The influence of standards and clinical guidelines on prosthetic and orthotic service quality: a scoping review

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Abstract

Standards and guidelines are an integral part of prosthetic and orthotic service delivery in the developed world underpinned by an assumption that they lead to improved services. Implementing them has a cost, however, and that cost needs to be justified, particularly in resource limited environments. This scoping review thus asks the question, "*What is the evidence of the impact of standards and guidelines on service delivery outcomes in prosthetics and orthotics*?"

A structured search of three electronic databases (Medline, Scopus and Web of Science) followed by manual searching of title, abstract and full-text, yielded 29 articles. Four categories of papers were identified: *Descriptions and Commentaries* (17 papers), *Guideline Development* (7), *Guideline Testing* (2) and *Standards implementation* (3).

No articles were explicitly designed to assess the impact of standards and guidelines on service delivery outcomes in prosthetics and orthotics. Studies tended to be commentaries on or descriptions of guideline development, testing or implementation of standards. The literature is not sufficiently well developed to warrant the cost and effort of a systematic review. Future primary research should seek to demonstrate if and how guidelines and standards improve the outcomes for people that require prostheses, orthoses and other assistive devices.

Keywords (MeSH)

Orthotic devices, Prostheses and Implants, Standards

Introduction

Prosthetic and orthotic services in developed countries are now delivered under a range of formal and informal regulation. This can be broadly divided into *standards* which have some legal or quasi-legal status and clinical *guidelines* (sometimes called recommendations) which are essentially advisory. Whilst these terms will be used in this sense in this paper it is acknowledged that there is some overlap in common usage and that the boundary between a legal requirement and an advisory recommendation is often not clearly defined.

There has been a long history of development of national and international standards in the field of prosthetics and orthotics led by a number of different organisations. The International Standards Organisation (ISO) *Technical Committee on Prosthetics and Orthotics (ISO/TC 168)* has operated since 1977 and currently includes 15 participating and 18 observing countries. The Committee aims to provide "*criteria against which to design new products*" leading to "*safe reliable products*" [1]. The Committee focuses on two areas: "*a system of nomenclature and terminology to allow parties involved in the prosthetic/orthotic treatment of persons with physical disabilities to apply a standard terminology*" and "*a system of test methods for the verification of the essential requirements on prosthetic/orthotic devices related to the safety of the users*". The Committee is now responsible for 17 standards, several include multiple parts (Table 1).

As well as specific standards for devices, there is an increasing emphasis on quality management or quality assurance standards for manufacturing processes. In the year 2000, the International Society for Prosthetics and Orthotics (ISPO) held a workshop that produced detailed recommendations on *Quality Management in Prosthetics and Orthotics* [2]. Whilst important at the time, most of these have been superseded in developed nations by more general national and international requirements for quality management across all industries. For example, the ISO 9000 family of standards were

designed to ensure that manufactures meet statutory and regulatory requirements with ISO 9001 outlining the requirements they must fulfil. Prosthetic and orthotic devices are classified as medical devices which are covered by more specific standards. *ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes* is harmonised with ISO 9001 but without the requirements to demonstrate continual improvement or consider customer satisfaction. *ISO 14971 Medical devices – applications of risk management to medical devices* establishes the detailed requirements for risk assessment required by ISO 13485.

A number of jurisdictions impose legal standards on either prosthetic and orthotic devices or the services responsible for delivering these. In the European Union, for example, most prosthetic components and devices are classified as *custom made* or *class I medical devices* (low risk) and are therefore subject to the provisions of the Medical Devices Directive (MDD) [3]. Manufacturers are required to work to international standards that have been harmonised with the MDD (e.g. ISO 14971 and 13485). While manufacturers must register with a *competent authority* this is essentially a self-certification scheme with little external oversight. While this example is specific to the European Union, similar legislative frameworks exist in other countries (e.g. United States Food and Drug Administration, [4]).

In some countries additional requirements are imposed by purchasing regulations; particularly where services are paid for directly or indirectly through state or private health insurance schemes. In the United States for example, orthotic and prosthetic devices supplied wholly or partly to Medicare must conform to the *Durable Medical Equipment, Prosthetics/Orthotics and Supplies* (DMEPOS) legislation. This requires suppliers to conform to the Medicare program's supplier standards and quality standards [5] and to be accredited by one of 10 national accreditation organisations approved by the Centres for Medicare and Medicaid Services.

