

Guidance on the commissioning of prosthetics 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 in general terms, the prosthetics service was the most effective of the three mobility services (orthotics, wheelchair services and prosthetics). On the whole, prosthetics services usually had the clearest sense of organisational direction, reasonable management information and the necessary scale of operation. The report concluded that where prosthetics services were shown to be delivering high-quality services they should, wherever practically possible, be established as the hubs of a hub-and-spoke model. These larger centres should seek to become centres of excellence and develop university affiliations with access to academic and technical facilities. It went on to say that commissioners should specify services that drive such a reorganisation forward, taking full advantage of the opportunities afforded by information technology, telecare opportunities, and clinical networks.

2. Why is it necessary to improve prosthetics services?

The Audit Commission's report *Assisting Independence* identified the need to improve the commissioning of all assistive technology services, including prosthetics services. This guidance has been prepared to help address this shortcoming. It tries to describe how prosthetics services should be commissioned as part of wider strategies to support independence.³ It is hoped that this guidance will also be relevant to service providers and users, and applied in the absence of locally agreed standards. It is also 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 business cases to support the improvement of prosthetics services.

There is currently some uncertainty as to how prosthetics services should be commissioned, whether by individual PCTs or as a specialist service. In view of the small number of prosthetics users, the best approach is likely to be as a specialist service. The National Specialised Services Definitions Set states that prosthetics should be commissioned as a specialist service (Box).

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 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.

Box

National Specialised Services Definitions Set: Prosthetics

All aspects of care provided to people with a congenital limb deficiency or who have had amputation of a limb (or limbs) with the exclusion of the surgical episode, should be regarded as specialised. Close links between the surgical team and specialist rehabilitation team should be established pre-operatively to ensure the best outcome. Contact with the service is typically lifelong.

Source: Department of Health

The service offers specialist assessment and review; prescription, provision and maintenance of prosthetic limbs and also a rehabilitation facility for more complex cases. The multi-disciplinary team includes a Consultant in Rehabilitation Medicine (CRM) with a special interest in prosthetics, prosthetists, specialist therapists and nurses, clinical counsellors and engineering personnel.

3. Structure of the guidance

The structure of the guidance is:

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

- Overall objectives
- How prosthetics services contribute to wider healthcare objectives
- Health economics arguments
- 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		
Matters to address	Key issues to consider	AC comment on the issues
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 prosthetics service is to:</p> <ul style="list-style-type: none"> provide suitable prostheses for all people who have lost a limb or part of a limb; provide a comprehensive service that includes consideration of comfort, posture, function, pressure relief and cosmesis; fit, maintain and repair artificial limbs in a responsive, rapid and effective manner; respond to changing medical and social needs of prosthetics users with provision of new artificial limbs when necessary. <p>Artificial limbs range from highly sophisticated pieces of equipment with integrated micro-technology to basic cosmetic limbs for occasional use. 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 the type, volume and quality of existing services the gap between (ii) and (iii); and plans to fill the gap using information to monitor progress in delivering commissioning objectives
	<ul style="list-style-type: none"> Commissioning care pathways 	<p>Prosthetics services need to be commissioned around care pathways, which describe an agreed and explicit route that a service user takes. For people requiring amputation, their rehabilitation can be optimised through the provision of care by integrated, multi-disciplinary, rehabilitation, prosthetic and social support teams. 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 (Appendix 1).</p>
	<ul style="list-style-type: none"> Meeting the requirements and standards of the NHS Plan and NSF for Older People and supporting the wider independence agenda 	<p>The NSF for Older People also specifies that commissioners must have established an integrated falls prevention strategy by April 2005: the users of artificial lower limb are one group at possible risk. The majority of users are in the latter category and are usually over age 65.</p>

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<p>Provision of services</p>	<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 60% of prosthetics services are currently running user groups.</p> <p>Commissioners must engage users in planning and specification of local prosthetics 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.</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 prosthetics services into wider rehabilitation services 	<p>The commissioning philosophy should be informed by an understanding of the needs of the service user and the considerable significance the typical user will attach to their prosthesis as essential to their independence. A prosthetic limb is an indispensable piece of equipment, making the difference between dependence and a reasonable quality of life: it is not simply a prescription item. Commissioning standards should reflect this.</p>

