

Diabetic Foot Ulcer Beyond Wound Closure: Clinical Practice Guideline

Deborah M. Wendland¹ , PT, DPT, PhD^{1,*}, Elizabeth A. Altenburger, PT, MSPT, Certified Wound Specialist², Shelley B. Swen, PT, DPT, Certified Wound Specialist, Certified Lymphedema Therapist-Lymphology Association of North America³, Jaimee D. Haan, PT, MBA, Certified Wound Specialist⁴

¹Department of Physical Therapy, Mercer University, Atlanta, GA 30341, United States

²Rehabilitation Services, Academic Health Center and Saxony, Indiana University Health, Indianapolis, IN 46202, United States

³Desert Oasis Healthcare, Palm Springs, CA 92262, United States

⁴Rehabilitation, Wound Management and Fitness, Academic Health Center, Indiana University Health, Indianapolis, IN 46202, United States

*Corresponding author: Dr Wendland, Department of Physical Therapy, Mercer University, 3001 Mercer University Dr. Davis Building, Ste 100 Atlanta, GA 30341, United States (wendland_dm@mercer.edu)

ABSTRACT

A total of 37.3 million Americans have diabetes, and 96 million more have prediabetes. Hyperglycemia, the hallmark of diabetes, increases the risk for diabetes-related complications, including skin breakdown and cardiovascular disease. Many clinical practice guidelines exist, but there are gaps regarding the best approaches to assess physical fitness and mobility in adults with diabetes; incorporate exercise into the care plan; and reload the diabetic foot after ulcer closure has occurred to avoid ulcer reoccurrence. The purpose of this clinical practice guideline was to review and assess previously published guidelines and address gaps within the guidelines specific to the following: best screening tools/tests and interventions to prevent a future reulceration, best screening tools and interventions to assess and address mobility impairments, best tools to measure and interventions to address reduced physical fitness and activity, best approach to reloading the foot after ulceration closure and, finally, whether improvement in physical fitness will positively change quality of life and health care costs. The Guidelines Development Group performed a systematic literature search and review of the literature. A total of 701 studies were identified. Following duplicate removal and exclusion for irrelevance, 125 studies underwent full-text review, and 38 studies were included. Recommendations were developed using a software assistant created specifically for guideline recommendation development. Recommendations resulted for physical fitness and activity inclusion and measurement for adults with diabetes and with or without foot ulceration. Exercise and physical activity should be prescribed according to the physiologic response of an adult with diabetes to exercise and preferences for optimizing long-term quality of life and reduce health care costs. Reloading following diabetic foot ulcer closure should include maximal offloading, especially during the first 3 months; loading should be titrated using a footwear schedule. Further research is necessary in the areas of exercise in the wound healing process and the assessment of methods to reload a newly reepithelialized ulcer to prevent recurrence.

Lay Summary. This Clinical Practice Guideline recommends that physical fitness and activity are included and measured for adults who have diabetes with and without foot ulceration. Exercise and physical activity should be prescribed according to the individual's current condition, physiologic response to exercise, and preference to optimize long-term quality of life and reduce health care costs.

Key words: Clinical Guidelines; Diabetes Mellitus; Diabetic Foot

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INTRODUCTION

Diabetes continues to cause significant mortality and debility worldwide. In 2019, diabetes was the seventh leading cause of death and a major contributor to the world's leading cause of death, cardiovascular disease. The *National Diabetes Statistics Report* of the Centers for Disease Control and Prevention states that 37.3 million Americans have diabetes and another 96 million people have prediabetes.¹

Hyperglycemia, a hallmark of diabetes, puts people at an elevated risk for diabetes-related complications. Included among complications of diabetes are vascular (micro and macro) changes as well as changes to the nervous system. Together, these changes increase the risk for plantar ulceration in people with diabetes. As many as 34% of people with diabetes experience plantar ulceration over their lifetimes.² Furthermore, those who have diabetic foot ulcerations that heal are at high risk for reulceration. Risk is highest immediately following wound closure, with 40% reulcerating within 12 months. Over 3 years, nearly 60% of people experience reulceration.²

Given the prevalence of diabetes and the impact of the disease on morbidity, health care providers must understand and have guidance on the most effective means of preventing and limiting the long-term comorbidities related to diabetes.^{3,4} In reviewing the major causes of hospitalizations for people with diabetes, the second most common discharge diagnosis after hospitalization is lower extremity amputation, which usually is preceded by a diabetic foot ulcer (DFU).⁵ Although numerous clinical practice guidelines (CPGs) exist for healing a DFU, there are gaps regarding how to best assess physical fitness and mobility in adults with diabetes and with or without a DFU; incorporate exercise into the care plan to effectively aid in the control of glycemia, either in preventing an ulcer or while managing an ulcer; and reload the diabetic foot after ulcer closure to avoid ulcer reoccurrence.^{6–10}

In the *Standards of Care in Diabetes—2023*, physical activity recommendations were given as part of the overall diabetes prevention recommendations.³ These recommendations listed physical activity as a component of obesity and weight management for the prevention and treatment of type 2 diabetes but did not specifically discuss how to incorporate physical activity into a plan of care for an adult with an ulcer or how to return to physical activity after ulcer closure.³ These guidelines also did not discuss assessing overall mobility as an adult with diabetes ages.⁴ Similarly, other guidelines regarding diabetes care for adults with a DFU, at risk for a DFU, or with a history of a DFU do not sufficiently address or provide tools for the management of fitness in patients with diabetes and skin concerns.^{6–8} What is not known is whether individual studies, reviews, or meta-analyses have tested or evaluated the answers to these important clinical questions, particularly in the context of a healing or closed DFU.

The purpose of this review was to assess previously published guidelines and address gaps within the guidelines specific to the following: best screening tools/tests and interventions to prevent an initial DFU or future reulceration, best screening tools and interventions to assess and address mobility impairments, best tools to measure and interventions to address reduced physical fitness and activity, best approach to reloading the foot after ulceration closure and, finally, whether improvement in physical fitness will positively change quality of life and health care costs. The authors believe that management of the DFU itself for healing has

been appropriately addressed in earlier CPGs. The CPG action statements resulting from this review are shown in [Table 1](#).

METHODS

Guideline Development Group

The American Physical Therapy Association (APTA) Academy of Clinical Electrophysiology and Wound Management (ACEWM) commissioned the development of an evidence-based CPG to address the paucity of information regarding people with a DFU related to areas that physical therapists address. Members of the ACEWM attended the CPG Workshop and began the process of developing a Guideline Development Group (GDG). Initially there were 2 physical therapists who were Certified Wound Specialists (E.A.A.) and another physical therapist in an academic position with a research agenda related to DFUs (D.M.W.). An additional physical therapist who was a Certified Wound Specialist and who had attended the CPG Workshop the previous year (J.D.H.) was also included in the initial group. To add breadth to the team, another physical therapist academician with expertise in ankle-foot management was added. Over the course of working on this document, 2 of the physical therapist members retired, 1 of whom agreed to continue as a consultant member. After the first member of the GDG retired, a new physical therapist who was a Certified Wound Specialist was added to the group (S.B.S.).

Review Team

At the time of the CPG Workshop, a number of stakeholders were identified to serve as members of the external review team. These members were included to add depth and breadth of expertise and included a patient, physician, podiatrist, physical therapist clinicians from other specialization areas as well as those with expertise in the field of DFU care. Some specific members of this group changed due to availability, but the general group make-up remained.

