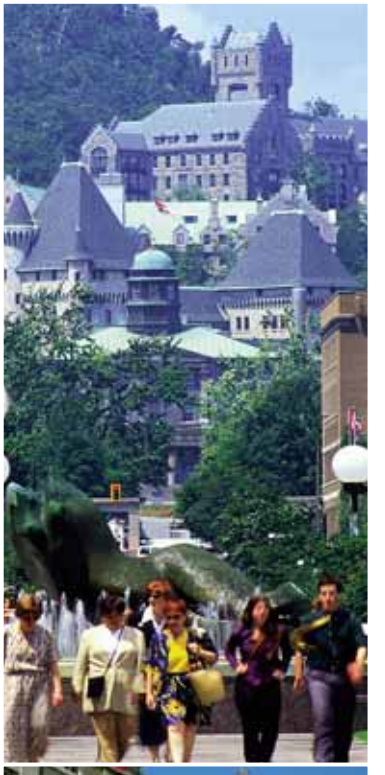
59th AGM & Educational Sessions

59e AGA et séances éducatives



CJHP JCPH

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

Vol. 59, Supplement 2 (AGM), August 2006
Vol. 59, Supplément 2 (AGA), Août 2006

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

Montréal
Rendez-vous
AGA 2006 AGM

Introducing nanoparticle albumin-bound (*nab*™) technology pioneered by Abraxis Oncology.

Nanoparticle albumin-bound (*nab*) technology is an important advance in cancer treatment. By encapsulating cytotoxic therapy in albumin in the form of nanoparticles, it exploits the distinctive properties of albumin, a natural transporter of hydrophobic molecules, and the unique nature of tumour vasculature.[1,2]

nab-enhanced therapeutic agents are captured by albumin receptors via the GP60/caveolin pathway. This pathway mediates drug transfer across blood vessels and wall barriers to preferentially deposit cytotoxic therapies to the tumour bed and tissue.[2,3,4,5]

nab technology opens the door to possibilities – increasing intratumoural concentration of cytotoxic therapy to improve efficacy while reducing toxicities, with the convenience of solvent-free delivery – in essence, helping cytotoxic therapies reach their full potential.[1,2,3]

Abraxis Oncology looks forward to starting the journey with *nab* technology in Canada soon, beginning with the treatment of metastatic breast cancer with Abraxane™ (nanoparticle, albumin-bound (*nab*) paclitaxel).

References

1. Gradishar WJ, Tjulandin S, Davidson N, et al. Phase III trial of nanoparticle albumin-bound paclitaxel compared with polyethylated castor oil-based paclitaxel in women with breast cancer. J Clin Oncol 2005;23:7794-7803. 2. Ibrahim N, Desai N, Legha S, et al. Phase I and pharmacokinetic study of ABI-007, a cremophor-free, protein-stabilized, nanoparticle formulation of paclitaxel. Clin Cancer Res 2002;8:1038-1044. 3. Nyman D, Campbell K, Hersh E et al. Phase I and pharmacokinetic trial of ABI-007, a novel nano-particle formulation of paclitaxel in patients with advanced non-hematologic activities. J Clin Oncol 2005 ; 23 :7785-7793. 4. Minshal RD et al. Endothelial cell surface gp60 activates vesicle formation and trafficking via Gi-coupled Src kinase signaling pathway. J Cell Biol 2000; 150:1057-1069. 5. Desai N, Trieu V, Yao Z, et al. Increased antitumor activity, intratumor paclitaxel concentrations, and endothelial cell transport of cremophor-free, albumin-bound paclitaxel, ABI-007, compared with cremophor-based paclitaxel. Clin Cancer Res 2006;12:1317-1324.

Abraxis Oncology

Dear Colleague:

It is with great pleasure that we invite you to join us in Montréal to "Rendez-vous" in la Belle Provence from August 12 to 15, 2006, for the Canadian Society of Hospital Pharmacists 59th Annual General Meeting and Educational Sessions.

The Educational Services Committee, chaired by Judy Chong, has assembled a fantastic educational program that will include *A Rookie Candidate's Federal Election Experience, Previews to Leadership, The Future of Residency Training in Canada* and *Turning your Leftover Projects and Posters into Real Publications.* This year we will run English and French concurrent sessions.

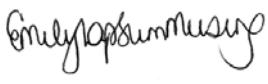
Included in our vendor exhibit program this year is the annual booth decoration challenge. This year our participating exhibitors will decorate their booths to reflect a decade of their choice in the history of Québec. Members can participate in the host committee events and win great prizes while networking and seeing the latest products and services. Please take time to visit and gain from exhibitors' expertise and acknowledge the tremendous support they offer to our event.

The 2006 Annual General Meeting is scheduled for Sunday, August 13 at 15:00. The AGM will provide all members an opportunity to hear about the many important initiatives that have helped advance hospital pharmacy in the past year. Reports from CSHP Council will include important updates on the many activities of our committees and task forces, CSHP's strategic plan, and our advocacy initiatives. The Wine and Chat immediately following the AGM offers an informal opportunity to continue the discussion with Council and staff of CSHP. It's important to make time in your busy AGM schedule to participate in the Wine and Chat, as Council needs to hear from you, our members.

This year's social events kick off on Saturday, August 12th, with the Eleventh Annual CSHP Research and Education (R&E) Foundation Fundraising Golf Tournament to be held at La Seigneurie Golf Course. All profits from this event will be donated to the R&E Foundation, supporting and promoting the practice-based research initiatives of CSHP's members. Register early as this event fills up fast!

The Montréal Host Committee, chaired by Visal Uon, has organized social activities, including an early morning Fun Run/Walk ending with breakfast at the Faculty of pharmacy, Fun Night at La Ronde Amusement Park, and our annual Past-Presidents' Dinner and Dance at La Tour de Montréal. The efforts of this year's Committee guarantee a memorable time.

AGM 2006: Montréal Rendez-vous. We look forward to seeing you and sharing the fun.



Emily Lap Sum Musing
BScPhm, MHSc, FCSHP
CSHP President

Myrella Roy
BScPhm, PharmD, FCCP
Executive Director

Cher collègue,

C'est avec grand plaisir que nous vous donnons rendez-vous à Montréal, dans la belle province, du 12 au 15 août 2006 pour assister à la 59e Assemblée générale annuelle de la Société canadienne des pharmaciens d'hôpitaux et à ses séances éducatives.

Le Comité des services éducatifs, présidé par Judy Chong, a élaboré un programme de formation fantastique qui comprendra les ateliers suivants : « Élections fédérales : l'expérience d'un nouveau candidat »; « Un aperçu du leadership »; « L'avenir des programmes de résidence au Canada » et « Transformez vos projets non réalisés et vos affiches excédentaires en vraies publications ». Cette année, les ateliers auront lieu simultanément en français et en anglais.

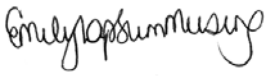
L'activité annuelle de décoration des kiosques fera à nouveau partie du programme d'exposition des fournisseurs. Cette année, les exposants devront décorer leur kiosque afin qu'il représente les événements survenus au Québec au cours d'une décennie de leur choix. Les membres peuvent prendre part aux activités préparées par le comité d'accueil et gagner de superbes prix tout en tissant des liens et en explorant les nouveaux produits et services. Nous vous encourageons à prendre le temps de faire le tour des kiosques pour tirer avantage de l'expertise des exposants et reconnaître l'important soutien apporté par les fournisseurs à cet événement.

L'Assemblée générale annuelle 2006 se tiendra dimanche, le 13 août à 15 h. Les membres pourront y recevoir de l'information sur les nombreuses initiatives majeures qui ont contribué au progrès de la pharmacie d'hôpital au cours de la dernière année. Le Conseil de la SCPH vous fera entre autres part des faits saillants concernant les multiples activités menées par nos comités et nos groupes de travail, et traitera du plan stratégique de la SCPH et de nos initiatives de valorisation. Vous aurez l'occasion de continuer à discuter de façon informelle avec le Conseil et le personnel de la SCPH en sirotant un verre de vin, immédiatement après l'AGA. Malgré votre horaire chargé, il est important que vous participiez au Vin et causette, car le Conseil doit connaître l'opinion de ses membres.

Le 11e tournoi de golf de la SCPH au profit de la Fondation pour la recherche et l'éducation, qui se tiendra au terrain de golf La Seigneurie le samedi 12 août, donnera le coup d'envoi aux activités sociales de cette année. Tous les profits générés par cet événement seront remis à la Fondation pour la recherche et l'éducation, en vue d'appuyer et de promouvoir les initiatives de recherche fondée sur la pratique menées par les membres de la SCPH. Inscrivez-vous le plus tôt possible, car les places sont limitées!

Le comité d'accueil de Montréal, présidé par Visal Uon, vous a préparé des activités sociales dont une Course/promenade pour lève-tôt suivie d'un petit déjeuner à la Faculté de pharmacie; une Partie de plaisir au parc d'attractions La Ronde; ainsi que le Dîner dansant des anciens présidents qui aura lieu à La Tour de Montréal. Grâce aux efforts déployés par le comité d'accueil de cette année, les moments que nous partagerons seront certainement mémorables.

AGA 2006 : Rendez-vous Montréal. Nous sommes impatients de vous rencontrer et de passer de bons moments en votre compagnie.



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* Product monograph and patient information available upon request.

References: 1. T.H. Conner et al. Am J Health-Syst Pharm Mar 1, 2005;62: 474-84
2. Data on file

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Continuing Education Credits

The Educational Services Committee

The Educational Services Committee (ESC) of CSHP has been working in conjunction with the local host committee and the national office for approximately 10 months on the content and format of AGM 2006. The ESC is comprised of a core committee of 10 hospital pharmacists as well as 8 corresponding members from the CSHP branches.

C.C.C.E.P.
Canadian Council on Continuing Education in Pharmacy

Crédits de formation continue

Le Comité des services éducatifs

Le Comité des services éducatifs travaille depuis près de 10 mois avec le Comité d'accueil et le personnel de la SCPH à l'élaboration du contenu et de la forme de l'AGA 2006. Le Comité comprend 10 membres principaux et 8 membres correspondants des sections de la SCPH.

Goal and Objectives for the 2006 AGM 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 pharmacist 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 and poster sessions
- To provide an opportunity for members of Pharmacy Specialty Networks (PSN) to meet

But et objectifs du programme de l'AGA 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 en pharmacie hospitalière en présentant des conférences sur les nouveautés touchant le rôle du pharmacien, la pratique de la pharmacie et les programmes de pharmacie
- Développer des habiletés pour un apprentissage continu par une participation active à des ateliers de formation axés sur la résolution de problèmes
- Donner aux participants des occasions de réseautage et d'échanges grâce au salon des exposants et aux séances d'affichage
- Donner l'occasion aux réseaux de spécialistes en pharmacie de se réunir

How to Get to the AGM

Air Canada has been appointed the official airline for CSHP's Annual General Meeting and Educational Sessions 2006. Please quote Reference Number CV061688 when making your travel arrangements.

As an AGM 2006 registrant, you will be offered the best available fare on all flights booked through Air Canada's Meetings and Conventions Sales Office. Be sure to tell your travel agent to refer to CV061688 in reference to your ticket and you could receive up to 50% off. Remember you will continue to accumulate your travel plan points while assisting CSHP.

You can book your flight in three convenient ways:

1. Through UNIGLOBE PREMIERE TRAVEL at 1-800-267-9372, or
2. Directly through Air Canada's Meetings and Conventions Sales Office at 1-800-361-7585, or
3. Through your preferred travel agent.

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Comment se rendre à l'AGA

La SCPH a désigné Air Canada comme transporteur officiel pour son Assemblée générale annuelle et séances éducatives de 2006. Veuillez mentionner le numéro de référence CV061688 lorsque vous effectuez votre réservation.

Comme congressiste de l'AGA 2006, vous aurez droit au meilleur tarif disponible pour tous les vols réservés auprès des Services réunions d'affaires et congrès d'Air Canada. Assurez-vous que votre agent de voyage cite le numéro CV061688 lors de la réservation ce qui vous permettra de profiter d'un rabais allant jusqu'à 50 % . Souvenez-vous que vous continuerez à accumuler les points dans votre compte de fidélisation tout en aidant la SCPH.

Vous pouvez réserver vos places d'avion selon l'une des trois options pratiques suivantes, en communiquant :

1. Avec UNIGLOBE PREMIERE TRAVEL à 1-800-267-9372.
2. Directement avec les Services réunions d'affaires et congrès d'Air Canada au 1-800-361-7585.

Suite à la page 10

MI, Stroke or Established Peripheral Arterial Disease (PAD)
PLAVIX (clopidogrel bisulfate) is indicated for the secondary prevention of atherothrombotic events (myocardial infarction, stroke and vascular death) in patients with atherosclerosis documented by stroke, myocardial infarction or established peripheral arterial disease.[1]

Acute Coronary Syndrome
PLAVIX, in combination with ASA, is indicated for the early and long-term secondary prevention of atherothrombotic events (myocardial infarction, ischemic stroke, cardiovascular death and/or refractory ischemia) in patients with acute coronary syndromes without ST-segment elevation (i.e., unstable angina or non-Q-wave myocardial infarction). These benefits of PLAVIX have been shown only when these patients were concomitantly treated with ASA in addition to other standard therapies. These benefits were also seen in patients who were managed medically and in those who were managed with percutaneous coronary intervention (with or without stent) or CABG (coronary artery bypass graft).[1]

PLAVIX is contraindicated in patients with a hypersensitivity to the drug substance or any component of the product or container and in patients with active bleeding such as peptic ulcers or intracranial hemorrhage. PLAVIX should not be used in patients who have active GI lesions with a propensity to bleed. As with other antiplatelet agents, PLAVIX should be used with caution in patients who may be at risk of increased bleeding from recent trauma, surgery or other pathological conditions.[1]

PLAVIX should be used with caution in patients with severe or moderate renal impairment and in patients with moderate hepatic impairment who may have bleeding diatheses. PLAVIX is contraindicated in patients with significant liver impairment or cholestatic jaundice.[1]

The most frequent adverse drug reactions (≥1%) with PLAVIX (with or without associated ASA) pooled from CURE and CAPRIE were hemorrhage and bleeding disorders (7.72%) including purpura (2.26%); any rash (1.68%); dyspepsia (2.02%), abdominal pain (1.82%) and diarrhea (1.09%).[1]

* Myocardial infarction (MI), stroke or cardiovascular (CV) death.

† In CAPRIE, PLAVIX provided an 8.7% RRR in combined stroke, MI and vascular death over 3 years§ vs. ASA in stroke, MI or PAD patients ($p = 0.045$). Absolute outcomes: PLAVIX 9.78%, ASA 10.64%. PLAVIX 75 mg o.d. ($n = 9599$); ASA 325 mg o.d. ($n = 9586$).[1]

‡ In CURE, PLAVIX+ASA provided a 20% RRR in combined stroke, nonfatal MI and CV death over 1 year vs. placebo+ASA in patients with UA or non-Q-wave MI ($p = 0.00009$). Absolute outcomes: PLAVIX+ASA 9.3%, placebo+ASA 11.4%. PLAVIX 300 mg loading dose, then 75 mg o.d. ($n = 6259$) or placebo ($n = 6303$) plus ASA 75–325 mg o.d.[1]

§ The long-term comparative clinical significance of these findings beyond 3 years is unknown.

REFERENCE: 1. PLAVIX Product Monograph.

An agreement between Bristol-Myers Squibb and sanofi-aventis for the codevelopment and marketing of irbesartan and clopidogrel, two compounds from sanofi-aventis research.

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Continued from page 8

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Ground Transportation

Via Rail is the official ground transportation for AGM 2006. The CSHP discount is 35% off the full adult economy class, minimum fare $15.00, OR 5% off the full adult VIA-1 or sleeper class fares. The discount fare applies to a maximum of two passengers per purchase and is valid from August 9 through August 19, 2006. Please refer to CSHP's promo number 10782. For schedule/fare information and reservations please call 1-888-842-7245. Taxis are readily available outside the terminal to take you to Le Centre Sheraton, which is three city blocks away.

Where to Stay for AGM?

Le Centre Sheraton

CSHP is pleased to offer a special room rate of $165.00 - single or double occupancy - at Le Centre Sheraton. All CSHP official conference-related meetings will take place at this property. The Conference rate of $165.00 will be guaranteed until July 7, 2006. Don't miss out - make your reservations early. You may make your reservations through Le Centre Sheraton's central reservations office at (800) 325-3535. When doing so, please remember to make reference to CSHP AGM 2006 for your conference rate.

AGM Social Events

In order to provide accurate dinner numbers to our host facilities, we encourage registrants to purchase tickets for both the Fun Night on Sunday and the Past-Presidents' Dinner on Monday prior to arrival at AGM 2006. Ticket sales are included on the AGM 2006 registration form. Tickets may be available on-site. Absolutely no tickets will be sold after 5 p.m. on Saturday, August 12, 2006. Thank you for your co-operation.

Suite de la page 8

3. Avec votre agent de voyage favori.

En vous assurant que le numéro CV061688 apparaît sur votre billet, vous apportez votre soutien à votre association. La SCPH vous en remercie.

Transport terrestre

Via Rail est le transporteur terrestre officiel pour l'AGA 2006. Un rabais de 35 % sur le plein tarif pour adulte en classe économique (minimum de 15$) OU de 5 % en classes VIA-1 ou voitures-lits est octroyé aux congressistes de la SCPH durant la période de validité du 9 au 19 août 2006. Le rabais est consenti à un maximum de deux passagers par achat. Veuillez citer le numéro de promotion 10782 de la SCPH. Pour obtenir des renseignements sur les horaires et les tarifs et effectuer vos réservations, téléphonez au numéro 1-888-842-7245. Des taxis attendent à la gare pour vous amener au Centre Sheraton à trois coins de rue.

Où loger durant l'AGA?

Le Centre Sheraton

La SCPH est heureuse de vous offrir un tarif spécial de 165$ pour une chambre en occupation simple ou double au Centre Sheraton. Toutes les réunions officielles du congrès de la SCPH se tiendront dans cet établissement hôtelier. Le tarif de 165$ du congrès est garanti jusqu'au 7 juillet 2006. Ne manquez pas cette occcasion et effectuez votre réservation sans tarder en téléphonant au bureau central de réservations du Centre Sheraton au (800) 325-3535. Lorsque vous téléphonerez, n'oubliez pas de mentionner l'AGA 2006 de la SCPH pour vous prévaloir du tarif du congrès.

Activités sociales l'AGA

Afin de fournir un compte exact des convives à nos établissements hôtes, nous encourageons les congressistes à acheter leurs billets pour la Partie de plaisir du dimanche et le Dîner des anciens présidents du lundi avant leur arrivée à l'AGA 2006. Vous pouvez vous procurer vos billets à l'avance en les commandant sur le formulaire d'inscription de l'AGA 2006. Les billets peuvent aussi être achetés sur place. Aucun billet ne sera vendu après 17h00 le samedi 12 août 2006. Merci de votre collaboration.

CSHP VISION 2006

A revitalized Society

The influential voice for hospital pharmacy

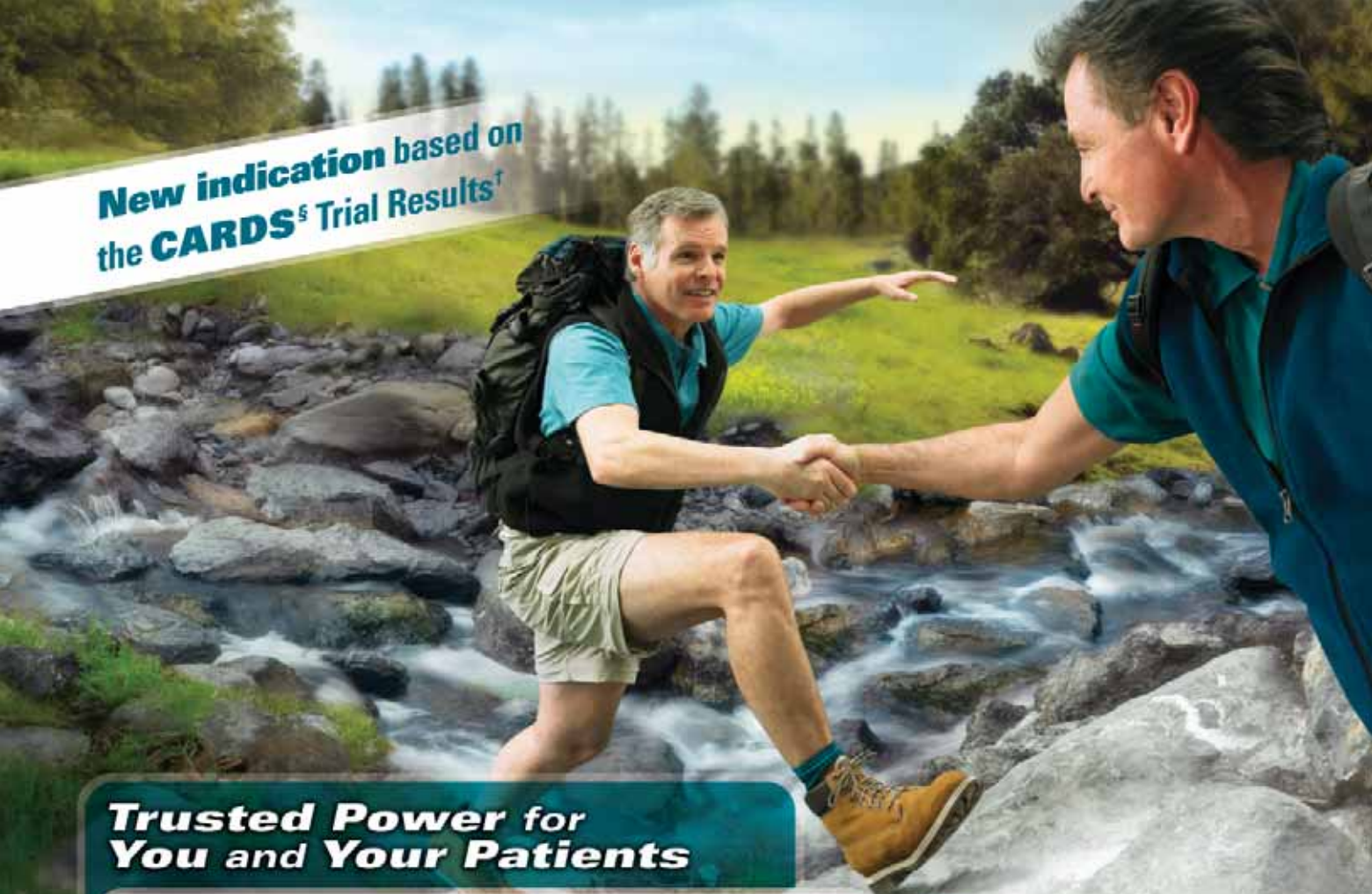
Inspiring and supporting our members

SCPH VISION 2006

Une Société redynamisée

La voix influente de la pharmacie hospitalière

Une source d'inspiration et de soutien pour nos membres



New indication based on the CARDS§ Trial Results†

Trusted Power for You and Your Patients

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

¥ When a >45% LDL-C reduction is required, patients may be started at 40 mg o.d.

Power

AND is indicated to reduce the risk of MI and stroke in patients with type 2 diabetes and hypertension without CHD but with other risk factors†[1]

Evidence

ONLY LIPITOR* is supported by 5 million patient-years of therapy in Canada[2£]

Trust

LIPITOR
atorvastatin calcium
tablets

power you can **trust**™

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 non-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 (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.

† LIPITOR is also indicated to reduce the risk of myocardial infarction and stroke in adult patients with type 2 diabetes mellitus and hypertension without clinically evident coronary heart disease, but with other risk factors such as age ≥55 years, retinopathy, albuminuria or smoking.

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 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.

§ CARDS = Collaborative Atorvastatin Diabetes Study.

