



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

**Department of Veterans Affairs** 

**Department of Defense** 

#### **Clinician Summary**

#### **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 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.

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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 health 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

The following recommendations were made using a systematic approach considering four domains as per the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach as detailed in the section on Methods and Appendix A in the full text LLA CPG. These domains include: confidence in the quality of the evidence, balance of desirable and undesirable outcomes (i.e., benefits and harms), patient or provider values and preferences, and other implications, as appropriate (e.g., resource use, equity, acceptability).

#	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 <sup>1</sup> ]).	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. F	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				

<sup>&</sup>lt;sup>1</sup> See the VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain. Available at: <u>http://www.healthquality.va.gov/guidelines/Pain/cot/</u>

#	Recommendation	Strength*	Category†				
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, patientsWeak forreceive physical rehabilitation and appropriate durable medicalequipment/assistive technology.						
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.						
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. F	Pre-Prosthetic Phase						
15.	<ul> <li>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.</li> </ul>						
D. I	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 offering further evaluation and interventions for factors that are associated with poorer outcomes such as smoking, comorbidities, psychosocial functioning, and pain.	Strong for	Reviewed, Amended				

\*For additional information, please refer to the section on Grading Recommendations in the full text LLA CPG.

<sup>+</sup>For additional information, please refer to the section on Recommendation Categorization and Appendix A in the full text LLA CPG.

#### III. Algorithm

The CPG follows an algorithm that is designed to facilitate understanding of the clinical pathway and decision making process used in rehabilitation of 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. Although the Work Group recognizes that not all clinical practices are linear, the simplified linear approach depicted through the algorithm and its format allows the provider to assess the critical information needed at the major decision points in the clinical process. It includes:

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

For each guideline, the corresponding clinical algorithm is depicted by 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.[2]

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.



#### A. Module A: Transdisciplinary Amputation Care Team Approach (TACT)

Abbreviations: TACT: Transdisciplinary Amputation Care Team

#### B. 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

## IV. Scope of the CPG

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 (versus a confrontational) 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]), observational studies, and diagnostic tests studies published between January 2007 and June 2016. It targeted 10 key questions (KQs) focusing on the means by which the delivery of healthcare could be optimized for patients during rehabilitation of LLA. The selected KQs 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.

# V. Guideline Work Group

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### VI. Patient-centered Care

VA/DoD CPGs encourage clinicians to use a patient-centered care (PCC) 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, PCC may decrease patient anxiety, increase trust in clinicians, [3] and improve treatment adherence. [4] 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.

# VII. 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.[5] 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.

# VIII. All Phases of Amputation Rehabilitation

#### **C. Patient Education**

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

Care and education for the patient with amputation 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. Clinicians should provide clear advice and information on, including but 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[6,7] (See the full VA/DoD LLA CPG for the Joint Commission's Performance Elements for Patient Education [8]).

#### D. Psychosocial Functioning

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

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 cope with psychological and social factors which influence his/her daily personal relationships, work, school, etc. In the case of a patient with LLA, this refers to how well the patient is able to carry on with his/her life despite his/her physical impairment. Periodic assessments of the patient should include inquiries into behavioral health status, social functioning, 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,<sup>2</sup> major depressive disorder,<sup>3</sup> PTSD and acute stress reaction,<sup>4</sup> or substance use disorder,<sup>5</sup> see the relevant VA/DoD CPGs.

#### E. Pain Management

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*)

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, when possible, it should be assessed with standardized and validated tools. Moderate evidence supports continuous assessment of pain throughout the perioperative and rehabilitation periods of individuals with LLA and assessments should include characteristics such as location, intensity, character, duration, timing, and aggravating factors or triggers.[9] These pain types include but are not limited to: residual limb pain, including neuropathic pain, phantom limb pain, 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.

