HPS Celebrating 40 years of pharmacy services

Autumn/Winter 2014

Newsline

Clinical contribution by HPS Pharmacies

Special 40 Year Anniversary Edition

HPS Pharmacies

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HPS Pharmacies' Special 40 Year Anniversary Edition

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HPS works to enable the delivery of premium pharmacy services to hospitals and other institutions, by its network of approved pharmacies. HPS Pharmacies are approved and regulated pharmacy businesses, operating under the HPS banner.

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Message from Tony Wyatt CEO

It is with great enthusiasm that I wish to announce that in 2014, HPS is celebrating its 40th year of business. It is an important time to reflect upon the growth and progress of HPS in those years and it fills me with pride to be a part of the successful company we have built. Our vision to provide the highest quality service has remained uncompromised and this dedication to excellence is what has allowed HPS to become the strong market leaders we are today. I wish to thank, on behalf of HPS, all of our clients, patients, suppliers and employees for their important roles in the success of the company.

The retrospective look at HPS' history on page 6 provides insightful reflection into the progress made over the years. From servicing 28 beds to thousands, HPS has experienced exponential growth and made many positive impacts on the industry.

Our commitment to continuous improvement is further highlighted by the reappointment of Dr Andrew Holsman as Chairman of the HPS Board. Dr Holsman's commitment to quality has provided HPS with a path of unparalleled innovation. Additionally, we are welcoming James Joughin to HPS with his appointment as a non-executive member of the Board. We look forward to James' contributions to HPS that is built on a foundation of business knowledge created with 28 years of corporate experience. The HPS community is applauding these appointments as they demonstrate a pro-active approach by HPS to improving our internal infrastructure ensuring sustainable and achievable growth for the future. To read more, please turn to page 10.

We are very excited about what the future holds for HPS and I am sure that the next forty years will continue to be as productive and fulfilling. As we celebrate an important milestone for HPS, I look forward to continuing this journey together.

Tony Wyatt
Partner / Chief Executive Officer

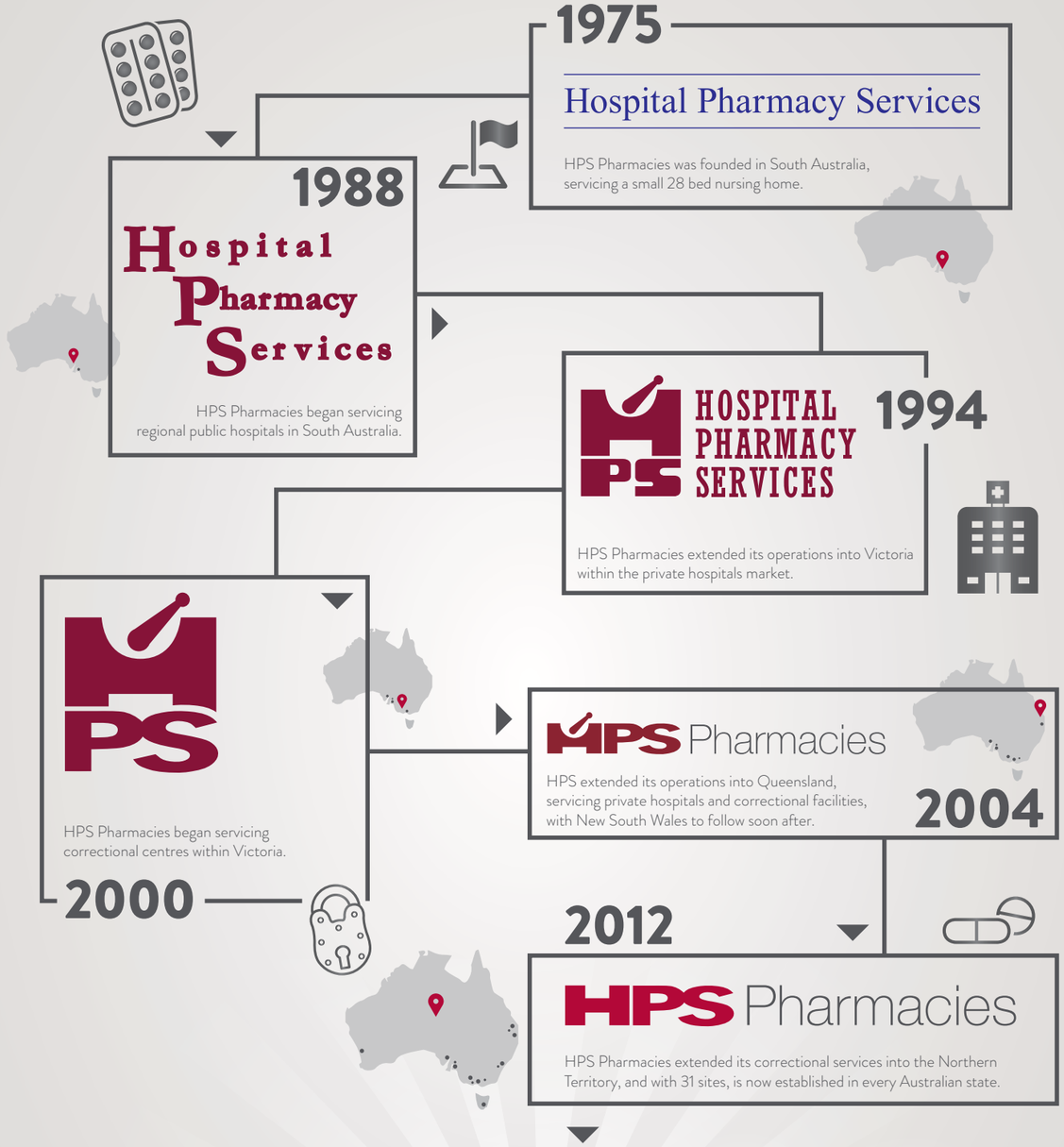
Message from Steve Yeo COO

As we welcome the second half of 2014, HPS and its network of pharmacies moves forward with renewed determination in the exploration for greater strategic growth. Integral to our growth are our partnerships with clients and suppliers. It is on this note that I am pleased to announce the extension of HPS' partnership with Symbion. As the preferred wholesaler of pharmaceuticals to HPS and its network of pharmacies, our relationship with Symbion is one that is imperative. Symbion are a growing national healthcare company which are equally dedicated to providing the highest quality. The partnership is built on a mutual commitment to long-term growth and a shared vision of innovation. With this shared vision we look forward to a future of continued success with Symbion and a path to further growth. To read more about this partnership, please turn to page 8.

HPS' relationship with our valued clients is further enhanced with our annual Procurement event. As Nicki Jackson discusses on page 12, the event is a very important part of the HPS calendar and provides an opportunity to solidify our supplier arrangements for the year ahead. Additionally, HPS is investing further into its development, with the appointment of Murray Outram to the newly created position of Executive Director – Human Resources. Murray is responsible for overseeing the strategic management of HR and enhancing leadership skills across the business. Senior appointments such as this are critical for sustainable growth within HPS and represent an investment to the development of our human capital, in-line with the core values of HPS.

With continued investments in our supplier and staff relationships, the future is promising for HPS and its clients and I look forward to sharing with you our upcoming developments as they unfold throughout the year.

Steve Yeo
Chief Operating Officer



HPS Celebrating 40 years of pharmacy services

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HPS Celebrates 40 Years Providing Quality Pharmacy Services

HPS Pharmacies can trace its roots back to a small community pharmacy servicing one 28 bed nursing home; 40 years later HPS and its network of pharmacies employs 400 staff, has over 280 valued clients and services thousands of hospital beds around Australia. This year marks the company's 40th anniversary and "is an opportunity to reflect on the last 40 years and a time to look ahead to the future and continue this momentum we have built" says HPS' Chief Executive Officer, Tony Wyatt.

Over 40 years, HPS Pharmacies has delivered unwavering commitment to a vision "to be the leading provider of innovative pharmaceutical services and solutions". From being an early adopter of computer dispensing technology in the 1970's, to designing and programming an electronic stock management system in the 1980's, the last 40 years for HPS Pharmacies have produced numerous ground-breaking systems. "Our systems and innovations are a culmination of HPS' unparalleled knowledge and experience within the pharmacy industry" says Ian Bell, Chief Information Officer.

HPS and its network of pharmacies are celebrating this milestone with an emphasis on the future. The business is positioned to continue adding to the positive impacts it has made over the last four decades with equal dedication, focus and energy. The strong position HPS holds as the market leader reflects the influence that a clear vision of innovation can yield. HPS and its network of pharmacies are dedicated to continuing their delivery of innovative solutions to fulfil client needs. As the industry has evolved, HPS has displayed a commitment to continuous improvement to remain not only up to date, but at the forefront of innovation. "In the coming 40 years, HPS and its network of pharmacies will continue this philosophy with the ever present priority of our valued clients in mind" says Tony.

Tony looks forward to the enthusiasm this milestone brings to the company. "Such a momentous anniversary like this is a testament to the company. With this occasion comes a sense of celebration and a renewed focus on our long-term vision with fresh eagerness".

Only four years after inception, HPS Pharmacies accepted an invitation to manage the pharmacy at Ashford Hospital, the company's first private hospital pharmacy. In 1986 the first oncology client was introduced to the group, in what would be the beginning of a strong oncology suite.

