



# The Future of Patient-Centered Wound Care

A Report Based on a Multi-Stakeholder Expert  
Summit Convened in Washington, D.C.



# Acknowledgements

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## Key Points

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1. Chronic wounds—generally defined as wounds that fail to show any evidence of healing after three months of treatment—affect an estimated 6.5 million Americans at a cost to the U.S. healthcare system of about \$25 billion each year. Those numbers are expected to grow as the U.S. population ages and as the obesity and diabetes epidemics continue.
2. Complications related to non-healing wounds are many, and patients are at an increased risk for severe pain, blood infections (sepsis), repeated hospitalizations, and, in some cases, amputations. Chronic wounds impose great restrictions on a patient's physical mobility and activities of daily living, often contributing to depression, anxiety, and other mood-related disorders. Chronic wounds also pose an increasingly stressful and significant burden on patients' caregivers. People with chronic wounds are also at risk of early death.
3. In recent decades, scientists have come to understand that angiogenesis—the growth of new blood vessels—plays a major role in healing wounds. This discovery has led to the development of sophisticated new treatments designed to stimulate angiogenesis—and therefore promote and encourage healing—at the wound site.
4. Despite the growing urgency of this “silent epidemic,” the quality of care given to patients and families with chronic wounds varies widely across the United States; a situation compounded not only by the paucity of good evidence-based research on therapies, but also by a lack of interprofessional care teams with specific education and training on how to care for people with chronic wounds. Significantly, wound care is not yet a recognized medical specialty.
5. Even when patients receive state-of-the-art care for their chronic wounds, their treatment plans may fail to take into account their living situation, health status, and personal preferences. Those plans also often fail to provide support and readily available resources for both the patient and his or her caregiver(s).
6. Stakeholders in the United States, such as patients, families, advocates, clinicians, researchers, and government policymakers, need to work together to overcome the current barriers that keep people with chronic wounds from receiving effective, high-quality, patient-centered care. Action is urgently needed to increase funding for evidence-based research and to develop “centers of excellence” that will provide optimal, individualized patient care. Such care prioritizes both the needs and desires of the millions of Americans and their caregivers who annually seek support and treatment for these debilitating wounds and chronic disease complications.

## Calls to Action

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1. Develop advocacy and funding resources to facilitate patient-centered wound care.
2. Increase public awareness about the care of chronic, non-healing wounds and about the need for caregiver support.
3. Develop a patient-centered research agenda promoting evidenced-based wound care treatments and best outcomes.
4. Improve and realign wound care treatment incentives to better address patient needs and values.



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# Introduction

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## A Major Health Challenge

Chronic wounds—generally defined as wounds that fail to show any tendency to heal after three months of treatment<sup>1</sup>—impose huge social and economic burdens. It is estimated that 6.5 million people in the United States are being treated for chronic wounds, at an annual cost to the nation's healthcare system of about \$25 billion.<sup>2</sup> These numbers are expected to rise substantially in the coming years due to the aging U.S. population and the growing obesity and diabetes epidemics.<sup>2</sup>

The care and management of chronic wounds is an urgent challenge for patients, caregivers, and providers. Complications related to non-healing wounds are many, and patients are at risk of severe pain, sepsis (bacterial blood infections), hospitalization, and, in some cases, amputations. Chronic wounds impose great restrictions on a patient's physical mobility and day-to-day activities, often leading to depression, anxiety and other mood-related problems,<sup>3</sup> as well as placing a significant burden on the family caregivers of the patients. Chronic wounds are also associated with early death. For example, the five-year mortality rate for diabetic patients whose non-healing wounds result in amputation is estimated at more than 50%—a rate higher than that for several types of cancer.<sup>2</sup>

Despite the seriousness of this increasingly prevalent chronic disease state, the average physician-in-training receives less than 10 hours of formal didactic education related to wound care,<sup>4</sup> and wound care is not yet formally recognized as a medical specialty. Not surprisingly, therefore, the quality of care given to patients with chronic wounds varies widely; a situation compounded by the paucity of translational evidence-based research on the effectiveness of therapies and a lack of universally recognized guidelines for care. Even when patients receive state-of-the-art treatments, plans are devised without consideration of their living situation, health status, or personal preferences. These plans do not consider the availability of community resources or the stress that they might place on caregivers. As a result, patients with chronic wounds frequently feel disengaged in decision-making regarding their care. They also often believe that their concerns about their wounds are not aligned with the concerns of their healthcare providers.

## The Science of Wound Healing

Angiogenesis—the creation of new capillary blood vessels—plays a critical role in the healing of wounds. The capillaries deliver oxygen, nutrients, and essential growth factors to the injured skin tissue, thus facilitating

the healing process. Insufficient angiogenesis is a hallmark of chronic wounds. Certain demographic groups, such as the elderly, smokers, heavy drinkers, and people with diabetes or other chronic illnesses, have an increased risk of complications related to insufficient angiogenesis and the development of chronic wounds.

There are three main types of chronic wounds: venous ulcers, diabetic ulcers, and pressure ulcers. All are associated with poor blood circulation caused by an impaired angiogenesis process. Venous ulcers, which are found primarily on the lower legs, occur when the tiny valves in veins become dysfunctional. Blood then pools in the veins, eventually making the overlying skin thin, inflamed, and susceptible to the formation of ulcers. Diabetic ulcers are caused by nerve and blood vessel complications related to the disease. Diabetes impairs the immune system and damages capillaries, thus enabling even small scratches and other skin injuries to become dangerously infected. Patients with advanced diabetes may not even notice infections at first, due to nerve damage that dampens the pain. Pressure ulcers are caused by a loss of blood circulation that occurs when pressure on the skin's tissue is greater than the pressure in underlying capillaries, thereby leaving the skin susceptible to damage. These wounds typically develop in people who are bedridden or whose mobility is severely limited. These wounds are found most often on the heels, shoulder blades, and sacrum (the triangular bone at the base of the spine).<sup>5</sup>

Wound healing is a highly complex process. The time required for a wound to repair itself can vary substantially. A typical surgical wound in a healthy individual takes 30 days on average to heal, while an arterial wound in a patient with severe atherosclerosis can take more than a year to heal completely. Fortunately for patients, the approach to treating a chronic wound has evolved during the past two decades from mere observation and selection of a topical dressing to the application of sophisticated technology developed from a growing base of scientific knowledge. Today, clinicians use growth factors, tissue-engineered products, bioactive matrices, mechanical devices, and hyperbaric oxygen to stimulate both angiogenesis and healing at the wound site.<sup>6</sup> Unfortunately, without systematically gathered evidence, these products may also give clinicians an unrealistic impression that all wounds can be healed with enough of the proper therapies when administered for a sufficient amount of time. Although the current range of therapeutic options may be appealing to clinicians, they come with a variety of caveats for patients, including pain, discomfort, expense, and inconvenience to both themselves and their caregivers. It is within this context that patient-

centered care comes into play.

