Medical Technology: Key facts and figures 2013

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

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Introduction

The third edition of the *Medical Technology: Key facts and figures* booklet provides updated data and statistics from 2013. The Medical Technology Association of Australia (MTAA) has been publishing this resource since 2011 to summarise available information on the medical technology industry.

The 2013 edition provides a valuable resource for those wanting to gain a better understanding of the medical technology industry in Australia and globally.

The Australian medical technology industry, which includes medical devices, diagnostics and medical imaging equipment, comprises a diversity of manufacturers and suppliers of medical technology from emerging Australian companies to global companies.

Medical technology saves and improves lives by detecting diseases earlier, and by providing more effective treatment options for patients and the healthcare system.

The industry is characterised by a high level of innovation, resulting in short life cycles for many products. Many medical devices undergo constant development based on feedback from healthcare professionals and advances in other sciences relevant to medical technology.

The Australian medical technology industry:

- had turnover of approximately $10 billion in 2012
- was responsible for 41,292 medical devices listed on the Australian Register of Therapeutic Goods (ARTG) (2013) (including IVDs and dental) with up to a million different devices linked to them
- included over 500 medical technology companies with products listed on the ARTG
- employed more than 19,000 people
- was mainly located in NSW (55%) followed by Victoria (24%) and Queensland (12%)
- imported goods to the value of $4.4 billion and exported goods to the value of $1.9 billion.

Globally the medical technology market was valued at US$325 billion in 2011 with a compound annual growth rate of 7% between 2005-11[1].

1. About MTAA

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 with products ranging from consumable items such as syringes and wound dressings, through to high-technology implanted devices such as cardiac pacemakers, defibrillators, hip and other orthopaedic devices. Products also include hospital equipment, surgical equipment and diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines.

MTAA members distribute the majority of the non-pharmaceutical products used in the diagnosis and treatment of disease and disability in Australia. Our member companies also play a vital role in providing healthcare professionals with essential education and training to ensure safe and effective use of medical technology.

1 World Preview 2018: A consensus view of the Medical Device and Diagnostic Industry, Evaluate Medtech.

2. What is a medical device? [2]

2.1. Definition

A 'medical device' is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related material:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support, of the anatomy or of a physiological process
- support or sustaining life
- control of conception
- disinfection of medical devices
- providing information for medical or diagnostic purposes by means of *in-vitro* examination of specimens derived from the human body

and

b) which does not achieve its primary intended action in or on the human body by pharmaceutical, immunological or metabolic means, but which may be assisted in its intended function by such means.

2.2. Comparing medical devices and pharmaceuticals

Medical Devices	Drugs
Industry Composition	
Over 80% small and medium-sized companies	Very large multinationals dominate
Active Components	
Generally based on mechanical, electrical, and materials engineering	Based on pharmacology and chemistry; now encompassing biotechnology, genetic engineering etc
	Pharmacologic properties and action of active ingredients are known, based on pre-clinical and clinical studies
	Standardised batch sizes, manufacturing processes and starting materials
	Products stable/generally stored at room temperature with a long shelf life
Product Development	
Wide variety of products and applications – from thermometers to x-rays	Products are usually in the form of pills, solutions, aerosols, or ointments
Designed to perform specific functions and approved on the basis of safety and performance	Product development by discovery, trial, and approved on basis of safety and efficacy
Often developed by health professionals	Products developed in laboratories by chemists and pharmacologists
How Products Work	
Most act through physical interaction with the body or body part	Products are administered by mouth, skin, eyes, inhalation, or injection and are biologically active; effective when absorbed into the human body. Often act systemically on the entire body
Intellectual Property Concerns	
Continuous innovation and iterative improvements based on new science, new technology, and new materials	Extensive research and development of a specific compound or molecule; takes several years for a new drug to enter the product pipeline
Product Life Cycle	
Short product life cycle and investment recovery period (~18 months on market)	Intensive patent protection, including data exclusivity and patent linkage, needed due to extensive product life cycle and long investment recovery period
Little patent linkage possible. Data exclusivity is important	
Innovation	
Majority of new products bring added functions and clinical value based on incremental improvements	Usually large step innovation
Support Provided	
Large investment in manufacturing, distribution, and training/education; plus need to provide service and maintenance (for many high tech devices)	Low manufacturing and distribution cost, and, in most cases, no training, service or maintenance costs

2 This definition is taken from the Global Harmonization Taskforce website, available at www.ghtf.org.

2.3. Benefits of medical technology

Medical technologies benefit lives in many ways, for example [3]:

- the use of coronary stents (artificial tubes that keep the arteries open) has halved the number of people suffering heart failure or dying from heart attacks
- patients who have an implantable cardiac defibrillator (ICD) have a 98% chance of surviving a cardiac arrest (versus only a 5% chance of survival without the device)
- surgical procedures benefit from advances in medical technology, e.g., the use of medical technology means endometrial ablation has a recovery time of just two to four days; the alternative (hysterectomy) necessitated six to eight weeks
- cataract surgery once required a stay in hospital of three to five days, but can now be undertaken in a day-care facility
- medical technology comprises 2-5% of national health expenditure. However appropriate use of medical technology reduces hospital stays by an average of 13%.

3. The medical technology ecosystem in Australia

The Australian medical technology industry is comprised of four distinct groups:

- Australian companies and Australian affiliates of multinational companies which undertake manufacturing in Australia for the domestic market and for export
- Australian companies which manufacture off-shore for import into Australia and for overseas markets
- affiliates of multinational companies which import into Australia and from time to time undertake clinical investigations in Australia and collaborations with Australian research institutions
- independent distributors which import and distribute medical technologies.

In addition, suppliers to the industry provide a range of services:

- design and prototyping services
- clinical investigation services
- regulatory affairs advice
- health economists
- market analysis and advice on strategies to get to market
- component manufacturing
- sterilisation services
- distribution.

3 Modified from www.eucomed.org/medical-technology/value-benefits.

4. Consumable medical technologies

Medical technology can be divided into consumables and implantable devices. Medical consumables are provided to patients in the community through a variety of stand-alone Commonwealth, state and territory schemes. A plurality of schemes tends to result in ad-hoc and inequitable allocation to consumers and act as a barrier to economies of scale for suppliers. Federal and state/territory schemes are listed below.

Federal schemes	
Repatriation Pharmaceutical Benefits Scheme (RPBS)	Administered by the Department of Veterans' Affairs (DVA). Provides access to certain medications, dressings and assistive devices for treatment of entitled veterans and war widows
Rehabilitation Appliances Program (RAP) National Schedule of Equipment	Administered by the DVA. Provides aids and appliances to eligible members of the veteran community to help them maintain their independence. A range of appliances are provided through six product groups
National Diabetes Services Scheme (NDSS)	Administered by Diabetes Australia and delivers diabetes-related products at subsidised prices, information and support services to over 1 million people with diabetes each year. Between July 2011 and February 2012 the NDSS supplied 2,665,082 units of product to registrants. Products include blood glucose testing strips, insulin pump consumables, reservoir, sharps and urine testing strips and products
Stoma Appliance Scheme (SAS)	Provides stoma related products (medicines and appliances) to individuals who have undergone either a temporary or permanent surgically created body opening (stoma). During 2011-12 approximately 40,000 people received products under the scheme
Continence Aids Payments Scheme (CAPS)	Assists individuals with permanent and severe incontinence to meet some of the costs of continence products
Epidermolysis Bullosa Dressing Scheme	The only federal scheme for modern wound care devices assists patients with Epidermolysis Bullosa. In 2011-12 166 people received subsidised dressings
Australian Hearing	Provides hearing device products and services and research by the National Acoustic Laboratories
External breast prostheses reimbursement program	Assists women who have had a mastectomy due to breast cancer with reimbursement for new or replacement external breast prostheses
Disability Care Australia (the national disability insurance scheme)	The government will provide $1 billion over four years for the first stage of the disability insurance scheme in launch locations for 10,000 Australians from 1 July 2013, increasing to 20,000 participants from 1 July 2014.

State/territory schemes	
ACT	ACT Equipment Scheme
	Domiciliary Oxygen and Respiratory Support Scheme
	ACT Spectacles Subsidy Scheme
NSW	EnableNSW
NT	Disability Equipment Program (DEP)
QLD	Medical Aids Subsidy Scheme (MASS)
SA	Independent Living Centre (ILC)
	Domiciliary Equipment Service (DES)
TAS	Community Equipment Scheme (CES)
	State-wide Continence Aids Scheme
	Spectacles and Intra-Ocular Assistance Scheme
	Home Oxygen Scheme
VIC	State-Wide Equipment Program (SWEP)
WA	Community Aids and Equipment Program (CAEP)

5. General health trends in Australia

Australia's life expectancy is among the highest in the world and stands on average at 82 years, two years above the OECD average. Current life expectancy for women is 84 years, compared with 80 for men. While Australians generally expect to live a relatively long life, there are differences between population groups. In particular, life expectancy at birth for Aboriginal and Torres Strait Islander Australians is more than ten years lower than for the non-indigenous population[4].

The leading causes of death in Australia are cancer and circulatory system diseases such as heart disease. Australia has achieved major gains in the fight against cardio-vascular disease (CVD). There has been a 79% fall from 831 deaths per 100,000 in 1968 to 174 deaths per 100,000 in 2010[5]. This can be contributed in part to advances in medical technology. The fight against cancers has been less successful (there are currently over 800 medicines in development for the fight against cancer[6]).

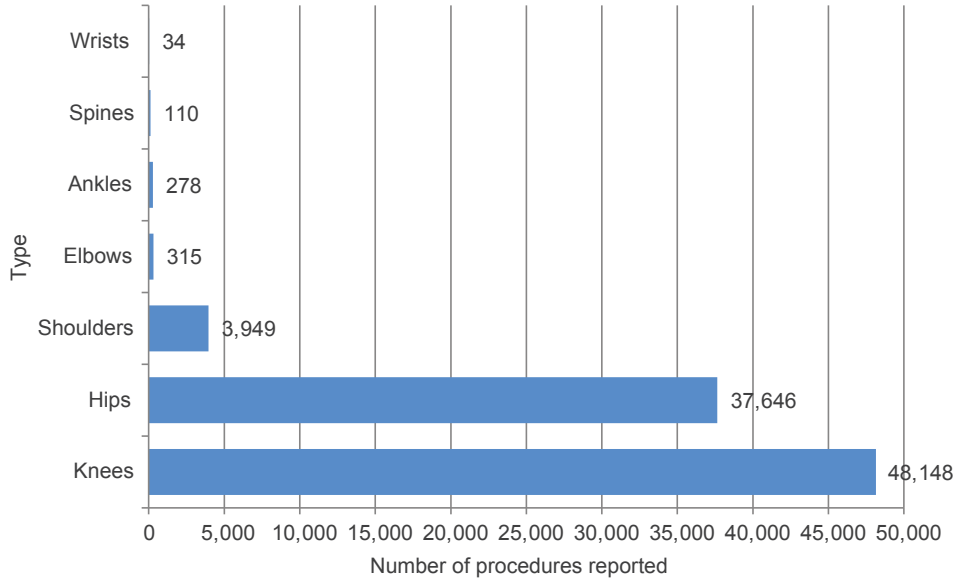
In 2011–12 63% of adult Australians were either overweight or obese[7]. The obesity rate in Australian adults is 25% (this is higher than the OECD average of 18%). Obesity rates in Australia have been increasing faster than in most other OECD countries over the last 20 years. Obesity's growing prevalence foreshadows increases in the occurrence of chronic conditions such as diabetes, CVD and asthma, and higher healthcare costs in the future. In 2010-11 over 265,000 potentially preventable hospitalisations were due to chronic conditions[8].

6. Implantable devices

The frequency of device implantation is increasing in the Australian population. In the last decade (2000-10) more than 10% of the population had a device implanted and the rate of implantation for most medical devices is increasing[9]. It is likely that the actual number of Australians with an implantable device is much higher as the 10% figure does not include implantation of pins, screws and plates due to fractures. Australian statistics do not take into account medical tourism or the growing numbers of procedures taking place in private clinics outside the hospital system.

The rise in hospitalisations for osteoarthritis has led to an increase in the number of joint replacements. Joint prostheses rates are on the rise (knee replacement rates have increased by 56% in the last decade)[10]. In 2012 the National Joint Replacement Registry (NJRR)[11] recorded joint replacement and revision rates in 155 private and 147 public hospitals. The NJRR reported 90,480 joint replacements in 2012. The majority were for knees (53%) and hips (42%).