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Longer term considerations	<ul style="list-style-type: none"> Financial planning 	Commissioning decisions are made annually through the local delivery plan but 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 likely future demand for the prosthetics service. The increasingly elderly population will create demands for prosthetic services. The majority of service users are people whose amputations are due to peripheral vascular disease, and have other medical conditions, such as diabetes mellitus, cardiac failure or respiratory problems. The number of amputees is declining and is estimated to be about 60,000.⁴ However, there may be future pressure from the increasing incidence of diabetes.</p> <p>The demand for prosthetics 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 Improvements in access including public transport and air-travel for disabled people Changing attitudes towards, and increased acceptance of, disability by the general public Greater expectations of prosthetics users
	<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.⁵</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.⁶</p>
Choice	<ul style="list-style-type: none"> Providing individuals with choice 	<p>Commissioning policy should reflect The National Service Framework for Older People (Ref.⁷). 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 prosthetics than have typically be supplied in the past.</p>

⁴ Department of Health and College of Occupational Therapists, *National Prosthetic and Wheelchair Services Report*, Department of Health, 1997.

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

⁶ HM Government, *Caring about Carers – A National Strategy for Carers*, 1999, The Stationery Office

⁷ Department of Health, *National Service Framework for Older People*, 2001

How prosthetics 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 prosthetics services to other health and social care priorities 	<p>Prosthetics service provision should be explicitly linked to the strategic aims of other key national/local policies/strategies, such as accident prevention and independence.</p> <p>Commissioners should also require prosthetics service providers to demonstrate work on clinical audit and clinical effectiveness, particularly around the issue of 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 wheelchair services: for example, social services, housing, education and the wider voluntary sector, including Independent Living Centres.</p>

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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 prosthetics services	<ul style="list-style-type: none"> Implications of not meeting current demand, for example the impact on community care policies and institutional care 	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 prosthetics use shows demand rising with age. However, it is important to recognise the often complex needs of prosthetics users who are younger adults and children.
Wider contribution to health and social care	<ul style="list-style-type: none"> Systematic re-assessment 	<i>Fully Equipped</i> argued that prosthetics 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 reviews should be consistent with the user's needs.
	<ul style="list-style-type: none"> Supporting independence 	<p>The additional cost of good hardware should be balanced against the better quality of life and decreased dependence for the users. When seen as a total package of care, it represents a good investment that improves mobility, independence, development in children and improves quality of life for users and their families.</p> <p>Younger prosthetics users are most likely to have changing equipment needs. Children will have a lifelong need for the highest quality of care.</p>

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 the introduction of technological improvements 	<p>Research into materials, science, ergonomics, and biomechanics is producing new techniques applicable to prosthetics manufacture. These include the production of lightweight alloy and carbon fibre frames, pressure relieving systems and interfaces. As a result, significantly improved artificial limbs are now available.</p> <p>In recent years, technical innovations have combined to make artificial limbs much more comfortable, efficient, and lifelike. Future innovations are likely to depend on the interaction between three powerful forces: amputees' demands, advances in surgery and engineering, and healthcare funding sufficient to sustain development and application of technological solutions.</p> <p>In the UK, the main cause of lower limb amputation is circulatory dysfunction. The prime reason for this is atherosclerosis, although up to a third of patients have concomitant diabetes. These people are usually in their sixties (or older), and most have additional health problems that limit their walking ability. In the United Kingdom there are about 5,000 new major amputations a year.⁸</p> <p>Prosthetic technology has advanced to a remarkable degree in the past two decades, driven largely by amputees' demand. Today, otherwise healthy individuals with mid-calf amputation should be able to participate in a full range of normal responsibilities, to walk without any perceptible limp, and to engage in recreational and sports activities.</p> <p>There are several developments that are predicted in prosthetic services.⁹</p> <ul style="list-style-type: none"> ▪ Direct skeletal attachment (osseointegration) of prostheses may be a routine option for some amputees ▪ Amputee demand for more versatile, higher performance prostheses with more lifelike external coverings will fuel further innovation ▪ The use of prostheses controlled by microprocessors to allow finely tuned movement will increase ▪ Future use of new prosthetic components is liable to be controlled by funding constraints in both developed and developing countries <p>Several decades ago, the Swedish physician Per Branemark developed a surgical technique to permanently</p>

⁸ *The amputee statistical database for the United Kingdom 1998/99*. Edinburgh: ISD Publications, 2000.

