

**From outcome measurement to improving health outcomes following lower limb amputation – A Narrative review exploring outcome measurement from a clinical practice perspective**

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**Abstract**

**Background:** Outcome measurement is essential to understand the impact of clinical interventions and the performance of services. Despite national and professional body encouragement, and successful examples of system level outcome measurement within some health care settings, many barriers still exist preventing outcome measurement from becoming embedded in clinical practice.

**Objectives:** To explore the status of outcome measurement in prosthetic rehabilitation, as applied in clinical practice, with a view to identifying areas of future work aimed at making outcome measurement in prosthetic rehabilitation a meaningful and useful reality.

**Study Design:** Narrative review

**Methods:** A literature search of four databases was undertaken, following the PRISMA principals appropriate to narrative reviews, and using the search terms outcome, measure\*, tool, scale, instrument, prosth\*, amput\* and limb loss. A total of 1116 papers were identified. Following screening 35 papers, focusing on four main themes, were included in the review.

**Results:** The four themes were 1) What outcomes should be measured? 2) How can these outcomes be measured? 3) What are the barriers to outcome measurement? and 4) What examples of routine outcome measurement currently exist in prosthetic practice?

**Conclusions:** Successful outcome measurement in clinical practice is multifaceted. Understanding and embedding value at every step is key to success. Addressing the questions of 'why', 'what' and 'how' we measure outcome may move us closer to a consensus. Routine outcome measurement at the clinical level should ensure data collection is valuable to clinical practice, makes use of IT solutions and has all important organisational buy in.

**Key words:** Outcome measurement, Prosthetic limbs, Amputation, Rehabilitation, Meaningful measurement, Clinical practice

## Background

Measuring health outcomes is especially relevant in today's increasingly evidence based health services. When facing increasing demands on resources, as well as the expectation of a culture of continual improvement, services need to consistently demonstrate their value and impact.<sup>1</sup> Outcome information can provide an understanding of the impact health services and interventions have on the health and wellbeing of patients.

The term outcome measurement can be better understood by breaking it down into the outcome being measured and the measurement tool used for the task. A health outcome can be defined as a change in a person's health status as a result of an intervention<sup>2</sup> and a measurement tool as a standardised instrument used in research and clinical practice to capture and evaluate this change.<sup>3</sup>

Within clinical practice, outcome measurement in the form of observed performance measures or patient reported measures (PROMs), can be used in a number of different ways. On an individual basis, the use of an outcome measure (OM) can be helpful to capture changes in a patient's status following an intervention or when monitoring patients over time.<sup>3</sup> This information can be shared with the patient to demonstrate progress throughout rehabilitation, and increase motivation, or can be used by the clinician to direct treatment planning or inform funding requests.<sup>4</sup>

A more co-ordinated approach to outcome measurement along a pathway of care can be described as routine outcome measurement (ROM). ROM is defined as "the systematic use of a standardised OM(s) in clinical practice with every patient as part of a standardised assessment practice guideline".<sup>5</sup> This systematic approach to outcome measurement can provide individual services with a wealth of information on the quality of care and interventions they are delivering.<sup>6</sup> Data can be used to direct and inform improvement work, and evaluate the changes resulting from new ways of working. When co-ordinated ROM is undertaken in a number of services, benchmarking can be undertaken<sup>7</sup> and a system-wide approach adopted.

This system-level approach to ROM can be useful in several contexts, especially if widely accessible. It allows comparison of the performance of different health care providers and gives patients valuable information on the best performing trusts, enabling informed decisions on where to receive care.<sup>1</sup> Benchmarking can also help to identify services where outcomes are good and use those as exemplars to raise standards across the NHS, reducing variation in the system. Collating large datasets concerning a specific population, such as lower limb amputation, can also be useful for research purposes to strive to understand, and influence, the factors that may have an impact on clinical outcome.

Outcome measurement is crucial to inform and therefore improve clinical decision-making daily. If health care services want to ensure they are delivering the most effective care they need information, specifically about the outcome of care, that can both direct the focus of meaningful improvement programmes and evaluate their impact.<sup>8</sup>

The potential for using ROM to evaluate, inform and improve clinical practice at the system level has been realised in several UK clinical settings. Two notable examples are the NHS PROMs programme and the UK Rehabilitation Outcomes Collaborative (UKROC).

The NHS England PROMs programme,<sup>9</sup> collects PROMs data for hip and knee replacements, before and after surgery. Data is collected nationally and allows comparison of surgical centres and informed patient choice of centres with the best outcomes. Crucially this programme is linked to the National Joint Registry (NJR) which collects implant safety data from across the UK on all joint replacement surgery.<sup>10</sup> Combining these data sets allows the value of joint replacement on patients' lives to be assessed, as well as a comparison of the performance of different implant componentry, providing evidence for interventions, service performance, patient safety and component selection.<sup>11</sup>

UKROC applies system-wide ROM in the context of rehabilitation and aims to provide data that can inform the provision of cost effective neuro-rehabilitation services in the NHS.<sup>12</sup> The collaborative developed a national clinical database combining data on rehabilitation needs, the interventions patients received and importantly their outcomes. Data collected was used to demonstrate that specialist neuro rehabilitation was a highly cost-effective intervention compared to potential lifelong care needs. This evidence led to significant investment in rehabilitation services throughout the NHS, alongside development of evidence based standards of care that have reduced variation across the system and driven up quality.<sup>13</sup>

However, even within these valuable examples of system wide ROM, engaging clinicians in outcome measurement is a challenge,<sup>14</sup> and it is widely acknowledged that OMs are not routinely used in clinical practice.<sup>4</sup> NHS policy<sup>15</sup> as well as prosthetic rehabilitation professional bodies, such as the British Association of Prosthetists and Orthotists (BAPO) and the British Associations of Chartered Physiotherapists in Amputation Rehabilitation (BACPAR), have issued encouragement and guidance on OMs in clinical services.<sup>16,17</sup> However their use has yet to become embedded and there is currently no UK outcome data collection initiative capturing the inherent usefulness of this information following amputation.<sup>4</sup> Despite the common view that it is due to ambivalence of clinicians<sup>18</sup> and a resistance to change and innovation amongst service providers,<sup>19</sup> a systematic review by Duncan and Murray exploring barriers and facilitators to OM use amongst allied health professionals (AHPs) suggests this is not the case. Successful implementation needs multifactorial efforts, overcoming barriers such as lack of time, unfeasible OMs, perceived lack of value in measurement and insufficient organisational support.<sup>4</sup>

This narrative review therefore seeks to explore ROM within the field of prosthetic rehabilitation by critically synthesising the current evidence regarding outcome measurement, as applied in clinical practice. By understanding what is already known about this subject, in this context, we hope to highlight areas for future work aimed at making ROM a meaningful reality following lower limb amputation, that has the potential to evaluate and direct improvements in the care provided to patients.

