

A wide-angle photograph of a city skyline, likely Nashville, Tennessee, viewed from a high vantage point. The foreground is dominated by a dense, lush green forest. In the middle ground, several tall buildings of the city skyline are visible against a hazy, overcast sky with some light clouds.

INVESTING IN ENTREPRENEURS THAT IMPROVE
HEALTHCARE

Investment Area of Interest:
Wound Care

February 2020

Executive Summary

Wound care is an attractive space for investors for several reasons, including the strong potential for innovation, the increasing prevalence and severity of chronic wounds, and the lack of a clearly dominant treatment in the market, not to mention the market's estimated 5.6% compounded annual growth rate between 2019 and 2025ⁱ.

Despite some estimates showing wound care accounts for over \$50 billion dollars of annual expenditure (over 10 times the annual budget of the World Health Organization), it is an area often overlooked by healthcare professionals and investors alikeⁱⁱ. This is surprising considering wound care is an increasingly expensive and serious health care problem due to demographic and epidemiologic factors such as population aging and the increase of comorbid diseases.

One reason wound care has been largely ignored by investors is because it is misunderstood. The space is often perceived as consisting primarily of topical wound bed products when a lot of the real potential lies within novel systemic wound treatments, services, and digital health. There may be opportunity for entrepreneurs and investors to generate significant value by applying more comprehensive expertise and novel solutions in a market where innovation by the incumbents has lagged the rest of the healthcare space.

Market Overview

Conservative estimates of chronic wound prevalence are around 2% of the general population in the United Statesⁱⁱⁱ. This suggests about 6.7 million Americans suffer from chronic wounds annually, comparable to the population suffering from heart failure or about the size of the entire population of Indiana. The estimated annual expenditure on wound care products is between \$5 and \$20 billion, while wound care services account for \$20 - \$60 billion^{iv}.

The graph below shows conservative estimates of past and projected growth in the global wound care market through 2022. Current cost estimates range from \$20 billion to \$50 billion per year.

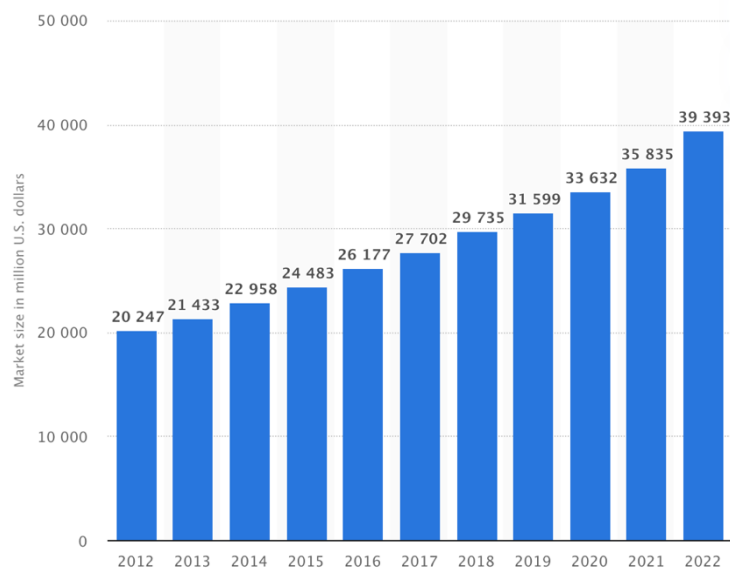


Figure 1. Total Global Wound Care Market from 2012 to 2022 (in US millions) (2018)

On a case-by-case basis, the most expensive wounds are arterial ulcers and pressure ulcers. In terms of setting, costs are primarily driven by hospital outpatient services. Hospital outpatient wound care resulted in expenditure between \$9.9 and \$35.8 billion, followed by inpatient care (\$5.0 to \$24.3 billion)^v. Surgical wounds and diabetic foot ulcers are the most prevalent wound types and drive the largest percentage of costs overall^{vi}. Surgical wounds account for between \$11.7 and \$38.3 billion while diabetic foot ulcers account for between \$6.2 and \$18.7 billion^{vii}. Not only do chronic wounds result in large amounts of healthcare expenditure, they also lead to huge productivity losses. Venous ulcers alone result in a productivity loss of 4.6 million workdays, affecting between 600,000 and 1.5 million Americans annually^{viii}. Other wound related injuries such as burns, endured by about 500,000 individuals Americans each year, result in hospitalizations costing more than double the cost of an average hospital stay^{ix}. There are many ways in which wound care places a serious burden on the United States and global health care systems, and this burden could be drastically reduced through innovation in both wound care products and services.

Wound Type	Prevalence (in US - 2010)	Estimated Annual Expenditure (in US - 2010)
All Chronic Wounds	6.5 million	\$25 billion
Venous Ulcers	600 thousand	\$2.5 - \$3.5 billion
Diabetic Foot Ulcers	2.3 – 3.45 million	\$9 - \$13 billion
Pressure Ulcers	2.5 million	\$11 billion

Data from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/#R63>

Patient Population and Demographics

More individuals suffer from chronic wounds than from lung cancer, breast cancer, colon cancer, and leukemia combined^x. The majority of patients suffering from wounds are frail individuals with severe chronic diseases like diabetes and cancer. Wounds do not typically manifest as a dangerous condition if the individual has no other pathological factors such as an underlying disease.

