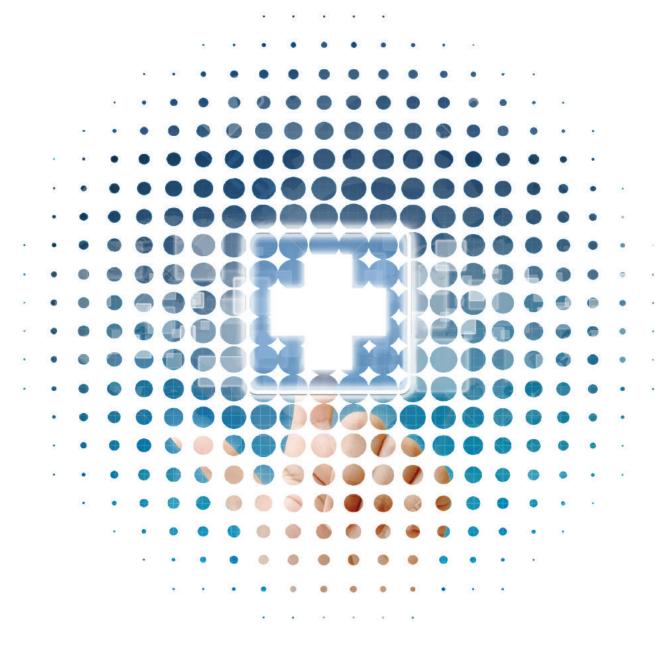
New Zealand Health Technology Review: 2016 New Zealand companies innovating to improve people's health











EXECUTIVE SUMMARY

THE health demands of populations in developed and developing countries have become a challenge for health systems to keep up with. The need for health technologies to deliver improved outcomes is now greater than ever. This is a direct consequence of the ageing demographics in developed nations and the increasing recognition of the relationship between good health and economic achievement in the developing countries.

New Zealand has an opportunity to deliver some of the technology innovations needed to address both the issues above through improving the performance of the clinical and health administrative workforce. Delivering these innovations will simultaneously improve our local economic performance and health outcomes.

The companies we report on in the New Zealand Health Tech Review 2016 are all highly motivated and capable of delivering some of the new technologies that will bring those improved outcomes to health systems and patients, both locally and on a global scale. One company, Fisher & Paykel Healthcare has already been innovating for 48 years and continues to grow internationally.

This review has been commissioned by the Medical Technology Association of New Zealand (MTANZ), New Zealand Health IT (NZHIT), the Consortium for Medical Device Technologies (CMDT) and Auckland Tourism, Events and Economic Development (ATEED) to assess the economic and Research and Development (R&D) dynamics present in the local health technology industry. We have defined health technology companies for the purposes of this report as those that produce and sell a medical device or a health IT product locally or internationally from New Zealand.

Our top level findings for the 2015 financial year are:

New Zealand's medical device and health IT companies earned an overall turnover of \$1.3 billion, contributing substantially to our national economy.

The majority of companies operate from Auckland and Christchurch and contributed \$948 million and \$33 million respectively to these regional economies.

The R&D spend from this sector was \$129 million (\$60m for health IT and \$69m for devices) with 83% of this spent locally.

Companies reported an average revenue growth of 29% for medical device and 35% for health IT companies.

There is good capability to bring first in class devices and health IT systems to the market despite the challenges of distance and scale.

The sector is developing a vast range of health technologies that span the elegantly simple to the highly complex, with most of the devices being in the lower risk groups for regulatory approvals.

There are 3089 people employed in permanent roles in health technology businesses (882 in health IT and 2207 in device companies) in New Zealand.

There is a high degree of domain expertise in health and many of the specialist health disciplines.

NZ companies are generally confident in navigating the international regulatory requirements, recognising this is both a barrier to entry and a competitive advantage.

¹ Previously the New Zealand Health IT Cluster (NZHITC)

² New Zealand Health Strategy – Future Direction, Ministry of Health, April 2016

THE very high levels of health domain expertise which has been identified as providing competitive advantage to local companies competing internationally, is also an asset for the industry's ability to deliver on the recently released New Zealand Health Strategy 2016 in achieving better health outcomes for New Zealanders.

Health technologies are a key enabler of improved healthcare services and support existing and new models of care. With the right investment in these technologies New Zealanders will enjoy increased health and economic prosperity.

The pipeline of smaller companies innovating in health technologies should be an important focus for further support in the health innovation ecosystem as these are the future stars that will enhance New Zealand's health and economic performance.

When working to enhance health care and economic prosperity for New Zealand, government agencies have a highly capable partner in the health technology industry.











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Health Technology as an economic opportunity for New Zealand

New Zealand has a vibrant health technology sector with 140 medical device and health IT companies, an active research community and entrepreneurial clinicians and health providers. There is an ecosystem of incubators, accelerators and investors with growing expertise in partnering health technology companies making this an exciting space for economic opportunities.

New Zealand companies have been developing health technologies for the local market for many decades. The oldest medical device company included in this review, Fisher & Paykel Healthcare started innovating in health technology 48 years ago and the oldest health IT company, Advanced Management Systems opened its doors 37 years ago. Companies have been exporting internationally for shorter periods - 46 and 15 years being the longest for medical device and health IT companies respectively.

The high technology export sector has been highlighted as the great economic hope for the New Zealand economy in various ways for many years. A number of medical device and health IT companies are identified as star performers leading export growth in the MBIE High Technology Manufacturing Report³, TIN 100 and TIN 100+ reports. However, the health technology industry as a specific sector has received relatively little public attention and analysis of its contribution and the challenges it faces.

In this review of the local medical device and health IT companies, we explore the dynamics of the health technology sector as a distinct industry, its' excellent export potential that some companies are already achieving, and the pipeline of highgrowth-potential start-ups and SMEs working towards substantial future growth. We identify that the industry contributed \$1.3 billion to the local economy in the 2015 financial year and explore the research and development (R&D) spending derived from that turnover.

Despite the high expectations of both patients and health system funders for better use of technology to improve health outcomes, it takes an innovation in patient care many years to achieve market launch and uptake in clinical practice. Achieving full clinical and commercial potential needs yet more patience, perseverance and the right capital, technical and professional support.

"Today, we are a global supplier of biological products to some of the world's largest multinational, diagnostic companies, in a growing and highly competitive market. This is a direct result of a commitment to continuous and ongoing investment over a 30 year period to drive our technical and commercial development. The need to innovate, adapt to changing global market needs and enhance our intellectual property position never diminishes for a company like Canterbury Scientific" Clive Seymour – Acting CEO Canterbury Scientific.

Health IT companies can generally reach the market faster than their medical device counterparts, but also have to navigate complex privacy, security and regulatory hurdles. Doing so requires advanced levels of capability and specialised skills. For health IT systems to deliver meaningful impacts on patient care and the health system, companies need deep domain expertise and collaboration with decision makers in the health system.

With both medical device and health IT companies, local implementation and refinement of their devices and systems is crucial as a stepping stone towards international success. Collaboration with the New Zealand health system a crucial element for success.

"The global orthopaedic epidemic is set to see hip replacements increase by 175% out to 2030; advanced manufacturing technology and custom solutions being developed in NZ are at the forefront of controlling this epidemic. New Zealand can be proud of our economic success in providing these clinical solutions."

Madeleine Martin – General Manager,
Ossis.

³ HIGH TECHNOLOGY MANUFACTURING REPORT, MBIE, JULY 2013 http://www.mbie.govt.nz/info-services/business/business-growth-agenda/sectors-reports-series/high-technology-manufacturing-report

Despite the high barrier to entry for medical devices, there is a strong perceived economic opportunity for the companies that can successfully achieve market entry. The companies surveyed report a very high level of optimism about commercial success in the international export market. Local companies are well prepared to tackle the regulatory hurdles and recognise the regulatory burden and need for appropriate quality systems as simply a cost of doing business. They however report some concerns about the ability to raise capital locally to meet both R&D and business development objectives.