£ A patient-year represents the total time of exposure to LIPITOR as defined by the sum of each patient's time on LIPITOR.[2]

Pfizer

Life is our life's work

References: **1.** LIPITOR (atorvastatin calcium) Product Monograph, Pfizer Canada Inc., November 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.

AGM 2006 at a Glance/ L'AGA d'un coup d'oeil

Educational Sessions/Séances éducatives

Sun., Aug. 13	08:30-15:00/Dimanche 13 août	8 h 30 - 15 h
Mon., Aug. 14	08:30-15:30/Lundi 14 août	8 h 30 - 15 h 30
Tues., Aug. 15	08:45-16:00/Mardi 15 août	8 h 45 - 16 h

Annual General Meeting/ Assemblée générale annuelle

Sun., Aug. 13	15:00-17:00/Dimance 13 août	15 h - 17 h

Registration/Inscription

Sat., Aug. 12	15:00-17:30/Samedi 12 août	15 h - 17 h 30
Sun., Aug. 13	07:30-17:00/Dimanche 13 août	7 h 30 - 17 h
Mon., Aug. 14	07:30-17:00/Lundi 14 août	7 h 30 - 17 h
Tues., Aug. 15	08:00-16:00/Mardi 15 août	8 h - 16 h

Exhibits/Kiosques

Sun., Aug. 13	10:00-15:00/Dimanche 13 août	10 h - 15 h
Mon., Aug. 14	10:00-15:00/Lundi 14 août	10 h - 15 h

Lunch/Exhibitors/Posters/ Déjeuner/Kiosques/Affiches

Sun., Aug. 13	12:00-14:00/Dimanche 13 août	12 h - 14 h
Mon., Aug. 14	12:30-14:30/Lundi 14 août	12 h 30 - 14 h 30

Social Events at a Glance/ Activités sociales d'un coup d'oeil

Saturday, August, 12/Samedi 12 août

Research and Education Foundation Fundraising Golf Event/
Tournoi de golf de la Fondation pour la recherche et l'éducation

07:00-16:00; first bus will depart at 06:00 from Le Centre Sheraton

7 h - 16 h; départ du premier autobus du Centre Sheraton dès 6 h

La Seigneurie Golf Course/Parcours de golf La Seigneurie

Limit: 80 golfers/Limite : 80 golfeurs

CHPRB Residency Mentorship Program Reception/ Réception du programme de mentorat de la SCPH pour les résidents

17:30-19:30

Le Centre Sheraton – Presidential Suite/Suite présidentielle

Opening Reception/Réception d'ouverture

18:30-22:30

Le Centre Sheraton – Salle de bal Drummond Ballroom

Sunday, August 13/Dimanche 13 août

Fun/Run Walk Event/
Course/promenade des lève-tôt

06:00-08:00; buses will depart at 05:45 from Le Centre Sheraton Lobby

6 h - 8 h; départ des autobus à 5 h 45 du Centre Sheraton Hall d'entrée

Wine and Chat/Vin et causette

17:00-18:00

Le Centre Sheraton – Salon 5

Fun Night at La Ronde/Partie de plaisir à La Ronde

19:00-24:00; first bus will depart at 18:15 from Le Centre Sheraton

19 h - 24 h; départ du premier autobus du Centre Sheraton dès 18 h 15

Monday, August 14/Lundi 14 août

Past Presidents' Dinner and Dance/
Dîner dansant des anciens présidents

La Tour de Montréal

19:00-01:00; buses will depart between 18:00-18:30 from Le Centre Sheraton

19 h - 01 h; départ des autobus de 18 h à 18 h 30 du Centre Sheraton

Upcoming Events/ Événements à venir

Professional Practice Conference (PPC) 2007
January 27-31, 2007
Westin Harbour Castle Hotel
Toronto, ON

Professional Practice Conference (PPC) 2008
January 26-30, 2008
Sheraton Centre Toronto
Toronto, ON

Professional Practice Conference (PPC) 2009
January 31-February 4, 2009
Sheraton Centre Toronto
Toronto, ON

Professional Practice Conference (PPC) 2010
January 30-February 3, 2010
Sheraton Centre Toronto
Toronto, ON

Annual General Meeting (AGM) 2007
August 11-14, 2007
Delta Regina
Regina, SK

Annual General Meeting (AGM) 2008
August 9-12, 2008
Saint John Hilton & Convention Centre
Saint John, NB

Annual General Meeting (AGM) 2009
August 8-11, 2009
TBA
Winnipeg, MB

Annual General Meeting (AGM) 2010
August 7-10, 2010
TBA
Halifax, NS

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CSHP 59th AGM and Educational Sessions/ 59e Assemblée générale annuelle et séances éducatives de la SCPH

Saturday, August 12 • Samedi 12 août

07:00-16:00 Research & Education Foundation Fundraising Golf Event

LA SEIGNEURIE GOLF COURSE

(First bus will depart at 06:00 from Le Centre Sheraton)

Have some fun and help raise funds for the R&E Foundation.

So you like to play golf… you are not the only one! Join us for a great day at La Seigneurie Golf Course. This course provides four levels of difficulty and will please you whatever your skill. You will also enjoy the breathtaking views of lakes, forests, and hills in the Mont Saint-Hilaire area.

Tournoi de golf de la Fondation pour la recherche et l'éducation

GOLF LA SEIGNEURIE

(Départ du premier autobus du Centre Sheraton dès 06h00)

Amusez-vous et contribuez à la collecte de fonds au profit de la Fondation pour la recherche et l'éducation.

Alors, vous aimez jouer au golf… vous n'êtes pas les seuls! Joignez-vous à nous pour une partie de plaisir au parcours de golf La Seigneurie. Ce parcours compte quatre niveaux de difficulté et vous comblera quelle que soit votre adresse. Vous serez aussi charmé par le panorama de la région du Mont Saint-Hilaire avec ses lacs, ses forêts et ses collines.

15:00-17:30 Registration/ Inscription

SALLE DE BAL FOYER

17:30-19:30 CSHP Residency Mentorship Program Reception
Réception du programme de mentorat de la SCPH pour les résidents

PRESIDENTIAL SUITE/SUITE PRÉSIDENTIELLE

18:30-22:30 Opening Reception

DRUMMOND CENTRE/OUEST

Dress: Casual

Hear ye! Hear ye! Fine ladies and noble lords! His Majesty the King of France invites you with a resounding drum roll to relive the glorious epic of New France. Rumour in the township has it that the royal court is preparing for a banquet. *Animation d'autrefois* invites you in the year 1749 to feast in the company of the governor, the Jesuit, the coureur de bois and a dozen other accomplices. An activity called "card money game" will transform each table into a feudal estate. The estate that collects the most "card money" by trading with the various characters will be the winner of the game. Come and join us for this fun-filled evening!

Réception d'ouverture

DRUMMOND CENTRE/OUEST

Tenue : décontractée

Oyez! Oyez! Gentes dames et nobles seigneurs! Sa Majesté le roi de France vous invite tambour battant à revivre l'épopée glorieuse de la Nouvelle-France. Le bruit court dans la bourgade que la cour royale se prépare pour un banquet. *Animation d'autrefois* vous invite, en l'an de grâce 1749, à festoyer en la compagnie du gouverneur, du jésuite, du coureur des bois et d'une douzaine de leurs complices. Une activité nommée « jeu de la monnaie de carte » transformera chaque table en une seigneurie. La seigneurie gagnante sera celle qui récoltera le plus de « monnaie de carte » en troquant avec les différents lurons. Venez vous joindre à nous pour cette soirée amusante!

Sunday, August 13 • Dimanche 13 août

06:00-08:00 Fun Run/Walk Event

Buses will depart at 05:45 from Le Centre Sheraton

Jack and Jill went up the hill
To stay lean and fit.
Jack said "Hey! Let's go this way."
And Jill came trotting after.
Up went Jack and Jill,
And there they found enlightenment.
To start off the day on the right foot,
Walk, run and then eat breakfast
At the Faculty of Pharmacy.

Course/promenade des lève-tôt

Départ des autobus à 05h45 du Centre Sheraton

À la claire fontaine
M'en allant promener,
J'ai trouvé la montagne si belle,
Que je l'ai escaladée.
Là étudient tes collègues,
Ils aimeraient t'y rencontrer.
Pour commencer la journée du bon pied,

On marche, on court et puis on déjeune
À la Faculté de pharmacie.

**07:30-17:00 Registration/
Inscription**

SALLE DE BAL FOYER

**08:15-08:30 Opening Remarks/
Remarques préliminaires**

SALLE DE BAL OUEST

**08:30-09:15 Plenary Session/
Séance plénière**

SALLE DE BAL OUEST

Run for it! A Rookie Candidate's Federal Election Experience

Karen Graham, BScPhm
Panacea Canada Inc.
Hawkestone, ON

09:15-10:15 Leading Change in Pharmacy Practice: The Role of the Pharmacist in the Healthcare System

SALLE DE BAL OUEST

Ross Tsuyuki, PharmD, FCSHP
University of Alberta
Edmonton, AB

**10:15-10:45 Break/Posters/
Pause/Affiches**

SALLE DE BAL CENTRE/EST

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

SALON 4/5

1. Clinical Pearls

Holding the Line! Updates on Emerging Infections

Daniel Thirion, PharmD
Hôpital du Sacré-Coeur de Montréal
Montréal, QC

Infliximab: New Role in Ulcerative Colitis

Co Pham, PharmD
Montreal General Hospital
Montréal, QC

What is New in Contraception?

Ema Ferreira, MSc, PharmD
Centre hospitalier universitaire Sainte-Justine
Montréal, QC

SALON JARRY

2. Management of Acute Agitation and Delirium: Are Atypical Antipsychotics Just Along for the Ride?

Susan Corrigan, PharmD
Burnaby General Hospital
Burnaby, BC

SALON 3

3. Revue de la douleur neuropathique

Patrick Bouchard, BPharm, MSc
Hôpital général de Montréal
Montréal, QC

**11:30-12:15 Concurrent Sessions/
Séances concomitantes**

SALON 3

1. Trésors cliniques

Appel aux armes! Une mise à jour sur les pratiques contre l'invasion des nouvelles maladies infectieuses

Daniel Thirion, PharmD
Hôpital du Sacré-Coeur de Montréal
Montréal, QC

Infliximab : nouveau rôle dans le traitement de la colite ulcéreuse

Co Pham, PharmD
Hôpital général de Montréal
Montréal, QC

Nouveautés en contraception

Ema Ferreira, MSc, PharmD
Centre hospitalier universitaire Sainte-Justine
Montréal, QC

SALON JARRY

2. Review of Articles that will Change Your Practice

Brenda Schuster, PharmD
Regina Qu'Appelle Health Region
Regina, SK

SALON 4/5

3. Diagnosis, Causes, Course and Rx of Alzheimer's Disease (AD)

Serge Gauthier, MD, FRCPC
McGill University
Montréal, QC

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

SALLE DE BAL CENTRE/EST

**14:00-15:00 Plenary Session/
Séance plénière**

SALLE DE BAL OUEST

National Pharmaceuticals Strategy

Robert Nakagawa, BScPhm, FCSHP
Ministry of Health
Victoria, BC

15:00-17:00 Annual General Meeting/ Assemblée générale annuelle

SALLE DE BAL OUEST

17:00-18:00 Wine & Chat/ Vin et causette

SALON 5

19:00-24:00 Fun Night at La Ronde

Dress: Sports Casual

First bus will depart at 18:15 from Le Centre Sheraton

Experience the adventure at La Ronde with rides galore, including "Goliath", the amusement park's and Canada's newest, biggest, and fastest roller coaster. Dinner will take place in a private pavilion overlooking a beautiful marina on the St. Laurence Seaway. Fun Night is for the entire family this year, so make sure you bring your spouse, kids, and friends. Young and old alike will enjoy an evening of great entertainment and great food. Don't miss it! Please note: tickets include a pass to the amusement park.

Partie de plaisir à La Ronde

Tenue : décontractée sport

Départ du premier autobus du Centre Sheraton dès 18h15

Venez vous étourdir dans les manèges de La Ronde et rencontrer « Goliath », le nouveau-né du parc d'attractions et les montagnes russes les plus hautes et les plus rapides au Canada. Le dîner sera servi dans un pavillon privé ouvrant sur une jolie marina au bord de la voie maritime du Saint-Laurent. Cette année, toute la famille a rendez-vous à la Partie de plaisir. Alors emmenez votre tendre moitié, vos enfants et vos amis. La folie des manèges saura gagner petits et grands. Soyez de la partie ! Veuillez noter que le prix des billets incluent le droit d'entrée au parc d'attractions.

Monday, August 14 • Lundi 14 août

07:30-17:00 Registration/ Inscription

SALLE DE BAL FOYER

08:15-08:30 Announcements/ Annonces

SALLE DE BAL OUEST

08:30-09:15 Plenary Session/ Séance plénière

SALLE DE BAL OUEST

The Future of Residency Training in Canada

Donna Woloschuk, PharmD, FCSHP
Winnipeg Regional Health Authority
Winnipeg, MB

09:15-10:00 Concurrent Sessions/ Séances concomitantes

SALON 4/5

1. Coming Attractions: Previews to Leadership

Shallen Letwin, PharmD, FCSHP
Fraser Health Authority
Vancouver, BC

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

Linda Vaillant, MSc, MBA
Association des pharmaciens des établissements de santé du Québec
Montréal, QC

SALON JOYCE

2. Tubercolosis (TB) – Emerging Issues in Pharmaceutical Care

Tom Chin, PharmD, FCSHP
St Michael's Hospital
Toronto, ON

SALON 3

3. Nouvelles approches d'anticoagulation en syndromes coronariens aigus

Chantal Pharand, PharmD
Hôpital du Sacré-Coeur de Montréal
Montréal, QC

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

SALLDE DE BAL CENTRE/EST

10:30-12:30 Workshops/ Ateliers

SALON JOYCE

1. Silk Purses out of Sows' Ears: Turning your Leftover Projects and Posters into Real Publications *(attendees are requested to bring to the workshop an abstract or "leftover project or poster" that they wish to turn into a full-length manuscript for "real publication")*

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

SALON 4/5

2. Evidence-Based Medicine Workshop – Appraising Systematic Reviews

Richard Slavik, PharmD, FCSHP
Vancouver Coastal Health Authority
Vancouver, BC

SALON 6/7

3. Heparin-Induced Thrombocytopenia: Fact or Fiction?

David Williamson, BPharm, MSc, BCPS
Hôpital du Sacré-Coeur de Montréal
Montréal, QC

4. PSN Session – ID/ Séances RSP – Infectiologie

SALON HEMON

Standardized Methods for Measuring Drug Use: Making Cents of the Data!

Bruce Dalton, PharmD
Calgary Health Region
Calgary, AB

Monique Pitre, BScPhm
University Health Network
Toronto, ON

Daniel Thirion, PharmD
Hôpital du Sacré-Coeur de Montréal
Montréal, QC

***C. difficile:* The Québec Experience**

Daniel Thirion, PharmD
Hôpital du Sacré-Coeur de Montréal
Montréal, QC

12:30-14:30 Lunch/Exhibitors/Posters/ Déjeuner/Kiosques/Affiches

SALLE DE BAL CENTRE/EST

14:30-15:30 Plenary Session/ Séance plénière

SALLE DE BAL OUEST

MOXXI Project: Linking Pharmacists, Physicians and Patients

Nancy Winslade, PharmD, MHPE
McGill University
Montréal, QC

19:00-01:00 Past-Presidents' Dinner and Dance

LA TOUR DE MONTRÉAL

Dress: Formal

Buses will depart between 18:00-18:30 from Le Centre Sheraton

For your last night in Montréal, you will have a great time high above the city lights:

- Discover the city from the top of La Tour de Montréal.
- Join us for a gastronomic dinner featuring regional cuisine prepared by one of the best caterers in town.
- Dance the night away with The Tuxedo Pop Orchestra.

Dîner dansant des anciens présidents

LA TOUR DE MONTRÉAL

Tenue : soirée

Départ des autobus de 18h00 à 18h30 du Centre Sheraton

Pour votre dernière soirée, Montréal est à vos pieds :

- Découvrez la ville du haut de La Tour de Montréal.
- Soyez des nôtres pour un dîner gastronomique mettant en vedette la cuisine régionale préparée par l'un des meilleurs traiteurs en ville.
- Dansez jusqu'aux petites heures du matin au rythme du Tuxedo Pop Orchestra.

Tuesday, August 15 • Mardi 15 août

08:00-16:00 Registration/ Inscription

SALLE DE BAL FOYER

08:30-08:45 Announcements/ Annonces

SALLE DE BAL OUEST

08:45-09:30 Plenary Session/ Séance plénière

SALLE DE BAL OUEST

Medication Use and Medication Management Standards

Sarah Taber, MHA
Canadian Council on Health Services Accreditation
Ottawa, ON

09:30-10:15 Concurrent Sessions/ Séances concomitantes

SALON JOYCE

1. Bridging Theory to Practice: Practical Considerations for Implementing Medication Reconciliation Strategies

Olavo Fernandes, PharmD
University Health Network
Toronto, ON

SALON 4/5

2. Appraoch to Anticoagulation in Acute Coronary Syndromes

Chantal Pharand, PharmD
Hôpital du Sacré-Coeur de Montréal
Montréal, QC

SALON 3

3. Jongler avec les chiffres : comprendre les résultats des études

Linda Lévesque, BScPhm, MSc, PhD
Queen's University
Kingston, ON

10:15-10:45 Break/ Pause

SALLE DE BAL FOYER

10:45-12:45 Workshops/ Ateliers

SALON HEMON

1. Silk Purses out of Sows' Ears: Turning your Leftover Projects and Posters into Real Publications *(attendees are requested to bring to the workshop an abstract or "leftover project or poster" that they wish to turn into a full-length manuscript for "real publication")*

Mary H.H. Ensom, PharmD, FCSHP
Women's and Children's Hospital of BC
Vancouver, BC

SALON 4/5

2. Evidence-Based Medicine Workshop – Appraising Systematic Reviews

Richard Slavik, PharmD, FCSHP
Vancouver Coastal Health Authority
Vancouver, BC

SALON 6/7

3. Thrombocytopénie induite par l'héparine : mythe ou réalité?

David Williamson, BPharm, MSc, BCPS
Hôpital du Sacré-Coeur de Montréal
Montréal, QC

12:45-14:15 Lunch Break/ Pause déjeuner

14:15-15:00 Concurrent Sessions/ Séances concomitantes

SALLE DE BAL OUEST

1. Short and Snappies

A New Analgesic: Whole-Plant-Canabis-Based Oral Mucosal Spray

Marie Claude Vanier, BScPhm, MSc
Cité de la santé de Laval
Montréal, QC

Respiratory Fluoroquinolones for Community-Acquired Pneumonia: Safety Considerations

Sylvie Carle, BPharm, MSc
McGill University Health Centre
Montréal, QC

SALON 3

2. En un clin d'œil

L'étomidate a-t-il une place dans nos chariots de réanimation?

Christopher Marquis, BScPhm
Centre hospitalier universitaire Sainte-Justine
Montréal, QC

Le défibrotide et la maladie hépatique veino-occlusive, vous connaissez?

Jean-Philippe Côté, BPharm
CHUQ Hôtel-Dieu de Québec
Québec, QC

15:00-16:00 Plenary Session/ Séance plénière

SALLE DE BAL OUEST

Disaster Planning: Lessons Learned from Hurricane Katrina

Philip McCrory Jr., RPh, BSPharm
Louisiana Department of Health & Hospitals
New Orleans, LA

16:00 Close of the 59th CSHP Educational Sessions/ Clôture de la 59e Assemblée générale annuelle

Organized by the Educational Services Committee of CSHP with assistance from the 2006 AGM Host Committee

Organisée par le Comité des services éducatifs de la SCPH en collaboration avec le Comité d'accueil de l'AGA 2006

Sunday, August 13 • Dimanche 13 août

Run for it! A Rookie Candidate's Federal Election Experience

Karen Graham, BScPhm, Panacea Canada Inc., Hawkestone, ON

This presentation will tell the story of how a former hospital pharmacist, while minding her own business in RR#1 Hawkestone Ontario, was somehow convinced to run in the recent federal election. A non-partisan discussion of what it's like to be a candidate, lessons learned and advice to politicians-to-be. Perspectives shared on leadership versus politics and what we need in all of our leaders in order to continue to thrive at local, provincial and national levels. No pharmacokinetics discussions or health economics analyses whatsoever. Guaranteed. Definitely no graphs or charts.

Goals and Objectives

1. To share my experience in the recent federal election
2. To perhaps inspire some folks to consider getting their names on ballots (this is a stretch since the talk is first thing on Sunday Morning and I know what CSHP AGMs are like)
3. To share some ideas on what it means to be a leader, anywhere, in 2006.

Self-Assessment Questions

1. Where and How do I want to make a difference?
2. What will I do right now to get started?

Leading Change in Pharmacy Practice: The Role of the Pharmacist in the Healthcare System

Ross T. Tsuyuki, BSc(Pharm), PharmD, MSc, FCSHP, FACC, Professor of Medicine (Cardiology) and Director, EPICORE Centre/COMPRIS, University of Alberta, Edmonton, AB

There is much to celebrate with regards to the contributions of pharmacists to patient care and improved outcomes. Yet, most of these 'victories' are not sustained and only embraced by a very small minority of pharmacists. This is a major threat to our profession.

Healthcare reform, is on the contemporary agenda. Pharmacists could be part of the solution, but currently are not. Pharmacists could be viewed as public health professionals and drug therapy experts – but this requires a major change in pharmacy practice.

To support this change in practice, we have formed the Centre for COMmunity Pharmacy Research and Interdisciplinary Strategies (COMPRIS). The vision of COMPRIS is: "Pharmacists engaged in patient-centered care, supported by high quality research evidence of its efficacy, empowered in their work environment, continuously developing their professional skills, and recognized for their important contributions to patient care". We conduct practice-based research (both hospital and community) which uses clinical trials methodology to demonstrate to value of proactive, responsible pharmacist care. We also provide methodology consultation, data management, and training for researchers. Finally, a branch of COMPRIS, called COMPRISactus is focusing on pharmacy practice and health policy change to make proactive, responsible, patient-centered care the new standard in pharmacy practice.

Goals and Objectives

Following this presentation, participants will be able to:

1. Identify the current pharmacy practice reality for our profession. Where are we in the responsible provision of patient centered pharmacy practice?
2. Identify the current challenges in our move toward patient-centered care
3. Recognize the real threats to our profession (if we don't' change our practice)
4. Discuss ways to be at the forefront of care

Self-Assessment Questions

1. Make a list of evidence-based and non-evidence based activities that you perform in your practice. What proportion of them have been shown to improve patient outcomes?
2. List 2 things that you can do differently to make your practice more patient-centered.

For further information on Leading Change in Pharmacy Practice, please see our full paper at www.epicore.ualberta.ca.

If you are interested in joining our coalition, please send an email message to ross.tsuyuki@ualberta.ca. We will keep you informed of our activities, progress towards our vision, and opportunities to help you lead change in pharmacy practice.

Acknowledgement: I would like to acknowledge the invaluable contributions of Theresa J. Schindel, BSP, MCE, FCSHP to this work.

Citation: Tsuyuki RT, Schindel TJ. Leading Change in Pharmacy Practice. Fully engaging pharmacists in patient-centered care.

Holding the Line! Updates on Emerging Infections

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

This 15 minute presentation will focus on recent practice changes in infectious disease. Over the past few years, this field has evolved tremendously with the emergence of several diseases including the SARS virus, Clostridium difficile associated diarrhea, avian flu, and the West Nile Virus. A very brief review of learning tools on treatment and prevention of these diseases will be presented. This will be followed by specific antimicrobial optimisation in view of the recently published literature. Since pharmacists have a wide scope of interventions in infectious diseases, from the bedside to hospital protocols, a quick listing of important opportunities including new practice guidelines, efficacy trials, safety reports, and drug interaction reports will be presented.

Goals and Objectives

1. To provide pharmacists with educational tools for improving their knowledge and practice in emerging infectious diseases.
2. To enable pharmacists to identify specific opportunities in their practice for improving patient care in the area of infectious diseases.

