HPS Pharmacies

Newsline

SUMMER EDITION 2012

Brunswick Private Hospital's State-of-the-art Redevelopment

HPS' Inaugural Gala Dinner and Awards Night

HPS' New National Corporate Office

leadership we inspire
innovation we create
respect we consider
accountability we perform
excellence we exceed

Managing Editor
Steve Yeo

Editor
Briar Buttfield

Front Image
An exterior view of Brunswick Private Hospital

Contributors
Sharon Anderson, Clinical Pharmacist, HPS – Modbury, Modbury Hospital, South Australia
Jean Ang, Oncology Pharmacist, HPS – Alexander Avenue, South Australia
Ricky Che, Pharmacist In-Charge, HPS – Pacific Private, Pacific Private Hospital, Queensland
Dina Dinh, Clinical Pharmacist, HPS – Melbourne Private, Melbourne Private Hospital, Victoria
Michael Soriano, Pharmacist In-Charge, HPS – Wakefield, Calvary Wakefield Hospital, South Australia
Catherine Treuel, Pharmacist, HPS – Sunnybank, Sunnybank Private Hospital, Queensland
Alan Yip, Clinical Pharmacist (Rehabilitation), HPS – Alexander Avenue, South Australia

Peer Reviewer
Janene Garde, Partner/Clinical Publicist, HPS Pharmacies, Victoria
Alan Yip, Clinical Pharmacist (Rehabilitation), HPS – Alexander Avenue, South Australia

Advertising
South Australia: Catherine Riedel **t** (08) 8177 8206

Marketing
Briar Buttfield **t** (08) 8177 8219 **f** (08) 8229 6309 **e** briarb@hospharm.com.au
Catherine Riedel **t** (08) 8177 8206 **f** (08) 8229 6309 **e** catheriner@hospharm.com.au
Danna-Lee Stoic **t** (08) 8177 8207 **f** (08) 8229 6309 **e** dannas@hospharm.com.au

Subscriptions
HPS Pharmacies, Corporate Office, Level 1, 5 Greenhill Road, Wayville SA 5034
t (08) 8177 8219 **f** (08) 8229 6350 **e** briarb@hospharm.com.au

HPS Pharmacies Partners
Kirsten Boyce, Agnes Chung, Dominic Coppola, Megan Farnsworth, Janene Garde, Samantha Greaves, Tin Huynh, James Ischia, Paula Kwan, Puneet (Sunny) Rewal, Sarah Thurlow, Tony Wyatt

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Message from Tony Wyatt CEO

With the ringing in of the New Year, we celebrate the close of another successful year for HPS Pharmacies and look towards 2012 and the exciting business developments it brings. In 2011, HPS' charter for growth was realised with the signing of a number of significant Pharmacy Service Agreements, including South Australia Prison Health Service, Melbourne IVF and another new state facility to be communicated early this year. It was also at this time that HPS unveiled its multi-million dollar nation-wide pharmacy software solution, HosPharm, providing the business with considerable operational improvements.

HPS experienced significant change across the organisation last year as the Executive team and HPS Pharmacies' Board paved the way to further enhance the longevity of the business. With this, the Senior Management and Executive teams were strengthened with the employment of several highly skilled and industry knowledgeable people. Most recently, Chief Information Officer, Ian Bell, who joined HPS Pharmacies in mid-December with extensive IT experience in both Australia and Europe. Previously, the creation of a dedicated Business Development division also renewed the business' focus on new and existing business and has further strengthened our position within the industry.

We are all excited about what the future holds for HPS Pharmacies and I am sure the year ahead will continue to be a productive and prosperous time for the business as we move further away from consolidation and into growth. I would like to personally thank our wonderfully dedicated staff and valued clients for your ongoing support and look forward to our continued journey together.

Tony Wyatt
Partner / Chief Executive Officer

Message from Steve Yeo COO

As HPS Pharmacies' Chief Operating Officer, I am extremely pleased with the corporate development achieved throughout 2011.

Our company's committed team of staff have been the foundation upon which this strong development has been built and in recognition of our key performers and to further expand HPS' culture of highly skilled and dedicated workers, the Executive team has introduced six annual peer nominated awards. The 2011 awards were presented at our inaugural Awards Night at the illustrious State Library in November, which was held in conjunction with HPS Pharmacies' Gala Dinner. To read more about each award, the nominees, and winners, turn to page 8.

HPS Pharmacies' second Management Group Conference for 2011 was also held in Adelaide the same weekend. This again proved to be a highly successful and productive conference and provided the business with the opportunity to challenge our processes and to explore potential opportunities for enhancing client services.

To continue the focus, HPS Pharmacies' Management Strategy Summit for 2012 was held earlier this month and brought together the company's Executive team and Senior Managers to discuss our strategic corporate plan for the year ahead.

HPS Pharmacies' success in 2011 has placed us in good stead to further strengthen our position as the nation's leading pharmacy service provider. We look forward to you sharing our success throughout 2012 as we strive to nurture our existing relationships and continue to establish new ones.

Steve Yeo
Chief Operating Officer

This page (left to right): Jane O'Connell, Director of Nursing, and Jacinta Summers, Allied Health Manager & Senior Physiotherapist at Brunswick Private Hospital, with Alan Tuxford, Regional Operations Manager, VIC/TAS/QLD at HPS Pharmacies.

Cover page: An exterior view of Brunswick Private Hospital.

Brunswick Private Hospital's State-of-the-art Redevelopment

HPS Pharmacies have proudly delivered pharmacy services to Brunswick Private Hospital for a number of years, forming a solid relationship with Healthe Care since they took ownership of the facility two years ago.

Brunswick Private Hospital is a comprehensive general medical and rehabilitation facility, delivering a range of inpatient services along with an extensive range of outpatient programs, and has recently undergone vast redevelopment works.

With stage one now complete, the hospital's facilities and services have been significantly enhanced, accommodating 40 rehabilitation beds, 27 beds for general medical services, physiotherapy consulting space, gymnasium, hydrotherapy pool, hyperbaric chamber, co-located imaging, pathology and pharmacy.

Alan Tuxford, HPS Pharmacies' Regional Operations Manager VIC/TAS/QLD says "Healthe Care has invested significantly in the redevelopment of Brunswick Private Hospital and has completely transformed the facility both inside and out to the extent that it is almost a new build.

"It is a wonderful development for the local community who will benefit greatly from the increased services offered at the one location.

"Brunswick Private Hospital is the only rehabilitation hospital in the local area, and with brand new state-of-the-art facilities, a GP clinic and specialist consultants on-site, the hospital with go from strength to strength."

HPS – Brunswick will be the first of HPS Pharmacies' sites to service a GP clinic in addition to the hospital. Alan believes the opportunity to provide pharmacy services to Brunswick Private Hospital's new GP clinic is exciting and will serve as the perfect tool in determining if this is an area HPS wants to focus on in the future and offer to other clients.

"HPS will effectively be operating two pharmacies in one, servicing outpatients as well as inpatients. The greatest difference to our other sites will be to provide a fast and efficient service to outpatients whilst continuing to effectively service the wards," says Alan.

In addition to delivering pharmacy services to the hospital, HPS has invested significant captial into redeveloping the pharmacy, which now includes a full retail service.

Alan says "the focus of the lines we will offer customers will revolve primarily around medications. We may offer toiletry items and the like for inpatients to purchase but we will have quite a different offering to other typical retail pharmacy outlets."

Tim Yeoh, Regional Manager at Brunswick Private Hospital says "the development will provide increased access to quality rehabilitation services within the local community and the new GP facilities will bring much needed additional GP's into the underserviced area.

"The first phase of the hospital's redevelopment was completed late last year and delivers best in class accommodation, purpose built gymnasium, and hydrotherapy pool, which are vital to enabling the nursing and Allied Health staff to deliver quality rehabilitation and medical services to their patients," he says.

The second phase of redevelopment is expected to be completed in mid 2012 and will deliver additional inpatient accommodation capacity to the hospital as well as a newly refurbished HPS Pharmacies site and a seven doctor GP clinic.

HPS Pharmacies refurbished pharmacy will be located towards the front of the hospital and will also be attached to the medical centre, offering two service delivery access points, enabling HPS to provide pharmacy services to both the GP clinic and hospital.

HPS Pharmacies' Chief Executive Officer, Tony Wyatt, says "the potential for growth at HPS – Brunswick is very exciting and we are exceptionally grateful that Healthe Care has given us the opportunity to be part of such an amazing redevelopment."

"...with brand new state-of-the-art facilities, a GP clinic and specialist consultants on site, the hospital with go from strength to strength."

– Alan Tuxford, Regional Operations Manager VIC/TAS/QLD

Picture: Mortlock Chamber, State Library of South Australia.

