
First and foremost HealthPACT congratulates Professor Lizbeth Kenny, HealthPACT Clinical Advisor on her recent Officer of the Order of Australia award for distinguished service to medicine as a clinician and researcher in the field of radiation oncology, and to executive roles with professional organisations nationally and internationally. She will officially receive the AO medal at a ceremony in May. Well deserved, Prof Kenny!

The next HealthPACT Committee meeting will be held in mid-March in Sydney, along with a meeting with the Australian Commission on Safety and Quality in Health Care (ACSQHC) to follow up from the workshop held in August 2016. HealthPACT and ACSQHC will complete further scoping of the identified projects for addition to the future work program. As well, a member of the MBS Review Taskforce will update HealthPACT on the progress of the Review.

As always, for any further information regarding any of the HealthPACT activities, please contact us. We would love to hear from you.

With best wishes

Brendon Kearney

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@HealthPACT1
Surgery, radiation therapy and chemotherapy are the standard methods of cancer treatment. Conventional radiotherapy uses photon (x-ray) energy to damage or destroy cancerous cells. However, as part of continued research into improved radiotherapy precision and biological effectiveness, there is increasing international interest into the use of particle therapy (i.e. protons or heavy ions) in the treatment of solid tumours. Proton therapy is the most commonly applied form of particle therapy in use around the world, however the use of carbon ions is also growing internationally and being actively researched.

The main potential benefits of particle therapy radiation primarily come from the physical distribution of its radiation dose. Conventional radiotherapy, using x-ray energy, deposits most of its energy near the skin surface, with a decreasing dose deposition along its path, including healthy tissue encountered before the target tumour (the entrance dose), the tumour itself, and healthy tissue beyond the tumour (the exit dose). In contrast, particle therapy radiation has a lower entrance dose and deposits most of its radiation energy to a specific depth, which is adjusted to correspond with the targeted tumour. As particle therapy radiation is mostly absorbed at this point, there is little or no exit dose. Therefore, particle therapy can reduce the overall radiation dose and treatment side-effects. Theoretically, this would lead to a reduction of radiation-induced secondary cancers; however there is not enough clinical evidence to date to support this assertion. Particle therapy is considered desirable when a tumour is located close to critical structures such as the brain or optic nerve. Compared to conventional radiotherapy, particle therapy has an ability to provide a curative dose without overdosing normal tissue.

For these reasons, proton beam technology has been adopted internationally for the treatment of a range of difficult to treat paediatric tumours, and tumours of the skull base, head/neck and central nervous system, with considerable ongoing international research into effectiveness against other malignancies. Although the use of carbon ion therapy has been described for radio-resistant tumours that are otherwise untreatable with conventional radiotherapy, or proton therapy, the use of carbon ions is still considered experimental, and further research is required into patient indications where therapeutic advantages are demonstrated. The generation of a particle beam requires a cyclotron or synchrotron to accelerate the particles to a clinical therapeutic velocity. Synchrotrons are necessary for the generation of heavy ion beams due to the increased energies required in accelerating heavy particles. The protons or heavy ions are then delivered through high vacuum ‘beamline’ structures to treatment rooms. Within the treatment room, the proton or carbon ion beam can be delivered through the use of a fixed beam or a gantry (Fig 5 and 8, respectively in the graphic over page), which rotates around the patient to deliver therapy beams toward the patient at the optimal combination of angles.

Particle therapy facilities have high installation and running costs, which have limited the adoption of this technology. Publicly reported proton beam facility costs range from approximately $34 million for a compact, single-room facility to approximately $260 million for a larger facility; and up to approximately AU$290 million for a heavy ion facility. Additionally, facilities have high annual maintenance and service costs, which are reported as approximately one-tenth of the purchase price. Further additional annual costs would include medical personnel and staff involved in service delivery, associated equipment (medical imaging and treatment planning facilities), administration and running costs (e.g. energy). As a result, a proton beam facility has a reported treatment fraction cost just over three times that of a conventional radiotherapy facility, and carbon ion has a reported treatment fraction cost which is almost five times more expensive.

Energy deposition of proton and carbon ions in comparison to X-rays
Despite these higher costs, particle therapy is rapidly growing internationally. As at January 2017, there are 56 proton beam facilities in operation, 39 facilities under construction, and a further 18 facilities planned. The majority of these are located in the United States, Japan, China and Europe. There were 10 carbon ion or combined carbon ion/proton facilities established in Japan, Germany, Italy and China, and four additional facilities either under construction or planned in Austria, China, South Korea and the United States.

Since the mid-1990’s, there has been interest in the potential establishment of an Australian particle therapy centre. Currently, the Australian States of New South Wales, Victoria, Queensland, and South Australia have expressed interest in hosting a facility. Given this interest, HealthPACT recommends a national approach to the potential introduction of this technology, including the development of appropriate patient treatment criteria, investigation of the long-term affordability, and consideration of equitable patient access.