Figure 1: The number of joint replacement procedures reported in 2012



Source: NJRR 2012[12]

4 OECD (2013), *OECD* Factbook 2013: Economic, Environmental and Social Statistics, OECD Publishing.
5 Australian Bureau of Statistics (ABS), Catalogue 3303.0 Causes of Death, Australia, 2010.
6 ABS, Catalogue 3303.0 Causes of Death, Australia, 2010.
7 COAG Reform Council 2013, Healthcare 2011–12: Comparing performance across Australia, COAG Reform Council, Sydney.
8 Ibid.
9 MTAA. The number of people in the Australian population with an implantable device. 2012. This report draws from a variety of sources including the NJJR, the AIHW, Hospitals Data Cubes, industry reports and published research results.
10 www.aihw.gov.au/media-release-detail/?id=60129543357.
11 National Joint Replacement Registry, www.dmac.adelaide.edu.au/aoanjrr.
12 Graph based on data sourced from National Joint Replacement Registry, https://aoanjrr.dmac.adelaide.edu.au/procedures-reported.

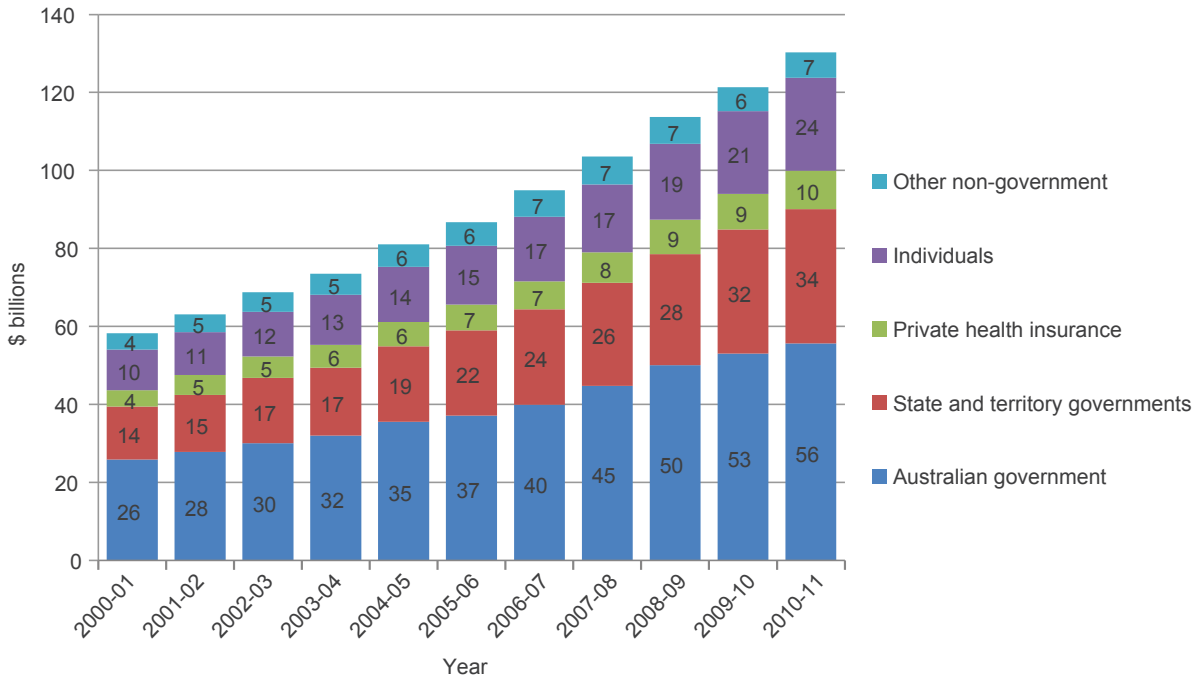
7. The Australian hospital system

Australia has 1,345 hospitals, 56% public and 44% private[13]. In 2011-12 about 9.3 million separations (episodes of care) took place in Australian hospitals. Public hospital separations counted for 5.5 million (60% of separations). Average length of hospital stay in 2011-12 was 3 days (2.3 days in public and 3.4 days in private hospitals). In 2011-12 2.4 million (26%) of separations included a surgical procedure[14]. The number of surgical separations increased between 2007-08 and 2011-12 by 2.6% on average for public hospitals and 3.7% for private hospitals each year. The most common surgical procedures performed for elective admissions involving surgery included lens extraction (198,000 separations) and excision of skin lesions (90,000 separations).

8. Health expenditure in Australia

In 2010-11, total health expenditure in Australia was 130.3 billion, or 9.3% of GDP, a decrease of 0.8% compared to the previous year. Government provided $90.1 billion (69%) of health expenditure, the contribution of the federal government was $55.6 billion (43%), while state and territory governments contributed $34.4 billion (26%). Non-government funding (private insurance, individuals and other non-government sources) provided the remaining 40.2 billion (31%). The average spending growth rate in the last ten years was 8.4%[15]. In 2011-12 57% of individuals over the age of 18 had private health insurance[16].

Figure 2: Total healthcare expenditure in Australia

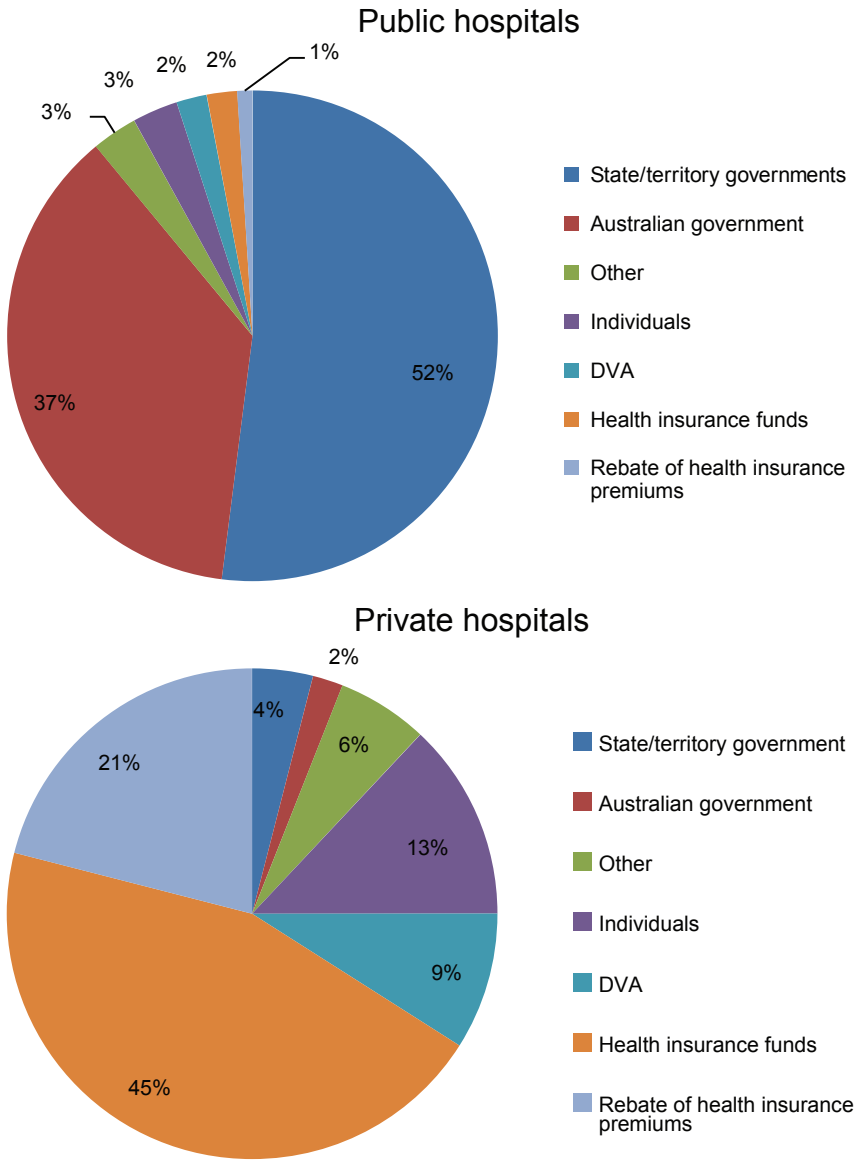


Source: AIHW 2012[17]

In 2010-11 an estimated $49.7 billion was spent on hospital services, about 3.7% of Australia's GDP or $2,227 per person. Hospital spending has increased by 5.4% every year on average between 2006-07 and 2010-11[18]. Spending on public hospitals is increasing faster than inflation[19].

13 Australian Institute of Health and Welfare (AIHW) 2013. Australian hospital statistics 2011–12. Health services series no. 50. Cat. no. HSE 134. Canberra.
14 AIHW. Australia's hospitals 2011-12 at a glance. Health services series no. 49. Cat. No. HSE 133. Canberra.
15 AIHW. Health expenditure Australia 2010-11. Health and welfare expenditure series no. 47. Cat. No. HWE 56. Canberra.
16 ABS. Australian Health Survey: Health Service Usage and Health Related Actions, 2011-12, 4364.0.55.002. http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4364.0.55.002Chapter1002011-12.
17 AIHW. Health expenditure Australia 2010-11. Health and welfare expenditure series no. 47. Cat. No. HWE 56. Canberra.
18 AIHW. Australia's hospitals 2011-12 at a glance. 2012. Health services series no. 49. Cat. No. HSE 133. Canberra.
19 AIHW. Australian hospital statistics 2011–12. 2013. Health services series no. 50. Cat. no. HSE 134. Canberra.

Figure 3: Sources of hospital funding (public and private hospitals)

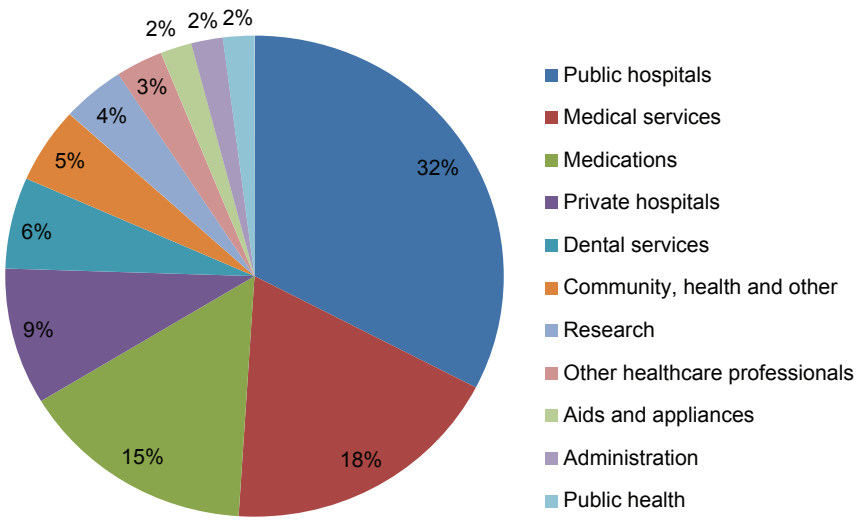


Source: AIHW 2012

The biggest areas of health expenditure were hospitals (public 32%, private 9%), medical services (18%) and medications (15%). Aids and appliances made up only 2% of total expenditure (administration costs were also 2%)[20]. In 2010-11 average expenditure on health was $5,796 per person[21]. Australians spend on average $1,082 each year on out of pocket medical costs (or 19.3% of total health expenditure)[22]. Consumers contribute the second largest source of funding for healthcare in Australia[23]. Australia is in the top five highest spending nations in the world when it comes to consumer contributions towards healthcare[24]. Our out-of-pocket costs are double that of the UK or France. The cost of healthcare is expected to increase. There are five working-aged people today to support every Australian aged 65 or over. By 2050 there will only be 2.7 working-aged people per aged person[25].

20 AIHW. Health Expenditure Australia 2010-11. 2012. Health and welfare expenditure series no. 47. Cat. no. HWE 56. Canberra.
21 Ibid.
22 Ibid.
23 AIHW 2012 Australia's Health 2012 (Cat. no. Aus 156). AIHW, Canberra.
24 Consumers Health Forum of Australia. Health Voices, Journal of the Consumers Health Forum of Australia, Issue 12, April 2013.
25 Intergenerational Report 2010 (Canberra: Commonwealth of Australia, 2010), Table 1.4, 10.

