



Medical Technology
ASSOCIATION OF AUSTRALIA

ANNUAL REPORT 2015





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ABOUT MTAA

Medical Technology for a Healthier Australia

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively, to provide better health outcomes to the Australian community.

MTAA represents manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. The range of medical technology is diverse, from familiar items such as syringes and wound dressings through to sophisticated devices such as pacemakers, defibrillators, hip and other orthopaedic implants. Products also include technologies such as robotic surgery equipment and complex hospital equipment, eHealth and remote monitoring devices, in vitro diagnostics, radiation therapy, diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines.

MTAA members supply the majority of the non-pharmaceutical products used in the treatment of disease and disability in Australia. They also play a vital role in providing healthcare professionals with essential education and training.

Our members also sponsor fellowships and fund research and development in hospitals, universities and research facilities, to ensure safe and effective use, development and commercialisation of medical technology.

Associate members are supporter or partner organisations and individuals who work with MedTech companies along the Medtech value chain from idea to the patient. They include legal, logistic, consulting practitioners, compliance agencies, health economists, researchers and universities, as well as industrial designers and product commercialisation specialists. They bring valuable expertise and input to the industry.

Corporate goals

1. To be recognised as the national body that represents the medical technology sector with a united voice
2. To ensure the medical technology sector is sustainable
3. To be an influential partner in the healthcare and industry policy debate
4. To provide leadership in ethical interactions with the Australian healthcare community
5. To deliver indispensable value to members.



Leadership



Influence



Collaboration



Integrity

MTAA values being an integral part of delivering excellence in healthcare and contributing to the well being of the country.



Message from the Chair

“We all know the lack of women in management is an issue and that we should act, but the evidence tells us that we haven’t.”

MESSAGE FROM THE CHAIR



Gavin Fox-Smith
BSc (USyd), GCertMktg (CSU),
MBA (Deakin) AFAMI CPM
Chairman

The changing political landscape has created uncertainty for business in recent times. The health and medical devices sector is not immune to these pressures and MTAA continues to work with our members to improve our business environment so that companies are able to meet the ever increasing demand for health services, systems, education, research and above all patient centred care. Over the last financial year we have made major contributions to State and Federal Government policy and debate which ensures our industry's challenges are heard and understood.

In this report, I'd like to shine a light on our efforts to fundamentally change the face and character of our industry by encouraging greater gender balance at senior management levels of MedTech companies. Earlier this year I had the pleasure of hosting the launch of "Women in MedTech", a series of events designed and run by MTAA to showcase and promote gender diversity in our industry. I am extremely passionate about increasing the participation of women in our industry, and the Board and Chief Executive are keen to actively support our members in this important area.

The case for employing more women in senior

roles is compelling: diverse management achieves productivity, profit and innovation gains. We all know the lack of women in management is an issue and that we should act, but the evidence tells us that we haven't.

The 2014 Report from the Workplace Gender Equality Agency reveals women comprise 26.1 per cent of key management personnel and 17.3 per cent of CEOs. One-third of employers have no female key management personnel, and 31.3 per cent have no other executives or general managers who are women¹.

Australian women do reasonably well in gaining management level roles in biotechnology, medical technology and healthcare technology, with 11.9 per cent of companies in the sector (among the ASX 500) having female executives in key management roles, as compared with just 4.8 per cent across all Australian businesses². But that still leaves 88 per cent of key management roles in healthcare technology that are held by men.

The medical technology sector reflects these broader statistics.

1. *Australia's gender equality scorecard*. Workplace Gender Equality Agency. November 2014 https://www.wgea.gov.au/sites/default/files/2013-14_summary_report_website.pdf

2. New awards recognise women in leadership in Biotech, MedTech and Healthcare Technology. BioMelbourne Network, 22 May 2015. http://www.biomelbourne.org/news_items/view/738

While we are a significant contributor to the Australian economy with over 500 companies, 19,000 people and a turnover of almost \$12 billion in 2014, this does not translate into being a significant contributor in gender diversity, especially at the top levels of our organisations.

The MTAA “Women in MedTech” series aims to tap into a rich diversity of talent, passion and capability to bring excellence in the healthcare sector. This will translate to improved wellbeing for Australians and a significant contribution to the success of our economy and society overall.

we represent, for example, in size, local versus overseas manufacturers and product focus, to name a few, and we will endeavour to reflect this on our Board.

This industry faces some major challenges and these are not just within Australia. Whether small, medium or large, companies need to prepare for the external, global and local challenges that will impact on our ability to deliver health solutions.

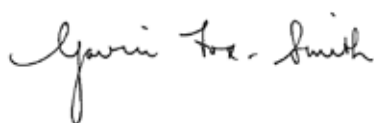
I wish to thank my fellow Board members and the many Committee chairs and volunteers who have worked

\$12 500 Companies
MedTech
19,000 people
Billion

MTAA is committed to workplace diversity and ensuring our employees and Board composition reflect the diversity of our membership, with a particular focus on encouraging the representation of women on the Board. The benefits arising from employee and Board diversity include accessing different perspectives and ideas and benefiting from all available talent.

However, diversity is not limited to gender: it also encompasses differences in ethnicity/race, age, sexual orientation, religion, physical and mental ability, experience and thinking styles. We must also acknowledge the diversity in the type of organisations

so hard to deliver on our vision for a healthier Australia. Under the energetic, member-focused leadership of our Chief Executive Susi Tegen and her outstanding team, we are well placed to deliver against the ambitious Strategic Plan upon which we have embarked. I look forward to sharing this journey with all of you.



Gavin Fox-Smith
Chairman

Board Strategic Plan

The Board holds an annual strategy planning meeting in June. This year the Board and Chief Executive(CE) resolved to move forward with the following goals (2015 - 18).

- *Ensure the MedTech Industry Blue Print has intergovernmental, industry, university and research sector support to build and demonstrate the social and health contribution that MedTech makes to patients.*
- *Create an Australian innovative environment for R&D, commercialisation, manufacturing, education and training, employment, trade, health and finance which add considerable economic benefits to Australia.*
- *Grow membership to represent the broadest range of MedTech categories.*
- *Pursue development of the MedTech sector in all Australian States.*
- *Further diversify MTAA's revenue streams with less reliance on fees.*
- *Promote an ethical industry by advocating for compliance with the MedTech Industry Code of Practice.*

A blue-tinted X-ray of a human spine, showing several vertebrae with surgical hardware (pedicle screws and connecting rods) implanted. A white 'R' marker is visible in the upper left corner. A large blue circle is overlaid on the right side of the image, containing a quote.

R

“This industry faces some major challenges and these are not just local. Whether small, medium or large, companies need to be prepared.”



Susanne Tegen
MBA (Melb), AA (Adel),
Grad Dip Ed (UNE), GCCM
(AGSM), FRALF, FAICD
Chief Executive

CHIEF EXECUTIVE REPORT

Medtech Industry Blueprint – Creating an Environment for Sustained Growth

Over the past year MTAA has continued to focus on our message that a robust Australian MedTech industry enables longer and better-quality lives for millions of Australians, fosters economic and social growth, and creates highly skilled jobs in an innovative manufacturing sector. The primary vehicle for this message is the MedTech Industry Blueprint.

It articulates the industry's relevance across the Australian economy and society in areas as diverse as research and development, rural/remote and indigenous health, finance, trade, manufacturing, employment, population ageing, small and medium business and economic development.

Input has been sought from many stakeholders including Federal and State Governments. The NSW Government in particular committed to a partnership to work on various components of the Blueprint, including an

Industry Workforce Study as one critical component.

The Blueprint will help plan the industry's growth and development. It will show MedTech's attributes and strengths such as significant research capability, a highly skilled workforce and ready access to the rapidly growing middle class markets in Australia and Asia Pacific. It will drive development of a more effective entrepreneurial culture to support innovative companies and individuals. It also identifies gaps such as a lack of sustained attention and long term planning from policy makers at all levels of government for this to occur.

It is critical that the Blueprint's vision is long term, that it reflects input from government and industry stakeholders. It must have clear and specific recommendations for State, Territory and Federal Governments, universities and industry.

Healthcare Access Improvements

Our Healthcare Access team has coordinated industry involvement in Department of Health (DoH) activities to refine Prostheses List processes including the vexed matter of benefit determination. Our efforts have ensured that fairer

and equitable processes have resulted. We have participated in discussions around the pricing of prostheses benefits and have shown that increasing utilization, not prices, is driving expenditure growth.

