#### To: Dr. John R. Potts MD, FACS ACGME Senior Vice President Surgical Accreditation

From: William J. Ennis DO, MBA, MMM President American College of Wound Healing and Tissue Repair

#### Date: 7.12.18

Dr. Potts,

Throughout my 25 year career I have advocated for the creation of a formal specialty in wound care. I, with several others, founded a 501c3, the American College of Wound Healing and Tissue Repair (ACWHTR), with the sole purpose of achieving that goal. For eight years the American College of Wound Healing and Tissue Repair has grown its membership, now over 400, held annual meetings and created white papers regarding the importance and life-saving value of wound care. The organization also facilitates post graduate fellowships in five academic institutions (UIC, Cleveland clinic, Wake Forest, Inova health, Stanford). At my home institution, the University of Illinois at Chicago, we have just selected our seventh wound care fellow in as many years. The most recognized wound organization in the United States, the Wound Healing Society, has endorsed our curriculum and is contemplating moving their annual meeting to align with ours each October. The goal of both organizations is to further consolidate the field, by merging meetings and societies in order to create a needed critical mass of clinicians and providers thereby speaking with one voice.

Wound care has become too expensive with much clinical variation and poor evidence. A unified, accepted, and credentialed fellowship program will provide a path to follow, consistency in training, help standardize care, improve outcomes and (hopefully) lower cost. In an effort to provide evidence of the need for such specialization, we have prepared an extensive document that highlights the problem, current status and proposed future state as we have envisioned it.

Through an agreed upon, consistent educational program, we believe that both the clinical care and safety of patients in the US will be improved. (pg. 3-5) There has been an explosion of scientific research and treatment options in the field of wound care. Although many specialties can be involved in wound care, there is minimal specific training and education, related to wound care in any of the existing programs. (pg. 17-18) There is an ever growing demand for physicians to provide wound care full time. Several large practice management companies have emerged that train and hire wound care physicians over the past several years. These physicians however do not receive a formal, medical education as they would in other specialties of medicine. There are many clinical and professional societies that have developed over the years due to the growing body of clinicians practicing in the area of wound care fellowship program and several now already exist. (pg. 37-41) There are currently 5 programs up and running and the college is in discussions with several more that are interested. As these programs recruit from existing residency programs and more fellows are enrolled there is a growing interest in developing new programs. We anticipate 20 programs would be a good base to allow for sustained growth of this new field initially and hope to achieve this within the first 3 years of approval, should that be achieved.

As the attached document outlines, the increase in the number and severity of chronic wounds will continue to increase in years to come. We feel that the ACGME will help provide a path to start the process of standardizing educational efforts in this new and exciting field.

After you have had a chance to review the attached document, I would very much like to have a meeting with you in order to present the formal curriculum documentation that we have put together. The Board and I are excited about this opportunity.

Sincerely,

William J Ennis DO, MBA, MMM

# Application to the Accreditation Council for Graduate Medical Education for Accreditation of a Fellowship Program in Wound Healing and Tissue Repair

Presented by the American College of Wound Healing and Tissue Repair and the University of Illinois at Chicago

7.12.18

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#### I. Executive Summary

Chronic wounds are an emerging "silent epidemic."<sup>1,2</sup> These non-healing wounds are common, costly, and difficult to treat. In parallel with current demographic trends, the prevalence of chronic wounds is expected to grow rapidly in coming years, with corresponding increases in the already enormous costs of treatment and lost productivity.<sup>2</sup> Treating chronic wounds requires an understanding of complex pathophysiologic mechanisms, multidisciplinary approaches, and an expanding array of advanced wound care technologies. Without a dedicated specialist to marshal these resources, patients may be juggled between disciplines and caregivers, with no expert to coordinate and champion their care. The results are prolonged recovery time, greater costs of care, further loss of productivity, and increased risk for death.

A wound care subspecialty is clearly needed to fill these gaps. This proposal describes the unmet need for wound care specialists, the currently minimal and unacceptable level of wound care education in medicine, and how accredited wound care fellowship programs can provide desperately needed standardization and expertise.

The statistics establish the need for a wound care specialty. Chronic wounds affect an estimated 6.5 million Americans; millions more may be affected as the population ages and risk factors grow in prevalence.<sup>2</sup> Chronic wounds are especially common and impactful in the most vulnerable people, including the elderly, residents of long-term care, and patients with common chronic diseases, such as diabetes.<sup>3,4</sup> Non-healing wounds also present a significant risk for death; the Agency for Healthcare Research and Quality estimates that pressure ulcers alone cause 60,000 deaths annually in the US.<sup>5</sup> The direct healthcare costs of chronic wounds total at least \$25 billion annually, but the true financial impact may be manyfold higher due to prolonged disability, lost productivity, and reduced quality of life.<sup>6,2</sup>

The vast scope of chronic wounds has fostered the emergence of a large and expanding market for wound care products. This nearly \$20 billion market comprises more than 5000 products, including both traditional (eg, gauze, bandages) and advanced wound-care products.<sup>7-10</sup> The advanced wound care market, which represents a broad class of sophisticated devices, dressings, and skin substitutes, is expected to double in coming years. The number, diversity, and rapid expansion of wound care technologies may overwhelm clinicians who are not wound care experts. The appropriate use of these technologies is further hampered by a dearth of high-quality evidence describing their clinical use. In the absence of clear guidance and strong evidence, industry steps in with its own research and marketing, further confusing clinicians and the optimal approach to clinical management.

The evidence-based management of chronic wounds depends on a multidisciplinary team led by individuals with specialized skills and knowledge. Optimal wound care often demands surgical, medical, rehabilitative, and other techniques in conjunction with sophisticated wound care devices and knowledge.<sup>11-13</sup> The best outcomes occur when

an individual with expertise in wound care leads and coordinates the treatment team. Indeed, studies of protocol-based treatment by multidisciplinary teams with expert guidance have demonstrated dramatic improvements in outcomes and greatly reduced costs compared to usual care. In one study, implementation of an evidence-based wound care protocol at a community hospital led to dramatic improvements in adherence to best practices and reduced average healing time by >50% and treatment costs by 75% per patient.<sup>14</sup> Together, these findings demonstrate the impact of and need for expertise in wound care management.

Unfortunately, few such experts are available. Variations in wound care derive from a lack of formal wound care education, limited high-quality evidence, inconsistent guidelines, and the diversity of clinical techniques used to support wound healing. Recent studies have found that medical students spend only about 10 hours of education on wound-related topics; a scant minority of US medical schools offer a formal wound healing elective.<sup>15</sup> Only some residency programs include further wound care education. The result is that most if not all clinicians who care for chronic wounds obtain their skills and knowledge through the course of clinical practice and without specialized training.

Wound care is a considerable clinical challenge. A wound care specialist must grapple with extensive medical histories, comorbid conditions, potential drug interactions, interdisciplinary coordination, and patient communication and education. Regardless of each clinician's primary training, wound care specialists must draw on knowledge and skills from both surgical and medical fields. The clinician must understand multiple surgical concepts and techniques, as well as medical disciplines ranging from dermatology and rheumatology to endocrinology and general medicine. Without question, the practice of wound management is as challenging, demanding, and complex as any field of medicine. The lack of a recognized wound care specialty leaves the field without experts to guide and coordinate clinical care, lead high-quality research efforts, and develop rigorous protocols and guidelines.

The creation of accredited wound care training programs will benefit clinicians, patients, and the broader healthcare system. Board certification will support the professional development of wound care practitioners, facilitate patient access to qualified providers, and allow health systems to ensure the knowledge and competency of their clinicians. Board-certified experts will facilitate research through academic centers and foster the development of standardized protocols and guidelines. Because wound care experts coordinate episodic care (ie, for as long as the wound is healing), the specialty acts to integrate rather than fragment care and will not introduce new conflicts over practice territory.

The time for accreditation is now. Evidence clearly indicates that a large and expanding patient population will benefit from care provided by experts with specialized knowledge and skills. And the diverse skills and knowledge required for wound

management can only be provided through formal training that is currently lacking throughout the process of medical education.

In response to this need, leaders in the field have developed nascent fellowship programs at 5 major centers, including the University of Illinois at Chicago, Stanford University, and the Cleveland Clinic. The American College of Wound Healing and Tissue Repair continues to encourage the development of wound care fellowships through the sharing of educational content, policies, procedures, and documentation. The College is also actively establishing a fund to support program development and creating an examination to be used across all fellowship programs. The ultimate goal is to achieve accreditation of a wound healing specialty by the Accreditation Council for Graduate Medical Education and certification by the American Board of Medical Specialties. By doing so, the College hopes to foster improved understanding and coordinated, standardized care of chronic wounds throughout the healthcare system to reduce patient morbidity and mortality and healthcare costs.