## Patient-Centered Care and Patient-Centered Outcomes Research

In theory, patient-centered care lies at the heart of the medical profession. In practice, however, a patient's desires often play a subordinate role, if any at all, in determining the course of action for treating most ailments, including chronic wounds. The Patient Protection and Affordable Care Act of 2010 seeks to raise the status of the patient's wishes about his or her own care through the establishment of the Patient-Centered Outcomes Research Institute (PCORI), which is charged with conducting research to provide information about the best available evidence in order to help patients and their healthcare providers make more informed decisions. Payers, including the Centers for Medicare and Medicaid Services (CMS) and private insurers, are also interested in patient-centered outcomes research as part of their mission to ensure that healthcare dollars are being spent in ways that provide the largest benefit for patients.

Patient-centered outcomes research (PCOR) has demonstrated the importance of patients playing an active role in all their healthcare decisions. As a result of this research, patients, along with their caregivers, are encouraged to communicate with their healthcare providers and make their voices heard when assessments are being made about the value of various healthcare options.

Here are some of the specific questions that PCOR encourages patients to ask to make better-informed healthcare decisions:

- "Given my personal condition and preferences, what can I expect will happen to me?"
- "What are my options and what are the benefits and harms of those options?"
- "What can I do to improve the outcomes that are most important to me?"
- "How can my clinicians and care delivery systems help me make the best decisions about my health and health care?"
- "What can I do to improve the outcomes that are most important to me?"
- "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"

PCOR informs patient decision-making by providing

assessments of the benefits and harms of preventive, diagnostic, therapeutic, and palliative interventions, and by offering comparisons of the outcomes from those interventions that matter to the patient, such as survival, function, symptoms, and quality of life. PCOR uses a wide variety of settings and a diversity of participants to address individual differences and barriers to implementation and dissemination, and it investigates ways of optimizing outcomes, while addressing burden to individuals, availability of services, technology, personnel, and other stakeholder perspectives.

Research on patient-centered outcomes also benefits therapy developers by providing new quantitative endpoints for clinical trials. Measuring such endpoints, however, requires the use of validated instruments that can accurately assess patient desires relative to a given medical condition or therapy. Several studies have highlighted the problems resulting from the lack of such instruments, including the difficulty in comparing results from clinical trials of different therapies and even in detecting meaningful drug effects. For example, a systematic review of 51 studies on interventions for cardiovascular incidents, such as a stroke, reports that there is no consensus across these studies on key clinical questions, such as how to measure outcomes, particularly those that are most germane to the patient, including mobility.<sup>7</sup> The research community has developed a number of condition-specific instruments to assess patient-centered outcomes, including ones for wound healing,<sup>8</sup> but these tools have not been widely used in clinical trials.

## The Multi-Stakeholder Expert Summit: Identifying Gaps and Planning the Future

Given (a) the rising social and economic burdens of chronic wounds, (b) the expanding scientific and technological advances occurring in the field, (c) the growing acknowledgement by the medical community that wound care needs to become a recognized specialty with board certification and evidence-based standards of care, and (d) the deepening understanding that caring for people with chronic wounds requires a coordinated, team-based approach that is patient- and caregiver-centered, the Angiogenesis Foundation decided in 2012 that it was an opportune time to bring together experts from the wound care stakeholder community to address the questions about how to best meet the needs of patients requiring chronic wound care. In collaboration with the American College of Wound Healing and Tissue Repair (ACWHTR), the Foundation facilitated an expert summit on Patient-Centered Outcomes in Wound Care.

The event, which was convened in Chicago, IL, on July 25, 2012, included 23 experts from across the country. The summit concluded with an identified set of actions and recommendations to advance the wound care field,<sup>9</sup> which were then disseminated to medical and public health policy leaders across the country.

By 2014, it was clear that many of the challenges discussed at the initial summit were still prevalent within the U.S. healthcare system, particularly the lack of a patient-centered approach to caring for people with chronic wounds. The Angiogenesis Foundation decided it was time to convene a second national expert summit, which would focus even more intently on patient-centered care. This second event, The National Multi-Stakeholder Summit on the Future of Patient-Centered Wound Care, was held in Crystal City, VA, outside of Washington, D.C., on October 16, 2015. It was co-chaired by Dr. William Li, President, Medical Director, and Co-Founder of the Angiogenesis Foundation, and Dr. Gary Gibbons, Director of the South Shore Hospital Center for Wound Healing in Weymouth, MA.

The second summit, similar to the one in Chicago, was not a traditional scientific meeting, but rather an interactive, professionally moderated set of short presentations and roundtable discussions that aimed to establish a dialog and agreement among the participants. The summit began with the 27 assembled experts introducing themselves and describing the single greatest opportunity today that could improve care for patients with chronic wounds. This was then followed by four short presentations that described current treatment

methods for patients with chronic wounds, including a presentation by two patients and a patient-advocate that told the compelling personal stories of how chronic wounds affect the lives of patients and their families.

Under the direction of a moderator, the experts engaged in a series of discussions that defined the desired future state of caring for patients with chronic wounds (based on patient/caregiver-centered outcomes) and outlined the barriers that lie in the path of achieving that state. They also identified the key gaps in the current care pathway for treating chronic wounds. The discussion then moved on to a robust action-planning session in which the participants devised specific steps that could be taken to overcome the barriers and bridge the gaps in wound care - steps that the participants believed would advance the field and make it more patient-centered. A graphic facilitator captured the key points of all these discussions, enabling the participants to visually review and validate the recorded content of their recommendations and conversations.

This white paper is a result of the open, comprehensive, and lively discussions that took place during the summit. It offers detailed summaries of the key points presented during the meeting.





## The Role of the Angiogenesis Foundation

Founded in 1994 and headquartered in Cambridge, MA, the Angiogenesis Foundation is the world's first 501(c)(3) nonprofit organization dedicated to conquering disease with approaches based on angiogenesis; the growth of new blood vessels in the body. Its global mission is to help people benefit from the full promise of angiogenesis-based medicine, and to make life, limb, and vision saving treatments available to everyone in need.

