

VOLUME I

The Wound Care Trend Report

Supported by Osiris Therapeutics, Inc. and in consultation
with the Association for the Advancement of Wound Care



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Dear Colleague,

On behalf of Osiris Therapeutics Inc., the Association for the Advancement of Wound Care (AAWC), and the National Association of Managed Care Physicians (NAMCP), we present to you the *Wound Care Trend Report, Volume I*, supported by Osiris Therapeutics, Inc. and in consultation with AAWC¹, the premier multidisciplinary professional organization dedicated to advancing the care of people with and at risk for wounds. This Report examines trends in wound care clinical practices and related managed care policies from two key perspectives: those of wound care specialists and managed care executives.

The 40-page Report combines findings from survey research with qualitative analysis for a comprehensive look at the wound care space. Two separate survey instruments were completed by 51 wound care specialists and 40 managed care executives at managed care organizations (MCOs). Where appropriate, survey responses were compared between the two groups.

Survey responses were analyzed by an independent Editorial Advisory Panel of wound care specialists and managed care executives who also provided expert commentary. Topics covered in the Report include: diabetic foot ulcers, cellular and/or tissue-based products (CTPs) or skin substitutes, medical policy, barriers to care, wound care guidelines, performance-based payments, and future trends. The Report reveals areas of common interest and potential collaboration between the two groups including: practice guidelines, educational needs, patient compliance, case management, and clinical research. “The Report serves to illustrate diverse perspectives of what constitutes appropriate wound management that are pervasive throughout the wound care community. It is also helpful in exposing the knowledge gaps among decision-makers when selecting wound care treatment regimens.” – AAWC CEO, Victoria Elliott.

Our organizations value customer relationships and appreciate the critical role all stakeholders play in the delivery of quality health care. It is our hope that this Wound Care Trend Report will improve communication between wound care professionals and MCOs and promote new ways of working together with the shared goal of achieving optimal health outcomes for the patients we serve.

Sincerely,

Louis A. Savant
Director, Market Access
Osiris Therapeutics, Inc.

Victoria E. Elliott, RPh, MBA, CAE
Chief Executive Officer
AAWC

W.C. (Bill) Williams III, MD
Executive Vice President
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¹AAWC physician members were surveyed for this Report and served as the wound care specialist advisory panelists. The AAWC did not have oversight of the Wound Care Trend Report study design or methodology and was not involved in the interpretation of the data.

The Wound Care Report, Volume I, supported by Osiris Therapeutics, Inc. and in consultation with the Association for the Advancement of Wound Care.

Introduction

The *Wound Care Report, Volume I*, supported by Osiris Therapeutics, Inc. and in consultation with the Association for the Advancement of Wound Care examines disease and practice trends in wound care from two perspectives: those of wound care specialists and managed care organizations (MCOs), including managed care medical directors. Two survey instruments were used to collect data. The Report features analysis and insights from an independent Editorial Advisory Panel. Report topics include: diabetic ulcers, cellular and/or tissue-based products (CTPs) or skin substitutes, medical policy, barriers to care, wound care guidelines, performance-based payments, and future trends.

In this Report, the terms “skin substitute,” “CTP,” and “cellular and/or tissue-based products” are used interchangeably to describe products derived from various human, animal, or engineered sources used as advanced therapies in the treatment of chronic and acute wounds:

- “Cellular skin substitutes” or “cellular CTPs” describe products from human or bioengineered sources with viable human cells.
- “Acellular skin substitutes” or “acellular CTPs” describe products from human, animal, or bioengineered sources without cells, or with nonviable or dead cells.

Editorial Advisory Panel on Wound Care

The Editorial Advisory Panel is composed of 8 physicians of whom 6 provided analysis and commentary for the Report, including 3 wound care specialists from AAWC and 3 managed care medical directors.

The wound care specialists are:

Caroline Fife, MD

Professor of Geriatrics
Baylor College of Medicine
Houston, TX
Chief Medical Officer
Intellicure, Inc.
Executive Director
US Wound Registry
The Woodlands, TX

Gary Gibbons, MD

Professor of Surgery
Boston University School of
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Medical Director
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Thomas Serena, MD

Founder and Medical Director
Serena Group
Hingham, MA

The managed care medical directors are:

Larry Hsu, MD

Medical Director
Blue Cross Blue Shield of Hawaii
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Fredrick May, MD

Medical Director
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Murray, UT

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Disease Burden

An estimated 23.1 million people in the United States have been diagnosed with diabetes at an annual cost of \$245 billion.¹

The Centers for Disease Control and Prevention (CDC) projects that the number of US adults with diabetes will rise from 1 in 10 US adults in 2008 to 1 in 3 US adults by 2050 if current trends continue. Fueling this growth are new cases of diabetes, predicted to increase from 8 per 1000 in 2008 to 15 per 1000 in 2050.²

Diabetic foot ulcers (DFUs) are a common complication of diabetes; 25% of diabetic patients will develop an ulcer in their lifetime.^{3,4}

Diabetic ulcers are challenging to treat due to the underlying manifestations of diabetes that can cause microvascular disease, lower extremity neuropathy, increased susceptibility to infection, and impaired cellular function.⁵⁻⁷

Wound healing in persons with diabetes is compromised further because these patients typically have several comorbidities and other risk factors for impaired healing, and compliance with treatment plans is frequently suboptimal. Standard, or first-line, wound care treatments (glucose control, promotion of revascularization, debridement, moist wound healing, and infection surveillance and management) have demonstrated wound closure rates of only about 24% at 12 weeks,⁸ and patients with diabetic ulcers commonly receive wound care treatment for several months. Randomized controlled trials (RCTs) have shown that adding advanced therapies, such as CTPs, as adjuncts to standard wound care in the

treatment of chronic wounds results in higher rates of wound closure compared with standard of care alone.⁹

The cost of treating chronic wounds and associated complications is significant. Nearly 15% of Medicare recipients (8.2 million people) had at least 1 wound or infection. Cost of wound care for Medicare recipients is conservatively estimated at \$32 billion, delivered mostly in outpatient settings.¹⁰

DFUs impose a substantial cost burden on public and private payers ranging from \$9 billion to \$13 billion annually in direct costs.¹¹

Wound-related infections are one of the most common complications of diabetic ulcers and are a significant risk factor leading to hospitalizations and amputations. A prospective study of 1666 diabetes patients showed those who develop an infected foot ulcer were 55.7 times more likely to require hospitalization, and 154.5 times more likely to have an amputation.¹²

Diabetes is a leading cause of non-traumatic lower extremity amputation. Between 14% and 24% of patients with diabetes who develop a DFU require amputation.¹³ The 5-year mortality rate following a lower limb amputation is reported to be almost 50%.^{14,15}

Wound duration is the leading independent risk factor for infection and amputation.¹²

In wounds that do not respond to standard wound care, advanced therapies and treatment strategies that can accelerate wound healing have the potential to prevent amputations, reduce costs, and save lives.

Methodology

The Wound Care Report, Volume I, supported by Osiris Therapeutics, Inc. and in consultation with the Association for the Advancement of Wound Care (AAWC), examines trends in wound care from two perspectives: those of wound care specialists, including physicians, podiatrists, and surgeons, and managed care executives at MCOs, including medical directors and pharmacy directors. The Report combines quantitative analysis using survey research with qualitative analysis and expert commentary.

Two separate survey instruments were used. Letters inviting wound care physicians, who are members of AAWC, and managed care executives to participate in the research were sent by fax and e-mail directing them to a dedicated Web site. An honorarium was offered. A total of 51 wound care specialists and 40 managed care executives completed the respective survey questions.

The two sets of survey responses were analyzed by an independent Editorial Advisory Panel, of which 6 members also provided commentary.

Most survey findings are presented as percentages in the charts and text. For all survey findings, “n” indicates the total number of respondents who answered each question. Percentages for some charts may not total 100% either due to rounding or because questions allow for multiple responses. Other survey findings are average responses using a scale of 1 to 100, where 1=lowest and 100=highest.

Wound Care Specialist Survey

A total of 51 wound care specialists completed the wound care survey.

More than three-quarters of wound care survey respondents, 77%, describe themselves as wound care specialists; 35% are podiatrists; and 28% are medical directors (n=51).

More than two-thirds of wound care survey respondents, 69%, practice in wound care centers; 28% are in single specialty practice; and 26% practice in community hospitals (n=51).

Almost half, 47%, of patient visits are reimbursed by Medicare or Medicare Advantage; 26% of patient visits are covered by private health plans; 19% are reimbursed by Medicaid or Managed Medicaid (n=50).

Managed Care Organization Survey

A total of 40 MCO executives completed the managed care survey.

Half of the managed care respondents are health plan medical directors; another 38% are pharmacy directors (n=40).

Nearly half of MCOs, 48%, are regional health plans. Thirty percent are national health plans; 15% are integrated health networks (n=40).

A total of 32% of members of responding MCOs are enrolled in commercial preferred provider organizations (PPOs); 28% are enrolled in health maintenance organizations (HMOs); 19% are enrolled in Medicare/Medicare Advantage plans; 17% are enrolled in Medicaid/Managed Medicaid; and 3% are enrolled in other types of plans (n=40).

Wound Care Specialist Perspective

Wound care specialists emphasize the need for basic “good wound care” as well as access to advanced wound care therapies to achieve optimal patient outcomes. Wound care specialists rely on personal experience and clinical evidence to make treatment choices. Skin substitutes containing living cells or CTPs are rated as having the best clinical outcomes of all advanced wound care therapies, according to

wound care specialists surveyed. Per survey respondents, the barrier to care seen having the greatest impact is lack of insurance coverage for advanced therapies.

Diabetic Foot Ulcers

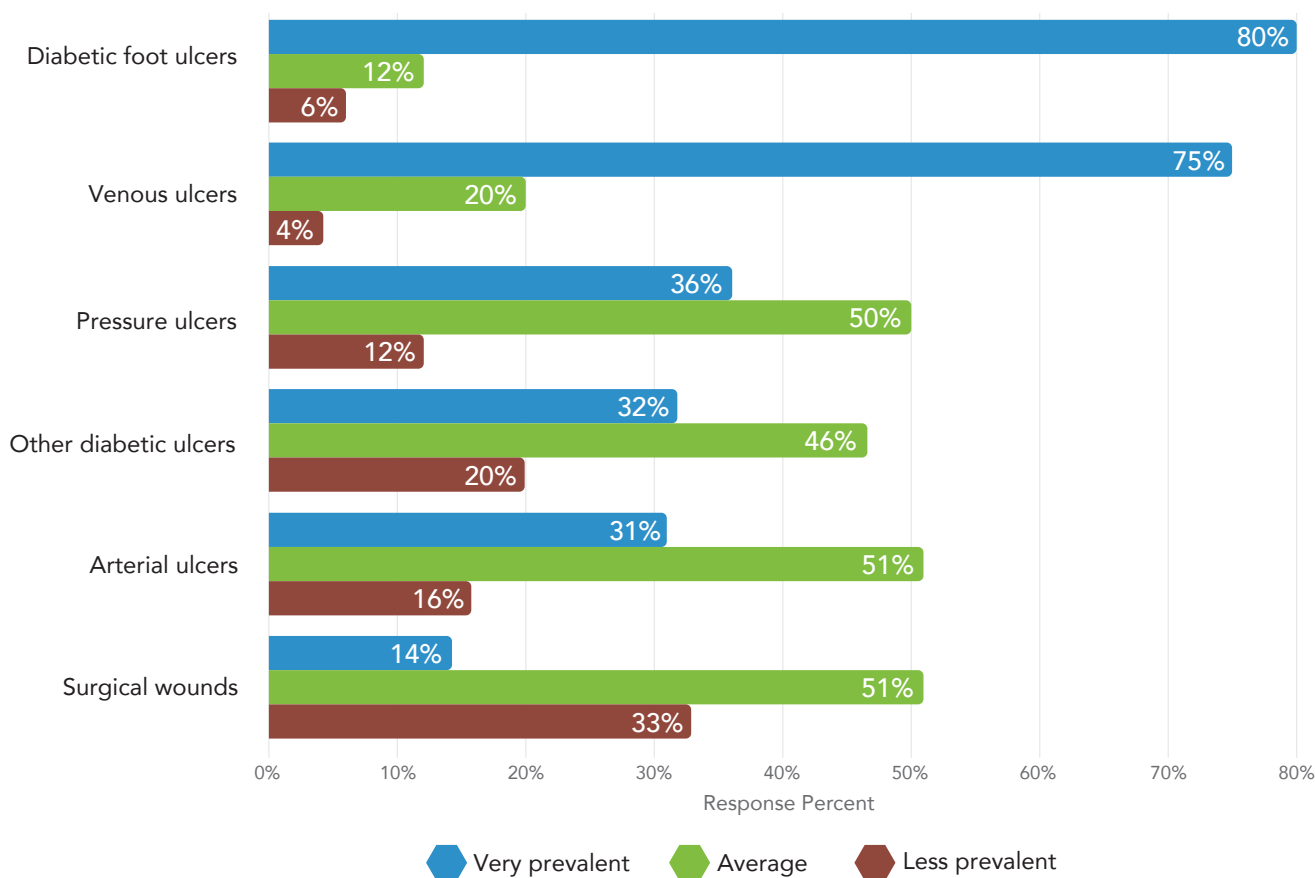
Diabetic ulcers are the most prominent type of non-healing ulcers seen by survey respondents (n=51) (Figure 1).

“The most prevalent and costly wounds in the US are surgical infections, followed by diabetic infections,” says Caroline Fife, MD, according to results of a study on prevalence and costs of wound care Dr. Fife co-authored.¹⁰ Many patients have more than 1 ulcer, she adds. The CMS data on wound type used in the study may not align with physician opinions noted in the survey because

| FIGURE 1 |

Considering only non-healing wounds that become chronic wounds, please estimate the prevalence of each wound type in your clinical practice:

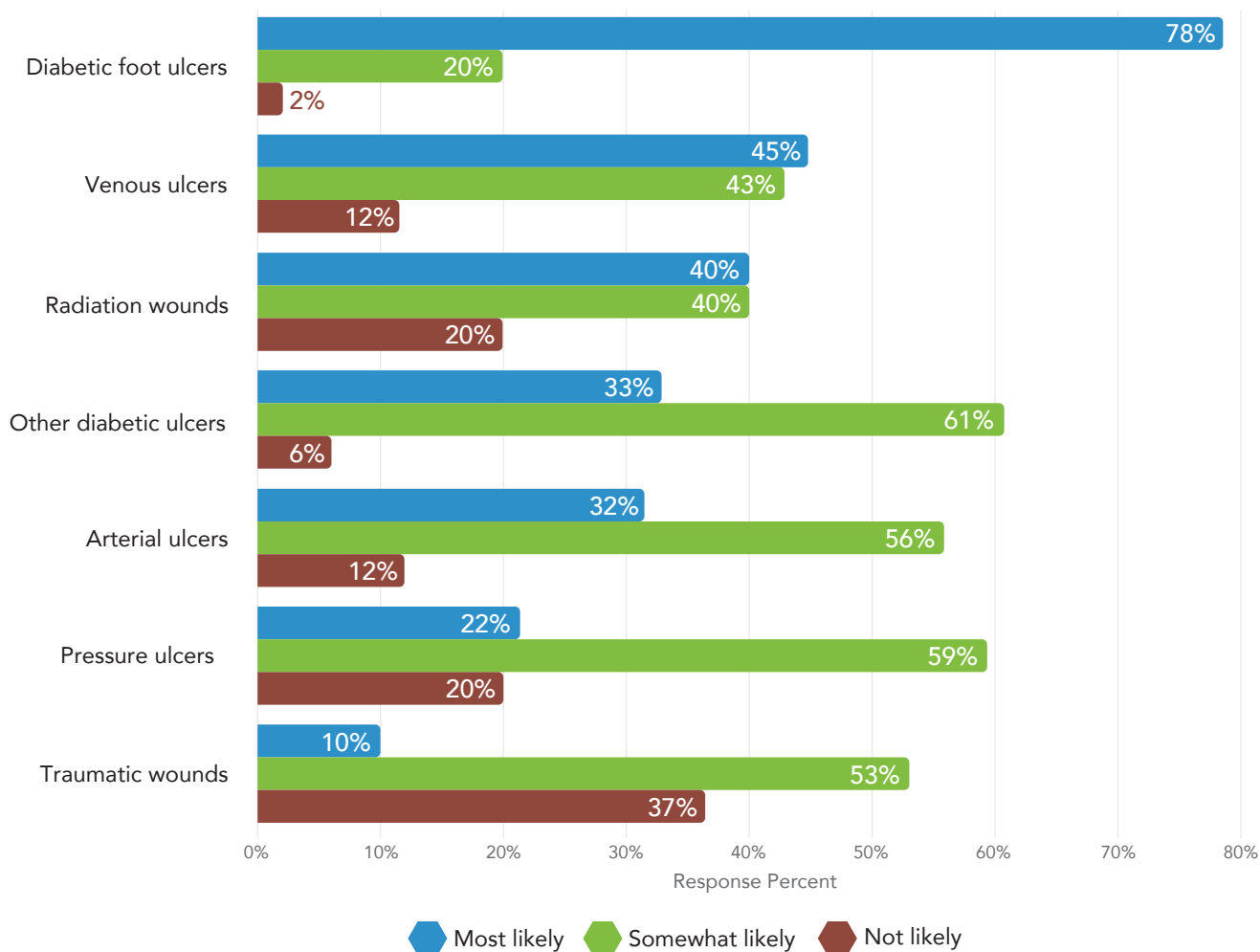
n=51 (Multiple responses)



| FIGURE 2 |

In your opinion, which types of chronic wounds are more likely to require treatment with advanced therapies to achieve complete healing?

n=51 (Multiple responses)



CMS ICD-10 coding does not always attribute the wound etiology consistently.

