

WOUNDS®

A Compendium of Clinical Research and Practice

Wound Care Centers:

Critical Thinking and Treatment Strategies for Wounds

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Abstract: Many wound care centers (WCCs) provide a specialized level of care using various wound care therapies and are managed by qualified healthcare professionals (QHPs) from different specialty backgrounds such as family medicine, podiatry, and plastic surgery. However, these QHPs are sometimes challenged by reimbursement issues, limited therapy and dressing options, reduced access to multidisciplinary team members, and cost-driven factors unique to WCCs. To help address these issues, a meeting was convened by an expert panel of WCC physicians to discuss best practices for treating complex patients in a WCC. This publication presents an overview of WCC challenges, describes a holistic approach to treating WCC patients, and provides clinical guidance on the decision-making process for selecting optimal treatment plans for the WCC patient. Clinical cases of atypical, surgical and chronic wounds seen in a WCC are also presented.

Key Words: wound healing, chronic wounds, advanced wound therapy, wound care center

INTRODUCTION

Review of wound care centers. An aging population with multiple comorbidities has led to an increasing prevalence of nonhealing wounds. Meanwhile, in the United States, reductions in acute care spending have driven more care to the outpatient setting.¹ In 2000, the Centers for Medicare & Medicaid Services (CMS) defined a payment system referred to as the Medicare Outpatient Prospective Payment System (OPPS), which was developed to allow people who were not sick enough to warrant acute care hospitalization the opportunity to receive complex services as outpatients. Hospital-based outpatient wound care departments (HOPDs) began to appear as a result of the new OPPS and acute care cost shifting.^{1,2} Reimbursement issues described in this publication largely center around CMS policies, which may or may not be similar to policies of private insurance companies.

Since the introduction of OPPS, HOPDs have been opening throughout the United States at a rapid pace, as have many other outpatient services. The rising number of malpractice claims, particularly those involving treatment of diabetic foot ulcers (DFUs),³ have also led to an increase in referrals of patients with DFUs and other complex wounds to wound care centers (WCCs) for specialized care.³ With diabetes on an unprecedented rise, these WCCs have become a necessity for patient health as well as a critical economic entity.

Wound care centers offer a specialized level of care with a variety of wound healing services typically not available in a private office. They are usually managed by qualified health care professionals (QHP) who come from many different specialty backgrounds. These QHPs may have expert training in family medicine, podiatry, vascular surgery, physical medicine and rehabilitation, plastic surgery, or other

specialties. All of these wound healing specialists bring their own unique professional training with them to the field, the WCC, and the patient experience. Importantly, WCCs are not meant to treat any patient who could just as easily be managed in a primary care physician's office. Local coverage determinations (LCDs) issued by Medicare administrative contractors determine which services are "medically necessary" or covered in the HOPD;⁴ however, in some cases, the provider is capable of treating the patient in the office but prefers to treat in a WCC. Additionally, a WCC may choose to provide preventive care after the wound has healed, which many LCDs specifically do not cover in HOPDs.

The term "wound care center" can refer to an HOPD or a free-standing wound clinic office of a QHP. The location (e.g., rural vs. urban or hospital vs. office building) can determine level of access to various specialties, as well as reimbursement

policies. Wound care is also performed in outpatient surgery centers, also known as ambulatory or same-day surgery centers, where surgical procedures not requiring an overnight hospital stay are performed. This topic was beyond the scope of the panel meeting, and therefore this publication will only touch on some of the most important points pertaining to site of service.

Centers for Medicare & Medicaid reimbursement for wound care centers. While CMS reimbursement for inpatient care is based on diagnosis-related groups (DRGs), outpatient care follows national coverage determination (NCD) and LCD guidelines with ICD-10 codes that were released in the spring of 2015. The level of reimbursement changes according to “site of care.” For billing purposes, WCC “sites” are classified as: 1) HOPD or 2) QHP office (wound clinic). The Medicare Physician Fee Schedule pays the physician more for service provided in a QHP office than in a facility. For example, for a procedure such as epidermal grafting in an HOPD, the costs of labor and supplies are bundled into the facility fee with a separate professional fee for application at a reduced rate; in an office, there is no facility fee and the physician does not take a site of service fee reduction.

Until recently, for most hospitals, outpatient WCCs have been productive cost centers and have been able to generate “spin-off” revenue for other hospital departments, such as imaging, interventional radiology and vascular suites, and the operating room (OR).⁵ Historically, the payment system for WCCs has been based on services and procedures performed, so the measure of success for HOPDs has been volume and payment for the services provided. However, a vast increase in use of outpatient services during the past 16 years has contributed to a considerable increase in the outpatient portion of Medicare costs.² Today, there are more than 1,000 outpatient WCCs in the United States¹ with staggering estimated annual expenditures of more than \$50 billion on “wound care services.”⁶⁻⁸

The CMS is now moving to gain control of the overwhelming costs of outpatient services. In 2014, CMS introduced numerous cost-saving measures including 1)

packaging the payment for cellular and/or tissue-based products for wounds, meaning the product and service for applying it are lumped into the same payment; 2) packaging all “add-on” procedures into “base codes,” so an HOPD receives the same payment rate for treatment of large or small wounds; and 3) assigning one payment rate for all levels of new and established clinic visits. Nearly every payer has limited the number of certain types of surgical debridements that can be performed annually on a wound.² This is only the beginning of an overhaul of OPps into a value-based payment system.

Future reimbursement will be based on quality of care and clinical outcome results, not just the quantity and type of care provided. The CMS is aiming to have more than half of Medicare payments be value-based by the year 2018, and by the year 2020, virtually all Medicare payments and nearly all private insurance payments will be value-based.⁹ Wound care professionals will be reimbursed based on achieving the highest quality outcomes at the lowest total cost of care (not necessarily using the lowest-cost products or procedures) with high levels of patient satisfaction.² Restructuring began with the requirement to report quality measures (QMs) under the Affordable Care Act, and an increasing percentage of hospital and physician revenue will be based on these measures.

Objective and purpose. Patients with chronic wounds treated by WCCs are generally very sick patients with comorbid problems, so that even small wounds often require extensive therapy.¹⁰ Wound care centers need to be proficient havens to which healthcare providers can refer patients with difficult wounds, so providers have confidence their patients are receiving the best possible care.³ These same WCCs must remain solvent in a new financial climate with a systematic focus on quality outcomes. The growing number of WCCs, the increased demands of QHPs who manage them, and the expanding patient complexities are challenging current hospital outpatient resources in unprecedented ways. Clinical and financial intricacies not present in inpatient wound management further complicate decision making in WCCs.

To help guide clinical decision-making, a panel meeting of wound healing specialists experienced in outpatient wound care was convened to discuss recommendations for managing patients with complex wounds in WCCs. The purposes of this publication are to identify challenges in managing WCCs and to summarize literature- and experience-based recommendations from the panel meeting to inform clinical practice in the holistic management of patients and wounds in a WCC. Challenges in achieving clinical outcomes in WCCs, as well as clinical wound healing strategies and dressing/therapy selection processes are addressed. Clinical case studies are also presented to demonstrate successful outcomes in a WCC.

METHODS

An expert panel of wound healing specialists experienced in the outpatient wound care setting convened March 17-18, 2016 in Dallas, TX, to discuss best practices for treating patients in a WCC. Panel members received a booklet of peer-reviewed studies selected by the sponsor (Acelyty, San Antonio, TX) for review prior to the meeting. The booklet included the most recent studies from the sponsor’s own internally updated database of publications on the topic of outpatient wound care management modalities, including advanced wound dressings, negative pressure wound therapy (NPWT), and epidermal harvesting. The meeting was moderated by one of the panel members (Jean de Leon, MD, FAPWCA) and recorded. Each panelist presented their individual clinical experience via case studies of atypical, surgical, and/or chronic wounds, and offered suggestions for providing treatment in the outpatient wound care setting. Each presentation included a moderator-guided roundtable discussion among presenters and other panelists. Following the meeting, cases and recommendations were grouped by subject and summarized by a medical writer. Follow-up communication with the panelists continued throughout development of the recommendations via email. All subject matter was approved by panel members.

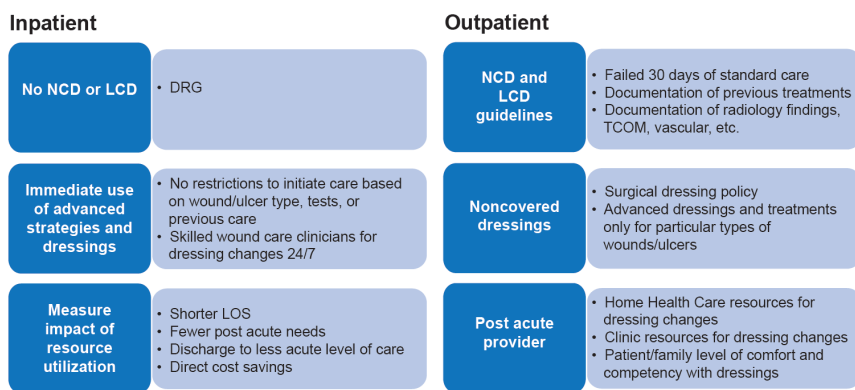


Figure 1. Site of Service for Inpatient and Outpatient Care
 NCD indicates national coverage determination; LCD, local coverage determination; DRG, diagnosis-related group; LOS, length of stay; TCOM, transcutaneous oxygen measurement.

RESULTS AND CHALLENGES IDENTIFIED

Panel members all agreed that many of the challenges related to achieving clinical outcomes in outpatient WCCs derive from site of service differences between inpatient and outpatient care (Figure 1).

Each panel member identified several challenges for achieving good clinical outcomes in WCCs, as well as recommendations on addressing these challenges, which are summarized below.

PRIMARY CHALLENGES FOR WOUND CARE CENTERS

Stringent, complex reimbursement policies. New, ever-changing NCD and LCD guidelines are complicated, yet important to follow and understand. In the acute care setting, there are no restrictions on immediate use of advanced strategies and dressings because all are reimbursed under a DRG. In contrast to the inpatient setting, a QHP planning treatment for a WCC patient must take into account the payer requirement for the patient to fail 30 days of standard wound care prior to receiving many advanced wound care therapies. Standard advanced wound care products/therapies that can be initiated immediately without the 30-day waiting period include collagen, oxidized regenerated cellulose/collagen (ORC/C), disposable NPWT, hydrocolloids and alginates. A sample list of advanced wound care therapies that typically require a 30-day failed course of standard wound therapy prior to use is provided in Table 1.

In order to obtain reimbursement, there must be thorough documentation of previous treatments, radiology findings, transcutaneous oximetry, hemoglobin A1c levels, and vascular tests prior to using advanced modalities in WCCs. Since time is of the essence when it comes to tissue loss and healing, and prompt, specialized intervention may preserve limbs and restore overall function, waiting the prerequisite 30 days before initiating an effective advanced therapy may not achieve the best outcome for the patient. However, this 30-day waiting period can be maximized by systematically addressing all patient and wound bed underlying factors, including matrix metalloproteinases (MMP) imbalances.

Since the majority of wound care payments are related to Medicare, it is important for QHPs to read and know the NCDs and LCDs that pertain to the wound care work they perform. Medicare administrative contractors who process claims for LCDs may update LCDs as often as they deem necessary. Therefore, it may be wise to designate an insurance specialist to review LCDs regularly – even monthly – to capture and implement these coding changes.

Site of care differences may also need to be explained to the patient. For example, when patients are seen by a QHP in an HOPD, the patients and Medicare receive two bills: one from the HOPD and one from the QHP. When patients are seen by a QHP in his or her office, the patients and Medicare only receive one bill. Notifying a patient in advance to expect one or two bills can be helpful.