### II. Wound Care: The Problem

### Summary

- Chronic wounds affect 6.5 million Americans<sup>2</sup>
- 15%-25% of patients with diabetes will develop a diabetic foot ulcer in their lifetime<sup>16</sup>
- 3% of adults over 80 years of age will develop a venous leg ulcer<sup>17,18</sup>
- Up to one third of patients in acute and long-term care will develop a pressure ulcers<sup>19</sup>
- In the US, 60,000 patients die each year due to pressure ulcers<sup>5</sup>
- Prevalence of major risk factors for chronic wounds is rising, including obesity, diabetes, and older age<sup>2</sup>
- Direct costs of chronic wounds are estimated to be \$25 billion per year in the US<sup>2</sup>
- Indirect costs of chronic wounds include reduced function, lost productivity, and lower quality of life<sup>16,20-22</sup>
- Multiple gaps in care have been identified, including low-level evidence, limited physician knowledge of wound care, and poor use of best practices<sup>23-32</sup>
- Gaps in practice contribute to variation in wound care, longer healing times, increased rates of amputation, and excess costs<sup>33,34</sup>
- Rapidly expanding wound care market includes advanced products that require specialized knowledge and skills<sup>7-10</sup>
- Specialized, multidisciplinary care improves outcomes and reduces costs<sup>11-13</sup>
- All of these factors support the need to establish a formal wound care specialty to coordinate and oversee wound care

#### Definition of the problem

Wounds may result from surgery, trauma, burns, or disease processes. Most acute wounds heal normally and require only basic care. More complex wounds take longer to heal and may require specific management. For example, an infected surgical site, traumatic wound, or burn may require antibiotic therapy, surgical debridement, or other forms of management. Chronic or non-healing wounds most often result from common disease processes, such as diabetes, are associated with significant morbidity and costs, and require the greatest expertise to manage.

A chronic wound has been defined as "a disruption of normal anatomic structure and function...having failed to proceed through an orderly and timely process to produce anatomic and functional integrity, or proceeded through the repair process without establishing a sustained anatomic and functional result."<sup>35</sup> In short, a chronic wound is one that does not progress through the normal healing process in a timely and predicted manner. The goal of wound management is to facilitate the healing process.

Chronic wounds have diverse etiologies and complex patterns of healing. Etiologies include, but are not limited to, trauma, diabetes, vascular disease, ischemia, pressure, infection, autoimmune diseases, and coagulopathies.<sup>36</sup> Mechanisms that negatively affect the wound healing process include infection, inflammation, impaired angiogenesis, inadequate connective tissue regeneration, excess scar formation, and delayed remodeling.<sup>35,37</sup> Caring for each wound pathology requires expertise from multiple disciplines and an understanding of each patient's and wound's unique treatment requirements.<sup>36</sup> As a result, the clinical management of chronic wounds requires a multidisciplinary approach, often including surgical, medical, nursing, and rehabilitative techniques, among others.

Without a wound care specialist to coordinate and direct care, patients with chronic wounds may not receive comprehensive and evidence-based management.

#### Burden of chronic wounds

Chronic wounds are common and costly. Patients with chronic wounds are expensive to manage and experience significant morbidity and mortality. In one retrospective study

of 1815 outpatients with chronic wounds, 28% died within 2 years.<sup>38</sup> According to the Agency for Healthcare Research and Quality (AHRQ), about 60,000 patients each year die as a direct result of pressure ulcers.<sup>5</sup> Chronic wounds also cause tremendous suffering, with profound effects on patients' physical health, socialization, ability to work, body image, and level of independence.<sup>39</sup> In fact, chronic wounds have been termed a "silent epidemic," as they affect a wide swath of the population and burden the health and economy of developed countries.<sup>2,1</sup>

According to the AHRQ, about 60,000 patients each year die as a direct result of pressure ulcers.<sup>5</sup> In the US, about 6.5 million patients suffer from chronic wounds.<sup>2</sup> Overall, it is estimated that 1%-2% of all individuals will develop a chronic wound during their lifetime.<sup>40</sup> A sharp rise in the prevalence and costs of chronic wounds is anticipated based on demographic trends, most notably the aging population and increasing prevalence of diabetes and obesity.<sup>2</sup>

A recently published paper addressed the increasing burden of non-healing wounds through the lens of demographic and cost implications.<sup>6</sup> This large retrospective study found that nearly 15% of Medicare beneficiaries (8.2 million) had at least one type of wound in 2014. Estimates of total Medicare spending for all wound types ranged from \$28.1 to \$96.8 billion, with greatest expenditures for the management of surgical wounds and diabetic foot ulcers.

Although chronic wounds may arise from a number of etiologies, most are categorized as vascular ulcers (venous ulcers and arterial insufficiency wounds), diabetic ulcers, or pressure ulcers.<sup>3,4</sup> The most common are **venous leg ulcers** (VLU), which affect ~1% of the population and 3% of people over age 80 years. They are the largest single group of leg ulcers treated in wound care clinics.<sup>17</sup> About 7% of VLUs remain unhealed after 5 years and 15% never heal or reoccur one or more times. Recurrence rates as high as 70% are reported with chronic VLU.<sup>18,41,42</sup>

**Diabetic foot ulcers**, resulting from a combination of peripheral vascular disease and neuropathy,<sup>43</sup> affect as many as 6% of patients with diabetes each year; 15%-25% of diabetic patients will have a foot ulcer during their lifetime.<sup>16</sup> These ulcers double the cost of care, compared to diabetic patients without foot ulcers, and precede more than 80% of lower extremity amputations in diabetic patients.<sup>16</sup> Up to a quarter of patients with diabetic foot ulcers have an amputation; mortality in the years following amputations may be as high as 50%.<sup>44,45</sup> Overall, diabetic foot ulcers have been linked to a 3-year cumulative mortality rate of 28%.<sup>44</sup>

The incidence of **pressure ulcers** in acute and long-term care ranges from 23.9%-38%.<sup>19</sup> Pressure ulcers pose significant problems, especially for patients who suffer from impaired mobility, inadequate nutritional intake, or a critical illness. For some patients, such as those with spinal cord injury, pressure ulcers are a leading cause of hospital readmission and a major source of morbidity and mortality.<sup>39</sup> Pressure ulcers also cause significant impairments in health-related quality of life.<sup>46</sup> In an AHRQ study of nursing home residents, 11% had a pressure ulcer, but only 35% of patients with a pressure ulcer of stage 2 or higher received specialized wound care services, as recommended by clinical practice guidelines.<sup>47</sup>

Only 35% of patients with a pressure ulcer stage 2 or higher received specialized wound care services, as recommended by guidelines.<sup>47</sup>

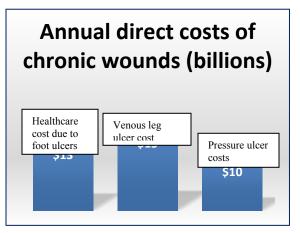
### Economic costs of chronic wounds

Chronic wounds impose a tremendous burden on the healthcare system and society. Although estimates of the costs of chronic wounds vary substantially, all are staggering. For example, a 2009 estimate placed the annual cost of chronic wound management at more than \$25 billion in the US alone.<sup>2</sup>

A more recent study (2014) used Medicare and private insurance databases to estimate the costs of diabetic foot ulcers.<sup>16</sup> Compared to matched controls with diabetes, patients with diabetic foot ulcers had many more hospitalization days, home healthcare days, emergency department visits, and outpatient visits. Incremental annual healthcare costs were about twice as high – from \$11,710 to \$16,883 per patient – for patients with diabetic foot ulcers compared to those without ulcers. Annual work-loss costs related to foot ulcers exceeded \$3,000 per patient. Based on the incidence of foot ulcers among diabetic patients – about 6% in some studies – the authors estimated that these wounds add up to \$13 billion per year to healthcare costs.

Using similar methods, the same group estimated that the management of VLU costs nearly \$15 billion per year in the US.<sup>48</sup> Patients with leg ulcers also lose about 2 million working days each year.<sup>20-22</sup> Similar costs have been reported for the management of

pressure ulcers. In 2011, the AHRQ estimated that pressure ulcers cost the US healthcare system \$9.1-\$11.6 billion per year.<sup>5</sup> In 2008, the Centers for Medicare and Medicaid Services (CMS) categorized hospital-acquired pressure ulcers as "never events" and modified reimbursement policies for these wounds, forcing hospitals to shoulder the costs of management and incentivizing systems to prevent and effectively manage these wounds.



Even higher chronic wound costs have been proposed. One group estimated that about one third of direct annual costs of treating diabetes were linked to the treatment of diabetic foot ulcers – totaling nearly \$39 billion in 2007.<sup>49</sup> In 2012, the American Diabetes Association estimated a total cost of \$245 billion for diabetes, of which \$176 billion were excess healthcare expenditures.<sup>50</sup> If one third of this value related to diabetic foot ulcers, the annual cost of this condition might well exceed \$50 billion.

These expenditures represent a significant portion of the entire healthcare budget. In the UK, wound management accounts for almost 4% of total healthcare costs, and wound costs continue to increase.<sup>51</sup> Overall, it is estimated that developed countries devote 2%-3% of their healthcare budgets to the management of chronic wounds.<sup>52</sup>

### The rising tide of chronic wounds

Demographic trends describe a sharp rise in the incidence and prevalence of major risk factors for chronic wounds, such as obesity, diabetes, vascular disease, and older age.

The US has the highest rates of overweight and obesity in the developed world. The prevalence of obesity among US adults is about 1 in 3 today, and is expected to reach 1 in 2 by 2030, an increase of 65 million obese adults.<sup>53</sup> In parallel with obesity, the prevalence of diabetes has risen dramatically. Currently, more than 30 million Americans have diabetes, and another 84 million are prediabetic. The rate of diabetes has tripled in the last 20 years, and projections suggest that as many as 1 in 3 Americans will have diabetes by  $2050.^{54}$  Finally, the US population is growing markedly older. The US Census Bureau projects that 20% of Americans will be  $\geq 65$  years of age by  $2030.^{55}$  Between 2014 and 2060, the percentage of people aged 65 or older will grow from 15% to 24%, an absolute increase of 9%.

