

The Australian Orthotic Prosthetic Association Inc.



**SUBMISSION TO THE
PRODUCTIVITY COMMISSION;**

**ORTHOTIC SERVICES IN THE PROPOSED
NATIONAL DISABILITY AND INSURANCE SCHEME**

In response to:

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Disability Care and Support Inquiry

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FORWARD

The Australian Orthotic Prosthetic Association (AOPA) Inc. is the peak professional body for Orthotist/Prosthetists in Australia. The AOPA Inc. applauds the initial work undertaken by the productivity commission in reviewing disability services in Australia. The commission's draft report acknowledges the fragmented, inequitable and inefficient system currently in place and the need for a paradigm shift in service delivery models and funding across Australia.

The AOPA Inc. welcomes the opportunity to contribute to the development and design of a National Disability Insurance Scheme (NDIS) and to respond to the recently released draft report into Disability Care and Support. The draft report is impressive in the depth and breadth of disability related issues it focuses on. The AOPA Inc. representatives have participated extensively in the forums and discussions, particularly in Sydney, Melbourne and Tasmania. The preparation of this submission has also included consultation with members, who represent 75% of the profession nationally, as well as other industry partners, including public and private practitioners, componentry suppliers and consumer representatives.

This submission addresses the proposed NDIS regarding **the provision of orthotic services** and follows from the Executive Summary to the Productivity Commission Inquiry in 2010 (submission no. 0387). The AOPA Inc. encourages the Commissioners to consider, in conjunction with this, our submission regarding prosthetic service delivery models and amputee care. Both submissions address key and specialized areas of disability services, however the following areas of commonality exist in our recommendations;

- Workforce concerns in orthotics and prosthetics, including issues with skills shortages, qualification and competency standards and extended scope of practice
- Support for consumer empowerment and a rights-based approach to disability services
- Alternative approaches to funding, including addressing unmet needs
- Alternative approaches to service delivery, including consideration of best practice models

Every attempt has been made to locate the relevant national and international research, models and frameworks to provide evidence-based options for improving disability services in Australia. The AOPA Inc. supports the development of a National Disability Strategy and looks forward to continuing consultation with the productivity commission regarding the future design of an orthotic service delivery model.

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EXECUTIVE SUMMARY

The proposed NDIS indicates an opportunity now exists to implement a national disability scheme which provides timely and appropriate care to all Australians requiring orthotic services. This transformation of the current service model has the potential to remove state based inefficiencies currently hampering quality service provision.

Australia's current disability service model is fragmented and cyclically-reliant due to a "rationing arrangement" for funding. It is too often affected by external pressures and issues, with the quality and timeliness of services dependent on the availability of funding rather than need. A national, needs-based approach, with local delivery, is essential to the provision of disability services. A rights based approach to disability services is essential, which would remove 'cause-based' funding. People with disabilities have a right to independence and community participation, which may involve mobilisation using aids and equipment. A new rights based disability strategy would guarantee these rights are provided in a fair and just manner and allow access to appropriate technologies.

The AOPA Inc. encourages the Commission to consult broadly with consumers and service providers to establish a platform of needs based service provision with a fundamental client and outcome focus. The delivery of future in line with best practice principles and internationally accepted and proven protocols will ensure a consumer outcome focus and the provision of optimal services and technology.

This submission will outline strategies which will support the design and implementation of an NDIS ensuring the empowerment of people with disabilities and the provision of innovative, timely and equitable orthotic services.

KEY MESSAGES

1. The aids and equipment for inclusion in the NDIS should follow internationally set standards by the ISO 9999:2007.
2. The AOPA Inc. supports a rights-based approach to the provision of services to people with disabilities, including the empowerment of people with disabilities to make informed choices regarding their health care.
3. Low-aid use should be perceived as a system failure, as it is often a result of the untimely funding of essential equipment.
4. Funding and service delivery for orthoses should not be affected by geographic location.
5. Funding and service delivery for orthoses should not be determined by “cause-based” eligibility criteria. A needs-based approach should be adopted.
6. Consumer choice must be supported, but within the safety of Government health professional registration and regulation schemes (NRAS) or through membership of self-regulating professional bodies.
7. The use of pre-fabricated orthoses should be restricted to short-term needs and prescribed according to need, rather than availability and cost saving.
8. Orthotic services should be viewed as a life-long commitment to mobility and participation and therefore the provision and funding of these services should be delivered accordingly.
9. Extended scope of practice is not a solution to concerns with potential ‘conflicts of interest’. The ‘double-checking’ and ‘pre-prescription’ processes are not in the best interest or safety of clients.
10. Minimal international data exists relating solely to orthoses for expenditure and service provision comparison.
11. Based on international statistics, the medical device market growth rate may be predicted at 10% per annum, and should be reflected in an annual review of funding.
12. Currently, Australian states have a very low ratio of orthosis provision per capita compared to international data, however data availability is limited. The AOPA Inc. supports a national data collection strategy.
13. Clients and service providers within the boundaries of the Fair Trade Act, have the right to access the information which affects the service they can provide and receive.
14. Clients have the right to access Modern and Advanced Orthotic Technology in order to enhance their quality of life and participation. Funding on a per device basis should reflect the current costs of equipment and enable consumers to access the technology which meets their needs.
15. Devices should be prescribed based on an assessment of need rather than according to a “Manual and Imprest List” with associated ceiling prices.
16. The AOPA Inc. encourages the use of The AOPA Inc. Orthosis Schedule 2009 and the development of cost boundaries in consultation with The AOPA Inc.
17. Cost boundaries should follow a principle of 90/10 and allow for the smooth processing of funding for Modern Orthotic Technology (90% of cases).

18. A list of orthoses and components should not be developed and used solely for funding approval purposes. It may be created for the accurate development of cost boundaries.
19. Cost boundaries should be reviewed and modified in line with costs, prices, technological advancements and the Australian CPI on an annual basis.
20. The principle of 90/10 should also allow for the prescription of Advanced Orthotic Technology.
21. Where a prescribed device falls outside the cost boundary, the client should be able to apply for excess funds where the prescribing Orthotist and other allied health team members can clinically justify the prescription through a thorough needs assessment and rationalising according to the ICF framework.
22. Where a prescribed device which falls outside the cost boundary and fails in its application for excess funds, the client should be entitled to use the maximum of the cost boundary and make a co-contribution.
23. Reviews, maintenance and repairs should be adequately funded such that they can occur in a timely manner.
24. Equipment refurbishment (recycling) must meet patient safety standards and be the most appropriate solution for the client within the boundaries of The TGA legislation for Grade 1 Medical Devices.
25. Medicare rebates should be available for the clinical services offered by Orthotists, to ensure the provision of orthoses to people with chronic disabling conditions is supported by funded clinical encounters.
26. For the provision of orthoses, funding should be provided for the associated clinical and therapy services, being “soft” orthotic technologies, and available as separate reimbursement items to the “hard” technology.
27. Prescription eligibility should be related to the core training and tasks of the profession and based on international standards and evidence-based practice.
28. The model of prescription and funding should support evidence based service delivery, rather than the service delivery being designed according to the prescription and funding processes.
29. Orthotic reviews must be incorporated into the NDIS orthotic service delivery model.
30. The introduction of validated outcome measures within the review process will ensure the service meets consumer needs, enable data collection and support self-regulation processes
31. In order to obtain NDIS reimbursement, orthotic prescriptions should be developed in consultation with a qualified Orthotist, as defined through membership to The AOPA Inc.
32. In order to obtain NDIS reimbursement, orthotic services, including the assessment, fitting and review of orthoses should be provided by a qualified Orthotist, as defined through membership to The AOPA Inc.
33. Orthosis funding packages should include the following costs; “hard” and “soft” technology over the life-span of the orthosis (to be determined) at an agreed hourly rate (to be determined), and component/materials expenses.
34. The NDIS budget for orthoses should have provision for unforeseen expenses relating to unbudgeted component and material repairs, and unforeseen replacements.

INTRODUCTION

The Australian aids and equipment need

The Australian Institute of Health and Welfare (AIHW) reported 1998 figures that 48% of people with a disability used some form of aid. Of this group, 40% were under the age of 65 years (AIHW, 2003). The ageing Australian population will have dramatically impacted on this figure. Aids and equipment have become an essential part of the health system to maintain independence and activity levels of those affected by disability. Mobility aids are the second most frequently used aid after medical aids in the 15-64 year age group (AIHW, 2003).

Definitions of Aids and Equipment

The International Organisation for Standards clearly defines *assistive products* for persons with a disability and states the devices to be excluded from the definition. These standards, which are internationally accepted, may provide overarching guidance as to the devices for inclusion and exclusion in the new NDIS (International Organisation for Standards, 2007).

An orthosis is an externally applied device used to modify the structural or functional characteristics of the neuro-muscular skeletal systems (refer Appendix One: orthotic terminology and designs, for full orthosis related terminology). Orthotists are allied health practitioners who work in an autonomous manner to provide clinical and technical orthotic care, and are responsible for the assessment, prescription, design, manufacture and fitting of orthoses to patients (ISO, 1989). Several professionals may fit a small range of orthoses in the course of their work (physiotherapists, chiropractors, podiatrists), however there are very few professionals who are qualified and trained to fabricate and fit custom-made orthoses. These professions include podiatrists (custom-made foot orthoses), occupational therapists (custom-made hand orthoses) and Orthotists (custom-made orthoses for all parts of the body). Only Orthotists are specifically trained in the assessment, prescription, design, manufacture and fitting of a vast array of custom orthoses for the entire body.

Key message:

1. *The aids and equipment for inclusion in the NDIS should follow internationally set standards by the ISO 9999:2007.*

Orthotic workforce

The Australian orthotic profession is a relatively mobile workforce however it is disproportionately represented around the major education facility, located in Melbourne. La Trobe University, Melbourne provides the only tertiary training facility for Orthotist/Prosthetists in Australia. With almost two decades of education at the Bachelor Degree level, the orthotic and prosthetic profession has shifted to a minimum education standard of Masters. Membership to

The AOPA Inc. requires a minimum qualification of *“Bachelor of Prosthetics and Orthotics from La Trobe University or an equivalent tertiary Prosthetic and Orthotic qualification . . .”*. In addition to a minimum tertiary qualification The AOPA Inc. requires its members adhere to defined standards and by-laws.