Clinical guidelines for prosthetic and orthotic service delivery have been published by a wide range of organisations (Table 2). ISPO has convened a series of consensus conferences focussing on different conditions, resulting in guidelines for prosthetic and orthotic management including: *Orthotic Management of Stroke* (2003, [6]), *Appropriate Lower Limb Orthotics for Developing Countries* (2006, [7]) and *Cerebral Palsy* (2008, [8]). Public and private healthcare providers often publish clinical practice or user management guidelines. Examples include those produced by: the NHS in the UK [9, 10], the Veterans Administration of the US Department of Defence [11], Anthem, a leading private provider of healthcare in the US [12, 13, 14, 15] and RSL Steeper, a British based prosthetic and orthotic service provider [16]. The International Committee of the Red Cross (ICRC) has produced a series of manufacturing guidelines for a range of prostheses and orthoses, primarily for use in resource limited environments [17, 18, 19, 20, 21, 22, 23, 24]. Some professional associations, such as the British Association of Prosthetists and Orthotists [25], also produce statements of best practice.

Guidelines relevant to prosthetics and orthotics are found within a broad range of documents, many not easily identified as guidelines at first glance. For example, guidelines have been developed by professional associations in related disciplines such as the American College of Foot and Ankle Orthopedics and Medicine [26] and the (UK) College of Occupational Therapists [27, 28]. Recent Dutch guidelines for amputation and prosthetic care were prepared by a consortium of professional bodies [29, 30]. Academic institutions and charities, such as Muscular Dystrophy UK [e.g. 31], are also occasional sources. Some systematic reviews, such as those published by the Cochrane Collaboration, include clinical guidelines [32]. A range of guidelines have also been developed by individual hospitals for their own use.

Given the number of guidelines and standards that have been developed over the last 40 years by organisations all over the world (Table 2), it seems reasonable to assume that these documents lead to improvements in clinical service delivery. The establishment of bodies such as the National Institute for Clinical Excellence in the UK is based on the assumption that this is the case. There is a much wider international movement towards the standardisation and regulation of procedures and practices across the whole spectrum of business activities. Considerable resources, particularly the time of highly experienced clinicians, are devoted to developing these guidelines as illustrated by a number of papers reporting on the guideline development process [9, 29, 33, 34].

Given the effort of producing and implementing standards and guidelines, it would be helpful to know whether these have led to benefits in healthcare outcomes for patients. This could be particularly important for services in low and middle income countries which tend to be less subject to such standardisation and regulation (except perhaps where these are delivered in association with international organisations such as the International Committee of the Red Cross). There may be considerable costs associated with moving to a more standardised approach and it would be useful to have a better understanding of the healthcare benefits in order to justify the expenditure of scarce resources.

A preliminary search of the literature suggested very few papers addressing these issues and it was thus decided to perform a *scoping* review to map the evidence in the scientific literature relating to the impact of standards, guidelines and recommendations on prosthetic and orthotic practice focussing on the specific question, *What is the evidence of the impact of standards and guidelines on service delivery outcomes in prosthetics and orthotics*?

Methods

The scoping review will follow the method proposed by Armstrong et al. [35] on behalf of the Cochrane Collaboration. Articles were searched for using three electronic databases considered most likely to contain records of relevant literature: Medline (accessed through OVID), Scopus and Web of Science. These database were searched using a combination of search terms and synonyms as part of a title, abstract and keyword search (Table 3). The search was limited to the last twenty years (1995-2015 inclusive) given the relatively recent adoption of standards and guidelines in prosthetics and orthotics. To improve the precision of the yield, articles relate to internal prostheses (e.g., dental or hip implants) were excluded as part of a specific search for this literature (Table 3). An exhaustive review of the grey literature was not conducted but where relevant material was known of in advance or encountered during the process of conducting the research this was included. Search results were exported into in a single Endnote® database (Thomson Reuters, Philadelphia, USA) and duplicates removed.

