

Guidance on the commissioning of orthotic services

1. Background

In March 2000, the Audit Commission published *Fully Equipped*, a report on the provision of some forms of equipment to older or disabled people by the NHS or social services in England and Wales.¹ The report concluded that assistive technology provides the gateway to the independence, dignity and self-esteem of some 4 million older or disabled people and for 1.7 million informal carers. But the current services were found to be unsatisfactory:

- there were unexplained variations in all aspects of service provision, bearing little relation to underlying levels of need; and
- the quality of services owed more to custom and practice, rather than to a considered view of the contribution that equipment services could make to the overall needs of the population.

In June 2002, the Audit Commission reviewed progress in a follow-up report, *Assisting Independence - Fully Equipped 2002*.² It found that while there had been significant progress in some assistive technology services, progress in improving the orthotics service was disappointing.

2. Why is there a need to improve the commissioning of orthotics services?

The Government has introduced a number of policies and initiatives that require improvements in the commissioning of orthotics services. These include:

- the National Service Framework for Older People(NSF(OP)), which details the Government's expectations of the services that should be available to older people, and the manner of their delivery as part of the NHS Plan³; and
- the National Service Framework for Diabetes (NSF(D)), which stresses the importance of an effective orthotics service to strategies to manage diabetes.

3. Commissioning guidance

The Audit Commission's report *Assisting Independence* identified the commissioning of all assistive technology services, including orthotics services, as a key weakness. This guidance has been prepared to help address this shortcoming. It tries to describe how PCTs should commission orthotics services as part of wider strategies to support independence.⁴ It is intended that service commissioners and providers will use the guidance to examine and audit their current performance against the standards and best practice/innovation set out below. The guidance may also be used as a resource to help develop commissioning standards and business cases to support improvements in orthotics services. The guidance will be particularly relevant to those orthotics services that are taking part in a current initiative by the Modernisation Agency, which has established a collaborative programme to support the improvement of orthotics services.

¹ Audit Commission, *Fully Equipped – The provision of disability equipment services to older or disabled people by the NHS and social services in England and Wales*. 2000, Audit Commission

² Audit Commission, *Assisting Independence - Fully Equipped 2002*. 2002, Audit Commission

³ <http://www.doh.gov.uk/nhsplan/contents.htm> and <http://www.doh.gov.uk/nsf/olderpeople.htm>

⁴ The terms, commissioning, and, purchasing, by health authorities are often used interchangeably. In this guide, commissioning is used as it includes wider responsibilities for assessing health needs and for strategic planning of services, rather than the term, purchasing, which has a narrower focus on contracting processes.

4. Structure of the guidance

The guidance is structured under the following headings:

1. Policy (What we plan to do and why)

- Overall objectives
- How orthotics services contribute to wider healthcare objectives
- Health economics
- Likely future developments for which commissioners need to prepare

2. Strategy (How we plan to do it)

- Understanding the underlying level of demand in the community
- Service description
- Statement of work to be performed

3. Delivering the service (Implementation and review)

- Method of working
- Performance management

Policy

Overall objectives		
<i>Matters to address</i>	<i>Key issues to consider</i>	<i>AC comment on the issues</i>
Service aims and underlying principles	<ul style="list-style-type: none"> Meeting the needs of people of all ages, including children, and responding whenever changes in their type or level of disability occur 	<p>The aim of the orthotics service is to:</p> <ul style="list-style-type: none"> provide suitable orthoses for all those with a permanent condition that impairs their ability to walk; provide a comprehensive service that includes consideration of comfort, posture, function, pressure relief and cosmesis; fit, maintain and repair orthotics equipment in a responsive, rapid and effective manner; respond to changing medical and social needs of orthotics users with provision of different orthoses when necessary. <p>An orthosis is 'an externally applied device used to modify the structural and functional characteristics of the neuro-muscular and skeletal system'.⁵ The main orthotic services involve the supply and fitting of orthopaedic footwear and a range of callipers, splints and surgical collars. All of these are intended to assist the functioning of a deformed or weakened part of the body. Users range from those with a slight temporary disability to those with severe chronic problems. Whilst recognising that three-quarters of orthoses are supplied to older people, the average cost of supply is considerably lower for that age group than it is for the younger age group who often have more complex needs and whose numbers also increasing at a rate of about 2 per cent per annum.⁶</p> <p>Orthoses range from highly sophisticated pieces of equipment with integrated micro-technology to basic fittings for occasional use. The majority of users are in the latter category and are usually over age 65. Nonetheless, correct fitting at whatever age is important. Getting the fit right from the start is an extremely cost-effective investment of skill and time if unnecessary re-fitting and reappointments and sometimes complete replacement of inappropriately fitted appliances are to be avoided.</p> <p>Effective commissioning requires a baseline audit and analysis to establish an understanding of:</p> <ol style="list-style-type: none"> the number of people currently needing services, and the likely future trends the type of services they require as part of the comprehensive facilitating of independence

⁵ International Standards Organisation Document ISO 8549-1:1989.

⁶ Department of Health and College of Occupational Therapists, *National Prosthetic and Orthotics Services Report*, Department of Health, 1997.