Figure 4: Recurrent health expenditure by area of expenditure* (2010-11)[26]



*Includes patient contributions and out-of-pocket expenditure on medicines

8.1. Public hospital funding (activity based funding)

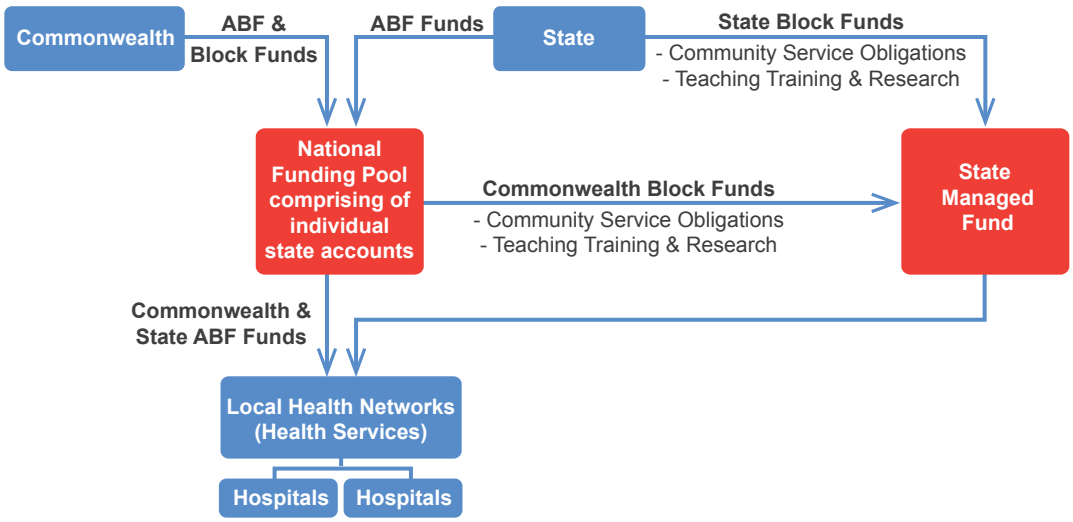
Australia's publicly funded healthcare system is facing increasing cost pressures. Spending on public hospital services in 2010-11 was calculated to be $38.9 billion, or 32% of recurrent expenditure[27]. It has been estimated that without changes to the existing funding approach expenditure on health services would consume the whole of state budgets by 2045-46. In previous years states and territories experienced growth in health spending of around 9%. This contrasts with the growth in state and local government tax revenues of approximately 6% per year over the same period of time[28].

In 2008 the federal, states and territories governments agreed on major reforms to the way public hospitals are funded and operated. In 2011 the Council of Australian Governments (COAG) established activity based funding (ABF) as the primary funding methodology for public hospital services throughout Australia. Under ABF public hospitals are funded according to the number and services they provide. As more services are delivered the federal government will contribute 45% towards efficient growth in 2014-15, increasing to 50% from 2017-18. 2013 will be a transitional year in which the total federal government funding is limited to the level set in the 2008 National Healthcare Agreement. Over the period 2014-20 the federal government will provide at least $16.4 billion in additional funding for public hospitals[29].

Australia adopted a hybrid approach to ABF that combines an open-ended case payment system (federal government funding being uncapped from 2014) and a capped budget allocation system (state funding: states will have agreements with Local Health Networks).

26 Data from AIHW, Health Expenditure Australia 2010-11. Supplementary tables, Table 4.3.
27 AIHW. Health expenditure Australia 2010-11. Health and welfare expenditure series no. 47. Cat. No. HWE 56. Canberra.
28 Department of Health and Ageing. (2011). National Healthcare Agreement 2011.
29 IHPA. The pricing framework for Australian public hospital services, www.ihpa.gov.au/internet/ihpa/publishing.nsf/Content/national-efficient-price-2013-14.

Figure 5: New funding process for public hospital services



Source: Department of Health, Victoria[30]

The Independent Hospital Pricing Authority (IHPA) is responsible for setting the National Efficient Price (NEP) based on episodes of care in public hospitals. The NEP is used to calculate the federal government's contribution to public hospital funding. The NEP for 2013-14 was set at $4,993 per National Weighted Activity Unit (NWAU). NWAUs express the price weights for all services that are funded on an activity basis and are set in the classification catalogues[31]. The NEP is based on the projected average cost for all NWAUs and is derived from the Hospital Cost Data Collection Round 15 (2010-11) and indexed at a rate of 4.7% per annum.

While most services will be funded on an activity basis some services are not suitable because their service volume is low or unstable, units for counting do not exist or there is no suitable classification system in place. These services will continue to be block funded. Adjustments to price weights exist for intensive care units, specialist paediatric and psychiatric services, indigenous patients, outer regional hospitals and remote and very remote locations[32].

Public hospital services	Classification systems used in public health services 2013-14
Acute admitted care	AR-DRG V6.x
Emergency services	URG/UDG V1.3
Non-admitted services	Tier 2 non-admitted services V2.0
Sub acute services	AN-SNAP V3.0
Specialist mental health services	AR-DRG V6.x/block funded services
Teaching, training and research	Block funded services

30 Department of Health, Victoria. The move to a national activity based funding model, 2012.
31 IHPA, The pricing framework for Australian public hospital services, www.ihpa.gov.au/internet/ihpa/publishing.nsf/Content/national-efficient-price-2013-14.
32 Ibid.

9. Medical technology and healthcare everywhere

The future of healthcare is in patient-empowering, information-leveraging technologies[33]. These include smartphone apps, sensor-embedded smart devices and remote patient monitoring. These have the potential to increase the efficiency of healthcare delivery and are blurring the line between medical devices/diagnostics and health IT. Combining patient empowerment and information/analysis may lead to two breakthroughs:

1. real time insights – timely information to assist health management, e.g. sensor monitoring of vital signs
2. efficiencies – low-cost means of delivering healthcare efficiently.

Chronic disease accounts for 75% of healthcare costs. Moving healthcare out of hospitals and into the home is one way of decreasing this cost[34]. Technologies such as smartphone apps and medical devices that can be remotely monitored and vital signs monitoring in the home empower patients.

Everyday objects, including medical devices, are increasingly becoming sensor-embedded and wirelessly connected. This has been termed "the medicalisation of consumer devices". In 2012 the UK's National Heath Service (NHS) began encouraging physicians to prescribe smartphone apps to patients. In 2011 44 million health-related smartphone apps were downloaded worldwide[35]. Monitoring services will account for 65% of the global mHealth market by 2017[36].

Technology innovation and the patient[37]

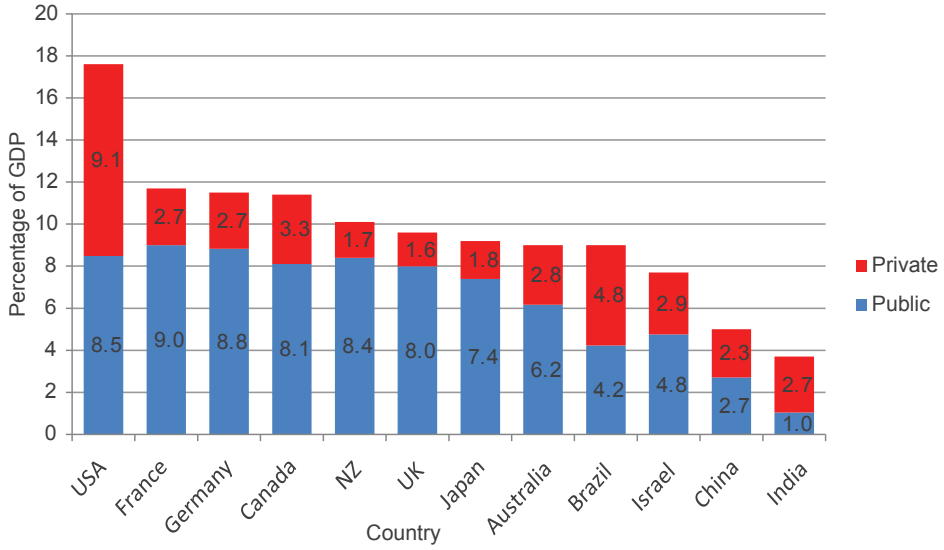
Technology enabler	Patient impact
Smart mobility	Ability to do the following from anywhere, at any time: • communicate with medical professionals • access health-related information to research conditions • obtain healthcare from remote communities • monitor/manage chronic disease • fitness/wellness programs and monitoring
Social networking	Tap into peer group knowledge to: • compare costs of different providers and physician practices • compare outcomes performance of different providers and physician practices • obtain peer advice on treatment and living with chronic conditions
Cloud computing	Enables: • delivery of "heavy weight" healthcare services and information to mobile devices • personal healthcare ecosystems, including secure storage of patient information
Big data analytics	Enables: • individualised healthcare services • targeted wellness and prevention • cost comparison of different providers.

33 Ernst & Young. Pulse of the Industry. Medical technology report 2012.
34 Ernst & Young. Progressions. The third place: healthcare everywhere. Global Life Sciences Report 2012.
35 Telecommunications: Mobile Healthcare and Medical App Downloads to Reach 44 million next year, Rising to 142 million in 2016, Finds, Juniper Research Limited. Telecommunications Weekly, 14 December2011, via Factiva, 2011 Telecommunications Weekly via VerticalNews.com.
36 Ernst & Young. (2013). mHealth. Mobile technology poised to enable a new era in healthcare.
37 Modified from: Ernst & Young. (2013). mHealth. Mobile technology poised to enable a new era in healthcare (page 17).

10. International health expenditure and trends

Public and private health expenditure for 12 major economies as a percentage of GDP is shown below. The total Australian health spend is just under half of that of the USA. India, Brazil and the USA have higher private expenditure on health than government contribution[38].

Figure 6: Total health expenditure as a percentage of GDP for 12 industrialised economies (2010)



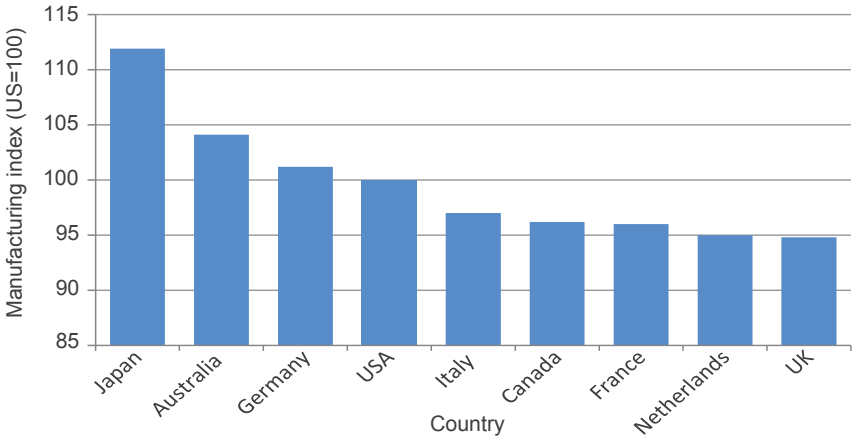
Source: WHO. World health statistics (2013)

- Health spending has stagnated world wide. Following a sharp decrease in 2010, health spending remained stagnant in 2011 (due to the impact of the global economic crisis and the concomitant decrease in both government and private health spending). Spending on health grew by 5% each year on average between 2000-09, while growth in 2010 and 2011 has been approximately 0.5% each year. The largest decreases in spending occurred in Greece and Ireland. The only OECD countries to increase spending on health were Israel and Japan[39].
- Annual sales of medical technology in Europe are approximately US$95 billion (or 33% of the world market). Around 80% of sales are from the small and medium sized enterprises (SMEs) sector[40].
- The medical technology sector employs around 500,000 staff in Europe[41].
- The European medical technology industry is growing at over 5% per annum[42].
- Each additional medical technology industry job created in the USA generates an additional 4.5 jobs across the country[43]. In the USA medical technology represents around 20% of total cost growth in healthcare. The largest components of the USA medical technology market are diagnostic imaging, cardiovascular procedures and *in-vitro* diagnostics (IVDs)[44].
- Despite the challenges of the current economic climate, net income for publicly held medical technology companies increased by 14% in the USA. This increase is less than the double digit figures of the past and financial performance is likely to continue to be challenged by low economic growth, austerity measures and imminent 2.3% medical device tax in the US[45].
- Canada has approximately 1,000 medical device companies and employs around 26,000 people. The size of the Canadian device market was US$6.3 billion in 2011 and had device exports of US$1.8 billion and imports of US$6.5 billion[46].
- Israel has 656 medical device companies. Israeli device companies are typically very small: 50% employ 5 or less people and nearly 70% of companies are still at the pre-market or non-commercial stage of product development. These start-ups are viewed as drivers of innovation and are often supported by venture capital and other investments. Overall production revenue (exports and local sales) for Israel was US$2 billion in 2011[47].

