

From outcome measurement to improving health outcomes after lower limb amputation – A narrative review exploring outcome measurement from a clinical practice perspective

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Abstract

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. This paper presents a narrative review which aims to describe the state of the outcome measurement evidence base in prosthetic rehabilitation, as applied in clinical practice, with a view to identifying areas for future work aimed at making outcome measurement in prosthetic rehabilitation a meaningful reality. A literature search of four databases was undertaken, following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis principals appropriate to narrative reviews, and using the search terms outcome, measur*, tool, scale, instrument, prosthe*, 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. Themes were: 1) What outcome domains should be measured? 2) How can these outcome domains be measured? 3) What are the barriers to outcome measurement? and 4) What can be learnt from examples of ROM in prosthetic rehabilitation? Findings suggest that successful outcome measurement is multifaceted. Understanding and embedding value at every step appears to be key to success. Addressing the questions of ‘what’ outcome domains to measure and ‘how’ to measure them, may help establish consensus. Routine outcome measurement practice at the clinical level should ensure data collection is valuable to clinical practice, makes use of information technology solutions and has organisational engagement.

Keywords

outcome measurement, prosthetic limbs, amputation, rehabilitation, prosthesis, value, clinical practice

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Background

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

The term outcome measurement can be better understood by breaking it down into the outcome domain being measured and the measurement tool used for the task. An outcome domain can be defined as an element of health (i.e. pain, physical function, emotional well-being, or social activity) that is changed by a particular intervention.² A measurement tool can be defined as a standardized instrument used in research and clinical practice to capture and evaluate this change.³

Within clinical practice, outcome measurement in the form of professional reported measures, performance-based measures, or patient/self-reported outcome measures (PROMs)³ 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 after an intervention or when monitoring patients over time.³ This information can be shared with the patient to review progress throughout rehabilitation, and increase motivation, or can be used by the clinician to highlight areas of concern, direct treatment planning, or justify requests for the funding of interventions or devices,⁴ for example, the National Health Service (NHS) England Microprocessor Knee Policy within the United Kingdom.⁵

A more coordinated 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 standardized OM(s) in clinical practice with every patient as part of a standardized assessment practice guideline.”⁶ This systematic

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approach to outcome measurement can provide individual services or departments with a wealth of information on the quality of care and interventions they are delivering.⁷ Data can be used to direct and inform improvement work and evaluate the changes resulting from services or departments developing new ways of working. When coordinated ROM is commenced in a number of services, benchmarking can be undertaken⁸ and a system-wide approach adopted, that is, undertaken across organizations that deliver the same services to a target population. This system-level approach to ROM can be useful in several contexts, especially if widely accessible. It allows comparison of the performance of different healthcare providers and gives patients valuable information on the best performing organizations, enabling informed decisions on where to receive care.¹ 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 data sets 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. If healthcare services want to ensure they are delivering the most effective care, they need information, specifically about the outcome of care, which can both direct the focus of meaningful improvement programs and evaluate their impact.⁹

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

The NHS England PROMs programme¹⁰ collects PROMs data for hip and knee replacements, before and after surgery. Data are collected nationally and allow comparison of surgical centers and informed patient choice of centers with the best outcomes. Crucially this program is linked to the National Joint Registry, which collects implant safety data from across the United Kingdom on all joint replacement surgery.¹¹ 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.¹²

UKROC applies system-wide ROM in the context of rehabilitation and aims to provide data that can inform the provision of cost-effective neurorehabilitation services in the NHS.¹³ The collaborative developed a national clinical database combining data on rehabilitation needs, the interventions patients received, and importantly their outcomes. Data collected were used to demonstrate that specialist neurorehabilitation was a highly cost-effective intervention compared with potential lifelong care needs. This evidence led to significant investment in rehabilitation services throughout the NHS, alongside the development of evidence-based standards of care that have reduced variation across the system and driven up quality.¹⁴