An increasing geriatric population leads to an increase in chronic wounds primarily because elderly patients are significantly more likely to be bedridden or suffering from impaired mobility, both huge risk factors for pressure ulcers. More than two thirds of patients hospitalized for pressure ulcers are 65 or older^{xi}. Currently, around 2.5 million individuals develop pressure ulcers annually and these can be fatal if not treated properly^{xii}. About 3.5% of the elderly population in the United States suffers from lower extremity ulcers with readmission rates up to 70%^{xiii}, and as the elderly population surges towards over 55 million (estimate for 2020), wounds will become an increasingly larger burden on the health care system. Data suggests a pressure ulcer will develop in 15% of elderly patients during their first week of hospitalization, but the incidence rate of pressure ulcers varies both within and between care settings. Incidence rates range from 0.4% to 38% in hospitals, 2.2% to 23.9% in skilled nursing facilities, and 0% to 17% home health agencies^{xiv}.

Diabetes poses an immense threat in the United States and globally. Projections show one third of Americans born in 2000 will develop diabetes in their lifetime^{xv}. Diabetic foot ulcers are a major complication associated with diabetes and the incidence of ulcers throughout a diabetic's lifetime is between 19% and 34%^{xvi}. Over 50% of diabetic ulcers become infected, with 20% leading to an amputation and 40% recurring within one year^{xvii}. Because individuals requiring wound care tend to be part of the vulnerable population, Medicare and Medicaid suffer heavily from the financial burden of chronic wounds, especially those related to diabetes. In 2016, one third of the population on Medicare had diabetes^{xviii}. In 2010, 28% of Medicare beneficiaries were obese, and this is projected to increase to 47% by 2030^{xix}. The extensive procedures involved in treating diabetic and bariatric related ulcers create an immense burden for individuals, insurance carriers, and the medical system at large.

Basic Scientific Description

A chronic wound is defined as a wound not responding to normal medical treatment within 30 days^{xx}. There are many causes including trauma, diabetes, cancer, and a variety of severe diseases resulting in an increased bacterial load or excessive proteases. Chronic wounds are most commonly seen in bariatric or elderly individuals.

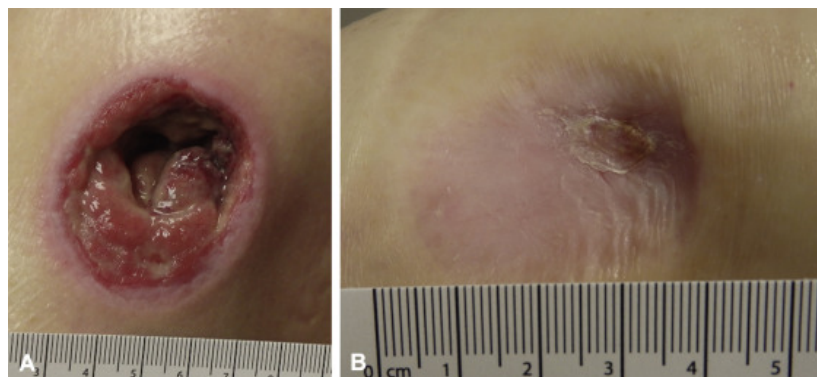
There are three main etiological categories of chronic wounds: venous ulcers, diabetic ulcers, and pressure ulcers^{xxi}. Venous ulcers are caused by dysfunctional blood circulation resulting from obstructed blood valves or veins. Risk factors include old age, obesity, previous leg injuries, deep venous thrombosis and phlebitis. Venous ulcers tend to be shallow and located in bony areas. They are both recurrent and persistent and can last for many months or years. Venous ulcers are best treated with elevation and traditional dressings adjunct to the standard of care: compression therapy. Successful healing rates range from 30% to 60% after about 6 months of proper treatment and 70 to 85% after a full year^{xxii}. Compression therapy is also effective for preventing recurrence after an ulcer has healed.



Diabetic foot ulcers are typically triggered by a simple bruise or scratch which goes unnoticed and untreated by a diabetic individual with hindered sensitivity due to nerve damage. These wounds affect individuals with diabetes who have peripheral neuropathy, lower extremity arterial disease, or both. Diabetic foot ulcers are most common under the big toes and on the balls of feet and the initial symptoms include drainage, swelling, irritation, redness, and odors^{xxiii}. During the initial diagnosis, diabetic foot ulcers are assessed for ischemia using ankle-brachial index and toe pressure measurements^{xxiv}. The provider may recommend an X-ray to determine if the ulcer was initiated by bone movement or loss of mass caused by hormonal imbalances resulting from the patient's diabetes. Diabetic foot ulcers are extremely prone to infection and the risk of infection is evaluated based on redness, swelling, and warmth. The treatment of diabetic foot ulcers has three main components: removing damaged tissue or foreign bodies, providing the patient with crutches or a wheelchair so they can reduce the pressure put on the foot, and infection control using antibiotics. In some cases, hyperbaric oxygen therapy is used as well. It is done using a chamber to expose the wound to 100% oxygen and heightened pressure and is intended to increase the delivery of oxygen to help fight infection; however, it has not yet been proven clinically effective^{xxv}. Using the standard treatment, diabetic foot ulcers typically heal within 12 weeks, but will recur in about one third of patients (typically those who do not adhere to the specialized footwear protocol recommended by their doctor)^{xxvi}.



Pressure ulcers are caused by the disturbed blood flow resulting from excess pressure on tissue from immobility. Commonly called bedsores, pressure ulcers typically develop on the heels, ankles, hips, tailbone, and other bony areas of the body which may be exposed to prolonged pressure. The major risk factor for pressure ulcers is any medical condition resulting in immobility; however, friction, shear, incontinence, loss of sensation, and poor nutrition and hydration can also play a role in the development of bedsores. The amount of time it takes to develop varies widely - it can be as long as a few days or as short as a few hours. The treatment protocol for a pressure ulcer depends entirely on the stage of the wound. Early stage sores are treated using mild soap and water, saline or antibiotic creams and simple dressings. Later stage treatments may require tissue removal, pain drugs, or even surgery. If discovered early, a pressure ulcer can heal in just a few days, but later stage ulcers can take anywhere from 3 months to a few years to heal^{xxvii}.



