

# News LETTER



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## President's Message

Dear colleagues and friends .

I hope that you all had a relaxing and revitalizing holiday. This is needed in order to be able to return to work with the focus and dedication that is expected from us as oncology pharmacists.

Meanwhile, as time goes by, the new ISOPP secretariat and committee chairs are installed and have started their activities. Following the Prague congress, the very next day, we had our new board meeting. On the agenda were the strategic planning for the next 4 years, the financial status and budget approval for 2011, new options and projects to initiate, new future directions for the website, new challenges for the standards committee, the preparation required to convert to the yearly elections, the preparation for a Request For Proposal (RFP) for our 2014 congress and many more items.

The congress itself can be called a great success with a good scientific program, an excellent attendance of 590 colleagues coming from 53 countries. What an opportunity to network!!

The education committee did a follow-up of the congress (see *Newsletter Vol12 No2 Ed.*) and the results of the questionnaire are inspiring us to continue on the same track and to even do better in the future. Also our industrial partners were very positive and some of them have already committed themselves to be in



ISOPP President relaxing at the APOPC meeting with fellow ISOPP members Harbans Dhillon and Lita Chew

Melbourne in 2012.

During the discussion for our strategic planning 4 main items were decided to tackle at first.

It is with great pleasure I can announce today that 3 out of those 4 have been started and that you already or in the near future can see the results:

1/ The ISOPP standards of safe practice are now accessible for free to everybody in the public section of the ISOPP website ([www.isopp.org](http://www.isopp.org)). ISOPP standards of safe practice are relevant to all people handling hazardous drugs and ISOPP understands the need for this work to be distributed as widely as possible throughout the world. ISOPP recognizes that the usefulness of this

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document globally and aims to provide for everyone interested regardless of their ISOPP membership status. This is the only standard on this topic that can rely on a global acceptance since it was produced under a global committee with wide consultation and therefore needs to be distributed to as many interested parties as possible.

ISOPP members will soon have access to an audit tool based on the standards to evaluate their own situation and can use this to compare their service to others in the same region or in different regions, to those with a similar or different type of hospital. The audit tool has been finalized by the standards committee and the publication committee is now looking at a suitable template for placing it on the website for membership distribution.

2/ ISOPP wants to be more active educationally and therefore is looking for opportunities to collaboration with other international societies and to organize events in the “non-congress” year.

In 2011 the following events will take place: an ISOPP-EBEWE education event in May to be held in Austria and an FIP-ISOPP congress day during the FIP congress in September in Hyderabad-India (final approval for this collaboration is pending at this time). Again, as details become available they will be placed on the website.

3/ The ISOPP website needs more interactive tools. As the website is our most important way of communicating with the membership, it needs to be an attractive tool which invites people to look very often (e.g. weekly), because of its updates, novelties, information and communication with other members. The education committee will submit monthly a “case of the month” related to your daily work, a question and answer education tool for you to try out. This should be able to be added to your own ‘continuing education’ requirements in your country.



4/ The membership committee and secretariat are in discussion right now about the membership fee structure in preparation for new applications and renewal of memberships for 2011. The decision-making process will be mainly influenced by other international societies and how they structure their membership tiers. Once this discussion has come to an end, I will announce on the website the decision and background of it.

As you can see, we have started with great enthusiasm and I am confident that with the committed people in the secretariat and the different committees we will be able to sustain that enthusiasm for a better and even more attractive “ISOPP life.”

Also soon a call for nominations will appear on the website. It was voted by the whole membership that we are now in a yearly process for elections. Half of the secretariat will be renewed every year. This will ensure some continuity between secretariat years and will reduce miscommunication.

In 2011 positions for secretary and 2 general secretariat members become vacant. In 2012 it will be for president elect, treasurer and 2 general secretariat members.

As an international society we also want to reflect that global variety in the composition of our secretariat and committee chairs. Looking at the present composition of the secretariat I want to ask for a solid representation from Europe in the upcoming nominations to fulfill this requirement since I am the only representative from Europe on the Secretariat. Of course, I do not want to exclude candidates from other parts of the world but I do want to encourage my European colleagues to nominate.

Dear ISOPP member,

As an Oncology Pharmacy Practitioner, you are interested in the “stability of anticancer drugs”. You can consult the free European database STABILIS on this website : [www.stabilis.org](http://www.stabilis.org)

This database is mainly used by pharmacists involved in the field of oncology with 16 anticancer drugs in the first 20 consulted monographs (with a total of 382 monographs of injectable drugs).

The database is translated into 24 languages and gives the information with pictograms. The database is very easy to use, a User’s guide is available.

We hope you will enjoy consulting it.

If you are interested to receive the quarterly Stabilis Newsletter, you can register freely on the Stabilis website.

With best regards

Dr Jean Vigneron

President of INFOTAB association FRANCE

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Website: [www.stabilis.org](http://www.stabilis.org)

There are no special skills needed nor any age requirement to be a candidate for general secretariat member, just the willingness to work/ contribute and cooperate with an open mind, remembering that ISOPP is an international society and has members with many and varied views.

My message to end with is “ Check it out !” Go to the website, use it for education, use the ability to ask your questions to more than 500 colleagues - people on the members discussion forum and also use it to communicate with us (the Secretariat). Everyone has questions sometimes and nearly everyone has answers they would like to share.

Greetings from Belgium  
Johan Vandenbroucke  
President ISOPP



## Introducing ISOPP Treasurer

JILL M. KOLESAR, Pharm D, BCPS, FCCP received a Doctor of Pharmacy and completed a specialty practice residency in oncology/hematology and a 2-year fellowship in molecular oncology pharmacotherapy at the University of Texas Health Science Center in San Antonio, Texas.

