VA/DoD CLINICAL PRACTICE GUIDELINE FOR REHABILITATION OF INDIVIDUALS WITH LOWER LIMB AMPUTATION

Department of Veterans Affairs

Department of Defense

QUALIFYING STATEMENTS

The Department of Veterans Affairs and the Department of Defense guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

This Clinical Practice Guideline is based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.

These guidelines are not intended to represent Department of Veterans Affairs or TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at www.tricare.mil or by contacting your regional TRICARE Managed Care Support Contractor.

Version 2.0 – 2017

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The Rehabilitation of Individuals with Lower Limb Amputation Work Group

With support from:

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&
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Version 2.0 – 2017

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I. Introduction

The Department of Veterans Affairs (VA) and Department of Defense (DoD) Evidence-Based Practice Work Group (EBPWG) was established and first chartered in 2004, with a mission to advise the "…Health Executive Council on the use of clinical and epidemiological evidence to improve the health of the population across the Veterans Health Administration and Military Health System," by facilitating the development of clinical practice guidelines (CPGs) for the VA and DoD populations.[1] This CPG is intended to provide healthcare providers with a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with lower limb amputation (LLA), thereby leading to improved clinical outcomes.

In 2007, the VA and DoD published a CPG for the Rehabilitation of Lower Limb Amputation (2007 LLA CPG), which was based on evidence reviewed through December 2006. Since the release of that guideline, a growing body of research has expanded the general knowledge and understanding of LLA. Improved recognition of the complex nature of this condition has led to the adoption of new strategies for rehabilitation of LLA.

Consequently, a recommendation to update the 2007 LLA CPG was initiated in 2016. The updated CPG includes objective, evidence-based information on the rehabilitation of LLA. It is intended to provide guidance to assist healthcare providers in perioperative, pre-prosthetic training, and prosthetic training phases of patient care. The system-wide goal of evidence-based guidelines is to improve the patient's health and well-being by guiding healthcare providers who are assisting patients in rehabilitation after LLA along the management pathways that are supported by evidence. The expected outcome of successful implementation of this guideline is to:

- Assess the patient's condition and in collaboration with the patient, determine the most appropriate rehabilitation plan
- Optimize each individual's functional independence, health outcomes, and quality of life
- Minimize preventable complications and morbidity
- Emphasize the use of patient-centered care

II. Recommendations

#	Recommendation	Strength*	Category†
A. All Phases of Amputation Rehabilitation			
1.	We suggest that patient education be provided by the rehabilitation care team throughout all phases of amputation rehabilitation.	Weak for	Reviewed, Amended
2.	We suggest an assessment of behavioral health and psychosocial functioning at every phase of amputation management and rehabilitation.	Weak for	Reviewed, Amended
3.	When assessing pain, we suggest that measurement of the intensity of pain and interference with function should be separately assessed for each pain type and location using standardized tools.	Weak for	Reviewed, Amended
4.	We suggest offering a multi-modal, transdisciplinary individualized approach to pain management including transition to a non-narcotic pharmacological regimen combined with physical, psychological, and mechanical modalities throughout the rehabilitation process (For the treatment of chronic pain, the 2017 VA/DoD CPG for the Management of Opioid Therapy for Chronic Pain recommends alternatives to opioid therapy such as self-management strategies, other non-pharmacological treatments, and non-opioids over opioids [see the 2017 VA/DoD OT CPG[1]]).	Weak for	Reviewed, New-replaced
5.	We recommend providers consider the patient's birth sex and self-identified gender identity in developing individualized treatment plans.	Strong for	Reviewed, New-added
6.	We suggest offering peer support interventions, including visitation by a certified peer visitor, as early as feasible and throughout the rehabilitation process.	Weak for	Reviewed, Amended
B. Perioperative Phase			
7.	Prior to surgery, we suggest that rehabilitation goals, outcomes, and other implications be included in shared decision making about residual limb length and amputation level.	Weak for	Reviewed, Amended
8.	There is insufficient evidence to recommend one surgical amputation procedure over another.	Not applicable	Reviewed, New-added
9.	We suggest the use of a rigid or semi-rigid dressing to promote healing and early prosthetic use as soon as feasible post-amputation in transtibial amputation. Rigid post-operative dressings are preferred in situations where limb protection is a priority.	Weak for	Reviewed, Amended
10.	We suggest performing cognitive screening prior to establishing rehabilitation goals, to assess the patient's ability and suitability for appropriate prosthetic technology.	Weak for	Reviewed, New-replaced
11.	We suggest that in the perioperative phase following amputation, patients receive physical rehabilitation and appropriate durable medical equipment/assistive technology.	Weak for	Reviewed, New-replaced
12.	We suggest, when applicable, treatment in an acute inpatient rehabilitation program over a skilled nursing facility.	Weak for	Reviewed, New-replaced
13.	We suggest the initiation of mobility training as soon as feasible post-amputation. In appropriate patients, this may include ipsilateral side weight-bearing ambulation with a pylon to improve physical function and gait parameters.	Weak for	Reviewed, New-replaced

[1] See the VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain. Available at: http://www.healthquality.va.gov/guidelines/Pain/cot/

#	Recommendation	Strength*	Category†
14.	We recommend instituting rehabilitation training interventions, using both open and closed chain exercises and progressive resistance to improve gait, mobility, strength, cardiovascular fitness and activities of daily living performance in order to maximize function.	Strong for	Reviewed, New-replaced
C. Pre-Prosthetic Phase			
15.	We suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces.	Weak for	Reviewed, New-added
D. Prosthetic Training Phase			
16.	We recommend the use of valid, reliable, and responsive functional outcome measures, including, but not limited to, the Comprehensive High-level Activity Mobility Predictor, Amputee Mobility Predictor, 10-meter walk test, and 6-minute walk test.	Strong for	Reviewed, New-replaced
17.	We suggest the use of a combination of measures with acceptable psychometric properties to assess functional outcomes.	Weak for	Reviewed, New-replaced
18.	We recommend an assessment of factors that are associated with poorer outcomes following acquired limb loss, such as smoking, comorbid injuries or illnesses, psychosocial functioning, and pain.	Strong for	Reviewed, Amended

*For additional information, please refer to Grading Recommendations.

†For additional information, please refer to Recommendation Categorization and Appendix C.

III. Background

A. Description of Lower Limb Amputation

a. Dysvascular Amputation

In civilian and elderly VA populations, the most common cause of LLA is dysvascular complications from diabetes, arteriosclerosis, smoking, or a combination of these. In these patients, amputation may occur when medical or revascularization options do not exist or have failed, when significant tissue loss has occurred, or when infectious complications can only be managed by surgical interventions.[2] In diabetic patients, protective and prophylactic foot care and early detection of any deformity or skin breakdown may prevent the development of ulcers and reduce the risk of amputation (see the VA/DoD CPG for the Management of Diabetes Mellitus in Primary Care).[2] Smoking cessation and control of cardiovascular risk factors, including glycemic control in diabetics, are additional approaches to the prevention of LLA.

Due to the systemic nature of arteriosclerosis and diabetes, patients with these conditions are at high risk for further complications to their amputated residual limb and/or amputation of the contralateral limb. In addition, they are at higher risk for other health problems such as cardiovascular disease, cerebrovascular accident, renal disease, peripheral neuropathy, etc. While this guideline focuses on rehabilitation of patients with LLA, preservation of the residual and contralateral limb, as well as the patients' general health, wellness, and functional independence remain integral parts of ongoing care.[3]

b. Traumatic Amputation

Trauma is another major cause of LLA, though not as common as dysvascular amputations.[4] Traumatic amputation may occur from a variety of causes, including motor vehicle and industrial accidents, electrical, chemical and thermal burns, and injuries associated with power tool or heavy machinery use.[5] Of particular concern to military and Veteran populations are amputations associated with combat-related injuries, such as those occurring from explosions, penetrating, or crush injuries. These injuries are also typically complicated by a multitude of other comorbid conditions (e.g., traumatic brain injury, post-traumatic stress, other soft tissue injuries).[4]

c. Other Causes of Amputation

Other less prevalent causes of amputation include malignant musculoskeletal tumors, infection, iatrogenic complications of vascular access procedures for other medical problems, and congenital limb development deficiency. The goal in treating musculoskeletal tumors with the lowest risk of recurrence is to remove the tumor and salvage the limb, while for tumors with high risk of local recurrence or metastasis, amputation is often indicated. Treatment of infection may require amputation when the initial treatment leads to vessel occlusion and extremity necrosis.[5] Chronic or recurring infection after total knee arthroplasty may also lead to transfemoral amputation.[6] Congenital limb deficiencies account for a small percentage of lower limb loss. Depending on the location of the deficiency, definitive amputation is performed at a time that considers skeletal growth, while also supporting physical, behavioral, and psychological development.[4]

[2] See the VA/DoD Clinical Practice Guideline for the Management of Diabetes Mellitus in Primary Care. Available at: http://www.healthquality.va.gov/guidelines/CD/diabetes/

d. Limb Salvage and Delayed Amputation

For severe limb injury, patients and surgeons are often faced with the decision between amputation versus limb reconstruction and salvage. While limb salvage may initially be the therapeutic option of choice, complications such as infection, chronic pain, or persistent dysfunction may result in delayed amputation. In some cases, the decision to attempt limb salvage may result in increased complication rates, increased pain, and more procedures than if a primary amputation had been performed.[5] To mitigate these risks, several scoring systems have been developed to assist with the decision to amputate or salvage the limb. Unfortunately, these systems may not accurately predict functional recovery and, therefore, should be used in combination with other criteria, including patient preferences.[7]

Unsuccessful attempts at limb salvage may result in increased morbidity and mortality. One study showed that there were a greater number of hospitalization days (49.8 days versus 24.3 days) and more operative procedures (6.7 procedures versus 1.6 procedures) for individuals who underwent delayed versus primary amputation surgery.[8] Additionally, a retrospective cohort study of 324 Service Members with combat-related amputations secondary to injuries sustained in Afghanistan or Iraq demonstrated better functional outcomes compared to those with limb salvage.[9]

B. Epidemiology and Impact

Each day, more than 500 individuals in the United States (U.S.) undergo amputation, and there are more than two million people in the U.S. living with upper or lower limb loss.[10] It is projected that there will be 3.6 million people living with upper or lower limb loss in the U.S. by 2050.[11]

e. Epidemiology of Non-Traumatic Amputation

Non-traumatic amputations due to diabetes mellitus and other disease processes have been increasing in the U.S. in recent decades. The Centers for Disease Control and Prevention (CDC) reported that the number of LLAs among diabetic patients increased from 55,000 in 1988 to 83,000 in 1997, then started to decrease again to 68,000 in 2009.[12]

An analysis of Medicare data from 2000 through 2008 showed that mortality rates were nearly twice as high for those with peripheral artery disease who had major LLA compared to similar patients that did not have LLA at 30 days (13.5% versus 6.9%), one year (48.3% versus 24.2%), and three years (70.9% versus 43.2%).[13] Age, history of heart failure, renal disease, cancer, and chronic obstructive pulmonary diseases were all independently associated with death after major LLA. Evidence also suggests that individuals with more proximal limb loss (transfemoral) have a higher risk of death compared to those with more distal locations.[13] In addition to diabetes and peripheral artery disease, it is estimated that cancers causing non-traumatic amputation account for less than 1% of amputations in the U.S.[11]

f. Epidemiology of Traumatic Amputation

There are approximately 30,000-40,000 injury-related amputations performed in the U.S. annually.[11] An analysis of the National Trauma Databank of civilian amputations indicated that in the U.S. from 2000-2004, traumatic LLAs were more common than upper limb amputation (59% versus 41%). Most amputations were caused by blunt injury (83%); 51% of those cases were caused by motor vehicle accidents and 19.4% caused by machinery accidents. Motorcyclists and pedestrians were more likely to

sustain LLA, while those involved with motor vehicle collisions were more likely to sustain upper limb amputation.[14]

C. Lower Limb Amputation in the Department of Veterans Affairs and the Department of Defense

a. Department of Veterans Affairs

Similar to civilian populations, the number of individuals with amputation(s) cared for in the VA and DoD medical systems has been increasing. Within five years of military separation, 99% of Service Members with combat-related amputations had transitioned their care to the VA.[15] The total number of Veterans with amputations being seen at VA facilities increased from 25,000 in fiscal year (FY) 2000 to almost 90,000 in FY 2016.[16] Annually, the number of patients undergoing an amputation procedure (of all levels, including digit amputations of both upper and lower extremities) increased from 5,270 in FY 2001 to 6,386 in FY 2015. Although some of this growth can be attributed to an increased number of combat injuries, the majority resulted from vascular disease; in FY 2015, 80% of patients undergoing amputation had diabetes compared to 75% in FY 2001. Many patients required multiple procedures; during the years 2010-2015, an average of 6,262 patients underwent an average of 9,205 amputation procedures.[17] To expand the care and treatment of Veteran patients at risk of primary or secondary limb loss, the Prevention of Amputation for Veterans Everywhere program was designed to help prevent or delay limb loss.[3]

b. Department of Defense

The Extremity Trauma and Amputation Center of Excellence database provided data on all conflict-related amputations (excluding fingers, thumbs, or toes) sustained by U.S. Service Members between January 1, 2001 and December 31, 2016. During this period, 1,710 patients (including 28 women) sustained at least one amputation. The majority of these amputations (73%) were a result of an improvised explosive device blast injury. Among the 1,710 patients who underwent an amputation, 84% involved the lower limb (76% one lower limb, 8% both lower limbs). Among the 1,574 lower limb amputation performed in these 1,439 patients, 56% were transtibal and 38% were transfemoral.[18]

Of the 1,710 Service Members who sustained a combat-related limb amputation from 2001 through 2016, 31% sustained amputations of more than one major limb.[18] While previous reports indicate the unique challenges associated with the rehabilitation of individuals with multiple limb loss, limited published reports exist to inform evidence-based decisions; therefore this CPG does not specifically address the care of individuals with multiple limb loss. The reader is referred to the textbook, “Care of the Combat Amputee,” for more information about rehabilitation for patients with multiple limb loss.[19]

D. Factors Affecting Rehabilitation of Lower Limb Amputation

The successful rehabilitation of patients with LLA is influenced by a variety of factors that include, but are not limited to, level of amputation, cognitive impairment, physical conditioning, social support, comorbidities, and psychological factors.[20] Amputations caused by vascular disease generally occur in aging populations with numerous other comorbidities such as cardiovascular disease, hypertension, renal

[3] See Veterans Health Administration Directive 1410, Prevention of Amputation in Veterans Everywhere. Available at: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=5364

disease, and arthritis.[13] To maximize functional outcomes and help patients reach their goals, these factors must be considered when developing individualized rehabilitation plans for Veterans or Service Members with LLA.

While the pathophysiology of traumatic amputations may be different than non-traumatic amputations, rehabilitation strategies and prosthetic component prescriptions for both should be focused on realistic patient goals with concentrated efforts directed to maximize functional recovery. The overall goals of rehabilitation after amputation are to optimize the patient's health status, functional independence, and quality of life.[21,22] Ongoing assessments and therapeutic interventions to address medical, psychosocial, physical, and functional limitations are necessary to achieve these desired outcomes.

IV. About this Clinical Practice Guideline

This guideline is intended to help improve the rehabilitative care of individuals with LLA in the VA and DoD systems. It is intended for VA and DoD healthcare practitioners including physicians (e.g., physiatrists, surgeons, primary care, podiatrists), prosthetists, physical therapists, occupational therapists, nurse practitioners, physician assistants, psychologists, social workers, nurses, and others involved in the care of Service Members or Veterans with LLA.

As with other CPGs, challenges remain with guideline development and the implementation and assessment of the eventual impact the guidelines will have on clinical outcomes. Principal limitations in forming comprehensive CPGs include existing gaps in clinical evidenced-based research that demonstrate sufficient efficacy of interventions. As elaborated in the qualifying statement on page one, this CPG is not intended to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual patient and are subject to change as scientific knowledge and technology advance and patterns evolve. This CPG is based on evidence available through July 2016 and is intended to provide a general guide to best practices. The guideline can assist care providers, but the use of a CPG must always be considered as a recommendation, within the context of a provider's clinical judgment and patient values and preferences, for the care of an individual patient.

A. Methods

The current document is an update to the 2007 VA/DoD LLA CPG. The methodology used in developing the 2017 CPG follows the *Guideline for Guidelines*,[1] an internal document of the VA and DoD EBPWG. The *Guideline for Guidelines* can be downloaded from http://www.healthquality.va.gov/policy/index.asp. This document provides information regarding the process of developing guidelines, including the identification and assembly of the Guideline Champions (Champions) and other subject matter experts from within the VA and DoD, known as the Work Group, and ultimately, the development and submission of an updated LLA CPG.

The Champions and Work Group for this CPG were charged with developing evidence-based clinical practice recommendations and writing and publishing a guideline document to be used by providers within the VA/DoD healthcare systems. Specifically, the Champions and Work Group members for this guideline were responsible for identifying the key questions (KQs) of the most clinical relevance, importance, and interest for the rehabilitation of LLA. The Champions and the Work Group also provided

direction on inclusion and exclusion criteria for the evidence review and assessed the level and quality of the evidence. The amount of new scientific evidence that had accumulated since the previous version of the CPG was also taken into consideration in the identification of the KQs. In addition, the Champions assisted in:

- Identifying appropriate disciplines of individuals to be included as part of the Work Group
- Directing and coordinating the Work Group
- Participating throughout the guideline development and review processes

The VA Office of Quality, Safety and Value, in collaboration with the Office of Evidence Based Practice, U.S. Army Medical Command, the proponent for CPGs for the DoD, identified five clinical leaders, Billie Randolph, PhD, PT, and Joseph Webster, MD from the VA and Andrea Crunkhorn, DPT, LTC Keith Myers, MD, and Paul Pasquina, MD from the DoD, as Champions for the 2017 CPG.

The Lewin Team, including The Lewin Group, Duty First Consulting, ECRI Institute, and Sigma Health Consulting, LLC, was contracted by the VA and DoD to support the development of this CPG and conduct the evidence review. The first conference call was held in March 2016, with participation from the contracting officer's representative, leaders from the VA Office of Quality, Safety and Value and the DoD Office of Evidence Based Practice, and the Champions. During this call, participants discussed the scope of the guideline initiative, the roles and responsibilities of the Champions, the project timeline, and the approach for developing and prioritizing specific research questions on which to base a systematic review (SR) about the rehabilitation of LLA. The group also identified a list of clinical specialties and areas of expertise that are important and relevant to rehabilitation of individuals with LLA, from which Work Group members were recruited. The specialties and clinical areas of interest included: physical therapy, occupational therapy, physical medicine and rehabilitation, nursing, pain medicine, psychology, and prosthetics.

The guideline development process for the 2017 CPG update consisted of the following steps:

1. Formulating and prioritizing evidence questions (KQs)
2. Conducting the SR
3. Convening a face-to-face meeting with the CPG Champions and Work Group members
4. Drafting and submitting a final CPG to the VA/DoD EBPWG

Appendix A provides a detailed description of each of these tasks.

a. Grading Recommendations

The Champions and Work Group used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to assess the quality of the evidence base and assign a grade for the strength for each recommendation. The GRADE system uses the following four domains to assess the strength of each recommendation:[23]

- Balance of desirable and undesirable outcomes
- Confidence in the quality of the evidence

- Patient or provider values and preferences
- Other implications, as appropriate, e.g.,:
    - Resource use
    - Equity
    - Acceptability
    - Feasibility
    - Subgroup considerations

Using this system, the Champions and Work Group determined the relative strength of each recommendation (Strong or Weak). A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they give a weak recommendation.

They also determined the direction of each recommendation (For or Against). Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.

Using these elements, the grade of each recommendation is presented as part of a continuum:

- Strong For (or "We recommend offering this option …")
- Weak For (or "We suggest offering this option …")
- Weak Against (or "We suggest not offering this option …")
- Strong Against (or "We recommend against offering this option …")

The grade of each recommendation made in the 2017 CPG can be found in the section on Recommendations. Additional information regarding the use of the GRADE system can be found in Appendix A.

b. Reconciling 2007 Clinical Practice Guideline Recommendations

Evidence-based CPGs should be current, which typically requires revisions of previous guidelines based on new evidence, or as scheduled, subject to time-based expirations.[24] For example, the U.S. Preventive Services Task Force (USPSTF) has a process for refining or otherwise updating its recommendations pertaining to preventive services.[25] Further, the inclusion criteria for the National Guideline Clearinghouse specify that a guideline must have been developed, reviewed, or revised within the past five years.

The LLA Guideline Work Group focused largely on developing new and updated recommendations based on the evidence review conducted for the priority areas addressed by the KQs. In addition to those new and updated recommendations, the CPG Work Group considered, without complete review of the relevant evidence, the current applicability of other recommendations that were included in the previous 2007 LLA CPG, subject to evolving practice in today's environment.

A set of recommendation categories was adapted from those used by the National Institute for Health and Care Excellence (NICE).[26,27] These categories, along with their corresponding definitions, were used to account for the various ways in which older recommendations could have been updated. In brief, the categories took into account whether or not the evidence that related to a recommendation was systematically reviewed, the degree to which the recommendation was modified, and the degree to which a recommendation is relevant in the current patient care environment and inside the scope of the CPG. Additional information regarding these categories and their definitions can be found in Appendix A. The categories for the recommendations included in the 2017 version of the guideline can be found in the section on Recommendations. The categories for the recommendations from the 2007 LLA CPG are noted in Appendix C.

The CPG Work Group recognized the need to accommodate the transition in evidence rating systems from the 2007 LLA CPG to the current CPG. In order to report the strength of all recommendations using a consistent format (i.e., the GRADE system) the CPG Work Group converted the USPSTF strengths of the recommendation accompanying the carryover recommendations from the 2007 guideline to the GRADE system. As such, the CPG Work Group considered the strength of the evidence cited for each recommendation in the 2007 LLA CPG as well as harms and benefits, values and preferences, and other implications, where possible. The CPG Work Group referred to the available evidence as summarized in the body of the 2007 LLA CPG and did not re-assess the evidence systematically. In some instances, peer-reviewed literature published since the 2007 LLA CPG was considered along with the evidence base used for that CPG. Where such newer literature was considered when converting the strength of the recommendation from the USPSTF to the GRADE system, it is referenced in the discussion that follows the corresponding recommendation, as well as in Appendix B.

The CPG Work Group recognizes that, while there are practical reasons for incorporating findings from a previous evidence review, previous recommendations,[28] or recent peer-reviewed publications into an updated CPG, doing so does not involve an original, comprehensive SR and, therefore, may introduce bias.

It is important to note that the 2007 LLA CPG based many recommendations on expert opinion alone and were therefore not considered to be evidence-based. While the USPSTF grading system allows for recommendations to be based on expert opinion alone, the GRADE system does not. Therefore, while the 2017 CPG Work Group recognized that many of the 2007 recommendations based on expert opinion alone contained valuable clinical concepts, these 2007 recommendations were not carried forward to this guideline update. However, some of these clinical concepts are discussed in the guideline narrative.

c. Peer Review Process

The CPG was developed through an iterative process in which the Work Group produced multiple drafts of the CPG. The process for developing the initial draft is described in more detail in Drafting and Submitting the Final Clinical Practice Guideline.

Once a near-final draft of the guideline was agreed upon by the Champions and Work Group members, the draft was sent out for peer review and comment. The draft was posted on a wiki website for a period of 14 business days. The peer reviewers comprised individuals working within the VA and DoD health systems as

well as experts from relevant outside organizations designated by the Work Group members. External organizations who participated in the peer review included the following:

- Amputee Coalition
- Human Engineering Research Laboratories, University of Pittsburgh
- National Center for Medical Rehabilitation Research, National Institutes of Health

The VA and DoD Leadership reached out to both the internal and external peer reviewers to solicit their feedback on the CPG. Reviewers were provided a hyperlink to the wiki website where the draft CPG was posted. For transparency, all reviewer feedback was posted in tabular form on the wiki site, along with the name of the reviewer. All feedback from the peer reviewers was discussed and considered by the Work Group. Modifications made throughout the CPG development process were made in accordance with the evidence.

B. Summary of Patient Focus Group Methods and Findings

When forming guideline recommendations, consideration should also be given to the values of the patients, who will likely be most affected by the recommendations. Patients bring perspectives, values, and preferences into their healthcare experience, which may vary from those of clinicians. These differences can affect decision making in various situations, and should thus be highlighted and made explicit due to their potential to influence a recommendation's implementation.[29,30] Focus groups can be used as an efficient method to explore ideas and perspectives of a group of individuals with an *a priori set* of assumptions or hypotheses and collect qualitative data on a thoughtfully predetermined set of questions.

Therefore, as part of the effort to update this CPG, VA and DoD Leadership, along with the LLA CPG Work Group, held a patient focus group prior to finalizing the KQs for the evidence review. The group met on May 24, 2016, at Walter Reed National Military Medical Center in Bethesda, Maryland. The aim of the focus group was to further the understanding of the perspectives of patients with LLA undergoing rehabilitation within the VA and/or DoD healthcare systems. The focus group explored a set of topics related to rehabilitation after LLA including knowledge of rehabilitation options, delivery of care, and the impact of and challenges related to LLA.

It is important to note the focus group was a convenience sample and the Working Group recognizes the limitations inherent in the small sample size. Less than 10 people were included in the focus group consistent with the requirements of the federal Paperwork Reduction Act, 1980. The Work Group acknowledges that the sample of patients included in this focus group may not be representative of all VA and DoD patients undergoing rehabilitation for LLA. The patient perspective and input provided, while invaluable, is not generalizable given the broad characteristics of various key demographic groups of persons with LLA. Further, time limitations for the focus group prevented exhaustive exploration of all topics related to rehabilitation and the patients' broader experiences with their care. Thus, the Work Group made decisions regarding the priority of topics to discuss at the focus group. These limitations, as well as others, were considered throughout the use of the information collected from the discussion for guideline development.

Recruitment for participation in the focus group was managed by the Champions and VA and DoD Leadership, with assistance from coordinators at the facility where the focus group took place.

The following concepts are ideas and suggestions about aspects of care that are important to patients and family caregivers that emerged from the discussion. These concepts were needed and important parts of the participants' care and added to the Work Group's understanding of patient values and perspectives. The Work Group considered the focus group feedback while assessing the strength of each recommendation and continued to consider the feedback throughout the LLA CPG development process. Additional details regarding the patient focus group methods and findings can be found in Appendix E.

