THE
SKY'S THE
LIMIT

CJHP
JCPH

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Le journal canadien de la pharmacie hospitalière

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AOÛT 2007

REGARDER
L'HORIZON,
C'EST
REGARDER
L O I N

60th AGM & EDUCATIONAL SESSIONS

60e AGA ET SÉANCES ÉDUCATIVES

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

60 YEARS ANS 1947·2007

CSHP
REGINA AGM 2007

Introducing
Pr Fludarabine Phosphate for Injection

A generic alternative to Fludara®...

FLUDARABINE PHOSPHATE FOR INJECTION is indicated for: Second line therapy in patients with chronic lymphocytic leukemia (CLL) and low-grade non-Hodgkin's lymphoma (Lg-NHL) who have failed other conventional therapies. Such patients should be treated only by physicians skilled in the use of chemotherapeutic agents.

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As we look to the future, we are proud to add Fludarabine Phosphate for Injection to our list of accomplishments. Teva Novopharm is part of Teva Pharmaceutical Industries Ltd., one of the world's largest generic pharmaceutical manufacturers.

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PAAB

Dear Colleague:

It is with great pleasure that we invite you to join us at the Annual General Meeting and Educational Sessions of the Canadian Society of Hospital Pharmacists (CSHP) in Regina, Saskatchewan, where "The Sky's the Limit", from August 11 to 14, 2007. This year CSHP will be celebrating its 60th anniversary!

The Educational Services Committee, chaired by Olavo Fernandes, has assembled a fantastic educational program that includes sessions such as *Prescribing by Pharmacists in Alberta: Where are we Now?; CSHP Hospital Pharmacy Management Leadership Survey Results; The Bottom Line on Dyslipidemia Treatment for Pharmacists; and Moving Forward: Pharmacy Human Resources for the Future.*

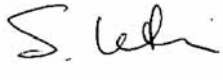
Included in our exhibit program again this year is the booth decoration contest. Premiering August 12 and 13, participating exhibitors will decorate their booths to reflect the new James Bond 007 movie, "The Sky's the Limit". Please take time to visit the exhibit hall to gain from the exhibitors' expertise and acknowledge the tremendous support they provide for our event. Members can participate in Host Committee events and win great prizes while networking and seeing the exhibitors' latest products and services.

The 2007 Annual General Meeting is scheduled for Sunday, August 12, at 3:00 pm. The AGM provides all members with an opportunity to hear about the many significant initiatives to advance hospital pharmacy that CSHP has participated in during the past year and is planning for the coming year. Reports from CSHP Council will include updates on the activities of our branches, committees, and task forces, including an update on CSHP's advocacy initiatives. A final status update on the 2003-2007 Strategic Plan will be provided, and the new 2007-2010 Strategic Plan will be unveiled. The Wine and Chat immediately following the AGM offers an informal opportunity for discussion with CSHP's Council and staff. It is 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 11 with the 12th Annual CSHP Research and Education (R&E) Foundation Fundraising Golf Tournament, to be held at Deer Valley Golf Course and Estates. All profits from this event will be donated to the R&E Foundation, supporting the practice-based research initiatives and targeted education programs undertaken by CSHP members. Register early as this event fills up fast!

The Regina Host Committee, co-chaired by Monica Lawrence and Doug Sellinger, has organized many other social activities, including an early morning Fun Run/Walk followed by breakfast catered by The Willow on Wascana; Fun Night at the Saskatchewan Science Centre; and our annual Past Presidents' Dinner and Dance at the Conexus Arts Centre. The efforts of this year's Host Committee guarantee a memorable time.

Join us in **Regina at AGM 2007 where "The Sky's the Limit"!** We look forward to seeing you there and sharing the fun.



Shallen Letwin
BScPharm, PharmD, FCSHP
CSHP President

Myrella Roy
BScPharm, PharmD, FCCP
Executive Director

Cher collègue,

C'est avec grand plaisir que nous vous invitons à venir nous rencontrer pour l'Assemblée générale annuelle de la Société canadienne des pharmaciens d'hôpitaux et ses séances éducatives qui se tiendront à Régina en Saskatchewan, là où « Regarder l'horizon, c'est regarder loin », du 11 au 14 août 2007. Cette année, la SCPH célèbre son 60e anniversaire.

Le Comité des services éducatifs, présidé par Olavo Fernandes, a élaboré un fantastique programme de formation qui comprendra entre autres choses les séances suivantes : *« La rédaction d'ordonnances par le pharmacien en Alberta : Où en sommes-nous? »; « Les résultats du sondage de la SCPH sur le leadership en gestion de pharmacie hospitalière »; « L'essentiel sur le traitement des dyslipidémies, à l'usage du pharmacien »; et « Aller de l'avant : Une mise à jour sur le projet des Ressources humaines en pharmacie de l'avenir ».*

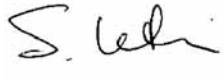
L'activité annuelle de décoration des kiosques fera à nouveau partie de notre programme d'exposition. Cette année, en première les 12 et 13 août, les exposants devront décorer leur kiosque sur le thème du nouveau film de l'agent James Bond 007, « The Sky's the Limit ». Nous vous encourageons à prendre le temps de visiter le hall d'exposition pour tirer avantage de l'expertise des exposants et reconnaître l'important soutien apporté par les fournisseurs à cet événement. 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 qu'offrent les exposants.

L'Assemblée générale annuelle 2007 se tiendra le dimanche 12 août à 15 h. Les membres pourront y recevoir de l'information sur les nombreux projets majeurs auxquels la Société a contribué au cours de la dernière année ou qui sont projetés pour l'année qui vient afin de faire progresser la pharmacie hospitalière. Le Conseil de la SCPH fera, entre autres choses, une mise à jour sur les activités menées par nos sections, nos comités et nos groupes de travail, incluant nos programmes de valorisation. Une mise à jour finale sur le plan stratégique 2003-2007 y sera présentée et notre nouveau plan stratégique pour les années 2007-2010 y sera dévoilé. Vous pourrez continuer de 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.

Cette année, les activités sociales commencent le 11 août avec le 12e tournoi de golf de la SCPH au profit de la Fondation pour la recherche et l'éducation qui se tiendra au « Dear Valley Golf Course and Estates ». Tous les profits de cet événement seront versés à la Fondation pour la recherche et l'éducation, en vue d'appuyer et de soutenir des projets de recherche fondés sur la pratique et des programmes ciblés de formation menés par des membres de la SCPH. Inscrivez-vous le plus tôt possible, car les places sont limitées!

Le comité organisateur de Régina, co-présidé par Monica Lawrence et Doug Sellinger, a arrangé plusieurs autres activités sociales dont une Course/marche pour lève-tôt suivie d'un petit déjeuner préparé par le « Willow on Wascana »; une Partie de plaisir au « Saskatchewan Science Centre »; ainsi que le Dîner dansant annuel des anciens présidents qui aura lieu au « Conexus Arts Centre ». Grâce aux efforts déployés par le Comité d'accueil de cette année, les moments que nous partagerons seront certainement mémorables.

Rendez-vous à **Régina pour l'AGA 2007, là où « Regarder l'horizon, c'est regarder loin »**. Nous sommes impatients de vous rencontrer et de passer de bons moments en votre compagnie.



Shallen Letwin
B Sc Pharm, Pharm D, FCSHP
Président de la SCPH

Myrella Roy
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Hospira

INTRODUCING

Pr Ceftriaxone
Sodium for Injection BP

Indications:

Ceftriaxone Sodium for Injection is indicated in the treatment of the following infections when caused by susceptible strains of the designated micro-organisms: lower respiratory tract infections, (complicated and uncomplicated), bacterial septicemia, skin and skin structure infections, bone and joint infections, intra-abdominal infections, meningitis and uncomplicated gonorrhea (cervical/urethral, pharyngeal and rectal). Please refer to the Indications and Clinical Uses section of the Product Monograph for the specific identification of causative organisms. Ceftriaxone Sodium may also be used as prophylaxis before vaginal or abdominal hysterectomy, coronary artery bypass surgery, or in patients at risk of infection undergoing biliary tract surgery.

Warning and precautions:

Ceftriaxone Sodium for Injection is contraindicated in patients with known allergy to Ceftriaxone, other cephalosporins or penicillins.

Pseudomembranous colitis has been reported with the use of Ceftriaxone Sodium for Injection. Mild cases of colitis may respond to drug discontinuation alone. Moderate to severe cases should be managed with fluid, electrolyte and protein supplementation as indicated.

*Product monograph and patient information are available upon request.

Complete product line

250mg Vial
1g Vial
2g Vial
10g Vial

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PD-198/1

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NEW CLINICAL DATA As referenced in new guideline recommendations

PrNEULASTA® *before* neutropenia.

A proactive approach to reducing the risk.[1,4]

- New consensus guidelines support the use of colony-stimulating factor (CSF) as primary prophylaxis when the risk of febrile neutropenia is approximately 20% (moderate risk)[3†‡]
- In a clinical study of breast cancer patients receiving docetaxel – a moderate-risk chemotherapy regimen – first- and subsequent-cycle Neulasta® reduced febrile neutropenia by 94% vs. placebo (1% vs. 17% for placebo, $p<0.001$)[1,4*]

Together for Life

AMGEN® Oncology

Neulasta® (pegfilgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs.[4]

Neulasta® is contraindicated in patients with known hypersensitivity to *E. coli*-derived proteins, pegfilgrastim, filgrastim, or any other component of the product. Neulasta® should not be used for PBPC mobilization. Very rare cases of splenic rupture have been reported following the administration of Neulasta.®[4]

The safety and efficacy of Neulasta® administered concurrently with cytotoxic chemotherapy, chemotherapy with delayed myelosuppression, or in patients receiving radiation therapy, have not been established. Neulasta® should not be administered in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy. Regular monitoring of hematocrit value, white blood cell count and platelet count

from the NCCN and ASCO[1-3]

is recommended. In all phase 2 and 3 trials, medullary bone pain, reported in 26% of patients, was the only consistently observed adverse reaction attributed to Neulasta® therapy.[4]

Product monograph available upon request.

† Regimens associated with an incidence of febrile neutropenia (temperature ≥ 38.2°C and ANC < 0.5 x 10^9/L) of approximately 20% in the absence of growth factor support.

‡ The use of regimens, if available, that do not require CSFs because of equal efficacy and lower risk of FN remains standard medical practice.

* Phase 3, multicentre, randomized, double-blind, placebo-controlled trial in patients with breast cancer (n=928) randomly assigned to placebo (n=465) or Neulasta® (n=463) on day 2 of each 21-day chemotherapy cycle of 100 mg/m² docetaxel. Patients who experienced febrile neutropenia in the double-blind phase were converted to open-label Neulasta® treatment for subsequent cycles of chemotherapy.

PAAB Member R&D

Neulasta®
(pegfilgrastim)
Right from the start.

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TRAMACET (tramadol hydrochloride/acetaminophen) is indicated for the short-term (5 days or less) management of acute pain. The recommended dose of TRAMACET is 1 or 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day. No overall differences with regard to safety or pharmacokinetics were noted between subjects ≥65 years of age and younger subjects. However, dose selection for an elderly patient should be cautious. Not recommended for patients under 18 years of age.

The most frequently reported events were in the central nervous and gastrointestinal systems.

TRAMACET is contraindicated in patients with a hypersensitivity to any component of the product and in any situation where opioids are contraindicated. It is not recommended for patients with liver disease.

TRAMACET should be used with caution in patients with increased intracranial pressure or head injury and in patients taking CNS depressants, SSRIs, neuroleptics (or anti-psychotics) and TCAs. It should be used with great caution in patients taking MAO inhibitors.

Patients with a history of anaphylactoid reactions to codeine and other opioids should not receive TRAMACET. Serious and, rarely, fatal anaphylactoid reactions have been reported in patients receiving tramadol.

Seizures have been reported in patients receiving tramadol within the recommended dose range.

Drug Abuse and Dependence Tramadol has a potential to cause psychic and physical dependence of the morphine-type (μ-opioid). The drug has been associated with craving, drug-seeking behaviour and tolerance development. Cases of abuse and dependence on tramadol have been reported. TRAMACET tablets should not be used in opioid-dependent patients. Tramadol can re-initiate physical dependence in patients that have been previously dependent or chronically using other opioids. Treatment with TRAMACET is not recommended in patients with a tendency to abuse drugs or a history of drug dependence, and in patients who are chronically using opioids.

Withdrawal Symptoms Withdrawal symptoms may occur if tramadol is discontinued abruptly. These symptoms may include anxiety, sweating, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, piloerection and, rarely, hallucinations. Other symptoms that have been seen less frequently with TRAMACET discontinuation include panic attacks, severe anxiety and paresthesias. Clinical experience suggests that withdrawal symptoms may be relieved by reinstitution of opioid therapy followed by a gradual, tapered dose reduction of the medication combined with symptomatic support. In patients with creatinine clearances of less than 30 mL/min, the dosing interval should be increased to not exceed 2 tablets every 12 hours. Dose selection for elderly patients should be cautious.

TRAMACET should not be used concomitantly with alcohol or with other products containing acetaminophen.

Please see TRAMACET Product Monograph for complete prescribing information.

REFERENCES: 1. TRAMACET (tramadol hydrochloride/acetaminophen) Product Monograph, JANSSEN-ORTHO Inc., July 2005. **2.** Smith AB, Ravikumar TS, et al. for the CAPSS-115 Study Group. Combination tramadol plus acetaminophen for postsurgical pain. *Am J Surg* 2004;187:521–7. **3.** IMS Correspondence dated March 15, 2005. **4.** Silverfield JC, Kamin M, et al. Tramadol/acetaminophen combination tablets for the treatment of osteoarthritis flare pain: a multicenter, outpatient, randomized, double-blind, placebo-controlled, parallel-group, add-on study. *Clin Ther* 2002;24(2):282-97.

TRAMACET* targets pain.

EXCELLENT EFFICACY AND SAFETY PROFILE

Pain relief with an excellent safety profile.

- Demonstrated efficacy in diverse patient types: osteoarthritis flare pain of the knee and hip, post-surgical (orthopedic and abdominal) and the elderly.[1¶]
- Excellent tolerability profile: low rates of constipation (5%), somnolence (9%) and vomiting (4%).[1]
- More than 400 million patient-days of experience worldwide.[3]
- Analgesia was rated "very good" or "good" in clinical trials for orthopedic or abdominal post-surgical pain and OA flare pain.[2,4†,α]

¶ TRAMACET 1 or 2 tablets (n = 69) significantly superior to placebo (n = 44) for pain relief ($p \leq 0.01$) in patients ≥65 years of age with OA flare pain.

† Multicentre, randomized, double-blind, active- and placebo-controlled trial in 305 orthopedic/abdominal post-surgical patients. Patients' overall medication assessments. TRAMACET group (n=98) vs. placebo (n=98), p=0.001: very good 41.9%, 22.7%; good 26.9%, 23.7%; no change 12.9%, 16.5%; poor 9.7%, 14.4%; very poor 9.7%, 22.7%.

α Multicenter, double-blind, placebo-controlled, randomized, parallel-group, add-on study of 10 days duration in 308 OA patients on NSAID or COX-2 selective inhibitor treatment. Patients' overall analgesic assessments. TRAMACET group (n=197) vs. placebo (n=111), p<0.001: very good 35.4%, 19.1%; good 45.6%, 37.3%; no change 13.3%, 31.8%; poor 2.1%, 4.5%; very poor 4.0%, 7.0%.

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PAAB Member R&D

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centrally acting analgesic

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The Hospital for Sick Children

The Royal Victoria Hospital of Barrie

Toronto East General Hospital

University Health Network

Vancouver Coastal Health-Providence Health Care Pharmacy Services

NEW CSHP SPONSORSHIP STRUCTURE

Starting with this year's AGM 2007 in Regina, CSHP's sponsorship structure will be changing.

New Time Frame!

All donations received within the previous calendar year will be included in the calculation of the sponsorship level.

For example, the sponsorship listing in the AGM 2007 final programme will reflect donations collected from January 1 to December 31, 2006.

New Levels!

Also new this year are the range of values associated with each sponsorship level.

New Addition!

Included in all totals will be donations given to CSHP branches.

NOUVELLE STRUCTURE DE COMMANDITE DE LA SCPH

À compter de l'AGA à Régina, cette année, la SCPH inaugurera une nouvelle structure de commandite.

Nouveau calendrier!

Tous les dons reçus au cours de l'année civile précédente seront comptabilisés pour déterminer l'échelon de commandite.

Par exemple, la liste de commandite dans le programme final de l'AGA 2007 reflètera les dons recueillis entre le premier janvier et le 31 décembre 2006.

Nouveaux échelons!

Notre structure de commandite étrenne aussi cette année une nouvelle échelle de valeurs.

Nouvelle addition!

Les dons remis aux sections de la SCPH seront dorénavant incorporés dans les totaux.

CSHP Sponsors 2006
Commanditaires de la SCPH en 2006

The following list reflects all CSHP sponsorship received from January 1 to December 31, 2006
La liste suivante reflète toutes les commandites reçues du premier janvier au 31 décembre 2006.

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$100 to $999

3M Canada Inc.
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Omega Laboratories Limited
Serono Canada Inc.

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 2007. The ESC is comprised of a core committee of 15 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 2007. Le Comité comprend 15 membres principaux et 8 membres correspondants des sections de la SCPH.

Goal and Objectives for the 2007 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 pharmacists' roles, pharmacy practice and pharmacy programs
- To promote life-long learning skills through active participation in problem-based workshops
- To provide registrants with networking and sharing opportunities through the exhibits program and poster sessions
- To provide an opportunity for Pharmacy Specialty Networks (PSN) to meet

But et objectifs du programme de l'AGA 2007

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 AGM

Air Canada and WestJet have been appointed the official airlines for CSHP's Annual General Meeting (AGM) 2007. Please quote the appropriate reference number when making your travel arrangements.

As an AGM 2007 registrant, you will be offered the best available fare on all flights booked through Air Canada Meetings and Conventions reservation service. Be sure to tell your travel agent to refer to JN9RMUE1 in reference to your ticket and you could receive up to 50% off.

With WestJet our members will receive 10% off all tickets booked using the convention number QC4415.

Comment se rendre à l'AGA

Air Canada et WestJet ont été désignés transporteurs officiels de l'Assemblée générale annuelle de la SCPH (AGA) 2007. Veuillez mentionner les numéros de référence appropriés lorsque vous voudrez réserver des sièges.

Les participants à l'AGA 2007 pourront profiter des meilleurs tarifs offerts pour tout vol réservé par l'entremise du service de réservation « Air Canada Réunions d'affaires et congrès ». Assurez-vous de dire à l'agent de voyage que le numéro de référence JN9RMUE1 s'applique à votre réservation et vous pourrez profiter d'un rabais pouvant s'élever jusqu'à 50 %.

Avec WestJet, nos membres recevront un rabais de 10 % sur tous les billets réservés en utilisant le code de congrès QC4415.

Continued on page 12
Suite à la page 12

Does your unit dose packaging offer all this?

Medi-Dose® does.

- ☑ Simple to Use–No Extensive Training Needed
- ☑ 1 and 2-dimensional barcoding–including NDC, Lot Numbers and Expiration Dating
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Medi-Dose works well in any pharmacy operation and can be used with all classifications of drugs (chemo meds, compounded drugs, controlled substances, etc). And it's affordably priced for all pharmacy budgets. For the best in manual unit dose packaging, ***check out Medi-Dose!***

Unit dose packaging the way it should be: Smart. Simple. Reliable.

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www.medidose.com

Continued from page 10

You can book your flight in four convenient ways:

1. Through UNIGLOBE PREMIER TRAVEL at 1-800-267-9372 or
2. Directly through Air Canada Convention Sales at 1-800-361-7585
3. Directly through WestJet Convention Sales at 1-877-952-4696 or
4. Through your travel agent quoting the above Reference Number.

Remember – you will continue to accumulate your travel plan points while assisting CSHP. By ensuring JN9RMUE1 (Air Canada) or QC4415 (WestJet) appears on your ticket, you help support your organization – in advance, we thank you.

Where to Stay for AGM?

Delta Regina

CSHP is pleased to offer a special room rate of $135.00 – single or double occupancy at the Delta Regina. All CSHP official conference related meetings will take place at this property. The Conference rate of $135.00 will be guaranteed until July 7, 2007. Don't miss out – make your reservation early. You may make your reservations through the Delta Regina central reservations office at (800) 209-3555. When doing so, please remember to make reference to CSHP AGM 2007 for your conference rate. You can reserve online by clicking "AGM 2007" at www.cshp.ca.

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 2007. Ticket sales are included on the AGM 2007 registration form. Tickets may be available on-site. Absolutely no tickets will be sold after 5 p.m. on Saturday, August 11. Thank you for your co-operation.

Suite de la page 10

Vous pouvez réserver votre vol de quatre façons commodes :

1. En appelant UNIGLOBE TRAVEL PREMIERE au 1 800 267-9372.
2. En appelant directement le service « Air Canada Réunions d'affaires et congrès » au 1 800 361-7585.
3. En appelant directement le service « WestJet Réunions d'affaires et congrès » au 1 877 952-4696.
4. En passant par votre propre agent de voyage et en spécifiant les numéros de référence mentionnés ci-dessus.

Souvenez-vous! Vous continuerez à accumuler des points dans votre compte de fidélisation tout en aidant la SCPH. En vous assurant que le numéro de référence JN9RMUE1 (Air Canada) et QC4415 (WestJet) est inscrit sur votre billet, vous contribuez au soutien de votre association. Nous vous en remercions à l'avance.

Où loger durant l'AGA?

Delta Regina

La SCPH est heureuse de vous offrir un tarif spécial de 135 $ pour une chambre en occupation simple ou double au Delta Regina. Toutes les réunions officielles du congrès de la SCPH se tiendront dans cet établissement hôtelier. Le tarif de 135$ du congrès est garanti jusqu'au 7 juillet 2007. Ne manquez pas cette occasion et effectuez votre réservation sans tarder en téléphonant au bureau central de réservations du Delta Regina au (800) 209-3555. Lorsque vous téléphonerez, n'oubliez pas de mentionner l'AGA 2007 de la SCPH pour vous prévaloir du tarif du congrès. Vous pouvez réserver en ligne en cliquant sur "AGM 2007" à www.cshp.ca.

Activités sociales de 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 2007. Vous pouvez vous procurer vos billets à l'avance en les commandant sur le formulaire d'inscription de l'AGA 2007. Les billets peuvent aussi être achetés sur place. Aucun billet ne sera vendu après 17h00 le samedi 11 août 2007. Merci de votre collaboration.