Jill is currently a Professor of Pharmacy at the University of Wisconsin and the Director of the Analytical Laboratory at the University of Wisconsin Comprehensive Cancer Center USA.

Dr. Kolesar practices in the Hematology and Oncology Clinics at the William S. Middleton VA Hospital in Madison, Wisconsin, managing the pharmacotherapy of ambulatory oncology patients and her research in pharmacogenomics includes the use of molecular markers to predict response and monitor efficacy of cancer chemotherapy. She has authored more than 100 abstracts, research articles, and book chapters, and as a principal investigator, she has received more than \$750,000 in research funding from the NCI, ACS and other sources. In addition, she holds 2 US patents for novel assay methodologies for gene expression and mutation analysis.

Jill is currently the Treasurer of the International Society of Oncology Pharmacy Practice (ISOPP). She serves on the editorial boards of Lexi-Comp's Pharmacogenomics Handbook, ACCP's Pharmacogenomics: Applications to Patient Care, the American Journal of Health System Pharmacy, the Journal of Oncology Pharmacy Practice, and the textbook, Pharmacotherapy: Principles and Practice. Jill has served ACCP on the Board of Regents and as the Chair of Hematology Oncology PRN, and on the National Cancer Institute Central IRB, as the Chair of the Adverse Events Subcommittee.



Rafting trip on the Snake River in Dinosaur National Park, Utah.  
Left to right: Lee, Jill, Tom (16), Emily (14), Eli (12), Zac (17), Josh (13)

On a personal note, Jill is married to fellow ISOPP member, Lee Vermeulen and the mother of five. Jill and Lee have an active household and they spend much of their free time traveling. Their family plans to visit all of the United States National Parks and has good start with visits to Denali, Dinosaur, Bryce, Zion, Grand Canyon,

Yellowstone, Grand Teton, Badlands, Wind Cave, Jewel Cave and Mt Rushmore so far. In addition to spending time with her family, Jill loves to read, run ski, scuba dive, garden, cook and can be occasionally talked into riding a roller coaster with the kids.

# Inadvertent Intrathecal Administration of Vincristine

Peter Gilbar, Toowoomba, Australia

In 2004 a young Australian man with Burkitt's lymphoma was erroneously administered vincristine intrathecally rather than via the intended intravenous route. Tragically this resulted in progressive neurotoxicity, paralysis and death in an otherwise potentially curable patient, and the incident received national media coverage. As with the majority of published cases, a series of human and system errors combined to make this event possible. At the time I was co-chair of the Committee of Specialty Practice in Cancer Services for the Society of Hospital Pharmacists of Australia and led the push to develop specific recommendations in a bid to prevent this error reoccurring. Guidelines were published in Australian medical<sup>1</sup>, pharmacy<sup>2</sup> and nursing<sup>3</sup> journals and an editorial published in JOPP.<sup>4</sup> A review of published case reports and recommendations to reduce occurrence were also published in an international oncology journal.<sup>5</sup> The main preventative strategy suggested was the abolition of the syringe as a means of vincristine administration with this method replaced by administration via a small-volume intravenous bag.<sup>6</sup> Although this is the safest and most effective way of eliminating accidental spinal administration of vinca alkaloids, this approach was criticized as potentially increasing the risk of extravasation injury. A retrospective study was conducted in Australian hospitals to determine the incidence of vinca alkaloid extravasation following administration via syringes or mini-bags.<sup>7</sup> The reported incidence of vincristine extravasation from syringes was 0.03% and 0.041% with small volume infusions, with the data strongly supporting the use of mini-bags. The push to prevent vincristine medication errors was supported

by international organisations such as the Institute of Safe Medication Practices in the USA and Canada, The United Kingdom Department of Health, and the Australian Council for Safety and Quality in Health Care. In 2007 the World Health Organisation through the WHO World Alliance for Patient Safety invited me to be part of an expert panel investigating this problem as further deaths had been reported in the USA, Spain and Hong Kong. Since 1968, there have been 55 reports of accidental vincristine spinal administration although only 23 have been published in the literature.<sup>5</sup> The WHO recommendations are:<sup>8</sup>

- 1) The labelling of vincristine should include a clear warning label that reads: "FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES".
- 2) Syringes should not be used for vincristine administration.
- 3) Vincristine should where possible be prepared by dilution in small volume intravenous bags (the "mini-bag" technique), rather than in a syringe, to protect against accidental administration via a spinal route.

Further investigation is being undertaken to develop a unique "lock and key" design of needles, syringes, catheters, tubing and bags so that medications intended for intravenous use cannot be administered via the spinal route and vice versa.<sup>8</sup>

The consequences of an inadvertent intrathecal administration of vincristine are devastating. This is particularly distressing as many of the reported fatalities have occurred in young patients with potentially curable malignancies. The best approach for managing this problem is by developing effective methods of prevention and incorporating them as standard practice in oncology/haematology units



around the world. Medical, nursing and pharmacy professions must work together to ensure that guidelines for prevention are universally adopted so that this tragic error can never happen again.