More details about the report can be found at the HealthPACT website.

References
NETWORKS AND RESOURCES

EuroScan International Network

The International Information Network on New and Emerging Health Technologies (EuroScan International Network) is a collaborative network of agencies for sharing information and development of methods for the early identification and assessment of new and emerging health-related technologies.

EuroScan is the leading global collaborative network that collects and shares information on innovative technologies in healthcare in order to support decision-making, and the adoption and use of effective, useful and safe health-related technologies.

HealthPACT has been a member of EuroScan for a number of years. HealthPACT shares all completed Technology Briefs and Reports on the EuroScan website, and in return can access other agencies’ assessments.

After 19 years the NIHR Horizon Scanning Research and Intelligence Centre in England has recently ended their term as the EuroScan Secretariat, and it is now managed by DIMDI (German Institute of Medical Documentation and Information) in Cologne, Germany.

For further information, please see the EuroScan website or email the EuroScan Secretariat.

GETTING TO KNOW …

Paul Fennessy, Victoria

How long have you been a member of HealthPACT?
Since 2006 I think, but have been involved prior to and since its inception in 2003.

Do you have a nickname?
Big Fenno (I’m the eldest of four boys).

Where did you grow up?
Suburban Melbourne.

What is your idea of perfect happiness?
Camping in the middle of nowhere (or beyond the reach of phone signals these days!) with a good book or 10.

What would your alternate career be?
A geologist.

What is the one thing you can’t say no to?
Apparently more work!

Where is your favourite place in the world?
Canadian Rocky Mountains (Banff, Jasper, Lake Louise).

What is your favourite concert you’ve been to?
Pink Floyd, but David Bowie comes close.

Do you have any phobias?
None, although I have a very healthy respect for snakes!

What hidden talents do you have that HealthPACT don’t know about?
Trivia king.

And finally, you’ve just been appointed as the Health Minister, what will your first priority be?
Consider voluntary commitment, closely followed by a statewide audit of health technology in public hospitals!
The Wireless Stimulation Endocardially (WISE™) CRT System was developed for patients with heart failure who are not responding to conventional cardiac resynchronisation therapy (CRT). The system is designed for patients with heart failure who already have a left ventricular pacing device or pacemaker. It comprises of an ultrasonic transmitter and battery, a receiver electrode, sheath and retrackable catheter for inserting the receiver electrode, and a device for programming and monitoring the system.

As the system detects a pulse from the patient’s pacemaker, it sends a pulse of ultrasound energy to the implanted electrode. The transmitter can vary both the intensity and duration of the ultrasound pulse to suit the pacing requirements of the patient. The receiver converts the ultrasound energy to electrical energy, delivering electrical stimulation to the left ventricle and causing it to contract in unison with the right ventricle. The wireless nature of WiSE™ can potentially reduce the complications associated with traditional pacemakers, and may improve the success rate of CRT for patients in whom conventional technology was unsuccessful.

The peer-reviewed WiSE™ CRT System study reported successful implantation in 13 of 17 patients. The serious safety issues experienced during the unsuccessful implantation of this device resulted in the early termination of this study and hence delivery system modifications were made to address these procedural complications.

Two conference abstracts described the results of the SELECT_LV study and reported one patient died, and eight patients suffered post-operative adverse events as a result of the procedure. Cardiac resynchronisation was achieved in 33 (97%) patients at one month and 31 (94%) patients at six months. Implant times were 69 minutes for the ultrasonic transmitter, and 68 minutes for the receiver electrode. Further results are expected from trials estimated to conclude in 2020 and 2021.

HealthPACT noted that implantation with the wireless left ventricular pacing system may be a treatment option for patients with infected pacemaker leads. Although the published literature to date reported few adverse events, more long-term patient outcome data is required before the WiSE™ CRT System is considered suitable for clinical practice.

HealthPACT does not support public investment in this technology in clinical practice at this time, and not until after consideration of published results of studies demonstrating clinical utility. Therefore, HealthPACT recommends that the evidence for the WiSE™ CRT System be reviewed in 24 months.

More details about the report can be found at the HealthPACT website.

References
This report was commissioned by HealthPACT in response to a referral from the Nationally Funded Centres (NFC). The NFC noted concerns in several jurisdictions in response to the increasing use, and the expanding indications for the use of both extracorporeal membrane oxygenation (ECMO) (for indications other than cardiac, especially respiratory care around peaks of activity during flu season, and tracheal stenosis in paediatric patients) and ventricular assist devices (VADs) (for example for indications other than as destination therapy, i.e. as a bridge to transplantation) within the public health system. These high-cost technologies require significant resources to establish and maintain, and as such represent a challenge to the jurisdictions in the formulation of policy around planning, service delivery and funding.