The companies developing and producing health technologies in New Zealand span a wide variety of clinical and health infrastructure needs, with some, such as Fisher & Paykel Healthcare and Orion Health making a relatively large impact on their markets relative to both their capital base and New Zealand's population size. New Zealand has few companies however that have reached the scale required to operate as true multinational corporations, with the majority of companies reviewed having a turnover of between \$1,000,000 and \$30,000,000 (the middle 50% of companies surveyed all fall within this turnover range).

Most companies feel the need to grow to reach their full potential, with the top factors influencing their growth prospects being:

- Identifying and pursuing new markets;
- Attracting skilled staff;
- Raising capital;
- Developing innovation in product portfolio; and
- Increasing efficiencies and reducing cost

In the late Sir Paul Callaghan's 2009 presentation*, "Transforming New Zealand's prosperity: the remarkable opportunity for physics", he identified the need for companies to exceed a revenue per employee of NZ \$143,000, for New Zealand's economic prosperity to improve . We find that health technology companies generated a revenue per employee of \$221,410 for the 2015 year. We did not find more recent benchmarks for an aspirational revenue per employee for productivity purposes.

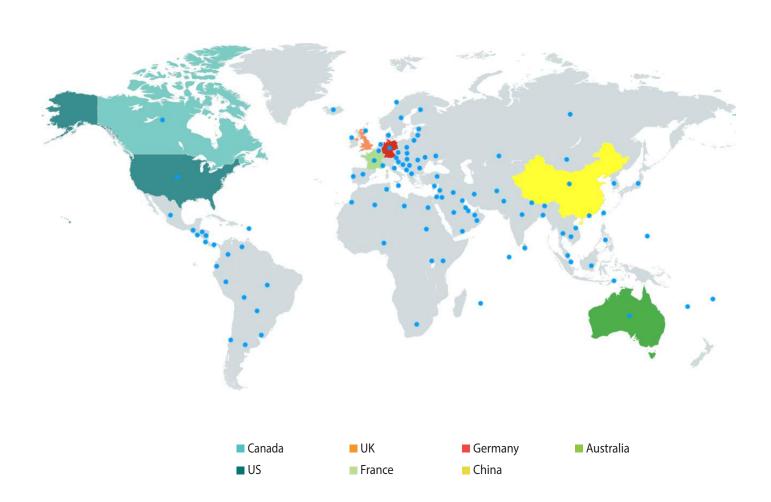
⁴ Copy of presentation slides provided on request

New Zealand's performance in health technology innovation

New Zealand companies sell medical technologies to 116 countries, with Fisher & Paykel Healthcare exporting to 114 countries. We found no clear pattern or preference for countries or blocks of countries emerging beyond Australia and the United States (US) as export destinations. A lack of clustering of export destinations suggests a low level of collaboration between local companies in their market access strategies.

The top markets for exporting NZ companies are:

- 1. Australia (21 companies),
- 2. US (16 companies),
- 3. UK (7 companies),
- 4. Canada (6 companies),
- 5. China, France and Germany (5 companies exporting to each country).



New Zealand is not alone in aiming for innovation to improve our economic performance. The G20 group of countries are all trying to understand how best to innovate to help achieve their growth targets as reported in the WIPO Global Innovation Index (GII). New Zealand was recently ranked number 15 (out of 141 countries) in this Index, ahead of Canada, Australia, Austria, Japan and Norway. We were placed 4th out of the 15 South East Asia/Oceania countries, where Singapore, Hong Kong and South Korea performed better than us.

The GII report's authors state:

("Foreign Direct Investment Confidence Index, which assesses likely foreign investment decisions by global business leaders, finds that investors are readily looking past emerging countries that boast low labour costs in favour of developed countries that are committed to—and can demonstrably show—continuous innovation.")

Arguably New Zealand boasts both relatively low labour costs for a developed nation as well as a high commitment to continuous innovation and should be expected to be of interest to

investors. Our report finds that capital raising is ranked third overall as a challenge facing businesses, so clearly there is further work to be done to showcase New Zealand's innovation in health technology to international investors.

The GII also reports that

("Although inventions have been successful in silos or pockets, far-reaching and scalable innovation has most frequently occurred within organized and government supported frameworks.")

If New Zealand is truly to take the number 8 wire mentality and turn it into products that meet rigorous international standards, we need to ensure that the silo that is the local health technology industry gains the right levels of support and policy frameworks to nurture its growth. Our report tries to understand some of the support that would be beneficial by assessing the opportunities and challenges the industry faces based on the opinions of our local industry leaders.

⁵ Cornell University, INSEAD, and WIPO (2015): The Global Innovation Index 2015: Effective Innovation Policies for Development, Fontainebleau, Ithaca, and Geneva. http://www.wipo.int/econ_stat/en/economics/gii/

The top challenge that local companies face is identifying and pursuing new markets,

which may be a reflection of the industry being relatively isolated from our international markets. Companies report that forming Advisory Boards with the right set of skills, developing local networks and attending international trade events are all helpful in increasing successful access to international markets. It is likely that attracting international investors, especially those that bring knowledge and networks would also enhance companies' success in penetrating new healthcare markets.

We find that two out of the top three challenges for local companies are similar to those faced by their international peers, i.e. the need for additional skilled staff and capital. In this light, it's encouraging to see the Government stating a commitment to fund more health research and providing increased funding for this aim by \$97 million, as many of the technologies produced by local companies and their highly skilled employees have their origins in health research.

Our respondents spent \$129 million on R&D activities (health IT \$60 million and devices \$69million) in the 2015 financial year with 83% of that being spent locally. Anecdotally NZ companies are more efficient with spending their research funding. Similar US and European companies raise more early funding but also spend vastly more; it is not clear however, if this higher early stage funding results in higher success rates, something our review was not intended to measure.

This perceived research efficiency is borne out by the findings on New Zealand's innovation in the GII report which looks at 79 indicators across innovation inputs and outputs. It covers areas including: innovation policies, egulatory environment, educational performance, market sophistication and knowledge and technology outputs. For detail of the factors assessed in the GII, see table 1 The Framework of the Global Innovation Index 2015

⁶ http://www.stuff.co.nz/national/politics/80093291/budget-2016-government-announces-97m-boost-for-health-research--biggest-in-history

⁷ Cornell University, INSEAD, and WIPO (2015): The Global Innovation Index 2015: Effective Innovation Policies for Development, Fontainebleau, Ithaca, and Geneva. http://www.wipo.int/econ_stat/en/economics/gii/

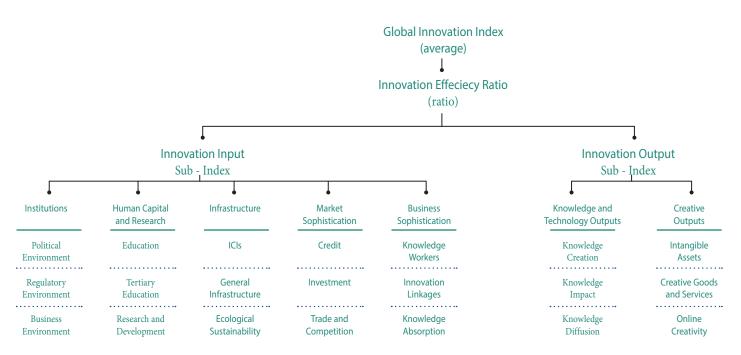


Table 1 - Framework for assessing innovation efficiency in The Global Innovation Index 2015

The areas that New Zealand scored particularly well on and that are relevant to health technology companies included:

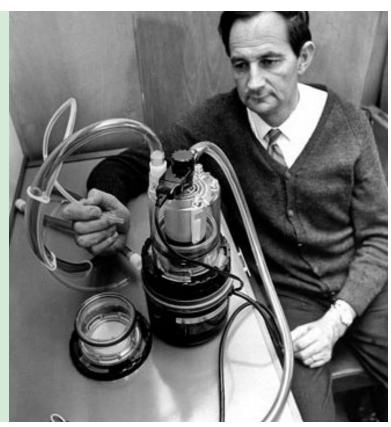
- Ease of protecting investors, ranking 1st;
- Residents applications for domestic patents relative to GDP 6th (although scoring for residents applying for international patents was lower, ranked 19th);
- Publication of Scientific & technical articles relative to GDP 7th;
- New businesses relative to population size ranked 1st.

