MINISTRY OF HEALTH
MANATŪ HAUORA

Emerging Health Technology Advice

February 2019
V0.3

For Orthotics

Introduction

The Emerging Health Technology (EHT) Team is part of the Ministry of Health Data and Digital Directorate, responsible for understanding and advising on the impacts of new technology across the health & disability system.

EHT are creating Technology Advice to

- give an introduction to where new technologies are being used in the health sector
- help set the scene for any future conversations had where the technology may be applied
- cover where the technology is currently in use
- highlight what impacts it may have to current models of care
- present general considerations for health sector stakeholders.

Our intended audience is those who are interested in whether emerging technologies will benefit their health deliverables, or who maybe just want a bit more information on what it's all about.

This document is not intended to endorse a specific product or device, but to provide a snapshot of what is happening both locally and internationally, and where the major health interest points are.

This is the first step into discovering a technology. There are many other aspects to consider, whether funding or technical, however we're not trying to cover everything – **merely start the conversation**.

For Orthotics

While this document looks at technologies that can assist and improve a specific medical device, this is only one aspect to be considered when looking to improve a patient's future overall experience. Revisiting and reviewing current business models, ease of interoperability between healthcare professionals, and the patient's involvement and ultimate ownership of their healthcare journey will be of equal importance.

What do we mean by **Emerging**?

We look at where the technology sits within McKinsey's Three Horizons of Growth.

Is it an improvement to the current model – like improved road tyres, or will it be disruptive – like driverless cars?

In this case, improving current orthotic technology sits within Horizon One and Two. Horizon Three (the disruptive space) would look towards managing genetic disorders and implementing completely new surgical techniques – can we resolve impairments so that there is no longer a need for orthoses?

How does this relate to the **Technology**?

The Horizon One and Two technologies are becoming readily accessible to people at home (eg, 3D printers) without controls over quality, safety and effectiveness. Is it our role to provide a standard for how you would use these technologies for your health outcomes?

Where does this all sit in the New Zealand **Health** context?

There are researchers and private companies beginning to offer these technologies and services, however it is still in its infancy compared to what is available overseas. Access to the latest technology and research is often self-funded and expensive.

What is Orthotics?

Orthotics is a medical speciality that focusses on the design and application of orthoses. An orthosis is an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system.

An orthosis may be used to:

- Control, guide, limit and/or immobilise an extremity, joint or body segment for a particular reason
- Restrict movement in a given direction
- Assist movement generally
- Reduce weight bearing forces for a particular purpose
- Aid rehabilitation from fractures after the removal of a cast
- Otherwise correct the shape and/or function of the body, to provide easier movement capability or reduce pain

There are many types of orthoses and they can range from simple shoe insoles to complex bracing and supports. Orthoses can be:

- **Off the shelf** – a product that has been pre-fabricated and requires no modifications
- **Customised** – an off the shelf product that requires some customisation to make it suitable for the patient's needs
- **Fabricated** – a bespoke solution that is fabricated to meet the patient's specific requirements

Under the International Standard terminology, orthoses are classified by an acronym describing the anatomical joints which they contain. For example, an ankle foot orthosis ('AFO') is applied to the foot and ankle, a thoracolumbosacral orthosis ('TLSO') affects the thoracic, lumbar and sacral regions of the spine. It is also useful to describe the function of the orthosis. Use of the International Standard is promoted to reduce the widespread variation in description of orthoses, which is often a barrier to interpretation of research studies.

Orthoses may be used as part of daily life for a number of long-term conditions, including but not limited to scoliosis, cerebral palsy, spina bifida, diabetes, osteoarthritis, polio, spinal cord injury or stroke. Equally, orthoses can be used in the short term for recover from injury or trauma, to realign or reduce pain as a component of other treatment (eg, medication, surgery, physiotherapy) programmes.

The major difference between orthotics and prosthetics is that while an orthotic device is used to enhance a person's limb, a prosthetic device is used to replace a limb entirely.