## **Methods**

### **Narrative approach**

A narrative approach was chosen for this review to allow for a broad exploration of the outcome literature within the prosthetic rehabilitation evidence base. This approach fits well with the narrative review methodology as it doesn't stipulate formulation of a specific research question, as required for scoping or systematic reviews (SR).<sup>20</sup> The narrative style also gives voice to the clinical narrative thread, which might be lost within the constraints of more systematic approaches.<sup>21</sup>

### **Search strategy**

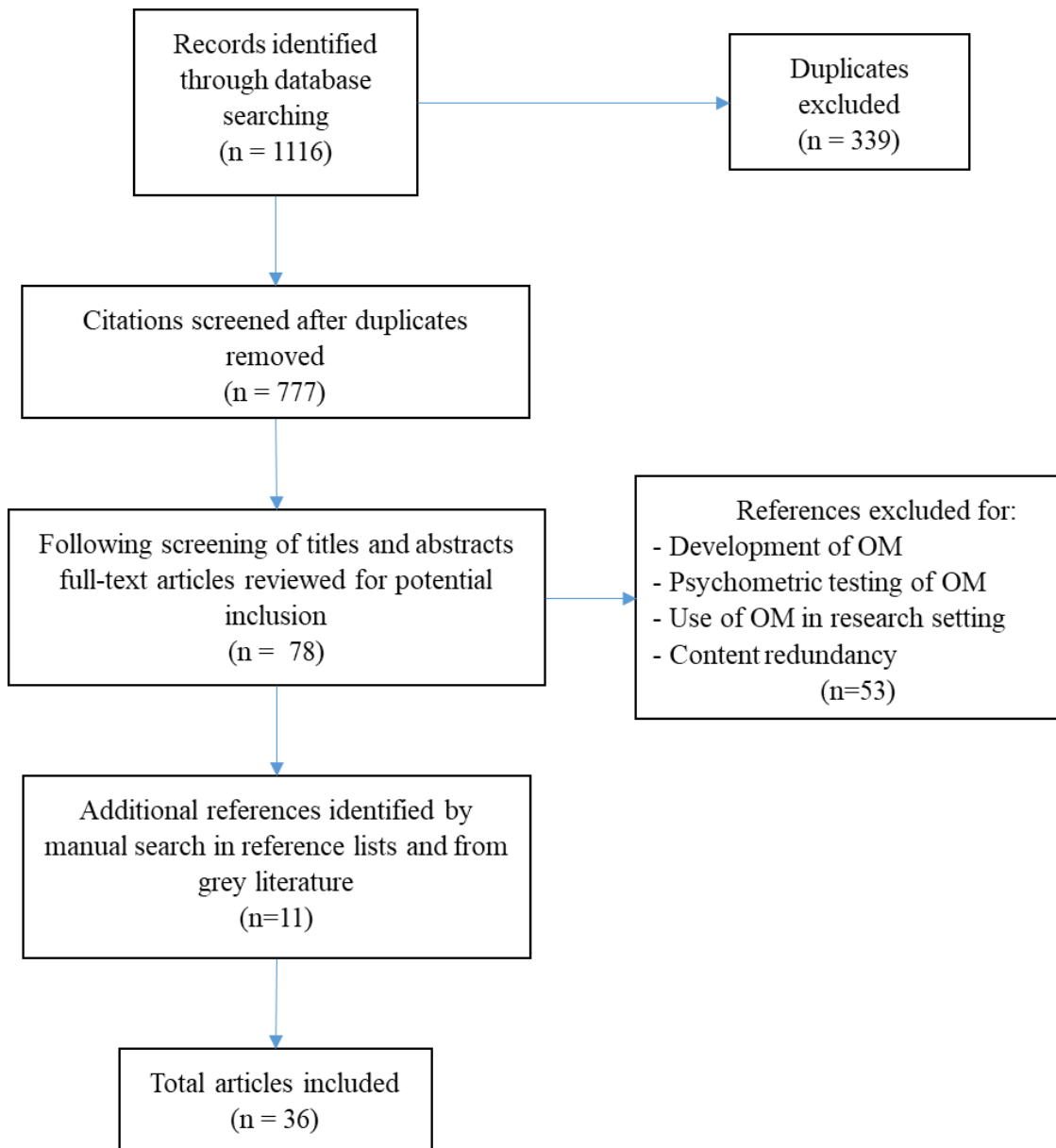
A literature search was conducted using the CINAHL, Medline, Science direct and PsychInfo bibliographic databases in July 2020, following the PRISMA principles appropriate to narrative reviews, as set out by Ferrari.<sup>21</sup> The key words outcome AND (measur\* OR tool OR scale OR instrument) were combined with AND (prosth\* OR amput\* OR "limb loss") and searched in titles and abstracts. An English language filter was then applied.

### **Search results**

1116 papers published between 1981 and 2020 were identified and 777 citations were screened once duplicates were removed. 78 articles were selected for full text review alongside an additional 11 identified from manual searches of reference lists and grey literature sources. This review yielded a number of SRs (10) exploring the development and psychometric properties of OM tools for use following lower limb amputation. Studies of individual OMs were therefore excluded to avoid

duplication. In total 36 papers were included in the narrative review. The process is described in the flow diagram in fig 1.

Figure 1. – Narrative review process flow chart



## Results

The findings from this search have been grouped into four main themes which have been posed as questions given the previously described issues regarding outcome measurement in the wider health care context. The four themes are 1) What outcomes should be measured? 2) How can these outcomes be measured? 3) What are the barriers to using OMs and 4) What examples of ROM currently exist in prosthetic practice?

### 1) What outcomes should be measured?

Deciding what is important to measure appears to be a significant challenge within the prosthetic rehabilitation literature. In 2014, a study by Heinemann et al.<sup>22</sup> reported finding 43 unique measurement instruments designed to capture outcome following lower limb amputation. In light of a wide variety of tools measuring an extensive range of different outcome domains, a number of authors have raised the issue that there is no consensus around which OMs should be used.<sup>23,24</sup> This is also evident in current UK Health Policy and professional guidance, where long lists of OMs are suggested in the Prosthetic National Service Specification,<sup>25</sup> the NHS Microprocessor Knee Policy,<sup>26</sup> the BACPAR OMs toolbox<sup>17</sup> and the BAPO OM guidance.<sup>16</sup> These recommendations offer too many options to feasibly use them all in clinical practice, and little consistency to aid consensus.