Documentation. Thorough, accurate documentation is helpful in securing reimbursement and maintaining profitability. Documentation can also be used to help hospitals manage risk, which further creates value for the WCC. The topic of electronic documentation in wound centers is complex as well as controversial and was not discussed in detail during the panel meeting. Nearly all hospitals have adopted electronic health records (EHRs), and there are a growing number of wound-specific EHRs that can be incorporated into existing outpatient EHR systems that include wound treatment algorithms with benchmark reminders, and allow for embedding photos, wound measurement documentation, and seamless communication with referring physicians.¹¹ The CMS has made it clear that point-of-care documentation is the standard to benefit from clinical suggestions and warnings of drug interactions, etc. with electronic prescribing. Ultimately, WCCs will need to establish quality measures and work with their own vendors to ensure the necessary measures are available in the EHR.²

Dressing and therapy options in wound care centers. Compared to acute care, there may be fewer dressings and advanced therapies available at WCCs. Treatments available in outpatient WCC include standard and some advanced dressings (e.g., collagen and silver), advanced wound therapies, and skin substitutes. Facility resources and reimbursement policies can contribute to the range of dressings and treatments available to patients at individual WCCs. Cost management requires that WCCs regularly balance the number of dressing stock-keeping units (SKUs) to include a complete dressing line but to eliminate duplicate dressings with the same mechanisms of action. Qualified health care professionals often have minimal input regarding what dressings are stocked, and stocked dressings sometimes change during a patient's treatment course for cost control.

In the acute care setting, regardless of the type of wound/ulcer or duration of the injury, care can be directed to obtain the most helpful diagnostic information and prescribe the most aggressive treatment strategy. For example, in acute care there is

Table 1. Therapies Available After a 30-day Failed Course of Standard Treatment

Type of Advanced Wound Care Therapy	Product Name
Culture-derived human skin equivalent	Apligraf (Organogenesis, Canton, MA) Epitel (Vericel Corp, Cambridge, MA)
Human fibroblast-derived dermal substitute	Dermagraft (Organogenesis, Canton, MA) OrCel Bilayered Cellular Matrix (Ortec International Inc, New York, NY)
Porcine small intestinal submucosa extracellular matrix	OASIS Matrix (Smith & Nephew, Hull, UK)
Amniotic membrane allograft	EpiFix Human Amnion/Chorion Membrane (MiMedx, Marietta, GA) AmnioBand Allograft Placental Matrix Membrane, (MTF Wound Care, Edison, NJ) GRAFIX Cryopreserved Placental Membrane (Osiris Therapeutics, Inc, Columbia, MD)
Acellular dermal scaffolds	GRAFTJACKET Regenerative Tissue Matrix (Wright Medical Technology, Inc, Memphis, TN; KCI, an ACELITY Company, San Antonio, TX, is licensed to market this product) PriMatrix Dermal Repair Scaffold (Integra LifeSciences, Waltham, MA) AlloMend Acellular Dermal Matrix (AlloSource, Centennial, CO)
Electrical stimulation	LifeWave (LifeWave Ltd, Petach Tiqwa, Israel)[bioelectrical signal therapy] Accel-Heal, a Synapse electroceutical technology (Synapse Electroceutical Ltd, Westerham, UK) [low-intensity pulsed current] Winner EVO Stim (Richmar, Chattanooga, TN) [Tru Stim Electrotherapy]
Systemic hyperbaric oxygen therapy	Sigma Hyperbaric Oxygen Therapy Chambers (Perry Baromedical, Riviera Beach, FL) H Model Pneumatic Hyperbaric Oxygen Chambers and E Model Electronic Hyperbaric Oxygen Chamber (Sechrist Industries, Inc, Anaheim, CA)
Negative pressure wound therapy	V.A.C. Therapy, ActiV.A.C. Therapy (KCI, an ACELITY Company, San Antonio, TX) RENASYS, RENASYS GO (Smith & Nephew, Hull, UK)

no insurance requirement that a plain film be performed to evaluate for osteomyelitis before any approval for an MRI. An inpatient is more likely to move directly to an MRI to evaluate for osteomyelitis, since an MRI is more sensitive, and there is a reasonable chance that plain film will not reveal osteomyelitis.

More advanced inpatient treatment can be applied to complex wounds/ulcers that have been open for less than 30 days but are starting to decline. For example, use of advanced skin substitutes and NPWT can be used to manage the wound for an inpatient with a surgical wound that will be even more difficult to improve after 30 days of failure. Similarly, a patient with a wound/ulcer may benefit from the use of collagen to help promote granulation, an alginate to help pack the depth, and bordered foam dressing to maintain the moist environment and remove exudate. An inpatient would receive all three dressings, but the CMS surgical dressing policy on a similar outpatient

would only cover the cost of one dressing in the wound/ulcer and one on the wound/ulcer, not three products.

Additionally, there are few advanced skin substitute options for pressure ulcers, compared to those for DFUs in the outpatient setting. However, in patients with comorbidities, such as patients with cancer on chemotherapy or post radiation, patients with rheumatoid arthritis on high dose immunosuppression, or nonoperative candidates with pressure ulcers, a more advanced strategy to stimulate fibroblast function and collagen and growth factor production could help advance the ulcer through the phases of healing and potentially prevent further complications and hospitalizations. Advanced care may be considered in the inpatient setting for these high-risk patients to reduce length of stay or reduce level of acuity in the next setting, but outpatients would not be covered for these therapies.

Cost reduction in wound care centers. All panel members stressed that cost containment

is critical in decision making. The “value proposition” of WCCs is now changing from generating revenue to saving overall costs.² A major challenge lies in meeting new OPPS regulations that demand an experienced wound center management team to manage documentation, processing, training, regulations, and financial review—all while reducing expenses.

It was the belief of panel members that WCCs can remain profitable, but only if managed well. Collecting data on patient population, wound types, healing rates and supply costs can assist in making more sound decisions concerning product selection. Each product or grouping of products (e.g., alginates, foams, collagens, etc.) should be evaluated with some level of evidence in literature and real-life data to stock the most cost-effective and efficient regimen of dressings at the WCC. The system of evaluating new products should be standardized and demand certain levels of evidence. Ideally, products are acquired

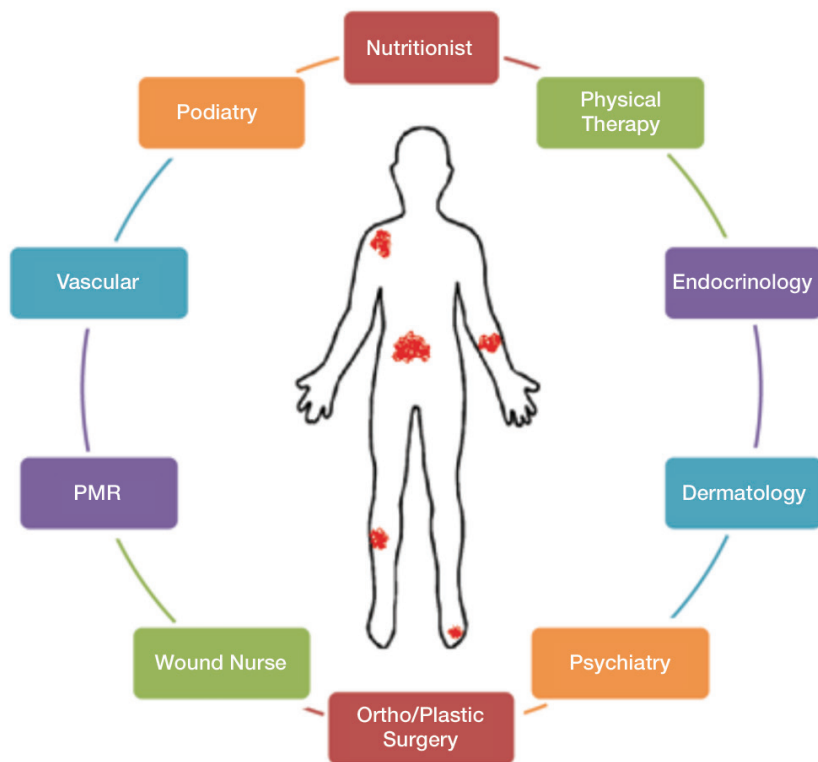


Figure 2. Range of Specialties Complex Wound Patients May Require for Treatment
PMR indicates physical medicine and rehabilitation; Ortho indicates orthopedic.

either to replace other SKUs or to add another valuable tool for patient care. Wound care centers can also create value and cost savings by assisting in reduction of length of stay and readmissions, and treating complex patients outside the hospital.

Delayed patient referral to wound care centers. All wounds/ulcers have the opportunity to become complex, and panel members stressed the importance of early referral and treatment. Often, non-wound care clinicians or primary care practitioners spend several weeks tending to a complex wound that fails to improve or actually worsens before the clinician decides to send the patient to a WCC.³ Non-wound care clinicians need to refer appropriate patients quickly to WCCs with access to specialties as soon as the need for specialty services is determined. Figure 2 shows the range of specialties a patient with a complex wound may need to access for adequate treatment.

It may be easier and faster for physicians to refer patients in urban vs rural settings because of greater access to specialty services. Regardless of setting, recognition and

referral to WCCs for surgical intervention or use of advanced wound management modalities (e.g., hyperbaric oxygen therapy and NPWT) may promote wound healing. When patients with diabetes are the priority, they are often referred early to a WCC. It is important for WCCs to provide consistently good care to maintain a good referral base.

Access to specialists. It is important to provide wound patients access to specialists when necessary because capabilities are increased and wounds can be treated more quickly. At a minimum, starting out, one QHP needs to be the champion for the wound program. However, it is necessary for the WCC to develop and access a network of specialists to achieve therapy goals. According to Kim and colleagues,¹¹ a multidisciplinary approach to wound care is the most important element to the success of a WCC because no single health care provider is adequately equipped with the skill, knowledge, and experience to provide comprehensive care for all complex wounds. Confounding elements include immune/protein deficiencies, coagulopathies, arterial/venous compromise,

medical comorbidities, peripheral neuropathic states, infectious conditions, and biomechanical abnormalities.¹¹

Hospital-based multidisciplinary WCCs provide patients with greater access to wound care specialists, advanced treatments, and diagnostic and surgical services. Some multidisciplinary models include plastic surgery and podiatry at their core, whereas other such centers have used podiatry and vascular surgery at their core.¹¹ To provide good care for outpatient complex wounds, there is a need for personnel whose training and expertise include soft tissue reconstruction, revascularization, and correction of biomechanical problems in lower extremity limb salvage. Rural, nonsurgical, and stand-alone clinics may address patient needs through referrals, providing patient follow-up after requested procedures.

Moving patients appropriately through care centers should also be a quality indicator. Just as private practice QHPs have a responsibility to refer patients to a WCC when patient wound care needs cannot be met, WCCs without the ability to close the wound have a responsibility to forward the patient to a specialist or clinic that can better address closure. This applies even if there is pressure from administration to retain these patients. Patients with certain comorbidities may require inpatient care if the patient is considered unable to be treated as an outpatient. The American Society of Anesthesiologists' Physical Status Classification System score can determine site of service (listed on the chargemaster). Surgeons in an inpatient setting can do things that outpatient care cannot do and often in an expedited fashion, and surgical intervention is optimized when the patient is improving, not getting worse. It is also important for each QHP to understand the scope of practice for each specialty within each state. Depending on where the wound is located on the body, treatment may be performed by an MD, DO, nurse practitioner, or DPM whose scope of practice varies from state to state, ranging from the hip in some states to only the foot in others.

Levels of wound care specialization among qualified health care professionals. There are

varying levels of wound care specialization among treatment providers. All clinicians have received varying degrees of education regarding wound management. Yet, wound care itself has advanced beyond what many clinicians have been taught, with rapid innovations in wound dressings and a repertoire of available in-clinic diagnostic tests. Indeed, wound healing has become a specialty, with fellowship programs offered at some academic centers.¹

Although there is more focus on wound care education today, there is strong evidence that there remains a lack of education about chronic wounds in the curriculum of medical students worldwide.¹² Gaps in teaching curricula on wound management span the spectrum from basic pathology to evidence-based care and assessment. It is especially important that QHPs have adequate knowledge of best practices in chronic wound care before arriving at a WCC.