38 WHO. World health statistic 2013, www.who.int/gho/publications/world_health_statistics/EN_WHS2013_Full.pdf.
39 www.oecd.org/health/health-systems/oecdhealthdata2013-frequentlyrequesteddata.htm.
40 www.eucomed.org/medical-technology/value-benefits.
41 www.eucomed.org/medical-technology/value-benefits.
42 www.eucomed.org/medical-technology/value-benefits.
43 The Lewin Group, Inc, State Impacts of the Medical Technology Industry, 2007.
44 Beever, C. & Karbe, M. The Cost of Medical Technologies. Maximising the Value of Innovation. Booz, Allen, Hamilton.
45 The Lewin Group, Inc, State Impacts of the Medical Technology Industry, 2007.
46 The World Medical Markets Fact Book 2012, Espicom, July 2012.
47 Meidata. Israel Medical Devices Industry. Market Overview. August 2012.

KPMG performs an annual survey of manufacturing costs internationally including manufacturing costs for medical devices. The results of the manufacturing costs index for nine countries are presented below[48].

Figure 7: Medical device manufacturing costs



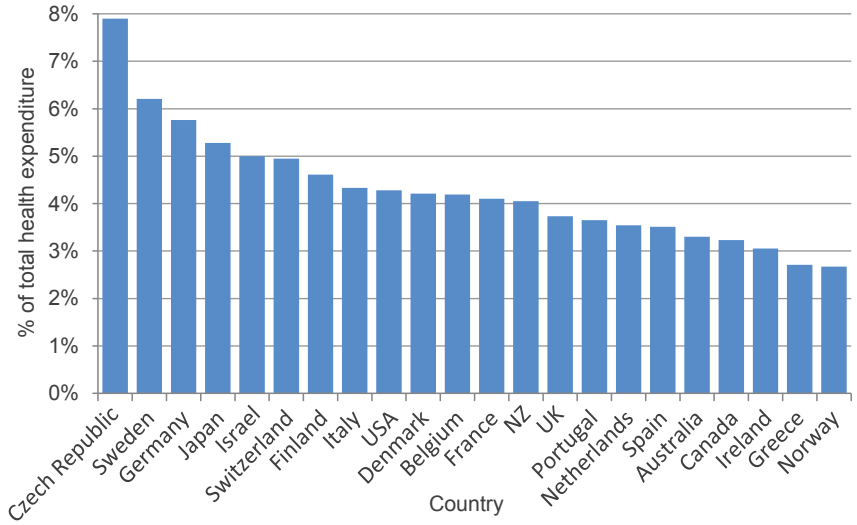
Source: KPMG 2012

10.1. Relative costs of medical technology

Medical technology is often blamed for the high cost of healthcare. Data from both local and international sources show that this assumption is incorrect. Data from the World Medical Markets Fact Book 2012 (Espicom) which covers expenditure on medical devices in 66 countries shows that expenditure on devices is relatively low compared to other health costs[49].

Of the 66 countries from which data are available Australia ranked 13th for total health spending per capita and 15th for medical device spending per capita. Australia was ranked 54th when measuring medical device spending as a percentage of total health spending, indicating that spending on medical devices is a small percentage of total health expenditure. There was a decline in spending on medical devices from 3.8% of total health spending in Australia in 2006 to 3.3% in 2011 (average 3.6% over the period). Australia ranked as low as 41st for medical device spending as a percentage of GDP per capita and device spending per capita accounted for only 0.29% of GDP per capita on average. The data suggests that in comparison to other countries spending on medical devices is relatively low in Australia and has only a minor impact on overall costs[50].

Figure 8: Medical technology expenditure as a percentage of total health expenditure in 2011 (per capita, current US$), for select high GDP OECD countries[51]



Prices in the health sector have grown faster than in the broader economy during the last decade. However, these costs have been driven by an increase in the volume of health goods and services purchased, rather than in the price of services. The increase in volume is due to population growth (rather than expenditure per person). Growth in total health expenditure is around 5.3% per year, versus growth in per person health expenditure of 3.9% per year[52].

48 Medical Device Manufacturing Costs (Competitive Alternatives: KPMG's Guide to International Business Location Costs. 2012 Edition).
49 World Medical Markets Fact Book. (2012). Espicom Business Intelligence.
50 Ibid.
51 Ibid.
52 AIHW. 2012. Australia's hospitals 2011-12 at a glance. Health services series no. 49. Cat. No. HSE 133. Canberra.

11. Value of the global medical technology industry

Globally, the medical technology market is valued at over US$325 billion per annum[53]. It is predicted that by 2018 global sales of US$440 billion will be achieved. A report by Evaluate MedTech that assessed data from 120 global medical technology companies reported that medical technology is set to outperform the prescription drug market with 4.5% growth per year (versus 2.5% per year for the prescription medication market). The IVDs segment is the largest segment of the medical technology market. Research and Development (R&D) in medical technology is growing at 3.3% per annum[54].

	Device area [55]	Worldwide sales (2011) (US$bn)	Worldwide sales (2018) (US$bn)	CAGR* % growth
1	*In-vitro* diagnostics	40.3	54.5	+4.4%
2	Cardiology	36.1	48.3	+4.3%
3	Diagnostic imaging	35.8	45.5	+3.5%
4	Orthopaedics	30.2	37.5	+3.1%
5	Opthalmic	23.0	33.9	+5.7%
6	Endoscopy	16.6	24.2	+5.5%
7	Drug delivery	15.6	19.9	+3.6%
8	Wound management	11.9	16.4	+4.6%
9	Dental	12.1	16.4	+4.4%
10	General & plastic surgery	10.7	15.9	+5.7%
11	Diabetic care	11.4	15.3	+4.3%
12	Nephrology	10.4	12.5	+2.8%
13	Ear, nose & throat	6.5	9.7	+6.0%
14	Healthcare IT	6.3	8.0	+3.3%
15	Neurology	4.9	7.3	+6.1%

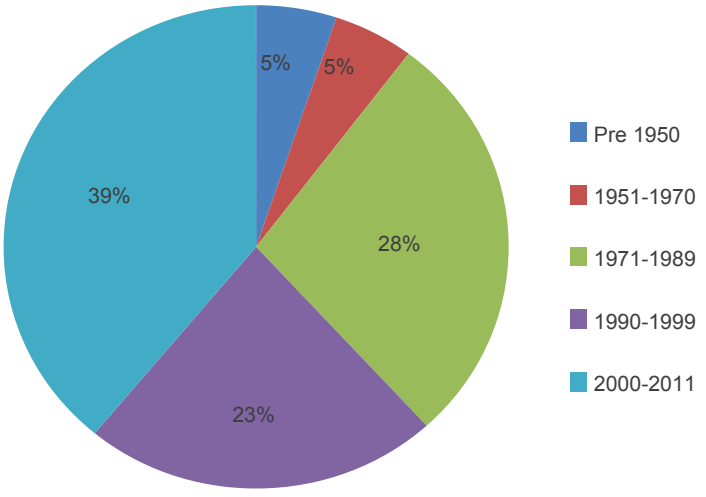
**Compound Annual Growth Rate*

12. Medical technology industry profile in Australia

12.1. Year of establishment

The medical technology industry has grown substantially since 1990 with the majority of companies (62%) established during the 1990-2012 period. Only 10% of medical technology companies operating in Australia were established prior to 1970. Through the 1950s and 60s the industry experienced sustained growth but it was not until post 1970 that more rapid expansion occurred. Almost 40% of companies were established post 2000.

Figure 9: Year of establishment



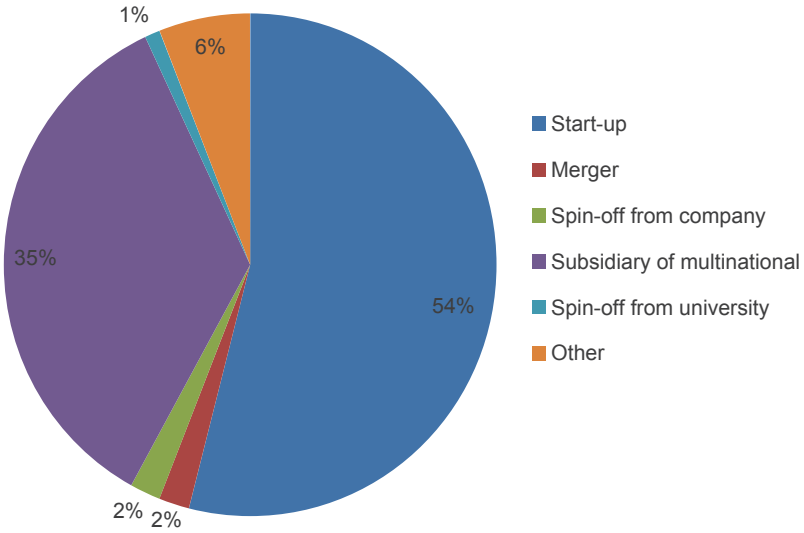
Source: MTAA industry wide survey 2012

53 Evaluate MedTech. (2012). World Preview 2018: A consensus view of the Medical Device and Diagnostic Industry.
54 Ibid.
55 Modified from Idib.

12.2. Company structure

The majority of Australian companies (54%) have grown from start-up companies. Over one-third (35%) of Australian companies were established as a subsidiary of a multinational company. Other companies were formed as spin-off companies from other companies (2%), spin-off companies from universities (1%) and mergers (2%)[56].

Figure 10: Company structure



Source: MTAA industry wide survey 2012

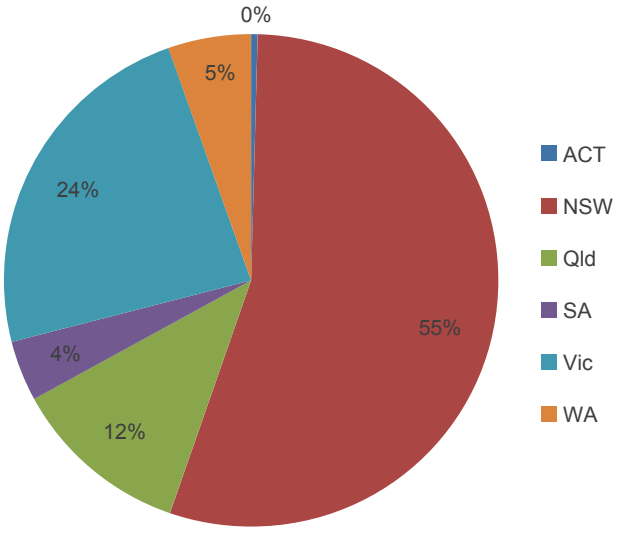
12.3. Number of companies

There are over 500 medical technology companies in Australia with products included on the ARTG. This number does not include IVD companies that supply medical devices (of which there are approximately 54) or dental companies (of which there are approximately 50).

12.4. Location of companies

The majority of medical technology companies (head offices) are located in NSW (55%) followed by Victoria (24%) and Queensland (12%).

Figure 11: Location of medical technology companies in Australia (%)



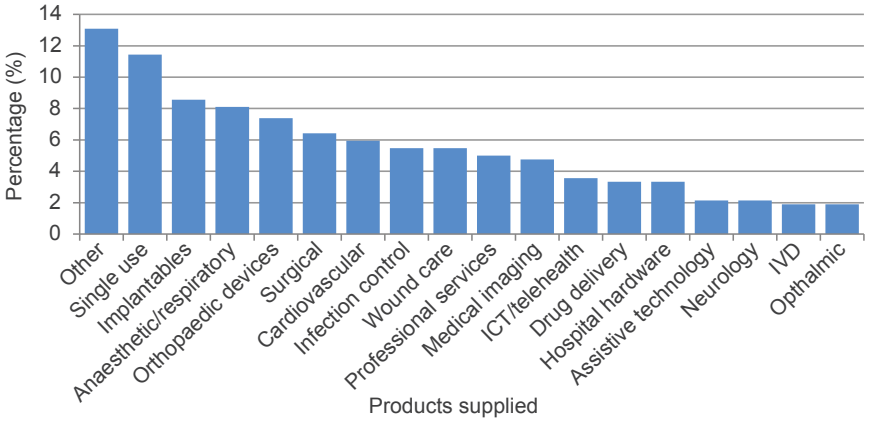
Source: MTAA database 2013[57]

56 Ibid. Another 5% of companies listed other as the origin of the company.
57 Data was available for 479 medical technology companies on the MTAA database.

12.5. Products supplied by companies

Medical technology companies develop, manufacture and supply a wide variety of devices. Principal products supplied or manufactured in Australia include single use technologies (11%), implantable devices (9%), anaesthetic/respiratory (8%) and orthopaedic devices (7%). The data was obtained through the MTAA industry wide survey (companies were able to select more than one category)[58].