In a scoping review inclusion criteria are often quite broad [35]. Articles were included if they provided some evidence or opinion on the impact of standards or guidelines on service delivery outcomes in prosthetics and orthotics. To ensure all relevant papers were included, more specific restrictions were not applied (e.g., on the basis of level evidence, study design or outcome measures). No restrictions were placed on language (although it is acknowledged that the search strategy is unlikely to yield many articles written in languages other than English). Given that the research question relates to their impact of standards and guidelines, the actual standards and guidelines themselves were excluded.

Two of the co-authors (ES-D and SF) first vetted the articles by title and abstract. Articles deemed irrelevant by both authors were excluded. Full text copies of the remaining articles were then

obtained. The purpose of a scoping review and is to provide an overview of the existing literature [35] and this was achieved by identifying a range of different topics covered by the included articles. (Articles could be included in more than one category.) The scope and nature of articles within each of these categories was then described. Given that this was a scoping review [35], no formal analysis of quality or meta-analysis of data was conducted.

Results

The database searches yielded a total of 4,638 articles once duplicates were removed. Manual review of title and abstracts yielded 62 articles for full text review. Of these, 29 of the papers contained information relevant to the research question. These papers were then categorised into four topics: *Descriptions and Commentaries* (17 papers), *Guideline Development* (7), *Guideline Testing* (2) and *Standards implementation* (3). The remaining 33 papers were found not to contain any relevant information once the full text had been obtained.

Descriptions and Commentaries.

Most articles in this category have been written to inform clinical staff of the implications of ISO standards [36, 37, 38], medical device legislation [4, 39, 40, 41, 42] and the DMEPOS regulations [43, 44, 45, 46, 47, 48]. Only four articles appeared to have been peer-reviewed [36, 38, 42, 49]. Three were in academic journals but had not been peer-reviewed (a letter to the editor [50], commentary [51] and news item[39]). One was a book chapter [37] and the others were in none peer-reviewed publications.

Three of these papers [4, 39, 51] describe differences in medical device legislation between the US and European Union (EU); highlighting that US legislation is more stringent and requires clinical justification for new class II (medium risk) and class III (high risk) devices. As most prostheses and orthoses are class 1 devices (low risk), however, this is of limited relevance.

Two editorials (opinion pieces) raise important issues about guidelines and standards for consideration by an academic audience. In an early paper, Pratt [36] criticised the ISO 9000 family of standards for focussing too heavily on the documentation of, and adherence to, written protocols rather than adopting more holistic approach such as Total Quality Management. More recently, Cutler [50] contended that recent clinical studies have been inappropriately incorporated into clinical guidelines developed by insurance companies to limit the options available for orthotic management.

Guideline development

These papers describe the processes used to develop clinical guidelines. Two [6, 52] include descriptions of the methods adopted at ISPO's consensus conferences. These reports describe how an organising committee invited a multi-disciplinary panel of international experts to attend a conference. At the conference, some experts presented papers on the evidence base, describing the level of evidence and exploring issues with the evidence. Conclusions and recommendations were then drafted by the organising committee and distributed to all participants for comment and approval before publication. A similar but more local process (specific to Scotland) is documented by Bowers et al. [53].

Another 4 papers [30, 34, 54, 55] report on implementation of a Delphi technique. Three of these articles related to the development of national guidelines in the Netherlands for prescription of lower limb prostheses [34], orthoses for patients with neurological disorders [54] and amputation and prosthetics of the lower extremity [30]. The fourth reports on the development of guidelines for the prescription of microprocessor controlled prosthetic knee units in south-east England [55]. These studies all appear to report high quality implementations of Delphi techniques that led to consensus statements that have since been adopted by the organisations that commissioned them.

Guideline testing

Two studies [56, 57] sought to determine how well existing guidelines were implemented in clinical practice among American paediatric physicians [56] and British podiatrists [57]. While both studies included some discussion about guidelines for orthotic provision, this was not the primary focus of either article. These questionnaire based studies generally report either poor knowledge of, or adherence to, national clinical guidelines. The one exception to this were a sub-set of podiatrists specialising in rheumatology within the British NHS where over 90% of respondents were aware of, and adhered to, guidelines [57]. There is, however, an obvious risk of bias in analysing the data from that sub-set of clinicians choosing to complete the questionnaire. Neither of these studies addressed whether compliance affected healthcare outcomes.