Janene Garde, Clinical Publicist, who joined HPS Pharmacies 30 years ago as the first of its 12 Partners to join the company, attributes this growth to a pioneering philosophy. "HPS Pharmacies' innovative approach to problem solving to meet the needs of clients during the financial downturn of the 1980's put HPS Pharmacies in high demand and generated many referrals from satisfied clients".

In 1988, HPS Pharmacies serviced its first public hospital in regional South Australia with the service goal to "offer pharmacy care to small rural facilities at a standard that can be compared favourably with teaching hospitals" says Janene. In the mid 1990's, HPS Pharmacies also began to expand interstate, extending to the Victorian private hospitals market. Following this, HPS Pharmacies experienced exponential growth and began to include correctional facilities, IVF clinics and veterinary clinics in its portfolio.

The knowledge and expertise gained over the past 40 years has placed the company in great stead to continue to make significant contributions to the industry.

Tony Wyatt, on behalf of HPS and its network of pharmacies, "would like to take this opportunity to thank our clients, patients, and suppliers for their ongoing support over the last 40 years and I look forward to continuing our successful partnerships in the future".

> *"In the coming 40 years, HPS and its network of pharmacies will continue this philosophy with the ever present priority of our valued clients in mind..."*
>
> – Tony Wyatt, Chief Executive Officer, HPS

HPS and Symbion Continue to Foster Valuable Partnership

> *We have grown together and have developed a strong trust in each other based upon open and honest communication…*
>
> – Dean Martin, National Manager of Hospitals, Symbion

HPS is excited to announce the continuation of its long-standing partnership with national healthcare company, Symbion. HPS has recently renewed its contract with Symbion for an extended term in order to continue collaboratively supporting client and patient needs to the highest standard.

Symbion is a large and growing national healthcare company which encompasses numerous facets of the industry including pharmacy services, hospital services and consumer products. Symbion's heritage can be attributed to a single retail pharmacy based in Adelaide in 1845 and was established with a direction to stand the test of time.

Nicki Jackson, National Procurement & Contracts Manager at HPS, works closely with Symbion. "The agreement we have with Symbion is the product of years of investment into the relationship; one which I look forward to continuing and strengthening over the coming years".

For several years, Symbion has been the preferred wholesaler of pharmaceutical products to HPS and its network of pharmacies. The success of this contract is built on shared values and an utmost dedication to patient care, as Dean Martin, National Manager of Hospitals at Symbion, has expressed. "We both have a deep commitment to the hospital pharmacy industry. We have grown together and have developed a strong trust in each other based upon open and honest communication".

Symbion support HPS and its network of pharmacies in the delivery of pharmacy services through several means. Optimisation of deliveries to its dispensaries nationally allow HPS to meet the needs of patients in the most efficient and timely manner. The after-hours and urgent patient care which HPS and its network of pharmacies delivers to its clients is facilitated with equal commitment by Symbion.

Steve Yeo, Chief Operating Officer at HPS is elated with the contract renewal. "Symbion have been an instrumental business partner during HPS' highly successful growth phase, and this relationship remains a key foundation piece to the success story that is HPS. Our strong partnership with Symbion has enabled HPS to develop and provide the highest quality pharmacy service that Australian healthcare providers need and expect".

HPS is committed to providing a consistently high quality of service to its clients; in an ever evolving industry, the quarantine methods Symbion has in place are integral in aiding HPS in this service. With Symbion, HPS and its network of pharmacies can pro-actively plan for potential drug shortages to ensure sufficient stock for our valued clients to continue operating at full capacity.

Both Symbion and HPS have a strong culture in innovation which highlights the mutual benefits of the partnership. Patrick Davies, Chief Executive Officer at Symbion acknowledges the importance in this shared focus. "Supporting the growth of HPS will drive our development and help retain our leading position in this dynamic market. We can only achieve this through strong partnerships with innovative customers like HPS".

Symbion's commitment to HPS is further evidenced by the ongoing support of HPS' internal management programs. The HPS annual Management Group Conference is sponsored by Symbion, and allows HPS' national management teams to meet together for strategy discussion and professional development programs.

HPS and its network of pharmacies is anticipating another productive, meaningful term with Symbion and looks forward to continuing to deliver the highest quality of client and patient value through the collaboration. With a shared long-term view, Symbion and HPS will continue to work together to further strengthen their market leading positions.

This page: Patrick Davies, Chief Executive Officer at Symbion with Tony Wyatt, Partner/Chief Executive Officer at HPS

Inset: Jason Cattonar, Chief Financial Officer at HPS; Tony Wyatt; Patrick Davies; Dean Martin, National Manager of Hospitals at Symbion and Steve Yeo, Chief Operating Officer at HPS.

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This page: James Joughin, Non-Executive Director; Dr Andrew Holsman, Chairman of the Board and Tony Wyatt, Partner/Chief Executive Officer at HPS – Corporate Office, South Australia.

Strengthening HPS' Governing Board to Reinforce an Era of Exceptional Growth

HPS has witnessed significant growth in the past year brought about by the opening of six new sites across the country. To sustain focus and continue HPS' charter for growth, investments in key areas of the business have been made. Subsequently, HPS' governing Board has reappointed Dr Andrew Holsman as Chairman for a further two year term, and appointed James Joughin as the first Non-Executive Director to the Board.

Dr Andrew Holsman has been an outstanding mentor, leading the corporate governance of HPS for six years and bringing the business into an era of exceptional growth. With over thirty years' experience in senior management and management consulting, of which 20 years were spent as a partner at Ernst & Young, Dr Holsman has established corporate procedures which strengthened risk management, accountability and governance standards. For Dr Holsman it has been a rewarding journey with promise for continued expansion on the horizon.

"HPS has grown from strength to strength in the past six years and I look forward to the prospects a further two year term brings, and hope I can continue to guide HPS towards greater success".

> *"HPS Pharmacies has grown from strength to strength in the past six years as a result of the strong community who work tirelessly to ensure the business exceeds industry standards..."*
>
> – Dr Andrew Holsman, Chairman of the HPS Board

The Board and Executive team are delighted with Andrew's reappointment as Chairman, and are confident the business will continue on its path of sustainability and evolution. Chief Executive Officer, Tony Wyatt, envisions a future of continued innovation under Andrew's guidance.

"Andrew continues to deliver a drive for innovation having helped build the foundations in which HPS thrive. HPS' position as industry leader could not have been achieved without the ingenuity and commitment to excellence delivered by Andrew. I speak on behalf of the HPS community in congratulating Andrew on his reappointment and express our excitement for the next two years".

To complement the capabilities of Dr Andrew Holsman, James Joughin is welcomed to the HPS Board with his wealth of experience and astute knowledge of business practices. James brings more than 28 years of corporate finance expertise, particularly in areas such as growth strategy and improving shareholder value. His profound understanding of Board responsibilities will provide further guidance on the future of HPS' corporate leadership. James is eager to collaborate with the Board to bring HPS' charter for growth to fruition.

"HPS has achieved significant success and I hope to employ my knowledge to streamline business practices and add further value to current and future projects".

Tony applauds James' appointment to the HPS Board as a fitting accompaniment to HPS' plans for strengthened leadership strategies.

"As HPS look to a future of strategic expansion, James provides a stable foundation of business knowledge and will assist in fostering HPS' relationship with our esteemed shareholders. HPS welcomes James to the community and we look forward to the new opportunities he will bring".

The combined depth and experience in strategic management and innovation brought by Dr Andrew Holsman and James Joughin will be invaluable as HPS continues its charter for growth with this further investment in developing a strong foundation from which to operate in the future.

From The Team

Zeyad Ibrahim

National Oncology Manager

HPS is committed to continuous quality improvement to ensure services to clients are delivered using innovative processes that emerge from leading industry research in-line with best-practice standards. As part of HPS' dedication to quality and excellence, and in-line with recommendations distilled from the latest industry research, HPS continues to deliver enhancements around its oncology service to the direct benefit of our valued clients and our patients.

In support of this focus, HPS Pharmacies' dedicated oncology team has worked with a number of clients to develop and implement service solutions designed to alleviate the on-site storage pressures often associated with fast moving products. These pressures typically arise due to the limited refrigeration space available within the client's facility and a need to have the patient specific products available at the point of service immediately following a medication request. Therefore HPS' oncology team has delivered solutions providing a more balanced approach to storage through the utilisation of both refrigerated and non-refrigerated mechanisms, coupled with the introduction of innovative light sensitive bags for select products.

As industry leaders, the service HPS Pharmacies delivers to its clients extends well beyond the bounds of pharmacy and clinical support. At the forefront of innovation, HPS is committed to working collaboratively with its clients to deliver robust solutions to many of the daily operational issues encountered by staff within the facility.

Nicki Jackson

National Procurement and Contracts Manager

As we enter the second half of 2014 the Procurement team can reflect on a challenging period for HPS, as we worked efficiently to ensure the business focused upon the April changes to the Price Disclosure list. Despite the challenges involved, the Procurement team are confident the resulting discounted prices will further improve HPS' delivery of services to clients and their patients.