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		<p>anchor false teeth into the jaw. His methods are now accepted worldwide as a routine method of dental restoration. In the past few years he has turned his attention to achieving similar results for upper and lower limb amputees and has generated similar controversy¹⁰. Preliminary results, and enthusiastic feedback from participating amputees, justify further exploration of this technique.</p> <p>If these prostheses prove successful long term (at least 10 years) direct attachment of an artificial limb to the skeleton may avoid difficulties inherent in creating custom-designed prosthetic sockets, where fitting comfort depends on volumetric matching to the amputation stump. Being a dynamic organ, the stump tends to shrink over time, though it may also swell with heat or weight gain, which can lead to chafing. With osseointegration, the prosthesis fit is unaffected by such volume changes.</p> <p>Innovative technologies will continue to be adapted from the aerospace and computer industries and applied to high performance artificial limbs whose function will more and more closely approximate to the missing limb.</p> <p>Initially, prosthetic innovations are often used sparingly, primarily by amputees with private funding particularly those who are competitive athletes. As experience is gained, manufacturers discover how to apply the same principles to moderate cost devices intended for less active individuals, and the performance of prostheses in general will gradually improve as a result.</p> <p>There is evidence that energy-storing prosthetic feet will reduce wear and tear on hips, thus reducing the incidence of hip replacements.</p>
	<ul style="list-style-type: none"> • Providing more choice to users 	<p>The increasingly older population will have an impact on demand for prosthetics services. Pressures on the service will also grow from implementing the stated government policy of providing more choice to users of the service.</p>
<p>Clinical audit, effectiveness and training</p>	<ul style="list-style-type: none"> • Commissioners need to provide guidelines for the involvement and education of professional staff 	<p>Commissioners should specify the need for providers to provide proper clinical audit and clinical effectiveness reviews. Particular attention should be paid to user satisfaction and the risk of developing sores at the point of fitting.</p> <p>Commissioners should also require that all service staff are adequately qualified and have a programme for continuing professional development.</p>

⁹ Marks LJ, Michael JW, Clinical review - Science, medicine, and the future - Artificial limbs, *BMJ* 2001;323:732-735 (29 September).

¹⁰ Lundborg G, Branemark P-I, Rosen B. Osseointegrated thumb prostheses: a concept for fixation of digit prosthetic devices. *J Hand Surg* 1996; 21A: 216-221.

Strategy

Understanding the underlying level of demand in the community		
<i>Matters to address</i>	<i>Key issues to consider</i>	<i>AC comment on the issues</i>
Current and projected levels of demand	<ul style="list-style-type: none"> Use of accurate data on the current levels of demand for the various types of equipment 	<p>Many prosthetics services lack accurate information about their workload, impeding proper management. They need to 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; and allocation of costs and overheads to each component part of the service.
Knowledge about the underlying level of need	<ul style="list-style-type: none"> Use of national and local public health data 	<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. Community Care Plans tend to rely heavily on broad prevalence data 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 prosthetics services. They provide clinical knowledge, as well as the ability to assess population needs and interpret information on the effectiveness of treatments.</p>

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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 prosthetics 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, though there is a continuing debate about what 'hub and spoke' actually means: there are several alternatives discussed in the introduction to this guidance.</p> <p>The hubs of the service need to provide services for initial assessment, advice on upper limb amputations and children; spokes should carry out day to day treatment to save disruption to education, employment and family life.</p> <p>The opportunities afforded by telemedicine should also be considered as a means of reducing the need for service users to travel long distances.</p>
Service standards	<ul style="list-style-type: none"> Assessment process 	<p>The service user and, where appropriate, his or her carers or enablers, must be fully consulted and meaningfully involved throughout the assessment process. Assessors must arrive at optimum recommended solutions to needs. Inability to provide must not be presumed, for whatever reason, and must not compromise or diminish the optimum assessment of what the clinical and lifestyle needs of the applicant require.</p> <p>Commissioners will wish to state that the least expensive solution should be prescribed provided that it will meet the service user's assessed clinical and lifestyle needs.</p>
	<ul style="list-style-type: none"> Waiting times 	Waiting times for each process should be set and monitored by commissioners and user groups.
	<ul style="list-style-type: none"> Provision of technical support services 	The provision of technical services can contribute to the overall cost and efficiency of the equipment service, for example, servicing and maintenance of equipment / equipment and electrical testing.
	<ul style="list-style-type: none"> Review, maintenance and inspections 	An annual review should be commissioned as a minimum standard, or as agreed with local user groups.
	<ul style="list-style-type: none"> Procurement arrangements 	Services should be tendered using the NHS PASA model contract