Assistive Technology

Assistive devices and technologies are those whose primary purpose is to maintain or improve an individual's functioning and independence to facilitate participation and to enhance overall well-being. They can also help prevent impairments and secondary health conditions

(World Health Organisation)

How are orthoses currently funded in New Zealand?

Patients wishing to access the crown-funded service must be referred by an approved healthcare professional, and either meet the Ministry of Health or ACC funding criteria. Orthotic assessments are performed by an orthopaedic specialist/surgeon or orthotist, or a hospital based physiotherapist, occupational therapist or podiatrist.

On 1 October 2003, DHBs were devolved responsibility for some long-term equipment and supplies in addition to their existing responsibilities, specifically orthotics and prosthetic services. DHBs will fund equipment and supplies for all age groups, regardless of whether it is for a short- or long-term need.

The current service specification for Orthotic Services - DOM110 is used in conjunction with the Community Health, Transitional and Support Services service specification.

Orthoses provided by other health professionals who are not part of this Orthotic Service, are included in their own relevant service purchase unit/inpatient event (eg, AH01005 Physiotherapy).

The current Service includes:

- Orthotic assessment, provision (production and fitting), and the review, repair and maintenance of orthoses
- education of Service Users, and their carers in the use of their orthosis
- timely communication with Service Users, and their carers, in the anticipated completion dates of fabrication or repairs of their orthotics.

Service Users are eligible people of any age, assessed by the Provider and/or appropriate prescribing agent/health professional, as requiring orthotics services and who meet the entry criteria.

This Orthotics Service Specification is now due for review within its five year review cycle.

The Mobility Action Programme

In Budget 2015 the Government allocated $6 million of new funding over three years to help improve care for people with musculoskeletal health conditions. This included increasing access to early community based advice, treatment, education to improve self-management, and rehabilitation to improve function and participation in activities that are important to them.

The Ministry intends to make public the interim evaluation report of the Mobility Action Programme in the week commencing 4th February 2019.

There are three entry paths to access the Service: acute, post-acute and longer term, described below.

Path	Description
Acute Services	Inpatient Services or orthosis required during an outpatient or emergency department event. People enter the Service via a health specialty, where the orthosis is required in relation to a medical or surgical intervention, Assessment, Treatment & Rehabilitation admission or provided during an emergency department or outpatient treatment.
Post-Acute Services	Orthotic Services required during Community or Outpatient events. People enter the Service via a health specialty or by referral from primary health care where they require Orthotic Services. Accident related acute events are included within this Service up to six weeks post discharge.
Long Term Services	Orthotic Services for repeat or ongoing assessments and / or orthoses indefinitely.People assessed with personal health (non-disability diagnoses) who have long-term support needs (over 26 weeks), or as having a disability may require Orthotic Services on a long term basis.

What is the potential of Orthotic technology?

From research to commercialisation, technology is more frequently being used to enhance the field of orthotics. It is no longer necessary for an orthosis to be a rigid exoskeleton structure with limited mobility. Soft materials, combined with sensors, advanced software and robotics are making it possible for devices to achieve natural motions, allowing more freedom and quality of life to the patient.

Technology	Opportunities	Limitations
3D Printing	• Anatomically customised orthoses created for the patient • Shorter creation time	• Limitations in quality & type of materials that can be printed • Set-up cost • Without access to accurate diagnostics, matching natural biomechanics is difficult (eg, Weight bearing CT scans)
Sensors	• Allows feedback loop to patient via lights, vibration, app notifications • Data collected can support clinical diagnostics and therapeutic decisions	• Battery life • Ensuring appropriate IoT security/cybersecurity for the device
Robotics	• Allows mobility and freedom for those who were not previously able	• Potential need for legislation for the device's software/cybersecurity • Cost to purchase and repair

3D Printing and Personalisation

With the recent advances in digital scanning technology, computer software and the advancement of manufacturing techniques, unique and personalised orthoses are more accessible. This allows a bespoke orthosis to be fabricated for the patient, to meet the patient's specific requirement. In order for these devices to be effective, they often need additional fitting and adjustment, which can take more than a few weeks to be delivered. 3D printing can significantly reduce the amount of time required to deliver orthotic devices to patients. This is especially important when creating orthotics for children, who may have grown between the time of initial consultation and final fitting.