Self-Assessment Questions

1. Where can I find educational tools for improving my knowledge and practice for the care of patients affected by emerging diseases such as the avian flu and C. difficile associated diarrhea?
2. Identify three opportunities or clinical aspects where pharmacists can optimize antimicrobial use.

Infliximab: New Role in Ulcerative Colitis

Co Q. D. Pham, BSc, BA, BScPharm, PharmD, Montreal General Hospital, Montreal, QC

The goal of this session is to provide pharmacists with the evidence and practical information for the utility of infliximab in ulcerative colitis (UC).

Biological agents mark the new landscape in inflammatory bowel disease (IBD) clinical therapy. Like all new therapies, these agents require extra vigilance on the part of health professionals. In IBD the application of infliximab in Crohn's disease (CD) has improved treatment options, and has recently shown to be important in UC. It is recognized that in acute UC exacerbations in patients refractory to steroids, that therapeutic options are limited. Commonly used immunosuppressive agents require careful monitoring and are not free of potential hazards. Although surgical options may be curative in UC, they produce a high rate of post-operative complications in up to 20% of patients. Therefore, a role for biologic options beyond current therapies is important.

Despite the general understanding that cytokine profiles in both UC and CD are different, recent evidence suggests that TNF-a may be important in the inflammatory cascade in UC, as in CD. Therefore, the application of infliximab, a chimeric monoclonal antibody anti- TNF-a may be able to reverse pro-inflammatory activities in UC, and prove to be an effective therapy.

A body of evidence for infliximab in UC has accumulated promoting the recent approval for this application by Health Canada. Indeed, infliximab is not a benign agent, and it is important that pharmacists managing UC patients recognize the new role and issues for infliximab therapy.

Goals and Objectives

1. To provide pharmacists with an understanding of the evidence for the application of infliximab in UC.
2. To enable pharmacists to recognize when the recommendation of infliximab may be important in UC.
3. To provide pharmacists with the controversies and issues related to infliximab in UC therapy.

Self-Assessment Questions

1. What is infliximab therapy?
2. When should infliximab be considered in the treatment of ulcerative colitis?
3. What are the issues with using infliximab in UC patients?

What Is New In Contraception?

Ema Ferreira, B.Pharm., M.Sc., Pharm.D., CHU Ste-Justine, Université de Montréal, Montreal, QC

The objective of this presentation is to provide up to date information to the pharmacist on the newer methods of hormonal contraception on the Canadian market.

In recent years, various new hormonal contraception products were released on the market. Not only did product formulations change but new routes of administration are now available.

Newer oral contraceptives contain lower oestrogen concentrations or different progestins. A new oral contraceptive that contains drospirenone, a new progestin with antimineralocorticoid activity is now available. This oral contraceptive could have potential benefits over other oral contraceptives on premenstrual symptoms, acne and weight gain.

Various routes of administration for hormonal contraception are now available including, intramuscular injections, implants, transdermal patches and vaginal rings. A vaginal ring, has been available on the Canadian market for over a year and offers an interesting alternative for women who desire a different route of administration.

Extended cycle hormonal contraception in increasingly popular and its risks and benefits will be discussed. Although several advantages on quality of life can be noted, long term effects are not yet known. Finally, a brief summary of products under study will be presented.

Goals and Objectives

1. To provide the pharmacist with up to date information on the newer methods of contraception on the Canadian market.
2. To discuss the risks and benefits of extended use of hormonal contraception.

Self-Assessment Questions

1. What are the claims to fame of the new oral contraceptive containing ethinylestradiol and drosperinone?
2. How is the new vaginal ring contraceptive used?
3. What do you say to a woman who wants to take her oral contraceptive for an extended period without stopping?

Management of Acute Agitation and Delirium: Are Atypical Antipsychotics Just Along for the Ride?

Sue Corrigan, BScPharm, ACPR, PharmD, Fraser Health Authority, Burnaby BC

Delirium is characterized by an acute change in mental status and fluctuating levels of consciousness. It may be associated with symptoms of disorientation, hallucinations, impaired cognitive functioning and agitation. Underlying etiology often involves an acute or chronic medical condition, medication use or substance abuse.

Acute agitation is characterized by motor restlessness with mental tension, heightened responsiveness to stimuli, irritability and decreased sleep. These symptoms will also fluctuate in severity over time. Agitation may be a component of many different clinical conditions: delirium, psychiatric illnesses (schizophrenia, acute mania or post-traumatic stress disorder), drug and alcohol intoxication or withdrawal states, medication toxicity, and many medical illnesses.

Atypical antipsychotics are widely prescribed for the treatment of schizophrenia, with increasing use for the management of mood disorders. The availability of formulations such as oral disintegrating tablets and intramuscular injections has recently led to increasing usage of atypical antipsychotics in the treatment of acute agitation.

A summary of the available evidence for the efficacy and safety of atypical antipsychotics for acute agitation will be presented. The assessment scales of agitated patients in clinical trials will also be discussed. The role of atypical antipsychotics and their place in therapy will be reviewed.

Goals and Objectives

To provide pharmacists with an overview of non-drug measures and pharmacotherapy strategies in managing an acutely agitated patient.

1. To review the efficacy evidence and the safety implications of using atypical antipsychotics to treat these patients.
2. To review preferred treatment strategies based on the etiology of the agitation.

Self-Assessment Questions

1. What are some safety concerns when treating an agitated patient due to substance intoxication with atypical antipsychotics?
2. What patient populations can be appropriately managed with atypical antipsychotics for acute agitation?

Revue de la douleur neuropathique

Patrick Bouchard, Bpharm, MSc, Hôpital Général de Montréal (CUSM), Montréal, Qc.

Le but de cette présentation est de familiariser le pharmacien à la prise en charge d'un patient souffrant de douleurs neuropathiques ainsi que de passer en revue les différents agents pharmacologiques disponibles.

La douleur est un symptôme subjectif d'intensité variable difficile à évaluer de façon quantitative. La douleur neuropathique a de multiples étiologies et peut prendre différentes formes. La plupart des études effectuées dans le domaine de la douleur neuropathique mettent l'emphase sur une population donnée avec une étiologie précise et non sur le type de douleur ressentie par le patient. Plusieurs médicaments sont utilisés à cette fin, mais peu d'entre eux ont l'indication officielle.

Outres les analgésiques traditionnels que sont les dérivés opiacés et anti-inflammatoires non-stéroïdiens, d'autres classes de médicaments, telles que les anti-arythmiques, anti-convulsivants et anti-dépresseurs ont été étudiées et utilisées avec un succès variable. Pour chaque classe de médicaments, le mécanisme d'action, l'expérience et l'évidence clinique supportant son utilisation ainsi que les doses et effets secondaires possibles seront discutés. L'arsenal thérapeutique est grand et les possibilités immenses pour qui sait s'y retrouver. Une approche sera proposée et le rôle du pharmacien dans le suivi et le succès de cette approche y est très important.

Buts et objectifs

1. Revoir brièvement la pathophysiologie ainsi que les causes de douleur neuropathique.
2. Discuter le rôle des analgésiques traditionnels (opioïdes, AINS) dans le traitement de la douleur neuropathique.
3. Souligner le rôle des différentes classes de médicaments non-traditionnels utilisés pour soulager la douleur neuropathique (ATC, anti-convulsivants, anti-arythmiques).
4. Énoncer des recommandations sur la prise en charge des patients réfractaires.
5. Développer une approche systématique au traitement de la douleur neuropathique
6. Discuter de l'importance du rôle du pharmacien dans le traitement de la douleur neuropathique.

Questions d'auto-évaluation

1. Est-il raisonnable d'utiliser des opioïdes pour traiter la douleur neuropathique ?
2. Par niveau d'évidence clinique, quels sont les médicaments de première ligne dans le traitement de la douleur neuropathique ?
3. Comment définir un échec au traitement de la douleur neuropathique ?
4. Quels sont les facteurs qui peuvent contribuer à exacerber la douleur neuropathique ?

Appel aux armes! Une mise à jour sur les pratiques contre l'invasion des nouvelles maladies infectieuses.

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

Cette présentation de 15 minutes portera sur les changements récents au niveau de la pratique en maladies infectieuses. Cette pratique a évolué rapidement au cours des dernières années avec l'émergence de plusieurs maladies dont le syndrome respiratoire aiguë sévère, la diarrhée associée au Clostridium difficile, la grippe aviaire, et le virus du Nile. Un sommaire des outils éducationnels portant sur le traitement et la prévention de ces maladies sera présenté. Ceci sera suivi d'une courte présentation sur les interventions spécifiques portant sur l'optimisation des antimicrobiens selon les récents publications. Puisque les pharmaciens interviennent à plusieurs niveaux dans le système de santé; soit du chevet du patient jusqu'au développement de protocoles; nous porterons une attention particulière aux nouvelles lignes directrices, aux études cliniques, à l'innocuité des médicaments, et aux interactions médicamenteuses.

Buts et objectifs

1. D'offrir aux pharmaciens des outils éducationnels afin d'améliorer le niveau de connaissances et de hausser la pratique dans le domaine des maladies infectieuses en émergence.
2. Identifier des opportunités précises au niveau de la pratique qui permettent d'améliorer les soins offerts aux patients dans le domaine des maladies infectieuses.

Questions d'auto-évaluation

1. Identifiez quelques endroits où l'on retrouve des outils qui permettent d'améliorer les connaissances et de hausser la pratique dans le cadre des soins offerts aux patients atteint d'une maladie infectieuses en émergence tels que la grippe aviaire, ou la diarrhée associée au C. difficile.
2. Identifiez trois opportunités ou aspects cliniques où les pharmaciens peuvent optimiser l'usage des antimicrobiens

Infliximab : nouveau rôle dans le traitement de la colite ulcéreuse

Co Q. D. Pham, B.Sc., B.A., B.Sc. Pharm., Pharm. D., Hôpital générale de Montréal, Montréal, Qc.

Cette présentation a pour objectif de fournir aux pharmaciens un aperçu des données qui confirment l'efficacité de l'infliximab dans le traitement de la colite ulcéreuse, et des renseignements pratiques à ce sujet.

Les agents biologiques sont au cœur des nouveaux traitements cliniques des maladies intestinales inflammatoires. Les professionnels de la santé doivent faire preuve d'une grande vigilance à l'égard de ces agents, comme pour toutes les nouvelles avenues thérapeutiques. En ce qui a trait aux maladies intestinales inflammatoires, l'infliximab a élargi l'éventail des traitements liés à la maladie de Crohn. De plus, son utilisation s'est récemment avérée importante dans la colite ulcéreuse. On sait qu'il existe peu d'options thérapeutiques pour les patients réfractaires aux stéroïdes qui traversent une crise aiguë de colite ulcéreuse. En effet, les agents immunosuppresseurs qui sont généralement utilisés nécessitent un suivi méticuleux, et des risques y sont tout de même associés. En outre, bien que les personnes atteintes de colite ulcéreuse puissent guérir à la suite d'une chirurgie, 20 % d'entre elles souffrent de complications postopératoires, un taux qui nous apparaît bien élevé. Par conséquent, au-delà des traitements courants, les thérapies biologiques jouent un rôle important.

Bien que tout le monde s'entende pour dire que la colite ulcéreuse et la maladie de Crohn ont des profils cytokiniques différents, des données récentes semblent indiquer que le TNF-a joue un rôle important dans la cascade inflammatoire de ces deux maladies. Ainsi, l'infliximab, anticorps monoclonal chimérique qui agit contre le TNF-a, pourrait faire inverser les activités pro-inflammatoires de la colite ulcéreuse, et s'avérer efficace pour traiter cette maladie.

De plus en plus de données confirment les bienfaits de l'infliximab dans le traitement de la colite ulcéreuse, ce pourquoi Santé Canada a récemment approuvé cet usage. En réalité, l'infliximab n'est pas un agent bénin. Il importe donc que les pharmaciens qui s'occupent de patients souffrant de colite ulcéreuse reconnaissent le nouveau rôle du traitement par infliximab, de même que les problèmes liés à celui-ci.

Buts et objectifs

1. Présenter aux pharmaciens les données qui confirment l'efficacité du traitement par infliximab chez les patients souffrant de colite ulcéreuse.
2. Permettre aux pharmaciens de reconnaître les cas où il est important de recommander le traitement de la colite ulcéreuse par infliximab.
3. Présenter aux pharmaciens les controverses et les problèmes liés au traitement de la colite ulcéreuse par infliximab.

Questions d'auto-évaluation

1. Qu'est-ce que le traitement par infliximab?
2. Dans quelles conditions le traitement de la colite ulcéreuse par infliximab devrait-il être envisagé?
3. Quels sont les problèmes liés au traitement par infliximab chez les patients souffrant de colite ulcéreuse?

Nouveautés en contraception

Ema Ferreira, B.Pharm., M.Sc., Pharm.D., CHU Ste-Justine, Université de Montréal, Montréal, Qc.

Le but de cette conférence est de fournir au pharmacien de l'information à jour sur les nouvelles méthodes de contraception sur le marché Canadien.

Depuis les dernières années, plusieurs nouveaux produits de contraception hormonale ont vu le jour. Non seulement les compositions des contraceptifs ont changé mais de nouvelles voies d'administration ont été commercialisées.

Du coté des contraceptifs oraux, on a vu les quantités d'oestrogènes diminuer et de nouveaux progestatifs commercialisés. On note, la venue d'un contraceptif qui contient un nouveau progestatif, la drospérinone qui a des activités antiminéralocorticoïdes. Ces effets pourraient conférer plusieurs avantages par rapport aux autres contraceptifs oraux sur les symptômes prémenstruels et périmenstruels, l'acné et la prise de poids.

Des voies d'administration différentes ont été également été commercialisées telles que les injections intramusculaires, les implants sous-cutanés, les timbres cutanés et les anneaux vaginaux. L'anneau vaginal contraceptif a été commercialisé il y a plus d'un an donnant ainsi une option de traitement intéressante aux femmes qui désirent une contraception hormonale efficace par une voie d'administration différente.

En plus des nouvelles méthodes, l'utilisation de la contraception hormonale en continu gagne de plus en plus de popularité et ses avantages et les désavantages seront discutés. Bien que plusieurs avantages puissent être nommés, les effets à long terme restent encore inconnus. Enfin, un bref résumé des produits à l'étude sera exposé.

Buts et objectifs

1. Fournir au pharmacien de l'information à jour sur les nouvelles méthodes de contraception hormonale sur le marché canadien
2. Discuter des avantages et désavantages de la contraception hormonale en continu

Questions d'auto-évaluation

1. Quelles sont les prétentions du contraceptif contenant l'éthinyl estradiol et la drospirenone??
2. Comment utilise-t-on l'anneau vaginal contraceptif ?
3. Que dites-vous à une femme qui veut utiliser son contraceptif oral en continu ?

Review of Articles that will Change Your Practice

Brenda G. Schuster, BSP, PharmD, Regina Qu'Appelle Health Region, Regina SK

Pharmacists are constantly challenged to stay up to date on important publications in the pharmacy and medical literature. This presentation will assist you by reviewing key publications from the last 6 months. The focus will be on those publications that may result in changes to your practice or provide important reference information.

Due to the nature of this presentation and the goal to focus on the most relevant information it has not been determined which key publications will be reviewed.

Goals and Objectives

1. To review key publications that have potential to result in changes to practice.
2. To provide pharmacists with an opportunity to assess what changes to their practice may be required.
3. To enable pharmacists to answer questions from patients and other health care professionals regarding these latest publications.

Self-Assessment Questions

Not applicable

Diagnosis, Causes, Course and Rx of Alzheimer's Disease (AD)

Serge Gauthier, MD, FRCPC, McGill Center for Studies in Aging, Montréal, QC

AD is a neurologic condition affecting predominantly people over age 65 (1:4 over age 85).

Genetics play a role in the age of onset (rare genes lead to AD at age 40 to 50, one common gene increase risk of AD at age 60-70). High blood pressure in mid-life is an accelerating factor. Protective factors include higher education, a good social network, gardening, controlling high blood pressure, possibly eating more folic acid and omega-3 rich foods, and drinking red wine in moderate amounts.

Over 8 to 12 years there is a gradual decline in memory for recent events, difficulty with words, less ability to plan a meal or fix the house, select clothes and put them on; may lead to anxiety/depression, agitation/aggression, followed by instability of gait and difficulty swallowing. Diagnosis is done by getting a history with family/friends. Memory tests and brain scans give confirmatory information. Not all people with memory complaints have AD or will get AD.

Management includes education and support to patient and family (essential role of the Alzheimer Society complementing community resources such as CLSC and VON), updating 'mandate' and power of attorney, monitor driving ability and safety at home, refer to day programs, respite care and long-term care if unable to stay home.

Medications available currently include antidepressants (Celexa, Zoloft, Effexor for example), medications increasing levels of the neurotransmitter acetylcholine (Aricept, Exelon, Reminyl), medication blocking partially the activity of the neurotransmitter glutamate (Ebixa), psychotropic drugs (Risperdal, Zyprexa, Seroquel).

Experimental treatments aim at reducing the aggregation of the protein ?-amyloid into insoluble plaques (Alzhemed, Flurizan, 'vaccine', AIT-103), or helping the brain heal itself (Sanofi-Aventis drugs).

Within 3 to 5 years it will be possible to assess individual risk for AD (as we currently do for heart attacks), and advice for prevention will be geared to that risk.

National Pharmaceuticals Strategy

Robert Nakagawa, BScPhm, FCSHP, Ministry of Health, Victoria, BC

Pharmaceuticals are a key component of the Canadian health care system, and represent the fastest growing and second largest area of health care expenditures in Canada. When used appropriately, pharmaceuticals save lives, treat diseases, and enhance the quality of life for millions of Canadians. To continue to effectively achieve these outcomes, critical challenges in pharmaceuticals management need to be addressed (i.e., access, safety & effectiveness & appropriate use, and sustainability).

As such, First Ministers have identified collaborative pharmaceuticals management as a priority for health care reform and renewal. Building on past and ongoing initiatives, First Ministers directed Health Ministers in September 2004 to develop and implement the National Pharmaceuticals Strategy (NPS). National in scope and building on existing expertise, the purpose of the NPS is to address the challenges across the drug lifecycle using an integrated, Federal, Provincial, Territorial collaborative approach.

Five key areas were established for priority focus (catastrophic drug coverage, expensive drugs for rare diseases, common formulary, real world safety & effectiveness, and purchasing & pricing), and an initial NPS Progress Report was provided to First Ministers in June 2006.

Goals and Objectives

To create an awareness of the background for and current status of the National Pharmaceuticals Strategy (NPS)

Monday, August 14 • Lundi 14 août

The Future of Residency Training in Canada

Donna M.M. Woloschuk, PharmD, M.Ed(Distance), FCSHP. Winnipeg Regional Health Authority, Winnipeg, MB

This year marks the 50th Anniversary of training pharmacists with exemplary skills in hospital pharmacy practice in Canada. In 1956, a joint committee of CSHP and what is now the Association of Faculties of Pharmacy of Canada caused our profession to create the first set of training standards for hospital practice, as well as what is now the accrediting body for pharmacy residencies (the Canadian Hospital Pharmacy Residency Board/CHPRB). Core content of our residency training programs has changed over time to include: (1) Direct Patient Care; (2) Drug Distribution & IV Services; (3) Drug Information & Literature Evaluation; (4) Practice Management & Drug Use Control; and, (5) Communication & Research. Since their inception, residency training standards have reflected a consensus regarding what residents need to learn to successfully complete the program ("curriculum-based" standards) rather than how residents are expected to perform upon graduation ("competency-based" standards). The last major change to the CHPRB Accreditation Standards occurred in 1998. Pharmacy and healthcare have changed substantially since then, and more changes will occur in the future (expansion of pharmacist roles, pharmacy credentials changes, etc). Our residency standard no longer aligns with other education and training standards. For those reasons through 2008, CHPRB will consult with stakeholders at CSHP Annual General and Professional Practice meetings as well as via on-line discussions, regarding competencies that should underlie the 2010 Residency Accreditation Standard. This presentation will prompt attendees to begin considering what they expect from residency graduates of the future, and provide the basis for future discussion about the new 2010 Accreditation Standard.

Goals and Objectives

At the end of this session, participants should be able to:

1. Describe the rationale for embarking on a major revision of residency training standards in Canada.
2. Explain the difference between curriculum-based and competency-based accreditation standards.
3. Describe the process that will be used to develop and obtain stakeholder feedback regarding the draft 2010 Accreditation Standards.

Self-Assessment Questions

1. Competency-based standards provide the list of what residents must learn to complete their program. True False (False)
2. A major revision of the Residency Accreditation Standard is required because of current and future changes in healthcare, the pharmacy profession, and pharmacy education in Canada. True False (True)
3. Accreditation standards are consensus documents that are only effective if they emerge from the collective wisdom and expertise of people who train and employ pharmacy practitioners. True False (True)

Coming Attractions: Previews to Leadership

Shallen Letwin, BSc. Pharm., Pharm.D., FCSHP, Fraser Health, Langley, BC, Emily Musing, BScPhm, MHSc, FCSHP, University Health Network, Toronto, ON, Linda Vaillant, B.Sc. Pharm., M.Sc., M.B.A., FCSHP, Association des pharmaciens d'établissements de santé du Québec (A.P.E.S.), Montréal, QC

Ever wonder what you and "The Lion King", "Snow White" or "Nemo" have in common? Do you consider yourself a leader? Have you ever imagined that your peers would ever consider you a leader? Well, if you have ever thought about pharmacy leadership, then you don't want to miss this session. Three dynamic pharmacy leaders will amaze you by discussing "pearls of wisdom". Come join us for our "triple-feature" presentation where leadership in clinical practice, leadership in pharmacy management and leadership in pharmacy organization will be discussed in a friendly manner. Don't miss out!

Goals and Objectives

1. To highlight to participants the wide range of leadership opportunities available to hospital pharmacists.
2. To provide participants interested in pursuing leadership as a career path some insights regarding the rewards and challenges within this field.

3. To review some of the "Disney Classics" and their relationship to … pharmacy leadership!

Self-Assessment Questions

1. What fascinating treasures has Emily found "under the sea"?
2. Why does Linda feel like "Simba"?
3. What makes Shallen happy… grumpy…bashful…dopey…?

Tuberculosis (TB) – Emerging Issues in Pharmaceutical Care

Tom Chin, BScPhm, PharmD, FCSHP, St. Michael's Hospital, Toronto and The University of Toronto, Toronto, ON

TB continues to be a global epidemic, and it is the leading cause of death from a curable infectious disease. In the industralised nations, several key factors are responsible for the rise and spread of TB, such as, HIV/AIDS epidemic, increased immigration from TB-endemic countries, increase in poverty, injection drug use and homelessness, increase in number of long-term care residents, and failure in adherence to anti-TB regimens. TB infection is different from TB disease, and understanding the pathophysiology of infection and disease is important in the care of these patients. Current first-line agents (isoniazid, rifampin, pyrazinamide, ethambutol, streptomycin) are effective but present challenging problems with adherence, side effects and toxicity, and multiple drug-interactions. There is a steady increase in the number of drug-resistant cases of TB, including multi-drug resistant TB (MDR-TB, defined as resistance to at least INH and rifampin). In Canada in 2004, drug resistant TB to at least one first-line agent was 12.4%, while MDR-TB was 0.9%. Understanding the mechanisms for development of drug resistance is important in the fight to reduce the risk of drug resistance. Current second-line agents are less effective and more toxic, and therefore present additional challenges in managing patients. Co-infection with HIV also presents new challenges, especially drug interactions, as well as clinical response. It is recognized that the current arsenal of drugs may be failing, and new and novel drugs, including moxifloxacin, an nitroimidazopyran and a diarylquinolone, as well as candidate vaccines are undergoing clinical testing.