While the majority of wound care is centered around these types of chronic wounds, wound care is also extremely pertinent to military, trauma, and sports medicine settings. Outside of the three main types of ulcers, many other types of wounds may require serious intervention including: surgical wounds, blunt trauma wounds, and burns. These are typically local instead of systemic, meaning the wound presents danger due to the depth and susceptibility to dirt and bacteria as opposed to a problem with the body's natural healing process.

The four normal healing stages are consistent to any type of wound. In order to prevent a chronic wound from developing there are many intricate interplays within the sequence of events below. This sequence must be followed to completion for a wound to be considered fully repaired; however, a wounded area will only ever recover about 70% of its initial tensile strength^{xxviii}.

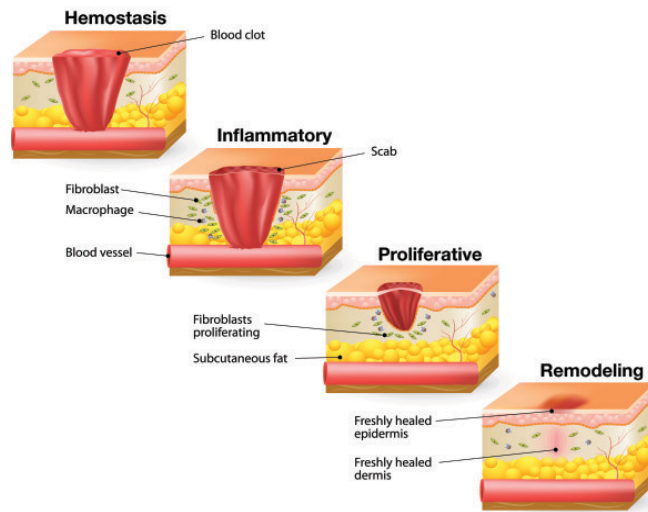



Figure 2. The Four Main Stages of Wound Healing (2015)

An important component of the healing process is the oxygen supply to and tension in the wound bed. Non-healing wounds typically have only one quarter of the tension necessary for the immune system to combat infection. Recent research also demonstrates certain nutrients such as protein, vitamins A and C, and zinc are essential to healing^{xxix}. Additionally, maintaining a moist environment around the wound bed is critical to expediting the wound healing process.

Mapping out the Industry - Products

There is currently a broad range of treatments to aid the wound healing process, whose effectiveness in a given situation is often debated. The most commonly used and longstanding treatment option is the use of dressings to protect the wound bed from the outside environment and promote the healing process. Current dressing options include:

Type	Description	Image
Gauze	Most suitable for minor injuries such as cuts; suitable for any area of the body	

<p>Films</p>	<p>Help medical professionals identify potential problems and monitor healing; often used for surgical incisions</p>	
<p>Hydrocolloids</p>	<p>Self-adhesive non-breathable dressings that create moist conditions and are impermeable to bacteria</p>	
<p>Hydrogels</p>	<p>Commonly used for burns, intended to help reduce pain and speed up the healing process</p>	
<p>Foams</p>	<p>Useful for varying degrees of severity; allow water vapor to enter to facilitate moist environment</p>	
<p>Alginates</p>	<p>Effective for absorbing liquid; require frequent and consistent changing</p>	
<p>Hydrofibers</p>	<p>Absorbent material that transforms into a cohesive gel upon contact with wound fluid</p>	
<p>Tissue Engineered skin substitutes</p>	<p>Stimulates healing by providing cells, soluble mediators, and materials needed for the extracellular matrix^{xxx}</p>	

Although wound care has traditionally relied on dressings, recently some other therapeutic approaches options have emerged, including:

Type	Description	Image
<p>Compression stockings/bandages</p>	<p>Pressure aids improvement in circulation</p>	
<p>Hyperbaric oxygen therapy</p>	<p>Individual enters a chamber and breathes oxygen under high pressure – improves blood supply</p>	
<p>Ultrasound and electromagnetic therapy</p>	<p>Sound waves or electromagnets are applied to the wound – heats tissue and may reduce pain</p>	
<p>Vacuum-assisted closure therapy (negative pressure wound therapy)</p>	<p>Device containing a pump that sucks fluid out of the wound, improving blood flow</p>	
<p>Skin grafts</p>	<p>Used when a wound is unable to heal on its own – requires skin from another part of the body</p>	

Large Players in the Product Industry:



Ethicon is the leading player in wound care products, with almost a quarter of the total market share. Their products are more expensive than their competitors'; however, they use their diversified range of products and bundling to their advantage to incentivize customers and secure hospital contracts.



Acelity plays a huge role in the negative pressure wound therapy and advance dressing sectors of the market, and therefore currently holds the second largest share of the overall market.



Medtronic holds a large portion of the wound closure market, but recently decreased their share of the overall market by selling their patient recovery business to Cardinal Health.^{xxxi} The business was sold along with their Deep Vein Thrombosis and Nutritional Insufficiency business for a total of \$6.1 billion. Medtronic aims to refocus on other high growth areas and claims they are using the proceeds to improve their balance sheet by paying down debt.



Cardinal Health holds a large share of the advanced wound care market and saw an increase in their overall market share with the acquisition of Medtronic's wound care product business, which included many well-known and commonly used brands. Cardinal Health expects to see huge benefits from this transaction, and anticipates over \$150 million in synergies by 2020^{xxxi}.

