HPS Pharmacies

Newsline

SPRING EDITION 2012

HPS and Calvary: From Strength to Strength

HPS Announces Associate Partner Program

Supporting Calvary's Oncology Ward Redevelopment

leadership we inspire

innovation we create

respect we consider

accountability we perform

excellence we exceed

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Front Image
(Left to right) Mark Doran, National Chief Executive Officer at Calvary, with Tony Wyatt, Partner/Chief Executive Officer at HPS Pharmacies

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Message from Tony Wyatt CEO

Further to HPS Pharmacies' announcements in Newsline's Winter edition with regards to securing a number of significant contracts, I am elated to announce the re-signing of yet another momentous agreement. HPS Pharmacies has been successful in negotiating and proactively re-signing with Calvary in the provision of pharmacy services nationally for a further extended term.

HPS Pharmacies has a longstanding relationship with Calvary, and we are delighted for the opportunity to add further value to the existing partnership through an extension of our services, and integration of our two companies in providing the highest quality of care to hospital patients around Australia. To read more, please turn to page 6.

I would also like to communicate a renewed focus of the role performed by Kirsten Boyce, Partner/Director of Strategic Management. Kirsten has been appointed to promote best practice and performance across business operations and provide an independent communication pathway for executive client stakeholders to the HPS' Board. This is an important position in line with HPS' growing portfolio in ensuring the continued consistent delivery of services nationally.

It is also with great pleasure that I announce HPS' exciting new Associate Partner Program. The program was developed by HPS' Partnership group and implemented in recognition of the high performing individuals within the business, further strengthening and diversifying the calibre of the existing Partner group. To read more, please turn to page 10.

As 2012 draws to a close, HPS Pharmacies continues to scale great heights in our charter for growth and we have enjoyed celebrating the many successes along the way. I would like to express my deep gratitude to each of our valued clients and associates for your support during what has been an exciting and prosperous year.

Tony Wyatt
Partner / Chief Executive Officer

Message from Steve Yeo COO

As we near the end of 2012, it fills me with great pride to reflect on the remarkable performance demonstrated by HPS Pharmacies over the past twelve months.

HPS' growth has been exponential, surpassing expectations and further cementing our position as the industry's leading national pharmacy service provider. The re-signing of numerous significant agreements has solidified the strong foundations of HPS and increased our national presence through the opening of several new sites. In addition, we have recently formed relationships with new clients, which we look forward to fostering and nurturing over time.

I would like to take this opportunity to thank our current clients who participated in HPS Pharmacies' 2012 Client Surveys. These annual surveys are an important tool for HPS to gain valuable feedback and insights so we can refine our operations and ensure we continue to evolve with our clients' dynamic needs to deliver the highest level of service.

In line with HPS' commitment to Corporate Social Responsibility, we will be donating over $2,000 to charities on behalf of our clients, whom raised $10 for every survey completed.

HPS Pharmacies' inaugural Orderbook Summit was held in the Barossa Valley earlier this month, providing our valued product suppliers with an opportunity to negotiate exclusive arrangements for the coming year in respect to product supply. The Summit was highly successful and developed strong business relationships, facilitating a greater understanding of HPS' performance and strategic plan moving forward.

The success achieved by HPS is underpinned by a committed and enthusiastic team of employees, and a client base built on strong relationship foundations. I would like to thank everyone for their support over the past twelve months and I look forward to more success in 2013.

Steve Yeo
Chief Operating Officer

This page: St Helen's Ward main corridor, at Calvary North Adelaide Hospital, and inset, patient room and waiting room.

Cover page (left to right): Mark Doran, National Chief Executive Officer at Calvary, with Tony Wyatt, Partner/Chief Executive Officer at HPS Pharmacies.

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HPS Supports Calvary North Adelaide's Oncology Ward Redevelopment

Founded by the Sisters of the Little Company of Mary, the Calvary North Adelaide Hospital is committed to providing a full range of services to cancer patients, including a 12 chair chemotherapy facility, dedicated oncology ward, supportive care practitioners, and high quality radiology and pathology services.

The hospital's oncology ward, St Helen, provides continuation of care for patients whose treatment requires hospitalisation. Built in 1969, the facility was recently in desperate need of upgrading to provide patients and their families with an environment which promotes positivity, healing and comfort.

After considerable planning, the Mary Potter Foundation instigated a capital campaign to raise $1million in funds to significantly redevelop the ward.

Tony Wyatt, HPS Pharmacies' Partner/Chief Executive Officer says "as sole financial sponsor of Mary Potter's Calvary Biography Program, HPS Pharmacies were elated to make a substantial donation to the Cancer Centre Ward Upgrade Appeal. This donation has enabled the hospital to bring their plans to fruition and improve their support and care to those in need".

The project has delivered increased private rooms, state-of-the-art inpatient care facilities, and improved family waiting and counselling areas.

The redeveloped ward has maintained capacity at 26 beds, but most importantly changed the current configuration to incorporate 16 private rooms, of which five have been newly built. These additional private rooms are vital for the type of care being provided and deliver patients and their family with a retreat to share time together.

St Helen also includes a four chair chemotherapy facility to complement the 12 chairs already available, which was an important addition due to the light and airy environment offered in the day treatment centre in Kimberly House. Capacity was often exceeded in Kimberly House, forcing patients to have their treatment in less comfortable surrounds upstairs in the hospital.

Where treatment becomes palliative, the St Helen's team are highly skilled in managing the needs of patients and families for whom active treatment and cure is no longer an option.

St Helen's location alongside the renowned Mary Potter Hospice ensures that patients have access to specialist palliative doctors along with their oncologist's ongoing involvement in their care. For some patients, they will move to the Hospice for their end of life care but for others this will be provided by the team at St Helen.

Sue Imgraben, Chief Executive Officer at Calvary North Adelaide Hospital, says she values the long-term business partnership that Calvary has with HPS Pharmacies and greatly appreciates the financial support HPS has delivered to the St Helen ward infrastructure upgrade.

"St Helen now delivers a much brighter and lighter environment for our patients, which is vital to their care, and the end result of the building project has been enhanced by the generous support from HPS. It means facilities for our cancer and oncology ward patients are greatly improved," says Sue.

HPS Pharmacies is proud to support the well-being of cancer patients through the delivery of quality healthcare to the community from beyond the business' normal pharmacy operations.

"[We]…sincerely appreciate the generosity of HPS Pharmacies in supporting the redevelopment of the St Helen ward."

– Sue Imgraben, Chief Executive Officer, Calvary North Adelaide Hospital

HPS Announces Associate Partner Program

It is with great pleasure and much excitement that HPS Pharmacies announces its new and exciting Associate Partner Program, developed by the HPS Partnership group.

The program was implemented in recognition of the high performing individuals within the business, and the development of robust succession plans in light of HPS Pharmacies' rapid growth and dominant market success.

Tony Wyatt, Partner/Chief Executive Officer of HPS Pharmacies says "the Partnership group, presently consisting of 12 individuals, recognised an opportunity to attract and assess talent for potential inclusion in the shareholder group, and thus strengthen and diversify the calibre of Partners, as the business continues to grow and succeed."

The HPS Pharmacies Partnership group has worked closely with the Board in the development of the Associate Partner Program, and the business is excited to provide a brief outline of the program below;

- An Associate Partnership is an exclusive offer made to select individuals, by way of stakeholder nomination and selection by the HPS Pharmacies' Board.
- The program is eligible to all employees of HPS Pharmacies, not only to pharmacists.
- An Associate Partner will remain an employee of HPS Pharmacies, and discharge their normal duties in addition to exclusive Associate Partner responsibilities.
- Associate Partners, whilst not yet having an equity stake in the business, will be entitled to attend the Partnership biannual general meeting and other stakeholder meetings as directed by the Board.
- Additional benefits will be extended to Associate Partners.

"...a commitment from the Partnership group in ensuring the continued success of HPS Pharmacies, through investment in its valued employees."

– Tony Wyatt, Partner/Chief Executive Officer, HPS Pharmacies

"The Associate Partner Program is a wonderful opportunity for the nominated candidate and the Partnership group to critically assess if there is a natural fit between both parties.

"This program represents a commitment from the Partnership group in ensuring the continued success of HPS Pharmacies, through investment in its valued employees," says Tony.

Accordingly, this new program provides a structured pathway for those exceptional performers within HPS Pharmacies that may wish to consider stepping into a partnership position.

In March this year, Mr Wyatt invited all Partners to put forward their nominations of employees for Associate Partner consideration. After much due diligence and analysis, the Board has offered the opportunity to a hand selected group of individuals within the business.