Goals and Objectives

1. Explain the development of TB disease in the vulnerable population.
2. Identify the risk factors and mechanisms for development of drug-resistant TB.
3. Discuss common and potential DRPs of current agents used for therapy of TB disease, and approach to management.
4. Discuss prospects for new antitubercular agents in the pipeline.

Self-Assessment Questions

1. What is the role of the pharmacist in preventing the development of drug-resistant TB?
2. How does the management of TB-HIV co-infection differs from that of monoinfection?
3. What is the role of fluoroquinolones in the treatment of TB?

Nouvelles approaches d'anticoagulation en syndromes coronariens aigus

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Au Canada en 2002, 32% de tous les décès chez les homes et 34% des décès chez les femmes étaient dus aux maladies cardiovasculaires (MCV), résultant en 74,626 décès. Selon Santé Canada en 1998, les MCV coûtent $18 milliards chaque année à l'économie canadienne. Il est estimé qu'il y a plus de 70 000 infarctus du myocarde (IM) annuellement au Canada et plus de 80% des patients admis à l'hôpital survivent.

Trois grandes études randomisées et contrôlées ont été présentées et publiées dans les derniers mois qui évaluaient l'efficacité et l'innocuité relative de 3 anticoagulants chez des patients présentant un syndrome coronarien aigu sans élévation du ST (NSTEACS) ou un IM avec élévation du segment ST (STEMI), soient l'héparine, l'enoxaparine et le fondaparinux. Chez 20 078 patients présentant un NSTEMI, l'étude OASIS-5 a démontre que le fondaparinux était supérieur à l'enoxaparine pour réduire le risqué de décès, d'IM ou d'accident vasculaire cérébral (AVC) à 6 mois et le risque de saignement majeur. Chez 20 506 patients présentant un STEMI devant recevoir la fibrinolyse, l'étude ExTRACT-TIMI 25 a démontré que l'enoxaparine était supérieure à l'héparine pour prévenir les décès et les IM jusqu'à 30 jours après l'événement, mais ceci au coût d'une augmentation des saignements majeurs. De l'autre côté, OASIS-6 a démontré que le fondaparinux réduisait la mortalité et les IM jusqu'à 6 mois après l'événement, sans augmenter les saignements et les AVC chez 12 092 patients présentant un STEMI et traité ou non avec la fibrinolyse ou par une intervention coronarienne percutanée. Ces résultats suggèrent que de nouvelles thérapies anticoagulantes pourraient être bénéfiques aux patients présentant un syndrome coronarien aigu.

Buts et objectifs

1. Permettre aux pharmaciens de mieux comprendre l'efficacité relative de l'héparine, de l'enoxaparine et du fondaparinux en syndromes coronariens aigus.
2. Décrire les risques relatifs et les coûts associés à chacune de ces thérapies anticoagulantes dans le contexte d'un syndrome coronarien aigu.

Questions d'auto-évaluation

1. Est-ce que tous les patients présentant un syndrome coronarien aigu devraient être traités avec le fondaparinux?
2. Lequel des anticoagulants est le plus sécuritaire pour le patient pour ce qui a trait aux saignements majeurs dans le contexte d'un infarctus du myocarde avec élévation du segment ST?
3. Est-ce que le coût associé à chaque traitement anticoagulant utilise dans le contexte d'une syndrome coronarien aigu (héparine, enoxaparine, fondaparinux) est équivalent?

Silk Purses out of Sows' Ears: Turning your Leftover Projects and Posters into Real Publications

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Did you know that only about one-fourth of the abstracts published in CJHP from 1992-1996 ever made it into publication as a full-length manuscript? How unfortunate to have gone to all that trouble – completing the project (that apparently was deemed worthwhile at some point or otherwise you would not have done it), passing the scrutiny of the abstract reviewers (thereby having your abstract accepted for presentation at a CSHP meeting), and finally, presenting your project results in a poster or podium format at a major national meeting – only to stop there! What a shame not to go the extra step to submit your hard work for publication as a full-length article!

As pharmacy preceptors, we have a great opportunity to encourage and support our fellow pharmacy practitioners, students, and residents to share their findings with the pharmacy community-at-large.

During this workshop, we will review 10 simple steps in "How to Turn an Abstract (Project or Poster) into a Full-Length Manuscript" as well as discuss in detail the manuscript submission process for the Canadian Journal of Hospital Pharmacy.

Step 1: Identify a Problem or Question

Step 2: Write the Proposal

Step 3: Perform the Study or Evaluation

Step 4: Write Abstract and Submit for Poster Presentation

Step 5: Request Critique of Poster Submission

Step 6: Present Poster and Seek Constructive Criticism

Step 7: Write First Draft of Final Manuscript

Step 8: Incorporate Revisions into Second (and Any Succeeding Draft(s)

Step 9: Submit the Final Manuscript to Journal

Step10: Await Reviewers' Comments

Goals and Objectives

1. Describe strategies to encourage pharmacy practitioners, students, and residents to submit projects for publication.
2. List 10 steps involved in turning an abstract (project or poster) into a full-length manuscript.
3. List components of journal reviewers' checklists/ appraisal forms.
4. Describe the manuscript submission process for the Canadian Journal of Hospital Pharmacy.

*Attendees are requested to bring to the workshop an abstract (or "leftover project or poster") that they wish to turn into a full-length manuscript (or "real publication").

Self-Assessment Questions

1. The poster presentation serves as a forum to receive peer review at a stage when appropriate modifications may be made to strengthen the final paper. T or F.
2. Prior to submitting your manuscript, it would be helpful to circulate it for review to:
   a. an expert in the topic area;
   b. a good editor;
   c. a good scientist or clinician unfamiliar (or not as familiar) with the topic area;
   d. all of the above.

   Answers: 1 – T; 2 – d

Evidence-Based Medicine Workshop – Appraising Systematic Reviews

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Evidence-based medicine (EBM) is the process of integrating the best evidence, the individual characteristics of the patient, and individual expertise into a decision-making process to optimize drug therapy. Searching, evaluating, and applying the best literature evidence to solve patient-specific, focused clinical questions are integral steps of EBM. The number of qualitative and quantitative systematic reviews (meta-analyses) is dramatically increasing, and clinicians need a systematic approach for retrieving and appraising this high-level evidence. This session will briefly review useful websites, electronic databases, and print journals to identify qualitative systematic reviews and meta-analyses. Methodological limitations and inadequate reporting in primary randomized controlled trials are associated with biased overestimations of treatment effects, and similar limitations exist with systematic reviews. The Quality of Reporting of Meta-analyses (QUOROM) statement was developed to help improve the quality of conduct and accuracy of reporting of meta-analyses. Although it has not been validated as a quality tool, it has been widely disseminated and advocated as a standard in the preparation, reporting, and appraisal of meta-analyses. The QUOROM statement utilizes a checklist and flow diagrams to review the title, abstract, introduction, methods, results, and discussion of these studies. Using literature examples, the QUOROM checklist and flow diagram will be applied, and its utility, strengths, and weaknesses will be discussed. An overview of methodological and statistical considerations, results interpretation, and potential biases and limitations of meta-analyses will also be reviewed. The application of results from systematic reviews and meta-analyses for clinical problem solving, education, and policy development will be discussed.

Goals and Objectives

1. To provide pharmacists with skills to search for, identify, and retrieve systematic reviews from the literature;
2. To review and apply the QUOROM statement, checklist, and flow diagram as a tool to help appraise published meta-analyses;

3. To highlight some of the essential quantitative elements, methodological controversies, and application of results of systematic reviews.

Self-Assessment Questions

1. Name one useful website, electronic database, and print journal for locating systematic reviews;
2. List the advantages and disadvantages of the QUOROM statement, checklist, and flow diagrams;
3. Define publication bias, statistical and clinical heterogeneity, and sensitivity analysis.

Heparin-Induced Thrombocytopenia: Fact or Fiction?

David Williamson, B.Pharm, M.Sc, BCPS, Hôpital du Sacré-Coeur de Montréal, Faculté de pharmacie, Université de Montréal, Montréal, QC

The goal of this session is to provide pharmacists with an understanding of the pathophysiology, the risk factors, the incidence, the diagnostic and the treatment of heparin-induced thrombocytopenia (HIT).

HIT is an immune syndrome related to heparin first described in the late 1950'. Considered as rare in the past, it is now considered as a common complication of heparin therapy and is associated with significant complications. HIT is an immune-mediated reaction that classically presents with a significant platelet count reduction (>50%) frequently associated with low platelet counts (< 150 X 109) and arises four to ten days following heparin therapy. In patients recently exposed to heparin (< 120 days), thrombocytopenia can arise within 24 hours.

The main complication of HIT is arterial or venous thrombosis. Risk factors include type of heparin (unfractionnated heparin > LMWH), population (surgical>medical> obstetrical), dose, length of treatment, and female sex. Diagnosis is based on clinical suspicion and demonstration of the presence of pathological HIT antibodies with an antigenic or functional assay.

Treatment includes discontinuation of all heparins, full anticoagulation with an alternative anticoagulant in all patients with suspected or confirmed HIT (with or without thrombosis), long-term anticoagulation (3-6 months) in patients with associated thrombosis and routine ultrasonography of lower limbs to rule out deep-vein thrombosis. Alternative anticoagulants approved for the treatment of HIT in Canada are danaparoïd, lepirudin and argatroban. These agents all have pharmacokinetic particularities and choice of the agent depends on bleeding risks and the presence of renal or liver failure.

Goals and Objectives

1. To provide pharmacists with an understanding how, when and why heparin-induced induced thrombocytopenia (HIT) develops
2. To provide pharmacists with an understanding of the clinical diagnosis of HIT and differentiate HIT form other common causes of thrombocytopenia
3. To enable pharmacists to optimally monitor and treat HIT

Self-Assessment Questions

1. What are the risk factors for HIT?
2. Is it reasonable to withstand alternative anticoagulation while awaiting for laboratory conformation of HIT?
3. What agent is alternative anticoagulant of choice in the presence of renal failure?

Standardized Methods for Measuring Drug Use: Making Cents of the Data!

Daniel J.G. Thirion, B.Pharm., M.Sc., Pharm.D., BCPS, Faculté de pharmacie, Université de Montréal, and Hôpital du Sacré-Cœur de Montréal, Montreal, QC., Bruce Dalton, B.Sc. Pharm., Pharm.D., Calgary Health Region, Calgary, AB., Monique Pitre, B.Sc.Pharm., University Health Network, Toronto, ON

Measuring drug use is essential in making decisions regarding therapeutics and formulary management. Standardizing this measurement offers the advantage of comparing use in different settings and levels. The World Health Organization (WHO) has developed the Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) system for classifying and measuring drug utilization. This method will be introduced and proposed as the national standard for Canadian pharmacists. The use of WHO DDD's also allows for the addition of various agents within a class or between classes by standardizing the unit of use. The benefits of studies using this system include measuring the impact of interventions on drug use, comparing results between different hospitals, and analysing relationships between drug use and events such as emerging bacterial resistance. Examples, limitations and practical considerations from the area of anti-infective drug utilization will be discussed and a brief review of world literature in this area will be provided. The planning stages of Canada-wide, central repository of anti-infective consumption data from participant hospitals will be discussed.

This will be followed by a practical application of measuring drug consumption in order to explore the relationship between antimicrobials and Clostridium difficile associated diarrhea (CDAD). On outbreak of CDAD has been affecting the southern area of Quebec since 2002. Antimicrobials play a key role in triggering the disease in exposed patients. A comparative risk of causing CDAD between different classes of antimicrobials has been proposed. The interplay between infection control and antimicrobial use will be discussed.

Goals and Objectives

To provide a knowledge base and understanding of international standards for measuring drug consumption.

- Identify the benefits of measuring drug consumption
- Identify methods for measuring drug consumption

- Identify the reasons for using the ATC/DDD standardized method
- Explain the process of measuring drug consumption
- Identify the international context and examples of application of this process to pharmacy practice

  Apply the process of drug consumption measurement to explore the relationship between antimicrobials and C. difficile associated diarrhea.

Self-Assessment Questions

1. Name 2 advantages of using the ATC/DDD system over other methods for measuring drug use
2. What do studies evaluate when using drug consumption measurement (with the ATC/DDD standard)?

MOXXI Project: Linking Pharmacists, Physicians and Patients

Nancy Winslade, B.Sc.Phm., Pharm.D., M.H.P.E., MOXXI Project, Faculty of Medicine, McGill University, Montreal, QC

Over the past 10 years, the Medical Office of the 21st Century (MOXXI) research project has evaluated e-based interventions designed to decrease preventable drug-related morbidity and mortality (DRMM). The electronic prescribing and medication management system developed via the project has specific functionalities and programs to support a focus on improving prescribing by family physicians. Early projects also emphasized the role of the community pharmacist in decreasing DRMM through primarily compliance assessment and support. Challenges faced by pharmacists lead to the recognition of barriers inhibiting the provision of direct patient care services in community pharmacies. Current research focuses on documenting and quantifying these barriers and identifying related factors that facilitate the provision of such services by community pharmacists.

During this session the MOXXI system will be demonstrated with emphasis on features important to pharmacists and preliminary results of the pharmacy research projects will be presented. These include evaluation of patients' receptivity to various direct patient care services; pharmacists' perceptions of patient receptivity to these services, and; pharmacists' perceived usefulness of the functionalities of the MOXXI system. These functionalities include electronic retrieval of prescriptions, computer printed prescriptions and availability of a physician specified therapeutic indication for each prescribed medication.

Finally, projects integrating the MOXXI system into the hospital environment will be reviewed and an opportunity provided for participants to identify potential linkages between hospital pharmacy medication systems and the MOXXI system.

Goals and Objectives

1. To introduce and demonstrate the electronic prescribing and medication management system being used by family physicians in the MOXXI Research Project in Quebec.
2. To discuss opportunities for improving continuity of care, and in particular pharmaceutical care, via the MOXXI system.

Self-Assessment Questions

1. What current systems are available within your institution that ensure accurate medication histories of admitted patients? How could a MOXXI-type system improve on these systems?
2. What key features do you believe should be included in a MOXXI-type system to facilitate pharmacists' provision of pharmaceutical care?
3. What primary barriers exist in your institution that would limit the adoption and / or utilization of a MOXXI-type system?

Tuesday, August 15 • Mardi 15 août

Medication Use and Medication Management Standards

Sarah Taber, MHA, Canadian Council on Health Services Accreditation (CCHSA), Ottawa, ON

The goal of this session is to provide pharmacists with an overview of CCHSA's draft medication use and medication management standards that pertain to managing medications and the delivery of pharmacy services within organizational settings.

Work to develop the standards began in 2004 with significant input from an expert working group, including representatives from ISMP Canada and several Canadian health care organizations. The group has provided CCHSA with content expertise in shaping the draft standards and advice on broader consultation.

The draft standards contain seven sections: selecting, securing, and storing medications; ordering and transcribing medications; preparing medications; dispensing medications; administering medications; monitoring clients and their medications; and, quality measurement.

The standards will be pilot tested as part of a larger testing plan for CCHSA's enhancements to its accreditation program. The standards will then be introduced as one of the enhancements to the program planned for launch in late 2007.

Goals and Objectives

1. To provide pharmacists with an overview of CCHSA's standards development process.
2. To provide pharmacists with an understanding of CCHSA's draft medication use and medication management standards.
3. To enable pharmacists to pose questions regarding the specific standards content.

Self-Assessment Questions

1. What are the main elements of CCHSA's draft standards?
2. How will CCHSA's new standards affect my department/team?
3. What aspects of our service need to be modified or improved to meet the standards?

Bridging Theory to Practice: Practical Considerations for Implementing Medication Reconciliation Strategies

Olavo Fernandes, BScPhm, ACPR, PharmD, Toronto General Hospital- University Health Network, Toronto ON

There appears to be a perceived high frequency of medication discrepancies occurring at both hospital admission and discharge. These medication discrepancies can be significant and lead to medication errors, drug related problems and adverse drug events. A "vulnerable moment" is a point at which a patient is at high risk for medication discrepancies and can often occur at an "interface of care". Patients are constantly moving from one health care setting (community, clinic, inpatient unit) to another and these interfaces present a challenge for the accurate and efficient transfer of medication information amongst patients and their health care professionals.

Medication reconciliation is a formal strategy of comparing a patients' actual medication use to admission, transfer and discharge orders. In this process, medication discrepancies are identified and addressed with the health care team. Medication reconciliation is one of the six key interventions of the national Canadian patient safety campaign entitled "Safer Health Care Now!" and is now incorporated in the 2005 CCHSA hospital accreditation standards.

To overcome the challenges created by gaps in medication transfer, pharmacists can employ both tools and practice models that incorporate the principles of medication reconciliation. Common medication discrepancy categories that occur on admission and discharge will be discussed along with proactive solutions to address them.

Goals and Objectives

- Characterize drug related problems on hospital admission and describe how they are related to gaps in medication information transfer among health care professionals and patients.
- Evaluate the patient safety impact of pharmacist medication assessments as part of a multidisciplinary practice model to reduce medication discrepancies.
- Highlight the key elements of an electronic tool to enhance the transfer and communication of medication information post discharge to health care professionals and patients.
- Outline practical considerations for pharmacists implementing medication reconciliation strategies for hospital admission and discharge.

Self-Assessment Questions

1. What are two of the most common types/ categories of medication discrepancies that occur on hospital admission and discharge?
2. List a number of key elements of information that should be included with hospital discharge prescriptions/ documentation that may serve to reduce discharge medication discrepancies.

Approach to Anticoagulation in Acute Coronary Syndromes

Chantal Pharand, B.Pharm., Pharm.D., BCPS, Faculty of Pharmacy, Université de Montréal and Hôpital du Sacré-Coeur de Montréal, Montréal, QC

In Canada in 2002, 32% of all male deaths and 34% of all female deaths were due to cardiovascular disease (CVD), resulting in 74,626 Canadian deaths. According to Health Canada's 1998 report, CVD cost the Canadian economy over $18 billion a year. It is estimated that there are over 70 000 myocardial infarctions (MI) in Canada each year. Over 80% of MI patients admitted to hospital survive.

Three large, randomised, controlled trials were presented and published in the past months evaluating the relative efficacy and safety of 3 anticoagulant therapies, unfractionated heparin, enoxaparin, and fondaparinux, in patients with non-ST-elevation acute coronary syndromes (NSTEACS) or ST-elevation myocardial infarction (STEMI). In 20 078 patients with NSTEMI, the OASIS-5 trial demonstrated that fondaparinux was superior to enoxaparin in reducing the risk of death, MI or stroke through 6 months and the risk of major bleeding. In 20 506 patients presenting with STEMI and scheduled to undergo fibrinolysis, the ExTRACT-TIMI 25 trial showed that treatment with enoxaparin was superior than heparin in preventing death or nonfatal MI up to 30 days after the event, but that came at the cost of an increase in major bleeding episodes. On the other hand, OASIS-6 demonstrated that fondaparinux significantly reduced mortality and reinfarction up to 6 months after the event without increasing bleeding and strokes in 12 092 patients with STEMI treated or not with fibrinolysis or percutaneous coronary interventions. These results suggest that new alternative anticoagulant therapies may provide benefit in patients presenting with ACS.

Goals and Objectives

1. To provide pharmacist with an understanding of the comparative efficacy of unfractionated and low molecular

weight heparin as well as fondaparinux in acute coronary syndromes.

2. To describe the relative risks and the cost associated with each of these anticoagulant therapies in the setting of acute coronary syndromes.

Self-Assessment Questions

1. Should all patients with acute coronary syndromes be treated with fondaparinux?
2. Which of the anticoagulants is the safest for the patient with regards to major bleeding in the setting of ST-elevation myocardial infarction?
3. Are the costs associated with each of the three anticoagulants used in the setting of acute coronary syndromes (unfractionated heparin, enoxaparin, fondaparinux) equivalent?

Jongler avec les chiffres: comprendre les résultats des études

Linda Lévesque, BScPhm, MSc, PhD, Département de Santé Communautaire et d'Épidémiologie, l'université Queen's, Kingston ON

Le but de cette session est d'apporter aux pharmaciens une compréhension des différentes mesures utilisées pour quantifier les bénéfices et risques d'un traitement et de démontrer les différences importantes entre celles-ci.

L'interprétation des données, par définition, ne peut être parfaitement objective, d'où l'importance d'adopter une approche systématique d'évaluation et d'applicabilité des résultats des études publiées. L'approche critique nécessite une bonne compréhension de ce que représentent les différentes mesures de l'effet d'un traitement et comment celles-ci peuvent influencer vos décisions cliniques.

Afin d'interpréter clairement les résultats pour une prise de décision éclairée, il faut comprendre comment ceux-ci ont été mesurés, comment ont les a calculés, et ce qu'ils représentent. Les mesures discutées incluent le risque relatif, la réduction du risque relatif, la différence ou réduction du risque absolu, le nombre de patients à traiter, le ratio risque-bénéfice, et la proportion de sujet sain.

Buts et objectifs

1. Comprendre les différentes mesures utilisées pour quantifier les effets d'un traitement
2. Démontrer comment la présentation d'un résultat peut influencer vos recommandations et décisions cliniques
3. Vous sensibilisez à la manipulation qui existe vis-à-vis la présentation des résultats et à l'importance du biais de perception

Questions d'auto-évaluation

1. Est-ce que la présentation de l'effet d'un traitement peut influencer la décision d'un clinicien ?
2. Quel est l'impact du risque de base sur l'ampleur de l'effet d'un traitement ?
3. Quelle est la meilleure façon de présenter les résultats d'un essai clinique randomisé ?

Thrombocytopénie induite par l'héparine : mythe ou réalité ?

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L'objectif de cette présentation est de fournir aux pharmaciens un aperçu de la physiopathologie, des facteurs de risque, de la prévalence, du diagnostic et du traitement de la thrombopénie induite par l'héparine (TIH).

Décrite pour la première fois à la fin des années 1950, la TIH est un syndrome immunitaire lié à l'héparine. Autrefois considéré comme étant rare, ce syndrome est maintenant vu comme une complication courante de l'héparinothérapie et il a été associé à des complications sérieuses. La TIH est une réaction d'origine immunologique habituellement caractérisée par une chute prononcée de la quantité de plaquettes (> 50 %) et à de faibles décomptes plaquettaires (<150 x 109). En général, elle surgit quatre à dix jours après le début de l'héparinothérapie. Chez les patients ayant été récemment exposés à l'héparine (< 120 jours), la thrombopénie peut survenir dans les 24 heures.

La principale complication de la TIH est la thrombose veineuse ou artérielle. Les facteurs de risques incluent : le type d'héparine (héparine non fractionnée > HBPM), la population (chirurgie > médecine> obstétrique), la dose, la durée du traitement et le sexe (féminin). Le diagnostic est fondé sur le soupçon clinique et la démonstration de la présence d'anticorps anti héparine-PF4 pathologiques à l'aide d'un test antigénique ou fonctionnel.

Le traitement inclut l'arrêt de toutes les héparines, une anticoagulothérapie complète avec un autre anticoagulant de tout patient soupçonné de souffrir de TIH ou chez qui la TIH a été confirmé (avec ou sans thrombose), une anticoagulothérapie à long terme (3 à 6 mois) chez les patients présentant une thrombose associée et une échographie ultrasonique systématique des membres inférieurs pour éliminer la présence de thrombose veineuse profonde. Les anticoagulants de remplacement approuvés pour le traitement de la TIH au Canada sont le danaparoïde, la lépirudine et l'argatroban. Ces agents ont leurs propres caractéristiques pharmacocinétiques et le choix de l'agent dépendra du risque de saignement et de la présence d'insuffisance rénale ou hépatique.

Buts et objectifs

1. Permettre aux pharmaciens de comprendre comment, quand et pourquoi la thrombopénie induite par l'héparine (TIH) se développe
2. Permettre aux pharmaciens de comprendre le diagnostic clinique de la TIH et de différencier la TIH des autres causes habituelles de thrombopénie
3. Permettre aux pharmaciens de surveiller de façon optimale la TIH et de la traiter

Questions d'auto-évaluation

1. Quels sont les facteurs de risques de TIH?
2. Est-il raisonnable de s'opposer à une anticoagulothérapie de remplacement en attendant la confirmation du diagnostic de TIH par le laboratoire?
3. Quel agent devrait être utilisé comme anticoagulant de remplacement en présence d'insuffisance rénale?

