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Using Translational Research to Assist Therapeutic Decisions in the Management of an Emerging Pathogen

Novartis Award

Pharmacoeconomics George Dranitsaris, Pauline Leung Using Decision Modelling to Determine Pricing of New Pharmaceuticals

Novopharm Award

New Programs in Patient Counselling Kathleen Collin Cocktails: Facts for Youth about Mixing Medicine, Booze and Street Drugs

Pfizer Award

Long-Term Health Care Susan K. Bowles Economic Evaluation of Oseltamivir Phosphate for Post-Exposure Prophylaxis of Influenza in Long Term Care Facilities

Pharmascience Award

Patient Care Enhancement Mario L. de Lemos, Robin K. O'Brien, Leela John, Suzanne Taylor, Lynne Nakashima Counselling Cancer Patients on Natural Health Products: Development of a Systematic Approach



Influence of Patient Satisfaction on Indicators of Quality of Clinical Pharmacy Practice

Apotex Award Marie de Haan, Mark F. Collins

Background: The quality of direct patient care service provided by pharmacists was assessed using a patient satisfaction survey. Opportunities for quality improvement were identified in patient counseling.

Objective: The purpose of this study is to measure the influence of patient satisfaction on performance indicators specific to the quality of counseling.

Methods: The intervention consisted of sharing results of the patient satisfaction survey with pharmacists. In addition, performance indicators were reported to pharmacists every 28 days. Data was measured for 4-weeks at baseline and for 4 and 8 weeks after the intervention. The primary endpoint was the change in incidence of counseling among patients seen by pharmacists. The secondary endpoint was the change in incidence of knowledge assessment among counseled patients. For both endpoints incidence was measured as a percent of patients as well as a percent of drug related issues.

Results: At baseline: 161 patients seen, 42 (26%) counseled, 33 (79%) assessed for improved knowledge. At 4 weeks: 98 patients seen, 25 (25%) counseled, 15 (60%) assessed for improved knowledge. At 8 weeks: 116 patients seen, 37 (32%) counseled and 32 (86%) assessed for improved knowledge. At 8 weeks as compared to baseline, there were more drug-related issues for which patients reported improved knowledge (78 % versus 59 %). While there was no change in the incidence of patient counseling, improvement in the incidence of knowledge assessment was observed.

Conclusion: Reporting on patient satisfaction did not influence the number of patients seen or counseled but, did result in a higher incidence of assessment for improved knowledge.

A Randomized Trial of Patient Self-Managed versus Physician-Managed Oral Anticoagulation

Aventis Award

Rubina Sunderji, PharmD, FCSHP, Kenneth Gin, MD, FRCPC, Karen Shalansky, PharmD, FCSHP, Cedric Carter, MB, FRCPC, Keith Chambers, MD, Cheryl Davies, RN, Linda Schwartz, RN, Anthony Fung MB, FRCPC

Background: Self-management of warfarin by the patient is an attractive strategy particularly if it improves anticoagulation control and can be done safely under minimal physician supervision.

Objective: To determine the effect of self-management (SM) compared to physician-management (PM) on maintenance of therapeutic anticoagulation.

Methods: This was a randomized, open-label 8-month trial. Patients 18 years or older were eligible if they were receiving warfarin for at least 1 month prior to enrolment and required anticoagulation for at least 1 year to a target international normalized ratio (INR) of 2.0 to 3.0 or 2.5 to 3.5. Exclusion criteria were known hypercoaguable disorder, mental incompetence, language barrier or inability to attend training sessions. Patients randomized to SM tested their INR using a point-of-care device (ProTime) and adjusted their warfarin doses using a nomogram. Patients randomized to PM received usual care from their general practitioner. The primary outcome was to demonstrate 20% improvement in anticoagulation control by SM.

Results: One hundred and forty patients were randomized (70 per group). Thirteen patients dropped out of SM early due to inability to self-manage. Based on intention-to-treat analysis, there was no difference in proportion of INR in range (SM 64.8% vs PM 58.7%, p=0.23) and time in target range (SM 71.8% vs PM 63.2%, p=0.14). Patients managing their own therapy spent less time below the therapeutic range (15.0% vs 27.3%, p=0.04). There were 3 major complications of thrombosis or bleeding, all in the PM arm. All patients who completed SM preferred to continue with this strategy.