Inset (left to right): Winners of HPS' Annual National Awards – Alan Tuxford, Michael Soriano, Kellie McOwat, Aleksandra Stankovic and Paula Kwan (absent: Steve Frost).

www.hpspharmacies.com.au

HPS' Inaugural Gala Dinner and Awards Night

HPS Pharmacies' Inaugural Gala Dinner and Awards Night, hosted in late November, was a spectacular event enjoyed by over 125 staff and their partners.

The event was a night to remember, and an impeccable way to celebrate the business' success throughout 2011.

The illustriously ornate Mortlock Chamber at the State Library of South Australia lent itself perfectly to an evening of elegance and laughs, with delicious food, top-notch wine, great company, and a celebration of some outstanding contributions from HPS Pharmacies' national teams.

Now a fixture on HPS' annual event calendar, the national awards epitomise HPS Pharmacies' core values of excellence, innovation, and leadership, and celebrates the achievements of individual team members and overall teams across a range of categories.

The six awards, introduced by HPS' management team, include:

"The Dr. Holsman Award for Innovation", recognising outstanding innovation at any level of the organisation;

"Corporate Team Member of the Year", recognising that individual whose conduct and contribution had a profound impact upon the business and its employees;

"National Pharmacy Manager of the Year", recognising the outstanding leadership of a Pharmacy Manager within a team environment;

"National Site of the Year", recognising the leading HPS Pharmacies site for financial and team performance;

"National Pharmacist of the Year", recognising the company's most outstanding pharmacy professional for contributions to HPS, its clients, and the field of pharmacy within healthcare;

"National Pharmacy Technician or Courier of the Year", recognising that individual whose conduct and contribution had a profound impact upon the business and its clients.

The awards were presented at the evening's official commencement by HPS Pharmacies' Chief Executive Officer, Tony Wyatt, and Chairman of the HPS Board, Dr. Andrew Holsman. The annual national awards are a new initiative within the business to encourage the recognition of high performers and promote a culture that nurtures value and hard work.

Tony said "the awards allow the opportunity for peers to vote and take ownership in celebrating the stars of our business."

The winners will be immortalised on HPS' Honours Board next month at HPS Pharmacies' new corporate office.

In addition to the HPS Pharmacies' Inaugural Gala Dinner and Awards Night, the last week of November also saw South Australia play host to the year's second Management Group Conference (MGC). The MGC was again a productive and effective weekend, and saw the early-stage development of numerous initiatives that will be rolled out throughout 2012.

Tony said "the collaborative environment created by the company's management team, brought together a unity of purpose and shared vision to continue into the New Year. It additionally allowed camaraderie amongst the management team, and built a strong foundation of relationships for the business to interact and enhance on."

National Award Winners

Congratulations to our award winners!

1. The Dr. Holsman Award for Innovation
Alan Tuxford
(Operations – Victorian Head Office)

2. Corporate Team Member of the Year
Steve Frost
(I.T. – Corporate Office)

3. National Pharmacy Manager of the Year
Aleksandra Stankovic
(John Fawkner, Victoria)

4. National Site of the Year
Calvary North Adelaide
(South Australia)

5. National Pharmacist of the Year
Michael Soriano
(Wakefield, South Australia)

6. National Pharmacy Technician or Courier of the Year
Kellie McOwat
(Alexander Avenue, South Australia)


120
50
125

HPS' New National Corporate Office

It was with great pleasure that HPS Pharmacies' Chief Executive Officer, Tony Wyatt, announced to the business in November that the HPS Board and Executive team had approved a substantial capital investment towards developing a new national corporate office facility.

The new corporate office will be located at HPS Pharmacies' Alexander Avenue site in Adelaide, amalgamating HPS Pharmacies' 35 corporate staff in one location. Also operating at these premises is HPS Pharmacies' existing pharmacy and oncology facility, comprising approximately 60 pharmacy staff.

Tony Wyatt says "the recent growth and development of HPS Pharmacies has led to the business rendering the dedicated corporate office, presently located at Greenhill Road in Adelaide, too small to accommodate the growing national corporate team.

"The ability for the new corporate office space to accommodate the entire national team [excluding HPS' established Victorian Office], will enable the business to secure the many synergies that can be achieved through the co-location of all national resources," he says.

HPS Pharmacies has been researching a range of potential new locations since December 2010. Having reviewed all possible alternative scenarios, the Executive team agreed unanimously to redevelop the Alexander Avenue site to accommodate the national corporate team in addition to the current site's operational team.

HPS Pharmacies' Strategic Projects Manager, Samantha Greaves, says "the new office is expected to be completed during the third week of February, with our existing premises on Greenhill Road to be vacated by the end of February.

"The office has been designed by highly reputable South Australian architects Woods Bagot, with building and re-fit works being managed by Schiavello, and I am excited to watch the progress as our plans come to fruition.

"HPS Pharmacies' corporate staff will enjoy purpose built facilities including three meeting rooms, a board room, open plan office area with 'hot-desks' for more mobile staff, an open plan executive suite and improved bathroom facilities with disabled access.

"Staff benefits include shared lunch facilities with the pharmacy staff, an outdoor courtyard area, and in the interest of encouraging cycling, running or walking to work, shower and locker facilities," says Samantha.

As Strategic Projects Manager, Samantha explains the number of challenges she has faced, including re-accommodating staff formerly working in the re-fit area for the duration of the renovations, maintaining a working pharmacy business at the site during the renovations and ensuring no disruption to services or timelines whilst meeting the budget.

"The new open plan design will utilise the available space more effectively and challenge our corporate staff to work more collaboratively. The aim is to create an atmosphere which facilitates effective communication."

Tony says "the amalgamation of our corporate office staff will have an indirect benefit to our clients as we strengthen communication and accessibility between corporate departments and provide strong national service to our operations teams. We are expecting this to be a seamless transition with no disruptions to our clients."

This is another exciting development for HPS Pharmacies, and another demonstration of the business' commitment to investing deeply in developing a strong foundation from which to operate into the future.

Pharmacy Business

Gentamicin Update

The expert writing group of the Therapeutic Guidelines: Antibiotics version 14 has recommended some changes in the use and monitoring of gentamicin. These changes were brought about in order to promote gentamicin use empirically while at the same time to discourage long-term use except for specified indications, in which case patients should be in a facility that has access to a computerised monitoring program and skilled personnel to interpret the information.

Empirical therapy (maximum of 48-72 hours) no longer requires concentration monitoring.

Indications for directed therapy include, but are not restricted to:

- **Infections when resistance to other safer antimicrobials has been shown.**
- **Combination therapy for serious Pseudomonas aeruginosa infections and brucellosis.**
- **Low doses as synergistic treatment for streptococcal and enterococcal endocarditis.**

Concentration monitoring for gentamicin is now only required after the first dose of directed therapy (day 3 of gentamicin).

For indications with once-daily dosing or less frequent dosing, there are computer programs like ALADDIN (*www.asainc.net.au*) and TCI Works (*www.tciworks.info/*) which automatically adjust for significant individual variations in volume of distribution and elimination rate. The previously published nomograms for gentamicin concentration monitoring and dosing are no longer recommended. The same is true for the graphical method included in the Australian Medicines Handbook 2010.

For indications requiring 8-hourly dosing, only trough concentrations (measured just before the next dose) should be measured and values kept below 1mg/L to minimise toxicity.

Always monitor for signs of vestibular or auditory ototoxicity.

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2. Antibiotic Expert Group. Therapeutic Guidelines: Antibiotic. Version 14. Melbourne: Therapeutic Guidelines Limited; 2010.

Tapping into Trial Drug

It seems the era of the stoic patient, who prefers the expert to make therapeutic decisions, is rapidly giving way to the informed patient who negotiates their care with knowledge gained from detailed research. In "*My Sister's Keeper*", Jodi Picoult explored both ethics and the potential for aggressive management and new technologies to extend survival beyond expectations. The unprecedented use of media by breast cancer sufferers in 2006 effectively forced PBS funding for Herceptin®, now reaching $80 million per annum.

A patient who is interested in "cutting edge" therapies to treat cancer can easily explore a number of portals detailing clinical trials of management tools and techniques, including drugs. It takes almost no time to identify 402 treatment focused trials currently open to new patients on the *Australian Cancer Trials* website, which searches for specifically cancer related trials included in the *Australia and New Zealand Clinical Trials Registry (ANZCTR)* and the US based *Clinicaltrials.gov*, which reports 116,000 trials from 178 countries. The *ANZCTR* is also one of the 11 primary registries providing data to the WHO's *International Clinical Trials Registry Platform*; meeting criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration as defined in guidelines finalised by WHO in 2010.