A New Analgesic: Whole-Plant-Cannabis-Based Oral Mucosal Spray

Marie-Claude Vanier, B.Pharm., M.Sc., Assistant clinical professor, Faculty of Pharmacy, Université de Montréal. Clinician, sanofi-aventis Chair in pharmaceutical ambulatory care. Cité de la santé de Laval. Family medicine clinic, Montréal, QC

Key words: multiple sclerosis, neuropathic pain, 9-tetrahydro-cannabinnol, cannabidiol

Health Canada has conditionally approved the first cannabis-derived prescription pain killer. Cannabis sativa extract (Sativex,) was approved in April 2005 as an adjunctive treatment for the symptom relief of neuropathic pain in patients with multiple sclerosis (MS). The approval is conditional on the manufacturer conducting more clinical trials to confirm efficacy.

Most published trials so far studied the drug in MS related symptoms. Limited data is also available in chronic non cancer pain. Other studies are ongoing in painful diabetic neuropathy, neuropathic pain, MS related spasticity and cancer pain. Early data in MS patients was discordant. Data from recent studies shows a modest but statistically significant improvement in pain and quality of sleep. Side effects were frequent but generally acceptable and often observed in the titrating phase. Frequent effects in placebo controlled studies were: dizziness (41,6%), fatigue (11,4%), nausea (10,2%), somnolence (8,4%), dry mouth (7,8%), mucosal irritation (7,8%) and intoxication like sensations (7,2%). Other side effects observed in phase III open prolongation studies were: headaches (8,7%), balance loss (5%), depressive mood (4%) and memory loss (3,1%).

Sativex is a highly standardised product of a 1:1 combination of 9-tetrahydrocannabinol (THC) and cannabidiol (CBD). It is available in pump-action spray providing 2,7mg of THC and 2,5mg of CBD per 100mL spray. The product is expensive (154$/5,5 mL). Approximate monthly cost for average dose (5 sprays/day) would be 462$. Considering its modest effect, side effects profile and high cost, Sativex use should be limited as adjuvant analgesic to unresponsive MS related pain until more data is available.

Goals and Objectives

1. To provide pharmacist with an overview of the research data supporting the use of whole-plant-cannabis-based oral mucosal spray as analgesic.
2. To enable pharmacists to answer other health professionals and patients questions related to whole-plant-cannabis-based oral mucosal spray use as analgesic.
3. To highlight important information to provide to patients starting a treatment with Sativex®.

Self-Assessment Questions

1. What is the approved indication for Sativex®?
2. What should patients starting a treatment with Sativex®, be told?

Respiratory Fluoroquinolones for Community-Acquired Pneumonia: Safety Considerations

Sylvie Carle, B.Pharm, MSc, McGill University Health Centre, Montreal, QC

The excellent activity of new fluoroquinolones (FQ) against a broad range of different respiratory pathogens has made them mainstays of treatment for community-acquired pneumonia. Generally, these drugs are well tolerated, but in recent years, several FQ have had to be withdrawn from the Canadian market because of safety issues.

Glucose homeostasis abnormalities have been reported with most of the FQ but occur rarely. Gatifloxacin was associated with a higher frequency of dysglycemias and recently withdrawn from the market. Cardiac safety is another concern regarding these agents. QT prolongation appears to be a class effect but there is a wide range of potency among members. The safest member of the class appears to be levofloxacin. Severe hepatotoxicity with FQ on the Canadian market is rare. Limited cases of severe liver abnormalities have been reported with gatifloxacin, levofloxacin and ciprofloxacin.

According to recent publications, FQ have also been associated with an increased risk of C. difficile- associated diarrhea.

FQ-induced adverse effects have not been reported to occur with increased frequency in the elderly. However, because of physiological changes in renal function and in case of certain comorbidities, some special considerations are necessary. Adverse reactions of the CNS as well as cardiotoxicity are of particular concern in this population.

Coadministration of FQ with divalent or trivalent cation-containing compounds inhibits FQ absorption. This interaction may have a potential impact on the emergence of resistance and/or lead to treatment failure. Co-administration of certain drugs, especially with other QT prolonging drugs should be avoided.

Goals and Objectives

1. To provide pharmacists with an understanding of the possible serious complications with the use of FQ, mainly glucose homeostasis abnormalities, QT prolongation, hepatotoxicity and possible C. difficile superinfections
2. To evaluate the risk of FQ use in the elderly
3. To identify major potential drug interactions with FQ

Self-Assessment Questions

1. What are the risks factors for QT prolongation in patients taking FQ?

2. Is it reasonable to avoid FQ use in order to prevent C.difficile associated diarrhea?
3. What are the clinical signs associated with CNS adverse effects in the elderly?
4. What concomitant drugs are contraindicated with FQ?

L'étomidate a-t-il une place dans nos chariots de réanimation?

Christopher Marquis, BSc(Pharm), candidat MSc,CHU Sainte-Justine, Montréal, Qc.

Le but de cette presentation est de discuter de l'impact de l'insuffisance surrénalienne et de sa durée chez les patients critiques ayant reçu l'étomidate comme agent inducteur lors de l'intubation.

En 1983, Watt et Ledingham publient une étude démontrant que l'utilisation comme sédatif de l'étomidate en perfusion continue augmente les risques de mortalité de plus de 50%. Depuis cette publication, plusieurs études avec méthodologie variable explorent les effets d'une dose d'étomidate sur des petits nombres de sujets. De plus, ces sujets sont issus de populations diverses, de femmes subissant des hysterectomies aux trottineurs en méningoccocémies.

Relançant la controverse des années 80 sur l'étomidate, Annane et coll. dans l'étude en 2002 sur les corticostéroïdes dans le choc septique excluent les patients ayant reçu de l'étomidate. De ces patients, 94% sont catégorisés comme insuffisants surrénaliens et une analyse de sous-groupe démontre un taux de mortalité chez les patients étomidate-placebo élevé.

Dans son étude de cohorte prospective de 60 enfants atteints de méningococcémie, Den Brinker et coll. observent une diminution de l'activité 11ß-hydroxylase ($p<0.05$) chez les non-survivants et trouvent, par régression multivariée, que l'intubation à l'étomidate est le seul facteur significatif ($p<0.001$) pouvant expliquer cette diminution. De leur côté, Schenarts et coll étudient l'incidence et la durée de l'insuffisance surrénalienne chez 18 patients de l'urgence étant intubés avec étomidate ou midazolam. À l'aide de test de stimulation à l'ACTH 250 mcg à 4, 12 et 24 heures post-intubation, les auteurs démontrent que 30% des patients sous étomidate par rapport à 100% sous midazolam ont un cortisol supprimé à 4 heures alors qu'à 12 heures, tous les patients, abstraction faite de leur inducteur, ont un cortisol normal.

L'incidence d'insuffisance surrénalienne chez les patients critiques nécessitant une intubation avec l'étomidate est élevée et s'explique par une diminution de l'activité 11ß-hydroxylase, enzyme formant directement le cortisol. La durée de l'insuffisance se situerait possiblement entre 4 et 12 heures, mais pourrait s'étendre sur plus de 24 heures. Par contre, l'utilisation du cortisol comme marqueur intermédiaire de l'insuffisance ne peut remplacer la détection des signes cliniques comme l'hypotension ou l'hypoglycémie. Aucune étude clinique avec une population bien définie étudiant les symptômes cliniques et les niveaux de cortisol n'existe à ce jour.

Buts et objectifs

1. Comprendre le mécanisme de l'insuffisance surrénalienne induite par l'étomidate.
2. Permettre aux pharmacien(ne)s d'identifier les patients à risque d'insuffisance surrénalienne cliniquement significative secondaire à l'étomidate et d'en estimer la durée.
3. Permettre aux pharmacien(ne)s de se familiariser avec les forces et les faiblesses des études actuelles concernant l'étomidate.

Questions d'auto-évaluation

1. Pourquoi l'étomidate a-t-il encore une place dans nos chariots de réanimation?
2. Quelle population critiquement atteinte nécessite un suivi surrénalien étroit après l'injection d'étomidate?
3. Nommer 2 interventions du pharmacien(ne) pouvant aider au diagnostic, monitoring et traitement d'une insuffisance surrénalienne secondaire à l'étomidate.

*Reprinted

Le défibrotide et la maladie hépatique veino-occlusive, vous connaissez?

Jean-Philippe Côté, B. Pharm. (candidat M. Sc.), Hôtel-Dieu de Québec, Québec, Qc.

Le but de cette présentation est de familiariser les pharmaciens avec l'utilisation du défibrotide dans le traitement de la maladie hépatique veino-occlusive.

La maladie hépatique veino-occlusive est une complication fréquente qui survient généralement dans le mois suivant la greffe de moelle osseuse. Dans la plupart des cas, un traitement de support est suffisant en attendant la résolution spontanée de l'état du patient. La maladie hépatique veino-occlusive sévère est toutefois associée à un taux élevé de mortalité et il n'y a pas d'évidence claire de traitement efficace. Le défibrotide est tout de même utilisé en traitement de cette pathologie sévère et est disponible au Canada via le Programme d'Accès Spécial. Aux Etats-Unis, l'utilisation du défibrotide pour traiter la maladie hépatique veino-occlusive n'est pas approuvée par la FDA mais le défibrotide figure sur la liste des médicaments orphelins pour cette indication.

Deux (petites) études rapportent l'utilisation du défibrotide en traitement de maladie hépatique veino-occlusive sévère. Son utilisation pourrait aussi s'étendre éventuellement à la prévention selon les résultats d'une étude récente (2004). Malgré le peu de données concernant son efficacité et puisque aucun autre traitement n'est prouvé efficace et sécuritaire, le défibrotide est utilisé lors de cas de maladie hépatique veino-occlusive sévère.

Buts et objectifs

- Présenter rapidement la maladie hépatique veino-occlusive.
- Présenter les résultats de 2 études concernant l'utilisation du défibrotide en traitement de la maladie hépatique veino-occlusive.

- Présenter le défibrotide (pharmacologie, pharmacocinétique, dose, ajustement, interaction).

Questions d'auto-évaluation

- Quelle serait la dose initiale de défibrotide utilisée en traitement de la maladie hépatique veino-occlusive sévère?
- L'utilisation du défibrotide est-elle associée à une incidence élevée de saignement chez ces patients?

Disaster Planning: Lessons Learned from Hurricane Katrina

Philip H. McCrory, Jr., BSc (Pharm), Louisiana Department of Health and Hospitals – Office of Public Health, New Orleans, LA

The goal of this session is to provide pharmacists with an understanding of the various roles they may be required to play during a disaster.

On August 29, 2005 Hurricane Katrina struck the continental United States along the Gulf Coast of Florida, Alabama, Mississippi and Louisiana. More than 1,000,000 people were displaced and over 200,000 homes were destroyed. Damage estimates go as high as $130,000,000,000.

In the aftermath of the hurricane there was major flooding in New Orleans and surrounding areas. This required a massive effort to rescue more than 60,000 people who were left stranded in their homes and in shelters. Additionally 3,200 patients and 12,000 staff and family members had to be rescued from area hospitals.

The Centers for Disease Control and Prevention (CDC) is responsible for managing the Strategic National Stockpile (SNS) program. This is a multi-tiered program designed to deliver a diverse assortment of drugs and medical supplies in response to a disaster, whether natural or man-made, anywhere in the United States.

In the aftermath of Hurricane Katrina the SNS was deployed to two states, Louisiana and Mississippi. This was the first time since September 11, 2001 that the SNS was requested.

Goals and Objectives

1. To provide pharmacists with an understanding of the various roles they may be required to play during a disaster.
2. To enable pharmacists to better assess plans for emergency preparedness.

Self-Assessment Questions

1. Is it reasonable to anticipate the need for maintenance drugs during an emergency requiring sudden long term mass evacuations?
2. What exceptions should be made during an emergency to allow pharmacists to meet the prescription needs of large numbers of evacuees?
3. What are some of the roles pharmacists may play during a large scale emergency?

Sunday, August 13 • Dimanche 13 août

Viewing/ Affichage: 10:15-10:45
Presentations/ Présentations: 12:15-14:00

1. Acid Suppressive Therapy Use on an Inpatient Internal Medicine Service
2. A Drug Use Evaluation Comparing Bivalirudin and the Combination of Heparin plus Eptifibatide in Elective Percutaneous Coronary Intervention
3. Implantation d'un programme de continuité de soins pharmaceutiques pour la clientèle atteinte de maladies respiratoires
4. Evaluation of the Quality of Warfarin Patient Information
5. Evaluation of Clinical Pharmacy Services in the Home Care Setting: A Pharmacy Pilot Project
6. The Evaluation and Implementation of a Process to Identify Patients Eligible for an Aromatase Inhibitor in the Adjuvant Treatment of Postmenopausal Hormone Sensitive Breast Cancer Patients in Newfoundland and Labrador
7. Impact of Pharmacy Intervention on Venous Thromboprophylaxis
8. Adherence to Canadian Diabetes Association Clinical Practice Guidelines in an Outpatient Diabetes Education Centre
9. Irinotecan Stability in Vials Following Puncture When Stored at 23C or 4C
10. Physical Compatibility of Pantoprazole (PANTO® IV) with 36 Medications during y-Site Simulation

Acid Suppressive Therapy use on an Inpatient Internal Medicine Service

Co Q. D. Pham, Pharm.D., Clinical Assistant Professor, Faculty of Pharmacy, University of Montreal, Pharmacist, Internal Medicine/Gastroenterology, McGill University Health Centre - Montreal General Hospital, Randolph E. Regal, Pharm.D., Clinical Pharmacist, Adult Internal Medicine/Infectious Diseases, Clinical Assistant Professor, University of Michigan Hospitals/College of Pharmacy, Thomas R. Bostwick, Pharm.D., at time of writing, Pharm.D. Student, University of Michigan, College of Pharmacy, Kara S. Knauf, Pharm.D., at time of writing, Pharm.D. Student, University of Michigan, College of Pharmacy

Purpose: Use of acid suppressant medications (ASMs) has increased in both frequency and breadth in recent years. Data have indicated that questionable use of ASMs for non-accepted indications is common.

Objectives: To assess the indications and prevalence for use of ASMs in medicine inpatients, upon admission and at discharge.

Methods: A retrospective chart review of 213 patients admitted to the University of Michigan Hospital non-critical care general medical service was conducted. Relevant medical history, ASM used, and indications were collected from both inpatient medical records and discharge medication lists.

Results: Of the 213 patients reviewed, 29% were taking ASMs prior to admission (33% PPIs). Once admitted, ASM use increased to 71% (152 of 213), with 84% PPIs, 11% H2RAs, and 5% combination. Based upon our criteria, only 10% (15 of 152) of those on ASMs were found to have an acceptable indication. In patients where any history of GERD was deemed as an acceptable indication (32 other patients), then 31% (47/152) had an acceptable indication.

For the 137 patients with non-accepted indications, 29% had no discernable indication, and 38% were prescribed ASMs for stress ulcer prophylaxis. A history of GI bleeds or PUD of >3 months since initial diagnosis or documented exacerbation of symptoms comprised 8%. The aforementioned group of GERD patients made up 23% of this group.

Compared to the 29% taking ASMs prior to admission, 54% (115 of 213) of patients were prescribed ASMs at discharge. If only recent exacerbations of GERD were deemed as long-term indication, then 10% (12 of 115) of these patients were found to have accepted indications. If all GERDs were acceptable long-term indications, 27% (31 of 115) would have met criteria for acceptable outpatient use.

Conclusion: There is considerable excess usage of ASMs in both the inpatient and outpatient settings.

A Drug Use Evaluation Comparing Bivalirudin and the Combination of Heparin plus Eptifibatide in Elective Percutaneous Coronary Intervention

Kerith Slagel, Kingston General Hospital, Kingston, Ontario, Michelle Methot, Kingston General Hospital, Kingston, Ontario, Catherine McLellan, Kingston General Hospital, Kingston, Ontario

Purpose: Bivalirudin used with provisional glycoprotein (GP) IIb/IIIa inhibitors in percutaneous coronary intervention (PCI) was shown to be non-inferior to heparin plus planned GP IIb/IIIa inhibitors, and associated with less bleeding. Bivalirudin was approved for use in elective PCI at Kingston General Hospital (KGH) in July 2004.

Objectives: To evaluate bivalirudin use with respect to the KGH criteria for use and to assess the differences between bivalirudin and the combination of heparin plus eptifibatide in time to sheath removal, time to ambulation, length of stay and bleeding complications.

Methods: A double cohort retrospective chart review of patients who received bivalirudin (n=30) and patients who received heparin plus eptifibatide (n=30). Patients were matched according to coronary lesion classification, number of diseased vessels, stent size and age.

Results: Patients who received bivalirudin had a shorter time to sheath removal (p=0.001), time to ambulation (p=0.036), length of stay (p=0.117) and a lower incidence of minor bleeding (p=0.01) compared with patients who received heparin plus eptifibatide. Four patients received planned PCI with bivalirudin two days after emergency PCI for an acute coronary syndrome.

Conclusions: Bivalirudin is used in the appropriate low risk population with few exceptions. The results support previously published studies that bivalirudin has a lower incidence of bleeding complications compared to heparin plus GP IIb/IIIa inhibitors. The use of bivalirudin in PCI may lead to greater patient comfort and may reduce hospital costs because of decreased nursing time and length of stay.Key Words: bivalirudin, eptifibatide, heparin, percutaneous coronary intervention, bleeding, ambulation

Implantation d'un programme de continuité de soins pharmaceutiques pour la clientèle atteinte de maladies respiratoires

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Introduction : La clientèle hospitalisée bénéficierait d'une continuité de soins pharmaceutiques accrue au retour à domicile en raison de la susceptibilité de présenter des problèmes reliés à la pharmacothérapie (PRP).

Objectif : Évaluer la faisabilité et l'impact d'une communication active d'un plan de transfert pharmaceutique (CAPTES) entre les pharmaciens d'hôpitaux et communautaires sur les soins pharmaceutiques prodigués dans la communauté chez des patients avec maladie respiratoire.

Méthodologie : Étude-pilote prospective, ouverte, randomisée en grappes et contrôlée. Les patients ont bénéficié soit d'une communication téléphonique active (Groupe CAPTES : histoire médicamenteuse à l'admission, appel au pharmacien communautaire au congé, transmission plan de transfert avec maximum de 3 PRPs ciblés), soit d'une transmission standard d'informations (Groupe témoin : histoire médicamenteuse à l'admission, plan de transfert sans PRP ciblé).

Résultats : Au total, 22 patients ont complété l'étude (période de suivi de 6 semaines). Le nombre médian de PRP gérés (3 vs 0; p=0,0001) et d'interventions effectuées par patient par le pharmacien communautaire (4 vs 0; p=0,0004) était statistiquement supérieur dans le groupe CAPTES comparativement au group témoin. La conformité à la médication figurant au dossier-patient de la pharmacie communautaire était similaire dans les deux groupes. L'observance à la médication était supérieure dans le groupe CAPTES, mais la différence avec le groupe témoin n'était pas statistiquement significative.

Conclusion : Cette étude pilote démontre qu'une communication active d'informations entre les pharmaciens des deux milieux permet d'augmenter le nombre de PRP gérés et d'interventions pharmaceutiques effectuées en milieu communautaire.

Evaluation of the Quality of Warfarin Patient Information

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Background: Warfarin is a very commonly used drug in patients with cardiovascular disease that has a high rate of complications, especially if not used carefully. There is evidence that safe management of high-risk drugs such as warfarin requires clear understanding by the patient of a number of key issues. Furthermore, adverse patient events have been linked to poor communication between patients and practitioners.

Purpose: This study was conducted to determine the quality, accuracy and reading level of warfarin information sheets (WIS) provided to patients by community pharmacies.

Methods: To establish a national reference standard for WIS, surveys were sent to the 47 members of the Thrombosis Interest Group of Canada (TIGC) who rated 62 items on a 5-point scale. The items that were rated as essential or important by at least 2/3 of the 32 respondents were retained and formed the reference standard. WIS representing those distributed by community pharmacies (independent and chain) in Ontario and patient information booklets developed by pharmaceutical companies were evaluated using the content checklist. The reading level of each WIS was assessed using two standardized formulas, the Flesch-Kincaid and SMOG scale.

Results: Analysis of individual information sheets, representing 98% of those distributed in community pharmacies in Ontario, found that, on average, the WIS contained 30 deficiencies (out of 50 reference elements). There were also a variable number of incorrect statements. The reading level of these information sheets ranged from a Grade 7 to 12 level. The average patient reads at a Grade 6 to 8 level and 25% of Canadians read below a Grade 5 level. The information booklets from the pharmaceutical companies contained, on average, 14.5 deficiencies.

Implications for Practice: Based on a national standard, many WIS fail to address important patient information and contain numerous deficiencies or incorrect statements that may hinder safe care and lead to unnecessary lifestyle restrictions. Most information sheets are also above the average patients' literacy level, impeding their comprehension and impact on health safety. A national standard WIS needs to be developed and widely utilized e.g. the warfarin patient information on the TIGC website (www.tigc.org).

Evaluation of Clinical Pharmacy Services in the Home Care Setting: A Pharmacy Pilot Project

Stacey MacAulay, South-East Regional Health Authority, Moncton, NB; Lauza Saulnier, South-East Regional Health Authority, Moncton, NB; Odette Gould, South East Regional Health Authority, Moncton, NB & Mount Allison University, Sackville, NB

Rationale: Home care is an increasingly important component of Canada's health care system. Despite the vast array of often-complex medication regimens utilized in home care, pharmacists have not traditionally been members of home care teams. Also, there is minimal literature describing pharmacist involvement in Canadian home care.

Objectives: The objectives were to determine (a) the number of medication-related issues identified by the pharmacist, (b) the acceptance rate and significance of pharmacist recommendations, and (c) satisfaction levels of patients and team members.

Methods: Clinical pharmacy services were provided to patients recently discharged from hospital who were at high risk of adverse drug events. Services were provided upon consult from a home care nurse for a minimum of 3 weeks. Examples of services included: comprehensive or focused medication regimen assessment, adverse drug event assessment, and compliance assessment.

Results: 30 patients (mean 81 years, 70% female) participated in the pilot project. Patients took a mean of 13.5 medications. 53% of patients received services for longer than 3 weeks. There was a mean of 3.6 medication-related issues identified and 4.3 recommendations made per patient. 74% of recommendations made to physicians were accepted, 5% were rejected, and the response to 20% is unknown. The mean significance of recommendations per patient was 4.1 (scale 1-6). Overall satisfaction scores were 9.6 and 9.9 for nurses and patients respectively (scale 1-10).

Conclusion: A wide variety of medication-related issues were identified and recommendations were made to optimize medication regimens. Both patients and team members were very satisfied with the clinical pharmacy services provided.

The Evaluation and Implementation of a Process to Identify Patients Eligible for an Aromatase Inhibitor in the Adjuvant Treatment of Postmenopausal Hormone Sensitive Breast Cancer Patients in Newfoundland and Labrador (NL)

Joy McCarthy MD, Jonathan Edwards BKin, Scott Edwards PharmD, Michael LeBlanc BPharm, Rick Abbott BPharm, Kara Laing MD

Rationale: The current ASCO guidelines recommend that hormone sensitive postmenopausal (HSP) breast cancer patients should receive an aromatase inhibitor (AI) at some point in their treatment plan. Three accepted treatment plans are 1) an upfront AI for 5 years 2) switching to an AI after 2-3 years of Tamoxifen or 3) an AI for 3-5 years after 5 years of Tamoxifen ("extended adjuvant"). Fifty percent of breast cancer patients develop a recurrence after five years of Tamoxifen (1).

