healthcare professional education, a public campaign with television advertising, a grade 2 program and a daycare program. Print materials have been developed and include posters, a Bugs and Drugs antimicrobial pocket reference for pharmacists and physicians, a pamphlet, and a 20 page parent guide. Both the pamphlets and parent guides have been translated in 8 different languages including French, Spanish, Traditional Chinese, Simplified Chinese, Vietnamese, Arabic, Farsi and Punjabi.

A website www.dobugsneeddrugs.org has been developed which includes information for healthcare professionals, teachers, childcare workers, and the public. The grade 2 and daycare programs, materials in translation, Bugs & Drugs book, and links to other relevant

websites are included on this website. The site averages about 4,500 hits per day.

Goals and Objectives

1. To provide pharmacists with information on an educational program that is available to healthcare professionals and the public to help address antimicrobial resistance.
2. To familiarize pharmacists with the Bugs and Drugs book - a reference for the management of infectious diseases.

Self-Assessment Questions

1. What is the importance of antimicrobial resistance with respect to community antibiotic use?
2. How can I best use the materials from the Do Bugs Need Drugs? program to improve antibiotic utilization?

Meeting the Challenges of Medication Reconciliation in Elective Surgery Patients: Verify, Clarify, and Reconcile

Virginia Carvalhana, BSc.(Hon), Pharm.D., Mount Sinai Hospital, Toronto, ON

Medication reconciliation is a step-wise approach to ensuring patient continuity of care. It encompasses a number of processes in which pharmacists make vital interventions. A thorough interview with the patient and/or caregiver with respect to current medications (dose, formulation, route of administration, frequency, etc), and allergy status prior to admission provides the foundation for medication reconciliation. These medications are subsequently clarified, and admission/transfer orders written by physicians are reconciled to optimize drug therapy at the particular stage in the continuum of care.

From a surgical perspective, there are a number of medications that should be discontinued, held, or substituted upon admission – a reconciliation process allows for identification of these, and other high risk medications that require further follow-up throughout patient admission.

In the wake of heightened awareness and concern regarding medication safety, medication error prevention, and seamless care, there is a growing pressure to employ strategies to eliminate “preventable errors” at all levels of patient care. Medication reconciliation is not a one-time procedure, but rather a continuous process that should follow a patient throughout the healthcare system.

The goal of this session is to provide pharmacists with a clear understanding of medication reconciliation; what it means, and how it is implemented.

Goals and Objectives

1. To provide a conceptual understanding of medication reconciliation and to review evidence supporting its implementation to practice.
2. To present possible procedures/tools that can be utilized to ensure optimize patient transfers, including those used at Mount Sinai Hospital.

Self-Assessment Questions

1. What is the definition of medication reconciliation?
2. List 5 barriers to obtaining a complete medication history?
3. List the fundamental steps of medication reconciliation?

Pharmacist’s Role in Medical Mission to Guyana

Reshma Dole, BSc(Pharm), Lakeridge Health Corp., Whitby ON

The goal of this session is to provide pharmacists with an opportunity to learn about the challenges and accomplishments of a multidisciplinary medical team mission and the important role of the pharmacist.

The medical mission organized through Ve’ahavta – the Canadian Jewish humanitarian and relief committee is unique in it’s structure compared to other programs as it includes a wide variety of disciplines, including physiotherapists, medical residents, physicians practicing in various fields and research assistants. The aim is to provide medical care to the neediest communities and to educate personnel within these communities to improve health care infrastructure and community development.

The team pharmacist is involved with the organization of medication supplies, procuring donated items through industry, fund-raising and determining which medications are of the highest priority.

Goals and Objectives

1. To provide pharmacists an insight into novel opportunities that may be available to them.
2. To raise awareness of charitable medical missions to underdeveloped countries and in particular the importance of pharmacists on such missions.

Self-Assessment Questions

1. What should a pharmacist take into consideration prior to undertaking a medical mission
2. What is the role of a pharmacist in a multidisciplinary medical team?
3. How do we measure the effectiveness of our team and raise awareness of issues concerning underdeveloped countries.

What Strategies can Pharmacists Use to Effectively Impact Prescribing Practices? An Evidence-Based Review

Janet E. Martin, PharmD, Coordinator, Pharmacy Services, London Health Sciences Centre

Prescribing of evidence-based drug therapies remains suboptimal, even for common drugs with a strong evidence base. Pharmacists are uniquely positioned to play an active part in optimizing patient care related to drug therapy. Achieving positive impact, however, continues to pose formidable challenges for pharmacists who are not (usually) the prescriber, and must therefore rely on strategies implemented through physicians to make changes in drug therapies.

The goal of this presentation will be to provide an evidence-based overview of the evidence for interventions that can be used to effectively impact physicians' prescribing practices. Secondarily, differences in intervention complexity, setting, sustainability, cost-effectiveness and impact on patient outcomes will be explored.

Evidence-based systematic reviews and meta-analyses of studies evaluating the impact of strategies targeting prescribing practices reveal that effective interventions include reminders (manual and computerized), audit and feedback, academic detailing, and patient mediated interventions. Less effective interventions included passive dissemination of information and didactic lectures. Multi-faceted interventions that include combinations of the above strategies have been shown to be more efficacious than single interventions. A number of additional candidate interventions (ie, formulary restriction, financial incentives or disincentives) have been inadequately evaluated in clinical trials. Furthermore, limited evidence has precluded reliable exploration of the effects of interventions in different settings (hospital versus community), sustainability of effect, cost-effectiveness, and patient clinical outcomes (changing not only prescribing practices, but also patient outcomes).

Rather than relying primarily on passive didactic lectures or dissemination of guidelines, pharmacists' efforts to positively impact prescribing practices should focus on proven strategies such as academic detailing, audit and feedback, reminders, and patient-mediated interventions.

Goals and Objectives

1. To explore the range of strategies available to pharmacists to positively impact prescribing practices based on the best available evidence.
2. To discuss the characteristics of interventions that are predictive of positive impact on prescribing behaviours.
3. To discuss the key shortcomings in the existing evidence base, and to suggest a future research agenda for evaluating interventions to influence prescribing.

Self-Assessment Questions

1. Name 6 different types of 'interventions' or 'strategies' that can be used to influence professionals' prescribing behaviours.
2. Which of these interventions are most effective for impacting prescribing behaviour?
3. What are some of the key gaps in this area that should be addressed in future research?

How to Integrate Evidence-Based Medicine into Your Daily Practice: Help for the Busy Clinician

Trudy Arbo, B.Sc.Pharm, ACPR, PharmD, Aaron Tejani, B.Sc.Pharm, PharmD

The goal of this workshop is to provide participants with effective and practical skills to evaluate and implement EBM into your current clinical practice. Throughout this workshop, we will discuss the importance of developing a clear and concise clinical question (using the PICO method) before attempting to search for a topic or clinical problem and learn how to formulate this type of question. We will also discuss the best places to search for quality summaries of the evidence (secondary resources) as well as learn (or re-learn) the important aspects of critically reviewing available evidence. This is an interactive workshop.

Goals and Objectives

1. To enable participants to develop clear and concise clinical questions in order to effectively and efficiently search for target clinical information.
2. Understand the hierarchy of evidence and the advantages and disadvantages of each level.

3. Provide participants with a list of 5 useful websites available to facilitate EBM implementation into clinical practice
4. Provide a number of resources to allow the participant to further knowledge in the realm of EBM.
5. Feel confident with current critical appraisal skills and be able to apply them to the evidence

Self-Assessment Questions

1. List two useful EBM websites and their main target audience. Also describe how this website could be useful to you in your current practice
2. Describe the aspects of PICO and why it is so important when searching for a clinical question.
3. Outline the value of a systematic review and meta-analysis and describe how to identify a good quality systematic review and meta-analysis.

Measuring Your Department's Progress in the Advancement of Pharmacy Practice and Patient Safety

Patricia Macgregor, B.Sc.(Pharm), The Scarborough Hospital, Scarborough, ON and Nancy Roberts, B.Sc(Pharm) FCSHP, The Moncton Hospital, South-East Regional Health Authority, Moncton, NB

Since 1985 the Hospital Pharmacy in Canada Annual Report (HPCR) (also referred to as the Lilly Survey), has collected information on hospital pharmacy practice in the Canadian environment. The survey is National, involving participants from acute care community and teaching hospitals from most Canadian provinces. Data for numerous indicators has been consistently collected since the inception of the report for the following practice areas:

- Demographics, including organizational management structures
- Clinical Pharmacy Services
- Drug Information and Drug Use Evaluation
- Drug Distribution
- Drug Purchasing and Inventory Control
- Human Resources
- Medication Safety
- Technology
- Education and Research
- Pharmacy Staffing and Drug Costs for Clinical Programs
  - Acute Care Hospitals
  - Pediatric Hospitals

During part one of the workshop participants will be introduced to the data, indicators, trends and key discussion points contained in the various chapters of the HPCR.

In part two of the workshop participants will conduct a mini self-operational review, preferably using their own pharmacy's survey data survey to benchmark their progress in the attainment of best practices and patient safety and to develop a customized working document for use in their own organization. Workshop participants will receive a template of the benchmarking power point presentation via email post conference.

Goals and Objectives

1. To become familiar with the data and indicators contained in the 2004 HPCR.
2. To learn how to effectively use the data to identify and prioritize opportunities to enhance pharmacy services and patient safety within the participants organizations.

Self-Assessment Questions

1. What is the average FTE pharmacist assigned to emergency departments in acute care hospitals?
2. What is the average drug cost per patient day for any defined clinical program in acute care or pediatric hospitals in Canada?
3. What % of adult acute care hospitals use bar codes in the medication systems process. What % at point of care?

The ABCs of RBCs: An Interactive Talk about Anemia in Chronic Kidney Disease

Jenny Ng, BScPhm, ACPR, Sunnybrook and Women's College HSC, Toronto, ON

Stephanie Ong, BScPhm, ACPR, University Health Network, Toronto, ON

Anemia in patients with chronic kidney disease (CKD) is caused by numerous factors, including decreased erythropoietin production, increased blood loss, decreased red blood cell survival, inflammation, and iron deficiency. This may result in decreased cognition and increased left ventricular hypertrophy leading to a decreased quality of life and morbidity in these patients.

Target hemoglobin in the CKD population differs from that of the general population. Controversies behind the target hemoglobin for the CKD population will be discussed in this session.

Treatment of anemia of CKD changed radically in the mid 1980s with the introduction of recombinant erythropoietin (rHuEPO) and recently there have been some additional therapies available to add to the armamentarium.

In addition to erythropoietin therapy, iron supplementation plays a significant role in the management of anemia of CKD. Iron indices are evaluated regularly in patients with anemia of CKD to ensure proper anemia management. Current tests available to evaluate a patient's iron status may not be ideal for the accurate evaluation. Oral supplementation is often inadequate for the maintenance of iron stores in hemodialysis patients due to issues with drug interactions, decreased absorption and poor tolerance. Various intravenous preparations are available and different dosing regimens have been evaluated for repletion and maintenance therapy.

In this workshop you will learn how to evaluate anemia of CKD, review the therapeutic options available for treatment and gain a better understanding of how to monitor these therapies when caring for patients with CKD related anemia.

Goals and Objectives

1. To provide an overview of the pathophysiology of anemia related to chronic kidney disease.
2. To review the treatment options available for anemia related to chronic kidney disease.
3. Highlight the targets required in the management of chronic kidney disease related anemia.
4. Discuss the monitoring parameters needed in the care of patients with chronic kidney disease related anemia.

Self-Assessment Questions

1. In addition to hemoglobin what other parameters can be monitored for anemia of CKD?
2. What are the differences between epoetin alfa and darbepoetin?
3. What parameters are measured to monitor for iron deficiency and what are the differences between iron replacement options for anemia of CKD?
4. What is Pure Red Cell Aplasia and how to do you monitor for it?

Efficient Prescription Triage

Christine Davis, BSc(Pharm), PharmD, Grace Hospital, Winnipeg

Prescription triage is a critical step in the pharmacy portion of the medication use process. Effective triage skills enable pharmacists to evaluate and dispense medication orders in a timely fashion, ensuring that drug orders are reviewed and medications are made available for patient care within realistic and safe time frames. Experienced pharmacists learn to use a variety of prescription triage schemes to manage drug order workload. Unfortunately, triage schemes are usually learned through trial and error rather than explicit instruction at entry to hospital practice. Triage schemes differ with respect to strengths and weaknesses. In this introductory skill-building workshop, participants will review various methods of prescription triage. Individual and small group practice examples will give participants an opportunity to practice prescription triage methods that, from our Region's experience, have been successful and simple to learn. At the end of this workshop, participants will have practiced a method of prescription order triage that maximizes time for problem identification and problem-solving, minimizes stress, and reduces the potential for error.

Goals and Objectives

At the end of this workshop, participants will be able to:

1. Compare and contrast the strengths and weaknesses of different triage schemes.
2. Use case examples to apply the Priority Categories Method of prescription order triage.

Self-Assessment Questions

1. What priority categories are useful for efficient prescription order triage?
2. What criteria can be applied to prescriptions to determine urgency of need?
3. What type of information should be memorized to increase triage speed?

Community-Acquired MRSA: An Emerging Pathogen

Gerald Evans, MD, Kingston General Hospital, Kingston, ON

Infections caused by community-acquired methicillin-resistant Staphylococcus aureus (CAMRSA) are an emerging important public-health problem. In recent years, MRSA infections have been increasingly described in individuals without risk factors for nosocomial-acquired

infection and principally in marginalized populations, such as, drug-using and homeless populations, and aboriginal and low-income communities. These CAMRSA strains display unique combinations of virulence factors and resistance traits. Infections due to CAMRSA are frequently associated with high morbidity and significant mortality. The majority of infections caused by CA-MRSA are skin and soft tissue infections. Severe pneumonia in children and a disseminated systemic infection resembling meningococcemia have also been recently described. CAMRSA can often be distinguished from nosocomial MRSA strains by note of their greater antibiotic susceptibility. This presentation will focus on an overview of CAMRSA and management of infections caused by this emerging pathogen.

Goals and Objectives

At the end of this session the participant will:

1. Know the epidemiology of CAMRSA and its common clinical presentations
2. Understand the proposed mechanism(s) for CAMRSA virulence
3. Be able to identify the correct initial antibiotic therapy for managing a CAMRSA infection

Infective Endocarditis – New Guidelines and Old Questions

Linda Dresser, PharmD, Mount Sinai Hospital, Leslie Dan, Faculty of Pharmacy, Toronto, ON

The goal of this presentation is to familiarize the practicing pharmacist with the new American Heart Association guidelines for the antimicrobial therapy and management of infective endocarditis (IE). These guidelines are also endorsed by the Infectious Diseases Society of America and represent the first update since 1995.

Despite advances in surgical, medical and critical care interventions IE remains a disease associated with significant morbidity and mortality. Since the previous guidelines there have been many advances in diagnosis and treatment of IE. We have seen the advent of enhanced echocardiography technology, the use of PCR and serology for in vitro microbiological diagnosis leading to the development and validation of clinical criteria for the diagnosis of IE. Concurrently, we have also seen increasing emergence of resistance to antimicrobial agents used in the treatment of IE necessitating the use of newer agents, and increasingly challenging therapeutic scenarios. We have seen the adoption of new dosing strategies, such as once-daily aminoglycosides, in the treatment of IE. Additionally, with the constraints of the health-care system and the move to increased ambulatory management of more disease states outpatient therapy for IE has become quite common.

The new guidelines offer an evidence based and expert opinion tool to assist clinicians in the management of this diverse patient population.

Goals and Objectives

1. To identify the new elements of the AHA Guidelines for the antimicrobial therapy and management of infective endocarditis as compared to the previous edition.
2. To discuss the strengths and weaknesses of the recommendations provided in the guidelines.
3. To illustrate through case presentations the application of the guidelines in clinical practice.

Self-Assessment Questions

1. What is the role of echocardiography in the diagnosis and management of IE?
2. How do I use the “Duke Criteria” to assess the diagnosis of IE?
3. Are all patients receiving an aminoglycoside as part of their antimicrobial regimen for IE candidates for once-daily dosing?
4. When is a patient with IE eligible of outpatient therapy?

Wednesday, February 1 ▪ Mercredi le 1er février

Drug Metabolizing Enzymes: Putting Pharmacogenetics to Practice

Mary H.H. Ensom, BS (Pharm), PharmD, FASHP, FCCP, FCSHP, University of British Columbia and Children's & Women's Health Centre of British Columbia, Vancouver BC

This presentation will focus on drug metabolizing enzymes and provide pharmacists with: a comparison of traditional therapeutic drug monitoring (TDM) and pharmacogenetics-oriented TDM; concrete examples of pharmacogenetics-oriented TDM in clinical practice today; an example of what is currently being studied in our lab; and a prospectus for the future.

In contrast to traditional TDM which cannot be performed until after a certain drug is administered to the patient, pharmacogenetics-oriented TDM can be conducted even before treatment begins. Other advantages include the following: does not require assumption of steady state (or patient compliance); often can be performed less invasively; can provide predictive value for multiple drugs rather than a single drug; provides mechanistic, instead of merely descriptive, information; and is constant over an individual's lifetime.

In current clinical practice, pharmacogenetic testing as it relates to drug metabolizing enzymes is already performed for a few drugs in a limited number of teaching hospitals and specialist academic centers. These specific drug metabolizing enzymes include: thiopurine methyltransferase (TPMT); the cytochrome P450 isoenzymes, CYP2D6, CYP2C19, CYP2C9, and CYP1A2; and the UDP-glucuronosyltranserase isoenzyme, UGT1A1. With the advent of new genetics tests and devices, a number of other drugs are expected to be potential candidates for pharmacogenetics-oriented TDM in the future.

Whether the clinical applicability of information gleaned from pharmacogenetic testing justifies its cost still remains to be determined. Before the vision of pharmacogenetics for the future is realized, prospective studies of pharmacogenetics-oriented TDM must be performed to determine its usefulness and value in optimizing therapeutic effects while minimizing toxic effects.

In our lab, we are studying the role of UDP-glucuronosyltransferase genetic polymorphisms on the pharmacokinetics and pharmacodynamics of mycophenolate in thoracic transplant recipients in the hopes that, in the future, patients' optimal mycophenolate dosage can be predicted even prior to their first dose.

In the future, in addition to targeting a patient's drug concentrations within a therapeutic range as in traditional TDM, pharmacists will likely be making dosage recommendations of individual drugs based on the individual patient's genotype. As we enter the era of personalized drug therapy, we will be able to identify not only the best drug to be administered to a particular patient, but also the correct, safe, and effective dosage the first time.

Goals and Objectives

1. To compare and contrast traditional TDM and pharmacogenetics-oriented TDM.
2. To discuss genetic variability in drug response as it relates to drug-metabolizing enzymes.
3. To list the specific drug metabolizing enzymes for which pharmacogenetic testing is already being performed in current clinical practice.
4. To provide examples of drugs undergoing pharmacogenetics-oriented TDM in current clinical practice.
5. To discuss other important concerns that need to be addressed before pharmacogenetics becomes a commonly used clinical tool.

Self-Assessment Questions

1. List 5 drugs for which pharmacogenetics-oriented TDM is currently being performed.
2. Describe how knowledge of specific metabolizer status can provide useful information on dosage recommendations for each drug listed in #1 above.

Drug Toxicity, Pharmacovigilance and Tailored Therapy

Sunita Bond Stenton, BSc (Pharm), PharmD, University of British Columbia and Children's & Women's Health Centre of British Columbia, Vancouver, BC

This presentation will focus on adverse drug reactions (ADRs) and provide pharmacists with: a description of the morbidity and mortality associated with ADRs; a comparison of traditional ADR reporting mechanisms and active pharmacosurveillance of ADRs; a discussion of factors that increase risk of severe ADRs in children; a description of the Genotype-specific Approaches to Therapy in Childhood (GATC) Project; a brief description of pharmacogenomics; and a discussion of the possibilities for tailored pharmacotherapy.

ADRs are a major cause of morbidity and mortality in both children and adults worldwide.

Each year 26,500 children die as a result of adverse drug reactions in the United States alone. ADRs are one of the top ten causes of death in North America, and in the United States, ADRs cost $100 billion per year as a result of life-long disabilities and hospitalizations. Similar frequencies of ADRs are reported globally. Approximately half of such ADRs are classified as idiosyncratic, caused in part by inherited genetic differences that are presently impossible to predict.

The GATC, an innovative, national project to study adverse drug reactions in children, has been awarded $8.4 million in funding from Genome Canada. This project is a transdisciplinary cooperation between experts from hospitals, universities, research institutes, children's advocacy groups and Health Canada. The goal of GATC is to prevent ADRs in childhood by identifying predictive genomic markers for specific ADRs. Within five years, GATC intends to incorporate these markers into a diagnostic tool that will be used to predict and prevent ADRs in children through specific dosing recommendations for commonly used drugs based on an individual's genetic make-up.

To collect the necessary ADR data, the GATC project will establish a hospital-based network of surveillance clinicians in select Canadian pediatric hospitals. These surveillance clinicians, with the assistance of other health-care professionals within each institution will identify children experiencing a suspected ADR, collect patient specific data, explain the project to the child and family members, and then arrange for collection of a DNA sample (either a blood or saliva sample). Samples from children experiencing ADRs will be compared genetically with samples from age-matched control populations (taking the same medication, but not experiencing the ADR).

The long-term goal for this project is to develop a user-friendly, and effective ADR monitoring tool and national database, to proactively prevent adverse drug reactions in susceptible children and to ultimately improve patient safety.

Goals and Objectives

1. To discuss morbidity and mortality associated with ADRs.
2. To discuss factors in pediatrics that increase risk of severe ADRs in children.
3. To list factors that influence ADR reporting and critical components of a meaningful ADR report.
4. To compare and contrast traditional ADR reporting vs. active pharmacosurveillance.
5. To introduce pharmacists to the Genotype-specific Approaches to Therapy in Childhood (GATC) Project.
6. To discuss potential for tailored pharmacotherapy based on a person's pharmacogenomic makeup.