However, even within these valuable examples of system-wide ROM, engaging clinicians in outcome measurement is a challenge,¹⁵ and it is widely acknowledged that OMs are not routinely used in clinical practice.⁴ NHS policy¹⁶ and prosthetic rehabilitation professional bodies, such as the British Association of Prosthetists and Orthotists and the British Associations of

Chartered Physiotherapists in Amputation Rehabilitation, have issued advocacy and guidance on OMs in clinical services.^{17,18} However, the use of OMs has yet to become embedded, and there is currently no UK outcome data collection initiative capturing the inherent usefulness of this information after amputation.⁴ Despite the common view that it is due to ambivalence of clinicians¹⁹ and a resistance to change and innovation among service providers,²⁰ a systematic review by Duncan and Murray⁴ exploring barriers and facilitators to OM use among 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 organizational support.

To make ROM a meaningful reality after lower limb amputation, which has the potential to evaluate and direct improvements in the care provided to patients, it is important to understand what is already known about outcome measurement within this context. As described above, there are many factors that may need to be identified and considered in this setting. Therefore, a narrative review has been undertaken to enable a broad approach to surveying and critically synthesizing the current state of knowledge on outcome measurement within the field of prosthetic rehabilitation and identify problem areas for future work that will have clinical value.

Methods

Narrative approach

A narrative approach was chosen for this review to allow for a broader exploration of the outcome measurement literature within the prosthetic rehabilitation evidence base. This broad approach fits well with the narrative review methodology because it does not stipulate the formulation of a specific research question, as required for scoping or systematic reviews, which may have resulted in relevant issues being overlooked.²¹ For example, a review of systematic reviews in Norway, generated to inform policy-making, found that the evidence base included in the systematic reviews was narrow and represented only a small proportion of questions relevant to public policy.²²

However, there has been much criticism of narrative reviews in the past, and they have often been described as inferior to systematic reviews.²³ Criticism includes the absence of a method that can be peer reviewed, or the potential introduction of conscious or unconscious bias by the researcher because they select studies to be included without any inclusion or exclusion criteria, or quality assessment.²⁴ More recently, Furley and Goldshmeid²⁵ challenged this hierarchical stance and suggested that narrative reviews should be seen as complimentary to systematic reviews rather than inferior. They suggested that the lens of the authors—in this case a range of experienced interdisciplinary international clinicians and academicians working within the field of prosthetic rehabilitation—can be used to help those viewing outcome measurement through a similar lens and to understand the implications of the evidence. Perhaps in a similar way to qualitative research, where the researcher is seen as part of the research process and encouraged to be reflexive about their impact, the role and assumptions of the researcher in narrative reviews should also be considered.

Greenhalgh et al²³ also suggested that narrative reviews can be an important start in a field where little is known or summarized about

a subject, such as outcome measurement in prosthetic clinical practice. This approach can help contextualize the evidence base and pose unanswered questions for more informed future work.²³ The voice of the clinical narrative thread may have been lost within the constraints of more systematic methodologies²⁶; therefore, this broad overview may be a useful starting point which sets the scene for more systematic approaches in the future. However, in light of published criticisms, in order for a narrative review to be meaningful, a rigorous approach should be adopted, using processes drawn from systematic reviews, such as search methods, selection criteria, data extraction, and interpretation.^{25,26}

Search strategy

A literature search was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis principles appropriate to narrative reviews, as set out by Ferrari,²⁶ and is described here in two steps. Step 1 describes the initial literature search and the selection of articles from reviewing titles and abstracts. Step 2 describes the selection of articles after full-text review and inclusion of additional papers identified through searching reference lists and gray literature sources.