A lack of knowledge by clinicians regarding appropriate wound management has been found to result in worse outcomes, and similarly, outcomes can be improved through appropriate education.¹³ Based on this evidence, many payers have begun to set a high bar for hyperbaric credentialing, in some cases requiring subspecialty board certification in undersea and hyperbaric medicine. Wound care certification programs are expanding and are available through several credentialing organizations. Panel members discussed the need to create a standard of practice in debridement due to its complexity and importance for healing. Using a curette requires proper training and understanding of anatomy. Quality of debridement will grow in importance as payers move toward reimbursement based on outcomes.

Patient compliance. In the hospital setting, needs are taken care of for the patient, and the patient may simply accept the assistance. All panel members stressed that compliant behaviors are much easier to control inside the hospital versus outside the hospital. In addition, outpatient social workers are often not available in WCCs to help facilitate treatment plans and navigate the patient through insurance hurdles. It is well accepted that not adhering to aspects of a well-considered plan of care may result in worsening condition,

increased comorbid disease, increased health care costs, and possibly death.¹⁴ Nonadherence includes behaviors such as ignoring/modifying a recommended treatment plan, an initial delay in seeking care, or use of tobacco products. It is motivated by numerous factors, including financial constraints, convenience, and fear. Nonadherence is not always intentional;¹⁴ socioeconomic status can impact the patient's ability to receive adequate nutrition and adjust activity levels.

Panel members agreed on the importance of collaboration between healthcare providers and every patient to achieve understanding of, and implications associated with, a mutually agreed upon plan of care. For example, patients who are nonadherent to offloading may not receive a graft. If patients smoke, have poor nutrition, or are noncompliant with glycemic management, they should be told in advance what the outcome might be, but not necessarily refused treatment. Nevertheless, panel members discussed that there remains a question as to whether one should use advanced modality treatments for any patient who will not quit smoking or eat properly. Also, insurance companies and/or CMS may require that patients quit nicotine products before they allocate funds for advanced care, shifting some of the responsibility back to the patient. Particularly in a climate moving toward quality-based payment, patient adherence will become an increasingly important consideration in determining treatment strategies.

Caregiver limitations. Whereas trained clinicians are available to change dressings in the inpatient setting 24 hours per day, dressing changes for WCC patients will be managed by the family or patient, home health care personnel, or the clinic. This creates additional challenges in achieving a good outcome. In addition to patient needs, the issue of who is handling dressing changes should also influence the treatment strategy and dressing choice.

Panel members stressed the importance of building a partnership with caregivers to help reduce stress and the risk of infection and to improve confidence and outcomes. It is wise to ask how caregivers learn best and to teach accordingly. This education can be expanded upon or simplified, according to

the education level, experience, and willingness of the caregiver. The questions they ask may be used as a guideline on how much information to provide. A good partnership between the WCC and the caregiver can also reduce phone calls, unnecessary visits, and patient expenditures when caregivers are confident enough to troubleshoot problems if the patient's condition changes.

HOLISTIC PREPARATION OF PATIENTS AND WOUNDS FOR HEALING

Definition of wound care. Wound care is a term that encompasses all elements of wound management, including the control of complications and comorbid conditions as well as management of minimal pressure ulcers, sepsis, infection, bodily function disturbance, dietary and nutritional issues, and procedures directly related to wound management.¹⁰ Medicare defines wound care as "care of wounds that are refractory to healing or have complicated healing cycles either because of the nature of the wound itself or because of complicating metabolic and/or physiological factors. This definition excludes management of acute wounds and care of wounds that normally heal by primary intention such as clean, incised traumatic wounds, surgical wounds that are closed primarily and other postoperative wound care not separately payable during the surgical global period." Several authors support the principle that a wound should denote a more acute situation caused by trauma or surgery while ulcer implies a chronic "wound."¹⁵ For the purposes of this publication, the terms wound and ulcer are used interchangeably.

Goals of wound care centers. Panel members agreed that the primary goal of a QHP is to heal wounds as quickly as possible using the most evidence-based and cost-effective treatments. However, goals for each patient differ, typically based on intrinsic and extrinsic factors of the patient. For example, U.S. Wound Registry data demonstrate that the average WCC patient lives with 8 comorbid diseases and 30% of patients being treated for wounds other than DFUs have diabetes as a complicating factor.⁴

According to the wound bed preparation paradigm established by Sibbald and colleagues,¹⁶ a holistic, multidisciplinary team

Table 2. Control of Intrinsic Factors Affecting Wound Healing

Patient Factors	
Nutritional Status	<ul style="list-style-type: none"> • Prealbumin is considered the preferred marker for malnutrition because it has been found to correlate with patient outcomes in various clinical conditions.¹⁹ • Prealbumin levels should be part of a nutrition workup prior to treatment and/or surgery. • Knowing the prealbumin level allows QHPs to recognize protein malnutrition early on and administer nutritional therapy as needed. • Other markers include total protein, total lymphocyte count, retinol-binding protein, C-reactive protein, and zinc.
Diabetes	<ul style="list-style-type: none"> • Careful control of glucose intake, with adequate insulin or appropriate medication is essential to optimize the healing rate. • Patients with diabetes should be encouraged to exercise, eat a healthy diet, and maintain good nutrition to regulate blood glucose levels. • Patients can also be taught body awareness, especially if they experience diabetic neuropathy, to regularly check for open wounds or pressure points that could develop into a wound. • MRI was the gold standard of all imaging modalities among panel members in diagnosing a Wagner 2 diabetic foot ulcer, which is supported by controlled evidence that has conclusively shown an MRI is the most accurate of the currently available imaging modalities in defining and ruling out bone and/or tissue infection.^{20,21}
Anemia	<ul style="list-style-type: none"> • Monitoring iron levels and balancing them with appropriate nutrition may reduce anemia, which has the ability to stall wound healing due to low oxygen levels.
Obesity	<ul style="list-style-type: none"> • Patients who are obese should be encouraged to track and reduce calorie intake, eat nutritiously, and exercise to drop weight. • Obesity and its inherent risks in stalling wound healing should be considered when determining cost-effective treatment strategies.
Nicotine Use	<ul style="list-style-type: none"> • Nicotine from tobacco products has a temporary effect on the tissue microenvironment and a prolonged effect on inflammatory and reparative cell functions leading to delayed healing and complications.²² • Patients should be educated on the benefits of smoking cessation and warned of the relationship between nicotine and stalled wound healing.
Osteomyelitis and/or Uncontrolled Infection	<ul style="list-style-type: none"> • The gold standard for diagnosing osteomyelitis is bone biopsy with histopathologic examination and tissue culture.²³ • Osteomyelitis treatment is complex and typically requires a multidisciplinary team involving radiologists, vascular and orthopedic surgeons, infectious disease specialists, and the WCC team. • Proper cleansing and debridement, as well as watching closely for pain and swelling during the wound healing process are important in helping to identify infection and avoid the occurrence of osteomyelitis.
Circulation	<ul style="list-style-type: none"> • Palpation of peripheral pulses should be a routine component of the physical examination and include assessment of the femoral, popliteal and pedal pulses.²⁴ • Where available, Doppler ultrasound, ankle brachial pressure index, and Doppler waveform may also be used.
Incontinence	<ul style="list-style-type: none"> • Teaching the patient strategies for managing incontinence through toileting programs, diet, pelvic-floor muscle training, clothing modification, and mobility aids can be effective in reducing occurrence of incontinence-associated dermatitis.²⁵
Pain	<ul style="list-style-type: none"> • Effective pain management depends on adherence to a treatment strategy, as well as careful and regular assessment and reassessment using a validated pain scale.²⁶ • Analgesia should be timed for maximum effect during dressing changes. • Prevention of trauma on dressing removal is fundamental to minimizing pain at dressing changes and careful concentration on the procedure may help to avoid or reduce the pain experienced. • Strategies include maintaining a quiet, nonstressful environment, gentle handling, avoiding prolonged wound exposure, and reassurance and frequent verbal checks with the patient during the procedure.²⁷
Psychosocial Factors	<ul style="list-style-type: none"> • Panel members stressed the importance for QHPs to develop good relationships with patients to figure out the psychosocial issues each patient is facing to determine what may potentially cause wound care/patient noncompliance. • Interventions that improve healing outcomes by reducing psychological stress may be considered, including frank conversations with the patient, psychology consults, meditation, and pharmacological agents commonly prescribed for treating mood and anxiety disorders.
Medications	<ul style="list-style-type: none"> • If a wound is stalled, QHPs should review the patient's treatment plan for concurrent patient medications and/or other supplements that can delay wound healing.

QHP indicates qualified health care professional.

Table 3. Panel-Recommended Markers to Evaluate for Nutritional Assessment

Marker	Reference range in healthy adults
Albumin	35-50 g/L
Total protein	60-80 g/L
Total lymphocyte count	1.0–4×10 ⁹ /L (20–40%)
Prealbumin	15-38 mg/dL
Retinol-binding protein	30-75 mg/L
C-reactive protein	< 5 mg/L
Zinc	70-100 µmol/L

approach to assessing the whole patient, treating the underlying causes (i.e., extrinsic and intrinsic factors) and addressing patient-centered concerns must be considered first. This can be followed by appropriate wound bed preparation to ensure good wound healing.

Thorough patient assessment. Managing wounds successfully requires an accurate patient evaluation and assessment using a multidisciplinary approach that moves beyond standard care. Comorbidities, medical history, and social support network should be noted in the assessment. The admitting clinician must be able to recognize common wound types and atypical characteristics in order to collaborate with the multidisciplinary team to identify the right treatment guidelines and the associated interventions without delay.¹⁷ Furthermore, educational deficits in basic wound assessment can result in failure to recognize early signs of infection or wound deterioration, which may result in the need for more expensive treatments, use of antibiotics, and hospital readmissions.¹⁷

A systematic and rational approach should be used to determine wound etiology, underlying causes, and an accurate diagnosis. Establishing the correct diagnosis may involve multiple steps, including a biopsy. A biopsy provides a histopathologic diagnosis and can also clarify the skin disorder when a treatment plan is not yielding results. Panel members recommended a wound biopsy if the wound is older than 2 months or if doubts exist with a stalled wound. The literature has reported that a biopsy should be done when a wound has: 1) failed to respond to standard treatment

during a 3-month period, 2) developed an exophytic and hypergranular wound bed, or 3) become painful and/or malodorous with changes in the amount of exudate in the absence of infection.¹⁸

CONTROL OF PATIENT FACTORS AFFECTING HEALING

Nutritional status. Panel members emphasized the importance of a nutritional assessment, which is often overlooked in their experience. Optimum nutrition is a key component in all phases of wound healing. Markers recommended by panel members to evaluate nutritional status of patients are listed in Table 3.