This lack of consensus is a major barrier to system wide ROM and raises two important unanswered questions within the field of lower limb prosthetic rehabilitation: *what* outcomes should be measured and *how* should they be measured? *What* outcomes should be measured will be discussed in this theme. *How* they should be measured will be addressed in the theme exploring OMs.

One approach identified in this review, is attempting to ascertain *what* to measure by exploring possible outcome constructs that capture the concept of health, as defined using a framework like the International Classification of Functioning (ICF).<sup>27</sup> This has been approached by Xu et al. who developed a core ICF set of domains which define health as it applies to people following amputation, with a view to exploring how these domains could be measured. Currently this work has yielded large numbers of constructs which may be impractical to capture in clinical practice. Importantly this approach does not give an indication of which constructs could be most meaningful to prosthetic users themselves, for whom the outcome of prosthetic rehab has the greatest impact.

A more patient-centred approach to outcome measurement in prosthetics was called for in a review by Gallagher and Desmond in 2007 who suggested measuring quality of life may be an important first step in this process.<sup>28</sup> Since then two studies have taken this patient centred approach further by using qualitative methods to explore the outcomes that matter to patients. McDonald and colleagues<sup>29</sup> used focus groups to explore meaningful outcomes when prescribing prosthetic feet, and Schaffalitzky et al.<sup>30,31</sup> explored user, clinician and wider stakeholder views on the outcome of prosthetic prescription via interviews, focus groups and a Delphi consensus process. Both studies focused on the prescription of components rather than holistic rehabilitation post amputation, and McDonald et al. only included six participants, however they found that qualitative methodologies work well to explore successful prosthetic prescription and highlighted outcome domains that were important to users such as balance and safety, independence, and importantly the need to capture psychosocial outcomes.<sup>30</sup>

Despite this valuable exploratory work consensus remains elusive in prosthetic rehabilitation and without understanding *what* to measure the next theme of *how* to measure it becomes even more challenging.

## 2) How can these outcomes be measured?

Ten SRs were identified in the prosthetic rehabilitation literature which collate and critique measurement tools designed for use following lower limb amputation (Table 1). The many OMs included in these reviews vary widely. Measures focus on different outcome domains (i.e. function, falls risk, mobility, quality of life or prosthetic use), and vary in the methodological quality of their development and their psychometric properties (i.e. the level of measurement, validity, reliability and responsiveness)<sup>32</sup>

The tools included also vary in length and format. Some are paper-based and others are available digitally via apps. Some measures are free to use whereas others have cost implications and this in itself can be a significant barrier in some healthcare settings. Many measures have been developed in English and have now been translated and validated in other languages, which is important for use in today's diverse society, and across the world. However, the challenges of using OMs in different languages is not just about translation. Ensuring the measure is meaningful in different social and cultural settings is often overlooked, i.e. measuring an individual's ability to stand from a chair may not be as meaningful in countries where much time is spent sitting or squatting at floor level. Considering these different approaches when attempting to make an informed choice of OM, as well as understanding and evaluating the many different psychometric properties, can make selecting tools almost un navigable for clinicians.

Despite the many measures available the quest for new measures continues and the future is focused on the digital arena. The PLUS-M OM, or item bank, consists of 44 different questions exploring the outcome construct of mobility. Each item is individually validated and calibrated on a single scale and the items can be used to develop specific short forms or be administered via Computer Adaptive Testing (CAT).<sup>39</sup> CAT uses algorithms to select items from the bank for individual patients based on their responses to previous questions.<sup>40</sup> This tailored approach has been able to achieve the same reliability with fewer questions therefore reducing the measurement burden on patients.<sup>39</sup> Despite the use of different questions with each patient the results are comparable as all items in the bank are drawn from the same scale. The PLUS M item bank also allows comparison of scores to a large development sample.

Despite the advantages of this approach, as with all OMs consideration must be given to the population used to develop and select items for the bank, especially in limb loss research which can over-sample people with traumatic limb loss<sup>41</sup> and those living in high income countries. This may raise questions about how transferrable OMs are to different populations and subgroups who were not well-represented by the development sample i.e. older dysvascular patients, or those from different social and cultural backgrounds.

However, whatever the measure the key concern highlighted in this review is responsiveness, or the ability to detect change when it has occurred<sup>22,33,36</sup> which is a priority when using OMs to evaluate rehabilitation interventions in clinical settings.<sup>42</sup> Many of the OMs identified in the SR lacked data regarding ceiling or flooring effects<sup>33,35</sup> and only three include a Minimal Clinically Important Difference (MCID) value.<sup>43-45</sup> The MCID is the smallest change in the score that indicates an important change for the patient.<sup>46</sup> Without these values, clinicians and patients do not know if the change they have recorded represents a meaningful improvement to patients' lives, whether clinical interventions were effective and, importantly, whether the investment in rehabilitation was justified. However MCID values may only be truly meaningful if the OM captures an outcome of importance to the patient in the first place.

### **3) What are the barriers to outcome measurement?**

Several studies (4) have explored OMs in prosthetic practice in an attempt to understand what factors may influence their use,<sup>47-50</sup> however it should be noted that two of them focus on the same group of clinicians.<sup>47,48</sup> The barriers identified in this review focus on the experiences of prosthetists, of whom only 28% - 44% describe themselves as routine users of OMs.<sup>36,47,48,50</sup> Interestingly a thesis study of physiotherapists working in amputation rehabilitation settings found that 100% used OMs regularly, but no information was available exploring the drivers for this level of engagement.<sup>36</sup> Therefore our understanding of the barriers to outcome measurement in prosthetic rehabilitation is limited to the perceptions of prosthetists, which may not reflect the views of the wider prosthetic rehabilitation multi-disciplinary team.

In all of the studies included in this theme, insufficient time was identified as a key barrier as clinicians struggled to integrate outcome measurement into their usual clinical routines.<sup>47,48,50</sup> This was compounded by an often described lack of confidence and knowledge of the tools themselves. Challenges are commonplace, including choosing a measure that is meaningful, psychometrically sound, and easy to use and interpret within a clinical session. These challenges are reportedly particularly difficult for many clinicians who lack knowledge and understanding in this highly technical field, which is not always covered at undergraduate level.<sup>47,48,50</sup>

An interesting finding from Hafner et al's 2017 study exploring perceptions of outcome measurement amongst 66 US prosthetists showed that a third of participants did not agree that outcome measurement provides useful data.<sup>47</sup> The issue of the value of outcome measurement for clinicians was highlighted again in the same study where prosthetists reported they were more likely to use the Amputee Mobility Predictor (AMP) measure than the quicker-to-administer Timed Up and Go (TUG). The authors discussed that this may be because the AMP was designed to guide the prescription of prosthetic componentry to insurance companies. This is supported by a study from Borrenpohl et al who found that regular OM use increased to 77% when prosthetists were specifically asked about using OMs to support payment claims.<sup>51</sup> These findings demonstrate the impact of perceived value in engaging clinicians in the measurement of outcome.