Australia has an estimated Orthotist/Prosthetist workforce of 320, of which 240 are members of The AOPA Inc. This represents a low ratio per capita of only one professional practicing in both orthotics and prosthetics per 66,445 population. According to The AOPA Inc. workforce survey (2010), individuals practicing solely as Orthotists represent 65% of the Australian Orthotist/Prosthetist workforce, suggesting a ratio of Orthotists per population of 1:108,612.

The British Association of Prosthetists and Orthotists (BAPO) reported a recommended ratio of Orthotists per population of 1 per 30,555 population (NHS Scotland, 2005). In Scotland the ratio is 1:100,000, in which a severe workforce shortage is identified (NHS Scotland, 2005). Available data for Belgium from 2004 indicates a ratio of 1:21,740, which is due to their generous funding model which is under review (Simoes, et.al, 2008). Based on the BAPO internationally accepted benchmark approximately 736 Orthotists would be required to meet Australian population demands. The low workforce numbers in Australia is directly linked to the lack of state based funding, rather than student intake rates.

A rights-based approach to the provision of disability services

The ability to access the environment and participate in community life is a basic human right. The United Nations Convention (2006) on the rights of persons with disabilities’ purpose is “to promote full and equal enjoyment of *all* human rights by persons with disabilities rather than a more restricted set of services and opportunities” (p.5). The AOPA Inc. supports the Australian Human Rights Commissions’ submission (submission number 0072) (2010). Consideration of all available technology and therapy options within the boundaries of evidenced based practice would be supportive of basic human rights within the context the proposed NDIS. The restriction of access to advantageous assistive technology is potentially discriminatory on the basis of disability.

Key message:

2. *The AOPA Inc. supports a rights-based approach to the provision of services to people with disabilities, including the empowerment of people with disabilities to make informed choices regarding their health care.*

BACKGROUND:

the current orthosis funding and delivery model

Fragmented and reactive funding models which result in the delayed provision of aids and equipment produce other system costs. These may include but not be limited to:

- ineffective rehabilitation
- increased hospital bed days
- mental health effects
- decreased community and employment participation
- increased sick days
- increased expenses associated with short term solutions such as repairs and maintenance and personal carers.

Historically, funding models have directly affected the method of service delivery, in which systems have developed based on funding cycles, rather than best practice models.

The result of delayed and reactive funding of orthoses

A number of AIHW reports indicate that personal assistance may be a less efficacious method of reducing the impairment associated with disability than the timely provision of equipment (AIHW, 2003). However, almost half of people aged 0–64 years with a reported need for assistance with self-care, mobility or communication in actuality received personal assistance only. The AIHW concluded that it is possible that ‘low aid’ use is off-set by increased use of personal assistance (AIHW, 2003). Mobility aids are environmental factors which have the potential to improve the quality of life for people with disabilities through empowerment and a greater sense on independence. They serve a far greater role than simply mobility and environment access and when contrasted to personal assistance, are a more cost effective, empowering and proactive long-term, enabling solution.

Key message:

3. *Low-aid use should be perceived as a system failure, as it is often a result of the untimely funding of essential equipment.*

Issues with variations between state models

The AIHW (2003) identified a number of key shortfalls in equipment provision, many of which are still present today. These include issues with cost, timeliness and availability of service, a restrictive range of equipment, and reduced supply of equipment from hospitals. Long-term sustainable funding is required however the system does not simply require an injection of funds. The implementation of a more robust and evidence-based model of service delivery is

essential. The removal of disadvantage based on location would ensure improved and equitable service quality, availability and timeliness across states and territories.

Government funding schemes currently use a “cause-based” determination of an individual’s need, in that the cause of disability determines eligibility. This often excludes people from accessing Government funding, but also creates a difference in funding entitlement according to disability cause. The removal of disadvantage based on the cause of the disability will ensure equal access to technology and services for all people with disabilities. The example below highlights the variation consumers experience due to cause and geographic based disadvantages:

A 21 year old female with unilateral lower limb paralysis due to a motor vehicle accident would be eligible through a Traffic Accident Insurance scheme for a stance control knee ankle foot orthosis and the associated private therapy sessions, valued at over \$10,000. However, should the cause of unilateral lower limb paralysis be due to a Cerebro-Vascular Accident, then upon discharge from the hospital setting, she would only be able to access funding for equipment according to the ceiling limit for a knee-ankle-foot orthosis, which may vary between \$1500 and \$3500, depending on which state she lives in.

Key message:

- 4. Funding and service delivery for orthoses should not be affected by geographic location.*
- 5. Funding and service delivery for orthoses should not be determined by “cause-based” eligibility criteria. A needs-based approach should be adopted.*

The issues with non-qualified practitioners

People with disabilities have the right to select their preferred treatment pathway, model of service delivery and supplier of equipment. Variations exist in the competency and qualifications of health professionals in Australia, and there are limited restrictions of title. This places consumers at risk when accessing those professions outside of the National Registration and Accreditation Scheme (NRAS). Funding schemes have a duty of care to consumers to ensure the services and equipment are provided by appropriately qualified and competent practitioners. Consultation with self-regulating professional bodies will assist with ensuring appropriate qualifications and high competency standards of the professional providing funded services through the NDIS.

Key message:

- 6. Consumer choice must be supported, but within the safety of Government health professional registration and regulation schemes (NRAS) or through membership of self-regulating professional bodies.*

The issues with a short-term view of orthotic service provision

The provision of orthotic devices for people with disabilities is based on a long-term process, encompassing assessment, prescription, orthosis provision and ongoing review. The development of a relationship between the consumer and Orthotist is highly encouraged. The provision of orthoses for people with disabilities is part of a commitment to ensuring long-term needs are met and not a single occasion of services. This highlights the importance of timely and proactive funding of repairs, maintenance and equipment replacement. The timeliness of these services is directly linked to consumer safety, as addressed further in this submission. The AOPA Inc. supports the appropriate use of pre-fabricated for short-term needs, however their prescription for people with long-term disabilities should be cautioned (refer Appendix One for definitions). Disability SA (2010) refers to the cost saving associated with supplying over 90% of its equipment from a range of standard non-customised equipment, which allowed “significant efficiencies to be delivered to clients requiring equipment” (p.8). The cost to the client and health system due to complications such as pressure sores, return appointments and decreased function outweighs the cost savings.

The provision of pre-fabricated orthoses or cheaper custom alternatives by non-Orthotists should be strongly questioned, as these often do not provide savings in the long-term. Orthotist’s prescriptions are based on the entirety of available orthosis options, however other professionals may prescribe based on their skill set and availability. Orthotists are the only health professionals able to prescribe and fit the full range of custom orthoses for the entire body. The Scottish Orthosis Service Review (NHS Scotland, 2005) identified major concern with the provision of orthoses by other professional groups. The same concern should be raised in Australia regarding the provision of pre-fabricated orthoses directly to patients in which an Orthotist is not involved in the assessment and fitting process.

Key message:

- 7. The use of pre-fabricated orthoses should be restricted to short-term needs and prescribed according to need, rather than availability and cost saving.*
- 8. Orthotic services should be viewed as a life-long commitment to mobility and participation and therefore the provision and funding of these services should be delivered accordingly.*

The issues with extended scope of practice

Extended scope of practice is a key feature of current Australian equipment schemes. Prior to approval and commencement of orthotic services the state systems require a follow-up assessment of need (double-checking) or a pre-prescription to be completed. This task is often undertaken by health professionals working outside their specialty. This inappropriate extended scope of practice is not due to workforce shortages but rather Government models, which are overly concerned with a ‘supplier’ of equipment also ‘prescribing’ equipment. In the case of therapy services, there does not appear to be as much concern, with a Physiotherapist able to prescribe and supply therapy without the inefficient ‘checks and balances’ process. A qualified Orthotist is an allied health professional and those with membership to The AOPA Inc. are bound by a Code of Conduct and Competency Standards, as are other

allied health professionals. Extended scope of practice in this instance is an unnecessary process which places the consumer at risk of sub-optimal management and service provision. This consumer risk is related to the potential for inappropriate prescription and orthotic treatment plan development. This issue and the related risks are outlined further in this submission and the appendices

Key message:

9. *Extended scope of practice is not a solution to concerns with potential 'conflicts of interest'. The 'double-checking' and 'pre-prescription' processes are not in the best interest or safety of clients.*

RECOMMENDATIONS:

the proposed NDIS orthosis funding model

Information regarding expenditure and service provision figures for orthoses in Australia is scant. This is an international issue, with the recent Belgium Health Technology Assessment into the cost-effectiveness of orthotic devices reporting “few specific data on the medical devices industry are being published” (Simoens, et.al, 2007, p.66). Further to this, comparisons between countries and Australian States are limited by inconsistent terminology and varying codes for devices. Some statistics regarding total expenditure, device provision and cost per capita exist, but very little research is readily available from the last five years.

International expenditure and service provision figures

In 2003, the global medical devices market was valued at €184billion. In this context, medical devices refers to a large number of products, varying from very high tech equipment such as MRI scanners, to mid-tech products such as pacemakers, electric wheelchairs and orthoses, to low-tech products, such as bandaging (Simoens, et.al, 2007). The US market is by far the largest and represents between 38% - 43% of the global market, with an annual growth rate in 2005 between 8% - 10% (Frost & Sullivan Market Insight [2006]: In Simoens, et.al, 2007). The European market represents between 30% - 34% of the world market and is the second largest behind America. It is these two markets that the majority of literature pertains to.

Average per capita spend on medical devices in 2002 for the 17 Western European Countries was €134, with Germany the highest with €230 and Greece at the bottom with €49 (Simoens, et.al, 2007). In comparison, NSW Health (2006) in their review of the Program of Appliances for Disabled People (PADP) summarised state based per capita spend on equipment as; NSW \$2.73 per capita, Victoria \$3.67 per capita and Western Australia \$3.16 per capita. The equipment types covered in this analysis included mobility devices, self-care, continence, oxygen, communication devices and home modifications, although there were slight variations between states. These figures appear extremely low compared to the European data however it is very difficult to determine the included and excluded devices with the calculations.

