



Patient-Centered Outcomes in Wound Care

A White Paper
by

The American College Of Wound Healing And Tissue Repair
Chicago, Illinois

and

The Angiogenesis Foundation
Cambridge, Massachusetts

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**the American College of Wound Healing and Tissue Repair
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EXECUTIVE SUMMARY

The approach to treating a chronic or delayed healing wound has evolved greatly over the past 15 years and is best carried out by multidisciplinary teams centered on the patient's specific situation and needs.

- A wide range of approaches and products are available for treating chronic wounds, though many of them lack adequate evidence demonstrating their benefits.
- Because physicians have a variety of options for treating their patients, they often times develop an unrealistic view that all wounds can be healed as long as patients receive enough of the proper therapy for a sufficient amount of time. However, this is not always the case.
- The range of therapeutic options, while appealing to physicians who want to heal their patients' wounds, come with a variety of caveats for patients, including pain, discomfort, inconvenience, expense, and burden to their caregivers.

Patients with chronic wounds do not feel engaged in the decisions made regarding their care. As a result, patient concerns about the care of their wounds are often not aligned with the concerns of their health care providers.

- Patient-centered outcomes research benefits all constituencies:
 - » It helps patients and their caregivers communicate and make better-informed health care decisions, allowing their voices to be heard when assessing the value of health care options.
 - » It helps payers ensure that health care dollars are being spent in ways that maximize benefits for patients.
 - » It helps treatment developers by providing important clinically meaningful endpoints for clinical trials.
- Patients must become an integral part of the wound healing enterprise by:
 - » Involving them during the education of physicians on wound care.
 - » Developing a system in which patients can provide input to health care professionals interested in wound care and clinical conditions associated with non-healing wounds.
 - » Creating mentorship-style relationships between health care professionals-in-training and patients. These relationships would empower patients and produce a new generation of health care professionals who encourage, rather than discount, patient input into the choice of care.
 - » Creating patient networks that would play an active role in providing patient support, educating health care professionals, and increasing public awareness about the causes and treatment of chronic wounds.

Patients, caregivers, and clinicians alike strongly believe that wound healing should be managed by teams of health care providers who would work together at wound care clinics to provide high quality care (centers of excellence). The staff at these wound care clinics would be thoroughly versed in both the medical and non-medical aspects of chronic wounds.

- These centers of excellence would have a mission to provide optimal, individualized care, and to inform the broader medical community about the need to refer their patients with non-healing wounds to specialized clinics when no improvement is noted after initial appropriate care.
- Centers of excellence would develop therapeutic approaches that prioritize the patient's needs and desires. This would require training health care professionals at these centers to engage in clear and honest dialogue with patients and their caregivers about available treatment options and the evidence to support those options.

Limited research funding on wound care and wound healing translates to a poor understanding of disease pathology and a limited ability to predict which patients respond or do not respond to different treatment modalities, detracting from the quality of patient care.

All clinical studies on wound healing technologies, methods, and products, regardless of the funding source, should include validated patient-centered outcome measures.

- Validated measures for patient-centered outcomes are needed for research studies.

Criteria must be identified and used as a basis for assessing wound care centers and the credentials of physicians who work as specialists in wound healing and as deliverers of evidence-based, high-quality wound care.

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BACKGROUND

Wound Healing

The incidence of non-healing cutaneous wounds in the United States is 5 to 7 million episodes per year, costing the nation's healthcare system an estimated \$20 billion annually. Patients suffering from chronic wounds – for example, diabetic patients whose non-healing wounds result in amputation – may have a mortality rate of up to 50 percent in five years – a rate similar to several types of cancer. Despite the complexity of non-healing wounds, the average physician-in-training receives under 10 hours of formal didactic education related to wound care, and only recently has the concept of wound care evolved with the goal of becoming a recognized formal medical specialty.

Wound healing is a complex process that involves a coordinated integration of numerous clinical and biochemical pathways involved in at least four continuous, overlapping phases that must take place in a precise and orchestrated manner. The phases of wound healing include hemostasis, inflammation, proliferation, and remodeling. The time required for a wound to heal 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 over a year to heal completely.

Wound-healing can be compromised by many factors, such as obesity, diabetes, smoking, vascular disease, infection, renal failure, cancer, and malnutrition. A classic example of a non-healing wound is diabetic foot ulceration. With decreased sensation and frequently concomitant-peripheral vascular disease, chronic ulcers can form easily in this growing population. With an estimated 36 million diabetic patients by the year 2030, the number of patients with chronic non-healing wounds will be increasing. Because of an aging society, there will be an increase in the number of surgical wounds, venous leg ulcerations, and pressure ulcers that will be at risk for non-healing. **Table 1** lists the most common causes of chronic, non-healing wounds.