Examples of standardized tools include:

- Visual Analogue Scale[<u>10</u>]
- Short Form McGill Pain Questionnaire[11]
- Pain Interference Scale[<u>12</u>]
- VA/DoD Pain Rating Scale<sup>6</sup>

<sup>&</sup>lt;sup>2</sup> See the VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide. Available at: <u>http://www.healthquality.va.gov/guidelines/MH/srb/</u>

<sup>&</sup>lt;sup>3</sup> See the VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder. Available at: <u>http://www.healthquality.va.gov/guidelines/MH/mdd/</u>

<sup>&</sup>lt;sup>4</sup> See the VA/DoD Clinical Practice Guideline for the Management of Post-traumatic Stress Disorder and Acute Stress Reaction. Available at: <u>http://www.healthquality.va.gov/guidelines/MH/ptsd/</u>

<sup>&</sup>lt;sup>5</sup> See the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders. Available at: <u>http://www.healthquality.va.gov/guidelines/MH/sud/</u>

<sup>&</sup>lt;sup>6</sup> See the Defense & Veterans Pain Rating Scale. Available at: <u>http://www.dvcipm.org/site/assets/files/1084/dvprs-front-vector.pdf</u>

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<sup>7</sup>]). (Weak for; Reviewed, New-replaced)

There are multiple pharmacological and non-pharmacological options for treating pain.[13] Given the heterogeneity of patient characteristics, there is likely to be variation in patient preference and response to treatments, therefore frequent adjustments to interventions should be considered.

There has been a recent shift in clinical practice away from long-term opioid use for chronic pain. In addition to the standard long-term harms from chronic opioid therapy (see relevant recommendations from the VA/DoD Opioid Therapy CPG<sup>7</sup> in <u>Table 1</u>), individuals with LLA may have several adverse effects to consider. Sedation and balance issues from opioids may impede the rehabilitation progress.

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

#### Table 1: Relevant 2017 VA/DoD OT CPG Recommendations

<sup>&</sup>lt;sup>7</sup> See the VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain. Available at: <u>http://www.healthquality.va.gov/guidelines/Pain/cot/</u>

2017 VA/DoD OT CPG Recommendation #	Recommendation	Strength of Recommendation
	<ul> <li>We recommend alternatives to opioids for mild-to-moderate acute pain.</li> </ul>	a) Strong for
	<ul> <li>b) We suggest use of multimodal pain care including non-opioid medications as indicated when opioids are used for acute pain.</li> </ul>	b) Weak for
18	<ul> <li>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.</li> <li>Note: Patient education about opioid risks and alternatives to</li> </ul>	c) Strong for

#### F. Gender Considerations

# 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)*

Although the majority of individuals with amputation in the United States are males, it is estimated that females make up to 35% of this population. [14] There are significant differences between male and female birth sex patients in areas such as successful prosthesis fitting, time in rehabilitation, use of coping selfstatements, and pain catastrophizing.[15-17] Evidence suggests prosthetic fitting is likely to be more successful for patients with a male birth sex compared to female birth sex.[15,16] Prosthetic satisfaction may depend on multiple factors, including socket comfort, function, and ability for the prosthesis to accommodate clothes and shoes, which is particularly challenging for patients with a female birth sex. Multiple factors influence prosthetic fit, including age, diagnosis of diabetes, and mean length of rehabilitation.[15,16] Women spend significantly more time in rehabilitation after successful fit of a prosthetic leg than men.[16] Women have also shown significantly greater use of coping self-statements compared to men.[17] Patients with female birth sex were significantly more likely to endorse beliefs related to personal control over pain, appropriateness of solicitous responses from others, and higher pain catastrophizing. Additional evidence reported that women are significantly more likely to have transfemoral amputations compared to men. [18] 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.

#### **G.** Peer Support

# 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*)

Involvement in some type of support program can be beneficial for both the patient and the family/caregiver.[<u>19</u>] The early involvement of family members and contact with other patients with amputations is important for the patient's psychological adjustment.[<u>20</u>] The Commission on the Accreditation of Rehabilitation Facilities (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.[19,21]

While initial introductory visits between a new patient and the peer visitor are best done in person, followup 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 peer visitor or support group.

## IX. Perioperative Phase

#### A. Preoperative Shared Decision Making

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)

Understanding the long-term implications of amputation level and residual limb length and working with the rehabilitation team to establish a plan can maximize the functional outcomes for the patient upon discharge. This understanding and team decision making needs to be initiated prior to surgery, when feasible, and should weigh factors surrounding the decision to amputate as well as the level and amputation. When setting goals and expectations, considerations of age, etiology, and comorbidities should be included, as they may influence the level of achievable outcomes for the patient.

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. The surgical procedure is often chosen based on the surgeon's preference and experience, or determined after a conversation between the surgeon and the patient, but 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.

