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**Development of a best practice statement on the use of ankle-foot orthoses
following stroke in Scotland**

Development of guidelines on AFO use following stroke

Keywords

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Abstract

A National Health Service Quality Improvement Scotland (NHS QIS) scoping exercise in 2007 identified the use of ankle-foot orthoses (AFOs) following stroke as a clinical improvement priority, leading to the development of a best practice statement (BPS) on AFO use after stroke. This paper outlines the development process of the BPS which is available from NHS QIS. The authors were involved in the development of the BPS as part of a working group that included practitioners from the fields of orthotics, physiotherapy, stroke nursing and bioengineering, and staff of NHS QIS and a patient representative. In consultation with an NHS QIS health services researcher, the authors undertook a systematic literature review to evidence where possible the recommendations made in the BPS. Where evidence was unavailable, consensus was reached by the expert working group. As the BPS was designed for the non-specialist and non-orthotic practitioner the authors also developed educational resources which were included within the BPS to aid the understanding of the principles underpinning orthotic design and prescription. The BPS has been widely distributed throughout the health service in Scotland and is available electronically at no cost via the NHS QIS website. As part of an ongoing evaluation of the impact of the BPS on the quality of orthotic provision, NHS QIS has invited feedback regarding successes and challenges to implementation.

Introduction

Stroke has been described as ‘rapidly developing clinical signs of focal and at times global disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin’ ⁽¹⁾. Among the potential difficulties that facing those who survive an acute stroke may face are speech deficits, depression, neuropsychological disorders, functional difficulties and mobility problems. Many of these mobility problems can be improved by the use of an ankle-foot orthosis (AFO), which if appropriately designed can improve control of the limb in both the stance and swing phases of gait ⁽²⁻⁴⁾.

Worldwide, the World Health Organisation has estimated that 15 million people suffer strokes annually, with five million left permanently disabled ⁽⁵⁾. Stroke is the most frequent cause of severe adult disability in Scotland, with approximately 8,500 diagnoses of first-ever stroke each year ⁽⁶⁾, and more than 70,000 individuals affected by the condition ⁽⁷⁾. A recent Scottish Government strategy document confirms stroke as a national clinical priority for the Scottish National Health Service (NHS) ⁽⁸⁾.

NHS Quality Improvement Scotland (NHS QIS) is a strategic health board which has a lead role in supporting the NHS in Scotland to improve the quality of healthcare. It does this by producing advice and evidence in a number of different formats, including best practice statements (BPS). These statements reflect the commitment of NHS QIS to sharing local excellence at a national level, and the current emphasis on delivering care that is patient-centred, cost-effective and fair.

As part of a scoping exercise commissioned by NHS QIS in 2007 ⁽⁹⁾, allied health professionals (AHPs) across Scotland identified the use of AFOs following stroke in adults as a clinical improvement priority. This was due to variations in clinical practice around the country, and a lack of familiarity with the evidence base for AFO use. It was therefore felt that a BPS on AFO use following stroke would be a valuable clinical tool. The BPS was designed primarily for the non-specialist practitioner, and to support local policies and procedures. NHS QIS best practice statements are produced by a systematic process (figure 1) and are underpinned by a number of key principles:

- they are intended to guide practice and promote a consistent, cohesive and achievable approach to care; their aims are realistic but challenging
- they are primarily intended for use by AHPs, registered nurses, midwives, and the staff who support them, but will also be of relevance to medical professionals
- they are developed where variation in practice exists and seek to establish an agreed approach for practitioners
- responsibility for implementation of these statements rests at local level.

Figure 1 has been removed from the submission

Figure 1. Key stages in the development of best practice statements

In addition to developing a BPS and sharing this with healthcare professionals across Scotland, the initiative also sought to share the work internationally and to develop resource material to support the implementation of the BPS.

Process

It has been recommended that the process of guideline development is best moderated by someone who is familiar with the scientific literature, and who has knowledge and clinical skill in the management of the condition ⁽¹⁰⁾. An educator in prosthetics and orthotics was recruited to lead the project and act as 'expert advisor'. The project was then advertised widely through the stroke managed clinical networks (MCNs), all relevant professional networks, charitable organisations and user groups. Expressions of interest were widely sought, ensuring that all relevant stakeholders were offered the opportunity to be involved in the project.