AGM 2007 at a Glance
L'AGA d'un coup d'oeil

Educational Sessions
Séances éducatives

Sun., Aug. 12	08:30-15:00 • Dimanche 12 août	8 h 30-15 h
Mon., Aug. 13	08:30-15:30 • Lundi 13 août	8 h 30-15 h 30
Tues., Aug. 14	08:30-16:00 • Mardi 14 août	8 h 30-16 h

Annual General Meeting
Assemblée générale annuelle

Sun., Aug. 12	15:00-17:00 • Dimanche 12 août	15 h-17 h

Registration
Inscription

Sat., Aug. 11	15:00-17:30 • Samedi 11 août	15 h-17 h 30
Sun., Aug. 12	07:30-17:00 • Dimanche 12 août	7 h 30-17 h
Mon., Aug. 13	07:30-17:00 • Lundi 13 août	7 h 30-17 h
Tues., Aug. 14	08:00-16:00 • /Mardi 14 août	8 h-16 h

Exhibits
Kiosques

Sun., Aug. 12	10:00-15:00 • Dimanche 12 août	10 h-15 h
Mon., Aug. 13	10:00-15:00 • Lundi 13 août	10 h-15 h

Lunch/Exhibitors/Posters
Déjeuner/Kiosques/Affiches

Sun., Aug. 12	12:15-14:00 • Dimanche 12 août	12 h 15-14 h
Mon., Aug. 13	12:30-14:30 • Lundi 13 août	12 h 30-14 h 30

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

Saturday, August 11
Samedi 11 août

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

Deer Valley Golf Course and Estates

07:00-16:00	First bus will depart at 06:45 from Delta Regina
7 h-16 h	Départ du premier autobus du Delta Regina dès 6 h 45

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 Milan Room-Delta Regina

Opening Reception
Réception d'ouverture

19:00-22:00 Umbria Ballroom-Delta Regina

Sunday, August 12
Dimanche 12 août

5 K Fun Run/3 K Walk Event
Course 5 km/marche 3 km des lève-tôt

06:30-08:00 Lobby-Delta Regina

Wine and Chat
Vin et causette

17:00-18:00 Verdi Room-Delta Regina

Fun Night
Partie de plaisir

Saskatchewan Science Centre

18:30-24:00	Buses will be departing the Delta Regina commencing at 18:30
18 h 30 - 24 h	Départ du premier autobus du Delta Regina à 18 h 30

Monday, August 13
Lundi 13 août

Past Presidents' Dinner and Dance
Dîner dansant des anciens présidents

Conexus Arts Centre

18:00-01:00	Buses will depart between 18:00 and 18:30 from the Delta Regina
18 h - 24 h	Départ des autobus du Delta Regina entre 18 h et 18 h 30

Upcoming Events
Événements à venir

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

Professional Practice Conference (PPC) 2011
January 29-February 2, 2011
Sheraton Centre Toronto
Toronto, Ontario

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
Delta Winnipeg
Winnipeg, MB

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

Annual General Meeting (AGM) 2011
August 6 -9, 2011
TBA
Vancouver, British Columbia

TAKE ADVANTAGE OF THE BEST PROFESSIONAL DEVELOPMENT OPPORTUNITY!

The Canadian Council on Health Services Accreditation (CCHSA) is looking for pharmacists to share their clinical knowledge of medication administration and reconciliation processes and health care expertise in the review of organizational practices.

As a surveyor with CCHSA you will be provided with the opportunity to not only expand your network and learn about leading practices in other organizations but you will be able to see them at work, and to bring "home" the innovations you observe.

Join the more than 450 health care professionals across Canada who survey on behalf of CCHSA and help drive quality in Canadian health services.

Find out more about this great professional development opportunity by contacting us at:

Canadian Council on Health Services Accreditation
Tel: 1-800-814-7769 Fax: 1-800-811-7088
surveyors@cchsa-ccass.ca
www.cchsa-ccass.ca

Membership Year 2007-2008

July 1, 2007 – June 30, 2008

Have you renewed your CSHP membership? By renewing your membership for the 2007/2008 year, you are invigorating our journey to advance patient-centred pharmacy practice in hospitals and related health-care settings. With you along, we can be heard!

For more information about CSHP membership, please visit us at www.cshp.ca/membership/index_e.asp.

Consider joining a strong professional organization today!

Membership Enquiries:

Please contact Robyn Rockwell
Membership Administrator
Tel.: (613) 736-9733, ext. 222
Fax: (613) 736-5660
Email: rrockwell@cshp.ca
www.cshp.ca

CSHP SCPH
60 YEARS ANS 1947•2007

Année de cotisation 2007-2008

1er juillet 2007 – 30 juin 2008

Avez-vous renouvelé votre adhésion à la SCPH? En renouvelant votre adhésion pour l'année 2007/2008, vous donnez de la vigueur au périple que nous avons entrepris, afin de faire progresser la pratique de la pharmacie axée sur le patient dans les établissements de santé. Avec vous dans nos rangs – nous pouvons être entendus!

Pour plus d'information sur l'adhésion à la SCPH, veuillez nous visiter à www.cshp.ca/membership/index_e.asp.

Songez à vous associer à cette puissante organisation professionnelle dès aujourd'hui!

Renseignements sur l'adhésion :

Veuillez communiquer avec l'Agente du service aux membres,
Robyn Rockwell.
Tél. : (613) 736-9733, poste 222
Téléc. : (613) 736-5660
Courriel : rrockwell@cshp.ca
www.cshp.ca

CSHP 60th AGM and Educational Sessions
60e Assemblée générale annuelle et séances éducatives de la SCPH

CSHP SCPH
60 YEARS ANS 1947•2007

Saturday, August 11 ▪ Samedi 11 août

07:00-16:00 **Research & Education Foundation Fundraising Golf Event**
Tournoi de golf de la Fondation pour la recherche et l'éducation

Deer Valley Golf Course and Estates (bus departs at 06:45 from Delta Regina). So you thought Saskatchewan was flat! Join us for the day and you will be pleasantly surprised at the challenge which awaits. Have some fun and help raise funds for the R&E Foundation.

Deer Valley's championship course provides the variety golfers enjoy; some holes possess stunning views of the valley, while others are nestled in the trees along the meandering Wascana Creek. Deer Valley Golf Course and Estates was created to provide golfers of all ages and skill levels with a fine playing experience while making the most of the stunning valley landscape. See you there.

15:00-17:30 **Registration**
Inscription

COAT CHECK

13:00-17:00 **Stakeholder Consultation Workshop: 2010 CHPRB (Residency) Accreditation Standards**
Atelier de consultation des parties prenantes : Normes d'agrément 2010 (résidence) du CCRPH

CAMPANIA ROOM

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

MILAN ROOM

19:00-22:00 **Opening Reception**
Réception d'ouverture

UMBRIA BALLROOM

Dress: Sports Casual

Join us to start off your conference experience with food, drink and free money! The sky's the limit as you bet it all on the tables in our CSHP casino. You may even be able to take home a wonderful prize, or feel free to relax and enjoy the evening reconnecting with old friends and colleagues.

Sunday, August 12 ▪ Dimanche 12 août

06:30-08:00 **5 K Fun Run/3 K Walk Event**
Course de 5 km/marche de 3 km des lève-tôt

LOBBY, DELTA REGINA

Dress: Athletic Wear

The sky's the limit as you run or walk through beautiful Wascana Park. Experience a peaceful morning run or walk in one of Canada's largest and prettiest urban parks. The path will take you around revitalized Wascana Lake ending with breakfast catered by Willow on Wascana.

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

COAT CHECK

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

UMBRIA BALLROOM

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

UMBRIA BALLROOM

Do Pharmacists Really Make a Difference? Reviewing the Recent Evidence

Mark Makowsky, BSP, PharmD, ACPR
University of Alberta
Edmonton, AB

09:30-10:15 **Prescribing by Pharmacists in Alberta: Where are we Now?**

UMBRIA BALLROOM

Tammy Bungard, BSP, PharmD
University of Alberta
Edmonton, AB

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

TRENTINO/TUSCANY/LOMBARDY C

10:45-11:25 **Short and Snappies**
En un clin d'oeil

1. Sitagliptin: A DPP-4 Inhibitor

CAMPANIA ROOM

Karen McDermaid, BSc, BSP, ACPR, CDE
Regina Qu'Appelle Health Region
Moosomin, SK

ACE Inhibitors/ARb Combinations in CKD – Should we CALMly COOPERATE?

Peter Ricci, BSP, ACPR
Regina Qu'Appelle Health Region
Regina, SK

10:45-11:25 **Concurrent Sessions**
Séances concomitantes

2. Guideline Pearls – Update from the CAP Guidelines

LOMBARDY A

Yvonne Shevchuck, BSP, PharmD, FCSHP
University of Saskatchewan
Saskatoon, SK

3. CSHP Hospital Pharmacy Management Leadership Survey Results

LOMBARDY B

Emily Lap Sum Musing, BScPhm, MHSc, ACPR, FCSHP, CHE
University Health Network
Toronto, ON

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

1. Clinical Trials that will Change Your Practice

CAMPANIA ROOM

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

2. Update from the CSHP Hospital Pharmacy Management Task Force

LOMBARDY A

Robin Ensom, PharmD, FCSHP
Vancouver Coastal Health &
Providence Health Care
Vancouver, BC

3. Innovative Pharmacy Practice Sites

LOMBARDY B

Role of the Pharmacist in the Operating Room

Johanna Proceviat, BScPhm, ACPR
St. Michael's Hospital
Toronto, ON

Role of the Pharmacist in the Renal and Transplant Clinics

Jennifer Dyck, BSP, ACPR
Regina General Hospital
Regina, SK

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

TRENTINO/TUSCANY/LOMBARDY C

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

UMBRIA BALLROOM

***Moving Forward:* Pharmacy Human Resources for the Future**

Kevin Hall, BScPhm, PharmD
Winnipeg Regional Health Authority
Winnipeg, MB

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

UMBRIA BALLROOM

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

VERDI ROOM

18:30-24:00 **Fun Night**
Partie de plaisir

SASKATCHEWAN SCIENCE CENTRE

Dress: Casual

Your evening will begin with a scenic tour of Wascana Centre, the jewel in the heart of Regina. Buses

will be departing the hotel commencing at 18:30 to the Saskatchewan Science Centre where the socializing will really begin!

You will be treated to gastronomic delights at a variety of international food stations with a menu designed and provided by one of Saskatchewan's top gourmet catering chefs. Experience hands on exhibits, build a Mars lunar lander with four fellow pharmacists, search for the August stars, relax and chuckle in the Corner Gas Theatre.

Monday, August 13 ▪ Lundi 13 août

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

COAT CHECK

08:15-08:30 **Announcements**
Annonces

UMBRIA BALLROOM

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

UMBRIA BALLROOM

How to Fit a Heart Attack into Your Busy Schedule!

Philip Jones
Consultant
Calgary, AB

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

1. **Mentorship Pearls**

   CAMPANIA ROOM

   Donna Woloschuk, BSP, PharmD, MEd(Distance), FCSHP
   Winnipeg Regional Health Authority
   Winnipeg, MB

   Shannan Neubauer, BSP, ACPR, PharmD, FCSHP
   University of Saskatchewan
   Saskatoon, SK

2. **Proton Pump Inhibitors: Defining Best Practices**

   LOMBARDY A

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

3. **Survival Guide – Tips for Making the Most of Your Residency**

   LOMBARDY B

   Jennifer Dyck, BSP, ACPR
   Regina General Hospital
   Regina, SK

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

TRENTINO/TUSCANY/LOMBARDY C

10:30-12:30 **Workshops**
Ateliers

1. **Medication Reconciliation: Every Patient, Every Time, That's Our Goal**

   CAMPANIA ROOM

   Barb Evans, BSP, ACPR, MSc, FCSHP
   Saskatoon Health Region
   Saskatoon, SK

2. **Using Learning Styles Theory to Improve the Quality of Teaching**

   LOMBARDY A

   Zubin Austin, BScPhm, MBA, PhD
   University of Toronto
   Toronto, ON

3. **Uncharted Waters: Documentation in Clinical Settings**

   LOMBARDY B

   Roland Halil, BScHon, BScPhm, PharmD
   Elisabeth Bruyère & Primrose Family Health Team
   Ottawa, ON

10:30-12:30 **PSN Sessions – ID**
Séances RSP – Infectiologie

VERDI ROOM

Combination Therapy for Gram Positive Infections

Linda Sulz, BSP, PharmD
Regina Qu'Appelle Health Region
Regina, SK

New Vaccines: The Why's and Why Not's

Ben Tan, MD, FRCPC
University of Saskatchewan
Saskatoon, SK

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

TRENTINO/TUSCANY/LOMBARDY C

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

UMBRIA BALLROOM

CSHP 2015 – Can YOU Hit the Target?

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

18:00-01:00 **Past Presidents' Dinner and Dance**
Dîner dansant des anciens présidents

CONEXUS ARTS CENTRE

Dress: Business Casual

Buses will depart between 18:00 and 18:30 from the Delta hotel. The evening will begin with cocktails served in the foyer of the Conexus Arts Centre with balconies that overlook Wascana Centre. You will then move into the theatre where you will dine under the stars. Count on an entertaining evening in the QUEEN city of the Plains, where excellent food, with Saskatchewan specialties, will be served. We have a surprise welcome, and the band "Men without Shame" will put on a high energy interactive show that gets everyone involved. So come out and join us for all the fun, because "the sky's the limit"!

Tuesday, August 14 ▪ Mardi 14 août

08:00-16:00 **Registration**
Inscription

COAT CHECK

08:15-08:30 **Announcements**
Annonces

UMBRIA BALLROOM

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

UMBRIA BALLROOM

Human Factors in Healthcare

Jonas Shultz, MSc
Calgary Health Region
Calgary, AB

09:15-10:15 **Metabolic Syndrome: Waist Not, Want Not!**

UMBRIA BALLROOM

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

10:15-10:45 **Break**
Pause

PRE-FUNCTION AREA

10:45-11:35 **Concurrent Sessions**
Séances concomitantes

1. **Technicians and Pharmacists Partnering for Successful Medication Reconciliation**

   CAMPANIA ROOM

   Lauza Saulnier, BScPhm, ACPR
   South-East Regional Health Authority
   Moncton, NB

   Melissa White, Pharmacy Technician
   South-East Regional Health Authority
   Moncton, NB

2. **This Medication will Prevent Strokes… and Other Lies We Tell Ourselves and Our Patients: Understanding and Communicating about Effect Sizes of Drug Therapy**

   LOMBARDY A

   Peter Loewen, BScPhm, ACPR, PharmD, FCSHP
   Vancouver Coastal Health/UBC
   Vancouver, BC

3. **Why is Mom so Confused? Considerations for Delirium in the Acute Care Setting**

LOMBARDY B

Susan Bowles, PharmD, FCSHP
Capital Health Authority
Halifax, NS

11:35-13:00 **Satellite Symposium (luncheon included)**
Symposium satellite (déjeuner inclus)

TRENTINO BALLROOM

Innovations in Glycemic Control: New Options for Treatment of Type 2 Diabetes

Hosted by: Merck Frosst Canada Ltd.

13:00-13:45 **Concurrent Sessions**
Séances concomitantes

1. **Change in My Pocket: Effective Change Management Strategies for Pharmacists**

CAMPANIA ROOM

Doug Robertson, MBA
Saskatoon Health Region
Saskatoon, SK

2. **Show Me the Evidence! Academic Detailing in Canada?**

LOMBARDY A

Loren Regier, BSP, BA
Rx Files Academic Detailing Program
Saskatoon, SK

3. **The Bottom Line on Dyslipidemia Treatment for Pharmacists**

LOMBARDY B

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

13:50–15:50 **Workshops**
Ateliers

1. **Medication Reconciliation: Every Patient, Every Time, That's Our Goal**

CAMPANIA ROOM

Barb Evans, BSP, ACPR, MSc, FCSHP
Saskatoon Health Region
Saskatoon, SK

2. **Using Learning Styles Theory to Improve the Quality of Teaching**

LOMBARDY A

Zubin Austin, BScPhm, MBA, PhD
University of Toronto
Toronto, ON

3. **Uncharted Waters: Documentation in Clinical Settings**

LOMBARDY B

Roland Halil, BScHon, BScPhm, PharmD
Elisabeth Bruyère & Primrose Family Health Team
Ottawa, ON

16:00 **Close of the 60th AGM & Educational Sessions**
Clôture de la 60e AGA et séances éducatives

Organized by the Educational Services Committee of CSHP with assistance from the 2007 Host Committee.

Organisées par le Comité des services éducatifs de la SCPH en collaboration avec le Comité d'accueil de l'AGA 2007.

Sunday, August 12
Dimanche 12 août

Do Pharmacists Really Make a Difference? Reviewing the Recent Evidence

Mark Makowsky, BSP, PharmD, ACPR, University of Alberta, Edmonton, AB

The goal of this session is to summarize important and recently published studies in the pharmacy practice literature so that pharmacists may evaluate their own practice and determine if the services they are providing are in fact "evidence-based."

In this era of evidence-based medicine, all health care professionals including pharmacists are being challenged to demonstrate the value of their services. Pharmacy practice researchers have answered this call, resulting in a recent surge in primary literature and systematic reviews investigating the impact of pharmacist care on various economic, clinical, and humanistic outcomes.

As the profession moves forward, pharmacists attain new responsibilities, and pharmacy departments re-examine the services that they provide; evaluation of this research and its translation into practice becomes a major challenge, especially in the context of patient-centered interdisciplinary team based care. Dr. Makowsky will highlight several studies and emphasize application of the results to pharmacy practice in Canada.

Pharmacists attending this session will be challenged to consider the implications of current pharmacy practice research studies on practicing pharmacists, pharmacy administrators, pharmacy educators, and the profession of pharmacy at large.

Goals and Objectives

1. To provide pharmacists with the highlights of important recently published pharmacy practice research studies.
2. To discuss the key elements of evidence based clinical pharmacy practice in the hospital setting.
3. To enable pharmacists to consider how best to translate the results of these studies into their own practice.

Self-Assessment Questions

1. How can I best communicate the value of my clinical services to physicians, nurse practitioners, or hospital administrators?
2. What changes do I need to make to my own practice based on the results of these studies?

Prescribing by Pharmacists in Alberta: Where are we Now?

Tammy J. Bungard, BSP, PharmD, University of Alberta, Edmonton, AB

The purpose of this presentation is to provide an overview of the progress made in Alberta to allow pharmacists to prescribe, and to describe the model for prescribing implemented with an outline of requirements for different types of prescribing by pharmacists.

In 1999 the Alberta government passed the Health Professions Act requiring all health professions to be regulated under this single Act. Each profession identified activities within their respective scopes of practices, and Pharmacy was successful in being granted the privilege of prescribing Schedule 1 drugs and blood products. In performing this role, there are several fundamental principles that must fulfilled – the pharmacist must be competent in the disease being treated and drug being prescribed, have adequate information to make the decision, have informed the patient, appropriately document the prescribing decision, and communicate this information to other healthcare providers.

The types of pharmacist prescribing encompass adapting prescriptions (altering the dosage, formulation or regimen; therapeutic substitution; and extending a prescription to ensure continuity of care), emergency prescribing, and additional prescribing authorization (initial access prescribing and managing ongoing drug therapy). While pharmacists must be on the clinical register and complete an orientation program in order to adapt prescriptions and prescribe in an emergency situation, an application process is mandatory for additional prescribing. This application contains information regarding the pharmacist's education and training, practice and experience, and collaborative relationships. Further, three care plans containing critical indicators (ranging from patient assessment to making professional judgments that maximize patient safety and desired health outcomes) must be submitted. Additional prescribing is anticipated to be offered to Alberta pharmacists in the fall, following the completion of a pilot process this summer. As Alberta pharmacists embark on this precedent setting practice enabling a proactive clinical role, they must be prepared to take responsibility for prescribing decisions.

Goals and Objectives

1. To provide an overview of the legislative changes within the Province of Alberta facilitating the pursuit of prescribing by pharmacists.
2. To outline the types of prescribing, namely adapting prescriptions, emergency prescribing, and additional prescribing authorization.
3. To highlight requirements for prescribing in any situation, and the application process for additional prescriptive authority.

Self-Assessment Questions

1. Compare and contrast pharmacist prescribing in your province with that being implemented in Alberta.
2. A 68 year old male patient with a history of a myocardial infarction (MI) last year informs you that he requires more metoprolol 50 mg bid, as he has run out (patient

has been taking metoprolol since his MI). Consider what fundamental principles of prescribing you would need to fulfill and what type of prescribing you may chose to perform in accordance with the Alberta model.

Sitagliptin: A DPP-4 Inhibitor

Karen McDermaid, BSc, BSP, ACPR, CDE, Regina Qu'Appelle Health Region, Moosomin, SK

Type 2 Diabetes is a global epidemic and affects more than 1.8 million Canadians. In 2000, the World Health Organization estimated that over 177 million people had diabetes. By 2025, this figure will top 300 million. One component of diabetes self-management is blood glucose control.

Therapeutic modalities for control of hyperglycemia include sulfonyureas, meglitinides, biguanides, thiazolidinediones, alpha-glucosidase inhibitors and insulin. Despite the use of intensive regimens combining several drugs, glycemic control declines over time in most patients with type 2 diabetes. A new therapeutic option, dipeptidyl peptidase-4 (DPP-4) inhibitors, inhibit the enzyme responsible for degrading incretin hormones. The slowing of the inactivation of the incretin hormones in turn helps to correct the defective insulin and glucagon secretion that marks type 2 diabetes. Clinical studies indicate hat DPP-4 inhibitors effectively stimulate insulin secretion, suppress glucagon release, and improve glucose control in patients with type 2 diabetes.

Goals and Objectives

1. To provide pharmacists with an understanding of the mechanism of action, indication, dose and side effects of sitagliptin.
2. To assist pharmacists with understanding the role of sitagliptin in the management of type 2 diabetes.

Self-Assessment Questions

1. What should patients inquiring about sitagliptin for management of type 2 diabetes be told?
2. At what point for blood glucose management would you consider the use of sitagliptin?

ACE Inhibitor/ARB combinations in CKD – should we CALMly COOPERATE?

Peter Ricci, BSP, ACPR, Regina Qu'Appelle Health Region, Regina, SK

The goal of this session is to provide pharmacists with an understanding of how to identify and treat patients with Chronic Kidney Disease (CKD) Stage 1-4 with albuminuria and the strength of the evidence supporting the treatment.

Albuminuria is a surrogate marker and a predictor of progression of CKD. Many hypertension and kidney randomized controlled trials use albuminuria as a surrogate endpoint and others examine hard endpoints (for example – need to initiate dialysis). The presence of diabetes mellitus may confound the treatment of albuminuria.

Goals and Objectives

1. To provide pharmacists with an understanding of some of the tools used to identify kidney damage and Chronic Kidney Disease
2. To provide pharmacists with an understanding of some of the treatment strategies for reducing the risk of CKD progression and to examine the strength of evidence with a direct focus on combination therapy with ACE-inhibitors and Angiotensin Receptor Blockers.

Self-Assessment Questions

1. What are the goals of therapy for the treatment of albuminuria?
2. What are the monitoring parameters for these therapies?
3. At what point should albuminuric CKD patients be treated with ACE/ARB combinations?