3D printing not only allows prototypes to be fabricated in a shorter time period, but also at a larger scale. 3D orthotic blueprints are already being shared open source between developers, in turn lowering cost and allowing better access and design thought sharing.

3D printing has the ability to fabricate objects in one piece, to remove seams that are susceptible to wear and tear, and if damaged, a replacement can be printed and sent to a patient without the need to re-visit a hospital.

It also shows how 3D printers, rather than replacing skilled orthosists, can be used as force multipliers, helping with the production workflow and allowing their products to become more sustainable.

Sensors

The addition of sensors to orthotics can have multiple functions eg, to allow adjustment of the orthosis as it moves through its motions, to give feedback to the user, or to collect data and feed back to the clinician. Sensors can also provide biofeedback in the form of vibrations, light pulses or even notifications to a patient or carers mobile device. Diabetic patients with peripheral neuropathy (loss of sensation to the foot) who wear 'smart shoes' could be notified if there is a likelihood of a foot ulcer occurring.

Another example, a full-leg brace has an ankle movement sensor that can transmit a signal to a hydraulic knee joint unit integrated into a carbon fibre frame along with electronics. In addition the knee angle sensor continuously measures the flexation of the knee joint and its angular acceleration. Entire gait cycle can be controlled dynamically and in real time. This allows the patient more focus on their surroundings, rather than constantly concentrating on the orthosis itself.

Robotics

There have been numerous advances in robotic prosthetics and orthotics over the recent years. These 'active' orthoses can range from a single joint focus to a full exoskeleton.

Robotics can be used in neuro-rehabilitation, such as hand impairment caused by stroke, spinal cord injury or muscular atrophy. Wearable robotic devices can support the use of the impaired limb in activities of daily living, and also provide at home rehabilitation training.

How is this technology being implemented in New Zealand?

Clinical research projects have been conducted in many of the New Zealand universities including:

University of Auckland

- Smart Splint - 3D printed carbon leg splints including sensors for rehabilitation

Victoria University of Wellington

- Cortex Cast – 3D printed lattice support cast.

There are currently no courses in prosthetics and orthotics available in New Zealand, however La Trobe University in Melbourne has a four year Bachelor of Health Sciences and Master of Clinical Prosthetics and Orthotics.

The New Zealand government has a stewardship role to encourage local companies to invest in research and development.

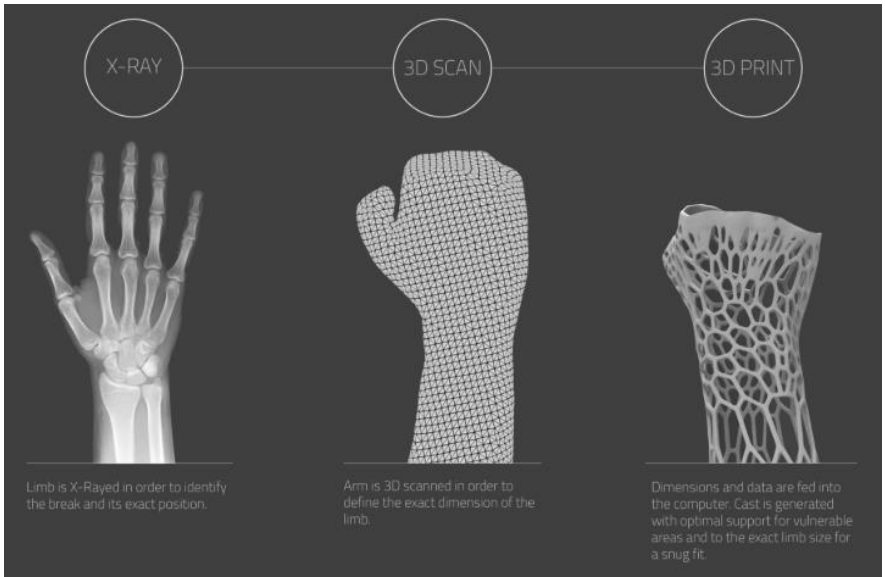
Callaghan Innovation has the legislated objective of supporting "science and technology-based innovation and its commercialisation by businesses, primarily in the manufacturing and service sectors, in order to improve their growth and competitiveness". Envisioned as an advanced technology institute, the agency works closely with various partners
(NZTE, MBIE, MFAT, universities, ITPs, CRIs, NZVIF, the venture capital community, Chief Science Advisor and Regional Business Partners) to accelerate commercialisation of ideas by advising businesses on innovation, providing research and technical services and funding business R&D.