Long-term functional outcomes, including improved walking ability, favor more distal amputation levels.[22-25] 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.[22,26] 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.

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

Of the various surgical procedures currently in use, only a few have been directly compared in nonrandomized observational studies (e.g., Burgess versus Ertl, Gritti-Stokes versus traditional transfemoral). No one procedure has been shown to be clearly superior to another or to lead to a clear advantage in prosthesis use.

#### B. Residual Limb Management

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)

Residual limb management is an important determinant of successful recovery from amputation.[27] Postoperative dressing strategies range from a simple soft gauze dressing and elastic wrap, to prefabricated semi-rigid and pneumatic sockets, to custom rigid dressings (removal and non-removable). Effective postoperative dressing management should maintain the integrity of the residual limb and should protect the residual limb, control and reduce edema, facilitate primary wound closure, maintain extension range of motion, and facilitate advancement to prosthetic fitting.

A soft dressing is viewed as 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.[27,28]

No studies found negative wound healing effects as a result of the application of rigid dressings.[29] 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 (IPOP)
- Prefabricated pneumatic IPOPs

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

#### C. Cognitive Screening

# 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)

Performing cognitive screening prior to rehabilitation may assist in development of appropriate goals and tailoring of the rehabilitation care plan. Cognitive function has associations with aspects of amputation rehabilitation and subsequent functioning.[30] 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.[30] Additionally, cognitive impairment is associated with a higher mortality rate and an undesirable variation in adherence to medical regimens for individuals with LLA.[30]

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.[30] 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.[30]

Cognitive assessment should always be coupled with continual reassessment of function and goals to help the patient reach their full functional potential. 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.

#### D. Durable Medical Equipment and Assistive Technology

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)

The benefits of implementing physical rehabilitation and the use of durable medical equipment (DME) and assistive technology (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 such items as wheelchairs, walkers, canes, residual limb supports, bedside commode, and tub transfer bench. 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.[<u>31,32</u>] Research also supports the use of DME and AT in the perioperative phase following amputation. 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.[<u>31,33</u>]

#### E. Inpatient Rehabilitation Program

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

Rehabilitation in an inpatient rehabilitation facility (IRF) has been shown to have distinct advantages compared to a skilled nursing facility (SNF). Patients that 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.[34-36] However, safety is often a concern with these patients; current evidence does not support making a recommendation for an acute inpatient rehabilitation setting rather than a SNF based upon safety alone.

#### F. Mobility Training

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)

Out-of-bed activities and mobility training in the early post-amputation period are generally well accepted rehabilitation practices. [32,37] 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. 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 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 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.[38] When the decision is made to utilize an early weight-bearing prosthetic device in the person with a transtibial level amputation, there are options for 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.[38]

#### G. Rehabilitation Training

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)

The intensity of the rehabilitation training intervention should be individualized to maximize the benefit and minimize potential complications of an exercise program with an inappropriate level of intensity for an individual. More intensive exercise-based interventions (part-to-whole resisted gait training and functional gait training) improve self-selected walking speed.[<u>39-41</u>]

Patient focus group feedback suggests that patients have increasing expectations for more robust rehabilitation following amputation and increased community reintegration. A higher level of reintegration requires strength, endurance, and skill. A main message from the patient focus group was for rehabilitation providers to use "real world" training and outcomes metrics tied to patients' preinjury level of function and evolving personal goals. Complex situations as noted by the patient focus group (e.g., walking through a crowded airport with luggage, 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 an 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.

Functional activities of daily living (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. Training should include these activities both with and without a prosthesis. Rehabilitation providers should provide an

opportunity for patients to discuss all aspects of functional ADLs, including challenges with being intimate with a significant other.

### X. 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*)

Microprocessor knees have been proven to reduce risk of falls and maximize patient satisfaction.[42,43] The prescription of microprocessor knees over non-microprocessor knees may improve an individual's ability to walk faster on level ground, walk more quickly on uneven surfaces, and descend more quickly downhill.[42] Falling is a major issue in patients with transfemoral amputations. The prescription of microprocessor knees is supported for individuals with complex medical conditions affecting balance as well as the geriatric population. These populations benefit from microprocessor knees, which have been demonstrated to decrease stumbles and prevent falls.[42]

There is insufficient evidence to support using one type of microprocessor knee over another, but the provider and patient should consider the many characteristics of each type of knee, especially the potential impact on the patient's functional level. Some knees may be best suited for the limited community ambulator while others are more appropriate for the highly active patient. A second consideration is the mechanism of charging the microprocessor knee; some have removable batteries and others have a port for a plug. A third consideration is 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.