Updates from the CAP Guidelines

Yvonne M. Shevchuk, BSP, PharmD, FCSHP, College of Pharmacy and Nutrition, University of Saskatchewan, Saskatoon, SK

Goals and Objectives

1. To provide pharmacists with an overview of community acquired pneumonia
2. To enable pharmacists to consider epidemiologic and specific patient risk factors to determine appropriate initial antibiotic therapy for patients requiring hospital admission for community acquired pneumonia

Self-Assessment Questions

1. In a patient who requires admission to hospital for CAP, what is an appropriate initial antibiotic choice?
2. When can a patient be switched from IV to oral therapy for CAP? What is the appropriate duration of therapy?

CSHP Hospital Pharmacy Management Leadership Survey Results

Emily Lap Sum Musing, BScPhm, MHSc, ACPR, FCSHP, CHE, University Health Network, Toronto ON

As part of a Leadership Task Force, CSHP implemented a survey to assess the views of current Canadian hospital pharmacy leaders. Responses were received from 10 provinces with respondents holding management positions over a wide range of years. There was representation from managers with both single site and multi-site responsibilities, reflective of Canada's regionalized settings.

The survey focused on capturing this group's views regarding:

- Relevant education and/or training for hospital pharmacy management,
- Positive influences and motivators to accepting a management position,
- Potential barriers and concerns related to moving into management and

- Current succession plans within their organization.

The summary of survey results will support both CSHP and current hospital pharmacy managers in identification and development of strategies to encourage individuals towards hospital pharmacy management as a career path. This information will also be of interest to those individuals that are considering moving into hospital pharmacy management in the future.

Goals and Objectives

1. To provide pharmacists with an understanding of the current demographics related to hospital pharmacy management.
2. To provide current hospital pharmacy managers with insight into succession planning strategies and ways to facilitate interest in hospital pharmacy management as a career path for their staff.
3. To give current hospital pharmacists who are interested in hospital pharmacy management an understanding of the knowledge and skills that would support their movement into leadership positions.
4. To share with hospital pharmacists the positive and negative aspects of hospital pharmacy management as perceived by current managers.

Self-Assessment Questions

1. As a staff pharmacist, what can I do to prepare myself for a position in hospital pharmacy management?
2. As a hospital pharmacy manager, what can I do to encourage interest in hospital pharmacy management and what steps can I take to develop a succession plan for the management positions within my department?
3. As an organization, what can CSHP do to promote and develop future hospital pharmacy leaders?

Clinical Trials that will Change Your Practice

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

The goal of this session is to provide pharmacists with a summary of several recent key clinical trials and to facilitate a discussion regarding how the new information should be incorporated into clinical practice.

Due to the nature of this topic, the actual trials to be discussed will be selected just prior to the presentation date to ensure the most up to date publications can be incorporated. The presenter will discuss two to three landmark papers that have broad reaching implications, targeting primarily a generalist audience. A case-based format will be utilized to highlight how the new evidence may impact a clinical scenario. The focus of the discussion will be on the potential implications of the evidence on current clinical practice, as opposed to an in-depth review of the trial design and methodology.

Goals and Objectives

1. To provide pharmacists with an update regarding recently published clinical trials that will impact their practice.
2. To discuss how this new evidence should be incorporated into current clinical practice.

Self-Assessment Questions

1. List two things that you will be doing differently in your clinical practice as a result of this presentation?
2. Which aspects of this new evidence will you NOT incorporate into your clinical practice and why?

Update from the CSHP Hospital Pharmacy Management Task Force

Robin J. Ensom, PharmD FCSHP, Vancouver Coastal Health and Providence Health Care, Vancouver, BC

Recent events have stimulated CSHP Council to strike a Task Force to: "Make recommendations on the role of CSHP in the development of future hospital pharmacy leaders and to propose an implementation strategy."

Formed in late 2005, this Task Force has examined the factors associated with a shortage of pharmacists prepared (both in term of training and willingness) to undertake a formal leadership role in institutional practice. The group broke into 4 working groups to examine different strategies to respond to this challenge and to develop recommendations to implement these strategies.

This presentation will briefly review:

- Factors contributing to the perceived shortage;
- The four target groups identified as important to effective succession planning for hospital pharmacist leadership; and
- Specific recommendations for CSHP and hospital pharmacists, in order to improve the situation.

Recommendations will have been recently presented to CSHP Council, so we hope to have a preliminary response from our executive and delegates, as well as lots of opportunity for discussion.

All hospital pharmacists are invited to come to the workshop with your opinions, experiences, ideas and questions.

Goals and Objectives

1. To provide hospital pharmacists with insight into strategies and plans to ensure effective hospital pharmacist leadership.
2. To hear what hospital pharmacists have to say about the progress of the Task Force.
3. To give hospital pharmacists ideas regarding what they can do to ensure effective hospital pharmacist leadership.

Self-Assessment Questions

1. What groups do we need to consider as we plan for future hospital pharmacist leaders?
2. What initiatives are CSHP considering to facilitate development of future leaders?
3. What can I do to ensure effective hospital pharmacist leadership in the future?

Role of the Pharmacist in the Operating Room

Johanna Proceviat, BScPhm, ACPR, St. Michael's Hospital, Toronto ON

Operating Room Pharmacy Satellites are fairly common within hospitals in the United States. However, there are relatively few in Canadian hospitals. The OR uses a significant amount of high-risk medications in a fast paced, high stress environment. The presence of an OR Pharmacy staffed with both pharmacy technicians and a clinical pharmacist has had many positive impacts on both patient care and drug costs/usage since its implementation approximately 10 years ago.

At St. Michael's Hospital, the OR Pharmacy Satellite is staffed by two pharmacy technicians and one pharmacist. The pharmacy technicians are responsible for drug procurement, preparation and distribution within the OR. This enables the pharmacist to focus on patient care throughout the peri-operative period, including screening patients presenting for elective surgery to ensure that the appropriate medications have been ordered and administered pre-operatively; providing drug information and recommendations to the physicians in the OR in a time-sensitive manner; and ensuring that the patient's usual medications are restarted in a timely manner post-operatively.

The pharmacist is also involved in developing and implementing medication safety initiatives. Past initiatives have included standardizing the contents of anaesthesia drug trays, and pre-printed pre-operative orders to ensure pre-operative antibiotics are administered in a timely manner, and that selection of antibiotics is based on the most recent evidence.

An OR pharmacist can have a positive impact on patient care in the peri-operative period, as well as monitoring drug costs and optimizing usage in this fast-paced environment.

Goals and Objectives

1. To introduce the audience to the role of a clinical pharmacist in the Peri-operative period, specifically within the OR.
2. To illustrate how pharmacy services are provided to the Operating Rooms at St. Michael's Hospital.
3. To expose the audience to various pharmacy driven initiatives to improve medication delivery and safety in the OR.

Self-Assessment Questions

1. What are 3 main responsibilities of an OR pharmacist?
2. What are 2 examples that illustrate the seamless care services provided by an OR pharmacist to surgical patients?
3. What is the process for drug distribution to the Operating Rooms at my practice site?

Role of the Pharmacist in the Renal and Transplant Clinics

Jennifer Dyck BSP, ACPR, Regina General Hospital, Regina SK

The goal of this session is to provide pharmacists with an understanding of the process used to establish two unique pharmacy practices. Benefits of each practice and potential future directions are also discussed.

A number of pharmacist prescribing initiatives are currently being established or have been shared in recent conferences and publications. One of these initiatives has existed for several years within the Regina Qu'Appelle Health Region (RQHR). A need was identified for pharmacists to expand their existing scope of practice to include a formalized process for renal anemia management. As a result of this need, a collaborative prescribing agreement was developed between the nephrologists and the renal pharmacists group. In order to be included within the prescribing agreement, pharmacists must successfully complete a training and certification process.

Despite having a provincial renal transplant program, there was not a dedicated local transplant pharmacist for the southern half of Saskatchewan until 2005. Again recognizing the need for the expansion of pharmacy services into a new practice, the RQHR established a part time pharmacist position. As the inaugural pharmacist, I was able to establish the scope of practice within the existing transplant program structure. A training and education process was also drafted anticipating that it could be formalized into a certification process.

Goals and Objectives

1. To provide pharmacists with an understanding of the process used to establish two different innovative pharmacy practices
2. To describe the challenges encountered within these innovative settings and the solutions utilized

Self-Assessment Questions

1. Distinguish between different prescribing models.
2. Name three possible triggers for the establishment of a new practice site.
3. What are common benefits associated with the innovative practice sites discussed?

Moving Forward: Pharmacy Human Resources for the Future

Kevin W. Hall, BScPhm, PharmD, Co-Chair, "Moving Forward: Pharmacy Human Resources for The Future", Winnipeg Regional Health Authority, Winnipeg, MB

Although there are many challenges facing the Canadian Health care system, none is more important than health human resources. The Health Council of Canada and the Federal Provincial/Territorial Advisory Committee on Health Delivery and Human Resources have both stated that the continued provision of high quality, accessible health care services depends on our ability to insure that we have the

right people, with the right skills, in the right place, at the right time.

In late 2005, Human Resources and Skills Development Canada (HRSDC) awarded over $1.4 million, to a pharmacy partnership, for a study of pharmacy human resources in Canada. The Canadian Society of Hospital Pharmacists is part of the coalition of Pharmacy organizations that are managing and participating in this initiative. "Moving Forward: Pharmacy Human Resources for the Future" is a 30 month initiative that has been charged with developing a comprehensive understanding of the pharmacy workforce in Canada and identifying the actions that must be taken to ensure a future pharmacy workforce that is "fit for its purpose."

A number of research projects have already been commissioned by Moving Forward and completed by the research groups that were selected to conduct the work. These include a compilation of the current knowledge of the pharmacy workforce in Canada, a study of the pharmacy technician workforce in Canada, and a study related to the credentialing and integration of internationally trained pharmacy graduates into Canada's pharmacy workforce. Studies of the existing pharmacist workforce, and its future role in the Canadian healthcare system, are underway.

Goals and Objectives

1. Provide a brief historical context related to pharmacy human resource issues that have confronted the profession of Pharmacy in Canada.
2. Promote a dialogue with the audience concerning a number of major changes that are likely to occur in the pharmacy sector over the next 5 to 10 years.
3. Encourage participants to consider the probable and/or possible changes that will occur in the future scope of practice of pharmacy technicians and pharmacists.
4. Encourage participants to envision what impact these changes are likely to have on future pharmacy manpower needs, and the qualifications required of each segment of the pharmacy workforce.
5. Encourage participants to create a roadmap for their own organizations that will insure that their future pharmacy workforce is fit for its purpose.

Self-Assessment Questions:

1. What changes are likely to occur, within the next few years, with respect to:
   - the accreditation of technician training programs, the certification of technicians and the regulation/licensure of pharmacy technicians?
   - the practice role and practice environment of community pharmacists?
2. What are the implications for hospital pharmacy and what might a "pharmacy human resources roadmap for the future" look like for your organization?

Monday, August 13
Lundi 13 août

How to Fit a Heart Attack into Your Busy Schedule!

Philip Jones, Calgary AB

This session is for busy, stressed pharmacists only! No others need attend.

With his dry sense of humour, Philip Jones tells stories, shows pictures and asks questions. He does not tell you what to do. No lectures. Instead, he gets you laughing… and gets you thinking.

Goals and Objectives

This entertaining, thought-provoking presentation encourages you:

1. to review your personal lifestyle choices,
2. to figure out how to deal more effectively with stress, and
3. to make just one positive change to help you live a longer, healthier, more productive life.

Self-Assessment Questions

1. Is your life directed by clearly defined principles?
2. Are your personal objectives clearly defined?

Mentorship Pearls

Donna M.M. Woloschuk, BSP, PharmD, MEd(Distance), FCSHP, Winnipeg Regional Health Authority, Winnipeg MB; Shannan Neubauer BSP, ACPR, PharmD, FCSHP, University of Saskatchewan, Saskatoon SK

Mentorship is a dynamic, altruistic, voluntary, open-ended, mutually beneficial and usually long-standing relationship between two persons. In this relationship, one person is considered to be "experienced and wise in one's profession" (the mentor) and the other person is less experienced (the mentee). Mentoring relationships guide development of personal learning, critical thinking, and social, career and/or professional development – often resulting in profound, positive changes in a person's life or career. Effective mentors are change-oriented. They are

competent, confident, and committed to transforming "potential" into "action" in others as well as in themselves. Mentors respect confidentiality and other boundaries associated with the mentoring relationship. They compliment, challenge, cajole, check, critique, catalyze, champion, and channel opportunity. At the right moment, mentors "let [mentees] go", in hope and expectation that the mentee will "pay it forward".

Mentoring offers many benefits. Mentoring enhances leadership skills and improves patient care, professional performance, and job satisfaction. Mentees report lower work-related stress, improved competence and confidence, stronger feelings of connectedness to an organization and its goals, and demonstrate greater resilience in times of uncertainty. For organizations, mentorship programs provide a magnet for recruitment, a tool for retention, and a means to develop committed leaders. The demand for mentorship greatly exceeds the supply of mentors. There is considerable debate and often, strongly held views, regarding the best method to enhance mentorship culture. Unstructured mentoring relationships usually have higher levels of mentor-mentee satisfaction, possibly because these relationships are more flexible, evolving as a result of individuals' true interests and preferences, and are of longer duration; however, structured mentorship programs generally offer a more effective way for organizations to enhance mentorship culture because they are goal directed, evaluated and measured. Structured programs are most effective if: (1) coordinated by a neutral third-party; (2) mentor-mentee matching is provided; (3) there are clearly defined goals and outcomes; (4) participation is equitable; (5) the program is evaluated; and, (6) mentorship training and support (e.g., political, financial, administrative) are provided. Presenters will briefly review the theoretical context for mentorship in pharmacy, and share personal stories that will compliment, challenge, champion and catalyze participant interest in mentorship.

Goals and Objectives

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

1. Differentiate between mentorship, preceptorship, modeling, coaching and facilitation.
2. Describe the characteristics of effective (structured versus unstructured) mentoring relationships.
3. Appreciate the value mentorship offers to both individuals in the relationship, as well to organizations and the profession.
4. Recognize their own mentorship capabilities and their role in transforming "potential" to "action".

Self-Assessment Questions

1. Another word for mentorship is preceptorship.
   ❑ True ❑ False (False)
2. Promotion of unstructured mentorship programs is the most effective way to establish or enhance mentorship culture in an organization.
   ❑ True ❑ False (False)
3. All members of the pharmacy profession (pharmacists, technicians, assistants) have the capacity to be a mentor.
   ❑ True ❑ False (True)

Proton Pump Inhibitors: Defining Best Practices

Brenda G. Schuster, BSP, ACPR, PharmD, Regina General Hospital, Regina Qu'Appelle Health Region, RxFiles Academic Detailing Program, Regina, SK

Proton pump inhibitors are a commonly prescribed class of medications. These medications are used in a variety of clinical settings including for the treatment of GERD, dyspepsia, peptic ulcer disease, prevention and treatment of NSAID associated complications, and as part of H. pylori eradications regimens.

The Canadian Optimal Medication Prescribing and Utilizations (COMPUS) identifies, evaluates, promotes, and facilitates best practice in drug prescribing and use among health care providers and consumers with the objective of optimizing drug-related health outcomes and promoting cost-effective use of drugs. The proton pump inhibitors were identified as a class of medications for review by COMPUS based on the potential over/under-use from initial projections, the size of patient population use, and the potential impact on health outcomes & cost-effectiveness. COMPUS is a nationally coordinated program, funded by Health Canada and delivered by the Canadian Agency for Drugs and Technologies in Health (CADTH), as a service to federal, provincial and territorial jurisdictions, and other stakeholders.

Numerous practice guidelines exist that address the use of proton pump inhibitors. COMPUS in their approach for identifying evidence-based best practices build on existing work. COMPUS identified and reviewed existing clinical practice guidelines and consensus document containing recommendations on the prescribing or use of proton pump inhibitors. The recommendations from these existing documents were synthesized with the input of clinical and other experts. The supporting references for information was reviewed by the PPI Expert Review Committee which identifies evidence-based best practice statements. At various states in the procedure, stakeholders, including patients, consumers, health care providers and pharmaceutical manufacturers had opportunities to provide feedback or input.

This presentation will highlight some practice statements for best practice prescribing of PPIs. The intent is that hospital pharmacists will be aware of this initiative and leave with an increased awareness of best practice prescribing for the proton pump inhibitors and have practical suggestions of ways to incorporate this information into their busy day, regardless of practice site.

Goals and Objectives

At the completion of this presentation the pharmacists should be able to:

1. Identify potential clinical situations where proton pump inhibitor prescribing is not consistent with best practice prescribing.
2. Identify key references and tools to assist in the best practice prescribing of proton pump inhibitors.
3. Link up with best practice initiatives from COMPUS (Canadian Optimal Medication Prescribing & Utilization Service).

Self-Assessment Questions

1. When is twice daily prescribing of proton pump inhibitors appropriate?
2. Do the patients I see in my practice still require long term use of a proton pump inhibitor? Has their therapy been appropriately reassessed?
3. What resources are available to support best practice prescribing of proton pump inhibitors?
4. What can I do to promote best practice prescribing of pump inhibitors?

Survival Guide – Tips for Making the Most of Your Residency

Jennifer Dyck, BSP, ACPR, Regina General Hospital, Regina SK

The goal of this session is to provide both pharmacy residents and their preceptors with helpful information for making the most of the residency process. Many parallels can be drawn between medical and pharmacy residents. While the quantity of literature is greater for stress and wellness in medical residency, the key concepts are similar for both groups.

Awareness of potential stressors and symptoms of unwellness is crucial for incorporating supports for residents in a timely manner. The difference between surviving a residency and thriving during residency involves utilization of resources, committing to a solid work-life balance, maintaining optimism and evolving as a self-directed practitioner. Seven habits of the self-directed learner will be presented.

The residency coordinator and preceptor also have key roles in the success of the pharmacy resident. Being aware of various learning styles, developing clear learning objectives at an appropriate knowledge level and including learning contracts with residents are ways by which to enhance the residency process.

Goals and Objectives

1. To provide pharmacy residents with practical information to thrive in a unique learning environment
2. To identify areas for residency coordinators and preceptors to improve the learning environment for pharmacy residents

Self-Assessment Questions

1. Identify threats and manifestations of unwellness.
2. List seven skills of successful self-directed learners.
3. Describe the process for developing a learning contract.

Medication Reconciliation: Every Patient, Every Time, That's Our Goal

Barb L. Evans, BSP, ACPR, MSc, FCSHP, Saskatoon Health Region, Saskatoon, SK

Adverse Drug Events (ADEs) occur with disturbing frequency, with communication problems between settings of care being a significant factor. Poor communication of medical information at transition points is responsible for as many as 50% of all medication errors and up to 20% of adverse drug events in hospitals.

Studies indicate unintended medication discrepancies, that represent errors, are common at the time of hospital admission.

Medication reconciliation is a standardized process designed to improve communication and prevent medication errors across the continuum of care, particularly at all interfaces of care. It is a formal process of:

- Obtaining a complete and accurate list of each patient's current home medications (name, dosage, frequency, route).
- Using that list when writing admission, transfer and/or discharge medication orders, and
- Comparing the list against the patient's admission, transfer, and/or discharge orders, identifying and bringing any discrepancies to the attention of the prescriber and, if appropriate, making changes to the orders. Any resulting changes in orders are documented.

Medication reconciliation is supported by the Canadian Council on Health Services accreditation requirements. The required organizational practices related to medication reconciliation within the Patient Safety Area of Communication include the following requirements:

- Employ effective mechanisms for transfer of information at interface points
- Reconcile the patient's medications upon admission to the organization, and with the involvement of the patient, and
- Reconcile medications with the patient at referral or transfer and communicate the patient's medications to the next provider of service at referral or transfer to another setting, service provider, or level of care within or outside the organization.

Goals and Objectives

In a workshop format:

1. Provide pharmacists with an understanding of medication reconciliation and review the evidence supporting this initiative.
2. Explore the various options for obtaining the best possible medication history in various settings.
3. Provide pharmacists with a basic understanding of the Improvement Model (Quality Methodology).
4. Review tools, techniques, processes, and strategies that can be adapted to any organization.
5. Discuss strategies to sustain and spread medication reconciliation throughout any organization.

Using Learning Styles Theory to Improve the Quality of Teaching

Zubin Austin, BScPhm, MBA, PhD, University of Toronto, Toronto, ON

The goal of this session is to provide pharmacist-educators with an understanding of how learning styles theory can be applied to improve the quality of teaching in the clinical setting.

Learning styles theory provides a unique perspective on understanding how learning and personal development occur. This presentation will review psychological theories of learning and introduce the Pharmacists' Inventory of Learning Styles (PILS), a validated tool designed to assist individuals in self-identifying learning preferences/styles. Approaches to teaching and learning that are most effective for different learning styles will be reviewed, as will strategies for optimizing learning environments based on individual needs. Participants will reflect upon how their own learning style shapes expectations of those they teach.

Goals and Objectives

1. To provide pharmacist educators with an overview of learning styles theory
2. To enable pharmacist educators to apply learning styles theory to improve the quality of teaching in the clinical setting

Self-Assessment Questions

1. Compare and contrast the behavioural, cognitivist, developmental and psychoanalytic approaches to learning.
2. Describe optimal teaching and learning strategies for each learning style.
3. Reflect upon how preceptors' learning styles shape expectations of those who they teach.

Uncharted Waters: Documentation in Clinical Settings

Roland Halil, BScHon, BScPhm, ACPR, PharmD, Elisabeth Bruyère & Primrose Family Health Teams, Ottawa, ON

The goal of this session is to provide pharmacists with effective tools for documentation of pharmaceutical care in clinical settings, both inpatient and primary care.

A comprehensive medication assessment is composed of multiple parts including chart review, patient interview, identification of drug related problems and development of solutions-based plans with appropriate follow-up. While the exact format of the final product can vary greatly based on the needs of the stakeholders, the techniques used to gather and organize this information can be standardized to focus our clinical thinking, convey detailed information concisely, meet our professional and ethical obligations and tangibly demonstrate our value to other care providers.

Essential components in documentation should include: identifying information, reason for referral, chief complaint, appropriate background information (both subjective and objective), drug related problems, solutions-based care plans, monitoring parameters and responsibility for follow-up. The addition of evidence-based references are not essential, but can only strengthen a chart note. The final goal should be about patient outcomes. Documentation that is imprecise, illegible, unsubstantiated or too verbose will not likely be implemented by prescribers, resulting in no intervention, defeating much of the purpose of a good chart note.

Good documentation is part art and part science. Development of our personal styles within the framework of a widely accepted standard can be aided by practice on patient cases, comparison with colleagues and discussion with mentors.