Solutions to address these barriers were also discussed in the same articles. The need for efficient measures, use of PROMs instead of more time consuming observed measures, and electronic data collection at the point of care, which is integrated with health records, were all suggested to help overcome time related barriers.<sup>47,48</sup> An educational programme focused on improving prosthetist knowledge and skills concerning outcome measurement was tested by Gaunard et al and was found to improve confidence, which was maintained one year later.<sup>47</sup> However these findings should be viewed with caution as they did not include a control group and participation in the studies may have been more attractive to those who were particularly interested in learning about outcome measurement.

### **4) What examples of ROM currently exist in prosthetic practice?**

Despite the many barriers identified in this review three examples of system wide ROM programmes in prosthetic settings were identified. Two are in the style of registries, and as with the NJR they attempt to link surgical information and interventions with outcome data to understand the impact of lower limb amputation on patients, health care providers and society. The other is a study exploring the use of system wide outcome measurement across a network of prosthetic clinics in the US, and how it could be used to inform quality improvement (QI) activities.

The two registries identified in this review are the Scottish Physiotherapy Amputee Research Group (SPARG) data initiative which collects data on all patients undergoing amputation in Scotland,<sup>52</sup> and SwedeAmp which is the national lower limb amputation registry from Sweden.<sup>53</sup> Both registries attempt to evaluate the whole process concerning lower limb amputation, collecting demographic details,

surgical and rehabilitation interventions, prosthetic supply and outcome. For SwedeAmp, uptake across the country has been slow and after 9 years the registry only captures 62% of amputations,<sup>53</sup> illustrating the challenges related to multidisciplinary system level data collection. In contrast, SPARG, which is a small group of 20 physiotherapists, currently captures 90% of amputations in Scotland and has done for over 20 years.<sup>52</sup> The unprofessional nature of the group may account for its success in data capture but also places a limitation on the scope of the data set.

Despite these challenges huge amounts of data are now available for analysis and these projects demonstrate what is possible. Further publications regarding the implementation of these registries will be invaluable learning for the development of similar projects elsewhere, including how the outcomes included were selected and why, how the data are linked to clinical practice and improvement activities, how data security was addressed in the post GDPR era, and how the barriers described in this review were overcome.

The authors of the third paper, focusing on using routinely collected PROM data to direct QI activity, also found initiation of this work challenging with only two of the seven clinics involved actually collecting enough data to undertake QI projects.<sup>49</sup> However, as the study was undertaken as research there was a higher administration burden, which was identified by the authors as the main factor for clinics dropping out.<sup>49</sup> Clinics that were successful demonstrated high levels of organisation related to the project, integrated data collection with their electronic records and had well defined pathways of care. Clinicians in these centres reported being motivated by the chance to use PROMs to improve the care they provided to patients, however expert external facilitation was crucial to increase QI knowledge, interpret aggregated data and translate ROM findings into improvement work.<sup>49</sup>

## Discussion

This review has identified many barriers to outcome measurement in prosthetic rehabilitation, however the examples of system wide outcome measurement presented here also give an indication of what may facilitate ROM in prosthetic clinical settings, and suggests that barriers can be overcome but important lessons may need to be learnt to ensure success.

Despite the fact that only the views of prosthetists have been explored regarding outcome measurement in prosthetic clinical practice, their experiences are mirrored by those of other AHPs documented in the wider literature. Insufficient time for both patients and clinicians to complete and score measures in time-pressured clinical consultations, difficulties in selecting a measure and interpreting results, combined with low confidence and limited knowledge of outcome measurement are all commonly reported.<sup>4,19,54-56</sup>

This review identified that establishing value in outcome measurement could be a potential facilitator to addressing barriers to implementation. This issue of value has been raised in previous ROM initiatives. A multi stakeholder consultation on the NHS PROMS programme in 2017 found that many clinicians and managers felt it was not worth continuing with the programme despite 8 years of data collection.<sup>57</sup> The consultation reported that the data collection was not useful to clinical practice, could not be used during clinical consultations and that reports took too long to be published, so findings were out of date.<sup>57</sup> This lack of perceived value was also described in mental health settings where clinicians felt that ROM using the Health of the Nation Outcome Scales (HoNOS) was overly bureaucratic, only concerned with performance management, lacked feedback of results and presented no relative meaning for their role.<sup>58</sup> It seems clear that establishing the value of ROM to clinical stakeholders is key for success.<sup>59-62</sup>

Much of this value may lie in addressing some of the key themes identified in this review. Understanding *what* is important and meaningful to measure and *how* to measure it effectively following



lower limb amputation could help make outcome measurement more useful and address the issues highlighted here around lack of consensus in the field.

A lack of consensus is not only seen in the prosthetic literature and attempts have been made to address the issue in several areas of health such as rheumatology<sup>63</sup> and women's health,<sup>64</sup>, especially when related to research. The reporting of numerous outcomes in clinical trials can make the synthesis and comparison of different studies near impossible.<sup>65</sup> This problem has led to the development of initiatives such as Core Outcome Measurement in Effectiveness Trials (COMET) who seek to develop consensus around *what* to measure through core outcome sets (COS) to be recorded in all clinical trials of a specific condition.<sup>66</sup> They also highlight that this approach can be useful to build consensus around outcome measurement in clinical practice.<sup>65</sup> COMET adopt a multi-stakeholder approach to identifying outcomes of importance and seek to build consensus that can then be championed by the stakeholders involved. Importantly COMET advocate the inclusion of patients at the centre of this process, ensuring that a COS is measuring what matters most to the people affected by the outcome of an intervention.<sup>65</sup>

The studies identified in this review by Schaffalitzky et al. and McDonald et al. have made some progress towards understanding successful prosthetic prescription from a user's perspective, especially focusing on the need to measure psychosocial outcomes.<sup>29-31</sup> Schaffalitzky et al. also highlight that clinicians and patients view important outcomes differently. This difference has been reported in other studies exploring UK orthotists perspectives of clinical outcomes,<sup>67</sup> and in the development of a COS for rheumatoid arthritis,<sup>68</sup> and suggests that when seeking to build consensus around important outcomes for measurement that the patient's voice is properly represented, especially in commonly used, but arguably less accessible, consensus building techniques such as Delphi.<sup>65</sup>