Further complicating the situation is the lack of formal education and training for physicians, nurses, and allied health care providers on the science and evidence-based clinical management of non-healing wounds. Guidelines for the care of chronic wounds do exist – the Wound Healing Society, for example, published its guidelines in January 2007 after a three-year development process – but because the majority of wound care approaches and products have not been tested in randomized, controlled clinical trials using consistent measures for outcomes, these guidelines lack the scientific evidence that the field deserves and that governs practice in virtually all other areas of modern medicine. In addition, the guidelines give scant attention to the needs and desires of patients when it comes to the care of their wounds.

Fortunately for patients, the approach to treating a chronic wound has evolved over the past 15 years from mere observation and selection of topical dressing to utilizing sophisticated technology developed from a growing base of scientific knowledge. There is now an appreciation of the need for a coordinated, multidisciplinary, team-based approach to treatment that recognizes a multitude of complex factors must be considered and managed, including a growing understanding of numerous interdependent molecular and cellular pathways that are dysregulated. Today, a wide range of approaches and products are available for treating chronic wounds, offering physicians multiple options for treating their patients. Unfortunately, without systematically gathered evidence, these products may also give physicians an unrealistic impression that all wounds can be healed with enough of the proper therapies when administered for sufficient time. The range of therapeutic options, while appealing to physicians, comes with a variety of caveats for patients, including pain, discomfort, inconvenience to themselves and their caregivers, and expense. It is in this context that patient-centered care comes into play.

Table 1. Common Causes of Chronic, Non-Healing Wounds

- Diabetes
- Vascular disease (venous & arterial)
- Infection
- Immobility
- Trauma
- Surgery
- Burns
- Radiation injury

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 a physician takes in treating most ailments, not just 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 health care 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 health care dollars are being spent in ways that provide the largest benefit for patients.

Patient-centered outcomes research (PCOR) helps patients and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

- "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?"
- "What are my options and what are the potential benefits and harms of those options?"
- "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?"

To answer these questions, PCOR assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision-making, highlighting comparisons and outcomes that matter to people. It also includes an individual's preferences, autonomy, and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life. PCOR incorporates a wide variety of settings and 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 can also benefit therapy developers by providing 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 stroke found that there was no consensus across these studies on key clinical questions, such as how to measure outcomes, particularly those that are most germane to the patient, such as mobility.¹ The research community has developed a number of condition-specific instruments to assess patient-centered outcomes, including ones for diabetes and stroke² and wound healing², though these instruments are not yet widely used in clinical trials.

The Expert Summit

Given the scientific and technological advances occurring in the wound healing field, the recognition that wound management requires a coordinated, team-based approach, and the growing need to establish wound care as a recognized medical specialty with board certification and evidence-based standards of care, the time has come to address the questions that need to be answered to best meet the needs of patients requiring chronic wound care. The American College of Wound Healing and Tissue Repair (ACWHTR) and the Angiogenesis Foundation, both 501(c)(3) nonprofit organizations, are well positioned to play the role of a neutral facilitator of such a review.

Working together, leaders of these two organizations decided that the emphasis of such a review should be on PCOR. As a first major step, ACWHTR and the Angiogenesis Foundation convened an expert summit that brought together a group of 23 patients, caregivers, practitioners, and health outcomes specialists to review the current status of patient centered outcomes research, review the current efforts at PCORI, present preliminary results from semi-structured patient interviews, and propose future research methods in wound care that incorporate patient outcomes. The Expert Summit on Patient-Centered Outcomes in Wound Healing involved nine patients with chronic wounds and their caregivers as active participants, and was convened in Chicago, Illinois on July 25, 2012. The desired outcomes for this meeting were to create a framework for patient-

centered outcomes in wound healing and identify areas that require further study and validation. This White Paper provides an overview of the group's discussions and presents a number of steps recommended to advance patient-centered care of chronic wounds.

The summit was an interactive, professionally moderated set of short presentations and roundtable discussions that established a dialogue and consensus among the participants. The summit began with participants introducing themselves and then naming the single factor they consider most important to patients suffering from a chronic wound. This was followed by two short presentations summarizing the goals of patient-centered outcomes research and what patients with chronic wounds report as important based on semi-structured interviews. Under the direction of the moderator, the assembled group then engaged in a series of discussions that defined a desired future state based on patient-centered outcomes and outlined the barriers that lie in the path of achieving that state. A graphical facilitator captured key points of the discussion, enabling the participants to visually review the content of their conversations. The group then prioritized those barriers according to two criteria: which barriers, if eliminated or reduced, would have the biggest impact on the desired future state of the field; and which barriers would yield to joint-action by multiple stakeholders in the wound healing community. The summit concluded by identifying a set of actions and recommendations that the participants believe would advance the wound care field.



Figure 1. A diverse group of patients, caregivers, advocates, clinicians, outcomes specialists, and researchers were convened for the Patient-Centered Wound Outcomes Summit, July 2012.