Standards implementation

Three disparate papers describe how different ISO standards have been implemented in relation to prosthetic components [58, 59, 60]. The first [59] reported on testing a range of prosthetic ankle foot units to ISO 10328 standards; concluding that these prosthetic ankles might not meet the requirements of military personnel serving in the field (although no data were provided to support this). The second study [58] presented a modification of ISO 10328 for prosthetic ankle foot units for use by children (based on data for a 12 year old boy weighing 45kg) concluding that a new device was suitable for use. The final paper [60] was a conference abstract appearing to report testing guidelines for prosthetic knee units for use in developing devices prior to formal testing to ISO 10328 concluding that it appeared adequate to test stance phase function but not swing phase function.

Discussion

While 29 articles were identified as having some relevance to the research question, none provided any objective evidence of the impact of standards and guidelines on service delivery outcomes in prosthetics and orthotics. Instead, articles tended to be commentaries or descriptions of guideline development, testing or the implementation of standards.

The absence of papers designed to address the research question, may reflect the difficulty of conducting such research. Whilst the publication and formal implementation of standards and guidelines are discrete events, they tend to reflect a more continuous process of improvements in service quality which is only partly driven by the formal documents. New guidelines are rarely introduced in isolation. More often they will be introduced alongside other transitions such as the implementation of new processes or equipment, changeover of staff or management, or a move to new premises. Given the broad consensus that standards and guidelines are effective it might also be considered unethical to deliver services without them to a control group. These issues make research in this area complex to design and execute because the influence of staff training, for example, must be controlled for to truly understand the effect of the guideline or standard itself. Another issue may be that few of those responsible for writing standards and guidelines see it as their responsibility to evaluate whether they are effective or not.

Another factor limiting this sort of research in healthcare, like other areas including manufacturing and service industries, is the assumption that the implementation of formal standards and guidelines is essential for the continuing improvement of service and product quality. Few people would seriously question this, and there is no particular reason why prosthetics and orthotics should be more critical of this than anyone else. There is, however, a particular issue in resource limited environments [61, 62] given that the implementation of standards and guidelines comes at a

considerable cost, both in terms of people and money. These costs often compete for the limited resources available to provide prostheses and orthoses as part of any service. Parver et al. [45] estimated that compliance with DMEPOS can cost a company between US$25,000-$250,000. It would be extremely useful to have some estimate of the potential benefits of this sort of investment to justify the expenditure of scarce healthcare resources; particularly in developing countries.

There were a number of limitations of this review. As is typically the case in a scoping review, the literature search was not exhaustive being restricted to the three most relevant electronic databases. Broad inclusion criteria were used deliberately in preference to the sort of specific criteria typically required to answer explicit research questions. Given the lack objective evidence revealed by this scoping review it is clear that it is too early to progress to any systematic review in this general area. Such a review can only be as strong as the underlying primary literature allows and it is clear if the question posed by this review is to be answered then a considerable amount of primary research will be required. Such research may be particularly important in areas were resources are most scarce. In conducting this and another recent scoping study [63] it was noted how few studies have assessed the effectiveness of overall service provision in prosthetics and orthotics (most focus at the level of device provision). A precursor to assessing the effect of guidelines and standards on service provision is clearly the existence of robust methodologies to evaluate service provision. To evaluate the effects of implementing new guidelines and standards, studies could then be designed to control for the confounding influence of organisational change or education that often occurs in parallel. An alternative would be document outcomes across a range of services differing in a range aspects and use some sort of correlation analysis to identify the most important predictors of those outcomes.

This review did not attempt any analysis of the motivation driving the development of standards and guidelines. Clearly any prospective evaluation must start off with an analysis of the original

objective of that development process in order to establish the most appropriate methodology and outcome measures to determine the extent to which that objective has been met.

This review has made a general assumption that guidelines and standards are useful without being specific about exactly how. Given the absence of any studies to test this hypothesis this is not seen as a particular issue but if such studies are planned then they should start off with an analysis of the aims of those standards and guidelines in order to guide how their effectiveness should be assessed.