Several Australian states independently gather data on the progress of local trials, such as *The Victorian Cancer Trials Link*, which has responded to consumer interest by minimising jargon, and creating an easy to navigate site based on patient diagnosis. The Victorian Cancer Agency aspires to increase patient participation in trials to 15% by 2020 and to increase the number of trials available to Victorians. While extending therapy options for current patients with poor prognosis, clinical trials offer the real potential of vastly improved outcomes for generations to follow.

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Pharmacy Practice Incentives

While medicines are of course prescribed to improve the health of patients, ineffective use, or adverse events, may not only compromise the sought after outcomes, but contribute to a new burden of care. Adverse events from medicines are now estimated to contribute to 190,000 hospital admissions per year in Australia, costing $660 million, let alone the number of patients who visit GPs, or the remaining multitude who manage as best they can within the community.

The launch of *Pharmacy Practice Incentives* sees an exciting investment into improving outcomes for patients by enabling pharmacists to actively offer quality services, information, and advice with the goal of improving management of medicines, minimise adverse events, and reducing the risk of hospitalisation. The program focuses on six areas of pharmaceutical practice, each with a defined initial set of elements that are expected to expand over the life of the current *Community Pharmacy Agreement*.

Pharmacists are now encouraged to assist those patients who struggle with medication compliance by releasing prescriptions in installments in what is called *Staged Supply*; or to simplify dose scheduling through providing *Dose Administration Aids*. Pharmacies that contribute to *Primary Health Care* offer health promotion, screening, risk assessment, or assistance to patients in managing diabetes, respiratory disease, cardiovascular disease, or mental health conditions. *Community Service Support* is based around providing particular programs including Needles and Syringes, Opioid Substitution, Return of Unwanted Medicines, staff training, or eHealth. Pharmacists who make *Clinical Interventions* to improve the management of a patient's medication, or who collaborate with other health practitioners in providing care, possibly using some of the incentives already described, is adding to the quality of care by *Working with Others*.

The opportunity to diversify away from the fundamentally supply oriented function of the Pharmaceutical Benefits Scheme towards an outcome and quality based service has been welcomed by our profession, with most pharmacies in Australia now registered to provide their particular contribution to this diverse and ambitious program.

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Planning the Drug Budget

It is no surprise that wages and salaries form 51.6% of recurrent expenditure in acute and psychiatric hospitals, but who has noticed that drugs fall into second place at 27.7%? As the budget season looms, it is worth attempting to apply some science to the drug portion of the budget rather than assuming any direct relationship to the CPI which was 3.5% for the 12 months to September 2011, where the subset of health scored 3.7% for the same period. Benchmarking against national statistics might be a helpful tool, but the challenge is to select the right statistic.

Pharmaceutical expenditure by Medicare increased a whopping 13.3% overall from 2009-10 to 2010-11, made up of 5% in pharmaceutical benefits, 2% in services, and a significant new investment in highly specialised drugs.

On drilling further into the ABS statistics for the health market, the changing patient mix in acute and psychiatric hospitals is demonstrated by a 2.8% rise in bed days, and a 5% rise in separations (6.7% in private hospitals) between 2008-9 and 2009-10. Same day patients are now recorded at 57.2% of separations. Income for this period rose by 8.3% while recurrent expenditure rose 9.5%. It is interesting that cost per patient per day in a 200 bed hospital measures at around double that of a 50 bed hospital.

With ever more sophisticated therapies and technologies available, the challenge for healthcare is to devise budgets that cannot only ensure survival, but take advantage of new opportunities.

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From The Team Update

Angie Lawson

Training & Development Consultant

Training and Development has commenced a review of the changing legislative landscape, particularly as it applies to the harmonised Work Health & Safety legislation due to be introduced throughout Australia in early 2012. These new laws are based on a national model and will provide businesses with operations in more than one State, such as HPS Pharmacies, greater uniformity in regards to compliance.

In addition to these changes, *Brodie's Law* was passed in Victoria in June 2011 after the tragic death of Brodie Panlock – a 19 year old cafe worker who committed suicide after being constantly bullied in her workplace. HPS Pharmacies are presently rolling out Workplace Anti-Bullying and Harassment training to each of our valued employees as we further educate our staff on the dangers of bullying and harassment in the workplace.

With the recent appointment of our Workplace Health & Safety Advisor to the Human Resources team, we anticipate further enhancing our staff training sessions to keep them abreast of the changing legislative environment.

As HPS' national Training & Development Consultant, legislative changes form only a fraction of my role. Other key areas include new system and program roll-outs, staff inductions and administering the company's Continuous Professional Education program.

Nicki Jackson

Procurement & Contracts Manager

I recently joined HPS as Procurement and Contracts Manager, a new role for HPS to support the business in their renewed national focus on business development. Using my background in fast moving consumer goods industries in the UK and Australia in both manufacturing and retail companies, I can bring my expertise in procurement and supply chain to strategic and operational decisions.

Further cementing our already strong client relationships is pivotal to ensuring the continued development and growth of HPS Pharmacies, as we strive to be a customer of choice with our suppliers. This in turn strengthens our relationships with our clients as we are able to ensure the constant supply of products or supply brand alternatives and be the first pharmacy service provider to stock new products. With a significant proportion of HPS Pharmacies' expenditure being product, our supplier relationships are key to negotiating cost savings to the business.

I am responsible for the procurement of 'indirects' such as phone and data providers, workwear and stationary, in addition to investigating procurement of commodity items from overseas.

The other main area of focus is managing and maintaining supplier contracts and enhancing HPS Pharmacies' sponsorship packages to further support the continuing professional development of our pharmacists, strengthen supplier relations through education, and secure additional revenue for the business.

I am currently working on projects to enhance HPS Pharmacies' business guidelines and strategies as they relate to procurement and contracts, including improvements to our existing systems and processes to ensure we always have access to reliable information so we can respond quickly to changes in the market.

Michael Soriano

Pharmacist In-Charge, HPS – Wakefield

In November, a number of HPS staff attended the 2011 SHPA National Conference in Hobart. The conference was a good opportunity for pharmacists to exchange ideas on medication management practices throughout the country and focused on the evolving role of pharmacists. It showcased the benefits of having pharmacists in non-traditional areas of healthcare such as pre-admission clinics, emergency departments, ambulance services, peri-operative suites and GP clinics.

Separate to this, the HPS Pharmacies' Management Group Conference (MGC) was also held in November and brought together the business' managers from across the country to share ideas, network and discuss operational topics. This two-day event was held in Adelaide and was strongly themed around Dr Edward de Bono's Six Thinking Hats theory. The metaphorical 'thinking hat' concept was integrated into a number of team building and leadership skill development activities and had the conference participants separate their thinking into six distinct categories.

The MGC provided a good opportunity for Site Managers and Pharmacists' In-Charge to look to the future and discuss the company's direction and shared vision for the next 12 months and beyond with our Senior Management and Executive teams. It was also a fantastic platform to brainstorm concepts to further enhance the services we provide our clients and patients.

Aleksandra Stankovic

Pharmacy Manager, HPS – John Fawkner

At HPS, we have extensive experience in the preparation of sterile medication and the manufacture of oncology products, which has positioned the company well to assist with oncology and renal trials such as those conducted by the John Fawkner Clinical Trial Centre (JFCTC) and the Melbourne Renal Research Group, in Melbourne.

As Pharmacy Manager at HPS – John Fawkner, my team and I are dedicated to providing pharmacy support to these valuable trials, ranging from medication management and preparation, to patient education and counselling. We are currently involved in several trials with the JFCTC aimed at improving the quality of life and prognosis of patients living with cancer, and with the Melbourne Renal Research Group to better the outcomes of patients living with kidney disease.

HPS has enjoyed a solid relationship with John Fawkner since 2008 and we anticipate this already strong foundation will be further cemented as HPS continues to deliver valuable services to the hospital.

HPS Pharmacies is also committed to the continuing professional education of future pharmacists both nationally and internationally. In the past year alone, HPS – John Fawkner has assisted the development of eight pharmacy students, including two interns, enabling the students to learn 'on-the job' as they rotate between each of HPS Pharmacies' Victorian sites. HPS Pharmacies has a strong intern program, and I am pleased to announce that two of our interns, Stephen Hon and Yuan Jun Lieu, have passed their final exams and can now work at HPS as qualified pharmacists. Congratulations Stephen and Yuan!

Capecitabine (Xeloda®) for the Treatment of Metastatic Colorectal Cancer

Catherine Treuel, Pharmacist
HPS – Sunnybank, Sunnybank Private Hospital, Queensland

Capecitabine (brand name Xeloda®, Roche Products) is available on the PBS for the treatment of metastatic colorectal cancer (MCC). Capecitabine is an oral medication that when used in combination with intravenous oxaliplatin forms the cytotoxic protocol commonly known as XELOX. XELOX offers several advantages over other more established regimens for MCC.