As a scientific organization, the Angiogenesis Foundation is independent of any individual, institution, or commercial entity, and, thus, it takes a unique approach to achieving its mission to help people lead longer, better, and healthier lives. It has helped propel innovative research involving both angiogenesis inhibitors and stimulators. Although much of this research has been pharmacological, promising studies involving nutrition and biomarkers are also being actively pursued. In addition, the Angiogenesis Foundation is constantly looking for ways to innovate by exploring new approaches to improve effective prevention and care pathways, including the use of innovative mobile devices and software that engage patients, as well as physicians, in managing both health and disease.

Angiogenesis-related research is being conducted across a remarkably wide variety of disease states. In recent years, profound angiogenesis-treatment breakthroughs have been discovered in oncology, cardiovascular disease, and ophthalmology, as well as in wound care. For example, tissue-engineered products approved by the FDA, including the bilayered skin substitute Graftskin (Apligraf®) and the fibroblast dermal skin substitute Dermagraft, contain living or cryopreserved cells on a matrix capable of secreting and releasing multiple angiogenic growth factors into the wound bed.

The Angiogenesis Foundation recognizes the challenges of optimizing patient care and outcomes with such paradigm-shifting discoveries as angiogenesis treatments for wound care. The foundation also deeply understands that to meet the goal of improving global health through angiogenesis-based medicine, the complex needs of all stakeholder groups involved, including patients, caregivers, patient-support organizations, physicians, researchers, scientists, industry leaders, regulators, policymakers, and funders, must be aligned and met. The Angiogenesis Foundation is committed to helping these groups work together to ensure that all people benefit from current and future advances in angiogenesis-based medicine.



Dr. William Li, President, Medical Director and Co-Founder of the Angiogenesis Foundation, welcomed participants. Participants were charged to bring their passion for improving care and outcomes to the dialogue through a patient-centered perspective.

# The Current State of the Field

The National Multi-Stakeholder Expert Summit on the Future of Patient-Centered Wound Care opened with welcoming remarks from co-chairs Dr. Gary Gibbons and Dr. William Li. They explained that this meeting was unique in that its participants would be asked to frame their discussions around a patient-centered perspective of wound care. In other words, the emphasis throughout the day would be on patient care rather than on wound care.

## An Overview

The opening remarks were followed by four brief presentations on the care of patients with chronic wounds. Dr. Gibbons described the growing burden of chronic wounds to individuals, families, and societies. Dana Davis of the Children's Diabetes Foundation in Denver, CO, Rosemarie DiMauro Satyshur, PhD, RN, of the University of Maryland School of Nursing, and patient-advocate Laurie Rappl of Simpsonville, SC, spoke about the real life impact of chronic wounds on patients and their families. Vickie Driver, DPM, MS, of the Association for the Advancement of Wound Care at Brown University, discussed the clinical care of patients with chronic wounds. Dr. Thomas F. O'Donnell, Jr., of Tufts University School of Medicine, ended the presentations with a discussion of patient-centeredness and the quality of wound care.

## The Growing Burden of Chronic Wounds

(Gary W. Gibbons, MD, South Shore Hospital Center for Wound Healing, Weymouth, MA)



The burden of caring for patients with chronic wounds - for the individual patients, their families, the medical community, healthcare payers, regulators, and the broader society - is enormous and growing. To address this urgent medical challenge, major changes need to occur - changes that will put patients, not the wounds, at the center of treatment and research efforts.

The economic costs of caring for people with chronic wounds is staggering. Research has shown that per-patient medical expenses for the estimated 900,000 Americans with diabetic foot ulcers are twice as high as for people with diabetes who do not have these wounds. Overall, treating diabetic foot ulcers adds about \$15 billion dollars annually to U.S. healthcare costs.<sup>10</sup> Even more prevalent are venous leg ulcers, which affect about 2.8 million Americans each year. These patients also use many more medical services than the general population, costing private and government payers up to \$18 billion a year.<sup>10</sup> The treatment of pressure ulcers, which affects about 26% of bed-bound hospitalized patients in the United States,<sup>11</sup> is estimated to add another \$11 billion a year to U.S. healthcare costs.<sup>12</sup> All of these estimates do not include the additional costs associated with treating wounds that result from trauma, surgery, peripheral artery disease, vascular malignancies, or radiation treatment.

To reduce both the economic and personal burden associated with chronic wounds, it is essential to diagnose and treat patients early on. The average cost of treating a person with a stage I pressure ulcer is, for example, more than 50 times greater than the cost of treating a patient with a stage IV ulcer.<sup>11</sup> Clinicians also need to practice evidence-based medicine. Currently, the quality of practice for treating patients with chronic wounds varies widely and often includes poor debridement (the removal of damaged tissue from the wound) and ineffective compression. Prior to entering a treatment study - and contrary to existing guidelines - 35% of patients with venous leg ulcers had not been debrided and 40% had not been adequately compressed within the previous 12 months. Furthermore, advanced therapies had been used to treat only 48% of those patients.<sup>13</sup>

Wide variation in practice leads to wide variation in outcomes. Often, wound care is left to "the lowest person on the healthcare totem pole," and such clinicians tend to be poorly trained in this field. Furthermore, care is often siloed, so that treatment choices depend more on the clinician's specialty than on any unified provider guidelines. Not surprisingly, research has shown that healing rates for chronic wounds are low. Among patients with venous leg ulcers, fewer than 40% are healed at 12 weeks<sup>14</sup> and only about 50% are healed at 24 weeks.<sup>15</sup> In addition, recurrence rates are high - between 60% and 70%.<sup>16</sup>

Too often clinicians treat the wound rather than the patient. Yet, most patients with chronic wounds - 83% in one study<sup>13</sup> - have two or more comorbidities that interfere with wound healing. The medical community needs to do a much better job at understanding the whole patient. It also needs to develop evidence-based,



coordinated standards of care for treating people with chronic wounds. Innovation and necessity have elevated the standard of care when it comes to the treatment of cancer patients. The medical community must bring to the treatment of chronic wounds the same high standard of care seen in oncology.

## Patients' Perspectives: The Real-Life Impact of Chronic Wounds

(Rosemarie DiMauro Satyshur, PhD, RN, University of Maryland School of Nursing, Baltimore, MD)



Chronic wounds are not generally accepted in society—a factor that leads many patients to hide their condition and its seriousness from others. Finding a doctor who is knowledgeable in caring for people with chronic wounds—and who will listen to the patient and treat each patient as an individual with specific medical and other needs—is an additional challenge, the patient-presenters said. As one noted, many doctors do not seem to understand that “each wound is attached to a patient.”