With our small yet diverse population, there should be encouragement for companies (both local and international) to use New Zealand as a test bed for their new innovations, allowing the opportunity for the public to be early adopters while also getting the evidence base necessary for successful commercialisation and adoption elsewhere in the world.

Orthotic funding is currently determined at a DHB level, and may differ from region to region. Therefore there is limited access to the latest technology via a publicly funded channel.

As New Zealand is predominantly in the research phase for the next generation of these medical devices, patients need to look overseas to access the latest technology. More often than not this is self funded, which highlights the inaccessibility and inequity for those who cannot afford this avenue.

The New Zealand Health Strategy has five strategic themes – People-powered, Closer to home, Value and high end performance, One team, and Smart System. Giving people the ability to access the latest technological advances is relevant to all these themes, and most importantly allows them to take ownership of their healthcare journey, enabling individuals to make choices about the care or support they receive.



(Cortex Cast)

Considerations for health sector stakeholders

Stakeholder	Opportunities	Risks
DHBs	• Increase scope of therapeutic offerings, more personalised for patients • Potential to lower overall operating cost over time • Adopt new models of care, promote interoperability • Better outcomes for patient	• Change in service model, workforce retraining • Workforce needs to adopt new skill set for new technology to become mainstream • Up front investment to cover cost of implementation • Ensure appropriate evidence for new technology • Economic benefits analysis
Ministry of Health	• Encourage adoption of new technology • Better health outcomes for specific population group in an earlier timeframe	• Potential for inconsistency and inequity of adoption over regions (Postcode lottery) • Need to review regulation of devices – Medsafe
Health Care Professionals	• Ability to offer new tech to patients • Adopting technology eg, 3D printing can replace tasks to better prioritise specialist's time	• Training has not been made available • Shift in workforce focus
Researchers	• Access to clinicians and patients • Improve clinical outcomes	• Research outcomes not adopted • Intuitively think the outcomes are better, evidence is harder to capture eg, subjective vs objective
NZ Public/Patients	• Accessing latest orthotic technology • Better quality of life & activities of daily living • Data collected can support clinical diagnostics and therapeutic decisions • Lower cost eventually as technology adopted	• Latest technology may not be funded, out of private financial reach • May need to travel to adopt new tech (not available within their DHB catchment)
ACC	• Change in eligibilities, more people can access • Keep in line with MOH eligibility criteria	• Increase in funding • Ensure appropriate evidence for new technology

DHBs – The 20 District Health Boards are responsible for providing or funding the provision of health services in their district. The funding for Orthotic services for eligible patients sits within this responsibility.

Ministry of Health – As the steward of the New Zealand health and disability system, the Ministry has an interest in the overall wellbeing of the New Zealand public and their journey through the healthcare system. Medsafe is responsible for the regulation of medical devices to ensure they are acceptably safe.

Health Care Professionals – Provide referrals, treatment and rehabilitation for patients with health conditions which require orthoses.

Researchers – Universities and private organisations are conducting clinical trials into how emerging technologies can benefit future fabrication of orthoses.

NZ Public/Patients – As users of the New Zealand healthcare system, the public needs to feel confident they have the best and safest access possible to the latest health procedures and technology.

ACC – the New Zealand Crown entity responsible for administering the country's universal no-fault accidental injury scheme.

Who else is reviewing their Orthotics policy?

In November 2015, NHS England published a report 'Improving the Quality of Orthotic Services in England'.