The areas that NZ scores were not as high included:

- The number of graduates in science and engineering where we ranked only 61st;
- Gross expenditure on R&D as a portion of GDP, ranking 29th;
- Gross capital formation as a portion of GDP, ranked 66th;
- Foreign Direct Investment net inflows relative to GDP, ranked 122nd;
- Proportion of gross expenditure on R&D financed from abroad, ranked 60th;
- Proportion of high and medium high tech manufacturers, ranked 66th;
- Communications, computer and information services exports as a portion of total trade, ranked 76th (despite ranking 15th for ICTs business model creation);
- FDI net outflows, as a portion of GDP ranked 120th.

Of interest relating to capital raising is that we were ranked 22nd for the number of Venture Capital deals relative to GDP, so it is possible that the difficulties of medical technology companies raising capital is related to the industry having a relatively low profile with VC firms or the industry risks being perceived as higher.

CASE STUDY FISHER AND PAYKEL HIGHLY FOCUSSED INNOVATION



New Zealand's most successful medical device manufacturer continues to innovate and has a rich portfolio of patents, yet continues to focus very narrowly on its unique capability to heat and humidify air for people to breathe.

The original concept to heat and humidify air to physiological levels in various clinical settings is critical to the success in a wide range of interventions, from invasive ventilation to chronic respiratory conditions and sleep apnoea.

Despite a long history of providing respiratory support to patients, clinicians continued to see patients suffer complications of their treatments such as lung damage from ventilation. Fisher & Paykel Healthcare identified this need early on and has spent decades refining its capability and technology in this narrow area within the health care spectrum of treatments.

The persistent aim to perfect the temperature and humidity while stopping condensation build-up in ventilation equipment, what others may overlook as a simple concept, has been a niche area for innovation that Fisher & Paykel

Healthcare has become a world leader in. With clinical trials showing reduction in complications patients are ultimately better off, and the value to the system is that people may be able to leave ICU earlier than they otherwise would have.

The company has expanded the focus only by applying their core capability on new areas where it is needed, such as in surgery and nasal high flow therapy, rather than trying to develop entirely different technologies.

With convergent technologies, the ability to provide data analytics has also emerged, but even this area fits neatly with the original company focus. With decades of experience working on the clinical and technological data in this field, Fisher & Paykel Healthcare is perfectly placed to help others make sense of it in treating patients.

Fisher & Paykel Healthcare shows not only that New Zealand has the technical and commercial capability to compete internationally at large scale, but also that local groups can identify meaningful areas of improvement for patients not readily identified by others and bring these to the market.

How Health Tech companies compare to other NZ tech companies

THE New Zealand TIN 100 Report 2015 included 25 health tech companies and the TIN 100 and TIN 100+ rankings can be seen in table 2 below. Fisher & Paykel Healthcare was ranked as the third largest company by turnover and Orion Health reached the ninth ranking. In addition to making the ranking in the TIN 100+ portion of the report, both SimplHealth (ranked 163) and Pacific Edge (ranked 186) made the ASB sponsored category for rapid growth: Ten Hot Emerging Companies 2015. Pacific Edge was also listed in the 2015 Rising Star category with a 3 year compound Average Growth Rate of 85.4%.

The pharmaceutical firms Douglas Pharmaceuticals (15th), AFT Pharmaceuticals (24th) and New Zealand Pharmaceuticals (25th) were also included in the TIN 100 Report 2015. However, as the pharmaceutical industry faces a different operating environment they were not included in our definition for health technology companies and not reviewed as part of our report.

Health Technology companies by our definition make up 13% of companies listed in the TIN 100 and TIN 100+.

Health IT companies (excluding Orion Health) reported an average growth of 15% for the 2013 – 2014 year (range 0 to 50%) and an average growth of 35% for the 2014 – 2015 year (range 2% to 122%). For both of these years the health IT companies beat the previously stated 11% long

run average growth rate for IT companies as measured in the MBIE High Technology Manufacturing report.

Medical device companies reported average growth rates of:

- 12% both including and excluding Fisher & Paykel Healthcare for 2013 2014;
- 29% for 2014 2015 including Fisher & Paykel Healthcare; and
- 33% when Fisher & Paykel Healthcare and outliers were excluded.

In comparison, the reported Compound Average Growth Rate of high tech manufacturing reported in the MBIE High Tech Manufacturing report was only 3.5% for the 2006 to 2011 years, acknowledging that this period included the GFC.

Innovation has
the potential to
change the
economic
landscape in
New Zealand"

lain Hosie – Revolution Fibres

How Health Tech companies work with the NZ health system

THE companies we interviewed expressed high levels of commitment to improving outcomes for patients and many see the need for employing health domain experts as a means of generating competitive advantage over international competitors.

With their products spanning such a wide variety of functions for the health system, it is no surprise to find that many companies had collaborated at some point in the R&D and deployment stages with local health care facilities from Universities and teaching hospitals to remote GP practices and all levels of primary, secondary and tertiary care.

The health domain expertise combined with the ability to find well focussed innovative solutions to todays' health challenges means that the local industry is well placed to deliver on each of the five strategic themes in the New Zealand Health Strategy 2016 – Future Directions:

One of the major challenges remains the ability to have a truly innovative solution to a clinical or health administrative problem implemented in the local care settings. There were a number of reasons for this raised, but the central point is that there is no clear process for introducing a new technology to the New Zealand health system, with companies needing to navigate continuously changing procurement groups, and negotiate with both regional and central agencies with overlapping mandates, and poorly coordinated responsibility for ultimate decision-making.

Closer to home

by supplying technologies that support remote care delivery and communications

Value and high performance

by automation, efficient communications and administrative functions as well as reducing error

One team

by streamlining clinical communication and integrating multiple functions and the input of clinical groups

Smart system

providing enhanced analytics, with devices that are connected directly into the health records and administrative systems.

People powered

enabling people in health goes hand in hand with digital technologies, like telehealth systems and mobile health apps, that enable health services to engage with people wherever they are located.

A recent independent review commissioned by the Director General of Health concluded that:

"the current structural arrangements of the Ministry, DHBs and private primary and NGO sectors make it harder than it needs to be to develop the capacity and capability required on the part of both funders and providers to run a more sophisticated system to fund health services."

A common theme identified by companies that responded to our review is that it is also harder than it needs to be to introduce innovations that provide enhanced patient care through the use of technology. We identify some of the challenges that companies have identified in the opinion based responses reported below. The companies reviewed have confidence that they can support one of the major recommendations of the "From Cost to Sustainable Value" report by supplying technologies for investment that:

"encourage a change in service mix and design that will improve the financial sustainability of the public health system over time as well as improve outcomes for the individuals involved."

In order to deliver the value sought by the health system and generate economic and employment value to New Zealand, the health technology industry should be recognised as a partner in providing combined health and economic prosperity for New Zealand.

Where companies already have a product range being used in health care, they generally find it somewhat easier to innovate within the bounds of that technology (incremental innovation), but companies that are developing a disruptive (or first in class) innovation generally find it very challenging to access early adopters within the health system.

The companies we reviewed have the capabilities and dedication to help achieve better health outcomes for New Zealand and are well prepared to meet the challenge laid down to the health system in the recent Capability and Capacity Review.

The review recommended that the MOH:

"Commission providers at the "coal face" to collaboratively co-create service solutions that address targeted population needs, utilising where appropriate, a long-term forward investment approach."