Step 1

The CINAHL, Medline, ScienceDirect, and PsycInfo bibliographic databases were searched in July 2020. The keyword outcome AND (measur* OR tool OR scale OR instrument) was combined with AND (prosth* OR amput* OR “limb loss”) and searched in titles and abstracts. An English language filter was used with no specified date range to include all relevant publications. This identified 1116 papers, which after the removal of duplicates was reduced to 777 records. The following selection criteria were used to identify relevant papers, from the 777 records identified, for full-text review:

Inclusion criteria were as follows:

- papers exploring how to measure outcome after lower limb amputation,
- papers that focused on outcome measurement in prosthetic clinical practice settings, and
- papers describing outcome measurement tool development or psychometric property testing for use after lower limb amputation.

The exclusion criterion was as follows:

- studies using outcome measurement for research purposes.

This resulted in 78 papers for full-text review.

Step 2

Step 1 yielded a number of Systematic Reviews (SRs) (10) exploring the development and psychometric properties of OMs for use after lower limb amputation. Primary studies of individual OMs were therefore excluded to avoid duplication. The following exclusion criteria were added:

- primary studies exploring the development of outcome measurement tools and
- primary studies exploring the psychometric properties of outcome measurement tools.

This resulted in 25 papers. An additional 11 papers were identified through searching of reference lists and gray literature sources. Thirty-six papers were therefore included in the narrative review. See Figure 1.

Critical assessment

Because the aim of this review was to explore the current state of knowledge, including gray literature, no formal critical appraisal tool was used to exclude any papers based solely on their quality. However, principles of critical appraisal were integrated throughout the review to evaluate and highlight any variability in the quality of the evidence. This approach was taken to ensure all key issues were included at this early scoping stage.

Data extractions and theme development

Key themes were developed to synthesize findings across the papers. This involved the lead author reading and critiquing the papers, and developing early concepts, which were discussed and refined with the wider team into a clear set of initial themes. These themes were then reviewed and posed as questions to directly address the narrative review aims to (1) survey the state of knowledge on outcome measurement within the field of prosthetic rehabilitation from a clinical practice perspective and (2) identify areas for future work aimed at making ROM a meaningful reality in clinical settings. The four themes are as follows:

- *What outcome domains* should be measured?
- *How* can these outcome domains be measured?
- *What are the barriers* to using OMs?
- *What can be learned* from examples of ROM in prosthetic rehabilitation?

Results

What outcome domains should be measured?

In 2014, a study by Heinemann et al²⁷ identified 43 unique measurement instruments designed to capture outcome after lower

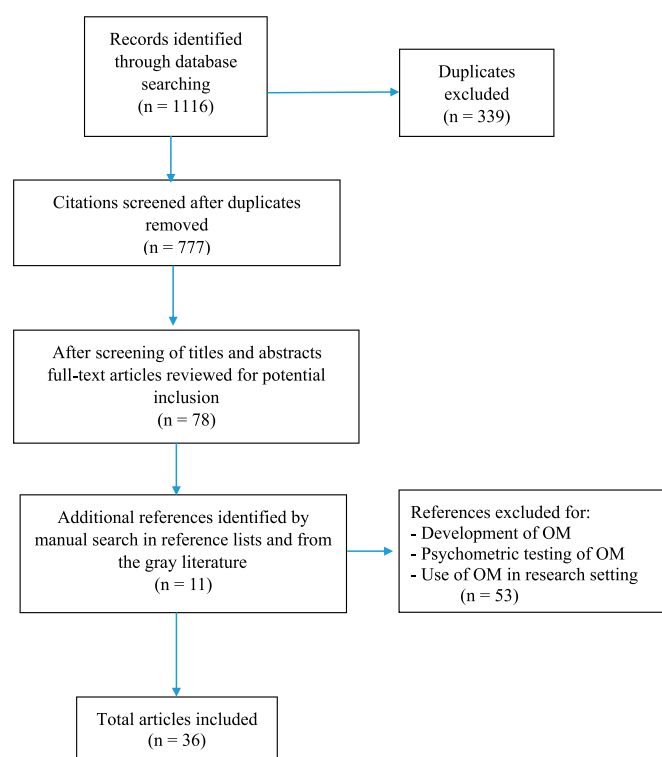


Figure 1. Narrative review process flow chart.