CPG Review: The ADAPTE Process

Following review of CPGs related to the management of DFUs and published up to the year 2015 ([Suppl. Material 1](#)), research questions were developed to address gaps in guidance within the existing CPGs. Research questions were determined following review of current practice guidelines. The intent of this CPG was to adapt current guidelines to assist in clinical practice decision-making surrounding the care of people with diabetes and foot ulceration that was not presently being addressed by any previously published CPG. The ADAPTE process uses the Appraisal of Guidelines for Research & Evaluation II (AGREE II) tool, which is an international tool designed to assess the quality of CPGs. Assessment is performed in 6 domains (scope and purpose; stakeholder involvement; rigor of development; clarity of presentation; applicability; and editorial independence) using a 7-point numerical scale, with 7 being the highest score.¹¹ When possible, feedback was addressed. Using the AGREE II tool, National Institute for Health and Care Excellence⁸ and Registered Nurses' Association of Ontario⁹ CPGs were determined to sufficiently guide wound management concerns in people with diabetes and foot ulceration and were accepted for the ADAPTE process. In 2017, the following questions were developed to facilitate additional clinical decision-making guidance in areas that were insufficiently addressed.

Table 1. Recommendations and Action Statements

Recommendation	Action Statement	Evidence Quality	Strength of Recommendation
I	Physical therapists and other health care providers who prescribe exercise for adults with a diabetic foot ulcer may prescribe interventions to maintain cardiovascular health and muscular fitness while minimizing weight bearing on the foot. In addition, an assistive device may be used as needed to improve balance and further reduce weight bearing in an adult with a current diabetic foot ulcer.	D	Weak
II	Physical therapists and other health care providers who evaluate physical fitness in adults with diabetes should measure physical fitness, including flexibility, strength, cardiorespiratory fitness, balance, and motor agility (evidence quality: C; recommendation strength: weak), AND may measure the level of physical activity, such as step counting and standing, across the continuum of care of an adult with diabetes.	D	Weak
IIIa	Physical therapists and other health care providers who prescribe exercise should prescribe a progressive moderate- to vigorous-intensity exercise program including aerobic and resistance training to adults with diabetes after considering the patient's disease state and limits for exercise AND depending on the patient's physiologic response to exercise in accordance with the patient's preference and resources.	A	Strong
IIIb	Physical therapists and other health care providers who prescribe exercise may use activity monitor-based counseling to increase physical activity.	B	Moderate
IV	Physical therapists and other health care providers managing closed diabetic foot ulcers may titrate tissue reloading (eg, standing, walking) on a newly closed diabetic foot ulcer, maintaining moderate to maximal offloading, especially during the first 3 months, and slowly titrating a return to shoe wear using a wear schedule.	D	Weak
V	All health care providers should encourage aerobic exercise, strength training, and/or physical activity for adults who have diabetes and can exercise safely to optimize long-term quality of life as well as reduce health care costs.	C	Weak

1. In an adult with diabetes, what are the best screenings/tests and measures to prevent initial foot ulceration?
2. In an adult with diabetes, what are the best interventions to prevent initial foot ulceration?
3. What are the best interventions to reduce the risk of future ulcerations?
4. In an adult with diabetes, what are the best test/measures to assess mobility impairments?
5. In an adult with a current diabetic foot ulcer, what are the best interventions to address mobility impairments?
6. Across the continuum of care of an adult with diabetes, what are the best tests and measures to assess physical fitness and activity?
7. Across the continuum of care of an adult with diabetes, what are the best interventions to address reduced physical fitness and activity?
8. What are the best methods to progressively load tissue after ulceration closure to prevent recurrence in adults with diabetes?

9. In an adult with diabetes, do physical fitness and activity optimize long-term quality of life as well as reduce health care costs?

Literature Search Strategy

In consultation with a medical librarian at Indiana University Health, search terms and a search strategy were identified to address each of these research questions. The following databases were searched according to the preestablished search terms (Suppl. Material 2): PubMed (MEDLINE) and Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search dates were inclusive from “1946 until present” when the searches were undertaken. Articles were restricted to human studies and English language only. References were reviewed for potential additional articles. The searches were initially carried out in January 2018. Over the time required during the first review process for this CPG, updates to other DFU-related CPGs were published.

Table 2. Questions 5 Through 9 Described in Population, Intervention, Comparator, and Outcome Terms^a

Question	Population	Intervention(s)	Comparator(s)	Outcome(s)
5	Adults with diabetes and current foot ulceration	Various fitness/exercise routines with various intensities, including aerobic and resistance training	No change in exercise or standard exercise used as an alternative exercise	Improved mobility in the context of wound healing
6	Adults with diabetes	Not applicable	Not applicable	Psychometric properties of tests and measures assessing physical fitness and activity
7	Adults with diabetes	Various fitness/exercise routines with various intensities, including aerobic and resistance training	No change in exercise or standard exercise used as an alternative exercise	Physical fitness (eg, VO ₂ max, VO ₂ peak, % METs, sit-to-stand test, 6-Min Walk Test, and blood pressure)
8	Adults with diabetes and closed ulceration	Progressive reloading of recently closed ulceration	Lack of progressive reloading of recently closed ulceration	Presence or absence of ulcer recurrence
9	Adults with diabetes	Physical fitness and activity	Lack of physical fitness and activity	Measures of quality of life; health care costs

^a % METs = metabolic equivalents, measured as percentages; VO₂max = maximum oxygen consumption; VO₂peak = peak oxygen consumption.

In 2019, the International Working Group on the Diabetic Foot (IWGDF)⁶ published their CPG update, which the GDG reviewed using the AGREE II tool. The GDG determined that questions 1 to 3, which were specific to the prevention of an initial ulcer or reulceration, were sufficiently addressed by the updated IWGDF CPG. These questions were then removed from this work as the IWGDF guidance for this area was accepted as put forth within their 2019 guideline (ADAPTE process). After the literature review for question 4 found no research specifically addressing assessment of mobility impairments for adults with diabetes, the GDG reviewed the CPG developed through the Academy of Neurological Physical Therapists to guide outcome measure selection for people with neurologic conditions.¹² The GDG decided to move this CPG into the ADAPTE process and used the AGREE II tool. The GDG determined that the CPG adequately guided the assessment of mobility impairments for people with diabetes, who often have neurologic involvement affecting their function. Thus, question 4 was also removed. The searches were rerun in March/April 2022 and again in February 2023 for the remaining questions (5–9) (Table 2) to locate any additional literature published since the last search. Only data from questions 5 to 9 will be reported in this CPG.

Studies to be included from the literature search were experimental, randomized controlled trials (RCTs), systematic reviews, meta-analyses, and diagnostic or prognostic retrospective studies. Reviews that were nonsystematic, descriptive studies, case reports, and nonscientific papers were excluded. The population was limited to adults with diabetes, but the type of diabetes was not specified (Table 3).