“In our 30 wound care centers we see 50% of patients with venous ulcers, 25% with diabetic ulcers, 15% with arterial ulcers, and 10% with pressure ulcers,” says Thomas Serena, MD. The most prevalent wound types may vary geographically and by practice.

Treatment with advanced therapies is most likely to be required for diabetic

ulcers, which are less likely to heal with standard wound care (n=51) (Figure 2). Figure 2 represents a stronger consensus on which types of wounds are likely to need advanced modalities. These advanced therapies include skin substitutes or CTPs, negative pressure therapy, MIST ultrasound, and hyperbaric oxygen.

About 30% of persons with a neuropathic DFU will heal within 20 weeks of commencing “good wound care,” according to a meta-analysis.⁸

Good Wound Care

The primary components of “good wound care” are controlling edema, blood glucose control, managing infection, wound debridement, off-loading (DFU), and weekly dressing changes to maintain a moist environment (n=51) (Figure 3), according to wound care specialists surveyed.

“Wound debridement should be at 100%,” says Gary Gibbons, MD.

FIGURE 3
Which of the following treatments do you consider to be the components of “good wound care”?

n=51 (Multiple responses)

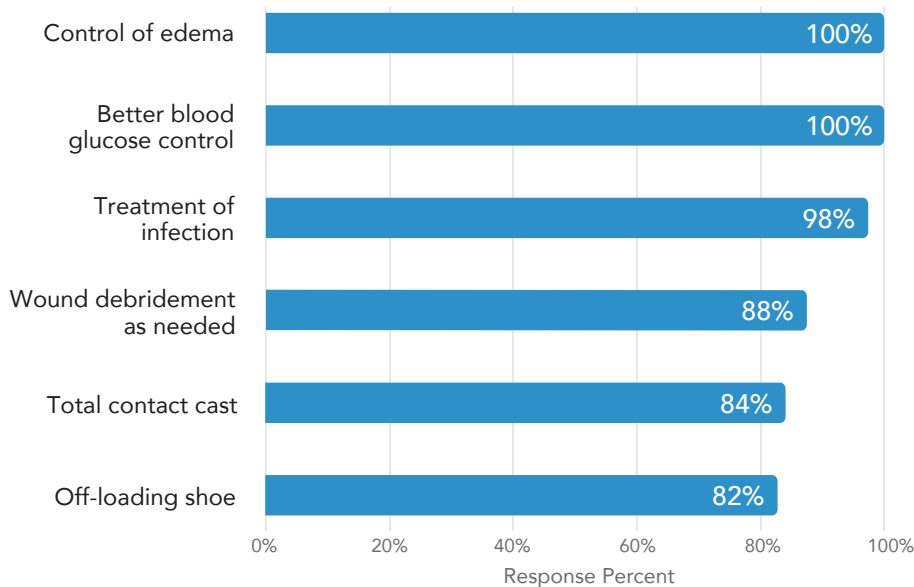
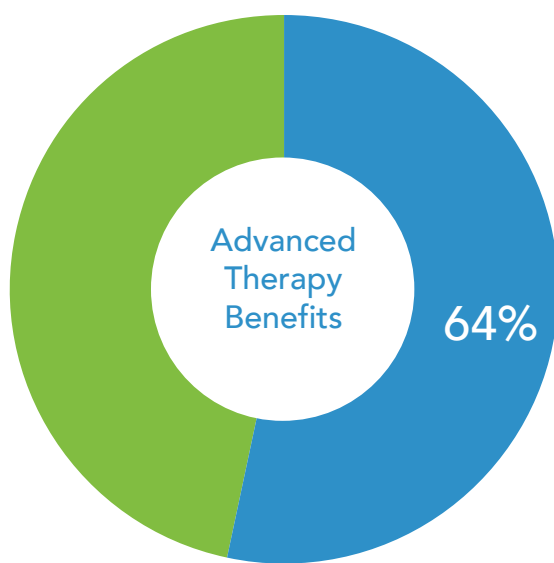


FIGURE 4
In your opinion, what percentage of your patients with diabetic foot ulcers would benefit from advanced therapies using a scale of 1% to 100%?

n=50



“Also important: vascular evaluation and treatment, compression for venous and combination ulcers, and nutrition assessment.”

“Off-loading should be higher than 82%,” adds Dr. Serena.

Wound care specialists estimate on average that 64% of their DFU patients would benefit from use of advanced therapies using a scale of 1% to 100%, where 1%=lowest and 100%=highest (n=50) (Figure 4).

Achieving Wound Closure

The most important factors contributing to wound closure for DFUs are off-loading, closely followed by adequate vascular perfusion, patient adherence to treatment regimen, no underlying osteomyelitis, and elimination of infection, each of which received 92% or more responses (n=51) (Figure 5). Early use of advanced therapies was mentioned by 53% of respondents.

“In my opinion, the most important factor contributing to wound closure for DFUs is adequate circulation,” says Dr. Fife.

“There is no single most important factor. They all are important together,” says Dr. Gibbons.

“What gets diabetics in trouble are neuropathy, vascular disease, and inappropriate response to infection,” he adds.

Cellular skin substitutes are the most prevalent advanced treatments used to treat DFUs, according to wound care specialists surveyed (n=50) (Figure 6).

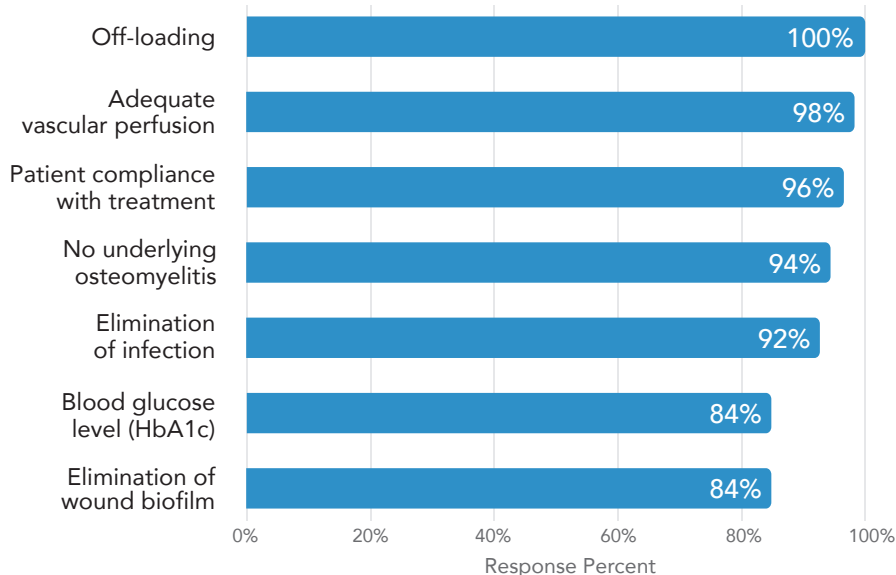
“We are seeing a national trend favoring the use of tissue-based products containing living cells,” says Dr. Serena.

“Our use of hyperbaric oxygen is around 8%,” says Dr. Gibbons. “Use

| FIGURE 5 |

In your opinion, what are the best predictors for achieving wound closure when treating DFUs?

n=51 (Multiple responses)



of MIST ultrasound is 20% and underutilized despite being well-studied and shown to be effective in different types of wounds.¹⁶ We use less negative pressure therapy than other sites.”

Cellular skin substitutes are rated by wound care specialists as having the best clinical outcomes of all advanced wound care therapies by a wide margin (n=50) (Figure 7), according to wound care specialists surveyed. Next are negative pressure therapy and hyperbaric oxygen.

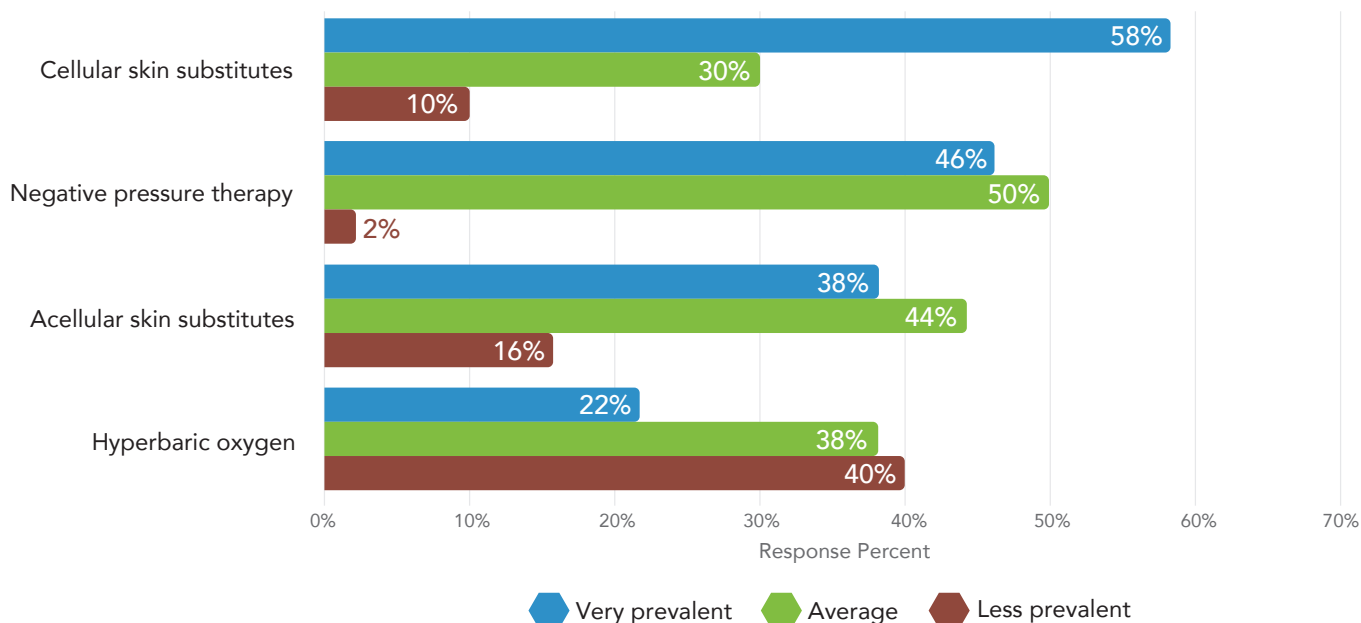
“It is not just about healing rates. Use of skin substitutes and MIST ultrasound can reduce pain and potentially reduce the need for opioids for pain relief,” says Dr. Gibbons. “Hyperbaric oxygen is controversial with few studies supporting its use in

Cellular skin substitutes are rated by wound care specialists surveyed as having the best clinical outcomes of all advanced wound care therapies.

| FIGURE 6 |

How prevalent are the following advanced treatments used for your patients with diabetic foot ulcers?

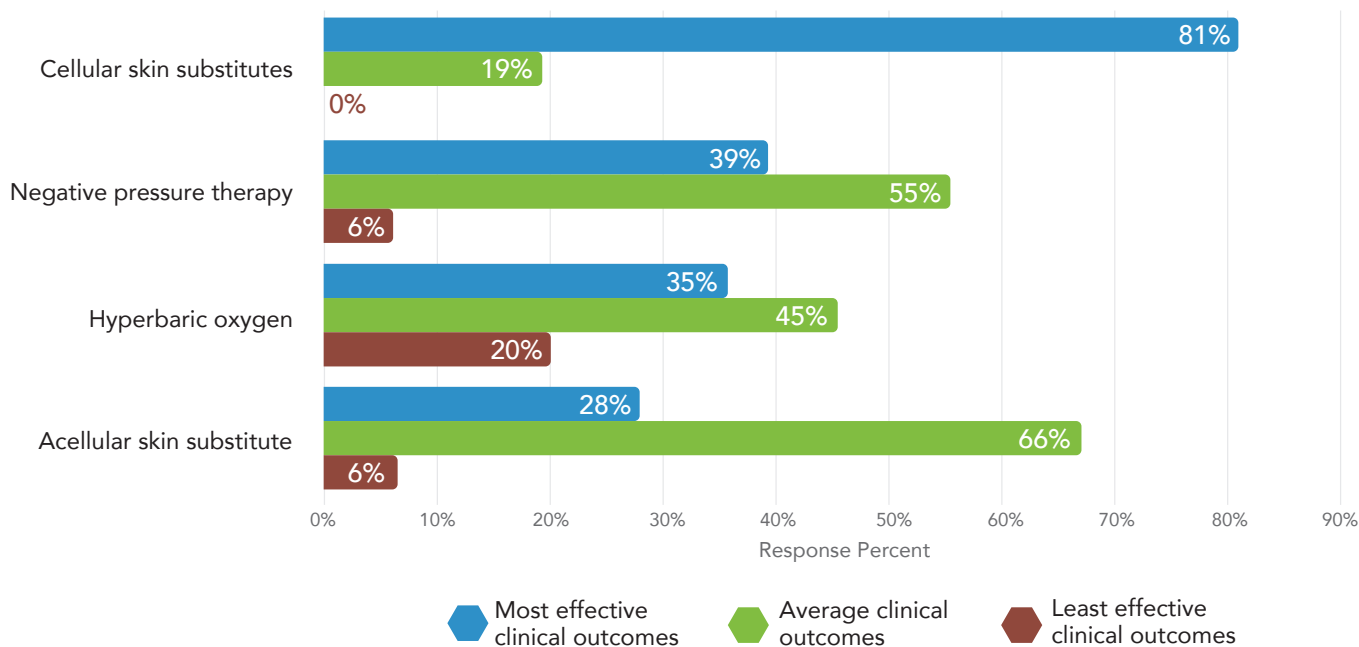
n=50 (Multiple responses)



| FIGURE 7 |

Which advanced therapies do you feel have the best clinical outcomes for wound closure for diabetic foot ulcers?

n=50 (Multiple responses)



wound care. The American Diabetes Association does not recommend its use for DFUs,” he adds.

Combination Therapies

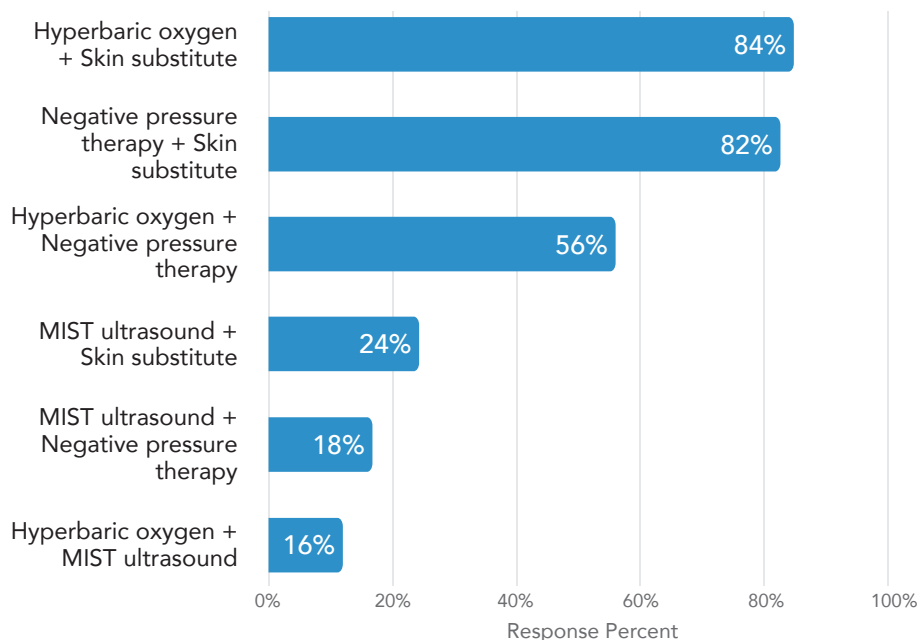
When asked about their experience with concurrent use of advanced therapies, wound care specialists report the best clinical outcomes using a combination of a skin substitute with hyperbaric oxygen, or skin substitute with negative pressure therapy (n=50) (Figure 8).