From Cost to Sustainable Value - An Independent Review of Health Funding in New Zealand https://www.health.govt.nz/system/files/documents/pages/from-cost-sustainable-value-oct15.pdf
The New Zealand Health System Independent Capability and Capacity Review - Suckling, Connolly, Mueller, Russell, June 2015 https://www.health.govt.nz/system/files/documents/pages/nz-health-system-independent-capability-capacity-review-oct15.pdf

CASE STUDY

TRANZSOFT PROVIDES

AN ELECTRONIC
HEALTH PROCUREMENT
COMMUNITY
INCREASING EFFICIENCY
OF HEALTHCARE
DELIVERY



Tranzsoft has 14 years' experience working on enhancing the efficiency of health service providers through electronic procurement and automated inventory and supply chain management.

Connecting hospitals and their key suppliers is a complex chain with each group using different systems. The varied needs of public and private health groups as well as primary through to tertiary providers are accommodated in a central Health eBusiness gateway with efficiency benefits to both suppliers and customers.

The Tranzsoft software enables multiple customers (hospitals and providers) to purchase through a single gateway with multinational suppliers integrating into each group's existing software systems.

The electronic community includes PHO's, DHB's, private hospital groups and a large number of multinational and small local suppliers.

Having a centralised portal allows smaller suppliers to enter the health system allowing more options to be available to DHB procurement groups.

Features that improve the health system efficiency include:

- Data accuracy (reduced error from manual entry by different people in multiple systems)
- Real-time ordering
- Traceability
- Lowered cost of doing business for purchasers and suppliers.

Surgical preference booking now also has custom configured surgical kits being made available via the cloud through from supplier to surgeon, including the consignment kit that device suppliers manage on behalf of hospitals.

For consignment surgical stock, Tranzsoft provides full supply chain and warehouse visibility as a SaaS:

- from the surgeon on the demand side;
- to the companies on the supply side; and
- within hospitals (CCSD to theatre and ultimately to finance for billing of items used)
- for surgical support consignment stock.

The result is the right surgical kit is available for use by the surgeon for a specific patient. The system can also ensure accurate data for the National Implant Register (supporting recalls and clinical research) and supports the Ministry of Health's e-Health vision.

Consignment stock has high cost implications when stock expires or is wasted and having visibility makes it more efficient for all. The right kit at the right time also reduces the number of operations needing to be re-scheduled, meaning people get treated on time.

Supporting the health system drive for efficiency, Tranzsoft's electronic community for purchase and supply in health let's New Zealand and Australian health procurement agencies focus on value rather than on transaction management.

METHODOLOGY OF THE REVIEW

THE review aimed to assess multiple factors relating to the success of the health technology industry, including commercial, employment, R&D, external operating environment and the local support ecosystem. The wide ranging nature of the review means that we identified high level themes, but did not necessarily identify detailed reasons behind all of the dynamics we identified.

Subsequent reviews on an annual basis may focus on more in-depth analysis of some of the themes identified here.

We sent questionnaires to all New Zealand based health technology companies on the contact lists of MTANZ, NZHIT, ATEED, and the CMDT (125 companies) and asked regional development agencies to verify that all health technology companies in their areas had been included. We received 49 (39%) responses, of which 33 (26%) were sufficiently complete for inclusion in the quantitative results.

We subsequently interviewed 24 companies evenly split between the medical devices and health IT industries and sought opinion based information about the dynamics of the industry, its challenges and opportunities as well as levels of optimism for operating in this complex and high risk market.

We have undertaken to keep company data confidential and report only aggregated information in a form that will not identify any individual company. One consequence of this is that segments of information that have a limited number of responses (such as the turnover and

R&D expenditure of companies based in cities other than Auckland and Christchurch) are not reported on.

When reporting data provided to us in company responses that is already publicly available (including the TIN 100 report data) we have reported this openly.

The income threshold for participation was set at the threshold for mandatory GST registration in NZ (\$60,000), so all participants were trading companies rather than pre-revenue start-ups with speculative data. We note that there are substantial numbers of health technology start-ups that are currently in development and we aim to monitor the progress of this pipeline of companies as some of them achieve market success.

Our data is likely to underrepresent each of the quantitative measures (such as total turnover and R&D spending) due to the relatively low response rate, however many of the non-responders are likely to be smaller companies and may be pre-revenue companies that fall below the threshold for inclusion.

REVIEW FINDINGS

Functions of the health tech products and systems

NEW Zealand companies manufacture products and develop systems that serve a wide range of functions in the health system. We have tried to get an idea of their functions rather than simply defining the outputs in terms of widgets and named systems.

Convergence of the two business models of providing medical devices as hardware with integral software is seen in a number of the companies. Companies making these complex devices can be particularly successful where they excel in both the manufacture of the device as well as providing data analytics to support the optimal use of their product in clinical practice, as seen in the Fisher & Paykel Healthcare case study.

Companies report providing or enabling the following functionality through the health IT systems they sell (reported as aggregated functionalities, not company specific):

- Electronic automation of administrative, logistics, inventory and transactional functions. Automation includes reducing the need for information to be entered manually with the corresponding higher level of reliability and reduced transcription errors;
- Process optimisation software that aids in workflow of staff, SOP training and audit as well as the optimal use of medical equipment;
- Enhanced and secure communications between health providers, patients and clinical groups, health administration groups, providers of medical technologies and insurance providers (private funders);
- Electronic health records and applications integrating with these software packages for prescribing, adherence, clinical, research (clinical and health systems research) CRM and planning purposes;
- Platforms supporting telehealth with integration of communications, data transfer analytics and planning, including for community care and emergency response;
- Track and trace solutions for complex sets of surgical loan stock and other logistics within the hospital system;
- Web based employee, payroll, rostering, authentication and workflow processing software;
- Video, audio, transcription, messaging, directory and communication technologies tailored specifically to health standards and needs;
- Digital tele-rehabilitation and patient information for multiple mainly chronic diseases;
- Gamification of health treatment, prevention and rehabilitation (both IT companies and device companies).

The vast majority of IT systems provided by NZ firms are cloud based and enable local and international scalability as systems are generally similar or identical when sold locally and internationally.

Medical device companies provide devices that provide the following functions or patient outcomes (clustered, not company specific):

- Telehealth and point of care devices for diagnosis, treatment, monitoring and rehabilitation purposes;
- Respiratory inhalers, monitors, humidifiers, resuscitators, ventilators, anaesthetic machines and accessories for surgical anaesthesia, sleep apnoea and various other respiratory indications (including companies other than Fisher and Paykel);
- Sensors for research and physiological or disease monitoring;
- Face masks, filtration products, wound dressings and skin scaffolds using nanofiber technology;
- Diabetes diagnostic, monitoring and management equipment including calibration for laboratories;
- Orthopaedic implants, including custom made implants using additive manufacturing (3D printing). The instruments used for implantation and support for manufacturing and clinical use;
- Laser-based wound imaging, accurate 3D measurement and sophisticated informatics for enterprise-wide wound management;
- Contract manufacturing of many components for local and multinational device manufacturers, including development and regulatory support for R&D, at both small and large scale. Component manufacturers work with multiple methods and materials, from simple plastics and metals to nanomaterials;
- Clinical analytics for multiple disease areas including diagnostic support for breast cancer screening;
- Support for installation, maintenance, calibration and optimal use of device systems in routine clinical practice, telehealth and laboratory practice.

The classes of medical devices being manufactured are largely lower risk devices according to the FDA class of device. One company reported manufacturing a Class III implantable device; six companies manufacture Class IIa and IIb devices and the remaining companies manufacturing only Class I devices. Of the companies that manufacture any Class II devices, most reported also manufacturing Class I devices in their product ranges.

The presence of Fisher & Paykel Healthcare as the major long term employer in NZ's health technology industry may have led to spill over effects of highly skilled people moving on to other areas of respiratory devices, although not all companies reported such a historic connection.

TYPES OF CUSTOMERS BEING SERVICED BY COMPANIES

The majority of companies supply their finished products and IT systems directly to hospitals including DHB hospitals in New Zealand, but there is a wide variety of other customer types that companies sell to.