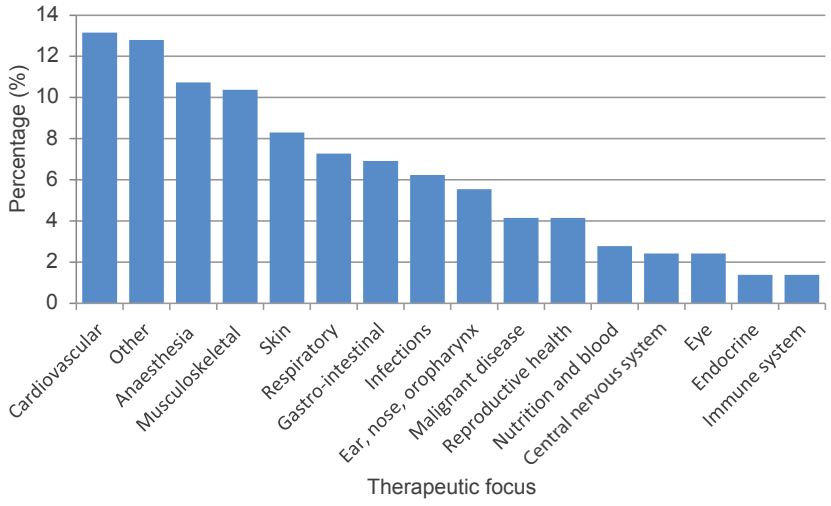
Figure 12: Principal products supplied in Australia



Source: MTAA industry wide survey 2012

The main areas of therapeutic focus for Australian companies are cardiovascular (13%), anaesthesia (11%), musculoskeletal (10%) and skin (8%).

Figure 13: Areas of therapeutic focus



Source: MTAA industry wide survey 2012

58 MTAA Industry wide survey 2012.

13. Employment in the medical technology sector in Australia[59]

The medical technology industry in Australia employs over 19,000 people[60]. Employees are highly qualified with 50% of staff having a tertiary qualification and 21% having a postgraduate qualification. Disciplines relevant to the medical technology industry include biomedical engineering, biological sciences, health economics, information technology, law, manufacturing, nursing, physical sciences, regulatory and quality, sales and marketing.

Of those employed in the medical technology industry, a large number are employed in the manufacturing sector. The Australian Bureau of Statistics (ABS) estimates that in 2009-10 there were 12,545 people employed in the medical technology manufacturing sector (this includes those in the medical and surgical equipment manufacturing sector, *n*=11,199 and those in the photographic, optical and ophthalmic equipment manufacturing sector *n*=1,346)[61].

14. Medical technology listed on the Prostheses List [62]

There are 9,863 devices listed on Part A and C of the February 2013 Department of Health and Ageing (DoHA) Prostheses List which are reimbursed by private health insurance. 70% of items on the Prostheses List are supplied by MTAA members[63]. The February 2013 list includes 1,222 changed billing codes, 774 of which are for new products (806 items were deleted). There are 119 (1.2%) gap-permitted prostheses. Following finalisation of relevant Health Technology Assessment (HTA) Review reforms, future Prostheses Lists will have only no-gap prostheses listed with a single benefit[64].

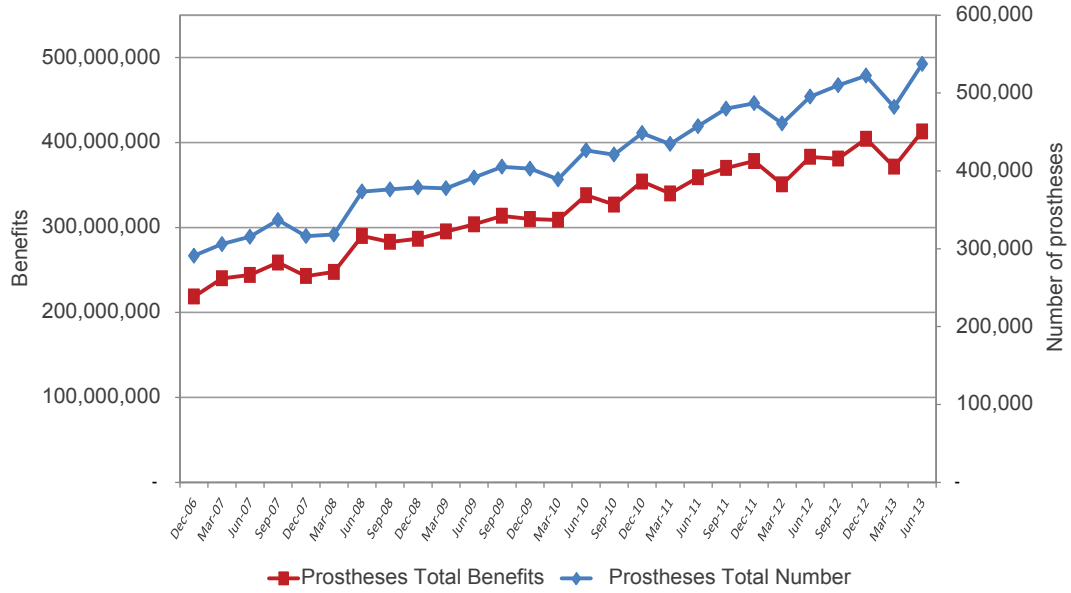
Prostheses list category	Number of products
Part A	
Specialist Orthopaedic	2,778
Spinal	1,379
Hip	1,143
Knee	1,102
General Miscellaneous	827
Plastic and Reconstructive	668
Vascular	522
Neurosurgical	432
Cardiac	319
Urogenital	212
Ophthalmic	207
Ear, Nose & Throat	166
Cardiothoracic	71
Orthopaedic	22
Plastic and Reconstructive*	3
Part C	
General Miscellaneous	8
Cardiac	4
Total	**9,863**

Source: MTAA analysis
**Bone Matrix Implants (artificial)*

In 2012 benefits of approximately $1.5 billion were paid by registered health insurers. Annual expenditure grew by 5.6%, while utilisation grew by 7%.

59 Ibid.
60 Estimate from MTAA database and MTAA industry wide survey 2012.
61 Sources ABS, Cat. No. 8159.0. Experimental Estimates for the Manufacturing Industry. 2009.
62 Figures do not include human tissue.
63 www.health.gov.au/internet/main/publishing.nsf/Content/prostheses-list-pdf.htm.
64 Prostheses list February 2013, www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-prostheseslist.htm.

Figure 14: PHIAC prostheses expenditure by quarter



Source: PHIAC 2013[65]

There are approximately 3,200 product items on the February 2013 Prostheses List that were also listed on the 2005 list (product category change not analysed). There were 6,672 items that could not be matched because of billing code changes. The matched items show that the average minimum benefits have decreased by $35.36 since 2005. If increases in the Consumer Price Index (CPI) are taken into account benefits should have increased by 23%. Actual increases have been in the range of 14%.

2,688 orthopaedic product billing codes on the February 2013 Prostheses List are tracked by the NJRR and are levied $316.22 each by government to cover the registry's $1.7 million annual operating costs. The levy follows determination of each of the biannual Prostheses Lists.

15. Medical device inclusions in the Australian Register of Therapeutic Goods (ARTG)

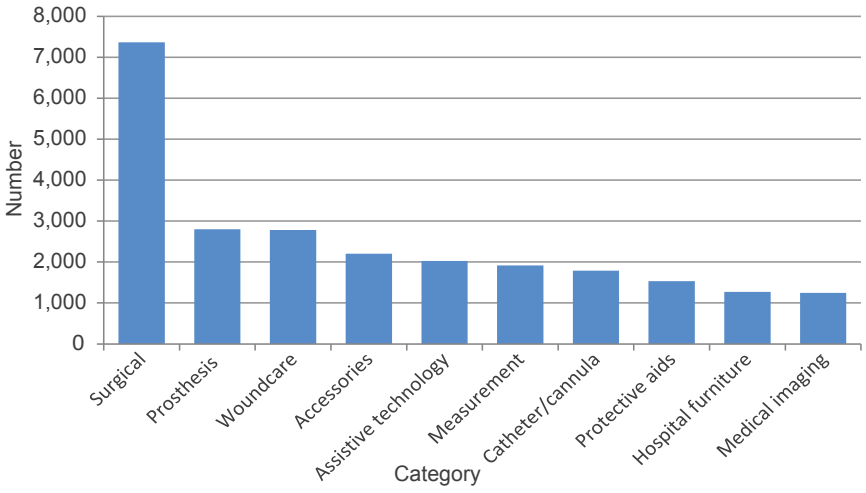
All medical technology products sold domestically or exported from Australia are regulated by the TGA and have to be entered in the ARTG before they can be supplied. New medical technologies are added to the ARTG daily. There are over 41,000 entries for medical devices in the ARTG (2013) (including IVDs and dental products) with an estimated 500,000 to one million different devices linked to them. The number of items in each class is show below.

Class	Number of ARTG entries	Risk Level and Regulatory Requirements	Examples
Class I	20,319	Low	Non-sterile dressings, wheelchairs
Class IM	412	Low to medium	Device with measuring function
Class IIA	1,692	Low to medium	Electrocardiographs, hearing aids
Class IIB	9,728	Medium to high	Non-implantable infusion pumps
Class III	3,057	High	Heart valves, aneurysm clips
AIMD	302	High	Pacemakers, neurostimulators

Items in the ten most common categories make up over 60% of items on the ARTG.

65 http://phiac.gov.au/industry/industry-statistics/prostheses/.

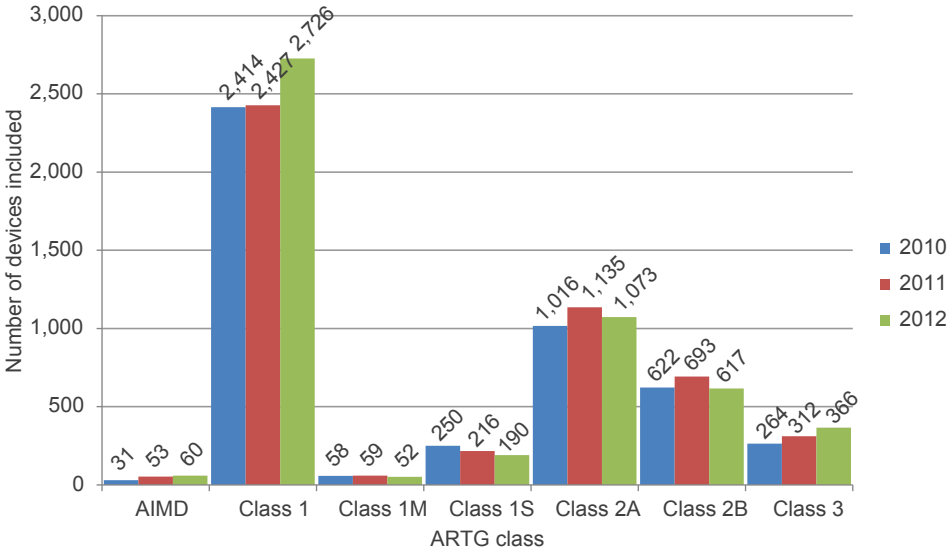
Figure 15: The most common medical technology items included on the ARTG



Source: ARTG

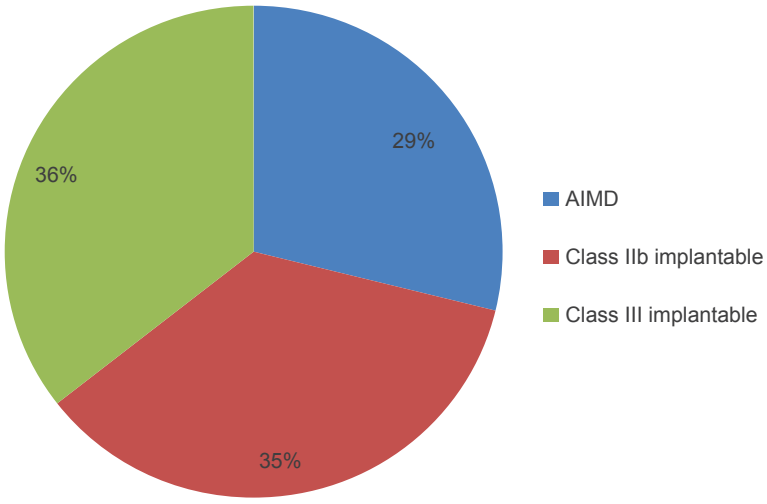
There has been a notable increase in Class III and AIMD devices entered in the ARTG over the past 3 years (see below).