“We will use MIST ultrasound or negative pressure therapy in conjunction with good standard of care, including wound debridement, wound bed preparation, and vascular evaluation and treatment,” says Dr. Gibbons. “For diabetics we also use off-loading; for venous leg ulcers we use compression.”

| FIGURE 8 |

Which combination of therapies do you feel to be the most effective when used concurrently to treat diabetic foot ulcers?

n=50 (Multiple responses)



Selecting Skin Substitutes

Wound care specialists rely heavily on their own personal experience and on peer reviewed published clinical evidence to make treatment choices for skin substitutes or CTPs (n=51) (Figure 9).

“Medical directors at health plans are often not impressed with study findings. This is because clinical trials typically don’t include the majority of patients treated in wound care

centers,¹⁷ where the healing rate is less than 50%,” says Dr. Fife.

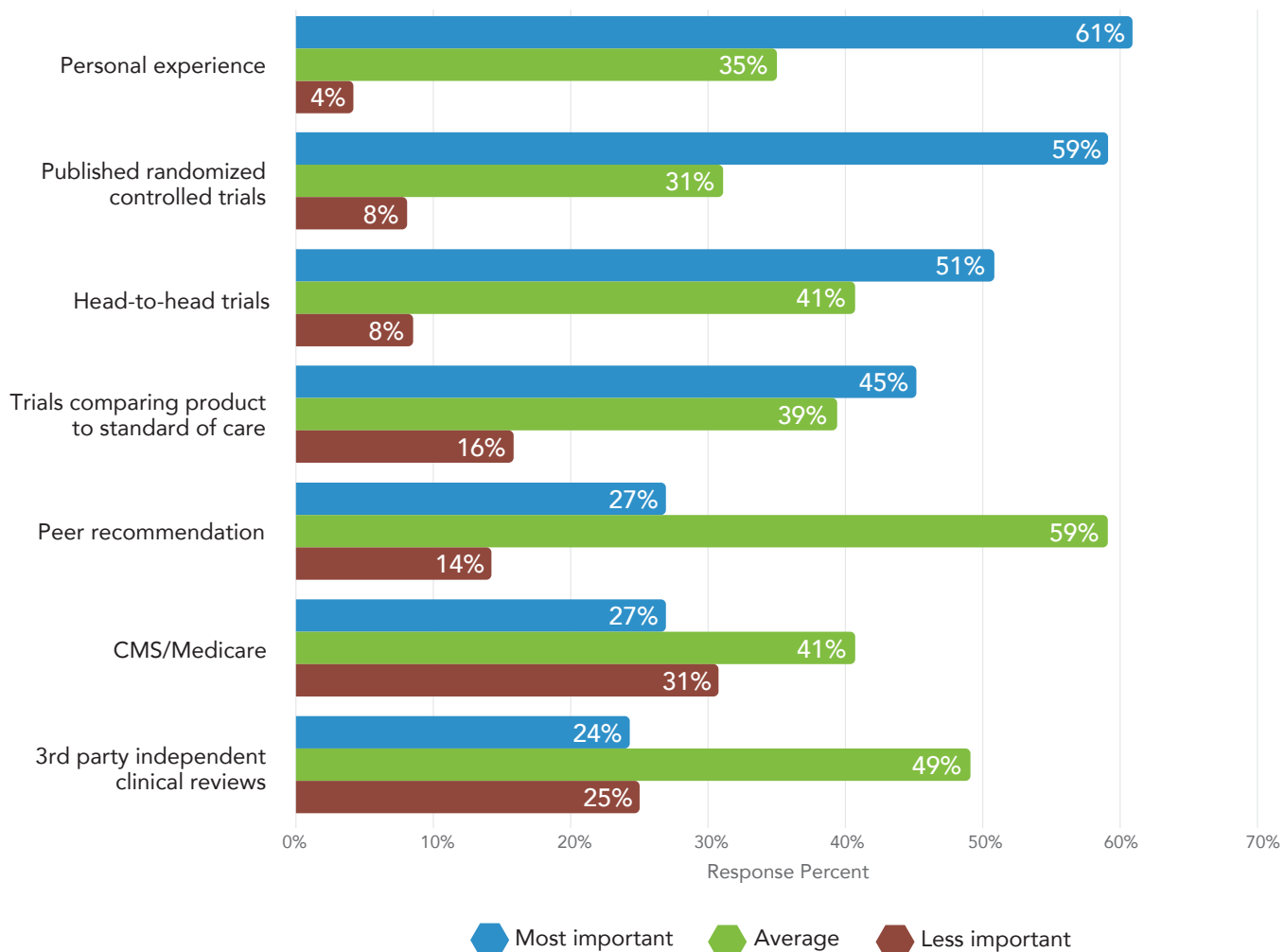
“The average real-world patient has 3 venous ulcers. Ulcers in non-study patients were 5 times the size of the ulcers enrolled in the trial and had arterial disease. Clinical trials are designed to see if a product will heal wounds faster. Thirty percent of patients with a venous ulcer have diabetes but patients with diabetes are usually excluded from venous ulcer trials because having diabetes can make ulcers harder to heal,” says Dr. Fife.

“We developed a mathematical model called the Wound Healing Index (WHI) that predicts whether a wound in the real world will heal,”¹⁸ explains Dr. Fife. According to the study authors, the DFU WHI “can validly predict the likelihood of wound healing among real-world patients and can facilitate comparative effectiveness research and identify patients needing advanced therapies.” Dr. Fife adds that “CMS accepts the WHI as the method by which wounds are risk stratified

| FIGURE 9 |

How important are the following resources when selecting a skin substitute product for your patients?

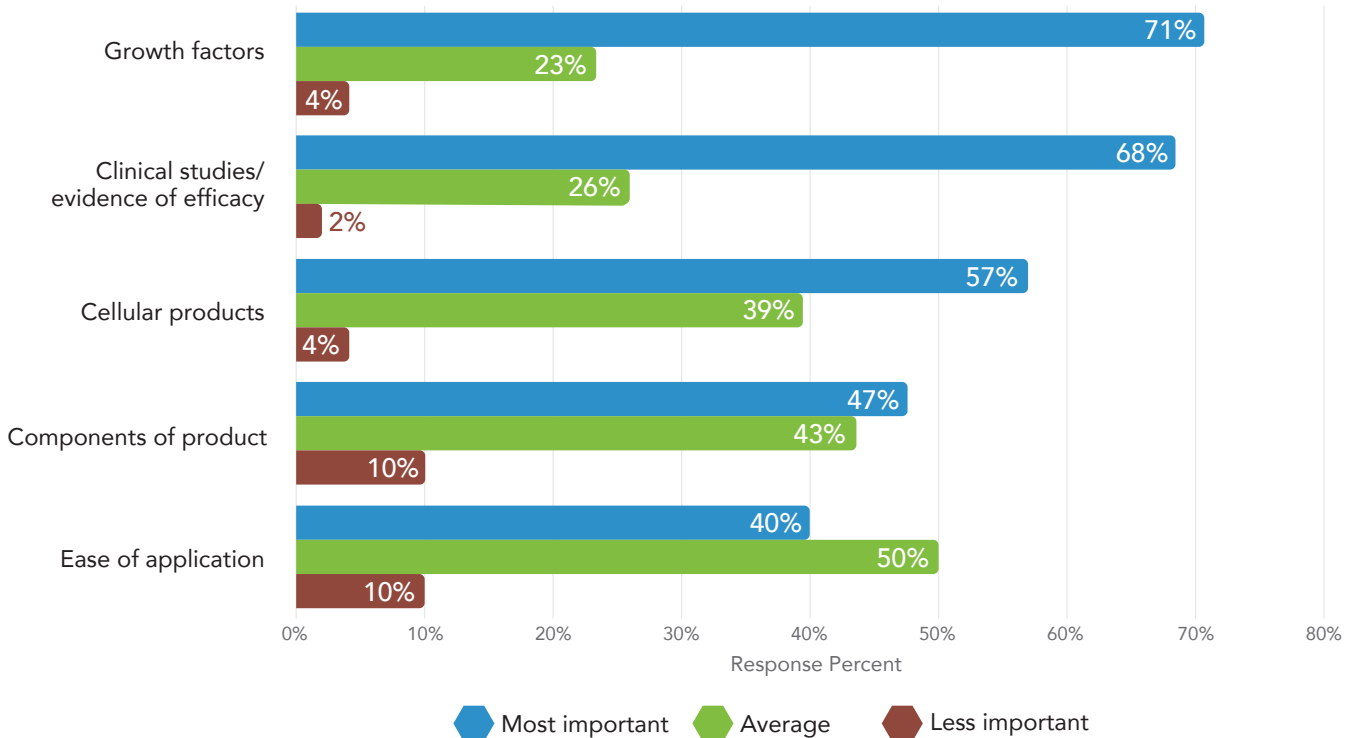
n=51 (Multiple responses)



| FIGURE 10 |

Which clinical factors are most important when selecting which skin substitute to use to treat a diabetic foot ulcer?

n=51 (Multiple responses)



for the purpose of reporting the quality measures for DFU, VLU, and pressure ulcer healing rate.” The WHI is only available through the US Wound Registry. Other predictive models for wound healing and outcomes are cited in this study.¹⁸

“Personal experience and knowledge of what works in our patient population are essential. We are all not treating the same patients,” says Dr. Gibbons. “We average 90 to 100 patients a day at our wound care center. These patients have multiple comorbid conditions. In addition to good standard wound care, we use amniotic membranes and collagen products.”

Clinical Factors

The presence of growth factors and published clinical evidence rank highest

among factors that influence treatment choices of a skin substitute (n=51) (Figure 10).

“I would list clinical studies first, then cellular products,” says Dr. Serena. “Use of products with living cells is expected to increase. There seems to be something special about products containing living cells,” he adds.

“Also important is ease of application and whether the product can be stored on a shelf or requires special handling,” says Dr. Fife.

Cost is the leading non-clinical factor in selecting a skin substitute to treat DFUs with 7 responses. Other factors receiving multiple responses are personal experience (5 responses), ease of application (4), efficacy/effectiveness (4), clinical results/outcomes (3), insurance coverage (3), and patient

compliance (2) (n=40) (chart not shown).

“Cost is a factor. Whether a product is covered is key,” says Dr. Gibbons. “Everything is being bundled forcing wound care specialists to pay more attention to individual components of care,” he says.

Barriers to Care

Barriers to care exist to treating patients with advanced therapies (n=51) (Figure 11). Lack of insurance coverage for advanced wound care therapies is the number 1 reason patients with DFUs do not receive advanced treatments they may need, according to survey respondents.

“Lack of insurance coverage and high out-of-pocket costs are barriers to

care,” says Dr. Fife. “As for patient compliance, it is easy to blame the patient,” she notes. “For patients with venous leg ulcers, I talk with them for 10 minutes on the importance of compression and draw a picture. Patients will say no one explained the need. With off-loading, I try to fit it with the patient’s lifestyle. Sticking to a diet is hard for everyone. We need to up our game and communicate better with our patients.”

“One major barrier to care is failure to practice evidence-based wound care,” says Dr. Gibbons. “Next is insufficient or lack of insurance coverage. There are data available to support the use of advanced wound care products.”⁹

“Our patients face lack of insurance coverage or large copays of \$200 or more that patients can’t afford,” says Dr. Serena.

“We get good results by first preparing the wound bed using debridement and off-loading. Then we will use advanced products,” says Dr. Serena. “It can be costly to treat large wounds. In such cases, we will put a piece of skin substitute in the middle of a large wound to jump start the healing process.”

“Patients with serious foot ulcers have to wait a month to use hyperbaric oxygen following treatment using the standard of care first,” says Dr. Serena. “Having a foot ulcer increases mortality by 47% among patients with diabetes, worse than most cancers.¹⁹ What if cancer patients were told they had to wait a month before starting treatment?”

“We have got to stop lying about our healing rates, claiming 80% to 90%,” says Dr. Serena. “Simply look at the healing rates in clinical trials where patients receive the best care. These ‘real’ numbers are far below reported

healing rates.¹⁷ Healing rates are a lie.” Dr. Fife agrees. “There is a fundamental disconnect between healing rates reported in clinical trials and those in the real world. Once products are used in the real world, the healing rates are 50% or less,” says Dr. Fife. “For many patients, their wounds are a symptom of their comorbid diseases. The average patient in a wound care center is taking 10 medications. Average length of stay at a wound care center is 7½ months.”

Expert Opinion

More than two-thirds of wound care specialists surveyed say that health plans do not seek their opinion when making medical policy decisions (n=51) (**Figure 12**).

Wound care specialists rate their knowledge of wound care and understanding of the emerging science

of wound care quite highly, averaging 81 on a scale of 1 to 100 where 1=lowest and 100=highest (n=51) (**Figure 13**).

Promising Trends

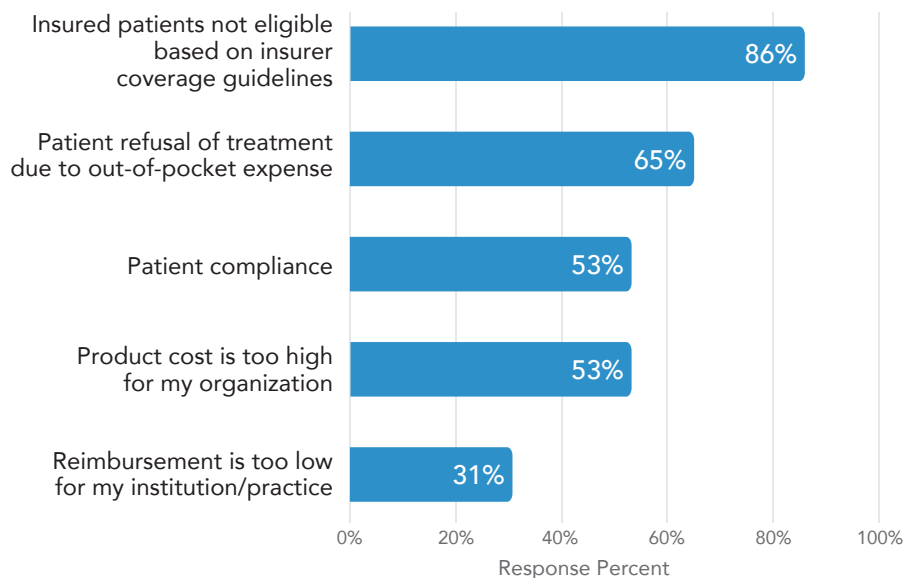
More advanced skin substitutes or CTPs (8 responses), stem cells (8), biofilm (5), biologics (4), regenerative medicine (2), and amniotic membranes (2) are named by wound care specialists as the most promising new treatment options to improve patient outcomes over the next 3 to 5 years (n=50) (chart not shown).

“The most promising trend would be for practitioners to follow the evidence,” says Dr. Gibbons. “Some studies show that wound care specialists are not doing so. For example, despite its proven benefit, only 5% of DFUs are off-loaded.²⁰ Once basic measures are taken, then

| FIGURE 11 |

In your opinion, what are the barriers to treating patients with advanced therapies?

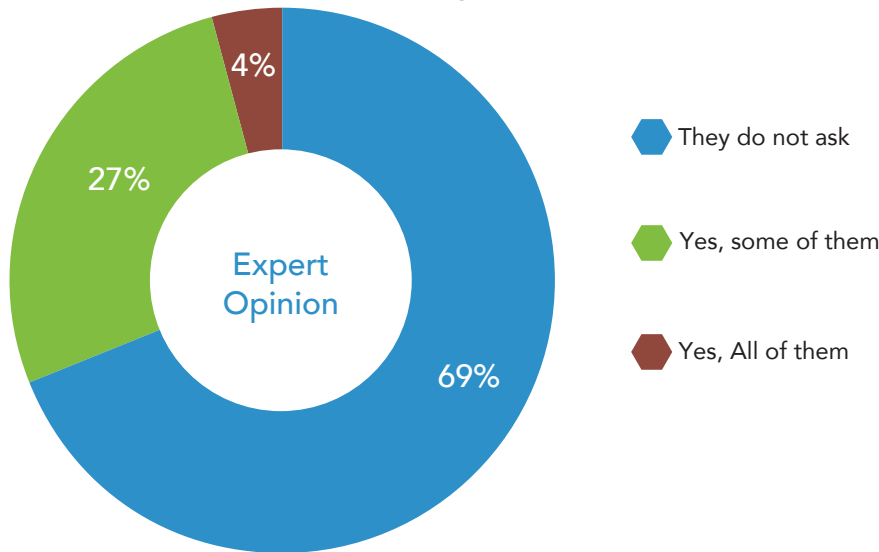
n=51 (Multiple responses)



| FIGURE 12 |

Do any health plans with which you contract ask for your expert opinion as to which treatments should be covered under their medical policy?

n=51

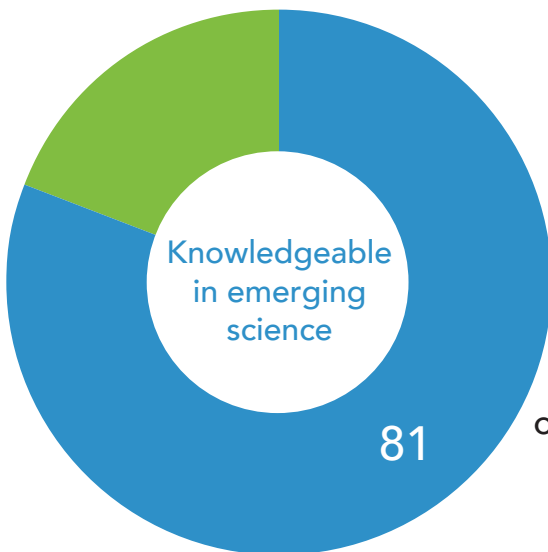


- They do not ask
- Yes, some of them
- Yes, All of them

| FIGURE 13 |

How knowledgeable are you in understanding the emerging science behind wound care, rating yourself on a scale of 1 to 100?

n=51



advanced therapy can be added.”