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		<ul style="list-style-type: none"> iii. the type, volume and quality of existing services iv. the gap between (ii) and (iii); and plans to fill the gap v. using information to monitor progress in delivering commissioning objectives
	<ul style="list-style-type: none"> • Meeting the requirements and standards of the NHS Plan and NSFs for Older People and Diabetes 	<p>The NSF for Older People also specifies that commissioners must have established an integrated 'falls prevention strategy by April 2005.</p> <p>The NSF for Diabetes requires that PCTs undertake a baseline assessment of population need HSC 2001/026 (Dec 2001). This needs to include access to orthotics services as part of primary prevention groups.</p> <p>The NSF(D) includes standards that state:</p> <p>Standard 11: The NHS will develop, implement and monitor agreed protocols and systems of care to ensure that all people who develop long-term complications of diabetes receive timely, appropriate and effective investigation and treatment to reduce their risk of disability...</p> <p>Standard 12: All people with diabetes requiring multi-agency support will receive integrated health and social care. Improving the commissioning of orthotics services is crucial to the realisation of both these standards.</p>
	<ul style="list-style-type: none"> • Commissioning principles 	<p>Orthotics need to be commissioned around care pathways, which describe an agreed and explicit route that a service user takes through health and social care services. Agreements between the various professionals involved will typically cover the type of care and treatment to be provided, the professionals involved, and the place where treatment or care will take place. The orthotics service covers many different categories of users, though each service user will have his or her own individual needs. Orthotic provision is a holistic clinical service, not just a means of supplying appliances or equipment.</p>

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Provision of services	<ul style="list-style-type: none"> Involving users and carers in planning the service and monitoring its delivery 	<p>A central theme of the NHS Plan, the work of the Modernisation Agency and one of the key components of clinical governance is the engagement of users and carers in service provision. Seeing the service through the user's eyes is vital. However, research by the Audit Commission has found that only one-third of orthotics services are currently running user groups, and many of these are not making an active contribution to service development.</p> <p>Commissioners must engage users in planning and specification of local orthotics services, and require that service providers develop and maintain continuing engagement with users and carers to support the operational review of the service. Better and more user engagement should in theory support a move away from the traditional medical model of care to the more acceptable social model with the aim of transferring power from the professional to the individual and concentrating on individual needs, allowing people to make their own decisions. Orthotics services should be tailored to individual's needs to achieve maximum self-reliance and independence for the user.</p> <p>Guidance on user engagement is available in <i>How to Consult your Users – An Introductory Guide</i>. Service First Unit 020 7270 1838 or www.servicefirst.gov.uk.</p> <p>The techniques for engaging users with special needs are also described in the RNIB's <i>See it Right</i> pack for advice on meeting information needs of people with sight difficulties. www.rnib.org.uk.</p> <p>Obtaining the views of children and their carers is described in <i>Can You Hear Us</i> from Save the Children www.savethechildren.org.uk.</p>
	<ul style="list-style-type: none"> Integrating orthotics services into wider rehabilitation services 	<p>Orthotics services should ideally be commissioned as an integral and important part of rehabilitation services. The commissioning philosophy should be informed by an understanding of the needs of the service user and the considerable significance that the typical user will attach to their orthosis as essential to their independence. An orthosis is often an indispensable piece of kit, making the difference between dependence and a reasonable quality of life, it is not simply a prescription item. Commissioners should set standards based on users' needs, not on referring to types and numbers of wheelchairs.</p>
Access to services	<ul style="list-style-type: none"> Referral from a health or social care professional vs. self-referral 	<p>There are a number of ways that users gain access to the orthotics service. They may be referred by a health or social care professional but progressive commissioners support self-referral from potential users/carers, as well as telephone requests from GPs.</p> <p>Orthotics service centres should introduce systematic re-assessment programmes for all users instead of relying on users to present themselves to their GP or put up with equipment that they find hard to use. This approach is likely to meet users' needs at an earlier stage, support user independence and reduce cost transference that could lead to more expensive care at a later stage in the acute and social services sectors. The frequency of the</p>

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		<p>reviews should be consistent with the prognosis. For example, a user with brittle bones will require regular reviews of the wear and tear of his or her callipers. This is crucial to avoid falls that cause fractures induced by calliper knee joint failure, for example.</p>
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Longer term considerations	<ul style="list-style-type: none"> Financial planning 	Commissioning decisions are made through the annual local delivery plan and should reflect the local health economy's 3 year Health Plan objectives.
	<ul style="list-style-type: none"> Future service demands 	<p>Commissioning of services should reflect the future growth in demand for the orthotics service. There are currently about 700,000 orthotics users in England, with a typical hospital seeing between 3,000 and 4,000 new referrals a year. It is estimated that the number of orthotics users will rise by 15 per cent per annum because of the increasing average age of the population.⁷ The demand for orthotics services is also influenced by:</p> <ul style="list-style-type: none"> Improvements in medical techniques and treatment resulting in the survival of many severely disabled people Changing attitudes towards, and increased acceptance of, disability by the general public Greater expectations of orthoses and their use
	<ul style="list-style-type: none"> Providing support for carers based on the national strategy for carers 	<p>The formal care system cannot begin to deliver the range, volume, flexibility of care and support for users of equipment that is provided by unpaid carers. Relatives and friends are the major deliverers of care and act as partners with service providers, while also monitoring the quality of services. The philosophy of support behind the NSF for Older People is equally relevant to those unpaid carers, who are increasingly becoming old themselves.⁸</p> <p>In many organisations, there is still a difficulty turning recognition of the pivotal role that unpaid carers play into practical forms of support. Significant progress is needed to deliver the vision that is set out in the National Strategy for Carers.⁹</p>
	<ul style="list-style-type: none"> Integrated falls strategy 	The NICE protocol on preventing falls at home, expected in 2004, will need to be considered by orthotics services

⁷ Stewart C, 1992. Orthotics evaluation and prescription. *Nursing Standard* 7; 1:27-30.