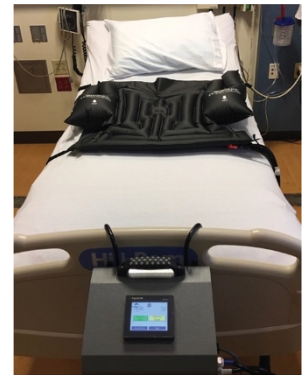
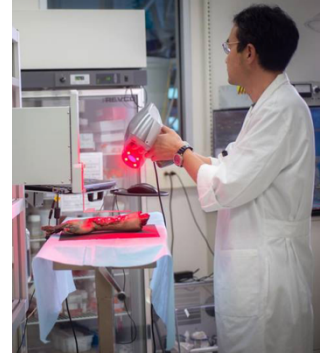


Medline has used competitive pricing strategically to position themselves as the fifth largest player in the wound care market. Historically, they have focused on traditional wound care products, but recently they have delved into the advanced wound dressing market as well.

Innovation Spotlight:

While these large companies temporarily dominate the wound care product market, there are others hard at work looking to transform wound care from a different angle. One example of a unique approach to wound healing is the use of a handheld 3D printer. Researchers at the University of Toronto and the University of Minnesota are in the process of developing a device with the ability to print cells or sheets of skin directly onto a patient's skin. The estimated cost of this device is only \$400¹. Another unique approach, developed by Sanuwave, is based on the shockwave technology. This type of treatment has met high safety standards and has been used for over 30 years for orthopedic applications and for the destruction of kidney stones¹. Sanuwave's device, dermaPACE, has been approved by the FDA for use on diabetic foot ulcers and also CE marked for advanced wound care.

Other companies focus on products indirectly related to wound care. For example, TurnCare prevents sacral-region vascular compression and provides immobile patients with the benefits of healthy movement and in turn reduces the likelihood of pressure ulcers. Another example of a tangential product was developed by a professor in Queensland. He created a diversion therapy product called Ditto, which distracts pediatric burn patients for long enough to change their bandages. It is clear that the potential for wound care product innovation extends far beyond the historically used dressings and bandages.



Mapping out the Industry - Services

Hospital Outpatient Wound Centers are the most common treatment setting, accounting for about 40% of chronic wound treatment. There are over 1,000 wound centers in the United States, some run directly by a hospital and others which contract with a wound management company^{xxxiii}. The wound center treatment approach is comprehensive, and the clinical staff

collaborates with the patient's caregivers and primary care physicians throughout the entire process. Physician offices, ambulatory surgery centers and home health also account for a large percentage of specialized wound treatment, about 35%. Around 20% of wounds are treated in an inpatient hospital setting and the remaining 5% are treated in Long Term Care Facilities^{xxxiv}.

The wound care service industry is not only inclusive of the physical centers where wounds are treated, but also important components such as revenue cycle management, consulting, clinical training, marketing, and mobile health. Historically, there have been a few large companies, like Healogics, which have covered every aspect of wound care management; however, there are now more wound care management options for healthcare facilities in the US than ever before. This is leading hospitals to abandon the one-stop-shop kind of wound care management companies they have traditionally used. For example, Healogics, which used to control almost half of the outpatient wound care centers nationally, recently lost a significant amount of their contracts due to cost-cutting and perhaps as a consequence of lawsuits surrounding false claims for improper billing^{xxxv}. Healogics was born out of Diversified Clinical Services, which was founded in 2006. The business model of Healogics (and many of the other wound care management companies) was historically centered around offering the full array of wound care services from revenue cycle management to training and consulting; however, smaller players are beginning to disrupt this strategy by offering each of these services individually. This new strategy is desirable for the wound care centers, because while the full array is valuable initially for planning, budgeting, training, and more, these services are not as necessary once the center is established.

However, it is unclear whether this strategy will be effective for a few reasons. First, Healogics has comprehensive data on every aspect of wound care. Second, health centers with involved management companies like Healogics tend to have better outcomes and higher patient volumes than their competitors. Large companies like Healogics have also established enormous market share; almost half of all patients treated in an outpatient hospital-affiliated wound center receive treatment in a Healogics facility^{xxxvi}. Perhaps, in the coming years Healogics will begin adapting their model to make it more flexible. Clearly, the wound care

services industry is being shaken up and there is great potential for new players and radical changes.

Large Players in the Services Industry:



Healogics is the national leader in wound care management. They offer a comprehensive solution for the entire continuum of care. Healogics has about \$300 million in annual revenue and nearly 350 employees^{xxxvii}. Healogics was acquired by Clayton, Dubilier & Rice for \$910 million.



Restorix also plays a big role in wound care management in addition to developing and managing centers of excellence specifically for hyperbaric medicine and amputation prevention. RestorixHealth has about \$27.1 million in annual revenue and 200 employees^{xxxviii}. RestorixHealth was acquired by Leonard Green and Partners in 2015 for an undisclosed amount.



WoundTech uses telehealth to reduce the cost and time spent caring for wounds. WoundTech partners with Managed Service Organizations, Independent Practice Associations, and large medical groups. They generate about \$44 million in annual revenue and have about 350 employees^{xxxix}.



Wound Care Advantage's primary services are managing wound care programs for hospitals and consulting for hospitals on their wound care needs. They operate under a more a la carte model and aid hospitals in new program development in addition to providing tools for hospitals wanting to manage their own wound care services. Wound care advantage has about \$25 million in annual revenue and 70 employees^{xl}.



AMT focuses on the long-term care setting for a variety of indications. Nationwide, they are the leading independent provider for wound care solutions in this setting. They help these facilities manage costs, increase education, properly document for reimbursement, and improve the quality of resident care. AMT has 183 employees and \$431.2 million in total revenue^{xli}.