The one area where a more comprehensive review might be useful would be to try and identify all guidelines that have been developed or are being developed Guideline development is an integral part of the contemporary approach to clinical service delivery and as a consequence very much a growth area. There is already evidence of overlap. It is likely that particular professional bodies and healthcare providers in specific geographic regions will continue to want to develop their own specific guidelines but an authoritative list, or even register, of existing guidelines would be an extremely useful foundation for supporting such activity.

Recommendations for Rehabilitation

One of the challenges for clinicians, and those responsible for managing clinical service delivery, is that services are required even where evidence as to how they are best provided is lacking. In the absence of evidence a judgement must be made based on informed opinion. None of the papers reviewed challenges the widely held opinion that modern healthcare services should be delivered in line with standard and guidelines, indeed most take this as axiomatic. Given this, it would appear sensible to continue to develop services in this way.

A more challenging question, given the wide and growing range of standards and guidelines available, is which to adopt? In the absence of any evidence as to which are more effective, the pragmatic response is to select those which appear most appropriate. This decision must include a consideration of the level of relevant knowledge and expertise of the authors, the overall relevance to the type of service being delivered and the context in which they are being delivered. Perhaps the most useful contribution of this report is to draw attention to the wide range of documents that are currently available (Table 2). If services are being delivered in a different context to those in which the documents have been written, which might often be the case in low and middle income countries for example, then they may need adaptation before being used as a basis for local service delivery. Adapting existing standards and guidelines will almost always be a cheaper and quicker alternative to starting from scratch.

Having more robust evidence of how services perform would allow for more informed decisions about how they should be delivered. The absence of evidence from external sources makes it even more important for local services to monitor their own performance to guide future development. An essential prerequisite for this is the collection and collation of output data as a component of routine service delivery. Once such data are available it would be extremely useful to see them published to allow comparison between different services to give insights into what works and what doesn't.

Conclusion

No articles were explicitly designed to assess the impact of standards and guidelines on service delivery outcomes in prosthetics and orthotics. Studies tended to be commentaries or descriptions of guideline development, testing or implementation of standards. The literature is not sufficiently well developed to warrant the cost and effort of a systematic review.

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Table 1 ISO standards for prosthetics and orthotics (P&O). Standards in italics are at the preparatory stage. Those with an asterisk are currently being revised.

Standard		Part	
ISO 8548	Prosthetics and orthotics -- Limb deficiencies	1:1989	Part 1: Method of describing limb deficiencies present at birth
		2:1993	Part 2: Method of describing lower limb amputation stumps
		3:1993	Part 3: Method of describing upper limb amputation stumps
		4:1998	Part 4: Description of causal conditions leading to amputation
		5:2003	Description of the clinical condition of the person who has had an amputation
ISO 8549	Prosthetics and orthotics -- Vocabulary	1:1989	Part 1: General terms for external limb prostheses and external orthoses
		2:1989	Part 2: Terms relating to external limb prostheses and wearers of these prostheses
		3:1989	Part 3: Terms relating to external orthoses
		4:2014	Part 4: Terms relating to limb amputation
ISO 8551:2003	P&O - Functional deficiencies - Description of the person to be treated with an orthosis, clinical objectives of treatment …		
ISO 10328:2006*	Prosthetics -- Structural testing of lower-limb prostheses -- Requirements and test methods		
ISO 13404:2007	Prosthetics and orthotics -- Categorization and description of external orthoses and orthotic components		
ISO 13405	P&O - Classification and description of prosthetic components	1:2015	Part 1: Classification of prosthetic components
		2:2015	Part 2: Description of lower limb prosthetic components
		3:2015	Part 3: Description of upper limb prosthetic components
ISO 15032:2000	Prostheses -- Structural testing of hip units		
ISO/DTS 16955	Prosthetics -- Quantification of physical parameters of ankle foot devices and foot units		
ISO/AWI 21063	*P&O - Soft orthoses -- Uses, functions, classification and description*		
ISO/AWI 21064	*Foot orthotics -- Uses, functions classification and description*		
ISO/AWI 21065	*P&O - Terms relating to the treatment and rehabilitation of persons having a lower limb amputation*		
ISO 22523:2006	External limb prostheses and external orthoses -- Requirements and test methods		
ISO/FDS 22675	Prosthetics -- Testing of ankle-foot devices and foot units -- Requirements and test methods		
ISO 29781:2008*	P&O - Factors to be included when describing physical activity of a person who has had a lower limb amputation(s) or …		
ISO 29782:2008	Prostheses and orthoses -- Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation		
ISO 29783	Prosthetics and orthotics -- Vocabulary	1:2008	Part 1: Normal gait
		2:2015	Part 2: Prosthetic gait
		3:	Part 3: Pathological gait (excluding prosthetic gait)