limb amputation. This wide variety of tools measured an extensive range of outcome domains, such as mobility, falls risk, balance, function, quality of life, socket comfort, psychological adjustment, and satisfaction with devices and services. In a number of cases, many tools or tests had been developed to capture the same domain, that is, mobility. Several authors exploring measurement tools have raised the issue that there is no consensus around which tools should be used.^{28,29} This plethora of tools and absence of consensus also seems to be evident in the current UK health policy and professional guidance, where long lists of OMs are suggested for use in the Prosthetic National Service Specification,³⁰ the NHS Microprocessor Knee Policy,⁵ the British Associations of Chartered Physiotherapists in Amputation Rehabilitation OMs toolbox,¹⁸ and the British Association of Prosthetists and Orthotists OM guidance.¹⁷ These resources seem to recommend the use of many different measures, with little consistency, and often include different measures that capture the same outcome domain.

This lack of consensus around measurement tools is a major barrier to system-wide ROM but may in fact be underpinned by another lack of consensus, that is, what outcome *domains* should be measured. This raises two separate unanswered questions within the field of lower limb prosthetic rehabilitation: *What* outcome domains should be measured and *how*, that is, with which tools, should they be measured? The studies identified in this review addressing *what* outcome domains should be measured will be discussed in this theme. Studies exploring *how* they should be measured will be reviewed in the theme exploring outcome measurement tools.

Three studies were identified that explored the theme of *what* domains should be measured. A study by Xu et al³¹ approached this question by exploring possible outcome domains that capture the concept of health, as defined using the International Classification of Functioning. The authors identified a core set of International Classification of Functioning domains which define health as it applies to people after amputation. Currently, this work has yielded large numbers of domains which could be measured. However, capturing them all may be impractical in clinical practice, and this approach does not give an indication of which of the domains may be most meaningful to measure, especially to prosthetic users themselves, for whom the outcome of prosthetic rehabilitation has the greatest impact.

A more patient-centered approach to outcome measurement in prosthetics was called for in a review by Gallagher and Desmond in 2007³² who suggested measuring quality of life may be an important first step in this process. Subsequently two studies have taken this patient-centered approach further by using qualitative methods to explore outcome domains that matter to patients. McDonald et al³³ used focus groups to explore meaningful outcome domains when prescribing prosthetic feet, and Schaffalitzky et al^{34,35} explored user, clinician, and wider stakeholder views on the outcome of prosthetic prescription through interviews, focus groups, and a Delphi consensus process. Both studies focused on the prescription of components rather than holistic rehabilitation postamputation, and McDonald et al³³ 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 not being in a wheelchair. Interestingly Schaffalitzky et al³⁴ also found that clinicians and patients often prioritized different domains, that is, quality of life, which was prioritized as a domain by clinicians but not by prosthetic users. Users

instead seemed to describe *the ways* in which their quality of life could be improved as the important domains. Because clinicians are most likely to select what outcome domains are measured, it is possible that services may not be capturing the outcome domains that really matter.

Despite this valuable exploratory work, domain consensus remains elusive in prosthetic rehabilitation and without understanding *what* domains to measure, achieving consensus around *how* to measure them becomes even more challenging. Despite this many of the studies identified in this review focus on how to measure outcome, which will be discussed in the next theme.

How can these outcome domains be measured?