A well-balanced diet with plenty of fruits and vegetables should be reinforced. An adequate intake of calories is required to promote anabolism, nitrogen and collagen synthesis, and healing. A daily intake of 30-35 cal/kg is recommended for patients of normal weight²⁸ and 35-40 cal/kg for patients who are underweight or losing weight.²⁹ During wound healing, protein intake is recommended at 2 times the recommended daily allowance of 0.8 g/kg/d (i.e., up to 1.5 g/kg/d) to allow for restoration of wound healing and any lost lean body mass.^{30,31} A decrease in lean body mass is of particular concern as this component is responsible for all protein synthesis necessary for healing.³⁰ A loss of more than 15% of total body mass will impair wound healing, and a loss of 30% or more leads to the development of spontaneous wounds such as pressure ulcers.³²

Certain vitamins, such as C and B-complex, and trace elements such as zinc, selenium, and copper are also essential for

wound healing.³⁰ Vitamin and mineral supplements are recommended when dietary intake is poor or deficiencies are confirmed or suspected.^{28,29} Restoration of deficient zinc levels can be performed by oral provision of zinc sulfate (220 mg three times daily).³³ Data indicate that correction of a zinc deficiency is beneficial while zinc supplementation over and above replacement has no added benefit in wound healing.³⁰ B-complex vitamins have been effective in lowering elevated homocysteine levels.³⁴

Deformities. Structural deformity has been identified as a risk factor for ulcer development and delayed healing in prospective studies.³⁵ In many instances, if deformities are not surgically corrected, the wound will not heal, or if the wound does heal, a subsequent breakdown is more likely to occur. Surgical correction of structural deformities has been successful in promoting wound healing in cases of underlying deformities such as hammer toe, hallux abducto valgus, and Charcot foot.³⁵

Although a thorough discussion of the pathophysiology and treatment of Charcot foot and ankle deformity is beyond the scope of this publication, panel members noted that surgical correction may be required to achieve therapy goals in patients with diabetes who also have Charcot foot. Recent trends in the literature advise earlier surgical correction of deformity and arthrodesis, based on the assumption that surgical stabilization leads to an improved patient-perceived quality of life.³⁶ Single and multistaged reconstruction protocols have been shown to achieve wound healing, deformity correction, and limb preservation in patients with Charcot foot and ankle deformity.^{37,38}

In addition to surgical correction, adequate offloading may be required in these patients with the gold standard method being the total contact cast (TCC).³⁹⁻⁴² Offloading with TCC has been reported to reduce inflammation and improve angiogenesis, fibroblast migration, and keratinocyte recruitment.⁴³ In addition, TCC may provide biomechanical benefits of redistribution of plantar pressure over a large surface area and decreased shear force. However, if surgical reconstruction is not

Table 4. Options for Offloading

Bed rest
Crutches, cane, walker, wheelchair
Knee rollator
Bracing (ankle foot orthosis, patellar bearing brace)
Padding (foam, silicone)
Orthotic inserts
Total contact cast

an option, long-term offloading options may be necessary (Table 4).

Diabetes. Panel members agreed that the influence of diabetes on wound healing is complex and multifactorial, affecting all stages of healing. Blood glucose levels, poor circulation, immune system deficiency, and diabetic neuropathy can influence wound healing in a patient with diabetes. Thus, it is critical for these patients to get the proper treatment plan in place as soon as possible. Careful control of glucose intake with adequate insulin is essential to optimize the healing rate because hyperglycemia causes tissue damage through the glycation of proteins. Proteins with a longer half-life, such as collagen, fibrin, albumin, and hemoglobin, build up advanced glycation end products, which can cause thickening of the basement membranes in microcirculation, leading to ischemia and impaired wound healing. A lack of insulin in diabetic wounds results in increased protein degradation and decreased collagen formation, reducing the body's ability to heal the wound.⁴⁴ Recent studies have also reported that patients with diabetes may have impaired cognitive abilities, which may impact patient compliance to treatment.⁴⁵⁻⁴⁷

Anemia. Low oxygen levels caused by anemia have the ability to stop or stall the normal wound healing progression, which leaves patients more susceptible to other complications such as infection. Treating this condition, usually marked by an iron deficiency, can be as simple as closely monitoring iron levels and balancing them with the appropriate foods.

Obesity. Patients who are obese take longer to heal from their wounds and are more likely to experience complications such as

infection, seromas, incision dehiscence, and anastomotic leaks during the wound healing process.^{48,49} The risk of wound infection is higher in these patients partly due to the avascularity of the surrounding adipose tissue.^{50,51} Avascularity decreases the body's ability to defend against infection because the lack of oxygen prevents neutrophils from effectively phagocytizing bacteria, thus increasing the bacterial load of the wound.⁵⁰ Reduced blood supply to the wound prevents necessary cells, including neutrophils and macrophages, from arriving at the wound site to guard against infection. Patients who are obese also need to be evaluated for protein malnutrition and treated accordingly.

Use of nicotine. Nicotine, an alkaloid poisonous substance present in all tobacco products, reduces cutaneous blood flow via vasoconstriction, stimulates release of proteases that may accelerate tissue destruction, suppresses the immune response and leads to an increased risk of infection.⁵² Inflammation and fibroblast proliferation are delayed in nicotine users, and the neutrophil cell count is increased.²² A decreased chemotactic responsiveness and migratory capacity of cells and an increased release of proteolytic enzymes can lead to connective tissue degradation.⁵³ Quitting use of nicotine products restores the tissue microenvironment rapidly and the inflammatory cellular functions within four weeks, but the proliferative response remains impaired.²²

Osteomyelitis and/or uncontrolled infection. Presence of osteomyelitis stalls wound healing and, if untreated, can irrevocably damage bone. Diagnosis of osteomyelitis can be difficult and should begin with a thorough wound inspection for exposed bone with cortical disruption and plain radiographs but may include a variety of imaging modalities.²³ In cases of proven osteomyelitis, C-reactive protein and erythrocyte sedimentation rate tests may be used to assess response to therapy or relapse.²³ Proper cleansing and debridement, as well as watching closely for pain and swelling during the wound healing process, are important in helping to identify infection and avoid the occurrence of osteomyelitis.

Circulation. Insufficient blood flow to the skin delays or sometimes prevents wound healing. Lack of arterial flow can directly

create tissue loss. Patients can be encouraged to enhance circulation by applying heat, stopping use of nicotine, elevating the wound when sitting, exercising more, and eating a healthy diet. To heal a leg or foot ulcer, a palpable dorsalis pedis pulse of ≥ 80 mmHg and brachial systolic pressure of ≥ 100 mmHg are necessary, especially if an arterial or ischemic wound is suspected. Palpation of a pulse should not be equated to having adequate blood flow to heal. Toe pressures and, in certain cases, transcutaneous oxygen measurement, may be useful for measuring local tissue perfusion.

Decreased perfusion or impaired circulation may be an indicator for revascularization, which is needed to achieve and maintain healing and to avoid or delay a future amputation.⁵⁴ The QHP must be able to differentiate between macrovascular disease, which can be surgically treated, and microvascular disease, which cannot be treated surgically. A patient with acute limb ischemia is a clinical emergency and may be at great risk unless managed effectively and immediately by a multidisciplinary surgical team with access to a vascular surgeon or interventionalist.⁵⁵

Incontinence. Incontinence-associated dermatitis (IAD) or moisture-related skin breakdown stems from the effects of urine, stool, and adult briefs on the skin. Proper cleansing, moisturizing, and protection are necessary for IAD prevention. Appropriate diagnosis, prompt treatment, and management of the irritant source are critical for effective treatment.³⁶ Caregivers should be encouraged to screen the patient's skin at least daily for persistent redness, inflammation, rash, pain, and itching, all signs of IAD.

Pain. Chronic pain delays wound healing⁵⁷ and painful wounds can result in vasoconstriction and decreased tissue oxygen.⁵⁷ Pain can be caused by the wound itself, interventions, or other wound pathology. Stress and anxiety from wound pain can indirectly impair wound healing by activating the hypothalamic pituitary-adrenal axis, which stimulates cortisol production and in turn can suppress the immune system.⁵⁸ Stress can be induced by anticipation of pain, such as prior to dressing changes,⁵⁹ which have been found to be a major contributor to wound pain.²⁶

Table 5. Medications and Supplements That May Delay Wound Healing

High doses of systemic steroids ⁶²
Immunosuppressive drugs ⁶³
Immunosuppressive rheumatoid arthritis medications (biologic and nonbiologic DMARDS)
Nonsteroidal anti-inflammatory drugs ⁶³
Antimetabolite cancer chemotherapy ⁶²
Vitamin E (>100 IU daily) ⁶²
Colchicine
<i>DMARDS: disease-modifying antirheumatic drugs</i>

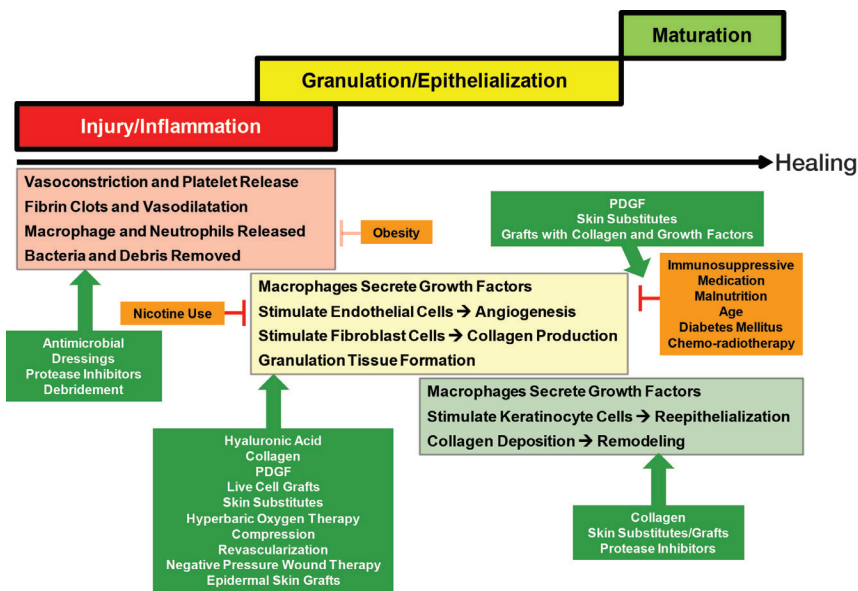


Figure 3. Inhibiting Wound Healing Factors and Their Cellular Level Effects
 PDGF indicates platelet-derived growth factor.

Psychosocial factors. Psychological stress has been shown to negatively impact wound healing. Patients who experience the highest levels of depression and anxiety have been found to be significantly more likely to have delayed healing of chronic wounds.⁶⁰ Patients who believe their wound and/or complications could pose severe consequences to their health and that the therapy will be effective or is beneficial are more likely to be compliant.⁶¹

Medications. Medications and supplements can adversely affect wound healing (Table 5). A medication review is important, especially if a healable wound is not progressing as expected. More than 100 IU daily of vitamin E should be avoided because it scavenges oxygen at the tissue level, limiting the oxygen

needed for wound healing. Wound progress may also stall during periods when a patient is undergoing chemotherapy, and use of antioxidants may even be contraindicated in this patient population.

CONSIDERATIONS FOR SPECIAL PATIENT POPULATIONS

Specific characteristics of special populations, such as aged (i.e., > 60 years) and immunosuppressed patients also need to be addressed.

Aged patients. The incidence of chronic ulcers related to diabetes, peripheral vascular disease, and mobility issues occurs with increasing frequency in the geriatric population. Skin of the aged has a decrease in water content, tensile strength, and junctional

integrity between the dermis and the epidermis, as well as a loss of subcutaneous tissue, vascularity, and diminishing stability of small blood vessels which compromises skin integrity.^{64,65} Many older patients are also on multiple medications, some of which may affect wound healing. Proper treatment and care must be taken to prevent excessive damage or injury to an aging person's integumentary system. Moisturizing dry skin may help prevent skin ulcers. Panel members discussed the importance of quick wound closure in elderly patients who are at greater risk for complications due to increased comorbidities. Amputation is generally not an option, and some panel members discouraged split-thickness skin grafts in this patient subset due to the serious donor site complications that can result. Palliative care and achieving a manageable chronic wound may be acceptable goals in some aged patients.