Clinicians also frequently fail to fully educate patients and their families about how to care for their wounds at home—and then become frustrated when patients appear not to practice good self-care. “Patients may seem non-compliant, but they really want to be,” a patient-presenter explained. “You need to give them the education to help them.” *Off-loading* the wound, which often involves extended periods of bed rest, introduces a wide range of problems for patients and their families, including severely restricting their ability to carry on with work or with even the most basic of daily activities. Clinicians often fail to acknowledge or address these problems when prescribing off-loading or other treatments for chronic wounds. They do not always understand that many patients are unable to afford the durable medical equipment that was prescribed to them to help with the healing of their wounds.

To assist patients with chronic wounds who have complex care needs, the healthcare community needs to adopt interprofessional team approaches, not just interdisciplinary ones. Each patient should be assigned

a collaborative team of healthcare professionals who work together to help the patient develop, understand, and comply with an effective treatment plan. Such approaches should also consider how having a chronic wound affects the patient’s entire family. “Chronic wounds are everybody’s problems, not just the patient’s,” said one patient-advocate. Patients want to be partners in their care, and generally want the treatments for their wounds to preserve as much of a normal lifestyle as possible. Those wishes need to be listened to and then incorporated into a jointly decided treatment plan—one that the patient’s entire healthcare team helps communicate and coordinate.

(Dana Davis, Children’s Diabetes Foundation, Denver, CO)



(Laurie M. Rapple, PT, Simpsonville, SC)



## Clinical Care of Patients with Chronic Wounds: What Do We Have Today and What Will We Have Tomorrow?

(Vickie R. Driver, DPM, MS, Association for the Advancement of Wound Care, Brown University, Charlestown, MA)



A variety of sophisticated new treatments designed to stimulate angiogenesis and regenerative healing at the wound site are available for physicians to use when treating patients with chronic wounds. However, few of those products have significant evidence-based research behind them and most clinicians do not receive the formal education required to effectively use those products.

Tissue-based therapy, using cadaveric allografts or amniotic membrane, is one of the most important modern treatments for wound care and other clinical applications. The amnion and chorion are placental membranes rich in growth factors and cytokines, for which compelling and definitive evidence exists supporting their role in wound angiogenesis, granulation, and recruitment of progenitor cells for healing.<sup>20</sup> Clinicians require formal education in order to differentiate products that are supported by the scientific and clinical evidence for wound management.

Further, selecting the appropriate treatment strategy - one based on the specific conditions of a specific patient's wound - is crucial for the successful healing of chronic wounds. New cell-based therapies (also called cell therapies or cytotherapies) are very promising, but it is not always clear which patients will respond to them. We do not understand when such treatments should be started or stopped.

The Food and Drug Administration has not approved a new drug for chronic wound care since 1997. Several experimental therapies have been explored since then, but most have proved disappointing in Phase II or Phase III clinical trials. The obstacles facing the development of new therapies for wound care are many, including the lack of a good wound-healing model for pre-clinical research, poorly understood targets, and clinical trial designs that do not match real-world settings. Clinical

trials all too often focus on the closing of the wound as the endpoint rather than on the full healing of the wound and the absence of complications.

It is obvious that the wound-healing field urgently needs new treatments. Fortunately, significant resources are now being directed toward developing those treatments. Currently, more than 20 compounds for the treatment of chronic wounds are being tested in Phase II and Phase III clinical trials. The research and medical communities need to make sure that the patient is at the center of those studies. Evidence-based, procedure-driven care that focuses on the patient should be the desired outcome.

## Patient-Centeredness and the Quality of Wound Care

(Thomas F. O'Donnell Jr, MD, Tufts University School of Medicine, Wellesley, MA)



In the past, medical care in the United States was hierarchical and physician-centric. Physicians engaged in only minimal conversation with their patients, leaving patients with very little input with regard to their treatment. Fortunately, this care-delivery model is being replaced with a patient-centric one. Today, many physicians encourage patients to become full participants in decisions about their medical care. Research has shown that such patient-centered care improves the health status of patients (including their own reports of their health) and increases the efficiency of care by reducing diagnostic tests and referrals.<sup>17</sup>

Patient-centered care is defined by the National Academy of Medicine (formerly known as the Institute of Medicine) as "providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions."<sup>18</sup> The Patient Protection and Affordable Care Act of 2010 helped to raise the status of patients' wishes about their care through the establishment of the Patient-Centered Outcomes Research Institute (PCORI). Still, the wishes of patients regarding medical therapy continue to play a subordinate role to those of their clinicians. This situation is frequently the case when



Making healthcare more accessible, safe, and patient-centered is one of the three objectives of the National Quality Strategy (NQS), which was first published by the U.S. Department of Health Agency for Healthcare Research and Quality in 2011. The key to the NQS is its measures of patient experience, including interpersonal aspects of care, such as patients' perceptions of how well their physicians discuss treatment options with them. Unfortunately, however, wound care is not a recognized medical specialty, so the development of wound care quality measures has been left to other medical specialties. The Centers for Medicaid and Medicare Services (CMS) also employs quality measures in its quality improvement, public reporting, and pay-for-reporting programs. Yet, of the eight NQF measures

In wound care, as in other fields of medicine, patient-centered care is replacing physician-centric care, and reimbursement based on quality rather than quantity of care is going to become the dominant form of payments to clinicians. We need better quality measures for chronic wound care—measures that include outcomes on how patients perceive value in the particular treatments they are receiving.





## A Discussion

After the initial presentations on the state of the field, the summit's moderator asked participants to build a more comprehensive picture of how the medical community currently cares for people with chronic wounds. The discussion opened with patients and practitioners describing the strengths and weaknesses of the care currently delivered. This was followed by a discussion on existing wound care assessment tools and treatment technologies.