⁸ Government Actuary Department. *Mid-2000 UK population estimates – United Kingdom: projected populations in 5 year age groups 2018-2038*. London: The Stationery Office, 2000

⁹ HM Government, *Caring about Carers – A National Strategy for Carers*, 1999, The Stationery Office

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Choice	<ul style="list-style-type: none"> • Providing individuals with choice 	<p>Commissioning policy should reflect The National Service Framework for Older People (Ref.¹⁰). Standard 2 of the NSF requires that: <i>NHS and social care services treat older people as individuals and enable them to make choices about their care.</i></p> <p>To comply with this policy, commissioners will need to specify the provision of a wider range of orthoses than have typically be supplied in the past.</p>
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How orthotics services contribute to wider healthcare objectives

<i>Matters to address</i>	<i>Key issues to consider</i>	<i>AC comment on the issues</i>
Joined-up commissioning	<ul style="list-style-type: none"> • The contribution of orthotics services to other health and social care priorities 	<p>Commissioners need to consider the impact that orthotics services have on wider commissioning objectives, such as the reduction of hospital admission rates and A&E attendances. Orthotics service provision should be explicitly linked to the strategic aims of other policies and strategies, such as accident prevention and independence. Good quality footwear supports independence in the community and helps to prevent accidents and an effective orthotics service is needed in view of the likely increase in the incidence of diabetes: good quality footwear can help prevent amputation.</p> <p>Commissioners should also require orthotics service providers to demonstrate work on clinical audit and clinical effectiveness, particularly around the contribution that the service makes to these wider health and social care priorities.</p>
Establishing partnerships	<ul style="list-style-type: none"> • Working with other agencies 	<p>Commissioners' service specifications should include the need for multi-agency working to meet the totality of users' needs. This will require liaison arrangements with the housing service for minor adaptations, the education department for special needs, and other mobility services, for example prosthetic, orthotic and community equipment services.</p> <p>The Health and Social Care Act 2001 introduces a statutory duty on NHS bodies to involve the public in service planning; and engage local councils via the work of their scrutiny committees. A range of agencies also need to be engaged in plans to develop orthotics services: for example, social services, housing, education and the wider voluntary sector, including Independent Living Centres.</p>

¹⁰ Department of Health, *National Service Framework for Older People*, 2001

Health economics		
<i>Matters to address</i>	<i>Key issues to consider</i>	<i>AC comment on the issues</i>
Meeting the needs of the local population for orthotics services	<ul style="list-style-type: none"> • Implications of not meeting current demand and underlying demand, for example the impact on community care policies and institutional care 	<p>Commissioners need to consider the extent to which the service they specify meets the underlying levels of demand in the community. They need to assess the current level of service coverage; the level of service it should ideally provide; and establish plans to bridge the gap between the two. Current age-specific prevalence of orthotics use shows demand rising steeply with age. However, it is important to recognise the often complex needs of orthotics users who are younger adults and children.</p> <p>Investment in orthotics and associated equipment services delivers high quality at low cost. Enabling people to remain independent in the community through the use of appropriate equipment is always preferable to admitting them for treatment into other parts of the healthcare system. Accordingly, commissioners will wish to have regard to the benefits to other parts of their commissioning responsibilities. For example, orthotics services are central to strategies to promote independence and prevent accidents. Standard Six of the NSF(OP) aims to reduce the number of falls which result in serious injury. Falls are a major cause of disability and the leading cause of mortality due to injury in older people aged over 75 in the UK.¹¹ Preventing falls in older people depends on identifying those most at risk of falling and co-ordinating appropriate preventative action.¹² Public Health strategies should aim to reduce the incidence and impact of falls.¹³ Over 400,000¹⁴ older people in England attend A&E departments following an accident¹⁵ and up to 14,000 people a year die in the UK as a result of an osteoporotic hip fracture.¹⁶</p> <p>Moreover, assistive technology has been demonstrated to be central to effective rehabilitation¹⁷; it improves quality of life¹⁸; it obviously enhances their life chances through education and employment; and it reduces morbidity at costs that are very low compared to other forms of healthcare¹⁹.</p>

¹¹ Health Education Authority (1999), Older People and Accidents; Fact Sheet 2. London: HEA.

¹² Nuffield Institute of Health and NHS Centre for Reviews and Dissemination (1996), Preventing falls and subsequent injury in older people. *Effective Healthcare Bulletin* 2(4), 1-16.

¹³ Health Education Authority (1998), *Accident Prevention among older people: approaches in practice, a series of case studies*. London: HEA.

¹⁴ O'Loughlin JL et al. 1993, Incidence of and risk factors for falls and injurious falls among the community dwelling elderly. *American Journal of Epidemiology*; 137:342-354.

¹⁵ DTI (1997), Home accident surveillance system data. London. DTI.

¹⁶ Melton LJ III 1988, Epidemiology of fractures. In Riggs BL and Melton LJ III (eds.) *Osteoporosis: Etiology, Diagnosis and Management*: 133-154. New York.

¹⁷ Enderby P et al , *Action Towards Improved Rehabilitation in Sheffield*, February 1998.

¹⁸ Ohlin, P et al *Technology Assisting disabled and Older People in Europe : The HEART Study.*: Swedish Handicap Institute for European Commission Directorate General XIII, *Stockholm*, 1995.

¹⁹ Mann W C et al , 'Effectiveness of Assistive Technology and Environmental Controls in Maintaining Independence and Reducing Home Care Costs for the Frail Elderly', *Archive of Family Medicine*, Vol. 8, May / June 1999.