LLA CPG Patient Focus Group Concepts	
A.	Recognize the importance of a transdisciplinary amputation care team and the necessity for patients to have a trusting relationship with their prosthetist.
B.	Consider patient-specific goals, values, and preferences and use shared decision making to develop a rehabilitation plan.
C.	Address strategies for pain and medication management across all phases of the rehabilitation process.
D.	Involve family caregivers and leverage peer networks to create support and motivation for patients with lower limb amputations.
E.	Consider unique challenges faced by different patient populations (e.g., females) during rehabilitation.
F.	Work with providers to ensure continuity of care and ease of access to preferred providers and prescriptions.

C. Conflict of Interest

At the start of this guideline development process and at other key points throughout, the project team was required to submit disclosure statements to reveal any areas of potential conflict of interest (COI) in the past 24 months. Verbal affirmations of no COI were used as necessary during meetings throughout the guideline development process. The project team was also subject to random web-based surveillance (e.g., ProPublica).

If a project team member reported a COI (actual or potential), then it was reported to the Office of Evidence Based Practice. It was also discussed with the LLA CPG Work Group in tandem with their review of the evidence and development of recommendations. The Office of Evidence Based Practice and the LLA CPG Work Group determined whether or not action, such as restricting participation and/or voting on sections related to the conflict or removal from the Work Group, was necessary. If it was deemed necessary, action was taken by the co-chairs and Office of Evidence Based Practice, based on the level and extent of involvement. No conflicts of interest were identified for the LLA CPG Work Group members or Champions. Disclosure forms are on file with the Department of Veterans Affairs Evidence Based Practice Program office and available upon request.

D. Scope of this Clinical Practice Guideline

Regardless of setting, any patient in the healthcare system should be offered access to the interventions that are recommended in this guideline after taking into consideration the patient's specific circumstances.

Guideline recommendations are intended to be patient centered. Thus, treatment and care should take into account a patient's needs and preferences. Good communication between healthcare professionals and the patient is essential and should be supported by evidence-based information tailored to the

patient's needs. Use of an empathetic and non-judgmental approach facilitates discussions sensitive to gender, culture, and ethnic differences. The information that patients are given about treatment and care should be culturally appropriate and also available to people with limited literacy skills. It should also be accessible to people with additional needs such as physical, sensory, or learning disabilities. Family involvement should be considered, if appropriate.

This CPG is designed to assist providers in managing or co-managing patients in rehabilitation for LLA. Moreover, the patient population of interest for this CPG is adults who are eligible for care within the VA and DoD healthcare delivery systems. It includes Veterans as well as deployed and non-deployed Active Duty Service Members and their adult beneficiaries. This CPG does not provide recommendations for rehabilitation of children or adolescents with LLA.

The literature review encompassed interventional studies (primarily randomized controlled trials [RCTs]) as well as observational studies, and diagnostic tests studies published between January 2007 and June 2016, and targeted 10 KQs focusing on the means by which the delivery of healthcare could be optimized for patients during rehabilitation of LLA. The selected KQs (see Table A-4) were prioritized by the Work Group from many possible KQs based on consensus as to their level of importance. Due to resource constraints, an extensive review of the evidence in all important aspects of care was not feasible for the update to this CPG.

E. Highlighted Features of this Clinical Practice Guideline

This 2017 edition of the VA/DoD LLA CPG is the first update to the original CPG. It provides practice recommendations for the care of populations undergoing rehabilitation for individuals with LLA. A particular strength of this CPG is the transdisciplinary stakeholder involvement from its inception, ensuring representation from the broad spectrum of clinicians engaged in rehabilitation of patients with LLA.

The framework for recommendations in this CPG considered factors beyond the strength of the evidence, including balancing desired outcomes with potential harms of treatment, equity of resource availability, and the potential for variation in patient values and preferences. Applicability of the evidence to VA/DoD populations was also taken into consideration. A structured algorithm accompanies the guideline to provide an overview of the recommendations in the context of the flow of patient care and clinician decision making and to assist with training providers. The algorithm may be used to help facilitate translation of guideline recommendations into effective practice.

This guideline is designed to address the key principles of rehabilitation and clinical care for patients with LLA. This CPG highlights the following goals to ensure quality care:

- Promote a patient-centered transdisciplinary team approach
- Address key aspects of the rehabilitation process that is focused on maximizing the patient's functional independence and quality of life, including: prosthetic selection and fitting, activities of daily living (ADL) and instrumental ADL training with and without a prosthesis, promoting physical conditioning, and optimizing pain and medication management
- Develop recommendations that are consistent with current evidence-based rehabilitation methods
- Provide rehabilitation care providers with an algorithm of appropriate rehabilitation interventions to improve the patient outcomes and reduce practice variation
- Provide primary care providers an algorithm to assist with the referral process
- Establish priorities for future research that will generate evidence for practice improvement

F. Patient-centered Care

VA/DoD CPGs encourage clinicians to use a patient-centered care approach that is individualized based on patient capabilities, needs, goals, prior treatment experience, and preferences. Regardless of setting, all patients in the healthcare system should be offered access to evidence-based interventions appropriate to that patient. When properly executed, patient-centered care (PCC) may decrease patient anxiety, increase trust in clinicians,[31] and improve treatment adherence.[32] Improved patient-clinician communication through PCC can be used to convey openness to discuss any future concerns.

As part of the PCC approach, clinicians should review the outcomes of past rehabilitation experiences and outcomes of possible future treatments with the patient. Additionally, they should involve the patient in prioritizing rehabilitation goals and setting specific goals regardless of the selected setting or level of care.

G. Shared Decision Making

Throughout this VA/DoD CPG, the authors encourage clinicians to focus on shared decision making (SDM). The SDM model was introduced in 2001 *Crossing the Quality Chasm,* a National Academy of Medicine (formerly the Institute of Medicine) report.[33] It is readily apparent that patients with LLA, together with their clinicians, make decisions regarding the level of rehabilitation they choose to engage in; however, these patients require sufficient information to be able to make informed decisions. Clinicians must be adept at presenting information to their patients regarding individual rehabilitation plans and appropriate locations of care.

H. Implementation

This CPG and algorithm are designed to be adapted by individual healthcare providers with consideration of local needs and resources. The algorithm serves as a tool to prompt providers to consider key decision points in the course of an episode of care.

Although this CPG represents the recommended practice on the date of its publication, medical practice is evolving and this evolution requires continuous updating based on published information. New technology

and more research will improve patient care in the future. The CPG can assist in identifying priority areas for research and to inform optimal allocation of resources. Future studies examining the results of CPG implementation may lead to the development of new evidence particularly relevant to clinical practice.

V. Guideline Work Group

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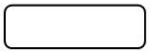
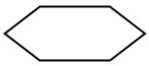
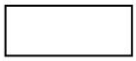
VI. Algorithm

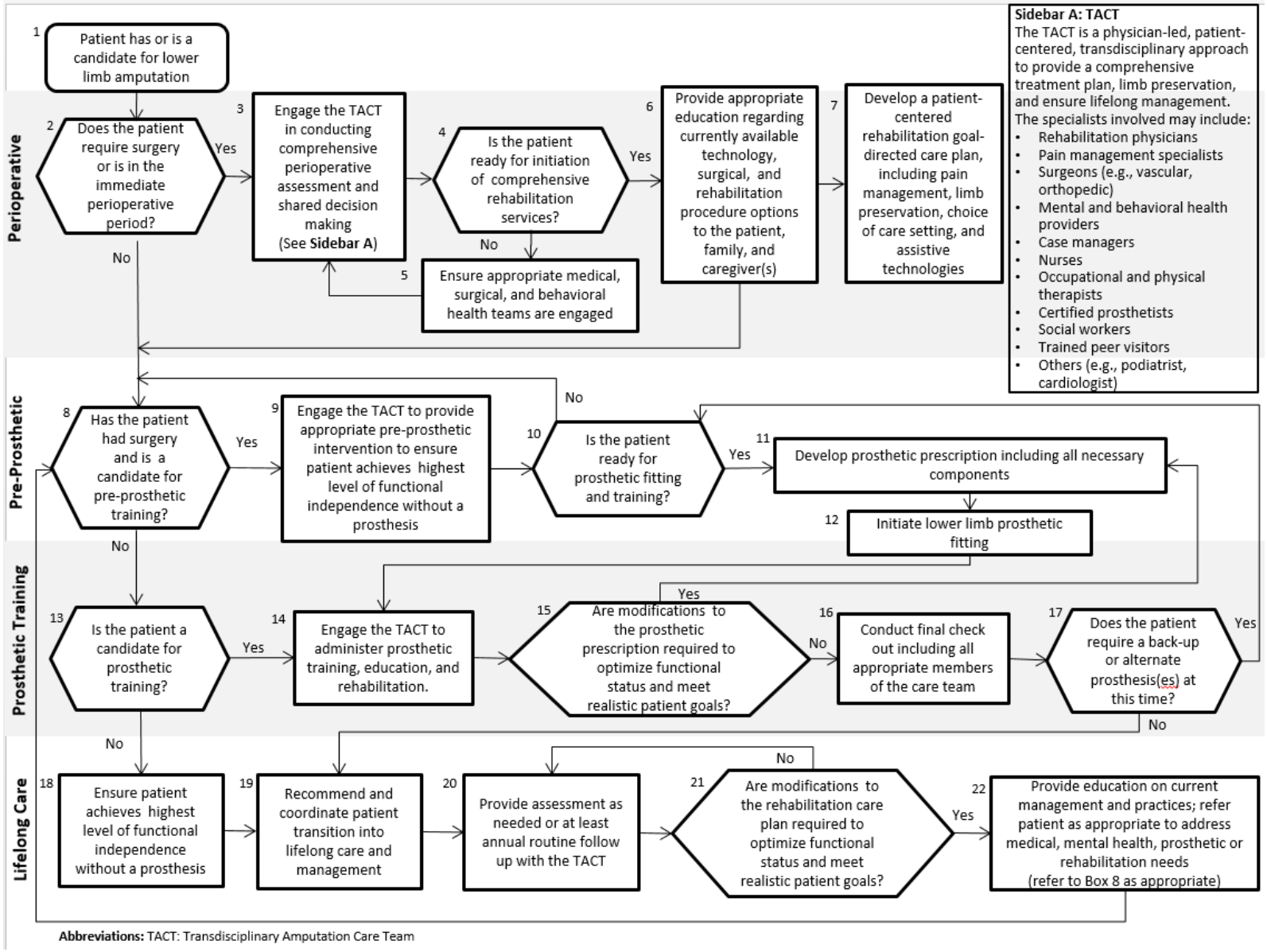
This CPG includes an algorithm which is designed to facilitate understanding of the clinical pathway and decision-making process used in rehabilitation of patients with LLA. The use of the algorithm format as a way to represent patient management was chosen based on the understanding that such a format may promote more efficient diagnostic and therapeutic decision making and has the potential to change patterns of resource use. Recognizing that some clinical care processes are non-linear, the algorithm format allows the provider to follow a simplified linear approach in assessing the critical information needed at the major decision points in the clinical process, and includes:

- An ordered sequence of steps of care
- Recommended observations and examinations
- Decisions to be considered
- Actions to be taken

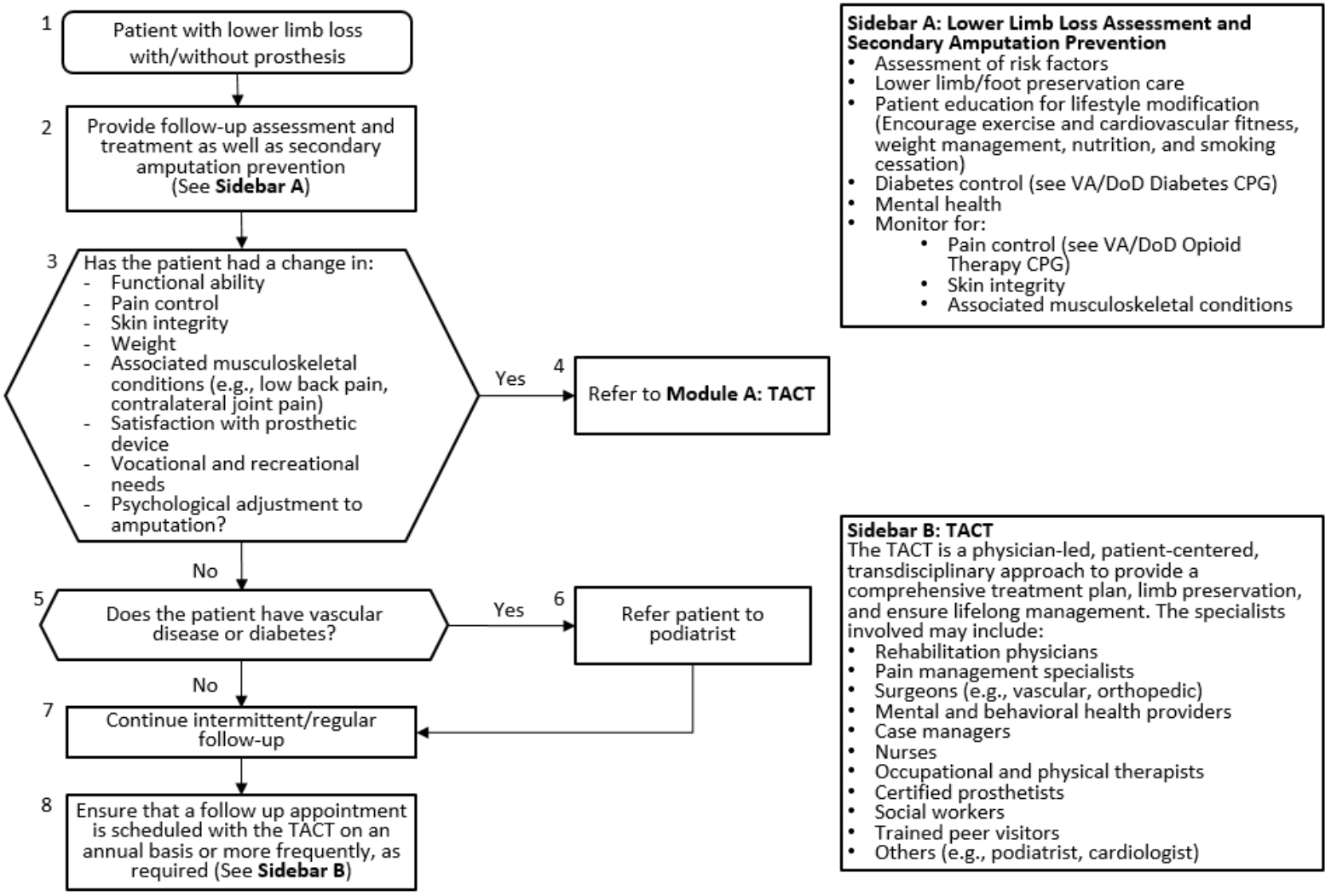
A clinical algorithm diagrams a guideline into a step-by-step decision tree. Standardized symbols are used to display each step in the algorithm, and arrows connect the numbered boxes indicating the order in which the steps should be followed.[34]

	Rounded rectangles represent a clinical state or condition.
	Hexagons represent a decision point in the guideline, formulated as a question that can be answered Yes or No.
	Rectangles represent an action in the process of care.

Module A: Transdisciplinary Amputation Care Team Approach (TACT)



Module B: Primary Care Follow-up and Lifelong Care



Abbreviations: TACT: Transdisciplinary Amputation Care Team; VA/DoD Diabetes CPG: VA/DoD Clinical Practice Guideline for Management of Diabetes Mellitus in Primary Care; VA/DoD Opioid Therapy CPG: VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain

VII. Discussion of Recommendations

A. All Phases of Amputation Rehabilitation

Recommendation

1. We suggest that patient education be provided by the rehabilitation care team throughout all phases of amputation rehabilitation.
   (Weak for | Reviewed, Amended)

Discussion

It is difficult to assess the relative effectiveness of different educational strategies, because multiple strategies are often "packaged" as one intervention and outcome measures may lack the sensitivity or specificity to detect the outcome of interest. Confidence in the quality of evidence from the 2007 LLA CPG is moderate to low in support of patient education pre- or post-amputation surgery.[35,36] Despite the moderate to low quality of the evidence, the benefits of providing patient education throughout all phases of amputation rehabilitation greatly outweigh the potential harms to the patient. Education is also valuable to patients, who generally prefer that providers use an SDM approach to develop their rehabilitation plan. Indeed, patient focus group members stressed the need for using an SDM model to develop a rehabilitation plan.

Care and education for the patient with amputation (traumatic and non-traumatic) is complex and requires multiple medical, surgical, and rehabilitation specialties. A transdisciplinary approach that creates a holistic technique, utilizing concepts or methods of multiple disciplines, is vital to LLA rehabilitation. In addition to the patient, members of the medical rehabilitation team may include the patient's support system, surgeon, physiatrist, physical therapist, occupational therapist, recreational therapist, prosthetist, nurse, social worker, behavioral health specialist, peer support visitors, and case manager. Topics on which clinicians should provide clear advice and information include but are not limited to: surgical interventions, residual limb length, amputation level, rehabilitation programs, prosthetic options, and possible outcomes with realistic rehabilitation goals in order for patients to make informed decisions regarding their care.[21,22]

The Joint Commission (JC) recognizes the importance of patient education in influencing the patient's outcome and in promoting healthy behaviors. The JC requires that the patient's learning needs be assessed by all disciplines involved in the care of the patient and that coordinated education and training be provided to the patient based upon those needs.[37] Table 1 provides some of the JC's patient education performance elements for patient education. The Commission on the Accreditation of Rehabilitation Facilities (CARF) also specifies patient educational requirements for Amputation Specialty Care Programs.[38] The concept of patient self-management may also require the assistance and support of external resources such as the Amputee Coalition.[39] Information on these resources should be made available to patients.

Once the patient's educational needs and preferred delivery method are identified, a plan should be implemented using appropriate verbal, written, and hands-on learning methods. All aspects of the patient education process should be documented in the patient's medical record throughout the continuum of care.

Table 1. Joint Commission's Performance Elements for Patient Education[37]

Patient Education Regarding Rehabilitation Techniques
Based on the patient's condition and assessed needs, the education and training provided to the patient by the organization include the following: ▪ An explanation of the plan for care, treatment, or services ▪ Basic health practices and safety including information on the safe and effective use of medications, nutrition interventions, and modified diets ▪ Discussion of pain, the risk for pain, the importance of effective pain management, the pain assessment process, and methods for pain management ▪ Information on the safe and effective use of medical equipment or supplies ▪ Habilitation or rehabilitation techniques to help the patient reach maximum independence

Recommendation

2. We suggest an assessment of behavioral health and psychosocial functioning at every phase of amputation management and rehabilitation.
   (Weak for | Reviewed, Amended)

Discussion

The LLA Work Group advocates for assessment of behavioral health and psychosocial functioning throughout rehabilitation based on the original evidence referenced in the 2007 CPG,[40-43] the support of two additional studies, including one RCT,[44,45] and the consideration that the potential benefit to the patient far outweighs potential harm. Additionally, patient focus group participants expressed a desire to have individualized mental health care treatment throughout their rehabilitation.

Behavioral health includes mental health diagnoses commonly occurring in individuals with limb loss, including depression, anxiety, and posttraumatic stress disorder (PTSD). Psychosocial functioning refers to the patient's ability to manage the psychological and social factors which influence his/her interpersonal relationships, and personally meaningful activities such as work and school. In the case of a patient with LLA, this also refers to how well the patient is able to participate in these activities despite his or her physical impairment. Evidence from the 2007 LLA CPG identified depression, anxiety, and posttraumatic stress as common behavioral health symptoms in individuals with limb loss, and also that psychosocial functioning was frequently correlated with aspects of limb loss (e.g., etiology, time since amputation).[40-43]

Subsequently, one large multi-site RCT examining an intervention to improve self-management following limb loss (including sessions devoted to developing coping strategies for mood, positive health behavior, enlisting social support, and engaging with community resources) found that self-management training improved behavioral health symptoms (depression) as well as functional limitations.[44] An additional cross-sectional quantitative study of 106 patients with LLA in 2015 found that problem-focused coping strategies and avoidance of emotion-focused coping strategies were significant correlates of posttraumatic growth following an amputation.[45] The problem-focused strategies noted were religious belief, acceptance, positive reframing, planning, and active coping.

Periodic assessments of the patient should include inquiries into behavioral health status and psychosocial functioning (including spiritual beliefs and coping mechanisms). These assessments should be repeated at

each phase of care, and should be part of long-term management. For patients at risk for suicide,[4] major depressive disorder,[5] PTSD and acute stress reaction,[6] or substance use disorder,[7] see the relevant VA/DoD CPGs.

Recommendation

3. When assessing pain, we suggest that measurement of the intensity of pain and interference with function should be separately assessed for each pain type and location using standardized tools. **(Weak for | Reviewed, Amended)**

Discussion

Pain management post-amputation is of utmost importance in promoting enhanced recovery, higher patient satisfaction, and lower cost of care. While pain is a subjective and individual experience, it should be assessed with standardized and validated tools when possible. Moderate confidence in the quality of evidence referenced in the 2007 LLA CPG exists to support continuous assessment of pain throughout the perioperative and rehabilitation period in individuals with LLA and that this assessment should include characteristics such as location, intensity, character, duration, timing, and aggravating factors or triggers.[46] These pain types include but are not limited to: residual limb pain, including neuropathic pain, phantom limb pain (PLP), other visceral or musculoskeletal pains, as well as pre-existing pain syndromes or comorbidities. Both pharmacological and non-pharmacological interventions should be considered and monitored for their effectiveness and/or side effects.

Though there was limited evidence on which to assess the strength of the recommendation, the Work Group determined that the benefits of assessing pain using standardized tools far outweigh any potential harms to the patient, as even small improvements in pain and function can improve an individual's quality of life. Patient focus group participants also expressed the desire to manage their pain after surgery and throughout all stages of rehabilitation and for providers to use an SDM approach when developing the treatment plan.

Equally important to measuring the intensity of pain is to consider the effects of pain on a patient's function. Little to no improvement in the intensity of pain may be seen, but a significant improvement in the patient's function may be considered a successful intervention. The Defense and Veterans Pain Rating Scale, when used with the supplemental questions that specifically measure the interference of pain on function, uniquely provides the ability to measure both the pain intensity as well as pain's interference on function.

[4] See the VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide. Available at: http://www.healthquality.va.gov/guidelines/MH/srb/

[5] See the VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder (MDD CPG). Available at: http://www.healthquality.va.gov/guidelines/MH/mdd/

[6] See the VA/DoD Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Reaction (PTSD CPG). Available at: http://www.healthquality.va.gov/guidelines/MH/ptsd/

[7] See the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorder (SUD CPG). Available at: http://www.healthquality.va.gov/guidelines/MH/sud/

Examples of standardized tools include:

- Visual Analogue Scale[47]
- Short Form McGill Pain Questionnaire[48]
- Pain Interference Scale[49]
- Defense and Veterans Pain Rating Scale[8]

Recommendation

4. We suggest offering a multi-modal, transdisciplinary individualized approach to pain management including transition to a non-narcotic pharmacological regimen combined with physical, psychological, and mechanical modalities throughout the rehabilitation process (For the treatment of chronic pain, the 2017 VA/DoD CPG for the Management of Opioid Therapy for Chronic Pain recommends alternatives to opioid therapy such as self-management strategies, other non-pharmacological treatments, and non-opioids over opioids [see the 2017 VA/DoD OT CPG[9]]). **(Weak for | Reviewed, New-replaced)**

Discussion

There are multiple pharmacological and non-pharmacological options for treating pain, and although the evidence is limited, the LLA Work Group suggests that a multi-modal, individualized approach to pain management be pursued for each patient due to the benefits for the patient.[50] Given the heterogeneity of patient characteristics, there is likely to be variation in patient preference and response to treatments. Frequent adjustments to interventions should be considered on an individual basis.

Pain is an individual experience that can vary based on multiple factors, including the patient's past medical history and experiences. All patients with LLA will likely experience some form of pain during the course of treatment and rehabilitation. The forms of pain that may be experienced include pre- and post-surgical pain, residual limb pain, neuropathic pain to include PLP, and other musculoskeletal pains. While PLP and phantom limb sensation (PLS) are common after limb loss (occurring in >80% of patients), these sensations generally improve over time and treatment should be reserved for pain that is disruptive of function.[51]

With the exception of some evidence to support the use of perineural catheters, there is limited evidence to support other specific pain interventions in the perioperative period.[52] Other pharmacological and non-pharmacological interventions that have been used, but for which there is insufficient supporting evidence, include: anticonvulsants, tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors, nonsteroidal anti-inflammatory drugs, transcutaneous electrical nerve stimulation, desensitization, scar mobilization, relaxation, hypnosis and biofeedback, mirror therapy, and interventional techniques such as neuraxial and regional analgesia as well as neuromodulation to include spinal cord stimulation. Recent evidence also suggests a potential benefit of repetitive transcranial magnetic

[8] See the Defense & Veterans Pain Rating Scale. Available at: http://www.dvcipm.org/site/assets/files/1084/dvprs-front-vector.pdf
[9] See the VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain. Available at: http://www.healthquality.va.gov/guidelines/Pain/cot/

stimulation for the treatment of PLP.[53] Continued research is needed to discover and support more effective pain management strategies, which minimize potential side effects.

There has been a recent shift in clinical practice away from long-term opioid use for chronic pain. For the treatment of chronic pain, the 2017 VA/DoD Opioid Therapy for Chronic Pain CPG (2017 VA/DoD OT CPG)[10] recommends alternatives to opioid therapy such as self-management strategies, other non-pharmacological treatments, and non-opioids over opioids (see the 2017 VA/DoD OT CPG Recommendation 1 in Table 2). It also recommends tapering to reduced dose or to discontinuation of long-term opioid therapy when risks of long-term opioid therapy outweigh benefits, and individualizing tapering based on risk assessment and patient needs and characteristics (see the 2017 VA/DoD OT CPG Recommendations 14-15 in Table 2). For the acute phase, the 2017 VA/DoD OT CPG recommends alternatives for mild-to-moderate pain, and if opioids are prescribed, it recommends "immediate-release opioids at the lowest effective dose with reassessment no later than 3-5 days to determine if adjustments or continuation of OT is indicated" (see 2017 VA/DoD OT CPG Recommendation 18 in Table 2). Patient education about opioid risks and alternatives to opioid therapy should be offered. In addition to the standard long-term effects from chronic opioid therapy, individuals with LLA may have several adverse effects to consider. Sedation and balance issues from opioids may impede the rehabilitation progress.