Goals and Objectives

1. To provide pharmacists with an understanding of various methods of documentation used in clinical practice
2. To allow pharmacists to compare and contrast strengths and weaknesses of various charting methods
3. To apply different charting systems to a hypothetical patient case

Self-Assessment Questions

1. What is the purpose of documentation in a clinical setting?
2. Which components of a medication assessment are necessary given the needs of your stakeholders?
3. Has my ability to create focused and concise notes been honed by practice on hypothetical cases?

Combination Therapy for Gram Positive Infections

Linda A. Sulz, BSP, Pharm D, Regina Qu'Appelle Health Region, Regina, SK

The goal of this session is to review the literature to determine whether or not there is sufficient evidence to recommend combination therapy for treating some infections due to gram-positive organisms.

Combination antimicrobial agents have been used to treat patients with various infections in an effort to achieve a better outcome (i.e. for synergy and thus "cure the patient" sooner, or to overcome resistance mechanisms to ensure continued susceptibility of the organism). However, the evidence for "double coverage" for certain organisms and/or infections is contradictory at best. There is a paucity of data and much of the information is limited to case reports or cohorts of patients, or includes only a small numbers of patients and has poor study design.

This review will not cover the use of combination therapy for acid-fast bacilli (e.g. TB, MAC) or for eradication of Staphylococcus aureus colonization.

Goals and Objectives

1. To know the strength of evidence for use of more than one antimicrobial agent for treating gram-positive infections.
2. To know the specific infections where combination therapy has proved effective in treating gram positive infections and the antimicrobial agents used.

Self-Assessment Questions

1. Is the evidence strong enough to support combination therapy for treating infections caused by gram-positive organisms? If so, what infections should be treated with combination therapy?
2. What antimicrobial agents in combination have been shown to be effective in treating patients with gram-positive infections?

New Vaccines – The Why's and Why Not's

Ben Tan, MD, FRCPC, University of Saskatchewan, Saskatoon, SK

Goals and Objectives

Using true and hypothetical clinical scenarios to highlight the following:

1. The differences in vaccine delivery and make-up of publicly-funded immunization programs in Canada.
2. The clinical indications for six relatively new vaccines in Canada:– Meningococcal C conjugate (Men-C-C) and Meningococcal ACWY conjugate (Men-C-ACWY), Pneumococcal conjugate 7 (PCV7), Varicella Zoster (VZV), Human Papilloma Virus (HPV) and Rotavirus (RV).
3. The contraindications and precautions for these vaccines.

CSHP 2015 – Can YOU Hit the Target?

Carolyn Bornstein, BScPhm, ACPR, Southlake Regional Health Centre, Newmarket, Ontario, President-Elect, CSHP

The purpose of this session is to introduce the CSHP membership to CSHP 2015. The speaker will describe the evolution of the Canadian document from the ASHP 2015 Initiative, highlighting the similarities, but also the uniqueness of the "Canadian" version.

CSHP 2015 is part of Vision 2010. It is introduced in the strategic objective, "CSHP will improve patient medication outcomes and safety by advancing practice excellence through CSHP 2015". CSHP is challenging its members to strive for practice excellence with measurable targets set for the year 2015. CSHP 2015 is a quality initiative. It is a patient-centred tool to help pharmacists strive for effective, evidence-based and safe medication use. The goal of CSHP 2015 is to engage all pharmacy practitioners in various practice settings, including primary care, to reflect on their current practices and to assist them in setting personal goals for practice excellence in the future. No doubt an investment of time and energy to evaluate how you deliver care and what changes and training is necessary to support practice excellence will be required. Who benefits from CSHP 2015? Pharmacy practice, but ultimately it will be our patients who will benefit the most.

CSHP 2015 consists of 6 goals and several supporting objectives. The goals target best medication use for hospitalized and non-hospitalized patients, evidence-based medication use, improving the safety of medication use including technology, and pharmacist involvement in community/public health initiatives. Measurable targets are included so that you have a goal to work towards. Members are encouraged to participate, to incorporate the CSHP 2015 objectives in various ways, including strategic plans/goals, patient improvement projects, new pharmacist services, residency projects and research projects to name a few. Before CSHP 2015 is officially launched, it is important to communicate and educate pharmacists about the document and encourage them to share what they learn with their colleagues in their practice setting. CSHP 2015 is a living, breathing document that all CSHP members are invited to embrace. CSHP plans to share your successes with your colleagues and our external stakeholders, including the public. We want you to learn from each other. Can YOU hit the target? We're sure that you can!

Goals and Objectives

1. To introduce CSHP 2015 to the CSHP membership
2. To describe the evolution of CSHP 2015 from ASHP's 2015 Initiative, highlighting the similarities and differences.
3. To present the 6 goals of CSHP 2015 and describe why pharmacists should embrace the new document and think about how they can incorporate it into their current practice now.

Self-Assessment Questions

1. What is the goal of CSHP 2015?
2. What are the 6 goals of CSHP 2015 and how will they affect the way I practice?
3. What are some of the ways I can incorporate CSHP 2015 into my current practice setting?
4. What will my role be in changing hospital pharmacy practice by 2015?

Tuesday, August 14
Mardi 14 août

Human Factors in Healthcare

Jonas Shultz, MSc, Calgary Health Region, Calgary AB

The goal of this presentation is to provide a basic introduction to Human Factors and human error. Moreover, specific recommendations will be outlined that have resulted from incorporating Human Factors into projects within the Calgary Health Region, many of which may be applicable to heath regions across Canada.

Human Factors involves understanding the interaction between people and the physical, cognitive, and technological aspects of their work. Estimates from the

Institute of Medicine have suggested that on average at least one medication is given in error to each hospital patient per day.[1] Similarities between medication names (i.e., look-alike and sound-alike names) and labels (i.e., look-alike packaging), as well as unsafe storage practices, have been cited as contributory factors.[2,3]

This presentation will discuss methodologies utilized in Human Factors to reduce medical error. Furthermore, these methodologies will be exemplified through practical examples and previous projects. These include the identification of read- and look-alike medications, specific guidelines that have been created to standardize the storage and labeling of medications, the development of a user-friendly narcotics sheet as well as methodologies to design and evaluate equipment.

[1] Aspden P, Wolcott JA, Bootman JL, Cronenwelt LR. Preventing medication errors. Washington (DC): National Academic Press; 2007. Quality Chasm Series.

[2] Cohen MR. Drug product characteristics that foster drug-use system errors. Am J Health Syst Pharm 1995;52(4):395-399.

[3] Lambert BL. Predicting look-alike and sound-alike medication errors. Am J Health Syst Pharm 1997;54(10):1161-1171.

Goals and Objectives

1. To provide a basic understanding of Human Factors and how it can be applied in health care.
2. To outline methodologies used in Human Factors and share specific recommendations that have resulted from previous projects.
3. To learn about safety initiatives that can be applied in other pharmacies or health regions.

Self-Assessment Questions

1. How can we make things more usable to reduce the likelihood of error?
2. Would our pharmacy or health region benefit from incorporating Human Factors?

Metabolic Syndrome: Waist Not, Want Not

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

Metabolic syndrome is a constellation of metabolic abnormalities associated with an increased risk of diabetes and coronary artery disease. These abnormalities include abdominal obesity, hypertension, dyslipidemia, impaired glucose metabolism, a prothrombotic state and a proinflammatory state. The metabolic syndrome is important to practitioners and to individuals affected due to its association with subsequent development of type 2 diabetes mellitus and cardiovascular disease. The pathogenesis of this syndrome has multiple origins, but obesity and sedentary lifestyle coupled with diet and unknown genetic factors interact to produce the syndrome.

Several diagnostic criteria are available to define Metabolic Syndrome. The most widely used and the one utilized within the Canadian Lipid Guidelines and the Canadian Diabetes Association guidelines is the definition published as part of the National Cholesterol Education Program Adult Treatment Panel III Guidelines.

Currently, no randomized controlled trials specifically examining the treatment of metabolic syndrome using hard endpoints are available to guide therapy. However, based on evidence from numerous clinical trials, it is clear that aggressive management of the individual components of the syndrome should occur and should be dependant upon the patient's stratified risk. The cornerstone of treatment of patients with Metabolic Syndrome is lifestyle intervention, with appropriate pharmacologic management of cardiovascular risk factors.

This presentation will review the current data surrounding metabolic syndrome and its management.

Goals and Objectives

At the end of the presentation, you should be able to:

- List the clinical criteria for Metabolic Syndrome and associated risk factors
- Describe prevalence
- Discuss the underlying cause
- List treatment goals
- Discuss therapeutic interventions

Technicians and Pharmacists Partnering for Successful Medication Reconciliation

Lauza Saulnier, BScPhm, ACPR, Melissa White, Pharmacy Technician, South-East Regional Health Authority, Moncton, NB

Medication reconciliation is one of the six targeted interventions of the Safer Health Care Now! Campaign. The goal of medication reconciliation is to prevent adverse drug events at all interfaces of care, for all patients.

Medication reconciliation is also a key component of the Canadian Council on Health Services Accreditation Patient Safety Goals and Required Organizational Practices. It is recommended that a process to reconcile patient medications at transfer points be a shared responsibility, involving the patient, medical staff, nursing staff and pharmacists.

The role of the pharmacy technician to support the delivery of direct patient care pharmacy services, including medication reconciliation from admission to discharge will be described. Various practice models and tools will be presented for empowering clinicians to enhance the role of pharmacy technicians.

Goals and Objectives

1. To describe the role of the pharmacy technician in conducting medication reconciliation from admission to discharge.
2. To outline strategies to successfully implement a multidisciplinary team approach to medication reconciliation.

Self-Assessment Questions

1. How can pharmacy technicians assist pharmacists and other members of the health care team in implementing medication reconciliation?
2. What are practice models and tools available to conduct medication reconciliation?

"This Medication will Prevent Strokes..." and Other Lies We Tell Ourselves and Our Patients: Understanding and Communicating about Effect Sizes of Drug Therapy

Peter Loewen, BScPhm ACPR, PharmD, FCSHP, Vancouver Coastal Health / UBC, Vancouver, BC

Goals and Objectives

Participants will have improved knowledge of how to evaluate effect sizes of drug therapy and will be better able to translate this into appropriate language for discussion with patients.

When communicating with patients, pharmacists frequently use language about the effects of drug therapy that might lead an informed observer to conclude that either they do not understand the evidence behind the therapy or that they are liberally applying their own values to the conversation, or both. When truly informing patients about the benefits and risks of drug therapy is the goal, skillful and flexible translation of scientific "facts" (eg, evidence) into conversations that are meaningful to patients but not (visibly) laden with our own biases is probably required. Through case examples and discussion of the best available evidence, we will examine some of the underpinnings of therapeutic decision-making and evidence-based practice, what patients hear when we talk, and what the "holy grail of pharmacotherapy" might look like and when it is relevant.

Reflecting on our own communication behaviors can be a powerful means for pharmacists to

1. identify areas where we need to more rigorously evaluate what we think we know;
2. scrutinize the language we use and potential differences between what we say and what we mean; and
3. make more conscious distinctions between providing information to assist patients in making informed decisions and providing advice about what decision they should make.

Goals and Objectives

1. participants will reflect on their own use of "qualitative quantification" and how patients interpret what they say
2. participants will be conscious of the "third pillar" of evidence-based medicine when communicating with patients
3. participants will be aware of instances when they are in "Holy Grail of pharmacotherapy" territory and apply the resulting decision-making and communication strategies effectively

Self-Assessment Questions

1. In what areas of my practice do I believe that it is possible to realize the opportunities created by there being "holy grail"-level evidence available to me?
2. What types of "qualitative quantification" am I prone to using in my conversations with patients, and what alternatives should I consider using?

Why is Mom So Confused? Considerations for Delirium in the Acute Care Setting

Susan Bowles, PharmD, FCSHP, Capital Health Authority, Halifax, NS

The overall goal of this presentation is to provide pharmacists with an understanding of delirium in the acute care setting. Delirium is characterized by the acute onset of confusion, in combination with a fluctuating course, attention deficits, disorganized thinking and/or a change in the level of consciousness. Delirium occurs commonly in hospitalized older persons, and is associated with significant morbidity and an increase in mortality. Importantly, the best treatment for delirium is its prevention. When delirium does occur, it should be viewed as a symptom, with identification and treatment of precipitating factors as the primary treatment strategy. Frequently, medications are an important precipitating or exacerbating factor. Pharmacologic intervention is not always necessary for management, depending upon the amount of distress that the person is experiencing in the course of their delirium.

Pharmacists have an important role to play in the prevention, recognition and management of delirium, thereby optimizing patient outcomes.

Goals and Objectives

At the conclusion of this presentation, participants will:

1. Be familiar with the clinical presentation of delirium.
2. Recognize important risk factors for delirium
3. Understand the indications for pharmacologic therapy of delirium as a symptom.
4. Be familiar with appropriate pharmacologic therapy for delirium when indicated.

Self-Assessment Questions

1. Which of the following medications is considered a "frail-friendly" choice in normalizing the sleep-wake cycle for an 86 year old female with a mixed hyper- and hypoactive delirium?
   - Trazodone
   - Lorazepam
   - Risperidone
   - Haloperidol

2. Which of the following would be considered an appropriate indication for the initiation of pharmacologic intervention in the management of delirium in an older preson?
   - Patient is constantly calling out "nurse, nurse – help me, help me."
   - Patient is sleeping most of the day.
   - Patient is experiencing visual hallucinations but is not distressed by them.
   - Patient expresses fear that some staff members are trying to hurt them.
3. Which of the following is NOT characteristic of the clinical presentation of delirium?
   - Unable to subtract serial 4's from 40.
   - Slow decline of cognition over the past twelve months.
   - Difficulty keeping track of a conversation.
   - Attempting to climb over the bed rails.

Change in My Pocket: Effective Change Leadership Strategies for Pharmacists

Doug Robertson, MBA, Saskatoon Health Region, Saskatoon, SK

This presentation examines the categories of change, and the leadership styles required to successfully navigate each category.

The first category is developmental change. This type of change is simply an improvement of what exists, where the new state is a prescribed enhancement of the old state. It is like changing a box into a bigger or fancier box. This type of change can be managed through training, communications, and process improvement.

The second category is transitional change. This involves the design and implementation of a desired new state. This is like changing from a box into something different, but recognizable, such as a sphere. This kind of change requires project management skills and tools (i.e.: a defined process and timetable).

The third category of change is called transformational change. This type of change, by definition, is when you don't know the outcome at first. Transformational change is like changing the box into something else, but you don't know what the "something else" is. It emerges throughout the process and requires continual course corrections to be successful. It is driven by the environment and client needs. In the end, our own thinking and character is transformed—not just the project we are working on. Transformational change requires a fundamental change to our mindset, where the organization is viewed as an emerging system, rather than as a predictable machine.

Do you have the leadership skills to navigate through uncharted waters? This is the challenge of transformational change.

Goals and Objectives

1. To provide pharmacists with an understanding of the different types of change, and how to recognize them.
2. To enable pharmacists to recognize the different leadership and management styles required to lead the three categories of change.

Self-Assessment Questions

1. Why is transformational change so difficult to recognize?
2. What kind of leadership style is required to lead transformational change?

Show Me the Evidence! Academic Detailing in Canada?

Loren Regier BSP, BA, RxFiles Academic Detailing Program, Saskatoon, SK

The goal of this session is to provide pharmacists with an understanding of the concept, the evidence behind, and the status of academic detailing in Canada.

Academic detailing involves the provision of objective, evidence based information via one-to-one or small group educational outreach visits. It involves an evaluation of the effectiveness and safety of medications, often digging beneath the marketing hype. The academic detailing session or "physician office visit" offers an educational service tailored to the physician's interests and needs. Systematic reviews from Cochrane and Health Technology Assessment reviews have found academic detailing to be one of the educational interventions that have an impact on prescribing.

Several academic detailing programs in Canada have joined to form the Canadian Academic Detailing Collaboration (CADC). The CADC is working together to develop materials, training programs and evaluation projects for academic detailing programs in Canada.

Goals and Objectives

1. To provide pharmacists with an understanding of the theory and evidence behind academic detailing
2. To review the status of academic detailing in Canada
3. To discuss the successes and challenges that surround the academic detailing environment

Self-Assessment Questions

1. What educational strategies have been found to be effective in changing prescribing practices?
2. What are the features that make academic detailing an attractive service to physicians?
3. What are two essential strategies in attempting to weigh the risks and benefits of a drug therapy?

The Bottom Line on Dyslipidemia Treatment for Pharmacists

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

Given advancements in pharmacy practice and current expectation that pharmacists take a more active role in and responsibility for medication management and patient health outcomes, pharmacists should be taking steps to identify and collaboratively manage patients with dyslipidemia. To emphasize where knowledge and skills of pharmacists should be applied in management of patients with dyslipidemia, the 2006 Canadian Cardiovascular Society Recommendations for the Diagnosis and Treatment of Dyslipidemia and Prevention of Cardiovascular Disease have been adapted for pharmacists. The development of these Canadian pharmacist practice guidelines are a part of the continuing national effort to recognize and advance the responsible and patient-centred role of the pharmacist in chronic disease management.

As key players in the healthcare system, pharmacists should be able to utilize their knowledge, skills, and relationship with patients to improve the management of dyslipidemia and prevent cardiovascular disease. Consequently, these practice guidelines emphasize the role of the pharmacists in all aspects of managing the disease: (i) identification and screening of patients; (ii) individual cardiovascular (CV) risk assessment; (iii) establishing appropriate lipid targets, based on CV risk; (iv) lifestyle modification; (v) implementing and monitoring appropriate drug treatment; (vi) ensuring patient adherence with treatment; and (v) specialty clinic referral, where appropriate.

Goals and Objectives

1. To provide pharmacists with an overview of the new 2007 Guidelines for the Management of Dyslipidemia and Prevention of Cardiovascular Disease by Pharmacists.
2. To enable pharmacists to take a more active and responsible patient-centred role in the chronic management of patients with dyslipidemia.

Self-Assessment Questions

1. For low and moderate-risk patients who are candidates for lipid-lowering treatment, what target LDL-C and TChol:HDL-C levels should be recommended by the pharmacist?
2. Whenever drug therapy is recommended, what laboratory testing should the pharmacist suggest to ensure that the patient is receives ongoing monitoring for the efficacy and safety of the drug regimen initiated?

Sunday, August 12
Dimanche 12 août

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

1. Development and Implementation of an Enhanced Pharmacy Technician Role in the Pharmacy Department at St Michael's Hospital
2. Development and Implementation of an Electronic Viewable Medication Profile
3. Building a Drug Library for the Baxter Colleague® CXE "Smart" Infusion Pump
4. Advancing Pharmacy Services in the Midst of Pharmacist Shortages
5. Successful Implementation of a Standardized Subcutaneous Insulin Order Set Including Basal, Prandial and Adjustment Scales
6. Development of an Electronic Pharmacy Patient Profiling System in the Era of Computerized Physician Order Entry
7. A Survey to Assess the Culture, Attitudes and Educational Needs of Front Line Hospital Health Care Providers Regarding Medication Incident Reporting in a Tertiary Teaching Hospital
8. Stability of Cefazolin, Ceftazidime, Ceftriaxone, Vancomycin and Meropenem in an Elastomeric Infusion Device (Accufuser®) at 4°C and Room Temperature (23°C)
9. Visual Y-Site Compatibility of Voluven® with 38 Other Intravenous Medications

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DEVELOPMENT AND IMPLEMENTATION OF AN ENHANCED PHARMACY TECHNICIAN ROLE IN THE PHARMACY DEPARTMENT AT ST MICHAEL'S HOSPITAL

Dara, C. Davies, P. Wells, J. St Michael's Hospital, Toronto, ON

There is an increasing demand for clinical pharmacy services and up-to-date electronic viewable medication profiles in this quaternary care hospital. It was identified that pharmacy technicians could assume a greater role in the drug distribution system to enable the transition of pharmacists to increased clinical duties, and to ensure complete medication order entry.

A scope document and analysis was performed on the current and future state of the pharmacy technician role. The current state document surveyed the pharmacy technician role in comparable Canadian academic institutions, while the future state reviewed the literature for innovative roles across North America.

The gap analysis determined maximal benefit for technician-check-technician (TCT) in the inpatient pharmacy services area (IPS). The goal was to have technicians perform the final product checks to allow the pharmacists to complete order entry and problem-solving. A healthcare-failure-mode-and-effects analysis (HFMEA) was performed to identify target areas in the drug distribution system to maximize efficiency and patient safety. It was decided to formally delegate checking functions from pharmacists to pharmacy technicians. To facilitate the delegation, a technician training manual was developed to standardize the checking procedure, weekly training was performed for each technician, and pharmacist documentation of order assessment and entry was standardized.

After a year, TCT has been fully implemented. A survey to evaluate the impact of TCT resulted in consensus that the technicians had assumed a technical aspect of the pharmacists' role. Job satisfaction improved for pharmacists (46% improved, 10% no change) while the technicians reported mixed feelings about job satisfaction (6% increased, 9% decreased, and 16% reported no change).

TCT has been an integral step in the transition of the department and institution to physician order entry and electronic medication administration records, and will enable further enhanced technician role development.

DEVELOPMENT AND IMPLEMENTATION OF AN ELECTRONIC VIEWABLE MEDICATION PROFILE

Salma Satchu, Andrea Ryl, Yin Hua, St. Michael's Hospital, Toronto, ON

Medications comprise an extremely important aspect of care in the acute, hospitalized patient population. Currently, at St. Michael's Hospital clinicians rely on a manual nursing medication administration record to obtain information on patients' medication regimens. With a plan to implement physician order entry over the next 2 years, an interim, integrated solution for convenient access to inpatient medication profiles was required.

An initial feasibility assessment was conducted to describe current processes and patterns of medication ordering, transcribing and entry into the pharmacy system. During the design phase, discussions were conducted with clinicians to determine optimal characteristics of the profile. A collaborative effort between the pharmacy and information technology departments resulted in the creation of the electronic Viewable Medication Profile (VMP) utilizing Active Server Page and Open Database Connectivity. Several versions of the tool were presented and modified based on clinician feedback. The final VMP displays medication orders from the pharmacy database for current and past admissions within a 90-day window. It is retrievable on demand, in real time through the web-based electronic patient record (Soarian Clinicals TM).

A 2-week pilot with education of staff and physicians on the utility and limitations of the VMP was conducted on the general internal medicine inpatient unit. Prior to hospital-wide implementation, a multi-disciplinary safety evaluation of the VMP was conducted using the Failure Modes and Effects Analysis (FMEA) framework. This analysis identified potential vulnerabilities of the tool and helped to define strategies to further minimize any process gaps. Subsequent hospital-wide education was designed to address vulnerabilities identified by the FMEA. Hospital-wide roll-out was completed in December 2006.

Convenient and comprehensive access to patient-specific medication information is essential for the provision of optimal care. The VMP provides clinicians with a supplemental tool that can be integrated into their workflow to facilitate medication management.