*[Save lives! Please institute WHO recommendations in your hospital. Editor]*

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# Report from the 5th SOBRAFO meeting

Curitiba hosted the fifth Brazilian meeting of oncology pharmacists April 16 through 18, 2010; it was promoted by SOBRAFO (Brazilian Society of Oncology Pharmacists). The Estação Convention Center is located in downtown Curitiba, in the same complex as the shopping Estação mall, with all of the facilities that a large shopping center can offer. Almost 600 registered participants were received in this meeting (77% pharmacists, 19% students, 4% other professionals) all of whom could attend an extensive program divided in 2 rooms.

The fifteen pharmaceutical companies who sponsored the event were present creating the possibility for constructive interaction between professionals and laboratory representatives. The laboratories distributed quality scientific material and showed participants new medicines. Each break, all participants had the opportunity to visit stands and to network.

Some highlights of the scientific program were the presence of 2 international pharmacists: Kristine Crews from the USA and Graziella Sassi from Italy.

Kristine is pharmacist and co-director of the pharmacokinetics shared resource at St Jude Hospital, in Memphis. She talked about the importance of clinical pharmacokinetics in oncology. In the pre-conference courses, she talked during 4 hours about the pharmacokinetics of 4 different drugs: methotrexate, tamoxifen, vancomycin and warfarin. The focus was to discuss renal elimination and how genetics



Ines, Ana Paula, Waldemar, Annemeri , Kristiana.

interferes in the metabolism. The most important take home message, was that although there is a potential for individualized dosage, there is still much to learn about the evaluation of drug exposure and the impact on disease progression and outcome.

Graziella Sassi, member of ISOPP and pharmacist from Turin, Italy talked about dosing in special patients (obese, underweight, children) and new treatments in immunotherapy.

Another pre-conference course discussed clinical trials in oncology; it was presented by Jeanine Nardin, from Curitiba. In Brazil there are not many pharmacists involved in clinical trials; it is still a field for pharmacists to discover.

This year our official opening it was different from usual and we invited a special professional to give us

a motivational speech. Oncology is an area that represents a great challenge to all professionals, including the pharmacist. For this reason we invited Waldemar Niclevicz, the first Brazilian to climb

the Mount Everest. As an alpinist, everybody has their own mountain and their own challenges. During one hour, Waldemar showed us the difficulties to reach his dream, each challenge and each accomplishment. Everybody is confronted with difficult paths and obstacles. Sometimes we need to wait for a "storm" to end before we can go ahead, but the most important part is: never give up on your dream! As an alpinist we should look at our "mountain." Before starting to climb, we should plan and organize a schedule. Then, as we climb, we need to stop in the storms, go ahead when there is a sun, and especially be patient and persistent.

Similar to past meetings, the lecture about bio-safety had a full room. This is a subject about which all pharmacists always want to learn more. For this reason, we always have to include it in our scientific program to present new findings and reinforce old concepts.

To complete these three days of special programs, we received more than 100 abstracts. In past meetings, we have received no more than 80. The topics ranged from auditing to pre-clinical trials. For four authors with the highest scores on their abstract submissions, we offered the opportunity to show their results during the oral platform and





they competed for the 3rd dendrix prize support to research. The abstracts chosen by the committee were:

- Method for detecting residues of fluorouracil in an environment handling of drugs (winner)
- Strategic management of chemotherapy in the health insurance
- Evaluation of the anti-proliferative activity of extracts from leaves and bulbs of *Allium tuberosum*
- The importance of pharmaceutical care in surgical antimicrobial prophylaxis in cancer patients

The lecture in most demand was a round table to discuss generic, similar and reference medicines. Representatives from the pharmaceutical society (SOBRAFO), the government (ANVISA) and the medical society (SBOC) participated in this session. Each one showed an opinion about each kind of medicine. SOBRAFO presented results from a survey applied to its membership pharmacists. In this survey, we asked about knowledge, trust, and problems found with these medicines. The results were surprising to the representative of ANVISA but not to us. In Brazil, sometimes the difference between generic, similar and reference medicines is clear, especially during the handling and in the packages and bottles.

To finish this meeting, on Sunday the

highlight was the round table about supportive care: thromboembolism, tumor lysis and nausea and vomiting.

As in the past meeting, SOBRAFO gave 1% of the value of registration to one non-profit entity, Little Prince Hospital in Curitiba.

In 2011, SOBRAFO will celebrate 10 years and will promote 5 regional symposiums in different cities. In November, a great dinner will celebrate and honor all pharmacists that contributed to what SOBRAFO is nowadays.

For the next meeting, in 2012, we will receive everybody in Brasilia, the country's capital. We hope to receive almost 900 participants. You are invited!

Annemeri Livinalli  
Secretariat member of ISOPP  
Technical scientific vice president – SOBRAFO

## Sponsored Membership Program

The ISOPP Secretariat recognizes the economic and cultural diversity among current and potential ISOPP members.

Given that personal or regional financial situations may affect a person's decision to become an ISOPP member or to continue their membership, the ISOPP Secretariat has approved a Sponsored Membership Fund to support members who can't afford their membership fees.

Upon presentation of a valid reason, a prospective or current ISOPP member may request a sponsored membership. Sponsored memberships are only valid during the year that they are approved. The request should be directed to the Chair of the Membership and Finance Committee. The request will be considered by the Secretariat and the Membership and Finance Committee. Any information provided will be held in strict confidence.

Requests for additional information about this program should be directed to the Chair of the Membership and Finance Committee:

Rosalyn Sims  
email: [rsims@dmc.org](mailto:rsims@dmc.org)

**A call for nominations for Secretariat members for the election in 2011 will be made soon. Start planning your nomination!**



# 2010 ISOPP XII Short Reports

By Komkrit Srisawai and  
Sukanda Denjanta (Thailand)

ISOPP XII was held in Prague, the Czech Republic during May 5-8, 2010 as the professional symposium jointly organized by ISOPP, the Czech Pharmaceutical Society, along with the first Medical Faculty and the Faculty of Pharmacy, Charles University, and the Teaching Hospital Na Bulovce.