“There are a lot of products out there. We favor living products. Those with living cells seem to have an advantage,”²¹ says Dr. Serena.

“It is interesting that so many survey respondents mention stem cells,” says Dr. Fife. “Biofilms are talked about at meetings but not stem cells so much. It would be in the context of revascularization. Better ways of delivering care are also listed, including prevention, personalized medicine, and evidence-based protocols.”

“Providing wound care is not being rewarded the way it should be,” says Dr. Gibbons. “Blood sugar control is often poor. We are not doing a good job with prevention or recognizing problems. We need to do more to educate patients. At our clinics we follow a patient-centered multidisciplinary approach, with an emphasis on evaluation, treatment, and prevention,” he explains.

“Health plans can’t just keep doing the same thing or will cost themselves out of business,” says Dr. Gibbons. The total cost of diagnosed diabetes increased to \$327 billion in 2017, according to the American Diabetes Association, up 26% over 5 years.²² The number of people with chronic, non-healing wounds is rapidly growing, reaching almost 7 million people in the US alone.²³ “Diabetes and wound care costs go up each year but improvement in care is lagging way behind,” notes Dr. Gibbons.

“Wound care specialists could accomplish more for patients by speaking with one voice,” says Dr. Serena. “We need to come together on quality measures, reimbursement issues, and do more for our patients.”

Managed Care Medical Director Perspective

MCOs stress the need for clinical studies to demonstrate that wound care products work. Patient compliance is seen as a major barrier to improving wound care. Skin substitutes are viewed as a promising therapy. MCOs predict rising costs as they seek to establish value.

Diabetic ulcers are the most prominent type of chronic wounds

among health plan membership of responding MCOs, significantly higher than all other types of chronic ulcers (n=39) (**Figure 14**).

“We are seeing an increase in the prevalence of diabetes and of diabetes that is poorly controlled leading to diabetic ulcers and other complications of diabetes,” observes Larry Hsu, MD. “Control of glycated

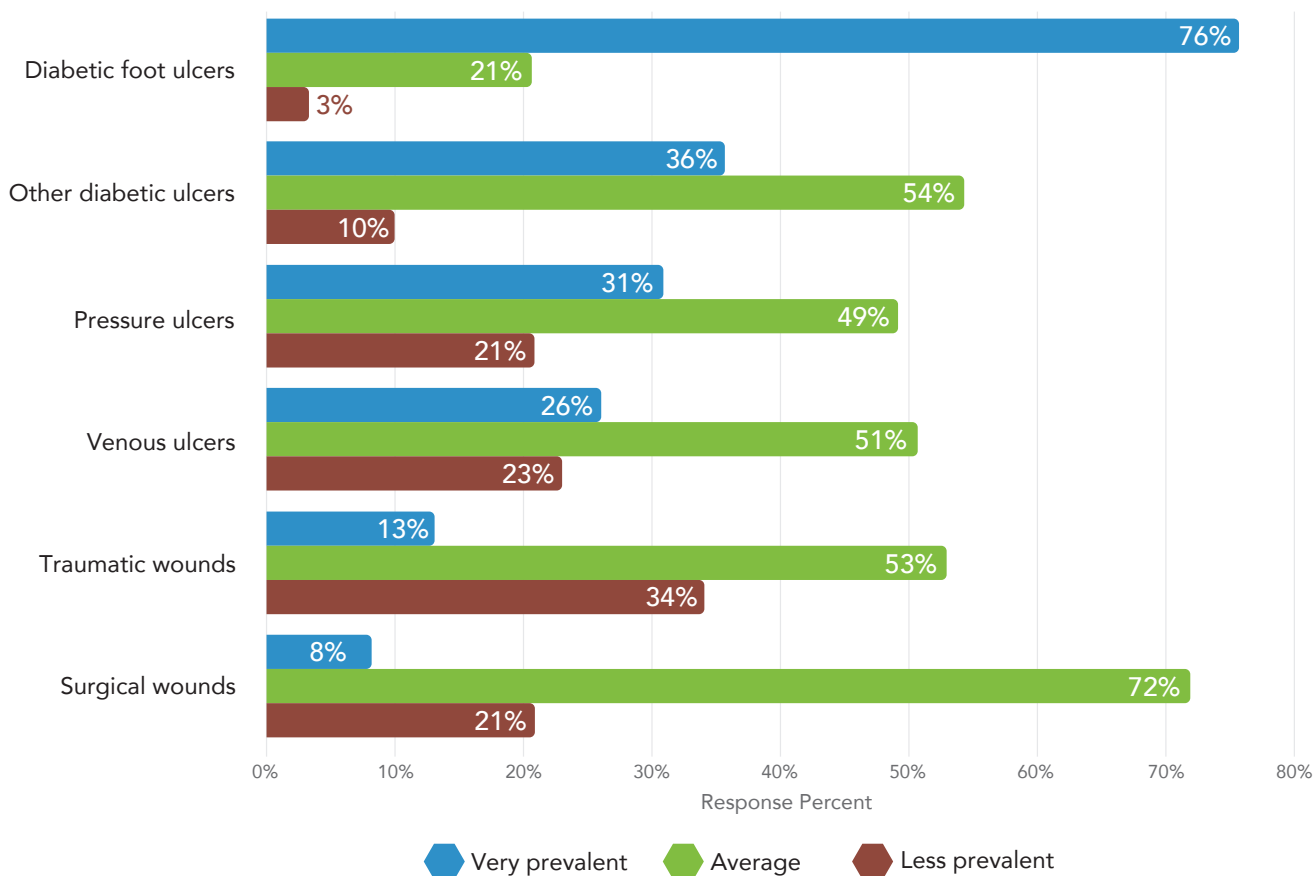
hemoglobin (A1c) levels is very important for diabetes prevention. Treatment of diabetic ulcers needs to be expanded to include diet and a multidisciplinary approach to the management of diabetes.”

“Often, wound care products are only studied in DFUs and only indicated for DFUs and so plans will limit coverage accordingly,” says Fredrick May, MD.

| FIGURE 14 |

In your estimation, which types of chronic wounds are most prevalent among your membership, based on your knowledge of claims data?

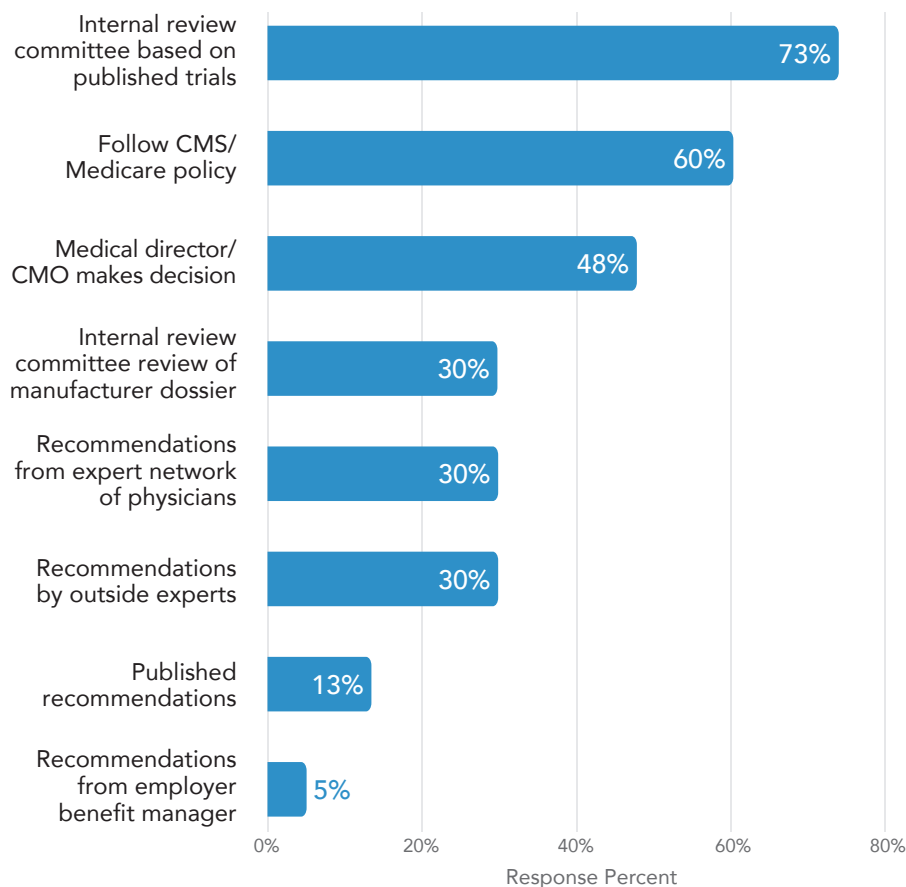
n=39 (Multiple responses)



| FIGURE 15 |

How does your organization develop medical policy for wound care products?

n=40 (Multiple responses)



“We need proof that products will work in other types of wounds before we will approve their use.”

“Risk of amputation underscores the need for proper treatment of wounds,” says Edmund Pezalla, MD.

Medical Policy

MCOs rely most on internal review committee evaluations of published clinical trials for developing medical policies for coverage of wound care products (n=40) (Figure 15). Sixty percent follow CMS policy.

“MCOs are familiar with CMS policy

and frequently follow its lead,” notes Dr. Pezalla.

“Medical policy needs to be evidence-based,” says Dr. Hsu. After published trials, he favors the use of guidelines developed by national professional societies. “However, unlike with new drugs, rigorous clinical trials are not required to launch wound care products. Many marketed products lack clear evidence of efficacy. Health plans want to know: where is the evidence?”

“We follow the product package insert in developing medical policy,” says Dr. May.

Advanced Wound Therapies

MCOs typically cover advanced therapies for all types of chronic non-healing wounds (n=39) (Figure 16).

Dr. Pezalla notes that most MCOs restrict the use of skin substitutes to chronic lower extremity wounds or diabetic ulcers because of limited clinical trial data for those indications. “Many products are approved for marketing but there is a lack of long-term outcomes data, such as whether a graft is successful,” he explains.

“The vast majority of chronic wounds are related to diabetes,” notes Dr. Hsu. “DFUs are the hardest to treat. Infection, vascular problems, plus poor management of diabetes combine to form the perfect storm.”

“New products have been approved for use, but it is difficult to say which therapy is best for an individual patient. How do new therapies compare with old? We don’t know. There is too much reliance on retrospective reviews and case reports, and too few patients are enrolled in studies. Also, no one is addressing the issue of cost,” Dr. Hsu adds.

Most MCOs do not spend much time managing chronic wounds relative to other services they manage (n=40) (Figure 17). Time spent averaged 15% of time available using a scale of 1% to 100%, where 1%=lowest and 100%=highest.

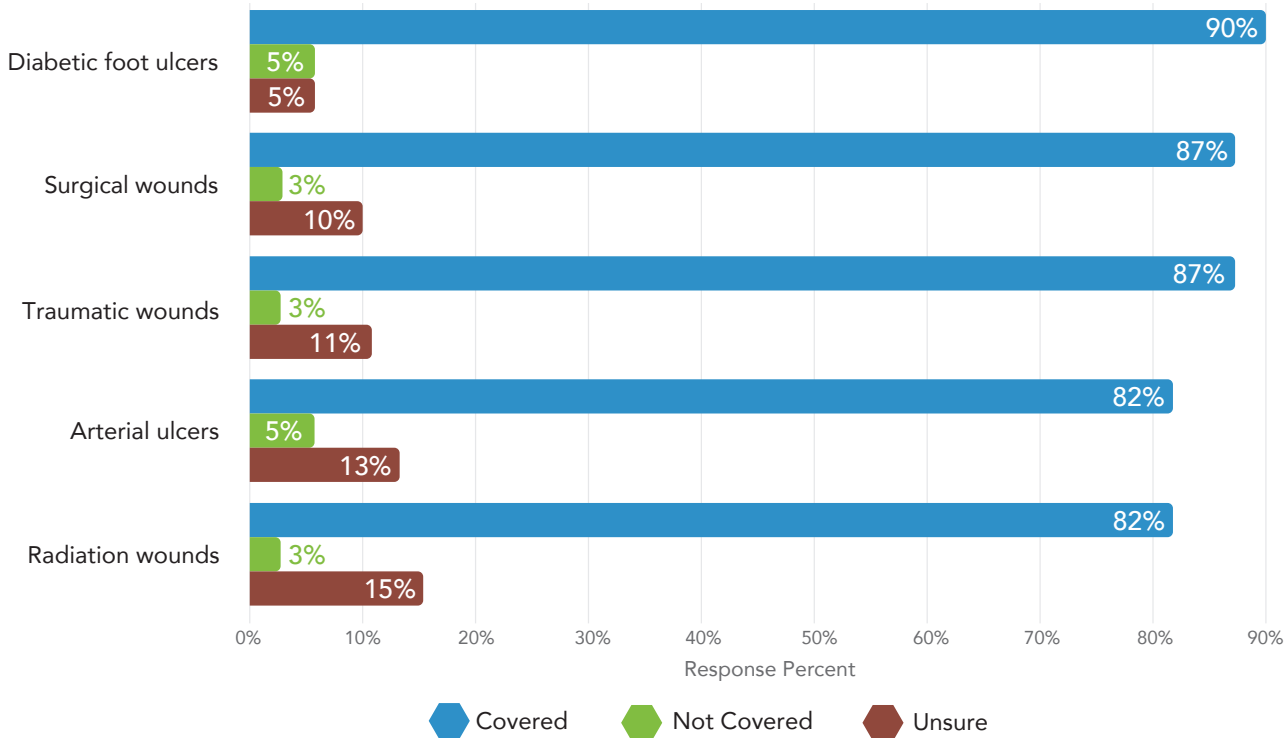
“The amount of time spent on wound care by health plan medical directors is not significant because many products are not covered or are subject to prior authorization or step edits,” says Dr. Hsu.

“We spend little time on wound care except to require prior authorization

| FIGURE 16 |

Which types of chronic wounds or ulcers are covered by your organization for treatment with advanced wound therapies?

n=39 (Multiple responses)



on costly treatments such as hyperbaric oxygen,” says Dr. May.

Wound debridement, treatment of infection, and controlling blood glucose levels are the top 3 clinical issues for good wound care and are addressed in the clinical policy of most responding MCOs (n=26) (Figure 18).

Case Management

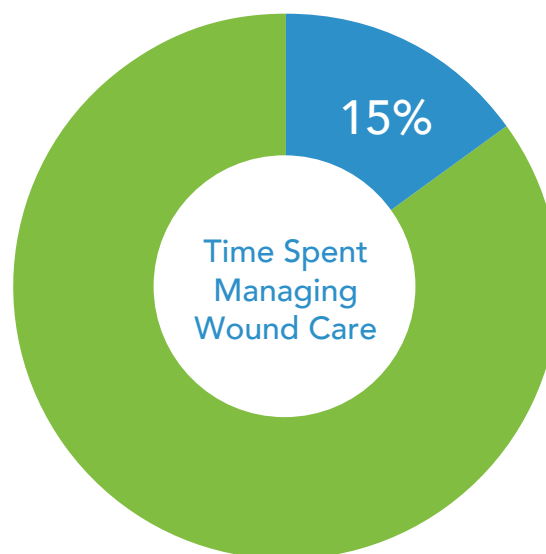
Sixty percent of MCOs report that they case manage chronic wounds as part of a diabetes case management program (n=40) (Figure 19).

“Most programs connect patients to providers in their local area and help with blood sugar control and nutrition,” explains Dr. Pezalla.

| FIGURE 17 |

How much time do you spend on the management of chronic wounds relative to all the services that you manage, using a scale of 1% to 100%?