Table 2 List to illustrate the variety of best practice guidelines that are currently available (note this is intended to be illustrative rather than comprehensive).

Document	Publisher	Reference
Prescription Custom Foot Orthoses Practice Guidelines (2006)	American College of Foot and Ankle Orthopaedics and Medicine	[26]
Knee orthoses for treating patellofemoral pain syndrome (2015)	Cochrane Library	[32]
Hand and wrist orthoses for adults with rheumatological conditions (2015)	College of Occupational Therapists (UK)	[28]
Best practice statement: Use of ankle-foot orthoses following stroke (2009)	NHS Quality Improvement in Scotland	[9]
Improving the Quality of Orthotics Services in England (2015)	NHS England	[10]
Splinting for the prevention and correction of contractures in adults with neurological dysfunction: Practice guideline for OTs and physiotherapists (2015)	College of Occupational Therapists and Association of Chartered Physiotherapists in Neurology	[27]
Clinical practice guidelines for rest orthosis, knee sleeves, and unloading knee braces in knee osteoarthritis. (2009)	French Physical Medicine and Rehabilitation Society (SOFMER)	[33]
Manufacturing guidelines:	International Committee of the Red Cross	
• Patellar tendon bearing orthosis (2006)		[17]
• Knee ankle foot orthosis (2006)		[18]
• Partial foot prosthesis (2006)		[19]
• Trans-tibial prosthesis (2006)		[20]
• Trans-femoral prosthesis (2006)		[21]
• Ankle foot orthosis (2010)		[22]
• Push-fit Syme prosthesis (2013)		[23]
• Syme prosthesis with medial window (2013)		[24]
Guidelines for exercise and orthoses in children with neuromuscular disorders (2003)	Muscular Dystrophy UK	[31]
Consensus-based recommendations of Australian podiatrists for the prescription of foot orthoses for symptomatic flexible pes planus in adults (2014)	International Centre for Allied Health Evidence, University of South Australia	[64]
Prosthetic best practice guidelines (2011)	RSL Steeper	[16]
Clinical practice guideline for rehabilitation of lower limb amputation (2007)	Department of Veterans Affairs, Department of Defense (USA)	[11]
Standards for best practice (2013)	British Ass^{n} of Prosthetists and Orthotists	[25]
Clinical utilization management guidelines (2015):	Anthem Inc..	
• Ankle foot and knee ankle foot orthotics		[12]
• Therapeutic shoes, inserts …		[13]
• Prefabricated and prophylactic knee braces		[14]
• Custom-made knee braces		[15]
Evidence based guidelines for amputation and prosthetics of the lower extremity (2015)	Netherlands Society of Physical and Rehabilitation Medicine (and others)	[29, 34]
Orthotic management of cerebral palsy: Recommendations from a consensus conference (2011)	International Society of Prosthetics and Orthotics	[65]

Table 3 Search terms and illustrative yields. Searches 1 to 6 were on the basis of title, abstract and keyword to increase sensitivity, search 6 and 9 were on basis of title and keyword. (* represents any number of wild characters, ? represents a single wild character).