The opening ceremony was held in the afternoon on May 5, 2010. A key focus of the opening session was about issues in cancer long term survivorship and the patients' perspective regarding to cancer treatment. The symposium was started with the plenary session with the interesting topics. A variety of session types - clinical, research, fundamentals, and poster presentation – met the needs of various participants. The scientific program was designed to activate discussion on the expert's platform aiming to enhance the understanding and sharing in oncology pharmacy practice. The program featured presentations on genetic and cell signaling changes associated with new anticancer targets and novel therapies, approaches to therapy individualization and the new results of related research projects. Another section was focused on GMP implementation to pharmacy compounding units and technological questions and needs. Robotic technology used in cytotoxic preparation was introduced. Other topics included new drugs and approaches in supportive care. All selected abstracts presented in this symposium were published in Journal of Oncology Pharmacy Practice, 2010. The second day of the conference, May 6, 2010 ended with the historical music concert performed by Collegium 419, a vocal ensemble specializing in baroque vocal music of the 16th –

18th century, held in oldest university in the middle Europe settled by Charles the IV in 1348, named Carolinum.

During the ISOPP general assembly session on the third day conference, the new ISOPP president, Mr. Johan Vandembroucke, introduced his ideas and vision speech. The special social event on this day was the Czech dinner at the Grand Monastery Restaurant Strahov, located near the Prague castle.

In conclusion, this ISOPP XII symposium was well attended, with a lively and enthusiastic atmosphere. The symposium gave the participants knowledge updating and sharing. Moreover, it was a great opportunity for pharmacy practitioners worldwide



Komkrit and Sukanda

to form new links with each other, or to consolidate their existing connections. Finally, we would like to express our gratitude for the generous support of the Australasian ISOPP committee for the travel grant towards attendance at the symposium for poster presentation. We were also grateful especially to Dr. Suphat Subongkot, Asia Pacific Oncology Pharmacy Society (Thailand) committee for giving us the great opinion on presentation preparation.

See you at the 2012 ISOPP XIII symposium in Melbourne, Australia!



The Charles Bridge and old town view from Prague castle



## Justine Hong, Melbourne, Australia

The 12th international ISOPP meeting was held from May 5 to 8 this year in Prague. The wide-ranging program comprehensively covered a large number of topics of interest to oncology pharmacists, with the program divided into three main streams, namely clinical, research and fundamentals. Below are some of my highlights:

One of the plenary sessions on the first day was by Sylvie Menard from Italy on a topic titled "from the patient's perspective". Being an experienced oncology researcher as well as having been a cancer patient herself, Sylvie gave a thought provoking presentation on the impact of research on patients and what this meant for their rights as patients and the impact on their quality of life.

Kim Stefaniuk from Princess Margaret Hospital in Canada gave an excellent presentation on new strategies in cancer pain management. Using a case study, an overview of pain mechanisms was given as well a discussion about new strategies for pain management. A particularly interesting phenomenon discussed was that opioid-induced hyperalgesia, where the patient

experiences increasing pain despite increasing opioids and pain control actually improves when there is a decrease in the opioid dose.

With many oncology patients using complementary and alternative medicines, Judith Smith from MD Anderson Cancer Centre gave a great talk on Herbal supplements in the oncology setting. Given that 16 to 20% of patients use complementary medicines in combination with prescription medicines and that many have the potential to interact with chemotherapy or alter immune function, this talk was good reminder about the importance of taking a complete medication history from patients.



## Robert McLauchlan, Melbourne, Australia. Chair of the ISOPP Standards Committee

Our 12th International Symposium was held in the magical city of Prague in May of this year. This is the second time this beautiful city has hosted our meeting, the first being in the year 2000. In the intervening ten years a lot has changed to retain the interest of visitors, much in the same way as the practice of oncology pharmacy has progressed and maintains the interest and enthusiasm of pharmacists. This symposium offered an enormous range of presentations built around the three themes of clinical practice, research, and the technical aspects of oncology pharmacy.

With a strong background in production, I was particularly interested in sessions highlighting advances in the area of safe handling. Over the four days of the symposium I attended a total of 14 presentations covering a number of aspects of cytotoxic reconstitution including preparation facilities, operating procedures, quality control, information technology, robotics, health monitoring and the use of closed systems. These sessions were presented by pharmacists from around the globe from Malaysia, Italy, United Kingdom, Denmark, United States,







Spain, Poland, Germany and Belgium. I would like to outline the content of just a few of these presentations.