William J. Ennis, D.O., MBA, President of the American College of Wound Healing and Tissue Repair and Professor of Surgery at the University of Illinois Hospital and Health Sciences System, welcomed the group and commented that this summit is a first of its kind in wound care. In his opening remarks to the summit, **William W. Li, M.D.**, president of The Angiogenesis Foundation and co-founding board member of the ACWHTR, explained that the Foundation is committed to establishing patient-centered outcomes in the wound care field to parallel the scientific and technological advances being made in wound treatments. “The missing voice is that of the patient and what they value when it comes to wound healing,” said Dr. Li. “We’re starting a dialogue that will inform researchers and policy makers on what is really important from the patient’s perspective.”

The Role of the American College of Wound Healing and Tissue Repair and the Angiogenesis Foundation

The ACWHTR was founded in December 2010 as a 501(c)(3) non-profit organization, based in Chicago, Illinois, committed to advancing the field of wound care through education, research, and advocacy. The College fosters the education and training of medical professionals including physicians, podiatrists, nurses, and physical therapists in the field of wound care. One major goal of this organization is to establish wound care as a board-certified medical specialty by creating fellowship programs, examinations, and certification processes, as accepted by the American Board of

Medical Specialties (ABMS). ACWHTR also generates public awareness of the problem of delayed healing wounds, helps to foster research and advance the development of new technologies, promote access to effective and appropriate therapies for all patients, and lead wound care education. These goals and objectives are being achieved through an annual meeting, membership for physicians, educational offerings and publications, and active involvement in health policy development.

Founded in 1994, The Angiogenesis Foundation is a Cambridge, Massachusetts-based 501(c)(3) nonprofit organization dedicated to conquering disease using a new approach based on angiogenesis, the process used by the body to grow new blood vessels. Based in Cambridge, Massachusetts, the Angiogenesis Foundation is committed to helping people around the world 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 as such, it takes a unique approach to achieving its mission to help people lead longer, better, and healthier lives. With the expertise and resources needed to understand the complex needs of multiple stakeholders, including patients, caregivers, physicians, researchers, scientists, industry leaders, regulators, policymakers, and payers, the Angiogenesis Foundation facilitates processes that achieve increasingly better outcomes for patients. It is in that spirit that both ACWHTR and the Angiogenesis Foundation believe programs such as this Expert Summit can make an impact for patients with chronic wounds.

CURRENT STATUS

To set the stage for the discussions, two experts gave brief presentations for background and context. Danielle Lavallee, Pharm.D., Ph.D., who leads the Patient Voices Project at the University of Washington's Surgical Outcomes Research Center, presented an overview of patient-centered outcomes research. William J. Ennis, DO, MBA, discussed the findings of a pilot study examining patient values in the care of their wounds.

The Basics of Patient-Centered Outcomes

Although the study of patient-centered outcomes has advanced in recent years, researchers in this field are still determining how best to assess the receiving end of medical care from a patient's perspective. An important milestone in the field was the establishment of PCORI in 2010 as part of the Patient Protection and Affordable

Care Act. Since its establishment, PCORI has defined patient-centered outcomes research, funded 50 two-year pilot projects, released a draft methodology report for public comment, and announced new funding opportunities. Importantly, patient-centered outcomes are often distinct from the endpoints that therapy developers use in clinical trials designed to receive regulatory approval.

Patient-centered research initiatives allow researchers to identify and select outcomes that the population of interest notices and cares about, such as survival, function, symptom relief, and health-related quality of life, and help to inform health decisions. Such studies provide information for selecting outcomes that meet the criteria for being clinically meaningful, patient-centered, and relevant to decision makers. Definitions of common patient-centered outcome terms are listed in *Table 2*.

Term	Definition
Functional status	An individual's effective performance or ability to perform those roles, tasks, or activities that are valued (e.g. going to work, playing sports, or maintaining the house).
Health-related quality of life (HRQOL)	Personal health status. HRQOL usually refers to aspects of our lives that are dominated or significantly influenced by our mental or physical well-being.
Quality of life (QOL)	An evaluation of all aspects of our lives, including, for example, where we live, how we live, and how we play. It encompasses such life factors as family circumstances, finances, housing and job satisfaction. (See also health-related quality of life).
Well-being	Subjective bodily and emotional states; how an individual feels; a state of mind distinct from functioning that pertains to behaviors and activities.

Table 2. Common patient-centered outcome terms defined^a

Traditionally, patient-reported outcomes have been defined as the patient's assessment of how they function or feel with respect to their health or associated health care. Patient-reported outcome metrics provide a patient's perspective on treatment benefit, allows for direct measurement of treatment benefit beyond survival, disease, and physiologic markers. They are often the outcomes of greatest importance to patients. Reports from patients may include the signs and symptoms reported in diaries, the evaluation of sensations and symptoms, reports of behaviors and abilities, general perceptions or feelings of well-being, and reports of satisfaction with treatment, general or health-related quality of life, and adherence to treatments.