Health IT companies in New Zealand provide software services, systems and enterprise solutions to:

- Hospitals including DHB hospitals and private hospitals;
- Ministry of Health and other centralised health system funders such as Health Alliance;
- Health insurers;
- Other health IT companies (in providing connectivity, supporting interoperability, middle ware, data analytics and process and systems optimisation);
- Pharmacies and pharmacy groups;
- Primary Health Organisations (PHOs);
- Primary care facilities and GP practices (both individual and group practices);
- Clinical research and academic groups;
- Directly to patients (Although much of the functionality is aimed at patient benefit, it is unusual for patients in New Zealand and international markets to pay directly for the use of health related IT systems).

Medical device companies provide both finished devices and components of devices as well as scientific equipment to customers such as:

- Hospitals, including DHB hospitals and private hospitals;
- Government procurement agencies such as PHARMAC and similar international agencies;
- Health insurers, Health Maintenance
 Organisations, Group Purchasing Organisations
 (US specific);
- Universities;
- Multinational companies (pharmaceutical companies, research laboratories);
- Pharmacies;
- Rehabilitation clinics;
- Primary health care organisations including GP,
 Physiotherapy and occupational therapy practices;
- Directly to patients.

TECHNOLOGY PLATFORMS BEING USED AND DEVELOPED

HEALTH technology companies are making use of the developments in multiple industries to solve health related problems in ways not previously possible. The companies we reviewed have embraced many technologies not typically applied in health and continue to innovate by further developing and refining their application of these technologies to solving health problems (see Case study on ARANZ Medical).

There is also a large overlap of software platforms and medical device platforms meaning that some companies that start out manufacturing a hardware product find that their optimal business model includes a focus on software providing the advantage of data analytics and feedback to enhance the clinical use of their device. Integrating communications functions with devices is a clear and growing trend locally and internationally.

Both the health IT and medical device companies that responded are applying novel and old technologies in ways not used before to improve patient outcomes. New uses for simple plastics are seen alongside newly developed artificial intelligence algorithms and new applications of X-Ray spectral characteristics in a novel spectral CT scanner.

Overall companies are generally utilising multiple technology platforms simultaneously to create complex offerings that outperform their competition and improve patient care.





ARANZ Medical arose out of the Applied Research Associates NZ Ltd, a private R&D organisation that developed an innovative handheld 3-D laser scanner and ground-breaking software to model very large 3-D datasets.

The applications for the technology have since been further developed, but are widely different, with one being in the mining and exploration sector and the other being for assessing wound healing.

ARANZ Medical offers both the hardware of the point of care laser scanner and the software to provide data capture, storage and analysis that help clinicians treating chronic wounds to monitor their patients' progress and react accordingly. The award-winning system includes an imaging device that precisely and consistently measures the area, depth and volume of wounds and their healing progress, and software to store and manage wound informatics integrating with electronic health records.

Wound care has been estimated to make up 5.5% of total expenditure on the health in some developed countries, or an annual cost to the US health care system of \$11 billion.

The high costs involved in wound care have resulted high research interest in the treatment of wounds and ARANZ has been able to supply a critical part of the clinical trials market with a product that objectively assesses wound care progress. ARANZ research customers have included organisations as diverse as the World Health Organisation, multinationals such as Smith and Nephew and Universities like Stanford School of Medicine

ARANZ Medical is now rapidly growing their market presence through building on this rigorous validation of their products value to clinicians and researchers. Clinical groups using the ARANZ Medical technology now include Kaiser Permanente, US Department of Veterans Affairs, Kings College Hospital in the UK and both Canterbury and Capital and Coast DHBs.

Through their experience in providing the hardware and software for clinical trials (a valuable market in itself), ARANZ have refined their product offering to provide precisely what clinical staff need to accurately document patient progress and capture this in their patients' health records

COMPANY DYNAMICS

Total revenues

We find that the health technology companies earned a total of \$1.317 billion for the New Zealand economy through both local activities and international exports. Medical devices companies contributing \$996 million (including a contribution from component suppliers of \$41.6 million) and health IT companies contributing \$321 million to the total.

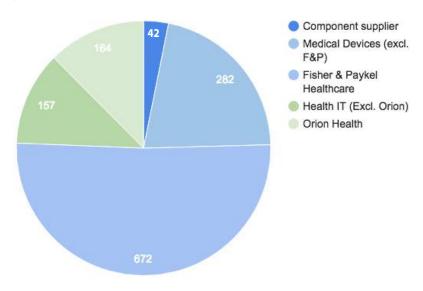
Table 2 Health technology companies ranked in the TIN 100 and TIN 100+ and level of ranking 10

	TIN ranking	Revenue (\$,000)
Fisher and Paykel Healthcare	3	672,300
Orion Health	9	164,000
OMNI Orthopaedics	26	72,000
Dynamic Controls	31	63,036
Buckley Systems	43	45,000
ADInstruments	50	35,000
Atlantis Healthcare	56	31,000
Medtech Global	74	22,032
Triodent	89	17,184
Howard Wright	97	15,000
Konnect Net	105	13,000
Metalform	124	10,000
Intrahealth systems	130	9,500
Sysmex	137	8,200
COMRAD Medical Systems	142	7,800
MoleMap NZ	152	6,800
Biomatters	157 equal	6,300
Canterbury Scientific 157 equal		6,300
SimplHealth	163	6,100
ARANZ Healthcare	170	5,400
Precept Health	175	5,000
Pacific Edge	186	4,132
Augen (NZ)	188	4,000
Optima	192	3,918
HSA Global	195	3,700
Total Revenue of TIN 100 (\$,000) and TIN 100+ Health Tech companies	1,236,702	
Revenue from 22 additional companies surve	80,244	
Total Health Tech revenue		1,316,946

^{10 2015} TIN 100 Technology Industry Analysis New Zealand 2015, eleventh edition, Technology Investment Network Limited

Graph 1 - Total turnover and export proportions by company type

(\$,000,000)



Total Medical Devices 996 (Export 94.30%)

Total Health IT 321 (Export 59.60%)

Total Health Tech turnover 1,317

Although there is not an absolute correlation, health IT companies tend to focus initially on achieving substantial commercial success in the local market prior to expanding into international markets, whereas medical device companies almost all need to succeed in the international market to achieve any scale. However, both health IT and medical device companies have solutions that are applicable to the domestic and export markets from the start.

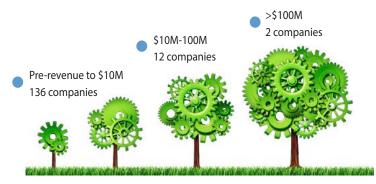
There has been substantial growth in the industry. A 2013 review of the health technology companies in New Zealand undertaken by Ernst and Young found that the combined health technology industry generated \$855 million turnover. This was comprised of \$620 million medical device industry revenue (excluding government grants) and \$235 million for health IT (including government grants). In 2013 95% of revenue from the medical devices industry was earned from exports, with 46% coming from exports for health IT companies.

With one company dominating the revenue for each industry group (Fisher & Paykel Healthcare for the medical device category and Orion Health for health IT) we have separated these companies out in some of our analyses to get a picture of how the other companies are performing.

The success of the health technology industry is likely to depend on both the existing large companies continuing to grow and these smaller but rapidly growing companies achieving sustainability and ultimately scale. We consider that the pipeline of smaller companies is thus an important focus for support in the health innovation ecosystem and it will be important to monitor their progress over time.

Prior work by the CMDT has identified the pipeline of health technology companies as totalling 150 companies with the breakdown of companies by revenue shown in Figure 1

Figure 1: Pipeline of New Zealand health technology companies by revenue



Research and Development

Companies are investing extensively in R&D, both in dollar terms and in the proportions of revenue spent on R&D. With most R&D done in-house, much of the cost is spent on research staff.

The majority of companies report having received some form of direct funding or grant support, with only seven reporting not having received any funding support. There were fewer companies however that reported direct R&D collaboration with DHB hospitals and Universities with only 12 companies reporting direct formal collaborations and many more expressing interest in doing so in the future if some of the challenges reported below can be overcome.