## Current Strengths

One positive recent development in the care of people with chronic wounds is the growing recognition that wound care is a specialty—one that needs to be formally acknowledged as such. In addition, the state of research regarding wound care has improved. It was found that growth factors such as platelet-derived growth factor (PDGF) exert potent effects on wound healing. Growth factor-based therapies include the only FDA-approved recombinant protein drug rhPDGF (becaplermin, REGRANEX® 0.01% gel), which is indicated for diabetic neuropathic lower extremity ulcers. Growth factors can also be delivered through autologous isolates of patient platelets such as Autologel, SmartPreP. Moreover, CD34+ endothelial progenitor cells (EPC) derived from bone marrow or from peripheral blood have been found to enhance angiogenesis in ischemic tissues, increase transcutaneous oxygen, improve ankle-brachial index (ABI), increase collateral vessels by angiography and improve healing of leg ulcers. Integra® Dermal Regeneration Template is an advanced skin replacement matrix that consists of a complex three-dimensional porous matrix that acts as a scaffold for cell migration and allows for regeneration of the dermal layer of the patient's skin. It can be used for diabetic foot ulcers. On the other hand, the summit participants pointed out

that much more research is still needed on the treatment of deep, complex wounds, particularly in patients with complicated comorbidities. In addition, patient voices need to be heard when determining endpoints for studies: What outcomes do patients value most?

Another major advance in the field of wound care is that patient-centered care is slowly replacing physician-centered care. Centers devoted to the treatment of chronic wounds can now be found across the country, although the summit participants stressed that many more such centers are needed.

## Current Weaknesses

One of the major weaknesses of the current approach to chronic wound care—and a major theme that ran through the entire summit—is that clinicians too often focus just on healing the wound. For clinicians, the treatment goal is closure of the wound; indeed, this is the outcome for which they get paid under the fee-for-service reimbursement model. Such a narrow focus fails to take into account that the prescribed treatment will affect other aspects of the patient's health, as well as his or her work and personal life. When clinicians prescribe off-loading to a patient, for example, they may not consider the impact that prolonged immobilization will have on other facets of the patient's physical and mental health. Similarly, they may not consider that putting a boot on a patient to cure an ulcer on the bottom of the foot may cause another ulcer on the shin.

In addition, clinicians all too frequently fail to listen to their patients with chronic wounds. One patient-advocate at the summit described how she had to argue with a physician to get him to prescribe antibiotics for what she recognized as early signs of an infection. He insisted (wrongly) that the patient's symptoms were



*The Expert Summit discussed the current state of the field.*

simply signs of menopause.

A problem related to this failure to listen is the tendency of clinicians to blame patients with chronic wounds for non-compliance. Many clinicians do not understand that what they ask their patients to do is sometimes neither realistic nor practical. For example, people with spinal cord injuries, who cannot feel the pain of pressure ulcers, are often asked by their clinicians to look for new ulcers with a mirror. But, as one of the summit's patient-advocates explained, a mirror may not show the patient anything. In addition, patients who are told they must stay in bed to enable their ulcers to heal may not have the resources to do so.

Another weakness in the current approach to caring for people with chronic wounds is that wound care is frequently viewed as a business, not as a medical specialty. Very few clinicians devote their career to it, and there is no certification—or even a baseline level of medical education—for the care of people with chronic wounds.

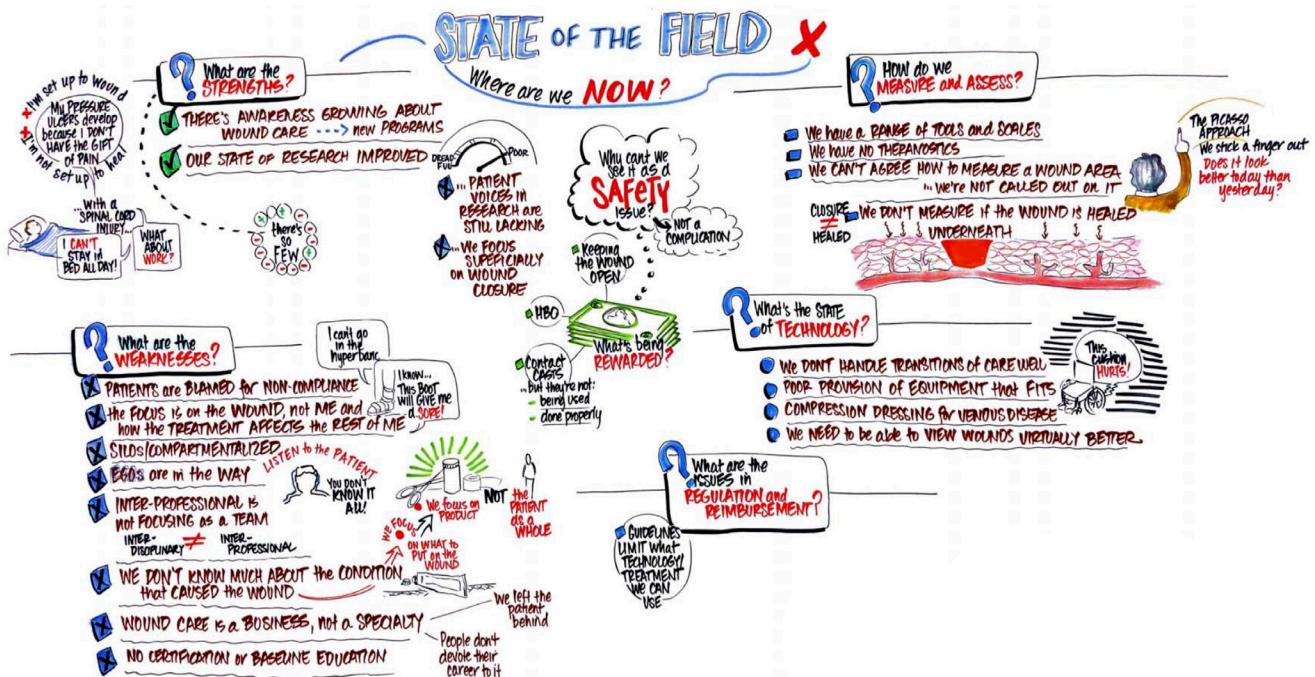
In addition, clinicians who treat people with chronic wounds may have little specialized knowledge about the specific disease or injury that has led to the wound's development. As a result, treatment often tends to be centered around what to put on the wound rather than on how to improve the underlying medical problem. Clinicians also tend to approach treatment from their own medical "silo," a factor that can impede their ability to treat the broader health issues faced by the patient.

The summit participants also stressed that interdisciplinary and interprofessional collaborative approaches to caring for patients with chronic wounds are seldom used—but much needed.