Figure 16: ARTG license starting dates



Source: ARTG

Figure 17: 2012 Prostheses list entries on the ARTG by device class



Source: ARTG

16. Value of the medical technology industry in Australia

There is no official data collected on sales of medical technology in Australia. MTAA calculates the size of the industry based on extrapolation of data from its database and from statistics collected by its contracted service provider UltraFeedback via an industry wide survey and the quarterly Market Barometer Online Survey (MBOS)[66]. This information is augmented by data obtained from the Manta Media website. Total revenue for the Australian medical technology industry for 2011-12 was over $9.6 billion. If sales of IVDs are also included ($800 million)[67] the revenue is $10.4 billion, and with the further addition of dental products ($671 million), around $11 billion[68]. Australia has 35 companies listed on the Australian Securities Exchange (ASX), making up 28% of total value (MCap=$13,812 million)[69].

The MBOS constitutes data from 18 of the largest MTAA member companies reporting their Australian quarterly revenue in medical devices. Data from the second quarter 2013 survey shows:

Sales Revenue Increases:

- sales for the second quarter 2013 were 13.8% higher than sales in the first quarter 2013. There was growth across all states and distribution channels (with the exception of other professional outlets)
- long-term MAT (moving annual total) sales across all areas have grown 4% (year over year)
- long-term growth of sales is driven via private hospitals 5%
- long-term growth of sales is stronger in WA (7.5%) than other states.

Service repair continues to grow for a second quarter with an annual growth of 20%. The largest segment is consumables which have grown 4.6%

Sales Revenue Decreases:

- equipment sales are experiencing a longer term decrease of 8.4%.

Growth of 5.4% per annum over the next five years for medical and surgical equipment manufacturing has been forecast[70]. Key external drivers are demand from hospitals and wholesales, an increase in medical and surgical products as a result of visits to doctors, increased capital expenditure on machinery and an increase in product demand as a result of improved health funding. While private hospitals/clinics represent about 10% of the market for industry products, this group is characterised by high-technology sales. A key driver of consumption in Australia is the ageing population.

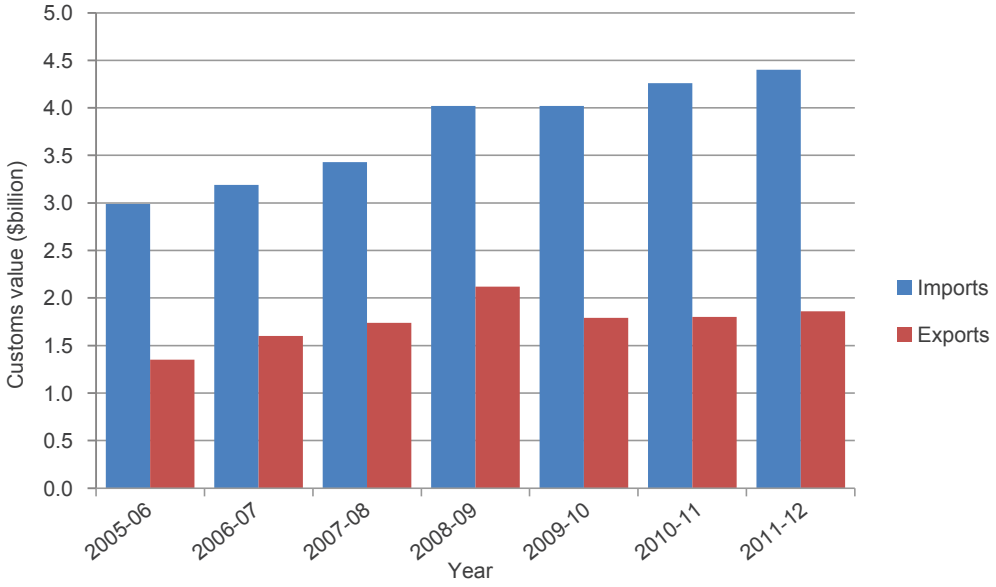
66 This information is augmented by data obtained from Manta Media: www.manta.com/world/Oceania/Australia/.
67 www.ivd.org.au/files/9913/1770/3601/IVD_annual_2011_WEB.pdf._
68 www.adia.org.au/DocumentViewer.aspx?ID=270.
69 PriceWaterhouseCoopers, (2013). For better or for worse: Life Sciences companies and the changing AUD. BioForum, Edition 44, Quarter 4 FY13, July 2013.
70 IBISWorld (2010). Rachel Lohan. IBISWorld Industry Report C2832. Medical and Surgical Equipment Manufacturing in Australia.

17. Imports and exports of medical technology in Australia

Nearly all medical technology products manufactured in Australia are exported, while the majority of medical technology products used in Australia are imported. Between 2011-12 the value of medical technology imports was $4.4 billion and the value of medical technology exports was $1.86 billion[71].

Australia imports significantly more medical devices than it exports (a net deficit in trade in medical technology). Even smaller countries such as the Netherlands achieve a positive balance of trade. There are several steps that can be taken to increase the sustainability of the medical technology sector which can contribute to a stronger healthcare system. A discussion paper released by the Future Manufacturing Industry Innovation Council identifies several factors that will support the robustness of Australian manufacturing. These include the capability to identify, design, develop, make and sell products that are in demand; maximise leverage from strong and sustainable partnerships through local and global supply chains; and seek markets in emerging growth economies[72].

Figure 18: Australian medical technology imports and exports (2005-12)



Source: ABS, International Trade: Customised Report for Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education

Top ten import and export products (2011-12) (according to value)

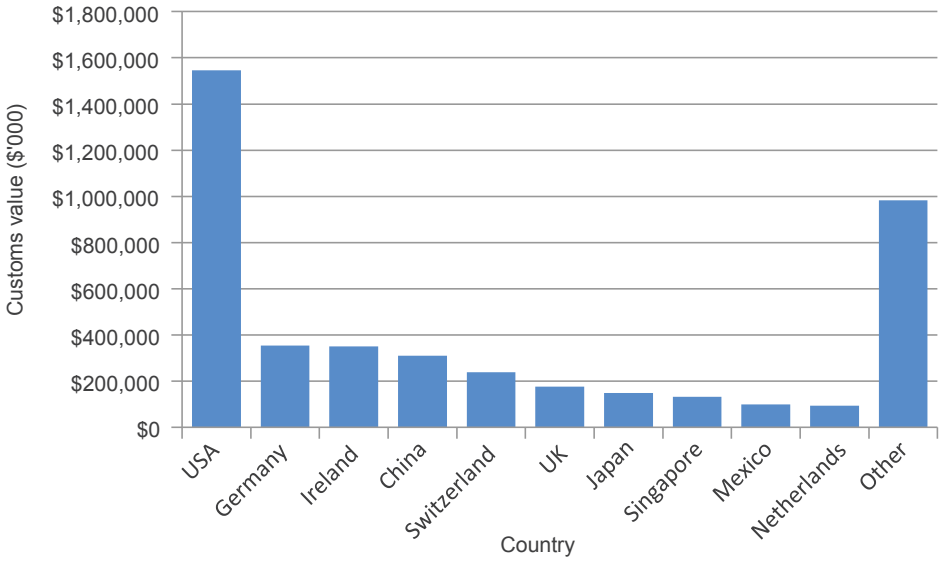
Top import items	Top export items
Other instruments	Respiratory
Artificial body parts	Artificial body parts
Imaging	Other instruments
Wound care	Hearing aids
Needles/syringes	Imaging
Spectacle components	Other
Cardiac	Spectacle components
Hearing aids	Needles/syringes
Orthopaedic	Optical/ophthalmic

71 Data obtained from ABS, International Trade: Customised Report for Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education.
72 Future Manufacturing Council. Trends in manufacturing to 2020. Canberra September 2011.

17.1. Imports

The majority of medical technology products are imported from the USA, followed by Germany and Ireland.

Figure 19: Top ten countries importing medical technology into Australia (2011-12)

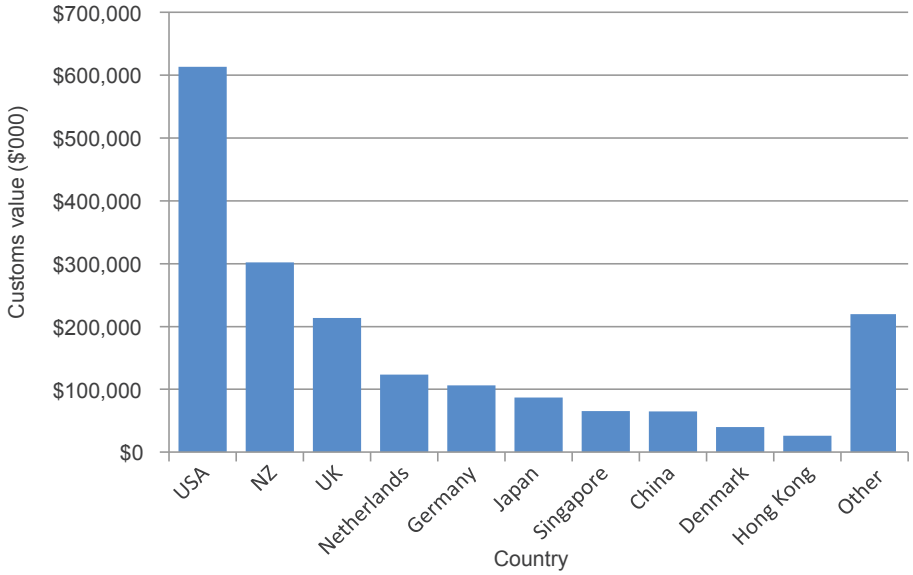


Source: ABS, International Trade: Customised Report for Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education

17.2. Exports

Australia's most popular export destination for medical technology is the USA, followed by New Zealand and the UK.

Figure 20: Top ten export destination countries from Australia (2011-12)

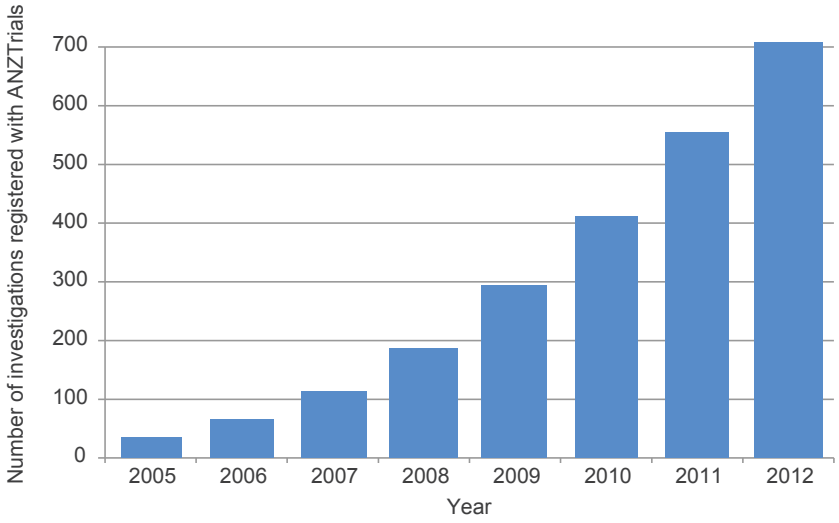


Source: ABS, International Trade: Customised Report for Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education

18. Medical technology and clinical investigations in Australia

Australia is internationally recognised for conducting high quality clinical investigations (medical technology investigations differ from traditional pharmaceutical randomised controlled *trials*). Clinical investigations represent a major investment in Australia - with an estimated worth of $1 billion per annum to the Australian economy, which includes more than $450 million of foreign investment[73]. The number of clinical investigations conducted in Australia continues to grow steadily. In 2012 there were 153 medical technology clinical investigations registered in Australia - a growth of 7% from 2011[74].