Tony offers, "on behalf of the Partnership group, I would like to take this opportunity to congratulate the successful Associate Partners and thank the Shareholders Committee and the Board for their significant efforts in developing this very exciting program, and delivering it to the business."

Congratulations to our new Associate Partners!

- **Jason Cattonar**, Chief Financial Officer, specialising in accounting and business finance.
- **Dion Hutchins**, Pharmacist In-Charge, HPS – Toowoomba, specialising in private hospital pharmacy services.
- **Brooke Kenny**, General Manager, Corrections and Health Facilities, specialising in business development.
- **Pan Kwong**, Pharmacist In-Charge, HPS – Knox, specialising in private hospital pharmacy services.
- **Photios Poupoulas**, Pharmacist In-Charge, HPS – Ashford, specialising in private hospital pharmacy services.
- **Aleksandra Stankovic**, Pharmacy Manager, HPS – Brunswick, specialising in private hospital pharmacy services.
- **Stephanie Tieu**, Pharmacist In-Charge, HPS – Calvary North Adelaide, specialising in oncology pharmacy services.
- **Alan Tuxford**, Regional Operations Manager – VIC/TAS, specialising in fertility and IVF pharmacy services.
- **Steven Yeo**, Chief Operating Officer, specialising in marketing, negotiations and business strategy.

HPS and Calvary: From Strength to Strength

"...we are excited to move forward with [HPS] as our pharmacy service provider."

– Arthur Yannakou, National Director, Private Hospitals, Calvary

HPS Pharmacies is pleased to announce the successful negotiation and proactive re-signing with Calvary in the provision of pharmacy services nationally for an extended term.

Tony Wyatt, Partner/Chief Executive Officer at HPS Pharmacies says "HPS has a longstanding relationship with Calvary, and is delighted for the opportunity to add further value to the existing partnership through an extension of its services, and integration of the two companies in providing the highest quality of care to hospital patients around Australia."

Currently, HPS Pharmacies delivers pharmacy services to all four Calvary hospitals in South Australia; however the renewed agreement allows HPS to commit to the dedication of resources in a number of upcoming projects that will see enhanced service efficiencies to particular sites.

Mr Wyatt says "there are many partnership opportunities on the horizon, which will be communicated in due course, providing a more integrated and responsive on-site service."

In August, Chief Executive Officers of the four Calvary hospitals and members of HPS Pharmacies' Senior Management team involved with the re-signing, attended a celebratory dinner of this momentous occasion (pictured left). The dinner also marked the farewell through retirement of Sharon Bingham, Chief Executive Officer at Calvary Central Districts Hospital, and provided an opportunity for HPS Pharmacies to thank her for continued support during her tenure.

"HPS welcomes Judith Walloscheck to the position and looks forward to developing a strong working relationship with her," says Tony.

Securing the contract with Calvary represents significant value to HPS Pharmacies and will deliver an exciting mix of new developments in South Australia as well as the opportunity to expand services within other states.

Steve Yeo, Chief Operating Officer at HPS Pharmacies says "the continuation of the strong partnership between HPS Pharmacies and Calvary is a testament to the tremendous value being generated between both businesses.

"It is wonderful to see such a strong and important partnership for HPS Pharmacies continue into another new phase. This next phase promises to be a truly exciting one, as HPS and Calvary unite to again complement each other's health charter and business growth plans for the future."

Arthur Yannakou, National Director, Private Hospitals at Calvary says "our relationship with HPS Pharmacies has strengthened over the many years of business interaction, and we are excited to move forward with them as our pharmacy service provider."

HPS Pharmacies' partnership with Calvary, has led to HPS becoming market leaders within the industry. With origins as a small South Australian based pharmacy service provider, HPS has been encouraged by Calvary to be at the forefront in ensuring staff, patient, and financial needs are met in an innovative manner.

Mark Doran, National Chief Executive Officer at Calvary, values the partnership with HPS Pharmacies specifically in their ability to deliver a safe and efficient service, innovative digital solutions, and holistic support in palliative care.

Calvary views the arrangement as a mutually beneficial strategic partnering. Mark says, "we have a rapidly changing healthcare environment that needs reform, so partnering with an organisation like HPS that is compatible in terms of values, philosophy and goals is more important than specific features of our commercial arrangements. The immediate benefits are about safety and efficiency, but longer term as the relationship deepens, it is about advantaging the partnership in ways that we don't yet fully understand but will reflect the impact of the digital information age and the move to more community based care.

"We value HPS's strengths and hope to build on them just as they would with us, and in this case I am confident we are joining strength with strength. In the future we may judge the ultimate value of a partnership on the new knowledge and skills that we have gifted to each other's organisations."

Left Page Center Image: (Left to right) Kris Salisbury, CEO at Calvary Rehabilitation Hospital, Tin Huynh, Partner/General Manager – Hospitals at HPS Pharmacies, Harold Kok, CEO at Calvary Wakefield Hospital, Arthur Yannakou, National Director, Private Hospitals at Calvary, Steve Yeo, COO at HPS Pharmacies, Tony Wyatt, Partner/CEO at HPS Pharmacies, Sharon Bingham, former CEO at Calvary Central Districts Hospital, Dominic Coppola, Partner/Regional Operations Manager – NT/SA/WA at HPS Pharmacies, Sue Imgraben, CEO at Calvary North Adelaide Hospital.

Pharmacy Business

Governance in a Changing Environment

The Australian Institute of Company Directors' Healthcare Forum 12 saw Shane Solomon, Chair of the Independent Hospital Pricing Authority (IHPA), present a session on activity based funding (ABF). He described his epiphany on the merit of ABF during his time as Chief Executive of the Hospital Authority in Hong Kong when birth rates escalated by 25% p.a. and block funding failed to support the needs of the affected hospitals.

As funding reflects workload, he proposed that ABF will reward hospitals who respond to patient needs rather than those that are fiscally defensive. The system will be fairer, improve transparency, and drive efficiency in service delivery.

The IHPA is to set the National Efficient Price (NEP) for public hospital services in readiness for the transition to ABF, when extra Commonwealth funding will flow equally from activity growth and the NEP. To support this, the IHPA must also clearly define "hospital services", how each should be funded, the loadings for unavoidable costs, and manage "cost shifting" practices.

The NEP for 2012/13 is $4,808 per 'Activity Unit' and the price for each service is derived from the number of its allocated units (e.g. 0.05 for anaesthetics). Australian NEPs currently range from $3,000 to $5,000, however Mr Solomon suggested that experience will mirror the 20% reduction achieved in Victoria over 18 years. To improve efficiency, hospitals will become innovative in reducing or avoiding hospital stays such as by electronic service delivery, hospital in the home, and medi hotels.

The forum aimed "to promote thought leadership in the healthcare field" through educating hospital board members who are increasingly independent and still adjusting to the particular forces at play, a challenging but imperative goal.

Further Information:

1. Independent Hospital Pricing Authority. IHPA. Sydney, Australia. Available from <www.ihpa.gov.au>. Accessed 1 October 2012.

Canine Chemotherapy

Pfizer's recent launch of the first drug in Australia specifically for treating cancer in dogs has been cause for excitement amongst veterinarians. Toceranib phosphate (PALLADIA) is an oral tablet indicated for recurrent cutaneous mast cell tumours where there is a large infiltrative single tumour, multiple tumours, or metastases involving lymph nodes.

Mast cells are formed in the bone marrow and are found in most tissues of the body, particularly where external pathogens may invade, such as the skin and mucosa. They assist in directing the immune response to viral, bacterial and allergenic pathogens.

Mast cell tumours are the most common malignancy of the skin in dogs, and presentation ranges from nodular, to soft subcutaneous lumps, or ulceration. They need biopsy and histopathologic grading to confirm diagnosis, likelihood of recurrence, and prognosis. Preferred treatment is surgical excision with wide margins, and progression to chemotherapy if needed, which until now has meant repeated veterinary visits for injections of adapted human products.

Toceranib phosphate (PALLADIA) is a multiple tyrosine kinase inhibitor, targeting cancer-specific processes, in this case by modulating the signalling pathways of some growth factors. It has both anti-angiogenic and anti-tumour activity.

It is predicted to be of low acute toxicity; however it does have undesirable non-target effects, including toxicity to haematopoietic organs and the developing foetus. Carers should observe 'safe handling' precautions when administering this cytotoxic medicine. Adverse effects are generally related to dose and include pain, stiffness, and weakness of the hind limbs, reduced white blood cell counts, and weight loss.

Pfizer have previously launched sunitinib (SUTENT) and axitinib (INLYTA), both tyrosine kinase inhibitors for treating human cancers; and have a pipeline of research including the development of protocols to combine PALLADIA with other chemotherapy drugs to improve outcomes for dogs and their owners.