In the midst of a busy term, the Procurement team were once more involved in HPS' highly successful Orderbook Summit, held in Adelaide earlier this year. Aimed to further develop and strengthen the businesses' relationship with suppliers and provide renewed outcomes for future business, the annual summit again exceeded expectations, providing suppliers with access to HPS' national $100 million order book and cementing themselves as HPS' preferred supply partners.

A particularly exciting outcome of the summit was the signing of a new wholesaler agreement with long-term partner Symbion, acquiring supply for an additional term. Since the summit in February, Procurement has worked diligently to implement these new arrangements across the business to ensure the service and supply of major products to clients is further strengthened.

On behalf of the Procurement team and HPS, I extend my gratitude to our valued suppliers for their overwhelming support and contribution to the phenomenal success of HPS' 2014 Orderbook Summit. The Procurement team look forward to working closely together with clients in the future to support our growing business.

Murray Outram

Executive Director of Human Resources

I joined HPS as Executive Director – Human Resources in January. This role was established to further promote HPS' charter for growth by providing strategic Human Resources (HR) support to HPS' Executive team and Board through the design and implementation of robust HR initiatives to the business.

Drawing on my thirty-nine years of expertise across the healthcare, services, manufacturing, and mining industries, and supported by an experienced and talented HR team, we will further enhance and foster the development of leadership, advance our management capabilities, facilitate the development of staff and simplify internal HR systems and processes across the business. As part of this progression, the HR function has been restructured to reflect a business partnership model in order to provide a single point of contact for employees within each region regarding all HR related matters.

In March, HPS' 2014 Employee Engagement Survey was distributed internally to gauge the current level of satisfaction across our entire workforce. Following an unprecedented 94% response rate, I am exceptionally pleased with the positive results and strong level of engagement across the business, and in line with our commitment to continuous improvement, we have commenced work to act upon the feedback received.

The coming months are particularly exciting for HPS' HR team with many of the projects on the HR Strategic Plan coming to fruition, further demonstrating our strong commitment to ongoing development to attract and retain our industry's leaders.

Vicki Poupoulas

Pharmacist In-Charge, HPS – Flinders

As Pharmacist In-Charge at HPS – Flinders, I am responsible for overseeing the day-to-day operations of the site and delivering on-site clinical pharmacy services to Flinders Private Hospital. The role is at the forefront of patient care, addressing immediate patients needs and facilitating direct collaboration with nursing staff.

Additionally, as the Quality Care Pharmacy Program (QCPP) Coordinator for HPS, my role involves regulating and implementing QCPP standards across all Section 90 licenced HPS sites. Recently, selected HPS sites in Victoria concluded their reaccreditation, achieving outstanding results. QCPP Accreditation under the program provides many benefits for both pharmacies and their patients, ultimately achieving patient confidence in their QCPP accredited pharmacy, knowing it is compliant with industry and professional standards.

Additionally, I am the Health and Safety Representative for South Australia, which involves representing the health and safety interests of workers in the SA work group (including Pharmacy Managers, Pharmacists In-Charge, Pharmacists and Technicians) and facilitating consultation and cooperation between parties. I also sit on the Workplace Health and Safety committee, working together to maintain our commitment to providing a safe and healthy workplace.

Looking ahead, I will be seconded to the role of Acting Pharmacy Manager at HPS – Alexander Avenue for nine months, and welcome the challenges and learning opportunities this will entail; delighted for the experience and exposure to participating in the optimisation of patient care practice in a variety of different ways.

Pharmacy Business

HPS' DrugAlerts Offer Unique Benefits to Clients

The industry's response to the recent suspected contamination of propofol injections has highlighted the contribution HPS' network of pharmacies makes to safe medicine management through its email bulletin *DrugAlert*, which swiftly and accurately notifies clients of drug supply or safety concerns.

Extending beyond the formal communications from the Government, *Therapeutic Goods Administration* (TGA), and distributors, HPS harnesses a nation-wide network of both client and teaching hospital practitioners, staff, and suppliers to facilitate the rapid dissemination of important medication issues as they surface. Notices about carbimazole and imipramine supplies have been a primary resource, generating direct enquiries from as far afield as England and Germany.

The topics communicated via *DrugAlert* are tailored to the services offered by HPS' clients, specifically focusing on those medicines that may impact ward operations. Early identification and communication of supply issues by HPS has often assisted HPS' clients to minimise the potential impact of stock shortages. Beyond detailing the medication advice, *DrugAlert* also provides guidance for managing the issue. This includes interim measures to source products, strategies such as accessing international brands through the *SAS* program (outlined in the Lecture Series article on page 26), or alternative products which may be used to meet patient needs.

This unique email service is available to HPS' clients, and those interested can subscribe via the HPS website homepage at http://www.hps.com.au

Good Medication Orders Get Better Results

Errors occur in the management of 5-20% of medications ordered in Australian hospitals; and up to 43% of these are preventable. An audit of medication charts in one NSW hospital confirmed these statistics, with "prescribing errors" and "prescription details incomplete" each contributing to around 13% of all clinical interventions.

Many of the "prescribing errors" related to the order not using the generic name. Proper implementation of the *National Inpatient Medication Chart*, which is mandatory for hospitals seeking accreditation, requires medicine names to be written in full using generic rather than brand names.

Prescribing using the generic drug name assists with:

- Reducing confusion between medications with names that sound-alike or look-alike
- Preventing and identifying duplicate orders of the same medication, and
- Identifying adverse drug reactions and class effects.

It should be noted that brand names vary between distributors, while generic names do not. Furthermore, generic names convey information about the class of medication, allowing staff to identify the indication and cross-check for unintended duplication, drug interactions, and allergies.

There are some exceptions, such as not allowing for interchange between the two brands of warfarin. In this case, medication orders should be written as: "*warfarin (Coumadin®)*" or "*warfarin (Marevan®)*". Including the brand name in the order may also be helpful to avoid confusion; for example *fluticasone/salmeterol 500/50micrograms (Seretide®)*, or *oxycodone 10mg (OxyContin®)*.

Of the "prescription details incomplete" errors, 17% related to the slow release box of the chart not being ticked. This indicated that the standard release form was to be administered, rather than the slow release form supplied. Ticking this box provides additional information that the dose must be swallowed without crushing, and to check carefully before breaking.

References for this article can be found in the online version published in the HPS Pharmacies Knowledge Centre, at http://www.hps.com.au

Duty of Care: Day Surgery

Patient commitment to day surgery is reflected in the national statistics, with around 1.34 million elective day procedures occurring within Australian private facilities annually.

The anxiety about the procedure that some patients may feel when admitted to hospital (that might define them as unwell) is decreased within day facilities. This ease contributes to the patient's eagerness to continue day to day activity promptly, such as trips to the local shops. Combined with the residual anaesthetic, patients may be overconfident in their ability to independently source the required medicines following discharge.

Desire to "just get home", late discharge, finding a pharmacy for patients who travelled, lack of money for those patients who followed instruction to "bring no valuables" to the procedure, and residual sedation may create barriers to sourcing prescribed medicines as planned. The *Australian and New Zealand College of Anaesthetists* advise that an anaesthetic may continue to affect the patient and inhibit driving ability for up to 24 hours, and occasionally longer. Their *Guidelines on Acute Pain Management* further states that "suitable analgesia should be provided for at least the first day after discharge with clear written instructions on how and when it should be used." As well as analgesia for both mild and stronger pain, day surgery patients may need a prophylactic antibiotic, and possibly a medicine targeted to the particular condition being treated.

HPS Pharmacies believe there is a duty of care to supply patients with all prescribed medicines upon discharge and is committed to working in partnership with clients to ensure this is achieved for all patients.

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AHPRA Examinations Measure Professional Pharmacy Standards

All candidates for Pharmacist Registration must undertake an oral examination to demonstrate their competency, based on standards set out in the *National Competency Standards Framework for Pharmacists in Australia*, November 2010.

As an *Australian Health Practitioner Regulation Agency* (AHPRA) Board Examiner, Sunny Rewal (Partner/Site Manager, HPS – Coburg) participates in the oral examinations in Victoria. The examination is designed to assess the candidate's knowledge, and his or her ability to apply that knowledge, by making sound judgments in practice situations.

Examiners must ensure the candidates seek to optimise therapy whilst minimising potential risks to the individuals, and do not cause harm to the patients in any of the exam scenarios. Examiners must remain neutral and are unable to provide feedback on the quality of the candidate's answers during the examination, including not giving any indication whether a question has been sufficiently dealt with.

Sunny has said candidates are generally nervous during the examination, but he tries to ensure they are calm and confident prior to commencement. He also says participation in the *AHPRA* Board Exams has provided an opportunity to establish networks with peers who have a wealth of knowledge and experience to share. It has also encouraged a deeper commitment to his own professional education, and the reward of contributing to his profession.

With the experience gained, Sunny hopes to contribute to further developing the HPS Pharmacies' Pharmacist Intern Program. Further instilling high competency will result in an enhanced quality of clinical service provision to all of HPS' valued clients.

Update on Treatments for Macular Degeneration

Tegan Asser, Locum Pharmacist
HPS – Alexander Avenue, South Australia

Age-related Macular Degeneration (AMD) is a significant cause of blindness in the elderly. AMD is characterised by progressive central vision loss, which is the part of vision critical to distinguishing fine detail. Loss of this vision restricts activities such as reading, driving, and facial recognition. AMD is a debilitating condition, which can lead to other problems such as an increased risk of falls, loss of independence, and the associated social and economic implications.