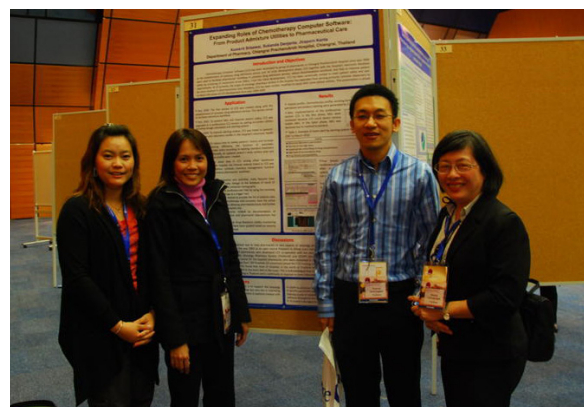
Most of the data we have on the potential hazards of occupational exposure to hazardous drugs come from epidemiological studies conducted over the last thirty years. From these studies it is impossible to quantify the risk to healthcare workers handling these agents. In Prague, Melissa McDiarmid from the University of Maryland presented findings from a multicentre study on the incidence of chromosome 5 and 7 abnormalities in workers handling antineoplastic drugs. Her work included measures of environmental contamination in the workplace, the detection of cytotoxics in the urine of workers, and the risk of associated chromosomal damage. She looked specifically at damage to chromosomes 5, 7 and 11, the signature chromosomal lesions associated with myelodysplastic syndrome and acute myeloid leukaemia. Melissa reported an incidence risk ratio (IRR) of 6.86 (95% CI 2.13-22.14 p value 0.001) for damage to either chromosome 5 or 7 in workers exposed to alkylating agents. This means exposed workers are almost seven times more likely to

exhibit these chromosomal abnormalities when compared to a non-exposed population. This quantifiable risk confirms the importance of all the current safe handling measures we have in place, and highlights the need for us to do more to protect operators manipulating these drugs on a regular basis.

The use of robotics is one way in which it may be possible to reduce staff exposure to hazardous drugs. Celestino Bufarini provided an update on the robotic installation at the Ancona Hospital on Italy's East Coast. This centre prepares around 20,000 chemotherapy items each year and their first robot was installed in 2007 with a second in 2009. From an initial handling capacity of just 5 drugs, the robots are now capable of preparing more than 45 different agents. The robots are now an integral part of the pharmacy workflow and an impressive 90% of the reconstitution work is now automated. This must reduce operator exposure to hazardous drug. However, we await further studies on the level of surface chemical contamination on the outside of products manufactured by robots.

In order for robots to function effectively (or at all!) there is a need for information technology to continually evolve. Felice Musicco, also from Italy, provided a fascinating overview on the use of Information Technology (IT) in oncology pharmacy today. He described how IT is having a major impact on prescribing, scheduling patient appointments, preparing, checking and administering cytotoxic drugs. On a side note, Felice is

the chair of the ISOPP Publications Committee, and he also provided data on how ISOPP members currently use the ISOPP website to share experiences and access information. In addition to the use of robots, the use of closed system drug transfer devices is another way in which it may be possible to reduce operator exposure to cytotoxic drugs. Ewelina Korczowska from Poland comprehensively detailed all of the devices currently available in Europe designed specifically for the manipulation of hazardous drugs. She outlined the development and



use of these products, and described how and when during the entire handling process, the devices are actually closed. Similarly Birgit Tans from Leuven in Belgium outlined the advantages and disadvantages of a number of commercially available devices and described her own experience in a 1900 bed institution preparing a staggering 60,000 cytotoxic preparations each year. Presentations are available to ISOPP members for download from the ISOPP website.

ISOPP Symposia continue to offer a unique educational opportunity and the chance to network with oncology pharmacists from around the world. The next international meeting will be held in the wonderful city of Melbourne, Australia in May 2012. Start making your travel plans now!

My attendance at ISOPPXII was partially funded by a grant from the ISOPP Australasian Regional Conference Organising Committee



# Pharmaceutical Care at CPO – Brazil

My name is Emiko Kobashikawa, I am a pharmacist at Centro Paulista de Oncologia -CPO (Paulista Oncology Center) where I started my work in oncology area in 1999. At that time, oncology was a new area for pharmacists in Brazil, because drug handling was considered a nurse's work.

CPO is a private clinic established in 1983 in São Paulo City and it is one of Brazilian's most respected oncology services, specialized in outpatient chemotherapy treatment. It a multidisiplinary team is composed of oncologists, hematologists, pharmacists, nurses, dietitian and physiotherapist.

Our pharmacy team consists of three

care. We analyze all medical prescriptions, from the therapeutic regimen, to its dosing, drug interactions, infusion volume, infusion time, drug incompatibilities, etc. The pharmacist is also responsible for pharmacovigilance where we generally receive side effects reported by nurses or physicians. We evaluate the information and report to the manufacturer or to ANVISA (equivalent to FDA in Brazil).

Last year, we received an accreditation by Organização Nacional de Acreditação (National Accreditation Organization) and all CPO practices were standardized. It was a great experience because we were able to make improvements in the clinical



We have created a routine of visiting our suppliers and transporters before starting the acquisition process. It provides more safety when using the products we selected.

By the end of 2009, due to an increasing number of oral chemotherapy regimens, we started a pharmaceutical care program to all patients receiving oral antineoplastic drugs, in order to provide patient orientation of how to correctly use the drug, contribute to treatment adherence and evaluate the possible drug interactions. The program is still ongoing, because we are still learning how to work in this new field. At the present moment we are writing an oral chemotherapy drugs' guide to the multidisciplinary team and leaflet to the patients.

To provide an effective and safe pharmaceutical care service, beyond pharmacotecnic, it is mandatory that the oncology pharmacist has good knowledge of therapeutic regimens, pharmacology and is updated.

Cancer treatment is continuously evolving and new therapy protocols emerge every day. I became an ISOPP member to keep up with newest tendencies and challenges. I believe is our job to ensure the safe and effective use of medications by providing optimal drug selection and best assistance to patients with the multidisciplinary team.