## Current Assessment Tools and Treatment Technologies

Dynamic changes in the microcirculation of chronic wounds are intrinsic to normal, delayed, and therapeutic promoted wound healing. The ability to image, assess, quantify, and monitor these changes is critical for clinical decision making in the wound care clinic, especially for difficult-to-heal wounds such as diabetic, venous, ischemic, and pressure-induced wounds. Specifically, while normal wound healing involves transient inflammation, early angiogenesis, and vascular maturation with tissue remodeling, chronic wounds are characterized by chronic inflammation, persistent attempts to initiate angiogenesis with hyperpermeable vasculature, and inability to develop matured microcirculation. The summit's participants agreed that currently there are no existing standardized tools for assessing wounds that everyone in the medical community agrees upon, and, therefore, the characterization of wounds is as variable as the people who assess them.

Imaging modalities are common in many specialties, but have only recently entered wound care practice. Indocyanine green (ICG) is a fluorescent dye that is used for wound microcirculation assessment and to monitor



Graphic Representation: State of the Field Discussion

evidence for clinical changes. Treatments to promote angiogenesis and healing will create permeability and vascular density changes that are captured qualitatively and quantitatively. Successful healing may be characterized by an increase in fluorescence signal detected followed by a serial decrease in fluorescence signal during vascular maturation and remodeling until the fluorescence matches adjacent or contralateral normal tissue. Recent advances in quantifying wound microangiography have made this a critical tool for assessing angiogenesis and progress during healing. Although microangiographic fluorescence is approved and used in wound care, the majority of wound care providers are still unfamiliar with the technology, and how it is used to make clinical care more efficient and outcomes better.

Diagnostic tools are missing for assessing underlying health problems that may be compounding the inability of the wound to heal. “The lack of rigor that is used to treat wounds from visit to visit is startling,” said one expert. Electronic medical records aggravate the problem because they limit the ways in which clinicians can describe the wounds.

To help reach patients in rural or other underserved areas, better technologies for virtually viewing a wound are needed, according to the summit participants. Telemedicine services need to be expanded, and new mobile technologies for assessing wounds need to be developed.

As for treatments, too often healing is defined as a wound that is closed, the summit participants pointed out. Yet closure does not mean a wound is healed underneath its surface. A few imaging technologies are available for evaluating what is going on below the surface, but these tools are not widely known or used by clinicians.

When it comes to treatments, guidelines often limit what technology/treatment can be used. For patients with diabetic wounds, guidelines support—and insurers will pay for—contact casts, although many patients are unable to wear them. Insurers will also pay for various forms of dressing and compression technologies, as well as for ongoing hyperbaric oxygen (HBO) therapy. In fact, HBO is now a board-certified specialty, although the rapid growth of that specialty has led to the technology sometimes being misused.

Various cushions and assisted devices, including protective casts and wheel chairs, are also used to help heal chronic wounds, although, as participants noted, these devices are often difficult for some patients to access and/or afford. Furthermore, it is essential that a device such as a wheelchair fit the patient for whom it has been prescribed. Too often, patients are given a standard, ill-fitting wheelchair, which may result in the

development of new wounds.

Some of the technologies used to treat people with chronic wounds do work, but many do not. The participants agreed that thus far there has not been a strong evidence-based approach to evaluating these treatment approaches. In addition, the technologies continue to focus only on treating the wound, not the patient as a whole.



# The Desired Future State of Care for Patients with Chronic Wounds

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The summit's experts next turned their attention toward imagining what the future state of care for patients with chronic wounds would look like in the U.S. if the healthcare community was completely successful in improving care and outcomes for these patients within the next five years; How would patients be assessed and treated? What types of clinical systems, care pathways, tools, treatments, and technologies would help fulfill patient priorities for successful outcomes? How would regulations and reimbursement work?

The key elements of that desired future state, as described by the summit's participants, are summarized below.

## Patient-Centered Care

- Patients with chronic wounds would have an interdisciplinary team of professionals caring for them, including a podiatrist, a social worker, a psychologist, and a nutritionist. The physical, emotional, social, and cultural needs of the patient would be recognized by all members of his or her clinical team, and would play a central role in devising a treatment plan and evaluating its progress.
- The patient, not the wound, would be at the center of this care; each patient would receive the right care, at the right time, by the right professional.
- Patients and caregivers would be listened to and respected by clinicians. Patients would not be blamed when their wound does not heal.
- The interests of patients, caregivers, clinicians, payers, and society would be integrated to create a more holistic approach to care. For example, treatment plans would offer affordable home health assistance, respite help for caregivers, transportation to clinician visits, and easily accessible exercise and physical therapy programs.
- Treatment for people with chronic wounds would be proactive rather than reactive. Reimbursement to clinicians and hospitals would be restructured in ways that reward efforts to prevent chronic wounds from developing and/or recurring rather than just to close the wounds.
- "Centers of Excellence" for caring for people with chronic wounds would be created across the country. These centers would have standardized measurements of care quality to ensure that all patients with chronic wounds receive high-quality treatment.
- Patients with chronic wounds would be able to access quality care quickly to avoid any delays in treatment that might complicate the healing of their wounds.
- Insurers would not limit patients with chronic wounds to a specific number of reimbursable treatment devices each year. At the same time, fee-for-service reimbursement would be re-structured to reward meaningful healing results to eliminate perverse incentives to repeatedly use ineffective treatments.
- Government health agencies would develop and implement a single coherent strategy for treating patients with chronic wounds.

## Evidence-Based Research

- Funding for patient-centered comparative effectiveness research would greatly expand, giving patients and clinicians better information about which treatments work best for healing chronic wounds in specific settings. Treatments that are shown to be ineffective would no longer be used.
- Registries of comparative effectiveness data on approved wound-healing products would be compiled to help inform treatment choices. Analyses of this data, which would be conducted by independent researchers, would help patients and clinicians learn more about how the products perform in real-world clinical applications.
- When the evidence demonstrates solid results, advanced therapies would be moved to the front of the treatment line to be used early in high-risk populations.
- Big data would be leveraged to create personalized, targeted treatments designed for specific patients in consideration of their needs and preferences.

## Effective Advocacy

- Patient advocacy would be more visible and more effective. Advocates for patients with chronic wounds would, for example, have a voice in such groups as the Patient Engagement Advisory Committee (PEAC), which was created in September 2015 by the U.S. Food and Drug Administration's Center for Devices and Radiological Health to ensure patient needs and experiences are included during the review of medical devices.
- Advocacy groups would use social media more successfully to spread expertise about caring for chronic wounds.
- Media campaigns would be initiated to educate the public at large—and policymakers—about chronic wounds. These campaigns would also help remove the social stigma currently associated with having such wounds.