Understanding the pathogenesis of AMD has led to new, more targeted developments for treatment. AMD starts as a malfunction in the retinal pigment epithelium (RPE), which is the layer of epithelial cells between the retina and blood vessels. Normally the RPE allows nutrients and oxygen to pass from the blood to the retina, and allows waste products from the retina to be eliminated in the blood. When the RPE is not functioning properly, waste products collect and form deposits (drusen) under the RPE. This can cause the RPE cells to die, leading to loss of vision via two different mechanisms, categorised as either dry or wet AMD.

Dry AMD occurs when the death of RPE cells causes retina cells above that area to die, resulting in a missing section of the retina. Wet AMD occurs when the death of RPE cells allows blood vessels to grow into the retina, and blood leaks from vessels into the retina. The growth of these blood vessels into the retina is known as choroidal neovascularization (CNV). CNV is categorised as subfoveal, juxtafoveal or extrafoveal, depending on its distance from the fovea (central part of the macula). The protein primarily responsible for allowing blood to leak into the retina is vascular endothelial growth factor (VEGF).

There is currently no treatment for dry AMD, therefore the focus of this article is treatments for wet AMD. It is important to note that treatment options for wet AMD are not curative. Treatment can slow progression of the disease and maintain vision for longer. Hence, the earlier the disease is diagnosed, the better the outcome. Medication is the mainstay treatment for wet AMD, with the most commonly used treatments being anti-VEGF medications. These inhibit VEGF, and thus prevent blood leaking into the retina.

Anti-VEGF Medications

There are two anti-VEGF medications approved by the TGA; ranibizumab (Lucentis®) and aflibercept (Eylea®). Bevacizumab (Avastin®) and pegaptanib (Macugen®) are anti-VEGF medications which are not registered by the Therapeutic Goods Administration for the treatment of AMD, however they have been used off-label. Ranibizumab was shown to be statistically superior to placebo in two trials; 90-92% of patients treated with ranibizumab maintained vision at 24 months compared to 53% of patients treated with placebo. Vision maintenence is defined as a loss of less than 15 letters in visual acuity.

Aflibercept was compared to ranibizumab in a head-to-head trial, and was shown to be as effective as ranibizumab for the treatment of wet AMD. Post-marketing studies for both will be needed to determine benefit beyond 24 months.

Based on data from the clinical trials, the most common adverse effects were ocular effects, such as;

- Intraocular inflammation, vitritis, blepharitis
- Retinal or conjunctival haemorrhage, visual disturbance/floaters
- Eye pain, foreign body sensation in eyes
- Increased lacrimation or dry eye, eye pruritus
- Increased ocular pressure
- Vitreous detachment, and
- Headache (ranibizumab).

Both ranibizumab and aflibercept are administered intravitreally, so systemic absorbtion is minimal. After injection of a standard dose of aflibercept, the plasma concentration is estimated to be more than 50-fold less than the concentration needed to have a substantial systemic effect.

Similarly, the systemic concentration of ranibizumab after intravitreal administration is much lower than the concentration required to inhibit the biological activity of VEGF.

The recommended dose of ranibizumab is 0.5mg or 0.3mg given via a single monthly intravitreal injection. The efficacy and adverse effects were comparable for the 0.5mg group and the 0.3mg group in clinical trials. The recommended dose of aflibercept is one 2mg intravitreal injection monthly for three months, then one injection every two months. Both ranibizumab and aflibercept are listed on the *Pharmaceutical Benefits Scheme* (PBS) for the treatment of subfoveal CNV due to AMD, as the sole PBS-subsidised therapy.

Photodynamic Therapy

Photodynamic therapy (PDT) with verteporfin (Visudyne®) is another treatment option for wet AMD. Verteporfin is a photosensitiser with treatment consisting of two steps; firstly verteporfin is administered via an intravenous infusion, and then laser light is used to activate it within the affected area of the eye. Activated verteporfin causes damage to the neovascular endothelium leading to blood vessel occlusion. Damaged epithelium also releases procoagulant factors, resulting in platelet aggregation. The activated drug specifically targets rapidly dividing cells, as seen with CNV, due to the specific receptor mediated uptake mechanism. This limits damage to the surrounding tissue.

In one clinical trial, PDT with verteporfin was found to be superior to placebo, with vision maintained in 59% of patients (versus 31% with placebo) at 24 months. Anti-VEGF medications are usually used in preference, however, because vision is maintained from treatment initiation, whereas vision continues to deteriorate for six months before stabilising with PDT/verteporfin. One trial found ranibizumab was superior to PDT with verteporfin; vision was maintained in 90% of patients treated with ranibizumab, versus 66% treated with PDT with verteporfin, at 24 months.

Other Therapies

Anecortave acetate (Retaane®) is a synthetic analogue of cortisol which has no glucocorticoid activity. It inhibits angiogenesis (the growth of blood vessels) in the eye, through several mechanisms which may include suppression of certain extracellular proteinases, inhibition of VEGF and blocking proliferation of retinal endothelial cells. It is administered as a posterior juxtascleral depot injection, 15mg every six months. Clinical trials show anecortave acetate is superior to placebo in inhibiting vision loss, and vision is maintained in approximately 73% of patients at 24 months versus 47% for placebo. In one clinical trial, anecortave acetate was found to be less effective than PDT with verteporfin, however there are no head-to-head trials against the newer treatments.

Laser photocoagulation was the first treatment for AMD. A thin beam of high energy thermal light is directed at the retina, sealing and destroying leaking blood vessels. Although it has shown benefit in certain specific circumstances, it is generally not recommended due to an increased risk of vision loss immediately following the procedure. In addition, only 10-20% of patients with neovascular AMD have the specific circumstances necessary to benefit from laser coagulation.

Conclusion

AMD is a debilitating progressive disease which results in vision loss. Although there is currently no treatment for dry AMD, treatment for wet AMD has improved enormously in recent years. The anti-VEGF medications ranibizumab and aflibercept are now the mainstay treatments for wet AMD. They have demonstrated good efficacy, with minimal side effects or systemic absorbtion. As a result, wet AMD now has less of a negative impact on the quality of life of patients with this disease.

References for this article can be found in the online version published in the HPS Pharmacies Knowledge Centre.

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Community-acquired Pneumonia: Antibiotic Stewardship

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Editor's Note: The author wishes to acknowledge the contribution of Michael Soriano to this article.

As a result of the revision of *Therapeutic Guidelines: Antibiotic (Antibiotic Guidelines) Version 14* and the national move towards implementing antibiotic stewardship programs in hospitals, HPS Pharmacies undertook a project to improve the implementation of the recommendations of the *Antibiotic Guidelines* for the treatment of community-acquired pneumonia (CAP) in three client hospitals.

The potential benefits of improving concordance with the *Antibiotic Guidelines* include:

- Increasing the use of narrow spectrum antibiotics, particularly in the initial empiric treatment of CAP
- Reserving broad-spectrum antibiotics for more acutely ill patients
- More appropriate drug choices in the management of CAP and bronchitis
- Reducing the development of resistant organisms in the hospital setting, and
- Offering patients treatments which represent the most up-to-date evidence-based therapy, ultimately resulting in the highest standard of medical care and service.

A retrospective audit of 52 patients admitted to three hospitals with a presumptive diagnosis of CAP was performed to determine each hospital's concordance with the current *Antibiotic Guidelines* (refer to Table 1).

Audit

The audit involved inspecting patient case notes for evidence of:

- Antibiotic choice (guidelines recommend intravenous [IV] benzylpenicillin rather than ceftriaxone)
- Duration of treatment (maximum five days of IV therapy, or until patient shows signs of improvement), and
- Length of hospital stay.

Results

Of the patients reviewed, pneumonia severity scoring was not documented in any of the medical notes, and in fact, not all measurements were available to make scoring possible (especially blood pH and blood gases). This highlights the controversies surrounding the use of pneumonia severity indices.

Hospital A:

Of the 21 patients included in the audit, five (23.5%) had a documented penicillin allergy and were appropriately prescribed ceftriaxone, as advised by the *Antibiotic Guidelines*. The remaining 16 were not compliant, as ceftriaxone and azithromycin were prescribed in all cases, regardless of the numerous variables such as patient age, comorbidities, prescriber, prior antibiotic use, and pneumonia severity. This result showed an overall concordance with the *Antibiotic Guidelines* of 23.5% within this hospital.

Initial treatment was extended beyond the recommended seven days in nine cases, with three patients being further discordant by not progressing to oral therapy. Only five patients had successful sputum cultures, and were changed to targeted therapy, before transitioning to oral antibiotics as their condition improved, as recommended by the *Antibiotic Guidelines*.

The average duration of inpatient antibiotic treatment was five days (2-10 days) and outpatient antibiotic treatment was five days (0-14 days). The total average length of treatment was ten days, and length of stay was 8.3 days.

Hospital B:

Of the 19 patients, only one had a documented pneumonia severity score, which was performed within the emergency department of a public hospital.