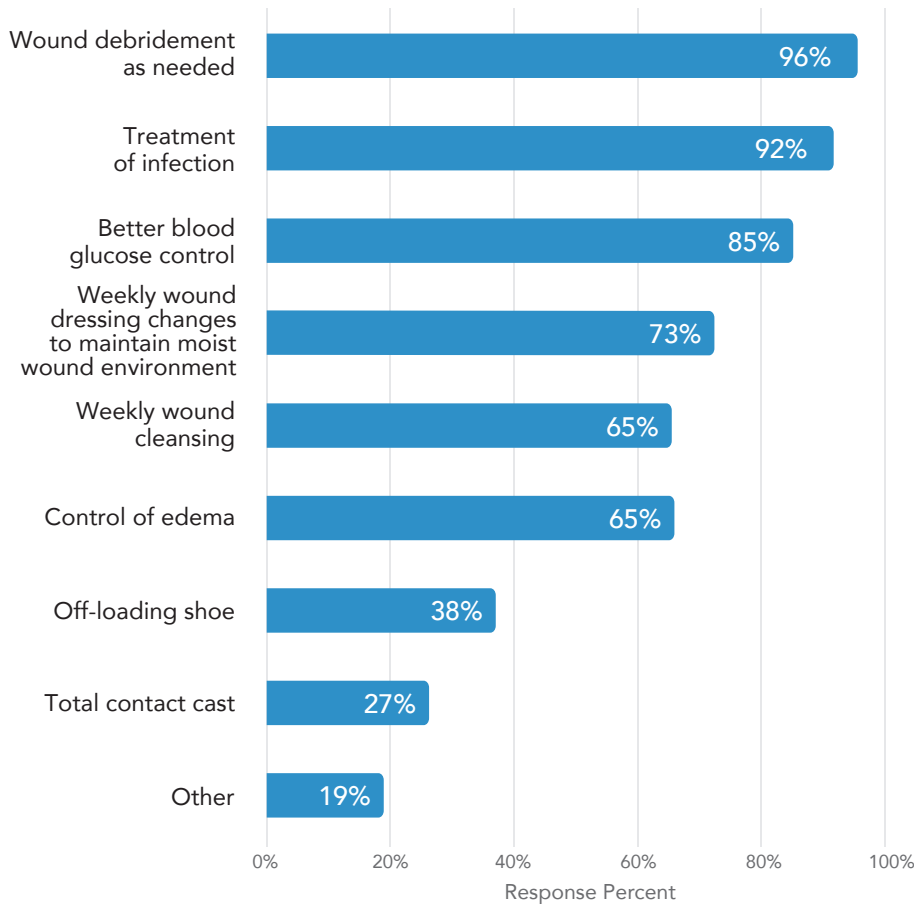
n=40



| FIGURE 18 |

Which of the following are addressed in the clinical policy?

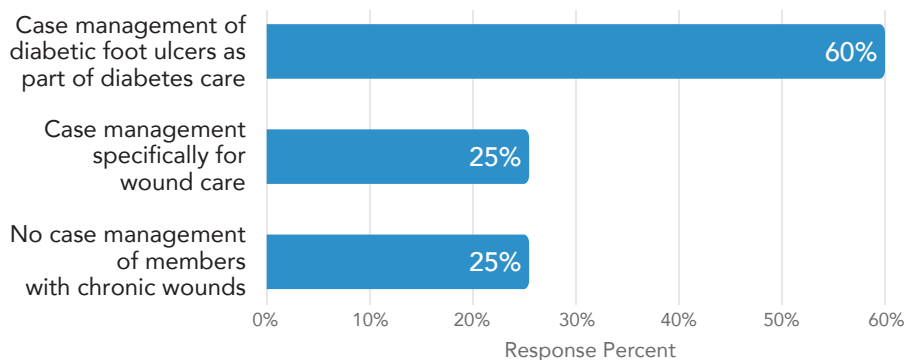
n=26 (Multiple responses)



| FIGURE 19 |

Do you provide case management for members with chronic wounds?

n=40 (Multiple responses)



“For patients with significant medical issues such as DFUs, this involves coordination of care to manage wound care as well as diabetes management,” says Dr. Hsu. “The better the A1c control, the better the patient outcomes for all aspects of diabetes care and avoidance of complications. Care is a balance between A1c control and safety issues, including prevention of hypoglycemia. Use of an insulin pump can improve A1c control and long-term management of diabetes,” he adds.

Thirty percent of MCOs responding say they track outcomes data of plan members with diabetic ulcers (n=40) (Figure 20).

“Health plans usually do not track outcomes data because their systems are claims-based, and organized according to the doctor’s diagnosis,” says Dr. Hsu. “Plans underestimate how much they spend on wound care,” he adds.

“It is difficult for MCOs to track patient outcomes,” agrees Dr. May. “Most plans don’t have direct access to such data.”

The best predictors for achieving wound closure are adequate vascular perfusion and patient adherence to the treatment regimen, agree 88% of MCO respondents (n=35) (Figure 21).

“Figure 21 is a good summary of healing factors,” says Dr. May.

MCOs suggest that an average of 49% of members would benefit from use of advanced therapies, using a scale of 1% to 100%, where 1%=lowest and 100%=highest (n=40) (Figure 22). However, there is a range of opinion as indicated by a median of 35%.

“This question is difficult for plans to answer,” says Dr. May. “We know

some patients don't get better but advanced therapy isn't necessarily the answer. I don't know the answer. In addition, patient compliance is an issue, especially with negative pressure therapy."

Negative pressure therapy provides the best clinical outcomes for wound closure, according to MCOs surveyed, followed by hyperbaric oxygen, and skin substitutes (n=40) (Figure 23).

Negative pressure therapy and cellular skin substitutes have the highest prevalence of use for DFU, followed by acellular skin substitutes, and hyperbaric oxygen. There is less use of MIST ultrasound (n=40) (Figure 24). If cellular and acellular skin substitutes are grouped together, their use for DFUs exceeds use of negative pressure therapy.

"Negative pressure therapy is widely used for DFUs," says Dr. May. "Skin substitutes can make wounds better. They can keep a wound clean and prevent infection, but they are expensive."

Combination Treatment

Most MCOs do not cover use of two advanced therapies used concurrently. Hyperbaric oxygen + skin substitute, negative pressure therapy + skin substitute, and hyperbaric oxygen + negative pressure therapy are most often used when plans do approve of combination therapy (n=31) (Figure 25).

"The concept of combination therapy makes sense," says Dr. Hsu. "But what is the best combination? We don't know. Where is the literature to support combination therapy? The studies are not there."

"There is no evidence anywhere that any of these combinations make for better wound care," says Dr. May. "We

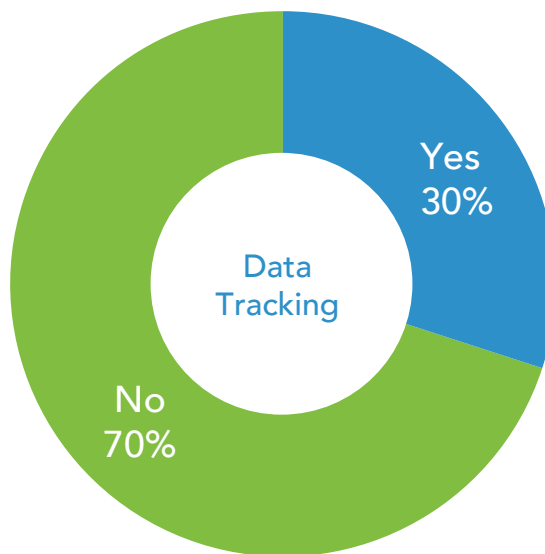


FIGURE 20 |

Does your health plan track any data around diabetic ulcers including time on therapy, time to wound closure, average number of days, etc.?

n=40
(Response Percent)

FIGURE 21 |

In your opinion, what are the best predictors for achieving wound closure when treating diabetic foot ulcers?

n=35 (Multiple responses)

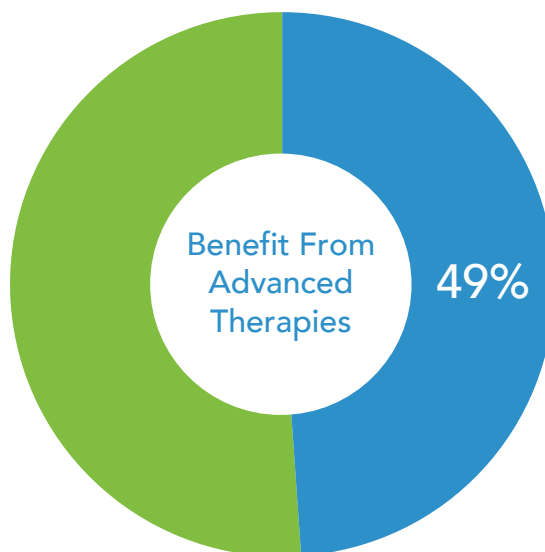
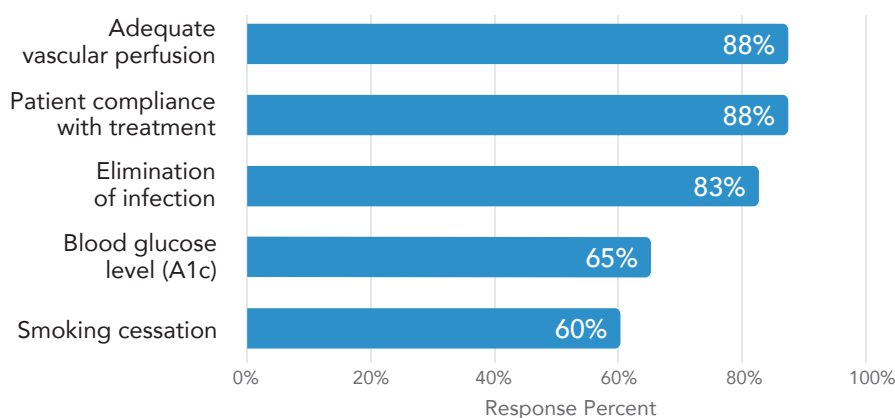


FIGURE 22 |

In your opinion, what percentage of your members with diabetic foot ulcers would benefit from advanced therapies using a scale of 1% to 100%?

n=40

FIGURE 23

Which advanced therapies do you feel have the best clinical outcomes for wound closure?

n=40 (Multiple responses)

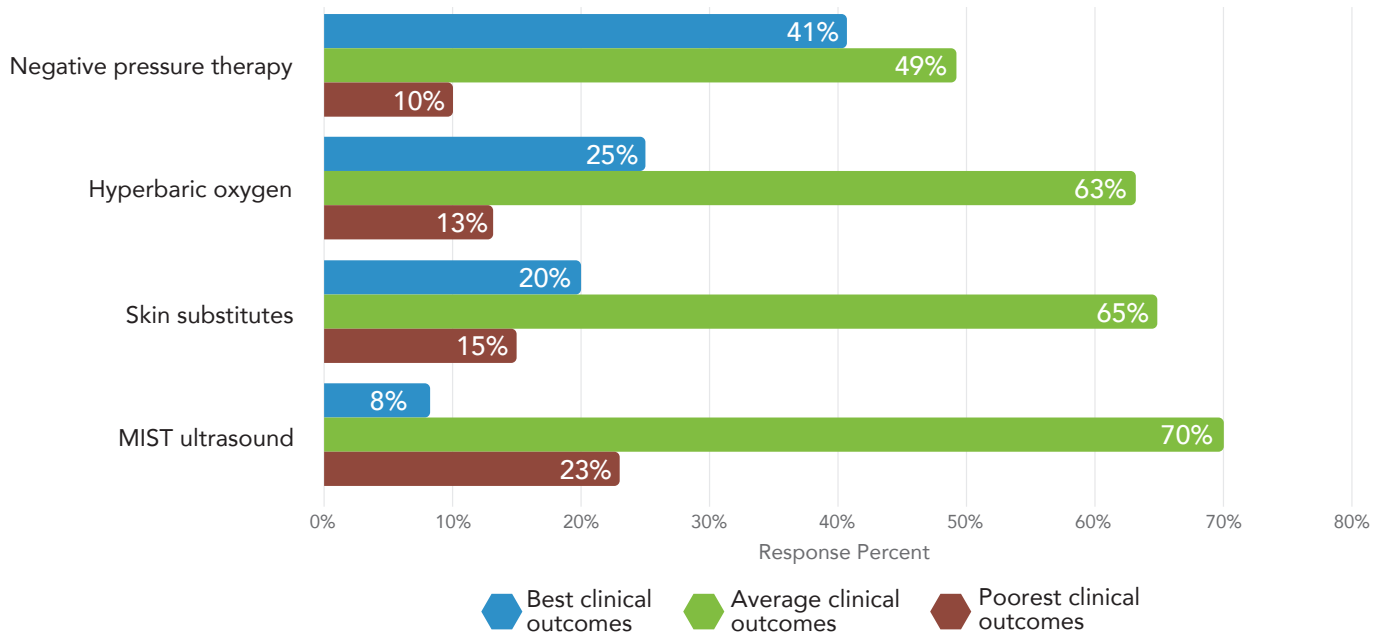
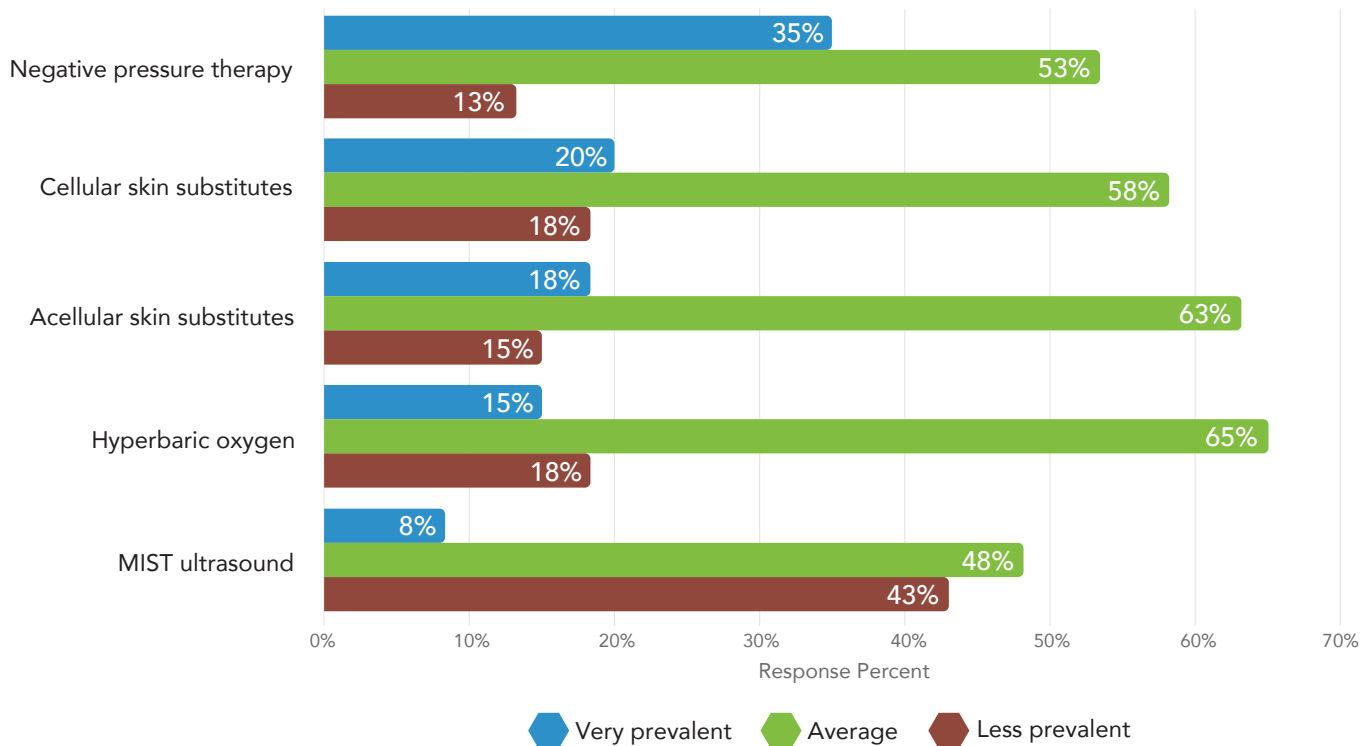


FIGURE 24

How prevalent are the following advanced treatments for your members with diabetic foot ulcers?

n=40 (Multiple responses)



don't have the studies to show efficacy and it is costly.”

Barriers to Treatment

Patient adherence/compliance is the number 1 barrier to treating patients with advanced wound care therapies. This is followed closely by lack of clinical evidence, and insurance coverage guidelines, according to MCOs surveyed (n=40) (**Figure 26**).

“Patient compliance is a very big problem,” says Dr. May. “It takes a long time for wounds to heal. The wound needs to be kept clean. Patients may not understand the necessity of follow-up care.”

“Patient adherence may include off-loading, changing the wound dressing, and keeping a negative pressure device attached,” say Dr. Pezalla.

“One barrier is the lack of evidence supporting many wound care products,” says Dr. Hsu. “Compliance is also an issue. Caring for a wound can be complicated.”

“It appears that a large number of plans cover most therapies,” says Dr. Pezalla. “There might be some lack of coverage for some advanced products for certain types of patients. This may have to do with interpretation of the clinical data as to which patients will benefit. Most diabetic ulcer patients have access to one or more advanced wound care options.”