Almost a third of patients with colorectal cancer have metastatic disease at the time of diagnosis. Another quarter of patients with colorectal cancer will go on to develop MCC. The prognosis for patients with MCC is fairly limited. Chemotherapy can increase time to disease progression and prolong survival.

Capecitabine is an alternative to infused fluorouracil (5-FU), a very effective agent used in many protocols for MCC. Capecitabine is a prodrug which was designed to undergo a three step enzymatic conversion to deliver 5-FU selectively to tumour sites over healthy tissue. Clinical evidence for capecitabine has shown it to have a similar efficacy and a reduced toxicity when compared to 5-FU.

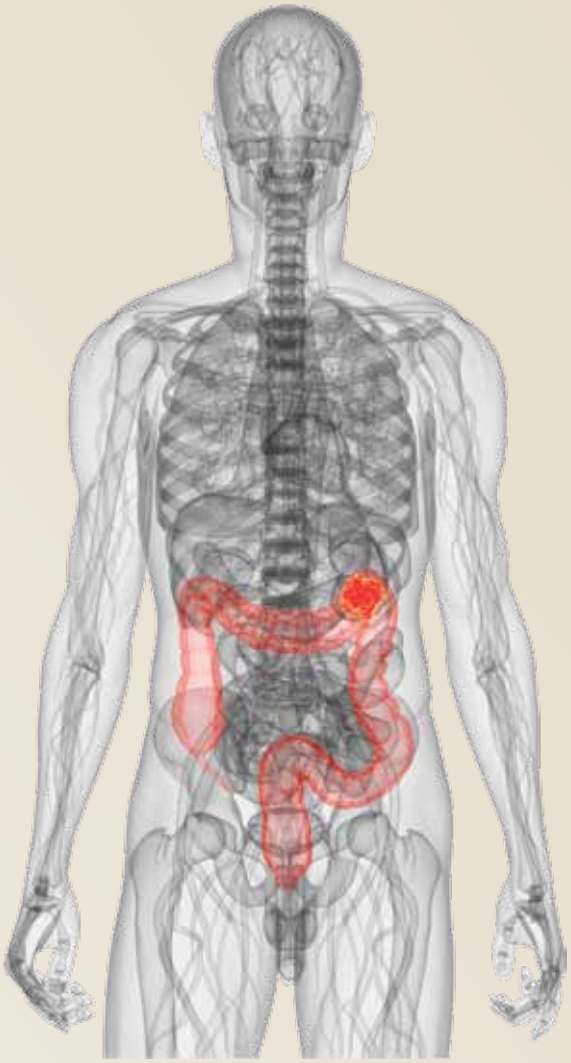
Many studies have investigated the efficacy of capecitabine compared to 5-FU in combination with oxaliplatin. Oxaliplatin and 5-FU form the cytotoxic protocol FOLFOX. There are various versions of this protocol which consists of an intravenous infusion of oxaliplatin, followed by an injection of 5-FU. The patient is then connected to a continuous infusion of 5-FU which ensures the constant delivery of intravenous 5-FU over one or two days depending on the protocol. FOLFOX4 and FOLFOX6 are two commonly used versions of FOLFOX as shown in Table 1.

Protocol	Day 1	Day 2	Day 3
FOLFOX4 (Repeated every 2 weeks)	Oxaliplatin infusion	Disconnect 5-FU infusion	
	5-FU injection	5-FU injection	
	5-FU continuous infusion	Connect 5-FU infusion	Disconnect 5-FU infusion
FOLFOX6 (Repeated every 2 weeks)	Oxaliplatin infusion		
	5-FU injection		
	5-FU continuous infusion		

Table 1. FOLFOX protocols.

FOLFOX6 involves one continuous infusion which lasts two days whereas FOLFOX4 requires the patient to return to the clinic on day 2 for another 5-FU injection, and then a second 5-FU infusion is connected. FOLFOX is repeated every two weeks.

In order to compare the efficacy of capecitabine with 5-FU in FOLFOX, the protocol XELOX was created. XELOX consists of an oxaliplatin



intravenous infusion on day 1 of every third week. Capecitabine tablets are taken twice a day for the first fourteen days of each three weekly cycle as shown in Table 2.

Protocol	Day 1	Day 1 to 14
XELOX (Repeated every 3 weeks)	Oxaliplatin infusion	Capecitabine tablets taken twice a day

Table 2. XELOX protocol.

In several clinical trials, XELOX has been shown to have similar efficacy to FOLFOX regimens in both the first and second line setting. Outcomes investigated include response rate, progression free survival, and overall survival. XELOX has been found to have efficacy comparative to the FOLFOX regimens as well as several advantages. XELOX only requires one clinic visit every three weeks for a two hour infusion of oxaliplatin. By comparison, FOLFOX requires two or three clinic visits for each fortnightly cycle. Therefore XELOX has a reduced impact on patients' daily lives. An indwelling central venous catheter is usually required for the administration of infused 5-FU which can lead to many complications including thrombosis and infection. These ports may not be required in a patient receiving XELOX which can be advantageous. Also, in studies capecitabine caused less grade 3 and 4 neutropenia, granulocytopenia and febrile neutropenia when compared with FOLFOX. There was however more grade 3 diarrhoea and hand-foot syndrome in the XELOX group.

Although there are benefits to using XELOX, this protocol may not be appropriate for some patients, for example those who are unable to be compliant with the capecitabine regimen. Capecitabine does interact with some medications including warfarin and phenytoin which is another consideration. Dose reduction may be required in elderly patients, and for those with renal impairment. Also, many clinicians may favour FOLFOX which has proven successful for many patients over many years. In some of the clinical trials, the survival results were slightly lower in the XELOX arm than the FOLFOX treatment groups although these results were not statistically significant.

Substitution of 5-FU with capecitabine has been used successfully in many protocols for the treatment of several types of cancer, but has not yet given definitive results for some protocols. FOLFIRI, a protocol which is similar to FOLFOX but with intravenous irinotecan used instead of oxaliplatin is also used for MCC. Clinical trials of capecitabine substitution in FOLFIRI have shown more toxicity and worse outcomes, although further investigation is necessary. Therefore, capecitabine may not always be an appropriate substitute for 5-FU.

More regimen options allow doctors and patients to find the most appropriate treatment choice to suit an individual's circumstances. Capecitabine is a useful substitute for 5-FU and the XELOX protocol offers many advantages.

References for this article can be found on page 30.

Early Access Protocol (EAP) on Abiraterone

Ricky Che, Pharmacist In-Charge
HPS – Pacific Private, Pacific Private Hospital, Queensland

A report on Protocol 212082PCR3001 - An Open Label Study of Abiraterone Acetate in Subjects with Metastatic Castration-Resistant Prostate Cancer Who Have Progressed After Taxane-Based Chemotherapy. This study is sponsored by Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

This is an open label, Early Access Protocol (EAP) which means that abiraterone acetate may be made available to patients with metastatic castration-resistant prostate cancer (CRPC) but who, for any reason, are not eligible for controlled clinical trial. It is anticipated that approximately 5,000 subjects will participate in this study worldwide. The purpose of this study is to collect information on adverse events (side effects) that occur during treatment with abiraterone acetate in patients with CRPC. To participate in this study, patients must have failed 1 or 2 chemotherapy regimens (1 of which contained a taxane such as docetaxel). Subjects must reside in areas where abiraterone acetate is not yet available through local healthcare providers. They must also not be eligible for enrolment into an available ongoing clinical study of abiraterone acetate.

The prostate is the gland below a man's bladder that produces fluid for semen. Prostate cancer is the second most common cause of death from cancer in men of all ages, although it is rare in men younger than 40. Prostate specific antigen (PSA) is often high in men with prostate cancer. However, PSA can also be high with other prostate conditions. Since the PSA test became common, most prostate cancers are found before they cause symptoms. Symptoms of prostate cancer may include problems passing urine, such as pain, difficulty starting or stopping the stream, or dribbling; low back pain; and pain with ejaculation. Prostate cancer treatment often depends on the stage of the cancer. How fast the cancer grows and how different it is from surrounding tissue helps determine the stage. Treatment may include surgery, radiation therapy, chemotherapy or control of hormones that affect the cancer. Very slow growing tumours may not require active treatment especially with little or no symptoms.

Patients selected for this study will be treated with abiraterone acetate and prednisone (or prednisolone) daily until progression of clinical disease (i.e. includes signs of clinical disease progression and/or clinical disease progression confirmed by radiographic and prostate-specific antigen [PSA] test results). Other reasons for discontinuation of treatment may include adverse events reported, initiation of other anticancer therapies, or the patient's inability to comply with dosing instructions. Patients will be followed for 30 days after the discontinuation of treatment with abiraterone acetate.