*Graphic Representation: Desired Future State of Care for Patients with Chronic Wounds*

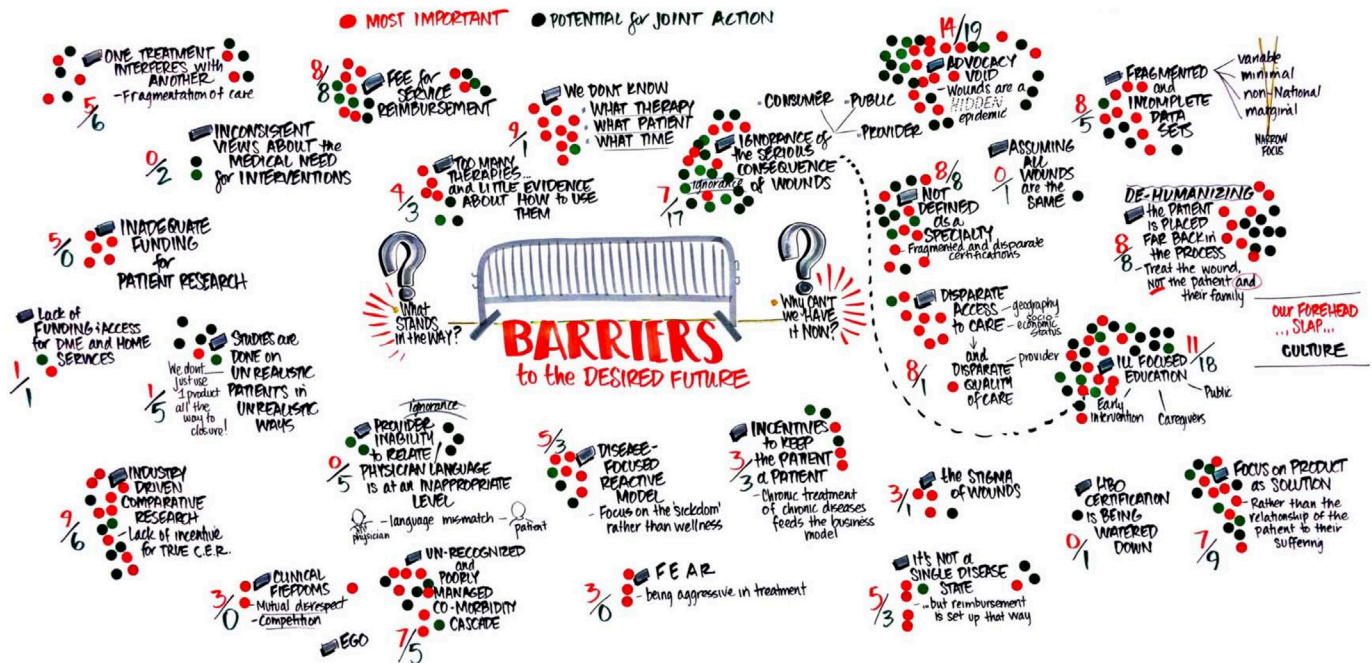
- Inadequate funding for patient-centered research.
- Inconsistent views among medical professionals about the need for interventions, a situation that leads to inconsistencies in reimbursement.
- A fee-for-service rather than a value-based model of reimbursement.
- Limited knowledge of diagnostics to understand the nature of a given wound and to decide which therapy would be most appropriate.
- Widespread ignorance of the serious medical, psychological, social, and economic consequences of chronic wounds.
- The failure (as yet) to establish wound healing as a board-certified medical specialty.
- Disparate patient access to quality wound care, due to geography, income, socioeconomic status, insurance status, and other factors.
- Treatment research that is conducted on non-representational patients in unrealistic settings.
- Therapies that are presented to patients and clinicians with limited evidence about their effectiveness.
- Few incentives for researchers to conduct comparative-effectiveness studies on wound-healing products and treatments.
- An absence of good, independent, evidence-based research on treatment outcomes, as well as an absence of research on treatments interventions themselves.
- The assumptions by many clinicians that all wounds are the same.
- A terminology language barrier between patient and providers, which interferes with effective treatment follow-through by the patient.
- The inability of some clinicians to see a patient as an individual, not as a wound.
- Reluctance by some clinicians to listen to the goals and wishes of their patients.
- The tendency of the current health-care delivery system to focus on sickness rather than on wellness.
- The fragmentation of wound care (wounds are not considered a condition like cancer or diabetes), which often leads to counter-productive or ineffective treatment.
- Financial incentives to keep the patient a patient.
- The social stigma associated with chronic wounds.
- An advocacy void, which keeps chronic wounds a hidden epidemic.
- The rapid growth of HBO, which sometimes has led to that technology being misused.
- The medical community's focus on products as being the solution to chronic wounds, an approach that often overlooks the patient's underlying medical condition and his or her needs and desires regarding treatment.
- A limited understanding by clinicians that chronic wounds are not a single disease state.
- Fear—of clinicians to be more aggressive with therapy, of patients about treatment outcomes, and of both clinicians and patients in terms of realistic expectations regarding therapy.
- Limited access and funding for durable medical equipment and home services related to wound healing.
- Little understanding of the disease pathophysiology of chronic wounds.

1. Which barriers, if removed, would have the biggest impact on moving toward the desired future state of care for people with chronic wounds?
2. Which barriers lend themselves to being removed or mitigated by joint action of a group of experts, such as those gathered at the summit?





Each participant was allowed to cast votes according to each of the two criteria. The results are shown graphically below:



Graphic Representation: Prioritized Barriers to Desired Future State

In terms of barriers that are most easily addressable through joint action, the three most important items, as expressed by the votes of the summit participants, can be summarized as follows:

1. **Weak advocacy.** Stronger voices are needed to advocate for more research funding and more effective, patient-centered treatments.
2. **Ill-focused educational efforts.** All stakeholders—patients, caregivers, clinicians, policymakers, and payers—need to become better educated about chronic wounds and their often devastating social, psychological, and economic effects on the lives of millions of Americans. For clinicians, this also means more comprehensive training on caring for people with chronic wounds.
3. **A lack of urgency.** The serious consequences of chronic wounds need to be made more widely known and more urgently addressed by all stakeholders.

Summit participants identified certain barriers as being extremely important but difficult to overcome. Many had to do with funding and conducting more patient-centered, evidence-based research (PCOR).