As these conditions increase in prevalence, the burden of chronic wounds will also increase, as will the need for specialists trained in evidence-based wound management. Projected annual growth rates for pressure and venous ulcers are 6%–7% in the developed world; diabetic ulcers are growing more rapidly at 9% annually.<sup>56</sup>

### Wound care market

Growth in the prevalence of chronic wounds is matched by growth in the wound care market. In 2016, the global wound care market totaled \$17 billion. It is projected to reach \$20.4 billion by 2021, a compound annual growth rate (CAGR) of 3.6%.<sup>7</sup> North America is expected to retain the largest share of the wound care market, despite rapid market expansion in Asia. Projected growth is supported by demographic trends (obesity, diabetes, aging), rising awareness of new wound care technologies, and



favorable government policies.<sup>7,8</sup> Acting to constrain market growth is the high cost of advanced wound care products along with a limited and inadequately trained provider base.

Segments within this market include traditional wound dressings and advanced wound care products. Traditional dressings include products such as gauze and

bandages that are commonly used in hospital, long-term care, and home settings. These dressings are generally used to cover and protect the wound during the normal healing process. Advanced wound care products include film and foam dressings, hydrogels, alginates, hydrocolloids, bioengineered skin substitutes, as well as devices for negative-pressure wound therapy and hyperbaric oxygen therapy.<sup>57</sup> These products are intended to be used by specialists to actively support healing of chronic and complex wounds.

Advanced wound care products are expected to be the fastest growing segment of the wound care market.<sup>7</sup> In 2015, the global market for advanced wound care products was valued at \$5.5 billion; it is projected to exceed \$10 billion by 2022.<sup>8,9</sup> Collagen-based bioactive dressings are forecast to show the highest growth rate within this segment. Four companies (Acelity, Inc., Smith & Nephew, MoLnLycke Healthcare, and ConvaTec) account for 54% of the advanced wound care market globally.<sup>9</sup>

The number, diversity, and rapid development of wound dressings and technologies may be overwhelming to most clinicians. Selecting among these options to optimize patient care requires thorough assessment of wound characteristics and a broad understanding of the features, applications, and evidence supporting different wound products.<sup>10</sup> However, few high-quality trials evaluating wound dressings have been published, and current evidence does not clearly support preference for specific products or categories of product.<sup>10</sup>

#### Gaps in wound care

Studies have identified **wide variation in the clinical care of wounds**.<sup>33,34</sup> The result is inconsistent treatment, increased costs, and reduced healing rates. Ineffective wound care also prolongs patient suffering, disability, and loss of productivity.

Poor use of evidence-based wound care has been demonstrated in multiple studies. For example, although most (~70%) chronic leg ulcers are venous ulcers, for which compression therapy is considered the gold standard, one US study found that only 17% of patients with venous ulcers received this therapy.<sup>58,1</sup> Similarly, an analysis of data on diabetic foot ulcer management from US Wound Registry found that off-loading, a commonly used technique to reduce pressure on the affected appendage, was vastly

underused in these patients.<sup>59</sup> Among 11,784 patients with 25,114 diabetic foot ulcers, off-loading was documented in only 2.2% of visits over 6 years. Patients managed with total-contact-casting (a lowercost, effective form of off-loading) had significantly fewer amputations (2.2% vs. 5.2%; P=0.001) and more healed wounds (39.4% vs. 37.2%). In another study, only 31% of participants with a lower limb ulcer had documentation of an appropriate investigation (ABPI or duplex assessment) in the previous 12 months.<sup>11</sup>

One US study found that only 17% of patients with venous ulcers received the goldstandard therapy.<sup>58</sup>

### Root causes of gaps in wound care

The roots of variation in wound care are multifactorial (Table 1) and include the lack of formal wound care education, guidelines based on limited evidence, and the diversity of clinical techniques used to support wound healing, which range from optimal moisture balance to restoration of blood flow to the wound, compression therapy, infection management, debridement, and innumerable dressings and medical devices.<sup>60-63</sup> As a result, many clinicians have poor knowledge of wound care, lack wound care skills, and have limited access to evidence-based guidelines.<sup>1</sup> A dearth of standardized care pathways also makes it difficult to track patients with chronic wounds, presenting a barrier to continuity of care. In addition to the myriad treatment options, another complicating factor is the lack data on the best ways to sequence therapies.

Table 1. Factors underlying gaps in the delivery of wound care.

- Limited formal wound care education
- Lack of provider skills and knowledge
- Lack of standardization
- Low-level evidence for wound care interventions
- Guidelines based on limited evidence
- Poor implementation of best practices
- Diversity of available wound care products and techniques
- Lack of recognized wound care specialty

The preponderance of low-level evidence is a significant challenge. Most clinical wound care studies are limited by inconsistent inclusion criteria, data measurements, and/or endpoint reporting.<sup>23</sup> Multiple Cochrane reviews of wound care interventions have identified only limited or low-quality evidence.<sup>24-28</sup> A 2012 study compared relevant publications in the fields of breast cancer and wound care to determine if research into wound care lags behind other specialties.<sup>29</sup> Over 5 decades, the authors found a 30-fold increase in publications on wound care – but a 70-fold increase in publications on breast cancer. High-quality studies (eg, systematic reviews, randomized controlled trials) were less common in wound care, as were published guidelines (76 on wound care vs. 231 on breast cancer).

Reasonable evidence does exist supporting the efficacy of certain wound care interventions, such as growth factors, platelet-rich plasma, and skin grafting/tissue replacement for diabetic foot ulcers.<sup>30-32</sup> These more robust trials were the result of using a pre-market approval (PMA) pathway to gain FDA approval, not unlike most pharmaceuticals. The overwhelming majority of wound care products, however, follow a 510K pathway through the FDA, which has much lower evidentiary requirements for the approval process. Even the PMA data were derived from a limited number of studies with small sample sizes or other design limitations. As a result, clinicians who care for chronic wounds must rely heavily on experts in the field.<sup>23</sup>

An evaluation of guidelines in chronic wound care found that most scored poorly on indexes of guideline quality, such as consideration of multidisciplinary panels, validity, testing, settings, cost impact, and methods of implementation.<sup>64</sup> Even when guidelines for wound care exist, implementation and appropriate therapy by physicians is variable and inconsistent.<sup>65</sup> Guideline adherence in all fields of medicine is less than optimal; in order to increase adoption, strong levels of evidence, medical society endorsement, and expert opinion are required. To combat these issues, clinicians must increase professional acceptance, funding, recruitment, and development of research and education in the specialized care for wounds. Research in the field of wound care is further hampered by the lack of one focused agency that would provide funding, such as the National Cancer Institute in oncology. This lack of guidance results in an even

heavier involvement by industry in sponsoring wound care research, which adds concerns for bias and selective reporting.

Other key issues noted by thought leaders include a lack of standardization, limited integration of multidisciplinary teams, and lack of a specialist or specialized unit

responsible for wound care.<sup>12</sup> Although wound care requires a coordinated, multidisciplinary effort, such teams are often not well integrated into existing clinical sites of care. Clinicians caring for patients with chronic wounds may be uncertain what expertise is needed or where to seek it. Healthcare providers may find it difficult to manage chronic wound patients across departments and disciplines. Patients too are often confused regarding what provider to see for wound care. The lack of integration across disciplines leads to gaps in primary care, health promotion, preventive medicine, early intervention, and continuity of care.<sup>66,12</sup>

Lack of a specific wound care specialist can lead to dispersion of responsibility for wound care, inconsistent wound care, and increased costs.

Finally, the lack of a specific wound care unit or specialist can lead to dispersion of responsibility for wound care among providers, inconsistent wound care, and increased costs. The lack of education and routine training for professional wound care and the huge variety of wound care products, procedures, and treatments pose additional problems.

Based on the results of multiple studies, one leading author concluded, "Doing the right thing in wound care is not easy" in the current healthcare environment.<sup>1</sup> A key challenge is a reimbursement system that favors the use of more expensive therapies over more economical ones.<sup>1</sup> Furthermore, decision makers do not always appreciate the importance of wound healing. As a result, industry has filled the need for guidance with

One leading author concluded, "Doing the right thing in wound care is not easy" in the current healthcare environment.<sup>1</sup> its own research and marketing. Indeed, the choice of wound therapies is often based more on marketing, expert opinion, and personal experience than strong evidence.<sup>67,57</sup> For example, many clinicians manage wounds according to traditional practices, despite evidence suggesting better alternatives.<sup>67</sup> Conversely, not all newer wound dressings are clearly superior to conventional dressings, as demonstrated by clinical

evidence, despite higher cost and widespread use.<sup>68-70</sup>

### Filling the gaps: Multidisciplinary wound care

The optimal approach to the management of chronic wounds should involve a multidisciplinary team that is coordinated by a wound care specialist.