Belgium is a small market, like Australia and represents 1.5% of the European market for medical devices. Reimbursed expenditure for orthoses in ambulatory care equated to €58million, or approximately 0.3% of total public health expenditure (Simoens, et.al, 2008). The Belgium market consists of 71% custom-made orthosis provision compared to 26% pre-fabricated (Simoens, et.al, 2007), which from the limited data available may be similar to that of Australia (35% pre-fabricated) of which the majority (90%) are compression and pressure garments (CAEP, 2010).

From 2000 to 2005 the Belgium market has seen a 58% increase in expenditure for outpatient orthopaedic devices, in line with the US annual growth (Frost & Sullivan Market Insight [2006]: In Simoens, et.al, 2007). This growth is thought

to be due to the ageing population, increasingly active and subsequently demanding healthcare consumers, increasing quality of life, continual innovation and introduction of new technology, increasing incomes and extensive health insurance schemes that facilitate access (Simoens, et.al, 2008). The facilitation of access by health insurance companies does not exist in Australia. Currently Private Health Insurance companies provide a maximum rebate which is below the ceiling prices of state funding schemes, resulting in those with insurance applying to their state scheme to assist with off-setting the difference (Pereira, 2011)

The NHS Scotland (2005) Scottish Orthotic Services Review involved an analysis of the entire orthotic services delivered across 100 sites by 52 full-time equivalent Orthotists for the 2002-2003 financial year. With an annual spend on orthoses of £10million, a total of 127,000 devices were provided to a population of 5,057,400 (end of June quarter 2003). Of these devices, 31% were lower limb orthoses, totaling 39,370 (NHS Scotland, 2005). The provision of devices in Scotland during that time period can therefore be calculated as 1 lower limb orthosis per 128 population (1:128). The Review (2005) also reports a variation in expenditure between NHS Boards from £1.04 to £3.23 per head of population per annum. There is a very clear link between expenditure and activity levels, in that the Boards with the highest expenditure report the highest activity levels per 1000 population. The range of activity levels vary from 48 orthoses per 1000 population to 9 orthoses per 1000 population (NHS Scotland, 2005).

Key message:

- 10. Minimal international data exists relating solely to orthoses for expenditure and service provision comparison.*
- 11. Based on international statistics, the medical device market growth rate may be predicted at 10% per annum, and should be reflected in an annual review of funding.*

International funding systems for orthoses

The international experience is difficult to assess due to extreme variations in the involvement of health insurance companies. The analysis of the European market by Simeons and colleagues (2008) identifies that prices in Sweden are determined by a system of public procurements at a regional level; France sets maximum prices for orthoses; the Netherlands has negotiated prices between health insurance funds, manufacturers or distributors, whilst in Belgium the prices are based on a 1992 model in which the 'Walkiers co-efficient' is applied to the mean price for each category of orthotic brace. The French price fixing model, although similar to Australian ceiling prices, takes into consideration trends in charges, income and volume of activity of practitioners and the companies involved (Simoens, et.al., 2008). Comparison with prices in the UK is also difficult due to the orthoses being provided at National Health Service (NHS) contract prices. The NHS employs or contracts Orthotists to provide these services, and therefore the prices do not include the actual services supplied by Orthotists (Simeons, et.al., 2007).

National expenditure and service provision figures

There is limited state based data regarding orthosis provision through the Government funding programs. The AOPA Inc. and members are committed to supporting a national strategy of data collection, which will support service review and audit processes and provide a national understanding of need. Disability SA (2010) reports an increase in the issuing of equipment from 1,941 items in 2006-07 to 6,097 items in 2009-10. For 2010 this represents 1 piece of equipment per 270 population, however there is no data available specific to orthosis provision. In Western Australia, the Community Aids and Equipment Program reported for the 2009-2010 financial year the provision of 1,257 lower limb orthoses (CAEP, 2010). This equates to approximately 1 lower limb orthosis per 1,827 population (1:1,827).

As the orthotics profession is under-resourced in Australia, areas such as data collection are poorly developed. Currently we are unable to definitely state the per capita spend on orthoses in Australia or the activity levels per 1000 population within each state, other than extrapolated data in Western Australia. The presence of individual state-based systems and numerous funding models also hinders the collection of evidence to support the need within the Australian population. The international per head expenditure and orthosis provision figures may provide the only indication or benchmark for funding allocation in Australia.

Key message:

12. Currently, Australian states have a very low ratio of orthosis provision per capita compared to international data, however data availability is limited. The AOPA Inc. supports a national data collection strategy.

National funding systems for orthoses

Most states have funding and ceiling limits for orthoses, which is publicly available information, except for Western Australia. The AOPA Inc. questions the fairness of denying service providers the right to access information regarding the program they work within and denying consumers the right to information which directly impacts the type of equipment they are eligible to receive. There are numerous fragmented funding schemes for the provision of equipment which are listed in the AIHW (2003) report into aids and equipment (table 2.2, p.9-13). Although some of the schemes have changed names, they are no less complex or restrictive in terms of access and equity.

Table 1 summarises the ceiling limits of each state-based system, specifically in relation to the provision of three main types of lower limb orthoses. Western Australia has published the most detailed data, outlining that of the 1,257 lower limb orthoses provided through the Community Aids and Equipment Program (CAEP) program in the 2009-2010 financial year, 58% were Ankle Foot Orthoses (AFOs), 35% foot orthoses and 1.7% were custom Knee Ankle Foot Orthoses (KAFOs). These three orthosis categories represented 94.7% of the funded lower limb orthoses for that financial year (CAEP, 2010) and should be considered representative of the national separation according to orthosis types. Table 1 outlines the variations in state ceiling limits.

Table 1 - Ceiling limits according to orthosis types for each state funding system.

STATE	FUNDING SCHEME	DEVICE CEILING FIGURE		
		Foot orthosis	AFO	KAFO
Victoria	SWEP	\$200	\$1200	\$2200
South Australia	DisabilitySA	Case-by-case basis*	Case-by-case basis*	Case-by-case basis*
Western Australia	CAEP ¹	\$300	\$650	Unknown
Queensland	MASS	\$250 - \$450	\$1100 + \$140 additional available	\$1800 - \$3500
New South Wales	EnableNSW	Case-by-case basis with income bands (means tested)	Case-by-case basis with income bands (means tested)	Case-by-case basis with income bands (means tested)
Tasmania	No scheme	Case-by-case basis*	Case-by-case basis*	Case-by-case basis*
Northern Territory	TIMES	Unknown – ceilings do exist	Unknown – ceilings do exist	Unknown – ceilings do exist
AOPA recommended²		< \$400	< \$1500	> \$1500

* A case-by-case basis allows for all submissions for funding to be considered, however the entire scheme is based on a “rationing arrangement”.

The AOPA Inc. can report however that the current CAEP ceiling limits are the lowest in the country. Further to this we are aware that all KAFOs prescribed are above the ceiling limit category and therefore require special applications. A KAFO is an essential piece of equipment for many people, and special applications are a timely and inefficient practice. The ceiling prices for these items can be compared to The AOPA Inc. recommended pricing range, which is outlined in the Orthosis Schedule 2009 (The AOPA Inc., 2009) (refer Appendix Two: The AOPA Inc. Orthosis Schedule 2009). Although a 2009 model, and currently under review, it provides a price indication for orthoses assessed, fitted and reviewed by an Orthotist. Modern Orthotic Technologies sometimes fit within The AOPA Inc. recommended price ranges, however Advanced Orthotic Technologies would far exceed the range indicated (refer to Appendix Three – Modern and Advanced Orthotic Technology). The CAEP ceiling prices falls well-short of the recommended ranges, being only 75% of the recommended price for Foot Orthoses and 43% of the price for Ankle-Foot Orthoses, which together represent 93% of the lower limb orthoses provided in Western Australia. This is a terrible funding situation for consumers in this state, with the only reason for their disproportionate funding being geographic location.

Of all the state-based funding arrangements and ceiling prices, the South Australian and Tasmanian model for funding are the most accessible and up-to-date for consumers. It would appear that most applications for funding are considered on a ‘needs-basis’. These models however are based on yearly “rationing arrangements”, in which State Managers of the funds must ensure the allocated budget is rationed for the entire year. Therefore, the application for

¹ Ceiling prices based on anecdotal information due to the lack of a publicly available document

² The AOPA Inc. recommended pricing in the Orthosis Schedule 2009 is currently under review

funding for costly items outside of the 'norm' are likely to be reviewed in light of the current budget status rather than on a 'needs-basis'. It can be assumed that these types of orthoses are more likely to be approved if the budget is in a healthy state.

The Queensland Medical Aids Subsidy Scheme (MASS) has loosely based their pricing on The AOPA Inc. Orthosis Schedule 2009, however it would still be restrictive of Advanced Orthotic Technologies. Although there are many areas for system improvements in the South Australian and Tasmanian system, the removal of a ceiling price allows for the prescription of Modern and Advanced Orthotic Technology on a needs basis. This system may be the closest to the concept of 90/10 for ceiling limits and availability, which allows for 90% of cases to be smoothly processed with access to Modern Orthotic Technology according to cost boundaries. Review of the remaining 10% of cases due to the complexity of clinical information and justification required, may allow for prescriptions for Advanced Orthotic Technology to be supported. This concept of inclusion and exclusion will be addressed further in this submission.

Key messages:

- 13. Clients and service providers within the boundaries of the Fair Trade Act, have the right to access the information which affects the service they can provide and receive.*
- 14. Clients have the right to access Modern and Advanced Orthotic Technology in order to enhance their quality of life and participation. Funding on a per device basis should reflect the current costs of equipment and enable consumers to access the technology which meets their needs.*
- 15. Devices should be prescribed based on an assessment of need rather than according to a "Manual and Imprest List" with associated ceiling prices*
- 16. The AOPA Inc. encourages the use of The AOPA Inc Orthosis Schedule and the development of cost boundaries in consultation with the Association.*
- 17. Cost boundaries should follow a principle of 90/10 and allow for the smooth processing of funding for Modern Orthotic Technology (90% of cases).*

Inclusions and exclusions

Currently Advanced Orthotic Technologies and many Modern Orthotic Technologies do not receive funding support due to restrictive 'lists' and ceiling prices. These applications require significant paperwork and subsequent delays which does not adequately address the 'needs' of people with disabilities. The current Statewide Aids and Equipment Program (SWEP) in Victoria funds less than 13% of the devices available to assist people with disabilities, being 82 of the 650 categories of the ISO 9999 (Layton, et.al, 2010). Clearly, the other 87% of categories are not associated purely with the 'wants' of people with disabilities, and have a more purposeful role in assisting with independence and participation. The risk to consumers of inappropriately prescribed devices due to restrictive availability is highlighted in Appendix Four: tables of risk related to orthotic practice.