A rigorous foundation of understanding important outcomes of prosthetic rehabilitation could lead to consensus and would direct the recommendation, or development of, a set of user-centred OMs. This set would also need to play its part in overcoming some of the barriers to measurement described here, such as capturing meaningful changes over time, feasibility of use and ease of interpretation in busy clinics, as well as not overburdening patients themselves. This process is unlikely to be as simple, as highlighted by the UKROC project when developing a national set for neuro rehabilitation. They describe a tension between identifying measures that have robust psychometric properties that generate data that is useful for quantitative analysis, and measures that are feasible to use in clinical settings, and that clinicians themselves *want* to use as part of the clinical decision making process.<sup>14</sup>

Usefully COMET have also defined 'Consensus-based standards for the selection of health Measurement Instruments', which is a systematic approach to identifying, selecting and assessing the quality of relevant tools, to capture the important outcomes agreed upon in a COS<sup>69,70</sup> thus defining a framework for *how* to measure outcomes.

It appears the final piece in the value puzzle may go beyond *what* to measure and *how* to measure it and focus on how outcome measurement data can be used. This review identified that many prosthetists felt that outcome measurement was not useful<sup>47</sup> which is supported by concerns described in the NHS PROMS programme consultation<sup>57</sup>, mental health examples<sup>58</sup> and the wider AHP literature.<sup>56</sup>

All of these examples report that the ability to use OM data as part of usual care to inform treatment planning and monitor the progress of long term conditions in real time is key.<sup>47,57,58</sup> The use of electronic records systems, as described by Heinemann as a facilitator of success<sup>49</sup>, is increasing rapidly throughout health care organisations and presents opportunities to develop IT that supports OM collection. Aims should be to integrate results with clinical records and present findings instantly, enabling real time use, as well as for locally owned reporting and upload to national data sets which could be accessed for research.<sup>71</sup> The UKROC programme attributed its consistent high quality data collection to the fact that OM data collated on their electronic system was available 'live' for clinicians. This access combined with careful integration of OMs into all aspects of clinical care, such as managing bed capacity

and discharge planning, ensured OMs were useful to clinical teams and promoted delivery of the best care.<sup>14</sup>

Although the use of electronic platforms could allow for less burdensome OM completion and real time feedback to clinicians, successful clinical uptake is likely to lie in the cost of the system as well as the accessibility of both the electronic version of the measure during data collection with patients, and the mode of presenting information and reporting in an accessible way for interpretation. A qualitative study of UK orthotists perceptions of outcome measurement identified technology as a potential enabler of OM use as long as it was usable, enabled interpretation of reports and met clinical need.<sup>67</sup>

Being able to interpret what OM data is telling us is another part of the puzzle, especially when using aggregated OM data.<sup>3,72</sup> Expert external facilitation was championed by Heinemann et al<sup>49</sup> and has been described as part of other system level OM initiatives.<sup>14</sup> Facilitation would be useful to support clinicians who report low levels of knowledge and confidence in using OMs, as well as working in busy clinical environments where there is often little time for anything other than treating patients.<sup>47,48</sup>

Developing partnerships with academic institutions or QI teams may help clinicians with the interpretation of findings and address educational needs through joint working. Academics often have highly developed data analysis skills and increasingly need to demonstrate the real-world impact of their work, for example in the UK's Research Excellence Framework and Knowledge Exchange Framework. Clinical academic roles, improvement fellowships or partnerships with universities could bridge the expertise gap between clinical practice, academia and QI.<sup>73</sup> This is critically important when attempting to translate outcome data into improvements in care. Outcome data itself does not inform what the underlying cause of a poor outcome is, and only indicates where a problem may lie. Further work, as described by Heinemann et al., is then required to investigate causes, implement change and evaluate its effectiveness.<sup>49,73,74</sup> Individuals with this valuable 'knowhow' may be critical to making outcome measurement really work in clinical practice.

## **Limitations**

It should be considered that this review identified OMs in the form of scales, tools or questionnaires and does not include other outcomes that may be in use clinically, or of importance to prosthetic users, such as hours of limb use or limb abandonment. A second limitation of this review is its narrative approach, however this broad overview is a useful starting point which sets the scene for more systematic approaches in the future to explore some of the themes identified here in more detail.

## **Conclusion**

This narrative review takes a broad look at outcome measurement in prosthetic rehabilitation from a clinical perspective and has demonstrated that successful implementation is complex and multifaceted. Understanding and embedding value at every step is key to success.

For clinicians reading this review, the take home message is that measuring the outcome of our interventions is important to understand the impact on patients and the performance of our services. However, it is more than just selecting an OM. Clinically we need to understand the 'why', 'what' and 'how' of outcome measurement. 'Why' measure, i.e. to inform at the individual or system level, 'what' to measure i.e. capturing outcomes that are meaningful, and 'how' to measure it i.e. the best tools for the job used in a systematic way that adds value to our practice.

Future work should consider all barriers to implementation and engage with patients and stakeholders throughout to overcome them. Consensus issues of *what* to measure and *how* to measure it need to be addressed, ensuring outcomes are meaningful to patients and measurement tools are accessible to use and interpret. Clinician led outcome measurement practice can then be developed in partnership

with HEIs or local quality improvement teams, focusing on making outcome measurement valuable to prosthetic rehabilitation services, to evidence and improve clinical practice.