BUILDING A DRUG LIBRARY FOR THE BAXTER COLLEAGUE® CXE "SMART" INFUSION PUMP

Salma Satchu, Rosemary Tanzini, Celina Dara, Andrea Ryl, Janice Wells, St. Michael's Hospital, Toronto, ON

Medication administration is a significant source of medication errors in the hospital setting. Intravenous (IV) infusions are particularly vulnerable because of the many steps involved in the preparation and administration of these products. One technology available to promote safe practice is a "smart" pump that supports the bedside use of pre-defined drug profiles.

In preparation for the hospital-wide introduction of Baxter Colleague® CXE infusion pumps with Guardian Feature (error reduction software), a failure modes and effects analysis (FMEA) was conducted to describe the steps involved in programming infusions on the current and new pumps. The FMEA highlighted vulnerabilities in the system where the potential for error was greatest.

A drug library working group, consisting of nursing and pharmacy staff, met biweekly for a period of 3 months to advise on decisions related to the design of the drug library, such as general principles, nomenclature, dosing limits and standardized concentrations. Additional activities included practice sessions and specific focus groups to identify clinical specialty-specific issues and to take inventory of IV infusion practices. Discrepancies between hospital-approved protocols and current practice were identified and reconciled. Clinical pharmacists were consulted as needed and served as resources during the building and final validation processes. The final drug library consists of 78 distinct drug profiles across 3 sub-libraries (adult critical care, adult general ward, pediatric).

The major challenges posed during the drug library build included tight timelines for development and implementation, heterogeneity of clinical areas, technical limitations of the pump, variations in nursing practice and a lack of standardized drug concentrations. It became evident that successful design of the library with meaningful impact on patient safety needed to be a collaborative process with all stakeholders involved. Evaluation of the new pumps through nursing focus groups and pump audits is being planned after the initial implementation period.

ADVANCING PHARMACY SERVICES IN THE MIDST OF PHARMACIST SHORTAGES

Susan Fockler, James L. Mann, Ross Memorial Hospital, Lindsay, ON

It has been said, "crisis causes change". Such was the case at the Ross Memorial Hospital (RMH) in the fall of 2005! Two full time pharmacists resigned, leaving only 1.4 FTE pharmacists and 4.6 FTE technicians (55% of budget) to service for this 175 bed community hospital located in Lindsay, Ontario. Years earlier, an operational review had been completed that supported the business case presented to Senior Administration for revamping services. Clearly the current emphasis on patient safety added significant support for proposed changes.

Over the last two years, our floor space has doubled, 8 technicians have been hired, drug distribution services have been enhanced and direct-patient care services have been added. In spite of several pharmacist vacancies, we have been able to advance our services by using consultants, delegating to technicians and creative recruiting strategies. Specifically, "self-employed" contract personnel have been used fill interim positions, lead projects and provide education. We have partnered with another hospital to implement a new computer system. Several companies are preparing proposals to update our Formulary. Our technicians are leading most drug distribution enhancements including point-of-use technology, a CIVA program and ISMP recommendations for opioids. We have extended technician responsibilities in dispensary supervision, medication reconciliation and on-call services.

In many ways our quest to advance pharmacy services has just begun. We are constantly looking for opportunities to tell others about the unique contribution we can make to patient care. We have been featured in the in-house "Monday Report", RMH awards program, local newspapers and posters at national professional meetings.

RMH is not unique. According to the 2005/06 Hospital Pharmacy in Canada compiled by Eli Lilly Canada Inc, 13.3% of hospitals across Canada have pharmacist vacancies. Our solutions to this challenge will be of interest to all hospital pharmacists.

SUCCESSFUL IMPLEMENTATION OF A STANDARDIZED SUBCUTANEOUS INSULIN ORDER SET INCLUDING BASAL, PRANDIAL AND ADJUSTMENT SCALES

Douglas Doucette, Mary Catherine MacSween, Michelina Mancuso. South-East Regional Health Authority, Moncton, NB

Problem: Mounting evidence consistently indicates that hyperglycemia in the hospital setting is associated with increased morbidity and mortality. Meticulous glycemic control has been show to improve clinical outcomes in this setting.

Design: Observational study evaluating the impact of a new Standardized Subcutaneous Insulin Order Set (SSIOS) for use in all hospital departments.

Setting: Level II Hospital in Moncton, NB, Canada.

Strategy for Change: To successfully implement SSIOS, a number of strategies were employed including: development of physician clinical order set by interdisciplinary committee based on a published protocol; education and "buy in" of providers; available support personnel; established institutional systems to effectively and efficiently manage the metabolic needs of this patient population; recruitment of "champions" for each discipline to facilitate implementation; introduce to one unit at a time to allow slow adaptation; measure and analyze glucometer readings prospectively to address issues and provide feedback to clinicians; work as a cohesive team across all disciplines.

Effect of Change: Pilot unit had 100% use of the SSIOS. In the 5 weeks prior to the SSIOS, 20% of total glucose meter reads were > than 10mmol (using standard sliding scale). Post 8 weeks using the SSIOS, only 10% of total glucose meter reads were >10mmol (50% reduction in hyperglycemic events). Monitoring will continue as the SSIOS is implemented on other units. Other outcomes such as surgical site infection will also be studied.

Lessons Learned: A variety of issues were identified that need to be resolved to ensure patient safety and successful implementation in the pilot unit and in other units. Pharmacists were able to contribute to this process as a member of the support team, in providing clinical and case-based education, and in assisting physicians and nurses with ordering and monitoring of patients for whom the SSIOS was prescribed.

DEVELOPMENT OF AN ELECTRONIC PHARMACY PATIENT PROFILING SYSTEM IN THE ERA OF COMPUTERIZED PHYSICIAN ORDER ENTRY

Ada Seto; Jin Huh; Monique Pitre; Manhim Chau, Toronto Western Hospital, University Health Network, Toronto, ON

Rationale: Paper-based communication of clinical and operational issues amongst pharmacists has the following limitations: non-standardized template for communication, frequent loss of information, limited accessibility, and inability to easily retrieve and analyze data. With the implementation of Computerized Physician Order Entry, the development of a computer-based pharmacy documentation system was needed to improve communication.

Description: Pharmacy Clinical Intervention Report and Track (P-CIRT) was developed and piloted at our institution in July 2005. Training sessions were provided to staff pharmacists in order to ensure compliance. Based on feedback collected from users over 21 months, the application has been updated to include new functionalities: 1) synchronization of patient visit information to reduce manual input, 2) interface between PCIRT and electronic patient records integrating lab values and medications from different applications onto one screen, 3) linking of specific patient issues with relevant lab data to enhance pharmaceutical care, and 4) selection of patient issues from a standardized database of medical terms (SNOMED®) to minimize uncategorized free-text input.

Results: Over the 21 months of the pilot project, 10490 patients and 32001 issues were documented by staff pharmacists. Communication and accessibility were improved as evident by 44 % of issues accessed by more than one pharmacist. Clinical data and workload statistics were easily retrieved by using database queries. A total of 7348 therapeutic interventions were logged by all pharmacists. Similar statistics have been achieved in the 2 months since the use of the upgraded application.

Conclusion: P-CIRT has overcome barriers to effective communication, standardized methods of documentation of pharmacy interventions, provided accessibility to documented information in a central location for all pharmacists without breaching confidentiality, and facilitated collection of workload statistics. Next steps include implementation at the other 2 sites of our institution and evaluation of the feasibility to answer research questions with PCIRT.

A SURVEY TO ASSESS THE CULTURE, ATTITUDES AND EDUCATIONAL NEEDS OF FRONT LINE HOSPITAL HEALTH CARE PROVIDERS REGARDING MEDICATION INCIDENT REPORTING IN A TERTIARY TEACHING HOSPITAL

Soltys I., Heffer M., Leung D., Toronto Western Hospital, University Health Network (UHN), Toronto, ON

Reason for Initiative: The Toronto Western Hospital interdisciplinary Safe Medication Practice Committee reviewed all hospital medication incidents and identified a need for an education initiative regarding the quality of medication incident reporting. The importance of medication safety staff education was also identified in our organizations accreditation report through the Canadian Council on Health Services Accreditation. In addition, the Pharmacy and Therapeutics Committee acknowledges that more education is needed to enhance awareness of physicians, nurses and allied health professionals concerning the process for reporting and methods of assessing medication incidents. This project is in line with our corporate goals and objectives outlined in the UHN Balanced Score Card where there is an indicator measuring success in reducing medication incidents.

Description of Initiative: This project was a joint initiative between the pharmacy and risk management departments. A survey was designed to assess the prevailing culture and attitudes towards medication incident reporting, the current knowledge base regarding the incident reporting process, awareness of hospital medication safety initiatives and the review and analysis process. In addition, the survey assesses the practical knowledge, comfort level and skill in accessing and filling out the medication incident e-form.

Evaluation of Initiative: The survey allowed us to identify focus areas for medication safety education initiatives that met the nursing unit specific needs.

Importance and Usefulness of Initiative for Pharmacists: Pharmacists are integral members of the organizations Safe Medication Practice Committee and act as leaders and advocates for medication safety as members of front-line health care teams. This survey will provide information regarding educational needs of staff with the goal of designing nursing unit specific seminars that will address these areas for knowledge and skill development. This project also facilitates pharmacists in our organization to collaborate with other disciplines to meet the medication safety needs of front-line staff.

STABILITY OF CEFAZOLIN, CEFTAZIDIME, CEFTRIAXONE, VANCOMYCIN AND MEROPENEM IN AN ELASTOMERIC INFUSION DEVICE (ACCUFUSER®) AT 4C AND ROOM TEMPERATURE (23C)

Scott E. Walker, Shirley Law, Department of Pharmacy, Sunnybrook Health Sciences Centre, University of Toronto, Toronto

Rationale: The Accufuser®, is a silicone-based elastomeric infusion device used to infuse drugs at a specified rate without a pump. Little information is available related to the stability of drugs stored in an Accufuser. Therefore, the objective was to determine reasonable beyond-use dates for 5 commonly used antibiotic solutions in the Accufuser® under recommended storage conditions.

Methods: On study day 0, vials of cefazolin, ceftazidime, ceftriaxone, vancomycin and meropenem were reconstituted and diluted in D5W or NS to prepare a low and high concentration of each antibiotic. Four 60-mL Accufusers of each concentration/solution were stored at room temperature and four were refrigerated. Concentration and physical inspection were completed on each solution on study days 0, 1, 2, 4, 7, 10, 14, and 18 or 21. Concentrations for each antibiotic were determined by a validated, stability-indicating, liquid chromatographic method. The time for concentration to decline to 90% of initial, based on the lower limit of the 95% confidence interval was calculated.

Results: All drugs degraded faster at 23C than 4C. Ceftazidime, cefazolin, meropenem and vancomycin degraded faster in D5W than saline. During all study periods 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: Storage at 4C should not exceed 7 days (ceftazidime 60-mg/mL in NS; meropenem 5-mg/mL in NS), 14

days (ceftriaxone 40-mg/mL in D5W or NS), or 21 days (cefazolin 40-mg/mL in D5W or NS; vancomycin 5-mg/mL in D5W or NS). These expiry dates allow for up to 6 hours storage at 23C during the product's shelf-life and are similar to those previously reported for these drugs in PVC minibags. Use of these expiry dates should only occur after consideration of sterility and the contamination rate in your IV additive program.

This study was funded through an unrestricted educational grant from Valeo Pharma, Kirkland, QC.

VISUAL Y-SITE COMPATIBILITY OF VOLUVEN® WITH 38 OTHER INTRAVENOUS MEDICATIONS

Scott E. Walker, Shirley Law, Department of Pharmacy, Sunnybrook Health Sciences Centre, and the University of Toronto, Toronto, ON

Rationale: Voluven® is a hydroxyethyl starch compound supplied as a clear, colourless liquid which contains 6 g of poly(O-2-hydroxyethyl) starch and 0.9 g of sodium chloride per 100 mL of water. Voluven® is a plasma expander and is often given with a variety of other drugs used in the acute care setting. Since no data is available on the compatibility of Voluven® with any medication, the objective of this study was to evaluate the physical compatibility of Voluven® with 38 other intravenous medications.

Methods: 38 drugs, each at 3 different concentrations in D5W, were selected for compatibility testing with Voluven® over a 24-hour period at room temperature. The 38 drugs selected were ampicillin, calcium chloride, calcium gluconate, cefazolin, ceftriaxone, ciprofloxacin, clindamycin, dimenhydrinate, dobutamine, dopamine, epinephrine, esmolol, fentanyl, furosemide, gentamicin, heparin, hydromorphone, insulin, labetolol, levofloxacin, magnesium sulphate, meperidine, methprednisolone, metronidazole, midazolam, morphine, moxifloxacin, multivitamins, nitroglycerine, norepinephrine, octreotide, phenytoin, piperacillin, potassium chloride, potassium phosphate, sodium bicarbonate, vasopressin and propofol. Mixtures judged as compatible had no evidence of a precipitate, colour change or evolution of gas.

Results: 36 of the 38 medications tested were observed to be compatible when diluted in D5W and then mixed with Voluven®. Mixtures of Voluven® and epinephrine resulted in a colour change within 4 hours following mixing. This colour change occurs in virtually all Voluven® – epinephrine mixtures and may be related to an increase of 2 pH units following mixing. Precipitation was observed at all concentrations when Voluven® were mixed with phenytoin.

Conclusions: Voluven® is incompatible with phenytoin and epinephrine. It is recommended that Voluven® and phenytoin never be infused together through a Y-site. Mixtures of Voluven® and epinephrine resulted in a colour change within 4 hours following mixing. Given the short contact time during a Y-site infusion, it is likely that epinephrine and Voluven® can be infused through the same Y-site. However, there is an increased risk of degradation, possibly related to the 2-pH unit increase following mixing and this risk increases as contact time increases (flow rates are reduced and or the length of tubing increases).

This study was funded through an unrestricted educational grant from Fresenius Kabi Canada

Monday, August 13
Lundi 13 août

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

1. Incorporation of a Pharmacist into a Stroke Prevention Clinic
2. Pharmacists Attitudes on a Drug Formulary System in Fraser Health: Results of a Cross-Sectional Qualitative On-Line Survey
3. Development and Use of a Prior Learning Assessment Survey in a Pharmacy Practice Residency Program
4. The Impact of the Cardiac EASE (Ensuring Access and Speedy Evaluation) Program
5. Evaluation of the Utilization and Effects of Drotrecogin Alpha (Activated) for Sepsis in Critically Ill Patients at a Community Acute Care Hospital
6. Linezolid Use Evaluation in the Fraser Health Authority
7. Pancytopenia Associated with Amiodarone Hydrochloride
8. Clinical and Economic Effects of a Therapeutic Substitution Policy for Proton Pump Inhibitors for Aboriginal Patients in Northern Communities in the Northwest Territories

INCORPORATION OF A PHARMACIST INTO A STROKE PREVENTION CLINIC

Adrienne J Lindblad, Jason Howorko, David Thompson Health Region, Red Deer, AB

Rationale: With the exception of anticoagulation management, publications on pharmacist involvement in secondary stroke prevention clinics are lacking. We describe the incorporation of a pharmacist into a stroke prevention clinic and outline the duties of a pharmacist in that role.

Description of Situation: A regional stroke prevention clinic was developed to minimize modifiable risk factors for stroke survivors to prevent recurrent stroke. A pharmacist was invited to participate in the care of clinic patients.

Program Implementation: The rationale for pharmacist involvement in a stroke clinic was reviewed. Evidence for pharmacist involvement in dyslipidemia and hypertension management suggest a positive effect of pharmacist involvement in stroke prevention. A discussion of the considerations given to such a position was performed.

Evaluation: A retrospective review of the quantity and types of interventions undertaken by a stroke pharmacist was conducted over a 6-month period using the health region's pharmacist workload measurement system. The clinic pharmacist became part of a collaborative team and made 432 drug-related interventions during the study period, representing 2.8 interventions per patient encounter. The majority of the interventions were related to patient education, medication reconciliation, initiation of

pharmacotherapy and preventing/resolving adverse drug reactions.

Usefulness to Practice: The incorporation of a pharmacist into a stroke prevention clinic is supported by the literature on risk reduction. Numerous drug-related issues can be identified and resolved by stroke clinic pharmacists.

PHARMACISTS ATTITUDES ON A DRUG FORMULARY SYSTEM IN FRASER HEALTH: RESULTS OF A CROSS-SECTIONAL QUALITATIVE ON-LINE SURVEY

Tejani A.M., Corrigan S., Letwin S., Lakhani A., Miyata M., Fraser Health Authority, Vancouver, BC

Rationale: Drug formulary systems (DFS) exist to promote evidence-based, rational, cost-effective drug therapy. However, in Fraser Health (FH) care facilities, it has been observed that despite the presence of a defined drug formulary and related policies, compliance with the DFS is less than ideal. Determination of the root causes related to non-compliance may enable improvements to the DFS.

Description of Situation: Pharmacists are generally the primary gate keepers of the DFS. Drug use evaluation within FH has identified a high rate of non-formulary drug use.

Steps Taken to Identify Issues: A cross-sectional qualitative on-line survey of all pharmacists in FH was conducted to help determine attitudes related to the DFS and identify barriers to successful implementation. Questions fell into the following broad categories: beliefs regarding the benefits /barriers of a DFS, communication /education regarding DFS decisions and policies, how do they deal with non-formulary drug orders, and beliefs about the decision-making process.

End Result: In general pharmacists believed that a DFS is a useful way to promote evidence-based, rational, cost-effective drug therapy. However, interruption of seamless care (due to formulary drug substitution) and the potential for subsequent increases in medication errors are major barriers. The majority of respondents did not attempt to have non-formulary drug requests changed to formulary alternatives. Reasons for this were: lack of education on the rationale for formulary decisions, lack of time and resources to have orders changed to formulary alternatives, and the lack of a clear non-formulary drug policy. Respondents indicated that DFS compliance would increase if these three barriers were improved upon by the administrators.

Importance and Usefulness: The survey identified attitudes in FH regarding the DFS. In addition, ways in which DFS implementation and management could be improved were identified.

DEVELOPMENT AND USE OF A PRIOR LEARNING ASSESSMENT SURVEY IN A PHARMACY PRACTICE RESIDENCY PROGRAM

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

Rationale: The Canadian Hospital Pharmacy Residency Board requires that residency programs consider a resident's prior learning when scheduling a course of study. Prior learning assessment (PLA) minimizes learning duplication, identifies areas requiring further study, promotes understanding of personal strengths and likes, establishes a professional development baseline, and prepares learners for the residency transition.

Description of concept: We reviewed literature, sampled existing PLA tools, and clarified our program's desired learning outcomes before creating our 133-item survey. The survey was revised twice (to eliminate redundant learning outcomes and to clarify questions). Respondents scored past experience, perceived ability and interest in domains such as clinical, professional practice, technology, drug distribution, practice management, communication, drug information, research and writing skills.

Results & Evaluation: We collated results from 19 surveys completed before residents started their programs. Overall, highest interest scores were to develop direct patient care, clinical problem solving, disease prevention/ wellness promotion and written communication skills. Interest scores greatly exceeded ability scores for: drug use evaluation, clinical rotations, practice management, drug information and research skills. PLA data have prompted development of new electives, better matching of residents to projects and practice sites, registration for additional courses (e.g., conflict resolution, Access® database), improved scheduling of learning experiences, and enhanced career counseling and mentorship.

Relevance: Effective 2006, residents complete the same survey at program exit, to validate residency learning and establish a career development baseline. We plan to apply PLA methodology for new staff orientation and training in the future.

THE IMPACT OF THE CARDIAC EASE (ENSURING ACCESS AND SPEEDY EVALUATION) PROGRAM

Tammy J. Bungard; Lucille D. Lalonde; Marcie J. Smigorowsky; Terry Hogan; Katherine M. Doliszny; Ghirmay Gebreyesus; Stephen L. Archer; University of Alberta, Edmonton, AB

Purpose: To describe the impact of a single point of entry, multidisciplinary, outpatient cardiology program, Cardiac EASE, on wait times for cardiology consultation and ascertainment of diagnosis/treatment plan.

Methods: Prior to implementing EASE (Pre-EASE) new consults were tracked. Billing and physician records were reviewed to determine the date of consultation and management plan. All patients referred to EASE within 2004 were included in the analysis. The primary outcome was the change in waiting time for cardiology consultation Pre-EASE vs during EASE, defined as the difference in time between the date of referral receipt and initial cardiology consult. Secondarily, we assessed the interval of time between referral and establishment of a final diagnosis/treatment plan.

Results: 309 patients were seen during Pre-EASE and 723 within EASE. No difference in mean [+SD] age (59.8 + 16.2 and 59.1 + 16.5 years) or gender (55% and 52% being male) was observed amongst the groups. Pre-EASE and during EASE, most patients were referred for CP (31.4% and 39.6%) and arrhythmias (26.9% and 28.2%), while fewer patients were referred for presyncope/syncope/valvular heart disease (11.7% and 13.3%), CAD (19.7% and 5.3%), and HF (6.2% and 9.1%). Most referrals Pre-EASE and during EASE were from Capital Health (63.8% and 58.9%), followed by central Alberta regions (24.9% and 22.0%), and northern Alberta regions (8.4% and 11.5%). Wait times were significantly reduced during EASE (24.0 + 13.1 days) compared to Pre-EASE (70.9 + 44.7 days) [$P<0.0001$]. The time between referral to determination of a final diagnostic decision and treatment plan was reduced from 123.3 + 85.5 to 61.3 + 75.6 days during EASE ($P<0.0001$).

Conclusions: The implementation of a novel program offering a single point of entry with a multidisciplinary consultative clinic significantly reduced wait times for cardiac consultation, while coordinating care to render diagnostic decisions in a timely fashion.

EVALUATION OF THE UTILIZATION AND EFFECTS OF DROTRECOGIN ALPHA (ACTIVATED) FOR SEPSIS IN CRITICALLY ILL PATIENTS AT A COMMUNITY ACUTE CARE HOSPITAL

Zahra Kanji, Lions Gate Hospital, North Vancouver, BC

Purpose: We developed pre-printed orders to facilitate the use of drotrecogin alpha because of its benefit mainly in severely septic patients with a higher risk of mortality, the risk of bleeding and the high cost of the drug.

Objectives: The primary objective was to evaluate the appropriateness of utilization of drotrecogin alpha. The secondary objective was to describe the patients receiving drotrecogin alpha, the efficacy and toxicity outcomes, and wastage with this agent.

Methods: A retrospective review of patients who received drotrecogin alpha from 2003 until April 2007. Patients were identified through a search of the orders database of the hospital's information system. Health care records were reviewed by a pharmacist using a predefined data collection tool.

Results: Of the 27 patients who received drotrecogin alpha during the study period, 26 (96.3%) were eligible for therapy. The mean Acute Physiology and Chronic Health Evaluation II score was 28 and the mean number of dysfunctional organs/systems was 3. The lungs (44.4%) and abdomen (40.7%) were the most common sites of infection. There was a greater incidence of gram-positive (41.4%) than gram-negative (20.7%) infections and 37.9% of cultures were negative. Twelve (44.4%) patients had died at 28 days. Two (7.4%) patients had a serious bleed during the infusion. Wastage of drotrecogin alpha totaled 145 mg in 10 (37%) patients, with the average wastage being 0.9 bags or 14.5mg of drug per patient. Half the wastage (70mg) occurred because supplies of drotrecogin alpha had been prepared prior to completing the current bag in patients whose therapy was interrupted, at a cost of approximately $4700.