Literature Review and Extraction

Covidence software (Veritas Health Innovation; www.covidence.org) was used for all of the literature reviews. Literature search results were imported into Covidence software, which removed study duplicates. Then, the titles and abstracts were independently reviewed by 2 reviewers using inclusion and exclusion criteria (Table 3). If the determination of the

reviewers was conflicting, then the reviewers came to consensus through discussion. If consensus could not be achieved, then “maybe” was selected. Both “yes” and “maybe” studies were moved forward in Covidence for full article review. Full-text reviews were completed by 2 independent reviewers for inclusion or exclusion. If exclusion was chosen, then the reason for exclusion was given. Any disagreements between reviewers, including reasons for exclusion, were discussed so that consensus could be achieved. Once an article was included, the studies were reviewed for risk of bias (quality appraisal) as well as for extraction of data. Studies were reviewed by 2 reviewers, and consensus on outcome was achieved through discussion. If consensus could not be achieved, then a third reviewer, a member of the GDG who served as the question champion, served as the tiebreaker. Data extraction was completed by the person serving as the tiebreaker. The accuracy of extraction was checked by the other reviewers.

Quality Appraisal

Quality appraisal was completed consistent with the *APTA Clinical Practice Guideline Process Manual*,¹³ except that the Physiotherapy Evidence Database was used to assess interventional studies, namely, RCTs.¹⁴ Systematic reviews were assessed using A Measurement Tool to Assess Systematic Reviews,¹⁵ diagnosis studies and cohort studies were assessed using a Scottish Intercollegiate Guidelines Network checklist,¹⁶ studies of measurement tools were assessed using the Consensus-Based Standards for the Selection of Health Measurement Instruments,¹⁷ and prognosis studies were assessed using the Best Bets tool.¹⁸

Article appraisal was undertaken by members of the GDG team. Additional reviewers were trained to use the Physiotherapy Evidence Database appraisal measure. Once training was completed and reviewers were consistent in their reviews, they were assigned interventional studies to review in pairs. All reviews were completed in duplicate such that consensus was achieved as described above.

Table 3. Title and Abstract Review Guidelines^a

Parameter	Description
Exclusion criteria	Nonadults or adults without diabetes Nonscientific articles: opinion papers, case reports, case series Descriptive studies Nonsystematic literature reviews Non-English articles Animal studies Participants younger than 18 years
Inclusion criteria, including quality appraisal tool to be used	Adult population Experimental studies RCTs (PEDro) Systematic reviews (AMSTAR 2) Meta-analyses (AMSTAR 2) Retrospective studies (choice of diagnostic or prognostic) Diagnostic/prognostic studies (SIGN)
Terms for exclusion of articles	Wound care (treatment of ulcer) Pediatric population Case studies Non-peer-reviewed studies

^aAMSTAR 2 = measurement tool to assess systematic reviews; PEDro = Physiotherapy Evidence Database; RCTs = randomized controlled trials; SIGN = Scottish Intercollegiate Guidelines Network.

Table 4. Definitions of Levels of Evidence^a

Level of Evidence	Definition
I	Evidence from high-quality systematic reviews, diagnostic studies, prospective studies, or RCTs
II	Evidence from lower-quality diagnostic studies, prospective studies, or RCTs
III	Evidence based on retrospective or case-control studies
IV	Evidence based on case series studies
V	Expert opinion

^aRCTs = Randomized controlled trials.

Each article was given a level of evidence, and the body of literature reviewed for each question was graded in a manner consistent with the *APTA Clinical Practice Guideline Process Manual*.¹³ Brief summaries of the meanings of levels of evidence and the grading of evidence are shown in [Tables 4](#) and [5](#), respectively.

Data Analysis

The original literature search was completed in March 2018, and repeat searches to ensure inclusivity of all studies were completed in March 2022 and again in February 2023. Articles were imported into Covidence software according to each question. Covidence software removed any duplication of literature within each question. Additional studies were removed because they were irrelevant through review of the title and abstract. The remaining studies underwent full-text review for inclusion. During the review process, IWGDF published new guidelines that included information answering questions 1 to 3.⁶ Question 4 was answered by a new guideline published by the Academy of Neurological Physical Therapists.¹² These questions were moved out of the guideline since the ADAPTE model was being used ([Table 6](#), which combined the content of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses + diagrams).

Development of Action Statements

Action statements were developed using Building Recommendations in a Developer's Guideline Editor (BRIDGE-Wiz) software; this software was developed to aid in the

authoring of unambiguous and actionable guidelines.¹⁹ The CPG development team worked through the process as a group following completion of article quality appraisal and extraction. Findings will follow with the action statement recommendations listed first, according to each question.

External Review Process

The external review process was consistent with that described by the *APTA Clinical Practice Guideline Process Manual*.¹³ The process was designed to facilitate a comprehensive, quality report while mitigating risk for bias or lapses in process. At the outset of the project, stakeholders were identified; they included a patient, representatives from medicine and podiatry, physical therapists from other specialization areas, and experts in DFU management (defined as people who have published in this area of practice). Additionally, methods experts were consulted. The draft document was sent to a group representing the above stakeholders for review, editing, and open comment. The feedback was taken and incorporated into the draft. The document was externally reviewed by representatives from the ACEWM, a CPG methodology expert, and association partners. The feedback from this body and any other delayed feedback were addressed, and the subsequent document was posted on the ACEWM website for public comment and review. Invitations for the public comment/review of the document were included in the ACEWM monthly newsletter, eblasts, and social media. Both ACEWM members and nonmembers were able to review and provide feedback. Suggested feedback

Table 5. Grading of Evidence^a

Grading of Evidence	Associated Level of Obligation	Definition
A	Strong	Recommendation based on high certainty for at least a moderate benefit/cost (based on level 1 or 2 evidence predominating)
B	Moderate	Recommendation based on high certainty for a slight or moderate benefit/cost or moderate certainty that benefit/cost is moderate (based on level 2 evidence predominating or 1 high-quality randomized controlled trial)
C	Weak	Recommendation with moderate certainty for slight benefit/cost or weak certainty for moderate benefit/cost (based on level 2–5 evidence)
D	Theoretical	Recommendation supported by basic science (not clinical trials) or peer-reviewed, published expert opinion
P	Best practice	Practice recommendation according to practice norms in which there is a clear benefit; expert opinion
R	Research	Limited/absent evidence or equivocal conclusions on present research

^aModified from Table 7 in the APTA Clinical Practice Guideline Process Manual.¹³

Table 6. Question Status and Literature Included

Question	No. of Initial Studies Found	No. of Studies Excluded Because of Duplication	No. of Studies Excluded Because Irrelevant	No. of Studies in Which Full-Text Review Was Completed	No. of Remaining Studies
1 ^a					
2 ^a					
3 ^a					
4 ^b					
5	268	18	246	4	3
6	117	0	85	32	1
7	71	1	38	32	28
8	107	5	64	38	0
9	138	3	116	19	6

^aRemoved because adequately addressed by the International Working Group on the Diabetic Foot 2019 guideline.⁶ ^bRemoved because adequately addressed by the Academy of Neurological Physical Therapists outcome measure guideline.¹²

and edits were considered and incorporated as appropriate. The document was submitted to *PTJ: Physical Therapy & Rehabilitation Journal* for editorial review concurrently to the secondary reviews and public feedback process. Comments were addressed.

Role of the Funding Source

APTA provided funding to support the development of this CPG. In addition, APTA's CPG Process Manual was used to guide its development. The views expressed do not necessarily reflect the official views of APTA.

ACTION STATEMENTS

QUESTION 5

In an adult with a current diabetic foot ulcer, what are the best interventions to address mobility impairments?

Recommendation I

Physical therapists and other health care providers who prescribe exercise for adults with a DFU may prescribe interventions to maintain cardiovascular health and muscular fitness while minimizing weight bearing on the foot. In addition, an assistive device may be used as needed to improve balance and further reduce weight bearing in an adult with a current DFU (evidence quality: D; recommendation strength: weak).