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### **References**

1. Devlin NJ, Appleby J, Buxton M. Getting the Most out of PROMs : Putting Health Outcomes at the Heart of NHS Decision-Making. [www.Kingsfund.org.uk](http://www.Kingsfund.org.uk) 2010. Accessed Jan 2020. <https://www.kingsfund.org.uk/sites/default/files/Getting-the-most-out-of-PROMs-Nancy-Devlin-John-Appleby-Kings-Fund-March-2010.pdf>
2. Wade D. Outcome measurement and rehabilitation. *Clin Rehabil.* 1999;13:93-95.
3. Robinson C, Fatone S. You've heard about outcome measures, so how do you use them? Integrating clinically relevant outcome measures in orthotic management of stroke. *Prosthet Orthot Int.* 2013;37(1):30-42. doi:10.1177/0309364612446650
4. Duncan EA, Murray J. The barriers and facilitators to routine outcome measurement by allied health professionals in practice: a systematic review. *Heal Serv Res.* 2012;12(96). <http://www.biomedcentral.com/1472-6963/12/96>.
5. Colquhoun H, Letts L, Law M, MacDermid J, Edwards M. Feasibility of the Canadian occupational performance measure for routine use. *Br J Occup Ther.* 2010;73(2):48-54. doi:10.4276/030802210X12658062793726
6. Kucukdeveci A, Tennant A, Grimby G, Franchignoni F. Strategies for assessment and outcome measurement in physical and rehabilitation medicine: An educational review. *J Rehabil Med.* 2011;43:661-672.
7. Stokes E. *Rehabilitation Outcome Measures.* 1st Editio. London: Churchill Livingstone Elsevier; 2011.
8. Mcgrail K, Bryan S, Davis J. Let's All Go to the PROM: The Case for Routine Patient-Reported Outcome Measurement in Canadian Healthcare INViteD essAY. *Healthc Pap.* 2010;11(4).
9. NHS Digital. NHS PROMS Programme. [www.digital.nhs.uk](http://www.digital.nhs.uk). Accessed June 2020. <https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/patient-reported-outcome-measures-proms>
10. Naitonal Joint Registry. National Joint Registry. [www.njrcentre.org.uk](http://www.njrcentre.org.uk). Accessed Oct 2020. [www.njrcentre.org.uk](http://www.njrcentre.org.uk)
11. Porter M, Armstrong R, Howard P, Porteous M, Wilkinson JM. Orthopaedic registries - the UK view (National Joint Registry): Impact on practice. *EFORT Open Rev.* 2019;4(6):377-390. doi:10.1302/2058-5241.4.180084
12. UKROC. UK Rehabilitation Outcomes Collaborative. [www.ukroc.org](http://www.ukroc.org). Accessed Dec 2020.

13. Turner-Stokes L, Poppleton R, Williams H, Schoewenaars K, Badwan D. Using the UKROC dataset to make the case for resources to improve cost-efficiency in neurological rehabilitation. *Disabil Rehabil.* 2012;34(22):1900-1906. doi:10.3109/09638288.2012.670042
14. Turner-Stokes L, Williams H, Sephton K, Rose H, Harris S, Thu A. Engaging the hearts and minds of clinicians in outcome measurement the UK rehabilitation outcomes collaborative approach. *Disabil Rehabil.* 2012;34(22):1871-1879. doi:10.3109/09638288.2012.670033
15. Department of Health and NHS England. How to Understand and Measure Impact: The Better Care Fund. www.england.nhs.uk. 2015. Accessed June 2020. <https://www.england.nhs.uk/wp-content/uploads/2015/06/bcf-user-guide-04.pdf>.
16. British Association of Prosthetists and Orthotists. Measuring Change: An Introduction to Clinical Outcome Measures in Prosthetics and Orthotics. www.bapo.com. 2015. Accessed June 2020. <https://www.bapo.com/wp-content/uploads/2019/02/Measuring-Change-BAPO-website.pdf>
17. Scopes J, Tisdale L, Cole M-J, et al. The BACPAR outcome measures toolbox: a step towards standardising outcome measures for physiotherapists working with lower limb amputees. *Physiotherapy.* 2015;101:1357-1358.
18. Meehan T, McCombes S, Hatzipetrou L, Catchpole R. Introduction of routine outcome measures: staff reactions and issues for consideration. *J Psychiatr Ment Heal Nurs.* 2006;13(5):581-587.
19. Trauer T, Gill L, Pedwell G, Slattery P. Routine outcome measurement in public mental health – what do clinicians think? *Australian Heal Rev.* 2006;30(2):144-147.
20. Noble H, Smith J. Reviewing the literature: Choosing a review design. *Evid Based Nurs.* 2018;21(2):39-41. doi:10.1136/eb-2018-102895
21. Ferrari R. Writing narrative literature reviews. *Med Writ.* 2015;24(4):230-235. doi:10.1037/1089-2680.1.3.311
22. Heinemann AW, Connelly L, Ehrlich-Jones L, Fatone S. Outcome instruments for prosthetics: Clinical applications. *Phys Med Rehabil Clin N Am.* 2014;25(1):179-198. doi:10.1016/j.pmr.2013.09.002
23. Rommers GM, Vos LD, Groothoff JW, Eisma WH. Mobility of people with lower limb amputations: Scales and questionnaires: A review. *Clin Rehabil.* 2001;15(1):92-102. doi:10.1191/026921501677990187
24. Condie E, Scott H, Treweek S. Lower Limb Prosthetic Outcome Measures: A Review of the Literature 1995 to 2005. *J Prosthetics Orthot.* 2006;18(1):13-45. doi:10.1097/00008526-200601001-00004
25. NHS England. Complex Disability Equipment - Prosthetic Specialised Services For People Of All Ages With Limb Loss. www.england.nhs.uk. 2015. Accessed June 2020. <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/01/d01-serv-spec-dis-equ-prosth.pdf>
26. NHS England. Clinical Commissioning Policy: Microprocessor Controlled Prosthetic Knees. www.england.nhs.uk. 2016. Accessed June 2020. <https://www.england.nhs.uk/wp-content/uploads/2016/12/clin-comm-pol-16061P.pdf>
27. Xu J, Kohler F, Dickson H. Systematic review of concepts measured in individuals with lower limb amputation using the International Classification of Functioning, Disability and Health as a reference. *Prosthet Orthot Int.* 2011;35(3):262-268. doi:10.1177/0309364611412821