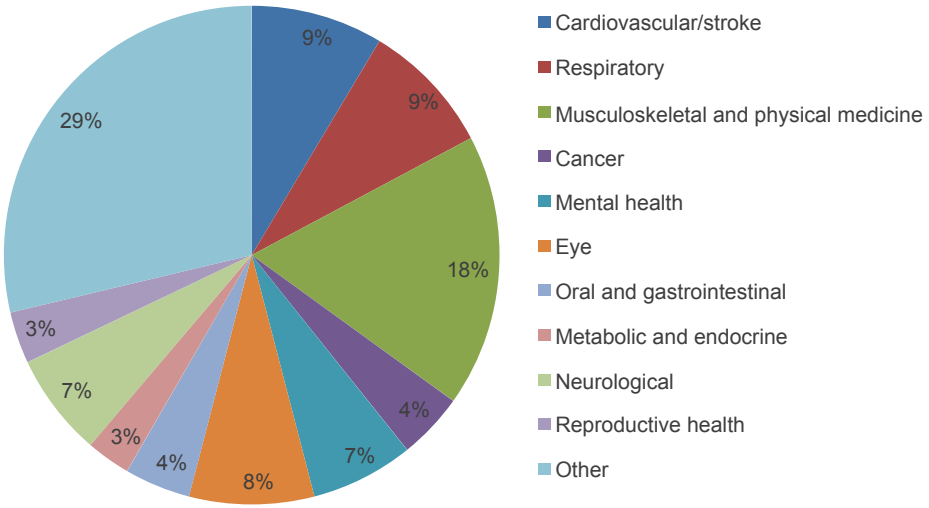
Figure 21: Cumulative number of medical technology investigations registered in Australia[75]



Source: Australian New Zealand Clinical Trials Registry (ANZCTR)

As the global competition for attracting clinical investigations continues to increase, there is a strong need for Australia to continue to attract the level of activity it has achieved in the last 20 years[1]. In recognising the need to remain competitive for global investigations, the Australian Government established the Clinical Trials Action Group (CTAG)[76] to identify and progress necessary reforms to secure Australia as a preferred destination for conducting clinical investigations. In March 2013 the IHPA released a discussion paper regarding the processes that apply to the development of a list of standard costs for conducting clinical investigations in Australia[77]. IHPA has been directed by the Australian Government to meet the recommendations provided by CTAG to enhance the clinical investigation environment in Australia and to improve the attractiveness of Australia as a destination for global research investment. Data from the second quarter 2013 survey shows IHPA have developed a list of standard costs of clinical trials in Australia for pharmaceuticals only (not for medical technology).

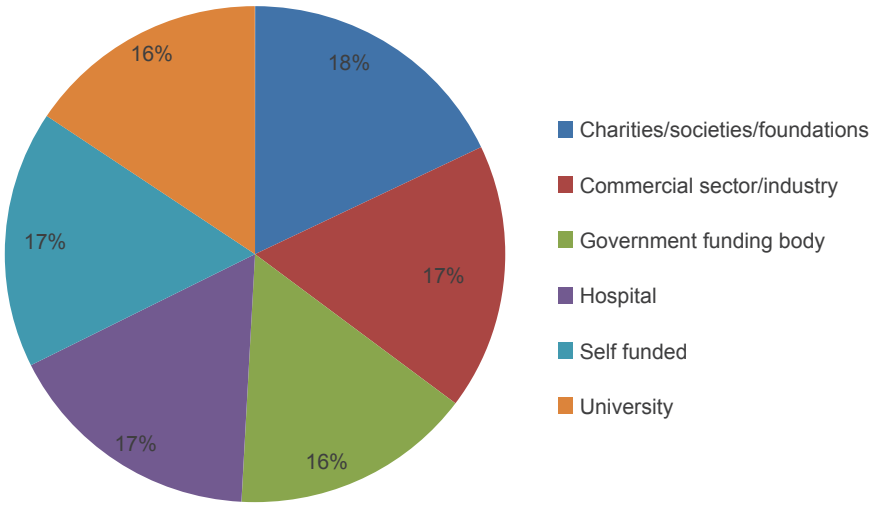
Figure 22: Medical technology investigations for different conditions (2012)



Source: ANZCTR

73 Australian Government. Clinically competitive: Boosting the business of clinical trials in Australia. Clinical Trials Action Group Report, 2011, www.innovation.gov.au/Industry/PharmaceuticalsandHealthTechnologies/ClinicalTrialsActionGroup/Documents/Clinical_Trials_Action_Group_Report.pdf.
74 Data provided by the Australian New Zealand Clinical Trials Registry (ANZCTR).
75 The number of trials may not be a true representation of all device trials in Australia – some industry sponsored trials may not be included.
76 The Clinical Trials Action Group (CTAG). http://www.innovation.gov.au/INDUSTRY/PHARMACEUTICALSANDHEALTHTECHNOLOGIES/CLINICALTRIALSACTIONGROUP/Pages/default.aspx.
77 IHPA's paper on the 'Development of a table of standard costs for conducting clinical trials in Australia'.

Figure 23: Funding source for medical technology clinical investigations (2012)



Source: ANZCTR

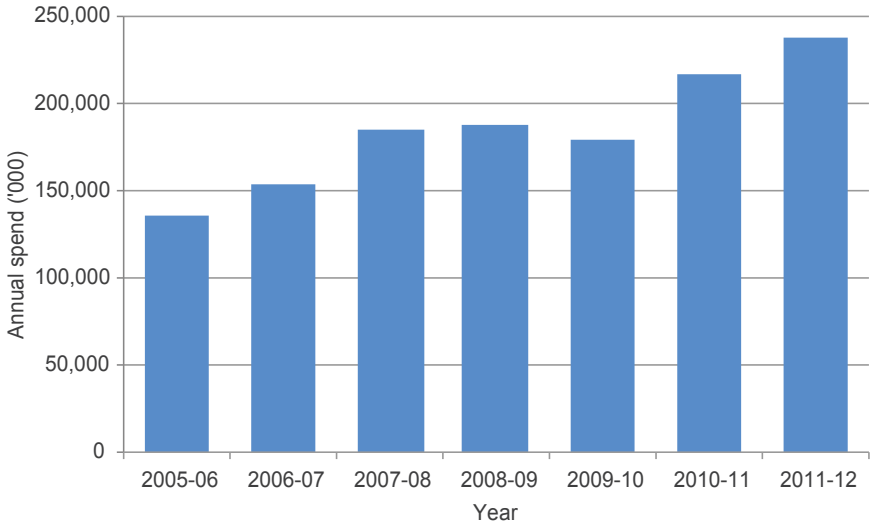
19. Innovation

19.1. Research and Development (R&D)

The annual spend for R&D in 2011-12 for medical and surgical equipment manufacturing was $237 million[78]. This is an increase of approximately $20 million (9%) from the previous year. There is a wide range of funding/government assistance available for medical technology companies in Australia[79]. A small number of venture capital (VC) firms in Australia invest in medical technology businesses (e.g. Brandon Capital Partners, Carnegie & Co, GBS Venture Partners Limited). The assets of Australian VC-backed companies make up only 0.3% of gross domestic product (GDP). However, it has been estimated that they contribute 10% of all business R&D expenditure, 13% of patent filings and 27% of patent citations[80]. For each dollar of assets, VC-backed companies innovate at a much greater rate than other companies. In Australia, companies backed by VC, spend on average 200 times more on R&D per employee. VC-backed companies comprise 36% of the healthcare equipment and services subsector[81].

78 81040D0009_201112 Research and Experimental Development, Businesses, Australia, 2011-12.
79 See, http://mtaa.org.au/about-the-industry/commercial/government-programs (link accessible for members).
80 AVCAL analysis, Cumming and Johan 2012. Patent numbers are winorised at the top 1% to exclude multinationals with very large numbers of patents filed in Australia.
81 S&P/Capital IQ, Australian Financial Review, company sources. Market capitalization figures as of 31.07.12.

Figure 24: R&D spend for medical and surgical equipment manufacturing

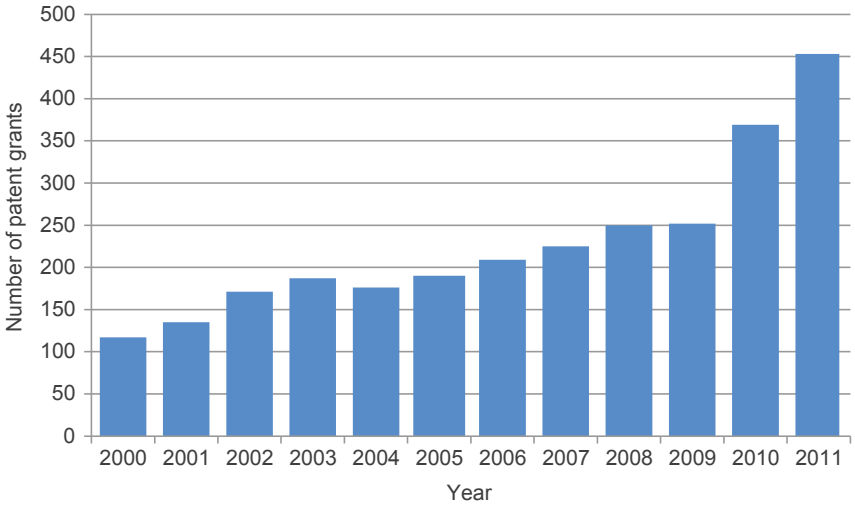


Medical technology companies provide a good indicator of innovation. The number of Australian medical technology patent grants has shown a steady increase since 2011.

19.2. Patent applications

Public health is a global challenge. The World Health Organization (WHO) and the World Intellectual Property Organization (WIPO) collaborate to respond to increasing demand and to ensure access to innovative, regulated medical technologies[82]. Medical technology patent applications made up 6.9% of the total number of applications between 1997-2011 (comparable to pharmaceuticals 5.9% and civil engineering 7.7%)[83]. Patent applications by medical technology companies provide a good indicator of innovation. The number of Australian medical technology patent grants has shown a steady increase since 2011.

Figure 25: Number of Australian medical technology patent grants (2000-11)[84]



82 World Health Organization, World Intellectual Property Organization and World Trade Organization (2012). Promoting Access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade.
83 http://www.wipo.int/ipstats/en/statistics/country_profile/countries/au.html.
84 WIPO Intellectual Property Statistics Data Center, http://ipstatsdb.wipo.org/ipstatv2/ipstats/patentsSearch.

20. Value of Technology project

Medical technology can deliver significant savings to the health system over time. Unfortunately, the benefits of medical technology are often poorly understood, insufficiently articulated and developed, and may be perceived as being a burden on the healthcare system.

MTAA developed the Value of Technology (VOT) project to contribute to an improved understanding of the impact of advances in medical technology on healthcare expenditure in Australia, and the associated costs and benefits for the Australian healthcare system and community. The outcome of the VOT research provides evidence-based support for a range of technologies that might not have strong Australian evidence to date and/or lack of funding.

20.1. Insulin pump therapy for diabetes mellitus

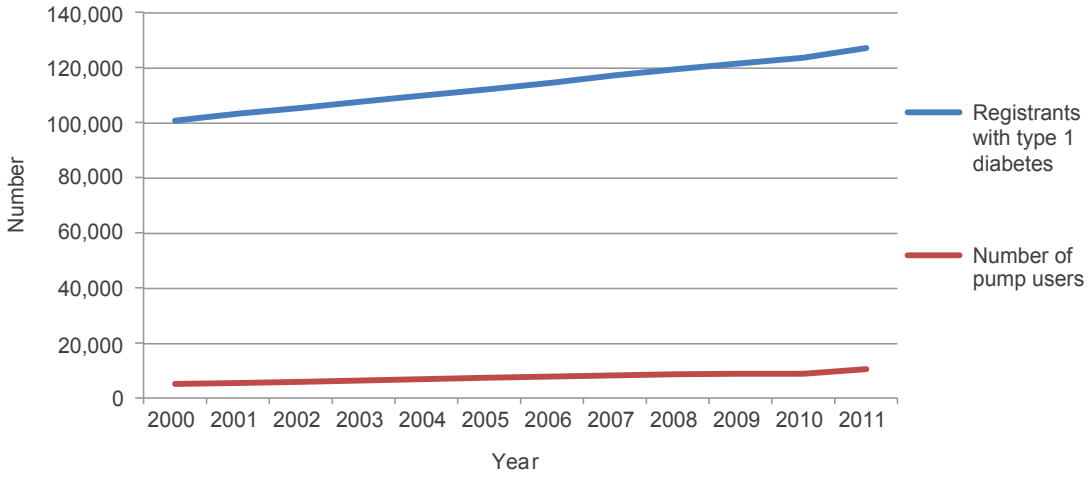
Around 1 million Australians have diabetes or approximately 4.5% of the Australian population[85]. Most have type 2 diabetes (90%). However, the common form in children and adolescents is type 1 diabetes.

Diabetes is the sixth leading cause of death[86]. It is also the cause of one in every 25 hospitalisations in Australia[87]. Diabetes places a large economic burden on the Australian healthcare system in terms of expenditure on hospitalisations, aged care, medications, diagnostic services and other out-of-hospital medical care[88]. Total allocated healthcare spending on diabetes was estimated to cost around $1.5 billion in 2008–09 - 2.3% of all allocated healthcare expenditure in Australia[89]. A recent report on the global health expenditure on diabetes estimated the total annual Australian healthcare expenditure for diabetes to reach US$10.9 billion by 2030[90].