Conclusion: The pre-printed order is facilitating the appropriate utilization of drotrecogin alpha. We have information on the patient population receiving drotrecogin alpha and on efficacy, toxicity, and wastage associated with the use of drotrecogin alpha at our institution.

LINEZOLID USE EVALUATION IN THE FRASER HEALTH AUTHORITY

Jennifer Bolt, Anisha Lakhani, Yasemin Arikan, Dale Purych, Fraser Health Authority, BC

Rationale: The usage of linezolid in Fraser Health Authority (FHA) has been rising steadily over the past two years. A recently published linezolid usage evaluation study involving select Canadian hospitals indicated over 40% of use was inappropriate. In FHA, linezolid was approved for limited indications involving resistant Gram positive infections. The purpose of this project was to evaluate linezolid use in FHA and make recommendations on appropriate use as necessary.

Objectives: The primary objective was to determine the appropriateness of linezolid utilization based on predefined, evidence based criteria for the treatment of resistant Gram positive infections. The secondary outcome was to characterize patient demographics, types of infections treated, and clinical outcomes associated with the use of linezolid.

Design: Retrospective chart review of adult patients who received linezolid in all acute care facilities in the FHA within a one-year period.

Results: A total of 124 patients received linezolid in FHA between January 1st, 2006 and December 31st, 2006. Of these, 68% of cases received linezolid appropriately based on the pre-defined criteria. In the remaining 40 cases, 92.5% (37/40) received linezolid for inappropriate indications, 5% (2/40) for inappropriate duration and 2.5% (1/40) got an inappropriate dose. Two most common inappropriate indications were: (a) use in patients in whom VRE was potentially a contaminant or colonizer (27.5%, 11/40), and (b) failing to use vancomycin as a first line agent against susceptible organisms (27.5%, 11/40).

Conclusion: The results of this study indicate that there is opportunity for improvement in linezolid prescribing in FHA. Opportunities include education on recognizing VRE as a contaminant versus an infecting agent, and optimizing the use of vancomycin, such as dosing strategies and guidelines, especially in patients with renal dysfunction. Education on approved indications for linezolid, its side effect profile, and patient affordability issues were also highlighted.

PANCYTOPENIA ASSOCIATED WITH AMIODARONE HYDROCHLORIDE

J. Chan, L. Chan, University Health Network, Toronto, ON

Amiodarone is used to treat superventricular and ventricular arrhythmias. It has many side effects that necessitate periodic laboratory monitoring. However, hematological monitoring is not routinely performed. We present a case of pancytopenia associated with amiodarone.

An 80-year-old male with a history of diabetes, chronic renal failure and fatty liver, was admitted for cardiac surgery. He had no known drug allergies or any history of hematological disorders. Post operatively, he developed sick sinus syndrome and was treated with oral amiodarone, which was continued after hospital discharge.

The patient was readmitted one month later with increased dyspnea and severe pulmonary hypertension. Chest X-ray showed areas of consolidation and ground glass opacity in the upper lungs, which was thought to be related to amiodarone toxicity. A CT scan of the chest was negative for pulmonary emboli. The patient's hemoglobin was 79, leukocytes were 1.4x109, platelets were 148x109 compared to hemoglobin of 97, leukocytes of 11.8x109 and platelets of 263x109 when amiodarone was first started. Abdominal ultrasound was negative for portal vein thrombosis-induced hypersplenism. Hematology consultation ruled out infectious and neoplastic causes. Amiodarone was discontinued as it was suspected to be associated with the low blood counts. His blood cell counts improved after amiodarone was discontinued and continued to improve. His hemoglobin was 103, leukocytes 3.6x109, platelets 210x109, two weeks after amiodarone was stopped.

A Naranjo Causality score of 6 suggested that amiodarone was a probable cause of the pancytopenia. The fact that amiodarone discontinuation led to a slow improvement trend and not a dramatic increase in his blood cell counts may be explained by the long half-life of amiodarone.

Although pancytopenia is rare with amiodarone use, serious hematological adverse effects including thrombocytopenia, agranulocytosis, aplastic anemia, hemolytic anemia and bone marrow granulomas have also been reported. Therefore, pharmacists should consider monitoring amiodarone-induced hematological toxicities.

CLINICAL AND ECONOMIC EFFECTS OF A THERAPEUTIC SUBSTITUTION POLICY FOR PROTON PUMP INHIBITORS FOR ABORIGINAL PATIENTS IN NORTHERN COMMUNITIES IN THE NORTHWEST TERRITORIES

Gaebel K[1], Toeg N[2], Levine MAH[1,3]
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F**unding Source:** AFN, CIHR/Alberta ACADRE Network, Abbott, Altana, AstraZeneca, Merck-Frosst, Purdue, Sanofi-Aventis

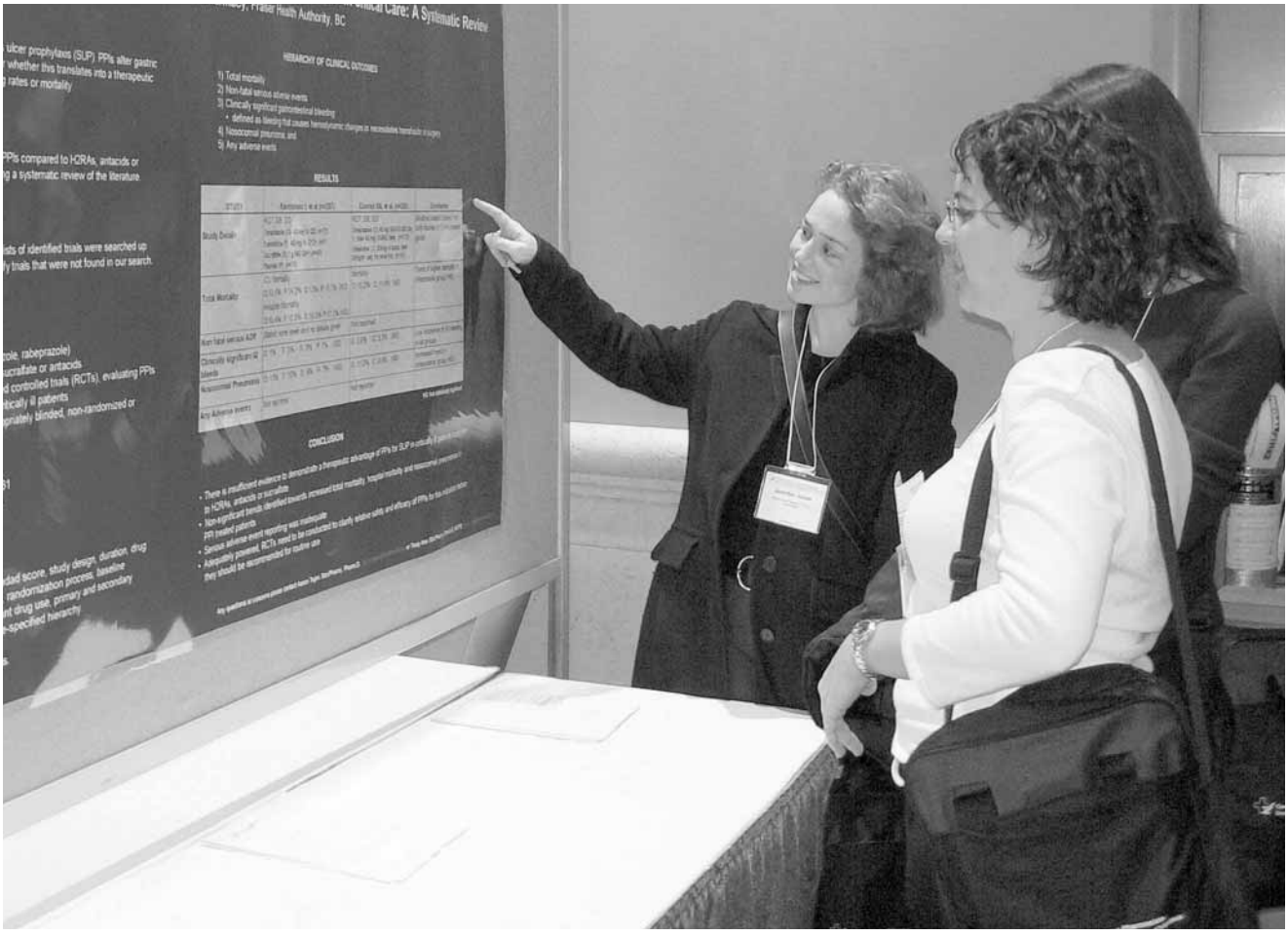
Background: Proton pump inhibitors (PPIs) used to treat gastroesophageal symptoms can vary greatly in price but are thought not to differ in clinical benefits. Health Canada's Non-Insured Health Benefits (NIHB) Program instituted a therapeutic substitution policy for PPIs as a cost containment strategy (CCS). The objective of this study was to determine the effect of this CCS on First Nations and Inuit people in northern isolated communities.

Methods: 5 pharmacies in the Northwest Territories identified a sample of patients subjected to the substitution policy. Eligible patients who provided informed consent received a face-to-face or telephone interview with a pharmacist using a standardized questionnaire.

Results: 41 of 66 patients identified consented to be interviewed; 69% female, mean age 57 years. 34 (83%) patients reported problems after the required PPI switch. Frequency for new or recurrent gastroesophageal symptoms varied from 17% (stomach pain) to 60% (heartburn). Problems were severe enough to send 19 (56%) patients to the nursing station, 6 (28%) to the hospital for assessment, with 1 requiring hospital admission. During the initial 15 month period of the program there was a net incremental drug cost of $55.41 per person due to drug wastage, delayed switching and switching back. A conservative estimate of additional healthcare service costs related to perceived health problems from the switch, paid by NIHB or the territorial health program, was $27,468.73 (n=19).

Conclusions: A majority of the patients sampled experienced problems following the PPI switch, possibly associated with diminished efficacy or adverse drug effects. Although causality is not proven, perceptions in this sample of patients influenced resource use resulting in no net savings (average incremental cost $725.38 per patient) during the first 15 months of the policy.

Keywords: Aboriginal, patient interviews, economic effect.



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a. rationale,
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c. study design and methods,
d. results of study including statistical analysis used,
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a. rationale for case report,
b. description of case,
c. assessment of causality,
d. evaluation of the literature,
e. importance of case to pharmacy practitioners.

Pharmacy Practice:

a. rationale for report;
b. description of concept, service, role, or situation;
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e. the concept's importance and usefulness to current and/or future practice.

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a. justification de l'observation clinique;
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a. justification du rapport;
b. description du concept, du service, du rôle ou de la situation;
c. mesures prises en vue de cerner et de résoudre le problème, d'apporter des changements, ou de créer et de mettre en œuvre un nouveau programme;
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- Use numerals to indicate numbers, except to begin sentences.
- Use only generic names of drugs, material, devices, and equipment.

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- Seule la première lettre du premier mot du titre doit être en majuscule.
- Les auteurs doivent être nommés.
- L'établissement auquel chaque auteur est affilié ainsi que la ville où se trouve cet établissement doivent être indiqués.
- Le corps du résumé (excluant le titre et les auteurs) ne doit pas dépasser 300 mots.
- Un tableau compte pour 30 mots.
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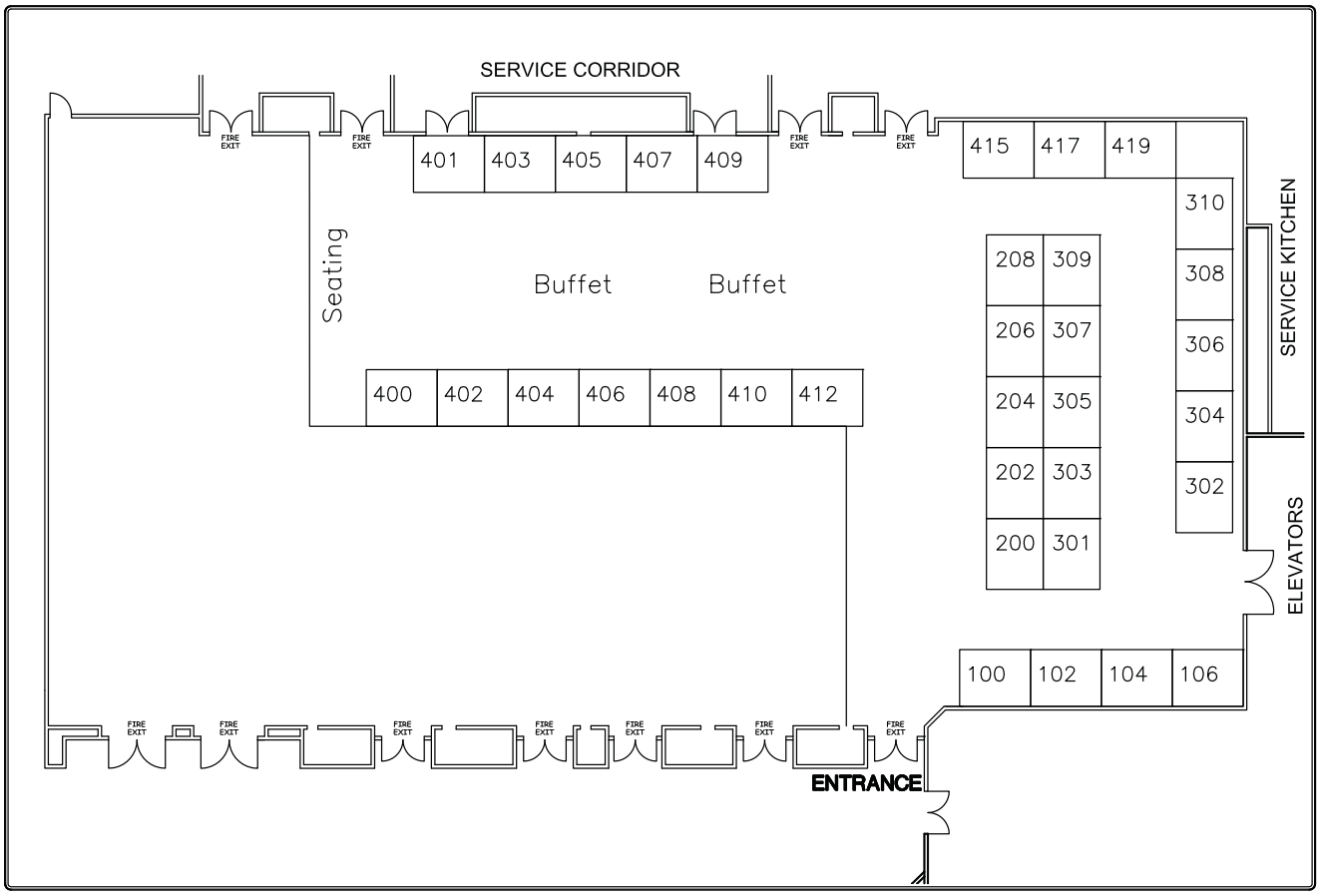
Plan du hall d'exposition



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Neulasta®

(pegfilgrastim)
Sterile Solution for Injection (Subcutaneous Use Only)
6 mg (10 mg/mL)

THERAPEUTIC CLASSIFICATION

Hematopoietic Agent – Granulocyte Colony-Stimulating Factor

INDICATIONS AND CLINICAL USE

Neulasta® (pegfilgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs.

Pediatrics (< 18 years of age): The safety and effectiveness of Neulasta® in pediatric patients have not been established.

CONTRAINDICATIONS

Neulasta® (pegfilgrastim) is contraindicated in patients with known hypersensitivity to *E. coli*-derived proteins, pegfilgrastim, filgrastim, or any other component of the product. For a complete listing of the components, see the Dosage Forms, Composition and Packaging section of the product monograph.

WARNINGS AND PRECAUTIONS

General

Very rare cases of splenic rupture have been reported following the administration of Neulasta® (pegfilgrastim). Splenic rupture, in some cases fatal, has also been associated with filgrastim, the non-pegylated form of Neulasta®. Patients receiving Neulasta® who report left upper abdominal or shoulder tip pain should be evaluated for an enlarged spleen or splenic rupture.

Neulasta® (pegfilgrastim) has not been evaluated for PBPC (peripheral blood progenitor cell) mobilization. Therefore, it should not be used in that setting.

Simultaneous Use With Chemotherapy and Radiation Therapy

The safety and efficacy of Neulasta® administered concurrently with cytotoxic chemotherapy have not been established. Because of the potential for an increase in sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy, Neulasta® should not be administered in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy (see DOSAGE AND ADMINISTRATION).

The safety and efficacy of Neulasta® have not been evaluated in patients receiving chemotherapy associated with delayed myelosuppression (e.g., nitrosoureas), mitomycin C, or myelosuppressive doses of anti-metabolites such as 5-fluorouracil (5-FU). Concomitant use of Neulasta® with 5-FU or other anti-metabolites has not been evaluated in humans, although it has been studied and shown to potentiate myelosuppression in animal models (see TOXICOLOGY).

The safety and efficacy of Neulasta® have not been evaluated in patients receiving radiation therapy.

Carcinogenesis and Mutagenesis

No carcinogenesis or mutagenesis studies were conducted with Neulasta®.

Potential Effect on Malignant Cells

Neulasta® (pegfilgrastim) and filgrastim are growth factors that primarily stimulate production of neutrophils and neutrophil precursors by binding to the G-CSF receptor. Overall, the possibility that Neulasta® can act as a growth factor for any tumour type cannot be excluded. Randomized studies have demonstrated that treatment with filgrastim following chemotherapy for AML does not adversely influence the outcome of treatment. The use of Neulasta® in AML, chronic myeloid leukemia (CML) and myelodysplasia (MDS) has not been studied.

Hematologic

Sickle cell crises have been reported in patients with sickle cell disease (specifically homozygous sickle cell anemia, sickle/hemoglobin C disease, and sickle/β+ thalassemia) who received filgrastim, the non-pegylated form of Neulasta®, for PBPC mobilization or following chemotherapy. Fatal cases are very rare. Physicians should exercise caution in considering the use of Neulasta® in patients with sickle cell disease, and only after careful consideration of the potential risks and benefits.

Leukocytosis

In clinical studies with Neulasta®, white blood cell counts of 100 x 10^9/L or greater have been reported in less than 1% of patients with cancer receiving myelosuppressive chemotherapy (n=930), and were not associated with any reported adverse clinical effects.

In studies of Neulasta® administration after chemotherapy, most reported side effects were consistent with those usually seen as a result of cytotoxic chemotherapy (see ADVERSE REACTIONS). Because of the potential for patients to receive full doses of chemotherapy on the prescribed schedule, patients may be at greater risk of thrombocytopenia, anemia, and non-hematologic consequences of increased chemotherapy doses (please refer to the prescribing information for specific chemotherapy agents). Regular monitoring of hematocrit value and platelet count is recommended. Furthermore, care should be exercised in the administration of Neulasta® in conjunction with drugs known to lower platelet count.

Respiratory

Adult respiratory distress syndrome (ARDS) has been reported in neutropenic patients with sepsis receiving filgrastim, the non-pegylated form of Neulasta®, and is postulated to be secondary to an influx of neutrophils to sites of inflammation in the lungs. Neutropenic patients receiving Neulasta® who develop fever, lung infiltrates, or respiratory distress should be evaluated for the possibility of ARDS. In the event that ARDS occurs, Neulasta® should be discontinued and/or withheld until resolution of ARDS and patients should receive appropriate medical management for this condition.

Sensitivity/Resistance

Allergic-type reactions, including anaphylaxis, skin rash, and urticaria, occurring on initial or subsequent treatment have been reported both with Neulasta® and filgrastim. In some cases, symptoms have recurred with rechallenge, suggesting a causal relationship. If a serious allergic reaction or an anaphylactic reaction occurs, appropriate therapy should be administered and further use of Neulasta® should be discontinued. Antibodies to filgrastim or pegfilgrastim have been reported, although no neutralizing antibodies have been reported (see ADVERSE REACTIONS; Immunogenicity).

Sexual Function/Reproduction

No studies evaluating sexual function or reproduction in humans were conducted with Neulasta®.

Special Populations

Pregnant Women: There were no pregnant women exposed to Neulasta® in clinical trials. Neulasta® should be used during pregnancy only if the potential benefit outweighs the risk to the fetus (see TOXICOLOGY).

Nursing Women: It is not known whether Neulasta® is excreted in human milk. Because many drugs are excreted in human milk, Neulasta® is not recommended for women who are breast feeding. Neulasta® should only be administered to a nursing woman if the potential benefit outweighs the risk.

Pediatrics (< 18 years of age): The safety and effectiveness of Neulasta® in pediatric patients have not been established.

Geriatrics (> 65 years of age): Of the total number of subjects with cancer who received Neulasta® in clinical studies (n=930), 139 subjects (15%) were 65 years or older and 18 subjects (2%) were 75 years or older. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients; however, due to the small number of elderly subjects, small but clinically relevant differences cannot be excluded.

Monitoring and Laboratory Tests

To assess a patient's hematologic status and ability to tolerate myelosuppressive chemotherapy, a complete blood count (CBC) and platelet count should be obtained before chemotherapy is administered. Neulasta® produced ANC (absolute neutrophil count) profiles similar to daily filgrastim, including earlier ANC nadir, shorter duration of severe neutropenia, and accelerated ANC recovery, compared with ANC profiles observed without growth factor support. Regular monitoring of hematocrit value, white blood cell count and platelet count, as clinically indicated, is recommended.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

See WARNINGS AND PRECAUTIONS regarding Splenic Rupture, ARDS, Allergic Reactions and Sickle Cell Disease.

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.

Safety data are based on 7 randomized clinical trials involving 932 patients with lymphoma and solid tumours (breast and thoracic) who received Neulasta® (pegfilgrastim) after non-myeloablative cytotoxic chemotherapy. Common adverse events occurred at similar rates between the treatment arms in both the filgrastimcontrolled trials (Neulasta®, n=465; filgrastim, n=331) and the placebo-controlled trial (Neulasta®, n=467; placebo, n=461). Most adverse experiences were attributed by the investigator as the sequelae of the underlying malignancy or cytotoxic chemotherapy. In the filgrastim-controlled trials, these adverse experiences occurred at rates between 15% and 72% and included: nausea, fatigue, alopecia, diarrhea, vomiting, constipation, fever, anorexia, skeletal pain, headache, taste perversion, dyspepsia, myalgia, insomnia, abdominal pain, arthralgia, generalized weakness, peripheral edema, dizziness, granulocytopenia, stomatitis, mucositis and neutropenic fever. A summary of the most frequently reported adverse reactions in these randomized clinical trials can be found in Tables 1 and 2.