Table 2: Relevant 2017 VA/DoD OT CPG Recommendations[10]

2017 VA/DoD OT CPG Recommendation #	Recommendation	Strength of Recommendation
1	a) We recommend against initiation of long-term opioid therapy for chronic pain. b) We recommend alternatives to opioid therapy such as self-management strategies and other non-pharmacological treatments. c) When pharmacologic therapies are used, we recommend non-opioids over opioids.	a) Strong against b) Strong for c) Strong for
14	We recommend tapering to reduced dose or to discontinuation of long-term opioid therapy when risks of long-term opioid therapy outweigh benefits. Note: Abrupt discontinuation should be avoided unless required for immediate safety concerns.	Strong for
15	We recommend individualizing opioid tapering based on risk assessment and patient needs and characteristics. Note: There is insufficient evidence to recommend for or against specific tapering strategies and schedules.	Strong for

[10] See the VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain. Available at: http://www.healthquality.va.gov/guidelines/Pain/cot/

2017 VA/DoD OT CPG Recommendation #	Recommendation	Strength of Recommendation
18	a) We recommend alternatives to opioids for mild-to-moderate acute pain. b) We suggest use of multimodal pain care including non-opioid medications as indicated when opioids are used for acute pain. c) If take-home opioids are prescribed, we recommend that immediate-release opioids are used at the lowest effective dose with opioid therapy reassessment no later than 3-5 days to determine if adjustments or continuing opioid therapy is indicated. Note: Patient education about opioid risks and alternatives to opioid therapy should be offered.	a) Strong for b) Weak for c) Strong for

Recommendation

5. We recommend providers consider the patient's birth sex and self-identified gender identity in developing individualized treatment plans.
   (Strong for | Reviewed, New-added)

Discussion

Research supports that there are significant differences between male and female birth sex patients in areas such as successful prosthesis fitting, time in rehabilitation, use of coping self-statements, and pain catastrophizing.[54-56] In two studies, evidence suggests more successful prosthetic fitting for patients with a male birth sex compared to female birth sex.[54,55] The patient focus group participants indicated that prosthetic satisfaction depended on multiple factors, including socket comfort, function, and ability for prosthesis to accommodate clothes and shoes, which is particularly challenging for women. Published evidence implicates multiple factors that influence prosthetic fit, including birth sex and gender, age, diagnosis of diabetes, and mean length of rehabilitation.[54,55] Women spent significantly more time in rehabilitation after successful fit of a prosthetic leg than men.[55] Another study reported significantly greater use of coping self-statements with women compared to men.[56] Although there was no significant difference between groups reporting residual limb pain or PLP, women were significantly more likely than men to endorse beliefs related to personal control over pain, appropriateness of solicitous responses from others, and higher pain catastrophizing. While men and women with limb loss did not significantly differ in their disability-specific pain, sex/gender differences in their experience of pain were significant and worthy of future clinical attention.

Additional evidence reported that women are significantly more likely to have transfemoral amputations compared to men.[57] The study found that women with peripheral arterial disease are at greater risk for compromise in daily functioning, have poorer quality of life, and more often present with critical limb ischemia and higher levels of arterial lesions, resulting in more proximal level amputation. Given that higher levels of amputation are associated with higher metabolic costs during ambulation and greater difficulty with socket fit, importance should be given to early and repeated screening of women with vascular disease.

Each of these studies looked at different aspects of care and all found differences between men and women. It is important that these issues and concerns are acknowledged and addressed as part of the comprehensive care of each patient. It is not known if these differences are attributable to birth sex differences or to gender-based cultural factors, thus the treatment of transgender Veterans and Service Members should attend to risk and resilience factors associated with both their birth sex and current gender identity.

There was moderate confidence in the evidence to support this recommendation. Confidence was supported by multiple studies drawing similar conclusions on differences between men and women across many areas of functioning. In this case, despite a lack of research, the benefits of addressing sex and gender-specific needs greatly outweigh the potential harms to the patient. Evidence was supported by other considerations, such as the patient focus group, which emphasized the importance of recognizing patient differences and designing treatment plans according to each patient's unique needs. The patient focus group participants also expressed concerns regarding the need for more female-specific prosthetic components. The size and weight of many prosthetic options that might be ideal for a man may be too heavy or oversized for some women.

Although the majority of individuals with amputation in the U.S. are men, it is estimated that women make up to 35% of this population.[11] As research continues to show differences among the groups, it is worth addressing the influence of birth sex and self-identified gender identity more extensively in future research. Many published studies have a limited number of female birth sex or transgender individuals included in their cohorts, which limits the ability to generalize results within these populations. There is a need to establish normative values and screening tools for these populations.

Recommendation

6. We suggest offering peer support interventions, including visitation by a certified peer visitor, as early as feasible and throughout the rehabilitation process.
   (Weak for | Reviewed, Amended)

Discussion

The quality of evidence for peer support interventions is low; however, it suggests that involvement in some type of support program can be beneficial for both the patient and the family/caregiver.[58] The early involvement of family members and contact with other patients with amputations is important for the patient's psychological adjustment.[59] The CARF Amputation Specialty Program requirements are consistent with literature suggesting that peer visits work best when the age, gender, and amputation level are considered and matched.[38,58] Patient focus group participants reported that peer support programs are often helpful following amputation as they provide opportunities for patients with amputation to relate to one another as well as share experiences and coping strategies. These factors indicate that the benefits of offering this component of care greatly outweigh the potential harms to the patient.

While initial introductory visits between a new patient and the peer visitor are best done in person, follow-up visits can be done more easily and frequently using phone, e-mail, or text messaging. For patients who are not a reasonable distance from a peer center, or live in an area with low population density, a clinical video telehealth visit (real-time video conference) may also be used to broaden the patient's access to a certified peer visitor or support group.

While peer and other support strategies should be considered prior to and immediately following amputation, when anxiety and adjustment problems may be more pronounced, more research is needed to determine the optimal timing, frequency, duration, and number of peer visits needed prior to or following amputation for positive outcomes.

B. Perioperative Phase

Recommendation

7. Prior to surgery, we suggest that rehabilitation goals, outcomes, and other implications be included in shared decision making about residual limb length and amputation level. **(Weak for | Reviewed, Amended)**

Discussion

Immediate health concerns for the patient are often at the forefront of decision-making discussions prior to amputation surgery, but long-term implications, specifically rehabilitation goals, need to be incorporated into the discussion due to the impact amputation level and residual limb length can have on these outcomes. Understanding the long-term implications of these decisions and working with the rehabilitation team to establish a plan of care following amputation surgery can maximize the functional outcomes for the patient upon discharge from care. This understanding and team decision making needs to be initiated prior to the amputation surgery, when feasible, and should weigh factors surrounding the decision to amputate as well as implications related to residual limb length and amputation level. Although the body of evidence supporting this recommendation is limited, there are great benefits to the patient and no known harms of this approach.

Long-term functional outcomes, including improved walking ability, favor more distal amputation levels. Patients with limb loss levels distal to the ankle were more likely to be able to walk one kilometer within one year of surgery compared to those with limb loss proximal to the ankle.[60] Similarly, patients with more distal levels of limb loss (transmetatarsal and toe limb loss) demonstrated an increased ability to complete ADLs relative to patients with more proximal amputation levels (transtibial or transfemoral limb loss).[61,62] Increased mobility and decreased wheelchair use have also been demonstrated for those with transtibial limb loss compared to transfemoral limb loss.[60] These factors can have a dramatic impact on quality of life.[63] Improvements in quality of life and mobility were also noted for patients with knee disarticulation as compared to transfemoral limb loss.[63] The potential advantages of more distal amputation should be weighed against the possible increased risks of undergoing revision surgery.

Preservation of longer residual limb lengths helps to optimize a patient's ability to ambulate. For patients with transtibial limb loss, a longer residual limb has been noted to improve walking distance.[60] A similar benefit was observed in patients with transfemoral limb loss who also demonstrated increased walking speeds with greater residual limb lengths.[64] While considerations should be made to ensure available clearance for desired componentry and the availability of adequate soft tissue for bone coverage and closure, preserving maximum residual limb length will likely lead to improved rehabilitation outcomes for most patients.

Including rehabilitation goals and outcomes in SDM may increase the time required to discuss implications of the surgical decisions with the patient and rehabilitation team. This burden, however, is outweighed by

the long-term benefit of determining the most appropriate procedures that will maximize the well-being and functional outcome of the patient. When setting goals and expectations, factors such as age, etiology of amputation, comorbidities, and preoperative condition should be included, as they may influence the level of achievable outcomes for the patient. More research is needed to determine the influence of these factors, and other potential confounders, as well as provide more clarity between functional benefits for or against joint disarticulations relative to a more proximal level of limb loss (e.g., ankle disarticulation versus transtibial limb loss).

Recommendation

8. There is insufficient evidence to recommend one surgical amputation procedure over another. **(Not applicable | Reviewed, New-added)**

Discussion

The end goal of any LLA surgical procedure is a well-healed and well-shaped residual limb that is free from pain or other complications with excellent soft tissue characteristics. While the surgical procedure chosen is most often related to the surgeon's preference and experience, or determined after a conversation between the surgeon and the patient, involving other members of the rehabilitation care team can better align expected surgical outcomes with expected rehabilitation outcomes. If there is uncertainty of the optimal length of the residual limb, pre-operative consultation with an experienced physiatrist or prosthetist should be considered.

Of the various surgical procedures currently in use, only a few (e.g., Burgess versus Ertl, Gritti-Stokes versus traditional transfemoral) have been directly compared in non-randomized observational studies. [65-70] No one procedure has been shown to be clearly superior to another, or to lead to a clear advantage in prosthesis use. Each procedure has its own advantages and disadvantages. More research is needed in this area to further outline the strengths and weaknesses of the available procedures beyond expert opinion.

Recommendation

9. We suggest the use of a rigid or semi-rigid dressing to promote healing and early prosthetic use as soon as feasible post-amputation in transtibial amputation. Rigid post-operative dressings are preferred in situations where limb protection is a priority.
   (Weak for | Reviewed, Amended)

Discussion

Residual limb management is an important determinant of successful recovery from amputation.[71] Although the Work Group considered post-surgical dressing care an essential aspect of amputation care, the evidence review did not identify any literature on post-surgical dressing options following transfemoral amputation that met inclusion criteria.

Low quality evidence supports rigid removable (RRD) or semi-rigid (SRRD) dressings following transtibial amputation to promote healing and early prosthetic use.[71,72] A fair quality SR and meta-analysis found sufficient evidence to produce four empirical evidence statements.[72] Providers may consider these statements in clinical decision making for postoperative care in transtibial amputation and as the basis for future research on post-surgical care for transfemoral amputation:

1. In persons with acute transtibial amputation (TTA) from vascular disease, vacuum-formed dressings are comparably effective at preparing the limb for prosthetic use and ambulation as measured by the number of days from amputation to prosthetic fitting, wound healing rate, and mobility compared with conventional Plaster of Paris dressings.
2. Following TTA, RRDs and SRRDs, with or without combined elastic compression, are more effective at reducing acute post-amputation edema volume compared with conventional elastic compression alone.
3. In persons with acute TTA, RRDs, compared with soft elastic dressings and bandaging, accelerate residual limb healing time and reduce hospitalization time and are comparably effective at reducing wound infection rate and time to prosthetic fitting.
4. In persons with acute TTA, articulated and non-articulated early walking aids are comparably effective at improving 10 meter walking velocity and quality of life.

In addition, a 2003 review found that "The literature supports that rigid plaster cast dressings result in significantly accelerated rehabilitation times and significantly less edema compared to soft gauze dressings, and prefabricated pneumatic prostheses were found to have significantly fewer post-surgical complications and required fewer higher-level revisions compared to soft gauze dressings."[71] This evidence was included in the 2007 LLA CPG.

Effective post-operative dressing management should maintain the integrity of the residual limb and should:[71]

- Protect the residual limb
- Control and reduce edema
- Facilitate primary wound closure
- Maintain extension range of motion
- Facilitate advancement to prosthetic fitting

Rigid or semi-rigid protective devices that cross the knee joint can consistently accomplish the aforementioned goals, when properly applied.[71] The decision making for the dressing begins pre-operatively; however, the course of surgery intraoperatively may affect the final choice of dressings, particularly if heavy contamination leads to the decision to perform an open amputation.

A 1971 study found that 6% of thigh-level rigid cast procedures required higher-level revisions, compared with 22% of soft gauze dressings; however, due to small study sample sizes (n=182 total; n=45 soft dressing, n=74 thigh-level rigid), there was insufficient statistical power to attain statistically significant differences.[73] Therefore, the generalizability of the results is unclear. The age of the study also demands that current research examine whether the findings could be replicated today.

Soft Dressings

A soft dressing is the least expensive and least time-consuming strategy, but may not be the optimal strategy to maintain residual limb integrity. Soft dressings may result in complications, including high local

or proximal pressures that impair healing, a tendency to loosen and fall off, and an increased likelihood of a knee flexion contracture.[71]

A very low quality RCT compared patient satisfaction between use of elastic bandage or custom-fit compressive sock.[74] Either can reduce edema, although there was no statistically significant difference between groups for patient satisfaction. Without a comparison to RRD or SRRD, this study serves to highlight the variability in residual limb management and the lack of research on this subject, and raises the question on how much of a role provider training impacts study outcomes.

Rigid or Semi-Rigid Dressings

No studies found any negative wound healing effects as a result of the application of rigid dressings. An SR stated that following transtibial amputation, primarily in dysvascular patients, RRDs and SRRDs were found to reduce acute post-amputation edema, healing time, hospitalization time, wound infection rate, and time to prosthetic fitting compared with elastic (i.e., soft) dressings.[72]

Rigid or semi-rigid dressings include:

- Short removable rigid casts
- Thigh-level, non-removable rigid casts
- Thigh-level, non-removable rigid casts with removable immediate post-operative prosthesis
- Prefabricated pneumatic immediate post-operative prosthesis

Selection of soft, rigid, or semi-rigid dressings should consider trade-offs for individual patients (e.g., protection of the limb, risk of infection, need to inspect the incision site and skin, other factors).

Based on the low quality evidence for transtibial amputation, the lack of evidence for post-surgical care of transfemoral amputation, and the difficulty with standardizing post-operative rigid dressings, this is a priority area for future research, education, and clinical training.

Recommendation

10. We suggest performing cognitive screening prior to establishing rehabilitation goals, to assess the patient's ability and suitability for appropriate prosthetic technology.
    (Weak for | Reviewed, New-replaced)

Discussion

Performing cognitive screening prior to rehabilitation may assist in development of appropriate goals and tailoring of the rehabilitation care plan. An SR reported that cognitive function has associations with aspects of amputation rehabilitation and subsequent functioning.[75] Associations exist between decreased cognitive function and failure of an individual with limb loss to be successfully fitted with a prosthetic device. Poor cognitive function is also related to overall decreased prosthetic device use, decreased mobility, loss of independence, and increased incidence of falls.[75] Additionally, cognitive impairment is associated with a higher mortality rate and an undesirable variation in adherence to medical regimens for individuals with LLA.[75]

The impaired cognitive domains of memory and executive function relate to the reduction of prosthetic device use and decreased functional outcomes. Verbal fluency, a measure of executive function, has been found to be predictive of prosthetic device use.[75] Cognitive status, particularly for individuals without comorbidities, can be predictive of long-term mobility. Memory in the acute phase following amputation is a predictor of long-term perceived health status and activity restriction. Visual memory is a predictor of mobility and locomotion. Dementia prior to amputation is predictive of increased mortality following amputation.[75]

This evidence supports assessing cognitive function, specifically memory and/or executive function, in patients immediately after LLA.[75] While adequate cognitive assessment is time-consuming for the clinician, valuable information can be gathered to help establish goals and determine prognosis. This testing should always be coupled with continual reassessment of function and goals to assure the patient will reach their full functional potential. Future research is needed to identify which specific cognitive tests provide predictive value while being practical for clinical use with this patient population. Timing of the screening should take into consideration potentially confounding comorbid conditions. Initial cognitive screening by the rehabilitation team may indicate the need for referral to the appropriate specialist for further cognitive testing. Continued reassessment may be indicated as appropriate.

Recommendation

11. We suggest that in the perioperative phase following amputation, patients receive physical rehabilitation and appropriate durable medical equipment/assistive technology.
(Weak for | Reviewed, New-replaced)

Discussion

Confidence in the quality of evidence is very low in support of patient participation in physical rehabilitation following amputation to include the use of appropriate durable medical equipment (DME) and assistive technology (AT); however, the benefits of implementing physical rehabilitation and the use of DME and AT following amputation greatly outweigh the potential harms to the patient. Types of DME and AT that are particularly relevant in the care of individuals with LLA include items such as wheelchairs, walkers, canes, residual limb supports, bedside commode, and tub transfer bench. An SR found that frequency of participation in occupational therapy sessions was significantly related to use of a prosthetic device.[76] A second study demonstrated the importance of physical rehabilitation for improved functional performance following LLA.[77] This study evaluated the efficacy of short intensive physical therapy versus usual care (i.e., supervised walking). The study found that intensive physical rehabilitation resulted in significant improvement in walking speed and weight tolerance on a prosthetic foot. While the identified studies were graded as very low quality, they demonstrate the positive benefits and functional outcomes for participation in physical rehabilitation following LLA, to include physical and occupational therapy interventions.[76,77]

Research also supports the use of DME and AT in the perioperative phase following amputation. An SR found that use of residual limb supports made wheelchairs more comfortable, helped protect the residual limb, and increased overall acceptance of the amputation.[76] Included in the SR was an article in which patients were educated in the use of residual limb supports for contracture prevention, edema control, and protection of the residual limb.[78] This study described prescription of appropriate DME and AT

following amputation as being a key intervention for promoting functional independence and safety during ADLs and mobility. The available evidence suggests the use of residual limb supports in the perioperative phase of rehabilitation, but it is insufficient in providing recommendations for specific types of DME or AT.

The research currently available to support perioperative rehabilitation interventions following amputation is limited. More research is needed to explore the pre-operative interventions and their effect on functional outcomes following LLA.

Recommendation

12. We suggest, when applicable, treatment in an acute inpatient rehabilitation program over a skilled nursing facility.
    (Weak for | Reviewed, New-replaced)

Discussion

A prospective cohort study of 297 patients supports that rehabilitation in an inpatient rehabilitation facility (IRF) has distinct advantages compared to a skilled nursing facility (SNF).[79] This study found that patients who received care in an IRF displayed improved quality of life, better ambulation and confidence in gait, increased prosthetic device use, improved success with mobility overall, and fewer complaints of pain with prosthetic device use compared to patients that received care in a SNF. These findings are supported by other research that demonstrated improved 36-item Short-Form Health Survey subscales for those in IRFs compared to those in SNFs.[80,81] Safety is often a concern with these patients, however, current evidence does not support making a recommendation for an acute inpatient rehabilitation setting rather than a SNF based upon safety alone.

Patients from the focus group acknowledged a preference for rehabilitation in a setting where treatment was specialized to their needs. Resource use, feasibility, and subgroup considerations are also important factors to consider when discussing rehabilitation settings with patients, as IRFs may not be easily accessible to all patients.

When determining this to be a “Weak for” Recommendation, the Work Group had low confidence in the quality of evidence. They also considered that benefits to the patients outweigh any potential harms. Patients from the focus group acknowledged a preference for rehabilitation in a setting where treatment was specialized to their needs. Resource use, feasibility, and subgroup considerations are also important factors to consider when discussing rehabilitation settings with patients, as IRFs may not be easily accessible to all patients.

Recommendation

13. We suggest the initiation of mobility training as soon as feasible post-amputation. In appropriate patients, this may include ipsilateral side weight-bearing ambulation with a pylon to improve physical function and gait parameters.
    (Weak for | Reviewed, New-replaced)

Discussion

While there is limited evidence to support out-of-bed activities and mobility training in the early post-amputation period, these are generally well-accepted rehabilitation practices.[77,82] During the early post-operative period, the clinician must consider several factors that may influence the timing, frequency, and intensity of mobility training. These factors include overall medical stability, hemodynamic stability, residual limb healing status, pain management, mental status, and fall risk. These variables and potential risks need to be weighed against the benefits of early mobilization, which include improvements in strength, cardiovascular fitness, bone health, and functional independence.

One consideration in the early mobilization after LLA is whether or not to utilize a weight-bearing prosthetic device in the early post-amputation phase before the residual limb is healed. In addition to the general benefits of early mobilization noted above, the potential advantages of using an early weight-bearing prosthetic device include facilitating early mobilization, gait re-education, accelerated stump healing, reduced complications, and facilitation of early definitive prosthetic fitting. The potential disadvantages of this intervention include the risk of skin breakdown of the residual limb, increased residual limb pain, and increased risk of falls. For some patients, there may be a psychological benefit from early prosthetic device fitting.[83] When the decision is made to utilize an early weight-bearing prosthetic device for a person with a transtibial level amputation, there are options for use of an articulated prosthetic device that includes a thigh cuff and knee joints or a non-articulated device that does not cross the knee. These devices can be initiated within the first week following amputation and may include simple pylon and foot structures with adjustable sockets or sockets that include pneumatic bladders for adjustability over time.[83]

While confidence in the quality of evidence examining the differences between articulated and non-articulated early weight-bearing prosthetic devices is very low, the evidence supports improved outcomes with the use of these systems.[83] In a controlled study, 29 subjects were randomized to receive either an articulated or pneumatic, non-articulated early weight-bearing prosthetic device. Subjects were included in the study if they were determined to tolerate an early walk aid and were expected to receive a functional prosthetic device in the long term. Subjects were excluded if they were non-ambulatory prior to the amputation surgery. The study noted improvements in both groups, but no statistically significant differences between the groups with regard to long-term walking ability up to four years after surgery. Limitations of this single study include a lack of outcome assessment blinding and an unclear randomization process.[83]

Access to early weight-bearing prosthetic devices has expanded through the introduction of several different prefabricated systems that are commercially available. Additional research is required to further delineate the risks and benefits associated with this intervention as well as to further determine the differences between articulated and non-articulated devices. Despite the need for additional

research, evidence suggests that mobility training should begin as soon as possible in the post-amputation phase of rehabilitation.

Recommendation

14. We recommend instituting rehabilitation training interventions, using both open and closed chain exercises and progressive resistance to improve gait, mobility, strength, cardiovascular fitness and activities of daily living performance in order to maximize function.
(Strong for | Reviewed, New-replaced)

Discussion

One SR and two RCTs provide evidence in support of this recommendation. The SR evaluated the effect of exercise programs on gait in patients with LLA, demonstrating that more intensive exercise-based interventions (part-to-whole resisted gait training and functional gait training) improved self-selected walking speed.[84] One RCT had mixed results examining the feasibility of a walking training program, using an interactive gaming platform, in improving walking in older adults with LLA.[85] There were no statistically significant differences for any result, although direction of effect favored active intervention versus cognitive training as measured by the 2-minute walk test, a step activity monitor, and the walking while talking test. One RCT examined the efficacy of proprioceptive neuromuscular facilitation techniques compared to traditional prosthetic training in improving ambulatory function in patients with transtibial amputation. The results favored intervention in regard to stride width and higher scores on the locomotor capabilities index.[86] The intensity of the rehabilitation training intervention should be individualized in order to maximize the benefit, as well as minimize potential complications that could occur when the intensity level is inappropriate for the individual.

Despite the lack of strong evidence to support this recommendation, the potential harm from these interventions is far less than the potential harm from immobility. There is some evidence, not included in the evidence review, to support early mobilization in the intensive care unit and throughout the inpatient stay.[87-92] Patient focus group feedback suggests that patients are shifting their expectations to demand more robust rehabilitation following amputation with higher expectations for reintegration into the community. A higher level of reintegration requires strength, endurance, and skill.

One of the main messages from the patient focus group was for rehabilitation providers to use real-world training and outcome metrics tied to patients' preinjury level of function and evolving personal goals. Training models that mimic real-world situations in anticipation of community reintegration are already a part of the rehabilitation process, although complex situations as noted by the patient focus group (e.g., walking through a crowded airport with luggage as others stop unexpectedly in the path, children running across the individual's path) may reflect a higher level of complexity than end points achieved in rehabilitation settings. Of note, fluctuations in weight was a consensus area of concern among the focus group participants as it directly impacts prosthetic device fit. Higher intensity exercise may play a lead role in maintaining basal metabolic rate and baseline calorie burn, and thus may be a useful tool across amputation-etiology patient populations.

Based on this patient input, functional ADLs should include transfers, practiced with and without a prosthesis, including sit to stand, bed to chair, chair to toilet and tub, into and out of a vehicle, and on and off the floor. Self-care training should include dressing, feeding, grooming, bathing, and toileting, with and

without a prosthesis. Rehabilitation providers should ensure that patients have the opportunity to discuss all aspects of functional ADLs, including challenges with being intimate with a significant other. Consistent with input from the patient focus group, adding more challenging real-world scenarios to the functional ADL training is essential to patient confidence and reintegration to community living.

C. Pre-Prosthetic Phase

Recommendation

15. We suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces.
    (Weak for | Reviewed, New-added)

Discussion

According to two fair quality SRs, microprocessor knees may reduce risk of falls and maximize patient satisfaction in limited and unlimited community ambulators.[93,94] Both reviews reported a decrease in stumble and fall frequency with accommodation and use of a microprocessor knee system relative to a non-microprocessor knee system.[93,94] The studies further support the prescription of microprocessor knees over non-microprocessor knees to improve an individual's ability to walk faster on level ground, uneven surfaces, and downhill, thus providing the user with an improved sense of security and improved overall satisfaction.[93,94] The Work Group considered that the benefits to the patients, particularly decreasing risk of falling, far outweigh potential harms. The patient focus group participants also expressed a desire to have access to prosthetic devices that fit well and maximize their safety and function, so patient values and preferences were another important consideration when assessing the strength of the recommendation.

Falling is a major issue in patients with transfemoral amputations. Increased number of falls, fear of falling, as well as deterioration in balance, coordination, and endurance, resulting in activity avoidance, decreased independence and mobility have all been reported in this population.[93] Therefore, the prescription of microprocessor knees is supported for ambulatory individuals with complex medical conditions affecting balance, as well as for the geriatric population. These populations benefit from microprocessor knees, which have been demonstrated to decrease stumbles and prevent falls by an SR included in our evidence review[93] and two SRs that were excluded because they were superseded by a more recent and comprehensive SR.[95,96]

There is insufficient evidence to support using one type of microprocessor knee over another, but the provider should consider the many characteristics of each type of knee when making a selection. Most importantly, the potential impact on the patient's functional level should be considered as there are a variety of microprocessor knee options available. Some knees may be best suited for the limited community ambulator[93] while others are more appropriate for the highly active patient.[72,97,98] Another consideration when choosing the right microprocessor knee for an individual is the mechanism of charging the knee; some have removable batteries, others have a port for a plug, while others have inductive charging systems. Still another consideration would be the default mode of the device when the power source is depleted. Some knees default to a locked knee while others default to free swing.