Patient-reported outcome metrics can complement traditional clinical study outcomes data, including survival and laboratory measurements, and they can be particularly valuable when more objective measures of disease outcomes are challenging to obtain, are long-term, or otherwise unavailable. As an example, the traditional outcome metric for a wound healing product might be time to complete wound closure, while the patient-centered outcome metric might be how the treatment impacts a patient's daily life, ability to engage in normal activities, or emotional well-being. It is important to remember that patient-reported outcomes are not always patient-centered outcomes, and researchers need to ensure that a patient-reported

outcome questionnaire focuses on outcomes that are important to the patient, not the investigator, by keeping the following questions in mind:

- Are patient-reported outcome measures meaningful to patients, i.e., patient centered?
- Do they capture patient experiences?
- Are the important outcomes measurable?
- Do questions reflect what patients think and feel about their experiences, i.e., beyond simply reporting symptoms and side effects?
- Are questions clear and concise?
- Is the length of the questionnaire appropriate?
- Is the time at which patient-reported outcomes are captured appropriate?

Patient-reported outcomes are developed by capturing information directly from patients through interviews, self-completed questionnaires, focus groups, diaries, and other data collection tools such as hand-held or mobile devices and web-based forms. Proxy reports from caregivers, health professionals, or even parents and guardians are not considered to be patient-reported outcomes. Patient-reported outcomes can also be collected using condition-specific or generic instruments. An example of the former in the wound healing field would be the Cardiff Wound Impact Schedule.³

To be patient-centered, it is important to be proactive in obtaining information directly from patients and their caregivers in order to understand what is truly important to them. Patient advisory groups and focus groups can be helpful. It is also critical to account for the diversity of patients and the impact of cultural factors on patient-centered outcome variables. To be meaningful, measurements of patient-centered outcomes should be fully integrated into point-of-care communication, quality improvement initiatives, and research efforts.

What Patients Say about Patient-Centered Outcomes

To assess what patient outcomes are of greatest importance to patients, Dr. Ennis led a pilot study at the University of Illinois at Chicago that surveyed six patients with chronic wounds who agreed to participate in a taped interview. These one- to two-hour interviews consisted of a combination of open-ended questions and Likert scale questions that had the patients rating their feelings on a scale from “strongly agree” to “strongly disagree.” The patients subsequently received a follow-up questionnaire via mail or email that contained more specific questions about the patient’s wound and the impact it has had on his or her life. Sample patient quotes obtained in this survey, as well as observations from interviewers, are included in *Figure 2*.

Items that were consistently top-ranked for impact on life included: “impact on family, wound drainage, and lack of participation in social activities. The lower ranked items, representing those of least concern to the six patients with chronic wounds, included: difficulty bandaging, sleep disturbance, and odor. The highest ranked wound-specific item was associated with the statement: “I was confident my wound would heal,” but the next highest ranking score was associated with the worrying about a “recurrence of the wound.” The bottom two wound-specific scores were given to appearance of the wound and difficulty with bandaging, two issues about which treatment developers are often concerned based on consulting physician input.

Patient Quotes:

"I just think there needs to be more focus on this area of medicine. We're an aging population. There needs to be more innovative, aggressive approaches. To me, this is an area of medicine that has gotten comfortable with standard procedures. Why? I don't know...other research areas are always growing; it seems like there's a level of complacency here. They need to catch up with the times."

"Finding people to work with you is half the battle, battling yourself is the other half."

"My family has been great, but I could see that I was wearing on them over the years."

"Doctors must admit when something is beyond them. There is no room for egos in medicine."

"Talking about 'complete healing' as the endpoint is almost a joke. It's fantasy land. There are chronic wounds with underlying problems that makes 'complete healing' unrealistic. To provide evidence that wound is 100% healed and provide a time frame for that can't be done. Let's not forget we are talking about a human body."

"Complete healing as the endpoint is meaningless because 'it sounds like I'll never get there.'"

Interviewer Observations

"I feel that the overarching theme that came across in all the patient interviews was the need for the restructuring of the doctor-patient relationship."

"Personally, for me this was a call to aspire to a higher standard on behalf of a patient, and a strong reminder of what type of a physician I should strive to one day become."

"For the most part of medical school, I saw rounds being done outside of the patient's room, but this project made me feel that perhaps even such fundamental old ways need to be re-structured and patient's treatment plan and condition should be discussed more at length at bedside since patients would like to be involved in the decision-making process and believe that this would lead to better outcomes."

"The two recurrent themes we encountered in each of the six patient interviews were: (1) Physicians must treat patients as equal partners in their health care, and, (2) there is a great need for more highly trained, competent professionals in the field of wound management."

"Patients feel that they are partners in their health care when physicians respect their opinions regarding the progress of their wounds, take time to understand their individual lifestyle goals and design treatment strategies that will help them achieve these goals, ranging from being able to walk to riding a motorcycle to sitting for 6-8 hours a day in law school."