Aggregate Evidence Quality

This is rated as D level or theoretical evidence (Table 5). Two systematic reviews and 1 scoping review that addressed a broader physical activity in adults with a DFU rather than explicitly mobility impairments were included. The evidence within these reviews was thus described as theoretical.

Benefits

Prescribed exercise may preserve functional capacity, minimize trauma, improve wound healing, and reduce risk of falls.

Risk, Harm, and Cost

There are potential costs related to the cost of the assistive device, overall wound treatment, and any lost income due to participating in an exercise program.

Benefit-Harm Assessment

There is a preponderance of benefit.

Value Judgments

The guiding principle behind the question development was to help health care providers optimize the physical fitness and activity of adults with a current DFU without harming the wound healing process. This is not widely considered a priority in adults with these medically complex issues, but we recommend that physical therapists and other health care providers who prescribe exercise consider developing exercise

programs for this population as the long-term impact on cardiovascular health and muscular fitness is a significant benefit.

Intentional Vagueness

The developers were intentionally vague about which interventions to use due to the lack of evidence supporting specific interventions. Three systematic reviews published between 2000 and 2023 assessed research of therapeutic exercise for adults with a DFU. All 3 systematic reviews found that there is a need for well-conducted RCTs to guide specifically which interventions are best to improve the cardiovascular health and muscular fitness of these adults without harming the healing response of the DFU.^{20–22} In addition, the developers expect that clinicians will select interventions that address each individual person's needs and goals. [Supplementary Material 3](#) shows an example for how fitness could be improved or maintained while in the period of offloading.

Role of Patient Preferences

Although the spectrum of exercise intervention is limited due to the need to minimize weight-bearing on the foot, exercise program prescription still should incorporate an adult's preferences to increase adherence and therefore optimize outcomes.²³

Exclusions

Modifications should be made for any adult with disease conditions that contraindicate a specific exercise intensity. Further, exercise should be performed only by adults within safe glycemic ranges. Colberg et al²⁴ provide detailed guidance on the management of glycemia with exercise.

Implementation and Audit

Clinicians may consider incorporating exercise prescriptions into the electronic medical record (EMR) as part of the complete plan of care for patients. Using scripted phrases or drop-down menu choices may increase implementation and improve standardization to allow for better auditing of outcomes. Finally, an annual audit of clinician inclusion of exercise prescription in the care plan for an adult with a DFU would reinforce implementation.

Research Recommendation

Research is needed to determine the most effective interventions to use while prescribing exercise for adults with a DFU. Although there is broad agreement that adults with diabetes benefit from exercise, there is little guidance on which interventions will provide that benefit while protecting the foot ulcer.

Supporting Evidence and Clinical Interpretation

In 2022, Brousseau et al²⁰ published a scoping review to determine the impact of physical activity on adults with a DFU. Although they identified 19 articles from 17 studies, they were unable to make specific recommendations due to the lack of research, especially RCTs, with strong methodology. They specifically called for high-level RCTs focused on physical activity prescription as there is no evidence to guide the components of physical activity. In 2022, Aagaard et al²¹ made similar recommendations in their systematic review that specifically looked for the impact that exercise has on health-related quality of life (HRQOL) compared to the risk of harm

that exercise may have on the DFU. Although there were 10 research articles related to exercise for adults with a DFU, none reported the impact on HRQOL, and the methodology did not allow for reliable conclusions related to exercise and harm. Finally, the systematic review of Wendland et al²² investigated the evidence of whether to determine if exercise, physical activity, walking step characteristics, or limb loading affects healing outcomes in people with a DFU. Secondly, they looked at whether the quantity of exercise, stepping activities, or limb loading affect the length of time to wound closure in people with a DFU. Because of large variation in step activity and group metrics, it was determined that no specific exercise recommendations could be made, although exercise appeared to facilitate more rapid DFU healing. All 3 of these articles made consistent recommendations for more research on the effect of exercise on wound healing.

QUESTION 6

Across the continuum of care of an adult with diabetes, what are the best tests and measures to assess physical fitness and activity?

Recommendation II

Physical therapists and other health care providers who evaluate physical fitness in adults with diabetes should measure physical fitness, including flexibility, strength, cardiorespiratory fitness, balance, and motor agility (evidence quality: C; recommendation strength: weak), AND may measure the level of physical activity, such as step counting and standing, across the continuum of care of an adult with diabetes (evidence quality: D; recommendation strength: weak).

Aggregate Evidence Quality

There was a single, level II article assessing the psychometric properties of tests of physical fitness, including physical function.²⁵ This article lacked blinding and had <80% follow-up among the participants. This is rated as C level or weak evidence.

Measuring the level of physical activity has been suggested by published expert opinion as being helpful in increasing physical activity. This is rated as D level or theoretical evidence.²⁶

Benefits

Measuring the physical fitness of a patient may facilitate the identification of a change in fitness that can affect functional ability and diabetes management. Early identification of decreased physical fitness provides a benefit to the patient and provider.

Measuring the physical activity of a patient may facilitate the identification of changes in activity that may indicate progression of the disease, new risk for falls, ulcerations, or functional decline.

Risk, Harm, and Cost

No adverse events were reported in the study of Alfonso-Rosa et al.²⁵ When assessing various components of physical fitness, there is a risk that an individual could experience a fall or injury during testing. This risk is mitigated by careful training and the inclusion of safety behaviors learned as a part of physical therapist education.

Table 7. Psychometric Data for Assessment of Fitness, Including Physical Function^{25,a}

Fitness Test(s) Assessed	Construct Measured	Relative Reliability Parameter and Score		Parameter of Measurement Error		% SEM	% CV
		ICC	95% CI	SEM	MDC		
Handgrip strength test	Upper body muscular strength	0.98 (dominant arm)	0.95–0.99	1.4	3.89 kg	5.2	10.62
Handgrip strength test	Upper body muscular strength	0.98 (nondominant arm)	0.96–0.99	1.56	4.32 kg	6.3	10.52
Handgrip strength test	Upper body muscular strength	0.98 (bimanual grip strength, kg)	0.96–1.00	1.49	4.13 kg	5.8	9.55
Right chair sit and reach test, cm	Lower body flexibility	0.94	0.84–0.98	2.7	7.5 cm	22	39.22
Left chair sit and reach test, cm	Lower body flexibility	0.93	0.82–0.97	3.25	9.01 cm	26.4	47.56
Timed “Up & Go” Test	Motor agility/mobility	0.98	0.95–0.99	0.31	0.85 s	3.5	6.46
6-Min Walk Test	Cardiorespiratory fitness	0.99	0.96–1.00	9.88	27.37 m	2.5	5.12
30-s sit-to-stand test	Lower body strength	0.92	0.79–0.98	1.21	3.35 times	9.6	17.6

^aCV = coefficient of variation; MDC = minimal detectable change; SEM = standard error of measurement.

The cost to the individuals who undergo testing is primarily their time and effort to be tested, including transport to the facilities for testing. If activity monitoring is employed, cost is in the device itself and potential risk for skin issues from the device, depending on the device used.

Benefit-Harm Assessment

There is a preponderance of benefit.

Value Judgments

Monitoring physical fitness in adults with diabetes as they age will positively affect the quality of their health. Using consistent physical fitness testing tools that have been psychometrically tested for a population with type 2 diabetes, particularly those with minimal detectable change (MDC) values, is helpful to recognize fitness change in this population. We recommend that standardized protocols be used to support the reliability of these tests across time and individual patient care episodes (Table 7).