Self-Assessment Questions

1. It is estimated that 95% of adverse drug reactions are never reported

   True False

2. List 5 barriers to identifying and reporting adverse drug reactions.

Trastuzumab Therapy for Early Breast Cancer

Flay Charbonneau, BSc(Pharm), RPh, Sunnybrook & Women's College Health Sciences Centre, Toronto, ON

Trastuzumab (Herceptin®) is a humanized monoclonal antibody developed to target the HER-2/neu receptor, which is overexpressed in 20-25% of breast carcinomas. It has greater antitumour activity in combination with chemotherapy than chemotherapy alone in these breast cancers and has been used either as monotherapy or with chemotherapy in metastatic breast cancer since 1999 in Canada. The usual development of drugs in oncology involves their use first in the metastatic setting, with progression to use in earlier stage disease as adjuvant treatments. Four independently run trials (NSABP-B31, NCCTG-N9831, HERA and BCIRG-006) involving more than 13,000 women with HER2-positive early breast cancer have each shown in their interim analyses that trastuzumab given with or after chemotherapy reduces the early risk of recurrence by around 50%. In practical terms for patients this means on average an almost 20% absolute improvement in their predicted 4 year disease-free survival (86 v 67%). The primary safety concern is the risk of cardiotoxicity associated with trastuzumab. The 3-year cumulative incidence of class III or IV congestive heart failure or death from cardiac causes in the trastuzumab group was 0.5% in the HERA trial, 4.1% in the B-31 trial and 2.9% in the N9831 trial. Patients who receive this therapy must undergo regular cardiac monitoring prior to and during treatment. The results of adjuvant trastuzumab therapy have been heralded as stunning, but they have also prompted many comments about equitable access and the overall costs to the health care system. Trastuzumab is one of the first targeted therapies to dramatically change the treatment of breast cancer.

Goals and Objectives

1. To provide pharmacists with an understanding of the data that has led to the widespread adoption of adjuvant trastuzumab therapy for human epidermal growth factor 2 (HER2/neu) over-expressing breast cancer.
2. To enable pharmacists to address questions from patients and other health care professionals about adverse reactions associated with trastuzumab and practical issues regarding dosing regimens and scheduling.

Self-Assessment Questions

1. What benefit does adjuvant therapy with trastuzumab provide to patients with HER2/neu over-expressing breast cancer?
2. What are the risks associated with adjuvant trastuzumab therapy?
3. What is the optimal dosing regimen/schedule for trastuzumab therapy?

Self-Management Support: A Pharmacist's Journey from "Sage on the Stage" to "Guide on the Side"

Elaine Chong, BSc(Pharm), ACPR, PharmD, BCPS, CIHR Strategic Training Post-Doctoral Fellow in Primary Healthcare Research, Vancouver, BC

Purpose: A service model using telehealth pharmacists to provide patient self-management support is being developed and evaluated as a collaboration between the BC Ministry of Health, BC NurseLine, and two health authorities in BC. The model tests the application of self-management and coaching principles by a health care professional (pharmacist) to support patients with diabetes or congestive heart failure (CHF).

Methodology: During the service, patients with medication challenges are referred to telehealth pharmacists for in-depth assessment and monitoring. The service includes individualized self-management support; monitoring of medication response; and drug therapy decision support. Pharmacists received specialized training on coaching strategies and patient self-management concepts. Each pharmacist set goals and action plans for their on-going skill development, and also provided a measure of their current confidence in using their new skills in practice.

Results: Nineteen pharmacists completed the training. Initially, pharmacists were most confident in their ability to explain what is meant by the term "patient self-management". The most commonly mentioned personal goal at the start of the project was "increase familiarity with/application of clinical guidelines" (37%).

Conclusions: This demonstration project will shed light on the feasibility of pharmacists using coaching principles in the provision of self-management support to patients with diabetes of CHF.

Goals and Objectives

1. To define patient self-management, and demonstrate an understanding of how pharmacists are able to provide self-management support.
2. To name three coaching strategies that assist in patient self-management.
3. To describe three examples of how patient self-management support can be incorporated into your own practice.

Self-Assessment Questions

1. What is patient self-management? Why is it important?
2. How can I transition from my role as a "sage on the stage" to a "guide on the side" as a clinical pharmacist?

Ventilator-Associated Pneumonia

Clarence Chant, BScPhm, PharmD, BCPS, St. Michael's Hospital and University of Toronto, Toronto, ON

Previous sessions have focused on the management of hospital-acquired pneumonia, of which ventilator-associated pneumonia (VAP) is a subset. This session will focus only on the literature on VAP and the recent published and unpublished guidelines by the American Thoracic Society (ATS) and the Canadian Critical Care Society (CCCS), respectively.

VAP is the most common infectious complications of critically ill patients in the ICU with an estimated incidence of 10-65%. The attributable mortality to VAP is controversial, but has been estimated to be 0-50% while attributable morbidity includes increased length-of-stay of 4-13 days. An additional US $10,000 in health-care spending has been suggested for each episode of VAP. Therefore strategies to prevent VAP as well as to efficiently manage it are essential.

Current management guidelines focus on the areas of prevention, diagnosis, and treatment. Several modifiable risk factors, some of which have been evaluated in randomized control trials, have demonstrated benefits in reducing the incidence of VAP and should be incorporated into current practice. Controversies continue to surround the utility of invasive diagnostic

technique such as bronchoalveolar lavage (BAL), but the recent results of the Canadian Critical Care Trials Group on VAP may shed some light on its utility. Finally, recent data on optimal antibiotic management, such as single vs combination therapy, duration of treatment, cycling, empiric choices, and the use of local therapy will also be reviewed.

Goals and Objectives

1. To provide an overview of current management recommendations for ventilator-associated pneumonia (VAP)
2. To compare and contrast the American Thoracic Society and Canadian Critical Care Society Treatment guidelines on VAP

Self-Assessment Questions

1. What is the level of evidence supporting the use of combination antibiotics for the empiric treatment of VAP?
2. What are 2 clinical settings in which BAL has been evaluated?
3. How are the approaches to guideline development different between the ATS and CCCS documents?

Challenges of NIOSH Guidelines for Pharmacy

Carolyn Bornstein, BScPhm, RPh, Southlake Regional Health Centre, Newmarket, Ontario

The goal of this session is to introduce pharmacists to the recommendations of the NIOSH Alert, Preventing Occupational Exposures to Antineoplastics and other Hazardous Drugs, issued September 2004.

The NIOSH alert is a comprehensive review of the risks of working with hazardous drugs (HD) in a health care setting. Recommendations for methods and equipment for personnel protection are included. It identifies potential sources of exposure, the routes and adverse effects of exposure to hazardous drugs. Case reports provide evidence of the exposure of health care personnel to hazardous drugs.

Recommendations for the safe handling of hazardous drugs include the use of personal protective equipment (PPE). The standards/quality of the PPE and what/when PPE is required varies with the situation/procedure within the pharmacy.

Transportation and storage requirements for HDs in the pharmacy are specific to insure the safety of all hospital personnel.

The type of biological safety cabinet (BSC) required will vary based on the types of HDs being prepared. Current suggestions are for a 100% total exhaust system (Class II Type B2) when volatizing HDs are prepared in the pharmacy. Closed system transfer devices are also recommended to contain/limit HD exposure of personnel preparing chemotherapy.

The physical facility requirements of an oncology preparation area are unique. In conjunction with the USP Chapter <797> standards, chemo clean room and anteroom requirements (including cleaning/decontamination) will be presented. Very specific housekeeping policies and procedures for these rooms (agents and frequency) is imperative to maintain cleanliness, but more importantly to limit/contain any possible HD contamination.

Goals and Objectives

1. To introduce pharmacists to the NIOSH Alert, Preventing Occupational Exposures to Antineoplastics and other Hazardous Drugs, issued September 2004.
2. To highlight the NIOSH recommendations that apply specifically to the pharmacy oncology preparation area.
3. To review the equipment and physical facility requirements of the pharmacy oncology preparation area to limit/contain HD exposure/contamination.

Self-Assessment Questions

1. What is the most common route of exposure for contamination of hazardous drugs and what measures will minimize it?
2. What are the more common hazardous drugs that can volatize during preparation?
3. What is the preferred agent for deactivating chemotherapeutic agents?

Review of Articles That will Change Your Practice

Kerry Wilbur, BScPharm, ACPR, PharmD - Vancouver General Hospital and UBC Faculty of Pharmacy, Vancouver, BC

Hundreds to thousands of articles pertaining to disease and drug therapy are published in global scientific literature annually. Over 300 journalists are employed as medical reporters for newspapers and television across North America. Pharmacists are bombarded with information from the lay and professional press and may face challenges in keeping abreast of reported advances that may not be directly relevant to their day-to-day clinical or administrative activities, but are significant nevertheless.

This session will highlight a handful of articles published this past year whose results will influence patient care and/or stir debate in upcoming months. You may not have encountered them in your own practice, but your friends and neighbours are dying to get your informed opinion.

Goals and Objectives

1. To explore practice implications generated by recent results of four noteworthy clinical studies.
2. To enable pharmacists to answer questions from patients and fellow staff regarding these key papers reported in 2005.

Self-Assessment Questions

1. How do I discover landmark or controversial studies?
2. What do I believe are the remarkable reports that will impact my practice in 2006?

Update on Pediatric Immunizations

James A. Tjon, BSPhm, PharmD, Hospital for Sick Children, Toronto ON

The goals of this session are to provide pharmacists with an understanding of: some of

the recent recommendations to the immunization schedules for various provinces and territories in Canada, an assessment of the impact of the pneumococcal and

meningococcal conjugate vaccines and the recent worldwide resurgence of pertussis.

With the introduction of new immunization programs across Canada, more children have access to publicly funded vaccines to prevent against serious infections. The recent recommendations to routine immunization schedules and eligibility criteria for publicly funded vaccines will be discussed.

The introduction of pneumococcal and meningococcal conjugate vaccines have allowed for children younger than 2 years of age to be effectively vaccinated against invasive infections caused by these organisms. The cost-effective impact of these agents will be reviewed, in light of new data in the literature.

Although enhanced vaccination coverage has significantly decreased the incidence of pertussis over the last several years, there has been a recent resurgence of this disease in many developed countries. The reasons and implications for this resurgence will be discussed.

Goals and Objectives

1. To highlight recent recommendations to routine immunization schedules for various provinces and territories in Canada and eligibility criteria for publicly funded vaccines.
2. To provide pharmacists with an understanding of the impact of pneumococcal and meningococcal conjugate vaccines in preventing invasive infections.
3. To provide pharmacists with an understanding of the reasons and implications for the recent rise in pertussis.

Self-Assessment Questions

1. What have been the direct and indirect effects of pneumococcal and meningococcal conjugate vaccines in the prevention of invasive infections?
2. How does the recommended immunization schedule for pertussis in Canada compare with other developed countries?

Ethical Conduct – Point and Counterpoint

Robin J. Ensom, PharmD FCSHP, Vancouver Coastal Health and Providence Health Care, Vancouver BC, Kevin W. Hall, PharmD, Winnipeg Regional Health Authority, Winnipeg MB

The goal of this session is to provide a stimulating and informative discussion of the risks and benefits of interaction with representatives of the pharmaceutical industry.

As pharmacists, interactions with representatives of the pharmaceutical industry are a necessary and important part of our jobs. We need to obtain product information, negotiate contracts, learn about new products, resolve supply-chain issues, and have numerous other reasons to make contact. Representatives of the pharmaceutical industry also seek us out for a variety of similar and different reasons. Each interaction creates the opportunity for a potential, perceived or real conflict of interest.

Two experienced pharmacy practice managers will provide their perspectives regarding the risks and benefits and how they approach these interactions. Scenarios describing specific situations will be used to probe the subtleties and characterize the criteria they use to determine which opportunities to embrace and which to avoid. Members of the audience will be invited to challenge the speakers with situations of their own and to provide their own perspectives.

Goals and Objectives

1. To provide pharmacists with an understanding of the risks and benefits of interaction with representatives of the pharmaceutical industry.
2. To encourage pharmacists to critically evaluate the ethics of their own interactions with the pharmaceutical industry.

Self-Assessment Questions

1. What are the differences between potential, perceived and real conflict of interest?
2. What factors should be considered when determining whether to accept an invitation from a representative of the pharmaceutical industry?
3. How can productive relations with the pharmaceutical industry be maintained while avoiding conflict of interest?

Methodological Issues in Critical Care Clinical Trials

DC Scales[1,2]; JO Friedrich[1]; A Kiss[2]; WJ Sibbald[1]; DA Redelmeier[2].

[1]Interdepartmental Division of Critical Care, University of Toronto, Ontario, Canada and [2]Institute for Clinical Evaluative Sciences, Toronto, Ontario, Canada

This session will review published critical care studies designed to detect mortality differences, and consider the consequences of searching for unreasonably large treatment effects. It will help pharmacists understand methodological issues that may contribute to studies being negative and potentially missed treatment effects.

Background: Critical illness carries a high risk of death, and any intervention that improves survival by even a few percent may be beneficial. However, designing trials to detect small mortality differences requires a rigorous study with a large sample size. Choosing to detect an unrealistically large minimal clinically important mortality difference will reduce sample size estimates, but will also increase the likelihood that any small effects will not satisfy statistical criteria for significance.

Major Teaching Points: Wide variability exists in the minimal clinically important mortality risk difference specified during the design of critical care studies. In some studies, an unreasonably large minimal clinically important difference may lead to underpowered analyses that are unable to detect important treatment effects, especially if early stopping rules for futility are also in place.

Potential Clinical Implications: Designing studies to detect unreasonably large differences between groups will decrease sample size requirements, but can waste study resources and involve patients in research that is destined to fail.

Conflict of Interest: None

Self-Assessment Questions

1. Why is it important to consider study size and the minimal treatment effect sought by researchers when evaluating a clinical trial?
2. How can I be sure that a negative critical care study was sufficiently powered to detect an important treatment effect?
3. What are potential problems with early stopping or futility rules?

Use of Recombinant Factor VIIa in Critically Ill Patients

Marc M. Perreault, M.Sc, PharmD, BCPS, Faculty of Pharmacy – Université de Montréal and The Montreal General Hospital. McGill University Health Center, Montreal, QC

The goal of this session is to provide pharmacists with an overview/understanding of recombinant factor VIIa, its mode of action, its therapeutic and potential side effects. Although initially developed for the treatment of bleeding in patients with hemophilia A or B with inhibitors to factor VIII or IX, there is increasing evidence of its potential in a variety of bleeding conditions associated with trauma, with liver disease, with surgery, with stroke as well as for anticoagulation reversal. The evidence extends from case reports to randomized controlled trials depending on the condition and published pivotal studies will be presented as well as ongoing research. Often used as a salvage therapy, efforts to correct coagulation abnormalities, to correct hypothermia and acidosis and to aggressively replace platelets remain essential.

In addition, the triad of coagulopathy, hypothermia and acidosis will be presented in relation to its impact on the efficacy of recombinant factor VIIa. Questions regarding timing of administration, dosing and safety will also be addressed.

Goals and Objectives

1. To provide pharmacists with an understanding of the role and potential benefit of recombinant Factor VIIa in the treatment of severe bleeding associated with trauma, surgery, liver disease and stroke.
2. To understand the influence of hemodilution, temperature and arterial pH in the development of coagulopathy and how this may affect factor VII.

Self-Assessment Questions

1. What are the benefits of recombinant Factor VIIa in the treatment of intracerebral hemorrhage?
2. Name the factors that will negatively impact the efficacy of recombinant Factor VIIa in controlling severe bleeding.

The Anatomy and Physiology of CPOE

Jeff Barnett, BSc(Pharm), M.Sc Candidate, BC Cancer Agency, Victoria BC

The goal of this session is to provide pharmacists with an understanding of issues that have lead to the need to implement Computerized Physician Order Entry Systems (CPOE) in Canadian Hospitals.

Goals and Objectives

1. To provide pharmacists with an understanding of some of key reasons for the current push to develop and integrate CPOE systems with Pharmacy
2. To enable pharmacists to gain an insight into some of the may issues around the development and implementation of CPOE

Self-Assessment Questions

1. What are the main issues that has lead to push for the implementation of CPOE Systems
2. What are some of the problems seen with computerization in Canadian Hospitals
3. What are the dangers of having non integrated systems in hospitals?

Anatomy and Physiology of CPOE – Patient Safety Issues

Michael Ritchie, B.Sc Phm, Sunnybrook and Women's College Health Sciences Centre, Toronto, ON

The goal of this presentation is to provide pharmacists with an insight into patient safety issues surrounding computer physician order entry (CPOE) systems in hospitals. Such systems have been touted to improve patient safety by eliminating or avoiding errors made during the manual order writing process in paper charts. CPOE enforces complete, legible order entry while offering the physician clinical decision support (CDS) on dosing, drug interactions, allergies as well as institutional prescribing policies. The literature is not overflowing with studies demonstrating improved patient safety post implementation of CPOE. While some studies have demonstrated improvements in the order entry process and resultant decrease in medication errors, others have found that CPOE may actually facilitate new types of errors. Physicians often ignore the multitude of CDS alerts of little or no significance at the risk of missing important ones. CDS systems do not provide a universal protection against entry of potentially high-risk orders. Many pharmacy systems also fail this task as demonstrated by a recent ISMP survey.

The shift from manual order entry process to computer order entry will also have important impacts on physician and pharmacist cognitive processes that are only now starting to come to light. While an important tool in the quest for more efficient and patient safety oriented health care, CPOE does not replace good pharmaceutical care.

Goals and Objectives

1. To provide pharmacists with an insight into patient safety issues surrounding computer physician order entry (CPOE) systems in hospitals.
2. To provide an insight as to how pharmacy practice may change as integrated CPOE/Pharmacy systems become more prevalent.

Self-Assessment Questions

1. How can CPOE prevent or facilitate medication errors?
2. What are the limitations surrounding clinical decision support in CPOE?
3. How will CPOE change the way pharmacists monitor patient's therapy?

Sunday, January 29, 10:00-10:45
Harbour Foyer

1. Genetic Variation in UDP-Glucuronosyltransferases and Metabolism of Mycophenolic Acid in Lung Transplant Recipients: A Preliminary Study
2. Limited Sampling Strategies for Mycophenolic Acid Area-Under-the-Concentration-Time Curve in Lung Transplant Recipients
3. Cyclosporine Absorption Profiling and its Limited Sampling in Lung Transplant Recipients
4. Pharmacokinetic Predictors of Treatment Efficacy and Adverse Effects Following Mycophenolate Therapy in Lung Transplant Recipients
5. The Use of Benzodiazepines for Insominia in Older Adults: Effect of Group Education on Readiness to Change and Knowledge
6. Suspected Drug Interaction between Clozapine and Clarithromycin Resulting in Prolonged Hospitalization
7. Implementation of an Insulin Protocol in Adult Critically Ill Patients
8. A Systematic Review of the Risk of Acquired Protein C Resistance in Women Taking Third-Generation over Second-Generation Combination Oral Contraceptives
9. Use of the Patient Medication List to Ensure Continuity of Care for Elective Surgery Patients
10. Selection of a Preferred Proton Pump Inhibitor in the Canadian Forces: A Drug Use Evaluation

Monday, January 30, 12:15-14:15
Metropolitan Centre/East

1. The Use of Proton Pump Inhibitors for Stress Ulcer Prophylaxis in Critical Care: A Systematic Review
2. Evaluation of a Comprehensive Medication Review Program in Urban Senior Centers
3. Medication Utilization Rates after Acute Myocardial Infraction in a Cardiac Rehabilitation Population
4. Delta-9tetrahyrocannabinol (THC)/Cannabidiol (CBD) Buccal Spray: Experience in One Patient
5. Implementation of a "Tech-Check-Tech" Program for the Preparation and Labeling of Selected IV Admixture Products Prepared in the Pharmacy Clean Room
6. Lamotrigine Induced Blood Dyscrasias – A Case Report
7. Seizures Associated with Fluoroquinolones: A Series of Case Reports
8. Implementation of Medication Reconciliation in a Rehabilitation/Complex Continuing Care Facility
9. Carbamazepine Toxicity Related to Amiodarone Use Prior to Cardiac Surgery
10. The Systematic Overview of the Relative Benefits and Risks of Insulin Sliding Scale Dosing Regimen in Stable Patients with Type 2 Diabetes in Hospitals
11. The Effectiveness of Interventions Designed to Reduce Meperidine Use in Hospital
12. A Drug Use Evaluation of Milrinone in Pediatric Critical Care Patients

Tuesday, January 31, 12:15-14:15
Metropolitan Centre/East

1. Pharmacy Seamless Care Project – What Do Community Pharmacists Need from an Acute Care Hospital to Improve Continuity of Pharmaceutical Care?
2. Testing the Utility of a Patient Medication Record in Chronic Pain Patients
3. Recruiting, Training and Evaluating Pharmacists Using Key Competencies
4. Development of a Strategy for Safe Dofetilide Prescribing and Monitoring
5. A Description of the Pharmacological Management of Acutely Agitated Patients in a Psychiatric Emergency Department
6. Entry-Level PharmD Programs in Canada: Some Facts and Stakeholder Opinions
7. Clinical Practice Guidelines for Community-Acquired Pneumonia: An Investigation into Creation, Characteristics, Quality and Compliance with Production Guides
8. Retrospective Methods of Measuring Practice Change of Pharmacists in Continuing Education
9. Systematic Protocol for Managing Drug Information Requests

Wednesday, February 1, 10:15-11:00
Harbour Foyer

1. The Confidentiality of Community Pharmacy Records is at Risk: A Survey of Designated Pharmacy Manager
2. Stability of Bortezomib Vials Reconstituted with 0.9% Sodium Chloride at 4˚C and Room Temperature (23˚C)
3. Stability of Naloxone Stored in Aqueous Diluents in Syringes at 4C and Room Temperature (23C)
4. A Prospective Randomized Study of 4% Citrate vs. Heparin for the Prevention of Bacteremia and Thrombosis in Patients with Hemodialysis Catheters
5. Implementation and a Randomized Controlled Evaluation of Pharmacist Medication Assessments in a Surgical Pre-Admission Clinic
6. Risk Assessment of Medication in a Pharmacy Clean Room
7. Successful Treatment to Guideline Recommended LDL-Cholesterol Targets in Heart Transplant Recipients
8. Development of a Comprehensive Training Program for New pharmacist Hires
9. In Vitro Modeling of IV Meropenem [500 mg q 6h vs. 1g q8h] in Acinetobacter Bacteraemia
10. Lowering of Serum Valproic cid Levels During Concomitant Therapy with Meropenem: A Clinically Relevant Drug Interaction

Sunday, January 29 ■ Dimanche le 29 janvier

Genetic Variation in UDP-Glucuronosyltransferases and Metabolism of Mycophenolic Acid in Lung Transplant Recipients: A Preliminary Study

Mary H.H. Ensom, University of British Columbia and Children's & Women's Health Centre of British Columbia, Vancouver, BC., Lillian SL Ting, University of British Columbia, Vancouver, BC., Olivier Bernard, CHUL Research Centre, Laval University, Quebec City, QC., Chantal Guillemette, CHUL Research Centre, Laval University, Quebec City, QC

Rationale:

There is wide inter-patient variability in the pharmacokinetics of mycophenolic acid (MPA) and MPA glucuronide (MPAG) in lung transplant recipients. The source of such variability is not fully elucidated, but genetics of the drug-metabolizing enzymes are a likely contributing factor.

Objective:

To assess associations between polymorphisms in UDP-glucuronosyltransferase (UGT) genes with the MPAG/MPA metabolic ratio in lung transplant recipients.