Patients will take four 250mg tablets (1000mg) of abiraterone acetate orally per day at least 1 hour before a meal or 2 hours after a meal any time up to 10pm everyday. Patients will also take 5mg of oral prednisone (prednisolone), twice daily. Each treatment cycle consists of 28 days and patients will take abiraterone acetate continually on a daily basis until disease progression is observed at which time abiraterone acetate will be discontinued and the dose of prednisone (prednisolone) reduced if clinically indicated.

The trial co-ordinator will conduct site visits; the initial site visit at Pacific Private Hospital having been on 9th December 2011. Interim monitoring visits will be scheduled every 17 weeks approximately. At the end of the study, or if the study or site is terminated early, a close-out visit will also be performed.

HPS will be responsible for ordering, receiving the material, storage of material under stated conditions, e.g. in this study, abiraterone acetate will be stored between 15º to 30ºC, maintain a temperature log daily and records for all supplies and receipts must be kept accordingly; including any destruction of abiraterone acetate.

Clinical trials and related schemes such as this early access program are very important in the advances of medicinal treatments. Clinical trials are designed at various stages of product development to determine an agent's effectiveness in the targeted disease; dose or dosage range including dose adjustments; and safety profile in a very stringent manner. Early access programs or drug familiarisation programs are made available to give specific types of patients access to a drug under development but close to marketing and/or those marketed very recently, where patients will otherwise not be able to obtain them. In this case, HPS Pharmacies is pleased to participate in helping make this drug available to a very specific group of patients whose treatment options are fast running out.

References for this article can be found on page 30.

Models in photograph are used for illustrative purposes only.

Agomelatine

For The Treatment of Major Depression in Adults Including Prevention of Relapse

Dina Dinh, Clinical Pharmacist
HPS – Melbourne Private, Melbourne Private Hospital, Victoria

Agomelatine (Valdoxan®, Servier) is a novel anti-depressant which was approved in 2010 by the Australian TGA for the treatment and prevention of relapse of major depression in adults. It was given marketing authorisation in the European Union in 2009 and is, interestingly, still undergoing phase three clinical trials in the USA.

Major depressive disorder (MDD) is the most commonly diagnosed depressive disorder based on criteria set out by the current Diagnostic and Statistical Manual of Mental Disorders and the International Classification of Diseases. Antidepressant agents are primarily indicated for the treatment of MDD, however, the spectrum of their use has been extended to other conditions such as generalised anxiety disorder, obsessive-compulsive disorder, panic disorder and some types of pain e.g. neuropathic.

The pathophysiology of depression is complex and whilst the monoamine hypothesis – the deficit in the functioning or amount of monoamines – still remains central to the understanding of the biology of depression, it is believed that there are also neurotrophic and endocrine factors – the neurotrophic hypothesis – which are also thought to be involved in the pathophysiology.

Most antidepressants work by increasing the level of monoamine neurotransmission, mainly serotonin, noradrenaline and dopamine, in the central nervous system. Classes of drugs indicated in MDD include selective serotonin reuptake inhibitors (SSRI), serotonin-noradrenaline reuptake inhibitors (SNRI), tricyclic, tetracyclic, and unicyclic antidepressants, and monoamine oxidase inhibitors.

Agomelatine is a naphthalenic compound with structural similarities to melatonin as shown in Figure 1.

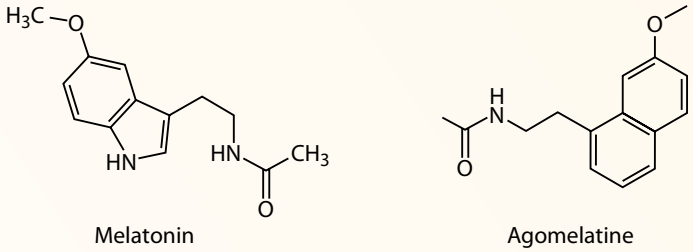


Figure 1. Structural comparison of melatonin and agomelatine.

Agomelatine differs from traditional antidepressants through its agonist actions at the melatonin M_1 and M_2 receptors, along with its antagonist effects at the serotonin $5HT_{2C}$ receptor. The agonist effects on the M_1 and M_2 receptors alone are not sufficient to have an antidepressant effect, but the combination of antagonist action at the serotonin $5HT_{2C}$ receptor has shown to produce a synergistic effect.

The agonist effects at the melatonin receptors are thought to restore normal circadian rhythms. Disturbances in circadian rhythms accompany endogenous depression in humans as well as being observed in animal models of depression. The $5HT_{2C}$ antagonist effect stimulates the release of dopamine and noradrenaline. Unlike many other antidepressants, there is no affect on serotonin release.

A 6 week, double-blind, randomised clinical trial concluded that agomelatine was significantly more efficacious than placebo. Depressed mood and sleep were also significantly improved and a similar safety profile was demonstrated. A second study comparing agomelatine and venlafaxine concluded that agomelatine seemed to be

an efficacious antidepressant, but with a better sexual side effect profile than venlafaxine.

A third study evaluating longer term treatment followed patients with MDD who responded to an 8 or 10 week course of agomelatine. These patients were randomly assigned to receive ongoing treatment with either agomelatine or placebo for a further 24 weeks. This randomised, double-blind trial found the incidence of relapse was lower with the agomelatine group when compared with placebo. The study confirmed that agomelatine is both safe and efficacious, as seen in other short term studies. It also identified that fewer early relapses were observed in those patients switched to placebo. The authors suggest that the underlying properties of the illness are reflected by the lack of discontinuation syndrome after agomelatine withdrawal, which can occur when stopping or reducing the dose of psychotropic medication.

Agomelatine appears to have a favourable side effect profile as demonstrated in several studies, where there was no clinically significant effect on QT interval, heart rate, blood pressure, or ECG tracings. Trials on agomelatine also showed no effect on body weight, and that the onset and quality of sleep were significantly improved.

Sexual side effects are particularly common with the standard antidepressants available on the market. In contrast to SSRI and SNRIs, agomelatine appeared to show no deleterious effects on sexual function in the clinical trials conducted. The favourable side effect profile may be due to the novel mode of action of agomelatine. The fact that it has a selective binding profile, and does not induce serotonin release or increase extracellular serotonin levels may attribute to its greater patient tolerance. As the majority of studies have only shown the adverse effects of agomelatine with relatively short term use, further information on the side effect profile with long term use will need to be obtained through post-marketing surveillance studies.

Agomelatine is rapidly and well absorbed after oral administration. The absolute bioavailability is low and there is substantial interindividual variability, with increases shown from concomitant smoking and oral contraceptives.

Metabolism is mostly via hepatic cytrochrome CYP1A2 and to a smaller extent CYP2C9 and CYP2C19. Caution should be exercised in patients taking other drugs that interact with these isoenzymes. Co-administration with potent CYP1A2 inhibitors such as fluvoxamine and ciprofloxacin is contraindicated. Fluvoxamine has been demonstrated to noticeably inhibit its metabolism, hence increasing agomelatine levels.

Liver function tests should be performed in all patients at the initiation of treatment; at approximately six, twelve, twenty four weeks, and when clinically indicated thereafter. Studies demonstrated that there were elevations of serum transaminases and upon discontinuation of therapy, levels usually returned to normal. Patients with a history of consuming large amounts of alcohol or taking drugs which may affect hepatic function should be prescribed agomelatine with caution.

The recommended dose of agomelatine is 25mg taken orally at bedtime which may be increased to 50mg after two weeks if there is no clinical improvement in symptoms. The manufacturer recommends that patients are treated for a period of at least 6 months (in line with the clinical trial conducted on relapse prevention) to ensure they remain symptom free. Currently, agomelatine is not listed on the PBS.

Agomelatine has been shown to be an efficacious antidepressant, and given its favourable side effect profile, as well as the lack of discontinuation symptoms with abrupt withdrawal, it is perhaps a good alternative choice for clinicians in the treatment of MDD.

References for this article can be found on page 30.

Systemic Lupus Erythematosus

Sharon Anderson, Clinical Pharmacist
HPS – Modbury, Modbury Hospital, South Australia

Systemic Lupus Erythematosus (SLE) is a chronic, relapsing multisystem disorder of connective tissue, probably of autoimmune origin.

SLE occurs primarily in women (90%) of child bearing age (80%), but can occur at any age (including neonates). It is far more common in non-Europeans.