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		<p>The NSF for Diabetes²⁰ (NSF(D) should be used as a means of justifying investment in orthotic services. The number of people developing diabetes is increasing. In England, the number of people with diabetes is predicted to rise dramatically – from 1.4 million to 3 million by 2010 because of the ageing population and increasing levels of obesity. The cost of diabetes treatment costs in excess of £2 billion a year. Hospital costs are six times higher for a person with diabetes than for a person without diabetes. Early intervention for foot problems can reduce amputations by two-thirds. As the introduction to the NSF(D) says, 'Targeted foot care for people at high risk could save hundreds of amputations a year.'</p> <p>Diabetes does not affect everyone in society equally. Significant inequalities exist in the risk of developing diabetes: those who are overweight, physically inactive or have a family history of diabetes are at increased risk. People of South Asian, African-Caribbean and Middle Eastern descent have a higher than average risk of Type 2 diabetes, as do poorer people. Socially excluded communities may risk receiving poorer quality care. Risk accumulates if people belong to more than one of these groups.</p> <p>Lower limb complications are common in people with diabetes. The cost to the NHS is high, with more occupied hospital bed days attributable to diabetic foot disease than any other diabetes-specific condition. These complications are associated with significant physical and psychological morbidity for people with diabetes. Approximately 25% of people with diabetes have clinically evident neuropathy, 20% have peripheral vascular disease and 5% have an active ulcer.^{21,22,23} The annual incidence of foot ulcers in people with diabetes is between 2% and 10% while the annual incidence of lower limb amputation is between 0.2% and 2.0% Foot ulceration, vascular insufficiency and neuropathic pain are the principle lower limb complications of diabetes and may result in amputation.</p> <p>Where systematic clinical review has been carried out, it often demonstrates the successful use of orthoses at low cost. For example, 15 per cent of people with diabetes will develop foot ulcers, leading to a loss of sensation, muscular control and pain. Untreated, these ulcers can have serious consequences. They are highly susceptible</p>
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- ²⁰ Department of Health, National Service Framework: Diabetes, Department of Health, 2002. <http://www.doh.gov.uk/nsf/diabetes.htm>.
- ²¹ Walters DP, et.al, The distribution and severity of diabetic foot disease: a community based study with comparison to a non-diabetic group. *Diabetes Medicine* 1992; 9:354-358.
- ²² Kumar S et.al. The prevalence of foot ulceration and its correlates in type 2 diabetes diabetic patients: a population-based study, *Diabetes Medicine* 1994; 11: 480-484.
- ²³ Neal HA, et.al. Diabetes in the Elderly, the Community Oxford Study. *Diabetes Medicine* 1989; 6: 608-613.
- ²⁴ Audit Commission, *First Assessment – A Review of District Nursing Services in England and Wales*, Audit Commission, 1998.
- ²⁵ Complications of Diabetes', *Effective Health Care*, University of York, Vol.5, No.4, August 1999.
- ²⁶ 'Improved Survival of the Diabetic Foot: The Role of the Specialised Foot Clinic', *Quarterly Journal of Medicine, New Series* 60, No. 232, August 1986, pp 763-771.
- ²⁷ Mc Cabe J et.al. Evaluation of a diabetic foot screening and protection programme. *Diabetes Medicine* 1998; 15: 80-84.
- ²⁸ Litzelman DK et.al. Reduction of lower extremity clinical abnormalities in patients with non-insulin-dependent diabetes mellitus. A randomised control trial. *Annals of International Medicine* 1993; 119: 36-41.
- ²⁹ Malone JM et.al. Prevention of amputation by diabetic education. *American Journal of Surgery* 1989; 158: 520-4.
- ³⁰ Mason J et.al. A systematic review of foot ulcer in patients with Type 2 diabetes mellitus. I: prevention. *Diabetic Medicine* 1999; 16: 801-812.
- ³¹ Uccioli L, et.al. Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care* 1995; 18: 1376:8.