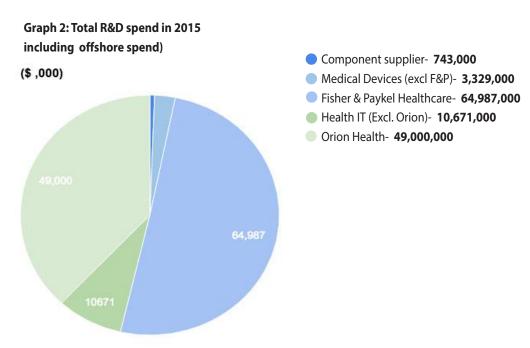
The collaborations included early product

development, pilot projects and clinical validation. It appears there are benefits to both companies as well as the research groups in these collaborations and it is an opportunity to create a pipeline that enhances or develops those skills that the industry needs.

Barriers to collaboration identified included the complex negotiation of IP ownership rights with collaborators as well as confidentiality. Companies that did collaborate however reported positive outcomes and an appetite to collaborate in further R&D projects under the right circumstances. It appears that different hospitals and Universities (and departments within Universities) have differing levels of capability to develop collaborations that would benefit the industry.

Table 3: Total R&D spend by company type in 2015 financial year.

Company Category	R&D expenditure reported as portion of turnover ¹¹ 2015 %	Portion of R&D expense spent in NZ
Component supplier	Insufficient data	88%
Medical devices (excl. F&P)	27% ¹² (6% to >100%)	84% (5% to 100%)
All Medical devices (excluding component suppliers)	24% (6% to 100%)	85% (5% to 100%)
Health IT (Excl. Orion)	19% (0% to 40%)	80% (9% to 100%)
All Health IT	20% (0% to 40%)	
Total for all health tech categories (excl F&P and Orion)	23% 0% to 100%	83%
Total for Health Tech R&D	23% (0 to 100%)	83% (excl Orion)



[&]quot;Used only proportions reported by companies, percentages may differ from \$ values due to incomplete reporting by some companies.

 $^{^{\}rm 12} Low$ reliability due to low numbers of reporting with wide variability.

¹³ Derived from total R&D and total Turnovers

The reported industry R&D spending was set against a background of government financial grants totalling \$6.7 million, representing only 5% of R&D investment.

The reported industry R&D spending was set against a background of government financial grants totalling \$6.7 million, representing only 5% of R&D investment. We did not explore whether any of the Government grants directly resulted in additional R&D investment, however with many of the Callaghan grants being in the form of matched funding it is likely that at least a portion of the Government support in this area led directly to more research being undertaken. There has also been recent evidence presented that direct R&D grants do stimulate innovation: The impact of R&D subsidy on innovation.

For the 2016 financial year (the year subsequent to the year being measured), companies report that they have budgeted to spend on average 25% on R&D (excluding Fisher & Paykel Healthcare and Orion Health). This amount consists of 18% for health IT companies and 36% for Medical device companies.

The majority of companies (64% of all companies) spend their full R&D budget in New Zealand thus resulting in downstream economic activity in dedicated prototyping, product development and design companies; research companies; universities and other research institutions as well as employment of dedicated R&D staff within their organisations. This study was not aimed at measuring economic multipliers related to the health technology industry, but clearly there will be substantial economic and employment multipliers as a result of the industry's economic success and high R&D needs.

Only 10 companies reported doing any R&D outside of New Zealand, split evenly between devices and health IT. Within these companies there was no measurable difference between Health IT and medical device companies in their proportion of R&D budget spent in New Zealand compared to offshore. A limited number of companies reported that they need to undertake R&D in the country to which they export, to gain country specific or health system specific insights and enhance customer acceptance of their technology.

¹⁴ The impact of R&D subsidy on innovation: a study of New Zealand firms, June 2015, Adam Jaffe and Trinh Le, Motu Economic and Public Policy Research

REGIONAL DISTRIBUTION OF COMPANIES

THE companies that responded are distributed mainly across two of our major New Zealand cities, with 18 being based in Auckland, and 10 in Christchurch. The rest were situated in Wellington (3), Tauranga (2), Dunedin (1) and Whangarei (1). This distribution is similar to the overall distribution of high technology manufacturing in New Zealand as shown in the 2013 MBIE report on high technology manufacturing.

The companies operating in the Auckland and Christchurch regions make a major contribution to the earning power of these cities and their

population, with the regional turnover and R&D spending shown in table 4.

Auckland region earned \$948 million total revenue from all the companies responding (\$111 million excluding Fisher & Paykel Healthcare and Orion Health) and Christchurch earned \$33 million. The corresponding export revenues for Auckland (\$817 million) and Christchurch (\$25 million) demonstrate the value of having these companies as drivers of regional economic performance.

Table 4: Regional distribution of company turnover and R&D spend

	Turnover (\$,000)	Export Turnover (\$,000)	R&D Spending (\$,000)
Auckland	947,631	816,746	123,631
Auckland Excl F&P and Orion	111,283	38,510	9,644
Christchurch	32,776	25,180	1,215

Auckland companies reported that 83% of their R&D costs were spent in New Zealand, while Christchurch reported spending 74% in New Zealand. It is not clear why more Christchurch R&D is undertaken outside of New Zealand but it is likely that as the regional health technology ecosystem matures and the post-earthquake recovery reaches completion the proportion would more resemble the Auckland proportion spent on local R&D functions.

When looking at the Google Earth distribution of NZ patent holders across New Zealand undertaken by Sean Hendy in 2011 it's not surprising to find both Auckland and Christchurch overrepresented. These locations also benefit from the support of their regional development agencies targeted at health technologies.

GROWTH RATES

Table 5: Total turnover and export proportions by company type

Sector	Turnover Growth 2013 to 2014 (range)	Turnover Growth 2014 to 2015 (range)	Export Growth 2013 to 2014 (range)	Export Growth 2014 to 2015 (range)
Health IT excl Orion	15% (0% to 50%	35% (2% to 122%)	Too few datapoints	48% (-78 to 200%)
Med device component suppliers	1% (-36% to 20%)	87% (-1% to 300%)	22% (10% to 50%)	146% (-1% to 400%)
Med devices excl F&P	17% (-10 to 34%)	64% (-5% to 323%)	20% (-3% to 33%)	30% (-26% to 105%)
Med devices incl F&P	16% (-10% to 34%)	59% (-5% to 323%)	19% (-3% to 50%)	27% (-26% to 105%)
All med devices (incl component	12%	29%	20%	70%
suppliers, excl outliers)				
Overall industry	13%	32%	17%	64%

*Growth rates were averaged from company reported growth rates, these were not weighted by turnover and therefore should not be used to project the overall industry growth.

Companies in the health IT sector reported an average growth of 15% for the 2013 – 2014 year (range 0 to 50%) and an average growth of 35% for the 2014 – 2015 year (range 2% to 122%). The health IT growth rates exclude Orion Health. For both years that we measured, the health IT companies beat the previously stated 11% long run average growth rate for IT companies as measured in the MBIE High Technology Manufacturing report.

Medical device companies reported an average growth rate of 12% both including and excluding Fisher & Paykel Healthcare for 2013 – 2014 year and a stronger 16% growth once the more volatile component supplier category was excluded. They had an average 67% growth for 2014 – 2015

including Fisher & Paykel Healthcare, and 59% once component suppliers were excluded. Excluding the outliers' growth which were two relatively small start-up companies, the medical devices category (excluding component suppliers but including Fisher & Paykel Healthcare) showed an average turnover growth of 29%.

The averages for medical devices in 2014 – 2015 are skewed by two relatively small companies each reporting a 300% and greater growth rate. Both of the outlying companies were starting off a relatively low turnover base. They therefore don't influence the overall growth of the industry in dollar values, but does illustrate the rapid growth potential of scalable medical technology companies.

MATURITY OF THE INDUSTRY

THE companies developing, manufacturing and selling health technologies locally and internationally represent a wide range of levels of company maturity both in terms of sustainable revenue and time in the market. Typically companies developing the highly specialised capabilities needed to develop and support medical technologies take many years to bring their technology through the R&D cycle and regulatory hurdles (including clinical trials and validation for products used in treating patients directly). One company that has been operating successfully for 31 years with numerous multinational companies as clients considers that it has the culture of a start-up in its operational, R&D and capital needs.