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Risk management	<ul style="list-style-type: none"> Health and safety 	<p>Commissioners should specify that prosthetics services must comply with manual handling regulations and with the Health and Safety at Work Act (HASAWA) 1974. These require that all equipment, including that in people's homes, must be checked regularly. However, hardly any services have made any provision for the significant costs involved in terms of staff time and vehicles, in implementing such procedures.</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>
	<ul style="list-style-type: none"> Controls assurance standards 	<p>Prosthetics services need 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.' Wheelchairs services are clearly included in this definition.</p>
	<ul style="list-style-type: none"> Device management procedures 	<p>There is also a general absence of device management procedures that included policies for the purchase, acceptance, decontamination, maintenance, repair, monitoring and replacement of prosthetics, and for the training of users and staff. Equipment purchasers and providers need to develop and implement suitable device management procedures to ensure that whenever equipment is used, it should be:</p> <ul style="list-style-type: none"> - suitable for its intended purpose; - properly understood by the professional user; and - maintained in a safe and reliable condition. <p>In addition to these concerns, commissioners need to specify the need for:</p> <ul style="list-style-type: none"> - planned preventative maintenance that follows manufacturer's guidance; and - adequate facilities and working conditions.
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.</p> <p>Information about the artificial limb and the clinical and technical support is important. Manufacturers usually provide information about the artificial limb to users, but in many cases the tone tends to be rather technical and legalistic. Prosthetics 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 should also be provided to develop the knowledge of 'expert' / established patients. They should also be engaged in service design and review.</p>

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Statement of work to be performed		
Matters to address	Key issues to consider	AC comment on the issues
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 some prosthetics 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>Prosthetics 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"> Penalties under the contract 	There is currently a marked absence of penalties under external contracts with few examples of contract penalties for failing to achieve performance standards.
Range of equipment / standardisation	<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. 	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.
Roles and responsibilities	<ul style="list-style-type: none"> Specifying clear roles and responsibilities 	<p>Commissioning standards need to specify arrangements for:</p> <ul style="list-style-type: none"> Assessment Authority to place orders/requisition equipment Installation of the equipment (where appropriate) Instructions for use of the equipment
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,</p>

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		staff and equipment data required operating the contract or service level agreement.
Hours of service	<ul style="list-style-type: none"> Access to the service 	<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 requests be dealt with within one working day and, if possible and depending on clinical need (for example, if a person depends on his or her prosthesis/es for independence, the ability to get to work or picking children up from school), on the same day. This is particularly important for prostheses users, given that most do not have a spare.¹¹</p>

¹¹ The British Limbless Ex-Service Men's Association has drawn to the attention of the Audit Commission that Ex-Service personnel who have lost a limb are entitled to a second or spare artificial limb. Further information can be obtained from www.blesma@btconnect.com

Delivering the service

Method of working		
Matters to address	Key issues to consider	AC comment on the issues
Resources	<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. However, commissioners will wish to specify certain minimum competencies and skills.</p> <p>The British Society of Rehabilitation Medicine is of the view that hub and spoke arrangements for the delivery of wheelchair 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) Prosthetist 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 Prosthetist Therapists Clinical bioengineer Orthotists Prosthetists Access to a consultant in orthopaedics A manager (usually the budget-holder) Wheelchair therapists Rehabilitation engineers A nurse