A steering group and working group were recruited, and included educators in prosthetics and orthotics, practitioners from the fields of orthotics, physiotherapy, bioengineering and stroke nursing, as well as NHS QIS staff and a patient representative. The role of the steering group was to drive the project forward, and to provide quality assurance, advice and expertise throughout the project. The working group consisted of the ten members of the steering group plus a further 11 individuals. This group had responsibility for developing and agreeing the content of the BPS, and met on six occasions during the life cycle of the project. The size and composition of the working group are important to promote effective discussion, eliminate professional bias and produce valid guidelines. As the working group included practitioners actually working in the field of stroke rehabilitation, it was able to make recommendations based not only on the available evidence, but also on clinical experience and knowledge of the practicalities of clinical life ⁽¹⁰⁾.

Membership of the virtual reference group was open to any interested party, and was drawn from across Scotland to ensure that the challenges of delivering stroke services in both urban and rural settings were considered. The first draft Drafts of the BPS were emailed to this wide group of individuals, networks and organisations, with a response rate of approximately 65% who provided feedback. All comments received following this consultation were debated by the working group, so that consensus was reached regarding proposed amendments to the working document. During two separate consultations, helping to inform the final version of the document. Following amendment, a second draft of the BPS was again circulated to the virtual reference group, and any additional comments were considered. It was also made available via the NHS QIS website during a six-week consultation phase, in order to make the draft widely accessible, generating additional responses from outwith the virtual reference group. All comments received following these consultations were debated by the working group, so that consensus was reached regarding proposed amendments to the working document.

The development of the BPS also benefitted from information gathered from surveys of AFO users and service providers about their experience and attitudes to the use of AFOs following stroke, which were run in parallel with the project.

Literature review

In order to inform the development of the BPS a systematic literature review on AFO use following stroke was undertaken, including work of both a qualitative and quantitative nature. The full literature review, together with recommendations for future research, was included in the BPS as an appendix. The search was not limited

to any study type, and was run in the databases of Medline, EMBASE, CINAHL, AMED, RECAL Legacy, and the Cochrane Library. Search terms included AFO, orthosis, orthotics, splints, stroke, hemiplegia, and hemiparesis. This search was supplemented by hand-searching reference lists and checking various websites (e.g. the TRIP database, SIGN and NICE). The following research questions were developed and answered according to the best available evidence:

- what are the effects of AFOs on the temporal and spatial parameters of gait?
- what are the effects of AFOs on the ankle and foot?
- what are the effects of AFOs on the knee?
- what are the effects of AFOs on the hip?
- what effect do AFOs have on the metabolic and cardiopulmonary cost of walking?
- what effect do AFOs have on muscle activity and muscle length?
- how do AFOs affect function and ability?
- what are the benefits of tuning AFOs? (changing sagittal plane alignment)
- what are the perceptions of AFO users regarding orthotic treatment?

While evidence was found for a number of benefits conferred by the use of an AFO following stroke, the quality of many papers was compromised by inadequate reporting and lack of transparency, with many failing to provide adequate detail on the subjects and/or the orthosis being investigated. In some cases it was considered appropriate to extrapolate evidence from the literature on the use of AFOs in cerebral palsy ⁽¹¹⁾.

Results

The best practice statement ⁽¹¹⁾, which was published in August 2009, makes 41 statements/recommendations under the following headings:

- service planning, access to services and clinical governance
- screening and referral
- patient assessment and indications for different AFOs
- biomechanical effects of AFOs
- non-biomechanical effects of AFOs
- review, monitoring and follow-up

Guidance was provided on how to demonstrate that recommendations were being implemented, and key challenges to implementation were identified at the end of each section. Recommendations relating to the effect of AFOs were justified either by citing the available published evidence, or where evidence was unavailable, by expert consensus of those involved in producing the BPS. In order to address the important issues of clinical governance, screening, referral and assessment, service provision, and review, monitoring and follow up, recommendations were made based on existing clinical guidelines where available ^(7, 12).

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During the process of developing the recommendations, it was recognised that there was a need for a nationally agreed method of screening patients to identify those for

whom referral to orthotic services was appropriate. The absence of such an agreed screening process raised concerns about equity of access to orthotic services around the country following stroke. As a consequence, the working group developed a screening tool that could be used by non-specialist practitioners to identify those who may might possibly benefit from AFO provision, and to initiate referral to orthotic services for detailed assessment. In recognition of the fact that the long-term care of patients would not necessarily involve an orthotist at every review appointment, a fitting/review tool was also developed to help non-orthotists identify those who would benefit from re-referral to orthotic services. Both tools were trialled and refined prior to being recommended for use, and included as appendices to the BPS as well as being made available electronically from the NHS QIS website (www.nhshealthquality.org).

As it was felt that many medical professionals and AHPs may be unfamiliar with the principles underpinning orthotic practice, it was considered important to develop and include as appendices to the BPS additional educational resources that would improve understanding of the reasons why the recommendations were being made.