This is due to the ageing population and early onset of chronic disease. Our increased staff oversight of the Medical Services Advisory Committee (MSAC) activities has better informed industry's submission to a review of their processes and we are well positioned to monitor and provide input to the MBS review announced by the Minister for Health, Sussan Ley in April 2015. The Access Team has also been integral to the production of the MTAA Fact Book, a compendium of

valuable industry data that has growing credibility in the healthcare resource arena and is considered invaluable by industry, government and investors.

The evidence based, MTAA Value of Technology publications will continue to promote and advocate for equitable access to clinically proven and cost effective medical technologies.

Consistency and Transparency in Procurement and Tendering

MTAA continues its advocacy with State and Federal Governments and private health purchasing departments to ensure transparency, consistency and equity in tendering processes which are too often lengthy and resource intensive. Our aim is to reach a best practice procurement and

tendering process where price alone does not determine the patient healthcare outcome. The burden of red tape and its stifling effect on innovation must be considered, along with the additional support and resources companies provide health facilities and researchers.

Code of Practice

The 9th edition of the Medical Technology Industry Code of Practice came into effect on 1 January following an extensive independent review in 2014.

The Review reinforced the value and strong member support for the Code and their determination to be seen as ethical operators committed to effective industry self regulation. Improvements to the Code, and the creation of a new Code Authority to administer it, ensures we have a strong ethical foundation from which to grow.

This year we have provided online Code training as a free service to members. This has had outstanding support with

more than 1100 participants completing the modules. Recognition of the Code continues to be a competitive advantage within the industry. Increasingly we are hearing from industry bodies such as hospital groups and professional colleges who wish to engage with our members due to their adherence to strong ethical standards.

We continue to urge state health agencies to make compliance with a monitored industry code a condition for participating in tendering processes. We are also working with several medical industry bodies and colleges who have also indicated their support for the Code as the

Controlling Costs – Standards for Third Party Vendor Credentialing

While the practice of vendor credentialing has become a major and costly issue for MedTech companies operating in the US and Canada, it is relatively new to Australia. Several providers have been independently approaching healthcare facilities and MedTech companies in an ad-hoc and unregulated manner.

MTAA is concerned that this will lead to increased costs to companies who may be required to credential their staff with multiple third-party providers and multiple processes and sites in order to gain access to different hospitals. These costs are ultimately passed along to the health care system.

MTAA believes it is essential that the requirements for vendor credentialing be defined to ensure patient safety and the continued effective interactions between clinicians and medical companies for the development and delivery of medical products across Australia.

With that aim, we engaged Standards Australia to facilitate an industry and allied stakeholder forum to determine the need and potential scope of an Australian Standard for vendors entering hospital and patient care settings.

industry 'gold standard' for ethical business practices and interaction between doctors and industry. MTAA continues to run a two day Code of Practice and ethical interaction

Member Outreach

Over the past year MTAA has improved its website to enable easier member access to a wide range of information. Professional development offerings have increased due to feedback from members, particularly availability of online learning.

Our annual conference and awards night in November featured quality international and national speakers and attracted an attracted increase attendance from members due to the breadth of topics and speakers. Our awards program attracted some outstanding candidates for the Kerrin Rennie Award for Excellence in Medical Technology and the Outstanding Achievement Award.

Throughout the year, seminars and networking events have provided further opportunities for members to come together and listen to a range of interesting speakers or provide feedback on a particular topic.

Our research activities have also continued to grow with further reports published as part of the Value of Technology program and within several journal articles during the year. It is crucial that all advocacy and policy is based on the facts produced by this research. This evidence-based approach has enabled MTAA to be accepted as a credible and authoritative voice for information about the value chain in MedTech. It has led to improved funding

workshop in Singapore for the industry in AsiaPac with Advamed and MTANZ, this year including the newly formed APACMed.

in areas such as tele-health solutions to better support both the ageing population and those with chronic illnesses outside the hospital setting.

I am very grateful for the talented and proactive people who work at our secretariat. Their support of our members across Australia is outstanding. I also appreciate the involvement and guidance I receive from Board directors. Their genuine engagement and support for our efforts have made the achievements of the past year possible. I wish to acknowledge Treasurer Graham McClean and Deputy Chairs Emma Cleary and Mark Taffa who have worked closely with me to ensure we diversify our income and drive growth.

Finally, I am very grateful for the support and counsel of the Chair, Gavin Fox-Smith. His vision for gender equity and breadth of membership informs many of our strategies. Gavin was preceded by Kevin Barrow who retired in late 2014. Kevin's strategic drive and many years of outstanding service to MTAA is very much appreciated by small, medium and large members.



Susanne Tegen
Chief Executive

The Right Environment for Business – Reducing Red Tape

MTAA supported transparency of decision-making by TGA, and the publication of information which substantiates the basis of the decision that has been taken. Transparency of decision making will lead to more consistent TGA decisions and an improvement in the quality of submissions.

By the end of 2014, an independent expert panel review was looking into the operations of the TGA in regulating therapeutic goods. The focus was on new ways to enhance the premarket scrutiny of the highest risk devices, while providing a significant reduction in overall regulatory burden for premarket assessment of devices.

We continue to work with our counterparts in the UK, EU and US to ensure that the progress of harmonisation is not slowed. We do this directly, through the International Medical Device Regulators Forum (IMDRF) and through the Global Medical Technology Alliance.



***“The right environment
allows businesses to
innovate and develop
new ideas, no matter
how small or large the
company.”***

BOARD DIRECTORS



Paul Braico BEng (UNSW), MBA (MGSM), GAICD
Vice President and Managing Director, Boston Scientific

Paul has 30 years' experience in the medical technology industry, working in diverse organisations including Australian manufacturing, medical equipment, medical distribution, and medical device multinationals. Prior to his current role, Paul has held several senior leadership roles in Australia and Japan.

Joined Board in June 2012.



Pat Callanan GAICD
Country Manager ANZ, American Medical Systems Australia Pty Ltd

Pat commenced his career in healthcare over twenty two years ago. Pat's experience in healthcare encompasses sales, marketing, sales management and senior management, working across a wide variety of surgical specialties to develop his understanding of healthcare and how to serve customers most effectively. Pat has been with American Medical Systems (AMS) since July 2010, having previously worked for large global device manufacturers Howmedica and Stryker. Prior to joining AMS, Pat was Managing Director for Advanced Surgical Technologies, a privately owned medical device distribution business.

Joined Board in October 2012.



Emma Cleary BBus (Deakin), ICAA AICD
Chief Financial Officer, Device Technologies Australia Pty Ltd

With over 25 years experience within the Medical Device, Managed Services, Professional Accounting and other industries, Emma has held a number of senior management roles both in Australia and overseas.

Emma is a Chartered Accountant and joined Device Technologies as CFO in 2005. More recently, Emma developed and launched Device Solutions, the Managed Services division of the company that focusses on improving patient diagnostics and care through the use of digital technology. Prior to joining Device Technologies, Emma held leadership positions with Pioneer International, Tenix Group, Ericsson and Bosch across Asia and Australia. Emma is MTAA Vice Chair.

Joined Board in October 2013.

Christopher Cowley FAICD, MBA

Managing Director, Varian Medical Systems Australasia

Chris was appointed Managing Director of Varian Medical Systems Australasia in 2009, having previously worked for Varian in the Middle East as Service and General Manager. Prior to his employment with Varian he studied, trained and worked as a Biomedical Engineer in the UK. Chris has been in the medical device industry as a customer and vendor for 28 years.

Joined Board in October 2014.



Lyn Davies Dip Bus Mgt PERSA ARATA LASA QLD AMACs

Managing Director, Tunstall Australasia Pty Ltd

As Managing Director of Tunstall Healthcare, Lyn Davies is responsible for the strategic direction, business growth and operational services delivery for the Asia Pacific Region. Lyn joined Tunstall in 2004 with 20 years' experience in customer service and 14 years in contact centre environments. She has worked with well-known organisations such as Logan City Council, Mater Hospitals, CITEC and the Queensland State Government, with experience in the development and implementation of small to large scale call centres and emergency response centres locally and internationally.

Joined Board in December 2013.



Gavin Fox-Smith BSc (USyd), GCertMktg (CSU), MBA (Deakin) AFAMI CPM

Managing Director, Johnson & Johnson Medical Pty Ltd

Gavin is one of Asia Pacific's most experienced health sector leader, with nearly three decades in the medical technology and devices sector. Gavin started his career with Howmedica Orthopaedics, where he served in several roles of increasing responsibility in sales and marketing, before being appointed Director of Marketing for Asia. He joined J&J Medical ANZ in 1997 as a Regional Business Director, holding diverse leadership roles in sales, marketing and general management across the J&J family, including Ethicon, EES, DePuy and Cordis.