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		<ul style="list-style-type: none"> ▪ A therapy helper ▪ Administrative staff ▪ A trained counsellor <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 rehabilitation engineers in therapy work and vice-versa.</p>
	<ul style="list-style-type: none"> • Arrangements for upper limb services 	<p>Upper limb amputees are very few. The age spread is much wider, ranging from new born babies with congenital limb deficiency. Service users will usually have normal life-expectancy and will therefore require life-time use of the service. The fitting and training in the use of upper limbs requires great skill – local services are unlikely to have the critical mass to support these services.</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>Flexible appointments should be offered.</p> <p>Provision should be made for home assessment or school assessment if appropriate.</p>
Facilities	<ul style="list-style-type: none"> • Secure, well ventilated and well organised workshop facilities 	<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 and custom-designed cleaning facilities.</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

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Procurement	<ul style="list-style-type: none"> Commissioners need to specify that there shall be adequate standards for procurement 	<p>Commissioner specifications should require that:</p> <ul style="list-style-type: none"> all equipment used 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 be undertaken through using NHS PASA national contracts.</p>
Continuous improvement	<ul style="list-style-type: none"> The service specification needs to include provision for mutually beneficial service improvements 	<p>There should be an expectation in the contract or SLA that the prosthetics service and the authority 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 	<p>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.</p>

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Performance management																
Matters to address	Key issues to consider	AC comment on the issues														
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 • 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>The <i>emPOWER</i> charter includes some recognised good practice standards for prosthetics services:</p> <ul style="list-style-type: none"> ▪ New prostheses / orthoses are to be delivered in 21 days after the initial clinic assessment ▪ Emergency repairs in 1 working day ▪ Waiting times for (non-emergency) appointments in not more than 21 days ▪ Items of special clothing (for example, stump socks) are to be provided ▪ 10 days continuing professional development for all prosthetists each year ▪ No more than an average of 5 patients per session ▪ provide alternative aids to daily living and independence where the user is unable to wear an orthosis or prosthesis. <p>The following fitting and delivery times should be specified:</p> <table style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: center;">Fitting</th> <th style="text-align: center;">Delivery</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">First Fitting</td> <td style="text-align: center;">Working Day 1</td> </tr> <tr> <td style="text-align: center;">Second Fitting and Test</td> <td style="text-align: center;">Working Day 3</td> </tr> <tr> <td style="text-align: center;">Final Fitting and Acceptance</td> <td style="text-align: center;">Working Day 7</td> </tr> </tbody> </table> <p>The following repairs and maintenance times should be specified:</p> <table style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: center;">Fitting</th> <th style="text-align: center;">Delivery</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">For service user in employment or education</td> <td style="text-align: center;">Same or Following Day of Request</td> </tr> <tr> <td style="text-align: center;">For service user not in employment or education</td> <td style="text-align: center;">Within 7 Working Days of Request</td> </tr> </tbody> </table> <p>Delivery times for the supply and repair of modular and conventional limbs (standard and priority times), from the date of order to the date of delivery (excluding delays outside of the control of the DSC or its prosthetic contractor) vary according to type of prosthesis and are available on request from the DSC.</p> <p><i>From fitting to independence / stabilisation</i></p>	Fitting	Delivery	First Fitting	Working Day 1	Second Fitting and Test	Working Day 3	Final Fitting and Acceptance	Working Day 7	Fitting	Delivery	For service user in employment or education	Same or Following Day of Request	For service user not in employment or education	Within 7 Working Days of Request
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For service user not in employment or education	Within 7 Working Days of Request															