Immunosuppressed patients. Immunosuppressive therapy is increasingly being used in clinical practice in conditions such as organ transplant and inflammatory bowel disease.⁶⁶ However, the interactions of immunosuppressive drugs with some of the inflammatory mediators has been shown to impair the wound healing process to various degrees.⁶⁷ Many of these drugs are essential for the patient's continuing health, but it is important to note they can have a deleterious effect on wound healing. Dose reduction or even avoidance of these drugs until complete wound healing is achieved has been suggested,⁶⁸ especially for the newer immunosuppressants, such as everolimus and rapamycin. Figure 3 lists several inhibiting factors of wound healing as well as their cellular level effects and therapies that may help address deficiencies.

WOUND BED PREPARATION

Wound bed preparation is defined as "the management of the wound to accelerate endogenous healing or to facilitate the effectiveness of other therapeutic measures."⁶⁹ Normal wound healing usually progresses through four phases (i.e., hemostasis, inflammation, proliferation, and remodeling/maturation),⁷⁰ which are sequentially regulated by the actions of chemokines, cytokines, growth factors, and proteases.

Table 6. Wound Infection Stages

Wound Infection Stages	Definition
Contaminated	Presence of nonreplicating organisms that do not impair wound healing
Colonized	Presence of replicating organisms that do not impair wound healing; absence of tissue necrosis
Critically Colonized	Presence of replicating organisms and impaired wound healing without a subsequent host response
Infected	Histological demonstration of tissue invasion by organisms and a subsequent host response; wound healing is impaired

Adapted from Gabriel et al.⁷³

The TIME (tissue, infection/inflammation, moisture balance, and edge of wound) concept provides an approach to local wound care and was based on the management of chronic wounds.^{16,71} The TIME₂ approach emphasizes the importance of the TIME concept and adds the role for correction of hypoxia.⁷² The 2011 update on wound bed preparation presented the DIME (debridement/devitalized tissue, infection/inflammation, moisture balance, and wound edge preparation/wound depth) concept and introduced categories of healable, maintenance, and nonhealable wounds.⁶²

Wounds are considered healable if the underlying cause or causes can be corrected or treated. The DIME approach emphasizes the importance of optimizing debridement, controlling infection and persistent inflammation, and moisture balance before addressing the edge effect for healable but stalled wounds. Evaluating wounds in terms of their ability to heal also facilitates development of more realistic therapy goals and treatment plans. Consistent with all of the wound bed preparation approaches discussed during the past decade is an emphasis on a holistic interprofessional team approach that addresses the concerns of the patient as well as causes of the wound.

Debridement. All panel members emphasized the importance of thorough debridement of eschar, necrotic tissue, and slough to optimize wound bed preparation. Various types of debridement can be used, including sharp/surgical, autolytic, ultrasonic, mechanical, enzymatic, and biologic. Chronic

wounds typically require repeated debridement to facilitate growth of healthy granulation tissue.

Infection. Infection is the result of a bacterial imbalance in the wound that causes a host reaction. Nonreplicating bacteria (ie, contaminated wound) or replicating bacteria that are not affecting the host (ie, colonized wound) do not impair wound healing (Table 6). The appearance of secondary symptoms (e.g., increased serous exudate or dark red granulation tissue) indicates a critically colonized wound in which the increasing bacterial burden is beginning to affect wound healing. In an infected wound, bacterial invasion of the tissue triggers symptoms in the host (eg, fever, warmth, edema, pain, and purulent drainage). Host resistance to infection is affected by adequate blood supply to the wound, age of the patient and whether the patient has diabetes, cardiac disease, and other comorbidities. Superficial critical colonization is treated with topical antimicrobials, while deep infection requires systemic antibiotics. The gold standard for measuring bacterial levels has typically been tissue biopsy and culture. Use of proper culture techniques (e.g., deep tissue culture under sterile conditions) may also assist physicians in identifying the appropriate antibiotic therapy. Furthermore, clinical signs of infection (eg, inflammation, purulence, cellulitis, and fever) can be used to identify which wounds to culture.⁷³

Inflammation. Persistent inflammation degrades growth factors and extracellular matrix more quickly than these can be

synthesized, stalling the wound healing process. Chronic wounds are characterized by increased activity of inflammatory cells, MMPs and elastase.⁷⁴ Use of topical growth factor therapy in an inflammatory wound environment has had a limited effect due to the binding of growth factors in the wound base by macromolecules⁷⁵ and insufficient penetration of growth factors into granulation tissue.⁷⁶ Grafts, including epidermal skin grafts, are also more likely to fail when there are excessive protease levels in the wound bed. Noninfectious persistent inflammation can be treated with topical and/or systemic anti-inflammatory drugs.

Moisture balance. Maintenance of optimal moisture balance in a wound is known to significantly improve healing. Insufficient moisture inhibits the functioning of growth factors and cytokines and impedes the migration of cells (e.g., fibroblasts and keratinocytes). Excessive wound fluid can result in maceration of the periwound skin and potentially lead to wound breakdown. A wide range of dressings have been developed to help manage moisture levels in wounds that have the ability to heal.

Oxygen supply. The state of wound oxygenation is a key factor in all major processes of wound healing. Extreme hypoxia, commonly found in chronic wounds, is not compatible with tissue repair.⁷⁷ Measurement of transcutaneous oxygen pressure (TcPO₂) during inhalation of pure oxygen or hyperbaric oxygen exposure has been employed to select patients for HBOT and values under 40 mmHg have been associated with poor ulcer healing in diabetic patients.⁷⁸

Many chronic wounds are stuck in the inflammatory phase due to impaired oxidative killing, a specific function of neutrophils that involves reactive oxygen species generation by nicotinamide adenine dinucleotide phosphate (NADPH) oxidase. Adequate oxygen supply provides normal NADPH oxidase function and regulates angiogenesis, extracellular matrix formation, and movement of cells.⁷⁹ Hyperbaric oxygen therapy has been shown to significantly increase TcPO₂ levels and promote angiogenesis.^{80,81}

Other endogenous factors. Other endogenous barriers to healing include reduced blood flow, edema/lymphedema, exposed

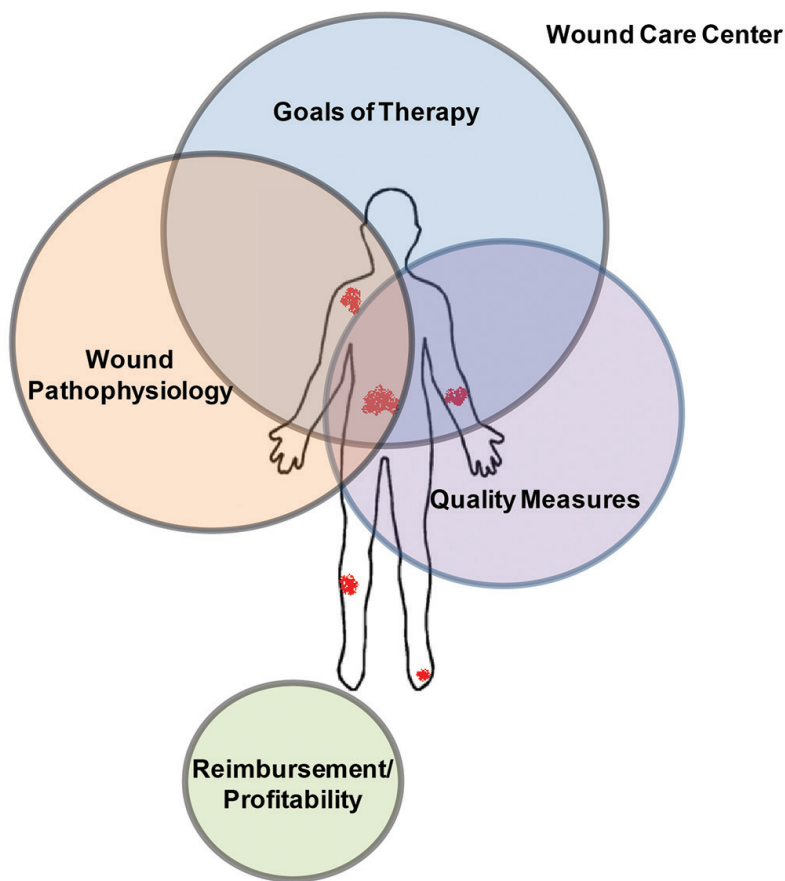


Figure 4. Wound Care Center Treatment Influences

structures and tunneling. Reduced blood flow in the diabetic foot is a complex scenario and is characterized by various factors relating to microvascular dysfunction in addition to peripheral artery disease.⁵⁴ Patients with edema/lymphedema in the lower extremities are at greater risk of developing lower leg wounds or delayed healing of current wounds.⁶²

Addressing exogenous factors. Exogenous factors (e.g., temperature, chemical,⁶² and mechanical stress) can also contribute to delayed wound healing. Cells and enzymes function optimally at body temperature. A temperature decrease of 2°C during dressing replacement can affect biological processes. Wounds should be insulated and not left exposed for longer than necessary.

Mechanical and chemical stress/trauma can also contribute to delayed healing. Protecting the wound from mechanical stress includes careful sharp debridement so as not to induce an inflammatory stage. The

use of wet-to-dry dressings for mechanical debridement is also discouraged because of the trauma caused to the wound bed. Some topical antiseptics are cytotoxic, and their ongoing use can damage cellular elements and the microcirculation of the wound. These antiseptics may play an important role in topical management of heavily contaminated acute traumatic wounds but should not be used for long periods on chronic ulcers because of chemical stress.

Holistic reassessment. When a wound deemed “healable” does not progress to healing as expected, reassessment is needed. Regular comprehensive assessment and documentation of the wound are essential for monitoring change and making decisions. If patient reassessment reveals no additional causes or other cofactors (e.g., medicines that delay healing), advanced therapies may be initiated to stimulate closure. This may also be the time to consider a biopsy or use of an offloading device, if

appropriate (e.g., in case of plantar foot). A weekly meeting at the WCC during which “outlier” wounds are discussed may be beneficial in gaining valuable insight from the interprofessional team.

Documented improvement of the wound and progression towards treatment goals—generally, healing—indicate that topical interventions are successful in improving the wound environment. Progress indicators include healthy or improving periwound skin, reduced wound size, healthy wound bed with no sign of infection, reduced dressing change requirements, and lack of or reduction in wound odor and/or pain.

CRITICAL THINKING IN DEVELOPING TREATMENT PATHWAYS

Selecting appropriate products and therapies. Once a complete assessment has been performed and patient and wound factors affecting healing are identified and addressed, it is time for the important task of choosing the optimal wound treatment. The method of choosing treatment should be systematically and consistently employed for all patients. Dressing choice must be based on the fundamental process of wound repair and adhere to the basic concepts in wound management. Modern outpatient wound care requires a honed ability to choose among many wound dressings within cost constraints of a patient’s insurance or home health agency, or appropriate allocation of the limited stock of dressings to best manage the wound over an acceptable time frame.¹⁴ Cost-effective management of this process demands a comprehensive understanding of dressing options and actions.

All panel members stressed that identifying which advanced dressings are available based on reimbursement policies, contract requirements, and when they can be applied is of prime importance when considering treatment strategies. Once options are identified, panel members recommended choosing a dressing or therapy based on critical concepts in wound healing to satisfy quality measures. The purpose of this section of the manuscript is to describe quality measures and provide dressing and/or therapy recommendations based on understood concepts in wound healing.