HPS Pharmacies is proud to be associated with the Brisbane Veterinary Specialist Centre, and Dr Rod Straw who was one of the first vets to use the medicine in Australia.

References:

1. Brisbane Veterinary Specialist Centre. BVSC. Albany Creek, Australia. Available from < www.bvsc.com.au>. Accessed 8 October 2012.

Collaboration Improves Safety

Identifying a complete and accurate list of your patient's current medicines may seem straight forward, but it has been repeatedly demonstrated that up to 67% of medication histories have at least one error. Over half these errors occur at transition of care, such as admission to or discharge from hospital, in which case an overlooked medicine more than doubles the chance of re-admission.

Proper medication reconciliation involves the four steps of interviewing the patient to gather the history, verifying it against appropriate sources, comparing and reconciling it with current orders, and ensuring that the orders are transferred to anyone involved in the patient's care. To understand properly the patient's current health, the history should explore not only prescribed, but also non-prescribed and over-the-counter medicines as well as complementary and herbal therapies, all of which might be taken regularly, occasionally, or have been recently ceased. We should also explore adverse drug reactions, allergies, and whether the patient is actually taking what is ordered.

A team from Johns Hopkins Hospital, Maryland USA, have published a study in the Journal of Hospital Medicine that discusses the benefits of collaboration between the nursing and pharmacy departments to achieve medication reconciliation. They proposed that significant cost savings were achieved through avoiding adverse drug reactions by committing around half an hour of nursing time to interview patients and gather information at both admission and discharge, supplemented with pharmacy support and advice. They potentially averted 27% of the unintentional discrepancies identified in 40% of their patients.

References:

1. Feldman LS, Costa LL, Feroli ER, Nelson T, Poe SS, Frick KD, et al. Nurse-pharmacist collaboration on medication reconciliation prevents potential harm. *J Hosp Med* 2012; 7:396–401.

2. McLeod SE, Lum E, Mitchell C. Value of Medication Reconciliation in Reducing Medication Errors on Admission to Hospital. J *Pharm Pract Res* 2008; 38:196–9.

3. Australian Commission on Safety and Quality in Health Care. Match Up Medicines. ACSQHC 2011. Available from <www.safetyandquality.gov.au/our-work/medication-safety/medication-reconciliation/match-up-medicines/>. Accessed 8 October 2012.

Plain English for All

One accreditation standard to become mandatory from January is *'Recommendations for Terminology, Abbreviations and Symbols used in the Prescribing and Administration of Medicines'*. The name itself is enough to daunt most of us but the principle is simple – when we use codes or abbreviations, mistakes will happen.

Training used to use Latin terminology – partly to give health practitioners a precise and consistent system for effective communication, partly because it reflected the origins of our conservative industry, but also because it maintained a separation between patient and practitioner. The variety of practitioners now authorised to administer medicines and the policy of involving and educating patients implies that information must now be in a form that is universally understood and avoids any codes or traditions which might be a source of misunderstanding or error.

Ten-fold dosage errors so easily happen when "U" is written to mean "units" but looks like a zero, or when a decimal point is not reinforced by either the presence of a leading zero (.2 instead of 0.2), or the absence of a trailing zero (2.0 instead of 2). Thousand fold dosage errors happen when "µg" is mistaken for "mg".

While abbreviations that are universal and in common use are okay, such as the term "prn" to mean "when required", the challenge for us all is to identify which ones really are common, as proven by the TV show Family Feud, which consistently amazed us with how few contestants could identify the most common answers given by 100 ordinary people. In fact we should now 'err on the side of caution' and write orders in full, in print, and using plain English.

Further Reading:

1. NSW TAG Safer Medicines Group. *Recommendations for Terminology, Abbreviations and Symbols used in the Prescribing and Administration of Medicines.* Australian Commission on Safety and Quality in Health Care 2011.

From The Team Update

Tin Huynh

General Manager – Hospitals

The 4th Annual National Cancer Centre Symposium was hosted by Informa Australia in Melbourne in late September.

This year's two-day event provided an insight into the construction and redevelopment of various cancer centres across Australia and focused on the improved facilities now offered by many of these centres.

It also highlighted how the modern cancer centre integrates allied health services into the overall design, with services such as pharmacy placed next to, or as close as possible to, patient treatment areas.

Case studies on development projects included large metropolitan cancer centres, such as the Peter MacCallum Cancer Centre and Olivia Newton-John Cancer and Wellness Centre, as well as non-metropolitan facilities such as the Ballarat Regional Integrated Cancer Centre.

The symposium also provided me with an opportunity to learn about innovative online fundraising models. I was fortunate enough to listen to the 'Dry July' story where three like-minded individuals (Brett MacDonald, Phil Grove and Kenny McGilvary) established an online fundraising platform that has raised over $6.8 million in funds to create better environments and support networks for cancer patients and their families.

Monica Guo

Business Analyst

I have recently joined the Finance team in the newly created role of Business Analyst. My role is to provide financial review and analysis for decision-making by the Board, Executive and Senior Management teams, thereby allowing HPS Pharmacies to deliver a more efficient service to clients.

A point of focus is ongoing competitor and market trend analysis and benchmarking. I am currently working on a model that will advise the level of services necessary to meet the industry benchmark, and provide the client with options for services they may add onto their existing contract. This model will ensure our service offering is more transparent and provide clients with the data to assist their decision-making.

At HPS Pharmacies we not only measure key performance indicators from a financial perspective but also non-financial performance such as client satisfaction. At the end of each quarter, I collect client feedback data from various department managers and summarise it in the Balanced Scorecard presented to the Executive team and Board. The Senior Management team are kept informed of all client satisfaction results, allowing them to both reinforce areas of strength and address any concerns raised.

Michael Soriano

Pharmacist In-Charge, HPS – Wakefield

In the coming weeks, HPS Pharmacies will launch its Antimicrobial Stewardship Program in preparation for the new National Safety and Quality Health Service Standards, which come into effect on 1st January 2013. These standards are published by the Australian Commission on Safety and Quality in Healthcare (ACSQHC) and include Antimicrobial Stewardship as a criterion for addressing Standard 3 (Prevention and Controlling Healthcare Associated Infections) .

Antimicrobial Stewardship (AMS) is an organised management program undertaken to optimise an organisation's use of antimicrobials and clinical outcomes.

Our robust program includes several modules of surgical prophylaxis audit tools, which have been designed to enable your clinical pharmacist to establish baseline data, assess the hospital's compliance to current guidelines, develop an action plan for intervention, assess the efficacy of the intervention and report the outcomes for documentation in clinical committees and accreditation requirements.

HPS Pharmacies' Antimicrobial Stewardship Program will entail a comprehensive set of guidelines that has been developed to:

- Assist hospitals in the compliance with accreditation requirements,
- Improve compliance to published guidelines,
- Improve the appropriateness of antimicrobial use,
- Reduce antimicrobial resistance rates, morbidity and mortality, and
- Reduce healthcare costs.

This program aims to align antimicrobial prescribing patterns with current guidelines to deliver improved clinical outcomes, improved patient safety and savings on treatment costs for our clients.

Lisa Hutton

Project Manager

HPS Pharmacies recently introduced a newly established Project Manager role, which I have seamlessly transitioned into the business.

This dynamic role is pivotal to the successful implementation of the critical internal and external projects currently being deployed across the business, including; upgrades to information technology infrastructure, improvements to a number of general business processes, and the planning of several new pharmacy sites due to open across the country in the coming year.

The creation of this role has enabled collaboration within the business from the various teams working on each project, by centralising the management process to deliver an efficient and dedicated resource. Given this, I work closely with a number of departments at our Corporate Office as well as many individuals at site level to ensure our projects are delivered on time and within budget.

As Project Manager, I am excited by the opportunities this new role presents to HPS Pharmacies and the positive impact I will be able to deliver now and in the future.

Ixabepilone in Metastatic Breast Cancer

Stephanie Tieu, Associate Partner/Pharmacy Manager
HPS – Calvary North Adelaide, Calvary North Adelaide Hospital, South Australia

Metastatic Breast Cancer

Breast cancer is the most prevalent malignancy among Australian women, accounting for 28% of all newly diagnosed cancers in women in 2006. Due to an increase in the number of available new treatments and early detection, the five year survival for women after diagnosis increased from 72.6% in the period of 1980 to 1987 to 88.3% between 2000 and 2006.

Metastatic breast cancer is defined by tumour spread beyond the breast, chest wall and regional lymph nodes to other organs or tissues in the body such as the brain, liver, lungs or bones. Most women with metastatic breast cancer have been initially diagnosed with early breast cancer, treated with curative intent, and then later experience metastatic recurrence.