Conclusions: Self-management was not significantly better then PM in maintaining therapeutic anticoagulation. This strategy was feasible and appeared safe in our study population.

Keywords: anticoagulation, warfarin, self-management

Cocktails: Facts for Youth about Mixing Medicine, Booze and Street Drugs

Baxa Award

Kathleen Collin, BSc(Pharm), Mary Paone, RN, MSN

Background: A round-table meeting involving more than 20 health care professionals at Children's Hospital identified the lack of information about interactions between prescription medications and street drugs as a major concern to health care workers and youth. It was decided to write a book with information about street drugs, and their interactions with the medications most commonly prescribed in Children's Hospital.

Objectives: First, to provide youth and health care workers with information about street drugs, alcohol, tobacco, and caffeine. Second, to provide information about any known drug interactions between 105 commonly prescribed prescription medications and 12 illicit drugs. Lastly, to prepare a reference that would be of use to youth, health care professionals, teachers, community workers, and parents or caregivers, and distribute this reference free to youth.

Methods: A questionnaire was distributed to all the outpatient clinics in Children's Hospital, asking for the ten most commonly prescribed medications. Consultation with professionals working with youth and in addiction medicine determined the 12 illicit drugs to be included in the book. Two undergraduate students were chosen to help with the research portion of the project. The 105 medications were divided into 3 lists, and both the students and the pharmacist determined the search criteria and databases. Tertiary references were reviewed, and primary articles, case studies and adverse reaction reports were obtained. The information found was reviewed, analyzed and summarized by the pharmacist. Ethics approval to conduct focus group meetings was obtained, and an all-day meeting of youth was held. During the meeting, the youth determined the content, layout, language, graphics and "feel" of the book.

Results: The book is used by health care professionals throughout the hospital to answer questions from youth about mixing their prescription medications with various street drugs. It is available in the Family Resource Library of the hospital. Copies are available on every ward and in every outpatient clinic, as a resource. Youth within the hospital or the outpatient clinics are offered this book at no cost. Community youth organizations throughout the province have been provided copies and hospitals across Canada have ordered copies of this reference.

Conclusion: The book, when given to a youth by a health care professional, opens the door to further dialogue between them about illicit drugs, their effect on health, and interactions with prescription medications.



Évaluation des risques d'interactions médicamenteuses chez les patients du Programme d'accès spécial aux médicaments

Baxter Award

S. Atkinson, A. Blanc, D. Lebel, J.-F. Bussières, B. Bailey, A. Bérard

Introduction: Le Programme d'accès spécial (PAS) de Santé Canada autorise, sur demande médicale écrite, l'achat de médicaments non commercialisés par les pharmaciens d'établissement pour le traitement de conditions sévères pour les patients hospitalisés ou ambulatoires. Il est raisonnable d'affirmer que ce système engendre le fractionnement du dossier pharmacologique ambulatoire du patient si des problèmes de communication existent entre les intervenants et qu'il nuit à l'évaluation globale du patient, entre autres par l'omission de détecter des interactions médicamenteuses.

Objectifs: Cette étude vise à évaluer la transmission de l'information entre les professionnels de la santé impliqués au niveau du PAS de même que les risques d'interactions médicamenteuses de niveau I à III chez les patients ayant recours à ce programme.

Méthodologie: Il s'agit d'une étude de cohorte rétrospective avec recrutement prospectif auprès de patients de 0 à 18 ans recevant un médicament du PAS (par ex. : cisapride, nitisinone, etc.) pour utilisation en ambulatoire. L'évaluation a été menée à partir de questionnaires administrés par une pharmacienne résidente, auprès des patients, de leurs médecins et de leurs pharmaciens.

Résultats: L'étude a inclus 65 patients, 38 médecins et 66 pharmaciens. Concernant la transmission de l'information, on observe que les médecins et les pharmaciens ont noté dans leur dossier la prise de médicaments du PAS dans 90 % et 17 % des cas respectivement. Quant aux risques d'interactions médicamenteuses, on observe que 7,7 % des patients, prenant un médicament du PAS avec au moins une interaction médicamenteuse de niveau I à III documentée, ont présenté une interaction médicamenteuse; cette proportion est de 12 % chez les patients utilisant du cisapride.