	Category	Search terms	Yield (Scopus)
#1	Profession	prosthetist* or orthotist* or pedorthist*or ((prosthetic or orthotic) with (technol*or technic profession* or workforce or personnel or practitioner)) or orthop*dic with (technol* or technic* or engineer* or meister*)	2,628
#2	Prosthetics	(prosthe* or artificial) with (limb* or arm* or leg or extremit*) or amput*	14,324
#3	Orthotics	orthotic* or orthos?s or brace or braces or bracing or splint* or corset* or (cervical with collar*) or cal*iper*	87,700
#4	Foot Orthoses	insole or (shoe* with insert*) or ((medical or orthop*ed or modifi* or adapt*) with (shoe* or boot* or footwear))	2,749
#5	P&O	#1 or #2 or #3 or #4 or ISPO	105, 866
#6	Exclusions	animal or denta* or prostho* or orthod* or maxillofacial or *mandibul* or palate or orbital or retinal or breast or audito* or cochlear or (prosth* with voice) or penile or penis or vascular or heart or vessel or neural or cardiac or buckl* or seism* or "train station" or railway	9,754,109
#7		#5 not #6	78,112
#8		#7 from 1995 to 2015	46,823
#9	Standards and guidelines	standard* or guideline* or recommendation* or consensus or audit or "best practice" or policy or policies or protocol* or pathway* or ISO or technolog* or CAD?CAM or intelligen* or low-cost	4,155,170
#10	Final yield	#8 and #9	4,638

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Table 1 ISO standards for prosthetics and orthotics (P&O). Standards in italics are at the preparatory stage. Those with an asterisk are currently being revised.

Standard		Part	
ISO 8548	Prosthetics and orthotics -- Limb deficiencies	1:1989	Part 1: Method of describing limb deficiencies present at birth
		2:1993	Part 2: Method of describing lower limb amputation stumps
		3:1993	Part 3: Method of describing upper limb amputation stumps
		4:1998	Part 4: Description of causal conditions leading to amputation
		5:2003	Description of the clinical condition of the person who has had an amputation
ISO 8549	Prosthetics and orthotics -- Vocabulary	1:1989	Part 1: General terms for external limb prostheses and external orthoses
		2:1989	Part 2: Terms relating to external limb prostheses and wearers of these prostheses
		3:1989	Part 3: Terms relating to external orthoses
		4:2014	Part 4: Terms relating to limb amputation
ISO 8551:2003	P&O - Functional deficiencies - Description of the person to be treated with an orthosis, clinical objectives of treatment …		
ISO 10328:2006*	Prosthetics -- Structural testing of lower-limb prostheses -- Requirements and test methods		
ISO 13404:2007	Prosthetics and orthotics -- Categorization and description of external orthoses and orthotic components		
ISO 13405	P&O - Classification and description of prosthetic components	1:2015	Part 1: Classification of prosthetic components
		2:2015	Part 2: Description of lower limb prosthetic components
		3:2015	Part 3: Description of upper limb prosthetic components
ISO 15032:2000	Prostheses -- Structural testing of hip units		
ISO/DTS 16955	Prosthetics -- Quantification of physical parameters of ankle foot devices and foot units		
ISO/AWI 21063	*P&O - Soft orthoses -- Uses, functions, classification and description*		
ISO/AWI 21064	*Foot orthotics -- Uses, functions classification and description*		
ISO/AWI 21065	*P&O - Terms relating to the treatment and rehabilitation of persons having a lower limb amputation*		
ISO 22523:2006	External limb prostheses and external orthoses -- Requirements and test methods		
ISO/FDS 22675	Prosthetics -- Testing of ankle-foot devices and foot units -- Requirements and test methods		
ISO 29781:2008*	P&O - Factors to be included when describing physical activity of a person who has had a lower limb amputation(s) or …		
ISO 29782:2008	Prostheses and orthoses -- Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation		
ISO 29783	Prosthetics and orthotics -- Vocabulary	1:2008	Part 1: Normal gait
		2:2015	Part 2: Prosthetic gait
		3:	Part 3: Pathological gait (excluding prosthetic gait)

Table 1 List to illustrate the variety of best practice guidelines that are currently available (note this is intended to be illustrative rather than comprehensive).