In addition to his current Managing Director role, Gavin is also Asia Pacific regional leader for ASP, Mentor and Acclarent, and chairs J&J Global Medical Services Marketing Council. Gavin MTAA Chair.

Joined Board in April 2012.





David Jolly RN

Managing Director ANZ, St Jude Medical Pty Ltd

David has worked in the health industry for over 30 years starting as a Registered Nurse, five years in the pharmaceutical industry followed by more than 20 years in the devices industry. Prior to taking up his role as Managing Director of SJM Australia in 2009 (and SJM New Zealand in 2011), David held several senior roles with Medtronic in Australia and internationally.

Joined Board in October 2013.



Philippa Lewis DipBus, ProfCertArb, GradDipLaw, MAICD, MIAMA

Chief Executive Officer & Executive Director, Simavita

Philippa has had over 30 years of local and international business experience across multiple industry sectors including retail, healthcare, construction, international technology transfer, franchising, patent management, import, distribution and manufacturing. In 2002 Philippa was recognized as one of the Zurich Business Leaders of the Year.

As the founding Managing Director of Simavita since 2008, Philippa has taken the company from start up to dual listing and global distribution. Prior to this Philippa was the Chief Executive Officer and founder of Sanicare, an Australasian business in textiles and non-woven adult incontinence products. Sanicare grew to be a market leader with over \$25M in turnover. In 2005 she sold the business to a FTSE-listed entity staying on as Executive Director

Joined Board in October 2014.



Graham McLean BSc (Hons) Geography FCMA CPA GAICD

President, South Pacific, Stryker Australia Pty Ltd

Graham has worked for Stryker for over 10 years and until recently was President for South Pacific (ANZ). He took up his current appointment in 2012 where he was appointed Managing Director having previously held a number of other roles including Finance and Operations Director and International assignments. Prior to working at Stryker, Graham had extensive international experience working in general management roles in food and drinks business, such as Lion Nathan, Smiths Snack foods, Guinness and United Biscuits in Europe and Australia. Having been raised in the UK, Graham has lived in Sydney for 18 years.

Joined Board in February 2013.

Doug North BA (ECU)

Managing Director, Surgical Specialties Pty Ltd

Doug is the major shareholder and Executive Director of Surgical Specialties. From 1984 – 2000, Doug worked in numerous sales roles at Howmedica including National Sales Manager. Following Howmedica's integration with Stryker he held the role of General Manager, Stryker NSW. Through 2000 to 2005, Doug established his own business and was the Exclusive Distributor in NSW/ACT for Smith and Nephew's Orthopaedic and Endoscopy products. In 2006, Doug established Surgical Specialties which now employs 90 staff across Australia and New Zealand.

Joined Board in April 2013.



Mark Taffa BBus (CSU)

Managing Director, Horten Medical Pty Ltd

Mark is the founder and Managing Director of Horten Medical a company distributing medical devices, established 2005. Actively involved in the healthcare industry for over 15 years, Mark has worked with both large multinationals and small business. At GE Medical Mark had product responsibility for all of Asia in digital imaging which included living in Singapore and consulting to the Brunei government on e-health. Mark has experience in running small scale local manufacturing of complex medical equipment for local and export sales. Mark is MTAA Vice Chair.

Joined Board in December 2013.



Andrew Wiltshire RN (Qld), BA (Media Studies), MBA (UNE), MAICD

Senior Director, Corporate Affairs, Medtronic Australasia Pty Ltd

Andrew has over two decades experience in the Australian medical technology and pharmaceutical sectors. As Senior Director, Corporate Affairs Andrew is actively engaged in efforts to positively promote industry to government, healthcare providers and the community for appropriate access to medical technologies. He oversees Medtronic's government affairs, PR, quality, regulatory and reimbursement initiatives in Australia and New Zealand.

Joined Board in October 2013.



Previous Board Director

Kevin Barrow, Managing Director, Australia and New Zealand, Becton Dickinson. Immediate past MTAA Chair.

Committees, Forums and Working Groups



COMMITTEES, FORUMS AND WORKING GROUPS

MTAA relies on the efforts and expertise of members on its various committees, forums and working groups. The Association's aim is to take a solid, evidence-based approach to advocacy, with the result that its views are sought

by policy makers and other key decision makers. MTAA would like to thank member companies for enabling their many staff in various areas of their businesses to participate in this vital work.

Access

MTAA's advocacy for reimbursement of currently unfunded medical technologies remains a high priority activity in support of patient access, doctor choice and better health outcomes for consumers. In this regard MTAA has concerns for access to innovative medical technologies in the community setting which, if not subsidized, may not be available to the majority of needy patients.

In the private health sector MTAA has lobbied for non-implantable medical technology used in surgery to be included on a reimbursement list. The Prostheses List criteria is an anachronism which has failed to keep pace with innovative but non-implantable medical technology which, for example, will see a drug-eluting stent reimbursed but not a drug-eluting balloon for which there is also solid clinical evidence.

Patients are reliant on health funds to provide ex-gratia coverage but such a process does not always ensure patient access to the clinically indicated products. This

unpredictable access can lead to inequalities of access between the private healthcare system and the public health system. It can also lead to cost-shifting of private patients to the public system. MTAA continues to advocate for a more consistent, transparent and equitable system covering these items.

There are limited pathways for the private and public health systems to identify and assess new technologies in a systematic way. MTAA will continue to work with HealthPACT and the Independent Hospital Pricing Authority to advocate for a national strategy to assess new technologies.

Meanwhile, 'tele-health', eHealth and remote monitoring offer the opportunity to keep many patients in their own home and communities and out of hospital taking pressure off health budgets.

Regulatory Affairs

The Regulatory Affairs Committee (RAC) is comprised of 19 regulatory professionals and deals with operational regulatory matters raised at the TGA's Regulatory and Technical Consultative Forum (RegTech) on a quarterly basis. The RAC met 8 times between July 2014 and June 2015.

Issues covered include:

- *the MTAA Submission to the Expert Panel Review of Medicines and Medical Devices Regulation Annual Charge Exemption (ACE) scheme which replaced the Low Value Turnover (LVT) scheme*
- *revision of the Uniform Recall Procedure for Therapeutic Goods; MTAA provided written feedback to the TGA Up-classification of hip, knee and shoulder joint replacement implants from Class IIb to Class III (see Orthopaedics report on page 19)*
- *industry training and preparation for the 2014 Device Sponsor Information Day held in Canberra.*

Access Committee

The Access Committee, a strategic committee reporting to the Board, steered MTAA policy deliberations during the reporting period, refining communications and coordinating activities with the Government Affairs and Policy Committee and providing input to the Reimbursement and Regulatory Subcommittees. The Access Committee met on four occasions during the reporting period.

The Access Committee continued to monitor the Department of Health's actions in attempting to improve processes of the Medical Services Advisory Committee (MSAC). It also convened ad hoc working groups to provide expert industry input to MSAC and Activity Based Funding (ABF) policy and process developments.

Reimbursement Subcommittee

The Reimbursement Subcommittee (RSC) is a subcommittee of the Access Committee. It met on five occasions during the reporting year. The primary focus of RSC is on Prostheses List reimbursement issues.

The Committee manages industry responses to Prostheses List policy developments and considers operational matters referred to it by the Access Committee and the MTAA Secretariat. The Reimbursement Subcommittee has contributed to policy development proposals provided to it by the Department of Health and the Prostheses List Advisory Committee, in particular input to the benefit determination policy for new products in new groups.

Renewal of the Prostheses List Guide has also been a focus of the Committee although it has been frustrating to note that the

2010 version continues to be the version displayed on the DoH website.

The Reimbursement Subcommittee has continued its constructive engagement with the Private Health Insurance branch of the DoH.

Members of the subcommittee met with senior department staff twice during the reporting period, which included product displays for departmental officials in Canberra. Now in their fourth year, these high level meetings provide the subcommittee with a platform of significant value to address important policy and procedural issues.

The RSC also provides supporting input to the deliberations of the Access Committee, and provided advice on training and information topics for MTAA events.

Regulatory Subcommittee

The Regulatory Subcommittee (RegSC) is a subcommittee of the Access Committee focused

on strategic regulatory issues affecting the medtech industry in Australia.

Activity Based Funding Expert Working Group

MTAA advocated strongly for the development of a process for incorporating new medical technologies into the Activity Based Funding (ABF) pricing framework to increase accessibility in the public hospital setting.

The Working Group was set up to discuss the impact of ABF for the industry, specifically the uptake of new technologies under the pricing framework for public hospital services. The Group represented MTAA at the Independent Hospital Pricing Authority (IHPA) Stakeholder Advisory Group Open Forum in March 2015. The purpose of the forum was to inform Phase One of an independent evaluation of the impact of the implementation of national ABF for public hospital services.