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		<p>to infection, leading to amputation in between 5 and 15 per cent of cases. Foot ulcers are one of the most costly aspects of treating diabetes, putting a heavy load on community services²⁴. However, the problem can be reduced by providing orthoses. One study found that orthotic shoes could reduce ulcers in people at high risk (the relapse or new ulcer rate in one year was 28 per cent in the intervention group, compared with 58 per cent among those who continued to wear their own shoes ($p=0.009$)²⁵ and Box).</p> <p><i>Box</i> Clinical effectiveness in specialist centres</p> <p>There are specific cases that demonstrate the effectiveness of multidisciplinary teams. In particular, the involvement of orthotists in treatment of the diabetic foot has proven extremely effective.</p> <p>A study at King's College Hospital, London (Ref.²⁶), was based around a specialised foot clinic for diabetic patients who presented with foot ulcers and, from this, a new organised approach to treatment was derived. Over three years, it achieved a high rate of ulcer healing and reduced the number of major amputations.</p> <p>The clinic brought together the skills of the orthotist, chiropodist, nurse, physician and surgeon to manage the distinctive lesions of the neuropathic and ischaemic diabetic foot. Essential aspects of management were specially constructed shoes, intense chiropody and precise antibiotic treatment. Healing was achieved in 86 per cent of neuropathic ulcers and 72 per cent of ischaemic ulcers. The relapse rate in users with special shoes was 26 per cent, compared with 83 per cent of patients who continued to wear their own shoes.</p> <p>The effect on amputations was also marked. In the two years the clinic was established, there were 11 and 12 major amputations annually. Three years after the clinic opened, only five major amputations were carried out. Minor amputations in the same period dropped from 27 and 29 in the two previous years to 15 per year.</p> <p><i>Source: Audit Commission</i></p> <p>Diabetes is the second most common cause of lower limb amputation (after trauma). Damage to the nerves (diabetic neuropathy) supplying the lower limbs can lead to a loss of sensation in the feet, thereby predisposing to the development of foot ulcers. Ulcers are exacerbated by the reduced perception of pain and trauma inflicted by foreign bodies, walking and tightly fitting shoes.</p> <p>Foot ulceration and lower limb amputation can be reduced if people who have sensory neuropathy affecting their feet are identified and offered foot care education, podiatry and where required, protective footwear. Prompt treatment of foot ulcers can reduce the risk of amputation. A number of strategies have been found to be effective in preventing lower limb complications. One of the most effective approaches is to identify those at increased risk of lower limb complications, through regular surveillance of all people with diabetes, and refer those identified as being at increased risk of lower limb complications to a comprehensive foot service. In one study,</p>
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		<p>the amputation rate was reduced to 0.1% (compared to an amputation rate of 1.2% in those not offered screening) by identifying those with high risk feet and referring them to a comprehensive foot care programme providing education, podiatry and protective footwear.²⁷</p> <p>Another approach is to provide foot care education to people with diabetes and follow-up reminders of the importance of foot care, combined with reminders to health care professional to examine people's feet and to discuss foot care during consultations. In one study, such an approach resulted in significant reduction within one year of serious foot lesions.²⁸</p> <p>Foot care education has also been demonstrated to be effective in reducing the recurrence of foot ulcers and amputation in people who have already has a foot ulcer and/or amputation.²⁹</p> <p>When ulceration occurs, prompt intervention can minimise both short-term and long-term disability, including amputation.³⁰ Appropriate debridement and assessment for possible abscess formation or osteomyelitis is essential, as is an assessment of the blood supply to the ulcerated foot.</p> <p>The use of specially designed footwear made of soft leather and designed to accommodate custom-moulded insoles and any foot deformities, can also reduce ulcer recurrence rates in people with a history of previous neuropathic foot ulceration.³¹</p>
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Likely future developments for which commissioners need to prepare		
<i>Matters to address</i>	<i>Key issues to consider</i>	<i>AC comment on the issues</i>
Equipment developments	<ul style="list-style-type: none"> Planning for technological advances 	<p>Research into materials, science, ergonomics, and biomechanics is producing new techniques applicable to orthotics manufacture. These include the production of lightweight alloy and carbon fibre frames, pressure relieving systems and interfaces, wheel and castor design and postural mechanics. As a result, significantly improved orthoses are available.</p> <p>The development of greater use of computer aided design and manufacture (CAD/CAM) needs to be anticipated: in future, the core skills of the orthotist are increasingly likely to move away from leather working into the field of CAD/CAM technology. For example, the orthotics unit at Roehampton Rehabilitation Centre has equipment to design peoples' insoles.</p> <p>There is also local evidence of the benefits of orthotic services having access to gait laboratory facilities. Proper understanding of gait has the potential to prevent unnecessary hospitalisation and contribute to more effective outcomes from orthopaedic surgery. Rotherham District Hospital's service makes use of such facilities.</p>
Clinical audit, effectiveness and training	<ul style="list-style-type: none"> Commissioners need to provide guidelines for the involvement and education of professional staff. 	<p>Commissioners should require that all service staff are adequately qualified and have a programme for continuing professional development.</p> <p>Commissioners should also specify the need for providers to provide proper clinical audit and clinical effectiveness reviews.</p>

Strategy

Understanding the underlying level of demand in the community																							
Matters to address	Key issues to consider	AC comment on the issues																					
Current and forecast levels of service demands	<ul style="list-style-type: none"> Use of accurate data on the current levels of demand for the various types of equipment 	<p>Many orthotics services lack accurate information about their workload, impeding proper management. Few have an accurate picture of the:</p> <ul style="list-style-type: none"> numbers of active patients/users (equipment services need regular review to ensure that records reflect real patients with real needs); numbers on waiting lists; cross-boundary flows; use of smaller items of equipment – for example, cushions/seating components; and allocation of costs and overheads to each component part of the service. <p>Orthotics services should be commissioned using the following currencies (Box)</p> <table border="1"> <thead> <tr> <th>Level</th> <th>Orthosis type</th> <th>Assessing clinician</th> <th>Features of clinical service</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>Fabric wrist support Soft collars Temporary fabric back support</td> <td>Nurse Therapist</td> <td>Temporary support for acute injury for pain relief and / or minimal mechanical stabilisation. Nurse must have access to qualified orthotist to refer complex / difficult cases.</td> </tr> <tr> <td>B1</td> <td>Ready-made ankle foot orthosis Light fabric knee support</td> <td>Therapist</td> <td>Temporary orthoses can be fitted as part of a clinically managed rehabilitation plan. Therapist must have access to qualified orthotist to refer complex / difficult cases.</td> </tr> <tr> <td>B2</td> <td>Custom-made fabric support Hosiery</td> <td>Orthotist</td> <td>Simple orthoses to meet longer-term needs.</td> </tr> <tr> <td>C</td> <td>Ready-made and made-to-measure orthoses (includes management of patients with polio, stroke, diabetes and cerebral palsy)</td> <td>Orthotist</td> <td>Orthotist should work as part of a multi disciplinary team.</td> </tr> </tbody> </table>		Level	Orthosis type	Assessing clinician	Features of clinical service	A	Fabric wrist support Soft collars Temporary fabric back support	Nurse Therapist	Temporary support for acute injury for pain relief and / or minimal mechanical stabilisation. Nurse must have access to qualified orthotist to refer complex / difficult cases.	B1	Ready-made ankle foot orthosis Light fabric knee support	Therapist	Temporary orthoses can be fitted as part of a clinically managed rehabilitation plan. Therapist must have access to qualified orthotist to refer complex / difficult cases.	B2	Custom-made fabric support Hosiery	Orthotist	Simple orthoses to meet longer-term needs.	C	Ready-made and made-to-measure orthoses (includes management of patients with polio, stroke, diabetes and cerebral palsy)	Orthotist	Orthotist should work as part of a multi disciplinary team.
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		D	Specialised orthotics Complex biomechanical and medical conditions - for example, scoliosis bracing, paraplegic walking orthoses, special seating	Orthotist	Experienced multidisciplinary team, including medical member.
		Source: <i>British Society of Rehabilitation Medicine (Ref.³²)</i>			
Knowledge about the underlying level of need	<ul style="list-style-type: none"> Use of national and local public health data to identify need 	<p>Commissioners need to establish systems for the identification of unmet need. The Director of Public Health's annual report should be a useful source of information. There are broad prevalence data available to inform commissioning, but there is currently little use by commissioners of their own data on unmet need, or data from other local sources.</p> <p>Public health staff have a role in the effective commissioning of orthotics services. They provide clinical knowledge, as well as the ability to assess population needs and interpret information on the effectiveness of treatments.</p>			

³²

British Society of Rehabilitation Medicine, *From Surgical Appliances to Orthotics – Towards an Effective Service*, Working Party Report, June 1999.