Innovation Spotlight:

Beyond innovation improving the typical services required for wound care, there is ample opportunity for improvement in digital health and telemedicine. One company doing just that is Tissue Analytics. While in graduate school, the founders noticed how archaic the method of measuring improvement was in wound care – it is simply done using a ruler – and they decided it was time for this to change¹. The company released their first version of the app in 2014 and released an updated version with 3D imaging in 2018. Their technology enables them to measure the wound with submillimeter precision using nothing more than a short video taken with the app¹.



Use of Ancient Methods

Recently, there have been controversial studies on the efficacy of silver, a longstanding and popular wound treatment. Silver was initially used because of its anti-microbial properties; however, concern over bacterial resistance has prompted additional investigation into which species and delivery methods are the most safe and efficacious. The studies revealed resistance will not develop as long as silver is released in an adequate concentration; however, this does not mean this is a straightforward treatment or problem to solve as it is very difficult to maintain the sufficient concentration level in a dressing over time. Currently, the most effective treatment uses nanocrystalline silver, which is in several Acticoat dressings developed by Smith & Nephew^{xlii}. While nanocrystalline seems to be the best option so far, there is still room for improved innovation to deliver silver to wounds in the appropriate concentration over time.

Similarly, iodine and antibiotic ointments have historically been go-to options for wound treatment, yet their levels of safety and efficacy have recently been re-examined^{xliii}. Povidone iodine, the most popular formulation, has recently been called into question due to fears centered around allergy, ineffective penetration, and toxicity^{xliv}. Unfortunately, these treatments remain popular amongst practitioners due to the lack of a clearly superior alternative.

Barriers to Effective Clinical Trials

Performing a clinical trial in wound care is difficult for a variety of reasons. The inherent nature of the wound plays a key role in these difficulties - it is nearly impossible to do blind studies due to the nature of the wound itself and the treatment options, which do not lend themselves easily to a placebo. The obstacles differ significantly depending on whether the treatment is for acute or chronic wounds. The prevalence of acute wounds is difficult to determine at any given time and varies considerably by season and geographic location. The issue with chronic wound trials is the age of the patients; they are often elderly, and there is a barrier to their participation in the trial due to immobility and commuting costs^{xiv}.

For these reasons and many more, clinical trials centered around wound care treatments are rarely randomized control trials and are typically funded by organizations solely as a means of proving their product is better than another. This provides the incentive to exclude patients who suffer from the most persistent wounds and/or comorbid conditions. The data is also vetted to exclude patients who need palliative care or amputations, resulting in overly optimistic study results which do not reflect real life outcomes.

The Social Disadvantage

Another unique issue faced by the wound care space is the lack of recognition and awareness. Even though more individuals suffer from chronic wounds than from lung cancer, breast cancer, colon cancer, and leukemia combined, wound care is largely neglected as a serious and global health problem^{xvi}. Although recently listed by NIH, wounds have not typically been established as a condition for funding, despite many less prevalent diseases having their own category^{xlvii}.

The lack of recognition of chronic wounds as a serious problem persists even more outside of the medical community. While there have been huge strides towards increasing awareness for health issues like breast cancer and mental illness, chronic wounds have not quite made the front page. The lack of attention to the cause is likely due to the populations primarily affected: vulnerable, elderly, and low-income; therefore, many individuals and families suffering from these conditions do not have the means to promote support for the cause. Additionally, the

more graphic nature of wounds may lead to the absence of discussion, as people are often uncomfortable or repulsed by the subject. Perhaps stigma and lack of awareness also play a role in patient's neglect of their own wounds.

Neglect of the Services Sector

Wound care services and wound care products are interdependent, with the improvement in either promoting improvement in the other. However, the majority of investments have historically been made in wound care products despite the highly correlated growth of the two sectors. More centers and services fuels the demand for product, so the disproportionate investment on the product side may be inefficient in growing the industry as a whole.

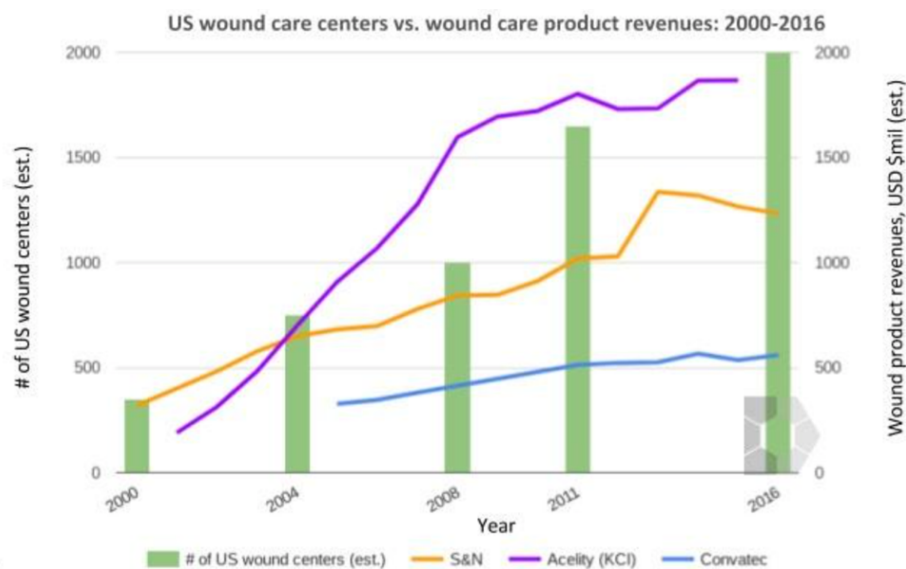


Figure 2. Wound Care Product Revenues (2017)

With innovations in the wound care services space lagging the rest of the healthcare industry, there could be opportunity for investment on the services side focused on areas such as digital health, data analytics, infrastructure, and delivery.