Six out of ten patients transferred from public hospitals were empirically prescribed antibiotics in concordance with the *Antibiotic Guidelines*. Of these six patients; four were maintained on compliant regimes, one was swapped to ceftriaxone and azithromycin, and one patient received targeted therapy following blood cultures. The

Audit Criteria	Hospital A	Hospital B	Hospital C
Concordance to *Antibiotic Guidelines*	23.5%	31.6%	14.3%
Average length of inpatient treatment	5 days	5.6 days	8 days
Average length of outpatient treatment	5 days	7 days	4.6 days
Average length of stay	8.3 days	11.11 days	10 days

Table 1. Summary of CAP Audit Results

remaining four patients transferred from public hospitals had initiated on ceftriaxone and azithromycin. One patient was maintained on these drugs for four days and prescribed doxycycline thereafter; one patient was changed to targeted therapy in response to sputum cultures; and two were treated as if they had penicillin hypersensitivity without any accompanying documentation (one patient received moxifloxacin for eight days with no documentation of hypersensitivity to penicillin).

Of those nine patients admitted, two were admitted directly into the intensive care unit and received ciprofloxacin IV, whilst four were prescribed ceftriaxone and azithromycin in the wards. A further three patients were appropriately treated with targeted antibiotic regimes following sputum and blood analysis.

The results for these patients showed a 31.6% concordance with the *Antibiotic Guidelines*, and an average length of stay of 11.11 days. Inpatient and outpatient antibiotic treatments were on average 5.6 days (2-29 days) and seven days (5-42 days) respectively. The total average length of treatment was 12 days, however this was skewed by three patients who had complications. Without these patients, the concordance to the *Antibiotic Guidelines* was 33.3%, and the total lengths of treatment and stay would be marginally reduced.

Hospital C:

Audit criteria was met by seven cases over a six month period. None of the patients in these cases had recorded allergies to penicillin, hence did not justify the use of ceftriaxone instead of penicillin. Three patients had sputum samples tested during their admission.

Three of the seven patients were admitted from public hospitals, two of these had commenced antibiotic regimes including benzylpenicillin IV and azithromycin, which correlated with the *Antibiotic Guidelines*. One of these two patients was then changed to ceftriaxone and azithromycin. The other patient maintained the original regime for two days, before being swapped to amoxycillin and clavulanic acid. This patient developed a rash after a further two days, and then ceased all antibiotic treatment. The third patient admitted from a public hospital had received ceftriaxone, azithromycin and gentamicin, and continued on ceftriaxone and azithromycin after transfer to Hospital C.

The trend of using ceftriaxone and a macrolide antibiotic for the empirical treatment of presumed CAP was mirrored in all patients directly admitted to Hospital C, along with one patient admitted from a private hospital emergency department.

All three patients who had sputum tests grew mycoplasma, justifying the use of a macrolide in their antibiotic regime, and the only patient to require a quinolone antibiotic did so because of their inability to tolerate a macrolide beyond seven days of therapy.

This hospital showed a 14.3% concordance with the *Antibiotic Guidelines*, and an average length of stay of ten days. The average length of inpatient and outpatient antibiotic treatments were eight days (1-16 days) and 4.6 days respectively. The total average time of treatment was 12 days.

Recommendations

The inappropriate use of third generation cephalosporins, such as ceftriaxone, has been linked to the development of antibiotic induced diarrhoea and antimicrobial resistant infections, including *Methicillin-Resistant Staphylococcus Aureus (MRSA)*. These complications can extend a patient's hospital stay, as well as increasing the complexity of treating bacterial infections in the wider population. Local and international opinion leaders, including *The South Australian Expert Advisory Group on Antimicrobial Resistance (SAAGAR)* have expressed concern over the frequent use of third generation cephalosporins as empiric treatment for CAP and the potential for "collateral damage" with their use.

Hospitals are therefore recommended to develop a guideline for the treatment of CAP which includes a pneumonia severity score and an initial antibiotic management plan which aligns with the recommendations of the *Antibiotic Guidelines*.

Intravenous amoxycillin or benzylpenicillin must be used for the empiric treatment of moderate to severe CAP, unless the patient has a documented non-anaphylactic allergy to penicillin or has a creatinine clearance of less than 30mL/min. Quinolone antibiotics, such as moxifloxacin, should be reserved for the empiric treatment of CAP in those patients with a documented anaphylactic allergy to penicillin.

The duration of intravenous therapy should be reviewed at every change of the intravenous catheter, and clinical improvement should guide the change to oral therapy as soon as possible.

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Regional Anaesthesia and Pain Management

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Regional anaesthesia, also known as nerve block, is used to block the sensation in a specific part of the body during and after surgery.

A reliable method to prevent pain from becoming chronic involves using a regional anaesthetic technique to block a pain stimulus near its origin, thereby eliminating acute pain as a post-operative risk factor. Regional anaesthetic techniques can be divided into two categories; central and peripheral techniques. The central techniques include neuraxial blockade (e.g. epidural anaesthesia, and spinal anaesthesia). The peripheral techniques can be further divided into brachial plexus blocks and single nerve blocks.

The aim of acute pain management is to achieve a comfortable, mobile patient with a sedation score of less than two. Patients often experience pain in the post-operative period which, if uncontrolled, can be associated with increased morbidity. Body systems which can be compromised by inadequate pain control include the respiratory, cardiovascular, neuroendocrine, musculoskeletal and gastrointestinal systems. The psychological effects of pain should also be considered. When left untreated, pain can lead to fear and psychological distress related to the patient's concerns regarding disability, loss of income, and underlying illness.

Local anaesthetics are widely used for the management of acute pain resulting from surgical procedures and child birth. When local anaesthetics are injected or infused into specific sites, they provide a loss of sensation to that region by reversibly blocking the transfer of peripheral nerve stimulation in that part of the body. The effect may be gained from a local anaesthetic alone, or enhanced by combination with an analgesic (e.g. ropivacaine with fentanyl). Local anaesthetics may also be administered in a continuous infusion, over several days, for effective post-operative pain control.

Long-Acting Local Anaesthetics

Bupivacaine is a long-acting agent, but has a relatively high potential for cardiotoxicity. It is used for minor and major nerve blocks, spinal anaesthesia and epidurals.

Ropivacaine is a long-acting agent that is structurally related to bupivacaine and mepivacine. It was developed as a safer alternative to bupivacaine, and is less cardiotoxic when accidentally administered intravenously. It is used for minor (e.g. field blocks and infiltrations) and major (e.g. brachial plexus) nerve blocks, spinal anaesthesia, epidurals, continuous peripheral nerve blocks (e.g. knee arthroplasty) and wound infiltration. Ropivacaine is the only local anaesthetic indicated for continuous peripheral nerve blocks.

Levobupivacaine is used for minor and major nerve blocks, spinal anaesthesia, epidurals, and wound infiltration; and is also less cardiotoxic than bupivacaine.

Short-Acting Local Anaesthetics

Lignocaine is a short-acting local anaesthetic. It has inherent potency, rapid onset, and a medium duration of action. The addition of a vasoconstrictor agent (e.g. adrenaline) greatly extends the duration of its effect.

Prilocaine has a similar clinical profile to lignocaine in terms of speed of onset and duration of effect. However, it is absorbed more slowly due to its lesser vasodilation effect. It also has less central nervous system toxicity than lignocaine.

Topical Anaesthetics

For topical anaesthesia, a local anaesthetic is applied to an area of the body's surface in the form of a spray, cream, gel or solution (with the aim of blocking activity in the pain receptors of the superficial nerves that lie immediately below the surface). The choice of local anaesthetic depends on the region which needs to be anaesthetised (refer to Table 1).

Regional anaesthesia offers numerous advantages over conventional general anaesthesia, including faster recovery time, fewer side effects (less nausea and vomiting and fewer thromboembolic events), minimal post-operative pain and no need for an airway device during surgery, or need for an anaesthetist during minor procedures. Hospital stays can be significantly reduced and the overall costs are also reduced.

Form	Uses
Topical Lignocaine	
Spray, 10%	Surface anaesthesia of mucous membranes prior to: • Otorhinolaryngology • Dental procedures • Introducing instruments and catheters into the respiratory and digestive tracts, and • Obstetric procedures.
Special Adhesive, 10%	Surface anaesthesia of the gums prior to: • Injection • Scaling, and • Fitting new dentures or orthodontic appliances. Temporary relief of pain associated with removal of teeth.
Ointment, 5%	Temporary relief of pain associated with: • Minor burns and abrasions of the skin including sunburn, insect bites, pruritus and sore nipples. Anaesthesia of mucous membranes and anaesthetic lubricant during examination and instrumentation. Surface anaesthesia of the gums prior to: • Injection • Deep scaling, and • Fitting new dentures.
Topical Solution, 4%	Anaesthesia of mucous membranes of the oropharyngeal, tracheal and bronchial areas e.g. endotracheal intubation.
Viscous Solution, 2%	Surface anaesthesia and lubrication for exploratory procedures (e.g. gastroscopy and rectoscopy).
Topical Lignocaine/Prilocaine	
Cream, 5% Patch, 1g	Anaesthesia of the skin prior to: • Needle or catheter insertions (e.g. vaccinations, and blood sampling) • Superficial procedures, and • Minor cosmetic procedures. Anaesthesia of leg ulcers to assist debridement. Anaesthesia of genital skin prior to superficial surgical procedures or infiltration anaesthesia.