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Service description		
Matters to address	Key issues to consider	AC comment on the issues
Service configuration	<ul style="list-style-type: none"> Integration of orthotics services with other assistive technology services and rehabilitation services 	<p>The reports <i>Fully Equipped</i> and <i>Assisting Independence</i> both proposed the development of a 'hub and spoke' arrangement across regions with specialist services at the centre supporting local services. The model of care has endorsement from Government and most professional organisations.</p> <p>Integration of community equipment services is an ideal time to consider the likely benefits of scale and service delivery that can be achieved by amalgamation of the orthotics service with other related services - there should be close links to enable the delivery of 'packages of equipment'.</p>
Service standards	<p>Commissioners should specify that the following minimum standards are achieved:</p> <ul style="list-style-type: none"> Waiting times Proportion of ready-made vs. made to measure orthoses Provision of technical support services Roles and responsibilities Procurement arrangements 	See performance indicators section below.
Risk management	<ul style="list-style-type: none"> Controls assurance standards (Appendix 1) 	<p>Orthoses services commonly fail to apply the DH's Controls Assurance Standards for Medical Devices to their equipment. DH guidance states that 'the term <i>medical device</i> covers a broad range of products, including those used every day for the treatment, or alleviation of an injury or handicap.' Orthoses services are clearly included in this definition.</p> <p>In addition, all NHS organisations are subject to legal and statutory requirements relating to 'the duty of care' that requires employers to provide competent and safe fellow employees, safe equipment and place of work, and a safe system of work.</p>
Information	<ul style="list-style-type: none"> Standard of information provided to service users 	<p>Commissioners should specify arrangements that provide information to service users at each step in the process from assessment to supply. Orthotics services need to provide information to users and carers in an accessible format, providing a helpline number (preferably a free-phone number.)</p> <p>Support and education should also be provided to develop 'expert' / established patients, not least to inform service development.</p>

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Statement of work to be performed		
<i>Matters to address</i>	<i>Key issues to consider</i>	<i>AC comment on the issues</i>
Duration of contract or service level agreement	<ul style="list-style-type: none"> Length of contracts or service level agreement 	<p>Best value is likely to be delivered by establishing long-term relationships with suppliers, albeit with appropriate break clauses that should be applied as necessary. Contracts of up to seven years have been established to good effect in other fields of assistive technology provision (for example, prosthetics) and the practice should be applied with orthotics services.</p> <p>Either party may terminate the contract even though the other party is not in default by giving six months written notice, or such other shorter period of notice as may be agreed between the parties. During the period of notice, both parties shall co-operate to ensure that the interests and needs of users may be met under whatever new arrangements are proposed.</p> <p>Orthotics services with in-house suppliers operating service level agreements are not in a contractual relationship in law but it is nevertheless valuable to place the arrangement on a quasi-legal footing with formal time periods for the relationship. This provides senior management with the opportunity to review the arrangement.</p>
Management of the SLA/contract	<ul style="list-style-type: none"> Meaningful data on patient numbers and throughput needs to be linked to actual performance 	<p>There is currently a marked absence of penalties under external contracts. There is an incentive for the contractor insofar as they won't be paid until they deliver, but there are few examples of contract penalties for failing to achieve performance standards.</p>
Range of orthoses	<ul style="list-style-type: none"> Commissioners need to establish a common range of standard equipment, agreed with service prescribers, with input from user representatives. 	<p>There is a difficult tension between the desire, on the one hand, to reduce costs by aggregating demand across a standardised equipment range; and, on the other hand, to meet users' demands for greater choice and variety of equipment. This tension is not clearly expressed or adequately resolved in many organisations.</p> <p>The establishment of a product selection group is a useful way to review and address service and budget performance and professional training.</p>
Records to be maintained	<ul style="list-style-type: none"> Patient records 	<p>Commissioning standards need to specify arrangements for maintaining documentation and complying with Caldicott standards on the confidentiality of patient records, especially where these are shared with social services/education department.</p> <p>Service providers should be required to maintain a database on behalf of commissioners which contains all client, staff and equipment data required operating the contract or service level agreement.</p>

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Hours of service	<ul style="list-style-type: none">• Opening hours	<p>Service contractors are commonly required to provide a daily Monday to Friday weekday service during the normal operational period of 0800-1700 hours; a call-out emergency service during the defined normal operational period; a call-out emergency service outside the defined normal operational period (including weekends and bank holidays).</p> <p>There should be a requirement that emergency repairs be dealt with within one working day.</p>
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Delivering the service

Method of working		
<i>Matters to address</i>	<i>Key issues to consider</i>	<i>AC comment on the issues</i>
Organisation	<ul style="list-style-type: none"> Organisational arrangements 	<p>The British Society of Rehabilitation Medicine is of the view that hub and spoke arrangements for the delivery of orthotics services is likely to offer the best combination of local delivery while centralising the necessary clinical expertise. Complex cases are to be referred for multi-disciplinary assessment at the hub of a hub-and-spoke model.</p> <p>Each spoke service should have:</p> <ul style="list-style-type: none"> A manager (usually the budget-holder) Orthotics therapists Rehabilitation engineers A nurse A therapy helper Access to a consultant in rehabilitation medicine Administrative staff <p>Each hub service should have:</p> <ul style="list-style-type: none"> Consultant in rehabilitation medicine Therapists Clinical bioengineer Orthotists Prosthetists Access to a consultant in orthopaedics A manager (usually the budget-holder) Orthotics therapists Rehabilitation engineers A nurse A therapy helper Administrative staff A trained counsellor