Figure 2. Quotes from patient interviews and patients who participated in the Expert Summit survey

Prioritizing Variables For Patient-Centered Outcomes

As the first step on developing an action plan for improving research on patient-centered outcomes in wound healing, the moderator asked each summit participant to name the single variable that is most important to patients. The list of variables included:

- Quality of life: “I don’t like laying in bed and I want to live life fully.”
- Proper training in wound care, beyond the application of bandages
- “Will my wound heal?”
- Addressing pain
- Management of wound drainage and frequency of dressing change
- Personal interactions with health care professionals
- Prevention of preventable wounds
- Should we heal the wound when treatment may be worse than the wound?
- Help patients understand why the wound developed and how to prevent it from recurring
- The ability to continue to care for others
- Doctor’s communications with caregivers
- “I don’t need to see six different doctors to get to the one doctor I really need to see.”
- Can we reach a level of comfort?
- Caregivers need to talk to one another and develop a plan
- Maintaining independent living
- The quality of available treatments
- Recurrence
- Doctors won’t pass along wound care cases to specialists in wound care
- How do we involve patients in the conversation?
- A general confusion of “who I’m seeing as my health care professional”
- Even expert wound care providers don’t know how to refer patients in their localities
- Identifying centers of wound care excellence
- Physicians hold on to patients and don’t refer to the experts
- Freedom to care for themselves
- Well-educated by their physician
- Good wound care should start with the patient’s goal, not the physician’s goal, and it’s a matter of asking the patient
- Access to equipment or dressings is often restricted by insurance companies
- Dealing with depression when nothing is happening to a wound
- Patient-empowerment through a Patient’s Bill of Rights.
- Patients need to know the care they can get
- Why aren’t patients getting mental health care as part of the wound care treatment plan?
- Doctors and nurses are not always on the same page
- Better training of nurses
- Have adequate health care team
- A wound is like a kaleidoscope, and there should be some sort of educational process with the patient and physician during the development of a plan
- Treat patients with humor and caring in a partnership
- Time to closure, cost of closure, and durability of closure
- It may be effective to spend more money up front to avoid spending more later and that decision must be made on a patient-by-patient basis

Against the identified items, the participants were then asked to rank the variables according to three criteria – importance to patients, clinical importance, and knowledge gaps. This was done using a dot-voting system in which the participants used color-coded dots to rank these variables. The dots were also coded according to whether the participant was a patient/caregiver or a clinician.

Importance to Patients	Clinical Importance	Knowledge Gaps
<ul style="list-style-type: none"> • Wound recurrence • Quality of treatment for wound care • Independent living • Personal interactions with doctors and health care professionals • Living a normal life • Receiving proper skilled care for wound healing 	<ul style="list-style-type: none"> • Mental health issues, specifically depression • Wound recurrence • Better communication among health care professionals • Prevention of preventable wounds • The unresolved question of whether the goal should be to heal all wounds • The patient's concern about whether his or her wound will heal • Pain • Mutual education between doctor and patient 	<ul style="list-style-type: none"> • Quality of treatment • The question of whether the goal should be to heal all wounds • How to prevent preventable wounds • How to create clarity for the patient concerning who is providing treatment • Providing skilled training for wound care • The factors that influence durability of closure, time to closure, and the cost of closure

Table 3. Categorization of variables for patient-centered outcomes

Importance to Patients

According to the summit participants as whole, variables that are most important to patients include:

- Wound recurrence
- Quality of treatment for wound care
- Independent living
- Personal interactions with doctors and health care professionals
- Living a normal life
- Receiving proper skilled care for wound healing

This prioritization is consistent with results of the patient survey, which noted that patients want to be able to live their lives independently, for the professional that cares for them to be well-trained, and the treatment team to confer not only amongst themselves but also to include patients and caregivers in order to provide well-coordinated and effective treatment that reduces or eliminates wound recurrence.

Parsing the data further, patients and caregivers ranked personal interactions with doctors and healthcare givers and the quality of the treatment as their two most important issues, while healthcare professionals believed that wound recurrence and communications with patients, caregivers, and other healthcare professionals were the two most important issues to patients and caregivers.

Clinical Importance

In terms of clinical impact, the participants identified the most important variables to be:

- Mental health issues, specifically depression
- Wound recurrence
- Better communication among health care professionals
- Prevention of preventable wounds
- The unresolved question of whether the goal should be to heal all wounds
- The patient's concern about whether his or her wound will heal
- Pain
- Mutual education between doctor and patient.

The patient and caregiver group, and the clinician group both identified three issues — wound recurrence, wound prevention, and whether the goal to heal all wounds is realistic — as their most important clinical issues, though clinicians also noted that pain relief and communication among the healthcare team were also major clinical issues.