Telehealth has particularly large potential to disrupt the way wound care is treated due to the common immobility of patients, lack of trained professionals, visual nature of the medical condition, variety of care settings, and lack of coordination between multiple sites of care^{xlviii}. Telehealth could reduce hassle and costs for patients in most desperate need, by eliminating the amount of travel required, especially for follow up appointments. Medicare, Medicaid and

some of the United Health Care and Humana plans already cover telehealth services for wound care and other carriers are starting to follow suit. However, it's important to also consider the barriers to telemedicine utilization in wound care including the complex reimbursement rules surrounding telemedicine, credential verification problems, inability to detect odor, and upfront costs for equipment. Nevertheless, if a company is able to navigate these difficulties, there could be enormous gains to be made from a wound care telehealth business.

Facilities like Joslin Diabetes Center and The University of Louisville Hospital's Burn Center are already using telehealth for follow-up appointments to monitor patients while reducing travel time and cost. AccentCare, a provider of post-acute home healthcare services in almost 190 locations, did a three-month pilot to determine efficacy of telemedicine for home health wound care. During this pilot, home health aides used the Synzi application to communicate with remote on-demand wound care specialists. AccentCare found significant cost savings and improved access, and they plan to roll out the program to more of their facilities^{xlix}. Currently, the majority of telehealth for wound care is on the provider side and must be adopted by the practices or health systems they work under; however, there is the potential for direct to consumer apps to disrupt the space. It is likely that in the coming years patients will be enabled and empowered to monitor their wounds themselves through the use of new apps and other technologies.

Market Potential

The wound care space is attractive for investment for several reasons. First, the demand for wound care is almost certain to continue increasing in the near future as the population ages. Additionally, there are several types of wounds requiring advanced treatment and many different causes resulting in these wounds. Therefore, even if one of the conditions acting as a risk factor for wounds becomes drastically less prevalent in the coming years, the demand for wound care will not cease to exist due to the plethora of other conditions predisposing patients to chronic wounds. In fact, 20% of chronic wounds are atypical, meaning they are caused by inflammation, infection, malignancy, chronic disease, or genetic disorders and do not fall within the typical chronic wound categories^l. Additionally, as many of the wounds requiring treatment are chronic, each patient requires large quantities of product and care. Estimates show the number of wounds requiring treatment increases by 15 percent each year^{li}.

Alongside the increasing prevalence of diabetes and the aging population, recent increases in drug injection have been connected to a rise in venous disease, leading to a heightened prevalence of venous ulcers. One study showed individuals who inject are about 35 times more likely to develop venous ulcers than individuals who have never injected^{lii}. The rise in heart disease and renal failure also play a role in the increasing prevalence of chronic wounds. These conditions are just a few of the many conditions causing advanced wounds and becoming increasingly prevalent, thus pointing at the desperate need for effective treatment.

Reimbursement

From a reimbursement perspective, wound care is attractive because it is supported by multiple revenue streams. Medicare is the most common source of funding for wound care, but private payer insurance is commonly used as well. Some patients also opt to purchase wound care product on their own if their insurance does not fully cover their needs or they prefer to have more. Private payers tend to closely mirror the guidelines set by Medicare^{liii}. Medicare estimates it spent between \$28.1 billion and \$96.8 billion for acute and chronic wounds in 2018^{liv}.

In the early 2000s, all wound care providers were placed on a prospective payment system. The system depended on the type of facility and differed between long-term acute care hospitals, skilled nursing facilities, and other wound care facilities. This resulted in a lack of communication between providers and problems such as wasteful duplicate testing. The reimbursement strategy for wound care changed in 2017 when the Quality Payment Program was put in place to shift physician incentives. This program, which rewards or penalizes physicians based on quality, advancing care information, clinical practice improvement activities, and total cost of care, fundamentally changed the way in which wound care patients are treated. It promotes the use of better information sharing via electronic health records, do-it-yourself debridement procedures, vascular procedures early on in the treatment plan, and leads doctors to select dressings based on patient needs instead of their insurance^{lv}.

Some Medicare Advantage plans, like CareMore, have been working towards proactive and preventative treatment of wounds. CareMore leverages the talent of nurse practitioners, who

treat diabetic wounds in place of primary care physicians. These nurse practitioners see the patients every day to ensure the wounds are healing properly and to change the wound dressings. They also treat their diabetic wound patients with a comprehensive approach by inquiring about their diet and potential stressors and educating them on wound care treatment and prevention. Their efforts have resulted in needing to reimburse only one third of the diabetic amputations resulting from gangrenous infections as compared with the typical Medicare fee-for-service program^{vi}.

On January 1, 2020, home health reimbursement shifted to the patient-driven groupings model. The primary objective of this model is to shift from volume focused billing to more quality-based reimbursement. The patient-driven groupings model (or PDGM) uses six clinical groupings which are based upon the cause of initial treatment. Wound care is one of the most frequent clinical groupings and accounts for the highest utilization of home health resources. The average reimbursement for wound care is slightly over \$2,000^{vii}. The reimbursement amount varies depending on the setting from which the patient came; patients who came from an institutional setting often get up to over \$500 more in reimbursement. Because wound care has one of the highest reimbursements under PDGM, there may be increased interest in providing wound care services among providers. Both product and services companies will need to adapt their strategies to fit increased and modified supply and demand for wound care.

Continued Growth

The wound care space is likely to become increasingly attractive as demographic and epidemiological trends propel the need for wound care products and services. Continued innovation should enable not only improvements in typical wound care products, but also services, digital health, and tangential markets. The anticipated growth in the wound care industry extends far beyond the United States.