Document	Publisher	Reference
Prescription Custom Foot Orthoses Practice Guidelines (2006)	American College of Foot and Ankle Orthopaedics and Medicine	[26]
Knee orthoses for treating patellofemoral pain syndrome (2015)	Cochrane Library	[32]
Hand and wrist orthoses for adults with rheumatological conditions (2015)	College of Occupational Therapists (UK)	[28]
Best practice statement: Use of ankle-foot orthoses following stroke (2009)	NHS Quality Improvement in Scotland	[9]
Improving the Quality of Orthotics Services in England (2015)	NHS England	[10]
Splinting for the prevention and correction of contractures in adults with neurological dysfunction: Practice guideline for OTs and physiotherapists (2015)	College of Occupational Therapists and Association of Chartered Physiotherapists in Neurology	[27]
Clinical practice guidelines for rest orthosis, knee sleeves, and unloading knee braces in knee osteoarthritis. (2009)	French Physical Medicine and Rehabilitation Society (SOFMER)	[33]
Manufacturing guidelines: • Patellar tendon bearing orthosis (2006) • Knee ankle foot orthosis (2006) • Partial foot prosthesis (2006) • Trans-tibial prosthesis (2006) • Trans-femoral prosthesis (2006) • Ankle foot orthosis (2010) • Push-fit Syme prosthesis (2013) • Syme prosthesis with medial window (2013)	International Committee of the Red Cross	 [17] [18] [19] [20] [21] [22] [23] [24]
Guidelines for exercise and orthoses in children with neuromuscular disorders (2003)	Muscular Dystrophy UK	[31]
Consensus-based recommendations of Australian podiatrists for the prescription of foot orthoses for symptomatic flexible pes planus in adults (2014)	International Centre for Allied Health Evidence, University of South Australia	[64]
Prosthetic best practice guidelines (2011)	RSL Steeper	[16]
Clinical practice guideline for rehabilitation of lower limb amputation (2007)	Department of Veterans Affairs, Department of Defense (USA)	[11]
Standards for best practice (2013)	British Ass^{n} of Prosthetists and Orthotists	[25]
Clinical utilization management guidelines (2015): • Ankle foot and knee ankle foot orthotics • Therapeutic shoes, inserts … • Prefabricated and prophylactic knee braces • Custom-made knee braces	Anthem Inc..	 [12] [13] [14] [15]
Evidence based guidelines for amputation and prosthetics of the lower extremity (2015)	Netherlands Society of Physical and Rehabilitation Medicine (and others)	[29, 34]
Orthotic management of cerebral palsy: Recommendations from a consensus conference (2011)	International Society of Prosthetics and Orthotics	[65]

Table 1 Search terms and illustrative yields. Searches 1 to 6 were on the basis of title, abstract and keyword to increase sensitivity, search 6 and 9 were on basis of title and keyword. (* represents any number of wild characters, ? represents a single wild character).

	Category	Search terms	Yield (Scopus)
#1	Profession	prosthetist* or orthotist* or pedorthist*or ((prosthetic or orthotic) with (technol*or technic profession* or workforce or personnel or practitioner)) or orthop*dic with (technol* or technic* or engineer* or meister*)	2,628
#2	Prosthetics	(prosthe* or artificial) with (limb* or arm* or leg or extremit*) or amput*	14,324
#3	Orthotics	orthotic* or orthos?s or brace or braces or bracing or splint* or corset* or (cervical with collar*) or cal*iper*	87,700
#4	Foot Orthoses	insole or (shoe* with insert*) or ((medical or orthop*ed or modifi* or adapt*) with (shoe* or boot* or footwear))	2,749
#5	P&O	#1 or #2 or #3 or #4 or ISPO	105, 866
#6	Exclusions	animal or denta* or prostho* or orthod* or maxillofacial or *mandibul* or palate or orbital or retinal or breast or audito* or cochlear or (prosth* with voice) or penile or penis or vascular or heart or vessel or neural or cardiac or buckl* or seism* or "train station" or railway	9,754,109
#7		#5 not #6	78,112
#8		#7 from 1995 to 2015	46,823
#9	Standards and guidelines	standard* or guideline* or recommendation* or consensus or audit or "best practice" or policy or policies or protocol* or pathway* or ISO or technolog* or CAD?CAM or intelligen* or low-cost	4,155,170
#10	Final yield	#8 and #9	4,638