When looking at company ages and their growth rates, the companies reporting rates of growth of 20% and over in the 2014-2015 year had an average age of 10 years (range 3 years to 15 years). At interview, many companies reported that they are entering substantial growth phases due to having reached the stage where they have product in-market, the requisite regulatory approvals are in place and are now in the business development stages that drive growth.

Overall though, the age of a company did not show a direct correlation with its growth rates; both new companies and those over 10 years old show high rates of growth in both the local and international market.

Table 6: Company ages by category

Type of Company	Number of Companies Operating in NZ	Avg. age in Years (range)	Number of Companies Exporting	Avg. export Age (range)
Health IT	15	14.1 years (2 to 37)	10	7.0 years (2 to 15)
Medical devices	16	17.1 (1 to 48)	11	12.0 (1 to 45)
Component suppliers	4	24.3 (6 to 63)	4	19.25 (3 to 46)

Medical device companies indicated that their success relies on exporting early on as the scale of the local market is not sufficient to support meaningful scale. Even the youngest companies that do not yet export identified the intention to export once their products were either successfully proven in trials, further developed or accepted by international regulators.

Both health IT companies and medical device manufacturers aim for local acceptance or validation of their products to gain international customer confidence. However while medical device companies cannot rely on the local market for a sustainable financial model, many IT companies are able to operate in a sustainable manner locally without ever exporting. To gain meaningful scale though, they too need to export.

¹⁵ For companies that have previously serviced a different industry and have re-focussed to healthcare the age of the company is considered to be the time spent in the health industry.

EMPLOYMENT

ALL of the companies interviewed reported employing highly qualified people, with substantial need for PhD qualified staff that have a deep understanding and working knowledge of the fields related to their respective technologies and the technology platforms that make them possible. Many of the companies also reported employing people from health care backgrounds, either with relevant academic qualifications in health or experience working at various levels of the health system.

The industry employs 3089 people in permanent roles (882 in health IT and 2207 in device companies) in New Zealand. In addition, there are 283 full time equivalent contractors in New Zealand as well as an additional 2576 people employed internationally.

Health IT companies other than Orion Health employed an average of 26 people each, while medical device companies employed on average 14 people excluding Fisher & Paykel Healthcare. Both Orion Health and Fisher & Paykel Healthcare employed large numbers of permanent staff internationally but of the other companies only 5 health IT companies employed any offshore staff (an average of 2 employees each), while 4 medical device companies employed between 130 and 0.2 FTEs abroad.

Attracting skilled staff was consistently in the top 5 challenges that companies reported needing to overcome to remain profitable (or become profitable) within a 2 year horizon. This was ranked second as the challenge that most companies face.

Companies staffing levels were generally indicative of high productivity levels or high value industries, with the ratio of revenue per employee of \$221,410 for the 2015 financial year (including NZ, international and contract staff).

One company identified that keeping staff for 10 years rather than young graduates leaving to get international experience is a major challenge, and is likely to be relevant to how NZ can grow the depth of capability that is needed in the health technology industry.

Spending on sales and marketing showed quite different patterns to that of R&D in the location where it is spent. The vast majority of the sales and marketing spend occurs offshore (\$194,084,000) and only a very small portion being spent onshore (\$976,000 in total or 0.5% of overall marketing and sales spend). This is most likely reflective of the export focus in this industry.

COMPANIES' OUTLOOK: ISSUES RAISED IN INTERVIEWS

OVERALL companies had a positive outlook about the operating environment in health, but identified a number of hurdles to achieving greater economic success and better health outcomes for patients. Medical device companies were consistently more optimistic about the export market than providing products to the New Zealand market, mostly due to the scale of the local health system compared to other countries, but also due to a number of other challenges encountered locally as described below.

Typically health IT companies were optimistic

about both the local and export markets and this may correspond with a greater portion of their revenues coming from New Zealand even once they are exporting. The exception to the revenue proportions being Orion Health may indicate that most health IT companies have yet to gain the scale needed to take advantage of the larger international market. Relatively few companies raised barriers to entry such as international procurement (ranked 7th) and international regulatory requirements (ranked 12th) as reasons to reduce their optimism (see graph 3).

OPPORTUNITIES AND MAKING THE MOST OF THEM

High Performing Health System

Most of the companies interviewed viewed New Zealand's health system as an advanced, complex system that generally works well, but is fertile for innovation due to a number of inefficiencies and gaps in optimal patient outcomes or administrative and other functions within the

Health Domain Expertise

A substantial number of companies have deep domain expertise in health related disciplines, and often employ people out of health related disciplines either directly or on a contract basis to ensure their devices and systems are well focussed on meeting the clinical or health system needs. A number of the inventors and developers

system. The New Zealand health system delivers relatively good outcomes compared to other OECD countries in terms of life expectancy, and has excellent research and academic medicine disciplines that are crucial to modern health technology innovation.

themselves are from a clinical or other health system background. Having domain expertise was identified by many companies as being a major factor that provides a competitive advantage after technical expertise in their respective technology platforms.

Working in Partnership

The high levels of domain expertise and connectedness with the health system create opportunities to identify and develop solutions to the challenges a modern health system faces. Combine this opportunity with the relative ease of developing, prototyping and testing technologies in New Zealand and this provides an efficient innovation ecosystem in which to develop products and the business models ultimately needed to get them to the patient.

Most companies are highly collaborative and describe a rich network of partnerships with research and development suppliers, clinical research groups and technology platform suppliers that they utilise to develop more comprehensive solutions able to deal with the complexity of the health system.

There is high engagement with industry associations and government agencies

Integrated Local Supply Chain

New Zealand companies show a high level of use of local suppliers of components and component systems, or integration between local software suppliers. Half of companies report the use or integration of at least one local component or system into their finished products. Aspects

E-health is Ubiquitous

New Zealand's widespread and long history of the use of electronic health records and a wellestablished unique identifier (the NHI number) provides high quality data with which to plan health interventions and evaluate impacts on the health system of innovations once they are implemented.

Many of the companies in health IT reported that a combination of first starter advantage (related to NZ previously being an early adopter in health IT systems) combined with sustained accumulation of domain expertise and aspects such as code

supporting the industry. Most companies belong to one of the industry associations or have active contact with the CMDT (60%). Relatively few companies were identified outside of this network and a large majority (74%) reported a medium to high awareness of the opportunities for support from local and central government agencies.

Government agencies such as Callaghan Innovation, MBIE, NZTE, Tertiary Education Commission (through the MedTech CoRE) and the regional groups such as ATEED and Canterbury Development Corporation have provided support to the industry. Companies value this support highly and believe that with further support targeted to the specific needs of health technology companies the industry would substantially accelerate its growth.

that support using local component suppliers included access to specialised skills, increased awareness of local capabilities and accreditation or compliance with standards including ISO 13485.

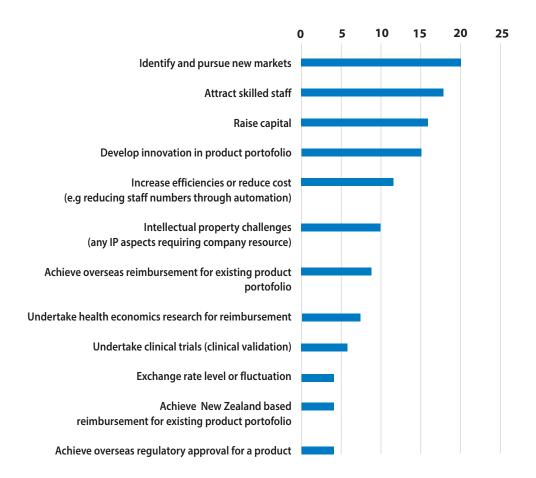
libraries and data are able to create an ongoing competitive advantage.

New Zealand has one of the world leading orthopaedic registries that holds data on implanted devices.