Emiko's team:

nurse - Bruna, pharmacist - Emiko, physician - Renata  
physiotherapist - Cintia, nutritionist - Debora

pharmacists and three pharmacy technicians. The pharmacist main responsibilities are: acquisition of drugs and materials, in order to assure it's ideal storage condition, handling, management of contaminated waste of chemotherapy and pharmaceutical

services delivered by our pharmacy and improved the safety and quality of care provided to our patients.

CPO has a great concern about the quality of the drugs used. This results in a greater responsibility to the pharmacy in drug acquisition.



# ASCO 2010 Highlights

## Possible New Treatment for Stage III/IV Melanoma

Ipilimumab, a monoclonal antibody against cytotoxic T-lymphocyte antigen 4 (CTLA-4), is an immune therapy directed against T-cells, was studied in patients with unresectable stage III/IV melanoma for whom previous treatment had failed. This is a population that really needs a new therapy, as the standard of care is currently hospice or a clinical trial. This study randomly assigned patients to receive ipilimumab (137 patients), ipilimumab and gp100 (403 patients), or gp100 alone (136 patients). All patients were required to be HLA-A2 positive. Ipilimumab 3 mg/kg was given once every 3 weeks for four cycles. The vaccine gp100 was given at a dose of 1 mg, also every 3 weeks for four cycles. The primary endpoint of the study was overall survival (OS). After 12 months, 46% of patients receiving ipilimumab alone, 44% receiving ipilimumab plus gp100, and 25% receiving gp100 were still alive. The hazard ratio (HR) for OS demonstrated a 32% to 34% reduction in the risk for death in the two ipilimumab arms compared with the vaccine arm alone ( $p = 0.0026$  for ipilimumab alone versus gp100;  $p = 0.0004$  for the combination versus gp100). Adverse events were predominantly immune response-related and included rash, colitis, diarrhea, and hepatitis. Grade 3 or 4 toxicities occurred in 10% to 13% of patients receiving ipilimumab. The rates of grade 3 or 4 events at specific organ sites were dermatologic ( $= 2.1\%$ ), gastrointestinal ( $= 7.6\%$ ), liver ( $1.1\%$ ), and pituitary ( $= 2.3\%$ ). Ipilimumab, while not yet approved by the FDA, appears to be a promising agent for the treatment of melanoma.

## Advanced GYN Malignancies: Results of GOG-0218

Carboplatin and paclitaxel (CP) is standard first line therapy in women with advanced ovarian cancer. GOG-0218 evaluated the role of

bevacizumab in front line therapy of gynecological malignancies. The double-blind, placebo-controlled, phase III trial enrolled nearly 1,900 patients with chemotherapy-naïve stage III or IV epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer. Women were randomly assigned to one of three treatment arms: (1) CP plus placebo during the induction phase (cycles 1 to 6), followed by placebo maintenance (cycles 7 to 22); (2) CP plus concurrent bevacizumab during induction, followed by placebo maintenance; and (3) CP plus concurrent bevacizumab during induction, followed by bevacizumab maintenance. After a median follow-up of 17.4 months (range: 0 to 50.7 months), PFS was significantly prolonged by 3.8 months with CP plus concomitant and maintenance bevacizumab compared with CP alone (14.1 months compared with 10.3 months, respectively; hazard ratio [HR] = 0.717;  $p < 0.0001$ ). Hypertension occurred significantly more often in the bevacizumab arms compared with the control arm ( $p < 0.05$ ), but the incidences of all other adverse events were similar across arms, including neutropenia (57.7% to 63.3%) and thromboembolic events (6.0% to 7.4%). Surprisingly, gastrointestinal perforation events were not significantly increased with use of bevacizumab (2.6% to 2.8% in the bevacizumab arms compared with 1.2% in the control arm), and bleeding complications were rare in all arms (0.8% to 2.4%). Despite these promising results, CP+bevacizumab is not yet recommended as standard of care, impact of bevacizumab on overall survival needs to be reported.

## NSCLC in the Elderly: Doublet Therapy is the Standard

Most elderly patients with NSCLC are treated with single agent therapy to avoid toxicity, while younger patients receive doublet and sometimes triplet therapy. A randomized phase III study

comparing a 3-weekly single agent therapy (gemcitabine 1,150 mg/m<sup>2</sup> or vinorelbine 30 mg/m<sup>2</sup>, d1, d8: arm A) with carboplatin AUC 6 every 4 weeks + paclitaxel 90 mg/m<sup>2</sup> (d1,8,15) doublet (arm B) in patients aged 70 to 89, PS 0-2 with advanced NSCLC enrolled 451 patients. Overall survival of the 313 pts analyzed at planned interim analysis was significantly longer in arm B (median: 10.4 months, 95%CI: [8.2; 15.0] vs. 6.2 months, 95%CI: [5.3; 7.5] for arm A, (HR = 0.60, 95%CI : [0.46; 0.78],  $p = 0.0001$ ). Median PFS was 6.3 months, 95%CI: [5.5; 6.9] in arm B vs. 3.2 months, 95%CI: [0.44; 0.70] (HR = 0.55, 95%CI: [0.44; 0.70],  $p < 0.0001$ ). Grade 3-4 haematological toxicities were significantly more frequent in arm B (17.9% vs. 54.1%). No significant difference was observed in early deaths (arm A: 23.7%, arm B: 16.6%), suggesting that the paclitaxel and carboplatin doublet provides a significantly longer survival in elderly pts with advanced NSCLC than current standard single agent therapy, with acceptable toxicity and should be considered standard therapy for this patient population.