Selecting Skin Substitutes

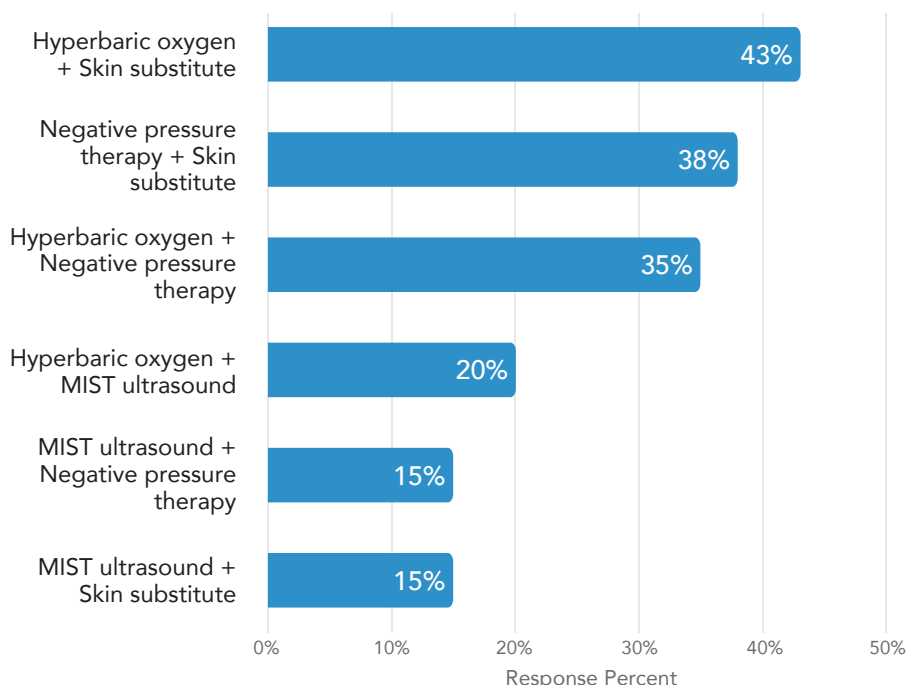
Clinical evidence from published studies is by far the most important factor in selecting which skin substitutes to cover to treat DFUs (n=40) (**Figure 27**).

“Respondents favor clinical studies, then wound size as most important factors. I agree,” says Dr. May.

| **FIGURE 25** |

Does your organization cover advanced therapies used in combination?

n=31 (Multiple responses)



| **FIGURE 26** |

In your opinion, what are the barriers to treating patients with advanced therapies?

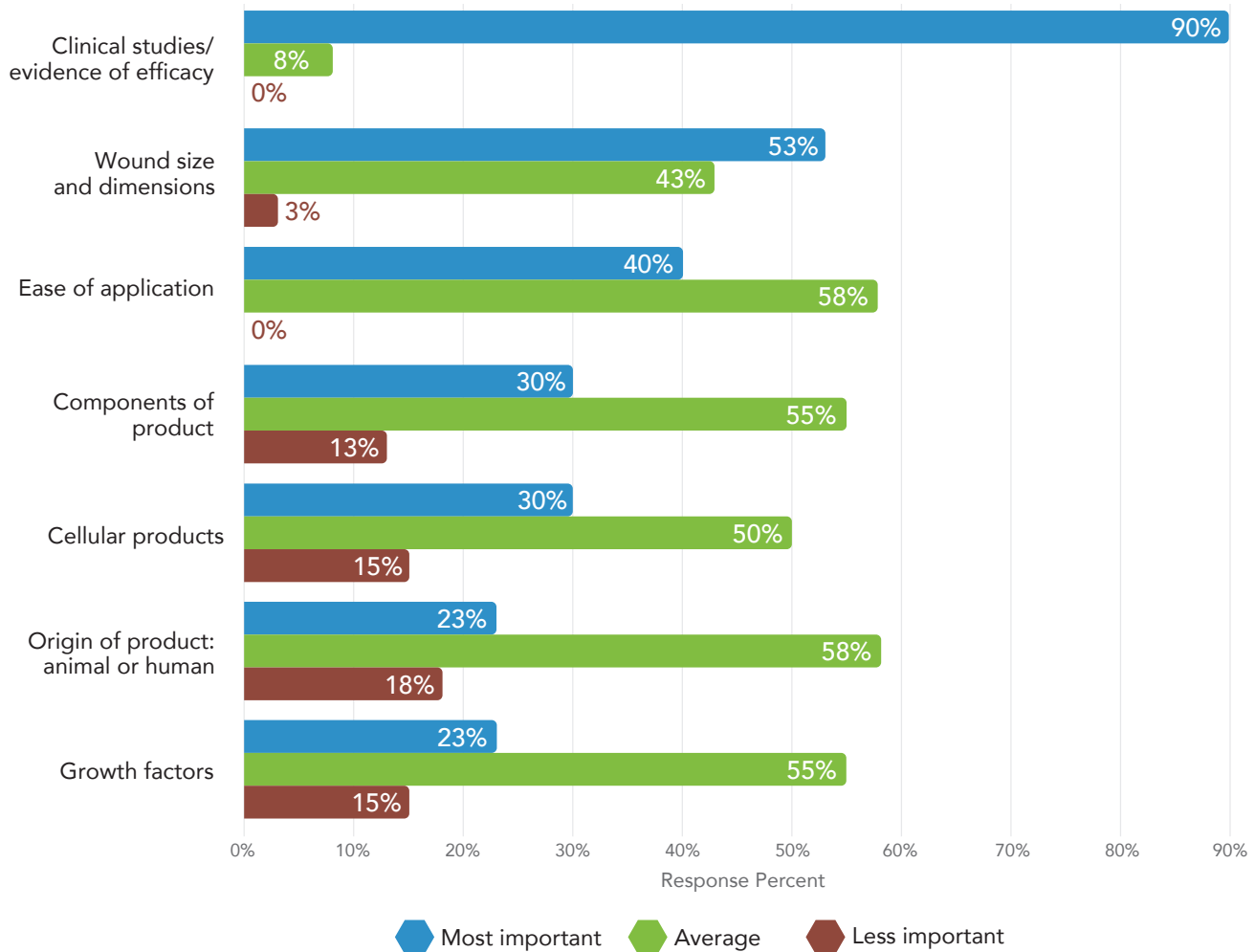
n=40 (Multiple responses)



| FIGURE 27 |

Which clinical factors are most important when selecting which skin substitute to use to treat a diabetic foot ulcer?

n=40 (Multiple responses)



Among non-clinical factors, cost (6 responses) is the most important factor influencing skin substitute product selection, followed by outcomes (4 responses) (n=26) (chart not shown).

“How does the wound respond? Outcomes are most important but then comes cost because it is a value statement. A treatment may have great outcomes but if it’s very expensive, such as hyperbaric oxygen, is there value?” asks Dr. Hsu.

RCTs are the most important reference for evidence when selecting skin substitutes for medical policy coverage, followed by trials comparing products with standard of care, and head-to-head trials, agree MCOs surveyed (n=40) (Figure 28).

“MCOs want to see evidence that a treatment works and under what circumstances,” says Dr. May.

“Is the new treatment better than the standard of care? If a new treatment is

not better and is more expensive, we won’t cover it,” says Dr. Hsu.

Quality vs Quantity

More than the number of studies (n=40) (Figure 29), MCOs rate study quality (n=40) (Figure 30) as having greater impact on their decision-making. Study quality averaged 78 versus 61 for quantity of studies using a scale of 1 to 100, where 1=lowest and 100=highest.

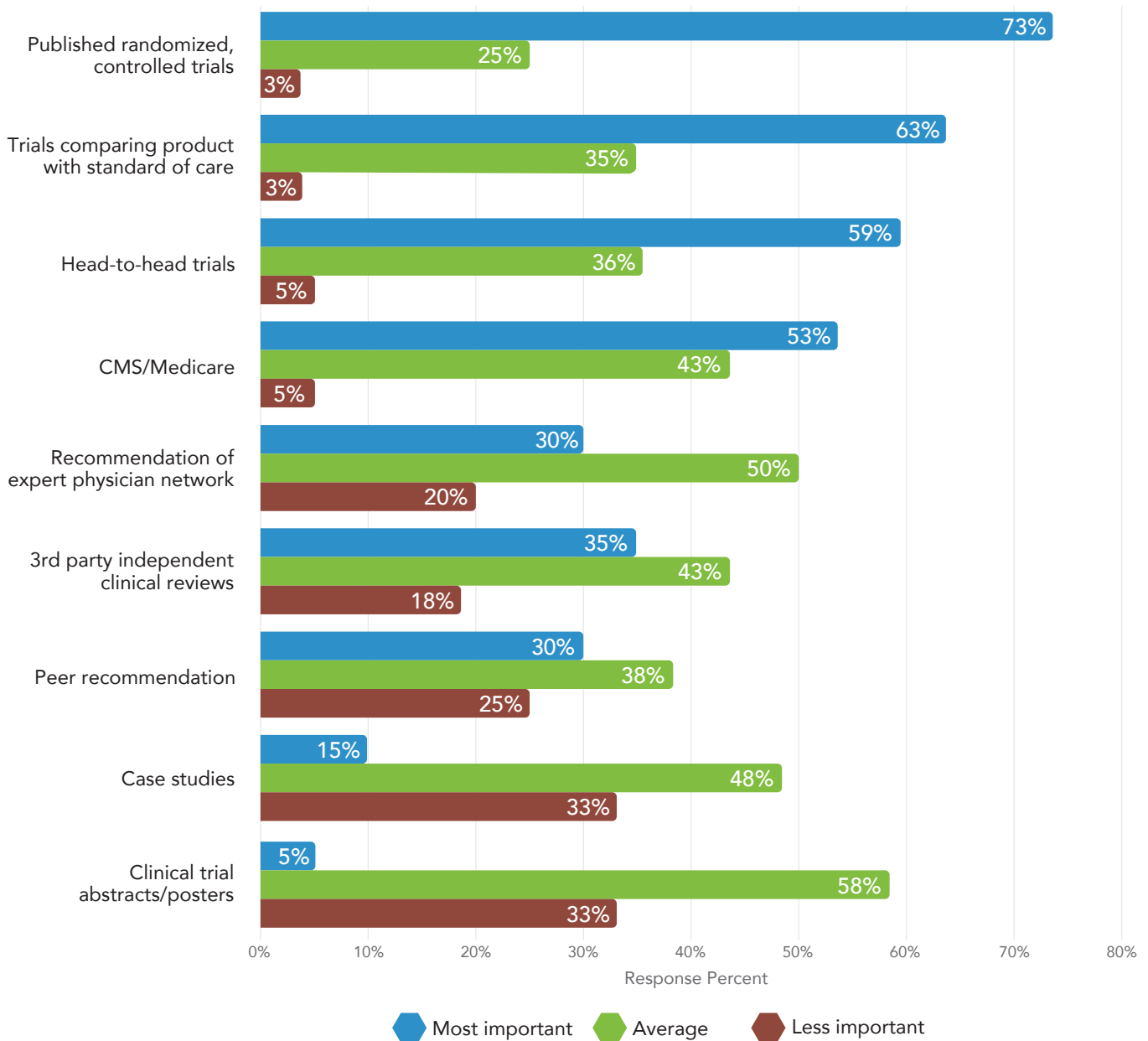
“Most diabetic ulcer patients have access to one or more advanced wound care options.”

– Edmund Pezalla, MD

| FIGURE 28 |

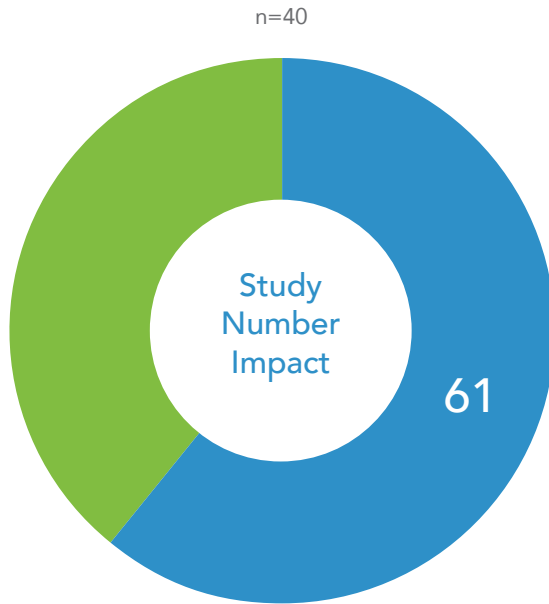
How important are the following resources when selecting a skin substitute product for your medical policy?

n=40 (Multiple responses)



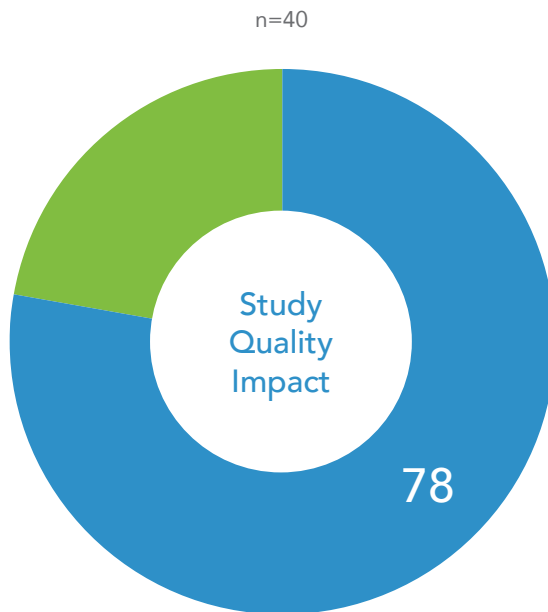
| FIGURE 29 |

How does the number of published studies about a product impact your decision using a scale of 1 to 100?



| FIGURE 30 |

How does the quality of published studies about a product impact your decision using a scale of 1 to 100?



A Look Ahead

Among promising trends seen in wound care, managed care respondents listed better control of diabetes (6 responses), skin substitutes (5 responses), and stem cell therapy (3 responses) (n=35) (chart not shown). One respondent notes: “Some of the artificial skin and soft tissue substitutes look quite promising.” Respondents also called for dedicated wound care clinics, early detection and monitoring, and targeted education efforts, including “wider knowledge in the lay community of wound care importance.” Six respondents indicated they were unsure or didn’t know.

“Number 1, diabetes has to be better controlled,” says Dr. Hsu. “Ideally a biologic skin substitute not only keeps the wound clean but blocks infection and promotes the vasculature for healing.”

“The skin substitutes we have now are very promising, as are products with amniotic components,” says Dr. May. “The problem is that we have little evidence that they work. Stem cells have potential, but we need the research.”

“There are a lot of new products and advances in active cells,” says Dr. Pezalla. “I expect that we will see more use of negative pressure therapy as it becomes easier to use. Meanwhile, we need to continue to focus on basic wound care, including debriding wounds, changing dressings, and off-loading.”

While 44% of MCOs review the costs of wound care as episodes of care, one-third use cost per treatment (n=39) (Figure 31).

Rising Incidence, Rising Costs

“Health plans are interested in better wound care because of the rising incidence of diabetes and DFUs,” says Dr. Hsu. “Plans are eager to look at the clinical trials that support one therapy over others so we may have the best outcomes and best value for the treatment of diabetic ulcers. Amputations need to be avoided. They are catastrophic. Beyond the clinical implications are socioeconomic and quality of life issues.”

“Plans can expect to pay more for wound care because of a confluence of factors: rising incidence of diabetes, an aging population, lack of A1c control, and more ulcerations,” says Dr. May. “We need to address the underlying pathophysiology of diabetes through prevention, addressing obesity, and better A1c control.”

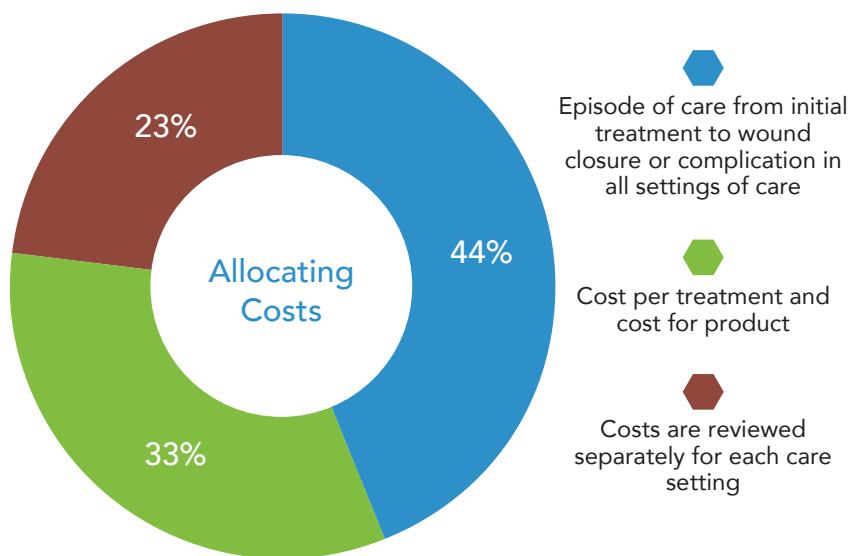
“Spending on wound care will increase. We will see more diabetes, more wounds,” says Dr. May. “Many therapies may not be effective because of poor patient compliance. Wounds get worse and cost more. As payers, we can’t control the whole system.”