The AOPA Inc. does not support the development of a list of inclusions and exclusions. Orthotic devices for people with disabilities are more commonly custom-made and incorporate a number of manufacturer supplied components within a variety of designs. It is difficult to singularly determine inclusion and exclusion based on device names or the components included. Refer to the example below:

Same generic orthosis name: both design s have the same title in their simple form but differ in design and function

Articulated Ankle-Foot Orthosis,

with polycentric ankle joints costed at \$750

double action ankle joints costed at \$2000

Same device components: both devices incorporate components from the same family, but differ in design

A double action ankle joint

within a polypropylene design costed at \$1000

within a carbon fibre design for \$2000.

The AOPA Inc. acknowledges that boundaries pertaining to cost are inevitable, however these boundaries must be inclusive rather than exclusive. The AOPA Inc. recommends a 90/10 approach, in which 90% of prescriptions and quotations are supported through a seamless process and 10% require further analysis and review. The 90% cost boundaries for each orthosis category should be established based on the cost of Modern Orthotic Technology (refer Appendix Three: Modern and Advanced Orthotic Technology). A structured review and modification process is required to ensure the cost boundaries are in line with changes in costs, prices, technological advancements and the Australian Consumer Price Index (CPI). Many Modern Orthotic Technologies, although commercially available for 10 years, are not available through current state funding, as the ceiling prices have not been updated in line with technological advancements and improved manufacturing techniques. United States medical device companies indicate that 80% of profits are from products introduced in the last 5 years (Frost & Sullivan [2006]: In Simoens, et.al, 2007). This suggests that the US funding system supports medical device advancements.

Key messages:

- 18. A list of orthoses and components should not be developed and used solely for funding approval purposes. It may be created for the accurate development of cost boundaries.*
- 19. Cost boundaries should be reviewed and modified in line with costs, prices, technological advancements and the Australian CPI on an annual basis.*

The 90/10 principle is an alternative to the development of an inclusion and exclusion list. The cost of Modern Orthotic Technology is an appropriate guideline for development of the 90% boundary. A model for addressing orthosis prescriptions that fall outside of the cost boundaries is required and The AOPA Inc. suggests the following two avenues for inclusion in the NDIS:

1. Consumers apply for access to funds in excess of the cost boundary

2. If unsuccessful in obtaining excess funds, consumers can apply for the full amount of available funding (maximum of the cost boundary) and co-contribute towards the prescribed device

Permitting a claim of unique circumstances will allow the consumer access to the most suitable orthosis where a significantly greater benefit than other alternatives is identified. The World Health Organization's International Classification of Functioning, Disability and Health (ICF) framework³ is an appropriate guide for assessing an orthoses' impact on life areas and therefore approving funding in excess of the cost boundary. Determination should occur via a panel of experts consisting of a Medical Specialist, an impartial Orthotist and a consumer representative. It is not appropriate for this decision to be made by an Assessor, being an Allied Health Professional, working outside their field of expertise. This flexibility to apply for excess funding is essential to ensure the potential for significant life enabling benefits from Advanced Orthotic Technology are not denied based on ceiling limits.

In the case where the application for access to excess funds is denied, consumers are provided with an avenue to apply for the maximum funding available within the cost boundary and make a co-contribution to purchasing the orthosis. Assuming the cost boundaries are up to date with the costs of Modern Orthotic Technology, then the client 'co-contribution' is minimized for those wishing to access Advanced Orthotic Technology.

Inevitably the proposed NDIS will need to determine the type of devices to be "included" and "excluded" in order to establish the 90% cost boundary. At this stage, it is extremely difficult for The AOPA Inc. to definitively recommend the orthoses, designs and components for inclusion within the cost boundaries, other than to suggest the NDIS differentiate based on Modern and Advanced Technology. We reiterate that the decision to fund equipment must be based on need and the potential enabling outcomes of the orthosis. The AOPA Inc. welcomes future consultation regarding these specifics, and in the meantime, points the Commissioners to Appendix Three which outlines examples of Modern and Advanced Orthotic Technologies and their estimated price ranges. At the very minimum, all Modern Orthotic Technologies should be within the cost boundaries.

Key messages:

- 20. The principle of 90/10 should allow for the prescription of Advanced Orthotic Technology.*
- 21. Where a prescribed device falls outside the cost boundary, the client should be able to apply for excess funds where the prescribing Orthotist and other allied health team members can clinically justify the prescription through a thorough needs assessment and rationalising according to the ICF framework.*
- 22. Where a prescribed device which falls outside the cost boundary and fails in its application for excess funds, the client should be entitled to use the maximum of the cost boundary and make a co-contribution.*

³ The AOPA Inc. encourages a thorough review of the approach undertaken by Layton and colleagues (2010) in their review of the Victorian Aids and Equipment Program.

Reviews, maintenance and repairs

Reviews, maintenance and repairs form an important part of the provision of an orthosis. An orthosis is not provided in a single occasion of service, but requires regular review and monitoring throughout its lifecycle. The timely and structured implementation of reviews ensures that minor fit, material integrity or function issues are addressed before the consumer is placed at risk or the orthosis becomes irreparable. Definitions of orthotic reviews, repairs, maintenance are provided in Appendix One. Disability SA (2010) states that “more people have had their equipment needs met by containing costs through significant increases in the equipment refurbishment (recycling) rate of 77%” (p.8). Whilst The AOPA Inc. supports the appropriate and timely repair and maintenance of equipment, it does not view this as an avenue of cost cutting. Appendix Three provides further definition of the term “refurbishment”.

The NHS Scotland (2005) review of orthotic services raised concerns with the cessation of routine or ongoing patient reviews. This was due to major issues with staffing rather than a cost cutting measure. As highlighted in further sections of this submission, recognition of the clinical role of the Orthotist and the provision of required funding will ensure reviews occurring, which improves outcomes, patient satisfaction and supports continuity of care. Recent litigation in New South Wales (as outlined below) highlights the inherent risk of an unresponsive repairs and maintenance program and inappropriate repair of equipment requiring replacement. Although the Court reported the claim of negligence was highlighted by “failing to replace the joint when the Orthotist knew the joint was badly worn”, the replacement of a joint within an orthosis is not a simple and inexpensive process and must also meet The Therapeutic Goods Administration legislation. Further risks associated with inappropriate repairs and maintenance is highlighted in Appendix Four: Tables of risk related to orthotic practice.

ORTHOTIC PROVIDER v JONES (February 2005)

In February 2000 a patient who had worn bilateral Knee-Ankle-Foot Orthoses (KAFOs) since contracting PolioMyelitis, fell and was injured when his KAFO gave way at the knee joint. He claimed damages from the Orthotist, stating that he was “advised to wear his old callipers ... whilst the new callipers were with [the Orthotist] for repair”; that the old KAFOs were “in a poor state of repair, the joints being worn, and were fastened at the knee joint by an elastic band”.

The claim of negligence was particularised by:

- Allowing the patient to wear KAFOs which the Orthotist knew were badly worn and in a poor state of repair.
- Allowing the patient to wear KAFOs in which the elastic had been replaced by the patient with inferior elastic.
- Failing to replace the joint when the Orthotist knew the joint was badly worn.
- Failure to warn the patient of the risk of injury when wearing the KAFO in such a state of repair.
- Failure to provide the patient with a replacement KAFO when the Orthotist knew of the risk of injury to the patient wearing a KAFO with an inferior and worn elastic band.

The verdict was in favour of the patient for \$50,000. This verdict was reversed on appeal due to the Orthotist submitting evidence of paperwork requesting funding approval for urgent repairs and replacement of the KAFO. Without the approval, the Orthotist was unable to proceed with repairs or replacement.

Key messages:

23. Reviews, maintenance and repairs should be adequately funded such that they can occur in a timely manner.

24. Equipment refurbishment (recycling) must meet patient safety standards and be the most appropriate solution for the client within the boundaries of The TGA legislation for Grade 1 Medical Devices.

The unmet need: “soft” vs “hard” technology

Currently orthotic service provision is funded exclusively through equipment provision and repairs. ‘Hard technology’ refers to the actual orthosis that is provided to the client. In contrast ‘soft technology’ is the associated clinical service, such as, reviews, maintenance and support services which is currently unfunded in each state. Although reasonable to expect the assessment, fitting and initial review to be included in the orthosis cost, this one-off cost does not include the submission of extensive funding paperwork, re-assessment (on funding approval), gait training, ongoing clinical support, and general maintenance and repairs outside of warranty (possibly over a 5 year period). The current structure does not acknowledge the clinical service provided by Orthotists and leaves the client with an ongoing out-of-pocket expense. The TV analogy used within the Independent Rehabilitation Suppliers Association (IRSA) (2010) submission (submission number 0477) clearly describes the frustration from an equipment suppliers’ point of view. Whilst this outlines the level of service and involvement from an Assistive Technology supplier, such as those providing wheelchairs or walkers, it doesn’t cover the lack of recognition of the clinical service provided by health practitioners also providing equipment. An example of an entire service encounter for a person with a disability requiring an orthosis is outlined below:

Mrs. Jones has Polio Myelitis and has been using the same Knee-Ankle Foot Orthosis for 15 years. A recent failure in the metal structure has forced her to contact a Medical Specialist regarding a replacement orthosis. The Medical Specialist completes an assessment and then requests an allied health professional develop a prescription for Mrs. Jones, which the Specialist signs-off. An Orthotist is requested to complete this assessment and the prescription (although sometimes this is completed by another allied health professional, requiring revision by an Orthotist upon funding approval). At this appointment, the Orthotist notes that the metal work is extremely worn and cannot be repaired as a long-term solution. As the funding delay for new equipment is approximately 3 months the Orthotist is however forced to weld the metal structure to enable Mrs. Jones to continue to ambulate. This does however contravene the TGA but ensures that Mrs. Jones is not at risk of a fall. This appointment and repair work takes 1.5 hours to complete and is not covered by state based funding. The Orthotist reschedules another appointment for a full assessment. The full assessment takes 1 hour to complete followed by 0.5 hours of paperwork for funding application and clinical justification to the relevant funding body, which is signed off by the Medical Specialist. The funding body on receipt of the application arranges an Assessor (an Occupational Therapist) to visit Mrs. Jones home to determine whether she really needs the orthosis to mobilise and to confirm that it really cannot be repaired. Over the next 6 months Mrs. Jones is seen on 2 more occasions of 1 hour each to maintain her orthosis. After

approximately 6 months and numerous urgent phone calls by both the Orthotist and Mrs. Jones the funding is approved. At this point, the Orthotist organises an assessment and casting appointment, in which the componentry is ordered, followed by a number of appointments for fitting and review (which are covered by the funding). Following successful fitting, the Orthotist continues to provide 6 monthly maintenance and review appointments of 1 hour until Mrs. Jones requires a replacement orthosis in approximately 5 years time. The total unfunded clinical service time provided to Mrs. Jones over a 5 year period (excluding major repair work post fitting) would be 15 hours.