Intentional Vagueness

The recommendation of who should evaluate the physical fitness of this population was intentionally vague to allow for inclusivity of all qualified health care providers. The type of fitness testing and activity monitoring within the recommendation was intentionally vague due to limited research to guide more specific recommendations. The studied tests are included in the supporting evidence and in Table 7 to provide some direction for clinicians.

Exclusions

Clinicians should use their clinical judgment when selecting tests and outcome measures. Certain tests should not be performed if contraindicated by the person's disease state. Care should be taken in cases in which balance is compromised. Tests should not be performed if contraindicated (eg, ambulatory test in the presence of a plantar DFU).

Implementation and Audit

Clinicians and facilities should establish competencies of physical fitness tests, including tests of physical function, before

performing them with their patients with diabetes. Alfonso-Rosa RM et al²⁵ provide specific tests descriptions. Annual training and practice could help facilitate excellent reliability with the performance of acceptable tests, including the handgrip strength test, chair sit and reach test (CSRT), the Timed “Up & Go” (TUG) Test, the 6-Min Walk Test (6MWT), and the 30-s sit-to-stand (30STS) test. Clinicians may also consider incorporating exercise prescriptions into the EMR as part of the complete plan of care for patients. Using scripted phrases or drop-down menu choices may increase implementation and improve standardization to allow for better auditing of outcomes. Finally, an annual audit of clinician use of performance testing would reinforce implementation.

Supporting Evidence and Clinical Interpretation

Selecting outcome measures with established psychometric properties is helpful to determine when actual change has occurred and whether that change is clinically relevant. Some tests which assess physical fitness, including physical function, have been assessed for psychometric properties in people with type 2 diabetes. Included among these tests are the handgrip strength test, the CSRT, the TUG Test, the 6MWT, and the 30STS test.²⁵ A high ICC as a measure of relative reliability using a test-retest design were found for all the tests assessed. Additionally, MDC scores were determined for each of the tests as well. Table 7 shows specific psychometric properties.²⁵

The handgrip strength test can be used, with excellent relative reliability, to assess upper extremity strength on both the dominant and nondominant sides. MDCs of 3.85 kg (dominant upper extremity), 4.32 kg (nondominant upper extremity), and 4.13 kg for bimanual testing were noted. The hand grip strength test is feasible because it requires commonly available equipment (handheld dynamometer) in clinical settings. The time required to administer the test is <5 min, including the minute of rest required between measures.²⁵

The CSRT can be useful to test lower extremity flexibility with excellent reliability for both sides. The MDCs were 7.50 cm for the right side and 9.01 cm for the left side. This test

is clinically feasible since it only requires a ruler and a chair for the individual to sit in. It takes <5 min to administer.²⁵

The TUG Test can be used to assess motor agility and general mobility (physical fitness and physical function) and has excellent relative reliability and an MDC of 0.85 s. These values, along with the short testing time (<5 min) and minimal required equipment, make this test clinically feasible.²⁵

The 6MWT can be used to assess the cardiovascular fitness of an individual. In individuals with type 2 diabetes, the test was shown to have excellent relative reliability and an MDC of 27.37 m. The 6MWT is feasible to assess cardiovascular fitness. It requires only a stopwatch and a hallway, both consistently available in clinics. This test takes <10 min to perform.²⁵

The 30STS test can be used to assess the strength of the lower extremities. The relative reliability of the test has been shown to be excellent. Furthermore, the MDC was found to be 3.35 repetitions. This test was feasible for its limited requirements, including short time frame. Additionally, unlike other similar tests, the completion of any repetitions will provide useful information.²⁵

A perspective paper addressing physical training and activity in people with diabetes and peripheral neuropathy suggests that baseline activity levels, from which to increase activity, may be quantified using an activity monitor.²⁶ Additionally, a meta-analysis has shown the use of activity monitors to be helpful in promoting physical activity.²⁷

Related Outcome Measures

There is a difference of opinion on which outcome measure to use for assessment. Other outcome measures have been used clinically to assess physical fitness; these include submaximal and maximal exercise testing (eg, treadmill tests, cycle tests),^{28–32} strength tests (eg, 1-repetition maximum, strength dynamometry),³³ walking tests of various durations (eg, 10-m shuttle),³⁴ and other sit-to-stand tests (eg, 10 times sit-to-stand or 5 times sit-to-stand).³⁵ These tests do not have available psychometric properties for a population with type 2 diabetes, including MDC scores. These tests may be more feasible depending on the patient's fitness level (eg, a 2-min walk test rather than a 6MWT for someone who is deconditioned).

Research Recommendation

Studies are needed to assess the psychometric properties of other physical fitness–related outcome measures, such as the 5 times sit-to-stand, in a population with diabetes (including both type 1 and type 2 diabetes). Further study on the psychometric properties of the tests included within the study (handgrip strength test, CSRT, TUG Test, 6MWT, and 30STS test) should be undertaken to include a population that is more generalizable to the population of interest.

Studies are needed to assess specific activity monitors for their feasibility, reliability, and accuracy for assessing physical fitness and activity in a population with diabetes.

QUESTION 7

Across the continuum of care of an adult with diabetes, what are the best interventions to address reduced physical fitness and activity?

Recommendation IIIa

Physical therapists and other health care providers who prescribe exercise should prescribe a progressive moderate- to vigorous-intensity exercise program including aerobic and resistance training to adults with diabetes after considering the patient's disease state and limits for exercise AND depending on the patient's physiologic response to exercise in accordance with the patient's preference and resources (evidence quality: A; recommendation strength: strong).

Recommendation IIIb

Physical therapists and other health care providers who prescribe exercise may use activity monitor–based counseling to increase physical activity (evidence quality: B; recommendation strength: moderate).

Aggregate Evidence Quality

Evidence for Recommendation IIIa included reports from 16 different RCTs^{28,29,31,33,34,36–48} and 3 meta-analyses.^{32,49,50} An additional 6 studies were interventional.^{30,51–55} Because of the meta-analyses and RCTs, level I and II evidence predominated. This is rated as A level, or strong evidence, and risk of bias information can be found in Table 8. Evidence supporting Recommendation IIIb was a single meta-analysis that included 21 studies reporting activity monitor–based counseling in people with type 2 diabetes.²⁷ Because of the lower quality of studies included within this meta-analysis, the evidence quality is rated as B or moderate evidence.

Benefits

The benefit of including exercise, both aerobic and resistance training, to people who have diabetes, is improved cardiorespiratory fitness and strength. Using activity monitor–based counseling may also be effective for increasing physical activity.²⁷

Risk, Harm, and Cost

The risks associated with moderate- to vigorous-intensity exercise, including both aerobic and resistance training, are typical of exercise for everyone and include overuse injury, fatigue, and death. In addition to the typical exercise risks, hypoglycemic episodes also pose a risk for people with diabetes.³ There may also be an increased risk for falls in the presence of peripheral neuropathy.⁵⁷

Benefit-Harm Assessment

There is a preponderance of benefit.

Value Judgments

The guiding principle behind question development was to help health care providers optimize the physical fitness and activity of adults with diabetes. We recommend that physical therapists and other health care providers who prescribe exercise consistently develop exercise programs for this population because the long-term impact on cardiovascular health and muscular fitness is a significant benefit.