Genetic, viral, stress, hormonal factors, exposure to UV light, and pregnancy appear to contribute to its onset. Some patients with gynaecological or lung cancers develop SLE. Drugs such as hydralazine, procainamide, ß blockers, isoniazid, and chlorpromazine may produce a benign SLE-like syndrome, which resolves on withdrawal of the drug.

The onset may be acute (with fever) or insidious (over months or years). Manifestations may occur in any area of the body, the more common being the skin, joints and bones, the kidneys, vascular system, heart, lungs, spleen, and Central Nervous System (CNS). Inflammation, pain, and organ damage result. Early menopause, miscarriage, and preterm deliveries also occur.

The more common forms are milder and if the acute phase is well controlled. The survival rate in Australia is over 90%, however, depending on what organ is being attacked by the autoimmune system, the disease may be life-threatening. The course is unpredictable.

In some patients the symptoms subside after the first presentation, others have periods of remission punctuated by 'flares', whereas others are continually unwell. There is currently no cure.

Diagnosis can be difficult and take years, as symptoms can be vague and variable and can mimic other disorders.

Symptoms include:

- Facial rash (present in 65% of patients). The Latin word lupus (meaning 'wolf') indicates the similarity between the rash and the facial markings of a wolf.
- Joint and muscle pain (present in 90% of patients, especially in the wrists, hands and feet). The joints are not usually deformed.
- Nephritis (in 80% of patients). This is sometimes the only presenting symptom.
- Leukopenia, thrombocytopenia, anaemia, thrombosis.
- Oral and mucosal lesions, Reynaud's phenomenon, and alopecia.
- Persistent high body temperature.
- Chest pain (due to pericarditis or pleurisy).
- Depression, interrupted sleep, seizures, visual disturbances, personality changes, impairment of cognition.
- Unrelenting fatigue.

Laboratory tests include:

- Anti-nuclear antibody (ANA) levels are raised in 95% of patients. However high ANA levels also occur in patients with rheumatoid arthritis, malignancies, and in some unaffected relatives of SLE patients.
- Anti-double stranded antibodies are highly specific for SLE as lupus macrophages attack the DNA in the cell nucleus. However these are only present in 25 to 30% of patients.
- There are increased erythrocyte sedimentation rate and decreased complement (C3 and C4) levels whilst active disease is present.

The diagnosis of SLE should also include assessment of renal function, and testing for leukopenia, thrombocytopenia and lymphopenia.

About 5 to 10% of patients show a false positive test to Syphilis.

Management of SLE involves multiple approaches and long-term lifestyle changes. Patients are generally managed by a GP and rheumatologist, with other specialties being involved as necessary. In addition to organ damage, issues of pain, fatigue, emotion and sleep must be addressed. UV exposure should be minimised. Physical activity should be encouraged as SLE patients are susceptible to cardiac disease

and osteoporosis. The quality of life can be improved by flare prevention – warning signs include increasing fatigue, pain, rash, fever, abdominal discomfort. Organ (particularly renal) transplant is employed. There are anecdotal reports of successful autologous stem cell recycling. Support groups are of use to some patients.

Medication can alleviate symptoms and help to control the over-active immune response. Treatment often consists of more than one of the following categories:

Anti-inflammatories decrease the production of prostaglandins which cause inflammation. NSAIDS such as ibuprofen together with analgesia are useful for joint pain, headache and pleurisy. The main side-effects are gastrointestinal, but in addition hypertension, and fluid retention may occur. COX-2 inhibitors such as celecoxib have been reported in recent studies as causing increases in heart attack and stroke. As patients with SLE are at an increased risk of renal and cardiac disease, these agents should be used with caution.

Antimalarials such as hydroxychloroquine produce anti-inflammatory and possible immunosuppressive effects, and are less toxic than other medications. In addition to alleviating skin and joint problems, they reduce the likelihood of flares and are often taken continuously. They may take 2 to 6 months before any benefit is seen. Side effects include phototoxicity, gastrointestinal upset, and rarely retinal toxity. Regular eye examinations are recommended.

Corticosteroids such as oral prednisolone are prescribed to about half of SLE patients. A short reducing course is highly effective in suppressing flares with skin and joint involvement. Long term treatment is employed for those with organ damage. Topical steroids such as betamethasone and triamcinolone are prescribed to treat small lesions but should not be used excessively on the face. Triamcinolone is sometimes used intradermally and intraarticularly. In SLE affectecing the CNS and other crises, methylprednisolone IV for 3 days can be used. The well-known side effects of corticosteroids are proportional to the dose and duration of treatment and include thinning of the skin and bones, weight gain and increased risks of diabetes, hyptertension, cataracts and infection.

Immunosuppressants decrease the activity of the immune system. They include methotrexate, cyclosporin, mycophenolate, leflunomide and azathioprine and are sometimes given together. It may take several months to see improvements. Side effects include liver, renal and pulmonary damge and the recognised consequences of immunosuppression. Hence their use is usually reserved for severe organ-threatening disease such as of the CNS, liver and kidneys, and as steroid-sparing agents. Due to suppression of healthy dividing blood cells, regular blood counts are necessary.

Biological disease modifying antirheumatic agents (bDMARDS) are humanised monoclonal antibodies that bind to the surface of normal and rogue B lymphocytes and other macrophages, resulting in their lysis. Normal B lymphocytes start to regrow about 6 months after the cessation of treatment. Rituximab is used off-label in Australia for lupus nephritis. A study in 2005 showed that a single dose could relieve symptoms of SLE for up to 12 months, but may take up to 2 years to deliver a completed response. Belimumab was approved by the FDA in March 2011 and is currently under consideration by the TGA. Side effects of bDMARDs include cardiac and pulmonary damage, and there is a risk of reactivation of hepatitis B, tuberculosis and of other infections.

Immunoglobulin Alpha (IGa) is present in high levels in patients with SLE in repsonse to immune stimulation. Anti-IGa agents are currently in clinical trial. The key issue is likely to be safety, as IGa plays key roles in viral immunity and tumour suppression.

Research continues to determine the specific mechanisms of autoimmunity and inflammation to better target drug therapies which do not suppress the entire immune system.

References for this article can be found on page 30.

HPS Pharmacies' Continuing Professional Development for Oncology Pharmacists

Ricky Che, Pharmacist In-Charge
HPS – Pacific Private, Pacific Private Hospital, Queensland

Continuing Professional Development (CPD) is an essential part of the pharmacy profession. The National Pharmacy Registration and Accreditation Scheme have laid out the requirements of CPD for pharmacist registration. Detailed information can be obtained from *www.pharmacyboard.gov.au/Registration-Standards.aspx* and the Society of Hospital Pharmacists of Australia website (*cpd.shpa.org.au/*).

CPD is classified into 3 groups:

Passive Learning
Reading journals, and attending lectures or conferences is regarded as passive learning (Group 1) activities and earn 1 point per hour of activity. Reading articles published in HPS Pharmacies' publications Newsline, and Drugline, or attending our lectures also contribute to these activities.

Active Learning
This sort of learning requires assessment. HPS pharmacists who present lectures to our client nurses can be considered as demonstrating knowledge improvement, and so the time taken to learn and prepare a lecture (but not the time to present) is equivalent to the active learning of Group 2 and earns 2 points per hour.

Providing Learning
Those pharmacists who research and write for the HPS Lecture Program facilitate knowledge improvement for the pharmacists who present them, and earn the right to 3 points for each hour of research and preparation. Contributors of articles for publishing in Newsline, Drugline, and in HPS' internal publication arena also provide education as well as satisfying the criteria of having their publication peer reviewed, and can claim 3 points per hour.

Pharmacists will require 30 CPD credits this period ending 30th September 2012, increasing to 40 CPD credits from 30th September 2013 onwards. Group 1 credits can only count up to a maximum of 50% of the total credits with the rest made up of Group 2 or Group 2 and 3 credits. With that in mind, HPS Pharmacies' oncology pharmacists have had discussions regarding how we can introduce an education element into our Oncology Focus Group meetings and at the same time capture some CPD credits.

Essentially, we are planning to step further from "journal club" type group discussion, where members all read and discuss interesting or relevant articles, and create some challenges to test our knowledge and learning; using a format to enable relevant CPD credits required for our annual registration to be claimed. After much discussion, we felt that the best way is to have two pharmacists prepare assessments on articles on a particular theme. One pharmacist will be working on the main body of the chosen theme and the other will be looking at specific aspects or specific types of treatment or drugs used. At the same time, both pharmacists will stimulate each other's thought process and give each other ideas as well as keeping each other on the task. Stephanie Tieu and I created the first session with the title "Maintenance Treatment of Metastatic Non-Small Cell Carcinoma (NSCLC)" with Stephanie focusing on the use of Tyrosine Kinase Inhibitors (TKI) in NSCLC. We followed the format used by other accredited bodies; that is by using a combination of multiple choice and worded questions. Participants answering the

questions and attaining over 80% correct answers will gain Group 2 points, otherwise, Group 1 points may be recorded. The authors who facilitate can then record Group 3 points. We have also agreed that we will have flexibility in the way we deliver the clinical education session so each oncology pharmacist can further develop their own style of writing and facilitating skills. As this is our first such official CPD session, we hope to further strengthen our skill base and continue to develop a robust process for the CPD sessions so that we have confidence that the CPD credits we claim will withstand audit by the Pharmacy Board of Australia. Figure 1 shows a short abstract from our chosen articles and sample questions.