Figure 3. Global Wound Care Market Projections (2019)

In fact, Asia Pacific has the highest rates of projected growth between 2019 and 2024. This is due to a variety of factors such as increases in healthcare expenditure and number of surgeries and a large patient population^{viii}. Wound care is a problem affecting nearly every country. For example, the United Kingdom spends 4% of the annual National Health Service budget on pressure ulcers alone^{ix}. Although Asia Pacific is expected to take the lead overall, advanced wound care plays the most prominent role in the growing market and is dominated by North America. The recent growth of the advanced wound care market is primarily driven by the moist wound dressing segment and is propelled by the increasing incidence of diabetic, venous, and pressure ulcers^{ix}. In terms of services, hospitals and clinics are expected to continue to hold the largest share, driven by increasing hospitalization for chronic wounds, longer hospital stays for diabetic patients, and heightening incidence of hospital-induced pressure ulcers. Overall, the wound care industry anticipates rapid growth in the coming years.

Companies to Watch:

Telehealth



Tissue Analytics is a wound care monitoring platform that enables accurate analysis of a wound based on simple images. These images can be taken on a smartphone and are assessed automatically.



Eliminates need for tracing and provides actionable insights on the healing process and percent of tissue in the wound bed.



Facilitates easy and accurate wound assessment, is integrated with all major EMRs and improves workflow using FHIR.



\$7.7M raised since founding in 2014
Series A raised in January 2018



Baltimore, MD
<https://www.tissue-analytics.com>

SWIFT

Swift Medical streamlines clinical and administrative wound care workflows from image capture and automatic risk scoring to assessment scheduling and claims submission.



The Swift Medical app improves efficiency throughout the entire wound healing process, from point of care to administration and analysis.



Swift Medical also offers measurement storage capabilities through a cloud backend and complete workflow management for nurses.



\$13.3 million raised since founding in 2015
Series A raised in March 2018



Toronto, Ontario
<https://swiftmedical.com/>

Healthy.io

Healthy.io turns the smartphone into a diagnostic device for several different medical conditions including chronic kidney disease, urinary tract infections, prenatal care and wounds.



Their wound care focused technology is based around calibration methods that enable measurement and documentation of a wound.



Their service results in increased consistency and empowers evidence-based care decisions.



\$90 million raise since founding in 2013
Series C of \$60 million raised in September 2019



Tel Aviv, Israel
<https://healthy.io/>



My Wound Doctor offers telehealth applications and services that lower the cost of wound care through mobile imaging and expert advice.



MyWoundDoctor offers mobile triage and consult applications, which support both providers and payers.



MyWoundDoctor is licensed in over 42 states and can support patients in a range of treatment settings such as hospitals, the ER, urgent care, prisons, and more.



Bootstrapped to date



Nashville, TN
<https://www.mywounddoctor.com>



Platform enabling live video consults and simple image sharing to help monitor a wound's progress and suggest treatments that promote healing.



Providers have the ability to select a comprehensive wound care management program, or a la carte options to support their current program.



Selected as 1 of 34 "companies to watch" in Venture Atlanta showcase.



\$2.6 million raised since founding in 2015



Savannah, Georgia
<https://corstrata.com>

SYNZI™

Synzi's virtual care communication platform connects home health aides with registered nurses and specialists and provides family members with the ability to virtually meet the aides prior to their first visit and to participate in virtual appointments.



Synzi enables providers to easily access their colleagues and can increase referrals by 40%. Their platform can save a health plan \$80,000 in monthly cost savings and \$8,000 for each hospitalization.



They have over 30 customers, and at least two of which (AccessCare and UMC HomeWorks) have mentioned plans to continue rolling out the program in additional facilities.



Unknown fundraising status



St. Petersburg, FL
<https://synzi.com>



WoundWiseIQ
WoundWiseIQ enables providers and patients to capture wound images and automatically calculates the wound area on a mobile device without storing any data.



Data is presented as a display of 8 automatically calculated wound elements along with comparative side-by-side images of the wound over time.



In 2019 WoundWiseIQ won the Long-Term and Post-Acute Care Shark Tank competition.



WoundWiseIQ is a solution developed by Med-Compliance IQ, which has raised \$430K in funding to date.



Columbus, OH
<https://woundwiseiq.com>

Electronic Health Records



Offers software as a service enabling providers to record clinical procedures and document financial results across a variety of different care settings.



Net Health represents the largest independent source of chronic wound benchmarking data in the entire industry.



Net Health's EHR product, WoundExpert, is used by 90% of wound clinics using paperless EHRs.



Net Health acquired Wound Care Strategies (the EHR system) in 2012.



Pittsburgh, PA
<https://www.nethealth.com/products/wound-care/woundexpert-software-wound-care-ehr/>



An EHR that is an intelligent learning system and provides clinicians with real time clinical decision support for podiatry and wound care.



Helps physicians ensure they are reaching higher quality scores, thus receiving higher levels of reimbursement.



Their artificial intelligence has been proven to deliver healing rates that are improved by 10%.



Received debt financing of an unknown amount in March 2018



The Woodlands, TX
<https://www.intellicure.com>



Upperline Health offers preventative care, wound care, telemedicine, and podiatric care via their network of top physicians across the country.



Upperline has partnered with an extensive network of health plans and community providers to deliver comprehensive lower extremity and wound care.



Upperline Health helps lower the number of Americans who will lose limbs to diabetes each year via proper care.



Raised \$30 million in a venture round in 2018, followed by a private equity round from Silversmith Capital.



Nashville, TN
<https://www.upperlinehealth.com/>



Founded in 1996, FCA Venture Partners has a long history of investing in successful healthcare entrepreneurs. We are passionate about building sustainable businesses and providing strategic value to our portfolio companies.

FCA invests \$3 - 6M in fast growing healthcare companies making processes in the industry faster, better, and cheaper while improving the quality of care and the patient experience.