Methods:

Following written informed consent, blood samples were obtained at 0,0.3,0.6,1,1.5,2,4,6,8,10 and 12 hours after mycophenolate mofetil administration to 15 patients. Concentrations of MPA and MPAG were determined by a validated high-performance liquid chromatography method with ultraviolet detection. MPAG/MPA ratios were log-transformed. Polymorphisms in the UGT1A1, UGT1A8 and UGT1A9 genes were identified by direct sequencing of polymerase chain reactions and compared to a reference sequence. Both heterogeneous and homogeneous polymorphisms were pooled as one group. One-way analysis of variance was used to correlate polymorphisms with PK metabolic ratios.

Results:

Three, seven and two known polymorphisms were investigated for the UGT1A1, UGT1A9 and 1A8 genes, respectively. Trends ($0.1<p<0.2$) were observed with higher MPAG/MPA ratios for the UGT1A8 A173G variant and lower MPAG/MPA ratios for the UGT1A8 variant C277Y. Due to the small sample size, no associations with MPAG/MPA ratios were observed for UGT1A1 and UGT1A9 promoter and coding region polymorphisms.

Conclusions:

This pilot study shows a trend toward correlation between UGT1A8 genetic polymorphisms and metabolic ratios of MPA. These observations prompt a larger study to identify UGT genes that could influence MPA metabolism to individualize immunosuppressive therapy in this patient population.

Encore Abstract – Clinical Research – Original Citation: Pharmacother. October 2005. In press

Limited Sampling Strategies for Mycophenolic Acid Area-Under-the-Concentration-Time Curve in Lung Transplant Recipients

Mary H.H. Ensom, University of British Columbia and Children's & Women's Health Centre of British Columbia, Vancouver, BC., Lillian SL Ting, University of British Columbia, Vancouver, BC., Nilufar Partovi, University of British Columbia and Vancouver General Hospital, Vancouver, BC., Robert D Levy, University of British Columbia, St. Paul's Hospital and BC Transplant Society, Vancouver, BC., K Wayne Riggs, University of British Columbia, Vancouver, BC

Rationale:

Pharmacokinetic monitoring of mycophenolic acid (MPA) may improve treatment outcomes of lung transplant recipients; however, it is impractical and costly to obtain MPA area-under-the-concentration-time-curve (AUC).

Objective:

To define optimal limited sampling strategies (LSSs) for MPA and to test their predictive performance in lung transplant recipients.

Methods:

Following written informed consent and upon administration of a steady-state mycophenolate mofetil dose, blood samples were collected at 0,0.3,0.6,1,1.5,2,4,6,8,10, and 12 hours from 19 lung transplant recipients. Plasma MPA concentrations were measured by a validated high-performance liquid chromatography method with ultraviolet detection and pharmacokinetic parameters analyzed by non-compartmental modeling (WinNonlin 4.1). Patients were randomly divided into the index (n=10) and validation groups (n=9). LSSs for estimating AUC were determined using the index group data by multiple regression analysis with forward stepwise elimination (Statistica® 5.1). Potential LSSs were restricted to 3 or fewer time points within the first 2 hours post-dose. The validation group data were used to test the predictive performance [coefficient of determination (r2), bias and precision] of LSSs developed. All concentrations and AUC values were normalized by log-transformation.

Results:

The correlation between AUC and single concentrations was generally poor (r2 range 0.18—0.73). The best LSSs for 2- and 3-concentrations were:

LogAUC=0.241LogC0+0.406LogC2+1.140 (bias=-5.82; precision=5.97%; r2=0.828)

LogAUC=0.153LogC0+0.327LogC0.6+0.354LogC2+1.000 (bias=-3.70%; precision=5.81%; r2=0.873)

Conclusion:

These are the first precise and accurate limited sampling strategies for predicting MPA AUC developed specifically for lung transplant recipients. These optimal and most clinically feasible LSSs are based collectively on the number of blood samples required, r2, bias and precision.

Encore Abstract – Clinical Research, Pharmaceutical/Basic Research, Pharmacoeconomic Analysis – Original Citation: Pharmacother. October 2005. In press

Cyclosporine Absorption Profiling and its Limited Sampling Strategies in Lung Transplant Recipients

Mary H.H. Ensom, University of British Columbia and Children's & Women's Health Centre of British Columbia, Vancouver, BC., Judith Marin, University of British Columbia, Vancouver, BC., Lillian SL Ting, University of British Columbia, Vancouver, BC., Nilufar Partovi, University of British Columbia and Vancouver General Hospital, Vancouver, BC., Robert D Levy, University of British Columbia, St. Paul's Hospital and BC Transplant Society, Vancouver, BC

Rationale:

Cyclosporine absorption profiling (AUC0-4hours) was suggested to be an adequate estimation of total area-under-the-curve (AUC0-12hours), however, information supporting this claim is lacking in the lung transplant population.

Objective:

To evaluate the correlation between AUC0-4hours and AUC0-12hours in lung transplant patients and to test the predictive performance of associated LSSs.

Methods:

Data from 14 stable lung transplant recipients from a previous study were used for the current study. Patients were divided into index (n=8) and validation (n=6) groups. Blood samples were collected at 0,1,2,3,4,5,6,8,9,10 and 12 hours after a steady-state cyclosporine dose and were analyzed by fluorescence polarization immunoassay. AUC0-4hours was analyzed by non-compartmental modeling (WinNonlin 4.1) and compared to AUC0-12hours. LSSs for estimating AUC0-4hours were established using multiple regression analysis with forward stepwise elimination (Statistica®). Predictive performance [coefficient of determination (r2), bias and precision] of the LSSs was measured using the validation group data.

Results:

The correlation between AUC0-4hours and AUC0-12hours was excellent (r2=0.976). As was the case for AUC0-12hours, the best LSS equation included 2 concentrations at 1 and 3 hours: AUC(ng.hr/mL)=1.03C1+2.87C3+105.5 (bias=-3.09%; precision=4.97%; r2= 0.996). Also in concordance with previous results, C0 is the best single-point predictor of AUC0-4hours (bias=-15.19%; precision=25.63%; r2= 0.996) whereas C2 did not demonstrate good predictive value (bias=-37.58%; precision=37.58%; r2= 0.621).

Conclusion:

For lung transplant recipients, an excellent correlation exists between cyclosporine AUC0-4hours and AUC0-12hours. The best LSS estimating both parameters uses C1 and C3. These results can be implemented and directly applied to management of lung transplant recipients.

Encore abstract – Clinical Research – Original citation: Pharmacother. October 2005. In press

Pharmacokinetic Predictors of Treatment Efficacy and Adverse Effects Following Mycophenolate Therapy in Lung Transplant Recipients

Mary H.H. Ensom, University of British Columbia and Children's & Women's Health Centre of British Columbia, Vancouver, BC., Lillian SL Ting, University of British Columbia, Vancouver, BC., Stephanie Tsang, University of British Columbia, Vancouver, BC., Nilufar Partovi, University of British Columbia and Vancouver General Hospital, Vancouver, BC., Robert D Levy, University of British Columbia, St. Paul's Hospital and BC Transplant Society, Vancouver, BC

Rationale:

Information on the best indicators of treatment response of mycophenolic acid (MPA) is lacking, especially in the lung transplant population.

Objective:

To identify pharmacokinetic parameters that may be used to predict treatment efficacy and adverse effects following mycophenolate mofetil (MMF) therapy in lung transplant recipients.

Methods:

Following informed consent, pharmacokinetic parameters of mycophenolic acid and its glucuronidated metabolites (MPAG and AcMPAG) were determined (via high-performance liquid chromatography with ultraviolet detection) from 21 lung transplant recipients on steady-state MMF therapy by serial blood sampling. Pharmacokinetic parameters [MPA area-under-the-curve0-12h(AUC); MPA maximum and minimum concentrations; MPAG AUC; AcMPAG AUC; MPAG/MPA and AcMPAG/MPA metabolic ratios] were calculated (WinNonlin 4.1), and patients' medical charts reviewed for incidences of rejection and adverse effects. Only incidences occurring while patients were on the same immunosuppressant regimen (prednisone and tacrolimus or cyclosporine) as the pharmacokinetics assessment day were considered for analyses (Fisher's-exact test).

Results:

Patients were: 11 males/10 females, mean (±SD) 4.6±4.2years post-transplant, 48.1±14.2years old and weighed 71.0±17.5kg. Pharmacokinetic indicators of treatment efficacy include:

Pharmacokinetic parameter Pharmacokinetic parameter categories Treatment efficacy parameter Significance p≤0.05 or 0.05<p≤0.2 MPA AUC >40 vs. <40 ?g*h/mL Infections p≤0.05 AcMPAG/MPA metabolic ratio >0.80 vs. <0.80 Anemia p≤0.05 AcMPAG AUC >50 vs. <50 ?g*h/mL Gastrointestinal toxicities p≤0.05 AcMPAG AUC >50 vs. <50 ?g*h/mL Infections 0.05<p≤0.2 AcMPAG/MPA metabolic ratio >3 vs. <3 Infections 0.05<p≤0.2 AcMPAG AUC >27 vs. <27 ?g*h/mL Anemia 0.05<p≤0.2 AcMPAG/MPA metabolic ratio >4 vs. <4 Gastrointestinal toxicities 0.05<p≤0.2 MPA AUC <32 vs. >32 ?g*h/mL Rejection 0.05<p≤0.2

Conclusions:

Although AcMPAG induces toxicity in vitro, this is the first study examining this metabolite in lung transplant recipients. MPA AUC, AcMPAG AUC, and AcMPAG/MPA metabolic ratio were the best predictors of clinical endpoints for lung transplant recipients on MMF therapy, and may be used in the future to individualize treatment response.

Encore Abstract – Clinical Research – Original Citation: Pharmacother. October 2005. In press

The Use of Benzodiazepines for Insomnia in Older Adults: Effect of Group Education on Readiness to Change and Knowledge

Valerie Leung, Debora Kwan, Carol Banez, Louise Nasmith, Toronto Western Hospital, University Health Network. Toronto, ON

About 10% of older adults use benzodiazepines long-term for insomnia, putting them at risk for harmful effects. Individuals are often reluctant to discontinue benzodiazepines due to lack of knowledge about potential risks. Time constraints frequently limit opportunities for individual counseling by pharmacists. Furthermore, there is little published regarding a systematic approach to group education for this specific population.

Our objective was to pilot an interactive group education program for older adults taking benzodiazepines for insomnia and to assess its impact on readiness to change and knowledge.

English speaking individuals >55, taking benzodiazepines for insomnia or interested in the topic were recruited from retirement homes and community centres. Educational sessions were conducted on-site. Participants completed a knowledge questionnaire pre and post intervention. Benzodiazepine users also completed a readiness to change questionnaire. Questionnaires were re-administered 1 month later.

Thirty-one individuals completed pre and post questionnaires. Eleven were on benzodiazepines. Twenty-two of 31 (71%) completed follow-up. Knowledge increased significantly post-intervention (p=0.0006) and at follow-up (p=0.0198) compared to baseline. Knowledge post-intervention vs. follow-up was not different (p=0.2050). No significant change was seen in readiness to change; however there was a trend towards moving from the precontemplation to contemplation stage from baseline to follow-up.

Research has shown group education to be effective and time efficient in promoting knowledge but not necessarily behavioural change in older adults. This study increased knowledge and potentially affected readiness to change. Further interventions aimed at affecting and measuring readiness to change should be considered in future studies.

Suspected Drug Interaction Between Clozapine and Clarithromycin Resulting in Prolonged Hospitalization

Loder, J. and Lamoure, J., London Health Sciences Centre, London, Ontario

There have been documented interactions between erythromycin and clozapine resulting in leucopoenia and seizure. To date there are no interactions with clarithromycin, though drug references do warn against the use of most macrolide antibiotics while taking clozapine. We present a case of neutropenia secondary to the combination of clozapine and clarithromycin.

A 61-year-old woman, with a 6-year history of clozapine controlled schizophrenia, presented with neutropenia (1.0x109/L) and leukopenia (2.3 x109/L) following routine blood work after a follow-up appointment. Hematological abnormalities observed were suspected to be caused by increased clozapine serum concentrations after initiation of clarithromycin therapy for bronchitis. Clozapine therapy was stopped immediately and clarithromycin was discontinued 5 days later when treatment for bronchitis was completed. Marked symptoms of psychosis returned 7 days after clozapine was discontinued necessitating hospitalization. Olanzapine was initiated, but was unsuccessful and she was started back on clozapine following approval from the clozapine support network (CSAN). Following rechallenge with clozapine, no neutropenia was noted. The patient was discharged after a 60-day hospital stay. It was postulated that clarithromycin inhibition of clozapine metabolism via isoenzymes CYP 1A2 and 3A4 was responsible for the leukopenia.

When the Naranjo Probability Scale was applied, this patient's case scored a 7, which indicates that clarithromycin is a probable cause of this ADR. This supports the suspicions that macrolide antibiotics, other then erythromycin, can cause adverse effects when combined with clozapine.

Implementation of an Insulin Protocol in Adult Critically Ill Patients

Christine Wynne, Rachel Damota, Michael Michenko, Mark Duffett, Hamilton Health Sciences, Hamilton, ON

Rationale:

Intensive insulin therapy to maintain blood glucose below 6mmol/L has been shown to reduce morbidity and mortality in critically ill patients in a surgical intensive care unit.

Objectives:

To implement a standardized insulin protocol and measure its effectiveness and safety in maintaining blood glucose in the target range in critically ill patients compared to conventional practice.

Study Design:

We preformed a prospective study in the adult McMaster ICU (Hamilton Health Sciences), an 8 bed adult medical/surgical ICU unit from January 2005 to August 2005. All patients who required an insulin intravenous infusion were managed using an Insulin Protocol developed by General ICU (Hamilton Health Sciences). Efficacy and safety were analysed using time to target blood sugar (4.5-7mmol/L), number of patients with blood sugars greater than 15mmol/L, number of patients with blood sugars less than 3.6mmol/L, average blood sugar, number of patients requiring D50W boluses, and number of blood sugars measured. These results were compared to retrospective conventional practice.

Results:

Twenty-five patients received the insulin protocol. Time to target blood glucose of 4.5-7mmol/L was 9.5h in the protocol group and 18.3h in the conventional group ($p=0.02$). There was no statistical difference in the incidence of hypoglycemia, number of patients with blood sugars greater than 15mmol/L, number of patients receiving D50W boluses, average blood sugar, and number of blood sugars drawn. Paired t-test and chi-squared tests were used for statistical analysis.

Conclusion:

Implementation of an insulin protocol in McMaster ICU of Hamilton Health Sciences was shown to be more effective and as safe as conventional therapy.

A Systematic Review of the Risk of Acquired Protein C Resistance in Women Taking Third-Generation over Second-Generation Combination Oral Contraceptives

Vivian Ng BScPhm, Hamilton Health Sciences – McMaster University Medical Centre, Hamilton, ON

Rationale:

Epidemiological studies have demonstrated that the risk for thrombosis is increased in women taking third-generation over second-generation combination oral contraceptives (OCs). However, plasma from OC users generally is resistant to the anticoagulant effects of activated protein C (APC) which may cause acquired APC resistance.

Objectives:

To establish the increased risk of acquired APC resistance, in third-generation over second-generation combination OC users.

Methods Used:

The Medline, Pubmed, Embase, Cinahl, IPA and Central databases were searched using MeSH, full text and keyword terms: [activated protein C resistance] and [contraceptives, oral] and [random*, trial, observational study, comparative study, or controlled study]. The references of all identified trials and review articles were appraised for relevant articles. Quality was assessed by type of study, number of participants and control of confounding factors.

Results of Review:

Of 163 studies found, 5 were included. Two demonstrated a statistically significant difference ($p<0.0001$ and $p<0.001$), 1 failed to, and 2 showed mixed results depending on the type of testing employed. Results could not be combined for statistical analysis as different APC resistance measurements were utilized.

Conclusion:

There is a lack of rigorous trials investigating the risk of acquired APC resistance across the two generations of OCs. It appears that 3rd generation OCs have a tendency to result in greater insensitivity to APC in participants' plasma. However, no clinically relevant endpoints were included analysis in any of the trials, thus the significance of this trend has yet to be determined.

Use of the Patient Medication List to Ensure Continuity of Care for Elective Surgery Patients

Zan Saleemi, St. Joseph's Health Care London, London, ON

Rationale:

Inconsistencies with documentation of home medications often result in drug-related problems on admission to hospital, such as missing medications, altered dosing regimens, and even inadvertent administration of medications that are not indicated for the patient.

Description:

The idea for the Patient Medication List originated in the Pre-admission Clinic. The form was intended to document home medications for all elective surgery patients. It would serve as the primary authoritative source of patient medication information on the chart, and could be completed in the clinic by the pharmacist, nurse or a physician. It was proposed that the form

should be filed in the "Database" section for easy access, and coloured for greater visibility. The potential to integrate surgery-specific information was quickly realized and the form was developed to allow documentation of pre-op instructions provided to the patient regarding their home medications.

Implementation:

The form was initially piloted for a month. However, overwhelming support for the form, led to its continued use until it was formally approved. Feedback from Nursing and Anaesthesia resulted in modifications that further enhanced the utility of the form. These included a pre-op confirmation of medications discontinued before surgery and/or those taken pre-operatively, and a section to record any pre-op anticoagulation and bowel prep protocols.

Relevance:

The Patient Medication List is now recognized as the primary source of patient medication information in the patient's chart and integrates documentation of important surgery-specific information that is relevant to the various health care personnel involved in the care of the patient.

Selection of a Preferred Proton Pump Inhibitor in the Canadian Forces: A Drug Use Evaluation

Janice Ma, Alan Gervais, and Régis Vaillancourt, Canadian Forces Health Services, Ottawa, Ontario

Purpose and Objective:

Preferential listing of a single drug is employed by many drug benefit programs to control costs associated with a therapeutic class of medications. Despite preferential listing, however, our program has continued to sustain significant expenditures for non-benefit proton pump inhibitors (PPIs). This drug use evaluation was performed to identify reasons for this anomalous usage pattern.

Design and Methods:

A database review using pharmacy claims information was performed to evaluate PPI usage in the Canadian Forces following implementation of the current policy. Members who received 1 or more prescriptions for a PPI from 2002 to 2005 were reviewed.

Results:

A total of 27,156 prescriptions for PPIs were identified for 2738 members. The preferred agent was used in 87% of such members. Of members not receiving the preferred agent (N=621), half had prior use of this PPI documented in the database. Inform

Monday, January 30 ▪ Lundi le 30 janvier

The Use of Proton Pump Inhibitors for Stress Ulcer Prophylaxis in Critical Care: A Systematic Review.

Dr. Trudy Arbo, Bsc(Pharm), Pharm.D, Dr. Aaron Tejani, Bsc(Pharm), Pharm.D, Fraser Health Authority, Burnaby, BC

Rationale:

Proton Pump Inhibitors (PPI) are used in critically ill patients for stress ulcer prophylaxis (SUP). PPIs alter gastric pH to a greater extent than H2RAs which may relate to reduced rates of clinically significant bleeding (CSB) due to stress ulceration.

Objective:

Is there a therapeutic advantage to the use of (PPI) compared to (H2RA), antacids, or sucralfate for SUP in critically ill patients.

Data Sources:

Medline, EMBASE, the Cochrane Library, and reference lists of identified trials were searched. Key authors in the area of SUP were contacted to identify trials that were not found in our search.

Study Selection:

Prospective, double-blind, randomized controlled trials (RCT) were included.

Data Extraction:

Our hierarchy of clinically relevant outcomes were: total mortality, non-fatal serious adverse events, CSBs, nosocomial pneumonia, and any adverse events.

Data Synthesis:

Our search revealed 2 trials. There was a low incidence of CSBs within the 2 trials making it difficult to determine any differences between groups. In PPI-treated patients, there were trends towards increased total mortality, hospital mortality, and nosocomial pneumonias. Total SAEs were not reported in the 2 trials.

Conclusion:

There is insufficient evidence to demonstrate a therapeutic advantage of PPIs for SUP in critically ill patients compared to H2RAs, antacids, sucralfate or placebo. There is some suggestion that there may be a therapeutic disadvantage in using PPIs for SUP in this population. Adequately powered, RCTs need to be conducted to clarify relative safety and efficacy of PPIs

for this indication before they can be recommended for routine use.

Evaluation of a Comprehensive Medication Review Program in Urban Senior Centers

Feng Chang, BSc.Phm., Pharm.D., St. Joseph Health Care, London, Mary Beth O'Connell, Pharm.D., Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit

Purpose:

This study examined if a comprehensive medication review program can increase patient knowledge of medications, identification and resolution of medication related problems, and utilization of preventative health measures in an urban dwelling, ethnically diverse and medically underserved senior population.

Method:

45 patients age 60 and older were recruited from 5 senior centres in downtown Detroit between January and July 2005. Patients completed health and medication assessment during individual appointments with a pharmacist. Satisfaction and learning were assessed immediately after and 3 months later. Descriptive statistics were used for analysis.

Results:

Patients were predominantly women (#36, 80%) and African American (#32, 71%) with a mean age of 76 years (60-92). Mean total medication use was 9.6 per patient. 429 medication related issues were identified (mean 9.5 per patient) with the top categories being needed education (23%), medication overuse (16%) and medication underuse (12%). To date, 23 patients (52%) have completed follow-up. 73% of the recommendations have been (53%) or will be implemented (20%). 65% (15) of these patients indicated they already discussed or will discuss the recommendations with their physicians. For preventative health, 67% of patients recommended vaccinations indicated willingness to get them. 58% of recommendations for increased calcium intake and 41% for increased vitamin D intake were implemented. Self-reported degrees of learning and satisfaction were high, post review and at follow-up.

Conclusion:

The high degree of medication related problems and recommendation acceptance observed indicates an opportunity for pharmacists to positively impact senior health through fulfilling unmet medical needs and promoting healthy behaviours.

This abstract has been submitted to ASHP Mid Year Clinical Meeting 2005

Medication Utilization Rates After Acute Myocardial Infarction in a Cardiac Rehabilitation Population

Claudia Bucci[1], Paul I.T. Oh[1,2]
[2]Toronto Rehabilitation Institute, Toronto, ON

Rationale:

Underutilization of secondary prevention medications in the acute myocardial infarction (AMI) population has been well-documented in the literature. To date, there has been no evaluation of the use of these medications in patients participating in a cardiac rehabilitation program.

Objectives:

To determine utilization rates of ACE inhibitors (ACEI), beta-blockers, ASA and statins for AMI patients participating in a 12 month cardiac rehabilitation program. A secondary objective is to determine if there are any trends in medication use according to patient age.

Methods:

Utilization rates were analyzed at baseline and 12 months for all AMI patients (1999-2003). An analysis of medication use according to age was also done. Data were analyzed using SPSS 13.