Finally, for the active user, additional options include activity modes and waterproof/water resistance features, if appropriate. More research is needed to understand which patient subgroups benefit most from access to microprocessor knee units.

There are inconclusive studies regarding differences in socket design, prosthetic foot categories, as well as advantages and disadvantages of various types of suspensions and interfaces. Each component of a prosthetic prescription should be carefully selected based on the capabilities and anticipated compliance of the user as well as the integrity and shape of the residual limb. Patient desired outcomes, patient goals, and the compatibility of the entire prosthetic system should also be a consideration when prescribing prosthetic components.

D. Prosthetic Training Phase

Recommendation

16. We recommend the use of valid, reliable, and responsive functional outcome measures, including, but not limited to, the Comprehensive High-level Activity Mobility Predictor, Amputee Mobility Predictor, 10-meter walk test, and 6-minute walk test.
    (Strong for | Reviewed, New-replaced)

Discussion

The use of outcome measures for periodic patient assessment at designated time points is an increasingly important element of evidence-based practice.[99,100] Using validated objective outcome measures throughout the rehabilitation process provides direct feedback to providers and patients regarding the efficacy of therapeutic interventions and progress towards established functional goals. The use of common data elements across healthcare institutions helps to standardize practice and improve the overall quality of healthcare delivery.

When choosing from the numerous outcome measures available, it is important to first select a measure that evaluates the construct of interest.[99,100] Other issues to consider include the administration burden to patient and provider. Administration burden includes the time to administer, associated costs, post-administration patient discomfort, and clinical logistics including the need for specialized equipment in order to perform the measure. There are multiple other factors to consider in this selection process including the level of measurement (e.g., nominal, ordinal, ratio), availability of reference or normative values, and cutoff scores. However, while all of these are important to consider, among the most important factors are whether or not the measure is valid, reliable, and responsive.

Outcome measures that are valid are identified as measuring the construct they are intended to measure. Reliability is a psychometric property that indicates that the test will consistently provide the same measure if no change has occurred. There are several forms of reliability that must be considered, including test-retest, interrater and intrarater reliability, and internal consistency. Finally, it is imperative to select measures that are sensitive or responsive to change. That is, the measure will reflect a clearly different value when true patient change has occurred.

Outcome measures may be population specific [101,102] or they may have more general utility. The Amputee Mobility Predictor (AMP) is a physical performance measure of functional mobility that takes

approximately 15 minutes to administer. It provides ordinal scale data and some studies, not included in the evidence review, suggest that the AMP has validity, reliability, and responsiveness.[103,104] Further, reference values are available so the rater may understand a patient's score relative to others of comparable etiology and functional level. A clinician, however, may require a more direct assessment of walking ability and may have less than five minutes available to conduct an assessment. In this case, some studies, not included in the evidence review, suggest that several outcome measures with validity, reliability, and responsiveness may be more appropriate, including the 10-meter walk test, the 2- or 6-minute walk test, or others.[103-107] The latter tests are not population specific and also have some reference data available from patients with amputations as well as from other diagnostic groups.[103-107] Refer to Table 3 for more information on physical performance measures with evidence of validity, reliability, and/or responsiveness.

This recommendation was supported by moderate confidence in the quality of evidence and the consideration that the benefits to patients of using valid, reliable, and responsive outcome measures would outweigh any potential risks or harms. More research is needed to validate wheeled and other mobility outcome measures.

Recommendation

17. We suggest the use of a combination of measures with acceptable psychometric properties to assess functional outcomes.
    (Weak for | Reviewed, New-replaced)

Discussion

Because rehabilitative care requires assessment of multiple domains including walking ability, balance, adjustment to prosthetic device use, quality of life, and others, it is suggested that multiple measures be used to assess outcomes following LLA. Further, it has been established that patient preference is a key component in fully assessing function in the patient with LLA.[72,98] In addition to selecting outcome measures that are valid, reliable, and responsive, it is important to include comparably robust measures from the patient's perspective. Some examples are the Locomotor Capabilities Index [108] and the Prosthesis Evaluation Questionnaire-Mobility Subscale,[109] both of which assess the patient's perception of his/her mobility capabilities. It may also be important to include an assessment of the patient's perceptions regarding his/her confidence with balance, in which case the Activities-specific Balance Confidence Scale will be useful.[110] See Table 4 for a list of patient-reported outcome measures which should be considered to complement the outcome measures of physical functional performance in Table 3.

In addition to the measures in Table 3 and Table 4, it is worth noting that other domains may require assessment. For example, it is often important to assess the location, severity, and type of pain (e.g., low back, joint, phantom limb). Other phenomena that may require assessment include a specific recall of the number of stumbles, semi-controlled falls, or uncontrolled falls, which may be included as part of a specific instrument or can be asked separately.[95,97,98]

In summary, it is important to utilize measures that assess performance and outcomes in multiple domains. Further, selected instruments should have strong psychometric properties including evidence of validity, reliability, and responsiveness to change. Finally, multiple outcome measures may be necessary to

thoroughly assess the patient and track progress. However, multiple factors have to be considered when choosing tests to assure minimal burden to the patient, the clinic and providers, and others.

Table 3. Measures of physical functional performance* [72,97,101-104,106,111-125]

	TUG	L-Test	AMPnoPRO	AMPPRO	4SST	Berg Balance Test	10MWT	2MWT	6MWT	HAI	SAI	CHAMP
Construct	Functional mobility	Functional mobility	Functional mobility	Functional mobility	Multi-directional stepping & dynamic balance	Balance	Walking ability	Walking ability	Walking ability & endurance	Walking ability on hills & ramps	Walking ability on stairs	High level mobility
Data Level	Ratio	Ratio	Ordinal	Ordinal	Ratio	Ordinal	Ratio	Ratio	Ratio	Ordinal	Ordinal	Ordinal
Admin. Time	≤5 min	≤5 min	≈15 min	≈15 min	≤5 min	≈15 min	≤5 min	≤5 min	≤10 min	≤5 min	≤5 min	≈15 min
Evidence of Sensitivity?	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes
Normative/ Reference Data Population and Values	LLA IQR: 9; Mn: 25; Md: 23; Rng: 16-41 (sec)	LLA: 33±15; TTA: 30±13; TFA: 42±17; Trauma: 26±8; PVD: 42±18; No WA: 26±6; WA: 43±18; WA <55 yo: 25±7 no WA ≥55 yo: 40±17 (sec)	LLA (K0/K1): 10±10; LLA (K2): 25±7; LLA (K3): 31±7; LLA (K4): 39±3 (score out of 43)	LLA (K0/K1): 25±7; LLA (K2): 35±7; LLA (K3): 41±4; LLA (K4): 45±2 (score out of 47)	TFA (K3/K4): 11-12±3; dysvascular TTA (fallers): 33±10; dysvascular TTA (non-fallers): 18±8 (sec)	TTA (K2, SACH foot): 51±8; TTA (K2, multi-axial foot): 55±3; TTA (K3/K4): 49±6 (39-56); LLA (varied level & etiology): 51±5 (32-56) (score out of 56)	Limb salvage: 8.9; TTA: 9.6 (sec)	LLA: IQR: 27; Mn: 53; Md: 48; Rng: 26-141 (m)	Limb-trauma/ salvage: 361±29; TTA (post-limb salvage): 391±57; TTA: 545±65; TTA: 570±80; LLA (K0/K1): 50±30; LLA (K2): 190±111; LLA (K3): 299±102; LLA (K4): 419±86 (m)	TFA (K3/K4): 11; TTA (K2, SACH foot): 7; TTA (K2, multi-axial foot): 7 (score out of 11);	TFA (K3/K4): 11; TTA (K2, SACH foot): 11; TTA (K2, multi-axial foot): 12 (score out of 13);	Male Service Members with limb loss: Mn±SD: 22±8; Rng: 1-35 (score out of 40)

*All included outcomes have evidence of reliability and validity.

Abbreviations: 2MWT: 2-minute walk test; 4SST: four square step test; 6MWT: 6-minute walk test; 10MWT: 10-meter walk test; AMP: Amputee mobility predictor; CHAMP: Comprehensive High-level Activity Mobility Predictor; HAI: Hill Assessment Index; IQR: interquartile range; K(0-4): Medicare functional levels; LLA: lower limb amputation; m: meter(s); Md: median; min: minutes; Mn: mean; noPRO: without a prosthesis; PRO: with a prosthesis; PVD: peripheral vascular disease; Rng: range; SACH: Solid-ankle cushioned-heel; SAI: Stair assessment index; SD: standard deviation; sec: second(s); TFA: transfemoral amputation; TTA: transtibial amputation; TUG: timed up and go; WA: walk aide; yo: years old

Table 4. Patient reported outcome measures* [97,104,108-110,115,117,126-128]

	ABC	PEQ-MS	OPUS	LCI-5	TAPES
ICF Domain	Activities	Activities	Activities, Participation	Activities	Activities
Data Level	Ordinal	Ordinal	Ordinal	Ordinal	Ordinal
Admin Time	5 min	5 min	6-30 min	10 min	5-10 min
Construct	Patient confidence in balance	Perceived potential for mobility	Perceived function & satisfaction with devices	Perceived potential for mobility	Adjusting to amputation & demands of wearing a prosthesis
Items	16	12	87 or 88	14	34
Scoring	Average all items (0%-100%)	Average all items (0-4)	Total score in each section	Sum of scores	Not applicable
Evidence of Responsiveness	Yes	Not applicable	Yes	Yes	Not applicable
Normative or Reference Values	PVD LLA 54%; non-PVD 75%; w/mobility device 45%; no mobility device 78%; total LLA 64%. TFA PVD 2.0 [97]; TTA PVD 2.3; TFA Trauma 2.7; TTA Trauma 3.0	TFA PVD 2.2 [97]; TTA PVD 2.5; TFA Trauma 2.8; TTA Trauma 3.1 [115]: MFCL K2 1.4; K3 2.6; K4 3.2	Quality of Life 40±10(0-62); Lower Limb Function 46±11(0-61); Satisfaction 46±11(0-63)	TTA (K2, SACH foot) 45±18; TTA (K2, multi-axial foot) 49±16	Not applicable
Cutoff Scores	Elderly fall risk 67% [117]; Low Mobility <50%; Moderate Mobility 50-80%; Physically Active >80% [128]	Not applicable	Not applicable	Not applicable	Not applicable

*All included outcomes have evidence of reliability and validity.

Abbreviations: ABC: Activities-Specific Balance Confidence Scale; ICF: International Classification of Functioning, Disability and Health; K(0-4): Medicare functional levels; LCI-5: Locomotor Capabilities Index-5: LLA: lower limb amputation; MFCL: Medicare Functional Classification Level; min(s): minute(s); OPUS: Orthotic Prosthetic User Survey; PEQ-MS: Prosthesis Evaluation Questionnaire-Mobility Subscale; PVD: peripheral vascular disease; SACH: solid-ankle cushioned-heel; TAPES: Trinity Amputation and Prosthesis Experience Scales; TFA: transfemoral amputation; TTA: transtibial amputation

Recommendation

18. We recommend an assessment of factors that are associated with poorer outcomes following acquired limb loss, such as smoking, comorbid injuries or illnesses, psychosocial functioning, and pain.
    (Strong for | Reviewed, Amended)

Discussion

Studies have shown that several patient-related factors, including comorbid trauma and/or illnesses, are associated with poorer outcomes following an amputation.[129,130] When determining this to be a "Strong for" recommendation, the Work Group had moderate confidence in the quality of evidence, and several other key domains also supported this to be a "Strong for" recommendation. While many of these comorbid conditions are common for individuals with acquired amputation, their potential impact on the overall health and quality of life of the individual make them essential for assessment when designing individualized rehabilitation plans. Thus, the benefits of addressing these factors greatly outweigh any potential harm. Resource use and feasibility considerations also support a "Strong for" recommendation, as the recommended assessments are feasible to perform in the clinical setting and do not require significant resources.

Further evaluations and interventions that address a patient's comorbidities improve the patient's overall health, and studies have shown that it also improves patient functional outcomes after an amputation. A retrospective cohort study including 4,250 patients demonstrated that the premorbid factors of chronic obstructive pulmonary disease (see the VA/DoD Chronic Obstructive Pulmonary Disease CPG),[11] congestive heart failure, myocardial infarction within the previous six months, renal disease on dialysis (see the VA/DoD Chronic Kidney Disease CPG),[12] a positive "do not resuscitate" status, and a generally low premorbid functional status were all associated with an increased mortality rate after amputation surgery.[129] A cross-sectional study of 368 patients also showed an association between the presence of comorbidities and functional outcomes after amputation. This study used the Trinity Amputation and Prosthetic Experience Scales (TAPES) to measure these outcomes. This includes subscales for prosthetic satisfaction, psychosocial adjustment, and activity restriction.[130] Additionally, the evidence showed an association between smoking and increased wound recurrence. In contrast, another retrospective cohort study did not find an association between comorbidities and functional outcome after amputation surgery; however, this study only included 256 patients.[131]

Vascular disease and smoking as well as overall health status can cause skin issues and impede post-operative wound healing and also lead to recurrence of wounds following surgery (see the VA/DoD Diabetes CPG).[13] This can delay the fitting of a prosthetic device and the ability of the person to function

[11] See the VA/DoD Clinical Practice Guideline for the Management of Chronic Obstructive Pulmonary Disease. Available at: https://www.healthquality.va.gov/guidelines/cd/copd/

[12] See the VA/DoD Clinical Practice Guideline for the Management of Chronic Kidney Disease in Primary Care. Available at: https://www.healthquality.va.gov/guidelines/CD/CKD/

[13] See the VA/DoD Clinical Practice Guideline for the Management of Diabetes Mellitus in Primary Care. Available at: http://www.healthquality.va.gov/guidelines/CD/diabetes/

with that device. It can also affect the patient's gait and pain levels. All of this leads to a decreased functional status and decreased patient satisfaction.

Obesity is another problem that should be closely monitored as it significantly contributes to many of the comorbid conditions already mentioned. Fluctuations in a patient's weight can also affect the proper fitting of the patient's prosthetic socket and produce problems with the residual limb (see the VA/DoD Management of Overweight and Obesity CPG).[14]

Although the evidence review did not identify publications related to perioperative assessments, clinicians should consider conducting a thorough medical assessment pre-operatively to evaluate the patient's physical condition, nutrition, infection risk, neuropsychiatric impairment (see the VA/DoD Major Depressive Disorder CPG and the VA/DoD Posttraumatic Stress Disorder CPG),[15,16] drug or alcohol use (see the VA/DoD Substance Use Disorder CPG),[17] and bowel and bladder function, as well as a review of systems (cardiovascular, respiratory, endocrine, skin, neurological, and musculoskeletal). Chronic low back pain is an issue that is often experienced after LLA, and should be monitored (see the VA/DoD Low Back Pain CPG).[18] General supportive counseling (e.g., eliciting and validating the patient's anxieties, fears, and concerns) may also be helpful.

VIII. Knowledge Gaps and Recommended Research

There are a number of areas which require focused research, from stronger evidence to support current recommendations to initial evidence to mature specificity of rehabilitation programs. In summary, the Work Group recommends research on rehabilitation dosing and timing; association of rehabilitation strategies with healthcare costs; and prescription parameters for technology, equipment, driver's training, home evaluation, home exercise program, and community integration by subgroups, including age, etiology, gender, or other defining population characteristics.

A. Training programs

To further guide training programs for rehabilitation of LLA, well-designed, clinically relevant studies examining balance interventions, outcomes, dosing, and treatment schedules are needed. More research is also needed to understand the effect of high-intensity training programs on comorbidities such as low back pain.

[14] See the VA/DoD Clinical Practice Guideline for the Management of Obesity and Overweight. Available at: https://www.healthquality.va.gov/guidelines/cd/obesity/

[15] See the VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder. Available at: https://www.healthquality.va.gov/guidelines/MH/mdd/

[16] See the VA/DoD Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Reaction. Available at: https://www.healthquality.va.gov/guidelines/MH/ptsd/

[17] See the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorder. Available at: http://www.healthquality.va.gov/guidelines/mh/sud/

[18] See the VA/DoD Clinical Practice Guideline for the Diagnosis and Treatment of Low Back Pain. Available at: http://www.healthquality.va.gov/guidelines/Pain/lbp/

B. Rehabilitation dosing

Further research is needed on high-dose versus low-dose rehabilitation, as well as dose timing. This should also examine subgroup considerations (e.g., age, etiology, gender, other population characteristics).

C. Patient factors and considerations

When setting goals and expectations, considerations between differences in age, etiology, gender, and comorbidities should be included, as they may influence the level of achievable outcomes for the patient. More research is needed to determine the influence of these factors, and other potential confounders. Clarity is needed between functional benefits for or against joint disarticulations relative to a more proximal level of limb loss (e.g., ankle disarticulation versus transtibial limb loss). Evidence is needed to better inform patients about amputation levels and the effect of level on key outcome variables. In addition, many areas of clinical decision making use patient decision aids to enhance SDM, and development of a tool for individuals with LLA may be useful.

D. Cognitive assessment

Continual reassessment of function and goals will reduce risk of setting a plan of care that will not allow the patient to reach their full functional potential. Future research is needed to specifically identify which cognitive tests provide predictive value while being practical for use in the clinic.

E. Perioperative LLA interventions

The research currently available to support perioperative rehabilitation interventions following amputation is limited. More research is needed to explore the pre-operative interventions and their effect on functional outcomes following LLA.

F. Prosthetic interventions

Access to early weight-bearing prostheses has expanded through the introduction of several different prefabricated systems that are commercially available. More research is required to further delineate the risks and benefits associated with this intervention as well as to further determine the differences between articulated and non-articulated devices.

There are inconclusive studies regarding differences in socket design, prosthetic foot categories as well as advantages and disadvantages of various types of suspensions and interfaces. A research goal should be to optimize mobility and function through the most effective combination of wheeled and artificial limb technologies.

Appendix A: Evidence Review Methodology

A. Developing the Scope and Key Questions

The CPG Champions, along with the Work Group, were tasked with identifying KQs to guide the evidence review of the literature on LLA. These questions, which were developed in consultation with the Lewin team, addressed clinical topics of the highest priority for the VA and DoD populations. The KQs follow the population, intervention, comparison, outcome, timing and setting (PICOTS) framework for evidence questions, as established by the Agency for Healthcare Research and Quality (AHRQ). Table A-1 provides a brief overview of the PICOTS typology.

Table A-1. PICOTS [132]

P	Patients, Population, or Problem	A description of the patients of interest. It includes the condition(s), populations or sub-populations, disease severity or stage, co-occurring conditions, and other patient characteristics or demographics.
I	Intervention or Exposure	Refers to the specific treatments or approaches used with the patient or population. It includes doses, frequency, methods of administering treatments, etc.
C	Comparison	Describes the interventions or care that is being compared with the intervention(s) of interest described above. It includes alternatives such as placebo, drugs, surgery, lifestyle changes, standard of care, etc.
O	Outcome	Describes the specific results of interest. Outcomes can include short, intermediate, and long-term outcomes, or specific results such as quality of life, complications, mortality, morbidity, etc.
(T)	Timing, if applicable	Describes the duration of time that is of interest for the particular patient intervention and outcome, benefit, or harm to occur (or not occur).
(S)	Setting, if applicable	Describes the setting or context of interest. Setting can be a location (such as primary, specialty, or inpatient care).

The Champions, Work Group, and evidence review team carried out several iterations of this process, each time narrowing the scope of the CPG and the literature review by prioritizing the topics of interest. Due to resource constraints, all developed KQs were not able to be included in the systematic evidence review. Thus, the Champions and Work Group determined which questions were of highest priority, and those were included in the review. Table A-4 contains the final set of KQs used to guide the systematic evidence review for this CPG.

a. Population(s)

Adults 18 years or older with lower extremity amputation treated in any VA/DoD clinical setting were covered in this evidence review.

b. Interventions

Table A-2 below lists the interventions that were covered in this evidence review. The interventions are listed according to the KQs they address.

Table A-2. Key Question Specific Interventions

Question	Interventions
1	Prosthetic interventions ■ Socket/interface (stump socket, below knee socket, above knee socket, through knee socket, hydrostatic design [HSD socket], patella tendon bearing design, patella tendon bearing socket, patellar tendon bearing [PTB] socket, total surface bearing [TSB] socket, ischial containment [IC] socket, ischial ramus containment [IRC] socket, knee disarticulation socket, hip disarticulation socket, vacuum-assisted socket system [VASS], total contact socket) ■ Suspension system (elevated vacuum, vacuum assisted suspension, anatomic fit, osseointegration, suspension sleeve, supracondylar, corset, pin suspension, locking mechanism, lanyard, thigh cuff, belt) ■ Knee (microprocessor, non-microprocessor, hydromechanical, polycentric, single axis, Mauch SNS, swing and stance, weight activated stance breaking, weight activated stance break (WASB), manual locking knee, C-Leg, Power Knee, hydracadence, Rheo knee) ■ Foot, ankle prosthetic components (energy storing and release [ES, ESR, ESAR], energy storing, dynamic response, solid ankle cushioned heel [SACH], flexible keel, flex foot, PROPRIO foot, Biom foot, single axis foot, multi-axial foot, running foot, cheetah) ■ Socket/ interface (stump socket, below knee socket, above knee socket, through knee socket, hydrostatic design, HSD socket, patella tendon bearing design, patella tendon bearing socket, PTB socket, TSB socket, ischial containment socket, IC socket, IRC socket, knee disarticulation socket, hip disarticulation socket, VASS, total contact socket)
2	Pre-operative rehabilitation interventions, including: ■ patient education, ■ core and hip strengthening, ■ equipment ordering; Interventions or combination of interventions in the immediate post-operative period, including: ■ dressing (soft dressing, rigid dressing, rigid dressing with weight bearing, removable dressing), ■ mental health screening/care, ■ strengthening, ■ flexibility training, ■ peer support, ■ protection of contralateral limb, ■ skin care, ■ pain management, ■ edema control, ■ fall prevention, ■ contracture prevention
3	Exposure ■ demographic factors (such as age, sex, race, education, marital status, social support), ■ comorbidities (such as diabetes, impaired cognition, posttraumatic stress disorder [PTSD], neurological complications), ■ characteristic of the amputation (such as traumatic vs. vascular, amputation level, local healing), ■ pre-amputation functional status/mobility (K-level), ■ pain level
4	Different approaches to gait and mobility training (treadmill, over ground, manual) including different timing of intervention

Question	Interventions
5	Tests being evaluated to predict outcomes ■ 6-minute walk test, ■ step activity monitoring, ■ amputee mobility predictor, ■ cut points, ■ timed up and go [TUG], ■ threshold values, ■ normative values, ■ minimal change, ■ psychometric
6	Exposure ■ Age group, ■ post-amputation period, ■ gender, ■ etiology, ■ pre-operative walking ability, ■ employment status ■ pre-operative morbidity, ■ obesity, ■ smoking history, ■ exposure to peer visitation
7	Surgical interventions ■ bone bridging, ■ targeted muscle reinnervation, ■ myodesis, ■ osseointegration ■ any others
8	Different levels of amputation and different lengths within the level
9	One tapering strategy or schedule
10	Issues unique to female gender, populations with varying gender identification

c. Comparators

Table A-3 below lists the comparators of interest to this evidence review. The comparators are listed by the KQ they address.

Table A-3. Key Question Specific Comparators

Question	Comparators
1	Different types of prosthetic components compared to other types of components
2	Different rehabilitation interventions compared with each other, no pre-operative rehabilitation, no rehabilitation
3	Patients lacking factors associated with better outcomes
4	Other approaches, different approaches compared to each other
5	Each test compared to another test
6	Subgroups with differences in exposures of interest (e.g., older versus younger patients, smokers versus non-smokers, etc.)
7	Standard surgical intervention or different advanced surgical intervention
8	Comparisons between different levels, between lengths within a level
9	Other approaches to prevent amputation in the contralateral non-amputation limb
10	Male gender

d. Outcomes

For all KQs, the following outcomes were of interest in the evidence review:

- changes in functional status
- walking ability
- quality of life
- patient satisfaction
- strength
- pain
- morbidity
- safety (falls)
- complications

For KQ 9, the following outcomes were of interest in the evidence review:

- amputation
- gangrene
- ischemia
- infection of the contralateral limb

e. Timing

The timing considered in the evidence review was pre-operative or post-operative periods as specified in each key question. There was no minimum follow-up.

f. Setting

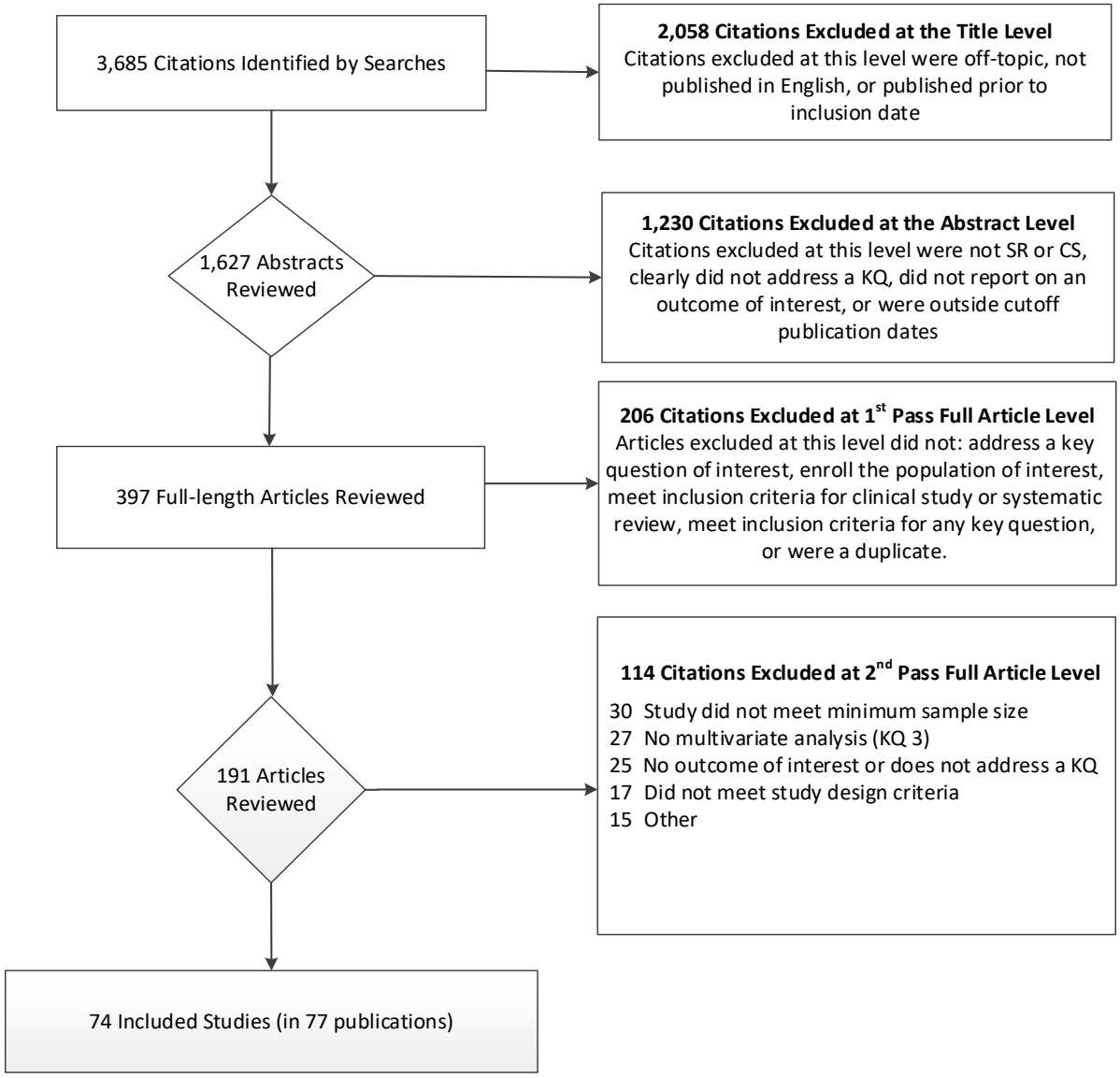
Any setting was of interest in the evidence review.