## NSCLC Patients with EML4-ALK Mutations Respond to PF-1066

PF-1066 is a selective, ATP-competitive, small molecule, orally bioavailable inhibitor of the ALK and MET/HGF receptor tyrosine kinases. EML4-ALK fusion oncogenes have been reported in approximately 4% of NSCLC. Patients with NSCLC and an ALK fusion oncogene were enrolled into an expanded cohort at the recommended phase II dose within the first-in-patient monotherapy trial of PF-1066. PF-1066 was given orally at a dose of 250 mg BID. In 50 patients evaluable for response; ORR is 64% and DCR 90%. The median duration of treatment is 25.5+ weeks. Gastrointestinal toxicities, including nausea (55%) and vomiting (39%),

were the most frequent adverse events. While ALK mutations are rare in NSCLC, patients with them experience a high response rate to the ALK inhibitor PF-1066. This drug as a single agent is currently being studied in a phase III trial.

### **New Tool to Assess Toxicities Related to EGFR Inhibitors: FACT EGFR**

EGFR inhibitors are well known to cause dermatologic toxicities that may lead to reduced quality of life, dose reduction or discontinuation of anticancer therapy. A questionnaire for assessing dermatologic toxicities related to EGFR inhibitors was developed and recently reported. The authors used a three-phase process for item generation, reduction and scale construction. First, a comprehensive

literature review was performed and all questions with potential relevance for patients with dermatologic toxicities were selected for further evaluation in the form of 62 EGFR-dermatologic toxicity specific items, including some from dermatologic QoL instruments such as the Skindex. Next, a survey and evaluation of these potential items by 12 dermatologic toxicity expert physicians and nurses and 20 patients was completed. Finally, the pilot questionnaire was administered to 24 patients with various stages of dermatologic toxicity. Item comprehension, relevance and overall content was assessed in semi-structured interviews. In qualitative interviews, patients and experts evaluated the importance of 62 items from the literature and the Skindex. Items identified as “quite

relevant” or “very relevant” by the majority of experts were retained. Item review and reduction resulted in a 38-item pilot questionnaire. A majority of patients determined the content of the pilot questionnaire to be relevant, comprehensive and easy to understand. Patient input resulted in the omission of 3 items, modification of 6 items, and the addition of 4 items. Final revisions resulted in the FACT-EGFR, consisting of 18 items encompassing well-being in 3 QoL domains: physical (7 items), social/emotional (6 items), and functional (5 items). Formal validation studies of the tool are underway. The FACT-EGFR is available at [www.facit.org](http://www.facit.org).

Jill Kolesar, ISOPP Treasurer.

## **APOPC Meeting Report**



The 3rd Asia Pacific Oncology Pharmacy Congress (APOPC) was held from 7-9 July 2010 in Singapore. The theme of the meeting was “Achieving Better Healthcare Outcomes in Cancer Patients”. The APOPC serves as a platform for practitioners in the areas of oncology pharmacy practice to come together to share, experience and best practices. The aim of the congress is to raise the oncology pharmacy practice standard in Asia and facilitate knowledge and skills acquisition to

deliver outstanding cancer care to our patients through evidence-based practice and scientific research.

A total of 25 speakers, including ISOPP president Johan Vandenbroucke, were invited from 8 countries from around the world. The topics covered included updates from major international

oncology meetings, controversies in the treatment of hematologic malignancies and solid tumour cancers, management of chemotherapy related toxicities, and best practice standards for safe handling of cytotoxic drugs. These topics were covered in the keynote address, 3 plenary sessions, 4 clinical sessions and 4 technical sessions. There were 12 poster abstracts at this meeting. More than 200 participants from 11 countries attended this meeting.

The keynote address was delivered by Professor Gary Yee from the University of Nebraska Medical Center, USA, in which Prof Yee talked about achieving better healthcare outcomes in cancer patients. In his talk, Prof Yee addressed the established roles for oncology pharmacy involving drug distribution, medication safety, supportive care, pharmacokinetic monitoring of cytotoxic drugs as well as the role of targeted therapy. Oncology has overtaken cardiovascular medicine as the leading contributor to the major prescription drug portfolios. This has led to the fact that cancer is now being looked at differently: as a chronic disease, dealing with unexpected side effects as well as the increased role of community pharmacy. He spoke about pharmacists becoming patient advocates and get more involved in the health policy decision-making and develop expertise in evidence based medicine.

The topic covered by the ISOPP president, Johan Vandenbroucke, was “Implementing ISOPP Standards”. In



his talk, Johan likened the ISOPP standards as the gold standard which harmonises technical with clinical oncology pharmacy, which had 2 clear goals in mind i.e. to improve quality and safety. He also stated that it is the responsibility of pharmaceutical companies to deliver contamination free drug containers of cytotoxic drugs and to provide certification of such. He also alluded to the safety for the patient in the correct composition, correct administration and the importance of sterility when providing reconstituted cytotoxic drugs. The future of the ISOPP standards is the inclusion of an audit tool.