Objective: Our Center made a decision to develop a process that will identify and initiate an AI in the extended adjuvant setting for HSP breast cancer patients. In the near future, this process could also be used to identify patients finishing 2-3 years of Tamoxifen and offered a switch to an AI. We are currently identifying patients currently on

tamoxifen for five years and including those who were receiving tamoxifen up to one-year post treatment.

Study Design and Method: Patient files who are estrogen receptor (ER) positive and/or progesterone receptor (PR) positive were found and pulled by flagging them in our Center's patient database (OPIS database). A research assistant, clinical pharmacist and medical oncologist ("AI Review Team") reviewed the corresponding charts at separate times. This systematic review narrowed the number of patients who would be eligible to receive an AI based on life expectancy and recurrence risk. Once considered eligible the patient's family physician was contacted by the medical oncologist to further screen the patient. This provided the necessary information for the AI review team to decide whether the patient would be contacted and offered an appointment with the medical oncologist. After a balanced discussion with the medical oncologist of the pros and cons of an AI in the extended adjuvant setting, the patient would make a decision of whether to take an AI upon completion of Tamoxifen.

Results: This project is ongoing however, 465 charts have been reviewed; 96 patients, or 20.6% of the total eligible population, have the potential to receive an AI in the extended adjuvant setting; 24 patients have already initiated therapy.

Conclusions: We conclude this to be a successful benefit for patients based on the current ASCO guidelines. By implementing this review, patients who are lost to follow-up with their general practitioner are able to continue with extended adjuvant therapy. This provides the patient with the opportunity to reduce the risk of recurrence and disease free survival. The simple design of this chart review promotes its use in other therapeutic settings.

References:

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Impact of Pharmacy Intervention on Venous Thromboprophylaxis

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Purpose: Venous thromboembolism (VTE) is a major complication for hospitalized patients and is associated with significant morbidity and mortality. Despite known risk factors and available guidelines, underutilization of VTE prophylaxis is widespread. To promote its use, the Jewish General Hospital (JGH) established a simplified prophylactic guideline based on the recommendations of the American College of Chest Physicians. Due to the advantages of once daily administration, pre-prepared syringes, less laboratory monitoring, and a decreased incidence of heparin-induced thrombocytopenia, enoxaparin, a low molecular weight heparin, was preferred over unfractionated heparin.

Objectives: To promote the use of proper thromboprophylaxis based on the JGH guidelines for VTE prophylaxis.

Design and Methods: After dissemination of the JGH guidelines through several knowledge-translation methods, the pharmacy study team verified its appropriate use. In the case of non-adherence, the attending physician was notified in writing. The prescribing pattern of VTE prophylaxis was monitored for 11 months. Seven weeks of daily interventions were documented followed by a 3-month period of weekly verifications. A 3-month pre- and post- intervention observation analysis was used to evaluate impact of the pharmacy intervention.

Results: The proportion of enoxaparin prescribed vs. total prescriptions for VTE prophylaxis increased from 8.3% pre- to 69.3% post-intervention. The total number of prescriptions for VTE prophylaxis increased by 28.95% ($p<0.0001$) from pre- to post-intervention.

Conclusions: Our results demonstrate the impact of pharmacy intervention on the prescribing of enoxaparin for VTE prophylaxis and its increased use which may contribute to a fewer number of VTE events.

Adherence to Canadian Diabetes Association Clinical Practice Guidelines in an Outpatient Diabetes Education Centre

Bethany C. Crossman, Anne Nguyen, Victoria C. Slavik; Lions Gate Hospital, North Vancouver, BC

Rationale: Better adherence to evidence-based practices results in better patient outcomes.

Objective: To determine the proportion of Lions Gate Hospital Diabetes Education Centre (LGH DEC) patients who met Canadian Diabetes Association 2003 Clinical Practice Guidelines recommendations.

Study Design and Methods: A retrospective chart review was performed on all patients with type 2 diabetes who were 19–69 years old and first visited the LGH DEC in 2004.

Results: There were 167 patients included. Median age was 54 years, median follow-up was 120 days.

The proportion of patients achieving initial monitoring parameters was high: A1C (155/167, 92.8%), lipid panel (136/167, 84.1%), and eye exam (95/119, 79.8%). Achievement of monitoring recommendations decreased with time: A1C every 3 months at 6 months (104/167, 62.3%) and at 18 months (4/89, 4.5%).

The proportion of patients achieving laboratory targets within the recommended timeframe was variable: A1C (108/116, 93.1%), FPG (51/115, 44.4%), LDL-C (50/151, 33.1%) and microalbuminuria (108/116, 28.6%).

The proportion of patients receiving recommended medications was low: A1C > 7% receiving an antihyperglycemic (36/64, 56.3%), BMI ≥ 25 kg/m2 receiving metformin (66/135, 48.9%), blood pressure > 130/80 mmHg receiving an antihypertensive (67/149, 45%), LDL-C ≥ 2.5 mmol/L receiving a statin (29/117, 24.8%), and high atherosclerotic risk receiving ASA (16/61, 26.2%).

Of note, targets and medications that address cardiovascular risk were among the least likely to be achieved.

Conclusion: The majority of patients met recommendations for initial monitoring. The next steps are to ensure monitoring is maintained, laboratory targets are achieved and appropriate medications are initiated.

Irinotecan Stability in Vials Following Puncture When Stored At 23C or 4C

Scott E. Walker[1, 2] MScPhm, John Iazzetta[1,2] PharmD, and Shirley Law[1], Dip Pharm Tech.
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Background: Irinotecan is packaged in amber glass vials to protect it from light. To ensure stability the air in headspace of the vials is replaced with nitrogen, but following puncture Mayne Pharma recommends that the contents of the vial be used immediately. In response to enquires on the stability of the vial, Mayne will provide in-house data indicating that the irinotecan in the vial is stable for 4 days at 30°C.

Objective: The objective of this study is to evaluate the stability of the 25 mL - 20-mg/mL solution of irinotecan in the original manufacturer's vial following puncture and storage at 4C and 23C. To maximize the rate of irinotecan degradation the nitrogen in the headspace of the vials was replaced with room air and exposed to ambient fluorescent lighting during storage.

Methods: On study day 0, the nitrogen in the headspace in each of 8 – 20-mg/mL vials was flushed with 40 mL of room air. Four vials were stored at room temperature and four were stored in the refrigerator. Concentration and physical inspection were completed on each solution on study days 0, 2, 3, 4, 7, 9, 11 and 14. Irinotecan concentrations were determined by a validated, stability-indicating, liquid chromatographic method.

Results: All solutions remained clear and colourless. During the study period all solutions retained more than 90% of the initial concentration. 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 the 25 mL - 20-mg/mL vials of irinotecan are chemically stable for up to 14 days at 4C or 23C under ambient fluorescent lighting and displacement of the nitrogen with room air, which typically occurs with multiple punctures and withdrawals.

Physical Compatibility of Pantoprazole (PANTO® IV) with 36 Medications during y-Site Simulation

Scott E. Walker[1,2] MScPhm, John Iazzetta[1,2] PharmD, and Shirley Law[1], Dip Pharm Tech.

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Rationale: Patients receiving intravenous (IV) pantoprazole often require concomitant IV drugs and solutions. No compatibility information has been published for the new formulation of pantoprazole (PANTO® IV, Altana Pharma Inc.).

Objective: To complete a visual compatibility study of pantoprazole with 36 IV medications in three intravenous solutions during simulated Y-site injection.

Methods: 36 drugs, each at three different concentrations diluted in dextrose 5% in water (D5W) or 3.3% dextrose/0.3% sodium chloride (2/3 D5W-1/3 NS), were selected for compatibility testing with three concentrations (0.16 mg/mL, 0.4 mg/mL and 0.8 mg/mL) of pantoprazole in sodium chloride 0.9% (NS). The 36 drugs were ampicillin, calcium chloride, calcium gluconate, cefazolin, ceftriaxone, ciprofloxacin, clindamycin, dimenhydrinate, dobutamine, dopamine, furosemide, epinephrine, esmolol, fentanyl, gentamicin, hydromorphone, regular insulin, labetalol, levofloxacin, magnesium sulphate, meperidine, methylprednisolone, metronidazole, midazolam, morphine, moxifloxacin, multivitamins, nitroglycerine, norepinephrine, octreotide, phenytoin, piperacillin, potassium chloride, potassium phosphate, sodium bicarbonate, and vasopressin

Solutions were inspected for colour change, clarity, visible precipitate and evolution of gas immediately after mixing and at 15 minutes, 1, 4 and 12 hours. The pH of each solution was measured prior to mixing.

Results: Pantoprazole IV was compatible with 22 of 36 drugs tested for up to 12 hours at 23∞C during simulated Y-site administration. Precipitation occurred with mixtures containing pantoprazole with norepinephrine, dobutamine, calcium chloride or magnesium sulphate. A colour change was observed and precipitation was gradually formed over the 12-hour study period with the following combinations when they were mixed with pantoprazole: octreotide, midazolam, labetalol and clindamycin. A colour change was observed with mixtures containing pantoprazole and potassium phosphate, hydromorphone, ciprofloxacin, moxifloxacin or levofloxacin.

Conclusion: We recommend avoiding Y-site administration of pantoprazole with calcium chloride, ciprofloxacin, clindamycin, dobutamine, hydromorphone, labetalol, levofloxacin, magnesium sulphate, midazolam, moxifloxacin, norepinephrine, octreotide or potassium phosphate.

Monday, August 14 • Lundi 14 août

Viewing/ Affichage: 10:00-10:30
Presentations/ Présentations: 12:30-14:30

1. Evidence and a Regional Drug Formulary: The Fraser Health Authority Experience
2. Joint Effort Clinical Pharmacy Services in Rural Hospitals
3. Establishment of an Admission Medication Reconciliation Program
4. Palliative Care Medication Kits
5. Cardiovascular Prevention and Therapy: The Mountain Population Report Card: How Good Are We Doing at Home?
6. Inadequate Empiric Antibiotic Therapy: Incidence and In-Hospital Mortality among Critically-Ill and Solid-Organ Transplant Patients
7. A Retrospective Comparison of Medication Regimen Complexity in Renal Transplant Recipients Receiving Calcineurin Inhibitors
8. Use of Concept Maps to Enhance Learning within a Traditional Model of Practice-Based Pharmacy Education
9. Implementation of a Prohibited List of Abbreviations in the David Thompson Health Region
10. Failure Mode Effects Analysis of the Pharmacy Preparation of Epidural Syringes
11. A Retrospective Comparison of Variable Concentrations versus Standardized Concentrations on 24-hour Drug Infusion Volumes in Paediatric Intensive Care Unit

Evidence and a Regional Drug Formulary: The Fraser Health Authority Experience

Aaron M Tejani (Fraser Health Authority, Surrey, BC), Bob Nakagawa (Fraser Health Authority, Surrey, BC), Shallen Letwin (Fraser Health Authority, Surrey, BC), John Rideout (Fraser Health Authority, Surrey, BC), Mits Miyata (Fraser Health Authority, Surrey, BC), Anisha Lakhani (Fraser Health Authority, Surrey, BC)

Rationale: In early 2002, the Fraser Health Authority (FHA) in South Western BC was created by an amalgamation of 3 geographic sub-regions in the province.

Description of Situation: In an effort to streamline the drug formulary process, 1 Pharmacy and Therapeutics Committee and 1 drug formulary were created. The main goal was to create a committee that makes decisions using the principles of evidence-based medicine (EBM) and represents all of FHA.

Development of a New Process: The following statements outline how an attempt has been made to ensure that the committee is guided by the principles of evidence-based healthcare when making their decisions: all new medications requested for addition to formulary now undergo a rigorous systematic review of the evidence using widely accepted methodology (i.e. methods used by the Cochrane

collaboration); all members of the committee and people making requests are required to declare perceived or actual conflict of interest; at each meeting members are given didactic and case-based education sessions on the principles and practice of evidence-based medicine.

Results of the New Process: The committee has met 8 times and reviewed 24 drug products. Requested drugs were not added to the formulary in 5 of 13 instances in concordance with the review of best evidence.

Importance: Each drug being requested for addition to the FHA drug formulary undergoes a standardized, comprehensive, and systematic review of best evidence. As a result, drug formulary decision-making in FHA is increasingly being based upon the principles and practice of evidence-based medicine.

Previous Publication: Tejani A, Nakagawa B, Letwin S, Rideout, Miyata M, Lakhani A. Evidence and a Regional Drug Formulary: Stories of Success and Challenges (Abstract). From Evidence to Policy to Practice 2006 Canadian Coordinating Office of Health Technology Assessment Invitational Symposium, Ottawa, Ontario

Joint Effort Clinical Pharmacy Services in Rural Hospitals

Joyce Totton, Interior Health, Golden, British Columbia, Pat Hunt, Interior Health, Creston, British Columbia, Kim Pritchard, Interior Health, Fernie, British Columbia, Darren Feere, Interior Health, Cranbrook, British Columbia

Rural hospitals without on-site pharmacists were being serviced by one on-site pharmacy technician with regional hospital pharmacists available for clinical services. With a new pharmacist position at a rural site, a goal was conceived to provide routine clinical pharmacy services to rural sites from a remote worksite. A joint effort clinical pharmacy service (JECS) to address this goal was collaboratively developed to be the responsibility of both pharmacists and pharmacy technicians using technology such as videoconference, teleconference, fax, scanner, and electronic charts.

The rationale use of antibiotics was chosen as the first JECS. A clear outline of the responsibilities of the pharmacist and pharmacy technician for data collection was determined and printed in order to formulate care plans and follow up. The development of a data collection and workflow system was at the discretion of the pharmacy technician. Clinical interventions were charted in the electronic medical record and the progress notes of the patient chart by the pharmacist. Patients identified to be candidates for JECS were followed daily by both the pharmacist and the pharmacy technician.

Clinical Interventions and Total Time – See table below.

Establishment of an Admission Medication Reconciliation Program

Penny Guimont, Maryann Gadawski and Susan MacDonald, Ross Memorial Hospital, Lindsay, Ontario

Reason for Initiative: Numerous patient safety initiatives, such as the Safer Healthcare Now! Campaign, have been developed to prevent adverse drug events throughout healthcare organizations. In addition, the Canadian Council on Health Services Accreditation (CCHSA) has set new patient safety goals, which include a medication reconciliation process for patient admission, transfer and discharge.

In conjunction with the new Ministry of Health initiative, which makes the Ontario Drug Benefit Profile available, the Pharmacy at our hospital focused on the development and implementation of an admission medication reconciliation program.

Description of Initiative: Due to inconsistencies with documentation of home medications, our initiative focused on obtaining the best possible medication history for patients admitted to the hospital. This involved the use of a full-time pharmacy technician, with the support of pharmacists, to obtain a complete and accurate list of each patient's current home medications. An admission medication order form was developed to document confirmed home medications and ultimately, physicians will use this form for admitting orders.

Evaluation: After 5 weeks and 118 patient interviews, our results indicate that 223 medication discrepancies were prevented. Identified discrepancies resulted in a change in the drug prescribed, the dose ordered or the frequency of administration. Other examples of impact include the avoidance of missed home medications or preventing the re-ordering of discontinued medications.

Importance and Usefulness of Initiative for Pharmacists: The establishment of an admission medication reconciliation program is considered the first step in complying with CCHSA standards. A complete and accurate admission medication list is vital to all members of the healthcare team, increasing efficiency and improving patient safety.

Palliative Care Medication Kits

Rachel Harris, Saint John Regional Hospital, Saint John, NB, Kelly Holt, Saint John Regional Hospital, Saint John, NB., Holly Glennie, Saint John Regional Hospital, Saint John, NB

Rationale/Description: There is a need to supply palliative medications to Extra-Mural Program (EMP) Nurses who provide end-of-life care in our community. Palliative Care Medication Kits were created to allow immediate access to medications needed in urgent palliative care situations in the home. Prior to the kits, if medications were needed after the hospital pharmacy was closed, a pharmacist had to be paged to come into the hospital to dispense the medications, or the patient would have to come into the emergency department to receive medications.

Methods: The kits consist of a secured box containing medications that may be required in the final days of a palliative patient's life. Three Palliative Care Medication Kits are located in the pharmacy department of the SJRH. The kits can be accessed during regular pharmacy hours. One additional Kit is stored in the Palliative Care Unit at the SJRH which can be accessed when the SJRH pharmacy is closed. Three

Clinical Interventions and Total Time*

Month	December		January		February		March			April		
	#	Time (min.)	#	Time (min.)	#	Time (min.)	#	Pharm Time (min.)	Tech Time (min.)	#	Pharm Time (min.)	Tech Time (min.)
Creston	12	0	22	4585	15	265	24	181	184	18	75	290
Fernie	6	50	4	15	10	170	20	101	182	18	179	361
TOTAL	18	50	26	4600	25	435	44	282	366	36	254	651

*Pharmacist position began in January, JECS begun in March # = total number of clinical interventions (JECS and non JECS)

JECS promotes rapid, evidence-based decisions to be made on behalf of the patient. More emphasis can be placed on the appropriate resources to achieve these goals.

additional kits are kept at two remote centers outside of the SJRH that can be accessed by EMP Nurses in those regions.

Outcomes/Results: A total of 28 kits have been dispensed to EMP Nursing Units from January 2005 to present.

Satisfaction surveys were distributed to EMP Nurses in our region who have access to these medication kits.

Conclusions: Palliative Care Medication Kits have provided a more easily accessible supply of medications required for end of life care in the community.

From the Pharmacy, Nursing and Patient perspective, the kits have been well received.

Cardiovascular Prevention and Therapy: The Mountain Population Report Card - How Good Are We Doing at Home?

Sylvie Labelle-Stimac, B.Sc. Pharm., Henderson Hospital, HHSC, Hamilton, ON, John Stimac, MD FRCP(C) , HHSC, McMaster University, Hamilton, ON, Basil Hassouneh, McMaster University, Hamilton, ON

Introduction: Several major randomized control trials have provided Class I level A and level B evidence for significant cardiovascular prevention in the appropriate risk groups. The drugs and dosages administered should correspond with the results of these trials.

Objectives: The purpose of this study is to evaluate the appropriateness of medical treatment aimed at cardiovascular prevention. Age and gender were also evaluated for predicting under treatment.

Design and Setting: Retrospective case study at McMaster University, a tertiary care center.

Methods: The medical records of 427 consecutive patients admitted between 2002 and 2004 with primary diagnosis of ACS or CHF were reviewed. All patients under 90 years of age with well-documented medical records were evaluated. Age, gender, as well as previously documented risk factors were determined, including history of CAD or left ventricular dysfunction (LVD). Preadmission medications and dosages aimed at cardiovascular prevention were carefully reviewed. This included: ASA, ACE-Is, Statins, and B-blockers. Past medical history was reviewed for asthma, COPD, and liver disease to accommodate for contraindications.

Results: In this study 369 patients were high risk and required an ASA; only 217 (59%) were actually treated with 100% receiving the appropriate dose. 270 patients either met the HOPE criteria or had significant LVD warranting an ACE-I; only 169 (62%) were treated with 42% receiving the optimal dose. 249 patients had significant risk including DM or hyperlipidemia warranting a Statin; 123 patients (49%) were treated with 70% receiving the optimal dose. 182 patients had history of MI or CAD requiring a B-Blocker; 60 were treated (33%) with 39% receiving the optimal dose. We could not identify gender or age relation to under treatment.

Conclusion: The majority of the treatment prescribed for the patients in this study targeted the correct risk groups (average over 85%). Nonetheless, significant percentage (average 48%) of patients with well-documented risk factors, CAD, or LVD are not receiving pharmacotherapy prevention. Moreover, significant percentage (average 62%) of those treated are not receiving optimal dose as recommended by current evidence. Significant improvement can be achieved in cardiovascular prevention by optimizing treatment.

Inadequate Empiric Antibiotic Therapy: Incidence and In-Hospital Mortality among Critically-Ill and Solid-Organ Transplant Patients

Bassem Hamandi[1], Anne Holbrook[1], Atul Humar[2], James Brunton[2], Manny Papadimitropoulos[1], and Gary Wong[1]

[1]Pharmaceutical Sciences, and
[2]Infectious Diseases, University of Toronto, Toronto, ON

Rationale: Empiric antibiotic therapy is often prescribed prior to the availability of culture results. In some cases, the organism which is ultimately isolated may not be susceptible (inadequate empiric therapy or IET). The incidence and importance of IET as a risk factor for hospital mortality among Canadian transplant and critically-ill patients is unknown.

Objectives: To determine the incidence and describe the clinical significance of IET as a risk factor for hospital mortality among critically-ill and solid-organ transplant patients.

Methods: This retrospective study evaluated all patients admitted to a transplant and medical-surgical intensive care unit from May 2002-April 2004. Organisms cultured and subsequently found to be susceptible to an antibiotic administered within 24 hours of the sample collection date, were deemed to be adequately treated.

Results: Of the 1675 admitted transplant recipients, IET was prescribed in 169/312 (54.2%) evaluable patients and 248/574 (43.2%) cultures. Among the 1411 admitted critically-ill patients, IET was prescribed in 113/215 (52.6%) evaluable patients and 164/362 (45.3%) cultures. Hospital mortality was significantly greater among patients receiving IET for both transplant (24.9% vs. 7.0%; $p<0.001$) and critically-ill cohorts (55.8% vs. 25.5%; $p<0.001$). Logistic regression analysis demonstrated that IET was an independent determinant of hospital mortality among transplant (OR, 4.91; $p<0.001$) and critically-ill patients (OR, 2.23; $p=0.046$). Prior antibiotic use, ICU-related infections, APACHE-II score, and lung transplantation, were also identified as predictors of hospital mortality.

Conclusion: IET appears to be an important determinant of hospital mortality among Canadian transplant and critically-ill patients.

A Retrospective Comparison of Medication Regimen Complexity in Renal Transplant Recipients Receiving Calcineurin Inhibitors

Muhammad Zuberi, Bassem Hamandi, Jennifer Harrison, Sara Ingram
University Health Network, Toronto, ON

Rationale: Nonadherence to immunotherapy is a risk factor for poor post-transplant outcomes. The number of daily doses and dosing frequency contribute to medication regimen complexity (MRC) and may affect nonadherence. Calcineurin inhibitor therapy may affect prescribing of concomitant medications thereby influencing MRC.

Objectives: To describe the number of daily dosing units (DDU) and daily dosing frequency (DDF) of medications in de novo renal transplant recipients (RTR).

Methods: Adult RTR from 04/2004 to 03/2005 were included if they survived to hospital discharge and received either cyslosporine (CSA) or tacrolimus (TAC).

Comprehensive discharge medication lists provided to all RTR were used to evaluate medication regimens according to DDU and DDF. DDU was defined as the cumulative number of doses per day for all prescribed standing medications. DDF was defined as the minimum number of dosing times per day for all prescribed standing medications.

Results: Ninety-five RTR were included (CSA n=38; TAC n=57). There was no difference in baseline demographics.

DDU for all patients was 19.09 ± 4.47 (mean ± SD). There was no difference in DDU between patients receiving CSA vs. TAC (19.24 ± 4.22 vs. 18.99 ± 4.66, $p = 0.791$). DDF for all patients was 6.13 ± 1.31. Patients receiving CSA had a significantly higher DDF (6.76 ± 1.32 vs. 5.70 ± 1.12, $p < 0.001$).

Conclusions: Medication regimens for RTR involve a large number of daily doses and a high dosing frequency. Selection of calcineurin inhibitor contributes to MRC. Greater awareness of MRC is needed to improve medication adherence.

Use of Concept Maps to Enhance Learning within a Traditional Model of Practice-Based Pharmacy Education

Muhammad Zuberi BScPhm[a], University Health Network, Toronto, ON

Purpose: A commitment to life-long learning is a core attribute for pharmacists to maintain and improve skills and knowledge. Many learning opportunities exist including attending seminars, formal teaching, and self-directed reading.

Enhanced learning often includes an experiential component that is based on a Constructionist pedagogy. This model proposes that learning is most effective when learners 'construct' something for others to experience.

Concept maps are graphical tools that facilitate constructionism. They are composed of concepts (boxes) and relationships (connecting lines).