In clinical trials comparing Neulasta® to filgrastim, medullary bone pain was reported in 26% of Neulasta®-treated patients, which was comparable to the incidence in filgrastim-treated patients. In the study comparing Neulasta® to placebo, the incidence of bone pain was 23% vs. 16%, respectively. This bone pain was generally reported to be of mild-to-moderate severity. Approximately 17% (for all bone pain type AEs; 10% for specifically "bone pain") of all subjects utilized non-narcotic analgesics and less than 6% utilized narcotic analgesics in association with bone pain. No patient withdrew from study due to bone pain.

Across all studies, no life-threatening or fatal adverse events were attributed to Neulasta®. There was only one serious adverse event (dyspnea) reported as possibly related to Neulasta® in a single patient. No events of pleuritis, pericarditis, or other major systemic reactions to Neulasta® were reported.

No clinically significant changes in vital signs were observed. No evidence of interaction of Neulasta® with other drugs was observed in the course of clinical trials (see WARNINGS AND PRECAUTIONS).

Table 1. Most Frequently* Reported Adverse Reactions in Randomized Clinical Trials with Filgrastim as Comparator

Body System and Preferred Term	Neulasta® (pegfilgrastim) (n=465)	Filgrastim (n=331)
Application Site		
Injection Site Pain	16 (3%)	9 (3%)
Body as a whole		
Pain	8 (2%)	4 (1%)
Chest Pain (Non-Cardiac)	4 (1%)	3 (1%)
Edema Periorbital	3 (1%)	0 (0%)
Fever	3 (1%)	4 (1%)
CNS/PNS		
Headache	20 (4%)	12 (4%)
Musculo-skeletal		
Skeletal Pain	96 (21%)	89 (27%)
Myalgia	32 (7%)	25 (8%)
Arthralgia	27 (6%)	19 (6%)
Back Pain	19 (4%)	26 (8%)
Limb Pain	12 (3%)	7 (2%)
Musculo-Skeletal Pain	5 (1%)	4 (1%)
Neck Pain	4 (1%)	3 (1%)

* Most frequently reported events were considered to be those events reported in ≥1% of the patients in the Neulasta® group.

Table 2. Most Frequently* Reported Adverse Reactions in Randomized Clinical Trials with Placebo Control

Body System and Preferred Term	Neulasta® (pegfilgrastim) (n=467)	Placebo (n=461)
Blood and Lymphatic System Disorders		
Leukocytosis	5 (1%)	1 (0%)
Gastrointestinal Disorders		
Diarrhea	9 (2%)	10 (2%)
General Disorders and Administration Site Conditions		
Pyrexia	8 (2%)	9 (2%)
Fatigue	3 (1%)	5 (1%)
Infections and Infestations		
Influenza	6 (1%)	5 (1%)
Musculoskeletal and Connective Tissue Disorders		
Bone Pain	62 (13%)	41 (9%)
Myalgia	26 (6%)	23 (5%)
Arthralgia	32 (7%)	19 (4%)
Polymyalgia	8 (2%)	7 (2%)
Musculoskeletal Pain	14 (3%)	5 (1%)
Pain in Limb	11 (2%)	5 (1%)
Back Pain	8 (2%)	4 (1%)
Polyarthralgia	5 (1%)	0 (0%)
Nervous System Disorders		
Headache	6 (1%)	2 (0%)
Skin and Subcutaneous Tissue Disorders		
Alopecia	8 (2%)	9 (2%)

* Most frequently reported events were considered to be those events reported in ≥1% of the patients in the Neulasta® group.

Less Common Clinical Trial Adverse Drug Reactions (<1%)

The following adverse drug reactions were reported at an incidence of <1% in controlled clinical studies (occurring in more than 1 patient, with higher frequency than filgrastim):

General Disorders and Administration Site Conditions: injection site bruising;

Infections and Infestations: rhinitis;

Nervous System Disorders: hypertonia;

Skin and Subcutaneous Tissue Disorders: periorbital oedema.

The following adverse events were reported at an incidence of <1% in controlled clinical studies (occurring in more than 1 patient, with higher frequency than placebo):

General Disorders and Administration Site Conditions: chest pain, pain.

Abnormal Hematologic and Clinical Chemistry Findings

Spontaneously reversible elevations in LDH, alkaline phosphatase, and uric acid of mild to moderate severity were observed. Most changes have been attributed to post-cytokine bone marrow expansion as well as to chemotherapy and metastatic disease. The incidences of these changes, presented for Neulasta® versus filgrastim and placebo, were: LDH (18% versus 29% and 18%), alkaline phosphatase (11% versus 16% and 12%), and uric acid (10% versus 9% and 13% [1% of uric acid reported cases for filgrastim and Neulasta® treatment groups were classified as severe]).

In clinical studies with Neulasta®, white blood cell counts of 100 x 10^9/L or greater have been reported in less than 1% of patients with cancer receiving myelosuppressive chemotherapy (n=930), and were not associated with any reported adverse clinical effects.

Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The incidence of antibody development in patients receiving Neulasta® has not been adequately determined. While available data suggest that a small proportion of patients developed binding antibodies to filgrastim or Neulasta®, the nature and specificity of these antibodies has not been adequately studied. No neutralizing antibodies have been detected using a cell-based bioassay in 46 (9%, n=534) patients who apparently developed binding antibodies. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay, and the observed incidence of antibody positivity in an assay may be influenced by several factors including sample handling, concomitant medications, and underlying disease. Therefore, comparison of the incidence of antibodies to Neulasta® with the incidence of antibodies to other products may be misleading.

Cytopenias resulting from an antibody response to exogenous growth factors have been reported on rare occasions in patients treated with other recombinant growth factors. There is a theoretical possibility that an antibody directed against Neulasta® may cross-react with endogenous G-CSF, resulting in immune-mediated neutropenia, but this has not been observed in clinical studies.

Post-Market Adverse Drug Reactions

Allergic Reaction

In post-marketing experience, allergic-type reactions, including anaphylaxis, skin rash, and urticaria, occurring on initial or subsequent treatment have been reported both with Neulasta® and filgrastim. In some cases, symptoms have recurred with rechallenge, suggesting a causal relationship (see WARNINGS AND PRECAUTIONS).

DRUG INTERACTIONS

Overview

Drug interactions between Neulasta® (pegfilgrastim) and other drugs have not been studied. Drugs such as lithium that may potentiate the release of neutrophils should be used with caution; such patients should have more frequent monitoring of their neutrophil counts.

Drug-Drug Interactions

Interactions with other drugs have not been established.

Drug-Food Interactions

Interactions with food have not been established.

Drug-Herb Interactions

Interactions with herbal products have not been established.

Drug-Laboratory Interactions

Interactions with laboratory tests have not been established.

DOSAGE AND ADMINISTRATION

Dosing Considerations

Neulasta® (pegfilgrastim) should be administered no sooner than 24 hours after the administration of cytotoxic chemotherapy (see WARNINGS AND PRECAUTIONS).

Renal impairment, including end-stage renal disease, appears to have no effect on the pharmacokinetics of Neulasta® and no dosage adjustment is required.

Recommended Dose and Dosage Adjustment

The recommended dosage of Neulasta® is a single subcutaneous injection of 6 mg, administered once per cycle of chemotherapy. Neulasta® should be administered no sooner than 24 hours after the administration of cytotoxic chemotherapy (see WARNINGS AND PRECAUTIONS).

Missed Dose

If a scheduled dose is missed, Neulasta® should not be administered less than 14 days before subsequent administration of cytotoxic chemotherapy.

Administration

Neulasta® is intended for subcutaneous injection only and should not be given by any other route of administration. Neulasta® should not be mixed with any diluents.

Neulasta® should not be vigorously shaken.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Neulasta® (pegfilgrastim) is a sterile, clear, colourless, preservative-free liquid for SC administration. Each single-use syringe (0.6 mL) of Neulasta® (10 mg/mL) contains 6 mg of pegfilgrastim (based on protein mass only). The product is formulated at pH 4.0 in 10 mM acetate, 30.0 mg sorbitol and 0.02 mg polysorbate 20. The quantitative composition (per 0.6 mL prefilled syringe) of Neulasta® is:

Pegfilgrastim	6 mg
Acetate	0.35 mg
Sorbitol	30.0 mg
Polysorbate 20	0.02 mg
Sodium	0.021 mg
Water for Injection USP q.s.	0.6 mL

Availability of Dosage Forms

Neulasta® is supplied as a preservative-free solution (0.6 mL) containing 6 mg of pegfilgrastim (10 mg/mL) in a single-dose syringe with a 27 gauge, ½ inch needle.

Neulasta® is provided in a dispensing pack containing one syringe.

STORAGE AND STABILITY

Neulasta® (pegfilgrastim) should be stored refrigerated at 2° to 8°C (36° to 46°F) and protected from light. Before injection, Neulasta® may be allowed to reach room temperature for a maximum of 72 hours. Neulasta® left at room temperature for more than 72 hours should be discarded. Freezing should be avoided; however, if accidentally frozen Neulasta® should be allowed to thaw in the refrigerator before administration. If frozen a second time, Neulasta® should be discarded.

Neulasta® should be visually inspected for discolouration and particulate matter before administration. Neulasta® should not be administered if discolouration or particulates are observed.

SPECIAL HANDLING INSTRUCTIONS

Neulasta® (pegfilgrastim) should not be vigorously shaken.

REFERENCES

1. Vogel CL, *et al*. First and Subsequent Cycle Use of Pegfilgrastim Prevents Febrile Neutropenia in Patients with Breast Cancer: A Multicenter, Double-Blind, Placebo-Controlled Phase III Study. *J Clin Oncol* 2005; 23:1178-1184.

2. American Society of Clinical Oncology. 2006 update of recommendation for the use of white blood cell growth factors: an evidence-based clinical practice guideline. *J Clin Oncol* 2006; 24(19):1-19.

3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology v.2 2005.

4. Neulasta® Product Monograph. 2006 Amgen Canada Inc.

Product Monograph available on request.

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FULL PRESCRIBING INFORMATION

Pr Tramacet*

37.5 mg tramadol HCl / 325 mg acetaminophen tablets

Centrally Acting Analgesic

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
oral	37.5 mg tramadol hydrochloride/325 mg acetaminophen tablets	none *For a complete listing of nonmedicinal ingredients see* **DOSAGE FORMS, COMPOSITION AND PACKAGING** *section.*

INDICATIONS AND CLINICAL USE

TRAMACET (tramadol hydrochloride/acetaminophen) is indicated for the short-term (five days or less) management of acute pain.

Geriatrics (> 65 years of age)

No overall differences with regard to safety or pharmacokinetics were noted between subjects ≥65 years of age and younger subjects. However, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal or cardiac function, of concomitant disease and multiple drug therapy.

Pediatrics (<18 years of age)

The safety and effectiveness of TRAMACET has not been studied in the pediatric population. Therefore, use of TRAMACET tablets is not recommended in patients under 18 years of age.

CONTRAINDICATIONS

- TRAMACET (tramadol hydrochloride/acetaminophen) tablets should not be administered to patients who have previously demonstrated hypersensitivity to tramadol, acetaminophen, opioids or any other component of this product. For a complete listing of nonmedicinal ingredients, see the **DOSAGE FORMS, COMPOSITION AND PACKAGING** section of the Product Monograph.
- TRAMACET is contraindicated in any situation where opioids are contraindicated, including acute intoxication with any of the following: alcohol, hypnotics, narcotics, centrally acting analgesics, opioids or psychotropic drugs. TRAMACET may worsen central nervous system and respiratory depression in these patients.

WARNINGS AND PRECAUTIONS

Seizure Risk

Seizures have been reported in patients receiving tramadol within the recommended dosage range. Spontaneous post-marketing reports indicate that seizure risk is increased with doses of tramadol above the recommended range. Concomitant use of tramadol increases the seizure risk in patients taking:

- selective serotonin re-uptake inhibitors (SSRI antidepressants or anorectics);
- tricyclic antidepressants (TCAs) and other tricyclic compounds (e.g. cyclobenzaprine, promethazine, etc.) or;
- opioids.

Administration of tramadol may enhance the seizure risk in patients taking:

- MAO inhibitors (see **Use with MAO Inhibitors and Serotonin Re-uptake Inhibitors**);
- neuroleptics or;
- other drugs that reduce the seizure threshold.

Risk of convulsions may also increase in patients with epilepsy, those with a history of seizures or in patients with a recognized risk for seizure (such as head trauma, metabolic disorders, alcohol and drug withdrawal, CNS infections). In tramadol overdose, naloxone administration may increase the risk of seizure.

Anaphylactoid Reactions

Serious and rarely fatal anaphylactoid reactions have been reported in patients receiving therapy with tramadol. When these rare reactions do occur, it is often following the first dose. Other reported allergic reactions include pruritus, hives, bronchospasm, angioedema, toxic epidermal necrolysis and Stevens-Johnson syndrome. Patients with a history of anaphylactoid reactions to codeine and other opioids may be at increased risk and therefore should not receive TRAMACET tablets (see **CONTRAINDICATIONS**).

Drug Abuse and Dependence

Tramadol has a potential to cause psychic and physical dependence of the morphine-type (μ-opioid). The drug has been associated with craving, drug-seeking behaviour and tolerance development. Cases of abuse and dependence on tramadol have been reported. TRAMACET tablets should not be used in opioid-dependent patients. Tramadol can re-initiate physical dependence in patients who have been previously dependent or chronically using other opioids. In patients with a tendency to abuse drugs or a history of drug dependence, and in patients who are chronically using opioids, treatment with TRAMACET is not recommended.

A Risk Management strategy to support the safe and effective use of TRAMACET under Schedule F has been established. The following are considered to be the essential components of the Risk Management strategy:

a) Commitment to not emphasize or highlight the scheduling status of TRAMACET (i.e. Schedule F of the Food and Drug Regulations; not listed under a schedule to the CDSA) in its advertising or promotional activities.
b) Inclusion of an approved fair balance statement in all TRAMACET advertising and promotional materials.
c) Provision of progress reports to TPD, MHPD and HECSB from the ongoing drug abuse surveillance program, including data from four key informant Canadian sites in the program.
d) Reassessment of the success of the risk management strategy 2 years post product launch.

Withdrawal Symptoms

Withdrawal symptoms may occur if tramadol is discontinued abruptly. These symptoms may include: anxiety, sweating, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, piloerection, and rarely, hallucinations. Other symptoms that have been seen less frequently with TRAMACET discontinuation include: panic attacks, severe anxiety, and paresthesias. Clinical experience suggests that withdrawal symptoms may be relieved by reinstitution of opioid therapy followed by a gradual, tapered dose reduction of the medication combined with symptomatic support.

Intracranial Pressure or Head Trauma

TRAMACET should be used with caution in patients with increased intracranial pressure or head injury. The respiratory depressant effects of opioids include carbon dioxide retention and secondary elevation of cerebrospinal fluid pressure and may be markedly exaggerated in these patients. Additionally, pupillary changes (miosis) from tramadol may obscure the existence, extent, or course of intracranial pathology. Clinicians should also maintain a high index of suspicion for adverse drug reaction when evaluating altered mental status in these patients if they are receiving TRAMACET (see **Respiratory**, **Respiratory Depression**).

Interaction With Central Nervous System (CNS) Depressants

TRAMACET tablets should be used with caution and in reduced dosages when administered to patients receiving CNS depressants such as alcohol, opioids, anaesthetic agents, narcotics, phenothiazines, tranquilizers or sedative hypnotics. Tramadol increases the risk of CNS and respiratory depression in these patients.

Use with Alcohol

TRAMACET should not be used concomitantly with alcohol consumption. The use of TRAMACET in patients with liver disease is not recommended.

Use with MAO Inhibitors and Serotonin Re-uptake Inhibitors

Use TRAMACET with great caution in patients taking monoamine oxidase inhibitors. Animal studies have shown increased deaths with combined administration of MAO inhibitors and tramadol. Concomitant use of tramadol with MAO inhibitors or SSRIs increases the risk of adverse events, including seizure and serotonin syndrome (see **Seizure Risk** and **DRUG INTERACTIONS**).

Gastrointestinal

Acute Abdominal Conditions

The administration of TRAMACET may complicate the clinical assessment of patients with acute abdominal conditions.

Hepatic/Biliary/Pancreatic

Use in Hepatic Disease

TRAMACET has not been studied in patients with impaired hepatic function. The use of TRAMACET tablets in patients with severe hepatic impairment is not recommended.

Use With Other Acetaminophen-containing Products

Due to the potential for acetaminophen hepatotoxicity at doses higher than the recommended dose, TRAMACET should not be used concomitantly with other acetaminophen-containing products.

Renal

Use in Renal Disease

TRAMACET has not been studied in patients with impaired renal function. Experience with tramadol suggests that impaired renal function results in a decreased rate and extent of excretion of tramadol and its active metabolite, M1. In patients with creatinine clearances of less than 30 mL/min, it is recommended that the dosing interval of TRAMACET be increased to not exceed 2 tablets every 12 hours (see **DOSAGE AND ADMINISTRATION**).

Respiratory

Respiratory Depression

Administer TRAMACET cautiously in patients at risk for respiratory depression. In these patients, alternative non-opioid analgesics should be considered. When large doses of tramadol are administered with anaesthetic medications or alcohol, respiratory depression may result. Respiratory depression should be treated as an overdose. If naloxone is to be administered, use cautiously because it may precipitate seizures (see **Seizure Risk** and **OVERDOSAGE**).

Carcinogenesis, Mutagenesis, Impairment of Fertility

There are no animal or laboratory studies on the combination product (tramadol and acetaminophen) to evaluate carcinogenesis, mutagenesis, or impairment of fertility.

A slight but statistically significant increase in two common murine tumours, pulmonary and hepatic, was observed in a mouse carcinogenicity study, particularly in aged mice. Mice were dosed orally up to 30 mg/kg (90 mg/m^2 or 0.5 times the maximum daily human tramadol dosage of 185 mg/m^2) for approximately two years, although the study was not done with the Maximum Tolerated Dose. This finding is not believed to suggest risk in humans. No such finding occurred in rat carcinogenicity study (dosing orally up to 30 mg/kg, 180 mg/m^2, or 1 time the maximum daily human tramadol dosage).

Tramadol was not mutagenic in the following assays: Ames *Salmonella* microsomal activation test, CHO/HPRT mammalian cell assay, mouse lymphoma assay (in the absence of metabolic activation), dominant lethal mutation tests in mice, chromosome aberration test in Chinese hamsters, and bone marrow micronucleus tests in mice and Chinese hamsters. Weakly mutagenic results occurred in the presence of metabolic activation in the mouse lymphoma assay and micronucleus test in rats. Overall, the weight of evidence from these tests indicates that tramadol does not pose a genotoxic risk to humans.

No effects on fertility were observed for tramadol at oral dose levels up to 50 mg/kg (350 mg/m^2) in male rats and 75 mg/kg (450 mg/m^2) in female rats. These dosages are 1.6 and 2.4 times the maximum daily human tramadol dosage of 185 mg/m^2.

No drug-related teratogenic effects were observed in the progeny of rats treated orally with tramadol and acetaminophen. The tramadol/acetaminophen combination product was shown to be embryotoxic and fetotoxic in rats at a maternally toxic dose, 50/434 mg/kg tramadol/acetaminophen (300/2604 mg/m^2 or 1.6 times the maximum daily human tramadol/acetaminophen dosage of 185/1591 mg/m^2), but was not teratogenic at this dose level. Embryo and fetal toxicity consisted of decreased fetal weights and increased supernumerary ribs.

Tramadol alone was evaluated in peri- and post-natal studies in rats. Progeny of dams receiving oral (gavage) dose levels of 50 mg/kg (300 mg/m^2 or 1.6 times the maximum daily human tramadol dosage) or greater had decreased weights, and pup survival was decreased early in lactation at 80 mg/kg (480 mg/m^2 or 2.6 times the maximum daily human tramadol dosage).

Use in Ambulatory Patients

TRAMACET may impair mental or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery.

Special Populations

Pregnancy

There are no adequate and well-controlled studies in pregnant women. TRAMACET should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Neonatal seizures, neonatal withdrawal syndrome, fetal death and stillbirth have been reported with tramadol hydrochloride during post-marketing.

TRAMACET should not be used in pregnant women prior to or during labor unless the potential benefits outweigh the risks. Safe use in pregnancy has not been established. Chronic use during pregnancy may lead to physical dependence and post-partum withdrawal symptoms in the newborn (see **Drug Abuse and Dependence**). Tramadol has been shown to cross the placenta. The mean ratio of serum tramadol in the umbilical veins compared to maternal veins was 0.83 for 40 women given tramadol during labour.

The effect of TRAMACET, if any, on the later growth, development, and functional maturation of the child is unknown.

Nursing Women

TRAMACET is not recommended for obstetrical pre-operative medication or for post-delivery analgesia in nursing mothers because its safety in infants and newborns has not been studied.

Following a single 100 mg i.v. dose of tramadol, the cumulative excretion in breast milk within 16 hours post-dose was 100 μg of tramadol (0.1% of the maternal dose) and 27 μg of M1.

Pediatrics (< 18 years of age)

The safety and effectiveness of TRAMACET has not been studied in the pediatric population.

Therefore, use of TRAMACET tablets is not recommended in patients under 18 years of age.

Geriatrics (> 65 years of age)

In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal or cardiac function; of concomitant disease and multiple drug therapy.

ADVERSE REACTIONS

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.

TRAMACET (tramadol hydrochloride/acetaminophen) tablets were administered to 1,437 patients during the double-blind or open-label extension periods in studies of chronic non-malignant pain. Of these patients, 503 were 65 years old or older.

Table 1.1 reports the cumulative incidence rate of the most common treatment-emergent adverse reactions by preferred term and extent of exposure for any time period for the most frequent reactions (4.5% or more for any time period). The most frequently reported events were in the central nervous and gastrointestinal systems.

Table 1.1: Cumulative Incidence of Treatment-Emergent Adverse Events by Preferred Term and Extent of Exposure[a] for All Tramadol/ Acetaminophen-Exposed Subjects in Pain Trials up to 3 months duration.

	37.5 tramadol/325 acetaminophen (N=1,437)		
Body System Preferred Term	**up to 7 days** **%**	**up to 30 days** **%**	**up to 90 days** **%**
Gastrointestinal System			
Nausea	13	17	22
Constipation	5	10	13
Vomiting	4	5	8
Dry Mouth	4	4	5
Dyspepsia	2	4	6
Diarrhea	2	5	7
Central and Peripheral Nervous System			
Dizziness	12	14	16
Headache	6	8	13
CNS Stimulation[b]	3	5	7
Psychiatric Disorders			
Somnolence	9	12	13
Insomnia	2	2	5
Skin and Appendages			
Pruritus	4	5	6
Body as a Whole			
Fatigue	3	4	5
Respiratory System			
Upper Respiratory Tract Infection	1	2	7

[a] Preferred term reported by ≥4.5% of subjects for any exposure period; estimates were obtained using the life table analysis.