Intentional Vagueness

The specific type of exercise was intentionally left vague because the best exercise for an individual is the exercise

Table 8. Risk of Bias

Study	Specified Eligibility Criteria	Randomization	Concealed Allocation	Similarity of Groups at Baseline	Participant/ Provider Blinding	Assessor Blinding	At Least 1 Outcome for >85% of Participants	Intention to Treat	Funding Source Reported
Lehmann et al ⁵⁴ (1997)	+	–	–	NA	–	–	+	+	In kind support from Boehringer-Mannheim Switzerland and Novo-Nordisk Switzerland
Kirk et al ³⁶ (2003)	+	+	+	+	–	–	+	–	None reported
Di Loreto et al ⁵⁵ (2005)	+	+	–	+	–	–	+	–	None reported
Cauza et al ³³ (2005)	+	+	–	–	–	–	+	–	Jublaumsfond of the Austrian National Bank (Project no. 8537)
Praet et al ³⁷ (2008)	+	+	+	+	–	+	+	+	Dutch Healthcare Innovation Foundation research grant from “OZ-zorgverzekering” healthcare insurance company; Dutch Ministry of Health, Welfare and Sports grant; in kind supplies support from A. Menarini Diagnostics Benelux, RScan International
Jakicic et al ³⁸ (2009)	+	+	–	+	–	+	+	+	NIDDK; National Heart, Lung, and Blood Institute; CDC grants
Johnson et al ³⁹ (2009)	+	+	–	+	–	–	+	+	Heart and Stroke Foundation of Canada
Reid et al ⁴⁰ (2010)	+	+	+	+	–	+	+	+	DARE trial supported by grants from the Canadian Institutes of Health (research grant MCT-44155) and the Canadian Diabetes Association (The Lillian Hollefriend Grant); and various other grants to support team members (see pp. 639–640 of reference)
Look AHEAD Research Group and Wing ⁵⁶ (2010)	+	+	–	+	–	+	+	+	DHHS through cooperative agreements from NIH; NIDDK; National Heart, Lung, and Blood Institute; National Institute of Nursing Research; National Center on Minority Health and Health Disparities; Office of Research on Women's Health; CDC; Department of Veterans Affairs; among other facilities and research centers (see p. 1574 of reference)
Ng et al ²⁹ (2010)	+	+	+	+	–	+	+	+	National Medical Research Council of Singapore (NMRC/0728/2003); in kind support of Abbott Laboratories
Karstoft et al ³¹ (2013)	+	+	–	+	–	+	–	+	Danish Centre for Strategic Research in Type 2 Diabetes (grants 09–067009 and 09–075724); Danish National Research Foundation (02–512–55)
Espeland et al ⁴⁵ (2013)	+	+	–	–	–	+	+	+	NIDDK; National Heart, Lung, and Blood Institute; CDC
Johannsen et al ⁴¹ (2013)	+	+	–	+	–	+	+	+	National Institutes of Health (DK-068298)
Andersen et al ³⁰ (2014)	+	–	–	+	–	–	+	+	FIFA Medical Assessment and Research Center (F-MARC) and Nordea-fonden, Denmark
de Sousa et al ²⁸ (2014)	–	+	–	+	–	–	–	–	Grants from the State of Sao Paulo Research Foundation
Krishnan et al ⁵³ (2015)	+	–	–	–	–	–	–	–	None reported
Senechal et al ⁴² (2015)	+	+	–	+	–	+	+	+	NIH Grant DK068298
Mendes et al ⁵¹ (2016)	+	–	–	–	–	–	–	–	Portuguese Foundation for Science and Technology (SFRH/BD/47733/2008)
Soa et al ⁵² (2017)	+	–	–	+	–	–	+	–	No external funding
Winding et al ⁴⁶ (2018)	+	+	+	+	–	–	+	–	TryFonden; Danish National Research Foundation (DNRF55); Capital Region of Denmark, Novo Nordisk Foundation, and Danish Diabetes Academy
Duruturk and Özköslü ⁴⁸ (2019)	+	+	+	+	–/+	+	+	–	Authors report no conflict of interest
Szilagyi et al ⁴⁴ (2019)	+	+	+	+	–	+	–	–	Authors report no conflict of interest
MacDonald et al ⁴⁷ (2020)	+	+	+	+	–	+	+	+	TryFonden; Danish Council for Strategic Research, grants 09–067009 and 09–075724; Danish Diabetes Academy grant; in kind support by Bayer A/S
Dominguez-Munoz et al ⁴³ (2020)	+	+	+	+	+	+	–	+	Regional Department of Economy and Infrastructure of the Government of Extremadura and European Social Fund (PD16008)

^a– = did not meet criteria; + = did meet criteria; –/+ = partially present; CDC = Centers for Disease Control; DARE = Diabetes Aerobic and Resistance Exercise study; DHHS = Department of Health and Human Services; FIFA = Federation Internationale de Football Association; NA = not applicable; NIDDK = National Institute of Diabetes and Digestive and Kidney Diseases; NIH = National Institutes of Health.

that the individual will complete. The literature support for exercise included various interventions ranging from walking to dancing to yoga to sport to resistance training along with various intensities.^{32,46,49,50,53,55} While not discussed in the included articles, previous studies report that improved self-efficacy and behavioral control likely increase exercise adherence.²³

Role of Patient Preferences

Exercise intervention should incorporate the preferences of adults with diabetes to increase adherence, therefore optimizing outcomes.²³

Exclusions

Modifications should be made for any adult with diabetes and disease conditions that contraindicate a specific exercise intensity. Furthermore, exercise should be performed only by adults within safe glycemic ranges.³

Implementation and Audit

Clinics and facilities should establish consistent inclusion of exercise prescription with their patients with type 2 diabetes. Annual training could facilitate the incorporation of a variety of exercises within an exercise prescription. Annual training could also include review of glucose monitoring with exercise to mitigate risk of exercise-related hypoglycemia.²⁴ Public health approaches to encourage walking or other similar exercises may also be successful. Inclusion of ticklers within the EMR may promote consistent exercise prescription to facilitate improved physical fitness and activity. Annual audit of follow-through may also serve to promote adoption of consistent exercise prescription among patients with diabetes.

Supporting Evidence and Clinical Interpretation

Studies have assessed the effects of a variety of different activities, including aerobic activity alone,^{29,31,33,37,39–42} resistance (strength) activity alone,^{29,33,40–42} aerobic activity combined with resistance (strength) training,^{40–42} and sport (eg, soccer, dance), on physical fitness.^{28,30,53} All types of exercise resulted in improvement in physical fitness and activity. Combined exercise patterns improved activity consistent with the approach taken. High-intensity interval training was especially helpful compared to continuous walking.^{31,52} [Supplementary Material 4](#) shows the findings. The selection of activity should also be considered in the context of an individual's overall health and ability to tolerate activity.^{4,24} It is important to consider the response to exercise in the presence of diabetes when prescribing and supervising exercise.^{3,4,24} Exercise and sport are not the only way to promote fitness and physical activity. A meta-analysis assessed the effect of activity monitor–based counseling in people with type 2 diabetes on physical activity compared to a control. With 8 pooled studies, an activity monitor–based counseling intervention was favored for increasing step count (physical activity) compared to a control without the intervention.²⁷

Consideration for musculoskeletal comorbidities is important because orthopedic comorbidities and complications can affect response to loading and exercise. Thus, it is advisable to gradually increase the intensity of training. The American College of Sports Medicine could be used as a guide for the appropriate progression of exercise.⁵⁸

Research Recommendation

Studies are needed to assess what are the best interventions to address physical fitness and activity in people with type 1 diabetes. Further investigation may be helpful to develop guidelines for intensity and timing of exercise to best address physical fitness and activity in all adults with diabetes.