“Costs will increase for both Medicare and commercial insurers,” says Dr. Pezalla. “More patients with cardiovascular disease are surviving longer. MCOs will turn to limited networks and lower-cost providers to try to contain costs.”

| FIGURE 31 |

How does your organization review the costs of care for chronic wounds?

n=39



Performance and Merit-based Payment

Wound Care Specialist Perspective

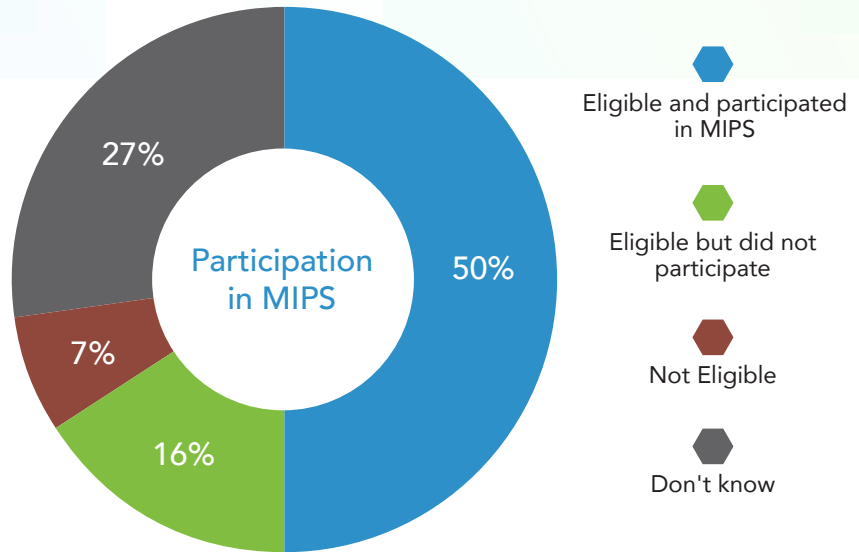
The Merit-based Incentive Payment System (MIPS) measures performance by physicians participating in the Medicare program. The goal of the Quality Payment Program, developed by CMS and effective January 1, 2017, is to reward advanced physician and hospital care on the basis of patient outcomes. Physicians receive a MIPS performance score that is a total of performance in 4 categories: quality measures; Advancing Care Information (ACI) (formerly “meaningful use”); Clinical Practice Improvement Activities (CPIA); and resource use (amount of money Medicare spends on a patient).²⁴

Half of survey respondents participated in MIPS in 2017 (n=44) (Figure 32). “This is more than I would have thought,” says Caroline Fife, MD.

| FIGURE 32 |

Please describe your participation in MIPS for 2017:

n=44



| TABLE 1 |

What MIPS did you submit related to wound care in 2017?

n=21

MEASURE	MIPS 1	MIPS 2	MIPS 3	Total	% of responses
MIPS 1 Diabetes: Hemaglobin A1c Poor Control	12	2	1	15	71%
MIPS 126 Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy - Neurological Evaluation	3	6	2	11	52%
MIPS 47 Advance Care Plan	1	5	4	10	48%
MIPS 110 Preventative Care and Screening: Influenza Immunization	3	3	3	9	43%
MIPS 127 Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention - Evaluation of Footwear	1	1	1	3	14%

Dr. Fife is the Executive Director of the US Wound Registry, a qualified clinical data registry (QCDR)—a CMS-approved entity that collects clinical data on behalf of providers and transmits it to CMS for the purpose of participating in the Quality Payment Program.

The quality measure for A1c in 2017 received the largest number of responses (n=21) (Table 1).

Quality measure scores averaged 67 on a scale of 1 to 100 for 2017 as reported by wound care specialists (n=36) (Figure 33).

A total of 52% of wound care specialist respondents expect to participate in MIPS for 2018 (n=36) (Figure 34). This represents a slight increase from 50% for 2017.

Poor control of A1c tops the list of MIPS related to wound care expected to be submitted by survey respondents for 2018 (n=22) (Table 2).

DFU off-loading is the quality measure reported most frequently, followed by DFU healing, adequate compression of VLU at each treatment visit, A1c, and plan of care (Table 3).

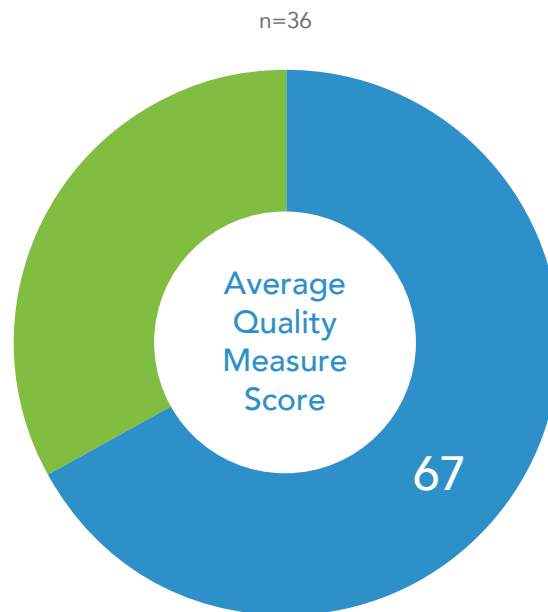
“Through the US Wound Registry, we reported off-loading for DFU, vascular screening, and compression for venous leg ulcers,” says Thomas Serena, MD. “We don’t report on A1c because we don’t manage the patient’s diabetes. We also don’t track whether the patient has had a flu vaccination. MIPS is a great idea, but the quality measures used need to be relevant to wound care.”

“Some MIPS quality measures are too general and overlap with primary care,” agrees Gary Gibbons, MD.

“I like quality reporting. I would continue to track quality measures even if MIPS were to go away,” adds Dr. Serena.

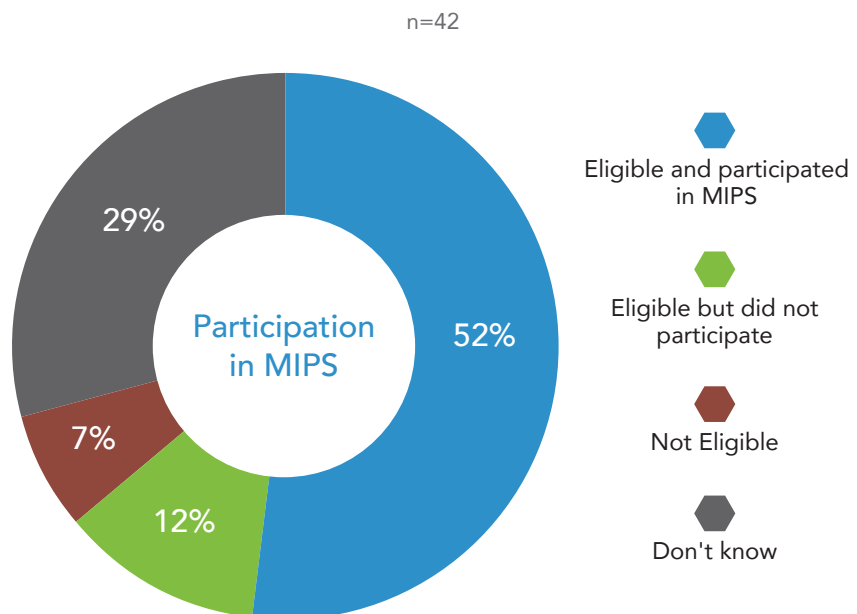
| FIGURE 33 |

For 2017, what was the outcome of your overall Quality Measure Score using a scale of 1 to 100?



| FIGURE 34 |

Please describe your participation in MIPS for 2018:



| TABLE 2 |

What MIPS related to wound care are you planning to submit in 2018?

n=22

MEASURE	MIPS 1	MIPS 2	MIPS 3	Total	% of responses
MIPS 1 Diabetes: Hemoglobin A1c Poor Control	15	0	1	16	73%
MIPS 126 Diabetes Mellitus: Diabetic Food and Ankle Care, Peripheral Neuropathy - Neurological Evaluation	2	7	5	14	64%
MIPS 110 Preventative Care and Screening: Influenza Immunization	3	1	4	8	36%
MIPS 47 Advance Care Plan	0	6	0	6	27%
MIPS 127 Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention - Evaluation of Footwear	2	1	2	5	23%

| TABLE 3 |

Please select which three wound care quality measures you would choose to report:

n=44

	% of responses
CDR1 Adequate Off-loading of DFU at Each Visit	50%
CDR2 DFU Healing or Closure	55%
CDR3 Plan of Care for DFU or VLU patients not achieving 30% closure at 4 weeks	18%
CDR5 Adequate Compression of VLU at each treatment visit, appropriate to arterial supply	36%
CDR6 VLU Outcome Measure: Healing or Closure	16%
CDR8 Appropriate use of HBOT for Patients with DFUs	16%
CDR9 or VLU Appropriate use of Cellular or Tissue Based Products (CTP) for Patients aged 18 Years or Older with DFU	5%
MIPS 1 Diabetes: Hemoglobin A1c Poor Control	23%
MIPS 47 Advance Care Plan	11%
MIPS 110 Preventative Care and Screening: Influenza Immunization	2%

“There are no MIPS quality measures directly relevant to wound care,” says Dr. Fife. “However, the US Wound Registry QCDR has developed a suite of wound care relevant quality measures which CMS has approved and for which national benchmark rates have now been established. These

measures can only be reported through the US Wound Registry QCDR and they include: DFU off-loading (the most commonly reported measures by those surveyed), adequate compression of VLUs at each visit, arterial screening of patients with non-healing lower extremity leg ulcers, and plan of care

for wounds that have failed to improve after 4 weeks. A1c is a standard MIPS measure that is also reported by some,” says Dr. Fife.

In addition, Dr. Fife notes that CMS recently published a proposed rule for an outpatient payment system that would pay for cellular products

in episodes of care rather than as a lump sum. “This would disincentivize multiple applications of cellular products. This could be combined with reporting the Appropriate Use and Plan of Care quality measures,” she explains. The final rule was published in November 2018.²⁵ No changes are planned for 2019 but CMS is looking to make changes in the payment method for 2020.

Wound care specialists are not confident that implementation of MIPS will lower cost of care, with responses averaging 24 on a scale of 1 to 100, where 1=lowest and 100=highest (n=41) (Figure 35).

“I think survey respondents are right not to feel confident that MIPS will lower cost of care,” says Dr. Fife.

Wound care specialists are slightly more confident that implementation of MIPS will improve patient care, with responses averaging 31 on a scale of 1 to 100, where 1=lowest and 100=highest (n=41) (Figure 36).

“If practices follow quality measures, healing rates go up,” says Dr. Serena.

“Wound care practitioners who reported the DFU off-loading, VLU compression, and arterial screening quality measures had 10% better healing rates of their DFUs and VLUs than practitioners who did not report those 3 measures,” says Dr. Fife.

Dr. Fife expects to see more use of performance-based payment systems. “MIPS is only a stop along the way to alternative payment models. Wound care doctors will be penalized if they don’t change their story. Episode of care won’t work if your care episode is 8 months and we don’t start telling the story that wounds are a chronic disease. Payers are going to start looking at quality measures that represent the total cost of care. If we don’t have a way

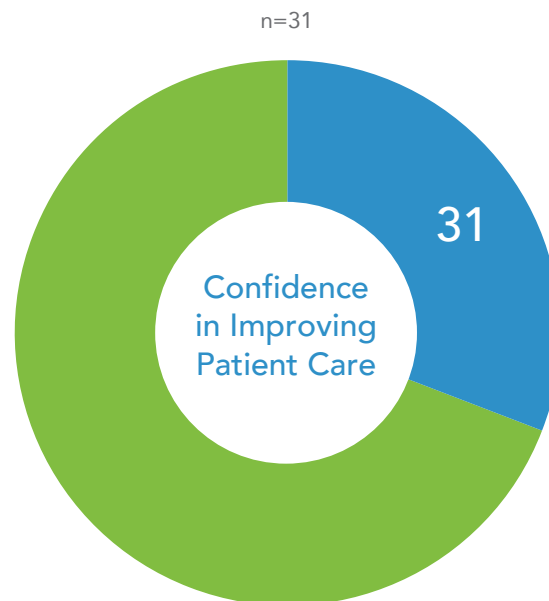
| FIGURE 35 |

How confident are you that implementation of performance-based payment plans will successfully lower costs of care using a scale of 1 to 100?



| FIGURE 36 |

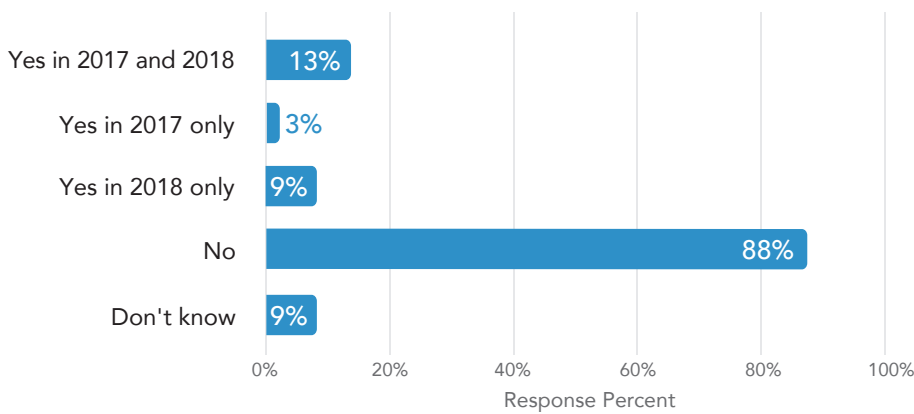
How confident are you that implementation of performance-based payment plans will successfully improve patient care using a scale of 1 to 100?



| FIGURE 37 |

For 2017 and 2018, did you offer any type of performance-based incentive payment plan for providers?

n=32

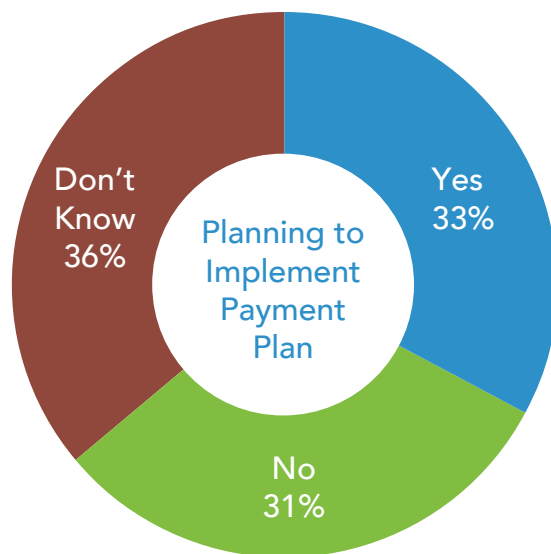


Only 13% of MCOs surveyed offered performance-based payment plans in 2017 or 2018.

| FIGURE 38 |

Are you planning to implement a performance-based incentive payment plan for providers in the next 1 to 3 years?

n=39



to identify which interventions lower cost of care, payers won't pay for any interventions," says Dr. Fife.

"Performance-based payments may improve patient care but I'm not sure it can reduce costs," says Dr. Serena. "Working with quality measures makes you a better doctor. Medicare has to allow specialists like wound care to choose their own quality measures. Getting a flu shot is not an appropriate quality measure for wound care. We don't have the infrastructure for such a system at present.

"Doctors already spend too much time on administrative functions. A study in *Annals of Internal Medicine* found that doctors spent 49% of their office day on electronic health records and other desk work.²⁶ Any savings achieved through quality measures has been lost in time spent tracking such measures," notes Dr. Serena.

MCO Perspective

Health plans have been cautious when it comes to offering performance-based reimbursement to providers. However, according to predictions, plans are 3 times more likely to offer such programs in the near future compared with the recent past. Designing programs specifically for wound care presents unique challenges.

Only 13% of MCOs surveyed offered performance-based payment plans in 2017 or 2018 (n=32) (Figure 37).

One-third of MCOs plan to implement such plans for providers in the next 1 to 3 years but 36% say they don't know and 31% say no (n=39) (Figure 38).

"I don't think there will be a significant increase in performance-based payments in wound care," says

Dr. Hsu. “It is hard to measure. What exactly is the formula for success? Is it a reduction in the size or depth of the wound? Decreased rate of infection? Preventing an amputation? Decreased cost? Who is going to measure improvement? Over what time period? CMS may want to do this for the Medicare population, but it will be a nightmare for those of us who administer Medicare plans. Additional resources would be needed to manage such programs.”