The results of multiple studies support the efficacy of protocol-based treatment and multidisciplinary teams for the effective management of pressure ulcers, venous stasis ulcers, and diabetic foot ulcers.<sup>71-74,11,75,12</sup> The multidisciplinary approach to wound care has led to  $\geq$ 50% improvement in outcomes by reducing both amputation rates and wound-related complications.<sup>76-80,75,81</sup>

#### Wound care centers: Lower costs, faster healing

The growth of wound centers and wound management services reflects the expanding and unmet clinical need for (and benefits of) specialized wound care. Wound management services are designed to treat chronic wounds throughout the healing process, minimize infections and other complications, restore patients to normal function, and prevent future chronic wounds.<sup>12</sup>

Studies of wound care clinics have demonstrated improved healing rates, reduced amputations, and lower healthcare costs. A 2013 study found that patients admitted to wound clinics accessed care less often, used a smaller range of providers, and had significantly improved healing outcomes.<sup>11</sup> Implementation of key indicators of evidence

based care also significantly increased. Following establishment of one hospital-based wound care center, 62% of recruited patients achieved healing or wound improvement.<sup>12</sup> An analysis of 5240 patients (7099 wounds) from the US Wound Registry, most with multiple comorbid conditions (diabetes, obesity, peripheral vascular disease), found that 65.8% of wounds healed during care at the wound center, with an average time to healing of 15 weeks

wound center, with an average time to healing of 15 weeks and a mean cost of \$3927 per wound.<sup>82</sup> A recently published study compared outcomes from over 600,000 wounds treated at hospital-based wound clinics that were managed by an outsourced company to those achieved at an academic center.<sup>83</sup> The results were reported using a modified intent-to-treat analysis in which few exclusions were used in order to emulate standard research findings. In this analysis, wound healing outcomes were comparable between groups, suggesting that the use of standardized protocols can produce outcomes approaching those at tertiary level centers. These results were reported at a population level, without risk adjustment; subsequent results from this group are forthcoming. However, the very large sample size in this study allows general conclusions to be drawn.

These findings demonstrate that access to wound management expertise can promote streamlined health services and evidence-based wound care, leading to efficient use of health resources and improved outcomes.<sup>11</sup> Furthermore, a rising number of malpractice claims related to chronic wounds, especially diabetic foot ulcers, have contributed to an increase in referrals to wound care centers, suggesting another advantage to specialized wound care.<sup>84</sup>

In studies of wound care clinics, >60% of patients achieved healing, quicker and at lower cost.<sup>12,82</sup> Consensus panels have advocated for multidisciplinary care teams to improve outcomes in critical limb ischemia, such as diabetic ulcers.<sup>49,85</sup> Multidisciplinary wound care has been shown to more than double amputation-free survival in patients with critical limb ischemia, compared to standard wound care.<sup>13</sup>

One study from a community provider in Canada demonstrated improvements in wound management and costs following a reorganization of the hospital's wound care protocols.<sup>14</sup> The use of traditional wound care products fell from 75% to 20% over 2 years, in line with best practice recommendations, and the frequency of daily dressing changes fell from 48% to 15%. Average time to healing fell from 51.5 weeks to 20.9 weeks in 1 year, and treatment costs were reduced by 75% per patient. The organization reported a net savings of \$3.8 million.

### Multidisciplinary care: Who's involved?

Optimal wound care requires coordinated contributions from many specialties. Core techniques of chronic wound care include surgical debridement and reconstruction, vascular assessment and management, infection prevention and treatment, glucose management, aggressive treatment of comorbid conditions, specialized wound therapies (eg, hyperbaric oxygen), nutritional guidance, rehabilitation services, and hands-on wound management (eg, dressing changes). Examples of these many disciplines are illustrated in Table 2.

Specialist	Contribution		
Plastic surgeon	Soft tissue reconstruction and coverage		
Podiatric surgeon	Wound care and surgical biomechanical management		
Orthopedic surgeon	Lower extremity skeletal reconstruction		
Vascular surgeon	Vascular assessment, open and endovascular		
Infontious discoss enosislist	intervention		
Infectious disease specialist	Wound infection management		
Endocrinologist	Aggressive glucose management		
Hospitalist	Acute inpatient management		
Internal medicine	Medical management of comorbidities		
Rheumatologist	Vasculitic and autoimmune processes		
Hematologist	Coagulopathic abnormalities, sickle cell, blood-based malignancy		
Psychiatrist	Behavior modification and psychological assessment		
Hyperbaric specialist	HBO therapy		
Interventionist (radiology, cardiovascular)	Assessment and endovascular intervention		
Nutritionist	Optimization of healing potential through counseling and supplementation		
Physical therapist	Rehabilitation and mobility training, energy-based wound therapies		
Orthotist/prosthetist	Orthotics, prosthetics, bracing, offloading		
Wound nurse	Wound care and patient education		
Medical assistant	Casting and dressing application		
Nurse practitioner/	Pre- and postoperative care, wound care, discharge		
physician assistant	planning, and patient education		
Anesthesiologist	Anesthesia and pain management		

Table 2. Examples of clinicians involved in the multidisciplinary care of chronic wounds.<sup>36</sup>

In summary, it takes a village to heal a wound. While the contributions of each member of the team are important, the best results are obtained when an individual assumes the role of point person for the care. A wound specialist, with didactic and clinical training in all aspects of the care process, can lead, coordinate, and drive the most cost-effective treatment plan, individualized for the patient's needs and goals of care.

### Can wound care be defined as a specialty?

The answer to whether wound care requires specialized training is evident in the practice itself. The physician providing care for a patient with a chronic wound is often confronted with an extensive medical history and comorbid conditions that contribute to the devitalization of the skin and underlying supporting structures.<sup>86</sup> Many patients with non-healing wounds have uncontrolled diabetes, cardiovascular disease, peripheral vascular disease, obesity, tobacco abuse, lymphedema, and mobilization obstacles.

These patients require meticulous attention to detail and close follow-up throughout the course of treatment.

The physician must possess excellent motivational and teaching skills to facilitate patient lifestyle changes and educate patients on their disease state, dressing techniques, and other forms of self-therapy. A comprehensive understanding of pharmacology and drug interactions is required, as most patients with chronic wounds are taking multiple medications that can impact the healing process. Age, functionality, independence (or lack thereof), and associated disease states can affect the goals and outcomes of wound healing and must be factored into the treatment plan.<sup>87</sup>

Also needed are skills in communication, negotiation, and change management in order to coordinate a multidisciplinary team of specialists focused on a unified objective. The physician must possess knowledge and understanding of surgical concepts and treatment outcomes in plastic, orthopedic, vascular, and general surgery in order to make appropriate, timely referrals. The physician must also command knowledge of dermatology, rheumatology, endocrinology, and general medicine to integrate the management of chronic disease states into a focused wound care therapy. Regardless of the physician's primary training background, he or she must draw on knowledge and skills from both the surgical and medical fields.

Communication with patients and family is paramount. An awareness of the social, psychological, spiritual, or existential concerns that are often involved with the possibility of limb loss and/or loss of independence and functionality is required to approach the wound patient in a holistic way. Many times, a patient has already received conflicting therapeutic recommendations from other healthcare professionals, leading to frustration that can easily be misdirected toward the wound physician. Given the broad base of knowledge and skills required, coupled with a paucity of clinical experience obtained from other medical disciplines, **the practice of wound management is as challenging, demanding, and complex as that of any other field in medicine**.<sup>87</sup>

The fact that many different types of clinicians have and will be involved in wound care does not eliminate the need for each group to achieve formal training and certification within their professional organization. Collaboration and negotiation will be required to achieve these goals. The general knowledge of wound healing physiology, factors that impact healing, general medical conditions, pharmacology, and treatment options could be taught in an interdisciplinary manner. Many universities are already adopting this type of educational experience. Ultimately, however, licensing and credentialing must be achieved through the specific organizational bodies that granted the individuals degree and scope of practice. A parallel pathway is also needed for currently practicing providers of all types to achieve certification while still maintaining their practice.<sup>86</sup> Again, there are many precedents in medical education that have allowed for practice-based pathways to proceed while formal programs are developed.

#### III. History of Wound Care

Methods of wound care date to the horizon of recorded human history. The oldest known written records, from over 4000 years ago, describe techniques familiar to modern caregivers, such as cleansing wounds, making plasters, and bandaging wounds.<sup>88,57</sup> The ancient Egyptians closed uncomplicated wounds with sutures; diseased wounds were managed open with debridement and antibacterial and anti-inflammatory therapies, such as powdered metals (mercury, zinc, silver, copper), vinegar, and honey. Bandages were made from linen soaked in grease, honey, oil, and lint, suggesting that these early caregivers recognized the principle of moist-wound healing.<sup>57</sup>

The science of wound care remained empirical, however, and some of these techniques, now recognized in modern wound care, were lost over time. Hippocrates, for example, promoted dry wound therapy and favored the development of pus, which came to be known as "laudable pus," a concept that persisted into the 19<sup>th</sup> century.<sup>57</sup> Wound debridement was abandoned until the 16<sup>th</sup> century. Silver nitrate for wound management was invented around this time, and recorded observations supported the efficacy of maggots for suppurating wounds. The scientific revolutions of the 19<sup>th</sup> century included initial efforts at skin grafting and even the culture of cells for wound grafts. Lister introduced the concepts of antisepsis/asepsis to surgical practice, reducing the incidence of wound infection.<sup>57</sup>

But the explosion in wound care research ignited in the 20<sup>th</sup> century. Initial discoveries included antibiotics and antiseptic dressings, followed by the reintroduction of moist wound healing techniques, medicinal honey, and even maggots.<sup>57</sup> In the last 40 years, numerous advanced techniques and products have been developed. These advances include hydrocolloids, film and foam dressings, successive generations of occlusive and semiocclusive dressings, alginates, growth factors, tissue engineering, negative-pressure wound therapy, hyperbaric oxygen therapy, and wound bed preparation techniques (Table 3).<sup>57,52,84</sup>