Results:

1829 patients were included in the analysis (mean age 52.9 years, 20% female). At baseline, 64.4% received ACEIs, 84.8% received beta-blockers, 92% received antiplatelet medication and 78.3% received cholesterol-lowering medication (of which 88.6% were statins). There was high utilization with these therapies throughout the program. In fact, ACEI and statin use increased significantly by 4% and 6% respectively ($p<0.05$). Analysis of medication use according to age (<65 yr vs. > 65 yr) showed no difference for ACEI and beta-blocker use but a slightly lower use for ASA and statin in the elderly ($p<0.05$).

Conclusion:

Overall, use of secondary prevention medications after AMI in this group of cardiac rehab patients is higher than that reported in the general population and was maintained over time. Our analysis reveals consistent use of these medications regardless of age subgroup.

Delta-9-tetrahydrocannabinol (THC)/Cannabidiol (CBD) Buccal Spray: Experience in One Patient

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Rationale:

In April 2005, Canada became the first country in the world to conditionally approve marketing of a cannabis-based pharmaceutical product for neuropathic pain in Multiple Sclerosis (MS) patients. This type of

pain is often difficult to control with the current treatment regimens available.

Case:

A 39 year old female in our Complex Continuing Care Unit with chronic progressive MS and intermittent uncontrolled trigeminal neuralgia, requested to trial this drug. Her usual medications included gabapentin, topiramate, transdermal fentanyl, codeine, venlafaxine, atorvastatin and baclofen.

Barriers to initiation included potential drug interactions involving cytochrome P450 enzymes, pharmacist and nursing education, logistical issues with storage and drug administration and a lack of published information.

Course in hospital was complicated by adverse effects to THC/CBD, breakthrough pain, depression, anxiety and an adverse event likely caused by a drug interaction.

Analysis:

This process involved co-operation between every member of the health care team working closely with the patient and her family. Despite the barriers, we were successful in implementing and continuing treatment with the buccal spray.

Implications for Practice:

Through our experience, we have identified issues regarding labeling and storage to the manufacturer, developed a procedure for ongoing training of staff and gained further information regarding drug interactions and the THC/CBD buccal spray.

Implementation of a 'Tech-Check-Tech' Program for the Preparation and Labeling of Selected IV Admixture Products Prepared in the Pharmacy Clean Room

Peter Davies, B.Sc. Phm, R. Ph. St. Michael's Hospital Toronto ON, Heather Hales, C.Ph.T. St. Michael's Hospital Toronto, ON

Reason for Initiative:

In order to improve utilization of pharmacy technician resources and reduce workload pressures on pharmacists during weekends, a tech – check – tech program was initiated to delegate to technicians the checking of the preparation and labeling of selected IV admixture products.

Description of Initiative:

A list of batch IV admixture products were identified as appropriate for checking under the tech-check-tech program. Specific types of products were excluded based on risk and complexity of preparation (For example chemotherapy and TPN). A new checking documentation form was designed to direct the technician in the order in which the product was to be checked and required the technician to initial each of the 6 critical points of product preparation. To be delegated to check, a technician was required to demonstrate 100% accuracy in checking the selected products for a five day period during which the delegating pharmacist performed a second check. A minimum of five deliberate errors were planted to ensure the technicians were able to identify all errors.

Evaluation of Initiative:

Over a one year period, 7 technicians underwent the delegation process. Of these 5 were successful and have been delegated to check the IV products under the tech-check-tech program.

Importance and Usefulness of Initiative for Pharmacists

The tech-check-tech program supported the successful delegation of checking selected IV admixtures to pharmacy technicians and decreased the involvement of pharmacists in checking functions. The program design and audit mechanisms ensured that technicians delegated under the program are able to identify errors and consistently check each of 6 critical points of product preparation.

Lamotrigine Induced Blood Dyscrasias – A Case Report

Yun, A. B.Sc.Phm; Lamoure, J. B.Sc.Phm., FASCP; London Health Sciences Center, London, ON

Lamotrigine is indicated for treatment and maintenance of bipolar disorder. Lamotrigine has been commonly associated with adverse effects such as dizziness, insomnia and skin rash. We report a case of blood dyscrasias associated with the use of lamotrigine.

A 37-year-old woman with a history of bipolar II disorder, post traumatic stress disorder, substance abuse and post partum depression, was admitted for the treatment of bipolar depression. Laboratory investigations shortly after admission showed no hematological abnormalities. On hospital day 6, lamotrigine 12.5mg hs was initiated and valproic acid was increased from 1000mg qhs on admission to 250mg qam and 1000mg qhs. On day 12, lamotrigine was increased to 25mg hs. Laboratory investigations on day 18 revealed leucopenia with a leukocyte count of 3.5x109/L. On day 19, the patient developed a rash on her upper chest, visual changes and had leukocyte, neutrophil and lymphocyte counts of 3.1x109/L, 1.3x109/L and 0.9x109/L respectively. Lamotrigine was discontinued. By day 21 her rash was resolved and by day 22 leukocyte and lymphocyte counts normalized to 4.3x109/L and 1.6x109/L, Neutrophils increased to 2.3x109/L by day 26. A Naranjo adverse drug reaction probability scale of 6 suggests a probable adverse drug reaction (ADR).

This case illustrates the potential for lamotrigine to induce blood dyscrasias and the importance of slow dose titration and blood cell count monitoring in patients initiated on this medication. Pharmacists should be aware of this uncommon ADR and its potential for morbidity.

Seizures Associated with Fluoroquinolones: A Series of Case Reports

L Shortridge, N Crown, C Bayliff, B Young. London Health Sciences Centre, London, ON

Fluoroquinolones are broad spectrum antibiotics frequently used in hospitalized patients to treat a range of infectious diseases. The incidence of seizures associated with fluoroquinolones has been reported to be <1%. Furthermore manufacturers of these antibiotics caution against their use in patients with CNS disorders.

We report 6 cases of possible fluoroquinolone-induced seizures. The mean age of the patients was 55 years (range 44 – 75). Four patients were male. Fluoroquinolones implicated in these cases were levofloxacin (n=4), ciprofloxacin (n=1) and norfloxacin (n=1). The indications for therapy were CAP (n=3), bacteremia (n=1), empyema (n=1) and UTI (n=1). Average time to seizure occurrence following initiation of therapy was 4.5 days (range 2-7 days). In 3 cases no previous history of seizures was documented. While 4 patients had renal insufficiency (serum creatinines ranging from 134-600mmol/L), dosage adjustments for renal function were made in only 1 case. Only 1 patient had a documented allergy to penicillin.

Several risk factors, including the presence of CNS disorders, renal impairment, and concomitant use of medications that decrease the seizure threshold were evident in these cases that would predispose one to the risk of seizures. Fluoroquinolones-induced seizures can cause substantial morbidity and greater vigilance needs to be exercised in prescribing and administering these drugs to patients with pre-existing risk factors.

Implementation of Medication Reconciliation in a Rehabilitation/Complex Continuing Care Facility

Lam J, Karakolis P, Chau T, Chan P, Cheng B, Europa R, Munger G, Goldbert D, Joshi P, Li M, Pharmacy Services, Providence Healthcare, Toronto, ON

Background:

Pharmacy conducted a pilot on medication reconciliation in 2003 mainly to address the problem of late admissions in the afternoon. Over time, it slowly evolved to other units as medical and nursing staff recognize the benefits of pharmacists reconciling medications on admissions from acute care institutions.

Method:

Pharmacists perform medication reconciliation as part of their pharmaceutical care process. The Admitting Department will remind the transferring facility to send the following records:

- Up-to-date Medication Administration Record
- Up-to-date Medication Profile
- Up-to-date warfarin Monitoring Record with complete history of INRs and warfarin doses

Pharmacists interview the patients to confirm the medication history from the supporting documentation. They review patient's own medications brought to the hospital including non-prescription and herbal products. If required, they consult with family members and/or patient's community pharmacy. After the medication reconciliation process is thoroughly finished, pharmacists write current medication orders on the physician's order to be co-signed by the physician. Physicians make the final decision whether to accept or modify the orders.

Results:

Pharmacists write new medication orders for 85% of all new admissions in collaboration with physicians. Medication discrepancies were identified proactively by pharmacists, which would enable physicians to make any intentional change if necessary, but eliminate any unintentional discrepancies. A complete Medication Administration Record can be printed in a timely manner. The service is well received by medical and nursing staff.

Conclusions:

Pharmacists play a critical role in medication reconciliation. Further study is required to substantiate the benefits of patient safety in this patient population.

Carbamazepine Toxicity Related to Amiodarone Use Prior to Cardiac Surgery

Michelle Methot, Glorianne Ropchan, Gerald Adams, Ron Koob, Jennifer Daley, Kingston General Hospital, Kingston, ON

Introduction:

Amiodarone is used for prophylaxis of atrial fibrillation prior to cardiac surgery. We present a case of carbamazepine toxicity related to addition of amiodarone therapy.

Description of Case:

A 58-year-old male presented to hospital with episodes of ataxia and visual perception changes 4 days before planned cardiac surgery. Amiodarone 400mg bid had been started 4 days previously. The patient's medication regime included lamotrigine 100mg bid, carbamazepine 400mg qam and 600mg qpm, hydrochlorothiazide 25mg daily and atorvastatin 20 mg daily. His carbamazepine level was 48 umol/L on admission. The therapeutic range is 17-42 umol/L. Carbamazepine dosage was adjusted according to serum levels and symptoms resolved. The patient underwent surgery and was discharged without incident 2 weeks after admission.

Analysis of Case:

A literature search revealed no reports of a drug interaction between amiodarone and carbamazepine. Amiodarone is an inhibitor of the cytochrome p450

3A3, 3A4, 2C9 and 2D6 isoenzymes. Carbamazepine metabolism occurs via the cytochrome P450 3A4 isoenzyme pathway. There are reports of other 3A4 isoenzyme inhibitors leading to increased carbamazepine levels such as erythromycin and nefazodone. It is likely that the introduction of amiodarone lead to an increase in serum carbamazepine levels which caused the patients' symptoms.

Implications for Practice:

Amiodarone is commonly used prior to cardiac surgery. Short-term use may lead clinicians to have less suspicion for potential drug interactions with amiodarone, of which there are many. It is important to monitor for potential interactions regardless of duration of therapy.

The Systemic Overview of the Relative Benefits and Risks of Insulin Sliding Scale Dosing Regimen in Stable Patients with Type 2 Diabetes in Hospitals

Hae-Suk Helen Shin, St. Joseph's Healthcare, Hamilton, ON

Rationale:

There are various management approaches to optimal glucose control in patients with type 2 diabetes in the hospital setting. Among them, the use of insulin sliding scale is widespread and only recently, its routine use has been questioned and there is a growing refute whether the sliding-scale insulin (SSI) is the best way to treat hospitalized diabetic patients.

Objective:

To assess the evidence for the relative risks and benefits of administering insulin using a sliding scale dosing regimen compared with any other types of diabetes regimens in stable adult hospitalized patients, with type 2 diabetes.

Methods:

Medline, PubMed, Embase, Cinahl, and EMB Reviews: CDSR, ACP Journal club, DARE, CCTR electronic databases (all up to August of 2005) were searched for trials that included insulin sliding scale regimens to any other diabetes regimen in adult stable patients with type 2 diabetes in the hospital setting. The study outcome included any relevant benefits and risks associated with insulin use. The study design, sample size, randomization, and number of baseline characteristics for analysis were extracted and each study was appraised for its strengths and weaknesses accordingly to its study design.

Results:

Five studies were included; 4 from the 1458 citations retrieved and 1 citation retrieved during preliminary search strategy synthesis that has not yet been indexed. Three of five studies found statistically significantly higher blood glucose levels (range: 1.2-2.78 mmol/L) during hospitalization in control (regimens inclusive of SSI) than the intervention. Two studies examined the length of hospital stay, both of which found non-significant difference between the control and the intervention. The rates of hypoglycemia were non-significant between two groups in all studies, except one study found higher risk of hypoglycemia (3.6% SSI vs. 1.4% no SSI, $p<0.01$) in control. Three studies reported that the rates of hyperglycemia were statistically non-significant between two groups. Two studies found that patient with SSI regimen were at higher risk of hyperglycemia: (20.5% SSI vs. 6.5% no SSI, $p< 0.01$) and RR ranging from 1.49 (CI:0.81-2.73) to 3.25 (CI: 1.23-8.60).

Conclusion:

The insulin sliding scale dosing regimen does not seem to offer benefits in better controlling blood glucose levels or reduce the risk of hypoglycemia or hyperglycemia during the hospital stay for stable adult inpatients with type 2 diabetes.

The Effectiveness of Interventions Designed to Reduce Meperidine Use in Hospital

Julia Groenestege, St Josephs Healthcare Hamilton, Hamilton, ON

The opioid analgesic meperidine has been used for over 60 years, despite significant and unique side effects and drug interactions compared to other opioids. To eliminate inappropriate meperidine use, other institutions have utilized a number of different interventions.

The objective of this review is to determine the best way to minimize meperidine use by determining what interventions have been done, and identifying how effective those interventions were.

A search was conducted using both MeSH and text terms in Embase, Medline, Cinahl and EBM Reviews databases. Terms for meperidine were combined with terms like drug utilization, continuing education, and practice patterns. Studies included had to have an intervention/education program/tool to modify/reduce/restrict the use of meperidine, an evaluation of meperidine use before and after, be in a hospital/institution, use any study design with a 2 group or 2 time-point comparison and be in English. Studies were analyzed qualitatively. Quality was assessed based on design, randomization, presence of a control group, similarity of groups, quality of the description of the intervention, quality of the intervention and length of follow-up.

The search returned 1417 non-duplicate citations. Seventy-eight were included by title, 31 of these were included by abstract and 12 were finally included for analysis.

All studies found a reduction in the meperidine use after some intervention, regardless of the population studied, with higher quality interventions associated with more significant reductions. Therefore, an intervention designed to reduce meperidine use should

be effective in any population, with higher quality interventions associated with larger reductions.

A Drug Use Evaluation of Milrinone in Pediatric Critical Care Patients

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Objectives:

To describe milrinone use in critically ill children, and to explore associations between milrinone dosing and efficacy (arterial-venous oxygen (AVO2) saturation difference) and toxicity (thrombocytopenia or arrhythmias).

Methods:

A retrospective drug use evaluation of milrinone was conducted. Eligible children were admitted to a pediatric critical care unit in the 6 months ending June 2004. Data on milrinone loading doses, rate and duration was summarized. The loading dose was compared with the recommended 50mcg/kg dose. Milrinone dosing was compared with renal function, and drug toxicities were described. Relationships between milrinone dose with efficacy and toxicity were evaluated using multivariable logistic regression.

Results:

Charts of 197 patients were included. In 146 (68.5%) patients, the initial loading dose was >80mcg/kg. In at least 65.9% of patients who received subsequent loading doses, the loading doses were administered in the range of 41-60mcg/kg. Milrinone was infused at a mean rate of 0.622±0.195 mcg/kg/min for a duration of 43.1 hours (median). There was no relationship between creatinine and milrinone maintenance dose (r2£0.0335). There was a trend suggesting that greater average milrinone dose rate, and longer duration, were associated with efficacy. No significant association was found between milrinone dosing and toxicity.

Conclusions:

Milrinone dosing in critically ill children was variable. Most loading doses were greater than recommended and infusion rate adjustment for renal dysfunction was not observed. Further research is needed to correlate milrinone pharmacokinetic differences and pharmacodynamic responses in order to guide milrinone dosing adjustment. This may lead to reduced clinical toxicity and improved outcomes.

Tuesday, January 31 ■ Mardi le 31 janvier

Pharmacy Seamless Care Project – What Do Community Pharmacists Need From an Acute Care Hospital to Improve Continuity of Pharmaceutical Care?

Grace Cheng, Vicky Agiannidis, Thomas Fong, Vinh Huynh, Kieu Mach, Michael Sung, Nazli Topors, Kevin Wong, Toronto East General Hospital, Toronto, Ontario

Rationale:

While the concept of seamless care is widely supported by the profession of pharmacy, implementation of services aimed to achieve seamless care remains inconsistent. At Toronto East General Hospital, we explored the needs of our community counterparts to facilitate the provision of pharmaceutical care (PC) to patients discharged from our hospital.

Objective:

To define gaps in the continuity of PC upon discharge from hospital, to understand needs of community pharmacists and to develop procedures to improve collaboration.

Methods:

A literature search was performed on barriers of and solutions for seamless care in patients after hospital discharge. A "Needs Assessment Form" was devised and used to survey community pharmacies in the vicinity. Results were analysed and action plan proposed.

Results:

Seventy-five out of the 85 pharmacies contacted agreed to participate in the survey. Forty-one surveys were returned (54.7%). Ninety-three percent (93%) of respondents cited barriers due to lack of patient information, 33.3% lack of time, 50% would like to receive admission medication history performed by hospital pharmacists and 40% would like to know about the hospital drug protocols. The concept of a Pharmacy Discharge Summary was supported by 94% of respondents. Information deemed useful included medications on discharge (90%), physicians' names and license numbers (88%), hospital diagnoses (58%) and medications upon admission (52%).

Conclusions:

In response to the survey the department will pilot a Pharmacy discharge summary sheet with continued dialogue with community counterparts. By better defining the needs of the community pharmacists we were able to devise tools to address current deficiencies.

Testing the Utility of a Patient Medication Record in Chronic Pain Patients

Amanda Ng[1], Marilyn Galonski[2], Allan Gordon[2], David Evans[2], Doug Gourlay[2], Suzanne Singh[2]

[1]*Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON*
[2]*Mount Sinai Hospital, Toronto, ON*

Rationale:

The safety and needs of patients on chronic pain medications require constant monitoring. Thus, there is a need for the development of a tool that allows clinicians to easily access and document changes in medication and pain.

Objective:

To develop, implement and evaluate the utility of a Patient Medication Record (PMR) for patients in the Wasser Pain Management Centre.

Methods:

A literature search was performed. After assessment of ideas and needs, a draft was developed. Revisions were made after further consultation with clinicians of the clinic. Three clinicians and one pharmacy student participated in the trialing process for a five-week period. A questionnaire was distributed to the participating clinicians after the five-week period for feedback.

Results:

No relevant information was found in the literature search. The PMR allows documentation of patient allergies, reason(s) for starting and discontinuing treatment, all medication and pain level changes, and additional notes on issues, such as adherence. Each double-sided page can track changes in ten appointments for 20 medications in a table. At least 35 patients were interviewed for their current medications in the five-week period. Some benefits include avoiding medication errors and unnecessary prescribing. The questionnaire revealed that all three clinicians find the tool practical, reasonably accurate, and are willing to use the PMR regularly. One of the clinicians found the initial interview stage time-consuming.

Conclusion:

The PMR appears to be a worthwhile and practical tool for tracking medication, pain and patient adherence.

Recruiting, Training And Evaluating Pharmacists Using Key Competencies

Tscheng DZ, Drug Information and Research Centre, Ontario Pharmacists' Association, Don Mills, ON, Gavura SR, Drug Information and Research Centre, Ontario Pharmacists' Association, Don Mills, ON

Rationale:

The Drug Information and Research Centre (DIRC) fields over 70,000 drug information (DI) requests annually. As the services of DIRC expand, the need to recruit pharmacists with specific skill sets also grows. Successful integration of new staff requires support through structured training and use of standardized performance evaluation tools that target these key skills.

Situation:

Previous recruiting efforts emphasized experience (e.g., extensive hospital practice or DI specialization), as the most important asset, followed closely by knowledge of DI resources. These criteria created a difficult recruiting situation.

Resolution and Implementation:

Changes in hiring criteria alone would not resolve the situation. First, key competencies were identified and used to develop our performance evaluation tools. The training program was then restructured to allow successful candidates to master these skill sets. Finally, new recruitment criteria were introduced based on the same competencies, rather than experience alone.

Results:

Results to date suggest no significant differences in the performance of new pharmacists and more seasoned staff, despite differences in initial levels of experience. New staff have integrated well into the team and upheld DIRC's service standards.

Relevance:

Selection, training and evaluation processes based on key competencies have been used to identify and support new DI pharmacists at DIRC. New recruits can be successful in their responsibilities with consistent messaging and active support to refine their skill sets. Other organizations engaged in recruiting and supporting pharmacists may find the use of key competencies to be a valuable approach.

Previously presented at CPhA Conference 2005

Development of a Strategy for Safe Dofetilide Prescribing and Monitoring

Nancy Rebellato, Helen Kang, Heather Kertland, St. Michael's Hospital, Toronto, ON

Rationale:

Dofetilide is an antiarrhythmic available through the Special Access Program on request by electrophysiologists. Initiation of dofetilide mandates a minimum 3 day hospital admission to monitor the QT interval, as there is a risk of torsade de pointes. It was determined that a standardized approach to the initiation and monitoring of dofetilide in hospital, as well as appropriate transfer of information to family physicians and community pharmacists was required to promote its safe and effective use.

Objectives:

To develop a strategy and tools to standardize the initiation and monitoring of dofetilide and a tool to transfer the information to the family physician and community pharmacist.

Methods:

Issues of procurement and dispensing of dofetilide were identified. In addition, the educational and process needs of the health care team to safely order

and administer dofetilide were determined. A variety of documents were created: 1) A pre-printed Dofetilide order form ensures appropriate dose selection and laboratory monitoring, 2) an information pocket card highlights the necessary monitoring parameters, contraindicated medications, dosage adjustment information and treatment of torsade de pointes, 3) a "Dear Doctor" and "Dear Pharmacist" letter was developed to transfer the monitoring information, contraindicated medications and precautions and 4) a medication pamphlet was developed as a teaching tool for the patient. Additional documents that will be developed are the requirements to become an authorized prescriber within the hospital and a procedure of how on-going supplies of dofetilide can be obtained. The documents were reviewed by the electrophysiologists and approved by the Pharmacy and Nursing and Pharmacy and Therapeutics Committees. To support this program, the pharmacist provided educational sessions to resident physicians and nurses.

Results:

The pharmacist-lead development of a "dofetilide program" ensures that the health care team members are aware of their responsibilities in caring for a patient receiving dofetilide and have the necessary knowledge and skills. It promotes safe prescribing of this medication that has potentially life-threatening adverse effects.

A Description of the Pharmacological Management of Acutely Agitated Patients in a Psychiatric Emergency Department

Rita Cheung, Center for Addiction and Mental Health, Toronto, Ontario, Albert Chaiet, Center for Addiction and Mental Health, Toronto, ON

Rationale:

Currently, a clear Canadian consensus does not exist on the first-line agents used to treat acutely agitated patients.

Objectives:

To characterize strategies used in the management of acutely agitated patients, with a primary focus on the agents used, dosing regimens, and other management measures at a Toronto psychiatric emergency department.