# Action Agenda

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In the final session of the summit, the participants discussed potential actions that they could take as a group, or together with colleagues outside of the assembled group, to overcome the top identified barriers. During that conversation, the group focused on four areas of possible actions:

- Develop advocacy and public awareness.
- Develop a patient-oriented research agenda.
- Improve and realign treatment incentives.
- Improve healing and outcomes for patients.

## Develop Advocacy and Public Awareness.

- Establish a strong, broad-based patient-advocacy organization for people with chronic wounds. The group could establish a national month and symbol for chronic wounds to drive education, awareness, and access to effective treatments.
- Create public service announcements (PSAs) for internet and television to educate the public about chronic wounds and to lessen the stigma associated with them and put a face to the condition. The messages should not instill fear, but should instead enlighten and motivate people to seek care from a wound care specialist.
- Identify high-visibility “hero” individuals with a history of chronic wounds who can become motivational spokespeople for public awareness campaigns.
- Create a national bill of rights for patients with chronic wounds; it could be modeled on the Wound Patient’s Bill of Rights developed by the Association for the Advancement of Wound Care.<sup>19</sup>
- Build a stronger presence on the internet, so that when patients or clinicians search for “wound care” they will be delivered to independent, high-level information rather than to advertisements for products.
- Advocate before the American Medical Association and other professional groups to get chronic wounds recognized as a specific disease entity and the caring for people with chronic wounds recognized as a medical specialty.
- Enlist support for all these advocacy and educational efforts from groups with overlapping

## Develop a Patient-Oriented Research Agenda.

- Develop a set of validated and meaningful clinical endpoints for use in wound care research.
- Include patient quality-of-life outcome measures in studies evaluating treatments. Review current measures to make sure they are capturing all relevant information.
- Establish an annual day during which wound-healing advocates would descend on Capitol Hill to advocate for more funding of research.
- Develop a collaborative wound care research consortium with members supporting each other’s research efforts.
- Advocate for increased funding for patient-centered research on wound care through existing organizations and committees, such as the Patient-Centered Outcomes Research Institute (PCORI) and the FDA’s new Patient Engagement Advisory Committee (PEAC).
- Support the development of a national registry for patients with chronic wounds and actively encourage physicians to participate in it. (Perhaps tie reimbursement to participation in the registry.) It is essential that the registry not be product-specific or agenda-driven.

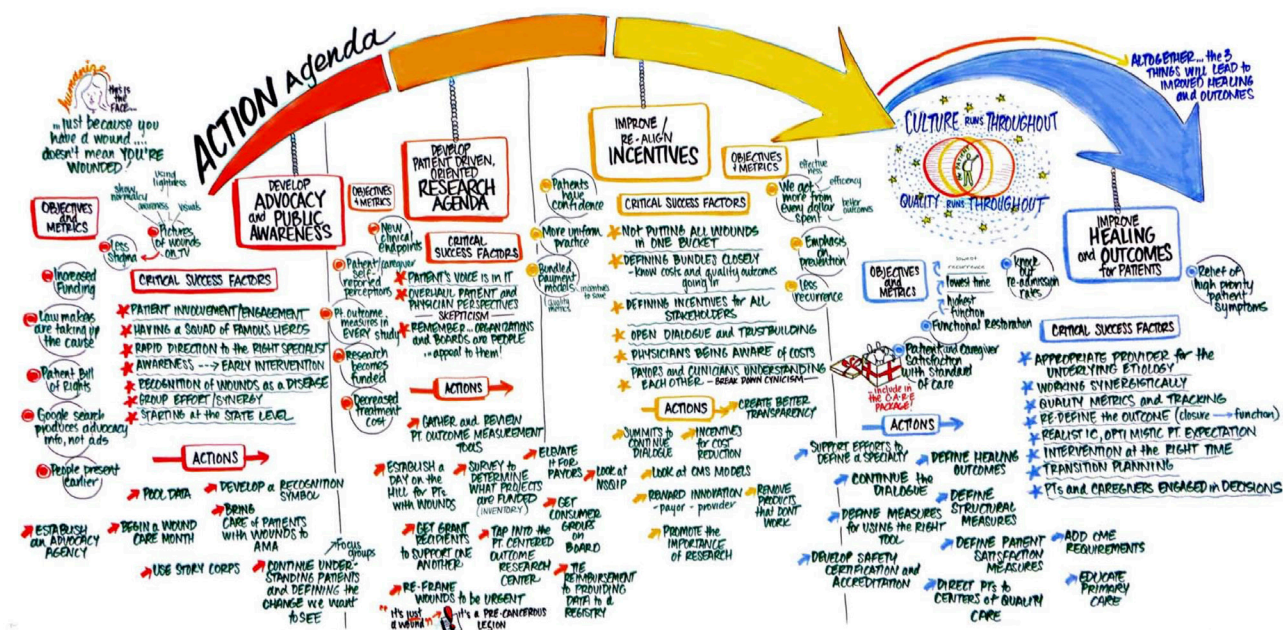


## Improve and Realign Treatment Incentives.

- Increase incentives for clinical care that focuses on prevention and non-recurrence rather than only on closure of wounds.
- Support Medicare's efforts toward establishing a bundled payment system, which reimburses providers for clinically-defined episodes of care. All wounds cannot be put in "the same bucket", however, and bundled payments need to reflect these differences.
- Develop clear definitions of incentives for each stakeholder group. Determine, for example, what would incentivize patients to be more fully engaged in their own care or payers to support specific treatments.
- Encourage clinicians to be more aware of the costs incurred by patients for different prescribed courses of treatment, such as their out-of-pocket charges for medications, office visits, and durable medical equipment. Also, educate clinicians on the psychological and social costs associated with

## Improve healing and outcomes for patients.

- Ensure that the caring of patients with chronic wounds involves interprofessional and interdisciplinary teams of providers. The physical, emotional, social, and cultural needs of the patient should be recognized by all members of this clinical team, and should play a key role in devising a treatment plan and evaluating its progress.
- Create a national network of “Centers of Excellence” for chronic wound care, and direct patients to those centers when wounds fail to improve after initial appropriate care.
- Develop a rapid care pathway for people with chronic wounds so that patients have timely access to treatment by a specialist. This pathway could be modeled on the quick access to care that occurs when a woman discovers a breast lump.
- Develop safety certification and accreditation for wound care.
- Create better metrics and tracking tools for measuring the effectiveness of various treatments.
- Redefine the desired outcome of wound care from closure of the wound to a return of patient



*Graphic Representation: Action Planning*

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