The Working Group also provided comment on MTAA's submissions to IHPA on a number of public consultation papers.

The RegSC met eight times between July 2014 and June 2015. Outcomes and key areas covered by the RegSC during this period included:

- active participation in consultation forums related to the Independent Review of Medicines and Medical Devices Regulations which commenced in October 2014; an important outcome was the MTAA Submission to the Expert Panel Review of Medicines and Medical Devices Regulation (input into the Review) lodged on 23 December 2014
- engagement with the TGA and other industry associations, and advocacy through the
- TGA-Industry Consultative Committee (TICC); the TICC meets twice a year (May and November) in Canberra to obtain input on corporate planning, budgeting processes and TGA performance
- regulatory harmonisation and international regulatory collaboration within the Global Medical Technology Alliance (GMTA), a subcommittee of the International Medical Devices Regulatory Forum (IMDRF) comprised of 23 industry associations from around the world including AdvaMed (USA), APACMed (Asia Pacific), BvMed (Germany) and CAMDI (China).

Code Authority

The Code Authority was established in January 2015 after release of the 9th edition of the Code of Practice. The Authority is a single, arms-length, independent body charged with administering the Code. It replaces the Code of Practice Committee, the Code Complaints Committee and the Code Monitoring Committee. Members of the Code Authority are appointed by the MTAA Board to represent companies, consumers and healthcare professionals.

The Code Authority had met twice as of 30 June 2015. Its first task was determining how to undertake its various functions in relation to Code monitoring and complaints handling. In the past year, a complaint was received from a member company against

the activities of a non-member company, which declined to have the complaint adjudicated by the Code Authority. Therefore, the matter did not proceed.

The Authority has also been tasked with increasing awareness and uptake of the Code by professional associations. In June the Australian Orthopaedic Association added a clause to its contract with exhibitors at its Annual Scientific Meeting, mandating compliance with the Code of Practice. The Code Authority will continue its work with external stakeholders over the coming year with the goal of driving ethical business practices and establishing a level playing field.

Commercial Issues

The Commercial Issues Forum and specific issues meetings canvassed a range of challenges faced by companies in their tendering process. It informed our discussions with ministers and secretaries of departments about the inconsistency, the resource intensive red tape and lack of transparency in tendering. Issues include the additional costs and lack of transparency associated with GS1 forced compliance.

Government Affairs and Policy Committee

The Government Affairs and Policy Committee is one of MTAA's three strategic committees, chaired by a Board member and reporting directly to the Board. It met five times during the reporting period. The Committee provides input to the strategic direction of the Association's government policy and advocacy agenda. The Committee focuses on developing industry responses to issues of major importance to industry sustainability. It also develops strategies to ensure effective working relationships with ministers, shadow ministers, MPs and departmental officials and ultimately that our business challenges are understood and addressed.

Code of Practice Review

MTAA overhauled the industry Code of Practice and introduced an independent Code Authority to oversee compliance. The 9th edition of the Code came into effect on 1 January 2015, having been approved by MTAA members at the AGM on 31 October 2014 following a six month review that involved extensive consultation with a wide range of stakeholders.

The primary purpose of the review was to ensure that the Code continues to reflect community, industry and regulatory standards and values. In addition, the review aimed to improve clarity and practicality of implementation of these standards.

The revised Code is intended to enable industry growth in an educative, self-regulatory environment that promotes transparency, fair competition, consumer protection and a level playing field for all.

The Code is the recognised industry standard for responsible interactions between MedTech companies and healthcare professionals (HCPs). It deals with sensitive issues such as sponsorship of conferences attended by HCPs, gift giving and hospitality.

The new Code Authority, including consumer, health care professional and industry representatives, will be responsible for Code compliance and administration.

In an important change that will improve transparency, MTAA has introduced confidential breach reporting. Anyone who has knowledge of a Code

breach can bring the evidence before the Code Authority while keeping their identity confidential. An example of a complaint circumstance in which the Code Authority may agree to accept a confidential breach report is the following.

Company 'A' and 'B' offer directly competitive medical technology to Institution 'C'. The rep from 'A' learns that 'B' has invited members of the procurement team of 'C' to an 'information night' at a top tier restaurant. 'B' wishes to alert MTAA about an alleged Code breach but is concerned that 'A' will retaliate and/or employees of 'C' will withdraw their patronage.

If the Code Authority determines that a request for confidentiality is unjustified in the circumstances, it may reject the request and provide the complainant with an opportunity to withdraw the complaint. If a confidential complaint lacks merit or is frivolous or vexatious, the Authority can exercise its absolute discretion not to pursue the matter further.

The industry's response to the new provision for confidential breach reporting will be monitored closely to ensure the measure has the desired effect of bringing to light and curbing non-compliant activity without adding to the administrative burden on MTAA members.

Clinical Investigations Interest Group

The Clinical Investigations Interest Group (CIIG), comprised of eight regulatory and clinical affairs professionals, represents the interests of the industry in negotiations with hospitals and healthcare authorities with regard to pricing of activities involved in clinical trials. The CIIG also collaborates with agencies such as the National Health and Medical Research Council (NHMRC) to streamline processes and make Australia a more competitive place for conducting clinical trials.

A key area of focus for the Group was consultations with the Independent Hospital Pricing Authority (IHPA) regarding the cost of clinical trials. IHPA was established to help reform Australian public hospitals and implement a system of activity-based funding in public hospitals.

The CIIG revised several clinical trial contractual documents (listed below) in the past year, and these are currently awaiting approval from the NSW health authorities. They include:

- MTAA Standard Clinical Investigation Research Agreement
- MTAA Standard Indemnity Form (for a clinical investigation)
- MTAA Indemnity Form
- MTAA Compensation Guidelines.

Orthopaedics Regulatory Working Group

The Orthopaedics Regulatory Working Group met regularly in 2014-15 to support member companies in issues related to the up-classification of hip, knee and shoulder joint replacement implants from Class IIb to Class III.

When hip, knee and shoulder joint replacement implants were re-classified from Class IIb (moderate to high risk) to Class III (high risk) a more stringent premarket

assessment had to be applied, involving both manufacturer's quality management system (QMS) and an assessment of the product design. This meant submitting a new application with assessment of the design dossier.

MTAA was able to negotiate with the TGA an extension to the transition period which had been due to end on 30 June 2015.

MBS Review

MTAA provided a submission to the Department of Health Medical Benefit Division (MBD) relating to the Medicare Benefits Schedule (MBS) Reviews. In the submission, MTAA expressed concerns regarding the process of the MBS Reviews including:

- the unrecognised but important role of industry
- the review process lacks transparency and consistency.

MBS Review examples of the percutaneous coronary artery interventions (PCI) and arthroscopic hip procedures were included in the submission to highlight these issues.

In 2014-15, MTAA held its first MedTech Forum on MSAC Update. The MedTech Forum focused on Health Technology Assessment (HTA) and provided an update on MSAC's submission, consultation and protocol processes, and on the role of the MBD in providing policy advice to the government that impacts on the medical technology industry.

The MedTech Forum concluded with a panel discussion involving each speaker, which provided an opportunity for attendees to participate.

Speakers included:

- Dr Richard Bartlett, then the First Assistant Secretary, *Medical Benefits Division (MBD): Primary role in providing policy advice to the Australian Government on the Medicare Benefits Schedule (MBS)*
- Prof. Robyn Ward, Chair of MSAC, *Medical Services Advisory Committee (MSAC): Reforms, stakeholder engagement and public consultation processes*
- Prof. Rosalie Viney, Director, Centre of Health Economics Research and Evaluation (CHERE), *Implementing guidelines for reimbursement in Australia: MSAC use of evidence and cost-effectiveness.*

Legal Counsel/ Compliance

The Legal Counsel/ Compliance Forum met three times in 2014-15. The Forum provides a platform for members to network, receive updates and discuss matters in relation to the Medical Technology Industry Code of Practice. It is open to personnel from member companies with compliance responsibilities or a general interest in the Code.

In 2014-15 the Forum provided feedback during the external Code review and helped formulate new Code FAQs. Members were also involved in the 3rd annual joint MTAA/ MTANZ/AdvaMed and now including APACMed, AsiaPacific Compliance Working Group meeting. The Forum also provided input into MTAA's response to the Expert Review of Medicines and Medical Devices Regulation.

Highlights



“With the release of the new Code of Practice training module, registrations jumped from 144 to 1142 in the final five months, an eight-fold increase.”

PROFESSIONAL DEVELOPMENT

In the 2014-15 financial year the professional development program continued to help deliver the skills and knowledge demanded by member companies of their

professional staff with close to 4000 industry professionals engaging in MTAA training during the year.