Table 1. Forms and Uses of Topical Lignocaine

The disadvantages of regional anaesthesia include a requirement for practice and skill in order to achieve the best results. Toxicity can occur if the local anaesthetic is given intravenously or if an overdose is injected. Some blocks require up to 30 minutes, or more, to be fully effective. Post-operative pain management may not always be effective, requiring the possible use of additional analgesia. There is also a risk of nerve damage, and the area where the nerve block was administered may be sore or tender for a few days.

Various types of regional block procedures are possible to achieve blockade of different regions of the body, for example:

Central blockade:

- *Spinal:* suitable for caesarean section and obstetric analgesia, hernia repair, hip and knee surgery, prostate surgery and most procedures on the foot or leg, and
- *Epidural:* suitable for labour pain, orthopaedic surgery, caesarean section, thoracic and breast surgery, gynaecological procedures and upper and lower abdominal procedures.

Upper extremities:

- *Brachial Plexus Blockade:* Interscalene block, Infraclavicular block, Supraclavicular block, Axillary block
- Wrist block, and
- Digital block.

Lower extremities:

- Sciatic nerve block, and
- Femoral nerve block.

Intravenous block:

- Bier's block.

After the block, verbal communication with the patient will often assist in identifying early signs of local anaesthetic toxicity (e.g. speech disturbances). Cardiovascular signs should be monitored. Rapid tachycardia will be detectable immediately if a solution containing adrenaline is accidentally injected intravenously.

Regional anaesthesia should only ever be conducted in an environment which is fully equipped and adequately staffed to provide safe general anaesthesia, should the need arise.

References for this article can be found in the online version published in the HPS Pharmacies Knowledge Centre.

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Medicines in Breastfeeding

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It is widely documented that breastfeeding provides babies with optimal nutrition. The formulation of breastmilk includes immune system components which provide the baby with a degree of immune protection, as well as all the baby's nutritional needs for the first six months of life. Other benefits for the baby include eyesight and cognitive development.

Breastfeeding is also very important in establishing the bond between mother and baby, and can aid maternal recovery in the post-partum period. Medicine use in the breastfeeding mother presents a unique dilemma to healthcare providers. The risks and benefits of the proposed medicine, to both mother and baby, must be carefully weighed in the context of the importance of continuing to breastfeed.

Factors Influencing Drug Transfer

The majority of drugs will inevitably pass into breastmilk to some extent, although the final concentration will vary widely between drugs. The mechanism of transfer between maternal serum and breastmilk is primarily through passive diffusion, that is, the passage of drug from a higher concentration in the maternal serum to a lower concentration in the breastmilk.

It is a common misconception that once present in breastmilk, drugs are 'caught' and any milk produced during the period of treatment must be discarded. This is not necessarily the case. In the same way drugs may passively pass into the breastmilk, they may pass back into the maternal serum for elimination when the maternal serum level lowers after a period of time.

There are several factors affecting how much drug will transfer into the breastmilk. Foremost of these is the concentration of the drug in the maternal serum, which itself is dictated by maternal drug absorption and elimination. Drugs which are poorly absorbed (or not absorbed at all) from the mother's gut will not pass into breastmilk (e.g. nystatin, psyllium, simethicone or sucralfate). Short half-life drugs will also pose a smaller risk to the baby as the drug will be eliminated quickly from maternal serum and expose the breastmilk to lower drug levels (e.g. lignocaine or permethrin).

The physical characteristics of each drug will also impact on its passive diffusion into breastmilk. Larger molecules (e.g. heparin or insulin), and drugs which are highly protein bound (e.g. phenytoin), are not physically able to pass into breastmilk. Low molecular weight drugs are much more likely to enter breastmilk. It is important to note there is increased permeability between the mammary alveolar cells in the first 72 hours post-partum. During this period, higher molecular weight drugs may pass through that may not be able to enter at a later stage.

The pH of each drug also will impact its concentration, as breastmilk is slightly acidic in comparison to blood. Ionisation of a weakly basic drug (e.g. erythromycin) occurs in breastmilk, which increases the drug's water solubility and inhibits its ability to pass back into the maternal serum.

Neonatal Considerations

Once a drug has passed into breastmilk and been ingested by the neonate, its clinical impact on the neonate depends on several factors. Firstly, the baby's exposure is reliant on the drug's absorption from the baby's gut. Drugs which have diffused into breastmilk after parenteral administration to the mother may be poorly absorbed orally by virtue of their physical characteristics. Examples include gentamicin, cefotaxime and adrenaline.

Secondly, the baby's ability to eliminate the drug will influence its overall effect. Neonatal kidney and liver functions are not as efficient as an adult's, which may cause drug accumulation. Furthermore, drugs which may have been safe for the mother to take during pregnancy may not be safe in breastfeeding. This is because, during pregnancy, elimination of the drug occurs through the mother's clearance systems, whereas after the birth the baby's systems alone must clear any drug passed through the milk.

Arguably the most important consideration in using drugs while breastfeeding is the degree of possible toxicity to the baby after exposure through breastmilk. Some drugs have a higher inherent potential for harm than others. Examples of drugs which should be avoided in breastfeeding for this reason are cytotoxics, cyclosporin, and ergotamine. Drugs which are routinely prescribed in higher doses to babies than they would be exposed to through breastmilk are unlikely to cause harm, although monitoring is recommended in these cases.

Maternal Considerations

Potential harm to the neonate is not the only reason certain drugs should be avoided in breastfeeding. A number of drugs impede the breastfeeding process itself by reducing milk production. These include pseudoephedrine, phenylephrine, diuretics, oestrogen, bromocriptine, and cabergoline.

General considerations for treatment of a breastfeeding mother include firstly avoiding drug therapy where alternatives are available, or if the drug is not clinically indicated. Consideration may also be given to interrupting breastfeeding if the course of treatment is less than 48 hours and the infant would be at risk from exposure. Resuming breastfeeding may be difficult if it is stopped for any longer than this. It may be useful for the mother to express and discard the milk during the interruption so her milk supply is not reduced. Interrupting breastfeeding may not be an option depending on the preferences of the mother, and the willingness of the infant to take a bottle.

Drug Selection and Dosing Guidelines

The following recommendations apply to drug selection for a breastfeeding mother:

- Use topical treatment where available (i.e. patches, inhalers, and creams)
- Use the safest drug within a therapeutic group, and one which is marketed for, or used in, infants under two years old (if applicable)
- Choose drugs with the shortest half-lives, highest molecular weight, or protein binding affinity
- Choose drugs with poor oral absorption
- Avoid newly marketed drugs
- Avoid the use of two or more drugs with similar adverse reactions, and
- Use the lowest dose which gives the desired outcome.

The risk to the infant may be further minimised by tailoring the dosage times with regard to feeding times. The timing of the drug's peak plasma level should be considered and breastfeeding should be avoided at this time. This may not be practical for babies who feed every couple of hours. Similarly, single daily dose preparations may be taken just before the infant's longest sleep interval to minimise the infant's exposure.

Conclusion

There are many variables to consider when treating breastfeeding mothers, and decisions must be made on a case-by-case basis. It is important to consider not only how much drug will pass into breastmilk, but also the magnitude of the potential impact the drug will have on the baby and/or the lactation process.

Treatment strategies must be individualised, with a view to minimising the risk to the infant and maintaining breastfeeding wherever possible. A strategy which enables the mother to receive appropriate treatment, while simultaneously allowing her to continue breastfeeding with minimal neonatal risk, will ensure optimal health outcomes for both the mother and baby.

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Irritable Bowel Syndrome: Symptoms, Causes and Treatments

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Symptoms of irritable bowel syndrome (IBS) will be experienced by one in five Australians during their lifetime, affecting women more often than men. It is important to note IBS does not cause lasting damage to the bowel or contribute to the development of more serious conditions, such as bowel cancer or colitis. The symptoms of IBS, however, are unpleasant and affect the sufferer's quality of life.

The onset of IBS often occurs in early adulthood; it is unusual for symptoms to first appear after 40 years of age. Symptoms of IBS include abdominal pain or cramping (which are often relieved by passing wind or faeces), abdominal bloating or distension, nausea, mucus in stools, altered stools (e.g. lumpy, hard, pellet-like, unformed), alternating diarrhoea and constipation, altered stool passage (e.g. straining or urgency), changes to frequency of defecation (more than three motions per day or less than three motions per week) and a sensation that bowels are not fully emptied after passing a motion.

There are three main categories of IBS: constipation predominant, diarrhoea predominant, and alternating between constipation and diarrhoea.

Causes of IBS

The causes of IBS are poorly understood, although it is thought intestinal dysmotility (abnormal contractions in the small and large bowel), visceral hypersensitivity, and psychosocial factors may contribute to symptoms through pathways mediated by serotonin and other enteric nervous system transmitters. Visceral hypersensitivity occurs when gastrointestinal processes (which are not normally perceived by individuals) are consciously experienced, and may be perceived as painful. A post-infective form of IBS exists where there is persistent inflammation of the colonic mucosa. This accounts for approximately 25% of diagnosed IBS cases. Strong emotions such as anxiety or depression can also affect the nerves of the bowel in susceptible people, causing IBS symptoms.