Category	Examples			
Dressing and topical therapies	Film dressings			
	Foam dressings			
	Acrylics			
	Alginates			
	Hydrocolloids			
	Hydrofibers			
	Oxidized regenerated cellulose			
	Micronized collagen			
Growth factors	Platelet-derived growth factor			
	Platelet-rich plasma			
Acellular dermal matrix	Xenograft dermis			
	Xenograft acellular matrices			
	Human dermis			
	Human pericardium			
	Placental tissues			
	Amniotic membrane allograft			
Tissue engineering	Bilayered skin equivalent			
	Culture-derived human skin equivalent			
	Human fibroblast-derived dermal			
	substitute			
Oxygen and pressure therapies	Negative-pressure wound therapy			
	Hyperbaric oxygen therapy			
Surgical techniques	Wound bed preparation			
Biophysical	Electrical stimulation			
	Diathermy			
	Pulsed electromagnetic fields			
	Low-frequency noncontact ultrasound			
	Extracorporeal shock wave therapy			
Stem cell therapies	Autogenous			
	Allogenic			

Table 3. Advanced wound care products and techniques.<sup>57,52,84</sup>

Historically, wound care was led by nursing. As dressings advanced and moist wound healing became state of the art, it was nurses, mostly wound ostomy continence nurses, who provided leadership, research, and primary care for these patients.<sup>86</sup> In time, each discipline made its own contributions. Physical therapists, for example, introduced the use of energy-based modalities such as ultrasound, electrical stimulation, and ultraviolet light; gait and exercise protocols; and offloading techniques, compression therapy, and manual lymphedema treatments.<sup>86</sup> Following the introduction of growth factor therapy, biological skin equivalents, negative pressure wound therapy, and systemic therapeutic options for wound healing patients, physicians began to enter the field. The growth of hospital-based outpatient wound centers attracted yet more physicians to the field.

The majority of new wound care products were categorized as medical devices. Manufacturers were unsure who the end user of their device would be, leading to fragmented sales and marketing campaigns. Wound care clinics were led by various healthcare providers, exacerbating patient confusion. Ultimately, insurance companies and Medicare began to question the number, frequency, and overall efficacy of many clinic-based procedures. Numerous wound care societies were created, each claiming to represent the field. Multiple groups created "certifying examinations" that would allow the clinician who successfully completed the process to be considered a wound care expert.<sup>86</sup>

Altogether, there are more than 5000 wound-care products available in the marketplace.<sup>88</sup> Most of these wound care products and technologies lack substantive evidence of efficacy from well-designed, randomized clinical trials.

As the field of wound care continues to mature, there is a critical need for rigorous training, research, evidence development, and advocacy to improve outcomes of patients with non-healing wounds.

### **IV. Current Physician Education in Wound Care**

The current status of physician education in wound care is extremely poor. Medical students in the US and other developed countries devote only a few hours to required wound-related education. Although some residency programs include wound-care education (eg, surgery, geriatrics), **many physicians will not receive any further education on wound care** during residency – or throughout their career. When a wound care center opens in a hospital, members of the existing medical staff are invited to participate, but often receive less than 1 week of didactic training before joining the center.<sup>86</sup> While this training is an improvement over current wound-care education, it is considerably less rigorous than participating in a formal residency and fellowship-based medical education.

The lack of wound-related education during medical school is worrying. In a retrospective study of wound education at 50 US medical schools, Patel et al. found that only a few hours were spent on wound-related topics across all 4 years of school.<sup>89</sup> The investigators used the American Association of Medical Colleges database, which collects information regarding medical curricula and accounts for all hours devoted to didactics, laboratory training, and clinical work. Their analysis found that fewer than 10 hours were devoted to education across all wound-related topics and all 4 years of school (Table 4). Similar findings were reported in a study of medical schools in Europe; mean total hours of required wound education at medical schools were 9 and 4.9 in Germany and the UK, respectively.<sup>15</sup>

Wound-related topic	Mean hours on wound education		ation	
	Year 1	Year 2	Year 3	Year 4
Physiology of tissue injury	0.5	0.2	0	0
Physiology of wound healing	2.1	1.9	0.3	0.1
Clinical wound care	0.4	2.1	1.2	0.4
Totals	3.0	4.2	1.5	0.5

Table 4. Hours of required education on wound-related topics at US medical schools.<sup>89</sup>

A more recent study distributed surveys to 134 US medical schools; of the 55 schools that responded, only 7 offered a formal wound healing elective.<sup>90</sup> At an additional 13 schools, wound care was taught as part of another clerkship (vascular, plastic, general, or burn surgery).

As noted, some residency programs include wound care education. For example, Accreditation Council for Graduate Medical Education (ACGME) requirements include education on pressure ulcer treatment and prevention during graduate education in geriatrics.<sup>87</sup> In practice, most postgraduate trainees are exposed to patients with nonhealing wounds. However, studies of practicing physicians and nurses have found that variations in provider knowledge of wound care do not correlate with years of experience, suggesting that gaps in care may best be addressed through formal education, rather than traditional "on-the-job" learning.<sup>33,91</sup>

Challenges in wound care education include a dearth of publications on education in wound care, guidelines based on limited evidence, the need for hands-on training with experts, and the wide diversity of wound-care products and supporting research by manufacturers.<sup>92-96,64,29</sup> There are few publications in the core medical journals and textbooks on the associated pathophysiology, clinical work-up, and appropriate therapy for managing these patients. Few physicians focus their practices in wound care as a full-time career, and currently there is little incentive to do so.<sup>87</sup>

### The path forward: Specialized education

The path to specialization will center on formal fellowship training at the graduate medical education level of accredited university centers. It should also address the needs of those physicians currently practicing in the field who could benefit from the didactic content but cannot take a year off to pursue formal training. Education for patients must be considered. Patient-centered outcomes are now frequently included in guideline development, and the voice of the patient must be incorporated throughout the education, research, and advocacy processes.<sup>86,97</sup> This broad effort to improve wound care begins with accredited educational programs and should be led by physicians who are board certified as wound care specialists.

### V. How Wound Care Fits: A Brief History of Medical Specialization

Beginning in the early 20<sup>th</sup> century, rapid advances in medical research and clinical practice drove a rise in medical specialization. Whereas previously physicians had practiced primarily as generalists, the expanding depth and breadth of medical knowledge and practice required some physicians to focus on specific areas of practice. Specialty societies grew to support these new areas of medical practice. In time, these societies sought to ensure that physicians practicing in these fields were qualified. In 1917, ophthalmology became the first medical specialty to create its own assessment board, with a goal of developing standards by which to recognize physicians who had the required knowledge and skills to practice competently in eye care.<sup>98,99</sup> Other disciplines followed.

Specialization in medicine grew rapidly following WWI and again after WWII. In 1933, the American Board of Medical Specialties (ABMS) was formed, which grew from 4 to 10 specialties within 2 years, and was followed by the American Board of Internal Medicine (ABIM) in 1936.<sup>98,99</sup> By the 1970s, there were 20 recognized specialties. Specialty boards now certify more than 120 specialties and subspecialties for MDs and DOs.

Proposals for new subspecialties have derived from specialty societies, often with the support of patient groups. Many subspecialties represent further specialization of larger subspecialties, such as cardiology. Others are multidisciplinary (eg, sleep medicine, geriatric medicine) and allow different pathways to certification from other boards.<sup>98</sup> As a multidisciplinary specialty, wound care fellowship programs accept applicants from a range of medical and surgical residency backgrounds.

### Benefits and risks of specialization

The beneficiaries of board certification of new specialties include practitioners, who wish to support their professional image; patients, who seek ways to select appropriate and qualified providers; and hospitals and health systems, who wish to ensure that physicians have the knowledge and competency required for practice in the field.<sup>98,100</sup> Board certification is also often cited by healthcare organizations to demonstrate the capabilities of their providers and give patients confidence in the care they will receive. Indeed, certification by specialty boards is increasingly important as an indicator of physician competency in the era of healthcare quality. Finally, board certification is required for medical privileges at many hospitals and for participation in some payer networks.<sup>99</sup>

Specialty certification also has legal implications. In malpractice suits, plaintiff attorneys frequently claim that a physician who is not certified is therefore not competent and should not have treated the plaintiff. Going forward, physicians without board certifications and the organizations they work for may be increasingly vulnerable to allegations of malpractice.<sup>99</sup>

Initially, board certification of specialty practice was hailed as a positive way for the profession to control potential dangers of specialization, such as unqualified practitioners claiming to be specialists.<sup>98</sup> Cited benefits of specialty boards extended beyond certification to education and elevation of clinical standards (Table 5).

Table 5. Potential benefits of medical specialty boards.<sup>99</sup>

- Elevation of standards of clinical practice in specialties
- Education of the public and other professionals about the capabilities of specialists
- Protection of the public from unqualified practitioners
- Establishment of requirements for education and training in specialty medicine
- Development of educational resources for the preparation of specialists
- Provision of oversight of examination processes tied to the granting of specialty certification

However, other leaders expressed concern that increased specialization would exacerbate the growing fragmentation and costs of medical care.<sup>101,98</sup> Increasing fragmentation of medicine may confuse patients and present barriers to access and continuity of care. Therefore, the creation of new specialties must be justified by a resulting benefit to patients and the healthcare system. Of note, **the specialty of wound care can act to integrate rather than fragment care**, as a wound care specialist coordinates the contributions of disparate disciplines, thereby ensuring continuity of care, rather than representing a distinct referral pathway for patients and clinicians to navigate on their own.