Knowledge Gaps

The biggest knowledge gaps, in the opinion of the participants as a whole, concerned:

- Quality of treatment
- The question of whether the goal should be to heal all wounds
- How to inhibit the development of preventable wounds
- How to communicate clearly to the patient which clinician is managing their wound care

- Providing skilled training for wound care
- The factors that influence durability of closure, time to closure, and the cost of closure.

Patients and caregivers felt that the most important knowledge gaps concerned mental health issues, wound recurrence, and the qualifications of the clinician from whom they were receiving care. In contrast, clinicians highly ranked wound recurrence, time and durability, cost of closure, and uncertainty regarding goals for healing all wounds in all patients, as the issues with the biggest knowledge gaps.

WHERE DO WE WANT TO BE?

Having identified the key issues to patients and their caregivers and clinicians, the participants then conducted a brainstorming session designed to answer the following question: If the wound healing community was completely successful at addressing the issues regarding wound healing, what would the world look like five years from now? Forming this picture of the desired future state began with identifying the perspective of patients, then that of caregivers, and finally the physicians and medical team involved in patient care for chronic wounds.

Patient and Caregiver Perspectives

From a patient's perspective, wound healing would be managed by teams of coordinated health care providers based at wound care specialty clinics. The staff at these clinics would be thoroughly versed in all of the medical and non-medical aspects of chronic wound healing, would have meaningful credentials, such as board certification in wound care, and would be able to convince patients that they were being treated by true and qualified specialists in the wound care field. These clinics would be Centers of Excellence with a dual mission of providing optimal, individualized care, and of reaching out into the larger medical community to educate all health care providers about the need to refer patients with non-healing wounds to these specialized clinics. Such outreach efforts would also extend to the public at large and would include efforts to establish patient and caregiver support groups that would benefit patients with wounds and promote the overall outreach mission of the clinics.

These centers of excellence would develop therapeutic approaches that prioritize the patient's needs and desires. This would require training for health care professionals working at the centers for engaging in honest dialogue with patients and their caregivers about all available options and the evidence to support those options. These centers should also be involved in clinical research and the development and validation of wound healing therapeutics.

For caregivers, the desired future state would provide them with easy access to the latest, most effective therapies for the patients, and all the necessary supplies for caring for the wound would be provided in the needed quantities and would be reimbursed. Caregivers seconded the idea that the desired future state would

involve centers of excellence for wound healing. As one caregiver put it, "It's aggravating when the doctor knows less than the caregiver [about wound care] and yet doesn't listen to what the patient or caregiver can provide as background." The sentiment voiced during this discussion was that treatment teams at specialized wound care centers would be more likely to recognize the knowledge gained by the caregivers of patients with chronic wounds, and solicit their input when developing treatment plans. It was also felt that centers specializing in wound healing would provide faster access to services, particularly when a patient needs immediate attention for an issue related to their wound.

Clinician Perspectives

Clinicians at the expert summit were even more adamant about the need to establish a network of team-based wound healing centers to which physicians in the general community would refer patients with recalcitrant non-healing wounds that failed to improve after 2-4 weeks of appropriate care. Too often, physicians not trained to care for chronic wounds will initiate therapies that do not work and can even make the wound worse. Such centers would build long-term relationships with patients, which from a clinician's perspective would improve long-term management of chronic wounds. Creating this network will require a substantial increase in the number of health care professionals who receive wound care training. In the desired future state, these centers of excellence would be staffed by trained podiatrists, plastic surgeons, general internists, infectious disease experts, vascular surgeons, prosthetic specialists, nurses, and social workers. Institutional support will be key to assemble this kind of trained and coordinated team, and that kind of support would be easier to build if centers were based at hospitals at which all participating clinicians, as well as the facility, are economically aligned.

Clinician participants noted that research has been suboptimal in this field, resulting in a substantial body of misinformation being disseminated at conferences and trade shows that does not benefit patients. In the desired future state, all training and practice would be evidence-based, rather than mentor-based, and the Federal government would increase support to generate that evidence through expanded emphasis on clinical research in wound healing.

Barriers and Prioritization

With the desired future state defined, the moderator then asked participants to list barriers that are standing in the way of reaching this state. The identified barriers included:

- Lack of research and funding
- Failure to prioritize this problem before a critical mass of an impacted population is reached
- Physicians do not listen to the goals and wishes of the patients
- Uneven competencies of wound clinicians
- Shortage of wound care providers who are well-versed in the current state-of-the-art
- Patient expectations in terms of time needed is unrealistic
- Limited knowledge of diagnostics to understand the nature of a given wound and which therapy would be appropriate
- Limited understanding of response to treatment
- Payers do not recognize the needs of wound care
- Lack of mentors to provoke interest in med students and to consider wound care as a critical problem
- If you cannot see your wound, you cannot evaluate the need for action
- Unawareness by FDA and CMS of the value of patient-centered outcomes in clinical studies
- Poor training of physicians of how to conduct and evaluate research
- There is no given blueprint to help physicians know where to start therapy
- Fragmentation of wound care - wounds are not considered a condition like cancer or other disease, and as a result there is no disease category and no specialty recognized to treat wounds
- Doctors need to learn the state-of-the-art for care
- Patient meekness and physician arrogance
- Better education of what patients need to know (lack of patient support groups)
- Absence of research support for evidence-based medicine
- Financial inequity driven by monetary burdens of being a physician caring for wounds
- Patients collectively do not have a voice
- Patients need to be better educated
- Economics of prevention
- Little understanding of the disease pathophysiology
- Psychological and sociological nature of wounds that make them a taboo subject