Food intolerances can trigger IBS and are usually the result of the impaired absorption of sugars found in foods. FODMAP is an acronym for fermentable oligosaccharides, disaccharides, monosaccharides and polyols; which are a group of sugars that are poorly absorbed by some people. When sugar molecules are poorly absorbed in the small intestine, they continue along the digestive tract, where they become a food source for the bacteria that colonise the large intestine. The bacteria digest and ferment these sugars which can cause IBS symptoms. Examples of these sugars are fructans and galactans (oligosaccharides), lactose (disaccharide), fructose (monosaccharide), sorbitol, mannitol, maltitol, xylitol and isomalt (polyols). Other dietary triggers may include fat, fibre, alcohol and caffeine.

Medications may also cause symptoms similar to IBS, such as constipation or diarrhoea as a side-effect. These symptoms are generally resolved if the offending medication is ceased or changed to another agent without the same side-effect profile.

Diagnosis of IBS

Diagnosing IBS is difficult as the symptoms experienced are not exclusive to IBS. Other illnesses such as diverticulitis, inflammatory bowel disease, coeliac disease, and polyps should be excluded. This may involve blood tests, stool tests and investigation of the bowel lining (by sigmoidoscopy, colonoscopy or barium enema).

For a diagnosis of IBS to be made the patient must have the presence of unexplained abdominal discomfort or pain for at least 12 weeks in the last 12 months (not necessarily consecutive), with at least two of the following three features:

- Pain is relieved by defecation
- Onset of pain is associated with a change in bowel frequency (either diarrhoea or constipation), or
- Onset of pain is associated with a change in the form of the stool (loose, watery or pellet-like).

Due to malabsorption of sugars, some food intolerances can be identified by breath hydrogen methane testing (more information can be found at <http://shepherdworks.com.au/disease-information/hydrogen-breath-testing>); this can be useful if food intolerance is the suspected cause of symptoms.

Treatment of IBS

There is no cure for IBS, and treatment involves identifying and avoiding triggers. This can include stress management, dietary, and lifestyle modification. Some people with IBS have associated depression or anxiety, the recognition and treatment of which may lead to the resolution of abdominal symptoms. Medications are helpful only for the minority of patients and are used to manage symptoms.

Identifying dietary triggers of IBS can be difficult, as the time taken for symptoms to appear after an offending food has been ingested varies, and is not always immediate. Symptoms may also last for some days. The process of identifying causative foods is best done under the supervision of a dietician. This usually involves keeping a food and symptom diary, and a systematic process of eliminating and reintroducing foods one at a time to see how symptoms respond.

If causative foods are identified, sufferers can reduce or eliminate their intake of these to reduce symptoms. Other dietary measures include reducing dietary intake of known gas producing food such as beans, lentils, brussel sprouts, onion, cauliflower and cabbage.

A minority of patients with IBS respond to medication. For exacerbation of diarrhoea the *Therapeutic Guidelines: Gastrointestinal* recommends trialling loperamide or cholestyramine. Other references also recommend trialling Lomotil® (diphenoxylate and atropine).

The *Therapeutic Guidelines: Gastrointestinal* recommends symptoms of constipation be treated in the same way as constipation in general. Initial measures are increasing dietary fibre, fluid intake and exercise. Laxatives which increase the bulk of the stools, stimulating the bowels to open, may be trialled if initial measures prove ineffective. These include Agiofibe®, Fybogel®, Metamucil®, and Normafibe®. It is important the patient also has an adequate fluid intake to avoid stools becoming hard.

Bulk-forming agents are not always effective, even for mild constipation, and may increase flatulence and bloating for some patients. Osmotic laxatives (e.g. sorbitol [check for malabsorption of polyols], lactulose, or macrogol) work by drawing water into the stools, which expand and soften them. These are a good choice, particularly where frequent use appears necessary.

Stimulant laxatives can be effective either alone (e.g. bisacodyl, or senna) or in combination with a softener (e.g. Coloxyl® with senna). These work by stimulating intestinal motility, but can cause or exacerbate abdominal cramps. Stool softeners as monotherapy have no proven effectiveness. Suppositories and enemas are usually reserved for faecal impaction. The prolonged use of any laxative should be avoided where possible.

Antispasmodic drugs may help to control abdominal pain and occasionally diarrhoea. The *Therapeutic Guidelines: Gastrointestinal* recommend:

- Hyoscine butylbromide 20mg orally four times a day when required
- Mebeverine 135mg orally three times a day when required, or
- Peppermint oil (0.2mL/capsule) one to two orally, three times a day when required (30 minutes before food).

There is some evidence to support the use of tricyclic antidepressants and selective serotonin reuptake inhibitors in decreasing IBS pain. Tricyclic antidepressants may also cause constipation, drowsiness and anticholinergic side-effects, which may limit their use.

The *Therapeutic Guidelines* recommend:

- Amitriptyline 10-25mg (orally) daily at night
- Nortriptyline 10-25mg (orally) daily at night
- Citalopram 20mg daily, or
- Fluoxetine 20mg daily.

Conclusion

Irritable bowel syndrome involves a range of unpleasant gastrointestinal symptoms. There are many triggers, and much regarding the pathophysiology of IBS remains unknown. Diagnosis is made by a medical practitioner, after assessing the patient using defined criteria and ruling out other causes of symptoms.

Treatment involves the identification and removal of triggers. Some food intolerances can be tested for and managed by a dietician. Medications may have a role in symptom relief for some sufferers.

References for this article can be found in the online version published in the HPS Pharmacies Knowledge Centre.

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Accessing Medicines through the Special Access Scheme

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Introduction

Medicines and medical devices are generically termed 'therapeutic goods' in Australia. The *Therapeutic Goods Administration* (TGA) website broadly defines therapeutic goods as products for use in humans, in connection with:

- Preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury
- Influencing, inhibiting or modifying a physiological process
- Testing the susceptibility of persons to a disease or ailment
- Influencing, controlling or preventing conception, or
- Testing for pregnancy.

Examples of therapeutic goods include bandages, medicines and complementary therapies.

Most therapeutic goods are evaluated for quality, safety and efficacy by the *TGA*, before they are be included on the *Australian Register of Therapeutic Goods* (ARTG), and supplied in Australia. The major legislation dealing with the regulation of therapeutic goods in Australia are the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Regulations 1990* (the Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Medical Devices Regulations).

Situations sometimes arise where a medicine, or a medical device, is required that has not been approved. In these instances, the therapeutic goods may be exempt under the Act, and do not require listing on the *ARTG* prior to supply. However, in such cases, the *TGA* is unable to guarantee the quality, safety and efficacy of the unapproved product and its use is therefore regarded as experimental.

Access to these exempt therapeutic goods is managed by the *TGA* through various mechanisms, including:

- The *Special Access Scheme* (SAS), categories A and B
- Clinical trials (CTN and CTX Schemes)
- Authorised prescribers, and
- Importation for personal use.

In order to access unapproved therapeutic goods under the *SAS*, medical practitioners must follow a specified application process.

Application Process

The *SAS* refers to an arrangement which allows for the importation and/or supply of unapproved therapeutic goods, on a case-by-case basis. The *TGA* does not make distinctions between different medicines or therapeutic classes, therefore, there is no list maintained by the *TGA* of *SAS* medicines or medical devices. With the exception of drugs of abuse where the manufacture, possession, sale or use is prohibited by State or Territory law, any unapproved therapeutic good can potentially be supplied via the *SAS*. For drugs of abuse, the supplier must also ensure they hold all the relevant permits and licences relating to the specific type of product. It is important for the supplier to also confirm whether the therapeutic product is controlled under the *Customs (Prohibited Import) Regulations 1956*.

Applications under the *SAS* are made to the *TGA* by medical practitioners, usually the treating doctor, who should have a thorough understanding of all the relevant and available information about the product prior to its use. They should also discuss treatment using an unapproved product with the patient and obtain their informed consent.

Specifically, the patient should be informed of the following:

- The product is not approved in Australia
- The possible benefits of treatment, including any risks and side effects, and
- Any alternative treatments using approved products which are available.

Patients are grouped into two categories under the scheme, with the determination of classification lying with the prescribing medical practitioner. The application process varies, depending on which category the treating medical practitioner deems to be more appropriate for the patient.

- **Category A** patients are defined as 'persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'.
- **Category B** patients are all other patients that do not fit the Category A definition.

The Patient	
Patient Details	• Initials • Date of birth (or age) • Gender • Patient ID or unit record number (if applicable) • Diagnosis, and • Previous approval numbers for the patient.
Clinical Justification	• An outline of the seriousness of the patient's condition • Details of past treatment • If other approved (non-*SAS*) treatments are available, and • Justification for the use of the unapproved product in preference to those treatments.
The Unapproved Product	
Product Details	• *For medicines:* active ingredient, trade name, dose form, supplier • *For medical devices:* name of device, supplier
Administration and Monitoring Regime	• Dosage • Route of administration • Duration of treatment, and • Details of proposed monitoring.
Efficacy/Safety Data	• Efficacy and safety data sufficient to support the proposed use of the product, and • Copies of reference articles from which the data have been obtained should be included.
The Prescriber	
Prescriber Details	• Name • Postal address • Phone number • Fax number • Signature, and • Date.