Study Design and Methods:

Patients who had received pro re nata (PRN) medication for agitation at the Centre for Addiction and Mental Health emergency department were followed for 72 hours. Items recorded included diagnoses, causes of agitation, PRN medications used, medications on admission, regularly prescribed medications, use of restraints and adverse events.

Results:

Ninety percent of patients were treated with oral medications for the first episode of acute agitation. The most common PRN medications administered for acute agitation included lorazepam, loxapine, and olanzapine. Monotherapy with a benzodiazepine was used most often. Lorazepam, loxapine and olanzapine were also most often prescribed as standing PRNs. Daily antipsychotic doses including standing and PRN doses never exceeded maximum recommended doses. The only documented side effect was sedation.

Conclusions:

Benzodiazepines remain the primary treatment of acute agitation in the CAMH emergency department. Use of the quick-dissolving formulation of olanzapine and loxapine are equally important at this facility. Most patients respond sufficiently to oral medications and intramuscular injections may not be necessary. Moderate doses of antipsychotics may be sufficient to manage the first episode agitation without requiring retreatment; reducing the overall risk of EPS and TD compared with higher doses or rapid dose titrations.

Entry-Level PharmD Degree Programs in Canada: Some Facts and Stakeholder Opinions

Peter J. Jewesson, Tamar Koleba, Judith Marin. Division of Clinical Pharmacy, Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC

Background:

The face of pharmacy education in Canada is about to change radically with the initiation of the first Entry-to-Practice Level PharmD (ELPD) degree program in the country. As we move toward a potential nation-wide change to our entry-to-licensure requirement, a review existing and planned programs is warranted.

Objective:

To provide updated information about existing pharmacy degree programs in Canada and the US, some characteristics of the "made in Quebec" ELPD degree program, and some stakeholder opinions about the merits of such a curricula conversion.

Methods:

We assessed multiple sources of information in order to gather information on the characteristics of existing and planned programs, and stakeholder opinions.

Results:

Eight provinces offer a total of nine pharmacy programs leading to a BSc (Pharm), BSc (Pharmacy) or BSP degree. As of 2005, the number of student enrolled in the first year of the 4-year programs ranged from 90 to 240, for a total of 1,137 students across all programs. In contrast, there are ~43,000 total students enrolled in programs at 89 colleges/schools of pharmacy in the US. The University of Montreal (UM) plans to transition from its existing baccalaureate program to an ELPD degree program in 2006. The new degree program will reportedly remain as a 4-year program, but will expand from eight to nine 4-month semesters in length. The number of required course

credits would increase from 142 to 164 credits (15%). Support for conversion to ELPD degree programs is divided, and six national stakeholder groups have declared their opposition.

Conclusion:

There are many parallels between pharmacy education in Canada and the US. While the likelihood of conversion to an all ELPD degree requirement in this country appears high, we also have an apparent absence of unified support for this transition. As our American neighbours watch this process play itself out, Yogi Berra's infamous quotation "...this is like déjà vu all over again" seems appropriate.

Clinical Practice Guidelines for Community-Acquired Pneumonia: An Investigation into Creation, Characteristics, Quality and Compliance with Production Guides

Peter J. Jewesson, Sandeep Gill, Division of Clinical Pharmacy, Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC

Background:

Several clinical practice guidelines (CPG) have been published by various organizations to enhance the quality of care for adult patients with community-acquired pneumonia (CAP). While guides for the development of quality CPG have been produced, no systematic assessment of the concordance across these guides, and the degree of compliance of existing CAP CPG has been undertaken.

Objective:

In this study we explore the evolution of CAP guidelines produced by four key organizations (IDSA, ATS, CIDS, BTS) over the past decade, assess their degree of compliance and identify any weaknesses found.

Methods:

We undertook a comprehensive literature search to identify CPG production guides and CAP CPG for the period 1990-2004. Criteria for quality CPG was extracted and concordance across guides assessed. Compliance with these guides was then determined for select published CAP CPG.

Results:

We identified at least 13 published guides for CPG, and 17 CAP CPG over the past 14 years. Ten CAP CPG produced by the four organizations were selected for review. Two guides were produced by organizations also responsible for CAP CPG. While there was general concordance across the guides with respect to the criteria for quality CPG, some deficiencies were seen in the domains of patient values, conflict of interest statements and declaration of funding sources. These shortcomings were also noted in the CAP CPG reviewed.

Conclusion:

Several guides for the creation of CPG have been published over the past several years. Some inconsistencies in the criteria for quality CPG exist. Published CAP CPG do not always adhere to all of the principles of good guideline production.

Retrospective Methods of Measuring Practice Change of Pharmacists in Continuing Education

Certina Ho, Sandra Winkelbauer, Drug Information and Research Centre, Ontario Pharmacists' Association, Don Mills, ON

Purpose:

The three-day Patient Care Certificate Programs (PCCP) organized by the Ontario Pharmacists' Association (OPA) employs a multifaceted approach in providing continuing professional development (CPD) to pharmacists. Teaching and learning strategies that may lead to increasing competence and clinical performance of participating pharmacists are incorporated. Consequently, it is worthwhile to explore the effect of these programs on practice changes of the participants.

Objectives:

This study had 3 objectives:

1. Examine the degree and nature of practice change of participants in OPA PCCP.
2. Compare the effectiveness of two retrospective self-reporting methods.
3. Identify the barriers to practice change.

Description:

A questionnaire was developed using two retrospective self-reporting methods – post + retrospective pretest and perceived change method – and mailed to 174 pharmacists who participated in 3 selected OPA PCCP.

Evaluation:

Forty-four pharmacists completed the questionnaire. Participants' perception of pharmacy practice was increased after attending the PCCP. Pharmacists who responded to the perceived change method expressed a greater degree and nature of practice change than those who responded to the post + retrospective pretest method. Pharmacists' behavioural change might depend on individual preference of teaching or learning methods and identification of barriers to practice change.

Importance and Usefulness for Pharmacists:

Literature on evaluation of continuing education for pharmacists is very limited. As the use of retrospective methods is becoming more popular in the evaluation field, findings from this study should encourage future evaluative studies in the field of CPD and contribute to the literature on retrospective methods of measuring change.

Systematic Protocol for Managing Drug Information Requests

Certina Ho, Dorothy Tscheng, Drug Information and Research Centre, Ontario Pharmacists' Association, Don Mills, ON

Rationale:

In responding to over 70,000 drug information (DI) questions from pharmacists and patients annually, the Drug Information and Research Centre (DIRC) recognizes that standardization of managing DI requests is essential. To ensure consistency among DIRC pharmacists in responding to DI requests, a standardized procedure needs to be in place.

Description:

DIRC pharmacists developed a systematic protocol, which includes an electronic prompting tool, embedded in a MS Access documentation database, and a schematic guide to aid pharmacists in collecting relevant background information and preparing the response to DI requests.

Implementation:

Senior DI pharmacists used previously answered DI questions and standardized cases to test the protocol. Once the nature of the request is clear, the DIRC pharmacist defines the category of the question (e.g., product identification, drug interaction, adverse drug reaction), which in turn activates the prompting tool. Category-initiated specific prompts then automatically display on the documentation screen of the MS Access database to assist the pharmacist in assessing the clinical situation.

End Result:

Armed with pertinent background information, the pharmacist utilizes this schematic, category-specific critical thinking pathway and relevant resources to systematically handle DI requests effectively and efficiently. Quality assurance evaluation of this protocol is ongoing.

Importance and Usefulness for Pharmacy Practice:

This systematic approach to managing DI requests can be applied in other practice settings, where pharmacists can use a similar protocol to hone their data collection, critical thinking, and analytical skills in addressing DI requests from patients, physicians, and other health care providers.

Wednesday, February 1 ▪ Mercredi le 1er février

The Confidentiality of Community Pharmacy Records is at Risk: A Survey of Designated Pharmacy Managers

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Rationale:

Prescription data stream from community pharmacy computers risking physician and patient confidentiality.

Objectives:

Surveying designated pharmacy managers about disclosure practices may identify strategies for protecting the confidentiality of information in pharmacy computers.

Methods:

Surveys focusing on the confidentiality of prescription data in pharmacy computers were sent to the designated manager of 500 randomly selected pharmacies in Ontario.

Results:

Surveys were completed by 49%, 240 of 490 designated managers. Half (48%) were aware physician-linked prescribing information and 31% were aware potential patient identifiers linked with prescriptions are disclosed to compilation companies. Most designated managers (91%) thought selling prescribing information identifying physicians was unacceptable and 85% thought selling potential patient identifiers was unacceptable. Most (86%) agreed the written consent of physicians should be required before prescribing information is disclosed and 58% disagreed that verbal consent adequately protected patient confidentiality. Many designated managers (70%) agreed that prescribing is negatively impacted when pharmaceutical sales representatives know prescribing histories. Most (88%) agreed patients would lose trust in pharmacists if patients knew potential patient identifiers were disclosed. Only four of 240 designated managers reported signing agreements to allow the sale of physician-linked prescribing information and only two signed agreements allowing the sale of potential patient identifiers from pharmacy computer systems.

Conclusions:

The confidentiality of health information in pharmacies is at risk. We recommend the Ontario College of Pharmacy (OCP) uphold their own standards and that pharmacists pressure the OCP to protect physician and patient confidentiality and thereby maintain public confidence in the profession.

Stability of Bortezomib Vials Reconstituted with 0.9% Sodium Chloride at 4°C and Room Temperature (23°C)

Scott E. Walker[1,2] MScPhm, Debbie Milliken[3] BScPhm, and Shirley Law[1], Dip Pharm Tech.

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Rationale:

The bortezomib product monograph indicates that reconstituted vials may be stored for up to 3 hours in a syringe, but total storage time for the reconstituted material must not exceed 8 hours when exposed to normal indoor lighting. The cost of each 3.5mg vial is $1,766. Based on the product packaging/vial size, there is the potential for considerable wastage that could amount to approximately $12,000 for a 5-cycle course of bortezomib therapy for a single patient, given the currently recommended dosage regimen. It is the intent of this study to evaluate the stability of bortezomib 3.5 mg vials reconstituted with 3.5 mL of 0.9% sodium chloride (NS) to produce a 1-mg/mL solution.

Methods:

On study day 0, 8 – 3.5 mg vials were reconstituted with 3.5 mL of NS to prepare 1.0 mg/mL of solution. 4 vials of were stored at room temperature and 4 were stored in the refrigerator. Concentration and physical inspection were completed on each solution on study days 0, 1, 3, 7, 10, 14, 21, 28, 35 and 42. The intervals for the study days used were consistent with the recommended dosage regimen from the product monograph. Bortezomib concentrations were determined by a validated, stability-indicating, liquid chromatographic method.

Results:

All solutions remained clear and colorless. During the study period all solution remained more than 90% of the initial concentration. During the study period the average absolute deviation from the known concentration for standards and QC samples averaged less than 4% and analytical reproducibility within a day (CV) averaged less than 2%.

Conclusions:

We conclude that 3.5-mg vials of bortezomib reconstituted with 3.5 mL of NS are physically and chemically stable for up to 42 days at 4C or room temperature.

Stability of Naloxone Stored in Aqueous Diluents in Syringes at 4C and Room Temperature (23C)

Scott E. Walker[1,2] MScPhm, Jeff Chan[3] BScPhm, and Shirley Law[1], Dip Pharm Tech.

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[2]University of Toronto, Toronto and
[3]Thunder Bay Regional Health Sciences Centre.

Rationale:

Epidural opiates are often used for pain relief. The previous epidural of choice included nalbuphine. However, this product has been taken off the market. Naloxone has been reported to be effective, but stability information is not available.

Objective:

The objective of this study was to evaluate the stability of naloxone (0.04 and diluted in either bacteriostatic saline, bacteriostatic water, 0.9% sodium chloride (NS) or sterile water for injection (SWFI) and stored at 24C or 4C for 33 days.

Methods:

On study 0, 24 – 3mL syringes were prepared each containing a 0.04 mg/mL of solution of naloxone through dilution of 1 mL of 0.4 mg/mL naloxone with 9 mL of either bacteriostatic saline, bacteriostatic water, NS or SWFI. 6 syringes were prepared for each diluent. 3 syringes of each diluent were stored at room temperature and 3 were stored in the refrigerator. Concentration and physical inspection were completed on each solution on study days 0, 1, 4, 7, 11, 15, 19, 21, 27 and 33. Naloxone concentrations were determined by a validated, stability-indicating, liquid chromatographic method.

Results:

All solutions remained clear and colorless. ANOVA detected a significant difference in concentrations between study day ($p<0.001$), temperature ($p<0.001$), but not diluent ($p > 0.14$). Nevertheless, the amount remaining on study day 33 was greater than 93.9%, in every solution, with 95% confidence. Solutions stored at room temperature lost, on average, 3.7% (95%CI) during 33 days of storage compared to 1.4% loss (95% CI) with solutions stored at 4C. During the study period the average absolute deviation from the known concentration for standards and QC samples averaged less than 4% and analytical reproducibility within a day (CV) averaged less than 0.64%.

Conclusions:

We conclude that 0.04 mg/mL solutions naloxone diluted in either bacteriostatic saline, bacteriostatic water, NS or SWFI are physically and chemically stable for up to 33 days at 4C or room temperature while stored in syringes, retaining more than 93.9% of the original concentration.

A Prospective Randomized Study of 4% Citrate vs. Heparin for the Prevention of Bacteremia and Thrombosis in Patients with Hemodialysis Catheters

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[1]*Department of Pharmacy, and*
[2]*Division of Nephrology, St. Paul's Hospital, Vancouver, BC*

Background:

The use of hemodialysis catheters is associated with a number of complications such as infection and catheter dysfunction. This prospective study compares the use of heparin to citrate as a hemodialysis catheter locking agent in the prevention of catheter related bacteremia (CRB) and catheter dysfunction (CD).

Methods:

Hemodialysis patients were alphabetically randomized to receive either heparin 1:5000 units or citrate 4% until their catheters were removed or the study completion date was reached.

Results:

A total of 53 patients were enrolled: 31 in the heparin group and 22 in the citrate group. Four episodes of CRB occurred in both groups. This translates into 2.6 episodes of CRB per 1000 catheter days for the heparin group and 2.4 for citrate (p=0.605). Catheter dysfunction (defined as use of alteplase for restoring catheter function) occurred in 36.4% of patients in the heparin group and 38.7% of patients in the citrate group (p=0.862). There was also no difference between the groups in terms of time to the first CRB or CD.

Conclusions:

The results show that citrate and heparin are not different in preventing catheter related bacteremia and catheter dysfunction. However, there were not enough patients in the study to conclude equivalence.

Implementation and a Randomized Controlled Evaluation of Pharmacist Medication Assessments in a Surgical Pre-Admission Clinic

Yvonne Kwan[1], Olavo Fernandes[1,2], Jeff Nagge[1], Gary Wong[1], Jin-Hyeun Huh[1], Deborah Hurn[1], Jana Bajcar[2];

[1]*University Health Network, Toronto, ON, Canada;*
[2]*Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON, Canada*

Purpose:

Post-operative hospital admission is a key vulnerable moment where patients are at increased risk of medication discrepancies. This study measures the impact of a combined intervention of structured pharmacist medication assessments in a surgical pre-admission clinic (PAC) and a post-operative order form on reducing medication discrepancies.

Methods:

In this randomized, prospective, parallel study, patients who had a PAC appointment prior to undergoing selected surgical procedures were eligible for inclusion. Patients were excluded if they were scheduled for discharge the same day as their surgery. Eligible patients were randomly assigned to the intervention arm (structured pharmacist medication assessment and generation of a post-operative medication order form) or standard care (nurse-conducted medication histories and surgeon-generated orders). The primary endpoint was the incidence of patients with at least one post-operative medication discrepancy related to home medications.

Results:

From April 19, 2005 to June 3, 2005, 310 patients completed the study after exclusions due to pending and cancelled surgeries and admissions to in-patient units not participating in the study. Of the 310 patients, 154 and 156 patients were randomized to the intervention and standard care arms respectively. In the intervention arm, 30 (19.5%) patients had at least one post-operative medication discrepancy related to home medications, compared to 68 (43.6%) in the standard care arm (p<0.001).

Conclusion:

A combined intervention of pre-admit pharmacist medication assessments and a post-operative order form can reduce post-operative medication discrepancies related to home medications. Pharmacist involvement in the PAC can improve patient safety during post-operative hospital admission.

Will be presenting at American College of Clinical Pharmacy Annual Meeting, October 23-26, 2005, San Francisco

Risk Assessment of Medications in a Pharmacy Clean Room

Norman Dewhurst, BScPhm, Pharmacy Resident, Peter Davies, BScPhm, Coordinator of Medication Systems, Janice Wells, PharmD, Pharmacy Manager, Jasna Stojanovski, Pharmacy Technician, St. Michael's Hospital, Department of Pharmacy, Toronto, Ontario

Reason for Initiative:

The Institute for Safe Medication Practices has identified classes of medication and specific medications as being "high-alert" risks. Many of these medications are used in a pharmacy clean room. In addition, the Canadian Council on Health Services Accreditation (CCHSA) has set new patient safety goals, which include ensuring the safe use of high risk medications and administration of parenteral medications. A pharmacy clean room would be impacted by these requirements. To fulfill these patient safety goals, a risk assessment of medications in the pharmacy clean room was undertaken.

Description of Initiative:

The risk assessment design included examining every medication located in or near the pharmacy clean room; documenting the concentration, product format, trade name and manufacturer, the risk potential of the product and the product for which it may be mistaken. The criteria used to assess risk were: concentrated electrolyte or sound alike/look alike potential with any

other product in the pharmacy. A predetermined weighting system was used to classify the risk potential as high, medium or low. After analysis of the degree and nature of risk potential, a series of recommendations were made with the goal to prevent medication near misses or incidents.

Evaluation:

Implementation and evaluation of the recommendations will be a future project.

Importance and Usefulness of Initiative for Pharmacists:

Identifying and prioritizing "at-risk" medications in a pharmacy clean room could be considered a first step to comply with CCHSA standards and to ensure patient safety pertaining to parenteral medications.

Successful Treatment to Guideline Recommended LDL-Cholesterol Targets in Heart Transplant Recipients

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Edmonton, Alberta.

Purpose:

The association between hyperlipidemia and development/progression of coronary allograft vasculopathy (CAV) is well-established. Consequently, the CCS Consensus Conference on Cardiac Transplantation recommends that this population be treated with statins to an LDL-cholesterol goal of <2.5 mmol/L. We sought to determine the proportion of patients reaching this LDL-target and evaluate the pattern of lipid-lowering agent use among our OHT recipients.

Methods:

The medical records of all adult patients transplanted since January 1996, who were >6 months post-OHT, and actively followed in our outpatient clinic were reviewed retrospectively.

Results:

135 patients were included; 126 (93.3%) patients at target, with an LDL<2.5 mmol/L. The mean LDL was 1.88±0.58 mom/L for all patients and 3.41±0.69 mmol/L for those not at target. Statins were used in 127 (94.1%) patients. The agents prescribed (mean dose±SD) were: atorvastatin (23.6±20.1 mg/day) in 117 (92.1%) patients, pravastatin (24±8.9 mg/day) in 6 (4.7%) patients and simvastatin (30±11.5 mg/day) in 4 (3.2%) patients. Reasons for not prescribing a statin included: LDL <2.5 mmol/L and non-ischemic indication for OHT (n=5), statin-induced myalgias (n=2), and statin-induced depression (n=2). Among the patients who failed to achieve target LDL, 5 were on a statin at the maximum recommended dose (n=2) or the maximum tolerated dose (n=3), limited by myalgias.

Conclusions:

It is possible to achieve an LDL-target of <2.5 mmol/L in a significant proportion of OHT recipients. Despite concerns regarding potential pharmacokinetic drug interactions between statins and calcineurin inhibitors, they can be safely combined when patients are followed regularly with close biochemical and clinical monitoring.

Development of a Comprehensive Training Program for New Pharmacist Hires

Kori Leblanc, BScPhm, ACPR, Salma Bhaloo, BScPhm, ACPR, St. Michael's Hospital, Toronto, ON

An opportunity to evaluate and revise the orientation of new pharmacist hires presented itself with the launch of a new pharmacy computer system. Given the current professional climate, it is believed that vacancies for pharmacist positions will continued to be filled by candidates with different levels of clinical experience and that a comprehensive standardized training procedure is essential to orient new staff to institutional and professional standards of practice.

Existing training documents were reviewed. Interviews were conducted with recently trained pharmacists. Strengths, weaknesses and improvements to current training procedures were identified including: the need for standardization, increased focus on problem solving, updating of materials to reflect current procedures and a method to assess skill and readiness for independent practice.

The revised training program included increased decentralized exposure to clinical areas and associated common drug related problems (DRP). Actual examples of DRPs requiring problem solving at the point of prescription processing were incorporated into an interactive learning tool. For computer training, tools were developed to reflect both simple and complex medication orders. An audit tool was created to gauge readiness for independent order entry. The overall training checklist was reviewed to ensure all aspects of current processes and procedures were updated.

The new training package has been used in the training of 5 new pharmacist hires. Initial informal feedback from new staff and trainers suggests that this standardized approach ensures a basic competency in technical performance and resolution of common DRPs, and an increase in pharmacist confidence which supports their readiness for independent practice.

In vitro modeling of IV Meropenem [500 mg q 6h vs. 1g q8h] in Acinetobacter Bacteraemia

Romina Marchesano, Sandra Walker, Scott Walker, Naveen Gnanabakthan, Shirley Law, Christine Watt, Andrew Simor

Objective:

The objective of this study was to determine, via an in vitro model of infection, whether the rate and extent of killing of a sensitive and multi-drug resistant strain of Acinetobacter baumannii differed when meropenem was administered at a dose and frequency modeling 500mg iv q6h vs. 1g iv q8h infused over 30 minutes.

Methods:

An in vitro model of infection using a 1-compartment model for meropenem was used. Two clinical isolates of A. baumannii were tested, a sensitive and multi-resistant strain (not resistant to meropenem and amikacin). 24-hour experiments were run using concentrations that resembled meropenem given by intravenous infusion over 30 minutes for 500mg q6h and 1g q8h regimens. Samples were taken throughout the 24 hours for quantification of meropenem and A.baumannii growth.

Results:

There was no statistically significant difference in % of time spent above the MIC (%T>MIC) between 500mg q6h and 1g q8h (p=0.48, 95% CI -34.94 to 52.38). When looking at the resistant strain only, meropenem remained above the MIC for a longer period of time in the 500mg q6h regimen compared to the 1g q8h regimen (p=0.0004, 95% CI 9.95 to 23.43). No difference was found for the sensitive strain. The extent of kill of A.baumannii was not statistically different between the two regimens (p=0.85, 95% CI -2056.85 to 2405.59). The 500mg q6h regimen achieved a 3 log reduction (99.9% kill) in less time than the 1g q8h regimen (p=0.0006, 95% CI -131.70 to -60.43).