Table 7. 2016 Sample U.S. Wound Registry Suggested Quality Measures in Wound Care

Adequate off-loading of DFU at each visit
Plan of care for VLU not achieving 30% closure at 4 weeks
Healing or closure of Wagner Grade 3, 4, or 5 DFU with HBOT
DFU healing or closure at 6 months
Appropriate use of HBOT for patients with DFU
Major amputation in Wagner Grade 3, 4, or 5 DFUs treated with HBOT
Plan of care for patients with DFU not achieving 30% closure at 4 weeks
Appropriate use of cellular or tissue-based products for patients with DFU or VLU
Preservation of function with a minor amputation among patients with Wagner Grade 3, 4, or 5 DFUs treated with HBOT
Diabetic foot and ankle care: comprehensive diabetic foot examination
Vascular assessment of patients with chronic leg ulcers
Patient-reported experience of care: wound outcome
Adequate compression at each visit for patients with VLU
Wound bed preparation through debridement of necrotic or nonviable tissue
Nutritional screening and interventional plan in patients with chronic wounds and ulcers
VLU healing or closure at 6 months
<i>DFU indicates diabetic foot ulcer; VLU, venous leg ulcer; HBOT, hyperbaric oxygen therapy.</i>
<i>Adapted from Quality Measures in Wound Care: 2016 U.S. Wound Registry Measures for Reporting.⁸⁴</i>

CRITICAL THINKING FOR SELECTION PROCESS

Panel members supported a concept of critical thinking in choosing outpatient wound treatment strategies. This concept combines use of the multidisciplinary team approach in good patient and wound bed preparation advocated by many authors, as well as a deep understanding of basic pathophysiological concepts in wound healing.

Critical thinking has been described as the process of intentional higher level thinking to define a patient's problem, examine the evidence-based practice in caring for that patient, and choose the most appropriate interventions that will improve the patient's condition while meeting the challenge in maintaining profitability in the outpatient wound clinic.

Product selection: What do you choose and why? With the availability of hundreds of dressing and therapy options to manage a wound, the selection process can appear

daunting. The panel members identified five major variables (Figure 4) to guide wound dressing/therapy selection. These are:

- Goals of therapy
- Quality measures
- Wound pathophysiology
- Reimbursement of product cost and professional fee for placement
- Wound care center product stock availability

Does dressing/therapy achieve goal of therapy? Once a diagnosis is determined, expectations and a plan of care should be established and communicated clearly to the patient. Panel members stressed that it is important to speak truthfully to the patient. Effectively communicating all risk factors to the patient that may impact his or her ability to heal can help reduce frustration and improve patient satisfaction. Usually, the ultimate goal of therapy is to achieve long-term wound closure. As the payment system shifts to one based on value, time to

closure is an increasingly important component of the goal of therapy. Treatment should be orchestrated to get a good outcome in a shorter length of time; however, it is important to ascertain early in the course of care if the wound is difficult to heal.⁸² Pain control and optimizing quality of life for the patient may be part of the treatment goals.

Does treatment help meet quality measures? It is estimated that by 2018, between 50% and 90% of Medicare physician fees will be tied to the quality (instead of volume) of care delivered.⁸³ Quality measures (QMs) are tools that are intended to quantify health care processes, outcomes, and patient perceptions; these measures are being used by CMS and many other organizations in various ways. Organizations are using quality data as part of physician compensation packages as well as to negotiate payment rates with insurers. The measures can have profound medicolegal, social, and professional implications. It is, therefore, imperative that measures be designed around interventions that are within the control of the provider to implement, are representative of best clinical practices, and actually reflect the services the provider offers. Data needed to report QMs are extracted from EHRs.

While the U.S. Wound Registry and other medical specialty societies have suggested several wound care quality measures, at the time of this publication, none have been adopted by CMS, the most likely reason being that wound care is not yet officially recognized by CMS as a medical specialty.⁸³ Successfully reporting these QMs will be imperative for financial survival in outpatient wound care in the future, and it is widely recommended by panel members and managers of the U.S. Wound Registry⁸³ that QHPs begin reporting "home-grown" QMs in preparation for the switch to value-based reimbursement.

The dressing or therapy for each wound chosen is based on the expectation that it will be instrumental in achieving QMs. In a value-based scenario, the most expensive products are the ones that don't work. Wet-to-dry gauze is not standard of care. In fact, CMS has listed wet-to-dry gauze dressings as a negative quality indicator. Table 7 contains some of the wound care-specific QMs

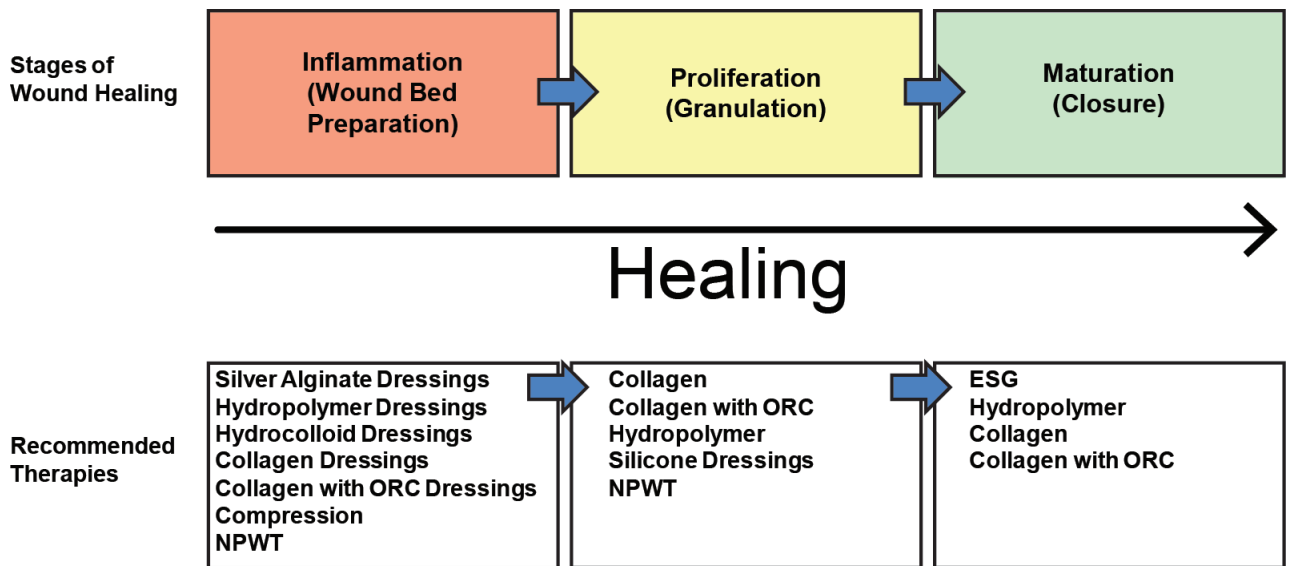


Figure 5. Stages of Wound Healing and Recommended Therapies
NPWT indicates negative pressure wound therapy; ORC, oxidized regenerated cellulose; ESG, epidermal skin graft.

for reporting that have been suggested by the U.S. Wound Registry.

Does the therapy address pathophysiological needs of the wound? Pathophysiological aspects involved in normal and impaired wound healing are detailed earlier in this manuscript. Panel members stressed the critical importance for QHPs to understand the complex clinical processes of normal and delayed wound repair, which allows QHPs to better determine the pathophysiological needs of each wound during assessment.

Pathophysiology is the study of the disordered physiological processes associated with or resulting from the disease or injury. Concepts in wound healing pathophysiology help determine the type of dressing/therapy needed, as well as when to transition to a different therapy. Table 8 displays a suggested list of dressings and therapies based on assessment and the suspected pathophysiological needs of the wound and Figure 5 summarizes recommended dressing/therapy use by wound healing phase.

Is the product/therapy reimbursed in this care setting? Payer reimbursement policies for products, therapies, and services rendered in WCCs are complex and ever changing. Currently, it is paramount to choose individual dressings and therapies only if they are reimbursed. However, a major shift toward quality-based reimbursement is on the horizon,

which will likely feature a bundled form of payment. To remain profitable, it is crucial that each WCC designate persons who closely follow the latest coverage rules that specify coverage indications, limitations, and/or medical necessity, covered/non-covered product codes, procedure codes and modifiers, covered diagnosis codes, utilization guidelines, and documentation guidelines.⁸⁷ While it is paramount to understand all of the current nuances of reimbursement in WCCs, future survival of each WCC will depend on how well QHPs are prepared for a reimbursement system tied to QMs.

Is the product/therapy available to the patient in the wound care center and at home? Before selecting a treatment, it is important to determine if the product or therapy is available to the patient both within the WCC and at home. Home health care agencies often have a narrow selection of products and avoid providing more expensive collagen or silver dressings, or even high quality foams and alginates. Unfortunately, this can limit the outpatient WCC in the type of wound care products they can use with patients who will be using home health agency services. In addition, certain dressings favored by QHPs may not be allowed in the clinic due to the hospital's contractual agreements with suppliers.

ATYPICAL WOUNDS: SPECIAL CONSIDERATIONS FOR TREATMENT

Atypical wounds are also known as wounds of unknown etiology and are caused by conditions or diseases that do not typically form a wound, such as autoimmune disorders, infectious diseases, vascular diseases and vasculopathies, metabolic and genetic diseases, neoplasm, external factors, psychiatric disorders, and drug-related reactions. Many systemic diseases can present with atypical wounds. The primary cause of the wound can be either the systemic disease itself (e.g., Crohn's disease) or an aberrant immune response due to systemic disease (e.g., pyoderma gangrenosum, paraneoplastic syndrome). It has been recommended to suspect causes, other than venous insufficiency, for lower leg ulcers if the wound has been present for longer than six months, has not responded to good care, or looks atypical, such as the presence of necrotic tissue, exposed tendon, livedo reticularis on surrounding skin, or a deep "punched-out" ulcer.⁸⁸ Laboratory tests (Table 9) are recommended to screen for atypical wounds.⁸⁸

Diagnosing an atypical wound. Tissue biopsy is recommended for differential diagnosis of inflammatory, microthrombotic, and bullous disorders such as nonatherosclerotic ischemic ulcers (i.e., vasculitis,

Table 8. Recommended Therapies Based on Wound Pathophysiological Evidence

Displayed pathophysiological factor(s)	Suspected cause	Suggested wound dressing/therapy
Prolonged inflammation	Elevated bioburden (impaired keratinocyte migration and leukocyte function; degraded cytokines and ECM; stress on local cells) ⁸⁵	Silver-ORC/ORC/collagen dressing Larval therapy Iodine- or honey-impregnated dressing Enzymatic debridement
Prolonged inflammation	Elevated protease levels (ECM degradation and dysfunction)	Silver-ORC/ORC/collagen dressing Collagen dressing Enzymatic debridement
Over-production of exudate	Inflammation Bioburden Limb dependency	Hydrocolloid Hydropolymer dressing Silver alginate Foam NPWT/disposable NPWT Some forms of hyaluronan
Wound bed desiccation	Moisture imbalance Mechanical debridement	Hydrogel Enzymatic debridement ⁸⁶
Delayed rebuilding of granulation tissue (angiogenesis)	Poor perfusion (tissue hypoxia) and/or ischemia-reperfusion injury	Compression NPWT/disposable NPWT HBOT
Delayed rebuilding of granulation tissue (angiogenesis)	Low transcutaneous oxygen measurement around wound	HBOT
Delayed rebuilding of granulation tissue (angiogenesis)	Degraded ECM components, growth factors, protein and receptors	Acellular dermal matrix Biosynthetic skin substitute Collagen dressing ORC/collagen matrix Hyaluronic acid PDGF (eg, becaplermin)
Delayed reepithelialization	Incomplete basement membrane Decreased activation of keratinocytes to proliferate and migrate Suppressed expression of multiple cytokines and growth factors	ESG STSG Epidermal growth factor
Weakened tissue during remodeling	Previous presence of a wound	Compression as needed HBOT Continued treatment plan as needed to help prevent wound breakdown

ECM indicates extracellular matrix; ORC, oxidized regenerated cellulose; NPWT, negative pressure wound therapy; HBOT, hyperbaric oxygen therapy; PDGF, platelet-derived growth factor; ESG, epidermal skin graft; STSG, split-thickness skin graft.

vasculopathy), inflammatory conditions, malignancies, infections, autoimmune bullous disorders, venous ulcers, neuropathic ulcers, medication-induced wounds, pressure ulcers, and traumatic wounds.⁸⁹ If a punch biopsy performed in an outpatient setting fails to confirm a suspected diagnosis in a wound that has failed other treatment measures, a surgical biopsy that can sample

a larger area of tissue may be indicated. In cases where the biopsy does not help diagnose the wound etiology, panel members recommended reviewing the patient's medical history again. For example, long-term hydroxyurea treatment can lead to atypical ulcers due to cell damage. Hydroxyurea selectively kills cells during the synthesis phase of the cell cycle (i.e., S phase) but does not

affect ribonucleic acid synthesis. This can affect basal keratinocyte and collagen synthesis. Some new oncology drugs also trigger skin reactions. Tracking the timing of chemotherapy is necessary, as it can be the cycle of the medication, not just the medication itself, causing the wound.