With its location in Nashville, roots with Clayton Associates and the McWhorter Family, and deep involvement in the growth of the U.S. healthcare community, FCA Venture Partners is poised to take advantage of disruptive opportunities that help move healthcare forward

Investing in Entrepreneurs that Improve Healthcare

110 Winners Circle North

Brentwood, TN 37027

615-326-4848 | www.fcavp.com

-
- i <https://www.360marketupdates.com/global-advance-wound-care-market-14591839>
- ii <https://www.woundsresearch.com/article/wound-care-outcomes-and-associated-cost-among-patients-treated-us-outpatient-wound-centers-d>
- iii <https://www.woundsresearch.com/article/wound-care-outcomes-and-associated-cost-among-patients-treated-us-outpatient-wound-centers-d>
- iv <https://seekingalpha.com/article/4235219-investing-in-advanced-wound-care-avoid-3-costly-mistakes>
- v <https://www.sciencedirect.com/science/article/pii/S1098301517303297>
- vi <https://www.apwca.org/news/5310449>
- vii <https://www.sciencedirect.com/science/article/pii/S1098301517303297>
- viii <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3036466/>
- ix https://www.researchamerica.org/sites/default/files/Burns_02_2018.pdf
- x <https://www.mobihealthnews.com/content/digital-wound-care-company-swift-medical-lands-116m>
- xi <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/>
- xii <https://www.liebertpub.com/doi/pdf/10.1089/wound.2019.0946>
- xiii <https://www.pharmacytimes.com/publications/issue/2004/2004-04/2004-04-7840>
- xiv <https://www.ncbi.nlm.nih.gov/books/NBK2650/>
- xv <https://clinical.diabetesjournals.org/content/23/2/51>
- xvi https://www.acponline.org/system/files/documents/about_acp/chapters/mt/2017/the_diabetic_foot_neiba_uer.pdf
- xvii <https://khn.org/news/when-wounds-wont-heal-therapies-spread-to-the-tune-of-5-billion/>
- xviii <https://www.kff.org/medicare/issue-brief/how-much-does-medicare-spend-on-insulin/>
- xix <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2015/06/04/medicares-big-fat-problem-fiscal-and-otherwise/>
- xx <https://aornjournal.onlinelibrary.wiley.com/doi/10.1002/aorn.12118>
- xxi <https://www.woundsource.com/patientcondition/chronic-wounds>
- xxii <https://www.aafp.org/afp/2010/0415/p989.html>
- xxiii <https://www.healthline.com/health/diabetic-foot-pain-and-ulcers-causes-treatments#symptoms-and-diagnosis>
- xxiv <https://www.uptodate.com/contents/management-of-diabetic-foot-ulcers>
- xxv <https://www.fda.gov/consumers/consumer-updates/hyperbaric-oxygen-therapy-dont-be-misled>
- xxvi <https://www.drugs.com/health-guide/foot-ulcers.html>

-
- xxvii <https://www.webmd.com/skin-problems-and-treatments/pressure-sores-4-stages#2-4>
- xxviii <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5350204/>
- xxix <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5350204/>
- xxx <https://www.ncbi.nlm.nih.gov/pubmed/29320588>
- xxxi <http://www.startribune.com/medtronic-selling-medical-products-business-in-6-1-billion-deal/419699743/>
- xxxii <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/>
- xxxiii <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/>
- xxxiv <http://woundcareawareness.com>
- xxxv <https://www.justice.gov/opa/pr/healogics-agrees-pay-2251-million-settle-false-claims-act-liability-improper-billing>
- xxxvi <https://www.linkedin.com/pulse/what-we-can-learn-future-wound-care-from-recent-healogics-mazuz/>
- xxxvii <https://www.owler.com/company/healogics>
- xxxviii <https://www.owler.com/company/restorixhealth>
- xxxix <https://www.owler.com/company/woundtech>
- xl <https://www.owler.com/company/thewca>
- xli https://rocketreach.co/american-medical-technologies-a-d-b-a-of-gordian-medical-inc-profile_b5cc29def42e0a59
- xlii https://www.nursingcenter.com/journalarticle?Article_ID=608156&Journal_ID=54015&Issue_ID=608155
- xliii <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5350204/>
- xliv <https://www.karger.com/Article/FullText/479150>
- xlv <https://www.woundsource.com/blog/why-clinical-trials-wound-care-are-so-difficult>
- xlvi <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/>
- xlviii <https://www.todayswoundclinic.com/articles/how-telemedicine-influencing-wound-care>
- xliv <https://homehealthcarenews.com/2019/06/wound-care-pilot-improves-outcomes-reduces-cost-for-accentcare/>
- i https://issuu.com/ewmapublications/docs/journal_of_the_european_wound_manag
- ii <https://www.sharedhealthservices.com/wound-care-services>
- iii <https://www.o-wm.com/content/clinicians-speak-out-innovations-products-and-practice>
- iiii <https://hme-business.com/articles/2018/02/01/wound-care.aspx>

-
- liv <https://www.liebertpub.com/doi/full/10.1089/wound.2019.0946>
- lv <https://www.o-wm.com/article/wound-care-reimbursement-things-are-changing>
- lvi <https://www.commonwealthfund.org/publications/case-study/2017/mar/caremore-improving-outcomes-and-controlling-health-care-spending>
- lvii <https://homehealthcarenews.com/2019/05/why-home-health-agencies-should-gear-up-for-pdgms-wound-care-opportunity%EF%BB%BF/>
- lviii <https://www.marketsandmarkets.com/Market-Reports/wound-care-market-371.html>
- lix <https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-015-0326-3>
- lx <https://www.marketsandmarkets.com/Market-Reports/advanced-wound-care-market-88705076.html>