Conclusions:

Meropenem 500mg q6h has at least equal antimicrobial activity as 1g q8h against a sensitive and multi-drug resistant strain of A. baumanii. Since the drug acquisition costs of meropenem 500mg iv q6h are lower than 1g iv q8h (~$100/day vs $150/day), this dosing regimen may be preferred.

Lowering of Serum Valproic Acid Levels during Concomitant Therapy with Meropenem: A Clinically Relevant Drug Interaction

Angela Trope[1], Beth Gamulka[2], Warren Walsh[3], Zulfikarali Verjee[3], Chris Parshuram[4]

[1]Department of Pharmacy,
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Meropenem is a carbapenem, beta-lactam antibiotic. Its broad spectrum of microbiological activity and low potential for inducing seizures, compared with imipenem, make it an ideal agent for treating invasive infections with the potential to induce seizures or in children with a predisposition to seizures.

We report a case of a child whose serum valpoate levels dropped to subtherapeutic levels (<70µmol/L) (therapeutic range 350-700µmol/L) during concomitant treatment with meropenem. Serum valproate levels which were within the therapeutic range prior to starting meropenem declined to <70µmol/L over 4 days during treatment with the antibiotic. Meropenem was discontinued and the dose of valproic acid was increased by 18%. Serum valproate levels returned to therapeutic concentrations over 3-7 days.

The change in valproate concentrations seen in our patient was similar to cases reported in the literature. The interaction, however, is inconsistently reported in drug resources. The interaction between meropenem and valproic acid is both unusual and intriguing. It is clinically relevant and the combination should be avoided.

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Piera T. Calissi, B.Sc.(Pharm.), Pharm.D.

Piera is Co-ordinator of Clinical Pharmacy Services at St. Paul's Hospital in Saskatoon and a Clinical Assistant Professor of Pharmacy at the University of Saskatchewan. She graduated with a Bachelor of Science in Pharmacy degree from the University of British Columbia in 1982 and a Pharm.D. degree from Wayne State University in Detroit, Michigan, in 1994. She completed a residency in hospital pharmacy practice at Royal Inland Hospital in Kamloops, B.C.

Piera's areas of interest include all aspects of chronic kidney disease. She currently provides pharmaceutical care to inpatient dialysis patients at St. Paul's Hospital. She is also involved in clinical research projects sponsored by the Renal Risk Reduction Center at the Nephrology Center of Excellence at St. Paul's Hospital and has conducted projects on erythropoietin resistance, hypertension, patency of hemodialysis catheters, and treatment of CAPD peritonitis. She acts as a preceptor to pharmacy students and residents and is a clinical instructor at the University of Alberta. She is the author of numerous publications and is a regular presenter in the area of chronic kidney disease.

Piera is an active member of the Canadian Society of Hospital Pharmacists and has served as the Saskatchewan Branch awards chair, treasurer and president. She has been awarded the CSHP Saskatchewan Branch Merit Award and Past President's Award.

Barbara L. Evans, B.S.P., ACPR, M.Sc.

Barb Evans graduated from the University of Saskatchewan with her Bachelor of Science degree in Pharmacy in 1986, completed a CSHP-accredited Residency in Hospital Pharmacy at the Royal University Hospital in 1987, and earned her Master of Science degree from the University of Saskatchewan in 1992. Following this she worked for one year as an Assistant Professor at the College of Pharmacy, University of Saskatchewan. In 1993, she was hired as the Clinical Coordinator for Saskatoon City Hospital. She moved to Royal University Hospital in 1997, where she assumed the role of Coordinator of Clinical Pharmacy Services.

During her career, Barb has been involved with the development of numerous policies, procedures, and programs in the Saskatoon Health Region. She is currently co-chair of the Region's medication reconciliation initiatives. Recent achievements include co-development of an orientation program for staff pharmacists, co-development of a performance feedback process for staff pharmacists, and development of the SHR antibiogram and aminoglycoside/ vancomycin adult dosing cards. Barb has also recently been responsible for training and mentoring six new staff pharmacists.

Barb has maintained a clinical practice in internal medicine since 1994 at Royal University Hospital. She provides patient-focussed care to individuals admitted to one of the clinical teaching units. She has supervised numerous pharmacy students and residents on internal medicine rotations. Barb has also been the Coordinator of the Saskatoon Health Region pharmacy residency program since 1999.

As a clinical assistant professor with the College of Pharmacy and Nutrition at the University of

Saskatchewan, Barb provides the respiratory and transplantation lectures to the third-year pharmacy students in their pharmacotherapy course. In addition, she has precepted numerous pharmacy students during their Structured Practice Experience Program. She is also an associate member of the Department of Pharmacology.

Barb has enjoyed active involvement in many pharmacy-related associations. Her various leadership positions within CSHP's Saskatchewan Branch include secretary, president-elect, president, past president, and past-past president, Awards chair, 1999 CSHP AGM Planning Committee co-chair, and Education Committee chair and financial co-chair. She has also served on numerous ad hoc CSHP Saskatchewan Branch committees such as the Pharmaceutical Care Steering Committee.

Barb has provided numerous inservices, presentations, and continuing education seminars to pharmacists, physicians, nurses, and allied health care professionals at the local, provincial, and national levels. She is currently a member of the Saskatchewan Lung Association expert committee for the development of a National COPD Trec Program for health-care professionals. She serves on numerous hospital committees as well as the provincial Drug Quality Assessment Committee. She has also been involved with numerous research and quality initiatives. Current research includes a clinical teaching unit discharge medications pilot, evaluation of current SHR vancomycin dosing strategies, and development of a pharmacist quality assurance program for monitoring vancomycin. Barb is also an editor for Therapeutic Choices.

Barb is truly honoured to receive a fellowship. She would like to acknowledge the wonderful group of enthusiastic and supportive pharmacists, technicians, and support personnel she works with on a daily basis.

Alfred Gin, B.Sc.Pharm., Pharm.D.

Alfred Gin earned his Bachelor of Science in Pharmacy degree at the University of Manitoba in 1984 and completed a hospital pharmacy residency at the Health Sciences Centre (HSC) in Winnipeg in 1985. He worked as a Staff Pharmacist in the Critical Care Satellite Pharmacy at the HSC from 1985 to1986. After working for a year, Alfred entered the Doctor of Pharmacy program at the State University of New York at Buffalo, completing his Pharm.D. in 1988.

Following completion of his Pharm.D, Alfred worked as a Clinical Pharmacist in Oncology/Infectious Diseases from 1988 to 1989 and as a Clinical Pharmacist in Infectious Diseases from 1988 to the present, at the HSC in Winnipeg. During this time Alfred has been active in the development and implementation of antimicrobial programs and the provision of clinical service and education in infectious diseases. He actively participates as an infectious diseases and research preceptor for the Winnipeg Regional Health Authority Pharmacy Residency Program. In addition to his position at the HSC, Alfred has cross-appointments as an Assistant Professor in the Department of Medical Microbiology in the Faculty of Medicine and as a Clinical Assistant Professor in the Faculty of Pharmacy, University of Manitoba.

Alfred has presented on numerous occasions at the international, national, and local level. In addition, he has published numerous papers on antibiotic reviews, antibiotic resistance, and various infectious disease topics in peer and non-peer reviewed journals. Alfred has been the recipient of several CSHP national and local awards (e.g. Glaxo Wellcome, Sandoz, Roche) since entering pharmacy practice. Research interests include antibiotic utilization, antibiotic resistance, and recently, C. difficile.

As a member of CSHP, Alfred has actively participated in the Infectious Diseases PSN and has served in many positions with CSHP's Manitoba Branch (e.g. Awards Committee member, president, branch website development, webmaster, and communications liaison). He participated in the CSHP national website redevelopment process and has served as a manuscript reviewer for CJHP. In addition, Alfred is a member of the Canadian Pharmacists Association (CPhA) and the CPS Editorial Advisory Panel. As a representative of CPhA, he has participated in the Infection Control and Prevention Alliance, Health Goals for Canada Expert Roundtable on Infectious Diseases consultative process and pandemic influenza planning. Alfred continues to participate in national, provincial and local committees and task forces.

Nicholas Honcharik, Pharm.D.

Nicholas Honcharik graduated with a Bachelor of Science degree in Pharmacy from the State University of New York at Buffalo in 1978 and completed a hospital pharmacy residency at the Medical College of Virginia Hospitals in 1979. He returned to the State University of New York at Buffalo in 1982 and obtained a Doctor of Pharmacy Degree in 1984.

Since 1979, Nick has focused his clinical practice in critical care. He has worked (practiced) in a number of facilities including the Medical College of Virginia Hospitals, the Buffalo General Hospital, and the Health Sciences Centre, Winnipeg (since 1986). Nick has developed and implemented numerous projects and protocols within the realm of critical care. Most recently he has been involved in the Canadian ICU Collaborative, and he was the primary Winnipeg lead for the implementation of a sedation assessment tool in all Winnipeg ICU's.

Nick has held a variety of positions within pharmacy management at the Health Sciences Centre since1988. Currently he is the Regional Pharmacy Manager, Professional Practice Development, within the Winnipeg Regional Health Authority. Major projects now underway are the development and implementation of regional clinical practice standards and the regional implementation of medication reconciliation.

Nick has been actively involved in the Canadian Society of Hospital Pharmacists. From 1999 to 2002, he was the Manitoba Branch delegate. In 1988, Nick was one of the founding trustee's of the Canadian Society of Hospital Pharmacists' Research and Education Foundation. Current activities include membership on the Governance Task Force and the Practice Standards Steering Committee.

Throughout his career Nick has been involved in pharmacy-related education. He has precepted undergraduate pharmacy students/residents and provided lectures/presentations to pharmacy students, nursing/allied health students, pharmacy staff, and community health groups. Currently he has an appointment as a clinical assistant professor at the University of Manitoba. Nick has published articles, engaged in research, and made numerous presentations at the provincial and national level. He has been honored with various awards recognizing his contributions to pharmacy practice and research.

Shallen Letwin, B.Sc.Pharm., Pharm.D.

Shallen Letwin graduated with a Bachelor of Science in Pharmacy degree from the University of Alberta in 1991. During his undergraduate years he was actively involved in the Pharmacy Students Undergraduate Society, holding the position of student president. Shallen started his hospital pharmacy career as a clinical pharmacist at Alberta Hospital Edmonton, where he developed new clinical pharmacy services in acute psychiatry.

Shallen went on to complete a Doctor of Pharmacy degree at the University of British Columbia in 1995. Throughout his career Shallen has been a Clinical Pharmacy Specialist in ambulatory care, neurology, and cardiology. He has also held clinical leadership positions as Regional Clinical Pharmacy Coordinator for the David Thompson Health Region in Alberta and the Fraser Valley Health Region in B.C.

Shallen has been active with many pharmacy-related organizations, including serving as CSHP's British Columbia Branch Education Programs chair; CSHP Alberta Branch Banff Seminar chair; Alberta Hospital Pharmacy residency examiner; Alberta Pharmaceutical Association vice chair, Practice Review Committee member; member of the College of Pharmacists of British Columbia Hospital Pharmacy Committee; assessor for the Pharmacy Examining Board of Canada; and most recently as CSHP's National president-elect.

Currently Dr. Letwin is a member of the Senior Pharmacy Leadership Team as Manager, Clinical Pharmacy Services, Drug Utilization Evaluation, Information and Research, for Fraser Health in British Columbia. He also maintains a clinical practice in an internal medicine ambulatory clinic, where he provides pharmaceutical care to patients with diabetes and cardiovascular disease. Shallen's work in this clinic has been recognized with the 2003 Pharmacy Practice Commitment to Care Award for Best Pharmacist-Physician Team. Shallen has also developed a medication assessment clinic in partnership with a community pharmacy, where he provides pharmaceutical care assessments to patients by appointment.

Shallen continues to be actively involved in teaching and education. He is a clinical assistant

professor in the Faculty of Pharmaceutical Sciences at the University of British Columbia. He is the section coordinator for endocrinology in the Doctor of Pharmacy Program and teaches diabetes to Pharm.D. and undergraduate students. Shallen is also the new course coordinator for a pharmacotherapeutics course for nursing students at the University College of the Fraser Valley.

Shallen has published papers and provided presentations locally, nationally, and internationally to pharmacists and physicians on various therapeutic topics. Recently Shallen presented the "Role and Training of the Hospital Pharmacist in Canada" at the International South China Cardiovascular Conference in Guangzhou, China. His professional interests include diabetes, heart failure, anticoagulation, and advanced patient care roles of the pharmacist. Shallen's research interests include initiatives that optimize and promote direct patient care by pharmacists.

Outside of pharmacy, Shallen enjoys cooking, reading, and running, and is also an avid skipper and reality TV show viewer! He enjoys time with his wife, Yvonne, and their two daughters, Hanna and Kate.

Susan Poulin, B.Sc.(Pharm.)

Susan Poulin earned her Bachelor of Science degree in Pharmacy at the University of Manitoba in 1972. In 1999 she became a Certified Asthma Educator. Susan's main areas of interest are respiratory diseases, pain management, palliative care, quality assurance, and drug use evaluation. She is currently the Drug Use Evaluation/Drug Information Pharmacist for the Regina Qu'Appelle Health Region (RQHR).

Throughout her career Susan has taken a leadership role in the development of guidelines and protocols within RQHR. For many years Susan has been a member of the Pharmacy and Therapeutics committee, the Antimicrobial Utilization Committee, and the Client Education Advisory Committee within the RQHR, where she has made a significant impact in defining and implementing policy related to medication use within the Region. She has also been a longstanding member of the Advisory Committee on Institutional Pharmacy Practice within the Province of Saskatchewan. She has served in many capacities in Regina and impacted patient care in all of them. As the Co-ordinator of Clinical Services and Education at the Regina General Hospital, she developed a quality assurance and certification program for the aminoglycoside monitoring service, assisted the Pharmacy and Therapeutics Committee in its endeavours, and was instrumental in the development of the hospital's Acute Pain Management Guidelines. As a member of the Pediatric Asthma Clinic Team, she worked with the physician and nurse to educate patients in self-management techniques. More recently Susan has been very involved in evaluating anticoagulant and antimicrobial use and subsequently developing guidelines and protocols. She also provides clinical support to the Palliative Care Program and seamless care to its patients.

Susan has been actively involved in education at various levels. She is a member of the Region's Residency Committee and serves as a preceptor for pharmacy residents and a supervisor for residency projects. She has been a presenter to pharmacists at both the national and provincial levels and has written several independent learning continuing education lessons. She has also been a regular presenter for the Continuing Medical Education and Continuing Nursing Education divisions of the University of Saskatchewan.

Susan has been active in CSHP and other pharmacy-related associations. She has served CSHP's Saskatchewan Branch in many capacities, including as a member of the Professional Practise Committee and Education Services Committee, and as branch president and national delegate. Susan has also served as the CSHP representative to the Canadian Council on Continuing Education in Pharmacy (CCCEP). She has been a reviewer for the CJHP and for the CCCEP Independent Study Program.

Outside of pharmacy, Susan enjoys playing tennis, reading, hiking, and spending time at the cottage with her husband Dennis and their sons, Michael and Eric.

Nancy L. Roberts, B.Sc. (Pharmacy)

Nancy Roberts received a Bachelor of Science in Pharmacy degree from Dalhousie University in 1982 and a diploma in Departmental Management from the Canadian Healthcare Association in 1993. Following graduation she joined The Moncton Hospital. She held various positions on staff and served as Director of Pharmacy Services for nine years before her appointment as Vice President, Planning and Professional Services, in June 2003. Her VP portfolio includes responsibility for quality improvement and patient safety; risk management; utilization; research; health records; and the professional services of clinical nutrition, occupational therapy, pharmacy, physiotherapy, psychology, respiratory therapy, social work, speech pathology, and audiology.

Nancy has been a very active member of the Canadian Society of Hospital Pharmacists (CSHP) and has contributed to the Society at both the Branch and National levels, serving on a number of committees and task forces, including as the New Brunswick Branch president from 1987 to 1989 and the National CSHP president for the 1994-1995 year. She is past-chairperson of and served six years on the Canadian Hospital Pharmacy Residency Board.

Nancy has been actively involved in research initiatives to support seamless pharmacy care services, and she is serving her fourth year as a member of the Editorial Board for the Hospital Pharmacy in Canada Survey.

At the provincial level, Nancy has served as the hospital liaison on the New Brunswick regulatory authority's council and as the provincial representative on the National Association of Pharmacy Regulatory Authorities' (NAPRA) National Continuing Competency Committee. She was a member of the New Brunswick Premier's Health Quality Council (January 2000 to January 2002) and is currently a member of the Provincial Primary Health Care Collaborative Committee and the NB Telehealth Working Group.

Nancy's contribution to the profession has been recognized by her peers through the receipt of the Canadian Society of Hospital Pharmacists Isabel E. Stauffer Meritorious Service Award (2004), the New Brunswick Pharmaceutical Society Meritorious Service Award (1999), and the CSHP New Brunswick Branch Gordon Kane Meritorious Service Award (1998).

David Rosenbloom, B.Sc., B.S., Pharm.D.

David Rosenbloom was Director of Pharmaceutical Services at Hamilton Health Sciences, in its various incarnations, from 1997 to 2002. He is a Professor of Medicine at McMaster University. He has been a member of CSHP since 1977.

As Director of Pharmacy, David was instrumental in making his hospital the first in Canada to remove potassium chloride concentrate from clinical areas. Other achievements include joining the Research Ethics Board of Chedoke-McMaster Hospital in 1982 and eventually chairing this Board from 1980 to 1988. David became a clinical trials researcher in the field of thromboembolism and played a major role in the design and conduct of studies and in the achieving of complex double-blind strategies that masked dosage form and route of administration of anticoagulants.

David continues to play a role in the patient safety movement in Canada, having collaborated in organizing and speaking at a number of national meetings and representing CSHP on the Canadian Coalition for Medication Incident Reporting and Prevention System. Most recently David has been successful in incorporating patient safety into the revised McMaster Medical School curriculum.

David continues in his work as an expert witness, which encompasses both civil and criminal cases. On the civil side, he has been an expert witness for the defence of a number of health professionals, including pharmacists. He utilizes the concepts of system failings rather than individual failings in presenting the evidence in a patient-safety framework. On the criminal side, David addresses the role of drugs (prescribed or otherwise) and alcohol as a determinant of an individual's behaviour. He has addressed audiences of lawyers, psychiatrists, psychologists, clinical pharmacologists, pharmacists, and even philosophers, on concepts such as how drugs affect consciousness. He has also addressed a group of women crime writers (Sisters-in-Crime) on some of the more interesting cases.

Richard S. Slavik, B.Sc.(Pharm.), ACPR, Pharm.D.

Richard Slavik earned his Bachelor of Science in Pharmacy degree at the University of British Columbia (UBC) in 1992, and completed a CSHP Hospital Pharmacy Residency program at Royal Columbian Hospital (RCH) in 1993. He earned his Doctorate of Pharmacy degree from Wayne State University in 1997. Richard began his hospital pharmacy career as a Staff Pharmacist at Royal Columbian Hospital from 1993 to 1995, and after receiving his Pharm.D. degree in 1997, he returned to RCH to work as a Clinical Pharmacy Specialist in Critical Care. In 1998 Richard accepted a position as a Clinical Pharmacotherapeutic Specialist in Infectious Diseases at Vancouver General Hospital, which transitioned into Critical Care in 1999.

Richard's direct patient care responsibilities have been in infectious diseases, neurosurgery, cardiac surgery, trauma, and general surgery. His current specialty is critical care, and he identifies and resolves drug-related problems in the ICU and provides clinical, educational, administrative, and research support in a multidisciplinary setting to optimize drug therapy for his patients. His areas of interest include evidence-based practice, critical care, cardiology, and infectious diseases.

In 1998 Richard was appointed as a Clinical Assistant Professor in the Faculty of Pharmaceutical Sciences at UBC, where he has provided extensive didactic, tutorial, and clerkship training for undergraduate, pharmacy residency, and graduate students. In 2004 he was promoted to Clinical Associate Professor, and in 2005 he received the Preceptor of the Year Award from the graduating UBC Pharm.D. class. Richard is very active in nursing education and medical training for the UBC Faculty of Medicine in Neurosurgery, Trauma, Critical Care Medicine, Emergency Medicine, Internal Medicine, and Infectious Diseases. He has been an invited speaker at local, provincial, national, and international conferences, and he has presented to patient and health professional groups in the community.

Richard has taken an interest in pharmacy research, and he has been involved in 16 research projects, which have resulted in numerous oral and/or poster presentations, published abstracts, and full publications. Richard is a recent co-recipient of a B.C. Heart and Stroke Research Grant for his work in the area of atrial fibrillation, and he was awarded the CSHP British Columbia Branch Review Article Publication Award in 2004.

Throughout his career, Richard has demonstrated consistent involvement, support, and leadership in CSHP and other professional associations. As a member of CSHP, he has held a variety of provincial positions, including British Columbia Branch president, and he has been a member of the CSHP National Website Development Committee, Research Committee, Pharmacists Prescribing Committee/Task Force, Western Branches Banff Seminar Planning Committee, Education Services Committee, and the AGM Host Committee. Currently he is the chair of the CSHP Research Committee and is a member of the Health Canada Pharmacy and Therapeutics Committee.

Richard would like to thank his family, friends, colleagues, and mentors who have made significant contributions and sacrifices to share in his professional and personal milestones.

Pat Trozzo, B.Sc. (Chem.), B.Sc.Pharm., BCPS

Pat Trozzo graduated with a pharmacy degree from the University of Manitoba and has worked in hospital pharmacy his entire career. He is currently an oncology pharmacist with the Saint Boniface Unit of CancerCare Manitoba. He has been working in oncology for nearly 15 years. His area of practice is in the treatment of gastrointestinal cancers as well as pain and symptom management. Pat is very active in the management of disease and treatment-related adverse effects and is a member of a multi-professional pain and symptom management team. Pat has a keen interest in palliative and end-of-life care and has worked on national initiatives to promote the role of the pharmacist in providing this care. As well, he has contributed a great deal to the education of health care professionals in palliative and end-of-life care.

Additionally, Pat has an appointment with the Faculty of Pharmacy, University of Manitoba, as a clinical assistant professor. His area of teaching is in oncology and pain and symptom management.

Pat is actively involved in CSHP's Manitoba Branch and currently serves as a member of the Branch Awards Committee. In the past he has

served as president, chair of the Education Committee, and chair of the Host Committee for the CSHP 2000 AGM in Winnipeg. Pat also serves as vice president of the Manitoba Pharmaceutical Association and chairperson of the Complaints Committee of the Association.

Peter J. Zed, B.Sc., B.Sc.(Pharm.), Pharm.D.