Treatment

The aims of treatment in women with metastatic breast cancer include control of the spread of the tumour, reduction in cancer related symptoms and complications, improved quality of life, function, and prolongation of life. Therapy can't be considered curative when the cancer has metastasised, however for women who respond well to treatment, it can be managed for an extended period of time.

Treatment of metastatic breast cancer is based on tumour biology and clinical history, hence characterisation of tumour status is important for patients; a detailed assessment of past treatments, timing and duration, and the patient's response during each treatment also need to be taken into account.

A large number of chemotherapy agents and combinations are effective in the treatment of metastatic breast cancer. Anthracycline and taxanes are generally considered to be the most effective. This has led to their incorporation into adjuvant chemotherapy regimens used in early breast cancer where the intention is to cure, thus many women with metastatic cancer will already have been treated with anthracyclines and/or taxanes, decreasing their usefulness in the metastatic setting, due to either resistance (inherent or acquired) or because the maximum safe cumulative dose of anthracycline is reached.

Resistance may be caused by the ability of cancer cells to alter membrane transport (decrease drug uptake into cell and increase ejection of drug from cell), alter the drug's target enzyme, enhance DNA repair, activate pro-survival pathways, and inactivate cell death pathways.

In clinical trials, to be able to show efficacy in metastatic breast cancer, a drug needs to demonstrate an improvement in one or more of the endpoints: response rate, time to tumour progression and overall survival.

Ixabepilone

Ixabepilone is a semi-synthetic analogue of epothilone B, a natural macrolide derived from the myxobacterium *Sorangium cellulosum*. It blocks tubulin polymerisation in a manner similar to taxanes, inhibiting the normal process of microtubule network leading to inhibition of mitosis and cell division, it however binds to a different site of the tubulin molecule which may account for sensitivity in taxane resistant cell lines.

Three key studies have investigated the efficacy of ixabepilone as monotherapy or in combination with capecitabine in patients with metastatic breast cancer who were pre-treated with, or resistant to, anthracyclines, taxanes, or capecitabine. Capecitabine is commonly used in the anthracycline and/or taxane pre-treated population.

A non-comparative, multicentre, multinational, phase II trial investigated the safety and efficacy of ixabepilone as monotherapy in 126 women with metastatic breast cancer resistant to anthracyclines, taxanes and capecitabine.[4] Ixabepilone 40 mg/m^2 was administered as a 3 hour intravenous infusion on day 1 of a 3-week cycle. Ixabepilone demonstrated efficacy and a manageable safety profile.

Fifty percent of patients achieved stable disease. Median progression free survival and duration of response was 3.1 and 5.7 months respectively. Median overall survival was 8.6 months. Noticeable treatment related events included peripheral sensory neuropathy, fatigue/asthenia, myalgia, and mucositis.

Two phase III trials investigated ixabepilone in patients with previously treated breast cancer. Study one[5] investigated 725 patients with resistance to anthracycline and taxane therapy. Study two[6] had 1,221 patients pre-treated with anthracycline and taxane. These studies compared ixabepilone 40mg/m^2 every 3 weeks plus capecitabine 1000mg/m^2 twice daily for 14 days (days 1 to 14) compared with capecitabine 1250mg/m^2 twice a day for 14 days of a 21 day cycle.

Both studies demonstrated significant improvement in progression free survival with the addition of ixabepilone to capecitabine. The median progression free survival with ixabepilone plus capecitabine versus capecitabine alone was 5.8 versus 4.2 months in study one and 6.24 versus 4.4 months in study two.

Ixabepilone plus capecitabine was well tolerated with a manageable toxicity profile. The most common adverse events observed were neutropenia which occurred in 68% of patients receiving ixabepilone plus capecitabine compared to 11% in patients receiving capecitabine alone, and peripheral neuropathy (22% vs 0%).

In October 2007, the FDA approved ixabepilone for the treatment of metastatic or locally advanced breast cancer in patients after failure of anthracycline and a taxane in combination with capecitabine or as monotherapy after failure of an anthracycline, a taxane and capecitabine.

While not yet considered for approval in Australia, ixabepilone may improve the range of available cytotoxic drugs in the treatment of metastatic breast cancer thus improving patient outcomes.

References for this article can be found on page 30.

The Safe Handling of Hazardous Drugs

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Figure 1. Cytotoxic drug symbol.

It is vital that prior to working in an environment that handles hazardous drugs, everyone understands the risks associated and how to minimise them. Whilst protocols and procedures can be compiled and established, it is important that everyone is aware of their importance. There are numerous resources, research articles, studies and guidelines that have been published regarding this subject.

A hazardous drug may display the traits of carcinogenicity, organ toxicity at low doses, genotoxicity, teratogenicity, and reproductive toxicity. These drugs are used in a variety of healthcare settings to treat cancer and other conditions such as rheumatoid arthritis, multiple sclerosis and auto-immune disorders. Often cytotoxic drugs have a purple sticker on them that displays a cell in late telophase (Figure 1) as a prompt to handle them according to Society of Hospital Pharmacists of Australia (SHPA), Australian and State guidelines.

Until further research and information becomes available it is probably advisable to adhere to the same guidelines when handling Monoclonal Antibodies (MABs), Bacillus of Calmette and Guerin (BCG), and tyrosine kinase receptor inhibitors.

There are many scenarios and a wide spectrum of people that can be at risk of occupational exposure to these medications (and related waste), particularly when:

- Preparing drugs
- Administering drugs
- Transporting drugs
- Storing drugs
- Handling patient waste
- Transporting and disposing of waste
- Cleaning up spills

Exposure can happen through skin contact, skin absorption, inhalation of aerosols/drug particles, ingestion, and sharps injuries. There have been a number of studies to determine the effects of occupational exposure to these drugs. Anderson[7] detected mutagens in the urine of pharmacist's working with cytotoxic drugs. Substantial amendments were then made to lessen exposure and risk to operators such as the use of *Cytotoxic Drug Safety Cabinets* or *Pharmaceutical Isolator Cabinets* to replace the older *Laminar Airflow Cabinets* which propel air towards the operator, possibly contaminated with the drug.

In 1984, Chrysostomou[8] found a link between the duration of exposure to cytotoxic drugs and mutation frequency in oncology staff. In 1983, deWerk Neal[10] monitored the general air of 10 hospital

High Risk	Low Risk	
Pharmacy Technicians/Operators	Supervisors and managers	Couriers
Oncology Pharmacists	Maintenance personnel	Waste handlers
Nursing and medical personnel	Stores personnel	Carers
Laboratory staff members	Cleaners	Ambulance Officers
Animal handlers (research)	On-site waste transporters	Patient transport personnel

Table 1. Bioavailability of Drugs eligible for IV to Oral Switch Therapy.

clinics and determined that fluorouracil and cyclophosphamide were being breathed by operators. This study highlighted the risk to staff of exposure to airborne cytotoxic aerosols under normal conditions – unless further special precautions are undertaken. More recently, Fransman[11] demonstrated that traces of cyclophosphamide were present on the foreheads, hands and forearms of; pharmacy technicians, cleaning personnel, and nurses that handled the drug whilst carrying out their normal duties. Worksafe Victoria[4] continuously emphasise that where a high standard of risk control is in place and adhered to, the effects upon the operator's health is reduced.

Of particular importance is the exposure of anti-neoplastic drugs to pregnant women and those of reproductive age. Selevan[9] in 1985 showed an association between exposure to cytotoxic drugs (particularly cyclosphosphamide, doxorubicin and vincristine) and foetal loss in nurses that were exposed during their first trimester. Fransman[12] showed that nurses exposed to anti-neoplastic drugs took longer to conceive, had a lower birth rate, and that there was a greater incidence of premature birth.

On the basis of these and other findings, the significance of adhering to the relevant standards and guidelines is highlighted. Worksafe Victoria advise that employers and staff who handle these hazardous drugs have an obligation to:

- Work to a risk management strategy
- Keep up-to-date with current practices and standards
- Consult with employees at key stages of risk strategy development i.e. the planning stage, during implementation, monitoring and review
- Assess policies and procedures on a regular basis

Only those employees that attain the required level of training and proficiency should be allowed to handle hazardous materials. The level of training depends on the staff member and potential for contact, as listed in Table 1.

Staff health is of paramount importance and so guidelines specify the required screening to identify if there are any changes due to occupational exposure to a hazardous substance. Full blood and lipids should be tested at baseline for all staff that are assessed as being at 'high risk'.