Confusing the issue further, multiple organizations may offer their own versions of a "certificate," although the criteria and rigor used to determine who receives a certificate may be poorly understood by patients and even clinicians. The proliferation of certifications for subspecialties includes a variety of unclear terms, such as general certification, initial certification, primary certification, special certification, certificates of added qualifications, certificates of special qualifications, etc.<sup>99</sup> Some organizations offering specialty certification have been short-lived and self-serving, whereas others have achieved broad recognition for excellence. To guide the selection of new specialties, rigorous criteria have been published (Table 6).<sup>102</sup>

Table 6. Criteria for recognition as subspecialty certification in internal medicine.<sup>102</sup>

- The discipline must have a unique body of knowledge that cannot be fully incorporated into the "parent" discipline.
- The discipline must have clinical applicability to be practiced in a form that is distinct from the "parent" discipline.
- The discipline must contribute to the scholarly generation of new information and must advance research in the field.
- There must be an important social need for the discipline and evidence that practice of the discipline improves patient care.
- To become competent in the discipline requires supervision and direct observation provided in formal training settings in order to achieve competence in the scope of practice.
- The minimum training period for demonstration of competence needed for certification is 12 months.
- Commonly, the discipline will involve complex technology or specific site-ofcare opportunities for learning that are best provided in the training setting.
- The positive value of certification in the new discipline must outweigh any negative impact on the practice of general internal medicine or an existing subspecialty or on the basic education in the core competencies of internal medicine.

## Professional push back

The creation of some subspecialties has been resisted by organizations and practicing physicians. One common concern is the "loss" of the patient to a new subspecialty. For example, the movement to create vascular medicine programs was countered by vascular surgeons, interventionists, and cardiologists, each of whom felt that they would cede practice territory and patients to the nascent subspecialists. Despite the involvement of these many specialists, no one was really "in charge" of the patient with peripheral vascular disease, and most clinicians merely treated its end-stage manifestations. Each group formulated their own guidelines and training programs. Today, the Vascular Medicine Society continues to offer fellowship programs and board certification, but they have not achieved status in the ABMS.<sup>86</sup>

It is worth noting that a wound care specialist should not encounter these challenges, as they would provide episodic care – that is, care specifically for the chronic wound – by bringing together necessary disciplines and techniques to provide evidence-based management. Once the wound is healed or an effective management strategy has been determined, the patient returns to whichever service oversaw their care before involving the wound care specialist.

Other new specialties have avoided political conflicts and achieved both ACGME and ABMS certification. For example, the American Academy of Hospice and Palliative Medicine has regulatory, payment, and policy status as a formal field of medicine.<sup>103,86</sup> Other fields have similarly gained status through achieving a certificate of added qualification through multiple potential entry points. For example, pain management certification can come through anesthesiology, physical medicine and rehabilitation, and neurology/psychiatry.<sup>86</sup>

### VI. Prior Attempts to Organize

In an effort to fill the void of a formal specialty in wound care, many organizations have been created with the intention of providing didactic knowledge, a sense of community, and examinations to determine qualifications. These groups have tended to be multidisciplinary, which mirrors the clinical practice in the field. Once the groups venture into examinations and credentialing, however, it becomes very difficult to maintain the integrity of each individual's scope of practice and licensure.

## Association for the Advancement of Wound Care (AAWC)

The Association for the Advancement of Wound Care (AAWC) is a multidisciplinary organization dedicated to the research and clinical application of evidence-based wound care. The AAWC was conceived in 1995. The Association's focus is on education, public policy, and the application of evidence-based wound care practice. The organization was founded as an offshoot of an already established large annual wound conference that was primarily attended by nursing. Over the years the organization grew and now has over 2,000 members. The meeting is as strong as ever and the organization continues to provide providers with much needed didactic knowledge, journals and, through collaboration with other organizations, provides examination preparatory courses.

## The American Board of Wound Medicine and Surgery (ABWMS)

The American Board of Wound Medicine and Surgery (ABWMS) is an independent, nonprofit evaluative organization. The Board of Directors is comprised of physicians who have distinguished themselves in research, education and patient care. The Board is responsible for determining the qualification criteria for examinees as well as the development and administration of the examination itself. The Board confers certification upon physicians based upon standards of excellence that lead to optimal patient care. The ABWMS certification provides assurance to the public healthcare consumers that a physician has successfully completed appropriate training, has accumulated the necessary experience in patient care, and has fulfilled the examination and continuing evaluative requirements established by the board.

In order to sit for the examination, candidates must meet the following eligibility requirements by the application deadline:

- 1. Be a currently licensed physician in the United States or Canada
- 2. Be certified or board eligible by a relevant primary board (ABMS, American Osteopathic Association [AOA], or equivalent)
- Have three years of experience in active practice of wound care documented by institutional Medical Director, Chief of Staff, or Chief Clinical Officer.
  OR
- 4. Be enrolled in or completed an ABMS or AOA approved training program and have completed a dedicated one-year wound medicine and surgery fellowship as documented by the fellowship director.
- 5. Complete and file an Application for the Certification Examination for Physicians in Wound Medicine and Surgery.

6. Pay the required fee.

### **ABWMS Fellowships**

The ABWMS is presently engaged in an aggressive effort to secure recognition by the ABMS and the AOA for the physicians it certifies. While the number of physicians - both MDs and DOs - certified by the Board continues to grow, the ABWMS is actively engaged in the development of fellowships in hospitals across the country by and with the help of its Diplomats. The existence and the number of fellowships is an absolute essential requirement for the recognition the ABWMS seeks

The ABWMS has developed a full curriculum for fellowship education and training. The Board wishes to encourage new fellowships in wound medicine and surgery that are consistent with its curriculum which, in turn, is consistent with the domains in which the ABWMS tests physicians.

The ABWMS currently provides a certification examination to MD or DO who hold board certification or eligibility in one of the boards recognized by the ABMS. The ABWMS appears to have the most rigorous qualifications to be eligible for wound care certification.<sup>104</sup>

## VII. American College of Wound Healing and Tissue Repair

The American College of Wound Healing and Tissue Repair (ACWHTR) is a 501(c)(3) nonprofit organization based in Chicago, Illinois committed to advancing the field of

wound care through education, research, and advocacy. The College fosters the training of medical professionals through the sharing of a physician-based, clinical fellowship curriculum developed in conjunction with the University of Illinois Hospital and Health Sciences System and allied healthcare colleges and programs. The ultimate goal of the organization is to designate wound care as a board-certified medical specialty. The mission of the College is to improve public health by leading the growth of a new integrated field of medicine and



surgery dedicated to the practice of modern wound healing and tissue repair. For patients with wounds, regardless of etiology or duration, the College seeks to ensure access to the appropriate evidence-based care and treatment to optimize their outcomes across all clinical sites of care.

The College was started by a group of key opinion leaders in wound healing from clinical, research, and industry settings. This group first met in December 2009 to discuss the creation of a wound care specialty and included William J. Ennis, DO, MBA; William Li, MD, The Angiogenesis Foundation; Dale Lupu, PhD, American Association Hospice and Palliative Medicine; Robert Kirsner, MD, PhD, University of Miami; Jeff Davidson, PhD, Vanderbilt University; Vickie Driver, DPM, MS, Boston University; Kelman Cohen, MD, Co-Founder Wound Healing Society; and William Marston, MD, University of North Carolina.

The group agreed that a specialty was needed, and several overall guiding principles emerged:

- The organization should serve as the credible physician voice for wound healing and tissue repair.
- The primary objective of the organization is to create a medical subspecialty in wound healing and tissue repair through creating fellowship programs, examinations, and certification processes.
- The college will use the guidelines as listed by the ABMS and ACGME to maximize acceptance and credibility.
- Through achieving this goal, the college will also
  - 1) generate awareness of the problem of non-healing wounds and help foster research and advance the development of new technologies;
  - 2) promote access to effective and appropriate therapies for all patients; and
  - $\circ$  3) assist in the development of health policy as it relates to the field.

These goals and objectives will be reached through the creation of an annual meeting, membership for physicians, educational offerings, journals, involvement in health policy

development, and the creation of multiple university-based wound care fellowship programs. The creation of the American College of Wound Healing and Tissue Repair in the United States is one step toward formalizing a physician wound care curriculum.

## **Board of Directors**

The College's Board of Directors includes leading wound experts from multiple fields

William J. Ennis, DO, MBA, MMM, CPE



After graduating, Phi Beta Kappa from the State University of New York at Stony Brook Dr. Ennis earned his medical degree from the New York College of Osteopathic Medicine. He has completed residencies and is board certified in General Surgery, Vascular Surgery as well as Family Medicine with a Certificate of added qualification in Undersea and Hyperbaric Medicine. He subsequently received an MBA from the Keller Graduate School of Management in Chicago and a Masters in Medical Management from the University of Southern California (USC). Dr. Ennis has been practicing wound care for 25 years and is currently the Catherine and Francis Burzik Professor of Wound Healing and Tissue Repair and Chief of the Section of Wound Healing Tissue Repair at the University of Illinois at Chicago (UIC). He is also founder and director of the first Wound Healing and Tissue Repair Fellowship in the United States, also at UIC. In addition, Dr. Ennis is a founding board member and President of the American College of Wound Healing and Tissue Repair, a 501(c)(3) non-profit educational organization that has a mission of bringing wound care to the level of a formal medical specialty. Dr. Ennis has published over 100 articles, abstracts and book chapters and has lectured through-out the world on wound care and vascular diseases.