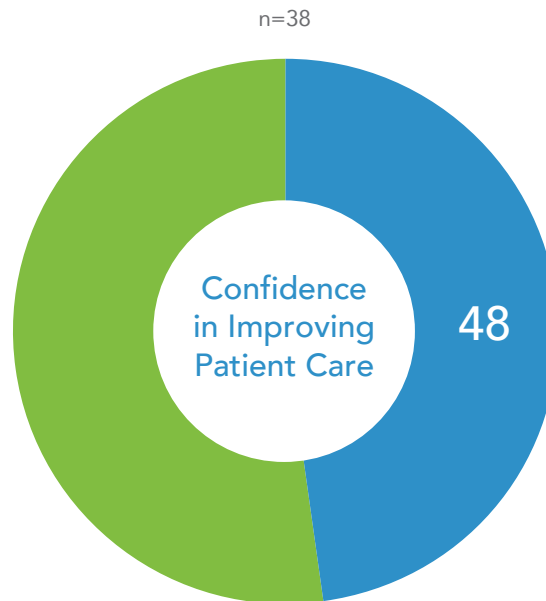
“Performance is difficult to measure in part because of the nature of wound care,” says Dr. Pezalla. “There are some quality metrics being used but they are not that exact or accurate and they don’t necessarily reflect patient outcomes. In the future, we will have better quality metrics. Pay for performance measures will be around managing diabetes generally, including blood sugar levels, etc., in addition to wound care.”

“Performance-based payments is a hot topic in all therapeutic areas,” says Dr. May, “but the usage of them is minimal. Most health plan medical directors hate them. They don’t think such plans save money. Focusing on outcomes sounds good but by the time you analyze the data and follow-up and agree on outcomes... is it total healing? This is difficult to achieve. How can providers make patients be compliant?”

MCOs are somewhat confident that performance-based plans will improve patient care with an average rating of 48, using a scale of 1 to 100, where 1=lowest and 100=highest (n=38) (Figure 39). They are slightly less confident that performance-based plans will reduce costs (n=39) (Figure 40) with an average rating of 44.

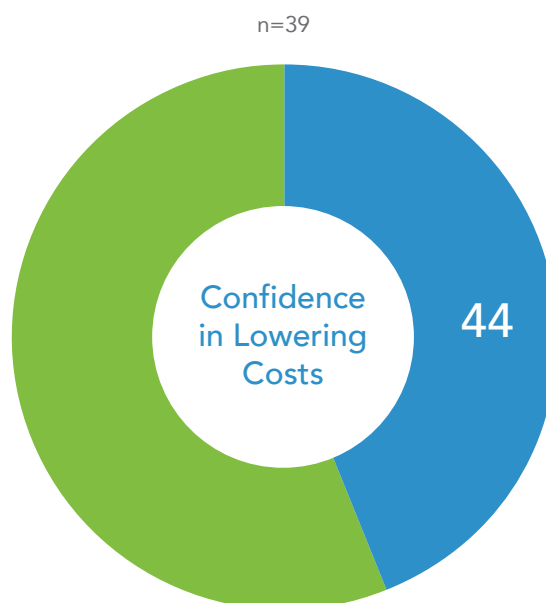
| FIGURE 39 |

How confident are you that implementation of performance-based incentive payment plans will improve patient care using a scale of 1 to 100?



| FIGURE 40 |

How confident are you that implementation of performance-based incentive payment plans will lower costs of care using a scale of 1 to 100?



Guidelines for Wound Care

Wound Care Specialist Perspective

Wound care specialists are highly aware of published consensus guidelines that provide recommendations for the management and treatment of DFUs (n=51) (**Figure 41**).

There are 5 wound care guidelines for treatment of DFUs:

- Guidelines for the treatment of Diabetic Ulcers, December 2006, by the Wound Healing Society²⁷
- The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine²⁸
- Diabetic foot disorders: A clinical practice guide (2006 revision)²⁹
- Emerging evidence on advanced wound care for diabetic foot ulcerations³⁰
- Consensus recommendations on advancing the standard of care for treating neuropathic foot ulcers in patients with diabetes³¹

“However, the guidelines are not being followed with regard to basic wound care practices,” says Gary Gibbons, MD. Rather than each group promoting its own guidelines that basically say the same thing, Dr. Gibbons says he would “prefer to see

one unified guideline on wound care that we can all practice.”

MCO Perspective

Only 40% of MCOs are aware of consensus guidelines for treating DFUs (n=40) (**Figure 42**).

“We can’t force physicians to use specific guidelines,” notes Fredrick May, MD. “Following guidelines does not necessarily mean the ulcers will heal.”

“Product manufacturers can increase awareness of wound care guidelines by offering continuing education programs around guidelines,” suggests Edmund Pezalla, MD.

Sixty percent of managed care respondents have a clinical policy that

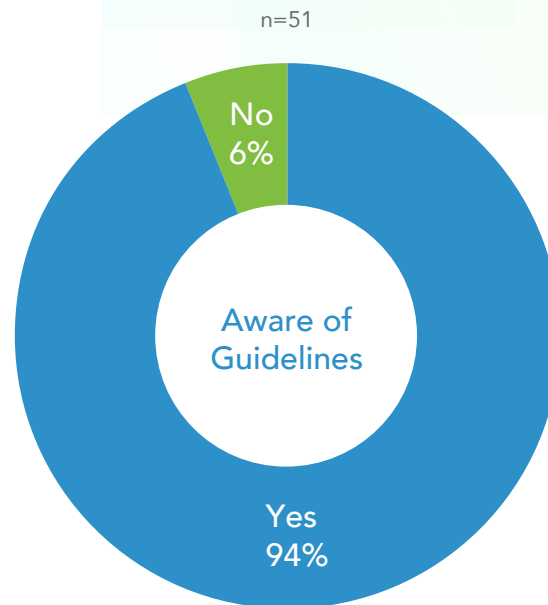
addresses standard wound care (n=40) (**Figure 43**). “We don’t do this,” says Dr. May.

“Medical policies do not address all treatments. This is because of a lack of studies,” says Larry Hsu, MD. “The consensus is not very clear. Therefore, policies are not able to address standard wound care practices in the real world.”

“Clinical strategies emphasize good cleaning of the wound, use of appropriate dressing, and treatment of infection,” says Dr. Pezalla. “It is hard for plans to tightly manage care. Most plans are trying not to be overly prescriptive. They want to provide choices for physicians and podiatrists who are working with patients. Plans

| FIGURE 41 |

Are you aware of any consensus guidelines for treating diabetic foot ulcers?



pay for benefits. For the most part, plans don't actually manage patients."

"Health plans welcome guidelines that are evidence-based and easy to use," says Dr. Hsu. "If guidelines are overly complicated no one will use them."

"I don't think guidelines help," says Dr. May. "No one has the perfect guideline. Every wound is a little different. Patient compliance is key."

"Guidelines are important," says Dr. Pezalla. "Guidelines provide an opportunity to discuss wound care products and the extent to which they are covered by health plans. There are a variety of products on the market. They may not all have the outcomes data plans are looking for or MCOs may not be aware that the guidelines recommend particular treatments for particular types of patients. Product manufacturers may need to educate the managed care medical directors better," says Dr. Pezalla. He suggests manufacturers compare and contrast the various wound care guidelines.

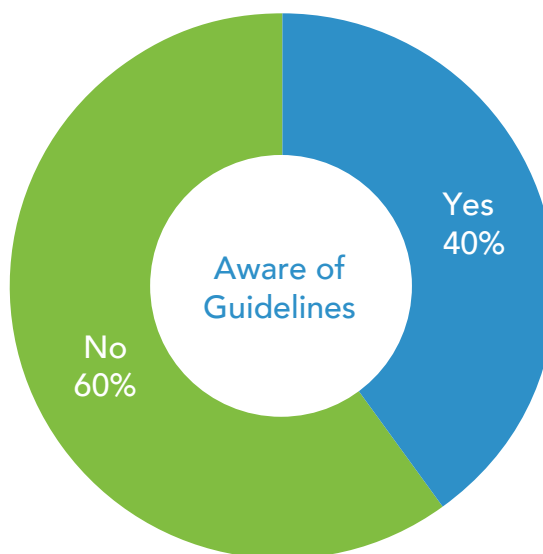
"Also, patients enrolled in clinical trials may not match real world patients who tend to have blood sugar levels that are less well controlled and to have worse nutritional status," says Dr. Pezalla. "Clinical trial patients also tend to be better educated and in better health. Product manufacturers can show that trial patient populations are representative and that they benefitted from the new therapy."

"If manufacturers are seeing policy issues where guidelines say that a particular product can be used for a certain type of patient but MCOs won't approve its use, manufacturers should enlist the help of their professional organization and approach the health plans as a group and show the evidence that supports the guidelines," adds Dr. Pezalla.

| FIGURE 42 |

Are you aware of any consensus guidelines for treating diabetic foot ulcers?

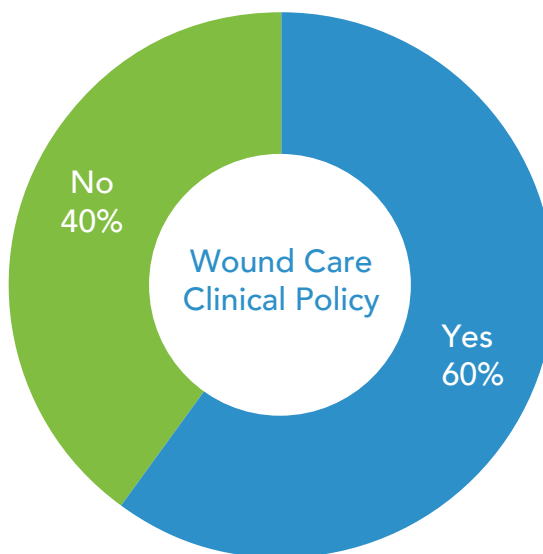
n=40



| FIGURE 43 |

Do you have a clinical policy that addresses standard wound care?

n=40



Wound Care Specialist and MCO Responses Compared

Diabetic Foot Ulcers

Diabetic foot ulcers are the most prevalent chronic wound type among patients of wound care specialists surveyed (n=51) and among members of MCOs surveyed (76%) (n=39).

Diabetic foot ulcers (78%) are the most likely chronic wound to require treatment with advanced therapies (n=51), according to wound care specialists. MCOs estimate that 49% of members with DFUs would benefit from advanced therapies.

Barriers to Care

Wound care specialists name “insured patient not eligible based on coverage guidelines” (86%) as the chief barrier to treating patients with advanced therapies, followed by out-of-pocket expense (65%), and patient compliance (53%) (n=51).

MCOs name patient compliance (69%) as the chief barrier, followed by lack of clinical evidence (68%) and insured patient not eligible (45%) (n=40).

Achieving Wound Closure

The best predictors for achieving wound closure when treating DFUs, according to wound care specialists, are off-loading (100%), adequate vascular perfusion (100%), and patient compliance (96%) (n=51).

MCOs list as best predictors for achieving wound closure when treating DFUs: adequate vascular perfusion (88%), patient compliance with treatment (88%), and elimination of infection (83%) (n=35).

Best Clinical Outcomes

Wound care specialists rate cellular skin substitutes (80%) as having the best clinical outcomes for wound closure, followed by negative pressure (39%) and hyperbaric oxygen (35%) (n=49).

MCOs rate negative pressure therapy as having the best clinical outcomes (41%), followed by hyperbaric oxygen (25%), and skin substitutes (20%) (n=40). However, only 30% of responding MCOs say they track clinical outcomes in wound care (n=40).

Out-of-Pocket Costs

Wound care experts (n=51) and MCOs (n=40) gave similar responses to survey questions on how often a patient decides not to receive advanced therapy because of the high out-of-pocket costs of 41 and 44, respectfully, on a scale of 1 to 100.

Prevalent Treatments

Cellular skin substitutes are the most prevalent treatment for DFU (58%)

(n=50), say wound care experts. For MCOs, negative pressure therapy is most prevalent, with 35% (n=40). However, if responses for cellular skin substitutes and acellular are combined, total equals 38%.

Selecting a Skin Substitute

Clinical factors most important to wound care specialists in selecting a skin substitute to treat DFUs are: growth factors (70%), clinical studies (53%), and cellular products (40%) (n=51).

MCOs listed as most important in selecting a skin substitute clinical studies (71%), wound size and dimensions (68%) and ease of application (57%) (n=40). Growth factors were listed last (23%).

Combination Therapies

Wound care specialists (n=50) and MCOs (n=31) view the same top 3 combinations of advanced therapies most favorably: starting with hyperbaric oxygen + skin substitute (84% vs 43%), and followed by negative pressure therapy + skin substitute (82% vs 38%), and hyperbaric oxygen + negative pressure therapy (56% vs 35%). Wound care specialists were twice as likely to use such combinations compared with the number of MCOs providing coverage for each combination of treatments.

Consensus Guidelines

Nearly all (94%) of wound care specialists (n=51) are aware of consensus guidelines for diabetic foot ulcers compared with 60% of MCOs (n=40).

Wound care specialists rate themselves as highly knowledgeable on the science of wound care (81%) (n=51) compared with 64% for how MCOs rated themselves (n=39).

Evaluating Resources

Personal experience (61%) is the most important resource for wound care specialists in selecting a skin substitute for patients, followed by published clinical trials (59%) and head-to-head trials (51%) (n=51).

Responding to a similar question on resources used to set medical policy on selection of skin substitutes, MCOs list published clinical trials as most important (73%), followed by trials comparing product to the standard of care (63%), and head-to-head trials (59%) (n=40).

Quality Over Quantity

Both wound care specialists and MCOs value quality over quantity when it comes to evaluating published studies. Average scores were 73 (n=51) and 59 (n=50), respectfully, for wound care specialists and 78 (n=40) and 61 (n=40), respectfully, for MCOs.

Prior Authorization

A greater proportion of wound care specialists (25%) (n=44) than MCOs (11%) (n=38) strongly prefer a more automated system for processing prior authorization requests.

Performance-based Plans

MCOs are more confident than wound care specialists that implementation of performance-based payment plans will both improve patient care (48) (n=38) and reduce costs (44) (n=39) compared with wound care specialists who averaged 31 (n=44) for patient care and averaged 24 (n=41) for cost reduction. Both groups were more confident that performance-based payment plans would impact patient care more favorably than costs.

A Look Ahead

Wound care specialists offered a wide-ranging and more detailed look ahead at promising trends in the wound care market that will improve outcomes over the next 3 to 5 years compared with MCOs (n=35). Wound care specialists were more in tune with the science and research on biofilm, DNA testing for bacteria, and advanced dressings.

Advanced skin substitutes or biologics (11 responses), stem cells (8), biofilm (5), and amniotic membranes (2) were

named by wound care specialists as the most promising new treatment options to improve outcomes over the next 3 to 5 years (n=50). Better ways of delivering care were also listed, including prevention, personalized medicine, and evidence-based protocols.

Among promising trends in wound care, managed care respondents listed better control of diabetes (6 responses), skin substitutes (5 responses), and stem cell therapy (3 responses). Other responses included early detection and monitoring and dedicated wound care centers. Six managed care respondents indicated that they were uncertain or didn't know.

Conclusions

Wound care is a highly specialized field that treats very complex patients with multiple comorbidities and risk factors that affect healing and lead to increased mortality. With the growing prevalence of diabetes leading to more chronic wounds, the rising cost of wound care is a concern for payers. More emphasis is needed on promoting basic standard wound care practices in conjunction with advanced wound care therapies. Implementation of quality measures specific to wound care is needed to encourage and support optimal outcomes and the delivery of quality care. Survey findings and interviews with experts reveal the following trends:

- 80% of surveyed clinicians say DFUs are the most common type of non-healing chronic ulcer they treat, followed closely by venous ulcers.
- 78% of wound care specialists also say DFUs are the most likely type of ulcer to require advanced therapies to achieve wound healing.
- Wound care specialists estimate on average that 64% of their DFU patients would benefit from advanced therapies.
- Cellular skin substitutes (products containing living cells) are rated by 81% of wound care specialists surveyed as having the best clinical outcomes of all advanced wound care therapies.
- 86% of clinicians say lack of insurance coverage for advanced wound care therapies is the #1 reason patients with DFUs do not receive advanced treatments they may need.
- 76% of MCOs surveyed say DFUs are the most prominent type of chronic wounds among health plan members.
- Most MCOs do not spend much time managing chronic wounds relative to other services they manage. Only 25% of MCOs surveyed say they specifically case manage wound care.
- MCOs suggest an average of 49% of members with chronic wounds would benefit from advanced therapies.
- Negative pressure therapy and cellular skin substitutes have the highest prevalence of use of all advanced wound care therapies. If cellular and acellular skin substitutes are grouped together, they exceed negative pressure therapy.
- Lack of published clinical evidence is the #1 reason given by MCOs surveyed for not covering an advanced therapy. Clinical evidence is by far the #1 criterion MCOs use in selecting a skin substitute for coverage.

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