Unlike other allied health professionals, Orthotists currently do not receive Medicare rebates or funding for clinical encounters. Orthotist/Prosthetists are one of the few allied health professions excluded from claiming a Medicare rebate under the Chronic Disease Management (CDM) Program. The goal of this program is to enable clients with a chronic illness to access multidisciplinary health services coordinated by their General Practitioner. As the services of Orthotists are not funded, clients are financially responsible for their consultations, reviews and repair appointments. The clinical service provided by Orthotists can be compared to other allied health services, such as a podiatry. In the case of a Podiatrist providing a callous debridement service, it is considered essential for the client to attend reviews and ongoing foot care appointments over an extended period of time, which is financially supported. Ultimately the lack of funding for complimentary orthotic clinical services influences the level of service and support provided to individuals with new equipment. This impacts on the success of equipment provision in improving quality of life and achieving mobility goals. Integration of the services of Orthotists into the CDM program will support the equipment and services funded through the NDIS and ensure high-risk consumers are afforded every opportunity for management and review by the appropriate health professional.

The 2007 review of the Belgium market for pre-fabricated orthoses concluded that the Belgium reimbursement model should allow for two reimbursements – one for the orthosis, and one for the services provided by Orthotists, such as “judicious product choice, patient advice and follow-up” (Simeons, et.al, 2008, p.201). Whilst this reimbursement model has been recommended to improve price transparency and promote impartiality of product selection by Orthotists, the current Australian market would benefit from a modified version. South Australia is the only state to publish comprehensive “unmet need” data regarding therapy services, reporting the total unmet need as 712 which represents 18% of the total unmet need in all areas of disability services (Disability SA, 2010). Considering the unfunded and under-utilised clinical services of Orthotists the figure provided for “unmet need” is unrepresentative of the real need. The appropriate funding and therefore supply of supportive orthotic clinical services will promote orthosis success, patient satisfaction and minimise consumer risk. The risk to consumers of poor patient management and review protocols is clearly highlighted in Appendix Four: Tables of risk related to orthotic practice.

Key messages

25. Medicare rebates should be available for the clinical services offered by Orthotists, to ensure the provision of orthoses to people with chronic disabling conditions is supported by funded clinical encounters.

26. For the provision of orthoses, funding should be provided for the associated clinical and therapy services, being “soft” orthotic technologies, and available as separate reimbursement items to the “hard” technology.

RECOMMENDATIONS:

the proposed NDIS orthotic service delivery model

There is a lack of level-1 evidence internationally in prosthetics and orthotics research. The British Association of Prosthetists and Orthotists (BAPO) and the NHS Scotland have produced a number of Best Practice documents and Clinical Service Guidelines, which The AOPA Inc. support. Many of these documents refer to key areas of service delivery such as; prescription development, orthosis review protocols and issues relating to qualifications and competency.

Orthosis prescription

Orthosis prescription and design are inextricably linked and should be completed by the same health professional. An Orthotist is the most highly trained health professional to complete this task. Throughout Australia the States all apply varying prescribing rights for lower limb orthoses and footwear, which are not based on internationally accepted standards or best practice. The BAPO (2003) Guidelines on Best Practice and the Scottish Orthotic Services Review (NHS Scotland, 2005) clearly indicate best practice regarding orthosis prescription and the clinical governance concerns relating to prescriptions by non-Orthotists. The risk to clients of inappropriately prescribed devices is severe and exacerbated by professionals without the appropriate qualifications and competency. These risks are highlighted in Appendix Four.

The EnableNSW draft prescription guidelines clearly indicate an Orthotist is an eligible prescriber of lower limb orthoses. In practice, EnableNSW requires a specialist or other allied health professional to prescribe as the Orthotist is not permitted to prescribe and then fit/supply the orthosis. Informal communication with a member of The AOPA Inc. outlines that “*what happens in my practice though is the specialist and allied health clinician will ask me for an opinion and then I provide them with a prescription for orthotic management. They just document this on the appropriate paperwork*” (Anonymous, 2011). EnableNSW (2011) in its recently released Policy Directive relating to Assistive Technology states a key objective of the service is “to provide timely, courteous and efficient service to consumers”, however this ‘pre-prescription’ approach is not a timely or efficient method of service delivery.

Orthotists have specialist knowledge and biomechanical understanding regarding footwear. The shoe is an integral component of a lower-limb orthosis and directly impacts on the success of the provided device. The inclusion of full prescribing rights for orthoses and footwear for Orthotists will ensure the entire footwear-orthosis combination is congruent and successful. Other allied health professionals are not specialists regarding orthoses pertaining to the entire lower limb and receive no or minimal formal tertiary training in this area. Therefore the most appropriate

health professional to prescribe footwear in the case of orthosis provision is an Orthotist who understands the entire treatment process and plan. A member of The AOPA Inc. clearly states their thoughts regarding the unfounded and poorly evidenced prescription eligibility criteria in NSW:

"I detest the lower limb orthoses guidelines as they allow Podiatrists, Pedorthists, etc the ability to prescribe lower limb custom orthoses including up to KAFO level. Also Orthotists are not allowed to prescribe extra-depth or custom footwear but the other disciplines are" (Anonymous, 2011).

The AOPA Inc. recommends the removal of pre-prescription and pre-approval processes as part of orthotic prescription and supply. The provision of services to consumers should be timely and based on needs, with pre-approval processes often resulting in substandard care due to system failures and inefficiencies. Therefore, prescription processes should be supportive of optimal service delivery, rather than an arduous administration and finance process. The case example below highlights the impact of a prescription and funding approval process which sits external to consumer treatment, which is inefficient and misses the opportunity to provide timely care.

Mr. Graham is a 54 year old man with cerebral palsy. He has no function in his right hand due to a severe spastic flexion position at the wrist. Many attempts have been made to 'splint' his wrist into a more functional position, which have been unsuccessful due to the strength of the spasticity. A multi-disciplinary consultation with a Rehabilitation Specialist, Occupational Therapist and Orthotist results in a recommendation for botulinum toxin (botox) to be injected into Mr. Graham's right wrist flexor muscles to paralyse them. This would provide the Occupational Therapist and Orthotist an opportunity to serially cast his hand and wrist to improve the position, and after this stretching process to provide a long-term orthosis to support and maintain the improved wrist position. The team submits an application for funding for the upper limb orthosis and Mr. Graham is scheduled for his Botox injections in 2 months. The botox injection proceeds at the scheduled 2 month appointment and is followed by 6 weeks of serial casting by the Occupational Therapist. Significant improvements in Mr. Grahams wrist position are achieved however the funding for the upper limb orthosis is not received within the 6 month period of the botox being active. Therefore the spasticity returns and without an upper limb orthosis the gains from the first round of botox and serial casting are lost.

Key messages

- 27. Prescription eligibility should be related to the core training and tasks of the profession and based on international standards and evidence-based practice.*
- 28. The model of prescription and funding should support evidence based service delivery, rather than the service delivery being designed according to the prescription and funding processes*

Orthosis review

Review is an essential component of any clinical practice, which allows for the development of an evidence base within the clinical environment. The NHS Scotland (2005) reports that an effective clinical review process also provides the client with enhanced continuity of care. This review identified that the majority of respondents routinely reviewed

their clients after having assessed and supplied an orthosis however the review patterns and regimes differed vastly between services.

Appendix Five includes an extract of the Scottish Guidelines for Best Practice regarding orthosis review. This states that “load-bearing devices which incorporate mechanical joint mechanisms eg, Knee, Ankle, Foot Orthoses and Hip, Knee, Ankle, Foot Orthoses, after initial review of 1-4 weeks, should, in the interest of patient safety, be checked for structural integrity on a 6 monthly basis”, and ‘at risk’ clients reviewed every 4-6 months (Scottish Executive, Health Department, 2001). The BAPO (2003) Best Practice Guidelines for orthosis assessment and review indicate that timeframes for review appointments are dependent of whether the presenting pathologies are simple or complex. In the case of simple pathologies a 20 minute review is recommended, which would be bi-annually for a load bearing device, and for complex pathologies, 40 minute review appointments should be scheduled between 2 to 3 times yearly depending on risk.

The AOPA Inc. does not support the adoption of an ‘acquittal process’ within the orthotic service delivery model. Many state based models are functioning well without this arduous and administratively focussed process. There is however a need to implement appropriate systems to ensure quality services and outcomes for consumers. The AOPA Inc. supports the introduction of quality measures, such as validated outcome measurement tools. There are limited validated tools specific to orthotics. Examples of successful tools include the Gross Motor Functional Classification System (Palisano, et.al., 2000) which is widely used for classification and post-surgery review in paediatric care and the Orthotic Prosthetic Users Survey which assess functional status, quality of life and satisfaction with devices and services (Heinemann et.al., 2003). A thorough review of potential quality measures is required, but in the presence of no clinically appropriate measure, at the least practitioners should be adopting patient satisfaction surveys and/or before and after film comparisons.

Key messages

29. Orthotic reviews should be incorporated into the proposed NDIS orthotic service delivery model

30. The introduction of validated outcome measures within the review process will ensure the service meets consumer needs, enable data collection and support self-regulation processes

Qualifications and competency to provide services

In the new disability service and funding model it is important that the proposed NDIS adopts best practice guidelines regarding qualifications and competency of health professionals to provide funded services. For those professions currently included in the National Registration and Accreditation Scheme (NRAS) this would simply require proof of registration, however for health professions currently outside the NRAS, a model to guarantee client safety is essential. The AOPA Inc. recommends the NDIS refer to self-regulating professional bodies and Associations regarding qualifications and competency standards essential for practice in Australia.