B. Conducting the Systematic Review

Extensive literature searches identified 3,685 citations published from January 2007 through July 2016 potentially addressing the KQs of interest to this evidence review. Of those, 2,058 were excluded upon title review for clearly not meeting inclusion criteria (e.g., not pertinent to the topic, not published in English, published prior to study inclusion publication date, or not a full-length article). Overall, 1,627 abstracts were reviewed with 1,230 of those being excluded for the following reasons: not an SR or clinical study, did not address a KQ of interest to this review, did not enroll a population of interest, or published prior to January 2007. A total of 397 full-length articles were reviewed. Of those, 206 were excluded at a first pass review for the following: not addressing a KQ of interest, not enrolling the population of interest, not meeting inclusion criteria for clinical study or SR, not meeting inclusion criteria for any KQ, or being a duplicate. A total of 191 full-length articles were thought to address one or more KQs and were further reviewed. Of these, 114 were ultimately excluded. Reasons for their exclusion are presented in **Figure A-1** below.

Overall, 74 studies (in 77 publications) addressed one or more of the KQs and were considered as evidence in this review. **Table A-4** indicates the number of studies that addressed each of the KQs.

Figure A-1. Study Flow Diagram



Abbreviations: CS: comparative study; KQ: key question; SR: systematic review

Table A-4. Evidence Base for Key Questions

Question Number	Question	Number of Studies and Type of Studies
1	In patients with lower extremity amputations, which prosthetic (socket/ interface, suspension system, knee, foot, ankle) optimizes patient function, safety, and quality of life for the following? a. Hip disarticulation; b. Knee disarticulation; c. Ankle disarticulation; d. Transtibial amputation; e. Transfemoral amputation; f. Partial foot amputation	5 SRs, 2 RCTs, and 4 randomized crossover trials
2	In patients with scheduled or post lower limb amputation, what is the effectiveness of rehabilitation interventions to improve outcomes?	2 SRs, 7 RCTs
3	For patients being considered for prosthesis, what factors (demographic, clinical, biologic, environment, socioeconomic) are associated with better outcomes?	4 SRs, 1 RCT, 7 cohort studies, 5 cross-sectional studies
4	In patients with lower limb amputation, what are the most effective gait training and mobility training interventions and timing?	1 SR, 2 RCTs
5	What are the most sensitive, reliable and validated outcome measures when assessing the outcomes of individuals with lower limb amputation?	1 randomized crossover study and 12 observational studies (in 16 publications)
6	In patients with lower limb amputation, do the optimal approaches to rehabilitation differ by patient subgroup/risk category (e.g., different age groups, gender, etiology, different post-amputation periods, premorbid conditions and other risk factors such as obesity, smoking history, and exposure to peer visitation)?	No studies identified
7	In patients with lower limb amputation, what are the benefits, risks, and outcomes associated with surgical interventions such as bone bridging, targeted muscle reinnervation, myodesis, or osseointegration?	1 SR, 6 retrospective cohort studies
8	In patients scheduled for lower limb amputation, what are the benefits, risks, and outcomes associated with the level of amputation and length within the level such as partial foot amputation compared to amputation at or below knee level?	2 SRs, 10 cohort studies, 1 cross-sectional study
9	In patients with lower limb amputation, what is the comparative effectiveness of various approaches to prevent amputation of the second limb or further amputation/progression of the first limb?	1 retrospective cohort study
10	What are the unique issues that need to be addressed specifically for female, transgender, and other gender identification living with limb loss? What gender/sex health related issues influence the rehabilitation process?	2 cohort studies, 1 cross-sectional survey
Total Evidence Base		**74 studies (in 77 publications)**

Abbreviations: RCT: randomized controlled trial; SR: systematic review

a. Criteria for Study Inclusion/Exclusion

i. General Criteria

- Clinical studies or SRs published on or after January 1, 2007 through July 31, 2016. If multiple SRs addressed a key question, the most recent and/or comprehensive review was selected. SRs were supplemented with clinical studies published subsequent to the SR.
- Studies must have been published in English.

- Publication must have been a full clinical study or SR; abstracts alone were not included. Similarly, letters, editorials, and other publications that were not full-length clinical studies were not accepted as evidence.
- Study must have enrolled at least 20 patients (10 per study group) unless otherwise noted (see Key Question Specific Criteria below).
- Study must have reported on an outcome of interest.
- Study must have enrolled a patient population in which at least 80% of patients had lower limb (rather than upper limb) amputation and were age 18 years or older. If the percentage was less than 80%, then data must have been reported separately for this patient subgroup.

ii. Key Question Specific Criteria

- For KQs 1, 2, and 4, acceptable study designs included SRs and individual RCTs not evaluated in SRs. If no relevant studies with these designs were found for a given KQ or sub-question, prospective nonrandomized comparative studies were evaluated for inclusion.
- For KQ 3, acceptable study designs included SRs or RCTs that statistically compared outcomes for patients with LLA and various risk factors to outcomes in patients without these risk factors. Observational studies were acceptable if they performed multivariate statistical analyses of the effect of co-occurring conditions on patient outcomes; the minimum patient enrollments were 100 for prospective studies and 200 for retrospective studies.
- For KQ 5, acceptable study designs included SRs, RCTs, or prospective cohort studies that compare the accuracy of different measures of function levels and their ability to predict prosthetic and rehabilitation outcomes
- For KQ 6, acceptable study designs included SRs, RCTs, or observational comparative studies that compare different rehabilitation strategies and assessed differential treatment effects in various subgroups of patients.
- For KQ 7, 8, and 9, acceptable study designs included SRs, RCTs, or any prospective or retrospective comparative study that addressed the question.
- For KQ 10, any study that identified issues unique to females or individuals with varying gender identification compared to males were included.

b. Literature Search Strategy

Information regarding the bibliographic databases, date limits, and platform/provider can be found in **Table A-5**, below. Additional information on the search strategies, including topic-specific search terms and search strategies can be found in Appendix F.

Table A-5. Bibliographic Database Information

Name	Date Limits	Platform/Provider
Bibliographic Databases		
The Cochrane Database of Systematic Reviews (Cochrane Reviews)	2007 to June 13, 2016	Wiley
CINAHL	2007 to July 6, 2016	Wiley
EMBASE (Excerpta Medica)	2007 to July 6, 2016	Elsevier
Health Technology Assessment Database (HTA)	2007 to June 13, 2016	Wiley
MEDLINE/PreMEDLINE	2007 to July 6, 2016	Elsevier
PsycINFO	2007 to July 6, 2016	OVIDSP
PubMed (In-process and Publisher records)	2007 to July 6, 2016	NLM
Gray Literature Resources		
AHRQ	2007 to July 7, 2016	AHRQ

C. Convening the Face-to-face Meeting

In consultation with the contracting officer's representative, the Champions, and the Work Group, the Lewin Team convened a three and a half day face-to-face meeting of the CPG Champions and Work Group members on September 20-23, 2016. These experts were gathered to develop and draft the clinical recommendations for an update to the 2007 LLA CPG. Lewin presented findings from the evidence review of KQs 1-10 in order to facilitate and inform the process.

Under the direction of the Champions, the Work Group members were charged with interpreting the results of the evidence review, and asked to categorize and carry forward recommendations from the 2007 LLA CPG, modifying the recommendations as necessary. The members also developed new clinical practice recommendations not presented in the 2007 LLA CPG, based on the 2016 evidence review. The subject matter experts were divided into two smaller subgroups at this meeting.

As the Work Group members drafted clinical practice recommendations, they also assigned a grade for each recommendation based on a modified GRADE and USPSTF methodology. Each recommendation was graded by assessing the quality of the overall evidence base, the associated benefits and harms, the variation in values and preferences, and other implications of the recommendation.

In addition to developing recommendations during the face-to-face meeting, the Work Group members also revised the 2007 LLA CPG algorithms to reflect the new and amended recommendations. They discussed the available evidence as well as changes in clinical practice since 2007, as necessary, to update the algorithms.

D. Grading Recommendations

This CPG uses the GRADE methodology to assess the quality of the evidence base and assign a grade for the strength for each recommendation. The GRADE system uses the following four domains to assess the strength of each recommendation:[23]

- Balance of desirable and undesirable outcomes
- Confidence in the quality of the evidence
- Values and preferences
- Other implications, as appropriate, e.g.,:
    - Resource use
    - Equity
    - Acceptability
    - Feasibility
    - Subgroup considerations

The following sections further describe each domain.

Balance of desirable and undesirable outcomes refers to the size of anticipated benefits (e.g., increased longevity, reduction in morbid event, resolution of symptoms, improved quality of life, decreased resource use) and harms (e.g., decreased longevity, immediate serious complications, adverse event, impaired quality of life, increased resource use, inconvenience/hassle) relative to each other. This domain is based on the understanding that the majority of clinicians will offer patients therapeutic or preventive measures as long as the advantages of the intervention exceed the risks and adverse effects. The certainty or uncertainty of the clinician about the risk-benefit balance will greatly influence the strength of the recommendation.

Some of the discussion questions that fall under this domain include:

- Given the best estimate of typical values and preferences, are you confident that the benefits outweigh the harms and burden or vice versa?
- Are the desirable anticipated effects large?
- Are the undesirable anticipated effects small?
- Are the desirable effects large relative to undesirable effects?

Confidence in the quality of the evidence reflects the quality of the evidence base and the certainty in that evidence. This second domain reflects the methodological quality of the studies for each outcome variable. In general, the strength of recommendation follows the level of evidence, but not always, as other domains may increase or decrease the strength. The evidence review used for the development of recommendations for LLA, conducted by ECRI, assessed the confidence in the quality of the evidence base and assigned a rate of “High,” “Moderate,” “Low,” or “Very Low.”

The elements that go into the confidence in the quality of the evidence include:

- Is there high or moderate quality evidence that answers this question?
- What is the overall certainty of this evidence?

Values and preferences is an overarching term that includes patients' perspectives, beliefs, expectations, and goals for health and life. More precisely, it refers to the processes that individuals use in considering the potential benefits, harms, costs, limitations, and inconvenience of the therapeutic or preventive measures in relation to one another. For some, the term "values" has the closest connotation to these processes. For others, the connotation of "preferences" best captures the notion of choice. In general, values and preferences increase the strength of the recommendation when there is high concordance and decrease it when there is great variability. In a situation in which the balance of benefits and risks are uncertain, eliciting the values and preferences of patients and empowering them and their surrogates to make decisions consistent with their goals of care becomes even more important. A recommendation can be described as having "similar values," "some variation," or "large variation" in typical values and preferences between patients and the larger populations of interest.

Some of the discussion questions that fall under the purview of values and preferences include:

- Are you confident about the typical values and preferences and are they similar across the target population?
- What are the patient's values and preferences?
- Are the assumed or identified relative values similar across the target population?

Other implications consider the practicality of the recommendation, including resources use, equity, acceptability, feasibility and subgroup considerations. Resource use is related to the uncertainty around the cost-effectiveness of a therapeutic or preventive measure. For example statin use in the frail elderly and others with multiple co-occurring conditions may not be effective and depending on the societal benchmark for willingness to pay, may not be a good use of resources. Equity, acceptability, feasibility, and subgroup considerations require similar judgments around the practically of the recommendation.

The framework below (**Table A-6**) was used by the Work Group to guide discussions on each domain.

Table A-6. Evidence to Recommendation Framework

Decision Domain	Judgment
Balance of desirable and undesirable outcomes	
▪ Given the best estimate of typical values and preferences, are you confident that the benefits outweigh the harms and burden or vice versa? ▪ Are the desirable anticipated effects large? ▪ Are the undesirable anticipated effects small? ▪ Are the desirable effects large relative to undesirable effects?	Benefits outweigh harms/burden Benefits slightly outweigh harms/burden Benefits and harms/burden are balanced Harms/burden slightly outweigh benefits Harms/burden outweigh benefits
Confidence in the quality of the evidence	
▪ Is there high or moderate quality evidence that answers this question? ▪ What is the overall certainty of this evidence?	High Moderate Low Very low
Values and preferences	
▪ Are you confident about the typical values and preferences and are they similar across the target population? ▪ What are the patient's values and preferences? ▪ Are the assumed or identified relative values similar across the target population?	Similar values Some variation Large variation
Other implications (e.g., resource use, equity, acceptability, feasibility, subgroup considerations)	
▪ Are the resources worth the expected net benefit from the recommendation? ▪ What are the costs per resource unit? ▪ Is this intervention generally available? ▪ Is this intervention and its effects worth withdrawing or not allocating resources from other interventions? ▪ Is there lots of variability in resource requirements across settings?	Various considerations

The strength of a recommendation is defined as the extent to which one can be confident that the desirable effects of an intervention outweigh its undesirable effects and is based on the framework above, which combines the four domains.[23] GRADE methodology does not allow for recommendations to be made based on expert opinion alone. While strong recommendations are usually based on high or moderate confidence in the estimates of effect (quality of the evidence) there may be instances where strong recommendations are warranted even when the quality of evidence is low.[133] In these types of instances where the balance of desirable and undesirable outcomes and values and preferences played large roles in determining the strength of a recommendation, this is explained in the discussion section for the recommendation.

The GRADE of a recommendation is based on the following elements:

- Four decision domains used to determine the strength and direction (described above)
- Relative strength (Strong or Weak)
- Direction (For or Against)

The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.

Using these elements, the grade of each recommendation is presented as part of a continuum:

- Strong For (or "We recommend offering this option …")
- Weak For (or "We suggest offering this option …")
- Weak Against (or "We suggest not offering this option …")
- Strong Against (or "We recommend against offering this option …")

Note that weak (For or Against) recommendations may also be termed "Conditional," "Discretionary," or "Qualified." Recommendations may be conditional based upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented. Recommendations may be at the discretion of the patient and clinician or they may be qualified with an explanation about the issues that would lead decisions to vary.

E. Recommendation Categorization

a. Recommendation Categories and Definitions

For use in the 2017 LLA CPG, a set of recommendation categories was adapted from those used by the United Kingdom National Institute for Health and Clinical Excellence.[26,27] These categories, along with their corresponding definitions, were used to account for the various ways in which recommendations could have been updated from the 2007 LLA CPG. The categories and definitions can be found in **Table A-7**.

Table A-7. Recommendation Categories and Definitions

Evidence Reviewed*	Recommendation Category*	Definition*
Reviewed	New-added	New recommendation following review of the evidence
	New-replaced	Recommendation from previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence
	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed but the recommendation is not changed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed based on review of the evidence
Not reviewed	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG, but for which the evidence has not been reviewed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has not been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed because it was deemed out of scope for the updated CPG

*Adapted from the NICE guideline manual (2012) [26] and Garcia, et al. (2014) [27]
Abbreviation: CPG: clinical practice guideline

b. Categorizing Recommendations with an Updated Review of the Evidence

Recommendations were first categorized by whether or not they were based on an updated review of the evidence. If evidence had been reviewed, recommendations were categorized as "New-added," "New-replaced," "Not changed," "Amended," or "Deleted."

"Reviewed, New-added" recommendations were original, new recommendations that were not in the 2007 LLA CPG. "Reviewed, New-replaced" recommendations were in the previous version of the guideline, but were modified to align with the updated review of the evidence. These recommendations could have also included clinically significant changes to the previous version. Recommendations categorized as "Reviewed, Not changed" were carried forward from the previous version of the CPG unchanged.

To maintain consistency between 2007 recommendations, which were developed using the USPSTF methodology, and 2017 recommendations, which were developed using the GRADE methodology, it was necessary to modify the 2007 recommendations to include verbiage to signify the strength of the recommendation (e.g., "We recommend," "We suggest"). Because the 2007 recommendations inherently needed to be modified at least slightly to include this language, the "Not changed" category was not used. For recommendations carried forward to the updated CPG with review of the evidence and slightly modified wording, the "Reviewed, Amended" recommendation category was used. This allowed for the wording of the recommendation to reflect GRADE methodology as well as for any other non-substantive (i.e., not clinically meaningful) language changes deemed necessary. The evidence used to support these recommendations was carried forward from the previous version of the CPG and/or was identified in the evidence review for the update.

Recommendations could have also been designated "Reviewed, Deleted." These were recommendations from the previous version of the CPG that were not brought forward to the updated guideline after review of the evidence. This occurred if the evidence supporting the recommendations was out of date, to the extent that there was no longer any basis to recommend a particular course of care and/or new evidence suggests a shift in care, rendering recommendations in the previous version of the guideline obsolete.

c. Categorizing Recommendations without an Updated Review of the Evidence

There were also cases in which it was necessary to carry forward recommendations from the previous version of the CPG without an SR of the evidence. Due to time and budget constraints, the update of the LLA CPG could not review all available evidence on rehabilitation of LLA, but instead focused its KQs on areas of new or updated scientific research or areas that were not previously covered in the CPG.

For areas of research that have not changed, and for which recommendations made in the previous version of the guideline were still relevant, recommendations could have been carried forward to the updated guideline without an updated SR of the evidence. The support for these recommendations in the updated CPG was thus also carried forward from the previous version of the CPG. These recommendations were categorized as "Not reviewed." If evidence had not been reviewed, recommendations could have been categorized as "Not changed," Amended," or "Deleted."

"Not reviewed, Not changed" recommendations refer to recommendations from the previous version of the LLA CPG that were carried forward unchanged to the updated version. The category of "Not reviewed, Amended" was used to designate recommendations which were modified from the 2007 CPG with the updated GRADE language, as explained above.

Recommendations could also have been categorized as "Not reviewed, Deleted" if they were determined to be out of scope. A recommendation was out of scope if it pertained to a topic (e.g., population, care setting, treatment, condition) outside of the scope for the updated CPG as defined by the Work Group.

The categories for the recommendations included in the 2017 version of the guideline are noted in the Recommendations. Recommendations 1, 2, 3, 6, 7, 8, 10, and 19 were carried forward from the 2007 LLA CPG using this method. The categories for the recommendations from the 2007 LLA CPG are noted in Appendix C.

F. Drafting and Submitting the Final Clinical Practice Guideline

Following the face-to-face meeting, the Champions and Work Group members were given writing assignments to craft discussion sections to support each of the new recommendations and/or to update discussion sections from the 2007 LLA CPG to support the amended "carried forward" recommendations. The Work Group also considered tables, appendices, and other sections from the 2007 LLA CPG for inclusion in the update. During this time, the Champions and Work Group also made additional revisions to the algorithms, as necessary.

After developing the initial draft of the updated CPG, an iterative review process was used to solicit feedback on and make revisions to the CPG. Once they were developed, the first two drafts of the CPG were posted on a wiki website for a period of 14-20 business days for internal review and comment by the

Work Group. All feedback submitted during each review period was reviewed and discussed by the Work Group and appropriate revisions were made to the CPG.

Draft 3 of the CPG was made available for peer review and comment. This process is described in Peer Review Process. After revisions were made based on the feedback received during the peer review and comment period, the Champions presented the CPG to the EBPWG for their approval. Changes were made based on feedback from the EBPWG and the guideline was finalized.

The Work Group also produced a set of guideline toolkit materials which included a provider summary, pocket card, and a patient summary. The final 2017 LLA CPG was submitted to the EBPWG in September, 2017.

Appendix B: Evidence Table

Recommendation	2007 Grade[1]	Evidence[2]	Strength of Recommendation[3]	Recommendation Category[4]
1. We suggest that patient education be provided by the rehabilitation care team throughout all phases of amputation rehabilitation.	B C None	[21,22,35,36] **Additional References:** [37-39]	Weak for	Reviewed, Amended
2. We suggest an assessment of behavioral health and psychosocial functioning at every phase of amputation management and rehabilitation.	B None None None None	[40-45]	Weak for	Reviewed, Amended
3. When assessing pain, we suggest that measurement of the intensity of pain and interference with function should be separately assessed for each pain type and location using standardized tools.	Expert opinion B None None	[46] **Additional References:** [47-49]	Weak for	Reviewed, Amended

[1] The 2007 VA/DoD LLA CPG used the USPSTF evidence grading system (http://www.uspreventiveservicestaskforce.org). Inclusion of more than one 2007 Grade indicates that more than one 2007 CPG recommendation is covered under the 2016 recommendation. The strength of recommendations were rated as follows: A- a strong recommendation that the clinicians provide the intervention to eligible patients; B- a recommendation that clinicians provide (the service) to eligible patients; C- no recommendation for or against the routine provision of the intervention is made; D- recommendation is made against routinely providing the intervention; I- the conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention; Expert Opinion- the recommendation was developed using expert consensus regarding clinical standard of care, but was not based on a review of the available evidence. None- indicates that the 2017 LLA CPG recommendation replaced or amended a 2007 LLA CPG recommendation for which there was no grade. Not applicable- indicates that the 2017 LLA CPG recommendation was a new recommendation, and therefore does not have an associated 2007 grade.

[2] The evidence column indicates studies that support each recommendation. For new recommendations, developed by the 2016 guideline Work Group, the literature cited corresponds directly to the 2016 evidence review. For recommendations that have been carried over from the 2007 VA/DoD LLA CPG, slight modifications were made to the language in order to better reflect the current evidence and/or the change in grading system used for assigning the strength of each recommendation (USPSTF to GRADE). For these "modified" recommendations, the evidence column indicates "additional evidence," which can refer to either 1) studies that support the recommendation and which were identified through the 2016 evidence review, or 2) relevant studies that support the recommendation, but which were not systematically identified through a literature review.

[3] Refer to the Grading Recommendations section for more information on how the strength of the recommendation was determined using GRADE methodology.

[4] Refer to the Recommendation Categorization section for more information on the description of the categorization process and the definition of each category.

Recommendation	2007 Grade[1]	Evidence[2]	Strength of Recommendation[3]	Recommendation Category[4]
4. We suggest offering a multi-modal, transdisciplinary individualized approach to pain management including transition to a non-narcotic pharmacological regimen combined with physical, psychological, and mechanical modalities throughout the rehabilitation process (For the treatment of chronic pain, the 2017 VA/DoD CPG for the Management of Opioid Therapy for Chronic Pain recommends alternatives to opioid therapy such as self-management strategies, other non-pharmacological treatments, and non-opioids over opioids [see the 2017 VA/DoD OT CPG[1]]).	I B I Expert Opinion C I	[50,52,53] **Additional Reference:** [51]	Weak for	Reviewed, New-replaced
5. We recommend providers consider the patient's birth sex and self-identified gender identity in developing individualized treatment plans.	Not applicable	[54-57] **Additional Reference:** [11]	Strong for	Reviewed, New-added
6. We suggest offering peer support interventions, including visitation by a certified peer visitor, as early as feasible and throughout the rehabilitation process.	C I	[58] **Additional References:** [38,59]	Weak for	Reviewed, Amended
7. Prior to surgery, we suggest that rehabilitation goals, outcomes, and other implications be included in shared decision making about residual limb length and amputation level.	None None	[60-64]	Weak for	Reviewed, Amended
8. There is insufficient evidence to recommend one surgical amputation procedure over another.	Not applicable	[65-70]	Not applicable	Reviewed, New-added
9. We suggest the use of a rigid or semi-rigid dressing to promote healing and early prosthetic use as soon as feasible post-amputation in transtibial amputation. Rigid post-operative dressings are preferred in situations where limb protection is a priority.	None B B None None None	[71-74]	Weak for	Reviewed, Amended

[1] See the VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain. Available at: http://www.healthquality.va.gov/guidelines/Pain/cot/

Recommendation	2007 Grade[1]	Evidence[2]	Strength of Recommendation[3]	Recommendation Category[4]
10. We suggest performing cognitive screening prior to establishing rehabilitation goals, to assess the patient's ability and suitability for appropriate prosthetic technology.	None None None None	[75]	Weak for	Reviewed, New-replaced
11. We suggest that in the perioperative phase following amputation, patients receive physical rehabilitation and appropriate durable medical equipment/assistive technology.	None None None None None None	[76-78]	Weak for	Reviewed, New-replaced
12. We suggest, when applicable, treatment in an acute inpatient rehabilitation program over a skilled nursing facility.	None None None	[79-81]	Weak for	Reviewed, New-replaced
13. We suggest the initiation of mobility training as soon as feasible post-amputation. In appropriate patients, this may include ipsilateral side weight-bearing ambulation with a pylon to improve physical function and gait parameters.	None	[77,82,83]	Weak for	Reviewed, New-replaced
14. We recommend instituting rehabilitation training interventions, using both open and closed chain exercises and progressive resistance to improve gait, mobility, strength, cardiovascular fitness and activities of daily living performance in order to maximize function.	None None None None None None None None	[84-86] **Additional References:** [87-92]	Strong for	Reviewed, New-replaced
15. We suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces.	Not applicable	[72,93-96] **Additional References:** [97,98]	Weak for	Reviewed, New-added

Recommendation	2007 Grade[1]	Evidence[2]	Strength of Recommendation[3]	Recommendation Category[4]
16. We recommend the use of valid, reliable, and responsive functional outcome measures, including, but not limited to, the Comprehensive High-level Activity Mobility Predictor, Amputee Mobility Predictor, 10-meter walk test, and 6-minute walk test.	None None	[101,102] **Additional References:** [99,100,103-107]	Strong for	Reviewed, New-replaced
17. We suggest the use of a combination of measures with acceptable psychometric properties to assess functional outcomes.	None None	[72,115] **Additional References:** [95,97,98,108-110]	Weak for	Reviewed, New-replaced
18. We recommend an assessment of factors that are associated with poorer outcomes following acquired limb loss, such as smoking, comorbid injuries or illnesses, psychosocial functioning, and pain.	None None None B B B B B B B None None None None None None	[129-131]	Strong for	Reviewed, Amended

Appendix C: 2007 Recommendation Categorization Table

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	1	1	Key disciplines to be consulted during the preoperative (when possible) and postoperative phases of rehabilitation care include: physiatry, surgery, physical therapy, occupational therapy, prosthetics, social work services, case management, mental health, nursing, nutrition, and recreation therapy. In addition, the following specialties should be available on a case-by-case basis: vascular surgery, plastic surgery, internal medicine, pain management, vocational therapy, and spiritual advisors.	None	Not Reviewed, Deleted	
CORE	1	2	The patient and family members (or other caregivers) should be an integral part of the interdisciplinary rehabilitation team.	None	Not Reviewed, Deleted	
CORE	1	3	Interdisciplinary rehabilitation team meetings should be conducted on a regular basis within the institution to facilitate communication and integration of a comprehensive treatment plan.	None	Not Reviewed, Deleted	
CORE	1	4	Outpatient amputation clinics should have interdisciplinary team participation for the periodic assessment of patients to ensure appropriate life-long care in order to preserve the quality of life, achievement of maximum function, and reduction of secondary complications.	None	Not Reviewed, Deleted	
CORE	2	1	Evaluations from all key team members should be included in the development of the treatment plan.	None	Not Reviewed, Deleted	
CORE	2	2	The treatment plan must address identified rehabilitation, medical, mental health, and surgical problems.	None	Not Reviewed, Deleted	

[1] The first three columns indicate the location of each recommendation within the 2007 LLA CPG.