Initiatives such as the standing trial population offer streamlined methods for both clinical and policy research.

CHALLENGES AND SUGGESTIONS FOR OVERCOMING THEM

Graph 3: Ranking of challanges faced by companies over a two year horizon.



The top ranking challenges faced by companies in a 2 year horizon to maintain or achieve profitability are shown in graph 3.

The challenges were ranked by frequency of reporting and the top five challenges are:

- Identifying and pursuing new markets
- Attracting skilled staff
- Raising capital
- Developing innovation in product portfolio
- Increasing efficiencies and reducing costs

An additional theme that was raised in interviews was that if the New Zealand is to gain the most benefit from the use of new technologies, it needs to become more comfortable with sharing information. Companies have high standards of integrity in protecting data and high legal and HISO type standards that they meet on a regular basis. Decision makers in health should become more comfortable with sharing the right levels of information to enable innovative solutions so that companies can work on the solutions that will meet their and patients' needs more closely.

The other issues raised during interviews are discussed in the context of each of the top 5 challenge:

IDENTIFYING AND PURSUING NEW MARKETS

companies consistently report a major challenge is gaining recognition of the value of truly innovative products and IT systems. This is a challenge both in New Zealand and in places like the US where there is a clear process for applying for funding of innovations such as gaining a CMS code (billing code set by the Centres for Medicare and Medicaid Services). Where there are existing similar products it appears easier to gain acceptance, than for true innovations that do not have an existing equivalent. If health care is to benefit from the disruptions that other fields have, there needs to be an ability to introduce true innovations (step change rather than incremental) in a safe and collaborative way.

Frequent changes in procurement groups in New Zealand cause unnecessary confusion and are difficult to navigate. The changes also do not necessarily achieve even relatively simple improvements that could be achieved through technology innovation.

The changes in purchasing practices also create a lot of uncertainty among companies developing health IT systems with a corresponding relatively high level of resource being spent on keeping up with the changes. It is hoped that if there are any further changes in the procurement processes, these will focus on making the process simpler and more transparent.

The National Health Committee was in the process of developing a system of introducing complex treatment innovations to the New Zealand health system, and it is hoped will continue to progress this work from its new position as the Strategic Technology Prioritisation and Innovation (STePIn) Team within the Ministry of Health. Companies also note there is a resource cost to continuously trying to understand where and how procurement decisions are made when there is constant change.

Similarly for R&D funding and support access, companies are mainly satisfied that there is an effective system in place but are concerned that there may be future changes which would again introduce confusion about how to access support. As one respondent phrased it: "Rather work with a system that is mostly workable than change everything and start again".

IT companies are able to bridge interactions between multinational companies, the health system management and clinicians with electronic solutions. However, in order to provide meaningful solutions, need to be able to openly discuss what each group's needs are. Once these needs are identified in partnership, each group can then continue to focus on its' area of core competence for the best use of resources.

ATTRACTING SKILLED STAFF

COMPANIES reported challenges in filling various technical and commercial roles partly due to the specialised nature of the health technology industry. Local networks go some way towards a solution, but further work remains to be done to ensure both recent graduates and experienced staff have the right skills to support company success.

Companies generally put a substantial amount of resource towards understanding, complying with and achieving accreditation relating to local and international standards (e.g. ISO, FIHR, HL7), with companies at times seeing this as a competitive advantage, and others simply as a well-defined method of developing their product range, even when standards are not absolutely required. Having the staff available to achieve these standards has been raised as one of the perceived shortages in the local support ecosystem.

Companies have differing approaches to needing to be in control of their IP, with trade secrets being important in health IT systems and patents being more important in medical device manufacturers. Many of the smaller companies can't afford in-house legal counsel or regulatory and clinical trials staff and look to the support ecosystem to help provide access to these skills. As the industry grows and is involved in more complex IP transactions between both local and international companies that support licensing and other uses of locally developed IP, this support ecosystem needs to grow with the industry.

There is a perceived shortage of specialised skills on some advisory and governance boards that may mean companies are not as efficient in achieving the quickest route to market, but rather learn by unnecessary trial and error. Advisory and governance roles within health tech companies are likely to need additional skills over and above the conventional board functions.

RAISING CAPITAL

MANY of the companies interviewed expressed a concern that the local investment community is not yet adequately equipped to invest in health technologies. The reasons varied from investors not being familiar with and comfortable with the international regulatory and research requirements and how this affects their investment risk; to investors not being prepared for the long development and market access cycles meaning

that a return on capital takes longer than some other industries. On the positive side, the regulatory burdens offer a barrier to entry that protects those companies able to successfully achieve approvals and meet a well identified clinical need.

DEVELOPING INNOVATION IN PRODUCT PORTFOLIO

MID-SIZED health IT companies raise the issue that it is more challenging to provide true innovation if they do not have access to an agile environment where the potential customer (e.g. a DHB department) has the flexibility to make decisions. With the move to more regionalised decisions on IT systems, the ability of groups to innovate with local solutions that have the right interoperability framework and apply the right standards should be preserved. The alternative of total regional control of decisions means that the enterprise solutions put in place will rarely be truly innovative or meet local needs.

Undertaking R&D in partnership or collaboration with Universities and DHB groups was identified as desirable in many cases, but there are still substantial concerns about the handling of intellectual property and commercially sensitive information that prevent some companies engaging in such collaboration.

Companies also expressed varying levels of ease of access to institutional support. Some report that accessing decision makers was relatively easy and others mentioning this was a challenge. One of the potential reasons for differences in accessing decision makers may relate to the brand familiarity of the company. There is a sense that a strong company brand helps not only in marketing, but also in gaining institutional support, collaboration and information sharing. Smaller companies were concerned that it's easier to get support when you're already successful and this should be addressed if we are to nurture the full pipeline of health tech companies.

Getting to know the local R&D and commercialisation networks was raised as an ongoing need by one experienced CEO, with expected benefits of further collaboration and developing shared understanding of their respective markets.

There is still a perceived gap between developing a technology and then wrapping a business model around it to ensure its' greatest chances of success. Once one government agency invests a large amount in R&D with a company there needs to be a reasonable likelihood of further support during the next phase of business development to prevent the original investment from ultimately being wasted. Such support for each step along the commercialisation route will require high level strategic planning and it's encouraging to see the Government developing a health research strategy that may contribute to some of this need for coordination.

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INCREASING EFFICIENCIES AND REDUCING COSTS

INTERNATIONALLY countries and insurers are seeking to reduce the cost of care, with outcomes based pricing, Health Technology Assessments, Group purchasing organisations and reimbursement cuts through competitive bidding means that there is major pressure for companies to compete on price and keep their own costs down.

Companies need to put resource into developing evidence of a value based offering, that in many cases require further research. Where companies can demonstrate a clear benefit to the patient over existing treatments there are still good opportunities for companies to sell successfully to the large international customers.

Developing scalable commercial business models requires the balance of investment in growth with financial discipline, but with R&D intensive industries such as health, companies report this is particularly challenging.

NOTES TO FINANCIAL CALCULATIONS:

FOR Orion Health, the period used was calculated from 2 half year results as the recent listing resulted in no full year reported results being available at the time of preparing the report. Due to the recent listing of Orion Health part way through the financial period being assessed (14 November 2014), there are some figures that are not available for inclusion in the report.

Pacific Edge turnover from exports is calculated using the proportion of US income in the half year results (Unaudited 6 months to 30 September 2015).

Where companies also produce products for non-medical industries (e.g. 3D printing for multiple industries) the turnover related to the medical business is included where possible. Not all companies reported the turnover in a way that enables the data to be disaggregated for this purpose.

For the companies that do not fit the definition of human medical technology companies (developing, manufacturing and selling medical devices and health IT systems), we have not included their information about financials in the report, but noted their other responses where appropriate.

Although all reasonable care was taken in preparing the report, the author does not accept any liability for errors that may have occurred at any stage of the report's compilation.

The report should not be used as a basis to make any investing or similar financial decisions as it is intended for policy development purposes.







Consortium for Medical Device Technologies CMDT