The main focus of the outcome measurement literature identified in this review was the development and psychometric testing of measurement tools themselves. Ten SRs were identified in the literature which collated and critiqued measurement tools for use after lower limb amputation (Table 1). The tools identified in the reviews varied in the quality of their methodological development and the different psychometric properties which had been investigated (i.e. the level of measurement, validity, reliability, and responsiveness).³⁶ Seven of the SRs used scoring systems to rate the quality of the instruments they included; however, different scoring approaches led to variation in recommended measures.³⁷⁻⁴³ This variation, in combination with large numbers of measures, and gaps in the reporting of psychometric properties for many measures, may contribute to a lack of 'gold standard' OM or OM consensus. In the most recent SR by Balk et al, the need for a core set of validated OMs is raised to enable comparability across studies and increase their overall value.³⁷

Among the many outcome measures described in these SRs, two reviews^{27,37} included measures that use item banks (Patient-Reported Outcomes Measurement Information System [PROMIS] and the Prosthetic Limb Users Survey–Mobility [PLUS-M]⁴⁴), which have interesting implications for clinical practice. An item bank, developed using item response theory,⁴⁵ consists of different questions exploring the same outcome domain, which are individually validated and calibrated on a single scale. The items from the bank can then be used as required by individual clinicians or researchers to develop specific short forms or be administered through computer adaptive testing.⁴⁶ Computer adaptive testing uses algorithms to select items from the bank for individual patients based on their responses to previous questions.⁴⁷ This tailored approach is able to achieve the same reliability with fewer questions therefore reducing the measurement burden on patients.⁴⁶ Despite the use of different questions with each patient, the results are comparable because all items in the bank are drawn from the same scale. Both the PROMIS and the PLUS-M item banks allow comparison of scores to a large development sample allowing clinicians to compare scores with normative data. In the case of the PLUS-M, these data are specific to the limb loss population. Normative data for an outcome measure can be useful for clinicians to compare individual patient or service outcome scores, giving meaning to scores because they are viewed in the context of the wider limb loss or general population. However, few measures for use after amputation have published normative data.⁴⁰

Despite the advantages of this approach, as with all OMs, consideration must be given to the population used to develop the OM or select items for an item bank, especially in limb loss research

Table 1. Summary of systematic reviews of outcome measure tools for use after lower limb amputation.

Authors	Outcome domains included	Key findings
Rommers et al 2001 ²⁸	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 ²⁹	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 ⁴³	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 ⁴⁰	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 ³¹	All domains measured after 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 ²⁷	Mobility Function Quality of life	This review replicated the review by Condie et al 2006 to update the evidence base. Only a few of the included measures present MCID 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 ³⁸	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 ⁴²	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 ⁴¹	Participation	34 measures and 94 subscales were identified, but most measures had limited evidence around psychometric properties.
Balk et al 2019 ³⁷	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.

Abbreviations: ICF, International Classification of Function; MCID, minimal clinically important difference.

which can oversample people with traumatic limb loss⁴⁸ 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, that is, older dysvascular patients, or those from different social and cultural backgrounds. This is a global consideration for the OMs described in the SRs. Many of the measures have been developed in English and although some have now been translated and validated in other languages, which is important for use in today's diverse society, and across the world, 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, for example, 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.

However, whatever the measure, a key concern highlighted in seven of the 10 SRs was responsiveness or the ability to detect

change when it has occurred,^{27,29,38-40,42,43} which is a priority when using OMs to evaluate rehabilitation interventions in clinical settings.⁴⁹ Many of the SRs described an absence of data regarding the ceiling or flooring effects of OMs.^{38,43} The presence of a ceiling or flooring effect limits a measure's ability to detect change at either end of its scale. In a population where outcomes of rehabilitation can vary substantially between young individuals with a transtibial amputation and more elderly dysvascular persons with a transfemoral amputation, this information is crucial to help understand whether a single measure can be used to capture the outcome of the limb loss population as a whole or whether different OMs are required for subsets of the population, that is, high activity patients, to generate more meaningful information for clinical practice.