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.

# XI. Prosthetic Training Phase

#### A. Functional Outcome Measures

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)* 

Using validated objective outcome measures throughout the rehabilitation process provides direct feedback to providers and patients regarding the efficacy of interventions and progress towards functional goals. When choosing from the numerous outcome measures available, it is important to first select a measure that evaluates the construct of interest.[44,45] Other issues to consider include the

administration burden to patient and provider, the level of measurement, availability of reference or normative values, and cutoff scores. 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. Finally, it is imperative to select measures that are sensitive or responsive to change to reflect a clearly different value when true patient change has occurred.

Outcome measures may be population-specific [46,47] or may have more general utility. The Amputee Mobility Predictor is a physical performance measure of functional mobility that takes approximately 15 minutes to administer. It provides ordinal scale data and has evidence of validity, reliability, and responsiveness.[48,49] Further, reference values are available to understand a patient's score relative to others of comparable etiology and functional level. If a clinician needs a more direct assessment of walking ability, several outcome measures may be more appropriate, including the 10-meter walk test, the 2- or 6-minute walk test, or others.[48-52] The latter tests are not population specific and also have some reference data available from patients with amputations and other diagnostic groups.[48-52] Refer to Table 2 for more information on physical performance measures.

#### **B.** Functional Outcome Assessments

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

Because rehabilitative care requires assessment of multiple domains including walking ability, balance, adjustment to prosthetic device use, quality of life, and others, multiple measures may be used to assess outcomes following LLA.[29,53] In addition to selecting outcome measures that are valid, reliable, and responsive, comparably robust measures from the patient's perspective are important to include. Some examples are the Locomotor Capabilities Index [54] and the Prosthesis Evaluation Questionnaire-Mobility Subscale,[55] both of which assess the patient's perception of their mobility capabilities. It may also be important to include an assessment of the patient's perceptions regarding their confidence with balance, in which case the Activities-specific Balance Confidence Scale will be useful.[56] See Table 3 for a list of patient-reported outcome measures to complement the outcome measures of physical functional performance in Table 2.

In addition to the measures in <u>Table 2</u> and <u>Table 3</u>, other domains may require assessment, such as the location, severity, and type of pain (e.g., low back, joint, phantom limb). Other phenomena that may require assessment include the number of stumbles, semi-controlled falls, or uncontrolled falls. This assessment may be included as part of a specific instrument or can be asked separately.[53,57,58]

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.

#### C. Evaluations and Interventions for Risk Factors

# 18. We recommend offering further evaluation and interventions for factors that are associated with poorer outcomes such as smoking, comorbidities, psychosocial functioning, and pain. *(Strong for; Reviewed, Amended)*

Further evaluations and interventions that address a patient's comorbidities improve the patient's overall health and functional outcomes after an amputation.<sup>[59]</sup> Additionally, there is an association between smoking and increased wound recurrence. Premorbid factors of chronic obstructive pulmonary disease,<sup>8</sup> congestive heart failure, myocardial infarction within the previous six months, renal disease on dialysis,<sup>9</sup> a positive "do not resuscitate" status, and a generally low premorbid functional status are associated with an increased mortality rate after amputation surgery. There is an association between the presence of comorbidities and functional outcomes after amputation.[60]

Vascular disease and smoking as well as overall health status can cause skin issues, impede post-operative wound healing, and lead to recurrence of wounds following surgery (see the VA/DoD Diabetes CPG).<sup>10</sup> This can delay the fitting of a prosthetic device and the ability of the patient to function with that device. It can also affect the patient's gait and pain levels. All of this leads to decreased functional status and patient satisfaction.

Clinicians should consider conducting a thorough medical assessment pre-operatively to evaluate the patient's physical condition, nutrition, infection risk, neuropsychiatric impairment,<sup>11,12</sup> drug or alcohol use,<sup>13</sup> 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.<sup>14</sup> General supportive counseling (e.g., eliciting and validating the patient's anxieties, fears, and concerns) may also be helpful. An additional consideration is the patient's weight; being overweight or underweight can impact the rehabilitation outcomes.<sup>15</sup> Fluctuations in weight can affect prosthetic fit.