Current research interests include microcirculation, healing outcomes, health economics, and regenerative tissue mechanisms. His outside interests include guitar, jazz music, basketball, triathlon racing, and reading. Dr. Ennis is married with 2 children.

#### Michael K. Lester



Mike Lester is an accomplished healthcare executive whose professional experience includes 35 years in the multi-site healthcare services and pharmaceutical life sciences fields. As the chief executive officer of multiple companies, he successfully capitalized, assembled top-tier management teams and implemented strategic and tactical business plans creating long-term value for employees, customers and shareholders. Prior to founding LifeStance Health, a behavioral health company, Mr. Lester was the founder and CEO of Accelecare Wound Centers, a comprehensive wound care and disease management company. Prior to that, Mr. Lester was a Venture Partner at Bain Capital and SV Life Sciences; founder and CEO of Radiant Research, a comprehensive clinical research company providing Phase I-IV study conduct and drug development services to the biopharmaceutical industry; founder and CEO of ContinueCare Health Systems, a high-tech home and alternate site infusion therapy company; and founder and CEO of Preferred Hospital Pharmacies, a successful pharmacy management company.

Mr. Lester was formerly a board member and President of the Texas State Board of Pharmacy. He serves on The University of Texas College of Pharmacy Pharmaceutical Foundation Advisory Council and is a member of the board of directors of LifeStance Health, Inc., Ventec Life Systems, Inc. and is a senior advisor to Silversmith Capital Partners. He holds a Bachelor of Science in Pharmacy from the University of Texas.

### Catherine (Cathy) Burzik



Catherine (Cathy) Burzik is a seasoned senior executive in the healthcare industry. Cathy has successfully led major medical device, diagnostic, diagnostic imaging and life sciences businesses. Cathy was most recently a general partner at Targeted

Technologies, an early stage venture capital firm focused on medical device, life sciences and biotech investments. Cathy is a member of the Board of Directors of Becton-Dickinson and Company (NYSE: BDX) and the Board of Directors of Haemonetics (NASDAQ: HAE). Cathy is the Chairman of the Board of Directors of the American College of Wound Healing and Tissue Repair. Cathy was formerly the President, Chief Executive Officer and Director of Kinetic Concepts, Inc. (NYSE: KCI), a leading medical device company specializing in the fields of wound care and regenerative medicine. She has extensive public and not-for-profit Board experience. Cathy has held executive leadership positions at Johnson & Johnson, Applied Biosystems, Inc. and Eastman Kodak Company. Cathy and her husband, Frank, are avid competitive ballroom dancers. They are both from Western New York and currently reside in San Antonio and New York City.





Geoffrey C. Gurtner is the Johnson and Johnson Professor of Surgery and Biomedical Engineering (by courtesy) at Stanford University. Clinically, Dr. Gurtner is the Director of the Stanford Wound Center and the Stanford Program in Applied Regenerative Medicine (SARM). He is the author of over 280 peer-reviewed publications and is an Editor for two major textbooks in the field: Grabb & Smith's Plastic Surgery and Plastic Surgery. Dr. Gurtner was awarded the James Barrett Brown Award in both 2009 and 2010 and has been named "researcher of the year" by the ASPS, AAPS, and numerous other professional organizations.

Dr. Gurtner runs an NIH and DoD funded laboratory examining how physical stimuli (mechanical and chemical) alter the human response to injury. This has led to the development of new technologies for which Dr. Gurtner has received 20 issued patents and 60 patent applications. Dr. Gurtner has founded several venture-backed start-up companies, including Neodyne Biosciences (www.neodynebio.com) and Arresto Biosciences, acquired by Gilead (NASDAQ:GILD) in 2011.

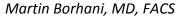
### Tom O'Donnell, MD, FACS



Thomas F. O'Donnell Jr. M.D. is the Senior Vascular Surgeon at Tufts Medical Center and the Benjamin Andrews Emeritus Professor and Chair of Surgery at Tufts University School of Medicine (TUSM). A graduate of Harvard College, where he concentrated in the Classics, he is a 1967 Cum Laude graduate of TUSM. At TUSM he was elected to AOA and served as class president and president of the student council. While serving as Chairman of the Department of Surgery at Tufts Medical Center and TUSM, he was asked by the trustees of Tufts Medical Center to serve as the CEO and President of that institution, a position he held for nearly a decade through 2004. He then returned to the full-time practice of vascular surgery and clinical research. Dr. O'Donnell completed his residency on the Harvard 5th Surgical Service at Boston City Hospital, which was interrupted by two years of service with the US Navy (1969-1971) and assigned to the US Marine Corps. His self-initiated research on heat-stress injuries among young Marines recruits at Parris Island during training exercises was published in the New England Journal of Medicine and JAMA and led to changes in the way Marine recruits were trained. For this work he received the U.S. Navy Surgeon General's Certificate of Merit.

His current particular areas of research have been chronic venous insufficiency and lymphedema, which were stimulated by his year of postgraduate work at St. Thomas's Hospital in London during 1974-1975 with Professors John Kinmonth and Sir Norman Browse. As Chief of the Division of Vascular Surgery and Director of the Vascular Fellowship from 1983-1993 at Tufts Medical Center, he has trained a long list of vascular fellows, many of whom hold leadership positions in academic surgery. This June he will complete his 41st year on the faculty of TUSM, where he has taught generations of medical students and has served on various medical school committees as well as the Board of Overseers of TUSM and the Sackler School from 2003-2007.

Over the last decade he has authored a number of systematic reviews and metaanalyses with his colleagues at Tufts Center for Evidence-Based Research, Joseph Lau and Ethan Balk, which also included three AHRQ Technology Assessments for CMS. He presented one of these systematic reviews, "Usual care in the management of chronic wounds: A review of the recent literature," at the April 2005 Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting on wound care. He recently co-edited The Clinical practice guidelines of the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF): Management of venous leg ulcers. The majority of his 182 articles in peer-reviewed journals, 67 Book chapters, and 15 videos/ films on techniques deal with vascular disease. He is a regular lecturer for the educational programs at national and regional vascular society meetings and named lectureships. He served as a clinical coordinator for a series of stem cell trials for patients with non-reconstructible vascular disease and advanced ischemia. Last July he was one of the presenters at the MEDCAC panel on lower extremity chronic venous disease. With a 40+ year interest in wounds, particularly venous ulcers, he has been a staff member of the Tufts Center for Wound Healing for over a decade. O'Donnell has served as the President of the Society for Vascular Surgery, the American Venous Forum, the New England Society for Vascular Surgery, the Eastern Vascular Society, and the Boston Surgical Society. He currently is on the editorial boards of: The Journal of Vascular Surgery, Phlebology and WOUNDS.





As of January 2007, Martin Borhani, MD joined the University of Illinois Faculty as Associate Professor of Clinical Surgery and Chief, Division of Vascular Surgery. He completed his General Surgery residency at UIC in 1999, after which he completed his Vascular Surgical Fellowship training at Washington University School of Medicine in St. Louis, MO. Dr. Borhani is board certified in General Surgery and Vascular Surgery and has extensive experience in all aspects of vascular and endovascular interventions.

Dr. Borhani has developed a beneficial and multidisciplinary relationship with the Division of Interventional Radiology, Division of Plastic Surgery and manages the Noninvasive Vascular Laboratory at the University of Illinois Medical Center at Chicago. Dr. Borhani has successfully expanded the Division of Vascular Surgery to now include the Section of Wound Healing and Tissue Repair led by William J. Ennis, DO. Dr. Ennis is renowned for his work in clinical wound care and has extensive research experience ranging from basic science research to multicenter clinical trials. This partnership provides comprehensive management of acute and chronic wounds.

In December 2010, Dr. Borhani became the recipient of the Theodore and Joanna Drugas Endowed Chair in Vascular Surgery at the University of Illinois Medical Center at Chicago. This Endowed Chair was established thanks to the generosity of Theodore and Joanna Drugas. Dr. Borhani is involved in the diagnosis, evaluation and management of all types of arterial, venous and lymphatic disease exclusive of that affecting the heart and intracranial vessels. His main goal is to continue to provide state of the art treatment in order to give all patients with vascular disease, the highest quality of life possible. Dr. Borhani maintains privileges at 4 hospitals in the Chicago Metropolitan area, creating available, accessible care for patients at multiple sites.

William W. Li, MD



William W. Li is Chief Executive Officer, President, and Medical Director of the Angiogenesis Foundation, a nonprofit organization he co-founded in 1994 to reconceptualize health and fighting disease through angiogenesis, the process used by the body to grow and maintain blood vessels. Over two decades, Dr. Li's leadership in the field of angiogenesis and its clinical translation has brought to the world 30 paradigmshifting treatments for wound healing, oncology, and ophthalmology. His vision, expertise, and global multidisciplinary networks are focused on conquering disease, and improving quality of life and the human condition through innovations in technologies and lifestyle.

Dr. Li's work engages the National Institutes of Health, Capitol Hill, the Vatican, World Economic Forum, Fortune 100 companies, and leading universities and medical institutions across North and South America, Europe, Australia, and Asia. Dr. Li's work has impacted more than 50 million people worldwide, and he is a TED Conference speaker.