[b] Composite of nervousness, anxiety, agitation, euphoria, emotional lability and hallucinations (coded under psychiatric disorders), and hypertonia and tremor (coded under CNS disorders).

Incidence at least 1% - Causal Relationship at Least Possible or Greater

The following lists treatment-emergent adverse reactions that occurred with an incidence of at least 1% in clinical trials with a population of 2,836 tramadol/acetaminophen-exposed subjects in the 18 acute and chronic pain studies combined.

Body as a Whole:	asthenia, fatigue, hot flushes
Central and Peripheral Nervous System:	dizziness, headache, tremor
Gastrointestinal System:	abdominal pain, constipation, diarrhea, dyspepsia, flatulence, dry mouth, nausea, vomiting
Psychiatric Disorders:	anorexia, anxiety, confusion, euphoria, insomnia, nervousness, somnolence
Skin and Appendages:	pruritus, rash, increased sweating

Among these, the most common (≥5% of subjects) treatment-emergent adverse events were nausea (14%), dizziness (10%), somnolence (9%), constipation (8%), vomiting (5%), and headache (5%). These data are consistent with data presented in Table 1.1.

Selected Adverse Events Occurring at less than 1%

The following lists clinically relevant treatment-emergent adverse reactions that occurred with an incidence of less than 1% in tramadol/acetaminophen clinical trials

Body as a Whole:	chest pain, rigors, syncope, withdrawal syndrome, allergic reaction
Cardiovascular Disorders:	hypertension, aggravated hypertension, hypotension, dependent edema
Central and Peripheral Nervous System:	ataxia, convulsions, hypertonia, migraine, aggravated migraine, involuntary muscle contractions, paresthesia, stupor, vertigo
Gastrointestinal System:	dysphagia, melena, tongue edema
Hearing and Vestibular Disorders:	tinnitus
Heart Rate and Rhythm Disorders:	arrhythmia, palpitation, tachycardia
Liver and Biliary System:	abnormal hepatic function, SGPT (ALAT) increased, SGOT (ASAT) increased
Metabolic and Nutritional Disorders:	weight decrease, hypoglycemia, increased alkaline phosphatase, weight increase
Musculoskeletal System Disorders:	arthralgia
Platelets, Bleeding and Clotting Disorders:	increased coagulation time, purpura
Psychiatric Disorders:	amnesia, depersonalisation, depression, drug abuse, emotional lability, hallucination, impotence, bad dreams, abnormal thinking
Red Blood Cell Disorders:	anemia
Respiratory System:	dyspnea, bronchospasm
Skin and Appendages Disorders:	dermatitis, erythematous rash
Urinary System:	albuminuria, micturition disorder, oliguria, urinary retention
Vision Disorders:	abnormal vision
White Cell and RES Disorders:	granulocytopenia and leukocytosis

Other Clinically Significant Adverse Experiences Previously Reported in Clinical Trials or Post-marketing Reports with Tramadol Hydrochloride

Other events which have been reported with the use of tramadol products and for which a causal association has not been determined include: vasodilation, orthostatic hypotension, myocardial ischemia, pulmonary edema, allergic reactions (including anaphylaxis and urticaria, Stevens-Johnson syndrome/TENS), cognitive dysfunction, difficulty concentrating, depression, suicidal tendency, hepatitis liver failure and gastrointestinal bleeding. Reported laboratory abnormalities included elevated creatinine and liver function tests. Serotonin syndrome (whose symptoms may include mental status change, hyperreflexia, fever, shivering, tremor, agitation, diaphoresis, seizures and coma) has been reported with tramadol when used concomitantly with other serotonergic agents such as SSRIs and MAOIs.

Other Clinically Significant Adverse Experiences Previously Reported in Clinical Trials or Post-marketing Reports with Acetaminophen

Allergic reactions (primarily skin rash) or reports of hypersensitivity secondary to acetaminophen are rare and generally controlled by discontinuation of the drug and, when necessary, symptomatic treatment. There have been several reports that suggest that acetaminophen may produce hypoprothrombinemia when administered with warfarin-like compounds. In other studies, prothrombin time did not change.

DRUG ABUSE AND DEPENDENCE

Tramadol may induce psychic and physical dependence of the morphine-type (μ-opioid) (see **WARNINGS AND PRECAUTIONS**, **Drug Abuse and Dependence**). Dependence and abuse, including drug-seeking behaviour and taking illicit actions to obtain the drug are not limited to those patients with a prior history of opioid dependence. The risk in patients with substance abuse has been observed to be higher. Tramadol is associated with craving and tolerance development.

A Risk Management strategy to support the safe and effective use of TRAMACET under Schedule F has been established. The following are considered to be the essential components of the Risk Management strategy:

a) Commitment to not emphasize or highlight the scheduling status of TRAMACET (i.e. Schedule F of the Food and Drug Regulations; not listed under a schedule to the CDSA) in its advertising or promotional activities.
b) Inclusion of an approved fair balance statement in all TRAMACET advertising and promotional materials.
c) Provision of progress reports to TPD, MHPD and HECSB from the ongoing drug abuse surveillance program, including data from four key informant Canadian sites in the program.
d) Reassessment of the success of the risk management strategy 2 years post product launch.

Withdrawal Symptoms

Withdrawal symptoms may occur if tramadol is discontinued abruptly. These symptoms may include: anxiety, sweating, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, piloerection, and rarely, hallucinations. Other symptoms that have been seen less frequently with TRAMACET discontinuation include: panic attacks, severe anxiety, and paresthesias. Clinical experience suggests that withdrawal symptoms may be relieved by reinstitution of opioid therapy followed by a gradual, tapered dose reduction of the medication combined with symptomatic support.

DRUG INTERACTIONS

Overview

In vitro studies indicate that tramadol is unlikely to inhibit the CYP3A4-mediated metabolism of other drugs when tramadol is administered concomitantly at therapeutic doses. Tramadol does not appear to induce its own metabolism in humans, since observed maximal plasma concentrations after multiple oral doses are higher than expected based on single dose data. Tramadol is a mild inducer of selected drug metabolism pathways measured in animals.

Drug-Drug Interactions

Use with Carbamazepine

Patients taking carbamazepine may have a significantly reduced analgesic effect of tramadol. Because carbamazepine increases tramadol metabolism and because of the seizure risk associated with tramadol, concomitant administration of TRAMACET and carbamazepine is not recommended.

Use with Quinidine

Tramadol is metabolized to M1 by the CYP2D6 P450 isoenzyme. Quinidine is a selective inhibitor of that isoenzyme, so that concomitant administration of quinidine and tramadol results in increased concentrations of tramadol and reduced concentrations of M1. The clinical consequences of these findings are unknown. In vitro drug interaction studies in human liver microsomes indicate that tramadol has no effect on quinidine metabolism.

Use with Inhibitors of CYP2D6

In vitro drug interaction studies in human liver microsomes indicate that concomitant administration with inhibitors of CYP2D6 such as fluoxetine, paroxetine and amitriptyline could result in some inhibition of the metabolism of tramadol.

Use with Cimetidine

Concomitant administration of TRAMACET and cimetidine has not been studied. Concomitant administration of tramadol and cimetidine does not result in clinically significant changes in tramadol pharmacokinetics. Therefore, no alteration of the TRAMACET dosage regimen is recommended.

Use with MAO Inhibitors and Serotonin Reuptake Inhibitors

Due to interference with detoxification mechanisms, interactions with MAO inhibitors have been reported for some centrally acting drugs (see **WARNINGS AND PRECAUTIONS**, **Use with MAO Inhibitors and Serotonin Reuptake Inhibitors**).

Use with Digoxin

Postmarketing surveillance of tramadol has revealed rare reports of digoxin toxicity.

Use with Warfarin-Like Compounds

Post-marketing surveillance of both tramadol and acetaminophen individual products have revealed rare alterations of warfarin effect, including elevation of prothrombin times.

While such changes have been generally of limited clinical significance for the individual products, periodic evaluation of prothrombin time should be performed when TRAMACET tablets and warfarin-like compounds are administered concurrently.

Drug-Food Interactions

When TRAMACET was administered with food, the time to peak plasma concentration was delayed for approximately 35 minutes for tramadol and almost one hour for acetaminophen. However, peak plasma concentration or the extent of absorption of either tramadol or acetaminophen were not affected. The clinical significance of this difference is unknown.

DOSAGE AND ADMINISTRATION

Dosing Considerations

TRAMACET (tramadol hydrochloride/acetaminophen) is not recommended for minor pain that may be treated adequately through lesser means where benefit does not outweigh the possible opioid-related side effects.

Do not co-administer TRAMACET tablets with other tramadol- or acetaminophen-containing products.

TRAMACET can be administered without regard to food.

The recommended dose of TRAMACET (tramadol hydrochloride/acetaminophen) should not be exceeded.

Recommended Dose and Dosage Adjustment

Adults

For the short-term (five days or less) management of acute pain, the recommended dose of TRAMACET is 1 or 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day.

Use in Renal Impairment

In patients with creatinine clearances of less than 30 mL/min, it is recommended that the dosing interval of TRAMACET be increased to not exceed 2 tablets every 12 hours.

Use in the Elderly

No overall differences with regard to safety or pharmacokinetics were noted between subjects ≥65 years of age and younger subjects. However, dose selection for an elderly patient should be cautious, in view of the greater frequency of decreased hepatic, renal or cardiac function, concomitant disease or drug therapy, and the potential for greater sensitivity to adverse events.

Pediatric Use

The safety and effectiveness of TRAMACET has not been studied in the pediatric population. Therefore, use of TRAMACET is not recommended in patients under 18 years of age.

Discontinuation

Withdrawal symptoms may occur if TRAMACET is discontinued abruptly. These symptoms may include: anxiety, sweating, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, piloerection, and rarely, hallucinations. Other symptoms that have been seen less frequently with TRAMACET discontinuation include: panic attacks, severe anxiety, and paresthesias. Clinical experience suggests that withdrawal symptoms may be avoided by tapering TRAMACET at the time of discontinuation (see **DRUG ABUSE AND DEPENDENCE**, **Withdrawal Symptoms**).

OVERDOSAGE

TRAMACET is a combination product. The clinical presentation of overdose may include the signs and symptoms of tramadol toxicity, acetaminophen toxicity or both.

Tramadol

Serious potential consequences of overdosage are respiratory depression, lethargy, coma, seizure, cardiac arrest and death. Fatalities have been reported in post-marketing in association with both intentional and unintentional overdose with tramadol. The initial symptoms of tramadol overdosage may include respiratory depression and/or seizures. In treating an overdose, primary attention should be given to maintaining adequate ventilation along with general supportive treatment.

Acetaminophen

Serious potential consequences of overdosage with acetaminophen are hepatic centrilobular necrosis, leading to hepatic failure and death. Renal tubular necrosis, hypoglycemia and coagulation defects also may occur. The initial symptoms seen within the first 24 hours following an acetaminophen overdose are: anorexia, nausea, vomiting, malaise, pallor and diaphoresis. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. Emergency help should be sought immediately and treatment initiated immediately if overdose is suspected, even if symptoms are not apparent.

Treatment of Overdose

A single or multiple overdose with TRAMACET may be a potentially lethal polydrug overdose, and consultation with a regional poison control centre is recommended.

In treating an overdose of TRAMACET, primary attention should be given to maintaining adequate ventilation along with general supportive treatment. While naloxone will reverse some, but not all, symptoms caused by overdosage with tramadol, the risk of seizures is also increased with naloxone administration. In animals, convulsions following the administration of toxic doses of tramadol could be suppressed with barbiturates or benzodiazepines but were increased with naloxone. Naloxone administration did not change the lethality of an overdose in mice. Based on experience with tramadol, hemodialysis is not expected to be helpful in an overdose because it removes less than 7% of the administered dose in a 4-hour dialysis period.

Standard recommendations should be followed for the treatment of acetaminophen overdose.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

Tramadol

Tramadol is a centrally acting synthetic opioid analgesic. Although its mode of action is not completely understood, from animal tests, at least two complementary mechanisms appear applicable: binding of parent and M1 metabolite to μ-opioid receptors and weak inhibition of re-uptake of norepinephrine and serotonin.

Opioid activity is due to both low affinity binding of the parent compound and higher affinity binding of the *O*-demethylated metabolite M1 to μ-opioid receptors. In animal models, M1 is up to 6 times more potent than tramadolin producing analgesia and 200 times more potent in μ-opioid binding. Tramadol-induced analgesia is only partially antagonized by the opiate antagonist naloxone in several animal tests. The relative contribution of both tramadol and M1 to human analgesia is dependent upon the plasma concentrations of each compound (see **Pharmacokinetics**).

Tramadol has been shown to inhibit re-uptake of norepinephrine and serotonin in vitro, as have some other opioid analgesics. These mechanisms may contribute independently to the overall analgesic profile of tramadol.

Apart from analgesia, tramadol administration may produce a constellation of symptoms (including dizziness, somnolence, nausea, constipation, sweating and pruritus) similar to that of opioids.

Acetaminophen

Acetaminophen is a non-opiate, non-salicylate analgesic.

Tramadol/Acetaminophen Combination

When evaluated in a standard animal model, the combination of tramadol and acetaminophen exhibited a synergistic effect. That is, when tramadol and acetaminophen were administered together, significantly less of each drug was needed to produce a given analgesic effect than would be expected if their effects were merely additive. Tramadol reaches peak activity in 2 to 3 hours with a prolonged analgesic effect, so that its combination with acetaminophen, a rapid-onset, short-acting analgesic agent, provides substantial benefit to patients over either component alone.

Pharmacokinetics

Tramadol is administered as a racemate and both the (-) and (+) forms of both tramadol and M1 are detected in the circulation. The pharmacokinetics of plasma tramadol and acetaminophen following oral administration of one tablet are shown in Table 1.2. Tramadol has a slower absorption and longer half-life when compared to acetaminophen.

Table 1.2: Summary of Mean (±SD) Pharmacokinetic Parameters of the (+) and (-) Enantiomers of Tramadol and M1, and Acetaminophen Following a Single Oral Dose of One Tramadol/Acetaminophen Combination Tablet (37.5 mg/325 mg) in Volunteers

Parameter [a]	(+)-Tramadol	(-)-Tramadol	(+)-M1	(-)-M1	acetaminophen
C_{max} (ng/mL)	64.3 (9.3)	55.5 (8.1)	10.9 (5.7)	12.8 (4.2)	4.2 (0.8)
t_{max} (h)	1.8 (0.6)	1.8 (0.7)	2.1 (0.7)	2.2 (0.7)	0.9 (0.7)
CL/F (mL/min)	588 (226)	736 (244)	—	—	365 (84)
$t_{1/2}$ (h)	5.1 (1.4)	4.7 (1.2)	7.8 (3.0)	6.2 (1.6)	2.5 (0.6)

[a] For acetaminophen, C_{max} was measured as μg/mL.

A single dose pharmacokinetic study of TRAMACET in volunteers showed no drug interactions between tramadol and acetaminophen. Upon multiple oral dosing to steady state, however, the bioavailability of tramadol and metabolite M1 was lower for the combination tablets compared to tramadol administered alone. The decrease in AUC was 14% for (+)-tramadol, 10.4% for (-)-tramadol, 11.9% for (+)-M1 and 24.2% for (-)-M1. The cause of this reduced bioavailability is not clear. Following single or multiple dose administration of TRAMACET, no significant change in acetaminophen pharmacokinetics was observed when compared to acetaminophen given alone.

Absorption
The absolute bioavailability of tramadol from TRAMACET tablets has not been determined. Tramadol hydrochloride has a mean absolute bioavailability of approximately 75% following administration of a single 100 mg oral dose of tramadol HCl tablets. The mean peak plasma concentration of racemic tramadol and M1 after administration of two TRAMACET tablets occurs at approximately two and three hours, respectively, post-dose.

Peak plasma concentrations of acetaminophen occur within one hour and are not affected by co-administration with tramadol. Oral absorption of acetaminophen following administration of TRAMACET occurs primarily in the small intestine.

Food Effects
When TRAMACET was administered with food, the time to peak plasma concentration was delayed for approximately 35 minutes for tramadol and almost one hour for acetaminophen. However, peak plasma concentration or the extent of absorption of either tramadol or acetaminophen were not affected. The clinical significance of this difference is unknown.

Distribution
The volume of distribution of tramadol was 2.6 and 2.9 L/kg in male and female subjects, respectively, following a 100 mg intravenous dose. The binding of tramadol to human plasma proteins is approximately 20%, and binding also appears to be independent of concentration up to 10 µg/mL. Saturation of plasma protein binding occurs only at concentrations outside the clinically relevant range.

Acetaminophen appears to be widely distributed throughout most body tissues except fat. Its apparent volume of distribution is about 0.9 L/kg. A relatively small portion (~ 20%) of acetaminophen is bound to plasma protein.

Metabolism
Following oral administration, tramadol is extensively metabolized by a number of pathways, including CYP2D6 and CYP3A4, as well as by conjugation of parent and metabolites. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% of the dose is excreted as metabolites. The major metabolic pathways appear to be *N*- and *O*- demethylation and glucuronidation or sulfation in the liver. Metabolite M1 (*O*-desmethyltramadol) is pharmacologically active in animal models. Formation of M1 is dependent on CYP2D6 and as such is subject to inhibition, which may affect the therapeutic response (see **DRUG INTERACTIONS**).

Approximately 7% of the population has reduced activity of the CYP2D6 isoenzyme of cytochrome P450. These individuals are "poor metabolizers" of debrisoquine, dextromethorphan, tricyclic antidepressants, among other drugs. Based on a population PK analysis of Phase I studies in healthy subjects, concentrations of tramadol were approximately 20% higher in "poor metabolizers" versus "extensive metabolizers", while M1 concentrations were 40% lower. In vitro drug interaction studies in human liver microsomes indicates that inhibitors of CYP2D6 such as fluoxetine and its metabolite norfluoxetine, amitriptyline and quinidine inhibit the metabolism of tramadol to various degrees. The full pharmacological impact of these alterations in terms of either efficacy or safety is unknown. Concomitant use of serotonin re-uptake inhibitors and MAO inhibitors may enhance the risk of adverse events, including seizure (see **WARNINGS AND PRECAUTIONS**) and serotonin syndrome.

Acetaminophen is primarily metabolized in the liver by first-order kinetics and involves three principal separate pathways:
a. conjugation with glucuronide;
b. conjugation with sulfate; and
c. oxidation via the cytochrome, P450-dependent, mixed-function oxidase enzyme pathway to form a reactive intermediate metabolite, which conjugates with glutathione and is then further metabolized to form cysteine and mercapturic acid conjugates. The principal cytochrome P450 isoenzyme involved appears to be CYP2E1, with CYP1A2 and CYP3A4 additional pathways.

In adults, the majority of acetaminophen is conjugated with glucuronic acid and, to a lesser extent, with sulfate. These glucuronide-, sulfate- and glutathione-derived metabolites lack biologic activity. In premature infants, newborns and young infants, the sulfate conjugate predominates.

Elimination
Tramadol is eliminated primarily through metabolism by the liver and the metabolites are eliminated primarily by the kidneys. The plasma elimination half-lives of racemic tramadol and M1 are approximately 5-6 and 7 hours, respectively, after administration of TRAMACET. The apparent plasma elimination half-life of racemic tramadol increased to 7-9 hours upon multiple dosing of TRAMACET.

The half-life of acetaminophen is about 2 to 3 hours in adults. It is somewhat shorter in children and somewhat longer in neonates and in cirrhotic patients. Acetaminophen is eliminated from the body primarily by formation of glucuronide and sulfate conjugates in a dose-dependent manner. Less than 9% of acetaminophen is excreted unchanged in the urine.

Special Populations and Conditions

Renal Insufficiency
The pharmacokinetics of TRAMACET in patients with renal impairment have not been studied. Based on studies using tramadol alone, excretion of tramadol and metabolite M1 is reduced in patients with creatinine clearance of less than 30 mL/min, adjustment of dosing regimen in this patient population is recommended. The total amount of tramadol and M1 removed during a 4-hour dialysis period is less than 7% of the administered dose based on studies using tramadol alone (see **WARNINGS AND PRECAUTIONS** and **DOSAGE AND ADMINISTRATION**).

Hepatic Insufficiency
The pharmacokinetics and tolerability of TRAMACET in patients with impaired hepatic function has not been studied. Since tramadol and acetaminophen are both extensively metabolized by the liver, the use of TRAMACET tablets in patients with hepatic impairment is not recommended (see **WARNINGS AND PRECAUTIONS** and **DOSAGE AND ADMINISTRATION**).

Geriatrics
A population pharmacokinetic analysis of data obtained from a clinical trial in patients with chronic pain treated with TRAMACET which included 55 patients between 65 and 75 years of age and 19 patients over 75 years of age, showed no significant changes in pharmacokinetics of tramadol and acetaminophen in elderly patients with normal renal and hepatic function.

Gender
Tramadol clearance was 20% higher in female subjects compared to males on four Phase I studies of TRAMACET in 50 male and 34 female healthy subjects. The clinical significance of this difference is unknown.

Pediatrics
Pharmacokinetics of TRAMACET tablets have not been studied in pediatric patients below 18 years of age.

STORAGE AND STABILITY
Dispense in a tight container. Store at 15˚C – 30˚C.

DOSAGE FORMS, COMPOSITION AND PACKAGING
TRAMACET tramadol hydrochloride/acetaminophen tablets are available in PVC or PP blisters containing 10 tablets.

TRAMACET tablets combine two centrally acting analgesics, tramadol and acetaminophen. The light yellow, film-coated, capsule-shaped tablets are engraved "J-C" on one side and "T/P" on the other side. Each tablet contains 37.5 mg tramadol hydrochloride and 325 mg acetaminophen as the active ingredients. Inactive ingredients are powdered cellulose, pregelatinized starch, sodium starch glycolate, starch, magnesium stearate, hypromellose, titanium dioxide, polyethylene glycol, yellow iron oxide, polysorbate 80 and carnauba wax.

Product Monograph available upon request.

JANSSEN-ORTHO

Janssen-Ortho Inc., Toronto, Ontario M3C 1L9
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TRPI052113E

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.

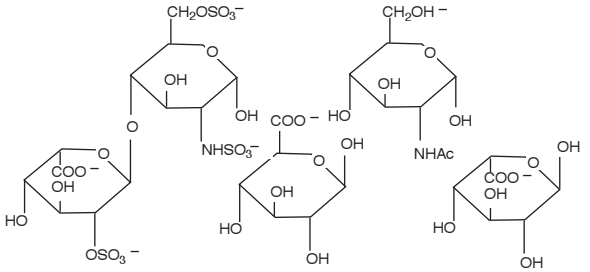
PHARMACEUTICAL INFORMATION

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. Vial stoppers do not contain natural rubber latex.

C504701 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.

C504710 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.

C504730 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.

C504801 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.

C504805 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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April 2006

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Please consult prescribing information for complete indications, warnings, precautions, adverse events and important patient criteria.

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