Most cytotoxic tablets and capsules are in blister packs, so generally the pharmacist will not need to take extra precautions when dispensing. However, when handling loose tablets (e.g. methotrexate) or when administering medications to patients, the nurses, carer, or pharmacist should always:

- Wear gloves
- Use separate counting trays from those used for non-cytotoxic medications
- Use separate, disposable counting spatulas
- Clean and rinse equipment properly after use
- Ensure tablets are not crushed or broken

A number of studies have evaluated various deactivating and decontaminating agents for use on surfaces contaminated with cytotoxic drugs. There are a number of factors to consider when selecting the most appropriate cleaning agent. Best practice would be to investigate exactly what to use before handling each drug (generally in the consumer medication information [CMI] leaflet). International standards recommend 'wipe sampling' of the surfaces before and after cleaning the most commonly used cytotoxic agents.

Investigation of lipophilic drugs, e.g. carmustine and paclitaxel can be done to ascertain that cleaning procedures are effective. Sodium hypochlorite (bleach) is the most efficient reagent to chemically degrade many cytotoxic drugs, and is often used, however, it is not effective with all cytotoxic drugs, e.g. dicarbozide and carmustine (under certain conditions). Alkaline cleaning agents (e.g. Decon-90 or Extran), 70% sterile alcohol and sterile water, either alone or in combination, also appear in the literature.

The agent used should be validated for the particular cytotoxic drug(s) that are/is present and for the surface on which it is being used. Particular attention is necessary to ensure that the cleaning agent used does not degrade the cytotoxic drug into other toxic components.

The purpose of this article is to thus highlight the importance of adhering to guidelines and standards. It is also for readers to gain an insight and an appreciation into the thought and research that has been compiled towards making the handling of hazardous drugs safer.

References for this article can be found on page 30.

IV to Oral Switch Therapy

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An ideal route of drug administration is the route that yields sufficient serum levels to produce the desired effect of the drug with minimal undesired effects. There are several advantages to support the prompt switch from IV to oral therapy, some of which are:

- Less costly
- Saves both medical and nursing time
- Patients are more likely to receive the medications at the correct time
- Potential reduction of risk in terms of adverse effects and errors
- Reduction of fear and discomfort to patient

Many patients in hospital continue to receive intravenous medications longer than necessary. Although intravenous medications may be more bioavailable and have greater effects, some oral drug preparations produce serum levels comparable to those of the intravenous form.

Considerations for IV to Oral Switch

The nurse, physician, pharmacist and in some cases even the patient can be good sources of information regarding the patient's ability to tolerate oral medications. If the patient is taking other medications by mouth, this may be an indication that the patient can be eligible for an IV to oral switch.

After 24-48 hours of intravenous therapy, patients should be reviewed for consideration of IV to oral switch therapy. The criteria to determine appropriateness of switching from IV to oral therapy should include, but are not limited to, the following:

- Observed clinical improvement
- Clinical markers showing a trend towards normal
- Oral route is not compromised
- Intact and functioning gastrointestinal (GI) tract
- Does not meet exclusion criteria
- Specific indications for prolonged IV therapy (high-risk infections)

Pharmacokinetic and Pharmacodynamic Issues

Dosage formulations and bioavailability are the main pharmacokinetic parameters to be considered. Intravenous medications have a bioavailability of 100% because they are administered directly into the blood stream. For oral medications, bioavailability may be less due to the variability in the rate and extent of dissolution of the oral dosage form and the total amount of the

<50%	50-80%	80-100%	
Aciclovir	Ciprofloxacin	Amoxycillin	Linezolid
Azithromycin *(well distributed into tissues)*	Dexamethasone	Clindamycin	Moxifloxacin
Morphine	Digoxin	Esomeprazole	Methylprednisolone
Ranitidine	Metoprolol	Fluconazole	Metronidazole
	Pantoprazole	Hydrocortisone	Paracetamol
		Ketorolac	Phenytoin
		Levetiracetam	Co-trimoxazole

Table 1. Bioavailability of drugs eligible for IV to oral switch therapy.

free drug absorbed into the systemic circulation taking into account other factors that might affect absorption, i.e. first pass effect.

The oral equivalent of an intravenous drug should possess pharmacokinetic properties that result in minimal disruption to the treatment course. The oral equivalent should have recognised benefits or an indication for the condition being treated and its use should be supported by evidence.

Exclusion Criteria

Listed are some criteria indicating that oral therapy may not be appropriate:

- Existing nil by mouth (NPO/non per os) order
- Nasogastric tube with continuous suction
- Severe/persistent nausea and vomiting
- GI transit time too short for absorption
- Active GI bleeding
- High doses of vasopressor medications
- Difficulty swallowing or loss of consciousness and no nasogastric access available
- Documented ileus or GI obstruction
- Continuous tube feedings that cannot be interrupted which is incompatible with the medication

Pharmacoeconomics

Switching medications from the IV to oral route results in direct cost reduction of not only the medicine but also the equipment used. Nursing time spent on the preparation, checking and administration of doses is also significantly reduced.

Two good examples that could be easily implemented in hospitals are paracetamol and proton pump inhibitors.

The analgesic efficacy of paracetamol is related to peak plasma concentrations. Since certain oral formulations of paracetamol achieve peak plasma concentrations close to those achieved with IV paracetamol, the IV formulation can only be justified in circumstances where the oral formulation cannot be given, i.e. significant/prolonged vomiting or enteral routes of therapy are unavailable.

The cost difference between IV and oral paracetamol preparations are more than one hundred fold. IV paracetamol consistently belongs to the top 20 pharmacy imprest cost drivers in private hospitals, especially surgical hospitals as protocols on IV to oral switch therapy are not common and the switch may not happen until the next medical or surgical review.

Aside from direct cost differences, administering oral paracetamol only requires one nurse for checking and administration and would normally take less than a minute to administer, whereas on the other hand, an IV dose needs two nurses for double checking and should be administered over a period of 15 minutes.

Need for Guidelines

An effective IV to oral switch program could result in over 70% reduction in IV paracetamol costs. It is well known that oral paracetamol is a lot cheaper and quicker to administer compared to IV paracetamol, but why do we still administer it for prolonged durations? Is it simply because of doctor's orders not being changed? Nursing staff perception on the IV formulation being more superior in efficacy? Or is there also an uncertainty on when to recommend or query a step down to oral therapy?

Empowering nursing staff to assess the ongoing need for IV therapy is the most effective way of driving such a program in the private hospital setting. Setting up guidelines on how to assess the eligibility of a patient to switch to oral therapy would provide nursing staff with a tool to refer to before making that query with the prescribing doctor. Once guidelines are in place and tested, doctors could be encouraged to prescribe a select group of drugs as IV/O instead of IV. This empowers nursing staff to use their clinical judgment, supported by the guidelines, to assess the most ideal route of drug administration for the patient at the time of administration.

Table 1 provides a summary of common drugs that may be considered for IV to oral switch therapy. Due to the differences in bioavailability of each drug, dose difference between IV and oral formulations should be considered, and the pharmacy consulted for dosing advice.

References for this article can be found on page 30.

Aseptic and Cytotoxic Training Program at Peter Mac

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Safe handling, preparation, distribution, storage and provision of cytotoxic substances, as well as the production of sterile agents is a highly specialised area within pharmacy. Treatment and preparation of these substances hence must occur in a highly contained environment, free of any microbial contamination (such devices exist: usually a Pharmaceutical Isolator or an A-Grade Laminar Air Flow Work Station [LAFWS]). These devices control pressure and air flow within a contained area, attempting to keep preparations sterile. It is also important for the safety of the patient, nursing staff and pharmacy staff that appropriate measures are taken to minimise any chance of contamination from the agents. Ensuring such steps are adhered to requires a thorough training and validation of employees within this industry.

My course was conducted 9–13th July 2012 at the Peter MacCallum Cancer Centre (Peter Mac) in East Melbourne. The *Aseptic and Cytotoxic Preparation Course* is important for learning the correct conventional sterile and cytotoxic preparation techniques, and gives an insight into operational logistics at Peter Mac itself. It is, in addition, an effective and important means of validating one's own department's aseptic and cytotoxic policies. There were a total of four participants in the course from different states, with different knowledge backgrounds, different working environments and differing levels of exposure to the technique of maintaining sterility within an isolation device, and its associated procedures.