[2] The 2007 Recommendation Text column contains the wording of each recommendation from the 2007 LLA CPG.

[3] The 2007 VA/DoD LLA CPG used the U.S. Preventive Services Task Force (USPSTF) evidence grading system (http://www.uspreventiveservicestaskforce.org). The strength of recommendations were rated as follows: A- a strong recommendation that the clinicians provide the intervention to eligible patients; B- a recommendation that clinicians provide (the service) to eligible patients; C- no recommendation for or against the routine provision of the intervention is made; D- recommendation is made against routinely providing the intervention; I- the conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention; Expert Opinion- the recommendation was developed using expert consensus regarding clinical standard of care, but was not based on a review of the available evidence. None- indicates there was no grade assigned to the recommendation in the 2007 LLA CPG.

[4] The Recommendation Category column indicates the way in which each 2007 LLA CPG recommendation was updated.

[5] For recommendations that were carried forward to the 2007 LLA CPG, this column indicates the new recommendation(s) to which they correspond.

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	2	3	The treatment plan should identify realistic treatment goals.	None	Not Reviewed, Deleted	
CORE	2	4	The treatment plan should identify and address plans for discharge at the initiation of the rehabilitation process. The discharge treatment plan should include needs for specialized equipment, evaluation of and required modifications of the discharge environment, needs for home assistance, and an evaluation of the patient's ability to drive (see CORE-9: Social Environment).	None	Not Reviewed, Deleted	
CORE	2	5	The initial treatment plan should be established early in the rehabilitation process and updated frequently based on patient progress, emerging needs, or problems.	None	Not Reviewed, Deleted	
CORE	2	6	The treatment plan should indicate the anticipated next phase of rehabilitation care.	None	Not Reviewed, Deleted	
CORE	3	1	Pain should be assessed at all phases of rehabilitation, preferably with a tool specific to pain assessment in patients with lower limb amputations. [Expert Opinion]	Expert Opinion	Reviewed, New-replaced	Recommendation 3
CORE	3	2	When assessing pain, standardized tools should be used. Examples include; Visual Analogue Scale (VAS), Short Form McGill Pain Questionnaire (SF-MPQ), and Pain Interference Scale (PIS). [B]	B	Reviewed, Amended	Recommendation 3
CORE	3	3	When possible, a postoperative treatment plan for pain control should be developed before surgery and be based on the preoperative pain assessment and treatment initiated. [I]	I	Reviewed, New-replaced	Recommendation 4
CORE	3	4	Measurement of the intensity of pain should be separately assessed at each site (i.e., phantom limb pain [PLP], residual limb pain [RLP], low back pain [LBP]) to achieve a thorough assessment of pain-related impairment. [B]	B	Reviewed, Amended	Recommendation 4
CORE	3	5	Prophylactic pain management should be considered prior to initiation of physical rehabilitation intervention. [I]	I	Reviewed, New-replaced	Recommendation 4
CORE	3	6	Narcotic analgesics should be considered in the immediate postoperative phase. [Expert Opinion]	Expert Opinion	Reviewed, New-replaced	Recommendation 4
CORE	3	7	Transition to a non-narcotic pharmacological regimen combined with physical, psychological, and mechanical modalities should be considered throughout the rehabilitation process. Treatment should target pain related to the residual/phantom limb and address pain in other body parts from a primary care approach. [C]	C	Reviewed, New-replaced	Recommendation 4

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	3	8	There is no consistent evidence to support or refute one specific type of pain control. Available modalities include: [I] a. Pharmacological: anti-seizure medications (e.g., gabapentin), tricyclic antidepressants (TCA), selective serotonin re-uptake inhibitors (SSRI), non-steroidal anti-inflammatory drugs (NSAID), dextromethorathane, and long-acting narcotics b. Epidural analgesia, use of patient controlled analgesia (PCA), or regional analgesia may be considered, although the benefit is unproven c. Non-pharmacological: transcutaneous electrical nerve stimulation (TENS), desensitization, scar mobilization, relaxation, and biofeedback. (See the VA/DoD Clinical Practice Guideline for the Management of Acute Postoperative Pain.)	I	Reviewed, New-replaced	Recommendation 4
CORE	4	1	Medical status including laboratory studies should be assessed and monitored as indicated to screen for infection, anemia, electrolyte imbalances, nutrition, and liver and kidney diseases.	None	Not reviewed, Deleted	
CORE	4	2	The comprehensive medical care throughout the phases of rehabilitation of patient with amputation should address: a. Cardiac and pulmonary function b. Assessment and monitoring for infection using laboratory and radiographic studies c. Assessment and management of diabetes and its complications to improve outcome and reduce the risk for complication and further amputation d. Assessment and management of peripheral vascular diseases to improve outcome and prevent complications such as claudication and residual limb ischemia e. Prevention of secondary complications such as venous thrombosis, embolism, heterotopic bone formation, contracture, and decubitus ulcers is necessary f. Attention to bone health.	None	Reviewed, New-replaced	Recommendation 18
CORE	4	3	Modifiable health risk factors should be assessed and education and treatment strategies to reduce their impact on morbidity and mortality should be implemented (e.g., smoking cessation, body weight management, diabetes management, hypertension control, substance abuse).	None	Reviewed, Amended	Recommendation 18

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	4	4	In special populations, such as traumatic amputation, upper motor neuron lesions and burns, the risk of heterotopic ossification (HO) should be recognized. Appropriate intervention for prevention of HO includes radiation, nonsteroidal medications, and bisphosphonate medications.	None	Not reviewed, Deleted	
CORE	5	1	A cognitive battery of testing should include: a. Intellectual functioning and attention/concentration along with working memory and speed of processing b. Executive functioning c. Learning and memory: short- and long-term, auditory and visual, recall, and recognition d. Self (and possibly family) reported cognition and emotional functioning.	None	Reviewed, Deleted	
CORE	5	2	Testing should be conducted by appropriately trained and certified individuals.	None	Not reviewed, Deleted	
CORE	5	3	Evaluations should include standardized tests, self-reporting, behavioral descriptions and subjective estimations from family and others, careful history taking, recognition of other possible comorbid factors (e.g., depression, dementia), and acknowledgment of the limitations and sources of variability and error in measuring psychometric performance.	None	Reviewed, Deleted	
CORE	5	4	Neuropsychological referrals should be specific and guided by preliminary mental status assessment by the rehabilitation team. Neuropsychological assessments should focus on the referring question and not provide specific medical advice.	None	Reviewed, Deleted	
CORE	6	1	Limb volume management is a critical issue throughout the lifespan of the individual. a. Apply an external compressive device to optimize the limb volume (postoperative rigid dressing, ACE wrap, shrinker, liner). b. Optimize overall fluid management by controlling congestive heart failure, renal failure, or dialysis treatments. c. Encourage the patient to maintain a stable body weight. d. Encourage the patient to wear an external compressive device when the prosthesis is not worn, especially during the early postoperative and prosthetic phases. e. Discourage dependent positioning of the residual limb in a wheelchair.	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	6	2	The patient should be educated about care and management of the residual limb including: a. Proper application of external compressive devices (ACE wrap, shrinker) b. Proper donning and doffing technique for the prosthesis c. Adjustment of prosthetic sock ply for limb volume change, if appropriate d. Proper hygiene of the residual limb and prosthesis e. Daily inspection of the residual limb for signs of abnormal pressure distribution f. Training with a long handled mirror to assist in the inspection of the residual limb.	None	Reviewed, Deleted	Recommendation 9
CORE	6	3	Interventions to prevent contracture at both the hip and the knee should be considered on an ongoing basis, especially in the early postoperative period and when the patient is an intermittent or marginal ambulator. a. Rigid dressing and knee immobilizers may be considered for the patient with a transtibial amputation to prevent knee flexion contractures. A number of early postoperative dressing strategies help to maintain range of motion of the knee. b. Initiate exercise programs to strengthen the quadriceps and gluteal muscles, along with active and passive range of motion exercises. c. Initiate proper positioning and begin a prone lying program. Do not place pillows under the knee to increase comfort as it increases the chance of contractures forming. d. Encourage ambulation and weight bearing through the prosthesis.	None	Reviewed, New-replaced	Recommendations 9, 13
CORE	6	4	Bony overgrowth may become painful at any stage of its growth and cause significant pain and limitations in prosthetic fittings. a. Use preventive measures where necessary in a high-risk population (radiation, bisphosphanates, NSAIDs). b. Due to reductions in soft tissue volume, the relative prominence of bony overgrowth may increase, resulting in the need for prosthetic modifications or replacement. c. Associated pain may be treated with prosthetic modifications and/or local injections. d. Surgical excision and possible limb revision is a last resort.	None	Not reviewed, Deleted	
CORE	6	5	Limb protection should be emphasized especially during the early phases when the risk of falls is greater. a. The patient should be instructed to wear an external protective device on the residual limb. b. An external protective device may include a postoperative rigid dressing or a prefabricated rigid dressing.	None	Reviewed, New-replaced	Recommendation 9

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	6	6	Skin and soft tissue should be monitored on a regular basis to detect any mechanical skin injury related to abnormal pressure distribution or signs and symptoms of infection. a. Abnormal pressure distribution should be prevented by ensuring that the prosthesis is properly aligned and the prosthetic socket fit is adequate and it should be modified as needed. b. Superficial infection (fungal, folliculitis, cellulites), or deep infection (osteomyelitis) should be treated early and aggressively to prevent deterioration of the residual limb condition that will have serious impact on the functional mobility of the patient.	None	Reviewed, Deleted	
CORE	6	7	Patients should be advised that a stable body weight is critical to long-term success.	None	Reviewed, New-replaced	Recommendation 18
CORE	7	1	Comprehensive assessment of the contralateral limb should include: a. Evaluating for the presence and severity of a sensory deficit b. Quantifying the presence and extent of a motor deficit c. Determining the arterial perfusion status of the extremity d. Evaluating the presence of deformity e. Evaluating for signs of acute or chronic abnormal pressure loading, including tissue redness, ulceration or callosity f. Inspecting the patient's footwear, including wear pattern.	None	Not reviewed, Deleted	
CORE	7	2	The patient and/or caregiver should be educated about strategies to protect the skin integrity of the foot (see Appendix D).	None	Not reviewed, Deleted	
CORE	7	3	Appropriate foot care as indicated should provide: a. Local foot care for callosities and nail care management by a health professional, especially in the context of sensory impairment or poor vision b. Footwear that can be adapted to meet a patient's mobility needs, and that can accommodate a foot deformity and/or an orthotic device c. Orthoses to optimize the pressure distribution on the foot or to substitute for muscle weakness or spasticity.	None	Not reviewed, Deleted	
CORE	7	4	Regular follow-up to evaluate the adequacy of the footwear or orthosis should be established.	None	Not reviewed, Deleted	
CORE	7	5	Specialized foot protection devices and/or mattresses should be considered for patients that are confined to bed or spend a considerable amount of time in the recumbent position.	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	8	1	Psychosocial functioning should be assessed at each phase of amputation management and rehabilitation. Assessment should focus on current and past symptoms of psychopathology, particularly depression, anxiety, and post-traumatic stress symptoms. [B]	B	Reviewed, Amended	Recommendation 2
CORE	8	2	Interventions need to focus particularly on depressive, anxiety and post-traumatic stress disorder (PTSD) symptoms, using empirically supported medical and psychotherapeutic treatments for depression and PTSD. [B] Refer to the VA/DoD Clinical Practice Guidelines on Major Depressive Disorder in Adults and Post-Traumatic Stress Disorder for management of these common problems.	B	Reviewed, New-replaced	Recommendation 18
CORE	8	3	Effective coping goals/strategies should be developed during psychotherapeutic or counseling interventions. [B]	B	Reviewed, New-replaced	Recommendation 18
CORE	8	4	During the assessment, examples of effective and ineffective coping strategies should be discussed with the patient, such as enlisting sufficient social support versus social withdrawal and disengagement and problem solving difficulties versus helplessness and passivity. [B]	B	Reviewed, New-replaced	Recommendation 18
CORE	8	5	Specific structured interventions for problems such as depression, anxiety, sexual difficulties, substance abuse or drug overuse, and pain should be considered. [B]	B	Reviewed, New-replaced	Recommendation 18
CORE	8	6	Interventions may operate through individual, couple, family, or group therapy modalities. [B]	B	Reviewed, New-replaced	Recommendation 18
CORE	8	7	Significant others should be included in psychotherapeutic and/or psychoeducational interventions as needed. [B]	B	Reviewed, New-replaced	Recommendation 18

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	8	8	The use of validated tools for assessment should be considered; some examples may include: a. Prosthesis Evaluation Questionnaire (PEQ) for psychometric assessment is a self-report questionnaire comprising 10 sub-scales: 4 prosthetic function scales, 2 mobility scales, 3 psychosocial scales, and 1 well-being scale. b. Trinity Amputation and Prosthetic Experience Scales (TAPES) for psychosocial evaluation is also a self-report quality of life questionnaire with nine sub-scales; 3 psychosocial scales, 3 activity restriction scales, and 3 satisfaction subscales. TAPES has the advantage of being able to predict residual limb pain, phantom limb pain, and the extent of prosthetic use. c. The Hospital Anxiety and Depression Scale (HAD) is a 14-item highly sensitive brief screening for anxiety and depression, commonly used in hospital settings. d. The SF-36 Health Survey measures the degree of burden or dysfunction a medical condition has in a patient's life.	None	Reviewed, New-replaced	Recommendation 17
CORE	8	9	Psychological components to multidisciplinary approaches to chronic pain management should be included as needed. [B]	B	Reviewed, New-replaced	Recommendation 18
CORE	9	1	A baseline assessment should be obtained and continuously updated throughout the rehabilitation phases. The assessment should include information about the existing social environment and support system: *Interpersonal Social Environment* a. Family and extended family b. Community - including workplace, employers/employees and co-workers c. Spiritual, religious, and cultural support d. Peer support system (see Core-10: Peer Support Interventions) *Physical Environment* a. Home environment – hazards and need for modification to address safety and accessibility b. Workplace c. Community – geographical location, distance from resources and services, and access to resources *Economic Environment* a. Sources of income and/or financial support.	None	Reviewed, New-replaced	Recommendation 2

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	10	1	Peer visitation strategies may be considered throughout the rehabilitation cycle, particularly early when anxiety and adjustment problems may be most pronounced. [C]	C	Reviewed, Amended	Recommendation 6
CORE	10	2	Peer support interventions may be a particularly useful aspect of pre-procedural patient education interventions. [C]	C	Not reviewed, Deleted	Recommendation 6
CORE	10	3	Peer visitation volunteers should receive structured training prior to performing peer visitation services. The Amputee Coalition of America (ACA) provides a reputable training certification program. [C]	C	Reviewed, Deleted	
CORE	10	4	Patients should be referred to peer support groups or similar resources, if available. [I]	I	Reviewed, Amended	Recommendation 6
CORE	11	1	Pre-procedural educational interventions should be provided to the patient before amputation, if possible, in order to decrease his/her fear, anxiety, and distress and to improve his/her post-procedural recovery. [B]	B	Reviewed, New-replaced	Recommendation 1
CORE	11	2	All members of the rehabilitation team should be involved in patient education as part of their interaction with the patient. [C]	C	Reviewed, Amended	Recommendation 1
CORE	11	3	Pre-procedural educational interventions should generally include information and a description of the specific procedures and events the patient will experience at the various phases of treatments, and continue throughout the continuum of care. [B]	B	Reviewed, Deleted	Recommendation 1
CORE	11	4	Educational interventions should also include sensory information, that is a description of sensations and other feelings/symptoms the patient may experience at various stages during and following the procedure. [B]	B	Reviewed, Deleted	
CORE	11	5	Educational interventions may also include coping skills training; cognitive behavioral coping strategies are likely to be the most effective strategies. [B]	B	Reviewed, Deleted	
CORE	11	6	General supportive counseling (e.g., eliciting and validating the patient's anxieties, fears, and concerns) may also be helpful. Open-ended questioning, active listening techniques, eliciting anticipation of future stressors, and eliciting and encouraging utilization of the patient's social support resources are important strategies irrespective of whether information-giving or coping skills training interventions are being used. [C]	C	Reviewed, Deleted	
CORE	12	1	Prior to the learning assessment, the health professional should assess the patient with a lower limb amputation for core concerns, potential fears, support limitations, and cultural history.	None	Reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	12	2	The best time to begin a learning assessment is determined on a case-by-case basis but often begins with the initial contact with the patient who has had a lower limb amputation and their family.	None	Reviewed, Deleted	
CORE	12	3	The learning assessment should use open-ended questions to obtain the following and additional, information: a. Patient/family's ability to cope with the health status, plan of care, prognosis, and outcome b. Patient/family needs, concerns, roles, and responsibilities c. Specific learning needs (knowledge, attitudes, skills) and educational level d. Barriers to learning, including physical and/or cognitive limitations, language, emotional or psychological, and financial difficulties e. Readiness to learn f. Patient preferences regarding learning methods.	None	Reviewed, Deleted	
CORE	13.1	1	The residual limb should always be properly positioned to avoid contractures that could interfere with future prosthetic fit and ambulation. In a transtibial amputation, the residual limb should be placed in knee extension when in bed. For a transfemoral or transtibial amputation, the residual limb should be kept in neutral alignment for adduction/abduction and internal/external rotation. At no time should a pillow be placed under the residual limb.	None	Reviewed, Deleted	
CORE	13.1	2	A prone lying program should be initiated with all patients who have a lower extremity amputation to avoid hip flexion contractures. Progressively advance the length of time from the patient's tolerance to 30 minutes twice per day if possible. (See Table 2. Summary of Interventions in Rehabilitation Phases for detailed interventions by phases of care.)	None	Reviewed, Deleted	
CORE	13.2	1	A strengthening program should be initiated for the major muscle groups of the upper extremities, trunk, and the residual and contralateral limbs in order to maximize functional use of the prosthesis and prevent the development of comorbidities such as low back pain.	None	Reviewed, New-replaced	Recommendation 14
CORE	13.2	2	Both open and closed-chain exercises and isokinetic and progressive resistance exercises should be included in the strengthening program.	None	Reviewed, New-replaced	Recommendation 14
CORE	13.2	3	Specific muscle groups to strengthen include hip extensors, hip adductors, hip abductors, abdominal musculature, back musculature, knee extensors, rotator cuff, and elbow extension.	None	Reviewed, Deleted	
CORE	13.2	4	A home exercise program should be designed and tailored to a patient's individual needs for use on a long-term basis.	None	Reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	13.3	1	A tailored cardiovascular training program should be initiated as soon as possible in the postoperative phase and continue throughout the rehabilitation process.	None	Reviewed, Deleted	
CORE	13.3	2	The cardiovascular program should include upper body ergometry regardless of the ability to use a lower extremity prosthesis.	None	Reviewed, Deleted	
CORE	13.3	3	Gait training should progress from use of an appropriate assistive device and increase to community distances as cardiovascular fitness improves.	None	Reviewed, New-replaced	Recommendation 14
CORE	13.3	4	Consultation to a cardiac rehabilitation program should be considered, particularly in patients with known cardiopulmonary disease or dysvascular amputation.	None	Reviewed, Deleted	
CORE	13.3	5	Higher level sporting activities should be pursued to supplement routine cardiovascular fitness in younger individuals with traumatic amputation.	None	Reviewed, Deleted	
CORE	13.4	1	Sitting and standing balance should be assessed throughout the rehabilitation process using standardized assessment tools such as the Berg or Tinetti Balance Assessment.	None	Reviewed, New-replaced	Recommendation 17
CORE	13.4	2	Interventions should start with sitting balance and progress to sitting weight shifts, then sit to stand, supported standing, single-limb balance, and dynamic balance training.	None	Reviewed, Deleted	
CORE	13.4	3	Balance should be challenged with a variety of activities such as weight shifting on a soft surface, rocker board, ball rolling under the sound foot, and step-ups.	None	Reviewed, Deleted	
CORE	14.1	1	The self-care component of functional ADL should include dressing, feeding, grooming, bathing, and toileting, with and without a prosthesis.	None	Reviewed, Deleted	
CORE	14.1	2	The transfers component of functional ADL should include the following, with and without a prosthesis: a. sit to stand b. bed to chair c. chair to toilet d. chair to tub e. vehicle transfers f. floor transfers.	None	Reviewed, Deleted	
CORE	14.1	3	Patients should be educated in strategies to prevent falls and improve safety.	None	Reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	14.2	1	Standardized measures of mobility can assist with outcome measurement and determine additional social support and equipment needs. Consider utilizing one or more of the following measures, but note that they may not be helpful in the young active individual with traumatic amputation (see Table 8. Advantages and Disadvantages of Recommended Assessment Tools): a. Amputee Mobility Predictor (AMP) b. Functional Independence Measure (FIM) c. Two-Minute Walk Test d. Timed Up and Go Test (TUG) e. Upper Extremity Ergometry.	None	Reviewed, New-replaced	Recommendation 16
CORE	14.2	2	The training program to improve mobility should include both the physical components of strengthening and cardiovascular fitness and practicing the actual activity.	None	Reviewed, New-replaced	Recommendation 14
CORE	14.2	3	Assistive devices (e.g., combination of canes, crutches, walkers, and manual and/or powered mobility) that the patient has demonstrated to be able to use safely and which improve the ability to navigate different environments should be prescribed.	None	Reviewed, New-replaced	Recommendation 11
CORE	14.2	4	A wheelchair should be prescribed for individuals with amputations who may experience times when they can not use their prosthesis(es) and/or assistive devices for mobility.	None	Reviewed, New-replaced	Recommendation 11
CORE	14.2	5	Advanced wheelchair mobility skills should be taught to navigate such environments such as stairs, escalators, curbs, uneven terrain, and soft surfaces (grass, sand, gravel).	None	Reviewed, New-replaced	Recommendation 11
CORE	14.2	6	Vehicle modifications should be prescribed for those who can not safely drive a vehicle due to right lower limb amputation, or left lower limb amputation with comorbidities to the right lower limb, or any individual with bilateral lower extremity amputations.	None	Not reviewed, Deleted	
CORE	14.3	1	Training in the use of public transportation, with and without a prosthesis, should be provided, if appropriate.	None	Reviewed, Deleted	
CORE	14.3	2	Endurance should be increased with ambulation to community distances if appropriate.	None	Reviewed, Deleted	
CORE	14.3	3	Information on organizations with opportunities for adaptive recreational activities should be provided.	None	Not reviewed, Deleted	
CORE	14.3	4	Driver's training and vehicle modifications should be pursued, if not already done. Any patient with a right lower extremity amputation should be evaluated and trained on a left foot accelerator. A patient with bilateral lower extremities amputation should be evaluated and trained in hand controls.	None	Reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
CORE	14.3	5	The patient's home should be evaluated for accessibility and information on home modifications should be provided.	None	Not reviewed, Deleted	
CORE	14.3	6	Patient's worksite should be evaluated for the potential need for accommodations to facilitate return to the work setting.	None	Not reviewed, Deleted	
CORE	14.3	7	Patients should be provided with a list of resources for information regarding amputations, support groups, and accessibility for people with disabilities.	None	Reviewed, Deleted	
A	1	1	Amputation should only be considered if the limb is non-viable (gangrenous or grossly ischemic), dangerous (malignancy or infection), or non-functional.	None	Not reviewed, Deleted	
A	2	1	Consider urgent surgery in severe life-threatening situations including infection and trauma.	None	Not reviewed, Deleted	
A	3	1	A thorough medical assessment should be completed preoperatively to evaluate the patient's physical condition, nutrition, infection, neuropsychiatric impairment, and bowel and bladder function as well as a review of systems (cardiovascular, respiratory, endocrine, skin, neurological, and musculoskeletal).	None	Not reviewed, Deleted	
A	3	2	Condition and function of the contralateral limb should be assessed including (see CORE-7: Contralateral Limb): a. Quantify the severity of the sensory deficit b. Observe for the presence of deformity c. Observe for signs of abnormal soft tissue loading d. Limb perfusion e. Education, specialized heel protectors, or specialized mattresses should be used to assure that the patient does not develop ulceration on the remaining limb.	None	Not reviewed, Deleted	
A	3	3	Baseline function should be evaluated prior to amputation surgery (see CORE-13: Physical Rehabilitation and CORE-14: Functional Rehabilitation): a. Range of motion (ROM) b. Strength c. Exercise endurance d. Balance e. Mobility f. Activities of daily living (ADL).	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
A	3	4	Pain control measures should be initiated in the preoperative period to optimize the postoperative rehabilitation (see CORE-3: Pain Management).	None	Reviewed, New-replaced	Recommendation 3
A	3	5	A psychological assessment and preparation strategies should be completed in the preoperative phase whenever possible (see CORE-8: Behavioral Health Assessment and Treatment).	None	Reviewed, New-replaced	Recommendation 2
A	3	6	A preoperative cognitive assessment should be conducted to assist in the process of determining the patient's ability to learn, adapt to, and utilize a prosthesis following surgery as well as the ability to participate in rehabilitation and to maximize functional independence and community reintegration (see CORE-5: Cognitive Assessment).	None	Reviewed, New-replaced	Recommendation 10
A	3	7	Patient's goals and priorities should be assessed prior to amputation surgery.	None	Reviewed, New-replaced	Recommendation 10
A	3	8	Assess patient's social environment, home and community environments, and support system (see CORE-9: Social Environment).	None	Reviewed, New-replaced	Recommendation 2
A	4	1	A unified, cohesive, and comprehensive treatment plan should be developed prior to surgery that includes specific interventions for treatment by the interdisciplinary rehabilitation team members and updated throughout the full continuum of care. (see CORE 2: Rehabilitation Treatment Plan).	None	Not reviewed, Deleted	
A	5	1	When possible, every effort should be made to correct controllable factors prior to undertaking surgical amputation, including (see CORE-4: Medical Care): a. Cardiovascular b. Pulmonary c. Metabolic d. Nutrition e. Psychiatric illness f. Risk factor reduction (including cardiovascular risk and diabetes mellitus risk reduction)	None	Not reviewed, Deleted	
A	6	1	Initiate appropriate rehabilitation interventions while the patient is awaiting amputation surgery, to maintain current function and prevent secondary complications (see CORE-13: Physical Rehabilitation; CORE-14: Functional Rehabilitation).	None	Reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
A	7	1	A discharge plan should be initiated early in the pre-operative period and updated throughout the rehabilitation process to address: a. Location of rehabilitation b. Social support/financial resources c. Home environment assessment d. Transportation e. Vocational considerations f. Durable medical equipment (DME).	None	Not reviewed, Deleted	
A	8	1	A learning assessment and identification of barriers to learning or communication should be performed preoperatively.	None	Reviewed, New-replaced	Recommendation 10
A	8	2	Patients scheduled for amputation should receive education regarding the procedure and the various components of postoperative care and rehabilitation activities, including (see CORE-11: Patient Education): a. Pain control b. Patient safety/fall precautions c. Prevention of complications d. Procedural/recovery issues: • Level of amputation • Prosthetic options • Postoperative dressing • Sequence of amputation care • Equipment e. Expectation for functional outcome f. Potential psychosocial issues g. Role of the rehabilitation team members.	None	Reviewed, New-replaced	Recommendation 1
A	9	1	Based on a clinical evaluation by the treating surgeon with input from the interdisciplinary rehabilitation team, the patient (or person giving consent) should be presented with all viable treatment options and the risks and benefits for the following: a. Level of amputation b. Management of postoperative wound c. Type of postoperative prosthesis.	None	Reviewed, Amended	Recommendation 7