Conclusion: Cette étude confirme qu'il existe des problèmes de transmission de l'information entre le pharmacien d'établissement et le pharmacien communautaire et qu'il existe un fractionnement du dossier pharmacologique qui mène à des interactions médicamenteuses. Cette étude suggère qu'il est important de revoir le fonctionnement du PAS et de s'assurer que toute ordonnance soit traitée par un pharmacien, incluant une obligation de diffusion de l'information.

Mots clés: programme d'accès spécial, interactions médicamenteuses, pharmacien, pédiatrie, cisapride

The Benefits of Pharmaceutical Care in an Emergency Room

Bristol-Myers Squibb Award Carlee Thorsen

Objective: To provide pharmaceutical care and continuity of care to patients admitted through the emergency room, then assess the satisfaction of the pharmacists and ER staff with this service.

Background: The purpose of this project was to trial, then evaluate an expanding role of a pharmacist in the ER.

Methods: A pharmacy resident was present in the ER at St. Paul's Hospital in Saskatoon, Saskatchewan for a total of 15 days between February 12 and March 7, 2003. The resident performed twenty-eight medication histories, and identified 61 drug-related problems. A project evaluation was distributed to pharmacy and ER staff. The evaluation assessed the usefulness of the pharmacy service in the ER.

Results: The resident made 56 recommendations to solve drug related problems, researched 17 drug information questions, 10 seamless care services provided from the hospital to community pharmacies, and medication counseling was provided to 3 patients. Both pharmacy and ER staff were generally satisfied with the service provided in the ER by the pharmacy resident.

Discussion: The pharmacist was often able to elicit a more current and accurate medication history than the nursing staff in the ER. A number of the recommendations made where medications were missed from the list on admission. All evaluation respondents determined that an ER pharmacist position would be well received.

Conclusion: This study supports the benefit of providing pharmaceutical care to admitted patients in the ER.

Keywords: emergency room, ER, pharmaceutical care, pharmacist, drug related problems

Re-evaluation of the Management of Community-Acquired Pneumonia at a Community Hospital after Implementation of a Pre-Printed Order

GlaxoSmithKline Award (Pharmaceutical Care) Vicki Wong BSc(Pharm), Zahra Kanji, BSc(Pharm), PharmD, Rajesh Mainra, MD, FRCPC, FCCP, Michael Boldt, MD, FRCPC

Background: A preprinted order (PPO) was implemented to improve the management of Community-Acquired Pneumonia (CAP).

Objective: To evaluate usage of the PPO and characterize management of CAP after PPO implementation.

Methods: A retrospective chart review of patients admitted with CAP in 2002: Group A (PPO), Group B (no PPO), and control group (2000 study)

Results: Of the 105 patients included, 42% had the PPO in their charts. Both Group A and B had a mean LOS of 7 days. Of Group A patients with and without Pneumonia Severity Index (PSI) scores, Group B patients and control group patients, 8%, 36%, 37%, and 16% respectively were inappropriately admitted. Guideline recommended cultures were performed in 63%, 25% and 47% of Group A, Group B and control group patients and usage of empirical antibiotics were consistent with the guidelines in 74%, 65% and 53% respectively. Of eligible Group A, Group B and control group patients, 67%, 65% and 64% respectively received step-down (SD) with group averages of 3.1, 5.4 and 2.5 days to SD. Of eligible Group A and Group B patients, 57% and 61% respectively had timely discharge with an average of 3.4 and 2.7 days to discharge.

Conclusions: After PPO implementation, inappropriate hospitalization decreased, while rates of cultures and empiric antibiotics usage consistent with the guidelines increased. LOS did not decrease and occurrence and timeliness of SD or ED did not increase.

Keywords: preprinted order sheet, community-acquired pneumonia, CAP



Thrombolytic Drug Use in Nova Scotia, Canada: An Application of the World Health Organization's Anatomical Therapeutic Chemical (ATC) / Defined Daily Dose (DDD) Methodology

GlaxoSmithKline Award (Pharmacy Administration) Ryan B. Sommers, (Hons)BSc, Ingrid S. Sketris, PharmD, MPA(HSA), George Kephart, PhD, Hoan Linh Banh, PharmD

The utilization of thrombolytic medications for acute myocardial infarction (AMI) events in acute care hospitals in the province of Nova Scotia (NS), Canada was studied to determine the effect of health regions and hospital size on the level and type of thrombolytic use. Data from the Nova Scotia provincial drugpurchasing database was combined with hospital information to construct regional, hospital size and temporal patterns in thrombolytic use per AMI event. The WHO's ATC / DDD methodology, a technique used to allow comparison of different types and dosages of medications, was used to construct drug utilization trends of streptokinase and alteplase between 1998 and 2001.