Table 1. Information Required by the TGA for Category B Patient Applications

Category A Patients

Medical practitioners may initiate supply to seriously ill patients without *TGA* approval, provided the *TGA* is notified within 28 days, using the Category A form.

After completing the Category A form, copies are sent to the supplier of the product and to the *TGA*. Generally, the supplier will be the dispensing pharmacist, regardless of whether they are based in a community pharmacy or a hospital pharmacy. The *SAS* Category A form gives the supplier the legal authority to supply the unapproved therapeutic good for that patient only.

In order to provide urgent treatment of very unwell patients, suppliers may stock these items in anticipation of receiving a completed Category A form. However, supply may only occur after the Category A form has been received.

Unlike Category B, the Category A application process only requires notification of the *TGA*. Letters of approval or acknowledgement are not issued, as such is not required prior to supply, partly due to the risks of adverse effects being less than the potential for benefit in this group of patients.

Category B Patients

Applications for Category B patients require approval from a delegate who represents the *TGA*. All approvals are given on a case-by-case basis to reflect the needs of different patients. Whilst medical practitioners are not restricted to using the Category B form, the application should be made in writing, where possible, and must include the same information as stipulated on the form. Table 1 shows the specific information required by the *TGA* for Category B patient applications.

Once approved, the *TGA* will send a letter of advice to the medical practitioner. Generally, medical practitioners can expect the *TGA* to prepare and post the response for commonly requested products approximately two business days after receipt of the application. However, the turnaround time for products not previously requested under the *SAS* may take longer.

Should there be an urgent clinical need for access to the product via the *SAS*, then applications should be notated with "Urgent: Fax Response ASAP" and faxed to the *TGA* directly. In a limited number of cases, phone approvals may be granted if the clinical need is extremely urgent.

Contact details for enquiries relating to the SAS:	
Email:	eps@tga.gov.au
Phone:	For Medicines: (02) 6232 8111
	For Medical devices: (02) 6232 8679
Fax:	(02) 6232 8112
Postal address:	The Medical Officer, SAS Office of Scientific Evaluation Therapeutic Goods Administration PO Box 100, Woden ACT 2606

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Understanding Pleural Effusion

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Pleural effusion is a build-up of fluid in the pleural cavity, which is the space between the visceral and parietal pleura. Small amounts of fluid are normally produced to lubricate and facilitate movement of pleural surfaces during the course of breathing. Fluid volume is maintained through the equilibrium of hydrostatic and oncotic pressures, and lymphatic drainage. The disruption of this balance may result in fluid accumulating in the pleura, causing pleural effusion.

Pleural effusion is a manifestation of underlying disease, which could be pulmonary (e.g. pneumonia), or non-pulmonary (e.g. cirrhosis and nephrotic syndrome), the most common being congestive heart failure, pulmonary embolism, pneumonia, and malignancy.

Transudates and Exudates

There are two types of pleural effusions: transudates and exudates. They are classified according to how the pleural fluid was formed and the biochemical criteria of the fluid. Some pleural fluid may have the characteristic of both.

Transudates involve a localised process; the imbalance of oncotic and hydrostatic pressures cause fluid to leak into the pleural cavity, such as in congestive heart failure. Transudates may also be caused by fluid migration from peritoneal spaces into pleural spaces, or by the migration (or incorrect positioning) of central venous catheters or nasogastric tubes.

Exudates tend to have a systemic process and a wide range of aetiologies. For example, exudates may be caused by:

- Inflammation of the pleura
- Pulmonary embolism or infarction
- Decreased lymphatic drainage of the pleural space
- Trauma
- Lung injury
- Vascular disruption
- Malignancy
- Increased permeability of blood vessels or pleural membranes
- Immunological aetiology (e.g. rheumatoid arthritis)
- Bacterial, viral or fungal infection (e.g. tuberculosis, pneumonia); or
- Drugs (e.g. nitrofurantoin, amiodarone, methotrexate, phenytoin, and isoniazid).

Signs and Symptoms

The symptoms of pleural effusion include progressive dyspnoea, cough, chest pain, fever, difficulty breathing, rapid and shallow breathing, low oxygen saturation, and anxiety.

Dyspnoea (shortness of breath) is the most common symptom. It is often due to the restricted movement of the diaphragm and chest wall while breathing, and underlying disease (such as obstructing endobronchial lesions or diaphragmatic paralysis) rather than hypoxia or the effusion itself. Some patients may experience non-productive mild cough, while patients with an underlying infection, such as pneumonia, often have productive cough with purulent or bloody sputum.

Chest pain is a result of irritation due to friction between pleural surfaces and the chest wall, diaphragm, and ribs during respiration. The pain can be mild to severe, and localised or disseminated to neighbouring areas.

Other symptoms indicating an underlying disease process may be present, such as nocturnal dyspnoea indicating congestive heart failure. Acute fever, purulent sputum, and chest pain may indicate pneumonia.

Diagnosis

Patients may not show any symptoms until sufficient fluid has accumulated in the pleural cavity. Chest pain and dyspnoea are non-specific symptoms, but are indicative enough for diagnosis. Detailed medical, occupational, and even social histories are important for an accurate diagnosis due to the diverse aetiologies. For example, a history of pneumonia suggests parapneumonic effusion (with or without empyema), whereas a history of cardiac, renal, or liver impairment may suggest transudative effusion. Exposure to asbestos may also induce pleural effusion.

Examination involves listening to the lungs, however clinical signs only present when the volume of effusion exceeds 300mL. More reliable findings include reduced tactile vocal fremitus (vibration on the chest during low frequency vocalisation), dullness to percussion (tapping), and asymmetrical (diminished or delayed) chest expansion causing diminishing, or no, breathing sound.

Effusions above 50mL show a blunt posterior costophrenic angle on an erect lateral chest X-ray. This initial diagnostic technique demonstrates that pleural effusion exists in the lung, but not more detailed radiographic pathology. Ultrasound and computed tomography (CT) indicate underlying transudate or exudate more accurately than chest X-ray, and are important to identify the incision site for interventional procedures (e.g. empyema drainage). Magnetic resonance imaging is the 'top of the range' modality, and is more sensitive than CT at differentiating benign or malignant aetiology of effusions.

If sufficient fluid is available, thoracocentesis (needle aspiration) may be used to sample the pleural fluid. It is performed when the cause of effusion is unknown, and treatment of the presumed aetiology is unsuccessful. Patients who are clinically stable, certain to have pleural transudates (such as those diagnosed with congestive heart failure), or who have undergone recent thoracic or abdominal surgery, do not require thoracentesis.

Pleural fluid analysis identifies the histology, chemical composition, any micro-organisms, and if malignancy is present. For example, exudate can be identified by the sample meeting Light's criteria, which compares the level of lactate dehydrogenase and protein concentrations in pleural fluid against normal serum.

Other useful tests include differential cell count, glucose level, pH, cytology, and Gram staining.

Specific tests for suspected causes should also be considered, such as percutaneous pleural biopsy, when tuberculosis or malignancy is suspected, or in cases where cytology or exudative effusions are not diagnostic.

Surgical Treatment

The treatments of pleural effusions usually aim at treating the underlying disease and relieving symptoms. Therapeutic thoracentesis is an adjunct to disease specific treatments for large and refractory effusions, as draining the fluid relieves some of the respiratory symptoms, and prevents ongoing inflammation and fibrosis of the pleura.

For larger and puslike effusions, such as parapneumonic effusions and empyema that cannot be drained by thoracentesis, suction via a chest tube inserted into the pleural cavity can remove the effusion. This technique is called tube thoracotomy.

Pleurodesis, or pleural sclerosis, aims at reducing the patient's symptoms and discomfort by insufflating an irritant such as talc or bleomycin into the pleural space, triggering inflammation. As the inflammation heals, a fibrosis is formed to bind the visceral and parietal pleura tightly, preventing recurrence of malignant pleural effusion.

Pharmaceutical Treatment

Specific pharmaceutical treatment for pleural effusions is dependent on the underlying cause. Treatment of the cause helps to resolve most transudative effusions. For example, patients with congestive heart failure, hepatic cirrhosis, nephrotic syndrome and pulmonary oedema will benefit from loop diuretics (e.g. frusemide) by reducing oedema. Pleural effusion should improve quickly once the diuretic is commenced.

Patients with malignant pleural effusion should be treated with appropriate radiotherapy, chemotherapy and/or surgical removal.

Anticoagulants (e.g. heparins) prevent ongoing or recurrent thromboembolic problems by inhibiting thrombogenesis, and are therefore used for pulmonary embolism.

Empirical antibiotics are used for parapneumonic effusion and empyema. Broad-spectrum therapies are used before fluid analyses are obtained, and may be replaced by spectrum specific therapies. Antibiotic selection should target the suspected causative micro-organisms, while considering the patient's age, comorbidities, duration of illness, residential setting, and local organism sensitivities. The antibiotic should also cover anaerobic organisms. Options may include clindamycin and extended-spectrum penicillins such as amoxycillin and clavulanic acid, tazobactam and piperacillin, and imipenem.

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