Code Training Made Free to Members

Participation rates in MTAA's professional development programs surged in 2014-15 thanks in part to the Board's decision to make training in the industry Code of Practice free of charge to members.

This makes it easier for members to meet their obligation under the Code to ensure all staff interacting with healthcare professionals are trained in the Code.

An extensive revision of Code training materials followed swiftly after the conclusion of the Review in late 2014.

With the release of the new Code of Practice training module, registrations jumped from just 144 in the first seven months of the year to 1142 in the final five months, an eight-fold increase.

Major Lift in Training Registrations

Our strategy includes an increase in uptake of MTAA training by others in the industry including non-members, PhD students and allied industries.

In another core area of training - operating theatre protocols - the release of the revised training in August 2014 resulted in nearly a three-fold increase in registrations (1519, up from 563 in the previous year).

Registration rates were up from the previous year across most areas of the program with 3571 registrations by industry professionals in training modules during the year, an increase of over 100% from

the previous year (this figure does not include participation in ad hoc seminars, conference sessions, and webinars).

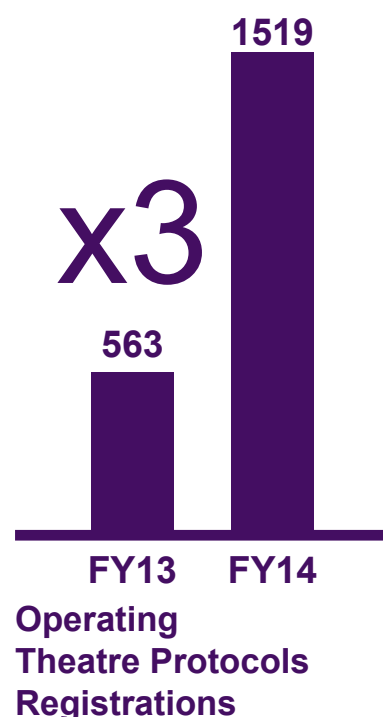
'Bundling' of training modules by course has proven popular with members. By committing to purchase a 'Training Series', members were able to save 20% over the cost of purchasing the modules separately. This initiative has increased the overall enrolment in MTAA training.

Graph 1 demonstrates the growth by financial year of member, non-member and other training completions.

Career Support Expanded

The career section of the MTAA website was further expanded to support the career choices available to people in the industry.

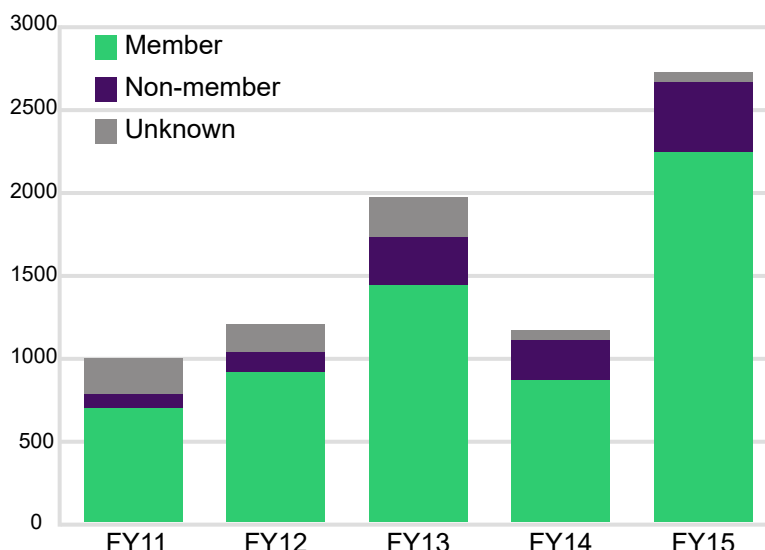
MTAA career support opportunities are designed to foster industry progression at varying stages of a person's career. For example, students can access a list of MTAA member companies that offer workplace learning programs via the *MTAA Workplace Learning Directory*.



There is a marked increase in FY 2012-2013 and FY 2014-2015. This is due to the two year rotation of operating theatre protocol training being

launched in these years and a resulting spike in registrations for this compliance training.

Training Modules Completed

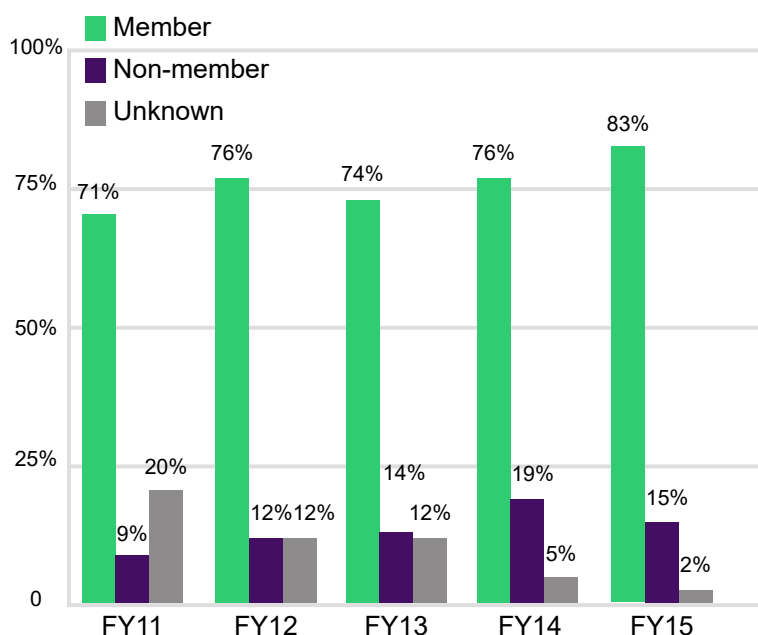


Graph 1: Training modules completed by financial year

Graph 2 presents the growth by financial year of member, non-member and other registrations. There is a marked increase in member training registrations this

financial year, possibly due to the release of module 2.1 Introduction to the Code of Practice (Edition 9) for free to members.

Completed Training



Graph 2: Member vs non-member completed training FY 2011 - 2015

Training Records Made Portable

In a move that will assist industry professionals throughout their careers, MTAA made training records fully portable and accessible to individuals through a secure online portal. Not only does this benefit the individuals and their employers by maintaining accurate and up to date records of their professional development, it enables MTAA to remain in contact with an ever-growing network of industry professionals as they move around the MedTech industry throughout their careers.

Information Sharing via 'Webytes'

Remodelled web-based webinars were rolled out to support the education of future, newly qualified and current industry personnel. One popular initiative was "Webytes," short online pre-recorded presentations to deliver information on topics of interest to the industry. Not only were these made available to members for free, but for the first time non-members could also access this learning for a fee. These were recorded by MTAA staff and external presenters.

ANNUAL CONFERENCE

The annual conference, MedTech 2014 was expanded to two days and attracted over 240 delegates from across the industry. The conference theme was: How IT is changing the medtech industry, and creating a healthier Australia

What Attendees had to Say...

"It was excellent; it was great!"

"I have been to meetings all over the world and I felt the administration was very effective. I certainly did not miss anything."

"I thought it was very professionally run. The emphasis on panel discussions ensured all aspects relating to a challenge were covered - this was excellent and made the content relevant to a diverse audience."

"The planning and organisation of the conference was excellent. The challenge is picking a subject which is relevant for all."

"Great use of an app for a conference. Just like being given something at registration desk eg: bag note paper pen."

"I think it went well, except that somehow I missed a box in the registration process for the dinner. Thankfully the organisers got in touch promptly to verify my rsvp."

"Great opportunity to network with industry colleagues in an enjoyable setting."

"The inclusion of clinicians onto the panels was very worthwhile."

"Communications were regular and informative leading up to the event."



The number of entrants in the MedTech industry awards program grows every year. We thank the distinguished members of the independent judging panel from across Australia for their time and commitment.

- Professor Anne Simmons, Graduate School of Biomedical Engineering, UNSW
- Professor Guy Maddern, RP Jepson Professor of Surgery, University of Adelaide and Surgical Director of ASERNIP-S
- Henry Ko, consumer representative, Consumers' Health Forum (CHF)
- Nick Shalley, independent industry representative
- Susi Tegen, CE, MTAA

ANNUAL INDUSTRY AWARDS

Kerrin Rennie Award

The 2014 Kerrin Rennie Award for Excellence in Medical Technology – *Improving Quality of Life* recognises the innovative and extraordinary contribution of medical technology in improving health outcomes of Australian patients.