Estimated rates of overall thrombolytic use per AMI event showed that thrombolytic use statistically differed in some study years and regions. Alteplase and streptokinase utilization also differed by hospital size, with larger hospitals using these medications at 69% of the level of smaller hospital thrombolytic drug utilization (p<0.05). Larger facilities were also more likely to use different types of thrombolytic medications than smaller hospitals (p<0.005).

This investigation has demonstrated that the ATC / DDD approach combined with routinely collected hospital drug purchasing and administrative information is a simple, descriptive tool that can aid drug utilization evaluations and allocation decisions.

Anti-Xa Monitoring of Enoxaparin for Acute Coronary Syndromes in Patients with Renal Disease

Hoffmann-La Roche Award Jessica M. Ma, BScPhm, Cynthia A. Jackevicius, BScPhm, MSc, FCHSP, Erik Yeo, MD, FRCPC

Purpose: By reviewing the standards of practice as set out by our hospital's guidelines, the goal of this study was to evaluate the appropriate use of anti-Xa levels as a surrogate marker to determine enoxaparin dosing for renally impaired patients.

Methods: A total of 72 separate acute coronary syndrome patient admissions were retrospectively reviewed. All patients had anti-Xa levels taken and a creatinine clearance <30 mL/min during enoxaparin therapy.

Results: The average anti-Xa level at the once and twice daily dose was 0.40 IU/mL and 0.72 IU/mL respectively. With twice daily dosing only 6% of the levels were in the target range compared to 36% with once daily dosing. Of the 22 events that had a change of dosing frequency from twice to once daily, 5% of anti-Xa levels were 0.5 IU/mL with twice daily compared to 68% with once daily. During hospitalization, 7% of patients died and 6% had a myocardial infarction. Minor bleeding was a common adverse event (8%).

Conclusions: Although the relation between anti-Xa activity, efficacy, and adverse effects has not been definitively established, anti-Xa levels can assist with dosing of enoxaparin in renally impaired patients. Our hospital guidelines are effective in adjusting dosing to reach target anti-Xa levels.

Tobramycin Pharmacokinetics in Febrile Neutropenic Children Undergoing Stem Cell Transplantation: Once vs Three Times Daily Administration

Mayne Pharma Award L. Lee Dupuis, MScPhm, FCSHP, Lillian Sung, BA, MD, FRCPC, Tracey Taylor, BScPhm, Mohamed Abdolell, BSc, MSc, Upton Allen, MD, FRCPC, John Doyle, MD, FRCPC, Anna Taddio, BScPhm, PhD

Purpose: Validated pediatric Q24H aminoglycoside dosing guidelines are not available. The objectives of this study were to describe the pharmacokinetic disposition of IV tobramycin in children undergoing stem cell transplant (SCT) following either Q8H or Q24H administration and to use this information to create initial Q24H dosing guidelines for this population.

Methods: In this randomized, double-blind, controlled study, children undergoing SCT received tobramycin either Q8H (2.5mg/kg/dose) or Q24H (<5yrs: 9mg/kg/dose; 5-<12yrs: 8mg/kg/dose; 12yrs: 7mg/kg/dose). Serum tobramycin concentrations were obtained 2 and 8 hours after the first dose. Parameters were calculated using first order, one-compartment equations. Initial Q24H dosing guidelines were derived using the parameters from all children to achieve a maximum serum concentration (Cmax) of 20-22.5mg/L and a drug free interval (time during dosing interval where concentration < 1mg/L) of at least 4 hours.