QUESTION 8

What are the best methods to progressively load tissue after ulceration closure to prevent recurrence in adults with diabetes?

Recommendation IV

Physical therapists and other health care providers managing closed DFUs may titrate tissue reloading (eg, standing, walking) on a newly closed DFU, maintaining moderate to maximal offloading, especially during the first 3 months, while slowly titrating a return to shoe wear using a wear schedule (evidence quality: D; recommendation strength: weak).

Aggregate Evidence Quality

This is rated as D level or theoretical evidence based on expert opinion.

Benefits

Progressively reloading tissue after ulceration closure may reduce an individual's risk of reulceration, allow scar tissue to mature, and lower the potential costs of reulceration to the larger health care system.

Risk, Harm, and Cost

The cost of progressively reloading tissue after ulceration closure includes the physical burden to the individual of remaining offloaded, the cost of appropriate diabetic footwear, the financial burden if the individual is unable to resume work roles, and the financial cost to the larger health care system for the prolonged treatment of the individual.

Benefit-Harm Assessment

There is a preponderance of benefit.

Value Judgments

The guiding principle behind the question development was to assist health care providers in protecting the newly closed wound tissue while transitioning the individual into their diabetic shoes, returning to full function, and avoiding reulceration.

Intentional Vagueness

The developers were intentionally vague about the exact steps to the transition to reloading as there is a paucity of evidence to support a specific approach.

Role of Patient Preferences

To prevent reulceration, reloading may be prioritized over patient preference. As a result, patient education promoting adherence is critical.

Exclusions

Patients who do not ambulate will not require reloading.

Implementation and Audit

Clinicians may consider adding a reloading schedule to their plan of care after closure of the DFU and include scripted phrases or drop-down menu options in the EMR to increase implementation and standardization for better outcomes. Finally, an annual audit of clinician use of a reloading plan would serve to reinforce implementation.

Differences of Opinion

Clinicians may have differences of opinion in the time line and extent of reloading as well as devices used.

Supporting Evidence and Clinical Interpretation

For this question, the supporting evidence included expert opinion but no research studies. There were 3 articles which described the expert recommended process for reloading the diabetic foot after ulceration closure.^{59–61} The postclosure protection time line given in each article varied: 3 to 4 weeks,⁵⁹ 1 to 3 months,⁶⁰ and no specific time line.⁶¹

Research Recommendation

There is a need for observational and prospective studies that assess postclosure loading to prevent reulceration and better understand the mechanism of titration of steps and standing with return to function.

QUESTION 9

In an adult with diabetes, do physical fitness and activity optimize long-term quality of life as well as reduce health care costs?

Recommendation V

All health care providers should encourage aerobic exercise, strength training, and/or physical activity for adults who have diabetes and can exercise safely to optimize long-term quality of life as well as reduce health care costs (evidence quality: C; recommendation strength: weak).

Aggregate Evidence Quality

Evidence included 5 interventional studies and 1 case-control study. Five found that physical fitness and activity optimize long-term quality of life,^{62–66} and 1 demonstrated reduced health care costs for adults with diabetes.⁵⁵ Three of these were not randomized^{55,63,66} and none were blinded. Five studies were level II quality,^{55,62,64–66} and 1 was level III.⁶³ This is rated as C level or weak evidence.

Benefits

Aerobic exercise or physical activity optimizes long-term quality of life and reduces health care costs.

Risk, Harm, and Cost

The risks are similar to any exercise or activity, including both aerobic training and resistance training, are typical of exercise for everyone and include overuse injury, fatigue, and death. In addition to the typical exercise risks, hypoglycemic episodes also pose a risk for people with diabetes.³

Benefit-Harm Assessment

There is a preponderance of benefit for aerobic exercise and physical activity for people with diabetes.

Value Judgments

The guiding principle behind the question development was to highlight benefits of engaging in aerobic exercise, strength training, or general physical activity for adults with diabetes. These may positively affect quality of life and reduce costs.

Intentional Vagueness

The recommendation of who should encourage aerobic exercise or physical activity for this population was intentionally vague to allow for inclusivity of all qualified health care providers. Additionally, the activity intensity within the recommendation was intentionally vague due to limited research on the impact of intensity on quality of life and health care costs to guide more specific recommendations.

Role of Patient Preferences

Self-selected activity should be considered as appropriate. Patient preferences were not discussed in the included studies, but self-selection of activity and goals may improve adherence. Previous studies report that higher levels of self-efficacy and behavioral control with exercise improve adherence in those with chronic disease.²³

Exclusions

For exercise safety, exercise modifications should be made for any adult with disease conditions that contraindicate a specific exercise intensity. Further, exercise should be performed only by adults within safe glycemic ranges. Colberg et al²⁴ provide detailed guidance on the management of glycemia with exercise.

Implementation and Audit

Clinicians may consider incorporating exercise prescriptions into the EMR as part of the complete plan of care for patients. Using scripted phrases or drop-down menu choices may increase implementation and improve standardization to allow for better auditing of outcomes. Finally, an annual audit of clinician use of an exercise prescription would serve to reinforce implementation.

Differences of Opinion

There were no differences of opinion.

Supporting Evidence and Clinical Interpretation

Aerobic exercise was predominant in the studies. Three studies used aerobic exercise solely,^{55,64,66} 2 used a combination of aerobic exercise and strengthening,^{63,65} and the last was a cross-sectional study which analyzed patients' fitness and health-related quality of life prior to 2 aerobic exercise trials (Table 9).⁶² The study of Abdelbasset et al⁶⁴ investigated the effect of aerobic exercise on quality of life in participants with diabetes who sustained burns. Although this study focused on participants with burns, they all had diabetes; therefore, this study answered our question.

Research Recommendation

Research is needed that assesses health-related quality of life and includes cost analysis of health care. Additionally, research is needed that assesses the relationship of physical activity and exercise, based on intensity, to health-related quality of life and health care costs.

Table 9. Health-Related Quality of Life (HRQOL) and Description of Costs^a

Study	Participants	Type of Exercise	Effects on HRQOL	Impact on Costs
Wiesinger et al ¹⁶⁶ (2001)	Type 1 DM; mean age = 40 y; treatment and control groups	Aerobic exercise with stationary bike for 1 h 2x/wk for 2 wk, 3x/wk for remainder of 4 mo	Significant improvement in HRQOL in treatment group compared to control group	
Bennett et al ¹⁶² (2008)	Type 2 diabetes; mean age = 56.9 y	VO ₂ peak fitness test used; no treatment intervention	Increased fitness correlated with higher HRQOL	
Abdelbasset and Abdelhalim ⁶⁴ (2020)	Type 2 diabetes and burns; mean ages = 47.8 y for treatment group and 46.3 y for control group	Moderate-intensity intermittent aerobic exercise for 40 min/d 3x/wk for 6 wk	Significant improvement in Burns Specific Health Scale score in treatment group compared to control group	
MacDonald et al ⁶⁵ (2021)	Type 2 DM; mean age = 53.6 y for treatment group, with structured exercise and individual meal plans; mean age = 56.6 y for standard-of-care group	Aerobic exercise and resistance training for 240–300 min/wk	Significant improvement in HRQOL in treatment group compared to control group	
Molsted et al ¹⁶³ (2022)	Type 2 DM; split into groups by municipality or hospital rehabilitation clinic; mean age = 69.8 or 62.6 y, respectively	Aerobic exercise and strength training for 1 h 2x/wk for 12 wk: interval aerobic exercise on ergometer bikes, circuit training with aerobic and strength training exercises	Positive changes in HRQOL in both exercise groups, more pronounced in municipality group	
Di Loreto et al ⁵⁵ (2005)	Type 2 diabetes; mean age = 62 y	Moderate-intensity aerobic exercise		Significant reduction in health care costs with energy expenditure of >10 METs/h/wk

^aDM = Diabetes mellitus; HRQOL = health-related quality of life; METs = metabolic equivalents; VO₂ peak = peak oxygen consumption.