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
A	9	2	The patient (or person giving consent) should be encouraged to ask questions. The surgeon should make every effort to answer those questions to the patient's satisfaction. The patient (or person giving consent) should be able to verbalize a good understanding of their treatment options at the end of the process.	None	Reviewed, Deleted	
A	9	3	Involvement of the patient's family and/or significant others should be encouraged.	None	Not reviewed, Deleted	
A	9	4	The patient (or person giving consent) must agree to the surgical and immediate post-surgical treatment plan.	None	Not reviewed, Deleted	
A	9	5	The informed consent process should be in compliance with institutional policy (satisfying The Joint Commission's requirements).	None	Not reviewed, Deleted	
A	10.1	1	The choice of amputation level should take in consideration the risks and benefits. The factors in the risk-benefit assessment include the patient's goals and priorities, the patient's general condition and risk of additional surgeries, the potential for healing of the limb, and the predicted probable functional outcome.	None	Reviewed, Amended	Recommendation 7
A	10.1	2	Optimal residual limb length: a. Transtibial • Optimum – length that allows space for the prosthetic foot and sufficient muscle padding over the residual limb – typically mid-tibia • Minimum – junction of middle third and proximal third of tibia just below the flair of the tibial plateau to allow sufficient tibia for weight-bearing. b. Transfemoral • Optimum – length that allows space for an uncompromised knee system – typically just above the condylar flair • Minimum – junction of middle third and proximal third (below the level of the lesser trochanter) to allow sufficient femur length/lever arm to operate the prosthesis. c. If there is uncertainty of the optimal length of the residual limb, preoperative consultation with an experienced physiatrist or prosthetist should be considered.	None	Reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
A	10.1	3	The potential for wound healing should be determined. The following may be considered: [I] a. Laboratory studies: • C-reactive protein to check for infection • Hemoglobin to check for treatable anemia to ensure an appropriate oxygenation level necessary for wound healing • Absolute lymphocyte count to check for immune deficiency and/or infection • Serum albumin/prealbumin level to check for malnutrition and diminished ability to heal the wound. b. Imaging studies: • Anteroposterior and lateral radiography of the involved extremity • CT scanning and MRI as necessary • Doppler ultrasonography to measure arterial pressure. c. Additional tests: • Ischemic index (II) is the ratio of Doppler pressure at the level being tested to the brachial systolic pressure – a II of 0.5 or greater at the surgical level is necessary to support healing. • Assess preoperative amputation TcPO2 levels – preoperative levels greater than 20mmHg are associated with successful healing after amputation. [A]	I A	Reviewed, Amended	
A	10.2	1	The appropriate postoperative dressing should be determined by the surgeon before surgery, recognizing that circumstances occurring during the surgery may necessitate changes. [I]	I	Reviewed, Deleted	
A	10.2	2	Consider the use of a rigid or semi rigid dressing to shorten the time to healing and readiness for prosthesis in dysvascular transtibial amputations. [B]	B	Reviewed, Amended	Recommendation 9
A	10.2	3	There is inconclusive evidence to recommend for or against a specific kind of rigid dressing. [I]	I	Reviewed, Deleted	
A	10.2	4	Properly fitted shrinkers should be used as soon as possible, after amputation. [I]	I	Reviewed, Deleted	
A	10.2	5	Patients with a bulbous transtibial limb are more likely to do better with a rigid dressing applied above the knee and changed every three to five days until they are able to tolerate a shrinker. [I]	I	Reviewed, Deleted	
A	11.1	1	Perform the appropriate amputation at the selected level, adhering to good surgical and amputation principles.	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
A	11.2	1	Appropriate postoperative dressing should be applied after amputation.	None	Not reviewed, Deleted	
A	11.2	2	The use of rigid postoperative dressings should be considered (which is preferred in situations where limb protection is the priority). [B]	B	Reviewed, Amended	Recommendation 9
B	2	1	The postoperative plan should include a care plan to address: a. Medical requirements b. Wound or surgical requirements c. Rehabilitation requirements including: • Prevent contractures • Reduce postoperative edema through the use of compression therapies • Protect the amputated limb from external trauma • Ensure patient safety	None	Not reviewed, Deleted	
B	3	1	For a closed amputation and primary closure, the following procedures should be performed: a. May apply sterile, non-adherent dressing secured with stockinet b. Apply a compressive dressing to reduce edema and shape the residual limb c. Monitor for infection d. Remove the sutures or staples per the advice of the surgeon	None	Not reviewed, Deleted	
B	3	2	For an open amputation, the following procedures should be considered: a. Staged closure at a later date may be required for wounds heavily contaminated from infection or trauma b. A vacuum-assisted-closure devise may be helpful for open wounds	None	Not reviewed, Deleted	
B	3	3	Residual limb management should continue with the focus on postoperative dressings, control of the edema and shaping of the residual limb, control of the pain, and protection of the residual limb from further injury. (See CORE-6 : Residual Limb)	None	Reviewed, New-replaced	Recommendation 9
B	4	1	A thorough medical assessment should be completed postoperatively to assess physical condition, nutrition, lack of infection, and bowel and bladder function as well as a review of systems (cardiovascular, respiratory, endocrine, skin, neurological, and musculoskeletal).	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
B	4	2	Treatment of pain should be started immediately and address the specific source of pain: a. Post surgical pain – appropriate edema control, liberal use of narcotics b. Neuropathic/phantom pain – consider use of anticonvulsant (e.g., pregabalin, gabapentin, antidepressants (e.g., SSRIs, or TCAs) c. Consider use of epidural or regional anesthesia.	None	Reviewed, Deleted	
B	4	3	Specific measures for deep vein thrombosis (DVT) and pulmonary embolism (PE) prophylaxis should be applied.	None	Not reviewed, Deleted	
B	4	4	A nutrition assessment should be documented and specific recommendations should be applied; referral to a nutrition specialist should be considered.	None	Not reviewed, Deleted	
B	4	5	A thorough sepsis workup for any signs/symptoms of systemic infection should be completed.	None	Not reviewed, Deleted	
B	4	6	Medical and surgical comorbidities resulting from polytrauma, such as that seen in combat casualties, are best managed in rehabilitation centers that provide interdisciplinary management including multiple medical and surgical subspecialties with trauma experience.	None	Reviewed, New-replaced	Recommendation 12
B	4	7	Bowel and bladder functions should be monitored to maintain fluid balance as well as to avoid urinary retention and constipation, which may be brought on by medications (particularly opioids and anticholinergics) and/or decreased mobility.	None	Not reviewed, Deleted	
B	4	8	Behavioral health support should be provided as necessary.	I	Reviewed, Deleted	
B	4	9	The following rehabilitation interventions should be initiated as tolerated: a. Range of motion (ROM) b. Strengthening c. Cardiovascular fitness and endurance d. Balance e. Mobility f. Functional activities and ADL.	None	Reviewed, Amended	Recommendation 14
B	4	10	Patient and family education on positioning, skin care, and pain management; preservation of the intact limb; and approaches to modify risk factors should be re-enforced from preoperative training.	None	Reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
B	5	1	Patients undergoing lower limb amputations should be assessed using a standardized approach like the one described in Table 9. Categories of Wound Healing (adapted from Smith, 2004). The depth and extent of involvement of the non-healing and nonviable skin, subcutaneous tissues, muscle, and/or bone will assist in the evaluation and treatment of problematic wounds.	None	Reviewed, Amended	Recommendation 18
B	6	1	Early revision surgery may be considered for wounds that are slow to heal, particularly in Category III, IV, and V wounds.	None	Not reviewed, Deleted	
B	6	2	Early vascular evaluation may be considered for patients with delayed healing and consultation for vascular intervention may be considered for patients with impaired peripheral arterial blood flow.	None	Not reviewed, Deleted	
B	6	3	Early evaluation and treatment for potential superficial and deep infections may be considered for patients with delayed healing. The evaluation may include wound cultures, laboratory studies, and radiological studies. Debridement, intravenous antibiotics, and/or revision may be necessary to achieve infection control.	None	Not reviewed, Deleted	
B	6	4	Early aggressive local wound care should always be initiated for any degree of wound breakdown. This may include the use of topical agents (regranex, aquacel silver, panafil)	None	Reviewed, Deleted	
B	6	5	Hyperbaric oxygen can be considered as an adjunct treatment for impaired wound healing.	None	Reviewed, Deleted	
B	7	1	Medical status should be assessed prior to proceeding to another level of care. The following criteria must be met prior to discharge to the next level of care: a. Hemodynamically stable b. Lack of systemic infection or an appropriate course of treatment in place c. Stable surgical site d. Acceptable bowel and bladder management e. Comorbid conditions addressed.	None	Not reviewed, Deleted	
B	8	1	Rehabilitative placement following a lower limb amputation should be based on the patient's medical status, current and anticipated function, ability to participate in rehabilitation interventions, social support system, and community resources.	None	Reviewed, New-replaced	Recommendation 12
B	8	2	To be discharged from acute care the patient's medical condition needs to be stable.	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
B	8	3	Patients are able to be discharged to home when: ■ Medically stable ■ Able to be mobile and transfer with available social support systems utilizing appropriate assistive devices (walker, cane, wheelchair) ■ Able to perform basic daily living skills independently or have a social support system to compensate for the deficiencies ■ There is an accessible home environment ■ There is access to continued rehabilitation interventions as needed.	None	Not reviewed, Deleted	
B	8	4	Patient who do not meet criteria for discharge to home may be referred to: a. Acute inpatient rehabilitation care when: • Able to follow a minimum of two-steps commands • Able to actively participate and benefit from at least two hours of therapy per day. b. Sub-acute rehabilitation care or an extended nursing facility when: • Able to follow single step commands • Able to actively participate in less than two hours of therapy per day.	None	Reviewed, New-replaced	Recommendation 12
B	8	5	Patients not meeting the criteria for discharge to a rehabilitation program (e.g., they do not meet the above cited criteria and nursing care outweighs rehabilitation care) may be discharged to a program that is primarily focused on skilled nursing care when: a. Medically stable b. Able to tolerate only a few hours of therapy per week.	None	Not reviewed, Deleted	
C	2	1	A thorough medical assessment should be completed upon admission to rehabilitation to include: cardiovascular, pulmonary, endocrine, neurological, bowel and bladder, skin and musculoskeletal.	None	Not reviewed, Deleted	
C	2	2	Special attention should be taken to assess the health of the contralateral leg and foot including vascular health, sensation, presence of deformity, abnormal skin or other tissue, and appropriate footwear.	None	Not reviewed, Deleted	
C	2	3	Assess the healing of the wound by monitoring: a. Wound closure b. Drainage or seepage c. Excessive redness or induration around the wound site d. Temperature of the surrounding tissue	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
C	2	4	Involve the surgeon in problems with wound healing and wound management regardless of the patient's disposition.	None	Not reviewed, Deleted	
C	2	5	Consult the specialized wound care team as needed.	None	Not reviewed, Deleted	
C	2	6	Protect the residual limb from external trauma to reduce potential complications, delayed wound healing and encourage mobility.	None	Reviewed, New-replaced	Recommendation 9
C	2	7	Residual limb management should continue with the focus on control of edema, shaping the residual limb and control of the pain. (See CORE-6: The Residual Limb)	None	Reviewed, New-replaced	Recommendation 9
C	2	8	Postoperative physical and functional assessment should be performed after amputation surgery and prior to postoperative rehabilitation. Include the following: a. Patient history, including • Past medical history • Home environment • Premorbid functional level – ADL, mobility, and cognition • Social environment (see Core-9: Social Environment [Support]) b. Physical assessment, including: • Range of motion (ROM) – bilateral hips, knees, and upper extremities • Strength – upper extremities and lower extremities • Sensation – involved limb and contralateral limb • Proprioception – involved limb and contralateral limb • Balance – sitting and standing c. Functional assessment including: • Mobility – current level of function and use of assistive devices (bed, transfers, ambulation) • Basic ADLs – eating, grooming, toileting, bathing, and dressing d. Screen for other impairments (e.g., vision and hearing, or other trauma)	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
C	2	9	Consider using standardized measures at admission and discharge to demonstrate progress and the efficacy of the rehabilitation process. The recommended tools for assessment include: a. Amputee Mobility Predictor (AMP) b. Functional Independence Measure (FIM) c. Two-Minute Walk d. Timed Up and Go Test (TUG) e. Upper Extremity Ergometry (See CORE-14.2: Mobility and Equipment)	None	Reviewed, New-replaced	Recommendation 16
C	2	10	Pain assessment should be performed by all members of the rehabilitation team.	None	Not reviewed, Deleted	
C	2	11	Patients should be assessed for pain and treatment should be based on etiology and initiated/continued to optimize rehabilitation.	None	Reviewed, New-replaced	Recommendation 3
C	2	12	Consider prophylactic pain management prior to the rehabilitation session. (See CORE-3: Pain Management)	None	Not reviewed, Deleted	
C	2	13	A psychological assessment should be completed if not done preoperatively.	None	Reviewed, New-replaced	Recommendation 2
C	2	14	Continuous monitoring of behavioral health should be performed by all members of the rehabilitation team. (See CORE-8: Behavioral Health Assessment and Treatment)	None	Not reviewed, Deleted	
C	2	15	A postoperative cognitive/neuropsychological assessment should be conducted if not completed preoperatively. (See CORE-5: Cognitive Assessment)	None	Reviewed, Amended	Recommendation 10
C	3	1	Members of the rehabilitation team should work with the patient to establish goals specific to their area of expertise.	None	Not reviewed, Deleted	
C	3	2	Goals should be written, be measurable, and be specific.	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
C	4	1	The following conditions, if present, require aggressive management: a. Hyperglycemia b. Cardiac, respiratory, renal, and metabolic c. Nutritional deficiency d. Major psychiatric illness e. Vascular lesions. (See CORE-4: Medical Care)	None	Reviewed, New-replaced	Recommendation 18
C	5	1	During the pre-prosthetic rehabilitation phase the following should be covered with the patient: a. Positioning b. Rehabilitation process c. Pain control d. Residual limb care e. Prosthetic timeline f. Equipment needs g. Coping methods h. Prevention of complications i. Safety and fall prevention (essential). (See CORE-11: Patient Education)	None	Reviewed, Deleted	
C	6	1	Rehabilitation goals should be documented in the treatment plan.	None	Not reviewed, Deleted	
C	6	2	The treatment plan should be updated by the rehabilitation team to reflect changes in the patient's status. (See CORE-2: Rehabilitation Treatment Plan)	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
C	7	1	Provide physical and functional rehabilitation interventions in the following: a. Residual limb management (teach care of the residual limb and the use of ACE wrap and shrinkers) b. Range of motion (ROM) (residual and contralateral limbs at the hip and knee) c. Strengthening (add trunk and core stabilization exercises; initiate a home exercise program) d. Cardiovascular endurance (tailored to patient's fitness level and progressed as tolerated) e. Balance (progress program to dynamic balance training). (See CORE-13: Physical Rehabilitation and CORE-14: Functional Rehabilitation)	None	Reviewed, Deleted	
C	7	2	Provide interventions to evaluate and promote community reintegration: a. Home evaluation and modification b. Mobility (progress single limb gait from the parallel bars to the use of an appropriate assistive device) c. Equipment (independent wheelchair mobility) d. Functional activities and ADL e. Driver's training and vehicle adaptation f. Vocational rehabilitation or return to school g. Recreation activities without a prosthesis. (See CORE-14: Functional Rehabilitation)	None	Reviewed, Deleted	
C	8	1	Patient's candidacy for a prosthesis should be determined by the rehabilitation team based on the patient's characteristics, goals, and an objective evaluation of their functional status. Some areas to be considered: a. Patient is willing and motivated to move forward for prosthetic rehabilitation b. Patient has the ability to understand and apply knowledge to the fitting and use of a prosthesis c. Contralateral limb will tolerate weight bearing d. Patient is in adequate physical condition to tolerate walking with a prosthesis e. Prosthesis contributes to quality of life or self image.	None	Not reviewed, Deleted	
C	9	1	Additional equipment to facilitate mobility and ADL is required for a patient with a lower extremity amputation.	None	Reviewed, New-replaced	Recommendation 11
C	9	2	The type of equipment should be based on the current and anticipated functional status.	None	Reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
D	1	1	Patients at K level "0" are not recommended for prostheses for ambulation or transfers.	None	Not reviewed, Deleted	
D	1	2	Patients a K level "1" are recommended for prostheses that meet the functional goals of limited and unlimited household ambulation.	None	Not reviewed, Deleted	
D	1	3	Patients at K level "2" are recommended for prostheses that meet the functional goals of limited community ambulation.	None	Not reviewed, Deleted	
D	1	4	Patients at K level "3" are recommended for prostheses as community ambulators with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.	None	Not reviewed, Deleted	
D	1	5	Patients at K level "4" are recommended for prostheses at the highest level of functioning typical of the child, active adult, or athlete.	None	Not reviewed, Deleted	
D	1	6	Prosthetic fittings typically should not begin until the suture line has completely healed, although in unusual circumstances prosthetic fitting and limited ambulation may start with a clean non-infected wound with granulation tissue.	None	Not reviewed, Deleted	
D	2	1	The prescription for a patient with a transmetatarsal amputation should include: a. Toe filler/arch support b. Custom/prefabricated Ankle-foot orthosis (AFO) with toe filler: c. Assessment adequate shoe fit	None	Not reviewed, Deleted	
D	2	2	The prescription for a patient with a transtibial/transfemoral amputation should include: a. Socket b. Socket interface c. Suspension mechanism d. Pylon e. Knee joint f. Foot/ankle. (See Appendix C for a listing of specifications.)	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
D	3	1	Initiate physical and functional interventions for prosthetic training as appropriate for the patient's functional goals: a. Residual limb management (donning and doffing of prosthesis, gel liners or socks as appropriate) b. Range of motion (ROM) c. Strengthening d. Cardiovascular fitness and endurance e. Balance f. Mobility g. Functional activities and ADL h. Equipment i. Driver's training j. Home evaluation k. Home exercise program l. Community integration.	None	Reviewed, New-replaced	Recommendation 14
D	3	2	A two-phase process may be considered for prosthetic fitting and training: a. Phase One: Preparatory (preliminary) prosthesis b. Phase Two: Definitive prosthesis.	None	Not reviewed, Deleted	
D	3	3	If only a definitive prosthetic is to be fitted, the fitting for the socket should be delayed until the residual limb is fully mature (usually three to four months) or until general stabilization occurs in the patient's weight and residual limb volume.	None	Not reviewed, Deleted	
D	4	1	Once basic prosthetic management has been completed, the focus should move to weight bearing with the prosthesis, standing balance, weight shifts, and equalization of step length.	None	Reviewed, Deleted	
D	4	2	Once the patient has mastered prosthetic ambulation with a walker or other assistive device, training on stairs, uneven surfaces, and ramps/inclines are recommended.	None	Reviewed, Deleted	
D	4	3	Prosthetic gait training should incorporate aspects related to the patient's home, work, and/or recreational environments.	None	Reviewed, New-replaced	Recommendation 14

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
D	5	1	Initial patient education in the use of a prosthetic lower limb should include: a. Demonstration and training in donning and doffing the prosthesis (dependent upon the type of prosthesis provided) b. Initial training in how to start ambulation (dependent upon the type of prosthesis provided) c. Instruction in accomplishing safe transfers taking in consideration the home environment d. Instruction in how to fall safely and get back up e. Instruction in daily self inspections of the residual limb for excessive tissue loading; if erythema is present upon removing the prosthesis and does not completely resolve in 20 minutes, the patient should be instructed to report it immediately f. Basic residual limb and prosthetic hygiene.	None	Not reviewed, Deleted	
D	5	2	If appropriate, the patient's caregiver should also be instructed in management and care of the prosthesis, proper transfer technique and safety.	None	Not reviewed, Deleted	
D	6	1	Patients who were not prosthetic candidates or candidates for a transfer prosthesis should be evaluated periodically to determine if their functional goals may be expanded to include ambulation.	None	Not reviewed, Deleted	
D	6	2	Patients with a prosthesis should be advised to report any of the following symptoms as they are signs that the prosthesis needs to be modified: a. Ongoing pain b. Skin breakdown c. Change in the ability to don and doff the prosthesis d. Change in the number of sock plies e. Change in the pattern of usage f. Change in functional needs or goals.	None	Reviewed, Deleted	
D	6	3	The prosthesis should be assessed at least once within the first year of prosthetic use to address: a. Stability b. Ease of movement c. Energy efficiency d. Appearance of the gait to determine the success of fitting and training.	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
D	6	4	Patients presenting with dermatologic problems require assessment and intervention: a. Contact dermatitis: assess the hygiene of the liner, socks, and suspension mechanism b. Cysts and sweating: assess for excessive shear forces and improperly fitted components c. Scar management: requires massaging and lubricating the scar to obtain a well-healed result without dog ears or adhesions d. Superficial fungal infections are common and will require topical anti-fungal agents for resolution.	None	Not reviewed, Deleted	
D	7	1	Additional equipment to facilitate mobility and ADL should be provided after lower extremity amputation with or without a prosthesis.	None	Reviewed, New-replaced	Recommendation 11
D	7	2	The type of equipment should be based on the current and anticipated functional status.	None	Reviewed, New-replaced	Recommendation 11
E	2	1	Patients with a prosthesis should visit the Amputation Clinic Team for an initial comprehensive visit to address any change in the condition of the residual limb.	None	Not reviewed, Deleted	
E	2	2	Patients with minor repairs or adjustments to the prosthesis should visit a prosthetic laboratory.	None	Not reviewed, Deleted	
E	2	3	Patients with a change in their medical condition should be seen by a primary care provider or physiatrist, in addition to their comprehensive follow-up with the Amputation Clinic Team.	None	Not reviewed, Deleted	
E	2	4	A follow-up appointment should be made at the time of the comprehensive visit with the appropriate clinic or provided at the patient's request, after a major medical or functional change, or after a referral/consultation is received.	None	Not reviewed, Deleted	
E	2	5	Patients with a lower limb amputation who are not prosthetic users should be seen by their primary care provider to manage comorbidities, evaluate medical risks, and maintain the health of the residual and contralateral extremity.	None	Not reviewed, Deleted	
E	2	6	If the function of a non-prosthetic user changes and he/she becomes a prosthetic candidate, an appointment should be made with the Amputation Clinic Team for consideration of prosthetic restoration.	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
E	3	1	The follow-up assessment for a prosthetic user should include: a. Patient's goals (i.e., new recreation, vocation, or community requirements) b. Functional assessment: • Gait and mobility • Residual limb health • Contralateral limb • Socket fit or residual limb volume • Strength and range of motion (ROM) • Changing needs for durable medical equipment (DME) • Activities of daily living (ADL) c. Secondary complications as a result of prosthetic use: • Pain control • Skin integrity • Associated musculoskeletal conditions (e.g., back pain and knee pain). d. Prosthetic assessment (repair, replacement, mechanical adjustment, new technology) e. Vocational and recreational needs.	None	Not reviewed, Deleted	
E	3	2	The follow-up assessment for a non-prosthetic user should include: a. Patient's goals b. Functional assessment • Residual limb health • Range of motion (ROM) • Strength • Gait and mobility • Changing needs for durable medical equipment (DME) • Activities of daily living (ADL) c. Secondary complications in the residual and contralateral limb: • Pain control • Skin integrity • Associated musculoskeletal conditions (e.g., back and knee pain) d. Vocational and recreational needs.	None	Not reviewed, Deleted	

2007 Module[1]	2007 Section	2007 Number	2007 Recommendation Text[2]	2007 Grade[3]	Recommendation Category[4]	2016 Recommendation[5]
E	4	1	Long-term follow-up should include an assessment and management of risk factors for secondary amputation including: peripheral vascular disease, diabetes, peripheral neuropathy or nerve injury, skin integrity, foreign bodies, bony deformities including heterotopic ossification, and a history of foot ulcers.	None	Reviewed, New-replaced	Recommendation 18
E	4	2	For the patient with vascular disease or diabetes, long-term follow-up should include appropriate foot care and patient education at every patient visit (see the VA/DoD Clinical Practice Guideline for Diabetes Mellitus - Module F: Foot Care).	None	Not reviewed, Deleted	
E	4	3	Patients identified to be at risk for limb-loss should be referred to an appropriate specialist.	None	Not reviewed, Deleted	
E	4	4	Encourage cardiovascular fitness to compensate for the increased metabolic cost of ambulation post-amputation.	None	Reviewed, New-replaced	Recommendation 14
E	4	5	Provide patient and family education regarding risk-modification to encourage a healthy lifestyle through increased exercise, improved nutrition, and smoking cessation (see Appendix D: Foot Care Interventions for Patients with Amputation).	None	Reviewed, Amended	Recommendation 18
E	5	1	Intermittent/regular follow-up should be provided to assess the patient's current needs, abilities, and goals.	None	Not reviewed, Deleted	
E	5	2	Life-long care should include monitoring the patient for psychosocial adjustment, skin disorders of the residual limb, pain, musculoskeletal impairments, cardiovascular disease, other chronic diseases, and the health of the contralateral limb and provision of appropriate foot wear for the contralateral foot.	None	Reviewed, New-replaced	Recommendation 18
E	5	3	A follow-up appointment should also be provided at the patient's request, after a major medical or functional change, or after a referral/consultation is received.	None	Not reviewed, Deleted	
E	5	4	For the prosthetic user, life-long care should also include surveillance for and management of secondary impairments associated with limb-loss; i.e., cardiovascular disease, accelerated degenerative joint disease of other joints, functional losses due to aging, and complications of prosthetic use.	None	Reviewed, New-replaced	Recommendation 18
E	5	5	For the prosthetic user, new technology should be considered but must be matched to the patient's function and goals, and followed with an additional period of gait training to help the patient learn to use new components. The latest technology is not always the best choice for the patient.	None	Reviewed, Deleted	

Appendix D: Participant List

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Aaron Turner, PhD, ABPP (RP) Director, Rehabilitation Psychology Puget Sound Healthcare System Seattle, WA	Deborah Velez, RN, MN, GNP-BC Nurse Practitioner VA San Diego Healthcare System San Diego, CA
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Appendix E: Patient Focus Group Methods and Findings

A. Methods

On May 24, 2016, as part of the effort to update this CPG, the VA and DoD Leadership, along with the LLA CPG Work Group, held a patient focus group at Walter Reed Medical Center in Bethesda, Maryland. Focus group participants included seven patients, including two females.