ECMO

ECMO is a technique that oxygenates and removes carbon dioxide from the blood. The technique is performed outside the body and can provide complete or partial support for heart and/or lungs, allowing the injured organs to recover. It is used for potentially reversible cardiac or respiratory failure that is refractory to conventional management. As such, ECMO is used for cardiac support where patients are unable to be weaned from cardiopulmonary bypass, support following cardiac surgery, cardiogenic shock, cardiomyopathy and myocarditis. ECMO may also be used as a bridge to the insertion of a VAD or heart transplantation.

The basic components of a traditional ECMO circuit include the pump, oxygenator, cannula, circuit components, and monitoring devices, as below.

![A typical ECMO system](image)

The use of ECMO for neonates and infants has remained steady since the late 1990s and is an established therapy for neonatal cardiac and respiratory distress. In the majority of cases, ECMO is used prior to surgery to correct congenital heart defects in neonatal and paediatric patients, meconium aspiration syndrome, congenital diaphragmatic hernia and persistent pulmonary hypertension of the newborn.

HealthPACT notes that the evidence base available to guide use of ECMO for children in current Australian clinical practice is constrained by the small numbers of patients and the heterogeneity of the circumstances of this patient cohort.

The number of adult respiratory ECMO cases reported to the Extracorporeal Life Support Organization registry increased from approximately 100 cases per year between 1996 and 2007 to 846 cases in 2012, largely due to its use during the 2009 influenza pandemic. There is evidence that centres with higher case volumes may have better outcomes, which may have implications for service delivery planning.

VAD

VADs are mechanical pumps that take over the function of the damaged heart in order to re-establish normal haemodynamics and end-organ blood flow. In addition, VADs can unload the patient’s heart, and for some patients this can result in the recovery of normal heart function. These devices can be used either as short-term or long-term support, and work in parallel with the native heart.

The most commonly used device is the conventional LVAD, where the function of the left ventricle is fully replaced. The LVAD requires several components, including: the pump, inflow cannula, an outflow conduit (surgically connected to the ascending aorta), driveline, controller, and batteries.

The development of ventricular assist devices for children has lagged behind that of adults due to the relatively small number of paediatric patients requiring LVAD therapy in comparison to the number of adult patients; the need for LVADs of different sizes to accommodate growth of the child, and as a result, increasing circulation; and the complex anatomy of congenital heart disease. It is unlikely that RCTs will be conducted in the paediatric population.
In mid-February, four members of HealthPACT were invited to travel to Sydney to attend the Health Technology Assessment (HTA) in Decision Making Workshop hosted by the Menzies Centre for Health Policy at the University of Sydney.

The workshop focussed on the application of HTA to assist decision making in resource constrained environments.

The keynote speakers were Dr Kalipso Chalkidou, Director, Global Health and Development Team, Imperial College London and Dr Yot Teerawattananon, Founding Leader of the Health Intervention and Technology Assessment Program (HITAP) & Senior Research Scholar of Thailand’s Research Fund. Prof Brendon Kearney, HealthPACT Chair, also gave a presentation about Horizon Scanning and Australian jurisdictional HTA initiatives.

A series of real-life case studies and experiences of attendees were used to illustrate issues arising in the application of HTA in the policy decision making process. Other topics discussed included the policy levers for investment and disinvestment decisions, the regional capacity for HTA and opportunities for collaboration.

Attendees appreciated the opportunity to meet and discuss HTA in practice using real world examples.

HealthPACT has made a number of recommendations regarding the appropriate use of ECMO and VADs in both paediatric and adult patients. More details about the recommendations can be accessed in the report found at the HealthPACT website.

References

Schematic of a continuous flow LVAD and their possible pump technologies. (Reprinted from Journal of the American College of Cardiology 65(23), ©2015, with permission from Elsevier).
Resuscitative endovascular balloon occlusion of the aorta (REBOA) controls non-compressible haemorrhage by using an inflatable balloon to temporarily block or occlude the aorta and redirect blood flow from the extremities to maintain brain and coronary circulation. REBOA is used as a bridge to definitive haemorrhage control with either surgery or other vessel blocking techniques.\(^1\)

The ER-REBOA\(^\text{TM}\) Catheter consists of an occlusion balloon with a rounded tip (P-tip\(^\text{TM}\)), a dual-lumen catheter shaft and a hub with extension lines that enables access to each lumen. Unlike other catheters used in REBOA, ER-REBOA\(^\text{TM}\) Catheters can be used with smaller diameter (7 Fr) arterial sheaths. This feature has the potential to overcome some of the complications thought to be associated with the traditional larger diameter arterial sheaths (including lower limb ischaemia and amputation).\(^2\)

The ER-REBOA\(^\text{TM}\) Catheter is not yet used in Australia however the REBOA intervention is performed in several hospitals across Perth, Melbourne and Sydney to treat traumatic injuries. Although the ER-REBOA\(^\text{TM}\) Catheter has received 510(k) approval from the United States Food and Drug Administration because of its similarity to other legally marketed devices, there are no human studies published on this device. Therefore, HealthPACT assessed the use of similar technologies to carry out REBOA.