<sup>&</sup>lt;sup>8</sup> See the VA/DoD Clinical Practice Guideline for the Management of Chronic Obstructive Pulmonary Disease. Available at: <u>https://www.healthquality.va.gov/guidelines/cd/copd/</u>

<sup>&</sup>lt;sup>9</sup> See the VA/DoD Clinical Practice Guideline for the Management of Chronic Kidney Disease. Available at: <u>https://www.healthquality.va.gov/guidelines/CD/CKD/</u>

<sup>&</sup>lt;sup>10</sup> See the VA/DoD Clinical Practice Guideline for the Management of Diabetes Mellitus in Primary Care. Available at: <u>http://www.healthquality.va.gov/guidelines/CD/diabetes/</u>

<sup>&</sup>lt;sup>11</sup> See the VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder. Available at: <u>https://www.healthquality.va.gov/guidelines/MH/mdd/</u>

<sup>&</sup>lt;sup>12</sup> See the VA/DoD Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Reaction. Available at: <u>https://www.healthquality.va.gov/guidelines/MH/ptsd/</u>

<sup>&</sup>lt;sup>13</sup> See the VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorder. Available at: <u>http://www.healthquality.va.gov/guidelines/mh/sud/</u>

<sup>&</sup>lt;sup>14</sup> See the VA/DoD Clinical Practice Guideline for the Diagnosis and Treatment of Low Back Pain. Available at: <u>http://www.healthquality.va.gov/guidelines/Pain/lbp/</u>

<sup>&</sup>lt;sup>15</sup> See the VA/DoD Clinical Practice Guideline for the Management of Obesity and Overweight. Available at: <u>https://www.healthquality.va.gov/guidelines/cd/obesity/</u>

	TUG	L-Test	AMPnoPRO	AMPPRO	4SST	Berg Balance Test	10MWT	2MWT	6MWT	HAI	SAI	СНАМР
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)

 Table 2. Measures of physical functional performance\*[29,46-49,51,58,61-75]

\*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; sec: second(s); TFA: transfemoral amputation; TTA: transtibial amputation; TUG: timed up and go; WA: walk aide; yo: years old

	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 [ <u>58</u> ]; TTA PVD 2.3; TFA Trauma 2.7; TTA Trauma 3.0	TFA PVD 2.2 [58]; TTA PVD 2.5; TFA Trauma 2.8; TTA Trauma 3.1 [65]: 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% [67]; Low Mobility <50%; Moderate Mobility 50-80%; Physically Active >80% [78]	Not applicable	Not applicable	Not applicable	Not applicable

#### Table 3. Patient reported outcome measures\* [49,54-56,58,65,67,76-78]

\*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

#### XII. Additional Resources

- Other VA/DoD Clinical Practice Guidelines:
  - Management of Chronic Kidney Disease in Primary Care; available at: <u>https://www.healthquality.va.gov/guidelines/CD/CKD/</u>
  - Management of Chronic Obstructive Pulmonary Disease; available at: <u>https://www.healthquality.va.gov/guidelines/cd/copd/</u>
  - Management of Diabetes Mellitus in Primary Care; available at: <u>http://www.healthquality.va.gov/guidelines/CD/diabetes/</u>
  - Diagnosis and Treatment of Low Back Pain; available at: <u>http://www.healthquality.va.gov/guidelines/Pain/lbp/</u>
  - Management of Major Depressive Disorder; available at: http://www.healthquality.va.gov/guidelines/MH/mdd/
  - Management of Opioid Therapy for Chronic Pain; <u>http://www.healthquality.va.gov/guidelines/Pain/cot/</u>
  - Management of Posttraumatic Stress Disorder and Acute Stress Reaction; available at: <u>http://www.healthquality.va.gov/guidelines/MH/ptsd/</u>
  - Management of Substance Use Disorder; available at: <u>http://www.healthquality.va.gov/guidelines/MH/sud/</u>
  - Assessment and Management of Patients at Risk for Suicide; available at: <u>http://www.healthquality.va.gov/guidelines/MH/srb/</u>
- Textbook of Military Medicine: Care of the Combat Amputee; available at: <u>http://www.cs.amedd.army.mil/Portlet.aspx?ID=3e4c64b4-3b35-483f-900b-a394a0ae45eb</u>

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