Peter Zed graduated from Memorial University of Newfoundland with his Bachelor of Science in Pharmacy degree in 1995, completed a hospital pharmacy residency at the Royal Columbian Hospital in New Westminster, B.C., in 1996, and earned his Doctor of Pharmacy degree from the University of British Columbia in 1998.

Following the completion of his Pharm.D. degree, Dr. Zed joined the Clinical Services Unit, Pharmaceutical Sciences, at Vancouver General Hospital (VGH) as a Pharmacotherapeutic Specialist in Emergency Medicine and was appointed as Clinical Assistant Professor in the Faculty of Pharmaceutical Sciences at UBC He held this faculty appointment until 2004 when he was promoted to Clinical Associate Professor. In 2002 he was appointed as an Associate Member in the Division of Emergency Medicine, Department of Surgery, Faculty of Medicine at UBC

Dr. Zed's clinical practice has evolved to include not only the application of pharmaceutical care to patients in the emergency department but also to include the development, implementation, and evaluation of various initiatives to improve the rationale use of medication in this setting. The development of various programs and initiatives has been recognized by numerous professional organizations and has benefited both VGH and other institutions who have adopted these programs.

Peter has served as an educator and mentor to pharmacy residents, Pharm.D. students, and medical residents, and has been involved in the ongoing continuing education of pharmacists, nurses, and physicians. He has served as primary preceptor for more than 50 clinical clerkships for residents and Pharm.D. students in both emergency medicine and in the application of pharmaceutical care, and has been the primary preceptor for numerous hospital pharmacy residency projects. He has been an active participant in the training of Pharm.D. students, teaching in Advanced Pharmacotherapeutics, a course where he has also served as course coordinator. He was recently awarded with the 2005 Preceptor of the Year Award for the UBC Doctor of Pharmacy Program. Peter has been invited to speak at over 50 local, national, and international conferences, and served as an editorial board member and peer-reviewer for a number of medical/pharmacy journals.

Dr. Zed has been involved as an investigator in numerous research projects involving the broad application of both clinical and practice-based research designed at improving pharmacotherapy for patients in the emergency department. Peter's research interests have been focused in many areas within emergency medicine, including pain and sedation management, cardiac arrest, acute coronary syndromes, thromboembolic disease, upper gastrointestinal bleeding, infectious diseases, and toxicology. Most recent research initiatives have focused on the evaluation of drug-related hospitalization and emergency department visits, and the implementation and evaluation of strategies to reduce this problem in Canadian hospitals. Peter has authored over 40 peer-reviewed publications and book chapters and has presented over 35 research abstracts at local, national, and international conferences. He has received numerous awards for his research work.

Dr. Zed has served the profession as chair or member of numerous institutional, university, provincial and national committees. He has served on the CSHP British Columbia Branch Executive Council in a number of roles, including two terms as Programs Committee chair, and as B.C. Branch president in 2001. He currently serves as a member of the CSHP National Research Committee and as a reviewer for the CSHP National Awards Program.

Outside of work, Peter enjoys hockey, football, golf, and most importantly, spending time with his family.

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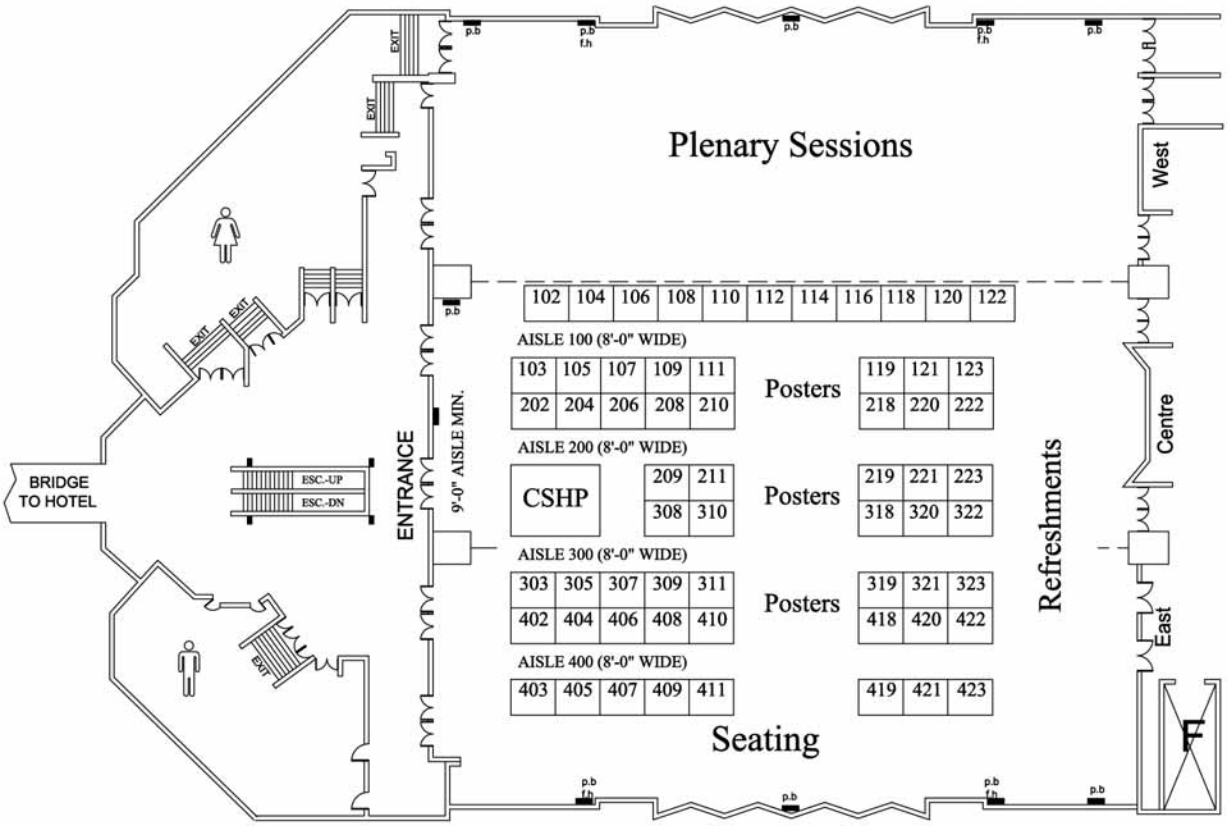

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THERAPEUTIC CLASSIFICATION: Lipid Metabolism Regulator

ACTIONS AND CLINICAL PHARMACOLOGY

Please refer to the Product Monograph for complete ACTIONS and CLINICAL PHARMACOLOGY information.

INDICATIONS AND CLINICAL USE

Hypercholesterolemia

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 IIa); Combined (mixed) hyperlipidemia (Type IIb), 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. An adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age with heterozygous familial hypercholesterolemia, if after an adequate trial of diet therapy the following findings are still present:

a. LDL-C remains ≥4.9 mmol/L (190 mg/dL) or
b. LDL-C remains ≥4.1 mmol/L (160 mg/dL) and:
   - there is a positive family history of premature cardiovascular disease or
   - two or more other CVD risk factors are present

LIPITOR also raises HDL-C and therefore lowers LDL-C/HDL-C and total-C/HDL-C ratios in patients with primary hypercholesterolemia and combined (mixed) hyperlipidemia (Fredrickson Type IIa and IIb dyslipidemia). In pooled data from 24 controlled clinical trials, LIPITOR raised HDL-C levels 5%-7% in primary hypercholesterolemic (type IIa) patients and 10%-15% in mixed (type IIb) dyslipidemic 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 IIa and IIb), 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 IDL-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:
LDL-C (mmol/L) = total-C - [(0.37 x (TG) + HDL-C)]
LDL-C (mg/dL) = total-C - [(0.2 x (TG) + HDL-C)][1]

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 prothrombic 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 fibres) should always be maintained and reinforced.

Prevention of Cardiovascular Disease

LIPITOR is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with ≥3 additional risk factors for coronary heart disease such as: age ≥55 years, male sex, smoking, type 2 diabetes, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminuria or proteinuria, ratio of plasma total cholesterol to HDL-C ≥6, or premature family history of coronary heart disease.

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 (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 nursing women: Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). LIPITOR should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the possible harm. If the patient becomes pregnant while taking LIPITOR, the drug should be discontinued immediately and the patient apprised of the potential harm to the fetus. Atherosclerosis being a chronic process, discontinuation of lipid metabolism regulating drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia (see PRECAUTIONS – Use in Pregnancy, Use in Nursing Mothers).

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).

1. Friedewald WT, *et al. Clin Chem* 1972;18(6):489-502.

Muscle Effects

Effects on skeletal muscle such as myalgia, myopathy and very rarely, rhabdomyolysis have been reported in patients treated with LIPITOR. **Very rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with LIPITOR and other HMG-CoA reductase inhibitors.**

Myopathy, defined as muscle pain or muscle weakness in conjunction with increases in creatine phosphokinase (CK) values to >10 times the upper limit of normal, should be considered in any patient with diffuse myalgia, muscle tenderness or weakness, and/or marked elevation of CK. Patients should be advised to report promptly any unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. Patients who develop any signs or symptoms suggestive of myopathy should have their CK levels measured. LIPITOR therapy should be discontinued if markedly elevated CK levels are measured or myopathy is diagnosed or suspected.

Predisposing Factors for Myopathy/Rhabdomyolysis: LIPITOR, as with other HMG-CoA reductase inhibitors, should be prescribed with caution in patients with predisposing factors for myopathy/rhabdomyolysis. Such factors include:
Personal or family history of hereditary muscular disorders; Previous history of muscle toxicity with another HMG-CoA reductase inhibitor; Concomitant use of a fibrate or niacin; Hypothyroidism; Alcohol abuse; Excessive physical exercise; Age >70 years; Renal impairment; Hepatic impairment; Diabetes with hepatic fatty change; Surgery and trauma; Frailty; Situations where an increase in plasma levels of active ingredient may occur.
LIPITOR therapy should be temporarily withheld or discontinued in any patient with an acute serious condition suggestive of myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis (such as sepsis, severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures).

LIPITOR therapy should be discontinued if markedly elevated CK 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, fibric acid derivatives, erythromycin, clarithromycin, niacin (nicotinic acid), azole antifungals or nefazodone. 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).

Hepatic Effects

In clinical trials, persistent increases in serum transaminases >3 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 >3 times the upper limit of normal and are persistent, the dosage should be reduced or the drug discontinued.

LIPITOR, as well as other HMG-CoA reductase inhibitors, 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.

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 (CoQ_{10}) 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.

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.

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 erythematous-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).

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.

Use in 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

Safety and effectiveness of LIPITOR in patients 10-17 years of age (N=140) with heterozygous familial hypercholesterolemia have been evaluated in a controlled clinical trial of 6 months duration in adolescent boys and postmenarchal girls. Patients treated with LIPITOR had a safety and tolerability profile generally similar to that of placebo. Doses >20 mg have not been studied in this patient population.

LIPITOR had no effect on growth or sexual maturation in boys and in girls. The effects on menstrual cycle were not assessed (see **ADVERSE REACTIONS** and **DOSAGE AND ADMINISTRATION** for Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10-17 years of age)).

Adolescent females should be counselled on appropriate contraceptive methods while on LIPITOR therapy (see CONTRAINDICATIONS and PRECAUTIONS, Use in Pregnancy). LIPITOR has not been studied in controlled clinical trials involving pre-pubertal patients or patients younger than 10 years of age.

Doses of LIPITOR up to 80 mg/day for 1 year have been evaluated in 8 pediatric patients with homozygous familial hypercholesterolemia.

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.

Elderly patients may be more susceptible to myopathy (see WARNINGS – Muscle Effects – Predisposing Factors for Myopathy/Rhabdomyolysis).

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 [creatine 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 Function

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: Based on post-marketing surveillance, gemfibrozil, fenofibrate, other fibrates, and lipid-lowering doses of niacin (nicotinic acid) may increase the risk of myopathy when given concomitantly with HMG-CoA reductase inhibitors, probably because they can produce myopathy when given alone (see WARNINGS – Muscle Effects). Therefore, combined drug therapy should be approached with caution.

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 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 triglycerides than LIPITOR monotherapy in both types of hypercholesterolemic patients.

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 drugs in this class, including atorvastatin, is increased with concurrent administration (see WARNINGS – Muscle Effects).

Coumarin Anticoagulants: LIPITOR had no clinically significant effect on prothrombin time when administered to patients receiving chronic warfarin therapy.

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. 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.

(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).

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 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 the 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. Caution should thus be exercised with concomitant use of these agents (see WARNINGS, Pharmacokinetic Interactions, Muscle Effects; PRECAUTIONS, Renal Insufficiency and Endocrine Function; DOSAGE AND ADMINISTRATION).

In healthy subjects, coadministration of maximum doses of 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. pre-existing 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 (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 QID) or clarithromycin (500 mg BID), which are both CYP3A4 inhibitors, increased plasma concentrations of atorvastatin by approximately 40% and 80%, respectively (see WARNINGS – Muscle Effects).

Protease Inhibitors (nelfinavir mesylate): In healthy adults, coadministration of nelfinavir mesylate (1250 mg BID), a known CYP3A4 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 creatine 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 include constipation, diarrhea, dyspepsia, flatulence, nausea, headache, pain, myalgia and asthenia.

The following additional adverse events were reported in clinical trials (not all 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.

Heterozygous Familial Hypercholesterolemia in Pediatric Patients (ages 10-17 years): In a 26-week controlled study in boys and postmenarchal girls (n=187, where 140 patients received LIPITOR), the safety and tolerability profile of LIPITOR 10 to 20 mg daily was similar to that of placebo. Adverse events reported in ≥1% of patients were abdominal pain, depression and headache (see PRECAUTIONS – Pediatric Use).

Laboratory Changes and Adverse Events

The criteria for clinically significant laboratory changes were >3 X the upper limit of normal (ULN) for liver enzymes, and >5 X ULN for creatine phosphokinase. A total of 8 unique subjects met one or more of these criteria during the double-blind phase. Hence, the incidence of patients who experienced abnormally high enzymatic levels (AST/ALT and creatine kinase) was >4% (8/187).

Five atorvastatin and one placebo subjects had increases in CK >5 X ULN during the double-blind phase; two of the five atorvastatin-treated subjects had increases in CK >10 X ULN. Two subjects had clinically significant increases in ALT.

Post-marketing experience: The following adverse events have also been reported during post-marketing experience with LIPITOR, regardless of causality assessment: Very rare reports: severe myopathy with or without rhabdomyolysis (see WARNINGS – Muscle Effects; PRECAUTIONS – Renal Insufficiency and Drug Interactions). Isolated reports: Gynecomastia, thrombocytopenia, arthralgia and allergic reactions including urticaria, angioneurotic edema, anaphylaxis and bullous rashes (including erytheme 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).

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.

Prior to initiating therapy with LIPITOR, secondary causes for elevations in plasma lipid levels should be excluded. A lipid profile should also be performed.

Primary Hypercholesterolemia and Combined (Mixed) Dyslipidemia, Including Familial Combined Hyperlipidemia

The recommended starting dose of LIPITOR is 10 or 20 mg once daily, depending on the LDL-C reduction required (see Table 1). 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. A significant therapeutic response is evident within 2 weeks, and the maximum response is usually achieved within 2-4 weeks. The response is maintained during chronic therapy. Adjustments of dosage, if necessary, should be made at intervals of 2 to 4 weeks. The maximum dose is 80 mg/day.

TABLE 1. Dose-Response in Patients With Mild to Moderate Hypercholesterolemia (Mean Percent Change from Baseline)[a]

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

The dosage of LIPITOR should be individualized according to the baseline LDL-C, total-C/HDL-C ratio and/or TG levels to achieve the recommended target lipid values at the lowest dose needed to achieve the LDL-C target (see Recommendations for the Management of Dyslipidemia and the Prevention of Cardiovascular Disease [Canada], summarized below in Table 2, and/or the Third Report of the US National Cholesterol Education Program [NCEP Adult Treatment Panel III]), and the patient's response. Lipid levels should be monitored periodically and, if necessary, the dose of LIPITOR adjusted based on target lipid levels recommended by guidelines.

Table 2. Canadian Recommendations for the Target Lipid Values Based on Level of Risk

Risk category	Target Levels		
	LDL-C level (mmol/L)		Total-C/HDL-C ratio
High† (10-year risk of CAD ≥20%, or a history of diabetes mellitus†† or any atherosclerotic disease)	<2.5	**and**	<4.0
Moderate (10-year risk 11%-19%)	<3.5	**and**	<5.0
Low††† (10-year risk ≤10%)	<4.5	**and**	<6.0

† Apolipoprotein B can be used as an alternative measurement, particularly for follow-up of patients treated with statins. An optimal level of apolipoprotein B in a patient at high risk is <0.9 g/L, in a patient at moderate risk <1.05 g/L and in a patient at low risk <1.2 g/L.

†† Includes patients with chronic kidney disease and those undergoing long-term dialysis.

††† In the 'very low' risk stratum, treatment may be deferred if the 10-year estimate of cardiovascular disease is <5% and the LDL-C level is <5.0 mmol/L.

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).

Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10-17 years of age)

In this population, the recommended starting dose of LIPITOR is 10 mg/day; the maximum recommended dose is 20 mg/day. Doses >20 mg/day have not been studied in this patient population. Doses should be individualized according to the recommended goal of therapy (see NCEP Pediatric Panel Guidelines, **INDICATIONS AND CLINICAL USE**). Adjustments should be made at intervals of 4 weeks or more.

NCEP Pediatric Panel Guidelines: Classification of cholesterol levels in pediatric patients with a familial history of hypercholesterolemia or premature cardiovascular disease is summarized below:

Category	Total-C (mmol/L [mg/dL])	LDL-C (mmol/L [mg/dL])
Acceptable	<4.4 [170]	<2.8 [110]
Borderline	4.4-5.1 [170-199]	2.8-3.3 [110-129]
High	≥5.2 [200]	≥3.4 [130]

Concomitant Therapy

See PRECAUTIONS, Drug Interactions.

Dosage in Patients With Renal Insufficiency

See PRECAUTIONS.

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.

For a copy of the Product Monograph or full Prescribing Information, please contact:

Pfizer

Life is our life's work

Pr ALTACE® ramipril

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 high 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 hypokalemia 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 afterload 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 renin 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; hyponatraemia; elevations 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 m^2 (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 m^2) 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 m^2 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, pregelatinized 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.

HEPARIN SODIUM Injection, USP

Anticoagulant

DESCRIPTION

Heparin Sodium Injection, USP is a sterile, non-pyrogenic solution of a highly purified sodium salt of heparin, a high molecular weight polysaccharide derived from porcine intestinal mucosa or beef lung. It is standardized in *vitro* according to the method of USP and is labeled in terms of USP units for use as an anticoagulant. It acts very rapidly and, even in large doses, is metabolized in the body and eliminated within 24 hours. It will not lyse existing thrombi or emboli.

ACTIONS

Heparin inhibits the clotting of blood and the formation of fibrin clots both in *vitro* and *in vivo.* In combination with a cofactor, it inactivates thrombin thus preventing the conversion of fibrinogen to fibrin. Heparin also prevents the formation of a stable fibrin clot by inhibiting the activation of the fibrin stabilizing factor.

Heparin Sodium inhibits reactions which lead to clotting but does not alter the normal components of the blood. Although clotting time is prolonged by therapeutic doses, bleeding time is usually unaffected. Heparin Sodium does not have fibrinolytic activity; therefore, it will not lyse existing clots.

INDICATIONS

Used in the treatment of thrombophlebitis, phlebothrombosis, and cerebral, coronary, and retinal vessel thrombosis to prevent extension of clots and thromboembolic phenomena. Also used prophylactically to prevent the occurrence of thromboembolism, and to prevent clotting during dialysis and surgical procedures, particularly vascular surgery.

When using Heparin Sodium Injection, USP in conjunction with dialysis machines or where the Heparin Sodium Injection, USP is added to glucose or saline, it is most important that the pH is not less than 5 for Heparin Sodium Injection, USP to act as an effective anticoagulant. Under pH 5 degradation sets in and with a pH around 4 or less there is very little Heparin Sodium Injection, USP activity. Likewise with pH over 8.5 there will be some degradation. Recent work has indicated that early hemodialysis is of value in cases of multiple trauma.

Heparin Sodium Injection, USP has also been used as an anticoagulant in blood transfusion samples, particularly when the presence of citrates, oxalates or fluorides might interfere with laboratory tests, such as electrolyte determination. Anti-inflammatory and diuretic activity has been obtained with Heparin Sodium Injection, USP, however, these properties have not yet been put to any widespread clinical use.

LOW-DOSE SUBCUTANEOUS HEPARIN

For the prevention of serious venous thromboembolic complications in high risk surgical patients.

CONTRAINDICATIONS

Patients with a generalized clotting disorder such as hemophilia, Christmas disease, idiopathic thrombocytopenic purpura and patients with active bleeding from a local lesion such as an acute ulcer or ulcerating carcinoma; patients who have had recent cranial, spinal, eye or ear surgery or trauma; hypersensitivity to heparin, including thrombocytopenia; severe liver damage; shock.

WARNINGS

1. Administration of large doses of Heparin Sodium Injection, USP should be delayed four hours postoperatively.
2. When any of the conditions mentioned under precautions are present, the advantages of Heparin Sodium Injection, USP therapy must be carefully weighed against the possibility of deleterious results.

PRECAUTIONS

The use of i.v. heparin in the treatment of ischemic stroke is controversial. Clinical trials investigating the benefits of heparin in ischemic stroke have been inconclusive. Heparin may increase the risk of clinically significant cerebral bleeding. Administration of an i.v. bolus of heparin is not recommended in the treatment of stroke. If heparin is used, brain imaging should be performed prior to initiation of therapy to exclude hemorrhage and estimate infarct size.

When considered for use in any of the following conditions, the advantages of heparin therapy must be carefully weighed against the risks: subacute bacterial endocarditis; increased capillary permeability; dissecting aneurysm; severe hypertension; during and immediately following major surgery, especially of the brain, spinal cord, eye or ear; conditions associated with increased bleeding tendencies such as hemophilia, thrombocytopenia and some purpuras; inaccessible gastrointestinal ulcers; ulcerative colitis; continuous tube drainage of stomach or small intestine; threatened abortion; menstruation; malignant hypertension.

Heparin Sodium Injection, USP should be used with caution in the immediate postoperative period. Bleeding may be concealed, as in the case of hemothorax.

In patients with a history of heparin-induced thrombocytopenia (HIT), heparinoids (e.g., danaparoid), lepirudin and ancrod are considered appropriate alternatives to heparin.

When used in therapeutic doses, heparin should be regulated by frequent blood coagulation indicators particularly the APTT. If the indicator is unduly prolonged or if hemorrhage occurs, heparin should be at least temporarily discontinued (see **OVERDOSAGE)**.