This was followed by a response in 2017 by the Health Education England (HEE) who published a report on 'The Future of the Orthotic and Prosthetic Workforce in England', which looked at the current issues facing the Prosthetic and Orthotic workforce.

The report was written following an HEE education summit, which was attended by delegates representing patients, clinicians, NHS England, NHS Improvement, HEE and various other bodies. HEE released a second paper one year later to follow up – highlighting there has historically been a low number of applications to undergraduate places to study prosthetics & orthotics.

Case Study – Rex Bionics

Rex Bionics was founded in 2007 by Auckland robotics engineers Richard Little and Robert Irving to develop innovative medical robotic technology to bring new-found mobility to users worldwide.

The company is engaged in the research and development, manufacture, and commercialisation of robotic devices designed to provide physiotherapy to and improve the physical and psychological well-being of people with mobility impairment as a result of spinal cord injury or other neurological trauma, such as stroke or traumatic brain injury, or neurodegenerative disease.

Rex Bionics develops and commercialises ReX, a hands-free, self-supporting, independently controlled robotic walking device for use in the rehabilitation of people with major mobility impairment.

There are two principal products: ReX and ReX P (Personal), which are targeted respectively at the professional neuro-rehabilitation clinic and personal homecare markets. The Company utilises RAPPER II, which is an open label, single arm, non-randomized, non-comparative registry study of Robot-Assisted Physiotherapy Exercises with the REX Robot powered exercise system preventing unsupported patient ambulation.

Until now, REX has most commonly been used by wheelchair users with a spinal cord injury, but has also been used by people who have suffered a stroke or other traumatic brain injury; and wheelchair users with multiple sclerosis, muscular dystrophy and cerebral palsy.

Rex Bionics is working with physiotherapists to develop the concept and practice of Robot Assisted Physiotherapy (RAP). In a session of RAP, REX lifts patients from a sitting position into a robot-supported standing position, allowing them to take part in a set of supported walking and stretching exercises, designed by specialist physiotherapists

Wheelchair users are at risk of developing numerous medical complications from extended periods of sitting. By enabling them to exercise standing up and to spend more time walking, REX may offer significant health benefits, including improved sleep, cardiovascular performance, maintenance of joint range, and a reduction in common abdominal problems. A programme of clinical trials is now under way to evaluate these potential benefits.

REX does not require the use of additional supports (eg, crutches), and is quick and easy for users to learn. Both REX is registered with Medsafe.

The REX is now also registered as a supplier under the Assistive Technology section of Therapeutic supports, custom prosthetics and personal mobility equipment of the Australian National Disability Insurance Scheme (NDIS)

Case Study – Andiamo 3D Printing Braces

Andiamo is a UK health tech company creating 3D printed braces, set up by parents honoring their son who died from cerebral palsy complications.

In 2012, Diamo Parvez was just nine years old when he died from complications with cerebral palsy. The disorder resulted in a painful tightening of muscles that often requires orthoses — splints and braces — to support the body.

Throughout Diamo's life, parents Samiya and Naveed had difficulty finding effective and comfortable orthoses. This meant regular trips to the hospital for fittings. Plaster casting is one part of this procedure.

Speaking of the hospital visits, Samiya said:

"We saw how much our son hated being pinned down for the plaster — he would scream and scream and it was a real struggle. I know kids who break down and start crying if their parents even drive past a hospital because they think they're going to get a plaster cast."

In all, the process could take up to six months to get right. Being young, Diamo would grow quickly and he would need to go through the procedure many times per year.

After Daimo's passing his parents established a company, Andiamo, in honor of their son. Focusing on the well-being of those who require the fittings, Andiamo makes use of 3D scanning and printing technologies. Travelling to patients, the scanning process to create new supports is more efficient than traditional methods.

By using 3D scanning and printing, Andiamo aims to cut waiting times for orthoses from six months to 48 hours. So far they've brought it down to two weeks. In addition, thanks to 3D scanning and printing, the orthoses fit better, are lightweight and less bulky.

(Source – BBC)

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