Atypical Wound Treatment. Usual wound care therapies are not effective in healing

Table 9. Laboratory Tests to Screen for Atypical Wounds

Hematologic tests	Chemistry tests	Immunologic tests (eg, autoimmune disorders, vasculitis)
Complete blood count with differential Sedimentation rate C-reactive protein Antithrombin III Protein C Protein S Factor V Leiden Peripheral blood smear Homocysteine Hemoglobin electrophoresis Cryoglobulins/cryofibrinogens Glucose-6-phosphate dehydrogenase Complement Fibrinogen/fibrin degradation products/D-dimers Prothrombin time/partial thromboplastin time	Kidney (eg, blood urea nitrogen, creatinine) Liver (eg, liver enzymes, hepatitis panel) Electrolytes Glucose Fasting lipids Hemoglobin A1c Amylase/lipase Iron Folate Ferritin Parathyroid hormone Calcium Phosphorus Magnesium Albumin Prealbumin Vitamins/minerals Aldolase Creatine kinase Transferrin	Antistreptolysin O titer Antinuclear antibodies Rheumatoid factor Quantitative immunoglobulins Serum and immune protein electrophoresis Complement (eg, CH50, C3, C4) Antineutrophil cytoplasmic antibodies and protoplasmic-staining Antineutrophil cytoplasmic antibodies Indirect immunofluorescence Antiphospholipid antibodies (eg, lupus anticoagulant, immunoglobulin G, immunoglobulin M, anticardiolipin antibodies)

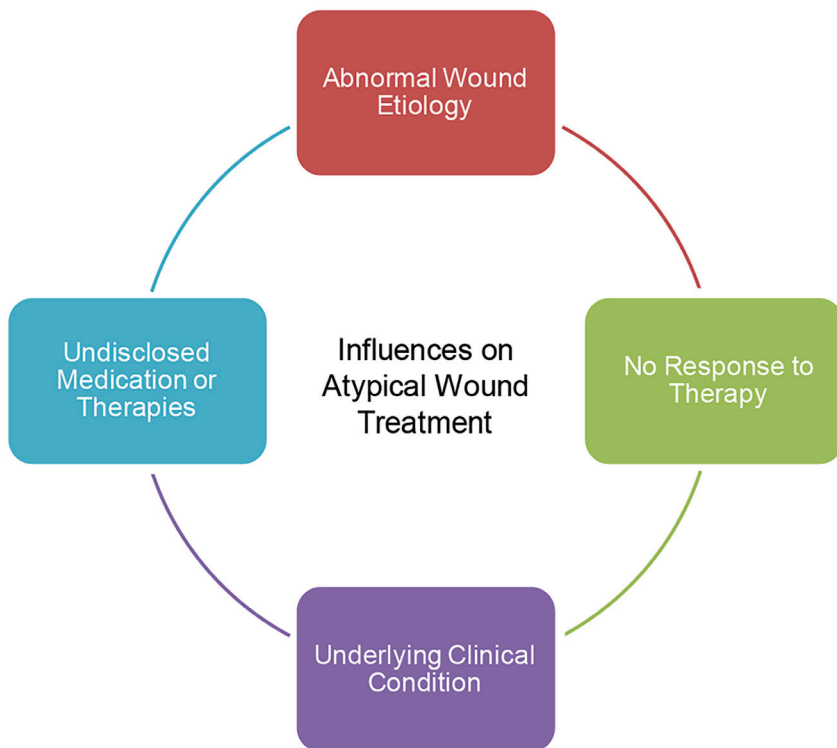


Figure 6. Influences on Atypical Wound Treatment in the Wound Care Center

atypical wounds, and controlling the underlying disease process is paramount. Evaluating and managing wound tunnels are

also important during this process. During treatment, it is important to understand proteases and inflammatory processes. Major

necrosis is often indicative of a highly proteolytic environment and increased tumor necrosis factor-alpha (TNF- α) levels.⁹⁰ Controlling inflammation and modulating TNF- α can allow wound healing. Infliximab is a TNF- α inhibitor that has emerged as a useful therapy for collagen vascular diseases or graft versus host disease. Reports in the literature describe successful use of infliximab to control underlying inflammatory processes so advanced therapies and dressings can be successful in wound closure.⁹¹ Panel members recommended use of skin substitutes and epidermal grafting for coverage of atypical wounds instead of split-thickness skin grafts, when needed. Figure 6 summarizes influences on atypical wound treatment in a WCC.

Case study: atypical lower leg tunneling wound. A 57-year-old active female presented with a nonhealing inflammatory lower leg ulcer of 3 weeks duration (Figure 7A). The patient's medical history included hypertension, thyroid disease, anxiety, osteoarthritis, gastroesophageal reflux disease, hepatitis, positive for purified protein derivative, cardiac syndrome X, arthroscopy, and thyroidectomy. Wound influences included circumscribed scleroderma and noncompliance.

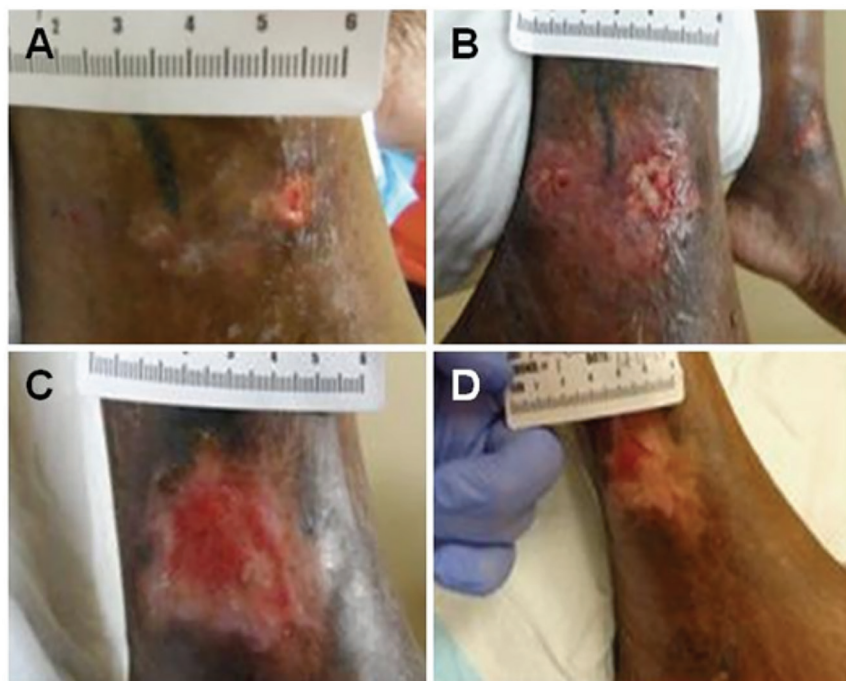


Figure 7. Representative atypical nonhealing wound. (A) Lower leg wound at presentation; silver-oxidized regenerated cellulose (ORC)/ORC/collagen was initiated in the wound. (B) A human fibroblast-derived dermal substitute was placed over the wound after 2 months; serial applications of the dermal substitute followed. (C) After 15 months, an epidermal graft was harvested and placed in the wound. (D) Two months later, the wound was healed.

Therapy goals for this patient were to promote granulation tissue formation, manage bioburden, and promote reepithelialization. Pathophysiological concerns were inflammation, minimized adherence, and bioburden control with concern for exudate management.

Treatment included five excisional subcutaneous debridements and five selective nonexcisional debridements that were performed as needed. Over the entire course of treatment, four cultures were taken; however, no antibiotics were required. Silver-ORC/ORC/collagen dressing (PROMOGRAN PRISMA Matrix, Systagenix, an ACELITY Company, San Antonio, TX) was used in the wound to assist in bioburden control. After two months, a human fibroblast-derived dermal substitute was placed over the wound (Figure 7B). Over the next 10 months, four subsequent dermal substitute placements followed. Silver-ORC/ORC/collagen dressings were continued between dermal substitute procedures. At 15 months after initial presentation, the wound was reepithelializing with healthy wound edges, and an epidermal graft was harvested using a commercially-available epidermal harvesting system

(CELLUTOME Epidermal Harvesting System, KCI, an ACELITY Company, San Antonio, TX) for placement over the recipient site (Figure 7C) to assist final closure. The wound was healed at 16 months (Figure 7D).

SURGICAL WOUNDS: SPECIAL CONSIDERATIONS FOR TREATMENT

Surgical site infections (SSIs) can be classified as superficial incisional, deep incisional, or organ/space according to their location, timing of onset, and local signs and symptoms.⁹² Diagnosis mostly depends on the subjective assessment of pain or tenderness, swelling, erythema, and purulent discharge from the wound, although no consensus on criteria has been established.⁹³ Signs of SSI typically show up at least 48 hours after surgery and within 30 days, or up to one year following insertion of a prosthesis, such as total hip or knee replacement.⁹⁴ Early diagnosis is critical for effective management. Outcomes in these patients are also heavily dependent on patient adherence to the treatment plan, as well as patient lifestyle factors, such as nicotine use and obesity.

Incision sites should be opened to remove sutures and infected material and to assist

drainage. There should be a low threshold for return to the operating room for washout and/or surgical exploration, debridement, and foreign body removal (eg, permanent sutures, mesh, sternal wires, hardware) in wounds that fail to improve.

Recommendations for the use of antibiotics in SSI have recently been published;⁹⁵ empirical antimicrobial choice is influenced by location and clinical presentation. Debridement of necrotic tissue is a key component of surgical wound management. Excessive exudate may be indicative of SSI or predisposal to increased bioburden. The goals of wound dressing products are to provide a moist wound bed, protect the open incision/wound bed from trauma or potentially harmful agents, manage drainage/exudate, and manage infection.⁹³ Dehiscent surgical wounds, such as sternal separation and abdominal incisions without evisceration, can be managed with NPWT.⁹⁶ If the wound deteriorates or fails to improve after 14 days, it is recommended that an alternative antiseptic/antimicrobial agent be used.⁹⁶ Major influences on surgical wound treatment in the WCC are depicted in Figure 8.

Case study: surgical wounds post liposuction. A 23-year-old female with no prior significant medical history presented with surgical wounds secondary to liposuction that damaged neurovascular bundles. Therapy goals were to address wound influences and achieve fast closure with good cosmesis. Pathophysiological concerns included overcoming necrosis, examining damage to blood flow system due to mechanical disruption (via liposuction), and to continue close evaluation for signs and symptoms of infection and inflammation.