28. Gallagher P, Desmond D. Measuring quality of life in prosthetic practice: Benefits and challenges. *Prosthet Orthot Int.* 2007;31(2):167-176. doi:10.1080/03093640600988633
29. McDonald CL, Cheever SM, Morgan SJ, Hafner BJ. Prosthetic Limb User Experiences with Crossover Feet: A Pilot Focus Group Study to Explore Outcomes That Matter. *J Prosthetics Orthot.* 2019;31(2):133-139. doi:10.1097/JPO.0000000000000240
30. Schaffalitzky E, Gallagher P, MacLachlan M, Ryall N. Understanding the benefits of prosthetic prescription: Exploring the experiences of practitioners and lower limb prosthetic users. *Disabil Rehabil.* 2011;33(15-16):1314-1323. doi:10.3109/09638288.2010.529234
31. Schaffalitzky E, Gallagher P, MacLachlan M, Wegener ST. Developing consensus on important factors associated with lower limb prosthetic prescription and use. *Disabil Rehabil.* 2012;34(24):2085-2094. doi:10.3109/09638288.2012.671885
32. Roach KE. Measurement of health Outcomes: Reliability, validity and responsiveness. *J Prosthetics Orthot.* 2006;18(6 PROCEEDINGS). doi:10.1097/00008526-200601001-00003
33. Deathe AB, Wolfe DL, Devlin M, Hebert JS, Miller WC, Pallaveshi L. Selection of outcome measures in lower extremity amputation rehabilitation: ICF activities. *Disabil Rehabil.* 2009;31(18):1455-1473. doi:10.1080/09638280802639491
34. Hebert JS, Wolfe DL, Miller WC, Deathe AB, Devlin M, Pallaveshi L. Outcome measures in amputation rehabilitation: ICF body functions. *Disabil Rehabil.* 2009;31(19):1541-1554. doi:10.1080/09638280802639467
35. Hawkins AT, Henry AJ, Crandell DM, Nguyen LL. A systematic review of functional and quality of life assessment after major lower extremity amputation. *Ann Vasc Surg.* 2014;28(3):763-780. doi:10.1016/j.avsg.2013.07.011
36. Scopes J. Outcome measures of physical function in adult unilateral lower limb amputees during prosthetic rehabilitation: use in clinical practice and psychometric properties. 2016. <https://eresearch.qmu.ac.uk/handle/20.500.12289/7422>.
37. Resnik L, Borgia M, Silver B. Measuring Community Integration in Persons With Limb Trauma and Amputation: A Systematic Review. *Arch Phys Med Rehabil.* 2017;98(3):561-580.e8. doi:10.1016/j.apmr.2016.08.463
38. Balk EM, Gazula A, Markozannes G, et al. Psychometric Properties of Functional, Ambulatory, and Quality of Life Instruments in Lower Limb Amputees: A Systematic Review. *Arch Phys Med Rehabil.* 2019;100(12):2354-2370. doi:10.1016/j.apmr.2019.02.015
39. Amtmann D, Bamer AM, Kim J, et al. A comparison of computerized adaptive testing and fixed-length short forms for the Prosthetic Limb Users Survey of Mobility (PLUS-MTM). *Prosthet Orthot Int.* 2018;42(5):476-482. doi:10.1177/0309364617728118
40. Cella D, Gershon R, Lai J-S, Choi S. The future of outcome measurement: item banking, tailored short-forms and computerised adaptive testing. *Qual Life Res.* 2007;16:133-141.
41. Amtmann D, Morgan SJ, Jiseon K, Hafner BJ. Health-related profiles of people with lower limb loss. *Arch Phys Med Rehabil.* 2015;96(8):1474-1483. doi:10.1016/j.apmr.2015.03.024
42. Beaton D, Bombardier C, Katz J. A taxonomy for responsiveness. *J Clin Epidemiol.* 2001;54:1204-1217.
43. Rushton PW, Miller WC, Deathe AB. Minimal clinically important difference of the L Test for individuals with lower limb amputation: A pilot study. *Prosthet Orthot Int.* 2015;39(6):470-476. doi:10.1177/0309364614545418

44. Franchignoni F, Trallesi M, Monticone M, Giordano A, Brunelli S, Ferriero G. Sensitivity to change and minimal clinically important difference of the Locomotor Capabilities Index-5 in people with lower limb amputation undergoing prosthetic training. *Ann Phys Rehabil Med.* 2019;62(3):137-141. doi:10.1016/J.REHAB.2019.02.004
45. Franchignoni F, Ferriero G, Giordano A, Monticone M, Gironi G, Burger H. The minimal clinically-important difference of the Prosthesis Evaluation Questionnaire - Mobility Scale in subjects undergoing lower limb prosthetic rehabilitation training. *Eur J Phys Rehabil Med.* 2020;56(1):82-87.
46. de Vet HCW, Terwee CB, Mokkink LB, Knol DL. *Measurement in Medicine: A Practical Guide.* Cambridge: Cambridge University Press; 2011. doi:10.1017/CBO9780511996214
47. Hafner BJ, Spaulding SE, Salem R, Morgan SJ, Gaunaud I, Gailey R. Prosthetists' perceptions and use of outcome measures in clinical practice: Long-term effects of focused continuing education. *Prosthet Orthot Int.* 2017;41(3):266-273. doi:10.1177/0309364616664152
48. Gaunaud I, Spaulding SE, Amtmann D, et al. Use of and confidence in administering outcome measures among clinical prosthetists: Results from a national survey and mixed-methods training program. *Prosthet Orthot Int.* 2015;39(4):314-321. doi:10.1177/0309364614532865
49. Heinemann AW, Ehrlich-Jones L, Connelly L, Semik P, Fatone S. Enhancing quality of prosthetic services with process and outcome information. *Prosthet Orthot Int.* 2017;41(2):164-170. doi:10.1177/0309364616637957
50. Young J, Rowley L, Lalor S. Use of Outcome Measures Among Prosthetists and Orthotists in the United Kingdom. *J Prosthetics Orthot.* 3(3):152-157.
51. Borrenpohl D, Kaluf B, Major MJ. Survey of U.S. Practitioners on the Validity of the Medicare Functional Classification Level System and Utility of Clinical Outcome Measures for Aiding K-Level Assignment. *Arch Phys Med Rehabil.* 2016;97(7):1053-1063. doi:10.1016/j.apmr.2016.02.024
52. Davie-Smith F, Heberton J, Scott H. A Survey of the Lower Limb Amputee Population in Scotland 2017. [www.knowledge.scot.nhs.uk](http://www.knowledge.scot.nhs.uk). 2020. Accessed Sept 2020. <https://www.england.nhs.uk/wp-content/uploads/2016/12/clin-comm-pol-16061P.pdf>
53. Kamrad I, Söderberg B, Örneholm H, Hagberg K. SwedeAmp—the Swedish Amputation and Prosthetics Registry: 8-year data on 5762 patients with lower limb amputation show sex differences in amputation level and in patient-reported outcome. *Acta Orthop.* 2020;3674. doi:10.1080/17453674.2020.1756101
54. Huijbregts M, Myers A, Kay T, Gavin T. Systematic outcome measurement in clinical practice: challenges experienced by physiotherapists. *Physiother Canada.* 2002;54:25-31.
55. Boyce MB, Browne JP, Greenhalgh J. The experiences of professionals with using information from patient-reported outcome measures to improve the quality of healthcare: A systematic review of qualitative research. *BMJ Qual Saf.* 2014;23(6):508-518. doi:10.1136/bmjqs-2013-002524
56. Jette D, Halbert J, Iverson C, Miceli E, Shah P. Use of standardised outcome measures in physiotherapy practice: perceptions and applications. *Phys Ther.* 2009;89(2):125-135.
57. NHS England. National Patient Reported Outcome Measures (PROMs) Programme Consultation Report. [www.england.nhs.uk](http://www.england.nhs.uk). 2017. Accessed June 2020. <https://www.england.nhs.uk/wp-content/uploads/2017/10/proms-consultation-report.pdf>.
58. Ride J, Jacobs R. Clinical Engagement with HoNOS. [www.healthylondon.org](http://www.healthylondon.org). 2018. Accessed