The participants were then asked to prioritize these barriers according to two different criteria:

1. Which barriers, if surmounted, would produce the biggest positive impact on the wound care field?
2. Which barriers are most addressable through joint action by the assembled participants and their networks?

Each participant was allowed to cast votes according to each of the two criteria. The results are shown graphically in *Figure 3*.

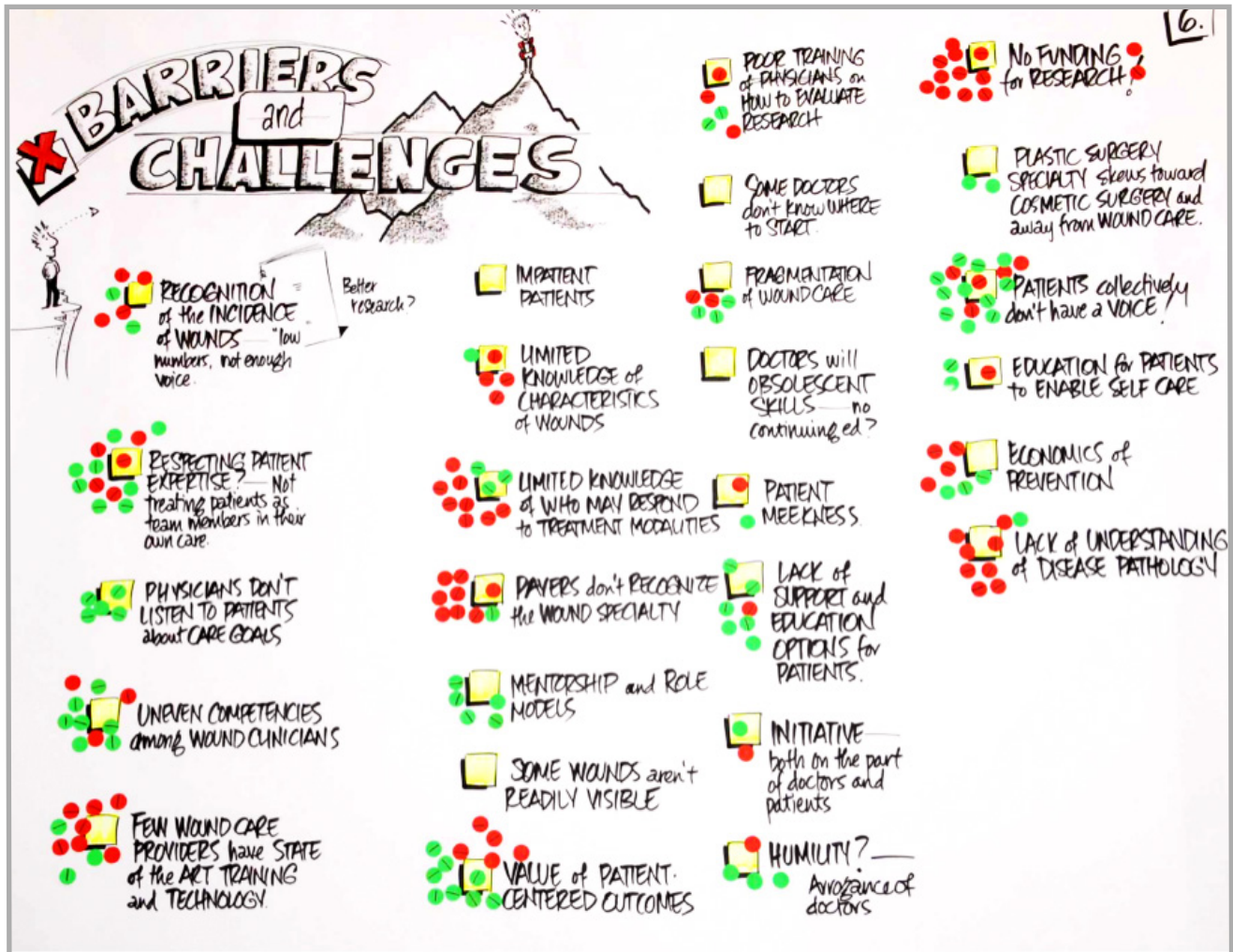


Figure 3. Prioritization of barriers and challenges identified by the Expert Summit participants. Red dots signify barriers that the participants prioritized as being most important, and green dots represent barriers that the participants identified as being most actionable by the wound care community.