Upon admission to the WCC (Figure 9A), the wound was initially treated with surgical debridement. No antibiotic therapy was required. Continuous NPWT (V.A.C. Therapy, KCI, an ACELITY Company, San Antonio, TX) was initiated at -125 mmHg to help promote granulation tissue formation and prepare the wound base for graft closure. After three weeks, the wound bed was 100% granulated, and NPWT was discontinued (Figure 9B). The patient then received HBOT for six weeks to encourage angiogenesis in a damaged wound field. Silver-ORC/ORC/collagen

COMPLEX CHRONIC WOUNDS: SPECIAL CONSIDERATIONS FOR TREATMENT

Chronic wounds have been defined as wounds that have “failed to proceed through an orderly and timely series of events to produce a durable, structural, and cosmetic closure.”⁹⁷ Some authors have classified chronic wounds as wounds that have been open for more than 90 days.⁹⁸ However, since the timeline for healing a normal or acute wound is usually four weeks, by definition, wounds could be considered chronic if they have been open for longer than three weeks (21 days).⁹⁹ More than 90% of all chronic wounds can be classified as venous ulcers, pressure ulcers, or diabetic ulcers. Although these three chronic wound types stem from different basic etiologies, there are general principles of wound pathophysiology and management that are applicable for all chronic wound types.

Mustoe et al⁸⁵ proposed a unifying hypothesis of chronic wound pathogenesis based on four main causative factors: local tissue hypoxia, bacterial colonization of the wound, repetitive ischemia-reperfusion injury, and an altered cellular and systemic stress response in elderly patients.⁸⁵ The TIME approach originally proposed by Sibbald et al⁸² stressed the importance of debridement, treatment of inflammation and infection, moisture balance, and addressing the wound edge effect for wound bed preparation.⁸² Both of these approaches point to the importance of decision making based on pathophysiological factors typically present in the chronic wound. Also, Shah⁷² proposed modifying the TIME approach to TIMEO₂, stressing the importance of hypoxia correction in wound bed preparation.

The individual role of each therapy may be improved by combining therapies to address the pathophysiological etiologies underlying the chronic wound. Mechanisms of NPWT, including edema reduction, removal of infectious materials, and promotion of perfusion, address several common pathophysiological etiologies underlying chronic wounds. Primary influences on chronic wound treatment in WCCs are shown in Figure 10. The ongoing challenge in outpatient chronic wound

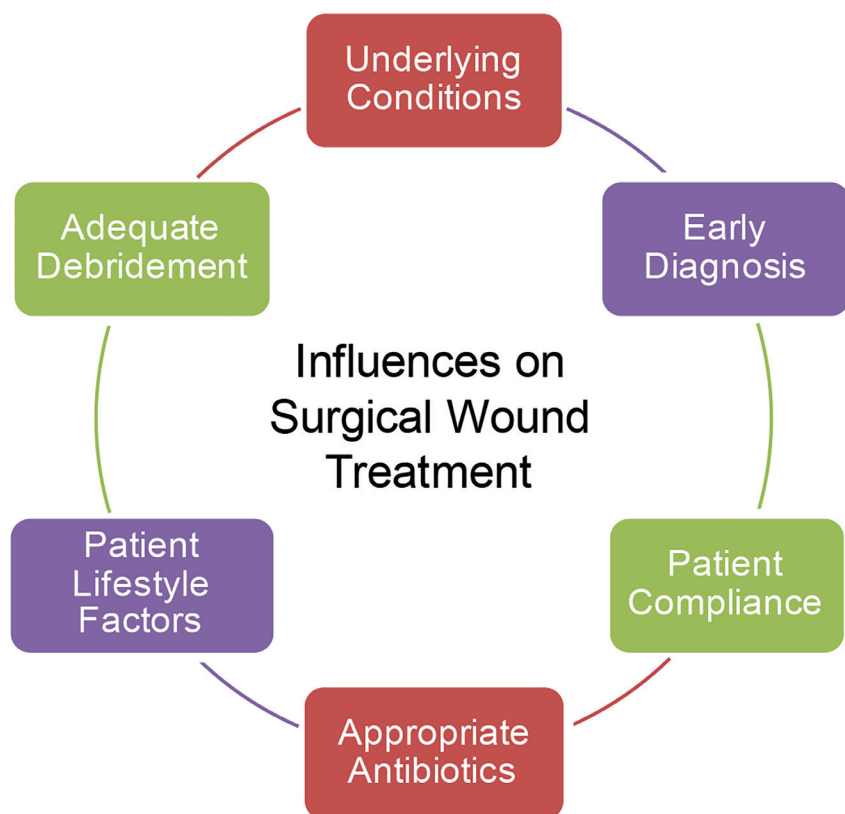


Figure 8. Influences on Surgical Wound Treatment in the Wound Care Center

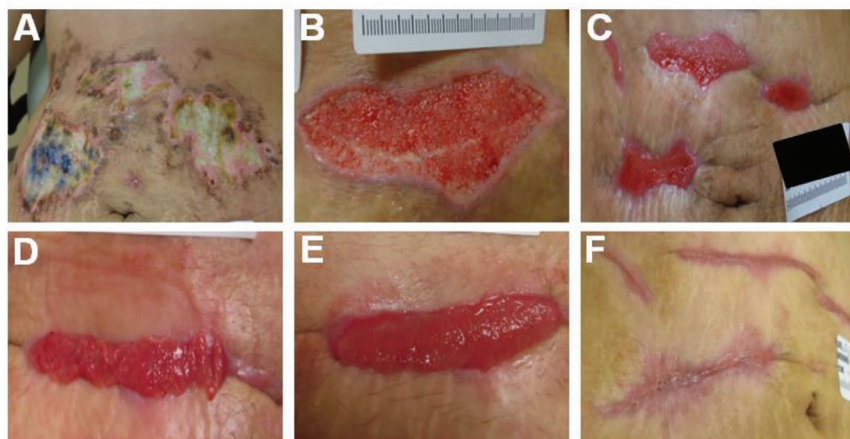


Figure 9. (A) Abdominal wound at presentation. (B) The wound displayed 100% granulation after 3 weeks of negative pressure wound therapy. (C) The wound at 9 weeks following hyperbaric oxygen therapy and silver-ORC/ORC/collagen dressings. (D) Application of epidermal grafts at 10 weeks. (E) The wound progressing towards closure at 13 weeks. (F) Wound fully closed with good cosmesis at 18 weeks.

dressings were used during this time to help manage bioburden. Figure 9C shows the wound progressing to closure at nine weeks. Ten weeks after patient admission, epidermal skin grafts were applied over the wound to encourage epithelialization in a

timely manner (Figure 9D). A nonadhering silicone dressing bolstered with an alginate was applied for four weeks. Wound size continued to decrease (Figure 9E), and the wound was closed with good cosmesis at 18 weeks.

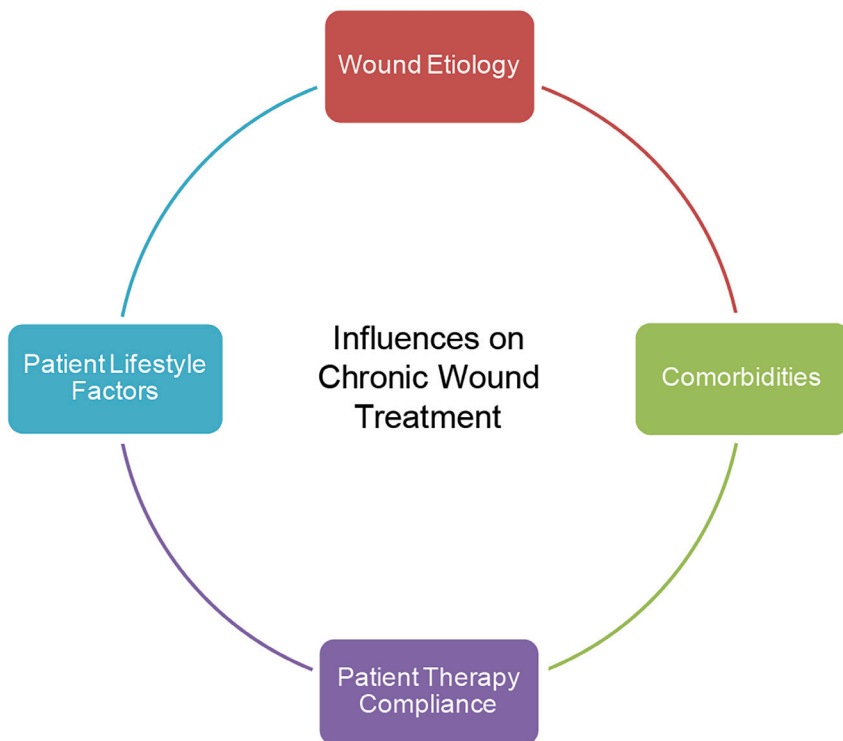


Figure 10. Influences on Chronic Ulcer Treatment in the Wound Care Center

for this wound were poor circulation, decreased collagen formation, and increased protein degradation.

Intravenous antibiotics (i.e., penicillin and vancomycin) were initially administered, followed by levofloxacin once final culture of *Pseudomonas* was confirmed. HBOT was administered with the goals of helping increase oxygen free radicals to inhibit bacterial metabolic functions, improving oxygenation, decreasing adherence of leukocytes to ischemic tissue, and increasing collagen synthesis. The patient underwent further surgical debridement and amputation of the third toe (Figure 11B). HBOT was continued after the amputation, and NPWT was applied for seven weeks to help promote granulation tissue formation (Figure 11C). Epidermal skin grafts were applied over the recipient site at week 7 to help achieve early epidermal coverage, as the patient refused a split-thickness skin graft. A nonadherent wound contact layer dressing (Mepitel, Mölnlycke Health Care, Gothenburg, Sweden) was applied and the wound continued to progress to closure (Figures 11D-11E). The wound was fully reepithelialized at week 17 (Figure 11F).

CONCLUSIONS

Outpatient wound care is continuously evolving to accommodate an increased number of patients with complex wounds needing specialized care. As of 2016, there is a renewed payer focus on cost containment, which includes reducing the amount of time it takes to heal a wound. In fact, a considerable amount of the direct and indirect costs of wound healing depends on time to closure. With the implementation of QMs, time to closure becomes even more of a consideration in outpatient wound management. Future reimbursement will depend in part on time to closure, and allowed treatments will likely differ from patient to patient, depending on comorbidities and lifestyle factors.

To help guide decision making for payers and QHPs, there remains a considerable need for controlled, comparative studies of dressings, therapies, and various combinations of each in managing a variety of wound types in a real world outpatient setting. Each of these comparative studies must include a robust cost analysis component. Even



Figure 11. (A) Infected deep abscess and diabetic foot ulcer infection following initial surgical debridement. (B) The wound at 1 week following third toe amputation, surgical debridement, and hyperbaric oxygen therapy (HBOT); negative pressure wound therapy (NPWT) was initiated. (C) The wound at 7 weeks, following HBOT and NPWT. (D) The wound at 8 weeks (1 week after epidermal graft placement). (E) The wound at 10 weeks. (F) The fully reepithelialized wound at 17 weeks.

care is judicious, cost-effective use of these evidence-based therapeutic tools to achieve quality measures.

Case study: chronic diabetic foot ulcer with exposed tendon. A 54-year-old male presented with an infected Wagner Grade 3 DFU with exposed tendon and a deep abscess post ini-

tial incision, drainage, and resection of third metatarsal head (Figure 11A). The patient had a prior medical history of hypertension. Therapy goals included debridement, promotion of granulation tissue formation over tendon and wound bed, and rapid closure. Among the pathophysiological concerns

with these studies, it will be increasingly difficult to obtain reimbursement for the more expensive therapies due to payer requirements for cost containment.

Challenges will continue to exist in WCCs because solving some of the issues requires government policy change, which is slow and not always favorable. Much of the successful operations of a WCC can be controlled by the QHPs within, and future survival of WCCs will be focused on the ability of the QHPs to provide quality- and evidence-based care within constraints of ever-evolving reimbursement policies and contractual agreements. This requires education, adaptability, and a deep understanding of concepts in wound healing, mechanisms of various therapies, and outpatient needs. This publication is meant to help guide QHPs in successfully navigating through the challenges of operating a WCC, and as wound care continues to evolve in the WCC, further refinement of these processes will be warranted.

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