This additional material included information on:

- basic mechanical & biomechanical principles
- biomechanics of normal and stroke gait
- biomechanical effects of AFOs
- tuning AFOs (adjusting sagittal plane alignment of solid AFOs for optimum function)
- footwear characteristics and their influence on outcomes

In addition to the full BPS, which runs to 60 pages, the key recommendations were summarised as a two-page 'quick reference guide' for ease of use in a clinical setting (see appendix).

Dissemination and implementation

The BPS (ISBN 1-84404-58-6) has been widely distributed throughout the health service in Scotland and is available to download at no cost via the NHS QIS website (www.nhshealthquality.org). All stakeholders involved in the development of the BPS have been tasked with promoting the document through their networks, and all NHS health boards in Scotland, through their stroke MCNs, have been charged by the Scottish Government with ensuring implementation ⁽⁸⁾, the ultimate responsibility for which rests with local health service managers. Steps have been taken to confirm that the appropriate people have been targeted through the dissemination process, and to confirm that the BPS is being used across all stroke services.

A number of measures are being undertaken to facilitate and support implementation including multi-professional in-service training events, short post-qualification courses at the National Centre for Prosthetics and Orthotics, and presentations at national scientific meetings.

Feedback has been invited from users of the BPS regarding specific successes or challenges relating to implementation, and the impact of the document on the quality of care provision. NHS QIS policy is that best practice statements are periodically reviewed and, if necessary, updated in order to ensure that they continue to reflect current thinking with regard to best practice. In this way experience gained from

working with the BPS can be evaluated and if appropriate, assimilated into future versions, as can any new scientific evidence and/or clinical guidelines.

Discussion

The NHS QIS best practice statement fully endorses the principles and recommendations contained in the 'Report of a consensus conference on the orthotic management of stroke patients' which was published by the International Society for Prosthetics and Orthotics (ISPO) in 2004 ⁽¹³⁾.

Although the ISPO However, the ISPO report had been in circulation for three years at the time of by the time the NHS QIS scoping exercise identified AFO use following stroke as a clinical improvement priority, clearly indicating it was clear that the recommendations it contained had not been universally adopted throughout Scotland. Many front-line clinical staff such as stroke nurses or physiotherapists whose position afforded them the opportunity to identify patients who might benefit from provision of an AFO remained unaware of the existence of the ISPO report and of the indications for AFO use following stroke. Some healthcare professionals remained unfamiliar with the evidence base for AFO use, while others were actually unaware of the existence of the ISPO report. It may be that the size of the ISPO report (more than 270 pages) or its cost at that time represented barriers to its adoption (although it is acknowledged that the full report has recently been made available to download from the ISPO website at no cost). It was felt that a smaller document written specifically for the non-orthotics specialist, that would be freely and widely available in all stroke nursing and rehabilitation settings, would be a valuable clinical tool in improving stroke services. It was also felt that the inclusion of educational material and the development of screening and review tools would

optimise engagement with the BPS and improve referral and re-referral rates to orthotic services. In addition, while international consensus provides sound foundations from which national protocols can be developed, by its very nature it cannot always adequately address national and local challenges of clinical governance and service delivery. The BPS was developed to address all of these issues, in the belief that this would provide country-specific guidance in the most accessible format.

Additionally, the development of the BPS provided an opportunity to update the literature reviews ^(2, 4) that had been conducted for the ISPO report, which were four years out of date by this stage. Recognising the importance of evidence-based practice, the literature was systematically searched for evidence in support of the recommendations made within the BPS, with recommendations that are supported by the literature referenced within the document. In the absence of evidence, consensus was reached by the multidisciplinary working group so that statements without references reflect the best current practice based on the multi-professional group's expert knowledge and clinical experience. While evidence was found for a number of benefits conferred by the use of an AFO following stroke, the quality of many papers was compromised by inadequate reporting and lack of transparency, with many failing to provide adequate detail on the subjects and/or the orthosis being investigated. In the absence of stroke-specific evidence, in some cases the working group considered it appropriate to extrapolate evidence from the literature on the use of AFOs in cerebral palsy ⁽¹⁴⁾.

Conclusions and recommendations

The development of this NHS QIS best practice statement is an example of educators in prosthetics and orthotics working in collaboration with service providers from a variety of professional backgrounds to produce guidance on practice in response to a need identified by those working in the field of stroke rehabilitation clinical service. Successful implementation will raise standards and promote a consistent, cohesive and achievable approach to the use of the use of ankle-foot orthoses following stroke. To assess the extent to which the BPS has influenced clinical practice an audit should be undertaken in due course. This model may serve as a useful framework for the development of further guidelines on stroke or other areas of clinical practice in other countries.

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