The course was conducted on-site at Peter Mac over five full days and is approved by the Pharmacy Board of Victoria and accredited by the Society of Hospital Pharmacists of Australia (SHPA), in accordance with their guidelines for sterile and cytotoxic preparation. A variety of topics were covered within the course, with tutorial and practical components making up the majority of the course. Some lecture topics included:

- Introduction to Cancer and Chemotherapy
- Cytotoxic Chemotherapy – An Overview
- Basis of Asepsis
- Principles of Safe Handling
- Standards of Practice
- Facilities
- Health Surveillance for Personnel
- Management of Cytotoxic Spills
- Working within the Cabinet
- Aseptic Techniques
- Admixture Preparation
- Technique Validation

The complete oncology technician needs to be competent in performing a broad range of duties within and outside of the cabinet, and it was pleasing that Peter Mac covered many of these concepts in sufficient detail.

Safety was also an important aspect of the course, appropriately, as it is an essential competence that we must possess.

It was beneficial to develop knowledge of isolators and LAFWS as devices for cytotoxic and aseptic handling. We were exposed to real LAFWS, first observing how they operate and then preparing 'dummy' products in them. Later in the week, we were validated on gowning techniques and aseptic operation in these environments. There was an appropriate integration of theory and practice, with much being learnt about fundamental needle and vial handling, and intravenous preparation.

Learning and practice was the main theme over the first three days of the course, followed by validation for the most part of the final two days. There were three separate validations, each considering and assessing different aspects of the overall 'competent' cytotoxic and aseptic preparation:

Fluorescein validation

Approximately 45 minutes in duration and completed separately by each technician in the presence of the assessor. Three separate activities were conducted involving manipulation and transfer of fluorescein from a vial into an intravenous bag each time. At the conclusion, the assessor examined the entire cabinet as well as all products for exterior presence of fluorescein as a test of the participant's manufacturing technique competency (fluorescein glows when examined under fluorescent light).

Broth validation

Approximately two hours in duration and completed independent of the assessor. Four different activities were completed using broth inside each vial and a series of manipulations were undergone, transferring the broth from one medium to another each time. The final products were submitted and incubated for two weeks, then examined for contamination. This validation was therefore an assessment of aseptic transfer and preparation technique.

Written assessment

Approximately 30 minutes in duration, it assessed theoretical knowledge of cytotoxics, asepsis and technique basis of knowledge.

Overall, the aseptic preparation and cytotoxic handling course was very beneficial and insightful. The course provided insight into oncology preparation and manufacture at Peter Mac, as well as validating manufacturing technique and refreshing general operations at HPS Pharmacies – Knox.

It was pleasing to confirm the techniques and overall delivery that HPS Pharmacies offer is of the highest calibre.

I thank HPS Pharmacies for the opportunity. I am confident that it will be for the company's betterment. It will only improve an already well streamlined and proficient oncology service and hence maintain our quality working relationship with nursing staff, as well as ensuring products of the highest quality continue to be provided for patient's chemotherapy treatment.

The course can be beneficial for future training of other new staff members and continuing education in the expanding oncology environment. This is extremely important because experience in this field is necessary, considering the potential health and occupational hazards that exist when handling, preparing and distributing cytotoxic agents. I therefore encourage anybody with any questions pertaining to preparation, handling and distribution of sterile and cytotoxic products to be in contact with your local HPS Pharmacies' pharmacist for advice.

References for this article can be found on page 30.

Amoxycillin Challenge

Akane Kajiwara, Fourth Year Pharmacy Student
The University of South Australia

I am a fourth year pharmacy student at UniSA. During my placement at HPS Pharmacies, I had a great opportunity to be involved in an antibiotic challenge to treat a child with amoxycillin allergy. The challenge was conducted by Dr Damien Chan, an immunologist consulting at *The Memorial Hospital*. The hospital has recently started an *Allergy Clinic* specialising in desensitisation. Dr Chan has had 10 years experience in immunotherapy at the *Women's and Children's Hospital*. The majority of his patients have been successfully treated and become able to take the medicines that they were previously allergic to, without reaction. Desensitisation can be used for patients at all ages, but Dr Chan specialises in children. As it was fascinating, I would like share the experience with you.

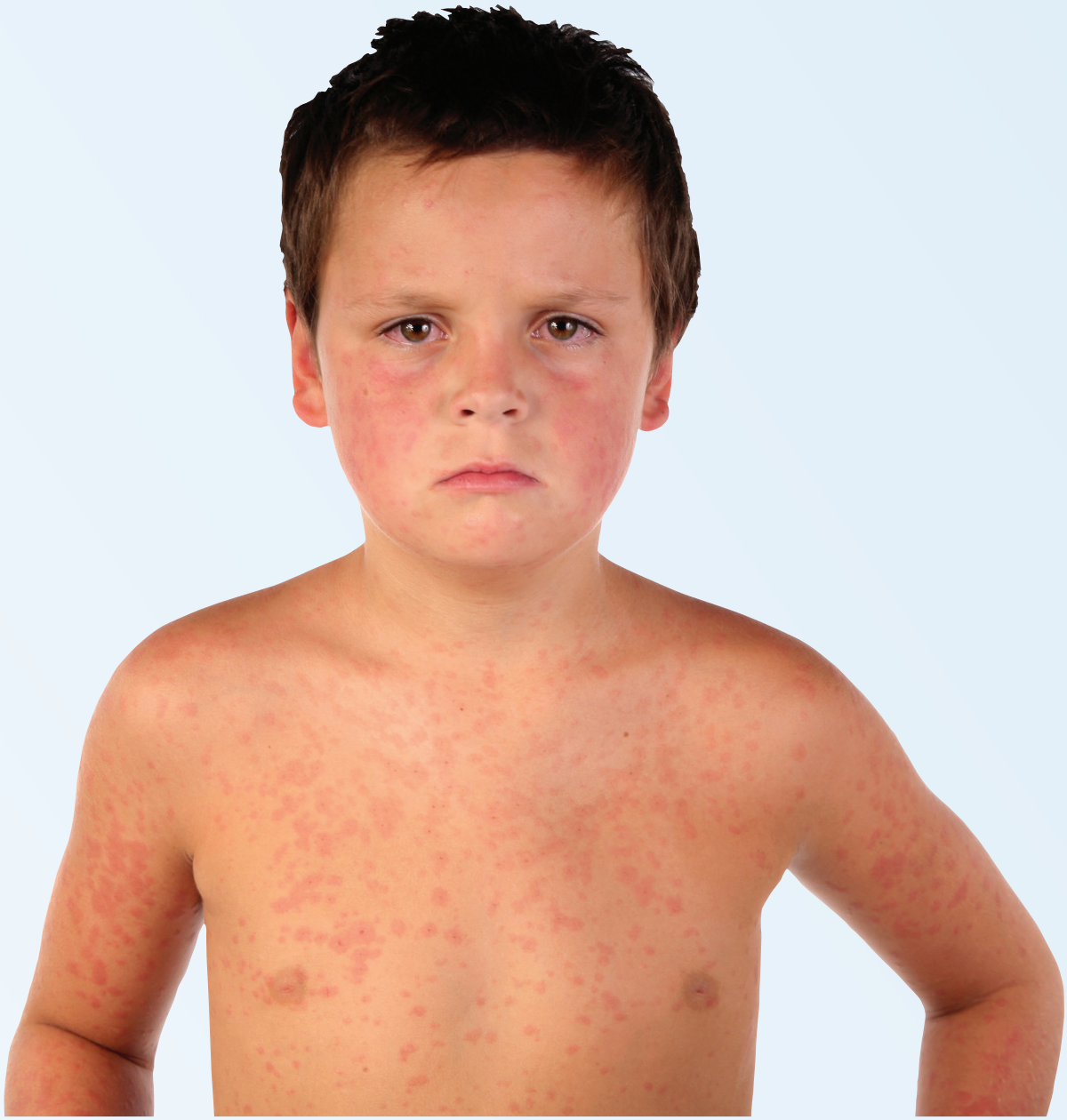
Allergic reactions are classified into two categories: *immediate* and *non-immediate* reactions.[1] The immediate reactions are mediated by specific IgE-antibodies and present within an hour from contact with allergens.[1] Symptoms are often serious including angioedema, anaphylactic shock and bronchospasm.[1] On the other hand, the mechanisms of the non-immediate reactions are not yet fully understood.[1] The non-immediate reactions are normally less serious such as skin rashes developing a few days after contact with the allergen.[1] Importantly, some viral infections cause skin rash,[5] so it is difficult to determine whether or not it is an allergic reaction.

Desensitisation for allergy is an immunotherapy which induces clinical unresponsiveness to allergens by gradually introducing repeated small amounts of the allergen.[2] The challenge has been successfully used to treat various kinds of allergies such as insulin allergy,[3] peanut allergy[6] and cow's milk allergy[4] in the past. The advantage of desensitising children to their drug antigens is that it allows them to avoid limitations to their future treatments. Particularly in children, infections which are not treated properly can result in serious consequences (e.g. loss of hearing from ear infections).