Heparin can prolong the prothrombin time.

Apparent resistance to heparin may be encountered in patients with acquired or familial AT III deficiency, because adequate levels of AT III are required for heparin's anticoagulant effect. Larger doses of heparin may be required initially in patients with various disease states due to alterations in their physiology, the pharmacokinetics of the drug, or elevations in levels of acute phase heparin binding proteins. Among these are febrile illness, infections associated with thrombosing tendencies, pulmonary embolism, myocardial infarction, extensive thrombotic disorders especially those associated with neoplastic disease and following surgery.

Heparin should be used with caution in the presence of severe hepatic or renal disease, or in patients with indwelling catheters. A higher incidence of bleeding may be seen in women over 60 years of age.

IM injections of other drugs should be avoided during heparin therapy to reduce the risk of hematoma formation and bleeding from the site. Most drugs can be given by another route (i.v. or s.c.).

For these reasons strict laboratory control of dosage is necessary. Heparin Sodium Injection, USP should be used with caution in patients with allergy. Patients on long term daily administration of Heparin Sodium Injection, USP should be observed for the possible development of osteoporosis and spontaneous fractures of ribs and/or vertebrae.

Drug Interactions:

Oral anticoagulants (i.e., warfarin) can contribute to a small extent to an increase in APTT. Heparin can contribute to an increase in PT. While these two drugs are given together, the fact that each may contribute to an increase in PT and APTT should be taken into account (see **PRECAUTIONS**).

Heparin is often started with or several hours after thrombolytic therapy. Close patient monitoring for clinical signs of bleeding is indicated. The APTT should also be monitored closely (see **DOSAGE)**.

Salicylates, other nonsteroidal anti-inflammatory agents, dextran, dipyridamole, clopidogrel, ticlopidine and GPIIb-IIIa antagonists (e.g., abciximab) interfere with platelet aggregation which increases the risk of bleeding. They should be used cautiously with monitoring for signs of hemorrhage. In addition, in some situations, when heparin is used in conjunction with GPIIb-IIIa antagonists the dose of heparin may need to be modified (see **DOSAGE: Coronary Surgery**).

Cefamandole, cefotetan, methimazole, propylthiouracil and valproic acid may cause hypoprothrombinemia and increase the risk of bleeding; monitoring for signs of bleeding is indicated. This may occur to a lesser extent with cefazolin, cefoxitin and ceftriaxone.

IV nitroglycerin may reduce heparin's anticoagulant effect and necessitate higher doses. This interaction has been reported to occur regardless of whether or not propylene glycol is used as a solvent for the nitroglycerin. The mechanism has not been conclusively documented. When i.v. nitroglycerin therapy is initiated, patients should be closely monitored to ensure anticoagulation remains adequate. Likewise, when nitroglycerin therapy is stopped, a decrease in heparin dosage may be necessary and patients should be monitored for signs of excessive anticoagulation.

Digitalis, quinine, ACTH, insulin, corticosteroids, antihistamines and nicotine have been reported to interfere with the anticoagulant effect of heparin; however, there is no substantial literature support to document these interactions.

Care must be taken where large doses of antibiotics and/or drugs containing amino groups are administered along with or prior to Heparin Sodium Injection, USP administration.

Drugs such as: Codeine Phosphate, Pethidine hydrochloride, Streptomycin, Erythromycin, Kanamycin, Neomycin, Novobiocin, Tetracyclines, Ampicillin, Penicillin G, Polymyxin B, Vancomycin, Hydrocortisone Sodium Succinate (S-Cortilean), Pentobarbitone, Promazine hydrochloride, Vitamin B complex, Vitamin C.

Heparin Sodium Injection, USP may complex with these drugs -- this complex may be reversible (Heparin rebound) and may result in excess bleeding at the surgical site. Extra protamine sulfate may then be indicated.

Although digitalis, quinine, tetracycline, antihistamines, and nicotine have been stated to interfere with the anticoagulant activity of heparin, there is no substantial literature support for such "interactions". The chemical interaction occurring between heparin and protamine is well known. This interaction is used clinically to antagonize the anti-coagulant effect of heparin.

Ethacrynic Acid: Intravenously administered ethacrynic acid can cause GI bleeding. However, a significantly higher incidence of GI bleeding has been attributed to the concurrent use of intravenous ethacrynic acid and heparin. Furosemide may be a safer alternative when diuretic therapy is indicated in the patient receiving heparin.

Acetylsalicylic Acid: In a review article of heparin therapy, it was advocated that concurrent acetylsalicylic acid administration be "scrupulously avoided". While documentation to support this interaction is incomplete, it would be prudent to avoid concurrent therapy. Acetylsalicylic Acid impairs the platelet release reaction and this platelet function defect combined with the anticoagulant effect of heparin may produce a hemorrhagic tendency.

Dextran: Limited data suggest that dextran and heparin may act synergistically when administered concurrently. Although the data are inadequate to document the clinical significance of this interaction, baseline laboratory measurements of anticoagulant activity should be obtained upon initiation of concurrent therapy as well as at frequent intervals during such therapy.

Pregnancy:
Heparin does not cross the placenta and has not been related to congenital defects. However, its use during pregnancy has been associated with a 13 to 22% risk of fetal mortality or prematurity. It is not clear whether severity of maternal disease or an indirect effect of heparin is responsible. Coumarin anticoagulants have been associated with a 31% incidence of unfavorable outcome and a definite drug-induced pattern of malformations has been demonstrated (fetal warfarin syndrome). However, the incidence of warfarin-induced fetopathic effects in the second and third trimesters is very low. In general, heparin is considered to be the anticoagulant of choice in pregnancy. Long-term usage (>3 to 5 months) of therapeutic doses of heparin during pregnancy increases the risk of osteoporosis and warrants careful monitoring of patients. Heparin therapy during the last trimester and immediate postpartum period is associated with a risk of maternal hemorrhage. Changes in pharmacokinetics during pregnancy require caution and close patient monitoring if heparin is used.

Reports of therapeutic failure with adjusted-dose heparin therapy in pregnant patients with prosthetic heart valves may have been due to inadequate dosing and/or monitoring or to an inherent lack of efficacy in these patients. The American College of Chest Physicians recommends that if subcutaneous heparin is used in pregnant patients with mechanical heart valves, it be administered every 12 hours and the dose adjusted to keep the mid-interval APTT at least twice the control, or an anti-Xa heparin level of 0.35 to 0.7 U/mL. In addition, some clinicians suggest an initial dose of 17,500 to 20,000 units s.c. every 12 hours.

Lactation:
Heparin is not excreted in breast milk because of its high molecular weight.

Please also refer to the pH requirements in hemodialysis under "INDICATIONS".

ADVERSE EFFECTS

Bone and Joint: Therapeutic doses of heparin administered for longer than 3 months have been associated with osteoporosis and spontaneous vertebral fractures. Recent reports indicate that osteoporosis may be reversible after discontinuation of heparin.

Hematologic: Bleeding is the most common side effect of heparin and is an extension of its pharmacological effect. The rate of occurrence is approximately 10% overall but may increase up to 20% in patients treated with high dose therapy. Risk of bleeding likely increases with APTT ratios above the recommended target range. Other risk factors associated with bleeding are: a serious concurrent illness, chronic heavy consumption of alcohol, use of platelet-inhibiting drugs, renal failure, age and female sex. Bleeding may range from minor local ecchymoses to major hemorrhagic events. Often the first sign of bleeding may be epistaxis, hematuria or melena. Bleeding may be from any site and can be difficult to detect, e.g., retroperitoneal bleeds. Bleeding may also occur from surgical sites. Petechiae or easy bruising may precede frank hemorrhage. A supratherapeutic APTT or minor bleeding during therapy can usually be controlled by adjusting the dosage or withdrawing the drug (see **OVERDOSAGE**).

Thrombocytopenia has also been described with heparin treatment. Heparin Induced Thrombocytopenia (HIT) is an allergic reaction. It has been reported to occur in 1 to 30% of patients treated with standard heparin. It has also occurred with the use of LMWHs, both in patients with a history of HIT and patients with no previous exposure to heparin. The risk of developing HIT may be lower with LMWHs, but cannot be reliably estimated until more patients have been exposed. It is thought to be more common with heparin derived from bovine lung (5-10%) than from porcine gut (2-5%). Two types of acute, reversible thrombocytopenia have been described. Mild thrombocytopenia most commonly occurs between 5 and 12 days after initiation of full dose therapy. Platelet count usually remains above 100 x 10^9/L, and heparin therapy does not necessarily have to be withdrawn. Platelet count may remain stable or even increase despite continued therapy; however, it should still be monitored. The more severe, delayed form of thrombocytopenia (platelets <100 x 10^9/L, is much less frequent, usually appearing 5 to 12 days after starting heparin therapy and recurs rapidly on rechallenge. It has occurred with low dosages and is not dose related. It is generally reversible; platelet counts usually begin to return to normal within 4 days of stopping heparin. Paradoxically, patients may develop thrombotic complications including arterial thrombosis, gangrene, stroke, myocardial infarction and disseminated intravascular coagulation. Thrombosis is due to "white clots" composed of platelets and fibrin that result from marked *in vivo* platelet aggregation. Patients receiving heparin acutely should have platelet counts monitored at least every 2 or 3 days.

Hepatic: Heparin has been reported to cause elevations of AST and ALT in approximately 27 and 59% of patients, respectively. Transient increases in serum LDH levels have also occurred. No clinical signs of liver dysfunction have been reported and the significance is not known, except that interpretation of liver enzymes for other purposes (i.e., liver disease) must take into consideration the possible contribution of heparin.

Hypersensitivity: Heparin-induced thrombocytopenia (see **ADVERSE EFFECTS**, Hematologic). Other allergic reactions to heparin are rare. The most common manifestations of hypersensitivity are chills, fever and urticaria. Asthma, rhinitis, tearing, headache, nausea, vomiting, shock and anaphylactoid reactions have also occurred. Vasospasm has been reported 6 to 10 days after starting heparin; the etiology is thought to be allergic. Vasospasm often appears in a limb where an artery has recently been catheterized. The affected limb is usually painful, ischemic and cyanotic. Protamine sulfate is of no use in hypersensitivity reactions.

Miscellaneous: Alopecia, affecting the entire scalp or confined to the temple, may occur. Itching and burning of the plantar surfaces of the feet. Suppression of aldosterone product, hyperkalemia (due to aldosterone suppression), priapism and rebound hyperlipidemia have also been reported.

Heparin Neutralization with Protamine
Bleeding which may occur during therapy with heparin can usually be corrected by withdrawal. Clotting time should then return to normal in 30 to 60 minutes provided venous clotting time is not longer than 15 minutes when the infusion is interrupted. Should withdrawal of Heparin Sodium fail to control bleeding, fresh, matched blood (not more than three days old) may be administered in quantities of 250 to 500 mL.

The most rapid means of counteracting the effects of heparin is intravenous administration of protamine sulfate injection. However, protamine is by itself an anticoagulant and therefore excess must be avoided. A dosing ratio of 1 milligram protamine for every 100 units of heparin remaining in the patient is the usual rule. It is recommended that protamine doses be guided by blood coagulation studies to determine if additional doses are required. The activated partial thromboplastin time (APTT) or activated clotting time (ACT) are adequate for this purpose.

Allowance should be made for the rapid removal of heparin from circulation. The rate of heparin removal from plasma is dose-dependent. However, it may be assumed that about 30 minutes after an intravenous injection, about 50% of the heparin is removed from circulation.

So the amount of protamine sulfate required to neutralize the heparin will be that of approximately half of that required for the original dose. For example, if 1,000 units required 10 mg of protamine sulfate for neutralization, half an hour after intravenous administration of a 5,000 unit dose, the amount of protamine sulfate required will only be approximately:

5 / 2 x 10 = 25 mg

Too rapid administration of protamine can cause severe hypotensive and anaphylactoid reactions. Facilities to treat shock should be readily available when administering protamine. The rate of protamine administration should not exceed 20 mg/min and no more than 50 mg should be given in any 10 minute period. Doses exceeding 100 mg in a short period of time should be avoided, unless there is certain knowledge of larger protamine requirements. Any excess protamine sulfate, not complexed to heparin, has its own intrinsic anticoagulant effect. However, one study found overdose of protamine up to 600 to 800 mg i.v. to have only minor, transient effects on blood coagulation.

OVERDOSAGE

Symptoms: Overdose may be manifested by excessive prolongation of the APTT or by bleeding. Bleeding may be internal or external, major or minor.

Treatment: See **Heparin Neutralization with Protamine.**

DOSAGE AND ADMINISTRATION

Please note:

1. Intramuscular injection (especially in the arm or thigh) and shallow subcutaneous injection is not recommended. The duration of effect is shortened and it is more likely to produce pain and hematoma.

2. Heparin Sodium activity is expressed in USP units and should be prescribed in units only.

The route of administration may be i.v. or s.c., depending upon the situation and the choice of the prescriber. Adequate heparin-induced anticoagulant therapy is present when the clotting time is elevated from 2 to 3 times normal as measured by the Lee-White method. Two types of dosage schedule are suggested: Heparin Sodium Injection, USP may be administered intravenously in a dose of 5,000 USP units every 4 hours or in a dose of 10,000 USP units every 6 hours, depending upon the results of a whole blood clotting time test performed at the bedside just prior to each additional dose. If the clotting time is less than twice normal, the next dose is increased by one-third to one-half. If the clotting time is more than $2\frac{1}{2}$ times normal, the next dose is decreased by one-third to one-half. If the clotting time is between 2 and $2\frac{1}{2}$ times normal, the regular dose is repeated.

SUBCUTANEOUS INJECTION TECHNIQUE

Use of a 1 mL tuberculin syringe with a No. 25 or No. 26 -$\frac{1}{2}$ inch needle is recommended.

STEP 1 Disinfect area with alcohol then apply pressure between finger and thumb to the dermal fold until the injection site is blanched.

STEP 2. Insert the needle into the raised, blanched area. Reduce the pressure on the skin and inject the Heparin Sodium Injection, USP slowly.

STEP 3. Withdraw the needle quickly and apply alcohol swab pressure to the site of injection for 5 - 10 seconds to prevent loss of the heparin.

DOSAGE

ADMINISTRATION		
METHOD	**FREQUENCY**	**RECOMMENDED DOSAGE***
Low-dose Subcutaneous†	Every 8 to 12 hours	5,000 units
Subcutaneous	Every 8 hours	10,000 to 20,000 units initially** then 8,000 to 10,000 units three times a day.
Intermittent Intravenous	Every 4 to 6 hours	10,000 units initially, then 5,000 to 10,000 units four to six times a day.
Intravenous Infusion	Continuous or Intermittent	20,000 to 40,000 units per litre at a rate of 15 to 30 units per minute.
Dialysis	See below	See below
Usual Pediatric Dose	Every 4 hours	By intravenous infusion, 50 units per kg of body weight initially, followed by 100 units per kg or 3,333 units per square meter of body surface, six times a day.

* Based on 68 kg of body weight (approx. 150 lbs)

† It is not necessary to monitor low-dose prophylactic Heparin Sodium Injection, USP

** Following immediately after an initial dose of 5,000 units i.v.

Dilution Instruction for IV Infusion:

Heparin Sodium Injection, USP may be diluted to 20,000 to 40,000 units per liter (or 20 units to 40 units/mL) with 5% Dextrose Injection; 0.9% Sodium Chloride Injection; 0.45% Sodium Chloride Injection; 5% Dextrose and 0.45% Sodium Chloride Injection; or 5% Dextrose and 0.9% Sodium Chloride Injection in PVC bag. Diluted solution may be stored up to 24 hours at controlled room temperature.

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.

THERAPY REQUIRED

1. Low Dose Subcutaneous Heparin Sodium

There is now good evidence that low dose heparin is effective in preventing serious venous thromboembolic complications in high risk surgical patients. The usually recommended dose is 5,000 units subcutaneously 2 hours before surgery and then 5,000 units given every 12 or 8 hours after surgery with the first dose given at approximately 12 hours after surgery. It is not necessary to monitor low dose prophylactic heparin.

2. Therapeutic Anticoagulant Action (immediate and short term)

The dose should be adjusted in keeping with the patient's clotting time which should be determined just prior to the injection during the first day of treatment. It is also recommended that, in order to help regulate dosage, the clotting time be determined on the second and third day of treatment. (The recommended method is the Lee-White whole blood method.)

Anticoagulation is adequate when the clotting time is 2 to 3 times the normal value.

Subcutaneous administration is usually employed for maintenance therapy after initial regulation.

3. Long Term Protective Anticoagulant Action

Subcutaneous administration of 15,000 units every 12 hours is usually employed. Daily injections of 20,000 to 30,000 units have also been employed with success. After initial regulation the dosage should be adjusted according to weekly to monthly clotting time determinations. Anticoagulant therapy should not be terminated abruptly but should be gradually reduced over 3 - 4 days.

4. Deep Venous Thrombosis and Pulmonary Embolism

Dosage of 20,000 units daily for 6 - 10 days has been of value.

5. Hemodialysis

(a) Multiple Trauma

Recent literature has suggested the use of early hemodialysis in multiple trauma.

(b) Chronic Renal Failure

The use of hemodialysis in this area has increased dramatically in recent years and may be in-hospital or home dialysis. It is most important to stress that the instructions for each equipment manufacturer's unit must be followed scrupulously.

The following is merely intended as an overall summary of possible general procedures:

- 3,000 units of Heparin Sodium Injection, USP is added to 1,000 mL of sterile saline as a dialyser flush prior to connection.
- Initial dosage: 5,000 units of Heparin Sodium Injection, USP into the venous shunt or 2,500 units into the arterial fistula needle.
- With the shunt type, the usual continuing dosage is 2,000 units per hour; with the fistula type, 1,500 units per hour by means of a suitable syringe and a pump to allow continuing infusion. Heparin Sodium Injection, USP reversal with Protamine Sulfate will be decided by the individual physician. Usually this is not done unless dialysis is being performed soon after surgery.

6. Coronary and Vascular Surgery

Patients undergoing total body perfusion for open heart surgery should receive an initial dose of not less than 150 units of Heparin Sodium Injection, USP per kilogram of body weight. Frequently a dose of 300 units of Heparin Sodium Injection, USP per kilogram of body weight is used for procedures estimated to last less than 60 minutes; or 400 units/kg for those estimated to last longer than 60 minutes.

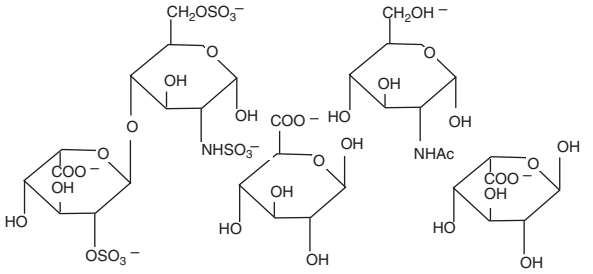
PHARMACEUTICAL INFORMATION

Drug Substance:

Proper Name: Heparin Sodium

CAS No.: 9041-08-1

Structural Formula:



(1) (2) (3) (4) (5)

Description: Heparin is a heterogeneous group of straight-chain anionic mucopolysaccarides, called glycosaminiglycans, having anticoagulant properties. Although others may be present, the main sugars occurring in heparin are: (1) α-L-iduronic acid 2-sulfate, (2) 2-deoxy-2-sulfamino-α-D-glucose 6-sulfate, (3) β-D-glucuronic acid, (4) 2-acetamido-2-deoxy-α-D-glucose, (5) α-L-iduronic acid. These sugars are present in decreasing amounts, usually in the order (2) > (1) > (4) > (3) > (5), and are joined by glycosidic linkages, forming polymers of varying sizes. Heparin is strongly acidic because of its content of covalently linked sulfate and carboxylic acid groups. In heparin sodium, the acidic protons of the sulfate units are partially replaced by sodium ions. Heparin sodium is derived from porcine intestinal mucosa, standardized for anticoagulant activity.

Stability and Storage Recommendations:

Store Heparin Sodium Injection, USP multidose vial at 15°- 30°C. Protect from freezing. Discard unused portion 28 days after initial puncture.

AVAILABILITY

Heparin Sodium Injection, USP is supplied in the following concentrations and package sizes.

C504001 1,000 USP Units/mL in 1 mL multidose vial in package of 25 vials. Also contains methylparaben 1.5 mg/mL, propylparaben 0.15 mg/mL. Sodium Chloride 9 mg/mL for isotonicity, and q.s. to 1 mL with Water for Injection. Porcine intestinal mucosa origin.

C504011 1,000 USP Units/mL in 10 mL multidose vial in package of 25 vials. Also contains methylparaben 1.5 mg/mL, propylparaben 0.15 mg/mL. Sodium Chloride 9 mg/mL for isotonicity, and q.s. to 10 mL with Water for Injection. Porcine intestinal mucosa origin.

C504031 1,000 USP Units/mL in 30 mL multidose vial in package of 25 vials. Also contains methylparaben 1.5 mg/mL, propylparaben 0.15 mg/mL. Sodium Chloride 9 mg/mL for isotonicity, and q.s. to 30 mL with Water for Injection. Porcine intestinal mucosa origin.

C504201 10,000 USP Units/mL in 1 mL multidose vial in package of 25 vials. Also contains methylparaben 1.5 mg/mL, propylparaben 0.15 mg/mL, and q.s. to 1 mL with Water for Injection. Porcine intestinal mucosa origin.

C504207 10,000 USP Units/mL in 5 mL multidose vial in package of 25 vials. Also contains methylparaben 1.5 mg/mL, propylparaben 0.15 mg/mL, and q.s. to 5 mL with Water for Injection. Porcine intestinal mucosa origin.

Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to use.

PPC PHARMACEUTICAL PARTNERS OF CANADA INC.
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PAAB

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 mOsmol/L.

Iron(III)-hydroxide sucrose complex has a molecular weight of approximately 43,200 daltons and a molecular formula as follows:

$$[Na_2Fe_5O_8(OH)\bullet 3(H_2O)]_n\bullet m(C_{12}H_{22}O_{11})$$

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 $^{52}Fe/^{59}Fe$ 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.

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, discolouration and leakage prior to administration, whenever solution and container permit. Solutions showing haziness, particulate matter, precipitate, discolouration 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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Product monograph available upon request.

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the sun would always shine, and no one would ever get ill.

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INDICATION Used in the treatment of thrombophlebitis, phlebothrombosis, and cerebral, coronary, and retinal vessel thrombosis to prevent extension of clots and thromboembolic phenomena. Also used prophylactically to prevent the occurrence of thromboembolism, and to prevent clotting during dialysis and surgical procedures, particularly vascular surgery.

Please consult prescribing information for complete indications, warnings, precautions, adverse events and important patient criteria

INTRODUCING

Heparin

Sodium Injection, USP

From

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