When considering the responsiveness of an OM, two important values exist to help clinicians interpret OM findings, the minimal detectable change (MDC) and the minimal clinically important

difference (MCID) values. The MDC is the smallest change that can be detected by the OM which is not due to an error in measurement, that is, a real change,⁵⁰ and the MCID is the smallest change in the score that indicates an important change for the patient, that is, a meaningful change.⁵¹ Five of the systematic reviews described OMs with these values.^{27,37,39,42} MDC (or its equivalent values, i.e. smallest detectable difference, smallest detectable change, and smallest real difference) was established for 20 measures, whereas three reviews identified only two measures with an MCID value.^{37,39,42} Although the MDC value can be useful clinically, without MCID values, clinicians and patients do not know whether the change they have recorded represents a meaningful change to patients' lives, whether clinical interventions were effective, and importantly, whether the investment in rehabilitation was justified. However, reflecting on the first theme of this narrative review, MCID values may only be truly meaningful if the OM captures an outcome domain which is meaningful to the patient's perception of recovery in the first place.

For clinicians, evaluating and understanding the OMs evidence base presented in these SRs to help make an informed choice of which OM to use can be challenging. This has been attributed to the technical nature and jargon-filled literature describing psychometric properties, as well as considerations over tool development and the appropriate population for use.^{29,39} This process may be especially challenging when considering ROM at the service or system level, where OM selection is not guided by an individual patient's problems or needs.

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 use⁵²⁻⁵⁵; however, it should be noted that two of them focus on the same group of clinicians.^{52,53} The barriers identified in this review focus on the experiences of prosthetists, of whom only 28%–44% describe themselves as routine users of OMs.^{42,52,53,55} 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.⁴² 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 multidisciplinary team.

In all the studies included in this theme, insufficient time was identified as a key barrier because clinicians struggled to integrate outcome measurement into their usual clinical routines.^{52,53,55} Although time was identified as a barrier, the studies did not objectively produce an actual time for OM administration, suggesting that time may be more of a perceived than an actual barrier. A further impediment to the use of OMs identified in these studies was 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 an undergraduate level.^{52,53,55}

An interesting finding from the study by Hafner et al⁵² exploring perceptions of outcome measurement among 66 US prosthetists

showed that a third of participants did not agree that outcome measurement provides useful data. 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 Predictor⁵⁶ measure than the quicker-to-administer Timed Up and Go.⁵⁷ The authors discussed that this may be because the Amputee Mobility Predictor was designed to guide the prescription of prosthetic componentry to insurance companies. This is supported by a study from Borrenpohl et al⁵⁸ who found that regular OM use increased to 77% when prosthetists were specifically asked about using OMs to support payment claims. These findings demonstrate the impact of the 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.^{52,53} An educational program 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 1 year later.⁵² However, these findings should be viewed with caution because 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.

What can be learned from examples of ROM in prosthetic rehabilitation?

Despite the many barriers identified in this review, examples of system-wide ROM in prosthetic settings were identified and have been explored in this theme to consider any learning for future work. A single study by Heinemann et al explored the use of routinely collected PROMs data to inform quality improvement (QI) activities across seven US prosthetic clinics.⁵⁴ The authors described the implementation of ROM as challenging with only two of the seven clinics involved actually collecting enough data to undertake QI projects.⁵⁴ However, because 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.⁵⁴ Clinics that were successful in implementing ROM demonstrated high levels of organization related to the project, integrated data collection with their electronic records, and had well-defined pathways of care. Clinicians in these centers reported being motivated by the chance to use PROMs to improve the care they provided to patients; however, expert external facilitation was described as being crucial to increase QI knowledge within the clinical team, interpret aggregated data, and translate ROM findings into improvement work.⁵⁴

Two further examples of ROM identified in this review can be found within national registries, and as with the National Joint Registry, they attempt to link demographic, surgical information and interventions with outcome data to understand the impact of lower limb amputation on patients, healthcare providers, and society. Although in some cases registries can operate separately from clinical settings and may seem inaccessible to clinical practice, they are often dependent on clinical services to collect and input data (i.e. the two examples included). This requires the implementation of data collection processes, including ROM, and therefore,

these examples have been included in this theme as they may provide interesting insights.