DISCUSSION

The purpose of this CPG was to review and assess previously published guidelines and address gaps within the guidelines specific to identifying screens and interventions to prevent an initial DFU or future reulceration, best screening tools and interventions to assess and affect mobility impairments, best tools to measure and interventions to address reduced physical fitness and activity, best approach to reloading the foot after ulceration closure and, finally, whether improvement in physical fitness will positively change quality of life and health care costs. During the process of developing this CPG, some of the questions were answered by updates to a DFU-related CPG,⁶ and 1 question was answered by a CPG addressing mobility assessment in neurologically involved patients.¹² Given that people with diabetes often develop neurologic changes (eg, diabetic peripheral neuropathy), the GDG determined this was an appropriate reference to another CPG.

With the GDG's focus on the remaining questions, the resulting importance of this guideline is to provide a review of literature to address how to treat patients so as to best recognize and address deficits in fitness and functional mobility. These areas are commonly addressed by physical therapists and explicit guidance may improve consistent inclusion of these components within the standard of care. Beyond addressing fitness and mobility, prevention of initial DFUs as well as recurrent DFUs is also critical.

Exercise improves fitness and physical activity in adults with diabetes. This can be achieved with a broad range of exercises, especially if the exercise is patient selected. While

much emphasis in previous guidelines is on the effects of exercise on glucose management, blood pressure control, and other physiologic markers, exercise also has a positive impact on fitness, quality of life, and the cost of health care.³ For patients to consistently benefit from exercise, health care providers should test the cardiovascular health and fitness of adults with diabetes whenever they access the health care system, rather than waiting until they present with a severe complication such as a DFU.

Offloading critical for DFU healing is well reported. Existing DFU-related CPGs provide clear direction for the treatment of DFUs until closure.^{6,8,9} The direction of postclosure care including a plan for the reloading process is a critical step toward the reduction of DFU recurrence. Expert opinion provides some direction for the reloading process, but little data-driven evidence exists to clarify the process.

While some evidence is clear, there are several areas that have gaps in the literature and a definite need for focused research. The effects of exercise on the wound healing process and the assessment of methods to reload a newly reepithelialized ulcer to prevent recurrence are research areas of high priority.

Limitations

There are several limitations to the development and outcome of this CPG. While the literature search was comprehensive, the search was initiated within 1 facility (ie, Indiana University Health) and subsequent searches occurred at a separate facility (ie, Mercer University). The very nature of library holdings

fluctuates. Literature meeting the inclusion criteria could have been missed because of selected search terms, holdings, or timing of the searches. Furthermore, any studies that were not written in the English language were not included. Other studies that may have been appropriate lacked psychometric data and thus full assessment regarding those properties was impossible.

The process of developing this CPG took 8 years. During this time, changes occurred within the GDG team, and the *APTA Clinical Practice Guideline Process Manual*¹³ was updated. With the update, 1 of the quality appraisals used (the Physiotherapy Evidence Database) was different than that described within the *APTA Clinical Practice Guideline Process Manual*.¹³ Despite these changes, this document still went through appropriate systematic processes.

Plan for Implementation and Process for Guideline Update

A CPG Implementation Team was created to determine needed resources and materials to drive knowledge translation which includes education and integration into PT practice. This group identified activities and products that needed knowledge translation and will evaluate the effectiveness of the CPG in changing practice. To better implement these guidelines, beyond specifically identified strategies for each recommendation, a checklist ([Suppl. Material 5](#)) can be used upon intake for all people with diabetes to facilitate prevention of initial ulceration and reulceration. Included within the checklist are the skin assessment, range of motion, monofilament testing, readiness to change assessment, and diabetes management (diabetes knowledge, control, and footwear). Also, resources to support implementation for electronic medical records (ie, phrases, triggers) ([Suppl. Material 6](#)) and knowledge acquisition with journal club article support are available ([Suppl. Material 7](#)).

Preliminary findings of the GDG for this guideline were presented at the APTA Combined Sections Meeting in 2023. This CPG will be open access, with the support of APTA and ACEWM. The *Journal of Clinical Electrophysiology and Wound Management* will publish an executive summary of this guideline. Awareness of this guideline will be further facilitated using social media highlights, ACEWM newsletters, and digital tools (eg, a podcast). Additionally, further development of support materials is planned and will appear on the ACEWM website.

CPGs should be updated every 5 years following publication according to guideline development best practice. Planned updates will include repeated searches of the literature for new, best available evidence. A similar approach will include the use of software (eg, Covidence) to facilitate the process to include or exclude articles (removal of duplicates, assessment by title/abstract, full-text review), perform critical appraisal, and perform extraction. The ACEWM has a plan in place to ensure this guideline will be updated.

SUMMARY

It is important to use existing CPGs regarding many aspects for the care of people with diabetes and DFUs.^{6,8,9,67} In addition, other aspects of care are important to include. Physical fitness and activity should be encouraged and

measured in adults with diabetes and with or without foot ulceration, ideally using measurement tools with demonstrated psychometric properties (eg, handgrip strength test, CSRT, TUG Test, 6MWT, and 30STS test). Exercise and physical activity should be prescribed according to the physiologic response of an adult with diabetes to exercise, skin integrity, and other comorbidities, while incorporating the patient's preferences and considering their resources. All health care providers should encourage aerobic exercise or physical activity in adults with diabetes safe to exercise to optimize long-term quality of life and reduce health care cost. Finally, following the closure of a DFU, tissue may be reloaded, maintaining moderate to maximal offloading, especially during the first 3 months; slowly titrating return to shoe wear using a wear schedule and appropriate "diabetic" footwear. Further research is necessary to better support specific guidelines for these recommendations, particularly those based on expert opinion.

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CRedit – CONTRIBUTOR ROLES

Deborah M. Wendland (Conceptualization [Equal], Formal analysis [Equal], Funding acquisition [Equal], Methodology [Equal], Writing—original draft [Lead], Writing—review & editing [Equal]), Elizabeth A. Altenburger (Conceptualization [Equal], Formal analysis [Equal], Funding acquisition [Equal], Methodology [Equal], Project administration [Lead], Writing—original draft [Equal], Writing—review & editing [Equal]), Shelley B. Swen (Formal analysis [Equal], Writing—original draft [Equal], Writing—review & editing [Equal]), Jaimee D. Haan (Conceptualization [Equal], Formal analysis [Equal], Methodology [Equal], Writing—original draft [Equal], Writing—review & editing [Equal])

SUPPLEMENTARY MATERIAL

[Supplementary material](#) is available online.

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CPG to address the paucity of information regarding people with a DFU related to areas that physical therapists address.

DISCLOSURES

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

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