A company can enter a product used in the diagnosis, prevention, treatment or management of disease and disability. The product must demonstrate evidence of significant contribution to improving patient outcomes by enhancing quality of life, technical excellence, and innovation.

The winner of the 2014 Kerrin Rennie Award was Reveal LINQ™ by Medtronic Australasia Pty Ltd.

The Medtronic Reveal LINQ™ ICM is a Miniature insertable heart monitor designed to help physicians quickly and accurately diagnose

irregular, and potentially lethal, heartbeats. Despite being the world's smallest ICM (about the size of a paperclip), the LINQ ICM has the same battery life, and more data memory, than other heart monitors.

Its cutting edge electronics allow never-before seen miniaturization with extreme levels of efficiency. The LINQ ICM battery is powerful enough to continuously and wirelessly monitor a patient's heart for up to three years. It sends relevant information to a clinician aiding in accurate diagnosis and determination of a treatment plan, potentially without a patient needing to visit a hospital or clinic, and all within a timely manner.

The physician can elect to receive notification via SMS allowing faster response times in emergency situations.



Medtronic Reveal LINQ™ ICM

Kerrin Rennie Award Finalists

EarlySense by WelchAllyn Australia

The EarlySense Contact-Free Monitoring System helps facilitate timely interventions for patients in non-ICU settings by adding a layer of care with continuous monitoring, drawing attention to those who may show early signs of deterioration and may

require clinical intervention. By utilizing contact-free piezoelectric sensor technology (no patient leads required), The EarlySense System continuously monitors a patient's Heart Rate, Respiratory Rate and Motion to assist clinicians in:

- Early Detection of Patient Deterioration and Avoiding Failure to Rescue
- Fall Risk Reductions
- Pressure Injury Prevention.

Real Time delivery of actionable data, together with patient management tools, empowers the medical staff

Zip® by Surgical Specialties

The Zip Surgical Skin Closure provides a non-invasive alternative to staples, sutures and glue for surgery and lacerations.

It is used by surgeons (orthopedic, general, cardiac, ob/gyn, plastic/reconstructive, dermatology) and emergency department physicians, and because of the device's ease of use, no suturing skill is required so the closure task using the Zip device can be delegated to a Physician's Assistant or RN.

The Zip has been shown to produce the cosmetic outcome of a meticulous suture closure with the application speed of staple, with a reduced risk of surgical site infection.

The device can save 5-10 minutes per procedure, which at an average of \$60/hr for OR time, can yield \$300-600 per procedure. Material costs is competitive with suture and glue closure. In the Emergency Room, no anesthetic injection is required, making closure with the Zip ideal on children.

to identify potentially critical situations. It provides proactive personalised patient care, allows the medical staff to reduce adverse events such as patient deterioration, pressure injuries (Decubitus) and patient falls.

Feedback from the first 500 cases included comments from patients about how comfortable the device was. Patients may shower with the device. The device uses biocompatible materials, including hypoallergenic skin adhesives, has a very low profile, is very flexible and extendible for applications on joints such as shoulders, hips, and knees for total knee joint replacement. It is compatible with most wound dressings, including silver-impregnated dressings.

Since it is adhered to the skin, at the physician's discretion the patient may remove the device at home by simply peeling it from the skin, like a Band-Aid®.

This award is endowed by the family of the late Kerrin Rennie, who was a long standing member of the Australian MedTech community.



Outstanding Achievement Award

Each year MTAA acknowledges an individual's outstanding achievement to the Australian medical technology industry. Nominations are open to individuals who have contributed in a significant

and outstanding way to the development of the medical technology industry. Nominations are accepted regardless of membership of the association or background.

Prof Karen Reynolds, Director, Medical Device Partnering Program, Flinders University was the recipient of the Outstanding Achievement Award for 2014 announced at the conference dinner on 13 November.

From the nomination:

"One of her most outstanding successes has been her pioneering development of the medical technologies industry in Australia through the Medical Device Partnering Program."

Her role is the Director of the Medical Device Research Institute (MDRI) and the Medical Device Partnering Program (MDPP) as well as Deputy Dean of the School of Computer Science, Engineering and Mathematics at Flinders University.


Bridging the divide between research and industry, She is considered as one of Australia's leading researchers in biomedical engineering. She is Chair of the College of Biomedical Engineers within Engineers Australia and is a member of the Therapeutic Goods Administration's Advisory Committee on Medical Devices. She has also been elected as the incoming Chair of the Academy of Technological Sciences & Engineering's Health & Technology Forum and is a member of the Premier's Science and Industry Council, providing advice to the South Australian Government on a wide range of issues related to science, research and development.

She has been recognised for her outstanding contributions, named South Australian Scientist of the Year 2012, elected Fellow of the Australian Academy of Technological Sciences (2011), and awarded Australian Professional Engineer of the Year (2010). In 2013 and 2012, She was named by Engineers Australia as one of Australia's 'Top 100 Most Influential Engineers'.





“The number of entrants in the MedTech industry awards program grows every year. We thank the distinguished members of the independent judging panel from across Australia for their time and commitment.”



“The VOT research provides support for advocacy for funding of a range of technologies that might not have strong Australian evidence to date and/or lack funding.”

VALUE OF TECHNOLOGY PROGRAM

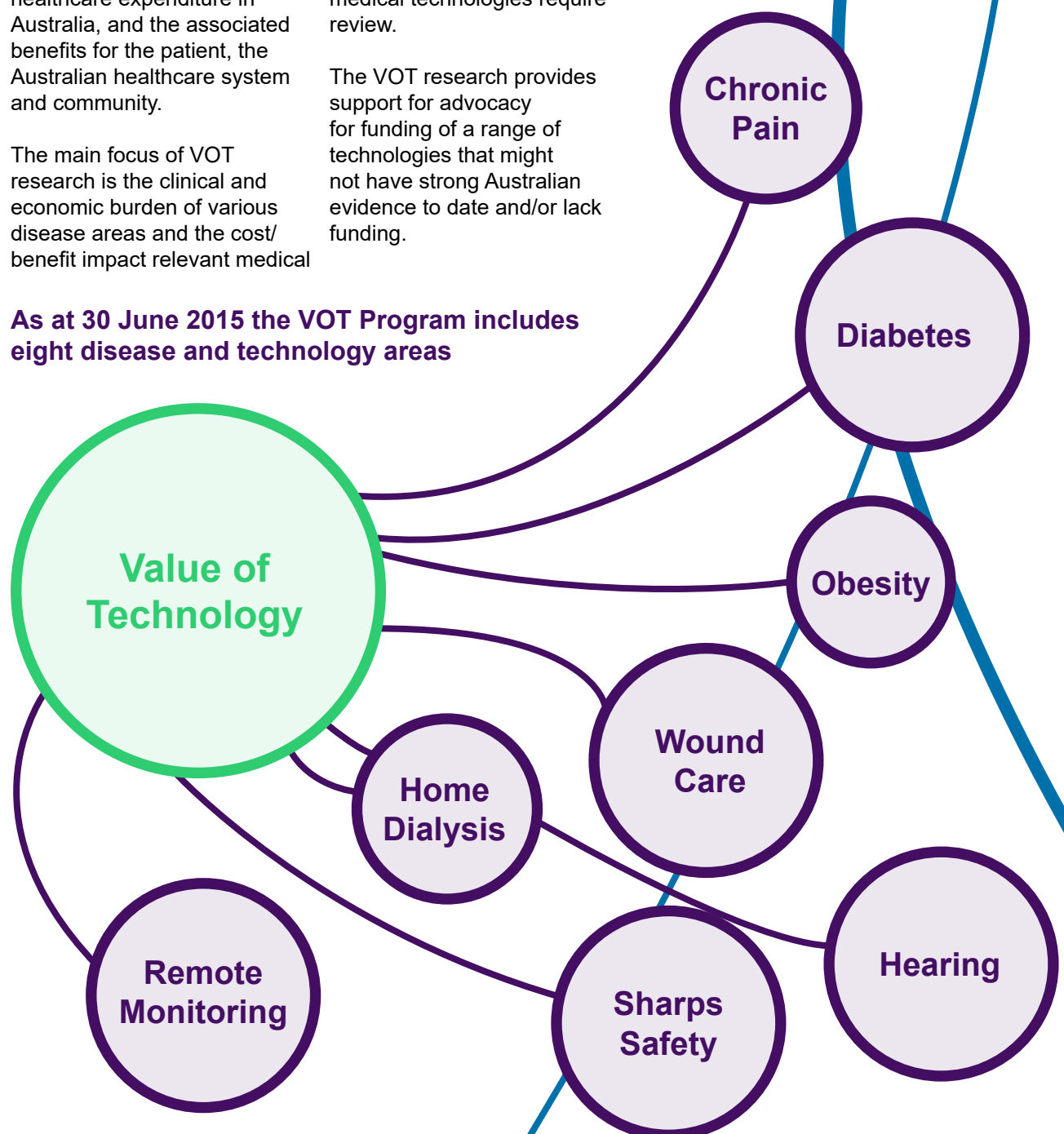
The Value of Technology (VOT) Program was established to improve the understanding of the impact of advances in medical technology on healthcare expenditure in Australia, and the associated benefits for the patient, the Australian healthcare system and community.