The aim of the focus group was to further the understanding of the perspectives of patients undergoing rehabilitation of LLA within the VA and/or DoD healthcare systems, as these patients are most affected by the recommendations put forth in the updated LLA CPG. The focus group explored patient perspectives on a set of topics related to rehabilitation of LLA in the VA and DoD healthcare systems, including knowledge of LLA rehabilitation options, views on delivery of care, and the impact of LLA and the challenges it poses.

Participants for the focus group were recruited by the LLA CPG Champions and Work Group members. Patient focus group participants were not intended to be a representative sample of VA and DoD patients who have experienced LLA. However, recruitment focused on eliciting a range of perspectives likely to be relevant and informative in the guideline development process. Patients were not incentivized for their participation or reimbursed for travel expenses.

The LLA CPG Champions and Work Group, with support from Lewin, developed a set of questions to help guide the focus group. The facilitator from Lewin, Clifford Goodman, PhD, led the discussion using questions prepared by the Work Group as a general guide to elicit the most important information from the patients regarding their experiences and views about their rehabilitation and overall care. Given the limited time and the range of interests of the participants, not all of the listed questions were addressed.

At the time of the focus group, three participants received care in the DoD healthcare system and four had experienced care through the VA system. Several individuals had also received private care at certain points, either immediately after their injuries when they received acute care at a private hospital, or later in rehabilitation when they used personal insurance to receive private care. However, at the time of the focus group, all of the participants were receiving care at Walter Reed Army Medical Center, and those who had transitioned to care under the VA had opted to return to Walter Reed for their continued care.

The following concepts are aspects of care that patients indicated were important during the course of the focus group discussion. Each of these themes was an important and needed aspect of participants' healthcare.

B. Patient Focus Group Findings

a. Recognize the importance of a transdisciplinary care team and the necessity for patients to have a trusting relationship with their prosthetist.

- Patients consider the most important care team relationship is with their prosthetist. Due to the sensitive nature of frequent physical interactions and the quality of life factors that depend on a good prosthetic fit, it is of utmost importance to have a prosthetist that will understand the patient's goals, preferences, and rehabilitation challenges.

- After the acute treatment phase has ended, patients typically see their primary care physicians rarely and only when necessary for such matters as prescription refills or rehabilitation referrals.
- Patients also value having a behavioral/psychological health professional as part of the transdisciplinary care team.

b. Consider patient-specific goals, values, and preferences and use shared decision making to develop a rehabilitation plan.

- Identify patient-specific goals associated with LLA rehabilitation, including, e.g., medication management, adapting to activities patients valued prior to their amputation, and addressing personalized "real world" obstacles in physical and occupational therapy settings.
- Use shared decision making to develop an individualized rehabilitation plan; discuss pros and cons of each option in conjunction with each patient's goals (e.g., level of function and mobility), priorities, values, and preferences.
- Maintain focus on patient goals and keep in close communication with members of the patient's care team throughout the rehabilitation process.

c. Address strategies for medication management across all phases of the rehabilitation process.

- After the acute stage of recovery from surgery when patients may be on strong medications, consider when and how to wean them from certain of those medications to reduce side effects and to reduce the risk of developing dependence.
- Discuss pharmacologic options in depth with the patient, including possible side effects (e.g., depression, anxiety, sleep loss, weight gain) that may significantly affect a patient's rehabilitation; seek to understand a patient's preference for reducing or eliminating certain medicines from their treatment plan.
- Be prepared to adjust or otherwise change treatment (e.g., tapering pain medication) subject to patient response, preferences, and changes in priorities and goals.

d. Involve caregivers and leverage peer networks to create support and motivation for patients with lower limb amputations.

- Facilitate peer visitation soon after a patient's amputation surgery to build a network of support. When appropriate, consider the nature of the patient's injury and their demographic characteristics in order to pair the patient with a peer who experienced similar challenges.
- Include family members early in rehabilitation discussions, especially regarding what to expect during each stage of rehabilitation.
- Build and maintain trust, respect, and support with the patient and their family.

e. Consider unique challenges faced by different patient populations (e.g., females) during rehabilitation.

- Recognize which patients may face particular or unusual types of challenges during their rehabilitation (e.g., female patients).

- Work with patients and their rehabilitation teams to provide personalized care and solutions to their particular challenges.

f. Work with providers to ensure continuity of care and ease of access to preferred providers and prescriptions.

- When planning rehabilitation, consider proximity of care sites and try to minimize travel and time requirements as appropriate.
- Work with providers to ensure continuity of care and ease of access to preferred providers.
- Understand the education and rehabilitation a patient may have received before transferring to a different health center.

Appendix F: Literature Review Search Terms and Strategy

A. Topic-specific Search Terms

The search strategies employed combinations of free-text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. Strategies for each bibliographic database follow this table.

Table E-1. EMTREE, Medical Subject Headings (MeSH), PsycInfo, and Keywords

Concept	Controlled Vocabulary	Keywords
Amputation/amputation stumps	**EMBASE (EMTREE)** above knee amputation amputation amputation stump ankle amputation below knee amputation foot amputation knee amputation leg amputation limb amputation lower extremity amputation thigh amputation through knee amputation transfemoral amputation transtibial amputation traumatic amputation **Medline (MeSH)** amputation amputation stumps amputation, traumatic amputees disarticulation **PsycINFO** amputation	amputee bilateral amputation disarticulation limb loss partial foot amputation transfemoral transtibial unilateral

Concept	Controlled Vocabulary	Keywords
Lower Extremity Sites	**EMBASE (EMTREE)** above knee prosthesis below knee prosthesis foot foot disease foot injury foot surgery hallux hip knee knee injury knee prosthesis leg leg injury leg prosthesis lower leg prosthesis toe toe injury toe phalanx **Medline (MeSH)** arthroplasty, replacement, toe artificial limbs foot foot bones foot injuries foot joints hallux knee knee injuries knee prosthesis leg leg bones leg injuries toe injuries toe joint toe phalanges toes	through knee

Concept	Controlled Vocabulary	Keywords
Artificial Limbs/ Prosthetics	**EMBASE (EMTREE)** above knee prosthesis ankle prosthesis below knee prosthesis electric limb prosthesis foot prosthesis hip disarticulation prosthesis leg prosthesis limb prosthesis lower leg prosthesis prosthesis prosthesis fixation prosthetic fitting **Medline (MeSH)** artificial limbs **PsycINFO** prostheses	air limb c leg computer assisted elevated vacuum implants intelligent prosthesis interface irc ischial containment ischial ramus containment knee unit microprocessor patella tendon bearing pin suspension prostheses prosthesis design prosthesis implantation prosthetic socket robotics signal processing socket suspension system total surface bearing user-computer interface vacuum assisted suspension

Concept	Controlled Vocabulary	Keywords
Pre- and Post-Operative Rehabilitation	**EMBASE (EMTREE)** exercise exercise movement techniques exercise therapy gait training kinesiotherapy mental health care occupational therapy patient education peer support physical activity physical education and training physical exercise physical exertion physical therapy physical therapy modalities physiotherapy range of motion rehabilitation rehabilitation care rehabilitation centers rehabilitation medicine rehabilitation nursing rehabilitation patient resistance training self care weight bearing **Medline (MeSH)** activities of daily living exercise therapy occupational therapy physical exertion physical therapy modalities rehabilitation rehabilitation centers rehabilitation nursing rehabilitation, vocational	contracture prevention contralateral limb core stability core strength edema control equipment order* fall prevention flexibility training hip strength home exercise manual training mental health screen* mobility training overground pain management post operative intervention* post operative rehabilitation pre operative intervention* pre operative rehabilitation removable dressing rigid dressing skin care soft dressing strengthening treadmill training

Concept	Controlled Vocabulary	Keywords
Pain Management	**EMBASE (EMTREE)** intractable pain limb pain pain phantom pain postoperative pain **Medline (MeSH)** pain pain, postoperative phantom limb **PsycINFO** chronic pain neuropathic pain pain pain perception	phantom limb pain residual limb pain
Surgical Interventions	**EMBASE (EMTREE)** limb salvage salvage therapy surgical technique **Medline(MeSH)** salvage therapy	amputation methods bone bridging burgess disarticulation Ertl hemipelvectomy lower extremity surgery myodesis osseointegration
Tests to predict outcomes from amputation surgery	**EMBASE (EMTREE)** psychometrics **Medline (MeSH)** psychometrics	6 min walk distance 6 minute walking test amputee mobility predict* cut point minimal change normative value* six minute walking distance six minute walking distance test six minute walking test step activity monitor* threshold value timed up and go timed up and go test TUG

Concept	Controlled Vocabulary	Keywords
Demographics	**EMBASE (EMTREE)** age demography educational status employment status female gender male marriage race social class transgender **Medline (MeSH)** age groups demography employment female gender identity male marriage social class transgender persons	gender gender differences woman women
Comorbidities	**EMBASE (EMTREE)** brain injury cognitive defect comorbidity comorbidity assessment diabetes mellitus neoplasm neurologic disease posttraumatic stress disorder **Medline (MeSH)** brain injuries cognition disorders comorbidity diabetes mellitus neoplasms stress disorders, post-traumatic	amputation level amputation location amputation site k-level* PTSD traumatic amputation vascular amputation

Concept	Controlled Vocabulary	Keywords
Outcomes	**EMBASE (EMTREE)** daily life activity employment functional independence measure functional status functional status assessment gait mobility assessment outcome outcome assessment patient satisfaction postoperative complication prognosis quality of life treatment outcome walking **Medline (MeSH)** activities of daily living cost of illness employment health expenditures health status independent living outcome assessment (health care) patient acceptance of health care patient satisfaction postoperative complications prognosis quality of life recovery of function self concept social adjustment social participation treatment outcome	outcomes

B. Search Strategies

Table E-2. MEDLINE (presented in OVID syntax)

Set Number	Concept	Search Statement
1	Amputation	'through knee amputation'/exp OR 'thigh amputation' OR 'bilateral amputation*' OR 'limb loss' OR 'lower extremity amputation'/exp OR 'leg amputation'/exp OR 'ankle amputation'/exp OR 'foot amputation'/exp OR 'amputation'/exp OR 'amputation stump'/exp OR 'above knee amputation'/exp OR 'below knee amputation'/exp OR 'knee amputation'/exp OR 'limb amputation'/exp OR 'traumatic amputation'/exp OR ((ankle* OR feet OR foot OR 'partial foot' OR hallux OR hip* OR knee* OR leg OR legs OR 'lower extremity' OR 'lower limb' OR 'through knee' OR thigh OR bilateral OR toe OR toes OR transfemoral OR transtibial) NEAR/3 (amputat* OR disarticulat*)):ab,ti

Set Number	Concept	Search Statement
2	Lower Limb	'thigh'/exp OR 'leg'/exp OR 'leg injury'/exp OR 'knee'/exp OR 'knee injury'/exp OR 'toe'/exp OR 'hallux'/exp OR 'toe phalanx'/exp OR 'toe phalanges'/exp OR 'toe injury'/exp OR 'foot'/exp OR 'foot injury'/exp OR 'foot disease'/exp OR 'foot surgery'/exp OR 'hip'/exp OR ((ankle* OR feet OR foot OR hallux OR hip* OR knee* OR leg OR legs OR 'lower extremity' OR 'lower limb' OR thigh OR toe OR toes OR transfemoral OR transtibial) NEAR/2 (diseas* OR injur*)):ab,ti
3	Prosthetic	'foot prosthesis'/exp OR 'ankle prosthesis'/exp OR 'above knee prosthesis'/exp OR 'below knee prosthesis'/exp OR 'electric limb prosthesis'/exp OR 'hip disarticulation prosthesis'/exp OR 'leg prosthesis'/exp OR 'lower leg prosthesis'/exp OR 'limb prosthesis'/exp OR 'prosthesis fixation'/exp OR 'prosthesis'/exp OR 'socket' OR 'interface' OR 'suspension system' OR 'knee units' OR 'knee unit' OR 'prosthetic socket' OR 'prosthetic fitting'/exp OR 'vacuum assisted suspension' OR 'air limb' OR 'total surface bearing' OR 'patella tendon bearing prosthesis' OR 'pin suspension' OR 'c leg'/exp OR 'intelligent prostheses' OR ((ankle* OR feet OR foot OR hallux OR hip* OR knee* OR leg OR legs OR 'lower extremity' OR 'lower limb' OR toe OR toes OR transfemoral OR transtibial) NEAR/3 (artificial* OR microprocessor* OR prosthes* OR prosthet*)):ab,ti
4	Socket/Interface	(stump OR 'below knee' OR 'above knee' OR 'through knee' OR hsd OR 'patella tendon bearing' OR 'patellar tendon bearing' OR ptb OR 'total surface bearing' OR tsb OR 'ischial containment' OR 'ischial ramus containment' OR ic OR irc OR 'knee disarticulation' OR 'hip disarticulation' OR vass OR 'total contact') NEAR/2 (socket* OR interface*)
5	Suspension	'elevated vacuum' OR 'vacuum assisted suspension' OR 'anatomic fit' OR 'osseointegration'/exp OR 'suspension sleeve' OR 'supracondylar' OR 'corset suspension'/exp OR 'pin suspension' OR 'locking mechanism' OR 'lanyard' OR 'thigh cuff' OR belt NEAR/2 suspension
6	Knees	(microprocessor OR 'non microprocessor' OR hydromechanical OR polycentric OR 'single axis' OR 'mauch sns' OR 'swing and stance' OR 'weight activated stance breaking' OR wasb OR 'manual locking' OR 'c leg' OR 'c-leg' OR power OR hydracadence OR rheo) NEAR/2 (knee OR knees)
7	Feet	'energy storing and release' OR es OR esr OR esar OR 'energy storing' OR 'dynamic response' OR sach OR 'solid ankle cushioned heel' OR 'flexible keel' OR 'flex foot' OR 'proprio foot' OR 'biom foot' OR 'single axis foot' OR 'multi axial foot' OR 'running foot' OR cheetah NEAR/2 (foot OR feet) AND (foot OR feet)
8	Combine Sets	1 OR 2
9	Combine Sets	3 OR 4 OR 5 OR 6 OR 7
10	Combine Sets	8 AND 9
11	Exclude Unwanted Publications	10 NOT (abstract:nc OR annual:nc OR book/de OR 'case report'/de OR 'case study'/de OR conference:nc OR 'conference abstract':it OR 'conference paper'/de OR 'conference paper':it OR 'conference proceeding':pt OR 'conference review':it OR congress:nc OR editorial/de OR editorial:it OR erratum/de OR letter:it OR note/de OR note:it OR meeting:nc OR sessions:nc OR 'short survey'/de OR symposium:nc)
12	Limit to Humans	Limit 11 to humans
13	Limit to English Language	Limit 12 to English language

Set Number	Concept	Search Statement
14	Limit by Publication Date	13 AND [2007-2016]/py

OVID syntax:

$ or * = truncation character (wildcard)

ADJ*n* = search terms within a specified number (*n*) of words from each other in any order

/ = search as a subject heading (note that terms preceded by an asterisk are searched as a major subject headings)

exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)

.de. = limit controlled vocabulary heading

.fs. = floating subheading

.hw. = limit to heading word

.md. = type of methodology (PsycINFO)

.mp. = combined search fields (default if no fields are specified)

.pt. = publication type

.ti. = limit to title

.tw. = limit to title and abstract fields

Table E-3. EMBASE

Set Number	Concept	Search Statement
1	Lower Limb Amputation	'through knee amputation'/mj OR 'thigh amputation':ab,ti OR 'bilateral amputation*':ab,ti OR 'limb loss':ab,ti OR 'lower extremity amputation'/mj OR 'leg amputation'/mj OR 'ankle amputation'/mj OR 'foot amputation'/mj OR 'amputation'/mj OR 'amputation stump'/mj OR 'above knee amputation'/mj OR 'below knee amputation'/mj OR 'knee amputation'/mj OR 'limb amputation'/mj OR 'traumatic amputation'/mj OR ((ankle* OR feet OR foot OR 'partial foot' OR hip* OR knee* OR leg OR legs OR 'lower extremity' OR 'lower limb' OR 'through knee' OR thigh OR bilateral OR toe OR toes OR transfemoral OR transtibial) NEAR/3 (amputat* OR disarticulat*)):ab,ti
2	Gait and Mobility Training	'gait training'/mj OR 'mobility training':ab,ti OR ((treadmill OR overground OR manual) NEAR/2 (training OR gait OR mobility)):ab,ti
3	Surgical Interventions	'surgical technique'/mj OR 'bone bridg*':ab,ti OR 'bone-bridg*':ab,ti OR (bone NEAR/2 bridg*):ab,ti OR 'myodesis':ab,ti OR 'osseointegration'/mj OR 'amputation methods':ab,ti OR (amputation NEAR/2 method*):ab,ti OR 'ertl':ab,ti OR 'lower extremity surgery':ab,ti OR 'hemipelvectomy':ab,ti OR 'disarticulation':ab,ti OR 'burgess':ab,ti
4	Tests to Predict Outcomes	'6 minute walking test' OR 'six minute walking distance' OR 'six minute walking distance test' OR 'six minute walking test' OR '6 minute walking distance' OR '6 min walk test' OR '6 min walk distance' OR 'step activity monitor*':ab,ti OR ('amputee mobility' NEAR/2 predict*):ab,ti OR 'cut point*':ab,ti OR 'timed up and go' OR 'timed up and go test' OR 'tug':ab,ti OR 'threshold value*':ab,ti OR 'normative value*':ab,ti OR 'minimal change':ab,ti OR 'psychometrics'/mj
5	Gender Designation	'gender differences':ab,ti OR 'female'/mj OR 'male'/mj OR 'transgender'/mj OR gender:ti OR transgender:ti OR female:ti OR women:ti OR woman:ti
6	Demographics, Comorbidities, Amputation Characteristics	'above knee amputation'/exp OR age/exp OR (amput* NEXT/1 (level* OR location* OR site*)):ab,ti OR 'below knee amputation'/exp OR 'brain injury'/exp OR 'cognitive defect'/exp OR comorbidity/exp OR 'comorbidity assessment'/exp OR demography/exp OR 'diabetes mellitus'/exp OR neoplasm/exp OR 'educational status'/exp OR 'employment status'/exp OR gender/exp OR (‘k-level’ OR 'k-levels'):ab,ti OR marriage/exp OR 'neurologic disease'/exp OR 'posttraumatic stress disorder'/exp OR race/exp OR 'social class'/exp OR ((traumatic* OR vascular) NEXT/1 amput*):ab,ti
7	Outcomes	'daily life activity'/exp OR 'functional independence measure'/exp OR 'functional status'/exp OR 'functional status assessment’/exp OR gait/exp OR 'mobility assessment'/exp OR outcome*:ab,ti 'outcome assessment'/exp OR 'patient satisfaction'/exp OR 'quality of life'/exp OR 'treatment outcome'/exp OR walking/exp

Set Number	Concept	Search Statement
8	Rehabilitation	'activities of daily living'/exp OR 'home exercise' OR 'phantom limb pain'/exp OR 'residual limb pain' OR 'range of motion'/exp OR ((preoperative OR 'pre operative') NEXT/2 rehabilitat*):ab,ti OR 'patient education'/exp OR (core NEXT/2 strength):ab,ti OR 'core stability' OR (hip NEXT/2 strength):ab,ti OR (equipment NEXT/2 order*):ab,ti OR ((postoperative OR 'post operative') NEXT/2 intervention*):ab,ti OR (soft NEXT/2 dressing*):ab,ti OR (rigid NEXT/2 dressing*):ab,ti OR 'weight bearing'/exp OR 'resistance training'/exp OR (removable NEXT/2 dressing*):ab,ti OR ('mental health' NEXT/2 screen*):ab,ti OR 'mental health care'/exp OR strengthening:ab,ti OR (flexibility NEXT/2 training):ab,ti OR 'peer support'/exp OR (contralateral NEXT/1 limb):ab,ti OR (skin NEXT/1 care):ab,ti OR (pain NEXT/1 management):ab,ti OR (edema NEXT/2 control*):ab,ti OR (fall NEXT/2 prevention):ab,ti OR (contracture NEXT/2 prevention):ab,ti OR 'physical education and training'/exp OR 'exercise'/exp OR 'kinesiotherapy'/exp OR 'physical activity'/exp OR 'exercise movement techniques'/exp OR 'exercise therapy'/exp OR 'self care'/exp OR 'physical therapy'/exp OR 'physiotherapy'/exp OR 'occupational therapy'/exp OR 'rehabilitation'/exp OR 'physical exertion'/exp OR 'physical exercise'/exp OR 'physical therapy modalities'/exp OR 'rehabilitation centers'/exp OR 'rehabilitation nursing'/exp OR 'rehabilitation patient'/exp
9	Combine Sets	1 AND (2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8)
10	Exclude Unwanted Publications	9 NOT (abstract:nc OR annual:nc OR 'book'/de OR 'case report'/de OR 'case study'/de OR conference:nc OR 'conference abstract':it OR 'conference paper'/de OR 'conference paper':it OR 'conference proceeding':pt OR 'conference review':it OR congress:nc OR 'editorial'/de OR editorial:it OR 'erratum'/de OR letter:it OR 'note'/de OR note:it OR meeting:nc OR sessions:nc OR 'short survey'/de OR symposium:nc)
11	Limit to Humans	Limit 10 to humans
12	Limit to English	Limit 11 to English
13	Limit by Publication Date	12 AND [2007-2016]/py

EMBASE.com Syntax:

* = truncation character (wildcard)

NEAR/*n* = search terms within a specified number (*n*) of words from each other in any order

NEXT/*n* = search terms within a specified number (*n*) of words from each other in the order specified

/ = search as a subject heading

exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)

mj = denotes a term that has been searched as a major subject heading

:de = search in the descriptors field (controlled terms and keywords)

:lnk = floating subheading

:it,pt. = source item or publication type

:ti. = limit to title

:ti,ab. = limit to title and abstract fields

Appendix G: Abbreviation List

Abbreviation	Definition
2MWT	two minute walk test
4SST	four square step test
6MWT	six minute walk test
10mwt	ten meter walk test
ABC	Activities-specific Balance Confidence Scale
ADL	activities of daily living
AHRQ	Agency for Healthcare Research and Quality
AMP	Amputee Mobility Predictor
AMPnoPRO	Amputee Mobility Predictor – no Prosthesis
AMPPRO	Amputee Mobility Predictor – with Prosthesis
AT	assistive technology
CARF	Commission on the Accreditation of Rehabilitation Facilities
CDC	Centers for Disease Control and Prevention
CHAMP	Comprehensive High-level Activity Mobility Predictor
COI	conflict of interest
CPG	clinical practice guideline
CS	comparative study
DoD	Department of Defense
DME	durable medical equipment
EBPWG	Evidence-Based Practice Work Group
FY	fiscal year
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HAI	Hill Assessment Index
ICF	International Classification of Functioning, Disability, and Health
IQR	interquartile range
IRF	inpatient rehabilitation facility
JC	Joint Commission
K(0-4)	Medicare functional levels
KQ	key question
LCI	Locomotor Capabilities Index
LLA	lower limb amputation
m	meter(s)
md	median
MeSH	Medical Subject Headings
MFCL	Medicare functional classification level
min	minutes
mn	mean
NICE	National Institute for Health and Care Excellence
OPUS	Orthotic Prosthetic User Survey
PCC	patient-centered care
PEQ-MS	Prosthesis Evaluation Questionnaire-Mobility Subscale
PICOTS	population, intervention, comparison, outcome, timing and setting
PLP	phantom limb pain

Abbreviation	Definition
PLS	phantom limb sensation
PTSD	posttraumatic stress disorder
PVD	peripheral vascular disease
RCT	randomized controlled trial
Rng	range
RRD	rigid removable dressing
SACH	solid ankle cushioned heel
SAI	stair assessment index
SDM	shared decision making
sec	second(s)
SNF	skilled nursing facility
SR	systematic review
SRRD	semi-rigid removable dressing
TACT	transdisciplinary amputation care team
TAPES	Trinity Amputation and Prosthesis Experience Scales
TFA	transfemoral amputation
TTA	transtibial amputation
TUG	timed up and go
US	United States
USPSTF	United States Preventive Services Task Force
VA	Department of Veterans Affairs
WA	walk aid
yo	years old

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