Results: 60 children were enrolled. Tobramycin concentrations were obtained immediately after the first dose in 45 children (mean age: 6.3yrs; range: 0.6-16.6yrs). After the first tobramycin dose, the elimination rate constant (ke) and volume of distribution (Vd) observed in the Q8H group were 0.340.094 hr-1 and 0.480.207 L/kg, respectfully. This group achieved a maximum tobramycin concentration at steady state (Cmaxss) of 5.81.80 mg/L and an area under the serum tobramycin concentration curve (AUC) of 28.38.19 mg/Lhr.

After the first tobramycin dose, the ke and Vd observed in the Q24H group were 0.430.115 hr-1 and 0.430.257L/kg, respectfully. This group achieved a Cmax of 17.87.19mg/L and an AUC of 55.818.96 mg/Lhr. Tobramycin Vd varied with age.

Initial Q24H tobramycin doses recommended to achieve the target parameters are: 0.5 - <9yrs: 10mg/kg/dose; 9-<12yrs: 8mg/kg/dose; and 12yrs: 6mg/kg/dose.

Conclusions: Children undergoing SCT who receive tobramycin Q24H should receive an initial dose based on age. Further validation of the proposed dosing guidelines is required.



Using Translational Research to Assist Therapeutic Decisions in the Management of an Emerging Pathogen

Merck Frosst Award

S.A. Zelenitsky, R.E Ariano, H. lacovides, G.K.M. Harding

Background: Over the past decade, Stenotrophonas maltophilia has emerged as a high-risk pathogen and important cause of opportunistic infections in hospitalized patients. However, treatment is complicated by the presence of high rates of resistance to multiple antibiotics except trimethoprim/sulfamethoxazole (T/S), which is often the drug of choice. Information regarding antibiotic pharmacodynamics is limited, and therefore our goal was to study T/S, ceftazidime, ciprofloxacin, gentamicin and tobramycin alone and in combination against S. maltophilia in an in vitro pharmacodynamic infection model.

Methods: Clinical S. maltophilia isolates were used to simulate bacteremia in an immunocompromised host. All isolates were susceptible to T/S and susceptible or intermediately susceptible to at least one other agent. Antibiotics alone and in combination were studied with doses administered Q12h for 48h. Individual antibiotic t_s were used in the model to simulate unbound antibiotic serum concentrations achieved with recommended doses in humans.

Results: T/S alone was bacteriostatic at best against all isolates despite susceptible MICs. Only ceftazidime alone was active against one isolate. Antibiotic combinations were significantly more active producing bacterial reductions of 1.3 to 4.0 log10 colony forming units (CFU)/ml at 24 h and 0.6 to 2.2 log10 CFU/ml at 48 h (p < 0.0001). Intra-experimental changes in MIC were not detected.

Conclusions: In conclusion, antibiotic combinations are significantly more active against S. maltophilia in vitro even if the individual agents are inactive alone or only intermediately susceptible based on MIC. These pre-clinical data support the use and further study of antibiotic combinations in the management of serious S. maltophilia infections.

Using Decision Modelling to Determine Pricing of New Pharmaceuticals

Novartis Award George Dranitsaris, Pauline Leung

Background: Decision analysis is commonly used to perform economic evaluations of new pharmaceuticals. The outcomes of such studies are often reported as an incremental cost per quality-adjusted life year (QALY) gained with the new agent. Decision analysis can also be used in the context of estimating drug cost before market entry. The current study used neurokinin-1 (NK-1) receptor antagonists, a new class of antiemetics for cancer patients, as an example to illustrate the process using an incremental cost of \$Can20,000 per QALY gained as the target threshold.

Methods: A decision model was developed to simulate the control of acute and delayed emesis following cisplatin-based chemotherapy. The model compared standard therapy with granisetron and dexamethasone to the same protocol with the addition of an NK-1 prior to chemotherapy and continued twice daily for five days. The rates of complete emesis control were abstracted from a double-blind randomized trial. Costs of standard antiemetics and therapy for breakthrough vomiting were obtained from hospital sources. Utility estimates characterized as quality-adjusted emesis free days were determined by interviewing 25 oncology nurses and pharmacists using the Time Trade-Off technique. These data were then used to estimate the unit cost of the new antiemetic using a target threshold of \$Can20,000 per QALY gained.

Results: A cost of \$Can6.60 per NK-1 dose would generate an incremental cost of \$Can20,000 per QALY. The sensitivity analysis on the unit cost identified a range from \$Can4.80 to \$Can10.00 per dose. For the recommended 5-days of therapy, the total cost should be \$Can66.00 (\$Can48.00-\$Can100.00) for optimal economic efficiency relative to Canada's publicly funded health care system.