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 Scotland⁵⁹ and SwedeAmp which is the national lower limb amputation registry from Sweden.⁶⁰ Both registries attempt to evaluate the whole pathway after lower limb amputation, collecting demographic details, surgical and rehabilitation interventions, prosthetic supply, and outcome information, in partnership with local clinicians and services. For SwedeAmp, the authors describe implementation across the country as slow, and after 9 years, the registry only captures 62% of amputations,⁶⁰ perhaps illustrating the challenges related to multidisciplinary system-level data collection. Despite this, data were collected on 5762 people after amputation; however, the size of the sample described in the presentation of outcome data collected at 12 and 24 months, using the EQ-5D-5L, had notably decreased to $n = 247$ and $n = 156$, respectively. No information was presented to explain this outcome measurement attrition, but insights from the project team would be useful to reflect on ROM in these settings.

By contrast, SPARG, which is a small group of 20 clinically based physiotherapists, currently captures 90% of amputations in Scotland and has been conducted for more than 20 years.⁵² The size and uniprofessional nature of the group may account for its success in data capture, alongside the availability of disaggregated data for benchmarking, and ongoing improvement work,⁶¹ but also places a limitation on the scope of the data set.

These projects demonstrate that system-wide data collection of outcome information is possible in this field. Further publications regarding the implementation of these registries, especially regarding ROM implementation and data collection by clinical partners, may have value for the development of similar projects elsewhere. The potential value of the experiences of the SPARG and SwedeAmp creators may also include understanding how the outcome domains were selected and why, how the data are shared with clinical practice, and how it informs local and national improvement activities, as well as how data privacy, security, and governance were addressed, and finally how the barriers described in this review were overcome.

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 learned 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.^{4,20,62-64}

This review identified that establishing value in outcome measurement could be a potential facilitator to addressing barriers to implementation. The issue of value has been raised in previous ROM initiatives. A multistakeholder consultation on the NHS PROMS programme in 2017 found that many clinicians and managers believed it was not worth continuing with the program despite 8 years of data collection.⁶⁵ The consultation reported that the data collection was not useful to clinical practice and could not be used during clinical consultations and that reports took too long to be published, so findings were out of date.⁶⁵ This lack of perceived value was also described in mental health settings where clinicians believed that ROM using the Health of the Nation Outcome Scale was overly bureaucratic, only concerned with performance management, lacked feedback of results, and presented no relative meaning for their role.⁶⁶ It seems clear that establishing the value of ROM to clinical stakeholders is key for success.⁶⁷⁻⁷⁰

Understanding *what* outcome domains are important and meaningful to measure, especially from the patient perspective, and *how* to measure them effectively after lower limb amputation could help make outcome measurement more useful to all stakeholders and underpin future consensus work. An absence of consensus on outcome measurement²⁹ is not unique to prosthetic rehabilitation, and attempts have been made to address the issue in several areas of health such as rheumatology⁷¹ and women's health,⁷² especially when related to research. The reporting of numerous outcomes in clinical trials can make the synthesis and comparison of different studies near impossible.⁷³ 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* domains to measure through core outcome sets (COS) to be recorded in all clinical trials of a specific condition.⁷⁴ They also highlight that this approach can be useful to build consensus around outcome measurement in clinical practice.⁷³ COMET adopt a multistakeholder approach to identifying outcome domains 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 center of this process, ensuring that a COS is measuring domains that matter most to the people affected by the outcome of an intervention.⁷³ The studies identified in this review by Schaffalitzky et al and McDonald et al have made some progress toward understanding the domains that define successful prosthetic prescription from a user's perspective, especially focusing on the need to measure psychosocial outcomes.³³⁻³⁵ Schaffalitzky et al also highlight that clinicians and patients view important outcome domains differently. This difference has been reported in other studies exploring UK orthotists' perspectives of clinical outcomes,⁷⁵ and in the development of a COS for rheumatoid arthritis,⁷⁶ and suggests that when seeking to build consensus around important outcome domains for measurement, that the patient's voice is properly represented, especially in commonly used, but arguably less accessible, consensus building techniques such as Delphi.⁷³