June 2020. <https://www.healthylondon.org/wp-content/uploads/2017/11/Clinical-engagement-with-HoNOS-REPORT-JUL-2018-FINAL.pdf>

59. Van Peppen R, Maissan F, Van Genderen F, Van Dolder E, Meeteren N. Outcome measures in physiotherapy management of patients with stroke: a survey into self reported use, and barriers to and facilitators for use. *Physiother Res Int*. 2008;13(4):255-270.
60. Skeat J, Perry A. Exploring the implementation and use of outcome measurement in practice: a qualitative study. *Int J Lang Commun Disord*. 2008;43(2):110-125.
61. Copeland J, Taylor W, Dean S. Factors influencing the use of outcome measures for patients with low back pain: a survey of New Zealand physical therapists. *Phys Ther*. 2008;88(12):1492-1505.
62. Russek L, Wooden M, Ekedahl S, Bush A. Attitude towards standardized data collection. *Phys Ther*. 1997;77(7):714-729.
63. Tugwell P, Boers M, Brooks P, Simon L, Strand V, Idzerda L. OMERACT: An international initiative to improve outcome measurement in rheumatology. *Trials*. 2007;8:1-6. doi:10.1186/1745-6215-8-38
64. Khan K. The CROWN Initiative: Journal editors invite researchers to develop core outcomes in women's health. *J Ovarian Res*. 2015;8(1):10-12. doi:10.1186/s13048-015-0133-7
65. Williamson PR, Altman DG, Bagley H, et al. The COMET Handbook: Version 1.0. *Trials*. 2017;18(Suppl 3):1-50. doi:10.1186/s13063-017-1978-4
66. COMET Initiative. Core Outcomes in Effectiveness Trials. [www.comet-initiative.org](http://www.comet-initiative.org). Accessed June 2020. [www.comet-initiative.org](http://www.comet-initiative.org).
67. Hall N, Parker D, Williams A. An exploratory qualitative study of health professional perspectives on clinical outcomes in UK orthotic practice. *J Foot Ankle Res*. 2020;13(1):1-11. doi:10.1186/s13047-020-00416-w
68. Kirwan JR, Hewlett SE, Heiberg T, et al. Incorporating the patient perspective into outcome assessment in rheumatoid arthritis - Progress at OMERACT 7. *J Rheumatol*. 2005;32(11):2250-2256.
69. Prinsen CAC, Vohra S, Rose MR, et al. How to select outcome measurement instruments for outcomes included in a "Core Outcome Set" - a practical guideline. *Trials*. 2016;17(1). doi:10.1186/s13063-016-1555-2
70. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol*. 2010;63(7):737-745. doi:10.1016/j.jclinepi.2010.02.006
71. O'Connell S, Palmer R, Withers K, Saha N, Puntoni S, Carolan-Rees G. Requirements for the collection of electronic PROMS either "in clinic" or "at home" as part of the PROMs, PREMs and Effectiveness Programme (PPEP) in Wales: a feasibility study using a generic PROM tool. *Pilot Feasibility Stud*. 2018;4(1):1-13. doi:10.1186/s40814-018-0282-8
72. Boyce M, Browne JP, Greenhalgh J. The experience of professionals with using information from patient-reported outcome measures to improve the quality of healthcare: a systematic review of qualitative research. *BMJ Qual Saf*. 2013;53(9):1689-1699. doi:10.1017/CBO9781107415324.004
73. Greenhalgh J, Dalkin S, Gibbons E, et al. How do aggregated patient-reported outcome measures data stimulate health care improvement? A realist synthesis. *J Heal Serv Res Policy*. 2018;23(1):57-65. doi:10.1177/1355819617740925

74. Hebenton J, Scott H, Seenan C, Davie-Smith F. Relationship between models of care and key rehabilitation milestones following unilateral transtibial amputation: a national cross-sectional study. *Physiother (United Kingdom)*. 2019;105(4):476-482. doi:10.1016/j.physio.2018.11.307



Table 1 – Summary of systematic reviews of OM tools for use following lower limb amputation

Authors	Outcome domains Included	Key findings
Rommers et al 2001 <sup>24</sup>	Mobility	19 different measurement tools were identified that differ in method and measuring range and there is no consensus about measuring mobility in the current literature.
Condie et al 2006 <sup>25</sup>	Mobility Function Quality of life	25 measurement tools were identified from 28 different studies. The complexity of studies makes it too difficult for clinicians to use the findings in the literature to inform their choice of outcome measure.
Deathe et al 2009 <sup>34</sup>	ICF* domain of Activity	17 instruments were identified but there is a lack of evidence about the responsiveness of all measures included.
Hebert et al. 2009 <sup>35</sup>	ICF domain of Body Function and Structure	16 measurement tools were identified but not many comprehensively validated tools exist to measure the domain of body function and structure. For all the tools identified in this review responsiveness to interventions has not been established.
Xu et al. 2011 <sup>28</sup>	All domains measured following limb loss	113 outcome measures were identified. 90% of the concepts measured could be linked to ICF categories and these categories could be used to develop an ICF core set for amputation.
Heineman et al 2014 <sup>23</sup>	Mobility Function Quality of life	This review replicated Condie et al 2006 review to update evidence base. Only a few of the included measures present MCID <sup>+</sup> values which is vital for tools to be clinically useful and significant work is required to develop both these values and population norms.

Hawkins 2014 <sup>36</sup>	Function Quality of life	21 different assessment tools were identified from 40 studies. Only 5 tools were used in more than 3 studies and the heterogeneity of the measures used makes it difficult to compare lower limb outcome studies.
Scopes 2016 <sup>37</sup>	Physical Function	37 measures were identified but there is a paucity of high quality studies exploring the psychometric qualities of outcome measures of physical function. The responsiveness of these measures is generally unknown and limits their use in evaluating the effectiveness of interventions.
Resnick et al. 2017 <sup>38</sup>	Participation	34 measures and 94 subscales were identified but most measures had limited evidence around psychometric properties.
Balk et al 2019 <sup>39</sup>	Function Ambulation Quality of life	50 instruments were identified but the numerous instruments available have variable psychometric properties, and there is no evidence as to whether tools designed for use or used prior to prosthetic prescription are predictive of outcome.

\*International Classification of Function

+Minimal Clinically Important Difference