Dr. Li received his undergraduate degree with honors from Harvard College, his medical degree from the University of Pittsburgh School of Medicine, and his clinical training in Internal Medicine at the Massachusetts General Hospital, a teaching hospital of Harvard Medical School. He has authored over 100 peer-reviewed scientific and clinical articles, book chapters, and abstracts, including publications in leading journals such as Science, Lancet, New England Journal of Medicine, and Nature Reviews. Dr. Li has held faculty appointments at Harvard Medical School, Tufts University, and Dartmouth Medical School. He holds an appointment as a member of the Medical Coverage and Analysis Committee of the Centers of Medicare and Medicaid Services. Dr. Li serves on the board of directors of the Angiogenesis Foundation, the American College of Wound Healing and Tissue Repair, and Wound Reach Foundation, as well as public and private companies focused on health and life sciences innovation.

### Medical fellowship program

The University of Illinois Hospital and Health Sciences System became the first academic sponsor for the fellowship concept and created a section of Wound Healing and Tissue Repair within the division of Vascular Surgery in January 2008. The fellowship is available for residents who have completed residency programs and are board-eligible in Internal Medicine, Family Medicine, or General Surgery.

Fellows rotate through various clinical services during 12 months of training and function as an integral member of the wound care team. During these rotations, fellows are given the opportunity to manage a large number of patients with a variety of wound care related problems. On these specialty rotations, the fellow gains critical insight into the role that each member of a multidisciplinary team brings to the program. Hands-on experience is gained in the operating room, clinical wards, and outpatient clinical settings.

In addition to this specialty experience, there are continuity of care clinics that the wound care fellow runs as the primary physician in charge. This real-world practice setting allows the fellow to gain experience in the work up, case management, and follow-up care that is required when running a hospital-based wound program. The program is funded through research grants, and the Graduate Medical Education department of the University of Illinois Hospital and Health Sciences System provides logistical support as well as benefits. The program is working with specialty colleges in order to apply for formal certification.

Dr. William Ennis was appointed as Chief of the Section. The first fellow was accepted in July 2008. Malgorzata Plummer, MD, completed the program on August 1, 2009, and is now an Assistant Professor of Clinical Surgery at the University of Illinois Hospital and Health Sciences System. A second fellow, Igor Altman, DO, MBA, graduated and is also now on faculty at the University of Illinois Hospital and Health Sciences System as an Assistant Professor of Clinical Surgery. A total of 7 fellows have now completed the program and are employed as wound care specialists.

The program allows the fellow to participate in the care of patients with non-healing wounds of any etiology, anatomical location, or site of care across the continuum of care. Hospital-based wound clinics, inpatient rounding and consultation, research, and sub-acute wound care are all included in the educational program for the wound care fellow.

Core content of the wound care fellowship at UIC. Rotations are either 2 or 4 weeks in duration, and the program total is 12 months. The curriculum is divided into core required rotations and a series of elective options. The goal of the program is to create well trained general wound care providers that would be comfortable running wound care programs at most hospitals. There are those applicants that want advanced training

and plan to practice in tertiary or University settings and the ACWHTR is now reviewing the potential to expand the program to 2 years for those interested candidates.

The College fosters the training of medical professionals through the sharing of a physician-based, clinical fellowship curriculum developed in conjunction with the University of Illinois Hospital and Health Sciences System and allied healthcare colleges and programs. The ultimate goal of the organization is to designate wound care as a board-certified medical specialty.

# VIII. ACGME Accreditation for Wound Care Fellowship The need for specialization

The creation of new subspecialties should be based on evidence that specific patient populations will benefit from the depth of knowledge and specific skills that are obtained through the specialized training and certification. Evidence from studies of wound care centers strongly supports the benefits of coordinated, multidisciplinary care for patients with chronic wounds and indicate that a broad and expanding patient population will benefit from specialized wound-care training for physicians.

The need for specialty training in wound care is driven by an expanding understanding of the mechanisms of healing (and a corresponding increase in wound care products based on this science) and the growing clinical need for practitioners who can coordinate the multidisciplinary care of patients with chronic wounds.

The discipline of wound care has made great strides, with growth in basic and clinical sciences. Over the last 30 years, wound healing has evolved from the use of simple gauze bandages to proteomics and gene analysis of wound tissue to inform therapeutic pathways. The advanced diagnostic and therapeutic modalities now available often require specialized knowledge to ensure appropriate utilization and application. Current formal medical education on wound care is inadequate to achieve this task. Indeed, the old paradigm for wound care training is outdated and outpaced by the substantial increases in technology and therapeutic options available and in development.<sup>86</sup>

Numerous factors support the need for a formal wound care specialty (Table 7). First, there will be continuous growth in the number of patients with non-healing wounds, driven by increasing prevalence of diabetes, an aging population, and an epidemic of obesity. These complex, multimorbid patients require coordinated and continuous management. Second, the current level of wound care provided by many non-specialized clinicians is inadequate, as evidenced by high rates of morbidity and mortality and limited use of guidelines and evidence-based practices. Third are the aforementioned rapid developments in wound science, therapies, and clinical practice. Fourth is the poor state of wound education, which remains a patchwork of review courses, certification exams, wound societies, and on-the-job training.<sup>86</sup>

In addition, wound care clinicians are becoming more involved in acute wounds, inpatient wound care, patient safety issues, and formulary development for hospitals. Although traditionally a nursing field, wound care now includes clinicians from all aspects of the healthcare delivery system. As in other medical fields, the physician involved in wound care will seek certification in order to validate his or her specialized expertise.<sup>105</sup> All of these factors support the need to establish a formal wound care specialty.

Table 7. Factors supporting the need to establish a wound care specialty.

- > Large and expanding patient population with chronic wounds
- Gaps in current wound care:
  - o Limited incorporation of guidelines and evidence
  - o Inadequate use of recommended therapies
  - o High rates of morbidity and mortality
  - o High cost of care
  - High rates of pain, disability, functional deficits, and reduced quality of life
- Rapidly advancing science and clinical practice, including advanced wound care imaging and therapeutic technologies
- Inadequate level of formal medical education on wound care
- Expanding involvement of wound care clinicians in acute wound care, inpatient wound care, patient safety, and formulary development

## Current status of wound care fellowships

Since 2008, additional fellowship programs have been created at 5 centers (Table 8). More than a dozen fellows have already enrolled in these fellowships, and several have graduated.

Center	Fellows
University of Illinois, Chicago	7
Stanford University	3
Innova Health	1
Wake Forest University	2 applicants
Cleveland Clinic	1 APN

#### Table 8. Established wound care fellowship programs.

## Planned growth in wound care fellowships and next steps

The ACWHTR plans to continue to encourage Universities to participate in the wound care fellowship program and will be sharing the content, policies and procedures and any required documentation needed to minimize barriers to entry. One of the main reasons listed by potential university partners is the lack of funding to pay for the wound care fellow's salary. The ACWHTR is actively seeking all sources of funding to help establish a central fund that could be accessed by programs in need of financial support.

As the number of programs increases it will become necessary to create a fellowship review process and begin implementing program evaluations. The college is also beginning the process of creating an examination that would be used across all of the programs. The long-term goal however is to achieve ACGME accreditation and ABMS approval so that the college can focus its attention on promoting the field of wound care, providing educational offerings for members, enhancing the wound community through a robust and innovative annual meeting, and through the creation of its own professional journal.

#### **IX. Summary**

Managing chronic wounds is a daunting medical and surgical challenge. Appropriate management requires skills and knowledge from diverse disciplines and an understanding of complex pathophysiologies. In the absence of wound care expertise, chronic wounds last longer, cost more, and cause more deaths. Studies of dedicated wound care centers and evidence-based wound care protocols demonstrate the impact of coordinated, expert guidance: shorter healing times, reduced costs, and a faster return to productivity.

Currently, opportunities for wound care education during medical training are limited. A wound care subspecialty, fed by accredited fellowship programs, is required to address the large and growing population of patients with chronic wounds. These fellowships offer the opportunity to improve the evidence-based and standardized management of chronic wounds through rigorous formal education in wound clinics and the general hospital population. Graduates of a wound care fellowship will further contribute by engaging in high-quality research, developing evidence-based protocols for wound care, educating their peers and patients on wound management, and coordinating diverse clinical skills, knowledge, and devices to foster healing and return patients to their lives.

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January 29, 2018

William J. Ennis DO, MBA, MMM, CPE President, American College Wound Healing and Tissue Repair Catherine and Francis Burzik Professor of Wound Healing and Tissue Repair, University of Illinois at Chicago Chief Medical Officer Healogics

Dear Dr Ennis;

At the meeting of the Board of Directors of the Wound Healing Society on January 24 we discussed your proposal for a Wound Care Fellowship. The consensus was that Wound Care has become a Specialty with specific and unique requirements. The number of Wound Care Practitioners in the US alone are many thousand and basic, translational and clinical wound healing researcher's amount to about one thousand of them. It was also noted that difficult to heal chronic wounds are increasing by approximately 6% every year driven by the increase in Type 2 Diabetes and the aging population. It was concluded that the wound care specialty needs a fellowship like the one Dr. Ennis is applying for.

Our Board also found your proposal excellent and addressing all pertinent aspects of a one-year Wound Care Fellowship.

Following the discussion there was a unanimous vote to endorse your fellowship application.

Sincerely,

Esg Enle

*Elof Eriksson, MD, PhD* President, Wound Healing Society