The main focus of VOT research is the clinical and economic burden of various disease areas and the cost/benefit impact relevant medical

technologies have on these diseases for the patient and for the Australian healthcare system. Funding mechanisms for patient access to these medical technologies require review.

The VOT research provides support for advocacy for funding of a range of technologies that might not have strong Australian evidence to date and/or lack funding.

As at 30 June 2015 the VOT Program includes eight disease and technology areas



Presentation of the VOT Program during 2014 - 2015

Government Submissions

The VOT report on diabetes and insulin pumps provided evidence-based support for the following submissions:

- Submission to the PBS on the Draft report for

Stage Two of the Diabetes Review on Insulin Pumps

- Submission on the Development of the National Diabetes Strategy

International and External Submissions

World Health Organization (WHO) Interim Report of the Commission on Ending Childhood Obesity. MTAA

Policy recommendations:

- National Health Priorities policies (including National Chronic Disease Strategy - National Diabetes Strategy) need to effectively prevent and reduce the health, economic, and social consequences of obesity and other chronic disease conditions. The prevalence of overweight and obesity among children and adolescents has shown little change in Australia and the rates remain high, and are therefore a cause for concern.
- Improve funding for patient access to appropriate clinical care and education, particularly for:
 - » At-risk groups - people with less education and socioeconomic status (SES) are more likely to be obese, and Indigenous communities
 - » Treatment and management of those who are obese
 - » Prenatal treatment – gestational diabetes access to appropriate clinical, quality care.

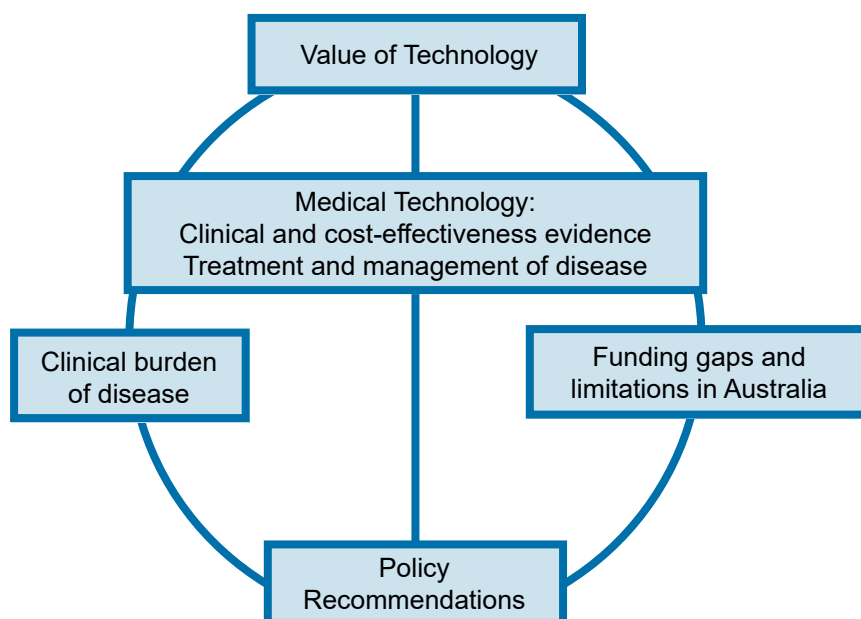
WHO Global Injection Safety Campaign. Global Medical

Technology Association (GMTA) submission paper to the WHO regarding the Policy Guidance on the “Use of safety engineered injection devices for injections”. MTAA recommends the introduction of nationally consistent policy and/or legislation aimed at preventing needlestick injuries (NSIs) in healthcare settings. Prevention measures must include the implementation and use of safety engineered injection devices (SEIDs) combined with relevant training and education.

Abstracts and Proceedings

An abstract based on the VOT report on diabetes titled “The ‘value’ of innovative technologies for diabetes treatment and management: Insulin pumps and continuous glucose monitoring systems” was published in the Journal of Diabetes & Metabolism 2014. 5:10. MTAA recommends the use of insulin pumps for children and adolescents with type 1 diabetes remains funded, while some subsidy for the use of insulin pumps should be provided for adults with type 1 diabetes and those with type 2 diabetes and gestational diabetes, who would clinically benefit from insulin pump use.

The VOT Program including the various research areas were showcased in the Research Australia’s eMagazine *grassROOTS Winter 2015 Edition*.



VOT Key Research Areas for 2014 - 2015

VOT key research areas and recommendations presented at the MTAA Annual Conference 2014:

Key Research Areas	MTAA Recommendations
1. Case study on out-of-pocket costs for non-implantables in Australian healthcare: Issues relating to reimbursement for catheter ablation for patients with atrial fibrillation (AF)	<ul style="list-style-type: none"> With the increasing epidemic of AF, funding for AF ablation services and equitable patient access to catheter ablation - an effective and cost-effective treatment option for AF – is critical. The 'Prostheses List' should be changed to a 'Medical Devices' list that more reasonably reflects the current and future state of medical technology and includes devices such as ablation.
2. Use of safety-engineered medical devices (SEMDs): To improve prevention of needlestick and sharps injuries in the healthcare setting	<ul style="list-style-type: none"> Australia Government to mandate the use of SEMDs in healthcare settings either through prescriptive legislation or policy. Further to the effectiveness of SEMDs in reducing NSIs and the cost savings that can be gained by the Australian healthcare system, the use and provision of SEMDs should be considered as an ethical issue of "who has the right to decide healthcare workers should risk injury".
3. Home dialysis as the 'first' treatment option for end-stage kidney disease (ESKD)	<ul style="list-style-type: none"> Home dialysis as the 'first' treatment option Home dialysis can provide cost savings to healthcare High out-of-pocket costs for home dialysis - Financial support on utility costs such as water and electricity usage should be more equitable Dialysis treatment by geographical location of residence - Government funding models should ensure home dialysis services are increased, particularly in rural and remote regions, and that Indigenous Australians with ESKD receive necessary quality care. Funding framework for renal services - inclusion of new and emerging renal technologies. Government strategies to include review and funding processes relating to new and emerging renal technologies that are cost-effective and provide better patient outcome.
4. Inequitable Access to Innovative Technologies for Diabetes Treatment and Management in Australia	<ul style="list-style-type: none"> Access to insulin pumps should be made available to those who would clinically benefit most from insulin pump therapy including: <ul style="list-style-type: none"> » those under the age of 18 or over the age of 18 (who have been using insulin pumps when they were younger) » women who are pregnant or trying to conceive » individuals with poor glycaemic control » individuals with high initial HbA1c » individuals with severe and/or unpredictable hypoglycaemia.
5. Evidence for Funding of the Treatment and Management of Chronic Wounds in Australia	<ul style="list-style-type: none"> Funding scheme for chronic wound care treatment and for the use of modern wound chronic devices (MWCDs) in the community setting to avoid patients being treated in costly hospital setting. Government funding for MWCDs: <ul style="list-style-type: none"> » To ensure sub-acute care medical products are provided to patients when needed for their care » To provide necessities to chronically ill or incapacitated patients in the community setting » To maintain an acceptable quality of life for patients who without government subsidy would not have adequate access to life supporting medical technology » To decrease the economic burden of chronic wounds by reducing hospitalisations and length of stay, reducing GP visits - releasing GPs for higher level of patient care, and avoiding inappropriate transition to residential aged care and achieving cost savings through maintaining people in their own homes.

SUBMISSIONS

MTAA contributed to a range of Federal and State Government policy reviews and consultations in the financial year 2013-14.