Concept mapping activities may promote more meaningful learning.

Objectives: To enhance practice-based pharmacy education by using concept maps.

Description: A reading package was developed to introduce core therapeutic topics for the Multi-Organ Transplant Unit. Each topic module contained learning objectives, recent reviews, and landmark trials.

Learners were encouraged to develop concept maps based on the modules by using software from IHMC CMapTools. Maps were intended to reflect new knowledge attained from the reading package, knowledge attained through providing pharmaceutical care, and prior knowledge.

Importance for Practice: Through concept maps, learners were able to quickly incorporate new knowledge into a broader therapeutic paradigm. To ensure learning objectives were attained, concept maps were reviewed by experienced transplant pharmacists. This facilitated further sharing and allowed for an ongoing process of updating and expanding the concept maps.

This initial positive experience has resulted in an expanded incorporation of concept maps into other areas of pharmacy practice, including clinical research project design.

Constructing concept maps is a simple way of promoting more meaningful learning.

Implementation of a Prohibited List of Abbreviations in the David Thompson Health Region

Linda Poloway, BScPharm, FCSHP, Patient Safety Coordinator, David Thompson Health Region

The David Thompson Health Region (DTHR) experienced a fatal medication error in June 2004 and an external review of the medication process was conducted. The review identified use of an error prone abbreviation as a contributing factor and recommended that a "standardized list of (error prone) abbreviations, acronyms, symbols, and truncated (stem) drug names that are not to be used throughout the organization" be developed. The region moved ahead to remove error prone terms from all clinical documentation beginning with handwritten medication orders.

A multi-disciplinary group established a list of 30 prohibited terms based on the ISMP US list of error prone abbreviations, symbols, acronyms and dose designations. Five to 7 terms would be introduced for implementation every 3 months. Presentations about the initiative were made and posters of prohibited terms distributed. Pharmacy reviewed all medication orders and identified use of prohibited terms. Each time a prohibited term was used a notice was sent to the writer advising them of the term(s) used and providing a reminder of the other terms not to be used. Compliance to the initiative was measured by the number of notices sent and the rate of use of prohibited terms relative to total medication orders written.

The DTHR model of implementing a prohibited list of terms will be adapted for roll out to all other Alberta health regions in 2006.

Encore Presentation

Failure Mode Effects Analysis of the Pharmacy Preparation of Epidural Syringes

Régis Vaillancourt[1], Colline Blanchard[1], Elaine Wong[1], Meechen Tchen[1], Brenda Martelli[1], Joanne Farris[1], Tim Laforce[1], Luisa Talia[1], Christopher Sorfleet[1]
[1]The Children's Hospital of Eastern Ontario, Ottawa, ON

Reason: To systematically and proactively evaluate the high-risk process of epidural analgesic syringe preparation.

Description: The Failure Mode Effects Analysis (FMEA) process involves 8 essential steps: 1) Selection of process/team: 2) Diagram the process 3) Brainstorm potential failure modes (FM) and their effects 4) Identify causes of FM 5) Prioritize FM 6) Re-design the process 7) Analyze and test the new process 8) Implement and monitor the new process. The team consisted of 3 pharmacists, 2 pharmacy technicians, 1 pharmacy aide, 1 RN, and 1 research coordinator: Five 2-hour sessions were conducted, identifying 5 processes and 46 potential FM with their causes and effects. FM were classified according to a Risk Priority Number (RPN) = severity (1-5) x detectability (1-4) x frequency (1-5) in order to assign a numerical classification of risk. FM with severity ratings of 5 are required to be addressed. 12 FM had a severity rating of 5 (one already had effective measures in place) with an associated RPN ranging from 5 to 60. Of the remaining FM the RPN score varied from 1.5 to 12, 11 improvement recommendations addressing the FM with a severity of 5 were proposed and are in various stages of implementation.

Importance and Usefulness of Initiative: The FMEA enabled the pharmacy to update the IV room processes and implement patient safety checks. Upon completion of the pharmacy initiated FMEA the working group recommended that an institution wide FMEA for the entire epidural process be initiated.

A Retrospective Comparison of Variable Concentrations versus Standardized Concentrations on 24-hour Drug Infusion Volumes in a Paediatric Intensive Care Unit

Régis Vaillancourt[1], Danica Irwin[1], Elaine Wong[1], Dermott Doherty[1], Margot Thomas[1], Christopher Sorfleet[1]
[1]The Children's Hospital of Eastern Ontario, Ottawa, ON

Rationale: Current practice is to use weight based variable concentration (VC) drug infusions in small children to avoid fluid overload. American guidelines recommend using standardized concentrations (SC) to reduce the risk of infusion errors.

Objectives: To establish that the drug infusion volume administered to Paediatric Intensive Care Unit (PICU) patients using the proposed SC will be no more than 10% greater than using current VC infusions over a 24-hour period.

Methods: A retrospective chart review was performed in order to calculate the 24-hour fluid volume related to VC drug infusions and compare this with the calculated volume that would be administered if SC were used.

Inclusion Criteria
- PICU patients receiving ≥1 continuous IV medication infusion(s) of a VC drug.

Exclusion Criteria
- PICU patients with a weight ≥ 20 kg.

Results: A total of 91 VC drug infusions (49 patient charts) were reviewed. Seven different drugs were identified and the total 24-hour fluid volume associated with each was calculated. A comparison with the calculated fluid volume using the proposed SC resulted in the following mean percent changes in fluid volumes: Dopamine (-20.05% +/- 20.94% n=13); Epinephrine (-8.68% +/-29.43% n=7); Fentanyl (4.17% +/- 33.43% n=12); Midazolam (0.0% +/-0.0% n=13); Milrinone (-23.10% +/- 16.92% n=13); Morphine (-1.20% +/- 46.99% n=30), Vasopressin (-28.33% +/-10.41% n=3). SC drug infusion volumes were no more than 10% greater than those using VC in 83.5% of infusions.

Conclusion: This evidence-based approach to the implementation of SC addresses potential concerns regarding increased fluid intake.

CSHP would like to recognize the generous contributions of the following speakers: La SCPH désire souligner les généreuses contributions des conférenciers suivants :

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Donna Woloschuk, PharmD, FCSHP
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Winnipeg, MB

Call for Abstracts for Posters

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Category

Author must specify the category that best suits the particular poster.

1. Clinical Research
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3. Case Reports
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5. Drug Use Evaluations
6. Systematic Reviews and Meta-Analysis
7. Health Professional Education
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Abstract Submissions

All abstract submissions must be submitted no later than 18:00 (Eastern Daylight Time) on October 6, 2006.

Abstracts MUST be submitted electronically, either online at CSHP's Web site (http://www.cshp.ca) or by e-mail to ddavidson@cshp.ca. Please provide 2 copies of your abstract. One copy should be blinded (remove authors' affiliations and identifying features in body of abstract). Please indicate in the filename which copy is blinded. Please submit your file in MS Word Format.

The following information must be included in your e-mail or online submission:

- Name of corresponding author
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- Title of abstract
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Abstract grading is blinded. Abstracts are selected on the basis of scientific merit, originality, level of interest to pharmacists, and compliance with style rules.

Encore presentations will be considered, in which case the original citation must also be submitted. Research in progress will not be accepted.

Accepted abstracts will be published in the AGM supplement of the Canadian Journal of Hospital Pharmacy.

Authors of accepted abstracts will be notified within 4 to 5 weeks. Expenses associated with the submission and presentation of the abstract are the responsibility of the presenter. Early registration fees will apply to all accepted poster applications. Guidelines for posters will be provided to authors of accepted abstracts.

Failure to comply with style rules could mean rejection of submission.

Sollicitation de résumés pour affiches

Conférence sur la pratique professionnelle 2007

au Westin Harbour Castle, Toronto, Ontario
du 27 janvier au 31 janvier 2007

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Catégorie

L'auteur doit préciser la catégorie qui convient à son résumé.

1. Recherche clinique
2. Recherche pharmaceutique ou fondamentale
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6. Revue systématique et méta-analyse
7. Éducation des professionnels de la santé
8. Analyse pharmacoéconomique
9. Initiative de sécurité pharmaceutique

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Les résumés doivent être soumis au plus tard à 18 h (heure avancée de l'est) le 6 octobre 2006.

Les résumés doivent être soumis par voie électronique, soit en ligne depuis le site Web de la SCPH (http://www.cshp.ca) ou par courriel à ddavidson@cshp.ca. Veuillez inclure deux exemplaires de votre résumé, dont l'un présenté en aveugle (sans les affiliations et les éléments d'identification de l'auteur). Veuillez indiquez le nom du fichier contenant le résumé en aveugle. Veuillez soumettre vos fichiers en format Microsoft Word.

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La notation est effectuée à l'aveugle. Les résumés sont sélectionnés en fonction du bien-fondé scientifique, de l'originalité, de l'intérêt pour les pharmaciens et de la conformité aux règles de présentation.

Les présentations répétées seront considérées ; dans un tel cas, la citation d'origine doit aussi être soumise. Les recherches en cours ne seront pas acceptées.

Les résumés acceptés seront publiés avec Le journal canadien de la pharmacie hospitalière, sous forme de supplément pour l'AGA.

Les auteurs des résumés acceptés recevront un avis d'ici quatre à cinq semaines. Les dépenses liées à la soumission et à la présentation du résumé reviennent au présentateur. Des frais réduits pour inscription anticipée s'appliqueront à toutes les

Style Rules

Title should be brief and should clearly indicate the nature of the presentation. Do not use abbreviations in the title. List the authors (presenter first), institutional affiliation, city, and province. Omit degrees, titles, and appointments.

Organize the body of abstract according to the selected category as follows:

Clinical Research, Pharmaceutical/Basic Research, Pharmacoeconomic Analysis:

a. rationale
b. objectives
c. study design and methods
d. results of study including statistical analysis used
e. conclusion of study (which should be supported by results presented).

Case Reports:

a. rationale for case report
b. description of case and problem
c. analysis of problem
d. importance of case to pharmacy practitioners.

Pharmacy Practice and Administration:

a. rationale for report
b. description of concept, service, role, or situation
c. steps taken to identify and resolve problem, implement change, or develop and implement new program
d. end result and evaluation (if any)
e. the concept's importance and usefulness to current and/or future practice.

Drug Use Evaluations:

a. purpose of report
b. objectives
c. design and methods used
d. results and cost analysis (if done)
e. conclusions and implication of results for institution and/or future pharmacy practice.

Systematic Review including Meta-Analysis

a. rationale for review of topic
b. objectives of review
c. methods used (specify search sources, study selection, study appraisal, study synthesis)
d. results of review
e. conclusion of review and implication to practice.

Health Professional Education:

a. purpose of educational activity
b. objectives
c. description of educational program or activity
d. end result and evaluation (if any)
e. the importance and usefulness of the program or activity for pharmacists.

demandes d'affichage acceptées. Les directives relatives aux affiches seront fournies aux auteurs des résumés acceptés.

Un manque de respect des règles de présentation pourrait mener au rejet d'une soumission.

Règles de présentation

Le titre doit être concis et indiquer clairement la nature du document. Évitez les abréviations dans le titre. Indiquez le nom des auteurs (le présentateur d'abord), l'affiliation à l'établissement, la ville et la province. Omettez des diplômes, les titres et les nominations.

Organisez le corps du texte, selon la catégorie choisie, comme suit :

Recherche clinique, recherche pharmaceutique ou fondamentale, analyse pharmacoéconomique :

a. justification
b. objectifs
c. conception de l'étude et méthodologie
d. résultats de l'étude y compris l'analyse statistique utilisée
e. conclusion de l'étude (étayée par les résultats présentés).

Rapport de cas :

a. justification du rapport de cas
b. description du cas et problématique
c. analyse de la problématique
d. importance du cas pour les pharmaciens.

Pratique et administration pharmaceutique :

a. justification du rapport
b. description du concept, du service, du rôle ou de la situation
c. mesures prises pour identifier et résoudre un problème, actualiser un changement ou développer et mettre en œuvre un nouveau programme
d. résultat et évaluation (le cas échéant)
e. importance et utilité du concept pour la pratique actuelle ou future.

Évaluation le l'usage des médicaments :

a. but du rapport
b. objectifs
c. conception et méthodologie
d. résultats et analyse des coûts (s'il y a lieu)
e. conclusions et incidences des résultats sur les établissements ou la pratique pharmaceutique future.

Revue systématique et méta-analyse

a. justification de la revue
b. objectives de la revue
c. méthodologie (y compris les sources de recherche, le choix, l'évaluation et la synthèse des études)
d. résultats de la revue
e. conclusion de la revue et incidences sur la pratique.

Éducation des professionnels de la santé :

a. but de l'activité d'éducation
b. objectifs

Medication Safety Initiatives:

a. reason for initiative
b. description of initiative
c. evaluation of initiative (if any)
d. importance and usefulness of initiative for pharmacists

Abstract Text

- Recommended font: Times 12.
- Capitalize only the first letter of each word of the title.
- List presenting author first.
- List each author's institutional affiliation and city.
- Abstract body (not including title and authors) is limited to 300 words.
- A table is equivalent to 30 words.
- A graphic is equivalent to 60 words.
- Do not indent the start of a paragraph.
- Use standard abbreviations.
- Place special or unusual abbreviations in parentheses after spelling them the first time they appear.
- Use numerals to indicate numbers, except to begin sentences.
- Use only generic names of drugs, material, devices, and equipment.

c. description du programme ou de l'activité d'éducation
d. résultat et évaluation (le cas échéant)
e. importance et utilité du programme ou de l'activité pour les pharmaciens.

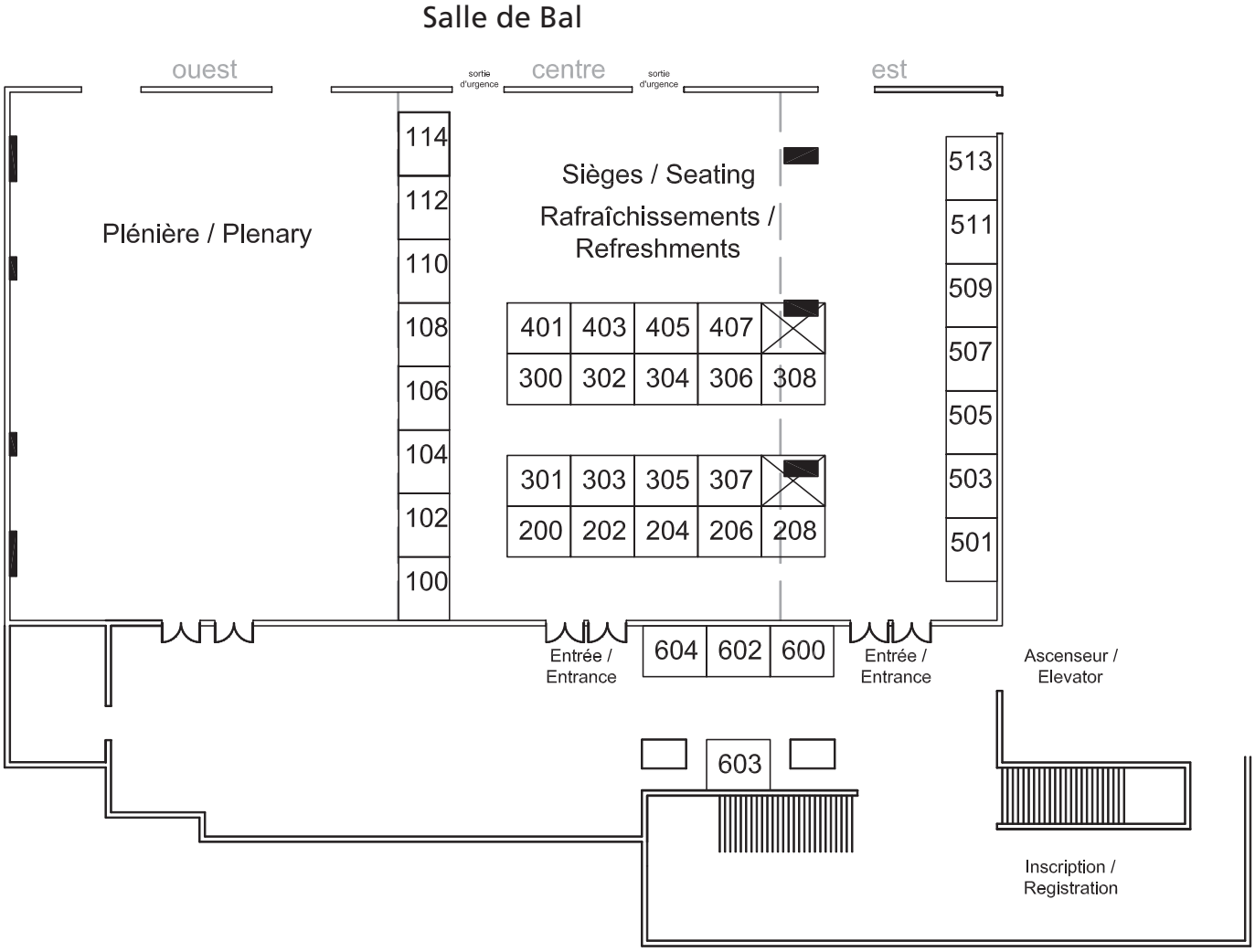
Initiative de sécurité pharmaceutique :

a. raison de l'initiative
b. description de l'initiative
c. évaluation de l'initiative (le cas échéant)
d. importance et utilité de l'initiative pour les pharmaciens.

Mise en page du résumé

- Police recommandée : Times 12.
- Dans le titre, n'utilisez les majuscules que là où elles s'imposent.
- Indiquez le nom de l'auteur-présentateur d'abord.
- Indiquez l'affiliation à un établissement et la ville de chaque auteur.
- Le résumé doit se limiter à 300 mots (sans inclure le titre et les auteurs).
- Un tableau vaut 30 mots.
- Un graphique vaut 60 mots.
- Pas de retrait au début d'un paragraphe.
- Utilisez les abréviations normalisées.
- Placez les abréviations spéciales ou inhabituelles entre parenthèses après le nom au long la première fois qu'elles figurent dans le texte.
- Utilisez la numération décimale pour indiquer les nombres, sauf en début de phrase.
- Utilisez uniquement les noms génériques des médicaments, de l'équipement, des appareils et des dispositifs.

Exhibitor Hall Floor Plan/Plan du hall d'exposition



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Apotex Inc.	509
AstraZeneca Canada Inc.	405
AutoMed Canada	511/513
Baxter Corporation	106
Bayer Healthcare	304
Berlex Canada Inc.	604
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Fresenius Kabi Canada	206
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Cardinal Healthcare	108/110
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Genpharm Inc.	208
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PrPlavix®

clopidogrel 75mg

PRESCRIBING INFORMATION

PrPLAVIX

clopidogrel bisulfate tablets
(equivalent to clopidogrel 75 mg)

THERAPEUTIC CLASSIFICATION

Platelet Aggregation Inhibitor

INDICATIONS AND CLINICAL USE

MI, Stroke or Established Peripheral Arterial Disease: PLAVIX (clopidogrel bisulfate) is indicated for the secondary prevention of atherothrombotic events (myocardial infarction, stroke and vascular death) in patients with atherosclerosis documented by stroke, myocardial infarction, or established peripheral arterial disease.

Acute Coronary Syndrome: PLAVIX, in combination with ASA, is indicated for the early and long-term secondary prevention of atherothrombotic events (myocardial infarction, ischemic stroke, cardiovascular death and/or refractory ischemia) in patients with acute coronary syndromes without ST-segment elevation (i.e., unstable angina or non-Q-wave myocardial infarction). These benefits of PLAVIX have been shown only when these patients were concomitantly treated with ASA in addition to other standard therapies. These benefits were also seen in patients who were managed medically and those who were managed with percutaneous coronary intervention (with or without stent) or CABG (coronary artery bypass graft).

Pediatrics (<18 years of age) No data available.

CONTRAINDICATIONS

Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the "**DOSAGE FORMS, COMPOSITION AND PACKAGING**" section of the Product Monograph. Active bleeding such as peptic ulcer and intracranial hemorrhage. Significant liver impairment or cholestatic jaundice.

WARNINGS AND PRECAUTIONS

Warnings and Precautions are listed in alphabetical order

General: As with other antiplatelet agents, when considering prescribing PLAVIX (clopidogrel bisulfate), physicians should inquire whether the patient has a history of bleeding. Clopidogrel should be used with caution in patients who may be at risk of increased bleeding from recent trauma, surgery or other pathological condition(s). If a patient is to undergo elective surgery, consideration should be given to discontinue PLAVIX 5 to 7 days prior to surgery to allow for the reversal of the effect. Platelet transfusion may be used to reverse the pharmacological effects of PLAVIX when quick reversal is required.

Gastrointestinal

Active GI Lesions: PLAVIX (clopidogrel bisulfate) prolongs bleeding time. Although PLAVIX has shown a lower incidence of gastrointestinal bleeding compared to ASA in a large controlled clinical trial (CAPRIE), PLAVIX should not be used in patients who have lesions with a propensity to bleed. In CURE, the incidence of major GI bleeding was 1.3% versus 0.7% (PLAVIX + ASA versus placebo + ASA, respectively). In patients taking PLAVIX, drugs that might induce GI lesions should be used with caution.

Hematologic

Thrombotic Thrombocytopenic Purpura (TTP): Thrombotic thrombocytopenic purpura (TTP) has been reported rarely following the use of PLAVIX, but it can occur anytime during the first year of exposure. Few cases have been reported after more than 1 year of exposure. TTP is a potentially fatal condition requiring prompt treatment with plasmapheresis. It is characterized by thrombocytopenia, microangiopathic hemolytic anemia (schistocytes [fragmented RBCs] seen on peripheral smear), neurological findings, renal dysfunction, and fever. TTP was not seen during clinical trials which included over 17,500 clopidogrel-treated patients. The incidence of reported TTP in worldwide postmarketing experience has been about 4 reported cases per million patients exposed, which is about 11 cases per million patient-years. The background rate of TTP in the general population is thought to be about 4 cases per million person-years.

Hepatic/Biliary/Pancreatic: Experience is limited in patients with moderate hepatic impairment who may have bleeding diatheses. As with any patient exhibiting hepatic impairment, liver function should be carefully monitored and PLAVIX should be used with caution. In the CAPRIE study, there were 344 hepatically impaired patients (Alkaline phosphatase >300 U/L, or ALT>120 U/L, or AST>75 U/L) and 168 received clopidogrel for a mean duration of 18 months. The adverse events were more common in this population, compared to the rest of the CAPRIE population, and more common in the clopidogrel (n=168) than in the ASA (n=176) group (any bleeding disorders, n=17 vs. n=14; any rash, n=11 vs. n=6; diarrhea, n=8 vs. n=3, respectively).

Perioperative Considerations: If a patient is to undergo elective surgery, consideration should be given to discontinue PLAVIX 5 to 7 days prior to surgery to allow for a reversal of its effect. Clopidogrel should be used with caution in patients who may be at risk of increased bleeding from recent surgery.

Renal: Therapeutic experience with clopidogrel is limited in patients with severe and moderate renal impairment. Therefore PLAVIX should be used with caution in these patients.

Special Populations

Pregnant Women: There are no adequate and well-controlled studies in pregnant women. Reproduction studies have been performed in rats at doses up to 500 mg/kg per day and in rabbits at doses up to 300 mg/kg per day and have revealed no evidence of impaired fertility or harm to the fetus due to clopidogrel. Because animal reproduction studies are not always predictive of a human response, PLAVIX should be used during pregnancy only if the potential benefits outweigh the potential risks to the fetus.

Nursing Women: Studies in rats have shown that clopidogrel and/or its metabolites are excreted in milk. Therefore, clopidogrel should not be used by lactating women.

Pediatrics (<18 years of age): Safety and effectiveness in subjects below the age of 18 have not been established.