I am optimistic that going through this process will not only help keep HPS Pharmacies' oncology pharmacists abreast of current research but also let us reflect on our own practices, and at the same time allow us to record CPD credits for registration. Once we have developed this into the required standard, we will have the potential to extend CPD support to HPS clients and their staff.

Extract 1: *"Therapies that have been studied in this setting in randomised trials to date include chemotherapy, molecularly targeted agents and immunotherapy approaches. Following the development of multiple new agents that show activity in NSCLC, and have a tolerable side-effect profile, there has been increasing interest in utilising them to maintain response to initial therapy after treatment with platinum-based doublets."*

Coate LE, Shepherd FA. Maintenance Therapy in Advanced Non-small Cell Lung Cancer Evolution, Tolerability and Outcomes. *Ther Adv Med Oncol.* 2011; 3(3):139-157.

Extract 2: *"In recent years, the epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs), gefitinib and erlotinib, which have promising activity and a favourable toxicity profile, have been used in the management of advanced non-small cell lung cancer (NSCLC)."*

Lin CC, Yang JC. Optimal Management of Patients with Non-Small Cell Lung Cancer and Epidermal Growth Factor Receptor Mutations. *Drugs* 2011; 71(1):79-88.

Sample questions:

1. Which of the following is not a suitable agent for single agent maintenance therapy in metastatic NSCLC?

A – carboplatin
B – pemetrexed
C – docetaxel
D – vinorelbine

2. The subtype of patients who benefit most from erlotinib are:

A – patients who show CR / PR with initial chemotherapy
B – patients who showed SD with initial chemotherapy

Figure 1: Article Extracts and Sample Questions.

Syndromes & Symptoms
Myelodysplastic Syndromes and Azacitidine

Jean Ang, Oncology Pharmacist
HPS – Alexander Avenue, South Australia

Myelodysplastic syndromes (MDS), formerly known as preleukaemia, are a group of disorders of haematopoiesis which lead to ineffective production of the myeloid blood cells in the bone marrow. MDS is not a common blood disorder. The incidence of MDS is highest among older people, with the median age of diagnosis in the range of 65 to 70 years old. According to the PBS website, there were 972 cases of MDS (4.6 per 100,000 head of population) reported in Australia in 2004. It is believe that this figure is underestimating the incident of MDS as patients who present with early stage of disease may fail to be investigated for other bone marrow abnormalities.

In normal blood cell development, bone marrow produces blood stem cells which then differentiate into 3 types of blood cells – red blood cells (RBCs), white blood cells (WBCs), and platelets. In MDS, stem cells are unable to produce healthy blood cells. The stem cells are either dying too early, or multiplying too quickly, causing too many abnormal cells in the bone marrow, yet not enough healthy blood cells in the circulation. Prognosis for MDS varies from patient to patient. Some high risk patients may progress into leukaemia and live only a few months. In most patients the cause of MDS remains unknown, however MDS can develop as a result of chemotherapy, radiation, or exposure to certain chemicals such as benzene. Patients with MDS usually present with symptoms such as anaemia, neutropenia, and thrombocytopenia. MDS can be diagnosed with a complete blood count, bone marrow biopsy, and chromosome testing.

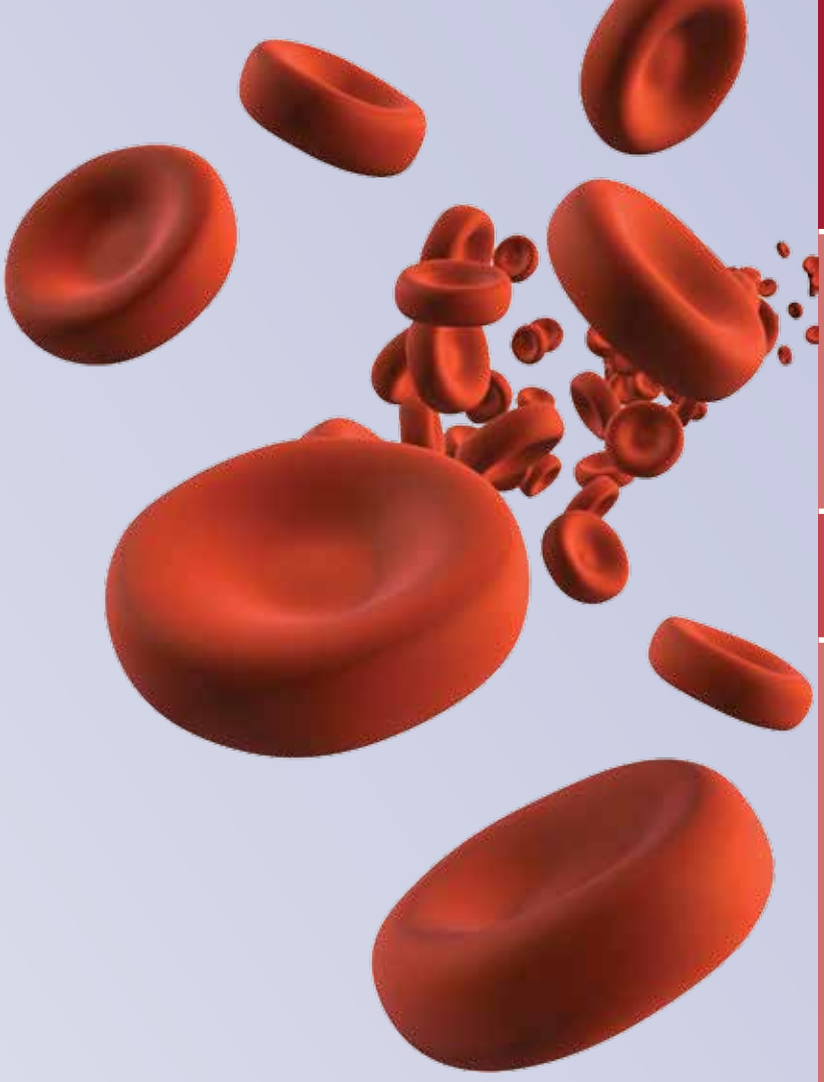
There are 3 ways to classify MDS: the French-American-British (FAB) classification system, the World Health Organisation (WHO) classification system, and the International Prognostic Scoring System (IPSS), this last being used by the Pharmaceutical Benefits Advisory Committee in Australia to set the criteria for PBS reimbursement of azacitidine.

IPSS uses cell type and blood counts of MDS patients to predict the prognosis of the disease, separates patients into lower-risk and higher-risks categories, and hence is able to assist doctors to determine a treatment plan for each patient.

There are two ways to treat MDS: supportive care and active treatment. Some of the signs and symptoms of MDS can be managed with supportive care, e.g. blood transfusions, growth factors and antibiotics. These methods can only lessen MDS symptoms and not treat the underlying disease. Blood transfusion can cause iron overload, transfusion related reactions, and infection. Growth factors such as erythropoietin (EPO) and granulocyte colony-stimulating factor (G-CSF) may help to generate more RBCs and WBCs respectively. Antibiotics may help to prevent or control infection.

Active treatments aim to control progression of the disease and lessen MDS symptoms. The active treatments include drug therapy (azacitidine), bone marrow transplant, and stem cell transplant.

Azacitdine is a chemical analogue of cytidine, a nucleoside found in DNA and RNA. It acts as a false substrate and potent inhibitor of methyltransferase, and hence inhibits cell growth by inhibiting DNA methylation. Azacitidine (Vidaza®, Celgene) is the first drug approved by the US Food and Drug Administration (FDA) for the treatment of all 5 FAB subtypes of MDS. Pierre Fenaux et al have demonstrated that azacitidine is the first drug therapy to significantly prolong survival in higher risk MDS patients versus supportive care (24.5 vs 15 months, P = 0.0001). The PBAC (September 2009



extraordinary meeting) recommended the listing of azacitidine on the PBS from 1st February 2011 as a Section 100 listing for the treatment of MDS in patients who meet the authority criteria: MDS intermediate-2 or high risk according to the IPSS, Chronic Myelomonocytic Leukaemia and Acute Myeloid Leukaemia.