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	<ul style="list-style-type: none"> • Staff required to deliver the service 	<p>The number of staff employed is a matter for the provider of the services. Some will choose to buy-in orthotic services from private companies, others will provide services in-house. However, commissioners will wish to specify certain minimum competencies and skills.</p> <p>Commissioners should also encourage job-redesign or job-enlargement within the clinical team. For example, it is worth considering the opportunity to increase the role of podiatrists and chiropodists in orthotic work, especially where these staff can provide services to low risk patients in the community at foot-health and diabetic clinics. These issues of skill-mix and methods of working are currently under review as part of the DH's Action on Orthopaedics project, due for completion in Spring 2003.</p> <p>Staff at the hub should be led by a medical specialist and have full orthotic, physiotherapy, clinic co-ordinator and administrative support. Access to a gait analysis laboratory and bio-engineers is also needed. The hub should be integrated with a specialised regional/sub-regional rehabilitation centre incorporating the prosthetics and wheelchair service with workshops and cast rectification facilities, physiotherapy and occupational therapy departments, clinical and bio-engineering facilities.</p> <p>The throughput of patients is also a matter for providers but commissioners should be aware that appointments of less than 20 minutes are likely to offer a poor service, especially given the need to document the intervention.</p>
	<ul style="list-style-type: none"> • Access to services 	<p>Local orthotics services should remain necessary for patients who have routine clinical problems so as to avoid long journeys for patients who require simple assessments and treatments. Spoke services should be developed at PCT level. Patients with more complex needs can then be referred to a more specialised central clinic. Each spoke should have adequate clinic space for some storage for small, low-cost common use orthoses.</p> <p>Services should also consider the scope offered by telemedicine links to prevent the need for patients to travel long distances.</p>
Assessment	<ul style="list-style-type: none"> • Streamlining the assessment process to meet the national target on response times 	<p>Commissioning standards should specify the routes by which the user is referred into the service.</p> <p>Requests for the local orthotics service should be allowed from any health services, social services, or voluntary agency; and more services are encouraging self-referral.</p> <p>Direct booking should be offered.</p> <p>Direct GP access to an orthotist should be supported by commissioners.</p>
Facilities	<ul style="list-style-type: none"> • Secure, well ventilated and well organised facilities and a refurbishment workshop 	<p>The minimum facility should include consultation, casting and fitting rooms and a small workshop for minor repairs and adjustments. Waiting areas must be suited to the needs of the patients and reasonably close to toilets and facilities for disabled people. There is a special requirement for accommodation and service provision in those</p>

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		<p>centres providing an orthotics service for children, including appropriate waiting and play areas.</p> <p>Assessment environments should have adequate waiting areas including suitable toilets for people with disabilities and transfer techniques that comply with best practice in manual handling (HSE code of practice L23).</p> <p>The service contractor needs to make provision for a store and all the resources needed to undertake the full requirements of the contract, including a technical workshop.</p> <p>In awarding contracts, commissioners should be satisfied as to the contractor's standing in respect of:</p> <ul style="list-style-type: none"> - Control of Substances Hazardous to Health regulations - Health and Safety procedures under the Health and Safety at Work Regulations 1974 - Minimum standards and the management of equipment provision for Hospital and Community-based Organisations are set out in MDA DB 9801, January 1998. - quality control procedures, practice and training - ability and technical capacity - recruitment procedures (particularly character references of staff who will have direct contact with service users) - personnel procedures (particularly training) - customer care procedures
Procurement	<ul style="list-style-type: none"> • Commissioners need to specify that there shall be adequate standards for procurement: • Responsibility/arrangements for purchasing equipment needs to be specified in the contract 	<p>Commissioner specifications should require that:</p> <ul style="list-style-type: none"> • all equipment purchased meets the requirements of the Medical Devices Directive • there is feedback on supplier performance to the NHS Purchasing and Supplies Agency • there is feedback on adverse incidents to the Medical Devices Agency <p>The purchase of equipment should ideally be undertaken through a consortium of service providers or by using NHS PASA national contracts.</p>

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Stock and equipment	<ul style="list-style-type: none"> Commissioners need to specify a catalogue of equipment including the range, types and specification of standard equipment 	Stock should be maintained at levels sufficient to meet demand – this will vary over time and should be monitored on a regular basis.
Ordering and requisitions	<ul style="list-style-type: none"> Procedure for ordering/requisitioning equipment from store Time scales for delivery/collection 	<p>The service contract should include the requirement to provide a computer system to receive and process service demands, support stock control and accounting arrangements to the authority to a standard that satisfies audit requirements.</p> <p>Ideally, the system should offer an electronic catalogue, and the facility to order on-line</p>
Continuous improvement	<ul style="list-style-type: none"> The service specification needs to include provision for mutually beneficial service improvements. The service specification needs to include arrangements to monitor complaints 	<p>There should be an expectation in the contract or SLA that the orthotics service and the commissioner will work together to deliver incremental improvements to the service.</p> <p>The service specification needs to state whether the contractor or the authority will be responsible for the monitoring of complaints. In most circumstances, it will make sense for the authority to receive and monitor complaints, as a means of checking on performance under the contract.</p> <p>The service provider should be required to establish a system for incident and near miss reporting and monitoring that complies with (i) the Clinical Negligence Scheme for Trusts; and (ii) with Medical Devices Agency equipment hazard warnings and reporting systems. The service provider should also be required to review all equipment incidents in liaison with the commissioners or with, for example, the equipment professional advisory group.</p>
Sub-contracting	<ul style="list-style-type: none"> Arrangements for sub-contracting parts of the service 	Sub-contracting of any of the service provider's responsibilities should not be allowed without prior written consent of the other parties, except for the hiring of agency staff in cases of emergency and other planned absence.