Children who undergo the challenge are carefully selected according to their allergy history. If they have an immediate allergic reaction to an antibiotic, they are not suitable candidates for desensitisation because the challenge could be life-threatening. In that case, the particular antibiotic and cross reacting antibiotics are avoided for life. However, if it is non-immediate, they could have a skin prick test to evaluate the reactions. The bottom line is that the skin test is not well-tolerated in young children as it is quite invasive. So, the challenge can be useful in both to test if the patients have a true allergy, and to desensitise those patients with an allergy. Once they successfully complete the challenge, they are likely to be desensitised for life.

Our patient was a two year old child with a suspected moderate amoxycillin allergy. The patient had previously experienced skin rash (red and flat but not itchy) developing a few days after he took amoxycillin, indicating that he is likely to have a non-immediate allergy. As discussed, since skin rash can also be caused by viral infections, we cannot be sure that he has a true allergy to amoxycillin. To avoid the trauma of skin testing, he was nominated to undergo the desensitisation process. Dr Chan designed a 5-day course of the challenge for him as shown in Table 1. I reconstituted and diluted a commercial oral amoxycillin (RANMOXY) syrup into the different doses and concentrations required for the protocol under the supervision of Ian Tindall, a compounding pharmacist at HPS – Alexander Avenue. The suspensions were yellow with a fruity flavour, which is designed to improve compliance.

On day 1, the patient was introduced to the diluted oral amoxycillin suspensions at fixed time intervals under direct supervision by the nurse and doctor. The patient's mother was with us and the child was observed for three hours in total. His body temperature, pulse and blood pressure were measured and the absence/presence of allergic reactions was checked every 30 minutes. They were all recorded. Treatments including adrenaline, hydrocortisone and oxygen pump are prepared for a potential emergency during the intervention. Fortunately, he did not have any allergic reactions during the testing, so he and his mother went home with a 4-day course of amoxycillin at a normal therapeutic dose to complete. His mother was advised to observe him carefully and report mild allergic reactions to Dr Chan or telephone 000 for an emergency. If there were any reactions, the patient would be diagnosed with amoxycillin allergy for life.



Time	Amoxycillin Dose	Proportion of Therapeutic Dose
0 minutes	0.125mg/2mL	1/1000th
30 minutes	1.25mg/2mL	1/100th
60 minutes	12.5mg/2mL	1/10th
90 minutes	100mg/10mL	8/10th
180 minutes	– (observation provided)	–
Days 2-5	125mg/10mL	Full therapeutic dose

Table 1. Amoxycillin Challenge Protocol.

From the parents' point of view, desensitisation of children's allergy can be frightening. However, the challenge is well organised and performed by experienced health professionals. The allergy clinic room is child-friendly with a TV and toys; and parent-friendly with comfortable reclining chairs and coffee. In this particular case, the patient looked relaxed and enjoyed playing with the toys during the challenge. His mother looked comfortable and trusted the clinic staff to conduct the challenge on him. She expressed that she was happy to let him undergo another challenge for cephalexin in a few weeks as he has a history of a similar reaction to cephalexin.

I found it interesting that children with drug allergies can be successfully treated with desensitisation. Also, as a pharmacy student, it was such a pleasure to see the good outcomes from our products in their treatment, since compounding pharmacists have few chances to witness patients undergoing their treatments. This opportunity allowed me to realise that pharmacists play an important role in a healthcare team. It was also great to receive feedback from the doctor himself on our preparation and labelling of the preparations. I realised that it is important to ensure that our presentation meets doctor's and patient's needs. For instance, we were asked to provide spare suspensions in case there were spills or emesis during administration. The lessons are very useful to improve our preparation in the future.

References for this article can be found on page 30.

Syndromes & Symptoms
New Treatments for Hepatitis C

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Hepatitis C virus (HCV) was discovered in 1989. Genotype 1 is still the most common of the six genotypes of the virus that have been identified to date.

The majority of people who contract HCV are asymptomatic. However in some individuals chronic infection can eventually lead to cirrhosis and subsequent life threatening conditions including liver failure, oesophageal varices and hepatocellular carcinoma.[8,10] Acute infection in adults leads to chronic infection in around 80% of cases. Approximately 120-130 million individuals are chronically infected with HCV worldwide.

In 2010 an estimated 297,000 people living in Australia had been infected with HCV.[11] In this group, an estimated 48,000 people had chronic HCV and moderate liver disease and 6,100 were living with HCV related cirrhosis.[11] Chronic HCV infection was the underlying cause of liver disease in 25% of patients requiring liver transplants in 2010.[11]

Infection amongst those admitted to correctional facilities is higher than the general population. In 2006, 34% of new prisoners and 56% of injecting drug users admitted to prisons in Australia had hepatitis C.[1] Transmission appears to occur predominantly among those with a recent history of injecting drug use.[10]

The aim of treatment is to achieve a sustained virological response (SVR), that is undetectable HCV-RNA 24 weeks after the end of treament.[5,9]

Interferon and ribavirin

Treatment for HCV is currently based on a combination of a pegylated form of interferon (peginterferon) and ribavirin. Interferon is an immunostimulant. Ribavirin interferes with RNA and DNA synthesis and hence viral replication.

This combination is not successful in all patients. Cure rates are much higher in those infected with genotypes 2 or 3 (80%) but only 50% in patients infected with genotypes 1 or 4.[5] Patients should be tested for genotype before treatment to determine dose and duration therapy.

For patients with genotypes 1, 4, 5 and 6, current treatment recommendations are for 48 weeks of treatment with peginterferon and ribavirin. Patients with genotypes 2 and 3 usually undergo a 24-week course of treatment, but this can be extended to 48 weeks if necessary.[3,4,5]

There are serious potential side effects with this treatment. Full blood count and liver biochemistry should be monitored every 4 weeks, more frequently for those with advanced liver disease or low pre-treatment haemoglobin.

Ribavirin can lead to significant haemolytic anaemia in up to 30% of patients. However a haemoglobin drop of more than 30g/L has been associated with improved SVR rates. If the patient's anaemia is symptomatic then the dose of ribavirin can be reduced but the dose should be increased again, if possible, once it improves as the success of treatment appears to be dependent on cumulative ribavirin exposure.[5]

Peginterferon commonly causes neutropenia and also thrombocytopenia. *Therapeutic Guidelines*[5] suggest that neutrophil count as low as $0.5x10^9$/L (normal $1.5\text{-}7.5x10^9$/L) is tolerable as long as the patient remains well and the count is monitored closely. Patients with conditions that predispose them to infection should also be monitored closely. Platelet counts are commonly allowed to drop as low as $30x10^9$/L (normal $120\text{-}400\ x10^9$/L), as long as the patient is asymptomatic and has no other risk factors for bleeding.[3,4,5]

Other common side effects of this medication regime include anorexia and gastrointestinal upset, skin irritations, sinusitis, dyspnoea, myalgia, dry mouth, insomnia, sweating and rigors.[9]

Drug interactions with ribavirin can occur up to 2 months after ceasing due to its long half-life.[9]

Protease inhibitors

Two newer medications, telaprevir and boceprevir, are protease inhibitors and work by binding to the non-structural 3 protease which is essential for viral replication. Rather than replacing current treatments, they are added to the standard peginterferon and ribavirin treatment for patients with HCV genotype 1.

These drugs demonstrate SVR increases above 25%, in patients with HCV genotype 1 when given in combination with peginterferon and ribavirin in both previously treated and untreated patients.[6,7,8] They should never be given alone as there are concerns that resistance is more likely to develop in the absence of peginterferon and ribavirin.

Both medications are metabolised by cytochrome P450. This means there is potential for many drug interactions. Co-administration with medications that have a narrow therapeutic window and are substrates of cytochrome P3A should be avoided. These include amiodarone,

cisapride, pimozide, quinidine, terfenadine, ergot derivatives, simvastatin, atorvastatin, oral midazolam and sildenafil. Also class 1a and class 111 antiarrhythmics should not be given with these medications.[3,4] Medications which may reduce the effect of boceprevir and telaprevir, through reducing plasma concentrations, include rifampicin, St John's Wort, carbamazepine, phenytoin and phenobarbitone.[3,4,9]

Caution should also be taken when these medications are given with other medications that prolong the QT interval in the heart, for example methadone, or in patients with a past history of QT prolongation.[3,4,9]

Telaprevir (INCIVO) comes as a 375mg film coated tablet. Dosage is 750mg eight-hourly with food for 12 weeks. The drug should be commenced when commencing peginterferon and ribavirin. HCV-RNA is tested at week 4 and 12. If there is insufficient response to treatment, all three medications are ceased. In patients responding to treatment, telaprevir is continued until week 12. Peginterferon and ribavirin are then continued alone for an additional 12 to 36 weeks.