The recommended starting dose of azacitidine for the first treatment cycle for all patients regardless of baseline haematology results is 75mg/m^2 daily for 7 days, subcutaneously (SC) or intravenously (IV), and repeated every 28 days. Some institutions follow the 5-2-2 rule where azacitidine is given for 5 days, 2 days break on the weekend then treatment is continued for another 2 days. Lyons et al evaluated 3 different azacitidine SC dosing regimens (azacitidine 75mg/m^2 5-2-2, azacitidine 50mg/m^2 5-2-5, azacitidine 75mg/m^2 5) in patients with MDS. In this Phase 2 study, Lyons concluded that "all three alternative dosing regimens produced haematologic improvement, RBC transfusion independence, and safety responses consistent with the currently approved azacitidine 7 days regimen. These results support azacitidine benefits in transfusion-dependent lower-risk MDS patients."

Side effects of azacitdine after subcutaneous injection may include nausea, vomiting, anaemia, thrombocytopenia, fever, diarrhoea, constipation neutropenia and injection site related reactions. Side effects for an intravenous infusion are similar to subcutaneous injection with the addition of small reddish-purple spots on the body, chills, weakness, and hypokalaemia. Other rare side effects may occur as well such as dizziness, chest pain, febrile neutropenia, myalgia, and malaise. Premedication for nausea and vomiting is required and $5HT_3$ antagonists are usually prescribed for this purpose. Patients may experience a transient drop in blood cell counts during the first few cycle of treatment, but the levels should begin to rise thereafter and the need of blood transfusion may be decreased. The dose can be increased to 100mg/m^2 if no beneficial effect is observed after two treatment cycles and if no toxicity other than nausea and vomiting is experienced. Treatment should be continued as long as the patient continues to benefit from azacitidine, and is recommended to be for a minimum of 4 to 6 cycles.

References for this article can be found on page 30.

Hospital Lecture Series
Prevention and Management of Stroke

Alan Yip, Clinical Pharmacist (Rehabilitation)
HPS – Alexander Avenue, South Australia

Stroke is the second leading cause of death (behind coronary heart disease) and is a leading cause of disability in Australia. There are approximately 60,000 new and recurrent strokes per year, where 20% of victims will die within one month, and 33% will die within a year. Approximately 1 in 6 patients who survive the first 2 days of a first stroke will have another over the next 5 years and as such secondary prevention plays an important role in minimising recurrent stroke risk.

There are a number of risk factors for stroke, many also associated with coronary heart disease, including but not limited to atrial fibrillation (AF), previous TIA / stroke, hypertension, smoking and diabetes. Effective lifestyle modifications such as smoking cessation, regular physical activity and a balanced diet are critical not only in reducing cardiovascular risk but also stroke risk. They are beneficial in both primary and secondary stroke prevention.

Patients with non-valvular **atrial fibrillation** have a stroke risk of between 2-18% per year, in which the CHADS2 index is used as a stroke risk stratification tool to determine the type of antithrombotic therapy used. A CHADS2 score ≥2 suggests high risk whilst a CHADS2 score of 1 and 0 suggests moderate and low risk respectively. The choice of antithrombotic therapy is based on a subjective assessment of relative benefits and harms, patient preference, access to INR monitoring and other factors (i.e. drug interactions).

A **transient ischaemic attack (TIA)** may be otherwise known as a minor or 'mini' stroke. The causes and symptoms of a minor ischaemic stroke and TIA are very similar. There is a significant risk of stroke within the first 48 hours post-TIA (5%), increasing to 10% at 2 weeks and then approximately 5-7% per year. As such, pharmacological therapy used in secondary stroke prevention should also be used in patients with TIAs. The ABCD tool is a prognostic indicator of the risk of subsequent stroke after TIA and has a maximum score of 7, where an ABCD score > 3 suggests high risk. The ABCD score should be considered in addition to other factors that precipitate the patient to be at high stroke risk including tight carotid stenosis, a new diagnosis of AF, or ≥2 TIAs (crescendo TIA) within the last week. Patients identified as high risk should be referred for urgent medical attention.

Antiplatelet therapy is indicated for patients who have an ischaemic stroke or TIA, where aspirin, clopidogrel, and dipyridamole with aspirin SR are available. It may also be considered in high-risk patients with AF where anticoagulant therapy is contraindicated. The use of antiplatelet therapy in 1,000 patients over 3 years is associated with 25 fewer stroke recurrences and thus all eligible patients should be on long term antiplatelet therapy (if not on anticoagulants).

Aspirin may be used as initial antiplatelet therapy, and it reduces the risk of subsequent strokes by 13%. Aspirin with dipyridamole SR reduces the relative risk of subsequent non-fatal stroke by 23% compared to aspirin therapy alone. It does not cause more bleeding than aspirin however adverse effects include headaches, hypotension, tachycardia and gastrointestinal adverse effects such as diarrhoea, nausea, and vomiting. It should be used with caution in those with unstable angina and recent MI as it may lead to vasodilatation-induced MI.

Clopidogrel is used as initial antiplatelet therapy for those unable to tolerate other antiplatelets and has a similar efficacy to aspirin with dipyridamole SR in preventing subsequent stroke with comparable bleeding risk. The combination of aspirin and clopidogrel is not recommended for post ischaemic stroke of TIA in patients who do not have co-existing acute coronary syndrome or a recent coronary stent. This combination is no more effective than clopidogrel alone in reducing secondary stroke risk but causes more life-threatening bleeds, nor is it a safer or more effective alternative to warfarin in people with AF.

Long term anticoagulant therapy should be used in patients with ischaemic stroke, TIA who have AF, or cardioembolic stroke (CHADS2 score ≥2). **Warfarin** reduces relative risk of subsequent strokes in non-valvular AF by 48% compared to aspirin; however it is associated with an increased absolute risk of major bleeding of 0.5-1% per year, increasing to13% in the first year of treatment for those ≥80 years. INR should be maintained within the therapeutic range more than 60-70% of the time to achieve overall benefits. **Dabigatran** is approved for preventing stroke in patients with non-valvular AF and at least 1 additional risk factor for stroke.

Major bleeding rates are similar between dabigatran and warfarin, however there is an increased risk of GI symptoms (dyspepsia) and major GI bleeds associated with dabigatran. Dose of 150mg BD reduces absolute risk of stroke or systemic embolism by 0.6% / year compared to warfarin whilst dose of 110mg BD is equivalent. Dabigatran does not have a specific antidote (unlike warfarin) and it should be avoided if a patient is suspected to be non-compliant as it can't be monitored. Moreover, patients taking warfarin with consistently therapeutic INRs may not benefit from a switch to dabigatran. If switching, stop warfarin and wait until INR < 2 before commencing dabigatran.

Dabigatran may be considered for;

(1) warfarin-treated patients who find it difficult to maintain a therapeutic INR,

(2) those at increased drug-drug or drug-food interactions with warfarin, and

(3) when INR monitoring is difficult or impractical.

Contraindications include: severe renal impairment, bleeding disorder, GI haemorrhage within 12 months, liver disease or severe hepatic impairment, uncontrolled hypertension, and concurrent commencement of verapamil therapy. The capsule should be swallowed whole with food as breaking, chewing or emptying the contents increases bleeding risk by increasing dose absorbed. The recommended dose of dabigatran is 150mg BD, but reduced to 110mg BD for patients ≥75 years old, who have moderate renal impairment, or who are at higher risk of major bleeding.

Only 72% of eligible patients are discharged from hospital on **blood pressure** (BP)-lowering medications although hypertension is a major risk factor for first and subsequent strokes, both ischaemic and haemorrhagic. Patients who are normotensive still benefit from a lower BP, with a 30% reduced odds of recurrent stroke, thus all stroke and TIA patients should receive BP-lowering medications (unless contraindicated by symptomatic hypotension). **ACE-Inhibitors** (alone or in combination with a diuretic) are recommended as first line therapy, however most antihypertensives are effective (except beta blockers).

The evidence for the management of **diabetes** is based on primary prevention however optimal control of blood glucose provides additional secondary prevention measures for stroke recurrence.

Lipid-lowering therapy should be used for all patients with ischaemic stroke or TIA, however only 77% of eligible ischaemic stroke patients are currently discharged from hospital on lipid-lowering therapy. **Statin** therapy reduces the odds of subsequent ischaemic stroke by 20%, but should not be routinely used for haemorrhagic stroke unless additional vascular risk factors are present (i.e. diabetes, ischaemic heart disease) due to increased haemorrhagic stroke risk.

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Dominic Coppola
Partner/Regional Operations Manager, SA/NSW/WA
t (08) 8193 9100

Alan Tuxford
Regional Operations Manager, VIC/TAS/QLD
t (03) 9627 8800