The AOPA Inc. queries the benefit of extended scope of practice in which prescriptions are developed and 'signed-off' by Medical Specialists and other Allied Health Professionals. These professionals often request quotes from Orthotists for unsighted patients. This results in unnecessary doubling up of assessment and paperwork as the Orthotist has to re-submit for the correct funding approval after assessment. Although 'checks and balances' are an essential component of a successful model for prescription, this 'pre-prescription' method is incredibly inefficient. The completion of assessments and prescription development by appropriately qualified and trained health professionals decreases process duplication, inefficiencies in the system and for the consumer and ensures optimal consumer service provision.

Currently the available state funding schemes have significant variations in the qualification criteria for fitting and supplying orthoses. State based schemes do not apply as rigorous criteria regarding qualifications and competency as other schemes, such as the Department of Veterans Affairs and Accident Schemes. In the absence of professional registration, these schemes demand membership of The AOPA Inc. and therefore guarantee their clients the highest level of safety available. Further to prescription, the provision of orthoses appropriately qualified and competent Orthotists ensures optimal fit and function of the orthosis for the consumer and meets international best practice standards.

The CAEP in Western Australia currently funds Ankle-Foot Orthoses provided by 'Bootmakers', foot orthoses by Pedorthists and a variety of orthoses provided by practitioners who are ineligible for membership to The AOPA Inc. This is not in line with The AOPA Inc's stance on appropriate qualifications, which is followed by DVA and insurance companies. Officially the MASS program only allows qualified Orthotists with membership to The AOPA Inc. to provide orthotic services to MASS clients however this policy is not very well policed. It appears that MASS only ensures each facility has one staff member holding membership to The AOPA Inc, and subsequently permits all other non-members within the facility to provide services.

Internationally the stance on qualifications and competency appears to be more clearly defined. The NHS Scotland (2005) states that "staff involved in the provision of orthoses should be able to demonstrate competency in their field of practice" (p.6). Further to this, The Scottish Orthotic Services Review (NHS Scotland, 2005) clearly indicated clinical governance concerns relating to prescription development and orthosis supply by non-Orthotists. Other European countries have defined qualification criteria, such as, the "delivery of orthoses by a recognised and registered Orthotist is a condition for reimbursement . . . in Belgium" (Simoens, et.al, 2007, p.99).

Key messages

- 31. In order to obtain NDIS reimbursement, orthotic prescriptions should be developed in consultation with a qualified Orthotist, as defined through membership to The AOPA Inc.*
- 32. In order to obtain NDIS reimbursement, orthotic services, including the assessment, fitting and review of orthoses should be provided by a qualified Orthotist, as defined through membership to The AOPA Inc.*

RECOMMENDATIONS:

An 'Orthosis Package' Model

The AOPA Inc. recommends the development of orthosis cost packages for the benefit of clients, allowing access to their preferred service provider. At this stage it is difficult to provide precise cost recommendations and life maintenance costs, as requested by the Commissioner at the Tasmanian Hearing. The AOPA Inc. has however attempted to provide a model for developing orthosis packages, which after thorough cost analyses may be able to be applied to the major orthosis device categories. An example for Ankle-Foot Orthoses is provided below:

Example Calculation of Cost Package: Ankle-Foot Orthosis

Components:

- *"Hard Technology" - Cost boundary for Modern Orthotic Technology (Appendix Three)*
- *"Soft technology" – Estimated expenses based on orthosis life-span, review and maintenance regularity and cost of replacement of major components and material (Appendix Six and Seven)*
- *Major repairs: materials and components*

Calculation for Ankle-Foot Orthosis: Complex Pathology and High Risk Client

- *Ankle-Foot Orthosis Cost Boundary: Estimated between \$1,500 and \$3,000*
- *Reviews and maintenance: 3 x 40 minute reviews annually over a 3 year life-span = 6 hours*
- *Repairs: Joints, straps and major component replacements (cost dependent on component used)*

Provision for unforeseen expenses such as component and material replacements during the repair and maintenance process, complete orthosis replacements due to irreparable damage and replacements due to shortened lifespans or changing client needs, within the NDIS budget is essential. This will allow for timely repairs and maintenance which will ensure client needs are met within a timely manner and function is continually maintained.

Key messages

33. *Orthosis funding packages should include the following costs; "hard" and "soft" technology over the life-span of the orthosis (to be determined) at an agreed hourly rate (to be determined), and component/materials expenses.*
34. *The NDIS budget for orthoses should have provision for unforeseen expenses relating to unbudgeted component and material repairs, and unforeseen replacements.*

CONCLUSION

The AOPA Inc. would like to thank the commissioners for the opportunity to continue contributing to the planning process of the proposed NDIS. It is universally agreed that the current disability system across Australia is in need of overhaul and redesign. The current funding arrangements do not meet current needs, and given the anticipated increase in the ageing population and demand for services, we are presented with an opportunity to replace the current defective system and build a modern and much needed best practice based program.

The quality of life of the population with disabilities in Australia has been dramatically affected by the inequitable state based system. There exists great disparity in services available dependent upon cause of disability, location and circumstance. The AOPA Inc. aims to continue to work collaboratively with the commission to design and implement a system which meets the needs of the Australian community which accesses orthotic services.

APPENDIX ONE: Orthotic terminology and designs

Terminology

Orthosis Classification.

The globally recognised system of classifying orthoses by the body part or anatomical joint(s) that they influence is used throughout this submission. Common abbreviations, which are used to simplify the nomenclature, are used throughout this submission. *Example:* A Lower Limb Orthosis influencing the Ankle and Foot region is classified as an Ankle-Foot Orthosis (AFO) (International Organisation for Standards, 1989).

Orthosis (pl. Orthoses).

An externally applied device used to modify the structural or functional characteristics of the neuro-musculoskeletal systems. Orthoses may be Prefabricated, Customised or Custom Made (International Organisation for Standards, 1989).

An orthosis is the true term for a brace or appliance that is designed and fitted external to the body in order to achieve one or more of the following goals:

- Control or alter biomechanical alignment
- Protect and support a healing injury
- Assist rehabilitation
- Reduce pain
- Increase mobility
- Increase independence.

Orthotist (pron: Ortho-tist).

An allied health professional who is clinically responsible for the assessment, prescription, design, manufacture and fitting of all types of orthoses to patients (International Organisation for Standards, 1989).

Pre-fabricated orthosis.

An off-the-shelf orthosis that is supplied in a set of pre-fabricated sizes and sides, such as Left Medium. Usually designed for short-term use only. Minor adjustments are usually made to ensure appropriate fit, comfort, function and safety.

Customised orthosis.

An off-the-shelf orthosis that has been modified (or customised) extensively to meet the specific needs of the client. Usually a more long-term design than a simple pre-fabricated orthosis

Custom-made orthosis.

A unique orthosis which is prescribed, designed, manufactured and fitted for a specific client. This service is only able to be provided by Orthotists.

Orthotic assessment.

The review of the overall condition of the patient by those involved in the treatment, and the recommendation by the orthotist . . . of the components and clinical fitting procedures best suited to the circumstances of that patient (International Organisation for Standards, 1989).

Modern Orthotic Technology.

Orthotic designs and components which have been introduced in the last 10 years and are now considered best practice prescriptions in many countries (Refer Appendix Three).

Advanced Orthotic Technology.

Orthotic designs and components which have been introduced in the last 3 years and are yet to become common practice (Refer Appendix Three).

“Hard” orthotic technology.

The actual equipment or orthosis which is fitted and supplied to the client.

“Soft” orthotic technology.

The associated orthotic clinical service supporting the provision of hard technology, such as assessment, prescription, reviews and maintenance services.



Orthosis designs

Name	Image	Definition
Foot Orthosis	(Sourced from: www.integrityfootorthotics.com.au)	<p>“An orthosis that encompasses the whole or part of the foot”</p> <p>(International Organisation for Standards, 1989).</p>
Ankle-Foot Orthosis	(Sourced from: www.apos.net)	<p>“An orthosis which encompasses the ankle joint and the whole or part of the foot”</p> <p>(International Organisation for Standards, 1989).</p>
Knee-Ankle-Foot Orthosis	(Sourced from: www.missionmd.net)	<p>“An orthosis that encompasses the knee and ankle joint and the whole foot or part of the foot”.</p> <p>(International Organisation for Standards, 1989).</p>
Spinal Orthosis	(Sourced from: NHS Scotland, 2005)	<p>For example; a Thoraco-Lumbar-Sacral Orthosis (TLSO)</p> <p>“An orthosis that encompasses the whole or a part of the thoracic, lumbar, and sacro-iliac regions of the trunk”.</p> <p>(International Organisation for Standards, 1989).</p>
Upper Limb Orthosis	(Sourced from: www.novitatech.com.au)	<p>For example a Wrist-Hand-Finger Orthosis (WHFO)</p> <p>“An orthosis that encompasses the wrist</p>

		joint, the hand, and one or more fingers". (International Organisation for Standards, 1989).
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APPENDIX TWO: The AOPA Inc. Orthosis Schedule (2009)⁴