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		<p>The number of visits for a primary patient to achieve a satisfactorily fitting limb will not normally exceed four from the time it is decided to supply a prosthesis (assessment/ cast/measurement, two fittings, delivery). This will apply to standard prescriptions. Unusual or special prescriptions may involve more visits. The DSC will provide statistics relating to visits required for provision of prostheses.</p> <p>For repairs</p> <p>All patients experiencing problems with their prostheses will be offered an appointment to be seen at the centre within five working days. This will be monitored through periodic sampling over at least 4 weeks per year.</p> <p>The waiting time for an appointment for emergency repairs at the Disablement Services Centre (DSC) will be no longer than 1 working day. This will be monitored through periodic sampling over at least 4 weeks per year.</p> <p>If a patient has previously made an appointment, emergency repairs will be carried out at the DSC on the day of the visit, dependent on the complexity of the repair. This will be monitored through periodic sampling over at least 4 weeks per year.</p> <p>Throughput</p> <p>The Disablement Services Centre shall provide the following statistics, for contract monitoring purposes on a quarterly basis.</p> <ul style="list-style-type: none">i. Number of new prostheses suppliedii. Number of repairs undertakeniii. Number of primary referralsiv. Number of primary referrals issued prosthesesv. Number of limb issues within contract timesvi. Number of limb repairs within contract times <p>Delivery and maintenance of the prosthesis</p> <p>Full compliance with medical devices agency standards</p> <p>All users are to receive a place on a tailored pathway of care with clinical review at three months.</p> <p>All equipment will be reviewed on the basis of a 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</p>
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		<p>monitored.</p> <p>Regular audit is to be undertaken, measuring the number of people who report that they are comfortable in their chair.</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> <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>
User/carer satisfaction	<ul style="list-style-type: none"> • Undertaking satisfaction 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> <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

KEY STAGES OF CARE FOR AMPUTEES

Stage	Stage description	Who involved?	Outcome(s) for audit purposes	Pertinent issues to be addressed
1	Initial consideration of amputation Contra-lateral limb care Provision of initial information and advice to patient	Patient Surgeon Chiropodist / Podiatrist Specialist Rehab Team Peer support, Charitable Organisations	Agreed optimal level of amputation, if needed Agreed documented potential outcomes, and care options. Plan of rehab process Well informed patient with realistic expectations. (audio tape record of discussions for patients future reference)	What access does the patient have to assessment by Specialist Rehab Team?
2	Phase 1 detailed assessment Gather information on patient circumstances, possibly by questionnaire and access visit (home), covering medical, physical, occupational, social and psychological issues. Provision of more detailed advice to patient after assessment. Offer of counselling services (where appropriate)	Patient Local DGH Social Services Dept (SSD) Specialist Rehabilitation Centre	Comprehensive knowledge base on patient. Review of rehabilitation plan. Well informed patient with realistic expectations. (audio tape record of discussions for patient's future reference.) Effective care co-ordination	Does the patient receive appropriate information and access to support worker/advocate? Does the patient have an appropriate timely rehabilitation assessment for present and future needs? Is there access to specialist counselling services ?
3	Discharge planning Consideration of equipment provision	Patient Rehab team Social services team	Initial discharge plan	Is discharge planning being carried out?
4	Pre-op physical improvement Pain relief, for example, epidural	Patient, Doctors Physiotherapists, nurses	Fitter patient and pain free.	

5	Amputation (Reconstructive surgery)	Experienced surgeon with awareness of rehab implications including limb components.	Appropriate amputation level Optimally functioning residual limb	Is there an awareness of implications of the amputation for rehabilitation by the surgical team? - selection of the appropriate amputation level
6	Phase 2 assessment and initial rehab. Complete stages 2 & 3. Stump protection / environment Assess for personal wheelchair. Early walking aids Home visit to patient to check discharge plan.	Patient, Nurses, Physiotherapists, Social Services, Occupational Therapist, Specialist rehabilitation team,	Review of rehab plan Basic independence for patient (safety, transfers) Final discharge plan	Has the rehabilitation / discharge plan been reviewed post amputation?
7	Cessation of acute intervention Equipment intervention (and other for example, crutches wheelchairs)	Patient Specialist rehab team	Seamless transfer from acute to out-patient and community services	What factors affect delay in discharge? Is there continuity of care with reference to seamless transfer?
8	Continuing care and review	All teams	Social integration Appropriate equipment provision including review of new technologies and components Full access to Specialist Rehab team	
9	Appropriate Prosthesis provision, education and continuing care	Patient Physiotherapist	Stabilisation of condition Planned outcomes achieved Management of anatomical changes	Are planned outcomes achieved? Are there any prosthetic prescription guidelines?

Source: Prosthetic Strategic Supplies Group

Appendix 2 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 prosthetics services:

Standard 3 Decontamination of reusable medical equipment

Requires a system to be in place which requires that all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are adequately managed.

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

Appendices

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.