A rigorous foundation understanding which outcome domains are most important after prosthetic rehabilitation could lead to a consensus on outcome domains for measurement both clinically and in research, which would then direct the recommendation, or development of, a set of accompanying OMs. This set would 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, and not overburdening patients themselves. This process is unlikely to be simple, as highlighted by the UKROC project when developing a national set for neurorehabilitation. They describe a tension between identifying measures that have robust psychometric properties that generate data that are 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.¹⁵

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 outcome domains agreed on in a COS,^{77,78} thus defining a framework for *how* to measure an outcome.

It seems 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 collected and used, which is described here as outcome measurement practice. This review identified that many prosthetists believed that outcome measurement was not useful⁵² which is supported by concerns described in the NHS PROMS programme consultation,⁶⁵ mental health examples,⁶⁶ and the wider AHP literature.⁶⁴

All 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 are key.^{52,65,66} The use of electronic record systems, as described by Heinemann as a facilitator of success,⁵⁴ is increasing rapidly throughout healthcare organizations and presents opportunities to develop IT that supports OM collection. One of the aims of outcome measurement practice could therefore 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.⁷⁹ 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.¹⁵

Although the use of electronic platforms could allow for less burdensome OM completion, collation, and real-time feedback to clinicians, successful clinical uptake is likely to lie in the cost of the system and 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.⁷⁵

Being able to interpret OM data may be key to outcome measurement practice and could improve acceptance, especially when using aggregated OM data.^{3,80} Expert external facilitation was championed by Heinemann et al⁵⁴ and has been described as part of other system-level OM initiatives.¹⁵ Facilitation could 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.^{52,53}

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.⁸¹ This is critically important when attempting to translate outcome data into improvements in care. Outcome data at the service or system level, without the context of the individual patient’s problems and goals, do not itself 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.^{54,61,81} Individuals with this valuable “know-how” may be critical to making outcome measurement practice really work in multidisciplinary clinical settings.

Limitations

Although a rigorous approach was taken in an attempt to address previous criticisms of narrative reviews,⁸² the broad nature of this specific review and the absence of critical appraisal tools may have led to potential bias in the selection of articles deemed as relevant to the aims of the review. For example, the selection of papers for inclusion within the review and the interpretation of the findings were based on what the authors believed was relevant to clinical practice. This could result in bias arising from the authors’ interpretations and possible “cherry-picking” of papers to address the review aims. However, recent publications by Greenhalgh et al²³ and Furley and Goldschmeid²⁵ challenge this criticism and suggest no reviews, even systematic ones, are unbiased and that the aim of a narrative review is to interpret the evidence and deepen understanding around a subject rather than just add to the continued assimilation of numbers.²³ This broad overview, with early scoping objectives, should be seen as 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.

It should also 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.

Conclusion

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

Measuring the outcome of interventions is important to understand the impact on patients and the performance of services. However, it is more than just selecting an OM. Clinically, there is a need to understand the “why,” “what,” and “how” of outcome measurement. “Why” measure, that is, to inform at the individual or system level, “what” domains to measure, that is, capturing outcome domains that are meaningful, and “how” to measure them, that is, the best tools for the job used in a systematic way that adds value to clinical practice.

Future work needs to engage with patients and stakeholders to develop outcome measurement solutions that consider and overcome the barriers to implementation highlighted in this review. The absence of consensus needs to be addressed around *what* domains to measure, and *how* to measure them, while ensuring outcome domains are meaningful to patients and measurement tools are accessible to use and interpret. Outcome measurement practice can then be explored in partnership with universities or local QI teams, which focuses on understanding and realizing the value of outcome measurement to prosthetic rehabilitation services, to evidence, and improve clinical practice.

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Supplemental material

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