Australian Orthotic Prosthetic Association		Orthosis Schedule		June
CLASSIFICATION	ORTHOSIS CODE	PRESCRIPTION CATEGORY 1=Prefab 2=Customised 3=Custom Made	PRICE CATEGORY A= <\$400 B= <\$1500 C= >\$1500	DESCRIPTIVE EXAMPLE
<u>CONSULTATIONS</u>				
Initial Consultation	I-CON-A	N/A	A	Client Ax (Gait analysis, motor/sensory). Orthosis prescription. Orthosis cast/measure
Subsequent Consultation	S-CON-A	N/A	A	Orthosis fit, review and/or adjustment
Comprehensive Consultation	C-CON-A	N/A	A	Comprehensive clinical Ax and prescription options. Orthosis cast/measure
External Consultation	E-CON-A	N/A	A	Initial, subsequent or extended consultation external to registered practice address (hospital/home)
<u>LOWER LIMB ORTHOSES</u>				
Foot Orthosis (FO)	FO-1-A	Prefab	A	Basic Insole, Gel Heel Cup
	FO-2-A	Customised	A	Modular Orthosis, Carbon Fibre Footplate
	FO-3-A	Custom Made	A	Custom made UCBL, Custom made Foot Orthosis
Ankle Foot Orthosis (AFO)	AFO-1-A	Prefab	A	Plastic Leafspring AFO
	AFO-2-A / AFO-2-B	Customised	A / B	Composite /Carbon Fibre AFO, Walking Boot
	AFO-3-B	Custom Made	B	Custom made Fixed or Jointed AFO/BK Caliper (plastic, composite or metal)
Knee Ankle Foot Orthosis (KAFO)	KAFO-2-B / KAFO-2-C	Customised	B / C	Femoral Fracture Orthosis, Thermoplastic or Composite KAFO
	KAFO-3-C	Custom Made	C	Custom made Jointed KAFO, Stance Control, Metal Caliper
Knee Orthosis (KO)	KO-1-A	Prefab	A	Soft sleeve/wrap (non-jointed)
	KO-2S-A	Customised-Soft	A	Soft Sleeve/wrap (jointed), knee immobiliser/wrap (with stays)
	KO-2R-B	Customised-Rigid	B	Plastic, composite or metal frame (jointed), Post Op ROM Knee
	KO-3-C	Custom Made	C	Custom made Plastic, composite or metal

⁴ Currently under review

Hip Knee Ankle Foot Orthosis (HKAFO)	HKAFO-2-B	Customised	B	
	HKAFO-3-C	Custom Made	C	ARGO, Twister Orthosis, Standing Frames
Hip / Pelvis Orthosis (HPO)	HPO-1-A	Prefab	A	
	HPO-2-B / HPO-2-C	Customised	B / C	Pavlik Harness, Van Rosen, Hip Abduction Orthosis
	HPO-3-C	Custom Made	C	Custom-made Hip Spica, Custom-made Hip Abduction Orthosis
Medical Grade Footwear (MGF)	MGF-1-A	Prefab	A	Postoperative footwear, unmodified Depth Width Footwear
	MGF-2-B	Customised	B	Extra Depth / Width, Splitsize, Club Foot Boots & Bar
	MGF-3-B	Custom Made	B	Custom made footwear from cast scan or tracing measurements
Footwear- Modification / Addition	FWM-A	N/A	A	Rocker sole, shoe raise, flare/wedge, T-strap, ferrule/plate

UPPER LIMB ORTHOSES

Shoulder Orthosis (SHO)	SHO-1-A	Prefab	A	Sling, Shoulder Immobiliser, Abduction Pillow
	SHO-2-B	Customised	B	Abduction Orthosis, ER Orthosis, Gunslinger Orthosis
	SHO-3-B / SHO-3-C	Custom Made	B / C	Custom made Abduction Orthosis
Elbow Orthosis (EO)	EO-1-A	Prefab	A	Soft sleeve/wrap (non-jointed) Tennis Elbow Orthosis
	EO-2-A	Customised	A	Post-op ROM Elbow
	EO-3-B	Custom Made	B	Custom made plastic jointed elbow, custom-made contracture control Orthosis
Wrist / Hand / Finger Orthosis (WHO)	WHO-1-A	Prefab	A	Soft thumb spica, or soft WHO
	WHO-2-A	Customised	A	Cock-up WHO, Palmar Control, Thumb Spica
	WHO-3-A / WHO-3-B	Custom Made	A / B	Custom-made resting WHO, Custom made contracture control WHO

SPINAL ORTHOSES

Sacral Orthosis (SO)	SO-1-A	Prefab	A	SI Belt, Trochanter Belt
	SO-3-A	Custom Made	A	Custom made from measure
Lumbo Sacral Orthosis (LSO)	LSO-1-A	Prefab	A	Sacro Cinch, Abdominal Binder, Hernia Belt (no stays)
	LSO-2-A / LSO-2-B	Customised	A / B	Corsets (with stays), Boston Brace

	LSO-3-B	Custom Made	B	Corset or rigid LSO made to cast
Thoraco Lumbo Sacral Orthosis (TLSO)	TLSO-1-A	Prefab	A	TLSO Corset
	TLSO-2-B	Customised	B	Anterior Hyperextension Orthosis, CASH
	TLSO-3-B	Custom Made	B	High Knight-Taylor brace (Rigid)
Cervical Thoraco Lumbo Sacral Orthosis (CTLSO)	CTLSO-2-B / CTLSO-2-C	Customised	B / C	Halo, Minerva, SOMI, Cervical Orthosis with Thoracic extension
	CTLSO-3-C	Custom Made	C	Milwaukee, Custom-made Minerva
Cervical Orthosis (CO)	CO-1-A	Prefab	A	Soft Collar
	CO-2-A	Customised	A	Hard Cervical Collars, Philadelphia
	CO-3-A	Custom Made	B	Custom made Collars
<u>MISCELLANEOUS ORTHOSES</u>				
Cranial Orthosis (CRO)	CRO-1-A	Prefab	A	Soft Protective Helmet
	CRO-2-B	Customised	B	Customised Helmet/face protector
	CRO-3-B	Custom Made	B	Custom made Cranial Remoulding Helmet, Custom made Proective Helmet
Compression Garments (CG)	CG-1-A	Prefab	A	Burns, Oedema, Lymphodema and D.V.T. garments
	CG-3-A	Custom Made	A	Custom made garments as above
<u>ADJUSTMENT/ REPAIR</u>				
Minor	ADJR-1-A	N/A	A	Replace velcro strap
Medium	ADJR-2-A	N/A	A	Replace Sole
Major	ADJR-3-B	N/A	B	Recondition KAFO/Caliper

APPENDIX THREE:

Modern *and* Advanced Orthotic Technology

Modern Orthotic Technology

There have been numerous advances in orthotic technology over the last two decades. Through-out this submission, Modern Orthotic Technology refers to orthosis designs and components which have been introduced in the last 10 years and are now considered best practice prescriptions in many countries. In Australia, the introduction of many of these components, designs and manufacturing techniques has been limited due to funding ceiling limits, which generally restrict Orthotists to the use of technology and techniques that were introduced many decades ago.

An example of Modern Orthotic Technology is the use of light-weight carbon fibre and laminated designs. Funding however often restricts the use of this technique with most Orthotists continuing to prescribe polypropylene (plastic) designs which were introduced in the 1970s. Both techniques have a place in the Australian market, however clients should be offered the option which is optimal for their clinical presentation. Examples of Modern Orthotic Technology prescriptions are:

Ankle-Foot Orthosis:

Custom-made laminated orthosis using metal double-action ankle joints, allowing adjustable range of motion. Including check fits and modern light-weight technology. Price range \$1500 - \$3000

Knee-Ankle-Foot Orthosis:

Custom-made laminated orthosis using a modern stance control knee joint and double action ankle joints, allowing a free knee during swing phase and stance stability, and adjustable range of motion at the ankle. Including check fits and modern light-weight technology. Price range \$3,500 - \$6,500.

Advanced Orthotic Technology:

The last 3 years has seen a significant advancement in componetry options within the orthotic market. Many of these advanced components incorporate neurotronic technology and sophisticated biomechanical alignment principles to provide increasing functional options for clients. Due to their recent release and often limited use, these components are often significantly more expensive than Modern Orthotic Technology.

An example of Advanced Orthotic Technology is the use of neurotronics to stimulate a dysfunctional common peroneal nerve to enable toe clearance during walking in an individual with drop-foot. A Modern Orthotic Technology option may be the use of a light-weight carbon fibre orthosis with ankle joints, however the Advanced Orthotic Technology option may be more suitable, such as in the case of swelling, scarring or a history of skin breakdown. These types of Advanced Orthotic Technology have a definite place in the Australian market and should be offered to

clients if they are the optimal orthotic proscripton with demonstrable benefits over the Modern Orthotic Technology option. Examples of Advanced Orthotic Technology prescriptions are:

Ankle-Foot Orthosis:

Neurotronics, such as Ankle-Foot Orthoses incorporating Functional Electrical Stimulation (FES)⁵⁵. Price range \$6500 - \$9500, with \$500 ongoing expenses per annum.

Knee-Ankle-Foot Orthosis:

Custom-made laminated orthosis using an *advanced* stance-control knee joint and double action ankle joints, allowing a free knee during swing phase and stance stability, and adjustable range of motion at the ankle. Including check fits and modern light-weight technology. Advanced componentry used. Price range \$6,500 - \$10,000.

⁵⁵ In this submission FES refers to the use of neurological stimulation to improve function, similar to the functional gains provided by an orthosis. This submission does not refer to FES as a therapeutic or rehabilitation tool.

APPENDIX FOUR:

Tables of risks related to orthotic practice

Table 2: Risks to clients when Orthotist/Prosthetists provide an inadequate clinical service

Risk	Potential Consequences
Inappropriate program design	Client does not achieve personal and mobility goals Further interventions, such as surgical and pharmacological Legal action taken
Inappropriate discharge from service with an orthotic device required for primary mobility	Client unable to adequately function at home, therefore increasing the need for carers and/or admission to care facility Re-hospitalisation for further rehabilitation Home and/or community based falls Reduced client confidence associated with falls Fractures and subsequent hospitalisation due to falls Development of muscular damage, such as contractures Death Legal action taken
Irregular client reviews to ensure components and materials are mechanically and technically sound	Failure of device resulting in inability to wear the device, impacting on functional, social and employment aspects of life Superficial injury due to material failure, increasing risk of infection, skin breakdown etc Failure of component/materials resulting in falls Reduced client confidence associated with falls Fractures and subsequent hospitalisation due to falls Death Legal action taken
Irregular client reviews to ensure the device fit has been maintained.	Superficial injury due to poor fit, increasing risk of infection and skin breakdown. Development of muscular damage, such as contractures Hospitalisation associated with superficial injury Further medical intervention required, such as revision amputation surgery, debridements etc Legal action taken
Poor client assessment and referral to allied health and medical specialists	Inappropriate prescription and management Poor assessment results in no referral to other medical team members, reducing clients functional and rehabilitation potential

Table 3: Risks to clients when Orthotist/Prosthetists inappropriately prescribe and/or design a device