Conclusions: The use of decision modelling for estimating drug cost before product launch is a powerful technique to ensure value for money. Such information can be of value to both drug manufacturers and formulary committees because it would facilitate negotiations for optimal pricing in a given jurisdiction.

Cocktails: Facts for Youth about Mixing Medicine, Booze and Street Drugs

Novopharm Award

Kathleen Collin, BSc(Pharm), Mary Paone, RN, MSN

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Conclusion: The book, when given to a youth by a health care professional, opens the door to further dialogue between them about illicit drugs, their effect on health, and interactions with prescription medications.



Economic Evaluation of Oseltamivir Phosphate for Post-Exposure Prophylaxis of Influenza in Long Term Care Facilities

Pfizer Award Nancy A. Risebrough, MSc Candidate, Susan K. Bowles, PharmD, FCSHP, Andrew E. Simor, MD, FRCP(C), Alison McGeer, MD, FRCP(C), Paul I. Oh, MD, FRCP(C)

The purpose of this study was to assess the cost-effectiveness of oseltamivir post-exposure prophylaxis during influenza A outbreaks compared to either amantadine or no post-exposure prophylaxis in long term care facilities (LTCF) with high influenza vaccination rates among both patients and staff. A hypothetical cohort of vaccinated LTCF residents was used to conduct a cost-effectiveness analysis based on decision analytic model from a single government payer perspective. Our main outcome measures were incremental costs (or savings) per influenza-likeillness case avoided compared to usual care. From a government payer perspective, this analysis showed oseltamivir was a dominant strategy as it was associated with the fewest influenza like illness cases with cost savings of \$1249 per 100 patients (2001 \$CDN) compared to amantadine and \$3357 per 100 patients compared to no prophylaxis. Costs for amantadine dose calculation and hospitalization for adverse events contributed to amantadine being a more expensive prophylaxis strategy compared to oseltamivir. Both prophylaxis strategies were more cost-effective than no prophylaxis. Despite high influenza vaccination rates, influenza outbreaks continue to emerge in LTCF necessitating cost-effective measures to further limit the spread of influenza and related complications. Although amantadine has a lower acquisition cost than oseltamivir, it is associated with a higher adverse event rate, lower efficacy and requires individualized dosing assessments leading to higher overall costs and more influenza-like-illness than oseltamivir. Our results suggest that the use of oseltamivir post-exposure prophylaxis is the most cost-effective strategy in preventing the spread of influenza in LTCF compared to the current standard of care of amantadine prophylaxis or as in some jurisdictions, no prophylaxis.

Counselling Cancer Patients on Natural Health Products: Development of a Systematic Approach

Pharmascience Award Mário de Lemos, BSc(Hons)(Pharm), MSc(Clin Pharm), PharmD, Leela John, BSc, BSc(Pharm), PharmD, Lynne Nakashima, BSc(Pharm), PharmD, Robin O'Brien, BSc, BSc(Pharm), PharmD, BCOP, Suzanne Malfair Taylor, BSc(Pharm), PharmD, BCPS

Background: 45-60% of cancer patients use natural health products (NHP). Many pharmacists find it difficult to advise these patients effectively. Our study explored the pharmacists' perceptions of the information needed to advise cancer patients on NHP and to develop a systematic counselling approach.

Methods: A focusgroup of five senior pharmacists from the British Columbia Cancer Agency was used to define the information needed to advise cancer patients on NHP, reasons behind these definitions, and to develop a counselling approach using laymen terms.

Results: Six categories of information emerged: definition of the pharmacist's role, evaluation of evidence using a single reliable reference, assessment of efficacy, assessment of toxicity, monitoring parameters for a therapeutic trial, and provision of a closure and opportunity to refer patients to psychosocial counsellors. For each category, the focus group described the information needed to communicate to the patient, the reasoning behind this information, and the means to obtain it. A patient counselling approach was developed based on these categories of information.

Conclusion: The findings provided a description and rationale of categories of information needed to advise cancer patients on NHP. These formed the basis of the development of a systematic, step-by-step approach to counselling these patients.