The findings of the included studies varied. The systematic review concluded that although REBOA was effective in elevating systolic blood pressure in patients with haemorrhagic shock, there was a lack of clear evidence supporting an improvement in mortality rate. One of the included comparative studies found that REBOA may lead to a higher death rate in surgically-treated severe trauma patients by significantly delaying time to primary surgery. The other comparative study concluded REBOA was a viable alternative to open aortic occlusion with similar outcomes observed. The case series study provided evidence on a seven French balloon catheter that is similar to ER-REBOA\(^\text{TM}\). Based on the results of this study, the smaller catheter appeared to be capable of achieving aortic occlusion equivalent to that of larger catheters without any access-related complications.

All of the included studies recognised the importance of continued, high-quality research into the efficacy of REBOA, as the current evidence base was limited to poor quality studies. Of particular interest is the investigation into use of smaller diameter catheters, such as the ER-REBOA\(^\text{TM}\) Catheter.

REBOA offers a small number of trauma patients improved survival with less physiological disturbance than current treatment options such as cross clamping the aorta. Although poor outcomes were noted, treatment with the REBOA may be considered a treatment of last resort for patients with few options.

HealthPACT does not support public investment in this technology in clinical practice at this time except under the auspices of an evaluation trial conducted in a clinical setting with clinical utility demonstrated in emergency situations. These trials should be conducted under close supervision in conjunction with other relevant groups which may include emergency physicians, retrieval specialists and surgeons. Therefore, HealthPACT recommends that the evidence for REBOA be reviewed in 24 months.

More details about the report can be found at the HealthPACT website.

References
Colour-changing bandages

Four UK hospitals are testing bandages that glow fluorescent green when a wound is close to infection. The dressing releases a fluorescent dye in small dots when a wound, such as a burn, becomes infected, allowing medics to treat it quickly. The technology, developed at the University of Bath, has potential to detect infection earlier, allowing improved treatment for burns patients as well as reducing the use of antibiotics, helping combat the threat of drug-resistant bacteria.

Currently, infections can take up to 48 hours to be visibly identified. Dressing and undressing wounds can also be painful for patients. Bandages such as these may take a lot of the guesswork out of injury assessment for doctors and patients alike.

The colour-changing bandage will provide an early-warning that infection is developing, allowing better and timelier treatment for patients. It will also prevent unnecessary tests in patients who do not have infection. Currently in cases of suspected infection precautionary courses of antibiotics are often prescribed. The colour-changing bandage could reduce this need, helping tackle the global problem of bacteria developing antibiotic resistance and saving expenditure on drugs.

If the trials demonstrate effectiveness then manufacturing could begin as early as 2017.

Scan4Safety

Six “Scan4Safety” pilot schemes funded by the UK Department of Health use bar codes to trace NHS patients and their treatments, manage medical supplies, and monitor equipment’s effectiveness. The bar codes are placed on wristbands, breast implants, replacement hips, medicines, and surgical tools, and each code can be scanned to show which member of staff administered each treatment, when, and where. This will enable patient tracking and assists in stock management by the registration of “use by” dates.

By using the barcode technology, NHS staff can keep track of hospital goods and order them automatically when needed.

This technology will also help to eliminate avoidable harm in hospitals, including errors such as patients being administered the wrong drugs and surgery being performed on the wrong part of the body.

Scanning enables accurate identification of the patient and fast upload of clinical data into patient records.

The Department of Health said that early results from the six pilot trusts suggested it could save £1bn for the NHS over seven years.
UPCOMING EVENTS ...

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NEXT MEETING ...

17 March 2017

The next HealthPACT meeting will be held on Friday, 17 March in Sydney. Topics discussed will be:

- Compendium of heart failure technologies
- Endovascular arteriovenous fistula creation systems
- Monarch™ external Trigeminal Nerve Stimulation System for drug-refractory epilepsy
- Sutureless aortic valve replacement in patients with severe aortic valve stenosis (Update)
- STAR™ Tumor Ablation System (Update)
- Endobronchial valves for patients with advanced heterogeneous emphysema (Update)
- Barricaid® prosthesis for partial annulus replacement (Update)

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