Risk	Potential Consequences
Inappropriate device selection	<p>Device does not provide client with the optimal outcome</p> <p>Client unable to adequately function at home and meet ADLs, therefore increasing the need for carers and/or admission to care facility</p> <p>Device does not immobilise limb therefore resulting in further medical intervention, such as fracture fixation</p> <p>Development of muscular damage, such as contractures</p> <p>Re-hospitalisation for further rehabilitation</p> <p>Home and/or community based falls</p> <p>Reduced client confidence associated with falls</p> <p>Fractures and subsequent hospitalisation due to falls</p> <p>Death</p> <p>Legal action taken</p>
Inappropriate selection of materials and components in the design of the device	<p>Provision of an inferior device which may not achieve its required functional goal</p> <p>Client unable to adequately function at home and meet ADLs, therefore increasing the need for carers and/or committing to care facility</p> <p>Superficial injury due to material selection, increasing risk of infection, skin breakdown etc</p> <p>Re-hospitalisation for further rehabilitation</p> <p>Home and/or community based falls</p> <p>Reduced client confidence associated with falls</p> <p>Fractures and subsequent hospitalisation due to falls</p> <p>Development of muscular damage, such as contractures</p> <p>Death</p> <p>Legal action taken</p>

Table 4: Risks to clients when Orthotist/Prosthetists inappropriately manufacture a device

Risk	Potential Consequences
Inappropriate selection of materials	<p>Device does not provide client with the optimal outcome</p> <p>Adverse reaction to materials requiring medical intervention and period of non-use of device</p> <p>Superficial injury due to material selection, increasing risk of infection, skin breakdown etc</p> <p>Materials failure resulting in home and/or community based falls</p> <p>Reduced client confidence associated with falls</p> <p>Fractures and subsequent hospitalisation due to falls</p> <p>Death</p> <p>Legal action taken</p>
Inappropriate manufacturing technique	<p>Provision of an inferior device which is prone to failure</p> <p>Failure of device resulting in hand/or community based falls and/or superficial damage to limb segments</p> <p>Re-hospitalisation for further rehabilitation</p> <p>Reduced client confidence associated with falls</p> <p>Fractures and subsequent hospitalisation due to falls</p> <p>Death</p> <p>Legal action taken</p>
Failure to observe the technical recommendations of components and/or the specifications of materials	<p>Provision of an inferior device which may not achieve its required functional goal</p> <p>Provision of a device with high failure risk, increasing the potential for home and/or community based falls and superficial limb damage</p> <p>Re-hospitalisation for further rehabilitation</p> <p>Reduced client confidence associated with falls</p> <p>Fractures and subsequent hospitalisation due to falls</p> <p>Death</p> <p>Legal action taken</p>

Table 5: Risks to clients when Orthotist/Prosthetists fail to observe regulations and protocols

Risk	Potential Consequences
<p>Failure to observe “single use” protocols</p> <p>Re-issue of a device or component which is designated as “single use only”</p>	<p>Provision of a contaminated device, exposing to client to infections such as MRSA or VRE</p> <p>Provision of a contaminated device exposing client to bacterial infection</p> <p>Hospitalisation associated with infection</p> <p>Death</p> <p>Legal action taken</p>
<p>Provision of device based on availability and/or funding not assessment, therefore not meeting manufacturer’s recommended prescription guidelines</p>	<p>Provision of an ineffectual device that does not meet client requirements</p> <p>Refer risks Table Two – Inappropriate device selection</p>
<p>Inappropriate recycling of components</p>	<p>Provision of a worn and unreliable component which is prone to failure</p> <p>Failure of device resulting in home and/or community based falls and/or superficial damage to limb segments</p> <p>Reduced client confidence associated with falls</p> <p>Fractures and subsequent hospitalisation due to falls</p> <p>Death</p> <p>Legal action taken</p>
<p>Failure to observe universal precautions</p>	<p>Inappropriate handling of a device contaminated, such as with MRSA and/or VRE</p> <p>Cross-contamination of clients due to device handling</p> <p>Hospitalisation associated with infection</p> <p>Death</p> <p>Legal action taken</p>

Table 6: Risks to clients when Orthotist/Prosthetists communicate poorly with the client and/or treating team

Risk	Potential Consequences
<p>Provision of insufficient or unclear information to client on the wear regime and use of a device</p>	<p>Client inappropriately dons the device, increasing potential for falls and superficial injury</p> <p>Client inappropriately wears the device, compromising the rehabilitation progress and outcome</p> <p>Home and/or community based falls</p> <p>Reduced client confidence associated with falls</p> <p>Fractures and subsequent hospitalisation due to falls</p> <p>Development of muscular damage, such as contractures</p> <p>Superficial injury and associated medical interventions</p> <p>Death</p> <p>Legal action taken</p>
<p>Ineffectual communication with the client's treating team</p>	<p>Device is removed from the treatment program due to a misunderstanding regarding its design and function</p> <p>Device is inappropriately integrated into the treatment program, increasing the potential for falls and development of pressure areas from a poor wear regime</p>

APPENDIX FIVE: Reviews, maintenance and repairs

Reviews maintenance and repairs fall under the definition of “soft” orthotic technology, which defines all the associated clinical services provided by an Orthotist. In contrast, “hard” orthotic technology refers to the actual provision of an orthosis by an Orthotist.

Definitions and descriptions;

Orthotic review.

A regular, planned appointment after the fitting and first review appointment, in which the Orthotist reviews the fit, function and ongoing appropriateness of the orthosis. Depending on the type of orthosis and client presentation, these may be conducted between 4-6 months, 6 monthly or annually. Regular reviews promote client safety and maximum functional gain.

Orthotic maintenance.

Within the regular, planned review appointment the Orthotist may conduct minor maintenance to the orthosis, such as the tightening of screws, replacement of worn springs and compressed padding. Regular maintenance prevents a major device failure and ensures client safety.

Orthotic repairs.

These are conducted outside of the review appointment due to time constraints. The need for repairs may be identified during a regular review or on request by the consumer. Repairs may be labour intensive and involve the replacement of major components, such as ankle joints, knee joints or uprights. This service is usually urgent and essential to the immediate safety of the client.

Orthosis ‘refurbishment’.

Usually refers to an entire maintenance process being undertaken for an orthosis. This is extensive orthotic maintenance that cannot be completed within a review appointment due to time constraints. An example might be the replacement of all orthosis straps, or the replacement of all custom made and hand-stitched leather components within a knee-ankle-foot orthosis. This type of maintenance is usually provided to extend the life-span of a device and is commonly completed in the current funding model as a ‘stop-gap’ measure whilst clients are waiting for funding approval. The cost of major refurbishment should be weighed against the cost of orthosis replacement.

APPENDIX SIX: Best Practice for Orthotic Patient Review

Sourced from:

Scottish Executive, Health Department. (2001). *"Guidelines for Orthotic Patient Review"*. HDL 2001 (16). Edinburgh. [Accessed 27/04/2011 from http://www.sehd.scot.nhs.uk/mels/HDL2001_16.htm].

Introduction

The review of patients following supply of orthoses is essential in order to confirm the efficacy of fit and function, user comfort and compliance, and is also an essential element of Orthotist training and professional learning. In addition to the clinical and technical necessity for patient review, this is also now essential in order to comply with the legislative requirements of Product Liability and the Medical Devices Directives, Quality Assurance, Clinical Governance and Audit. It must be realised that it is neither practical nor appropriate to set one rigid or uniform review procedure for all patients, as this will, in some instances, require to be tailored to reflect the needs of each individual in respect of their pathology and/or occupational or domestic circumstance. The following policy is, therefore, merely an outline of that which is considered to be the minimum necessary in order to meet the collective needs of the present clinical, technical, professional and statutory requirements.

Review Categories (General)

1. Adults

As a general rule, all patients should be reviewed within **1-4 weeks** following initial orthosis supply, and a minimum of **one yearly** thereafter.

2. Children

Due to the continuing changes such as occur in children consequent to growth, they therefore of necessity, generally require more frequent and continuous review than that of adults with similar pathologies/orthoses. Accordingly, they, following initial review of **1-4 weeks**, should typically be reviewed on a **4-6 monthly** ongoing basis.

Special Categories

1. Load bearing orthoses

In order to comply with manufacturers' guidelines in respect of compliance with Product Liability Legislation and Medical Devices Directives, load-bearing devices which incorporate mechanical joint mechanisms eg, Knee, Ankle,

Foot Orthoses and Hip, Knee, Ankle, Foot Orthoses, after initial review of **1-4 weeks**, should, in the interest of patient safety, be checked for structural integrity on a **6 monthly** basis.

2. 'At risk' category patients

Any patient deemed at risk due to their pathology will require to be seen, after initial review of **1-4 weeks**, on a regular and ongoing basis within a typical minimum time scale of **4-6 months**. For example, patients with neuropathic type disorders, such as diabetes mellitus, who are at risk of developing, or who have existing ulceration, or those who are suffering from other acute conditions will, of necessity, require to be seen on an even more frequent basis.

Patient Information and Guidance

All patients supplied with orthoses should be given clear and written instructions on the use and care of their orthosis, be made aware of their responsibility in complying with the review guidelines and of the importance of their advising the orthosis provider of any problems arising as soon as possible.

APPENDIX SEVEN: Best practice – orthotic service times

Sourced from:

British Association of Prosthetists and Orthotists [BAPO]. (2003). *Guidelines for Best Practice. No. 4. Assessment and Review*. BAPO. UK. [Accessed 20/04/2011 from <http://www.bapo.org/docs/guideline-no%5B1%5D.4-assessment-review,-issued-mar-03.pdf>].

Orthotic Patient Treatment Times

All times have been rounded to the nearest twenty minutes. In most cases, the contact times have been rounded up, but in some instances these have been rounded down. These contact times include the requirement to make a clinical note of the episode of treatment.

These contact times are for guidance and it is expected that in some instances longer time slots will be required. The treatment times tabled below refer to the amount of time required to deal with a single disabling condition requiring one orthotic device. Multiple disability would require more time slots to be booked.

Table 7 Recommended Treatment Times for Orthotic Patients

	Simple pathology (minutes)	Complex pathology (minutes)
Initial assessment	20	40
Measurement Specification	20	40
Trial Fitting	20	40
Supply	20	40
Review	20	40

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