In terms of barriers addressable through joint action by the participants, the most important items were ranked as follows:

1. Patients collectively do not have a voice
2. Not treating patients as part of the team in their own care
3. Uneven competencies among wound care clinicians
4. Little value currently placed on patient-centered outcomes
5. Few options for support and education of patients
6. Physicians do not listen to patients about care goals
7. Few mentorship opportunities and role models
8. Limited knowledge of who may respond to treatment modalities

While there was widespread agreement that limited research funding and the barriers associated with poor understanding of disease pathology and limited knowledge about predictive markers to a given treatment modality are major obstacles to moving the field forward, the participants did not view joint action as effective in addressing those barriers. However, three items did rank high in both importance and the ability to take coordinated action:

1. Giving patients a collective voice
2. Building an atmosphere that respects the patient's expertise in designing a course of therapy, and,
3. Creating an ethos that appreciates the value of patient-centered care for chronic wounds.

RECOMMENDED ACTIONS

In the Summit's final activity, the participants discussed potential actions that they could take as a group, or together with colleagues outside of the assembled group, to overcome the identified barriers. Based on these discussions, participants developed the following set of recommendations for the wound healing stakeholder community:

- Develop criteria for credentialing physicians, healthcare clinicians, and care centers in wound healing. ACWHTR has started such an effort and should solicit input from both patients and clinicians as it establishes wound care as board certified medical specialty in wound care. It was noted in the discussion that payers should support such efforts because the results would provide them with metrics for reimbursement.
- Establish a set of validated patient-centered outcome measures specific to chronic wound healing.
- Create a consensus in the research community that clinical studies on wound healing technologies, methods, and products, regardless of the funding source, should include validated patient-centered outcome measures.
- Include patients as an integral part of the wound healing enterprise by:
 - » Involving them in the education of physicians. It was noted by patient participants that they would be enthusiastic about sharing their experiences.
 - » Developing a system of mentorship in which patients mentor health care professionals on wound care issues, as well as other patients. Creating mentorship relationships between health care professionals-in-training and patients would both empower patients and produce a new generation of health care professionals who are encouraged to include rather than discount patient input into the decision of their care.
 - » Creating patient networks that would play an active role in providing patient support, and increasing public awareness about both the causes and treatment of chronic wounds. It was noted that many of the existing and emerging nonprofit organizations with an interest in wound healing should engage in a concerted, responsible educational campaign and create a volume of voices.
- Advocate for sponsored funding to create patient registries. Such registries would be an invaluable source of the data needed to answer many of the questions raised at this meeting. Governmental and private support for registries could help eliminate product-specific and agenda-driven registry projects.
- Approach the Veteran's Administration as a partner in establishing a nationwide network of chronic wound support groups, given the demographics of its patient base.

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EXPERT SUMMIT PARTICIPANTS

Ann Achufusi
University of Illinois-Chicago

Audrey Sui
University of Illinois-Chicago

Barbara Bates-Jensen, RN, Ph.D.
University of California, Los Angeles

Charles Rakis
Patient

Charles Turkelson, Ph.D.
Center for Medical Technology Policy

Christopher Chiang, M.D.
University of Illinois Hospital & Health Sciences System

Danielle Lavalley, Pharm.D., Ph.D.
University of Washington

Denise Norman
Transitional Care

Diane Meyer
Patient

Eve Lesondak
Patient Caregiver

Irene Lewnard
University of Illinois-Chicago

Kassi Campbell
Patient Caregiver

Lisa Corbett, APN
Hartford Healthcare Corp.

Mary Ferguson
Patient

Paul Meyer
Patient Caregiver

Robert Frykberg, DPM
Carl Hayden Veterans Administration Medical Center

Terrance Barker, JD
Patient

Terrance Barker Sr.
Patient Caregiver

Thomas O'Donnell, M.D.
Tufts University School of Medicine

Vickie Driver, DPM
Boston University, American Association for the Advancement of Wound Care

William J. Ennis, DO, MBA
University of Illinois-Chicago, American College of Wound Healing and Tissue Repair

William W. Li, M.D.
The Angiogenesis Foundation

Wilma Rowcliff
Patient

Other Contributors

Robert Mittman
Susan Perry
Diana Saville
Katya Margolin
Lisa Aurora
The Angiogenesis Foundation
Cambridge, MA, USA

For More Information

Contact:

Dr. William Ennis
American College of Wound Healing and Tissue Repair
840 S. Wood, Mc 958 | Chicago, IL 60612 USA
wjennis@uic.edu



The **Angiogenesis**
Foundation 

One Broadway, 14th Floor, Cambridge, Massachusetts 02142 USA
617.401.2779 | info@angio.org | www.angio.org