ADVERSE REACTIONS

Adverse Drug Reaction Overview: The safety profile of clopidogrel has been evaluated in clinical trials in more than 17,500 patients and further assessed during postmarketing experience. Of the patients who participated in 2 large double-blind international clinical trials, CURE and CAPRIE, approximately 50% were elderly patients (>65 years) and 9000 patients were treated for 1 year or more. The most frequent adverse drug reactions (≥1%) with PLAVIX (with or without associated ASA) pooled from CURE and CAPRIE were hemorrhage and bleeding disorders (7.72%) including purpura (2.26%); any rash (1.68%); dyspepsia (2.02%), abdominal pain (1.82%) and diarrhea (1.09%) (see "**Clinical Trial Adverse Drug Reactions**"). The most serious adverse drug reactions pooled from CURE and CAPRIE were bleeding and clotting disorders (1.48%) including gastrointestinal hemorrhage (0.54%), hemorrhagic ulcer (0.13%) and hemothorax (0.01%); blood disorders: agranulocytosis/granulocytopenia (0.05%), thrombocytopenia (0.07%) and aplastic anemia (0.01%); skin disorders: any rash (0.08%) and bullous eruption (0.01%). The overall incidence of study drug discontinuation because of adverse events was similar in both groups in CAPRIE (PLAVIX 11.9% and ASA 11.9%). In CURE, study drug discontinuation occurred in 5.8% of patients with PLAVIX plus ASA and 3.9% of patients with placebo plus ASA.

Clinical Trial Adverse Drug Reactions: Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

CAPRIE: With few exceptions (see Table 1) the overall tolerability of PLAVIX was similar regardless of age, sex and race. However, in women there was a slightly higher incidence of bleeding disorders in the clopidogrel group (11.36% vs 9.88%).

Clinically Important Adverse Events: The clinically important adverse events observed in CAPRIE were the following: *Neutropenia and thrombocytopenia:* Although these events were observed, PLAVIX was not associated with an increase in the incidence of neutropenia or thrombocytopenia. *Granulocytopenia:* Granulocytopenia (<1200/mm^3) occurred in 8 patients taking PLAVIX and 14 patients taking ASA. Among those, severe granulocytopenia (<450/mm^3) was observed in 4 patients (0.04%) that received PLAVIX and 2 patients (0.02%) that received ASA. Two of the 9599 patients who received PLAVIX had neutrophil counts of zero. None of the 9586 patients who received ASA had neutrophil counts of zero. Although the risk of myelotoxicity with clopidogrel appears to be quite low, this possibility should be considered when a patient receiving clopidogrel demonstrates fever or other signs of infection. One case of aplastic anemia occurred on clopidogrel treatment. *Bleeding and clotting disorders*: One case of Henoch-Schonlein purpura (acute visceral symptoms: vomiting, diarrhea, abdominal distension, hematuria, renal colic) was reported in a patient taking PLAVIX. The patient recovered without sequelae within 1 month. Rare cases of platelet count ≤30,000/mm^3 have been reported. *Skin disorders*: There was no notable difference between treatment groups in the incidence of bullous eruptions (0.23% PLAVIX vs. 0.16% ASA). One case of a severe bullous eruption was reported in a patient taking PLAVIX. *Hepatic and biliary disorders*: The overall incidence of hepatic and biliary disorders was similar in patients treated with clopidogrel (3.5%) compared to ASA (3.4%). The most frequent events were increased liver enzymes and bilirubinemia. A summary of the clinically relevant adverse effects observed in CAPRIE are presented in Table 1. In CAPRIE, patients with a known intolerance to ASA were excluded from the study.

Table 1: Summary of Adverse Events – CAPRIE Trial

Adverse Event	PLAVIX (%) (n=9599)	ASA (%) (n=9586)
Hemorrhages or bleeding		
– intracranial hemorrhage	0.4	0.5
– gastrointestinal hemorrhage	2.0	2.7*
– requiring hospitalization	0.7	1.1
– purpura (primarily bruising and ecchymosis)	5.3*	3.7
– epistaxis	2.9	2.5
– eye bleeding	0.8	0.5
– with conjunctival†	0.3	0.2
– with sequelae†	0.1	0.1
Platelet		
– severe thrombocytopenia (0≤x<80,000/mm^3)	0.1	0.1
– thrombocytopenia (0≤x<100,000/mm^3)	0.2	0.2
Skin		
– rash	4.2*	3.5
– severe†	0.1	0.1
– leading to discontinuation†	0.5	0.2
– pruritus	3.3*	1.6
Gastrointestinal		
– peptic, gastric, duodenal ulcer	0.7	1.2
– diarrhea	4.5*	3.4
– severe†	0.2	0.1
– leading to discontinuation†	0.4	0.3
– dyspepsia	5.2	6.1*
– constipation	2.4	3.3*
– stomatitis	0.2	0.1
– nausea	3.4	3.8
– abdominal pain	5.6	7.1*
– gastritis	0.8	1.3*
Cardiovascular		
– heart and rhythm disorder	4.3	5.0*
– pulmonary embolism	0.4	0.2
Sensitivity/resistance		
– allergic reaction	0.9	1.0
Body as a whole		
– influenza-like symptoms	7.5	7.0
– fatigue	3.3	3.4
– pain	6.4	6.3
– headache	7.6	7.2
– coughing	3.1	2.7

* Statistically significant difference between treatments (p≤0.05).
† Patients may be included in more than 1 category.

The numbers of patients discontinuing due to adverse reactions in CAPRIE are shown in Table 2.

Table 2: Patients Discontinued Because of Adverse Experiences in CAPRIE (Percentage of Patients)

	Study drug permanently discontinued	
Adverse Experience	PLAVIX (%) (n=9599)	ASA (%) (n=9586)
Rash	0.9	0.41*
Diarrhea	0.42	0.27
Indigestion/nausea/vomiting	1.9	2.41*
Any bleeding disorder	1.2	1.37
Intracranial hemorrhage	0.21	0.33
Gastrointestinal hemorrhage	0.52	0.93*
Abnormal liver function	0.23	0.29

* Statistically significant, p<0.05.

CURE

The clinically important adverse events observed in CURE are shown in Table 3.

Table 3: Summary of Adverse Events – CURE Trial

Adverse Event	PLAVIX + ASA (%) (n=6256)	Placebo + ASA (%) (n=6303)
Hematologic		
Thrombocytopenia	0.3	0.4
Neutropenia	<0.1	<0.1
Gastrointestinal		
– leading to discontinuation	0.9	0.8
Abdominal pain, dyspepsia, gastritis, constipation	11.7	12.5
Peptic, gastric, duodenal ulcer	0.4	0.3
Diarrhea	2.1	2.2
Skin		
Rash or other skin disorders	4.0	3.5
– leading to discontinuation	0.7	0.3

In CURE, PLAVIX was given with ASA and was not associated with a significant increase in life-threatening or fatal bleeds compared to placebo given with ASA; the incidences of non-life-threatening major bleeding and minor bleeding were significantly larger in the PLAVIX + ASA group. The incidence of intracranial hemorrhage was 0.1% in both groups. The principal sites for major bleeding were primarily gastrointestinal and at arterial puncture sites. In patients receiving both PLAVIX and ASA in CURE, the incidence of bleeding is described in Table 4.

Table 4: Incidence of Bleeding Complications (% Patients) – CURE Trial

Event	PLAVIX + ASA* (n=6256)	Placebo + ASA* (n=6303)	p value
Life-threatening bleeding	2.2	1.8	0.13
Fatal	0.2	0.2	
5 g/dL hemoglobin drop	0.9	0.9	
Requiring surgical intervention	0.7	0.7	
Hemorrhagic strokes	0.1	0.1	
Requiring inotropes	0.5	0.5	
Requiring transfusions (≥4 units)	1.2	1.0	
Other major bleeding	1.6	1.0	0.005
Significantly disabling	0.4	0.3	
Intraocular bleeding with significant loss of vision	0.05	0.03	
Requiring 2 or 3 units of blood	1.3	0.9	
Major bleeding†	3.7‡	2.7§	0.001
Minor bleeding¶	5.1	2.4	<0.001
Total with bleeding complications	8.5	5.0	<0.001

* Other standard therapies were used as appropriate. All patients received ASA 75–325 mg daily (mean = 160 mg).
† Life-threatening and other major bleeding necessitating transfusion of ≥2 units of blood.
‡ Major bleeding event rate for PLAVIX + ASA was dose-dependent on ASA: <100 mg = 2.6%; 100–200 mg = 3.5%; >200 mg = 4.9%.
§ Major bleeding event rate for placebo + ASA was dose-dependent on ASA: <100 mg = 2.0%; 100–200 mg = 2.3%; >200 mg = 4.0%.
¶ Led to interruption of study medication.

The number of patients with bleeding that met the criteria for major bleeding established by the Thrombolysis in Myocardial Infarction (TIMI) trial was 68 (1.09%) in the clopidogrel group and 73 (1.16%) in the placebo group (relative risk, 0.94; p=0.70). The number with bleeding that met the criteria for life-threatening or severe bleeding established by the Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries (GUSTO) trial was 78 in the clopidogrel group and 70 in the placebo group (relative risk, 1.12; p=0.48). Some patients had more than one bleeding episode. Ninety-two percent (92%) of the patients in the CURE study received unfractionated or low molecular weight heparin, and the rate of bleeding in these patients was similar to the overall results. There was no excess in major bleeds within 7 days after coronary bypass graft surgery in patients who stopped therapy more than 5 days prior to surgery (event rate 4.6% PLAVIX + ASA; 5.5% placebo + ASA). In patients who remained on therapy within 5 days of bypass graft surgery, the event rate was 8.9% for PLAVIX + ASA, and 6.2% for placebo + ASA, which was not significantly different.

Thrombocytopenia: In CURE, the number of patients with thrombocytopenia (19 PLAVIX + ASA vs. 24 placebo + ASA) or neutropenia (3 vs. 3) was similar.

Gastrointestinal: In the CURE trial, the incidence of gastrointestinal events (e.g., abdominal pain, dyspepsia, gastritis and constipation) for patients receiving PLAVIX + ASA was 11.7% compared to 12.5% for those receiving placebo + ASA. The incidence of peptic, gastric or duodenal ulcers was 0.4% for PLAVIX + ASA and 0.3% for placebo + ASA. The incidence of diarrhea for patients receiving PLAVIX + ASA was 2.1% compared to 2.2% for those receiving placebo + ASA. The incidence of patients withdrawing from treatment because of gastrointestinal adverse reactions was 0.9% for PLAVIX + ASA compared with 0.8% for placebo + ASA.

Rash and Other Skin Disorders: In the CURE trial, the incidence of rash or other skin disorders in patients receiving PLAVIX + ASA was

4.0% compared to 3.5% for those receiving placebo + ASA. In the CURE trial, the incidence of patients withdrawing because of skin and appendage disorder adverse reactions was 0.7% for PLAVIX + ASA compared with 0.3% for placebo + ASA. Other clinically relevant adverse drug reactions pooled from CAPRIE and CURE studies with an incidence >0.1% as well as serious and relevant adverse drug reactions with an incidence <0.1% are presented below:
Central and Peripheral Nervous System Disorders: Uncommon: dizziness and paraesthesia. Rare: vertigo.
Platelet Bleeding and Clotting Disorders: Uncommon: bleeding time increased, platelets decreased.
White Cell and RES Disorders: Uncommon: leucopenia, neotrophils decreased, eosinophilia.
Postmarket Adverse Drug Reactions: The following additional adverse reactions were reported in marketed use, however a causal relationship with clopidogrel has not been clearly established. *Blood and lymphatic system disorders:* Very rare: serious cases of bleeding, mainly skin, musculoskeletal, eye (conjuctival, ocular, retinal) and respiratory tract bleeding, epistaxis, hematuria and hemorrhage of operative wound, hematoma; cases of bleeding with fatal outcome (especially intracranial, gastrointestinal and retroperitoneal hemorrhage).Very rare: agranulocytosis, aplastic anemia/pancytopenia, thrombotic thrombocytopenic purpura (TTP). Some cases of TTP resulted in fatal outcomes (see "**WARNINGS AND PRECAUTIONS**"). TTP was not observed in clinical studies involving more than 11,300 patients receiving clopidogrel (including over 7000 patients treated for 1 year or more). *Cardiovascular disorders:* Very rare: hypotension, often related to bleeding or allergic reaction. *Immune system disorders:* Very rare: anaphylactoid reactions. *Psychiatric disorders:* Very rare: confusion, hallucinations. *Nervous system disorders:* Very rare: taste disturbances. *Vascular disorders:* Very rare: vasculitis. *Respiratory, thoracic and mediastinal disorders:* Very rare: bronchospasm. *Gastrointestinal disorders:* Very rare: colitis (including ulcerative or lymphocytic colitis), pancreatitis. *Hepatobiliary disorders:* Very rare: hepatitis, abnormal liver function test. *Skin and subcutaneous tissue disorders:* Very rare: Maculopapular or erythematous rash, urticaria, pruritus, angioedema, bullous dermatitis (erythema multiforme, Stevens-Johnson syndrome, eczema, lichen planus). *Musculoskeletal connective tissue and bone disorders:* Very rare: arthralgia, arthritis, myalgia. *Renal and urinary disorders:* Very rare: glomerulopathy, elevated blood creatinine. *General disorders and administration site conditions:* Very rare: fever.

DRUG INTERACTIONS

Overview: *Anticoagulant drugs* In view of the possible increased risk of bleeding, anticoagulant drugs should be used with caution as tolerance and safety of simultaneous administration with clopidogrel has not been established. Risk factors should be assessed for individual patients before using clopidogrel. Because of the increased risk of bleeding, the concomitant administration of warfarin with clopidogrel should be undertaken with caution. Clinically significant adverse interactions were not detected in the CAPRIE, and/or CURE studies where patients received a variety of concomitant medications including ASA, diuretics, beta-blocking agents, angiotensin converting enzyme (ACE) inhibitors, calcium channel blockers, lipid-lowering agents, coronary vasodilators, antidiabetic agents (including insulin), antiepileptic agents, hormone replacement therapy, unfractionated and/or LMW heparin, and glycoprotein IIb/IIIa inhibitors. A review of the clinical trial data indicates that there is no evidence of an interaction between PLAVIX and atorvastatin. In CAPRIE, patients on HMG CoA reductase inhibitors and clopidogrel experienced a higher incidence of bleeding events (primarily epistaxis). Patients on HMG CoA reductase inhibitors and ASA experienced a higher incidence of intracranial hemorrhage. There is no known pathophysiological or pharmacological explanation for this observation. At high concentrations in vitro, clopidogrel inhibits isoenzyme CYP 2C9 of the cytochrome P450 system. Accordingly, PLAVIX is unlikely to interfere with the metabolism of drugs such as phenytoin, tamoxifen, tolbutamide, warfarin, torsemide, fluvastatin, and many non-steroidal anti-inflammatory agents. There are no data with which to predict the magnitude of these interactions. Caution should be used when any of these drugs is coadministered with PLAVIX. No clinically significant pharmacodynamic interactions were observed when clopidogrel was coadministered in clinical studies to investigate drug interaction with atenolol, nifedipine, or both atenolol and nifedipine. The pharmacodynamic activity of PLAVIX was slightly enhanced by the coadministration of phenobarbital, however this was not considered to be clinically significant. Pharmacodynamic activity of PLAVIX was not changed with the coadministration of cimetidine. Pharmacodynamic activity of PLAVIX was not significantly influenced by the coadministration of estrogen.
Drug-Drug Interactions: The drugs listed in this Table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Table 5: Established or Potential Drug-Drug Interactions

Agent	Ref	Effect	Clinical Comment
ASA	CT	Potentiated effect of ASA on collagen-induced platelet aggregation	ASA (2 x 500 mg once) did not modify clopidogrel-mediated inhibition of ADP induced platelet aggregation. PLAVIX (75 mg) and ASA (75–325 mg) have been administered together for up to 1 year.
NSAIDs	T	Increase occult gastrointestinal blood loss (with naproxen coadministration)	Potential increased risk of gastrointestinal bleeding with concomitant administration of NSAIDs.
Injectable Anticoagulants (Heparin)	CT	No effect	Clopidogrel at steady state did not modify effect of heparin on coagulation in healthy volunteers. Coadministration of heparin had no effect on platelet aggregation inhibition induced by PLAVIX.

Table 5: Established or Potential Drug-Drug Interactions (Cont'd.)

Agent	Ref	Effect	Clinical Comment
Oral Anticoagulants (Warfarin)	T		Because of the increased risk of bleeding, the concomitant administration of warfarin with clopidogrel should be undertaken with caution. (See "**WARNINGS AND PRECAUTIONS**").
Digoxin, Theophylline, Antacids	CT	No effect	There was no modification of the pharmacokinetics of digoxin or theophylline with the coadministration of PLAVIX at steady state. Antacids did not modify the extent of PLAVIX absorption.
Atenolol, Nifedipine	CT	No effect	No clinically significant pharmacodynamic interactions observed, with atenolol, nifedipine or both atenolol and nifedipine.
Phenobarbitol	CT	Slight increase pharmaco-dynamic activity of PLAVIX	Increase not considered clinically significant.
Cimetidine	CT	No effect	Pharmacodynamic activity of PLAVIX not changed with coadministration.
Estrogens	CT	No effect	Pharmacodynamic activity of PLAVIX not significantly influenced by coadministration.

Legend: C = Case Study; CT = Clinical Trial; T = Theoretical

Food or Herbal Product Interactions: There is no interaction of PLAVIX with food since administration of PLAVIX with meals did not significantly modify the bioavailability of clopidogrel. Interactions with herbal products have not been established.
Drug-Laboratory Interactions: None known.

OVERDOSAGE

Overdose following clopidogrel administration may lead to prolonged bleeding time and subsequent bleeding complications. Appropriate therapy should be considered if bleeding is observed or suspected. A single oral dose of clopidogrel at 1500 or 2000 mg/kg was lethal to mice and rats, and at 3000 mg/kg to baboons.
Treatment: No antidote to the pharmacological activity of clopidogrel has been found. Platelet transfusion may be used to reverse the pharmacological effects of PLAVIX when quick reversal is required.

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment
MI, Stroke or Established Peripheral Arterial Disease: The recommended dose of PLAVIX is 75 mg once daily long term with or without food.
Acute Coronary Syndrome: PLAVIX should be initiated with a 300 mg loading dose and continued long term at 75 mg once a day with ASA (80 mg–325 mg daily). No dosage adjustment is necessary for elderly patients or patients with renal impairment.
Missed Dose: If a dose of PLAVIX is missed, it should be taken as soon as possible. However, if it is close to the time of the next dose, disregard the missed dose and return to the regular dosing schedule. Do not double dose.

STORAGE AND STABILITY

For blisters, store between 15º and 30ºC and protect from moisture. For bottles, store between 15º and 30ºC.

SPECIAL HANDLING INSTRUCTIONS

None.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage Forms: PLAVIX is available as pink, round, slightly biconvex, film-coated tablets engraved with "75" on one side and "1171" on the other side.
Composition: Each 75 mg tablet contains 97.9 mg of clopidogrel bisulfate which is the molar equivalent of 75 mg of clopidogrel base. Nonmedicinal ingredients: mannitol, microcrystalline cellulose, low substituted hydroxypropylcellulose, polyethylene glycol 6000, and hydrogenated castor oil. The pink film coating contains lactose, hypromellose, titanium dioxide, triacetin and red iron oxide. The tablets are polished with Carnauba wax.
Packaging: PLAVIX is available in cartons containing a blister of 28 tablets and bottles containing 500 tablets.

Product Monograph available upon request.

REFERENCE:
1. PLAVIX Product Monograph.

An agreement between Bristol-Myers Squibb and sanofi-aventis for the codevelopment and marketing of irbesartan and clopidogrel, two compounds from sanofi-aventis research.

sanofi aventis

Bristol-Myers Squibb
Pharmaceutical Group

Member
PAAB R&D

LIPITOR atorvastatin calcium tablets

power** you can **trust™

PrLIPITOR* (atorvastatin calcium) 10 mg, 20 mg, 40 mg and 80 mg tablets

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 in the pediatric patient

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). 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.

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)]

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 **REFERENCES**).

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 at least 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.

LIPITOR is also indicated to reduce the risk of myocardial infarction and stroke in adult patients with type 2 diabetes mellitus and hypertension without clinically evident coronary heart disease, but with other risk factors such as age ≥55 years, retinopathy, albuminuria or smoking.

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; PRECAUTIONS – Pharmacokinetic Interaction Studies and Potential Drug Interactions, Cytochrome P-450-mediated Interactions**).

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 kinase (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 CPK levels occur or myopathy is diagnosed or suspected. The risk of myopathy and rhabdomyolysis during treatment with HMG-CoA reductase inhibitors is increased with concurrent administration of cyclosporin, 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; 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 – Pharmacokinetic Interaction Studies and Potential 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 **PRECAUTIONS – 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, Endocrine Function; DOSAGE AND ADMINISTRATION**).

Terfenadine: 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 CYP 3A4 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 CYP 3A4 inhibitor, and atorvastatin (10 mg QD) resulted in increased plasma concentrations of atorvastatin. AUC and C_{max} of atorvastatin were increased by 74% and 122% respectively.

Patients with Severe Hypercholesterolemia

Higher drug dosages (80 mg/day) required for some patients with severe hypercholesterolemia (including familial hypercholesterolemia) are associated with increased plasma levels of atorvastatin. **Caution should be exercised in such patients who are also severely renally impaired, elderly, or are concomitantly being administered digoxin or CYP 3A4 inhibitors** (see **WARNINGS – Pharmacokinetic Interactions, Muscle Effects; PRECAUTIONS – Pharmacokinetic Interaction Studies and Potential Drug Interactions; DOSAGE AND ADMINISTRATION**).

Drug/Laboratory Test Interactions

LIPITOR may elevate serum transaminase and creatine kinase 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. The 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 kinase. 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-Market Adverse Drug Reaction: 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, Pharmacokinetic Interaction Studies and Potential Drug Interactions**). Isolated reports: Gynecomastia, thrombocytopenia, arthralgia and allergic reactions including urticaria, angioneurotic edema, anaphylaxis and bullous rashes (including erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis) and fatigue. These may have no causal relationship to atorvastatin.

Abnormal Hematologic and Clinical Chemistry Findings

Ophthalmologic observations: see **PRECAUTIONS**.

Laboratory Tests: Increases in serum transaminase levels have been noted in clinical trials (see **PRECAUTIONS**).

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 patient's LDL-C reduction required (see Tables 1 and 2). 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

Note: LDL-C = low-density lipoprotein cholesterol.

† 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 – Pharmacokinetic Interaction Studies and Potential 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 (National Cholesterol Education Program) 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/Laboratory Test 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.

1. Friedewald WT, *et al. Clin Chem* 1972;18(6):489-502.

For a copy of the Product Monograph or full Prescribing Information, please contact:

Pfizer Canada Inc.
Kirkland, Quebec
H9J 2M5

Life is our life's work

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.

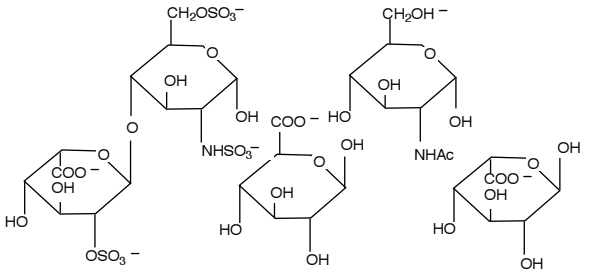
PHARMACEUTICAL INFORMATION

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.

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the sun would always shine, and no one would ever get ill.

Unfortunately it's not a perfect world. You know it and we know it. That is why important drugs like Heparin are available to you and your patients.

Heparin is now available from Pharmaceutical Partners of Canada. It is manufactured to USP Standards, and we're producing it on a continuous, reliable basis. As for our experience, PPC's supplier has been producing high quality Heparin in the U.S. for 15 years. That's a track record you can feel good about.

PPC's goal is to provide a dependable supply of quality products, always competitively priced.

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

PPC

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