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Performance management		
<i>Matters to address</i>	<i>Key issues to consider</i>	<i>AC comment on the issues</i>
Monitoring and reporting system / performance measures	<p>Specification of a range of key performance indicators, for example:</p> <ul style="list-style-type: none"> • activity levels/throughput • proportion of bespoke vs. ready made items • waiting time from referral to assessment • waiting time from assessment to order • waiting time from order to delivery / use • clinical effectiveness • regular management reports 	<p>Prescription of the orthosis</p> <p>Percentage referral forms containing adequate data.</p> <p>Services should acknowledge that they have received a referral – copy to the referer and to the user.</p> <p>The service user should be given a named contact.</p> <p>Target: Referral to clinical assessment: 80% seen in 30 days; and all in 50 days.</p> <p>Appropriateness of the prescription – all users should agree objectives of the intervention – target of 100% objectives achieved. Did the assessment meet the objectives? (This will need to be done through sampling.)</p> <p>The most effective NHS orthotics services are able to treat 90% of their users with ready-made footwear, rather than bespoke footwear.</p> <p>All service users/carers are to receive information about their orthosis.</p> <p>Full compliance with medical devices agency standards</p> <p>All users are to receive a placed on a tailored pathway of care with clinical review at three months.</p> <p>All equipment will be reviewed on the basis of planned maintenance programme.</p> <p>The number and proportion of users whose care deviates from the agreed pathway of care is to be reported and monitored.</p> <p>Regular audit is to be undertaken, measuring the number of people who report that they are comfortable in their orthosis.</p> <p>A multi-professional care plan is to be prepared for each individual, to reflect their own goals and objectives of care. The proportion of people who report that they have achieved their goals is to be reported.</p>

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		<p>Maintenance and repair standards are to meet the minimum standards set out in the DH Controls Assurance Framework for medical devices.</p> <p>Repair response times are to be agreed with providers, service commissioners and users' groups.</p> <p>The underlying level of unmet need and the eligibility criteria that will be applied are to be estimated with reference to local data for example, the annual report of the director of public health.</p> <p>Inappropriate referrals are to be monitored.</p>
User/carer satisfaction	<ul style="list-style-type: none"> • Undertaking surveys 	<p>The service provider should be required to interview service users and referrers in random samples, in order to gain their views on the service. One approach is to undertake a one-week every six months, of all clients delivered to and referrers placing orders. A written report on the outcome of the survey should be sent to commissioners.</p>
	<ul style="list-style-type: none"> • Dealing with and monitoring complaints 	<p>The service provider shall set out clear written procedures for dealing with the service users or their relatives', carers' or their advocates' complaints. These procedures should include but not be limited to, a written record of all complaints and action taken to deal with that complaint.</p> <p>If the service users or their relatives, carers or their advocates are not satisfied after following the service provider's procedure for dealing with complaints, the service provider must refer them to the commissioner of the service.</p>

Appendix 1 Controls Assurance Standards

All controls assurance standards conform to a common framework model for internal control. Of the 21 standards, the following have a direct influence on orthotics services:

Standard 8 Governance

The framework for all the standards, it aims to deliver assurance to stakeholders in relation to meeting an organisation's objectives. Assurance can be given with reference to independent assurance processes (internally and external) and achievement of satisfactory outcomes, or results.

Standard 9 Health and safety

Requires a managed environment which provides for the health, safety and welfare of patients, staff, visitors, contractors and all others who are affected by the activity of the organisation. Whilst most of this standard addresses occupational health and safety, the Health and Safety at Work Act covers non-employees, for example patients and visitors. Thus the spirit of the standard involves a commitment to public safety.

Standard 11 Infection control

Requires that there is a managed environment which minimises the risk of infection, to patients, staff and visitors. HSC 1999/049 (Infection Control) sets out the key activities that should be undertaken by all NHS organisations in respect of infection control.

Standard 13 Managing and purchasing supply

Requires there to be an environment whereby purchasing and supply activity is managed to meet the needs of the organisation through the consistent delivery of best value and the appropriate management of risk, and that it complies with relevant statutory requirements.

Standard 14 Medical equipment and devices management

Requires a system to be in place to minimise all risks associated with acquisition and use of medical devices. The term 'medical device' covers a broad range of products including those used every day in most health care settings and can be defined as any instrument, apparatus, appliance, material or healthcare product, excluding drugs, used by a patient or client.

Standard 16 Professional and product liability

Requires all goods and services, including professional advice, supplied by the organisation are properly managed to minimise potential liability risks.

Standard 17 Records Management

Requires a systematic and planned approach to managing records from the moment a record is created until its ultimate disposal. The organisation must be able to control both the quality and quantity of information it generates, can maintain that information in a manner that effectively services its needs and those of its stakeholders, and can dispose of the information appropriately when no longer required.

Standard 18 Risk management (core standard)

Requires a risk management system in place which conforms with the generic principles contained in the Australian Risk Management Standard AS/NZS 4360:1999 and meets NHS and other requirements in respect of managing risks, hazards, incidents, complaints and claims.

Standard 20 Transport:

Requires the organisation to demonstrate improvement in reducing environmental and other risks associated with transport.

Standard 21 Waste management:

Requires that segregation, handling, transport and disposal of waste is properly managed to minimise the risk to the health and safety of staff, patients, the public, and the environment. Unless properly managed, clinical waste can present significant risk to the health and safety of staff, patients, the public and the environment, and hence can pose potentially significant risk to the organisation.