Insulin pump therapy is currently the only type of treatment that replicates normal insulin secretion by a healthy pancreas. This is especially important for individuals with type 1 diabetes, for whom insulin therapy is necessary for survival.

As of 30 June 2011 there were 10,510 insulin pump users in Australia[91]. Since the inclusion of insulin pump consumables on the National Diabetes Services Scheme (NDSS) in 2004, there was a slight growth in the use of insulin pumps in Australia. However, the proportion of Australians with type 1 diabetes who use insulin pumps remains relatively low, representing only 10% of individuals with type 1 diabetes[92].

Figure 26: Number of patients with type 1 diabetes versus number of pump users



Source: NDSS[93]

85 AIHW. Diabetes, www.aihw.gov.au/diabetes/.
86 ABS. Diabetes in Australia: A Snapshot, 2007-08. 2011. ABS cat no. 4820.0, www.abs.gov.au/ausstats/abs@.nsf/mf/4820.0.55.001.
87 ABS. Australian Health Survey: First Results, 2011-12. 2012. ABS. cat no. 4364.0, www.abs.gov.au/ausstats/abs@.nsf/Lookup/4364.0.55.001main+features12011-12.
88 AIHW: Dixon T. 2005. Costs of diabetes in Australia, 2000–01. Bulletin No. 26. Cat. no. AUS 59. Canberra: AIHW.
89 AIHW. 2013. Diabetes expenditure in Australia 2008-09. Cat. no. CVD 62. Canberra.
90 Zhang P. et al. (2010). Global healthcare expenditure on diabetes for 2010 and 2030. *Diabetes Research and Clinical Practice, 87(3)*:293-301.
91 National Diabetes Services Scheme, www.ndss.com.au.
92 AIHW. 2012. Insulin pump use in Australia. Diabetes series no. 18. Cat. no. CVD 58. Canberra.
93 Data provided by NDSS.

Clinical benefits

Insulin pump therapy is recommended as a treatment option for children and adults with type 1 diabetes due to the numerous clinical benefits it provides compared with multiple dosage injections (MDI) therapy. These benefits include:

- reduction in HbA1c levels[94]
- decreased glucose variability
- fewer episodes of severe hypoglycaemia
- improvement in individual's quality of life (QOL)[95].

The use of insulin pumps is also recommended for adults with diabetes with the following conditions:

- poorly controlled blood glucose levels
- severe hypoglycaemia who suffer frequent episodes
- lives in rural and remote regions (via remote monitoring)
- pregnant women who require tight glucose control with respect to the outcome of pregnancy[96].

Cost-effectiveness

Insulin pump therapy is shown to be cost-effective compared to MDI therapy, where the costs per quality-adjusted-life-years (QALY) are estimated to range from US$16,992 for the USA to £34,330 for the UK. In the USA, US$50,000 per QALY is often considered as cost-effective whereas in UK, around £30,000 per QALY gained is likely to be considered as cost-effective[97].

An Australian study reported the incremental cost-effectiveness ratio (ICER) of insulin pump therapy compared to MDI therapy to be around $74,147 per QALY and $74,661 per QALY for adults and adolescents with type 1 diabetes, respectively. This suggests that the use of insulin pump therapy is 'good value for money' in Australia[98].

The main cost benefits of insulin pump therapy include improving glycaemic control and prevention of complications, thereby reducing the costs of diabetes-related hospitalisations - where hospital costs for diabetes and diabetes-related complications accounts for 50% of overall healthcare expenditure for diabetes[99].

20.2. Safety engineered medical devices

A 'safety engineered medical device' (SEMD) is a 'non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident'[100].

In Australia at least 18,000 healthcare professionals suffer from a needle stick injury (NSI) every year[101].The true NSI rate in Australia is likely to be higher due to the high rate of under-reporting of NSIs (ranging between 30-80%)[102,103]. Therefore, there are likely to be over 30,000 NSIs occurring in Australia every year.

NSIs can occur in any healthcare facility where needles and sharp objects are used, such as public and private hospitals, dental and veterinary clinics, medical research facilities and pathology laboratories. The types of devices associated with NSIs include needles, scalpels, and metal and glass objects.

94 HbA1c is a measurement of glycated haemoglobin or glycohaemoglobin level to determine how well the individual's diabetes is being controlled.
95 Craig M.E. et al. for the Australian Type 1 Diabetes Guidelines Expert Advisory Group. National evidence-based clinical care guidelines for type 1 diabetes in children, adolescents and adults, Australian Government Department of Health and Ageing, Canberra 2011, www.apeg.org.au/portals/0/guidelines1.pdf.
96 Phillip M. et al. (2007). Use of insulin pump therapy in the pediatric age-group: consensus statement from the European Society for Paediatric Endocrinology, the Lawson Wilkins Pediatric Endocrine Society, and the International Society for Pediatric and Adolescent Diabetes, endorsed by the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care, 30(6):*1653-62.
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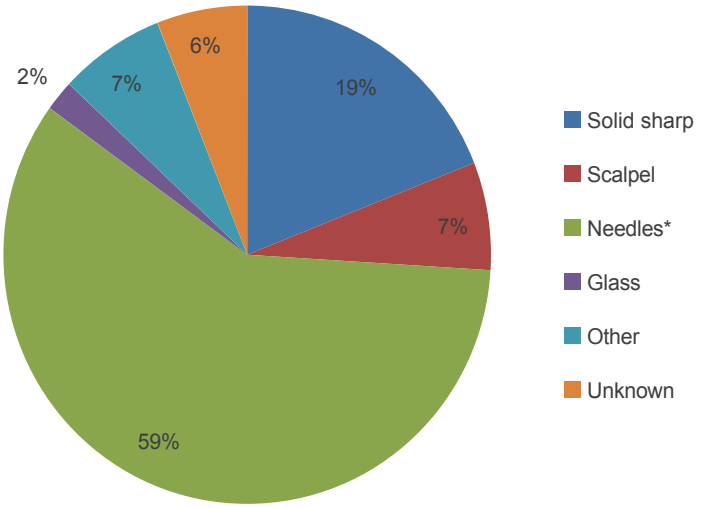
99 Colagiuri S. et al. (2009). DiabCo$t Australia Type 1: Assessing the burden of Type 1 Diabetes in Australia. Canberra: Diabetes Australia.
100 OSHA Bloodborne Pathogens Standard 1910.1030b, www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051.
101 Murphy C. (2008). Improved surveillance and mandated use of sharps with engineered sharp injury protections: a national call to action. *Healthcare Infection, 13:*33-1107.
102 Perry J. & Jagger J. (2003). Healthcare worker blood exposure risks: correcting some outdated statistics. Advances in Exposure Prevention. 2003, www.healthsystem.virginia.edu/internet/epinet/HCW-risk-update-AEP.pdf.
103 Lee J.M. et al. (2005). Needlestick injury in acute care nurses caring for patients with diabetes mellitus: A retrospective study. *Current Medical Research and Opinion, 21(5):*741-47.

Figure 27: Types of devices involved in NSIs[104]



*Includes hypodermic needles (32%), winged-tip needles (12%), intravenous (IV) stylets (6%), phlebotomy needles (3%) and other types of hollow-bore needles (6%).

The greatest hazard associated with NSIs is the transmission of blood borne pathogens such as hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV), which is the virus that causes acquired immune deficiency syndrome (AIDS)[105]. Around 80% of reported NSIs in Australia involve a contaminated needle[106].

NSIs are associated with substantial costs for the Australian healthcare system and can increase morbidity and/or mortality risk for the injured healthcare worker due to exposure to bloodborne pathogens[107]. Additionally, NSI can result in great stress for the injured healthcare professional and their families[108].

Clinical benefits of SEMDs

The usefulness of SEMDs is well established, and healthcare organisations are encouraged to consider their use (according to the *NSW Health Policy Directive: Sharps Injuries – Prevention in the NSW Public Health System 2007*)[109]. Post-implementation of SEMDs can reduce NSIs by over 80%, and in conjunction with training and guidelines, can reduce injuries by over 90%[110].

Cost-effectiveness of SEMDs

The introduction of SEMDs in the healthcare industry has been shown to be cost-effective[111]. Cost savings of around US$4,000 per NSI prevented have been estimated[112]. When accounting for the high risk NSIs prevented and reduced, SEMDs prove to be extremely cost-effective. In May 2013, MTAA conducted an economic evaluation which showed that the implementation of SEMDs in all Australian hospitals would result in an average cost savings of $18.6 million per year[113]. The cost savings would further increase to at least $36.8 million per year if the costs of post-exposure prophylaxis (antiviral) treatment and HCV treatment were included. Furthermore, the estimated cost savings are likely to be higher as the savings did not include the costs associated with treating chronic HCV (i.e. the cost of HCV only included the treatment costs for low risk injuries) and the costs associated with HIV treatment. Further to cost savings, the use and provision of SEMDs is also an ethical issue.

104 Perry J. et al. (2009). EPINet report, 2007 percutaneous injury rates. International Healthcare Worker Safety Center 2009, www.healthsystem.virginia.edu/internet/epinet/EPINet-2007-rates.pdf.
105 Centers for Disease Control and Prevention. Workbook for designing, implementing, and evaluating a sharps injury prevention program. 2004, www.cdc.gov/sharpssafety/index.html.
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107 O'Malley E.M. et al. (2007). Costs of management of occupational exposures to blood and body fluids. *Infection Control and Hospital Epidemiology, 28(7):*774-82.
108 Worthington, M. et al. (2006). Post-traumatic stress disorder after occupational HIV exposure: two cases and a literature review. *Infection Control and Hospital Epidemiology, 27(2):*215-17.
109 NSW Government. Policy Directives and Guidelines: Sharps Injuries - Prevention in the NSW Public Health System, http://www0.health.nsw.gov.au/policies/pd/2007/pd2007_052.html.
110 International Health Care Worker Safety Center at the University of Virginia Health System, www.Healthsystem.Virginia.Edu/internet/epinet.
111 United States General Accounting Office. Occupational safety: selected cost and benefit implications of needlestick prevention devices for hospital, 2000.
112 Roudot-Thoraval F. et al. (1999). Costs and benefits of measures to prevent needlestick injuries in a university hospital. *Infection Control and Hospital Epidemiology, 20(9):*614-17.
113 MTAA. Value of Technology: Needlestick and Sharps Injuries and Safety-Engineered Medical Devices. Appendix Section: Economic Evaluation to Estimate the Cost Savings for the Implementation of SEMDs in Australian Hospitals, www.mtaa.org.au/docs/vot/vot-needlestick-and-sharps-appendix-cost-savings.pdf?sfvrsn=0.

21. Selected medical technology milestones (1816-2008)[114]

1816 – Stethoscope invented

1842 – First surgical operation using anaesthesia with ether

1851 – Ophthalmoscope invented

1852 – Hyperdermic needle syringe with plunger invented

1855 – Laryngoscope invented

1895 – First documented medical use of x-rays in medical imaging

1896 – Sphygmomanometer (mercury-based blood pressure meter) invented

1901 – First electrocardiograph (ECG or EKG) machine

1920 – Band-Aid invented

1922 – Insulin first used to treat diabetes

1924 – First electroencephalogram (EGG) performed

1927 – First practical modern respirator (iron lung) invented

1943 – First electron linear accelerator designed for radiation therapy developed

1945 – First practical human haemodialysis machine developed

1947 – First stereotactic devices for human neurosurgery invented

1948 – Plastic contact lens developed

1949 – First implant of intraocular lens

1953 – Heart/lung bypass machine first used in surgery on humans

1955 – Ultrasound first used on pregnant women

1958 – First cardiac pacemaker implanted. Artificial heart valve developed

1962 – First hip replacement using a metal femoral head (hip joint) placed within a polyethylene acetabular cup (hip socket)

1965 – First portable defibrillator installed

1972 – Computed axial tomography (CAT) scan for brain invented

1975 – First recorded positron emission tomography (PET) image

1977 – First image of a human in a whole-body magnetic resonance imaging (MRI) scanner

1978 – First cochlear implant surgery

1982 – First permanent artificial heart implant

1985 – Implantable cardiac defibrillator (ICD) approved by US Food and Drug Administration (FDA)

2000 – First robotic system for general laparoscopic surgery approved by FDA.

2003 – Drug-eluting stent for clogged arteries approved by FDA

2004 – 64-slice CT scanner approved by FDA

2008 – Commercial hybrid PET/MRI scanner produced.

114 Adapted from National Center for Health Statistics. Health, United States, 2009: In Brief – Medical Technology. Hyattsville, MD, 2010.

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