This medication should not be used in patients coinfected with hepatitis B. Telaprevir is not recommended in patients with moderate or severe hepatic impairment, or those with decompensated liver disease.[3]

Common adverse reactions include anaemia, pruritus, rash, nausea and diarrhoea. Stevens-Johnson syndrome has been reported in patients taking telaprevir. The addition of telaprevir increases the incidence of anaemia compared to standard treatment alone. If this occurs it is suggested that the dose of ribavirin is reduced, rather than that of telaprevir. Hyperbilirubinaemia, hyperuricaemia, hypokaleamia, decreased lymphocyte and platelet counts and increased LDL and total cholesterol are also more common when telaprevir is added to standard treatment. However all appear to normalise by the end of treatment.[7]

Boceprevir (VICTRELIS) is available in a 200mg capsule. The recommended dose is 800mg three times a day, with food. Unlike telaprevir, boceprevir should not be initiated until week five of peginterferon and ribavirin therapy.

Response is tested at week 8. For patients with undetectable HCV-RNA treatment is continued with all three drugs until week 28. Those patients with detectable HCV-RNA at week 8, treatment is continued until week 24, and then retested. If there is still detectable HCV-RNA all three medications are discontinued. Patients with no detectable HCV-RNA continue all three drugs until week 28, then peginterferon and ribavirin alone until week 48.[4]

Common adverse reactions include fatigue, anaemia, nausea, headache and taste disturbances. Almost half of the patients given boceprevir develop anaemia compared to about a third of those given peginterferon alpha and ribavirin alone.[6] This is commonly treated with erythropoietin. Patients with galactose intolerance disorders should not take boceprevir.

These two medications offer exciting potential in the treatment of HCV resistant to standard treatment. Boceprevir and telaprevir appear comparable in terms of sustained virologic response, relapse, or discontinuation of therapy for patients treated with both standard-dose therapy durations and response-guided therapy durations.[2] Both telaprevir and boceprevir have been approved by the Therapeutic Goods Administration for the treatment of genotype 1 HCV, becoming the first new treatments in more than a decade. Both medications were recommended for PBS listing as Section 100, Highly Specialised Drugs at the July meeting of the Pharmaceutical Benefits Advisory Committee.

References for this article can be found on page 30.

Hospital Lecture Series
Complementary Medicines in Cardiovascular Disease

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The term 'complementary medicines' encompasses many medicinal products, and may include herbal preparations, vitamins, minerals, nutritional supplements and traditional medicines such as those from Chinese, Ayurvedic (Hindu), and Aboriginal cultures. Complementary medicines are also often called 'alternative' or 'natural' medicines. 'CAM' is normally used to refer to all substances which can be categorised as complementary and alternative medicine.

The Therapeutic Goods Administration does not require scientific evidence of efficacy in order to list complementary medicines, such as is required for registered medicines; instead, their availability may be based on acceptance of traditional knowledge, potential health benefits, and evidence that they will "do no harm".

Half of Australians use CAMs, spending above $2.3 billion annually, the majority being women between 40 and 60 years of age, well educated, and well paid. The widespread use of CAMs may be driven by a number of factors, including:

- a desire for good health and wellbeing
- a desire for some self-control in the management of their health
- a lack of trust in orthodox medicine
- a deep-rooted belief that complementary medicines are safer than prescription medicines, because they are 'natural'

These perceptions are enhanced by the many media reports of serious adverse effects associated with commonly used medications.

Adverse Effects

Although, in many cases, convincing scientific evidence to support the safety and efficacy of CAMs is lacking, their use in patients with cardiovascular disease is widespread, increasing the potential for interactions with prescription medicines. In addition, though widely perceived to be natural and therefore safe, many CAMs do have side effects. When used in combination with prescription medicines, the risk of adverse effects may increase. This can be very important in patients with cardiovascular disease, where:

- they may be taking medications with a narrow therapeutic index (e.g. warfarin)
- they may be taking multiple medications
- they may be frail and elderly
- kidney/liver function may be impaired

Table 1 provides just a small sample of some of the potential effects and problems when CAMs are used in patients with cardiovascular disease. Information available varies in quality, relying on actual case reports or results from animal studies and human clinical trials. Many interactions may be theoretical only or of limited clinical significance.

Surgery Risk

Risks associated with the use of CAMs in patients undergoing planned surgery should be identified and assessed. A number of CAMs may increase the risk of complications during or after surgery. Those with antiplatelet or anticoagulant effects can increase the risk of bleeding, when used in combination with antiplatelet medications such as aspirin or clopidogrel, anticoagulants (warfarin), or NSAIDs with antiplatelet activity. CAMs which need to be treated with caution include fish oil, chamomile, dong quai, ginkgo, ginger, guarana and ginseng. Others, such as St John's Wort, commonly used for depression and other mood disorders, may interfere with the action of pre-operative or anaesthetic medications.

The use of CAMs must always be discussed with medical practitioners before planned surgery; some may need to be ceased 7-14 days beforehand as indicated in Table 1.

Numerous complementary medications are purported to be beneficial in patients with cardiovascular disease, though the evidence is not always convincing. Coenzyme Q10 is one such medication, widely

CAM	Common Uses	Adverse Effect of Interaction
Angelica (dong quai)	Gynaecological disorders	↑ Risk of bleeding with anticoagulants (e.g. warfarin), antiplatelet drugs (e.g. aspirin, clopidogrel), NSAIDs (e.g. ibuprofen) **
Bilberry	Circulatory problems, diarrhoea	**
Capsicum	Shingles, trigeminal/diabetic neuralgia	**
Celery	Arthritis, gout, fluid retention	**
Chamomile	Insomnia, eczema, colic	**
Coenzyme Q10	Congestive Cardiac Failure (CCF), Hypertension (HT), statin adverse effects	↓ Effect of warfarin Additive antihypertensive effects
Evening primrose oil	Atopic eczema, premenstrual syndrome (PMS), rheumatoid arthritis (RA), multiple sclerosis	**
Fish oil	Cardiovascular disease, atrial fibrillation (AF), RA, high triglycerides	**
Garlic	High cholesterol, HT, heart disease	**
Ginger	High cholesterol, motion sickness	**
Ginkgo	Poor circulation, cognitive disorders	**
Ginseng	Immune system, cognitive function	**
Glucosamine	Osteoarthritis	↑ Effect of warfarin
Grapefruit juice	Weight loss, cardiovascular health	↑ Effect of statins, calcium channel blockers (CCB)
Green tea	Cognitive performance, weight loss	↓ Effect of warfarin (contains vitamin K)
Guarana	Weight loss, enhanced athletic performance, cognitive function	↑ Heart rate, BP, additive effect with diuretics **
Hawthorn	CCF, HT	May potentiate digoxin, antihypertensives, nitrates, erectile dysfunction medicines
Red clover	Menopausal symptoms, benign prostate hypertrophy (BPH), bone mineral density (BMD)	**
Saw palmetto	BPH, increased sexual vigour	**
St John's Wort	Depression, seasonal affective disorder (SAD), PMS, menopausal mood symptoms	↓ Effect of pre-op medications (e.g. midazolam, fentanyl, propofol), CCB, warfarin, and statins ↓ Levels of digoxin/amiodarone ↑ Effect of clopidogrel

*Table 1. Uses and Interactions of some CAMs. **Should be stopped 7-14 days before surgery.*

advocated to reduce or prevent side effects such as myalgia in patients on 'statin' therapy. Its routine use is probably not warranted, but it may have a place in patients who do develop myalgia whilst on a statin. Garlic may be of benefit in patients with hypertension, whilst evidence for the use of ginseng and ginkgo in cardiovascular disease is not convincing. There is, however, compelling evidence for the beneficial effects of fish oil for primary and secondary prevention of heart disease, AF, and hypertriglyceridaemia.

An Ethical Dilemma for Pharmacists

Some consumers may insist on purchasing a CAM, even when scientific evidence for its benefit is lacking, and there is potential for adverse effects and interactions with their prescription medications. In these situations, consumers should be fully informed of any potential risks, and strongly encouraged to keep their GP, cardiologist, or any other relevant health professionals up-to-date with any complementary medicines they are taking. This may be particularly important if surgery is planned in the future.

A respect for the consumer's right to have some self-control in the decision-making about their health management will encourage good communication, and increase the likelihood of disclosure of any alternative therapies to enable suitable management.

References for this article can be found on page 30.

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