One of the other topics covered by Jude Lees, a senior pharmacist from the Royal Adelaide Hospital Cancer Centre in Australia, was “Safe handling of Oral Anticancer Agents”. Given a choice between oral or parenteral chemotherapy, patients are often likely to have a preference for oral chemotherapy, primarily because of the convenience of being able to take their medications in the comfort of their own home. This choice is particularly true for patients receiving palliative treatment. At the same time, most patients are unwilling to sacrifice efficacy for convenience, according to a broadly referenced study<sup>1</sup> regarding palliative oral chemotherapy. Other potential patient advantages for the use of oral chemotherapy include: a sense of empowerment in managing their treatment, less frequent visits, and less time spent waiting for



intravenous setup and infusion. The ideal oral chemotherapy patient needs to have good communication skills with a willingness and ability to adhere with the intellectual discipline to commit fully to the programme. Some of the reasons cited for non adherence were side effects, patient wants a “drug holiday”, patient does not believe in the treatment, patient thinks they know better, taking more or less than the prescribed dose, the regimen does not fit in the lifestyle, rituals or culture and deliberate overdose. Some of the problems that patients face are not being able to open the packages the drugs come in, cannot take the tablets or capsules especially having swallowing difficulties in head and neck cancers, nausea and vomiting and becoming confused and forgetful. In promoting patient adherence, the following should be followed:

- Ensure patients receive instruction in safe handling procedures for their medication
- Provide information about their specific diagnosis and the oral agent that has been prescribed for their treatment
- Ensure patients understand the number of pills to take, when and how to take them
- Help patients to understand how to identify, manage and report side-effects
- Provide round-the-clock contact information for assistance from medical staff
- Provide printed materials, individualized calendars, and in

some cases pre-loaded pillboxes to assist patients in their medication use

These were some of the topics addressed at APOPC 2010 in Singapore. On the whole, the participants went away with a lot of knowledge after having found new friends, forged old friendships and having had some time to look around Singapore, done some shopping, enjoyed the sights and the wonderful cuisine that Singapore has to offer.

See you at the next APOPC in 2012!

Reference 1. Liu G, Frassen E, Fitch M, Warner E Patient preference for oral versus intravenous palliative chemotherapy. J Clin Oncol 1997;1122-1129.

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# MASCC 2010

I was fortunate enough to attend the Multinational Association of Supportive Care in Cancer/International Society for Oral Oncology (MASCC/ISOO) Symposium in Vancouver June 24-26, 2010. This conference was well attended with over 800 delegates from 51 countries. A variety of health care professionals participated in the symposium including physicians, nurses, pharmacists, dieticians, social workers and dentists.

Pharmacists were well represented at the MASCC/ISOO symposium as delegates, conference planners, speakers, poster presenters and study groups members. Jude Lees,



an ISOPP member from Australia and Chair of the MASCC Membership Committee, planned an evening out for pharmacists to network with their international peers. It was a fun night that brought together pharmacists from the UK, US, Australia and Canada.

One of the highlights of the symposium was hearing about pharmacist participation in research. James Gilmore, from Atlanta, Georgia, USA presented a proffered paper: "Hemoglobin Trends among Patients with Anemia with Concomitant Chemotherapy in the Community Oncology Clinic Setting". His research looked at the impact of increased restrictions for erythropoiesis-stimulating agents (ESAs) on patient hemoglobin levels. James also had an interesting research poster looking at dosing of palonosetron



Another highlight of the symposium were pharmacist-speakers who addressed the theme of the Symposium; "Communication: The Key to Care". Mario de Lemos, Provincial Drug Information Coordinator for the BC Cancer Agency, provided a pharmacist's perspective on communicating with patients about Complementary and Alternative Medications (CAMs) using a structured approach, while ISOPP member Joe Bubalo, Oregon, USA was invited speaker on the topic of managing nausea and vomiting in patients having high dose chemotherapy, in the session on Unmet Needs in CINV

Posters on a broad range of topics from clinical roles in specific supportive care areas, toxicity monitoring, drug interactions, implementing guidelines,

to health informatics were presented by pharmacists from UK, Singapore and USA. Canadian pharmacists, both MASCC members and non-members, were very well represented thanks to strong publicity about this meeting via CaPHO.

Please see the MASCC website ([www.mascc.org](http://www.mascc.org)) for highlights of the symposium, abstracts, awards and more. Information about the MASCC symposium for 2011 in Athens, Greece, June 23-25, can also be found there. Be sure to mark that date in your calendar.

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## New Australasian Editor for JOPP

Dr. Alexandre Chan has been selected to be the editor for the Australasian region.

Dr. Chan is an Assistant Professor with the Department of Pharmacy at National University of Singapore (NUS) and a Clinical Pharmacist at National Cancer Centre Singapore (NCCS). His clinical and research interests include oncology supportive care, oncology drug interactions, and management of toxicities associated with targeted agents.

He is currently certified by the U.S. Board of Pharmacy Specialties as Board Certified Pharmacotherapy

Specialist and as a Board Certified Oncology Pharmacist.

Alex has great interest in supportive care research and drug utilization research. He has authored book chapters and published over 30 manuscripts in various peer-reviewed medical and pharmacy journals, including Lancet Oncology, Annals of Oncology, Supportive Care in Cancer, Clinical Therapeutics and Annals of Pharmacotherapy. He has also delivered lectures at numerous regional and international pharmacy conferences. Alex is an active member of professional organizations such



as American College of Clinical Pharmacy, International Society of Oncology Pharmacy Practitioners and Multinational Association of Supportive Care in Cancer.

## ISOPP XIII – Melbourne May 9 -11, 2012.

For many people visiting Melbourne in Australia means quite a long journey. As this is the case, why not plan to combine the visit with some holiday time.

Melbourne is a beautiful city situated at the base of mainland Australia on the edges of Port Philip Bay. Exciting city life, excellent shopping, many cultural facilities and

sporting venues can be found within Melbourne itself while short forays into the countryside can lead to ocean beaches, rolling vine covered hills and unique wildlife. Short plane trips can take you to the 'red' centre of the country or to the world heritage listed Great Barrier Reef. Start planning your visit today!