2015

- Submission to the Competition Review - June 2015
- Submission to the WHO Interim Report of the Commission on Ending Childhood Obesity - June 2015
- Submission to The National Diabetes Strategy - June 2015
- Draft Guidelines for Preparing Investigative Assessment Reports for the MSAC - May 2015
- Comments on IHPA's Draft Work Program 2015-16 - May 2015
- Submission to the Review to Strengthen Independent Medical Research Institutes - February 2015
- Submission to the Public Consultation Paper on the IHPA Teaching, Training and Research Costing Study - February 2015
- Submission to Tasmanian Green Paper - February 2015
- Pre-budget submission 2015-16 - February 2015
- Comments on WHO Global Injection Safety Policy - February 2015
- Submission to the Review of Medicines and Medical Devices Regulation - January 2015

2014

- Submission to the 'Review of Group 9 accessory products under the Stoma Appliance Scheme' - December 2014
- Submission to the Department of Industry on CRC Programme Review - November 2014
- Submission to Boosting the commercial returns of research - November 2014
- Submission to the Medical Benefits Division (MBD): Medicare Benefits Schedule (MBS) Reviews - October 2014
- Submission to the Senate Select Committee on Health - September 2014
- Submission to the PBS on the draft report for stage two of the diabetes review of insulin pumps - August 2014
- Submission to Senate Economics References Committee's Inquiry into Australia's innovation system - August 2014
- Comments on IHPA's draft pricing framework 2015-16: Activity based funding for Australian public hospitals - July 2014

All submissions and position papers can be accessed on the MTAA website at www.mtaa.org.au.

External Representation

MTAA represented members on a range of external committees and stakeholder groups.

- Alliance for Sharps Safety and Needlestick Injury Prevention in Healthcare - **Susan Martland (Acting Chair to February 2015), Prema Thavaneswaran (Secretariat)**
- APACMed – **Susi Tegen**
- Australia MedTech Pharma Dentistry industry Alliance – **Susi Tegen**
- Bariatric Surgery Registry Steering Committee – **David Ross**
- Breast Device Registry Steering Committee – **David Ross**
- Cardiac Device Registry Steering Committee – **David Ross**
- Cardiac and Cardio-thoracic Clinical Advisory Groups – **Bernard O'Connor (industry adviser)**
- Global Medical Technology Alliance (GMTA) – **Susi Tegen**
- Group of 6-International MedTech Industry CE network – **Susi Tegen**
- Hip and Spinal Clinical Advisory Groups – **Warwick Kitt/David Ross (industry adviser)**
- Home Dialysis Advisory Group – **Alessandra Doolan**
- HTA Aus Think Tank, member – **Alessandra Doolan**
- IHPA Stakeholder Advisory Committee – **Prema Thavaneswaran**
- Knee and Specialist Orthopaedic Advisory Groups – **Peter Abrahamson (industry adviser)**
- National Joint Replacement Registry Consultative Committee, member – **David Ross**
- Ophthalmic Clinical Advisory Group – **Robert Kitchen (industry adviser)**
- Prostheses List Advisory Committee – **David Ross (to Aug 2014); Nick Shalley (from Feb 2015)**
- Urogenital and Vascular CAGs – **Nick Shalley (industry adviser)**



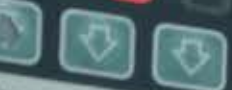
AIR IN LINE
DOOR OPEN
STOPPED
LOW BATT



RATE mL/h
VOL LIMIT mL
SET



10



INFUSED mL
79
CLEAR
C



PRIME
INFUSE/STANDBY



SILENCE



SEC



MTAA MEMBERS



a Novartis company





MTAA Associate Members

- The Bioadvisory Group Pty Ltd
- Brandwood Biomedical Pty Ltd
- BSI Group
- Covance Pty Ltd
- Five Corners Pty Ltd
- Healthcare Placement Solutions
- IDE Group
- Intelog Business & Healthcare Performance Group
- Medtechnique
- Open Sesame Consulting
- Regulatory Concepts Pty Ltd
- SJ Alder Pty Ltd
- Slate Hill Consulting Pty Ltd
- Sue Akeroyd & Associates
- The SPD Company Pty Ltd

COMMITTEES

Access Committee

Gavin Fox-Smith
(Chair)(to Feb 2015)
Mark Taffa (Chair)
Robyn Chu
Hilary Crilly
Libby Day (from Feb 2015)
George Faithful
Laurence Fong (from Aug 2014)
Sarah Griffin (to Dec 2014)
Ruth Shennan
Falko Thiele
Rachel Todd (from Feb 2015)
Andrew Wiltshire

Clinical Investigations Working Group

Falko Thiele (Chair)
Catherine Bourgeois
Lindsey Jasicki
Susan Hopkins
Paul Christensen
Adele Hosseini
Christy Thiel

Code Authority (from Jan 2015)

Nick Shalley (Chair)
Hugh Cameron
Camilla Chan (to May 2015)
John Cooper
Chris Cowley
Dawn de Cruz
Henry Ko

Code of Practice Committee (to Jan 2015)

George Walck
(Independent Chair)
Paul Braico
Camilla Chan
John Cooper
Michael Goldberg
Patricia Greenway
Michelle Wagner

Government Affairs & Policy Committee

Andrew Wiltshire (Chair)
David Cain (to Dec 2014)
Rachel David
Richard Dowling
Chris Harnett (from Aug 2014)
Jodie Jansen (to Aug 2014)
Phillippa Lewis

Susan Martland (to Mar 2015)
Michael Reynolds
Graeme Shelley (to May 2015)
Michael Simmonds

Orthopaedic Committee

John Cooper
Maurice Ben-Mayer
(from Jan 2015)
Graham McLean (to Dec 2014)
Gray Mitchell (to Sep 2014)
Craig Moy
Doug North
Warren Ballinger
Darryl Harkness
(from Oct 2014)
Ralph Jennings

Orthopaedic Regulatory Working Group

Gary Burgess (Chair)
Pamela Caterson
David le Cheminant
Lucile Ferrand
Fiona Hall
Sue Hunter
Ramon Ippolito
Elizabeth Ibrahim
Lachlan McKenzie
Alisa Rawlings
Phillippe Robertson
Ruth Shennan
Chrissy Tomarelli
Samantha Tham

Regulatory Affairs Committee

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Minta Chen (to Dec 2014)
Diane Compton
Ana Cuk (to Dec 2014)
Laleetha Devi
Leanne Etherington
Yihye Freeman
Ian Frigerio (to Dec 2014)
Rebecca Gaudin (to Dec 2014)
Sue Hunter (to Dec 2014)
Natasha Kshetrapal
Delwyne Lauten
Richard Malyn
Lachlan McKenzie
Naeema Mohamed
Meryl Musson
Michelle Nguyen-Ly
Kevin Samuels
John Selakovic (to Dec 2014)

Crissy Tomarelli
Heena Vyas (to Sep 2014)
Juliana William
Heather Winslade
Fleur Winslade
Susanne Winter
David le Cheminant
Smitha Viswanatha

Regulatory Subcommittee

George Faithfull (Chair)
Jenny Bennell
Hugh Cameron
Christine Cuthbertson
Mahesh Datar
Darren Forrest
Rebecca Gaudin (to Dec 2014)
Renee Hardley
Sue Hunter
Mary Kennell (to Dec 2014)
David le Cheminant
(to Dec 2014)
Ruth Shennan
Samantha Tham
Tony Uhe
Elizabeth Van Den Akker

Reimbursement Subcommittee

Robyn Chu (Chair)
Darren Bear (to Dec 2014)
Sheryl Dunlop
Laurence Fong (to Feb 2015)
Michelle Frost (from Feb 2015)
Kevin Guinee (from Feb 2015)
Sue John
Rose Mollica-Merchant
(to Apr 2015)
Craig Moy (to Dec 2014)
Sue O'Malley
Lloyd Prescott

MTAA Secretariat*

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Chief Executive

David Ross MBA (SCU), GDipStratStud (ADC), DipMilStud (UNSW)
Director Healthcare Access

Val Theisz MSc RAC
Director Regulatory Affairs

Allison Fox GDipMgt (aib)
Director, Business Operations

Alessandra Doolan BMedSc (Hons I), PhD (Medicine), MPH (Syd)
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Avril Douglass BBus (Marketing)
Conference Manager

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Fiona Landis BComms Media Production (CSU)
Industry Policy Manager

Kerri Lukas
Executive Assistant

Roslyn Mitchelson BA (UTAS), GCert Sustainability Management (Syd)
Industry Policy Manager

Melinda Padovan
Office Administrator

Fiona Shipman DTeach (UTS), BA (Macq), MCommsMgt (UTS)
Professional Development Manager

Prema Thavaneswaran BSc (Hons I) (Adel), PhD (Adel), MPH (Qld)
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Code of Practice Manager

Kara Young BMedia (UNSW)
Marketing and Communications Coordinator

MTAA also acknowledges the work of current/past employees and contractors, Pam Davis, Scott McClellan, Alina Hughes, Marion Demann, Warren Mitchell, Gary Burgess, Lea Rushton, Chris Szeleczky and Marnie Cartwright who have contributed to specific projects over the last year.

*At the time of printing



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